TU Delft

GRADUATION PROJECT

# CREATING HOSPITAL-FRIENDLY VIRTUAL REALITY GLASSES


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27 MAY 2019 - 4 NOVEMBER 2019 // MASTER: DESIGN FOR INTERACTION

CHAIR: DR. IR. JOHAN MOLENBROEK // MENTOR: IR. CAROLINE KROON

# I - Table of Contents

# II - Executive Summary

Creating hospital-friendly Virtual Reality (shortened to VR) glasses starts with the context and market research, since it is an unfamiliar topic and this research aims in finding and validating the problem and the goal for the project. Alongside this, the stakeholders (SyncVR, the hospital, the government, the nurses and the patients) and challenges (feasibility, hygiene and user experience) of the project have been defined in order to firmly ensure a direction for the project.

This project takes dialysis patients as its target group. Taking a small group makes it possible to empathize and work towards a solution for this group. Dialysis patients experience lots of pain at a frequent rate (every couple of days) when the needles for blood purification are injected into their body. Distracting them from this pain not only helps them feel less pain, but also helps the nurses in doing their job in a calmer way.

The Oculus Go VR glasses are a consumer product and are not suited for medical purposes due to the material of the headgear and thus require a complete revamp in material, functioning, shape and production. The second section of this project focuses on researching individual aspects that solves these challenges.

The decision is made to create a product that is made by mixing two components together, which cure in the timespan of an hour into a silicon product. There are multiple reasons behind this decision, but the main ones are to make the production feasible and to preserve a properly cleanable and hygiene material. Silicone is known to have greatly desirable material qualities that allow it to stretch and fit many different head shapes, alongside being non-toxic and washable under high temperatures.

The final design for the project has gone through multiple iterations and has a unit cost of approximately 12 euros at a production size of 1000 units. This design resolves the usability issues as well as the hygiene issues with the current headgear alongside providing a feasible way for a startup like SyncVR to manufacture this. The final design should theoretically be washable and re-usable, although testing this has fallen outside the scope of this project.

# III - Introduction

This project is initiated in co-operation with the company SyncVR.

SyncVR develops software applications for the Oculus Go Virtual Reality glasses for the purpose of calming patients in hospitals prior to a painful treatment, such as injections for dialysis patients.

Their products are in use for pilot tests at many hospitals across the Netherlands (like the Maasstad Hospital in the south of Rotterdam for example) and their use proves to be very meaningful for patients.

There is however a major issue, which this graduation project is tackling. These virtual reality glasses are designed and manufactured for the general consumer at their homes and not for patients inside a hospital.

The problem that the current implementation evokes (as partially seen in Figure 1) is that it does not comply to the hygiene laws as laid out by the government and hospitals.

The Maasstad Hospital does their best to work as hygienic as possible with this device, but a real solution needs to be created against this problem.

The challenges of the project are therefore split in three:

1. Redesigning the Oculus Go to suit hygiene laws and hygiene policies of the hospitals.
2. Redesigning in such a way that the user experience for patients and nurses is enhanced in a meaningful way for both: a comfortable experience for patients and ease of use (equipping and reuse) for nurses.
3. Designing a product that can be created by a startup like SyncVR in a feasible way.

This report is intended to be read with two pages side-by-side for an improved reading experience.

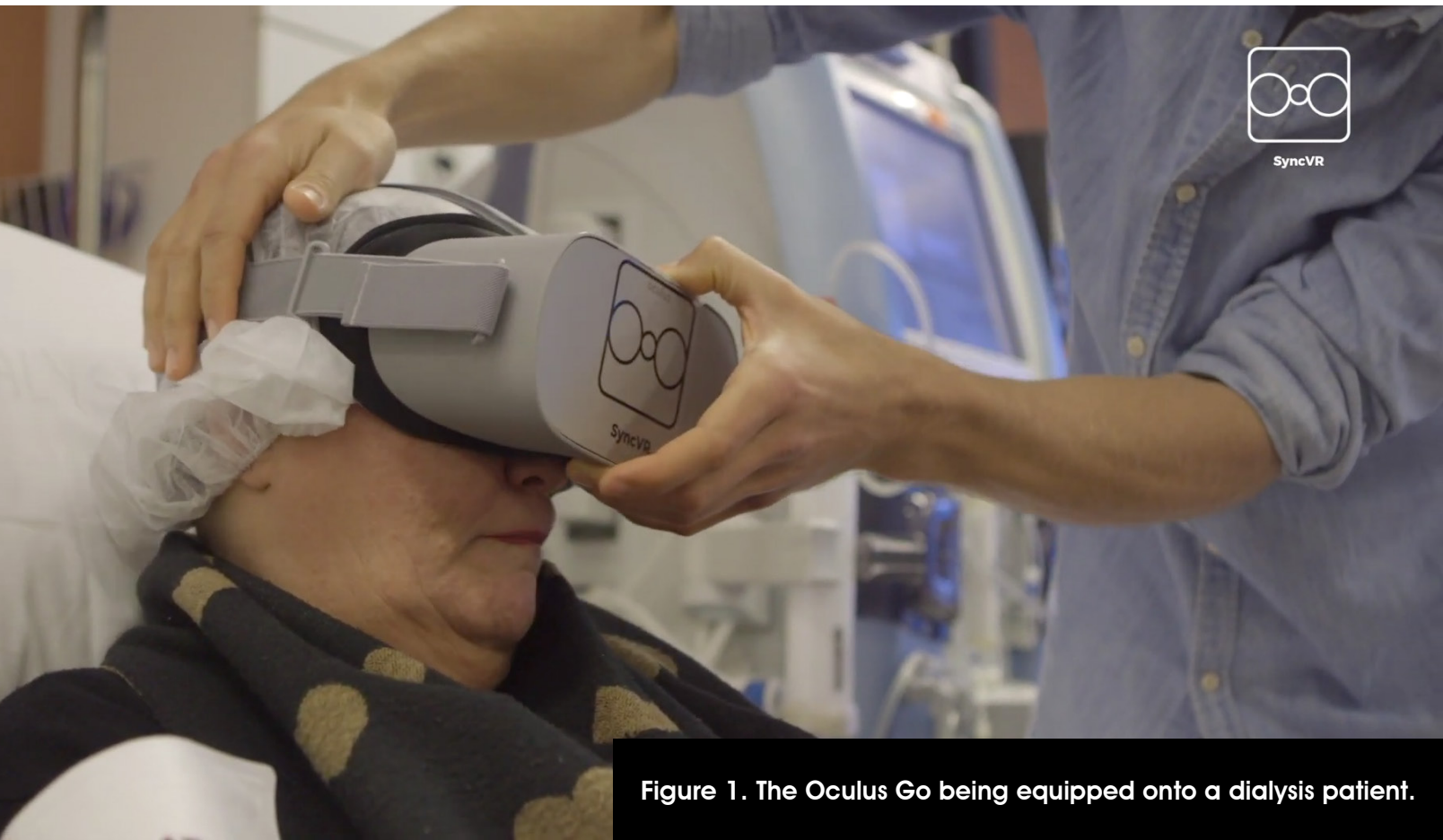



**Figure 1. The Oculus Go being equipped onto a dialysis patient.**

# IV - Coaching Team

The Coaching Team for this project is specifically chosen for the challenges this project faces: user experience (chair: dr. ir. Johan Molenbroek) and hygiene & feasibility (mentor: ir. Caroline Kroon).

This project is significantly improved with their aid and support.

## Chair: Dr. Ir. Johan Molenbroek

On the topic of user experience, the comfort for patients cannot be compromised. For this reason, the chair of this project is none other than Dr. Ir. Johan Molenbroek, an expert in the field of facial biomechanics.

He is the author of the design tool DINED, which consists of a visualisation that aids students in finding measurements of body parts. Next to several other significant achievements, he is an author of multiple papers that are aimed at facial biomechanics, such as his most recent papers "Contact pressure analysis for wearable product design" (2019) and "Estimation of Facial Contact Pressure Based on Finite Element Analysis" (2020).

## Mentor: Ir. Caroline Kroon

This project cannot be compromised on the topics of hygiene and feasibility either. Ir. Caroline Kroon is an expert on the field of bringing ideas and concepts from sketch towards production of technical high quality products.

She has experience in working with startups and has a great understanding of how tough it can be for a startup to develop products, especially without much experience from the leadership of the startup.

She helps in ensuring that the project stays feasible and supports in the technical aspects, like manufacturing and production.

**Figure 2. The chair of this project: Dr. ir. Johan Molenbroek (on the right) and the mentor of this project: Ir. Caroline Kroon (on the left) during the kick-off meeting of the project.**

# V - Company

The company that this graduation project is executed in co-operation with is **SyncVR**.

The CEO and founder of this startup, Floris van der Breggen, describes that it is their vision to implement VR as a tool in aiding patients in various ways in hospitals and that they want to end up providing the all-in-one VR package for hospitals.

As of this project, their product (an app called "SyncVR Fear- and Pain-relieving treatment") is a VR application where-in content, such as videos, animations, games and more, tailor-made for the end-user are displayed to their users.

This content is created by SyncVR themselves or which rights are obtained by SyncVR in a legitimate way.

SyncVR has control to show specific content to specific VR glasses so that the patient sees content that is made for their needs and desires.

They keep developing new and unique ways of catering to the needs of the hospital and this project is no difference to that vision.


**Figure 3. SyncVR**

# VI - Oculus Go

This project contains references to components of the Oculus Go. These components are specifically highlighted here in order to avoid confusion when reading through the report.

**The Oculus Go Case** consists of:

- **Power Button**

Turns on the Oculus Go (and has a small light indicator next to it to indicate that the device is turned on.

- **Volume Buttons**

Allows the user to increase and decrease the volume of the speakers inside the Oculus Go.

- **Connection Base**

Only visible when detaching (pulling) the side-brackets out from the sides.

### Side-brackets

The brackets on the side of the Oculus Go Case. These are removable by pulling them out and on the location where it's connected to the Oculus Go, the Connection Base will be visible. The main purpose of the side-brackets is to be to hold the headband in place.

### Headband

Comfortable cotton strap that spans across the back and top of the head when worn.

### Facial Interface

Comfortable mask in front of the Oculus Go with the purpose of protecting the face against the discomfortable edges of the Oculus Go Case.


**Figure 4. Oculus Go Parts Terminology**

# CONTEXT

## Introduction

The goal of this section is to find out more about the context and the market. From there onwards, the challenges of the project are defined. This section is finished with the goal and the vision of the project.

# RESEARCH

## Section Content

# VII - Current Context

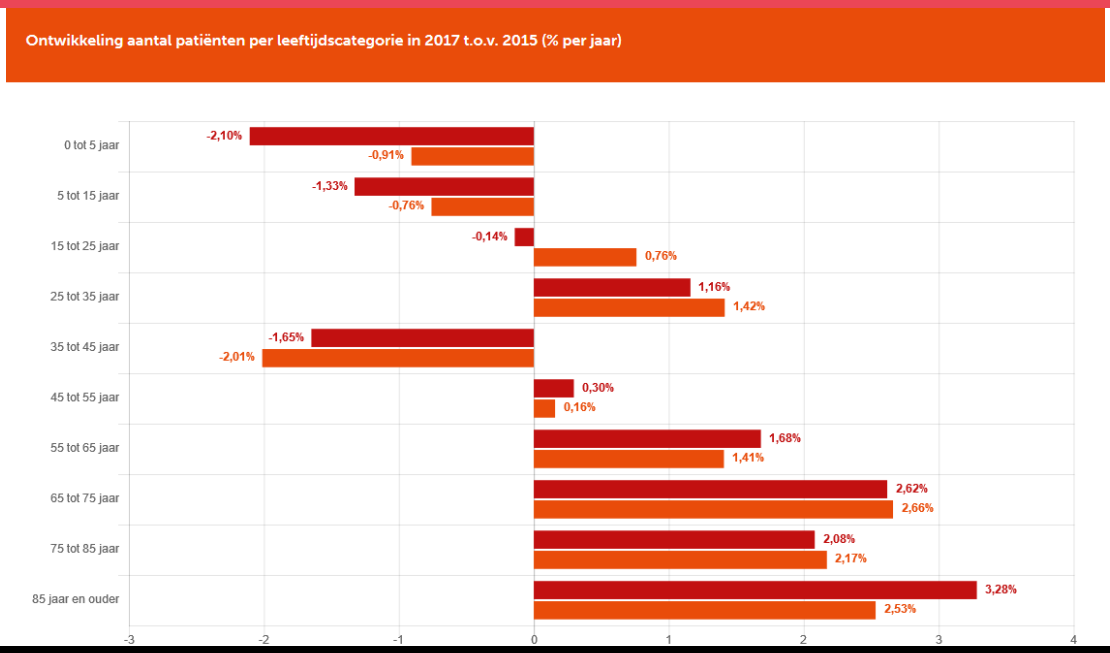



**Figure 5. Growth chart indicating the growth in amount of patients in hospitals (red) and citizens in the Netherlands (orange) per age group between 2015 and 2017, displayed in % per year (Nederlandse Vereniging van Ziekenhuizen).**

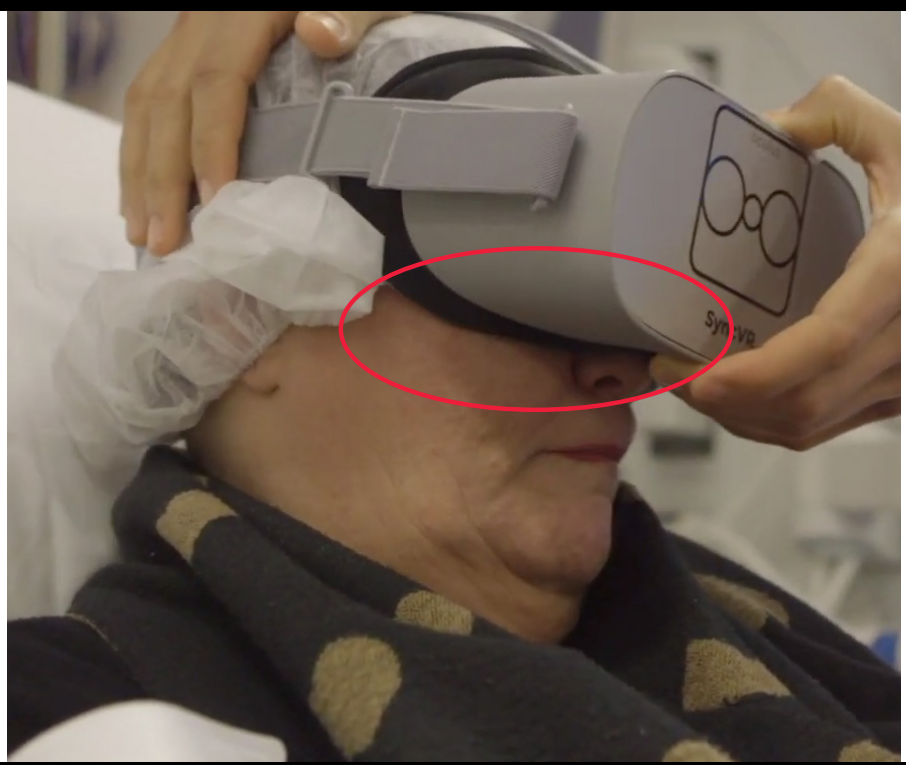


**Figure 6. Photo of an actual patient in the current context. The red circle indicates the area where the face touches the facial interface and therefore potential risks to bacteria spreading.**

# and Market Research

This chapter discusses the current context; what are nurses and patients going through as of the start of this project and why is a change necessary at all?

Patients usually feel fear when they go through what they consider to be a painful or risky treatment. It is precisely at these times that the patient should be calm so the care professionals (doctors, nurses etcetera) are able to perform the treatment properly.

SyncVR's primary short-term goal is aiding both these patients and the care professionals in hospitals in the Netherlands.

As of the beginning of 2018, the amount of hospitals in the Netherlands has grown to 79 (Deuning & Limburg). The amount of patients being treated in these hospitals approximates to 8,3 million (Nederlandse Vereniging van Ziekenhuizen).

In Figure 5 is a growth chart which indicates the differences in age groups of patients visiting hospitals and citizens in the Netherlands between 2015 and 2017. This chart clearly depicts that there are less children between age 0 and 25 in hospitals, some of which corresponds with the citizens in the Netherlands aging over time. What is even more remarkable is the large one-sided growth in citizens and patients of ages 55+ years old.

Dialysis is a process of cleaning the blood of a person whose kidneys are not functioning as they should. This is usually diagnosed when patients are at an older age. Thus, when looking at patients, this project takes dialysis patients as the starting point.

This process is preceded by a surgery where a shunt is placed and connected to the veins of the patient. This shunt is generally suited for more frequent injections (Nieren.nl).

After the surgery, patients visit the hospital frequently (three times per week on average) for long sessions (approximately four hours long) to get their blood cleaned through a dialysis machine. The most often used method is one where the nurse injects two large needles in the arm of the patient into the shunt. This way, the dialysis machine is connected to the veins of the patient. One needle transfers the blood to the device, the device then purifies this blood and the blood is transferred back into the body of the patient through the other needle.

The start of this process can be very painful as these needles are made of steel and are relatively thick (+/- 1.5mm or more) in order to allow a high enough blood flow (see Figure 7).

Virtual Reality glasses can help aid in combatting this pain (Nieren.nl) and the fear of it. As of the start of this project, the nurses equip these patients with a hairnet prior to equipping them with the Oculus Go. They then clean the facial interface and headband with microfiber clothes and equip the patient with the headband.

After the injection is performed, the nurse removes both the Oculus Go and the hairnet. The facial interface and headband are cleaned once again with microfiber clothes and the Oculus Go is stored for the next use. The hairnet is thrown into a trash bin.

The interaction of equipping the patient with a hairnet and the Oculus Go at the same time can feel very clunky to the nurses. The main challenge here is that the hairnet moves around on the head and confirming it properly takes some time which nurses do not have.

Next to this, as can be seen in Figure 6, this method leaves a large area between the face of the patient and the facial interface that is not protected. Bacteria can traverse from the face of the patient into the facial interface, which is not cleaned properly afterwards. Only the surface is cleaned with microfiber clothes, and bacteria can remain stuck inside the material.

Tabel 1.4.2

| Bloedflow | Naalddikte (gauge) |
|---|---|
| <300ml/min | 17gauge (1.5 mm) |
| 300-350ml/min | 16gauge (1.6 mm) |
| >350-450 ml/min | 15gauge (1.8 mm) |
| >450ml/min | 14gauge (2.0 mm) |

**Figure 7. Blood flow related to needle thickness (Verpleegkundige Werkwijze Access & V&VN Dialyse en Nefrologie).**

# VIII - Project Challenges

SyncVR has communicated an initial problem statement, which defined as seen on the bottom of this page.

This statement highlights the first challenge of the project: "Hygiene". The headband and facial interface of the Oculus Go are currently a big bottleneck for solving this problem. These two parts are mostly made of porous textiles. The issue with these textiles is that bacteria can enter through the holes that are formed by the fibre connections. By doing so, these bacteria get stuck in between the material. Cleaning the parts thoroughly enough so all bacteria are removed is not possible manually and removing and re-equipping these parts from the Oculus Go takes a lot of time from nurses.

The second major challenge of this project is the topic of "User Experience".

This is a very important subject as the users are the people who use the product on a daily basis. The target group for this project are nurses and patients.

Nurses equip the headband onto the patients, whereas patients wear the headband. The design thus needs to be quick and easy to use for the nurses and comfortable for patients.

The patients in this project are considered to be of the age range 50-80. This is done to make the project more realistic and to have measurements (head sizes and shapes) to design towards.

The third and final major challenge of this project is "Feasibility".

SyncVR is a startup and does not have a large financial capital like many other startups. This means that the entire lifecycle (from manufacturing to end of life) of the design needs to happen in a viable fashion.

The Oculus Go is therefore stripped down to a base product (see "Chapter XXIII - Feasibility" on page 74), onto which a design is to be connected.

The attachments give a more in-depth explanation including interviews, usage tests, prototyping and more about these specific subjects.

These challenges are the three pillars of this project. Every choice that is made during the project is based on a balanced decision between all three challenges.

**SYNCVR CREATES VR APPLICATIONS FOR PATIENTS IN HOSPITALS. THESE HOSPITALS HAVE A STRICT REQUIREMENT FROM A HYGIENIC PERSPECTIVE AND THE CURRENT OCULUS GO DOES NOT MEET THESE STANDARDS.**

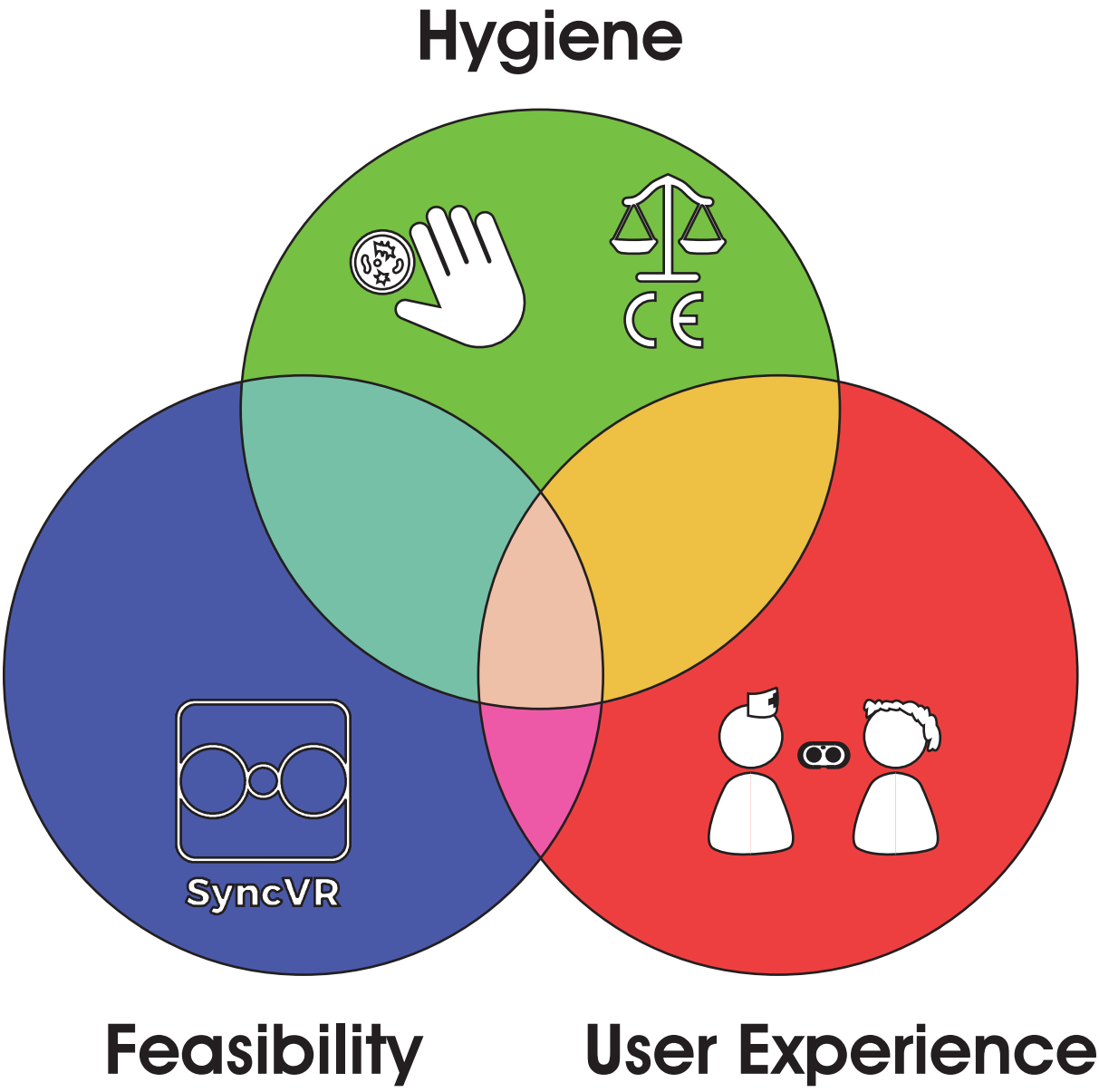



**Figure 8. The challenges of this project illustrated with the main stakeholders in visualised: SyncVR for Feasibility, Nurses & Patients for User Experience and Hospitals & Governments for Hygiene.**

# IX - Design Goal and

## LIKE A DAP BETWEEN TWO FRIENDS

Figure 9. "Atlanta Braves' Mark Teixeira, right, gives a dap to former teammate Hank Blalock before a baseball game between the Braves and the Texas Rangers on Tuesday in Arlington, Texas" (Townnews.com)

# Interaction Vision

## Design Goal

Every design project has a goal it works towards. The so-called "what" of a project, the thing it aims to achieve. Fewer projects contain the "how", the method of achieving this goal. What interactions are people interested in and why? What are their qualities and how can these qualities be translated into the ideas that bloom out of them?

This goal and vision create a more targeted vision on what to focus on and on how to achieve this goal. The goal of this project is summarized below in a single sentence.

The key element here is the fact that there are two target groups. Nurses who use the product and patients who wear the product.

This connection is preferred to be detachable, because nurses should not be in charge of cleaning the design. This is not in their line of tasks or responsibilities and takes too much of their time while it can be done better differently. It should either be disposed of or cleaned automatically.

## Interaction Vision

An interaction vision is a symbolic representation of what the desired interactions within a certain problem are.

This interaction vision (see Figure 9 on page 16) is created for nurses specifically as they are the people who will be interacting with this design on a daily basis.

The vision displays two men in the major league baseball giving each other a dap (in other words: shaking one hand and hugging with the other).

This interaction is representative of the desired interaction in the product. The connection should be firmly connected to the Oculus Go (the dap), but should also be disconnected with ease (both Mark and Hank can let go of the hug whenever they would like to).

They both want this hugging handshake to be really firm, but the disconnection is as simple as letting go of each other's hands.

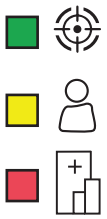
The qualities of interaction here are:

- The hugging handshake, symbolic for an easy and firm connection,
- The ease of letting go, symbolic for an easy disconnection.

As this design goal and interaction vision are formed, research can be initiated to work towards them.

The goal of this project is

**TO DESIGN A DETACHABLE CUSTOM HEADGEAR FOR THE OCULUS GO THAT IS SUITED FOR QUICK AND EASY USE BY NURSES AND FOR COMFORTABLE USE BY PATIENTS (AGE 50-80) IN HOSPITALS.**



# DESIGN

## Introduction

The Design Research section aims to work towards the design goal mentioned in the previous section, while finding out what the stakeholders each need and meeting their wishes and demands.

# RESEARCH

## Section Content

# X - Usability Research

User Experience is a very important aspect of this project as mentioned in "Chapter VIII - Project Challenges" on page 14. The primary aim for this project is to provide a design that allows for an easy use for nurses.

Nurses are the stakeholders of the project who will interact with this design the most: multiple times throughout every single day.

Cleaning the product manually is undesired for them. Manual cleaning always leaves room for errors in inconsistency and takes a lot of time from nurses, who are in a huge shortage of time in the first place.

This is why the decision has been deliberately made at the start of the project to choose for a detachable connection. Whether the product is disposed of or cleaned automatically, this connection should not take a lot of time from nurses.

It is shown in Figure 12 on page 25 that applying the specific interactions of equipping the patient with the connection and unequipping them from the connection takes the most amount of time.

This is under the presumption that nurses (if they want to work properly under the hygiene conditions that are required) should have to detach and re-attach the facial interface and the headband after every individual use.

When looking specifically at the interaction of connecting and disconnecting the design, there are various methods of connecting an object to another object. The key here is to find out which one works the best for nurses and why.

For this reason a usage test is performed during this project. Prior to this usage test, several quick prototypes are created to test a series of different types of interactions. The goal here is to create as many different (combinations of) interactions as possible and test these. Finding out the criteria that these nurses care the most about and why is the key to designing a product that will get used in hospitals in the future.

As mentioned in the conclusion of the usage test in the attachments:

*Their interactions seem to be oriented on how quick and easy they can initially understand the mechanic and how quick they can then afterwards apply the connection onto the Oculus Go.*

*Each individual interaction tested seems to have its benefits and downsides. It does not seem to matter much which specific interaction is being used, as long as the two criteria (easy and quick) are met.*

The quicker, the better; which indicates that they prefer being able to connect and disconnect both sides of the design at the same time.

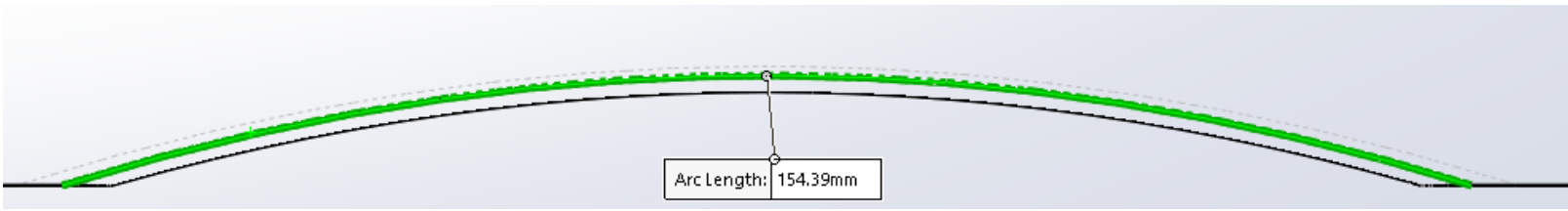
After several iterations of attempts at designing a feature like this, a hook-like design is found to be really optimal.

It connects and disconnects quickly while at the same time being easy to understand, interactable with two hands at the same time, steady and stable.

The loops on both sides in the design are strengthened with a 1mm thick vivak frame in the center of the to allow for an easier connection. The frame makes the flexible material mentioned in "Chapter XIV - Material, Production and Costs" on page 29 more rigid. This means that it's easier to position and rotate it on the hooks of the Oculus Go.

Figure 10. Nurses participating in the usage test during the ideation phase of this project.

# XI - Ergonomy




Deselect all

**Populations**

- Dutch adults, dined2004
- Dutch adults, dined2003
- Dutch adults, dined1982
- Dutch elderly, geron1998
- Dutch children, kima1993
- Dutch elderly, gdvv1984
- Dutch Growth, growthdiagrams
- Dutch students, delstu2016
- Dutch students, delstu1986
- International, international
- Chilean children, chile2012
- CAESAR (NL, TU Delft only), caesar
- CAESAR (USA, TU Delft only), caesar-usa
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CAESAR (NL, TU Delft only), caesar - more
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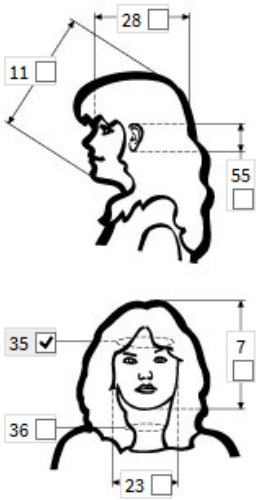



**Measures**

- Standing, length/depth
- Standing, width/circumference
- Sitting, length/width/depth
- Head
- Hand
- Foot
- Joint excursion
- Force excercise
- Other

combined measures

select: all, available, none

hide selection panel

mean and sd | single measure | set percentiles | set measurements

| populations | CAESAR (NL, TU Delft only) 99, mixed | |
|---|---|---|
| measures | P5 | P95 |
| Head circumference (mm) | 529 | 595 |

Figure 11. TOP: The improved radius of the headband. BOTTOM: Head circumference CAESAR P5-P95 (Molenbroek, 2017).

# Research

The other stakeholders when looking into User Experience are the patients. For patients, there seem to be three significant demands or wishes:

- The design should fit on their head.
- The design should be able to carry the Oculus Go reliably.
- The design should feel comfortable.

What shape is preferred and is a band at the top necessary? The band at the top helps in making the Oculus Go sit more stable on the head, but if properly equipped, this seems to be a very minor and neglicible improvement. In small tests, the band at the top does not seem necessary at all and introduces complexity to the product with regards to sizing and production for little reasoning.

For this reason, the top band has been left out of the design.

The rest of the design works and has probably been tested rigorously by the design team of Oculus themselves. While optimizations to these designs are performed during this project and are further recommended after the project, these are not considered to be major design changes.

The size and flexibility of the design is another challenge however. Heads exist in different shapes and sizes. Some heads are more circular than others; other heads are more oval-shaped. Some heads are larger and some heads are smaller. This makes designing a product that fits all head sizes almost impossible.

For this reason, a material with a large flexibility needs to be chosen, more information about this can be found in "Chapter XIV - Material, Production and Costs" on page 29.

A large flexibility in the allows it to fit on different headsizes and -shapes without permanently deforming (while still in its elastic phase). This means that after every single use, the design should return back to its original shape and size.

Research is also performed on the necessity of retention systems that can retract the material, which turns out to be unnecessary thanks to the large flexibility of the material.

In order to meet this demand, "Design Changes" on page 122 demonstrates an extensive research on all these demands or wishes with the final material of choice.

As seen in Figure 11, the final design of the headband (radius of 154mm) is smaller than the P5 headsize (radius of 264mm), as the elongation of the material has been taken into consideration here.

With the elongation of the chosen material (the Dragon Skin FX-Pro), the forces exerted onto the head with this stretch are minimal (between 4.5 and 6.0 Newton), but strong enough to hold the headband and the Oculus Go on the head.

The material is also proven to be strong enough to easily hold the Oculus Go; it is capable of lifting over 120 Newton in its elastic phase, after which it immediately breaks without any seeming plastic deformation.

The frame mentioned at the end of "Chapter X - Usability Research" on page 20 helps in keeping the material even more rigid and stiff, which in turn makes the material much stronger at the loops that connect onto the Oculus Go.

Lastly, because of the skin-like feel of silicone, the design feels very comfortable on the head with minimal pressure as mentioned before.

This design can be a one size fits all, but might require one or two more sizes to narrow the range of pressure exerted onto the head of the patient.

# XII - Usage Scenario

It is crucial to pay close attention to the user experience between nurses and this product and between patients and this product. These interactions point to many problems that can be resolved for an improved quality of life. This phase aims to design a creative solution for nurses, whereas the next phases (especially the final phase) have more emphasis on the comfort for patients.

## Current Scenario

The current interactions for nurses is displayed in Figure 12. It is a big hassle for nurses to clean the headband. Not only is it hard to clean porous surfaces, using products with porous surfaces at all is against the advice of the infection prevention. Besides, these surfaces are being cleaned with alcohol, which is against the advise of Oculus themselves.

**To clean your Oculus Go headset:**

- **Use a dry cloth to clean the outside of your headset.**
- **Use non-abrasive anti-bacterial wipes to clean the straps and the facial interface foam. Don't use alcohol or an abrasive cleaning solution.**

(Oculus)

Equipping and unequipping the patient with the Oculus Go is also a huge time-sink. Even if the disconnecting and reconnecting the headband is not the case, the headband usually needs to be affirmed onto the head of the patient with a hairnet, which makes it a very clunky experience.

## Desired Scenario

The desired scenario displays the desire to significantly decrease the time it takes for the headband to be cleaned properly by ensuring a quick connection and disconnection, so the design of this project can be washed separately later on and so this task is not one the nurses have to worry about.

A quick analysis makes it clear that this entire cleaning process:

- Is very long-winded. It takes a long time to get everything cleaned.
- Should either be automated (cleaning in a washing machine) or disposable to save the precious time of nurses.

The connection and disconnection are usage tested as seen in ("Chapter XXIV - User Experience" on page 76).



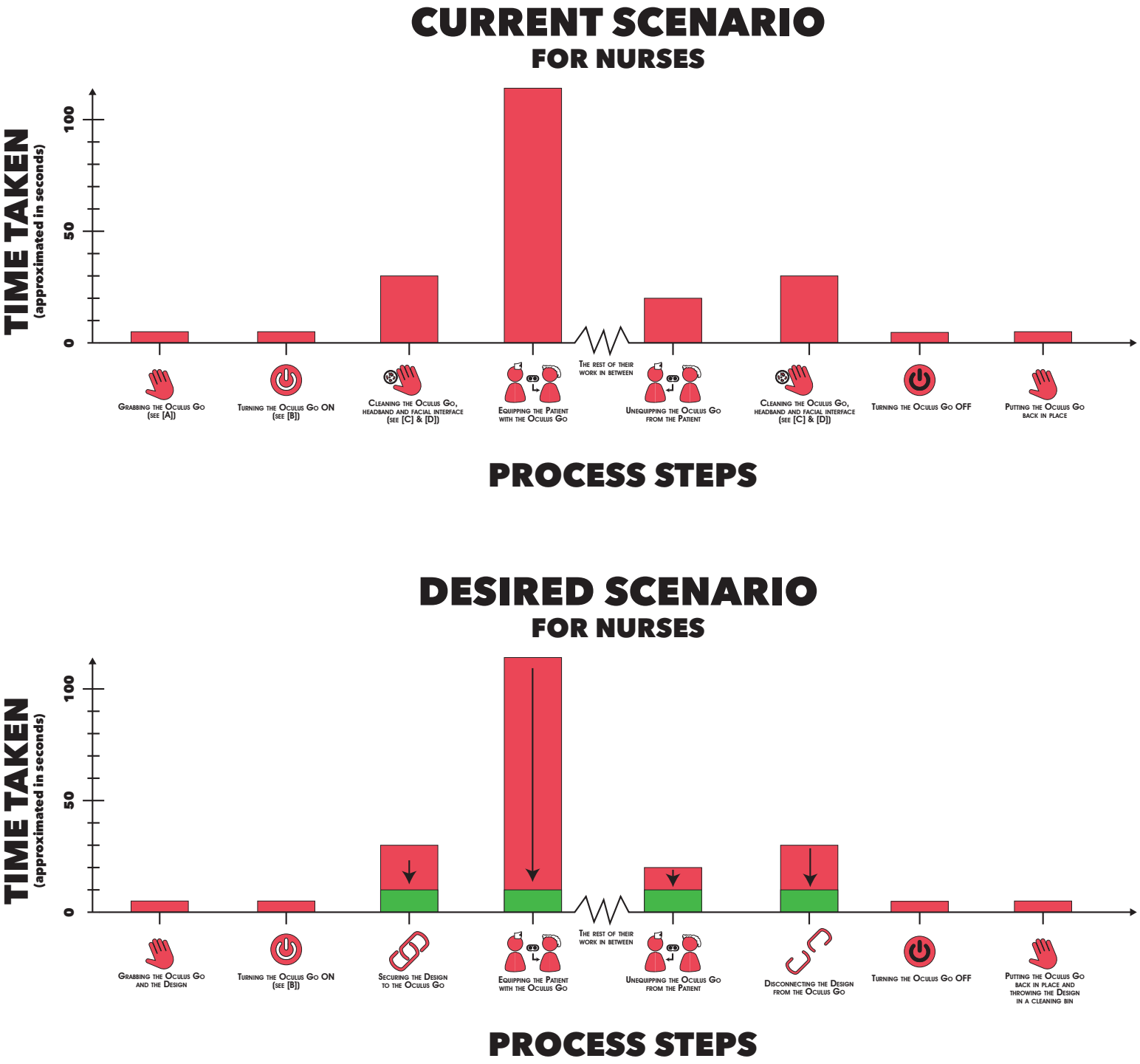




Figure 12. (LEFT) Displays the current scenario for nurses. (A) displays the Oculus Go in an off position. The nurse has to turn the Oculus Go on (B) and clean the entire facial interface (C) and the headband (D). (RIGHT) Current and Desired Scenario for the interaction between the Oculus Go, headband and nurses.

# XIII - Hygiene

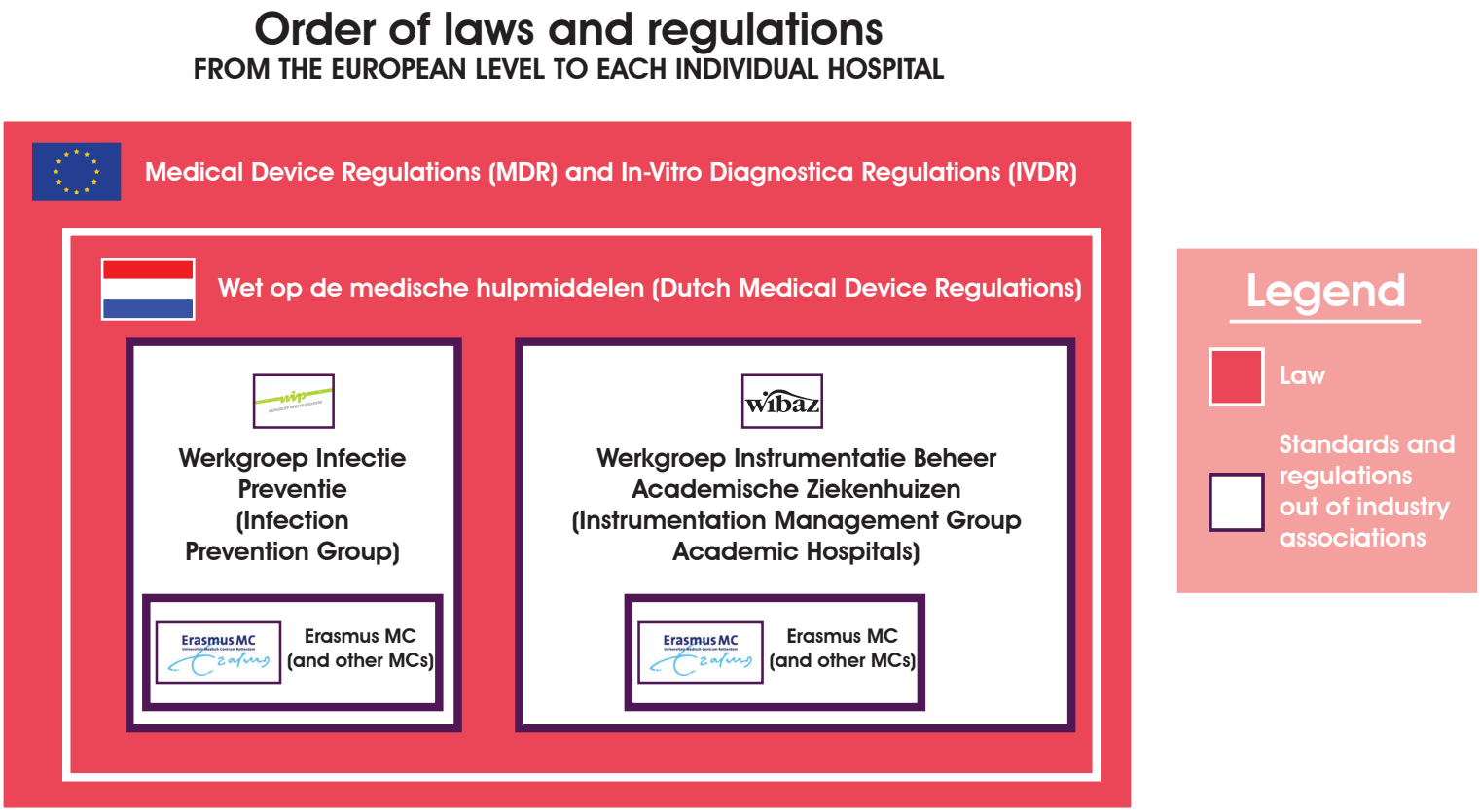



Figure 13. Illustration displaying the order that laws, standards and regulations are currently implemented (courtesy of Sebastiaan Notenboom).

# Framework

Hygiene is the biggest reason that this project has been requested and initiated in the first place. The product needs to be as clean as possible when being used by the patient. This chapter aims to resolve questions as:

- What is hygiene and how do different departments of a hospital approach this challenge?
- Are there any rules and regulations from the government or the European Union that need to be considered?
- What design choices should be made in consideration of this topic?

Hygiene is defined by the Cambridge Dictionary as "the degree to which people keep themselves or their environment clean, especially to prevent disease".

Hygiene has three degrees according to the Spaulding classification as seen in Figure 14. This classification indicates the level of hygiene that is necessary for different purposes. Merely cleaning a surgical tool is not sufficient for example, while sterilizing tools used for administration is an overkill. Hospitals may or may not have more in-depth subcategories within these classifications. This is decided individually by each hospital.

Several interviews with professionals from the Erasmus Medical Center (Erasmus MC) are performed for the purpose of this project. The Erasmus MC has a variety of departments that is involved in hygiene, but the two major departments in charge for hygiene are the units Infection Prevention and Central Sterilisation. The former is mainly in charge of instructions and research on the field of manual hygiene, whereas the latter is in charge of automatic hygiene and the highest level of hygiene: sterilisation.

The best way to preserve hygiene is to use disposables. By using a new product every single time, there is no risk of contamination at all. This is however not that feasible for a startup like SyncVR, because their production size and therefore their unit costs will be too high for disposables. Options to preserve hygiene by automatic cleaning seems to be the most preferred option. This takes away workload from the nurses as well as providing a reliable and clean alternative for disposables.

It is possible to automatically clean with regular washing machines to a certain level of disinfection. The "A0 Thermal Disinfection Concept" on page 67 mentions a way to disinfect by washing the product above 60-70 degrees Celcius.

With regards to rules and regulations, there are European laws that regulate medical devices. These laws are further detailed on government level.

This project contains an elaborate research as to whether this design will end up becoming a medical device or not. This research is concluded in "Final Verdict on Medical Device Regulations" on page 73, wherein the conclusion states the following:

*The design is not a medical device in itself; it is not intended by SyncVR for the purpose of diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of diseases or any of the other aspects. However, if the design supports a medical device, it means that the design itself will become the accessory for aforementioned medical device. In such a case, the design will need to follow all the rules mentioned in these regulations and will require a CE marking.*

Any further choices to be made in the design are that the surface of the product should preferably not contain holes or inconsistencies. These make cleaning them (even in a washing machine) that much more difficult, inconsistent and unreliable.

| Categories | Application | Examples | Level of disinfection |
|---|---|---|---|
| Critical | Enters normally sterile tissue or the vascular system | Surgical instruments, scalpels, biopsy forceps, injection needles, sphincterotomes | Sterilization |
| Semicritical | Contact with intact mucous membranes | Endoscopes | High-level disinfection |
| | Vulnerable to infection | Thermometers | Intermediate or low-level disinfection |
| Noncritical | Touches only intact skin or not touches skin | Stethoscopes, blood pressure cuff, bed pans, stretcher car | Low-level disinfection |

**Figure 14. Table displaying the Spaulding Classification (Lee et al, 2013) and (Spaulding, 1957).**

# XIV - Material,

Material and production are always a major challenge when dealing with the feasibility of a project to a company, especially when the company is a startup.

The goal of this chapter is to provide insight in what the design is made of (the material), how the design is produced and the costs per unit when producing in batch.

## Material

The preferred material for this project is a material that fits the following set of demands or wishes:

- Susceptible to high amount of elongation ("Chapter XI - Ergonomy Research" on page 22 describes a material that preferably stretches out so it can fit on a larger variety of heads.
- Non porous surface.
- Strong enough to lift the Oculus Go.
- Comfortable feel.

Non porous surfaces mean that any woven materials like clothes are off the table, since they consist of woven threads and there are gaps in between these threads within which bacteria can get stuck.

The materials for this project require flexibility the most. A material with a low Young's Modulus that is able to soak in a lot of strain. The material also requires to be resistant to high temperatures of up to 90 degrees Celcius and requires to be resistant to water since it needs to be cleaned in water (see "A0 Thermal Disinfection Concept" on page 67).

Next to this, the material needs to be producable in a way that is not injection molding or 3D printing, as explained further in this chapter.

Furthermore is also mentioned that the choice is made to go for a Room Temperature Vulcanizing (RTV) Silicone. Next to the reasoning for the sake of production, silicones are a very desired material for their material characteristics.

Silicone is a material that feels like a skin, is not toxic, non-porous repels water and covers a wide range of temperatures. This range of temperatures and water resistance cause thermically disinfecting to be possible. Silicones are also a non-sticky material, which means that if any dirt or dust gets on the surface, it is still easy to clean it as nothing will actually get stuck on the surface.

Silicones are a widely used material in a variety of industries, such as electronics, household and automobile. More importantly, silicones are used in healthcare as well when using implants for example.

All these reasons make it an incredibly clear choice: RTV silicones are the desired choice, but which one?

At the start of the project, the ZA 00 Traslucido silicone is used for a test sample. The test concluded with the findings that this specific silicone breaks very easily and that there is a large difference when choosing amongst silicones.

The feasibility of the project still needs to be kept in mind, however. There is no option for this project to keep trying different types of silicones to find the best silicone out there for this design as these small test bottles are relatively expensive. There just needs to be an option that works in this case.

For this reason a visit to the FormX store in Amsterdam is made with the purpose of asking an expert on some advice regarding this choice.

This is when the materials manufactured by the company Smooth-On are introduced to the project. They provide a large variety of silicons in different categories as seen in the separate document in the attachments provided by Smooth-On.

This data chart shows materials with their properties and makes it clear that platinum-cure silicone rubbers are the optimal choice for the following reasons:

- Relatively short cure time, meaning it can be produced and be ready at a relatively quick pace.
- High elongation of 600-1000%.
- Perfect useful temperature range for thermal disinfection.

When feeling the samples at the store in FormX, the choice is made to prototype with the Dragon Skin FX-Pro. With a claimed and proved elongation of approximately 700-800%, this silicone should be proper for a functional prototype. It is a very strong silicone that does not tear easily and feels really comfortable on the skin when fully cured.

It is recommended to perform further research into material choice to find out whether an even more optimal silicone could be used in the future project.

# Production and Costs


**Figure 15. The chosen material: Smooth-On's Dragon Skin FX-Pro Silicone.**

| | Product Name | A:B Mix Ratio By Volume | A:B Mix Ratio By Weight | Mixed Viscosity (ASTM D-2393) | Pot Life (ASTM D-2471) | Cure Time @ 73°F/23°C | Shore A Hardness (ASTM D-2240) | Specific Gravity (g/cc) (ASTM D-1475) | Specific Volume (cu. in./lb.) (ASTM D-1475) | Die B Tear Strength (ASTM D-624) | Tensile Strength (ASTM D-412) | Shrinkage (in./in.) (ASTM D-2566) | Elongation at Break % (ASTM D-412) | Useful Temperature Range | Color |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Tin-Cure Silicone Rubber | Mold Max® 10 | N/A | 100A:10B pbw | 15,000 cps | 45 min. | 24 hrs. | 10A | 1.15 | 24.1 | 100 pli | 473 psi | 0.001 | 529% | -65°F/-53°C to 400°F/205°C | Light Pink |
| | Mold Max® 10T | N/A | 100A:10B pbw | 14,000 cps | 45 min. | 24 hrs. | 10A | 1.09 | 25.4 | 87 pli | 405 psi | 0.0025 | 586% | -65°F/-53°C to 400°F/205°C | Translucent |
| | Mold Max® 14NV | N/A | 100A:10B pbw | 7,500 cps | 40 min. | 4 hrs. | 14A | 1.12 | 24.7 | 87 pli | 490 psi | 0.002 | 600% | -65°F/-53°C to 400°F/205°C | White |
| | Mold Max® 15T | N/A | 100A:10B pbw | 20,000 cps | 45 min. | 24 hrs. | 15A | 1.08 | 25.6 | 94 pli | 490 psi | 0.002 | 600% | -65°F/-53°C to 400°F/205°C | Translucent |
| | Mold Max® 20 | N/A | 100A:10B pbw | 25,000 cps | 45 min. | 24 hrs. | 20A | 1.18 | 23.5 | 110 pli | 555 psi | 0.001 | 512% | -65°F/-53°C to 400°F/205°C | Light Pink |
| | Mold Max® 27T | N/A | 100A:10B pbw | 30,000 cps | 45 min. | 24 hrs. | 27A | 1.11 | 25.0 | 110 pli | 575 psi | 0.002 | 400% | -65°F/-53°C to 400°F/205°C | Translucent |
| | Mold Max® 25 | N/A | 100A:5B pbw | 25,000 cps | 60 min. | 24 hrs. | 25A | 1.18 | 23.5 | 130 pli | 577 psi | 0.001 | 375% | -65°F/-53°C to 400°F/205°C | Purple |
| | Mold Max® 29NV | N/A | 100A:10B pbw | 10,000 cps | 40 min. | 6 hrs. | 29A | 1.17 | 23.7 | 96 pli | 417 psi | 0.002 | 361% | -65°F/-53°C to 400°F/205°C | Yellow |
| | Mold Max® 30 | N/A | 100A:10B pbw | 25,000 cps | 45 min. | 24 hrs. | 30A | 1.18 | 23.5 | 125 pli | 577 psi | 0.002 | 300% | -65°F/-53°C to 400°F/205°C | Pink |
| | Mold Max® XLS® II | N/A | 100A:10B pbw | 30,000 cps | 40 min. | 24 hrs. | 30A | 1.22 | 22.7 | 110 pli | 550 psi | 0.001 | 375% | -65°F/-53°C to 400°F/205°C | Blue |
| | Mold Max® 40 | N/A | 100A:10B pbw | 45,000 cps | 45 min. | 24 hrs. | 40A | 1.14 | 24.3 | 120 pli | 550 psi | 0.004 | 250% | -65°F/-53°C to 400°F/205°C | Mint Green |
| | Mold Max® 60 | N/A | 100A:3B pbw | 20,000 cps | 40 min. | 24 hrs. | 60A | 1.45 | 19.1 | 63 pli | 398 psi | 0.0015 | 132% | -65°F/-53°C to 560°F/294°C | Red |
| | Mold Max® Stroke® | N/A | 100A:10B pbw | Brushable | 30-45 min. | 16 hrs. | 30A | 1.18 | 23.5 | 125 pli | 577 psi | 0.002 | 300% | -65°F/-53°C to 400°F/205°C | White |
| | OOMOO® 25 | 1A:1B pbv | 100A:130B pbw | 4,250 cps | 15 min. | 75 min. | 25A | 1.34 | 20.6 | 40 pli | 240 psi | 0.0025 | 250% | -65°F/-53°C to 400°F/205°C | Light Blue |
| | OOMOO® 30 | 1A:1B pbv | 100A:130B pbw | 4,250 cps | 30 min. | 6 hrs. | 30A | 1.34 | 20.6 | 40 pli | 240 psi | 0.0025 | 250% | -65°F/-53°C to 400°F/205°C | Lavender |
| | Poyo® Putty 40 | 20A:1B pbv | 100A:6B pbw | Putty | 3-5 min. | 30 min. | 40A | 1.30 | 21.3 | 85 pli | 450 psi | 0.003 | 250% | -65°F/-53°C to 400°F/205°C | Light Pink |
| Platinum-Cure Silicone Rubber | Mold Star® 15 SLOW | 1A:1B pbv | 1A:1B pbw | 12,500 cps | 50 min. | 4 hrs. | 15A | 1.18 | 23.5 | 88 pli | 400 psi | <0.001 | 440% | -65°F/-53°C to 450°F/232°C | Green |
| | Mold Star® 16 FAST | 1A:1B pbv | 1A:1B pbw | 12,500 cps | 6 min. | 30 min. | 16A | 1.18 | 23.5 | 88 pli | 400 psi | <0.001 | 440% | -65°F/-53°C to 450°F/232°C | Blue-Green |
| | Mold Star® 19T | 1A:1B pbv | 1A:1B pbw | 11,000 cps | 3 min. | 12 min. | 19A | 1.08 | 25.6 | 90 pli | 420 psi | <0.001 | 470% | -65°F/-53°C to 450°F/232°C | Translucent |
| | Mold Star® 20T | 1A:1B pbv | 1A:1B pbw | 11,000 cps | 6 min. | 30 min. | 20A | 1.08 | 25.6 | 90 pli | 420 psi | <0.001 | 470% | -65°F/-53°C to 450°F/232°C | Translucent |
| | Mold Star® 30 | 1A:1B pbv | 1A:1B pbw | 12,500 cps | 45 min. | 6 hrs. | 30A | 1.12 | 24.7 | 88 pli | 420 psi | <0.001 | 339% | -65°F/-53°C to 450°F/232°C | Blue |
| | Dragon Skin® FX Pro | 1A:1B pbv | 1A:1B pbw | 18,000 cps | 12 min. | 40 min. | 2A | 1.062 | 25.0 | 61 pli | 288 psi | <0.001 | 763% | -65°F/-53°C to 450°F/232°C | Translucent |
| | Dragon Skin® 10 NV | 1A:1B pbv | 1A:1B pbw | 6,000 cps | 15 min. | 75 min. | 10A | 1.07 | 25.8 | 90 pli | 400 psi | <0.001 | 663% | -65°F/-53°C to 450°F/232°C | Translucent |
| | Dragon Skin® 10 Very Fast | 1A:1B pbv | 1A:1B pbw | 23,000 cps | 4 min. | 30 min. | 10A | 1.07 | 25.8 | 102 pli | 475 psi | <0.001 | 1,000% | -65°F/-53°C to 450°F/232°C | Translucent |
| | Dragon Skin® 10 Fast | 1A:1B pbv | 1A:1B pbw | 23,000 cps | 8 min. | 75 min. | 10A | 1.07 | 25.8 | 102 pli | 475 psi | <0.001 | 1,000% | -65°F/-53°C to 450°F/232°C | Translucent |
| | Dragon Skin® 10 Medium | 1A:1B pbv | 1A:1B pbw | 23,000 cps | 20 min. | 5 hrs. | 10A | 1.07 | 25.8 | 102 pli | 475 psi | <0.001 | 1,000% | -65°F/-53°C to 450°F/232°C | Translucent |
| | Dragon Skin® 10 Slow | 1A:1B pbv | 1A:1B pbw | 23,000 cps | 45 min. | 7 hrs. | 10A | 1.07 | 25.8 | 102 pli | 475 psi | <0.001 | 1,000% | -65°F/-53°C to 450°F/232°C | Translucent |
| | Dragon Skin® 20 | 1A:1B pbv | 1A:1B pbw | 20,000 cps | 25 min. | 4 hrs. | 20A | 1.08 | 25.6 | 120 pli | 550 psi | <0.001 | 620% | -65°F/-53°C to 450°F/232°C | Translucent |
| | Dragon Skin® 30 | 1A:1B pbv | 1A:1B pbw | 30,000 cps | 45 min. | 16 hrs. | 30A | 1.08 | 25.7 | 108 pli | 500 psi | <0.001 | 364% | -65°F/-53°C to 450°F/232°C | Translucent |
| | Smooth-Sil® 935 | N/A | 100A:10B pbw | 40,000 cps | 45 min. | 24 hrs. | 35A | 1.18 | 23.5 | 115 pli | 650 psi | <0.001 | 300% | -65°F/-53°C to 450°F/232°C | Blue |
| | Smooth-Sil® 936 | N/A | 100A:10B pbw | 21,000 cps | 60 min. | 24 hrs. | 36A | 1.21 | 22.9 | 110 pli | 550 psi | <0.001 | 170% | -65°F/-53°C to 450°F/232°C | Blue |
| | Smooth-Sil® 940 | N/A | 100A:10B pbw | 35,000 cps | 30 min. | 24 hrs. | 40A | 1.18 | 23.4 | 100 pli | 600 psi | <0.001 | 300% | -65°F/-53°C to 450°F/232°C | Pink |
| | Smooth-Sil® 945 | 1A:1B pbv | 1A:1B pbw | 30,000 cps | 25 min. | 6 hrs. | 45A | 1.24 | 22.3 | 120 pli | 700 psi | <0.001 | 320% | -65°F/-53°C to 450°F/232°C | Purple |
| | Smooth-Sil® 950 | N/A | 100A:10B pbw | 35,000 cps | 45 min. | 18 hrs. | 50A | 1.24 | 22.3 | 155 pli | 725 psi | <0.001 | 320% | -65°F/-53°C to 450°F/232°C | Blue |
| | Smooth-Sil® 960 | N/A | 100A:10B pbw | 30,000 cps | 45 min. | 16 hrs. | 60A | 1.25 | 22.2 | 110 pli | 650 psi | <0.001 | 270% | -65°F/-53°C to 450°F/232°C | Green |
| | Sorta-Clear® 12 | 1A:1B pbv | 1A:1B pbw | 6,000 cps | 40 min. | 12 hrs. | 12A | 1.07 | 25.9 | 80 pli | 320 psi | <0.001 | 590% | -65°F/-53°C to 450°F/232°C | Translucent |
| | Sorta-Clear® 18 | N/A | 100A:10B pbw | 21,000 cps | 60 min. | 24 hrs. | 18A | 1.08 | 25.6 | 80 pli | 425 psi | <0.001 | 545% | -65°F/-53°C to 450°F/232°C | Translucent |
| | Sorta-Clear® 37 | 1A:1B pbv | 1A:1B pbw | 35,000 cps | 25 min. | 4 hrs. | 37A | 1.08 | 25.6 | 105 pli | 600 psi | <0.001 | 400% | -65°F/-53°C to 450°F/232°C | Translucent |
| | Sorta-Clear® 40 | N/A | 100A:10B pbw | 35,000 cps | 60 min. | 16 hrs. | 40A | 1.08 | 25.6 | 120 pli | 800 psi | <0.001 | 400% | -65°F/-53°C to 450°F/232°C | Translucent |
| | Rebound® 25 | 1A:1B pbv | 1A:1B pbw | Brushable | 20 min. | 6 hrs. | 25A | 1.14 | 23.5 | 102 pli | 515 psi | <0.001 | 690% | -65°F/-53°C to 450°F/232°C | Orange |
| | Rebound® 40 | 1A:1B pbv | 1A:1B pbw | Brushable | 20 min. | 6 hrs. | 40A | 1.14 | 23.5 | 106 pli | 486 psi | <0.001 | 324% | -65°F/-53°C to 450°F/232°C | Green |
| | EcoFlex® Gel | 1A:1B pbv | 1A:1B pbw | 9,300 cps | 15 min. | 2 hrs. | 000-35 | 0.98 | 28.0 | N/A | N/A | <0.001 | 1,000% | -65°F/-53°C to 450°F/232°C | Translucent |
| | EcoFlex® 00-10 | 1A:1B pbv | 1A:1B pbw | 14,000 cps | 30 min. | 4 hrs. | 00-10 | 1.04 | 26.6 | 22 pli | 120 psi | <0.001 | 800% | -65°F/-53°C to 450°F/232°C | Translucent |
| | EcoFlex® 00-20 | 1A:1B pbv | 1A:1B pbw | 3,000 cps | 30 min. | 4 hrs. | 00-20 | 1.07 | 26.0 | 30 pli | 160 psi | <0.001 | 845% | -65°F/-53°C to 450°F/232°C | Translucent |
| | EcoFlex® 00-30 | 1A:1B pbv | 1A:1B pbw | 3,000 cps | 45 min. | 4 hrs. | 00-30 | 1.07 | 26.0 | 38 pli | 200 psi | <0.001 | 900% | -65°F/-53°C to 450°F/232°C | Translucent |

**Figure 16. A page in the tech charts of Smooth-On (full tech charts are provided as a separate document in the attachments), displaying the properties of some of the materials.**

## Production

When producing products of any plastic or rubber, in the current day of technology, two production methods rise above most others: injection molding and 3D printing (see Figure 17 and Figure 18).

There are other methods like vacuum forming and thermoforming, but the flaw in these methods is that they usually limit the shape of the product in a single direction, which ends up unviable for the design of the product.

Injection Molding (see Figure 17) is a method where a mold and the machine are purchased up front. This brings large costs with itself that can accumulate to tens, if not hundreds of thousands of euros. The machine is fed material (at this point solid) through the feeder hopper at the top, after which the screw moves the material through the heaters into the mould. This heat causes the material to melt and become liquid.

Because of the narrow entry, the liquid material is then pushed into the mold with a relatively high pressure and cools down inside the mold. As the material reaches a reliable solid state, it is pushed out and this process is rinsed and repeated.

This method is as of this project a widely used technology to create cases and parts for products for a very long time. The benefit here lies in the mass production, winning a profit on each single product, which breaks even and surpasses the investment initially put into the mold.

When looking at a startup like SyncVR, this method has an upfront cost that is too expensive. Their batch of products will not reach the counts tens of thousands of products or even more to make it worth the investment that is put into the mold and the machine.

The other popular and more recent production method is 3D printing. Here a single device accurately prints a 3D model that is fed into the printer through a file. 3D printers have become more and more advanced over the years and humans are capable of printing for cheaper and with wider varieties of materials than ever before. The problem in this method is the unit costs however. Printing a single rubber-like product.

According to an employee at the Applied Labs of the faculty Industrial Design Engineering in the TU Delft, the costs for printing a rubber-like product like the design displayed in Figure 24 on page 41 costs over 200 euros in costs at the Applied Labs and would cost way more including labour costs.

This thought process is further elaborated upon in "Chapter XXVII - Production Study" on page 108.

RTV Silicone seems to be the perfect middle ground, where the mold does not have to be that expensive and the unit costs are also manageable if a washable product is used.

The two components of RTV silicone harden inside the mold, so no pressure or high temperatures are used in this process, allowing for molds to even be 3D printed as demonstrated from "Chapter XXVII - Production Study" on page 108 onwards.

## Costs

When looking at 3D printing the mold itself, two options of printing exist; the cheaper, but less detailed Fused Deposition Modeling (FDM) printing and the more expensive, but more detailed and reliable Stereolithography Apparatus (SLA) printing.

Printing molds requires knowledge about the print time and weight of the prints. Printing the mold through FDM would make it weigh approximately 2750 grams and would take 10.4 days (source: the Ultimaker Cura software). For printing through SLA, only knowledge about volume is required, which results in approximately 9 liters of resin (source: the Formlabs PreForm software).

When looking at the costs of printing all the molds with pricing stated on Makerpoint (https://www.makerpoint.nl/nl/solutions/diensten/3d-printen/):

- Purchasing through FDM would approximately cost 1250 euros (without discount, 250 hours x 5 euros/hr).
- Whereas purchasing an FDM printer and filament (Ultimaker 3 and 11 kilograms of filament), would cost 3500 euros + 2,75 kg x 25 euros = 3570 euros.
- Purchasing through SLA would approximately cost 26.000 euros (without discount, 3 euros x 8703cc),
- Whereas purchasing an SLA printer and resin itself (Form 3 and 9 liters of resin), would cost 4000 euros + 9x400 euros, which is a total of 7600 euros.

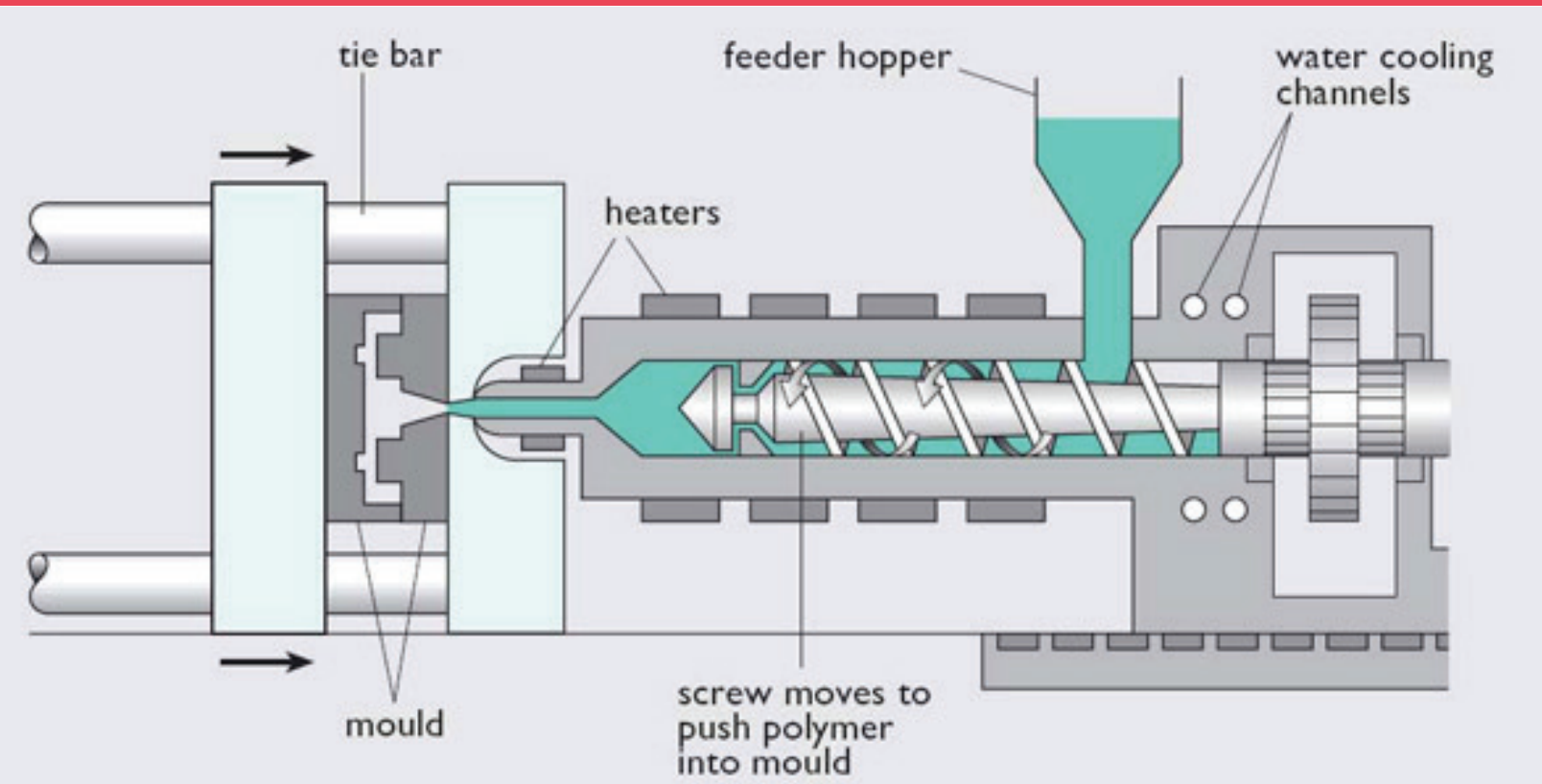



Figure 17. Visualisation explaining injection molding, retrieved at 15 August 2019 from https://aplusplastics.com.au/about/what-is-injection-moulding/

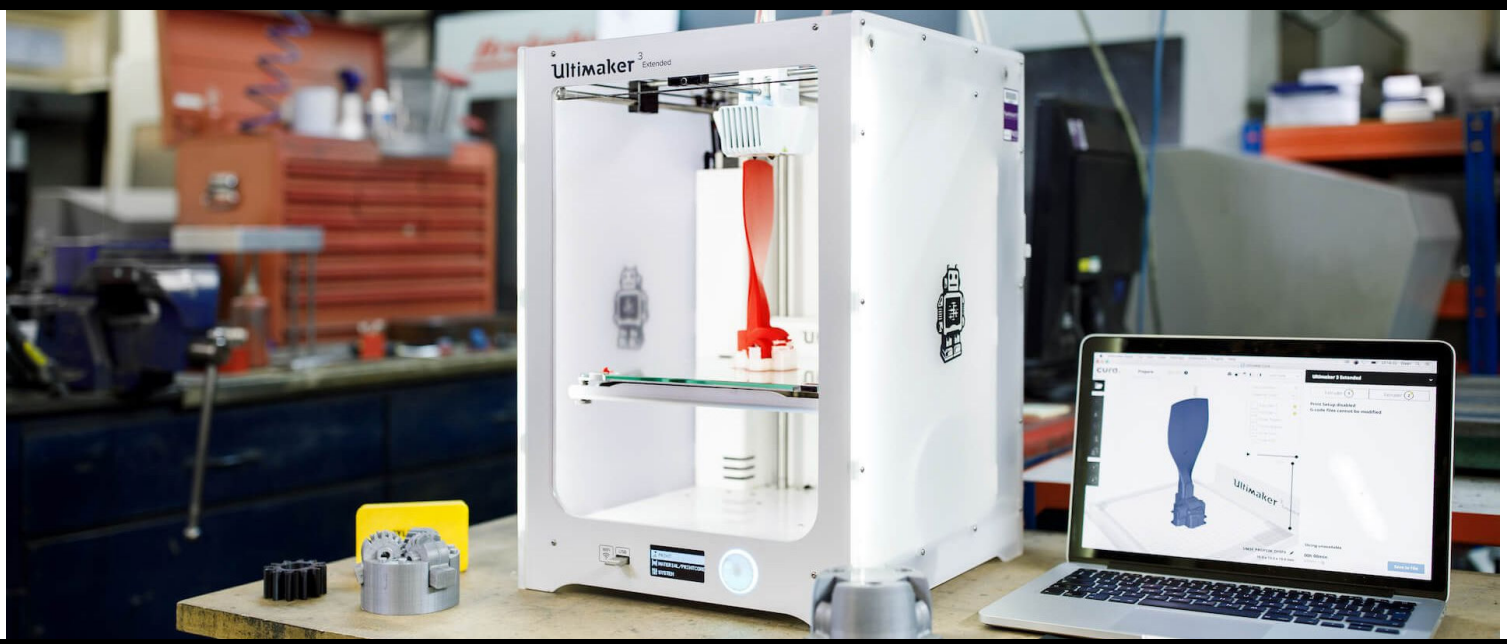



Figure 18. Photo displaying a 3D printer (Ultimaker) and the software that comes with it (Cura), retrieved at 15 August 2019 from https://ultimaker.com/en/blog/52652-the-five-key-3d-printing-applications

| Product | | price € | discnt | Qt | BO | price disc | vat | price net € |
|---|---|---|---|---|---|---|---|---|
| skinproxxx | Dragon Skin FXPro /399.16 kg | 11445.00 | 6 | 1 | | 10758.30 | 21 | 10758.30 |

| | | |
|---|---|---|
| | payment costs | |
| your VAT: | shipping costs | |
| our VAT: NL 822851659B01 | Total costs | 0.00 |
| terms: Pre Paid | total VAT 21% (BTW) | 2259.24 |
| trading currency: EUR | Invoice Amount € | 13017.54 |

Geachte Yasir Tüfekçi,

Wij danken u voor uw aanvraag. U vindt onze offerte in de bijlage.

Lead time: voor een drum unit is 10 werkdagen
Transittijd met zeevracht is 6-8 weken
Kiest U voor de optie van zeevracht, willen wij U graag 6% korting aanbieden.

**Figure 19. Offer from FormX for a mass delivery of 400kg of the Dragon Skin FX-Pro**

Override Mass Properties... Recalculate

Include hidden bodies/components

Create Center of Mass feature

Show weld bead mass

Report coordinate values relative to: -- default --

Mass properties of selected components
Coordinate system: -- default --

The center of mass and the moments of inertia are output in the coordinate
Mass = 8964.52 grams

Volume = 8703414.34 cubic millimeters

Surface area = 733314.05 square millimeters

Center of mass: ( millimeters )
X = 79.81
Y = 44.54
Z = -55.24

Principal axes of inertia and principal moments of inertia: ( grams * square n
Taken at the center of mass.
Ix = ( 1.00, 0.00, 0.00) Px = 60376070.81
Iy = ( 0.00, 0.99, -0.16) Py = 67468135.61
Iz = ( 0.00, 0.16, 0.99) Pz = 90483626.02

Moments of inertia: ( grams * square millimeters )
Taken at the center of mass and aligned with the output coordinate system.
Lxx = 60376073.80 Lxy = 4550.62 Lxz = -692.79
Lyx = 4550.62 Lyy = 68027380.26 Lyz = -3543811.83
Lzx = -692.79 Lzy = -3543811.83 Lzz = 89924378.39

Moments of inertia: ( grams * square millimeters )
Taken at the output coordinate system.
Ixx = 105520707.02 Ixy = 31873938.99 Ixz = -39526419.8
Iyx = 31873938.99 Iyy = 152489959.99 Iyz = -25602858.9
Izx = -39526419.85 Izy = -25602858.97 Izz = 164814515.1

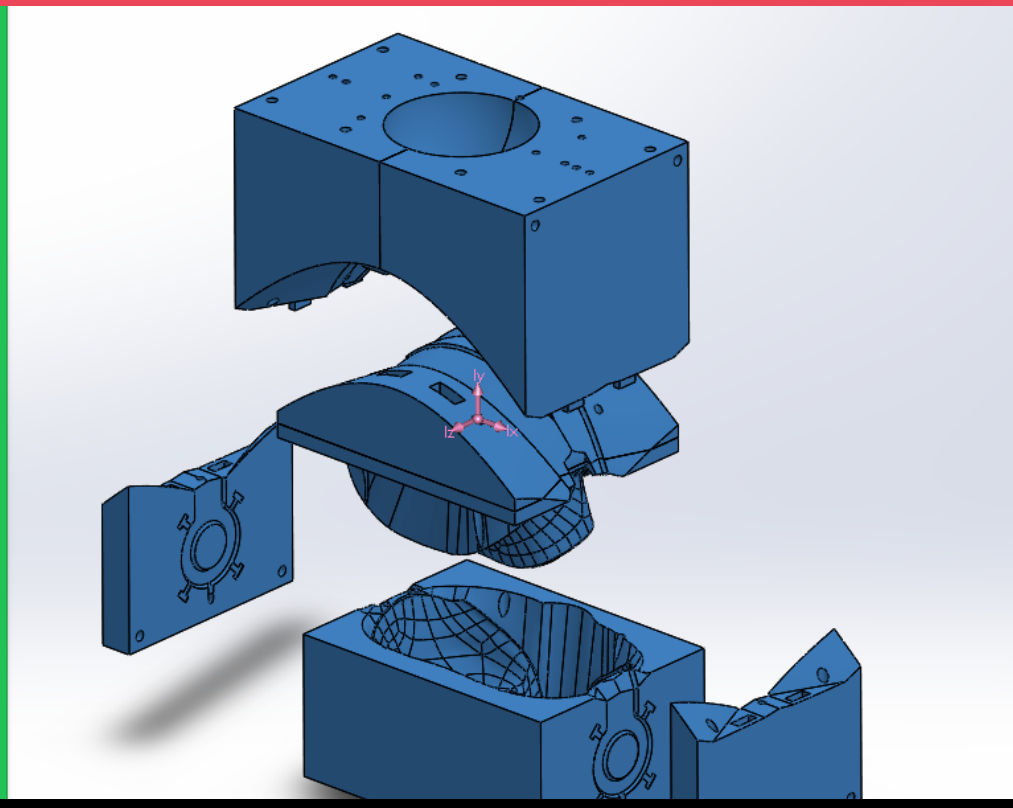


**Figure 20. Screenshot displaying the volume of the entire mold (3D printing is however performed with 20% infil, which this does not account for)**

Report coordinate values relative to: -- default --

Mass properties of Headband v4 - Full Design v2
Configuration: Default
Coordinate system: -- default --

Density = 0.00 grams per cubic millimeter

Mass = 281.30 grams

Volume = 273102.16 cubic millimeters

Surface area = 95370.50 square millimeters

Center of mass: ( millimeters )
X = -102.81
Y = 2.20
Z = -79.21

Principal axes of inertia and principal moments of inertia: ( grams * square n
Taken at the center of mass.
Ix = ( 1.00, 0.00, 0.00) Px = 614984.03
Iy = ( 0.00, -0.19, -0.98) Py = 1396630.05
Iz = ( 0.00, 0.98, -0.19) Pz = 1605331.45

Moments of inertia: ( grams * square millimeters )
Taken at the center of mass and aligned with the output coordinate system.
Lxx = 615003.39 Lxy = -293.93 Lxz = 3907.24
Lyx = -293.93 Lyy = 1597844.51 Lyz = 38812.40
Lzx = 3907.24 Lzy = 38812.40 Lzz = 1404097.64

Moments of inertia: ( grams * square millimeters )
Taken at the output coordinate system.

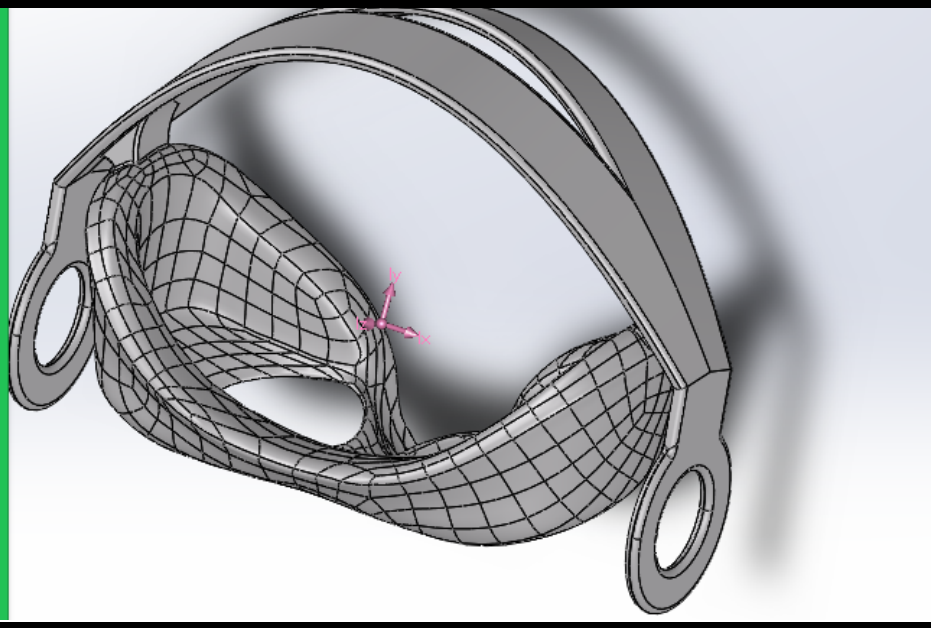


**Figure 21. Screenshot displaying the mass properties of the final design**

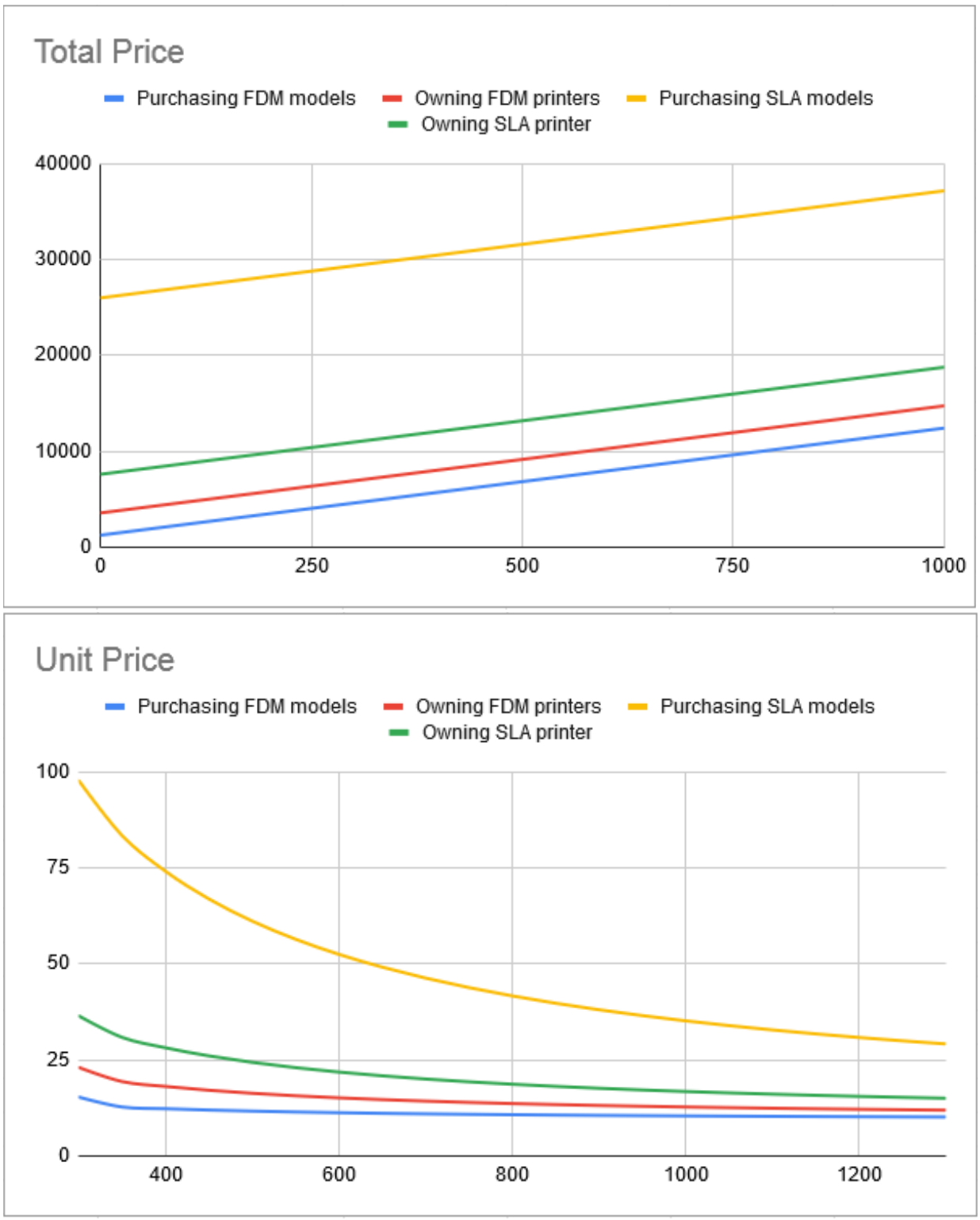



**Figure 22. Graphs displaying the relation between the total price and the unit price (y-axis) and amount of units (x-axis) over a larger unit ratio.**

In terms of production itself, this product can be manufactured in the Netherlands by hiring pupils in the secondary education between 15 and 18 years old (paid for approximately 4 euros per hour on average as found in https://www.rijksoverheid.nl/onderwerpen/minimumloon/bedragen-minimumloon-bbl-opleiding/bedragen-minimumloon-bbl-2019) and educating them to work with a series of vacuum pumps (approximately 150 euros each) per employee working simultaneously. Older employees will usually guarantee more accuracy and therefore a higher quality of work, but will be more expensive.

A full cycle of production consists of a preparation phase and a finishing phase.

The preparation phase consists of fixing the mold together, pouring the materials into a cup, mixing them together, vacuuming the cup, letting the cup vacuum, releasing the vacuum, pouring the mixture into the mold.

The finishing phase consists of pulling the mold apart, trimming the edges and packaging the glasses.

During the time in between the preparation and finishing, the material is curing inside the mold. In the mean time, the employee can work on the preparation or finishing phase of another unit to work in a more efficient manner. The cure time depends on each

In experience throughout this project and some guesstimations, both phases take approximately 15 minutes each, making the total production time approximately 30 minutes, which results in 2 euros per unit in labour costs.

The total costs and unit costs are calculated and visualised in Figure 22. It is apparent that the FDM methods are cheaper. At a unit count of 1000, the unit price reaches 10-12 euros depending on whether a printer is bought or whether the printing service is outsourced to another company.

Having the flexibility of printing multiple molds for a much more efficient workflow and adjusting molds on the go, however, tilts the favor to owning FDM printers. The filament prices are incredibly cheap and if a mold becomes defect for any apparent reason, it can be easily replaced without having to find a third party to replace it for SyncVR.

This project has also proven that FDM printed molds are not damaged in any way if the molds are prepared properly.

This material, production and cost analysis proves the feasibility of this project is real with a unit cost of 12 euros at 1000 units. SyncVR confirms that this unit size is realistic for them in the near future.

Approximately 72% of these costs are the material costs themselves. It is therefore highly recommended to optimize the use of the material as much as possible and to perhaps choose for a cheaper material that still meets all wishes and demands.

The attachments provide more context in prototypes, production and more information to support this chapter.

# XV - Program of

A program of wishes and demands is a list of criteria that is set up in order to allow for judgement in design decisions. All decisions that are made during the process originate from the demands and wishes that are listed in this program.

**LEGEND**

¤ Demands
+ Wishes

## 1. PERFORMANCE

¤ The design of this project must be able to carry the weight of the base product, which is approximately 361 grams (see Figure 23).

¤ The product must be mountable onto the Oculus Go at a quicker pace than the original headband and facial interface, which is 100 seconds to two minutes (see "Chapter X - Usability Research" on page 20 and "Chapter XII - Usage Scenario" on page 24).

+ It is desirable for the product to be able to withstand unintended use of the product; such as pulling, stretching, falling and the sorts, up to a force of 50 Newton.

## 2. ENVIRONMENT

+ The product should be disinfectable. This means that the material must be able to withstand the temperatures of thermal disinfection (70-90 degrees Celcius) and be immersed in water without being damaged (see "A0 Thermal Disinfection Concept" on page 67).

+ It is preferred that the surface does not contain holes. Bacteria and the likes have an easier time getting into these holes and cleaning them is more difficult (see "Chapter XIII - Hygiene Framework" on page 26).

## 3. PRODUCTION VIABILITY

¤ The design of this project must be viably produced or manufactured for a startup like SyncVR that does not have a large budget (see "Chapter XIV - Material, Production and Costs" on page 29).

+ It is desired to keep the costs of production as low as possible to keep it as viable as possible, preferably lower than 15 euros per unit (see "Chapter XIV - Material, Production and Costs" on page 29).

## 4. PACKAGING

¤ The design of this project must be packaged properly and in a hygiene manner (cleaned and disinfected) prior to transportation to the hospitals (see "Chapter XVII - Lifecycle" on page 44).

## 5. SHAPE & GEOMETRY

¤ This project must contain research with regards to the shape and geometry of the product (see "Chapter XI - Ergonomy Research" on page 22).

## 6. NORMS AND STANDARDS

¤ This project must contain research with regards to the European Medical Device Regulations (MDR) and must give advice on whether the design should be considered a medical design or not and why (see "Chapter XIII - Hygiene Framework" on page 26).

## 7. ERGONOMY

¤ The design of this project must meet the ergonmical requirements as seen "Chapter XI - Ergonomy Research" on page 22.

## 8. RE-USE AND END OF LIFE

¤ This project must contain information on what happens at the end of life of the design (see "Chapter XVII - Lifecycle" on page 44).

This list of criteria is further referred to in the rest of the project to substantiate the decisions that are made.

# Wishes and Demands


Figure 23. Weight of the base product

# PRODUCT

## Introduction

The Product Design section describes the final design of this project, including the designs of the mold and product and a description about the lifecycle, from birth to end.

This is the cumulative result of the research performed in the previous section.

# DESIGN

## Section Content

# XVI - Design

The design is separated into two parts: the product design and the mold design. Both aim to resolve the demands and wishes of this project.

## Product Design

The product design consists of several components that are merged to one; each with their own function and research. These components are the:

1. Connection
2. Headband
3. Facial Interface

The connection is an outcome of a combination of usage tests and iterative trial and error. These tests and iterations can be found in the attachments of this report.

The connection is a loop that can be connected on to a 3D-printed hook. This hook only needs to be printed twice for each Oculus Go and can be periodically cleaned together with the Oculus as it is clicked onto the connection base and secured with silicone glue.

The headband and facial interface evolve throughout to project and follow the shape and size requirements as set in "Chapter XI - Ergonomy Research" on page 22 with the understanding that the flexibility of the material means that a retention feature is not necessary and would introduce unnecessary complications to the product.

## Mold Design

The mold design has seen design iterations as well. The first mold (milled in foam) aims to prove the feasibility of using this production method in the first place. This mold only contains the headband portion of the design.

As the design is iterated upon, the second mold (printed in 3D) aims to unify the entire design into a single mold. The mold does get more complicated because of this decision, but the trade-off here is that if the mold is separated into multiple pieces, an assembly stage needs to take place after production.

So the choice here is between a more complicated mold, which is produced and prepared once over an assembly stage after production, that will bring extra costs with itself for the production of every individual unit.

This mold also introduced the material that is used during the remainder of this project and preparation of the mold using a sealant and vaseline as described in "Chapter XIV - Material, Production and Costs" on page 29.

The third and final mold of this project includes the final design, including all changes to the design and meeting the demands set in "Chapter XV - Program of Wishes and Demands" on page 36.

## Prototype Execution

All molds have been prototyped and the design iterations following up on them improved the next mold.

The prototypes themselves are improved as the production technique is further optimized. The final prototype for this project serves the functional purpose of demonstrating improved usability.

Two versions of the protype are produced in the final mold:

- The first version is one where the material is vacuumed separately, mixed together and vacuumed for a longer period of time afterwards. The reason for this is to remove as many bubbles from the material as possible. The insights for this prototype are that the material did not manage to go through the entire mold as it cured too quickly.
- In the second version, the material is directly mixed and vacuumed as shortly as possible without leaving too many bubbles in the material. The reason for this is to try and allow the material more time to pass through the mold. The insights for this version are similar to the first version.

A hypothesis for fixing these problems is to cool the material down prior to vacuuming it by either putting the material in a fridge or a freezer (the material should be able to withstand the cold temperatures of a freezer).

It is really easy to apply onto the Oculus Go and equipping a person with it takes approximately five to ten seconds. Unequipping takes even less time. The connection is firm and steady. These insights are confirmed in a small-scale private test and is recommended to be usage tested with nurses.

Figure 24. TOP: The prototype equipped (equipping takes approximately 10 seconds), BOTTOM: The Final Design

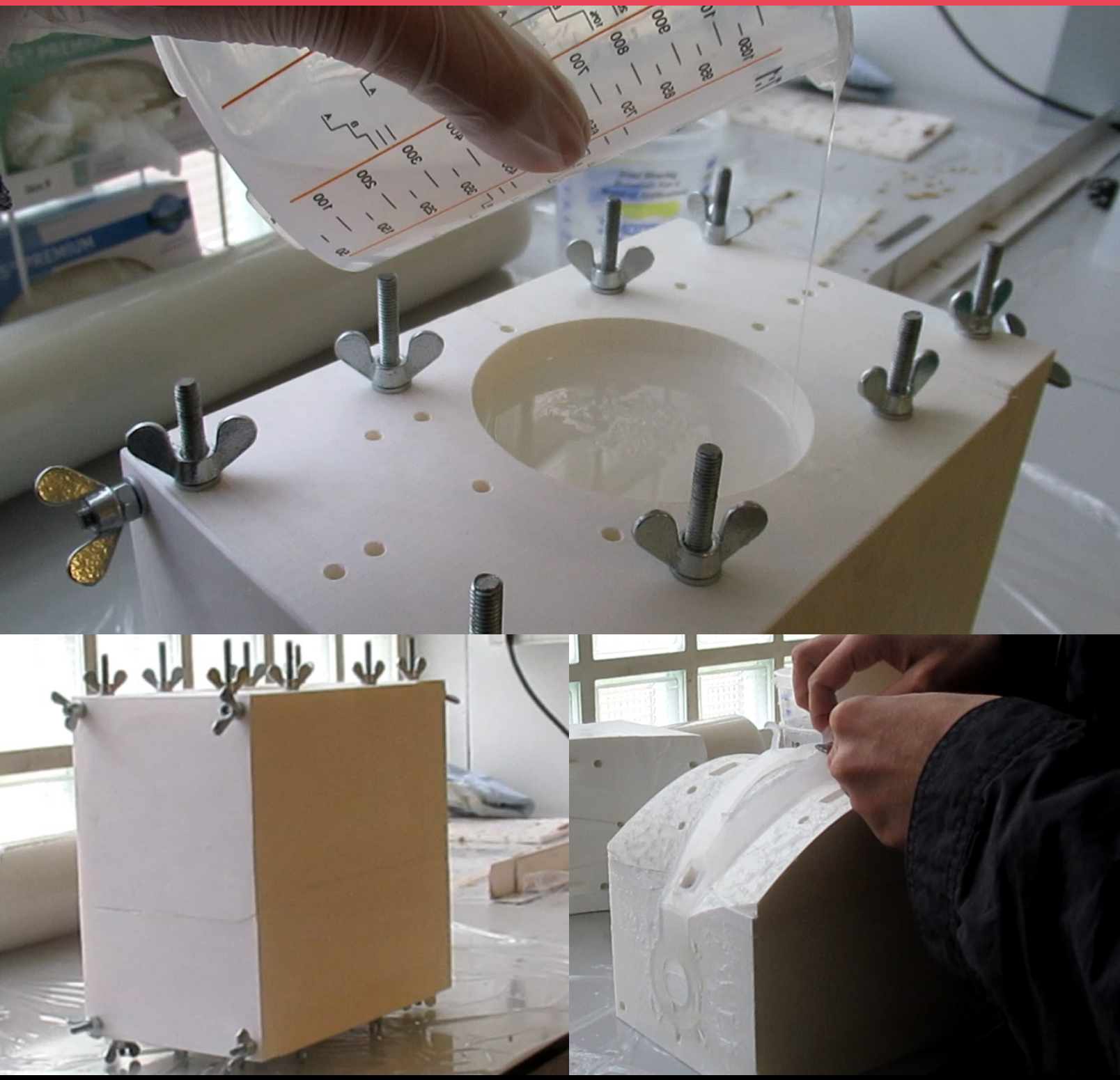


Figure 25. The Final Mold (TOP: Pouring the mixed and vacuumed silicon into the mold, BOTTOM LEFT: The silicon is curing inside the mold, BOTTOM RIGHT: The product is being taken out of the mold).


**Figure 26. The Final Prototype**

# XVII - Lifecycle

## Introduction

The lifecycle of a product means a description of all the steps, from production to use and end of life. The reason this description is desired is to gain insights in how the product will reach the users, what will happen after usage and at the end of life.

## Lifecycle

A visualisation for the lifecycle can be found in Figure 25.

### Product R&D

The product starts with an iterative Research and Design (R&D) phase, similar to this project. After the R&D phase is completed up to SyncVR's content, the production cycle will begin. In the mean time it is preferred to keep researching and designing improvements to the current product or creating a product line that creates opportunities to use the design on a collection of different headsets. Improvements in this field are recommended in "Chapter XVIII - Recommendations" on page 48.

### Production and Packaging

During R&D, SyncVR develops a strategy for production and packaging. Whether this is done internally at their office, at an external manufacturer in the Netherlands or one abroad is a choice that needs to be made as well. Recommendations on how the production should be executed are mentioned in "Chapter XIV - Material, Production and Costs" on page 29.

### Transportation

After producing a batch, this batch needs to be shipped, trucked or transported in another way to the destination. As SyncVR grows and depending on the location of producing, they may end up deciding to arrange storage locations and distribution centers to allow for quicker responses and deliveries.

### Use

The product is used once on a single patient. The desired user experience scenario is described in "Chapter XII - Usage Scenario" on page 24.

### Collection

After a single use, the product is collected by either SyncVR or the hospital staff. This is where the product is first checked on whether it is still intact. If the product is damaged beyond repair, it is sent to a garbage disposal, which marks the end of life.

The most preferred scenario is one where the cleaning and re-packaging happens inside the hospitals themselves. However, many hospitals do not have these commodities. This means that they need an external party to do the cleaning for them. In this case, the product is collected by SyncVR and transported to the location where the cleaning will happen.

### Cleaning and Re-packaging

If the product is intact, it is cleaned and disinfected first and packaged right afterwards. This may require a separate cleaning center (be it external or internal) to demonstrate this process to hospitals interested in purchasing the product. After re-packaging, the product is transported back to the hospital in batches in order for another single use per product.

### End of Life

If the product is not intact and cannot be repaired, the product ends at a garbage disposal. Room temperature vulcanizing silicone is a single-direction chemical process. Reverting this process or recycling the final product does not seem possible with the available technology as of this project.

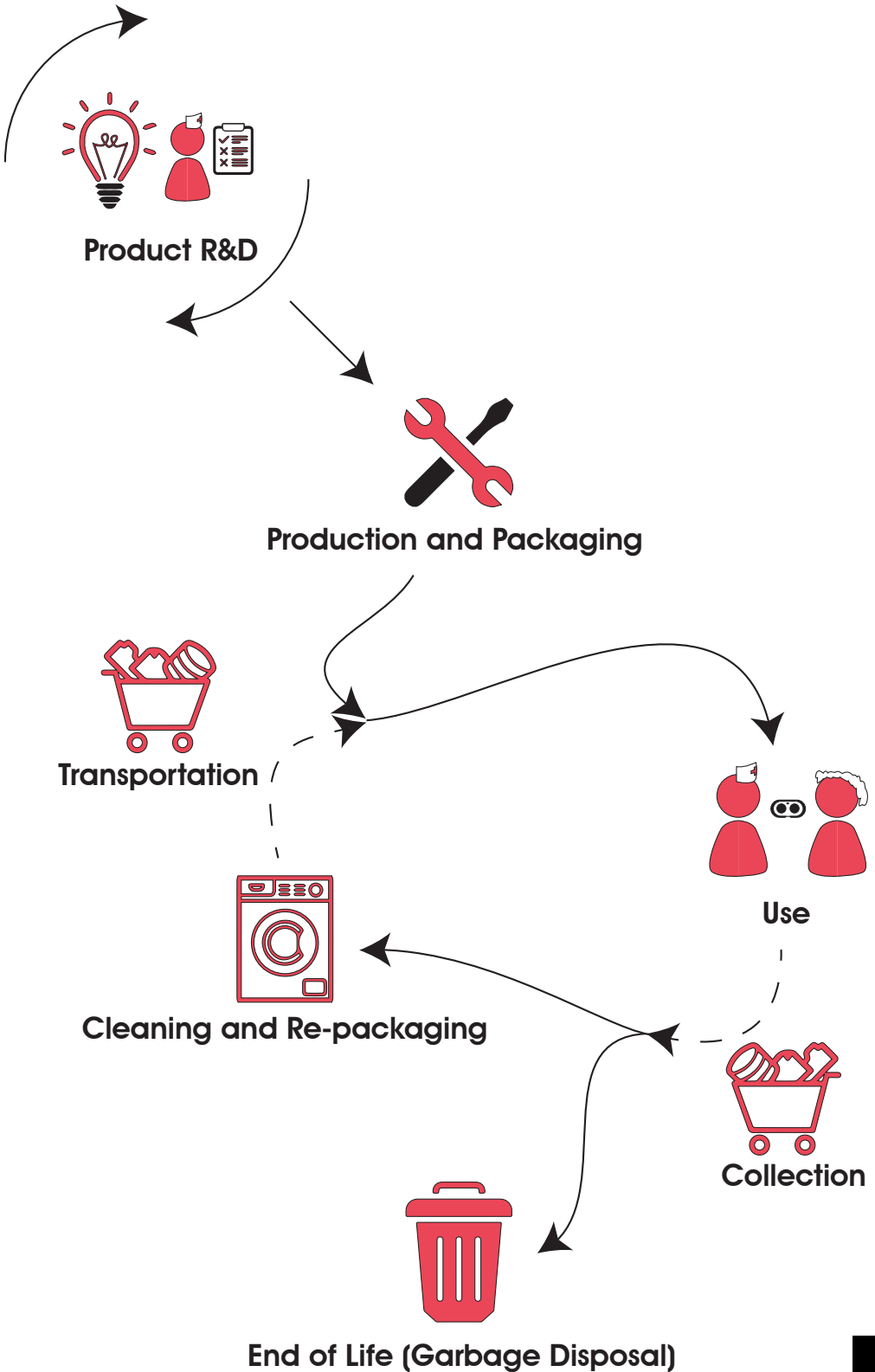



Figure 27. The Product Lifecycle

# EX

# TRAS

# XVIII - Recommendations

This project is executed in a timespan of five months. Design Projects usually take way longer than aforementioned timespan, mainly due to the sheer amount of work in researching and substantiating the different decisions that come in play when designing a fully fledged product.

This section explains all recommendations towards SyncVR that a future designer, design agency or graduate student can pick up and move forward with.

The list of recommendations is:

- Confirming the feasibility by finishing the prototype by fixing the problem where the material is not properly flowing through the mold (by possibly cooling the material to elongate the pot life).
- The tests mentioned in "Chapter XXIX - Design Changes" on page 122: Usage test for patient comfort and a physical test to find out the material resistance to thermal disinfection.
- Optimization to the model shapes and size, which allows for less material and therefore a lower cost (thus a higher feasibility).
- Researching other material possibilities (cheaper or less sloppy ones with a similar mechanical strength).
- Coming up with alternative disposable designs that are much cheaper but do not need to be cleaned and therefore do not require high versatility in terms of temperature or water resistance.
- Setting up an actual production line within SyncVR.
- In case SyncVR's software ends up becoming a medical device, implement changes necessary to conform with these regulations and provide a clear path for SyncVR to follow in getting their CE marking.

# XIX - Scientific References


- Desmet, P., Wassink, P., & S. (2002-2013). PrEmo (Product Emotion Measurement Instrument). Retrieved from http://diopd.org/premo-product-emotion-measurement-instrument/
- Deuning, C., & Limburg, W. (n.d.). Ziekenhuiszorg | Cijfers & Context | Aanbod | Volksgezondheidenzorg.info. Retrieved October 15, 2019, from https://www.volksgezondheidenzorg.info/onderwerp/ziekenhuiszorg/cijfers-context/aanbod.
- Oculus. (n.d.). Taking Care of Your Oculus Go. Retrieved June 12, 2019, from https://support.oculus.com/1594015150689599/
- Ford, S. R., Chenault, K. H., Bunton, L. S., Hampton, G. J., McCarthy, J., Hall, M. S., ... & Leach, F. R. (1996). Use of firefly luciferase for ATP measurement: other nucleotides enhance turnover. Journal of bioluminescence and chemiluminescence, 11(3), 149-167.
- Molenbroek, J. F. M. (2017). DINED CAESAR Project. Retrieved September 5, 2019 from https://dined.nl/en/database/tool
- Nederlandse Vereniging van Ziekenhuizen. (n.d.). Ziekenhuiszorg in cijfers. Retrieved from https://ziekenhuiszorgincijfers.nl/geleverde-zorg-in-ziekenhuizen.
- Nieren.nl. (2018, March 18). Aansluiting op de hemodialysemachine: de shunt. Retrieved from https://www.nieren.nl/bibliotheek/17-hemodialyse/205-aansluiting-op-de-hemodialysemachine-de-shunt.
- Lee, Y., & Park, J. (2013). Steps of Reprocessing and Equipments. Department of Internal Medicine, Dongguk University College of Medicine, Gyeongju, Korea.
- Rosenberg, U. (2003). Thermal Disinfection – The A0 Concept and the Biological Background. Zentralsterilisation. 11. 115.
- Spaulding, E. (1957). Chemical disinfection and antisepsis in the hospital.
- Verpleegkundige Werkwijze Access, & V&VN Dialyse en Nefrologie. (n.d.). Verpleegkundige aanbevelingen - Deel 3 - Technische aspecten. Retrieved from https://dialyse.venvn.nl/LinkClick.aspx?fileticket=xGOIAF8rmr4=&tabid=1679&portalid=11&mid=13808.
- Volksgezondheid, M. V. (2016, August 15). Veilige Toepassing van Medische Technologie in de medisch specialistische zorg. Retrieved June 19, 2019, from https://www.igj.nl/documenten/convenanten/2016/08/15/veilige-toepassing-van-medische-technologie-in-de-medisch-specialistische-zorg. PDF with the agreement can be found on the webpage, authors of the agreement are the NVZ, NFU, Revalidatie Nederland and ZKN.

ATTACHMENTS

# XX - Conclusion

The project concludes with a functional prototype that is supported by a product and a mold design. These designs have substantial research backing them up. The research performed for this project aimed to help all stakeholders at the same time, while at the same time fulfilling the challenges of the project.

The goal of creating a detachable connection that is significantly easier and quicker to equip onto the Oculus Go has been met. The redesign takes merely a couple of seconds to apply instead of the over 100 seconds it takes the current headgear to apply.

Next to that, the production technique allows the product to have a relatively small investment cost paired with a feasible unit cost of 12 euros for a washable product.

This design is made of silicone, a non-toxic, non-porous and washable material that can elongate and fit many different shapes of heads relatively comfortably.

The design does not need to conform to the rules and regulations of the Medical Device Regulations of the European government as of the end of this project, since the SyncVR software it is not a medical device.

The project concludes with a list of recommendations for a future graduating student to bring the project from a functional prototype to actual production.

# XXI - Reflection

***This section is a personal reflection on the project and is therefore written in first person.***

The project had a very challenging start. Finding out how to approach this properly and finding entry to the real environment was a challenging task to begin with. Reflecting back, there are plenty of decisions that I made adaptively that improved the flow of the project.

At the start of the project, I was trying to maintain a high priority with regards to my planning and noticed that took a lot of time from me; time which I should rather invest into the project itself.

This shift alongside the contacts from SyncVR in the Erasmus Medical Centre and the Maasstad Hospital sped up the entire process as I was able to get in touch with other professionals through my initial contacts in both hospitals.

The contact with the expert infection prevention allowed me to get in touch with other experts and further clarify on how this product could end up actually following the hygiene rules of hospitals in a proper manner. The contacts inside the Maasstad Hospital allowed me to usage test the first prototypes with actual nurses. This really showed how problematic the initial interaction was by proving that it took two nurses over 100 seconds to connect the headband and facial interface to the Oculus Go.

From here onwards, the focus was mainly on the last challenge: feasibility. Lots of research with regards to production, material and the shape/size of the design.

I really do feel like the second phase went a lot smoother with the direction and contacts settled. The third phase was however filled with struggles and could be better performed if I had zoomed out a little more. I took way longer than necessary in figuring out on how to work with the silicone, but I do like that my approach always contained multiple purposes. I was improving production and creating test samples for the shapes and size tensile tests at the same time for example.

All in all, I learned a lot during this project and all these experiences lead to an improved version of myself in the future. I would like to thank everyone involved in their helping hand in this project.

# ATTACH

# MENTS

# RESEARCH

## Introduction

This section in the attachments carries the research with regards to the challenges of the project and elaborates on them.

The three main challenges (Hygiene, Feasibility and User Experience) each carry or refer to their individual research methods, such as interviews, usage tests and scientific research.

The goal of this section is to generate valuable information that supports the design in the rest of the project.

# PROCESS

## Section Content

# XXII - Hygiene

This chapter in the attachments contains interviews and research about hygiene.

In order to comply to the laws and regulations that are in place to prevent contamination and preserve healthcare safety, the importance of hygiene in product design for target groups in these environments is vital.

## Summary

Hygiene is defined by the Cambridge Dictionary as "the degree to which people keep themselves or their environment clean, especially to prevent disease".

The Erasmus Medical Centre (referred to as the Erasmus MC) categorizes these degrees of hygiene into three sub-categories as per Spaulding Classification:

- Cleaning
- Disinfecting
- Sterilisation

As can be concluded from the interviews with the staff from the Erasmus MC, the design for this project does not need to be sterilised, but does need to be cleaned and disinfected or disposed.

However, the Erasmus MC is not the only organization that has a say in this matter. There are European and Dutch laws and other regulations that the device has to follow as well (see "Interview with Sebastiaan Notenboom (Program Coordinator Medical Technology)" on page 65.

The goal of this chapter is to gain insights in the field of hygiene by interviewing professionals in and outside of hospitals. The context surrounding hygiene does not merely stop at the question on whether to clean or disinfect, it encompasses the entire field of how deep this design can be introduced into hospitals (intensive care departments for example) and what rules and regulations play a major part in this design's existence.

The following pages contain these interviews and insights.

## Legend

Law

Standards and regulations out of industry associations

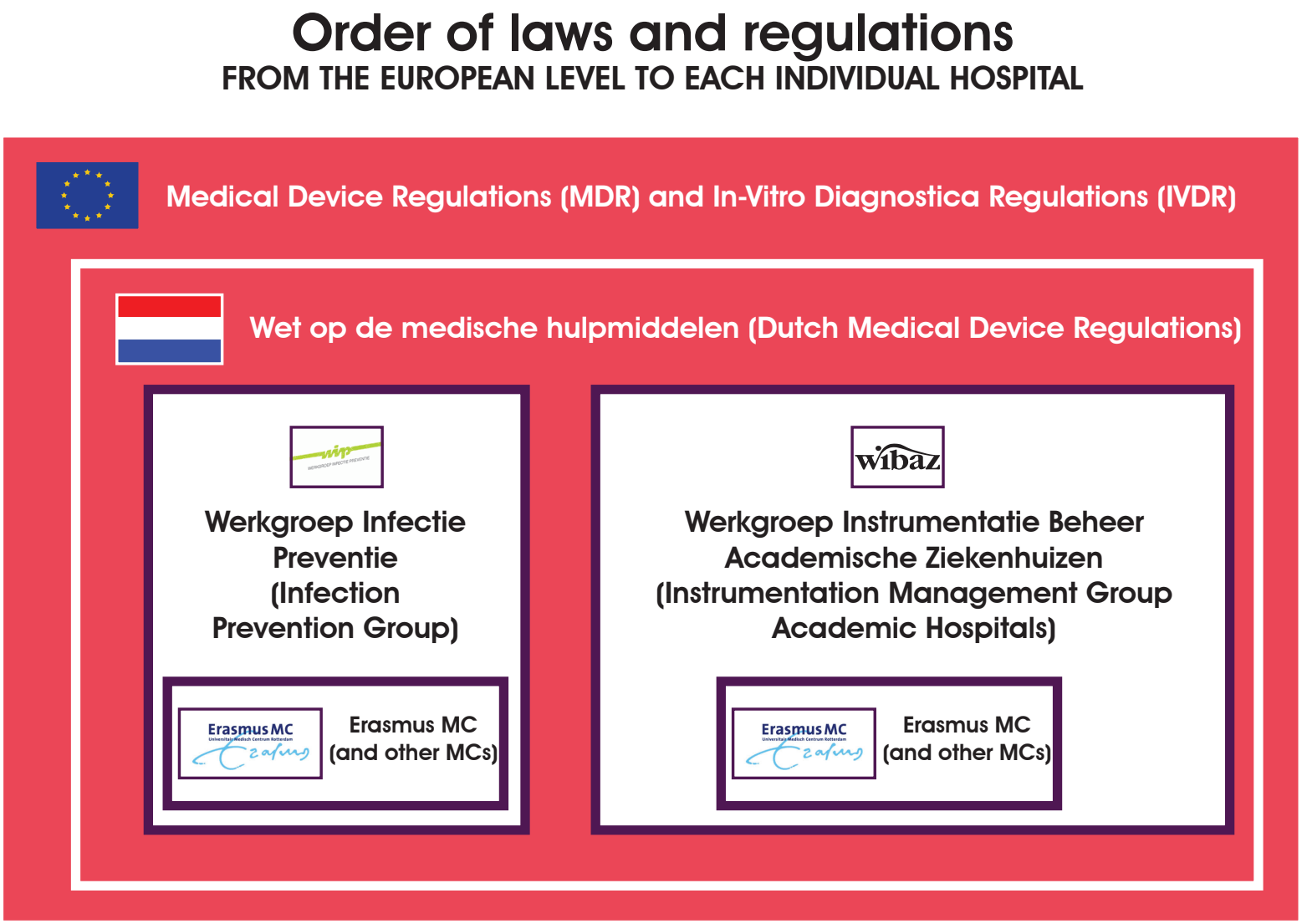



Figure 28. Illustration displaying the order that laws, standards and regulations are currently implemented (courtesy of Sebastiaan Notenboom).

# ATTACHMENTS

## 1. Interview with Jitske Oeyen (Expert Infection Prevention)

At the start of this project, an interview was held with Jitske Oeyen. She is an expert with regard to infection prevention at the Erasmus Medical Centre (Erasmus MC) in Rotterdam. She has been working full-time for a year in this field and part-time whilst studying in the hospital in The Hague for a year and a half.

The goal of this interview is to provide more insights into hygiene itself (the levels of hygiene and how the ensure hygiene at the Erasmus MC).

She starts by explaining how the Workgroup Infection Prevention (WIP) was dissolved several years ago, but that her colleagues and her use these regulations as a groundwork for forming the regulations that they apply for the Erasmus MC.

She proceeds to explain how the Erasmus MC approaches their cleaning method towards products. There are three different levels of hygiene:

- Cleaning (everything is cleaned before and after use)
- Disinfecting (required if the product came in touch with wounds, blood etcetera)
- Sterilisation (required if the product came in touch with opened up body parts or organs, usually during surgery).

They often pay careful attention to a manual, so this is very helpful to keep in mind that this is required for the final concept.

They clean first, then disinfect and sterilise last if the latter two steps are necessary (in that specific order).

The Erasmus MC only uses four cleaning agents for manually cleaning or disinfecting the products they use:

1. Water with microfibre cloths (cleaning)
2. Alcohol, i.e. ethanol 70% (disinfecting smaller surfaces).
3. Chlorine (disinfecting)
4. Hydrogen peroxide (disinfecting)

They have to be very careful with certain cleaning methods, because there are certain bacteria like the MRSA that start to get used to a certain agent and becomes immune against these agents.

The Experts Infection Prevention (DIP in short) executes various tasks within the Erasmus MC. The DIP is split up into two segments: the front office and back office.

In the front office, they answer all specific questions that are asked by hospital staff and patients.

In the back office, they set up rules and regulations and are each individually responsible for a theme or department and perform audits for regulations. Next to this, they also educate others, amongst new infection prevention members (internists) and other students that are studying in the field of microbiology.

Jitske's specific departments are the Daniël den Hoed and Dijkzigt departments of the Erasmus MC alongside the colleagues of general and technical services.

This department is making sure that the Erasmus MC is being accredited by important institutions such as Niaz-Qmentum.

There are also plenty of other accreditation institutions like the NIAZ-Qmentum that they seem to be working towards getting accredited by.

She provides some advice with regard to materials and products as well:

- The product needs to remain intact (should not tear or break).
- To be able to clean the product, the material should have a smooth surface (as little surfaces as possible) and it should be cleanable and disinfectable easily.
- The material should not be porous like cotton or velcro, however this can be washed in a textile shop at a temperature of 60 degrees Celcius.

The Department of Infection Prevention (for the sake of this report, in short: IP) does not check up on all medical resources and tools. It would be too resource intensive for them to check up on every syringe, needle etcetera. Therefore they have a specific price threshhold and all products above this threshhold are checked on. They have an advisory role in whether a product is approved or not.

She refers to other departments like the Central Sterilisation Department that fill another role in this field. It is evident that it is necessary to map out the entire process that a product goes through to enter a hospital.

Figure 29. Photo containing me (Yasir Tüfekçi) on the left and the expert infection prevention (Jitske Oeyen) on the right.

## ATTACHMENTS


Figure 30. Photo containing Jolanda Buijs (Expert Sterile Medical Resources)

## 2. Interview with Jolanda Buijs (Expert Sterile Medical Resources)

In order to guarantee whether the outcome of this project needs to be sterilisable, an interview was executed with Jolanda Buijs. She works at the Central Sterilisation Department (CSA) of the Erasmus MC as the expert in sterile medical resources and as the expert on the field of cleaning scopes across a period of seven years after having over a decade of experience in other fields within the Erasmus MC.

She works on a variety of tasks, including:

- The compliance of all medical devices to the law and regulations,
- Documenting whether the CSA can clean, disinfect or sterilize the medical resources if needed.
- Making sure that the resources they use themselves are being maintained properly periodically.

The difference between the IP (see page 58) and the CSA is that the manual cleaning is done by the Department of Infection Prevention and automatic cleaning (in specialized washing machines) is done by the CSA.

Medical technology (usually electronic devices) are different to medical resources and there is a separate department that is in charge of policies regarding this.

Jolanda Buijs explains that there is a Spaulding Classification (see Figure 29) and elaborates upon this by mentioning a major difference between disinfecting and sterilising:

- When disinfecting, microorganisms are killed, but they can still reproduce.
- When sterilising, microorganisms are killed, but their ability to reproduce is also stopped.

The chance for a living microorganism to be present on a surface that has been sterilised should be smaller than 1/1.000.000.

In the CSA, they act in a similar way as the IP. They clean first, then disinfect and sterilise last. In each step they aim to reduce the bio-burden, up until they reach the chance mentioned above.

They cannot take a step out of this process, so even if something needs to be sterilised, it must be disinfectable.

The specialized washing machines they use are unable to merely clean. They either clean and disinfect (in a single step) or sterilize afterwards.

In these washing machines, they clean at 55 °C, they perform a thermical disinfection at 90 °C and finally steaming at 134 °C.

With scopes (as they are more vulnerable and would not last through such a process), they utilize a different machine that clean at 35 °C and a chemical disinfection at approximately 40 °C.

Their machines disinfect at a high-level disinfection. The main reason for using machines is the guaranteed quality that machines can deliver at any given day.

There are specific machines that also clean porous materials such as textiles, but whether those would be able to disinfect as well is uncertain.

| Categories | Application | Examples | Level of disinfection |
|---|---|---|---|
| Critical | Enters normally sterile tissue or the vascular system | Surgical instruments, scalpels, biopsy forceps, injection needles, sphincterotomes | Sterilization |
| Semicritical | Contact with intact mucous membranes | Endoscopes | High-level disinfection |
| | Vulnerable to infection | Thermometers | Intermediate or low-level disinfection |
| Noncritical | Touches only intact skin or not touches skin | Stethoscopes, blood pressure cuff, bed pans, stretcher car | Low-level disinfection |

**Figure 31. Table displaying the Spaulding Classification (Lee et al, 2013) and (Spaulding, 1957).**

## 3. A WAY OF MEASURING HYGIENE (ATP-MEASUREMENTS)

**A**denosine **T**ri**P**hosphate (ATP) is an energy molecule found in all organic matters. What this essentially means is that if a person touches an object, ATP may be present on this object. If another person touches this object as well, this same ATP and other molecules can be transferred over from one person to the other.

Being able to detect ATP means that you are able to find whether these molecules are present (or whether they are not present). As explained before, more ATP means more risk of contamination.

**How is ATP measured?**
One of the most popular methods is using luciferase.

This step by step method is illustrated in Figure 31 on page 63.

1. The person testing for ATP (refered to as tester from here onwards) uses an ATP surface test tool to take a sample of a surface.
2. The tester inserts the test tool into their ATP test device.
3. The device provides an output to the tester on the value of ATP found in the test.
4. The tester takes action accordingly by reporting results to the infection prevention department for example.

**What happens inside the device?**
Researchers have found out that ATP interacts in a special way with an enzyme in fireflies called luciferase.

Figure 30 displays the chemical formula for this. "In the first reaction enzyme-bound luciferyl adenylate is formed, and during the second reaction oxidation by molecular oxygen leads to the formation of a cyclic dioxetanone with release of AMP; this is followed by decarboxylation and formation of an excited oxyluciferin mono-anion biradical (2). This excited molecule decays with production of light followed by a slow release of oxyluciferin from the enzyme (3)" (Ford et al., 1996).

So the device detects this light that is produced by this reaction and is invisible to the eye. It is even moreso true that the more light there is, the more ATP is present on the test material as seen in Figure 32 on page 63.

This test can be used to detect whether the concepts in this project can be cleaned sufficiently in case this route is chosen. By measuring whether they fall under the hospital's threshhold, a large risk of the contamination can be prevented.

The reaction occurs in two steps:

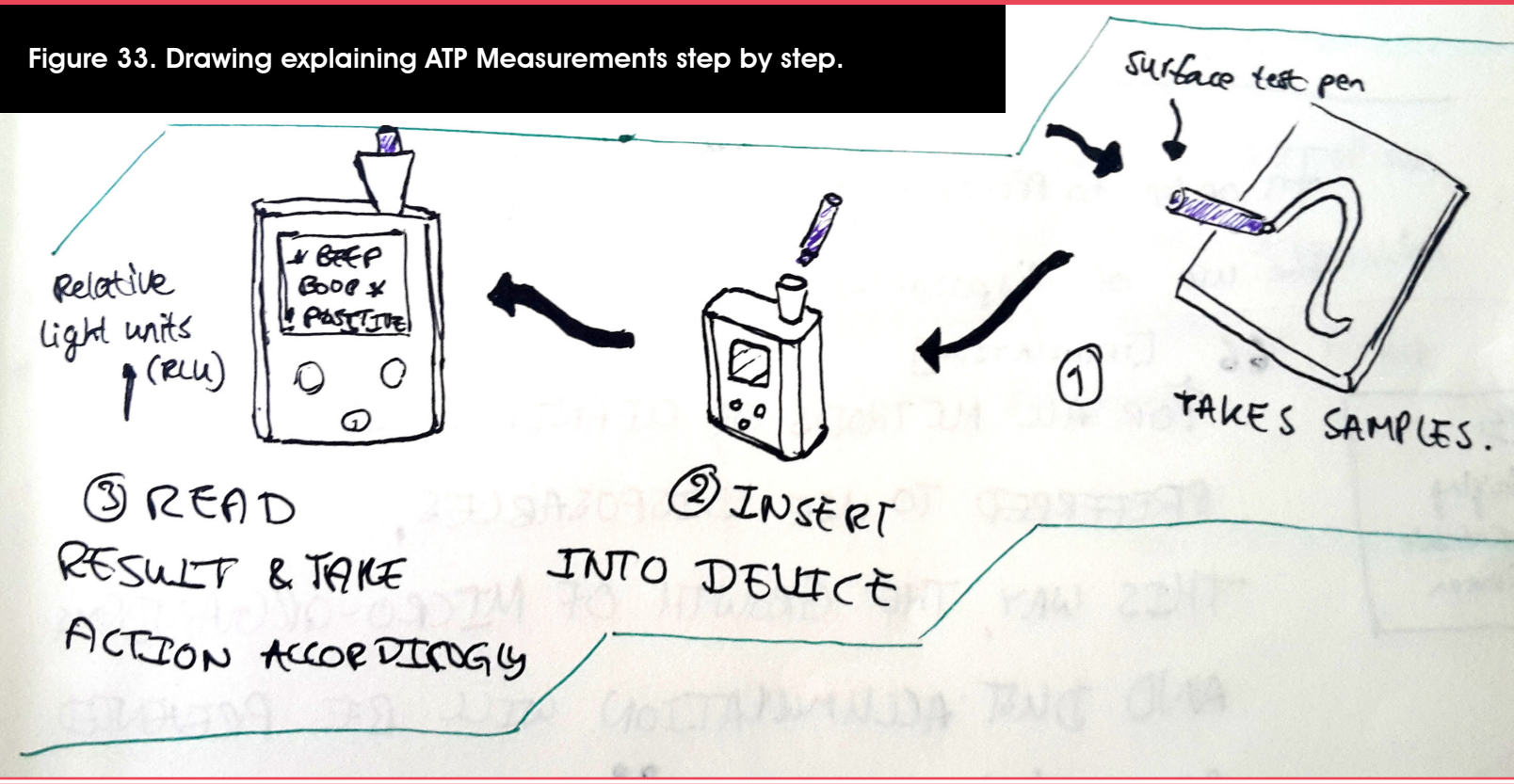
$$FL + LH_2 + MgATP \longleftrightarrow FL{-}LH_2 - AMP + PP_i$$

$$FL - LH_2 - AMP + O_2 \longrightarrow Light + OL + AMP + FL + CO_2$$

where FL = firefly luciferase, $LH_2$ = luciferin and OL = oxidized luciferin.

**Figure 32. Chemical formula that shows how firefly luciferase and ATP produce light (Ford et al., 1996).**

Figure 33. Drawing explaining ATP Measurements step by step.



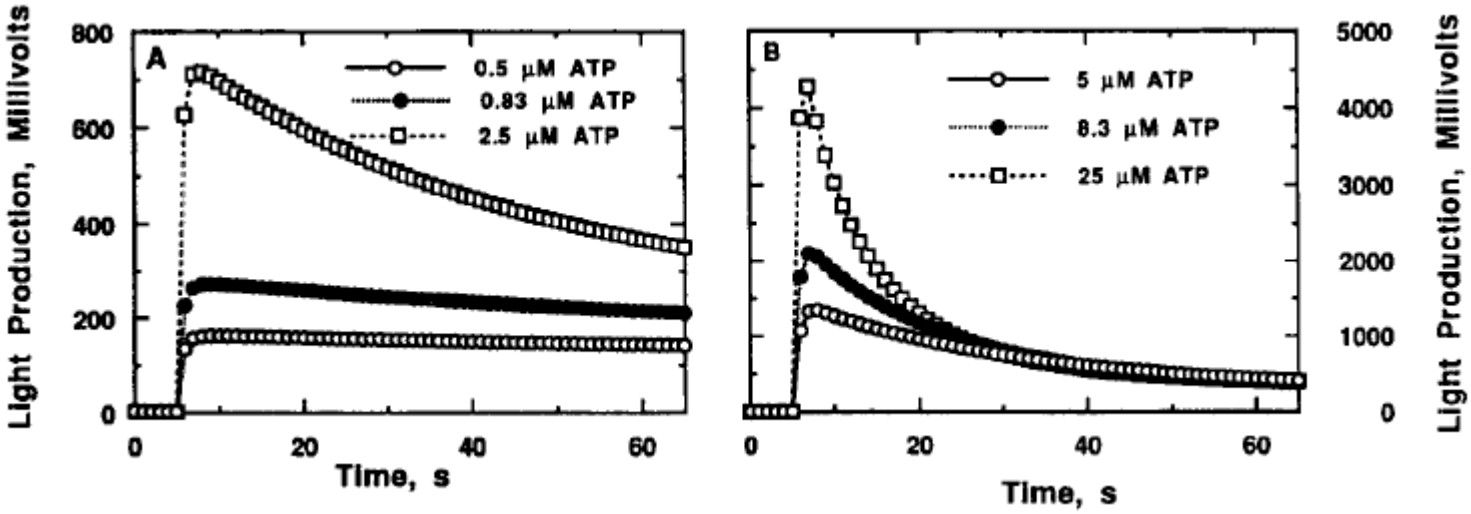




Figure 34. Graphs illustrating that the more ATP there is present, the more light production will take place (Ford et al., 1996).

## ATTACHMENTS


**Figure 35. Photo containing Sebastiaan Notenboom (Program Coordinator Medical Technology).**

## 4. Interview with Sebastiaan Notenboom (Program Coordinator Medical Technology)

Sebastiaan Notenboom is a Program Coordinator for Medical Technology within the Erasmus MC and is responsible for creating and implementing policies that are connected to external laws and regulations. He performs these tasks on a hospital-wide level and checks up on whether this all complies to aforementioned laws and regulations.

The goal of this interview is to find out where the focus is when looking at rules and regulations (i.e. where does the research start).

The Erasmus MC has co-operated within the NFU (Dutch Federation of Universitary Medical Centers) and together with the NVZ (Dutch Association of Hospitals) to create an agreement with regard to medical technology.

The official name of this agreement is "convenant 'Veilige toepassing van Medische Technologie binnen de Medisch Specialistische Zorg'" (translates as "agreement 'Safe application of Medical Technology within the Medical Specialistic Care'").

This agreement (Volksgezondheid, 2016) contains information in aspect to the lifecycle phases of medical resources are.

The starting point of the lifecycle is at the point that the product has already entered the market up until the product is disappeared entirely out of the organization.

Product development, bringing the medical device on the market, having it certified by the CE marking etcetera are all aspects of the lifecycle of a product that are excluded from this agreement.

Sebastiaan Notenboom has looked at how products currently enter the Erasmus MC (the purchasing process) and has made sure that this is aligned with aforementioned agreement.

The agreement descibes a product report for example, including a risk-analysis, an evaluation plan, possible trainings and education and a motivation as to why the Erasmus MC is purchasing this medical device.

Sebastiaan continues to draw the illustration (Figure 34) on a whiteboard. He explains that the design needs to start top-down, where the MDR and IVDR are most important. This could result in the necessity that the Oculus Go needs to be re-certified as a medical device, which has different laws and regulations this product needs to follow.

The most crucial step here is to figure out whether the Oculus Go must become a medical device or whether an alternative way is possible.

Sebastiaan has been an incredible help to this project by referring to productcategory owners and others who can expand the network that is needed to turn this project into a success.

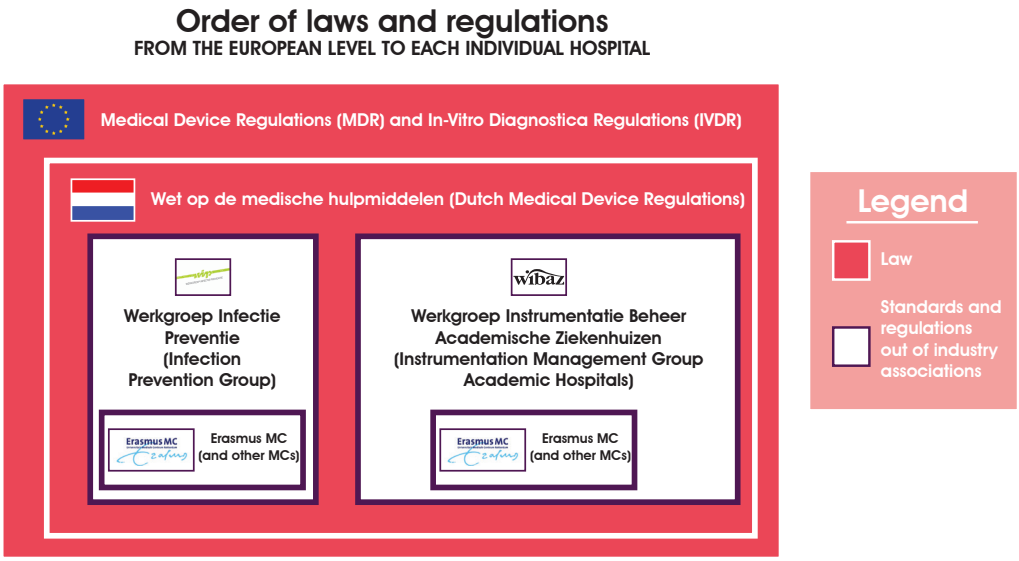



**Figure 36. Illustration displaying the order that laws, standards and regulations are currently implemented.**

$$A_0 = \sum 10^{(T-80)/z} \Delta t$$

($\Delta t$ = selected time period in seconds, T = temperature of the load in °C (lower limit-value = 65 °C), z = 10 (°C))

"An $A_0$ = 60 is generally viewed as being an acceptable minimum for devices coming into contact with intact skin, provided that it is unlikely that these products are contaminated with large quantities of heat-resistant pathogenic microorganisms. It is stressed that this treatment presupposes a low bioburden prior to disinfection as well as the absence of heat-resistant microorganisms with a potential to cause serious diseases".

An $A_0$ = 60, based on the formula, means 80 °C/60 sec or 90 °C/6 sec or 70 °C/10 min, etc.

**Figure 37. Formula and explanation around the A0 thermal disinfection concept (Rosenberg, 2003).**

## 5. A0 Thermal Disinfection Concept

The A0 Thermal Disinfection Concept (Rosenberg, 2003) explains that there is a way to disinfect products in a thermal fashion.

Rosenberg mentions the following two important aspects about this concept:

- "The parameters governing disinfection with moist heat in washer-disinfectors are newly defined and controlled by means of the A0 value in the standard prEN ISO 15883-1 (Washer-disinfectors – Part 1: General requirements, definitions and tests)."
- "Bacterial spores, which are the most resistant of all microorganism, have an average value of z = 10 °C (1). This z value is also employed in the A0 concept, despite the fact that spores are not an explicit goal targeted by thermal disinfection. Selection of the z value can be seen, however, as a safety reserve when defining disinfection parameters."

The A0 stands for a parameter that indicates the level of disinfection that is being applied. The formula in Figure 35 explains the rest of the story.

Regular washing machines can reach these temperatures reliably. However, since mechanically washing will take some time to thoroughfully clean the product, it is wise to go for a lower temperature and a higher duration. somewhere in between 65 and 70 degrees Celcius would be optimal for this case.

Please note that the lower-limit value is set at 65 degrees Celcius, so a temperature lower than this is not recommended.

## ATTACHMENTS

Figure 38. Photo containing Amando Heesterman

## 6. Interview with Amando Heesterman

Amando Heesterman is the organisation advisor for the Erasmus MC. In his work he combines the ideas of employees with the plans of the board of directors.

The goal of this interview is to gain more insights in the introduction of their patient tablets.

This interview started with the question regarding the rules and regulations for medical devices: what is a medical device? Their insights are as follows: a medical device is a tool (or resource) used in treatments.

The Erasmus MC works hard to ensure a high quality of care to its patients so the patients can recover as quickly and as comfortably as possible. They use the newest technologies to guarantee this high quality of care.

So when the idea of introducing tablets to patients came forward, the following question arose: How can they improve the quality of life for patients as well as possible?

They introduced these tablets for patients to support in the general and technical services that they provide to patients.

With this tablet, patients can request a glass of water, a meal an extra pillow or blanket etcetera, whenever they want to. They can also control the light and temperature in their room, the awnings of their room.

By using this tablet, the patient is in control of their own wishes and needs.

While this can all help in a quicker recovery, the tablet does not intervene in the treatment of the patient. This is the reasoning as to why their decision is made to not classify this tablet as a medical device.

These tablets are such a success, that doctors and nurses would like to utilize such tablets in order to possibly aid them in their decision making process. However, if the software supports actions like these, the tablet will be classified as a medical device according to Amando Heesterman.

This leads to the following question: is data from patients being stored on the tablets?

Amando Heesterman responds that this is not the case. The tablet is coupled with a room. They can even detect that the tablet is near a specific room to verify this. The tablet is also integrated with their electronic patient dossier. Inside the system, the patient is identified through the room number. This is how the patient name can be shown to the patient specifically, without needing a medical device.

What they are struggling with as of this interview is to show the patient who their head practitioner and nurses are through this same way. This could serve a general task (providing the patient with a name for easier communication for example). At the same time, however, this could lead the decisions being made because this data is being shown on the device, which in turn could impact the care itself. There is thus a fine line that they are very careful with.

His opinions with regards to the design for this project align with what is stated in "Summary of contacts with experts in the medical device regulations" on page 72.

He does have his concerns with regards to the software that is running in the Oculus Go. The software claims a reduction of pain and fear, which comes really close to becoming a therapeutic device and thus in turn a medical device.

The design of this project can be used with the glasses independently without the software and for the purposes of info- and/or entertainment and should thus not be a medical device on its own.

## 7. Interview with William Boender

In order to find out the boundaries of the current design with regards to departments within hospitals, an interview was performed with William Boender, the teamleader Care (Intensive Care & Medium Care).

The intensive care unit contains 21 beds and employs 120 employees.

Infectionprevention is always a goal in their mind. It is very important that the risk of contamination is decreased to as low as possible.

He mentions very strict rules that they follow and gives recommendations with regards to the case in general; mainly that any holes that are open need to be coverable. The case also must be able to be cleanable with microfiber clothes.

He also prefers disposables over reusable washed products. Disposables just decrease the risk of contamination to the room itself, which prevents a lot of risk to any bacteria surviving the cleaning phase itself.

In the case of a reusable and cleaned product, they want a highly detailed cleaning facility; where used products enter a dirty room, are put into a washing machine and are taken out of the washing machine in a clean room. These facilities are checked upon with a team from within the hospital in order to guarantee high standards.

These conditions are currently very difficult to meet for SyncVR.

As a startup, investing in such a space and guaranteeing this high level of cleaning to their products is going to end up too challenging in the short term.

Creating disposables sounds like a more reasonable alternative. This does however amplify the fact that these increasing costs would need to be covered somehow. This

Figure 39. Photo containing William Boender (Team leader Intensive Care of the Maasstad Hospital)

## 8. Summary of contacts with experts in the medical device regulations

During the project, the question surrounding whether this design is going to end up becoming a medical device or not has been a very difficult one to answer.

The design itself is not a standalone product that fulfills any of the conditions as seen in Figure 38 on page 73, however is still used in medical context with a medical target group.

Advisor EU regulations and CE-Marking Ton Durieux confirms this in an e-mail by explaining that this design would essentially belong to become an accessory for a medical device.

This in turn means that the design is not a medical device, as long as the device it belongs to as an accessory is not a medical device.

With this information, one final question remains; how does one ensure that this hypothesis is true? Is this design really an accessory of a medical device and can this be verified somehow?

This question has been asked to several experts in the field.

Claire Hostmann (Senior policy officer Medical Technology at the Ministry of Health, Welfare and Sport) mentions in a phone call that the manufacturer themselves (in this case SyncVR) claims whether their product is a medical device (or not) in a report like this one and why. The regulations mention the intended use specifically, so the company must also elaborate upon this.

The intended use seems to be the leading factor in defining whether this becomes a medical device or not and in SyncVR's intentions, this is not a product that actively prevents diseases for example. It's just a band that is being worn on the head with the intended use of carrying the Oculus Go.

The manufacturer has to be very clear in the reasoning and elaboration. In case an inspector from the Health and Youth Care Inspectorate checks up on the design, they will usually provide a first warning if the elaboration is insufficient in proving the intended use.

There is however no way to guarantee whether this design ends up becoming a medical device or not and thus there is always a risk involved in defining it as such or not defining it as one. This risk is confirmed in phone calls with Sylvia van Etten and Mirjam van der Gugten (consultants at NEN).

There are consultancies that help in providing a more clear path through the rules and regulations, but the risk will always remain at the manufacturer.

## Final Verdict on Medical Device Regulations

The final verdict on the subject of Medical Device Regulations is as follows.

The Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance as to be found on http://data.europa.eu/eli/reg/2017/745/2017-05-05) states in Article 2 the following about the definition on the design within this project:

"'accessory for a medical device' means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s);"

The design is not a medical device in itself; it is not intended by SyncVR for the purpose of diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of diseases or any of the other aspects. However, if the design supports a medical device, it means that the design itself will become the accessory for aforementioned medical device. In such a case, the design will need to follow all the rules mentioned in these regulations and will require a CE marking.

As of time of this project, the design is supporting the SyncVR software inside of an Oculus Go. Both of which are not intended to be medical devices.

All these reasons combine together in the verdict that this design is considered not to be a medical device. However, if SyncVR considers their software to become a medical device, this design will automatically become an accessory for a medical device and will have to correspond to the Medical Device Regulations.

SyncVR decides whether or not this design becomes a medical device by making their intentions clear on their own software. If the SyncVR software ends up becoming a medical device, this design will need to follow the Medical Device Regulations as well.

*Article 2*

**Definitions**

For the purposes of this Regulation, the following definitions apply:

(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

— providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,
and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.
The following products shall also be deemed to be medical devices:

— devices for the control or support of conception;

— products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

**Figure 40. The definition of a Medical Defice in Article 2 of the European Medical Device Regulations.**

# XXIII - Feasibility

An analysis of the scope of this project is necessary for knowing the boundaries of the project and makes the project more manageable and feasible.

This project starts with the following problem statement from the company: "How can we make the Oculus Go be hygienic enough so it essentially becomes a medical product?"

When asked about the boundaries of the redesign for this project, Floris van der Breggen (CEO of SyncVR) responds with no boundaries. This means that redesigning the entire case of the Oculus Go and putting the electronics of the Oculus Go in this new case is an option.

The biggest question when tackling the scope of this project is thus whether the redesign should entail:

- A single case for multiple VR devices made by Oculus,
- The entire case of the Oculus Go,
- Only the parts of the Oculus Go that touch the body.

The parts that touch the body are the facial interface (the cushion that touches the face) and the headband (the cotton headstrap) (see "Chapter V - Company" on page 7 for more information about the terminology).

There are several factors that play a role in this decision. SyncVR does allow this project to have a large scope, but it is a startup without any experience or employees in the field of design engineering, manufacturing and distribution. Since the financial budget of this company is also very limited, it is not feasible at all for SyncVR to create a custom case.

Even though a custom case would allow for a more creative approach to resolving the problem at hand, by providing more ways of reaching a desired interaction for the end-users with regard to ease of use and comfort, the feasibility for the company takes a leading priority here.

Designing a custom case that fits multiple VR devices made by Oculus is even more of a long-term approach. The reason for this priority is that SyncVR is looking for short-term solutions to eventually allow themselves for a more long-term solution and this project contributes to aiding that goal as well.

By going for the goal to design an connection for the Oculus Go specifically, the Oculus Go is stripped down to a base product.

The redesign will replace the headband and facial interface of the Oculus Go in a way that is hygiene for hospitals while creating an ease-of-use experience for nurses and while preserving a comfortable experience for patients.

By being able to be (re-)attached and detached easily, the cleaning procedure will be easier and an option for disposables will open up as well.

It is decided that the project will be limited to designing a custom detachable connection for the Oculus Go Virtual Reality glasses. This redesign will be replacing the original facial interface and the headband of the Oculus Go.


Figure 41. Figures A and B display the stripped down product that forms the base to design an connection for. Figures C and D display a degree of creative freedom that can be achieved by removing the side-brackets.

# XXIV - User Experience

Usage Tests are performed with the goal to gain qualitative and quantitative insights in how users experience different ideas and to find aspects that the design can be improved upon.

This chapter in the attachments contains resources used in usage tests and analysis done after usage tests for this project.

Usage Tests in this project use two resources: the Usage Test Sheet and the PreMo Tool.

## Preparative Documents

### Usage Test Sheet

This is a standard sheet (see Figure 40 on page 77) where the nurses provide informal permission for video and recording footage for the purpose of this usage test.

The sheet has an age and department field with the aim to see if there are any differences in these ranges.

Marking a tick on the (1) photo and (2) recording boxes means that they allow (1) photos and (2) video recordings without any blurring. They are able to write down whether they do not want to be recorded, but are fine with blurring if that is the case.

During the phase 1 usage test, all nurses of the dialysis department agreed to be fully recorded without blurring.

The Usage Test sheet contains quick information fields for every concept, in order to make the usage test modular as mentioned in "Pilot Test" on page 78.

### PrEmo Tool

This is an adaptation on the PrEmo Tool of the Delft Institute of Positive Design.

As mentioned by this institute (Desmet et al, 2002-2013).
"PrEmo is a non-verbal self-report instrument that measures seven positive and seven negative emotions. The unique strength of PrEmo is that it combines two qualities: it measures distinct emotions and it can be used cross-culturally because it does not ask respondents to verbalize their emotions. In addition, it can be used to measure mixed emotions. PrEmo data can be useful for evaluating the emotional impact of existing designs (e.g. for creating an emotional benchmark), or for creating insights in the relationship between product features and emotional impact that are valuable in an early design stage."

PrEmo is an online tool however and the visualisations are animations. In a previous project during the master of Design of Interaction, this tool is adapted to be used on paper during usage tests. The adaptation can be found in Figure 41 on page 77.

The analysis for this adaptation is custom-made for this project.

Name: _____

Age: ____ | Department: _____

Photo: ☐ | Recording: ☐ | Date: _____

| IDEA # | TIME SPENT | PREMO TOOL EMOTIONS |
|---|---|---|
| COMMENTS | | |
| IDEA # | TIME SPENT | PREMO TOOL EMOTIONS |
| COMMENTS | | |
| IDEA # | TIME SPENT | PREMO TOOL EMOTIONS |
| COMMENTS | | |
| IDEA # | TIME SPENT | PREMO TOOL EMOTIONS |
| COMMENTS | | |
| IDEA # | TIME SPENT | PREMO TOOL EMOTIONS |
| COMMENTS | | |
| IDEA # | TIME SPENT | PREMO TOOL EMOTIONS |
| COMMENTS | | |

**Figure 42. The Usage Test Sheet**

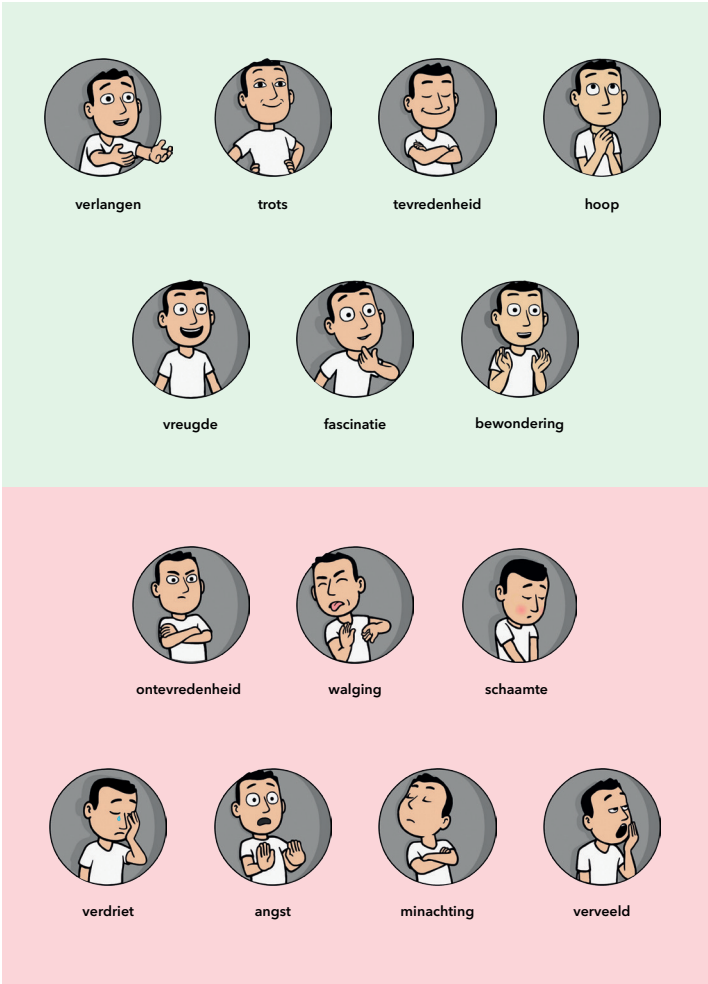



**Figure 43. PrEmo Tool (Product Emotion Measurement Instrument) (Desmet et al, 2002-2013).**

ATTACHMENTS

## Pilot Test

A usage test often starts with a pilot test. The function of a pilot test is to test the initial setup and thought process of the usage test.

### Thought Process

Nurses do not have a lot of time to spend. For this reason, the pilot test is designed to be modular. This means that the pilot test has a base duration and an iterative core that can be shortened or lengthened as per request of the nurse.

So, in this case, there are eight prototypes. The ideal situation would be that all nurses would test all eight prototypes. This is impossible, however, due to their unpredictably limited time for the usage test. Here, the nurse can choose how many prototypes they want to test.

### Preparation

Necessary tools:

- All eight prototypes for fixture
- Three (semi-)prototypes for adjustment
- Custom head (see Figure 65 on page 99)
- Camera with tripod.
- Oculus Go stripped down with the headband and facial interface separate.
- Usage Test Sheets (see Figure 40 on page 77)
- PrEmo tool (see Figure 41 on page 77).

Location: Cafetaria for the Personnel of the Maasstad Hospital.

### Execution

Step 1:
Have all tools set up an positioned.

Step 2:
Introduce nurse to the test and explain purpose. Ask for the amount of time they have.

Step 3:
Ask for permission for photos and/or audio/video recording.

Step 4:
Ask the nurse to try equipping the Oculus Go with headband and facial interface first onto the custom head.
- Pay careful attention to the order of choice, interactions and experiences. Look past prototyping mistakes and figure out which interactions are more positive than others and why.
- Measure time taken.
- Ask PrEmo experience after this process.

Step 5:
Allow the nurse to choose a prototype and to equip our test user with the prototype.
- Pay attention to the same points as in step 4.

Step 6:
Repeat step 5 for as many prototypes as the time allows for.

Step 7:
Close everything off with an interview based off of insights that are gained in step 5-6.

Step 8:
Thank the nurse for their time and find a new nurse to continue testing.

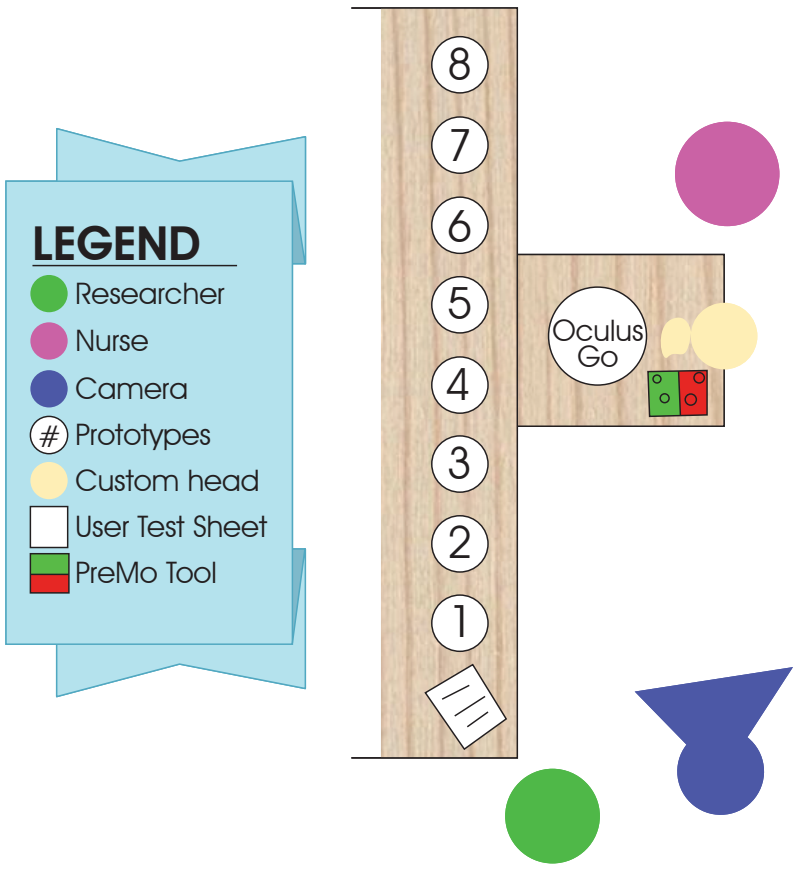



**Figure 44. Visualisation of the plan for the pilot test and photos of the actual setup.**

## ATTACHMENTS

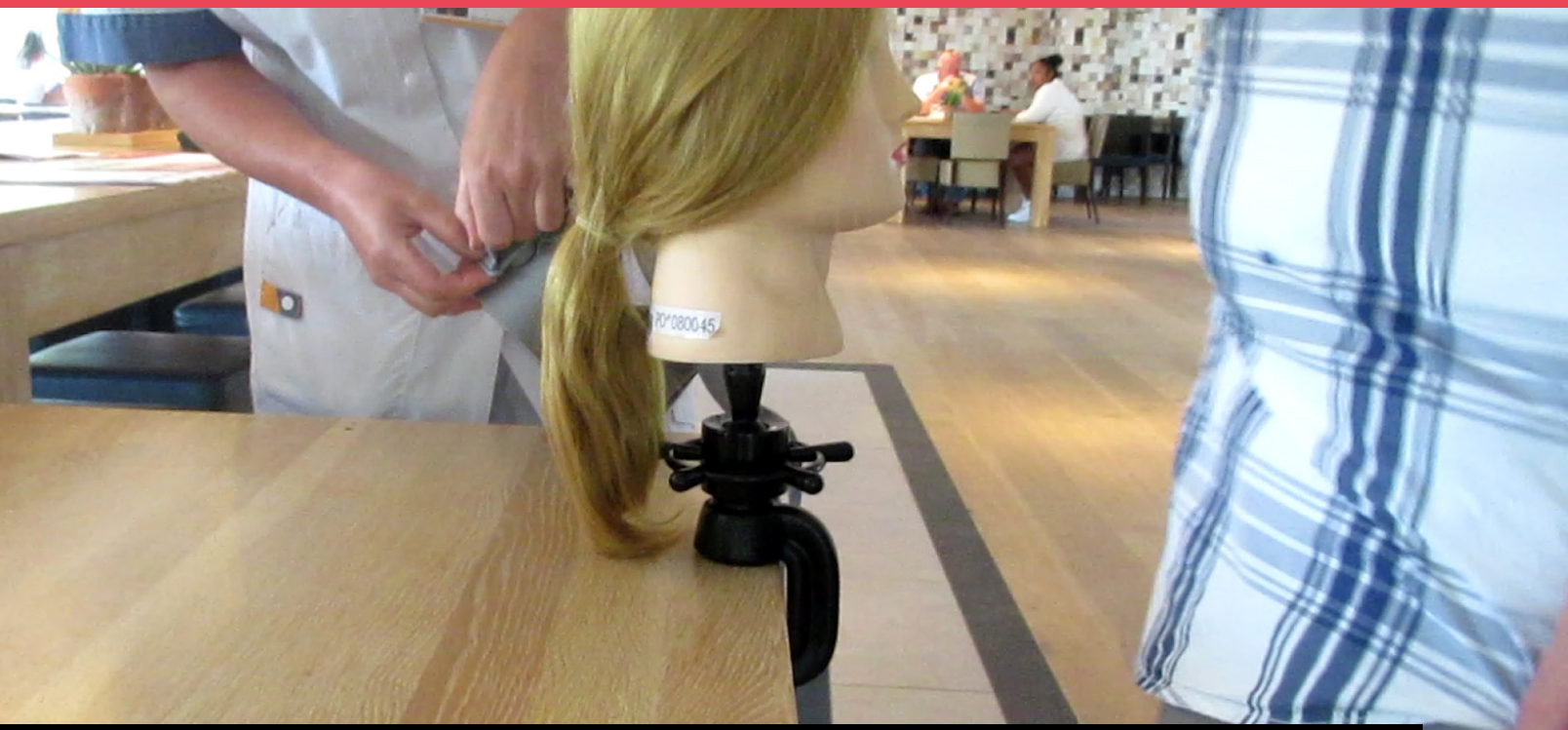


Figure 45. A nurse struggling with pushing the headband through the side-brackets during the pilot test.

Figure 46. Two participants who work at the dialysis department, during the pilot test. The participant on the right is explaining that you cannot fully clean the part that stays on the Oculus Go with this prototype.

**Analysis**
At first sight, it was very difficult to find any nurses that were willing to contribute to the usage test. There was namely a presumption that nurses would have a break of an entire hour and that after their lunch, they would be able to help out with the usage test.

The lunch break is indeed between 12:00 and 13:00, but it happens in shifts. The first shift only has a thirty minute break, after which they have to leave so the second shift can arrive. Because of this, there is always a number of staff on the department to aid patients in their needs. This made it very hard to find any nurses willing to participate during this time.

The participants were furthermore evidently struggling with securing the headband and facial interface onto the Oculus Go Case. This struggle was so evident, that it took them over two to three minutes to fully secure. This shows once again that the current interaction is incredibly undesired.

The Usage Test Sheet and PrEmo Sheets worked really well.

The custom head seems to be mostly unnecessary though, because the prototypes are aimed at securing the band to the case and not on the head (a problem that phase 2 tackles). The nurse in Figure 43 on page 80 was struggling with the head itself and the securing thereof, so the custom head seems to be redundant for the usage tests in this specific phase.

Other remarks related to the actual prototypes are remarkable. Some remarks are related to the hygiene of the features that would be fixated on the connection base. Others are like the one in Figure 45. This is a discussion where the bi-directional adjustability speaks against the likes of prototype #8 for example, that uses tie-wraps to tighten the strap.

The participants in the pilot test generally preferred the clicking interaction over screwing and preferred to keep the product simple (e.g. the springs felt awkward).

**Evaluation**
The Pilot test is a success even with the minor setbacks. It shows that the cafetaria for the personnel of the Maasstad Hospital is not the right place to test for this. In communication with one of the team leaders of the dialysis department (Cora Kreuk), she assisted in planning Clinical Lessons. This changes the entire structure of the usage test, but allows for more nurses to participate, which is a huge benefit to the project.

It is also clear that a ranking system at the end of the session helps in finding differences in the preferences.

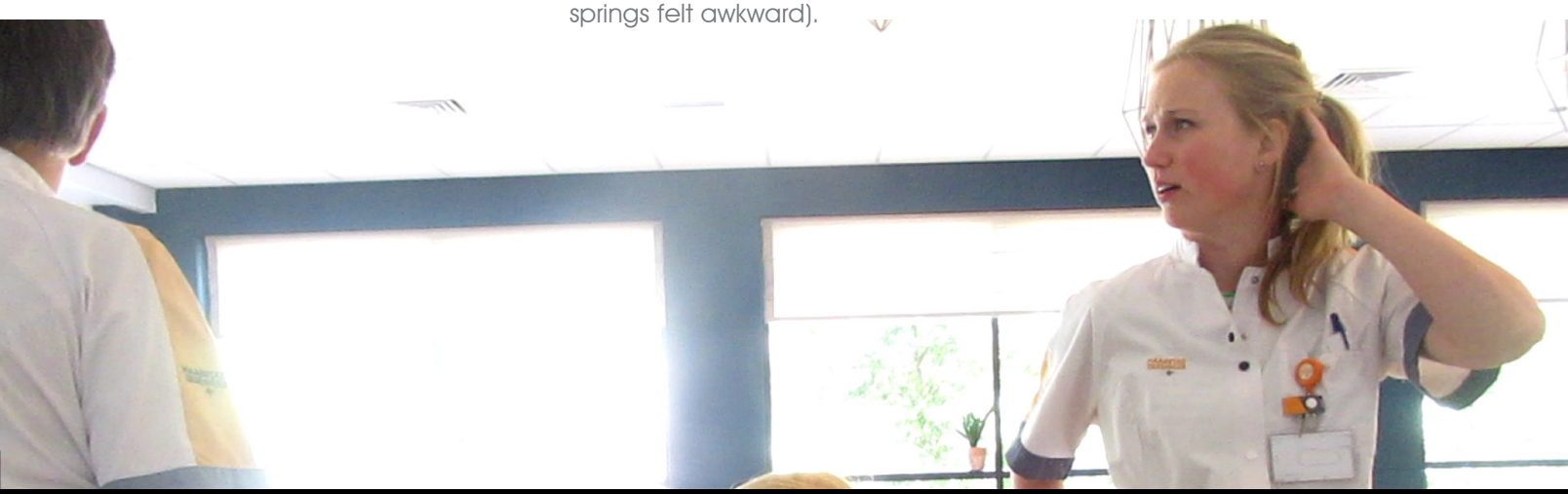


**Figure 47. A discussion erupted where she mentions that she would prefer the adjustability to be bi-directional. To the question: "But is it really important that you are able to release the pressure in case the headband becomes too tight?", she answers: "If the patient says: 'Oh no, this is too tight!', then you do not want to be obliged to throw that one away and use a different headband."**

ATTACHMENTS

## Phase 1 Usage Test

### Thought Process

The Usage Test is developed as per evaluation of the Pilot Test on page 78.

The Usage Test takes place during two Clinical Lessons. Between 14:45 and 15:30, nurses have 45 minutes for this lesson. During these lessons, they get educated about certain topics. An example is one that happened at the start of this project for SyncVR, where the staff of SyncVR made an appointment and presented the SyncVR glasses to most nurses that were present during this lesson. During this specific session, nurses learned how to use the glasses and what to do when something went wrong.

This usage test takes place during such a lesson as well, but instead of learning something specifically, they get to deliver input in a subject that will eventually return to help them.

A lesson like this is not like a single person usage test, so the execution needs to be revamped.

First of all, since there will be up to eight nurses present at the same time, it is unmanageable to document everyone's opinions, emotions and actions. For this reason, each nurse is handed a Usage Test Sheet themselves and each duo is handed a PrEmo Tool. Each nurse is also handed a single prototype.

The researcher is in charge of presenting, operating the camera and asking questions during their interactions.

### Preparation

Necessary tools:

- All eight prototypes for fixture
- Camera with tripod.
- Oculus Go stripped down with the headband and facial interface separate.
- Usage Test Sheets (see Figure 40 on page 77)
- PrEmo tool (see Figure 41 on page 77).

Location: Kitchen for the Personnel working at the Dialysis department of the Maasstad Hospital.

### Execution

Step 1:
Have all tools set up an positioned.

Step 2:
Start the clinical lesson by a short explanation of the purpose of the project and the usage test. Explain the Usage Test Sheet, Premo Tool and the rotation to be performed in step 4.

Step 3:
Ask for permission for photos and/or audio/video recording.

Step 4:
Nurses have a single prototype in front of them. In step 2, they are instructed to explore the interaction of securing the connection and take an approximation of the time it took them to complete this task.

Step 5:
They write down the number of the prototype on the Usage Test Sheet, following up with the time it took and the emotion they experienced while working with the prototype. They are also requested to write down comments and explain their thought process as well as possible. In the mean time, the researcher is video recording the nurses going through these steps and is asking questions to spark a conversation.

Step 6:
Repeat step 4 for all prototypes, these steps usually take a full minute for each prototype.

Step 7:
Close everything off with a general conversation about their experiences and request them to rank all the prototypes.

Step 8:
Thank the nurses for their time and clean up.

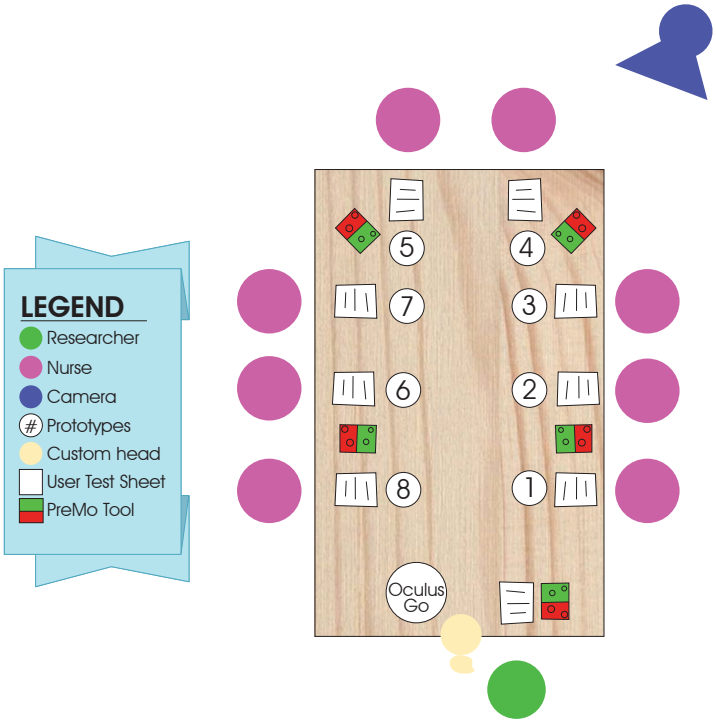



**Figure 48. Visualisation of the plan for the usage test and photos of the actual setup.**

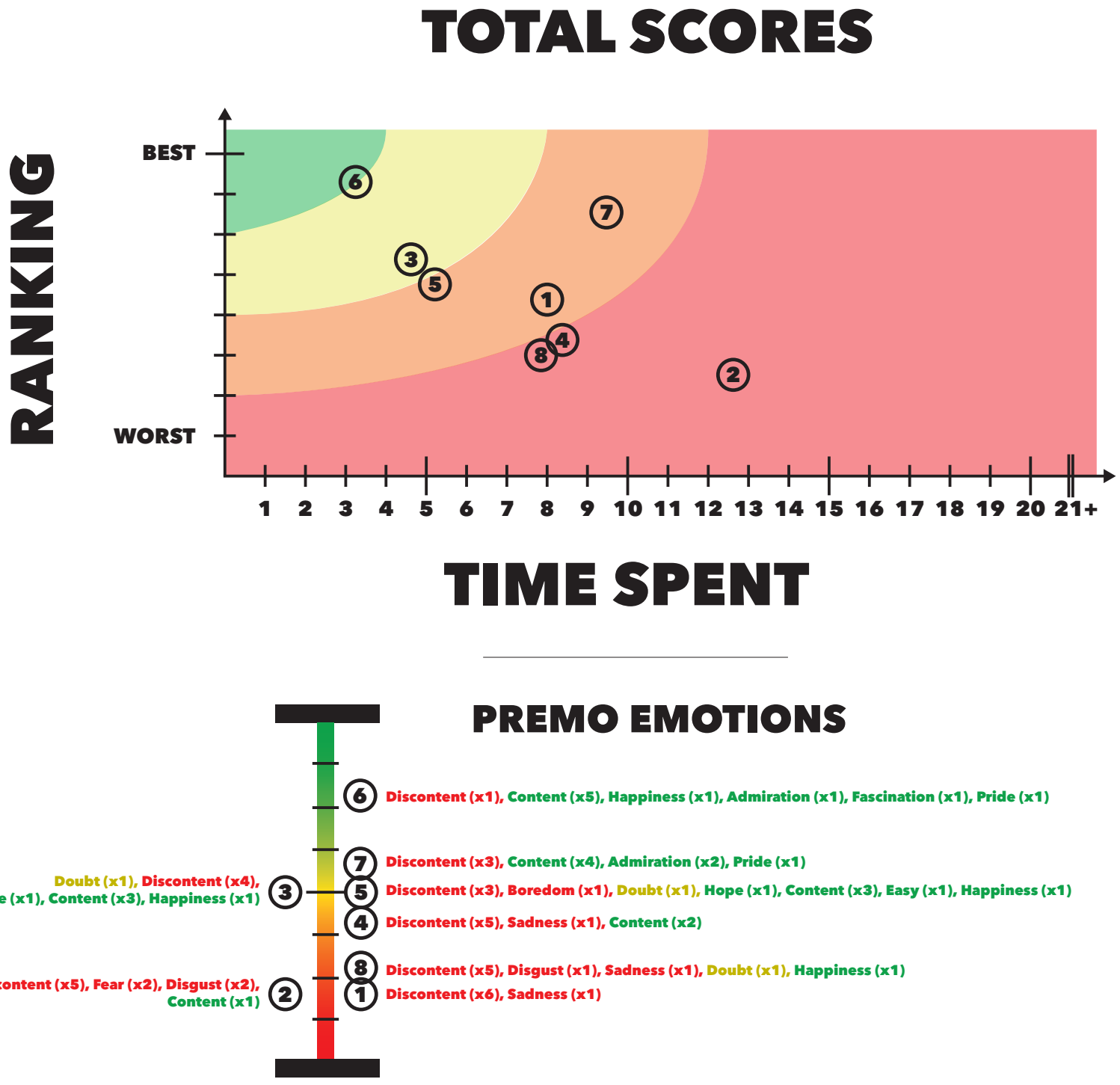



Figure 49. Visualisation of the total averages on the quantitative data of the usage test.

**Analysis & Evaluation**
Twelve nurses participated in this usage test during the clinical lessons and provided their feedback by testing as many prototypes as they could within their time.

When looking at the prototypes specifically and how they are rated, the average of all scores and emotions can be found in Figure 47 on page 84.

These scores show that prototype #6 is the most desired prototype. It is also evident from the qualitative analaysis that this prototype is just simple and easy. In Figure 53 on page 90, one of the nurses just stares at this prototype and seems to wonder that it was just that easy.

The surface is straight (and thus easy to clean), the clip very clearly indicates how it should be applied and the fixture is sturdy, but not too sturdy as to where the disconnection would be too difficult.

Prototype #7 (the one with the screwing cap) also seems to impress the nurses. Even though this connection took longer on average to secure, the interaction was smooth and the nurses thus experienced more overall positive emotions when interacting with this prototype.

Prototype #5 and #3 are seemingly tied and both have their individual reactions. The complaints were often related to the prototypes, but looking past those specific remarks is a deeper problem.

Prototype #3 mainly revolves around the hook and pulling this hook through holes creates environments where securing hygiene is going to stay difficult, since cleaning holes is difficult.

Prototype #5 has a similar issue as a snap fit usually requires a gap or a hole as well. However, gaps for snap fits have proven to be minimalistic (like a small bridge) and yet sturdy, whereas a hook will still remain unstable. For this reason, prototype #5 seems to be more viable in the longer run and is chosen as the third proposed prototype going into phase 2.

## ATTACHMENTS

Their interactions seem to be oriented on how quick and easy they can initially understand the mechanic and how quick they can then afterwards apply the connection onto the Oculus Go.

Each individual interaction tested seems to have its benefits and downsides.

It does not seem to matter much which specific interaction is being used, as long as the two criteria (easy and quick) are met.

Especially interactions that can be applied at the same time (e.g. #3 and #6, which can be attached at the same time on both ends). This means that the connection can be performed even quicker and will take even less time.

As expected, some of the deficiencies in the prototypes did show some prototypes more negatively than the interactions should have been. #3 is a very viable interaction for example, but the problem with this specific prototype was that it didn't actually lock in properly. And vice versa #2 was being applied very easily, but was being removed in such a difficult way that it was being rated much lower than it could have been if the prototype allowed for an easy release.

Prototypes #6, #7 and #5 have been chosen to be proposed to the coaching team and the company.

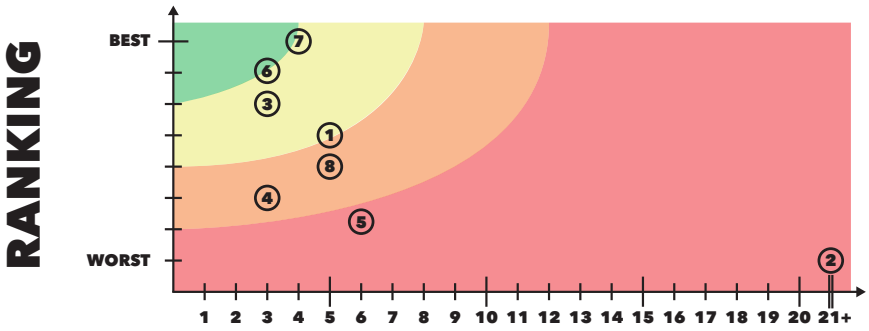
The other prototypes do stay in mind however, since the interactions seem to be mainly focused on ease and quickness of use.

With their input, phase 2 is initiated.

The next pages shows some qualitative analysis per individual test participant.

Figure 50. Photos of the usage tests in practice.

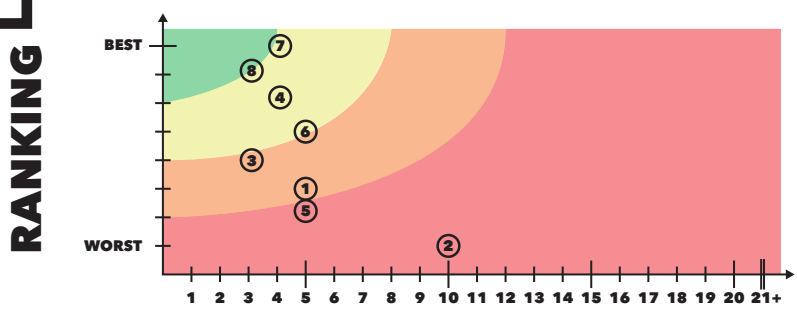
## ERWIN, AGE 63




| | COMMENTS | PREMO |
|---|---|---|
| 1 | Handy adjustment system. | Did not fill in. |
| 2 | It is difficult to get the band back on the suction mechanism. | Did not fill in. |
| 3 | Simple and quick system. | Did not fill in. |
| 4 | Easier than #7. Pressing in the clip can be too heavy. | Did not fill in. |
| 5 | Clumsy click system. | Did not fill in. |
| 6 | No comments. | Did not fill in. |
| 7 | Quick and easy to screw loose and tight. | Did not fill in. |
| 8 | A bit harder than #3. | Did not fill in. |

Figure 51. Usage Test Results of Erwin. In the photo, he is screwing the last part of prototype #7. He does not even look at the prototype while doing so, because he feels that the interaction comes so natural and easy to him.

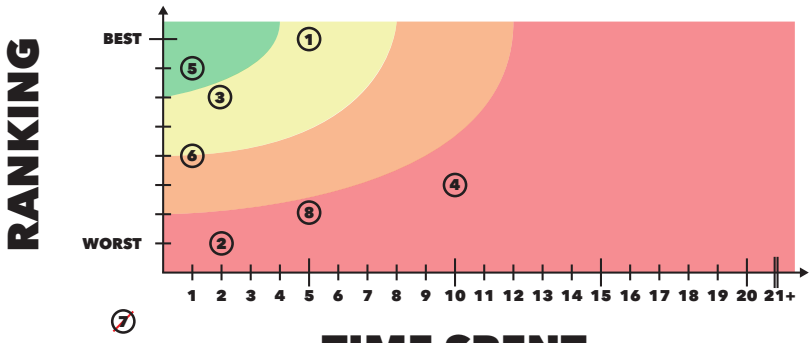
## JANINA SAKKO, AGE 47




| | COMMENTS | PREMO |
|---|---|---|
| 1 | I don't think this is so easy. | Discontent |
| 2 | I don't like the pointy ends on the suction cups. I think it's unhandy. | Fear |
| 3 | Is a bit loose, may fall off easily. | Hope |
| 4 | If the clips fit well, this would be superb | Content |
| 5 | Too big. Cumbersome. | Discontent |
| 6 | The clips are too big, can fall off quickly. | Discontent |
| 7 | I think this is a great idea. It can't fall off and is secured well. | Admiration |
| 8 | Simple, yet functional. | Happiness |

Figure 52. Usage Test Results of Janina Sakko. In this moment during the recording, she mentions (in contrast to other nurses) that she considers prototype #8 to be simple, yet functional and rates this prototype very highly.

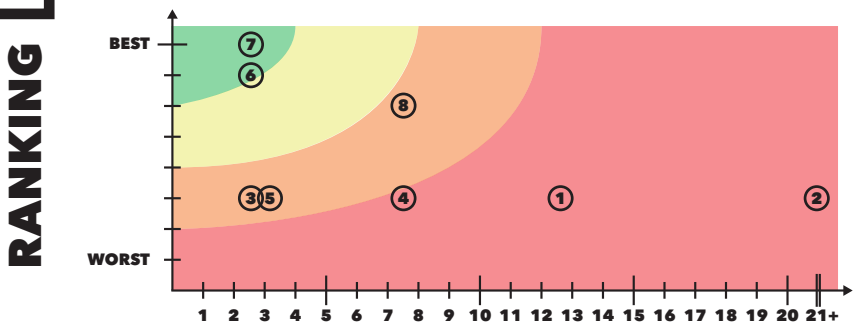
## SIHAM BALLACHI, AGE 32




| | COMMENTS | PREMO |
|---|---|---|
| 1 | This was easy to secure. | Did not fill in. |
| 2 | I don't know what to think of this. | Did not fill in. |
| 3 | This is easy to secure. | Did not fill in. |
| 4 | I did not manage to apply the clips. | Did not fill in. |
| 5 | This went very fast. | Did not fill in. |
| 6 | I think this will go loose easily. | Did not fill in. |
| 7 | *No documentation available.* | Did not fill in. |
| 8 | I am content about this. | Did not fill in. |

Figure 53. Usage Test Results of Siham Ballachi. In the photo, she is trying to connect the clip of prototype #4. She is struggling to find the way to connect the clip onto the connection base, which goes to show that even if something fits on the connection base, it may be more desirable to create a custom connection for it specifically.

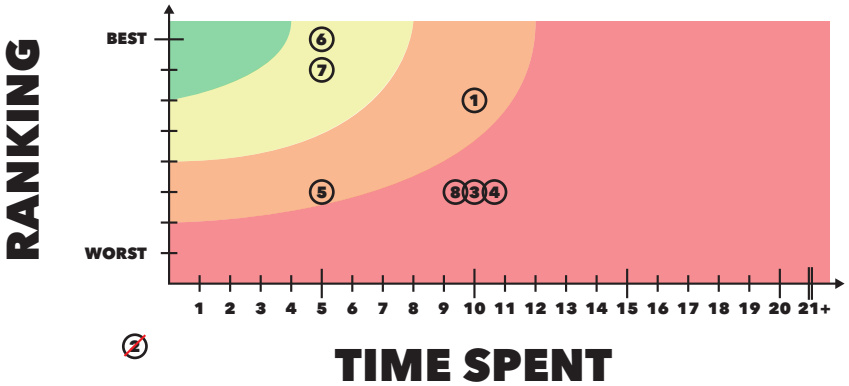
## MARIA LOPES, AGE 25


| | COMMENTS | PREMO |
|---|---|---|
| 1 | You need to pull the clip loose first, which takes a lot of time, but I think it will stay secure. | Discontent |
| 2 | Did not manage to disconnect the suction cup. | Discontent |
| 3 | Easy to hook in, but am questioning whether it will stay secure. | Doubt |
| 4 | Too small clips, they don't fit. | Discontent |
| 5 | Looks handy, but the band is too wide and too heavy. | Doubt |
| 6 | Big clamps, easy. | Pride |
| 7 | Screwcap is great. | Content |
| 8 | Not sure what I think of this. | Doubt |

Figure 54. Usage Test Results of Maria Lopes. In this photo it is clear that she is struggling a lot with disconnecting prototype #2. Afterwards she even shakes her head and gives up, since the connection is far too tight to disconnect. This is a great demonstration where both the interactions for both fixture and the disconnection need to be smooth.

## HENRIKE, AGE 23




| | COMMENTS | PREMO |
|---|---|---|
| 1 | Clipsystem is still handy. Looks a bit big and and hefty. | Did not fill in. |
| 2 | No documentation available. | Did not fill in. |
| 3 | Not really handy and also not secure. | Did not fill in. |
| 4 | Not so handy. | Did not fill in. |
| 5 | Clicksystem is handy. | Did not fill in. |
| 6 | Simple and Quick and looks rather secure. | Did not fill in. |
| 7 | Simple and Quick | Did not fill in. |
| 8 | If this becomes secure, I will think it's handy. | Did not fill in. |

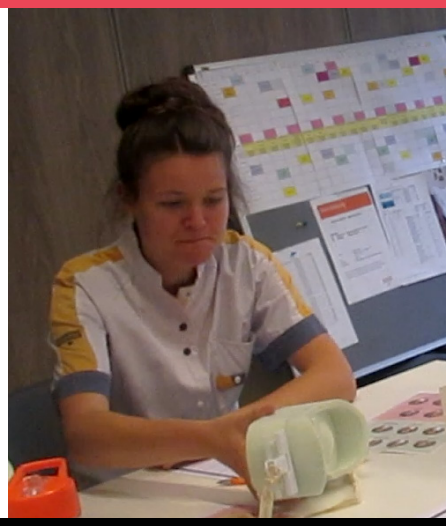
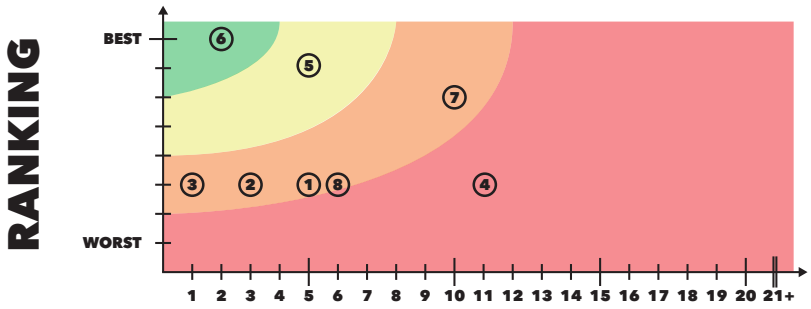


Figure 55. Usage Test Results of Henrike. In the photo, she looks satisfied at prototype #6. It is easy and quick to use, and she considers it sturdy enough.

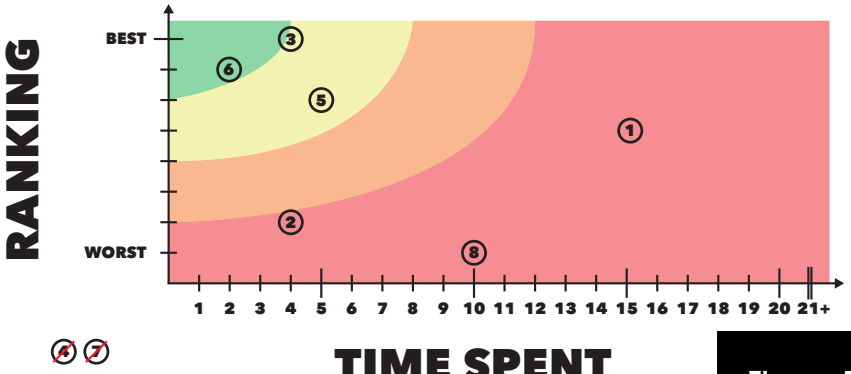
## KWLIU, AGE 45




| | COMMENTS | PREMO |
|---|---|---|
| 1 | Pressing onto the VR glasses isn't nice. | Discontent |
| 2 | Demands some power, and pressing against VR glasses isn't nice. | Discontent |
| 3 | No comments. | Discontent |
| 4 | No comments. | Discontent |
| 5 | No comments. | Content, Happiness |
| 6 | You can secure both at the same time! I didn't expect it to be this practical!! | Admiration, Fascination |
| 7 | No comments. | Content, Pride |
| 8 | Tie-wraps are an inconvenient material. | Discontent |

Figure 56. Usage Test Results of Kw Liu. In the photo, she is busy pulling on the screwing cap of prototype #7. This indicates how unclarity in design can cause unintended use.

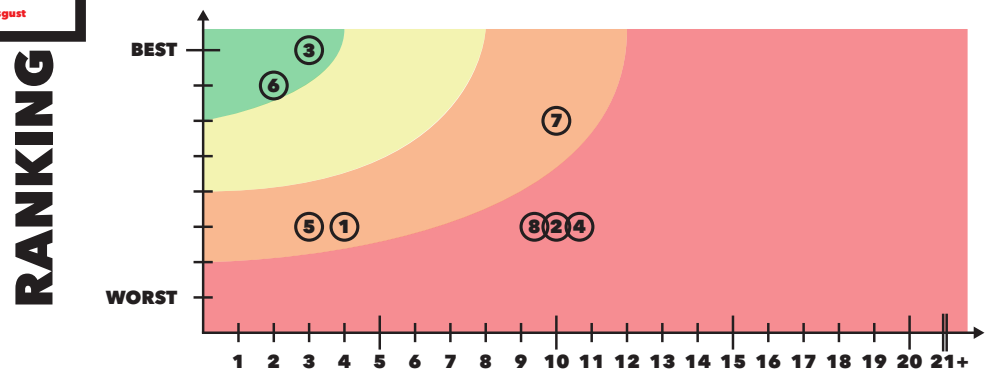
## HANNEKE GROOTENDORST, AGE 50




| | COMMENTS | PREMO |
|---|---|---|
| 1 | Too big, unhandy to hold while securing. | Discontent |
| 2 | Unhygienic, lets loose easily, too heavy. | Disgust |
| 3 | Simple and quick to secure. | Content |
| 4 | *No documentation available.* | *Did not fill in.* |
| 5 | Easy to secure, but how to clean this? | Easy |
| 6 | Easy to secure. | Content |
| 7 | *No documentation available.* | *Did not fill in.* |
| 8 | Hard to secure, after positioning, you have to tighten it. | Disgust |

Figure 57. Usage Test Results of Hanneke Grootendorst. In the photo, she is in the process of connecting the second part of prototype #1. She needed to use her upper legs as support in order to connect the snap fit, as it requires quite some force. This shows that it is very important to find a fine balance between a sturdy fit and an easy application.

## SUZANNE SLOB, AGE 28

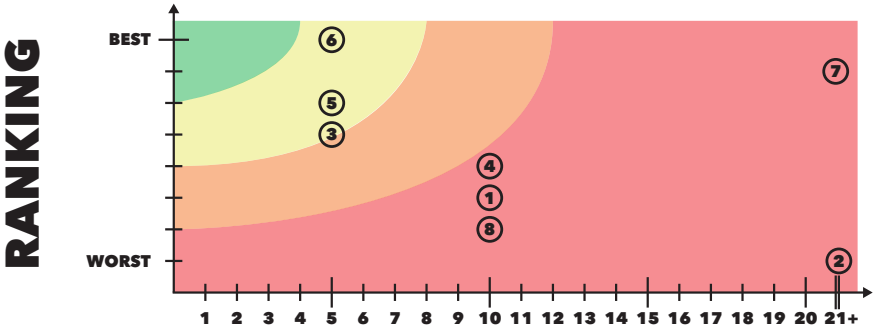



| | COMMENTS | PREMO |
|---|---|---|
| 1 | Can get dirty easily. | *Did not fill in.* |
| 2 | Got loose after securing. | Discontent |
| 3 | Simple and Quick, takes little time. | Content, Happiness |
| 4 | Doesn't click easily. | Discontent |
| 5 | Bacteria will get in here easily, hard to clean. | Hope |
| 6 | Very easy. Is this easy to clean? | Content |
| 7 | It took a little while before I got the hang of it, but afterwards it was a very easy system. | Content, Admiration |
| 8 | Was hard to secure, can get dirty easily. | Discontent |

Figure 58. Usage Test Results of Suzanne Slob. In the photo, she is looking critically at prototype #8 and notices that when connecting straps like tie-wraps to a product, it could introduce other hygiene issues.

## ATTACHMENTS

# KELLY VAN KATWIJK, AGE 25

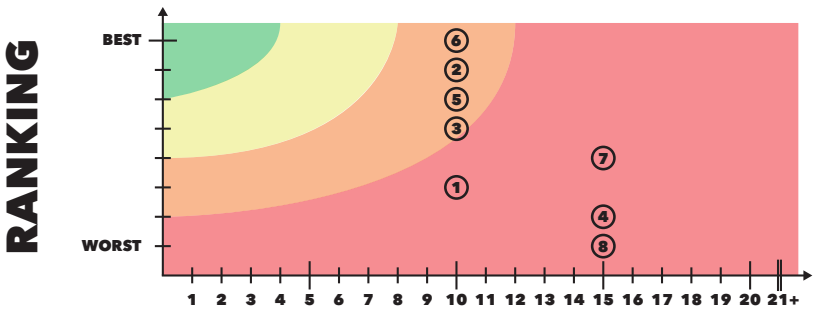



| | COMMENTS | PREMO |
|---|---|---|
| 1 | Doesn't look sturdy enough. | Did not fill in. |
| 2 | Disconnecting seems unsafe to me. | Fear, Discontent |
| 3 | Falls off easily. | Discontent |
| 4 | Unhandy. | Discontent |
| 5 | Unhygienic. Disposable bands are too expensive. It is sturdy, quick and easy. | Discontent |
| 6 | Easy | Content |
| 7 | Easy. Sturdy. | Content |
| 8 | Clicksystem is necessary, otherwise not sturdy | Discontent |

Figure 59. Usage Test Results of Kelly van Katwijk. In the photo, she is trying to open the snap fit of prototype #1. It is evident that she is struggling with this and that a smoother interaction helps in making her experience faster and more comfortable.

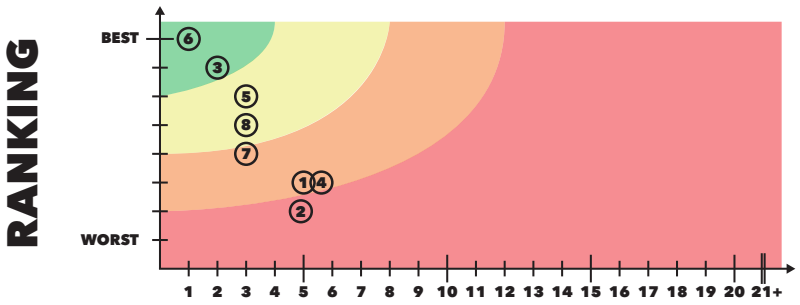
Figure 60. Usage Test Results of Cees. In the photo, he is turning the screwing cap of prototype #7. He likes the interaction, but rightfully criticizes that the headband is turning as he is screwing, which would need a solution in case this becomes a concept.

# CEES, AGE 60+




| | COMMENTS | PREMO |
|---|---|---|
| 1 | Did not fill in. | Sadness |
| 2 | Did not fill in. | Content |
| 3 | Did not fill in. | Discontent |
| 4 | Did not fill in. | Sadness |
| 5 | Did not fill in. | Content |
| 6 | Did not fill in. | Content |
| 7 | Did not fill in. | Discontent |
| 8 | Did not fill in. | Sadness |

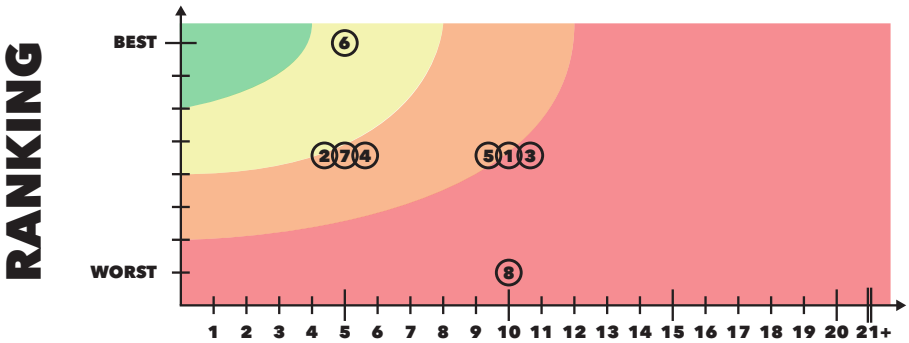
## MARIANNE, AGE 22




| | COMMENTS | PREMO |
|---|---|---|
| 1 | Did not fill in. | Discontent |
| 2 | Did not fill in. | Disgust |
| 3 | Did not fill in. | Content |
| 4 | Did not fill in. | Discontent |
| 5 | Did not fill in. | Boredom |
| 6 | Did not fill in. | Happiness |
| 7 | Did not fill in. | Discontent |
| 8 | Did not fill in. | Discontent |

Figure 61. Usage Test Results of Marianne. In the photo, she is looking at prototype #4 after connecting it to the headset. She is discontent, however. The prototype was unclear in how to connect the clip to the connection base.

## RIA GEERS, AGE 63




| | COMMENTS | PREMO |
|---|---|---|
| 1 | Unhandy. | Discontent |
| 2 | Doesn't stay connected. | Discontent |
| 3 | Not sturdy. | Discontent |
| 4 | If further developed well enough, it could end up handy. | Content |
| 5 | Too massive. Not well cleanable. | Discontent |
| 6 | Easy (everything has to be cleanable thoroughfully). | Content |
| 7 | Could be handy. | Discontent |
| 8 | Not sturdy, unless caps are going to be used. | Discontent |

Figure 62. Usage Test Results of Ria Geers. Even though she saw the hook mechanism of prototype #3, understood it very quickly and was able to interact and connect quickly, she was discontent with this interaction, because she felt that this connection would not be sturdy enough. This does not necessarily mean that the hook mechanism is necessarily bad, it just means that the prototype was lacking in this case.

# DESIGN

## Introduction

This section contains the design activities of the project.

The results of the research activities demonstrated in the previous section are implemented in the design activities performed in this section.

# PROCESS

## Section Content

# XXV - Connection

Developing ideas is a creative phase in which it is imperative to have a large subset of ideas that can be tested and validated on their functions.

In this ideation phase, the main purpose is to explore the primary problem in user experience and find potential solutions.

"Chapter IX - Design Goal and Interaction Vision" on page 16 demonstrates that nurses experience a huge problem. They are namely experiencing the daily use when it comes to the Oculus Go and are experiencing an inability to clean the headband and the facial interface sufficiently. This design needs to cater to their needs first, so the people using it multiple times every single day can benefit the most from the redesign.

For the generation of many ideas for one or two purposes, it is often preferred to use a mindmap. In this case, the mindmap (see Figure 61) is visualized in rings which indicate that the further away the post-its are put on the whiteboard, the more estimated steps there are in completely connecting the design to the Base Product.

These ideas are mostly one or a combination of click-, pull-, push- and rotation-related interactions with the aim of reaching a wide variety of different interactions to find out what nurses prefer the most.

These ideas are just seeds of thoughts. These seeds need to be translated into actual interactions. On the following pages, these ideas are translated into physical prototypes with the aim of usage testing them.

# and Adjustment

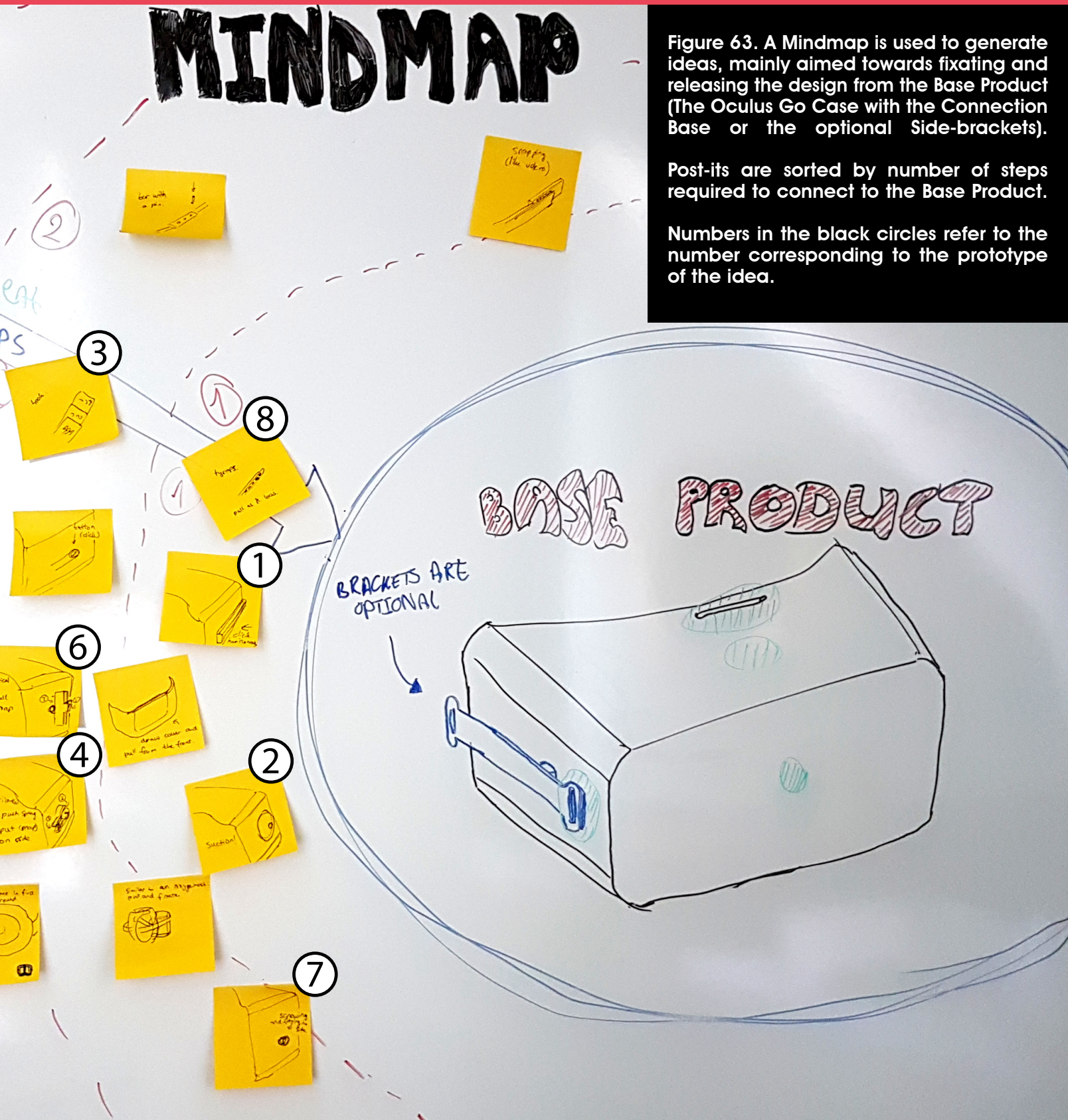



Figure 63. A Mindmap is used to generate ideas, mainly aimed towards fixating and releasing the design from the Base Product (The Oculus Go Case with the Connection Base or the optional Side-brackets).

Post-its are sorted by number of steps required to connect to the Base Product.

Numbers in the black circles refer to the number corresponding to the prototype of the idea.

## ATTACHMENTS

Protoypes make it possible for designers to test whether the interactions they aim for in their designs meet the interactions that the users actually experience. Prototypes are thus in a way a bridge between ideas and usage tests.

The ideation phase demands many prototypes on a small scale. It is about proving that certain interactions work better than others. For this reason a combination of Rapid Prototyping and Physical Models has been chosen.

In Rapid Prototyping, designers use 3D software to create 3D models of their prototypes and use various methods such as Foam milling (sculpting a block of a soft foam) and/or 3D printing (literally printing a 3D model as a little plastic product).

For this project the decision has been made to Foam mill 3D models of an Oculus Go. The reason behind this process is that some ideas have custom fixtures that will not fit on the current Oculus Go. These ideas have a bit more creativity in them, but are still viable.

On the actual product, a 3D printed model could be clicked onto the connection base to create any specific fixture possibility that is decided upon.

The prototypes used in the fixtures themselves are mostly purchased from stores that are specialized in highly diverse articles, such as the Big Bazar, Action or Xenos.

Ideas that could not easily be prototyped by using or modifying already existing products, were created in different ways, such as modeling and 3D printing (see #7 in Figure 72 on page 103) or by using tie-wraps (see #8 in Figure 73 on page 103).

Anything that needs to be fixed onto the foam milled Oculus Go models is fixed using glues or double sided adhesive tapes.

A custom head that can be fixed onto a table (see Figure 65 on page 99) is purchased from Haarshop.nl. The purpose of this head in this project is to serve as a patient during the usage tests of phase 1 and 2 so nurses can fit the prototypes on this head if deemed necessary.

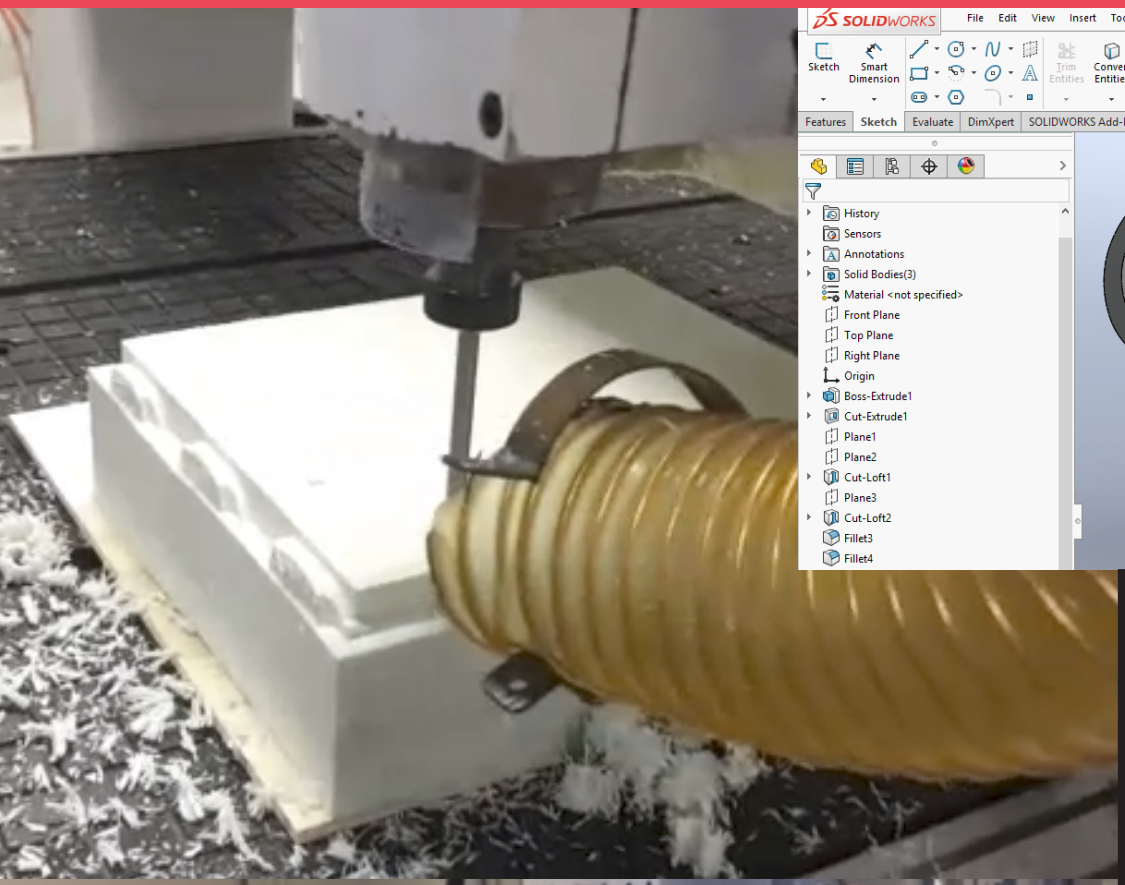
The prototypes themselves are shown on pages 100 to 103. They are all different ways to secure a ribbon (which is a temporary replacement for the design that is going to be a comfortable headwear for the patient) onto the Oculus Go models.

These prototypes serve their purpose in "Chapter XXIV - User Experience" on page 76 as nurses interact with them and explore which interactions fit the best to their needs.


Figure 64. Big Bazar and Action (© Maassluis.nu).



Figure 65. Xenos (© AD).



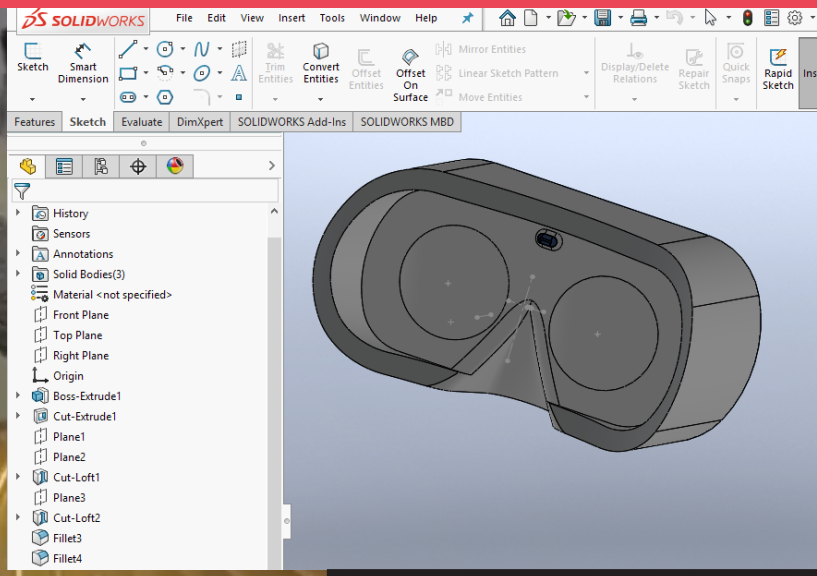




Figure 66. Foam milling the Oculus Go Models at the Model Making and Machine Lab (PMB) of the Faculty Industrial Design Engineering at the Delft University of Technology.

Figure 67. Custom head that can be fixed onto a table that serves the purpose of patients during functional usage tests.

## ATTACHMENTS

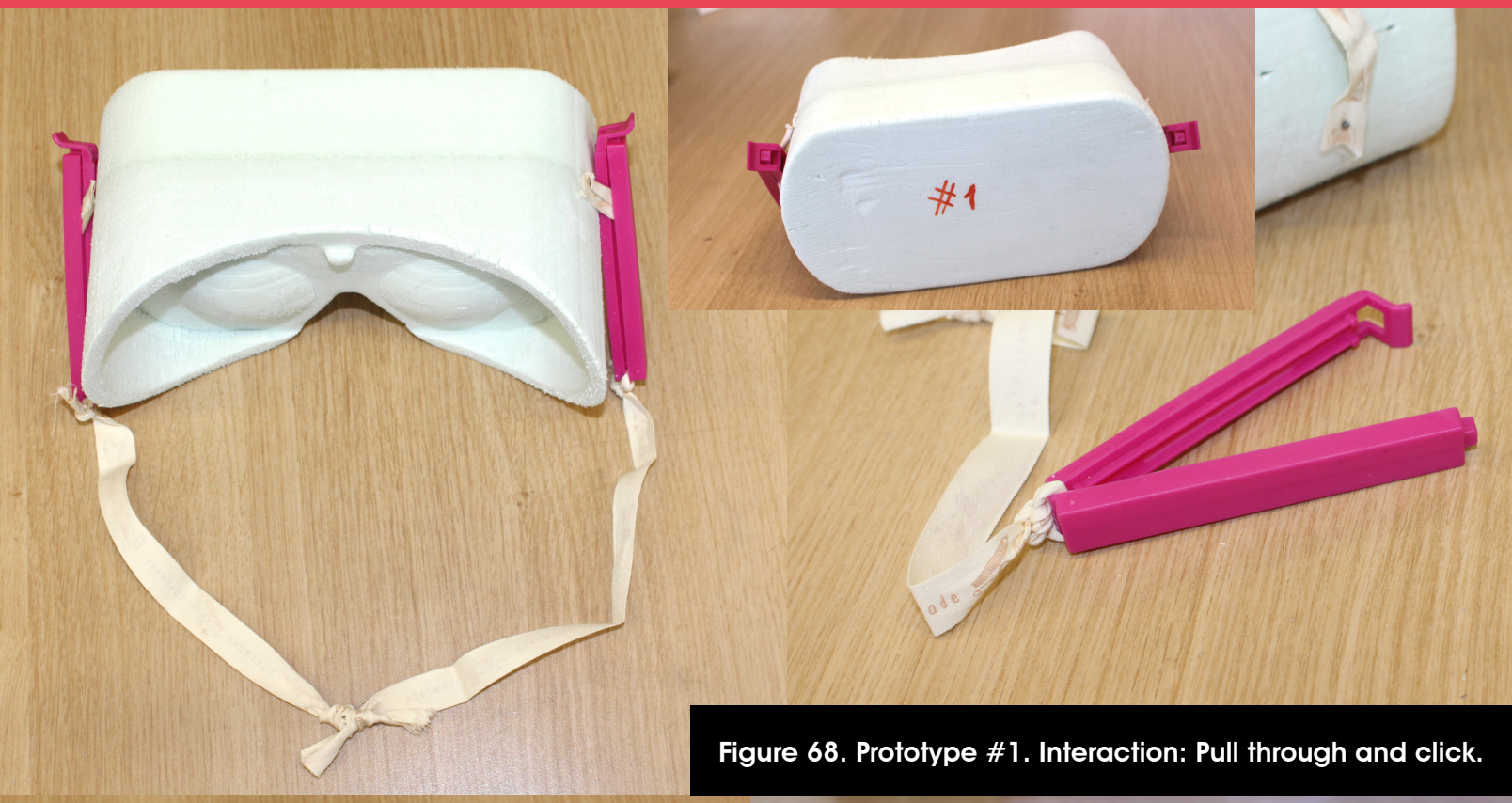



Figure 68. Prototype #1. Interaction: Pull through and click.

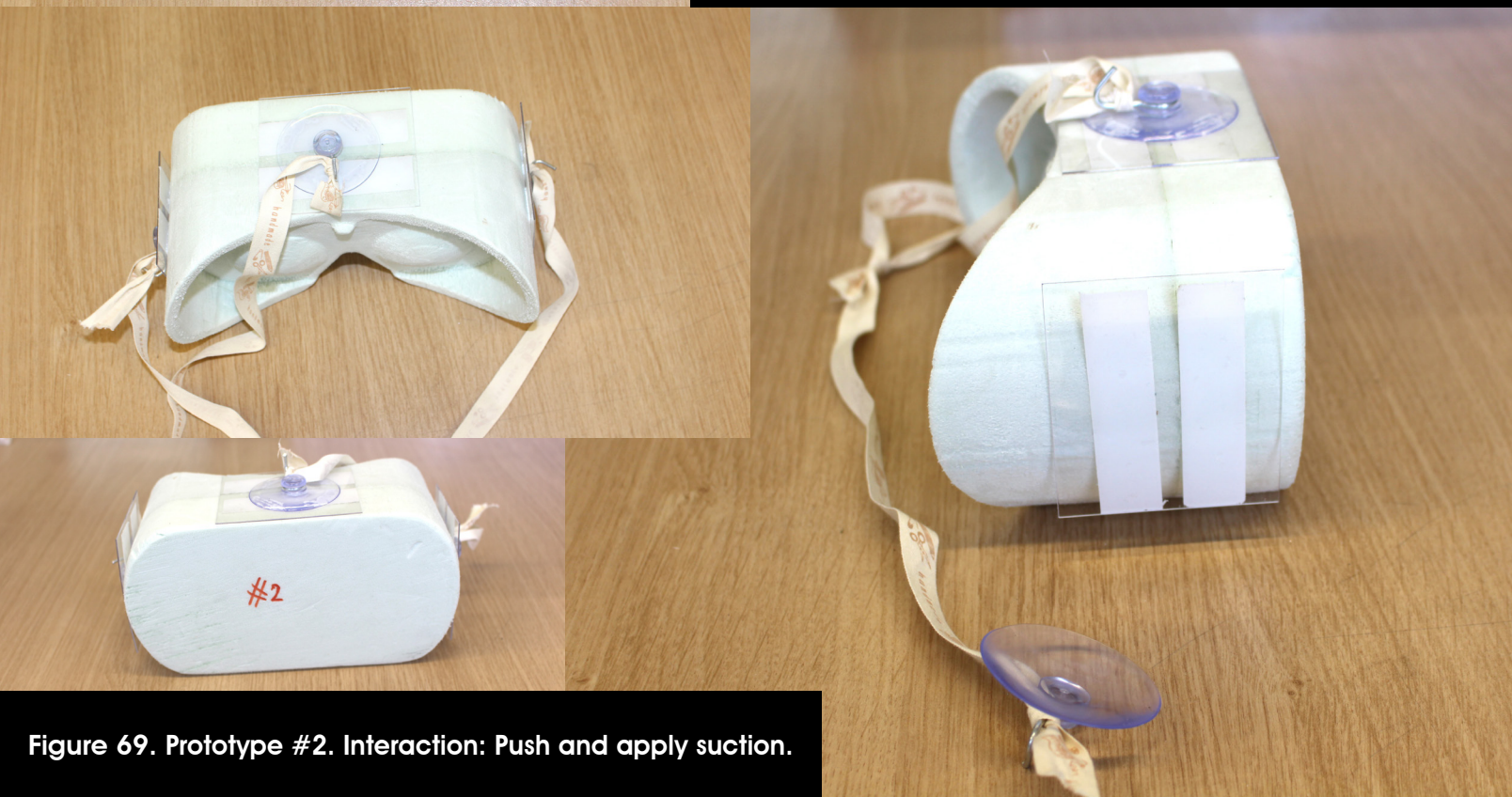



Figure 69. Prototype #2. Interaction: Push and apply suction.

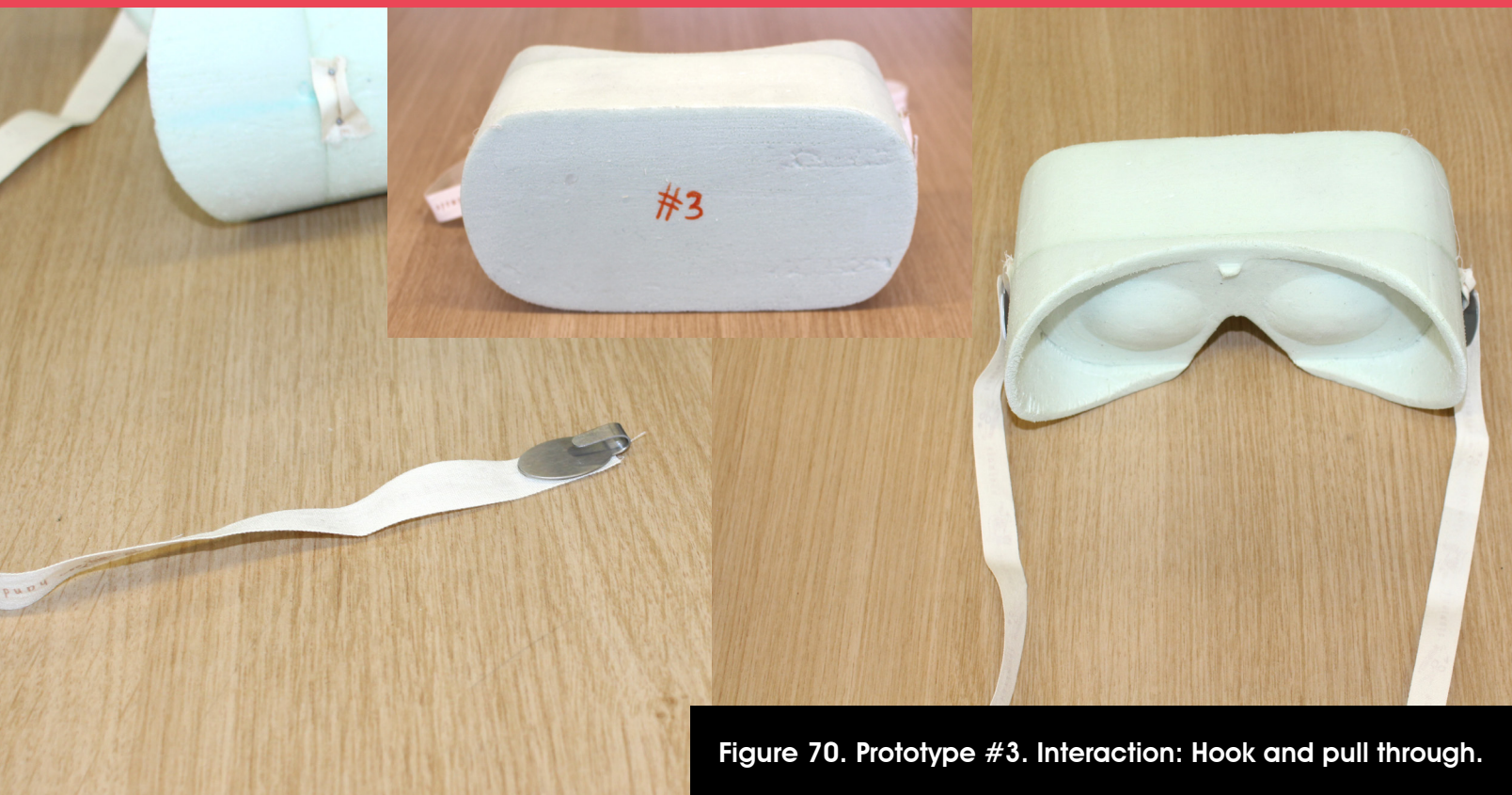



Figure 70. Prototype #3. Interaction: Hook and pull through.


Figure 71. Prototype #4. Interaction: Push and position.

## ATTACHMENTS


Figure 73. Prototype #5. Interaction: Position and click.

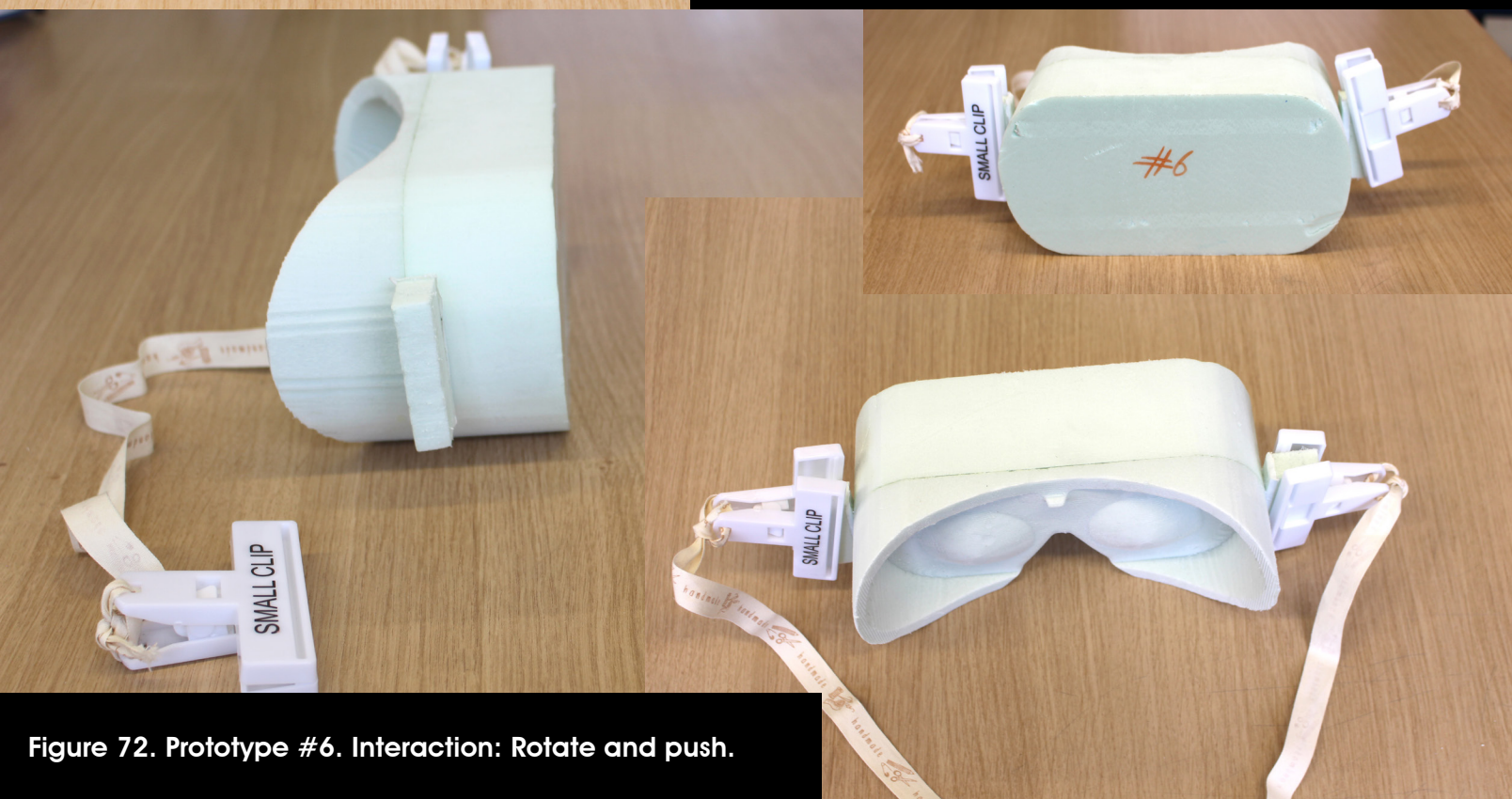



Figure 72. Prototype #6. Interaction: Rotate and push.

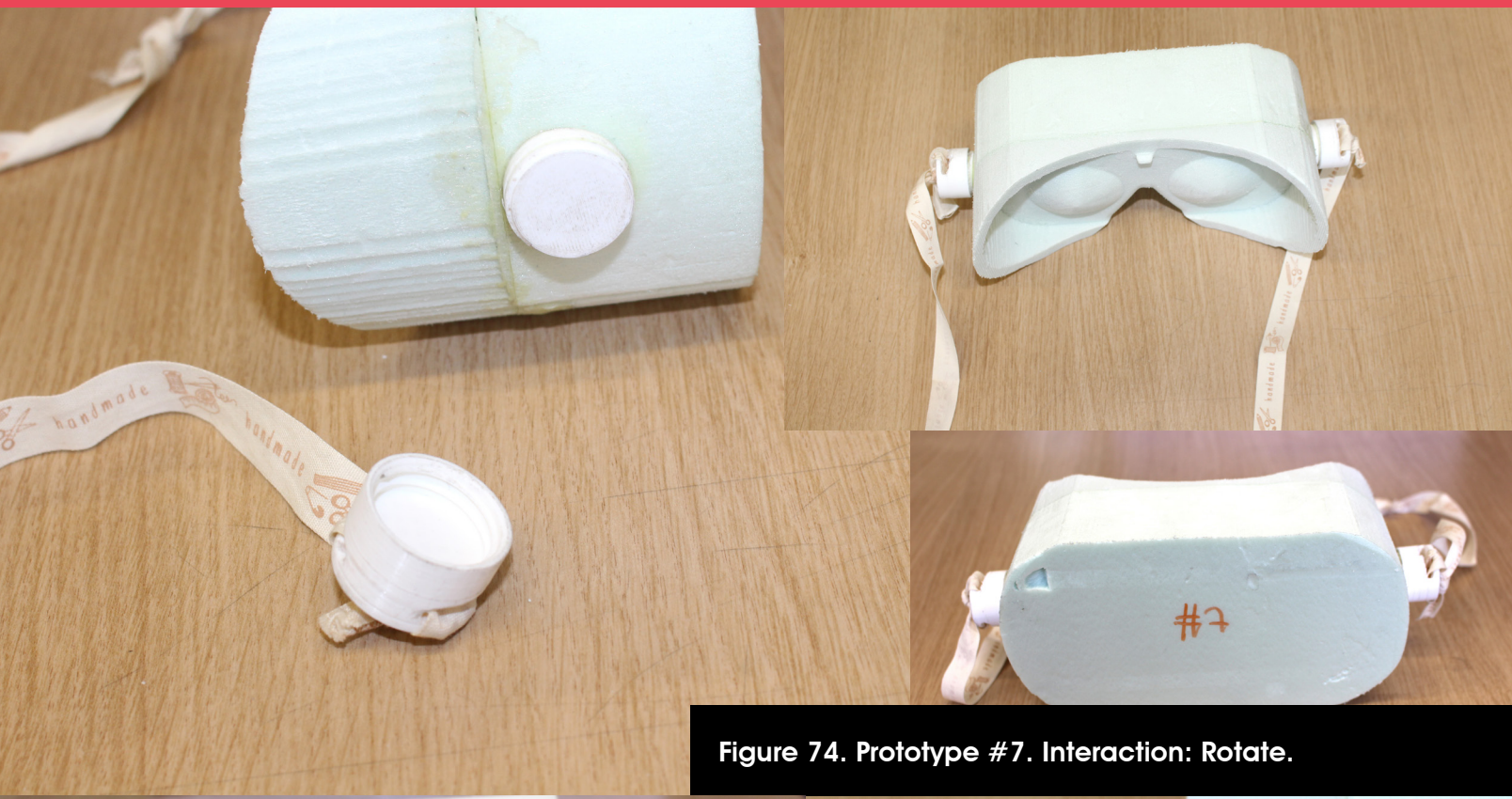



Figure 74. Prototype #7. Interaction: Rotate.

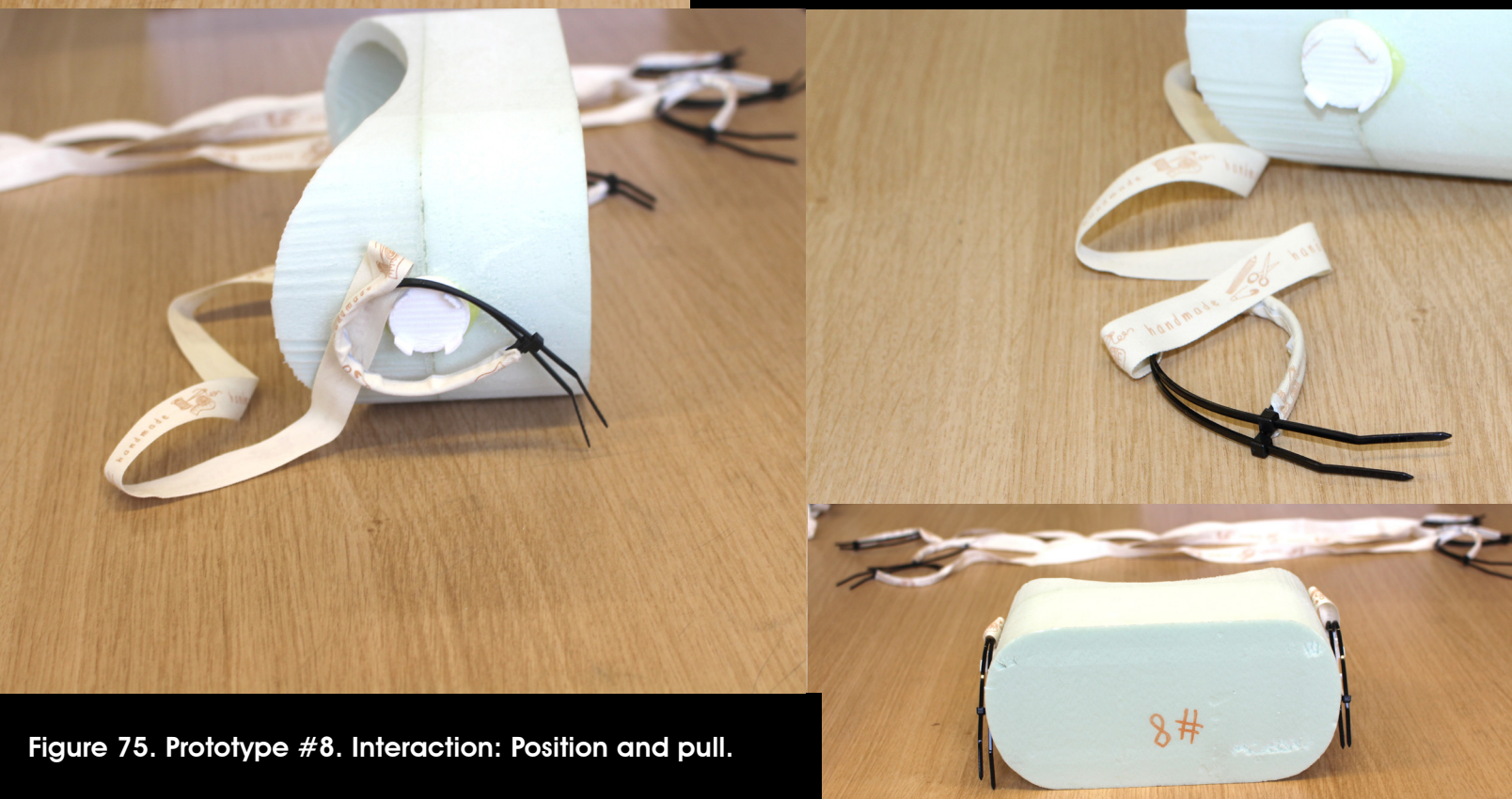



Figure 75. Prototype #8. Interaction: Position and pull.

# ATTACHMENTS

The conclusion of "Chapter XXIV - User Experience" on page 76 indicated that there were three options chosen as the best ones out of the test.

The goal of this part is to analyse a possible connection and adjustment mechanic to find out how well it works.

## Analysis

When looking in an in-depth way on interaction opportunities, the conclusion mentioned that the interactions needed to conform to three simple rules:

1. Easy connection
2. Firm connection
3. Proper adjusting to the head of the patient
4. Easy disconnection

With these three in mind another possible connection possibility is explored.

## Bayonet Mount

A bayonet mount is a mount that has two ends: a male and a female (see Figure 74 on page 105).

This mount has been included in a design of the full design as seen in

When designing this into the second prototype an important piece of insight that was not foreseen is gained: Both the male and the female component need to be produced out of a rigid and stiff material for the lock to be possible.

What this means is that the headband (produced in a flexible material) needs to be connected to a custom produced (in a more stiff material) male or female part of the bayonet mount. While this is not an impossible task, it is definitely a huge challenge for a small startup like SyncVR and is something that is desired to be more long-term than short term.

This insight is gained after creating the second mold and is further implemented in the design in "Chapter XXIX - Design Changes" on page 122.

## Adjustment possibilities

Everyone has a differently shaped head. Creating a single size that fits all heads is a very difficult task, so an idea for incorporating a retention system rose.

Retention systems are currently a widely used feature in cycling helmets. While lots of variants exist, the mechanic works similar in all of them: a circle retracts, rotates, pulls or moves the headband in such a way that it either contracts or pulls it together in some way.

With a retention system, a headband can usually be tightened on the go.

In the small usage test performed with nurses in the Maasstad hospital (see Figure 80 on page 110), the nurses raised concerns that hairs would get stuck inside the gaps that are in these specific models.

Producing and connecting this to a silicon headband also proves to be a challenge. Next to this, the silicon proves to be flexible and can actually stretch for long phases. More information about this can be found in "Chapter XXVIII - Surface and Geometry Study" on page 118.

Finding a proper connection that confirms to the three rules seems to be a challenging act. The final change in a more suiting connection can be found in "Chapter XXIX - Design Changes" on page 122. In terms of adjustment, the chosen silicon in "Creating the second prototype" on page 111 demonstrates in "Chapter XXVIII - Surface and Geometry Study" on page 118 that the strain is indeed very large and that the material (through its elastic properties) itself can stretch out and adjust itself elastically.

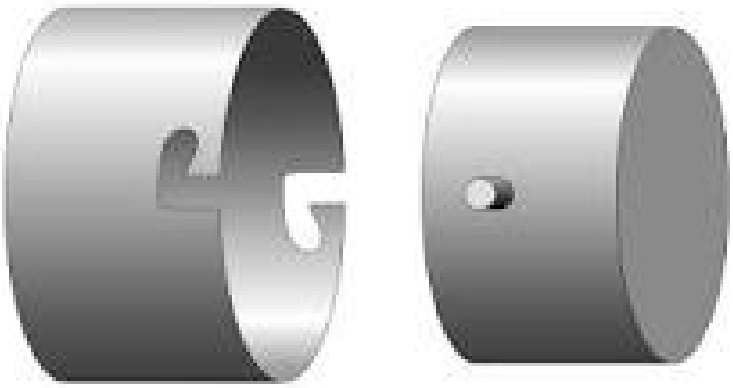


Figure 76. Bayonet Mount (retrieved from: https://commons.wikimedia.org/wiki/File:Bayonet-mount-01.svg)

Figure 77. Various helmet retention systems tested on whether the retention system concept was suitable for this project.

# XXVI - Headband

Figure 78. Scanning the facial interface of the Oculus Go, so it can be imported as a 3D model.

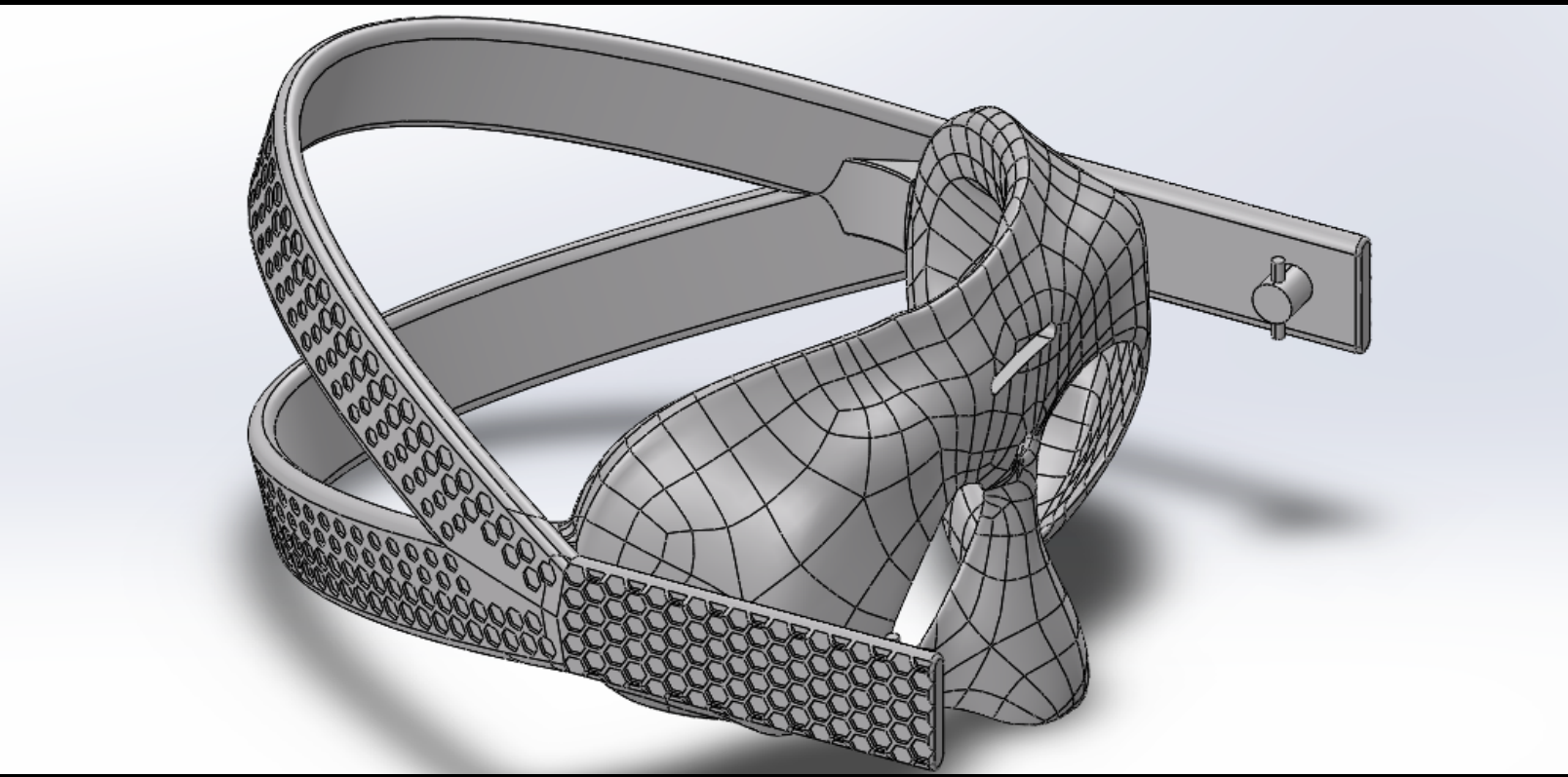


Figure 79. The design at the end of phase 2 with the bayonet connection mechanic, headband and facial interface.

# and Facial Interface

## Headband

The headband is the part that spans across the back of the head. The facial interface is the part at the front that connects the face with the Oculus Go.

The goal of this chapter is to find out proper initial designs for these that can be connected to the connection base mentioned in the previous chapter (see "Chapter XXV - Connection and Adjustment" on page 96).

Due to time restrictions of the project and therefore limitations in time, these design processes are shortened to single week iterations in which it is also attempted to produce these.

The headband could have taken many different shapes with multiple lines, complicated shapes constructed in multiple triangles and more.

In the end, the decision is made to keep everything as simple as possible.

One single band that splits in two, so the split covers the majority of the back of the head is a shape that is being used in many existing products already.

The overhead band does not seem necessary for the design. This was tested shortly with the existing headband and facial interface and feels just as comfortable while making production a lot easier.

The first headband (without the facial interface) is produced by using a foam model. This test serves to validate the production method in the first place.

## Facial Interface

The current facial interface does not seem to contain any flaws with regards to its shape. Since it is custom made to already fit on the Oculus Go and SyncVR is permitted to use the same model, this is the simplest option that does not need any testing or design processes.

The facial interface is taped to a tripod so it hangs independently in the air, after which it is scanned into a 3D model. This 3D model is then further cleaned up and imported into the rest of the design in SolidWorks.

## Merged Concept

These components are all merged together and the model as seen in Figure 77 on page 106 rises.

The goal of this merged concept is to prove production viability and to find points of improvements with regards to production.

For this reason, the surface of the second prototype has a hexagon surface on the outer surface. This proves how detailed the material can enter smaller surfaces and whether a millimeter bars (that separate these hexagon areas) are too narrow.

This merged concept is further produced and analyzed in "Chapter XXVII - Production Study" on page 108.

# XXVII - Production Study

In order to provide more transparency on whether this project is feasible at all, the designs cannot just end up in a software model. They need to be created and improved upon.

The goal of this chapter is to find out how this product can be produced in a feasible way and to find improvements in the production method.

## Finding a desired material

The desired material for this product is any flexible non-porous material. Flexilble, because it needs to be able to adapt to a (small variety of head shapes and sizes. Non-porous, because bacteria can fit in gaps in the material, which is undesired. There is a wide range of materials that fit this requirement, including a variety rubbers, thermoplastic elastomers (TPE) and thermosets.

## Finding the production method

Finding a feasible production method is a challenging task. There are several production methods that come to mind at first. They all have their benefits and downsides however:

### Injection Molding

Injection Molding is the most widely used production method to date. Plastic (usually in the form of granules) enters a large machine through a funnel. In this machine (see Figure 17 on page 31), the plastic is pushed through heaters inside the machine by a large screw into a mold. The high pressure and temperatures in this production method demand a very sturdy (often aluminum or steel) mold.

This mold and the machine require a large investment, often in scales of tens of thousands of euros, which pays off in the long term as the mold then lasts for so many units, it ends up producing more to cover up for these upfront costs and a profit later on.

### Vacuum- and Thermoforming

There are other methods like vacuum forming and thermoforming. These methods include a mold that a material is being heated and shaped or vacuumed and pulled into. Due to their nature in being a single direction, the flaw in these methods is that they usually limit the shape of the product, which ends up unviable for the design of this project.

### 3D Printing

3D printing is a more recent production method, where a single device accurately prints a 3D model that is fed into the printer through a file. 3D printers have become more and more advanced over the years and humans are capable of printing for cheaper and with wider varieties of materials than ever before. The problem with 3D printing is however that there are very large unit costs paired with printing, especially with the desired materials.

### Using existing products or materials and modifying them

One other idea is to use existing sheets, cut them by using a press, lasercutters or other methods and to assemble sheets together using an a@issembly line. The foreseen problems here are that this will create problems in the field of hygiene (gaps and edges that cannot be cleaned due to pieces that are being attached to each other) or will not provide a fully fledged product.

### Room temperature vulcanizing silicone

For the project, this was an unknown production method. This production method uses two different components, which after mixing them together, harden out to a silicone. While it has some upfront cost, it does not have the high unit costs of a 3D printed model. One big downside of this method is however that the chemical reaction is irreversible, which means that recycling the outcome is not possible.

The challenges are a tough one to crack. Choosing a different material would allow for a more feasible product, but would in turn sacrifice comfort and ease of use for patients. With this desired material:

- Injection molding is not viable for SyncVR yet. The upfront cost here is too expensive. Their batch of products will not reach the counts tens of thousands of products or even more to make it worth the investment that is put into the mould and the machine.
- Vacuum- and thermoforming has the huge downside of having such little freedom in the shape of the design.
- 3D printing will have very large unit costs (a minimum of 200 euros for printing a headband this size in a TPE material).
- Using existing products and assembling them opens up for inconsistency problems with gaps and will therefore not meet the standards of a hygienic product.

The Room temperature vulcanizing (RTV) silicone seems to be the most ideal solution here. It has some upfront costs (creating a relatively cheap mold), with some higher unit costs (the two component silicone), which aligns in the middle between injection molding and 3D printing.

Figure 80. (Open) foam mold that is milled and attached by some sticks and tape to align and fix parts together.


Figure 81. The two-component silicone that is used to create the first silicone concept prototype.

## ATTACHMENTS

Figure 83. First production sample.

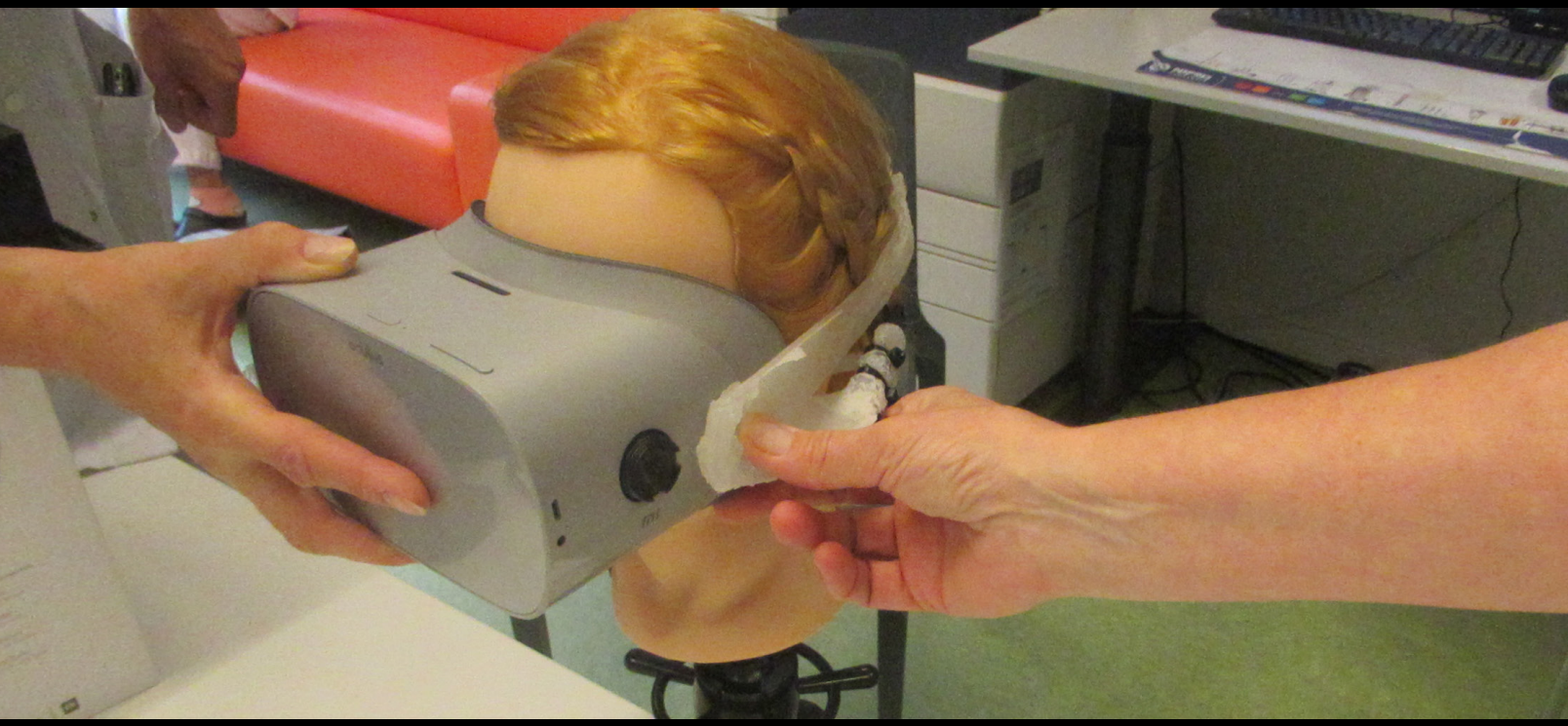


Figure 82. Small usage test with the dialysis nurses to get some quick feedback with regards to the headband, the silicon material and the retention system.

### Creating the first prototype

With this analysis, a 3D model is created and the first mold is milled in seven parts (see Figure 78).

The foam mold is filled with the ZA 00 Traslucido two-component silicone to test out this production method in the first place.

After putting the mold together, aligning it with some sticks, faping it and surrounding it with elastic bands, the silicon is poured into the hole on the top of the closed mold. The curing time is waited upon and after several hours the first sample is pulled out of the mold, after which a retention system is applied onto it to test this type of system out as well, as seen in Figure 81.

The flaws in this first production attempt definitely show.

- The mold needs two entry points instead of a single one (which caused the bottom part to be completely empty,
- The mold itself needs better sealing and tightening applied on the inner surfaces,
- The mold needs holes that lead back up so it can be guaranteed that the entire mold is filled,
- The mold itself needs to become more rigid. Foam is very soft and can be accidentally deformed in a really easy way, which creates inaccuracies in the model later on.
- This sample seems promising, the silicon stretches, feels decent and performs up to some standards. but is relatively brittle. This specific material breaks really easily when you pull it slightly.
- The material still contains holes, which is undesired; these bubbles need to be limited as much as possible.

This attempt is also shown to nurses in the dialysis department to get their feedback on working with a custom silicone headband and with a retention system like this.

Their input is that they like a stretchy material like this as it allows for some adjustment. They like the retention system, but fear that hairs can get stuck in between all the gaps in the mechanic and therefore prefer a closed system. The material of the headband is (as expected) too soft and tears realy easily. They would like to see a much tougher and tear resistant material.

This input aligns with the initial insights.

### Creating the second prototype

With this input, the second prototype is created. As mentioned in "Chapter XXVI - Headband and Facial Interface" on page 106, this prototype includes the facial interface as well, which complicates the design.

After creating the model as seen in the same chapter, the mold for the model is created (which proves to be a rather big challenge on it's own with the facial interface).

This improved seven part mold can be seen in Figure 82 on page 112.

The mold has two entry points at the top and has some channels that lead out through the side. The mold is 3D printed instead of milled foam blocks for a more rigid structure to the mold (see Figure 83 and Figure 84 on page 113).

These same figures also display that a sealant (SuperSeal) is being used to cover the texture of the 3D printed mold and make the surface smooth, which in turn makes the surfaces of the silicone model smooth when molding.

Vaseline is applied on the side of the molds to ensure that the mold parts essentially glue together to prevent the silicone from slipping through the sides of the mold parts.

The last major point of improvement was finding a better material. At this point it is obvious that a stronger silicon is needed. After searching and talking with a couple of distributors, hearing their advice and visiting a store and having a physical example in hands, the decision is made to test the Dragon Skin FX-Pro from Smooth-On.

When feeling the physical example, the Dragon Skin FX-Pro feels very prone to stretching. Smooth-On claims a 763% elongation at break, which is surprisingly high. The pot life (which indicates the amount of time that you have to pour the silicon into the mold) is also significantly larger at 12 minutes.

The two components are stirred and poured into the mold, after which the entire mold enters a vacuum chamber with the hypothesis that the vacuum chamber should get rid of the bubbles inside the material.

## ATTACHMENTS

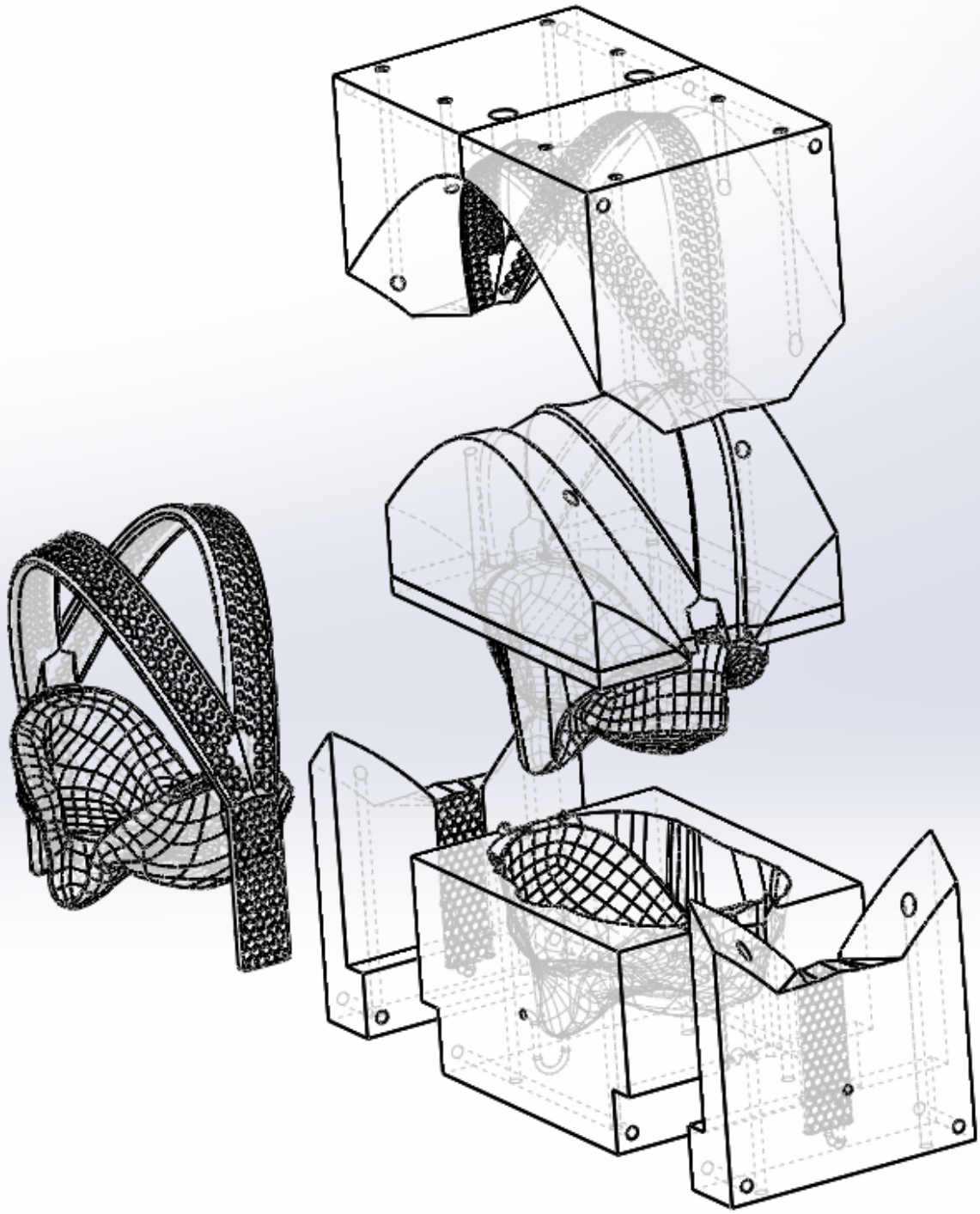


Figure 84. Mold and design of the second prototype.


Figure 85. LEFT: The sealing that is used to seal the surface that the silicon will touch during the molding process. RIGHT: Applying this sealing to the mold with a paintbrush.

Figure 86. Applying vaseline to the sides of the mold aids in closing the mold parts onto each other.

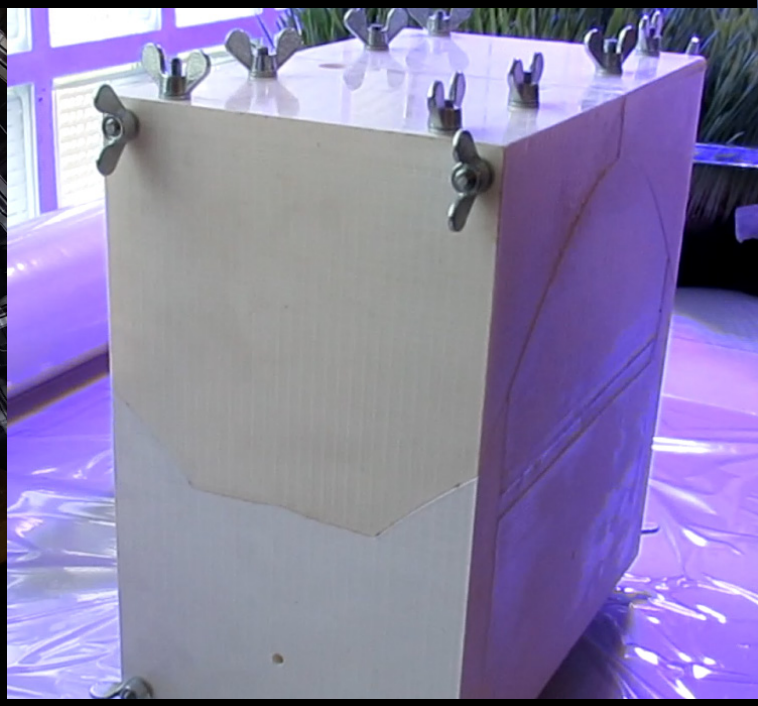


Figure 87. The mold in its closed state, all firmly attached with threaded rods and wingnuts.

## ATTACHMENTS

After molding, the second prototype feels really good. The surface of the material is smooth, the material itself is really strong (tear resistant) and the prototype exits the mold better than anticipated.

While this second prototype is a large improvement, it still has its flaws.

- When designing the exit tunnels, these should have ended at the top instead of the side due to communicating vessels. Because it was designed this way, the silicon started leaking out these holes before the entire mold was filled, causing parts of the mold to not be filled properly.
- Two holes at the top for entry is a good improvement, however the content needs to be poured in such a way that it's being poured through both holes at the same time. This can be done by incorporating the funnel into the mold for example.
- There seem to be air pockets inside the mold, which means that the mold needs more exit tunnels that exit at the surface level.
- The material itself still has holes and large bubbles remaining throughout the prototype, despite attempts at vacuuming the mold as the silicone is curing. This problem definitely needs to be solved.
- The entire prototype feels a bit sloppy, which makes one wonder: can it actually lift an Oculus Go and how strong is the material?
- The size of the headband feels very loose, since it is designed without any stretch in mind, it probably needs to be tightened significantly with substantiated decisions.

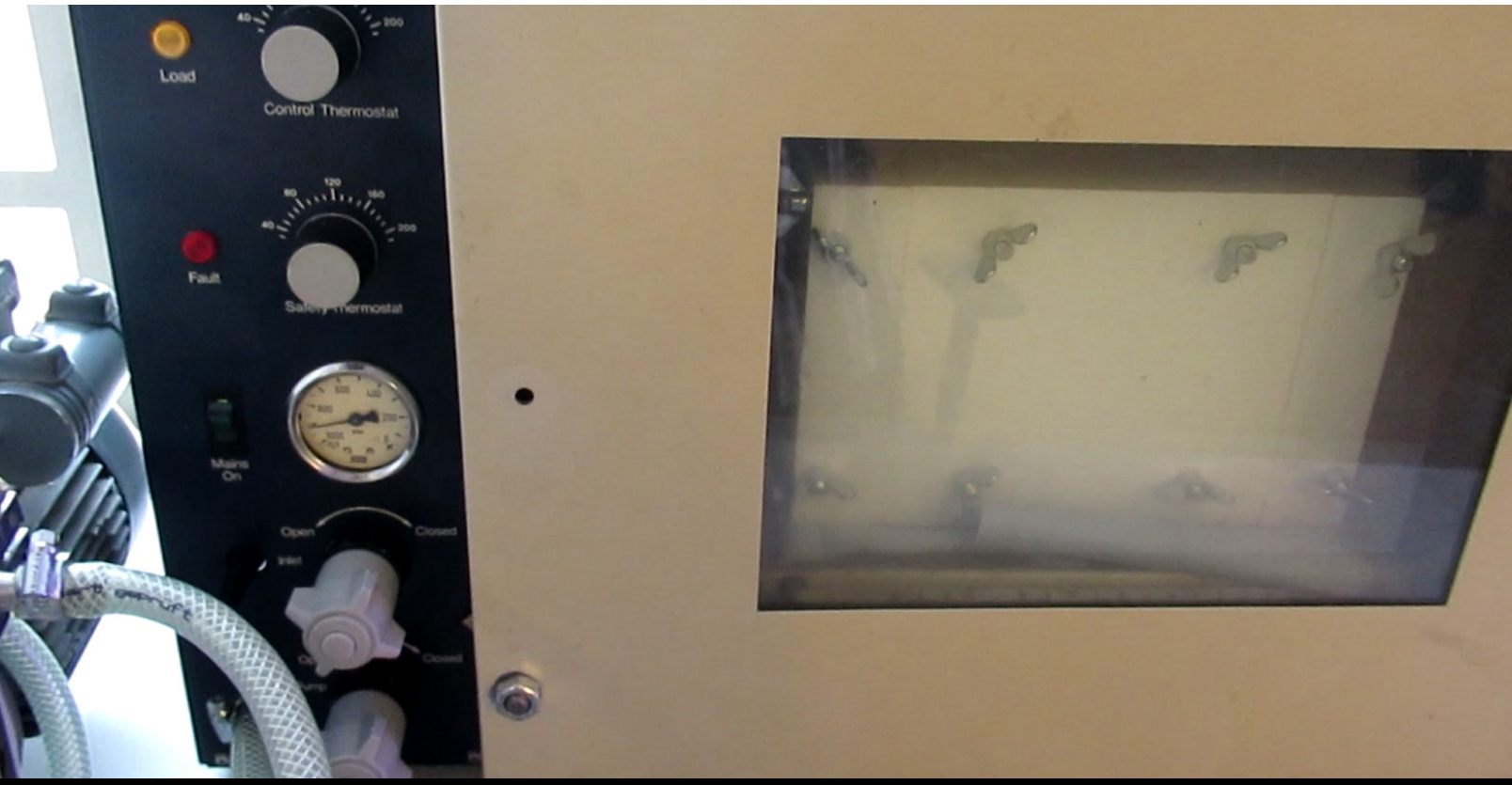



**Figure 88. The mold filled with silicon is being vacuumed inside an oven (serving as a vacuum chamber without heating turned on) that is connected to a vacuum pump.**

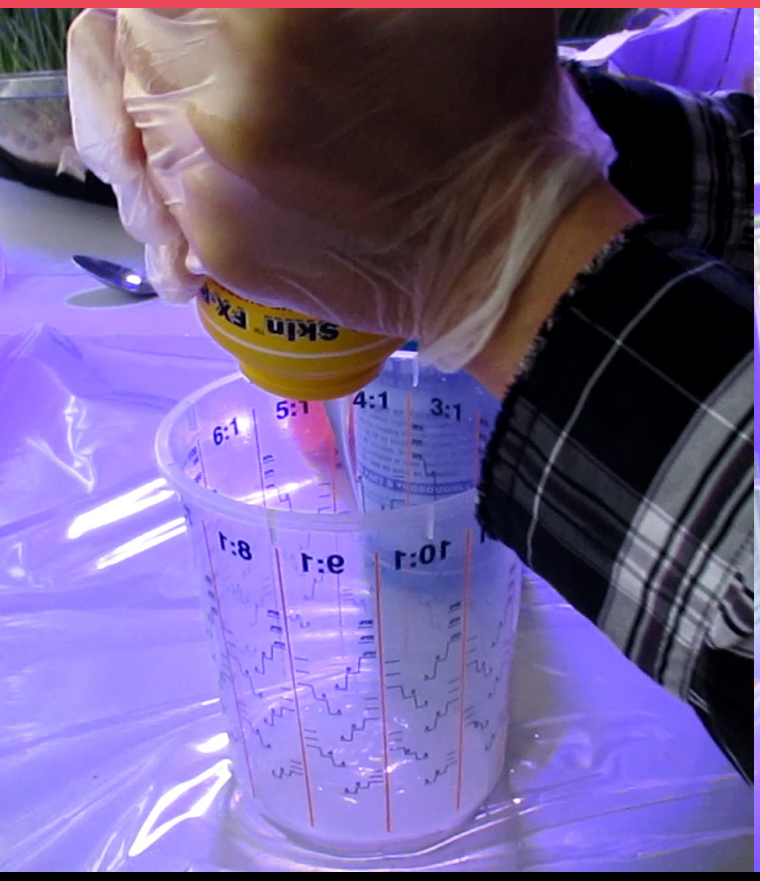



Figure 89. Pouring the components of the Dragon Skin FX-Pro into a mixing cup.


Figure 90. Pouring the mixed components of the Dragon Skin FX-Pro through a funnel into the mold.

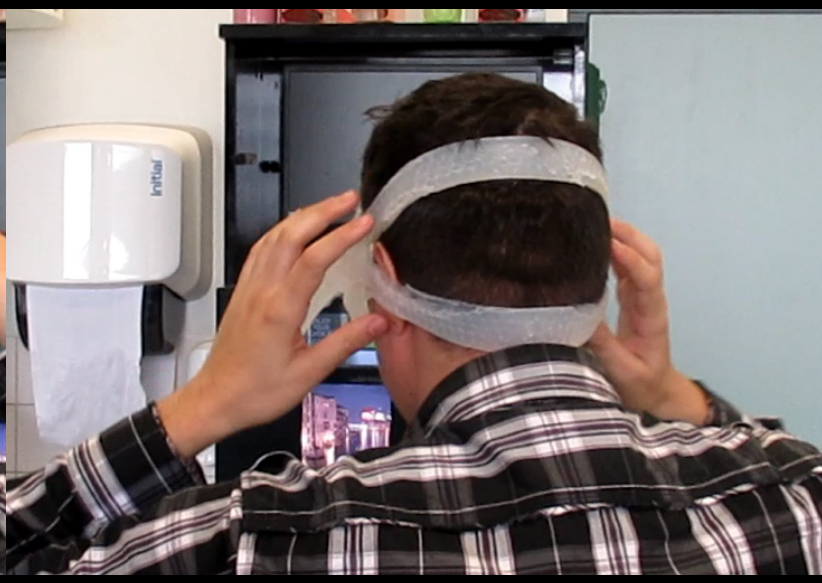


Figure 91. The second prototype seen from the front and back.

# ATTACHMENTS

As stated, one of the biggest problems stated in this chapter is that the prototypes kept having bubbles through the surface. In order to solve this problem, a production study is performed.

So what is going on? When trying to solve a problem like this, it is crucial to find out why the bubbles exist in the first place.

When initially pouring the material in a mixing cup, the liquid seems to be pretty bubble-free. However, when mixing the components together and when stirring thoroughfully, air gets stuck in between and cannot get out.

The first thought that comes to mind is thus to vacuum the material in the cup first and to vacuum the mold all together afterwards.

This attempt is performed alongside the first shape and geometry study.

As seen in Figure 90, this proved to not work properly at all.

After the first production study and some discussions with people who have had experience with RTV silicone, a massive flaw was discovered.

The reason the mold was being vacuumed while the silicone was curing in the mold was with the intention to remove any possible bubbles that could occur after entering the mold.

The pouring process has to however be one that should be executed carefully and in an uninterrupted manner. Vacuuming as the silicone is curing inside the mold works counterproductively.

What happens when putting a material in vacuum is that the air bubbles grow in size and try to find the shortest path out of its trap (the mold). When the material is inside the mold, the growing air bubbles push out the material and leave the mold only partially filled. Once the silicone hardens, the shape of the bubbles that could not escape in the mold are left behind.

These air bubbles that are trying to escape are really tiny outside of vacuum. However, since they grow inside the vacuum and push the material out, they essentially destroy the material.

Putting the material in a vacuum separately prior to mixing it together is another idea that further improves getting all the bubbles out beforehand.

The material should thus be vacuumed before (both components separately), then mixed together and vacuumed together for a short period of time, then poured into the mold and left alone. By doing so, it is ensured that the bubbles are removed from the material as well as possible.

In the following chapters, these actions are performed and figures with samples without bubbles can be found.

This study tackles one of the biggest problems stated in "Chapter XXVII - Production Study" on page 108 by gaining an in-depth understanding on how air bubbles interact in a vacuum and solves this problem by reversing the vacuuming process.

Figure 92. Shape and Geometry samples with the first production study.

ATTACHMENTS

# XXVIII - Surface and

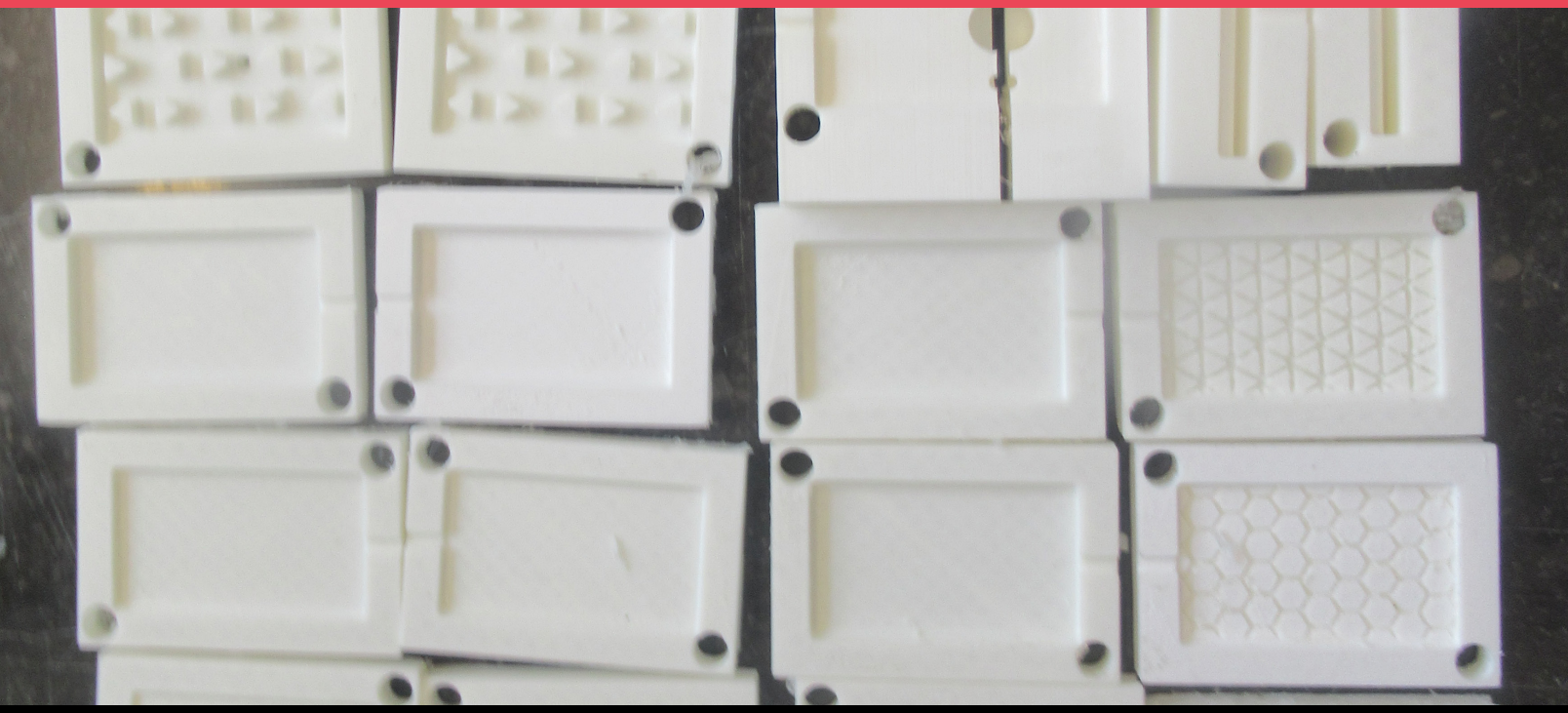


Figure 94. First shape and geometry molds

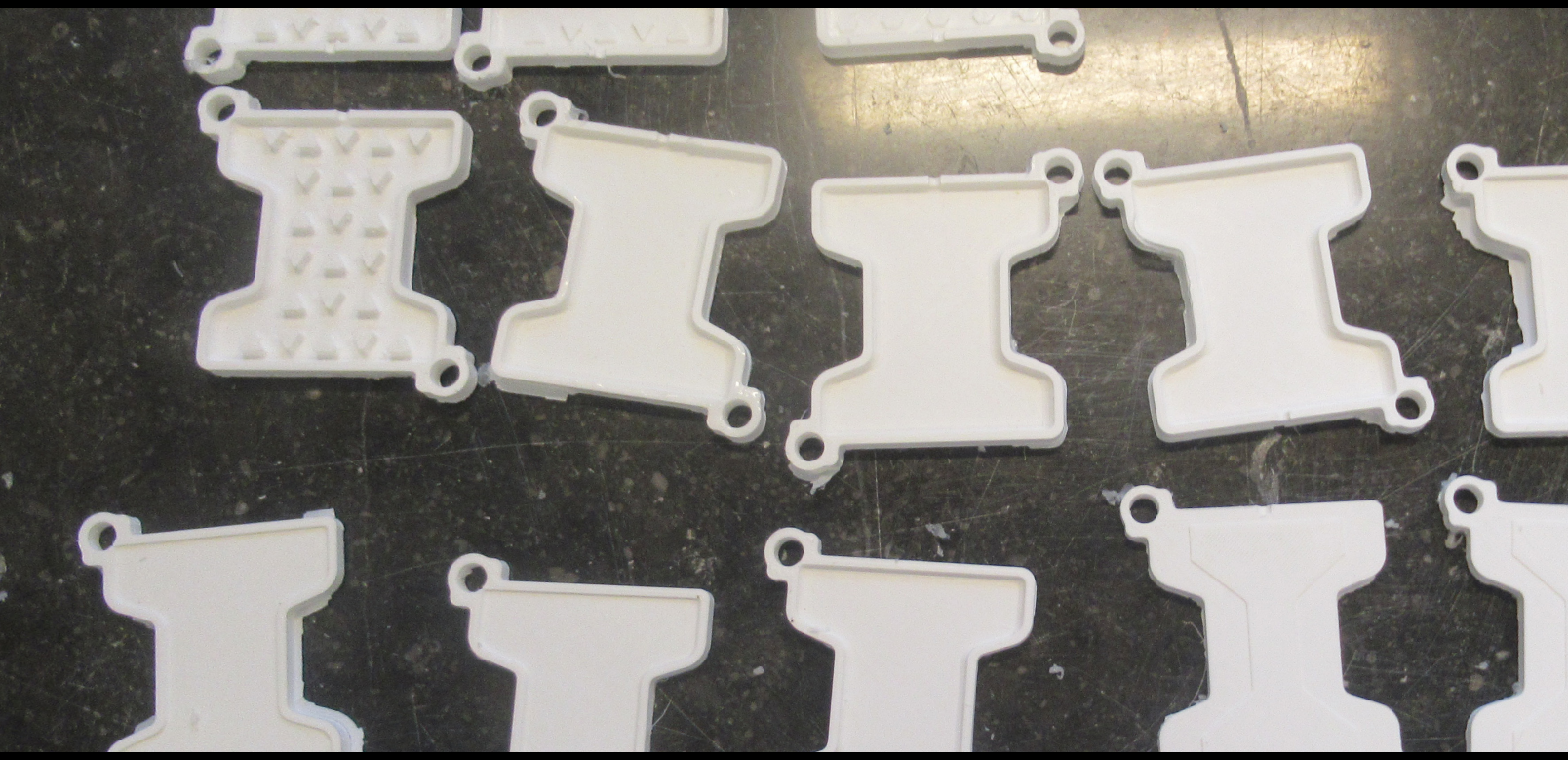


Figure 93. Second shape and geometry molds

# Geometry Study

The shape and geometry analysis serves several purposes:

- Finding out whether the material in its current shape (the intersection was determined to be an oval with 6mm thickness and 30mm wide) is strong enough to lift and hold the Oculus Go,
- Finding out whether material can be saved by having a smaller intersection or by having (partial) cuts through the material,
- Finding out how much a small frame of 1mm thickness influences the stiffness of the material,
- Verifying the claimed 763% elongation at break of the manufacturer,
- By creating molds for this study, "Chapter XXVII - Production Study" on page 108 is supported as well.

This is done by creating small samples and by putting them through tensile tests, wherein the material is being pulled until it breaks.

## Preparing the tensile tests

Since this is the first time these tensile tests are being performed, an assumption was made that the samples needed to be in a square shape. This proved to be wrong, and new molds are created in an I-shape.

The reason for this is that the mission grabs onto the top and bottom of the samples, which will cause the material to break at the top or bottom instead of the middle, which impacts the results in a negative way.

The samples that are being used are in a decent variety of thickness and shapes:

- Clean and smooth surface (without cuts) with an intersection of 2, 4 and 6mm thick.
- The same samples, but strengthened with a plastic frame (vivak, 1mm thick transparent copolyester) in the center of the intersection.
- 6mm thick samples with 1mm deep triangle and hexagon-shaped cuts on top of the surface.
- 6mm thick samples with triangle shaped cuts through the entire surface.

All samples are produced and tested three times each to maintain some accuracy.

## Tensile tests analysis

After producing, the samples with a plastic frame felt a lot less sloppy. This is a desired for the sides that are directly attached to the Oculus Go. One remark for this test is that the material is being pulled straight upwards due to the limitations of the machine, instead of perpendicularly as in the real scenario.

When testing, the samples with a frame were not really prone to proper testing. While definitely stronger, the machine was not able to hold on to the frame inside the soft silicone and kept letting go. This means that the samples with the frames were not testable. The other samples passed more than satisfactory through the test however. As seen in Figure 94 on page 121, the material has an elongation at break that averages around the claim of the manufacturer. All samples are able to carry the weight of the Oculus Go multiple times.

Even though the real scenario is a bit different, this does prove that the material should be strong enough to carry the Oculus Go without any problems.

The graph on the right of Figure 94 on page 121 shows that during the entire stretching phase, the material stays in an elastic phase and breaks abruptly at the end. This is important to notice, since this means that no matter how much the material is stretched, it should always return to its original shape.

The 6mm thick samples with 1mm cuts in the surface seem to be as strong as the 4mm thick samples without any cuts. The samples with cuts through the entire surface perform even worse, since it acts as multiple thinner intersections, which breaks more easily. Cuts in the surface make it so bacteria cannot be cleaned as easily and is thus preferably avoided. And even though the 2mm samples look strong enough on paper, they feel too flimsy to be reliable.

For this reason the decision is made to continue with a 4mm thickness alongside the entire headband and to strengthen the sides that are connected to the Oculus Go with a 1mm thick frame.

The tensile tests prove that the material is indeed strong enough to lift an Oculus Go and that the intersection can be optimized to 4mm thick to save some material. A 1mm thick frame is applied on the sides that are connected to the Oculus Go to ensure a stronger connection. Cutting holes in the surface is not desired since the cons (less hygiene) outweigh the pros (similar strength). The elongation at break is also verified at a similar one that the manufacturer claims.

These insights are further incorporated in the design changes.

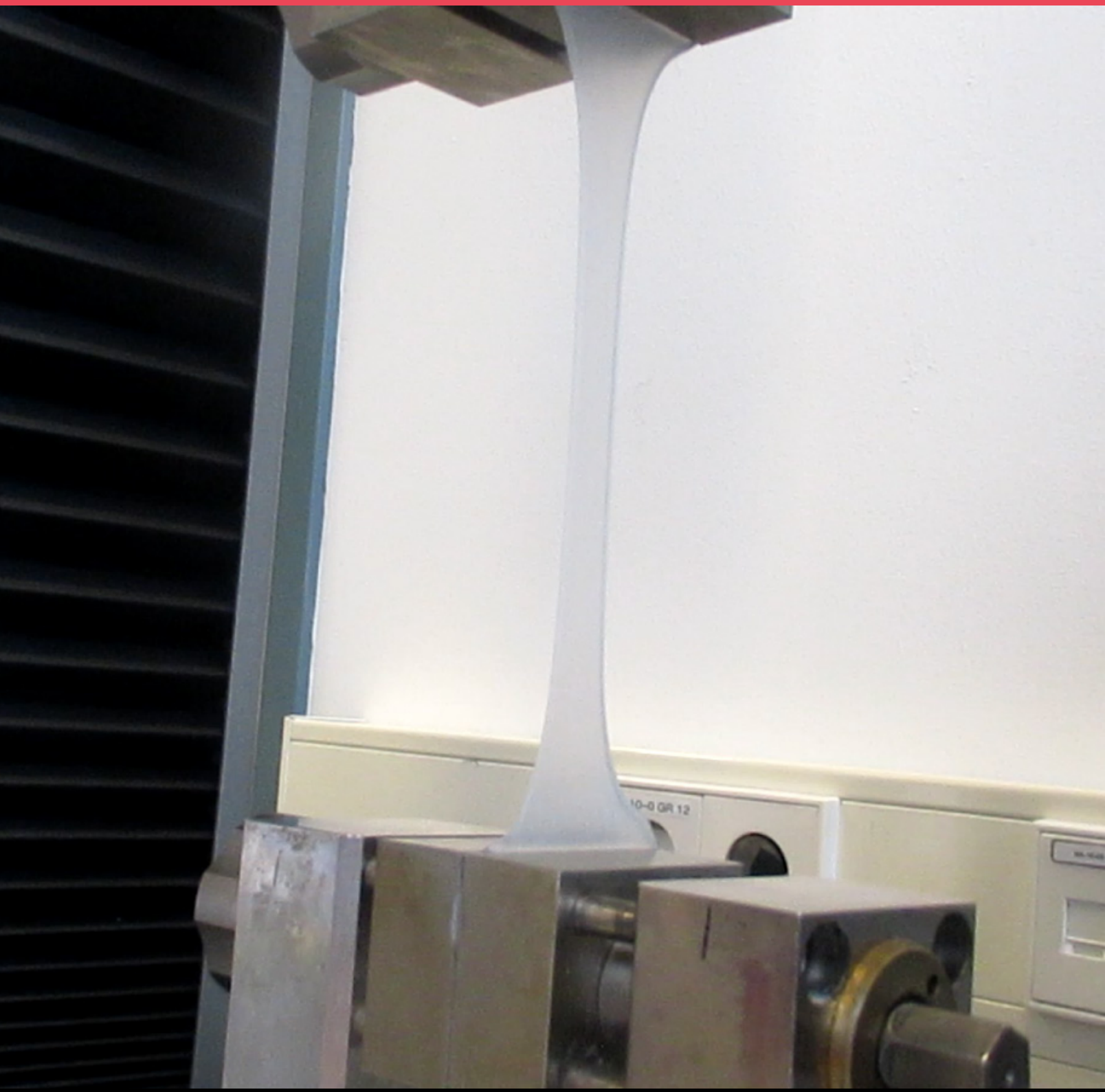


Figure 95. Tensile stress testing one of the samples.

| | h | b | $A_0$ | Peak detection | $\varepsilon_{tB}$ |
|---|---|---|---|---|---|
| | mm | mm | mm² | N | % |
| Triangle_6_1_S1 | 6 | 30 | 180 | 173.5797119 | 733.6871 |
| Triangle_6_1_S2 | 6 | 30 | 180 | 150.821228 | 1116.918 |
| Triangle_6_1_S3 | 6 | 30 | 180 | 180.6908569 | 639.8702 |
| Triangle_6_a_S1 | 6 | 30 | 180 | 112.663063 | 880.1372 |
| Triangle_6_a_S2 | 6 | 30 | 180 | 119.8165665 | 700.6462 |
| Triangle_6_a_S3 | 6 | 30 | 180 | 96.73806 | 741.6316 |
| Straight_4_f_S1 | 4 | 26 | 104 | 126.6127777 | |
| Straight_4_f_S2 | 4 | 26 | 104 | 86.96716309 | |
| Straight_4_f_S3 | 4 | 26 | 104 | 123.7238998 | 736.8135 |
| Straight_4_S1 | 4 | 26 | 104 | 121.5823746 | 777.5168 |
| Straight_4_S2 | 4 | 26 | 104 | 137.5142975 | 784.1576 |
| Straight_4_S3 | 4 | 26 | 104 | 85.42339325 | 1013.558 |
| Hexa_6_1_S1 | 6 | 30 | 104 | 193.7164307 | 810.3037 |
| Hexa_6_1_S2 | 4 | 26 | 104 | 187.8763123 | 720.3544 |
| Hexa_6_1_S3 | 6 | 30 | 180 | 137.3813019 | 987.83 |
| Straight_6_S1 | 6 | 30 | 180 | 217.5148468 | 922.5433 |
| Straight_6_S2 | 6 | 30 | 180 | 201.0355682 | 885.6168 |
| Straight_6_S3 | 6 | 30 | 180 | 179.484314 | 799.9662 |
| Straight_2_S1 | 2 | 22 | 44 | 56.54623032 | 774.2622 |
| Straight_2_S2 | 2 | 22 | 44 | 57.64574432 | 703.5843 |
| Straight_2_S3 | 2 | 22 | 44 | 60.78857803 | 674.965 |

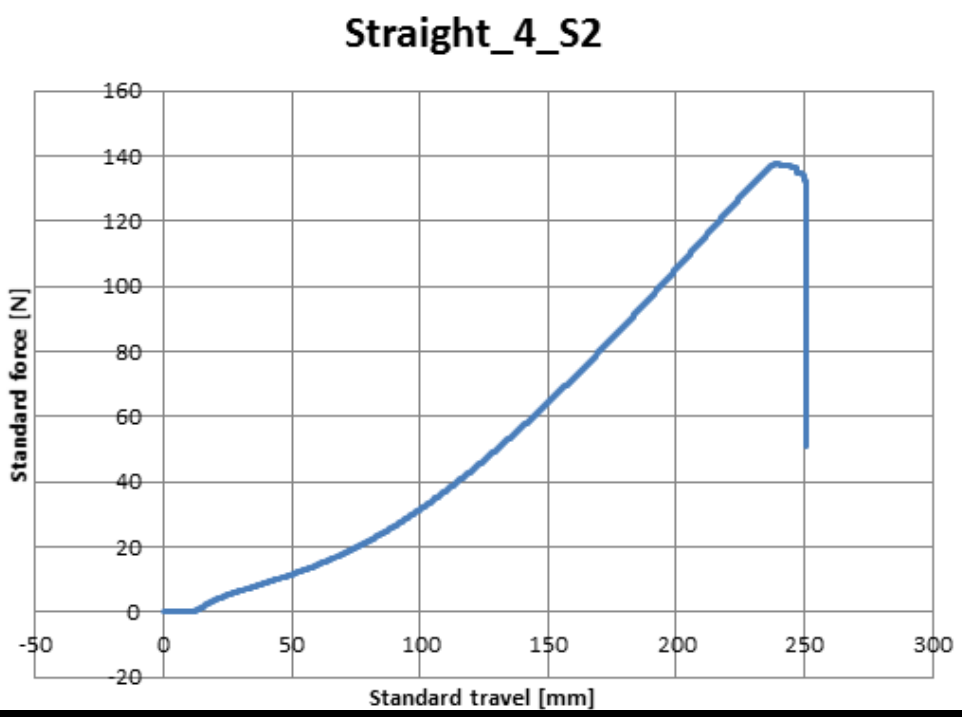



Figure 96. LEFT: Relevant data for all samples. RIGHT: The Elongation (x-axis in mm) / Force (y-axis in N) of the second smooth surface 4mm thick sample.

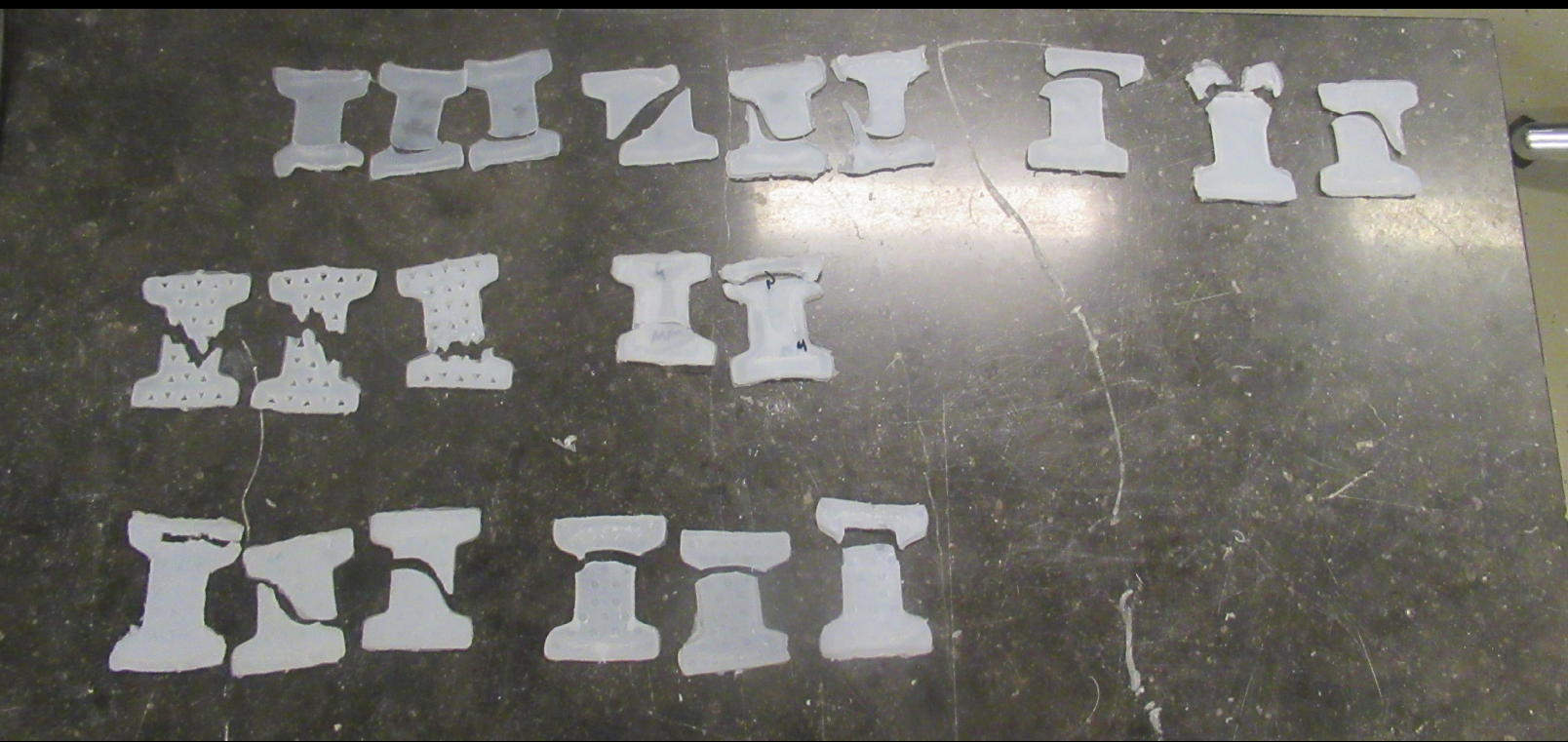


Figure 97. All samples after the tensile tests.

# XXIX - Design Changes

The insights from "Chapter XXVII - Production Study" on page 108 and "Chapter XXVIII - Surface and Geometry Study" on page 118 are combined with the insights gained from "Chapter XXVII - Production Study" on page 108 to implement improvements for the final product and mold design of this project.

## Summary of Improvements

- The mold should support more exit tunnels at expected air pocket locations.
- Exit tunnels must exit at the top.
- Mold requires a funnel for smooth entry of the silicone mix.
- The Dragon Skin FX-Pro with an oval intersection of 4mmx26mm meets the demands and wishes listed in "Chapter XV - Program of Wishes and Demands" on page 36.
- The material needs to be vacuumed separately, mixed afterwards and vacuumed again. Afterwards, the material cures inside the mold without any intervention or vacuum.
- The sides need to be strengthened with a 1mm thick frame.

Some of the remaining improvements are:

- The bayonet connection needs to be replaced with a similar connection mechanic that works.
- The headband needs to be tightened to account for the validated strain.
- Confirming that the Dragon Skin FX-Pro can in fact be used in thermal disinfection.

## Changing the bayonet mount

The bayonet mount is desired because of an easy (dis-) connection and firm connection.

This mount is however not feasible in production and needs to thus be replaced. Instead of a complicated bayonet mount, the decision has been made to leave the connection simple: a single loop that is stretched and attached onto a hook, which is pre-emptively clicked onto the Oculus Go. This preserves the easy (dis-) connection and a firm connection. The hook seen in Figure 98 is 3D printed and clicked onto the Oculus Go.

## Tightening the headband

The headband in the second prototype is too loose, since it's designed to fit the average head. For this reason, some stretch is desired so the headband fits in a slightly pressured way on the head of the patient. On the bottom part of Figure 101 on page 125 a screenshot from DINED.nl (Molenbroek, 2017) is shown with antropomorphic measurements taken between 1998 and 2000 in Europe and North America. These measurements include the head circumference for P5 and P95 of the population. Dividing these values by two results in their radius, 264.5mm and 297.5mm respectively. The respective part of the headband that touches this area has been redesigned to be 154mm, which leaves a strain of between approximately 71.5% and 93.1%, well in range of the allowed strain of 763%. When looking at the results of the tensile tests performed in "Chapter XXVIII - Surface and Geometry Study" on page 118, the material requires between 4.5N and 6.0N throughout the entire band to stretch in order to reach this value.

These forces are considered to be relatively weak and therefore the pressure should be fine to deal with. Even in unintended user interactions, where a user would stretch the headband further than anticipated, the user would have to stretch the headband to a length of 1175mm (1.2 meters) with a force of over 120 Newton in order to break the headband. This is not considered a regular use-case and is thus not accounted for.

Due to time limit in the project, there has not been any time to test this in the field with patients. This test is recommended to be executed as per "Chapter XVIII - Recommendations" on page 48.

## Confirming resistance to Thermal Disinfection

Due to time limit in the project, this test could not be performed. However, the manufacturer confirms (in a phone call) that the material is both resistant to water and is well capable of being put in environments of 80 degrees Celcius (see Figure 96). This test is also recommended in "Chapter XVIII - Recommendations" on page 48.

All aforementioned design changes are implemented in the 3D models and the mold is printed.

| | | | | |
|---|---|---|---|---|
| Dragon Skin® FX Pro | 288 psi | <0.001 | 763% | -65°F/-53°C to 450°F/232°C |
| Dragon Skin® 10 NV | 400 psi | <0.001 | 663% | -65°F/-53°C to 450°F/232°C |
| Dragon Skin® 10 Very Fast | 475 psi | <0.001 | 1,000% | -65°F/-53°C to 450°F/232°C |

**Figure 98. Tech sheet from Smooth-On that shows that the temperature range of the Dragon Skin FX-Pro is well within the ranges of thermal disinfection.**

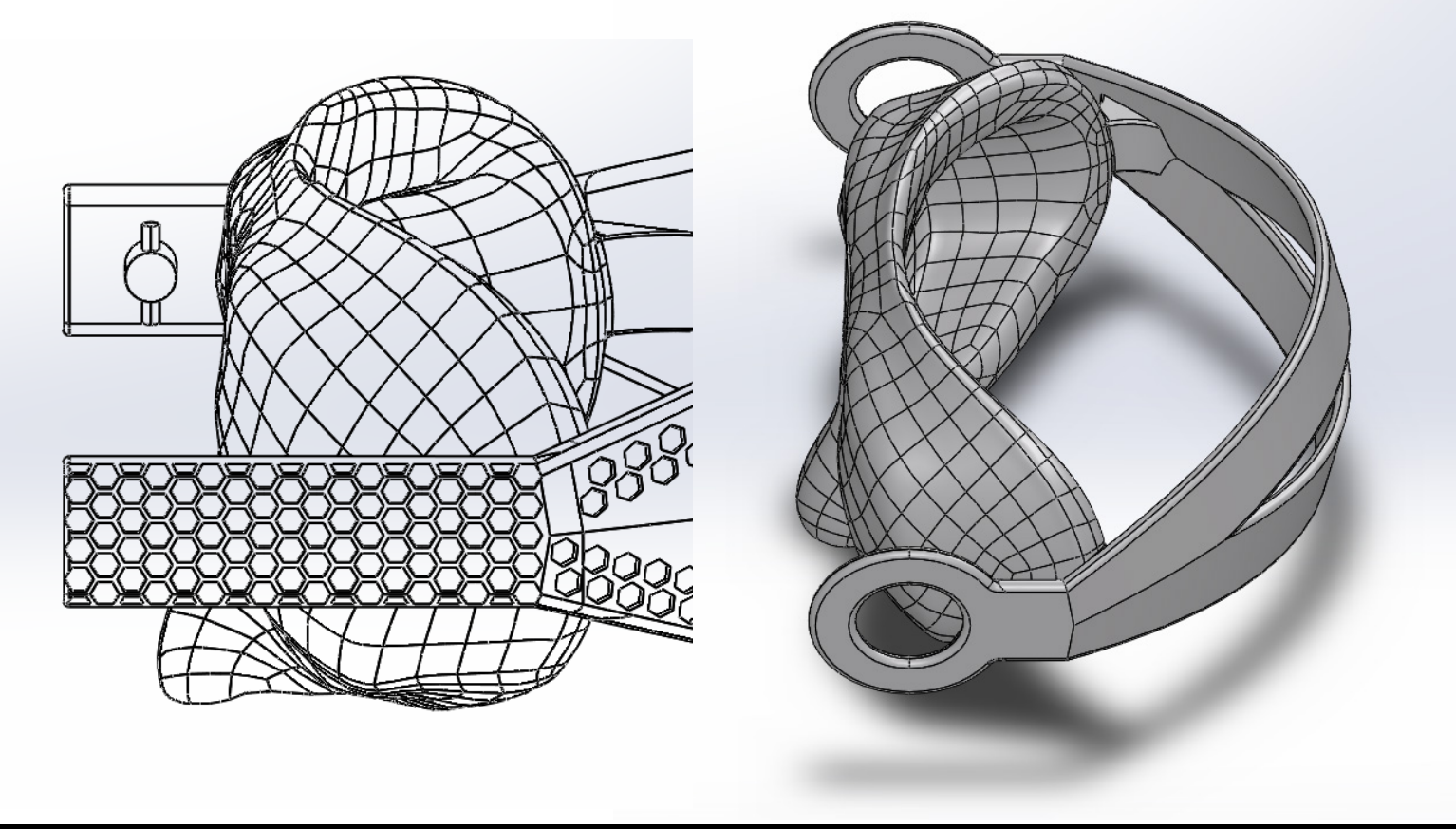


Figure 99. Improvements from the bayonet mount to the loop and a shorter length on the sides, which ensures a stretched connection, confirming the design to the Oculus Go in an even tighter way.

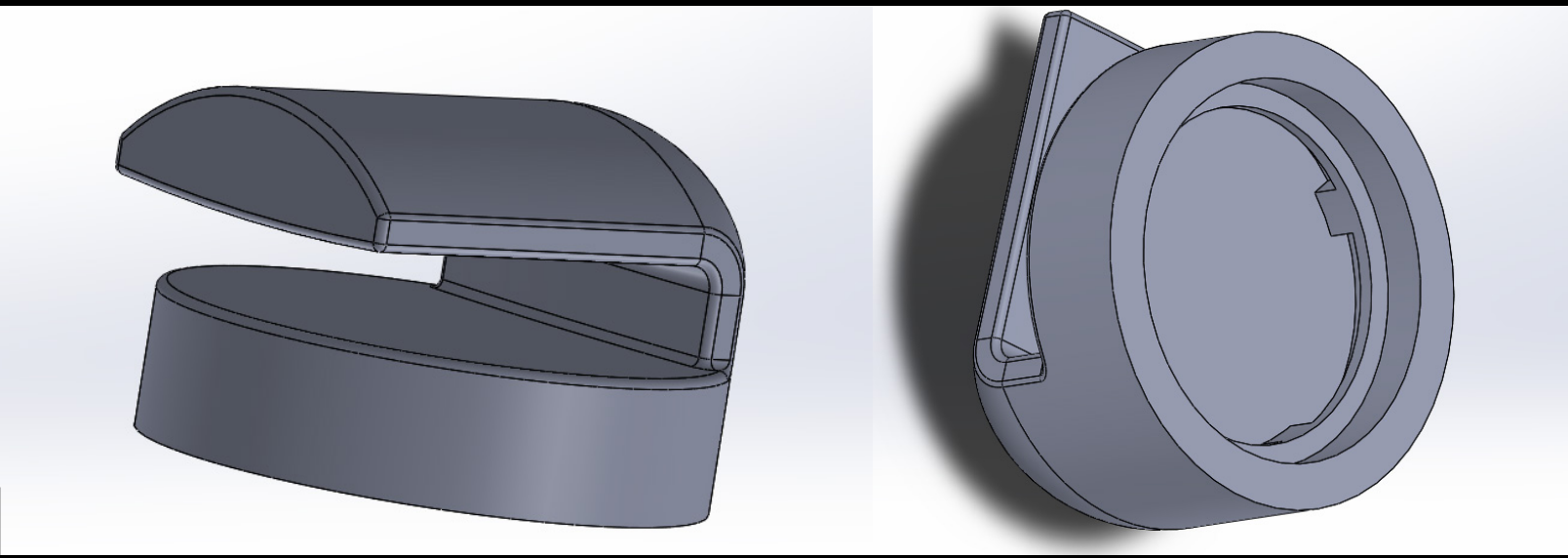


Figure 100. The hook that is 3D printed and clicked onto the Oculus Go.

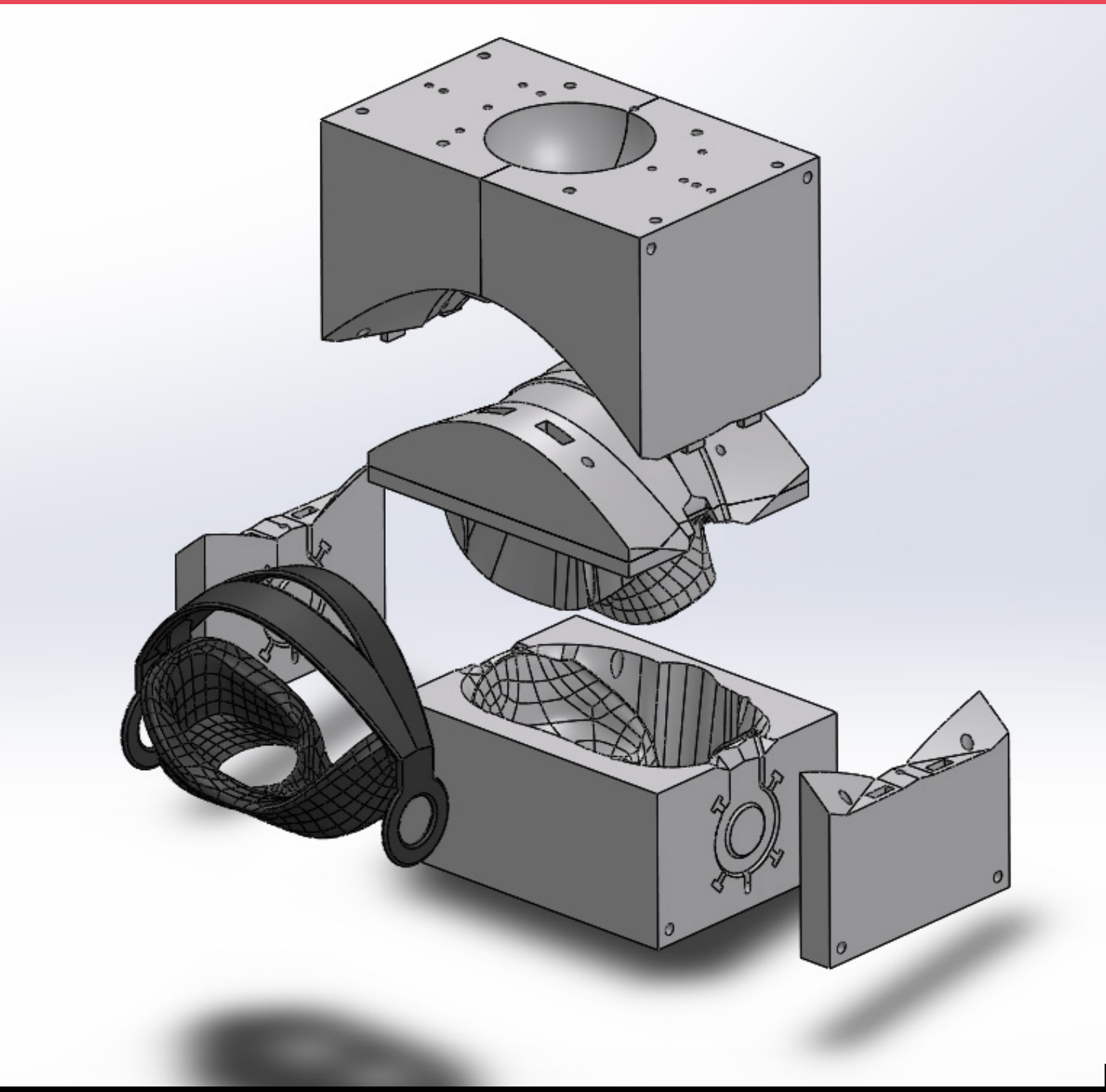


Figure 101. Mold and design of the third and final prototype.

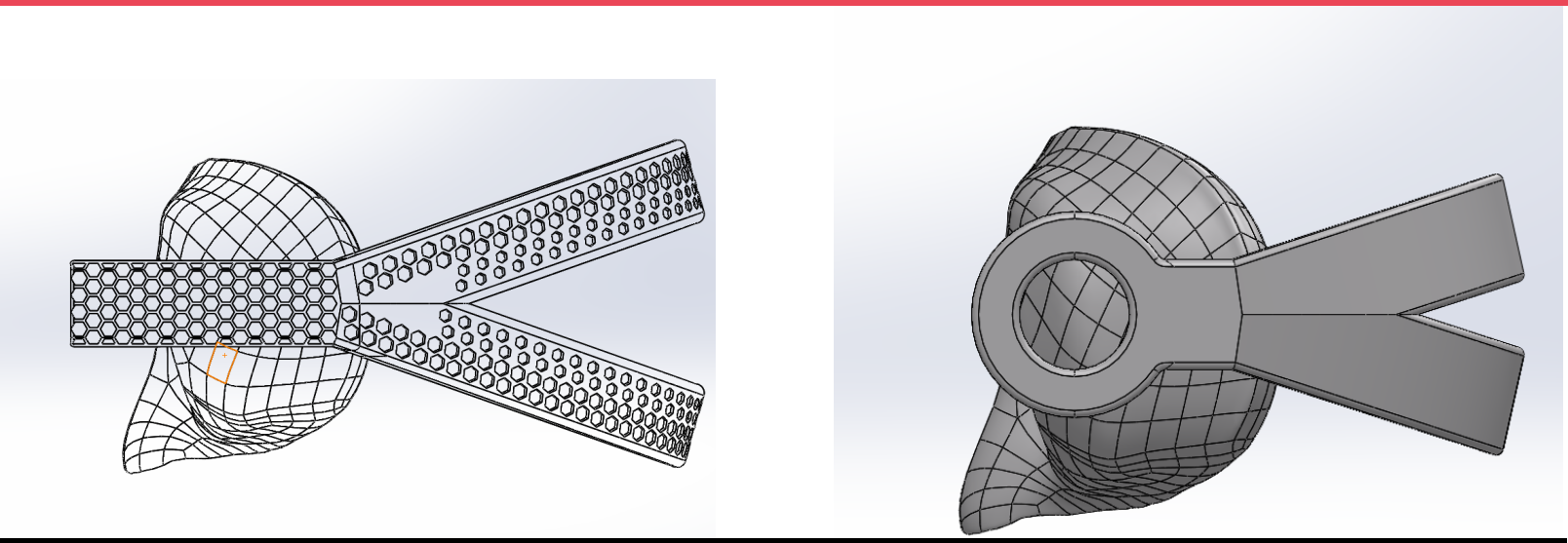


Figure 102. Improvements with regards to the length ot the headband.

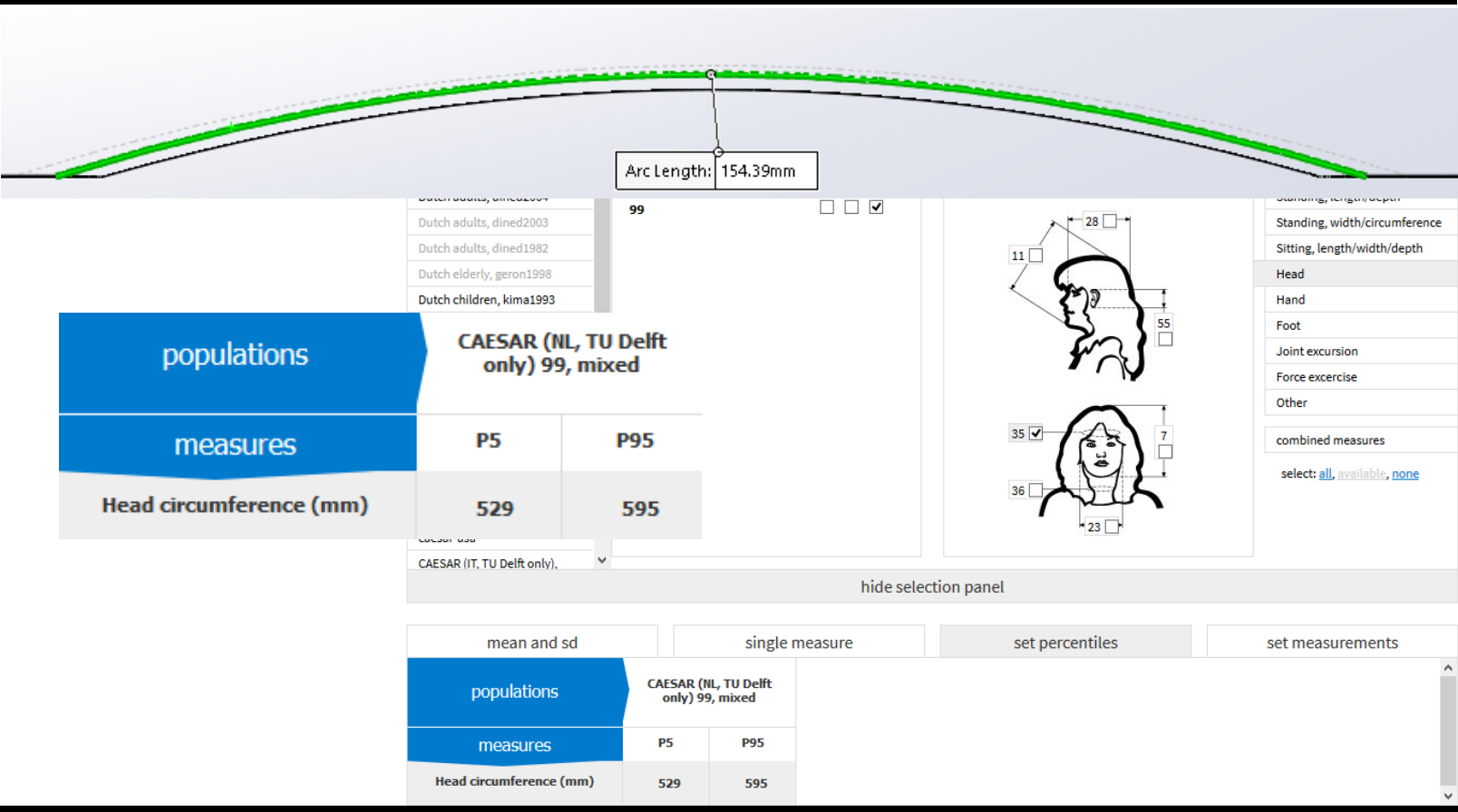



Figure 103. TOP: The improved radius of the headband. BOTTOM: Head circumference CAESAR P5-P95 (Molenbroek, 2017).

# CREATING HOSPITAL-FRIENDLY VIRTUAL REALITY GLASSES

This project is a graduation project for the master Design for Interaction at the faculty of Industrial Design Engineering at the Delft University of Technology. The project is initiated in co-operation with the company SyncVR.

SyncVR develops software applications for the Oculus Go Virtual Reality glasses for the purpose of calming patients in hospitals prior to a painful treatment, such as injections for dialysis patients. Their products are as of this project in use for pilot tests at multiple renowned hospitals in the Netherlands and their use proves to be very meaningful for patients.

There is however a major issue, which this graduation project is tackling: these virtual reality glasses are designed and manufactured for the general consumer at their homes and not for patients inside a hospital. The problem that this product experiences is that it does not comply to the hygiene laws as laid out by the government and hospitals.

The challenges of the project are therefore split in three: (1) Redesigning the Oculus Go to suit hygiene laws and hygiene policies of the hospitals, (2) Redesigning in such a way that the user experience for patients and nurses is enhanced in a meaningful way for both: a comfortable experience for patients and ease of use (equipping and reuse) for nurses and (3) Designing a product that can be created by a startup like SyncVR in a feasible way.

This project received an embargo from the Delft University of Technology near the end of the project. This means that the project and this report must stay within confidentiality until 4 November 2021. If you are to find confidential information about this project (e.g. this report or parts of it) outside of confidential protection, please alert us by sending an e-mail to yasirtufekci@gmail.com.

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**Yasir Tüfekçi** is the student who executed the project and documented all of his progress, learnings and results in this report.

After this graduation project, Yasir aims to start his career by working as a designer in the healthcare sector. His biggest goal in life is to help others. He therefore aims to work in teams to create state of the art technology to aid healthcare professionals in their work. His aspirations are to help build new tools similar to how MRI scanners revolutionized the ability for healthcare professionals to detect and diagnose illnesses ahead of time.