Interface Concept Design for Filters in a Dialysis Device

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MASTER THESIS

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Abstract

Chronic kidney disease (CKD) affects more than 10% of the global population and it has emerged as one of the leading causes of mortality worldwide. [1] Dialysis is a treatment for individuals suffering from CKD, with the purpose to replace the lost kidney function. There are two main types of dialysis, Peritoneal dialysis (PD) and Hemodialysis (HD).

This thesis project aims to examine if the burden for dialysis patients can be minimized by improving the user interface for water consumables i.e. filters, in a home dialysis device. The filters are used for purification of water, which is essential for creating dialysis solution.

This will be done through an iterative design process using the Double Diamond Design method with a human centred design (HCD) approach. User research has been performed in the form of semi-structured interviews with several home dialysis nurses. Data obtained from these interviews was analysed in a thematic analysis. Literature review within the field of medical device design and human factors engineering (HFE) was also performed in order to provide a solid foundation for the thesis.

The results of the thesis are user needs, product specifications and a number of suggested concepts, developed with the aim of fulfilling the user needs and targeting the product specifications.

Keywords: product development, dialysis, human factors engineering, usability, human centred design

Sammanfattning

Njursjukdomar drabbar mer än 10% av världens befolkning och är en av de vanligaste dödsorsakerna. [1] Njursjukdomar kan behandlas med dialys, vilket är en behandlings som syftar till att ersätta njurarnas förlorade funktion. Det finns två huvudtyper av dialys, peritonealdialys (PD) och hemodialys (HD).

Detta examensarbete syftar till att undersöka huruvida går att underlätta för dialyspatienter genom att förbättra användarvänligheten för olika förbrukningsartiklar såsom filter, som är en del av en dialysmaskin för hembruk. Filtren används för att rena vatten, vilket är nödvändigt för att skapa dialyslösning.

Det har varit en iterativ designprocess som följt ramarna för Double Diamond Design-metodiken. Ett människocentrerat (HCD) synsätt har applicerats på samtliga steg genom hela processen. En användarundersökning har gjorts i form av semistrukturerade intervjuer med flera hemdialyssjuksköterskor. Data från dessa intervjuer har därefter genomgått en tematisk analys. En litteraturstudie inom medicinteknik och human factors engineering har genomförts för att ha en solid grund för arbetet.

Examensarbetets resultat är framtagna användarbehov, såväl som produktspecifikationer och ett antal föreslagna koncept framtagna med syfte att förbättra användarvänligheten, uppfylla användarbehoven och produktspecifikationerna.

Nyckelord: produktutveckling, dialys, ergonomi, användbarhet, design.

Acknowledgments

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I am especially grateful for the nurses at the home dialysis clinic in Lund, who dedicated their time and shared their expertise with me. It was one of the most educating and rewarding experiences during the project. Thank you for that!

Last but not least, I would like to thank everyone else who have supported me throughout the thesis project. Especially Simon and Lydia.

Malmö, May 2023

Mathilde von Gertten

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List of acronyms and abbreviations

APD	automated peritoneal dialysis
AV	arteriovenous
CAPD	continuous ambulatory peritoneal dialysis
CKD	chronic kidney disease
DRO	disposable reverse osmosis
ESRD	end stage renal disease
HCD	human centred design
HD	hemodialysis
HF	human factors
HFE	human factors engineering
HHD	home hemodialysis
IHD	In-centre hemodialysis
PD	peritoneal dialysis
R&D	research & development
RO	reverse osmosis

1 Introduction

In this section, background and introduction to the project is given. It presents the purpose of the thesis, as well as context and limitations.

1.1 Background

This master's thesis is about how water consumables i.e. filters can be integrated in a dialysis device and how their implementation affects the interaction between human and device. The project is performed in association with Baxter, a company which works within the field of medical technology. Baxter specialises in the research, development, manufacturing and marketing of products and therapies for a variety of healthcare areas, including dialysis. Dialysis is a treatment used for individuals with chronic kidney disease (CKD). CKD affects more than 10% of the global population and it has emerged as one of the leading causes of mortality worldwide. [1] The treatment uses dialysis solution to replace the function of the lost kidney function.

Clean water is an essential part of dialysis, and for this Baxter has water devices for home use, which treat tap water to a high level of purity. The purified water is then mixed with concentrates to achieve the desired composition to be able to use it for dialysis solution.

Water consumables such as a carbon Filterpack and disposable reverse osmosis (DRO) membrane are used in an initial purification step, and then Ultrafilters are used for a second purification. The water consumables must be changed at a regular frequency, once every 6 months, as their capacity reduces over time.

Being able to perform dialysis treatment at home offers the patients a sense of freedom as they will not have to spend hours in a dialysis clinic several times every week. However, home dialysis also requires dedicated time and energy from the patient to put into their treatment. To enhance the patients' independence and user experience, and to minimize cost for Baxter, the filter exchanges need to be performed with ease, without the need for a service technician to visit the patient.

1.2 Project purpose

This thesis project aims to examine if the burden for home dialysis patients can be minimized by improving the user interface for water consumables i.e. different water filters, in a dialysis device. The overall goal is to examine how the exchange of water consumables affects usability and thereafter propose concepts that will ease the filter exchange and improve usability of the device, so the users can manage the filter exchange independently while feeling safe and confident about the task.

To be able to generate concepts that ease the exchanges of water consumables, user needs regarding this routine maintenance will be identified. From the identified user needs as well as needs from the company, product specifications will be stated. The product specifications will act as a starting point for the concept generation.

1.3 Delimitations

- The aim is to make minimum to no changes to the filters themselves – focus lies on the connection mechanism.
- The designated space for the water consumables in the device may not be altered, dimensions are set.
- The thesis project is on a conceptual basis meaning that functioning prototypes and user testing will not be included.
- Due to confidentiality, some activities and steps performed in the process such as decision making or results, may not be fully presented in the report.

2 Theory

This section aims to introduce essential theory and methods which has been used in the project.

2.1 Dialysis

Dialysis is a treatment for patients who suffer from chronic kidney disease, which is a condition where the kidneys have lost approximately 85% of their function. This results in build-up of waste products and extra fluid in the body, as the kidneys are not able to clean the blood as supposed to. The purpose of dialysis treatment is to replace the lost kidney function. As of today, there is no treatment that cures chronic kidney disease and patients will need treatment for the rest of their lives, or until they get a transplant. [2]

There are two main kinds of dialysis: hemodialysis (HD), and peritoneal dialysis (PD):

Hemodialysis (HD)
In HD, waste products and extra fluid are removed from the body by filtrating the blood through a filter called a dialyzer. The treatment uses a HD machine which pumps the blood from the patient, through the dialyzer, and then back again to the patient. The treatment requires continuous access to the blood vessels and therefore the patient needs an arteriovenous (AV) fistula or graft, which is inserted during a smaller operation prior to initiating dialysis. The patient’s blood volume goes through the dialyzer several times during a treatment session.

HD can be performed in a dialysis clinic, so called in-centre HD (IHD) or at home (HHD). When choosing HHD, patients get thorough training in how to perform the treatment themselves. This enables more flexibility to adjust the treatment sessions according to their daily life. For IHD, the patient need to travel to the clinic 3-5 times a week and educated staff, most commonly nurses, perform the treatment and manage the HD machines during treatment. [3]

Fig. 1. AK98, a HD machine by Gambro/Baxter which can be used both in clinic and at home. [4][3]

Peritoneal dialysis (PD) - PD uses the lining of the abdomen, the peritoneum, as a filter to remove waste products and excessive fluid from the body. The peritoneum is a semipermeable membrane which surrounds many organs and has plenty of blood vessels. To perform PD, the patient needs a catheter which is inserted into the abdomen during operation prior to initiating treatment.

During treatment, dialysis solution is led through the catheter into the abdomen. Once the fluid has entered the abdomen, the blood is filtered and cleaned by the processes of osmosis and diffusion. The patient's blood has an elevated level of waste products, such as urea and creatinine, which travels through the peritoneum and dissolves into the dialysis solution, as the body strives to achieve equilibrium. When the concentration of the waste products in the dialysis solution has reached the same level as the blood, the solution is drained from the abdomen, and exchanged with new clean dialysis solution and the process starts again.

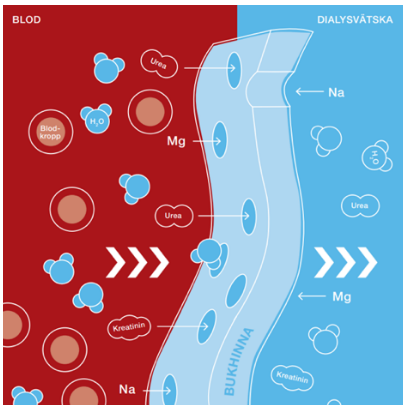

Fig. 2. Illustration of how the peritoneum acts as a filter, which waste products such as creatinine and urea pass to enter the dialysis solution. [5]

There are two forms of PD: Continuous ambulatory peritoneal dialysis (CAPD) and automated peritoneal dialysis (APD). The main principle is the same for both, what differs is how the fill and drain of dialysis solution are performed.

CAPD uses gravity to exchange the dialysis solution and it is performed manually. The bag of dialysis fluid is hung above the patient, usually on a drip stand, which allows for gravity to transport the solution downwards and into the abdomen. Once the fill through the catheter is finished, the bag is disconnected, and the patient can continue with their daily life. The dialysis solution is in the abdomen for approximately 4-8 hours until it is time for solution exchange. The patient connects a drain bag, which is placed below the patient - usually on the floor, to the catheter and the used solution is drained. The exchanges usually take around 20 minutes. Most patients do four exchanges every day.


Fig. 3. To the left: A sleeping patient performing APD treatment while being asleep. A cycler handles the exchanges. To the right: A

patient during a CAPD treatment session which usually lasts for 20 minutes. [5]

In contrary to CAPD, APD uses a machine called a cycler (seen to the left in fig. 3 above) which controls the solution exchanges. APD is usually performed during night-time, when the patient is sleeping as the treatment lasts between 8-12 hours. This means that during the day, the patient will not have to dedicate any time to do the manual bag exchanges as with CAPD. A benefit with this treatment is that patients can pursue their normal everyday activities without needing to do any dialysis during the day. A web-based IT-service can be linked to the cycler, enabling health personnel to access treatment data and follow the patient's treatment stats without the patient going to the hospital. [5]

2.2 Design of medical devices and Human Factors Engineering

For successful development of safe and usable medical devices, one vital aspect is Human Factors Engineering (HFE), which can be translated into the knowledge of human capabilities in relation to technology. HFE takes the nature of human error and human fallibility into consideration, and studies humans' role in complex systems. By implementing HFE principles throughout the product development process, errors can be limited, and safety and usability can be enhanced, resulting in safer products with greater user experience. The primary HFE concern in design processes of medical devices is to ensure that the devices can be used safely. This goes hand in hand with usability, since devices that are not designed with usability in mind often are more prone to user error; they are both difficult to learn to use and difficult to use which in the end may result in an unsafe device. Other benefits with applying HFE principles are decreased training time for operating the device, improvement of task performance and increased chance for commercial success.

Hand in hand with HFE goes Human centred design (HCD), which is a design approach which places human behaviour, capabilities, and needs in the centre of the process. [6 p.8] Good communication, especially between machine and human is crucial to obtain a successful design. When a user is interacting with a device, possible actions should be clearly indicated, as well as what is currently happening and what is about to happen next.

2.3 Double Diamond Design Process

The Double Diamond design process is a theoretical framework commonly used in innovation and product development. It describes specific steps which creates a divergent-convergent design process. These steps, or phases, are Discover, Define, Develop and Deliver. [7]

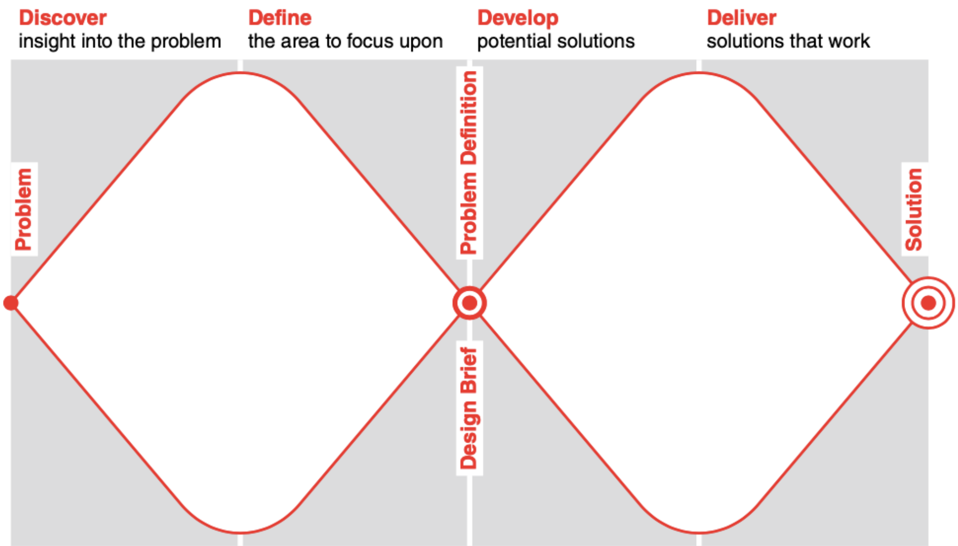

Fig. 4. Visualization of the Double Diamond design process. [7]

The goal of the first phase, *Discover,* is to get a thorough understanding of the challenge at hand and to examine various aspects of it, as well as to learn about the users. It is important to not make assumptions about what the user needs. This phase aims to provide a solid base of knowledge to ensure well-grounded decisions later in the process. To achieve this, I have performed a review of relevant literature and conducted semi-structured interviews to gain insight into user needs. Benchmarking was also performed in this phase.

The second phase, *Define*, aims to narrow down and to choose certain areas that will frame the design challenge. The research performed in the previous phase was analysed with a thematic approach and the results were used to further define the problem and identify user needs. The company also provided personas that were a source used in this phase.

The third phase, *Develop,* aims to explore and generate ideas that will be turned into concepts that fulfil the user needs and product specifications. The perspective is wide, and the goal is to find as many different solutions as possible. Brainstorming and sketching were used when creating concepts.

In the last phase, *Deliver*, the perspective narrows down again. In this phase, the aim is to choose a final concept to develop further and prototype. Pugh's concept selection method is a method commonly used in this phase.

For this thesis project, focus will lie within the first three phases; *Discover*, *Define* and *Develop*.

3 Discover

This section contains activities performed in the first phase of the Double Diamond design method. The overall aim is to gain knowledge within relevant fields to achieve a solid foundation for the thesis project.

3.1 Medical device design

The foundation for the following section is the ANSI/AAMI HE75, 9th Edition, 2018 - Human factors engineering - Design of medical devices, which is a widely known standard for medical devices. This standard provides detailed Human Factors Engineering design guidance. It is published by the Association for the Advancement of Medical Instrumentation (AAMI) and the American National Standards Institute (ANSI). [9] This standard will hereafter be mentioned as "HE75".

3.1.1 **Usability**

According to HE75 [8 p. 21] there are primary usability questions for evaluating the usability in medical devices:

- How easy is it to learn to use the device? How soon will the intended user feel comfortable using the device?
- Once learned, how efficiently can the device be used?
- Do users remember how to use the device after several days, weeks, or months of non-use?
- Does the device prevent users from making errors so help users recover from their errors?
- Are users satisfied with the device?
- Is the device design appropriate for the capabilities and limitations of users?

To answer these questions, knowledge and understanding for the user group and the use environment, is essential. Medical devices for home use will be used by a wide range of users, but the HE75 suggest that a typical user can be seen as a 75-year-old woman caring for her 72-year-old spouse. Age-related impairment in vision and hearing is uncommon, as well as age-related decrease in muscle strength and memory problems. All of these factors need to be considered when designing medical devices for home use. This includes the design of the device itself, the design of its manuals and documentation, as well as the training that the user receives. If not properly designed, use errors might occur, which potentially could injure users. The user might experience the responsibility for use and maintenance of the device stressful, and as a result they might abandon the device. [8 p. 428]

3.1.2 **Connections in medical devices**

To classify connections, frequency i.e. how often the connections are used, and in which environment and circumstances the connections are used, is studied. Factors that contribute to high risk connections are: a) if the connection is directly made to the patient, b) if it is made frequently, c) if it is made under stress in a critical clinical environment e.g. an emergency room. In opposite to high risk connections, low risk connections can be linked to lower frequency, meaning they are made only occasionally and under less stressful conditions. The purpose of classifying connection is to help identify risks associated with the connectors and discuss how the risk can be reduced. Risk associated with connections are determined with consideration to both probability and severity of injury which is associated with each connection, and then the frequency of the connection must be added. Common connection failures that impose a risk are misconnections, disconnections and failed connections. [8 p. 246]

To minimize the risk of misconnection, the connectors should be differentiated from each other, which can be made both actively and passively. Active differentiators use unique physical features to help the user differentiate one connector from another, before the connection is even attempted. Each connector should be clearly unique both with regards to other connectors in the device, but also with regards to any other connector that is used in relation to, or close to the device. Examples of active differentiators are unique colour coding, unique labels, unique geometry and unique alignment marks.

Passive differentiators instead aim to allow the user to identify an incorrect connection as it is happening. Examples of passive differentiators are unique pin configuration, unique key and shoulder configuration and electronic identification. [8 p.250]

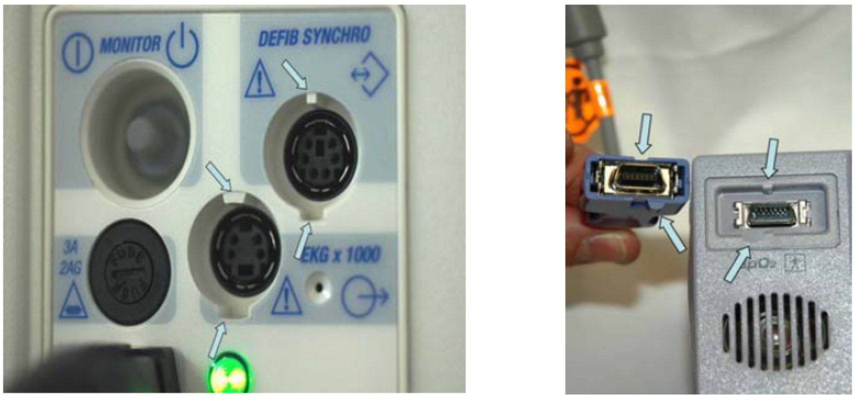

Fig. 5. To the left: Showing unique key and pin configurations. To the right: Unique shoulder and key configurations. [8 p. 253]

3.1.3 **Ease of Maintenance**

Medical devices used in a home environment by lay users should require no or minimal maintenance. The user should not be expected to perform any repairs of the device. The required maintenance should be easily performed without special tools and it should be comparable to maintenance linked to common consumer products used in the home, such as changing a light bulb or changing batteries in a smoke detector. If a device has batteries that should be changed, the battery status should be clearly indicated in a way that makes it easy for the user to perceive and understand the current battery level. For parts that must be replaced periodically, the location in the device must be easily accessible and the different parts must be easy to identify. If the replacement requires fine motor skills, a tool or a mechanism that makes it easier by holding the part in the correct position could be provided. [8 p.437]

3.1.4 **General considerations**

Medical devices for home use should be easy to learn how to use and the operation of them should be as intuitive as possible. Users tend to master medical devices more easily if they are similar to products they already have experience with. Since there might be large variations in capabilities and limitations in the user group, medical devices for home use should be as adjustable as possible to fit the wide group. This can be manifested through offering a range of adjustments e.g. brightness on visual displays and volume on auditory alarms and reminders.

The degree of education amongst users as well as literacy and other capabilities varies, it is therefore important that user training and manuals are easily understood. Learning styles may also vary, therefore manuals and training materials could be provided in various formats such as written manuals, photographs, videos etc. to satisfy the broad spectrum of users.

Aesthetics and unobtrusiveness are sometimes not prioritized in design of medical devices. As a result, they can be experienced as intimidating and complex. This can be avoided by incorporating a friendly design, by for example hiding any visible wiring and tubing and choosing pleasant colours. [8 p.428]

3.2 User research

The overall goal with this part of the data collection is to get a better understanding of the specific users and their abilities and needs. The activity will result in specified user needs. Ullrich & Eppinger [9 p. 74] argue that it is important since it:

- ensures that the product is designed for the intended user and meets their needs
- identifies latent needs, as well as explicit ones
- provides a fact base that will justify product specifications
- develops a common understanding of customer needs among the team

3.2.1 **Interviews**

Interviews can be performed in four main ways: unstructured, structured, semi-structured and group interviews, also called focus groups. [10 p. 268] The aim for this project was both to gain knowledge about users' feelings and impressions regarding maintenance activities linked to home dialysis as well as learning about the patient group in general. Therefore, semi-structured interviews seemed to be the most appropriate method in this case as the method uses both closed and open questions. For some parts it was important that the interviewees felt that they could speak as freely or briefly as they wanted with no certain expectations about the answers, and for other parts more specific answers were desired. The questions were pilot tested on one HF engineer at Baxter, to ensure they were comprehensive. Minor changes were made after the pilot test.

3.2.2 **Recruitment criteria**

The primary target for the interviews was home dialysis nurses who had been working with home dialysis patients for at least 12 months, to ensure a proper amount of experience with this patient group. The aim was to interview four to six different nurses, and it ended up being four of them. Future studies should also include interviews with the primary users, dialysis patients. However, due to time restrictions this was out of the scope of this paper. The decision to interview nurses was based on the fact that they have valuable insights into patients' abilities and needs, and the hope were that they therefore could communicate the needs of several different patients. The interviewed nurses had experience in teaching the patients and caregivers how to operate the dialysis machine. Therefore, they had knowledge about which parts patients usually find challenging when interacting with the dialysis machine in a home environment. It was of interest to talk to nurses working with HD as well as PD. The interviews were performed at SUS, Skåne University Hospital situated in Lund.

3.2.3 **Ethical considerations**

Ethical considerations are of great importance when performing user research. According to the Swedish Ethical Review Authority, education within a bachelor- or master's degree is exempted from the requirement of ethical approval. [11]

Before initiating the interviews, participants signed an informed consent form (see appendix B). The purpose was to ensure that the participation was voluntary and that the participants were aware of their right to withdraw their consent at any time. Information regarding what data would be collected and how it was going to be handled was presented. The informed consent form stated that all participants would remain anonymous and that recorded material and transcripts would be deleted once the master thesis was finished.

3.2.4 **Collecting Data**

The interviews lasted for approximately one hour each and were audio recorded, as this allowed me to fully focus on the conversation and not having to take notes constantly. The collected data was mostly qualitative and related to impressions, opinions and thoughts. Some quantitative data was attained such as the number of years' experience of working with home dialysis and whether or not the respondent had been working with PD (yes/no) and other close-ended questions.

3.2.5 **Data analysis**

The interviews were transcribed manually as this allows to catch nuances in the conversation, and to be able to interpret the content. The relatively small sample group also made the manual transcription possible, even though it was quite time consuming. Since the interviews were semi-structured, large parts were open conversations. Some parts were not relevant for the thesis, and those were not transcribed. But that consideration was made strictly and only parts that were clearly out of context were cut out, to make sure to not miss anything that could be of relevance. The manual transcription was an excellent way to get familiar with the data thoroughly.

During the interviews, patterns from the respondents' answers started to emerge. The transcripts were consulted repeatedly to re-confirm these findings. This was done by applying a thematic analysis approach, which is a method that identifies, analyses and reports patterns and themes within data. [21] According to Sharp et al., a theme: *"represents a pattern of some kind, perhaps a particular topic or feature found in the data set, which is considered to be important, relevant, and even unexpected with respect to the goals driving the study."* [10 p. 321] For something to be considered a theme, it is therefore needed to capture something important in relation to the purpose of the research.

When performing the thematic analysis, a six-phase framework by Braun & Clarke [12] was used as a framework since it offered a flexible but yet clear guidance. The six phases were:

1. Become familiar with the data
2. Generate initial codes
3. Search for themes
4. Review themes
5. Define themes
6. Producing the report

However, the analysis was not a linear process with one phase simply following the previous one, it was more of an iterative process. The themes and patterns were identified mainly in an inductive manner, but some specific research questions were also in mind leading to a combination of an inductive and deductive analysis. Since the interviews were conducted in Swedish, all quotations are translated in order to make sense in this written report.

1. *Become familiar with the data*
   Since the interviews were conducted by me, and I did the transcribing manually, I already had an initial impression of the data and an idea of identified themes. But to immerse myself in the data become even more familiar with the content, the transcripts were printed and re-read. They were then more systematically examined to see whether the initial impressions were confirmed or not. Early impressions were noted, and important parts were highlighted and formed into a list with initial ideas about themes and patterns. Each transcript was given equal attention.

2. *Generate initial codes*
   Organisation of the data in a meaningful and systematic approach was initiated already in the previous phase, when the highlighting was done. Additional coding was done by writing notes that summarised the essence of the highlighted parts. Consistency was examined to see if similar patterns were present across all respondents.

3. *Search for themes*
   Similar segments from the transcripts were grouped together with regards to the coding. This was done in a systematic yet iterative way, and themes started to emerge. To organise individual findings and ideas, affinity diagramming [10 p. 322] was used as a tool for systemising the data and to ease the identification of themes from transcripts. The idea at this stage was to gather many themes, to have a diverging approach.

4. *Review themes*
   When a theme was established, all the data relating to that theme was re-read and reviewed. This iterative approach resulted in the combination of some of the initial themes as they overlapped, and others were removed since they did not seem of relevance to the goal of the study, or there was not sufficient data to support them, or data was too diverse.

5. *Define themes*
   This phase relates very much to the previous phase, and they were to some extent done in parallel. The overall aim was to identify the essence of each individual theme, but also how each theme relates and differs from the other themes. The themes should by now have a clear definition, and the final names for the themes were decided in this step.

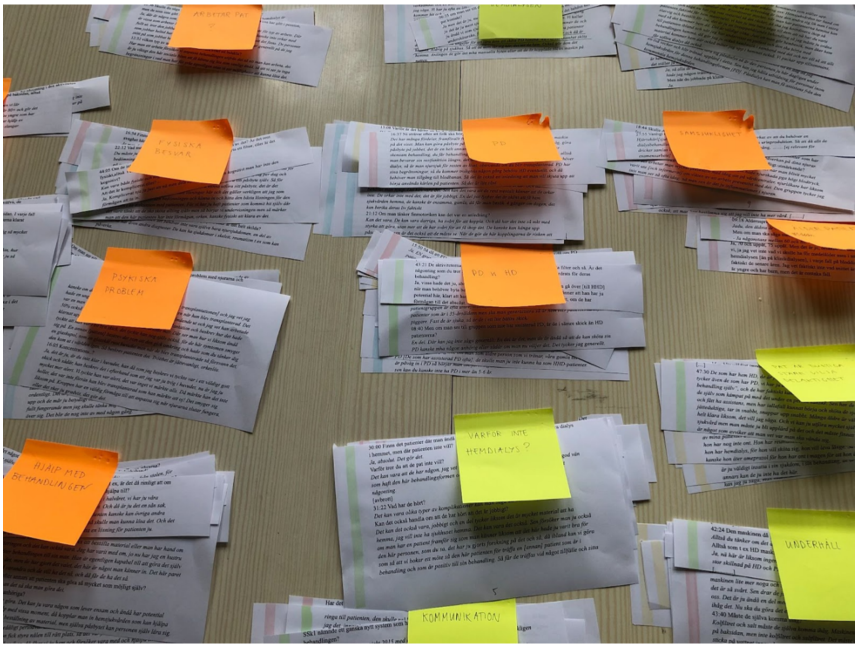

Fig. 6. To identify themes, the transcripts were printed, relevant parts and patterns were cut out and then grouped with other similar paragraphs. Suggestions for theme names were written on post it notes.

3.2.6 **Results thematic analysis**

The thematic analysis of the transcripts resulted in 8 themes which are presented below.

- *Nurses* - Background of the nurses, their experience and their work tasks.

- *The Clinic* - Describes the clinic and the different types of treatment it offers.

- *Patient characteristics* - Who are the patients and what characteristics need to be considered when designing for this user group?

- *Help with treatment* – What kind of help do patients get with their home treatment?

- *Maintenance routines HHD* - This theme describes the maintenance activities linked to HHD.

- *Home dialysis patients - One homogenous group?* - How PD- and HHD patients differ.

- *Why not home dialysis?* - Reasons and factors that make home treatment not suitable.

- *Specific issues with treatment* – Describes which parts with the current home treatment patients may find challenging.

In order to enhance the readability, certain themes have been abbreviated in this report. For those interested in the complete and detailed versions of the themes, these can be found in Appendix C.

3.2.6.1 Nurses

Four dialysis nurses were interviewed. All of them have +15 years of experience of working with dialysis, which implies that they have met many different patients and have great experience in working with this patient group.

The nurses' primary work task is education, where they educate both new patients and health personnel in performing dialysis in a home environment. When a patient first comes to the home dialysis clinic, they are trained daily in performing the treatment. The training lasts 1-3 weeks for PD and several months for HD, before they can manage treatment by themselves at home.

The nurses work very closely with their patients and have daily contact with them in the beginning. Home visits are also common. The nurses usually follow the same patients for many years and get to know them quite well, as the patients need treatment for the rest of their lives, or until they get a kidney transplant.

The nurses were initially seen as secondary users, but when visiting the clinic, it was apparent that the nurses interact daily with the devices when they educate patients. They can therefore be seen as primary users to some extent, when the device is used in a clinical environment. This, and the fact that they have great experience of working with dialysis patients in versatile ways showed that they have deep knowledge in patients' abilities and needs.

3.2.6.2 The Clinic

The clinic offers three types of home dialysis: Home hemodialysis (*HHD), PD* and *Assisted PD*. Aside from the nurses, the patients have contact with doctors, dieticians and physiotherapists, but the nurses are by far the ones that have the most patient contact. At the clinic there are also dialysis technicians who install and do maintenance on the machines in patients' homes.

PD
As of today, the clinic has 60 PD patients, and approximately 20 of the patients do APD, the rest do CAPD. The clinic has a goal of initiating a majority (>60%) of new patients on PD.

Assisted PD
About half of the PD patients have Assisted PD, which can be both APD and CAPD. Nurses and assistant nurses from the home care unit visit the patient in their home and assist with treatment. How often they visit, and what tasks they assist depends on the needs of the patient, and this vary greatly.

Trembling of the hands, impaired vision and reduced dexterity are mentioned as factors for needing assistance as these impediments may lead to patients failing with the connection of the tubing. Reduced strength makes it hard to lift the bags with dialysis solution.

> "*If you have a cycler, it's 5 litre bags that need to be lifted and put on the machine. It is physically challenging. Also, if you have the 2 litre bags (CAPD), you need to do it four times a day. Getting a bag, open the bag, reach up and hang it on the drip stand. It can be challenging, especially if you have a disability, or if you just don't have the energy*"

Cognitive barriers mentioned as a reason for needing assistance include learning disabilities and dementia. Some patients manage their treatment by themselves but need assistance with ordering dialysis material, while others need assistance for every step in the treatment.

The social aspect of getting assisted PD is also mentioned, as some older patients tend to be lonely, and their lives can be enriched by the daily visits from the home care unit.

HHD
The clinic has around 30 patients performing HHD. As of today, it is not possible to get assistance when performing HHD, as it is with PD. HHD patients receive several months of training of how to perform their treatment at home. When they are ready,

their machine is installed in their home by a dialysis technician from the hospital. Aside from the dialysis machine, a water treatment system is installed.

3.2.6.3 Patient characteristics

Age - All nurses claim that there is a large variety in the patients' age. For HHD, it is stated that many patients are between 40-70 years old. Sometimes they train patients in their 80's, however this is uncommon. It is mentioned that the patients that perform their HD at home in general are younger than those receiving HD in a clinic.

For PD, there seems to be even more variation. One nurse said:

"*Well, my oldest patient is 98 and the youngest 30*"

The fact that PD can be assisted, allows for elderly and comorbid patients to have PD, patients who otherwise would not be able to have their treatment at home. At the same time, PD is seen as a first treatment choice, and the clinic has the goal of putting >60% of incident patients on PD. It was carefully stated that many PD patients tend to be between 60-80 years old.

Patients performing APD with a cycler are generally younger than those doing CAPD. It was implied that elderly who do CAPD appreciate the simplicity of the manual bag exchanges and not needing to interact with a machine.

> *"Many of our elderly patients are happy with their manual bag changes during the day, to them it's not a big deal, but our younger patients, they have the cycler. We have some young adults, they might go to school or work during the day, and for them it's favourable to use the cycler during night, then they won't have any set times for treatment during the day"*

Work – Out of the younger patients, many try to keep working, but it varies to what extent they manage. It is more common that the patients work 50% or 75% compared to full time. Many patients are retired as well.

Comorbidity - Many of the patients are comorbid, especially the elderly. Diabetes, heart diseases and high blood pressure tend to be the most common. Patients with diabetes are mentioned as a patient group that is becoming more and more common. Arthritis is also mentioned, but it is not as common as the other diseases mentioned above.

Gender – Among patients, there were more men than women. It was mentioned that many of the men who performs HHD have an actual interest in the technical part with the water treatment and filters etc., whereas some of the women, especially the elderly, view the technical part as something that unfortunately needs to be done. It is uncommon, but the maintenance part may rule out some patients, especially elderly women who feel that they won't manage. The nurses reported that they do not see this difference between men and women in younger patients.

Patient empowerment - It is mentioned that the majority of patients show great compliance. They are dedicated to their treatment and do not complain unnecessarily, they are focused on managing this themselves and being independent. The nurses support their empowerment and independence, and emphasize that they focus heavily on patients' abilities instead of disabilities, they always try to find solutions for the patient to manage their home treatment by themselves.

Physical and mental limitations - Fatigue and reduced energy is very common among uremic patients. This might make the learning part harder, and patients might need more time to learn the different steps of treatment.

The most common physical issue identified is reduced muscle strength in general, but also specifically in hands. Kidney failure itself is a process that affects the body's ability to maintain muscle mass. Some patients struggle with lifting the bags with dialysis fluid. Other patients have the strength but may lack dexterity, making it hard to succeed with connections. Reduced sense of touch in hands is also common, especially among diabetes patients, and the importance of using materials that are easy to grip is mentioned.

Some of the elderly patients may struggle with bending down, and that they have reduced flexibility overall in their body. Some elderly patients can also have reduced grip strength, but that's not something that's specific for dialysis patients, more elderly in general.

It was concluded that the patient's characteristics such as age, comorbidity, physical- and mental limitations vary a lot, and diverse needs have to be considered in the design process to ensure that as many as possible can access the device. This indicates the need for universal design principles.

3.2.6.4 Help with treatment

To what extent patients receive help with their home treatment varies. Some do not need any help whatsoever, others have full assistance from the home care unit, and for some people, a family member might help with certain tasks. If we ignore the group that has assisted PD, it is ideal that the patients can perform all, or at least a majority of activities by themselves and will not have to rely on relatives, and a majority of patients actually do manage their treatment all by themselves. But at the same time, it is not unusual to get some help from relatives.

When talking more specifically about a filter exchange that would occur every 6 months and if it would be a limiting factor that would rule out some patients one nurse says

> "*It should not fail because of that, if a patient can manage all the other elements of treatment, we would manage that in some way, that's how we work here, we really try to find solutions to make it work*".

3.2.6.5 Maintenance routine HHD

There are almost no maintenance activities at all linked to current PD treatment. However, patients who do HHD have to perform maintenance linked to the HD machine and water treatment system.

Fig. 7. Image showing the back of the HD machine from Fresenius that the clinic uses.

Every third month, the HHD patients change two filters that are located on the back of the HD machine. The filters can be seen in both fig 7 and fig 8.

Fig. 8. Filters located on the back of the HD machine. They are changed every third month.

The machine drains these filters before exchange. When asked if this activity is something the patients complain about or struggle with, one nurse seemed almost surprised and answered that she had never heard anything about that. Another nurse explained that maybe some could find it a bit finicky, but then the nurses can guide via phone, or if the patient lives nearby, they might do a home visit.

The filters are located at a height of approximately 50 cm, and on the question if the location of the filters is problematic, the nurses answer that it depends. One nurse brings forwards one example; that a very tall patient with arthritis struggles to bend down, whereas for other patients it's no problem at all.

One nurse argues that there is more acceptance for maintenance routines that are done seldom being "a bit finicky", whereas activities that are done with every treatment must work smoothly, otherwise it can create frustration and limit a patient from performing home treatment.

> *"these filters are changed every third month, it's not a big deal. However, connecting the Theranova filters that you do every treatment… [swears]"*

Once a month (for most patients - some need to do it every other week, depending on water quality) the patients exchange a carbon filter in the water treatment system.

Fig. 9. Image showing a carbon filter with a wrench, similar to the ones that are changed monthly by HHD patients. [13]

There is no automatic reminder for this carbon filter and it is not drained before exchange. Some patients struggle with securing the filter tight enough, then a wrench tool is provided to help them.

Other maintenance activities the HHD patients perform include changing a 5 litre jar of a disinfection solution, which is placed low, on the back of the machine. It can be seen in fig. 7. How often this is changed depends on treatment.

There is also a fan in the machine which the patients should clean from dust every now and then. It was explained that the fans are similar to the ones in stationary computers.

Fig. 10. Image showing the fan that needs to be cleaned from dust every now and then.

My overall impression is that compared to the rest of the treatment, and what it means to be a dialysis patient in general, the maintenance is not seen as a big deal. In the beginning, it may feel like a lot of different tasks and filters, which might result in a feeling of overwhelming. Even though routine maintenance was not seen as a very challenging part of treatment, one nurse said "*Everything that can be made simpler would of course make it easier for the patient*" emphasizing that improvements always are appreciated. Suggestions for improvements were automatic reminders and fewer different tasks so patients won't have to remember how several different activities should be performed.

3.2.6.6 Home dialysis patients - One group?

In the previous theme, HHD patients' experience of maintenance of the HD machine was presented. It is of importance to investigate if, and in such case how, the abilities and characteristics of PD patients differ from those of HHD patients.

It was stated that the age of home dialysis patients varies a lot, but those who perform PD without assistance are stated to generally be more like the group that perform HHD.

When asked if PD patients would manage similar maintenance with filter exchanges that HHD patients do, one nurse explained that she thinks that many would, and for those who would not, they would get assistance by the home care unit. The impression was that many would manage, if they were just taught how to do it but the learning period would be a bit longer, as there would be more steps in the process. PD patients are used to connecting a lot of tubing, something one nurse described could be an advantage.

My initial thought was that HHD patients have less physical and mental limitations compared to PD patients, since HHD is more complex and requires more education and effort. Apparently, that generalisation is not accurate. There are PD patients who are young and relatively healthy and those who are a bit older but still are quite capable, and of course, also those who are very sick and need a lot of assistance.

3.2.6.7 Why not home dialysis?

There are many reasons to why dialysis in a home environment is not suitable. There can be patients who need HD and want to do home treatment but cannot physically or mentally perform the treatment themselves and since there is no assisted HD, home treatment is not an option for them. Since PD patients have the right to assistance in Sweden, a patient can receive assisted PD without to the necessary grip strength and mental ability to learn how to perform their own treatment.

On the other hand, there can be patients who are quite capable, but they are not motivated nor interested in home treatment. The lack of motivation and interest was the most commonly mentioned reasons that make patients not suitable for home treatment.

Reasons to why a patient may feel that they do not want treatment at home can be that they have the impression that it is too advanced, especially HHD. If they have IHD, they are used to nurses in the clinic managing their treatment and the machines and might feel that they could never manage all of this on their own. Other reasons can be that the machines are big and will make their home feel like a hospital with all the tubing together with the material and equipment that need to be stored. Sometimes it can be a family member who does not want the HD machine in their home, mentioning that the machines are not discreet and not the prettiest interior pieces so to say.

Mental health issues such as dementia, depression and addiction are mentioned as issues that make patients not appropriate.

Another reason to why some patients does not want treatment at home is the social aspect of going to a clinic. Getting dialysis in the clinic can be something patients, especially those who live alone, value as it enriches their life and they socialize with the nurses and other patients.

3.2.6.8 Specific issues with treatment

For PD, the interviews indicated some obvious patterns regarding what aspects the patients think is the hardest with this treatment. To lift the bags with dialysis solution was the first. This includes lifting them to the storage when they are delivered to the patient's home, and carrying the bags every day for the treatment.

Storage and disposal of both material and waste were also mentioned as burdens, especially with PD, where the treatment creates a lot of waste, such as empty bags and boxes. When new dialysis material is delivered, which is usually done weekly or bi-weekly, the delivery person can take the waste with them, but it still needs to be stored during the week.

Regarding changing filters on the HD machine, one thing mentioned is that the filters have tiny plastic covers that need to be removed before usage. This is sometimes forgotten which then leads to issues, since the water cannot enter the filter. One nurse mentioned leakage as a result.

The relatively low placement of some filters is usually not an issue when everything goes as planned. If there is a problem with the filter, then the placement could be an issue, especially for patients who struggle with bending down.

It was mentioned that to prepare a HD machine, there are many different parts: different tubing and connectors to mention two. It would be convenient if this could be simplified and include fewer different parts. She also mentioned the wish for feedback, so one knows when something is secured.

"You just want to hear a 'click', then you know it's properly attached".

Clamps on the tubing for the APD cycler are mentioned as hard to open and close; it requires quite some grip strength and dexterity to be able to manage them.

3.3 Benchmarking

Benchmarking was used as a tool to get insight into how other existing products with similar functions work. The purpose is to be able to reveal strengths and weaknesses of the competition, as well as gaining inspiration.

When scouting for RO filters currently on the market, it seems like most options on the market have a similar design, which is inserted from below and twisted to secure, see fig. 11. Since the filters that will be implemented in the device are located at a rather low height, it might not be optimal to insert the filters straight from below. Clear indication in which position the filter is properly aligned with the connector will be needed if this way of inserting the filter is chosen, as well as indicators for which way to turn for releasing and tightening. It could be favourable to use a connector that can be tilted outwards to get better access to the filter, but it could also be that this increases the difficulty, since then both filter and connector are able to move, meaning that the two parts need to be aligned. It might be easier to do a connection if one part is fixed.

The current DRO implemented in the prototype of the device uses this "insert-from-below" design, and it is especially hard to remove the DRO, since it requires pulling downwards after the twisting motion is finished. If you pull too hard, the filter hits the ground. It could be of value to test if other "insert-from-below" filters on the market are easier to connect and remove, before this standard type of mechanism is condemned.

Fig. 11. Images showing different "insert-from-below" filters [14][15][16][17]

Other ways of exchanging filters can primarily be seen in under the sink water filter systems for residential use, which can be seen in fig. 12. Many use a horizontal loading of the filter, which could be favourable to implement in the device. It would be of value to test this to see what pros and cons this method offers.

Fig. 12. Different under the sink water filter systems for residential use. [18][19][20]

The initial thought was that this horizontal loading could offer better usability, since it is very clear how to align and where to insert the filters. If the filters have the exact same shape, it could be beneficial to colour code each connection to prevent the error of misconnection. If the filters have different sizes, that solves itself, as it won't be possible to insert the filter in the wrong opening, similar to the classic toy shape sorter, with bricks in different shapes, seen in fig. 13 below.

Fig. 13. The classic shape sorter toy, where each shape only fits in one certain place. [21]

4 Define

In this section, the findings from previous phases are used to further define and frame the design challenge to get a thorough understanding of the problem.

4.1 Solving the right problem

In university, the essence of engineering education is to solve problems. The problems come ready to address, like nice little packages wrapped by the professors. However, in the real world, problems are not delivered as ready-to-be-opened packages. One could take the easy road, be presented with an initial problem and immediately start to solve the given problem. But how do you know that the given problem is actually the real problem? How can you know if your solution will be successful if you have not even thought about the root causes to the problem, and if the problem you have been given is actually the real problem and not just a symptom?

When success is measured in progress and deliverables, getting to the bottom with root causes is often neglected. It takes time and effort to develop a thorough understanding of a problem, time that could be used to work on the given problem to be able to fast deliver a solution. It is tempting to immediately jump to a solution for the stated problem, but this might lead to more harm than good as Dan Norman points out [6 p.218]

"A brilliant solution to the wrong problem can be worse than no solution at all"

4.2 Redefined Problem Description

Insights from the Discover phase lead to the creation of a more structured and defined problem description:

Summarize what difficulties there are with the current connections for the filters and specify what is required in a solution that enables users to perform filter exchanges with ease. From there, state criteria that possible solutions can be evaluated against. Propose different concepts

4.3 Use specification

4.3.1 **Intended users**

The intended users of the system are peritoneal dialysis (PD) patients with chronic kidney disease (CKD) or end stage renal disease (ESRD), and their caregivers as well as health personnel such as nurses, nephrologists, and dialysis technicians. All intended users will receive training for the tasks that are expected to be performed for treatment and maintenance of the device. The patients may have physical and or mental limitations. However, none of the user groups are expected to possess any specific limitations. The user groups are described below.

4.3.1.1 Patients

The primary users of the system are the patients who perform PD therapy at home. The user research showed that common physical and mental limitations in this patient group are fatigue, loss of touch sensation, limited strength, limited mobility and impaired vision. Since the physical and mental limitations in these patients vary, it is decided either that the patient is capable of performing treatment themselves, or that they may need assistance. Assisted PD is available through the health care system in some European countries, Canada and Australia. [22]

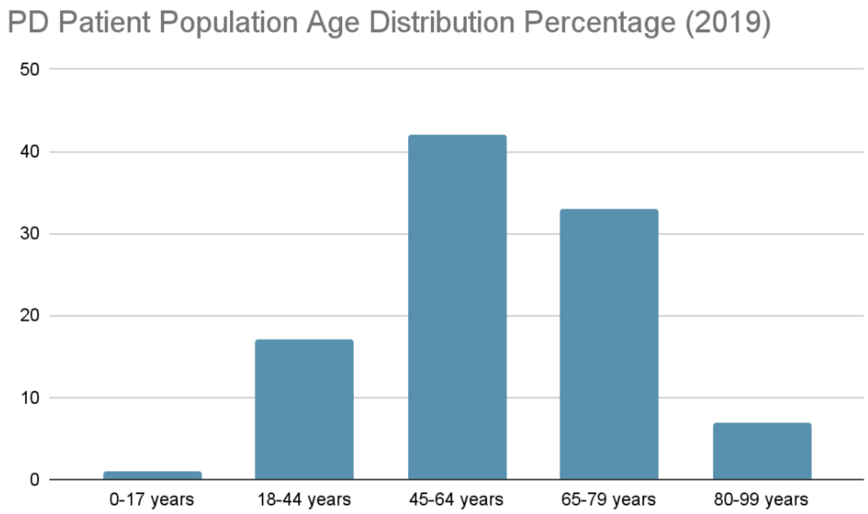

Fig. 14. Diagram showing the age distribution of PD patients in the U.S. 2021. Statistics from the Annual report 2021 from U.S Renal Data System.

According to the Annual Report 2021 from United States Renal Data System (USRDS) [36], 42% of PD patients in the U.S are between 45-64 years old, and the number decreases with increasing age; 32% of the patients being between the ages of 65-79 and 7% being between 80-99 years old. Regarding gender, PD tends to be more common for males than females, 57% of the PD population in the U.S. being male and 43% female. [23] This (gender and age) tends to be similar in Sweden, as similar results came out from the user research where home dialysis nurses were interviewed.

4.3.1.2 Caregivers

Caregivers are lay adults (e.g., spouse, child, friend etc.) who assist a patient with performing PD treatment at home. To what extent they are involved in the patient's care varies e.g., from only ordering and carrying supplies to completing all necessary steps within treatment.

4.3.1.3 Medical staff

This group primarily consists of nurses who interact with PD patients in various ways. The nurses can also be seen as primary users when the dialysis device is used in a clinical environment. They educate and train patients in the beginning, and then continue to care for the patients and follow up treatment regularly. In addition to their higher nursing education, they also receive specific training for dialysis. Other medical staff that might interact with the device are Nephrologists, who are doctors whom specialize in the care of kidneys. They diagnose, treat and manage acute and chronic kidney diseases. They possess the main responsibility for determining and prescribing appropriate dialysis therapy to the patient.

4.3.2 **Use Environment**

The device is primarily intended for use by patients and caregivers in a home environment. However, it will also be used in a clinical environment, in a dialysis clinic, where the training of new PD patients is done. The training takes place at set times and the device will not be used in acute situations.

4.3.2.1 Home environment

The device will primarily be used in the patient's home, which is an environment that varies widely due to both lifestyle and socioeconomic factors.

Patients living in areas with high social deprivation index score (SDI) tend to be less likely to receive dialysis at home, compared to those residing in wealthier neighbourhoods. Whether patients live in an urban or rural area also play a role, where a higher percentage of rural patients use home dialysis treatment compared to those living in more urban areas. [24] One obvious reason for that is if you live far away from a dialysis clinic, it becomes inconvenient to travel several times every week to get treatment.

When maintenance is to be performed, the home environment is expected to be well-lit, although the system as a whole will also be used in low lighting conditions, as treatment is commonly performed during night. Patients are expected to dedicate time and attention to perform their PD therapy, but there is a possibility that distractions and interruptions could occur. Reminders about maintenance will be sent out ahead of time, so maintenance will not be done suddenly or in an acute situation.

4.3.2.2 Clinical Environment

The system could also be used in a hospital, in a dialysis clinic which is seen as a clinical environment. It could be both in an individual room, or in a bigger common treatment area, which could have more activity and noise. The environment is expected to be well-lit. The user is expected to set aside dedicated time to use the system, although distractions such as noise and interruptions from other machines, patients or health personnel may occur.

4.3.3 **Device user interface**

The device user interface includes all interaction between the user and the device [25 p.10], and for this thesis project, it is the interface used for performing routine maintenance on the device. The physical interface can be seen in the images below.

Fig. 15. Two images showing the physical interface for water consumables in the device with filters from left to right: Filterpack, DRO and Ultrafilters. The left picture is taken when bending down, the right one is taken from eye height, sitting.

The physical interface currently consists of 3 types of filters, from left to right: A Filterpack, a DRO and 2 Ultrafilters. The filters are located in a section that is partitioned from the rest of the device, with the purpose to gather all water consumables in one designated area and to separate them from the electronics in the device. More specific information regarding the water consumables will not be presented in this report due to confidentiality.

The connections for the filters can be classified as “Accessory connections - to and from equipment” and the risk is graded low to medium. [8 p. 247] Since there are several filters, it is important to differentiate the connectors which can be made both using active and passive methods.

Whether the final concept should include improvements for all three kinds of filters or just some of them was left open. It was stated that minimum to no change to the filters themselves was desirable. The physical dimensions for the space in the device designated for the water consumables were more or less set and no changes were desired for this.

The company has previously performed user research and a market study, where specifically the connection to the DRO was pointed out as problematic. Critique was that the DRO was finicky to connect, and especially removing the filter was difficult and required quite some force. More details about the results from this research market study will not be given due to confidentiality.

4.4 User needs

Knowledge gained from the literature review, and statements and insights from the interviews were interpreted into user needs regarding filter exchanges in the device. At this stage, it was thought about *what* the device could do or provide, and not *how* it might be done, meaning that technical solutions were neglected at this stage, and some needs might not even be possible to fulfil, but the idea is to have a wide perspective at this stage, to ensure no need gets neglected. Similar user needs were grouped together through colour coding and 4 major themes emerged, which the needs were sorted under:

Need for physical effort to be minimised:
Need for materials which allow good grip
Need for tasks to be ergonomically designed
Need to be able to perform maintenance with reduced muscle strength
Need to be able to perform maintenance with reduced grip strength
Need to be able to perform maintenance with reduced flexibility
Need for lightweight consumables
Need for clear visibility

Need for mental effort to be minimised:
Need for being reminded in sufficient time ahead
Need for synchronised maintenance tasks
Need for maintenance to be intuitive
Need for easy access to instructions
Need for feedback when filters are properly connected
Need for design that is friendly and not intimidating
Need for design that signs simplicity
Need for the maintenance to be easy to guide via phone
Need for flexibility:
Need for accessibility (independent of age, height, disability etc)
Need for adaptability
Need for possibility to order water consumables both from internet and phone
Need for safety:
Need for error prevention
Need to minimise spillage
Need for design that decrease risk of infection

Table 1. User needs regarding the interaction with water consumables.

4.5 Product Specification

Once the user needs were listed, the process of stating what the device could offer in order to fulfil the needs was initiated. The aim was to provide more specific guidance of how to design and engineer the product, as the user needs are often express in the "language of the customer" and leave much room for subjective interpretation. Apart from user needs, other parameters such as needs from Baxter and theory of medical device design were also considered when stating the specifications. The specifications were sorted into two levels at this early stage:

- Necessary: It is a product requirement and must be in the final solution.

- Desirable: Could add value if implemented, but not a requirement.

The purpose of ranking the specification is to establish what is required and must be prioritized, as there will always be some trade-offs in the end, and then it is of value to know which parts that cannot be compromised on. Specifications may be altered many times throughout the development process, as new findings are made continuously. Furthermore, it may also be of value to rank the specifications later on in the process.

Specification	Ranking	Rationale
Function		
Filters should mate properly and connect without leaking	Necessary	HE75 17.2.4.3
Filters and connectors should withstand pressure of up to * Bar	Necessary	Baxter need
Filters and connectors should be able to operate between *-* °C	Necessary	Baxter need
Minimise physical difficulty of filter exchange		
The design eases alignment of filter and connector	Necessary	User research, HE75 17.4.2.5
Filters should be within reach from sitting position	Necessary	User research
Filters and connectors should be clearly visible from eye height, sitting	Necessary	User research
Force and torque needed to exchange filters should be suited to the abilities of the user group	Necessary	User research
Filters should weigh <* kg	Necessary	Filters should not weigh more than dialysis solution bags, to ensure filters not being the limiting factor
Allow for aid tools e.g. wrench tool	Desirable	User research
Minimize mental difficulty of filter exchange		
Filter exchange should be intuitive	Desirable	User research, HE75 17.2.1
Easy access to instructions	Necessary	User research, HE75 17.6.3
Each pair of filter and connector should have active differentiators and be easy to identify even with tactile impairment	Necessary	User research, HE75 17.4.2

Feedback should be given when filter is properly attached	Necessary	User research, HE75 17.6.3
Feedback should be visual, audible and tactile	Desirable	HE75 17.4.2
Audible feedback or reminders should use frequencies below 2500 Hz	Necessary	HE75 25.3.2.3.
Device should remind user about filter exchanges	Necessary	User research, HE75 13.3.6
Reminder should be adjustable (Timing, volume)	Desirable	User research, HE75 25.2.2
Option for automatic order of filter when reminder is sent out	Desirable	User research
Allow for ordering of new filters both via internet and phone	Necessary	User research
The design should be friendly and not intimidating	Desirable	User research, HE75 25.2.9
Error and hazard prevention		
It should not be possible to connect wrong filter (misconnection)	Necessary	HE75 17.2.1
Minimize, collect and drain potential spillage	Necessary	User research
Protective covers on filter should be clearly visible	Necessary	User research
Protective covers on filter that don't need to be removed	Desirable	User research
The connections should be robust to prevent accidental disconnection	Necessary	HE75 17.2.4.4
Connecting mechanism should not injure user	Necessary	HE75 17.2.1

Table 2. Product specifications derived from the user research performed at *Hemdialysen* in Lund, and the standard HE75. *= confidential

There are other types of specifications as well, such as specifications regarding sustainability, manufacturability and overall cost, which are very much relevant within the development of the device, but those are not addressed in this thesis as it focuses solely on the usability. Other departments within Baxter will address these areas.

5 Develop

In this section, some of the developed concepts and methods used are presented.

5.1 Ideating & Conceptualizing

With all the insights from the Define phase, the next step was to generate ideas and turn them into concepts. With the list of specifications, table 2, as a foundation, brainstorming was used as a method to generate many different ideas and to keep the perspective wide. At this stage, technical feasibility was neglected. The purpose was to have a large amount of ideas and to not criticize any idea. The ideas were at this stage visualized with very quick and simple sketches on post it notes, two examples are shown in fig. 16. From there, an initial evaluation was done through discussions with members from the R&D team at Baxter. The idea was not to sift out any ideas at this stage, rather to discuss what was good and bad in each idea and take it from there and see if ideas could be developed further, either on their own, or combined.

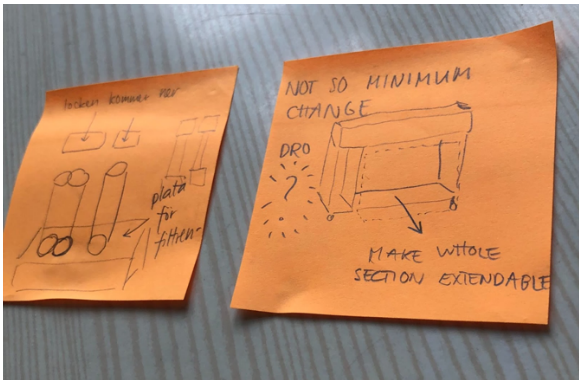

Fig. 16. showing two of the quick sketches on post-it notes from brainstorming sessions.

When thinking about possible routes forward, it seemed like there were two main alternative routes to take. The first would be to work only with one of the filters, the DRO, since a previous study performed by the company had pointed out that this particular connection as problematic. (Due to confidentiality, this study will not be described further.) If the other two kinds of filters and connecting methods are not pointed out as problematic, why change them? This way of approaching the challenge could be pursued either by designing a new connection method for the DRO that perhaps the company can manufacture themselves, or secondly by scouting for an already existing solution that the company can buy. Since RO-membranes are used in residential under the sink water filtration systems, there already is quite a large market for these, so chances are that there might be an already existing solution that fulfils the requirements.

The second approach is to fully overhaul the filter situation, to see if all filter connections can be improved. Perhaps to see if the same connection method can be used for multiple filters, this could improve the overall user experience, in a way that it would be fewer connecting methods the user will have to learn and understand. However, the previous user study performed by the company had also concluded that it does not matter if it is one mechanism or several different ones, as long as they are easy to use. However, my interpretation of those results is that it is not necessary for them all to be connected the same way, however it could still add value as it minimizes the mental load of understanding and learning several different connection methods compared to one. Also, during the interviews at Hemdialysen, several of the nurses mentioned that many different tasks may lead to a feeling of overwhelming.

The initial aim was to develop a physical interface for the filters, but the user needs showed that there is much more to the filter exchanges than the actual physical mechanism for connecting the filters. Therefore, some concepts touch more specific parts of the interaction between user and device, whereas others focus more on the physical connection of the filters. Some concepts touch all of the filters, whereas others target only one of them at a time. One concept does not exclude the other, they can work as combinations as well.

With the purpose of narrowing down potential routes forward, an initial evaluation of the ideas was made. All of the user needs presented in table 1 were to some extent a foundation, as well as input of what is feasible from an economic and technical perspective from the R&D team at Baxter, as my part solely was regarding the usability linked to the activity of exchanging water consumables. This step led to deciding which ideas to continue to work with and to generate concepts from.

5.2 Concepts

5.2.1 **Physical Concepts**

Concept A "Minimum change"

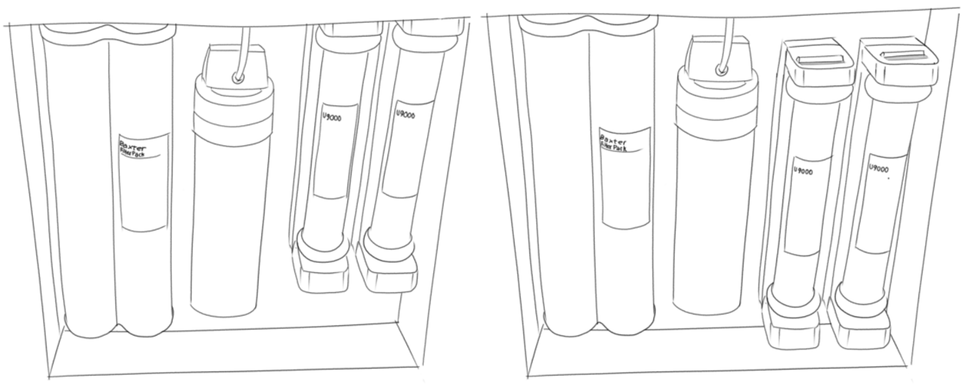

Fig. 17. Sketch of the current filter set-up to the left, and to the right. This illustrates how the lowering of the Ultra Filters could look, making the handles visible on the top of the connector, instead of having them facing downwards, as it is in the current design where they are not visible.

The aim for Concept A is to change as little as possible, but still be able to enhance usability. The Filterpack is kept as it is in the current design. Improvements with signifiers to support affordance could probably be done, but the existing mechanism is currently not physically available in Lund, it is located at the company's office in the U.S, therefore it is hard to investigate it further. For the Ultrafilters, the current connection mechanism will be kept, improvements to enhance usability will be made such as lowering their position and turning them upside down. This will improve the accessibility, as the user won't have to bend down as far to connect the filters (the handle that connects the filter are currently facing downwards). Placing the handle on the top instead will make it clearly visible, with the purpose to invite to interaction. The bottom of the space works as a dripping tray to collect and drain spillage. A sensor here could be added to detect potential leaks. As for the DRO, the idea is to source it from another supplier, who can supply a filter housing with better connection mechanism that fulfils product requirements.

Concept B "A little more change"

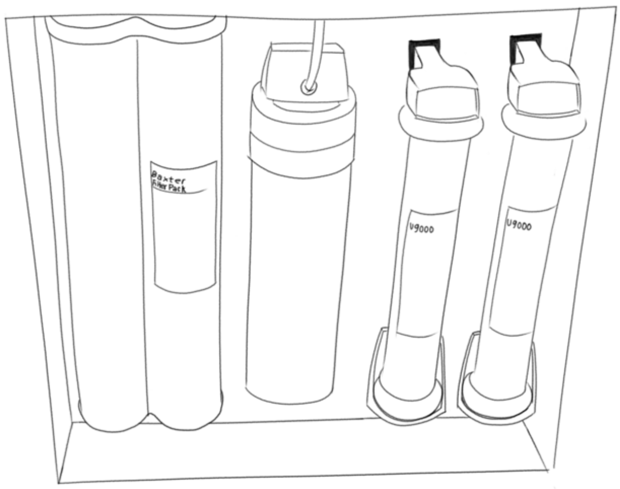

Fig. 18. Sketch of how the implementation of a connection method for the Ultrafilters (the two filters to the right) from another Baxter device could look.

This concept also targets the Ultrafilters, but with a bit more change. Another connecting mechanism, found when doing internal benchmarking, will be implemented for the Ultrafilters. It comes from a HD machine, manufactured by Baxter, which also uses Ultrafilters. This connecting method offers better accessibility, as the user won't have to bend down as much. Since this mechanism is developed by Baxter, it will not be described further in this report.

Concept C "Artis UF holder for all filters"

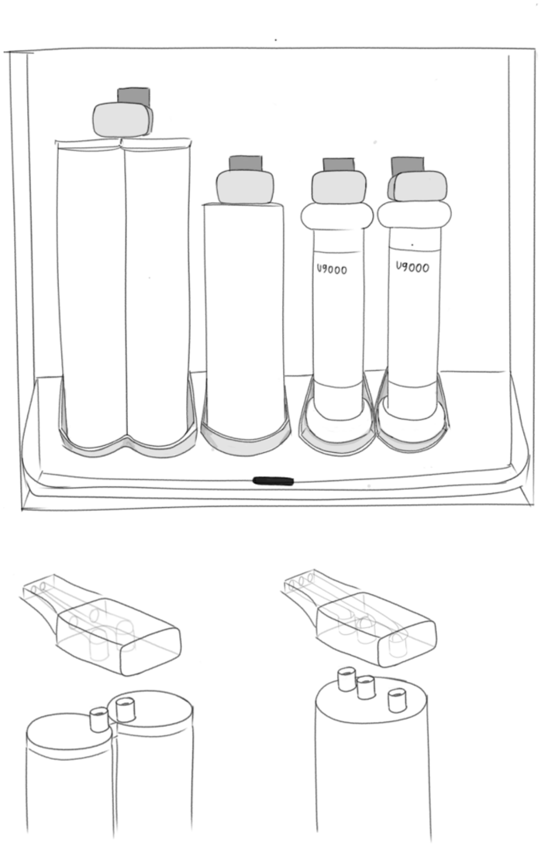

Fig. 19. Sketches of how a connection method from another Baxter device could be implemented for all the filters in this project. The inlets and outlets of the Filterpack and DRO would need to be redesigned.

This concept uses the same connection method as concept B does for the Ultrafilters, but here it will be implemented for all of the filters. All of the filters will now be connected in the same way to minimize the mental load of performing and remembering multiple different steps. It is clear which position each filter should have, as there is an active differentiator; the bottom part in which the filters are placed. They are shaped differently depending on which filter goes there.

The Filterpack and DRO would need to be redesigned to have inlet and outlet in vertical directions, and these would be placed slightly asymmetrical to ensure that they cannot be inserted the wrong way, this will act as a passive differentiator. It would be favourable with some kind of vertical attachment, so the filters stay in place when lifting the handle to remove the filter. Otherwise the user would probably have to hold one hand on the handle, and one the filter to ensure that it stays in place. Underneath the filters, there is a tray that collects and drains spillage.

Concept D "Insert from above"

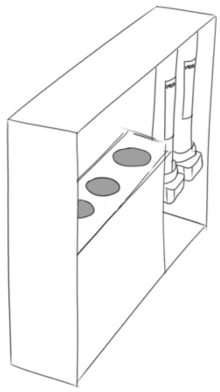

Fig. 20. Sketch of how the device could look if the Filterpack and DRO were to be inserted from above.

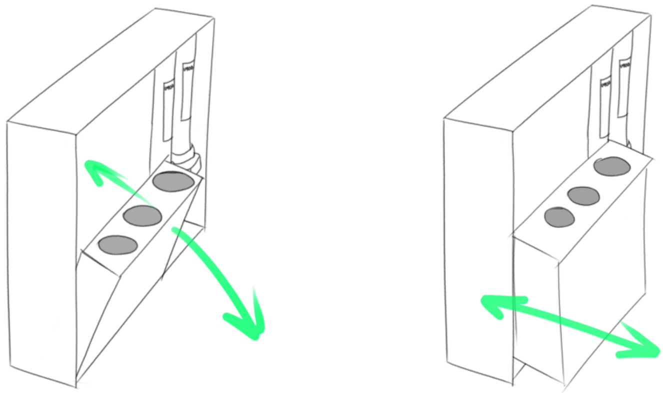

Fig. 21. Sketches illustrating how the filter section could be tilted (left) or extended (right) to make it less hidden and improve accessibility.

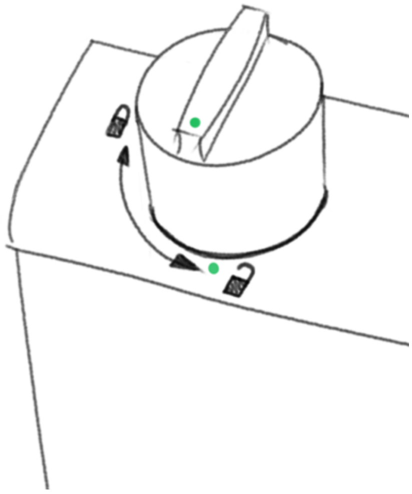

Fig. 22. Sketch of how to use signifiers to show the affordance.

This concept focuses on the Filterpack and the DRO. The Ultrafilters are kept as they are in this concept. The filters are inserted upside down and from above. This solution requires check valves since it is not possible to completely drain the filters prior to exchange. The idea is that each filter will have its own slot, and since the filters vary in size and shape, the slots will be active differentiators. This also resembles the shape sorter toy, fig. 13. The option to either tilt or pull the section out offers increased visibility and better accessibility, since the user will not have to bend down to see where to connect the filters.

The filters will be secured by twisting motion, preferably 90 degrees. Different signifiers will be used to promote the affordance; the green dot will show the correct position. An arrow tells the user to twist the filter. Icons in the shape of a closed and open padlock communicates the direction of the different actions. The locking mechanism could for example be a bayonet mount, but other locking mechanisms could also be explored, such as some kind of sliding lock.

Concept E “Horizontal insertion”

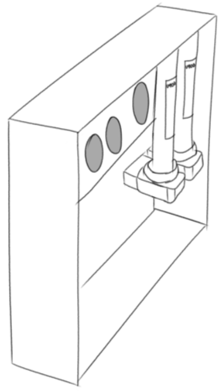

Fig. 23. Sketch of how a concept allowing for horizontal insertion of the filters could look.

This concept is similar to the previous one, but instead the filters are inserted horizontally and located higher up to improve ergonomics. This concept requires major changes in the device to be able to fit the filters in a horizontal position.

Concept F “Extend whole section”

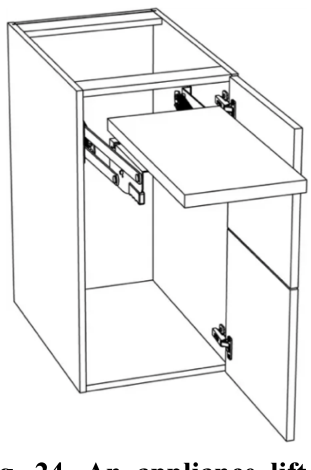

Fig. 24. An appliance lift, which is commonly used in kitchen drawers to minimize lifting of heavy kitchen appliances. [26]

This concept is not about the specific connections of each filter, instead it focuses on how the position of the section for water consumables is currently a bit inaccessible, and how this can be modified to improve accessibility. This concept simply consists of installing an appliance lift, which is commonly used in kitchen drawers. This concept can be combined with any of the other concepts targeting the connections.

5.2.2 **Interaction & Service Concepts**

Concept G "Instructions"

Instructions could be presented on a screen and could include videoclips of how the exchange is done step by step. It would provide the user with clear visual, and perhaps even audio guidance on how to perform the task. It could be a video showing someone doing the exchange, or an animation created in a CAD software. However, from the user research, one insight was that some users, especially elderly, seem to prefer to read instructions from paper, instead of having them on a screen. This shows the need for flexibility, to offer instructions both on paper and on screen. A good addition could be to attach instructions with illustrations on the inside of the door, that way the user won't have to remember where they put the instructions when it's time for the exchange. The ergonomics is not optimal, but nevertheless it adds value as those instructions will stay where they are. Instructions on paper could also be in the package with the new filters.

An additional way of accessing instructions could be by scanning a QR code that is printed on the label on the filter.

Concept H "Automatic ordering system"

The ordering of material was pointed out in the user research as something that can be an additional burden to the patient. Why not automatize this task?

When the device notifies the user that the water filters will need to be exchanged in some time, there could be the option for automatic ordering of these consumables. This requires that the user has some kind of account or user profile where their address is stored, so they won't have to type in their address.

On a screen on the device, following sequence could take place:

“The water filters in the lower part of the device will need to be exchanged within 2 weeks. Would you like to order a set of new filters to “address stored in user profile”?
(YES/NO)
YES -> 1 x Filter pack 1 x DRO 2 x Ultra Filters will be sent to “address stored in user profile”.
Confirm?
(YES/NO)
YES ->Filters are ordered to “address stored in user profile”, you will get an order confirmation e-mail.

It can also be done even more automatic, as a subscription:
“The water filters in the lower part of the device will need to be exchanged within 2 weeks. A new set of filters will be delivered to “address stored in user profile” within a week. If you have questions or would like to change the address, contact customer service +999999 or customerservice@companyname.com

5.3 Concept screening & selection

5.3.1 **Method**

Performing a structured concept selection offers multiple potential benefits according to Ulrich & Eppinger [9 p. 148], such as creating a customer-focused product as the concepts are evaluated against criteria based on customer needs and creating a competitive design when also studying competitors’ products. Other profits are that it makes group decisions easier and offers a structured record which motivates why certain design decisions were made.

Concept selection is commonly made with a two-step process, where the first step is called *concept screening* and the second step is *concept scoring*. Both steps can be performed using Pugh’s matrix, which evaluates concepts against a reference concept, which in this case is the current design. The concept screening aims to quickly narrow down the number of concepts and to find improvement opportunities for the concepts, whereas the concept scoring is a more refined comparison which is done when the concepts are more defined and have been improved. In both steps, the aim is to present the concepts with the same level of detail to be able to make unbiased decisions.

In this thesis project, some generated concepts go through the first step, the concept screening. The concepts intended for screening were the concepts covering the physical connection mechanism: concept A, B, C and D. Concept E also covers this, but it exceeds the current dimensions of the designated space, and requires major changes in the device, therefore it will not be taken further.

This concept screening will give the company a suggestion of direction on how to further develop the concepts into functioning prototypes. The concepts were portrayed by both simple sketches and written descriptions where the key features of the concept were communicated. Criteria based on user needs, product specifications as well as medical device design theory, were put in the screening matrix. The criteria were not weighed at this stage, as it is difficult to pursue detailed quantitative comparisons when the concepts are in this early stage. The idea is rather to map the strengths and weaknesses with each concept and to decide if the concepts are better or worse than the current design. In the screening, the following scoring is used:

Relative Performance	**Rating**
Worse than reference	-
Same as reference	0
Better than reference	+

5.3.2 **Results**

Criteria	*Current design*	*Concept A*	*Concept B*	*Concept C*	*Concept D*
Accessibility	0	+	+	+	+
Prevents misconnection	0	0	0	+	+
Eases alignment	0	0	0	+	+
Ease of handling & use	0	+	+	+	+
Low number of actions needed	0	0	0	+	+
Prevents spillage	0	0	0	0	+
Collects & drains spillage	0	+	+	+	+
Visibility of filters and connectors	0	+	+	+	+
Total score rank	0	4	4	7	8

Table 3. A concept screening matrix used for comparing concepts with the current design, based on Pugh's concept selection matrix.

In the concept screening, Concept D “Insert from above” received the highest ranking, closely followed by concept D “Artis for all”. The result is not surprising, as these concepts target all of the filters and are more of a complete makeover with enhanced usability in mind. However, it is important to have in mind that these criteria are solely linked to usability. If other parameters were to be applied at this stage, such as cost, manufacturability, implementation time and technical feasibility, to mention some, the ranking would most definitely differ.

6 Discussion

This section contains reflections regarding execution of the thesis project and results, as well as suggestions for further development.

6.1 Defining the scope

I was given the freedom to work with all four of the filters, or to choose one of them to focus on. The thought was to treat all the consumables as a system – since they all should be changed at the same time and to try to find a solution that works for all of them. If I instead would have chosen one filter to work with, for example, the Ultra Filter, then I would probably have had gotten further in the developing process, probably with functioning prototypes and testing. This decision would have resulted in more time with actually designing and testing different connecting methods. In retrospect, I think that it maybe could have been a more favourable approach for a thesis work, as it sometimes felt messy and as too big of a challenge to work with all of them at the same time. However, as for Baxter's development of this medical device, my impression is that it is favourable to treat the different filters as a system.

Initially, the thought was that (more or less) functioning prototypes should be the main result of the thesis. I did not get that far in the process and there are several reasons to the change of plans. The initial intention was that there was no need to perform user research as a part of the thesis, as the company already had performed a market research and I would be given the results. However, as the thesis project begun, it became apparent that the available information was not sufficient to provide the necessary basis for the thesis project. It was therefore needed to perform user research to be able to grasp the bigger picture and to get a solid understanding of the abilities and challenges of the user group. As well as to fulfil the academic requirements for the thesis.

The thesis project is a collaboration with a large company, and conducting the thesis in parallel with several other teams who might have slightly different visions of how the thesis should be conducted and what it should contain led to unnecessary confusion which took both time and focus from the actual thesis work. The initial time plan (see appendix A) of the thesis in relation to the plans of the HFE team did not really align, which eventually led to taking the decision to perform the thesis with a more independent approach, which probably could have been done sooner to be able to perform thesis activities more freely.

Several meetings were held to discuss expectations and to define the scope of the thesis, even so, unclarities and confusion arised regarding what tasks should be perform at what stage. But needless to say, this has truly been a great learning opportunity, from being accustomed to the university environment where tasks and timelines are nicely arranged, to be part of a large corporation where many workstreams work in parallel and with different priorities. One of the biggest lessons is that communication is key and that unforeseen events can always occur, and things might not go as planned or be delayed. The fact that things might not go as planned or are delayed is neither uncommon or wrong, what is important is to be able to be flexible, communicative and creative.

6.2 Process reflections

One major challenge I stumbled across just in the final stages of the thesis was how difficult it was to properly evaluate a concept based on rapid sketches. To some extent it felt arbitrary. It would have been favourable to make Lo-Fi prototypes in parallel with the conceptualizing. It is difficult to imagine how well a concept fulfils a criterion based on user needs without seeing actual users interact with a prototype. It is also important to shape the criteria in a way so that the concepts actually can be evaluated against them, which I found challenging, but hopefully that is something that gets easier with experience.

Some of the product specifications tend to be a bit vague. For example, “Filter exchange should be intuitive” and “The design should be friendly and not intimidating”. It would be interesting to explore this further, how can something be classified as intuitive? Can you measure how intuitive something is? Is there general impression intuitiveness? Are there cultural differences? The same goes for striving towards a friendly design. How can a design be friendly? Are there general friendly attributes? Does a Scandinavian user perceive friendliness in the same way as an American, or Asian user?

6.3 Further development

To further validate the user needs, more user research and observing users interacting with the water consumables is needed. It is of importance that the user research covers dialysis patients as well as their closest relatives and caregivers. Preferably the research should be done in several countries to grasp cultural differences if the idea is to eventually launch the product internationally.

The next step, to continue working with the concepts, would be to begin to make prototypes and to further define the concepts. Perhaps some concepts can be combined.

When the concepts are more defined and when prototyping and user testing has begun, they are ready to go through the second step of concept selection, concept scoring which can be made with the Pugh Matrix. To be able to make a justified concept selection, it is of importance that criteria touching on other aspects than usability is part of the matrix. This could be criteria regarding cost, manufacturability, sustainability, implementation time and technical feasibility to mention some.

As the testing and prototyping has begun, the criteria can be weighed according to importance, and the concepts can be rated and compared more thoroughly against each other, e.g. with the following scoring.

Relative Performance	**Rating**
Much worse than reference	1
Worse than reference	2
Same as reference	3
Better than reference	4
Much better than reference	5

But, before putting too much effort in developing the mechanical connection mechanism, I believe more research needs to be done regarding what users find the most challenging in the activity of exchanging water consumables, and how prioritised it is in relation to all other activities the user is supposed to perform. Another important question is how many of the home dialysis patients would actually do the exchange themselves, and to further define the targeted user group. If the budget was unlimited, endless amount of improvements of the physical interface of the water consumables could be done. The user could be passive, where a completely automated interface exchanges the filters, with the aim to minimize the workload for the patient. On the other hand, the user could be active, and the device passive, meaning that the user performs all of the steps. One must thoroughly evaluate how the overall user experience with the device is affected by the filter exchanges. If not, risks are that the solution might be over engineered and not fulfilling the actual needs of the user, and not adding value that matches its implementation cost. A Cost- benefit analysis is a method that could be used for this.

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Appendix A

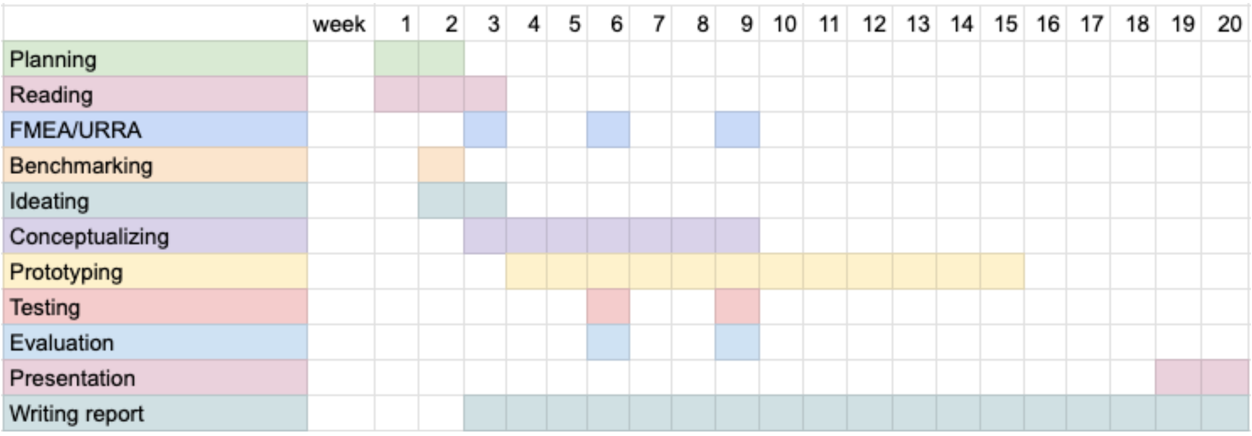

Fig. A.1 Initial time plan for the thesis project, presented as a Gantt chart.

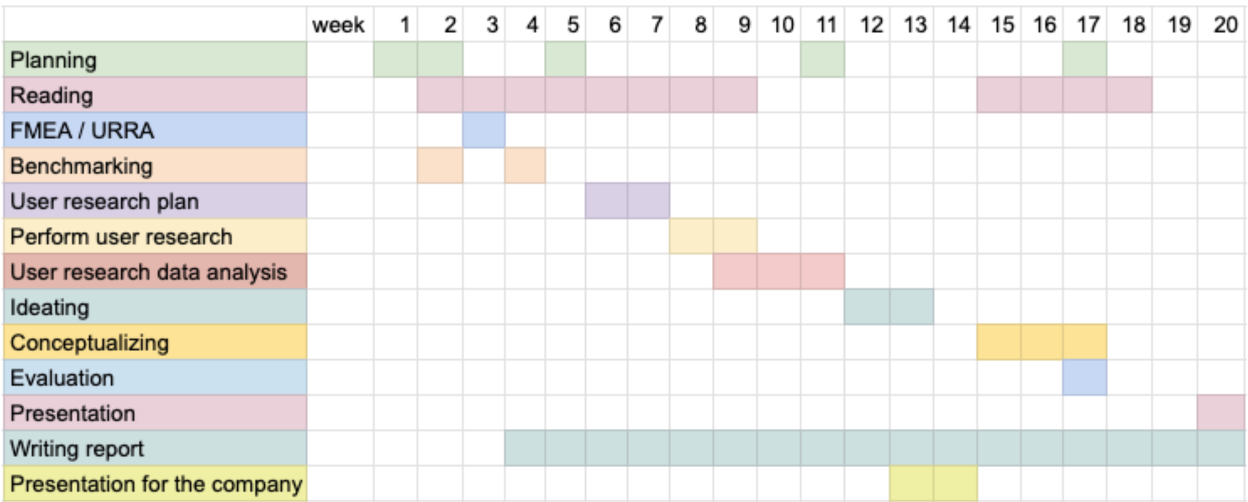

Fig A.2 Actual time plan for the thesis project.

Appendix B

Informerat samtycke för medverkan i intervju

Syfte
Intervjun ingår i ett examensarbete inom produktutveckling vid LTH Lunds Universitet. Syftet med intervjun är att få kunskap om hemdialys och ökad förståelse för vad som krävs för att skapa god design och användarvänlighet kopplat till denna specifika patientgrupp. Intervjun syftar även till att få en inblick i hur det är att vara dialyspatient och hur livet påverkas av behandlingen.

Genomförande
Intervjun genomförs av mig, Mathilde von Gertten, och den beräknas ta 45-60 min. Intervjun är sk semi-strukturerad, vilket innebär både konkreta frågor och ett friare samtal kring din uppfattning av dialyspatienter och deras behov i vardagen. Om du vid intervjutillfället samtycker kommer intervjun att spelas in för att jag i efterhand ska kunna säkerställa en korrekt tolkning av samtalet. Under intervjun kan du välja att avstå från att besvara frågor om du önskar. Deltagandet är frivilligt, och du förbehåller dig rätten att när som helst, utan särskilt förklaring, avbryta intervjun och dra tillbaka ditt deltagande.

Sekretess
Allt material från intervjun kan komma att användas i examensarbetet, såvida du inte väljer att avbryta din medverkan. Dina svar kommer att hanteras konfidentiellt. Endast jag samt mina handledare vid Lunds Universitet kommer att ha tillgång till inspelat material. Du kommer att vara helt anonym och resultaten kommer inte att kunna kopplas till dig. Inspelat material raderas när examensarbetet är slutfört.

Kontaktuppgifter

Om du har frågor kring intervjun eller examensarbetet är du välkommen att kontakta mig via mail:
jup14mvo@student.lu.se

Frivilligt deltagande
Jag intygar härmed att jag frivilligt ställer upp på intervju enligt beskrivning ovan.

Datum, ort: ___________________________________

Signatur: ___________________________________

Namnförtydligande: ____________________________

Appendix C

Nurses

Four dialysis nurses were interviewed. All of them have +15 years of experience of working with dialysis, which implies that they have met many different patients and have great experience in working with this patient group. The nurses also have experience from working with both PD and HD, and some also of IHD (in-clinic HD). Some of the nurses had previous experience of working at a manufacturer, Gambro, being involved with the development of dialysis equipment.

The nurses' work tasks vary a lot. Their primary work task is education, where they educate both new patients and health personnel in performing dialysis in a home environment. When a patient first comes to the home dialysis clinic, they are trained daily in performing the treatment, 1-3 weeks for PD and several months for HD, before they can manage it at home. The other health personnel they train can be nurses and assistant nurses from the Home care unit (*Hemsjukvården*) or medical students. Another part of their job is caring; they care for and give advice to their patients whom they have regular phone contact with, and they meet their patients who come on monthly- or bi monthly visits, or even more often if they need.

The nurses work very closely with their patients and have daily contact with them in the beginning of treatment. Home visits to patients are also common. The nurses can follow the same patients for many years and get to know them quite well, as the patients will need treatment for the rest of their life, or until they get a kidney transplant, which far from everyone gets.

The nurses were initially seen as secondary users, but when visiting the clinic, it was apparent that the nurses interact daily with the machines when they educate patients. They can therefore be seen as primary users to some extent, when the device is used in a clinical environment. This, and the fact that they have great experience of working with dialysis patients in versatile ways showed that they have deep knowledge in patients' abilities and needs and that it was the right decision to start with the nurses.

The Clinic

The clinic offers three types of home dialysis: HHD, PD and assisted PD. Aside from the nurses, the patients have contact with doctors, dieticians and physiotherapists, but the nurses are by far the ones that have the most patient contact. At the clinic there are also dialysis technicians who install and do maintenance on the machines in patients' homes. The technicians can, if needed, visit a patient if there seems to be something wrong with the machine.

PD

As of today, the clinic has 60 PD patients, and approximately 20 of the patients do APD, the rest do CAPD. The clinic has a goal of initiating a majority (>60%) of new patients on PD. The nurses mention several benefits with PD, one being that it has cardiovascular benefits, as it can be seen as a gentler treatment than HD. Another benefit is perceived freedom. When performing PD, the patient is not attached several hours in the daytime to a machine in the same way as when performing HD. Another advantage is to keep the blood vessels intact for as long as possible, as for most patients, dialysis is a lifelong treatment, and they may eventually need HD when PD is no longer enough. In those cases it is favorable to have good access to the vessels.

Assisted PD

About half of the PD patients have assisted PD, which can be both APD and CAPD. Nurses and assistant nurses from the home care unit, visit the patient in their home and assist with their treatment. How often they visit, and what tasks they perform depends on the needs of the patient, and this vary greatly.

Trembling of the hands, impaired vision and reduced dexterity are mentioned as factors for needing assistance as these impediments may lead to patients failing with the connection of the tubing. This might lead to them touching the connection and contaminating it, which can result in complications such as infections. Impaired hearing can make it hard to respond to alarms and reduced strength makes it hard to lift the bags with dialysis solution. One nurse described this as followed:

> "*If you have a cycler, it's 5 litre bags that need to be lifted and put on the machine. It is physically challenging. Also, if you have the 2 litre bags (CAPD), you need to do it four times a day. Getting a bag, open the bag, reach up and hang it on the drip stand. It can be challenging, especially if you have a disability, or if you just don't have the energy*"

Cognitive barriers mentioned as a reason for needing assistance include learning disabilities and dementia. Some patients manage their treatment by themselves but need assistance with ordering dialysis material, while others need assistance for every step in the treatment.

The social aspect of getting visits is also mentioned, as some older patients tend to be lonely, and their lives can be enriched by the daily visits from the home care unit.

HHD

The clinic has around 30 patients performing HHD. As of today, it is not possible to get assistance when performing HHD, as it is with PD. HHD patients receive several months of training of how to perform their treatment at home. When they are ready, their machine is installed in their home by a dialysis technician from the hospital. Aside from the dialysis machine, a water treatment system is installed.

Maintenance routine HHD

There are almost no maintenance activities at all linked to PD treatment. However, patients who do HHD have to perform maintenance linked to the HD machine.

Fig. C1. Image showing the back of the HD machine from Fresenius that the clinic uses.

Every third month, the HHD patients change two filters that are located on the back of the HD machine, which can be seen below.

Fig. C2. Filters located on the back of the HD machine. They are changed every third month.

The machine drains these filters before exchange, so they are relatively dry when removed. Two clamps need to be loosened, and then the filter can be removed. Minor drips can occur. When asked if this activity is something the patients complain about or struggle with, one nurse seemed almost surprised and answered
"No, that I have never heard about actually"
Another nurse said "Sure, maybe some would find it a bit finicky, but then we can guide via phone. And if the patient lives nearby, we might make a home visit and do it [the filter exchange] with them"

The filters are located at a height of approximately 50 cm, and on the question if the placement of the filters is problematic, the nurses answer that it varies between patients. One nurse brings forwards one example; that a very tall patient with arthritis might struggle to bend down, whereas for other patients it's no struggle at all.

One nurse argues that there is more acceptance for maintenance routines that are done seldom being "a bit finicky", whereas activities that are done with every treatment must work smoothly, otherwise it can create frustration and limit a patient from performing home treatment.

> *"these filters are changed every third month, it's not a big deal. However, connecting the Theranova filters that you do every treatment… [swears]"*

Once a month (for most patients - some need to do it every other week, depending on water quality) the patients exchange a carbon filter in the water treatment system.

Fig. C3. Image showing a carbon filter with a wrench, similar to the ones that are changed monthly. [13]

There is no automatic reminder for this carbon filter, meaning that the patient needs to keep track of when they last changed it. This filter is not drained before exchange, so it is filled with water and needs to be carried carefully, otherwise spillage could occur. Some patients struggle with securing the filter tight enough, then a wrench tool is provided to help them. The nurses make a home visit when it's time to change the carbon filter for the first time, so they can assist if needed. When the filter needs to be changed for the second time, the nurses may call to remind the patients to change them, but after that they are supposed to remember and manage this monthly exchange by themselves.

One nurse concludes that it is for sure a bit of maintenance linked to HHD, but it is not the tasks themselves that is the hardest part for some. Just remembering when to perform the different tasks and how to perform each one can be a lot, especially with the tasks that are not done on a daily or weekly basis and that do not have automatic reminders, such as the carbon filter.

The maintenance linked to changing filters etc. was not seen as something that commonly ruled out patients for home treatment. It was mentioned that in the beginning, it may feel like a lot of different tasks, which might result in a feeling of overwhelming, but they take it step by step when they teach the patients how to perform it. Even though routine maintenance was not seen as the most difficult part of treatment, one nurse said "*Everything that can be made simpler would of course make it easier for the patient*" emphasizing that improvements always are appreciated.

Other maintenance activities the HHD patients perform include changing a 5 liter jar of a disinfection solution, which is placed low, on the back of the machine. How often this is changed depends on treatment.

There is also a fan in the machine which the patients should clean from dust every now and then. It was explained that the fans are similar to the ones in stationary computers.

Fig. C4. Image showing the fan that needs to be cleaned from dust.

When asked about patients' impressions and attitudes towards exchanging filters themselves, the nurses gave the impression that it is not seen as a big deal, compared to the rest of the treatment and what it means to be a dialysis patient in general. It was mentioned that some patients do not change the filters as often as they are supposed to, primarily the ones without automatic reminders as patients then might forget it. However, eventually the machine starts to send out alarms, and then the filters will then need to be changed to be able to perform treatment.

In general, it seems like there is acceptance for the required maintenance. Patients manage and do not complain, at least not to the nurses. The low placement of filters is an issue to some, but since they are changed so seldom, it is not seen as a big deal. To remember *when* to change filters is mentioned as a struggle to some, showing the need for automatic notifications that imply when it is time for filter exchange. The fact that the carbon filter is not drained before exchanging was not stated as an issue, although it would be easier if it was drained first as the risk of spillage would decrease. It would also reduce the weight of it. My impression is that there were many different routines, with different time intervals and that some patients felt overwhelmed initially. This shows the need for synchronized maintenance routines, and a need for them to be as intuitive as possible to decrease the amount of work for the patient.

Home dialysis patients - One group?

In the previous theme, I presented HHD patients' experience of maintenance of the HD machine. It is of importance to investigate if, and in such case how, the abilities and characteristics of PD patients differ from those of HHD patients.

It was stated that the age of home dialysis patients varies a lot, but a majority of patients linked to this clinic seems to be between 60-80 years old for PD and 40-70 years old for HHD. The patient group that has assisted PD stands out, as they in general are older and more comorbid, hence they have the need for assistance. The group that perform PD without assistance are stated to generally be more like the group that perform HHD.

When asked if PD patients would manage similar maintenance with filter exchanges that HHD patients do, one nurse explained that she thinks that many would, and for those who would not, the home care unit would do it.
She explained that she thinks many would manage, if they were just taught how to do it but the learning period would be a bit longer, as there would be more steps in the process. PD patients are used to connecting a lot of tubing, something one nurse described could be an advantage.

My initial thought was that HHD patients have less physical and mental limitations compared to PD patients since their treatment is more complex and requires more education and effort. Apparently, that generalisation is not accurate. There are PD patients who are young and relatively healthy and those who are a bit older but still are quite capable, and of course, also those who are very sick and need a lot of assistance. The nurses also talk about PD being a first alternative when a new patient needs dialysis, and some PD patients eventually become HHD patients.

Why not home dialysis?

There can be many reasons to why dialysis in a home environment is not suitable. There can be patients who need HD and want to do home treatment but cannot physically or mentally perform the treatment themselves and since there is no assisted HD, home treatment is not an option for them. Patients need to be able to physically grip, move and connect the equipment and also have the cognitive ability to learn and take in information to be able to perform their treatment, that goes for both PD and HHD. Since PD patients have the right to assistance in Sweden, a patient can receive assisted PD without to the necessary grip strength and mental ability to learn how to perform their own treatment.

On the other hand, there can be patients who are quite capable, but they are not motivated nor interested in home treatment. The lack of motivation and interest was the most commonly mentioned reasons that make patients not suitable for home treatment. Perhaps a doctor, or a relative think that home treatment is the right option, but the patient themselves is not motivated enough to do it. An example mentioned was a patient, a young adult, who did not know if he was on the transplant-list or not, and did not seem to care. According to the nurse this is a sign that shows that a patient is not engaged or interested enough in their own health to be able to perform treatment at home.

Mental health issues such as dementia, depression and addiction are mentioned as issues that make patients not appropriate. Patients that are not careful and do not understand the risks are not suitable for home treatment.

Reasons why a patient can feel that they do not want treatment at home can be that they have the impression that it is too advanced, especially HHD. If they have IHD, they are used to all the nurses in the clinic managing the treatment and the machines, and might feel that they could never manage all this on their own. Other reasons can be that the machines are big and will make their home feel like a hospital with all the tubing, together with other material and equipment that need to be stored. Sometimes it can be a family member who does not want the machine in their home.

Another reason to why some patients do not want treatment at home is the social part of going to a clinic. Getting dialysis in the clinic can be something patients, especially those who live alone, value as it enriches their life and they socialize with the nurses and other patients.

Specific issues with treatment

For PD, the interviews indicated some obvious patterns regarding what aspects the patients think is the hardest with this treatment. To lift the bags with dialysis solution was the first. This includes lifting them to the storage when they are delivered to the patient’s home, and carrying the bags every day for the treatment.

Storage and disposal of both material and waste were also mentioned as burdens, especially with PD where the treatment creates a lot of waste, such as empty bags and boxes, that needs to be taken care of. When new material is delivered, which is usually done weekly or bi-weekly, the delivery person can take the waste with them, but it still needs to be stored during the week.

One specific issue was how much force that was required to connect the Theranova-filter (a filter used when performing HD) to the tubing, and that it needed to be tightened several times to be properly secured. This connection is done with every treatment session. I got to try it for myself and was surprised by how much friction there was in the connection and it was quite a struggle to get it all the way in, and the plastic had edges that made my palms hurt when trying to secure the twist fit.

Regarding changing filters on the HD machine, one thing mentioned is that the filters have tiny plastic covers that need to be removed before usage. This is sometimes forgotten which then leads to issues, since the water cannot enter the filter. One nurse mentioned leakage as a result.

The relatively low placement of some filters is usually not an issue when everything goes as planned. If there is a problem with the filter, then the placement could be an issue, especially for patients who struggle with bending down.

It was mentioned that to prepare a HD machine, there are many different parts: different tubing and connectors to mention two. It would be convenient if this could be simplified and include fewer different parts. She also mentioned the wish for feedback, so one knows when something is secured. “You just want to hear a ‘click’, then you know it’s properly attached”. Clamps on the tubing for the APD cycler are mentioned as hard to open and close; it requires quite some grip strength and dexterity to be able to manage them.