

Development of a Design Concept for Dialysis Concentrate Packages

Master Thesis in Industrial Design Engineering

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CHALMERS TEKNISKA HÖGSKOLA
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Product and Production Development
division of Design & Human Factors Engineering

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Cover: A prototype of a concept for the secondary package.

PREFACE

This master thesis was carried out in the spring of 2011 in cooperation with the medical technology company Gambro Lundia AB, located in Lund, Sweden. The thesis comprises 30 units of credit (i.e. 20 weeks of studies) and is the final work of the master's program Industrial Design Engineering at Chalmers University of Technology.

I would like to thank my examiner Anna-Lisa Osvalder and supervisor Lars-Ola Bligård at the department of Product and Production Development, division of Human Factors Engineering, Chalmers University of Technology for feedback and for guiding me through the project and educated me in methodology and tools used for the analysis work. I also want to thank my supervisor Fredrik Ericsson at Ergonomidesign AB for support and feedback through the project and the master students at IKDC for welcoming me to the "exjobb's fika".

I also want to thank my contact Caroline Andersson at Gambro, the people in the brainstorming session, the participants in the usability test and all the other people at Gambro who has supported me and provided me with all their help.

Last but not least I would like to thank the people at the dialysis wards in Lund, Karlskrona and Malmö for taking the time to be interviewed and letting me study their work.

Göteborg, June 2011



Anna Hallgren

ABSTRACT

There is a desire for dialysis concentrate packages that are lightweight, quick to mount to the machine and easy to dispose. The box packages today are cumbersome to open and flatten, for some sort of box packages the nurses have to jump on it before it can be disposed. The new concept shall support dialysis operators with an ergonomically designed user interface with good usability.

The following three questions were set for the project.

What needs and wants does the users have on a dialysis concentrate package?

Which are the most important usability aspects for a concentrate package?

How can a dialysis concentrate package with good usability look like?

The final package concept consists of a primary concentrate package, a secondary box package and a design proposal for how the concentrate could be attached to the dialysis machine. The box concept uses a way of flattening which requires less force than the existing box. The package concept of the concentrate provides the user with a convenient grip and takes up a smaller volume after usage than the existing Gambro packages for dry concentrate. The improvements of the concentrate packages will lead to better working conditions for dialysis nurses and hopefully increase the level of satisfaction with concentrate packages.

SAMMANFATTNING

Det finns ett behov av dialyskoncentratförpackningar som är lätta viktmässigt, som går snabbt att montera på maskinen och som fungerar bra i sophantering. Många av dagens sekundärförpackningar är svåra att öppna och platta ihop, en del måste användaren hoppa på för att få den platt. Det nya konceptet som togs fram skulle förse dialyssjuksköterskorna med ett ergonomiskt utformat användargränssnitt med god användbarhet.

För projektet sattes följande frågeställningar upp.

Vilka behov och krav har användarna på en dialyskoncentrat-förpackning?

Vilka är de viktigaste användbarhetsaspekterna hos en koncentrat förpackning?

Hur kan en dialyskoncentratförpackning med god användbarhet se ut?

Det slutliga konceptet består av en primärförpackning för dialyskoncentrat, en sekundär lådförpackning och ett design förslag på hur förpackningen skulle kunna monteras på maskinen. Lådförpackningen för dialyskoncentrat-förpackningarna har en vikningsprincip som är kräver mindre kraft att vika i ihop än ordinära existerande förpackningar. Förpackningskonceptet för koncentratet förser användaren med ett handvänligt grepp och tar upp mindre utrymme i hanteringen efter användning jämfört med existerande Gambro förpackningar för tort dialyskoncentrat. Förbättringarna med den nya koncentratförpackningen leder till bättre arbetsförhållanden för dialyssjuksköterskor och ökar förhoppningsvis tillfredsställelsen med dialyskoncentrat-förpackningar.

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1 INTRODUCTION

In this chapter background information to the project is described, as well as the purpose, goal, questions and delimitation.

1.1 Background

Dialysis is medical treatment method used all over the world and saves many lives of people every day. The dialysis system function as an artificial kidney for people with lost or partial kidney function. This project concerns the handling with dialysis concentrates, which has an essential role in the dialysis treatment process.

The handling of the concentrate is important to consider in order to provide good physical working conditions, support an intuitive usage and to prevent use errors. To implement the human factors in the development of medical equipment is required from authorities and also an area to work on in order to compete with competitors' products.

The collaborating company Gambro Lundia AB is a Swedish medical technology company developing and manufacturing products for dialysis e.g. dialysis machines, dialyzers and dialysis concentrates. The concept is first and foremost aimed to be implemented on the Gambro dialysis machine AK 96[®]. The AK 96[®] monitor is used both at dialysis wards at hospitals and at homes by patients themselves. It is a relatively basic dialysis machine without high-tech features. It is primary used in developing countries and for home dialysis because it has fewer functions, is less expensive and is small in relation to other dialysis machines.

1.2 Purpose

The project concerns a user centred approach applied on the development of concepts of containers for dialysis concentrate valid for dialysis machines. The concentrate package shall support dialysis operators with an ergonomically designed user interface for dialysis treatment. The interface should be as intuitive as possible and have good usability.

1.3 Goal

The goal is to make a new design in the lower segment that is better than Gambro's existing packages from a user perspective. The new concentrate package will primarily be designed for one of Gambro's hemodialysis machines (the AK 96[®] monitor), but should also be adaptable for other dialysis machines in the future. The issue of where and how the containers should be attached to the monitor will also be considered. The new package concept will also seek for improvements of the secondary package, the box. Concepts will be developed and in the end of the project prototypes of the final concepts of containers will be made in order to make usability tests with primary users.

1.4 Questions

In order to fulfil the purpose and goal the following questions where set for the project.

- What needs and wants does the users have on a dialysis concentrate package?

- Which are the most important usability aspects for a concentrate package?
- How can a dialysis concentrate package with good usability look like?

1.5 Delimitations

- The user studies of the usage are limited to Swedish dialysis wards.
- The graphics for the user interface on the screen menu are not developed within this project.
- Detailed design, material selection and cost estimations are not specified in the overall concept design.

1.6 Thesis Outline

The report is primarily written to be read by other students in the product development field. Hopefully it will also become a reference in the work and documentation of the further development of packages at Gambro.

The report structure is illustrated in the picture below.

The results are presented in four chapters named after the phases in the work procedure.

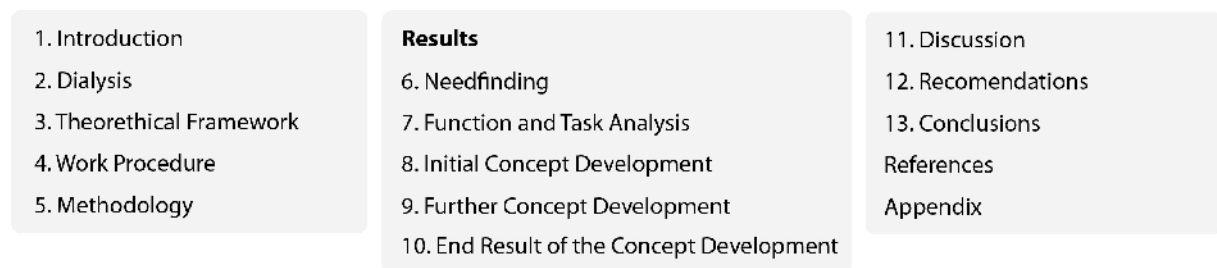


Figure 1-1 Report structure.

Introduction – introduction to the project.

Dialysis – description of the dialysis process, the concentrate and the dialysis machine.

Theoretical Framework – introduction to the theory of the project.

Work Procedure – description to the work process.

Methodology - the methods used are described briefly.

Results – the results of the project are described in chronological order and divided into four chapters.

Discussion - thoughts and reflections based on the project.

Recommendations – recommendations to the company for further development.

Conclusions – conclusions drawn from the project.

2 DIALYSIS

In this section the dialysis treatment, dialysis machine and dialysis concentrate will be described so that readers who not are familiar with dialysis will get an introduction to the area.

2.1 Dialysis treatment

Dialysis is a treatment method to compensate for lost or poor kidney function. The main function of the dialysis process is to do the kidneys job i.e. to regulate salt and water and to clean the blood. The kidney function can be damage by a chronic kidney disease or acute kidney injury. The most common reasons for kidney diseases are diabetes, urinary infections and genetic kidney disease (Larsson, 2000). Patients without any kidney function need the dialysis to continue their lives. Most of the dialysis patients have to come to the hospital at least three days a week and the treatment lasts for about 3.5-5h each time. Many patients may thanks to the dialysis live an active life and have a good quality of life even if they have a serious disease.

There are two different types of dialysis processes, hemodialysis and peritoneal dialysis. Hemodialysis is the most commonly used dialysis treatment methods and is a treating method where the blood is circulating in the dialysis machine and cleaned by passing through a dialyzer where the waste products diffuse to the dialysis concentrate. The peritoneal dialysis is a treating method where the dialysis fluid is introduced into peritoneal cavity through a catheter in the abdomen and peritoneum function as a dialysis filter in a dialyzer (Gambro Basics). The master's thesis work concerns development of concentrate package for hemodialysis only.

The dialyzer of the dialysis machine is an artificial kidney. The dialyzer has a filter which main function is to separate the waste products from the blood. The blood pass on one side of the filter and on the other side there is a flow of dialysis concentrate. The waste products in the blood pass the membrane in the dialysis filter while the filter stops the protein molecules and corpuscles.

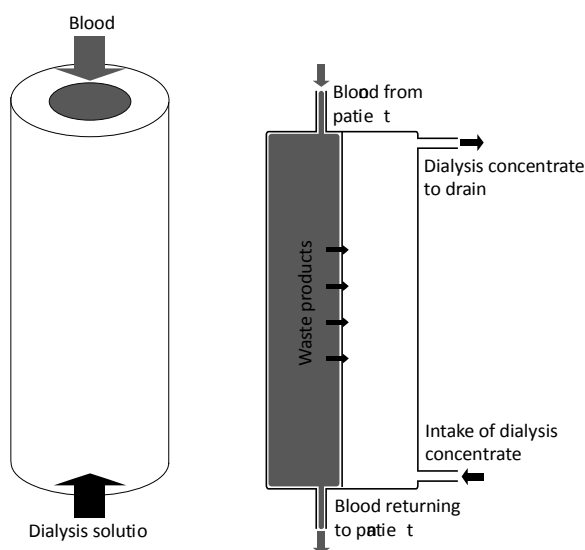


Figure 2-2 Principle of a dialysis filter.

2.2 The Dialysis Machine

The dialysis concentrate package will primarily be developed for the Gambro dialysis machine AK 96®. This machine is the smallest dialysis machines in Gambro's product range hence a more basic machine than the larger ones. The AK 96® machine is mostly sold to dialysis wards in developing countries but it is also used for home dialysis where it is used by the patients themselves in their homes.

The main parts of a dialysis machine are the blood pump which pumps the blood to the machine, the dialyzer that is cleaning the blood and an air trap to control that there are no air in the system. There are also a lot of controlling detectors such as blood pressure monitors, conductivity sensors for the concentrate etc.

There is a range of different liquid solutions needed for the dialysis process. First there is a saline concentrate, used for the priming of the machine before the treatment starts. Further on there are two different dialysis concentrates A and B, which are mixed together and then flow through the dialyzer during the dialysis process. The concentrates are diluted with cleaned water before it comes to the dialyzer. To prevent the blood from clotting, heparin can be added in form of an injection in the tube of the flow path.

2.3 The Dialysis Concentrate

The dialysis concentrate comes in contact with the blood in the dialyzer. The purpose of the dialysis concentrate is to balance the quantity of different substances, to uptake the waste products from the blood and to remove waste liquid. The concentrate has to have a mixture similar to the blood.

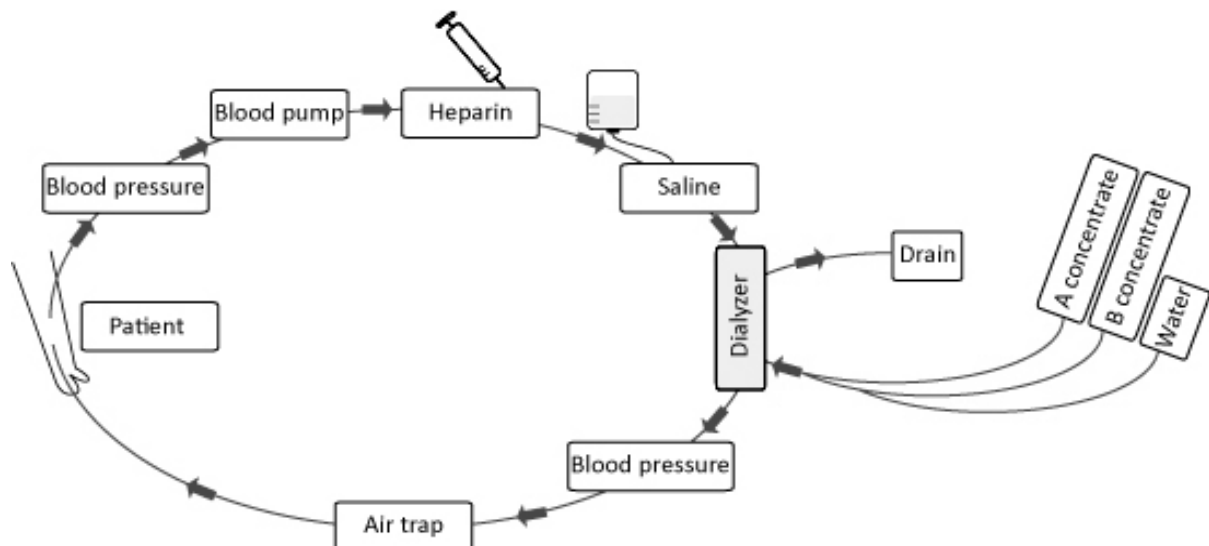


Figure 2-3 The dialysis process.

The dialysis fluid is made from an acidic concentrate (A) and a bicarbonate concentrate (B). The acidic concentrate is available in different mixtures while the bicarbonate only is made of bicarbonate. The bicarbonate is available either as a liquid or as a dry concentrate. Each type of liquid is distributed in packages that are connected to the machine during the treatment. The A and B concentrates are mixed in the dialysis machine and then transported to the dialyser. A more detailed description of the existing concentrate products can be found in section 6.2.

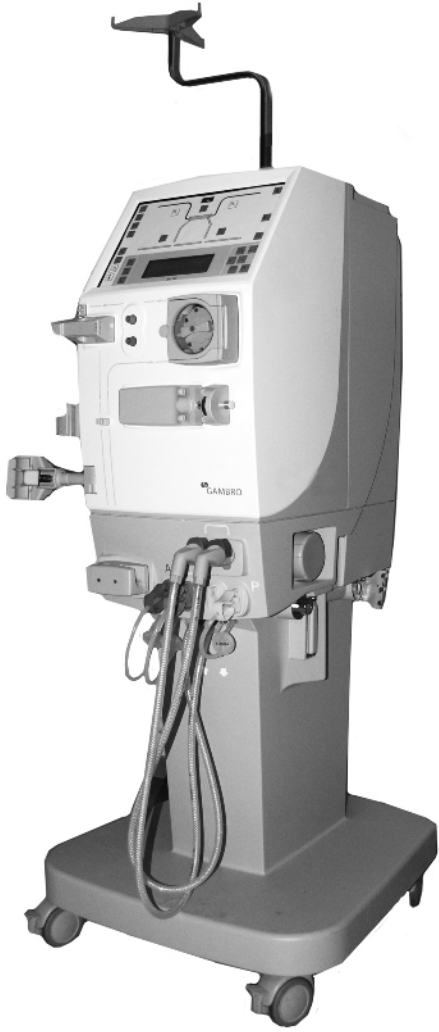


Figure 2-4 AK 96® monitor



Figure 2-4 Storage of concentrate at a dialysis ward.

3 THEORETICAL FRAMEWORK

In this chapter the theoretical background for the studies within the human factors area are presented. The following text is a brief introduction to the human factor engineering area and its primary purpose is to give an orientation for readers who are not familiar with this field.

3.1 Product Interaction

Product interfaces are everywhere a human has to interact with a product; it could for example be a vending machine, a coffeemaker, a teacup or a dialysis concentrate package. The principle of the human – product/technology interaction is that the human and product collaborates in a specified context in order to achieve a specified goal.

The purpose of human technology interaction theory is to design a system that contributes to a functional and collaboration between human and the technology, where the human ability to operate the system is considered, while the effect of the human limitations are prevented. In order to achieve a good product interaction all components need to be considered; the human, the technology, the environment and the task.

The product development within this project mainly considers static interface design i.e. products that doesn't change appearance over a sequence of actions. It can be compared to dynamic interfaces, which are represented in GPS, control rooms, cameras etc.

3.2 Usability

A central theme in human centered design is usability. There are many different definitions of usability. A commonly used definition is the ISO definition, (International Standard Organisation). ...the effectiveness, efficiency and satisfaction which specified users can achieve specified goals in particular environments (ISO DIS 9241-11). This definition defines that the usability of a particular product depends on who the actual users are, the intended goal to achieve with the product and in what context the product is aimed to be used. The disadvantage of this definition when applied to this type of projects is that the fulfilment of the goal can be misunderstood. The goal with e.g. dialysis treatment is to treat the patient but this is not what the usability aspects aims to measure, the usability aims to the human interaction with the product. Another definition of usability is Nielsen's definition. Nielsen defines usability with five components i.e. easy to learn, efficient to use, easy to remember, few errors and subjectively pleasing (Nielsen, 1993). This definition is more interaction oriented and is therefor more appropriate to use for this kind of project.

By considering a high level of good usability in the product development process, the product can gain advantages over competitive products at the market. Usability is also important to consider in order to fulfil the safety requirements for the usage, to prevent health problems of users and last but not least; the usability of products used in the workplace can also have an effect on the level of job satisfaction amongst that organization's workplace (Jordan, 1998). The better usability of the product, the more satisfied the users will be and more users will prefer the product and hence it contributes to good economy for the manufacturing company. The importance of

satisfaction was stated by Göransson (2001) as: It is what the user feels and thinks about the product that matters, not that much if the product is efficient to use.

Below is an explanation of some good principles for the work of usable design. The following principles are considered within this project and are inspired by Jordan.

-Compatibility- ensuring that the way a product works fits in with users expectations based on their knowledge of other types of products and the “outside world”

-Considerations of user resources- the design of the interaction process of information and actions will consider the demands of the users resources during interaction.

-Feedback- designing so that the system gives meaningful information to the users actions.

-Error prevention and recovery- design to minimize the risk of errors and make it possible to recover from potential errors quickly.

-User control- designing a product so that the user has control over the actions taken by the product.

-Visual clarity- design so that information is displayed so that it can be read quick and easy.

-Explicitness- designing cues for the function and how to operate the product.

Further the level of usability can be measured in respect to the product’s effectiveness, efficiency and satisfaction. The evaluation is performed by predefined measureable goals for each aspect of usability. Jordan’s definitions of the three measures are:

-Effectiveness - the extent to which a goal, or task, is achieved.

-Efficiency - the amount of effort required to accomplish a goal.

-Satisfaction - the level of comfort that the user feels when using a product and how acceptable the product is to users as a vehicle for achieving their goals.

3.3 Aesthetics

Historically, medical device companies have focused on the effectiveness of the therapy or process that their device performs with little regard to the product’s aesthetic appearance. Users opinions of the usability of a product are affected by the product’s aesthetics, not just its inherent usability (Kossak, Gellatly, Jandrisits, 2007). Every artefact express something, either it is intentional or not the user will get an impression.

The benefit of a conscious design language is important in many aspects. Consistent design strategy aims to control that the products are designed in a uniformed way even if there are many designers involved in the many different product development projects in a company. A strong characteristic in design within the brand will lead to branding.

Aesthetics can also be used in the purpose of guiding the user in the function of the product and its interaction. A strategy for this is to use the gestalt laws. The study of gestalt is the way in which formal elements relate to one another, how they are organized into wholes, how they are arranged to create harmony, contrast, dynamism (Monö, 1997).

The gestalt laws are principles based on the human perception. The gestalt laws consist of four categories, i.e. proximity, similarity, closure, and good continuation. Things that

have something in common such as buttons and regulators should be arranged close to each other. Things that have the same meaning or function should look similar. Closure means that the human use to read objects with missing parts as complete based on known knowledge. Continuation means that the human use to consider predictably extensions as part of e.g. a line and that line are then followed.

Semantics is the study of the product sign as a message. Semantics deals with the message in the design i.e. what does the product want to describe, express, exhort, identify? The semiotic perception comes from signs that can be heard, seen, felt, smelt or tasted.

The product has four semantic functions:

to describe: purpose, mode of operation

to express: properties

to exhort: reactions

to identify: a product, its origin, kinship, location, nature or category

(Monö, 1997)

Semantics can effectively be used for expressing the function of the product, e.g. how it will be gripped and how it will be operated e.g. by rotation or pull. Other semantic functions are: What the product express by its shape, e.g. lightness, stability. What brand identity values will the product elicit? What social values will the product express? Monö describes the current product sign as the market's conception of the way in which a product's principal function is traditionally represented in its gestalt.

3.4 Physical Ergonomics

When designing for people a target population of users are defined. The principal factors to take into account are in general sex, age, nationality and occupation (Pheasant, Haslegrave, 2006). When designing products for a wide population with many nationalities the smallest and largest measures are considered and then measures are set that are considered to be acceptable for the target group. Anthropometric measures for different nationalities, ages and occupations are limited and therefore estimations have to be made based on the accessible data. For this project the standard standing posture was taken into consideration for estimating the height and placement of the concentrate package module. The body dimension, shoulder-grip length, was also taken into consideration for defining the placement of the module. The measures taken into consideration for this project is based on the user described in the section User Description in chapter 6. The Scheme of zones for convenient reach was studied when evaluating how well the concentrate attachment can be reached. In the design of medical equipment it is also essential to avoid involvement of inconvenient twisting, rotations, small grips and hard pressing. Many nurses already have tension in wrists and fingers.

The grip strength varies a lot between individuals but varies also depending on what kind of grip the human is using. Some grips are more convenient for the user while other causes tension to a larger extent. The grip strength is greatest when the wrist is in its neutral position – reducing progressively as the wrist moves away from the neutral position in any direction e.g. flexion, extension, radial deviation and ulnar deviation. The grip strength is limited when the wrist is flexed because the flexors are shortened and

thus the capacity to generate tension is diminished. When the wrist is in its neutral position, the handle will be in an angle of 100-110 degrees to the axis of the forearm. (Pheasant, Haslegrave, 2006)

If the working level is too high, the shoulders and upper limbs will be raised, leading to fatigue and strain in the muscles of the shoulder region. If any downward force is required in the task, the upper limbs will be in a position of poor mechanical advantage for providing it. If the working level is too low the trunk, the neck and head will be inclined forwards with consequent postural stress for the spine and its muscles. In general 100-250 mm below elbow height for downward pushing forces is recommended for adults. (Pheasant, Haslegrave, 2006)

Approximately 90% percent of the population has a dominant right hand and the remaining 10% have a dominant left hand. The product design will preferably be designed for both left and right handed people, if one group has to be promoted, the right handed users will be chosen since this group is dominant. (Pheasant, Haslegrave, 2006)

3.5 Cognitive Ergonomics

In order to make a product interface with good usability the designer must have some insights in the human cognitive processes. When interacting with a product the user must take a lot of decisions about their handlings. Decision making look different depending on what kind of action the human is to do and what strategy the human use for performing the task. In 1983 Jens Rasmussen developed a model to categorize decision making, it was called the SRK model. The SRK model describes the human decision making process as three levels of behaviour i.e. skill- rule- and knowledge based. On the skill based level are activities that are made unconsciousness. Rule based activities are made by routines, old knowledge and rules. The knowledge based activities need active problem solving, for example in the interaction with new products. These three levels are often combined in the decision making process. (Osvalder, Ulfvengren, 2008) For example when opening a new kind of box package first time, most users may use a combination of knowledge based problem solving combined with rule based decision making derived from the users previous knowledge of how a package is used to be opened.

In a usage situation a user usually have a mental model for how an artefact is functioning and how it is supposed to be operated. The user uses the mental model in order to predict an occurrence, find reasons for errors, help for decision-making, understand task sequences, and recall information. The designer's goal is to design the product so that the intended interaction matches the users' mental model. If the product differs from the users mental model use errors can occur and the user can feel irritation.

Use errors can be categorized into five error types that are based on why the user is performing a use error. This categorization is based on GEMS, Generic Error Modelling System. The categorization of use errors can be useful when e.g. evaluating a product or system. Once identified a reason for the error it is easier to find an appropriate solution for the problem. The five categories are: (L) Lapse –the user is forgetting the intention of the action. (S) Slip – failed attention during execution. (R) Rule-based mistake –

misapplication of good rules, i.e. well-known rules are used incorrectly to make a decision. (K) Knowledge-based mistake – wrong decisions based on own conclusions drawn from prior knowledge and known rules. (V) Violations –intended act or omission of act that violates present regulations and/or instruction e.g. breaking rules. (Reason, 1990)

4 WORK PROCEDURE

The work procedure of this master thesis will be based on the development process, *Utvecklingsprocessen ur ett människa maskinperspektiv*, (*The Development Process from a Human-machine Perspective*), developed by Lars-Ola Bligård. It is an iterative process with four continuous activities, i.e. planning, information collection, evaluation, documentation and six sequential phases i.e. identification of needs, function & task design, conceptual design, detailed design, mechanical design, use and maintenance. Each of the sequential phases includes a loop of analysis, idea generation and synthesis. This Master Thesis will include all of the four continuous phases and the three first sequential phases that end up with a conceptual design solution.

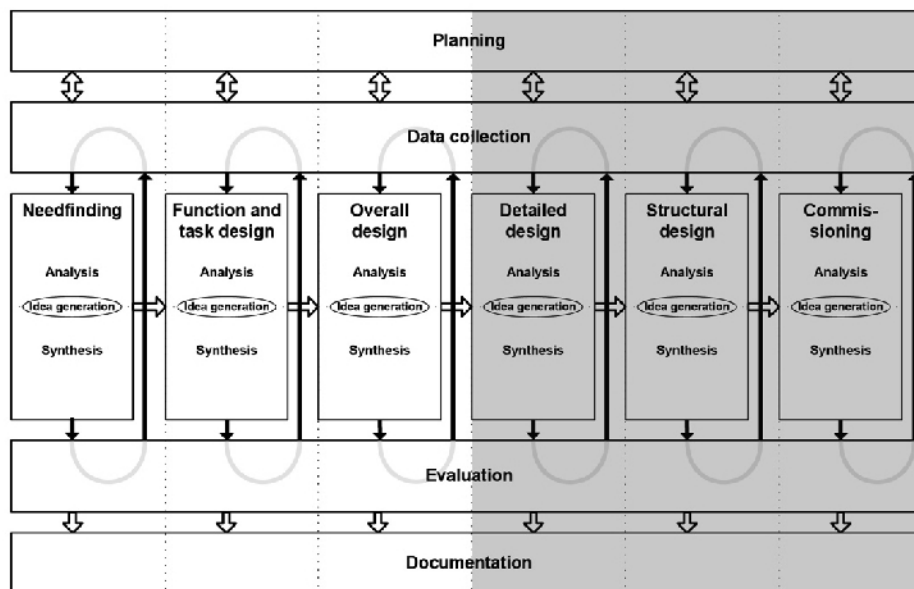


Figure 4-5 Illustration over the work procedure. (*Utvecklingsprocessen ur ett människa maskinperspektiv*, Lars-Ola Bligård.)

4.1 Continuous Activities

During the product development there are activities that are ongoing during the whole process, i.e. planning, information collection, evaluation and documentation. These activities will be described further in this section.

4.1.1 Planning

The planning is a dynamic phase that will be developed more into detail during the project and changes can be done as the project proceeds. The planning includes defining aims and goals and to set up a plan for when the activities will be done.

4.1.2 Information Collection

The information collection is done continuously from the project start till the end. This phase aims to collect information about: the product, the usage, the environment, the company (Gambro), standards, technical solutions for the product and previous studies.

4.1.3 Evaluation

The evaluation aims to measure how the goals and requirements are fulfilled.

Evaluations are made continuously to detect weakness early in the development process in order to diminish the cost for changes. The evaluation will elevate the following five aspects: usefulness, utility, usability, function, risks; with testing and verification.

4.1.4 Documentation

The documentation is done continuously and aims to clarify and communicate the development process. The documentation phase contains e.g. method descriptions, instructions for usability tests, protocols from observations, sketches, risk analyses, list of demand, documentation of the process etc.

4.2 Sequential Phases

In the development process there are also some phases that are followed after one another. In this project three sequential phases were elaborated i.e. Needfinding, Function and Task Design and Overall Design. These phases will be described further in this .

4.2.1 Needfinding

The goal of the first sequential phase is to describe the content and boundaries of the project work. The activities are e.g. to describe the stakeholders, research of existing products, use and users, define the need from the use and users etc.

4.2.2 Function and Task Design

The aim of this sequential phase is to clarify the function and usage of the product. In this phase starts the development. The activities are e.g. function analysis, develop the aimed usage of the product, transform users needs to product demands, develop ideas and solutions for the interaction, aesthetics, and function.

4.2.3 Overall Design

The goal of the concept development phase is to come up with an overall design of the product. This phase will result in product concepts of a concentrate package, a box and a concept for how the package will be attached to the dialysis machine.

5 METHODOLOGY

In this chapter the methods used are described briefly in alphabetical order. The aim is to introduce readers that are not familiar with the terms and methods.

5.1 Brainstorming

Brainstorming is a method for generating of a large number of ideas. In the brainstorming session about 4-8 people are gathered, preferably from different expertise areas. The idea is to generate as many ideas as possible and to combine and build upon colleagues' ideas, no criticism is allowed during the brainstorming session. (Cross, 2004)

5.2 Cognitive Walkthrough (CW)

The Cognitive Walkthrough analysis aims to theoretically analyse if the user will complete the actions correctly. The potential use errors are categorized into five categories that explain why the user is performing a use error. The classification is: L (lapse), S (slip), R (rule-based mistake), K (knowledge based mistake), and V (Violations). These error types are described more into detail in section 3.5. (Bligård, & Osvalder, 2009)

5.3 Function Allocation

The function allocation method aims to specify what tasks will be performed by the human and what should be performed by the machine. The purpose is to identify when it is needed or beneficial to let the machine support the human and what tasks the human do better than the machine.

5.4 Function Analysis

A function analysis aims to identify why the product exists, its main function, necessary functions and desirable functions and how this can be achieved. The analysis results in a list of requirements that is used as a checklist and for concept evaluation within the product design development.

5.5 Hierarchic Task Analysis (HTA)

The HTA diagrams aims to identify, organize and represent the user interaction by breaking a task into subtasks. The task analysis ends up with a framework that defines the relationship between different subtasks within the task in respect to chronology and hierarchic level. The HTA diagrams also function as a ground structure to base analysis methods on further in the project. (Sandom, & Harvey, 2004)

5.6 Image Board

An image board is a collection of images which purpose is to inspire and convey expressions. There are different types of image boards e.g. usage boards, styling boards

mood boards and lifestyle boards. The general idea of the image board is to collect inspiration on a particular theme and to communicate intentions within the project group or for the client.

5.7 Interviews

Interviews can be organized in different ways such as structured, semi structured and unstructured. Structured interviews are performed after predefined questions. Semi structured interviews contains open questions as well as closed questions. Unstructured is a more free type of interview and doesn't follow any interview plan. (Lantz, 2007)

5.8 KJ Analysis

Data from e.g. interviews and the user studies can be analysed by KJ analysis that is a method to group the information into categories. The method can be used to organize information from a data collection or brainstorming session etc.

5.9 Morphological Matrix

A morphological matrix is a method used for categorizing and combining ideas into concepts in a structured way. A number of sub-problems or sub-areas are first specified. Then all the generated ideas are grouped into these categories. The next step is to combine the sub-ideas and form concepts.

5.10 Osborne's Idea Spurring Checklist

This is a method used in the idea generation phase. The idea of the method is to trigger new ideas for solving the problem by using the following eight words: Adapt? Modify? Magnify? Minify? Substitute? Rearrange? Reverse? Combine? (Österlin, 2004)

5.11 Predictive Human Error Analysis (PHEA)

This is a theoretical error analysis where an expert is evaluating the concept. The aim of the analysis is to detect potential use errors.

In the appliance of this method the category "detect" was replaced by "prevention". The aim of adding "prevention" to the analysis was to start an investigation of how the concept can be improved for prevention of the actual use errors.

5.12 Rapid Prototyping

Rapid prototyping is a manufacturing process for prototypes or small series. A CAD-file with the product model is sent to a 3D printer that writes the product in a polymeric material. There are many different types of rapid prototyping processes at the market, some are writing the product by layers while there is another method is hardening the material at places where there will be material and the remaining material can easily be removed.

5.13 Scenario

A scenario is a storyline about the user's use of the product. The persons involved in the use case are hypothetical users of the product and the description aims to be realistic and mirror a real use situation. (Cross, 2004)

5.14 Several Criteria Method - Elimination Method

There are many different methods for concept evaluation. For this project Several-Criteria Method was used. This is a method where the concepts are evaluated against criteria. The level of fulfilment is graded 0 – 3 and a total score can be calculated of each concept.

5.15 Sketch Models

Sketch models are three-dimensional models that are created early in the concept generation phase in the purpose of evaluate a function, proportions, volume, geometry etc. The benefit of sketch models is that it is a quick way to make a representation of the product, often many versions of sketch models are made for the product during the design development.

5.16 System Description

A system description is performed in order to get an overview of the human-machine system and how the elements in the system are linked to each other. The system description visualizes how material, energy and information connect the elements in the system.

5.17 Use Profile

A use profile is a way to classify the users' relation to product. The relation is investigated under the categories; use experience, influence and responsibility of use, emotional responsibility to the product and degree of interaction with the product. (Janhager, 2005)

5.18 User Studies

The user studies aims to observe the actual usage in its real context. The user interaction with the product will be studied; unpacking, mounting, usage, demounting, as well as the product context; how the people are organized, activities around the product, other products or systems close to the product etc. From the user study essential requirements from the context and the usage situation are to be identified. (Jordan, 1998)

5.19 User Tests

User test is an evaluation method that can be used in different stages in the development process. The purpose is to evaluate how a concept or product is in a usage situation. E.g. Does the user understand how the product is aimed to be operated? Does the user's

mental model correlate to what the product is communicating? Etc.

5.20 What if?

What if? is a risk analysis method which is performed theoretically by an analyzer. The idea is to go through possible errors, hazardous situations and accident events and ask what if...happens? Then try to find an answer of the question and estimate the likelihood and consequences. (Bligård, in press)

6 NEEDFINDING

Needfinding is the first of the three phases in the work procedure where results from the studies are presented. The needfinding phase aims to identify the product's aim, the users, the environment and the usage. Advantages and disadvantages of the existing concentrate products have also been investigated together with the users in order to collect information about the users need, expectations and experiences. The information is based on information gained from user studies at three Swedish hospitals.

6.1 Dialysis concentrates

Today the dialysis concentrates are available in different concentrations and mixtures and different kind of packages in different price ranges. The dialysis concentrates are packed either in large canisters, smaller bottles, cartridges or flexible packages of different sizes. Some packages are smaller since it has a higher concentration and are added with water in the machine. Normally one package is estimated to last for one treatment. The packages is usually delivered to the dialysis ward once a week and stored in a storage room until they will be used.

6.2 Existing Products - Advantages and Disadvantages

In this section existing dialysis packages are evaluated from a users perspective, the information is based on interviews and user studies at dialysis wards in Sweden. The visited hospitals used Gambro products and hence the study is limited to these products.

6.2.1 Secondary Package –Cardboard Box

The secondary packages are holding the concentrate from factory to the hospital. As an example the SelectBag® One is made of cardboard and has a weight of 6 kg when filled (6 packages in each). The concentrate packages are usually distributed to the dialysis wards in these cardboard packages and stored in storage rooms until they will be used. At some hospitals the pharmacy personnel unpack the packages. When the packages are unpacked the secondary packages are flattened and put in containers for recycling. When opening the new packages with knife it's a risk

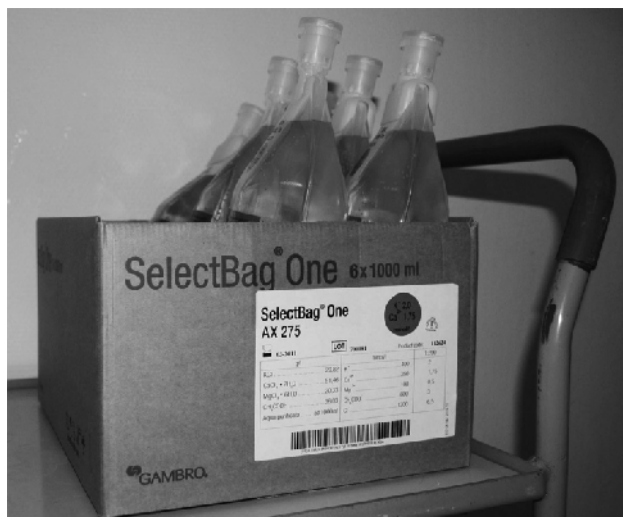


Figure 6-6 Secondary package

for concentrate packages to break inside the package. There is also a risk that the nurses hurt their hands when opening and flattening the packages. One of the interviewed nurses expressed that it is difficult and time consuming to fold the empty packages, and she often has to jump on them in order to get them flat. Another interviewee pointed that the folding of the packages is a “dirty” job and often the next working situation is a “clean” working task with high ordinance of cleanness.

6.2.2 Canister

Canister packages are made of rigid plastics and contain either 6 litres or 10 litres of concentrate. The canister package is rarely used in Sweden but common in developing countries and some western countries e.g. Germany. At one of the visited dialysis ward they used the canister when they had machinery problems with the SelectBag® One. The canisters are connected to the dialysis machine by a pick-up tube that is put in the canister. When the tube is attached it is a gap around the opening that could be a hygienic risk for the patients. The canisters are heavy to carry when they are filled and they are bulky to store before and after usage. The lid is hard to open and they often use a special tool to open it. The users appreciate the handle of the can to ease the bearing. When the dialysis concentrate is in use the canister is usually standing on the floor and in some cases on the tray at the lower part of the machine. Sometimes the remaining concentrate after a dialysis treatment is saved up to one week.



Figure 6-7 Canister.

6.2.3 SoftPac™ (Type 1)

The SoftPac™ is a semi flexible package available in two sizes 3 litres and 5 litres. These packages are quiet heavy and hard to handle since they are difficult to grip and they doesn't have any handles. The package has holes at the top where the package can be hooked to the dialysis machine. The package is connected to the machine by a connector. To empty the package after usage the user has to cut the package with a scissor.



Figure 6-8 SoftPac™ (Type 1)

6.2.4 SoftPac™ (Type 2)

This is a flexible package of 5 litres volume, with a handle in one of the short sides. This package is connected by a spike. The flexible package is supposed to be hooked to the machine but the visited users find it too heavy to hook to the machine when the package is filled. Usually it is laid down and hooked only occasionally in the end of the dialysis in order to empty it properly. Another difficulty with hanging the package is the issue of see the opening, which is at a low height at the bottom of the package.

The flexible package is bulky to handle before use and uptakes large space in the storage rooms. On the other hand it's easy to handle after usage, when it is a flat. Before the package is connected to the machine, a membrane has to be removed from the package. This membrane is somewhat difficult to grab.



Figure 6-9 SoftPac™ (Type 2)

6.2.5 SelectBag® One

The SelectBag® One is a semi flexible package containing one litre which is connected to a holder at the left side of the dialysis machine. This packages is commonly used to the Gambro machine AK 200™ S, but doesn't fit dialysis machines of other brands. The SelectBag® One package is popular among the nurses since it is small, light and easy to grip. The package is large enough for dialysis treatments of normal length but for long dialysis treatments it has to be changed during the ongoing treatment, which is time consuming.



Figure 6-10 SelectBag® One

The Package has a lid to open before it's connected to the holder. Some nurses experience this cap to be hard to open and it doesn't provide any good grip. When put into the holder the membrane in the opening breaks. Most of the interviewed users appreciate the flexibility of the package but someone pointed out a risk for leakage if the user presses the packages too hard when the package is open.

After the treatment there use to remain concentrate in the package. This liquid is supposed to be emptied automatically by the machine but the emptying process takes about 5-10 minutes and often the nurse doesn't have the time to wait until it's totally empty. The nurses want to start the disinfection program as soon as possible in order to get the machine ready for the next coming patient. Therefore the packages are thrown directly into the trash bin or in some cases emptied manually in the drain. Since the concentrate smells, this is not a good solution from a user perspective.



Figure 6-61 Attachment of cartridges and SelectBag® One on a AK 200™ S dialysis machine. The cartridge holders look the same as on the AK 96® dialysis machine today.

There are sometimes troubles with the machinery when using the SelectBag® One on the AK 200™ S machine. When problems occur the machine sends alarms, gives error messages and the dialysis process stop. The nurses select the type of concentrate in the menu but it doesn't correspond to the measured conductivity that results in an error message about wrong product. The way to come around this problem is to change to another kind of concentrate package e.g. cans.

6.2.6 BiCart® / SelectCart®

The B concentrate and the salt are in cartridge packages in



Figure 6-11 Cartridges.

form of powder. These packages are connected to the holders on the left side of the dialysis machine. Water is mixed with the powder inside the cartridges during the dialysis process and is automatically emptied after use, but about $\frac{1}{4}$ of the powder will usually remain after a treatment of normal length and is not possible to remove without tearing the package with some kind of tool. All visited users dispose the cartridge packages without emptying them. The users have difficulties with the caps at the top and bottom of the packages since they are too small to grip and hard to remove. There is a “parking place” for the caps aimed for placing the caps during the treatment, but these haven’t been used at the visited wards. Some throw them away; other users save them on other places until it’s time to remove the cartridges from the machine, replace the caps and throw it in the trash bin. Some dialysis wards had a cutting machine before to use for opening the BiCart[®] and SelectCart[®] packages in order to empty them and recycle the plastics. This cutting tool was dangerous and cumbersome to use according to the interviewees who had experience from this.

6.3 Summary of the Package Trial

- All the interviewed nurses preferred flexible packages like the SelectBag[®] One before rigid plastic except one who liked packages like BiCart[®] better.
- Small packages are preferred especially after treatment when the packages will be disposed.
- The weight of the product is important, the lighter the better.
- The time it takes to prepare the machine before a treatment, the priming, is very valuable and should not be too long.
- To empty the concentrate container should be easy, fast and not cause health problems for the users. The best would be if the machine empties the container automatically, while the nurse is cleaning the machine.
- The packages should be easy to dispose; small, lightweight garbage is preferred.

6.4 Task Description

The primary user’s interaction with the concentrate packages are described by charts, HTA (Hierarchical Task Analysis) diagrams which describes the relation between the subtasks for performing the main task, in this case to connect the concentrate package to the machine. Interaction with two types of packages are analyzed, SelectBag[®] One and a canister. These diagrams can be found in appendix B.

6.5 Interviews

Ten semi structured interviews were held with nurses from the visited hospitals. The results from the interviews were coherent to a large extent but some subjective thoughts about how they liked the products differed slightly among the individuals. The interviewees were both male and female and had between 4 and 24 years work

experience of dialysis. Also some more informal chatting with patients was held in order to hear about their picture of dialysis and how they found the dialysis equipment. Some of them operated the dialysis machines themselves. A few of the interviewed nurses had previous experience of central distributed concentrate i.e. the concentrate is delivered to the machine through pipes from a central at the ward. The amount of different concentrate packages and systems used gave a wide insight in the handling of concentrates today. The data gathered from the interviews and user studies were analysed by using KJ analysis.

6.6 Before During and After Analysis

Before During and After, is a description of the overall interaction with the dialysis concentrate at the hospital.

Before

The concentrate packages are delivered to the dialysis ward about once a week. The packages are packed in boxes e.g. six SelectBag[®] One packages a 1 kg in one cardboard box. Until the usage the packages are stored in a storage room at the dialysis ward. At some hospitals the packages are unpacked by the pharmacy personnel and then delivered to the wards on trolleys. In the preparation of the dialysis treatments the nurses pick up the concentrate packages of the right concentrations for each patient. Before the treatment starts, the nurse opens the concentrate package and connects it to the machine. The type of concentrate then has to be confirmed in the screen menu.



Figure 6-7 Trolley with dialysis concentrates.

During

Concentrate packages can in some cases run out during an ongoing treatment. In this case the package has to be changed which causes an unwanted stop in the treatment.

After

After the treatment the concentrate package is detached from the machine. Remaining concentrate in canisters can be saved up to one week. In the SelectCart[®] and BiCart[®] packages there is usually some concentrate remaining after a treatment that cannot be emptied. The SelectBag[®] One automatically empties after the treatment. Then the package will be put in the trash bin. At some dialysis wards there is a system for sending the used packages for recycling. Finally the nurse cleans the machine and starts a disinfection program of the concentrate flow path.

6.7 System Description

Dialysis concentrate is a part of a system and cannot be isolated; therefore a system description was performed. This system description is a simplified graphical overview of the elements involved in the dialysis treatment and illustrates how the interactions are organized.

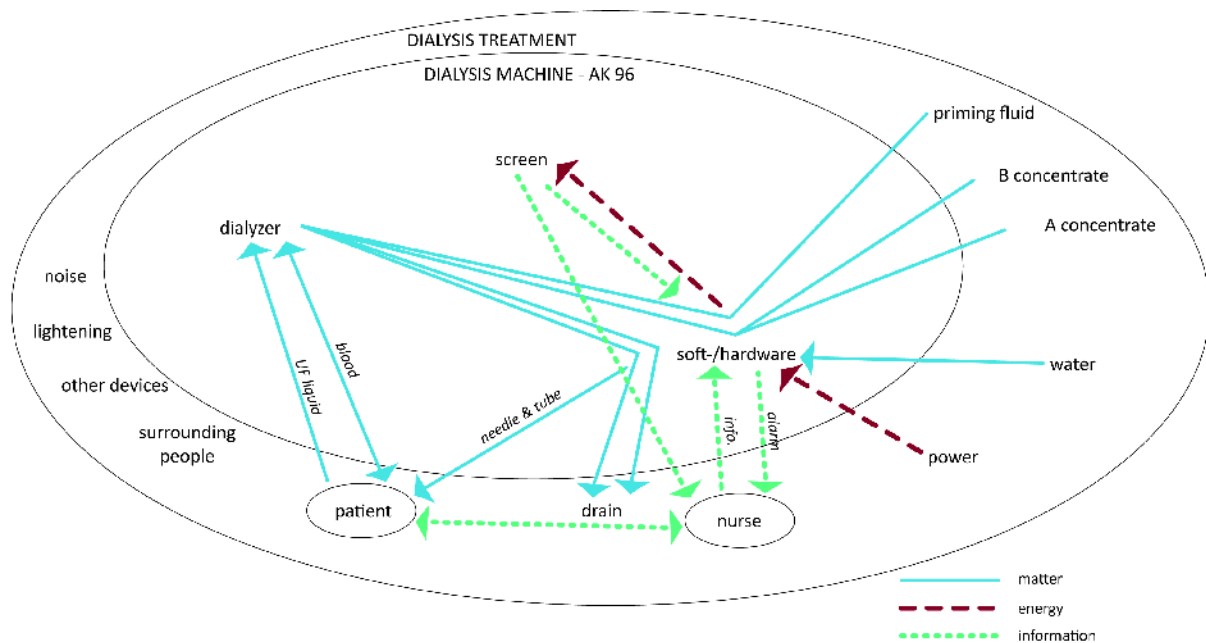


Figure 6-8 System description over the dialysis treatment process.

The system consists of three primary factors, the dialysis machine, the patient and the nurse. The machine consists of the main components; screen, dialyzer and software/hardware, which are placed in the inner area of the system description. Into the machine system come matter, energy and information in form of concentrates, water intake, power, and information from the nurse. During the treatment the patient is connected to the machine by tubes and blood from the patient is circulating through the dialyzer and UF liquid is taken from the patient. The system of the machine, nurse and patient is also affected by outer factors like lightening, other devices and noise.

The nurse is interacting with both the patient and the dialysis machine. The nurse gets information about the status from the screen, gets alarms from the machine, gives information to the machine by interacting with the control panel and has a two-way communication with the patient. See picture above.

6.8 User Description

Designing for usability includes designing for a specified user group. In the following text the aimed user group is described. The dialysis concentrates as well as the dialysis machines are primarily handled by nurses working at dialysis wards. The patients themselves in home environment can also handle the dialysis machine, but this is a minor market. The Gambro dialysis concentrates are distributed to hospitals all over the world. The nurses can be both male and female, of different nationalities and are aged about 20-65 years old. The education of the nurses can differ between different regions of the world. The experiences of dialysis treatment and the handling of concentrates differs a lot from user to user depending on how long time they have been working with dialysis. At the visited wards the learning period for the dialysis nurses differs between 6 weeks and three months. Within his period the nurse will be educated to operate the dialysis machine independently, needle the patients and learning other kind of work at the ward. The nurses always have colleagues to ask for help or for discussions whenever they need. Often they work in teams of two or three nurses per four - six patients. Apart

from the nurse there are also other types of users involved in the interaction with the product. Below the types of users are categorized according to the model of (Janhager, 2005).

User type	Who?	Explanation
Primary user	Nurse	Primary user uses the product for its primary purpose.
Secondary user	Manufacturer/ Salesperson/ Technician	Secondary users interact actively with the product but doesn't use it for its primary purpose.
Co user	Nurse colleagues/ Physician	The co-users are those who cooperate with the primary user or secondary user.
Side user	Patient	Side users are affected by the product's function.

Figure 6-9 Analysis model after Janhager 2005 applied on a dialysis machine

The nurses start and finish between two and five dialysis machines each per day. Many dialysis nurses have ache in their hands and joints because of repetitive twisting and pressing moments in the daily work.

The nurses have a large degree of responsibility in their handling with the dialysis, if something goes wrong it can affect the health of the patients. The Dialysis machines have a great system for detecting and warn the user for potential use errors. However some types of mistakes, laps and slips can still happen and the challenge in the product design is to prevent these and to make it possible recover from errors.

Regarding use errors related to the dialysis concentrate there is a risk to connect wrong type of concentrate mixture. If this happen, the nurse have to look in the medical record and find out what the consequences will be for the patient. Sometimes the dialysis has to be interrupted and the concentrate has to be changed. The nurse can also ask a physician for advice.

6.9 Use Profile

The following chart is an overview of the primary user's relation to the concentrate product. It locates what important aspects to focus on in the interaction design. The aspects of high importance are located where the base of the triangle meets the coloured area. E.g. in the second row ergonomics and stress factors are considered to have an importance of high extent since the product has a high frequency of use.

importance of high extent ▼
importance of low extent ▲

	Categories	Degree of performance	Extent of importance of the product
Use experience	Length of use and education	Newcomer Experienced Specialist	easy to understand and use
	Frequency of use	Rare Occasional Frequent	ergonomics stress factors
Influence and responsibility of use	Influence on the choice of product	No influence Some influence Great influence	adaptability
	Influence on the use situation	No influence Some influence Great influence	physical ergonomics confidence
	Responsibility in use	No responsibility Some responsibility Great responsibility	reliability confidence
Emotional relationship to the product	Ownership	Use of general product Use of rented product Use of owned product	easy to use characteristics adaptability
	Social aspects	Of little importance Of some importance Of great importance	aesthetics/sence characteristics
	Mental influence of product	No mental influence Some mental influence Great mental influence	semantics aesthetics/sence
Degree of interaction with the product	Cognitive interaction	No cognitive interaction Some cognitive interaction Great cognitive interaction	semantics
	Physical interaction	No physical interaction Some physical interaction Great physical interaction	physical ergonomics

Figure 6-10 Use profile applied on a dialysis machine. Analysis model after Janhager, (2005).

One can see in the use profile analysis chart that the reliability and confidence are important aspects to consider since the user have great responsibility in the use situation. On the other hand the adaptability is of low or general importance as well as the semantics and aesthetics, due to the minor importance of social aspects and moderate level of cognitive and physical interaction.

6.10 Context Description

At some wards the patients are treated in rooms of about four patients, while other dialysis wards have another organization with about ten patients in one room and a desk in the middle where the nurses control and overview the patients. It could be compared to an open office environment where many machines are placed in one room. There are more noises that affect the users in the larger rooms since there are more

people chatting as well as more noises from the machines that have a background noise and are sending out loudly alarms now and then. The patients have the ability to press an alarm button whenever they need help from the nurses. The patients' alarm, as well as the machine alarms sends out in the corridor and in the lunchroom.

The patients are coming regularly to the hospital, usually 2-5 days a week and the nurses know them well. The working day is planned in the morning, the nurses know which patients are coming and what treatment they will have and for how long each treatment is estimated to take. But unexpected changes can always happen depending on how the patient feels and if something happens in the treatment process.

The dialysis machine is used daytime at the dialysis wards and the lightening in the room comes from the daylight and fluorescent lamps. At one of the visited dialysis wards, they used upright laps as a complement, since they had experienced annoying screen glare on the machine monitors caused by florescent lamps.

At the dialysis wards they often use two different types of A-concentrate packages, each of different types of concentrates in order to individualize it for the patients' actual status. There is often a need to have a complement to the SelectBag[®] One since it causes problems in the start now and then. Another reason for using different concentrate packages is that they often have different types and a brand of machines and all packages doesn't fit all types of machines. The Gambro BiCart[®], SelectCart[®] and CleanCart[®] packages are for example designed to fit a special holding device which are only common on the Gambro dialysis machines. The customers are then forced to buy the whole concept from the company. Competitors are also using their own concepts of concentrate packages and holding devices.

6.11 Scenario



Figure 6-11 Dialysis treatment.

It is seven a clock in the morning and the nurses at the dialysis ward are preparing the machines. Maria one of the nurses, is preparing an AK 200[™] S dialysis machine for a normal HD (hemodialysis) treatment. She brings all equipment e.g. tubes, dialysis filter, needles and concentrates from the storage rooms. Then she mounts the concentrates to the machine and the tubes, dialyzer and the saline. Then she starts a priming program which aims to check if the system is ok and that there is no air in the tubes. Maria is documenting in the patient's medical record what fabricate number (called LOT- number) there are of the equipment e.g. tubes, filter, dialysis machine and the concentrates. Some packages have a removable LOT- number sticker that can be placed in the medical record. Maria prefers the stickers since it is easy and prevents writing errors.

At half past eight John a 55 years old patient comes to the ward. The nurse Maria checks his weight and she calculates that he has got 2,2 liters more than his dry weight today. She asks if John wants to drink something during the dialysis. John wants a glass of juice and hence 2.4 litre of liquid will be removed today. The weight, flow rate and medicine are also documented. Maria sticks two needles into Johns so called fistula in his left forearm. Now it's time to start the dialysis so she connects the tubes to Johns arm. The blood will circulate in the dialysis process for four hours. During the treatment Maria will come and check the blood pressure, pulse and the machine settings. John usually watches TV and eats breakfast during the dialysis treatment.

The machine sends an alarm when it is finished. One of the dialysis tubes is reconnected to the saline bag and the blood in the tubes is given back to the patient. The machine starts to empty the A-concentrate package (SelectBag[®] One) and the liquid in the B-concentrate (BiCart[®]) and the salt (SelectCart[®]). Maria removes the second needle from John's arm and gets some help from a colleague to remove the tubes from the machine and to clean it.

The BiCart[®], SelectCart[®] and SelectBag[®] One packages are removed and then Maria starts the heating program. Maria wants to start the heating program as soon as possible, since another patient will use the machine in the afternoon, so she often removes the SelectBag[®] One from the machine before it has been emptied and empties it manually, but it is acidic and smells terrible so she wishes there where a better way to empty the container.

John's weight is checked again and then it's time to leave the dialysis centre for today. He visits the dialysis centre on Monday, Wednesday and Friday, every dialysis treatment is four hours long. It's kind of a part time job, he says.

6.12 Design Specification

Who is the user? The primary users are nurses at the dialysis ward or private operators using dialysis at their homes. The secondary user is the passive patient. Home dialysis is a minor market where the patient is operating the machines themselves and hence a patient could also be considered as a primary user.

What is the product aimed for? The container will provide the dialysis process with concentrate.

Where? The product is aimed to be used at the dialysis ward and in homes. The product will most probably initially be introduced in developing countries like the Chinese market. The package has benefits for clinical use even if it is more obvious for home use.

How? The package is distributed to the hospital in box packages. The concentrate packages are then unpacked and connected to the machine before each treatment.

When? The interaction with the product is mainly when preparing for a treatment and after the treatment when cleaning.

Why? The concentrate is used in the dialysis process to clean the blood. The package for the concentrate aims to hold the concentrate in the distribution before the usage and during the treatment.

For how long time? The concentrate is used during the dialysis treatment. A normal dialysis treatment is about four hours long. The primarily user's physical interaction with the product is when unpacking the concentrate packages, when mounting it to the machine and when taking it from the machine and handling the waste.

6.13 Aim of Usability

The aim of the usability for the project is to develop a concept for handling with dialysis concentrate by dialysis nurses primarily. It would be an advantage but not a must to make a design with a high level of intuitiveness so that a user can understand the interaction first time. The ability to do the right operations after learning the system is more important since expert users use it. The users operate the dialysis concentrates frequently every workday but it should be easy to remember the operation sequences after e.g. a couple of weeks of holiday. Further the system should satisfy the users in the user interaction, not irritate the users and it should prevent use errors and enable the ability for recovering.

6.14 Rules and Guidelines

In the medical technology field there are many regulations for the product development in form of standards and guidelines. For human factors there are IEC 60601-1-6 and IEC 62366 to follow. An additional standard is used as a guideline to the process, namely the American National Standard HE75 that has to be fulfilled for products exported to the United States. The standards concern the process of developing user centred products for medical devices. The process must for example involve the users in the some activities of the development phases, such as usability testing of prototypes.

7 FUNCTION AND TASK DESIGN

The aim with the function and task design development is to specify the function and usage of the new product that will be developed. In this phase the requirements of the product is specified and a system goal, usability goals and utility goals are set.

7.1 System Description of the Dialysis Fluid

The chart below is an illustration of the flow path and a description of the user interaction with the dialysis fluid. The picture is a metaphor of a heliocentric solar system where the user is the “sun”.

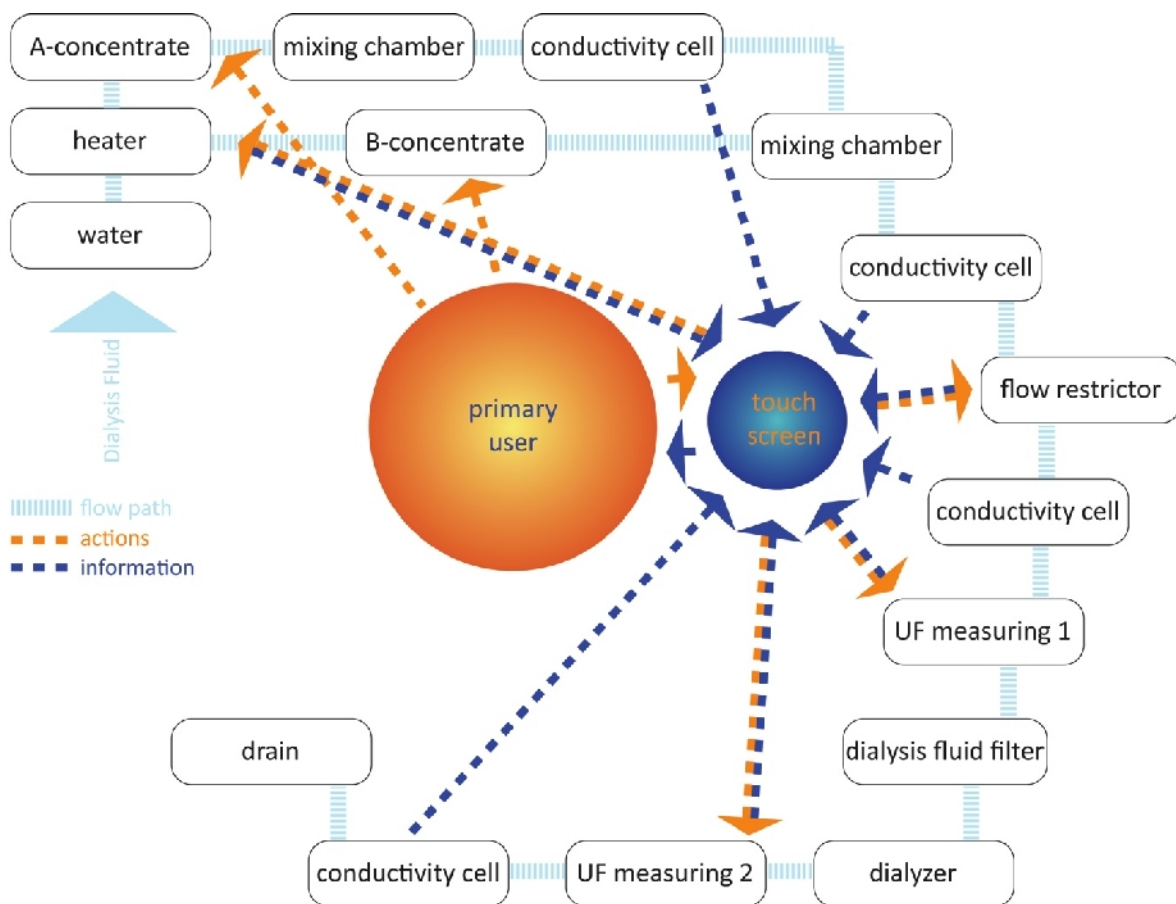


Figure 7-12 System description of the dialysis fluid

The primary user performs user actions in terms of physical interaction with the A-concentrate package, B-concentrate package and with the touch screen. The touch screen transfers the user actions to the:

flow restrictor - wanted flow rate

heater – wanted temperature of the dialysis fluid

UF-measuring cells – settings for the draw liquid are set, where the differences of the volume in cell 1 and 2 is the drawn volume.

The user can read information on the screen about the actual temperature of the dialysis liquid, the flow rate, the UF-volume, and the type of concentrate (conductivity cell). All

information is available in the screen menus whenever the user needs it. In the schematic picture above components of minor importance without interaction with the primary user are disregarded in this flow chart, e.g. valves and pumps.

For the redesign it would be beneficial to provide the user with supporting information on the screen about how the concentrate packages are supposed to be attached to the machine, step by step.

7.2 Function Allocation

In order to decide what functions the user will make and what functions the machine will do, a function allocation analysis was made for the new package concept. Some functions are suitable or necessary to let the user do while others can be done automatically by the machine system.

Today the LOT-number is a number on the package label that will either be written in the medical record or pasted in the analogue record by a sticker. A new technique is available for digital decoding of such LOT-numbers and it is assumed that this technique will be applied to the machine when the new package is launched. This kind of transference from human task to machine task is an advantage since the user will have one task less and the risk of decoding wrong number will also be decreased.

The decision of when the concentrate has been mixed should be taken by the machine and communicated by information to the user. It is important that the user can see that the concentrate has been mixed and that the visual appearance of the solution doesn't say anything else than the information from the machine.

In the task allocation chart (appendix D) the human's functions are at the left side while the machine's functions are set to the right. The tasks related to the dialysis concentrate are marked with boxes and the arrows indicate the workflow. This Function Allocation analysis considers the main tasks; some tasks of minor importance have been neglected in order to highlight the main tasks that are essential for the design of the concentrate interaction.

7.3 Function and Task Analysis

In the function and task diagram the identified requirements for the package concept are listed and categorized into three categories:

Main function, **N**ecessary function, **D**esirable function

Task Requirements

Assist the dialysis process with dialysis solution	M
Secondary or primary package that is impenetrable to water	M
Ability to mount without leak	N
Ability to see the concentrate through the package	N
Know when the concentrate has been mixed properly	N
Know that the solution has the right proportions	N
Ability to let the package stand when filled	D
Be connected to the dialyze machine	M
A connector placed at the <i>base</i> of the holder	N
Have a conic shape at the base of the concentrate container	N
Empty the concentrate container within 20 seconds	D
Ability to disinfect all components that will have contact with the dialysis fluid	N
Available in 4-5 formulations	N
Contain 1,8 litre of powder, i.e. 1800 g	N
Contain a chamber that can assist the FCH with dialysis fluid	D

Use Requirements

Ability to handle easily when filled with liquid	D
Quick and intuitive to connect to the dialysis machine	N
Have the A concentrate on the right side and B-concentrate on the left side order to be consequent with existing "standards"	D
Clear differentiations of the different mixture packages	N
Lightweight and small	N
Be connected to the machine at a convenient height	N
Avoid interaction which can cause tension in e.g. fingers, arms, legs and back	N
Ability to fold/ flatten package after use	D
Have a removable LOT number on the concentrate package	D
Prevent wrong attachment of package	N
Max 10 minutes to do the FCH check + priming	D

Context Requirements

Ability to connect to the AK 96 dialyze machine	M
Ability to connect to other brands/types of dialysis machines	D
Ability to clean around the connector	N
Not be in the way of other components	N

Secondary Package Requirements

Secondary or primary package that is impenetrable to water	M
Packages shall be arranged on an EU-pallet	N
Packages shall be easy to grip and carry	N
Packages shall contain a package leaflet (A5)	N
One package shall not weight more than 10 kg	N

7.4 System Goal

The system goal is to provide the users with a good package concept for dialysis fluid that is based on dry concentrates.

7.5 Usability Goals

The goals for the handling with the dialysis concentrate are listed below and derive from expertise estimations. The following goals are measurable and aim to be used in tests of design concepts later on by usability verification.

7.6 Measures for Efficiency

The handling with the concentrate should have a high level of efficiency, in terms of reach the goal within a short time and with few errors.

80% of the first time users should be able to prepare the dialysis concentrate within 10 minutes, without guidance. (The machine activities e.g. priming, are not included in the time estimation)

80% of the first time users should be able to remove the package and clean the concentrate machinery within 5 minutes, without guidance. (Disinfection program is not included in the time estimation)

7.7 Measures for Effectiveness/ Guessability

It would be an advantage but not a must to have a design with a high level of intuitiveness so that a user can understand the interaction first time.

80% of first time users should be able to prepare the dialysis concentrate before the treatment.

7.8 Measures for Effectiveness/ Learnability

Ability to do right operations after learning the system.

80% of the users should be able to prepare the dialysis concentrate properly second time.

7.9 Measures for Effectiveness/ Memorability

To remember the operation sequences after e.g. some weeks of holiday.

90% of the users should be able to interact with the product correctly after 5 weeks absence.

7.10 Measures for Satisfaction

The system should satisfy the users in the user interaction.

Not more than 20% should feel irritation when handling with the concentrate package.

80% of the users should feel confident and know that they have performed the task

properly first time.

90% of the users should rate the package to be comfortable to use.

These usability goals were updated later on and can be found in the test plan for the usability test in appendix I.

7.11 Utility Goals

The following goals describe how well the machine will fulfil the system goal. The inputs to these aspects derive from investigations from the need identification.

- The time it takes to prepare the concentrate for treatment should not exceed the time it takes to finish the priming
- The machine should easily detect the right concentration, (conductivity).
- Ability to disinfect the components that are in contact with the concentrate fluid.

7.12 Aesthetics

The Gambro products don't follow any design guidelines today. The design jobs are outsourced to design consulting firms in e.g. France and Italy. The lack of in-house designers and or design manager is probably a reason for the diversity in the design language of the product assortment.

In 2007 a graphic profile was developed for Gambro, which provides design guidance for primarily two-dimensional designs such as labels, product sheets, package prints etc. The graphic identity manual provides user restrictions for the logo and colour scheme etc. These guidelines will be considered when dealing with the concept development of logo and label design within this project.

7.13 Aesthetic guidelines

- Express honest
- Express safe
- Express hygienic
- Fit in the Gambro product assortment

7.14 Environmental Aspects

The concentrate packages are consumption products with a short lifetime and hence it has a significant role from an environmental point of view, not least from the material perspective. The most important aspects to consider are the type of material used, the amount of material, the ability to recycle the material and the energy used in the usage situation.

7.15 Environmental Guidelines

- The energy used for the disinfection should be minimized

- Reduce the weight. Do not over dimension
- Reduce the volume in the transportation- make the package able to pile up
- Make it possible to empty the package entirely
- Simplify the flattening of the package material

7.16 Usability Guidelines

Usability guidelines aren't measurable in the same way as usability requirements or usability goals. The guidelines aim to be guidance for the developing process in order to achieve a high level of usability. The guidelines derive from theoretical studies (T) and field studies (F).

Clear differentiation in labeling design	F
Informative graphics or form ornaments guiding user actions	T/F
Good contrast of the text on the label	T,F
Be consistent	T
Provide feedback of the user's actions and statuses of the process	T
Feedback of what the machine is doing and how long it will take	T/F
Guiding instructions on screen for next user action, when necessary	T/F
Explain reasons for errors and how it can be solved	T
Provide ability cancel and exit	T
Minimize the number of user input	F

7.17 What if? – Risk Analysis

A risk analysis was performed and applied on a general dialysis concentrate package concept. The purpose and goal of this analysis was to look for potential problems and errors with the developed package concepts and look for improvements and solutions.

1. What if the user chose the wrong concentrate from the storage room?

If the dialysis treatment has started the nurse has to take a look in the patient's medical record and determine what the consequences will be for the patient. In some cases the dialysis concentrate must be changed.

1.1. What if the user has to replace the package?

The dialysis treatment has to be stopped so that the dialysis concentrate package can be changed.

1.2. What if the package is filled with liquid?

The concentrate package has to be emptied by pressing a button in the screen menu, before it is removed.

2. What if the package breaks?

Here we have two scenarios:

-Before it is connected e.g. in the distribution- *Then dry powder can leak out from the package.*

-After it is filled with liquid- *Then the concentrate fluid can leak.*

2.1. What If the concentrate get in contact with skin?

Nothing serious happens, the concentrate isn't fretting.

2.2. What if the user doesn't see that a new package is broken when connecting it?

The package isn't vacuumed any longer; the user will notice that the package has abnormal properties.

3. What if the package doesn't empty?

The user has to empty it manually by pressing a button in the screen menu.

4. What if the machine doesn't read the conductivity?

This is a technical aspect that will not be considered within this master's thesis. It is important that this issue will be solved for the final product since conductivity problems in general cause irritation and unsatisfied users, according to interviews with nurses.

5. What if the package isn't correctly connected to the machine?

The machine will detect this problem. A description of it will appear on the screen with information about what is wrong and how it can be corrected by the user.

6. What if the user doesn't confirm that the treatment is finished?

The concentrate package will not empty. A reminder will appear in the screen menu.

7. What if the user doesn't remove the package after treatment?

The machine can not start the disinfection program. A message will appear on the screen with information about what is wrong and how the package can be removed.

8 INITIAL CONCEPT DEVELOPMENT

After the need specification and the function analysis, the idea generation phase took form. Drawing pictures on papers carried out ideas, one idea led to another and so forth. Image boards in form of a function board and shape board was used for input as well as Osborne's idea spurring checklist. Most of the ideas were based on the existing AK 96[®] machine as a starting-point and it was a help to have a specified product to relate the ideas to. The physical machine was available during the idea generation that was a good advantage and made it easier to estimate proportions, heights and volumes.

The concentrate package concept contains three products:

- a concentrate package which contains the concentrate
- a concentrate module to which the concentrate package is attached
- a box for transportation and storage of the concentrate packages

8.1 Ideation

The first brainstorming phase considered generation for overall concepts for how a concentrate could possibly look like and how and where it could be attached to the machine. Below are the main ideas from this ideation phase presented. Illustrations can be found in appendix C.

8.1.1 Cond-in-Bag (A)

The container contains a simple conductivity meter (pad on the bag) that change colour when the appropriate conductivity has been reached (i.e. when the powder has been dissolved and the product is ready for use)

8.1.2 Supporting Holder (B)

The dialysis concentrate is delivered in a flexible bag. The bag is filled with powder already from the manufacturing. In order to support and protect the bag it is hooked in a holder at one side of the dialysis machine. However the bag can be of a simple type since the holder will support it.

8.1.3 TopTray (C)

The dialysis concentrate is packed in a large bag with a conic shaped bottom. The bag is connected to the top of the machine. The concept assumes that the machine has a concave top in order to fit the conic shape of the bag. Frames at the four sides will support the bag. The machine height should be able to adjust, so that the user can mount the package at a convenient height. The one-time bag can be of a simple type.

8.1.4 ConicBag (D)

The package has the shape of a cone that is flat-welded at the top. The package has holes at the top aimed for hooking the package to one side of the machine (it could also be a clip or other fastening method). The user clicks the package's connector to the inlet/outlet connector at the machine, and then she fastens the top of the package by hooks or similar.

8.1.5 Colored Compartments (E)

One oblong dialysis fluid container on each side of the dialysis machine, integrated in the machine. One compartment for the B- concentrate and one for the A- concentrate. The compartments are in red/ blue transparent polymer in order to visualize which one is for the acidic and bicarbonate respectively. The main idea of this concept is to have colour coded containers and to have the dialysis compartments nicely interacted with the machine at the front of the machine and the user interaction is at a convenient height.

8.1.6 Push (F)

The powder package is pushed into a compartment with connection to a built-in container. The water inlet is suggested to be placed at the bottom of the powder package and the water flow will go up to the larger compartment above the powder package, where it will be mixed to a dialysis fluid. The best advantage of this idea is that less package material is needed since the package is smaller, the dialysis fluid is in a closed system and the user interaction is easy.

8.1.7 Re-Pac (G)

The powder is packed in a relatively small package, about 2 litres. The user removes a foil and pours the powder into a container that can be reused. The dialysis fluid container could either be portable e.g. have wheels, or be stationary. Package material will be saved. Another advantage could be that the dialysis fluid can be mixed at another place in advance and then be connected to the machine, when its time to start the machine.

8.1.8 Cart (H)

The dialysis concentrate is packed in a cartridge like the BiCart[®] package which has an inlet in the base and an opening at the top that is connected to a larger built-in compartment. The water will pass the cartridge and be mixed with the powder.

8.2 Brainstorming Workshop

18 co-workers at Gambro participated in the workshop and were divided into three sub groups with competences and specialist knowledge within a wide range of disciplines. The first case for the workshop participants was to generate ideas that fulfilled two given constraints. Then the three groups gathered and shared their ideas and had discussions. Before the next session each group got additional constraints. After the last idea generation, the groups presented solutions by sketches and explanations for all the workshop participants. After the workshop the ideas were documented by short and concise explanations.

The workshop generated in about forty different ideas in total for how the package can look like and how the connector can be designed etc. These ideas are not presented in the report. The workshop contributed with new discussions, new restrictions and possibilities, and some changes in the requirement list.

8.3 Task Analysis

The task analysis in the previous chapter was updated and further developed into detail

according to the new information collected. The requirements are categorized for the concentrate package, module and box respectively.

Main function (M), Necessary function (N), Desirable function (D)

ID	Task Requirements for the Overall Concept (T)		Evaluation method
T1	Assist the dialysis process with dialysis solution	M	check
T2	Primary package that is impenetrable to water	M	check
T3	Be connected to the dialyze machine	M	check
T4	Available in 4-5 formulations	M	check
T5	Contain 1,8 litre of powder, i.e. 1800 g	M	check
T6	Know when the concentrate has been mixed properly	N	check
T7	Know that the solution has the right proportions	N	check

CONCENTRATE PACKAGE

Task Requirements for the Concentrate Package (TC)			
TC1	Connection at the top and base of the package	N	check
TC2	A filter must be implemented to the outlet connector on the package	N	check
Use Requirements for the Concentrate Package (UC)			
UC1	Clear differentiations for the different mixture packages	N	test
UC2	Lightweight and small	N	test
UC3	Avoid interaction which can cause tension in e.g. fingers, arms, legs and back	N	test
UC4	Ability to fold/ flatten package after use	D	check
UC5	Have a removable LOT number on the concentrate package	D	check
UC6	Have a LOT code on the package that can be read digital	D	check
UC7	Avoid heavy load on the users body	N	check
UC8	Ability to mount without leak	N	check
UC9	Ability to see the concentrate through the package	N	check

MODULE

Task Requirements for the Module (TM)			
UM5	Ability to disinfect all components that will have contact with the dialysis fluid	N	check
Use Requirements for the Module (UM)			
UM1	Attachment of concentrate to the machine at a convenient height	N	test/check
UM2	No separate components that can be lost	D	check
UM3	Avoid heavy load on the users body	N	check
UM4	Design so that the package can't be attached wrongly	D	test/check
Context Requirements for the Module (CM)			
CM1	Ability to connect to the AK 96 dialyze machine	M	check
CM2	Ability to connect to other brands/types of dialysis machines	D	check
CM3	Ability to clean around the connections	N	check
CM4	Not be in the way of other components on the machine	N	check

BOX

Task Requirements for the Box (TB)			
TB1	Packages shall be arranged on an EU-pallet	N	check
TB2	Packages shall contain a package leaflet (A5)	N	check
TB3	Possible to pile efficiency	N	check
TB4	Possible to pack efficiency in the factory	N	check
TB5	Use cardboard as primary package material	N	check
Use Requirements for the Box (UB)			
UB1	Packages shall be easy to grip and carry	N	test
UB2	One package shall not weight more than 10 kg (Gambro's guideline)	N	check
UB3	Possible to flatten the package easily	N	check
UB4	Avoid heavy load on the users body	N	check
UB5	Avoid sharp edges for the handles	D	text/check
UB6	Easy to open the package	N	test

8.4 Discussion of Possibilities

At this stage a number of ideas and solutions had been developed and it was time to sum up its benefits and disadvantages. Here follows a discussion about the alternatives of sub solutions for the concept design. E.g. how a container can be attached to the machine, advantages and disadvantages with having an included VS separate container and a discussion about how the time aspect can be considered in the concept design. The discussion is based on literature, field studies and personal thoughts and opinions.

8.4.1 Placement of the Container

In order to provide the users with good physical ergonomics the attachment of the concentrate container should be at a convenient height that is easy to reach and control. The most convenient height is about 50-250 mm below the elbow height (Pheasant, Haslegrave, 2006). However from a mechanic point of view, it would be an advantage to set the concentrate container at a low height in order to achieve a low centre of gravity so that the machine becomes stable. A low placement of the container is a disadvantage in the users' perspective, assumed that the users need to interact with the container by bending their knees and back. Some early ideas suggested a placement on the top of the machine, e.g. the TopTray and the BoyeFunnel, this placement is good from a functional point of view but poor for the users' physical working situation since it forces the users to stretch their arms above the shoulders with a load of about 2 kg when the product is filled with concentrate. The challenge is to integrate the dialysis concentrate container to all the other equipment on a dialysis machine that competes with the space. Today the dialysis concentrates are attached at the sides of the dialysis machine and leave the front side for the tube set and screen etc. Since the concentrate in the normal case only needs interaction before and after treatment this priority seems reasonable.

The total space of the dialysis machine is critic; the challenge is to make the machine as flexible as possible. The space at the dialysis ward is limited and many dialysis wards strive to take as many patients as they can in each room. A concentrate container placed at the side of the dialysis machine shouldn't be too bulky since the width of the machine

is one of the critic parameter when it comes to stack many dialysis machines and beds side by side along the walls in a treatment room. Also in the home environment is the space limited and a compact machine is preferred also here.

8.4.2 Included VS Separate Container

A dialysis concentrate container could either be included as a part of the dialysis machine or separated from the machine in form of an external one-use compartment. The advantage of having an included container in the machine would be a nicely uniformed design where the concentrate concept is integrated in the machine. Then the package for the concentrate could be just as small as the volume of the concentrate and hence package material can be saved. On the other hand does the included container need to be disinfected after the treatment, which means that a certain amount of disinfection liquid has to be heated up, then cleaning the compartment and finally the machine has to cool before next treatment can start. This process will probably be both time consuming and energy intensive. If an included compartment is be used, then it must be combined with an efficient way of disinfect the compartments.

The alternative to the included container is to have a disposable separate container in which the concentrate is distributed. This container has to be big enough to take the added water. The separate container is only used once and hence it doesn't need to be disinfected. The external container can be shaped in many ways and has many options for how and where it can be connected to the machine.

8.4.3 Time Aspects

The time is an important aspect when it comes to the effectiveness of the concentrate concept, especially at hospitals. It will take a certain time to dissolve the powder and a certain time to disinfect the machine between the treatments. It is important to shorten the time in order to increase the effectiveness in the work and organization at the dialysis wards. In the package design the time aspects can be considered by e.g. thinking about how the concentrate can be dissolved faster.

Another way to shorten the start up time is to do things in parallel. It would be an advantage if the function check, priming and conductivity measurement could run at the same time as the concentrate dissolves. By talking to experts, function check and priming could run during the dissolved without causing any problem. The conductivity is a more challenging thing to solve since the conductivity meters in the machine need concentrate from the container in order to obtain a cond-value. If concentrate is taken from the container before the solution is dissolved the concentration will be unbalanced, this is not accepted. One way to measure the conductivity value of the concentrate would be to have a conductivity cell inside the container, sending out the value to the machine. The conductivity cell could also give redundant direct feedback to the user by changing colour to green when the solution is ready to use. However, for home dialysis the time aspect is less important, the patient is usually treated over the night while the patient is sleeping and the efficiency is less important when the machine only is used for one person.

8.5 Concept Generation

The idea generation phase resulted in a bunch of ideas (see 8.1 and appendix C) which had to be categorized and evaluated, some was eliminated other pursued. The concepts were evaluated against the 10 most relevant and most important requirement from the Task Analysis.

These requirements were:

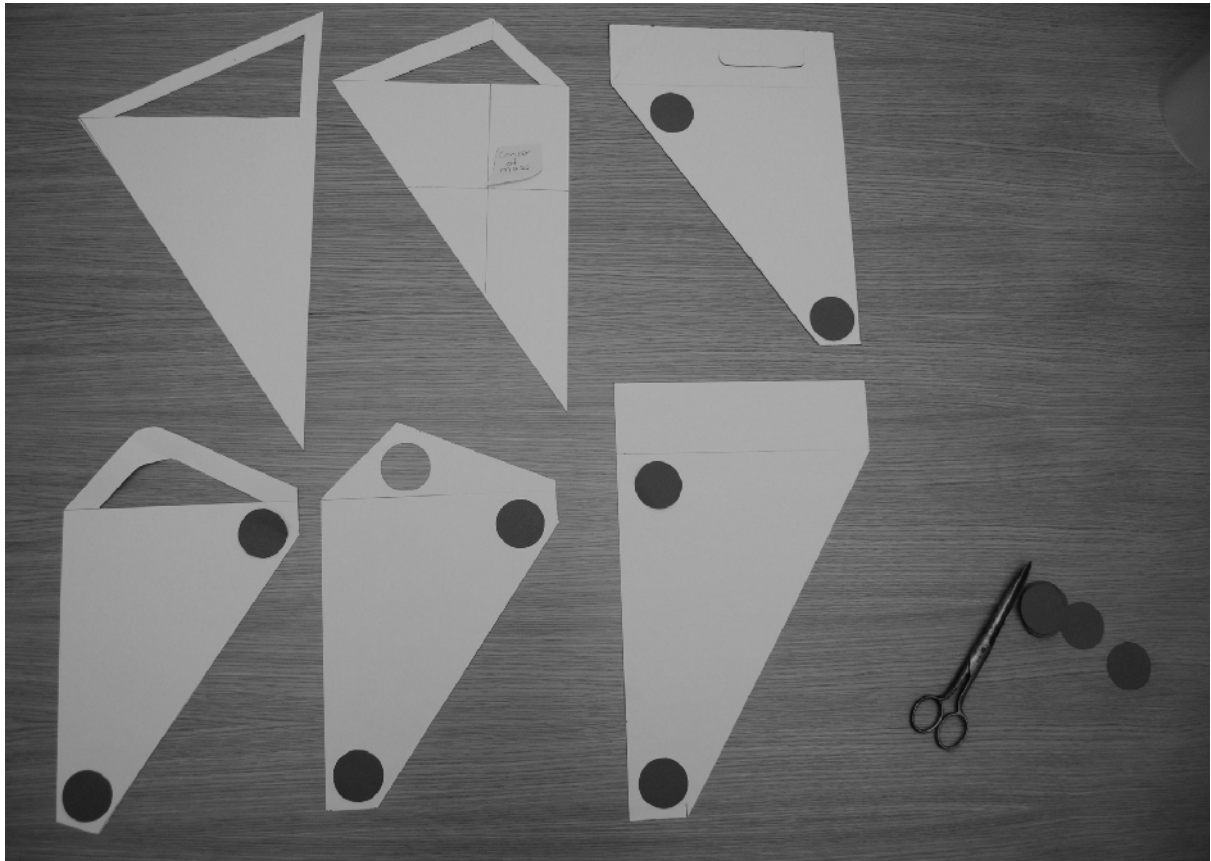
- Take up small volume in use
- Small and lightweight package before and after use
- Potential for fast cond-check
- Potential to fast dissolution
- Potential to adapt the concept profile to BiCart
- Potential for low production cost for package
- Potential to empty the package automatic after use
- Potential to stack and pile efficient in a secondary package
- Adaptable to the AK 96 dialyze machine
- Ability to disinfect all components easily

From the elimination matrix, the concept based on a flexible bag (E) was considered as having the best qualities for further development.

9 FURTHER CONCEPT DEVELOPMENT

In this section the further development of the concentrate package will be described. The methods used for the idea generation were primary sketching and making physical sketch models. Analysis methods such as Predictive Human Error Analysis and Cognitive Walkthrough were used in order to evaluate and improve the concepts.

9.1 Paper Models



*Figure 8-1*The shape of the package, proportions, handle design and placement of inlet and outlet was investigated by paper models.

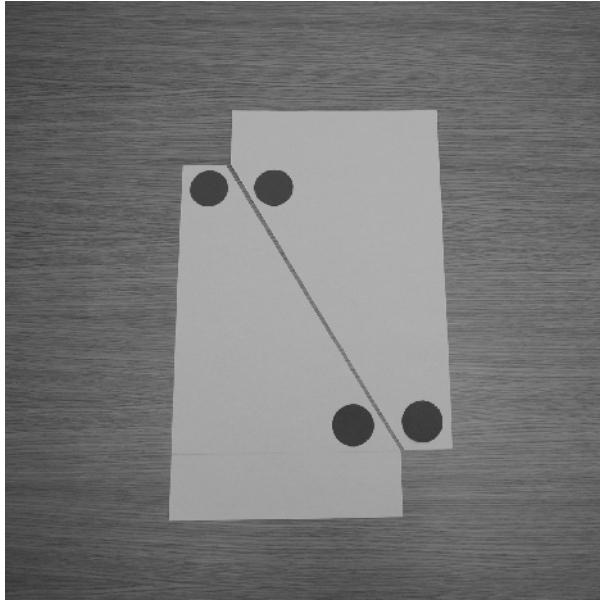


Figure 9-2 Test of package principle.



Illustration 9-3 Figure 8-3 Filled packages.

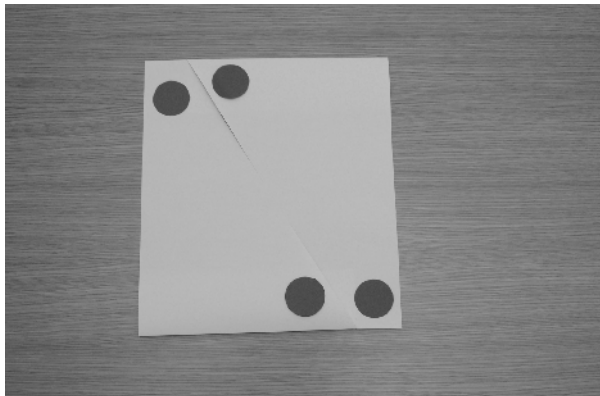


Figure 9-4 The handles are folded.



Figure 9-5 The placement of connections are investigated.

The purpose of the paper models (figure 9-1, 9-2, 9-4) was to try out different shapes, searching for an ideal shape and look for variations in handle design etc. The green circles are symbolizing the area that will be connected to the machine. The package has two connections to the machine, one for the water to come in at the top and one to deliver the concentrate, placed at the lower part of the bag. The bag is provided with a handle that aims to support the load of the filled concentrate package when the user is to attach the package to the machine. The user will hang the package and then fasten the package to the machine by the two connections. The handle is placed right above the centre of mass so that the package will be hanging balanced in its right position. A balanced package does not need any support and the users two hands are hence free to attach the inlet and outlet of the package to the machine while the package is hanging in a balanced position right in front of the connection areas.

9.2 Attachment

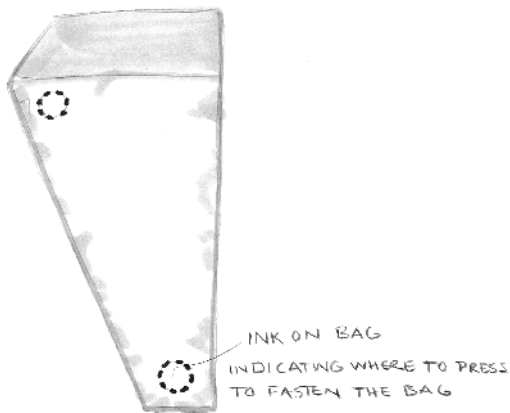


Figure 9-6 The package has graphic circles indicating where to press in order to attach the concentrate package to the machine.



Figure 9-7 The package is attached to the right

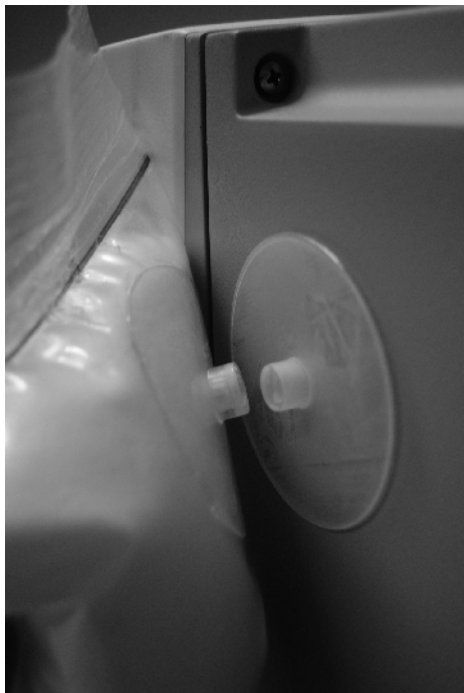


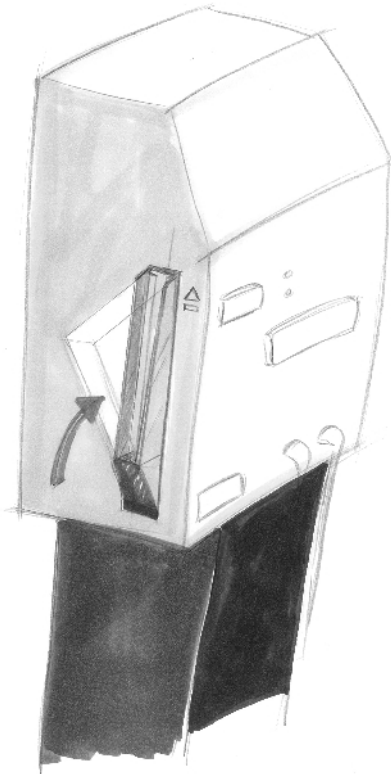
Figure 9-8 Connection of the concentrate package on the dialysis machine.



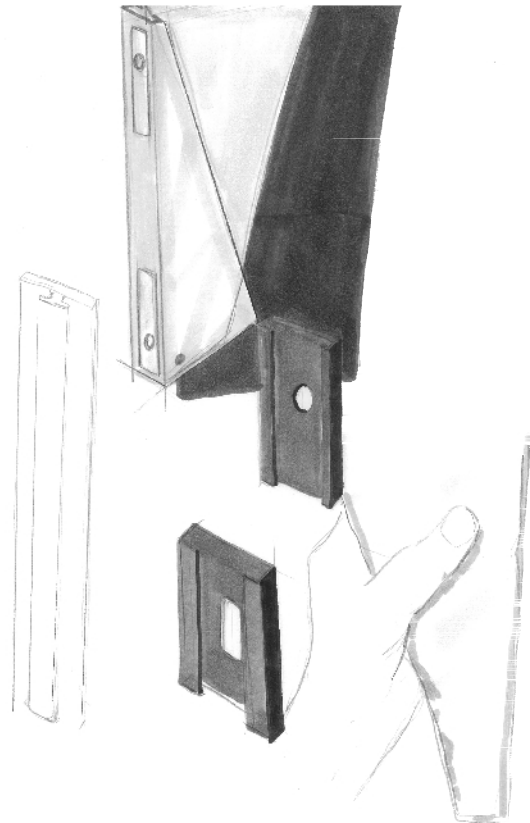
Figure 9-9 Another attachment principle, where the package is attached by rotating a handle 90 degrees, screw to fasten.

The pictures above illustrate ideas for how the package could be attached to the machine, e.g. by snap buttons that will grab around the connection or fastened by rotating a handle. Different shapes of handles were drawn in the purpose of finding out the best grip and the most communicative shape that tells the user how it is aimed to be handled, e.g. by rotation or by pushing. Some disadvantages of this concept were identified such as high precision needed, rotation of wrist, and transversal forces on the machine that could cause movement of the machine.

Experimentation with physical sketch models lead thereafter to a new idea of how the package can be attached to the machine. The package was rotated 90 degrees and the connections were placed at the longer edge instead. A new direction of the package concept was found which provides advantages for the user in form of less precision needed to attach the package, no rotation in wrist needed, better grip and less force needed to attach the package to the machine.



*Figure 9-10 Attachment of concentrate.
The package will fall into the machine.*



*Figure 9-11 Ideas for the rail and the grip
to hold the package.*

The new concept idea of the concentrate package has a track along the longest edge, so that the user can attach the package to the machine by pushing the package down in a holding device. The rail is pulled down in a track of the holding device so that the package will fall into its correct position.

Position the package in the track and pull it down in the holder with support from the weight of the package. Then you press the package into the machine so that the holder is aligned with the side of the machine and you hear a click! When the package is in place, the package will be automatically connected to the system and a sharp spike that prick the membranes on the package. The same principle is used for the cartridge packages today. The membranes on this package may have to be more thin so that less force is needed to get the package open.

After the treatment the user press the eject button to get the holder out of the machine, then the user removes the package from the holder. The package could also be removed manually by having a handle on the holding device or a handle on the package. However an automatic eject button is considered to be the best solution since it the most convenient alternative for the user.

In order to achieve connections without leakage a sealing is implemented inside the connecting tubes on the package. A spike will prick the sealing when the package is attached to the machine. In the development of the design of the connection, construction elements were taken from the existing Gambro package design of the CleanCart®. The inlet and outlet connections of this product have been on the market for a long time and are also used for other Gambro products such as SelectCart® and BiCart® packages.



Figure 9-12 The CleanCart® package used today.

CleanCart® packages have a cylinder with a filter and a membrane. The cylinder is connected to a holding device with a seal that prevents the connection from leakage.

9.3 Implementation on the Machine

A benefit of having two connections on the package, one inlet and one outlet, is that it follows the tradition of Gambro products and it may therefore be easier to implement the new concentrate package to the existing system in the Gambro dialysis machines.

During the further concept development many different alternatives of placement of the concentrate module was discussed. The most important aspect was to set the attaching device at a convenient height for the users, a limiting constrain is that the module must fit to the existing AK 96 dialysis without too many changes in the design and another challenge was to find a place for the compartment where it doesn't collides with other equipment on the machine or in the context of the machine.

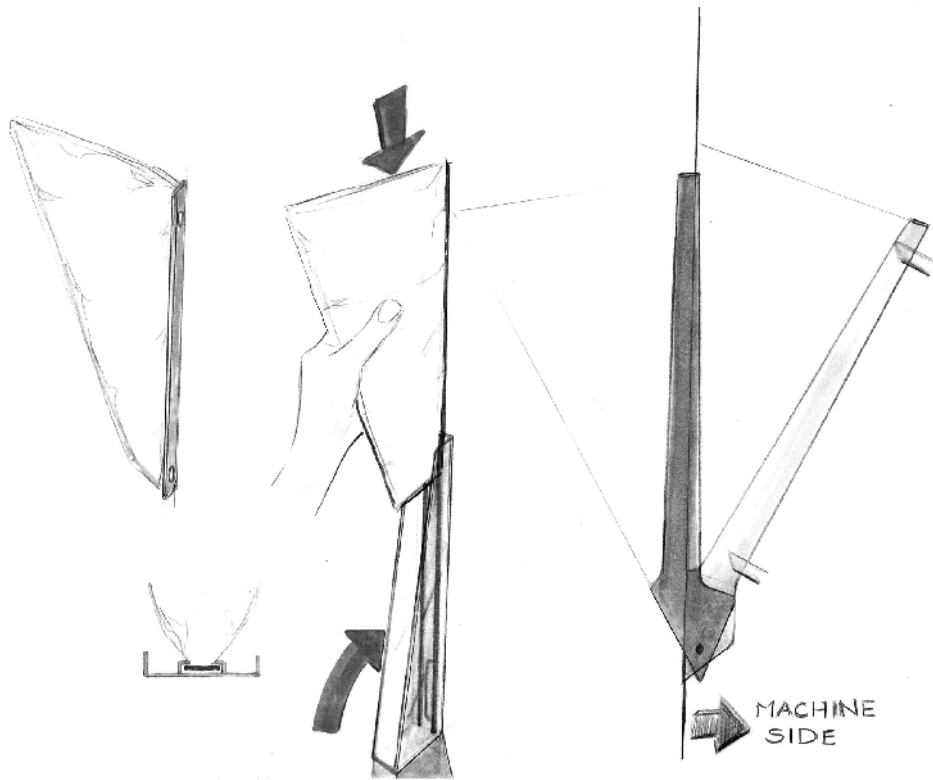


Figure 9-13 Attachment of the concentrate package. The rail on the package is attached to a track. The package will fall into the machine.

9.4 The Holding Device



Figure 9-14 Sketch model of the holding device and concentrate package.

This device aims to be attached inside the concentrate module described in text and by pictures later on in this chapter. The triangular shape of the holding device could be associated by semantics to the package's shape. The paper model in the middle (figure 9-15) could mislead the user so that the user may think that the package is supposed to be attached upside down. To avoid this confusion, the shape of the holding device was changed for the next sketch model. The shape of the holding device placed to the very right guides the user to attach the package with the smaller side at the base. The placement of the holding device was not decided at this stage. An evaluation of where the package could be attached to the machine is described later on in the concept development.



Figure 9-15 Three versions of holding device sketch models.

9.5 One VS Two Connections

Another brand at the dialysis concentrate market has a dry concentrate container with one connection at the top of the package and a tube that goes down to the lower part of the container where the dissolve solution is. Gambro's dry concentrate packages have a tradition of having one connection at the top where the water comes in and one connection at the base where the concentrate is taken out. By keeping the tradition at Gambro of having two connections the implementation of the new design will probably be easier, less expensive.



Figure 9-16 Model of the concentrate package.

9.6 Disinfection

The machine parts have to be disinfected after every treatment. The disinfection means that heated fluid goes through the system of components and removes depositions and bacterium. For this process the connections at the machine has to be connected.

One idea is to attach a separate cleaning part in the same way as you attach the concentrate package. Another idea is that you leave the package in the holding device and let the disinfection solution pass through the package; this assumes that the package is empty after the treatment.

To leave the package in the machine during the disinfection means that you don't have to do any extra manoeuvres for the cleaning, this is an advantage from a user's perspective. The volume of the package is rather large but could maybe be decreased mechanically before the disinfection starts. The challenge with this idea is to achieve an empty package at the end of a treatment.

9.7 Concept Development of the Concentrate Module

The illustrations in figure 9-17 illustrate alternatives for where the concentrate package can be attached to the machine. The four alternatives were evaluated theoretically based on anthropometrics, manufacturing aspects and common sense.

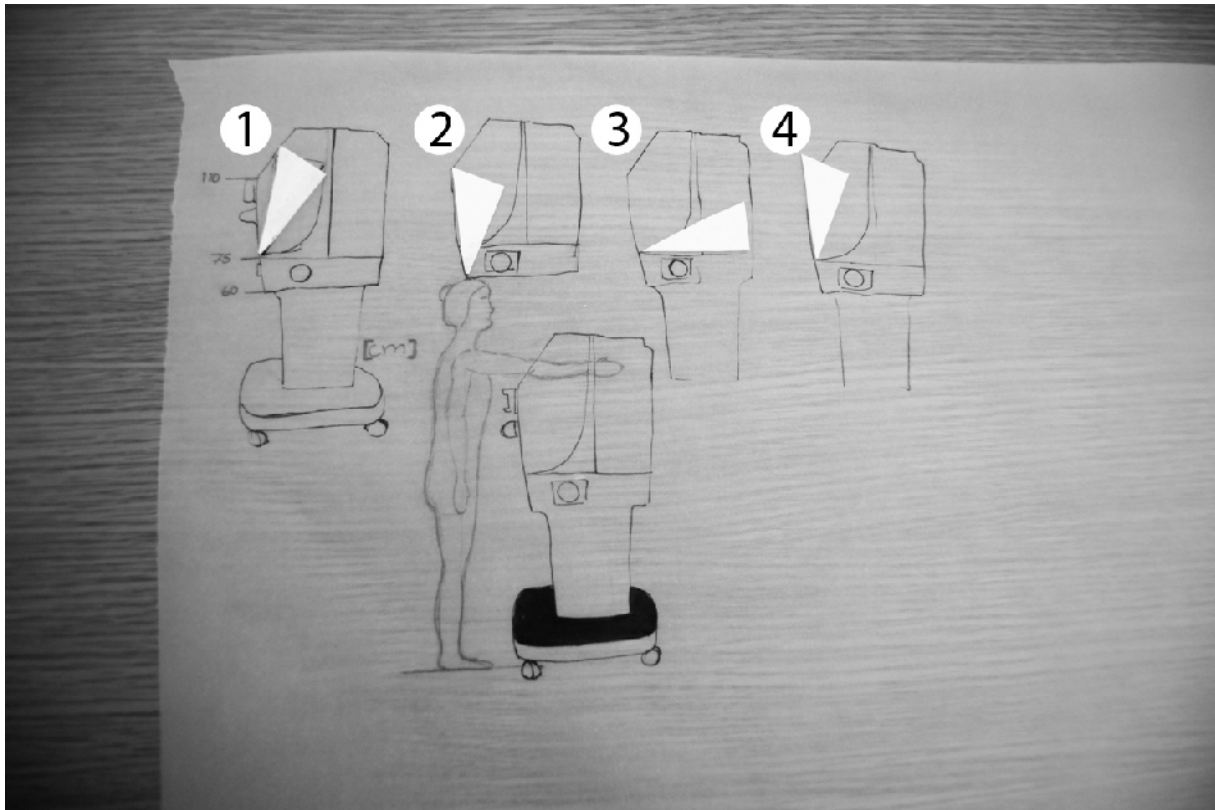


Figure 9-17 Evaluation of the placement of the concentrate module.

- (1) This was considered as the best placement. The package will be attached at a convenient height and the module will have a natural connection to the machine
- (2) The package is aligned with the surface on the front of the machine when the package is in use. A disadvantage is that the attached concentrate module would have to stretch over a split line in the existing monitor design.
- (3) This placement would be difficult to manage in reality of technical reasons since the inlet may have to be on a higher level than the outlet.
- (4) The package would hide the screen so that the view from the right side is limited.

The theoretical evaluation led to further development of the placement illustrated in the upper left corner. Mock up model in cardboard was made in the purpose of evaluating proportions, shape, height and reach. Before the computer modelling took over, two paper models where evaluated. The evaluation lead to increased with from 60-68 mm and a chamfer on the right side in order to provide more free space for the hand when inserting the package in the holding device.

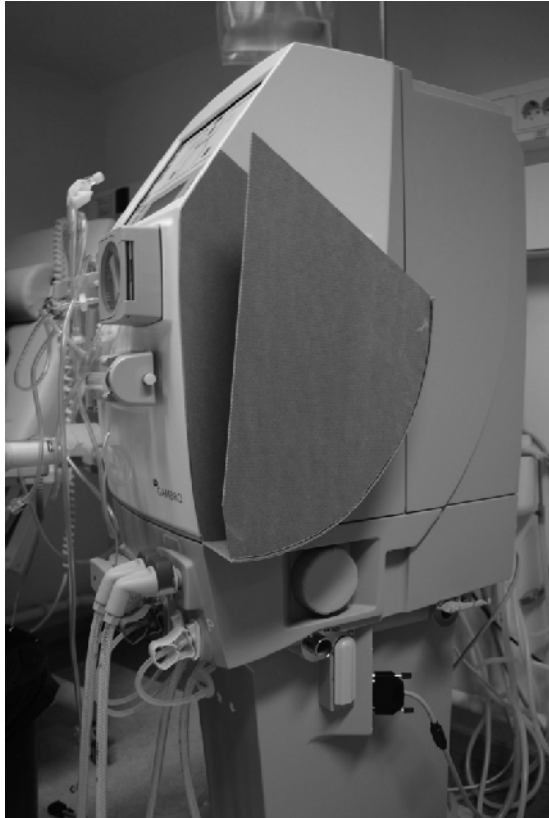


Figure 9-18 Sketch model of the concentrate module.

9.7.1 Predictive Human Error Analysis (PHEA)

The PHEA analysis was made in the purpose of detecting use errors in the handling of the concentrate package and evaluating the consequences of these errors. The results of the PHEA analysis was considered in the further development and was used as a theoretically background for the test plan of the user test.

Essential Findings from PHEA

- The package and holding device must be designed so that the user is unable to attach the package upside down.
- The concept must be designed so that the user will understand that the package has to be pulled all the way down in the holding device.
- Instructions may be necessary as a complement on the screen for novice users, how attach and detach the concentrate package.
- Prevent the user from detaching the concentrate during a treatment by locking or have an alarm.

9.7.2 Cognitive Walkthrough (CW)

The main tasks in the HTA diagram where evaluated by cognitive walkthrough. The potential use errors where categorised into type of error and thereafter a limited analysis of how the error can be recovered was made. None of the predictive use errors will lead to hazardous situations for the patient. However the detected potential use errors can lead to inefficient usage due to time loss for problem solving, irritation and dissatisfaction

Essential Findings from CW

- All of the detected potential use errors except two were associated to novice users, knowledge users (K).
- Guidance on the screen would be appropriate, especially for novice users.
- The usage would be more efficient if the user can get a reminder when an action is forgotten, e.g. to “close” the holding device.
- Semiotic functions will be advantageous to use in the design, especially for knowledge users. E.g. to illustrate the correct position of the package.

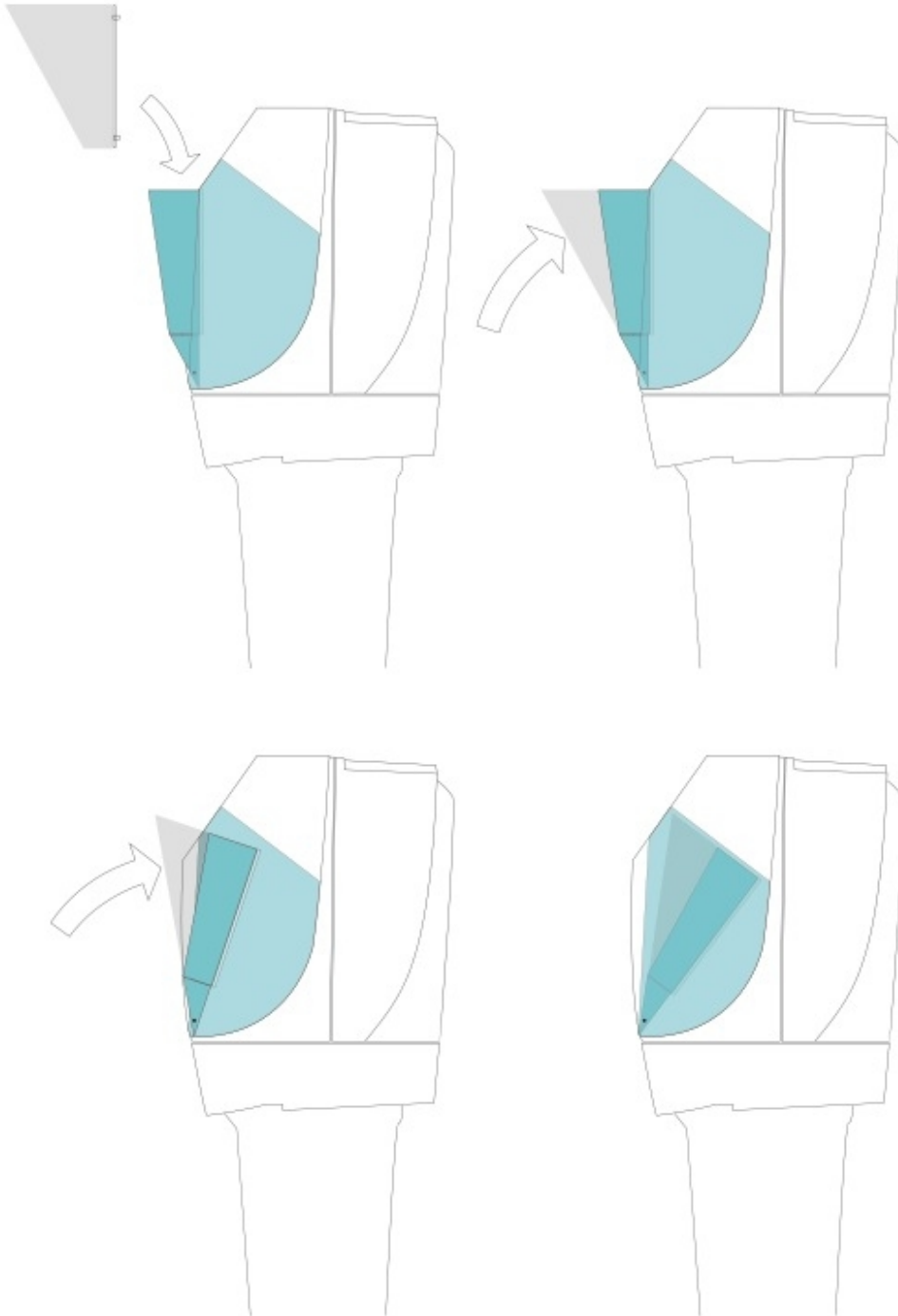


Figure 9-19 Illustration over the principle of the attachment of the concentrate package and how it falls down into the concentrate module. At the same time as it falls into its right position, the membranes will be pricked.

9.8 Concept Development of the Box

The sketches below are results of an early ideation session over the box design. The main purpose was to search for ideas for how the package could be simple to open and easy flattened for the end users. On the top in the image is a package that is opened by removing a rubber band that is wrapped around the package. The sketch to the left illustrates boxes that are opened by removing the two gables that are grabbed tight around the package. The general idea of the illustrated boxes is that no tool is needed for opening the boxes.

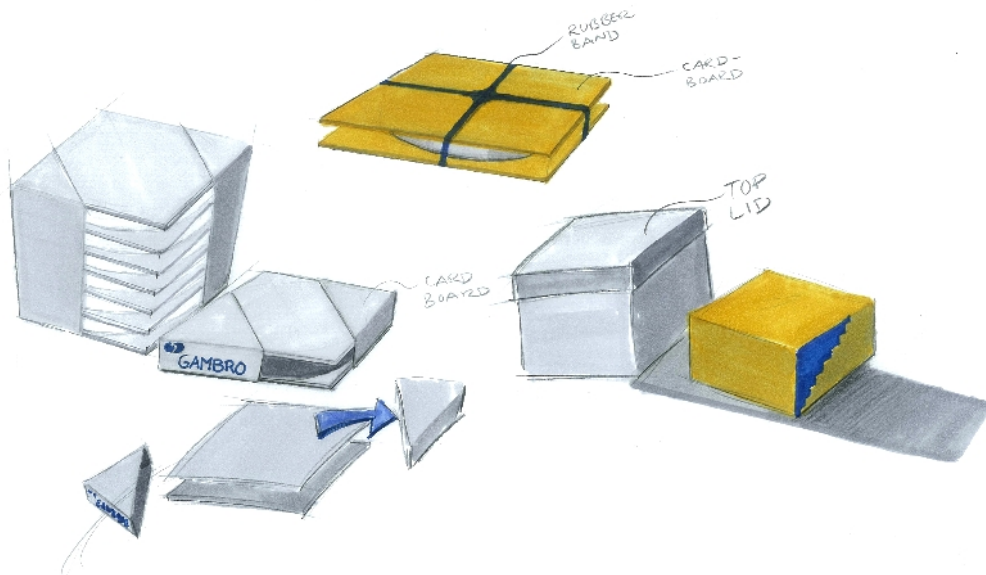


Figure 9-20 Sketches for the box concept.

Below is an idea of opening principle illustrated. The basic idea is that the user breaks a perforated line on top of the package to open it.

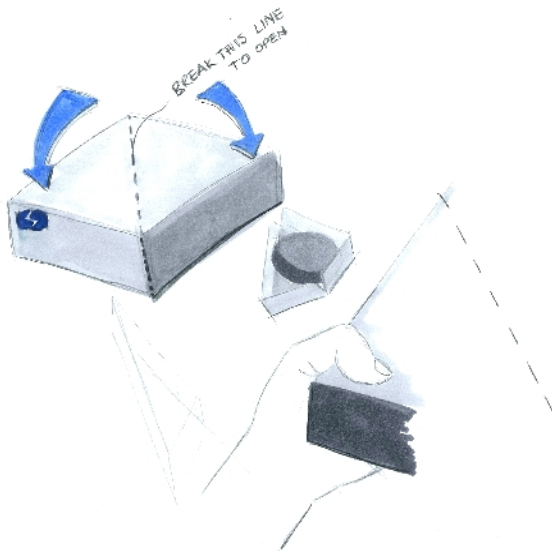


Figure 9-21 Sketches for the box concept.

In the next picture a smart collapsing principle is presented. A bisect of the triangles are pre perforated so that it makes it possible to fold along these lines. The feature makes it possible to flatten a volume with an easy handling. This principle was further developed in the concept development. The sketch to the left illustrates an interior with pockets for each package. The package got a slightly more luxurious touch by adding the Gambro colours on the inside.

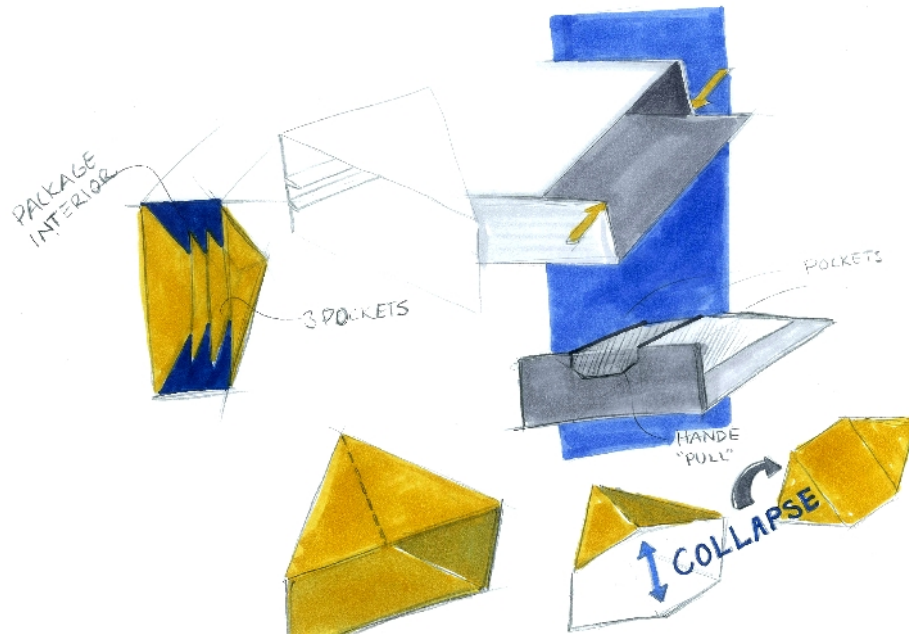


Figure 9-22 Sketches for the box concept.

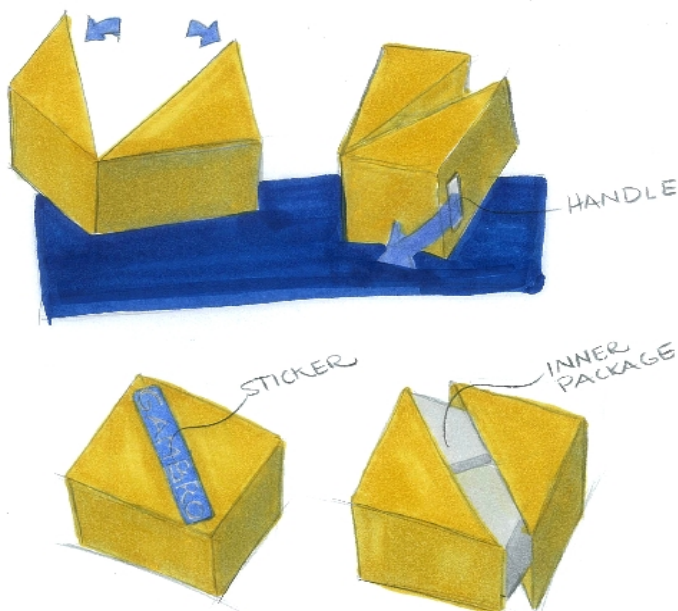
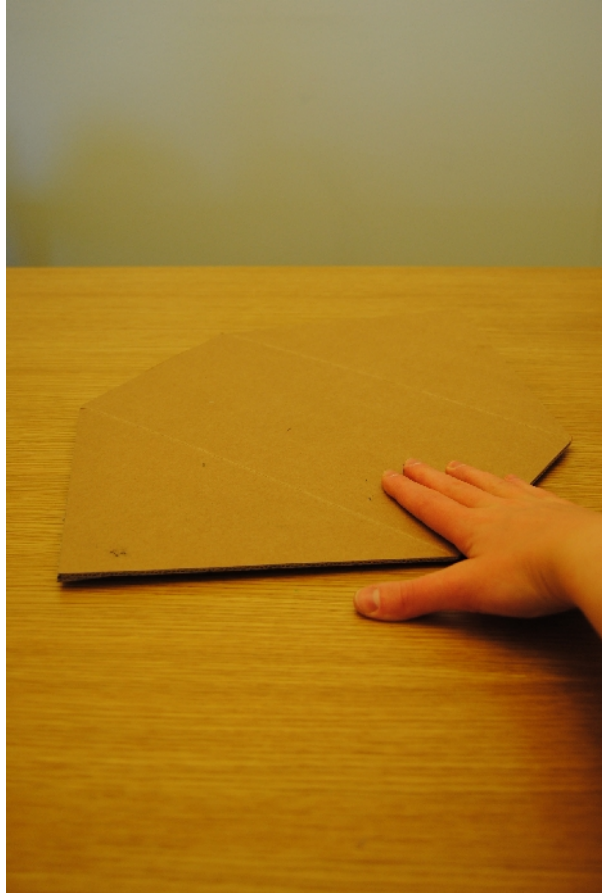
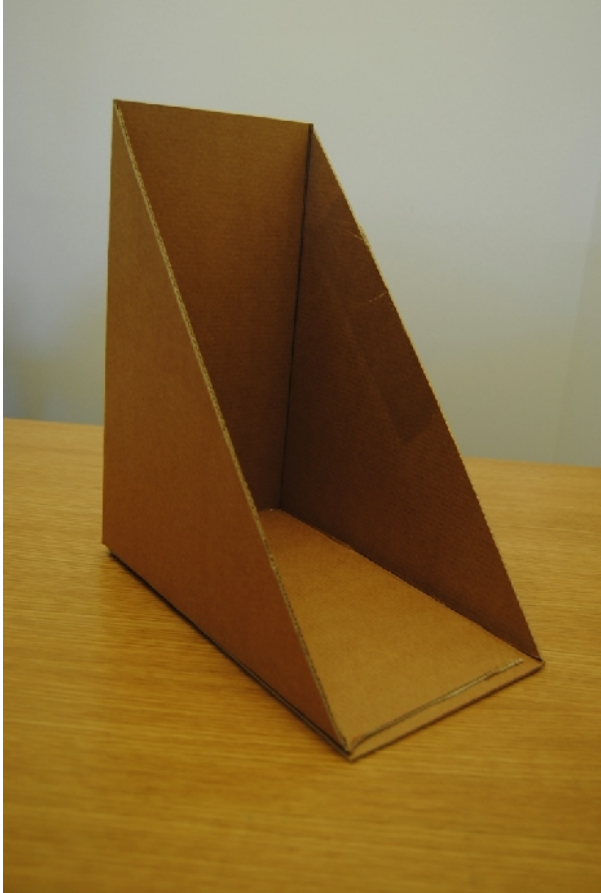


Illustration 1: Figure 9-23 Sketches for the box concept.

The package on top in figure 9-23 makes use of the easy collapsible principle described above. The box is provided with two handles on opposite sides. The box in the lower left corner is closed by a sticker in form of a label. To the right is a package that contains an inner package in order to make the package even more stable. The extra material for the later could be discussed, since the package is loaded mainly on the corners, an inner package may not be necessary.



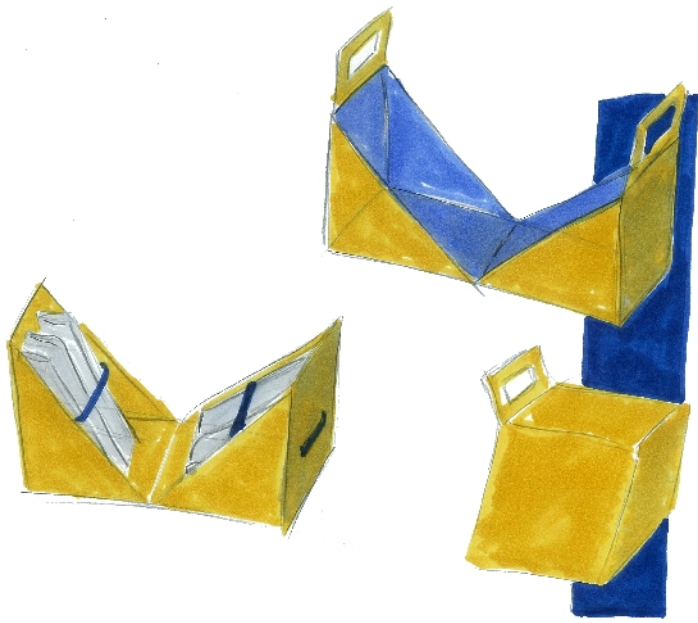


Figure 9-28 Sketches for the box concept.

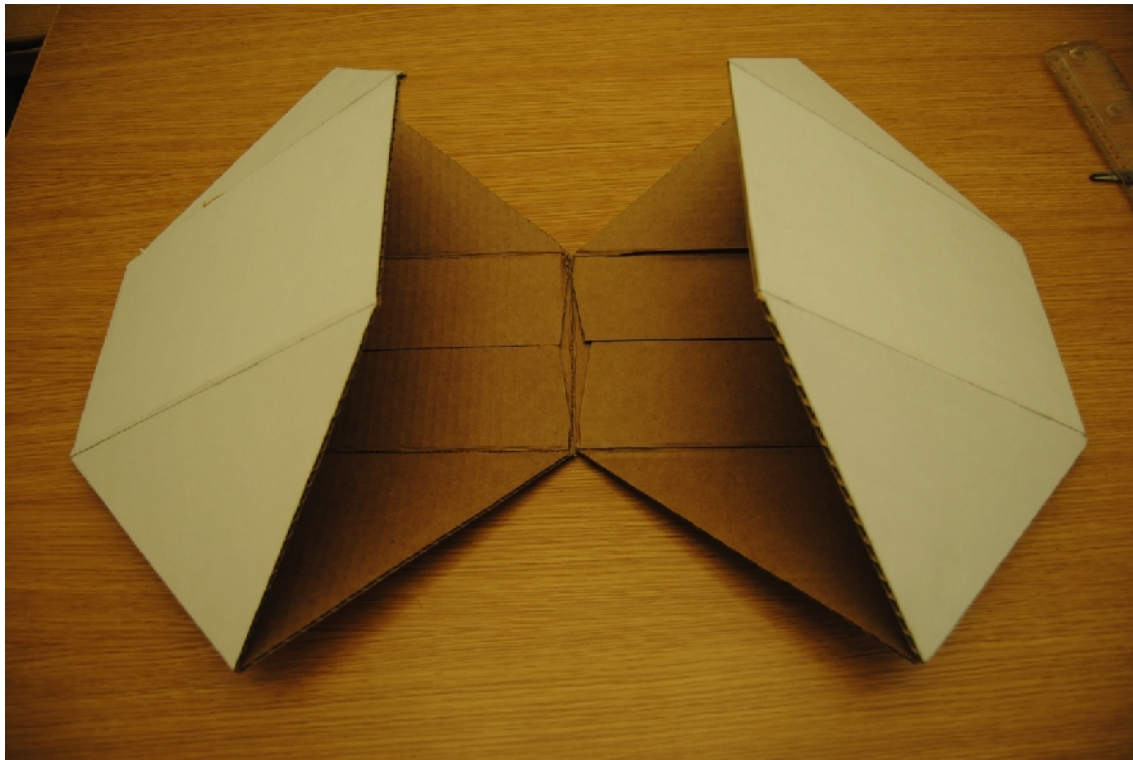


Figure 9-29 Folding principle of a box aimed for four packages.

The packages in figure 9-28 are provided with handles for easy carrying. To the left is a strap holding the packages in place. The strap could also be used as a handle for carrying the box. One important aspect to consider for handle design is to make the holding area wide enough for distribution of the pressure on the hand. There are some guidelines for handle measurements. A handle should be 115x50mm to fit adult's hands. (Pheasant, Haslegrave, 2006)



Figure 9-30 A Folded box.



Figure 9-31 Box concept.



9-32 Box concept.

9.9 Load and Size of the Box

The box concept consists of boxes of different sizes, all based on the same folding principle. The advantage of packing the product in boxes of different sizes is that the customers have different wishes, depending on how the unpacking is done. At hospitals where pharmacy personnel unpack the concentrates, large packages are preferred, while patients that are handling and unpacking their concentrates themselves may prefer smaller and less heavy packages. All the packages have a long side of 295 mm and a short side of 260 mm, which makes it possible to pile packages of different sizes efficiently. Each primary concentrate package has a weight of 1.8 kg. Each box could contain either 2, 3, 4, or 6 packages. A small package is easy to carry and the user can choose to take two or three packages at a time if the load is relative small. A small box could be beneficial for home dialysis where a fewer amount of concentrate packages are handled, a small packages can more easily be stowed and handled. However a box that contains more packages is an advantage at hospitals where a larger amount of packages are unpacked at a time, a larger box results in a more rational unpacking.



Figure 9-33 Boxes with 2, 4 respectively 6 concentrate packages in each.

Examples of packaging and loading.

2 packages	3.6 kg
3 packages	5.4 kg
4 packages	7.2 kg
5 packages	9.0 kg
6 packages	10.8 kg

10 END RESULT OF THE CONCEPT DEVELOPMENT

In this section the final results from the concept generation are presented. The concentrate package, the concentrate module and the box concept are presented one by one.

10.1 Concentrate Package



Figure 10-34 Model of the concentrate package.

The concentrate package is made of a flexible plastic film that can be flattened after use that is an advantage compared to the cartridge packages today which takes up a large volume after usage. The flexibility of the package makes it possible reshape slightly after the hand when grabbed. The rail is made of a rigid polymeric material since this feature has to have some stiffness. For the model in figure 10-34, the rail was 3D printed from a CAD-model.

A triangular shape of the package will provide the user with a comfortable grip which fit different sizes of hands, the package has a smaller grip at its lower part and larger at its top. The shape is also designed to be easily piled and fit the dimensions of an EU pallet. A tertiary purpose of the shape is to make the package stand out from other concentrate packages at the market today so that it will catch some attendance from the customers.

The function of the concentrate package is comparable with the BiCart[®] package today; the package has an inlet at top and an outlet at its base. The volume of the package is minimized and last for one treatment. The measures of the package are 250 mm long and a short side of 220 mm.

The measurements of the concentrate package were decided upon distribution aspects to optimize the properties for efficient packing and piling on an EU pallet. Other aspects that had important impact on its shape were associated with the human interaction. The importance of providing good ability to grip the package and having a uniformed shape

that easily can be grabbed and carried.

On the long side of the package are the two connectors positioned on a rail. The purpose of the rail is to position the package in the holding device on the machine. In order to prevent the user from attaching the package upside down, the rail is shaped so that it is smaller at its base and only fit the track when the base of the package is attached to the base of the holding device. (A final model was made by rapid prototyping that is very similar to the paper model in picture 9-14). The model in figure 10-34 is an attempt to illustrate the idea of the package and how the rail is attached. However the rail could possibly be designed further in the detailed concept development so that it becomes more integrated with the package and preferably be produced in a less stiff material.

The placement of the label is so that a right-handed user easily can read the text when holding the package. The most important and the most frequently used data are placed on the main label on the front of the package. Other necessary data is placed on the other side of the package. The LOT-number and the expiration date is data that is printed separately on the label and hence these numbers are placed on the same label.

10.2 Concentrate Module

The concentrate module is aimed to hold the concentrate package when attached to the machine. The module is placed to the right of the machine at a height that is convenient for attaching the concentrate package for most of the users. The module is mounted on the machine and implies an increased width of 68 mm on this side, this is not more than the extra space the cartridges of today uptake when they are in use. The shape of the module has been integrated nicely in the existing dialysis machine design elements by imitating the curves of the AK 96 dialysis machine and using the same light blue colour so that it doesn't stand out. The purpose is that the module should integrate with the rest of the machine. The module is also integrated so that it doesn't break any split lines.

For attachment of a concentrate package, the user presses the eject button to open the holding device, then the package is attached in the holding device by placing the package rail in the track of the device. In order to optimize the hand ergonomics the holding device is slightly tilted so that the user will pull down the package in an angle of 110 degrees. This angle is recommended in the ergonomics literature since the wrist is in a neutral position in this angle. Inconvenient rotations and twists are eliminated from this concept. The package will fall down in the holding device into the concentrate module and the membranes will be picked so that the package will open. Seals protect the connections in order to prevent the concentrate from leaking.

After the treatment, the nurse presses the eject button to get the empty package out of the concentrate module and the package can then be removed from the holding device. The eject button will be placed at the front of the machine, close to the module so that it easily will be associated to the module according to the gestalt law of proximity. The module will also have an embossed line on its right side, semantically indicating where the position of the concentrate container when it is placed in the module. The aim with this is that this feature will guide the user in the interaction with the concentrate module, to easier understand how the package is attached.

When the connections are to be cleaned, the attachment device is designed to be removed from the concentrate module by pulling out the axis. How the interaction of this could be like was not developed further in this stage of the overall design.

The model of the concentrate module below where drawn in the Solid Works and 3D printed by rapid prototyping.



Figure 10-35 Attachment of the concentrate.



Figure 10-36 Attachment of the concentrate.

10.3 Box Package

The box package concept consists of a series of package of different sizes which all are based on the same folding principle. The packages can easily be flattened to a flat package without using any tools and the folding requires a limited amount of force. The opening of the triangular shaped package is right below the handle. The package was meant to be opened by using a normal snap-off blade knife. Later on in the usability tests the test participants had complaints about this and the packages will therefore be designed to be opened without any need off tools. To open the box, the user will grab a fly and drag so that the package will open.

Within the package concept two box types can be distinguished, the triangular and the rectangular. Both of the package types have the same length of width i.e. two triangular packages becomes a rectangle when piled. The triangular package can also easily be carried two by two in one hand by holding in the two handles so that the packages form a rectangle of 295x260 mm (external dimension). The arrangements on an EU pallet is described in appendix L.

The package concept also includes a package with integrated handles, perforated in the cardboard on the sides of the box. This kind of handle is preferred for the package distribution since this box doesn't have anything that can choke up or takes up extra space.

The triangular shaped package is somewhat abnormal from the standard box that causes attention and curiosity which may strengthen the product recognition and differentiates it more from competitors' packages which are considered as advantages at the market. At the same time as the box challenge the norms for how a concentrate package looks like; it doesn't disadvantage the piling of packages.

To have a handle on the primary concentrate package was evaluated in the early concept development, but considered as unnecessary after the usability test. The packages will most probably be grabbed and if the user is to carry e.g. four packages at the same time, the packages can be piled on each other. The handle would also be destructing when the package is to be attached to the machine.

The packages are supposed to be white on the outside since it gives a hygienic appearance as stated in the aesthetic guidelines. The inside of the packages will have the company's core colour of blue in order to express the brand and give an more exclusive feeling and put some added value to the unpacking dialysis concentrates.

For the manufacturing a so called wrap around method is used. Wrap around means that the concentrate packages are positioned on the sheet and then the sheet is wrapped and glued around the concentrate packages by robots. This method is efficient for large product series.

Compared to the BiCart[®] packages today, the new package concept is an improvement in many areas. Less material is used for the Bag package that is an advantage from an environmental point of view. To empty a cartridge package from remaining concentrate after a treatment is almost impossible with the existing cartridge packages used today. Providing the users with an ability to empty the concentrate package may be easier to implement on a flexible bag package like this, by adding a perforated line, a notch or other kind of opening in the detailed design.



Figure 10-37 Box for two concentrate packages.



Figure 10-38 The packages can be packed and piled efficient.

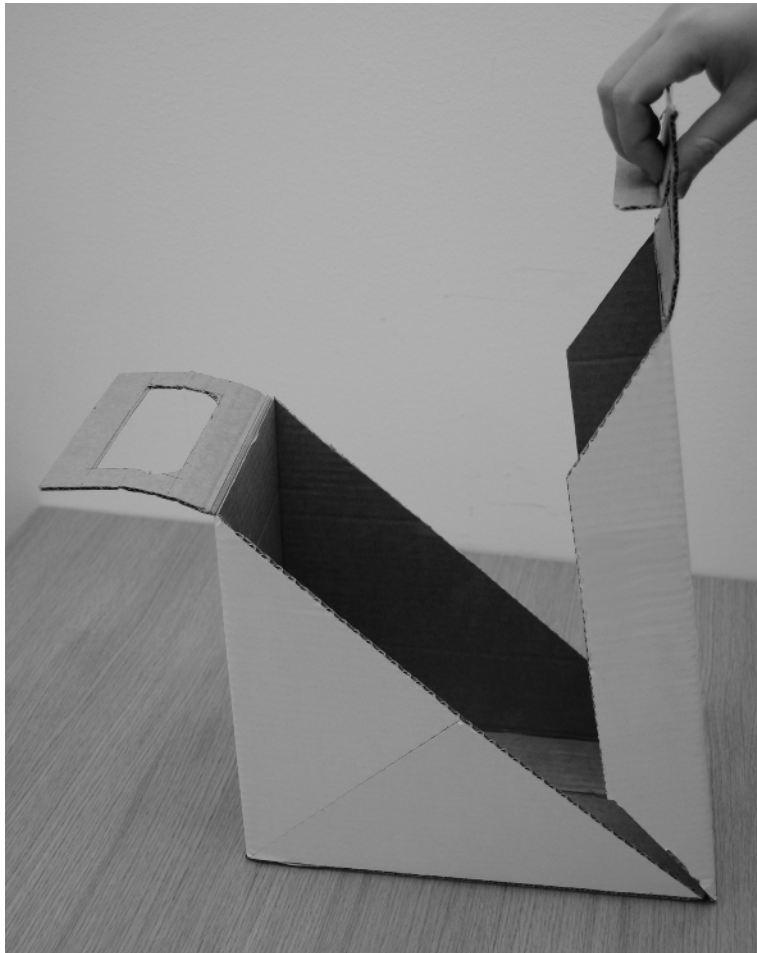


Figure 10-39 Opening of the package.



Figure 10-40 Two packages can be carried in a efficient way.

10.4 Usability Tests

In order to evaluate the package concepts from a users' point of view, six usability tests was performed. The usability tests concerns evaluation of the box package and the concentrate package and contained one practical part where the user investigated the new product concept and got some tasks. This explorative session was followed up by a discussion with interview questions. The usability test aimed to test the opening of the box package and the flattening after use. The test participants where also asked to write down the LOT-number of the primary concentrate package. The following discussion concerned the users experience of the packages, what they liked or disliked with the handle, the opening, flattening, size, load, shape and more. The test plan and the results can be found in appendix I respectively in appendix J.

The usability tests aimed to evaluate the developed concepts. This user test was held early in the developing and its function is to find out what can be improved more than in the purpose of validation. The usability test verified some areas that a further development should take into consideration. The usability test also confirmed some assumptions.

10.4.1 Opening of the Box Package

The test participants ravelled the package; they didn't notice that there was a more simple way to open the box. The reason could be that the concentrate packages today don't have any smart opening so they don't look for it. However the test results indicate that a graphic illustration should be added to the package describing how the package is intended to be opened. Once learned the user will know how the box is intended to be opened. After test number two, a graphic symbol of a scissor was added to the package. The results indicated that a symbol was needed. In the following tests the users found where and how the package was intended to be opened.

10.4.2 Folding the Box

All the test participants appreciated the folding of the box once they got the idea of the principle. The first two test participants did not open the box the way it was intended and hence the package could not be folded correctly. The participants who opened the package correctly, did also intuitively found how the package was aimed to be folded.

10.4.3 The Handle

Most of the participants liked the handle. The handle was easy to see and easy to grip, even thought some would prefer a less sharp handle. The shape of the triangular package gives the user a choice to carry 2 boxes x two packages in one hand in a convenient way.

10.4.4 Size of the Box

One participant in the usability test would prefer to increase the size of the box so that it can take four packages or more. The others preferred the small box with two packages because of the weight.

10.4.5 The Bag Package

The package has a good grip, no one complained over the package size, shape or material. The triangular shape felt new and different from other packages, in a good sense. The flexibility of the packages contributes to a good grip and the packages can

also be stuck on each other. An other advantage mentioned was that the package takes up much less volume after use and the package material is also less heavy. All the participants found the LOT – number of the package and they also understood that the LOT-number label could be removed and pasted in the medical record.

10.4.6 Other Data

The users appreciated that the package concept doesn't force the user to use any great pressure and rotation. In the discussion the test users came up with some interesting proposals for how the concept could be improved. E.g. some wanted an easier opening of the box. Graphics on the package describing the opening and folding principle was suggested for supporting novice users.

In the usability tests of the box and concentrate package the adaptability was acceptable and the users where positive to the concentrate package concept. Some results indicated on things that should be changed in order to achieve a higher level of usability. The concentrate module was evaluated theoretically by PHEA and CW and discussed with the participants in the usability test in order to collect feedback from people with a background in dialysis treatment.

10.5 Conclusion of the Concept Development

The end result of the concept development is a design proposal for how a concentrate package concept developed to increase the usability can look like. However more work is needed for implement the findings from the usability tests and to define the products further. The developed box concept uses a folding principle that makes it easier for the user to flatten the package. The box concept consists of different sizes of boxes from 2-6 packages in each. Small boxes are preferred form a usage perspective since they are easier to handle and carry. The concentrate package is made of flexible package that easily will be flattened after usage so that it becomes small and easy to dispose. The flexibility of the package contributes to a comfortable grip that was appreciated in the usability test.

11 DISCUSSION

Designing of products with a high level of usability requires many iterations of e.g. usability testing, evaluation, development etc. Within this project the amount of iterations were limited due to the time limitation for the project. The concepts need further development and later evaluations in order to fulfil the usability requirements.

11.1 Answers to the Questions

In this section the answers to the three questions for the project are discussed. These three questions were first presented in section 1.4.

- A) What needs and wants does the users have on a dialysis concentrate package?
- B) Which are the most important usability aspects for a concentrate package?
- C) How can a dialysis concentrate package with good usability look like?

a) In summary the users want a dialysis concentrate package to be easy to grip i.e. made of a flexible material, small and lightweight, easy to open, easy to attach to the machine, easy to empty the package and easy to flatten after usage.

b) The investigated use requirements are presented in section 7.3. Further more usability guidelines for the product are presented in section 7.16.

c) The usability evaluations indicates that clear visual clues for the aimed opening is essential for guiding users who meet the product for the first time. Further the easy flattening of the secondary package was regarded as one of the most important usability aspects and was appreciated in the evaluation tests. The end result of this project can be seen as a concept that have a good potential to reach a high level of usability.

11.2 Delimitations

Three limitations were set for the project in order to focus the study to the chosen topic area and make it practical realizable with the available resources. It is assumed that the three limitations did not affect the end result but would result in a more specified concept regarding material, detailed design and manufacturing methods and costs. It would have been interesting to evaluate the product act in developing countries where the products primarily is aimed to be used. However the nurses situation in those countries would probably not be very different from the studying objects and it is assumed that the actual usability requirements are similar in all of the selling areas.

11.3 Fulfilment of Goals and Guidelines

In this section the fulfilment of the project goals and the guidelines described in chapter 1, 7 and section 8.3 will be discussed.

11.3.1 Fulfilment of the Purpose and Goal

The aim of the project was to develop concepts that support the dialysis operators with an ergonomically designed user interface with a high level of usability. The project has resulted in suggestions of how and where the concentrate container is attached to the dialysis machine and the package concepts has been evaluated in usability tests

according to the project plan. It is believed that the project has fulfilled the project aim.

11.3.2 Fulfilment of Usability Goals

Since the usability test didn't test the attachment of the concentrate package, the usability goals for this could not be verified within the project. To evaluate these goals a realistic full function prototype must be produced.

11.3.3 Fulfilment of Aesthetic Guidelines

The aesthetic guidelines could not be evaluated truly based on the concept models. It is somewhat difficult to evaluate test models from an aesthetic viewpoint in this early stage of the development since the products have some differentiations from a final product. It is however assumed, based on subjective estimations, that the concepts have a potential to fulfil the aesthetic guidelines. An evaluation with test participants would be preferred to state that the goals are fulfilled.

11.3.4 Fulfilment of Utility Goals

The utility goals considered technical aspects that were not aimed to be tested within this project.

11.3.5 Fulfilment of Environmental Guidelines

Most of the environmental guidelines have been considered satisfactory in the concepts. The weight of the concentrate package has been minimized as well as the material used. The volume is also minimized so that the packages are piled efficiency in the transportation and storage. The issue of emptying the concentrate package after use was not investigated in the concept development since there was no time for this, however a discussion of possibilities for this was made but not executed. Estimation for the energy used for the disinfection was not made. However the connection to the machine is quite similar as for the existing cartridge packages used today. It is assumed that the energy for disinfection should therefor not exceed this. The flattening of the package easily before disposal was another environmental guideline that has been fulfilled successfully.

11.3.6 Fulfilment of Usability Guidelines

Some of the guidelines have been fulfilled within the concept models and others are included in the theoretical development of the concepts. However the concepts doesn't include any features that are contradict from these guidelines.

11.4 Work Procedure

The characteristics of the used work procedure are the many iterations and the focus on the user during the concept development. The work procedure was appropriate to use for this project and many of the suggested methods where applicable in the work process. The framework for the work procedure was used for structure the work in the initial planning phase and and gave suggestions for usable methods and tools during the project work. The disadvantage of the work procedure was that it is somewhat strict in its structure. When working alone in a project the need of formality is less important than work in a large project team. To have a clear work procedure becomes more important in extensive projects with many participant and projects running during a long time. However when designing devices within the medical industry it is a law

saying that the developers must follow a process that involves the user during the product development. By applying a work procedure like this that implements the users perspective, these requirements will be fulfilled. If I would do this project again I would have spent less time in the initial needfinding phase and put more resources for the concept development. The needfinding is very important in order to specify the users, usage and environment but for this project it wouldn't be necessary to go so deep into the descriptions of the user and usage by user classification and use profile. If there where more time available, at least one more iteration of the concepts would be preferred in order to make improvements after the usability tests.

11.5 Field Studies

Three dialysis wards where studied in order to gain an understanding of the usage situation, the context and the users. All three of them were placed in south of Sweden of practical reasons. The usage situation, users' education and context will most probably differ somewhat from e.g. developing countries. One can assume that the principle of the usage and the function of the product is the same worldwide but some circumstances will probably differ. The importance of a low budget product is more prioritized in developing countries, the quality of the water is variable, the education of the operators differ and also hygiene etc. However many of the gained opinions from the users about the function and usage of the existing products could probably also be applicable to product design also for other countries as well.

When designing for dialysis nurses, the developer must have insights in the usage the users and the environment in order to meet the users needs, wants and expectations. The user studies together with the interviews were the most valuable source for information in the project. No literature can tell the developers how the actual users experience the products; it must be investigated at site for a satisfactory result. In most important information from the field studies was related to the handling of the used packages that was worse than expected. This project could not be done satisfactory if field studies where not possible.

11.6 Concept Development

Concentrate packages today doesn't really have any current product sign, the variety of product varieties are too wide and differentiable to distinguish any archetype of this type of product. The lack of a stereotype and product sign opens up for creativity for how a concentrate package could look like.

The concept development phase started by sketching and creation of paper models and sketch models in the purpose of trying out different solutions for the problem. The practical work was necessary for testing and evaluate ideas in an early phase of the project. Development of sketch models is a fast and inexpensive method to try out different concepts. Especially when it comes to how products are to be hand-held, the possibility to try, feel and experience the product is invaluable and necessary.

11.7 Usability Tests

As test participants, in-house people at Gambro Lundia AB with previous experience of working as dialysis nurses were selected. The test participants differ from the actual end

users since they are not active in dialysis healthcare today. Further the test group only consisted of Swedish people while the actual end users are people from different cultures all around the world. Since the test participants were Swedish, the test instructions, interviews and discussions were held in Swedish to minimize the risk for misunderstanding. The amount of test participants (six persons) was considered as being satisfactory for this kind of usability test.

The test model was a representation of the final product and the model has some limitations compared to the final product. This may affect the user test and the test results will therefore be regarded as giving a hint for the level of usability of the developed concept and how it can be improved. For example the test models of the boxes have some imitations of perforating lines that differs from machine made products. This could have affected the test results in the user tests.

It would have been an advantage to have many physical models available of different box sizes in order to give the test participant opportunity to try out the load and size physically of the different boxes. Since the model making of boxes was very time consuming, only one size of box was evaluated in the usability test. Most of the test participants said that they would prefer a small box that contains two packages before a larger package. It would have been interesting to have tested if the result would be different if the users also had the opportunity to try boxes with 4-6 concentrate packages in the same test session and let them compare the weight and sizes physically.

Some users preferred to open the box by tearing the handle from the package. This method to open the box was not expected, on one hand it requires more force but at the same time no tool is needed. The usability test obviously indicated that graphics is necessary for guiding the user to open the box the way it is intended, without a symbol of a scissor no one understood the opening, with the scissor symbol all opened the package correctly. At the same time, graphics for how the package is folded is probably not necessary since the users, according to the usability test, may understand this intuitively, given that the package has been opened correctly.

The idea of the test was to carry out as much information as possible for how the concept function in interaction with the user and how it could be further improved. With that aim, it becomes less important to make the test sessions identical and hence variations in the tested product, such as attempts to improve the product, are accepted. The usability test and especially the discussions after the test triggered the development in a positive way. It would have been interesting to involve people more also in the ideation phase by discussing the ideas from a usage perspective at a theoretical level.

11.8 Final Concepts

It is believed that the end result of the developed concepts have qualities that can improve the handling with dialysis concentrate packages in the future. However further development of the concepts is necessary to reach a high level of usability. Many aspects have been improved, such as easier handling of waste, less package material used and an easy removable LOT-number label etc. while other aspects have to be further developed and defined more in detail.

The diversity of the whole package concept, consisting of a primary concentrate package, a secondary box package and a module to fasten the concentrate package, is a quite large concept. This resulted in an overall concept for the interaction between the human and the products and the interactions among them. More detailed and defined designed concepts was not possible to develop within the predefined timeframe. After complete this project one could see that within this timeframe of twenty weeks, it could have been enough to develop just a box concept or just the primary package for the concentrate. To increase the number of delimitations a more defined concept would have been able to develop.

The final end result of the box concept does not have any inner package, as suggested in the ideation. It is assumed that the load on the packages will be on the corners when piled and hence an inner package is not necessary for the stabilization. This hypothesis could be proved by a practical test. By not having an extra inner package, package materials will be saved and the opening of the package will also be less cumbersome.

In the discussion of possibilities for the new concentrate package (section 8.4), different alternatives of where to attach the package was declared. Since the final end concept has a small volume and is quite lightweight, only 1.8 kg, the package may not affect the stability of the machine. If the machine is loaded with concentrate packages on each side for example A concentrates on one side and B concentrate on the other, then the stability may actually be even better than it is today.

To have a separate package or a built in container for the concentrate was discussed for the concept generation in section 8.4.2. The end concept is developed as a separate package. The benefits of this, compared to the built-in-container, is an effective usage which does not need any disinfection of the container, since the container is disposed after each treatment. One could think that it is an environmental waste to use a throw away package, but on the other hand, the disinfection after every treatment for a built in container means an essential amount of water that has to be heated up by energy. The disinfection also implies delays in form of time between the treatments when waiting for the machine to be disinfected and then cooled before next treatment can be performed. Since the information collected from the user studies and interviews regarded the time aspect as an important area to prioritize in order to reach high efficiency, the concept of the built in container was disqualified.

It was not claimed from the project start that the box concept should contain different sizes of boxes containing different numbers of primary packages. As the development proceeded an advantage of providing different markets with different box sizes was detected. Since the markets have different needs and wants regarding the box size, all markets would be more satisfied if the size is customized to their handling of packages. The meet of the customers' need and request would weight out the extra cost of producing e.g. two package sizes instead of one.

12 RECOMMENDATIONS

The following recommendations are aimed for Gambro for further development of the package concepts.

12.1 General

- Use test participants continuously in the product developing process in order to evaluate concepts from the usage point of view.
- Also assess aesthetic evaluations with test participant. It could e.g. be performed by questionnaires, chart diagrams and discussions based on frameworks for aesthetic evaluations.

12.2 Concentrate Package

- Change the cartridge concentrate packages to flexible packages. Flexible packages are more preferred by the users. Flexible packages are easy to dispose.
- Develop a rail on the concentrate package so that it is easy to attach to the module without too much precision.

12.3 Concentrate Module

- The concept of the concentrate module has to be further evaluated by usability tests and the function also has to be developed.

12.4 Box Package

- Develop the package concept further and find a package concept that provides a smart opening solution that is intuitive and doesn't require any tool to open.
- There is a need from customers for easy foldable packages and further investigation of this is suggested.

13 CONCLUSION

- Dialysis nurses have many thoughts about the existing concentrate packages at the markets today and also wishes for improvements in a future product. The user studies and interviews at the visited dialysis wards emphasized the importance of concentrate packages that are efficient to use so that it does not interrupt the loaded schedule of treatments. A concentrate package concept must also meet the needs of a lightweight product that is easy to handle and easy to dispose etc.
- Nurses often have discomfort with ergonomic issues; especially aspects related to hand ergonomics such as tension in finger joints and wrists. The source for these problems is their daily interaction with medical equipment that doesn't meet their ergonomical needs for a good physical environment. Grips such pinch grips should be prevented, as well as interactions that implies rotations of the wrist, heavy loading and bending.
- A dialysis concentrate package that supports good usability meets the users needs of an effectiveness, efficiency and satisfactory product. It must be designed for the specified users, in the particular environment and for the whole product cycle of interaction, e.g. unpacking of the concentrate, attachment of the concentrate package and dispose of the package material after treatment.
- It is an advantage to work at the site of the collaboration company during the project since you have a lot of expertise for the product nearby to ask for technical possibilities, direct feedback on concepts during the process etc. It is easier to keep the company involved in the design process and decision-making and make them aware of how the work proceeds. To have this collaboration may increase the potential for making a design that satisfies the company and is implementable to the existing products.
- In order to reach the goals of high usability products, many iterations including user evaluations are necessary, especially for comprehensive concept development. The concepts must be evaluated continually and dialogue with the actual users is an invaluable advantage for developers in order to get on the track to a winning product.

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Appendix A: Interview Questions

Ten semi structured interviews were held with nurses from three different hospitals. The amount of field studies and interviewees were enough to get a differentiated feeling of the objects for the study's purpose. The results from the interviews were coherent to a large extent but some subjective thoughts about how they liked the products differed slightly among the individuals. The interviewees were both male and female and had between 4 and 24 years work experience of dialysis. Also some more informal chatting with patients was held in order to hear about their picture of dialysis and how they found the dialysis equipment. Some of them operated the dialysis machines themselves. A few of the interviewed nurses had previous experience of "central distributed concentrate" i.e. the concentrate is delivered to the machine through pipes from a central at the ward. The amount of different concentrate packages and systems used gave a wide insight in the handling of concentrates today.

Interview objects: primary users, (nurses)

Amount of interviews: 10

Inledande faktauppgifter

Sjuksköterska? Annat?

Under hur många år har du arbetat med dialysvård?

Användare

Vilka är det som använder dialysapparaten? (sjuksköterskor, undersköterskor, läkare, patienter?)

Hur mkt träning krävs för att en användare ska kunna hantera en dialysapparat på egen hand?

Hur många starter/avslut gör ni per dag?

Hur många är det som startar upp en behandling?

Användning

Oberoende av vilka typer av konzentratförpackningar som används:

Vad tycker du om hanteringen av konzentrat? Hur går det till?

Vad har ni för olika typer av konzentratförpackningar?

Hur upplever du hanteringen av de produkter du använder?

Uppskattar du hanteringen av hårda eller mjuka förpackningar bäst? Varför?

Hur använder du skalan på förpackningen?

Hur tycker du att det fungerar att förbereda konzentratet inför en dialysbehandling?

Hur gör du för att kontrollera att du gjort på rätt sätt?

Har det hänt att det blivit fel? Gick det att åtgärda?

Hur förvarar ni konzentraten när de inte används?

Jämförelse mellan olika konzentratförpackningar

Är det någon förpackning som du föredrar framför andra? Varför?

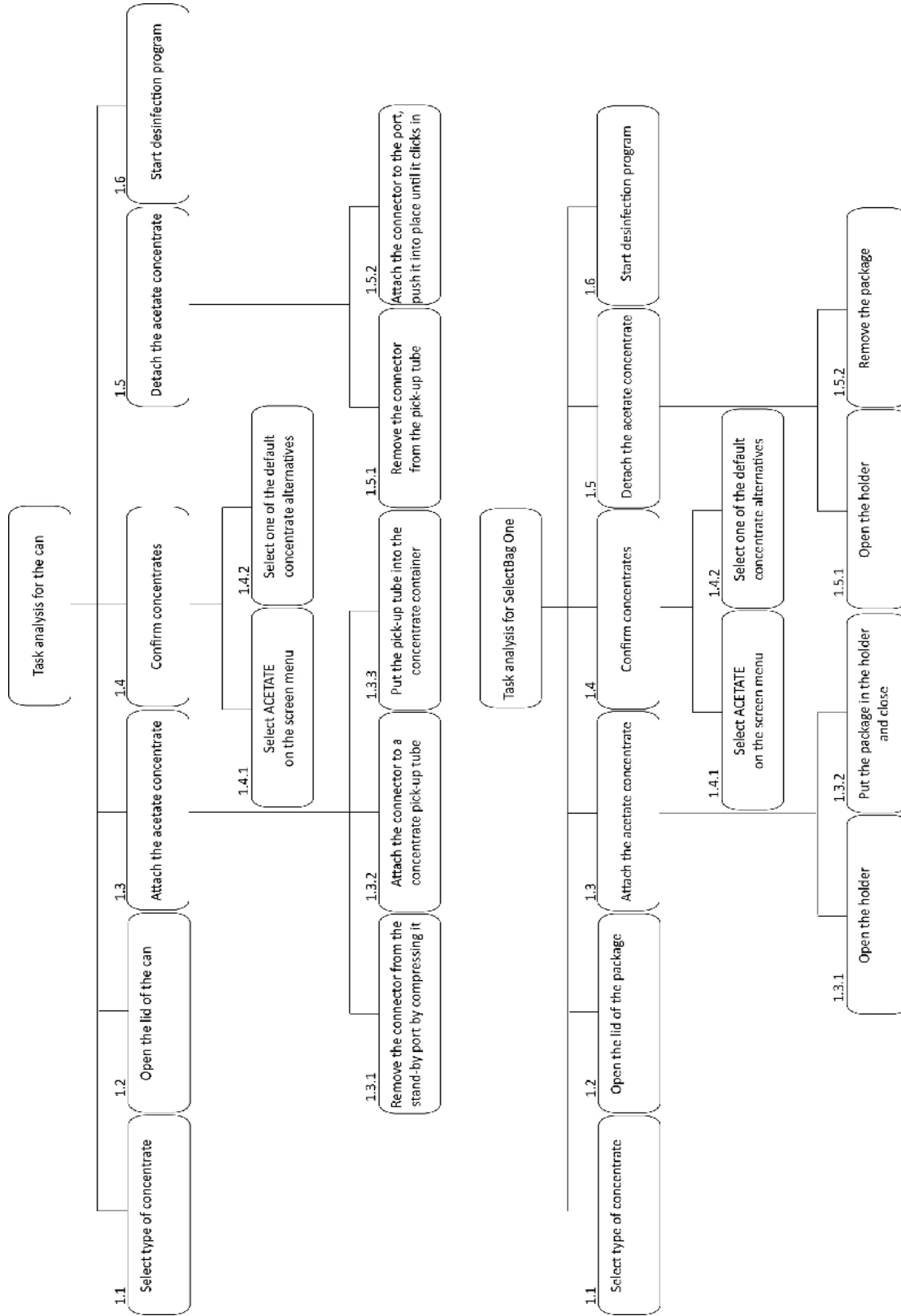
Är det någon förpackning du tycker mindre om? Varför?

Önskemål

Vad tycker du är viktiga egenskaper hos en konzentrat-förpackning?

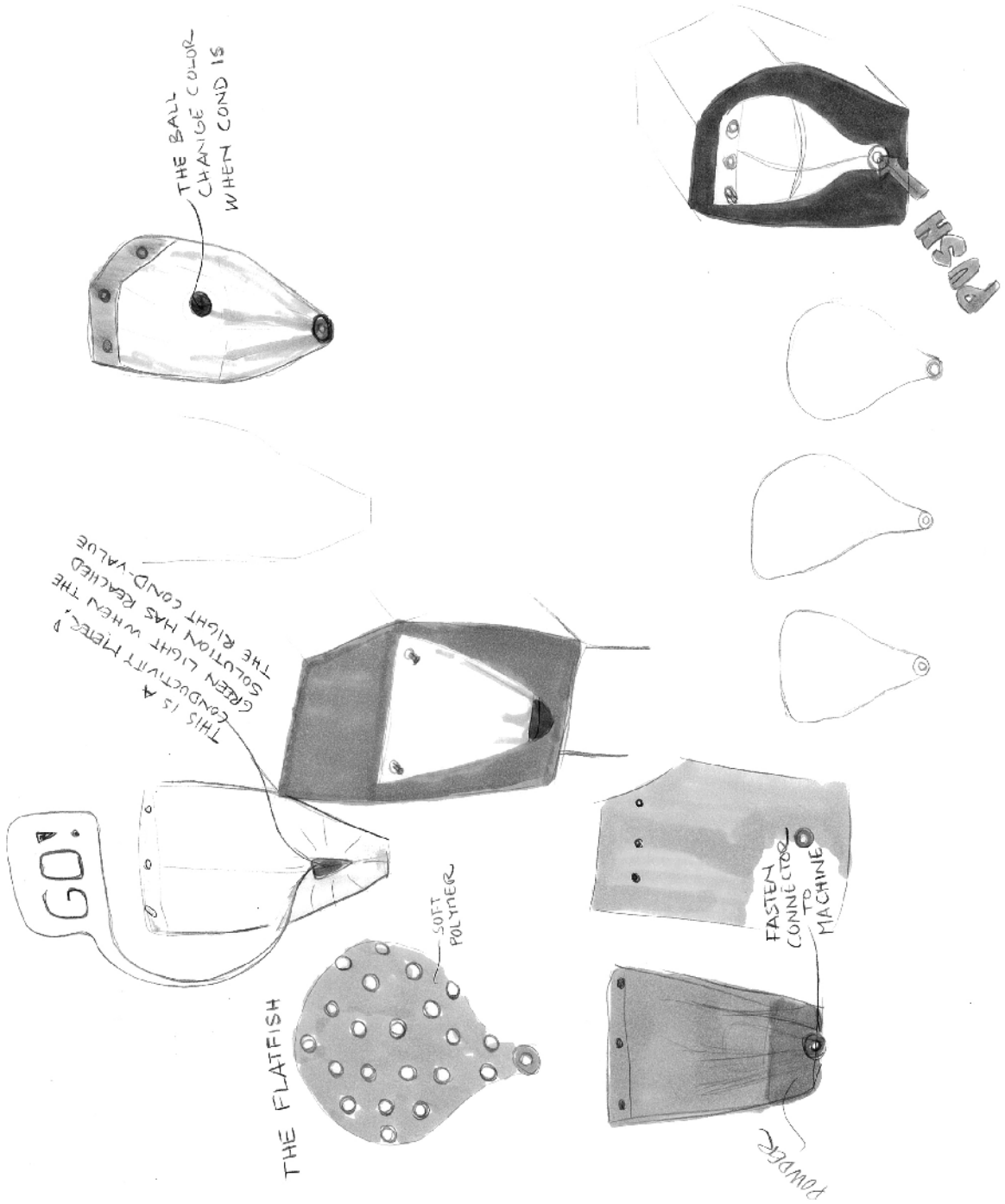
Hur skulle du önska att hanteringen av dialyskonzentrat var utformad i framtiden?

Appendix B: Existing Work Flow – HTA

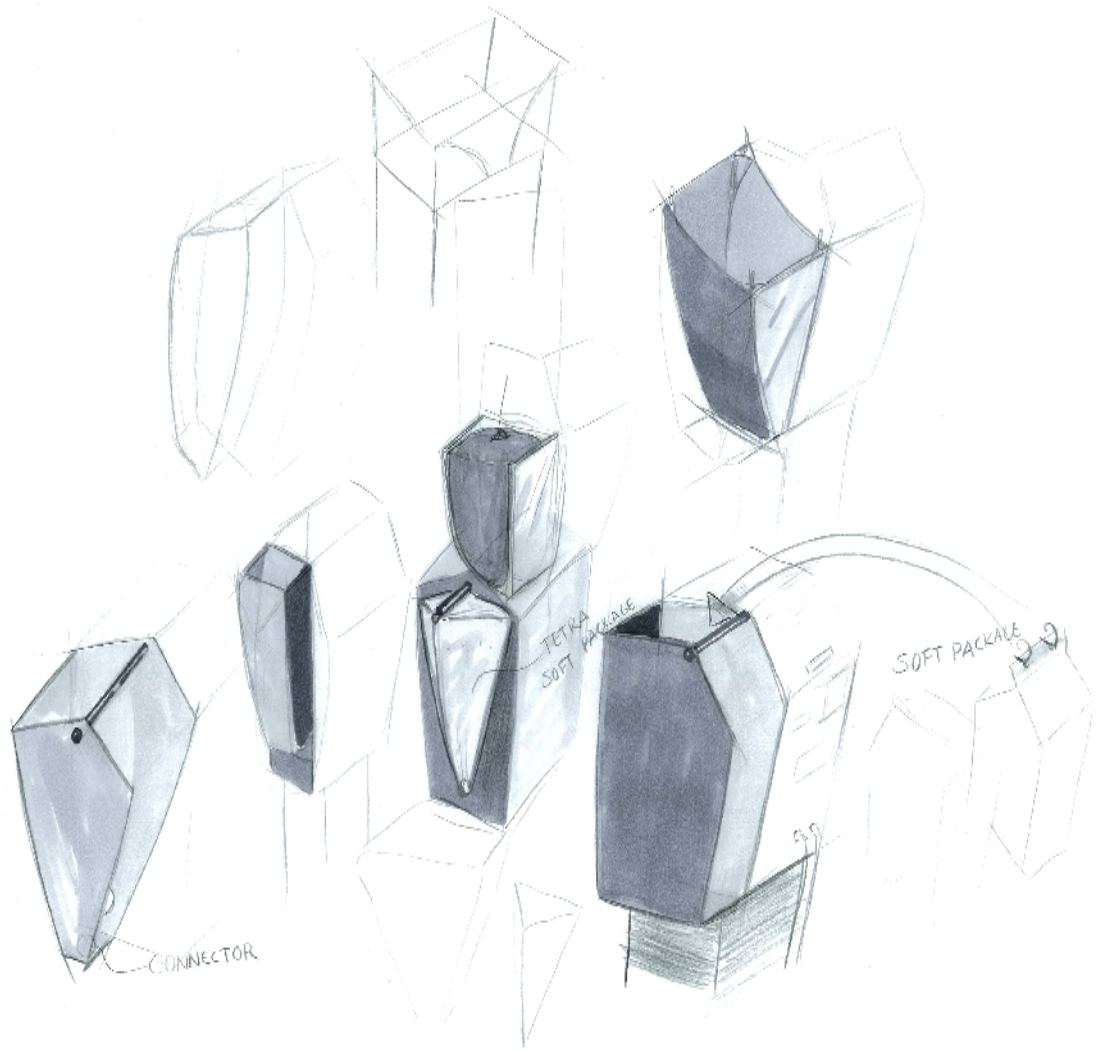


Appendix C: Sketches

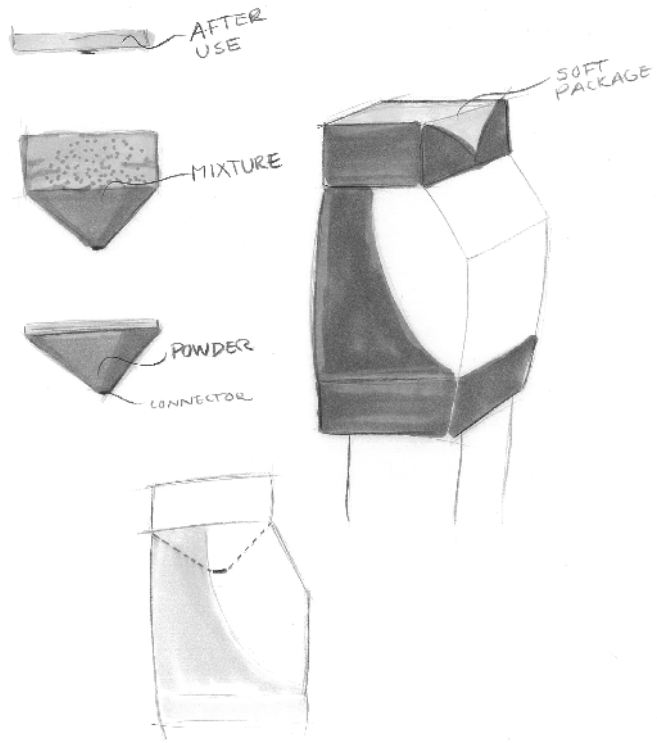
A



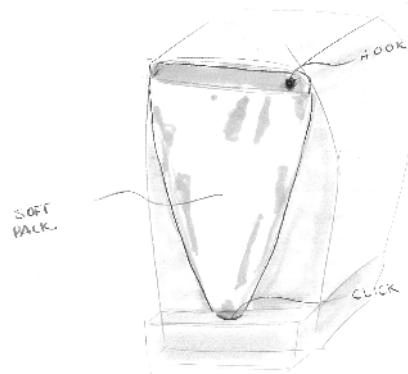
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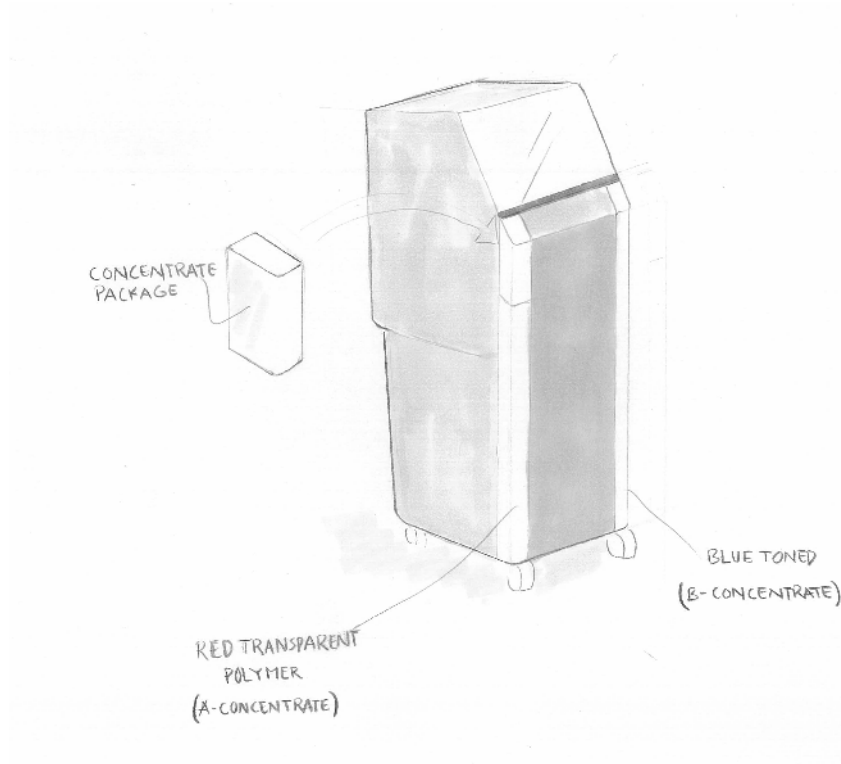
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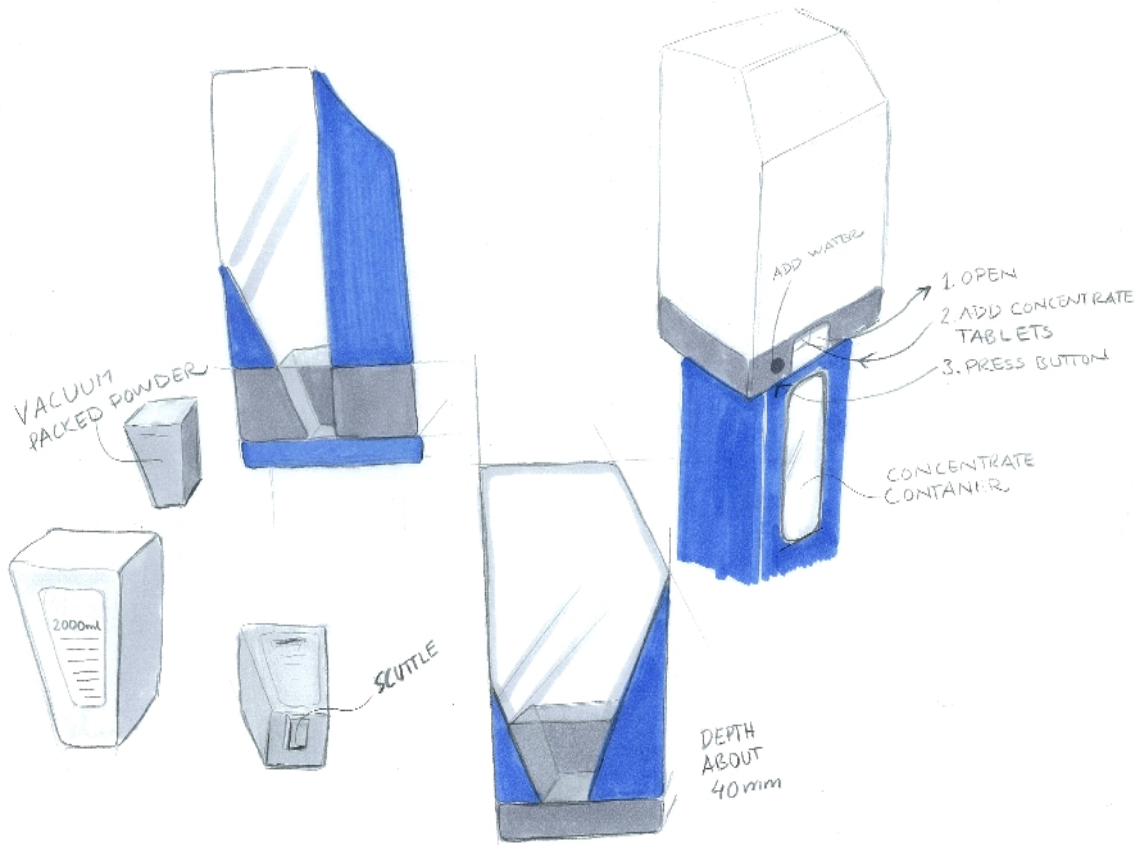


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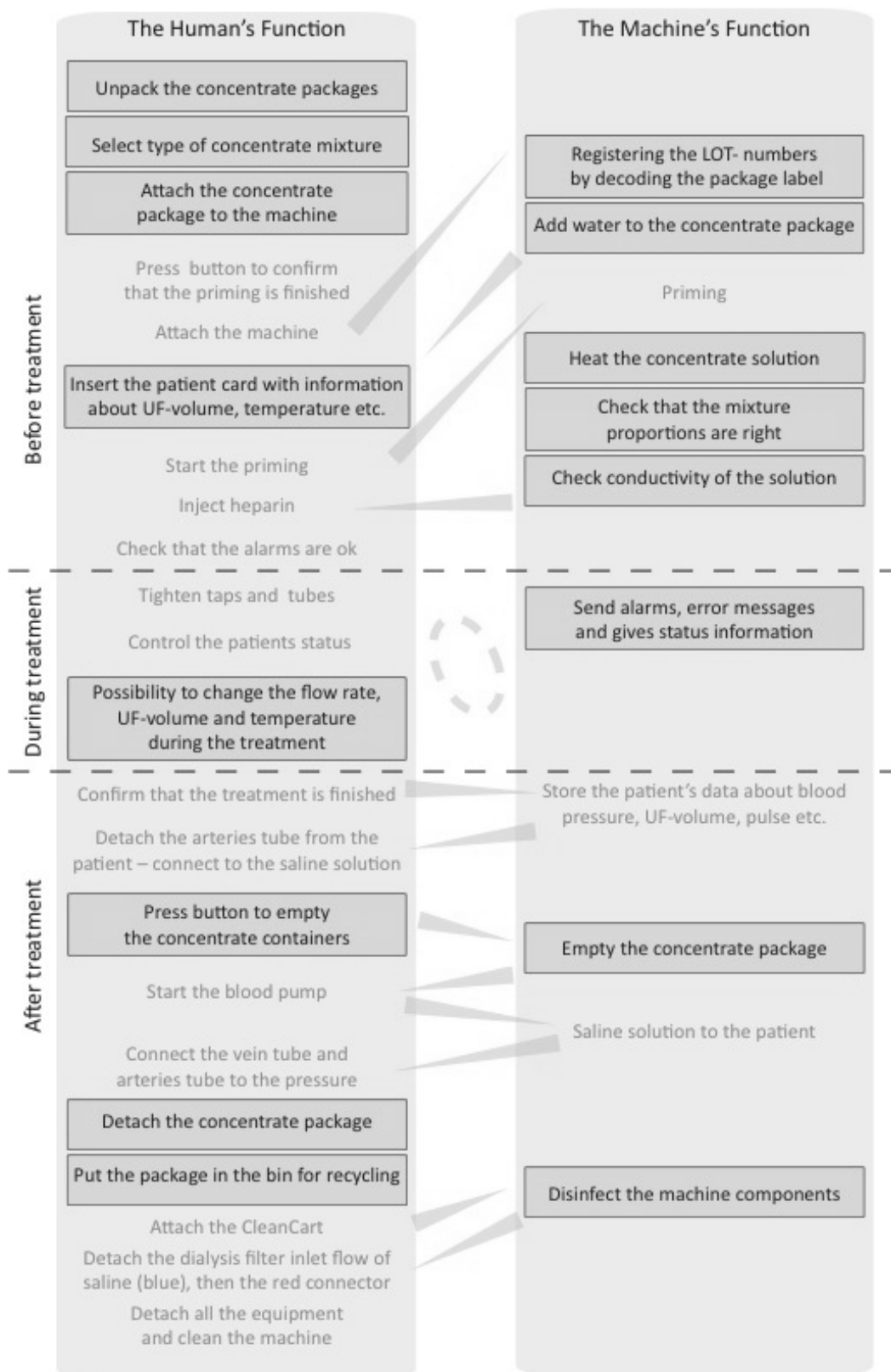
E





F

Appendix D: Task Allocation



Appendix E: Cognitive Walkthrough (CW)

CW - Concentrate Container - Concept Analysis

Operation: HTA: 1.2.1 & 1.4.1 Open the holding device

Questions	Success / Failure Story	Problem Type	Prevention
1. Will the user be trying to achieve the right effect?	Probably	K (new users)	Automatic opening
2. Will the user be able to notice that the correct action is available?	Probably	S (does 'nt notice)	Use gestalt laws- make associations
3. Will the user associate the correct action with the desired effect?	Yes	-	
4. If the correct action is performed, will the user see that progress is being made?	Yes	-	

Operation: HTA 1.2.2 Pull down the package in the holding device

Questions	Success / Failure Story	Problem Type	Prevention
1. Will the user be trying to achieve the right effect?	Yes	-	
2. Will the user be able to notice that the correct action is available?	Not certainly	K (new users)	Use semiotics
3. Will the user associate the correct action with the desired effect?	Yes	-	
4. If the correct action is performed, will the user see that progress is being made?	Yes	-	

Operation: HTA 1.2.3 Close the holding device

Questions	Success / Failure Story	Problem Type	Prevention
1. Will the user be trying to achieve the right effect?	Not certainly	L	Reminder on the display
2. Will the user be able to notice that the correct action is available?	Probably	K (new users)	Explanation on the display
3. Will the user associate the correct action with the desired effect?	Yes	-	
4. If the correct action is performed, will the user see that progress is being made?	Yes	-	

Operation: Clean the holding device

Questions	Success / Failure Story	Problem Type	Prevention
1. Will the user be trying to achieve the right effect?	Yes, when dirt is visible	-	
2. Will the user be able to notice that the correct action is available?	Probably	K (new users)	Use appropriate semiotics
3. Will the user associate the correct action with the desired effect?	Yes	-	
4. If the correct action is performed, will the user see that progress is being made?	Yes	-	

Appendix F: Predictive Human Error Analysis (PHEA)

PHEA - Concentrate Container - Concept Analysis

Questions:

1. What happens if the user performs an incomplete operation or omits an operation?
2. What happens if the user performs an error in the sequence of operations?
3. What happens if the user performs this function at the wrong time?
4. What can the user do wrongly in this operation?

ID no.	HTA ID	Error	Why?	Consequences	Prevention	Recovery
1	1.2.2	Place the package upside down in the holder.	Unawareness sloppy.	The inlet will be attached to the outlet and vice versa which will cause problem. The connections have different functions and hence differently constructed and must therefore be attached correctly.	Make it impossible to attach the package upside down to the machine in order to provide a user friendly interface, e.g. by designing a track that eliminates the risk of wrong attachment. Or make the two connections different so that the inlet cannot be attached to the outlet and vice versa. The holding device can be shaped so that the user gets a semantic hint of how the package will be attached.	The user may understand that the package should be attached the other way round if it doesn't fit.
2	2.1 / 1.4	The user doesn't know how to open the holding device.	Does not understand the eject button.	The holding device will not open.	Description / reminder on screen. Blinking light at the eject button.	Try again. There is only one button around the holding device so the options are not too many.
3	1.2.2	The user does not place the package all the way down in the holding device.	The user is in a hurry/ sloppy/ doesn't notice that it isn't properly attached.	The package sticks up and prevents the user to close the holding device.	The construction is designed so that the holding device can not be closed if the package is not properly pulled down.	Just pull the package down until you reach the stop. The user will feel and see when the package reaches the bottom of the holder.

4	1.2.3	The user doesn't close the holding device before treatment.	The user forgets to close it.	The machine will not start.	Reminder on screen.	Close it.
5	-	Open the holding device during the treatment.	By mistake or misunderstanding.	Potential for leakage. The treatment may stop.	Alarm. Information on screen about what is wrong and how it can be helped. The best would be if it could not be opened during the treatment, except in special cases such as in case of the package is empty and must be changed to a new one or if problem has occurred with the package so that is must be changed.	Close it.
6	1.2.2	Place a half-filled package in the holding device.	The user want to save remaining concentrate for another treatment. Economic reasons.	The package will most probably run out during the treatment and must be changed, which implies stop in the treatment process.	Inform the nurses. The consequence of the action is not that serious, the product mustn't be designed so that the action is impossible to execute. It is up to the user to decide whether a half-filled package should be attached or not. The machine can provide the user with information about how much concentrate the package contains and calculate an estimation of how long time the package will last with the actual settings (flow rate, treatment duration).	Never attach a used package in the holding device. Alternatively, the nurse wants to attach a used package of economically/eco-friendly reasons and decides to do so.
7	-	The user does not attach the priming device after the treatment.	The user forgets to attach the device.	The priming will not start.	Information / reminder on screen about what is wrong and how it can be recovered.	Attach the device.

Appendix G: Verification of the Concept

Task Analysis - Fulfillment

Main function (M), Necessary function (N), Desirable function (D)

ID	Task Requirements for the Overall Concept (T)	Fulfillment		
T1	Assist the dialysis process with dialysis solution	M	OK	
T2	Primary package that is impenetrable to water	M	OK	
T3	Be connected to the dialyze machine	M	OK	
T4	Available in 4-5 formulations	M	NOT INVESTIGATED	
T5	Contain 1,8 liter of powder, i.e. 1800 g	M	OK	
T6	Know when the concentrate has been mixed properly	N	NOT INVESTIGATED	shown on the screen
T7	Know that the solution has the right proportions	N	NOT INVESTIGATED	shown on the screen

CONCENTRATE PACKAGE

Task Requirements for the Concentrate Package (TC)				
TC1	Connection at the top and base of the package	N	OK	
TC2	A filter must be implemented to the outlet connector on the package	N	OK	
Use Requirements for the Concentrate Package (UC)				
UC1	Quick and intuitive to connect to the dialysis machine	N		
UC1	Clear differentiations for the different mixture packages	N	NOT INVESTIGATED	
	Avoid interaction which can cause tension			
UC3	in e.g. fingers, arms, legs and back	N	OK	
UC4	Ability to fold/ flatten package after use	D	OK	
UC5	Have a removable LOT number on the concentrate package	D	OK	
UC6	Have a LOT code on the package that can be read digital	D	IDEA NOT PROVED	exist on other packages today
UC7	Avoid heavy load on the users body	N	OK	
UC8	Ability to mount without leak	N	NOT INVESTIGATED	same principle applied on CleanCart today
UC9	Ability to see the concentrate through the package	N	OK	

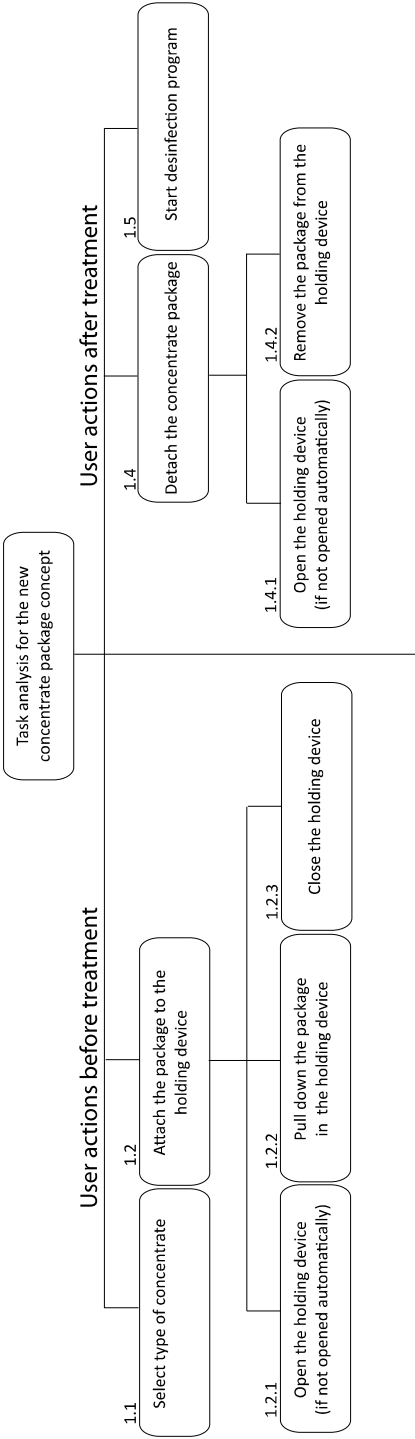
MODULE

Task Requirements for the Module (TM)				
UM5	Ability to disinfect all components that will have contact with the dialysis fluid	N	IDEA NOT PROVED	theoretically developed
Use Requirements for the Module (UM)				
UM1	Attachment of concentrate to the machine at a convenient height	N	OK	
UM2	No separate components that can be lost	D	OK	
UM3	Avoid heavy load on the users body	N	OK	
UM4	Design so that the package can't be attached wrongly	D	OK	
Context Requirements for the Module (CM)				
CM1	Ability to connect to the AK 96 dialyze machine	M	IDEA NOT PROVED	form design proved, function not proved
CM2	Ability to connect to other brands/types of dialysis machines	D	NOT INVESTIGATED	
CM3	Ability to clean around the connections	N	OK	
CM4	Not be in the way of other components on the machine	N	OK	

BOX

Task Requirements for the Box (TB)				
TB1	Packages shall be arranged on an EU-pallet	N	OK	
TB2	Packages shall contain a package leaflet (A5)	N	OK	
TB3	Possible to pile efficiency	N	OK	
TB4	Possible to pack efficiency in the factory	N	NOT INVESTIGATED	
TB5	Use cardboard as primary package material	N	OK	
Use Requirements for the Box (UB)				
UB1	Packages shall be easy to grip and carry	N	OK	
UB2	One package shall not weight more than 10 kg (Gambro's guideline)	N	OK	2-5 packages OK, 6 packages=10,8 kg
UB3	Possible to flatten the package easily	N	OK	appreciated in user test
UB4	Avoid heavy load on the users body	N	OK	
UB5	Avoid sharp edges for the handles	D	OK	some complaints in user test
UB6	Easy to open the package	N	OK	some difficulties to understand in user test

Appendix H: Work Flow for Attachment of the New Concentrate Package – HTA



Appendix I: Test Plan for the Usability Test

Test Plan for AK 96 Concentrate Package

Purpose

The purpose of the user test is to evaluate and see how the developed concept works from a user's usage perspective. The findings from the user test can hopefully be useful for the further development of concentrate packages. The user tests aims to detect risks related to the handling and collect the users' subjective impression and experience of the product.

Scope

The package concept will be tested on in-house people at Gambro, of secrecy reasons nurses from hospitals cannot be involved in the user tests. Six user tests will be performed within this test session. People with a background in health care will be preferred as test participants.

Test Environment

The user tests will be held in a usability lab aimed for user tests at Gambro in Lund.

Test Area

Some potential use errors was detected by the theoretical error analysis PHEA (see Methodology), these has been improved a bit by the further concept development and special attention will be held on the potential use errors ID 1-4 in the PHEA.

The user tests will include the process from that the user chose type of concentrate, opens the box and so forth until he/she removes the package from the machine and prepares the machine for disinfection.

Procedure

The test participants will follow a scenario that is read aloud by a test leader. The user will also get the tasks described on a piece of paper so that he/she can read it again if necessary.

The test users will not get any training or instructions for how the product works before the test starts. The users haven't even seen the product before. This is because the purpose of the test is to see how the product expresses its function and usage and the first impression of the product is interesting for the study.

Before the test starts the test leader and the observer will introduce the test users to the test.

The users will be encouraged to talk aloud about their handlings during the test.

After the usability test there will be a summary concerning the overall impressions and feedback on the product.

Each test is estimated to take 45 minutes to complete.

Material

The exterior of an AK 96 dialysis machine will be used; the software and display will not be available for the user. The product to be tested is a functional model developed for the test situation. The model is a simplified version of the product and hence it will not work as automatically as the real product will do. The test leader will in some case assist the user test prototype so that the automatic features are simulated.

User Tasks for the Usability Test

(Only task number 1.1. and 1.2. was performed in the usability test)

1.1. Unpack and fold the box package

The task to the test participant will be “Du ska nu förbereda en dialysbehandling för en patient genom att packa upp en koncentrationförpackning. Vik sedan ihop kartongen och släng i kartongåtervinningen”

- The test participant is expected to open the box the way it is intended to be opened.
- The test participant is expected to understand how the package can be flattened.

1.2. Write down the LOT number

The task to the test participant will be “Skriv ned vad förpackningen har för LOT nummer.”

- The test participant is expected to find the LOT number on the label.

1.3. Attach the concentrate package to the machine

The task to the test participant will be “Montera koncentrationförpackningen på maskinen.”

- The test participant is expected to understand how the package is expected to be attached to the holding device by the product’s semantic features. The test participant will attach the package and close the compartment properly.

1.4. Remove the package from the machine

The task to the test participant will be “Nu är behandlingen avslutad och det är dags att ta ut koncentrationförpackningen”.

- The test participant is expected to open the compartment and remove the package from the holding device.

2.1 Directly after the pilot test there will be time for a discussion with the participants about their subjective impressions and experience from the user test.

Usability goals

Measures for Effectiveness/ Guessability

80% of first time users should be able to understand how the package is aimed to be attached to the machine. (Task 1.3)

80% of first time users should be able to understand how the box is aimed to be opened. (Task 1.1)

60% of first time users should be able to understand how the box is aimed to be flattened. (Task 1.1)

Measures for Satisfaction

Not more than 20% should feel irritation when handling with the concentrate package first time. (Interview)

80% of the users should rate the package to be more wanted than the existing 6-10 liter canister. (Interview)

80% of the users should rate the package concept to be comfortable to use. (Interview)

The rationale for the limit of 80% is decided since the risk analysis for the task has low severity rate. 60% is set for a task that doesn't affect the usage at all, but a correct handling will ease the handling. 20% is set for the limit of uses that may feel irritation. Irritation may not lead to a disaster but should be avoided.

Documentation

Besides the test leader there will be one person who will be observing and documenting the test. The observer is sitting in another room and following the test through a window, the talking from the test room will be hard through microphone and loudspeaker.

The following data will be collected and evaluated:

- Use errors
- Incidents, where operator intentions conflicts with handling
- Assists/prompts, where the operator gets stuck and needs some support to continue
- Test participant comments
- Subjective ratings from the participant

Evaluation

Focus for the evaluation was to evaluate guessability and satisfaction for the package concept.

Appendix J: Data from User Tests

Data Collection

Tp 1

Products: Box version no: 1 - Hatched line indicating opening. & Flexible concentrate package version no: 1

Solved independently (I) Solved with Guidance (G) Failed (F)

Task no:				Comments - usage
	I	G	F	
1A) Open the box the way it is intended to be open.			x	Hittar inte den avsedda öppningen. Använder kniven och skär längsmed sidorna. Tyckte att det kändes som att den borde ha kunnat öppnats på ett smidigare vis.
1B) Flatten the box the way it is intended to be flattened.			x *	Eftersom TP öppnade förpackningen felaktigt gick det inte att utföra vikningen korrekt.
2) Find the LOT number and write it down.	x			Hittade LOT numret snabbt och förstod att man också skulle kunna riva loss klisterlappen med numret.

- The result from the previous task made it impossible to complete this task correctly.

Data Collection
TP 2

Products: Box version no: 1 - Hatched line indicating opening. & Flexible concentrate package version no: 1

Task no:				Comments - usage
	I	G	F	
1A) Open the box the way it is intended to be open.			x	Hittar inte den avsedda öppningen. TP tycker att det finns många sätt att öppna förpackningen på. Öppnar boxen genom att sticka in handen i öppningen i sidan och drar upp locket. Tycker att detta sätt är enkelt och smidigt, speciellt om man har värk i händer.
1B) Flatten the box the way it is intended to be flattened.			x *	Eftersom TP öppnade förpackningen felaktigt gick det inte att utföra vikningen korrekt. TP river sönder förpackningen för att få den mindre. TP upplever att det går relativt enkelt.
2) Find the LOT number and write it down.	x			Hittade LOT numret snabbt och förstod att man också skulle kunna riva loss klisterlappen med numret.

* The result from the previous task made it impossible to complete this task correctly.

Data Collection
TP 3

Products: Box version no: 2 - Hatched line indicating opening and an illustration of a scissor. & Flexible concentrate package version no: 1

Task no:				Comments - usage
	I	G	F	
1A) Open the box the way it is intended to be open.			x	TP förstår vid vilken sida som förpackningen ska öppnas. Tror att det är en perforering längst upp vid handtaget. TP river av handtaget så att förpackningen öppnas. Tycker att handtaget är något i vägen vid öppnandet. Öppnar sedan kartongen från sidan och tycker att det går ganska lätt.
1B) Flatten the box the way it is intended to be flattened.			x *	Eftersom förpackningen öppnades på sidan i uppgift 1 A, gick det inte att utföra vikningen på det vis som var tänkt. River upp förpackningen och viker sedan ihop kartongen, dock på ett lite mer krångligt vis än det tänkta sättet.
2) Find the LOT number and write it down.	x			Hittade LOT numret snabbt och förstod att man också skulle kunna riva loss klisterlappen med numret.

* The result from the previous task made it impossible to complete this task correctly.

Data Collection**TP 4**

Products: Box version no: 2 - Hatched line indicating opening and an illustration of a scissor. & Flexible concentrate package version no: 1

Task no:				Comments - usage
	I	G	F	
1A) Open the box the way it is intended to be opened.	x			TP förstår vid vilken sida som förpackningen ska öppnas. Använder kniven för att skära ett jack, river därefter av handtaget. Öppnar korrekt.
1B) Flatten the box the way it is intended to be flattened.	x			Viker ihop förpackningen korrekt utan anmärkning.
2) Find the LOT number and write it down.	x			Hittade LOT numret snabbt och förstod att man också skulle kunna riva loss klisterlappen med numret.

Data Collection
TP 5

Products: Box version no: 2 - Hatched line indicating opening and an illustration of a scissor. & Flexible concentrate package version no: 1

Task no:				Comments - usage
	I	G	F	
1A) Open the box the way it is intended to be opened.	x			TP förstår vid vilken sida som förpackningen ska öppnas. Efterfrågar sax eftersom det är en sax-symbol. Använder sedan kniven för att öppna förpackningen. Öppnar helt korrekt, ingen anmärkning.
1B) Flatten the box the way it is intended to be flattened.	x			Viker ihop förpackningen korrekt utan anmärkning.
2) Find the LOT number and write it down.	x			Hittade LOT numret snabbt och förstod att man också skulle kunna riva loss klisterlappen med numret.

Data Collection
TP 6

Products: Box version no: 2 - Hatched line indicating opening and an illustration of a scissor. & Flexible concentrate package version no: 1

Task no:				Comments - usage
	I	G	F	
1A) Open the box the way it is intended to be opened.	x			Tittar på förpackningen och ser sax symbolen. TP förstår vid vilken sida som förpackningen ska öppnas. Tar kniven för att öppna, skär bort handtaget.
1B) Flatten the box the way it is intended to be flattened.	x			Viker ihop förpackningen genom att vika efter perforeringarna inåt. TP anar att man skulle kunna vika ihop förpackningen på annat vis eftersom paketet blev lite knöligt. Funderar och kommer själv på hur förpackningen viks på det sätt som det var tänkt.
2) Find the LOT number and write it down.	x			Hittade LOT numret snabbt och förstod att man också skulle kunna riva loss klisterlappen med numret.

Appendix K: Data from Interviews with Test Participants

All of the test persons were former dialysis nurses, currently working at Gambro in Lund. TP 1,2,4,5,6 were female and TP 3 was a man. The interview discussions were held in Swedish since all of the interviewees were Swedish. A summary of the results are presented in English in section 10.2.

The interview was held directly after the user test. When questions 1-5 were answered, the test participants got an explanation for how the package was meant to be handled, how the box can be opened and flattened and how the concentrate package is aimed to be connected to the machine,

1. Vad tycker du om kartongförpackningen?

TP 2: Den tar inte så mycket plats. TP 3: Helt OK. Formen känns osmidig. Kanske inte så lätt att ta ner från en hylla. Handtaget känns OK att bära i men klumpigt. Passar en stor manshand utan problem. Förpackningen känns för bred för att greppa med en hand så man får använda två. Önskar större låda som rymmer mer. TP 6: Mycket smidig förpackning.

2. Hur är kartongen att öppna?

TP 1: Hittade inte naturligt var jag skulle öppna förpackningen. TP 2: Väldigt lätt att öppna, jag är vad vid att man får slita och dra. TP 3: Lätt att öppna. Man ser lätt var man ska öppna den men inte självklart hur man ska göra efter att handtaget är bortrivet. TP 4: Bra, men gillade inte att använda kniven. Önskar att öppningen hade perforering så att man enkelt kan riva upp förpackningen. TP 5: Inte van att använda brytbladskniv, jag är vänsterhänt. Lätt att skära genom pappen. TP 6: Skulle hellre vilja riva upp förpackningen än att använda redskap. Skulle vilja ha en perforering eller/och att det finns något att dra i. Inga problem att öppna den annars. Väldigt logisk att öppna upp.

3. Hur är kartongen att vika ihop?

TP 1: Kändes konstigt att vika ihop den, hittade inte hur man skulle göra. TP 2: Visste inte hur det var tänkt... Hur enkelt som helst om man vet hur man gör. TP 3: Lätt att riva itu och vika. TP 4: Den var ju väldigt enkel att vika ihop. TP 5: Enkelt att vika ihop, inga problem. TP 6: Det var inte så krångligt. Det var ju färdiga perforeringar som visade hur det skulle vikas.

4. Hur är kartongen bära?

TP 1: Bra att bära, bra handtag. TP 2: Jag tror att jag skulle använda handtaget. Bra att

handtaget har en vikning så att det inte finns någon skarp kant. TP 3: Känns lättburen. Bra handtag. TP 4: Provade inte det. Handtaget verkar smart att bära i. TP 5: Handtaget bör vara mjukt så att det inte känns vasst. SSK har ofta torra händer eftersom man tvättar händerna hela tiden. Bra att det var ett handtag.

5. Hur många konzentratförpackningar skulle du önska att det var i varje låda?

TP 1: Tror att det blir lagom med två förpackningar. Lagom vikt. TP 2: Verkar tungt att bära en låda med fyra förpackningar TP 3: 4 stycken i alla fall. Speciellt på klinik. Kanske färre för hemdialys. TP 4: Tror inte att det skulle vara fler förpackningar, det är tungt nog. Hade varken varit bra för miljön eller ekonomiskt att ha dem singelförpackade. TP 6: (om större förpackning) Kanske ur miljösynpunkt men arbetsmässigt så tror jag inte det är bra, det blir för tungt, det är så många tunga lyft. Bra med två förpackningar ur arbetsmiljösynpunkt. Skulle vara bra om möjligheten fanns att man kunde välja mellan en liten eller en större förpackning. Hemdialyspatienter får förpackningarna levererade och behöver inte bära på dem själva, så i detta fall kunde det vara bra med en större förpackning (göller hemdialys i Sverige).

6. Vad tycker du om påsförpackningen?

TP 2: Känns annorlunda med den trekantiga formen. Helt bra att hålla. Bra att den man kan få ett bra grepp genom att förpackningen formar sig efter handen. TP 3: Ligger bra i handen. Den känns skön. Kändes naturlig att hålla i. Man skulle kunna tänka sig att ha ett handtag på men det är nog inte nödvändigt. Kan staplas på varandra och man kan bära flera på samma gång. TP 5: Bra att den blir mindre efter användning än BiCart® förpackningarna idag. Skulle vilja testa hur det hade varit om förpackningen var större i relation till innehållets mängd, som en vetekudde. Hade kanske fallit lättare runt handen. Inga problem att bära den med två händer. TP 6: Lätt att ta i. Annorlunda mot hur de ser ut idag. Vikten kan nog upplevas som tung. Viktigt att man slipper tryck och vridmoment. Viktigt att få bort tyngden så snart som möjligt, att man bara hartyngden när man sätter i förpackningen. En påse bör räcka till en behandling för att slippa flera arbetsmoment.

7. Hur tycker du att konzentratförpackningen (påsen) är att handha?

Mycket komplicerad 1 2 3 4 5 **Mycket smidig**

TP 1,2,3,5,6 valde 4 på skalan TP 4 valde 5.

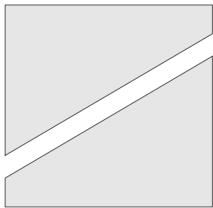
Merparten av användarna uppgav att tyngden på förpackningen gjorde att den inte nådde nivå 5 på skalan.

Övrigt:

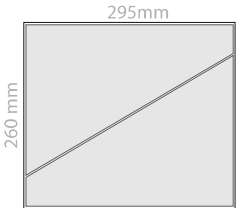
TP1: Kartongförpackningen känns smidig att vika ihop om man vet hur man gör. Man kanske skulle kunna trycka upp... Gillar den trekantiga grejen med den här (primärförpackningen). Verkar enkelt att montera förpackningen. Bra att man undviker vridmoment och tryck. TP 2: Det var svårt att veta hur man skulle öppna eftersom det var första gången jag såg den. Man kanske kan ha en liten instruktion som talar om hur man

kan vika ihop kartongen första gången. Man är så van som sjuksköterska att det inte finns något bra sätt att öppna och vika ihop lådorna, man är så van att stampa ihop kartongerna. Vikningen känns himla enkelt. Fiffigt! Jag är så van att man bara river sönder allting. TP 3: Önskar möjlighet att kunna öppna utan kniv. Kanske kunde vara en flärp på lådan som man kan dra i för att få upp förpackningen. Mycket fiffig vikningsprincip. Gillar lådan mycket mer efter att ha fått instruktion för hur den är tänkt att öppnas och vikas. TP 5: Väldigt enkel att vika, mycket smidig, man behövde inte använda någon kraft. TP 6: Inga konstigheter att vika ihop förpackningen. Lätt att stapla.

Appendix L: Arrangement on an EU - Pallet

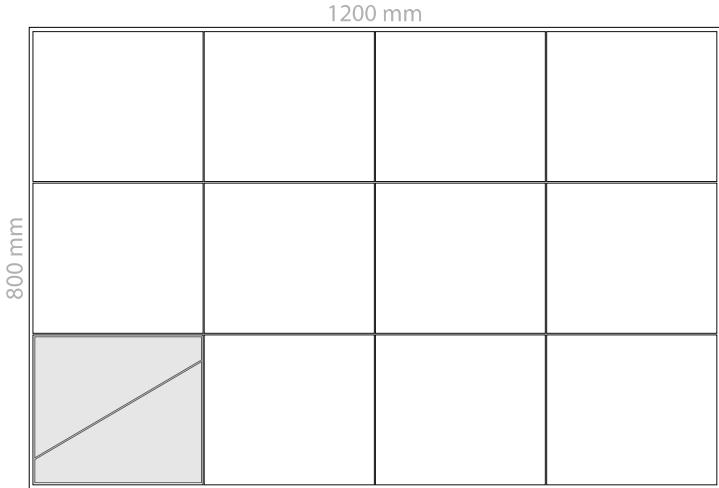


Two concentrate packages.



The packages are packed in a cardboard package; three layers with two packages on each layer i.e. 6 packages in each box.

Box dimensions 295x260mm



EU - pallet
Each layer takes 12 boxes.
Pallet dimensions 1200x800 mm

Appendix M: Proposals for the Rail

