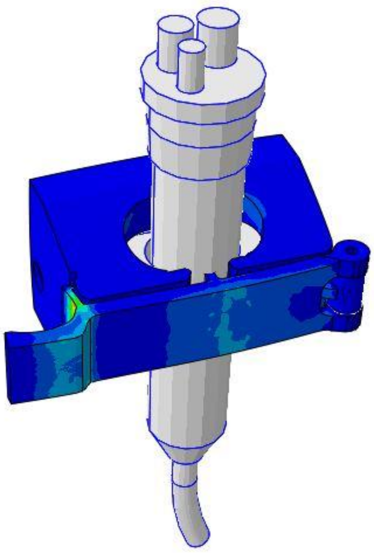
Master Thesis

Analysis and redesign of Air Level Detector

Karl Ludvigsson & Jimmy Bengtsson

Division of Machine Design • Department of Design Sciences
Faculty of Engineering LTH • Lund University • 2014



LUND UNIVERSITY

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ISRN LUTMDN/TMKT 14/5497 SE

Preface

This Master Thesis is the final part of the Master of Science education in Mechanical Engineering with Product Development at Department of Machine Design LTH, Lund University. It has been conducted at Gambro AB, Lund from January until May 2014.

We would like to thank our mentors at Gambro, Mattias Olsson and Peter Sendelius. You have supported us through the whole project and given us very useful feedback on our work.

We also would like to thank our mentor at Scanscot Technologies, Johan Kölfors, for all your help with the simulations in Abaqus. Your support was a very important part of the project.

There are a lot of helpful people at Gambro, both consultants and employees, which have been a great help for us. We would like to give a special thanks to Ulf Quensel, Hendrik Lindgren, Ann-Margret Håkansson, Lars Tornblad, Willy Larsson and Johan Kristofferson for all your help.

Finally, thanks to our mentor and examiner at the faculty of engineering at Lund University, Per Kristav and Damien Motte.

Lund, May 2014

Karl Ludvigsson

Jimmy Bengtsson

Abstract

Gambro is one of the biggest developers and manufactures of machines for hemodialysis treatments in the world. One component on their machines, the air level detector (ALD), has been identified to have a possibility to be further improved from usability perspective. The ALD is located at the front of the machine and has the function to hold the venous drip chamber in place and detect whether or not it contains fluid. The venous drip chamber is a part of the blood line, which is a disposable product that is changed between every treatment. The function of the drip chamber is to capture air that is left in the blood line, so it does not reach the patient. The ALD should be compatible with a universal blood line, which means that the size and stiffness of the drip chamber may vary. The ALD detects the content of the drip chamber with ultrasonic sensors. When air gets captured by the drip chamber the blood level decreases, and if it gets too low the ALD alarms and stops the treatment.

The most important improvement areas that Gambro has identified with the ALD are that it may make use of less force to apply the drip chamber and to further simplify cleaning of it. They have also identified a possible improvement to avoid the hatch breaking. The purpose of this project is to analyze why improvements may be needed and find a new solution. The analysis started with a finite element simulation of the ALD to find out its weaknesses. Then interviews were performed with service staff and clinical advisors to see what they thought should be improved with the ALD. The last step of the analysis was to perform simple tests of the ALDs from Gambro and also from other manufacturers. The conclusions from the tests pointed at that there is a lot of potential for improvements.

A lot of concepts were generated in the development process and two were chosen to be further developed. The development method of these was to make a new design, do a simple simulation, study the stresses, and then redesign the concept. Of the two concepts that were further developed, one had significantly lower stresses than the other and was therefore chosen to be the final design. This chosen concept was then tested, both practically and virtually. The practical test was performed together with a sensor, to see that they work together. The virtual tests were performed with finite element simulations of different scenarios that could appear during the use of the ALD. The conclusions of the tests were that the ALD works together with the sensor, and has stresses below the fatigue limit.

Keywords:

Gambro, Abaqus, product development, finite element analysis, dialysis.

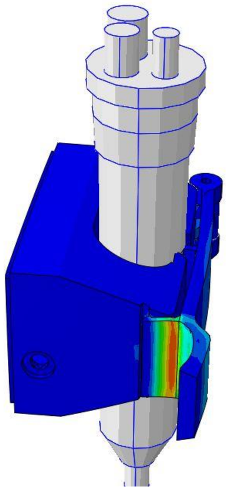
Sammanfattning

Gambro är ett företag som utvecklar och tillverkar dialysmaskiner för hemodialysbehandling av njursjuka. De har upptäckt att användarvänligheten på deras maskiner kan förbättras och en av de komponenter som har förbättringspotential är luftvakten. Det är denna komponent som detta projekt riktar sig mot. För att förstå vad luftvakten är till för, behöver man först förstå grunderna i hur en hemodialysbehandling fungerar. Innan behandlingen börjar applicerar sjuksköterskan ett nytt slangsett och filter på maskinen. Eftersom patientens blod går genom dessa, byts de ut mellan varje behandling. Efter detta sköljs slangarna och filtret med saltlösning för att få bort luften ur dem, vilket kallas ”priming”. Patienten får två nålar i armen där blodet ska ut ur respektive in i kroppen. Behandlingen går sedan till så att blodet går ur patienten, genom filtret, där det renas, och sedan tillbaka in i kroppen på patienten. Reningen sker genom diffusion mellan blodet och en dialysvätska inuti filtret. En del av slangsättet är vendroppskammaren som monteras i luftvakten, se figur 1. Den har till uppgift att samla upp luft som blivit kvar i slangsettet. Normalt är den fylld med blod, men när den fångar upp överbliven luft sjunker blodnivån. Därför har man en luftvakt som övervakar ifall blodnivån i vendroppskammaren blir för låg. Ifall detta inträffar ska behandlingen stoppas så man inte riskerar att luft pumpas in i patienten. Gambro har identifierat två större förbättringsmöjligheter med luftvakten. Den första är att det kunde krävas mindre kraft för att applicera kammaren i luftvakten, eftersom man har observerat arbetsskador hos sjuksköterskor. Den andra är att ifall det blir ett blodläckage, eller om man spiller något på luftvakten, vilket händer då och då, så kunde den vara enklare att rengöra. Detta eftersom vätska rinner in inuti själva luftvakten. Detta kan leda till att bakterier växer där, vilket innebär en hälsorisk.

Figur 1. Luftvakten

Metoden som användes i projektet är från Ulrich och Eppingers bok *Product Design and Development* [1], men var modifierad något för att passa in i projektet.

Vilka förbättringsmöjligheter som fanns med den tidigare luftvakten identifierades med hjälp av tre olika metoder. Den första var att, med beräkningsprogrammet Abaqus, göra en simulering som identifierade vilka svagheter luftvaktens konstruktion har. En resultatbild från denna är presenterad nedan i figur 2, och visar att om den går sönder så är det själva snäppfästet som gör det. Denna slutsats bekräftades också under intervjuer, som var nästa metod. Gambros servicepersonal och klinikrådgivare blev intervjuade och kom med värdefulla kommentarer kring vad som behöver förbättras. De största förbättringsområdena som kom upp var användarvänlighet och rengöringsmöjlighet. Det kom även upp att det finns väldigt många olika slangsett, och därmed också många olika kammare, som luftvakten ska passa till. Detta eftersom ett universalslangsett ska kunna användas på maskinen. Kammarnas diameter visade sig variera mellan 18 och 24 mm, och även styvheten varierar mycket. Till sist testades också luftvakten av projektgruppen, då de tidigare slutsatserna bekräftades ytterligare. Den största konkurrenten Fresenius luftvakt testades också, och då stod det klart att det finns mycket stor förbättringspotential hos Gambros luftvakt. Under detta test väcktes också tanken på att byta givarteknik i luftvakten eftersom Fresenius använder sig av en kapacitiv givare istället för en med ultraljud som Gambro har. En kapacitiv givare ger en mycket större möjlighet att få luftvakten användarvänlig, eftersom den inte kräver att kammaren ligger an så hårt mot sensorerna som ultraljudet kräver.



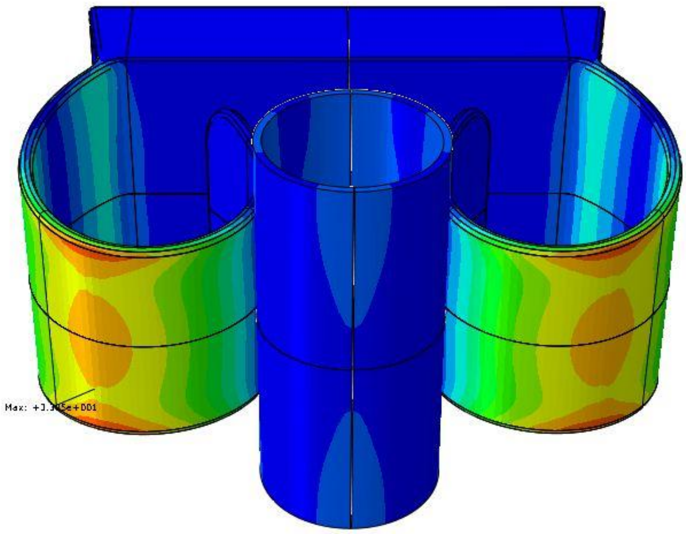
Figur 2. Resultat av simulering i Abaqus.

De identifierade kraven sammanställdes till kundkrav och sedan, med hjälp av en benchmarkstudie av konkurrenters luftvakter, till en målspecifikation. Denna kunde sedan användas till utvärdering av konceptförslag. Många konceptförslag togs fram och det två bästa valdes sedan ut för att vidareutvecklas. Vidareutvecklingen gjordes med hjälp av enkla simuleringar i Abaqus där spänningarna studerades för att iterera fram en bra lösning. Till sist valdes ett slutgiltigt koncept vilket är presenterat i figur

3. Det nya konceptet är tänkt att använda en kapacitiv givare precis som Fresenius gör i sin luftvakt. En undersökning gjordes också för att välja material till den nya designen.

Figur 3. Det slutliga konceptförslaget.

Det sista steget i projektet var att testa konceptet. Detta gjordes genom en rad simuleringar i Abaqus som speglade olika scenarion. Resultatet från en av dessa är presenterade i figur 4. Denna simulering visar hur en stor och hård kammare appliceras i luftvakten. Simuleringarna visade att spänningarna i luftvakten beror mycket på vilken friktionskoefficient det blir mellan kammaren och luftvakten. Om man lyckas få en friktionskoefficient på en bit under 0.3 kommer luftvakten att hålla under den livstid som är specificerad. Konceptet skrevs till sist ut i en 3D-skrivare och testades ihop med en kapacitiv givare. Det visade sig fungera som förväntat.



Figur 4. Resultat från simulering.

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1 Introduction

Gambro is a company which develops and manufactures dialysis machines for treatment of kidney diseases. They have identified possibilities for improvements regarding the usability on their machines and one component that has these possibilities is the Air Level Detector (ALD). Therefore the ALD will be analyzed and then redesigned to be easier to use and maintain the same function. This chapter will also give an introduction to what dialysis is and what the ALD's function is.

1.1 Gambro’s history

It all began in 1961 when Professor Nils Alwall invented the world's first artificial kidney. Along with industrialist Holger Crafoord they founded the company Gambro in 1964. The name is an abbreviation of "Gamla Brogatans Sjukvårdsaffär Aktiebolag". The production took off in 1967 when Gambro started mass producing dialysis machines and artificial kidneys for single use. Since then the company has grown and today they have over 8000 employees, with 13 manufacturing facilities in nine countries and conduct sales in more than 90 countries. They are now one of the leaders in developing, manufacturing and supplying products and therapies for kidney and liver dialysis. In 2013 Gambro was bought by Baxter, which is an American medical company. They now go under the name Baxter Gambro renal.

1.2 What is dialysis?

1.2.1 Overview

Dialysis is a form of treatments which is used when the kidneys have stopped working or are down to a very low capacity, [2]-[4]. But what does the kidney do in your body? The kidneys function is to clean the blood from waste and harmful substances. Another function the kidneys have is to remove abundance fluid from the body. When the capacity of the kidneys decreases or completely stops they are unable to do their tasks which results in fluid and toxins remaining in the body.

To treat this, dialysis is used. It has the function to replace the kidneys, purify the blood and remove abundance liquid. There are two types of dialysis treatments, hemodialysis and peritoneal dialysis where hemodialysis is the most common and represents 89 % of the treatments. Since this thesis regards hemodialysis the peritoneal dialysis is not described in detail. The main difference is that in hemodialysis the blood is cleaned outside the body through a dialysis machine and in the peritoneal dialysis the cleaning is performed inside the body. The patients' abdominal cavity is then filled with dialysis fluid and the peritoneum will act as a filter, as seen in figure 1-1. It is individual which treatment is best suited to the patient.

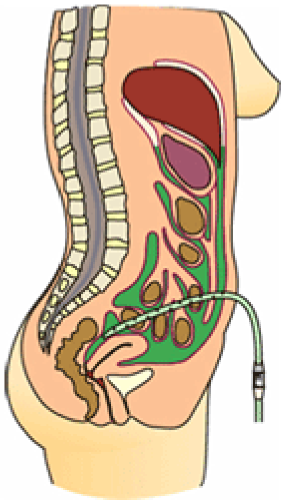


Figure 1-1. Peritoneal dialysis, [5]

In hemodialysis the blood is filtered and purified by a dialysis machine. This is normally done at a clinic, but can also be done at home after the patient has received necessary training. Usually a patient needs four hours of treatment, three times a week, but it varies from patient to patient.

All patients do not suffer from chronic kidney problems, and instead need dialysis treatment after for example a car accident, where the kidneys have been damaged. Majorities of the patient who have been treated with dialysis have permanent kidney damage and will have to undergo a kidney transplant to retain their kidney function. Unfortunately not all patients are suitable for transplantation, and kidney donors do not exist in a sufficient quantity. This makes dialysis to a lifelong treatment for a large amount of patients.

1.2.2 Patient preparations

Before the dialysis can be performed, the patient must undergo some preparations in order to facilitate the treatment [2]-[4]. Since hemodialysis purifies the blood outside the body in a dialysis machine, the patient need a blood vessel that can handle the blood flow, and also is adapted to a large number of weekly injections. To achieve this, a surgical procedure usually is performed in the forearm of the patient. An artery, which carries blood from the heart, is put together with a vein, which carries blood back to the heart. The blood flow in the vein increases, and after a few months they have formed a fistula, which is suitable for repeated sticks from a needle.

1.2.3 The kidney's function and possible diseases

The kidneys' function is to clean the blood of waste products, which the body does not want [2]-[4]. To keep the blood pressure at a good level, the kidneys also needs to handle the excess fluid which the body cannot take care of. This fluid then leaves the body through the urine.

One reason that one may need dialysis treatment can be kidney failure. There may be many different factors which can cause kidney failure, but the most common is diabetes, or severe kidney inflammation. If this happens, the kidneys won't function properly, leading to toxic products and excess fluid remaining in the body.

If the kidneys' capacity falls below 10 % of its normal value, due to for example diseases or damage caused by an accident, the patient needs to undergo dialysis or have a kidney transplant. In some cases a person can use a modified diet and medication to help the kidneys sufficiently to avoid dialysis treatment.

1.2.4 How does hemodialysis work?

When the patient undergoes hemodialysis, the blood is purified outside the body, [2]-[4]. This is done by leading the blood out from the blood vessel through the dialysis tubing, as seen in figure 1-2. The blood is then passed on to the dialyzer, also called the artificial kidney. The dialyzer includes a filter consisting of a large number of small tubes, similar to straws, in which blood passes through. On the opposite side and in the opposite direction passes the dialysis fluid. Dialysate is produced of tap water, which is purified to a very high level in treatment plants, available at dialysis clinics or at home. The treatment plant is then connected with the dialysis machine which adds salts and bicarbonate to the fluid and then heats it up to body temperature. Diffusion lets waste products to pass the filter and is then flushed away by the dialysate, as seen in figure 1-3. In the opposite direction electrolytes and bicarbonate are added to the blood from the dialysis fluid. The pressure differential between the blood and the dialysis liquid make it possible for the excess liquid present in the patient to be removed. The amount of excess fluid varies from patient to patient. If the patient has no own production of urine, it is not uncommon to remove between two and three liters of fluid.

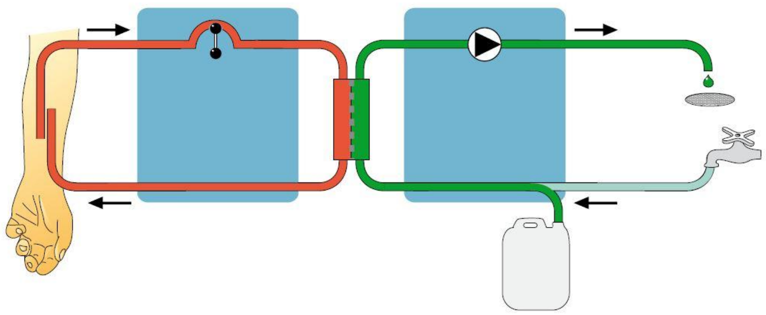


Figure 1-2. Hemodialysis, [6]

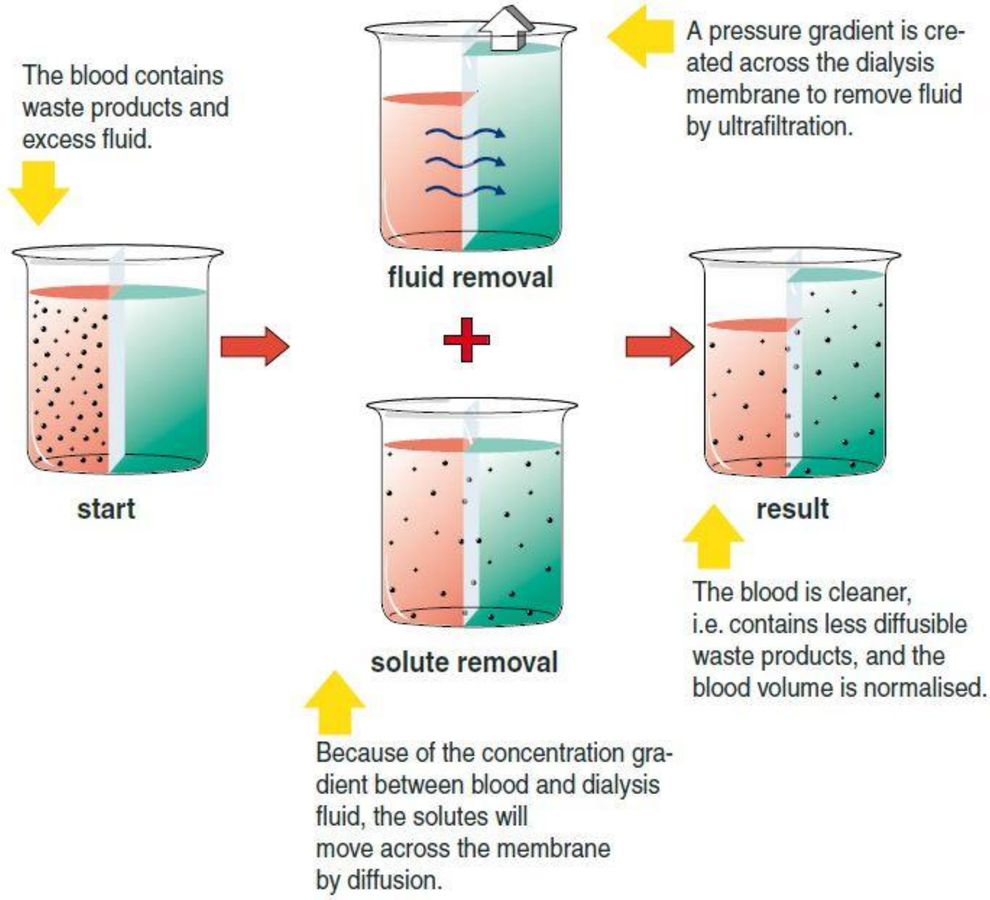


Figure 1-3. Purification off blood using dialysis liquid, [6]

It is most common that the treatments are performed at dialysis clinics which not necessarily have to be at a hospital. However, this is very demanding for the patient who needs to go to a clinic three times a week and be there for four hours at a time. Instead of go to a clinic, it is increasingly common to have the treatment managed by the patient at home. The advantages of this are that the patient can control what time the dialysis treatment should be performed and then have more control over his or her life.

1.2.5 The treatment

Before the treatment can start the patient is weighted to determine how much fluid needs to be removed during the treatment [2]-[4]. The nurse then begins to apply a new blood line and a new filter to the dialysis machine. Then the priming procedure starts, which means that the filter and blood line are flushed with saline solution to remove the air from them. In the beginning of the treatment the patient is given a drug called heparin, which prevents blood from clotting in the filter and tubes. The patient is then attached to the machine through the fistula and the blood pump starts carrying blood through the tubes and filter where it is purified and then returned to the patient. The settings of the machine are set differently for each patient to fit their individual needs. After the treatment the machine is sanitized before the next treatment begins. This is usually done by running hot water and citric acid through it. The filter and blood line is replaced to the next treatment.

1.3 The Air Level Detector

1.3.1 What does it do?

The air level detector (ALD) has, as the name says, the task of detecting air. It uses ultrasonic sensors to determine if there is blood or air in the venous drip chamber, which is a part of the disposable blood line. The blood line for the machine is universal, so it should be able to use any manufacturer's blood lines and gain the same functionality. The different manufacturer's blood lines can have very different properties. One thing they have in common is a drip chamber that fits in the ALD. The drip chamber is there to be a trap for air that is left in the tubes after priming. The priming is done to take away the air, but it cannot take away all of it. During treatment the drip chamber will be filled with blood, but if there would be a leakage or if the priming was poor, the blood level in the chamber will decrease. The ALD then alerts and stops the treatment when it detects air, so the user can notice it and take necessary actions. There are some things that can make the air detecting harder. Sometimes the blood turns into foam on the surface. The ALD should also detect this as air. The blood can also coagulate in the drip chamber, making a thin layer of coagulated blood cover the inner surface. It is important that the ALD does not detect this as blood when the chamber is empty.

1.3.2 History

Gambro's ALD is basically an old design which has been refined over the years. The current design can be seen below in figure 1-4. The first version was on the AK-5 machine, which was introduced in 1974 and can be seen figure 1-5 and 1-6. Back then it had no hatch to hold the chamber in place, but the rest of the ALD looked the same as now except from the color, which was white back then.

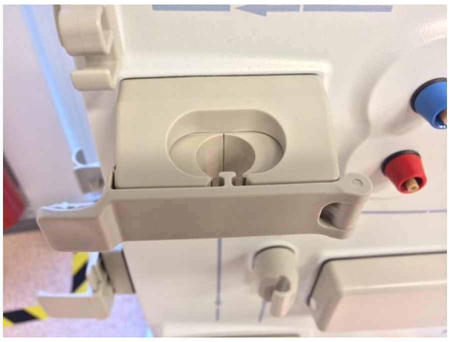


Figure 1-4. Today's design of the ALD

Figure 1-5. AK-5

Figure 1-6. The ALD on the AK-5 machine

In 1977 the AK-10 machine was introduced but it had the same ALD as AK-5. An improvement of the AK-10 machine was introduced in 1981. It was called AK-10 BCM and was the first machine with Gambro's BiCart system for bicarbonate. It had a hatch on its ALD which was in a transparent plastic material, see figure 1-7 and 1-8. The hatch was introduced to help the user to push the drip chamber against the sensors, making the signal better and more stable.

Figure 1-7. AK-10 BCM

Figure 1-8. The ALD on the AK-10 BCM

In 1988 Gambro introduced their AK-100 machine, see figure 1-9 and 1-10. Earlier dialysis machines have had a ratio of 80 % hardware and 20 % software. Now this ratio was reversed, so the machine in much greater degree automatically oversaw and regulated the treatment. The ALD on this machine had a new hatch which was white to match the rest of the components.

Figure 1-9. AK-100

Figure 1-10. ALD at AK-100

In 1990 Gambro introduced the AK-90 which was a smaller machine developed to fit the Japanese market, see figure 1-11. This model also became popular for home dialysis. The AK-90 were then developed into AK-95, released in 1995, were the ALD changed color to the gray one which is the same today, see figure 1-12. The gray color makes the injection molding of the plastic easier to perform. The box standing next to the machine in figure 1-12 is a WRO-machine, which is a water purifying machine, adapted to supply one dialysis machine with water.

Figure 1-11. AK-90

Figure 1-12. AK-95

In 1996 the AK-200 was introduced which was a development from the AK-100. The AK-200 machine is still in production with the same looks but with a different inside than back then.

To the AK-96 model, in 2007, the ALD’s hinge was reinforced due to problems with corrosion. It was also given a rounder form, see figure 1-13 and 1-14. It was rotated 180 degrees so the hatch was opened from the left instead for the right. This new ALD was also put on the AK-200, but there it was not rotated.

Figure 1-13. AK 96

Figure 1-14. The ALD on the AK-96 machine

1.3.3 How to apply the drip chamber

ALD uses ultrasound to detect air and foam in the venous drip chamber [7].

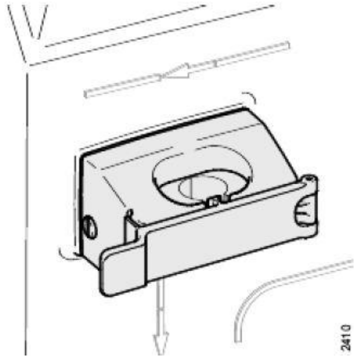


Figure 1-15. [7]

Before placing the venous drip chamber into the ALD the hatch needs to be open. The cover is opened by pressing on the center of the cover while pulling on the handle [7].

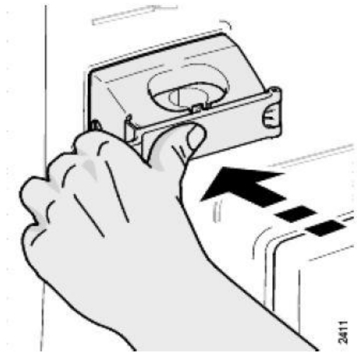


Figure 1-16. [7]

ALD is adapted to a venous drip chamber with a diameter of 22 mm [7].

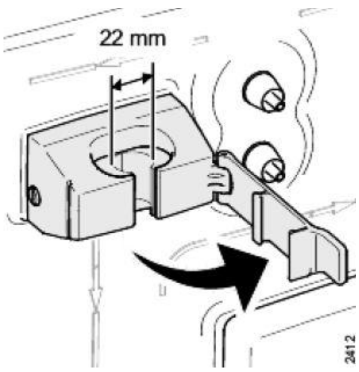


Figure 1-17. [7]

The venous drip chamber is placed by squeezing it in the center while insert it into the ALD [7].

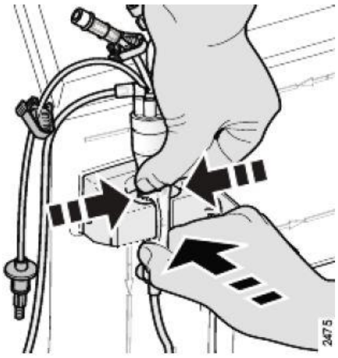


Figure 1-18. [7]

Press on the center of the venous drip chamber until it ends up right [7].

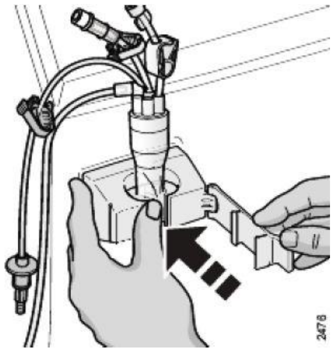


Figure 1-19. [7]

Close the hatch until it clicks. Adjust the chamber if necessary [7].

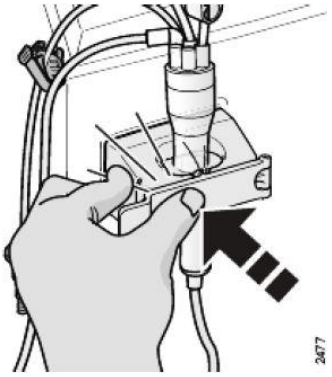


Figure 1-20. [7]

Venous drip chamber properly applied to the ALD.

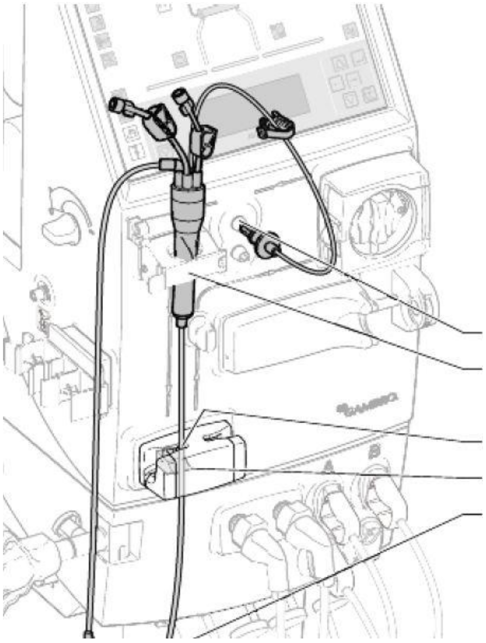


Figure 1-21. The drip chamber applied to the machine, [7]

1.3.4 The problems with the ALD

There are two major problems with the ALD. The first one is that the ALD is requiring too much force when applying a chamber, which reduces its usability. This leads to that the nurses who operate the machine experience pain in hands and fingers, according to *Hand- och handledssmärtor hos dialyssköterskor* [8].

The second problem is that the risk of leakage into the machine is too large due to the gaps between parts, see figure 1-22. If there is a leakage of blood from the chamber the blood drips into the machine and then it is almost impossible to clean. To clean the inside of the ALD the component needs to be removed from the machine which the clinics cannot do. This leads to that the blood that has flowed into the machine remains there and bacteria can grow, which causes a health risk.

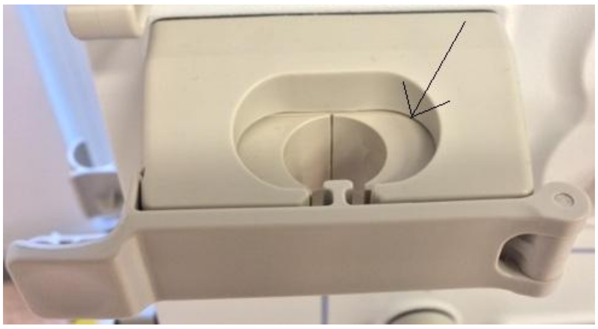


Figure 1-22. Gaps between parts.

2 Aims

The aims of the project are to create a clear picture of what the possibilities for improvements are with Gambro's existing air level detector and use this data in order to develop a new concept, which should be the best on the market. It should also show that finite element calculations are a good tool to use in product development projects. The project will have a mechanical orientation, but possible sensor techniques will also be investigated. It should result in CAD material for manufacturing.

2.1 Objectives

The actions that will be performed are the following:

- Analysis of the current design
- Identify customer needs
- Establish target specifications
- Concept generation
- Concept selection
- Concept development
- Concept testing

3 Method

A modified version of the Ulrich & Eppinger product development process [1] will be used to develop the ALD. The actions that will be performed are analysis of the current design, identifying customer needs, establish target specifications, concept generation, concept selection, concept development and concept testing. A big part of the method will be the analysis of the current design and concept testing where finite element analysis will be performed to evaluate the existing ALD and the new concepts.

3.1 Product development process

The Ulrich & Eppinger product development method [1] have been modified to fit this project. The workflow can be seen in figure 3-1. Following actions were performed:

- Analysis of the current design
- Identifying customer needs
- Establish target specifications
- Concept generation
- Concept selection
- Concept development
- Concept testing

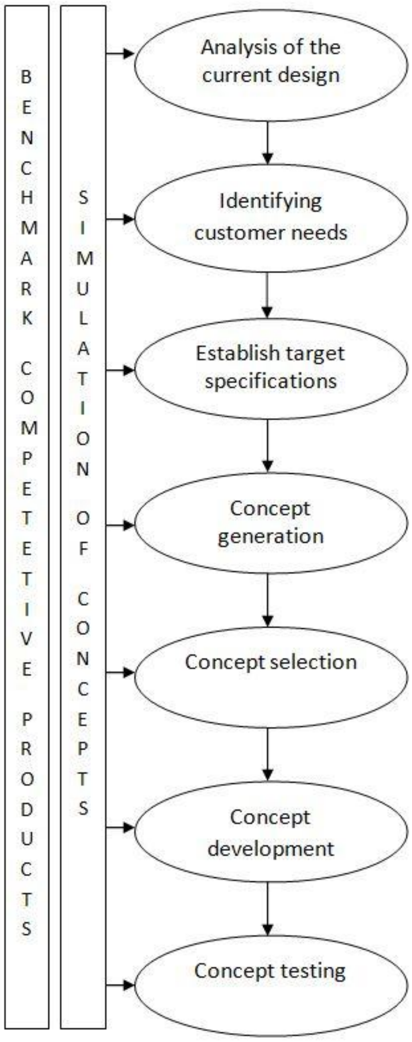


Figure 3-1. The product development process

3.1.1 Analysis of the current design

The current design will be analyzed with the following methods:

1) Finite element analysis of the products functions.
2) Interviewing people with experience of working with the product.
3) Simple tests of the product.
4) Mission statement.

The first three of these were performed parallel and not in a straight line like it is presented.

3.1.1.1 Finite element analysis

The finite element analysis will be performed with the software Abaqus/CAE. The simulations will be set up according to the following methodology:

1) Define the purpose and output of the simulations.

    What should be simulated and what metrics should be the output?

2) Define materials and material models for the simulations.

    What material is used and how can this be modeled in a simulation? The simulation is first set up with a simple material model which then can be refined if necessary.

3) Set up a FE-model for the test.

    Mesh the parts. Define boundary conditions, loads, interactions etc.

4) Perform a convergence study.

    Find out if the mesh is fine enough.

5) Interpret the results.

    What do the results mean?

6) Reflect on the results and the process.

    Does the simulation show a lifelike picture of the concepts function and are there any possible error sources?

This is an own created method developed to fit the project. The actions are not always carried out in a straight line as presented. It usually requires iterations.

3.1.1.2 Interviews

Interviews will be performed with experienced Gambro personnel which has a lot of contacts with the customers. The purpose of this is to identify what advantages and disadvantages the existing ALD has. These will then be analyzed to identify what business opportunities there are in developing a new ALD.

3.1.1.3 Tests

Simple function tests will be performed in Gambro’s lab with the purpose to understand the functionality and the deficiencies of the ALD. This is a simple way to confirm the conclusions from the interviews and simulations. Other manufacturers of ALD will also be tested.

3.1.1.4 Mission statement

The result of the analysis of the current design will be a mission statement. It will be set up according to Ulrich & Eppinger [1, pp.66-69].

3.1.2 Identifying customer needs

The customer needs will be identified by studying documents from earlier development projects that Gambro have performed. Personnel at Gambro which have had experience from customer contact will also be interviewed to find more information.

According to Ulrich & Eppinger [1, pp. 73-90], identifying customer needs is done in 5 steps. Under some steps follow a description of what it means and how it will be implemented in this project.

1) Gather raw data from customers

    a) Interviews with Gambro personnel with a lot of experience of customer contact. The approach of the interviews will be an open discussion about what advantages and disadvantages the ALD has and what should be included in a new design.

    b) Studying Gambro's existing documentation about the product. What kind of documentation there is will be investigated.

2) Interpret the raw data in terms of customer needs

3) Organize the needs into a hierarchy of primary and secondary.

4) Establish the relative importance of the needs.

    The needs are given a relative importance factor which shows how important each need is relative to each other. These factors will later be used to compare different concepts to each other. The factor will be set on a scale of 1-3 where 3 is the most important and 1 is the least important. Some factors are easier to set than others. To set the harder ones interviews will be done with the same interviewees as earlier in the process.

5) Reflect on the results and the process

    When the customer needs are set, it is important to reflect on what could have been done differently and possible error sources. The reflection will be done by considering the questions from Ulrich & Eppinger [1, pp. 87-88].

3.1.3 Establish target specifications

According to Ulrich & Eppinger [1, pp. 91-116] the target specifications are established with 4 steps. Under each step follows a description of what it means and how it will be implemented in this project.

1) Prepare a list of metrics.

2) Collect competitive benchmarking information**.**

    Gambro has machines from the biggest competitors in their lab. Their solutions for the air detector will be compared to Gambro's own. This will be done by measuring and testing the different machines and the results will be put into a matrix to get a good overview of them.

3) Set ideal and marginally acceptable target values.

    Two different target values are set: an ideal value and a marginally acceptable value.

4) Reflect on the results and the process.

    Reflections will be made by considering the questions from Ulrich & Eppinger [1, pp. 111].

3.1.4 Concept generation

Concept generation is performed in 5 steps which are in turn divided into sub steps.

1. Clarify the problem

    This will be done using function diagrams and decompose the problem into sub problems.

2. Search externally

    Externally means outside the project group. The search paths that were used are:

    a) Experts

    b) Literature

    c) Benchmarking

3. Search internally

    Concepts were generated both individual and in group sessions.

4. Explore systematically

    This was done using classification trees.

5. Reflect on the solutions and the process

    Reflections will be made by considering the questions from Ulrich & Eppinger [1, pp. 139].

3.1.5 Concept selection

Concepts will be selected with Ulrich & Eppinger's two-stage methodology [1, pp. 143-163].

3.1.5.1 Concept screening

The most important criteria are put into a matrix. In this case the primary and some of the secondary customer needs will be used. The different concepts are then compared to the existing ALD. If a concept is fulfilling a criteria better than the reference it gets a plus (+), if it is worse it gets a minus (-) and if it is the same it gets zero (0), see table 3-1. If a concept gets more plusses than minuses it is worth keeping in the selection process. When the concepts are ranked they also can be combined to fulfill the criteria even better. The best concepts are then chosen to be taken forward to the concept scoring.

Table 3-1. Rating for the Concept screening

Relative performance	Rating
Worse than reference	-
Same as reference	0
Better than reference	+

3.1.5.2 Concept scoring

The criteria are broken down to a lower level, i.e. there are more criteria to take under consideration. In this case most of the secondary customer needs will be used. The different customer needs are given a relevance factor in relation to each other. 100 % is distributed between the criteria. This is then put into the concept scoring matrix.

The concepts are then given a grade from 1 to 5 with the criteria as in table 3-2. Each grade are then multiplied with the relevance factor of the criteria and then summarized into a total score. The concepts can then be combined and improved to get an even higher score. The concept(s) with the highest score are then chosen for further development.

Table 3-2. Rating for the Concept scoring.

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

When the concept scoring is done it is important to reflect on the process. Questions that were considered are from Ulrich & Eppinger [1, pp. 157-158].

3.1.6 Concept development

In the Ulrich & Eppinger product development process [1] this step is integrated in the other steps. In this project it was considered better to make this an own step since it is a big part of the work.

In the concept generation the basic things about how the concepts will look and work are determined. After this the concepts needs to be developed to work in reality. This takes a lot of effort so first a concept selection is performed to determine which concepts should be further developed.

In this project the concept development was performed with an iterative process, where a design first was set, and then simulated with some quick simulations to get an estimation of what needed to be improved. It was then improved and simulated again, see figure 3-2. When the quick simulations showed a good result a more advanced simulation was performed to see if the quick simulation was accurate. When a design that seems to work was found, it is time to go forward to more advance tests and simulations in the concept testing.

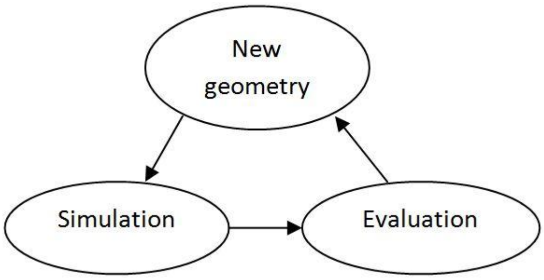


Figure 3-2. The iterative development process.

3.1.7 Concept testing

Ulrich & Eppinger [1, pp. 165-180] advocates a 7-step method for testing product concepts. This method will not be strictly followed. Instead of just testing the concept on customers, simulated tests also will be performed. The simulated tests will only show the functionality and the robustness of the concept and not how it is perceived by the customer. The simulated tests follow the same methodology as the FE-simulations in the analysis of the current design, described in chapter 3.1.1.1. A prototype will also be made and tested together with a sensor to determine if they work together.

4 Analysis of the current design

The analysis of the current design was performed with three different methods. A finite element analysis was performed to see what weaknesses the ALD has in its design. Interviews were performed with Gambro service technicians and clinical advisors to see what they see as the weaknesses of the ALD. Both the finite element analysis and the interviews said the same thing. If the ALD breaks, it is the snap fit at the hatch that breaks. The interviews also gave a lot more information regarding for example usability and cleaning of the ALD. The third action was testing the ALD of Gambro and also of other manufacturers. These tests confirmed the conclusions made in the earlier steps. The gathered information was then used to make a mission statement for the project.

4.1 Finite element analysis

4.1.1 Purpose

The purpose of the finite element analysis was to define what the problems are with the existing design. They should show different scenarios were it does not work properly. This will highlight the big advantages of using finite element calculations in product development projects. The questions that should be answered are:

If the ALD breaks,

- Where does it break?
- When does it break?

The first question should answer which areas are most vulnerable and the second should answer in what situation it breaks.

4.1.2 Cases

There are two situations that need to be simulated to get a clear picture of the problems; opening and closing. The hatch should react differently in these situations, due to the different load cases. To be able to simulate the opening of the hatch, the closing must be simulated first because it introduces stresses in the snap fit. Therefore these two situations were performed in the same simulation, where the hatch first was closed and then opened. The stresses in the hatch should be highest if the user push and pull at the end of the hatch when closing and opening it. The simulation should therefore reflect that situation.

4.1.3 Material model

The plastic parts of the ALD are made of polyoxymethylene (POM) type plastic called Hostaform C9021. The material is manufactured by Celanese (earlier Ticona). Material information was received from the material database Campus Plastics [9]. Material data is presented in table 4-1.

This plastic material has a hyper elastic behavior (see figure 4-1), which is characterized by a nonlinear behavior with a steeper stress-strain curve in compression than in tension. It is only linear in a small area from about -60 to 40 MPa. Even so, it was modeled as linear elastic since that requires less material data, modeling- and solving time. It was not considered necessary to get exactly the right stresses in the model. The important thing was to see where the maximum stresses were and a more complex material model was not necessary to gain those results.

Table 4-1. Material data for Hostaform C9021 [9].

Material data	
Name	Hostaform C9021
Type	POM
Elastic modulus	2850 MPa
Poisson's ratio	0.35
Density	1.41 g/cm^3
Yield strength	64 MPa

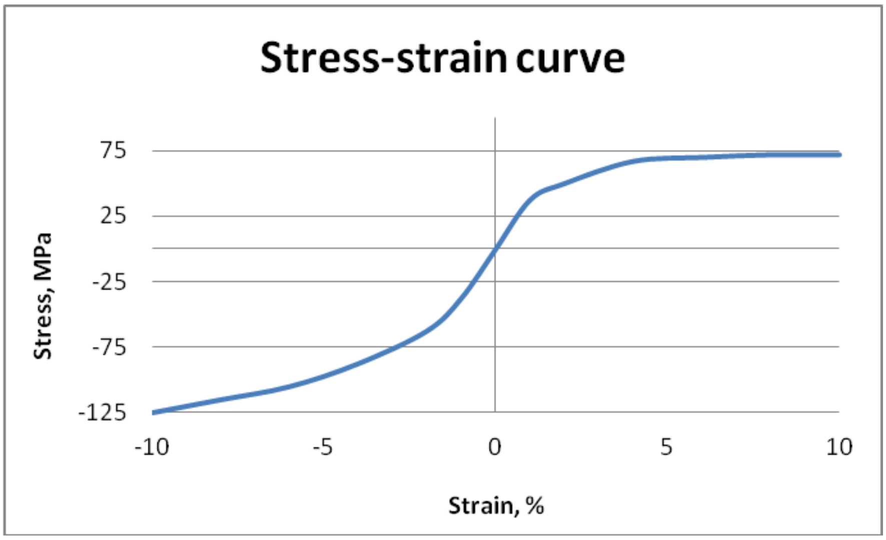


Figure 4-1. General stress-strain curve for POM, [10]

4.1.4 Set up

The model was set up in the Abaqus/Explicit solver, since it is better than the standard solver when you have a lot of contact between different parts, and especially when one of the parts is sharp like the snap fit. The main reason for this is that the explicit solver does not require iterations which the standard solver does. Instead of iterations it uses a lot of very small time increments [11].

The simulation was divided into three steps. In the first step the hatch was closed, in the second it was released so it could get equilibrium in the slot, and in the third it was opened again. What is meant by hatch and slot is shown in figure 4-2 below.

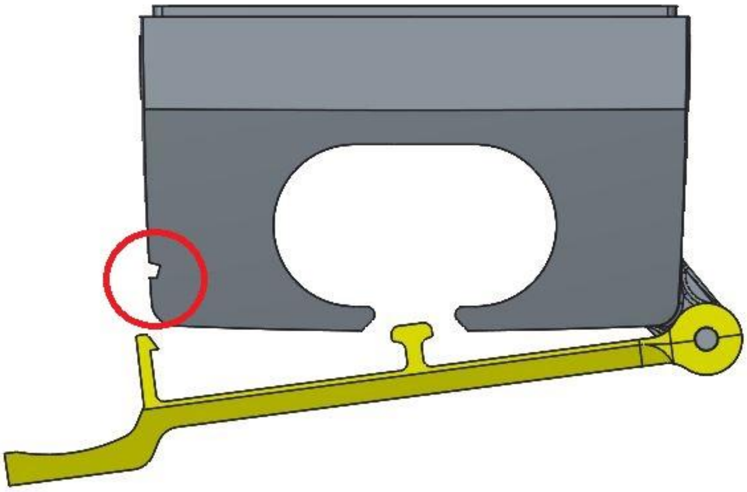


Figure 4-2. The hatch (yellow) and the slot (red ring).

The time settings are very important for the calculation time. You should use as small time as possible to get a low calculation time, but if you set it too small the model can start oscillate. Different time settings was therefore tried to find a low calculation time with small oscillations in the model. The final time settings were set so the first and last step took 0.08 seconds and the second took 0.03 seconds. I.e. the whole simulation reflects 0.19 seconds.

4.1.4.1 Mesh

To be able to mesh the parts properly they were first modified in a CAD software. Rounds and drafts were removed to get planar surfaces that can be meshed in a good way. The screw towers for attaching the ALD to the machine were also removed since they are not needed for this analysis. Modifications were only made where they were considered to have a very small impact on the results.

What elements that should be used and how the model should be meshed were discussed with Johan Kölfors at Scanscot technologies [11]. Ideally hex elements should be used but the geometries in these parts were too complex so tetrahedral elements had to be used instead. The elements used are called “C3D10M: A 10-node modified quadratic tetrahedron” and are often used in these kinds of simulations. They are good at calculating the stresses at the elements integration points, but not as good at extrapolating the stresses to the elements surfaces. To get more accurate stresses at critical surfaces they were covered with very thin membrane elements.

They were made 0.001 mm thick so they add minimal stiffness to the model. The membrane elements used are called "M3D3: A 3-node triangular membrane". The surfaces which were covered were the whole hatch, since that is the part that deforms the most and not as accurate stresses was needed in the housing. This is a well-known method along Abaqus users when using this type of elements.

When using Abaqus/Explicit the size of the smallest element in the model is most important to the calculation time. The number of elements is not as important. Therefore, much effort was put into making the smallest elements as big as possible.

The housing was meshed with a global mesh size of 1.5 mm, see figure 4-3. It then needed to be refined where the snap fit has contact with it, because that is a critical region in the model with a lot of contact. The refinement is shown in figure 4-4. In some regions, a little material needed to be removed to get elements that did not have too sharp corners or were too thin. These regions are shown in figure 4-5 and 4-6.

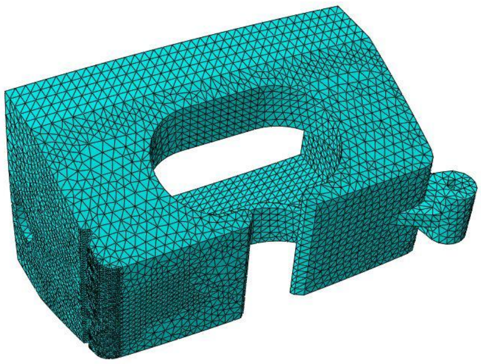


Figure 4-3. Mesh

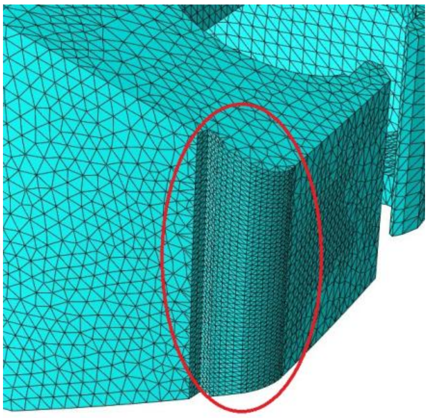


Figure 4-4. Refinement

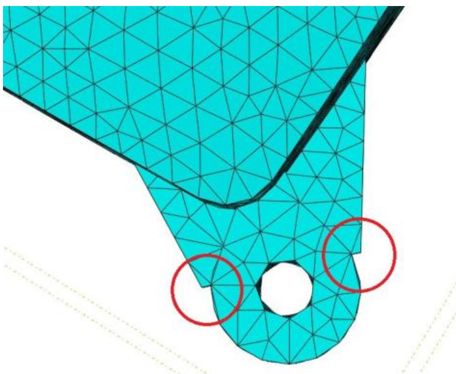


Figure 4-5. Mesh modification 1

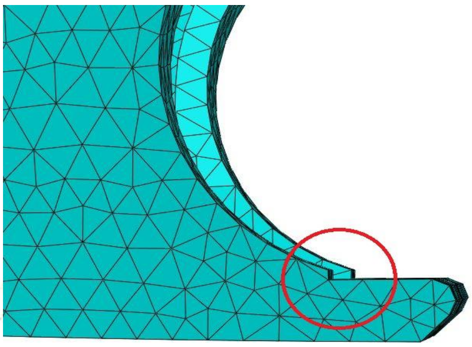


Figure 4-6. Mesh modification 2

The hatch was also meshed with a global mesh size of 1.5 mm, see figure 4-7 and 4-8. To get a smooth mesh some surfaces had to be combined with a virtual topology, since they were very small. That means that surfaces are combined so the element boundaries aren't forced to be at their shared line. Some material had to be removed around the hinge (see figure 4-9) to not get badly formed elements. All rounds were removed except the ones around the snap fit, because that is the most critical area of the model and must be modeled as realistic as possible.

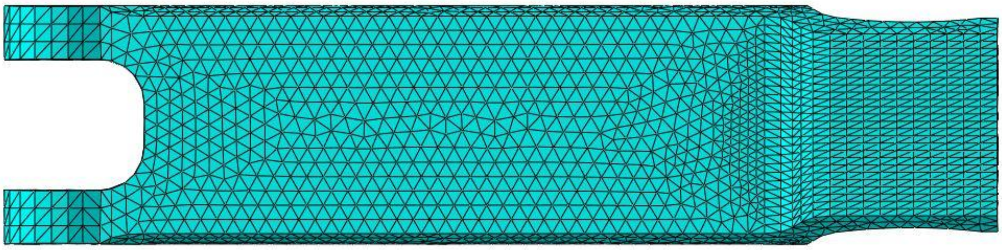


Figure 4-7. Mesh at the front of the hatch

Figure 4-8. Mesh at the back of the hatch

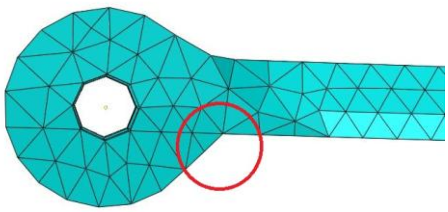


Figure 4-9. Mesh modification on the hatch

The finished mesh had approximately 80,000 elements and 20,000 nodes.

The chamber and the inner halves were set as display bodies. This mean that they were not participating in the simulations and were therefore not meshed. Their purposes were simply to show that they are there.

4.1.4.2 Boundary conditions

Four boundary conditions were applied to the model, one on the housing and three on the hatch. The back side of the housing was set to be fixed, see figure 4-10. A symmetry boundary condition was applied at the point where the closing later will start. The point is marked with red in figure 4-11. The boundary condition was applied with a displacement condition were the X- and Z-rotation and the Y-direction were set to zero and the other degrees of freedom were set free. This way the movement of the hatch will act symmetrically around the middle horizontal plane of the model.

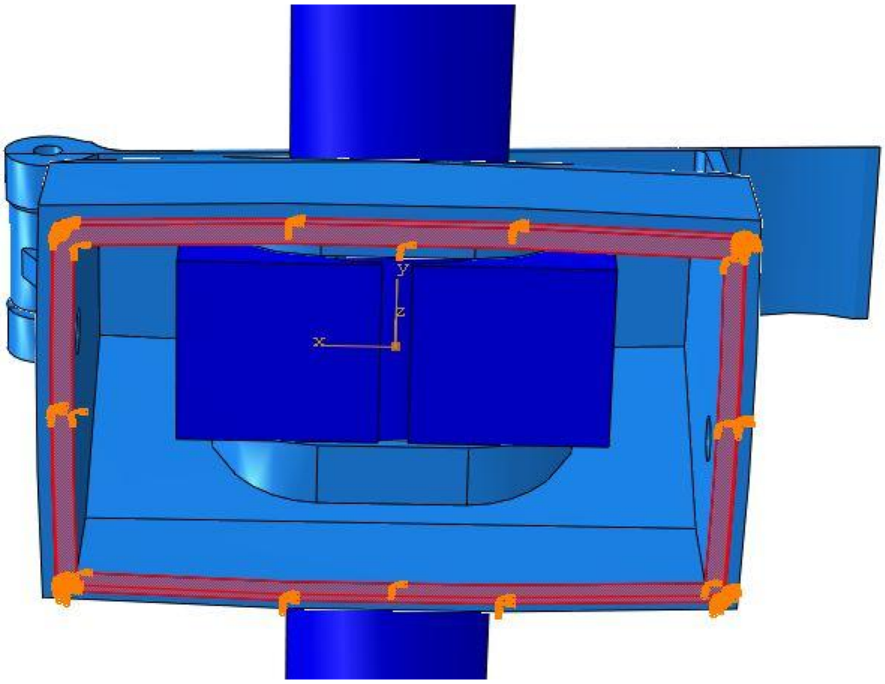


Figure 4-10. Fixed boundary condition

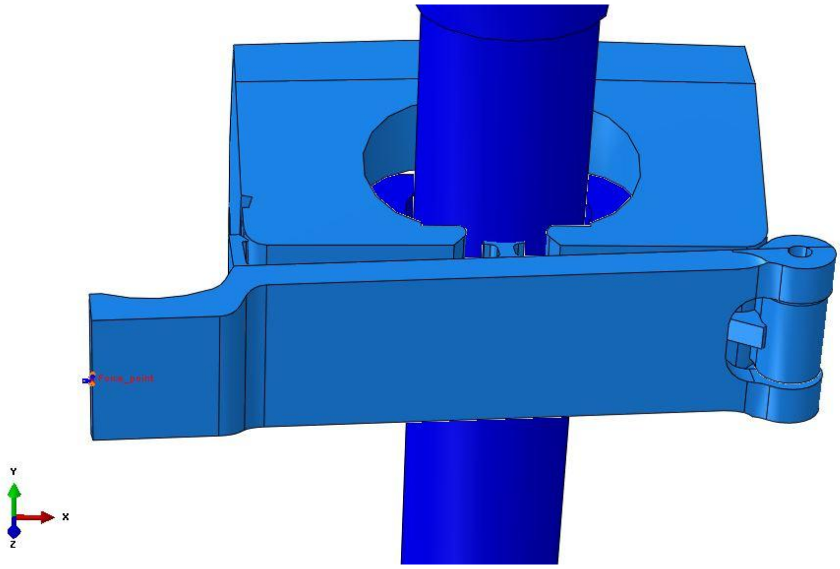


Figure 4-11. Symmetry boundary condition

The movement of the hatch was performed with a displacement boundary condition, applied at the same point where the symmetry was applied, see figure 4-12. The displacement was set to 9 mm in the negative Z-direction and all other degrees of freedom were set as free, causing the hatch to rotate around the axel of the hinge. This boundary condition was only active in the closing step.

In the release step the displacement were inactive so the hatch could get equilibrium in the closed position.

A new displacement was introduced in the opening step at the same point and with the same distance as in the closing step, but in the opposite direction.

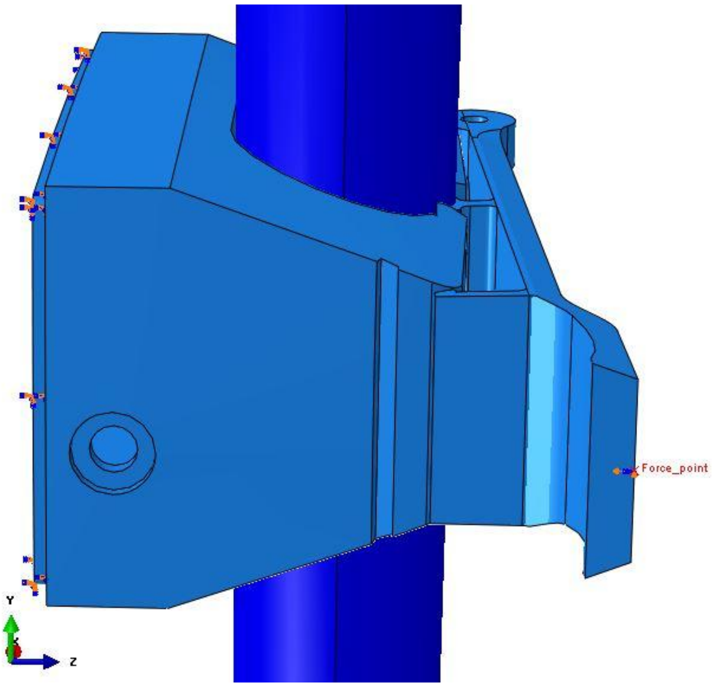


Figure 4-12. Displacement boundary condition

4.1.4.3 Contact

The contact between the hatch and the housing was modeled with two surface to surface contacts. These are presented in figure 4-13. A general contact definition was not possible to use, due to different properties of the model. The first contact was the one by the snap fit (to the left in figure 4-13) and has a frictional tangential behavior with a friction coefficient of 0.1. The friction coefficient was simply an estimated value since it was not a critical part of the model. It was just needed to get some resistance for the snap when it slides over the surface of the housing. To get the snap fit to slide over the edge of the slot in a smooth way the normal behavior of the contact was set to exponential. The pressure at zero clearance was set to be 100 MPa and the clearance at zero pressure was set to 0.05. These values were established by testing different values to find suitable ones.

The second one was the contact between the hatch and the housing, seen to the right in figure 4-12. It was set to a frictionless contact since these surfaces won't slip as much against each other and are close to planar. The normal behavior was set to "Hard" contact since the contact pressure at these surfaces not will be that high. That means that no contact force will be transferred between the surfaces until the moment when they get in contact, and then no penetration between the surfaces is allowed.

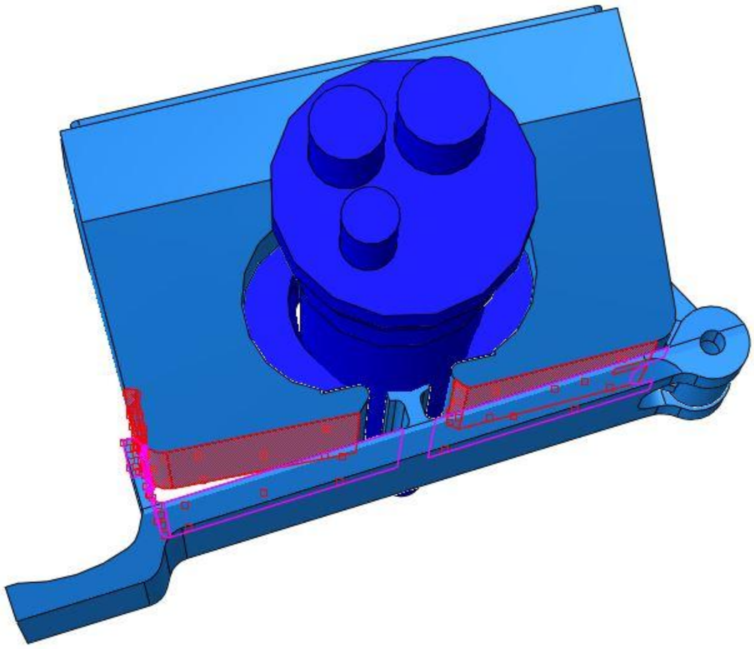


Figure 4-13. Contact

4.1.4.4 Connectors

To simulate that a stiff chamber was applied to the ALD a connector element was introduced in the model. It was connected between two points, one at the hatch and one in the middle of the housing (marked in red in figure 4-14). The connector was defined as a cartesian connector with nonlinear spring properties. The spring was set to have a spring coefficient of 90 N/mm if the hatch was closing, and no stiffness if it was opening. The spring stiffness was determined by testing different stiffness values and compare the model with how the ALD is behaving in real life.

The top point in figure 4-14 was given a fixed boundary condition to keep it in place. To make the model really realistic it would be connected to the housing in some way but this was considered to make very little difference. The housing is much stiffer than the chamber and therefore the chamber will absorb most of the deformation.

The point at the hatch in figure 4-14 was connected to it with a distributing coupling constraint. This constraint is described later in chapter 4.1.4.5.

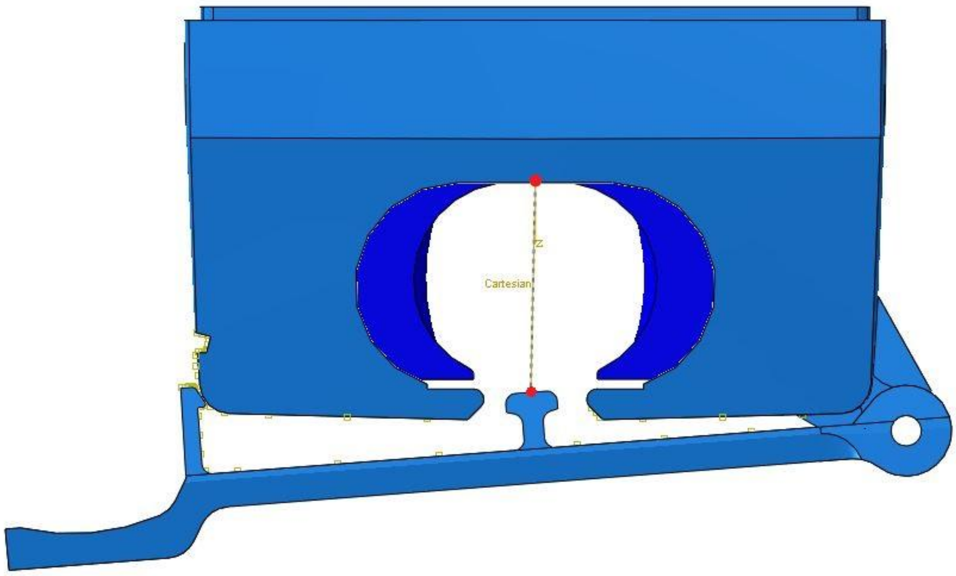


Figure 4-14. Connector to represent the chamber

4.1.4.5 Constraints

1. The pin that holds the hinge together was removed and the hinge were instead modelled by a series of constraints. The used constraint is called a kinematic coupling constraint, and five of these were used. This constraint connects a point to a surface so the surface always has the same distance to the point and cannot rotate in relation to it. The surface then acts rigid in relation to the point. Three reference points were placed in the holes of the hinge where the pin should be, one in the hole of the housing and one in each hole of the hatch. These points were then connected to their holes with a kinematic coupling constraint, where all degrees of freedom were constrained, see figure 4-15. The points in the hatch were also connected to the point in the hole of the housing. Here the rotational degree of freedom in the Y-direction were set as free, so the points can rotate in relation to each other and function as a hinge.
2. Another type of constraint was used to connect the point where the displacement was applied to the hatch. This type is called a distributed coupling constraint. The difference between this constraint and the kinematic constrain is that this does not constrain the distance between the surface and the point to be fixed so the surface can deform during the simulation. The constraint is presented in figure 4-16.
3. The point marked in red in figure 4-17, used for the connector, was also given a distributing coupling constraint. It was connected to the surface on the hatch marked in figure 4-17.

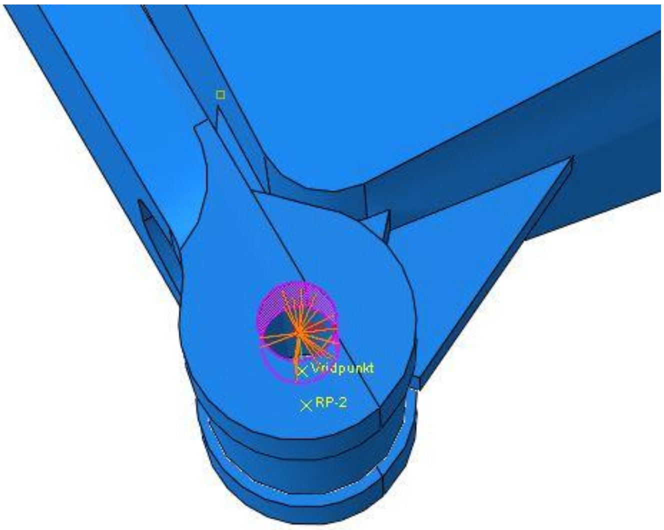


Figure 4-15. Kinematic coupling constraint

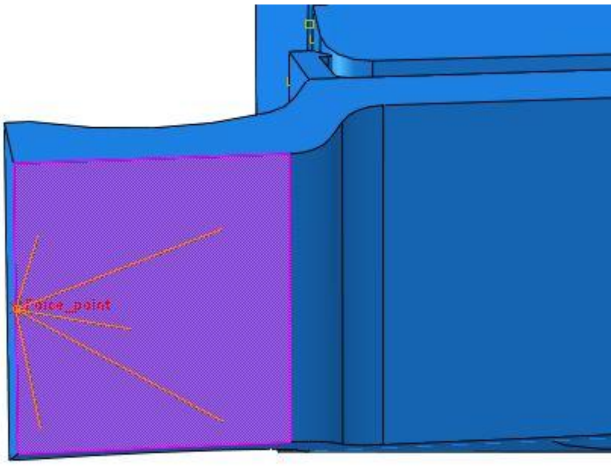


Figure 4-16. Distributed coupling constraint

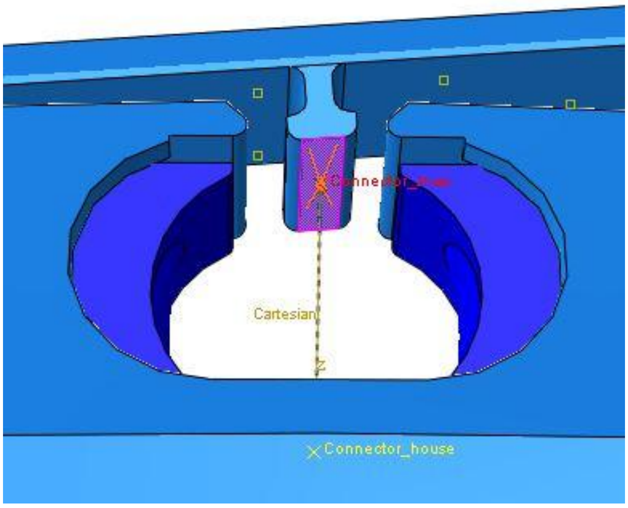


Figure 4-17. Distributing coupling.

4.1.5 Results

Pictures of the results are presented in figure 4-18 through 4-22. The only place where the stress levels are critical is by the snap fit. Since the material model not is as advanced as it should be to get accurate stresses, no numbers are presented in the figures. The results are taken from the moment just before the snap fit enters the slot. That is the moment were the stresses are the highest.

As seen in figure 4-20 through 4-22, the stress distribution is uneven in some areas. That it because the stresses vary too much between the nodes so no averaging could be made by Abaqus, since the default settings are that they cannot vary more than 75 %. It could be made more even by adding more elements to the region, but this would increase the calculation time. Since not the exact right stresses were needed it was considered unnecessary to use more time for this simulation.

When looking at figure 4-21, you see a very fast transition from a green area to a red by the round to the snap fit. This is also an area where the mesh could be made finer to get a smoother transition and more accurate stresses.

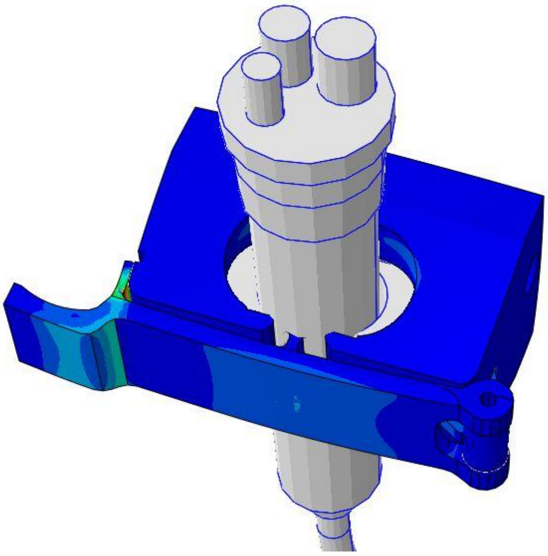


Figure 4-18. Result view 2

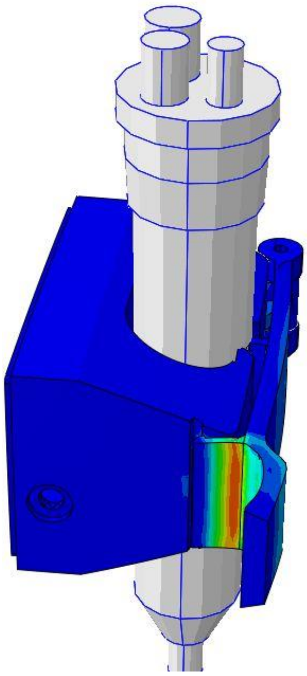


Figure 4-19. Result view 3

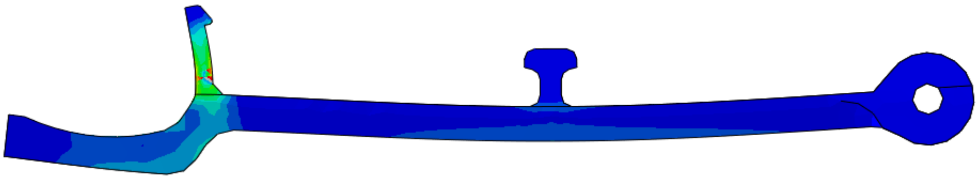


Figure 4-20. Stress in the hatch.

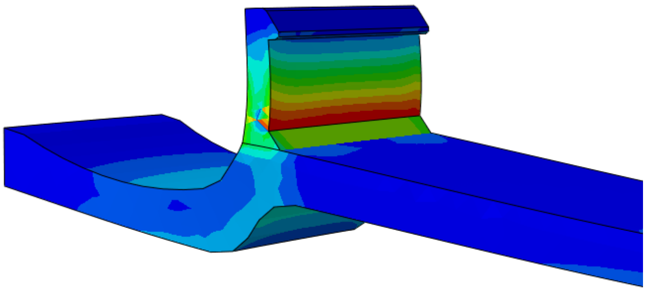


Figure 4-21. Stress in the snap fit.

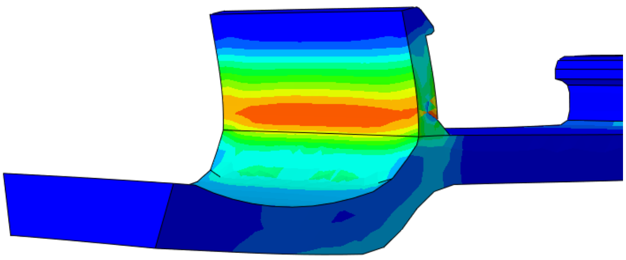


Figure 4-22. Stress in the snap fit.

4.1.6 Conclusion

The simulation of the ALD clearly indicates that if the hatch breaks it will break at the snap fit when the hatch is closing. Since the material model used in the simulation is an approximation the stress levels are not accurate. They can be considered to be right in relation to each other, i.e. the red area are most certainly the area that has the highest stress levels, but how high it is the simulation does not tell.

4.2 Interviews

Interviews were performed with Gambro's technical support [12], [13], clinical advisor [14] and technical service [15], [16]. They have had a lot of contacts with the customers over the years and therefore know a lot about the customer needs. The overall perception of the ALD is that it works well but it has a very low user-friendliness. It is very hard to get the drip chamber in place especially if you use a stiff chamber. It takes a lot of force and it is easy to get injuries in hands and wrists if you use it a lot. Another problem is that the hatch breaks sometimes and this happens usually during the opening of it.

The technical support [12], [13] can also see a difference in failures on the different machines AK-96 and AK-200, though they have the same ALD. The difference between them is that they are placed with the hatch in different directions. On AK-200 the hatch should be opened with the right hand and on AK-96 it should be opened with the left. This has led to more failures for AK-96 because most people use the right hand anyway, and then you need to apply more force to open the hatch since you cannot use your thumb as described in chapter 1.3.3.

A big problem, that all interviewees are consistent about, is that the ALD is very hard to keep clean. It has a lot of areas that are difficult to access when cleaning. Also, if you spill something on it, or if there would be a blood leakage on to it, you can be certain that it will leak into the machine through the gaps between the parts. It is also common that nurses spray the machine with a cleaning solution and then wipe it when cleaning, even if this is not the recommended way to clean the machine. The cleaning solution then leaks into the ALD and further into the machine. According to the technical service [15], [16] it also happens that the nurses pour 70 % alcohol over it, to get a better connection between the chamber and the sensors, if the ALD does not work properly. The big risk of leakage and the cleaning problems increases the risk of spreading diseases between the patients and is a very big problem.

There is only one of the competitors that use an ALD on their machine, and that is Fresenius. The other competitor, such as Braun and Nikkisso, only uses a bubble detector on their machines, which is an air detector placed on the tube after the drip chamber. Fresenius has both an ALD and a bubble detector. The Fresenius 5008S can also control the fluid level in the drip chamber automatically. On Gambro’s machines AK-96 and AK-200 there is an ALD but no bubble detector and on the Artis model there is a bubble detector but no ALD. It needs to be investigated whether or not the ALD is needed. A bubble detector could be better.

4.3 Tests

By testing the use of the ALD the problems that came up during the interviews were confirmed. The tests were performed by simply applying and removing drip chambers with different stiffness values several times in the AK-96 machine. It was confirmed that it takes a lot of force to fit the chamber into the ALD but it also varies a lot depending on what chamber you use. The stiffer the chamber is, the harder it is to apply. Removing is easier because you can simply drag it upwards from the top with one hand. You cannot apply it from the top because the springs make the hole to small. It is very understandable that nurses get injuries in hands and wrists due to repeatedly using the ALD.

The same tests were also performed with the Fresenius machines called 4008S (figure 4-23) and 5008S (figure 4-24). The ALD on the 4008S model is similar to AK-96, though it is easier to apply the chamber in it because of a bigger insertion hole. The one on the newer 5008S model is very different from the others. Instead of an ultrasonic sensor it uses a capacitive sensor which allows an air gap between the sensor and the chamber. This allows a much more usable design of the ALD and the Fresenius 5008S is a very good example of that. You can both apply and remove the chamber quickly with one hand and it does not matter how stiff the chamber is.

Figure 4-23. ALD on Fresenius 4008S

Figure 4-24. ALD on Fresenius 5008S

4.4 Is the ALD needed?

If the ALD is needed depend a lot on how good the priming of the machine works. If the priming works poorly there will be a lot of air left in the tubs when the treatment starts. Air can also find its way into the blood line in other ways. The air will then gather up in the drip chamber and the fluid level there will decrease. If the machine only has a bubble detector and no ALD the fluid level can decrease under the drip chamber and a further distance down the tube before the detector can notice it and stop the treatment. When the fluid level is that low it is very hard and complicated to increase the fluid level again and continue the treatment. You need to choke the flow in the tube on two places and then suck the air out with a syringe. You also need to do this very gently to not get problems with the pressure.

If the machine has an ALD and the fluid level starts to decrease it stops the machine earlier, when there is still a little fluid left in the drip chamber. By then it is much easier to increase the fluid level and continue with the treatment. You only need to press a button.

The conclusion of this is that if the machine has a very good priming process which can guarantee that the tubes contains no air, the need of an ALD will be low and you can use a bubble detector instead. But if the priming does not guarantee that the tubes are free of air, which is the case right now, the ALD is very useful and increases the usability of the machine.

4.5 Mission statement

The conclusions of the interviews and tests were that the usability of the ALD on AK-96 could be improved significantly and that Gambro's biggest competitor has a much better solution. Improving the usability of the ALD would make Gambro's machines more competitive towards their biggest competitors. From the collected information a mission statement was established and can be studied in table 4-2.

Table 4-2. Mission Statement

Mission Statement: Air Level Detector Project	
Product Description	• An air level detector that detects if the fluid level in the drip chamber falls under a certain level.
Benefit Proposition	• Best usability on the market • Long service intervals
Key Business Goals	• Product introduced in the Spring 2015 • Be the biggest manufacturer of dialysis machines in the world.
Primary Market	• Dialysis clinics
Secondary market	• Home dialysis patients
Assumptions	• Compatible with AK-96 • Radical difference in design
Stakeholders	• Nurses • Patients • Retailer • Sales force • Service center • Manufacturing operations

5 Identifying customer needs

The customer needs were identified by first gathering raw data from old development projects and from interviews with Gambro staff with customer contact. The data received from this was then translated into terms of customer needs. The needs were then given a relative importance on a scale from 1 to 3 where 3 is the most important. The biggest challenge with the project turned out to be making the ALD user friendly and easy to clean. The current sensor technique makes it hard to establish this but it could be changed to one that allows better usability.

5.1 Raw data

First of all Gambro's product specifications form an earlier development process was studied to interpret what specifications that should be reused. Then interviews were performed with Gambro's technical support [12], [13], technical service [15], [16] and clinical advisors [14], [17] and [18] to get an overview of the problems with the ALD and verify that the chosen specifications were accurate. The statements from the interviews are listed in appendix B.

5.1.1 Old specifications

Earlier product specifications for the ALD contained the requirements in Appendix C. After each requirement follows a comment on if it is going to be used in this development process or not, and if it is going to be changed in some way. The focus was on mechanical parts of the ALD so requirements of electrical character were often not included.

5.2 Customer needs

The raw data from the old specifications (see table 5-1) and the interviews (see Appendix B) were translated into terms of customer needs. First five primary needs were set, which are very broad. These were then divided into secondary needs that are more focused on one function.

Table 5-1. Customer needs

Nr.	Primary needs	Secondary needs	nr.2
1	Good usability	Functions with different chambers	1
		Prevents the drip chamber from falling out.	2
		Apply chamber with one hand	3
		Remove chamber with one hand	4
		Fits both left and right handed	5
		Easy and quick to apply chamber	6
		Easy and quick to remove chamber	7
		Does not cause work injuries	8
2	Easy to keep clean	Withstand exposure to cleaning solutions	9
		No leakage into the machine	10
		Surfaces that are easy to clean	11
		No areas that are difficult to access	12
3	Detects the content of the drip chamber	Detects if there is low fluid level	13
		Detects blood foam as air	14
		Functions with different humidity	15
		Functions with different temperatures of the fluid	16
		Functions in different room temperatures	17
4	Withstand transportation	Random vibrations	18
		Bumps	19
		Varying humidity	20
		Temperature differences	21
5	Long life time	Long time before fatigue	22
		No service intervals	23
		Withstand solar radiation	24
		Long mean time between failure	25

5.3 Relative importance

The relative importance was set with help of the reference persons interviewed earlier [12], [13] and [15]-[18]. The importance was given on a scale from 1 to 3 where 3 is the most important. Each interviewee got to set grades on the needs. The mean grade was than calculated for each need and rounded to the closest whole number. These are presented in table 5-3.

The interviewees all had similar opinions about the needs. Everything was very important, except that you should be able to apply and remove the chamber with one hand, and that it should fit both left and right handed. These three needs were given all the grades 1, 2 and 3 from the different persons. Worth to mention is that two of the seven interviewees were left handed and therefore thought that it was really important that it should fit them.

Table 5-2. Primary and secondary needs

Nr.	Primary needs	Secondary needs	nr.	Imp.
1	Good usability	Functions with different chambers	1	3
		Prevents the drip chamber from falling out.	2	3
		Apply chamber with one hand	3	2
		Remove chamber with one hand	4	2
		Fits both left and right handed	5	2
		Easy and quick to apply chamber	6	3
		Easy and quick to remove chamber	7	3
		Does not cause injuries	8	3
2	Easy to keep clean	Withstand exposure to cleaning solutions	9	3
		No leakage into the machine	10	3
		Surfaces that are easy to clean	11	3
		No areas that are difficult to access	12	3
3	Detects the content of the drip chamber	Detects if there is low fluid level	13	3
		Detects blood foam as air	14	3
		Functions with different humidity	15	3
		Functions with different temperatures of the fluid	16	3
		Functions in different room temperatures	17	3
4	Withstand transportation	Random vibrations	18	3
		Bumps	19	3
		Varying humidity	20	3
		Temperature differences	21	3
5	Long life time	Long time before fatigue	22	3
		Long service intervals	23	3
		Withstand solar radiation	24	3
		Long mean time between failure	25	3

5.4 Reflection

The customer needs were established by interviewing people with a lot of customer contact within the company, thus all information is from a second source. Interviewing the actual customers would have been better but it was a lot of people from Gambro who wanted to visit the clinics. This made it hard to do it for this project. The interviewed people were considered as good enough sources.

Some of the people that were interviewed were participating more in the development process. All of them gave good comments but not as many were needed in the later process. Therefore a couple of them were chosen for further participation. These were the clinical advisor Ann-Margret Håkansson [14] and the service technician Johan Kristoffersson [16].

Most of the needs that came up during the identification of customer needs were obvious. It was easy to see that it was hard to apply the chamber and that a blood leakage during a treatment would cause a leakage into the machine. At first it was a little surprising that the hatch breaks more often at AK-96, but when thought through it is not surprising at all, since the hatch is in the opposite direction from the AK-200. Since most people are right handed they use there right hand to open the hatch and then they cannot do it the proper way, which results in higher stresses and fatigue in the snap fit. A theory from service technician Johan Kristofferson [16], who is left handed, was that left handed people are used to designs fitted for right handed, and therefore can either use there right hand or find a way to do it in a good way with the left hand. Right handed people are not used to use their left hand to the same extent. What is surprising is that the old ALD does not fulfill most of the customer needs that were identified. It is very surprising that Gambro hasn’t done anything to make it better in usability and cleaning in so many years.

6 Target specifications

The target specifications are based on the customer needs and are measurable metrics. A target value and a target range were set for each of these metrics. Practical test was performed on the competitor's machines and drip chambers to find reasonable values to have as targets. The targets were set high since the new ALD should be better than the competitors.

6.1 List of metrics

To be able to evaluate the customer needs they need to be measurable. Therefore a list of metrics was prepared and coupled to the customer need, see table 6-1. An explanation of each metric is then presented in table 6-2.

Table 6-1. List of metrics

Metric no.	Customer needs	Metric
1	5	Time to apply the soft chamber
2	5	Time to apply the hard chamber
3	6	Time to remove the soft chamber
4	6	Time to remove the hard chamber
5	2, 3, 5, 6	Spring constant
6	15	Functional fluid temperature
7	1	Drip chamber diameter range
8	8	Resistance to cleaning solutions
9	10, 11	Easy to clean
10	10	Surface finish
11	21	Number of loading and unloading cycles of chamber without degradation.
12	22	Service interval
13	3, 6, 7	Maximum opening force if a hatch (or similar) is used without chamber
14	3, 6, 7	Maximum opening force if a hatch (or similar) is used with chamber

15	2, 5, 7	Maximum closing force if a hatch (or similar) is used without chamber
16	2, 5, 7	Maximum closing force if a hatch (or similar) is used with chamber
17	18	Bump test
18	23	Resistance to solar radiation
19	17	Maximum deflection when vibrating
20	2, 5, 7	Force needed to apply chamber
21	3, 6, 7	Force needed to remove chamber
22	12	How to detects low fluid level
23	13	Detects blood foam as air
24	4	Equal handling for left and right handed
25	9	Possibility of leakage into the machine
26	9, 10	Number of parts
27	14	Humidity range with function
28	16	Temperature range with function
29	19	Humidity range without function
30	20	Temperature range without function

Table 6-2. Explanation to the list of metrics

Metric No	Explanation
1-2	It is important to measure the time it takes to apply the chamber on the ALD because it is a measurement of how customer friendly the design is. Due to variation of the chambers is the test done on a hard and a soft chamber.
3-4	When the treatment is finished, it is important that the removing of the chamber is quick and easy. Therefore, the time it takes to remove a soft and a hard chamber from the ALD will be measured.
5	The spring constant in the ALD is measured, because if the spring is to stiff the chamber is hard to remove and apply.
6	The ALD shall maintain its functionality at different fluid temperatures.
7	The chambers are designed differently depending on the supplier. It is therefore important for the ALD to work with different sizes of chambers.
8	The clinics uses different kinds of cleaning solutions and the ALD then needs to be designed to withstand different kinds of solutions. The resistance are graded from 1-5, where a 5 represents good resistance and a 1 represents poor resistance.

9	The ALD needs to be designed to be easy to clean to keep away bacteria. Though it is hard to put a unit on how easy it is to clean. Instead a grade from 1 to 5 is used, where a 5 represents a design that's easy to clean, and 1 represents a design that's difficult to clean.
10	The surface should not be too rough as it becomes too difficult to clean. Therefore the surface roughness is measured.
11	The ALD shall withstand a number of loading and unloading cycles of the chamber without degradation. This is therefore measured to make sure that the design is robust.
12	The service interval for the machine is 2 years, but the ALD should function without service during the machine lifetime.
13-16	To reduce work injuries, the force to apply and remove the chamber should be reduced. Therefore are the forces during opening and closing of a soft and a hard chamber measured.
17	It is essential that the ALD manages bumps during transport and during operation to maintain its functionality. The ALD must meet the standards for bumps
18	The material must withstand solar radiation in order to not degrade over time. The material in the ALD must then be determined.
19	To maintain the function of the ALD shall the deflection during a vibration test not be too large.
20-21	To reduce work injuries, the force to apply and remove the chamber should be reduced. These forces are hard to measure. Therefore the forces are during applying and removing of the chamber graded from 1-5 where a 5 is a large force and a 1 is a small force.
22	There are different techniques of how to determine the blood level. Different techniques require different properties from the holding device of the ALD. The technology of the ALD for each design needs to be determined.
23	The ALD shall detect blood foam as air. The different concepts are examined to see if they will detect blood foam as air.
24	A good design of the ALD is designed for both right handed and left handed. The different concepts are tested to see if they are suitable for both right handed and left handed.
25	In order to facilitate cleaning of the ALD, no liquid shall be able to leak into the machine. The different models are graded from 1-5 where a 5 represent a no possibility of leakage and a 1 represents high possibility of leakage.
26	To minimize the costs and lower the possibility of leakage into the machine, the number of parts shall be reduced. The sensors and cables are not included.

27	The ALD will be used in many different climates and shall withstand different level of humidity while maintaining its functionality.
28	The ALD shall withstand different temperatures while maintaining its functionality. It can vary a lot between different parts of the world even if it is used indoors.
29	The ALD shall withstand different level of humidity during transportations without damage. The humidity varies more during transportation than during the usage.
30	The ALD shall withstand different level of temperatures during transportations without damage. The temperature can vary a lot during this phase.

6.2 Benchmarking

6.2.1 Air level detectors

Benchmarking was performed on Fresenius two different ALD's and Gambro's own. These are presented in figure 6-1 through 6-3. The other competitors do not use ALD's on their machines. Some of the target specifications were hard, or took a lot of effort, to measure. Some of these were not worth the effort so they weren't measured. The values for Gambro's ALD were easier to get hold of since the specifications were available.

Figure 6-1. ALD on Fresenius 5008S

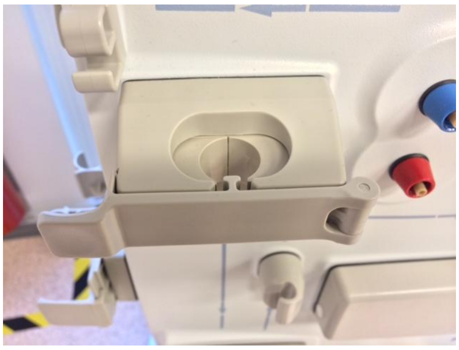


Figure 6-2. ALD on the AK 96 and AK 200

Figure 6-3. ALD on the Fresenius 4008S

The time to apply different chambers was simply measured by clocking different persons when they applied and removed the chamber. Mean values of the measurements are presented in table 6-3.

To measure different forces a Newton meter was used. A number of measurements were performed at each specific metric and the mean value is presented in table 6-3. The ALD's were also disassembled to count the number of parts and determine which sensor methods they used.

All metrics was not worth the effort measuring. Therefore some fields are left empty in the table.

Table 6-3. Benchmark

No.	Metric	Measured unit	Gambro AK-96	Fresenius 4008S	Fresenius 5008S
1	Time to apply the soft chamber	[s]	5.23	2.8	1.15
2	Time to apply the hard chamber	[s]	12.84	6.35	1.01
3	Time to remove the soft chamber	[s]	2.18	1.725	0.73
4	Time to remove the hard chamber	[s]	1.5	1.76	0.81

5	Spring constant	[N/mm]	2.51	-	-
6	Functional fluid temperature	Min/max [°C]	18-35 °C	-	-
7	Drip chamber diameter range	[mm]	20-23	16-22	18-24
8	Resistance to cleaning solutions	Grade 1-5	3	3	3
9	Easy to clean	Grade 1-5	1	2	3
10	Surface finish	Ra	2 ± 0.5	-	-
11	Number of loading and unloading cycles of chamber before failure.	Number of cycles	>18,720	-	-
12	Service interval	Years	2 years	-	-
13	Maximum opening force if a hatch (or similar) is used without chamber	[N]	22	21	-
14	Maximum opening force if a hatch (or similar) is used with chamber	[N]	54	21	-
15	Maximum closing force if a hatch (or similar) is used without chamber	[N]	11	-	-
16	Maximum closing force if a hatch (or similar) is used with chamber	[N]	50	-	-
17	Bump test	Pass [Y/N]	Yes	-	-
18	Resistance to solar radiation	[Y/N]	Yes	-	-
19	Maximum deflection when vibrating	%	-	-	-

20	Force needed to apply chamber	Grade 1-5	5	2	1
21	Force needed to remove chamber	Grade 1-5	3	2	1
22	How to detects low fluid level	Method	Ultrasound	Ultrasound	Capacitive
23	Detects blood foam as air	Sub [Y/N]	Yes	Yes	-
24	Equal handling for left and right handed	Sub [Y/N]	No	No	Yes
25	Low possibility of leakage into the machine	Grade 1-5	1	3	4
26	Number of parts	Number of parts	11	10	7
27	Humidity range with function	Min/max % humidity	15-85 %	-	-
28	Temperature range with function	Min/max [°C]	10-40 °C	-	-
29	Humidity range without function	Min/max % humidity	10-90 %	-	-
30	Temperature range without function	Min/max [°C]	-20-70 °C	-	-

6.2.2 Drip chambers

The ALD should be compatible with a lot of different drip chambers, since the AK-96 should work with a universal blood line. There are too many different chambers on the market to take all into account, so a number of chambers were chosen. These are shown in table 6-4 below. “D” and “d” represents the largest and smallest diameter on the chamber. The stiffness was determined by squeezing on the chamber. A high number represents a stiff chamber and a low number represents a soft chamber.

Table 6-4. Drip chambers

Manufacturer	Model	D (mm)	d (mm)	Length	Stiffness	Picture
GAMA	DIS 06-16 (9b)	21.6	19.5	87	3	
NINGBO	TX-JB-12 (5A) (ak-d)	22.5	19.5	118	2	
NINGBO	TX-JB-12 (ak-F)	22.5	19.5	118	2	
Allmed	AV/203/1+B	20.5	19.5	80	1	

DIALINE	71AV/0576,AP	22	21	81	1	
B. BRAUN A/V Systems	AVSET 721061200	22	20	98	2	
ALLMED	AV/200/4+B (1C)	23	20	87	1	
BRAIN	DORA-BL-004 (4B)	23	20	88	3	
BRAIN	DORA-BL-002 (3A)	24	19	80	2	

FRESENIUS	Gambro AK 200 (8C)	22	20	100	3+	
GAMBRO	BL 10-E2AP-PL	21.5	20.5	106	1	
GAMBRO	GMB-AV36S	24	20	94	2	
GAMBRO	GMB-AV31	21.5	19	98	2	

6.3 Target specifications

Based on the benchmarking information, shown in table 6-3 and 6-4, and the old product specifications from Gambro, the target specifications were set. The goal is to have the best ALD on the market so the target values were set to be better then, or at least as good as the best ALD on the market.

Table 6-5. Target values

Metric no.	Metric	Range	Goal
1	Time to apply the soft chamber	<3	1
2	Time to apply the hard chamber	<3	1
3	Time to remove the soft chamber	<2	1
4	Time to remove the hard chamber	<2	1
5	Spring constant	-	-
6	Functional fluid temperature	18 - 35	18 - 35
7	Drip chamber diameter range	18 - 24	18 - 24
8	Resistance to cleaning solutions		Excellent
9	Easy to clean	3 - 5	5
10	Surface finish	<3	<3
11	Number of loading and unloading cycles of chamber without degradation.	>18,720	>18,720
12	Service interval	2	2
13	Maximum opening force if a hatch (or similar) is used without chamber	<22	<20
14	Maximum opening force if a hatch (or similar) is used with chamber	<20	<20
15	Maximum closing force if a hatch (or similar) is used without chamber	<15	<11
16	Maximum closing force if a hatch (or similar) is used with chamber	<25	10 - 20
17	Pass bump and vibration test (Storage and transportation)	Yes	Yes
18	Resistance to solar radiation	Yes	Yes
19	Maximum deflection when vibrating	-	-
20	Force needed to apply chamber	<2	1
21	Force needed to remove chamber	<2	1
22	How to detects low fluid level	Capacitive or Ultrasound	Capacitive
23	Detects blood foam as air	Yes	Yes
24	Equal handling for left and right handed	Yes	Yes
25	Possibility of leakage into the machine	<2	1
26	Number of parts	<5	1
27	Humidity range with function	15 - 85 %	15 - 85 %
28	Temperature range with function	10 - 40 °C	10 - 40 °C
29	Humidity range without function	10 - 90 %	10 - 90 %
30	Temperature range without function	-20 - 70 °C	-20 - 70 °C

6.4 Reflections

The target specifications and target range were set from practical tests, product catalogues and requirements from existing designs. As seen in table 6-3, some values are missing. They are missing because of problem finding proper values. Some were hard to measure and some were just not so important that it was worth the effort to measure them.

The target values are set high to find a design that is better than all the competitors. It is necessary to have high requirements to find a very good concept.

There is no need to develop different versions of the ALD. It should have the same functions regardless on which machine it will be applied to. The Gambro machines have designs that match each other so the appearance is not a problem either.

7 Concept generation

Before the concepts were generated the problem needed to be clarified. This was done by decomposing the problem into sub problems, which then were solved individually. There are two problems which needs to be solved, how to hold the chamber and how to detect fluid. To visualize different approaches of how to solve these problems classification threes were used. A lot of concepts were then generated both individually and in group. The concepts were then combined and refined to fit the customer needs as good as possible.

7.1 Clarifying the problem

7.1.1 Decomposition

The problem was decomposed in several steps which go more and more in to detail. The work flow of the decomposition can be followed in figure 7-1 and 7-2 bellow.

The basic functions for the ALD are to detect the content of the chamber and to hold the chamber in place. These were the two sub problems on which the focus in the project will lied.

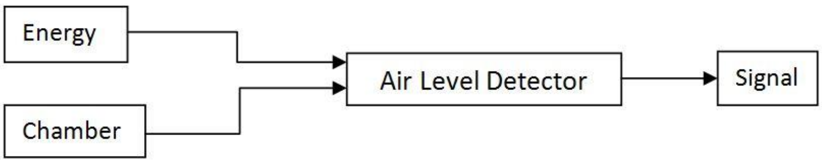


Figure 7-1. Function diagram 1

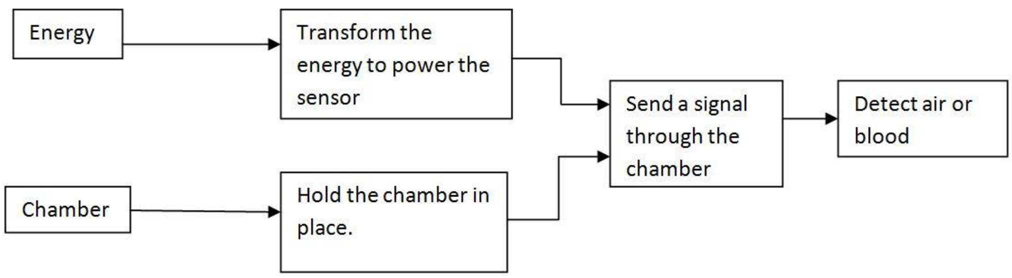


Figure 7-2. Function diagram 2

Two sub problems:

1. Hold the chamber in place.
2. Detect fluid or air.

7.1.2 Focus

Since this project has a mechanical orientation most focus was on holding the chamber in place. However, different detection methods require different properties from the holding method. This must be taken under consideration when designing the holding method.

7.2 Detect fluid or air

After a discussion with an electrical engineer [19] at Gambro there were three alternatives on how to detect fluid or air in the chamber. These are presented in figure 7-3 below.

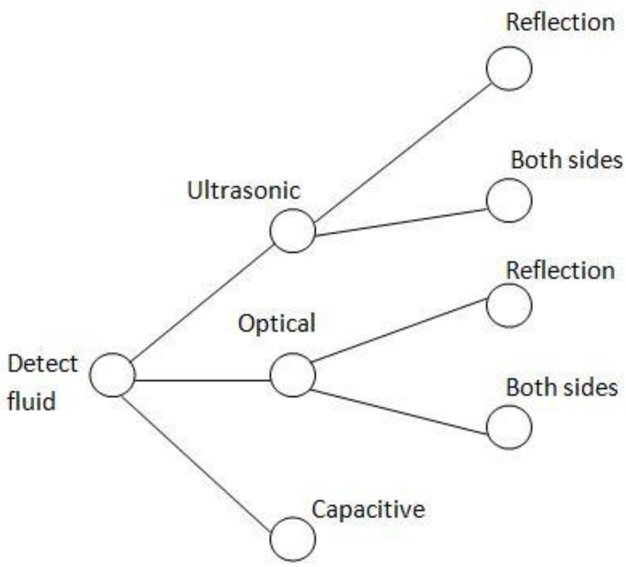


Figure 7-3. Classification tree of how to detect fluid

7.2.1 Ultrasonic sensor

The first one is an ultrasonic sensor. This can be used in two ways. Ether you have the transmitter on one side of the chamber and the receiver on the other, se figure 7-4. In the other method both the receiver and transmitter are on the same side of the chamber. The signal then reflects on the chamber's side to the receiver, see figure 7-5. To use ultrasound requires very good contact between the sensors and the chamber. If there is a little air gap between the chamber and the sensors, problems with false alarms often occur. Also, if you have the transmitter and the receiver on different sides they must be parallel to each other. This limits the freedom of the design of the holder.

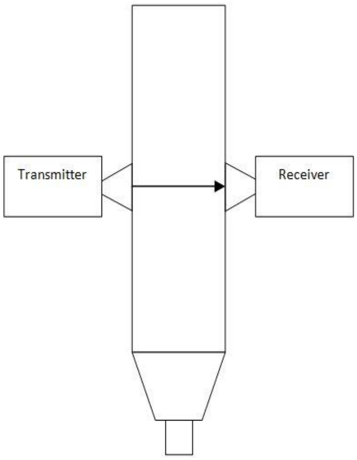


Figure 7-4. Ultrasonic sensor

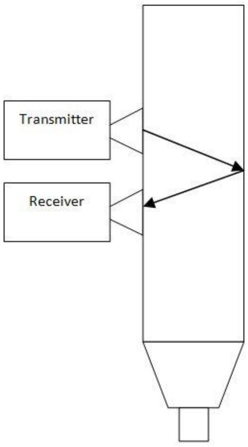


Figure 7-5. Ultrasonic sensor with reflection

7.2.2 Capacitive sensor

The next alternative is a capacitive sensor which Fresenius uses on their 5008S model. This technique allows more flexibility in how you place the sensors. The transmitter and receiver do not have to be parallel and it does not require as good contact between the sensors and the chamber. It even allows a small air gap between them, see figure 7-6. A problem with this technique is that it could detect all fluids and will even detect a hand as fluid. Therefore the holder needs to be designed to prevent this if a capacitive sensor is used. Another disadvantage is that a capacitive sensor cannot detect bubbles like an ultrasonic sensor can. To come around this problem it could be combined with a bubble detector placed under the chamber.

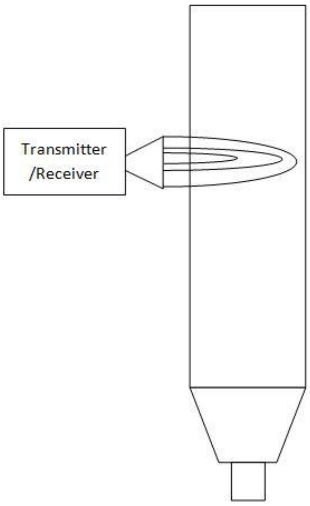


Figure 7-6. Capacitive sensor

7.2.3 Optical sensor

The last sensor method is an optical sensor. The transmitter and receiver could be placed in the same way as the ultrasonic sensors, see figure 7-4 and 7-5. This would give a very good flexibility on how to place the chamber since the sensor and the chamber does not need to be so close to each other. Though it would get problems if the lighting in the room was bad, and it could only detect blood in the chamber, and not the priming solution since it is transparent. Detecting blood foam could also be problematic. This limits the possibilities with this method a lot. Also, if the blood would coagulate against the inner surface of the chamber, this sensor would detect it as blood.

7.3 Holding the chamber

Since holding the chamber means holding a cylindrical object, other solutions where a cylindrical object is held were studied. For example broom and tool holders for fastening on walls. The proposals that would be possible to use were put into a classification tree to get an overview. The classification tree is presented in figure 7-9 below. The classification tree contains both feasible and unfeasible suggestions. No suggestions were taken away.

Different concepts were then proposed from the classification tree. A simple CAD model was made of each concept, and those are presented in figures 7-10 to 7-22 below, with a small description of how the concept should work.

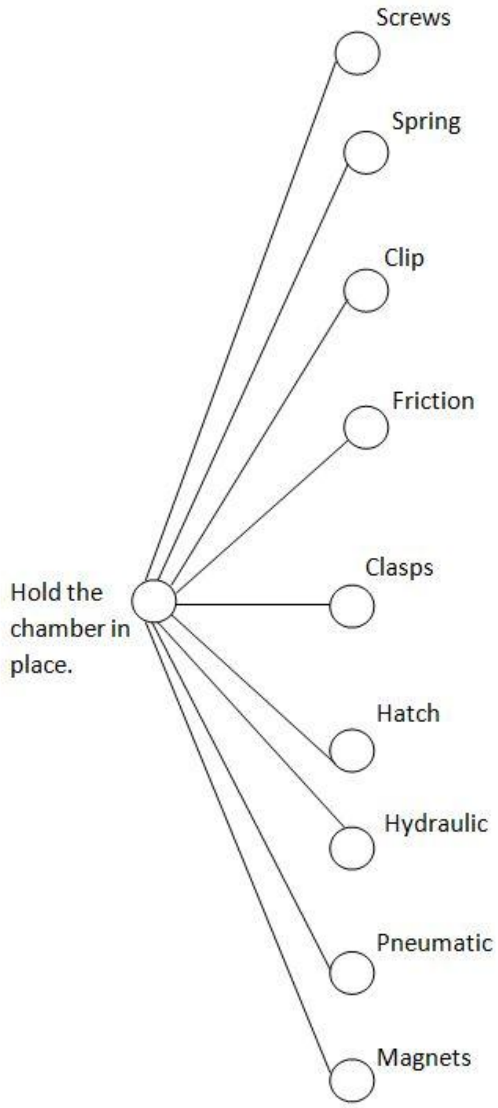


Figure 7-7. Classification tree of how to hold the chamber

7.3.1 Concept A

This is inspired by the ALD on Fresenius 5008S. The chamber is simply pressed in between the two holders. The holders have springs that make them press against the chamber. This concept would only work with a capacitive sensor or maybe with an ultrasonic with reflection, since there is only one surface to place the sensor at.

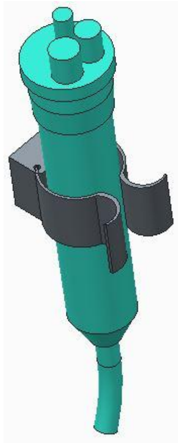


Figure 7-8. Concept A

7.3.2 Concept B

Holding the chamber is not the only way to keep it in place. This concept holds the chamber by the tubes so the chamber if free. The arrows in figure 7-11 show where the tubes will be held. This concept would be extremely easy to clean since it allows very smooth surfaces that are easy to wipe. The challenge would be to make it user friendly and have a good enough connection between the chamber and the sensor. It would not work to have an ultrasonic sensor from both sides on this concept, and probably not one with reflection ether.

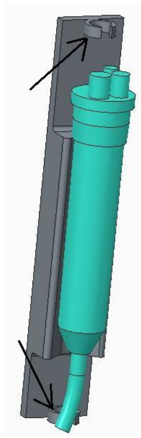


Figure 7-9. Concept B

7.3.3 Concept C

This concept is inspired by the holders for rope on sail boats. The two parts holding the chamber has springs which make them want to rotate against the chamber. The chamber is inserted from below and dragged down to sit tight to the sensors, which are placed in the holders. A good thing with this concept is that it would work with all sensor types. Cleaning around the moving parts could be hard.

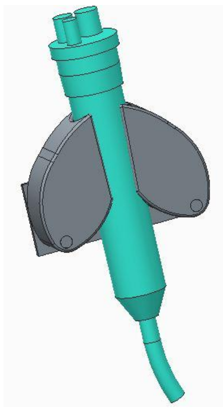


Figure 7-10. Concept C

7.3.4 Concept D

This design is a holder for hanging tools, brooms, etc. on to walls. To apply the chamber you simply press it against the yellow rubber part in the middle and it folds in around the chamber. It is very flexible for different dimensions of chambers. It also could work with all sensor techniques. It could be a problem that it is hard to clean around the moving parts.

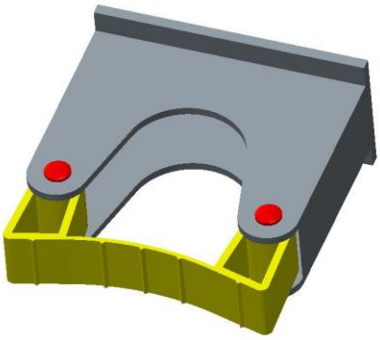


Figure 7-11. Concept D

7.3.5 Concept E

Two rolls helps to insert the chamber. The material around is flexible so the chamber can be pressed in from the front. It cannot be used with a two sided ultrasonic sensor but the others are possible. The cleaning can be a problem around the rolls.

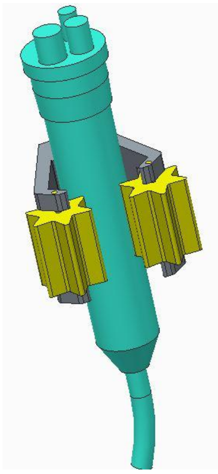


Figure 7-12. Concept E

7.3.6 Concept F

This concept aims to be easy to use. It has one rounded movable part that springs against the chamber and enables the use of chambers with different dimensions. The rounded shape allows the chamber to be mounted from above or from the font. A capacitive or an ultrasonic sensor would function with this concept.

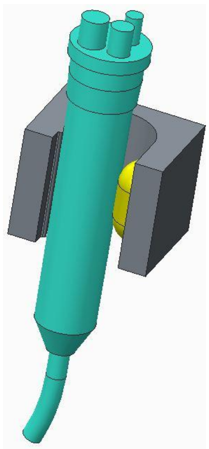


Figure 7-13. Concept F

7.3.7 Concept G

This concept has no movable parts which reduce the risk of leakage into the machine. The chamber can be applied from above or from the front. The material will be flexible which will enable the concept to fit chambers with different dimensions. This concept would work with both a capacitive and an ultrasonic sensor with reflection.

Figure 7-14. Concept G

7.3.8 Concept H

This concept is inspired from a broom holder and the idea is to apply the chamber from the front. The hook is movable and puts a pressure on the chamber which holds it in place. Due to the movable hook the concept will work with different dimensions of chambers. The concept has some areas that are difficult to access which could lead to difficulties during cleaning. This concept will only work with a capacitive or an ultrasonic sensor with reflection.

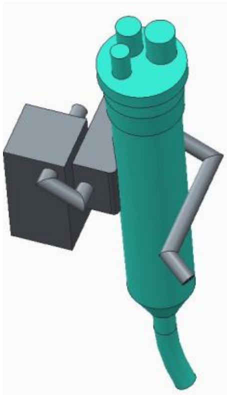


Figure 7-15. Concept H

7.3.9 Concept I

This concept aims to be easy to clean. Since there are no movable parts the risk of leakage into the machine will be decreased. The rounded shape makes it easy to clean and apply the chamber from above or from the front. The material will be flexible which allows the holder to fit chambers with different dimensions. Its shape makes it only compatible with a capacitive or an ultrasonic sensor with reflection.

Figure 7-16. Concept I

7.3.10 Concept J

This concept aims to be very flexible in size. It has one movable part which is attached to a spring and enables the possibility to use chambers with different dimensions. The idea is to apply the chamber from the front. The concept is compatible with a capacitive or an ultrasonic sensor with reflection.

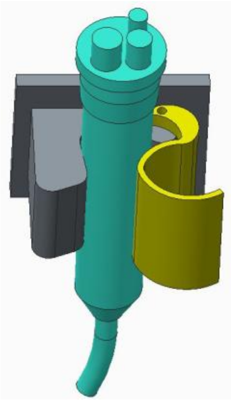


Figure 7-17. Concept J

7.3.11 Concept K

This is an improved version of the old ALD. Instead of applying the chamber from the front, it is instead applied from the top. This would make it much easier to apply the chamber. To make this possible chamfers are made at the insertion hole. Another improvement is to make one of the movable parts fixed so you only need one spring. This would cut the costs of the ALD a lot since the adjustment screws for the springs are very expensive.

Figure 7-18. Concept K

7.3.12 Concept L

This is also an improvement of the old ALD. To make it easier to insert the chamber from the front the gap was made bigger. One of the movable parts was made fixed and the other moves aside when you open the hatch. This way it is easy to apply the chamber and you get good contact to the sensors when you close the hatch.

Figure 7-19. Concept L

7.3.13 Concept M

This is inspired of the ALD at Fresenius 4008S. The difference is that the sensors are placed behind the chamber and in the hatch. The sensor in the back has a spring so it adjusts to the size of the chamber. The snap fit to close the hatch is also replaced to get a hatch that is easier to close and open.

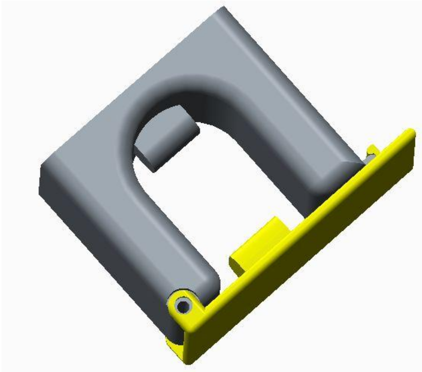


Figure 7-20. Concept M

7.4 Reflection

During the concept generation thirteen different concepts were generated. The designs are quite different from each other, since all ideas from the authors have been taken in to account. As external sources, broom and tool holders have been used as an inspiration to some of the designs. This was done because they have a similar function as the ALD, when holding the chamber in place. More concepts could have been generated, but due to the time period of the project it was considered that thirteen designs were enough. It is the authors' perception that all possible solution techniques that are feasible have been covered.

The ALD has two functions and they are to hold the chamber in place and detect fluid. Therefore the function diagrams become quite simple. Different functions diagram and alternative ways to decompose the problem was considered unnecessary.

8 Concept selection

Selecting which concept to go forward with is a very critical part of the development process. It is therefore important to have an objective and methodical way of doing this. The method used in this project is described in chapter 3.1.5 and is about using matrices and weighing the different concepts based on different criteria. This is done in two steps where the first is called "concept screening" and the second is called "concept scoring". The first step eliminates out the worst solutions, and the second does a more detailed analysis of the ones that are left to choose the best one. The criteria used in the selection process are based on the customer needs determined earlier. The importance of the needs is also included in the concept scoring step. Two concepts were chosen to be taken forward to the concept development process. These were the concepts I and G.

8.1 Concept Screening

The concept screening is performed to eliminate the worst concepts and only keep the ones with potential in the development process. The concepts are compared to a reference design that the new design should be better than. The criteria used in the screening were the ones that were possible to consider in this early stage. The ratings are set by the project group, according to the rating method described in chapter 3.1.5.1 and table 3-1. In this project two screenings were performed with different references. Gambro's ALD was the reference in the first one and the Fresenius 5008S ALD in the second one.

8.1.1 First screening

The first screening was performed with the old ALD as a reference, see table 8-1. This is to determine whether the new concepts are better than the old one. This screening clearly shows that all of the concepts are better than the old ALD. The only thing the old design is better at is to hold the chamber in place. It is very hard to get the chamber to fall out of the old holder once it is applied. That the new concepts do not hold the chamber as hard is not considered a problem. The chamber does not need to be held as hard as the old ALD holds it. It is not exposed to major loads when it is applied. Though, it should be taken in mind that the sensors need to have a good connection to the chamber, if ultrasonic sensors are used.

Table 8-1. First screening with the current design as reference.

	Concept													
Selection Criteria	A	B	C	D	E	F	G	H	I	J	K	L	M	Ref
Function with different chambers	+	-	0	+	+	+	+	+	+	+	+	+	+	0
Fits both left and right handed	+	+	+	+	+	+	+	+	+	+	+	0	0	0
Apply chamber with one hand	+	0	+	+	+	+	+	+	+	+	+	0	0	0
Holds the chamber in place	-	-	-	-	-	-	-	-	-	-	-	0	0	0
Easy and quick to apply chamber	+	+	+	+	+	+	+	+	+	+	+	+	+	0
Easy and quick to remove chamber	+	+	+	+	+	+	+	+	+	+	+	0	+	0
Low possibility of leakage into the machine	+	+	+	+	+	+	+	+	+	+	0	0	+	0
No areas that are difficult to access	+	+	0	0	0	+	+	0	+	+	0	0	0	0
Sum +'s	7	5	5	6	6	7	7	6	7	7	5	2	4	0
Sum 0's	0	1	2	1	1	0	0	1	0	0	2	6	4	8
Sum -'s	1	2	1	1	1	1	1	1	1	1	1	0	0	0
Net Score	6	3	4	5	5	6	6	5	6	6	4	2	4	0
Rank	1	4	3	2	2	1	1	2	1	1	3	5	3	6
Continue?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N

8.1.2 Second screening

To pick the best concept new concepts screening had to be done, since all concepts got through the first one. Instead of using the current ALD as a reference, the Fresenius ALD from the 5008S model was used. That is considered as one of the best one on the market, and is therefore the one the new design should aim to be better than. The results of the second concept screening are shown in table 8-2. The concepts F, G, I and J turned out to be the ones that are better than Fresenius 5008S and where chosen for further evaluation. The only thing in the matrix that the new concepts were better than Fresenius at was that they were easier to clean. You could also add that the new concepts have fewer parts than the reference, which not is shown in the table. This makes them less complex and cheaper. The concepts A, D and E turned out to have the same score as the reference. The aim of this project is to find a concept that is better than the reference and the number of concepts also needed to be reduced to have time to develop them. These three concepts were therefore not chosen for further development.

Table 8-2. Second screening with Fresenius 5008S as reference.

	Concept													
Selection Criteria	A	B	C	D	E	F	G	H	I	J	K	L	M	Ref
Function with different chambers	0	-	-	0	0	0	0	-	-	0	-	-	-	0
Fits both left and right handed	0	0	0	0	0	0	0	-	0	0	-	-	-	0
Apply chamber with one hand	0	-	-	0	0	0	0	-	0	0	-	-	-	0
Holds the chamber in place	0	-	+	0	0	0	0	-	0	0	+	+	+	0
Easy and quick to apply chamber	0	-	-	0	0	0	0	-	0	0	-	-	-	0
Easy and quick to remove chamber	0	0	0	0	0	0	0	0	0	0	-	-	-	0
Low possibility of leakage into the machine	0	0	0	0	0	0	0	0	+	0	-	-	-	0
No areas that are difficult to access	0	+	0	0	0	+	+	0	+	+	-	-	-	0
Sum +'s	0	1	1	0	0	1	1	0	2	1	1	1	1	0
Sum 0's	8	3	4	8	8	7	7	3	5	7	0	0	0	8
Sum -'s	0	4	3	0	0	0	0	5	1	0	7	7	7	0
Net Score	0	-3	-2	0	0	1	1	-5	1	1	-6	-6	-6	0
Rank	2	4	3	2	2	1	1	5	1	1	6	6	6	2
Continue?	N	N	N	N	N	Y	Y	N	Y	Y	N	N	N	N

8.2 Concept scoring

The concept scoring started with setting up the matrix. Which criteria that should be included and how they should be weighted were thought through deeply. It is important that they really reflect how good the concepts are so that the most suitable concept gets the highest points.

The criteria are based on the customer needs, but the first one needed to be rewritten to fit the rating system, so a high grade corresponds to fulfilling the criteria. The weights were then based on the relative importance of the customer needs. The grade and the weight of the criteria were multiplied to get the weighted score. The reference for the concept scoring ratings were Fresenius 5008S and the reference got the grade 3 at all criteria. The grades for the concepts were then set according to the rating method, see table 3-2. The scores are presented in table 8-3 below.

Table 8-3. Concept scoring

		Concept							
		F		G		I		J	
Selection Criteria	Weight	Rating	Weighted score	Rating	Weighted score	Rating	Weighted score	Rating	Weighted score
Low sensitivity to different chambers	0.125	3	0.375	3	0.375	2	0.25	3	0.375
Apply chamber with one hand	0.083	3	0.249	3	0.249	3	0.249	3	0.249
Remove chamber with one hand	0.083	3	0.249	3	0.249	3	0.249	3	0.249
Fits both left and right handed	0.083	2	0.166	3	0.249	3	0.249	2	0.166
Easy and quick to apply chamber	0.125	3	0.375	3	0.375	3	0.375	3	0.375
Easy and quick to remove chamber	0.125	3	0.375	3	0.375	3	0.375	3	0.375
Does not cause injuries	0.125	3	0.375	4	0.5	4	0.5	3	0.375
No leakage into the machine	0.125	3	0.375	4	0.5	4	0.5	3	0.375
No areas that are difficult to access	0.125	3	0.375	4	0.5	5	0.625	3	0.375

Total Score	0.999	2.914	3.372	3.372	2.914
Rank		2	1	1	2

Below follows motivations of why the different concepts got the ratings presented in table 8-3.

Low sensitivity to different chambers: Concept F, G and J received a rating of 3 since they should be compatible with approximately the same sizes of chambers as the Fresenius 5008S. Concept I on the other hand got the rating of 2 because it only flexes in one place, which could result in high stresses if a large chamber was applied.

Apply chamber with one hand: All concepts received a rating of 3 because a chamber could be applied with one hand as easy as in the Fresenius 5008S ALD.

Remove chamber with one hand: All concepts received a rating of 3 because a chamber could be applied with one hand as easy as in the Fresenius 5008S ALD.

Fits both left and right handed: Concept G and I received a rating of 3 because they have a symmetric shape which concept F and J do not have. That is the reason why concept F and J received the rating 2.

Easy and quick to apply chamber: All the concepts received a rating of 3 due to that a chamber could be applied as easy as in the Fresenius 5008S ALD.

Easy and quick to remove chamber: All concepts received a rating of 3 due to that a chamber could be removed as easy as in the Fresenius 5008S ALD.

Does not cause injuries: Concept G and I received a rating of 4 because they are made of one single part, which means that you cannot squeeze your fingers between any parts. Concept F and J on the other hand are made of multiple parts and has the same risk for injuries as Fresenius 5008S. They were thereby given the rating 3.

No leakage into the machine: Concept G and I received a rating of 4 since they were made of one single part, which means that there are no gaps between parts where leakage could occur. Concept F and J on the other hand were made of multiple parts which makes the risk of leakage greater than in concept G and I. The risk was considered to be the same as for the Fresenius 5008S ALD so they received the rating of 3.

No areas that are difficult to access: Concept I received a rating of 5 due to a non-complex design which makes it very easy to clean. Concept G received a rating of 4 because it has enclosed areas that could be difficult to access. Concept F and J received a rating of 3 due to that they are made of multiple parts which makes the areas between the parts hard to access.

8.3 Reflection

This concept selection method helped to choose the concepts by getting values of how good the different concepts are. It is really good to have to motivate why a certain concept is chosen. The hard part was to set up the matrices so the rating of a concept really reflected how good it was. The matrices had to be changed more than once during the process to fulfill that.

To get more accurate values some more parameters need to be added to the matrix. Two concepts got exactly the same rating which indicates that something is left out or the grading system is not exact enough. Both of these concepts were considered worth to further develop so that they had the same rating was not considered a big problem.

9 Concept development

Two concepts were selected to move forward to concept development, concept G and I. To develop them further, the material needed to be chosen. This was done by some simple hand calculations, FEM-analyses with different materials and a discussion with Gambro's plastic expert. A POM-type plastic called "POLYform C M20" was selected to be the material best suited for the concepts, since it had the lowest stress levels and best stress distribution. The next step was to improve concept G and I to find designs with the lowest possible stresses. This was done using the iterative process described in chapter 3.1.6. Finally the concept versions G-5 and I-6 were compared, as seen in figure 9-9 and 9-16, to determine which design to continue with. Concept G-5 had lower stresses, was easier to clean and did not stick out as much from the machine as concept I-6. Concept G-5 was therefore chosen to move on to concept testing.

9.1 Material

Which material a concept will use is critical for how the geometry of the concept will be designed. Therefore the material was chosen before setting the final design of the concepts. Several materials were considered and are presented below. Advice about plastic materials was taken from Lars Thornblad [20], development engineer at Gambro.

9.1.1 POM

POM (polyoxymethylene) is an engineering plastic. Due to difficulties with its production, there are only a few manufactures that sell POM. Some general properties are presented in table 9-1. Today POM is used in a variety of applications. Examples of these are ski bindings, chain links, cog wheels and snap locks. All this according to the textbook *Värt att veta om plast* [21, p. 21].

The biggest reasons why POM is considered for the ALD is that it has very good spring and fatigue properties which is very important in the new designs. It also has good resistance to chemicals. The current ALD is made from a POM copolymer and it has proven to function very well. It needs to be determined whether a homo- or a copolymer is best suited for the design. The differences of these are shown in table 9-6. In table 9-2 through 9-5 a variety of material candidates are presented. These materials were chosen for their low elastic- and flexural modulus. The lower these two are the smaller the stresses will be. This is later proven in chapter 9.1.4.

Table 9-1. General properties for POM, [21, p. 21]

Properties of POM	
+	The stiffest non-reinforced engineering plastics
+	The mechanical properties are not significantly affected in the temperature range from -40°C to +80°C
+	High toughness without additives
+	High fatigue resistance
+	Good creep resistance
+	Good spring properties
+	Does not absorb fluid
+	Good resistance to solvents
+	Excellent friction and wear properties
-	Maximum continuous use temperature is 80°C
-	Sensitive to sharp corners

Table 9-2. Mechanical properties for Hostaform 9021 C, Copolymer, [9]

Hostaform 9021 C	
Tensile Modulus	2850 MPa
Yield Stress	64 MPa
Yield Strain	9%
Poisson ratio	0.35
Density	1410 kg/m^3

Table 9-3. Mechanical properties for RTP 800 DEL, Homopolymer, [22]

RTP 800 DEL	
Tensile Modulus	2410 MPa
Flexural Modulus	2690 MPa
Yield Stress	62.7 MPa
Flexural Strength	89.6 MPa
Yield Strain	>10%
Poisson ratio	0.35*
Density	1410 kg/m^3

Table 9-4. Mechanical properties for POLYform C M20, Copolymer, [23]

POLYform C M20	
Tensile Modulus	2400 MPa
Flexural Modulus	2100 MPa
Tensile Stress	60 MPa
Flexural Strength	87 MPa
Yield Strain	14%
Poisson ratio	0.35*
Density	1410 kg/m^3

Table 9-5. Mechanical properties for EDGETEK 5230 Natural 1, Copolymer, [24]

EDGETEK 5230 Natural 1	
Tensile Modulus	2340 MPa
Flexural Modulus	2340 MPa
Yield Strength	64.1 MPa
Flexural Strength	91 MPa
Tensile Elongation (Break)	40%
Poisson ratio	0.35
Density	1410 kg/m^3

Table 9-6. Differences between Homo and Copolymer, [25, p. 131]

Homopolymer	Copolymer
Higher tensile strength	Higher creep strength
Higher tensile Modulus	Thermal stability
Harder	Lower water absorption
Better fatigue strength	Withstands hot water and alkali better
Higher heat distortion temperature	Easier to injection mold which leads to shorter cycle times
Maximum of 85 °C operating temperature	Maximum of 100 °C operating temperature
Lower friction	

In figure 9-1 below a fatigue curve is presented. The ALD should withstand approximately 20,000 cycles of loading and unloading. As seen in the fatigue curve the maximum stress with 20,000 cycles are about 40 MPa. A little margin was added to that so the maximum stress allowed was set to 35 MPa. This is the limit used later in the development and testing process.

In figure 9-2 a stress-strain curve is presented. It shows a typical hyperelastic behavior. But when the stress is between -35 and +35 MPa it is very close to linear. This means that a linear material model could be used as a good approximation in FE-simulations in this case.

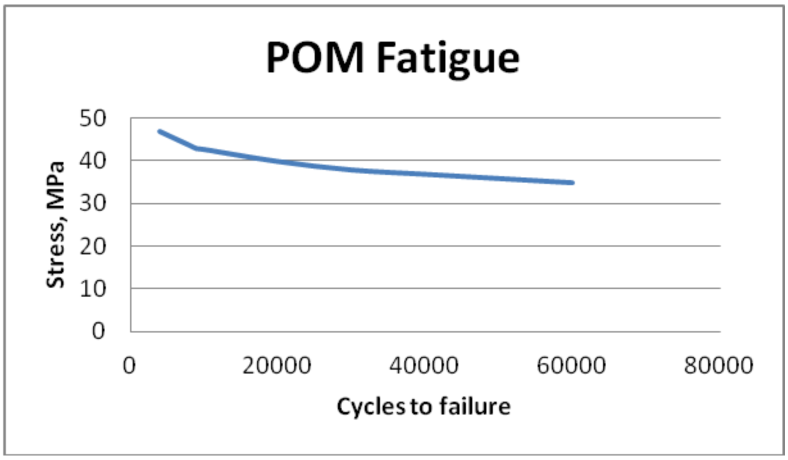


Figure 9-1. Flexural fatigue curve of POM, [10]

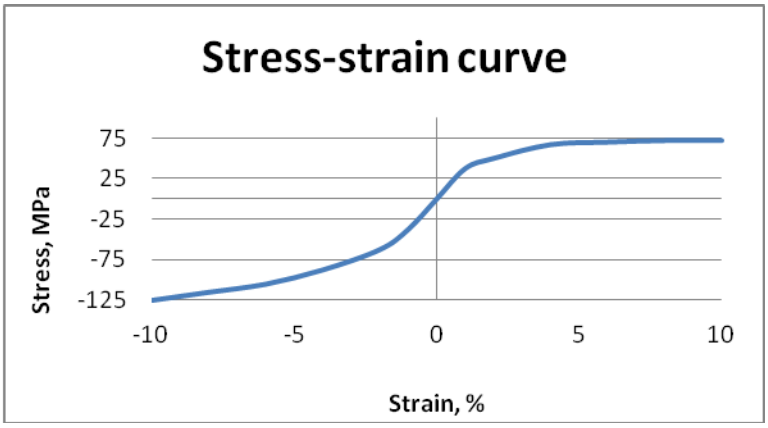


Figure 9-2. Stress-strain curve of POM, [10]

9.1.2 PC/ABS

PC/ABS is as the name refers to a mixture of polycarbonate (PC) and acrylonitrile butadiene styrene (ABS). Normally the mixture contains 10-50% ABS. PC is a relative expensive plastic but mixed with the cheaper ABS the material becomes cheaper but still holds the positive properties from PC and ABS. Today PC/ABS is used in a variety of applications. Examples of these are automotive components such as instrument panels, housings and lamp housings. All this according to the handbook *PLAST HANDBOKEN – en materialguide för industrin* [25].

The ALD on Fresenius 5008S is made out of PC/ABS, suggesting that this material also would function with Gambro's new design. The general properties of PC/ABS are presented in table 9-7 below. One example of a PC/ABS plastic is then presented in table 9-8. This example was chosen because its properties seemed to fit best for the application. As seen in the table the tensile modulus and yield strength is about the same as for the POM materials. The big difference is the yield strain which is much lower than for POM. This indicates that POM would be a better choice, since it is more ductile. As seen in table 9-7, PC/ABS can be attacked by different chemicals which POM shows better resistance to.

Table 9-7. General properties for PC/ABS, [25, pp. 127-130], [26]

Properties of PC/ABS	
+	High stiffness
+	High tensile and flexural strength
+	Very impact resistant
+	Resistant to weak acids, aliphatic hydrocarbons, paraffin, alcohols (except methanol), oils and fats.
-	Limited scratch resistance
-	PC / ABS is attacked by oxidizing acids, bases, ammonia, methanol, aromatic and chlorinated hydrocarbons.

Table 9-8. Mechanical properties for Bayblend FR3050, [27]

PC/ABS	
Tensile Modulus	2400 MPa
Yield Stress	60 MPa
Yield Strain	5%
Poisson ratio	0.38
Density	1190 kg/m^3

9.1.3 Steel wire

Steel wire would be a good choice if the plastic materials were shown to be too weak. Steel has very good spring- and fatigue properties. There is no doubt that the ALD could be designed to withstand the stresses if it was made of steel wire. The greatest disadvantage with steel is that it would be much more expensive than plastic. Since about 15,000 pieces a year will be made an injection molded component would be the cheapest alternative. Bending of wire is much more expensive in high volumes. With steel wire the holder had to be made from at least two parts, one plastic housing and one steel holder part.

Due to the named disadvantages, steel wire is the third alternative if not any of the plastics would work.

Table 9-9. Mechanical properties for Spring Steel ASTM A228,[28]

ASTM A228 (Spring steel)	
Modulus of Elasticity	210 GPa
Tensile Strength	2 GPa
Poisons Ratio	0.313
Density	7850 kg/m3

9.1.4 Determination of material

After a conversation with Lars Thornblad [20], POM was considered to be the material best suited for the designs. The reason for this is that POM has better spring properties, creep strength and fatigue resistance compared to PC/ABS. POM is also more ductile with high yield strain. A POM copolymer was also considered to be the best alternative due to high creep strength and thermal stability compared to a POM homopolymer, as seen in table 9-6.

The material should not be too stiff and also have a high tensile stress to fit the designs. As seen in figure 9-3, there is a linear relationship between the stresses and the tensile modulus, when the strain is constant. To reduce the stresses the material needs to have a low tensile modulus. The material also needs to have a high yield strain due to the large deformation.

“POLYform C 20M” was selected as the material best suited for the designs. It has approximately the same tensile modulus as “EDGETEK 5230 Natural” and lower flexural strength which makes it better suited. It was also easier to access material data for this material which makes it easier to use in the FE-simulations.

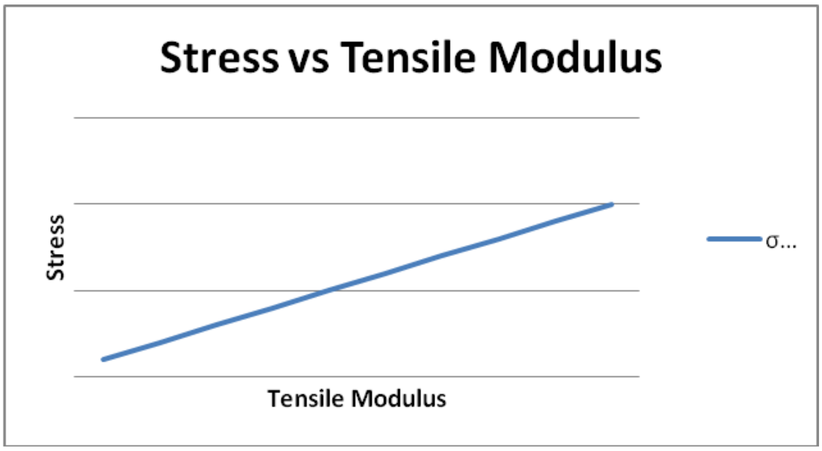


Figure 9-3. Relationship between the stress and the tensile modulus when the strain is constant.

9.1.5 Material thickness

Since a plastic material was chosen to be the number one choice for the ALD, the thickness of the material needs to be determined. The thickness is the most important parameter for the stresses, since the deflection of the holder is constant. To get low stresses a small thickness should be chosen, but there has to be some stresses in the material to get a good holding force from the holder. Some different thicknesses were tried in the simulations and 1.7 mm was decided to be a suitable thickness for the design. This will later be proven in chapter 10 where more advanced simulations are performed.

9.2 Concept G

There were two big challenges to get this concept to work properly. The first one was to make it as easy to clean as possible, and the second one was to find a design where the stresses weren’t too high when applying the chamber. The ALD has to work properly for about 20,000 cycles of applying and removing the chamber so it is important to consider fatigue of the material.

How easy it was to clean was determined just by estimation when looking at the geometry. A simple FEM-model was made in Abaqus/CAE to get an estimation of the stresses. More advanced models were made later in chapter 10. The workflow of the development process is described in chapter 3.1.6.

9.2.1 FEM-model

Since the geometry is symmetric in two directions only one fourth of the geometry was simulated, to get shorter calculation time. The model was meshed with tetrahedral elements, called “C3D10: A 10-node quadratic tetrahedron”. Just as the elements used in the analysis of the current design (see chapter 4.1.4.1) these elements are good at calculating the stresses at the integration points, but bad at extrapolation to the surfaces. Therefore all surfaces were covered with thin membrane elements, just as in earlier simulations. The membrane elements used are called “M3D3: A 3-node triangular membrane”. The membrane elements were made 0.001 mm thick i.e. they are so thin that they add a minimal stiffness to the model. It was meshed with a global mesh size of 1 mm. The mesh is presented in figure 9-4 and contained about 40,000 elements and 60,000 nodes. Of course the number of elements and nodes varied from the different design proposals.

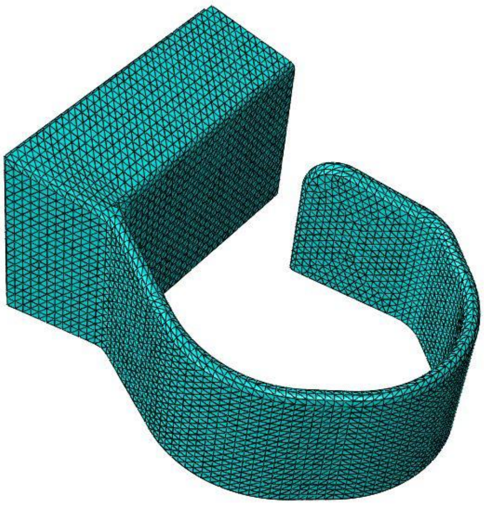


Figure 9-4. Mesh for concept G-4

A fixed boundary condition was applied to the back of the ALD were it will be screwed to the machine, see figure 9-5. Symmetry boundary conditions were applied, in the X and Y directions, on the cutting surfaces in these directions. A displacement, which corresponds to applying a chamber with 24 mm diameter, was then applied at a point on the wing marked in red in figure 9-6. The point was then connected to the surface on the holder, where the chamber will be in contact when it is applied, see figure 9-6. This was done with a distributing coupling constraint, which is described in more detail in chapter 4.1.4.5. The size of the displacement depended on how close together the two wings were on the current design. This was measured in the CAD-model before setting up the model. In this boundary condition the displacement in the Z-direction also were set to be zero, representing the chamber keeping the holder from moving in that direction. This is a big approximation which may have a great influence on the result. Whether this approximation was good or not will be determined in chapter 10 with more advanced simulations. The Abaqus/Standard solver was used to solve the problem since there is no contact in the model.

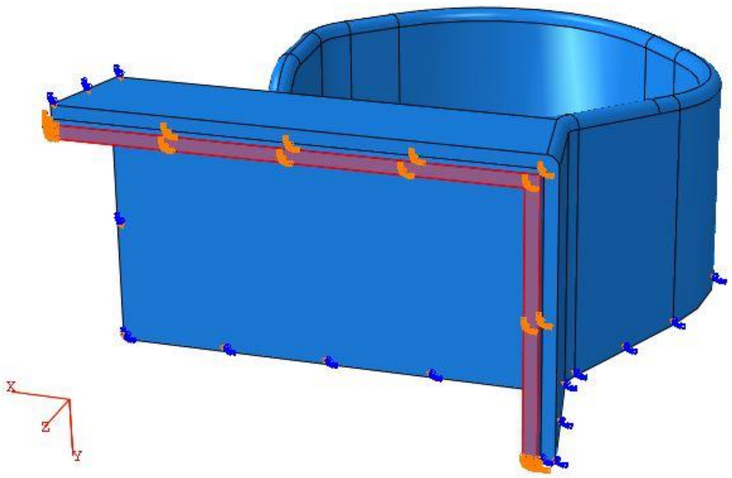


Figure 9-5. Fixed boundary condition

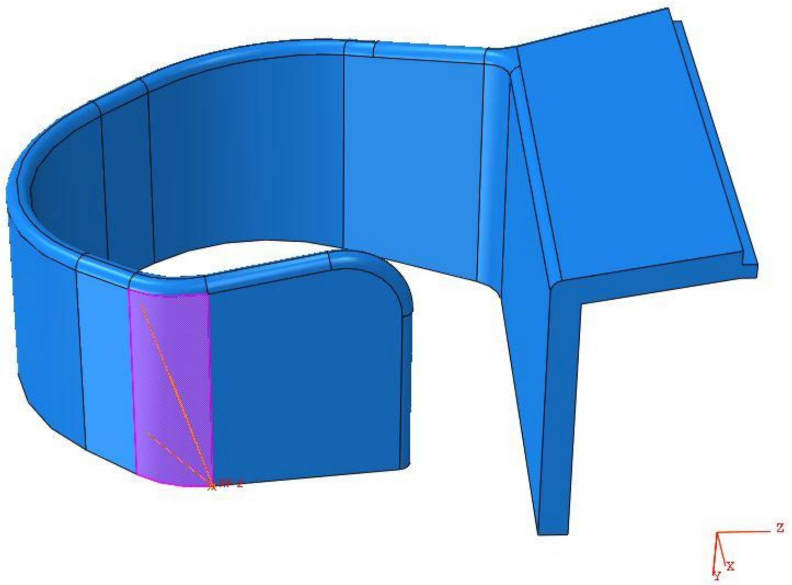


Figure 9-6. Distributed coupling constraint

9.2.2 Concept development

If possible the ALD should be made of plastic since that is the cheapest material. The FEM-model described earlier was used to evaluate and refine the design. The first version of the concept is G-1 in figure 9-7 below. This was then developed into a plastic and a steel wire version. The focus was then put into G-2 to find a plastic version that could withstand the deformation. As shown earlier in chapter 9.1.1 the stresses need to be lower than 35 MPa to not risk fatigue within the ALD’s lifetime. When simulating G-2 it showed stresses much higher than that, see figure 9-8. It needed to be redesigned to get a lower stress level.

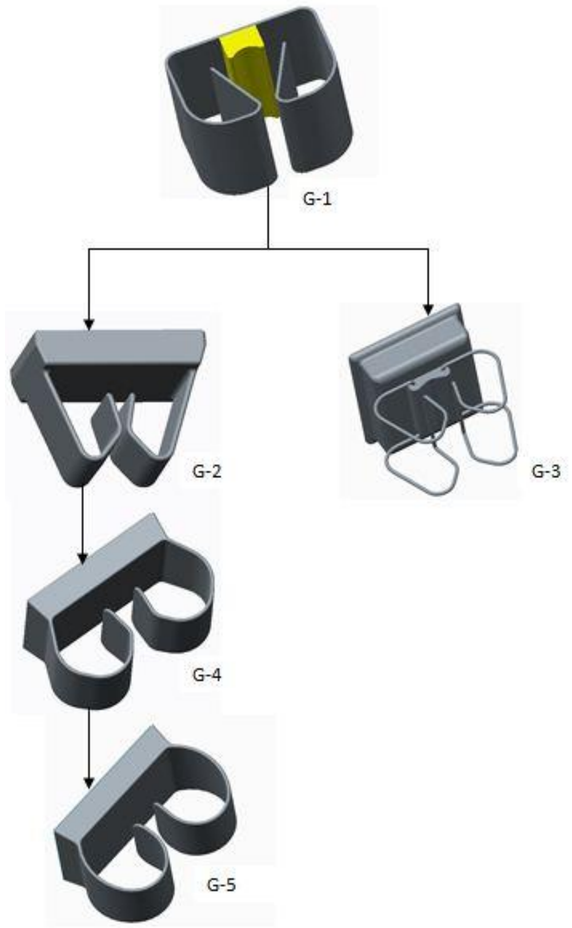


Figure 9-7. Concept development of concept G

To get a more smooth stress distribution the design was given a rounder form. A simulation of G-4 showed that this was a very good strategy, so the geometry was made even more round. This resulted in G-5 which shows a good distribution of the stresses, as seen in figure 9-9. The stresses are about 25 MPa which is well under the goal of 35 MPa. Concept G-5 is therefore the design that is taken forward in the process.

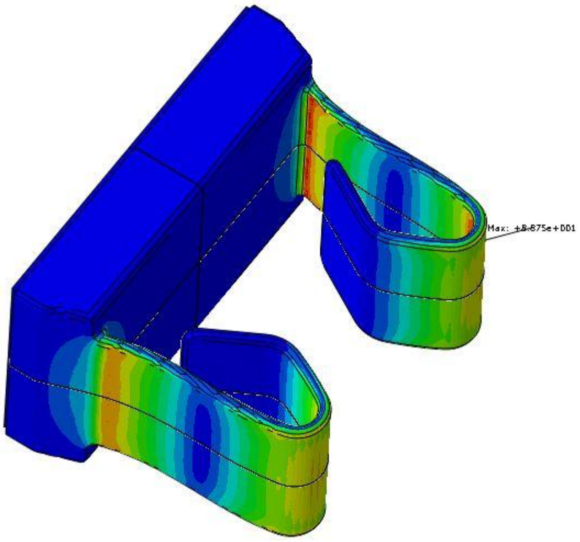


Figure 9-8. Concept G-2, stresses of 89 MPa

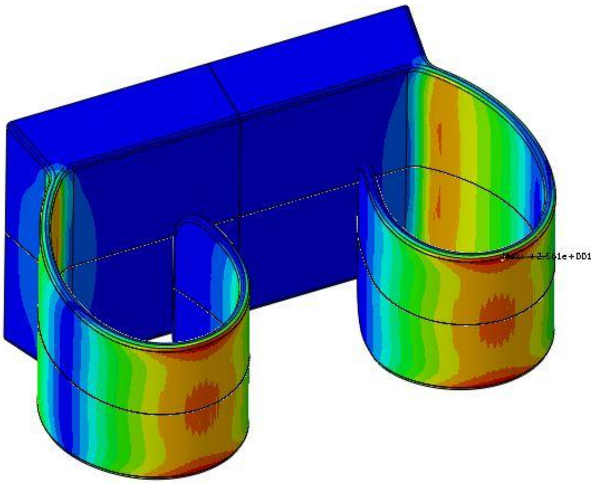


Figure 9-9. Concept G-5, stresses of 25 MPa

9.3 Concept I

The development of concept I faced the same challenges as concept G. The holder needed to be easy to clean and a geometry that could withstand the deformations needed to be found. The cheapest material to use would be plastic. Therefore a series of plastic geometries first was generated and simulated, to find a design with low stresses.

9.3.1 FEM-model

A similar model as for concept G was set up to get a first estimation of how high the stresses were and how they were distributed. The same boundary conditions and mesh type as earlier was used, se chapter 9.2.1. You can also see them in figure 9-10 through 9-12.

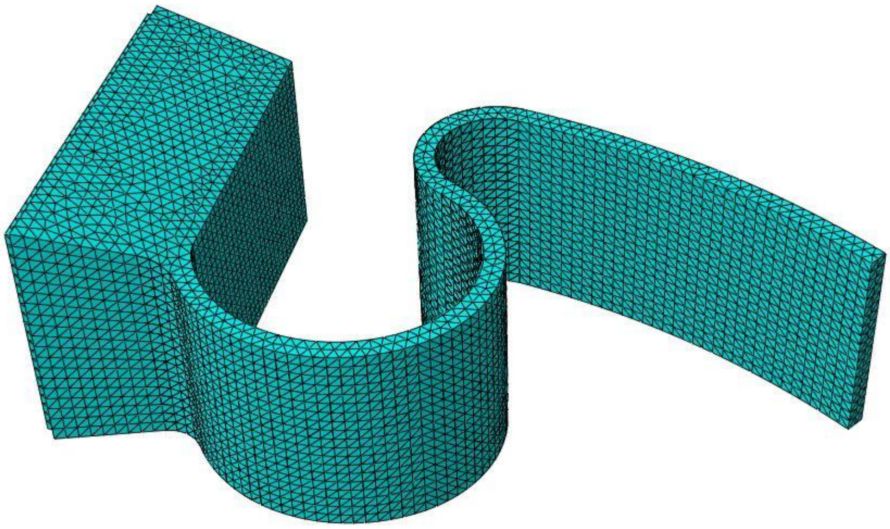


Figure 9-10. Mesh

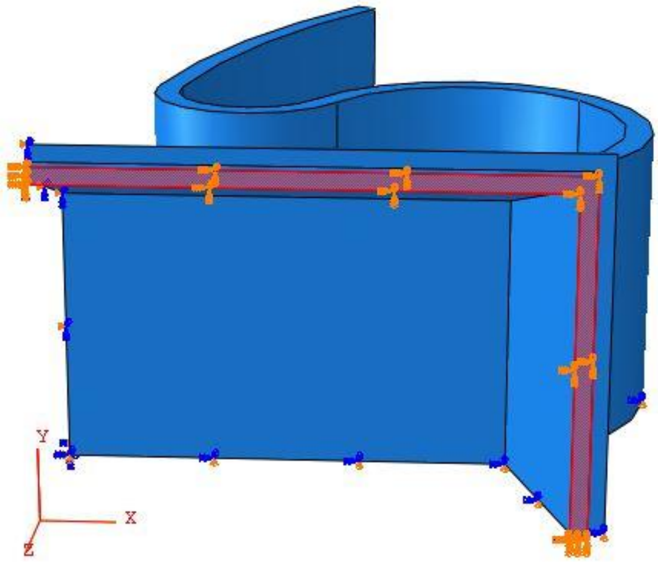


Figure 9-11. Fixed boundary condition

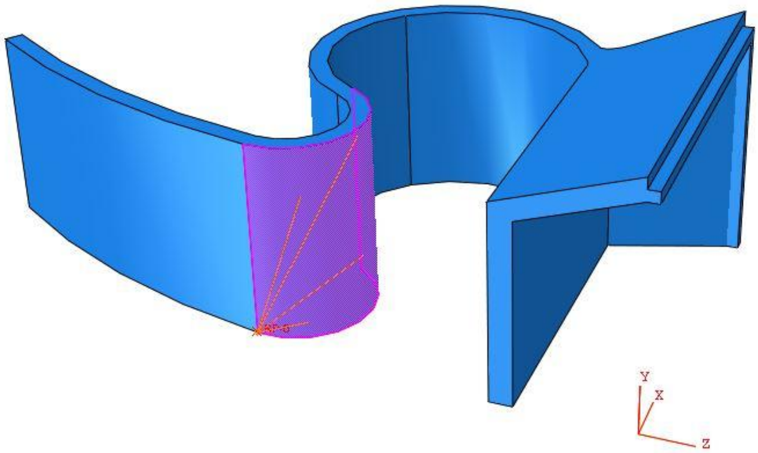


Figure 9-12. Distributed coupling constraint

9.3.2 Concept development

The original concept was developed into two different concepts, one with plastic material and one with steel wire. Since the plastic concept is much cheaper than the steel concept the effort was put into finding a plastic design that could withstand the deformations.

The FEM analysis of concept I-2 showed to high stresses and it needed to be redesign. Two different versions were created, concept I-4 and I-5. As described in 9.2.2, a rounded shape was the way to go to get a smooth stress distribution, and thereby reduce the stresses. This on the other hand made the design a bit larger than expected, so a smaller design, named I-4, was also generated. I-4 also showed to high stresses, as seen in figure 9-13. I-5 on the other hand, showed a reduction of the stress levels compared to the other designs, see figure 9-14. An even more rounded concept called I-6 was generated and showed stresses of 31 MPa, which meet the requirements of stresses lower than 35 MPa. This design was taken forward in the process.

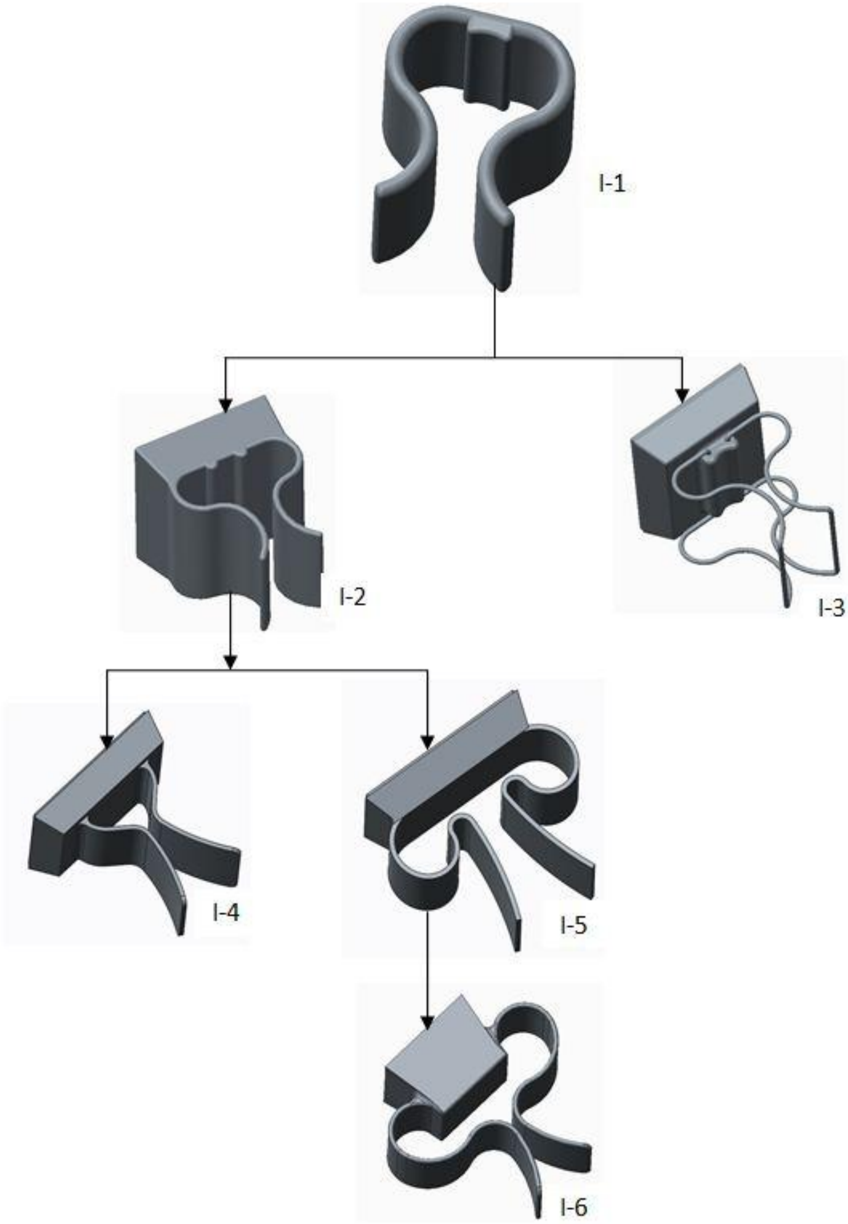


Figure 9-13. Concept development of concept I

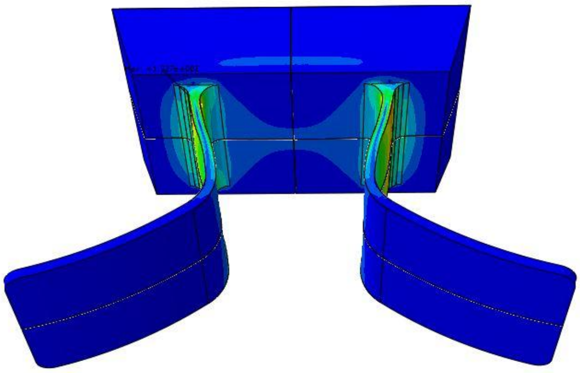


Figure 9-14. Concept I-4, stresses of 130 MPa due to the displacement

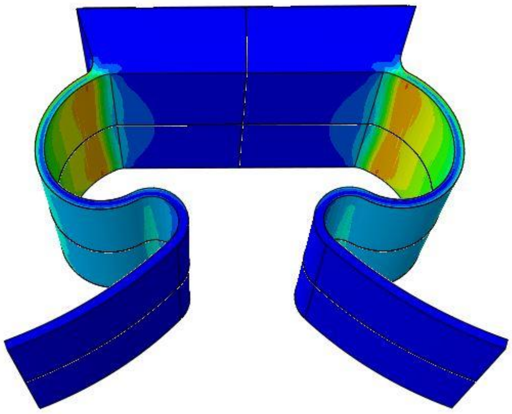


Figure 9-15. Concept I-5, stresses of 57 MPa due to the displacement

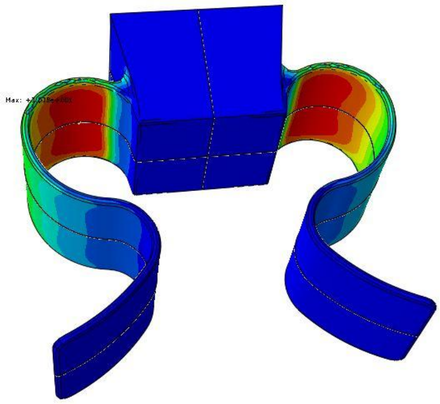


Figure 9-16. Concept I-6, stresses of 31 MPa due to the displacement

9.3.3 Concept selection

After the iterative development process two designs remained; G-5 and I-6. A plastic design was considered the most appropriate, due to it is lower costs than a steel wire design. To make the plastic design to function after the 18,720 cycles the stresses needs to be less than 40 MPa, but the goal is to get under 35 MPa. The result from the FEM analysis of G-5 and I-6 can be seen in figure 9-9 and 9-16. The stresses in concept I-6 were 31 MPa which is less than 35 MPa. On the other hand concept G-5 only shows stresses of 25 MPa, which indicates a longer lifetime for that concept.

The size of the concepts should also be considered. They have approximately the same width but concept I-6 is protruding longer from the machine. This is also a disadvantage for concept I-6 since that makes it easier for people to bump into it.

Concept G-5 would also be easier to clean. It could be hard to clean concept I-6 between the wings and the machine.

Due to the named arguments, concept G-5 was chosen to be the concept to take forward to the concept testing. After making the selection drawings were made of the concept, which are presented in appendix D.

9.4 Attachment to the machine

How the ALD should be attached to the machine was specified, since the same screw holes as before should be used. The interface on the machine is shown in figure 9-12. The big hole in the middle is intended for cables and the four small holes are for the screws.

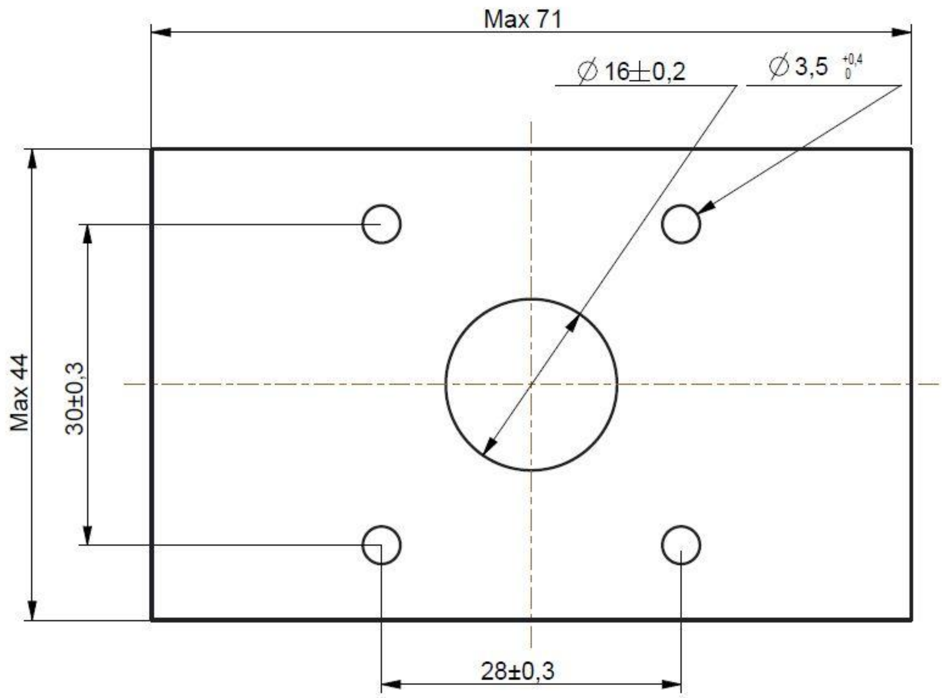


Figure 9-17. Dimensions of the attachment interface on the machine.

The risk of sink mark on goods accumulation needs to be reduced. To solve this are the ribs, and the screw towers dimensioned according to [21, pp. 138-141]. To reduce the risk of leakage into the machine an O-ring seals around the attachment. The final design to the attachment can be seen below in figure 9-18.

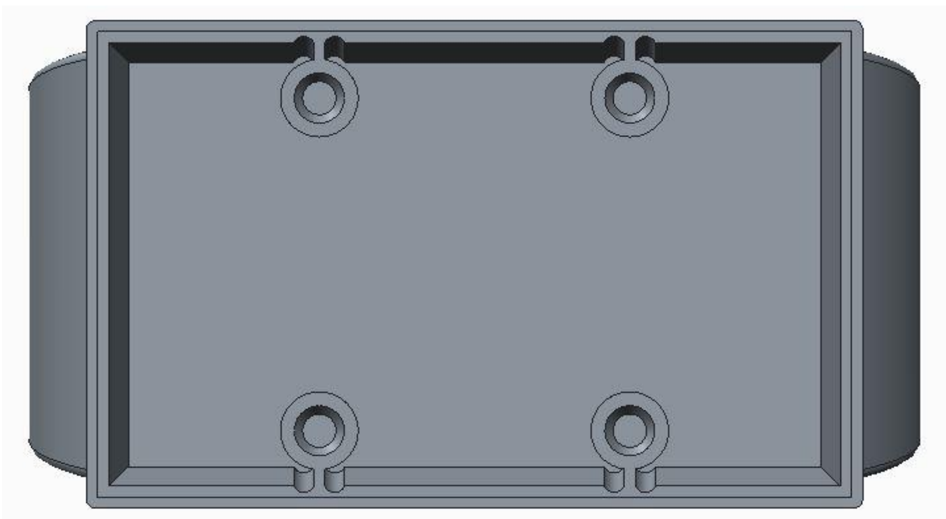


Figure 9-18. Backside of concept G-5.

9.5 Reflection

“POLYform C M20” was selected as the material most suitable for the designs. It can be discussed if more material needs to be tested. Given the time constraints, it was considered that the material investigation was thorough enough. “POLYform C M20” meets the requirements and will be used in the more advanced FEM analysis in the concept testing chapter.

Concept G and I was selected for further development after the concept scoring. After the iterative development process, described in chapter 3.1.6, two final designs were chosen, concept G-5 and I-6. As seen in figure 9-1 the stresses in the design need to be less than 35 MPa to withstand the specified 18,720 cycles, with a 5 MPa safety margin. The FEM analysis shows that a maximum stress of 31 MPa in concept I-6, but concept G-5 on the other hand only shows a maximum stress of 25 MPa which give the concept a good safety margin. This concept was therefore selected to move on to the concept testing.

The attachment was designed quite similar to the old design to make it work well with the machine. There is, however some small difference between the attachment of the new and old design. In the old design there were some sink marks caused by goods accumulations which is not desirable. To reduce the risk of sink mark was the new attachment dimensioned according to [21, pp. 138-141]. This will make the ALD’s appearance better.

10 Concept testing

Concept G-5 was selected to be further tested. Both virtual and practical tests were performed. The virtual tests were performed by FE simulations of different scenarios that occur when using the ALD. Practical tests were performed by testing the performance of the holder together with a sensor. The tests showed that the new concept should work in reality, but had some limitations that should be considered when setting the final properties of it. The most important one is the friction coefficient between the chamber and the ALD. It is important that it is not too high because the stresses depend a lot on it, but it cannot be too low either because the chamber needs to remain in the ALD after it is applied. The friction coefficient has to be measured to be sure of how big it is.

10.1 FE simulations

10.1.1 Purpose

The simulations were performed to get the answers to the following questions.

1. How high are the stresses when applying and removing the chamber in the holder?

2. How much force is needed to apply and remove the chamber?

3. How hard does the holder hold the chamber?

4. Could vibrations cause any problems for the ALD?

10.1.2 Cases

Three different models were made to find the answers to the questions above. One of them also needed to be made with four different types of chambers. The scenarios was the following

1. **Apply and remove the chamber**.

   This model should help getting the answer to the first two purpose questions. It was performed only with the large and hard chamber since that causes the most strain, and thereby the highest stresses.

2. **Apply and then lift the chamber.**

   This model should help getting the answer to the third purpose question. It was performed with four different chambers, since it was hard to estimate which chamber would get higher or lower holding force and both the highest and the lowest holding force were wanted.

3. **Vibration test.**

   Gambro’s own specifications say that the machine shall withstand random vibrations in a certain frequency interval. Vibrations were therefore simulated to find the eigen modes for the holder.

10.1.3 Chamber material

To be able to simulate a soft chamber, a good estimation of its stiffness was needed. It was received by doing a practical test, and then simulate the same test and trim the simulation to behave the same as the practical test. The practical test was to put the chamber on a table, then push on to it with a Newton meter and measure the force needed to achieve a certain deformation, see figure 10-1.

Figure 10-1. Test of the elastic modulus of the chamber.

The same test was then simulated with a simple Abaqus model. There were two parts in the model, the chamber and the table. The chamber was modelled by a pipe shell and the table by a rigid plate. The table was set to be fixed and the chamber was constrained to not move in the X- and Z-direction. A load corresponding to the measured force in the practical test was applied on the red area in figure 10-2. The red area corresponds to the circle form used on the Newton meter. The load was applied as a surface traction in negative Y-direction, which means that the force always follows that direction and does not change when the chamber deforms.

The result of the last iteration of this simulation is presented in figure 10-3. The tensile modulus used in this model was 200 MPa. This will be used to simulate a soft chamber in simulations later on.

To simulate a hard chamber a tensile modulus of 1500 MPa was used. This was just an estimated value which probably is much higher than all chambers on the market. A high value was taken to be on the safe side.

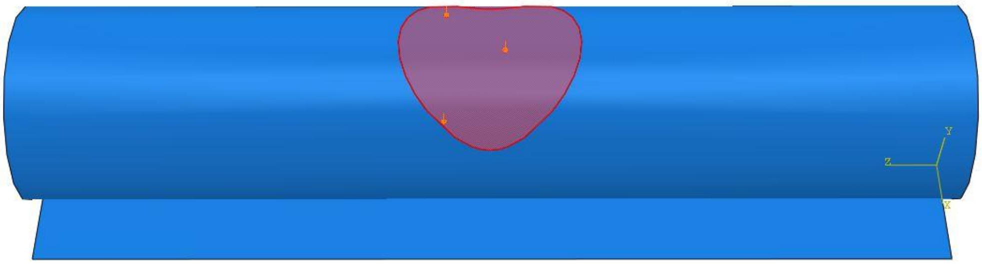


Figure 10-2. The chamber stiffness model.

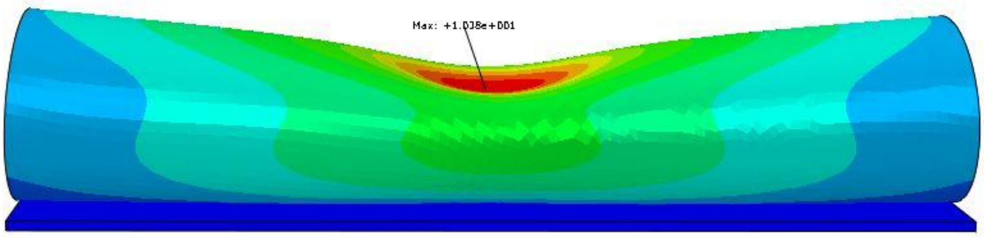


Figure 10-3. Simulated deformation of the chamber.

10.1.4 Holder material

The material chosen for the holder is a POM type plastic called “POLYform CM20”. It is described in more detail in chapter 9.1.1. This plastic has a typical hyperelastic behavior, as shown in the stress-strain curve in figure 9-2. But at the interval -35 to 35 MPa, which is the interval that the holder should be in, the stress-strain curve is very close to linear. Therefore a linear material model will be used in the simulations. Since the tensile and flexural modulus differs from each other (see table 9-4) the biggest of these will be used to be on the safe side. The Young’s modulus used for the simulations was therefore 2400 MPa.

10.1.5 Convergence analysis

A convergence analysis was performed to determine how fine the mesh needed to be in the simulations. The first model, which is presented in chapter 10.1.6, was solved with different meshes and the stresses were compared to determine the right mesh size.

Two of the mesh seizes are presented below. The first one, in figure 10-4, has a global mesh size of 0.9 mm and is the one used in the simulations later. The second one, in figure 10-5, has a global mesh size of 0.7 mm. When studying the results in figure 10-6 and 10-7 you see a nearly identical stress distribution. The maximum stresses in the models differ just with about 0.1 MPa, and that number must be considered small enough in this case. Therefore a global mesh size of 0.9 mm is fine enough.

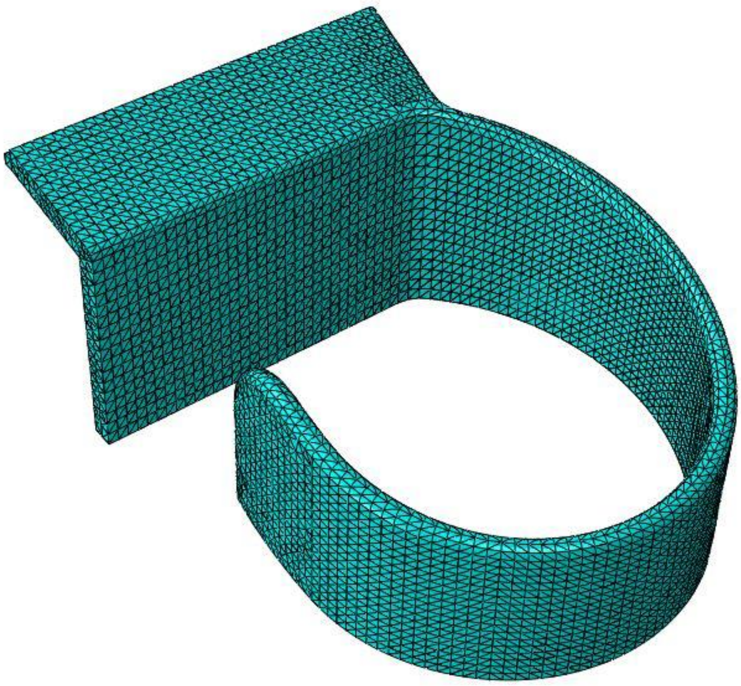


Figure 10-4. Global mesh size of 0.9 mm.

Figure 10-5. Global mesh size of 0.7 mm.

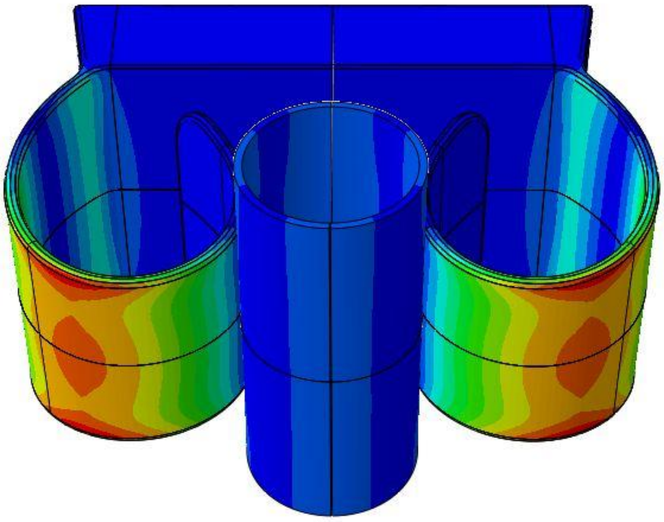


Figure 10-6. Results with global mesh size 0.9 mm.

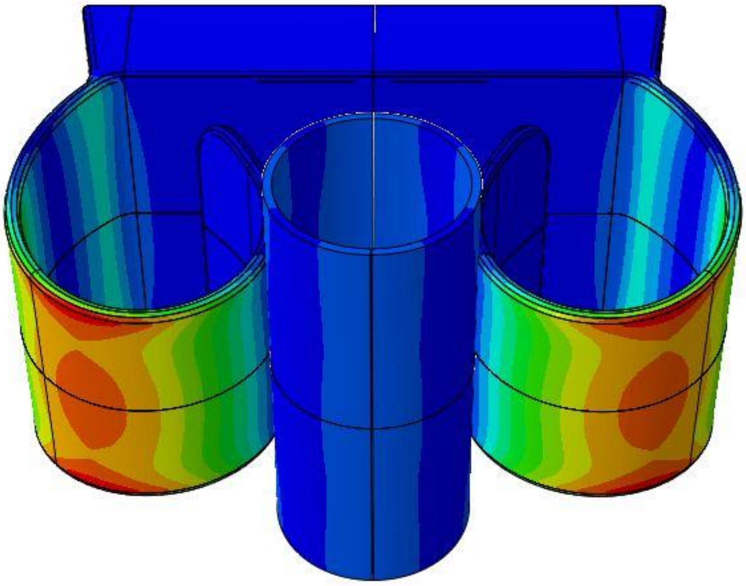


Figure 10-7. Results with global mesh size 0.7 mm.

10.1.6 Applying and removing the chamber

This problem is symmetric in two directions and therefore only one fourth of the model was simulated, and then mirrored, to get a short calculation time. It was modelled without screw towers since they have a very small impact on the stresses in the rest of the model. The model was set up in Abaqus/Explicit since there is a lot of contact between the chamber and the holder. Three steps were applied to the model. First the chamber was applied, then it was released to get equilibrium and then the chamber was removed from the holder. Different time settings were tried to find settings were the calculation time was as small as possible, without too much oscillations. The final ones were that the first and last step took 0.05 seconds and the release step took 0.01 seconds, i.e. the whole simulation reflected 0.11 seconds.

10.1.6.1 Mesh

The mesh for the holder was generated with the same elements as in chapter 4.1.4.1. Tetrahedral solid elements and thin membrane elements on the surfaces were used to get accurate stresses. Since the explicit solver was used, a lot of effort was put into getting elements with good shapes and thereby a low calculations time. A lot of partitions and virtual topologies were used to get cells and surfaces that could be meshed in a good way. The holder was meshed with a global mesh size of 0.9 mm, which made the shortest element length about 0.3 mm. Why this particular mesh was used is described earlier in chapter 10.1.5. The used mesh is presented in figure 10-4.

The chamber was modelled as a shell with the thickness 1 mm. It was meshed with shell elements of the type called “S4R: A 4-node doubly curved thin or thick shell, reduced integration, hourglass control, finite membrane strains”. The surface of the chamber was divided into several areas to be able to apply the boundary conditions later. The partitions were made so the areas fitted a global mesh size of 0.9 mm, see figure 10-8 and 10-9.

The size of the problem was approximately 63,000 elements and 128,000 nodes.

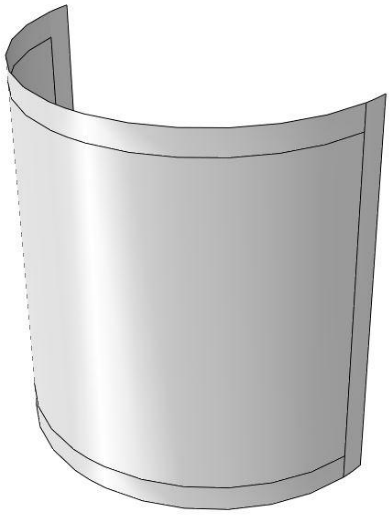


Figure 10-8. Partitions of the chamber

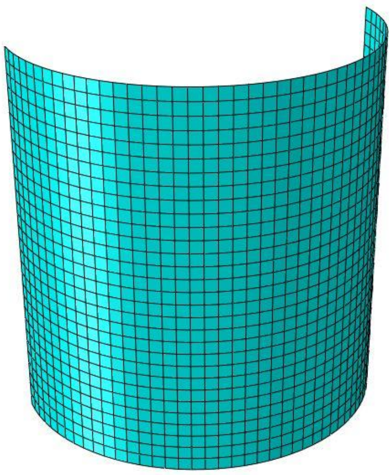


Figure 10-9. Mesh for the chamber

10.1.6.2 Boundary conditions

The back side of the housing was set to be fixed since it later will be screwed to the machine, see figure 10-10. The model has symmetry in two directions so symmetry boundary conditions were applied in the X- and Y-directions, see figures 10-11 and 10-12.

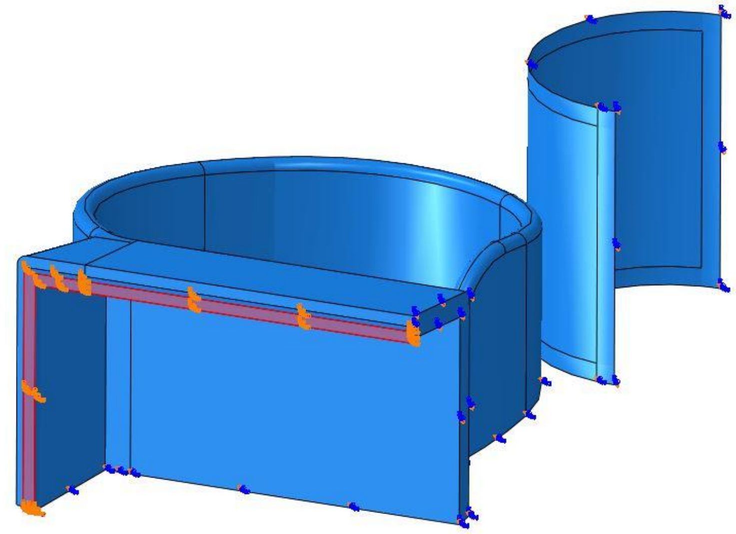


Figure 10-10. Fixed boundary condition

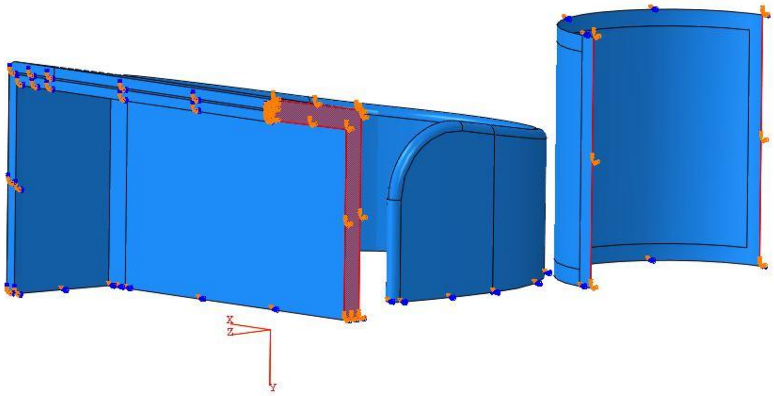


Figure 10-11. Symmetry boundary condition in the X-direction.

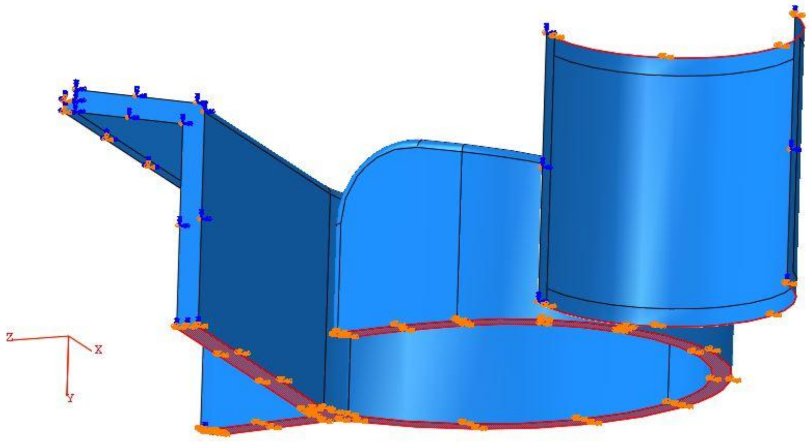


Figure 10-12. Symmetry boundary condition in the Y-direction.

The chamber was applied in the first step with a displacement boundary condition. The displacement was applied to a point connected to the middle surface of the chamber, with a distributing coupling constraint, see figure 10-13. This type of constraint was described in more detail earlier in chapter 4.1.4.5. The displacement boundary condition is presented in figure 10-14, where it was applied to the point named RP-2 to the right in the figure. The size of the displacement was 31 mm in the positive Z-direction.

The second step was a release step to get equilibrium. In this step the fixed and all the symmetry boundary conditions were the same and the chamber were set free in the Z-direction.

In the third and last step another displacement was applied, now in the negative Z direction, to remove the chamber from the holder. The size of the displacement was 35 mm to be sure the chamber went all the way out. All other boundary conditions were kept the same in this step.

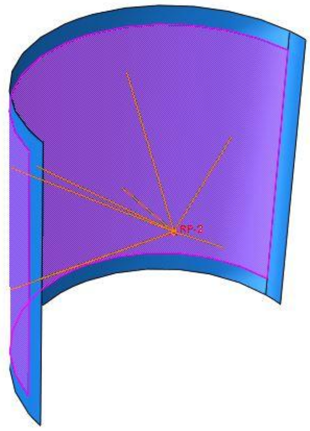


Figure 10-13. Distributed coupling constraint.

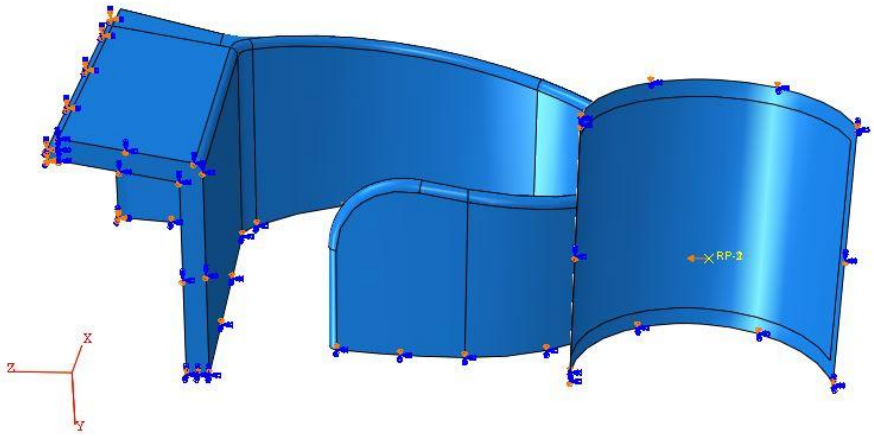


Figure 10-14. Displacement to apply the chamber.

10.1.6.3 Contact

The contact in the model was modelled with general contact, where three contact pairs were defined, see figure 10-15. The chamber had contact with the wing and the back of the holder, and the wing also had contact with the back of the holder. Since no surfaces are sharp in this model, the normal behavior of the contact could be modelled as “Hard”.

The tangential behavior was modelled with the penalty method and friction was applied. The size of the friction coefficient turned out to have a big influence to the stresses, and it is very uncertain how big it is going to be. Therefore, different friction coefficients were tested to examine its influence on the stresses. These coefficients were 0.1, 0.2 and 0.3. These numbers were chosen because the friction coefficients should be somewhere between them. The simulation was very time consuming so there was not time to test more coefficients.

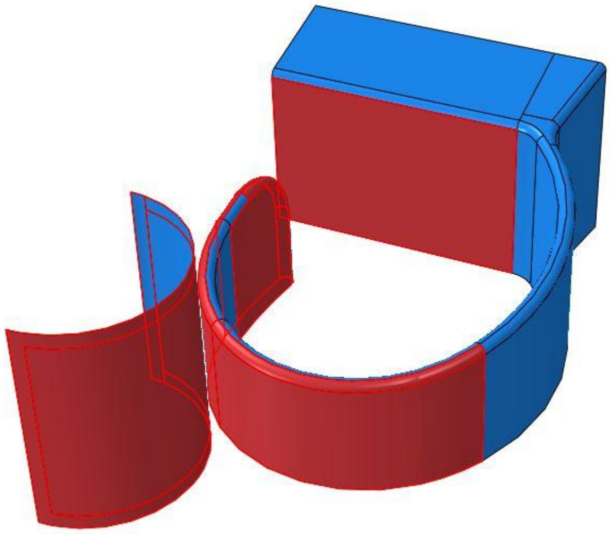


Figure 10-15. General contact definition.

10.1.6.4 Results

As taken up before, this model was made with different friction coefficients to determine the influence of it. The results from these are presented below.

10.1.6.4.1 Friction coefficient of 0.1

When the friction coefficient is 0.1 the stresses are about 29 MPa when applying the chamber and 27 MPa when removing the chamber. Result figures are presented in figure 10-16 through 10-18 below. These stresses are well under the goal of 35 MPa.

The holder shows an uneven stresses distribution, where the wings go over to the housing, when removing the chamber, see figure 10-18. This problem is discussed earlier, in chapter 4.1.5, and is due to too coarse mesh. The uneven distribution is not where the stresses are highest and therefore it wasn't considered as a big problem. It was not worth the time to rerun the simulation with a finer mesh.

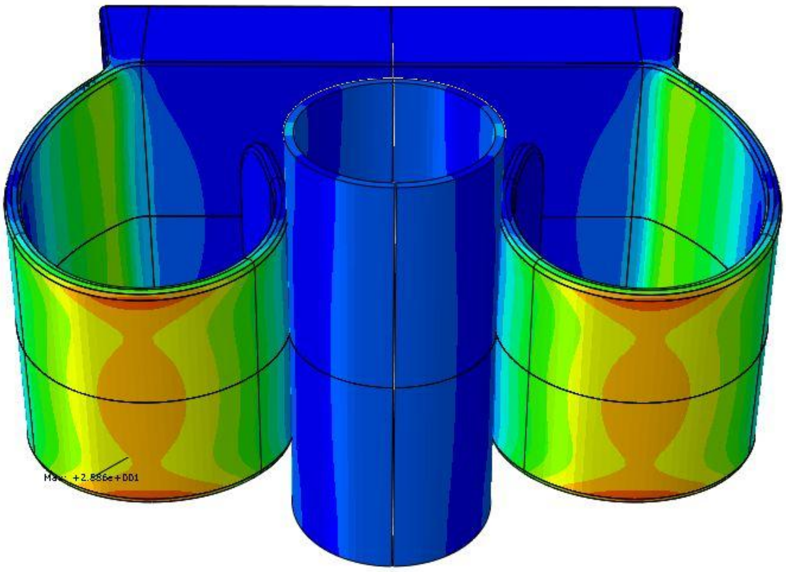


Figure 10-16. Stress distribution with a friction coefficient of 0.1, when the chamber is applied, seen from the front.

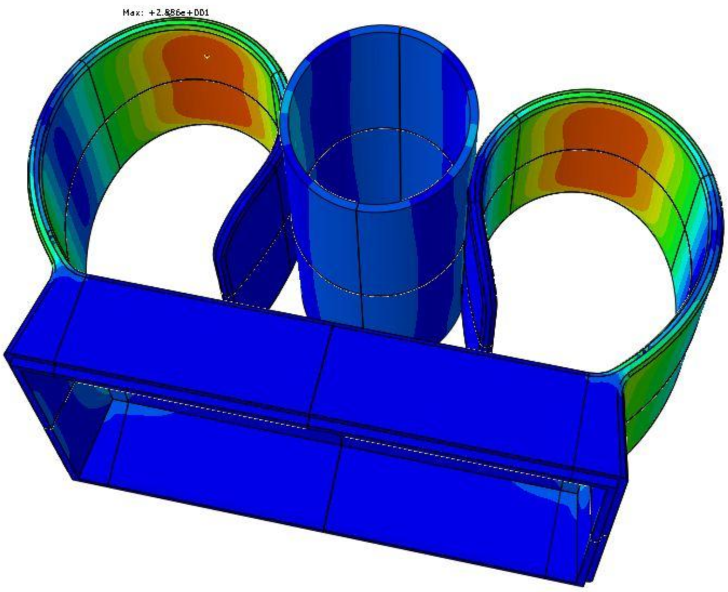


Figure 10-17. Stress distribution with a friction coefficient of 0.1, when the chamber is applied, seen from the back.

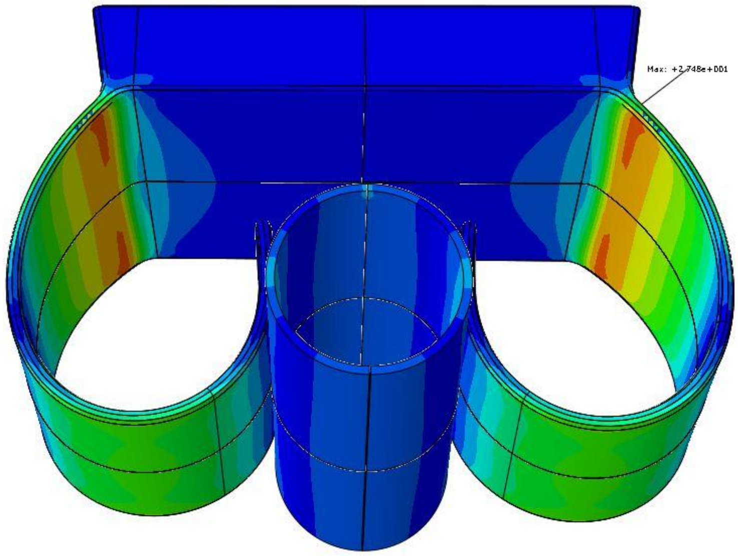


Figure 10-18. Stress distribution with a friction coefficient of 0.1, when the chamber is removed.

10.1.6.4.2 Friction coefficient of 0.2

As seen in figure 10-19 through 10-21, the highest stresses when the friction coefficient is 0.2 is about 33 MPa. That is under the goal of 35 MPa.

The wings are close to touch the back of the holder when the chamber is applied. With a little higher friction they probably do touch the back, which could be a problem.

When the chamber is removed the stresses are about 29 MPa which also fulfills the goal.

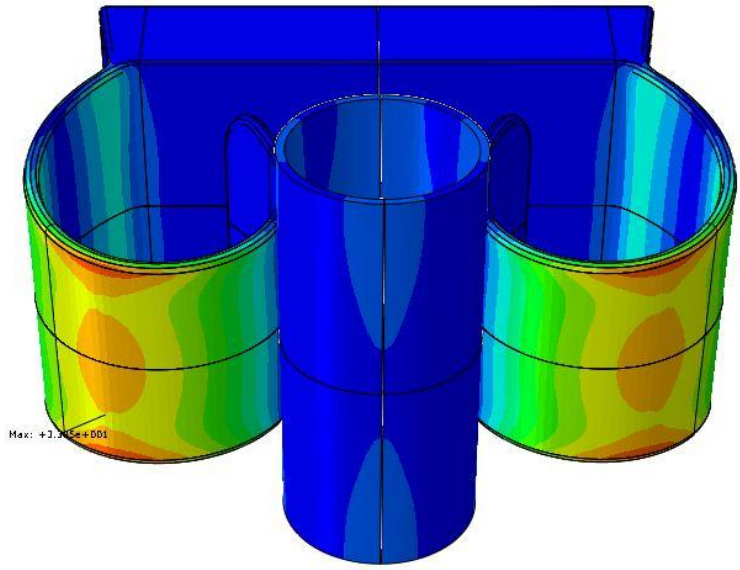


Figure 10-19. Stress distribution with a friction coefficient of 0.2, when the chamber is applied, seen from the front.

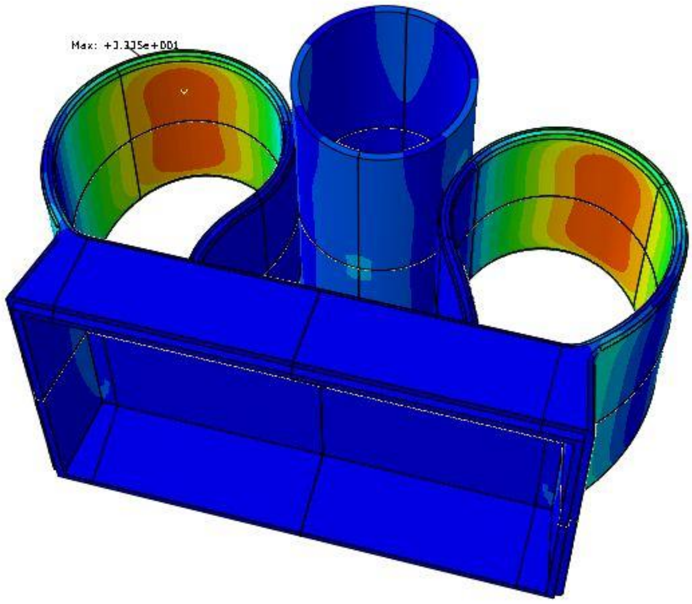


Figure 10-20. Stress distribution with a friction coefficient of 0.2, when the chamber is applied, seen from the back.

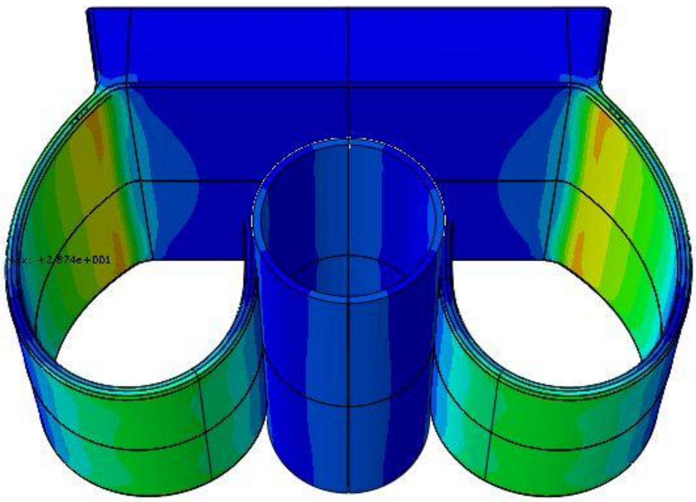


Figure 10-21. Stress distribution with a friction coefficient of 0.2, when the chamber is removed.

10.1.6.4.3 Friction coefficient of 0.3

When the friction coefficient was set to 0.3, the highest stresses in the holder were about 39 MPa, when applying the chamber, as seen in figure 10-22 and 10-23. That is a little bit over the goal of 35 MPa but under 40 MPa which is the fatigue limit. This means that the friction coefficient needs to be lower than 0.3 to fulfill the goal.

In this simulation the wings just touches the back side of the housing when the chamber is applied. If this would happen in reality it could cause abrasion on the back of the holder, which not is desirable. It should be avoided if possible.

The stresses when removing the chamber has not increased that much from the previous model, as seen in figure 10-24. It is about 30 MPa.

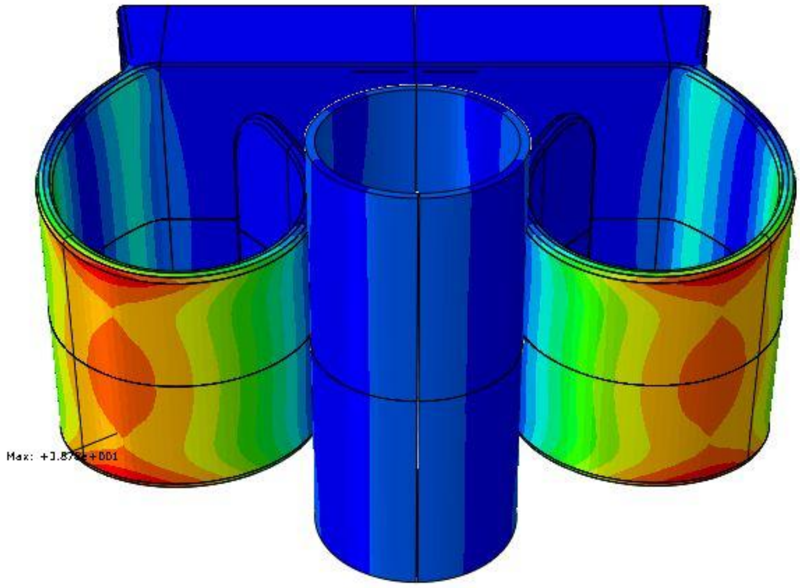


Figure 10-22. Stress distribution with a friction coefficient of 0.3, when the chamber is applied, seen from the front.

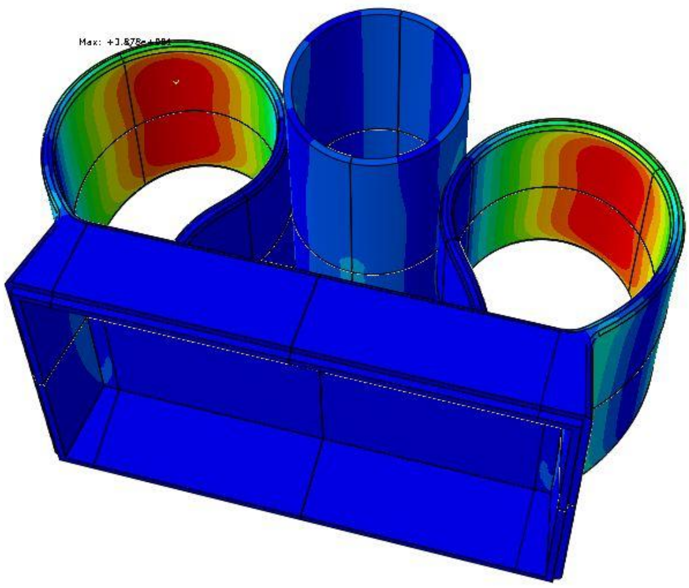


Figure 10-23. Stress distribution with a friction coefficient of 0.3, when the chamber is applied, seen from the back.

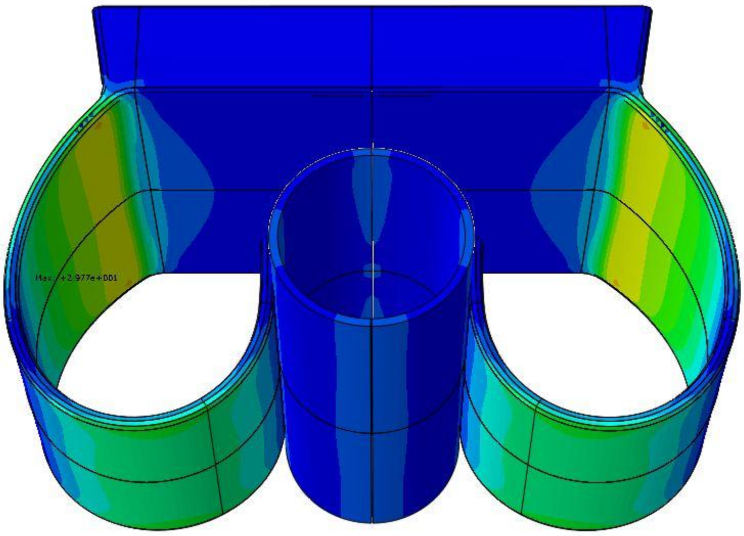


Figure 10-24. Stress distribution with a friction coefficient of 0.3, when the chamber is removed.

10.1.6.5 Conclusion

The stresses when applying and removing the chamber depends a lot on the friction coefficient. As seen in figure 10-25 the stresses increase with the friction coefficient. To keep the stresses below the goal value of 35 MPa the friction coefficient can be maximum something between 0.2 and 0.3. But the friction cannot be too low since the chamber needs to be held in the ALD after it is applied. Some practical tests needs to be performed to determine what surface the ALD should have to get the right friction properties.

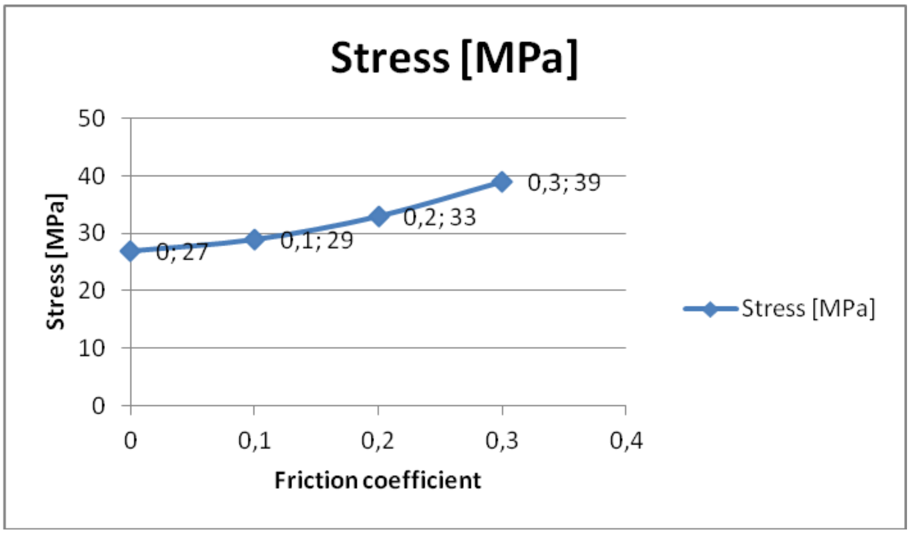


Figure 10-25. Relation between the stress and the friction coefficient.

The force needed to apply the chamber in the ALD also depends on the friction coefficient. As seen in figure 10-26 it also increases with the friction coefficient as soon as the friction gets over 0.1. Since the stresses increases, the force must increase to. With the highest friction coefficient simulated the force to apply the chamber was only 10 N, which is considered to be very low compared to the current design. There should be a very low risk for injuries to the nurses with this level of applying force.

The force needed to remove the chamber does not show the same relation to the friction coefficient, as seen in figure 10-27. Since the stresses did not increase that much with the increased friction this was the expected result.

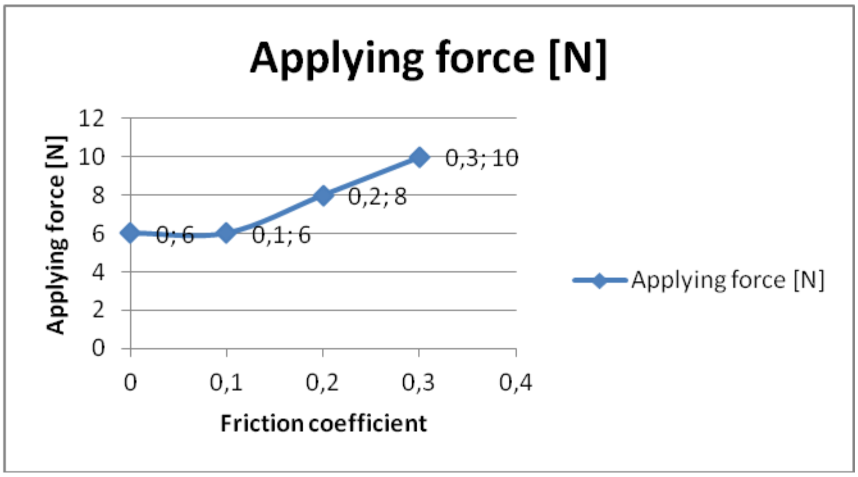


Figure 10-26. Relation between the force needed to apply the chamber and the friction coefficient.

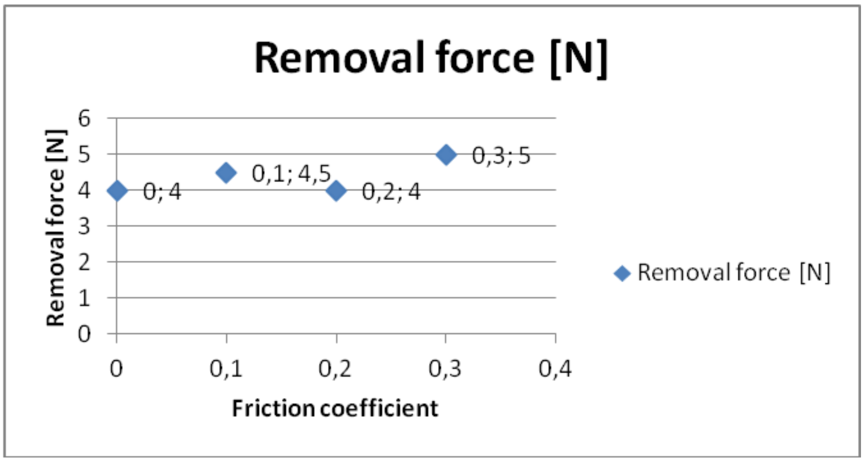


Figure 10-27. Relation between the force needed to remove the chamber and the friction coefficient.

10.1.7 Apply and lift the chamber

This problem is only symmetric in one direction so one half of the holder was modelled. Since it is very similar to the previous model, it was also set up in Abaqus/Explicit. The two first steps were the same as for the previous model so they used the same time settings. The third step was changed to a lifting step, where the chamber was lifted 2 mm in the Y-direction. The reaction force in the chamber was then studied to get the holding force. The time settings for this step were set to 0.01 seconds so the whole simulation reflected 0.07 seconds.

10.1.7.1 Mesh

The mesh was set up exactly like the previous model. The only difference was that the holder was mirrored in the XZ-plane, making the mesh twice as big, and the chamber was made twice as long in the Y-direction. The mesh is presented in figure 10-28 below. The size of the problem was approximately 123,000 elements and 246,000 nodes.

Figure 10-28. Mesh

10.1.7.2 Boundary conditions

A fixed boundary condition was applied at the back of the holder just as before, see figure 10-29. This model is symmetric in one direction so a symmetry boundary condition was applied in the X-direction, see figure 10-30. A symmetry boundary condition in the Y-direction was also applied to the chamber to keep it from moving in that direction in the two first steps, see figure 10-31. It was then deactivated to the lifting step.

The chamber was applied in the first step with a displacement just as in the previous simulation. The release step was also the same. The third step was a lift step where the chamber was lifted with a displacement in the Y-direction of 2 mm, see figure 10-32. The displacements on the chamber were, as before, applied to a point connected to the middle surface of the chamber with a distributing coupling constraint, see figure 10-33.

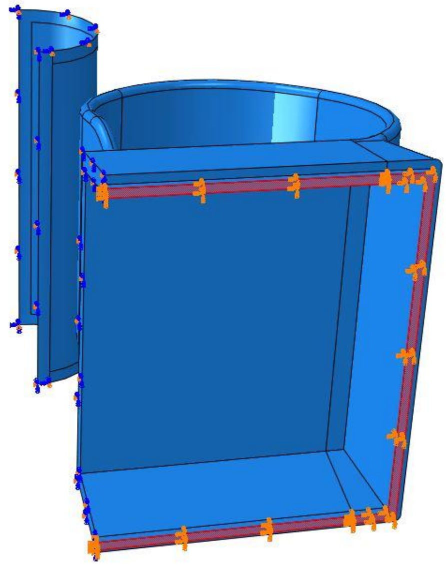


Figure 10-29. Fixed boundary condition.

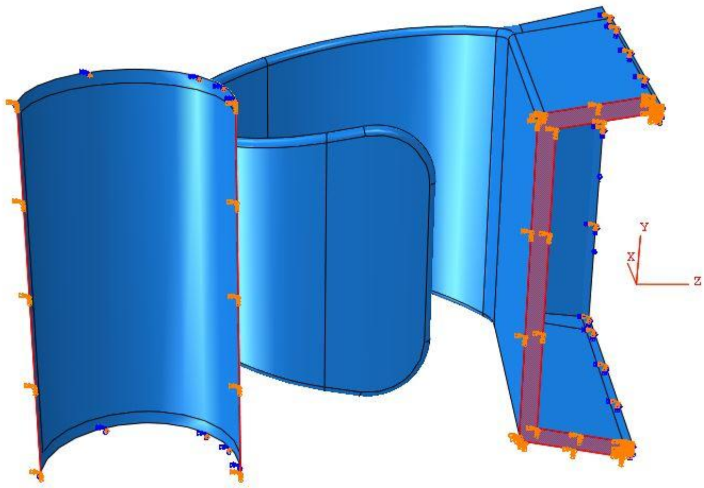


Figure 10-30. Symmetry in the X direction.

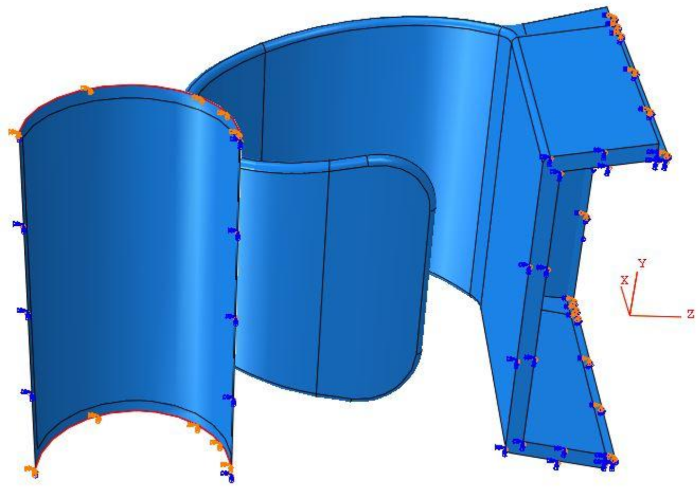


Figure 10-31. Symmetry in Y direction.

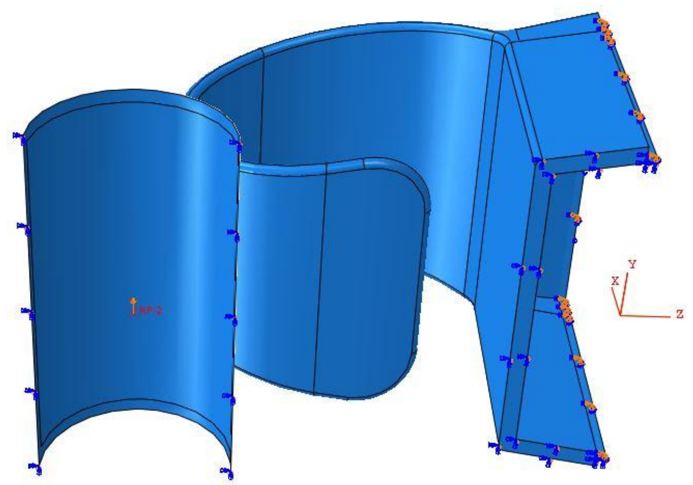


Figure 10-32. Displacement to lift the chamber.

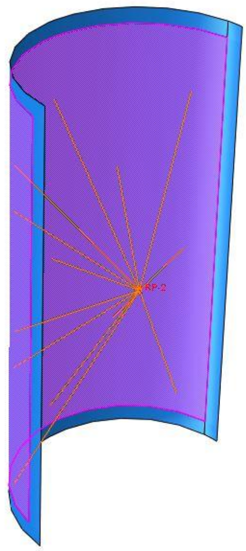


Figure 10-33. Distributing coupling constraint.

10.1.7.3 Contact

The contact was modelled with the same general contact definition as in the previous model. A friction coefficient of 0.2 was used since the stresses were too high when it was 0.3, as shown earlier.

10.1.7.4 Results

As expected the holding force depend on how much the wings deflect, i.e. how big and stiff the chamber is. There is a very little difference between a hard and soft chamber when the chamber is small, as seen in figure 10-34 and 10-35. That is simply because the deflection and stress are nearly the same in both cases.

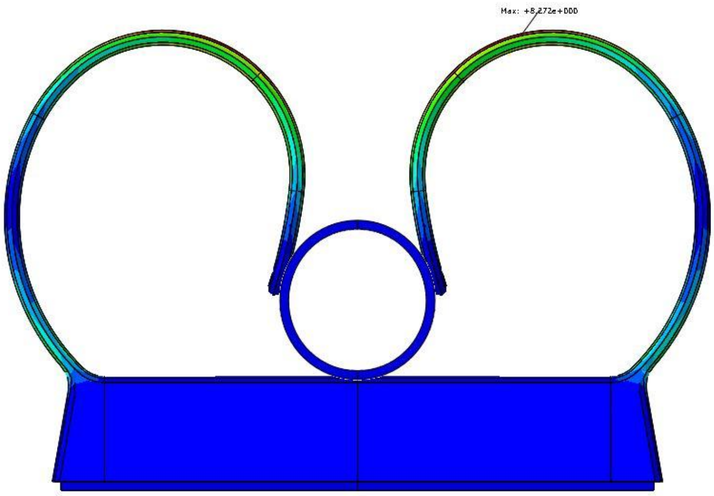


Figure 10-34. A small soft chamber applied in the ALD.

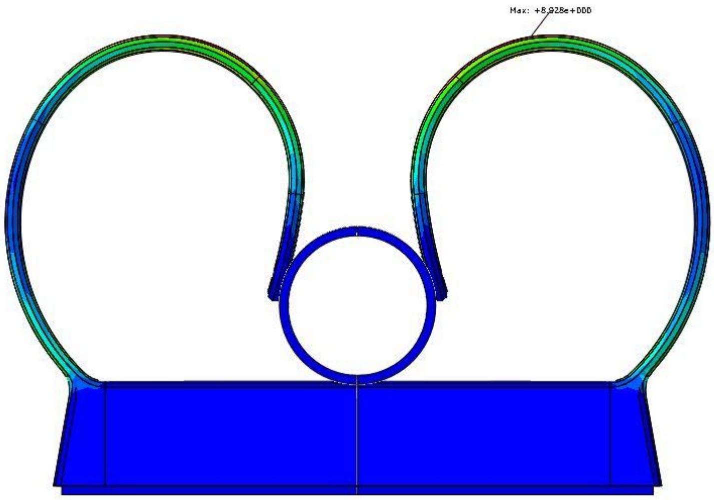


Figure 10-35. A small hard chamber applied in the ALD.

When the chamber is big the holding force depend a lot more on the stiffness of the chamber since the difference in deflection varies a lot more. As seen in figure 10-36 the soft chamber is squeezed together a lot by the holder and thereby causes a much smaller deflection. Figure 10-37 shows that the big chamber barely deforms at all. In figure 10-38 the holding forces are presented and they indicate that the holding force depend most on the stress and deflection of the holder and not so much of the contact area. The level of the holding force is considered to be enough to keep the chamber in place but not high enough to cause any injuries to the user.

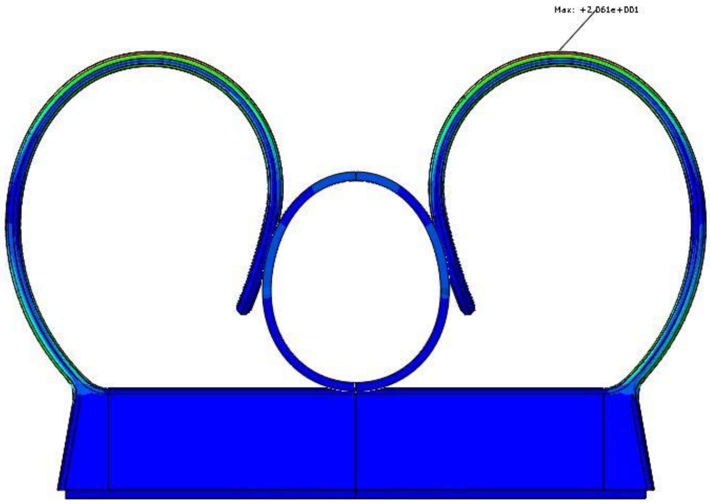


Figure 10-36. A big soft chamber applied in the ALD.

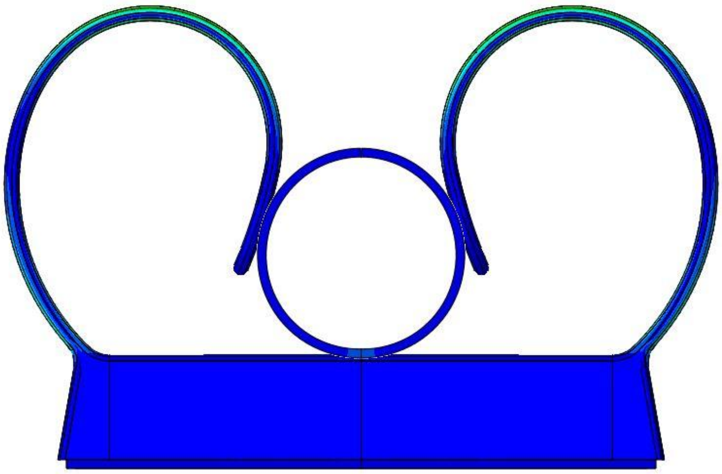


Figure 10-37. A big hard chamber applied in the ALD.

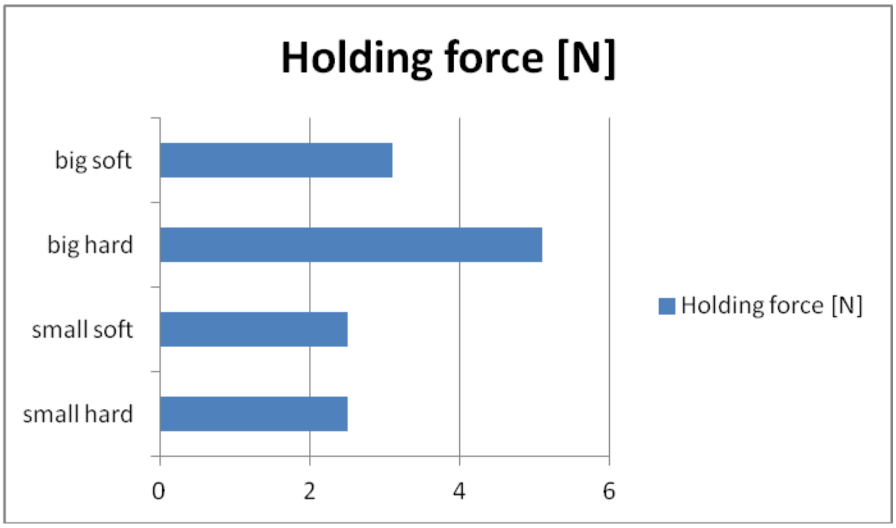


Figure 10-38. Vertical reaction force when lifting the chamber.

10.1.8 Vibrations

The vibration analysis was performed without the chamber since no chamber is applied in the holder during transportation. One fourth of the holder was simulated, due to the symmetry, and the boundary conditions and mesh on the holder were the same as in chapter 10.1.5 except from that it was solved in the standard solver.

The simulations show that the ALD has two eigen modes within the frequency area 0-200 Hz, as seen in figure 10-39 and 10-40. It is hard to determine if these could be a problem. But since the requirements are that it should withstand these vibrations during transportation, a packaging could be designed to avoid any problems. It is good to have this in mind when taking the concept in use.

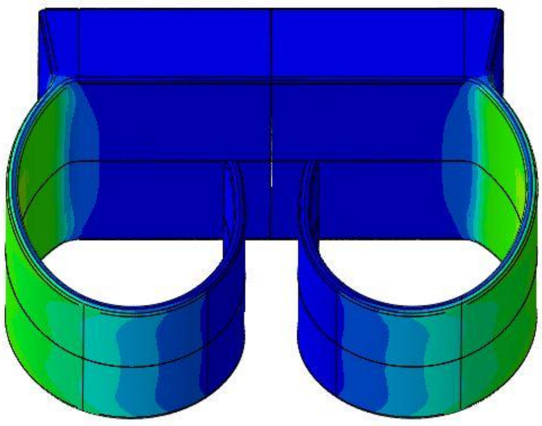


Figure 10-39. First eigen mode with a frequency of 81 Hz.

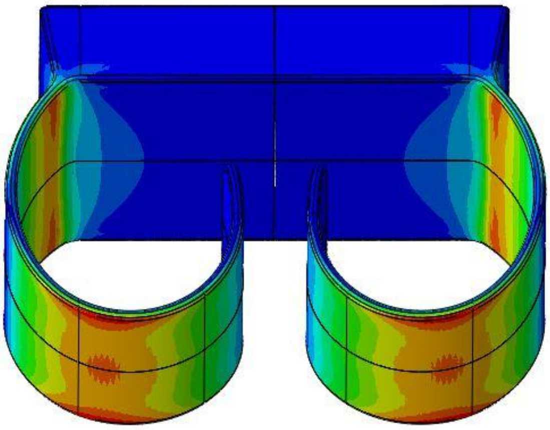


Figure 10-40. Second eigen mode with a frequency of 159 Hz.

10.2 Practical tests

A physical model needed to be made to see if the concept would work in reality. This was done using Gambro's own 3D-printer and is shown in figure 10-41. It was important to use a material as similar to the chosen material POLYform C M20 as possible, to make the prototype behave as much like the real model as possible. The prototype was selected to be made of VeroWhitePlus and its mechanical properties are presented in table10-1. VeroWhitePlus has similar mechanical properties to POLYform C M20 as can be seen in a comparison between table 10-1 and table 9-4.

Figure 10-41. Prototype of the new concept.

Table 10-1. Mechanical properties of VeroWhitePlus, [29]

VeroWhitePlus	
Tensile strength	49.9 MPa
Modulus of elasticity	2495 MPa
Elongation at break	15-25 %
Flexural Modulus	2137 MPa
Flexural Strength	74.6 MPa

To symbolize that the prototype was mounted on the real machine a test rig was set up. A capacitive sensor was applied to the backside of the prototype to detect liquid. A venous drip chamber was applied and filled with priming fluid to simulate the blood. The fluid level in the chamber was controlled by a syringe as seen in figure 10-42. When the sensor detects fluid it was shown in an increase of amps on the voltage source.

As expected the sensor detected the fluid in the middle of the holder. The detected level is shown in figure 10-43. A problem than can occur when using a capacitive sensor, is that the sensor can detect the wrong things. An example is that the sensor can detect the user’s fingers. This happens when the fingers get to close to the sensors measuring range. In this case this is not a major problem due to the measuring range is only 5 mm. Under normal circumstances the fingers will never get to close to the sensor, but it is important that the user knows about it. Even if the sensor detects the user’s fingers when there is no liquid in the chamber, the user can see that the chamber is empty and stop the treatment, since the user needs to be close to the machine to have the fingers there.

Another problem when using a capacitive sensor is that it will detect even a small amount of fluid. This means that if the liquid flows along the inner surface of the chamber the sensor will detect fluid even though the fluid level is under the chamber. This can be a problem if the chamber is mounted in an angled position. It can be solved by mounting the chamber in a vertical position, or using a different capacitive sensor which is to only detect larger amount of fluid.

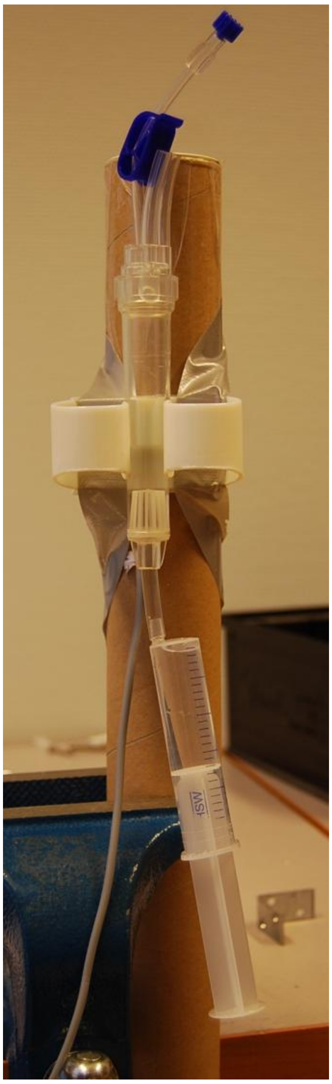


Figure 10-42. The test rig

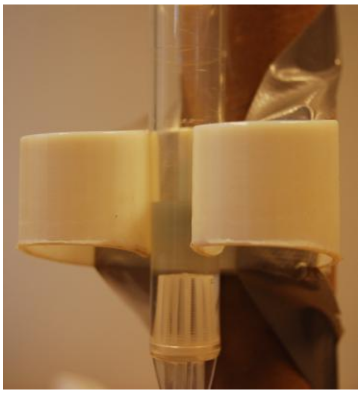


Figure 10-43. The fluid level that was detected.

11 Conclusion and recommendations for further studies

This chapter summarizes the workflow and conclusions from the report and presents recommendations for Gambro. The concept which was developed would improve Gambro's dialysis machines. However, some more tests of the concept needs to be performed to determine that it really works in reality. Another recommendation is that Gambro starts using computer based calculations in their development process. That could save both time and money.

11.1 Conclusion

The old ALD has not changed in great detail since it was designed in 1974 and it has thereby not kept pace with the market of dialysis machines. There are possibilities to improve the usability and ease the cleaning of it. Improvements can also be introduced to avoid the hatch breaking.

Interviews with Gambro personnel and FE-analysis was made to find out why the hatch breaks. As seen in the result from the FE-analysis, it complied with the reality. This means that if a FE-analysis had been used in the development process of the ALD the problem with the hatch could have been avoided. FE-analysis is a technique which goes hand in hand with the development process. It is also a technique that is gaining ground and will become increasingly important in the future.

To make the new ALD function properly, two questions had to be answered:

- How to hold the chamber in place?
- How to detect the fluid?

These questions are dependent on each other. If an ultrasonic sensor is used, the design of the holder becomes more limited than if a capacitive sensor is used. This is due to that the ultrasonic sensor needs a good contact surface to the chamber to work, which a capacitive sensor does not. The freedom in the design a capacitive sensor brings was the biggest reason why it was used in the new design.

There are some issues with the current design that needs to be improved. These are:

- The hatch on the ALD sometimes breaks.
- The force needed to apply and remove the chamber could be smaller.

- Decrease the possibility for leakage into the machine.
- Make it easier to use for left handed.

With the freedom in design the capacitive sensor brings, the design could be made in a non-complex way. The new design was also made into a single part to minimize the possibility of leakage into the machine and lower the costs.

To make the new ALD more users friendly for both right and left handed users, a symmetric design was considered the way to go. That means that it does not matter in with which hand the chamber was applied to the ALD.

The new design also needed to be more adapted to easily apply and remove the chamber. This is of paramount importance, since users can hurt their hands and fingers if the load for applying a chamber is too big. To make this possible, inspiration was taken from broom holders which are designed for quick application and removal. The wings that hold the chamber are shaped in a way that flex in two places. The benefits of this are that the force needed to apply and remove the chamber is reduced and the hatch is no longer necessary. This leads to a reduced risk of work injuries for the users.

To find a design which meets the requirements, an iterative development process which is described in 3.1.6 was used. The final design can be seen in figure 11-1. This design was adapted to be very easy to keep clean and have high usability. The design was also made in a single part which makes the risk of leakage into the machine very small.

The holder also needs to withstand 18,720 cycles without fatigue failures. This made it important to find a proper material that satisfies the requirements. To find the material properties that were needed was FE-analysis used. POLYform C M20 was selected to be the material that best suited the designs.

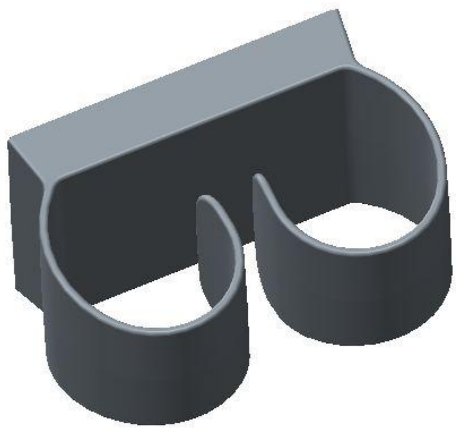


Figure 11-1. The final design

It is not just benefits with the new design, but there are also some disadvantages compared to the old design. The major disadvantage with using a capacitive sensor is that it won't detect bubbles as the ultrasonic sensor does. Despite this the benefits of the capacitive sensor was considered to exceed the disadvantage. The solution to this is to combine the new design with a bubble detector already available on the Artis-machine produced by Gambro.

There are also some risks with the new design. The old design made it almost impossible for the chamber to fall out, but since the new one does not have a hatch the chamber are not held as hard. Even so, the new design is considered to hold the chamber hard enough, since it is not exposed to any major loads during the usage. What could be cause problems is if the user accidently would pull a tube, but that should happen very rarely.

11.2 Recommendations

The old ALD was designed in 1974 and a lot has happened since then. The ultrasonic senor used in the current ALD makes excessive demands on the holder which is not accepted by the market today. The market wants a holder that is adapted to be very user-friendly and easy to keep clean, which an ultrasonic sensor cannot satisfy. Fresenius, Gambro's biggest competitor, has switched to a capacitive sensor instead of an ultrasonic in their ALD. This has made it possible for their design to outperform Gambro in usability. The recommendation to Gambro is that a capacitive sensor is the way to go, to have a competitive product.

This report shows a design proposal for the ALD using a capacitive sensor. The design aims to be very user-friendly and of a non-complex design which reduce the cost compared to the current design. If Gambro choose to change to a capacitive sensor this design is a perfect start for further studies. As seen in the chapter 10 the design does meet all the requirements of holding the chamber in place which can be considered to be good. There is however some work left to be done with the capacitive sensor. In the practical test done in chapter 10, an industrial sensor was used. This sensor however does not meet all the goals and whishes Gambro has, but it shows that a capacitive sensor undoubtedly will work in the ALD. Gambro is also recommended to develop a custom sensor that meets their goals and then combine it with the holder presented in chapter 10.

This report also aims at showing Gambro the benefits of using FE-simulations in the development process. Gambro is a company large enough to have their own simulation department. As shown in this report, an FE-simulation could be very useful in the development process. The FE-simulations in chapter 4.1 shows that the hatch will eventually break due to fatigue in the current design. This affects the company with high costs and disappointed customers. If instead, an FE-analysis had been used, this problem would have come up already in the development process and could have been avoided.

More benefits with using FE-analysis are that it is much less expensive and time-consuming than regular test with prototypes. Instead of making tests with prototypes these tests could be done with computer simulations. When a design which meets the requirements in the FE-analysis has been found, one single prototype can be produced and tested. If the analysis was made right this would be the only prototype needed.

11.3 Reflections

The used development method worked very well, but some adjustments were made to make it fit the project perfectly. To have a structured way of working in this kind of development project is very important. Most of all it is a way to ensure the quality of the project. We learned that it is important to take time to analyze the problem carefully before stating to work with the new concepts. Otherwise you risk that to forget important specifications when generating new concepts and do a lot of work to no use.

The concept selection process was a very good part of the method. The selection matrices were a great help when choosing concepts and get clear arguments to why a certain concept was chosen. During the process we noticed that the concepts can get very different grades depending on what criteria you put into the matrix. It is therefore of great importance that the identification of customer needs and the importance of these are done carefully. If you miss something or set the importance wrong, the grades can be misleading.

To include computer based simulations in the development process is a very good way to shorten the time and lower the costs of the development. We are very satisfied with the simulations we made and think that Gambro could use the same method in future development projects. The hard part of doing the simulations was to decide what was going to be simulated. It is very important to choose relevant scenarios and it is not always obvious which ones that is.

We have had a very good time working with this project and we have learned a lot that we most certainly will use in the future.

References

[1] Karl T. Ulrich & Steven D. Eppinger, (2012). Product Design and Development. McGraw-Hill Education (Asia) , New York, USA

[2] Vårdhandboken (Electronic). http://www.vardhandboken.se/Texter/Dialys-hemodialys/Oversikt/ 2014-01-29

[3] Sjukvårdsupplysningen (Electronic). http://www.1177.se/Skane/Fakta-och-rad/Behandlingar/Bloddialys---hemodialys/?ar=True 2014-01-29

[4] Wikipedia (Electronic). http://sv.wikipedia.org/wiki/Dialys 2014-01-29

[5] Gambro (Electronic). http://www.gambro.com/en/ca-en/Patient-information/Living-with-kidney-disease/Treatment-options/Peritoneal-Dialysis/, 2014-04-11

[6] Gambro (Internal material Gambro). Gambro Education Department (1996). Gambro BASICS. Gambro Svenska Försäljning AB, Lund, Sweden

[7] Gambro (Internal material Gambro). AK96 Dialysmaskin Operatörsmanual

[8] Svensson, A, Hellstrand Peterson, C and Grop, I. (2003). Hand- och handledssmärtor hos dialyssköterskor, Röda korsets Högskola, Stockholm, Sweden

[9] Campus Plastics (Electronic) http://www.campusplastics.com/campus/en/datasheet/HOSTAFORM+C+9021/Ticona/163/59b16839/SI 2014-03-26

[10] DuPont (Electronic) http://www2.dupont.com/Plastics/en_US/assets/downloads/design/DELDGe.pdf, 2014-04-01

[11] Kölfors, Johan, Head of Software Department, Scanscot Technology, personal conversation, January 24, 2014

[12] Ekdahl, Johan, Technical support, Gambro AB, personal conversation January 30, 2014

[13] Ohlsson, Håkan, Technical support, Gambro AB, personal conversation January 30, 2014

[14] Håkansson, Ann-Margret, Senior clinical advisor, Gambro AB, personal conversation January 30, 2014

[15] Svensson, Fredrik, Service Leader Denmark, Gambro AB, personal conversation February 7, 2014

[16] Kristoffersson, Johan, Manager Technical Service Nordic, Gambro AB, personal conversation February 7, 2014

[17] Ny, Jörgen, Clinical Human Factors Technician, Gambro AB, personal conversation February 19, 2014

[18] Wennerberg, Anna-Karin, Clinical Consultant, Gambro AB, personal conversation March 3, 2014

[19] Lindgren, Henrik, Electrical Engineer, Gambro AB, personal conversation February 10, 2014

[20] Thornblad, Lars, Development Engineer, Gambro AB, personal conversation March 26, 2014

[21] Bruder, U. (2012). Värt att veta om plast, Bruder Consulting AB, Karlskrona, Sweden

[22] Prospector IDES (Electronic)
RTP 800 DEL, http://prospector.ides.com, 2014-03-31

[23] Prospector IDES (Electronic)
POLYform C M20, http://prospector.ides.com, 2014-03-31

[24] Prospector IDES (Electronic)
EDGETEK 5230 Natural 1, http://prospector.ides.com, 2014-03-31

[25] Edshammar.L.E, (2002). PLAST HANDBOKEN – en materialguide för industrin, Industrilitteratur AB, Lidingö, Sweden

[26] Röchling (Electronic)
http://www.formaterm.se/wp-content/uploads/PC_ABS_prod_beskrivning.pdf 2014-03-26

[27] Campus Plastics (Electronic)
http://www.campusplastics.com/campus/en/datasheet/Bayblend%C2%AE+FR3050/Bayer+MatSc/22/78b2056a/SI?pos=28 2014-03-26

[28] Matweb (Electronic)
http://www.matweb.com/search/DataSheet.aspx?MatGUID=4bcaab41d4eb43b3824d9de31c2c6849&ckck=1D, 2014-04-28

[29] STRATASYS (Electronic)
http://engineering.usask.ca/documents/facilities/specs/Eden_FullCure800.pdf, 2014-04-14

Appendix A: Work distribution and time tables

Table 0-1. Work distribution.

Tasks participation in %	Karl	Jimmy
Mission statement	70	30
Product specification	50	50
Collection of material relating to current design	40	60
Research and choice of material model	60	40
Calibration of material model	60	40
Design and simulation of the FE model	80	20
Evaluation of results	70	30
Benchmark of competitors	20	80
Design proposals for improvement	30	70
Design and simulation of the FE models	70	30
Evaluate and choose design	50	50
Prepare opposition	50	50
Prepare presentation	40	60
Write report	40	60
Write article	20	80

It was a very balanced participation of the workload. Karl was a bit more involved in FE-simulations and Jimmy was more involved in the designs of the new concepts. Both parties were satisfied with the distribution of the work.

Table 0-2. Time plan from the beginning of the project

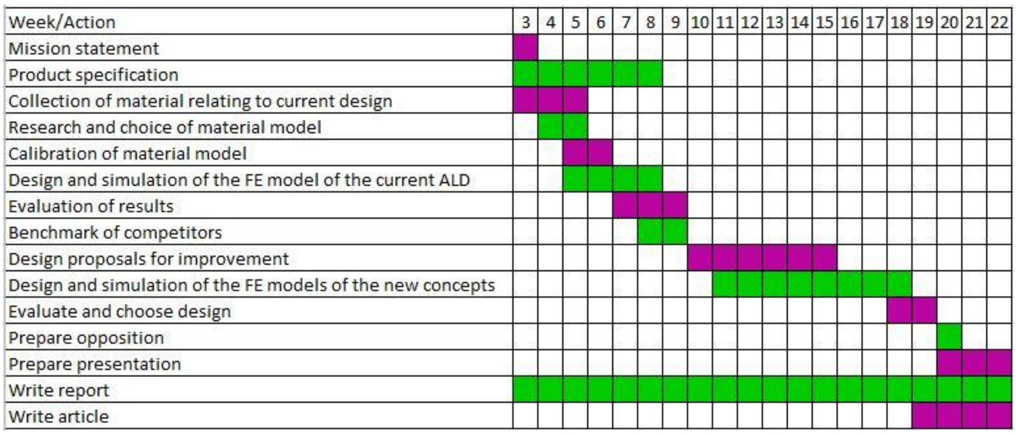
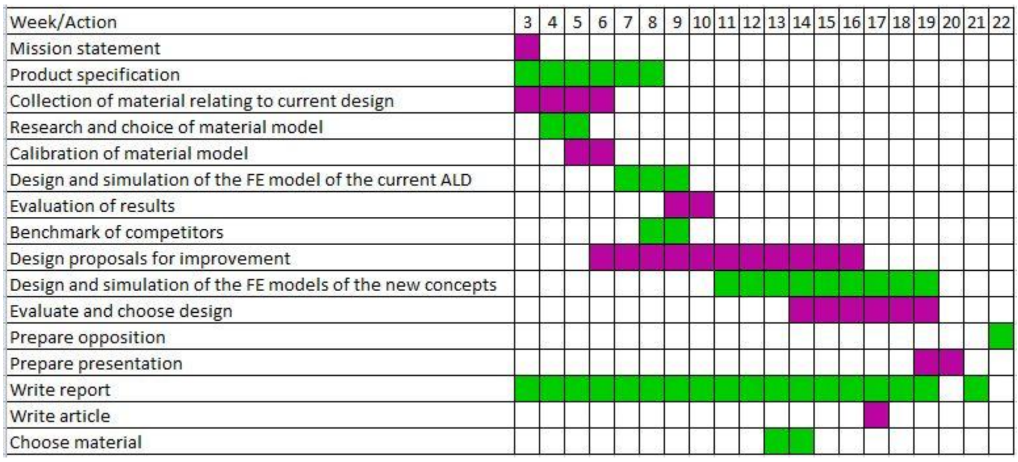


Table 0-3. Outcome of the time plan.



As seen in table 13-2 and 13-3 the time schedule was kept very well with a few adjustments. The FE-model of the old design was done a week late due to problem with the Abaqus-license. The design proposals for improvement started a bit earlier than expected but took a bit longer. This is because the iterative process as described in 3.1.6 was used. It was the same reason why “Design and simulation of FE models” and “Evaluate and choose design” took a little longer than expected. On the other hand the article only took one week to write. A new action, Choose material, came up during the project. This can be explained by the new concepts requiring a material with certain properties that needed to take into account.

Appendix B: Statements from interviews

	Raw data
	Technical support, Johan Ekdahl and Håkan Ohlsson [12], [13]
1	It is hard to apply the chamber in the ALD.
2	Leakage leaks into the machine.
3	Nurses sprays cleaning solutions on the machine instead of the washcloth
4	You should use hypochlorite or isopropanol for cleaning but often chloride or tensides is used.
5	The hatch sometimes breaks when opening it.
6	The AK-96 has more problems because the ALD is attached for left handed.
7	Many problems caused of bad cables to the sensors.
8	Brazing is a sensitive method to attach the cables to the sensors.
9	Would be good to get rid of the hatch.
10	Less movable parts.
11	Easy to calibrate.
12	Would be good to have a bubble detector too.
13	The new ALD is the pretty much the same as the one on AK-5.
14	Make it service free if possible.
15	The hinge has been reinforced because it used to corrode.
16	Hospal (Phoenix) has a similar ALD.
	Senior clinical advisor, Ann-Margret Håkansson [14]
17	It is hard to apply the chamber in the ALD.
18	Nurses get injuries in hands and wrists.
19	The ALD on Fresenius 5008S is very good.
20	The ALD is a health risk because of it is so hard to keep clean.
21	It makes no harm to put 30-40 ml of air in the patients but they don't feel good about it.
22	Use bubble and air detector so coagulated blood doesn't become a problem.
23	Use few parts.
24	Customers often clean with stronger cleaning solutions such as chloride.
25	To not have an ALD is like shooting yourself in the foot.
26	Fluid leaks into the ALD.

27	It is easier to apply a softer chamber.
28	The tubes are often cold when they are applied.
29	It should fit both left and right handed.
	Technical service Nordic, Fredrik Svensson and Johan Kristoffersson [15],[16]
30	Hard to apply the drip chamber.
31	The hinge breaks sometimes but mostly the snap.
32	Hard to clean.
33	It functions well.
34	Must replace it if there is a big blood leak on it.
35	Patients are often weak in the fingers.
36	Works okay.
37	Have to replace it if there is a low calibration value on AK-200.
38	Calibration value depends a lot on temperature.
39	Works good with soft chambers.
40	The sensors do not break.
41	Only a bubble detector makes it hard to resolve problems when alarming.
42	Pours 70 % alcohol on it when it doesn't work.
43	No difference between AK-96 and AK-200.
44	Never replaced due to bad material.
45	Fresenius adjusts the level automatically.
46	Gambro loses customers due to the bad usability.
	Clinical human factors technician, Jörgen Ny [17]
47	It is not clear how the chamber should be applied.
48	Many press the hatch at the wrong place.
49	Sometimes there are problems with the connection between the sensors and the chamber.
50	The chamber stays in place when it is applied.
51	It is hard to keep clean.
52	You don't want false alarms.
53	It is more important that it is quick to remove than apply.
54	The chamber doesn't need to sit so tight.
55	It is an ergonomic catastrophe.
56	If it would be removable for washing it wouldn't be used.
57	You get better marginal and it feels safer to have an ALD than a bubble detector.
58	Would be good if the chamber always was placed on the same level.
59	You don't need the ALD if you have a system free of air.
	Clinical consultant, Anna-Karin Wennerberg [18]
60	Many are uncertain about in what height the chamber should be applied.

61	Many users get hurting hands and wrists.
62	It is impossible to clean.
63	It would be good if everybody puts the chamber in the same level.
64	The hatch is unnecessary.
65	Maybe it is not needed. Could use a bubble detector instead.
66	It is easy to adjust the level at AK-200.

Appendix C: Old specifications

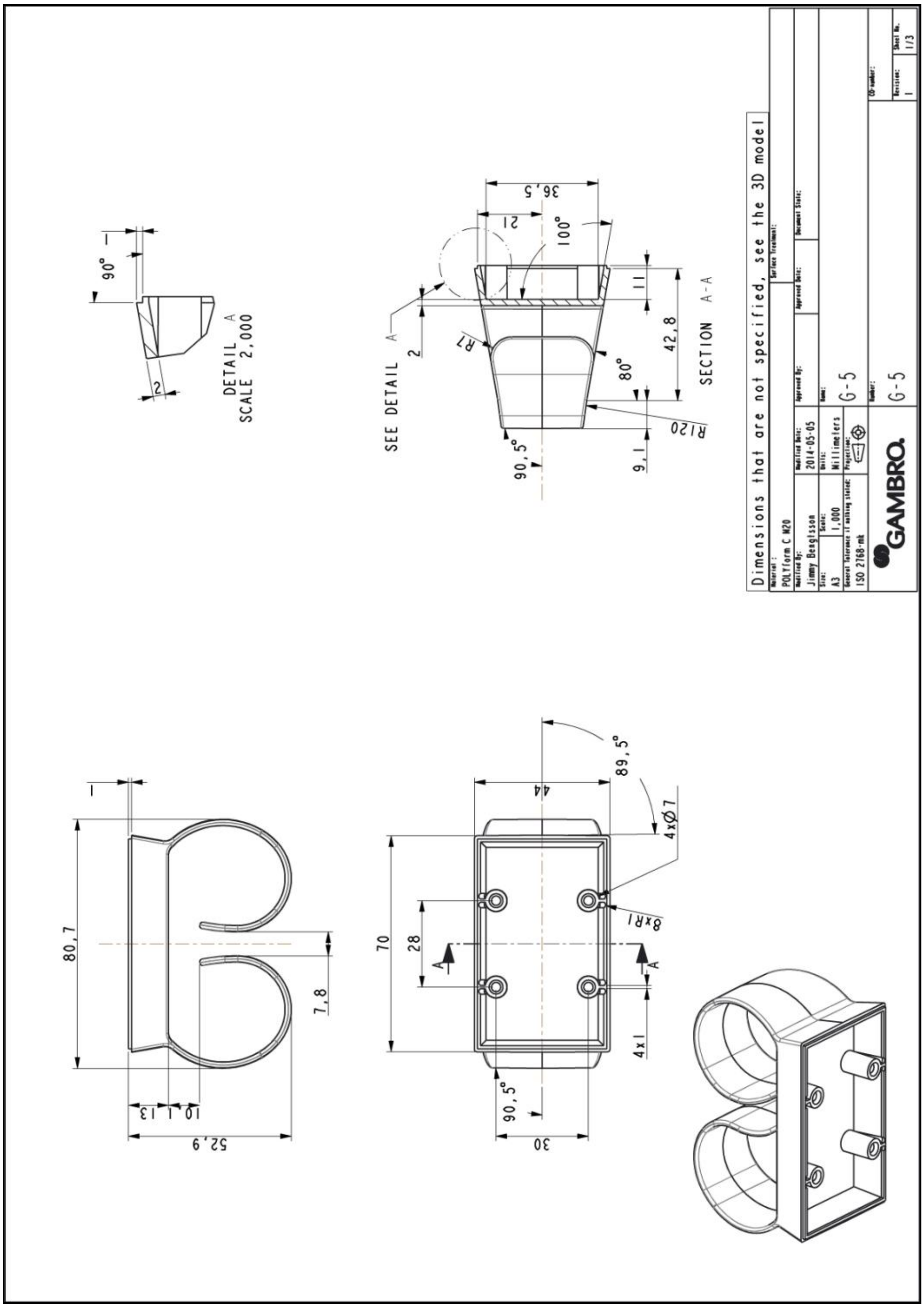
In Gambro's system requirements "shall" is used for mandatory requirements and "should" is used for optional features which are not mandatory but eligible.

	System requirements	Comment
1	The requirements are valid for drip chambers in all approved blood lines, at least the following subset: BL207B, BL105, A-5.129-B4/V-5.129-X, T50424A	These specific blood lines will not be included but similar ones will.
2	The ALD unit shall detect a low fluid level in the drip chamber.	The most important requirement.
3	The ALD unit shall detect blood foam as air and thus low fluid level in the drip chamber.	Will be included.
4	The ALD unit shall have a response time of maximum 2s (on system level) for a low fluid level alarm.	Will not be included.
5	The ALD unit shall function with a fluid temperature between 18-35 °C.	Will be included
6	The mounting of the drip chamber in the ALD shall be perceived as easy by a trained nurse.	Will be included
7	The ALD unit shall prevent the drip chamber from falling out.	Will be included
8	The ALD unit shall have a maximum closing force of 20N if a hatch (or similar) is used.	Will be included but a hatch will not necessarily be used.
9	The ALD unit should use ultrasound transmission as detection method.	Will not be included.
10	The ALD unit shall function with drip chamber diameter range 20-23 mm.	Will be included but the range may be changed

11	The ALD unit shall be adjustable (for different drip chamber diameters) by operator within 30s without any use of tool.	There will be higher demands in this matter.
12	The ALD unit cables shall withstand a pull out force of at least 20 N applied for 2 minutes at room temperature.	Will not be included.
13	The ALD unit shall fit the interface on AK-96.	Will be included.
14	The ALD unit shall have an outer boundary of maximum 50x95x45 mm (LxWxH).	Will be included.
15	The ALD unit shall be mounted on the monitor housing by means of four screws.	Will be included.
16	The ALD unit shall be free from burrs.	Will be included.
17	The ALD unit shall have a minimum radius of 0.5 mm on edges and corners in contact with the drip chamber.	Will be included.
18	The ALD unit shall withstand a standard random vibration test.	Will be included.
19	The ALD unit shall withstand a standard bump test.	Will be included.
20	The ALD unit shall withstand a storage temperature of -20°C to +70°C during 96 hours without degradation.	Will be included.
21	The ALD unit shall withstand storage humidity of 10 to 95% RH (non condensing) without degradation.	Will be included.
22	The ALD unit shall withstand an operating temperature of +10°C to +40°C without degradation.	Will be included.
23	The ALD unit shall withstand operational humidity of 15% to 85 %RH (non condensing) without degradation.	Will be included.
24	The ALD unit shall fulfill EMC requirements. To be tested on a system level.	Will not be included.
25	The ALD unit shall withstand exposure to normal indoor solar radiation without any surface degradation, cracking in materials or other effects on surface.	Will be included.

26	The ALD unit shall withstand exposure to cleaning solutions without any surface degradation, cracking in materials, other effects on surface or degradation.	Will be included.
27	The ALD unit output signal settling time after mounting of the drip chamber shall be maximum 10s (on system level).	Will not be included.
28	The ALD unit shall withstand at least 18,720 repeated drip chamber loading and unloading cycles without degradation. (Info: loading and unloading includes closing and opening of hatch, if applicable).	Will be included.
29	The ALD unit shall have a service interval of minimum two years.	Will be included.
30	The ALD unit shall be perceived as easy by a trained nurse to clean.	Will be included.
31	The ALD unit shall have a MTBF (mean time between failure) of minimum 600,000h.	Will not be included.
32	The ALD unit shall have an exterior surface finish of Ra 2.0 ±0.5.	Will be included.
33	The ALD unit shall be marked with Gambro Part number in text.	Will not be included.
34	The ALD unit transmitter- and receiver cables shall have a temperature rating of minimum 80°C.	Will not be included.

Appendix D: Drawings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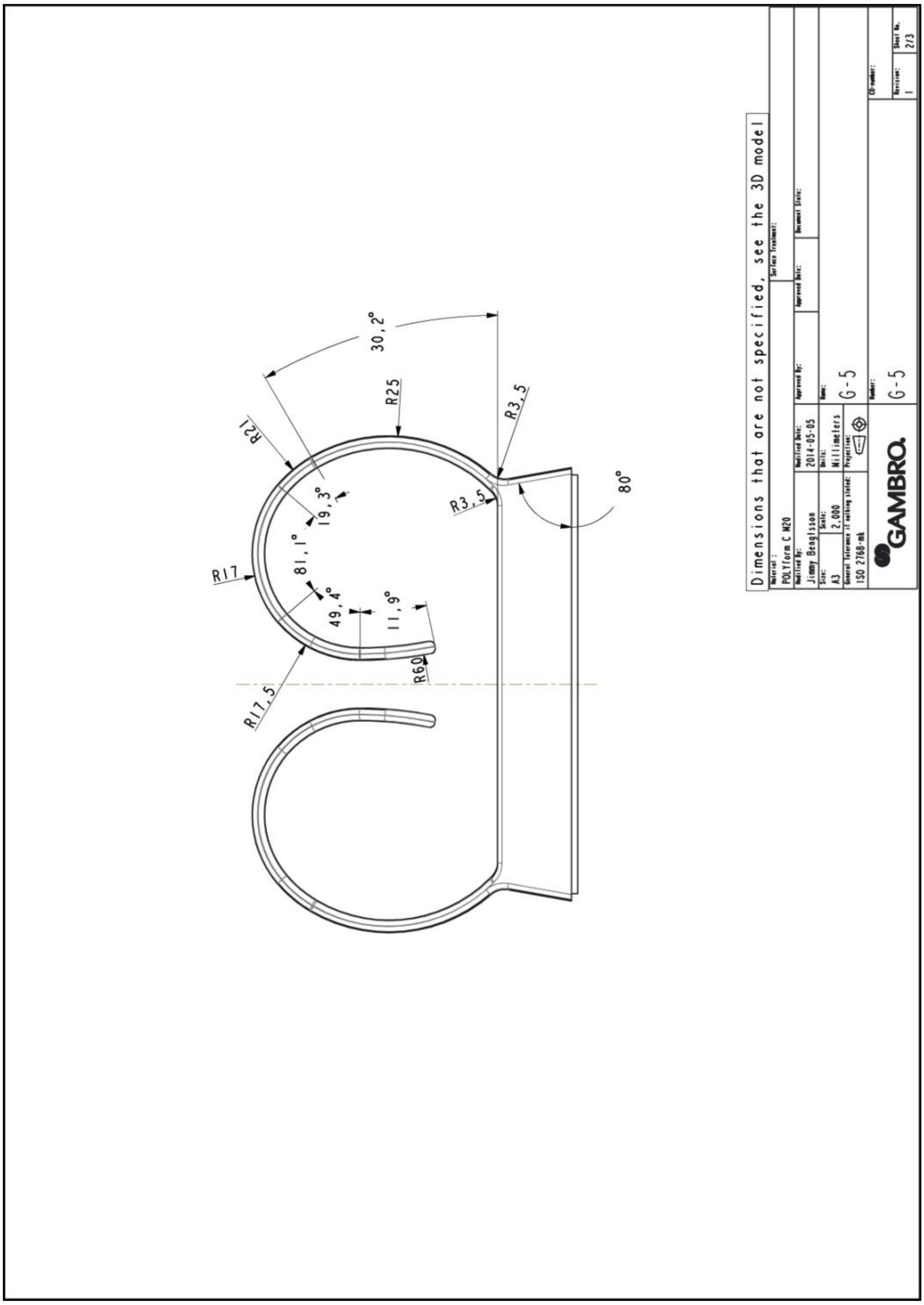
POLYform C M20
Jimmy Bengtsson
2014-05-05
A3
1,000
Millimeters
ISO 2768-mk
G-5
GAMBRO.
1/3
DETAIL A
SCALE 2,000
SEE DETAIL A
SECTION A-A
36,5
21
100°
42,8
80°
R120
R7
90,5°
9,1
89,5°
4xØ7
8xR1
80,7
52,9
70
28
44
30
7,8
4x1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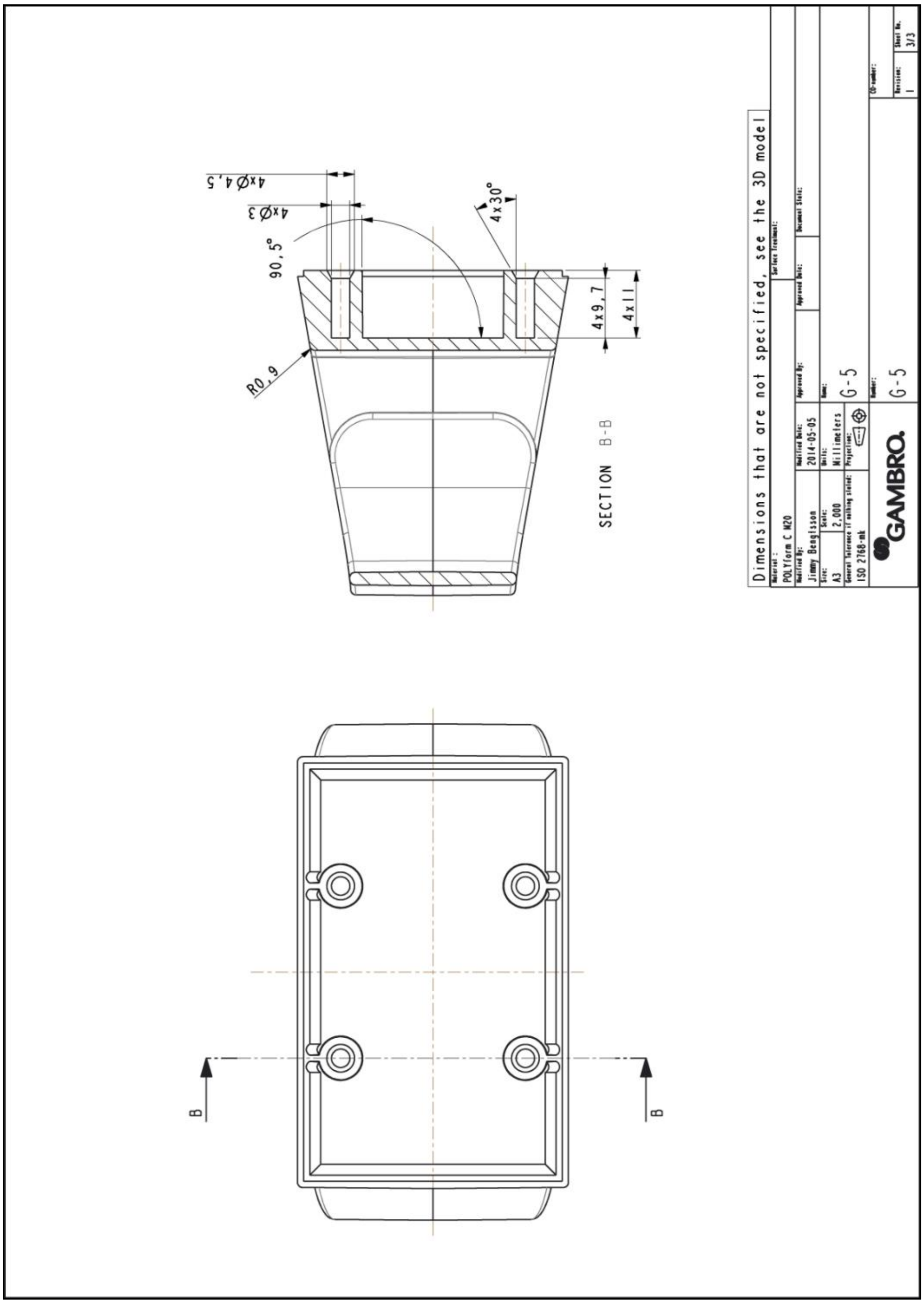
Modified By:
Jimmy Bengtsson
Modified Date:
2014-05-05
Size:
A3
Scale:
2,000
Units:
Millimeters
General tolerance if nothing stated:
ISO 2768-mk
Name:
G-5
Number:
G-5
Revision:
1
Sheet No.
2/3
GAMBRO.
30,2°
R25
R3,5
R21
19,3°
R3,5
80°
81,1°
R17
49,4°
11,9°
R60
R17,5



Dimensions that are not specified, see the 3D model
SECTION B-B
POLYform C M20
Jimmy Bengtsson
2014-05-05
A3
2,000
Millimeters
ISO 2768-mk
G-5
G-5
GAMBRO.