Designing a kidney perfusion machine

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Abstract

Today, it is difficult to take care of organs that could have been donated to patients. In Sweden around 92 000 people die every year yet less than 200 of them become kidney donors. UGLK Science AB has developed a patented technology for restoring kidney function which increases the time window for donations significantly.

In this project, the exterior of the kidney perfusion machine used for this technology is designed. The appearance of the machine must communicate stability and reliability to the user and must be designed so that it achieves a certain level of usability. To find such a design, the starting point for the project was data from the company in the form of different user needs, spatial requirements, and risk analysis. The components related to user interaction was heavily focused on in both ideation and evaluation. The components in question were a touch screen, pumps, handles and a disposable kit in direct contact with the organ.

The most important aspects were how to move the machine, what it looks like when it runs programs and how well the user can connect the kidney and start different programs. The finished concept is intended to be simple and stylish, where the absolute biggest focus has been on placing the touch screen in a place where it is accessible in the parts of the process that it needs to be.

The developed concept communicates reliability to the user by showing what the user needs to see and access to ensure safe use. Mutual trust between machine and human can provide safer use and more kidneys ready for transplantation.

Keywords: usability, reliability, kidney perfusion, interaction, risk analysis.

Sammanfattning

Idag är det svårt att ta vara på organ som hade kunnat doneras till behövande patienter. Av 92 000 döda i Sverige blir endast 200 njurdonatorer. UGLK Science AB har en patenterad ny teknologi som gör att fler njurar kan användas för donationer.

I detta projekt designas utsidan av maskinen som är en del av denna teknologi som använder sig av njur-perfusion. Maskinens utseende måste kommunicera stabilitet och förtroende hos användaren och ska vara utformat så att den uppnår en viss nivå av användbarhet. För att hitta en sådan design var utgångspunkten för projektet data från företaget i form av olika användarbehov, rumsliga krav och riskanalys. De komponenter som användaren ska interagera med fick störst fokus i både idégenerering och utvärdering. Komponenterna i fråga var en touchskärm, pumpar, handtag och en engångsprodukt som fästs i maskinen och är det som är i kontakt med organet.

De viktigaste aspekterna blev hur man kan flytta maskinen, hur den ser ut när den kör program och hur väl användaren kan koppla på njure och starta olika program. Det färdiga konceptet är tänkt att vara enkelt och stilrent, där det absolut största fokuset har varit på att placera touchskärmen på ett ställe där den är nåbar i de delar av processen som den behöver vara det.

Det utvecklade konceptet ger användaren förtroende för produkten genom att visa det användaren behöver se och komma åt för att säkerställa en säker användning. Ömsesidigt förtroende mellan maskin och människa kan ge säkrare användning och fler njurar redo för transplantation.

Nyckelord: användbarhet, förtroende, njur-perfusion, interaktion, riskanalys.

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Lund, May 2022

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1 Introduction

This section presents the background, some theory, and the method for this project.

1.1 Background

The need for donated kidneys remains high and the waiting lists are long. In Sweden around 92 000 people die every year yet less than 200 of them become kidney donors (UGLK Science AB, 2022). The donors are people who spend their last minutes in hospitals, making the retrieval of organs within the current time limit of 30-60 minutes after cardiac arrest possible. The reason for this short window of time is the fast deterioration of kidneys with no blood circulation. To be able to donate a kidney to another patient, many steps must be performed within this time limit, which contributes to the global kidney shortage as well.

1.1.1 **UGLK Science AB**

UGLK Science AB is a Swedish company within the field of medical technology with a patented technology for restoring kidneys up to four hours after cardiac arrest, increasing the time window for donations significantly (UGLK Science AB, 2022). This can in turn increase the number of donated kidneys in Sweden alone to over 5000. The system uses ex-vivo organ perfusion and consists of a perfusion machine, a disposable organ reservoir and perfusion fluids.

1.1.2 **Current machine**

The development of the machine is an ongoing process, with the solution at the beginning of the project at a proof-of-concept phase. This means that the machine works but is not designed to fit the user and the user needs. The machine, or OPP, (organ perfusion platform) is designed for resetting the kidney function of two kidneys at once using one disposable kidney set (DKS) per kidney and the solutions provided by UGLK Science. This design has the organ reservoirs, which are a part of the DKS, where the kidneys are placed, lowered onto the top surface, and provide the possibility to adjust the height of the machine. The machine has two screens and two keyboards placed on both ends, each controlling the perfusion of one of the two kidneys, as seen in the sketch in figure 1.1. After redesigning the OPP, a clinical trial will be performed by the transplantation surgeon using the in house manufactured machine from UGLK.

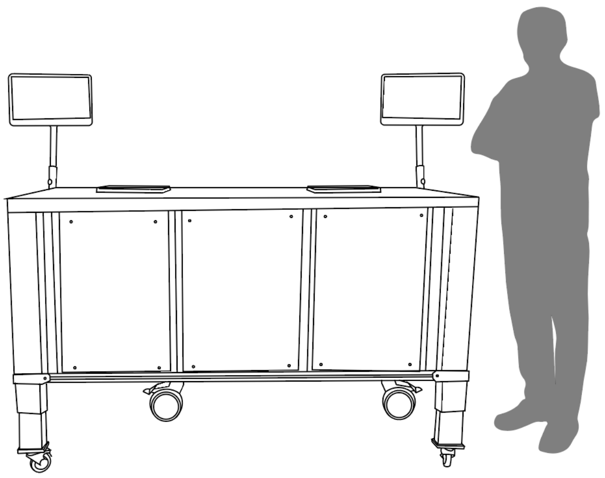

Figure 1.1: Sketch of the OPP at the start of the project.

1.2 Mission statement

The mission for this project is to create a new exterior for the in-house manufactured machine to be used in a clinical trial at the hospital. The design should focus on usability as well as the trust the machine communicates with the user. Since the machine is to be used in a medical environment a risk analysis should be performed concerning the user process and with the final design in mind. The design should be an improvement of the current machine. For future designs within the area, this project should help determine in some way the elements of such designs which are important for the user and the patient. Engineering design, as well as design for manufacturing and design of the DKS is out of the scope for this project.

1.2.1 **Challenges**

In this project, one main challenge was the fact that the machine is to be used in an environment where there are very high requirements on hygiene. To make sure the design of the machine met these requirements risk analysis was part of the project.

The other main challenge was understanding the process and user journeys to ensure the design is made with the user in focus. For this application the most important part is how the user uses the device and how the device relates to the user, therefore the design choices should be made in favour of the user.

Another important aspect of the design challenges is how to ensure trust for the design, both with the user and the patients. The user must feel comfortable enough to use the machine, or the goal of more kidneys for transplantation can never be reached, and the patient must trust the machine to provide a kidney with restored kidney function without worrying about infection. To communicate this sense of security to the user and patient creates a challenge, not only because of the difficulty in defining how this can be communicated, but because of the difference in experience and preferences between different users and patients.

1.3 Theory

1.3.1 **Organ perfusion**

The technology used is called ex vivo perfusion, which means that instead of placing a donated organ on ice, the organ is placed in a machine simulating a human body pumping blood through the organ (Johns Hopkins Medicine, 2022). Not only does this restore organ function, but it also helps transplant experts to evaluate the donated organ before transplanting it into a new patient.

1.3.2 **Medical device design**

When designing medical devices, it is important to keep in mind that some users will or have worked a long shift and might be tired (Wiklund, Weinger, & Gardner-Bonneau, 2010). The device must therefore not create too much physical or mental work since caregivers are likely to seek shortcuts if they experience that the device distracts them or creates difficulties when preforming more prioritized tasks. It is also important that devices that are used often and that are likely to be subjected to impacts have components adapted for that environment, such as rigid structure or crack-safe screens.

1.3.3 **Design research**

1.3.3.1 Knowledge in the world

A concept presented by Don Norman is designing with the goal of putting knowledge in the world. It is the idea of letting the users know less to be able to use a product and not demanding them to have the same knowledge in the head (Norman, 2013). This way of designing often require the use of signifiers, such as different symbols, that communicate different functions to the user. It can be a symbol showing the user how to turn a product on or off, or a handle showing the user how to hold a product. Putting knowledge in the world is positive in the sense of not demanding too much of the users, and not require them to learn how to use a product before using it but designing a product using many signifiers can result in a messy looking design, which might make users less eager to use the product. Of course, some products will still require the user to have knowledge in the head, and it can be desirable in some cases. A simple looking product could look very easy to use and the user might not realize the amount of attention needed to use the product properly, which in turn could lead to errors occurring.

1.3.3.2 Complexity

Complexity is good, confusion is bad (Norman, 2013). Designing products with high complexity is a difficult task and requires the designer to find a good balance between restricting users and other people. Some products with high complexity are only to be used by qualified users and must therefore restrict unqualified users from using them. This could be done by showing some amount of complexity which in turn could discourage the unqualified users from attempting to use the product. Showing complexity could also be used to make the qualified users aware of the amount of attention the product needs them to have to ensure safe and successful usage.

1.3.3.3 People make errors

Since all people make errors, it is important that the design ensures that errors resulting in negative experiences do not occur, or at least the risk of them occurring reduced as much as possible (Norman, 2013). The user should be able to perform tasks without the design hindering them but should not be able to perform the incorrect tasks. This is important to consider during the risk analysis, since some slips or errors could result in damage to the kidney or the users, and by discussing the possible errors, control measures can be taken to prevent these errors from occurring (SIS-CEN ISO/TR 24971:2020).

1.3.3.4 Pleasurable products

In *Designing Pleasurable Products,* W. P. Jordan discusses how products or objects can be seen as things with personalities, where the goal of the user experience is extended from usability to pleasure (Jordan, 2000). A hierarchy of customer needs is presented with functionality as the first need to fulfill, usability the second and pleasure as the third and last. Jordan points out that the different aspects used in research on usability very seldom includes the user's personality traits and only on factors such as age, education, or profession. Usability is defined by the International Standards Organisation as « the effectiveness, efficiency, and satisfaction with which the specified users can achieve specified goals in particular environments » (ISO DIS 9241-11). This definition is, according to Jordan, a reflection on the views on usability within research that do not include the emotional responses from the users. This reference is not a new reference, and does perhaps not reflect the views of usability in research today, but to consider the emotional responses of users can be a good approach for projects when looking for the possibility to improve the user experience and encourage the user to use the machine.

1.4 Method

When designing a product, it might be better to focus on the process and trust it will lead to a solution instead of focusing too much on finding a solution (Fredrick, 2007). Focus should always be on the current phase of the process. Shortcuts should be avoided to allow the process to lead the designer to the final design. The designer should allow themselves to explore alternative solutions instead of focusing on one idea too early in the project. The exploration should be holistic, and the decisions should be made when many choices have been explored.

The overall method for this project was an iterative design process since the machine was under development at the company parallel to this project. New data and new needs and requirements were found throughout the project, and therefore the end of phases such as data gathering, and ideation were set to fit the time frame of the project. To have some sort of structure or plan, the activities performed were listed as seen in table 1.1.

Table 1.1 Description of activities preformed throughout the project.

Activity	Description
Planning	The first part of the project should consist of the creation of a plan for the larger parts of the project.
Exploring context	After planning, the area in which the machine is to be used should be explored to find needs and to understand the user. This includes data gathering and analysis.
Ideation	To find a new design ideation must be a part of the project. This phase should start as early as possible since it can be used to find new ways of exploring the context.
Risk analysis	Since this project handles a device for medical technology, risk analysis must be a part of the project to ensure safe usage of the machine.
Prototyping	A digital prototype of the design should be created to show all elements of the design, and physical prototypes could be created if possible.

The activities presented for this project was inspired by the process presented by Wikberg-Nilsson, Ericson and Törnlind (Wikberg-Nilsson, Ericson, & Törnlind, 2021). This process can be seen in figure 1.2, and the process for this project can be seen in figure 1.3. When testing ideas, the focus at first is not verifying, but learning. The lessons from the tests can then be used for identifying new needs and performing the task "explore context" once more, creating an iterative process. The approach of trusting the process was used during the ideation phase, which was the largest part of the project. To find the design that focuses on the user, the focus was moved from solving problems to gaining empathy for the user. This was done by participating in experiments and by reading user interviews conducted by the company.

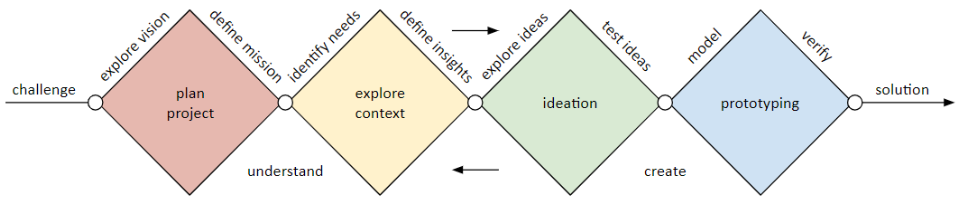

Figure 1.2 The product development process presented by Wikberg-Nilsson, Ericson and Törnlind.

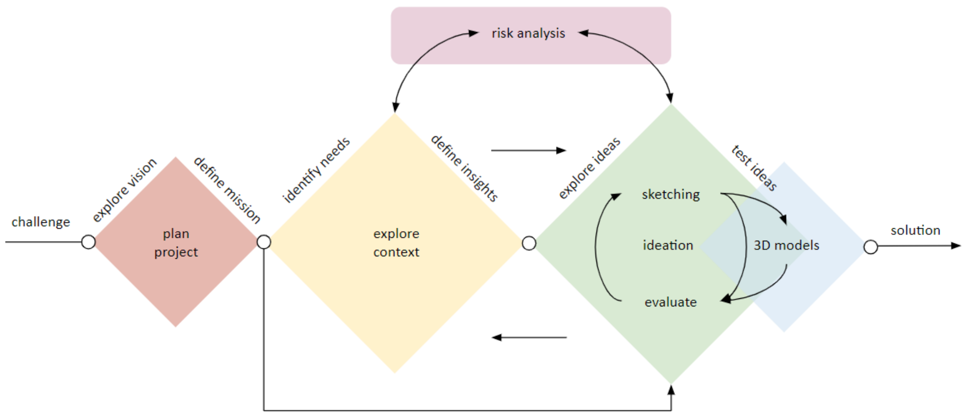

Figure 1.3 The process for this project.

1.4.1 **Explore context**

The activity explore context consisted of data gathering, analysis, the identification of needs and defining the specifications.

1.4.1.1 Data gathering and analysis

Data was gathered from the company, both technical data and user data. Other ways of gathering data were gathering information on similar machines for organ perfusion from different companies and field observations.

Competitive testing, looking at similar machines, was primarily used to understand the context better, but also to find aspects that could be improved or features that could be useful to fill the user needs for this project. The field observations were performed when observing the users during an experiment with the current machine. This experiment was performed in a laboratory environment and not all aspects of the process, such as transportation, could be observed since they were not performed. As mentioned, participation in the experiments was important to gain empathy and understanding for the users and their needs. Since the ideation started early, the sketching was used to better understand and explore the context and helped to find the questions that needed answers and to figure out what type of data that was needed.

A survey with stability in simple shapes was used to understand how people perceive stability in objects. It consisted of digital sketches of silhouettes and shapes with depth where the person should rank shapes from most to least stable or simply state if they perceived the shape as stable.

1.4.1.2 Metaphor

To understand the machine better, a metaphor was used where every part of the machine was grouped to fit a component in the metaphor. This was also a way of categorizing the components and to make sure no component that the users interact with was forgotten when designing the machine.

1.4.1.3 Identifying needs

To identify needs, the user requirements presented by the company was used as a starting point, since they were generated with interview data as basis. Other user needs were identified with statements from experiments or other meetings with the user and translated to needs similar to the definitions by Ulrich and Eppinger (Ulrich & Eppinger, 2012).

1.4.2 **Ideation**

1.4.2.1 Sketching

The ideation started early in the project with sketching in both 2D and 3D. As mentioned earlier, the sketching was at the start of the project used to find areas where more information was needed. The phase started early in the process with sketches based on the data that existed at the time. As new information was given, new sketches were made, and the earlier ones could be revisited to find inspiration or other ways of designing for the new requirements. Different approaches were taken when sketching, for example focusing on a sterile barrier or focusing on the different tasks presented in the user flow chart by the company (figure 2.2). The tasks could for example be mounting the DKS in the machine or cleaning the machine.

1.4.2.2 Needs

The user needs were also used when finding new ideas. One or two needs were selected, and concepts were generated with focus on the selected needs. One way of finding new ideas is looking at the product as a living object with a personality with which the user has a relationship (Jordan, 2000). This was primarily used to identify the emotions the machine should make the user feel and the first impression the machine might give.

1.4.2.3 SCAMPER

After some ideas were generated, they were re-visited using SCAMPER, where the questions substitute, combine, adapt, modify, put to other use, eliminate and reverse are used to find new ideas hidden in the previously developed ones (Wikberg-Nilsson, Ericson, & Törnlind, 2021). To use this method some concepts must be generated since they are the basis of the method. The idea is that this method is something that experienced designers do without actively asking the specific questions, but it can be useful to put into words when the designer is less experienced. The new ideas were then evaluated and tested against the user needs and risk analysis.

1.4.3 **Evaluation**

To evaluate the concepts, discussion with the company (or users) was the method most frequently used due to the lack of physical prototypes in 1:1 scale. Evaluating the concept by comparing it to the specifications (and risk analysis) was also a method used for testing the concepts.

After developing many concepts and using the method SCAMPER, the user tasks presented by the company seen in the flow chart in figures 2.1 and 2.2 were used to define how the user would move around the machine depending on the evaluated concept. Here, the understanding of how the user wants to move was important to evaluate properly.

The remaining concepts were evaluated and altered in SolidWorks (3D CAD) to understand the geometry of the sketches. It was also used to evaluate the ideas from a manufacturing point of view, to determine how realistic the concepts were.

1.4.4 **Risk analysis**

Since the field of the project is medical device design, risk analysis was an important part of the project. The risk analysis was performed in collaboration with the company and their risk management experts with workshops for each step of the process. The standard ISO 14971:2020 with the guide ISO/TR 2497:2020 were used to make sure the correct process was followed. Risk management was a process performed throughout this project but was not finished since the risk management process is done throughout the lifetime of the medical device to document new hazards or risks that can be discovered at any stage from data gathering to disposal. This project only covered the part within risk management called risk analysis, which is the first part of the risk management process where hazards and risks are defined (SIS-CEN ISO/TR 24971:2020).

During the ideation phase of the project, different risks were kept in mind when evaluating concepts. The risk analysis was in a way always present, and was many times used to kill some darlings. Since the idea was to keep the approach holistic, the risks were often not thought of as individual risks, but more of a general feeling and vibe. They were sometimes used when evaluating concepts by simply asking the question “does it feel safe?” and motivating why or why not.

2 Exploring context

Designing a very complex machine requires understanding regarding the process and usage of said machine. This part of the report focuses on the gathering and analysis of information, and results in needs for the development of a new design.

2.1 Data

Gathering data was a long process since new data was presented by the company throughout the project in terms of requirements and changed components, and new questions that could be answered by gathering more data arose during the different phases surpassing the exploring phase. A large portion of the data was provided by or found at the company, such as information about the system, user requirements and raw data from experiments and interviews. The raw data gave insights in how the company had found the user requirements and was used to potentially find more user needs.

2.1.1 **Safe working environments**

2.1.1.1 Ergonomics

The machine is something that users are to interact with, and the interaction should be free of discomfort or harm to the user. This includes ergonomic use in terms of working position, sound, and light. The appropriate working height is the same height as the user's elbow, which since people are different, varies (Arbetsmiljöverket, 2021). Guidelines presented by Arbetsmiljöverket suggest working height for women between ca 80-110 cm and for men between ca 100-140 cm. The user should not have to reach too much which means a limited working surface, which by Arbetsmiljöverket is set to an inner area of 30cm*80cm and an outer to 45cm*135cm, where the inner is more frequently used and the outer one used in very short amounts of time (no static work). If a product is portable, it must be either light and small enough to be carried or pushed on the floor. A product that is supposed to be lifted cannot weigh more than 25 kg, and if it is difficult to carry it close to the body, no more than 15 kg. If a product is pushed or pulled it should provide the possibility to grab with both hands at elbow height. If not, the risk of damage to shoulders or back increases.

2.1.1.2 Cleanliness

When designing something that is to be used in a medical environment some requirements are more important than others. One of the most important requirements is the requirement cleanliness, where the machine must be clean enough to provide safety for both the user and the kidney. The machine must be possible to clean in the way presented in the guidelines at the hospital, with soap and disinfectants. The DKS, which is the part connected to the kidney, must meet the requirements for sterility. Sterility is defined as the device being free from living organisms, which means that the probability that a living microorganism exists on the device is equal to, or less than, one in a million (SS-EN 556-1/AC:2006, 2006).

2.1.2 **Data from UGLK Science AB**

A lot of the data gathered was provided by the company. Since the machine was under development at the company, new data and updates were given throughout the duration of the project. The data provided consisted of user data and technical data in many different forms, for example interviews, CAD-files and user requirements and specifications for the new machine.

2.1.2.1 User data

An important part of understanding what to design is to understand the users. If you do not know who you are designing for, you cannot justify design choices in the same way as when you understand the users and the user needs. Since the users for this machine are very specific, the user data was mainly provided by the company and consisted of user interviews, observations from previous experiments and user requirements.

The notes from previously performed experiments entailed errors from a user perspective as well as possible risks when these situations occur. One error that occurred was a clamp on a tube being closed instead of opened, with the reason of having two sides primed at once and not being able to always see both sides. Many of the errors had to do with the screen freezing or the mousepad being difficult to manoeuvre, which is not within the scope of this project since it has to do with the technical parts. Other errors had to do with the user intentionally performing a task in a less desirable way, for example not using the dosage mechanisms provided by the machine and creating their own.

User interviews were performed by the company and the answers were a great source of information regarding new requirements. An interview with one of the users gave information on how they work with other machines, for example the Lifeport Kidney Transporter (Organ Recovery Systems, 2022). One thing the user pointed out was the positive experience of using transparent materials for lids and for the sterile drape, so it is possible to see the organ and the machine during perfusion.

A flow chart of how the machine is used was created by the company after these interviews. At the hospital, the machine has four users when taking perfusion, surgery, transportation, and cleaning into account. One user is responsible for transporting the machine from storage to preparations. This user only touches the outside of the machine. The next user, the perfusionist, prepares the perfusion process by readying the machine with the DKS, solutions, and the priming, where the solutions are connected to the DKS and mixed in the system before connecting the kidney. After the priming the machine is transported to the surgery where the kidney is placed in the reservoir and the gas plugged in. Here the new user is the surgeon responsible for preparing the kidney for perfusion and connecting it to the machine. The machine is checked for leakage. The perfusionist then transports the machine to the preparation room and start the perfusion process. Before the last 30 minutes of perfusion the machine is transported back to the surgery and the kidney is, when the perfusion is done and the surgeon has deemed the kidney suitable for transplantation, transplanted into the patient. The machine is then placed in storage again.

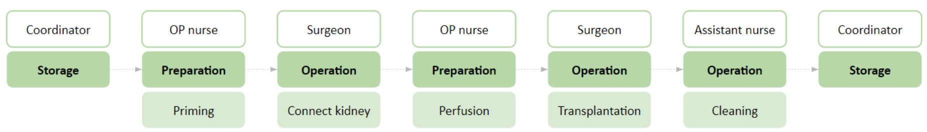

Figure 2.1: Flow chart of the usage of the machine (translated and simplified version).

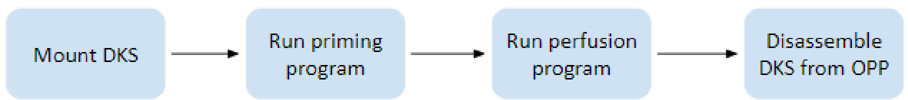

Figure 2.2: Flow chart of the user tasks related to the machine (simplified version). Connecting the kidney is not included since it is a task related to the DKS.

2.1.2.2 User requirements

The user requirements presented by the company were set based on the interviews performed by the company and the comments from previous experiments. These are great guidelines for what the new machine could be. The first requirement is that the machine should only allow perfusion for one kidney at the time. This is related to the ability to move the machine within the hospital, which is also e requirement presented by the company. The current machine is designed for two kidneys due to a previous requirement of transportation and had to provide placement for the two possible donated kidneys from one donor.

Other requirements concern the safety of the users, for example minimizing the risks of users cutting themselves on the machine and as mentioned provide an appropriate working height and comfortable ways of grabbing the machine while moving it. The design must prevent dirt from getting trapped in for example parting lines and allow the user to easily discover and remove dirt according to the cleaning procedures at the hospital.

Time is of the essence and the machine must be designed in a way that allows the user to mount the DKS safe and quickly and is moveable by only one user. This effects the size, which is also limited by the maximum footprint set to 60cm*60cm.

2.1.2.3 The current system

The system used for the process of reconditioning kidneys consists of the OPP, DKS and solutions. A short description of the OPP and DKS at the start of the project can be seen in table 2.1 and figure 2.3. Since the goal for this project is to find a new design for the OPP (i.e. the machine), one might think to exclude the DKS from the thought process, but since the user interacts with both components the design and size of the DKS must be considered when designing the OPP. The design of the DKS is however not within the scope of this project.

Table 2.1 Description of the DKS and OPP

OPP	The OPP consists of a computer, a screen, an external heater cooler unit, an external source of gas, three pumps and a casing to hold it all in place. The OPP allows the user to recondition two kidneys at once.
DKS	The DKS consists of a reservoir for the kidney, filters etc. and tubing connecting everything. The DKS is what connects the kidney to the OPP by connecting the kidney to a cannula and connecting the solutions through a spike line. The DKS is connected to the OPP by placing the tubes in the pumps and connecting gas and sensors.

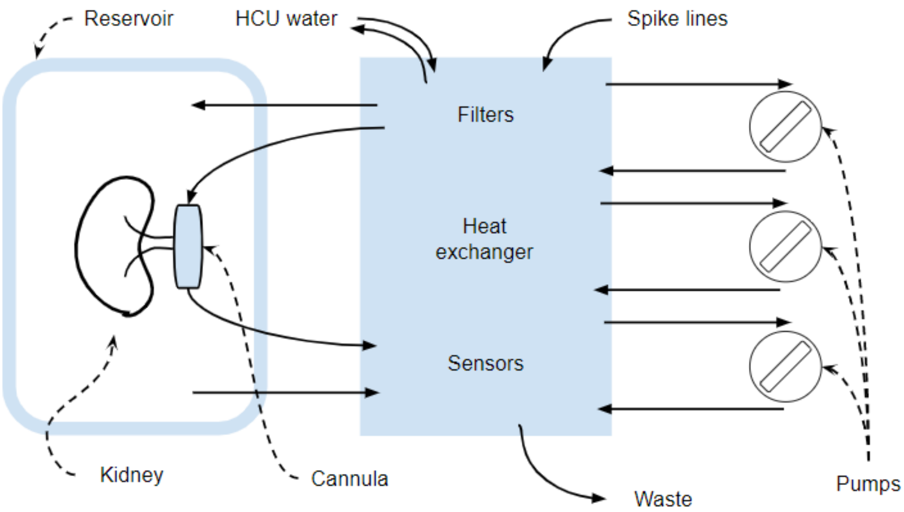

Figure 2.3 Schematic overview of the DKS connecting the kidney and pumps (OPP). Blue represents parts of the DKS and continuous arrows represents connections made by the tubing (also part of DKS). Dotted arrows describe components in the figure.

The user interacts with the DKS when mounting and de-mounting it, when connecting and transplanting the kidney, and when taking samples. In turn, the DKS is connected to the machine through the pumps, sensors, gas and HCU (heater cooler unit). Since the kidney is connected to the DKS, the placement of the DKS is important and will be a part of this project, but the DKS itself is thought of more as a black box, connecting the kidney with the machine.

2.1.3 **Field observations**

This data was gathered when observing an experiment conducted by users from the research team and the company. When observing the experiments, some parts of the process that are crucial yet difficult to perform were noted, such as priming the machine and preparing it for a kidney. The difficulties were mostly associated with handling the DKS, which is a rather complex part. There are many tubes that can be squeezed at this point and the DKS is a large part which sometimes requires more than one user to properly mount. The DKS is lifted above the OPP and lowered into the cavity designed to fit the DKS. When preparing the machine for perfusion, a number of steps must be completed before starting the programs. This was done by the user who was, because of the current design, squatting or sitting on a stool to reach the parts of the machine that were interacted with when performing the different tasks to prepare for the process. Complaints from the user did not concern the position they were in, but the tubes being in the way of each other.

Another thing that was noted was how the users used the top of the machine as a work bench, which in the laboratory environment is ok, but should be avoided unless that is the purpose of this surface. It was also sometimes unclear how much the user should double check the clamps and how they should double check them. Should the user use their understanding of the process to check that everything is in order, or should they follow a protocol? Where could this protocol then be presented, and how short could it be?

The screen was tested using a computer mouse and a number pad and later using a touch screen. When using the mouse and number pad, it was easy to click and the user was provided with feedback through the mechanic design of the buttons. The touch screen provided feedback with sound, which was nice but could maybe get annoying if the user is required to click many times. One big difference was the working height, since both the touch screen and the regular screen was placed at the same height. This forced the user to work in a less comfortable position when using the touch screen since the user had to lift their arms more than usual. However, the screen was not used very frequently, and the user never complained during the tasks entailing interaction with the touch screen.

During other experiments, the touch screen was lowered to allow good working height, which was positively experienced, with the only comment being that the screen was not visible from all sides of the machine. When determining what part of the process the machine was currently in, the user had to look at their own notes, the wall clock, or the values on the screen.

An important part for the clinical trial is taking samples from the DKS to observe and document different concentrations. When taking these samples, the user squatted to reach the tap, which was experienced as a bit uncomfortable. One or two drops were spilled throughout the experiment when tacking samples.

2.1.4 **Stability survey**

An important aspect of communicating reliability and safety to the user is having a stable-looking product. To determine what users could perceive as stable, a survey on stability was sent out. The replicants were asked to select shapes or simple sketches that they thought to be stable and were allowed to leave comments and additional thoughts to not miss any information. Since some replicants could get annoyed or tired while answering a survey, the questions demanding answers in written text were always optional, as were the questions concerning the replicants backgrounds.

The fist questions were about how narrow a block could be before it felt unstable. Many replicants testified to comparing the shape to real-life objects, such as bookcases, vases, and flowerpots.

The results from this survey were that in many cases replicants answered very similar to each other and in other cases they did not. Answers were scattered at the most concerning carts with angles as seen in figure 2.3, but with the cart on the left experienced as most stable by most. Most of the replicants were engineers or engineering students, and a few came from other fields, such as nurses, teachers, and retirees.

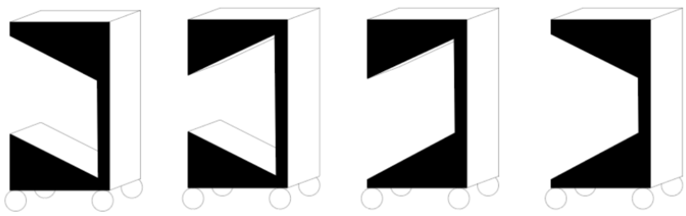

Figure 2.4 Image from the stability survey where people answered more different from each other when ranking the carts from most to least stable.

2.1.5 **Similar machines**

Today there are some organ perfusion machines that can be used for inspiration. Some of them are designed for other organs but have similar components and requirements, for example keeping the organs in a sterile environment, and are great sources of information on how this can be achieved. The investigated machines all seem to be designed for transport and are either equipped with wheels or small enough to carry and place on trolleys found in hospitals. When transporting them the organs are covered with at least two lids, one that is part of the aseptic field and one that is not. Most of the machines are white or partially white with details in grey, blue or with a metallic look.

2.1.5.1 XPS: XVIVO perfusion

The XPS from XVIVO is a perfusion machine for donated lungs (XVIVO, 2022). This machine is one of the larger ones and seem to be permanently mounted on wheels, as seen in figure 2.4. The organ chamber (globe shaped) is placed on one end and the controls on the other. Connecting the two sides is the tubing, pumps etc. that are placed in the open space below the screens in figure 2.4. Everything you need is mounted on this machine, for example the drip stand and gas tube. The tubing is not covered up, which means that the user can always see it. To separate the organ chamber from the rest of the machine and keeping it in a sterile environment, a drape is used for protection.

The machine has two screens, one seen from the side with the organ chamber and one visible from the opposite side. The latter is a touch screen where the user can control the machine.

When transporting the machine the user can grab the handle on the side with the controls, which all seem to be placed close to elbow height.

2.1.5.2 OCS: TransMedics

The Organ Care System (OCS) is a product from TransMedics (TransMedics, n.d.). This machine exists for lungs, heart, and liver, but have the same outer design for every organ (see figure 2.5). The organ is placed in an organ chamber design for the specific organ (lung, heart, or liver) placed in the top right part of the open machine with the screen and controls to the left. When transporting the organ, a lid protects the organ and the rest of the machine. The only thing visible is the screen with the controls. To transport the machine, it is placed on a custom-made cart and rolled away to the next location and lifted off the cart if transported in an ambulance.

The working height of the machine appear lower than the guidelines presented by Arbetsmiljöverket. When transporting it, the machine can be pushed in front of a user or pulled with the use of a handle on the same side as the screen which can be pulled out when needed. The handles on the middle of the machine are used when lifting the product into an ambulance or other vehicle.

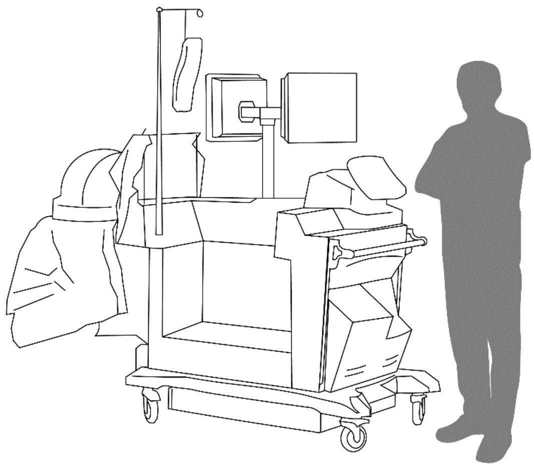

Figure 2.5 Sketch of the lung perfusion machine XPS by XVIVO Perfusion. Silhouette of human for approximate scale.

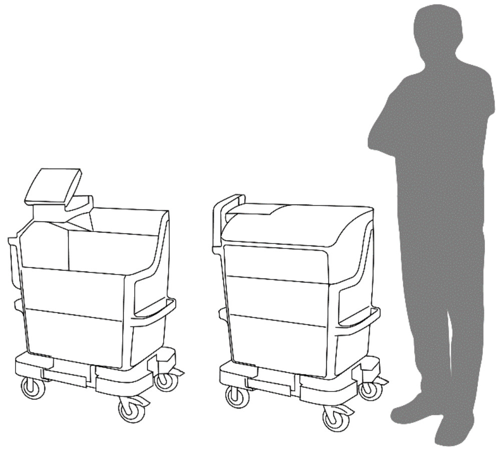

Figure 2.6 Sketch of the OCS from TransMedics. Left: open machine with angled screen, right: closed machine with lowered screen and raised handle. Silhouette of human for approximate scale.

2.1.5.3 OrganOx metra: OrganOx

The OrganOx metra from OrganOx (for liver perfusion) has a similar closed design to the OCS aside from the fact that when using the machine almost all components for perfusion are visible (OrganOx, 2016). The sketches in figure 2.6 shows the machine with and without casing. The organ chamber is placed on the right side of the machine when in use. Since it is transparent and placed on top of the machine, the organ is visible from the side as well as the top when the casing is off.

When transporting it the machine is covered with a casing with a window for the screen and placed on a cart, as seen in figure 2.6. It has handles for lifting it up onto a bench or placing it in an ambulance. It also differs from the OCS since the machine has wheels attached to the bottom, though they are smaller than the ones on the cart. The machine is fastened to the cart using some sort of clips.

2.1.5.4 Lifeport Kidney Transporter: Organ Recovery Systems

The Lifeport Kidney Transporter has a similar design to the machine at the beginning of the project with the organ chamber lowered into the top surface of the machine but differs a lot in size and in complexity regarding perfusion process (Organ Recovery Systems, 2022). This product can be carried or rolled on a cart, it has a simple design and limited controls suggesting an automated or much simpler process. The outer design is soft, with sounded corners and a matte surface, see figure 2.7. One side of the machine houses the pump and other moving parts, whereas the other side houses the organ chamber and a box for ice used to cool the kidney.

When using the machine, it is prepared by one person while another prepares the kidney. The organ chamber has two lids, one completely sterile and one that is sterile on the inside but not the outside. When mounting the inner lid, the entire machine aside from the organ chamber is covered with a transparent sterile drape which also allows the user within the aseptic field to use the controls. The drape is removed after the inner lid is mounted. The lid covering the machine when transporting the machine is opened using two handles that are turned 90˚ and grabbed to lift the lid off the machine.

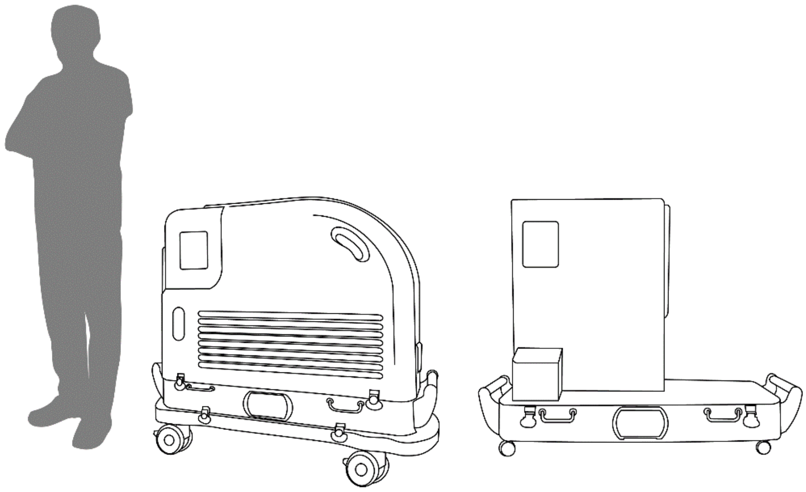

Figure 2.7 Sketch of the OrganOx metra with human for approximate scale. Left: machine with protective casing placed on cart, visible screen in top left corner, right: machine without casing.

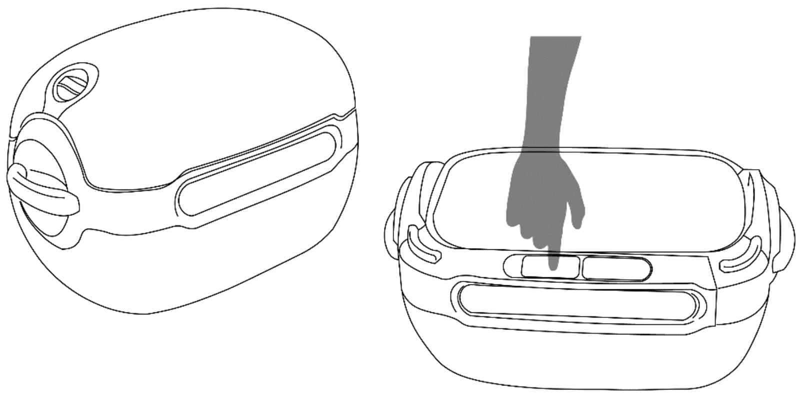

Figure 2.8 Sketch of the Lifeport Kidney Transporter with a hand for approximate scale. Left: machine ready for transportation, right: machine without outer lid with controls visible.

2.2 Data analysis

2.2.1 **User data**

When looking at the flow chart describing the usage of the machine, the most frequently performed activity is the transportation of the machine between different rooms. This means that the transportation must be an easy process for the users, with very little preparation required, for example covering the reservoir. The transportation itself must be a task that anyone of the users can perform without help from an additional user since the transportation is done by the user who performed the task prior to the transportation.

The errors that occurred during the experiments are good indicators on where changes must be made. For example, when a user performs a task in an incorrect manner, the new design should restrict the user in such a way that they perform the task the way the designer intended. This can also be done by communicating the possible risks of performing the tasks incorrect.

2.2.1.1 User requirements

The first requirement is having only one kidney in the machine, which will minimize the risk of the user being distracted from their tasks and can prevent errors such as forgetting to open clamps since there will only be one side to prime. It will also affect the size and allow the machine to fit a smaller size.

The machine shall only be moved but only indoors at the hospital. This effects the choice of transportation method and allows the design to be adapted for indoor transportation. Requirements of protecting the machine and kidney from weather are therefore not necessary and only concern the transportation of the finished machine to the hospital.

The requirement concerning the footprint is based on the room in which the machine will be stored at the hospital during the clinical trial and the space they have left for it. There are many things that effect the possibilities to meet this requirement, for example the weight of the machine. When comparing this requirement to that of allowing appropriate working height, it seems that the machine must be relatively tall, or weigh less so that it can be designed very small and carried. This will create some difficulty when designing the machine and finding a design that is, looks and feels stable.

When it comes to designing the machine in a way that enables the user to find dirt, prevents dirt from getting trapped in parting lines and allows the cleaning procedures commonly used at the hospital, the surfaces of the machine are in focus. It is unlikely that parting lines can be designed in a way that ensures no dirt gets trapped, but it should be a factor when making design choices, and the choices should be made in a way that prevents dirt from getting trapped. Avoiding parting lines as a feature all together could be a way to prevent dirt from getting trapped in them. The placement of the possible and unavoidable parting lines is also something that affects the probability of dirt getting trapped in them. If the design should make it easy for the user to discover dirt, it could be a good idea not to have hidden surfaces, so the user does not have to look in too many places, or to make the possible dirty places visible from as many angles as possible.

To allow easy mounting and connecting of the DKS, not only the connections themselves should be easy to use and few enough, but how the user can reach them and from what angles the user can reach them are important. Five minutes is a generous amount of time, and it should not take this long, but as previously stated, the connections that are supposed to be made factor into the amount of time needed. The design of the machine should not add more time to this task than already needed for connecting the connections.

The machine must prevent damage on the kidney, but it must also prevent harm being inflicted on those in direct contact with the machine, i.e., the users. Therefore, there is a requirement stating that the surfaces shall be designed in such a way that no user can cut themselves and one regarding the maximum noise level. The noise level can be reduced by designing the casing in a way that directs emanated noises away from the user, or by muffling the noise with other components or softer materials. This is important since the machine should not create noises that can annoy or tire the user, aside from alarms notifying the user of actions that need to be taken or warnings.

2.2.2 **Field observations**

The observations gave greater understanding of the process and how the user must perform some of the tasks. When participating and not only observing the issues found were mostly related to the screen and user interface. The main issue was the risk of clicking the wrong thing due to the controls being placed too close to each other or being too small. This indicates the need for a new and more user centred design of the graphical user interface (GUI) or a larger screen. The design of the GUI is not part of the project and is not further investigated.

The wish to have the screen visible from more angles was viewed as important, since it is useful for the user to see some of the values there when looking at the kidney. It is also possible that instructions could be shown on the screen, and the user would then need to see them when for example mounting the DKS. It is arguable that the way of the determining the current part of the process by checking notes and the clock is sufficient, but it could be valuable to have a quicker way for the user to find out how much time remains till the next step. This will be even more important when introducing different users to different parts of the process.

When taking samples from the machine, there is a risk of spilling a few drops, and this risk will most likely not be possible to eliminate unless the samples are taken automatically. The negative consequences can however be minimized by ensuring that the drops do not cause damage to the user or the machine. The working height when taking samples and mounting the DKS could also be improved to make the users as comfortable as possible.

2.2.3 **Similar machines**

2.2.3.1 Open machines

The investigated machines are all "naked" at some point, where the tubing, fluids and the organs are visible. This is necessary when the machine is prepped for perfusion, but it might not always be necessary, for example when transporting the machine. The only machine without a cover is the XPS from XVIVO, which could be because of the size of it, since it is larger than the others. But what effect does moving parts have on the safety of the organ? How can the process be affected by vibrations when the parts are not fixed in one place or by having the tubes out in the open? This machine could perhaps not be placed anywhere in the hospital.

2.2.3.2 Transportation

Both the machine from TransMedics and OrganOx are lifted onto surfaces such as working benches or ambulances for transportation, and the size of them would require at least two users to lift them. What happens if these users are not matched in height or strength? Can the machines handle tilting, and if so, how much? The answer to this was not found, but there must be some tilting allowed since the machine is quite large and lifted by two users.

The removable cart for the machine from TransMedics appear to be a very good solution which allows the machine to be transported in a safe way on ground and stand stable in an ambulance. However, this cart must be brought in the ambulance, or the destination must provide a cart when the machine arrives.

2.2.3.3 Screens

Some machines have touch screens, which many people prefer since it is a space saver. Essentially the only thing you need is a screen, and the interface can be very similar to interfaces using computer mouses and keyboards, with the added need of larger buttons and some limitations regarding manual inputs since the keyboard would cover a large portion of the screen. Another issue with touch screens is if you want the screen to be seen during transport but eliminate the risk of someone accidentally touching the controls, there must be some sort of cover. The machine from OrganOx has such a cover, by letting the outer lid cover the screen, but showing it through a window. This is a very physical cover, but the cover could also be locking the screen, which instead could result in the user forgetting to unlock the screen again and getting frustrated when it “does not work”.

The XPS from XVIVO Perfusion have two screens, where the one visible from the sterile side, the side with the organ camber, is simply for viewing and not a touch screen, which could be a way of minimizing the risk of the user within the aseptic field using this screen in a non-desirable way and limiting the controls to the user on the opposite side. It could also be a way of reducing costs, since the user on the sterile side is only supposed to view the screen, and a touch screen could result in higher costs in procurement and maintenance.

The Lifeport does not have a touch screen, instead it has small displays with buttons on the side of them where you can enter data and start programs. Here, the buttons and half of the displays are covered with the outer lid, leaving only displays showing information about the process and organ visible. This also reduces the risk of someone accidentally changing values or starting the wrong program.

2.2.3.4 Beauty over function

The Lifeport has a very neat design with a matte finish and less details. Perhaps it is the size of it that make it feel as well-developed product. The clean and symmetric exterior might also contribute to this emotion. However, the Lifeport is not perfect. The handles used to open the lid are small and can be misinterpreted as only a locking mechanism and not handles. Since the lid is almost completely symmetric, it is possible for the user to place it with the wrong orientation when closing it. The only detail showing the correct orientation of the lid is a small countersink on the edge of one side, allowing the user to view the displays even with the lid closed.

2.2.3.5 Wheels

The wheels of the machines are the ones determining the footprint in most cases. This is most likely to achieve a stable product. When looking at other machines or carts within the medical field, many of the ones with wheels have wheels that result in a larger footprint than if there were no wheels at all. How many of these designs require this placement of the wheels, and are there some that are designed this way to follow the convention? These questions led to an added part to the stability survey where the person answering should rank different placements of wheels as more or less stable.

2.2.4 **Perceived stability**

Based on the responds to the survey, it was clear that people have similar views on the stability of objects. The only questions where people agreed less were those where the shape got more complicated, as seen in figure 2.3 and where the placement of wheels was discussed using the images in figure 2.8. Since the footprint and the height remained the same, the cart in the middle was perceived as most stable, and not the one to the right. The similarity in the responses indicated that people often have the same experience and that their sense of stability is good.

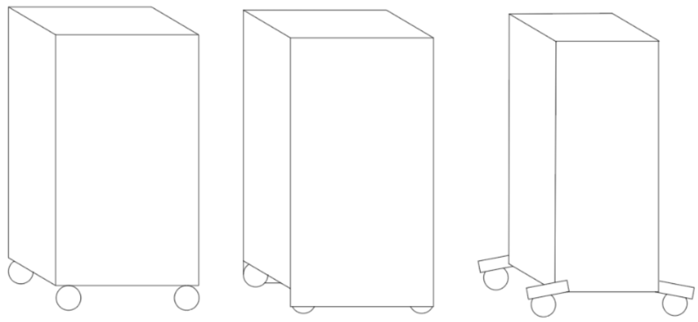

Figure 2.9 Image from the survey where the placement of wheels (without changing the footprint) was the difference.

2.3 Metaphor

To better understand the machine and the process, a coffee machine was used as metaphor. The components of the perfusion system were categorized to fit the part of a coffee machine, such as the coffee, the filter, filter holder, pot, water, power button, and the pipe guiding the water. One of the difficulties with this metaphor was that the finished coffee does not represent the goal of the process, instead the used coffee grounds are the goal and represent a kidney ready for transplantation.

Table 2.2 Components in the metaphor translated to the machine.

Coffee machine	Perfusion system
Coffee grounds	Kidney
Filter	Reservoir (DKS)
Filter holder	Holder for the reservoir
Coffee pot	Waste bag (DKS)
Coffee	Waste
Water	Solutions, blood, gas
Power button	Keyboard/controls
Water pipe	Tubing (DKS)
Heater	Pumps, HCU

Prior to this exercise, the waste had not been considered when sketching, and the sole result from the process was seen as the kidney. The waste (fluids) is pumped out of the reservoir and collected in a bag. This bag is then disposed as biohazardous waste. Here, other ways to remove waste from machines can be used as inspiration, since the bag would most likely have to be placed low and there could be a risk of puncturing it. One example of other ways of removing waste is collecting the waste in a bin or compartment and emptying it when the machine is cleaned.

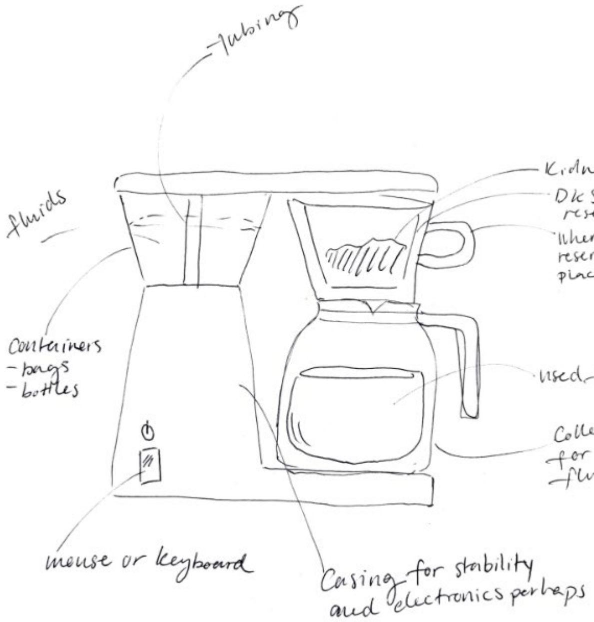

Figure 2.10 Sketch of the metaphor used to understand the components better.

2.4 Identifying needs

To identify the needs for the machine, the goal of the machine is a good starting point. The goal is to deliver more kidneys for transplantation, and the machine should achieve this goal, which led to the need of delivering kidneys. Within "delivering kidneys" the needs to reset kidney function and transport the kidney can be found. To better understand the needs of the user, data from interviews with the user provided by UGLK Science AB was analysed as well as given needs and requirements. The experiences from the field observations were also used as inspiration when identifying the needs.

Some of the generated needs are presented in table 2.4.1 and the remaining in appendix D. The needs presented here are the ones that had the most influence on the ideation and were used as inspiration and tests during the ideation phase.

Table 2.3 Selected needs

Statement	***Need***	**Need no.**
The goal is to transplant more kidneys.	*The product should not discourage the user from using it.*	**4**
The machine is moved between different rooms	*The machine should allow indoor transportation*	**6**
Transportation	*The product should be transportable.*	**8**
	The machine should be moveable by one user.	**9**
The design must prevent the machine from tipping or falling over.	*The product should be stable.*	**10**
The user should not be discouraged from using the machine.	*The machine should communicate usability to the user.*	**11**
It should be comfortable to grab and move the machine.	*The machine should be ergonomic.*	**13**
It can be difficult to use the touch screen with the drape.	*The machine should provide controls that are easy to use with a drape.*	**16**
It is difficult to connect the DKS.	*The machine should allow the user to mount the DKS in an easy way.*	**17**
The machine is placed in the corridor during the perfusion process.	*The machine should be easy to place in a corridor.*	**18**
The maximum footprint for storage is 60 cm * 60 cm.	*The machine should be possible to store.*	**24**

3 Ideation

In this chapter the ideation and design concepts are presented. The tests of the different concepts as well as the last steps towards the final design are also described.

3.1 Sketching

The ideation phase started early in the project and part of it was used to better understand the limitations and possibilities of how this machine could be designed. This resulted in new questions, but also resulted in many early sketches and ideas being obsolete since they did not fit the user requirements set later in the process, for example the requirement concerning desired footprint.

Questions that arose when sketching had a lot to do with where the users would like to be in relation to each other and where they are limited because of the design. One important question was how the location of the reservoir in relation to the pumps and controls effects the safety. This was not a new question per se, but when investigating different placements, the reality of this issue was realized. There are many things that effect the possibilities, such as how much space is needed for the tubing, pumps, cooling system etc. The tubing could maybe be organized in a way that would make it easier for the user to see which tube goes where. Another factor when deciding on how close the components can be was when the user needs to be able to reach the different parts. This was clarified by the flow chart of the machine in figures 2.1 and 2.2, but what if something unexpected happens that changes the areas with which the user needs to interact? Here, the risk analysis was used for finding the possible situations where error could occur, and the control measures taken to assure that they do not occur.

It is also important that the working height is appropriate for all users, and if the heights are non-adjustable, it creates quite the puzzle. Many early sketches resulted in designs that are based on placing components lengthwise with the reservoir on one end and the controls on the other with the pumps and tubing in-between, which at the start of the project seemed to take up a lot of space. This changed as changes to the DKS was made by the company.

3.2 Separating the sterile and non-sterile area

An important part of the machine should be to separate the sterile are from the non-sterile area. There are many ways of separating two parts of a product, but first, they must be defined. The sterile part of the machine is the inside of the DKS, which means that it can be separated from the rest of the machine using a lid. Separating can mean more than just creating a barrier. It could mean separating the different tasks physically by placing the control station with a distance to the reservoir.

One way of creating physical distance between the two areas commonly used in products today is the sterile drape. This creates a larger aseptic field by being placed in a way that covers the parts of the machine that originally was not part of the aseptic field. Other solutions seen in the similar machines are the lids covering the organ chamber or reservoir and the long distances between organ chamber and controls seen in the XPS (figure 2.4).

More things that could be done to separate the two parts are placing them at different heights, which seem to be the case in the OganOx metra, but it seems odd to place the controls higher than the organ chamber since it must be less ideal to work above the organ in terms of contamination risks.

3.3 Concepts

Here some of the developed concepts are described. Some concepts are developed for specific parts of the machine or process, and do not entail details of the entire machine. Other concepts are developed to describe the machine more as a whole and not detailed.

3.3.1 **Concept 1**

This concept was developed after the experiments and with some of the generated needs in mind. One of the main things in focus when designing this concept was the need for a stable product and how a product can communicate stability to a user. A product in another field that must communicate stability was used as inspiration: the stroller. This product also fills the need for transportation. One factor regarding the stroller communicating stability could come from convention and the way people or users imagine a stroller would look like. The other factor is that parents will not buy the stroller if the stroller looks unstable, and if the machine reminds users of a stroller, they might either immediately assume that it is stable or demand more stability than if it did not remind them of a stroller. Another need used when generating this concept was the need of storability, where the holder for the reservoir is hinged to make the machine take up less space when stored but allow the DKS to take up a more space.

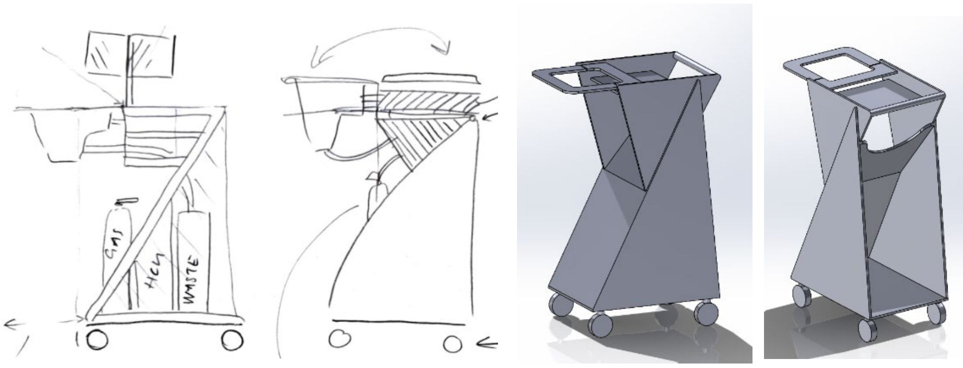

Figure 3.1 Sketches on paper and in Solidworks of concept 1.

3.3.2 **Concept 2**

This is a partial concept developed with the activity “mount DKS” in mind. When mounting the DKS, the user must lift the DKS above the machine and fit it in the cavity created for it. If the machine is designed with a working height of around 1 meter, the DKS must be lifted high, and the user’s sight might be blocked by it making it difficult to fit it in the cavity. This led to the idea of designing one side of the machine with a lowered part, which would allow the user to move the DKS into position from one direction without lifting so high. The part on the left in figure 3.2 is 3D-printed or injection moulded to make it easy for the user to clean it by wiping it off. To avoid dirt getting stuck in the parting line between this plastic part and the rest of the machine, the edge is designed with a distance to the “main body” to make sure no fluids can run in the parting line and get stuck. The plastic part is also equipped with tracks to make sure the tubes are mounted correctly.

The concept was combined with the idea of placing the screen close to the reservoir, to make the user look there more often (see figure 3.2). The concept is developed with only the upper part of the machine in mind, which in this case is 3D-printed or injection moulded. Here, handles are added on the side of the machine to nudge the user to use both hands when transporting the machine.

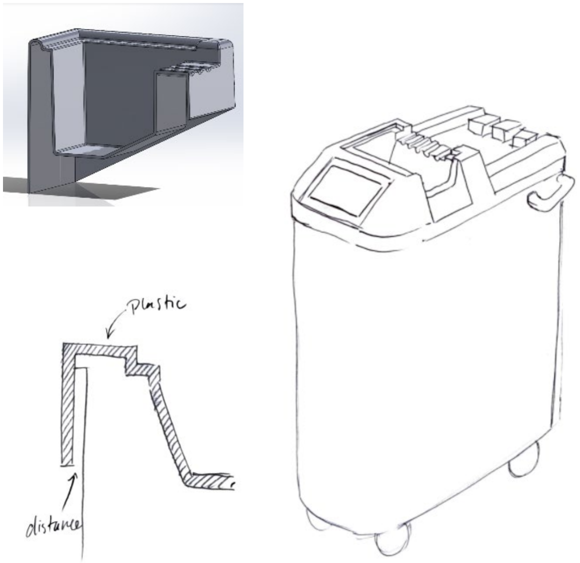

Figure 3.2 Sketches on paper and in Solidworks of concept 2.

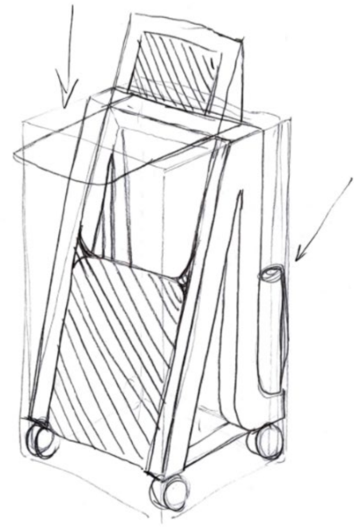

Figure 3.3 Sketch of concept 3.

3.3.3 **Concept 3**

The goal with this project is reducing the number of surfaces that might be used for offloading to zero. Therefore, the machine is designed with the front tilted and the holder for the DKS is folded up when in use. The screen is placed at the top of the machine. Essentially the concept consists of two A-shaped sides with hatches covering the inside of the machine.

3.3.4 **Concept 4**

This concept was inspired by the answers to the stability survey. The question with different carts in figure 2.3 that included more than perpendicular lines was the question with the most scattered answers. However, the first cart, shown in figure 3.4, was perceived as most stable and was used as inspiration. The handles are in this concept placed on the sides of the machine, but at the top, by letting the edge be the handles. To allow the user to walk closer to the machine there is space between the wheels that prevents the user from hitting their feet on the machine while walking.

Figure 3.4 Sketches and model of concept 4.

Figure 3.5 Sketch models of concept 5.

3.3.5 **Concept 5**

When developing this concept, the fact that the machine will stand still most of the time was used as starting point. The machine should then be designed in a way that allows the user to easily place the machine parallel and close to a wall. This led to the handles being placed in a way that would force the user to push it while standing on the long side of the machine. The display is then placed on the side facing out so it would be visible for people passing by. One of the models convex on the side with the screen, which is another way to tell the user which side should be facing the wall and which side should be facing out.

3.3.6 **Concept 6**

This concept focuses solely on the handles to the machine. To allow the user to move the machine standing in different positions could be positive in the sense of letting the user use different grips and perhaps make it easier to turn and place the machine where it should be placed. The handle can be reached on both the short and the long side of the machine, allowing the user to move the machine in more directions than straight ahead.

Figure 3.6 Models of concept 6.

3.3.7 **Placement of components**

To test different ways of placing the components that could be placed on the top on the machine, a sketch model of the top in 1:1 scale was created. Foam was added on the sides to test handles in a certain direction and to soften the corners of the cardboard to make it feel more real.

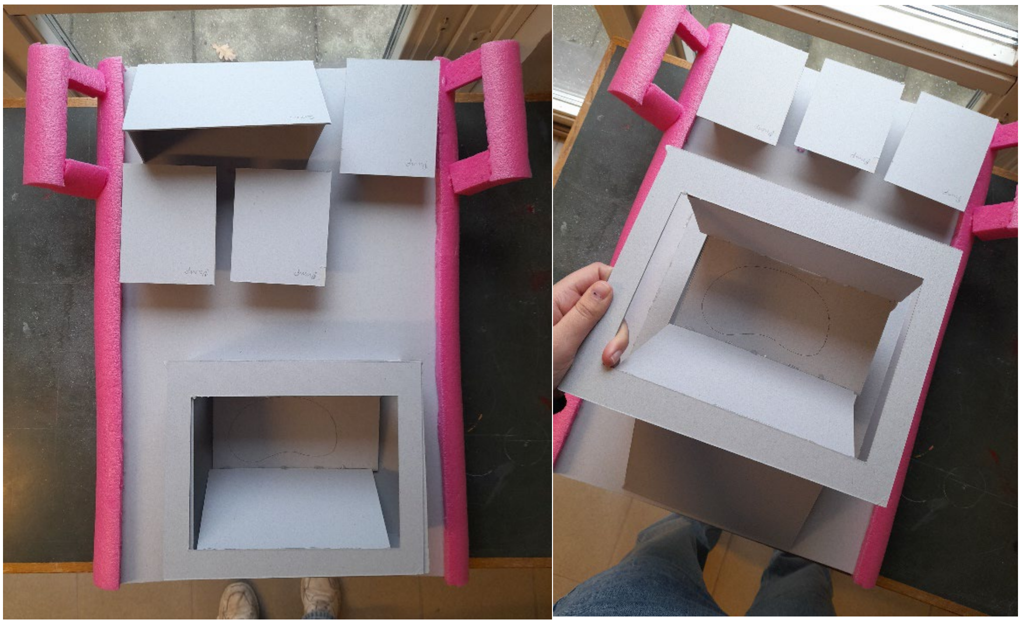

Figure 3.7 Pictures of the model used to investigate different placements of components.

3.3.8 **Concept discussions**

When discussing the concepts with the company it was noted that the direction of the machine is more important than what was previously assumed. If the machine is longer than wider, it feels wrong to push it on the long side, since it feels like it might tip over, even if it will not. Softer shapes were positively perceived, but if the machine was more streamlined it was experienced as something that is moved fast, which might not be suitable. The possibility of moving or adjusting the position with only one hand was something that could be a necessity for the user. This created requirements on how the handles can and should be placed, for example could two handles on the side be difficult to control with one hand. There was also a discussion concerning the different positions from which the user could reach the kidney. When connecting the kidney there are two users performing the task, and they must both have visible access of the kidney.

The placement of the screen was also discussed since it should be visible for the users when priming the machine, when connecting the kidney and when passing the machine while it is placed in the corridor. Having a screen that can be flipped was discussed as a possible solution but should be avoided as it could complicate the machine and would result in moving parts, which is less desirable. The screen should also be placed further from the reservoir to make separating the sterile and non-sterile area easier. Since the interaction with the screen could be reduced to viewing, a higher placement could be more suitable. The screen could also be placed below the top surface if the number of times the user must touch the screen are few.

The rounded shape on the reservoir side in concept 6 was experienced as nice but could create issues when fitting the electronics in the machine, since they are not adapted to this shape. A round shape would create space that is not used, and to take up more space than necessary might be a not so good idea, since there is limited space at the hospital. However, this shape results in less surface area on top and could make it easier to manoeuvre the machine around corners at through doorways. It could be more important to have a machine that looks nice that one that uses space in the most efficient way, since a nice-looking machine might make users more eager to use it and feel safe when using it.

3.3.9 **Specifications**

To move forward with the ideation, specifications were set. These specifications were set based on needs and comments from the company and can be seen in table 3.1. The goal was to limit the next part of the ideation and to have some decisions made.

These specifications were used when developing the final concept, deciding on features the machine should have, and for testing the previous concepts to find parts that could or could not be used in the final concept. They were also used as guides when using the method SCAMPER on the old concept to find new solutions that could incorporate the wanted functions and meet the specifications. The controls for the machine can be either a touch screen or a display and buttons, but not a keyboard and computer mouse.

Table 3.1 Specifications

Need no./task	*Specification*	*Unit*	*Value*	*Spec no.*
4	Room for one DKS			1
1	Separate sterile and non-sterile area.			2
13	Center of reservoir is placed at good working height.	cm above floor	80 - 100	3
9, 13, 18	Handles allow different grip positions.	amount	> 2	4
13	Screen placed at good working height.	cm above floor	80 - 130	5
Connecting the kidney	Positions from which the reservoir is reached simultaneously.	amount	> 2	6
10, 18, 24, direction of machine	Footprint	cm^2	< 60 x 60	7
17	Time to mount DKS	minutes	< 5	8

3.3 Generating the final concept

When generating new concepts, some of the features from the old concepts were included, such as room for your feet and the lowered part of the machine to allow the user to mount the DKS faster. Then new concepts were sketched and evaluated using the method SCAMPER. Sketches from this phase can be seen in figure 3.8. To limit the design choices, new requirements were set for the final concept.

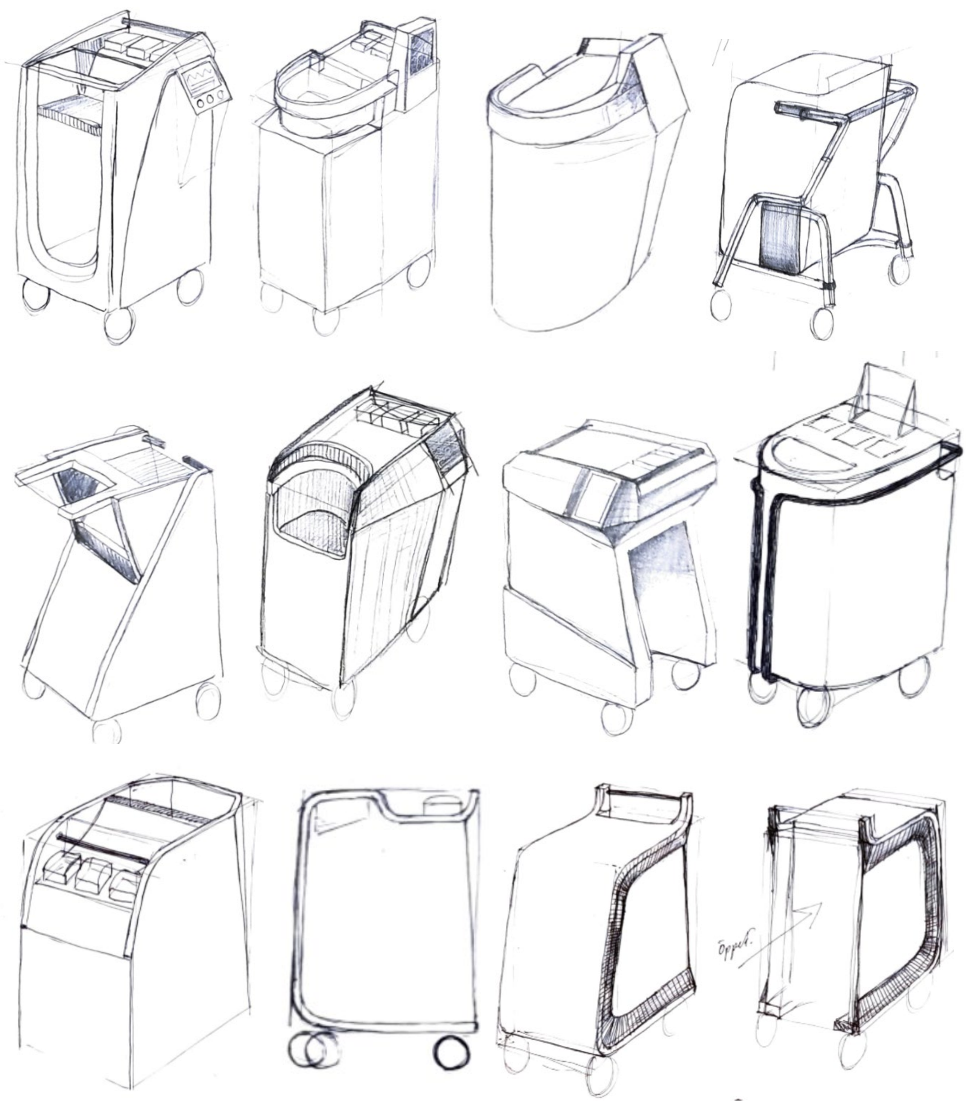

Figure 3.8 Sketches from when the method SCAMPER was used.

3.3.10 **Defining the focus of the final design**

There are parts of the machine that remain undefined, such as the back and the top of the machine since the design of the DKS remains undefined. The final concept only includes the casing and the placement of parts the user will interact with. The back of the machine is left undecided due to lack of time for the project and limited information on what the casing of the machine should entail. Precise placements of the waste bag, gas tube, power cord and sample taking were not defined, but the waste bag and gas tube could be placed and accessed through the back of the machine. The sample taking is defined by the DKS, which is out of the scope for this project.

3.3.10.1 Silhouette

During the final stages of design, it was decided to not have anything placed at a height above the reservoir. This was to limit the choices due to lack of time, and to ensure stability. Features such as integrated drip stand seen on some of the sketches in figure 3.9 and a high screen were therefore not considered further.

After imagining the machine in real size, it was decided to keep the different sides of the machine very simple. A mood board was created to have some idea of the overall look of the machine. Bright, soft colours, straight lines and rounded edges were features that were included in the final design.

3.3.10.2 Placement of the screen and controls

The screen should be visible during many of the phases and be easy to access during them. Therefore, placing it on the side of the machine could be a good idea. If you pass it in the corridor, it would be visible, if you stand on the same side when connecting the kidney or priming, it would be visible. For the final stages of concept generation, the screen is a touch screen.

3.3.10.3 Placement of the handle

To avoid having handles and screens blocking the user's view of the DKS and pumps, they were not placed on the same side. If the machine could have been larger, then it might have been possible to have them placed on the same side. Since the screen is placed on the side of the machine the handles should be placed on the back of the machine.

Table 3.2 Decisions made for the final concept

The screen	*The screen should be placed on the side of the machine.*
The screen	*The screen is a touch screen with a hinge.*
The pumps	*The pumps are assumed to be placed at working height.*
Drip stand	*No integrated drip stand.*
Shape	*The shape should be simple with rounded features.*
The handle	*The handle should be placed on the back of the machine.*

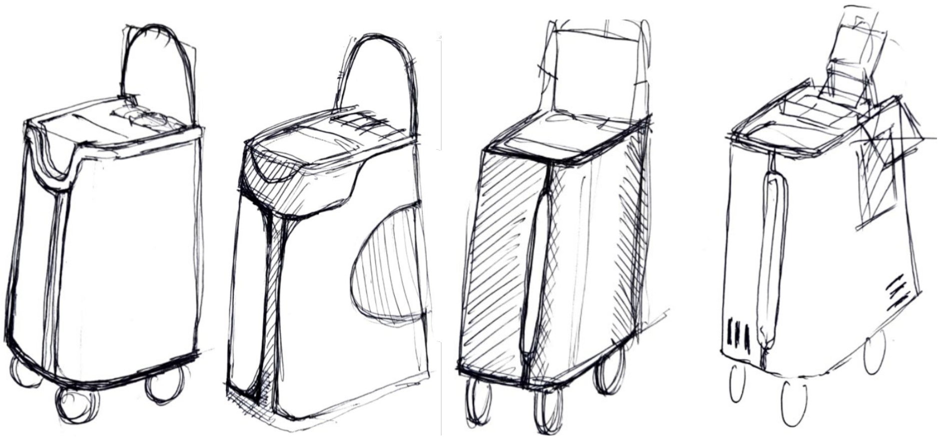

Figure 3.9 Sketches from finding the final concept. The drip stands on the sketches were removed according to the specifications for the final concept.

4 The new OPP

In this chapter, the final design of the machine and the decisions made are presented. The concept entails the exterior of the machine and placements of some components.

4.1 The final concept

The final design of the machine consists of a case made of bent sheet metal connected using a plastic strip with a LED-strip, a plastic edge on top with a pocket for the screen, a touch screen that can be flipped to face the machine, four wheels, second bent sheet of metal closing the machine. There is a small draft angle to the machine making the bottom slightly larger than the top and a straight handle placed on the back of the machine connecting the two outer pieces of sheet metal. The machine is painted white with plastic details in grey.

The outer metal sheets connected with the LED-strip and the inner metal sheet is connected similar to a tennis ball, where two equal surfaces are connected at the edges. Visualizations of the final concepts can be seen in figures 4.1-4.5 and in appendix C.

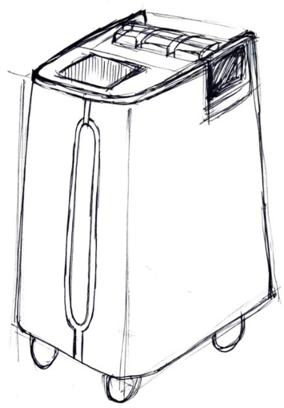

Figure 4.1 Sketch of the final concept.

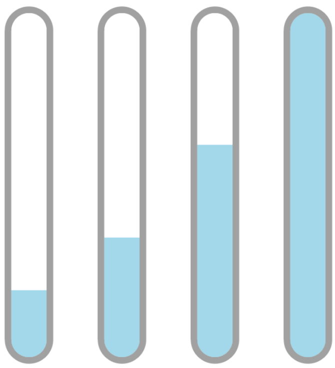

Figure 4.2 Sketch of how the LED strip would light up as the started process proceeds. Blue symbolizes light.

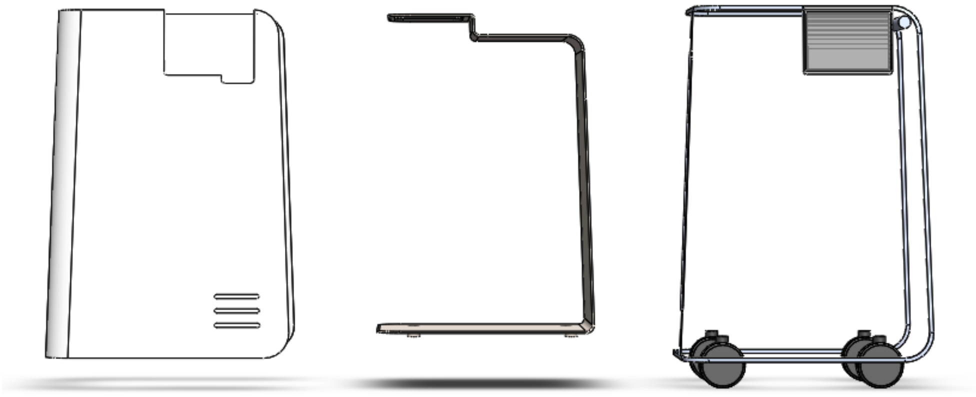

Figure 4.3 CAD of the final concept. Left: Outer metal sheet. Middle: Inner metal sheet. Right: Edge, LED strip, screen, handle and wheels.

Figure 4.4 & 4.5 Renderings of the final concept. Left: Screen aligned with the angle of the machine. Right: Screen placed with an angle of 30° to the side of the machine.

4.1.1 **Details**

4.1.1.1 Screen

The screen is placed on one of the longer sides of the machine where the metal sheet has a cut out and the plastic part creates a pocket for it. It can be flipped and viewed from the opposite side of the machine which is where one of the users might stand when connecting the kidney to the DKS. Placing the screen on a pole could have simplified the design in a way, but it was deemed more important to keep the machine as low as possible.

4.1.1.2 Pumps

The pumps are placed at working height on the same side as the handle. This allows the user to place the tubes in the pumps standing in a comfortable position, and not squatting or leaning too much.

4.1.1.3 Handle

The handle is placed on the back of the machine to allow the user to push the machine in front of them, similar to a shopping cart. A one-hand grip is possible when moving the machine.

4.1.1.4 The back of the machine

The back of the machine remains undefined due to lack of time. It could be a desired feature to leave it open since it would allow the user to access parts of the machine that could be placed there, for example the gas tube, waste bag or HCU.

4.1.1.5 The edge

The machine has an edge that follows edge of the outer metal sheet. This edge gives the machine a more finished look and enhances the feeling of the two surfaces (outer and inner sheet) meeting. To not cut this edge too much, the top part of the screen, when facing out from the machine, has the same shape as the edge.

4.1.1.6 The fan

The machine will need fans to cool down the electronics on the inside. To avoid the cut outs for the air flow disturbing the overall look of the machine, the cut outs are designed to mirror the shape of the LED-strip.

4.1.1.7 Gas

One task the user must perform at some stage is changing the gas tube. This is why the gas tube should be easy to access as in the final concept: through the back of the machine. Here it is difficult to avoid having the user bend or squat, which according to Arbetsmiljöverket is acceptable for tasks rarely performed (Arbetsmiljöverket, 2021).

4.1.2 **The personality of the machine**

The machine should feel safe, that was very important since the users should feel comfortable using it and trust it to work as it should. But are there other feelings the machine should communicate? To make the machine feel kind, and nice, many rounded features were included. The colours are soft and inspired by those used on the Lifeport, since the exterior of this machine was experienced as nice.

4.1.2.1 Stability

To communicate stability to the user, the small draft angle was added to the sides of the machine. The wheels are also slightly covered by the sides of the machine to enhance the angle and to make the machine feel less wobbly. One important design feature of the machine that makes it feel more stable is that there are no parts making it taller than working height (except for when the screen is flipped).

4.1.2.2 Trust

The simplicity in the design is a way to communicate trust, since a simple and clean exterior can communicate confidence and in turn trust. The DKS is visible, which lets the user see what happens in the machine and the organ. This can make the user feel trust since the user does not feel that things happen without their knowledge. The LED-strip can communicate trust in a way if the user is aware that it exists and that it displays how far into the current phase the machine is. Then the user will trust the machine to communicate this to them, and not feel insecure on when it is time for the next phase.

4.2 The prototype

To better illustrate the LED-strip and the shape of the machine a prototype was constructed in scale 1:5 (length). The prototype was 3D-printed using white PLA filament and the LED-strip was constructed using twelve 3 mm LEDs, resistances, wires, and an Arduino Nano. The finished prototype can be seen in figure

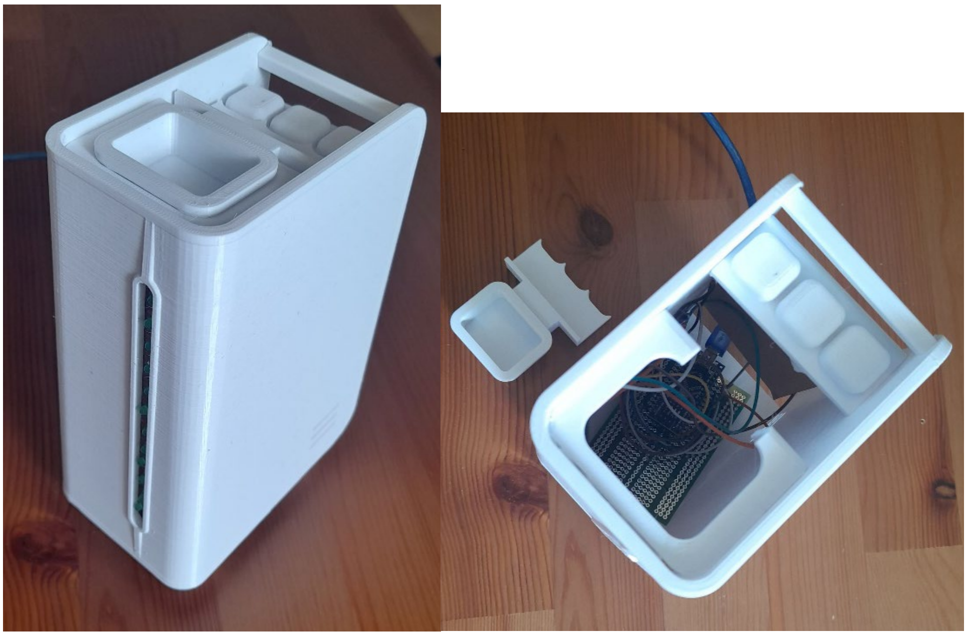

Figure 4.6 & 4.7 The 3D-printed prototype.

Figure 4.8 & 4.9 The prototype with the LED-strip lit, illustrating time passed.

4.3 Why this final concept?

4.3.1 **Determining the working heights**

To design the machine with appropriate working heights you must first determine the parts of the machine that should be adapted to this height. As stated in 2.1.3 the user did not complain about the working height when interacting with the DKS, but if they were to perform this task very often, they might get uncomfortable. The placement of the tubing should therefore be somewhat adapted to this height, which is set by Arbetsmiljöverket to around 1 meter (Arbetsmiljöverket, 2021). However, the requirement of allowing good working height when connecting the kidney should be more prioritized, since the task demands more precision from the user. The main part determining the height is then the reservoir where the kidney is connected, or more specifically the bottom of the inside of the reservoir, since this is what determines the height at which the kidney is placed.

4.3.2 **Placement of the reservoir**

Where on the machine the organ chamber should be was first only thought of as an issue concerning sterility, keeping the kidney safe from infection risks, but later the extent of how this effected the machine was realised. Not only does it affect the safety of the kidney, but it effects the user's working height and where the other components should be placed, since many of them should also be placed where the user could access them easily.

Placing the reservoir near an edge might seem less safe, since the kidney would then be closer to non-sterile surfaces but might be safer since the user will be able to stand closer to the reservoir and have better reach when connecting the kidney.

4.3.3 **Controls**

The machine was first controlled with a mouse and number pad as described under but later with a touch screen. Having a touch screen reduces the number of components but is something that should be adapted to achieve a good working height. The downside of having a touch screen is the ability to use it with aseptic technique. When the sterile field is open, the screen should be covered to allow a sterile user to use it. This cover, especially in combination with gloves, can affect the ease of use by affecting the sensitivity of the screen.

4.3.3.1 Placement of touch screen

One very important, and difficult decision was where to place the screen and the controls. Assuming the screen is a touch screen, it should be placed in an angle at good working height to allow the user to view and click the screen as comfortable as possible. If the machine is in the shape of a cuboid there are four sides on which the screen could be placed (see figure 4.10) to allow good working height.

Placing the screen on side IIII in figure 4.10 would be placing it close to the reservoir, which is both positive and negative, but mostly negative. It would allow the user to easily check the screen and kidney simultaneously but would create an unwanted distance between the edge and the reservoir that could make it more difficult to connect the kidney and could result in the user accidentally clicking the screen with their body.

If the screen is placed on one of the longer sides, I or III, the machine would be asymmetrical unless there is one screen on each side. Assuming there is only one screen, it would be easy to glance at when the machine is placed against a wall. If placed on one of these sides, the screen could be placed closer to the side with pumps (and most likely handles) which would allow users to reach the kidney from the same side as which the screen is placed without it being in the way or without the risk of a user accidentally clicking the screen with their body. There are however more issues with having the screen on the side, for example how to keep the user aware of the screen while moving the machine. If the user is unaware of the screen, they might accidentally hit a wall with it. To avoid this, the screen could be an adjustable screen which folds into the side creating a symmetrical look. The remaining issue is how to view the screen from the opposite side. If the screen can be flipped manually the user could view it from the opposite side and the short sides, but not from the side where it is placed. To allow this, the screen would have to be two screens viewable from both the side where it is placed and the opposite side where another user might stand.

The side remaining, II, is where the handle should be placed. If the screen is placed on this side, it must either be adjustable to allow users to view it from the opposite side when connecting the DKS and the kidney or be two screens, one visible from the side with the reservoir and one visible (and clickable) from the side with the handles. Since the machine is quite small on this side, the handle will not be very long (around 40 cm) which makes it difficult to place the screen on the handle, which could have been a good solution on how to place an adjustable screen. The handle cannot be in the way of the screen either, creating some difficulties when deciding on how to place it. If however, the handle was moved, the screen could indeed be placed here.

Since the machine is elongated, it not desirable to add too much to the height of the machine. The machine is also fairly small, why two screens might seem excessive. An additional screen would also result in more parting lines which results in more places where dirt might stick or where it might be more difficult to clean.

This led to the machine having one adjustable screen placed on side II at working height.

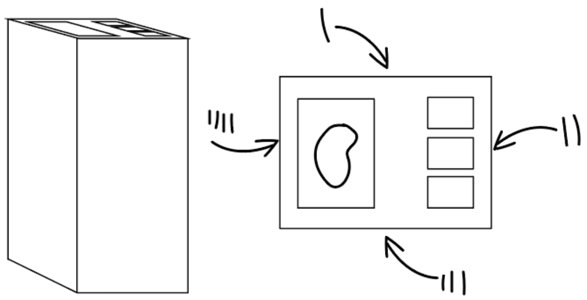

Figure 4.10 Discussed placements of the screen.

4.3.3.2 Placement of other controls

As previously mentioned, touch screens do have down sides such as difficulties when using them with gloves or accidentally clicking them. If the screen is merely a display with no touch function, it could be combined with other types of controls for example the mouse and number pad from the experiments. If the controls are assumed to be placed on the same surface as the display, meaning if you have an adjustable display, the controls will move with it. This would cause the controls to be placed upside down when turning the display toward the opposite side. Having the controls upside down at this stage could cause some issues if the user is required to use them in this position, but if the user should not, having them upside down might signal this to the user and it would be avoided.

The controls could also be placed on a non-adjustable surface, which would ensure them staying in the correct position. Then the user might be annoyed if they cannot reach or use the controls in an easy fashion independent from how the display is adjusted. The controls cannot be placed in a way that would make the user's hands block the display while using them, since they should be able to see what they are doing. Controls could be placed in more than one location to allow the user to use them while standing on different sides of the machine, but too much freedom is not always positive.

Since the user only need to access the controls when priming and starting perfusion programs, having the controls on the same side as the display would most likely be sufficient. If the display is only facing inward when mounting the DKS and connecting the kidney, the controls could even be placed on the same surface, since the user only views the screen during these tasks.

4.3.3.3 Alternative controls

So, what would be the ultimate choice of controls? Of course, there are many options such as the previously mentioned touch screen, mouse and number pad, but the tasks the user performs with the controls might be limited to starting different programs, which could be done with a few buttons or wheels. Combined with a good GUI, the number of buttons could be limited to very few, some for moving through a matrix or list and one for confirming a choice. Wheels are good for navigating lists or tuning parameters, but if the controls are used when the sterile field is open, they will be covered with a sterile drape, which could make it difficult to turn the wheels. The same goes for a computer mouse, why touch and/or buttons might be the best choice. Buttons can be designed in a way that minimizes visible parting lines by covering them. This is seen in the similar product Lifeport, where the user interacts with a number of displays using a small amount off buttons.

4.3.4 **Sample taking**

Sample taking was one of the activities that could have been more analysed but was not since it related too much to the DKS. It would have been nice if the final design offered a space for sample taking that would have been an improvement to the current situation where the user must squat to reach the sample tap. If the user could take every sample from the top of the machine, there would not be any discomfort when doing so. The other aspect of the sample taking that affects where it would be suitable to place the tap is that the side with used for samples are pressurized and can result in a few drops being spilled when taking samples. Therefore, it might be good to have the area for samples separated with a barrier, perhaps a part of the DKS, that prevents the drops from staining the OPP. The drops would most likely not cause any harm or result in any hazardous situation but might cause the machine to look dirty and not as nice and protective as before.

4.3.5 **The back of the machine**

As mentioned under 4.1.1, the final design does not have a defined design for the back of the machine, except for the handles. There are however several features that could be included on this part of the machine, for example access to the gas tube and waste bag. The main issue with the back of the machine was that too many features could have been placed there and could then interfere with each other. For example, the handle in the final concept could be in the way if the pumps were placed lower. If the screen would have been placed on or above the handle, the area where the user could grab the handle would be too small. If the handle was placed below the screen it would have to be placed low enough to allow the user to flip the screen, and then it could be uncomfortable for the user to move the machine. To avoid some of these issues with interfering features, the pumps were placed at working height and the screen on the side.

This does not remove the need to access the gas tube and other parts of the machine, and it must be possible for an authorized user to service the machine. One idea could be keeping the back open, allowing all users to access the machine. This could result in unauthorized users making changes they should not, and it could be better to have only the gas tube (and possibly the waste bag) easily accessible and the other parts hidden behind a hatch or something similar.

4.3.6 **Placing the machine up against a wall**

When the machine is running programs, it will be placed with one side against a wall. Below, the aspects influencing the orientation of the machine when placed by a wall are discussed. The two options are placing it lengthwise or with the shorter side facing the wall.

4.3.6.1 Location and orientation of the screen

The screen should be visible when the machine is running programs, therefore it is likely that the user would place the machine with the screen facing out from the wall. If the screen is placed on the longer side, as in the final concept, the user might place the machine with the screen side facing out or flip the screen and have the opposite side facing out. If the machines are covered with a drape, the screen should not be flipped and it would instead require a distance between the machines to keep the handle accessible (see figures 4.11-4.12 for examples).

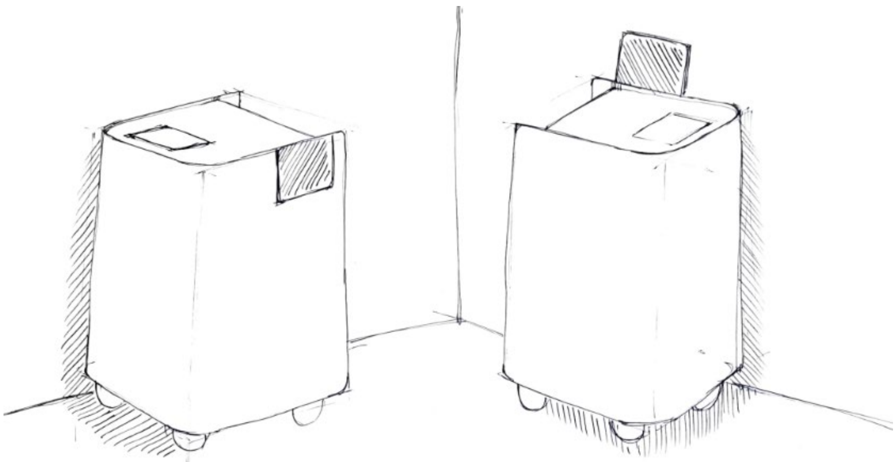

Figure 4.11 How the machine could be placed close to a wall.

Figure 4.12 How two machines could be placed close to a wall.

4.3.6.2 Handles

In the final concept, the handle is placed on the back of the machine. This nudges the user to place the machine with the back side facing out but can conflict with the location of the screen. It is assumed that the user would prioritize the screen facing out rather than the handles. The handles should still be placed where the user could access them easily, for example on the back side as in the final concept.

4.3.6.3 Number of machines

Since humans have two kidneys it is most likely that there will be two machines working at once. They would then be placed alongside each other against the wall but does not have to have the same orientation. Examples on how they could be placed are illustrated in figure 4.13. To avoid the machines taking up too much space further from the wall, it would be best to place them lengthwise, as seen in the top left corner and bottom right corner in figure 4.13. Placing them facing the same direction could result in difficulties when trying to access the handle on the machine placed in front of the other. It would depend on how close to each other they are placed. Instead, if they are facing each other, one of the screens might not be visible (unless flipped) and the LED stripes would be more difficult to see (see figure 4.12).

If the machines would have to be placed with a distance when oriented lengthwise, it might be better to place them with the front facing the wall. That would mean that the back side is now facing out and if the screens are placed on the long side, one would be blocked (unless flipped). The screens should then be placed on the back side, and the handle would become two handles placed on the side.

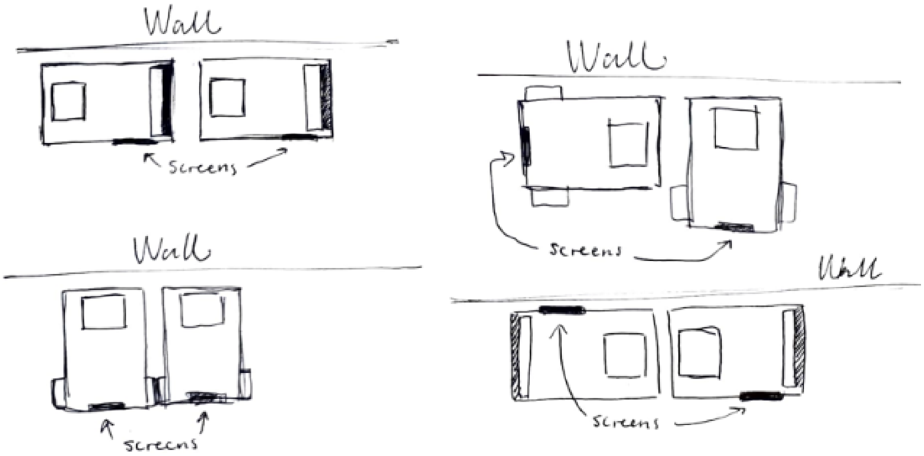

Figure 4.13 How two machines can be placed besides each other.

4.3.6.4 Other features

As mentioned above, the LED strip also affects the way the user wants to place the machine. Since the LED strip communicates where in the current phase of the reconditioning process the machine is timewise, the user should not let the LED strip face the wall. The most suitable way to place the machine is seen in figure 4.12.

5 Risk analysis

In this chapter, discussion and findings from the risk analysis is presented. The risk analysis was performed in collaboration with the company, with their standards as a basis, and is not presented in its whole due to confidentiality at this stage.

The risks were used to define requirements and specifications for the final design.

5.1 What is risk analysis?

The risk analysis is a part of a larger concept called risk management, which is something that is performed during the entirety of a products lifetime, which includes feedback from usage and the disposal at the end. Because of the time limit of this project, the only part of the risk management performed was the risk analysis. The risk analysis includes identifying hazards and hazardous situations, estimating the risks and foreseeable misuse (SIS-CEN ISO/TR 24971:2020, 2020). As mentioned under 1.4.4, the standards Medical devices – Application of risk management to medical devices (ISO 14971:2019) and Medical devices – Guidance on the application of ISO 14971 (ISO/TR 24971:2020) were used. The methods presented in ISO/TR 24971:2020 where the ones used during the risk analysis phase. Risks are defined to able risk control measures to avoid the occurrence of hazardous situations.

5.2 Identifying hazards or hazardous situations

When identifying hazards and harms, it is assumed that no risk control measures have been taken. That means that even the ones that exist and the hazards that are already prevented by the current design should be part of the risk management file, so they are not forgotten. The other thing to keep in mind is what harm means and how it is defined. For example, in a coffee machine, if the pipe guiding the water is broken there might be a leak. But the harm is not the leak, the harm is what the leak could cause, for example someone falling due to slippery floor. In this case, the hazard is the broken pipe, the hazardous situation is someone falling due to slippery floor, and the harm is someone getting hurt. The steps in-between, the leak that causes a wet floor, are a sequence of events that lead to the hazardous situation of someone falling and the harm when someone gets hurt. Parts of the process when identifying the hazards and hazardous situations are presented below.

5.2.1 **Characteristics of safety**

To identify the different aspects of which the risk analysis should be performed you first have to identify characteristics of safety (SS-EN ISO 14971:2020, 2020). The most central characteristic for this project was usability. Other characteristics concerning the machine were cleanability, sterility, compatibility, moveability, and ergonomics. Cleanability, moveability and ergonomics are linked to usability since cleaning and moving the machine are part of using the machine, and ergonomics are a part of how the user can use the machine in a safe way. Sterility is a safety characteristic that the machine must fulfil to make sure users and patients are safe from infection. The user can of course influence the sterility by for example using the machine in a less appropriate way, which is discussed under 5.2.2. Compatibility describes how the machine must fit in the environment it is to be used, the hospital. Every phase of the usage must be possible to perform within this environment. For example, part of the usage is moving the machine. If the environment in which it is used is the ocean, it must be moveable on or under the surface. In this case, the hospital has floors, and the machine must be compatible with the floors to ensure moveability within the hospital.

5.2.2 **Reasonably foreseeable misuse**

One thing that could lead to hazardous situations and possible harm is if the machine is used in a way not intended by the manufacturer. To identify the possible ways this could occur, different scenarios were discussed. One way the machine could be misused is if it is used as a work bench or a surface for unloading. This was noted during the experiment and could be something that the design should prevent but it could also be something that the machine should provide the user with if necessary. A common solution when wanting to avoid users placing objects on surfaces is to make them tilted so the objects would fall off. This is also used on roofs to make snow fall off the roof to protect the roof from collapsing.

5.3 Risk analysis as a design perspective

In this project, the risks found when performing the risk analysis with the company were used to evaluate the generated concepts. Often these evaluations were not documented and only used as “things you should have in mind”. One example was trying to minimize the amount of parting lines to eliminate parting lines where dirt could get trapped, depending on how these parting lines are constructed.

When designing the handles, the risk analysis perspective was central. The way handles are constructed affects how the user behaves when moving the machine. Handles reminding the users of other products that move fast, for example bikes, could have the effect of users moving the machine too fast and not as careful as desired. Allowing the user to easily grab the handle with one hand could lead to the user attempting to move the machine with only one hand and lose control over it due to the weight of the machine.

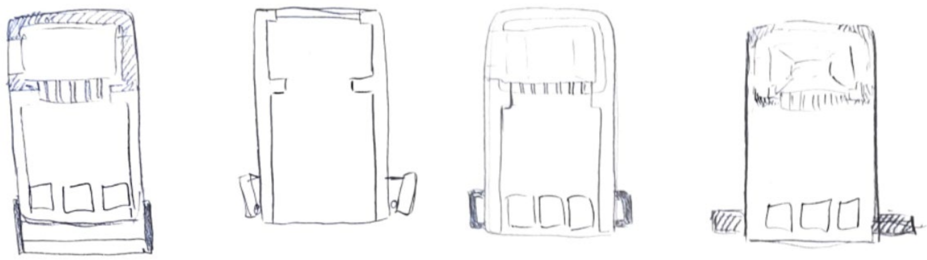

Figure 5.1 Sketch of different handles.

5.4 Evaluation of final concept

The final evaluation of the final concept was to once again look at it from a risk analysis perspective. As mentioned, this perspective was always present when evaluating concepts and making decisions regarding the final concept. Since the full risk analysis is confidential, this part only entails discussion on how it was applied to the final concept.

5.4.1 **Moving the machine**

The final concept is more or less a shell for the machine but with a selected placement of the reservoir, size and location of the screen and shape and location for the handle. The handle indicates to the user where they should be when moving it and can indicate if the machine should be pushed or pulled. In this case, the machine should be pushed to ensure that the machine remains within the visual field, but since the handle is executed in a very simple manor, users might be more creative when using it. Perhaps they would manoeuvre it similar to a shopping cart with one or two hands and in several directions. As mentioned under 4.1.1, the weight of the machine could limit the possibilities of moving it using a one hand grip. Therefore, this handle might not be suitable since to some it might look as if you can move it with one hand. If a user attempts this and loses control over the machine, a hazardous situation can occur with possible harm to users or kidney as a result. This is however unlikely, since the user will most likely realize this quick enough and adjust to a two-hand grip. Then, the size of the handle could be an issue for some users. Since the handle has a length slightly smaller than the short side of the machine (around 40 cm) it might be difficult for a person with larger hands or broad shoulders to find a comfortable way of moving the machine, which could lead to them grabbing the machine a different way and perhaps on areas where it can lead to hazardous situations.

5.4.2 **Mounting the sterile drape**

A very important aspect of the design is to allow the user to open the sterile field in a safe way. It is done by covering the machine with a sterile drape and then opening the lid to the reservoir. By definition, this way of opening the sterile field is a risk control measure currently used in many similar machines to minimize the risk of contamination. Covering the final concept with a sterile drape should not be an issue, assuming that the screen is positioned in a way that allows the drape to fold easily around the edges, preferably with an angle smaller than 90˚ to the side of the machine. If the screen is flipped to be visible from the opposite side, it can be in the way of the drape which could lead to users fixing the issue by for example tearing or folding the drape. This would result in the drape being incorrectly mounted and possible harm to the kidney by contamination.

This probability of this risk is difficult to say, since the users are aware of how to apply aseptic techniques but are also known to adjusting drapes to fit better according to themselves (Allenbach, 2022).

5.4.3 **Cleaning the machine**

The machine is white, which allows the user to find dirt easily. The parting lines must be constructed in a way that prevents dirt from getting trapped, which should be possible in the final concept. When different materials meet, constructing safe parting lines can sometimes be difficult and the final concept do have such parting lines. Hazardous situations can occur if dirt gets trapped and the users are not able to notice or clean it properly, which could lead to possible harm to the next user or kidney by increasing the risk of infection.

6 Discussion

In this section discussion about the final concept, the goals and the process can be found.

6.1 Discussion on the final concept

6.1.1 **Does the design fit the field?**

As mentioned, designing medical devices differs from other products because of the environment in which they are used. The devices should not be difficult for the users and should not make the users want to take shortcuts. The new design is simple, easy to move and easy to store due to the simple shape. It could perhaps be improved to better sustain impacts by adding bumpers to the lower edges.

As mentioned under 5.4.2 it is possible that the users might adjust the drape to fit when the screen is flipped, which is one of the ways they could take possible shortcuts since they might believe that having the screen oriented this way when the sterile field if open is better. Then it might be worth discussing if the screen should be able to be oriented this way, or perhaps the gap for adjustments could be limited to 90˚. When placing the machines against a wall next to each other, they would then have to be oriented in the same direction, which could cover the LED-strip of one of the machines if they are not placed with more space in-between.

6.1.2 **Communicating reliability to the users**

The machine should communicate reliability to the user, that was one of the goals stated at the very beginning of this project. To understand how that could be done, the field observations, or experiments, where a great source of input. Attempting the role of a user gave understanding of what you need to rely both on the machine and yourself. During the first observations, the machine felt difficult, and you were less eager to control it, since there was some understanding of which consequences doing something very wrong could have. During the second and third, the machine felt more approachable, even though it was the same as before.

The knowledge of the machine resulted in confidence to use it. This resulted in the desire to see the process and with that see the tubing and pumps to feel in control of what was happening. What about users that have more knowledge of the kidney than the machine? Do they wish to understand more about the technical aspects and have it accessible in the same way? Perhaps, but maybe they would rather want to see the kidney to feel the same sense of control. To feel the confidence you need to run the machine safely, maybe all you need is knowledge of one of the two, kidney or machine. If so, how does one use this to communicate reliability to the users? One way could be finding the balance between showing the interior and not. Parts that demand user interaction must be accessible by the correct user and invisible to those who does not possess the knowledge to use them. For example, if the machine has three pumps and the user is unsure of which is which, and aware of this uncertainty, when one pump spins fast they might get worried since it might be the pump pumping the mixture of fluids into the kidney. What if the pump runs faster than it should and causes damage to the kidney? Perhaps the user would stop the pump only to discover that it was the pump connected to the heat exchanger and there was no risk of damaging the kidney. A user with more knowledge of the kidney would most likely want to see the kidney, assess the risk of damaging it by letting the pump run and observing the kidney to make sure it was a false alarm.

The approach presented by Jordan (2000) of viewing products as things with personalities gave the idea of mutual trust between user and machine where the machine must rely on the user to perform the tasks in a correct manor. Since there is no real way for the machine to feel these things, the design of the machine must somehow communicate this to the correct user, for example by reminding them of another product they are familiar with or demanding authorization in the form of a personal code.

6.1.3 **What is the back of the machine?**

In this report, the side referred to as the back of the machine is the side where the user would stand when moving the machine within the hospital. This is because it is the side furthest from the reservoir which is considered the most central point of interaction and thus “the front”, and because when moving the machine this side is placed first. It also relates to where visible design features have been added in the final concept. The front has an LED strip that lights up and should be visible as much as possible, just as the back have almost no design features and should perhaps not be visible at all times. When the back needs to be visible is determined by what type of interaction would happen there. The handle in the final concept should be accessible and if the user needs to change the gas tube, the back should be accessible as well.

6.1.4 **Handles**

The handle on the final concept is not very large, less than 40 cm long. For someone with large hands, this might be too small to be able to move the machine in a comfortable way. Handles could be placed on the side, or if the machine could be longer, be placed vertically on the back edges to allow a more flexible grip.

6.1.5 **Other features**

6.1.5.1 Lid

The lid in question would be an outer lid that would be a part of the OPP and not the DKS. This is not included in the final design but can be seen in sketches in Appendix B. A lid could help complete the design and give it a more finished and completed look.

6.1.5.2 Movable parts

One goal for the final design was to limit the number of movable parts as much as possible. Movable parts can create confusion and require hinges or similar connectors, adding parts that could break or cause hazardous situations. Therefore, the idea of having a telescopic solution with an inner and outer part seen in figure 6.1 was not further discussed. This concept was created to save space during storage and when running the programs. The part with the keyboard and screen should then move and uncover the DKS when the user needed to see the pumps and tubes. As mentioned, this concept was not further developed due to the presence of many movable parts, which would require the tubes and cords in the machine to adapt to the current position of the outer part.

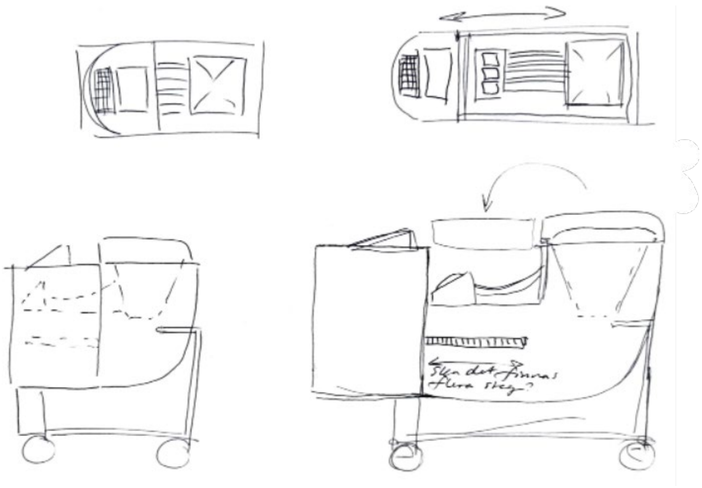

Figure 6.1 Sketch of an early concept with large movable parts.

6.1.5.3 Drip stand

An integrated drip stand was a feature up for discussion. This was not a need stated by the users but could simplify some of the tasks. The drip stand is needed when adding fluids to the DKS, which is done when priming and when adding blood. By having an integrated drip stand, the bags with fluid would always be hung at the correct distance from the DKS, allowing a design with shorter spike lines. If the users themselves must adjust the distance between the machine and the bags, the spike lines must be long enough to allow a span of distances noticeably greater than the necessary distance.

6.1.5.4 Where to take samples

As mentioned under 3.1.1, the DKS is what determines where samples are taken. How the user should access the sample taking tap is however something the machine can affect. The user should be able to take samples in a comfortable position and not have to squat or lean too much, which means that the DKS should be placed in a way that allows the user to do so. Samples are taken when the machine is covered by a drape, and the user must somehow take samples through or by going under the drape. To find a good solution for this, a new thesis project could be a good idea.

6.1.6 **Moving forward**

6.1.6.1 GUI

One of the next steps for the machine is designing the GUI (graphical user interface) for the touch screen. A good GUI is very important for the user experience and a bad GUI is sometimes the only thing the user remembers about the design, no matter how great the rest of it is.

6.1.6.2 Balance in the design

The final design is feature heavy to the left if viewed from the back. This is something that could be improved by adjusting the placement of some features or adding details. For example, the LED strip is placed slightly to the left for no reason other than it was how it was sketched. The screen on the side had already caused some asymmetry and if the LEDs would have been centred it could have conflicted with the screen.

6.1.6.3 Parting lines

As mentioned under 5.4.3, the way parting lines are constructed affects the safety of the machine. How to construct safe parting lines where different materials meet could be something worth investigating further.

6.1.6.4 Colour

The colour is only selected as white for the final concept. Which white is not defined, and the colour of the frame around the LED strip and the edges are not more defined than that they are darker than white, with a metallic finish. For future development of this concept the colour should be more defined.

6.2 Reflections on the process

6.2.1 **Method**

One part of the method for this project was trusting the process and allowing oneself to explore alternative ideas and concepts and not choose a final design too fast. This sounds like a good idea, and is a good method to some extent, but for a shorter project with a clear deadline, it might have been better to make some decisions sooner. Then there could have been more time to visualize the final concept with more rendered pictures and a full scale physical prototype.

6.2.1.1 Visualization

Determining the size of the machine was in a way very simple, since there were some requirements given concerning the size. The most difficult part concerning size was imagining the size of the machine and how the machine would look and feel if it was paced in front of you. This was why many of the ideas generated when trying to find the final concept were not eliminated until thew were modelled in 3D. In the sketches they appeared to be a reasonable size with a good number of details, but when looking at them in a computer and when comparing them to real objects, they simply looked wrong. It would most likely have been more useful to work more in 1:1 scale, and to spend less time sketching.

6.2.1.2 Gathering data

There is such a thing as knowing too much when designing a product, since having too much knowledge can lead to killing ideas before they are fully developed. However, it could have been a good idea to search for knowledge within the area of medical device design to gain new perspectives and perhaps evaluate some of the design choices. This was attempted at the very beginning of the project, but the lack of knowledge at that point led to the use of wrong search words on the wrong platforms. When this would have been useful it had been forgotten until the very end of the project, and there was simply not enough time left. This led to the focus being solely on the machine and the user process with the knowledge from the development team as basis. It is impossible to know if another perspective would have resulted in a different design, but it might have resulted in a different analysis of the design.

6.2.1.3 Other methods

A method that could have been used more in this project, especially when selecting the colours and design features, is mood boards. One mood board was created at the end of the project, but it would have been useful to ally this method sooner to get a better idea of the feeling and vibe the new design should have. The reason it was not used sooner is simply that it was not thought of due to the large amount of time and focus spent on sketching and testing and comparing different placements of the screen and handles.

6.2.2 **Size of project**

This project could have been much smaller if it was more defined and should perhaps have been more defined at the start. The difficulty was to know how much was necessary to know about the machine and its components as a designer. It was very easy to get stuck when trying to make decisions since new information was found throughout the project. Perhaps it would have been easier to work further from the company and not so close, with the risk of the project resulting in more unrealistic concept. One way to limit the project could have been to only look at the casing and the placement of the reservoir, handle, and screen, since the placement of the pumps and the design of the DKS was unclear. Suggestions to the sample taking were not included in the final design, since it relates too much to the design of the DKS (the same goes for the waste bag).

6.2.3 **Time management**

Overall, the time management for the project was acceptable, but if it could be re-done more time would be spent finalizing the concept and less time would be spent on understanding the current machine. It is difficult to say if the time spent understanding the machine could have been spent on other activities or if that would have resulted in too little understanding of the context and a less realistic final concept. Some decisions should have been made quicker to move forward in the project faster, and to find the final concept sooner, which then could have been more finalized and prototyped with a physical model.

During the final phase of design, too much time was spent taking detours and changing the placement of the pumps to better fit the development at the company, when instead it might have been a better idea, considering what the purpose of this project is, to simply make a decision and stick to it. This detour took about a week, and it would have been nice to use that week to build a full scaled prototype or to make more detailed renders and work more with the report.

The time plan was close to reality aside from some activities, such as setting specifications, were done in a shorter period of time and planning was preformed more than once to update the plan as the project prolonged. One could argue that the time spent setting specifications were more than one week, since it was in a way done throughout the entirety of the ideation phase as decisions were made concerning the final concept. A comparison of the plan and the outcome can be seen in appendix A.

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Appendix A Time plan

In this appendix the time plan for the project is presented and compared to the outcome. They are presented as Gantt-charts, with different colours for different activities.

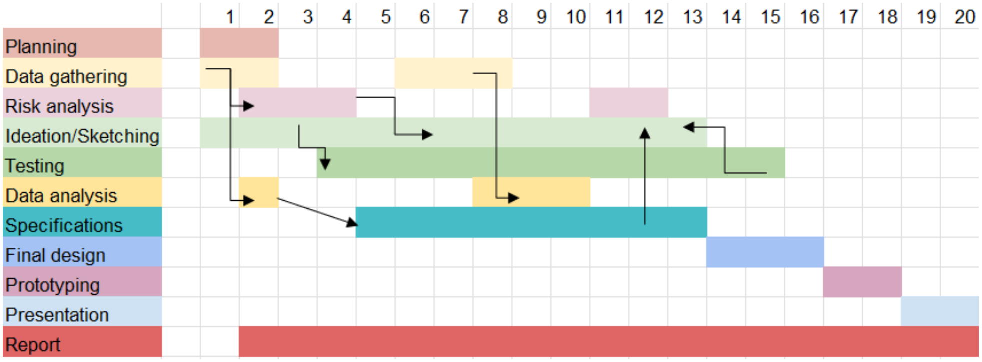

Figure A.1 The time plan for this project. The numbers represent weeks starting with 1 as the first week of the project.

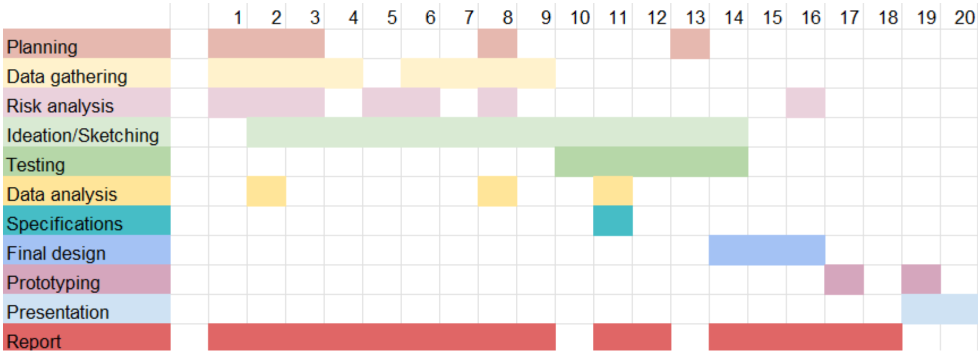

Figure 0.1 The time spent on different tasks for this project.

Appendix B Selected sketches

In this appendix, some of the sketches from the latest part of ideation are presented. These were at one point thought of as the sketches for the final concept but were discarded after modelling the machine in 3D and finalizing the specifications.

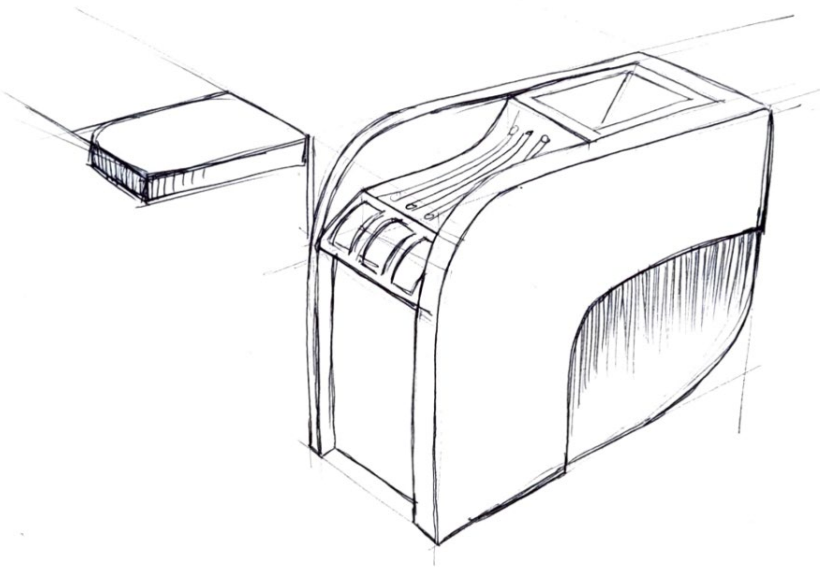

Figure B.0.2 Sketch from early stages of ideation with movable surface for controls.

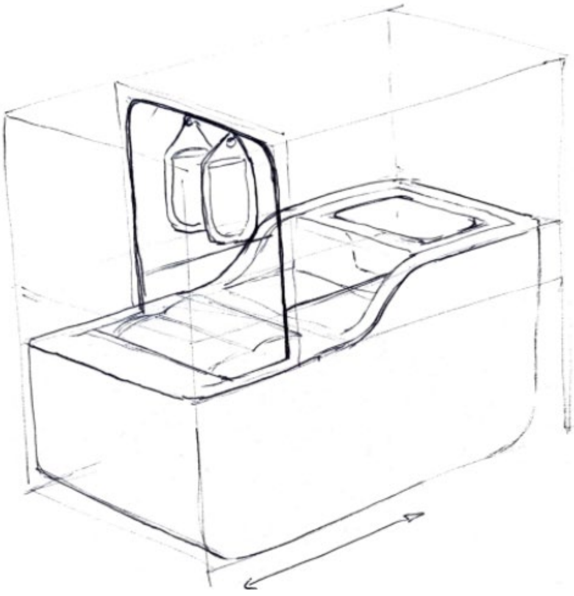

Figure B.0.3 Sketch of a smaller concept with integrated drip stand.

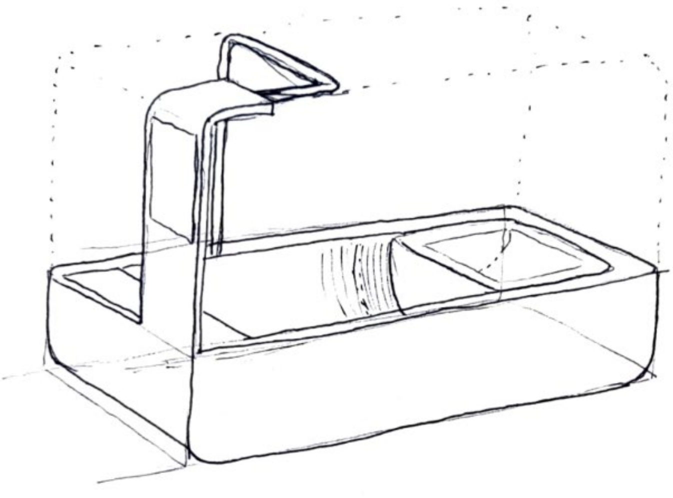

Figure B.0.4 Sketch of a concept inspired by OrganOx metra with an integrated drip stand.

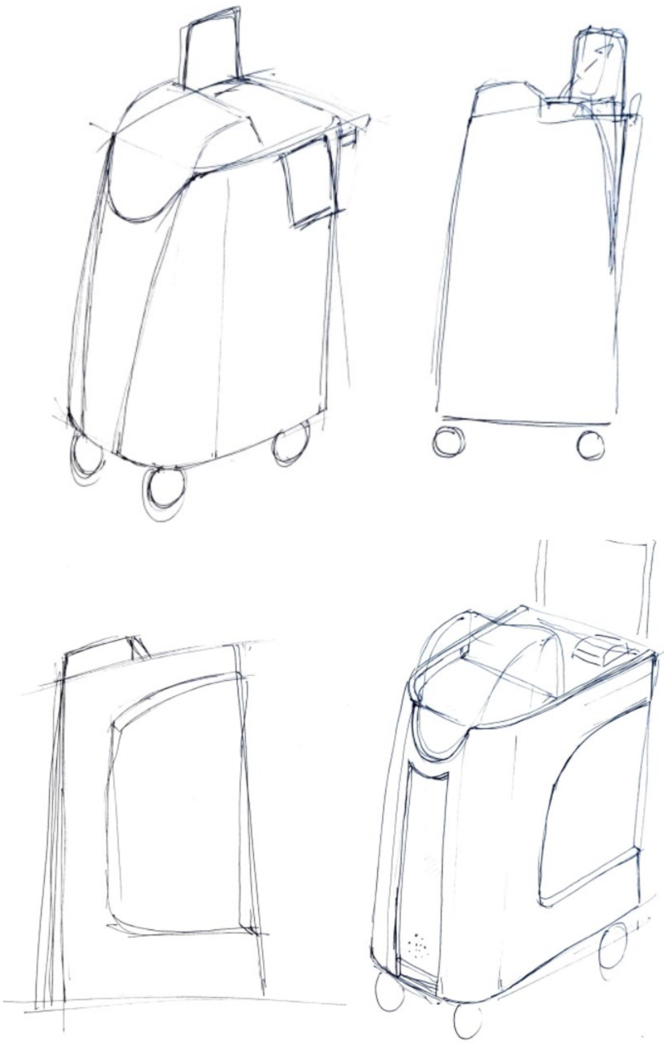

Figure B.0.5 Sketches from the final stages of ideation, post SCAMPER. The concepts had lids, integrated drip stands and a shell in plastic protecting the machine from impact.

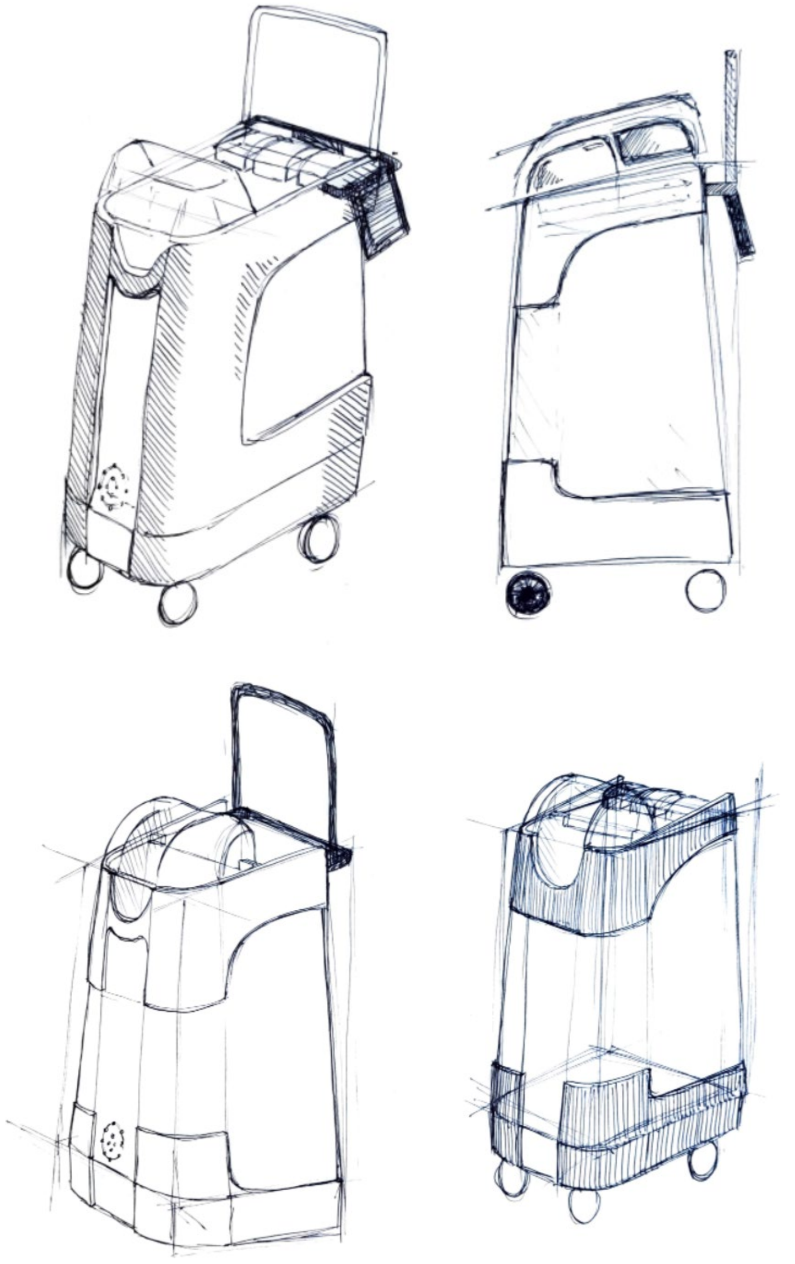

Figure B.0.6 More detailed sketches of concepts during the final stages of ideation. The concepts have a tilted top edge to make the reservoir seem more accessible,

Appendix C Renderings

In this appendix renderings of the final concept that are not presented in the report are found.

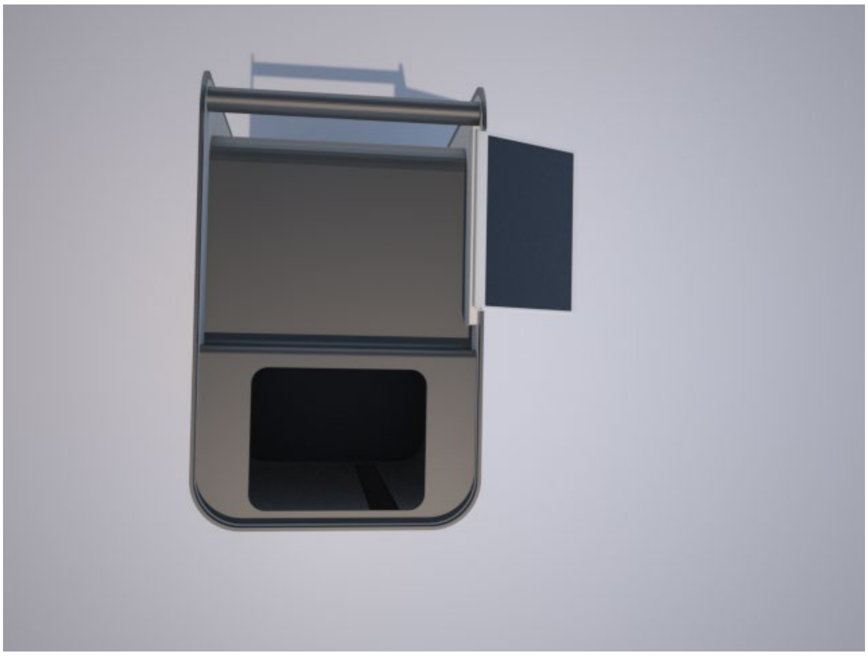

Figure C.1 The final concept seen from above with angled screen.

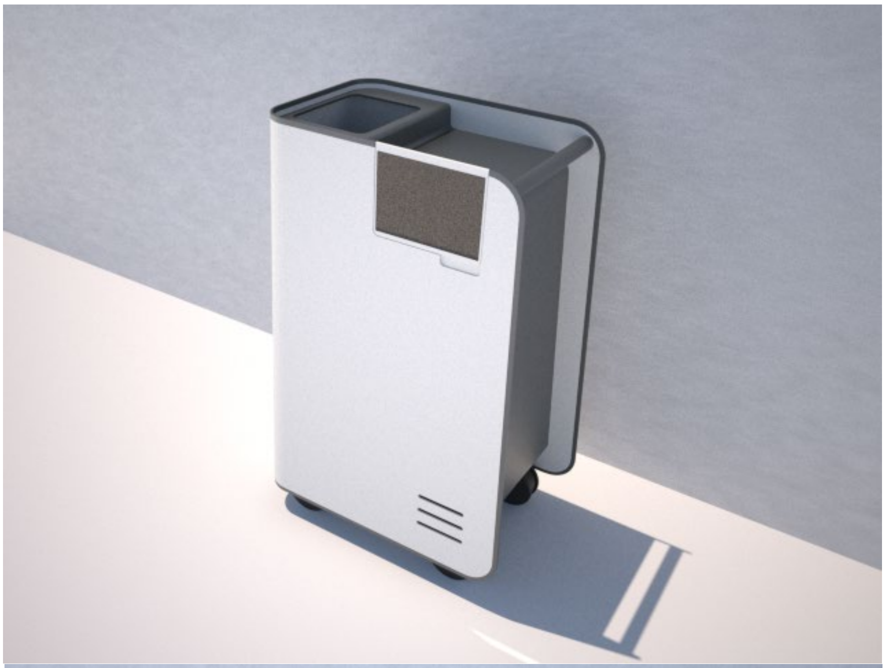

Figure C.2 The final concept as seen from behind.

Figure 0.7 The final concept seen from behind with the screen at a 60˚ angle.

Appendix D User needs

In this Appendix the complete table with identified needs is presented.

Table D.1 Needs

Statement	***Need***	**Need no.**
The kidney must be protected from possible infection	*The machine should prevent infection*	**1**
The goal is to transplant more kidneys.	*The machine should deliver kidneys ready for transplantation.*	**2**
	The machine should restore kidney function.	**3**
	The product should not discourage the user from using it.	**4**
The machine should be designed for the reconditioning of one kidney.	*The machine should allow space for one DKS.*	**5**
The machine is moved between different rooms	*The machine should allow indoor transportation*	**6**
The users should not hurt themselves when using the machine.	*The product should not inflict harm on the user.*	**7**
Transportation	*The product should be transportable.*	**8**
	The machine should be moveable by one user.	**9**

The design must prevent the machine from tipping or falling over.	*The product should be stable.*	**10**
The user should not be discouraged from using the machine.	*The machine should communicate usability to the user.*	**11**
	The machine should not be intimidating.	**12**
It should be comfortable to grab and move the machine.	*The machine should be ergonomic.*	**13**
The machine should not be used as a work bench.	*The machine should prevent misuse.*	**14**
Spills should not compromise the safety of the user or the patient.	*The machine should prevent dirt from getting caught.*	**15**
It can be difficult to use the touch screen with the drape.	*The machine should provide controls that are easy to use with a drape.*	**16**
It is difficult to connect the DKS.	*The machine should allow the user to mount the DKS in an easy way.*	**17**
The machine is placed in the corridor during the perfusion process.	*The machine should be easy to place in a corridor.*	**18**
The user must be able to clean the machine.	*The machine should collect the waste.*	**19**
	The machine should be designed in a way that gives the user easy access to possibly dirty surfaces.	**20**
The user must be able to change the gas tube.	*The machine should provide easy access to the gas tube.*	**21**
The user takes samples.	*The machine should provide possibility for easy sample taking.*	**22**
	The machine should not allow dirt from samples to get stuck in the machine.	**23**
The maximum footprint for storage is 60 cm times 60 cm.	*The machine should be possible to store.*	**24**