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Design and Usability development of a CPAP device

- *For safe sleeping*

Master of Science Thesis in the Master Degree Program, Industrial Design Engineering

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Gothenburg, Sweden 2015

Department of Product- and Production Development
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And last but not least…

Thanks Chalmers for these fun and interesting years!

Abstract

This master thesis work is carried out on behalf of i3tex, a consulting company working with product development in various business areas. The project concentrates on a user-centred approach for developing a medical device for use in a home environment. The development process, including how to work with usability aspects to ensure a user-friendly product, is a key deliverable.

The product in focus is a CPAP (Continuous Positive Air Pressure) device. It is mainly used to treat sleep apnoea, a sleep disorder that causes the breathing to repeatedly be interrupted during sleep due to blocked airways. A CPAP device keeps the upper airways open by applying a positive air pressure through a tube and a mask. In this project the iSleep 25, a CPAP device developed by Breas in 2004, is used as a reference product.

The project follows the ACD^3 process (Lars-Ola Bligård), which is a product development process with a man-machine focus. In the process, the product goes from being abstract to concrete via a number of steps where the product becomes increasingly detailed.

The foundation of the development work is a theoretical framework with useful guidelines and an exploration of the typical users and their needs, the use context, and the CPAP market. Two main user groups were identified – sleep apnoea patients and medical professionals working in sleep laboratories. The product has been developed with both user groups in mind.

Based on the acquired knowledge about the users and the use context, a modified use procedure could be defined. Technological applications such as telemedicine provide new possibilities in the medical domain, some of which have been implemented to create an updated use procedure for patients and medical personnel.

The project covers surface design of the CPAP device as well as design of the graphical user interface. These parts have been developed parallelly to create a complete and unified product. The appearance and expression of the product is based on value words defined by the project workers with the users in mind. The value words are Simple, Reliable and Humble. Moodboards for each of the value words were created and turned into form drivers that could then be transformed into form concepts and interface concepts.

The form concepts were combined with functional solutions using a morphological matrix. It generated many concepts that were then reduced to three final concepts, complete with sub-functions such as handle, physical interface layout and defined position for the tube outlet, etc. Quick mock-ups were then created for evaluation with CPAP users.

The architecture of the menu was based on the menu structure of the iSleep 25, but was rearranged to better meet the users' needs and requirements. The graphical part of the interfaces was developed together with the menu structure since the two are heavily connected. Four interface concepts were evaluated by CPAP users online via example images of the interfaces.

Finally, detailed concepts consisting of a more refined outer shape and an improved interface were developed. It was validated through a usability test with eight participants. In the test, the interface was shown on a smartphone that was placed as a dummy display. The images were streamed to the smartphone from a computer controlling the interface via a PowerPoint presentation. The product was refined further based on input from the usability test, and then realised through CAD renderings.

Contents

1. Introduction

The rapid technology development that we see today quickly makes technical products out-dated. This is also true for medical devices, and modern technology opens up many possibilities that were not available a few years ago. Medical devices have to be safe and easy to use for people with various disabilities and illnesses, which further calls for frequent development and updates of out-dated products.

The complexity and demands regarding usability and safety are even greater for home health care devices since home environments and capabilities of individual patients vary greatly.

This master thesis is about how a medical device for home environment use can be developed through a user-centred design process. The thesis is to be carried out in cooperation with the consulting company i3tex, who work with product development in various business areas. They want to improve their portfolio within usability by presenting it through a product. The product for the project is a CPAP device which is used to treat people who suffer from sleep apnoea and is supposed to be used for home health care. The reference product which is used as a starting point was developed about ten years ago and the user interface is out-dated. This CPAP device is called iSleep 25 and was developed by the Swedish company Breas.

1.1 Sleep apnoea

Sleep apnoea is a common sleep disorder, with about 300 000 people suffering from it in Sweden alone. The condition means that the person's breathing is repeatedly interrupted during sleep. These pauses in breathing could last from seconds up to minutes and can happen up to 30 times per hour. This happens because the airways get blocked which results in that little or no air gets through to the lungs and the rest of the body. Sleep apnoea causes the sleep cycle to be continuously interrupted with many negative health effects as a result. There can be many underlying reasons why people develop apnoea, but people that are overweight as well as people over the age of 50 are more likely to get it.

At many hospitals and care centres there are special sleep clinics where people suffering from sleep apnoea can get help by caregivers specialised in sleep disorders. In this project, personnel at the sleep laboratory at Sahlgrenska University Hospital were utilised.

1.2 CPAP therapy

CPAP stands for Continuous Positive Air Pressure, which is the main treatment against sleep apnoea.

A CPAP device works by keeping the upper airways open by applying an air pressure, through a tube and a mask, during both inhalation and exhalation (Figure 1). The air pressure is generally achieved by an air compressor that works to maintain the desired airway pressure despite the inhalation and exhalation of the patient.

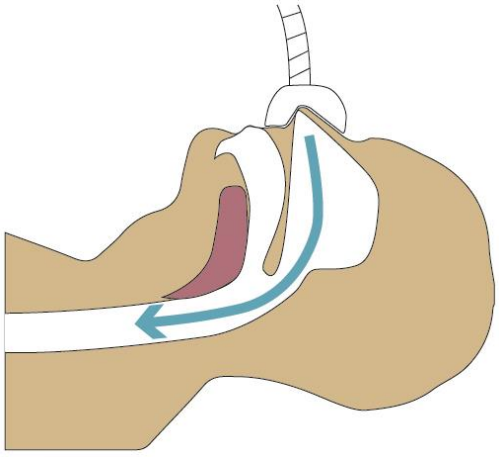


Figure 1 - CPAP therapy

A CPAP device normally includes the parts shown in Figure 2. It has a display with buttons to control the menu, a tube outlet to connect the air tube, a humidifier, an air filter, some kind of data storage and sometimes also a handle.

It is powered by electricity and works by compressing air using a compressor wheel inside the device. The air is led to the patient through the air tube and a mask. If a humidifier is used, it heats up and humidifies the air before sending it through the air tube.

Figure 2 - Common parts of a CPAP device

1.3 Purpose

Demonstrate the procedure of working with usability in product development by designing a user friendly CPAP device based on an existing product.

1.4 Aim

To design a user friendly CPAP device that is well adapted to the needs and requirements of the target users, considering the expression and design of both the physical form and the user interface.

The new product should:

- be adapted for use by the patient itself in a home environment
- have an appropriate expression for the intended use
- fulfil usability requirements which can be validated through usability tests
- meet current standards for medical devices

1.5 Delimitation

Due to broad scope resulting from developing both the surface design and the interface, the following delimitation has been applied to the project:

- Packing and designing of interior components such as motor, electronics and sound absorption will not be included
- Design of a new ventilation mask and air tube will not be considered
- The focus will be on adult users
- Stakeholders like family members and home health care staff will not be considered
- The interface will be done in Swedish
- The costs of the final product has not been covered
- Choice of materials has not been included

1.6 Abbreviations & definitions

CPAP = Continuous Positive Air Pressure
AHI = Apnoea Hypopnoea Index
cm H_2O = pressure unit used for air pressure in CPAP devices

2. Procedure

In this chapter the process of the project is described, including which methods were used and why. The structure and the chapters of the report follow the same steps as the process of the project, which is presented in Figure 3.

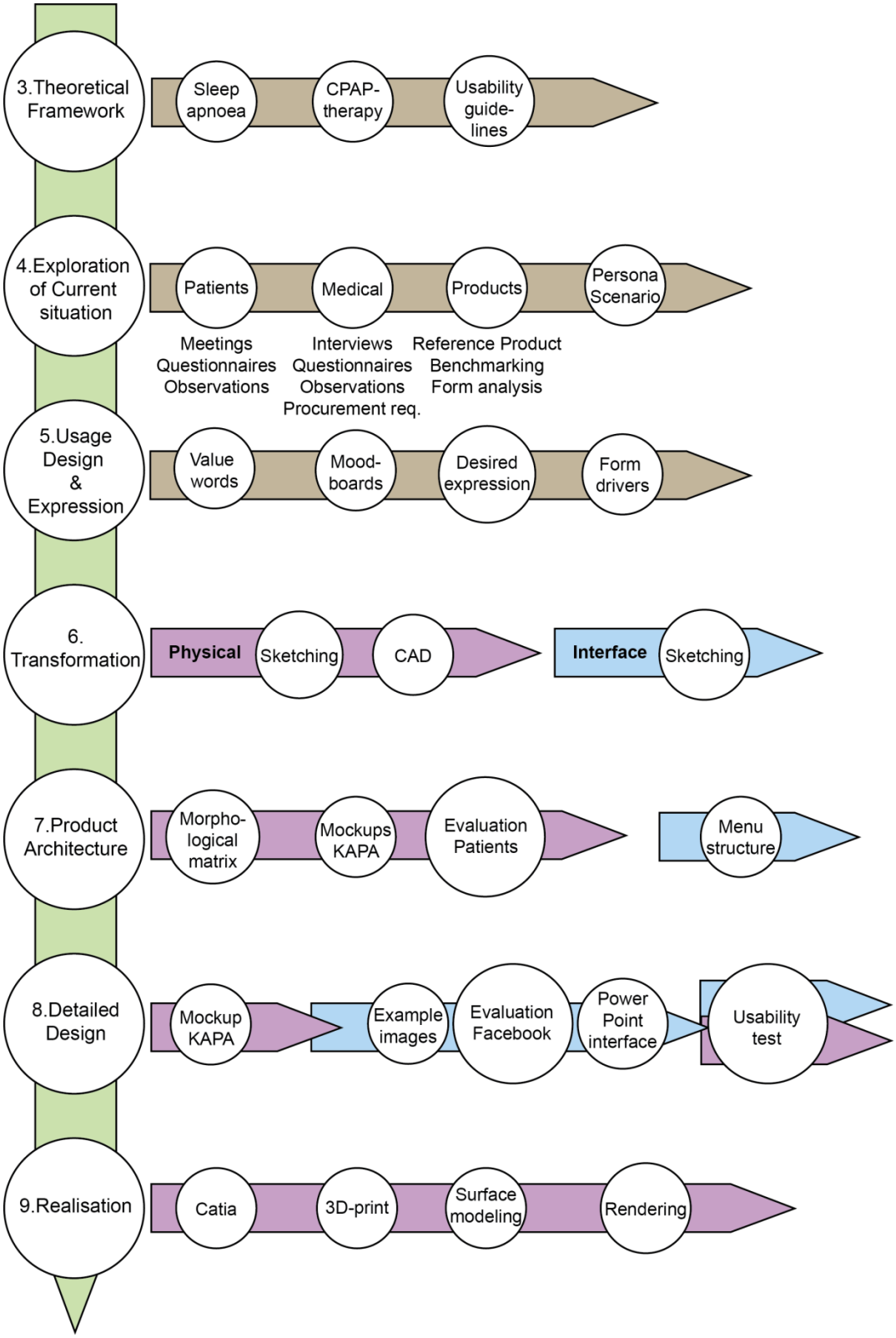


Figure 3 - Procedure of the project

The process was based on the ACD^3 process developed by Lars-Ola Bligård with support from Eva Simonsen. It is a product development process from a human-machine perspective which makes it suitable process for this project since it is user-focused development project. The process goes from abstract to detailed through the steps Needs specification, Usage design, General design, Detailed design, Construction, Production and Usage launch (Bligård, 2015). In this project, the Need specification is covered by a theoretical framework and an exploration of the current use situation. The last three steps are replaced with a Realisation step which includes the construction of a CAD model and production of a 3D printed model. The steps described in this procedure chapter correspond to the main chapters of the report.

2.1 Theoretical framework

The project was initiated by a research phase where information about the topic was gathered in order to get a solid foundation to build the design on. In particular, information about sleep apnoea and CPAP treatment was gathered, but also general theory and guidelines for designing medical devices for use in home environments. The guidelines worked as a check-list when developing the concepts later in the project.

The information was mainly found through Google Search and Google Scholar by entering relevant keywords. Some content was also found in the ISO standard for medical devices.

2.2 Exploration of the current situation

An exploration of the current situation was made to get a general impression regarding the users, the CPAP market, how the CPAP is used and the context of usage.

2.2.1 Users and context

It is important to research the context in which the product will be used in order to design a product that is well adapted to the actual usage. The user insights were mainly acquired by interviews, questionnaires and observations. Questionnaires were distributed both online and on paper, and observations were performed face to face as well as through Facebook groups.

2.2.1.1 Patients

The patients is the main user group, meaning that it is important to get their opinions about CPAP devices and the treatment, as well as to understand how they use the products. They have a more personal relation to the CPAP device than the medical personnel.

Questionnaire

Two questionnaires were sent out online, one Swedish and one English (see Appendix 1). The English one was filled out by one person and was sent out through an American Facebook page for people on CPAP treatment. The Swedish one was sent out through a Swedish Facebook page for people suffering from Sleep Apnoea and heavy snoring. A slightly modified version on the questionnaire was later also sent via email to members of the local Sleep Apnoea Association in Gothenburg. It was filled out by a total of nine people, including the answers from Facebook.

The questions were related to the usage and habits of the user, for example which settings they use the most and how they interact with the device when getting ready for bed.

Observation

The Facebook groups also appeared to be useful for long-term observation of use patterns and common concerns and issues with existing products. The groups were also used for receiving quick replies on specific questions as well as photographs of the users' bedroom environment and CPAP setup. The project writers asked if the users could take photos of their setup and some persons

agreed to share how it looked like in their home. Observation and interaction with users through social media was a very effective method that saved a lot of time and effort by not having to visit users' homes which was the initial intention. It also gave a solid understanding of the CPAP users' situation and needs.

Meeting patients

A few sleep apnoea patients were talked to briefly at the annual meeting of Gothenburg's local Sleep Apnoea Association. A few subjects were quickly discussed about their use behaviour and their opinion about their current CPAP device. This was also a good opportunity to meet many target users at the same time and get an understanding of the user demographic.

2.2.1.2 Medical personnel

The personnel at the sleep laboratory were included in the study since they are the other main user group of CPAP devices. They use and interact with the product in a different way compared to how patients use their own CPAP device. They often interact with many different devices every day and have a more professional use perspective.

Interviews

A few interviews were performed at the sleep laboratory. An interview is a method for collecting data from individuals. The purpose of the method is to get insight of what the user does and thinks (Bligård, 2015). Also previous experience, opinions and expectations are possible outcomes of the method.

An expert interview (see Appendix 2) was performed with Jan Hedner who is a professor and medical doctor with much knowledge within sleep disorders and CPAP treatment. A semi-structured interview was used, where some questions were prepared. This structure was chosen because there was only one interview of this kind and qualitative data was desired. However, it was not followed fully since Hedner talked freely about the subject and answered thereby some of the questions. He talked about sleep apnoea, the background of CPAP treatment and the view on the treatment from a clinical perspective.

Observation

A visit to Sahlgrenska hospital's sleep laboratory was made with the aim to see the real context the clinical users work in, what their work process looks like and what tasks they perform. Observations give information about the users' behaviour in a specific situation, which cannot be collected by just asking questions. The method gives a very clear image of how the users actually do and not what they say they do (Bligård, 2015). Optimally, the users should not know that an observation is performed. This was however not possible since it was taking place during meetings between nurses and patients.

This observation followed an interaction process between nurses and patients, where a CPAP device was handed out for the first time to a patient. The observation started with an information session together with other new CPAP users and continued after that in a private room, where a nurse introduced a CPAP device to a patient. The nurse performed her usual procedure and we as observers tried to interfere as little as possible.

A short interview was performed with the nurse in private (see Appendix 3). The interview was semi-structured and the questions were mainly about the process when and how the patients and hospital come in contact with each other. It was also asked about the CPAP devices that are used at the sleep laboratory at Sahlgrenska.

Procurement requirements

From the visit at Sahlgrenska it came to our knowledge that the region Västra Götaland has their own requirements list for purchasing CPAP devices to the health care. The region was contacted and a list regarding design and usability aspects was sent back to us.

Requirements from this list will be found in the requirements list for this project.

Questionnaire

A questionnaire was handed out to nurses at the sleep laboratory in order to receive a slightly bigger diversity of what individual nurses thought about CPAP devices and the work related to the devices. The questionnaire consisted of eight questions (see Appendix 4) and five replies were received.

This way of collecting information was also chosen because clinical personnel are very busy and difficult to get in touch with. Since the interviewer is not present and cannot ask the questions directly to the subjects, it is important to formulate the questions well (Bligård, 2015). Otherwise the answers might differ from what is actually asked for.

2.2.1.3 Personas and scenarios

A scenario including two personas, one patient and one nurse, were created based on a summary of the typical user groups. A persona is a made up description of a user, which can describe the personality more than just a user profile (Bligård, 2015). This was done to make the demands and preferences of the users more tangible, which then was used for further design work.

The personas were put into a scenario which shows how it can look like when a person is diagnosed with sleep apnoea. This was done to create a more realistic and tangible picture of how it is like to suffer from sleep apnoea and be treated with a CPAP device.

2.2.2 Product

A product research was performed to get a better understanding of what CPAP products there currently are on the market. One specific CPAP device, namely the reference product, was studied on a detailed level.

2.2.2.1 Benchmarking

To understand the market a benchmarking was done. Aspects that were considered include how existing products are designed, what they express in terms of form and composition, what functions they have and how their interface looks. Benchmarking is important in order to be able to develop a successful product. As a part of the benchmarking, several competition matrices with axes like "Medical - Everyday product" and "Stable - Unstable" were created to know where to position the product concept in the competition landscape regarding aesthetics.

The product specifications and images were found both through Internet searching and through live demonstrations of the most popular CPAP devices.

2.2.2.2 Reference product

The reference product was also investigated. The functionality and interface from the Breas iSleep 25 worked as a starting point to build from, but were later modified to better suit the development of a new product. This step also included a meeting with Stephan Söderholm, the industrial designer who designed the iSleep range.

2.3 Usage design and expression

The theory and the current situation were the foundation for the third step, which is the usage design and the desired expression of the developed product. This is our vision of the project.

2.3.1 Desired usage

A new and modified usage situation was developed with the current usage situation as a basis, and the whole process from initial sleep apnoea diagnosis to successful CPAP therapy was reconsidered. This included implementing new technological solutions and deciding on where to position the product in relation to the competition.

2.3.2 Expression

The desired product expression is an important part of the concept development since it defines what the product communicates and what feelings it evokes in the users based on form, colours, composition, etc.

2.3.2.1 Value words and moodboards

Value words describing the desired expression were created to define and develop a suitable product expression. The words were selected based on the findings from the user research and benchmarking and were presented via moodboards, one for each value word. Moodboards are used to create a certain feeling, mood, message etc. (Bligård, 2015). They communicate these aspects which then can be helpful during the ideation phase and the continuous work.

The meaning of the value words in this specific project were clarified by a number of supporting words, that later turned into more tangible and concrete form drivers that could be translated into form concepts. Form drivers can be used to describe the form in order to make it easier to develop the desired design, for example use *round shapes* when designing a product that should look kind. Finally, a summarised moodboard was created, which included all three value words and form drivers as well as expression images showing how the words can be represented in products, interfaces and in general.

2.4 Transformation

From the vision, the design of the CPAP started to be visualised and take form in the transformation.

2.4.1 Physical product

A large number of form concepts were developed throughout the project, mainly by sketching. The sketching was based on the experience gathered during benchmarking and the inspiration received from the research. The moodboards, value words and the expressions further contributed to the form concept development. This phase was partly structured since the sketches first were drawn to express the value words separately and then to developed from that. The intention was to create several shape concepts with the right expression.

A few sketches were transformed into quick CAD mock-ups in order to get a feeling for how they look in 3D. It can be difficult to make quick sketches that show shapes and volume in a correct way. After this it was decided to move on with three basic shapes that fulfilled the value words, had the right expressions and were realistic.

2.4.2 Interface

The graphical user interface was initiated based on the value words, previously gathered inspiration images, benchmarking of other similar products and the usability guidelines found during the research phase.

The inspiration images were found by searching on websites like Designspiration, Pinterest and Google Images, using keywords the value words and other words related to medical device design. A large amount of images were gathered, and then reduced to a few that were put into the categories "Data", "Look and feel", "Menu" and "Symbols and icons".

The interface concepts were developed by first making some rough sketches, followed by increasingly refined digital mock-ups. Adobe Illustrator was used for the digital concepts. Since the menu structure was developed simultaneously with the interface, the concepts evolved along with the menu architecture. Various typefaces, colours, icons and layouts were tried out in the different concepts.

2.5 Product architecture

This step includes more specific design decisions, both regarding the physical design and the interface. The aim is to get more refined concepts with defined elements.

2.5.1 Physical product

The three selected form concepts were put as a base into a morphological matrix together with part solution elements which resulted in about 20 function concepts. A morphological matrix is used to generate solutions by combining functions and part solutions (Bligård, 2015). These concepts were then rated by using logic to see if the different part solutions would interfere with each other in some way. Many concepts got the highest rating and therefore the selected concepts of the remaining ones were based on our subjective opinions and the concepts' feasibility. Three concepts were chosen.

Quick mock-ups were then made using KAPA® board to get a feeling for the overall volume, shape and handling of the conceptual CPAP devices. Part solutions such as handle and humidifier position were included in the mock-ups, as well as button and display positions and fonts. The volume and dimensions were based on other CPAP devices that were included in the benchmarking.

The mock-ups were evaluated briefly by three CPAP users. The evaluation was individual where they got a feeling for the concepts. They shared their opinions about the shapes, the positioning of all the elements, typefaces and font sizes as well as different functions and solutions. The subjects evaluated the all the concepts at the same time. A form of questions (see Appendix 5) was used to have some kind of structure.

A number of design decisions were taken with the evaluation results as a basis to further develop the concepts. At this stage, mock-ups in CAD were made to allow easy modification and to be able to quickly try out different ideas. Sketching was also used to develop and elaborate ideas.

2.5.2 Interface

The entire menu structure from the reference product iSleep 25 was mapped out on a wall using Post-it notes. All menu entries, settings and options were included, which gave a good overview of the menu.

The menu structure was then modified and re-arranged since it was found that the existing menu structure and interface was not optimal for how users actually use the CPAP device, based on the user research done earlier.

The next step was to decide what physical buttons to include, as well as how to navigate the menu. The benchmarking results were used here in order to get an idea of how competing products' user

interfaces look like and what seemed to be the industry standard at the moment. Deciding on what kind of buttons the CPAP would have was done parallel to reorganizing the menu structure, as these aspects heavily affect each other.

2.6 Detailed design

Here, the details about both the physical and interface concepts were defined. These were then validated through a usability test.

2.6.1 Physical product

After evaluating the physical product concepts with the help of CPAP users, a final concept was developed. A KAPA® board mock-up was made with the purpose of giving a feeling for the shape and volume, as well as work as a model for usability tests.

The model was made more detailed than the previous mock-ups. Manufactured buttons were added, and it was filled with clay to explore the weight and balance of the product. Another purpose for this was to give a more realistic feeling for the subjects during the usability test.

2.6.2 Interface

When it comes to the design of the graphical user interface, the research on interfaces of other products was used. Several interface concepts were produced in Adobe Illustrator based on product research and the acquired insight about the user category. The value words were particularly useful in order to have a reference for the expression of the interfaces. Some example images were made for each concept, showing and describing the layout and the idea behind the concepts.

Four of them were selected and evaluated online in two different Facebook groups for CPAP users. Some key example images for each of the concepts were presented next to each other, and the users were asked to comment which of the concepts they preferred and why. There were a total of about 20 comments from both groups. After this, one concept was decided to work further on based on the comments.

The chosen graphical interface concept was developed and refined further, based on user comments gathered during the Facebook group evaluation. One of the concepts was clearly favoured over the others, and consequently this concept was the basis for the final graphical interface.

2.6.3 Usability test

A usability test was constructed in order to explore and validate both the physical design and the interface. In a usability test a real user gets to try out the design during a controlled situation (Bligård, 2015). This was done with help from real users - both patients and medical personnel. There were three patients who participated and a total of five nurses and doctors. The test had a different setup and approach for the two user groups. The patients performed the test one at the time. Due to time limits, the medical personnel did the evaluation together and everyone did not participate throughout the whole session. Since we knew that there were not going to be many test subjects, it was planned to focus on qualitative data. With few participants, a qualitative approach is usually more valuable. To get quantitative data, such as time to perform tasks, number of actions and number of errors, Nielsen (1993) suggests that at least five participants should be used. Aspects that were tested were how to navigate through the menu interface, adjust various settings, understand the feedback, and note why errors occur.

Test environment

The test environment is important when it comes to usability tests. According to Jordan (1998) the ideal environment for tests where people are supposed to interact with a prototype is in usability

laboratories. This kind of laboratory was used for the patients, where they can perform the test without being disturbed. The test with the medical personnel was taking place at the sleep laboratory.

The test followed a Wizard of Oz technique. This means that the response from the product is not real but a human have to simulate the response of it (Buxton, 2007). In this test, one person was the wizard while the other person was the test leader, who guided the test subject through the test and also took notes. The test was filmed and approved by the subjects

The prototype

The menu interface images were as mentioned created in Illustrator and then linked together in PowerPoint into an interactive menu representation. All the menus were in Swedish. The physical prototype that was used was the KAPA® board model. It was modified to fit a Samsung Galaxy S3 smartphone into it. The phone was placed inside the model to function as a display. Since a Wizard of Oz-method was used the interface was controlled through a separate computer. Its screen was duplicated to the smartphone using a program called Splashtop. When the test subjects said their actions out loud the test leader who controlled the computer changed images accordingly. For example, the test subject would turn the dummy control dial one step to the right to go down in the menu, and the wizard then changed PowerPoint slide to match the user's action.

Test procedure

The test was started by introducing the test subjects about the project and what the purpose of the evaluation was. It was explained how the test was going to proceed. The subjects were asked to think out loud and describe every choice they made. To make it easier the test leader can ask questions or encourage the subjects to elaborate their thoughts. This can help to clarify underlying causes to problems.

A few initial questions were asked regarding age, how long they have used their own CPAP device and what they usually do with it in terms of changing settings and using functions. It was considered interesting to hear how used they are to interact with a CPAP device since it might influence the test results.

The test consisted of various tasks which were based on typical user scenarios. The test leader read the scenario out load and then gave the subject the task on a note. The subjects were supposed to try and solve the tasks one at the time, such as setting a wake-up alarm and review certain sleep data. When they felt ready with a task they were asked how sure they were that they solved it correctly. This is a way of testing the feedback. There were nine tasks for the patients and six for the medical personnel (see Appendix 6 & 7).

Results

All the input gained from the test were considered and discussed. Both the interface and the physical parts of concept were modified based on these results to finalise the design.

2.7 Realisation

In the final step of the process, the concept was finalised and realised for delivery to i3tex. This is where the result takes shape and where the physical product and the interface are merged into a complete product.

2.7.1 Physical product

With the input from the usability test, the final physical design was modelled in CATIA V5. It consisted out of three main parts and was 3D-printed at Chalmers University. The printed model is

designed so that a Samsung Galaxy S3 (or similar sized) smartphone can be placed inside it and be used as a display together with a software such as Splashtop as in the usability test.

The product was also modelled in the surface modelling program Autodesk Alias in order to make a more detailed CAD model that was better suited for rendering. Some details that were added are two USB ports (one to charge e.g. a mobile phone and one for sleep data storage), a filter for the air intake, a slot for the power supply, a tube and split lines.

Finally, renderings were made with the real-time rendering software Autodesk Showcase. Plastic materials in light and dark grey were chosen for the main shape and the sides. Plastic was chosen for the tube, with a striped bump map assigned and a rubber end for air tight connection to the CPAP device's humidifier container. Adobe Photoshop was used to map a display image on the display surface, and reflections were added to make the product look more realistic.

2.7.2 Interface

The last details were modified based on the feedback from the usability test. These last changes were done using Adobe Illustrator and the final set of interface images were then imported into PowerPoint for delivery of a PowerPoint presentation containing the parts of the menu that was created for the usability test.

3. Theoretical framework

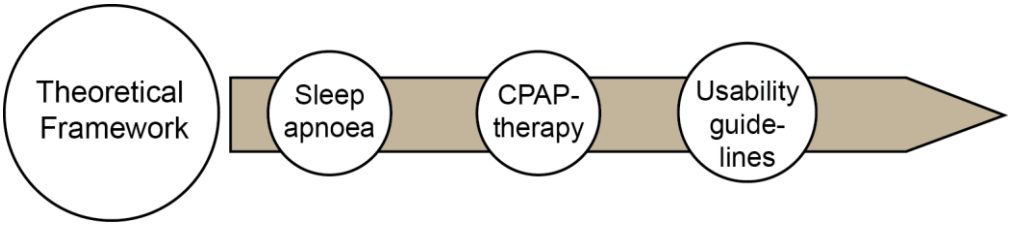


Figure 4 - Process of the theoretical framework

Relevant theory and guidelines regarding usability, medical device development and design will be gathered in this chapter, as well as theory about sleep apnoea and CPAP therapy. The theoretical framework also includes relevant standards and regulations.

Purpose: To gather necessary theory and information to support the development work.

Result: A knowledge base and a set of guidelines.

3.1 Sleep Apnoea

As mentioned in the introduction, sleep apnoea is a sleep disorder which means that a person's breathing is repeatedly interrupted during sleep many negative health effects as a result (Hjärt-Lungfonden, 2014).

3.1.1 Types of sleep apnoea

According to NIH (2009), there are three types of sleep apnoea; OSA, CSA and mixed.

3.1.1.1 OSA – Obstructive Sleep Apnoea

OSA is the most common type of sleep apnoea. This is caused by a physical block to the airflow during sleep (Figure 5). When being awake, the throat muscles help to keep the airway stiff and open which allows air to pass through to the lungs. However, when sleeping, these throat muscles relax and the throat becomes narrower. This is normal and should not affect the airflow to the lungs. But when having sleep apnoea the airway gets blocked and not enough air reaches the lungs. When air squeezes past the blockage it can start a snoring.

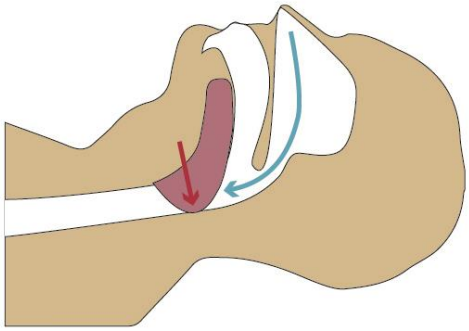


Figure 5 - Obstructive Sleep Apnoea

Reasons for the blockage can be:

- Throat muscles and tongue relax more than normal
- Tongue and tonsils are too large

- Overweight, which thickens the wall of the air pipe
- The shape of the head and neck
- Aging, which reduces the brain's ability to control the throat muscles

Everyone can suffer from sleep apnoea but these factors can enhance the risk:

- Overweight
- Above 40 years old
- Large neck size
- Enlarged tonsils or tongue
- Small jaw bone
- Allergies
- Sinus problems
- Biological

3.1.1.2 CSA - Central Sleep Apnoea

CSA is not very common. Here the airway is not blocked. This type is instead caused by the brain failing to send the right signals to the muscles that help with the breathing. Thus, the body will not make any effort to breathe. Since there is no blockage snoring dos not normally happen for people with CSA. The main reasons behind CSA can be heart disorders, stroke, and brain tumours.

3.1.1.3 Mixed apnoea

Some people suffering from sleep apnoea have a combination of OSA and CSA. This condition is called mixed apnoea.

3.1.2 Symptoms

Symptoms of apnoea can be fatigue and sleepiness during daytime. Slower reaction time, concentration difficulties, learning problems, headaches, forgetfulness, irritation and vision problems are also common. It can affect your behaviour in such ways as belligerence, moodiness and decreased drive. Due to the apnoea, some people fear to fall asleep which can lead to insomnia and depression. The disease can increase risks of accidents occurring, particularly related to driving or working (Sömnapné, 2011).

Many are not aware of having breathing difficulties during sleep and waking up several times every night. Thus, they do not know they might have apnoea and often it is others who note that something is wrong. Often, relatives also suffer from the disease but in an indirect way. Due to the snoring many have trouble of getting a good night sleep. To diagnose this disease, a sleep study called polysomnography is made (NHLB, 2009).

3.1.3 Consequences

The direct consequence of sleep apnoea is that the body and brain does not get enough oxygen. The oxygen level drops and at the same time carbon dioxide builds up in the bloodstream (Sömnapné, 2013). The heart rate will also decrease and even less oxygen is transported throughout the blood system. The body wants to breathe and the brain signals it to wake up to prevent the person to suffocate. This often happens with a snort or choking sound (NHLB, 2009) and in order to restore the oxygen levels the person takes big breaths which leads to a temporary increased heart rate. This will move you out of deep sleep and into light sleep and disturb your sleep.

Sleep is very important for a person's complete life and a lack of it can have large consequences (Sömnapné, 2013). Reduced sleep and repeated increases and decreases in heart rate, blood pressure and oxygen level in your blood, can result in stress hormones which furthermore can affect

your health. The body will be exposed to great stress when it instead is supposed to rest and recover. This is not sound and if apnoea is untreated there is an increased risk for diabetes and liver diseases, high blood pressure, heart attacks, stroke, obesity, stress, pain and more (Sömnapné, 2013).

3.1.4 Treatment

There are several ways of treating sleep apnoea and depends on the severity of the disease. The goals when treating sleep apnoea are to get a regular breathing during sleep and get rid of the symptoms. A mild apnoea can be treated by making changes in your life, such as sleeping on your side, exercising, quit smoking and drinking. If the apnoea is more severe, surgery can be appropriate, but more common is using a CPAP device (NHLB, 2009).

3.1.4.1 CPAP (Continuous Positive Air Pressure)

CPAP was invented in 1980 by the Australian physician Colin Sullivan (National Sleep Foundation, 2015) and was introduced in Sweden in 1986 (Swedevox, 2014). It was in the 1990's that CPAP really had a breakthrough in the Swedish healthcare system and since then the technology and amount of users of CPAP has increased dramatically (Gillström & al., 2014).

A CPAP device keeps the airway pressure constant during inhalation and exhalation. This is generally achieved by an air compressor that works to maintain the desired airway pressure despite the inhalation and exhalation of the patient (Antonescu-Turcu & Parthasarathy, 2010). The air pressure from the CPAP device splints the airway open (see Figure 1). This prevents the upper airway to collapse, which is what happens in patients with Obstructive Sleep Apnea (OSA) as described above.

There is solid evidence that the life quality of people suffering from OSA can be improved with the use of CPAP and bi-level PAP therapy (Barbé et al, 2010)(see below). Improvements include reduced daytime sleepiness and traffic accidents due to sleepiness. On the other hand, it can decrease venous return, increase abdominal muscle effort and provoke anxiety (Antonescu-Turcu & Parthasarathy, 2010). Further, the mask can cause skin problems such as pressure sores, and the patient can experience sinus pain and oral and nasal dryness. However, CPAP is still regarded as one of the most cost-effective and least toxic forms of medical therapy (Ayas & al., 2010).

Modern CPAP devices are compact thanks to minituralisation of electronics, but the size is often limited by the size of the air compressor that is needed to achieve the desired output pressure (Antonescu-Turcu & Parthasarathy, 2010).

3.1.4.2 Bi-level PAP

A bi-level Positive Airway Pressure device can handle variable pressure settings between the inspiratory and expiratory cycles (Antonescu-Turcu & Parthasarathy, 2010). The benefit with this technology over the CPAP is lower pressure for the patient to exhale against with lower abdominal muscle effort following as a consequence (Antonescu-Turcu & Parthasarathy, 2010). Due to a greater pressure during the inspiratory cycle, the inspiratory flow limitation in the upper airways is also decreased. In addition, the respiratory muscles are less loaded and the respiratory tidal volume (the normal amount of air volume during inhalation or exhalation) is greater compared to when using a CPAP device. However, some research suggests that the functionality in the bi-level PAP device can cause emergent central sleep apnoea (CSA) due to the patient switching from breathing spontaneously and receiving breathing aid from the device (Hedner, 2015).

3.1.5 Telemedicine

Telemedicine means "healing at a distance" (WHO, 2010) and is made possible by Information and communication technologies (ICTs). The purpose of telemedicine is to improve patient outcomes by

increasing access to medical information and care. It can be used were distance is a critical factor to exchange information for diagnosis, treatment and disease prevention, and more (WHO, 2010).

For this project, this is relevant since the design should be adapted to the users. Telemedicine has many advantages, such as the possibility of serving people in remote areas, but the biggest benefit of telemedicine is the savings of time, cost and effort for patients (Khatri & al., 2011). It reduces the need for patients to travel to appointments, staff to be available, administrative tasks and organisational work.

Another important advantage of telemedicine is that less traveling to the hospital reduces the amount of emission of greenhouse gases due to less driving. Appointments that are necessary without telemedicine, such as providing the sleep clinic with sleep data from the CPAP device, can be avoided, with a reduced negative environmental impact as a result.

3.2 Medical technology

This chapter contains definitions, regulations and other relevant information regarding medical technology in general and home health care in particular.

3.2.1 Medical devices

The definition of a medical device is very broad, but it is basically an instrument or a machine which is intended to be used for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease (ISO, 13485, 2003).

More and more medical devices are used to observe and treat people (ISO, 62366, 2007). More non-medically trained users such as the patients themselves are also increasing due to healthcare development. This requires higher demands on the device so that it is understandable for the user. Use errors that are caused by bad usability can have terrible consequences. Therefore it is important to implement a usability methodology when developing new devices and interfaces.

3.2.2 Home health care

According to the World Health Organization, "*health is a state of complete physical, psychological and social well-being, not only the absence of illness.*" (WHO, 2003). Health care in the home environment can improve the patient's overall health due to increased social interaction with family and friends and an increased feeling of freedom from not having to stay an inpatient.

Designing user-friendly medical devices is a complex task. Designing medical devices for use in home health care is an even greater challenge due to heterogeneous target consumers and home environments (Bitterman, 2010). The device might be operated by the patient him/herself, a family member, a caregiver, or a combination of them, which complicates the design process (Klatzky & al., 1996). The devices' operation modes and settings therefore has to be adapted for users with variable and unpredictable experience, background, age, etc. (Lathan & al., 1999)

3.3 Usability

The concept usability can generally be described as how easy a product is to use, but there is much more to it than that. The ISO-definition of usability says: "…the extent to which a product can be used with effectiveness, efficiency and satisfaction by specific users to achieve specific goals in a specific environment" (Jordan, 1998). Effectiveness is to what extent a goal or task can be fulfilled and thus what the result is. Efficiency is the degree of effort which is needed to achieve a goal.

Satisfaction is what the user is experiencing during usage and interaction with the product (Jordan, 1998). Usability can be seen as a fundamental condition to achieve a good experience of a product and is therefore important to have as a base for this product. The experience is affected by the properties of the different factors in the system image below (Figure 6).

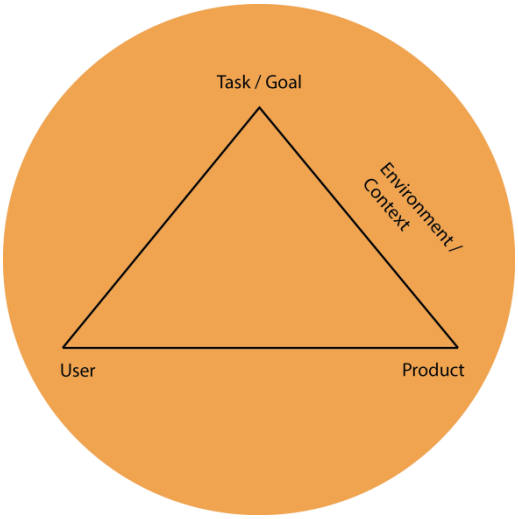


Figure 6 - Usability factors

3.4 Design guidelines

The following guidelines have been derived and summarised from various sources, such as the ICE 62366 standard, FDA (Food and Drug Administration), Patrick Jordan and a number of articles. They were used to guide the design of the CPAP device and worked as a checklist of things to consider during the process.

3.4.1 User considerations

It is important to consider that end users might have a variety of capabilities. Martin, et al. (2008) suggests that a designer should design for users with a range of:

- Physical abilities (sizes, mobility, dexterity, coordination, flexibility, strength etc.)
- Sensory abilities (vision, hearing, tactile) - consider different lighting situations.
- Cognitive abilities - consider cognitive impairment, previous experience, expectations etc.

The wide range of potential consumers increases the importance of implementing human factors (factors that occur in the interaction of a design and its user) and inclusive design principles in the design process in order to achieve a high level of usability (Martin & al, 2008). Additionally, safe and optimal use of home care devices can be restricted by varied situations in the home environments. Households are commonly non-sterile, cluttered, non-optimally lit, dusty and noisy (Lathan & al., 1999). Therefore it is important to have in mind where and how the equipment is going to be used and stored within the home environment, at the workplace, in public areas etc. Another challenge is ever changing design trends and styles, which makes compatibility with interior design in the home difficult. Home health care devices should also avoid the image of sickness and disability (Winters & Story, 2007).

Devices used in the home environment are exposed to more hazards than in e.g. a hospital (FDA, 2014). The chance for use or user error and potential harm is greater in the home, which is why risk management is extra important here. One way of minimising risk is to control access to certain device functions, such as preventing the patient from changing settings entered by the caregiver (FDA, 2014).

3.4.2 Usability

In this section, some of the most useful guidelines are presented and separated according to source.

3.4.2.1 Jordan's 10 principles for useful design (Jordan, 1998)

- **Consistency:** Internal consistency means that similar tasks are solved in a similar way within the product.
- **Compatibility:** External consistency means that tasks which are solved with the product are solved in a similar way in other products.
- **Consideration of users' resources:** When designing how a product should be operated the user's resources, such as hands and perceptions, during interaction are taken into account.
- **Feedback:** The feedback the user gets during the interaction with the product must clearly be indicated and provide meaningful information about the result of the actions.
- **Error prevention and recovery:** The product is designed so that the risk for user errors is minimized and is easily and quickly recovered.
- **User Control:** When designing the product and its interface, the user's perceived control and the actual control should be equally great. If the user has little control he should also be aware of it.
- **Visual Clarity:** The product is designed so that information quickly and easily can be read without confusion.
- **Prioritisation of functionality and information:** If the product has many features, it should be designed so that the key features and the most important information is easily accessible to the user.
- **Appropriate transfer of technology:** Making appropriate use of technology developed in other contexts to enhance the usability of a product.
- **Explicitness:** Clues given by the product's design give hints of how to use it.

3.4.2.2 FDA - Do it by design (Sawyer, 1996)

- Ensure that the association between controls and displays is obvious.
- Design control knobs and switches so that they correspond to the conventions of the user population (as determined by user studies and existing medical device standards).
- Use colour and shape coding, where appropriate, to facilitate the rapid identification of controls and displays. Colours and codes should not conflict with universal industry conventions.

- Space keys, switches, and control knobs sufficiently apart for easy manipulation. This will also reduce the likelihood of inadvertent activation.
- Make sure that controls provide tactile feedback.
- Design procedures that entail easy-to-remember steps.

3.4.2.3 Handbook of Human Factors in Medical Device design – Software User Interfaces (Weinger & al., 2010)

- **Focus on User Tasks:** Make user interfaces task oriented, allowing users to quickly access options, take action, and confirm the results.
- **Provide User Guidance:** Provide step-by-step procedural instructions rather than leaving the user to infer the proper operational sequence from an array of options.
- **Menu Depth:** Generally, people prefer menu systems that are relatively shallow, requiring the user to navigate no more than two or three levels deep in a menu hierarchy to reach the desired content/options.
- **Menu Breadth:** Generally, people prefer menu systems that do not have an overwhelming number of top level options.
- **Alignment Grid:** Generally, screen content should ascribe to an alignment grid that gives the screen a consistent, orderly appearance.
- **Legibility:** Select a font style, size, and resolution that users will be able to read correctly during the full range of use scenarios, including high-workload and time-pressured periods.
- **Text Style:** On-screen text should have a simple style that is optimized for legibility. Normally, this means using sans serif fonts.
- **Text Size:** The recommended character size of critical information is 1/150th the viewing distance. The recommended character size of important, but noncritical information is $1/300^{th}$ the viewing distance.
- **Figure-to-Ground Contrast:** Text and its associated background should have sufficient contrast to ensure readability. An effective test of the legibility of coloured pairings, particularly for people with impaired colour vision, is to check the pairing when displayed in grey scale.
- **Text Capitalization:** Using ALL CAPITAL LETTERS can draw attention to important textual information. Capitalization can also be an effective way to indicate the top level of a set of hierarchical labels.
- **Use of Graphics:** Graphics can be used to convey more information in less space than required by text.
- **Screen Density:** Screens tend to look best when 20% to 30% of the total screen area is blank**.**
- **Units of Measure:** Data entry fields should include units of measure (e.g., “psi,” “mmHg,” and ”bpm”) of the associated parameter.
- **Nonreliance on Colour:** Considering that about 10% of some adult populations have impaired colour vision, colour should not be used as the sole means of coding information.

3.4.2.4 Standards and regulations

The ISO 62366 (2007) is an international standard to provide safety in medical devices. It describes a usability engineering process and provides guidance on how to implement and execute the process. This process is based on regular usability methodology, but is more focused to minimise use errors and accompanying use-associated risks.

This is a summary of how the process of the usability standard looks like.

1. **Specify the application of the medical device**
   In this stage, the most important characteristics about the device usage situation are identified:

- Intended medical indication
- The Operating principle, meaning how the device's mechanism works.
- Users and their characteristics
- Aspects to list can be: age, gender, linguistics, cultural, education and disabilities. Some characteristics might affect the usability
- Context of use and its conditions. Specific situations can also change where the demands also change. E.g. storage, transport, day/night, home, hospital, stressful situation, one-time users etc.

2. **Identify the device's frequently used functions**
   The most frequently used functions which involve user interaction with the medical device should be identified. The usability regarding these functions is the most crucial since they are used the most.
   Identify hazards and hazardous situations related to usability
   In this stage the characteristics of the device that could impact safety are identified. A risk analysis can be made to identify and specify the risks. Methods such as CW, PHEA and FMEA can be used here.

3. **Identify the device's primary operating functions**
   The primary functions are those functions that relate directly to the safety of the device and also include the frequently used functions identified earlier. Identifying common and worst-case scenarios can be done to put the functions into a context.

4. **Develop the usability specification**
   In this stage, the specification of requirements which involves the usability aspects is created. The test users and the test use scenarios are also defined. The specification should be used as a framework when designing the device.

5. **Design and implement the user interface**
   With the usability specification as foundation the user interface should be designed.

6. **Verify the user interface design**
   The design should be verified against the requirements in the usability specification and redesigned as necessary.
7. **Validate the usability of the medical device**
   In the final stage, the device is tested to ensure that the user requirements are met. The test should be carried out under actual or simulated conditions, together with actual users. Validation needs to be carried out by representative people not directly involved in the design of the user interface. This can be done through a usability test.

3.4.3 Colour in medical devices

Colour is a powerful tool that can be used to make products more intuitive and user-friendly, and thereby increase their functionality. According to Forma Medical Device Design (Forma, 2015),

colours in medical devices should be used to increase functionality and encourage a desired emotional response in the user.

Colour plays an important role in users' emotional response when interacting with a product (Forma, 2015). White is associated with sterility and purity, which is why it often is appropriate in medical environments. However, it can seem too sterile and is heavily used in the industry which makes light grey a good alternative to stick out. Another reason for why light colours, particularly light grey and white, are frequently used in medical devices is that it implies that they are kept clean and sterile, since dirt will show easily (Forma, 2015). Blue and green are often perceived as being calming and reassuring. Soft tones of these colours are therefore common as accent colours in medical devices.

3.5 List of requirements

A summary of the requirements that were found in this chapter is presented below.

Table 1 - Requirements from theoretical framework

Requirement	**Origin** (user, external)	**Method** (Observation, interview, facebook, questionnaire, ISO, research...)
Must be possible to lock on constant pressure and pressure intervals	To make the treatment effective	Procurement requirement
The pressure settings must be lockable	To not let patients change pressure	Procurement requirement

3.6 Main conclusions

- Sleep apnoea is a very common medical condition, and many suffer from it without knowing it.
- CPAP therapy is an effective treatment that works well for most patients and does not require any surgical operation.
- There are many useful usability guidelines to support development of medical devices.

4. Exploration of the current situation

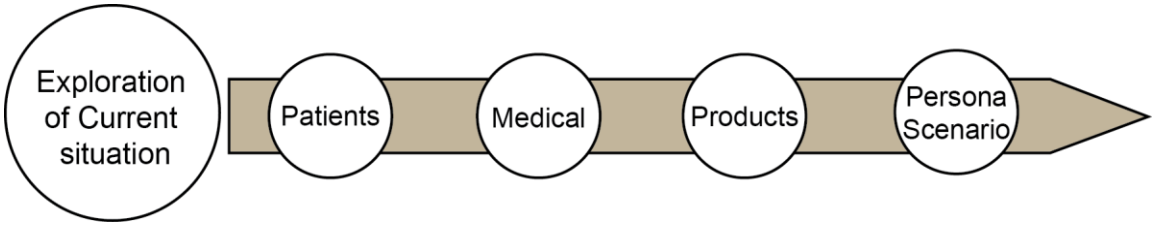


Figure 7- Process of exploration phase

The current situation was investigated to get an understanding of who the users are and the context in which the CPAP devices are handled and used. In this chapter the result of the exploration phase is presented.

Purpose: To get a general impression of the market, the use of CPAP devices and the current usage context for patients and nurses interacting with the products.

Outcome: A thorough understanding of the users based on the findings of the current usage circumstances. Examples of typical users are presented in form of personas and scenarios.

4.1 Users

As mentioned earlier, the two main users that have been identified during the research phase are patients and medical personnel (nurses and doctors). It is these two groups that the project has been focusing on, even though there are other minor user groups such as relatives, partners, home care personnel etc. They have been left out of the scope since the two main end users have the most relevant opinions about CPAP treatment and devices. It was also found that opinions differ between patients and medical professionals since the patients have a more personal relation to the device and the nurses a more professional.

4.1.1 Patients

This chapter covers the use of CPAP devices from the patients' perspective, from prior to diagnosis, via accustomisation, to use behaviour and successful CPAP treatment. This process is a result from the interviews with both patients and medical personnel.

4.1.1.1 From diagnose to successful treatment

It is important to map the process from when a patient is diagnosed with sleep apnoea until the patient is sleeping well with the help of a CPAP device to get a good overview of the current usage situation. The steps identified in a typical process at the sleep clinic at Sahlgrenska are the following:

Prior to diagnosis

For many CPAP users it starts with their partner experiencing difficulty sleeping due to loud snoring or noticing their partner frequently waking up with shortage of breath. It is also common for the person with sleep apnoea to contact their primary health care centre after feeling very tired during the days and never feeling fully rested, or needing frequent toilet visits during the night. The caregiver at the primary health care centre gives the patient a referral to a sleep clinic to undergo a sleep study.

Sleep study and diagnosis

A sleep study is a monitored sleep test to evaluate the sleep. It is done in order to analyse sleeping and breathing patterns and other sleep related problems. The study can be made at home or at a sleep lab. It may take some time before the patient gets to do a sleep test. For example, in Västra

Götalandsregionen it can take up to two years, depending on the patient's medical condition (Hedner, 2015). During the sleep study various measurements are registered, including movement of chest and stomach, body position, oxygen level, heart rate, air flow, snoring and number of apnoeas (Sahlgrenska, 2010).

If the doctor decides to treat the sleep apnoea with a CPAP, it should be tested by the patient during one night. This test is called a titration study and is done in order to calibrate the machine in relation to the patient's condition (SleepEducation, 2014). The purpose is to find the optimal air pressure to prevent the blockage in the airways. However, it was found during a visit to a local sleep clinic that the titration study is rarely performed this thoroughly. Instead, at this clinic, an information meeting is held by the nurse, followed by a short mask fitting test where the patient gets to try the different mask types in order to find the one that fits the best and has minimal leakage. The pressure is pre-set by the manufacturer and is rarely changed, unless a doctor has ordered otherwise. Many CPAP machines today have automatic pressure adjustment, and they are typically pre-set to change between a minimum and maximum value depending on the patient's breathing (Hedner, 2015). After the handout of the CPAP device, the patient takes it home to try it out for a brief period of time.

Accustomisation

It is recommended that the patient gradually increase the CPAP use, starting with an hour or so per day to get used to it more easily. The background research has shown that many people express difficulty with getting used to sleeping with the CPAP, especially the mask. Some patients quickly adapt, while for others it may take several weeks or months. If there are any issues preventing successful CPAP treatment, the patient might need to re-visit the sleep clinic. Common reasons for re-visits include getting another mask, changing the pressure settings or add a humidifier.

Roughly 30-50 % of the patients trying the CPAP treatment never get used to sleeping with it (Hedner, 2015). The most common problems are related to the mask, for example that it feels awkward to sleep with. These patients can try other treatments, such as oral appliances or surgery. However, mask related issues and alternative treatments will not be addressed in this project due to the set scope.

After three months there is a standard follow-up procedure to see how well the treatment is working. This applies to all patients. The patients are all contacted over phone where the nurses ask about the patients' opinions regarding the initial period of therapy. They ask if the patients believe the treatment is working, if their sleeping has improved, if there are any side effects. It is also wanted to know how many days it has been used during the previous few months, the average usage time (minimum of 4 hours per day, which is the requirement for continued therapy) and if the AHI (apnoeas per hour) has decreased. If the therapy is not working the patient can wait another 3 months for a new evaluation since it is common that patient has not gotten used to the therapy. The patient can also drop in to the clinic for various adjustments. These adjustments could be wrong pressure, the mask does not fit, a humidifier is desired or a different treatment is needed.

Procedure of using the CPAP

When it is confirmed that the CPAP therapy is successful, the patients take the device home and continue the treatment. From this point it is the patients' responsibility to contact the clinic if any complications occur or if any spare parts to the machine are needed. In other words, the clinic has no insight of how well the treatment proceeds.

According to the data collection done initially, CPAP users typically follow this daily usage procedure:

- fill up the humidifier (if having one) with either distilled water or cooled boiled water
- start the pre-heater
- perhaps adjust the humidity level depending on season
- connect the tube (if put away during the day)
- put on the mask (usually while sitting)
- start the machine by pressing a button or breathe into the mask and the machine will automatically start
- turn off the light and sleep (for some users the pressure ramps up to the set level)

The patients do not change the pressure settings on their own. This is done by a nurse prior to distribution at the sleep clinic. Some users check the AHI, hours of therapy last night and leakage in the morning. Some can see it on the display of their machine, while others have a computer program and load the data via a memory card.

Home environment

The home environment is an important aspect to consider since the device is supposed to be used at home, mostly in the bedroom. Therefore, a depiction of the context was made. These pictures of various CPAP-setups come from patients at the Facebook-pages and test subjects who agreed to share them (Figure 9 - Figure 11).

Figure 9 - Lamp on top on CPAP

Figure 8 - CPAP hidden, separate alarm clock

Figure 10 - CPAP on floor

Figure 11 - Tube turned towards bed

The first thing that can be seen is that the CPAP devices are placed on the bedside table or below (floor, shoe box etc.), meaning that the patient most likely sits or lies down when interacting with it. The device can also be placed on each side of the bed depending where the user sleeps. In several cases there are a lot of other objects, besides the CPAP device, on the bed side table, such as lamps and alarm clocks. In figure 6 and 7 the tube is directed towards the bed which lead to the CPAP device's front is turned away from the bed. In figure 5 the CPAP device is hidden in a box, which, according to the interviews made, is significant for many other users. The device is also often put against a wall.

4.1.1.2 User studies

Various data was gathered from interviews and questionnaires to further get to know the target users and their usage behaviour.

Meeting users

The visit to the annual meeting of the local sleep apnoea association in Gothenburg gave a lot of good information regarding the patient user group and what kind of people a CPAP device should be designed for (Figure 12). It was noticed that most of the people at the meeting was overweight and over 50 years old. They were typically not very interested in technology and changing settings and reviewing sleep data. Many of them used older mobile phones without touch screens and some used glasses and had poor eye sight. When asked about their current CPAP device, they could barely tell what brand it had and it was clear that they represented the type of user who simply presses the start button and go to sleep.

Furthermore, it was asked about what properties that are important for a CPAP to have. The general impression was that it should be small, subtle, quiet and reliable.

Figure 12 - Meeting CPAP users

Questionnaires

The questionnaires that were sent to people on CPAP therapy, through email and Facebook groups, provided a good view of use behaviour and opinions about their machines. Some conclusions that could be drawn from the answers are:

- Most users bring their device when traveling, especially if it's more than a couple of days, since they don't want to risk all complications associated with sleeping without it.

- Some users feel embarrassed and avoid talking about their CPAP with friends since they sometimes are met by jokes. Other users don't hesitate to talk about it and let others know that it has changed their life.
- Most users leave the CPAP device on their bedside table (or similar) during the day, but it's common to put away the mask and tube.
- The patient is more concerned with how it feels to sleep with a pressurised mask, and how well it fits, than the functionality of the CPAP device itself. The patient rarely changes any other settings than the humidity level.

Observation of Facebook groups

The Facebook groups were continuously monitored and a lot of input came from this. It was clear that there are people who are interested in CPAP treatment and statistics about it. Many questions are asked which indicate that they want to learn more and that it is difficult to understand their treatment and device. This could be about how a certain setting is adjusted, what a specific word means or if a value is good or bad. It is clear that there is a great insecurity among the patients. Many problems about masks, keeping the device clean and complaining that they are embarrassed about it, were posted as well.

Every day in the feed there were pictures of people who post how they look like with their mask on. They often looked tired as a consequence of their sleep apnoea. This was a good way of further understanding the demographics of the patients, which were mostly men over 50. Many also post how well they have slept or not slept. There is generally an encouraging atmosphere where people tell others to keep going and give compliments of how well they are doing.

4.1.1.3 User persona & scenario

To get a more tangible situation of the users a persona was made and put into a scenario.

Figure 13 Persona Kent Jonsson (Santello, 2015)

Kent Jonsson (Figure 13) is 56 years old and lives in Borås, about 60 km from Göteborg with his wife Gun, 49. They live in a medium size villa in a quiet area and have a small garden with a veggie patch where they spend a lot of their spare time. Kent works as a biology teacher at the local high school. For several years, Gun had difficulties sleeping at night because of her husband’s heavy snoring. Kent

is overweight, and has always had a high BMI. The last decade his weight problem has gotten worse because of a knee injury that limits his capabilities of exercising, which he did frequently before the injury.

A few years back he experienced increasing daytime drowsiness. He was always tired and rarely felt fully rested. This started affecting his job since he found it more and more difficult to concentrate for longer periods of time, and he would easily fall asleep during the lunch breaks. He also dosed off while watching TV in the evenings and his wife noticed that he got increasingly annoyed and seemed generally unsatisfied with his current situation.

This eventually led to Kent contacting his Primary Health Care Centre where he explained his current situation and got a referral to the sleep clinic at Sahlgrenska University Hospital in Göteborg. It took almost a year before Kent got an appointment with a nurse at the clinic who decided to do a somnography test to see if he had sleep apnoea. He got measurement equipment with him to take home and instructions on how to setup the equipment the following night. The day after he went back to the clinic with the equipment and the data was analysed at the clinic. The data showed an AHI of 34 and he was diagnosed with Obstructive Sleep Apnoea, OSA. Within three weeks Kent got called for an information meeting and CPAP distribution at the clinic.

At the meeting, a nurse named Majt informed him and four other OSA patients about sleep apnoea and CPAP therapy. She showed them what causes an apnoea, how CPAP keeps the throat from collapsing as well as the different types of masks. Kent then got a brief run-through of how the CPAP device works, how to start it, use the ramp function and how to review basic sleep data. He then got to lie down and rest for a few minutes with each mask to feel which of them that fit the best. Kent chose the full mask since it had minimal leakage and his ResMed S9 Auto was kept at the pre-set pressure value of 8-12 cm H_2O.

The first few nights sleeping with the CPAP and mask, Kent did not get many hours of sleep. He felt really awkward with the mask and felt embarrassed even with his wife. He found it difficult to get used to the airflow in his face and he felt very dry in his nostrils in the mornings. After two weeks of trying, he went back to the clinic for a drop-in meeting with a nurse to get the mask replaced. He got the type with nasal pillows to try, which worked much better. He also got a humidifier to avoid getting dry nostrils. After three more weeks he could finally sleep for several hours in a row and felt more rested than for many years. After three months of using CPAP nightly he could sleep almost a whole night without waking up, and his AHI was down below 1. He feels as if he has got a new life and is happier and more energetic than for years, and he can do his job as normal again and even has energy left for the garden.

4.1.2 Medical personnel

The other main user group, hospital personnel (nurses, doctors), at the sleep clinics are important users of the CPAP device, since they are handling these devices on a daily basis and do most of the setup and calibration to fit the different patients. The nurses do most of the interaction with the CPAP before and when a patient for the first time receives the device.

4.1.2.1 Interviews

During the first visit at the sleep clinic at Sahlgrenska hospital, an hour long interview was held with Jan Hedner, professor in sleep medicine (Figure 14). The interview was done during the research phase of the project and gave valuable input on the history and development of CPAP devices. It also provided a medical perspective on new technologies and the procedure and management of CPAP

distribution to people suffering from sleep apnoea. Most of the information gathered from this interview can be found in chapter 3 - Theoretical framework.

Figure 14 - Meeting with Jan Hedner

4.1.2.2 Observations

Every time a CPAP is handed out to a patient there is first a brief information session about sleep apnoea and CPAP therapy. This is done together with other patients. After the common presentation about sleep apnoea and CPAP therapy in general the patient goes into a room together with a nurse to try out a mask and show how the CPAP device works.

It was noticed that there was a lot of information in a short amount of time for the nurse to communicate and for the patient to take in and understand. The observed patient has sleep apnoea and is exhausted which makes it difficult to understand everything the nurse says. The nurse also seemed stressed due to heavy workload. Therefore it is important that the CPAP device is easy to explain and understand. The meeting between a nurse and a patient is described more in detail in a scenario in 4.1.2.4 below.

At the sleep lab they were currently using three different brands of CPAP devices - ResMed, Philips and Fisher & Paykel. It is partly the nurses who have decided this based on opinions from patients and their own personal experience. The Västra Götaland region has established a document with procurement requirements for acceptable CPAP devices in hospitals and such. Which device that is handed out to patients at the sleep clinic is determined by what models that currently are available.

The nurse was asked about how a good CPAP should be and the answer she said was simple. No extra functionality, such as a built in alarm clock or lamp, is necessary. She thinks that a CPAP is made for treating the patient.

4.1.2.3 Questionnaire

The questionnaires that were handed out to four nurses gave valuable input on what medical professionals think about different products, what settings they change and when, and what is most important regarding interaction and usability. Some conclusions that could be made (with the small amount of answers in mind) include:

- The CPAP model that the nurses use most often is ResMed S9. They regard it as easy to use and a benefit is that it is consequent with ResMed's ventilators.

- Most common settings to adjust are:
    - Pressure
    - Turning off autostart
    - Fitting mask (setting for testing leakage on a new patient, 10 cm H_2O pressure)
- Most important when interacting with the menu is that it has a simple interface and good overview.
- Less important for the interface is that it is aesthetically appealing and that it's quick.
- It is somewhat important that it is difficult to do wrong and that you get feedback when doing right.
- They are overall very positive towards telemedicine since it would allow them to help more patients and save time. They want to access the data via the web and want a good overview of the data with the possibility for reviewing more details if needed.
- They are not as convinced when it comes to changing settings from a distance. Has to be totally safe so that they know that the settings are correct. Some would like to change pressure settings from a distance.
- Opinions about products from CPAP brands:
    - Breas - most negative. Poor quality of humidifier, complicated data treatment, difficult to use for patients
    - ResMed - overall positive. Easy for patients and clinicians, reliable, data easy to understand, good quality.
    - Respironics - Easy to use for patients and clinicians, good quality, looks good, sometimes difficult to treat data.

4.1.2.4 Nurse persona & scenario

A persona was created to communicate how a typical user within the medical staff user group looks like in an easy-to-understand way. A scenario of a typical CPAP distribution procedure is also included.

Figure 15 - Persona Majt (Pixabay, 2015)

This is Majt (Figure 15). She is on her way to the hospital where she works as a nurse. She is 48 years old and has been working as a nurse for 19 years. Her position at the hospital is at the sleep laboratory, where people come to receive help against sleep disorders. Majt enjoys helping people and it is therefore important for her to take good care of the patients. At the same time, many want help which leads to shortage of time and limits her potential of helping as much as she would like to.

The work procedure is similar from day to day. Today she is going to hand out CPAP devices to new patients. First she holds an information meeting about sleep apnoea and what the disease actually is. This is a common information meeting and there are currently five people listening to her.

After the meeting Majt takes one of the patients, a man, into a room to introduce the CPAP device which is going to treat the disease. The other patients are placed in different rooms and talks alone with a different nurse. Discretion and personal space is important for her and the patient. On her way to the room, Majt picks up the bag containing the CPAP and its different parts. In Västra Götaland region, the CPAP devices are handed out for free.

She is a little stressed since she has to prepare for the night's sleep study. This is nothing unusual, because being a nurse is very stressful. There are limited resources and many patients who should get a comfortable visit.

Inside the room there is a bed where she asks the patient to sit down. She unpacks the CPAP on the bed and introduces all the parts. The CPAP device itself is placed on a small table next to the bed. Majt stands in front of the patient and the table is placed between them. The device's display is situated on the top of the device so she has to tilt it up in order for both the patient and her to be able to see it at the same time. She keeps holding it like that with one hand and navigates the menu with the other while she keeps explaining. The physical buttons also make it easier to handle the device without looking.

Majt turns the machine on and enters the regular patient mode. Each top menu is shown and explained. She shows how to start it, how to navigate and also what is important to think about when using a CPAP. This could be to the importance of cleaning the device or using the device as much as possible even if it is uncomfortable in the beginning. However, she does not have time to explain everything. Since the patient has not started the treatment yet, he is probably tired and has troubles of taking it all in. There is lots of new information presented in a short amount of time so therefore it is important for Majt to be very structured and clear when showing the CPAP's functions. It is also important for her to express trust and kindness to make her patients feel comfortable and safe.

The hospital uses three different CPAP machines. She likes that these are similar when it comes to functions, navigation and information presentation. Majt's job involves a lot of show and tell and she appreciates when it is simple. A simple product will make it easier to explain how it works and will contribute to give the impression of being a professional when interacting with the patients. It will save time which will give her more time to explain as much as possible. She wants the patient to feel safe and well-informed when leaving.

An important step is to try out the mask which the patient likes the most and fits the best. Majt gives the first mask to the patient and helps him to adjust it. She enters the clinical mode in the CPAP interface and starts the machine to let the patient try it for the first time. The air flow is started at a low pressure since the patient never experienced this before. It is important to see if the mask leaks anything when attached to the patients head. Majt usually leaves the room for a few minutes in order for the patient to easier be able to feel how the mask fits. The same procedure is done with the other mask. The device should be able to show if the leakage is acceptable or not. The fitting process is tested at a pressure of 10 cm H_2O. If the patient is having trouble deciding what mask to choose, she presents some pros and cons about them and also what other patients usually prefer.

When Majt has gone through everything she packs the device back into the bag and gives some final information about practical issues, such as travelling with it, going through security at airports and

how to get spare parts. She also tells him that they will contact him in three months to see how the treatment is working out. She likes to have good communication with her patients.

After three months Majt calls the patient for the follow-up. She asks him over the telephone if he sleeps better and if there are any problems. According to the regulations she also has to get some statistics about the usage of the machine. She asks him to enter the sleep report menu. She guides the patient through the menu and asks him to read some numbers back to her. The information is used to see if the treatment is actually working or if any adjustments have to be done.

After this it is the patient's own responsibility to use the CPAP device. Majt and her colleagues cannot keep track if everyone is using their devices as they are encouraged to. This has led to that many CPAP devices are not used which means that much money is spent in vain.

4.2 Products

In this section, the reference product Breas iSleep 25 is studied in detail. Additionally, the current competitor landscape is explored in terms of form, function and expression.

4.2.1 Reference Product - Breas iSleep 25

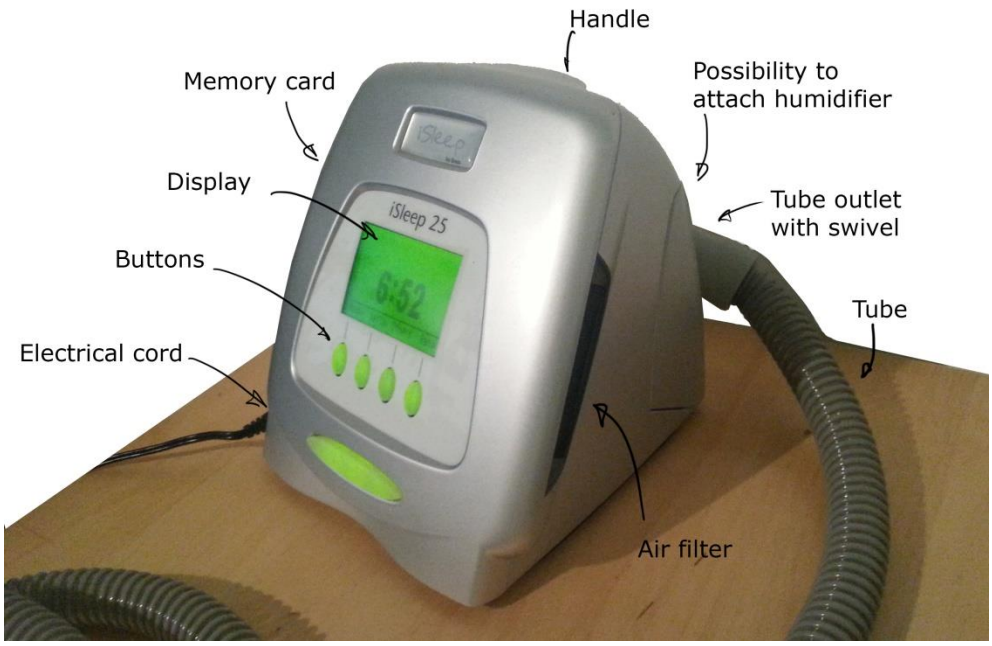


Figure 16 - Breas iSleep 25

Breas Medical AB is a product development company focusing on home care ventilation and sleep therapy products (Breas Medical AB, 2004). Breas was founded in Gothenburg, Sweden in 1991 and was recently acquired by the American investment firm PBM Capital.

They have several ventilators and CPAP devices, but their bi-level CPAP called iSleep 25 will be used as a reference product in this project (Figure 16). It was released by Breas in 2004 and is still in use in some sleep clinics today.

The "i" in iSleep stands for intelligent, which points to the in-built functionality of automatically adjusting the pressure levels depending on the patient's breathing pressure (Breas Medical AB,

2004). It has manual settings for the pressure applied during breaths triggered by the patient itself as well as the pressure applied between patient triggered breaths. It also has a ramp setting which enables the patient to set the device to gradually increase the pressure from a start value to the desired pressure level. Ramping makes it easier for the patient to fall asleep and for new users to get used to the CPAP therapy (Breas Medical AB, 2004).

It can be used for all three types of sleep apnoea (obstructive, central and mixed), both in a clinical setting and in the home (Breas Medical AB, 2004). A humidifier can be attached to the back of the CPAP to humidify the air to avoid nasal dryness.

There are two different user modes - home and clinical. The home mode is intended for patients and has limited capabilities to change advanced settings, while the other mode is for clinical personnel and has all settings unlocked. A break-down of the different menu systems including the setting ranges are shown in Figure 17 and Figure 18 below.

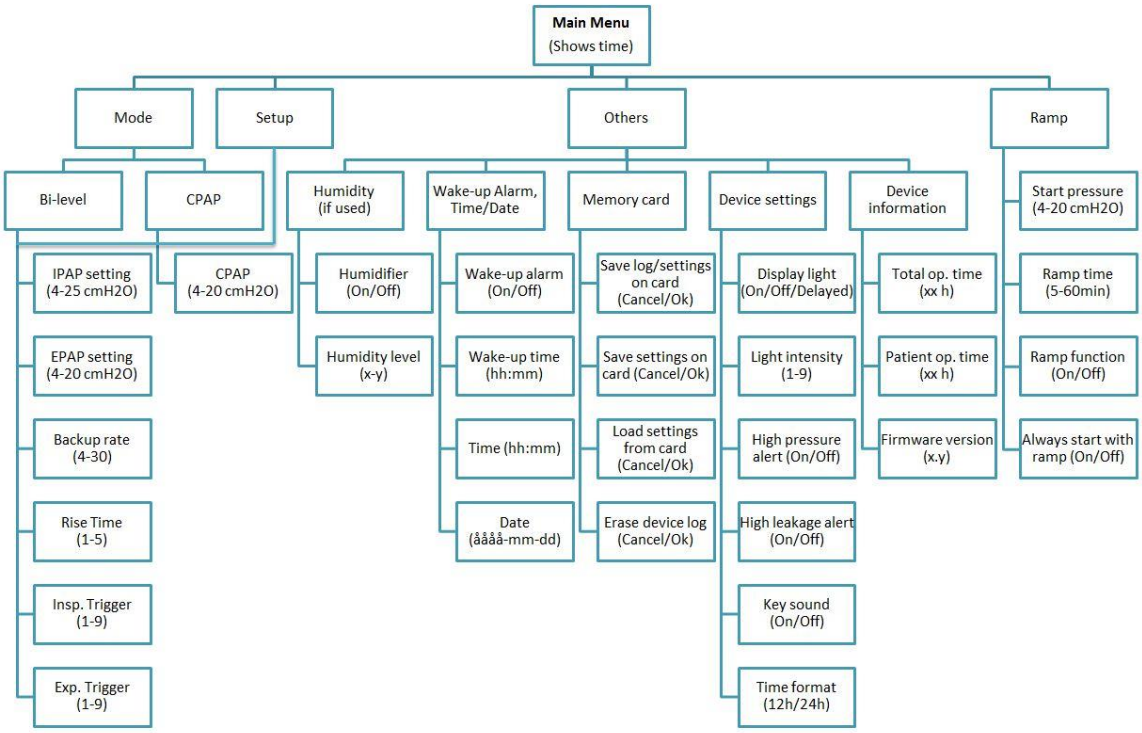


Figure 17 - Clinical mode

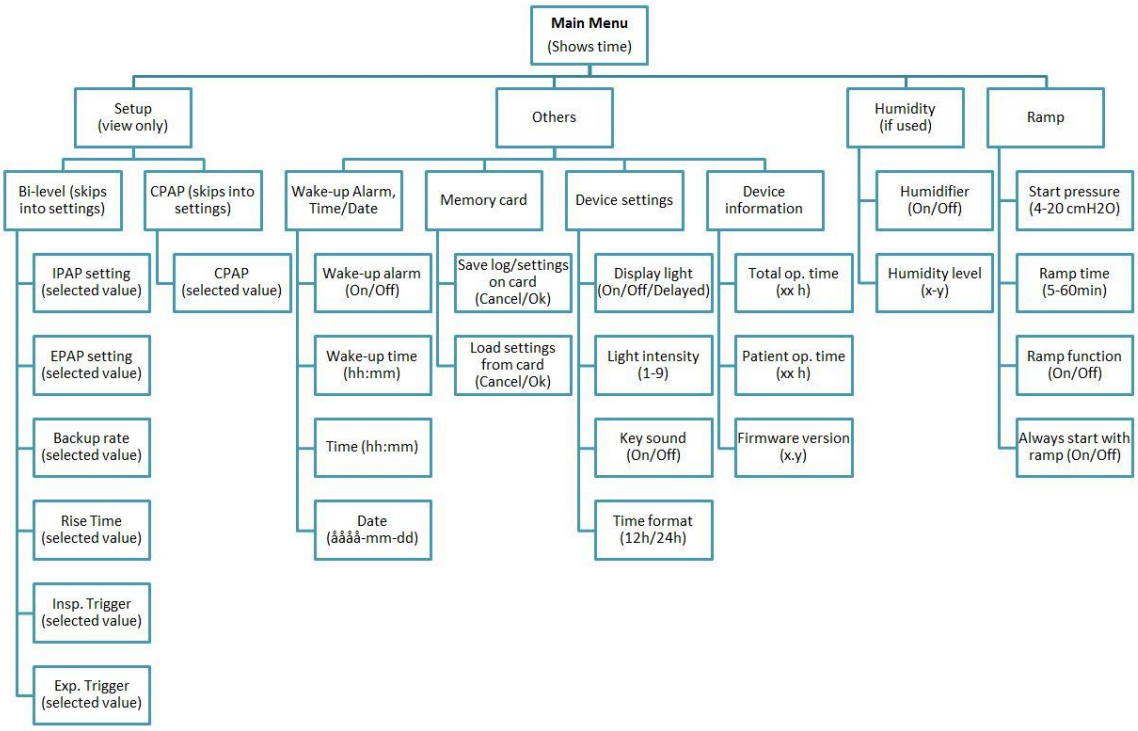


Figure 18 - Home mode

There are some functional differences between the two modes but the only functional differences are that in the Home mode, pressure settings cannot be changed. When entering the Setup menu the patient can only see the current pressure settings, but is unable to modify them.

The clinical mode can be unlocked by holding the two middle buttons for a few seconds. Apart from the pressure settings being available, the main menu looks slightly different, with the menu entries *Mode, Setup, Others* and *Ramp* compared to the Home mode's *Setup, Others, Humidity (if connected)* and Ramp.

The iSleep has a separate button for starting CPAP therapy. When holding down the button for 1 second the air flow starts. If the button is pressed quickly while the air flow is running the device enters snooze mode which is a lower air pressure. To turn it off the air flow the button is held down again. The buttons and display have a yellowish background light, which makes it visible during dark conditions.

The iSleep 25 is designed by the industrial designer Stephan Söderholm. A meeting was arranged to get his perspective on how to design a user-friendly CPAP device. He explained how his development process looked like and shared some tips on what to think about.

4.2.2 Benchmarking

The result of the benchmarking about other products, their functions and aesthetically expression is described below.

4.2.2.1 Functions

From the benchmarking some common functions used in CPAP devices were found. Most devices are navigated through buttons or a control dial. A control dial is a combined navigation and selection element. It is rotated to navigate the menu and pressed to select menu items. An example of such a

control dial is shown in Figure 19. Only a few were encountered were a touch screen was used. Some devices can also be connected to a mobile phone and is controlled through an application.

Figure 19 - Control dial

Most of the newer models had autostart, which means that the air flow starts when the patient starts to breathe into the mask. It was also possible with several devices to log and view sleep data, such as number of apnoeas per hour, hours used previous night and if the values are good or not good.

When it comes to the humidifier there are some models where it is integrated and some where it is attachable. For example, on the iSleep 25 the humidifier is exchangeable which means that a part of the CPAP device is removed and then exchanged with the humidifier.

4.2.2.2 Form Analysis

A few CPAP devices were explored by looking at pictures of them and analysing their form and expression. Some of them could be studied in physical form, at the sleep lab at Sahlgrenska and at the annual meeting of the local sleep apnoea association. These studies gave an idea of what other products express and worked as input when discussing the form and expression of the product being designed. These analyses were entirely subjective.

Figure 20 - Breas iSleep 25

Breas iSleep 25 (Figure 20**)**
It feels playful and friendly due to round shapes and light colour and playful logotype. It does not feel qualitative because of wide split lines and a plastic feeling, and there are a lot of different radii and shapes. It reminds of a clock radio because of the upright design and large clock that is always visible.

Fisher & Paykel ICON+ (Figure 21**)**
Clean and professional look thanks to large surfaces and simple design. Sleek and qualitative expression given by consistency and even split lines, feels like an elegant product. It reminds of an OBH Nordica toaster or a speaker rather than a medical product. The control dial looks like a volume dial. It has a stable and robust look both due to the cube-like shape and the dark colour, also that it's larger at the base than at the top. Silver and black works well to create a professional look.

Figure 21 - Fisher & Paykel ICON+

Philips REMstar System One (older / newer) (Figure 22)
The brick-like design makes it look stable and sturdy, and the dark colour adds to the feeling of stability. It looks a little "plasticy" and bulky but still quite consistent and simple. The old version looks more sleek and elegant than the new one, since the new version has an elevated part in silver which makes it look more complex. The older one is not the most professional nor the most playful, not the most qualitative nor the cheapest looking, but it looks simple to use and inviting rather than complex.

Figure 22 - Respironics REMstar (old/new)

ResMed AirSense 10 (Figure 23)
It looks well-designed and modern, and looks more like a consumer product (e.g. speaker) than a medtech product. It looks fairly professional due to its design and shape with interesting textures and split lines, but looks friendly and simple and inviting at the same time. It is not the most stable-looking CPAP, but it doesn't look like it will tip over if you push it, since it has a low and wide shape rather than tall and skinny. Button to the right is adapted for right-handed people; a left-handed user would cover the screen with the hand.

Figure 23 - ResMed AirSense 10

DeVilbiss IntelliPAP (Figure 24)
It looks bulky and very medical, yet friendly and playful due to round shapes and large radii and colourful humidifier canister. The medical feeling of it is mostly due to the white grey colour. It reminds of a foot bath or a copying machine. It looks quite cheap since the shapes and split lines are not very homogenous. It doesn't feel inviting and it looks like it's made for professionals rather than consumers since the symbols on the buttons look complicated and designed for clinical staff.

Figure 24 - DeVillbiss IntelliPAP

ResMed S9 (Figure 25)

This CPAP deice looks like an old cassette player rather than a medtech product and feels both playful and professional. The round shapes make it look more playful and the sharp edges more professional. The large and sweeping surfaces contribute to its professionalism. Its rectangular and short form makes it feel stable and together with the neutral colour also a little subtle. The shiny interface might give it a plastic and cheap look. Even though it is kind of clean, it looks a bit advanced due to extra features.

Figure 25 - ResMed S9

Breas Z1 (Figure 26)

This device is smaller than the other ones and reminds of a sound recorder or alco-meter. Bright colours make it feel fresh and clean. The holes indicate that there is a function of something going in or out, like sound or air. The broad split lines make the product feel divided, but at the same time homogenous since it is the same everywhere. Its round shapes make it feel playful which also contributes to it standing out. Its few elements make it feel simple, though the whole form is kind of complex. The compact form results in a stable feeling.

Figure 26 - Breas Z1

4.2.2.3 Competitor matrices

Several matrices were made in order to further explore the competitor landscape in terms of what they express. The values on the Y axis were in all matrices "Consumer product" and "Medical product", with X axles like "Simple" and "Complex" or "Playful" and "Professional". An example of such a matrix is shown in Figure 27 below. The rest matrices can be found in Appendix 8.

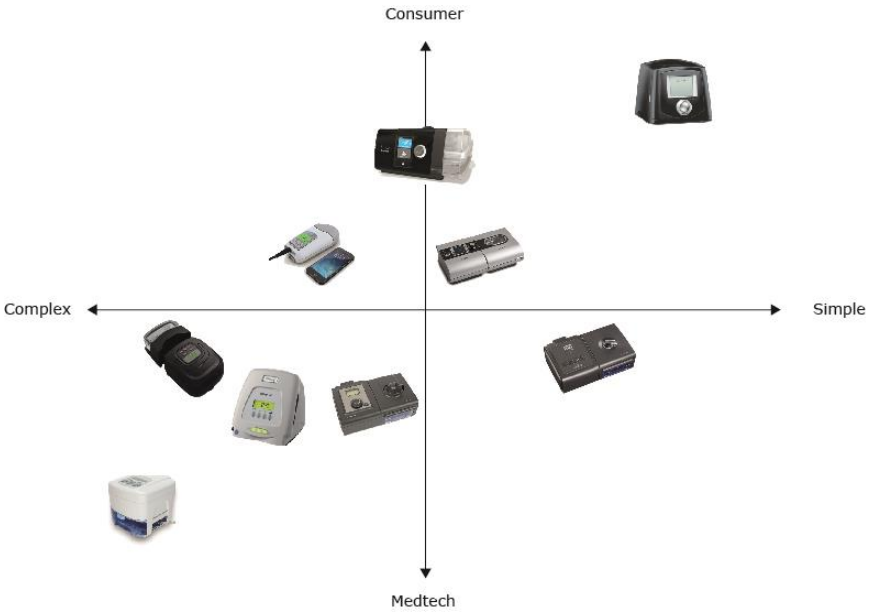


Figure 27 - Example of competitor matrix

4.3 List of requirements

A summary of the requirements that were found in this chapter is presented below.

Table 2 - Requirements found during the exploration phase

Requirement	**Origin** (user, external)	**Method** (Observation, interview, facebook, questionnaire, ISO, research...)
Have a small size	Limited space on bedside table, travelling	Observation of photos, interview with patients, Questionnaire patients
Have a display	To view interface menu	Procurement requirement
Display visible while sitting/lying in bed	User wants to see display from bed (users often place CPAP on floor, boxes etc.)	Observation of photos, interview with patients
Display visible while standing	When nurses explain how the CPAP works	Observation nurse
Tube not on the back	Shortest way to the bed User can place CPAP on either side of the bed Minimize damage to the hose	Observation of photos, Interview with patients, Questionnaire patients
Automatic pressure adjustment	Easier to provide the correct pressure	Benchmarking, interview nurse
There must be a medical mode separated from a patient mode	The patient should not be able to change all settings	Interview with patients, nurses. Benchmarking
No pressure settings in patients mode	Patients should not change pressure	Benchmarking, interview nurse
Include a humidifier	To moist the throat	Interview with patients, nurses. Benchmarking
Humidifier connectable	50% usage (in Västra götaland)	Interview nurse
Adjust humidity level and temperature	To moist the throat	Interview & questionnaire with patients, nurses. Benchmarking
Should be able to carry	To lift up from bag, move at home	Observation nurse, interview patients
Have ramp function	It is easier to fall asleep	Benchmarking, interview with patients
Readable display in darkness	The device is used at night	Guidelines
View average usage time and total usage time	Min. usage time for continued CPAP therapy is 4 hours/night	Interview with nurse
View hours of usage time previous session	Statistics interests some people	Interview with patients
View AHI	To see how effective the treatment is	Interview with nurse
Be able to see if statistics are good or bad	Patients have difficulty knowing if a value is good or bad	Interview patients, interview nurse
Integrated wake up alarm	Avoid need of multiple objects on bedside table	Observation of photos, questionnaire
Physical buttons are preferred	Nurses wants to look at the patients while talking to them	Interview nurse

Be able to test mask fitting	To see if the mask fits the patient, common adjustment	Observation nurse, interview nurse
Show if the mask leakage is acceptable or not	Nurses use the CPAP to evaluate the mask fitting	Observation nurse, interview nurse
How good is the mask fitting	Is it perfect or just over acceptable?	Observation, Benchmarking
Easy and quickly adjust pressure	Common adjustment	Questionnaire nurse, guidelines
Easy and quickly turn OFF autostart	Common adjustment	Questionnaire nurse, guidelines
Be able to transfer data to the doctor/nurse	For analysing the data	Interview nurse
Must have an air filter	To clean the ingoing air	Procurement requirement
At least have the same menu functions as iSleep25	The reference product should be the foundation of the menu	Project requirements
Should be quiet	Min. disturbance during night	Interview with patients
Mask-off alarm	To avoid sleeping without mask	Questionnaire patients
Wishes		
App in phone to control CPAP	For convenience	Questionnaire patients
Clock and Alarm clock	To save space on bedside table	Questionnaire patients
USB port for charging phone	For convenience	Questionnaire patients
Low-voltage lamp	To save space on bedside table	Questionnaire patients
Soft music playing when waking up to help getting back to sleep	To help falling asleep	Questionnaire patients
Notifications of alarms and why the alarm occured	To minimize need of technical support	Questionnaire patients
Non-measurable requirements		
Should be subtle	To not stick out too much	Interview with patients
Should be reliable	To make the user feel safe	Interview with patients
Should be simple	Easy to understand, nothing unnecessary	Interview with nurse

4.4 Main conclusions

- There are two main user groups of CPAP devices – patients and nurses. A CPAP device should in first hand be adapted for the patient users, since they are the ones who will use it the most.
- Sleep apnoea is a serious condition that makes life tough to live due to constant tiredness.
- CPAP therapy is often highly appreciated by patients once it works satisfactory since they feel like it has given them their life back
    - However, for many it is troublesome getting used to sleeping with the mask and the constant airflow

- Nurses want to keep it as simple as possible since they often handle many different devices on a daily basis. They want as little extra functionality as possible, while some patients see an advantage in including things like alarm clock and night light.
- Nurses perform mask fitting tests on a daily basis. This task has to be easily done and the function should not be hidden at the bottom of the menu tree.
- Many patients are ashamed of their condition. It is important that the CPAP does not look like a medical device, but rather an ordinary consumer product that fits well into the home environment.
- Modern CPAP devices look less and less like medical products.
    - They follow the overall trend of increased connectivity to support telemedicine
    - Some have touchscreens and functions like Spotify-plugins
    - Many patients do not want the device to look like a medical device
- A new type of ultra-portable devices have started to appear on the market

5. Usage design and expression

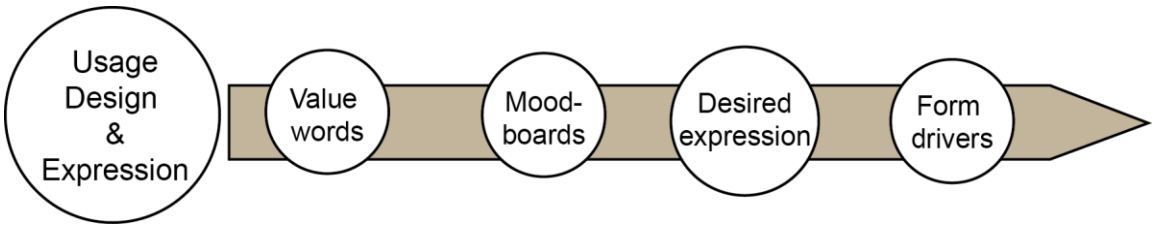


Figure 28 - The process for chapter 5

A new context was made up where the new design concept is the reality instead of the reference product. A new and modified usage situation was developed with the current usage situation as a basis, and the whole process from initial sleep apnoea diagnosis to successful CPAP therapy was reconsidered. This included implementing new technological possibilities and deciding on where to position the product in relation to the competition regarding aesthetic expression.

Purpose: To come up with a direction for the continued work.

Result: This step will result in a usage situation that is different from the situation given by using the reference product. Another result is a description of what the project writers want the final product to be in terms of expression, functions, etc.

5.1 Usage

Thanks to new technological possibilities like telemedicine, the sleep clinics' process of managing CPAP patients and devices as well as the patients' procedure of using them and getting support can be reconsidered. Additionally, with today's technology, data about how the patient is sleeping can be logged and then viewed for both the patient and the nurses. The difference in usage situation is presented in the following scenario.

Phil is a software developer at a small IT company in Gothenburg (Figure 29). He is 36 years old and lives with his cat Diablo 40 minutes outside the city. He does not have a car, and can work from home most of the time. He spends a lot of time in front of his computer and lives a quite unhealthy lifestyle and eats fast food and drinks soda most days.

Figure 29 - Persona Phil

Phil has had trouble sleeping for over a year and is almost always tired. He recently contacted his local health-care centre and got a referral to the sleep clinic at Sahlgrenska where he was diagnosed

with sleep apnoea. Since Phil is interested in how his treatment is progressing he has been checking the information available in the CPAP device's sleep log regularly. It has been interesting to see how many hours per night he has used it and if his AHI has decreased from when he was diagnosed. He likes that it is easy to use which made it faster to understand.

After using his new CPAP device for three months he was connected by the sleep clinic for a follow-up. He was asked to either visit the clinic or submit the use data from his machine. He prefers to upload the requested data via Wi-Fi to a server where the nurse at the hospital could check Phil's log. The nurse confirms that Phil's AHI had decreased, but not as much as desired. Therefore she connects her job computer to Phil's CPAP device and increases the air pressure. A request is sent to the device and Phil has the choice to either accept the changes or decline them. He accepts them since he knows it is from Sahlgrenska Hospital.

In this case both Phil and the nurse could save time and effort with the help of telemedicine. Without it this situation would have looked different since Phil would have had to travel to the hospital just to transfer the data and change the pressure setting. It would cost him both time and money and would have a negative impact on the environment. A physical meeting would also require more organisation and time from the nurse's already tight schedule.

5.2 Expression

Opinions of what expression the product should have come from the research phase, the user studies and the benchmarking, as well as our subjective opinions as designers. The following summary of desired expressions was the basis for the value words that were chosen to represent what product expressions to aim for.

5.2.1 Desired expressions

Many patients express that they want a discrete CPAP device, which can be interpreted as a small physical size and a subtle design that does not stand out. They also value quietness in form of low noise level. A product that does not look like a typical medical device is also desired by many users as a product that looks more like an ordinary consumer product fits better into the home environment and is less likely to remind the patient of hospitals and diseases.

Nurses expressed that the most important thing is that it is easy to use, which should also be expressed with a simple form language. A way to make it look simple is to have few elements in the design. Too much features can be interpreted as too complex and might give a clinical expression. Reliability is also a key expression in a medical device such as this one since it has to be trusted by the users. A stable and qualitative expression can be argued to contribute to a feeling of reliability and safety, as do darker colours, a sleek design and a professional look. In this case, professional look refers to a simple design with large surfaces, consistency and few colours rather than a cluttered design with many details and varying shapes, which could be interpreted as more playful. At the same time it should not feel stiff, sterile or hostile, but approachable and friendly.

Contrast between light and dark colours, and between round and flat surfaces or sharp corners can give the product a modern and professional expression that feels both stable and reliable at the same time as approachable and user-friendly. Some examples of products with this expression are shown in Figure 30 below.

Figure 30 – Expression discussion

5.2.2 Benchmarking matrices

The benchmarking of other products and what they express helped with the positioning of the desired expression for the new design. The users wanted the device to be discrete, simple and reliable. It was also desired for the device to not remind of a medical device. The red marks in the matrices are the desired position for the new concept. For example, in the second matrix the mark is towards consumer product look and between playful and professional (Figure 32). It is desired that the design should be professional, which indicates quality and reliability, but it should still express playfulness and kindness. Adjacent products to the marks can help to understand what design features give a certain expression. For example in the first matrix (Figure 31), the Fisher & Paykel CPAP device is simple due to its few elements and large surfaces. The rest of the matrices can be found in the appendix.

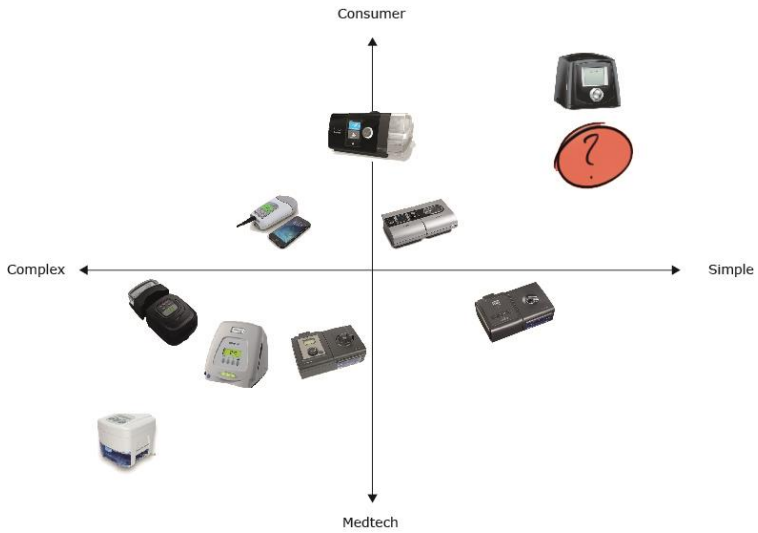


Figure 31 - Benchmarking matrix

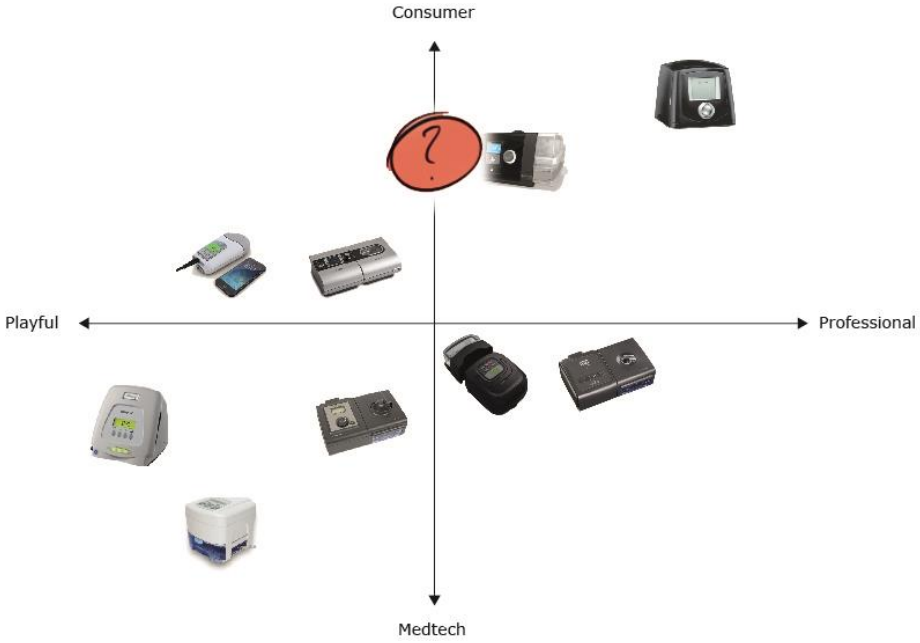


Figure 32 - Benchmarking matrix

5.2.3 Value words

The desired expressions are summarised with three value words, namely *Simple, Reliable* and *Humble.* These words incorporate most of what the product should express and stand for based on input from the end-users. The three values are explained with supporting words to concretise and explain what they mean in this particular project. The support words, together with images that communicate the value words make up the moodboards shown below in Figure 33. The reason why images were chosen to describe the words was that a word can mean different things, and the pictures help to convey what exactly is meant by the word. The images convey a feeling, something not words do in the same way.

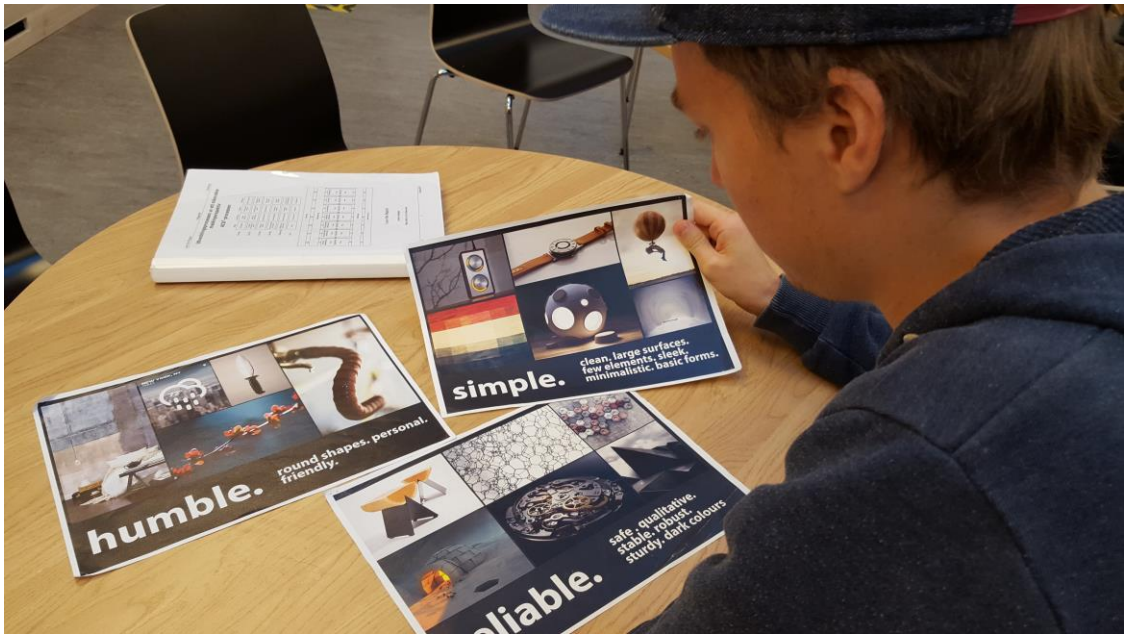


Figure 33 - Moodboards

5.2.4 Form drivers

To be able to turn these value words and desired expressions into something tangible, they were turned into form drivers. For example, to express simplicity it should have basic elements and to be humble it should have round shapes. A summarised moodboard was created, which included all three value words and form drivers as well as expression images showing how the words can be represented in products, interfaces and as a feeling (Figure 34).

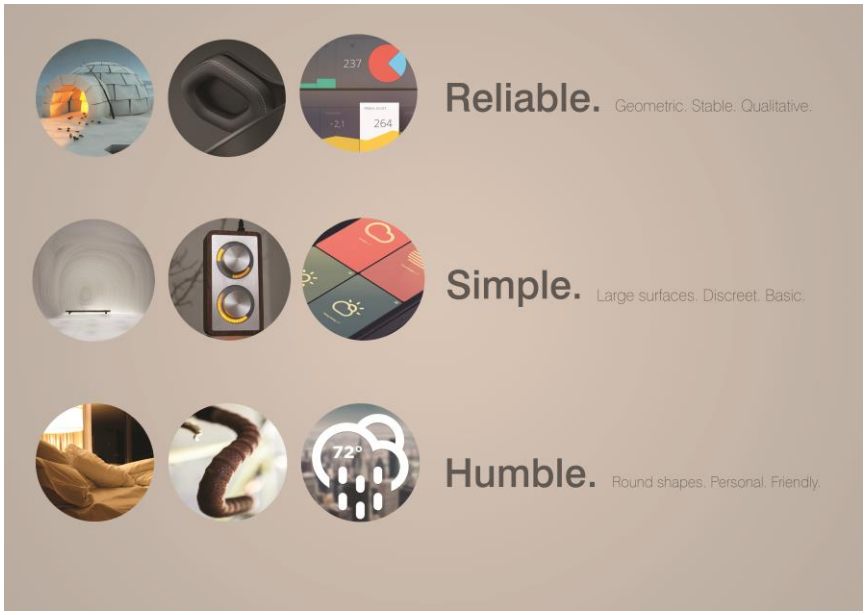


Figure 34 - Summarised moodboard with form drivers

5.3 List of requirements

A summary of the requirements that were found in this chapter is presented below.

Table 3 - Requirements from chapter 5

Requirement	Origin	Method
Should be prepared for tele medicine	For people can send the sleep data from home	Patients interview
Should not look like a classic medtech product	Suites the home environment better, reminds of diseases	Designers
Express Humble, Reliable, Simple	Value words based on users	Designers

5.4 Main conclusions

- New technological possibilities such as telemedicine make it possible to reconsider the current procedure of managing and using CPAP devices, both for patients and professionals.
- The expression of a medical is important since it has to communicate that it is safe and reliable in order to be trusted by the user.
- The expressions of the current products on the market vary a lot, from toy-like to professional looking devices.

6. Transformation

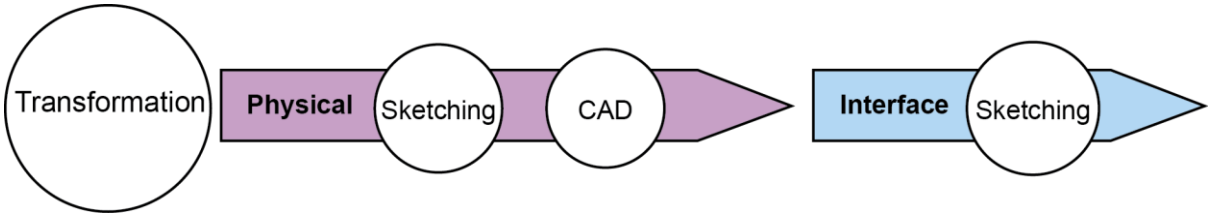


Figure 35 - Process of the transformation phase

From the usage design and expression, the design of the CPAP device started to be visualised and take form. This step consists of a transformation of the desired design ideas to physical representations and interfaces.

Purpose: To develop and explore many initial ideas and concepts based on earlier findings and transform them to more concrete concepts.

Result: A few rough physical concepts to proceed from and several variants for the interface.

6.1 Physical product

The form of the physical product was started simple by sketching. When being satisfied with a form, it was further investigated by doing simple 3D-models.

6.1.1 Sketching

Many sketches were drawn to investigate different basic forms (Figure 36). The approach was to draw something that was simple, reliable, humble, or had all three expressions at the same time. The sketches evolved with inspiration from each other.

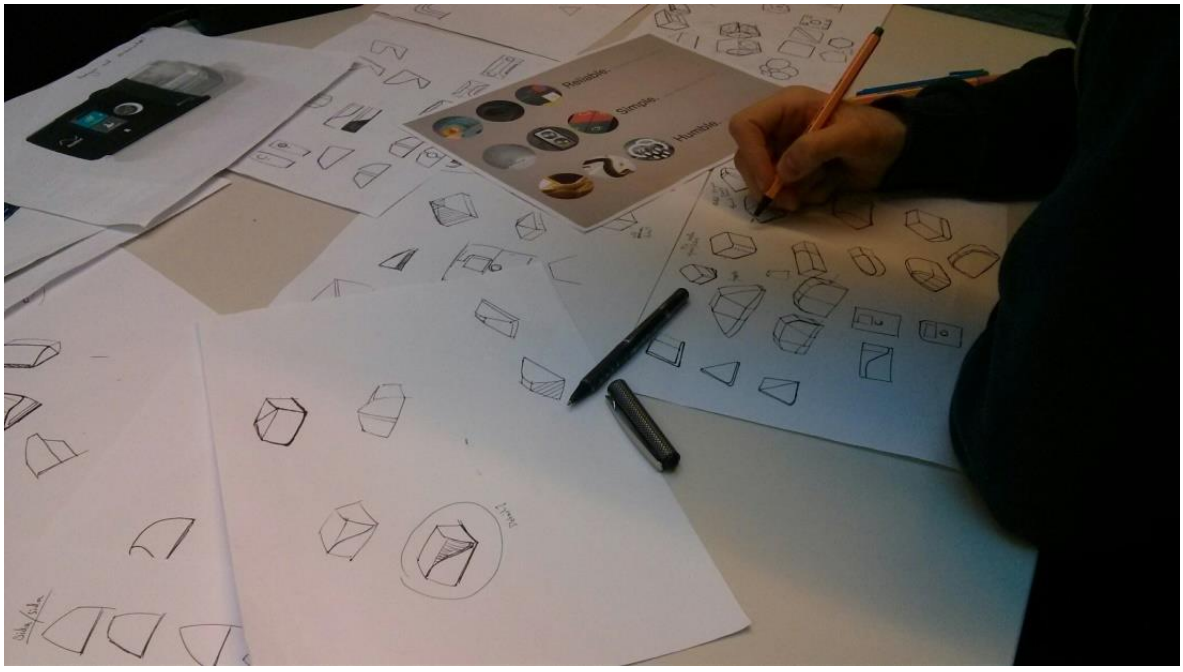
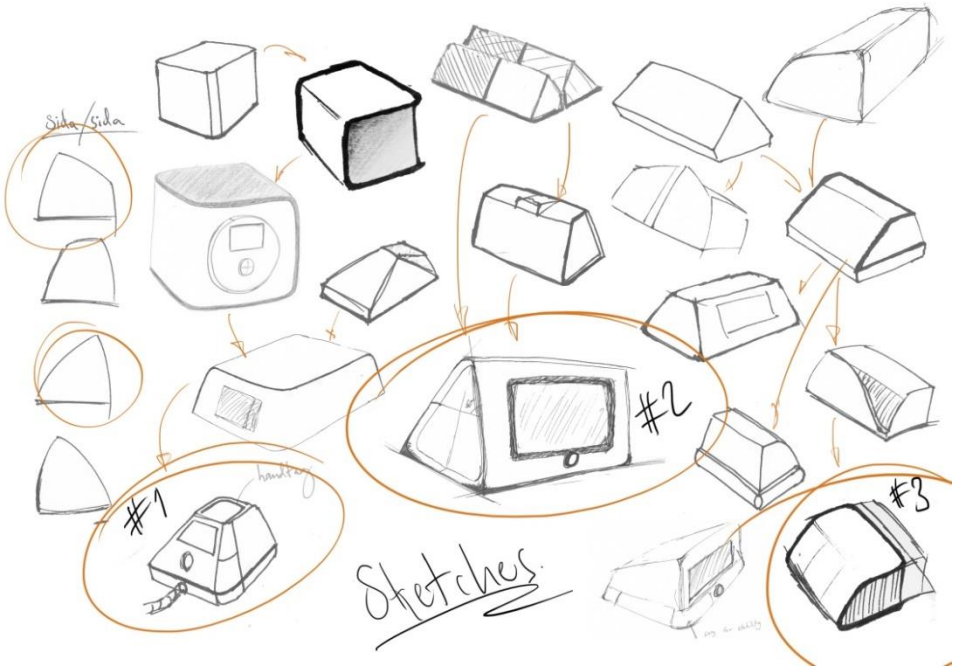


Figure 36 - Concept sketching



Finally there were three shapes which expressed the value words according to the project writers' subjective judging. The chosen three forms are the numbered sketches in Figure 37.

Figure 37 – Sketch evolution

6.1.2 CAD mock-ups

Quick mock-ups were made using CATIA V5 to get a feeling for the 3D shape and volume of the sketched concepts. It was also done to be able to quickly try out variations of the basic shapes in order to test if slight variations would change the expression. A brief form analysis follows each figure below.

Concept #1 – Tank (Figure 38)

It feels stable and would sit well on the table or other flat surface. It is bulky and looks heavy and does not look very humble, although it has soft features and round edges.

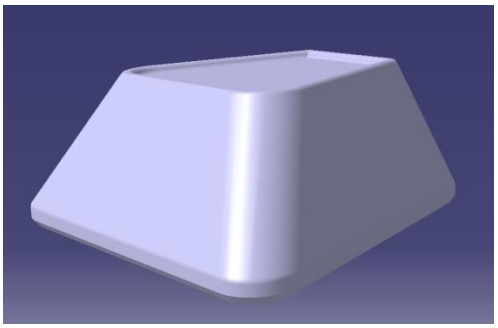


Figure 38 - Concept #1 - Tank

Concept #2 – Triangle (Figure 39)

This concept feels less stable and reliable than the other ones, but not unstable enough to tip over easily. The radii of the three ends of the triangle can be modified to give it various characteristics, where soft edges would give it a humble expression. A rail along the bottom could be added to make it more stable.

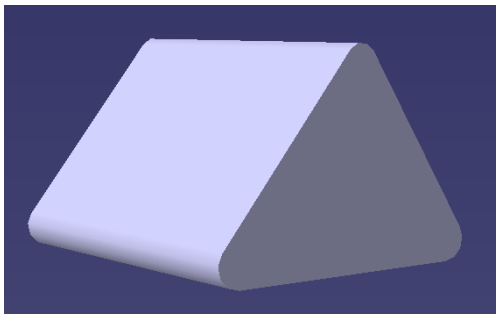


Figure 39 - Concept #2 - Triangle

Concept #3 – Slope (Figure 40)

This concept is more stable than the Triangle due to the larger volume and more block-like shape. It feels reliable due to its stable expression and consists of simple shapes.

One thing to mention is that these forms do not have any dimensions yet, only proportions.

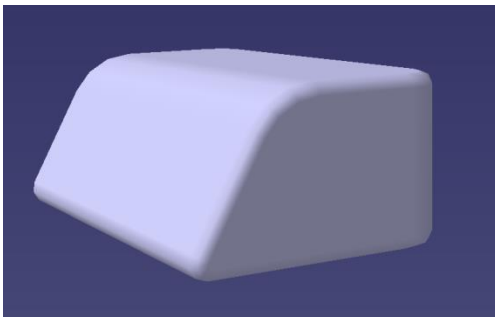


Figure 40 - Concept #3 - Slope

6.2 Interface

The development of the interface was initiated after the value words had been set. Since the menu structure was developed in parallel with the aesthetics of the interface, the concepts evolved along with the menu architecture. During this phase, no new menu structured had been developed, therefore the first concepts are examples of how it can look like.

6.2.1 Inspiration

Inspiration was gathered by searching for and analysing existing interfaces, menus and ways of presenting data and information. The sources used were mainly Google Images, Designspiration, Pinterest. Key words included the value words "humble", "simple" and "reliable" as well as words like "interface", "menu", "medical", "data", "sleek", "friendly", "geometric" and "trust".

The images showed different ways of presenting an interface. For example, they showed how colours can be used to separated values in graphs, they showed that you can find more information under a menu by adding an arrow, selected menus can be of a different colour. The way of showing symbols inside a circle was considered humble, safe and simple. The simple interfaces have a minimalistic feeling where nothing unnecessary is used.

6.2.2 Interface sketches

Some rough hand-sketches (Figure 41) and digital mock-ups of the interface (Figure 42 - Figure 46) were produced in order to convert the desired look and expressions into interface ideas. How the interface is designed depends much on how the device is supposed to be manipulated by the user and how the final menu structure looks like, which were not decided at this point. Instead, the goal became to explore different expressions with colours, symbols and typefaces.

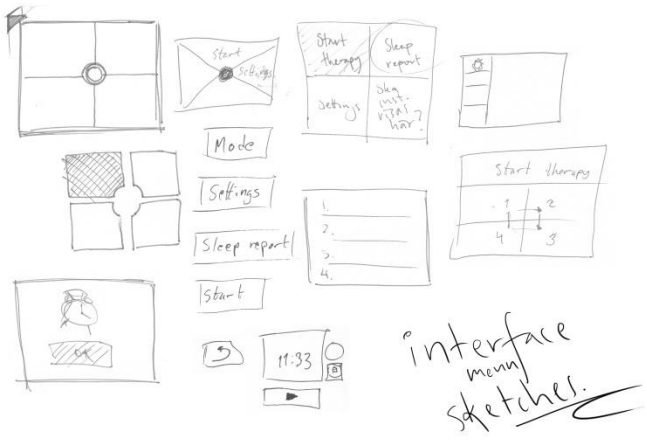


Figure 41 - Interface sketches

It was difficult to explore expressions with only paper sketches. Thus, a number of layouts and designs of the home screen were developed in Adobe Illustrator and different colours and colour schemes were explored to achieve the desired expression. At first, a dark interface was wanted. There were several reason for that - it is trendy, it felt reliable and it does not light up and glare as much if the display is used during night.

Figure 42 - Interface concept 1

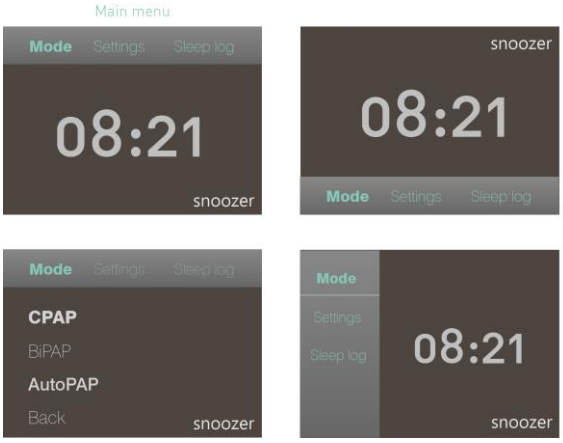


Figure 43 - Interface concept 2

Figure 44 - Interface concept 3

Figure 45 - Interface concept 3

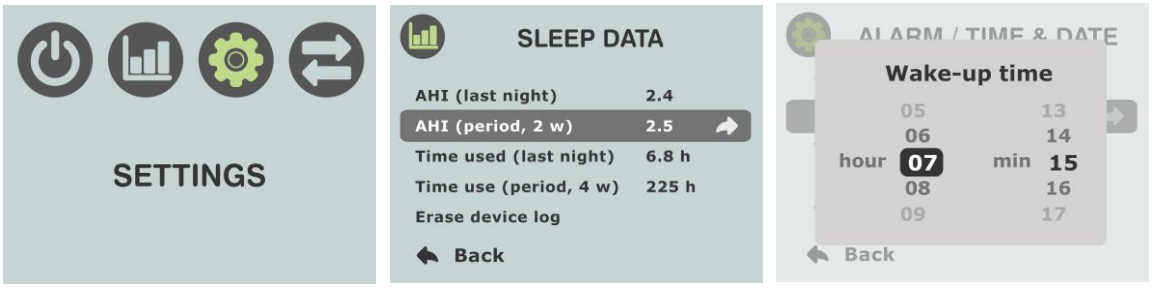


Figure 46 - Interface concept 4

6.3 Main conclusions

- Sketching is the most powerful tool for trying different ideas fast, but it is difficult to get a feeling for the 3D shape and volume.
    - For this purpose, quick CAD mock-ups work well
- When making concepts for the interface, digital mock-up making with e.g. Adobe Illustrator is a great tool. In this case, sketching did not work as good.
- It is difficult to design the physical part of a product together with the interface so that they "speak the same language" at this time of the project. However, it worked to some extent to design both parts towards the same value words and form drivers.

7. Product architecture

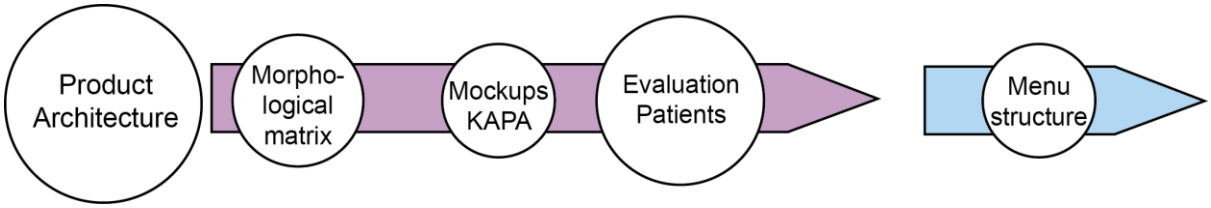


Figure 47 - Process of the product architecture phase

This step includes further exploration of the physical form of the device, as well as development of the interface with a complete menu structure, functions (e.g. buttons or touch display) and a more refined graphical design.

Purpose: Explore, suggest, test and decide on what elements should be used in the product, both externally and within the interface.

Result: One more refined concept with defined functions, elements and their positions. A finished menu structure.

7.1 Sub-solutions

The product should include various functions which can be solved with different sub-solutions. The most important functions considered for this project were; the type of handle, the position of the tube outlet, how to view the display, how to navigate the interface menu and the type of humidifier. A few solutions for different functions were both inspired by other products in the benchmarking and created by brainstorming.

It was desired to be able to lift and carry the device. The device would be possible to carry with one hand since the other hand might have to hold on to the tube and cords. This could be solved by a handle. Three different types of handles were suggested (Figure 48). One was of a tip-up type, which is folded up when using it. Then there were two handles which were integrated into the form of the CPAP device - one for just fingers and one for the whole hand.

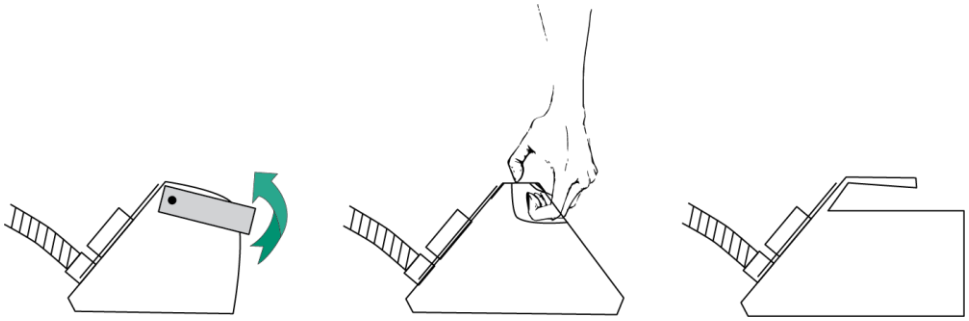


Figure 48 - Handle solutions

The tube outlet's position seemed, from the research phase, preferred on the front towards the bed. However, it was desired to test different positions, such as the side and the back as well.

Based on information gathered during the research of the users' situation it was desired to be able to see the display both when standing up and sitting down. If the product has an angle on the front, the display could be fixed to it. This could also be solved by an adjustable display which could be rotated to achieve the right angle. The third solution was to view the display on a mobile phone via an application.

The different alternative solutions of controlling the menu were: a control dial, buttons, touch screen or via an application in a smart phone.

When it comes to the humidifier it could either be integrated in the device, meaning that it is always a part of the device. It could also be external and removable, which means that the humidifier is a separate device which can be connected and disconnected. The last solution was to have it exchangeable, which means that a part of the CPAP device is removed and then exchanged with a lid or similar.

7.2 Morphological matrix

The sub-functions were combined with the three basic forms shown in chapter 6.1.2 to generate more complete concepts using a morphological matrix (Table 4).

Table 4 - Morphological matrix

Functions	**Solutions ->**				
Basic form	Triangle	Tank	Slope		
Handle	Fixed	Integrated finger	Intergrated hand	Foldable	
Tube outlet	Side with swivel (right/left)	Back (high) with swivel	Back (low)	Front (right/left)	Top
Menu control	~~Touch display~~	Control dial	~~Buttons~~	~~App (no display)~~	~~App (additional)~~
Humidifier	Integrated	Removable	Exchangable		
View interface	Fixed angle	Adjustable angle	App		

A total of 19 concepts were generated through the morphological matrix, equally distributed between the three basic forms, see Appendix 9 for full list.

Although these concepts were created, it was decided that the menu was going to be manipulated with a control dial. According to the initial user research this interaction type is intuitive and user-friendly, and since it is widely used in other CPAP devices as well as in other products such as microwave ovens and car stereos it is also familiar for many people. The other Menu control sub-solutions were also ruled out in favour for the control dial. The touch screen idea, for example, did not seem appropriate for this kind of product due to lack of haptic feedback and the good eyesight and dexterity needed to navigate properly, which in this case is an important usability factor. Controlling the menu from a smartphone application was also excluded since the CPAP device is required to have a display on the device itself. Also, a user should not have to own a smartphone in order to use the CPAP device. As seen when meeting users, many are using regular mobile phones without the ability to install applications.

The idea was to then give each concept a grade based on how well the different part solutions could be combined and how they would work together. But since almost all concepts worked well and received the highest score, the method instead came to be a subjective decision of combining elements into three concepts - one concept for each of the basic forms. The final concepts were combined in Table 5:

Table 5 - Three architectural concepts

Solutions	Concept 1	Concept 2	Concept 3
Basic form	Triangle	Slope	Block
Handle	Integrated for fingers	Integrated for hand	Foldable
Tube outlet	Front left bottom	Left side low with swivel	High on back with swivel
Menu control	Control dial	Control dial	Control dial
Humidifier	Integrated on left side	Integrated on top	Integrated on top
View interface	Fixed angle	Fixed angle	Fixed angle

7.3 Concept evaluation

Quick KAPA® board models were made (Figure 49) to be able to let CPAP users evaluate the form and basic architecture of these concepts. Apart from the elements mentioned above, the relation between the screen and the control dial was also evaluated (Figure 50). The striped parts of the models represent the humidifier. The displays are printed papers with different fonts and sizes.

Figure 49 - Making of KAPA® board mock-ups

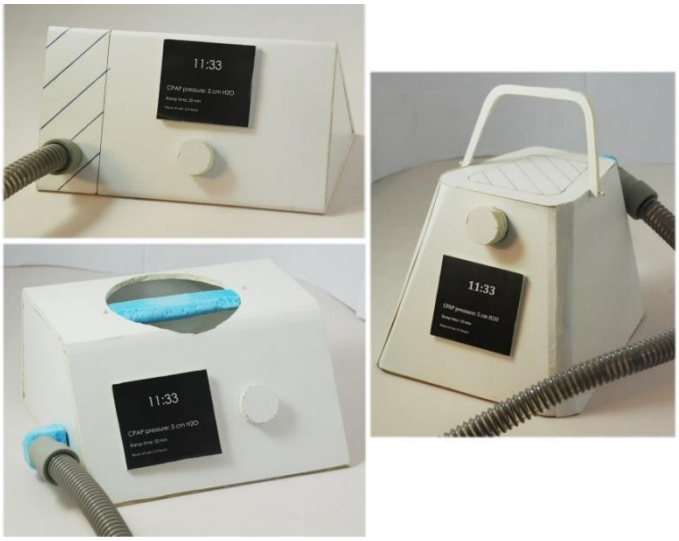


Figure 50 - KAPA® board mock-ups

The evaluation was done with three CPAP users, all male ranging from 25 to 68 years old. They were asked about their CPAP use procedure and then got to evaluate the concepts (see Figure 51). The evaluation consisted of interacting with the product, trying the different solutions, functions and positions of the basic elements. Common for all the participants is that all of them rarely navigate the menus and change settings on their own CPAP devices. They merely turn the device on and off and use the standard settings. See Appendix 5 for more information about the evaluation.

Figure 51 - Concept evaluation

Evaluation result

Some design decisions could be made on the basis of the evaluation results. The models were all a little too large in size, and the ability to bring the device when traveling was mentioned as an important factor by two of the participants. The form that was lowest in height and the handle on top were favoured over the other solutions due to neatness, portability and ease of access to the grip. A flat back to enable positioning against the wall was also considered an advantage in optimizing space efficiency.

Further, the tube outlet should be positioned so that the tube is pointing towards the patient while sleeping to maximise tube length and minimise entanglement and interference with other objects on the bedside table. One participant mentioned that if the tube outlet is placed on the back of the device, the display would be turned away from the user since it is desired to turn it so that the tube is pointing towards the bed.

Regarding the display and control dial positioning, the evaluation showed that the control dial should be placed either under or to the right of the display, and that the display should be placed as high up as possible. If the control dial is placed above the display the hand will block the display when interacting with the display. One person highlighted that, depending on what side the user is sleeping, there might arise problems if the control dial is placed beside the display.

Three different angles of the front face were tested, ranging from 55 to 65 degrees. The concept with a 55 degree slope was favoured, but a slightly lower angle would have been even better according to two of the subjects. This is because the display is often viewed while sitting on the bed, or standing up looking down on the CPAP device as in the case of when nurses show new CPAP users how to navigate the menus. Since the display also should be visible when lying in bed, the angle of the display is a compromise and cannot be completely upright or flat.

Regarding the humidifier container it was clear that it should not be integrated, but detachable so that it can be removed to get a smaller device when traveling for example. Another advantage with a detachable humidifier is that just over half of the CPAP users in Västra Götalandsregionen actually use a humidifier, and being able to use the CPAP without it is beneficial for both the healthcare providers and the sustainability aspects. The evaluation did not result in any clear favourite position, which can be explained by the fact that none of the subjects use a humidifier and did not have insight into how it is to remove, fill and clean the container. However, one feature that was mentioned was the ability to see the water level when the container is attached to the CPAP device.

After the evaluation was made, a final architectural concept was decided. The concept consists of these part solutions:

Form: Triangle
Handle: Fixed integrated finger
Tube outlet: Front left bottom
Menu control: Control dial to the right of the display
Humidifier: Exchangeable on the left side
View interface: Fixed angle of 50 degrees

7.4 Interface

The complete menu structure was derived from the reference product Breas iSleep 25, including functionality such as clinical mode and the limits of the different settings. Initially, the idea was to keep the functionality for the iSleep and just rearrange the menu structure, but it made more sense to go through the menu items and remove unnecessary ones and add others that would improve the user experience. This was because with new technology comes new functions which were not available when the iSleep was created. To be more user-friendly, the menu structure was revised and reorganised with the help of user research, usability guidelines and benchmarking to see what works well in other similar products.

After a few iterations, the result is a menu structure that has the most frequently used menu items most easily accessible and a maximum depth of three steps from the home screen for any setting or information (Figure 52). All menu items were divided between two main menus accessible from the Home screen. Settings for functions such as slowly increasing pressure (ramp), humidifier and wake-up alarm were placed under User Options. Information about the sleep quality and therapy efficiency, as well as the Share sleep data features were placed under Sleep Info. In addition, a settings overview showing the selected mode, pressure range, current pressure, wake-up alarm time, ramp time, ramp pressure, and humidity level is presented in a status bar on the Home screen.

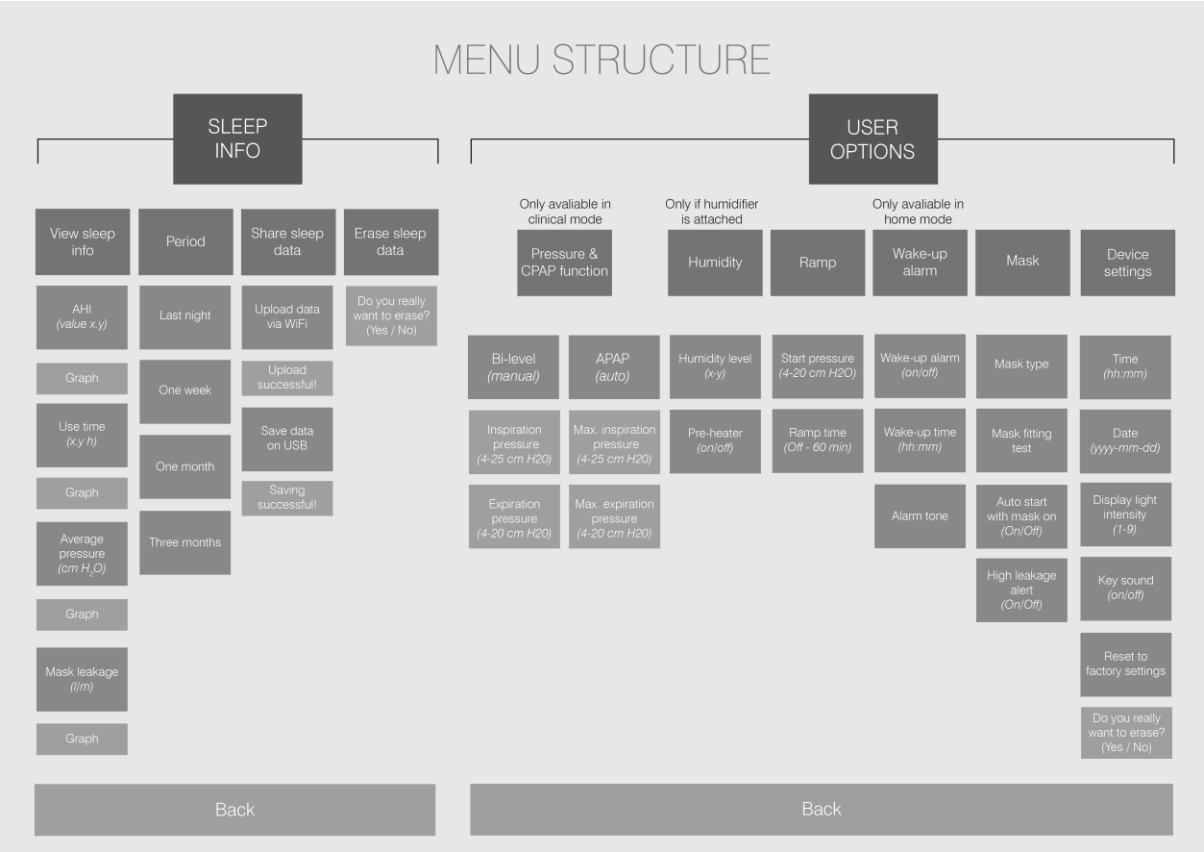


Figure 52 - Menu structure

One typical user behaviour that became apparent during the user research was that most CPAP users rarely or never navigate the menus to change settings or review sleep data. They simply start the airflow and go to bed, with the settings that were set by the doctor or nurse at the sleep clinic. For this reason, a separate button was added that only is used to start and stop the airflow.

Some settings, mainly pressure mode and pressure settings, are for clinical personnel only and should not be accessible for patients, other than in rare cases. Therefore, there is a sub-menu under User Settings called Pressure & Mode. This menu item is normally hidden, but appears when pressing the Start/Stop button and the control dial button together for three seconds. This manoeuver is difficult enough to do accidentally, but easy enough for clinical personnel to remember. There is of course a chance that the patient somehow learns how to do this manoeuver and override the settings provided by the doctor or nurse, but the worst case scenario is that the CPAP therapy works less effectively and sleep quality decreases (Hedner, 2015).

The visit to the sleep clinic at Sahlgrenska University Hospital showed that nurses do a mask fit test with every patient that is prescribed with CPAP therapy. It is therefore important that this function is easily accessible. The mask fit test can be accessed through the Settings menu under Mask, but can also be started by pressing the control dial button and holding it down for three seconds.

7.5 List of requirements

Table 6 - Requirements from the product architecture phase

Have rubber on the underside	For friction when pressing buttons	Observation patient
Possible to change language	For customization	Benchmarking, usability test nurse & patient (for confirmation)
Have a control dial	Intuitive and effective way of navigating	Benchmarking, usability test nurse & patient (for confirmation)
Have a separate Start button	For the users who just is interested in starting the air flow	Observations patients, interview patients
Lower than 13cm	Which was the height of the lowest mock-up models	Mock-up test patients
Tube turned towards bed		Mock-up test patients
Control dial to the right of the display	Association with display obvious, right handed	Mock-up test patients
The humidifier placed to the left	So that the tube is not in the way of the display	Mock-up test patients
Have a 50 degrees display angle	To see read it from several angles	Observation nurse. mock-up test
Possible to see the water level	To see how much water there is left	interview patient, nurses
Enter the clinic mode by holding down both buttons for 3 seconds	So the patients does not enter the mode by accident	Procurement requirements
The mask fitting test should be fast to access	Common function for nurses	Observation nurse

7.6 Main conclusions

- It is good to include a step targeting the architecture of the product in order to get all elements in place in an orderly and thought through way
    - For this purpose, a morphological matrix is a useful tool
- For evaluating basic concepts, KAPA board models are very useful and are quick and easy to make.
- It is important to include actual users when choosing concepts. Rough evaluations with users at an early stage are very valuable and effective.
- There are two main type users within the patient user group – those who are not interested in their sleep statistics and different functionality of their CPAP device, and those who are. The former is by far the bigger of the two groups and most patients simply turn the device on and go to sleep.

8. Detailed design

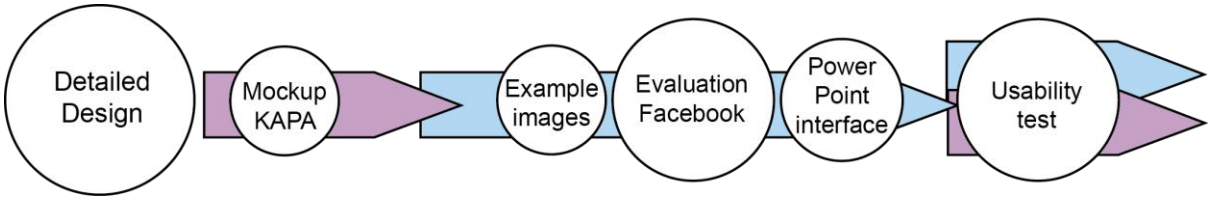


Figure 53 - Process of the detailed design phase

Here, the details about one concept should be defined. The different physical elements (e.g. buttons, handles, display, the form of them) and interface elements should be defined (symbols, colours, font, text size).

Purpose: Investigate how the device and its elements should behave during interaction with the user.

Result: Detailed descriptions of the physical design and the interface. How to navigate through the interface should be described. This should be validated through a test with actual users.

8.1 Physical product

This is a presentation sketch of the different elements in the selected concept. There are a few other elements which also are part of the design. An air filter is added since it is a requirement from the region. A slot for a removable USB-stick for log storage was added in case the patient wants to share the sleep data when visiting the sleep clinic or does not have access to Wi-Fi. An USB port was added since there were many patients who wanted that extra feature to charge their phones. This was a minor and easy element to add. Lastly there is a rubber layer under the CPAP device to create friction against the surface it stands on. When interacting with the mock-ups it was noted that they slid away when pressing a button. The different parts of the detailed concept are presented in Figure 54.

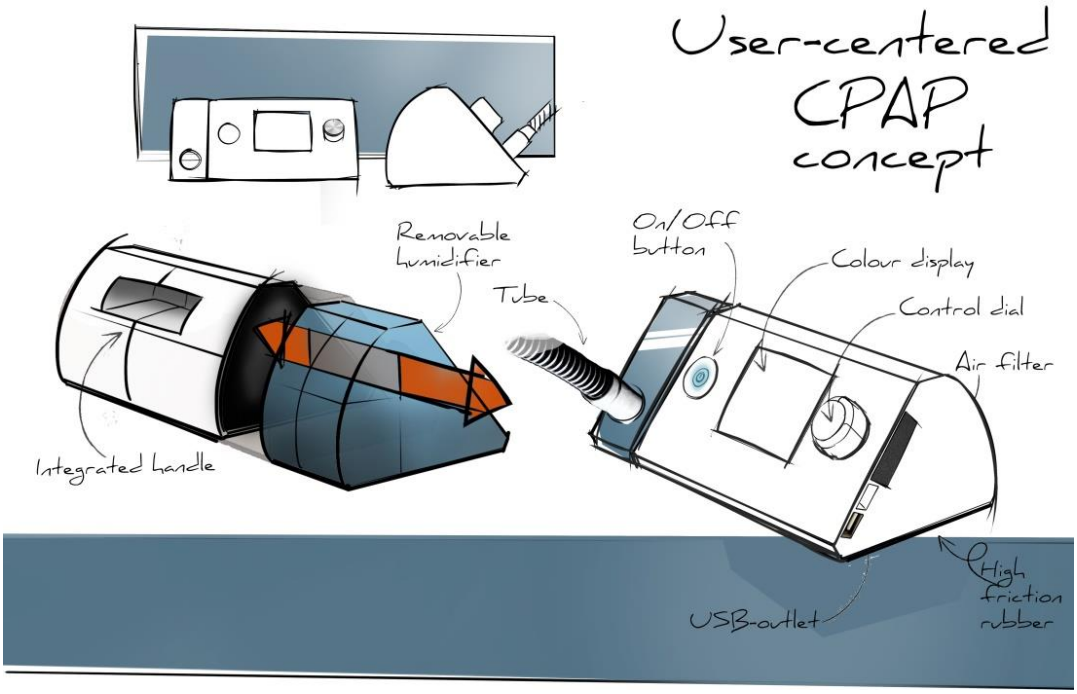


Figure 54 – Description of detailed concept

With the concept evaluation results as input, together with previously found requirements and guidelines, a final concept for the physical product was developed and a mock-up was made (Figure 55). It was based on the most liked concept Triangle with some modifications and improvements.

Figure 55 - Mock-up of final concept

The whole device was scaled down in size compared to the mock-ups and it was made lower to increase portability. The dimensions were set to a width of 200 mm, a height of 90 mm and a depth of 125 mm. These measurements were chosen based on estimations of the needed volume for internal components. This estimation was confirmed to be acceptable by Marko Koivumäki at i3tex who has been involved in packing internal components in CPAP devices before (Figure 56). The slope of the front face was flattened slightly to 50 degrees to allow the display to be viewed both when lying, sitting and standing.

Figure 56 - Testing model size

The back was modified to a curved surface to increase the internal volume compared to the Triangle concept and to improve the grip of the integrated handle on the back. The lower part of the back was kept flat as desired from the evaluation of the mockups. The handle was made wide enough, 130 mm, for the user to be able to lift the device in its centre of mass both when using the CPAP

without humidifier and with the humidifier container filled with 450 ml of water, which is the maximum level. The handle width and the weight distribution were tested by filling the mock-up model of the final concept (Figure 57) with clay. The weight of the device was estimated based on the weight of other CPAP devices with similar size, and a piece of clay with the same weight was put in the mock-up model. The humidifier container was filled with a piece of clay weighing around 400 grams and the balance when grabbing the handle was tested both with and without the container. The test led to a decision to make the handle a little wider to allow the user to always be able to grab the device with good balance.

Figure 57 - Mock-up with clay

The display was placed in the middle of the CPAP device for symmetry reasons, and as high as possible to make it easier to see from above. The control dial was placed to the right of the display after eliminating placing it above (due to blocking by the hand when interacting with the control), below (due to limited space for the hand when turning the dial), to the left (since most of the population is right-handed) and on the sides or on the top (since it is better from a usability point of view to have the control close to the display it interacts with).

The control dial should be possible to both rotate for navigation and to push as a button for selection. The rotation element is separated from the button, which means that only the outer part can rotate, see Figure 58. The reason for this was that users had used a similar dial, where the button also can rotate. Some complaints about this were found during the research phase, and the reason was that they accidentally pushed down the button and made a selection when they were just trying to navigate. The dial also has 16 steps when rotated. This is to enhance the usability with tactile feedback.

A dummy control dial was used for the mock-up (Figure 55) in the usability test later on. However, this dial did not have the wanted form and dimensions. The control dial should have the dimensions and increments as shown below. This was based on the dummy control dial, which had similar dimensions. Later, in the usability test, none of the participants complained about the dial, but for the final concept it was still made three millimetres higher and with a more ergonomic grip to improve the usability.

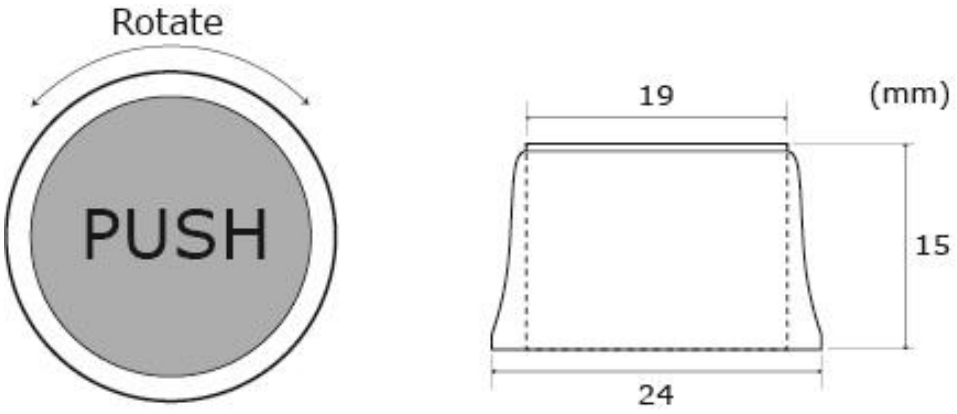


Figure 58 - Control dial details

The humidifier container was designed to have the same form as the main CPAP device to be more integrated, both visually and physically. The container is attached to the left side of the device and can be easily grabbed and detached in order to fill it with water and clean it. The reason for placing it on the left side instead of the right side is that the tube outlet is placed on the front of the container, which could result in the tube interfering with the right hand when interacting with the control dial to the right of the display.

For the users without humidifier (which is around 50 % of the CPAP users in Västra Götalandsregionen according to Professor Jan Hedner at Sahlgrenska University Hospital) or users wanting to use the CPAP without humidifier when traveling for example, a side panel is provided. When the humidifier is replaced by the side panel, the tube is instead attached to a swivel on the panel's side, allowing the tube to be pointed forwards.

8.2 Interface

Concepts for the graphical design of the interface were developed along with the structure of the menu. Some iteration was therefore necessary. At first, the idea was to have four main menu entries, namely "Start therapy", "Settings", "Mode" and finally "Sleep data" for the patient menu and "Mask fit test" for the clinical menu. However, after deciding to add a separate Start/Stop button for the airflow and a hotkey for starting the mask fit test, these four menus were reduced to two.

Many different colour schemes were tested and discussed. Mid-reds and mid-greens were avoided to reduce the risk of colour blind users to confuse the different menus and icons, since red/green colour blindness is the most common form, according to Colour blind awareness (Awareness).

Different concepts were designed to each correspond to one of the value words (simple - nr. 2, reliable - nr. 1 & 3 and humble - nr. 4 in Figure 59). Graphic elements such as icons, fonts and colours were selected to suit the different concepts, with the "reliable" concept using darker colours and icons and fonts with sharp edges, and the "humble" concept using lighter colours and rounder icons and fonts. Finally, four interface concepts were evaluated by users to find which one to go forward with. This was done by selecting four example screens from each of the four concepts, which all viewed the same menus, and presenting them to two Facebook groups for CPAP users, one American and one Swedish group. There were 20 answers and the "humble" concept (nr. 4 in Figure 59) with light blue background was clearly favoured in both groups since it was plain and easy to read.

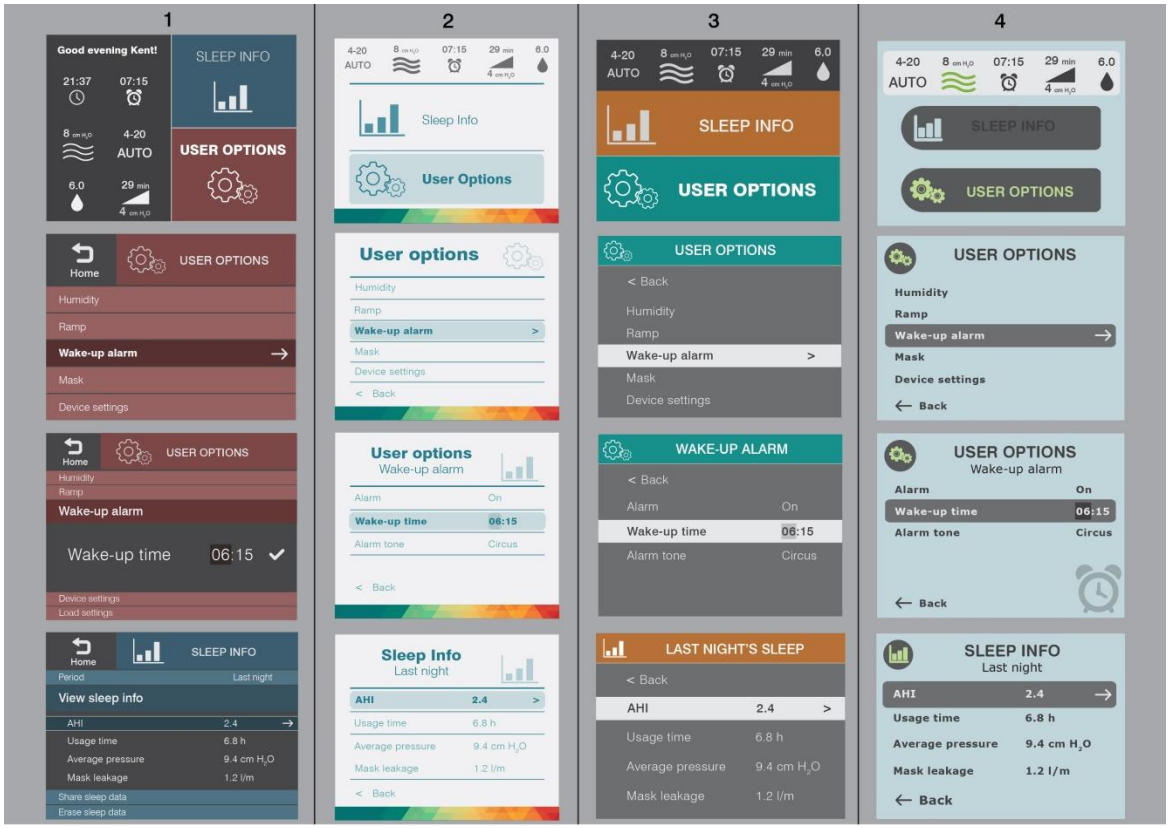


Figure 59 - Interface concepts

8.2.1 The humble concept

The favoured concept was then developed further, and more menu images were made to be able to test it with CPAP users in a usability test. Some tasks were selected for the test participants to perform, and the complete set of menu images needed to perform those tasks was then made according to the menu structure shown in Figure 52. The different parts of the interface are described below. Example images of the menu are shown in Swedish since they were made in Swedish for the usability test. However, the general concepts can still be understood.

8.2.1.1 Elements and construction

In stand-by mode, with the airflow inactive, only the current time is shown in a light blue circle. When the airflow is activated using the designated Start/Stop button to the left of the display, the image in Figure 60 is shown, stating the current time as well as "Airflow active". This way, the user who is only interested in starting CPAP therapy without changing any settings can simply turn the airflow on and go to bed, without activating the menu.

Figure 60 - Stand-by screen

If the control dial button is pressed, or the dial is turned, the device leaves the stand-by mode and the home screen is shown together with a greeting in the status bar at the top that is shown for two seconds (Figure 53). This was done to contribute to a nice experience for the user.

The status bar shows current settings and what functions are active. Active functions are indicated by highlighted icons (Figure 53). The left symbol states the pressure interval and the current mode, Auto or Bi-level (manual). The second symbol shows if the airflow is on or not. The middle one is a Wake-up alarm icon showing the set wake-up time. The fourth symbol shows if the ramp function is active and what the ramp time is set to, and the right-most icon states the humidity level. The humidity symbol is only visible if a humidifier is connected; otherwise there is an empty slot.

The menu is made up of two main menu entries shown on the home screen - Sleep Info and User Options (Figure 62). The currently marked menu row is highlighted with a light green colour and a grey bar as seen in Figure 62. In the other menus the selected menu row is highlighted with a grey bar and white colour (Figure 63). To go down to the row below, the control dial is rotated one step clockwise, and to go up it is rotated to the left. To go deeper into the selected menu, the control dial button is pressed.

Where there is a deeper step in the menu, the selected row has a white arrow to the right, and where a value is changed on the same menu depth, pressing the control dial highlights the value, and it is changed by rotating the dial (Figure 63). At the bottom of each menu page there is a Back button that jumps back one step (Figure 65). When pressing Back, the Back button on the previous page is pre-selected to allow users to go back to the home screen quickly.

The reason for not having a Home button that jumps all the way back to the Home screen is that the menu depth is never deeper than three steps, and that it would give the interface an extra row. This kind of product is not interacted with very often, perhaps once a day for the most frequent clinical users. Therefore, a designated physical home button on the front of the product is not motivated.

Figure 61 - Status bar greeting

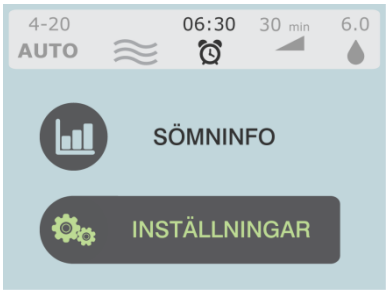


Figure 62 – Home screen

Figure 63 – Sub-menu layout

Figure 64 – Changing value

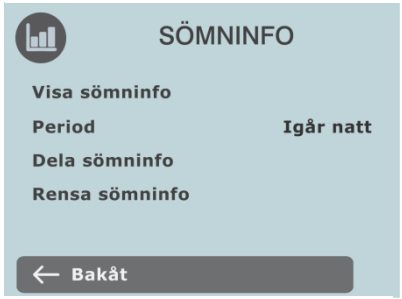


Figure 65 – Back button

The sleep data is visualised on the display in different graphs. For example, average CPAP use time per night is shown in a bar chart (Figure 68) where the user can choose to show the data from last night, over one week, one month or three months. The threshold for minimum use time (4 hours) is marked with a dashed line. Values above are green with a thumb up, and nights with use time below are marked with orange with thumb down to clearly show what nights have given good or poor CPAP therapy. There are a number of horizontal help lines to guide the user's eye to the value on the Y axis. This was implemented to motivate the patient to use the device more.

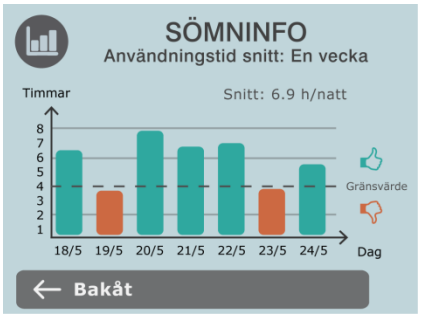


Figure 67 - Bar chart with sleep info

The data of average AHI (apnoeas per hour) are shown in a line diagram (Figure 68). A threshold is shown with a dashed line, and good and poor values are marked as in the above example.

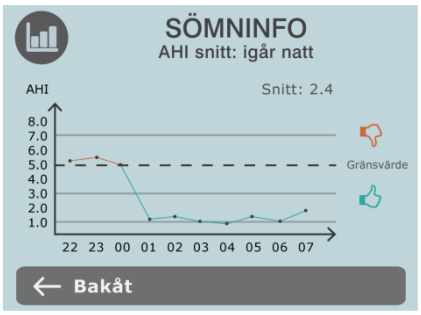


Figure 66 - Line diagram for AHI

One new technology that was implemented was telemedicine, which enables CPAP patients to exchange sleep data logs with the sleep clinic from their home, as well as receive setting changes from their nurse without having to physically come to the sleep clinic. This is done by selecting Dela sömninfo (Share sleep data) seen in Figure 65. This can be a major advantage for both hospitals and patients since it can save time and resources if managed in a good way.

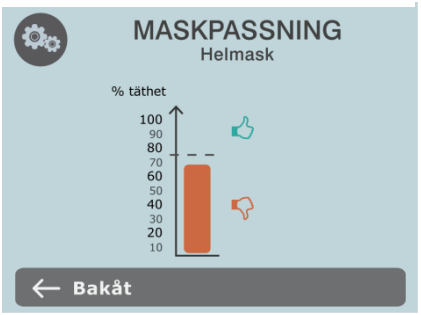


Figure 68 – Mask fitting screen

When a mask fitting test is initiated (through the menu or by holding the control dial button for three seconds), a bar chart (Figure 68) appears. This menu page shows what kind of mask is being tested and how good fit it has. The mask fit is measured in per cent based on how much it leaks. During the test, the pressure will change continuously and the bar is fluctuating around the threshold until the test is finished and the result is shown with a value and a thumb indication (Figure 69). After the test, the buttons Back and Redo test appears, with the Back button pre-selected. Several mask types often are tested after each other, but mask type has to first be changed in the previous menu.

Figure 69 – Mask fit result

8.2.1.2 Fonts

Two fonts were used in the interface - Verdana and Swis 721. Verdana was chosen as a main font for the smaller sized text in the menu rows since it is designed specifically to improve readability on digital screens (Fonts.com). For larger text like headlines, the font Swis 721 is used. It was chosen due to its clean and basic look, large amount of variations and good visual compatibility with Verdana.

8.2.1.3 Colours

The light blue was chosen as the background colour due to its calming and reassuring properties (according to the colour theory chapter found in chapter 3.3.3), is considered to be appropriate for a medical device. The light green for highlighting text in selected menu rows on the home screen was chosen for the same reason. The dark grey works as a good contrast colour and feels less serious than black, which does not seem suitable for a menu in a medical device. The turquoise-like green and orange were chosen to communicate positive and negative (which was reinforced by the thumbs). Mid-green and mid-red were not used to avoid problems for users with colour-blindness. In the stand-by mode, most of the screen is dark grey to not be too bright at night.

8.3 Usability test

A usability test was made to evaluate the concept - both the physical and the interface. In the test, both patients and medical personnel participated. The test consisted of a number of tasks presented as scenarios which they were to solve.

Figure 70 - The prototype used in the usability tests

8.3.1 Patients

All test subjects managed to complete every task that were handed to them, some with less effort and some with greater. The biggest issue in the beginning of the test was to get used the control dial, which everyone did after a short while.

One thing that was commented early on was regarding the blue circle in the standby screen. They thought it was too bright and would probably be annoying when trying to sleep. A less bright screen was desired.

One of the objectives in the test was to test how well they could navigate through the menus. There were no big problems with finding the correct functions and menu. The only issue was to understand the name of some functions or menus. For example, one subject asked what AHI and humidity level meant. However, this was because they were not all used to exploring a CPAP device this thoroughly and did not know everything the device could do. They all thought that the menu structure was logical, they managed to find even though they were not familiar with the all of the functions. In the end of the test, a scale from 1 to 5 was used to rate how easy it was to navigate through the menus. In the scale, 1 was impossible and 5 meant impossible to do wrong. All subjects gave grade 4.

They all seemed sure that they had completed the tasks correctly. This was due to the feedback they received from the interface. There were many positive comments about the status bar, which gave feedback in several ways. However, some thought that it was possible to change the values through the bar, but they learned quickly that it was not possible. A scale from 1 to 5 was also used here to rate how easy it was to understand their actions. In the scale, 1 meant guessing and 5 meant being 100% sure on everything. All subjects rated the interface a 4.

Even though two of the subjects were not interested in studying the sleep data they found it interesting. Overall the statistics were presented in a clear way, but the line chart which showed the AHI value was difficult to read because the graph line was too thin. The bar diagram was much easier to read. One thing that was mentioned in the bar diagram was two lines that were confusing. The subject seemed to think they represented some kind of limit while they were just helplines for different values.

The patients had only complained on one aspect for the physical design, which they thought was a little bit heavy. Apart from this, there were mostly positive comments. One of the participants, who also participated in the mock-up test, thought that this mock-up looked less angular and had a more effective form than the previous concepts. With the broader bottom area and the added weight it felt stable and the handle was comfortable. He also thought it looked good, even though it was only a KAPA® board model.

Overall the subjects understood the prototype well and were satisfied with its design. However, there were some changes that were going to be made based on the usability test with the patients. These were:

- Make the standby screen darker
- Change AHI to apnoeas per hour
- Change the line chart to a bar chart
- Remove lines in the graphs

8.3.2 Medical personnel

Since the medical personnel did the test together and everyone did not participate during the whole session, the focus was also here to get qualitative input.

Also the nurses thought that the status bar was a clever function. They liked that they could see the most important settings in the same place. However, they had some input about the symbols. They did not quite understand the air flow symbol. They suggested a symbol of a fan instead.

During the architecture phase it was thought that the position of the tube outlet had a downside since it had to been detached to be able to fill the humidifier. However, one of the nurses thought said, "I think you should detach the tube every day to aerate it. It is good that you force the patients to do it."

They found the way of entering the clinical mode and starting the mask fitting test very intuitive. They were used to pressing down buttons for a few seconds to find "hidden" functions. They all thought it was good that it is possible to run the mask fitting test both by going through the menu and through a shortcut. This saves time and the nurse can talk to the patient at the same time.

One extra feature they wished for was to see the current pressure while testing the masks. This was because they want to test the pressure on both 5 cm H_2O and 10 cm H_2O, since most masks are a

good fit at pressure 5 cm H_2O. Furthermore, they liked that it can be seen not only if it is a good fit but also how good it is.

The only thing they had trouble doing was they were going to turn off autostart. They did not enter the correct menu and the reasons for that were that they thought this function could belong in several sub-menus and the name of a sub-menu Pressure & Mode was a bit unclear in Swedish (Tryck & Läge).

When the nurses navigated through the menu structure they saw that the autostart was set to ON. They thought autostart should instead be pre-set to OFF. This is because it is the first time the patients try a CPAP treatment and should therefore not be surprised by a self-starting airflow, which can be perceived as very repelling.

The nurses preferred not to have the humidifier attachable/detachable. Partly due to economic reasons, but also because they have to spend more time explaining, since none receives a humidifier the first time. This would save time at the information session and the patients already get enough information that first day. Another medical reason is that it is best for the body if it can handle the air as it is.

They would like to be able to reset the settings of a device, both sleep data and pressure settings. This is because when a device is returned, both the sleep data and the rest of the settings should be reset to default before it is adjusted for a different person.

The nurses also wanted to make the standby screen darker. Then they had some questions about how long before the display goes into standby. They thought that there should be different time for clinical and patient mode. This is because the interface should always go back to patient mode when it is started from standby, and the nurses have to change many settings and they do not want the screen to go back to standby mode, and thereby patient mode, if they do something else for a minute. The nurses suggested for it to be three minutes for nurses and one minute for patients. If the airflow is on, it should take ten seconds to go to half-dimmed and another 20 seconds for standby.

To sum up the test, the medical personnel understood the prototype well and gave the interface a 4 on both scales of how easy it was to find and understand. There were some changes that were made based on their input. These were:

- Change the name Tryck & läge to Tryck & (CPAP)Funktion
- Be able to reset the settings, both sleep data and pressure & mode settings.
- Move Autostart to Pressure settings.
- Autostart should be pre-set to OFF
- Change the air flow symbol to a fan
- Standby screen darker
- Air flow on - 10 seconds to go half-dimmed, another 20 seconds for it to go into standby
- Air flow off - stand by after: 1 minute for patients, 3 minutes for nurses
- Interface should always go back to patient mode when it is started from standby
- I want to see the current pressure when testing

8.4 List of requirements

These are the last requirements that came up during the project. The requirements have evolved and the final merged list of requirements can be found in Appendix 10.

Table 7- Requirements from the detailed design phase

Dimensions 200*90*125mm	Small size for users, fit internal part	Patients
Capacity of humidifier 450 ml	To have enough water for one night	Interview with nurses
It should be balanced when lifting it	A stable product gives a more reliable impression	Designers
Equipped with Wifi	To use tele medicine	Benchmarking, theory
Have a removable usb-stick	To save settings and log data, bring to clinic	Interview nurses
Have a USB-port	To charge your mobile phone	Questionnaire patients
The control dial should have 16 steps	To enhance the haptic feedback	Guidelines
Be able to reset settings and sleep log	When a device is given to a new user	Usability test nurses
Autostart should be pre-set to OFF	To not scare first-time-users	Usability test nurses
Air flow on - 10 seconds to go half-dimmed, another 20 seconds for it to go into standby (not during mask fitting test)	To make it easier to fall asleep	Usability test nurses
Interface should always go back to patient mode when it is started from standby	To prevent patients to enter clinical mode	Usability test nurses
Air flow off - stand by after: 1 minute for patients, 3 minutes for nurses	To have time for adjustments and not go back to patients mode for nurses	Usability test nurses
View current pressure at mask fitting	To better evaluate the mask	Usability test nurses

8.5 Main conclusions

- Simple mock-ups contribute a lot when developing this kind of products for this kind of project. Form, size, weight and balance are factors that can be evaluated with them.
- The utilizing of the Facebook groups worked good for a quick evaluation of the interface.
- To be able to only push a button to start the device was appreciated by the users.
- The status bar in the interface gave the most positive feedback, especially among the nurses.
- All the users liked the design concept.
- A rough mock-up or prototype can give much response about a design even though it is not final.

9. Realisation

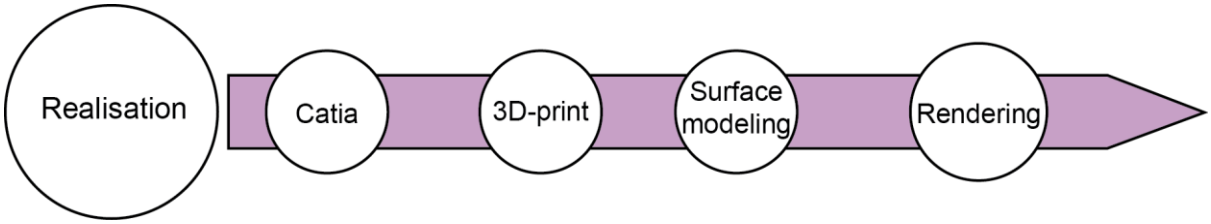


Figure 71 - Process of the realisation phase

In the last step the final concept was visualised in various ways to communicate the final results.

9.1 Physical product

A CAD version of the mock-up was created in CATIA V5, including all the elements. It was then prepared for 3D printing, and finally printed in plastic at the Faculty of Product Development at Chalmers University. The purpose of the printing was to hand over a permanent model to i3tex, which can be used in the future, for example for usability tests. The model has a slot for fitting a smartphone (with similar size of Samsung Galaxy S3) to use as a display with a streaming program in the same way as done during the usability test in this project (Figure 72). The slot can also be used to fit a piece of cardboard with a printed image for example.

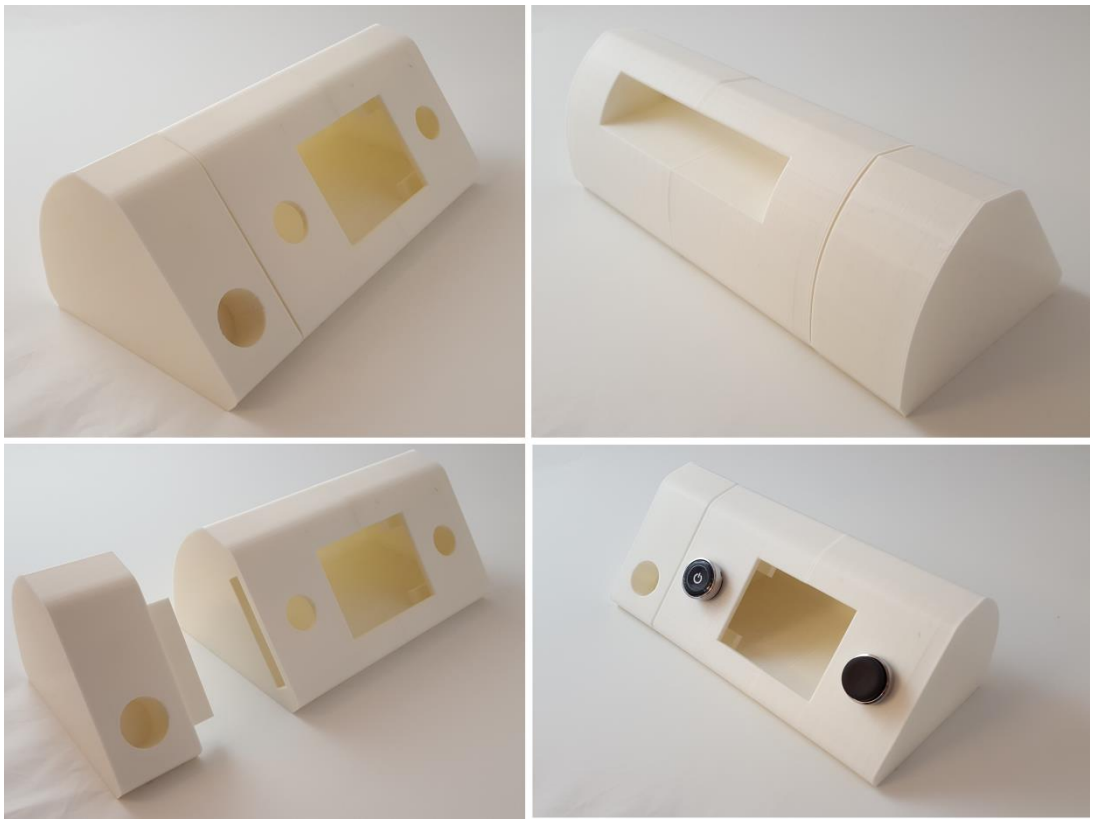


Figure 72 - Printed 3D model

Adobe Photoshop was used to try out different small variants of the final design, before modelling the complete design. Minor changes were tried out, with some contrasts between colours and aesthetics details (Figure 73).

Figure 73 - Photoshop sketches

Below are images of the CAD model that was created with Alias and rendered with Showcase (Figure 74 & Figure 75). Some simple animations were also made with Showcase for presentation purposes. The final concept has a bigger bottom than top to be stable and express reliability. The geometric edges are combined with round forms which make it look reliable, qualitative and humble at the same time. The few element and large clean surfaces contribute to its simplicity. The contrast between light and dark colours, and between round and flat surfaces or sharp corners give the product a modern and professional expression. Not like a classic medtech product.

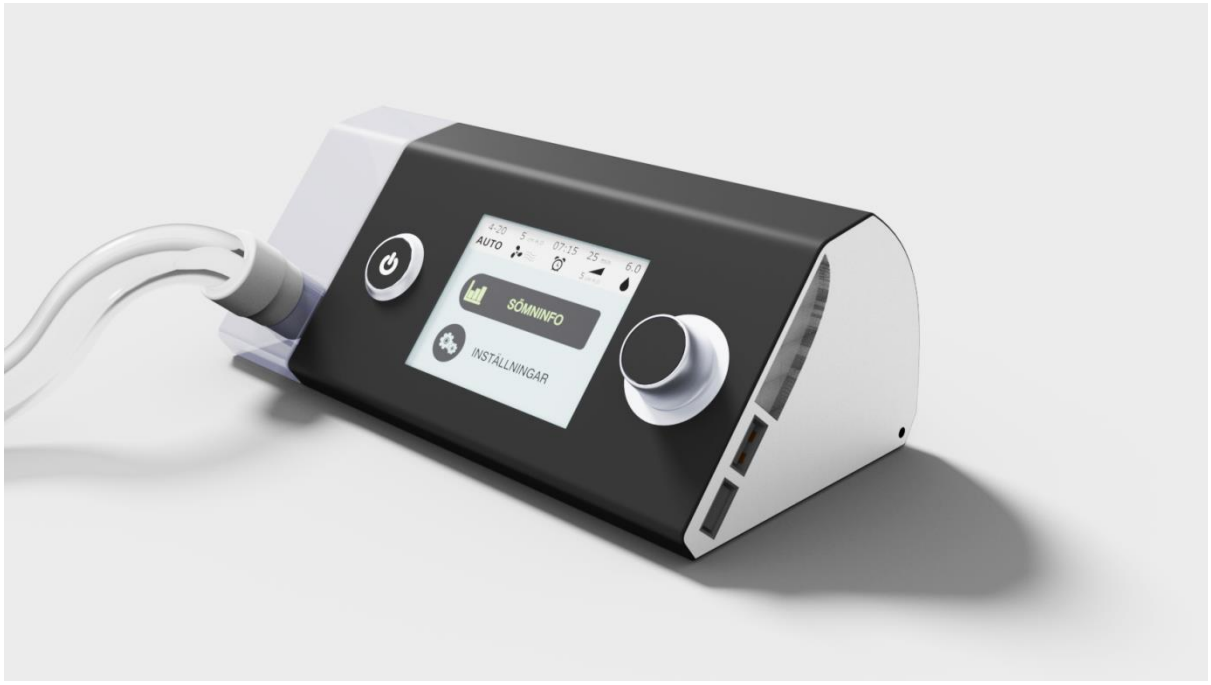


Figure 74 - Showcase rendering of front

Figure 75 - Showcase rendering of back

When the humidifier is not used, it is replaced by a lid which covers the side of the CPAP device. There is a swivel placed on the lid where the tube is attached. This swivel can rotate to make the tube more flexible.

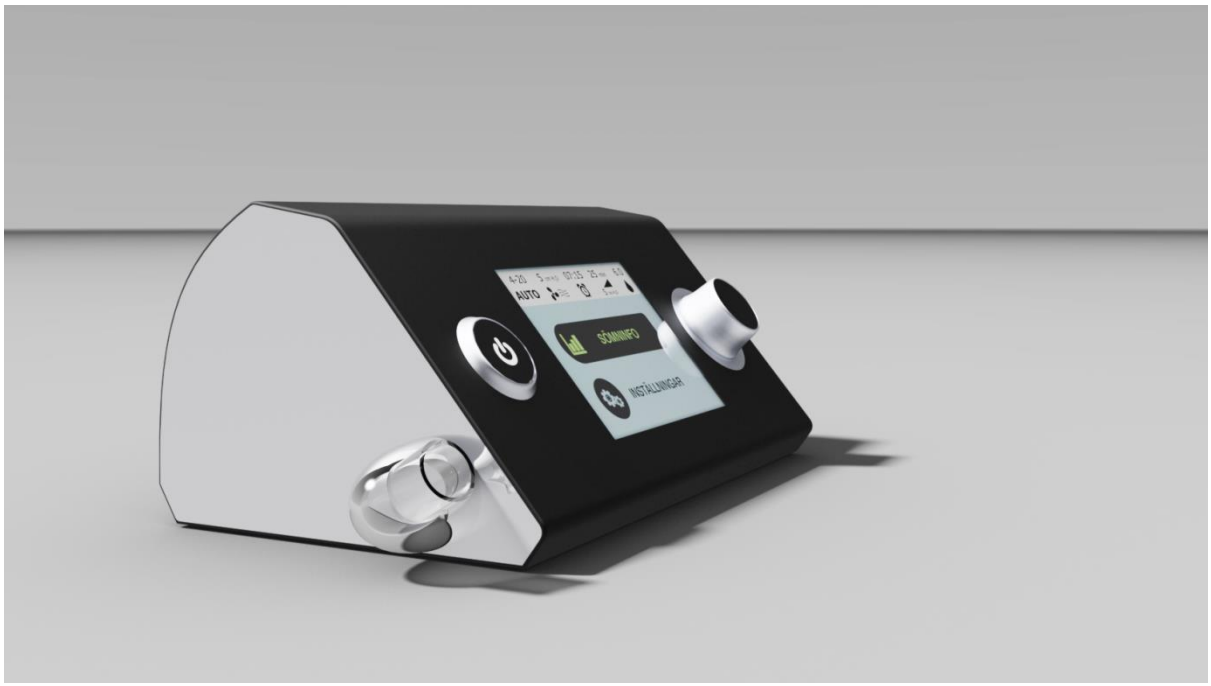


Figure 76 - CPAP device without humidifier

Figure 77 - CPAP device with swivel

9.2 Interface

The interface was finalised based on final consideration and feedback from the usability test using Adobe Illustrator. Some of the final modifications are presented below:

The colours of the stand-by screen (Figure 78) were changed to black background and dark grey circle after receiving comments about the colours being too bright, which could be annoying during the night.

The status bar symbol for air pressure (Figure 79) was modified by adding a fan to clarify that it symbolises air pressure. Some of the usability test participants commented that the previous symbol reminded them of waves, which could be misinterpreted as a symbol for the humidifier.

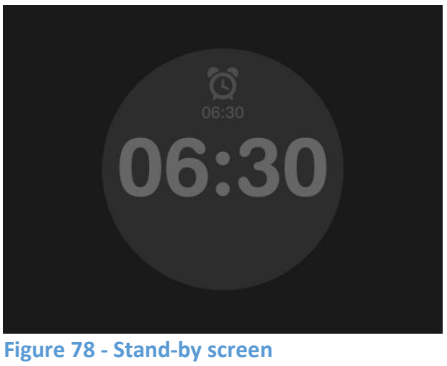


Figure 78 - Stand-by screen

Figure 79 – Home screen

As seen in Figure 82, the menu row for pressure settings was changed from Pressure & Mode to Pressure & CPAP function (Tryck & CPAP-funktion). This was done due to comments from the nurses participating in the usability test that Mode was unclear, at least in Swedish. The clinical personnel also expressed that it would be better to write Last night (Senaste natten) instead of Yesterday night (Igår natt) since not all users use their CPAP device every night (Figure 81). One of the usability test participants from the patient user group had trouble understanding the help lines in the sleep info diagrams and thought they were confusing rather than helpful so they were removed (Figure 80).

Figure 82 - Pressure settings

Figure 81 – Sleep info

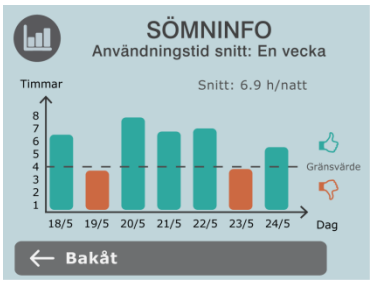


Figure 80 – Updated bar chart

The chart presenting the average AHI for the selected time period was modified from being a line diagram to being a bar chart (Figure 83) because it gave a better and clearer overview.

Current pressure was added to the mask fitting test image according to a comment by a nurse at the sleep lab at Salhgrenska (Figure 84). She wished to be able to see the current pressure as a test with low pressure of 5 cm H_2O is often done first, followed by a test with 10 cm H_2O pressure.

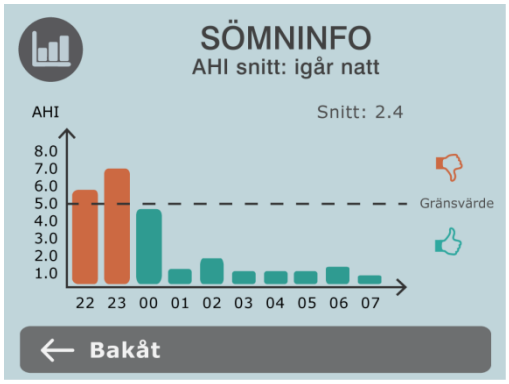


Figure 83 – Bar chart instead of line diagram

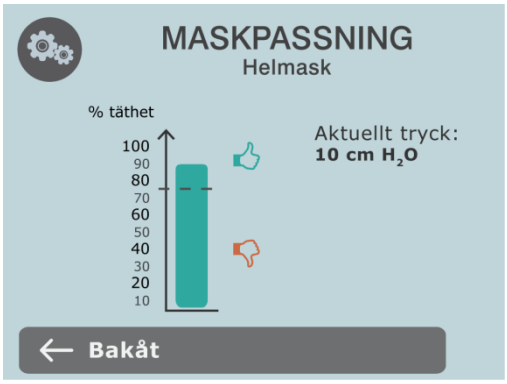


Figure 84 – Mask fit screen

When all corrections had been made, the interface images were linked together in PowerPoint, to make it possible to navigate through the different menus. Not all the images in the complete menu structure were created, just a few example menu entries to be able to communicate and test the idea of the interface and its components.

9.3 Main conclusions

- When the humidifier is not used, it is replaced by a lid with a swivel which covers the side of the CPAP device.
- The device together with the interface has a simple, reliable and humble expression and it does not remind of a medical technical product.

10. Discussion & conclusions

The discussion and conclusion is merged together in this chapter. Here, subjects such as the process of the project, methods used, functions of the new concept and designing a user-centered product are discussed.

10.1 The process

The project was carried out according to the ACD[3] process developed by Lars-Ola Bligård (who was also our supervisor) with support from Eva Simonsen. It is a very straight-forward process that starts wide and abstract with identifying what is needed to initiate the product development. In this case, this was done by researching the related medical condition (sleep apnoea) and the treatment (CPAP) as well as getting to know the users, both on the clinical and the private side. The insight of who the users are and what they need has been crucial in this project.

The method that quite unexpectedly gave a lot valuable insight was observing CPAP users via two different Facebook groups. It gave a very honest view of sleep apnoea patients' reality and what they go through. Since both of us became members of these groups, we got daily posts on our Facebook walls with members showing pictures of themselves wearing their new CPAP, complaining about how uncomfortable it is to sleep with, inspiring others with how they have managed to get rid of their sleeping problems thanks to CPAP, and posting news about new products, apps etc. This contributed to building a thorough understanding of the users' situation. One potential drawback with using social media is that people might not behave as they would normally, and may act less serious for example.

The process continues with taking this knowledge and applying it by developing the usage design - how to fulfil the users' needs. In this project, the constraints regarding the end deliverables was that it should be a physical product that is more modern and user-friendly than the Breas iSleep 25 thanks to new possibilities allowed by e.g. new technology. As a consequence, this step came to be about developing a user-friendly CPAP device with an expression that was appropriate for a medical product being used in a home environment. If the scope would have been different, this step could have allowed freer thinking and include other directions than specifically a CPAP device.

Throughout the project, the interface and the physical design have been developed parallelly. The initial idea was to develop these two components in close connection so that the expression of the interface was synchronised with the expression of the physical product. In reality, this was difficult to achieve and they have rather been developed separately, but towards the same value words. However, some parts are highly correlated between the interface and the outer shape, such as what kind of buttons to have and where to put them. In this case, the graphical interface and the physical design affect each other a lot and had to be developed together.

In the Transformation step, the expression and usage design were translated into something more tangible. For us, this was a new way of working with product development, but it ended up working well.

The expression of a form or product is highly subjective, and in this project we chose to not let the subjects evaluate the expression. Instead, we developed the form based on the product research and other gathered inspiration. In hindsight, it would have been a good idea to at least let the usability test participants evaluate the expression of the final concept. However, in this case it would probably not have given that much valuable information since the detailed design was not finished and thereby no renderings or similar. Instead, they would have evaluated the white KAPA® board mock-up, which would not be suitable for a fair evaluation.

According to the one of the objectives of the project, the concept should meet the usability standard for medical devices, which specifies a process to develop and validate a safe product. However, during the project a different process has been used. Nevertheless, we made sure that the standard process was included in our process. The standard reminds a lot like a regular usability process, which we have been using, but with more focus on safety. The safety aspect has been considered with examples such as the separated modes, the easy navigation and the feedback.

The book describing the ACD^3 process suggests a number of methods for each step. We ended up using only a few of those methods, simply because we did not feel the need of using them, and there is no point in using methods "just to use them". Our project has mostly been about understanding the users and their needs and developing the product based on that knowledge, and then backed it up with helpful guidelines. The procedure has basically been: gather knowledge, design, test, redesign, test, etc.

10.2 Evaluation methods

The creation of mock-ups resulted in many positive after effects. It helped us to see and understand our concepts better by interacting with something real and not only with computer programs or sketches. For the users we met it also worked as a mediating object, which creates a discussion. We think it is easier to talk about a subject if there is an object to speak around.

The information collected from the usability test at Sahlgrenska was more extensive and elaborated than the information gather at the first visit and the questionnaire. This might have depended on that we were more familiar with the situation this time and we could interpret more information. It could also have been due to the concept of testing a new product with experienced users, since they know what they expect from it. Also here the prototype works as a mediating object which generates discussions and thoughts. These qualitative meetings seemed to give more valuable information than the questionnaires.

We would have wanted more people to evaluate our concept in the usability test. The reason for having few subjects was because it was difficult to come in contact with CPAP users who were willing to participate. More test subjects would have meant that a more quantitative study could have been made. It would also have resulted in a more secure validation that the interface is simple enough. The few participants involved in this project gave more of a hint of how much they understood and what they liked. It could have been appropriate to arrange another test once the final changes were made in order to get a final confirmation that the changes were good. The result was nevertheless positive since all subjects managed to solve all tasks and were satisfied of how it was done.

Due to the few real users directly involved the project has been focusing on qualitative input. This works well in this kind of projects since you really get to know and understand the users more deeply. By involving users, qualitative information can be gather which is not possible to find just by reading about the subject from a book. On the sleep clinic for example, the test became more of a discussion were the participants commented and questioned each other. That is more rewarding than to only look at a task were where 2 out of 3 did it correctly. The close involvement with users, through interviews, observations and prototype test has given us a great possibility to develop a user customized product, which they understand and like.

One feature which received a lot of positive response was the status bar. Particularly the medical personnel liked it, since they quickly can see the most important settings in one place instead of separate menus. This would save time which is much valuable in their stressful context.

One thing was mentioned by the sleep clinic regarding the thumbs up or down charts in the interface. Deciding if a value is good or bad might not be so easy to say because it is much more complex than that. If we take the AHI as an example, there are other factors that decide if it is good or bad than just the number. Factors such as type of sleep apnoea, other diseases or what AHI the patient had before the therapy started also affect how good the AHI value actually is. The statistics in the sleep data is more of a hint for the patient. The medical personnel will use more factors when looking at the sleep quality.

One challenge with developing a product with different user groups is that they have different opinions about it. For this product the medical personnel have a more professional perspective to the CPAP device and patients have a more personal relation to it. It seemed that the nurses wanted to have as few functions as possible to perform what it is aimed to do. The patients on the other hand have more wishes about the functions, which they think will improve the product. We think it is important to not do exactly what the users say but to use your instincts as a designer to use the user desires in the best manner.

10.3 Telemedicine

When it comes to implementing telemedicine into medical devices, there are both pros and cons about it. Some positive aspects are that the patients do not have to travel to the sleep clinics and such for check-ups, and that the hospital is supervising the patient's sleep quality. This saves time and has also a positive impact on the environment. On the other hand the nurses thought that the physical meetings are good to not completely lose the contact with the patients. Many patients feel safe when they visit the hospital and get to speak to a doctor or a nurse face to face. Jan Hedner was also not sure if telemedicine would save time for the medical personnel, since they would have so many more to keep track on. A system where telemedicine is a reality would require some sort of prioritization system for those who have the worst problems and the sleep data cannot be checked every day but rather a few times per year. Since diseases and such can be a sensitive subject, the concept of telemedicine will be affected by the integrity question. Who should have access to the patient's file and have control over the CPAP device?

10.4 Finishing words

During this project, the process and way of working has been more important than the product itself. The goal was not to create a revolutionizing product, but rather creating a concept that has the potential to be well suited for the users and liked for features they interact with. The fact that the product has been developed in an increasingly detailed manner close to typical end-users has resulted in a product that is above all user friendly, which was the aim of this project. The final concept received positive feedback from both user groups during the evaluation, which indicates that it would fit into their context.

The look of the product is quite discrete and is not too bold, which is line with what most users wanted. It has the basic features that can be expected from a modern CPAP device, and some additional features that should satisfy the users, such as the possibility to upload sleep data and charge the phone via the USB port.

Here are some final points to connect the conclusions to the initially stated goals:

- The purpose and aim of the project were to demonstrate the usability design process by designing a user friendly CPAP device, considering the expression and design of both the physical form and the user interface. This is exactly what the result of this project is.

- We set out to fulfil usability requirements and meet current standards for medical devices. Generic usability guidelines were used to facilitate the design decisions related to the user interface, and the development steps suggested in the ISO standard for medical devices were well met due to the use of the user-centred ACD3 process.

- A thorough understanding of the users' needs was developed early in the project, and kept on growing during the whole process. This led to a final result that is well adapted for use by the intended users in the intended context, and has the appropriate expression.

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Appendix

Appendix 1

Questionnaire Patients

Vi studerar till ingenjörer inom produktutveckling och design på Chalmers här i Göteborg och gör just nu vårt examensarbete. Där ska vi designa en ny, användarvänlig CPAP. Eftersom den ska vara lättanvänd är det viktigt att utgå från användarnas behov och önskemål i utvecklingen, så därför vill vi fråga vad ni tycker är viktigt och om ni har några tankar och idéer kring problematik med befintliga CPAPer och hur de kan förbättras.

Namn: Ålder: Kön: Diagnos:

1. ***Hur kommer det sig att du använder en CPAP och hur gick det till när du påbörjade behandlingen?***

2. **Hur länge har du använt den?**

3. **Vilken modell har du?** Har du provat någon annan, har du hört andras kommentarer?

4. **Hur tycker du att den fungerar? Vad är bra / dåligt? Hur kan det förbättras?**

    a. Har din inställning gentemot CPAPen ändrats med tiden?

5. **Hur går du till väga när du ska gå och lägga dig? Vilken funktion använder du oftast?**

6. ***Är det någon funktion du saknar?*** **(Extra inställning, kombinerad med annan produkt?)**

7. Tycker du att den är lätt att använda och förstå?

8. **Vilka egenskaper är viktigast? Välj 3.**

    a. Diskret

    b. Pålitlig

    c. Hållbar

d. Tyst
e. Stabil
f. Portabel
g. Lätt
h. Avancerad
i. Liten
j. Modern

9. Tycker du att den passar in i din hemmiljö?
    a. Om ja - varför?

    b. Om nej – varför inte?

10. ***Var gör du av den under dagen då den inte används?***

11. ***Hur gör du med CPAPen när du åker hemifrån?***

12. **Är du intresserad av detaljerad information om pågående behandling, (såsom en summering av nattens sömn)? Vilken information vill du kunna se? App/moln**

13. Vad anser du om möjligheten att vårdgivaren på distans kan granska hur bra du sover och justera inställningarna på din CPAP?

Appendix 2

Interview structure Sahlgrenska sleep clinic / Jan Hedner

1. Hur länge har det funnits CPAPer i Sverige?

2. Hur länge har sömnlabbet funnits?

3. **Vilka kommer hit? Hur har de uppmärksammat det?**

4. **Ser man någon trend I vilka och hur många som drabbas av sömnapné?**

5. **Hur går det till från att en patient hör av sig med misstanke om sömnapné till det att han/hon får en lyckad behandling?**

6. Hur ofta kommer patienter in på återbesök? Vad görs då?

7. Hur skiljer sig behandlingen mellan OSA och CSA?

8. Vad är de största orsakerna till följdsjukdomar? Dålig sömn, syrebrist, stresshormoner...?

9. **Hur brukar patienters inställning vara till CPAP-maskiner?**

10. **Har ni flera CPAP:er att välja bland? Vilken föredrar folk I sån fall?**
    a. Någon skillnad mellan åldrar, kön?

11. **Vilka inställningar gör användarna?**
    a. **sjukhuspersonalen**
    b. **patienten**
    c. Samlade användarfeedback

12. **Tycker du att det är någon funktion som saknas?**

13. **Vill man genom maskinen ge feedback om statusen av patientens sömn? (Oroar man patienten då?)** Finland.

14. **Ser du/användarna några problem med dagens CPAPer?**

    a. **Sjuksköterskor?**

    b. **Patienter?**

15. Ser du något kompenserande beteende hos patienter?

16. **Vilka risker finns det och vilka skador kan uppstå? Worst case scenario? (patienterna/sjuksköterskor)**

    a. Går det att förebygga?

17. Vid designen av en CPAP, vad är viktigast för sjukhuspersonal? (Ergonomi, estetik, material, touch, knappar)

    a. Patienten?

18. Ser du någon trend inom CPAP-utvecklingen?

19. **Finns det några patienter som brukar vara villiga att ställa upp på intervjuer etc.?**

Appendix 3

Questions - head nurse

Hur går det till från att en patient hör av sig med misstanke om sömnapné till det att han/hon får en lyckad behandling?

Hur ofta kommer en typisk patient tillbaka på återbesök?

Vad är anledningen?

Hur många patienter kallas på återbesök "i onödan" (det visar sig att inställningarna redan är bra)?

Hur många CPAP:er ställer ni i genomsnitt in åt patienter under ett skift?

Vilka tillverkare och modeller köps in till avdelningen? Vilken modell används mest, en favorit? Fördelning mellan olika modeller?

Vad är det som avgör vilken modell som används för olika patienter? (diagnos, personliga preferenser, etc.)

Hur ofta lämnas CPAP:er tillbaka? Vad beror det på? (reklamation, ogillas av patient, etc.)

Var vänder sig patienten när produkten inte fungerar som den ska? Får ni ofta frågor om hur produkten fungerar?

Hur ser du på att ge patienten möjlighet att komma åt fler funktioner? Vill man som vårdgivare behålla kontrollen?

Vad anser du om touch-displayer i stället för traditionella knappar/reglage?

Appendix 4

Frågeformulär – Sjuksköterskor

1. Vilken CPAP-modell använder du oftast?
    a. Vad anser du om hur lätt den är att använda?
2. Vilka inställningar gör du normalt i menyn?

3. Vad är viktigast när du ändrar inställningar i menyerna?
   Rangordna alternativen. 1=viktigast, 5 = minst viktigt

___ Att det går snabbt

___ Att du är säker på att du har gjort rätt (t.ex. får feedback i form av ljudsignal)

___ Att menyn är estetiskt tilltalande

___ Att det är svårt att göra fel (t.ex. inte för små knappar)

___ Att det är tydligt och överskådligt

___ Annat: _____

4. Vad anser du om möjligheten att få patientens sömnrelaterade data på distans? Varför?
    a. Hur skulle du vilja ta del av denna data?
5. Vad anser du om möjligheten att kunna ändra CPAP:ens inställningar på distans? Varför?
    a. Hur skulle du vilja ändra dessa inställningar?

6. Ser du några problem med handhavandet och/eller användandet av nuvarande CPAP:er? I så fall vilka?

7. Vad anser du om CPAP:er från följande tillverkare?
    a. Fisher & Paykel
    b. Breas
    c. ResMed
    d. Philips Respironics

Appendix 5

Namn: Ålder: Kön:

* Design och utveckling utifrån användarens behov och förutsättningar.
* Fokus på de delar av CPAPen som användaren kommer i kontakt med under normalt användande.
* För tillfället fokuserar vi bara på de fysiska delarna, men kommer sedan även att designa menyn.

1. Hur ser din procedur ut när det gäller användning av din CPAP, från att du vaknar på morgonen till att du går och lägger dig på kvällen?

2. Var gör du av den under dagen då den inte används?

3. Använder du befuktare? Hur går du tillväga för att fylla på och rengöra behållaren?

4. Hur ofta flyttar du den? Var i så fall?

5. Vilken av formerna tycker du bäst om? Varför? Är det något du skulle vilja ändra för att göra den ännu bättre?

6. Vilket av handtagen tycker du verkar mest praktiskt? Varför? Har du något förslag på en bättre lösning?

7. Vilken placering av display och kontrollhjul tycker du bäst om? Varför? Är det något du skulle vilja ändra för att göra den ännu bättre?

8. Vilken placering av slanguttag tycker du bäst om? Varför? Är det något du skulle vilja ändra för att göra den ännu bättre?

9. Vilken placering av vattenbehållare tycker du bäst om? Varför? Är det något du skulle vilja ändra för att göra den ännu bättre?

10. Kan du läsa all text på "displayen"? Något som är för litet?

11. Vilket typsnitt tycker du bäst om?

12. Om du skulle göra en egen CPAP, hur skulle den se ut? (inkludera alla delar diskuterade ovan)

Appendix 6

Tasks Patients

Inledande frågor

Ålder:

Vilken CPAP-modell har du?

Hur länge har du haft den?

Vad gör du med din CPAP? Något mer än att starta den?

1. Det här är din nya CPAP. Ta den från väskan och ställ den på bordet.
   Om de inte använder handtaget - fråga varför?

   a. Har du något första intryck? (form, storlek, vikt, uttryck, påminner den om något etc.)

2. Förklara hur testet kommer att gå till:
   a. Display - inte touch
   b. Vredet - det går att vrida höger, vänster och trycka ner den.
   c. förklara att subjektet bör säga till att när denne vrider höger, vänster eller trycker in knappen

   d. Vi kommer att läsa upp ett antal scenarion, där det ingår uppgifter som du ska lösa med hjälp av produkten.

   e. think out loud - protocol. Tänk gärna högt. Varför gör att du gör de val du gör.

   f. Vi tar det lugnt och känn ingen stress. Det är konceptet vi utvärderar - inte dig.

   g. Ok att filma/spela in ljud?

3. Nu har du placerat CPAPen på sin plats. Du har gjort dig klar för att sova.
   Berätta och visa hur du nu går tillväga enligt dina rutiner.
   Starta sedan luftflödet på maskinen. *Starta iSleepen.*

   Tror du att du har gjort rätt? Varför?

   a. Stäng av luftflödet igen

4. Nu är det ett nytt scenario. Igår tyckte du att lufttrycket var lite för högt för att kunna somna. Därför vill du att trycket ska börja på 4cmH2O och sedan långsamt höjas under 30

min tills den når standardtrycket. Hur går du tillväga?

Säg till när du känner dig färdig.

5. Imorgon måste du passa en tidig tid. Du måste kliva upp 06.30. Vad gör du?

   Starta luftflödet och Gå tillbaka till hemskärmen.

   a. Tror du att du har gjort rätt på de två föregående uppgifterna? Varför?
   b. Hur tolkar du symbolerna på Hemskärmen?

6. Nu är det morgon och det här händer (*alarmsymbol på startskärmen och ringsignal*). Vad skulle du göra?

7. Efter att du vaknat vill du kunna se hur många sömnapnéer per timme du har haft under natten? Hur går du tillväga?

   a. Hur många apnéer per timme hade du?
   b. Är det ett bra eller dåligt värde?

8. Du vill även se hur många timmar i snitt per natt som maskinen har varit aktiv den senaste veckan.

   a. Vad var snittet?
   b. Med ny teknik kan du skicka din statistik till din mottagning hemifrån.
      Hur tror du att man gör det?
   c. Tror du att du har gjort rätt? Varför?

9. Nu vill du ta ut och göra rent fuktaren. Hur skulle du gå tillväga?

   Har du några synpunkter angående detta?

Hur enkelt var det att hitta i menystrukturen? 1 omöjligt 5 det går inte att göra fel

1	***2***	***3***	***4***	***5***

Hur lätt var det att förstå vad du gjorde.....? 1- gissade mig fram 5 - 100% säker på allt

1	***2***	***3***	***4***	***5***

Visste du var i systemet du befann dig?
Förstod du vad alla knapptryckningar innebar?
Hur upplevde du designen och layouten?

VI kan bläddra igenom interface igen...

Var det något du inte förstod? Hur man gör något, innebörd, medicinska termer, symboler etc.

1. Presentera de fysiska aspekterna av designen (handtag, fuktare, vinkel, usb, osv)
2. Vad tycker du om den fysiska designen på produkten? Skulle den fungera utifrån dina behov?
3. Några förbättringsförslag?

Appendix 7

Tasks nurses

Vi gör det här o det här. Mockup...

Inledande frågor

Ålder:

Hur ofta brukar du interagera med en CPAP?

Vad gör du då?

Ok att filma/spela in ljud?

En annan sköterska har precis gjort en genomgång om sömnapné för patienter som ska börja använda CPAP. Nu ska du visa hur den används.

1. Det här är CPAPen som patienten ska få. Ta den från väskan och ställ den på bordet.
   Om de inte använder handtaget - fråga varför?

   Lifts it up with both hands. Mentions afterwards that no other model which they use have a handle. They liked the S8-model which had a handle.

   a. Har du något första intryck? (form, storlek, vikt, uttryck, påminner den om något etc.)

2. Förklara hur testet kommer att gå till:
   a. Display - inte touch
   b. Vredet - det går att vrida höger, vänster och trycka ner den.
   c. förklara att subjektet bör säga till att när denne vrider höger, vänster eller trycker in knappen
   d. Vi kommer att läsa upp ett antal scenarion, där det ingår uppgifter som du ska lösa med hjälp av produkten.
   e. think out loud - protocol. Tänk gärna högt. Varför gör att du gör de val du gör.
   f. Vi tar det lugnt och känn ingen stress. Det är konceptet vi utvärderar - inte dig.

3. Nu har du placerat CPAPen på sin plats. Du har gjort dig klar för att förklara hur den här fungerar.
   Berätta och visa hur du nu går tillväga enligt dina rutiner.
   Starta sedan luftflödet på maskinen. *Starta iSleepen.*

   Tror du att du har gjort rätt? Varför?

   a. Stäng av luftflödet igen

4. Det är nu dags att testa ut en lämplig mask för patienten. Hur går du tillväga steg för steg och hur säkerställer du att masken är lämplig?

5. En patient kommer in för att han tycker att han sovit dåligt den senaste veckan. Du vill du kunna se hur hans sömnkvalitet varit. Du vill se hur många timmar per natt i snitt denne har använt maskinen samt även dag för dag.

   Hur går du tillväga?

   a. Är det ett bra eller dåligt värde?

6. Samma patient tycker att det är irriterande att luftflödet startar då han sätter på sig masken. Han vill gärna att du stänger av det.

7. *Hur enkelt var det att hitta i menystrukturen? 1 omöjligt 5 det går inte att göra fel*

1	***2***	***3***	***4***	***5***

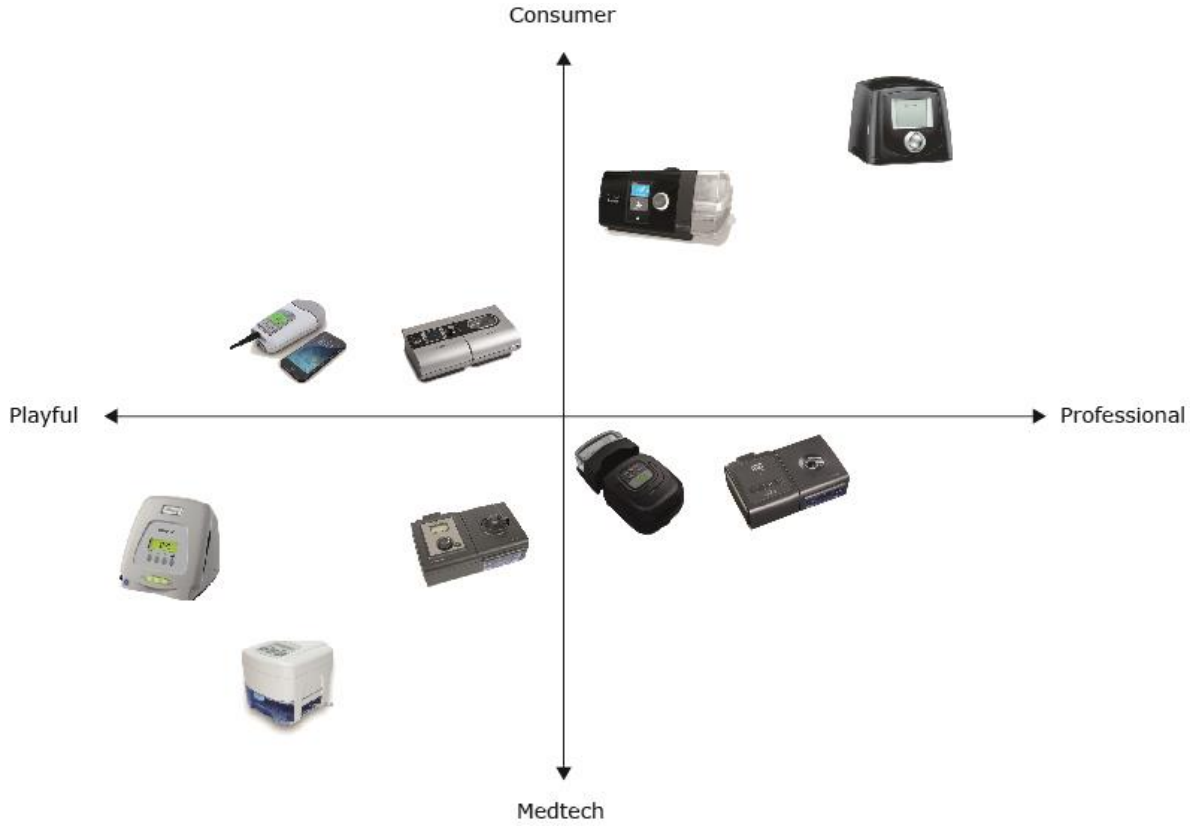
Hur lätt var det att förstå vad du gjorde.....? 1- gissade mig fram 5 - 100% säker på allt

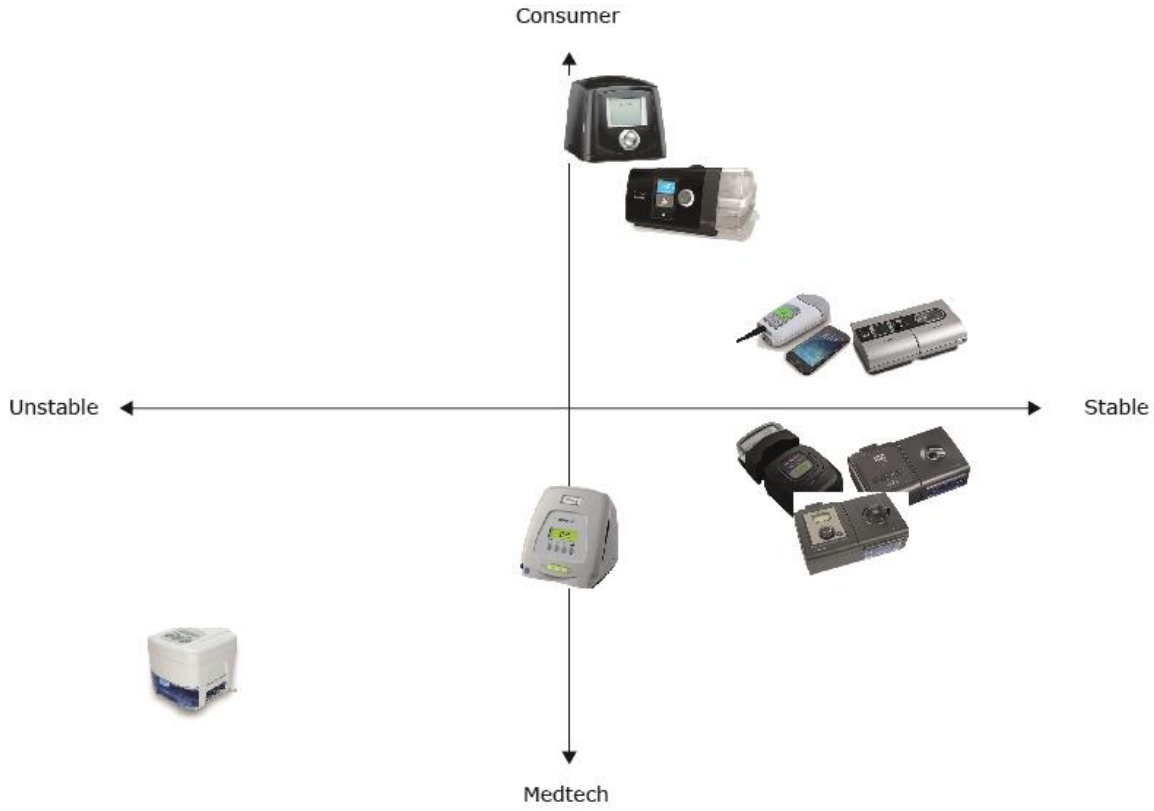
1	***2***	***3***	***4***	***5***

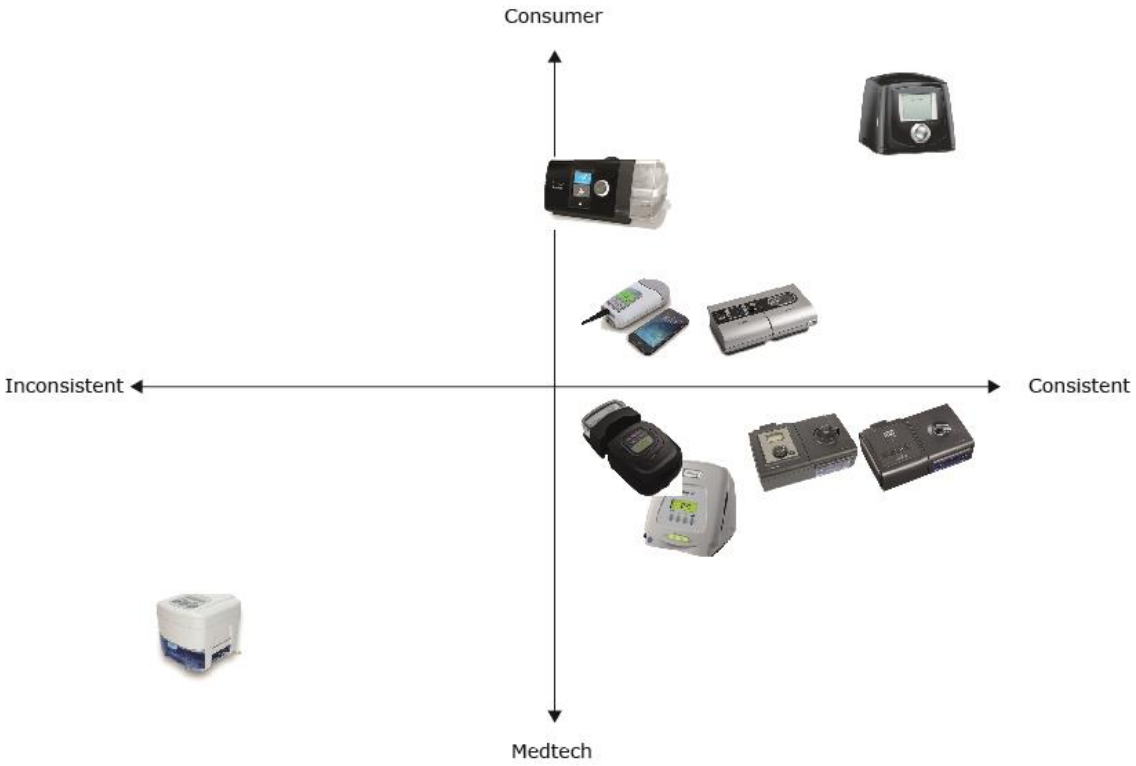
Visste du var i systemet du befann dig? Förstod du vad alla knapptryckningar innebar? Hur upplevde du designen och layouten? Fysiska aspekterna..

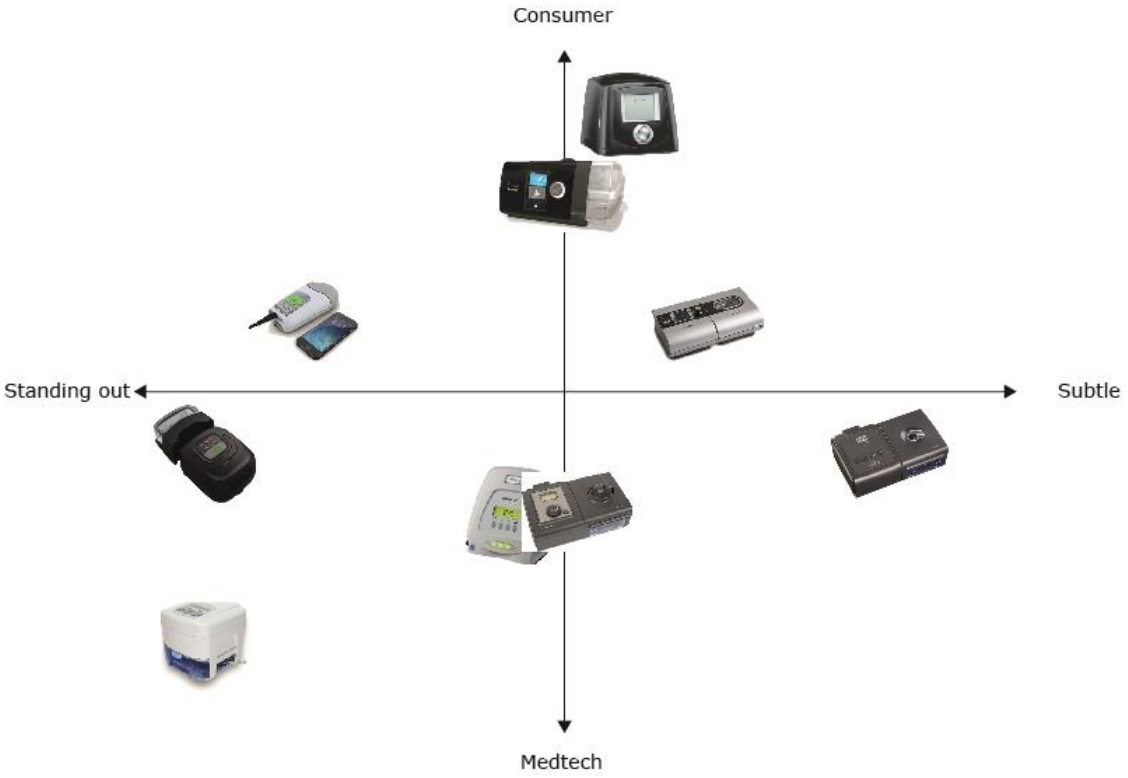
Appendix 8

Benchmarking matrices






Consumer
Inconsistent
Consistent
Medtech


Consumer
Standing out
Subtle
Medtech

Concept	Basic form	Handle	Tube outlet	Menu control	Humidifier container	View interface	Validity
Concept 1	Triangle	Fixed integrated hand	Side with swivel (left)	Control wheel	Removable	Fixed angle	5 (all parts work)
Concept 2	Triangle	Fixed integrated finger	Back (low)	Control wheel	Integrated	Adjustable angle	5 (all parts work)
Concept 3	Triangle	Foldable	Back (high) with swivel	Control wheel	Exchangable	Fixed angle	4 (exchangable not optimal)
Concept 4	Triangle	Flexible (amp type)	Front (right)	Control wheel	Removable	Fixed angle	4 (tube on front not good)
Concept 5	Triangle	Fixed integrated hand	Top with swivel	Control wheel	Integrated	Adjustable angle	5 (all parts work)
Concept 6	Slope	Fixed integrated finger	Front (left)	Control wheel	Exchangable	Adjustable angle	5 (all parts work)
Concept 7	Slope	Flexible (amp type)	Side with swivel (right)	Control wheel	Integrated	Fixed angle	5 (all parts work)
Concept 8	Slope	Fixed integrated hand	Top	Control wheel	Integrated	Fixed angle	5 (all parts work)
Concept 9	Slope	Foldable	Back (low)	Control wheel	Removable	Adjustable angle	5 (all parts work)
Concept 10	Slope	Flexible (amp type)	Back (high) with swivel	Control wheel	Removable	Fixed angle	5 (all parts work)
Concept 11	Block	Fixed integrated finger	Front (right/left)	Control wheel	Exchangable	Fixed angle	2 (handle difficult, tube/exchangable takes too much space,
Concept 12	Block	Fixed integrated hand	Back (high) with swivel	Control wheel	Integrated	Adjustable angle	5 (too little space for wheel?)
Concept 13	Block	Flexible (amp type)	Back (low)	Control wheel	Removable	Adjustable angle	3 (low tube and remvable dont work tgh)
Concept 14	Block	Foldable	Side with swivel (right/left)	Control wheel	Integrated	Fixed angle	5 (all parts work)
Concept 15	Block	Fixed integrated hand	Top	Control wheel	Removable	Adjustable angle	3 (removable and handle doesnt work)
Concept 16	Block	Foldable	Back (high) with swivel	Control wheel	Integrated	Fixed angle	5 (all parts work)
Combined concept 1	Triangle	Fixed integrated finger	Front left bottom	Control wheel	Integrated on left	Fixed angle	Integrated handle on the back maximises the area on the front for display and control
Combined concept 2	Slope	Fixed integrated hand	Left side low	Control wheel	Integrated on top	Fixed angle	Integrated container on top, combined with handle to lift CPAP if it's rotated
Combined concept 3	Block	Foldable top	Back (high) with swivel	Control wheel	Integrated on top	Fixed angle	Foldable handle on top, humidifier container accessed through a lid on top, lift up container to fill

Appendix 10

Requirement	**Origin** (user, external)	**Method** (Observation, interview, facebook, questionnaire, ISO, research...)
Pressure settings		
Must be possible to lock on constant pressure and pressure intervals	To make the treatment effective	Procurement requirement
The pressure settings must be lockable	To not let patients change pressure	Procurement requirement
Automatic pressure adjustment possible	Easier to provide the correct pressure	Benchmarking, interview nurse
There must be a medical mode separated from a patient mode	The patient should not be able to change all settings	Interview with patients, nurses. Benchmarking
Enter the clinic mode by holding down the start button and control dial for 3 seconds	So the patients does not enter the mode by accident	Procurement requirements
No pressure settings in patients mode	Patients should not change pressure	Benchmarking, interview nurse
Dimensions 200*90*125mm	Observation of photos, interview with patients, Questionnaire patients, fit internal part,	Observation of photos, interview with patients, Questionnaire patients
Display		
Have a display	To view interface menu	Procurement requirement
Have a 50 degrees display angle	To see read it from several angles	Observation nurse. mock-up test, Observation of photos
Readable display in darkness	The device is used at night	Guidelines
Air flow on - 10 seconds to go half-dimmed, another 20 seconds for it to go into standby (not during mask fitting test)	To make it easier to fall asleep	Usability test nurses
Interface should always go back to patient mode when it is started from standby	To prevent patients to enter clinical mode	Usability test nurses
Air flow off - stand by after: 1 minute for patients, 3 minutes for nurses	To have time for adjustments and not go back to patients mode for nurses	Usability test nurses
Tube & Humidifier		
Tube placed towards the bed	Shortest way to the bed User can place CPAP on either side of the bed Minimize damage to the hose	Observation of photos, Interview with patients, Questionnaire patients

Include a humidifier	To moist the throat	Interview with patients, nurses. Benchmarking
Humidifier connectable	50% usage (in Västra götaland)	Interview nurse
Adjust humidity level and temperature	To moist the throat, not integrated	Interview & questionnaire with patients, nurses. Benchmarking, Mockup-test
The humidifier placed to the left	So that the tube is not in the way of the display	Mock-up test patients
Capacity of humidifier 450 ml	To have enough water for one night	Interview with nurses
Possible to see the water level	To see how much water there is left	interview patient, nurses
Functions		
Have ramp function	It is easier to fall asleep	Benchmarking, interview with patients
View average usage time and total usage time	Min. usage time for continued CPAP therapy is 4 hours/night	Interview with nurse
View hours of usage time previous session	Statistics interests some people	Interview with patients
View AHI	To see how effective the treatment is	Interview with nurse
Be able to see if statistics are good or bad	Patients have difficulty knowing if a value is good or bad	Interview patients, interview nurse
Be able to reset settings and sleep log	When a device is given to a new user	Usability test nurses
Integrated clock and wake up alarm	Avoid need of multiple objects on bedside table	Observation of photos, questionaire
Be able to transfer data to the doctor/nurse	For analysing the data	Interview nurse
Should be prepared for tele medicine	For people can send the sleep data from home	Theory, Interview patients
Equipped with Wifi	To use tele medicine	Benchmarking, theory
Notifications of alarms and why the alarm occured	To minimise need of technical support	Questionnaire patients
Possible to change language	For customization	Benchmarking, usability test nurse & patient (for confirmation)
Autostart should be pre-set to OFF	To not scare first-time-users	Usability test nurses
Buttons		
Have physical buttons	Nurses wants to look at the patients while talking to them	Interview nurse
Have a control dial	Intuitive and effective way of navigating	Benchmarking, usability test nurse & patient (for

		confirmation)
The control dial should have 16 steps	To enhance the haptic feedback	Guidelines
Control dial to the right of the display	Association with display obvious, right handed	Mock-up test patients
Have a separate Start button	For the users who just is interested in starting the air flow	Observations patients, interview patients
Mask fitting		
Be able to test mask fitting	To see if the mask fits the patient, common adjustment	Observation nurse, interview nurse
To start mask fitting test – hold down the control dial for 3 seconds	Common function for nurses	Observation nurse
View current pressure at mask fitting	To better evaluate the mask	Usability test nurses
Show if the mask leakage is acceptable or not	Nurses use the CPAP to evaluate the mask fitting	Observation nurse, interview nurse
Show how good the mask fitting is	Is it perfect or just over acceptable?	Observation, Benchmarking
Other Features		
Have a handle	To lift up from bag, move at home	Observation nurse, interview patients
It should be balanced when lifting it	A stable product gives a more reliable impression	Designers
Must have an air filter	To clean the ingoing air	Procurement requirement
USB port for charging phone	For convenience	Questionnaire patients
Have rubber on the underside	For friction when pressing buttons	Observation patient
Have a removable usb-stick	To save settings and log data, bring to clinic	Interview nurses
Non-measurable requirements		
Should be subtle	To not stick out too much	Interview with patients
Should be reliable	To make the user feel safe	Interview with patients
Should be simple	Easy to understand, nothing unnecessary	Interview with nurse
Should not look like a classic medtech product	Suites the home environment better, reminds of diseases	Designers
Express Humble, Reliable, Simple	Value words based on users	Designers

Master of Science Thesis PPUX05

Design and Usability Development of a CPAP device
Master of Science Thesis in the Master Degree Program, Industrial Design Engineering

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