



Master Thesis

Design of a scalable tremor suppression
brace for Essential Tremor patients.

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Delft University of Technology
Faculty of Industrial Design Engineering
Master Integrated Product Design

Master thesis

Design of a scalable tremor suppression brace for Essential Tremor patients

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| Preface

In the last few years I have been specializing and learning more about Integrated Product Design during my Master at the Faculty of Industrial Design Engineering at TU Delft. In this Master thesis project the multiple tools and skills that have been thought to me during my masters have been applied to create a result that can be used for further development of a tremor suppression brace.

The collaboration between a company and university has been challenging, but the interesting subject and positive energy that was present at the start up made me push myself to deliver. I hope you will enjoy reading this report as much as I enjoyed working on this project.

Enjoy,
Stijn Jagers



| Abstract

This report presents a design proposal for a product that will suppress the tremor of patients diagnosed with Essential Tremor (ET). People suffering from ET are restricted in their ability to function in everyday life, due to a constraint of performing delicate movements. Simple tasks, such as drinking and eating are a great challenge for individuals diagnosed with ET.

STIL B.V. works on the development of an alternative solution to dampen a forearm tremor. STIL B.V. is developing a product that dampens the tremor by actively counteracting the movement of its users. With this, the product offers tremor patients a solution that does not involve surgery or use of medication.

The project focuses on finding improvements for the STIL product by developing a solution for recently diagnosed ET patients with an invalidating forearm tremor. The final goal was to create a product that would improve the life quality of its users, by giving individuals with ET back control over their arms. ET patients often mentioned that it is difficult to be in a group or participate in a social activity. Awkward situations occur frequently, making them socially shy. The objective was to help patients regain social confidence by making use of the product.

The final product proposal exists from two parts, a brace and an active dampening element (Exshell). The brace contains a force sensor that is able to measure forearm tremors. The Exshell contains an active dampening element to stabilize the arm. At the start of this project the development of the brace, the part that has contact with the skin, was not yet started. A simple elastic band combined with a coarse vibration measurement principle was used for the prototypes.

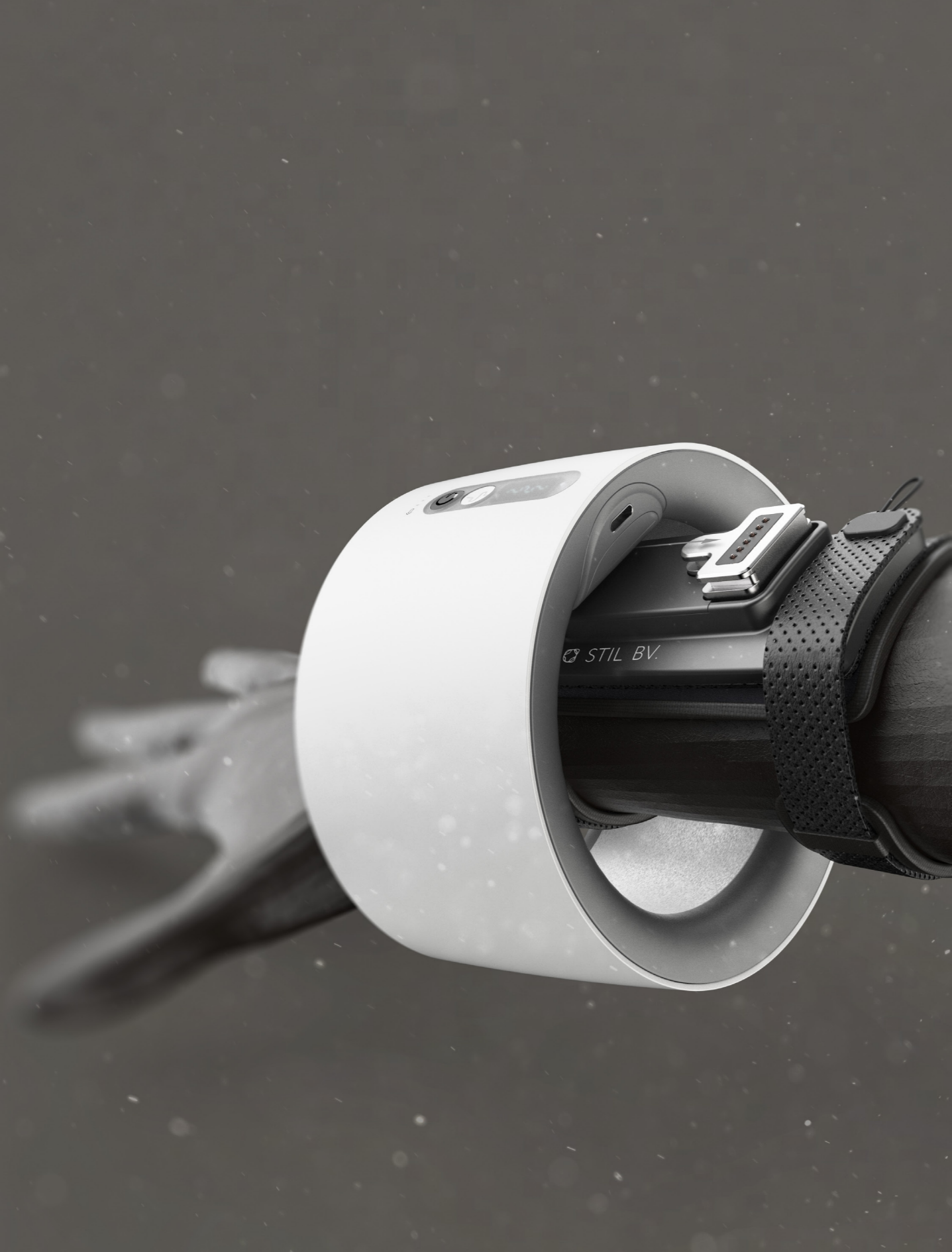
The final result of this project is a fully functional brace design that is easy to use by tremor patients and is able to measure a forearm tremor. An efficient attachment method to the users arm and a redesigned forearm tremor sensor have been designed, made and tested. Additionally a set of different brace sizes has been developed to create a comfortable design for an as large as possible target group.

To stimulate the use of the product, a brace has been designed that is as comfortable as possible. This has been done by making an optimized ergonomic design for ET patients. The brace can be worn all day by the user and when needed the Exshell can be slid over the wrist and actively counteract forearm tremors.

An ergonomic test on healthy individuals has been conducted in order to discover the fit of the different developed brace sizes. The used scaling method for different sizes proved to be effective and by offering five different sizes a comfortable fit can be offered to almost everyone.

The usability and functionality of the brace design has been validated during a patient test. The test showed that the brace is easy to use for tremor patients, can effectively measure a patients tremor and that the measured results can be used for the further development of a tremor suppression algorithm.

The final design result presents a proposal of how the future product of STIL BV. might look like. The results from the analysis and validation phase have been combined and a future vision of the products embodiment is presented.



| Glossary and Abbreviations

Terms related specific to this graduation project

The product

This term is used when the battery, exshell and the brace are mentioned. It refers to the final prototype, the Beta (Chapter 2).

The brace

This is the part that is in contact with the users skin. This part does not include the exshell.

The exshell

This is the active damping element that is slid around the wrist and that is attached to the brace.

The project

Refers to the activities and results related to the graduation project.

Other abbreviations and terminology

BMI

Body Mass Index

CBC

Community Based Cohort

CD

Critical dimensions. Dimensions of high interest

CES

Cambridge engineering selector

Congenital

Present from birth

FEA

Finite element analysis

Grasshopper

Parametric 3D modelling tool used in Rhino

GPA

Generalized procrustes analysis

IPD

Integrated Product Design

IDE

Faculty of industrial design engineering

Metacarpal bones

The longer bones found in the intermediate part of the hand

Metaphalangeal bones

The small bones found above the metacarpal bones

Paraview

3D analysis software

Pathological

Any deviation from a healthy condition.

PJM

Patient Journey Map

Propranolol

A medicine (betablocker) that lowers blood pressure and oxygen use of the heart. Side effect is the suppression of a tremor for tremor patients.

P-value

Probability value, significance

Ulna

The long bone found on the medial side of the body (close to the pink)

Upper extremity

The limb. Exists of the arm up to the shoulder.

Radius

The long bone found on the medial side of the body (close to the thumb)

Rhino

3D modelling software

SD

Standard deviation

SP movement

Supination to pronation movement

Solidworks

3D modelling software

| Reader's guide

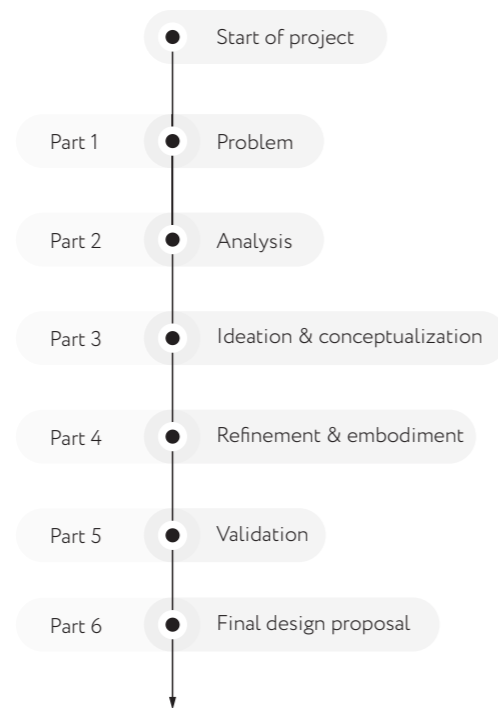


Figure 1 Project approach.

The structure of this report is based on the design cycle as proposed by Roozenburg and Eekels (1995). The report takes you through each of the phases and explains the used methods, approaches and findings made during each of these cycles. The report has been separated in a set of parts to clearly mark the start and end of a phase (Figure 1). Each report part exists of a set of Chapters that explains the reader about the gathered information, conducted research and found results.

In the analysis and validation phase each Chapter contains a conclusions and design implementation section. These parts are added to clearly communicate the made conclusions and design implications for the project.

A design consideration is used for the eventual development of the concepts and final product proposal. These findings have been added in the list of requirements and have been used for proof of principle tests.

A conclusion section can be recognised by the following symbol:



A design consideration can be recognised by the symbol below:



| Contents

PART 1 Assignment & approach		PART 2 Analysis		PART 3 Ideation & conceptualisation		PART 4 Refinement & Embodiment		PART 5 Validation		PART 6 Final Design proposal	
Project introduction	16	Tremor	27	Introduction of the new force sensor	58	Brace size determination	82	Prototyping	98	Final brace design	114
STIL brace	18	Target group and market exploration	29	Design direction	60	Functional brace properties	84	Ergonomic validation	102	Final product design	116
Project scope	22	Field research	32	Ideation	61	Exshell embodiment	90	User interaction validation	105	Future improvements	118
		Understanding the user	34	Proof of principle test	62			Tremor analysis validation	112	Expected costs	120
		Anatomical and physiological considerations	39	Concepts	70					Project evaluation	122
		Ergonomic research	44	Brace concept selection	76					Acknowledgements	123
		Medical regulations	55	Final brace concept	78						
PART 6 References		PART 7 Appendix									

Assignment & approach

Part 1 introduces the concerned project partners and introduces the reader to the initial project assignment. The product and start up's development plan is explained in order to better understand the starting point of the project. The project scope and the approach show the desired project results and the advancements for the start up.

1.1 PROJECT INTRODUCTION

1.2 STIL BRACE

1.3 PROJECT SCOPE

Project introduction

People suffering from a tremor are restricted in their ability to function in everyday life. Simple tasks, such as drinking and eating are a great challenge for individuals with such movement disorder. These tremors occur among people with Parkinson's Disease, Essential Tremor and Multiple Sclerosis. Current treatments are mostly ineffective and can give many unwanted side effects.

STIL B.V. works on the development of an alternative solution to dampen the tremors of patients. A product is being developed that dampens fore arm tremors by actively counteracting the movement of its users. With this, the product offers tremor patients a solution that does not involve surgery or medicine use.

The project is focused on tremor patients with an invalidating forearm tremor. The final goal is to create a product that will improve the life quality of its users, by giving individuals with ET, Parkinson's and other related diseases back control over their arms. The user is in need of a product that gives back the feeling of having a stable arm movement without being limited by the brace.

The goal of this thesis is as follows:

"The anti-tremor technology developed by STIL needs to be integrated into a working product. In this assignment a wrist brace that is used for the prototype validation is designed. Goal is to create a prototype that can be used for user testing at the Reinier de Graaf hospital and can serve as a starting point for commercialization."

STIL brace

The final goal of STIL is to develop a product that exists of two parts; an active damping element (Exshell) and a brace that is worn around the wrist that is used to attach the exshell to the arm. A brief overview of the product's working principles, the expected schedule of STIL B.V. and the state of technology at the start of the project of the different product parts is presented.

1.3.1 Working principles

The goal of the product is to dampen the forearm tremor of tremor patients by using anti-vibrations. These anti vibrations are actively generated by the product. The same principle is used in noise cancelling technology in modern headphones. Just as noise canceling uses anti-sound to dampen out sounds, so will the brace of STIL use an "anti-vibration" to dampen out tremors of its users. The proof of principle was tested at the TU Delft, resulting in a 94 % theoretical tremor suppression during the first tests (De Lange, 2016). An overview of de Langes thesis results and working principle can be found in Appendix II.

1.3.2 Development plan

To reach this final product goal, STIL B.V. has split up its development process into different phases. Each project phase comes with a new prototype that aims to get closer to the first fully working product. A timeline of the startups development plan is shown in Figure 2. Synchronous with this graduation project (February to July 2019) the first prototype, the Alpha 1, was being built. Alpha 1 was developed in order to test the functional principle of the product and is the first prototype to suppress an actual tremor. After validation, the development of the second prototype, the Alpha two, will be started (Figure 2).

1.3.3 State of technology at the start of the project

The components of the Alpha 1 prototype have been used as a reference and starting point for the developments made in this project. An overview of the full product system is presented in Figure 3. In the following section the working principles of each of the product components is explained to clarify the product use, functionality and to show the state of each product component at the start of the project.

Exshell

The exshell is the actuator that will generate the anti-vibrations to dampen a tremor. The Exshell uses the proposed working principle of de Lange's Thesis and works by generating forces in a specific direction with the help of inertial loading. Inertia is the resistance of a body to any change in its velocity. Inertial loading makes use of inertia to apply a force on a body, hereby changing the objects direction. This is the component that exerts a force on the users body to suppress a forearm tremor.

Part of the exshell are the control electronics. This is the brain of the product that receives and transmits signals from the force sensors and exshell. It also manages the power supply from the power unit to the different product components.

The brace (Wrist enclosure and force sensor)

The brace is the part that is in direct contact with the skin. The brace exists of two components, a wrist enclosure and a force sensor. The brace needs to transfer the forces generated by the exshell to the

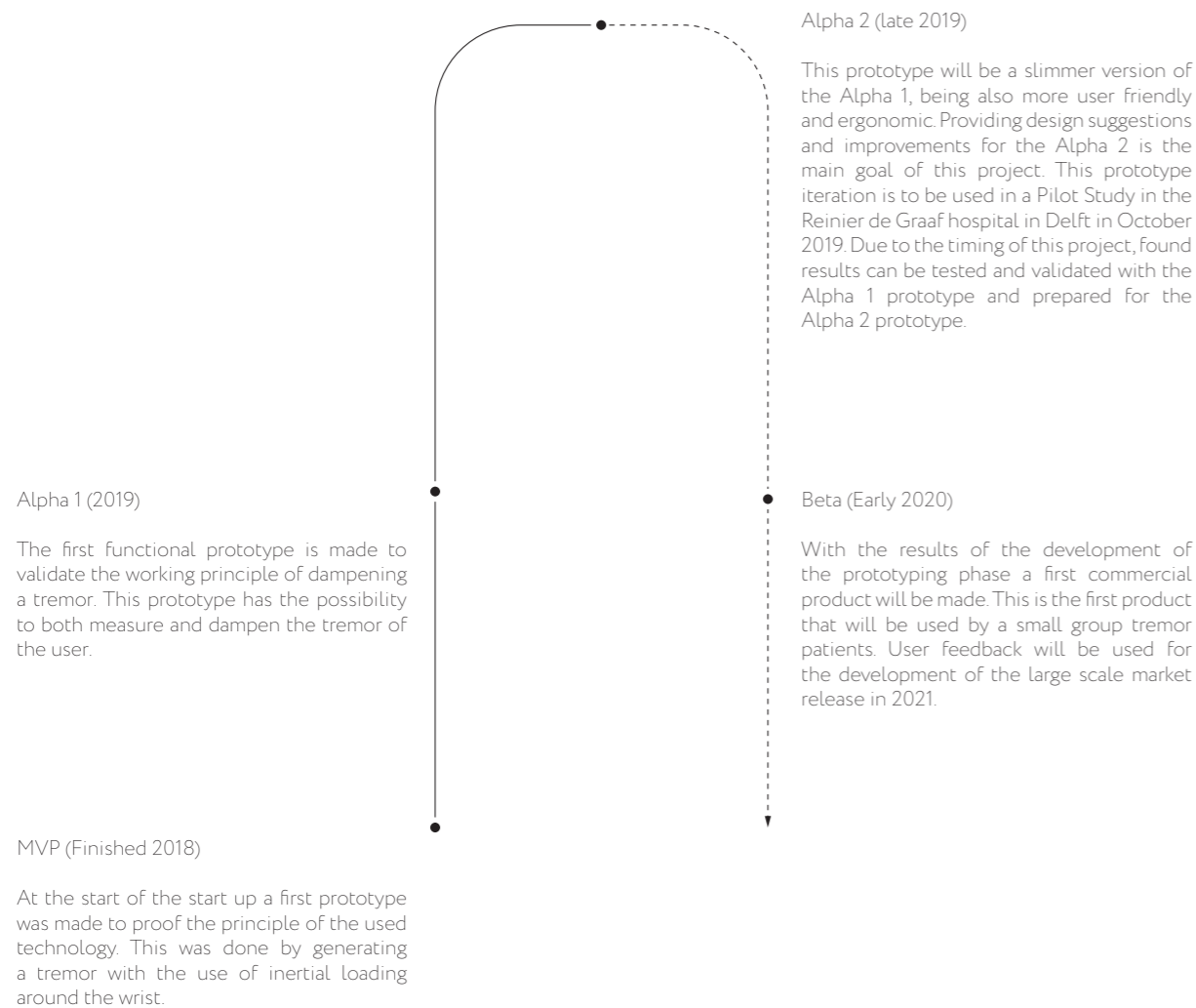


Figure 2 The product development plan is split up in different stages that work toward the finalization of a next iteration of the product. By using this strategy it is tried to achieved significant improvements with each iteration, so that the Beta will be a fully working product that can be used by tremor patients.

user. Additionally the brace also needs to communicate the tremor to the sensor in order to provide usable data for the control unit. The brace is the part that is worn around the wrist and to which the exshell is connected to during use. At the start of the project the used solution existed of a simple elastic band as shown in Figure 3.

To generated anti vibrations the product needs information about the tremor that the user is experiencing. In order to do so, the magnitude and direction of the tremor need to be analysed and measured. The solution at the start of the project used a set of four seperate force sensors to collect the needed data. The placement of these sensors was (and is) crucial for a usable measurement. Tremors that can be dampened by the brace are tremors in two directions in the lower arm (Chapter 3.1). For a proper analysis of these tremors, the sensors need to be able to only measure forces that are generated in the two degrees of freedom in the frontal plane. The sensors should only measure forces that occur in these two degrees of freedom, so a design that uses a system that prevents forces from other directions from happening is needed.

Initial product use

At the start of the project the notion of how the Alpha 2 prototype will be used is as depicted in the use case scenario as depicted in Figure 2.

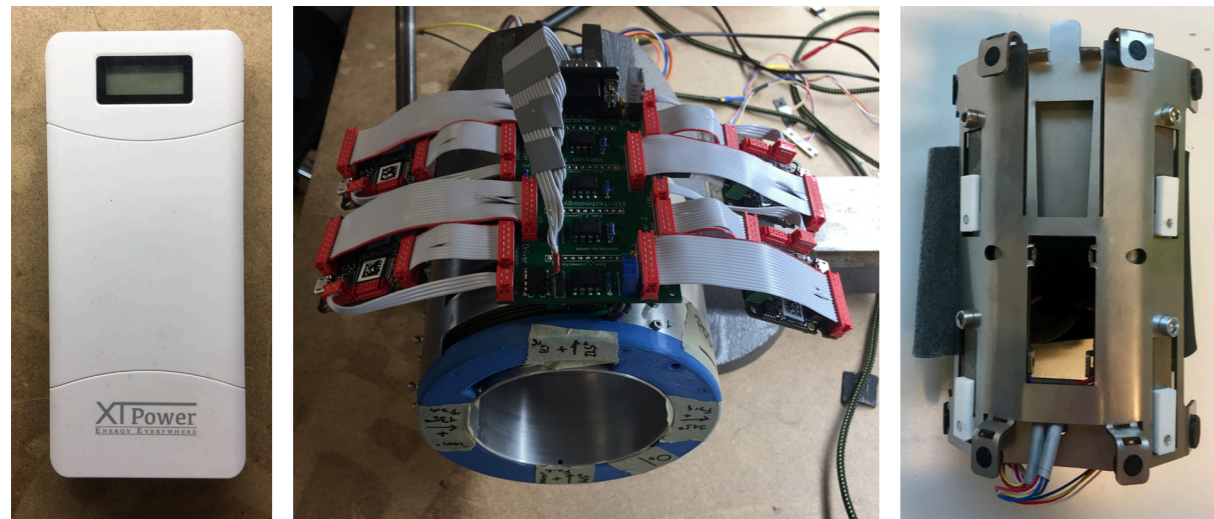
The steps explain how the current process of putting on the product and product activation is imagined. How the final product exactly will be put on and activated was still undecided at this phase of the project. This storyboard has been used to determine what dimension of the brace and shell are of importance for the development of the product (see Chapter 2.6).

The scenario shows the different elements of the product. As can be seen in the scenario, it is expected that the Exshell will have a notable weight and volume that can be tiresome for the user to wear all day. A solution is presented that describes a situation that lets the user wear a brace for a longer period of time, while the Exshell is only attached when stabilization is needed. To optimize the products ease of use, the brace will only have to be attached to the body at the start of the first use. The brace can be worn all day after ensuring a proper fixation

to the arm. In this scenario the brace will have to be comfortable enough to be worn all day if desired by the user.

➡ Design considerations

- The exshell will dampen a forearm tremor by applying force on the users forearm. With the help of anti-vibrations forearm tremors will be dampened.
- The exshell will have to be slid over the hand in order to connect to the brace.
- The force sensor needs to have the possibility to measure forces in two directions.
- The exshell has a limited battery life that will depend on the power supply source.
- It is expected that fixation of the brace is a difficult task for a tremor patient. It is therefore desired that the brace has a design that is comfortable enough to be worn all day by the user.
- The user should have the possibility to wear the brace all day.



Power supply

Exshell

Brace

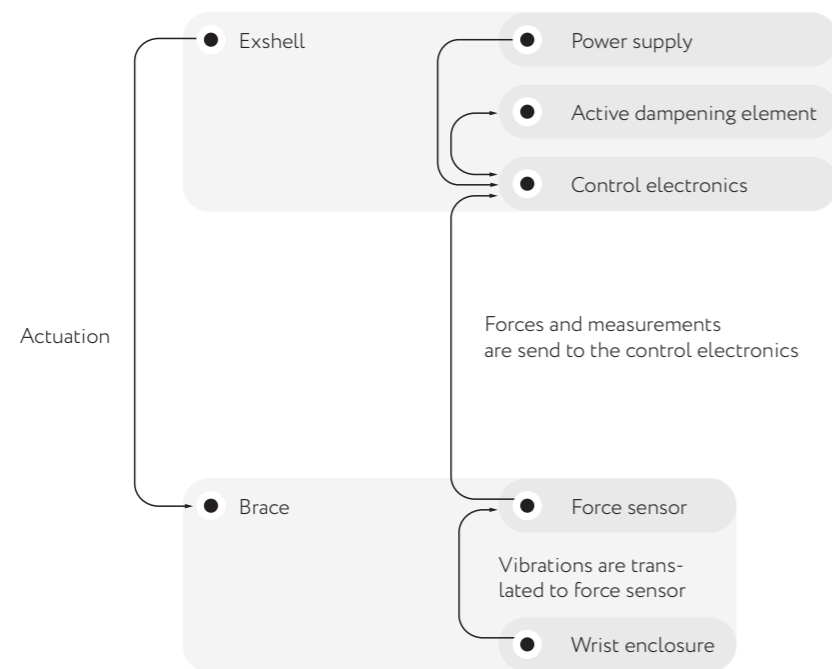


Figure 3 Block diagram of the different subsystems found in the product that is being developed by STIL. The grey areas show what subsystems are found in each of the main systems. The added pictures show the state that each system was in at the start of the project.

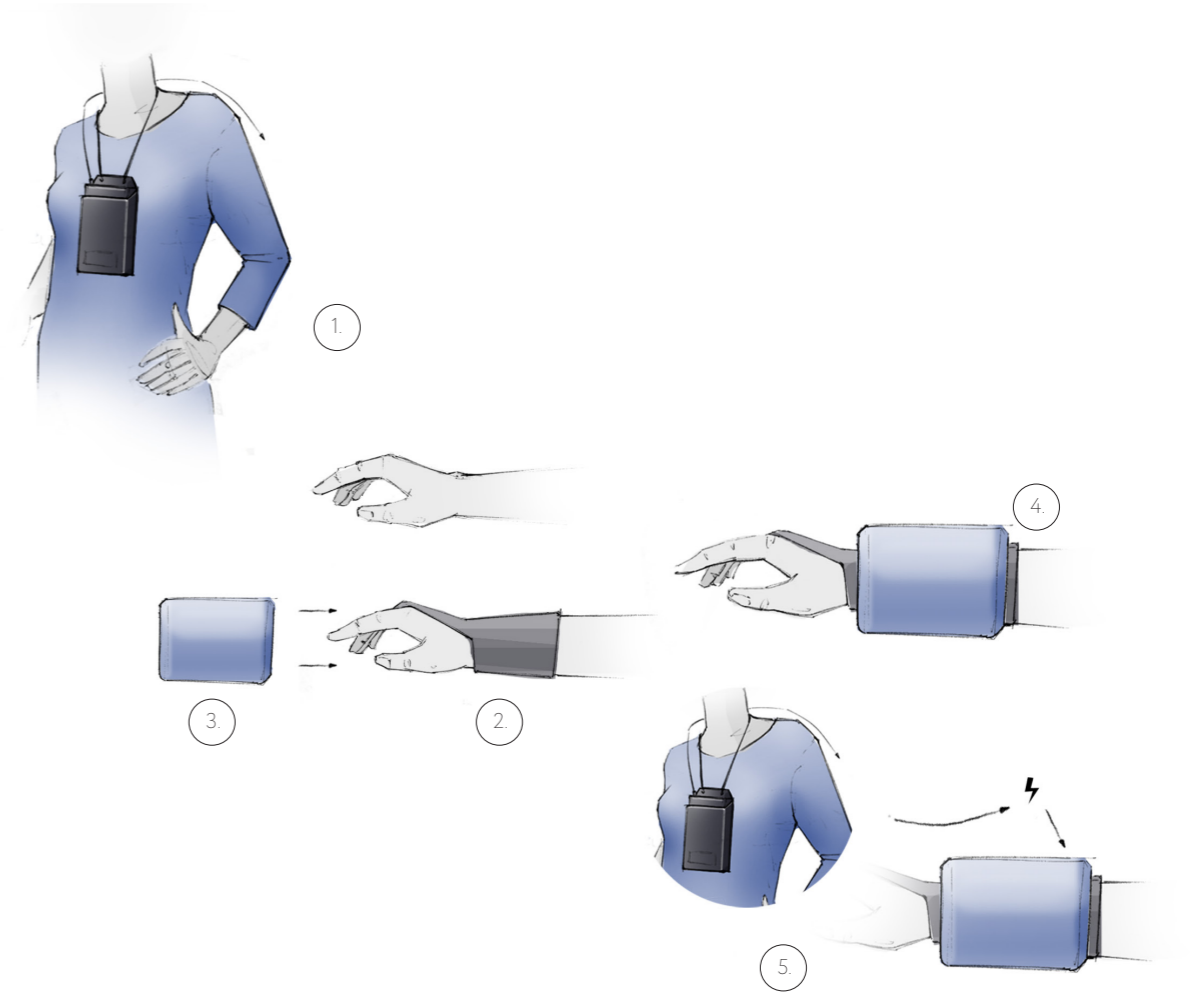


Figure 4 Use case scenario of the Alpha 2.

1. For the so-called Alpha 2 an external battery will be used. The location of the battery will be either around the neck or another part close to the body. The power supply cables will lead from the battery to the product.
2. The brace, the part of the product that is in contact with the skin, will be put on. It fits neatly around the wrist of the user.
- 3., 4. The shell, the active element of the product, is slid over the hand and connected to the brace.
5. The power cables are connected to the shell and the product can be activated.

Project scope

A challenge of this project is the multidisciplinary aspect of the to be designed product. In order to set the project boundaries and to define what my responsibility was in this project, a more specific scope was defined by making an overview of the development state of each of the main components.

To create a comprehensive design proposal for the final product, it was needed to include each of the main components at a certain moment of the project. The different development stages each product element was in, made it necessary to introduce each part in the project at a different stage. How this is implemented in the project can be found in Figure 5

As seen in Figure 5 the terms Proof of principle and proof of concept are used. The wrist enclosure was in a proof of principle state at the start of this project. This means that no solutions had been explored or tried for a user friendly and functional design. The development of the brace has been the main challenge in this project and large parts of the project research is specifically focused on the elaboration and detailing of the wrist enclosure and force sensor.

The wrist enclosure design is influenced by the functional principle of the force sensor. At the start of the project a proof of principle test was done for a specific sensor design. As seen in the component overview in Figure 3 the principle solution was still very bulky and improvements needed to be made in order to include the working principle in the brace design. A new, more efficient sensor design is proposed in this project and is used for the final development of the brace. This was done by applying the proof of principle concept into the brace design. The development of this principle was realized in

close collaboration of a mechatronics student. The development of the force sensor is introduced in part 3.

The development of the so-called Exshell already was in a more elaborated stage at the start of the project. Initially the goal of this report was to design and suggest an embodiment for the Alpha 2 prototype. However to many uncertainties about the dimension and used components of this prototype during this project were present, therefore appearance and user experience suggestion for the final future product of the beta product are suggested.

A detailed flowchart, explaining how this was implemented in the design cycle of Roozenburg and Eekels (1995) can be found in Appendix I.

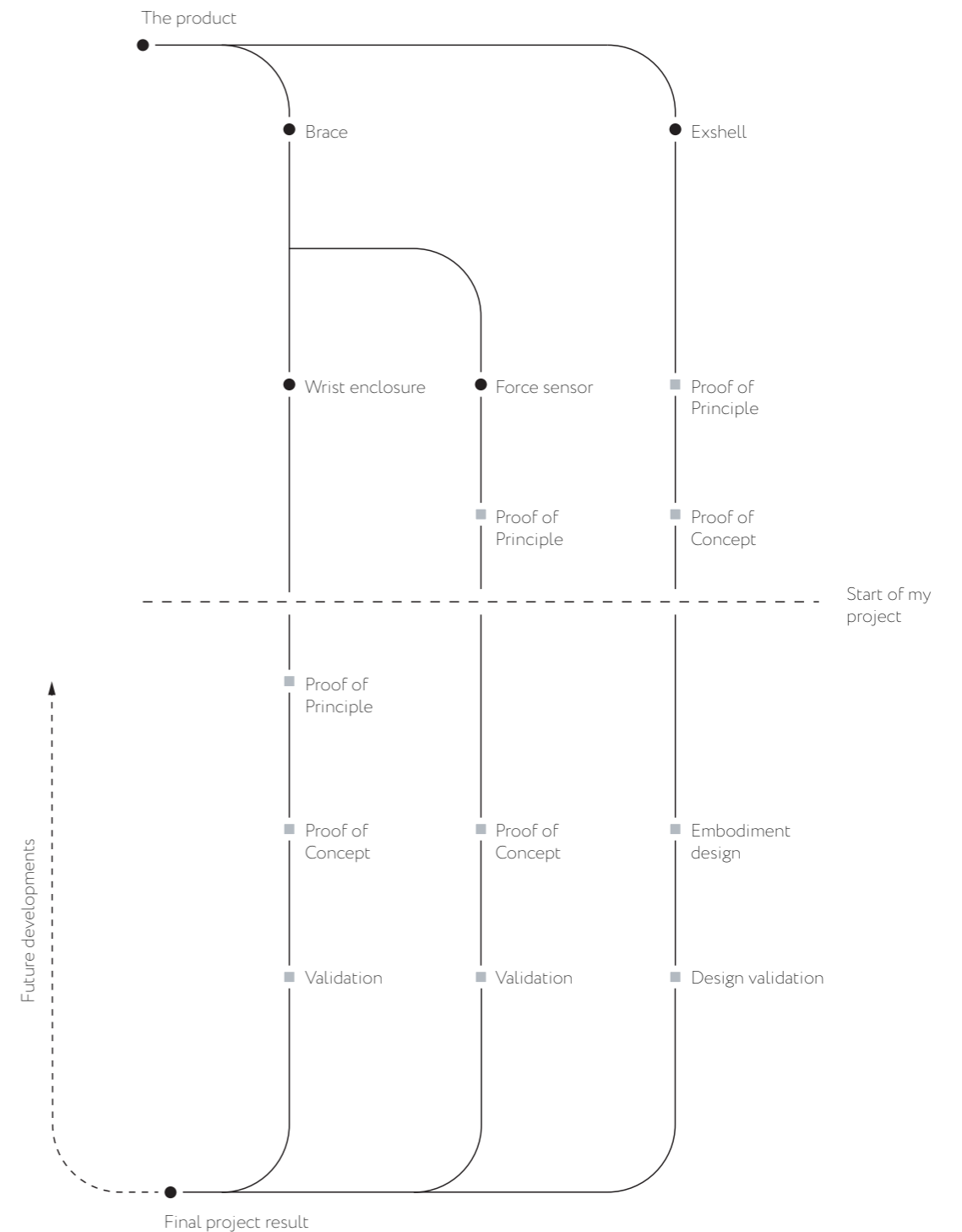


Figure 5 State of each product component at the start of my project. The elements mentioned after the dashed line have been included in this projects scope.

Analysis

The analysis phase discusses findings made during the literature, field- and user research. The main goal was to get a better understanding of ET patients and to find out more about the challenges and requirements that come with the design of a medical grade wrist brace. Firstly more about the disease is explained, before going deeper into the user and target group. Hereafter the analysis phase explains about the challenges that are needed to be solved for the design of a wrist brace.

2.1 TREMOR

2.2 TARGET GROUP AND MARKET EXPLORATION

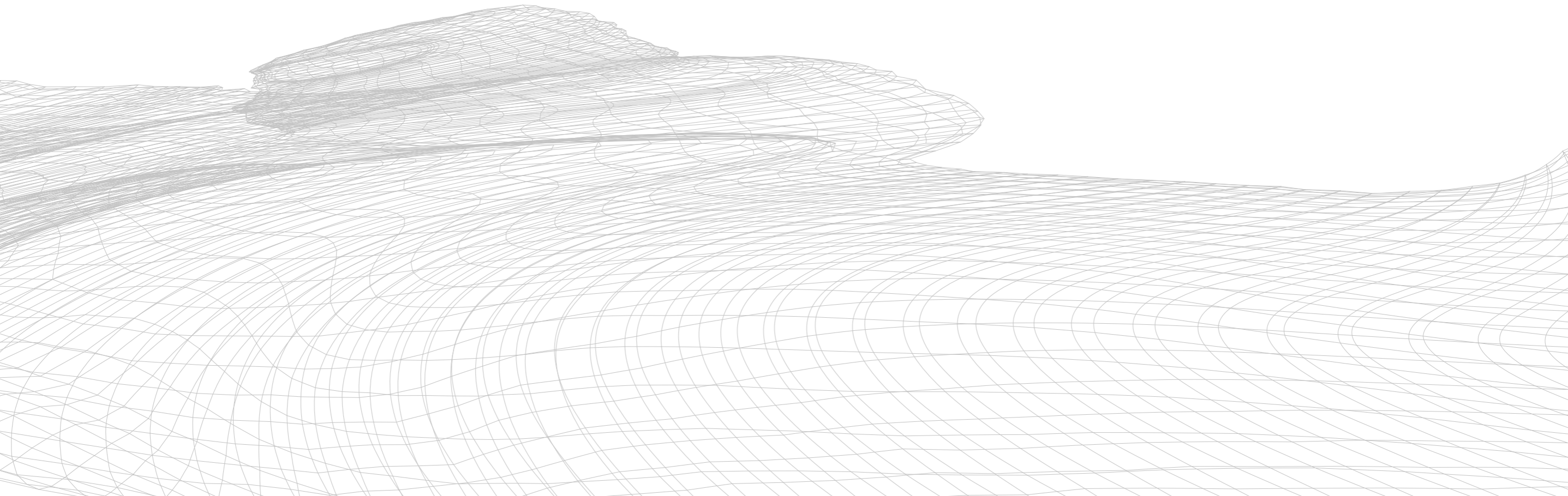
2.3 FIELD RESEARCH

2.4 UNDERSTANDING THE USER

2.5 THE UPPER EXTREMITY

2.6 ERGONOMIC RESEARCH

2.7 MEDICAL REGULATIONS



Tremor

A brief explanation of tremor causes, symptoms of a tremor patient and the difference between different types of tremor related diseases is presented. Knowing more about tremor related diseases and what symptoms individuals are experiencing will help to empathize with patients and make it easier to think of concrete solutions during the concept development phase.

2.1.1 Tremor origin

When an individual is experiencing a tremor, it can best be described as an involuntary rhythmical movement of the body as a result of involuntary contractions of the muscles (Deuschl et al, 1998). Tremors in the human body can occur in any limb and depending on its location, it varies from anywhere between 3-5 Hz in the elbow joint, 8-12 Hz in the wrist to 17-30 Hz in the Metacarpal-phalangeal joint (start of the fingers) (Hallet 1998).

A tremor arises when errors occur during the communication of signals in the human body. To move a limb, muscles will need to either contract or relax. The state of a muscle group is determined by a signal that is sent from the central nervous system (CNS) to the muscle. These signals are created by several different feedback loops that are present in the human body. As depicted in Figure 6 signals from the brain are sent through the CNS, to the neuro-muscular control loop. The CNS includes the brain and spinal cord and is responsible for translating received signals into actions in all parts of the body. From the CNS, the signals continue to the Peripheral Nervous System (PNS) and are distributed to the desired muscle groups. When the signal arrives at the targeted muscle group a change in state occurs, resulting in a movement in the skeletal

system. Sensory organs send feedback about the position, velocity and force to the CNS to ensure a correct movement. A correction is made when there is a deviation between the desired state and actual state (Van der kooij et al. 2008).

A tremor manifests itself when either abnormalities in the CNS or errors in the Feedback loops occur (De Lange, 2016). How a tremor reveals itself to a patient depends on what type of error occurs. There are different types of tremors that a patient can experience, a clear overview of different tremor types was made by Buijink et al. (2012) and Rubchinsky et al. (2007), categorizing each type of tremor by its activation conditions (Table 1).

How a tremor tends to act depends on the disease one is diagnosed with. Many disorders and diseases come with neurological signs other than solely a tremor (behavior change). When a patient shows more than one neurological sign, it is called a combined tremor. A well known example of a disease that comes with many other neurological signs is Parkinson's. Parkinson's patients experience increased stiffness of the muscles and cognitive impairment accompanies the tremors. When patients are solely experiencing physical effects of a tremor it is called an isolated tremor.

2.1.2 Kinetic action tremor

In this report there will be a focus on individuals with a kinetic action tremor (Table 1). This mostly occurs at people who are diagnosed with Essential Tremor (ET). ET is one of the most common pathological tremor disorders occurring at 4% of the people above 65 years (E. D. Louis and J. J. Ferreira, 2010). People are diagnosed with ET when they are experiencing a kinetic action tremor (see Table 1) with no other neurological signs (isolated tremor).

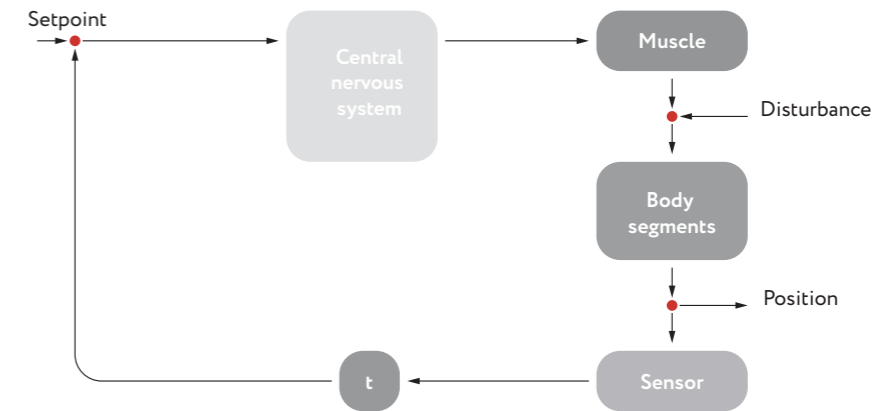


Figure 6 Feedback Scheme for neuromuscular control. Van der Kooij et al. (2008) take a point in the brain (setpoint) as the origin of a signal that will run through the CNS to the muscles. An external force can create a disturbance that lets the body segments be in a different state (i.e. speed, position) than desired. Sensory organs can measure this difference and send feedback back to the brain. A signal from the sensory organs to the CNS, that has a specific timedelay (t), is sent to provide feedback about the muscle states. When a deviation between the sensory state and the setpoint occurs a correction, an error signal is formed which is used as a new input for the CNS.

This type of tremor manifests itself during the coordination of a voluntary movement, making it very difficult for these patients to execute motoric tasks such as writing, eating and shaving. Most commonly people think of Parkinson's patients when talking about tremor, but most Parkinson's patients experience a rest tremor, which is different from the type of tremor ET patients experience.

Historically, Essential Tremor (ET) was seen as a type of isolated tremor, since it was described as a mono-symptomatic disorder consisting primarily of an action and/or postural hand tremor. In the last decade this assumption is being challenged by a growing literature describing associated disturbances of many other body functions (Elbe, 2013). Other disturbances of balance, personality, mood, hearing and cognition are also found in some individuals diagnosed with ET (Louis, 2010). In this report the assumption that ET covers a large group of yet unspecified diseases having a kinetic action tremor with similar symptoms is used.

The severity and level that a tremor impedes an ET patient from carrying out their daily activities differs per patient. The categorization made by Elbe

and Marsden et al. (2013) for different ET categories is depicted in an overview of causes and related symptoms of ET (Appendix III). The symptoms and causes are classified into four types. These different types show how the severity of a tremor can influence the lifestyle of individuals suffering from ET. Patients with a tremor that falls in type 2 and up are seen as patients that are eligible for the solution developed by STIL, because this group experiences tremors that can impede the lifestyle of a patient.

2.1.3 Tremor treatments

There are currently three available methods to treat tremor symptoms (Grimaldi, 2010). Each method will be shortly described:

Pharmacological treatment

The most common treatment against tremors is the use of medication. Different types are available, the most common prescription for ET patients is propranolol, a medicine (betablocker) that lowers blood-pressure and reduces oxygen use of the heart and

Type	Subtype	Description	Physical Examination
Rest Tremor		Tremor which manifests when the muscles are not voluntarily activated and are completely supported against gravity.	Rest forearm on legs, flexed elbows and palms in supinated position.
Postural Tremor		Appears only when actively compensating against gravity.	Keep arms and fingers in stretched position.
Action Tremor	Kinetic tremor	Occurs during the coordination of a voluntary movement.	Finger tapping
	Intention tremor	Tremor during visually guided movements towards a target, where the highest intensity occurs when the target is almost reached.	Finger tapping
	Task specific tremor	Tremor whilst performing a highly skilled motor task, like handwriting.	Writing down a sentence
	Isometric tremor	Isometric muscle contraction that is not accompanied by movement.	Making a fist or contraction against static object

Table 1 Types of tremor adapted from Buijink et al. (2012)

suppresses a tremor. A downside of medicine use are the side effects and the change that the medication does not work. By trial and error prescriptions are optimized for each patient, making it an unpredictable treatment Rehman (2000).

Surgical treatment

If the use of medication is not sufficient enough surgical treatment can bring relief. Surgically, tissue in the brain can be altered or electrodes can be inserted to reduce the tremor of a patient. There is no certainty that the mentioned surgery methods will be successful and changes of complications are high (Giltray, 2016).

Assistive devices

The product that STIL is developing falls under this category. An analysis of competitors that are working on assistive solutions for tremor patients can be found in Chapter 2.2

➔ Design considerations

- ET patients experience an (kinetic) action tremor. Making it especially difficult to carry out precision tasks. This makes them an interesting target audience.
- Parkinson's patients suffer mostly from a rest tremor. A type of tremor that manifests itself during rest situations.
- Causes of ET are still unknown and it is possible to happen to anybody. On average tremors start to occur at a higher age (40 years and up).
- In this report the assumption that ET covers a large group of yet unspecified diseases having a kinetic action tremor with similar symptoms is used.
- ET Patients that have a tremor of a severity that impedes them from executing daily activities are being targeted in this project (level 2).

2.2 ANALYSIS

Target group and market exploration

An estimation of the target group and - market has been made. Additionally the market has been analysed on competitors and comparable products have been studied for interesting materials, cost price and working principles.

2.2.1 Target group

Specifying a more specific target group was needed for the estimation of the batch size of the first generation products (beta), concept selection and the aesthetic phase.

The main target group of interest will be any Dutch patient that experiences an action tremor of an intensity that could benefit from the STIL product (Type 2 and up, Appendix III). The average moment that a tremor starts to occur for this broad target group is 40 years or older (Hubble et al. 1997). The higher age should be taken into account during the (aesthetic and user interaction) design process, but should not result in a design that cannot be used by younger individuals. The initial focus on Dutch patients will make market implementation more easy.

A large number of ET patients have never been officially diagnosed and therefore can be difficult to come in contact with. Lorenz et al. (2011) compared a set of outpatient- and a community based cohort (CBC) (n=100) individuals on ET symptoms. The CBC was selected for their likeliness of having ET by a genetic database. It was found that in the CBC 95.6% recognized their tremor, but only 26.7% had ever contacted a doctor for their tremor. Reasons for not contacting the doctor given by Lorentz et al. included: "tremor was very mild, tremor has been existent for many years without any signs of impairment, tremor was not perceived as a symptom of a disease". This information has been taken into account in estimations for the estimated initial target

market as shown in Figure 64.

2.2.3 Competitors

The to be designed product is unique in the world, because of its method of dampening a tremor. Nevertheless there are several other companies working on the development of a tremor dampening solution that offers an option for people that are looking for alternative treatments of ET. The different solutions that currently are being developed or sold by competitors use different solutions to reach the same goal of enabling users to improve the execution of every day activities. An overview of other solutions for dampening a tremor is depicted in Figure 8. A more detailed table adapted from STIL B.V. can be found in Appendix IV

2.2.4 Exploring existing brace solutions

A market and patent analysis (Appendix V,VI) of existing wrist braces was made to discover how other companies design a confection brace. Since the working principle of the to be developed brace is unique in comparison to other solutions, only a non-specific analysis could be made. By comparing braces that serve different purposes it was possible to discover some interesting aspects that can be used for the development of the brace. A more detailed overview of the braces that are depicted in Figure 7 can be found in Appendix V, containing more information about sizes, prices and functions.

➔ Design considerations

- How to interest and motivate patients that are not actively looking for solutions can be a challenging task. Future research is needed to determine more precisely how to approach these hard to reach users.
- The product that is being developed by STIL is unique and can not be compared with other solutions on the market. This gives the company the possibility to release a benchmark design.
- Most braces are delivered in three to five sizes, offering adjustability by adding straps that can be altered to create a better fit.
- Most braces are sold for under fifty euro's. Only when complexity is added (Mobius x8, Flex-guard) a wrist brace quickly becomes more expensive.
- Braces usually are made for either the left or the right hand. This will result in a more ergonomic brace.
- It is interesting see how stiff materials are combined with padding and textile. The used materials in these braces can be used as a reference during the concept development phase.



Figure 8 From top to bottom: a. WOTAS, a product that takes full control of arm movements. b. Steadiglove, a tool that passively dampens tremors with counterweights. c. Gyroglove, a tool that use gyroscopic forces to stabilize the arm. d. Lyftware, a tool that uses stabilization techniques to smoothen the tremor. (Images adapted from company websites, 2019)



Figure 7 A selection of different braces that are currently being sold on the market. A selection of different designs and functions are displayed to show the diversity of wrist braces. (Images adapted from Amazon, 2019) More details about the depicted brace designs can be found in appendix V.

Field research

As a part of the user research, a series of interviews have been conducted and an analysis of an already performed questionnaire was made. The interviews aimed to find new insights in user needs and tried to discover how, if and when a patient would like to use the product. Analysing the questionnaire results gave insights into the difficulties and problems an ET patient is dealing with during daily life activities.

2.3.1 Interview

Several different conversations have been organized with both specialists and patients. Two interviews with ET patients have been conducted, an interview with a Parkinson's patient, conversations with ergo-therapists during a Parkinsons information meeting at the Sofia rehabilitation centre in Delft on the 1st of May 2019 and a interview with "wearable designer". A short summary of each conversation can be found in Appendix VII. The conclusions drawn from the conducted conversations with patients and professionals helped to better understand the needs of the user. An overview of the most interesting conclusions is presented.



Interview conclusions

A clear distinction needs to be made between patients that have been having a tremor since birth and patients that have been diagnosed with ET on a later age. How people look at their tremors depend on how the tremor influences their lifestyle. Congenital ET patients organize and structure their lives to have as little tremor related obstructions as possible during daily activities. Therefore motivations of congenital ET patients for a solution are different to patients that are diagnosed with ET in a

later life stage. A reason for a congenital ET patient to buy the product would come from a social perspective. A stable arm will help a ET patient to blend better with the healthy subjects in group activities.

During the interviews, Jasper mentioned that he is not fond of buying medical equipment from an online platform. It is possible that more potential users have the same perception of on-line shopping. This will influence how the product should be presented to the future user.

2.3.2 Questionnaire

In 2018 STIL conducted a questionnaire as part of their feasibility study. The questionnaire (n=53) had not yet been analysed thoroughly, since it mainly had been used to see if there was an interest in having a potential solution for suppressing a tremor.

The questionnaire was shared with members of a tremor group on Facebook. Members of this group varied by gender, age and had different backgrounds. An overview of questionnaire results can be found in Appendix VII Some of the most interesting responses on open questions have been transcribed and added as a suffix in Appendix IX.

Besides the questions about interest in the product, participants have been asked questions concerning everyday live situations and specific symptoms. Because of this profound questionnaire there was no need to set up a new plan to do a large scale questionnaire. The analysed results of this questionnaire have been used for a patient journey map, personas and use case analysis. A view noticeable findings are discussed in in the conclusion section.



Questionnaire conclusions

The questionnaire respondents had been requested to think about what situations or events intensified their tremors. Stress and nervousity are seen as the most prevalent reasons that triggered a participants tremor.

Half of the participants replied that they were using medication to suppress their tremors. Of these medications Propanolol was the most commonly used medicine. The reason most participants are not using any medication is due to the severe side effects that these medications have. Some of the respondents mentioned that medication gave them a restless feeling and made them aggressive.

The participants have been asked to specify the body part at which the tremor manifests itself the most. It was found that having a tremor in the lower extremities (hands and forearm) is the most frequent location. It should be noted that patients often mentioned to have a more severe tremor in either their left or right hand.

The numbers found with the questionnaire have been compared with numbers found by a study that questioned 487 consecutive individuals diagnosed with ET by Whaley et al., (2007). Remarkably the numbers of diagnosed patients with affected arms was much higher (97%) in the research conducted by Whaley et al., also voice tremors have been found in 67% of the patients in this research, something that was not mentioned in the questionnaire.



Design considerations

A tremor in the forearm usually is more dominant in either the right or the left hand. The product will therefore be designed to be used on only one arm. This choice is also supported from a financial point of view.

An unobtrusive, modest design was desired by the interviewees.

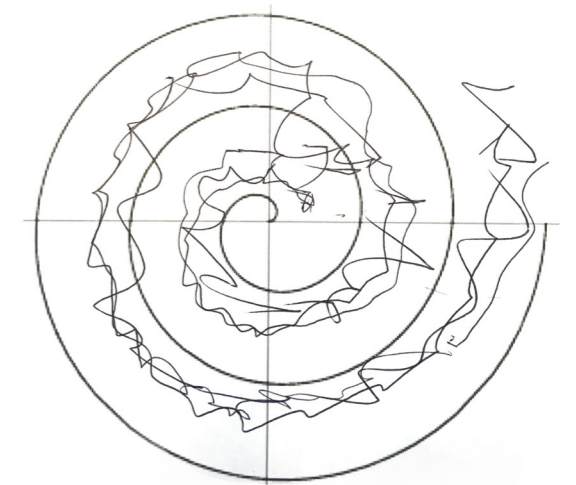


Figure 9 Archimedean spiral by Jasper. This type of spiral is commonly used as a mean to test the severity of ones tremor. The patient is ask to draw a series of spirals. A distortion in the spiral indicates the presence of a tremor.

“My tremor usually gets worse when I try to stop it. For example, when I am visiting the barber or dentist.”

“My most awkward experiences were when I just started to get my tremor. I got ashamed and angry with myself, because I tried to avoid social contact with people.”[⊛]

[⊛]Two examples of the testimonials that are presented in Appendix,IX translated from Dutch.

Understanding the user

A profile of the future user has been made with the help of a series of personas. This was followed up with a patient journey map that was made to discover aspects that can improve the user experience of the product. Having a better understanding of the future user will be useful to create an outline for - and confirm specific product features. This will help the company to better target the users, fulfill potential user needs and plan a market implementation strategy.

2.4.1 Personas

Personas are used as a means to better depict the targeted users. The personas in this project describe fictional characters that represent archetypical people with a tremor that fit well within the chosen target group. The characteristics and testimonials are based on answers from the interviews and questionnaire conducted by STIL. The personas are used as a reference when thinking about use cases or product requirements and aim to cover an as wide as possible set of potential users that fit within the chosen target group. This led to three types of potential users. A more elaborated version of each persona is presented in Appendix X.

The “Gosh, tell me more!” woman.

This is a professional that has to learn how to deal with her tremors. Tremors are a new development in her life and her tremors make it very hard to work and do creative activities. The tremors started a few years back and have progressed to an intensity that obstruct her from performing her work properly. Since she has a decent income, she has the freedom to explore and try out different treatments.

The “Thank god, finally a solution.” man.

This persona represents the retired people that have been trying out many medications, but still have not found any fitting solution. These users do not like the side effects that most of the medications have and also the serious risks of surgeries like, DBS (deep brain stimulation) and thalamotomy (the precise destruction of the thalamus, the brain part responsible for involuntary movements), scares them. If they had the opportunity of trying out an orthosis that would reduce their symptoms, they would be very interested.

The “Tremor for life” guy.

People with a congenital tremor have learnt to live with their tremor. This persona has adapted his lifestyle in such a manner, that his tremor does not conflict his daily activities. Nevertheless he would like to be less of an exception during group activities and he would like to pay for a solution that stabilizes his arms.

2.4.2 Patient Journey map

The patient journey map in this report focuses on finding new possibilities that will improve the user experience of the product. A patient journey map usually focuses on the experience of a patient that has symptoms that can be cured. This is done by offering a tool that helps to visualize the different stages of a specific treatment or healing process, with this incorporating human aspects by looking at what actors play a role in each stage of the treatment.

This patient journey is different to a conventional patient journey map, since this patient journey map analyses a treatment that only suppresses symptoms of the patient. This results that there is no clear

revalidation period. Instead a period of product use is introduced. Another few little adaptations to the conventional patient journey as proposed by Goossens et al. (2019) have been made. With this, it has been tried to find better solutions for this specific project. Adaptations include the inclusion of distributors to the actor involvement and interdependencies overview. Conventional patient journeys do not include stakeholder according to Goossens et al. In this journey the distributor will mostly have indirect contact with the customer, but the inclusion of STIL will give a view of STIL's involvement during the treatment of the patient. Additionally, desired product actions and assets have been added to the timeline overview. This is useful for the use case analysis and can be used to determine the desired assets of the product.

As preparation of the patient journey map the patient has been analysed by looking at the involved actors and their interdependencies. The conducted interviews, analysed questionnaire results and existing literature functioned as a basis for the development of this patient journey map.

Actors

The actors, people and objects who are contributing to the mental state of the patient, have been mapped and categorized. On the next following pages Figure 10, Figure 11 (and in Appendix VI) show what - and how actors play a role in the lives of tremor patients. In the figures actors that frequently interact with the patient are placed closer to the center. An individual relies on help from close actors depending on the severity of the disorder. This results that many actors are involved in the lives of ET patients. To reduce cluttering the actors have been grouped into categories in Figure 10. This was done based on the responsibilities of each actor for the patient as shown in Appendix XIII

Non-Human actors - Non human actors are objects that help the patient with managing their tremors. A medicine that was frequently used by patients with ET is Propranolol, participants of the questionnaire mentioned a daily dose between 10 and 160 mg. Many participants of the questionnaire mentioned that they had been experimenting with other alternative medicines. CBD oil was tried by many with mixed results. A common comment by people with an Essential Tremor is that alcohol also

lessens the severity of their tremors.

Social actors - Social actors are of great importance for tremor patients. In the questionnaire conducted by STIL, participants frequently mentioned that social situations were experienced as being very stressful. Consequently they became socially shy and became anxious to spill drinks or cause other inconveniences during receptions and parties.

Also, depending on the intensity of the tremor and the patient's age, a patient will rely greatly on the support of their close relatives with day to day care tasks.

Healthcare actors - Participants of the questionnaire responded that most contact and consultations happened through their GP and/or caregivers. Contact with specialists, neurologists, ergotherapists and physiotherapists, only happens on set appointments (3 months to a yearly interval). Specialists are mostly having an advisory role, giving information about treatments. Caregivers and GPs take responsibility for direct contact. Patients are expected to approach these caregivers with question about help with daily tasks and questions about medicine.

Caregivers and specialists can have contact with close relatives about family care and treatments. Also, with approval of the patient, treatment information can be used for research and educational purposes.

Supportive Actors - Support groups organize events to give advice to patients. Patient problems and potential new treatments and solutions are presented on such events. Support groups (for either ET or other disorders an individual is suffering from) manage several different online pages to provide patients with information (i.e., perspectief.uwv.nl). Generally a patient has very little contact with its insurance for advice.

The journey

The full patient journey map can be found in Appendix XII As stated, a modified version of the pa-

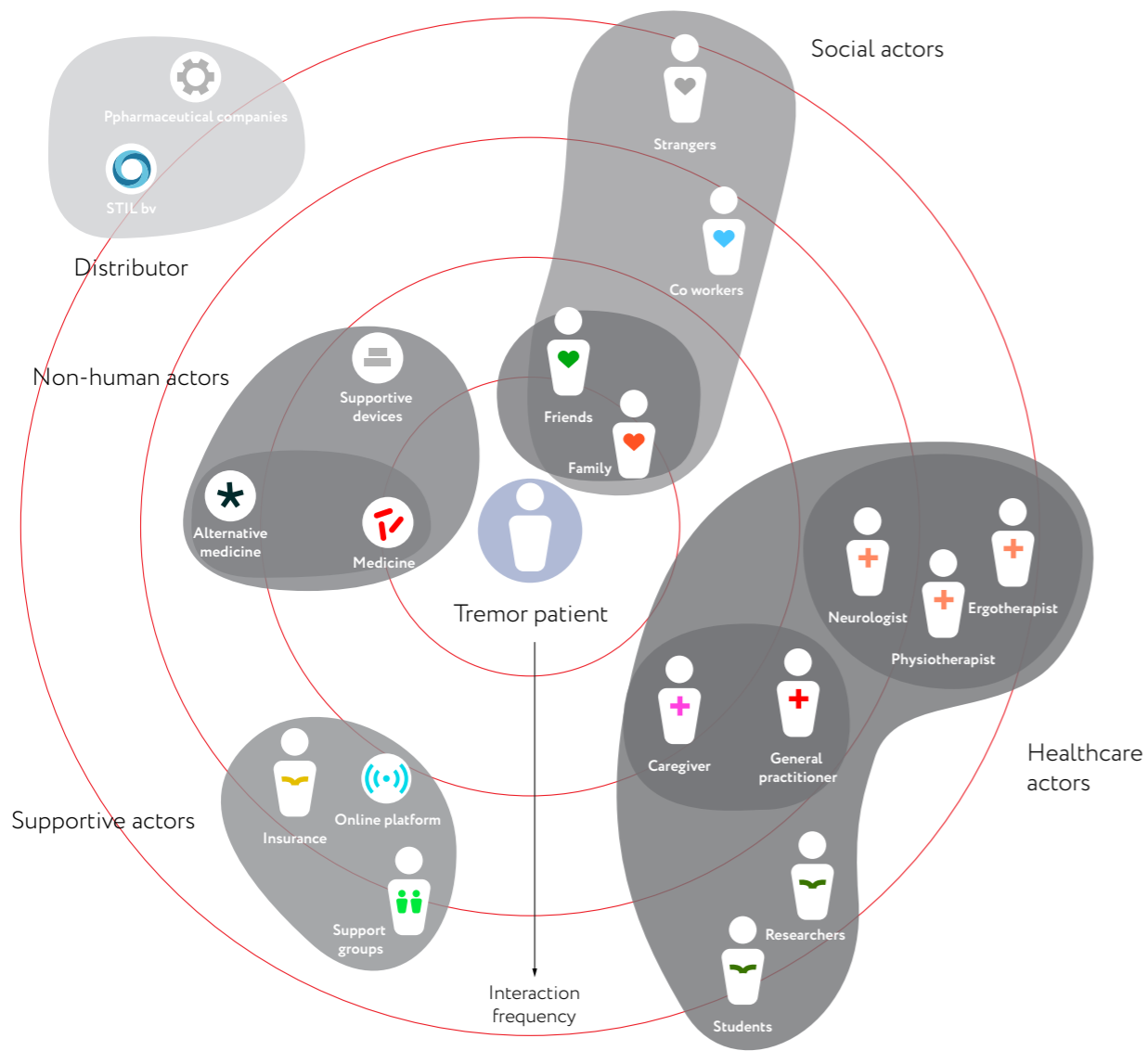


Figure 10 Actor involvement. The relevant actors that contribute to the mental state of the patient during the diagnosis phase and use of the product have been gathered and placed in a circular pattern. Actors with comparable responsibilities have been grouped and placed within one of the five subcategory clouds (grey, red, yellow, green and blue). Depending on the frequency of interaction with the patient each actor has been placed closer or further away from the patient (placed in the middle).

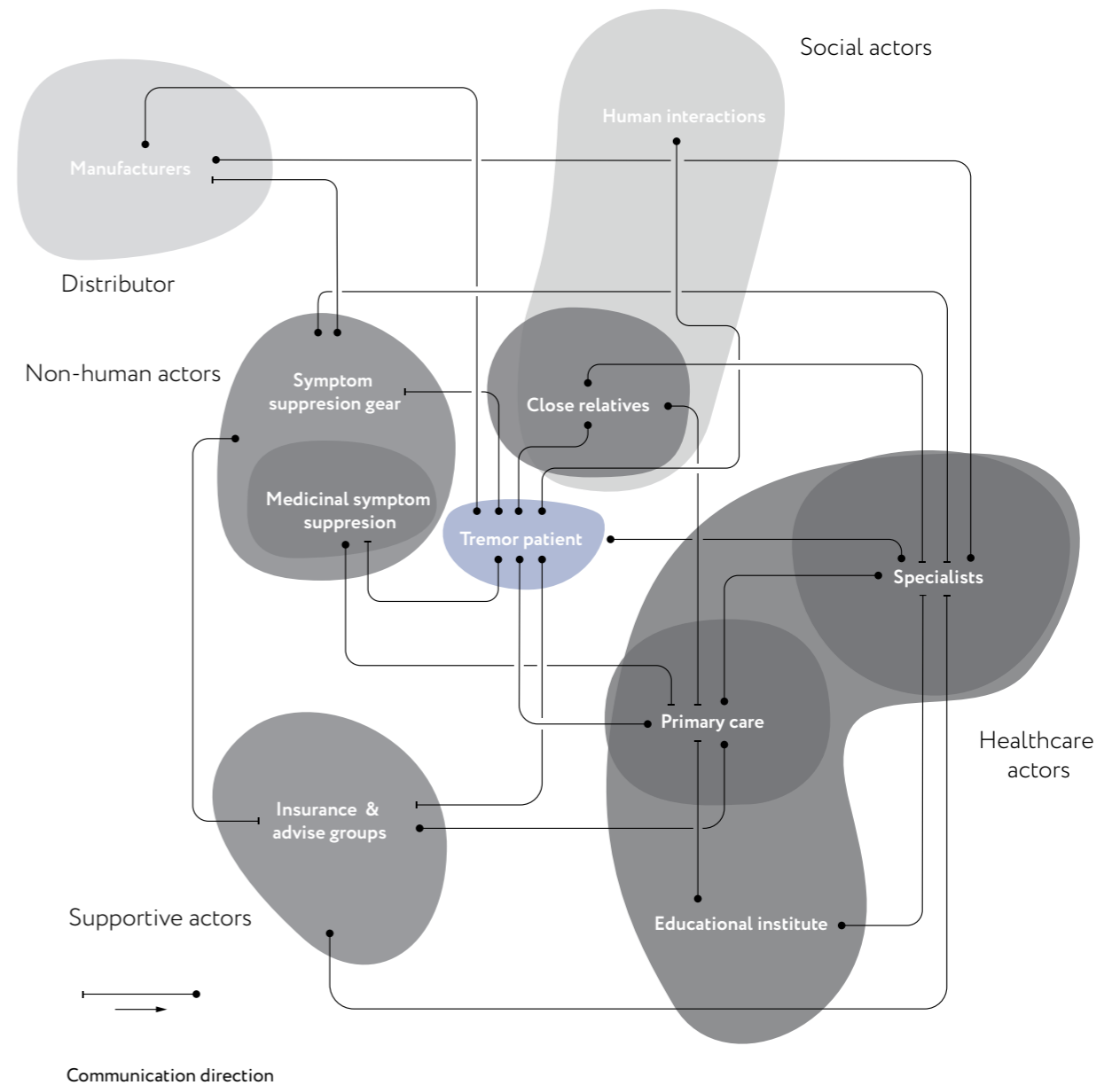


Figure 11 Actor interdependencies. The actor categories that have been categorized in this figure have been grouped and interdependencies between each group has been mapped. Interdependencies are depicted with a black line. When communication between both actor groups occurs a line is drawn with two ballheads, if unidirectional communication occurs a line is depicted with a line- and ballhead.

tient journey map was used in order to get relevant results for this specific problem. The Patient Journey map has been split into three sections; the time frame, the user and the product. Each section focuses on a different aspect of the patient journey. These aspects have been distributed on the vertical axis.

Conclusions

- The patient relies on the mental support of its close relatives. The effects of a tremor can have a great impact on the confidence and social life of an individual. Husband, wife and/or family are of great importance during periods where the patient has frustrations because of its tremors.

- People diagnosed with ET do not often visit a GP or specialist. Once a diagnosis and proper treatment has been given, it sometimes can take years before a patient visits a GP or specialist again. Only when complications occur a patient will consult a specialist. Creating awareness of the existence of the product by STIL during the first consultations is critical for a higher change of success. It can be difficult to reach patients again once they have been diagnosed and are using proper medication.

- A large group of patients (mostly elderly) are likely to be not familiar with ordering medical devices and medication through an online platform. Elder patients tend to go by the advice of a GP or a specialist. Creating awareness at caregiver- and specialist actors, and making them advise the product, will improve the credibility and likeliness of sales of the product shortly after being diagnosed with ET.

- Another approach to reach potential customers can be to create awareness through trade magazines and/or patient groups. Although patients have little contact with their GP or Specialist, some of them are members of patients group of either another disease, or specifically for ET tremors.

- Getting new equipment is always an exciting moment and if technology works and proves what it promises, it can create a lasting positive connection between the user and product. For the

product of STIL it is important to make a good first impression important to have a good first impression, because the expectations are high and probably the user will be very curious about the functionality of the product. The targeted users are very likely to have very little experience with this type of technology and therefore the product needs to be as intuitive as possible and ready to use with its first use.

- Motivations for buying a brace are not always user centered. Besides from being able to eat, cook and practice hobby's, patients would love to be able to participate in group activities without being an exception.

- With the results of the Patient journey map a use case analysis was made. The use cases are depicted in Appendix XII and helped to define situations that can be improved with the help of the product.

➔ Design considerations

- It is advised to sell the product through professional sales channels, e.g. by prescription or via insurances. This requires the product to meet medical grade standards.

- An online platform will have to be made to inform and explain the user on how to use the product and arouse interest in the product.

- A successful first use and a proper packaging is important for the acceptance of the product.

- An unobtrusive design is desired in order to meet the needs of the user.

2.5 | ANALYSIS

Anatomical and physiological considerations

To discover the practical limitation for the design of a wrist brace an analysis was done on the elements of a human arm that can be seen as relevant for the design of a brace. The anatomy and physiology of the upper extremities (forearm and wrist) have been analysed and noticeable findings have been shared in this report section.

2.5.1 Anatomy of the upper extremities

The forearm and wrist, exist of a combination of elements that have to be considered when designing a product that is in direct contact with the forearm. The forearm exist of a complex combination of bones, muscles, tendons, ligaments, nerves and arteries. The to be designed brace should not obstruct any of these systems in the human body from functioning. Human Anatomy & Physiology by E. Marien and Hoehn (2016) served as valuable source of information for the discussed information in this section. With the help of a heatmap the found points of attention have been visualized.

Muscles

Most of the movement in the wrist is regulated by muscles that are located in the forearm. The forearm, which can be sub-categorized in the anterior- and posterior forearm (front and rear side of the arm), contain a system of muscles that are responsible for the flexion and extension of the forearm, wrist and fingers (Figure 12). During muscle contraction a change in shape of the specific muscle group can be observed. Delicate hand movements result in a constant play between the anterior- and posterior muscle activity during flexion and extension. The different muscle states can be troublesome when wearing a product that fits tightly around the arm, because the product can hamper muscle move-

ments. An experiment on shape change of the forearm during different movements was done, results are shown in Chapter 2.6.3. Knowing where muscles have their origin, might help finding locations that can be used for clamping points of the brace. In Appendix XVII an overview of potential brace contact points has been given, these results have been included in the heatmap of Figure 12.

Joints, arteries and nerves

On the anterior side of the wrist, the carpal tunnel can be found. This tunnel leads tendons and nerves into the wrist. The tendons are connected to muscles found in the anterior forearm. They are responsible for the flexion of the fingers. The carpal tunnel also contains the median nerve. When extensive pressure on the carpal tunnel is applied for a long period of time, numbness in thumb, middle and index finger can occur. This syndrome, the carpal tunnel syndrome, can be caused by a swollen wrist, inflammation in the wrist joint or alcohol abuse. Treatment is possible by surgically releasing pressure in the wrist joint. It should be avoided that the brace causes symptoms (excessive pressure) that can be related to carpal tunnel syndrome.

Skin

The skin is the part of the body that is in direct contact with the orthosis. The skin can be divided into three layers, epidermis, dermis and hypodermis (Figure 13). The skins elastic behavior and need to transpire, have been important challenges that needed fitting solutions in the conceptual phase.

The skin has an inhomogeneous structure and highly anisotropic behavior, meaning that how it reacts on forces depends on the circumstances and lo-

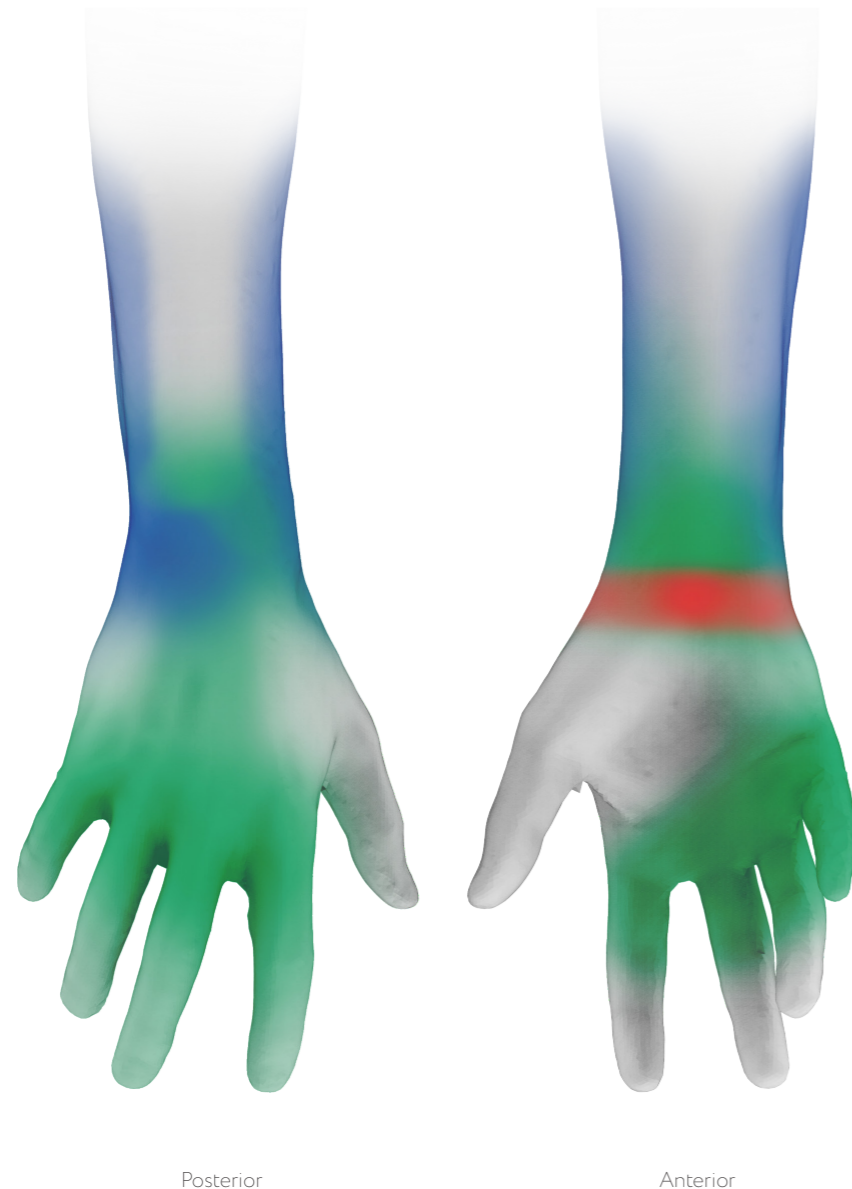


Figure 12 A heat map showing interesting locations and locations that need extra attention during the design process. Green; Locations that can be used as contactpoints for the brace. As found in the analysis performed in Appendix XVII. Blue; Location that have little tissue between the skin and the bones. I.e. Head of the ulna. Red; Sensitive area's, avoid applying pressure on these locations. (Carpal tunnel).

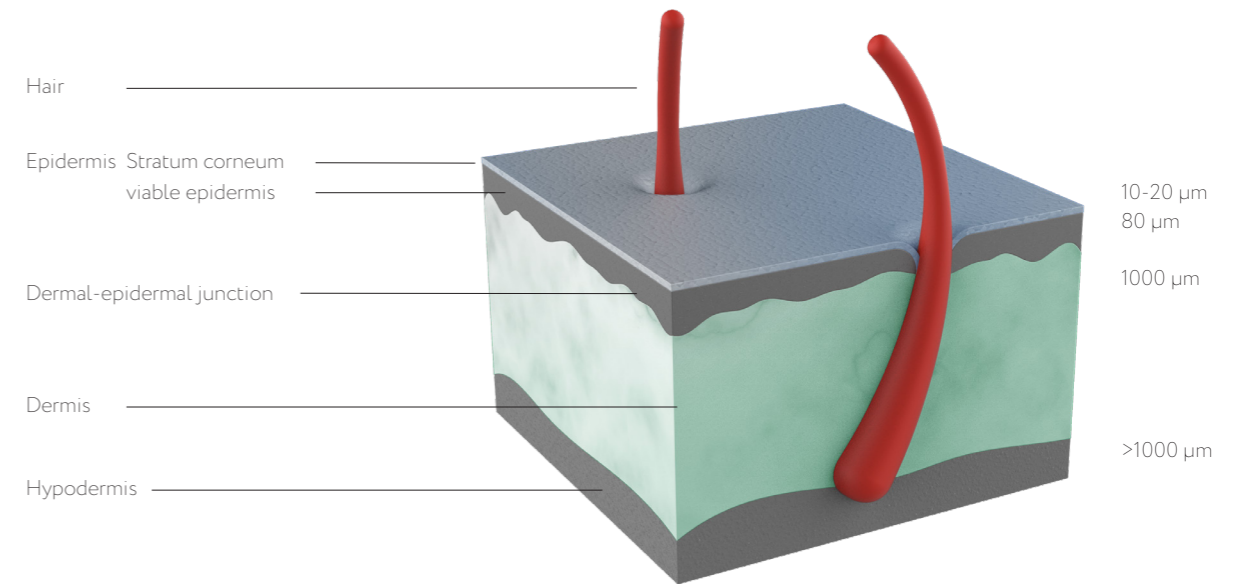


Figure 13 Schematic representation of skin layers

cation. Numbers about the skin's maximal allowed pressure and its elasticity behavior show a lot of variation (Kalra, 2016).

When the skin is subjected to long term shear forces, even with small deformations, large deformation in the hypodermic fat layer occur. This deformation is reversible and without any permanent damage (Geerligs, 2009). Most probably this type of deformation will occur while wearing an orthosis for a long time.

People transpire to keep their body temperature within control. Sweat glands are found all over the body and are responsible for the production of sweat. These glands, which are also present around the forearm, need to have the possibility to make sweat. The product can get slippery or itchy if sweat regulation is not managed properly.

2.5.2 Movements

In orthosis design much research has been done on pressure distribution and positioning of wrist braces. When designing an orthosis usually a restriction

or limited degree of freedom of a specific movement is a desired goal. For this specific brace design it is opposite. Contrary to splints or other braces, it is tried to make a design that will limit the user as little as possible in its movability. A study in splint design rules and mechanics was done with the notion that, when understanding how to design an orthosis that restricts a specific movement, it is also possible to create a design that will maintain freedom of movement in all degrees of freedom, while keeping proper connection to the skin.

Lessons from wrist orthosis design

When designing a splint usually a three-point-pressure system is created. This results in a system that restricts a specific movement. These simple lever systems are applied intentionally in splint applications, restricting movement to improve the healing process of a patient. During the design of these splints it is tried to minimize stresses on the skin and soft tissue. Much studying on reduction of these internal forces and stresses has been done in splint design and can be applied for the design pro-

cess of the new brace. A step by step explanation as proposed by Pitts and Fess (2014) of the design of splint can be found in Appendix XVI.

There is a direct relation between the contact area and the exerted force on the skin tissue. In an ideal situation it is tried to distribute forces as evenly as possible over an as large as possible contact area. This will result in lower pressures on the skin. Besides, one needs to avoid locations where the surface between skin and bone is little, applying excessive forces on these locations quickly results in discomfort by the user. Location that have little tissue between the bone and skin have been coloured blue in Figure 12.

Contact surfaces of an orthosis should contour the skin as precise as possible. A solution to compensate for imperfections in the contact between orthosis and skin is the addition of padding. This will reduce point loading at certain pain points, making a brace or orthosis more comfortable.

Shear forces can be very harmful for soft tissues and should therefore be avoided as much as possible. It is essential that the brace is secure and stable on the extremity. This will avoid any unneeded shear forces. A quick fix for any shearing is to properly round off any edges and provide proper padding. Shearing easily happens around locations of anatomic joint axes. Since the brace will not be custom made, it can happen that a minor misfit can create a unwanted shear force on the soft tissue. Fess (1995) states that deformation, thus shear forces on the skin, and not pressure is experienced as uncomfortable. This means that as long as pressure is evenly distributed this will not be experienced as uncomfortable.

In hand therapy tension is often used to remodel the soft tissues in the upper extremity. Small amounts of tension, around 0.1 to 0.3 N, have found to be acceptable without any discomfort complaints (Palousek, 2014). Commercial braces have found to apply up to six times higher forces, which is a cause why many users often complain about using a brace. In the new to be designed brace, preferably no tension forces will be applied to the users arm.

Degrees of freedom (DOF) and Range of motion (ROM)

Interesting joints in the forearm and their degrees of freedom have been described in Figure 14. The joints of the wrist and the supination to pronation movement of the forearm are complex movement that are needed to take into account during the design process.

The range of motion of the movements as depicted in Figure 14 are given in Table 10. Van der Vaart (1995) conducted a large scale research on arm movements and made an overview of movements in the human forearm. These ROM values are used as a guideline for the minimal ROM the brace has to give to the user.

➔ Design Considerations

- The brace should take into account that subdermal changes occur during the execution of movements. Muscles contract and bones move. The product should allow to let this happen freely.
- Some areas on the forearm should be treated with care. Applying pressure on areas where little tissue between skin and bone is present can result in discomfort. The carpal tunnel is known for causing problems in the hand when excessive pressure is applied for a longer period of time (carpal tunnel syndrome).
- The skin behavior has to be taken into account during the design of the brace. The hypodermic fat layer deforms under the skin while being exposed to pressure for a long time and show complex elastic behavior.
- Shear forces on the skin are the main causes for discomfort. It should be tried to minimize these as much as possible.
- The skin needs to have the freedom to sweat. A solution to manage body fluids needs to be integrated in the design of the product.
- The contact between the brace and the skin is important to consider. Larger contact areas that follow the contour of the arm reduces point loads on the skin.

- Freedom of movement should be achieved as good as possible. The ranges of motion described in Table 10 should be used as a guideline for the development of the brace.

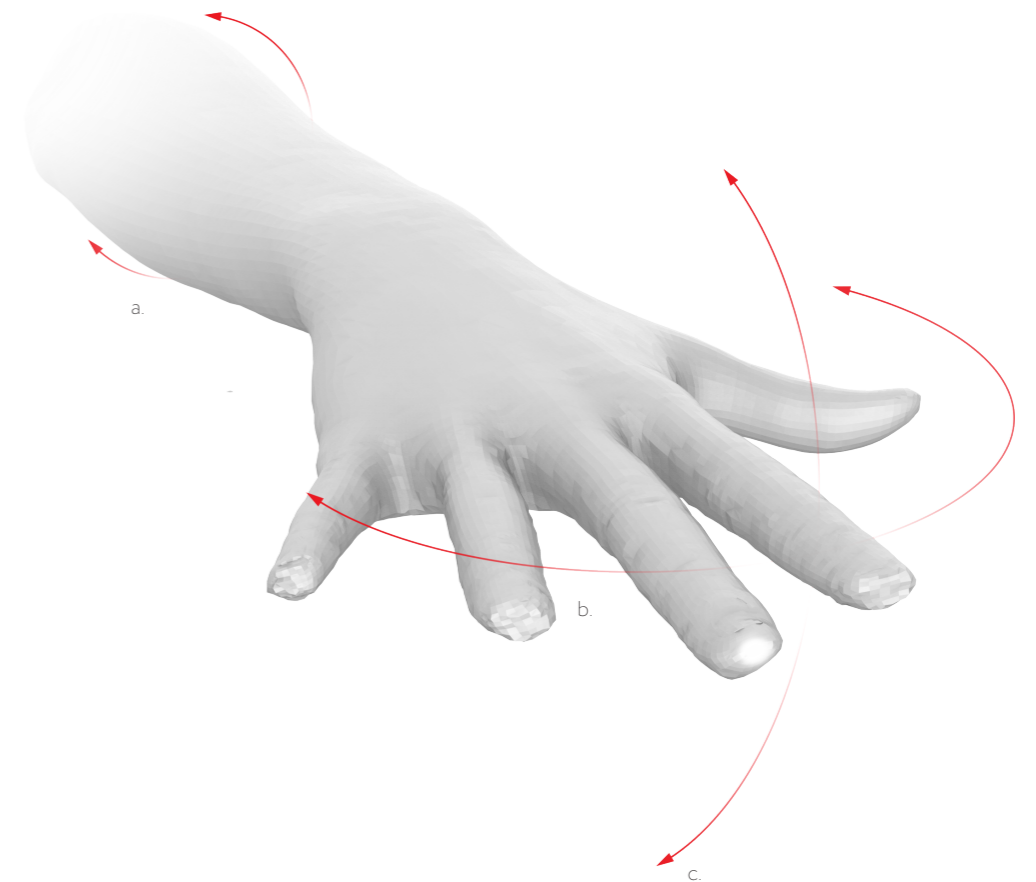


Figure 14 a. Supination & pronation in the forearm (ulnar and radius). The supination pronation movement is described by Joseph (1982) as "the movement in which the head of the radius rotates and its lower end crosses over the medial side of the ulna so that the hand faces backwards. Supination is the restoration of the pronated forearm to the anatomical position in which the radius lies alongside the ulna and the hand faces forwards." Supination is defined as a local rotation of the radius along the ulna. **b.** Radial- and ulnar deviation in the wrist. **c.** Flexion and extension in the wrist. Flexion and extension of the wrist happens around the extremity of the radius and the scaphoid and lunate carpals. The combination of carpals and the radius form an ellipsoidal joint.

Ergonomic research

It is desired to create a design that offers maximal comfortability to an as large as possible set of users. An analysis was done to discover the variance in the forearm, possible dimensions for the final product and the shape of the human forearm.

For the final product the exshell will be offered in a single size. This is a requirement from the company, since the development of different sizes of the exshell is not viable with the current financial budget. For the exshell the inner diameter was determined based on the dimensions of the human hand. A combined research of available data and a test (n=35) was done for the shell. Other ergonomic dimensions are found not to be of relevance for the development of the exshell.

The brace will have the possibility to be scaled and sized. For the brace a large data analysis of available literature was done for size determination. Subsequently a set of arm shapes have been determined with the help of 3d software. These shapes have been combined with the found dimensions and will be used as the fundament to design the product with.

The final part of this Chapter discusses the deformations that occur in the forearm by analysing a set of 4D scans of the forearm in different postures.

Findings of this Chapter are briefly summarized in the findings sections and considerations that have



Figure 15 For both the shell and the brace it is needed to create a fitting design for as many people as possible.

influenced the design process are noted in the design considerations section at the end of the Chapter.

2.6.1 Forearm dimensions and variations

As people vary in appearance, they also differ in size. The size of a body part can rely on many different factors, such as genetics, diet and training. For the design of the product, a sizing method needed to be developed in order to help future customers to find the correct brace size.

Design for almost all

When a product that is in direct contact with the human body is being designed, anthropometrics start to play an important role for a comfortable product experience. A requirement from the company was the possibility to create a range of product sizes that would fit almost all for both the shell and the brace.

A difference between male and female participants has been made during the analysis of dimensions. This was done due to the significant difference between body dimension of different genders (Jee, 2015). Additionally data from different ethnic groups was collected, to see how dimension change between these groups.

Size determination of the product depends on the acceptable variation between different individuals and the amount of adjustability of the product. There will be lesser of a need for different sizes if the product has a lot of adjustment possibilities. In an ideal situation a user would not experience the need of adjusting the brace at all. Nonetheless most

currently available commercial wrist braces come with a certain amount of adjustability in order to make it possible to cover a maximal sample size with as little as possible different product sizes (Appendix V). Offering less variation of the product lowers the investment costs, making it a cheaper product. Due to the target group of this project, it will be desired to have as little needed adjustments before use as possible, since this is a difficult task for the user. Ten braces have been compared to see how many different sizes other wrist brace manufacturers offer to customers, what dimensions they use for sizing and the adjustability of the brace (Appendix V). It was found that commercially available wrist braces are often offered in one to five different sizes.

How many of each size will be made depends on the size of the target group and the dispersion of each of the dimension of interest.

Dimensions of special interest

In anthropometric databases the human hand and forearm are described by many different parameters of which not all are relevant for the design of the product. In order to determine relevant hand measurements, an overview of the process of putting on the product and placement of the product helped identify a series of dimensions of special interest. These so-called critical dimensions (CD), have been determined with the help of the scenario (Figure 4). As described in the scenario the process of putting on the product is split up into five phases. These phases explain the relevance of the CD. In a chronological order the brace is put on, optionally tightened, and then the shell is connected to the brace. The different phases in the scenario found on page 21 (Figure 4) explains the urge of knowing the size of the inner diameter of the shell (CD1). For the brace, which will have skin contact around the wrist (CD2), forearm (CD3) and optionally the palmar area need to be determined. How each dimension was determined is described below.

CD1 - The inner diameter of the shell depends on the smallest diameter an individual can comfortably put his or her hand through. Little information about this dimension could be found in literature. Therefore a test was conducted to find more information about the optimal inner diameter of the shell. At the YesDelft Incubator random people have been questioned to put their hand through a printed cylinder.

Additionally their hand width (distance between metacarpal-phalangeal joints) was measured with a calliper. The relation between hand width and hand diameter was researched to see if a hand diameter advise could be given based on the hand width.

CD2 - In literature the wrist is described by its width and its circumference. Both dimensions are collected and compared to each other. Jee et al. (2015) described the wrist breadth as the distance from the most lateral point on the wrist to the most medial point of the wrist. The circumference is determined by taking the superficial distance around the edge of the wrist.

CD3 - The forearm circumference or breadth are rarely described in literature. Fillali (2011) did research on the difference between the circumference of athletes versus non-athletes. The forearm circumference was taken at its greatest point in this research.

CD4 - In traditional glove making the hand circumference is used as the critical dimension for the size of the glove. By using the hand circumference, other dimension, such as palm length and hand length, can be derived within a certain error range (White, 1980). The hand circumference is the superficial distance around the metacarpal bones (Jee et al., 2015).



Overview of found dimensions

Table 2 on the next page shows the pooled standard deviation and average percentiles of the previously determined anthropometric measurements of the human forearm. These values have been derived from the collected data shown in the table in Appendix XVIII and the research conducted at the YesDelft Incubator. The found results are discussed.

CD1 - A regression analysis was performed to discover if a relation could be found between the hand diameter and hand breadth. A distinction between female (n=14) and male (n=20) results was made. For female test subjects a linear correlation coefficient (r) of 0.76 was found, for male subjects r was found to be 0.74, which suggest a strong relation between the breadth of a hand and the minimal diameter a

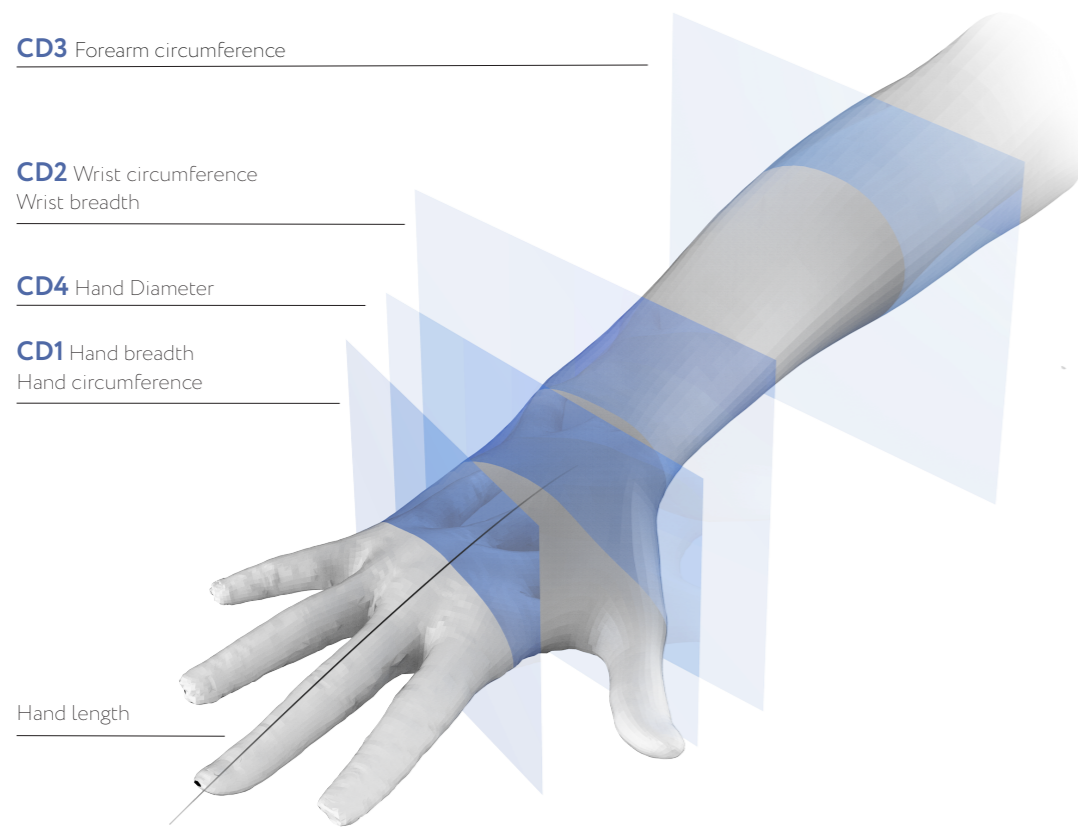


Figure 16 An overview of the dimension of special interest.

	n	S.D.	P50 mf	P5 mf	P95 mf	P95 f	P95 m
Wrist circumference	18177	8.7	157.7	143.4	172	160.0	192.6
Wrist breadth	603	4.0	56.7	50.1	63.3	58.2	67.3
Hand breadth	-	6.0	79.9	70.1	89.7	83.8	95.2
Hand circumference	8967	11.5	203.8	184.9	222.7	198.1	235.0
Hand Diameter	35	4.5	74.6	67.2	82.0	78.9	84.1
Hand length	-	12.0	183.3	163.6	203.0	188.4	207.6
Forearm circumference 80 (male)		15.4	277.9 (male)	252.7 (male)	-	-	303.1

Table 2 Overview of the critical hand dimension for future users (mm). P = Percentile, mf= male and female combined, f = female, m = male. By research the average, standard deviations and upper boundaries, scaling factors could be determined for the brace that could be used for the size determination of the brace after the concept selection. How this is done in the final concept is discussed in Chapter 4.2

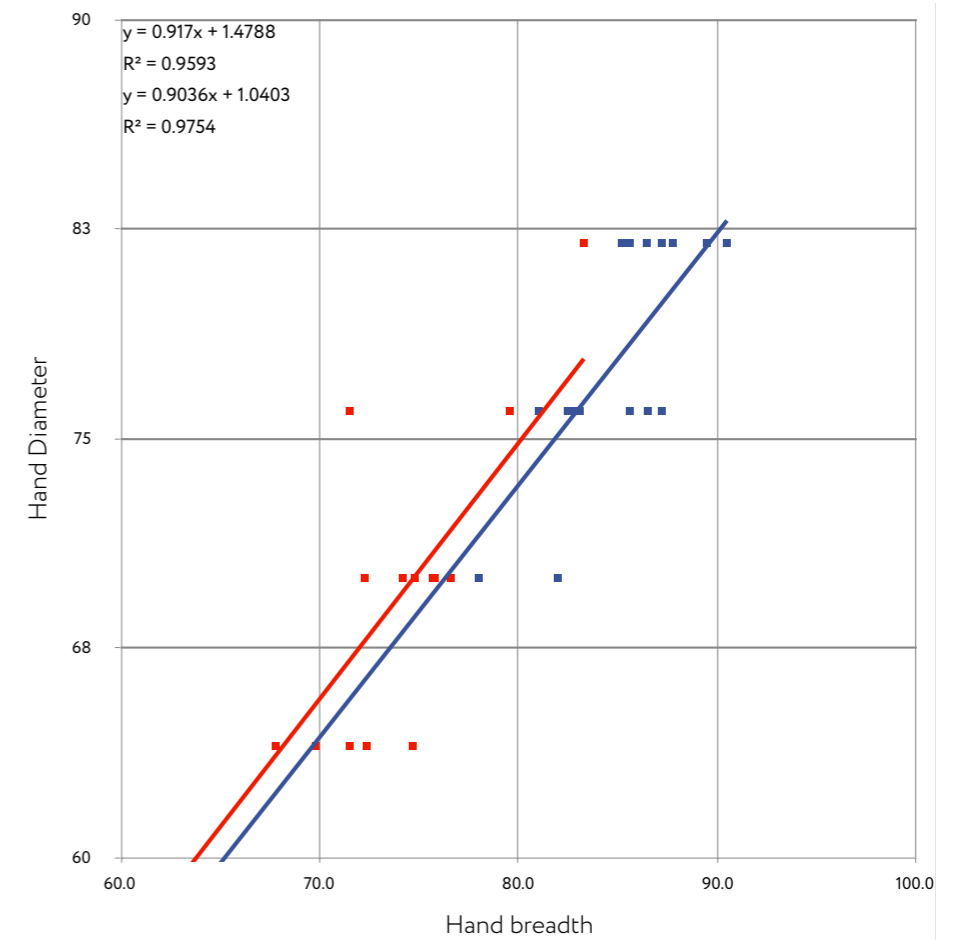


Figure 17 Linear regression overview of the relation between hand diameter (y) and hand breadth (x).

Part	Regression Equation (mm)		Standard error
Shell	Male Hand Diameter	= 0.90 ° Male Hand Breadth + 1.04	4
	Female Hand Diameter	= 0.91 ° Female Hand Breadth + 1.48	6
Brace	Male Hand Length	= 0.42 ° Hand Circumference + 98.3	9.9
	Male Palm Length	= 0.23 ° Hand Circumference + 55.7	5.7
	Female Hand Length	= 0.62 ° Hand Circumference + 59.4	7.3
	Female Palm Length	= 0.29 ° Hand Circumference + 45.6	4.6
	Male and Female Hand Length	= 0.47 ° Hand Circumference + 87.6	8.3
	Male and Female Palm Length	= 0.23 ° Hand Circumference + 56.0	5.6

Table 3 Regression equations found by analysing (shell) the test results and adopted from White (1980) (brace).

human put its hand through. Figure 17 shows the relation between the hand diameter and hand width. The found linear regression equation can be used for future hand diameter estimations (Table 3). Relevant P-values have been added in Table 2.

CD2 - The wrist is described in anthropometric databases by its width, depth and circumference. Comparing the S.D. of each of these mean values shows a large difference between each measurement method. Wrist measurements with a high deviation tell more about the subjects, because it means that this dimension is more subjective to change between different individuals. Wrist circumference, rather than the width is therefore a good measurement to use as a dimension for the determination of CD2.

CD3 - Fallahi (2011) did research on hand measurements between athletes that make extensive use of their arms. For both athletes and non athletes the standard deviation was relatively high in comparison with other dimensions of the forearm. A reason for this high S.D. is that the amount of muscle and fat tissue that is present in the forearm is highly dependent on lifestyle and genetics.

CD4 - Like the wrist, a similar conclusion can be drawn for CD4. The hand circumference is a common measurement for hand anthropology. White (1980) derived a set regression equations from his large scale study in the American army. These equations show the relation between different hand dimensions. This makes it possible to estimate the Palm and hand length within a certain error range, both possibly useful measurements, with only the hand circumference measurement.

2.6.2 Shape determination

Solely a dimension is not sufficient when a product that is in direct contact with the body is designed. A Generalized Procrustes Analysis was performed with the datasets provided by Huysmans (2009) in order to determine the optimal shape at the location of each critical dimension. A GPA analysis helps to define an average shape of a large group of 3d data. It takes the average from the provided 3d data and forms a new shape that is based on the input. I was able to perform this analysis method thanks to pre-

pared models and script provided by Huysmans.

Approach

Using the GPA method requires a lot of computing power. To speed up the process a selection of the available human 3d models was made based on known data found in the accompanied excel sheet.

No data about the wrist breadth or any other relevant human dimensions was directly available in the dataset accompanied with the 3D models, it was therefore needed to come up with an alternative approach to select each of the human 3D models for its hand dimensions. It was assumed that gender and the body mass index (BMI) are of high influence for the scale of CD2 and CD3 due to fat and muscle tissue build-up in the forearm. These parameters have been used to filter the models to find relevant data.

For the shape analysis an Italian 3D dataset set was used. The Italian 3D dataset proved to be a more useful dataset than the also available Dutch Dataset, since this set of scans (n=800) had more intact scan results of the human wrist than the Dutch 3D dataset.

The mean - (P50mf) and two outlier shapes (P5f and P95m) have been determined, in order to compare how a forearm shape changes between people with different forearm dimensions.

The average shape has been determined with the help of Paraview 5.6.0 and the code as described in Appendix XVIII. The average and extreme shapes have been determined by taking ten samples that lay closest to P50mf BMI, P5f with the lowest BMI and P95m with the highest BMI value (Figure 18). After this selection and analysis the shapes have been imported into Rhinoceros 5.0 and have been oriented at three points. The aligned 3D models have been sliced at the three previously determined CD locations (and the contours have been grouped and aligned). Results are depicted in Figure 19. Together with the values of the critical dimensions, these found 3D shapes can be scaled accordingly to fit a specific CD.

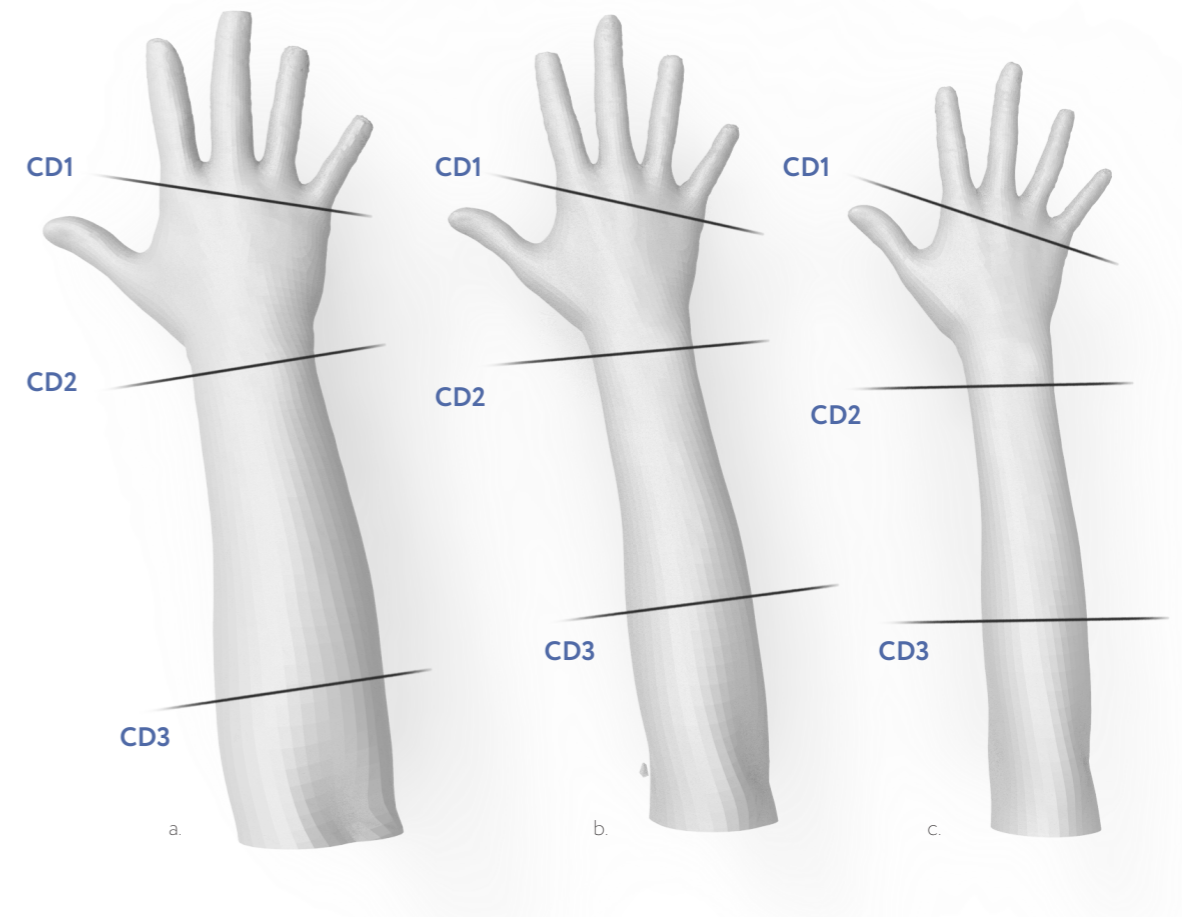


Figure 18 Overview of the results from the GPA analysis. Each shape was determined by taking the 10 values that matched the desired P values. From left to right: a. P95m with the highest BMI values. b. P50mf BMI. c. P5f with the lowest BMI

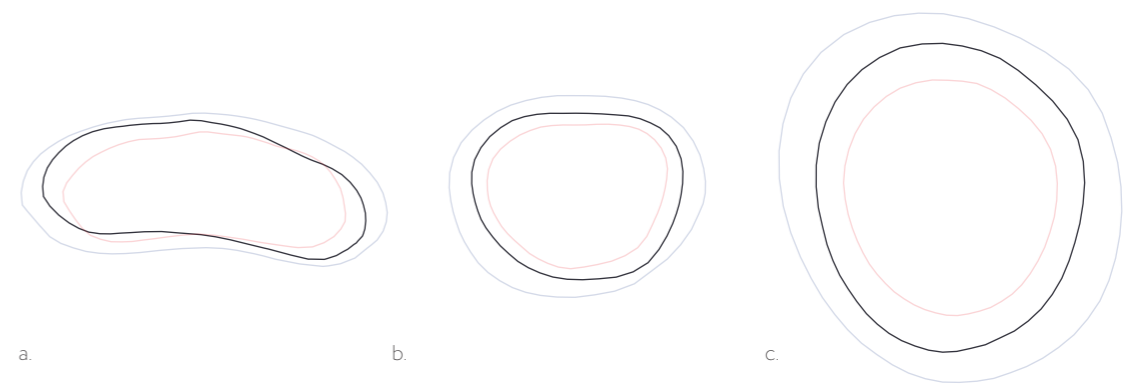


Figure 19 The section views of the hand at CD1 (a), wrist at CD2 (b) and forearm at CD3 (c). Scale 1:2; P5f BMI in red; P50mf in dark grey; P95m in blue.

Forearm shape findings

The used shape determination method resulted in the crosssections and 3D shapes as depicted in Figure 18 and Figure 19. Other crosssections and dimensions can be extracted from the same 3D model.

After comparing the circumferential shapes of Figure 18 with the data found in Table 2 a close match was found for the P50 mf BMI wrist circumference (161 mm) and hand circumference (200.7 mm). The relation between the measurements found in the dimensional research of Chapter 2.6.1 meant that these made 3D shapes can reliably be used for the shape of the brace.

Looking at the other determined extreme shapes for P5f BMI and P95m BMI, it can be seen how the arm shape changes for people with larger dimensions. The cross sections of these shapes show that a larger wrist of forearm circumference shows a comparable shape as to a smaller arm. This meant that the P50 shape of the arm can be scaled uniformly to match larger dimensions.

The shape of the P50mf hand is quite different to the other shapes of the P5f BMI and P95m BMI. It might be assigned to a deviation in hand postures between the user 3D scans

2.6.3 Forearm deformation

To see how the cross-sectional shape of the forearm changes and how the skin deforms during different movements an experiment was conducted to gather more information and insights about this movement. The deformation of the upper extremities has been analysed by making a 4D scan of my right forearm. The arm was moved in several different positions to find out how muscles and bone positions influence the cross-sectional shape of the arm. Simultaneously a series of pictures was taken to look at the movement of the human skin.

Method

The 3d scan installation at the faculty of Industrial design engineering was used as a mean to make the

4D scan of the arm. The arm was moved, consecutively from a true neutral position to an supination to pronation -, flexion to extension - and ab- to adduction movement. Output was a series of 3D .obj scans and bitmaps. A selection of frames has been used to create section views with. The section views were made with a simple grasshopper script, that aligned each of the scans on the elbow and split each of the object of several interesting points on the arm. Hereafter the contours have been exported to Illustrator for post-processing.

Results

Figure 21 shows the section view of the arm at several different locations for the chosen movements. As a reference a neutral position was (supinated arm position) used in each of the movements. This is depicted as a grey line in the overview. This position was a suitable reference since it occurs in each of the analysed arm movements. Incomplete section views are the result of incomplete 3D scans.

During the scans a series of pictures was taken (Figure 22) on the next page. Each picture shows the arm in a different extreme state. The black lines shows how the skin moves and stretches while performing these movement. The black line was drawn on the

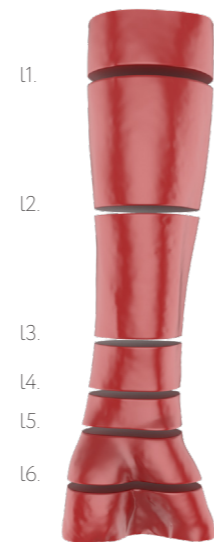


Figure 20 Overview of how the arm has been "cut". The forearm has been sliced on six potentially interesting locations. These locations have been chosen based on the potential relevance for the design of the brace.

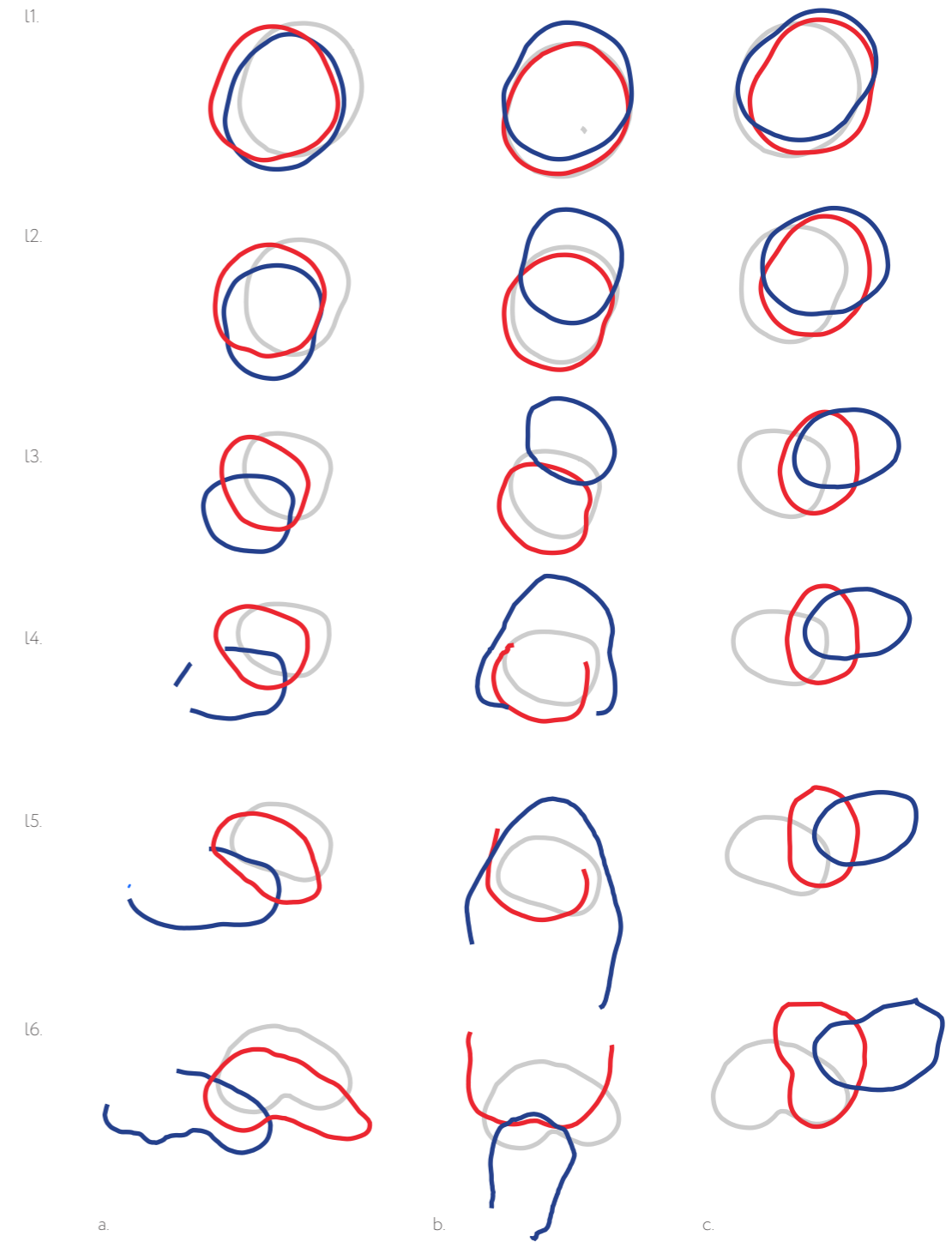


Figure 21 a. ab- to adduction, b. radial flexion and extension, c. supination to pronation. The slicing locations as shown in Figure 20 resulted in a series of section views for each different movement during the test. The orientation of each section view to each other is as it was after slicing, showing the change of location during the different arm movements. The grey lines are used as a reference for each movement, showing how the arm changes relative to this neutral arm position.

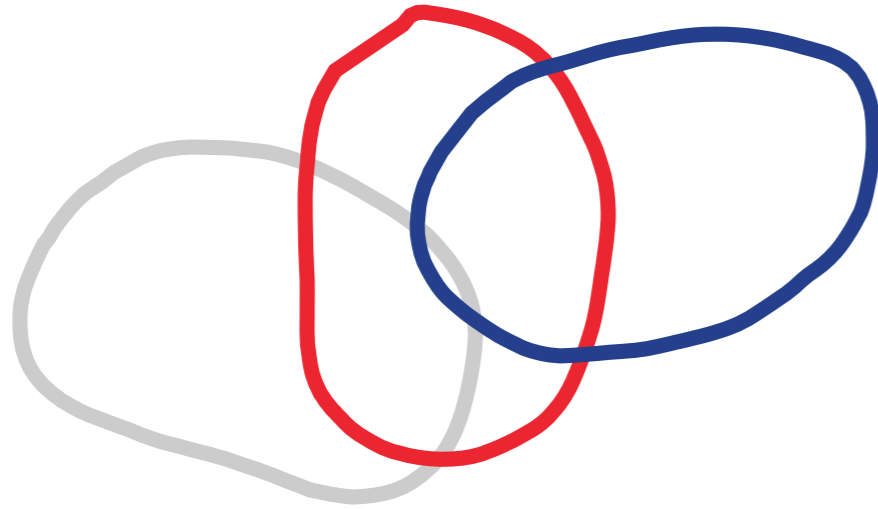


Figure 23 Close up of the supination to pronation movement in the slimmest part of the wrist (figure 15c).



Figure 22 Skin torsion in the forearm during different movements. a. Supination to pronation movement b. Flexion and extension. c. Radial- and ulnar deviation.

arm while keeping it in a neutral position.

Forearm deformation findings

- Comparing each of the 3 different movements shows that during a specific movement not only deformations occurs in shape the of the arm, also displacements in space are present in the forearm location. This makes the data from movements a and b difficult to analyse on deformities, since the set cutting points on the neutral position move in space during the execution of a movement.

- Most interesting is the change of shape of the forearm during the supination to pronation movement. A close up of of the the section view is presented in Figure 23. In this picture it can clearly be seen how the radius rotates around the ulna as explained in Chapter 2.5.2. A challenge will be to develop a solution that will let this movement occur without restrictions.

- Analysing the skin deformities by looking at the pictures, showed that larger skin deformations occur closer to the wrist during each of the movements. Additionally the skin stretches as the movement changes, making it possible to move the forearm without being restricted by the skin. It appears that the skin also slides over the muscle and bone tissue, since the skin does not change location as much as expected during the supination to pronation movement.

2.6.4 Remarks on the results

With the help of modern technologies more accurate advise for anthropomorphic shapes can be given. The combination of using existing measurements and 3D data was a new method (for me) to determine how a product should be sized. Some considerations on the used methods are given.

Dimensions of interest (CD)

The critical dimensions give estimations about the circumference and length of several different parts. It is not yet decided if all these dimensions are needed for the to be designed concept.

Shape determination

Shape determination and providing info about the

CD's would have been more easy if the desired measurements already would have been available in the datasheets that accompanied the 3D models. Now some assumptions had to be made in order to estimated the shape of the forearm. It would have been more easy if the 3d models directly could have been selected on wrist circumference in the accompanied datasheet. This would have made the dimensioning a lot easier.

Test results

The test for the inner shell diameter used four sizes of ring diameters. This gaves in inaccurate results, since the stepsize between each ring was 6 mm. It would nevertheless have taken a lot of preparation time and would have complicated the testing a lot if the user would have had to try out many different ring diameters. The outliers of the handdiameter test are difficult to justify. It is possible that other abnormalities, such as arthritis, result in a less flexible hand, making it difficult to squeeze a hand through a small diameter.

The inner diameter determined for the shell can be very large for individuals with small arms. This can obvious downside of the single sized shell.

Ethnicity

The 3d data used in this research is from italian origin. If the Dutch database had better quality scans a different shape might have been found. Also how to use the found Korean and sudanese data can be questioned. Currently they have been included in the pooled determination of average values. Since the primary target market is aiming for Dutch individuals, found averages can be lower than measurements of the Dutch population.

➔ Design consideration

- Dimensions of the human forearm vary between people. It is therefore needed to design a brace that can be worn on both large and small arms. Male and female individuals have a significant difference in most of the bodies dimensions.

- Size determination of the product depends on the acceptable variation between different indi-

viduals and the amount of adjustability of the product.

- Using an inner diameter of 82 mm for the exshell will make it possible for 95 % of the people to fit their hand through. This will be used as diameter size for the Alpha 2
- Looking at the linear regression analysis of the hand breadth and hand diameter, it can be found that people with a maximum hand breadth of 88 mm for females and 90 mm for males, will still be able to fit their hand through the product (using a 82 mm diameter). People with a larger hand breadth will experience difficulties with putting their hand through the exshell.
- The average brace will use the dimensions and the shape as determined in Table 2 and Figure 18 a guideline for the different sizes.
- Dimension with a large SD will need extra care. When these dimensions are present in the final concept it is likely that more different sizes will be needed.
- The found 3D forearm shape of the wrist and upper forearm can be linearly scaled or to achieve different sizes. This will make it more easy to develop a 3d model that can be scaled parametrically.
- The deformation that occurs in the forearm during the supination to pronation movement is very important to take into account for the comfort of the product.
- The skin can freely move over the muscle and bone tissue. This is a problem that will have to be considered during the concept phase.

2.7 ANALYSIS

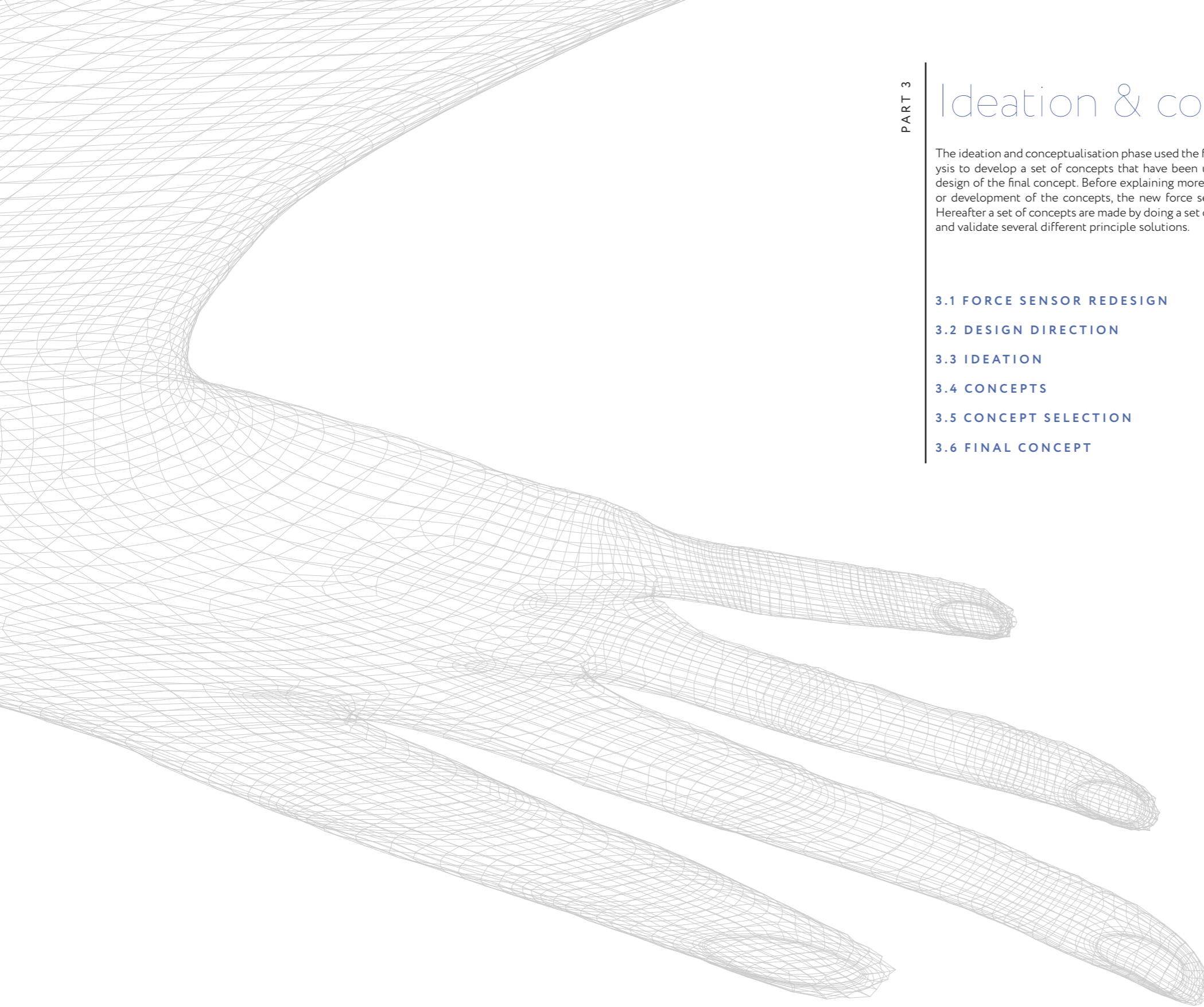
Medical regulations

In order to be eligible for a medical grade product certificate, a product will have to pass a series of tests and meet up with set regulations for the specific problem it is trying to be solved. In Europe the CE certification is used as a mean to grade the level of health and safety of a device. The product that is being designed by STIL will have to comply with the European conformities in order to be legally sold to customers.

The product that is being developed by STIL falls in Class 2a medical devices, this is a class where products try to physically or mechanically act with the user (CE, 2019). A set of documents have been provided by STIL that describe regulations and requirements for this type of product. Relevant requirements for the development of this project have been added in the list of requirements as can be found in Appendix 17.

➔ Design consideration

- The product will have to meet the regulations set by the European Council for a class medical 2a product.



Ideation & conceptualisation

The ideation and conceptualisation phase used the findings from the done analysis to develop a set of concepts that have been used as a reference for the design of the final concept. Before explaining more about the design direction or development of the concepts, the new force sensor design is introduced. Hereafter a set of concepts are made by doing a set of small experiments to test and validate several different principle solutions.

3.1 FORCE SENSOR REDESIGN

3.2 DESIGN DIRECTION

3.3 IDEATION

3.4 CONCEPTS

3.5 CONCEPT SELECTION

3.6 FINAL CONCEPT

Force sensor redesign

As stated in Chapter 1.3 the force sensors proof of principle was already conducted by the engineers from STIL. Nevertheless the design as it was at the start of the project was very bulky and a more efficient design was needed to improve the design and functionality of the product. A brainstorm was organized on how to redesign the force sensor. The results from this brainstorm will be used for the development of the functional prototype of the to be developed concept. A short explanation of the functional principle of the force sensor is presented in Figure 25. The redesigned sensor is presented in Figure 26. This concept served as the starting point of the further made developments of the force sensor.

The to be used redesigned sensor principle exists of a set of strain gauges that measure the deformation of the surface it is mounted to. A strain gauges has a change in its resistance when being subjected to strain forces in a specific direction. This change in resistance can be used for a force measurements. The measured forces can be used for analysis to dampen a tremor. The new sensor design offers many advantages to the old principle. It can be made a lot smaller, which makes it a lot more easy to integrate the sensor into an ergonomic wrist enclosure design. Additionally the new sensor creates the possibility to integrate a firm connection point between the Exshell and brace.

Further details about the implementation and functionality of the force sensor concept in the final concept can be found in Chapter 4.3.

➔ Design consideration

- A rigid connection point to the wrist enclosure is needed for the redesigned force sensor. Otherwise force readings will become inaccurate.

- The brace will be attached to the exshell via the connection point that will be made on the far end of the force sensor. This will create an arm that makes it possible to measure forces in the required directions.
- The force sensors needs to have the ability to deform without coming in contact with other parts of the wrist enclosure.
- Other than the contact point between the force sensor and the exshell, no other parts of both arm or wrist enclosure can touch the the exshell. This will create a distortion in the force readings.

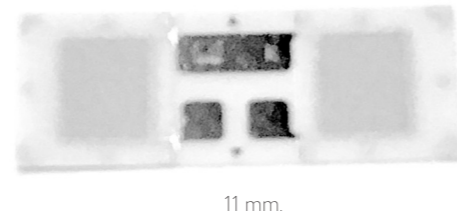


Figure 24 Picture of the used half bridge strain gauge in the force sensors design.

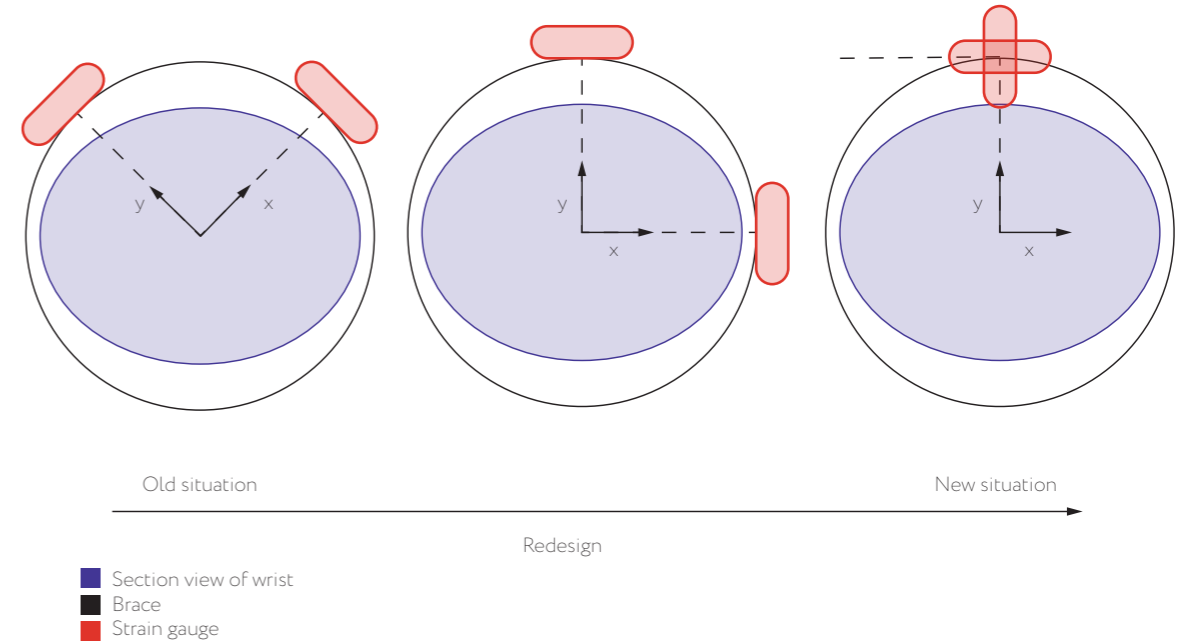


Figure 25 The force sensor needs to measure forces in both the x and the y direction. This is needed to properly analyze the tremors in the forearm of a user. In the old design this was done by placing a set of force sensors perpendicular to each other as depicted on the left. In this design one sensor measures the forces in the x-direction and the other force in the y-direction. The redesign uses the same principle, but thanks to a reorientation of the sensors a smaller and more compact design can be achieved.

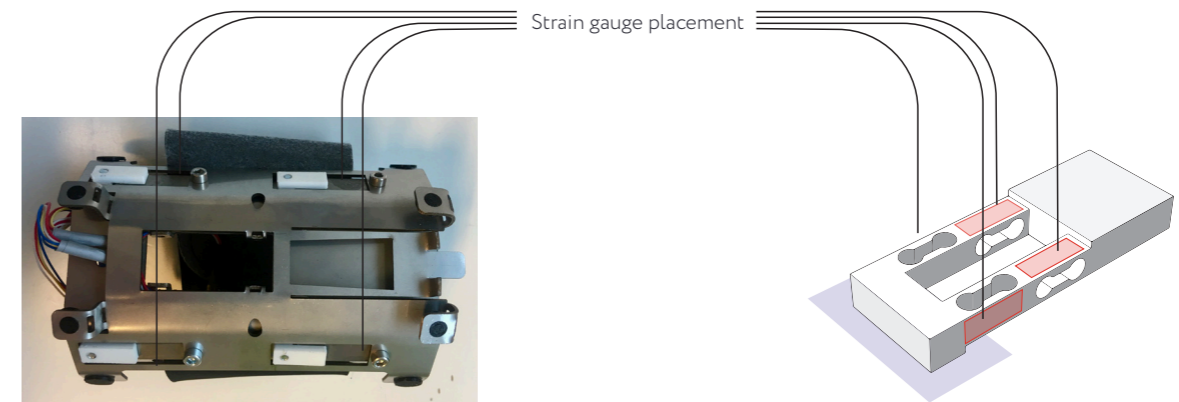


Figure 26 The suggested redesign concept is shown on the right. It can be seen that the same amount of sensors is used as in the original concept, only in a design that can be made much smaller. The blue part of the sensor will be connected to the wrist enclosure, the grey part will be connected to the exshell. When a tremor in the arm occurs a force will be exerted on the force sensor. The direction and magnitude will be measured by the strain gauges and an anti vibration will be generated by the exshell.

Design direction

The findings made in the analysis phase are used as guidelines for the further development of the brace. With the help of the findings a problem statement and a set of goals has been made that are used for the selection of concepts and validation of the final design

Regain social confidence

The interviewees and questionnaire respondents often mentioned that it is difficult to be in a group or participate in a social activity. Awkward situations occur frequently, making them socially shy. The product that is being developed by STIL offers the possibility to help patients to enable them to participate in group activities again without being an exception. Making a modest solution that stabilizes the forearm of the patient can improve the confidence of the user.

Make an easy to use and comfortable product

A user will not use the product if the cons outweigh the potential benefits of the product. The product should add as little discomfort to the user as possible. An efficient and comfortable design is needed in order to let user the enjoy the freedom of having stable arms again.

“Design an embodiment for the STIL working principle, such that recently diagnosed ET patients regain social confidence and functionality during every day activities.”

Problem statement

With the collected information a problem statement was made. This statement concretely summarizes the desired final result of this project. The statement is described on the bottom of this page.

Design goals

With the found results a set of design goals, sub-functions and requirements that the product has to fulfill has been made. A comprehensive overview can be found in Appendix XVIII.

An overview of the goals can be seen on the right. The goals cover different functions that aim to optimize the functionality, use and production of the product. Each goal covers a set of sub functions and has been used as a mean to select concepts with in a later stage.

1. Facilitates forearm damping.
2. Is comfortable.
3. Is easy to use.
4. Is non-obtrusive.
5. Is a safe to use device.
6. Can be used by almost all.
7. Can be produced for the estimated target market.
8. Is durable.

Ideation approach

The ideation phase existed of a series of cycles that served to confirm and find solutions for the challenges found during the analysis phase.

A set of design challenges have been made based on the found results in the analysis phase. For each separate design challenge an idea generation session was held to come up with potential solutions. This resulted in a series of principal solutions for each challenge. Before including the design solutions into a morphological map a small proof of principle test was done in order to test the functionality of each idea. The results of these proof of principle test can be found on the following pages.

Part of the concept generation process was the making of a morphological map (Appendix XX). The morphological map was made to create a structured overview of the to be solved challenges and their potential solutions. On the y-axis a set of challenges had been chosen that needed a fitting solution in order to get a working design. After making the morphological map, a series concepts have been designed by grouping the partial solutions into potential concepts. These concepts can be found in Chapter 3.5

Proof of principle tests

A series of experiments have been done that focus on the change of shape of the forearm, the sensor attachment plate and usability of the brace. These problems are expected to be potential bottlenecks for the comfort of the brace and therefore need to be tested. A set of different principle solutions have been designed to test and find the best solutions for each problem. Working principles that can be used in the product have been used in the morphological map during the concept development.

A summary of each proof of principle test is given on the following pages, addressing the following challenges:

1. To test possible solutions for the design of the sensor attachment point.
2. To test possible solutions for the clamping around the wrist.
3. To test the different attachment - and closing methods of the brace.
4. To try out different solutions to minimize the movement of the skin over the bones and muscles without compromising on comfort.

3.4.1 Sensor attachment point

Problem

During the pronation to supination movement the skin tends to deform (Figure 22). This deformation can result in shear forces on the skin around the edges of the brace. For the sensor attachment point a (large) surface is needed to reduce the point pressure on the skin and attach the base of the sensor on. Since a stiff plate is expected to show different mechanical behavior as skin during the supination to pronation movement, it is likely that unwanted forces and shearing on the skin will occur. Looking

at different solutions to create a large (stiff) surface area where the sensor connects to the skin will create an understanding of how to optimally design this contact plate.

Test

An extreme situation was created to test how different potential sensor plate solutions would behave during the rotation of the forearm. These different solutions have been compared with the natural deformation of the skin during the pronation to supination movement (Figure 30a). Goal was to find a solution that would show a similar displacement as the skin during the rotation of the forearm. The hypothesis was that this would result in smaller shear forces on the skin, resulting in a more comfortable brace.

The test was done by taping either a stiff or compliant construction around the forearm. Clamping locations included the widest part of the forearm and the slimmest part of the wrist.

Conclusion

The behavior of the skin can be difficult to take into account when working with stiff materials. The most promising solutions showed the possibility slide around the thicker part of the forearm (E). This will relief the skin from any shear stresses around this area. The kinematic solution would result in a more ergonomic design that is better able to adopt to the deformation of shape of the forearm during the pronation to supination movement. Nevertheless it is not yet sure if a kinematic solution can be combined with the current force sensor set-up. Suitable solutions that can be used in the morphological chart are:

B. This is most flexible solution. Due to the possibility to deform on the left and right side of the "plate" and its clamping location, this solution behaves comparable to natural skin.

D. Clamping the plate around the wrist and forearm will create a larger area to transfer the forces from the exshell to the arm. The kinematic solution offers the possibility to adapt to the change of the arms shape during movements.

E. By clamping solely around the wrist the stiff wrist plate has the possibility to slide over the forearm during movements, herewith reducing shear forces on the skin.

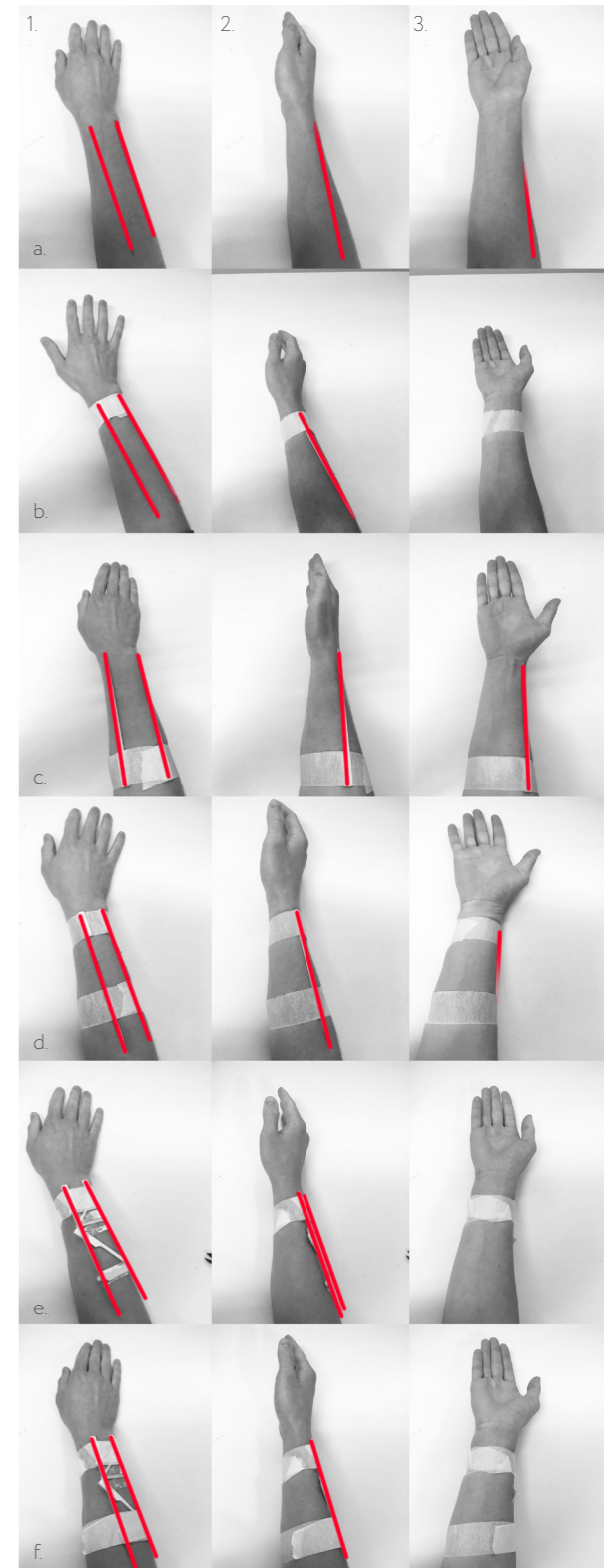


Figure 27 On the right an overview of the different sensorplate solutions is given. A supination to pronation movement was made in order to see how each potential partial solution would react to this movement. The red lines show the sides of the plates and can be compared to the natural skin deformation shown in situation a. A short explanation of each principle is given. a. Natural skin deformation during pronation to supination movement. b. kinematic solution, fixed around wrist. c. Kinematic solution, fixed around forearm. d. Kinematic solution fixed around wrist and forearm. e. Stiff sensor plate solution fixed around wrist. f. Stiff sensor plate fixed around wrist and forearm.

3.4.2 Straps around the wrist

Problem

During the pronation to supination movement of the forearm a sub-dermal shape deformation occurs. As found during the analysis phase the deformation occurs due to the movement of the ulna around the radius. The made 4d scans (Chapter 2.3.3) showed a large change of shape around the wrist area. It is desired to have a brace design that allows the arm to freely make the pronation to supination movement, while having an enclosure that prevents any movement in the x,y direction from happening. This is needed in order to let the exshell function properly. It was expected that a material that can easily be deformed (like a watch wrist band) would be experienced as comfortable, while still meeting the requirement of restricting any x,y movements.

Test

A series of bands have been designed to test what different properties can do for the experienced comfort of the user. (Figure 35) The bands used different materials and bending methods. The bands have been made to fit around the slimmest area of the wrist. This location was chosen because at this point the largest deformations occur and there is no possibility of sliding up and down the arm due to the shape of the arm.



Conclusion

Most discomfort is experienced on the outer edges of the wrist when the fully enclosed stiff solution was tried (figure 34.b). A less stiff plastic (**d.**) that can deform during the SP rotation was experienced as comfortable. Also a stiff top and - lower part was not experienced uncomfortable, when the outer edges of the wrist have the possibility to deform. Suitable design options for the morphological chart therefore are **b., d. and f.**

In the final product the contact area with the skin will be larger which is a product property that will need to be considered during the embodiment phase. For now, this property has not been taken into account, since this test was solely about finding solutions to comfortably create a usable enclosure around the wrist.



Figure 28 A set of six different types of enclosures around the wrist has been made. Each one of them was designed to test different material behavior. **A.** Stiff plastic combined with flexible fabric. **b.** Stiff plastic with flexible material on the edges of the wrist. **c.** fully enclosed stiff plastic solution. **d.** fully enclosure flexible plastic. **e.** Slim neoprene plastic. **f.** Neoprene in combination with a stiff plastic enclosure.

3.4.3 Clamping methods to enclose the arm

Problem

To attach the brace firmly to the arm an easy to use closing or attachment method needed to be found. Ease of use is especially of high importance due to the severe tremors ET patients can have.

Test

Several different methods have been tested with a series of mock-ups that each had a different closing mechanism or clamping method. The mock-ups have been made to fit for myself, but also fit most large males. A few of the mock ups have been taken to the visit at the Parkinson's cafe and were given to patients with a tremor. Other mock-ups have been tested on myself, keeping ease of use and comfort in mind.

The mock-ups can be categorized in four groups, each category is depicted and described in Figure 37

a. is a mock-up that relies on a form fit, it is slid over the wrist and stays put by following the ergonomic shape of the arm.

b., c. are preformed mock-ups that follow the ergonomic shape of the shape of arm. C. clamps around the arm. It is a stiff structure that clamps around the arm thanks to its shape. B. has an added line mechanism that can be tightened and closed in order to create a better fit.

d., e., f. are mock-ups that make use of preformed shapes that can be closed by locking the enclosure into place. In these mock-ups velcro was used, but alternative locking mechanisms are possible.

Conclusion

A preformed shape makes it much easier to open and close a brace. Brace e. and f. were very easy to open and close thanks to their open preformed design. Making use of straps as done in mock-up version d. increases the difficulty to put on the brace, because of the closed loop that the hand has to go through. Also the options of using lines (b.) to

tighten the brace was experienced as difficult and strenuous. Using an ergonomic sleeve as was done in mock up a. resulted in a comfortable fit, although putting on the mock up was difficult due to the limited stretch of the used material. Solutions that can be used for the development of concept are: **a., e. and f.**



Figure 29 Asking Parkinson's patients to try out different mock ups at the Parkinson's cafe gave insights on how users experience the different closing mechanisms.



Figure 30 On the right a series of different mockups for the wrist enclosure are presented, each mockup uses a different method to enclose the wrist. **a.** A sleeve that is slid around the wrist, following the form of the arm to stay put. **b.** A preformed plastic enclosure that is tightened around the wrist by pulling on a strap. **c.** A Stiff enclosure that clamps around the arm. **d.** Two velcro straps that are looped around the arm and can be tightened individually. **e.** A preformed strap with a simple velcro closing point. **f.** Same closing mechanism as e, but at a location closer to the slimmest point of the wrist.

3.4.4 Anti slip methods

Problem

It is needed that the connection to the human body is firm, in order to facilitate a proper translation of forces from the brace to the exshell. As minimal sliding of the brace on the skin should occur to facilitate clear force reading. During the making and testing of mockups it was found that the elasticity of the skin and its freedom to move over muscles and bones can negatively influence the placement of the brace on the skin.

Test

A view different possibilities to improve the brace from moving on the skin without restricting comfort have been tried. The mockups were tested on comfort and the amount of fixation on the skin of the user. Each mockup is shortly described and depicted in Figure 38.

- a.** Next to a strap around the wrist, a loop of an elastic material was added around the finger. An extra attachment point could result in a better fixture (3 point fixture)
- b.** Same as A, but looped around the thumb
- c.** Another version of the loop around the finger, with an added stiff beam.
- d.** Same closing mechanism as A and B, but without the finger loop.



Conclusion

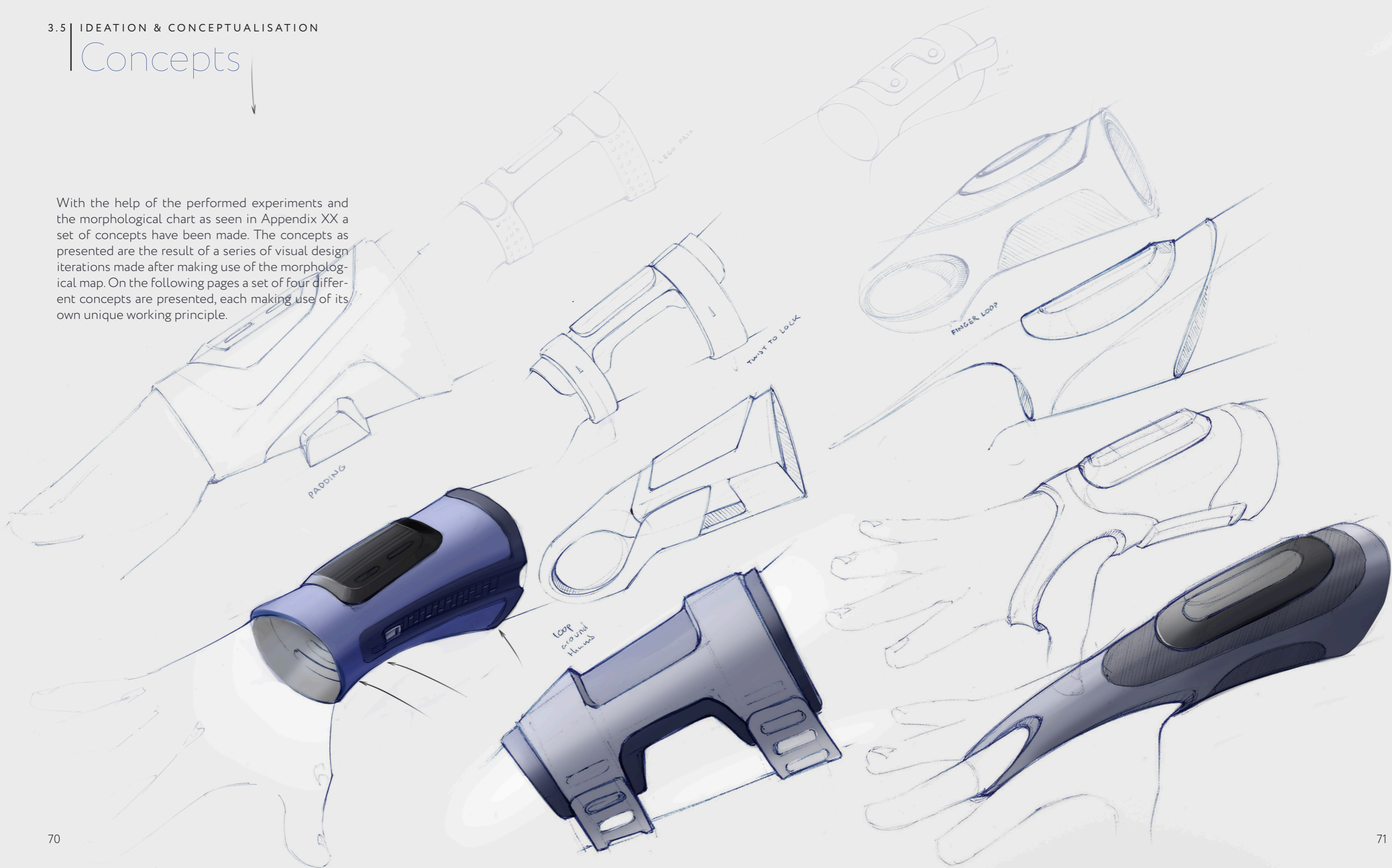
The loop for both mockup A,B and C did not function properly enough to function as a method to better stabilize the brace on the skin. The sub-dermal movement of the skin is a difficult problem that is hard to solve without restricting the arm from moving or causing discomfort. A loop around one of the fingers can be used as an attachment method but has to little benefits in contrast to the added discomfort during the use of the brace.



Figure 31 A set of four variations was made to test different methods to ensure a better fixation of the brace on the forearm. All mockups use a two-strap closing mechanism to ensure the brace of staying put on the forearm. Each variation is briefly explained: **a.** A neoprene loop is added around the finger. **b.** A neoprene loop is looped around the thumb. **c.** An extended stiff plastic plate is added to the brace. **d.** A reference mock up. Stays in place thanks to the strap that is attached to the arm like a watch strap behind the head of the ulna

Concepts

With the help of the performed experiments and the morphological chart as seen in Appendix XX a set of concepts have been made. The concepts as presented are the result of a series of visual design iterations made after making use of the morphological map. On the following pages a set of four different concepts are presented, each making use of its own unique working principle.



3.5.1 Sleeve zipper

A solution that offers users a brace that has a soft design that can be worn all day without having unwanted forces on the arm.

Working principle

The brace connects to the arm by making use of a sleeve that tightly fits around the forearm. The brace is put on by sliding the sleeve over the hand, hereafter being tightened by closing the sleeve with a zipper or comparable closing mechanism. The front part of the sleeve is made of a flexible material that stretches when the sleeve is slid over the hand. When the zipper is closed a snug sleeve around arm is created that is deformable, yet little stretch is possible thanks to the chosen materials. Anti slip strokes (Silicone strips) are used to prevent the brace from sliding on the skin. This type of strokes can also be found in wetsuits and bike racing pants.

The sensor connects to only one side of the brace,

herewith offering the possibility to let the rear side of the sensor plate slightly slide over the sleeve. The sensorplate can easily be removed from the sleeve, offering the possibility to wash the sleeve after use.

Keypoints

- The pliable sleeve results in a comfortable fit.
- The sensor plate can easily be removed and attached to the sleeve. This makes the concept easy to wash.
- Due to the materials used in this concept, different color and finishing options can be offered to the customer.
- The closing mechanism has been already proven to be functional in multiple different applications (wetsuits, shoes, dresses)

Potential threats

- Difficult to scale design and fit for large target group.
- Can get uncomfortable during warm circumstances.
- Zipper can be harmful to skin while closing.

3.5.2 Duostrap

An easy to adjust design that can be made to fit for a large user group. Making use of two straps creates a large contact area to optimize the connection and force translation of the exshell to the brace.

Working principle

Two straps are used to attach the brace to the forearm. One strap prevents unwanted sliding and movement of the brace (left strap in below), while the other strap prevents the brace from "bouncing" on the arm when forces are transferred from the exshell to the brace (right strap in concept drawing). Like a watch, the left strap is located just behind the head of the ulna, herewith preventing the brace from sliding on the arm. The right strap is made of a material that has little friction on the skin and has the possibility to slide over the skin during the supination to pronation movement of the arm. This prevents the occurrence of shear forces on the skin around the edges of the wrist straps.

The straps are preformed in a shape that follows

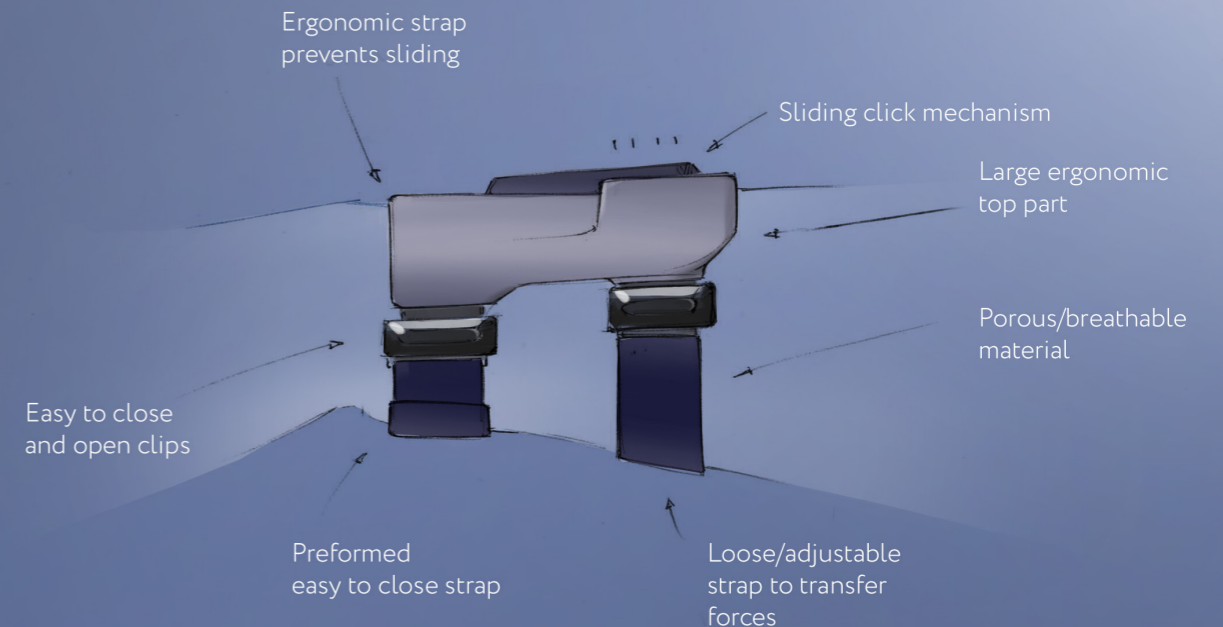
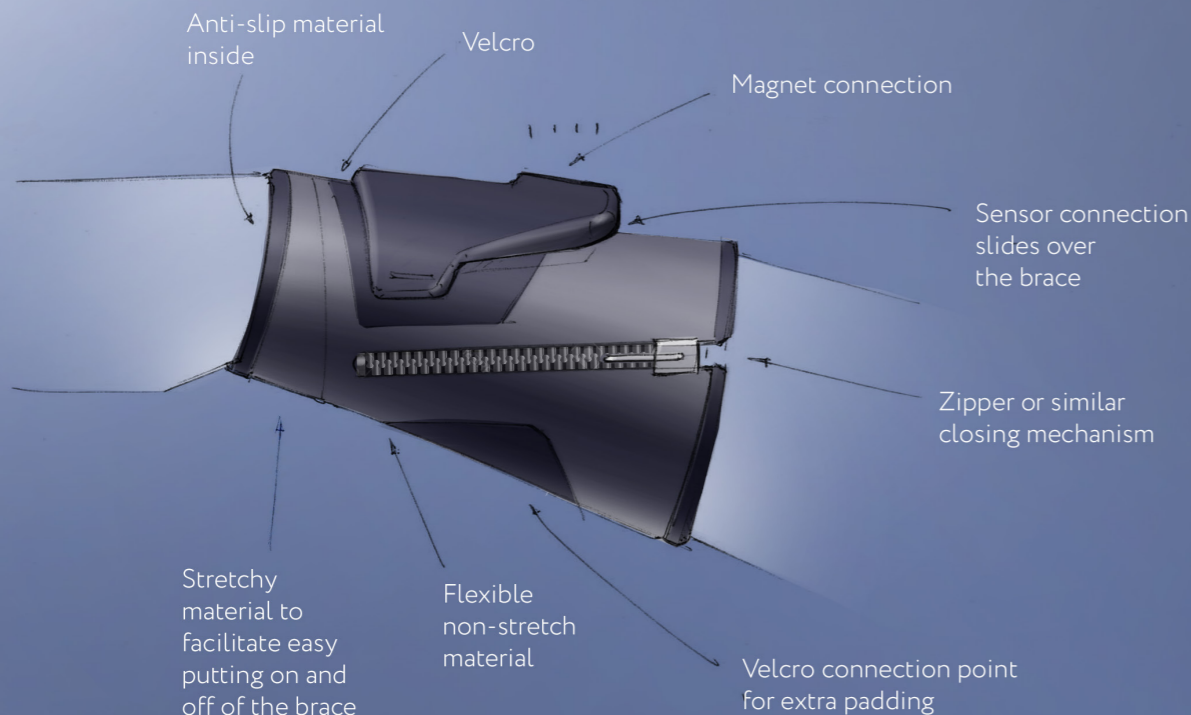
the forearm contour. This is done to make closing the clips more easy while having a tremor, because the user will only have to connect the connection points of the clips to each other. Having the possibility to adjust the length of each strap gives the user the freedom to customize the fit of the brace.

Keypoints

- The possible to adjust the length of the straps will reduce the amount of sizes that will have to be offered to customers.
- Using two straps creates the possibility to create a more rigid connection between the brace and arm thanks to the possibility of using a larger sensor contact plate.

Potential threats

- Finding a functional closing clip can be difficult.
- Sensor plate is large and it can be difficult to make a fitting design for a large user group.



3.5.3 Compliant sleeve

A strap around one of the fingers prevents the brace from sliding on the skin. The larger compliant sensor plate facilitates good force translation from the exshell to the forearm, while keeping account with the change of shape in the forearm during supination to pronation movements.

Working principle

The brace is put on by sliding the hand through the sleeve by stretching the fabric a little. Hereafter one of the fingers is looped through a strap which will prevent sliding and twisting during use. The material of the finger strap has the ability to stretch and deform, making it still possible to make a palmar and dorsal flexion movement.

For the sleeve, a thin breathable fabric will be used that has flexible properties to make it possible to stretch while sliding over the hand. The sensor contact plate exist of two plates with a connection in the middle left. This U shape makes it possible to

deform during the supination and pronation movement thanks to its compliant design.

Keypoints

- The pliable sleeve results in a comfortable fit.
- The sensor plate can easily be removed and attached to the sleeve. This makes the concept easy to wash.
- Due to the materials used in this concept, different color and finishing options can be offered to the customer.
- Sensor plate deforms with movement of arm.
- (Creates a slight tension on the wrist during the palmar and dorsal flexion movement.)

Potential threats

- Difficult to scale design and fit for large target group.
- Can get uncomfortable during warm circumstances.
- Fingerloop can generate friction between fingers

3.5.4 Twist strap

This concept focuses on creating an as compact as possible solution in order to provide an as minimaly intrusive design as possible. A single ergonomic strap keeps the force sensor into place. The sensor plate uses two compliant joints to compensate for the deformation and stretch in the skin.

Working principle

The single strap of this concept is attached like a watch around the wrist. The slim strap prevents slipping by creating a ergonomic fitting loop. The sensor plate is larger than the slim strap, so that forces from the exshell can be transferred properly to the user. Thereby the contact-plate has an middle part (contain the sensor) that is slightly lifted of the skin, creating a gap to provide ventilation and offer the possibility to cool the skin. A set of deformable connections on the left and right of the sensor give the sensor attachment plate the freedom to deform a little during the rotation of the arm, herewith minimizing shear forces on the skin.

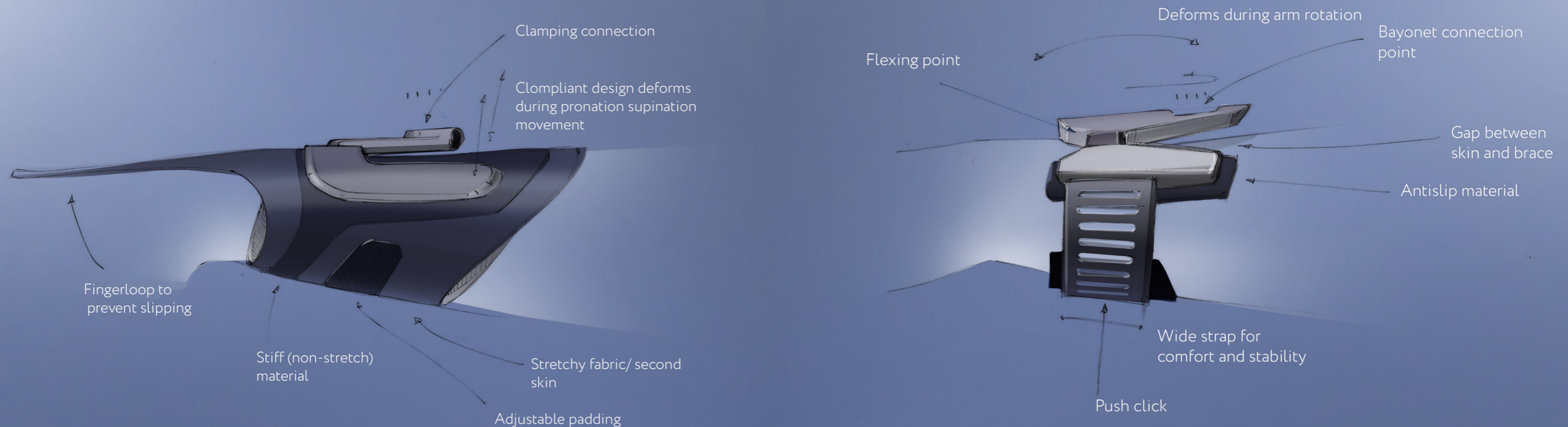
The strap can be interchanged like a watch strap to provide different styles to the user. Also the possibility to use a tightening mechanism comparable to the Mobius brace can be used (see 2.2).

Keypoints

- The compact design results in a slim and little intrusive solution.
- The sensor plate takes deformation of the arm into account.
- The strap can be styled and adjusted to the needs of the user.
- The gap underneath the sensor created by the design will give the skin the opportunity to transpire.

Potential threats

- Straps edges can create shear forces on the skin
- Subdermal skin deformation will decrease air gap over time.
- Flexing point increases production complexity.



Brace concept selection

A summary of the concept selection process is given.

Selection criteria

The concepts have been evaluated with the help of the weighted criteria method. Each of the previously described concepts has been evaluated on its relevance to the goals as described in Chapter 3.2 and Appendix XIX. To each concept a score was given for each of the main criteria. As stated in Chapter 3.2, each goal represents a set of subfunctions and requirements that are elaborated in Appendix XIX. In order to take into account the importance of the criteria a weight was given to each one of them. The sum of the weighted scores of each criterium resulted in a score as can be seen in Table 5. The scores of each concept have been visualized in a radar chart in Figure 32.

Selection

The concept selection was partially based on the results of the weighted criteria method and partially on the discussions held with the TU Delft supervisors and employees of STIL. During the discussions it was found that some improvements still could be made by making minor adjustments to the concepts. Also each of the partial solutions was evaluated to see if one could be better used in the final design. These co-evaluation sessions resulted in a final concept as is presented in Chapter 3.7 and uses the main principles of the Duostrap concept.

Goal	Weight	Sleeve zipper		Duostrap		Compliant sleeve		Twist strap	
1. Facilitates forearm damping.	30	6	180	8	240	10	240	7	210
2. Is comfortable.	25	9	225	9	200	7	175	7	175
3. Is easy to use.	25	8	200	7	175	7	175	9	225
4. Is non obtrusive.	20	7	140	7	140	5	100	9	180
5. Is safe to use.	20	5	100	8	160	7	140	8	160
6. Can be used by almost all.	20	5	100	20	200	5	100	9	180
7. Can be produced for the estimated target market.	20	10	200	10	200	10	200	7	140
8. Is durable.	15	7	105	8	120	6	90	5	75
Total score			1250		1435		1220		1345

Table 5 This tables shows how each concept scores for the set design goals. The scores (in blue) have been multiplied by the weight, resulting in a value (in black) that is summed up to get a final total score for each concept.

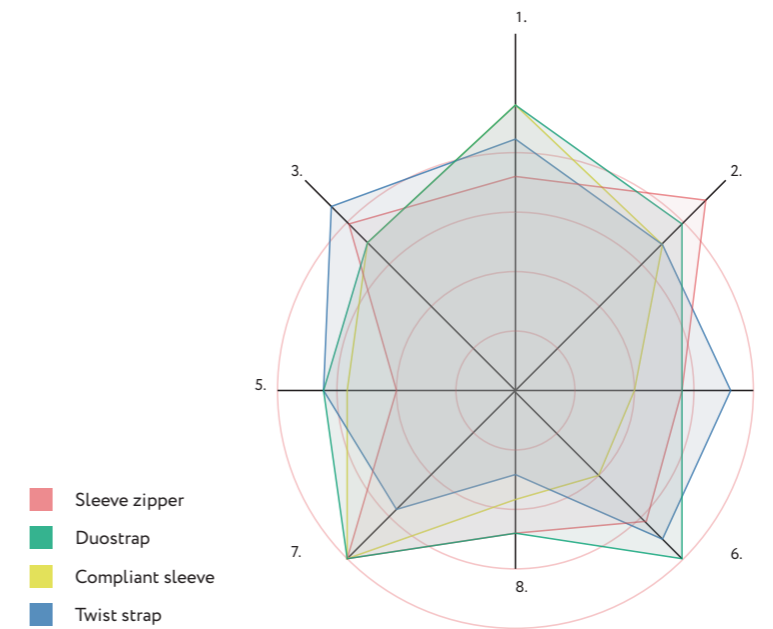
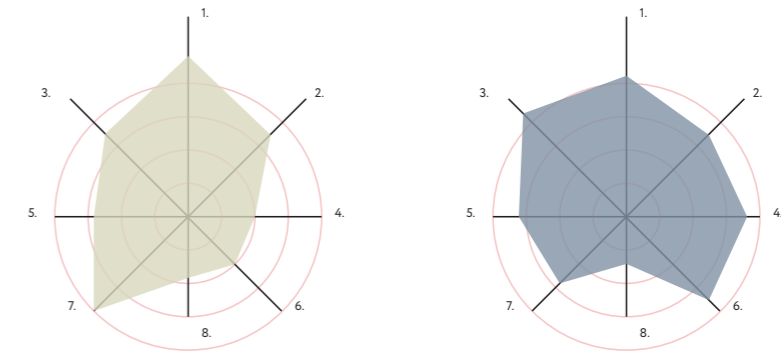
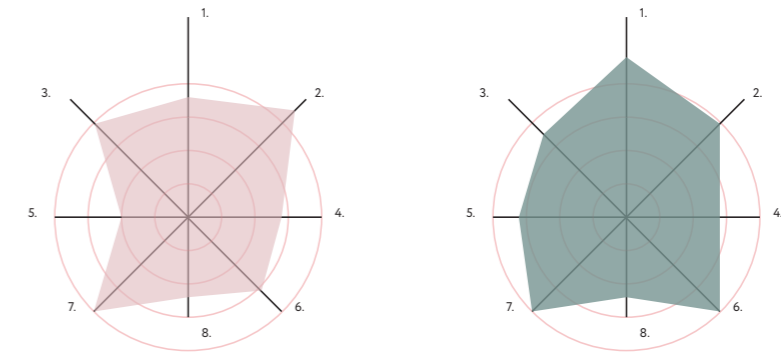


Figure 32 A radar diagram shows how each of the concepts scores in comparison to each other. The black lines shows the highest weighted score that can be given to a concept for each goal. These scores correspondent with the values attributed to the concepts in Table 5. The most important goals are placed on the top of the graph and the lesser important goals are placed on the bottom.

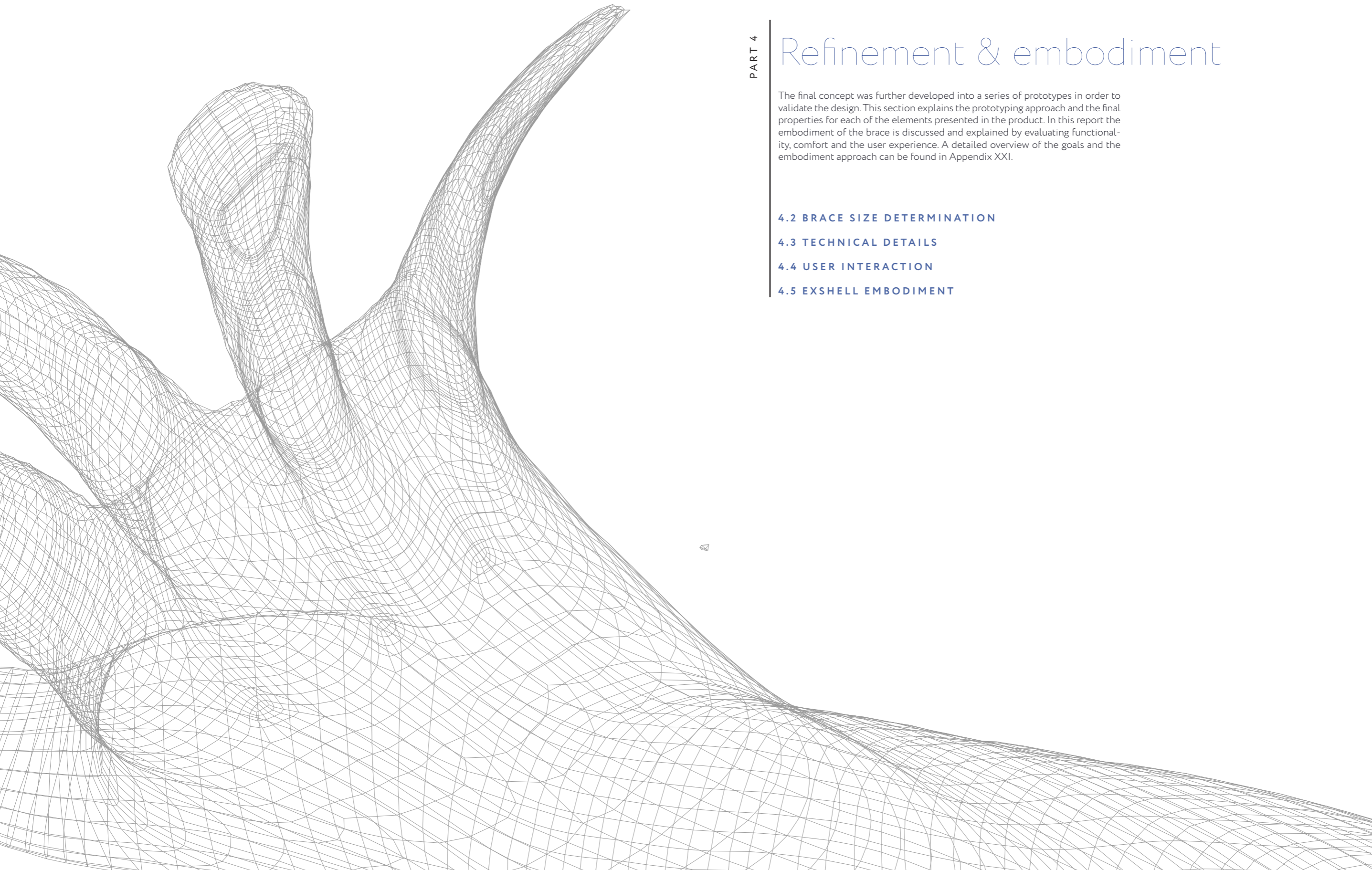
Final brace concept

After the selection of the concepts an extra iteration was made to include the received feedback and possible improvements for the brace. The final concept covers the set goals by using a combined set of solutions from the presented concepts. An overview of the concept that will be validated in the embodiment and evaluation phase is presented in Figure 33. This figure points out the main functions and functionalities of the brace.

This concept is mainly based on the Duostrap concept proposal. The addition of a laminated design, adjusted closing mechanism and the force sensor have played a big role in the final embodiment of this final concept. In the embodiment phase each design decision is explained and tested.



Figure 33 The final brace concept. This image is the result of the findings from the conceptual face. This 3D model has been used as the starting point of the ergonomic validation and functional tests. Added improvements have been numbered: 1. A functional force sensor design that can be easily attached to the exshell. 2. A easy to use ergonomically placed closing and opening mechanism. 3. Extra padding added on locations that need extra care 4. Laminated design to provide a balanced solution between stiff, flexible and soft materials.



Refinement & embodiment

The final concept was further developed into a series of prototypes in order to validate the design. This section explains the prototyping approach and the final properties for each of the elements presented in the product. In this report the embodiment of the brace is discussed and explained by evaluating functionality, comfort and the user experience. A detailed overview of the goals and the embodiment approach can be found in Appendix XXI.

4.2 BRACE SIZE DETERMINATION

4.3 TECHNICAL DETAILS

4.4 USER INTERACTION

4.5 EXSHELL EMBODIMENT

Brace size determination

One of the design challenges for this project was to make a design that could be worn by almost all. This meant that for the selection of a suitable production technology for the brace, technologies such as 3d scanning and 3d printing have been left out of the consideration. In this project a commercial product that is made in batches and a not custom product is designed. To meet the requirement of offering a brace that can be used by almost everybody, a brace design that could be scaled and mass produced in different sizes was used.

4.2.1 Size determination

For the final concept not all of the previously researched dimensions of interest in Chapter 2.6 are of relevance. For this specific design the wrist circumference and the forearm circumference are important to take into account. In order to develop a series of different sizes a critical dimension needed to be determined (CD) that could serve as a mean to communicate a size to the customer. The wrist circumference was used as the dimension of the brace to function as the CD, since it is an easy to determine dimension (for the customer). Additionally, this dimension is more important than the forearm circumference, since the brace needs to ensure a more firm enclosure around the wrist than the strap around the forearm in order to keep the brace put.

To choose the right sizes a revisit on the normal distribution of the wrist circumference was done. In the ergonomic research it was already stated that male and female individuals have a significant difference in many dimensions. This also applies for the wrist circumference. To analyze the difference between male and female individuals an overview of the normal distributions of the wrist circumferences for male, female and combined average was made (Figure 34). A subdivision as seen in this figure has been made to determine the several different sizes.

The five proposed sizes resulted in a step-size of roughly 15 mm between each dimension. Variation in wrist circumference between these dimensions is covered by the adjustability of the straps.

For the prototypes three different sizes have been made and validated (Chapter 5.2), but as can be seen in the graph an addition of a XS and XL size is needed to take the difference of male and female dimensions into account. It was expected that with the three made braces for the ergonomic test 90% of the population would find a fitting solution, leaving out the 5% smallest and 5% largest individuals. See Chapter 5.2 for the results of the ergonomic tests.

4.2.2 3D Model creation

No relation was found in literature between the forearm circumference and wrist circumference. Therefore a linear uniform scaling was applied in the development of the 3d model. As a starting point the average arm shape as determined in Chapter 2.3.2 was used. The forearm has been resurfaced to make it usable for 3D modeling in Solidworks (Appendix XXIV). The resurfaced shape has been used as the starting point of the brace design. The surface could be scaled uniformly in order to comply with the desired wrist circumference dimensions as depicted in Figure 34. All parts of the wrist enclosure depend on this surface, so when a different scaling factor is applied on the surface, the straps, padding and force sensor connection point will change shape to fit the new size, while still making use of the same force sensor. With the help of the 'surface flattening' tool it was possible to create patterns for the straps that could be used for the creation of the different sized prototypes. In Appendix XXIV a step by step explanation of the modeling process is given.

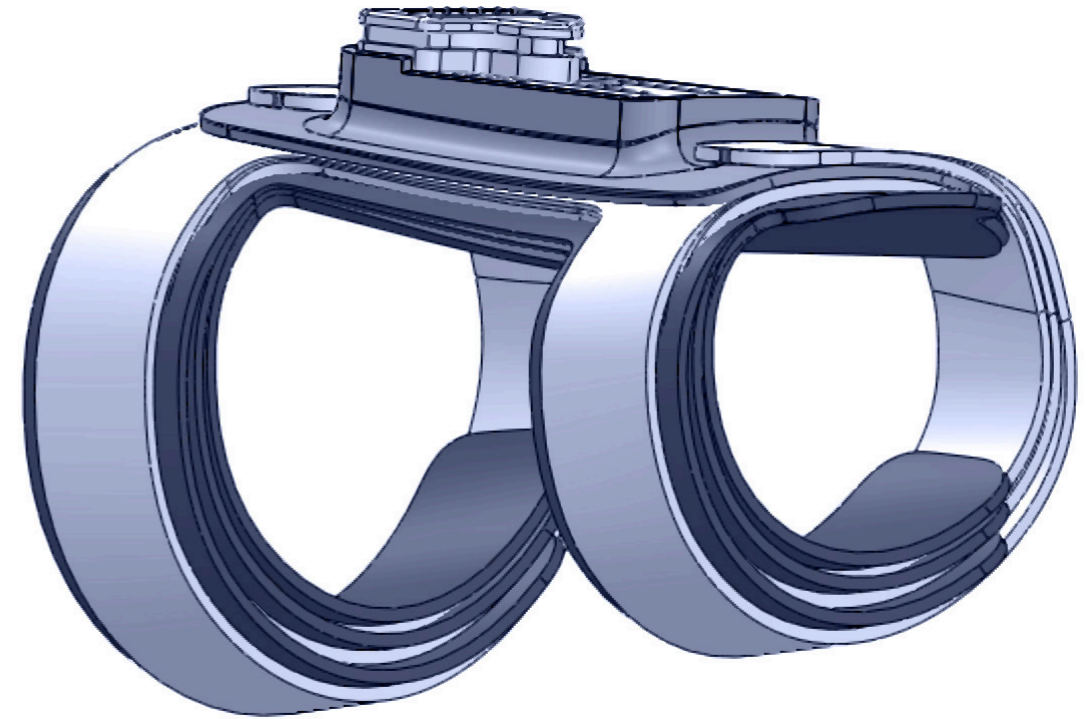


Figure 35 The three scaled sizes in Solidworks (S, M, L) that have been made for the prototype validation. It is interesting to see how everything scales except from the parts that are related to the force sensor.

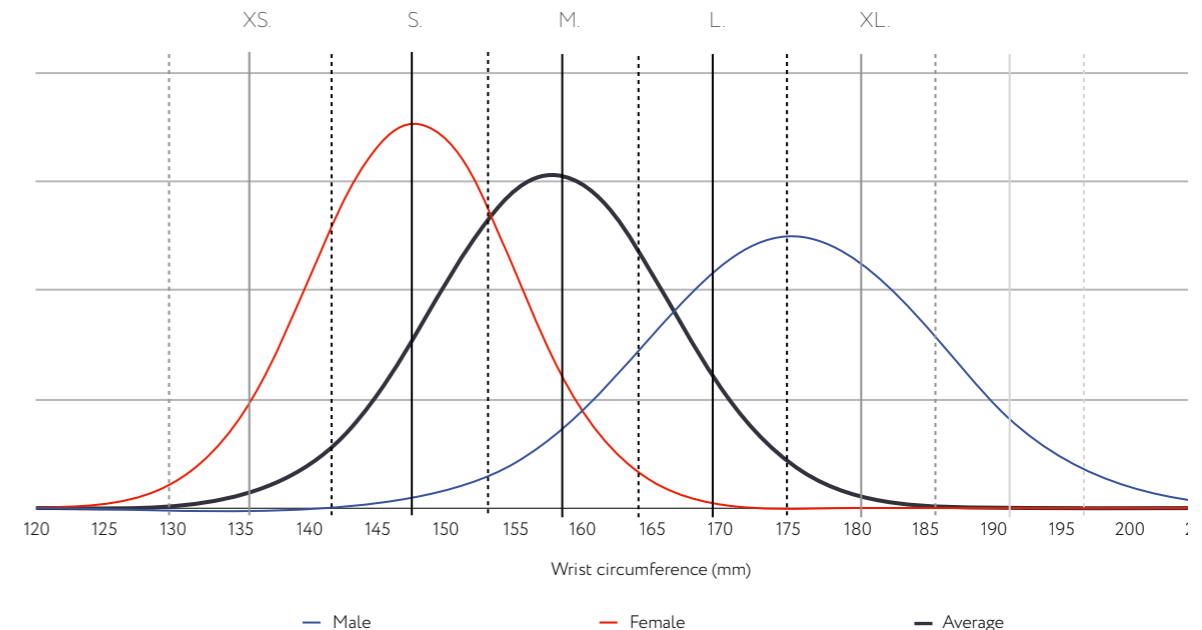


Figure 34 The normal distribution of the wrist circumference. The sizes are separated by the area in between the dashed lines.

Functional brace properties

An overview of the reasoning behind the final properties of the functional prototype is presented. Each of the key elements of the brace will briefly be discussed and made choices will be explained. As a reference Figure 36 is used in the text to refer to part numbers. This exploded view presents the parts that are present in the final prototype used for user - and functional testing. Each section is concluded with a short explanation of the used parts for each of the described key elements.

4.2.1 Force sensor position and functions (2,3,4,5,6)

The force sensor design as depicted in Figure 37 is the result of the development process of making an as small as possible force measuring sensor that can be integrated in the chosen brace concept. The final design is the result of a series of compromises between form and function and producability that have been made during brainstorm sessions at STIL.

The force sensor works by reading force magnitudes in two direction. As stated and explained in Chapter 3.1 this is needed for a proper analysis of a patients tremor. Two bars are placed next to each other with both two force sensors (strain gauges, see part 5, Figure 36) attached to them, these sensors can read forces in the x and y direction. Two strain gauges for each orientation are used to get more precise measurement results and an increased durability of the design.

The top of the force sensor, that is exposed to the user, is a multifunctional element that both connects the Exshell to the brace and transfers the measured signals by the force sensors to the control unit in the Exshell. The shape of this connection point for the functional prototype was determined by the used production technique and the goal to

create an as rigid as possible connection to the Exshell. The signals from the force sensors are transferred from the brace to Exshell by a set of pogo pins (see part 3).

In the next section each force sensor component is explained more precisely, elaborating in more detail on the chosen material/part, shape and function. Wiring solutions (cable management) have been left out of the digital images but can be seen in Figure 39.

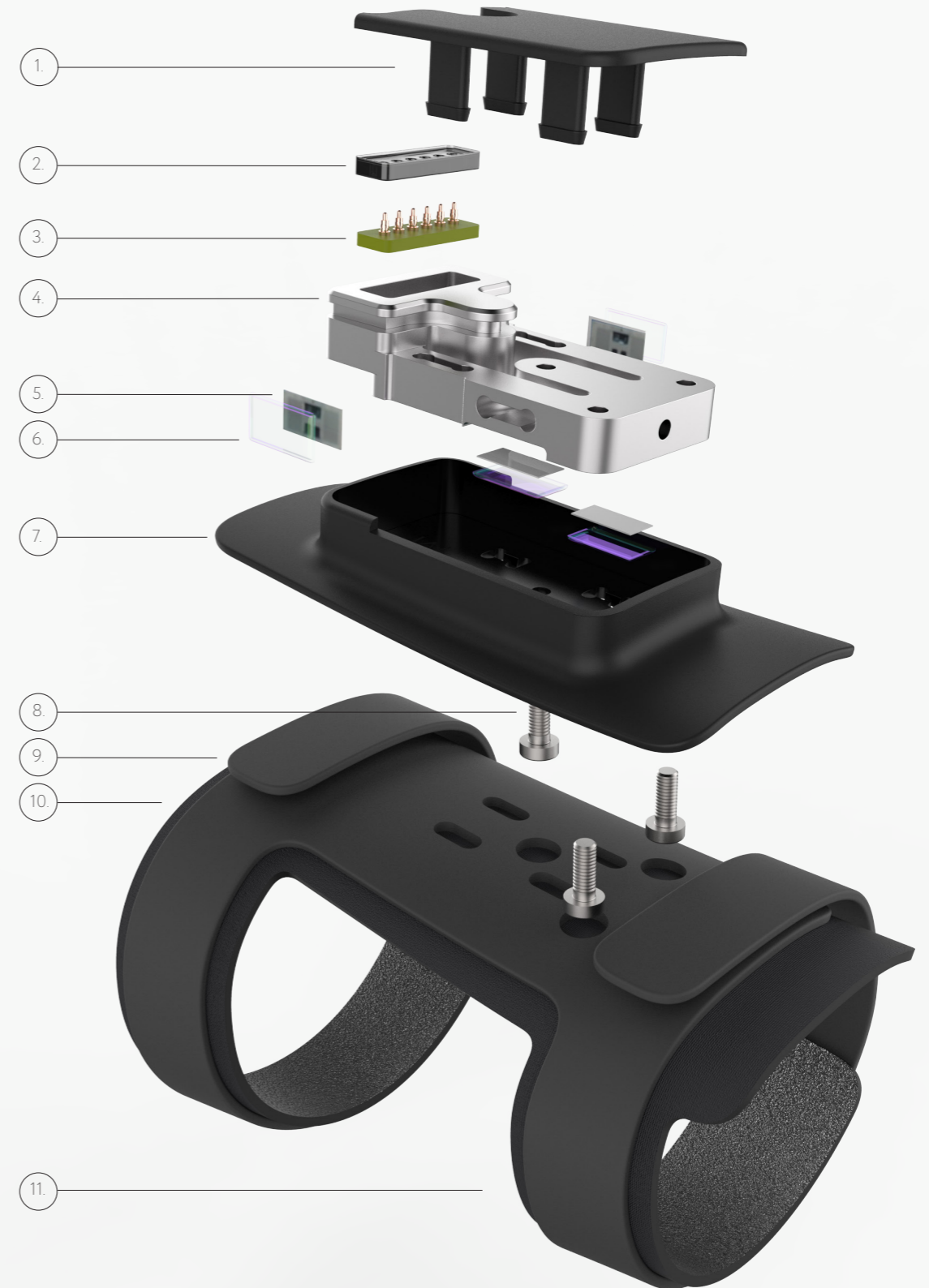
Force sensor body (4)

The force sensors body needs to exactly deform at the location of the chosen strain gauges. In order to do so a cutout was made close to each sensor to create local stress concentrations to improve its performance. Also the contact area with both the wrist enclosure and exshell has been optimized to create an as rigid as possible connection. This resulted in the T-shaped contact point shapes as seen in Figure 37.

The force sensor body will be made from Aluminum 7075. This is a strong type of Aluminum that can withstand higher forces than other types of aluminum without experiencing plastic deformation thanks to its high Youngs modulus. After a finite element analysis (FEA) was performed (Appendix XXV) the force sensor design was optimized for performance and production. The sensor has been produced in the workshop of Industrial Design En-

Figure 36 >> Component overview of the functional prototype.

1. Forces sensor cover
2. Epoxy protection of the pogopins
3. PCB with pogopins
4. Force sensor body
5. Half bridge strain gauge
6. Strain relief coating
7. Force sensor contact plate
8. M3x8mm Screws (ISO 14580 TX)
9. Plastic straps
10. Velcro
11. Neoprene padding



gineering with the help of a CNC milling machine. Design adaptations for this specific production technique were required in order to make the design producible. The technical drawing of the force sensor can be found in Appendix XXIII. Results of the produced force sensor can be seen in Figure 39 and Chapter 5.1.

Pogo pins (2,3)

In order to transfer the signals measured from the brace to the control electronics and apply a current on the strain gauges in the exshell, a connexion was needed that would transfer the readings from the force sensor with as little distortion as possible to the control unit. Pogo pins are a solution that is widely used in many devices in order to achieve such a connection. For this prototype a small pogo pin type was used (2.8 free height, Farnell, 2019). This made it possible to keep the prototype design very small. The conjoining PCB was designed by de Jong (2019) and was used for the final prototypes.

A design consideration that needed to be taken into account during the development of the prototype was the "travel distance" of each pin and the length of each pin. Each pin has a certain travel (0.8 mm), which meant that each pin needed to be pushed inward in order to make a firm contact. This meant that precise tolances were needed. Also the length of pins was a point of concern. In order to prevent that excessive forces would occur on the connection of the pogo pin to the PCB, a layer of epoxy glue (2.) was added to function as a stress relief element.

Strain gauge (5,6)

The strain gauges have been selected with the help of the engineers from STIL. A set of so-called "half-bridge" strain gauges are used to measure the forces in each direction (DA63K2.2/350_E). A strain gauge has multiple applications (to measure strain, material expansion, etc.), but in this specific design it used as a force sensor. The deformation in the force sensor body is translated to a force reading that can be analysed by the control electronics. In order to analyze these signals, the signals needs to be amplified by an amplifier. This component is integrated in the exshell (HBM Benelux 2019).

4.2.2 Force sensor housing (1,7,8)

The force sensor is housed in a stiff plastic shell to minimize deformations of the brace that can cause inaccuracies during the analysis of force readings in the forearm. The force sensor contact plate and - cover are designed to discreetly hide the sensor and is connected (glued) to the more flexible straps and padding.

A set of screws (M3x8 torx screw) assures that the force sensor body is properly mounted to this base plate.

Force sensor contact plate and cover (1,7)

The design of both the force sensor cover (1.) and force contact plate (7.) are designed for injection moulding (Figure 47). It has been tried to design parts that can be made by simple injectionmoulding moulds. Currently no draft angles are used in each part (that have been optimized for 3d printing), but these can be added in future versions.

The force sensor cover has a set of snap fingers that keeps the cover locked to the contact plate. These fingers have a offset of 0.5 mm from each side of the force sensor body, so no distortions will occur due to contact with the force sensor body (deformation of the sensor body is 0.3 mm when a load of 100 N is applied, see Appendix XXIV).

With the help of CES, a material analyzation database, a choice of the to be used material has been made in the injection moulding phase. Using Polycarbonate will result in a stiff yet high quality part (see Appendix XXV). For the made prototypes a black type of PLA has been used.

4.2.3 Straps, closing mechanism and padding (9,10,11)

The straps will have to keep the brace put, facilitate forearm dampening and have to be comfortable. During the development and prototyping phase several different solutions have been tried. Finally, a laminated design was used to optimize the properties of the straps. It was desired to minimize the possibility to stretch each of the straps in order

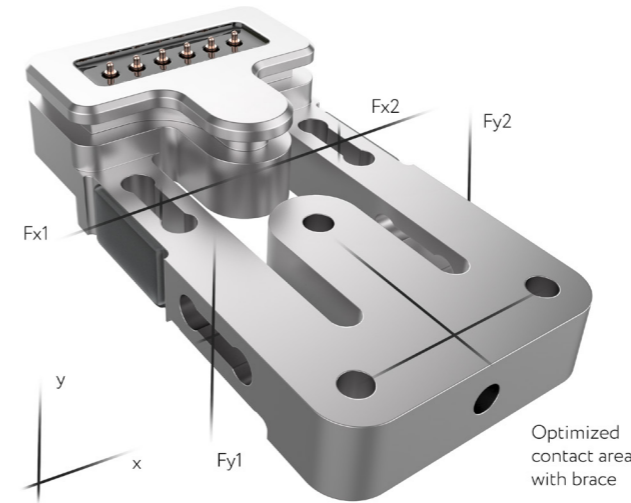


Figure 37 The force sensor body exists of two strain gauge bars. One side the force sensor is connected to the exshell. The other side is connected to the brace. The exshells connection is as explained in Figure 38. The T-shaped connections are used for a optimal rigid connection

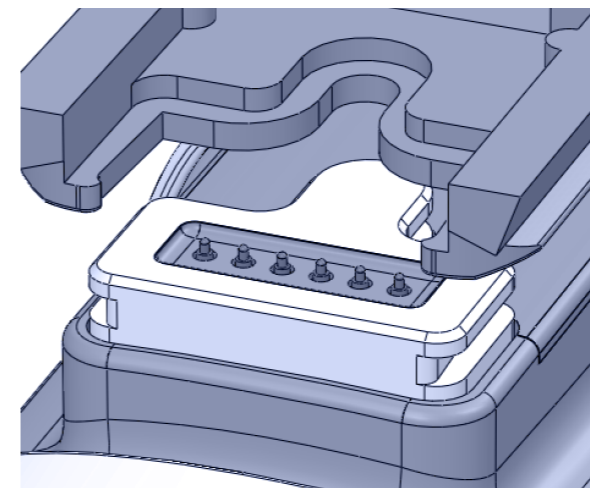
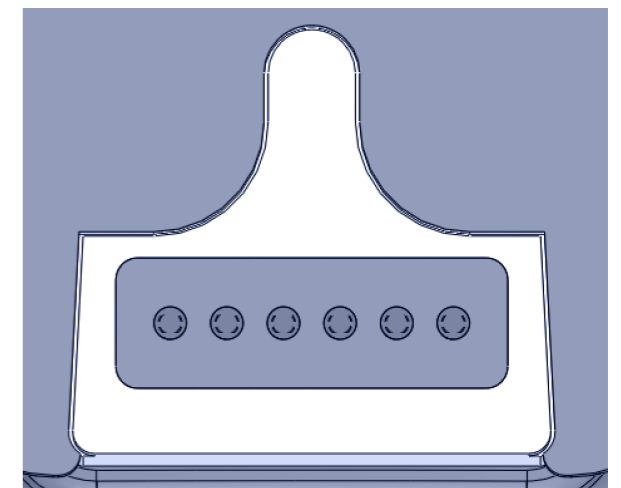


Figure 38 Current solution to connect the force sensor to the exshell. The force sensor is slid into the right position and a small notch will assure a firm connection (right bottom). Notice the slight draft that was added to the connection sides.



Figure 39 The cables from the force sensor have been guided from the sides of the sensor to the bottom of the pcb that contained the pogo pins.



to facilitate the translation of forces. This is why a plastic outside was added on top of a soft neoprene padding. An additional benefit of using a plastic strap rather than a fabric strap is that plastic can be preformed into a desired shape to make it an easier to use product by making it a less difficult to close the product. The neoprene padding on the inside of the straps is 3mm wider than the plastic outside in order to minimize shear forces around the edges of the straps.

The straps are attached to the brace on the upper side of the arm. This location was chosen based on the observations made during the tests with Jasper. It showed that Jasper used his body as an extra resting point (Figure 47) to perform delicate tasks. Placing the closing point on top of the brace makes it possible to rest the brace on the body while still keeping the possibility to close the brace firmly. Making use of velcro increases the flexibility of the product by offering the user the possibility to exactly adjust the tension of the straps on the skin.

The advantage of using two straps rather than one wide strap is the possibility to adjust each strap individually, creating the possibility to have better adjustability and a more tight fit around the wrist than around the forearm if desired. Also, the slim straps will minimize the contact with the users skin without compromising on functionality or comfort.

Some technical details, concerning grading and material selection are discussed for both the straps and the closing mechanism.

Closing mechanism (9)

For the final prototype a type of medical graded Velcro was used (Stockx, 2019). The contact area was made as large as possible to provide optimal "adhesion". For a future prototype different closing mechanisms can be considered. Velcro proofed to be functional thanks to the freedom to let the users precisely adjust the tension of the strap on the skin.

Straps (10)

The straps in the prototypes are designed to be made in different sizes. This requires a production method that is suitable for small batch sizes. In the ergonomic and functional prototypes cutouts of a

medical thermoplastic has been used (Stockx, 2019). More about the applied grading techniques can be found in Chapter 4.1. A foldout pattern of each strap size was made with the help of the "flattening" tool in Solidworks 2017. Each pattern was exported as .dxf and has been used as a cutting pattern (Figure 41). The prototypes have been hand cut (Chapter 5.1), but for larger batch sizes a die cutting process can be considered.

In order to shape the straps it was necessary that a thermoplastic plastic was used, because this type of plastic can be formed to fit a specific shape when it is in its glass phase. For the prototype Orthopedic plastic was used. The plastic was heated in warm water of 65 C and fold around a 3d printed mould.

Padding (11)

As stated in the description of the straps, the padding was added to minimize shear forces on the skin and prevent point loading. The padding has an offset of 3mm around all edges of the brace and a larger offset of 9 mm on the top of the brace close to the wrist.

An additional feature of the padding is to allow the skin to breathe and transpire. Different types of padding have been considered. Neoprene is a material that was especially well suited for the desired application, since a medical graded type of material was found that was already being used more frequently in the design of splints and braces (Stockx, 2019).

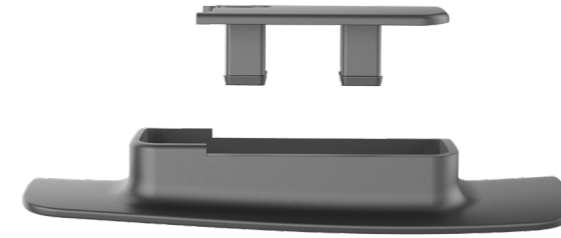


Figure 40 The force sensor contact plate and topplate have been designed to be injection moulded.



Figure 42 During the interview with Jasper a test was done with a set of different, existing, braces. It was found that Jasper used his body as an extra resting point for stability

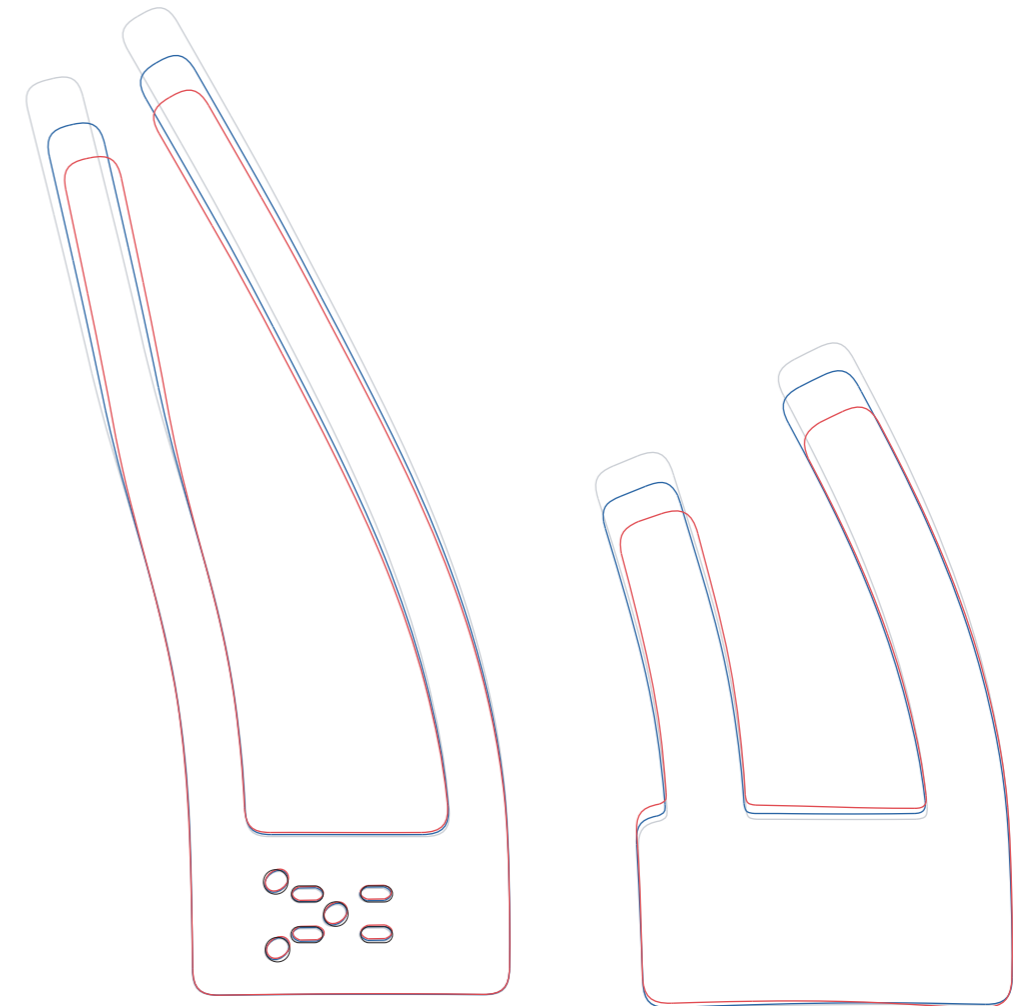


Figure 41 The pattern of the straps and neoprene padding. It can be seen how the scaling affects the pattern shape. Red = Small. Blue = Medium and Grey = Large.

Exshell embodiment

In this section the exshell is introduced. The exshell is an important element for the user experience of the product and therefore is included in the report. No details about production, or detailed working principles of the exshell are explained, since this is out of the project scope. Only a design suggestion is given based on the step by step use case scenario as is presented in Figure 45.

In this use case scenario the functions of the product are explained and the reasoning behind the chosen product display present on the exshell is given. The use case scenario has been used to design an "interaction unit" that communicates all necessary signals to the user and an embodiment for the exshell. Output and signals from this element can be found in Appendix XXVI.



Figure 43 The exshell and brace attached to an arm.

4.3.1 Interaction unit

Buttons

Figure 44 shows the different buttons that are used for the control of the product. The current goal of the product is as described in the use case scenario. The functionality of the product as proposed in this figure, resulted that only two buttons are needed to control the product. The buttons as shown in Figure 44 function to activate and change modes of the product. A suggestion to use voice control is added to make it easier for tremor patients to control the product.

Display states

A small display combined with a simple RGB LED is used for communication to the user. A set of display modes have been designed (Appendix XXVI) that will fit the different needed states that are being described in the use scenario in Figure 45. A simple minimal language was chosen to communicate to the user.

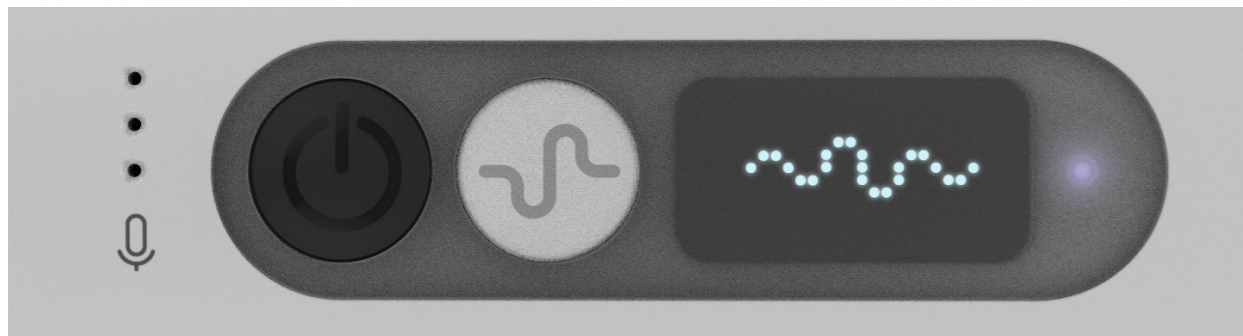


Figure 44 The interaction unit has been placed prominently on top of the product for easy control and clear signal communication. From left to right: A microphone that can be used for voice commands, a on and off switch, a switch that can be used to change product states. A display to communicate signals to the user.

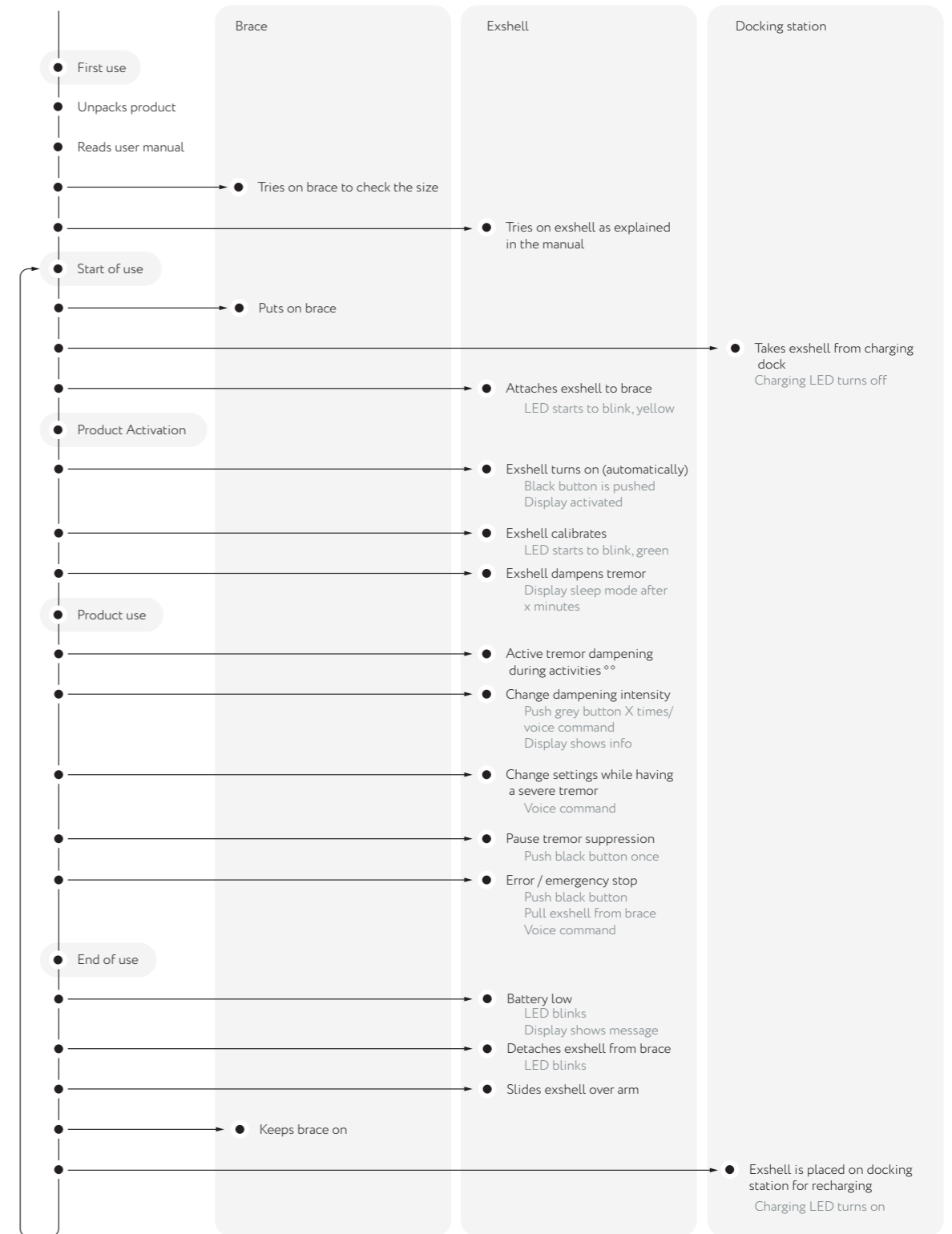


Figure 45 The expected usecase scenario. Different options are described and each related display state is explained.

4.3.2 Exshell shape

Due to the symmetric shape of the exshell, a fear was present that it would be unclear for the user how the exshell would need to be slid over the arm. An asymmetric design of the force sensor connection is introduced to create a clear distinction between the “front” and “rear” side of the exshell. The made design is supposed to make it more easy for the user to know how he/she should slide the exshell over the wrist and connect it to the brace. Figure 46 and Figure 47 show the made design suggestion. User test results are discussed in Chapter 5.3

Connection to brace

The connection of the force sensor is achieved by a snap fit connection as displayed in Figure 46. The connection has been placed directly underneath the interaction unit so that the user will get some visual cues about the alignment of the Exshell.



Figure 46 The embodiment design tries to communicate to the user that this is the side to connect the force sensor too.

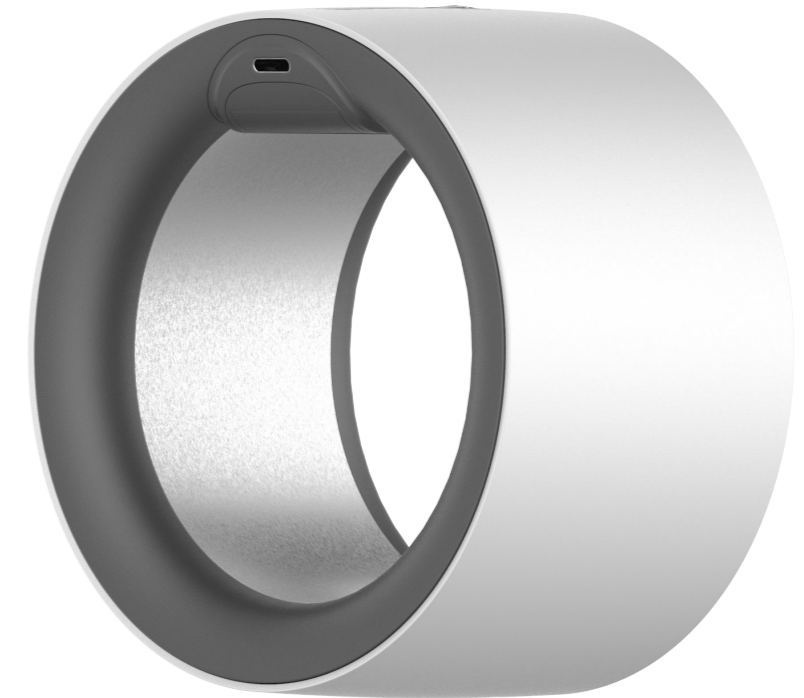
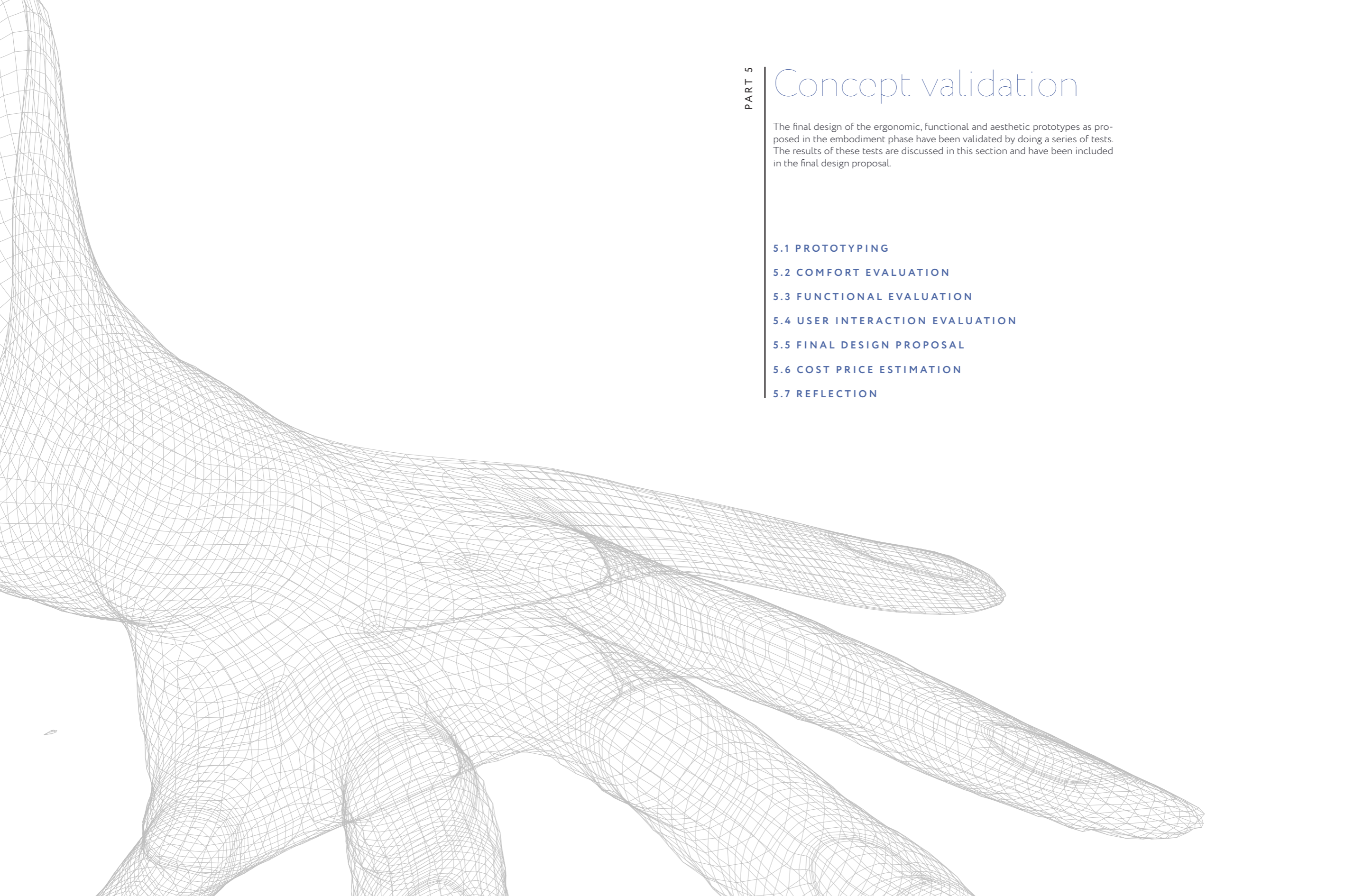


Figure 47 The front side has a notch that makes it uninviting to try to connect the force sensor to.



Concept validation

The final design of the ergonomic, functional and aesthetic prototypes as proposed in the embodiment phase have been validated by doing a series of tests. The results of these tests are discussed in this section and have been included in the final design proposal.

5.1 PROTOTYPING

5.2 COMFORT EVALUATION

5.3 FUNCTIONAL EVALUATION

5.4 USER INTERACTION EVALUATION

5.5 FINAL DESIGN PROPOSAL

5.6 COST PRICE ESTIMATION

5.7 REFLECTION

Prototyping

A short explanation of the used prototyping techniques for the mock ups, ergonomic prototypes and the functional prototype is presented.

Mock up prototyping

Due to the complexity of the used shapes in the product, an experimental prototyping technique for stiff components has been tried, that significantly reduced the time needed to model each prototype iteration. Rather than directly modeling around the surface of the arm, with complex 3d shapes in 3d computer models, an extra step was used to achieve usable prototypes. A short step by step explanation and overview of the used prototyping approach is given in Appendix XXVIII.

Production of the prototypes for ergonomic tests

A variation of the described technique for the production of mock up prototypes has been used for production of the final prototypes of the ergonomic test. The moulds and materials that have been used in the final ergonomic prototypes are designed in accordance with the decisions made in Chapter 2.6 and 4.1. A few pictures of the prototyping process can be seen in the collages in Figure 48.

Production of functional prototype

In collaboration with the workshop of the faculty of Industrial Design at the TU Delft and the engineers from STIL a working prototype was produced to test if the brace could read forces and translate it into usable signals. The force sensor has been produced by using a CNC milling machine. The results and the making process are visualized in Figure 49,55,56.



Figure 48 Some snapshots of the prototyping process. for the ergonomic prototypes used for ergonomic tests. A set of special moulds (top photo) have been made to shape the thermoplastic into the desired sizes. The results are shown on the photo on the bottom.

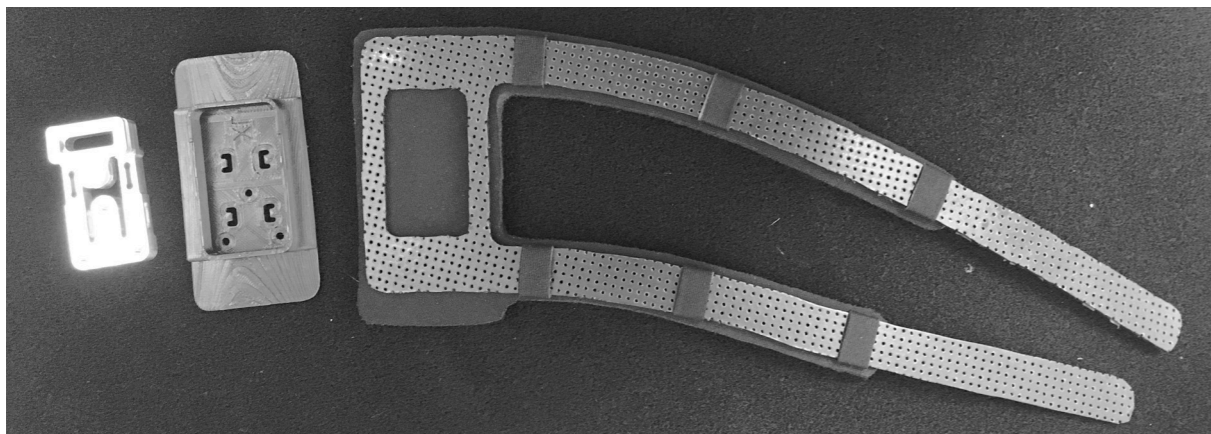


Figure 49 Making process of the functional prototype. The pcb's have been developed by de Jong (2019), other parts of the force sensor have been made in collaboration with the PMB workshop at the faculty of Industrial Design and at the workshop of STIL.



Figure 50 The functional brace worn during the user test.



Figure 51 The full product worn during the user test.

Ergonomic validation

The ergonomic validation aimed to find answers and points off improvement for the fit and longterm use of the different brace sizes. The goal, method and findings will be shortly discussed for each test.

5.2.1 Longterm use without added weight

The individuals who participated in this test do not have a tremor, since the goal of this test was to validate the ease of use and comfort of the concept. A group of users (n=9) have tested the ergonomic brace concepts for periods from 1 to 4 hours. The users have been asked to put on the brace and perform activities while having the brace around their wrist. It was important to let the user use the brace for a longer period of time in order to see how the skin would react during longterm use of the brace.

Method

Three brace prototype for the right arm have been made in accordance with the sizes determined in Chapter 2.6 and 4.1. Before use, the subjects have been asked to measure their wrist circumference. Depending on this dimension an individual received either a small, medium or large version of the ergonomic prototype. No hints have been given before the user put on the brace. After a x amount of time the users have been asked to fill in an evaluation form. Results of this form can be found in Appendix XXX. An overview of the marks that were made on the users arms is added in Appendix XXVIII

Results

In general the brace was received positively, little negative remarks were made. Some noticeable remarks and findings are discussed:

- The neoprene padding that was added on

the inside was too short, this resulted that the plastic strap created pressure marks on the skin. Some participants mentioned this resulted in a itchy feeling on the skin.

- Some users had a wrist circumference that would have needed an XS or XL. These participants made remarks about the straps either being too short or too long. Using a too large brace results in straps that are sticking out and restrict wearing a sweater. Too short straps resulted that the velcro got loose and didn't close the loop properly. A different type of velcro called duallock (3M) might improve the closing mechanism.

- An often mentioned remark is the lack of feedback of knowing when the brace is tightened well enough. This can be solved by properly explaining the desired tension in the user manual or by making marks on the brace, informing the user about the desired tightness. After explaining the participants that the straps need to have the same tightness as a watch strap, it usually was understood.

- Only one participant who wore the brace on the wrong arm (left instead of right), mentioned that during the SP movement an uncomfortable pressure was exerted on her wrist.

5.2.2 Longterm use with added weight

Although the future product will be actively generating anti vibrations, it was interesting to conduct a test to let people experience how it is to wear such an added weight. The same method as with the test without weight has been used in the test with the added Exshell. Additionally to this, a representation of the future Exshell, was worn by the user. The representation of the Exshell has been made

by making a weighted mock up (Figure 51). Results of the question list that was filled in after the test can be found in XXXI.

Results

- The test subjects mentioned that they got used to the added weight over time, only after removing added weight, they mentioned that they felt relieved.
- Writing and using a computer mouse became very difficult with the Exshell attached to the users arm. Activities that require your arm to rest on a table become very difficult to perform while wearing the exshell. This was especially the case for individuals with small arms.
- No complaints about comfort of the brace were experienced during this test.

Conclusion

The brace design is a success. The users found the brace easy to use and did not mention insurmountable complaints. The large size of the exshell was a cause for complaints, but due to the technological restrictions it is not likely that this can be reduced any time soon. The received feedback has been included into the final design proposal.



Figure 52 Receiving feedback from a test subject during the ergonomic test.



5.3 | VALIDATION

User interaction validation

A test was conducted to discover the level of usability of the STIL product. It has been tried to discover painpoints and to validate the current embodiment design of the brace and exshell. For this test a tremor patient, called Tom, was used (Figure 53).

Method

To find out the usability level of the tested prototype product, Tom had been asked to put on the brace and attach the exshell to the brace. A few simple experiments have conducted and after this Tom was asked to put off the brace and exshell. This experiment was finalized with a questionnaire containing questions about the usability and experience of the product. The question list contained questions about the user experience and comfort of the product (containing open / likert scale questions). Some of the questions have been adapted from a standardized user test questionnaire set up using the d-quest (Wessels, 1998) format. A full overview of the experiments protocol can be found in Appendix XXXII.

The experiment was conducted in a controlled room that was cleaned and prepared to optimize the test. Video recordings have been made and analyzed. See Appendix XXXIII for the test set up.

Results

The most noticeable moments during the user test can be found in Appendix XXXIII. Overall the product use and attachment method was positively received by Tom. Some minor improvements can be made in order to improve the product. Results from

the questionnaire can be found in Appendix XXXIV. Some important findings are discussed:

- Tom easily slid the exshell over his arm, but he did not immediately find the right connection position. At first the exshell had an improper connection to the brace. After he figured out that the connection was placed directly underneath the display he quickly managed to connect the exshell to the brace. After taking off the brace he noted that he heard a clicking sound when the exshell detached from the brace. Tom mentioned that if he would use the product again, he would probably find it more easy to connect the exshell to the brace.
- The end of the strap was too long and was perceived as annoying by Tom. He suggested to have shorter straps.
- Before putting on the exshell Tom rethightened the brace several times. It seemed that he had difficulties with finding the correct tightness of the wrist straps.

Figure 53 << For this test and the tests on the following pages a tremor patient was used as a test subject. Tom de With is suffering from Parkinson's and has been diagnosed 4 four years ago. He found out about STIL through a short newspaper article in a local newspaper and was very motivated to help by serving as a test subject. More about Tom in Appendix VII.

Tremor analysis validation

In the following tests the made force sensor will be validated and tested on a tremor patient. The validation has been done by analyzing the result from the sensors output. The sensors measured the difference in current with a 1000 Hz sample frequency. The sensor data has been gathered in serial plot, a software tool to analyse sensor data. The output of each test has been converted to a .csv file and a comparative overview has been made for all of the tests for both of the sensor directions in excel. Output from channel 1 represents the forces Y direction, channel 2 represents the forces in the X direction (Figure 54)

5.4.1 Sensor validation test

Goal

Test the sensors functionality and validate its design.

Method

The exshell, with attached force sensor has been exposed to a vertical impact force of 3N. The force was generated by letting a steel bar of 300 gram drop on the far edge of the exshell (see set-up in Appendix XXXV). This was done in different situations in order to discover the influence of the brace and the skin on the accuracy of the sensor. Three different situations have been tested to see the influence of each of these variables:

1. The force sensor mounted to a firm fixated point
2. The force sensor mounted on the brace around a solid body
3. The force sensor mounted on the brace on a human arm

For each impact a recording has been made in serial plot. The protocol of each experiment can be found in Appendix XXXVI.

Results

As can be seen in Figure 56,60 a clear reading of the impact force can be seen by the force sensor. The data shows the current difference during the impact force. Compared to the ideal situation (E1), the force read out was 8 % less high when the sensor was attached to the brace around a solid body (E2) and 38 % less high when the brace and sensor was attached to the arm (E3). Although there is a significant amount of dampening occurring in the skin, the force was clearly visible by the sensors readings. The difference in behavior of the sensor attached to an arm or solid object should be taken into account in the tremor dampening algorithm, since this could influence the amplitude of the to be generated anti vibrations.

The sensor can clearly recognise the direction of the force. Channel 2 is hardly affected by the force applied in the direction of Channel 1 in this test set up.

Due to the dampening effect of the human tissue, it is likely that some calibration is needed before use in order to estimate the amplitude of a tremor.

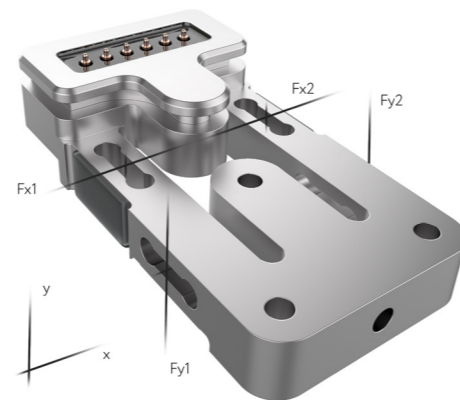


Figure 54 Sensor output. Channel 1 represents force in the y direction. Channel 2 represent forces in x direction.

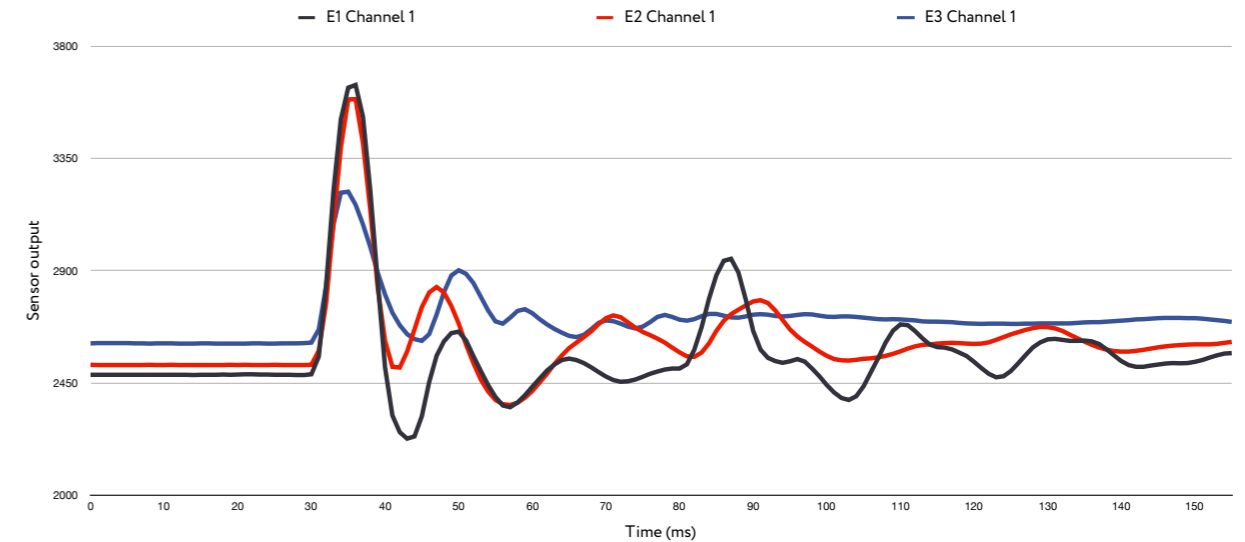


Figure 56 Output after letting a small weight drop from a set height on the outer edge of the exshell. Channel 1 displays the force in the Y direction.

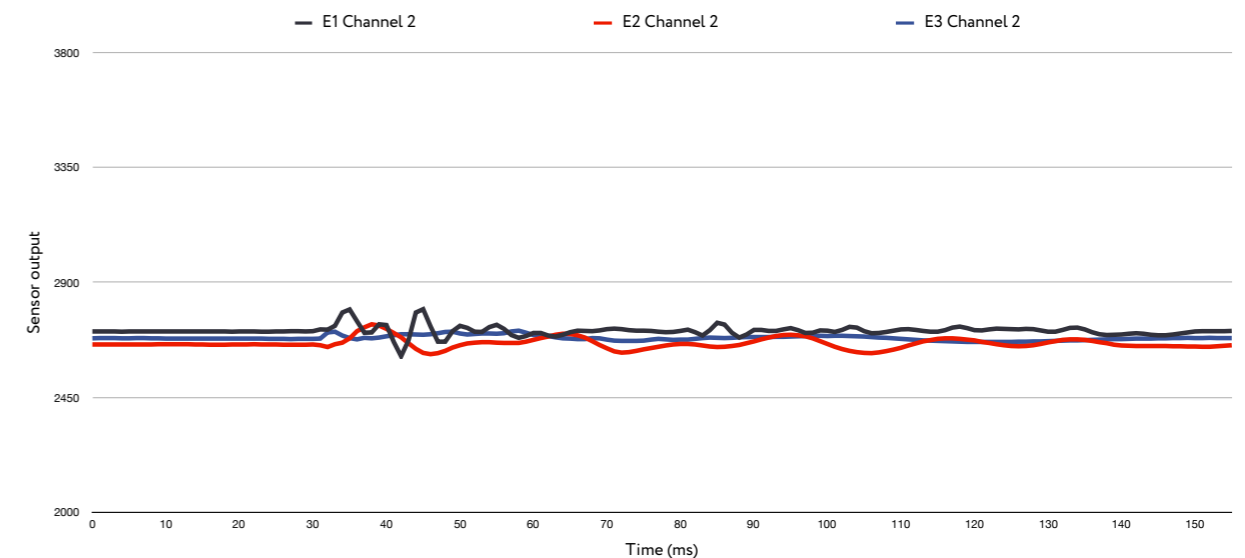


Figure 55 Output after letting a small weight drop from a set height on the outer edge of the exshell. Channel 2 displays the force in the x direction.

5.4.2 Sensor performance test

During this test it has been tried to measure the tremor of a tremor patient during different situations. Findings can be used for the improvement of the tremor dampening algorithm and evaluation of the brace design.

Method

A test with a tremor patient has been conducted to see if it is possible to measure a tremor in a tremor patients forearm. An experiment was set up that tried to discover how and if the force sensor could recognize the tremor of the tremor patient. For this test the functional prototype as seen in the prototyping section was used. A set of five experiments have been conducted to discover the sensors output in different situations. An overview and short explanation of each experiment can be seen in Figure 57. Results are presented on the next pages.

A full overview of the experiments protocol can be found in Appendix XXXVII. The results have been plotted in the graphs on the next pages. Channel 1 displays the change in current in the y direction (up and down) and channel 2 (left and right) displays the force in the x direction (Figure 54). The sensor used a sample frequency of 1000 Hz, and a recording of 10 seconds was made for test 1 and 2. The length of test 3,4,5 depended on the duration of the requested movements.

Results

The results and potential interesting findings for future developments are discussed. On the following an overview of the found results for each experiment is present. As can be seen in Figure 58,59,60,61 and 62 a clear reading could be made of the tremor in both measurement directions. Besides from this excellent finding other results have been found during the several different experiments. The result of each experiment is briefly discussed in the caption of each figure.

Conclusion

- The sensor output suggests that it is possible to determine the magnitude and direction of a tremor patients tremor.
- The dampening intensity of the to be made exshell will have to take the tissue behaviour of the users body into account. The human bodies muscle and skin tissue functions as a damping system, reducing the intensity of forces that are applied to the skin.
- The force sensors gave an accurate output during the several different experiments. The sensors accuracy makes it possible to clearly differentiate the tremor from other forces during different movement. The found results can be used for further development and experiments to improve the tremor dampening algorithm.
- A point of attention for future development is the output of the force sensor in experiment 5. In an ideal situation only channel 2 would have shown a change in value, how to compensate for the unwanted change in the output of channel 1 will have to be researched. Potential solutions, such as the introduction of multiple clamping points around the arm will go at the expense of the users comfort and simplicity of the product.
- It is difficult to tell if the movement of the skin over the muscle and bone tissue influences the sensors output. It has been shown that a significant amount of dampening occurs while wearing the brace around the forearm, due to the elastic behaviour of human tissue. In order to discover the sensors behavior during dynamic movements a different comparative test is needed.

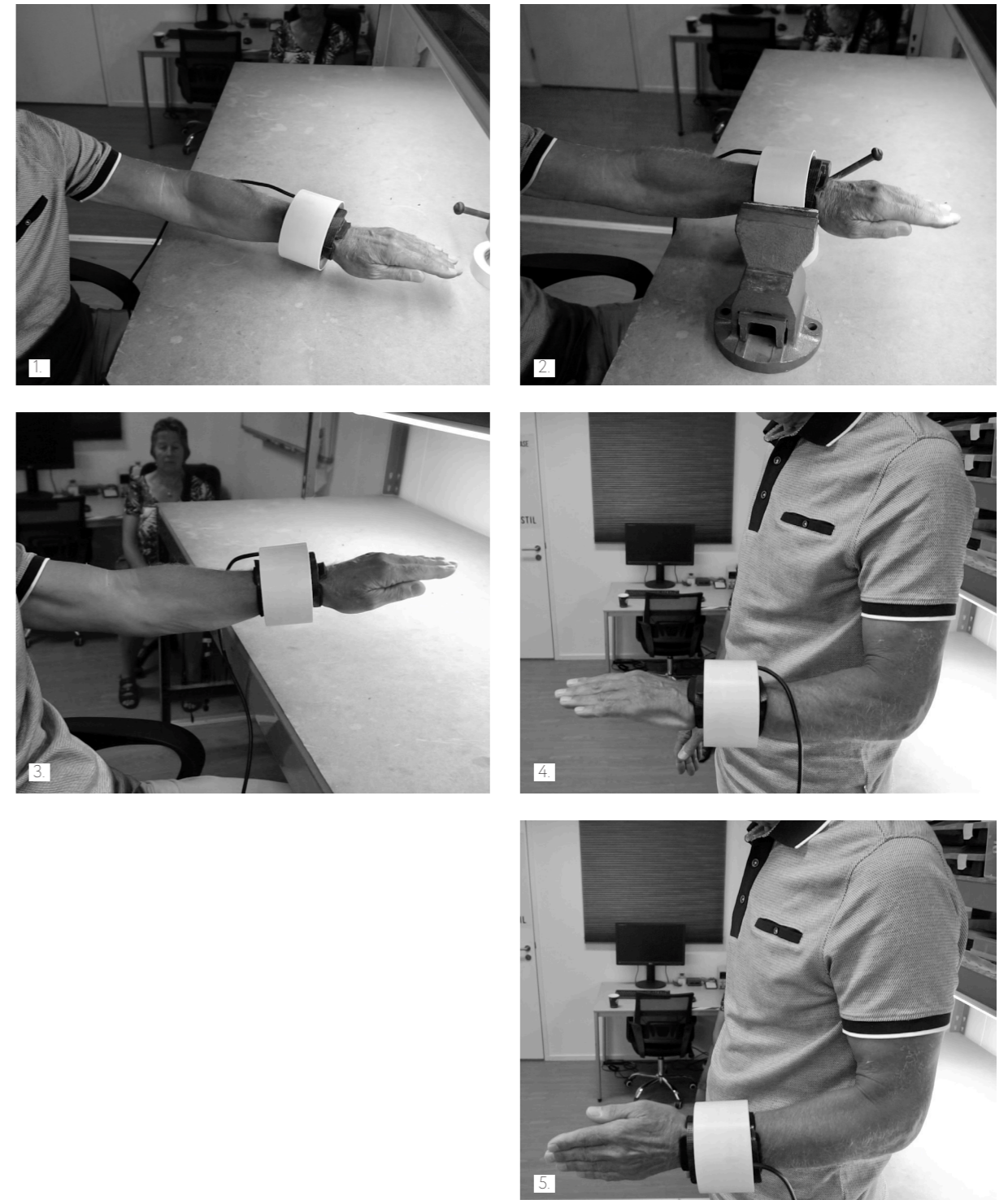


Figure 57 Visual overview of the performed experiments. **1.** Sitting with extended arm in sagittal plane, palm down, trying not to move (There is no contact with the table.) **2.** Sitting with extended arm in sagittal plane, product attached to vise, palm down. **3.** A supination to pronation to supination movement. **4.** Elbow next to body, flexion and extension of elbow joint, palm facing transverse plane. **5.** Elbow next to body, flexion and extension of elbow joint, palm facing sagittal plane

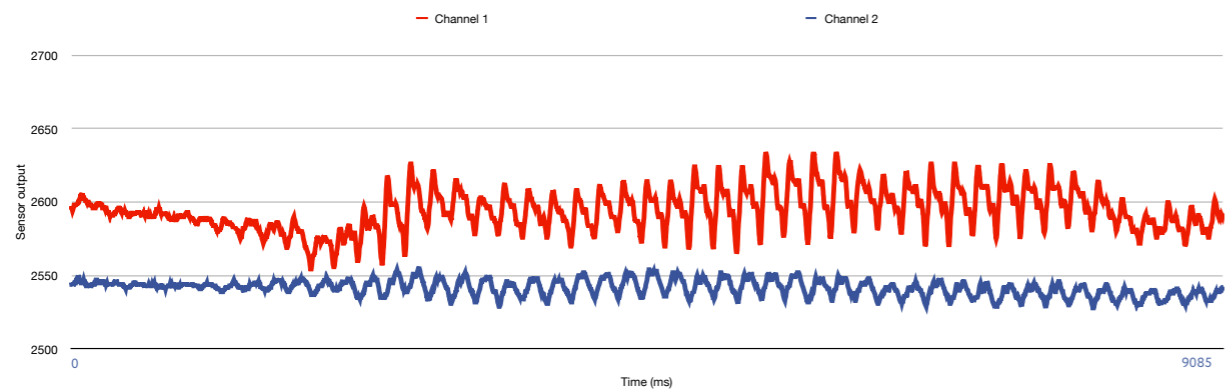


Figure 58 Test 1: Sitting with extended arm in sagittal plane, palm down, trying not to move (There is no contact with the table.)
 This plot shows the output of the force sensor in a situation that the product is in a hypothetical idle state. It was desired to get data from the product in this state, because it is needed to know how the arm behaves before the product is activated. In this neutral state it can be clearly seen that the tremor patient experiences a forearm tremor that was more dominant in the y direction.

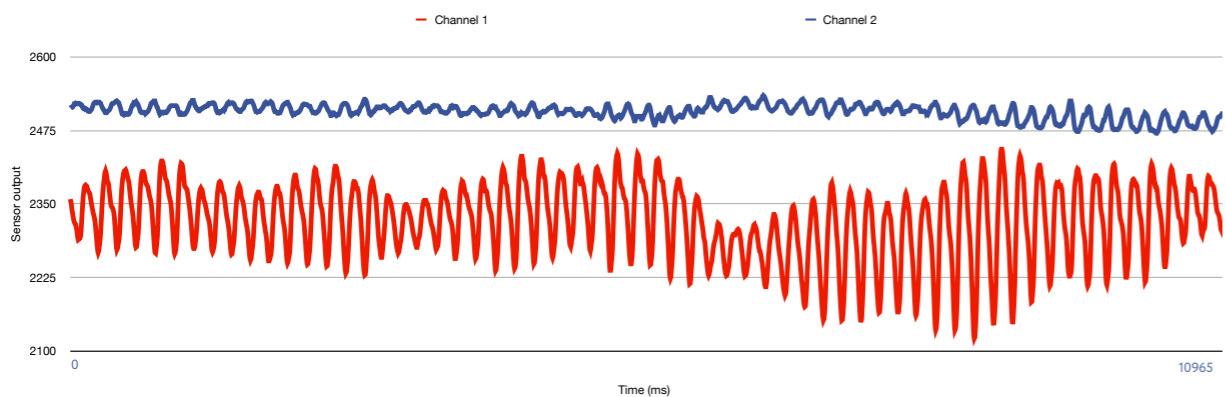


Figure 59 Test 2: Sitting with extended arm in sagittal plane, product attached to vise, palm down.
 An experiment to get the most clear force readings was conducted. By clamping the exshell in a vise, it was possible to obtain a more clear force reading. In this set up there is no possibility to move, making the tremors measured readings from the sensor more expressive. In this figure it can be seen that the readings from channel 1 differ from experiment 1. The more negative value output of channel 1 can be assigned to the position of the arm in the vise. Probably the tremor patient let the arm rest in the brace. Resulting in a more negative force on the force sensor in the y direction.

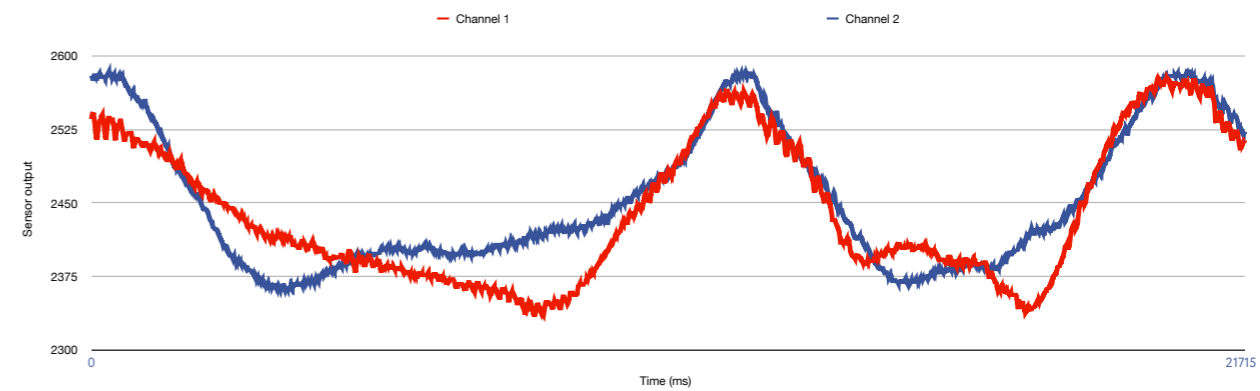


Figure 60 Test 3: A supination to pronation to supination movement.
 This plot shows the supination to pronation movement. It is interesting to see how the force sensor reacts to this movement. A change in both the y and x direction can be observed. The movement has been repeated twice, which results in the displayed repetitive pattern. With the help of software these kind of large sensor output changes can be filtered in order to find the forces caused by the patients tremor (with the help of so called low pass filters).

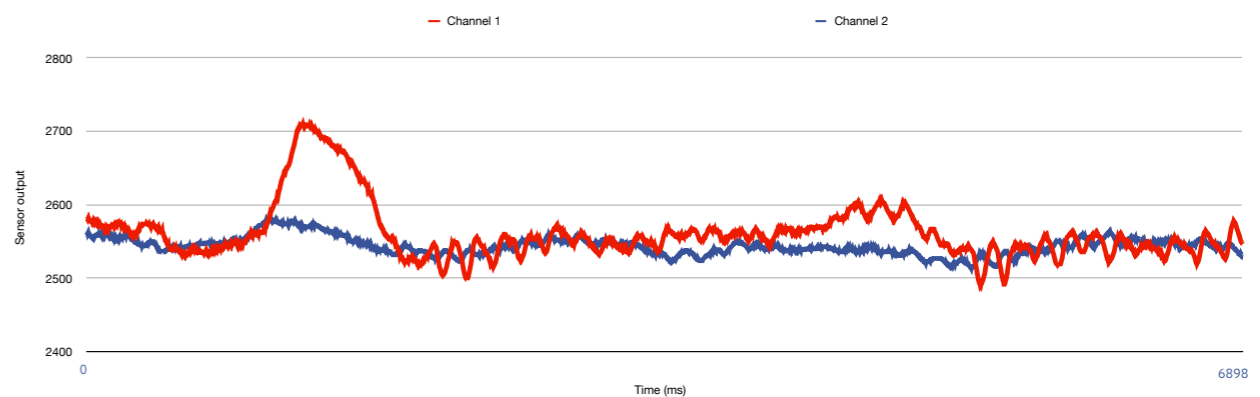


Figure 61 Test 4: Elbow next to body, flexion and extension of elbow joint, palm facing transverse plane.
 With the conducted movement a clear force change in the y direction is observed (Channel 1). The flexion and extension of the elbow while keeping palm facing down results in forces in vertical direction as displayed by the output of channel 1.

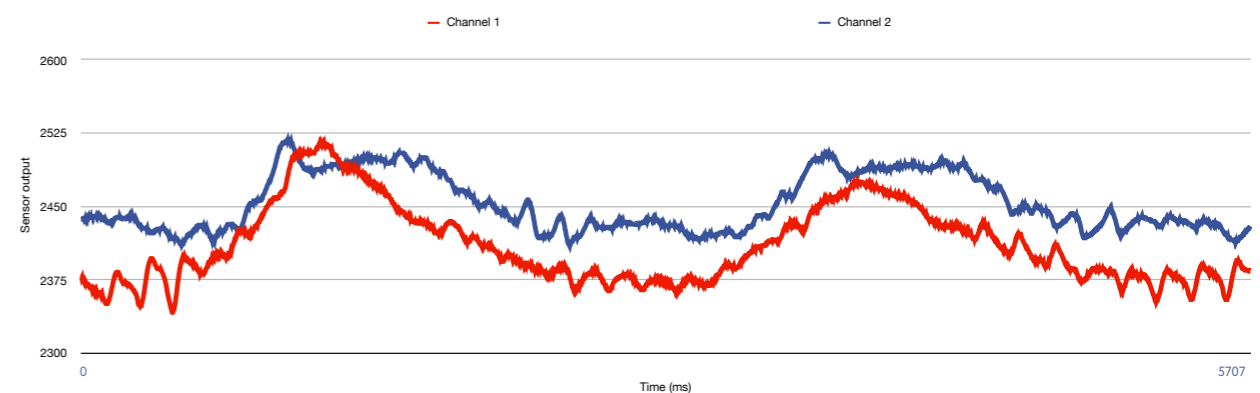
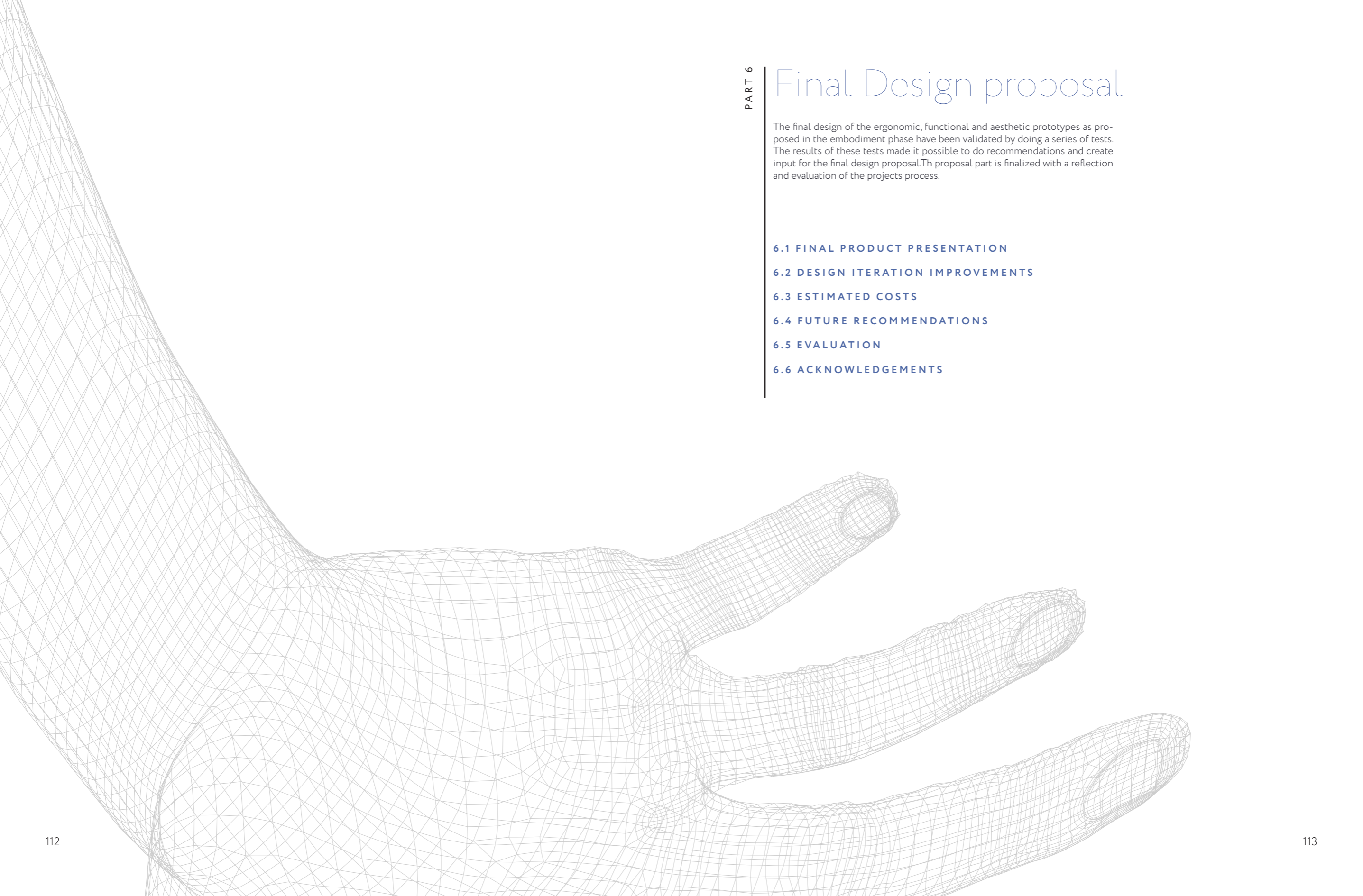


Figure 62 Test 5: Elbow next to body, flexion and extension of elbow joint, palm facing sagittal plane.
 The same up and down movement as in experiment 4 has been conducted, but now with the palm facing the sagittal plane. This test would ideally have resulted in a clear force sensor output that showed a clear change in the x direction (channel 2), but as can be seen a change in both channels occurs. This can be assigned to the fixation location of the brace to the exshell. Since this is not placed in the centre torque occurs in the force sensor, resulting in an unrealistic sensor output.



Final Design proposal

The final design of the ergonomic, functional and aesthetic prototypes as proposed in the embodiment phase have been validated by doing a series of tests. The results of these tests made it possible to do recommendations and create input for the final design proposal. The proposal part is finalized with a reflection and evaluation of the projects process.

6.1 FINAL PRODUCT PRESENTATION

6.2 DESIGN ITERATION IMPROVEMENTS

6.3 ESTIMATED COSTS

6.4 FUTURE RECOMMENDATIONS

6.5 EVALUATION

6.6 ACKNOWLEDGEMENTS

Final Brace design

The feedback of the validation phase has been included in the final design proposal. This resulted in the design as seen in Figure 63. The made changes and final material selection will be briefly discussed. Discussed changes have been numbered and refer to the numbers in Figure 63.

Adapted strap design

The straps have gone through several design iterations during this project. Small adjustments with each cycle have resulted in the design as depicted on this page. Improvements that are a direct result of the validation phase included the addition of small fabric loops on the end of the strap (1), a new type of velcro (3M Dual lock) and more padding on the inner edge of the brace (2). An extra fabric stroke has been added to the padding for more durability (3).

Force sensor connection plate redesign

During the prototyping process it was found that the force sensor connection plate was not stiff enough for the used prototyping material. Extra material has been added on the edges of the force sensor connection plate and a set of shallow ribs have been added on the bottom (4) (Appendix XXXVIII). In order to include the new type of velcro, which was very thick, a redesigned edge was made (5).

Connection point redesign

During the validation phase it was found that the epoxy protection around the edges of the pogo pins was very difficult to apply and did not protect the pogo pins properly enough (Appendix XXXIX). A new plastic protection cover was designed that offers better protection to the pogo pins (6).

Colour, Material and Finishing changes

The proposed finishing as presented in the embodiment phase is difficult to achieve. The presented final design uses materials and colors that are realistic and within the start ups (financial) capacity.

Removable padding

A set of loops and velcro have been added on the padding. This makes it possible to remove the neoprene padding, so that it can be washed and cleaned (7).



Figure 63 The final brace design.

Final Product design



Expected costs

An overview of the expected costs of the brace is presented. The exshell, packaging and needed accessories have been excluded from this cost price estimations. An cost estimation is given for the estimated target market is given. The final costs may still vary since some part costs have been estimated.

view resulted in an expected rounded cost price of:

130 €

6.4.1 Potential target market

The target market STIL currently is focusing on is less specific than the target group that has been discussed in this report. STIL aims to sell the product to any patient with a tremor in the Netherlands that is open for new innovations (early adaptors and innovators), but the target group in this report will be more specific in order to take into account only a small percentage is actively looking for solutions.

In this report individuals that are perceived to be likely to buy the product in an early phase are early adaptors and innovators (Rogers, 2002) who experience a moderate to severe impairment in everyday life. How to contact and motivate patients that are not actively looking for solutions can be a challenging task and should be taken into account in the future market strategy of STIL.

An overview of the potential target market estimation made by STIL and the proposed estimation is given in Figure 64.

6.4.2 Costprice estimation

The estimated target market has been used for the cost price estimation. A full overview of the cost price estimation can be found in XXXIX. An overview of this table is presented in Figure 68 Costs that are estimated have been colored red (investment costs for moulds etc. are still unknown). Labor costs for the assembly, that is expected to be done at STIL, is colored blue. Taking the sum of this over-

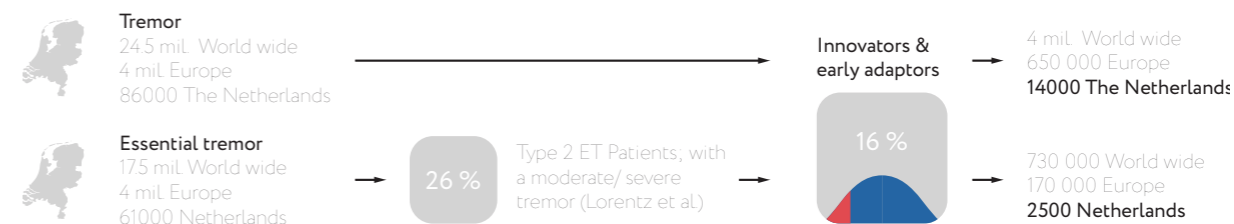


Figure 64 Potential target market estimation as approached by STIL (above) and the expected target market size for the first generation of braces (below). Numbers of the initial estimation have been provided by STIL.

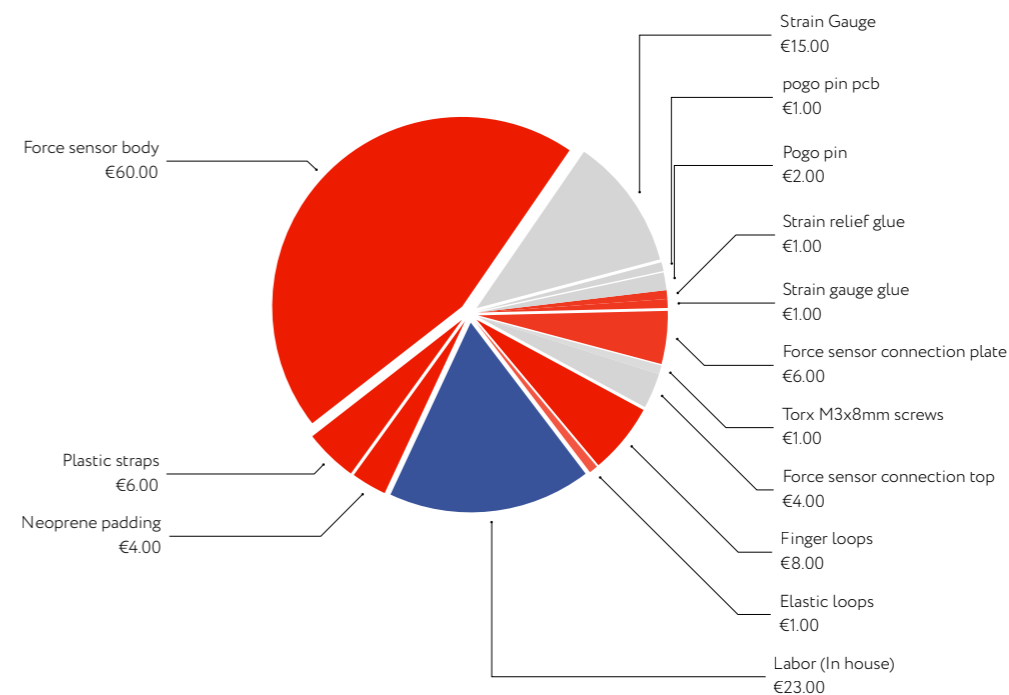


Figure 65 Cost price estimation. Uncertain costs are colored red. Known costs are colored grey and labor is colored blue. Most of the needed investments are still uncertain, but an estimation has been made in order to understand the potential price of the brace.

Future improvements

Some recommendation that can be included in future product developments are discussed.

Optimize sensor design

The functional principle of the sensor has been proven with the tests in the validation phase. Although the redesigned sensor is a lot smaller than the original sensor design, it can still be improved. Different production methods can be considered in order to make the design more compact. Also research can be conducted on a sensor design that contains only two strain gauges. Since the measurements gave very clear results, it might be possible to redesign the sensor in such a manner that only two strain gauges are needed. This can result in a design that is even more compact, increasing the freedom to improve its form and functionality.

Prevent torque on force sensor

The current fixation point of the force sensor is not in the centre of the exshell. This resulted in torque being applied on the force sensor when the arm is rotated. How and if this influences the ability to dampen a tremor is not clear. If it appears that this restricts the tremor dampening algorithm from functioning properly, it will be needed to explore alternative solutions.

Sensor output and forces

The output of the sensor will have to be linked to a magnitude that corresponds with a patients tremor. Research is needed to link the output values of the sensor to real forces. This will be needed for the tremor dampening algorithm.

Minimize Exshell weight

Tom mentioned that the total appearance of the product was quite bulky. It is unlikely that the full embodiment will get any smaller than it is in its current state any time soon, but in order to meet with

the users needs it good to keep pushing the developments to make the full design smaller and lighter.

Validate display design and functionality

The display design proposed in this report has not yet been validated or tested. Only a static display was used in the user tests. How and if the proposed display lay out and signals work will need more research. It is advise to start investing more time in this when a functional prototype is available.

Minimize sliding on the skin

As mentioned several times in this report, a perfect fixation of the brace on the body is difficult to achieve due to the natural behavior of the human skin and muscle tissue. How much the dampening behavior and natural freedom of the skin to move will complicate the ability to properly dampen a tremor is still uncertain.

Provide feedback on correct fit

During the ergonomic test and user validation test it was found that users often experience difficulties with finding the right tightness. This feeling will have to be developed by the user by using the product more often. The current principle does not facilitate the possibility to provide feedback to a user, but has the advantage that it is easy to adjust.

Explore different sales channel opportunities

During the user research it was found that it can be potentially difficult to reach tremor patients. How to reach out to the customer will need future research.

Research different possibilities with the brace design

The proposed brace design showed a lot of potential, both the sensor and found strap design can be used for different purposes. It can be interesting to

see if this principle to measure forces in the arm can be applied in different fields that need information about the movement of arm.

Also the principle of clamping an object to the fore arm by using the proposed strap design can be useful. Instead of mounting a sensor to the arm, it can also be used to connect a phone or a different object to the brace.

Scalable design

During the scaling of the brace, some parts only showed minor adaptations. Some parts, such as the force sensor connection plate, can be made usable for all brace sizes. This can lower the investments needed for the injection moulding moulds.

Topplate connection

Currently a snap fit design is suggested for the connection of the topplate to the sensor connection plate. The durability of the product might improve if these snap fingers are replaced for a more rigid solution.

Writing problems

During the user tests with the Exshell mock up it appeared that users experience difficulties with writing and using a computer mouse while having the Exshell attached to the arm. It should researched how to minimize the inconvenience of these activities.

Docking station development

In the use case scenario in Chapter 4.3 a docking station is suggested for the charging of the exshell. This stocking station will need to be developed in order to make easy charging of the Exshell possible.

Project evaluation

When I stumbled upon this project during the summer of 2018 I had no clue that STIL would become such a big part of my life over the last half year. This project has been a great challenge and in the last few months I have worked really hard to get the results that are presented in this report. I was able to apply all of the skills that I have learnt in the last few years during my master and several internships. I achieved the personal goals that I have set for myself at the start of the project and learned a lot more along the way.

This project enabled me to discover how to develop complex ergonomic products. Not only did I learn a lot about complex surface modeling. I also discovered how to find the correct human dimensions and shapes needed to work with. The human 3d data set provide by Huysmans was fun to work - and play with and resulted in very usable results.

The made discoveries and final embodiment are promising and I am excited that I was able to let a tremor patient test and use the final brace design. The measured results and feedback from a real patient are great. The final result checked many of the set up requirements, although it still will be exciting to see if the final design will function properly the soon to be finished functional exshell.

Although I am very happy about the final result of the project, it was sometimes very difficult for me to make this project fit within the design methods as educated at the Faculty of Industrial design. I took part in a larger project, delivering several specific design elements that contributed to the development of the total project. This made it difficult to work with the design cycle as proposed by Roozenburg & Eekels. Some parts of the analysis have appeared to be difficult to implement in the final result. Although it was very interesting to discover more about the users behavior and needs, the final

concept only uses very little of these findings. The made discoveries are more interesting for future market implementation strategies of the company.

The final result overshoot the original assignments goal of developing a prototype that could be used for testing at the Reinier de Graaf hospital in Delft. Not only a proposal that can be used for the clinical tests has been done, the first steps and suggestions for a larger scale production already have been made. It is therefore exiting to see how these results will be used by STIL during their product development in the upcoming years.

Acknowledgements

This project would not have been the same without the much help that I got from so many people. I would like to dedicate this last section of the thesis to thank some of you who helped me with my challenges during this project.

First of all, a word of thanks to all the people from STIL. Ijsbrand de lange, Nicola Pambakian, Babette Zwaard and Tim Sprang. You supported me, gave me great advise and helped me bringing my ideas to reality. My results would not have been the same without the great knowledge and facilities that have been offered to me at this great start-up.

Next, I would to thank the other graduates and interns that were around me all the time at STIL. Jouke de Jong and Hugo van der Kort, it was great to collaborate with you guys. The merge of different skills has been exceptionally interesting and educational. Your knowledge and skills helped making it all come true.

Anton Jellema and Wilfred van der Vegte, thank you for your coaching and support and thank you for your honesty during the feedback sessions. During these sessions you confronted me with remarks and feedback that made me reconsider and reflect myself on my work. You forced to me to be sharp and to be critical on my deliverables.

The functional prototype would not have existed without the people of the workshop at the Faculty of Industrial Design Engineering. Rene van de Schuur once again delivered some excellent work for my project.

At last I would like to thank my family and girlfriend for being such great guinea pigs and mental supporters. Thank you all for your fresh insights and guidance during life and this project.

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Stijn Jagers op Akkerhuis. July, 2019.



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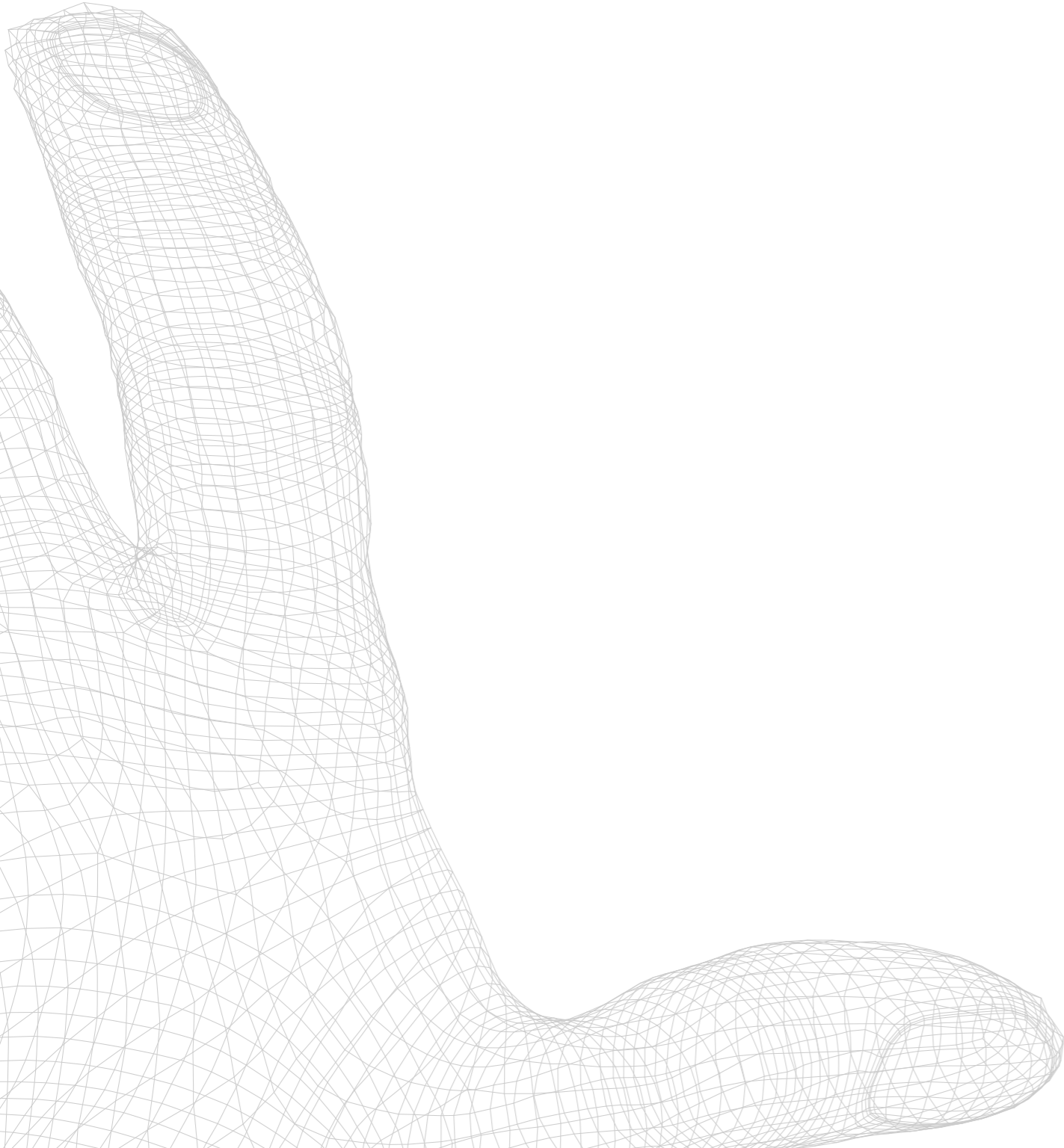
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PART 8 | Appendix

I	PROJECT APPROACH
II	FUNCTIONAL PRINCIPLE
III	TREMOR TYPES
IV	COMPETITORS
V	OTHER WRIST BRACES
VI	PATENT ANALYSIS
VII	INTERVIEWS
VIII	QUESTIONNAIRE RESULT
IX	QUESTIONNAIRE REMARKS
X	PERSONA'S
XI	ACTOR RESPONSIBILITIES
XII	PJM
XIII	USE CASE ANALYSIS
XIV	STORYBOARD
XV	DEGREES OF FREEDOM
XVI	ORTHOSIS DESIGN PRINCIPLES
XVII	POTENTIAL BRACE CONTACT POINTS
XVIII	ANTHROPOMETRIC DATA OVERVIEW
XIX	LIST OF REQUIREMENTS
XX	MORPHOLOGICAL MAP
XXI	EMBODIMENT GOALS
XXII	FEA ANALYSIS
XXIII	PRODUCTION DRAWING, FORCE SENSOR
XXIII	SOLIDWORKS MODEL
XXV	CES ANALYSIS
XXVI	INTERACTION UNIT
XXVII	APPEARANCE SUGGESTIONS
XXVIII	MOCK UP PROTOTYPING
XXIX	ERGONOMIC TEST: USER MARKS
XXXI	ERGONOMIC TEST 2: EVALUATION FORM
XXXII	PROTOCOL A: USABILITY TEST 3RD OF JULY
XXXIII	USER VALIDATION OVERVIEW
XXXIV	USER VALIDATION QUESTIONNAIRE
XXXV	TEST SET-UP FUNCTIONAL TEST
XXXVI	PROTOCOL B: SENSOR VALIDATION TEST
XXXVII	PROTOCOL C: FUNCTIONAL EXPERIMENT
XXXVIII	FORCE SENSOR CONNECTIONPLATE REDESIGN
XXIX	POGO PIN DAMAGE
XL	ESTIMATED COSTPRICE

Project approach

By making use of the design cycle as proposed by Roozenburg and Eekels a fundament is provided for having a structured approach for the design process. During each phase several iterations are included to find as good as possible solutions.

A challenge in this project is the goal to design a product that can be worn by the majority of the targeted users. To keep development lean in the early stages, quick iterations can be made by testing on a small test group. After a design direction has been chosen an optimization to make the brace fit for the target group is done.

Information has been gathered by making use of a combined literature, user and experimental research. This midterm report is finalized with a overview of the found results. These findings have been used to make a set of goals that can be used for validating several different concepts. Experiments or information that have found to be useful for the learning process, but are not relevant for the report have been added as a suffix in the Appendix.

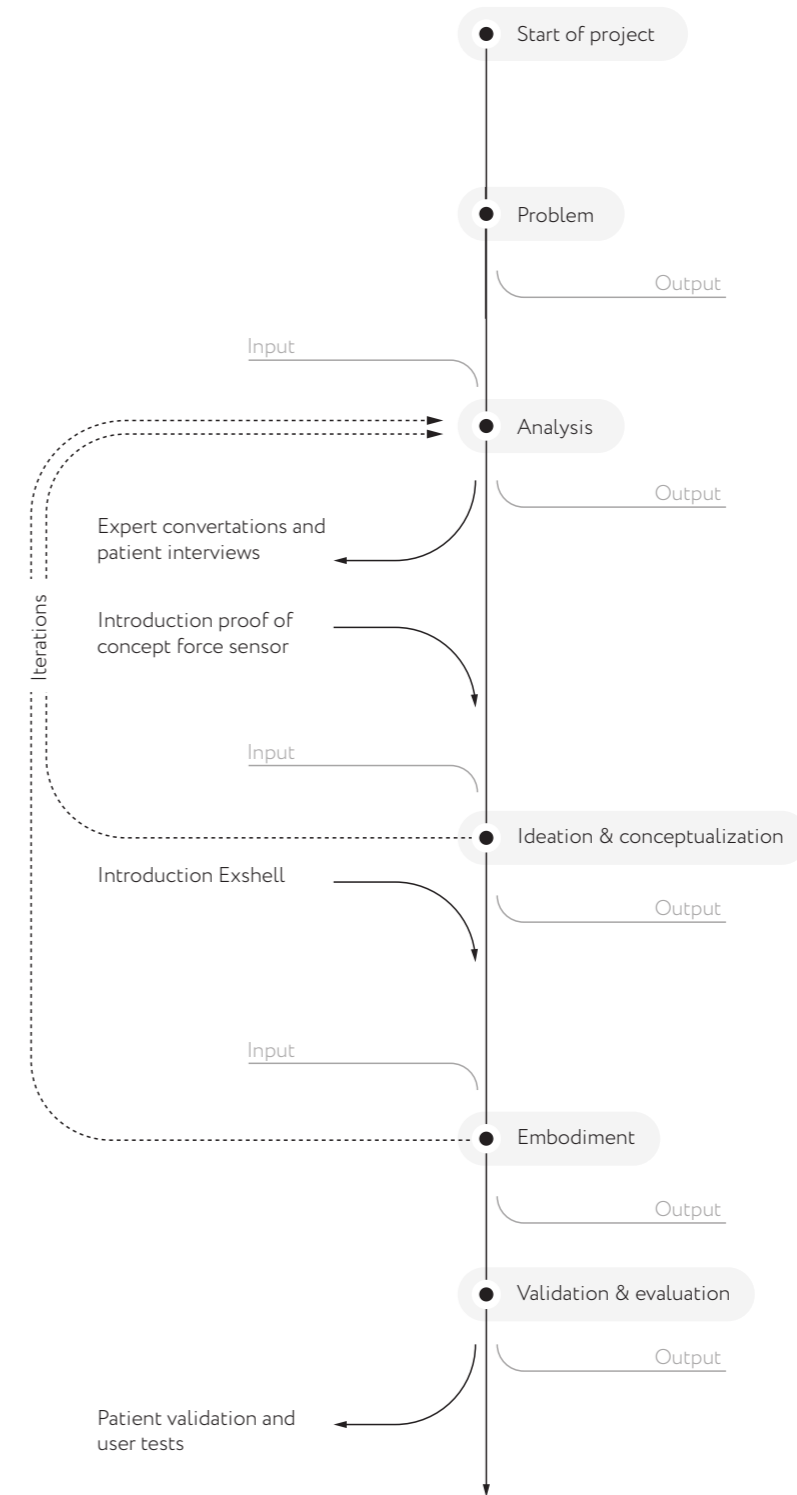


Figure 66 The full design process of this project.

Functional principle

A) Force generation

Centrifugal forces always point radially outwards from the origin of rotation. However, two counter-rotating orbiting masses ($\omega_1 = -\omega_2$) following a similar circular trajectory will impose centrifugal forces in a symmetric way, therefore effectively exerting a sinusoidal force along one axis only. This principle, as illustrated in Figure 3, underlies the basis of operation of the ECROM actuator. The plot in Figure 4 shows the decomposed and resulting centrifugal forces in x and y direction. Because both masses are counter-rotating, the decomposed centrifugal forces along the x-axis cancel each other out, whereas along the y-axis an amplified sinusoidal force will be generated. An extra benefit of this principle is that gyroscopic forces are not present since the masses counter rotate, effectively cancelling out gyroscopic precession. Seeing as the actuator can generate sinusoidal forces, it will also be capable of counter-acting sinusoidal forces, such as tremor.

B) Altering Force direction

The direction of the output force relates to the the point on the circular trajectory where the two counter-rotating orbiting masses intersect. In the case of Figure 3, the point where the two masses intersect is collinear to the y-axis, thus force generation will be guided in the direction of this axis. By controlling the angular velocities of the masses individually, the point of intersection could in theory be shifted to anywhere on the circular trajectory. This allows the

actuator to freely alter force direction but keep the output force unchanged. This is a necessity for an absolute force actuator used in tremor suppression, since the global orientation of the arm will change during movement, but the local tremor force direction will remain the same. C) Varying Force amplitude Tremor amplitude is highly time-variant thus the actuator needs to be capable of changing force output. Centrifugal forces, indicated in Equation 1, are dependent on mass (m), radius (r) and angular velocity (ω).

$$F_{cf} = m r \omega^2 \quad (1)$$

The angular velocity has to match the tremor frequency to create a similar frequency force output, so this can not be altered to vary force amplitude. Changing the mass is theoretically possible but is hard to accomplish in practice. This makes changing the radius the best option for altering force output while the ECROM is operating. The radius r is defined as the distance between the centre of orbit and the Centre of Mass (CoM) of the orbiting mass. By splitting the mass and separating the halves, the combined CoM will shift inwards. This combined CoM, depicted in Figure 5, then effectively decreases the overall radius of the eccentricity, thereby decreasing the centrifugal force. Using this strategy, the output force can be altered without the need of actually decreasing the radius of the mass.

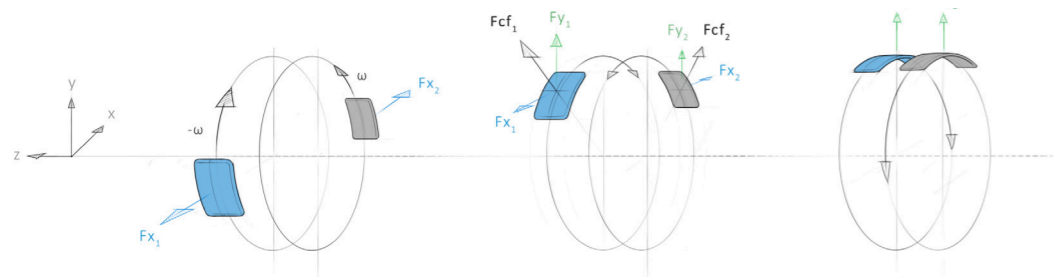


Figure 67 Eccentric Counter Rotating Orbiting Masses concept: two masses counter-rotate around a similar origin and such generate a harmonic force. F_{cf} corresponds to the centrifugal force inflicted by the eccentric rotation of a mass around the z-axis. The centrifugal force can be decomposed into the angle dependent forces F_x and F_y . The angular velocity, represented by ω , is assumed to be constant. Adopted from Ij de Lange (2016)

Tremor types

	Symptoms	Cause
Type 1	Mild hand tremulousness that is produced by enhanced mechanical reflex oscillation.	Tremor is produced by hyperadrenergic states (eg, anxiety, drug withdrawal), thyrotoxicosis, and tremorogenic drugs such as lithium and valproic acid. The tremor frequency decreases with inertial loading of the hand.
Type 2	More severe than type 1. Involves the lips chin, tongue, voice, head, and sometime even the legs.	Produced by a central neurogenic oscillation at a frequency that is not a function of limb inertia or reflex arc length. Most patients with this tremor have not been diagnosed by a physician.
Type 3	Type 3 ET is severe, disabling tremor of the magnitude that often leads to stereotactic surgery.	A natural progression of type 2 ET in some patients, but there are reasons to believe that this is not always the case. Many type 3 patients do not have a family history, and other subtle neurologic signs are often overlooked by clinicians.
Type 4	A nonspecific action tremor of the upper limbs that is believed to be secondary to a specific disease, such as hereditary demyelinating neuropathy, dystonia, and Parkinson disease.	The clinical characteristics of ET in the upper limbs are nonspecific, and identical action tremor can be the sole presenting symptom in patients with Parkinson disease and dystonia.

Table 7 Tremor types adapted from Elbe and Marsden (2013)

Competitors

	Lifeware Spoon	GyroGlove™	WOTAS	Steadiglove	STIL
Commercieel beschikbaar	✓	✗	✗	✗	Q2 2020
Compact & lichtgewicht	✓	✓	✗	✓	✓
Beïnvloed vrijwillige beweging niet	✓	✗	✓	✗	✓
Universeel gebruik	✗	✓	✓	✓	✓
Onderdrukt pols- en onderarm tremor	±	✗	✓	✗	±

Table 8 Potential competitors adapted from Stil (de Lange, 2016).

Other wrist braces

Brand	Sizes (cm)	Method	Left & Right	Adjustability	Price	Function
a. Ossur, exoform palmar wrist brace	S M (16.5-19.7) L	Wrist circ.	No	yes, two straps to adjust wrist circumference and hand width	9.60	Palmar tunnel syndrome
b. Mueller Green Fitted Wrist Brace	SM/MD (12.7-20.3) L/XL (20.3-25.4)	Wrist circ.	No	Yes, two straps to control compression	13.50	Palmar tunnel syndrome
c. Copper Compression Arthritis Gloves	Small Medium Large	-	Comes as pair	No	25.95	Arthritis, Palmar tunnel syndrome
d. Stroke Hand Brace	-	Fits 8.9 to 10.2 width of MP Joints, and wrist to finger tip length of 20-24	No	Bend to fit construction, extra long wrist strap	45.50	Treats moderate flexion contractures
e. Vive Wrist Brace	Universal Ergonomic Fit	-	No	Wraps around wrist	10.00	
f. Mobius X8 Wrist Brace	S/M 4.6-5.8 M/L 6.1-7.4	Wrist breadth	Yes	Strap and chord to adjust wrist circumference	200.00	limit wrist ROM in flexion extension direction
g. Flo-Form Medical BendEase Hand Splint	Small Medium Large	Width of MCP Wrist to fingers	No	4 Foam padded straps		Corrective, Supportive Brace for Comfort & Pain Relief
h. Sparthos Wrist Support Sleeves	S 12.7 - 15.9 M 15.9 - 20.6 L 20.6 - 23.5 XL 23.5 - 29.2	Width of MCP Wrist to fingers	comes as pair	no	16.00	Corrective, Supportive Brace for Comfort & Pain Relief
i. Flexmeter Wrist Guard	Small 6.3-6.8 Medium 6.9-7.87 Large 8.2 >	Hand width	comes as pair	2 straps to adjust wrist and lower arm circumference	60.00	Protects wrist against sprains
j. DonJoy ComfortFORM Wrist Support Brace	XS 11.4 - 14.0 S 14.0 - 16.5 M 16.5 - 19.0 L 19.0 - 21.6 XL 21.6 +	Wrist circ.	No	3 straps to adjust wrist and lower arm circumference	15.00	Sprains and strains, Carpal Tunnel Syndrome
k. Push Sports wrist support	One size	Wrist circ.	Yes	Yes, two straps around the wrist	15.00	Corrective, Supportive Brace for Comfort & Pain Relief
l. Push Med Wrist Brace Splint	size 1 (13-15) size 2 (15-17) size 3 (17-19) size 4 (19-21)	Wrist circ.	No	Yes, one strap around the wrist	67.50	rest without impeding your hand function

Table 9 An overview of the explored wrist brace solutions. Size determination method are described in the "method" row. If a brace is specially made for a left or right hand is described in the "left & right" row.

Patent analysis

An overview of patents that relate to attach methods of wrist braces was made. A short discription and interesting elements are mentioned. This analysis was done to discover what types of braces are already existing and how competitor create a proper fixture around the wrist.

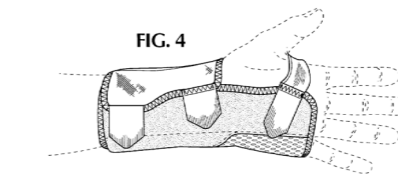
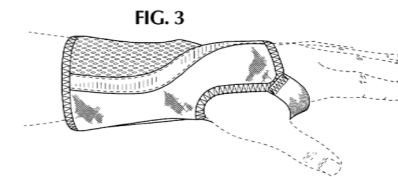


Figure 69 - US D477,409 S, Jul. 15, 2003.

"The ornamental design for a wrist brace."

Interesting aspects
Ergonomic shape, attachment method, different materials.

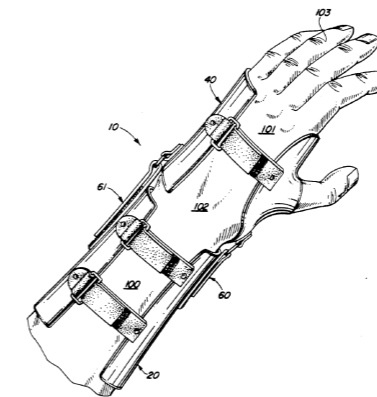


Figure 68 - US5,279,545, Jan. 18, 1994.

"The present invention is directed towards a wrist brace to be worn on an individual so as to provide support and limit the movement of the individuals wrist."

Interesting aspects
Limited degrees of freedom, location of straps and splints

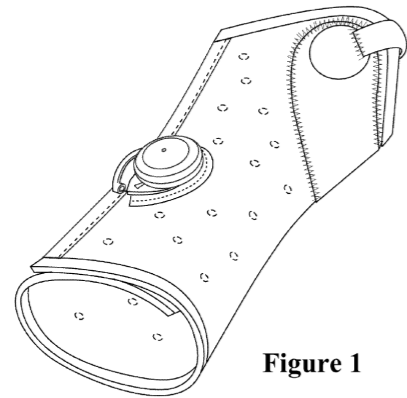


Figure 1

Figure 70 US D665,088 S, Aug 7, 2012.

"The ornamental design for a wrist brace, as shown."

Interesting aspects
Attachment method, patching work

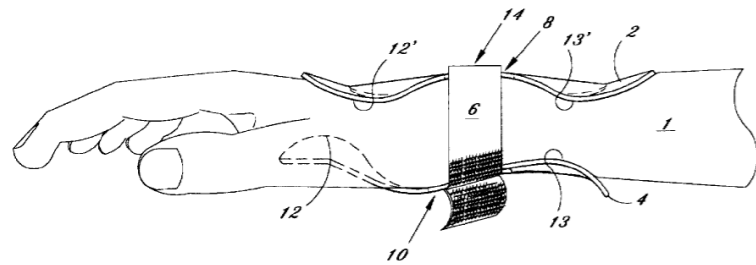


Figure 71 5,672,150, Sep. 30, 1997.

"An opposing force wrist brace is provided that immobilizes the wrist while permitting full use of the fingers and hand."

Interesting aspects
Clamping location, splint shape

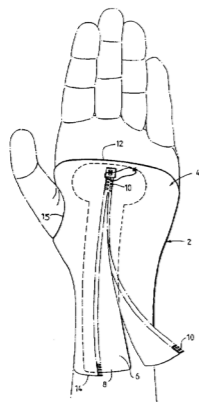


Figure 72 - 5,725,490, Mar. 10, 1998

"A wrist brace comprises a sleeve adapted to extend from the hand region of the wearer to a forearm region of the wearer. The sleeve can be made from a material which is elastic in both the circumferential and longitudinal directions."

Interesting aspects
Closing method

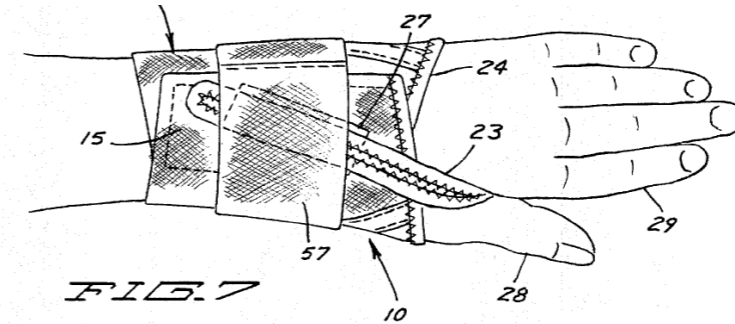
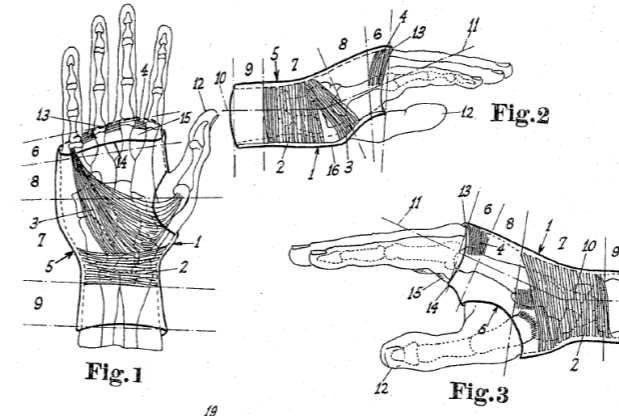


Figure 75 - 3,327,703, June 27, 1967.

"This invention relates to wrist braces and has to do more particularly with an improved elastic brace which, in addition to supporting and stabilizing the wearer's wrist, is designed to maintain the wrist in healing position while at the same time permitting sufficient voluntary flexing movement to prevent atrophy or a weakening of the muscles due to inactivity which would result if the wearer's hand were completely immobilized." Takes into account bone and muscles.

Figure 73 - 5,513,657, May 7, 1996.

"A flexible, elastic wrist brace for use by person's requiring wrist support for engaging in rigorous activity. The brace offers generalized support to the wrist as well as lateral support to limit up and down flexure of the wrist, side to side flexure and longitudinal rotation."

Interesting aspects
Loop around thumb (number 23), closing method

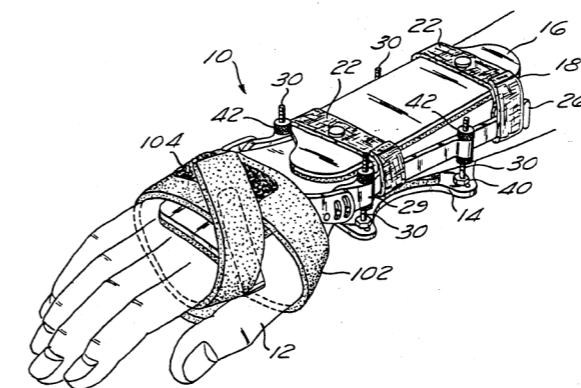


Figure 74 - 5,254,078, Oct. 19, 1993.

"A brace for supporting a wrist is disclosed which is specifically adapted to allow controlled regulated movement of the wrist during a healing process. The brace is formed by an anterior forearm plate which has a pair of elongate struts attached thereto."

Interesting aspects
Allows regulated movement

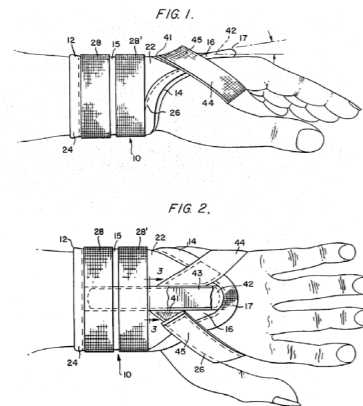


Figure 76 - 421,966, Sep. 23, 1982.

"A brace for supporting the human wrist comprising a flexible pad having a main body, a substantially triangular projection extending therefrom, and a rigid angled reinforcing member positioned parallel to the metacarpals and centrally of the projection and main body for applying pressure to the wrist and dorsal area of the hand."

Interesting aspects
Compact, fabric alignment

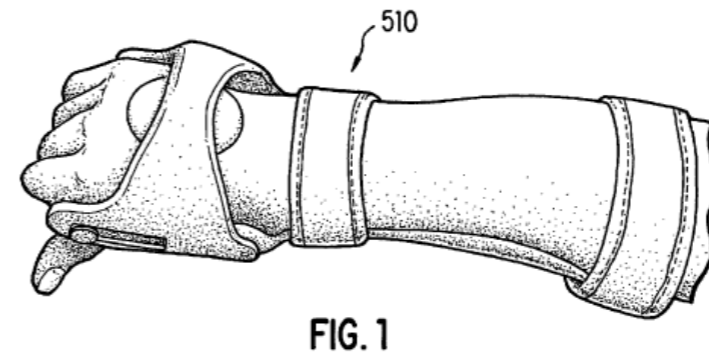


FIG. 1

Figure 82 - US 6,592,538 B1, Jul. 15, 2003.

"The present invention relates to Orthopedic devices including a Support member which is configured to the actual or desired shape of a user's body part and is removably attached to the user by a Support Structure."

Interesting aspects
Ergonomic shape, attachment method, different materials.

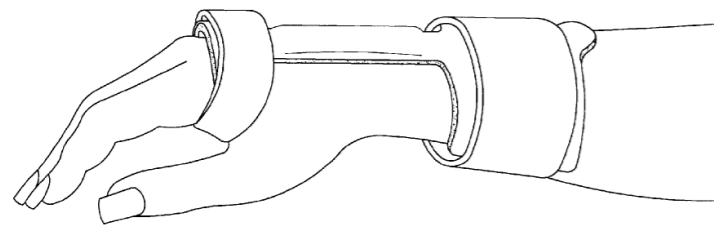


FIG. 8

Figure 77 - 421,966, Sep. 23, 1982.

Figure 78

"A brace for supporting the human wrist comprising a flexible pad having a main body, a substantially triangular projection extending therefrom, and a rigid angled reinforcing member positioned parallel to the metacarpals and centrally of the projection and main body for applying pressure to the wrist and dorsal area of the hand."

Interesting aspects
Simple, much padding applied in design

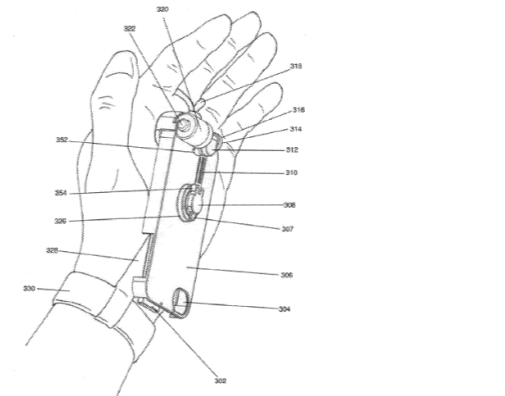


Figure 81 - US 2005/0197609 A1, Sep. 8, 2005.

"Systems and methods are disclosed to conveniently carry a mobile device, among others, on a wrist brace."

Interesting aspects
Makes of a special attachment point.

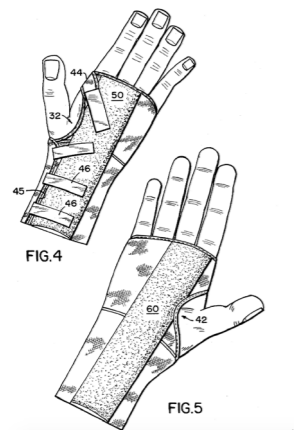


Figure 79 - 5,728,059, Mar. 17, 1998.

"A slit sleeve wrist support includes a sheet of elastic fabric that is wrapped around the wrist and hand and fastened with hook and loop fastener straps. The sheet has a proximal edge to be positioned around the arm and a distal edge to be positioned at the hand near the fingers."

Interesting aspects
Attachment method, suggested materials

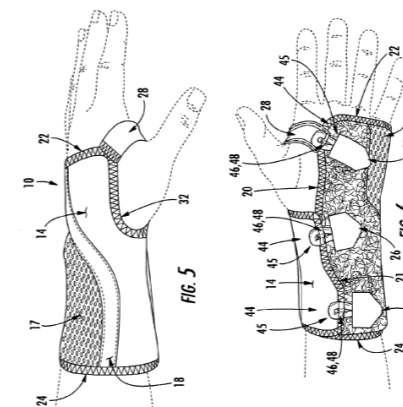


Figure 80 - US 2005/0197609 A1, Sep. 8, 2005.

"Wrist brace having twistable elements and method of using the same. A reversible wrist brace includes a sheet of flexible material that overlies and Supports a wearer's wrist."

Interesting aspects
Reversible design (inside out), attachment method

Interviews

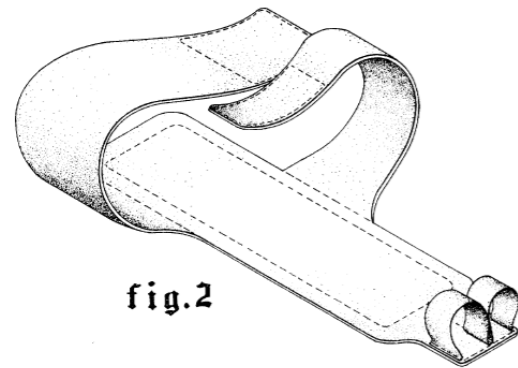


Figure 84 - Des. 270,556, Sep. 13, 1983.

"The ornamental design for a sports wrist brace, as shown."

Interesting aspects
Loops around fingers

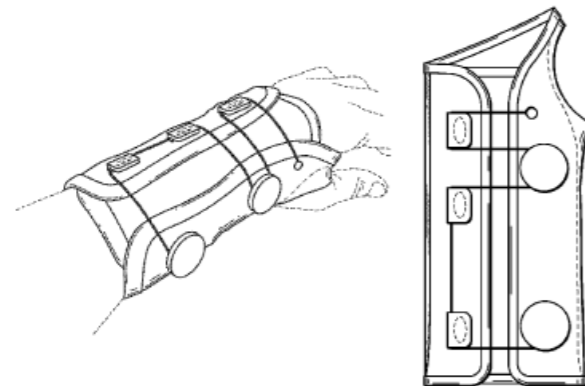


Figure 83 - US 2013/0240578 A1, Sep. 19, 2013.

"The ornamental design for a wrist brace, as shown and described."

Interesting aspects
Uses a string as attachment method

Interviews

Several different conversations have been organized with both specialists and patients. Two interviews with ET patients have been conducted, followed up with a series of conversations with ergotherapist during a parkinsons information meeting at the Sofia revelation centre in Delft on the 1st of May 2019 and a interview with "wearable designer". A short summery of each conversation is given.

Jan Douwe (24)

Jan Douwe has had his tremor since birth. It never restricted him from doing anything, since the tremor was not of an intensity that it became difficult to perform tasks for him. Nowadays he avoids handwriting as much as possible, which is not that difficult with most work being done on computers.

He never really experienced any difficulties with his tremor, although people used to joke about his handwriting on highschool. He is not that concerned about his future, he will just find out how the tremor will develop over time.

Jasper (43)

This interview was a follow up of an interview STIL had with Jasper in December 2018. In this interview more specific questions about everyday life, symptoms and needs have been asked (full interview in Appendix VII).

Jasper has an action tremor, making it very hard for him to do simple tasks. such as writing, drinking coffee, etc., because the tremor manifests itself the most during the coordination of a voluntary movement. His disorder is the result of a cerebral hemorrhage during birth. Jasper could not think of a life without tremors, it has always been this way. He would be worried if the tremor would all of a

sudden disappear, it became part of his personality.

The medication that Jasper uses is called Propanolol. (This is a betablocker that lower bloodpressure and heartrate, a positive side effect of this medicine is that it also reduces tremor of ET patients). He is in good control of his medicine usage, as he mentioned that against doctors prescriptions he sometimes adjusts his cure when he knows that a stressful event is going to happen (during a performance). He does not frequently visit the doctor, because there is no need or risk of progression of his tremor.

A reason to get the brace for Jasper, would be to be like everybody else. Always being the exception can be quite tiresome. Having stable arms would make life a lot easier during many social situations.

Jasper mentioned that he would love to have stable hands during activities such as, eating, cooking and doing hobbies.

Anneke

Anneke is a designer of wearable products and has been involved in the development of several projects that show many similarities to this project (nightbalance). During the conversation with Anneke some useful tips on how to properly design a wearable product were given.

When you are designing a wearable product less is usually more. Anneke stated that, when she is designing sports gear, sporters tend to prefer to wear as little as possible. In a ideal situation an athlete would feel "naked" while wearing a brace. It is thus needed to create an efficient design that smartly makes contact with the human body, optimizing the skin contact area. Anneke suggested to use pliable materials that form to the users body for better comfort and add padding on sensitive areas.

Interview Jasper - 27-3-2019

Naam: Jasper Coenraadts
Leeftijd: 40 jaar
Geslacht: Man
Werk: PKF Wallast, informatica

Symptomen

Doel:
Achterhalen hoe een patient omgaat met zijn symptomen en onderzoeken hoe een brace zou kunnen helpen met het verhelpen van deze moeilijkheden.

1. Wie helpt u met de activiteiten die niet meer lukken?

Er is nooit zonder geweest. Ik heb al 40+ jaar mijn tremor en heb dan ook leren leven met mijn trillingen. Eigenlijk kan ik dus alles wel, maar op mijn eigen manier.

2. Hoe ervaart u uw tremors? Hoe gedragen deze zich? (Vanuit een technisch perspectief; verandering over tijd en hoe snel, alleen in arm, moeite met bewegen van pols)

Hoe de tremor zich gedraagt is totaal willekeurig. Veranderingen gaan over uren en maanden. Vaak heb ik zelf niet door dat ik weinig/veel trillingen heb, maar krijg ik van mijn omgeving te horen dat de trillingen verandert zijn.

Er treden geen spontane veranderingen op.

Eerder gestelde vragen

// Bij welke handelingen ervaart u de meeste last van een tremor en in welk lichaamsdeel uit dit zich het meest?

// Wat kunt u nu niet meer dat u graag weer zou willen kunnen?

// Hoe beperkt het hebben van een tremor uw dagelijks leven?

Behandeling

Doel:
Achterhalen waarom een gebruiker voor een brace zou kiezen niet voor het gebruik van medicatie.
Achterhalen met wie de gebruiker contact heeft omtrent de behandeling.

3. Wat doet een neuroloog voor u?
Wat doet een huisarts voor u?

Ik bezoek bijna nooit de dokter of Neuroloog. Wel ga ik naar een psycholoog voor mijn epilepsie en mijn verleden met depressies.

Ik ben al lang geleden gediagnostiseerd en heb dus sindsdien slecht eens in de zoveel jaar contact bij een arts of neuroloog.

4. Heeft u contact met de verzekering? Hoe speelt deze een rol bij uw behandeling?

Nee niet echt.

5. Wat zou een rede zijn voor u om het product van STIL uit te proberen?

De brace zou handig zijn voor sociaal verkeer. Ik zou graag eens geen uitzondering willen zijn. Ik zou graag zelf willen kiezen of ik op val op juist niet. Daarnaast zou ik graag een oplossing voor mijn tremor hebben om een ander een plezier te doen.

Ook bij activiteiten als eten, koken en het uitvoeren van mijn hobbies lijkt het mij fijn om de brace te hebben. Zo heb ik moeite met het omslaan van bladmuziek in mijn koor. Zou graag willen dat andere niet rekening met mij hoeven te houden.

6. Bent u betrokken bij praatgroepen of andere gerelateerde patiënten groepen?

Naast ET heb ik door mijn hersenbloeding ook last van epilepsie. Ik ben niet betrokken bij een patient groep voor ET, wel ben ik actief bij een groep voor epilepsie patienten. Ik vind zelf dit probleem dan ook zwaarder dan de tremor.

Eerder gestelde vragen

// Wat doet u zelf om de trillingen tegen te gaan?

// Wat voor een behandelingen heeft u zoal geprobeerd?

// Wie geef u medische ondersteuning en vind u dat er genoeg tijd aan u wordt

besteed?
// Wat vind u van uw huidige behandeling? Zijn er bijwerkingen?
// Heeft u zelf weleens nagedacht over mogelijke oplossingen?

Product

Doel:
Vaststellen van nuttige functies en product eigenschappen.
Bepalen in welke situaties het product het meest gebruikt zal worden.
Vaststellen wat de gebruiker zou doen met het product wanneer deze niet bruikbaar is (lege batterij).

7. Wanneer u weet dat de brace maar 1 uur werkt op een volle batterij, welk moment van de dag zou u hier dan gebruik van maken?

Voornamelijk tijdens koken en het uitvoeren van mijn hobbies (zingen).

8. Zou graag hulp willen bij een eerste gebruik van het product?

Ja graag wel. Ik vind het niet erg om hulp te krijgen hierbij. Heb liever niet dat ik dingen fout doe. Ik weet niet zo veel van al die technologie af.

Heeft u wel eens moeite met nemen van uw medicatie voor het onderdrukken van uw tremor?(Zou u interesse hebben om feedback over uw tremor van het product te krijgen? Zoja, hoe zou u dat graag terug zien?)

Ik heb het best aardig onder controle. Soms neem ik wel wat extra als ik weet dat ik iets belangrijks heb (noemt als voorbeeld een optreden met zijn koor).

Extra informatie over de intentietijd van de tremor heeft Jasper geen behoefte aan.

Eerder gestelde vragen

// Wat vindt u van het dragen van een brace?

// Zijn er nog knelpunten of andere dingen waar u tegen aan loopt?

Verkoop

Doel:
Verkoop kanalen bepalen.
Kijken of een online verkoop platform potentie zou hebben.

9. Hoe blijft u op de hoogte van de ontwikkelingen omtrent tremors?

Mijn ergotherapeut heeft mij wel eens handige tips gegeven. (voorbeeld over een eierdop met zuignap)

10. Waar zou u kijken als u naar oplossing voor ET gaat zoeken?

Ik zou naar een huisarts/specialist gaan. Ik zou op prikborden of in probleem gerelateerd bladen kijken. Ik weet dat er een interessant tijdschrift voor WAOers is dat mogelijk interessant is.

Misschien is het goed om bij andere grotere paraplu groepen contact te zoeken. Dan kan je vanuit daar doorsijpelen naar kleinere doelgroepen.

Misschien contact zoeken met revalidatie centra (NAH)

11. Zou u een brace via een website durven aan te schaffen?

Ik zou graag het product eerst een keer vast houden. Ik vertrouw het internet niet genoeg hiervoor. Liever bestel ik geen medische apparatuur via het internet. Ik verkrijg iets dergelijks liever via een gespecialiseerde detailhandel (meditheek).

Eerder gestelde vragen

// Als we een soortgelijke brace maken om een tremor tegen te gaan, zou u bereid zijn deze zelf aan te schaffen?

Test

Doel:
Achterhalen of het de gebruiker lukt om zijn/haar hand door een cylinder met een diameter van 81 mm te stoppen.
Kijken of de gebruiker potentie ziet in het huidige concept.

Tijdens het tonen van het plaatje met de ring en ossur brace reageert hij positief. Wel is een van de eerste opmerkingen dat hij liever een onopvallend oplossing zou zien met minder opvallende kleuren. Op die manier past het beter bij hem.

Hij heeft zelf ook nagedacht over het gebruiken van hoesjes en andere manieren van het persoonlijk maken.

Interview Tom - 5-4-2019

Naam: Tom de With
 Leeftijd: 68 jaar 23-01-1951
 Geslacht: Man
 Werk: Pensioen (Voorheen Instrumentmaker TU Delft Natuurkunde)

Symptomen

Doel:
 Achterhalen hoe een patient omgaat met zijn symptomen en onderzoeken hoe een brace zou kunnen helpen met het verhelpen van deze moeilijkheden.

1. Wie helpt u met de activiteiten die niet meer lukken?

Geen hulp nodig

2. Hoe ervaart u uw tremors? Hoe gedragen deze zich? (Vanuit een technisch perspectief; verandering over tijd en hoe snel, alleen in arm, moeite met bewegen van pols)

Voornamelijk van mijn de linker arm. Vooral in groepen bij het tillen van bijv. koffie en gebak etc. last. In deze situaties ondersteunt Tom zijn linker arm met zijn rechter. Trilling wordt erger bij gespannen momenten, noemt tandarts als voorbeeld

Eerder gestelde vragen
 // Bij welke handelingen ervaart u de meeste last van een tremor en in welk lichaamsdeel uit dit zich het meest?
 // Wat kunt u nu niet meer dat u graag weer zou willen kunnen? -
 // Hoe beperkt het hebben van een tremor uw dagelijks leven? -

Behandeling

Doel:
 Achterhalen waarom een gebruiker voor een brace zou kiezen niet voor het gebruik van medicatie. Achterhalen met wie de gebruiker contact heeft omtrent de behandeling.

3. Wat doet een neuroloog voor u?
 Wat doet een huisarts voor u?

4 Jaar geleden gediagnostiseerd. Eerst contact gehad met verschillende doctoren. De eerste dokter verweet het aan ouderdom. Daarna een nieuwe dokter die hem doorverwees naar een fysio, welk hem vertelde dat het waarschijnlijk toch iets anders was. Toen in contact gekomen met de neuroloog welk hem vertelde dat hij Parkinsons had (er is een scan gemaakt ter bevestiging).

Tegenwoordig 1x per jaar lang de neuroloog. (Noemde dat hij niet graag zou wisselen van neuroloog.)

Oom van Tom heeft ook Parkinsons gehad, het zit in de familie.

4. Heeft u contact met de verzekering? Hoe speelt deze een rol bij uw behandeling?

5. Wat zou een rede zijn voor u om het product van Stil uit te proberen?

Tom neemt niet graag medicijnen en ziet dit als een goed alternatief.

6. Bent u betrokken bij praatgroepen of andere gerelateerde patiënten groepen?

Tom vermeed bewust praatgroepen etc. omdat hij niet graag geconfronteerd wordt met hoe de ziekte (Parkinsons) zich ontwikkeld bij andere.

VIII | APPENDIX

Questionnaire results

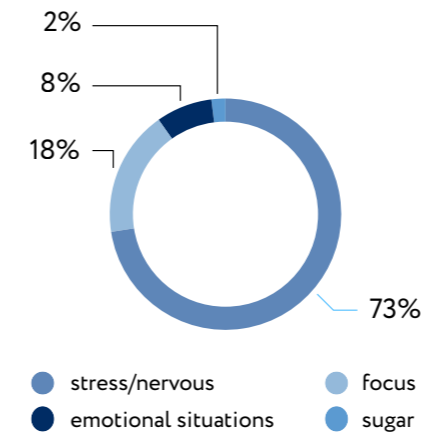


Figure 87 Tremor triggers. The questionnaire respondent have been asked to think about what situations or events trigger their tremors. Stress was seen as one of the most frequent reasons that triggered a tremor.

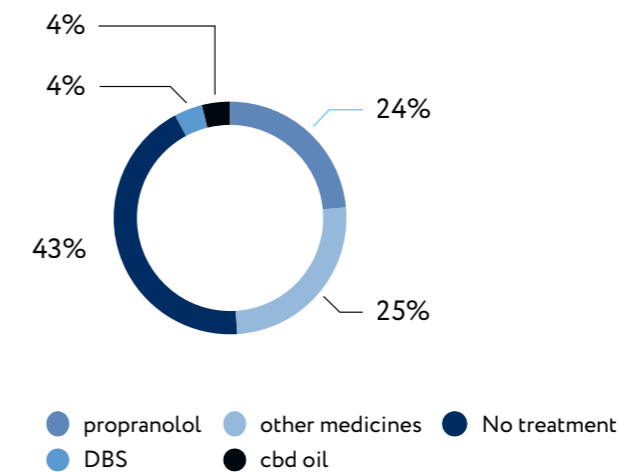


Figure 86- Treatment. Most frequently respondents replied that they were not using any medication. Half of the participants replied that they were using medication to suppress their tremors. Of these medications Propanolol was most common. The reason most participants are not using any medication is due to the severe side effects that these medications have. Some of the respondents mentioned that medication gave the a restless feeling and made them aggressive.

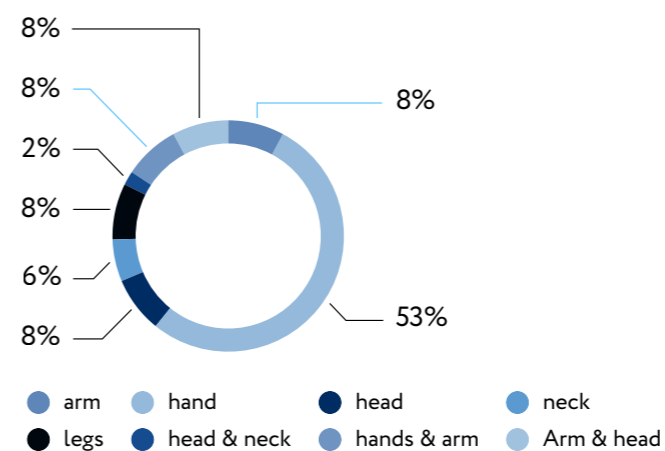


Figure 85 The participants have been asked at what spot they experienced the most prevalent tremors. A pie chart has been made to create an overview of what the most frequent tremor locations are. It can be seen that having a tremor in the lower extremities (hands) is the most frequent location. It should be noted that patients often mentioned to have a more severe tremor in either their left or right hand.

Questionnaire remarks

Complaints about social situations

“People often do not know what an essential tremor is, but are very interested about how you cope with it and what causes the tremors.”

“The tremor increases with stress, fatigue, during emotional situations (also while experiencing happiness) and during my menstruation.”

“My tremor usually gets worse when I try to stop it. For example when I am visiting the barber or dentist.”

“When I relax and take some time for myself my tremor usually decreases. I put my hand on my belly and try to make contact with my inner peace. Whenever I think about my shaky hands, tremor intensifies. Also, in the morning my tremor is worse than during night times.”

“My tremor decreases whenever I go for a walk or have a good conversation.”

“The most social awkward situations occurred when I was still going out a lot (about two years ago). I always felt like everybody was looking at me.”

“My most awkward experiences were when I just started to get my tremor. I got ashamed and angry on myself, because I tried to avoid social contact with people.”

The most awkward period of my life was during my puberty. When you start going to bars and your social network increases, you will need to explain your tremor time after time. Often I have to slurp out of full glasses, that is something I am very ashamed of.”

“I don't like it to be with people I don't know.”

General remarks about living with a tremor

“Tremors are most annoying whenever I stretch my arms with my palms faced upwards. Think of situations where I have to carry a cup of coffee or a small plate.”

“Tying my shoelaces is very difficult for me, also grabbing something of the ground or paying in a shop are difficult tasks for me to fulfill.”

“Fine motoric skills such as brushing the teeth of my son or typing long texts at work are difficult.”

Solutions that help patients to cope with their tremors

“I usually ask for a straw when I order a drink. Also I use my right hand when eating with a fork, cause this hand is a little more stable. When I try something difficult (stringing beads to a cord) I often just stop and try again on a different moment when my tremors are less severe. During receptions I often do not drink.”

“I grab glasses with two hands. I can't stop it, they try to suppress it, it will only make it worse.”

“Breathe slowly and focus on the part I want to move. In extreme cases it stabilizes one hand with the other hand.”

“Curse in silence and continue with what you are doing.”

“Avoid all social contact, but I can't really do that all the time. As a human I still have sort of a life.”

Activities patients would love to do again

“I would love to be able to go to receptions without already being nervous beforehand about what I should eat/drink.”

“I would love to be a social person again, nowadays I keep on the background a little because I have such severe tremors.”

“I feel restricted by my tremors. I don't spontaneously decide to visit somebody anymore.”

How others respond on their tremors

“Dependent per person, but most people don't believe that it is a disease (even my friends sometimes say that I should stop shaking that much).”

“People who know me will help me, others who don't know what I have will usually ask why I am shaking that much and will tell me that I look nervous.”

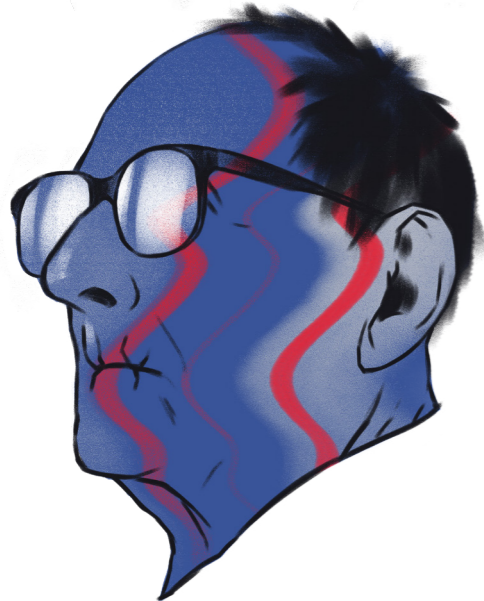
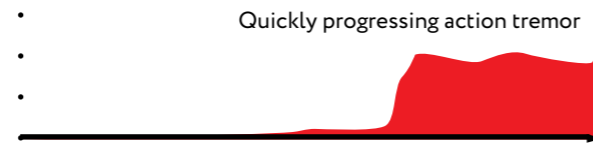
Persona's



The "Gosh, tell me more!" woman

Age | 42 Occupation | Graphic designer
Interests | Modern art, Field hockey, cooking

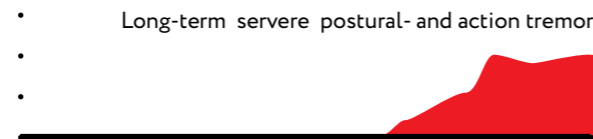
"I started experiencing a tremor in my fingers a few years ago, since then it quickly progressed in my hands and arms. I am experiencing difficulties with fullfilling my daily work nowadays." **



The "Thank god, finally a solution." man

Age | 70 Occupation | Retired Lawyer
Interests | Cars, technology, politics

"I often think about the days that I stil had stable hands lately. I have been considering getting DBS, but I am a little scared for the side effects. This option looks great to me!" **



Additionally to the information of the personas identity, a curve showing how a tremor can possibly progress over a life time was added. This wass done to help creating an understanding of how much the sudden appearance or lifelong presence can affect its users. How a tremor progresses over a life can be of influence for a patients choice of looking into solutions.

Overview of actor responsibilities

Actor group	Actor	Responsibility
Non- Human actors	Medicine	Reduce tremor symptoms
	Alternative medicine	Relax patient Reduce tremor symptoms
	Supportive devices	Reduce tremor symptoms Give support when needed
Social actors	Friends	Monitor general wellbeing of patient Undertake fun activities
	Family	Provide primary care support Monitor general health of patient Undertake fun activities Provide mental support
	Coworkers	Monitor general wellbeing of patient Help with daily activities
Healthcare actors	Strangers	Give patient an uncomfortable feeling Tend to ask weird questions to patients Give care advise Help with daily activities
	Caregiver	
	General Practitioner	Diagnose Write recipes for patient Give psychological support Monitor health Evaluate progression of symptoms
	Neurologist	Diagnose Monitor health Give treatment advise
	Physiotherapist	Gives advise and designs tools Give advise to GP and Neurologist Evaluate progression of symptoms
	Ergo-therapist	Exercise with patient Increase mobility of patient Evaluate progression of symptoms Communicates with other specialists
Supportive actors	Researcher	Evaluate symptoms for research Come with potential solutions
	Students Insurance	Learn about disease & Contact patients for questions Gives financial advise about treatments Gives psychological support
Distributors	Support groups Online platform	Gives advise about treatments Gives psychological support
	STIL BV Pharmaceutical companies	Deliver effective products Deliver effective products

PJM

Timeframe

This patient Journey map makes use of a lengthy time frame. Taking into account that usually an ET tremor gets more progressive over the span of a life, a timeframe of many years was used (blue line). Some key moments during the use and purchase of a brace have been worked out on a more detailed level (red line). Since there is no current product, or any other product that is comparable with the STIL brace, a hypothetical series of events is suggested

after the purchase of the STIL brace.

User

The series of events are based on the conversations with tremor patients and the Questionnaire conducted by STIL. Only key events that have a great impact on the emotion of the user have been included.

The involved actors and painpoints relate to the

involvement and interdependency overview in Figure 5. The timeline shows how and when the patient comes in contact with other actors.

The emotions as they are currently depicted are a possible reaction to the events that the patient is experiencing. The emotions have been included to get an overview of the user experience during the chosen timeframe. As a guide for selecting fitting emotions the emotion toolkit provided by Desmet (2002) was used.

Product

The described features in the product section are use cases and experiences that the patient is hav-

ing during the events. The actions lead to desired product assets. The assets as described in the patient journey map give examples of useful product features that can add value to the product.

The journey

Making a short hypothetical storyboard helped to create an understanding of the events, emotions and thoughts that the user experiences. The storyboard can be found in Appendix XVI.

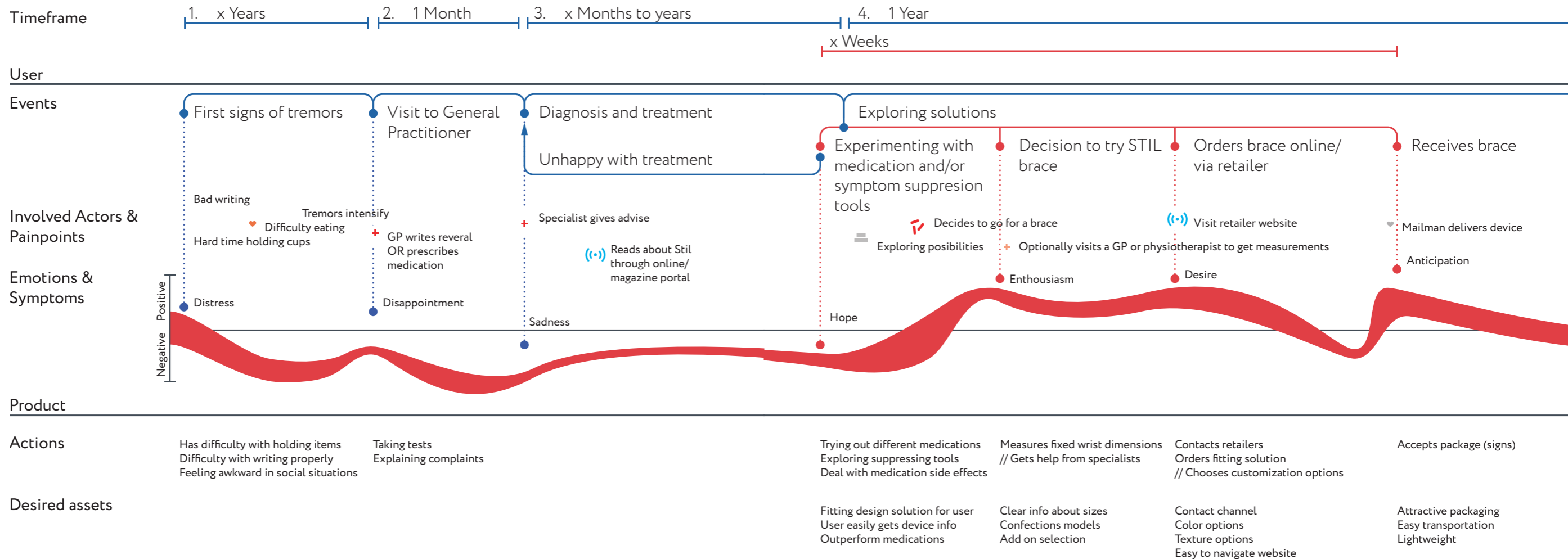
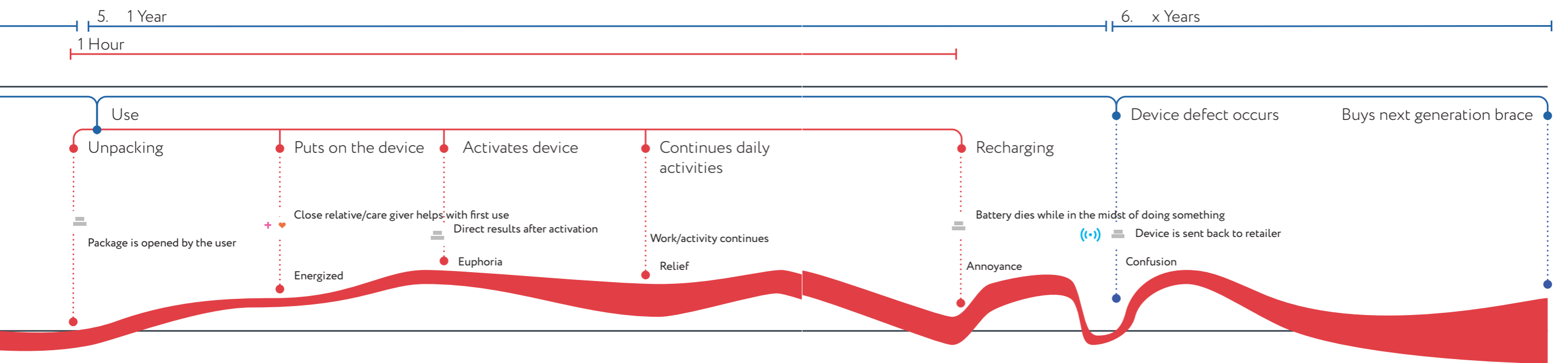


Figure 88 Patient Journey map



The package is opened by the user
User finds manual and reads it

Brace is put on only by the user
// Together the brace is put on

Pushes activation button
Reacts to force applied by device

Work
// Use case scenarios

Remove device
Store device
Clean parts

Send back device

Clear user instructions
Easy to open packaging
'Plug and play' device

Clear user instructions
Easy to open packaging
'Plug and play' device
Can be put on by user

// Use case analysis

// Use case analysis

Battery live indication
Storage equipment
Easy to clean after use

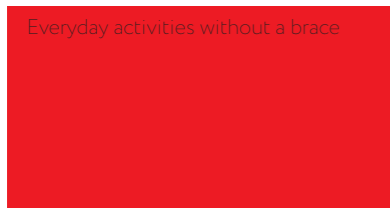
Indication of defects
Easy contact channels
Quick repair service

Legenda:

- Longterm
- Shortterm
- Event
- Related emotion

Use case analysis

As a part of the user analysis, an use case analysis was made. This was done in order to discover what kind of tasks the brace eventually will need to fulfill.



Doing groceries

Getting wallet out of pocket
Tapping/dipping debit card
Picking coins out of wallet



Dining and eating food

Picking up food
Using a spoon for soup
Putting food into the mouth



Holding a cup

Clamping mug handle
Putting hands around a cup
Move cup without spilling



Driving car and bike

Clamp hands around steering wheel
Push small button on dashboard
Navigate through traffic



Picking up small things

Reach out to pick up part
Pinch fingers together



Precise movements
Making little strokes and wipes
Avoid touching sensitive body parts



Brushing teeth

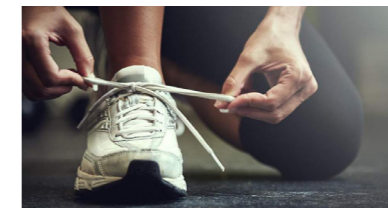
Repetive back and forth movement
Applying toothpaste on toothbrush



Shaving



Squeezing and using force



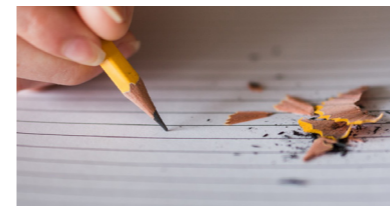
Tying shoe laces

Picking up laces
Pinching chords and applying force
Making precise movements



Fine cutting works and embroidery

Complex movements
Opening and closing of the hand



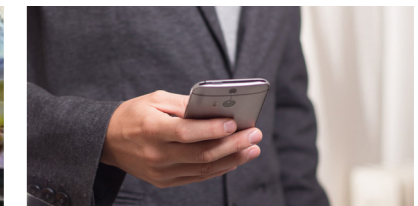
Writing

Many repetitive complex movements
Applying precise force on paper



Making art

Need of good hand eye coordination
Making precise movements



Using a tablet and holding a phone

Picking up phone from flat surface
Prevent phone from falling
Typing, swiping and other gestures

First use



Unpacking
Breaking seals
Tearing open packaging material



Reading manual
Easy to read
Flipping pages
Digital version with videos and sound



Assembly of separate parts
Putting the brace together
Insert battery etc.



Charging the brace
Placing brace on charging pad
Insert charging cable
Find power supply

Day to day use

Putting on the brace
Slide brace over wrist
Tighten parts

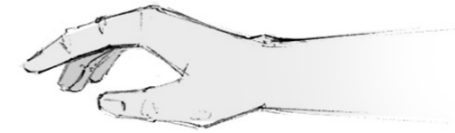
Turning on the brace
Activate brace with command/action
Tremor is stabilized

Recharging the brace
Charge at work with
Charge at home

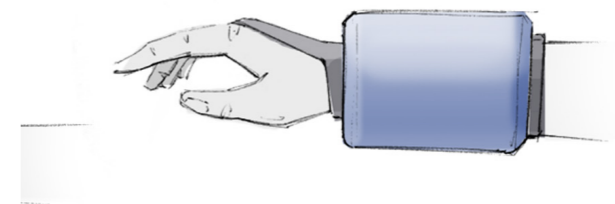
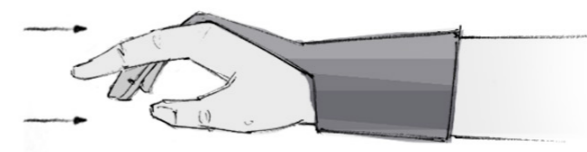


Adjusting settings
Touch buttons/ screen
Feedback to user

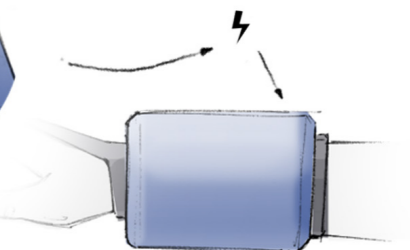
Turning the brace off
Give the turn off command
Push button
Tremor in arm returns



Taking off the brace
Loosen brace
Done with unstable hand



Cleaning the brace
Disassemble parts
Wipe parts
Put 'dirty' parts under faucet



Deep cleaning
Put parts in washing machine
Open brace and clean components
Replace damaged parts with spares

Storyboard

1. The user, in our case called X, has been having difficulty with writing lately. X notices that when he is trying to keep his hand STIL, a slight tremor occurs. It's frustrating since he does not know what it is, but it definitely makes it hard to take notes during work. At first he blames it on many things, but when he realizes the tremors do not stop and only progress for the worst, he decides to visit the doctor. He wants to know what is going on.

2. He makes an appointment to visit the general practitioner and is welcome to come the week after for a consult. The GP is legally allowed to diagnose and prescribe medication, since it is clear that X is showing symptoms of a tremor. X is shocked as has to get used to the fact that he has to live with a tremor. He is not looking forward to be dependent on medication.

3. X is getting annoyed off all the side effects of the medication. After a few months and different combinations and dosages of medications later, he decides to get experimental. He tries a CBD oil, since he read online that this could help against many ailments, including tremors. No much succes, online a numb feeling is what X experiences with these ointments and homeopathic medications. He now has contact with a neurologist who understands the difficulties of medication. He suggests to look at something new, the STIL brace.

4. X is positive about the new suggestion that was made by the neurologist (or somebody else) and goes to the website. After choosing the right size he orders the brace. He really is looking for to receive the brace at home!

5. The first X wants to do when he receives the package is to try out the brace. He has been waiting for

the brace patiently. After struggling with putting on the brace for the first time, he is finally ready to put test the new solution. Amazed and surprised about how the brace feel and works, he tries to write a few works. X is impressed.

6. X dropped the orthosis from his desk. Now the product makes a weird noise while wearing it. The product is send back for maintenance. Maybe a next generation is available soon?

Degrees of freedom

Joint	Movement	Dempster	Houy	Schnelle	AAOS*	ISOM**
elbow	flexion	142 (10)	138 (7)	130-140	150	150
	extension	0 (0)	0 (0)	0	0	0
forearm	supination	113 (22)	107 (17)	70-85	80	90
	pronation	77 (24)	65 (13)	60-80	80	80
wrist	ulnar abduction	47 (22)	31 (5)	70-85	80	90
	radial abduction	27 (9)	22 (5)	60-80	80	80
	palmar flexion	90 (12)	68 (10)			
	dorsal flexion	99 (13)	62 (9)			

Table 10 Range of motion for different movements in the upper extremities. As the can be seen in the table many variations exist between measurements due to different set ups and measuring standards. Vaart (1995) suggests to use the numbers from the AAOS (*American Academy of Orthopaedic Surgeons) and ISOM (**International Standard Orthopaedic Measurements) for extremities, because of the large variety of age and physical build between each individual. Adapted from Vaart (1995).

Orthosis design principles

Principle	Implication
1. Understanding the force systems	Know when to use three-point orthotic designs and when to use two-point pressure orthotic designs.
2. Increase the area of force application	Wider orthotic components decrease pressure and increase comfort.
3. Increase mechanical advantage	Longer orthotic components decrease pressure and increase comfort.
4. Use optimum rotational force	Application of corrective force is most efficient at a 90-degree angle.
5. Consider torque effect	The further away from the main focus joint a force is applied, the greater the torque on that joint will be. Be careful to not exceed tissue and/or pain thresholds.
6. Control reaction at secondary joints	Prevent subluxation of joints proximal and/or distal to the primary focus joints within longitudinal rays.
7. Consider reciprocal parallel force effect	- Middle reciprocal pressure in a three-point pressure orthosis equals the sum of proximal and distal forces. Monitor the area under middle-reciprocal-pressure components carefully for soft tissue breakdown.
8. Use appropriate outrigger systems	- Outriggers must be of sufficient strength to support pull from traction devices (for example, rubber bands). - As joint motion changes alter outrigger length to maintain a 90-degree angles of pull. Carefully align orthosis joints/hinges with corresponding anatomical joints.
9. Incorporate articulated components appropriately	
10. Increase material strength through contour	Contoured material provides strength to orthotic components.
11. Eliminate friction	- Eliminate orthosis slippage or 'pistoning' on the extremity as clients move. - Design orthosis according to key skin creases to ensure that orthotic material does not impede desired joint motion.
12. Avoid shear stress	- High shear stress causes soft tissue breakdown. - Monitor extremity for pressure from orthosis edges. - When possible, widen narrow components that contract the extremity. - Monitor soft tissue beneath narrow orthotic components.

Table 11 Range of motion for different movements in the upper extremities. As can be seen in the table many variations exist between measurements due to different set ups and measuring standards. Vaart (1995) suggests to use the numbers from the AAOS (American Academy of Orthopaedic Surgeons) and ISOM (International Standard Orthopaedic Measurements) for extremities, because of the large variety of age and physical build between each individual. Adapted from Vaart (1995).

Potential brace contact points

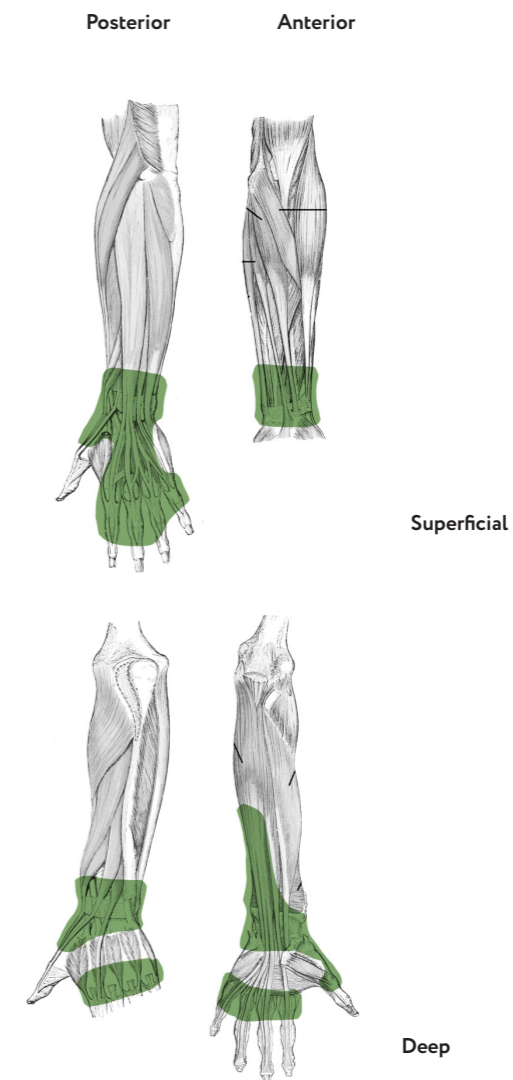


Figure 89 An analysis of potentially interesting points of connection to the skin was made by looking at the anatomy of the human arm. Points that are potentially interesting contact points have been marked blue.

Anthropometric data overview

Wrist circumference	Research	ethnicity	gender	n	mean (mm)	SE (m)	S.D.	SE	v(%)
	Jee, Yun (2015)	Korean	m	167	175.8			10.9	6.2
	Jee, Yun (2015)	Korean	f	154	156.2			8.9	5.7
	Reckelhoff et al. (2015)	USA	m	51	174.3			11.7	6.7
	Reckelhoff et al. (2015)	USA	f	31	150.7			6.7	4.4
	White (1980)	USA, Air control trainees (1961)	m	680	176	0.02		11.4	0.02
	White (1980)	USA, USAF Flying pers. (1967)	m	2420	175.8	0.01		9.1	0.02
	White (1980)	USA, USAF Basic Trainees (1952)	m	3326	174.5	0.01		10.2	0.01
	White (1980)	USA, USAF Women (1968)	f	1905	149.6	0.01		7.1	0.00
	White (1980)	USA, US Army Women (1977)	f	1331	147.1	0.01		6.9	0.01
	White (1980)	USA, US Army Women (1946)	f	8112	147.1	0.00		8.1	0.00
	Fallahi (2011)	Filipines	Athletes	40	180.2			9.1	5
	Fallahi (2011)	Filipines	Non-athletes	40	172.3			8.6	5
Wrist breadth		Sudanese	m	100	55.9			5.4	9.7
		Sudanese	f	100	49.2			3.6	7.3
	Jee, Yun (2015)	Korean	m	167	61			3.0	4.9
	Jee, Yun (2015)	Korean	f	154	55.4			3.5	6.3
	Reckelhoff et al. (2015)	USA	m	51	60.1			4.3	7.2
	Reckelhoff et al. (2015)	USA	f	31	52			2.6	5
	Imrhan (1993)	Americans of Vietnamese origins	m	41	64.1			5.7	8.9
Wrist depth	Reckelhoff et al. (2015)	USA	m	51	60.1			4.3	7.2
	Reckelhoff et al. (2015)	USA	f	31	52.3			2.6	5
forearm circumference	Fallahi (2011)	Filipines	Athletes (m)	40	289.2			14.9	5.15
	Fallahi (2011)	Filipines	Non-athletes (m)	40	266.6			15.8	5.93
hand diameter	Sneyder (1977)	NL	male 10 y	134	59			4	6.8
	Sneyder (1977)	NL	male 11 y	143	62			5	8.1
	Sneyder (1977)	NL	male 12 y	78	64			4	6.3
	Sneyder (1977)	NL	female 10 y	136	59			4	6.8
	Sneyder (1977)	NL	female 11 y	151	61			4	6.6
	Sneyder (1977)	NL	female 12 y	79	n.d.			4	
	Stil (2019)	NL	m	21	77.7			3.9	5
	Stil (2019)	NL	f	14	69.9			5.5	7.9

hand breadth	Sneyder (1977)	NL	male 10 y	134	71			4	5.6
	Sneyder (1977)	NL	male 11 y	143	73			4	5.5
	Sneyder (1977)	NL	male 12 y	78	74			4	5.4
	Sneyder (1977)	NL	female 10 y	136	69			4	5.8
	Sneyder (1977)	NL	female 11 y	151	71			4	5.6
	Sneyder (1977)	NL	female 12 y	79	72			5	6.9
	Stil (2019)	NL	m	21	84.9			3.0	3.5
	Stil (2019)	NL	f	14	74.3			4.0	5.4
	Dined (2004)	NL	m (31-6)	-	91			4	4.4
	Dined (2004)	NL	f (31-60)	-	81			4	4.9
	Dined (n.d.)	USA	m	-	85			3	3.5
	Dined (n.d.)	USA	f	-	75			5	6.7
	White (1980)	USA, USAF Flying pers. (1967)	m	2420	88.9			4.1	4.6
	White (1980)	USA, USAF Basic Trainees (1952)	m	3326	87.4			4.6	5.3
	White (1980)	USA, USAF Women (1968)	f	1905	75.4			5.8	7.7
	White (1980)	USA, US Army Women (1977)	f	1331	78.2			3.8	4.9
	White (1980)	USA, US Army Women (1946)	f	8112	75.4			5.1	6.8
Hand circumference	White (1980)	USA, USAF Flying pers. (1967)	m	2420	215.6			9.4	4.4
	White (1980)	USA, USAF Basic Trainees (1952)	m	3311	214.9			14.7	6.8
	White (1980)	USA, USAF Women (1968)	f	1905	183.1			9.1	5
	White (1980)	USA, US Army Women (1977)	f	1331	184.4			8.6	4.7
Hand length	Dined (n.d.)	USA	m	-	190			9	4.7
	Dined (n.d.)	USA	f	-	170			9	5.3
	Dined (2004)	NL	m	-	194			10	5.2
	Dined (2004)	NL	f	-	179			8	4.5
	Fallahi (2011)	Filipines	Athletes (m)	40	212			14.7	6.9
	Fallahi (2011)	Filipines	Non-athletes (m)	40	203			8.6	4.2
Palm length	Fallahi (2011)	Filipines	Athletes (m)	40	122			10.4	8.5
		Filipines	Non-athletes (m)	40	118			5.9	5

Script for GPA analysis by Toon Huysmans:

```

from vtk.util import numpy_support
pdi = self.GetPolyDataInput()
pdo = self.GetPolyDataOutput()
pdo.DeepCopy(pdi)
meanPts = mean([numpy_support.vtk_to_numpy(pd.Points)
for pd in inputs], 0)
pdo.GetPoints().SetData(dsa.numpyToVtkDataArray(meanPts,
"Points"))
    
```

List of requirements

Goal	Sub function	Requirement
1. Facilitates forearm damping.	1a. Brace transfers antivibrations generated by the exshell to the user.	1a1. The brace does not change location on the users skin during a corrective force from the exshell. 1a2. Antivibrations generated by the exshell are not hampered in in any direction.
	1b. Brace allows clear force measurements by sensors.	1b.1 The sensor does not slide or move on or over the skin during use. 1b.2 The brace minimizes sliding of the product on the skin during use. 1b.3 No movement of the exshell is possible when exshell is attached to the brace. 1b.4. The brace prevents sliding by using friction and/or a form fit solution.
2. Is comfortable.	2a. (Beta) Product is compact and light weight.	2a. (Beta) Product does not weigh more than 350 grams. 2b.1 Brace can be worn a full workday (8 hours) without causing irritations to the user.
	2b. Brace does not irritate skin after being worn for a long period of time.	2b.2 Product can be worn on hot days (30 degrees Celsius) without causing noticable discomfort. 2b.3 The product allows produced sweat to evaporate. 2b.4 The brace absorbs produced sweat in order to prevent skin irritation. 2b.5 Product does not get warmer than 40 degrees Celsius.
	2c. Brace takes arm deformation during movements into account.	2c.1 Used materials do not cause shear forces on the skin during movements. 2c.2 Used materials do not cause stress concentrations on the skin during movements.
	2d. Brace produces as little unwanted forces on the skin as possible.	2d.1 Brace exerts minimal pressure on the lower part of the wrist close to the carpal tunnel. 2d.2 Brace minimizes shear forces around the edges of the brace. 2d.3 The brace avoids contact with areas where little tissue is found between bone arm skin (styloid process of ulna).
3. Is easy to use.	3a. Can be put on by an ET patient.	3a.1 Product can be put on while having severe tremors (type 3) within 20 seconds. 3a.2 Small product parts can be handled by an ET patient without extra needed tools.
	3b. Brace can be cleaned.	3b.1 Brace parts that have direct skin contact can either be washed in a washing machine or cleaned with a damp cloth. 3b.2 No gaps or holes that can collect debries are present in the product.
	3c. The Brace is compact	3c.1 Product can be stored in a small bag of 40 x 30 x 18 cm (Eastpack dimensions). 3c.2 Brace can be stored in a storage bag.
	3d. Product communication is easy to understand.	3d.1 Product clearly communicates signals to the user in compliance with the medical regulations for a 2a certification ^o . 3d.2 Use cues and instructions meet up to medical regulations for a 2a certification ^o .
4. Is non-obtrusive.	3e. Brace can be worn underneath clothing	3e.1 The product does not have any sharp corners on the outer side. 3e.2 The brace can be worn underneath a shirt.
	4a. Product has a design that fits the lifestyle of the target group.	4a.1 Product has a design that can be adapted for special occasions. 4a.2 The product uses colors and shapes that are neutral. 4a.3 Product does not have exposed electronics. 4a.4 Product information (serial number, ce marking) is not distracting.
	4b. The product should not restrict the user from making and movements.	4b.1. Product allows the user to use his/hers hands while resting them on the table. 4b.2 Product allows the user to use his/hers hands while making small repetitive movements. 4b.3 The brace should not limit any of the movements that can be made in the forearm.
	4c. Product is silent.	4c. Product produces white noise sound (almost silent).

5. Is a safe to use device.	5a. The products materials comply to the requirements needed to meet medical 2a regulations.	5a.1 The used materials have to be non-toxic and non flammable. 5a.2 The used materials will have to take into account the compatibility with biological tissues, cells and body fluids. 5a.3 The product will have to meet with any defined chemical or physical specification.
	5b. The products design complies to the requirements needed to meet medical 2a regulations.	5b.1 The risks posed by parts wearing, degradation or processing residues is reduced as much as possible. 5b.2 Product avoids user from getting unintended cuts or pricks. 5b.3 Allows easy and safe handling. 5b.4 The product will have to be able to come in contact with materials, liquids and substances (during normal conditions) without causing dangerous situations. 5b.5 Product minimizes the risk of explosion or fire or any unwanted heat during use. 5b.6 Product can be safely and effectively adjusted, calibrated and maintained. 5b.7 The product will have to be designed according to ergonomic principles. 5b.8 Errors likely to be made during (re)fitting are made in impossible by design or construction 5b.9 Accesible parts shall not attain potentially dangerous temperatures under normal conditions of use.
6. Can be used by almost all	5c. Used signals in the product, labels and symbols comply to the requirements needed to meet medical 2a regulations.	5c.1 The function of the controls and indicators shall be clearly specified on the devices. 5c.2 The information and instructions provided by the manufacturer shall be easy for an unexperienced person to understand and apply. 5c.3 The name or trade name of the product. 5c.4 The lot number or the serial number of the device preceded by the words LOT NUMBER or SERIAL NUMBER or an equivalent symbol, as appropriate; 5c.5 The date of manufacture 5c.6 Warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device, and to any other person. 5c.7 An indication that the device is a medical device. If the device is intended for clinical investigation only, the words 'exclusively for clinical investigation';
	6a. The brace has an ergonomic shape and dimensions.	6a.1 Brace shape complies with shapes as determined in Figure 18. 6a.2 The ex shell has a inner diameter of 82 mm 6a. 3 Can be worn by users with CD between P5 mf and P95 mf (Table 2) 6b. The brace has a scalable parametric design.
7. Can be produced for the estimated target market.	6b. The brace will be delivered in different sizes.	
	7a. Production costs do not get to high.	7a. Production costs of product do not exceed 25% of estimated sales price of 3000 euros per product.
8. Is durable.	7b. The beta product can be produced for the estimated innitial target market.	
	8a. Product is scratch resistant 8b. Product can withstand unintended use 8c. Product	8a. Product parts that can be in contact with surfaces or objects has a scratch resistant coating or material. 8b.1 Product can withstand a fall of the table. 8b.2 Product has an idle state for energy saving

Table 12 List of goals, sub functions and derived requirements.

Morphological map

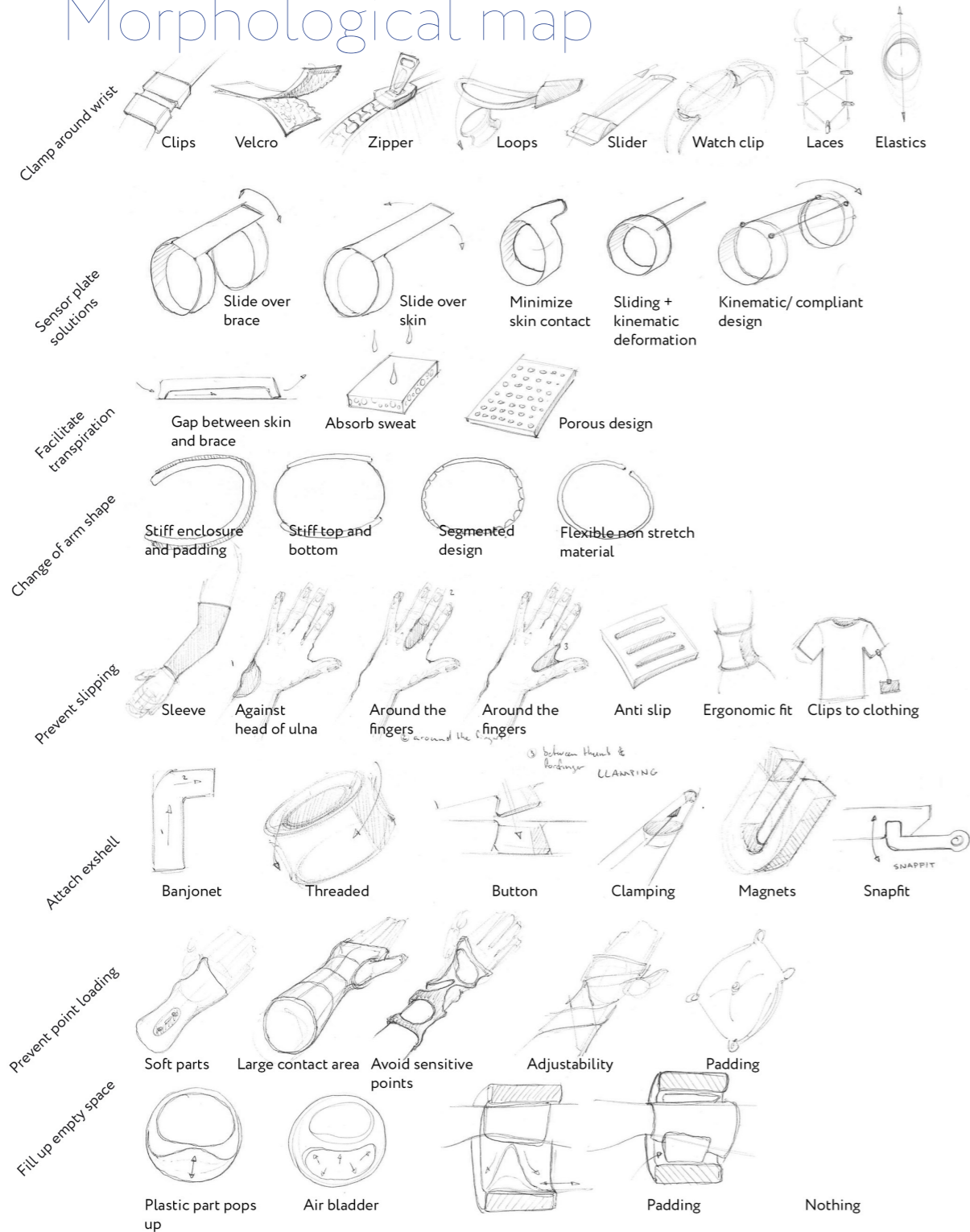


Table 13 Morphological chart.

Embodiment goals

The embodiment phase aims to create a series of prototypes that can be used for the validation and improvement the suggested brace concept and overall (aesthetic) experience of the product. The embodiment phase has been split up into several different sections in order to make it possible to test each of the main goals of the product. With the results of the evaluation sessions improvements can be suggested for the future development of the product. Each test and the goals it is trying to solve are shortly described below. The results will be discussed in the evaluation and validation part.

Test 1: Ergonomics and comfort

A set of different sized braces has been made to test if people with large and small forearms can use the product. Different types of tests including short and longterm use test with and without the exshell have been conducted. Information about the determination of the sizes can be found in section 4.2.

Test 2: Force translation and force readings

By making a functional prototype it can be tested if the force sensors can measure the direction and magnitude of a forearm tremor. This prototype was developed together with the engineers of STIL, so that it directly could be used for the development of the product. More information about the technical specifications can be found in section 4.3.

Test 3: User experience and aesthetic appearance

The product has been evaluated on its looks and functions in order to discover what the targeted user thinks of the aesthetics and proposed use of the product. A colour, material and finishing study was done to discover desired aesthetic appearances of the product. This test aims to find a design language that can be used for the future product

(beta). The initial project goals initiated the idea of designing an embodiment for the Alpha 2. This has been dismissed, since this product prototype still contains a lot of elements that are too bulky and in an very early phase of development. It would make no sense to use this prototype as a reference for the future product. Putting effort in making a design language that suggests the looks and use scenario of the Beta product would more information about the desired final product.

FEA Analysis

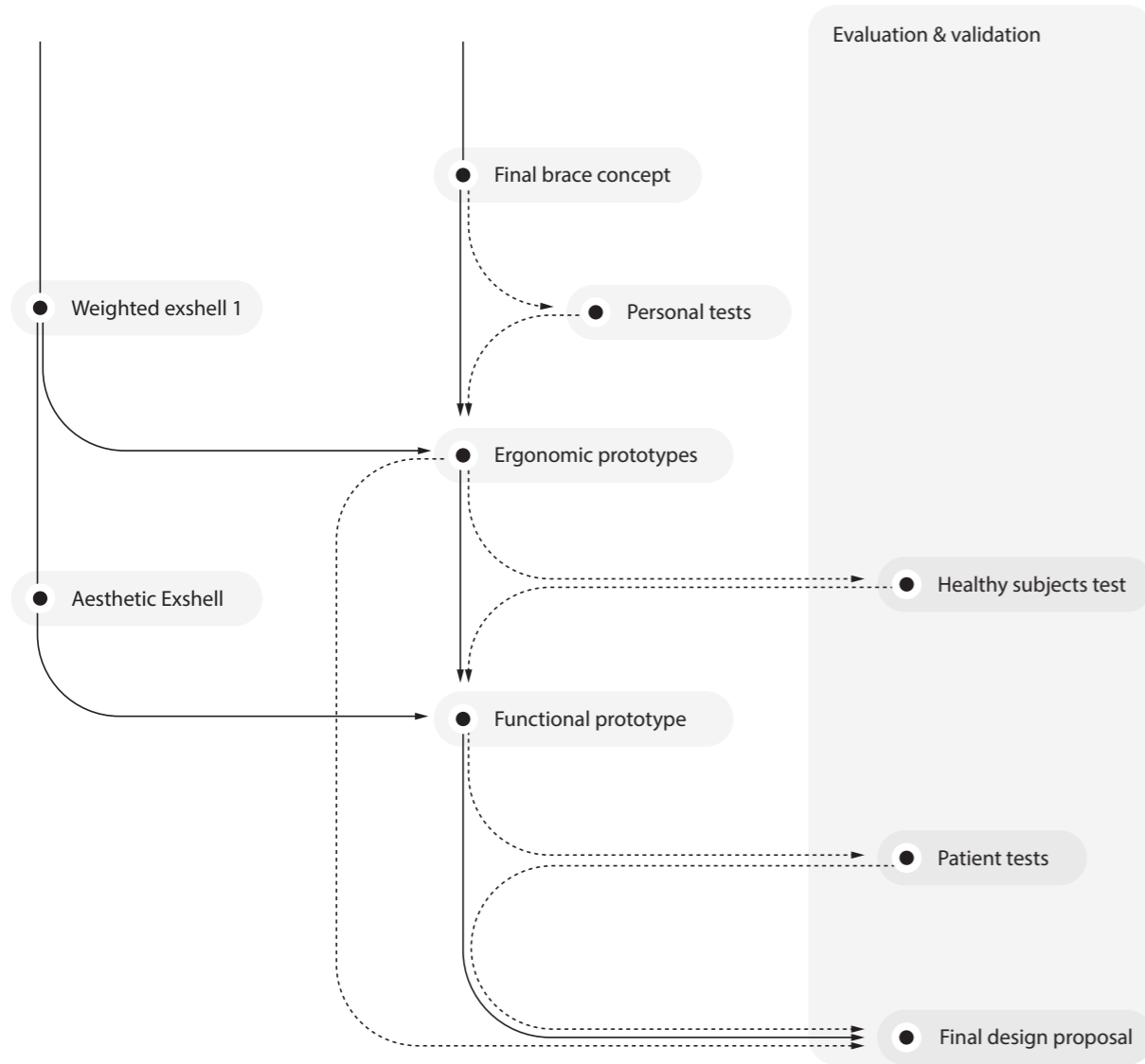


Figure 91 The flowchart shows the prototyping and evaluation process. The results of the tests performed with the prototype have been used for the validation and evaluation of the product. As can be seen in the chart, the exshell is introduced in this section.

The build in simulation tool of Solidworks was used as a tool to validate and improve the design of the force sensor. A force of 100 N was applied in different situations to ensure that stress concentrations occurred on the right location and no yielding in the material would occur. The chosen material was Aluminum 7075, a high grade material that was available at STIL.

The following images show the stresses (von Mises) within the force sensor body and the resulting deformation of the applied load for each different situation.

The yield strength of AL7075 is $9.5 \cdot 10^7 \text{ N/m}^2$, it can be seen that in none of the situation any yielding occur, while showing stress concentrations around the desired spots.

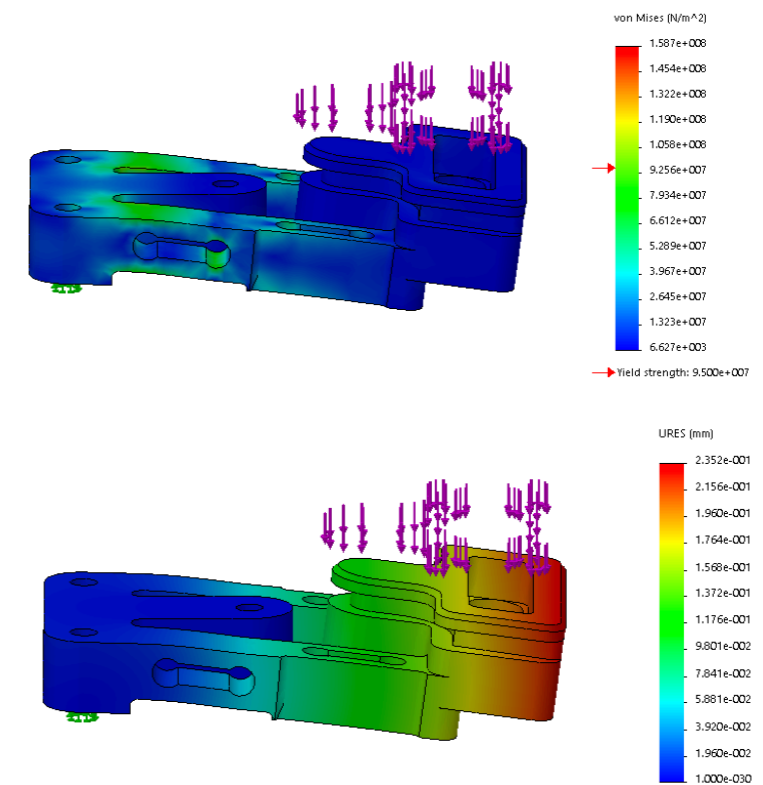


Figure 92 Vertical loading

Production drawing Force Sensor

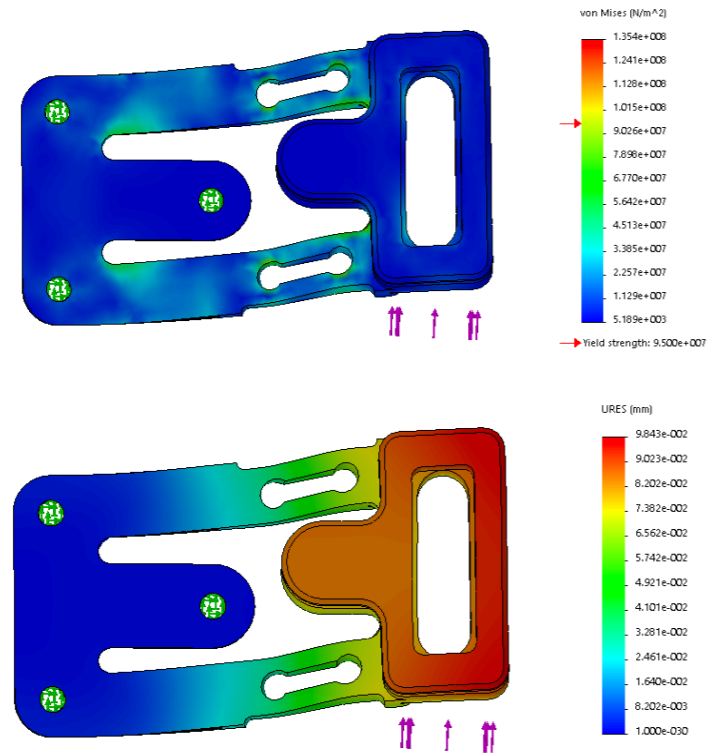


Figure 93 Horizontal loading

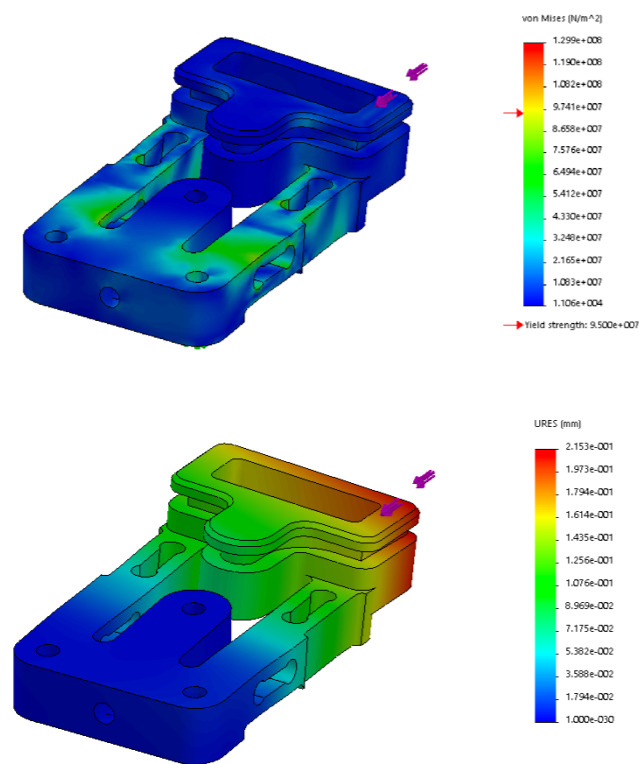
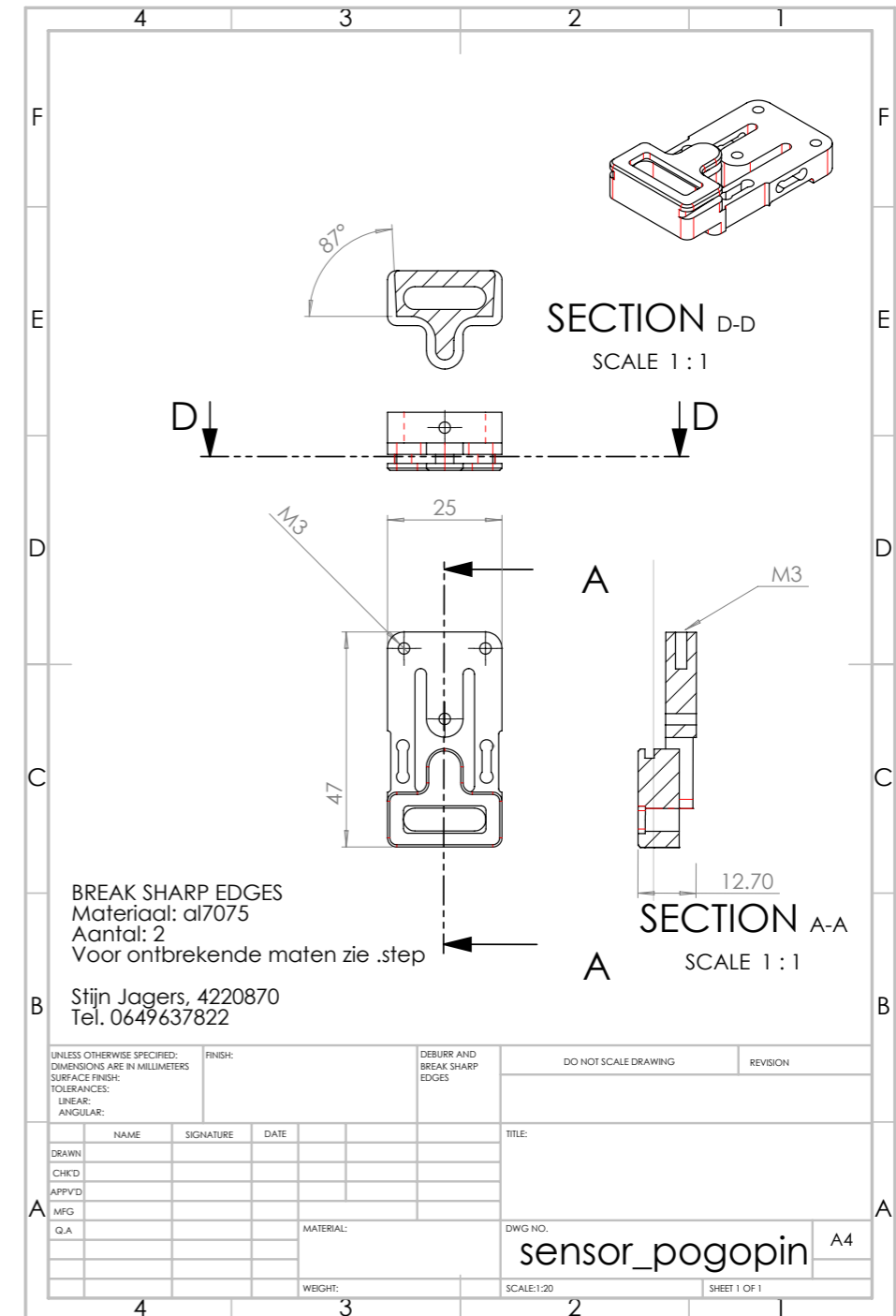
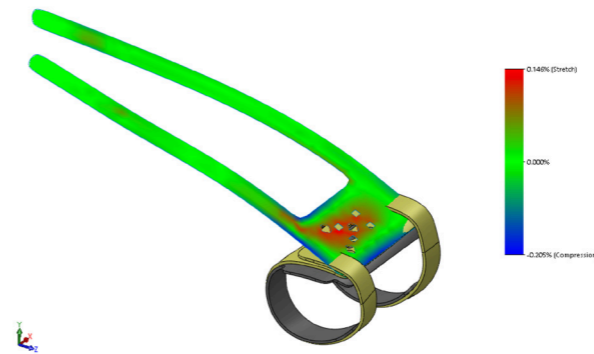
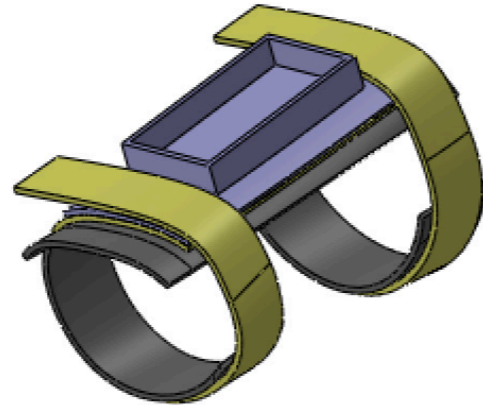
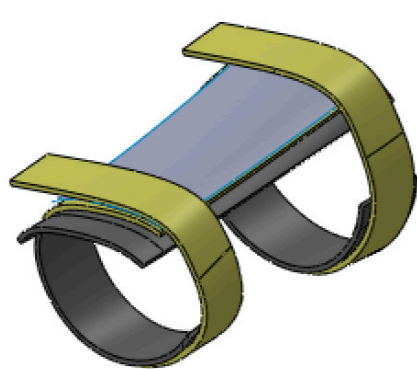
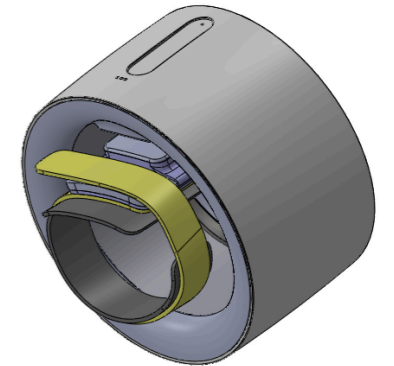
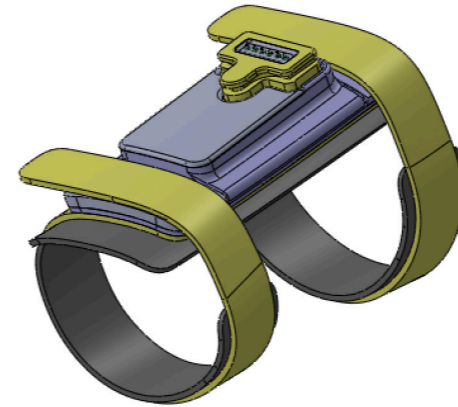
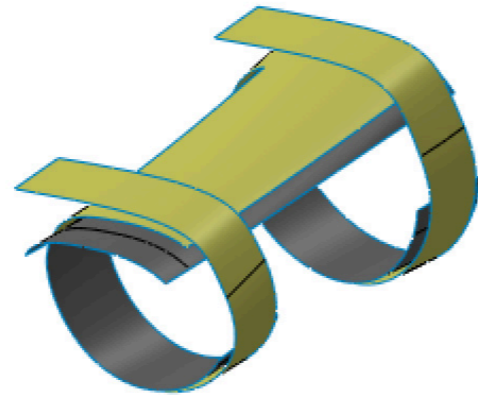
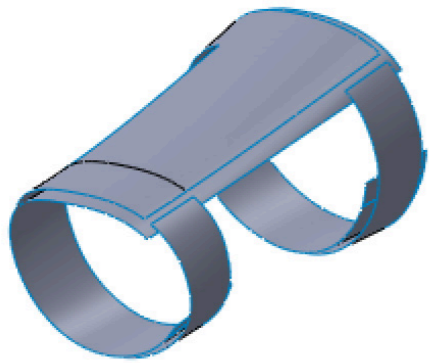
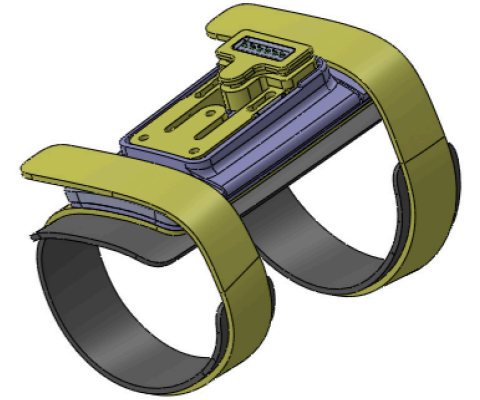
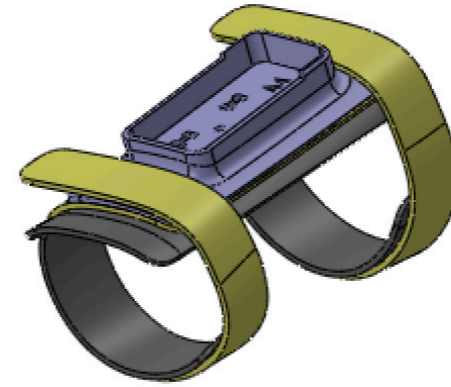
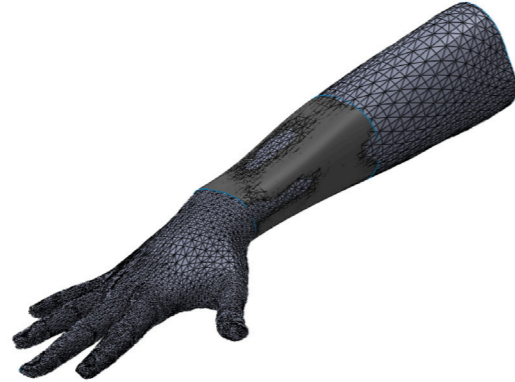


Figure 94 Slanted loading



Solidworks model



CES analysis

An analysis in CES was performed on interesting materials for the force sensor connection plate. A comparison between price, producibility and costs was made. This resulted in the over as seen below.

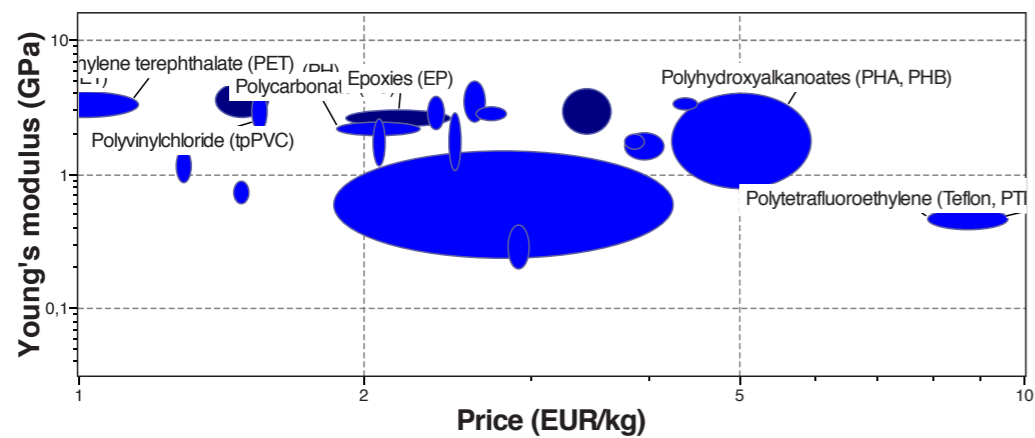
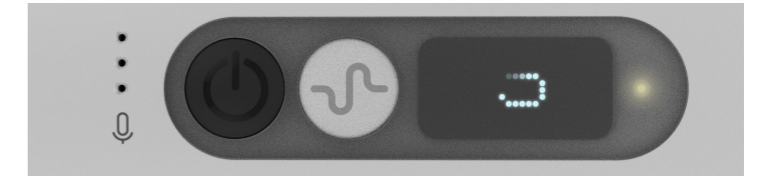


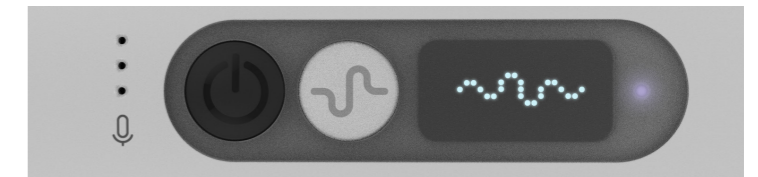
Figure 95 CES analysis

Interaction unit

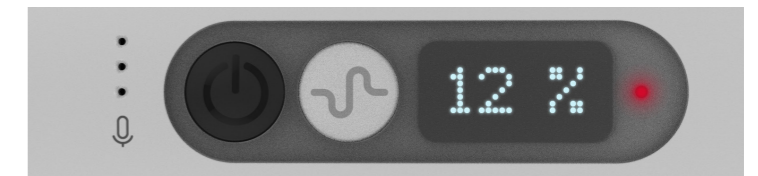
Calibration mode. LED display shows rotating symbol until the product is calibrated.



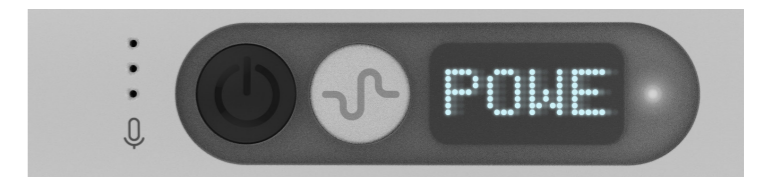
Voice control mode. Wiggly shapes moves on displayed to let the user know that the product is in voice control mode. Also, a blue light starts to blink.



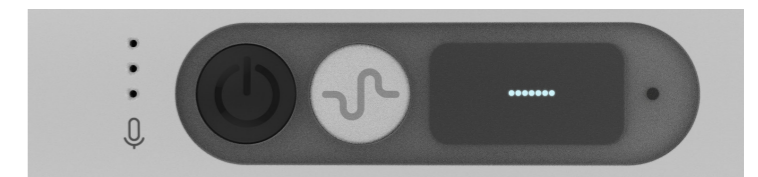
Battery low. Red led starts to blink, battery percentage is displayed.



Change state mode. Messages are display by sliding over the screen from left to right. White light blinks



Product in use. A simple, discrete, LED pattern is displayed to let the user now everything is OK.



Idle mode. Display and LED are turned off.



Error mode. Something is wrong

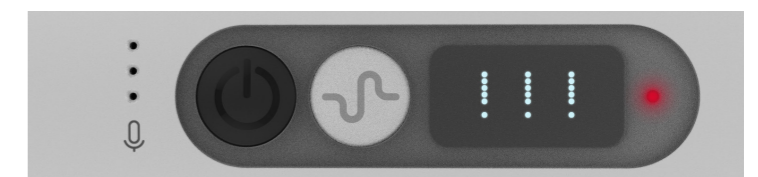


Figure 96 The needed display states to communicate signals and messages to the user.

Appearance suggestions

A study was done on what colors and surface finishes would result in a product appearance that would fit the potential user. It was tried to design a range of colors that would fit the target group and chosen personas as good as possible. It is unlikely that it is (directly) possible to offer a series of different colors to the customers. Each appearance is shortly explained. More detailed images can be found in Appendix XXVII.

Mariana blue

This appearance is made with modern people who are willing to try out new technologies. They are not afraid of showing their gadgets to others and talk about their solution against ET.

Vanilla Gold

Made for elderly who are looking for an unobtrusive design that fits their modest lifestyle. The product looks clinical, yet has a slightly was color to make it fit with the users skin tone.

Samurai Grey

An professional appearance. It obviously is a device that contain some sort of technology, yet it does not scream for attention.

Logo

A logo that would fit the rest of the projects presentation was designed. It is not designed to function as a replacement for the companies logo, but the new logo better fits the design language that is tried to be achieved. For the visual communication of this project the logo will used a the new brand image of still. 3 options have been designed and shared with people for input.

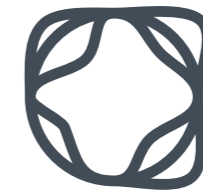


Figure 97 Logo options for the final presentation and communication of this project.

Mock-up prototyping

Due to the complexity of the used shapes in the product, an experimental prototyping technique for stiff components has been tried that significantly reduced the time needed to model each prototype iteration. Rather than directly modeling around the surface of the arm with complex 3d shapes in 3d computer models, an extra step was used to achieve usable prototypes. A short step by step explanation of the used prototyping approach is given :

1. A mould of the shape of the arm was made by sticking strokes of paper around a 3d printed arm shape.
2. The mould was cut into a potentially interesting shape for the brace and flattened.
3. The flattened version of the potential brace design serves as a pattern and is digitalized and converted to a 3d shape.

4. This 3d shape was printed in PLA or cut out from orthopedic plastic.

5. This plastic version of the pattern has been put in hot water to make it elastic and is folded around the 3d printed arm shape. By heating plastic to the point where it showed plastic behavior the shapes could be formed and altered to take an ergonomic shape. After cooling the plastic, the pattern preserves the shape of the arm and can be used for testing.



Ergonomic test: user marks



Ergonomic test: evaluation form

Ergonomic test results									
	1	2	3	4	5	6	7	8	9
name	M lammes	FB. Lammes	B. Zwaard	H van der korf	J de Jong	R boersma	I. Jagers	M. Jagers	L. Schumacher
Gender	F	M	F	M	M	M	F	F	F
Age	85	85	25	26	21	29	20	27	22
Wrist circumference (mm)	145	183	136	160	176	176	158	150	
Used brace	S	S	M	L	L	M	S	S	S
Duration	3	3	3.5	3	3.5	1	1	1	1
Performed activities while wearing the brace	televisie kijken en gebastocued	Gezeten, bbq. Gegaaien, tv (tennis) gekken	Typing, Ping pong, Eating, writing	Ping pong, desk work, eating, walking	Workshop activities, eating, table tennis, typing	Zithen, These drinken	In rust, gezellig theesdrinken met de familie	Sociale interactie, twee drinken, schrijven	eten, drinken, wc bezoeken, handen wassen, sociale interactie
How did you experience wearing the brace?	eenvoudig	geen probleem. Geen edema in hand of vingers	Comfortabel als het niet te strak zit. Anders een beetje belemmering rond de pols. Geen scherpe delen, geen last van krassen. Misschien niet te goed voor mijn pols door de bandjes wat te lang en staken uit. Daardoor ging mouw er niet makkelijk overheen. Anders had het wel gekund.	Comfortable, no nuisance during typing or mouse handling. Does become sweaty during physical activity	Very nice, had no pain or discomfort caused by the brace	Positie, niet anders dan het dragen van een horloge in het begin voel je het zithen. Later gaat dat gevoel weg. Halverwege het uur heb ik de brace een beetje lastig omdat deze half over de knokkel zat. De brace zat beter half uur, maar bij draaiing van de pols beweegt de huid meer over het bot. Bij draaien is de weerstand minder (2e half uur)	Comfortabel, maar weerstand tijdens het draaien van mijn arm, vooral met naar binnen toe kantelen. Verder geen pijn bij draaien. Het draaien is niet erg moeilijk dat je hem aan hebt. Bij de draai beweging, bij het drinken van thee voel je hem een beetje drinken aan de bovenkant.	Het voelt prettig aan, zacht aan de huid. Geen jeuk of afknelling. Bij het schrijven merk ik dat er tel meer druk op staat. Bij het gewoen draagen heb ik mijn pols niet erg uitgesproken is. Blijft wel aan andere hun kleding hangen bij bv omhelzingen.	Zat comfortabeler naarmate de tijd vorderde. Toen merkte ik het bijna niet meer. Merkte wel dat de brace langzaam meer over mijn pols kwam. Het knobbeltje op mijn pols is erg uitgesproken is. Blijft wel aan andere hun kleding hangen bij bv omhelzingen.
How did you experience putting on the brace	geen probleem	makkelijk	Goed, makkelijk met 1 hand om te doen. Geen moeilijkheden of onduidelijkheden.	Once the right strap is found it is quite easy. Velcro location on the front strap was not ideal.	quite nice, but hard to know if the brace is put on tight enough.	De positie is nog vrij te interpreteren. De vorm is wel goed. Je hoeft niet echt moeilijk te doen. Het klittenband hecht nog niet zo goed. Het stukje neopreen wat langer maken zou fijn zijn	Gemakkelijk, twijfel over hoe strak het hoort.	Het ging heel gemakkelijk, ik zag alleen moeilijk wat de boven en onderkant van de brace waren. Bij het omdoen wist ik nog niet zo goed hoe strak ik hem moest doen. Overall vond ik het dragen prettig.	Ging erg makkelijk omdat het al voorgevormd was. Wel vermeldelijk om hem op de knobbeltje vast te maken, dat moet duidelijk gecommuniceerd worden.
Other remarks		ik kreeg mijn hand erg moeilijk door de witte ring.					Door brace aan linker arm in plaats van rechts.	Door het dragen van de brace had ik wel af en toe meer aandacht voor de arm. (ik moest er een beetje aan wennen, maar later volde ik hem al niet meer)	

Ergonomic test 2: evaluation form

Ergonomic test results with weight

	1	2
name	B. Zwaard	J de Jong
Gender	F	M
Age	25	21
Wrist circumference (mm)	136	176
Used brace	S	L
Duration	2	3
Performed activities while wearing the brace	Computer work, writing	Typing, Ping pong, writing
How did you experience wearing the brace?	De exshell was erg groot en stak aan de onderkant een stuk uit. Typen en schrijven was daardoor lastig. Pols in een andere hoek om toch uit te kunnen voeren. Daardoor wel lamme arm. Schrijven en typen kan niet met arm op tafel laten rusten. Dus arm omhoog wat vermoeiend is.	Comfortable most of the time. Writing on a table is a bit hard to do. Typing is fine for me. You do notice the added weight while playing table tennis. The brace stays comfortable.
How did you experience putting on the brace and exshell?	Omdoen van de brace zelf gaat goed met 1 hand. Exshell klemt waardoor het bevestigen en loskoppelen aan de brace vrij zwaar gaat.	Oke, but maybe because I already know how it works. It is quite snug.
Other remarks		

Protocol A: Usability test 3rd of July

General preparation

Material checklist:

Chair
Left-handed Brace
Mockup Exshell
Camera
Tripod

Preparation

- Set up test environment (chair, tripod, cover/move secret materials)
- Inform patient about what will be done: filmed and recorded experiments
- (Sign NDA)
- Ensure mounting around the wrist
- Ensure data is correctly being displayed
- Test logging
- Ensure safe environment

Experiment : Wearing and using the product

Goal

Discover the ease of use of the product for a tremor patient.

Preparations

- Set up test environment
- Place chair in room
- Clean up a table
- Set up tripod
- Cover/move any unwanted objects in the area
- Prepare (mock up) product
- Clean brace
- Ensure Exshell connection works
- Put the product in a box

Instructions (step by step)

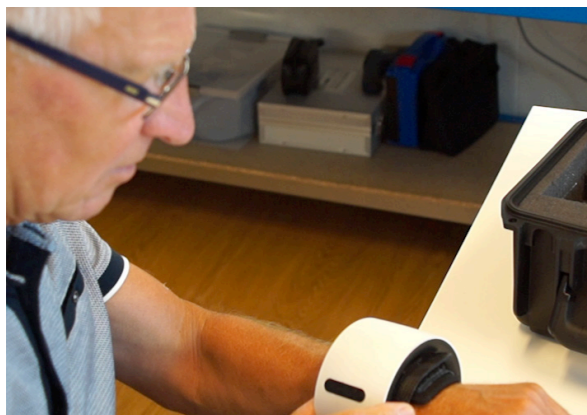
- Explain the test will be about the product
- Tell him his actions will be recorded
- Start recording
- Explain how the product works and what the purpose is of each part
- Explain the desired tightness of the brace (just as tight as a watch strap)
- Hand over the product (in the case) to the user. (Do not ask him to sit, he can do so himself if he wants to.)
- Ask the patient to put on the product (brace and exshell) and tell him to think out loud and share his thoughts
- Draw Archimedean spiral (Form 1)
- Ask the patient put off the product and tell him to think out loud and share his thoughts
- Turn off camera(s)
- Share questionnaire with the patient and let him fill it in (Form 2). Depending on patients preference this can be noted on laptop, paper or on voice record.

User validation overview



The test set up. A room was prepared to create an optimal testing environment.

User validation questionnaire



An overview of some interesting moment during the user test.

Form 2: Questionnaire Usability test STIL brace

Eerst volgen een aantal specifieke vragen met betrekking tot het comfort en het om- en afdoen van de STIL brace. Er wordt hierin onderscheidt gemaakt tussen het binnenste gedeelte, de 'polsbrace' en het buitenste gedeelte dat de tremor dempt, de 'demper'. Kies steeds één antwoord door een kruisje in het hokje te zetten.

1. In hoeverre was u in staat zelfstandig de polsbrace om te doen?

- In staat om te doen, zonder moeite
 In staat om te doen, met een beetje moeite
 In staat om te doen, met veel moeite
 Niet in staat om te doen

2. In hoeverre was u in staat zelfstandig de demper om te doen?

- In staat om te doen, zonder moeite
 In staat om te doen, met een beetje moeite
 In staat om te doen, met veel moeite
 Niet in staat om te doen

3. In hoeverre was u in staat zelfstandig de polsbrace af te doen?

- In staat om te doen, zonder moeite
 In staat om te doen, met een beetje moeite
 In staat om te doen, met veel moeite
 Niet in staat om te doen

4. In hoeverre was u in staat zelfstandig de demper af te doen?

- In staat om te doen, zonder moeite
 In staat om te doen, met een beetje moeite
 In staat om te doen, met veel moeite
 Niet in staat om te doen

5. Heeft u ergens last van gekregen na het dragen van de brace? (rode plekken, irritaties, pijn aan de huid, spieren of pezen etc.)

- Nee

6. Waren er bepaalde plekken op de arm, pols of hand, waar de brace niet prettig aanvoelde? (bijv. drukpunten, knellingen etc.)

- Nee

Met de volgende vragen wordt uw ervaring met de STIL brace in kaart gebracht. Kies steeds slechts één antwoord door er een kruisje in het hokje te zetten.

7. Hoe tevreden bent u over de afmetingen van de STIL brace? (maat, hoogte, lengte, breedte)

- Totaal niet tevreden
 Niet tevreden
 Min of meer tevreden
 Tevreden
 Zeer tevreden

Test set-up functional test

8. Hoe tevreden bent u over het gewicht van de STIL brace?
 Totaal niet tevreden
 Niet tevreden
 Min of meer tevreden
 Tevreden
 Zeer tevreden
9. Hoe tevreden bent u over de verstelmogelijkheden van de STIL brace?
 Totaal niet tevreden
 Niet tevreden
 Min of meer tevreden
 Tevreden
 Zeer tevreden
10. Hoe tevreden bent u over het sluitingsmechanisme van de brace?
 Totaal niet tevreden
 Niet tevreden
 Min of meer tevreden
 Tevreden
 Zeer tevreden
11. Hoe tevreden bent u over het comfort van de polsbrace?
 Totaal niet tevreden
 Niet tevreden
 Min of meer tevreden
 Tevreden
 Zeer tevreden
12. Hoe tevreden bent u met het principe om de demper over de pols te schuiven?
 Totaal niet tevreden
 Niet tevreden
 Min of meer tevreden
 Tevreden
 Zeer tevreden
13. Hoe tevreden bent u over de bevestigingsmethode van de demper aan de brace?
 Totaal niet tevreden
 Niet tevreden
 Min of meer tevreden
 Tevreden
 Zeer tevreden
14. Hoe tevreden bent u, alles bij elkaar genomen, over de STIL brace?
 Totaal niet tevreden
 Niet tevreden
 Min of meer tevreden
 Tevreden
 Zeer tevreden

Heeft u verder nog opmerkingen, suggesties of andere dingen die u kwijt wil?



Protocol B: Sensor Validation test

General preparation

Material checklist:
 Data logging system
 Brace and Ex Shell
 Vise
 Plastic arm
 Sensor fixation object

Preparation:

- Set up test environment
- Set up weight sensor
- Ensure data is correctly being displayed
- Test logging
- (expand) ensure safe environment: careful to stairs, shocks, whatever. Even if it sounds stupid, put some lines

Remarks:
 weight of 309 grams was used for validation. dropped from 10 mm height.
 Channel 1 = Y direction, Chanel 2 = X direction 1khz frequency

Experiment 1: Force sensor clamped to solid body

Goal:
 Measure clear force sensor signal in a perfect scenario

Instructions:

- Clamp sensor to solid body
- Start logging data
- Drop weight vertically on exshell
- Stop logging and store files in a

folder with format YYYYMMDD_SENSORVALIDATION_EXPERIMENT1

- Check the correctness of data

Experiment 2: Force sensor clamped on brace, attached to a stiff object.

Goal:
 See the influence of the brace on the measurements of the force sensor

Instructions:

- Clamp sensor in brace
- Attach brace to 3d printed arm
- Start logging data
- Drop weight vertically on exshell
- Stop logging and store files in a folder with format YYYYMMDD_SENSORVALIDATION_EXPERIMENT2
- Check the correctness of data

Experiment 3: Force sensor clamped on brace, attached to human arm.

Goal:
 Measure influence of human skin and tissue on force sensor readings.

Instructions:

- Clamp sensor in brace
- Attach brace to human
- Start logging data
- Drop weight vertically on exshell
- Stop logging and store files in a folder with format YYYYMMDD_SENSORVALIDATION_EXPERIMENT3
- Check the correctness of data

Protocol C: Functional Experiments Patient test 3rd of July

General preparation

Material checklist:
 Data logging system
 Brace and Ex Shell
 Vise
 Chair
 (Glue clamp for vise fixation)

Preparation:

- Set up test environment (chair, tripod, cover/move secret materials)
- Inform patient about what will be done: filmed and recorded experiments
- (sign NDA)
- Ensure mounting around the wrist
- Ensure data is correctly being displayed
- Test logging
- Ensure safe environment

Experiment 1: Sitting with extended arm in sagittal plane, palm down, trying not to move

Goal:
 Measure the tremor of a user with the product in an idle state.

Instructions:

- Explain the test will last 10 seconds and we need to collect data
- Let the patient put on the product
- Help patient to assume correct position; Sitting, arm extended in sagittal plane
- Start filming
- Log 10 seconds of data
- Stop filming
- Stop logging and store files in a folder with format YYYYMMDD_PATIENTNAME_EXPERIMENT1

- Check the correctness of data

Experiment 2: Sitting with extended arm in sagittal plane, product attached to vise, palm down

Goal:
 Get an as clear as possible reading of the patients forearm tremor.

Instructions:

- Explain the test will last 10 seconds and we need to collect data
- Connect Exshell to vise
- Connect brace to user
- Help patient to assume correct position; Sitting, arm extended in sagittal plane, aligned with exshell in vise, palm facing down
- Start filming
- Log 10 seconds of data
- Stop filming
- Stop logging and store files in a folder with format YYYYMMDD_PATIENTNAME_EXPERIMENT2
- Check the correctness of data

Experiment 3: Elbow next to body, supination to pronation movement

Goal:
 Discover force sensor behavior during complex arm movements.

Instructions:

- Explain the test will last 10 seconds and we need to collect data
- Connect Exshell to brace
- Help patient to assume correct position; Elbow next to body, forearm extended in sagittal plane, palm down

- Show how to make the movement
- Start filming
- Log 10 seconds of data
- Tell the user to make a supination to pronation movement with the forearm. From palm facing down to up.
- Stop filming
- Stop logging and store files in a folder with format YYYYMMDD_PATIENTNAME_EXPERIMENT3
- Check the correctness of data

Experiment 4: Elbow next to body, flexion and extension of elbow joint, palm facing transverse plane

Goal

Discover force sensor behavior during complex arm movements.

Instructions

- Explain the test will last 10 seconds and we need to collect data
- Connect Exshell to brace
- Help patient to assume correct position; Elbow next to body, forearm extended in sagittal plane, palm down (facing transverse plane).
- Show how to make the movement
- Start filming
- Log 10 seconds of data
- Tell the user to make a flexion and extension movement in sagittal plane. From extended position to farthest position, back to extended position.
- Stop filming
- Stop logging and store files in a folder with format YYYYMMDD_PATIENTNAME_EXPERIMENT4
- Check the correctness of data

Force sensor connection plate redesign



Figure 98 Old (left) vs. new (right) sensor plate connection design. Ribs on the bottom have been added and the top layer has been made thicker.

Pogo pin damage

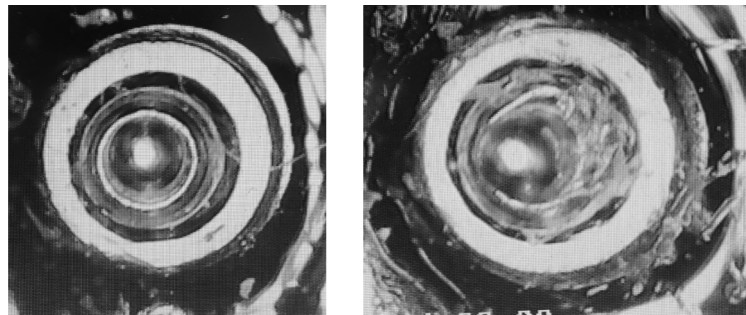


Figure 99 Undamaged vs. Damaged pogo pins

Estimated costprice

	Extra investments	Material costs	Amount per batch/order	Unit price	Units per product	Costs per brace
Neoprene padding		40	18	2.22	1	3
	Die	300	2500	0.12	1	1
Plastic straps		52	12	4.33	1	5
	Die	300	2500	0.12	1	1
Force sensor body		60	1	60	1	60
Strain Gauge		366	100	3.66	4	15
pogo pin pcb		1.67	5	0.33	1	1
Pogo pin		807.5	2500	0.32	6	2
Strain relief glue		70	3000	0.02	4	1
Strain gauge glue		56	3000	0.02	4	1
Force sensor connection plate		2.2	62.5	0.04	1	1
	Mould	12000	2500	4.8	1	5
Force sensor connection top		2.2	250	0.01	1	1
	Mould	6000	2500	2.4	1	3
Torx M3x8mm screws		0.23	1	0.23	3	1
Elastic loops		17	500	0.03	6	1
Finger loops		4	1	4	2	8
TAX 9%						9.9
costs ex. (BTW)						110
Labor (In house)		time (hours)	Hourly wage			
		1.5	15.6			23
Total costs						133

Table 14 An estimation of the costprice was made. Red rows represent uncertain costs. These have been estimated. Green rows are known costs. Blue rows represent labor costs.

