



A. Project brief

DESIGN
FOR OUR
future



IDE Master Graduation

Project team, Procedural checks and personal Project brief

This document contains the agreements made between student and supervisory team about the student's IDE Master Graduation Project. This document can also include the involvement of an external organisation, however, it does not cover any legal employment relationship that the student and the client (might) agree upon. Next to that, this document facilitates the required procedural checks. In this document:

- The student defines the team, what he/she is going to do/deliver and how that will come about.
- SSC E&SA (Shared Service Center, Education & Student Affairs) reports on the student's registration and study progress.
- IDE's Board of Examiners confirms if the student is allowed to start the Graduation Project.

 **USE ADOBE ACROBAT READER TO OPEN, EDIT AND SAVE THIS DOCUMENT**
Download again and reopen in case you tried other software, such as Preview (Mac) or a webbrowser.

STUDENT DATA & MASTER PROGRAMME

Save this form according to the format "IDE Master Graduation Project Brief_familyname_firstname_studentnumber_dd-mm-yyyy". Complete all blue parts of the form and include the approved Project Brief in your Graduation Report as Appendix 1 !



family name	VAN DER STOEP	6307
initials	E.N. given name	ELINE
student number	4556488	
street & no.		
zipcode & city		
country	THE NETHERLANDS	
phone		
email		

Your master programme (only select the options that apply to you):

IDE master(s): ☒ IPD ☐ Dfl ☐ SPD

2nd non-IDE master: _____

individual programme: _____ (give date of approval)

honours programme: ☐ Honours Programme Master

specialisation / annotation: ☒ Medisign ☐ Tech. in Sustainable Design ☐ Entrepreneurship

SUPERVISORY TEAM **

Fill in the required data for the supervisory team members. Please check the instructions on the right !

** chair	RICHARD GOOSSENS	dept. / section:	HCD, AED
** mentor	LAURA MARCHAL CRESPO	dept. / section:	CoR, HRI
2 nd mentor			
organisation:			
city:		country:	

comments
(optional)

-  Chair should request the IDE Board of Examiners for approval of a non-IDE mentor, including a motivation letter and c.v..
-  Second mentor only applies in case the assignment is hosted by an external organisation.
-  Ensure a heterogeneous team. In case you wish to include two team members from the same section, please explain why.



Procedural Checks - IDE Master Graduation

APPROVAL PROJECT BRIEF

To be filled in by the chair of the supervisory team.

chair	RICHARD GOOSSENS	date	20 - 02 - 2023	signature	Richard Goossens - IO Digitally signed by Richard Goossens - IO Date: 2023.03.06 09:44:08 +0100
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CHECK STUDY PROGRESS

To be filled in by the SSC E&SA (Shared Service Center, Education & Student Affairs), after approval of the project brief by the Chair. The study progress will be checked for a 2nd time just before the green light meeting.

Master electives no. of EC accumulated in total:	50	EC	☒ YES all 1 st year master courses passed
Of which, taking the conditional requirements into account, can be part of the exam programme	30	EC	☐ NO missing 1 st year master courses are:
List of electives obtained before the third semester without approval of the BoE			

name	Robin den Braber	date	06 - 03 - 2023	signature	Robin den Braber Digitaal ondertekend door Robin den Braber Datum: 2023.03.06 13:11:36 +0100
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FORMAL APPROVAL GRADUATION PROJECT

To be filled in by the Board of Examiners of IDE TU Delft. Please check the supervisory team and study the parts of the brief marked **. Next, please assess, (dis)approve and sign this Project Brief, by using the criteria below.

Does the project fit within the (MSc)-programme of the student (taking into account, if described, the activities done next to the obligatory MSc specific courses)?	Content:	☒ APPROVED ☐ NOT APPROVED
Is the level of the project challenging enough for a MSc IDE graduating student?	Procedure:	☒ APPROVED ☐ NOT APPROVED
Is the project expected to be doable within 100 working days/20 weeks ?		
Does the composition of the supervisory team comply with the regulations and fit the assignment ?		
- also approved for Medisign		comments

name	Monique von Morgen	date	21 - 03 - 2023	signature	
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IDE TU Delft - E&SA Department /// Graduation project brief & study overview /// 2018-01 v30	Page 2 of 7		
Initials & Name	E.N. VAN DER STOEP 6307	Student number	4556488
Title of Project	Redesign of a minimally-supervised portable hand trainer		

Redesign of a minimally-supervised portable hand trainer

project title

Please state the title of your graduation project (above) and the start date and end date (below). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

start date 20 - 02 - 2023

20 - 07 - 2023

end date

INTRODUCTION **

Please describe, the context of your project, and address the main stakeholders (interests) within this context in a concise yet complete manner. Who are involved, what do they value and how do they currently operate within the given context? What are the main opportunities and limitations you are currently aware of (cultural- and social norms, resources (time, money,...), technology, ...).

This project has been set up at the Motor Learning and Neurorehabilitation (MLN) Lab of the University of Bern and has been transferred to the lab's location at the Cognitive Robotics department within 3mE of TU Delft. The lab's research focuses on using robotic assistance and immersive Virtual Reality (VR) to aid motor learning and neurorehabilitation of people after neurological injuries, specifically stroke.

The portable hand trainer for minimally-supervised therapy is one of their currently ongoing projects that I will be working on during the course IDE Master Graduation Project. This project specifically focuses on rehabilitation of the hand and forearm after a stroke. The first two design iterations have been developed at the University of Bern. Figures of the hand trainer can be seen on the next page. Recently, a feasibility and usability study has been performed at TU Delft in collaboration with therapists from the Rijndam Rehabilitation center and healthy participants, showing room for improvement on several aspects of the design. This project will make improvements on the current design of the portable hand trainer.

The target group of the project are stroke patients. Their age, gender and type of stroke they suffered from still needs to be defined. The focus is to enable these patients to do therapy at home. Parties and organizations that have interest in the project are the Rijndam Rehabilitation center and Erasmus MC since they provide rehabilitation devices to patients and collaborate with the MLN Lab.

A good opportunity of the project is the multidisciplinary research environment which offers good collaboration with mechanical and biomechanical engineers from 3mE, neuroscientists and medical professionals from the Erasmus MC and the Rijndam Rehabilitation center. We are planning to set up a smaller and multidisciplinary collaboration team that is closely working together to brainstorming and allow for easily accessible and fast testing. Another opportunity of the project are the great resources to model new prototypes and the final prototype using the facilities, knowledge and experience of the MLN Lab and the workshops at the IDE and 3mE faculty.

Some limitations exist to the project. The access to people that have had a stroke is limited and may require substantial bureaucratic effort, due to ethical and organizational limitations. However, we will try to involve people after stroke into the prototype design as much as possible.

space available for images / figures on next page

introduction (continued): space for images



image / figure 1: Current design of the hand trainer in use



image / figure 2: Current design of the hand trainer in use

PROBLEM DEFINITION **

Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 30 EC (= 20 full time weeks or 100 working days) and clearly indicate what issue(s) should be addressed in this project.

Patients that are recovering from a stroke need frequent and high-intensity training to regain their upper-limb capacity. This will eventually result in better performances and higher quality of their daily lives. Robotic devices are often used to help patients with their rehabilitation and so does the minimally-supervised hand trainer. Currently, much time and effort is required to set up robotic devices for patients to be used at home, which leads to frustration and abandonment. Also, robotic devices tend to be bulky, expensive and complex in use. Thus, this project is tackling the challenge to develop an user-friendly hand trainer that can easily be taken home and be used with minimal supervision.

The starting point of this project will be the product design after the second iteration, that is shown on the previous page. Improvements will be made based on the findings of the feasibility and usability study that has recently been performed, combined with the findings from new research and usability studies during the iterative design process of this graduation project. The main goal of the project is to make improvements on the hardware of the device (ergonomics, ease-of-use and appearance). In addition, advice will be given on the graphical user interface of the software.

The rehabilitation phase of the people after stroke (=the target group) who will be using the device needs to be defined. Additional user exclusion criteria need to be identified.

Excluded from the scope of this project is the software and the electronic components needed for the device. Also excluded is a formal usability study with stroke patients.

ASSIGNMENT **

State in 2 or 3 sentences what you are going to research, design, create and / or generate, that will solve (part of) the issue(s) pointed out in "problem definition". Then illustrate this assignment by indicating what kind of solution you expect and / or aim to deliver, for instance: a product, a product-service combination, a strategy illustrated through product or product-service combination ideas, In case of a Specialisation and/or Annotation, make sure the assignment reflects this/these.

I will design and improve the current design of the portable hand trainer for minimally-supervised therapy of people after a stroke, enabling more functional, ergonomic and motivating rehabilitation training.

The goal of this graduation project is to deliver an improved product design of the portable hand trainer for minimally-supervised therapy in comparison to the current design. More specifically, the redesign will be based on insights from the iterative design process, including context analysis, literature research, ideation, prototyping and user testing. In order to validate whether it has been improved, the redesign will be tested and evaluated at the end of the project. The goal is to deliver a working final prototype that is (hardware only) ready for user testing with healthy subjects.

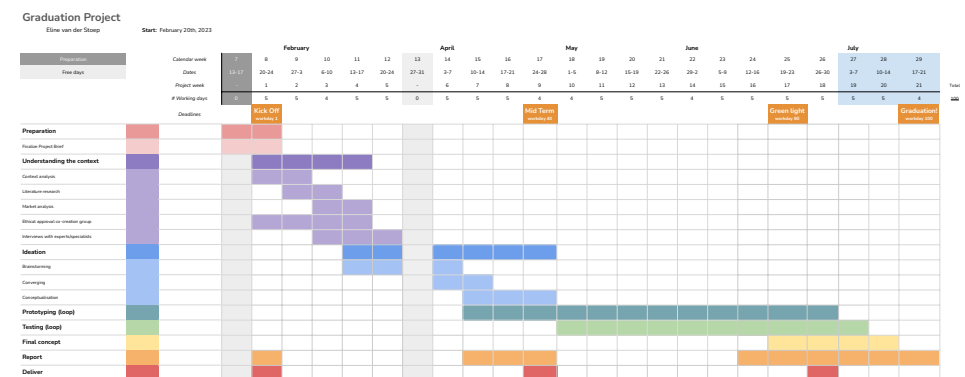
PLANNING AND APPROACH **

Include a Gantt Chart (replace the example below - more examples can be found in Manual 2) that shows the different phases of your project, deliverables you have in mind, meetings, and how you plan to spend your time. Please note that all activities should fit within the given net time of 30 EC = 20 full time weeks or 100 working days, and your planning should include a kick-off meeting, mid-term meeting, green light meeting and graduation ceremony. Illustrate your Gantt Chart by, for instance, explaining your approach, and please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any, for instance because of holidays or parallel activities.

start date 20 - 2 - 2023

20 - 7 - 2023

end date



The planning is based on what I want to deliver at the mid term, green light and graduation day. Every activity in the planning will extend for at least 2 weeks in order to take enough time to create, collaborate and evaluate on each activity. I want to incorporate two-week sprints, since the MLN lab has biweekly meetings to discuss difficulties and other matters related to our projects. I have indicated the prototyping and testing phase as loops, since I want to alternate between prototyping and small scale testing several times. Eventually, between the green light and graduation day, I would like to finish with a working prototype that can be tested with healthy patients. I have included some public holidays and a personal holiday in week 13.

The graduation project will be done in 100 days. The graduation day is now planned on July 20th.

MOTIVATION AND PERSONAL AMBITIONS

Explain why you set up this project, what competences you want to prove and learn. For example: acquired competences from your MSc programme, the elective semester, extra-curricular activities (etc.) and point out the competences you have yet developed. Optionally, describe which personal learning ambitions you explicitly want to address in this project, on top of the learning objectives of the Graduation Project, such as: in depth knowledge a on specific subject, broadening your competences or experimenting with a specific tool and/or methodology, Stick to no more than five ambitions.

This project at the MLN lab attracted my attention because I have great affinity with designing in the healthcare sector and great focus lies on designing a physical product rather than a service design. I follow the specilisation program Medisign within IDE and am specifically interested in neurological design contexts. Next to that, the MLN lab team and good resources seems a good place to get the most out of my graduation project.

During the bachelor and master at IDE, I have already gained experience in designing medical products. Together with five fellow students I have worked on an improved design for a patient monitoring system to be used at home for elderly people. Individually I have done a project to empower the mobility of people who are blind from birth and another project focusing on helping children with Duchenne connect and play with other children. Moreover, I have done an internship at a startup that is developing a headcam with streaming platform for surgeons to allow quick sharing of the surgeon's perspective to students, co-workers and other specialists.

I believe I can use the experience from IDE projects and the internship to tackle the design challenge of redesigning the minimally-supervised hand trainer. But I also believe I can learn a lot from the experience and knowledge of the MLN lab team and specialists. An extra challenge will be to integrate my IDE perspective into this 3mE project. I do have experience in working in a multidisciplinary team, which will be helpful.

I have put down my personal learning goals for the graduation project:

- gain in depth knowledge about stroke and the rehabilitation process
- improve on (rapid) prototyping skills, especially CAD modeling and 3D printing
- gain experience in co-creating with experts, clinical staff and (if approved) patients after stroke
- gain more experience in preparing and performing extensive user testing
- gain basic experience in electronical components needed for the working device

FINAL COMMENTS

In case your project brief needs final comments, please add any information you think is relevant.

B. HREC approval

The HREC approval consists of the following documents:

1. HREC checklist

2. Device report
3. Data management plan

Delft University of Technology HUMAN RESEARCH ETHICS CHECKLIST FOR HUMAN RESEARCH (Version January 2022)

IMPORTANT NOTES ON PREPARING THIS CHECKLIST

1. An HREC application should be submitted for every research study that involves human participants (as Research Subjects) carried out by TU Delft researchers
2. Your HREC application should be submitted and approved **before** potential participants are approached to take part in your study
3. All submissions from Master's Students for their research thesis need approval from the relevant Responsible Researcher
4. The Responsible Researcher must indicate their approval of the completeness and quality of the submission by signing and dating this form OR by providing approval to the corresponding researcher via email (included as a PDF with the full HREC submission)
5. There are various aspects of human research compliance which fall outside of the remit of the HREC, but which must be in place to obtain HREC approval. These often require input from internal or external experts such as [Faculty Data Stewards](#), [Faculty HSE advisors](#), the [TU Delft Privacy Team](#) or external [Medical research partners](#).
6. You can find detailed guidance on completing your HREC application [here](#)
7. Please note that incomplete submissions (whether in terms of documentation or the information provided therein) will be returned for completion **prior to any assessment**
8. If you have any feedback on any aspect of the HREC approval tools and/or process you can leave your comments [here](#)

I. Applicant Information

PROJECT TITLE:	Usability study of a device for unsupervised upper limb rehabilitation
Research period: <i>Over what period of time will this specific part of the research take place</i>	March 2023 – March 2024
Faculty:	Industrial Design Engineering, 3mE
Department:	Human Centered Design, CoR
Type of the research project: <i>(Bachelor's, Master's, DreamTeam, PhD, PostDoc, Senior Researcher, Organisational etc.)</i>	Master Thesis
Funder of research: <i>(EU, NWO, TUD, other – in which case please elaborate)</i>	TUD
Name of Corresponding Researcher: <i>(If different from the Responsible Researcher)</i>	Eline van der Stoep
E-mail Corresponding Researcher: <i>(If different from the Responsible Researcher)</i>	e.n.vanderstoep@student.tudelft.nl
Position of Corresponding Researcher: <i>(Masters, DreamTeam, PhD, PostDoc, Assistant/ Associate/ Full Professor)</i>	Master student
Name of Responsible Researcher: <i>Note: all student work must have a named Responsible Researcher to approve, sign and submit this application</i>	Alex Ratschat
E-mail of Responsible Researcher: <i>Please ensure that an institutional email address (no Gmail, Yahoo, etc.) is used for all project documentation/ communications including Informed Consent materials</i>	A.L.Ratschat@tudelft.nl
Position of Responsible Researcher : <i>(PhD, PostDoc, Associate/ Assistant/ Full Professor)</i>	PhD

II. Research Overview

NOTE: You can find more guidance on completing this checklist [here](#)

a) Please summarise your research very briefly (100-200 words)

What are you looking into, who is involved, how many participants there will be, how they will be recruited and what are they expected to do?

<i>Add your text here – (please avoid jargon and abbreviations)</i>
We want continue the development and evaluation of a device for hand- and forearm rehabilitation of people after stroke. We want to gain insights on the ergonomics, functionality and user experience. The issues found at each development stage will be used to further improve the device. Accordingly, the device will change over time.
We plan to recruit up to 20 participants (healthy participants, and experts working in rehabilitation, engineering and design (“stakeholder group”)). They will be recruited via personal contacts from TU Delft, Erasmus Medical Center, and Rijndam Revalidatie.
The healthy participants will be joining in a single-session, while the stakeholder group will be joining fo approx. 3 sessions.The healthy participants will be instructed and asked to setup the hand training device and perform a set of exercises using a computer game. The feasibility of the hand trainer will be evaluated using metrics, such as the game score, type and number of errors, number of times the emergency button is pressed and the time spent

to perform a task. The stakeholder group will be asked to share feedback about the device and potential improvements in co-creation sessions and interviews.

During the experiment, audio recordings will be taken. After the exercises, the participants will provide feedback in semi-structured interviews and/or answer questionnaire(s).

b) **If your application is an additional project** related to an existing approved HREC submission, please provide a brief explanation including the existing relevant HREC submission number/s.

Add your text here – (please avoid jargon and abbreviations)

In a previous experiment running in June 2022, the usability of a novel device for sensorimotor hand training was studied. To investigate the potential applicability of the device in the rehabilitation of neurological patients (i.e., stroke), a usability study with healthy participants was performed. The usability issues found in this study are used for further development.

HREC submission number/s: Letter_of_Approval2216

c) **If your application is a simple extension of, or amendment to,** an existing approved HREC submission, you can simply submit an [HREC Amendment Form](#) as a submission through LabServant.

III. Risk Assessment and Mitigation Plan

NOTE: You can find more guidance on completing this checklist [here](#)

Please complete the following table in full for all points to which your answer is “yes”. Bear in mind that the vast majority of projects involving human participants as Research Subjects also involve the collection of **Personally Identifiable Information (PII)** and/or **Personally Identifiable Research Data (PIRD)** which may pose potential risks to participants as detailed in Section G: Data Processing and Privacy below.

To ensure alignment between your risk assessment, data management and what you agree with your Research Subjects you can use the last two columns in the table below to refer to specific points in your Data Management Plan (DMP) and Informed Consent Form (ICF) – **but this is not compulsory**.

It’s worth noting that **you’re much more likely to need to resubmit your application if you neglect to identify potential risks**, than if you identify a potential risk and demonstrate how you will mitigate it. If necessary, the HREC will always work with you and colleagues in the Privacy Team and Data Management Services to see how, if at all possible, your research can be conducted.

ISSUE	Yes	No	If YES please complete the Risk Assessment and Mitigation Plan columns below.	Please provide the relevant reference #	
				DMP	ICF
			MITIGATION PLAN – what mitigating steps will you take? <i>Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.</i>		
A: Partners and collaboration					
1. Will the research be carried out in collaboration with additional organisational partners such as: - One or more collaborating research and/or commercial organisations - Either a research, or a work experience internship provider¹ <i>¹ If yes, please include the graduation agreement in this application</i>		x			
2. Is this research dependent on a Data Transfer or Processing Agreement with a collaborating partner or third party supplier? <i>If yes please provide a copy of the signed DTA/DPA</i>		x			
3. Has this research been approved by another (external) research ethics committee (e.g.: HREC and/or MREC/METC)? <i>If yes, please provide a copy of the approval (if possible) and summarise any key points in your Risk Management section below</i>		x			
B: Location					
4. Will the research take place in a country or countries, other than the Netherlands, within the EU?		x			

If YES please complete the Risk Assessment and Mitigation Plan columns below.					Please provide the relevant reference #	
ISSUE	Yes	No	RISK ASSESSMENT – what risks could arise? <i>Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!</i>	MITIGATION PLAN – what mitigating steps will you take? <i>Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.</i>	DMP	ICF
5. Will the research take place in a country or countries outside the EU?		x				
6. Will the research take place in a place/region or of higher risk – including known dangerous locations (in any country) or locations with non-democratic regimes?		x				
C: Participants						
7. Will the study involve participants who may be vulnerable and possibly (legally) unable to give informed consent? (e.g., children below the legal age for giving consent, people with learning difficulties, people living in care or nursing homes,).		x				
8. Will the study involve participants who may be vulnerable under specific circumstances and in specific contexts, such as victims and witnesses of violence, including domestic violence; sex workers; members of minority groups, refugees, irregular migrants or dissidents?		x				
9. Are the participants, outside the context of the research, in a dependent or subordinate position to the investigator (such as own children, own students or employees of either TU Delft and/or a collaborating partner organisation)? <i>It is essential that you safeguard against possible adverse consequences of this situation (such as allowing a student's failure to participate to your satisfaction to affect your evaluation of their coursework).</i>	x		Members of the TU Delft (students, employees) might be recruited for the experiment. They could potentially be in a dependent or subordinate position to the investigators.	The participants will be provided with sufficient information to make an informed decision on whether or not to participate. All participants can discontinue the experiment at all times without any negative consequences according to the informed consent form.		
10. Is there a high possibility of re-identification for your participants? (e.g., do they have a very specialist job of which there are only a small number in a given country, are they members of a small community, or employees from a partner company collaborating in the research? Or are they one of only a handful of (expert) participants in the study?		x				
D: Recruiting Participants						
11. Will your participants be recruited through your own, professional, channels such as conference attendance lists, or through specific network/s such as self-help groups	x		Members of the TU Delft (students, employees) might be recruited for the experiment through the 3mE Communications Department and IDE Communications Department. They could potentially be in a dependent or subordinate position to the investigators.	The participants will be provided with sufficient information to make an informed decision on whether or not to participate. All participants can discontinue the experiment at all times without any negative consequences according to the informed consent sheet.		
12. Will the participants be recruited or accessed in the longer term by a (legal or customary) gatekeeper? (e.g., an adult professional working with children, a community leader or family member who has this customary role – within or outside the EU; the data producer of a long-term cohort study)		x				

If YES please complete the Risk Assessment and Mitigation Plan columns below.					Please provide the relevant reference #	
ISSUE	Yes	No	RISK ASSESSMENT – what risks could arise? <i>Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!</i>	MITIGATION PLAN – what mitigating steps will you take? <i>Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.</i>	DMP	ICF
13. Will you be recruiting your participants through a crowd-sourcing service and/or involve a third party data-gathering service, such as a survey platform?		x				
14. Will you be offering any financial, or other, remuneration to participants, and might this induce or bias participation?		x				
E: Subject Matter Research related to medical questions/health may require special attention. See also the website of the CCMO before contacting the HREC.						
15. Will your research involve any of the following: • Medical research and/or clinical trials • Invasive sampling and/or medical imaging • Medical and In Vitro Diagnostic Medical Devices Research		x				
16. Will drugs, placebos, or other substances (e.g., drinks, foods, food or drink constituents, dietary supplements) be administered to the study participants? <i>If yes see here to determine whether medical ethical approval is required</i>		x				
17. Will blood or tissue samples be obtained from participants? <i>If yes see here to determine whether medical ethical approval is required</i>		x				
18. Does the study risk causing psychological stress or anxiety beyond that normally encountered by the participants in their life outside research?		x				
19. Will the study involve discussion of personal sensitive data which could put participants at increased legal, financial, reputational, security or other risk? (e.g., financial data, location data, data relating to children or other vulnerable groups) <i>Definitions of sensitive personal data, and special cases are provided on the TUD Privacy Team website.</i>	x					
20. Will the study involve disclosing commercially or professionally sensitive, or confidential information? (e.g., relating to decision-making processes or business strategies which might, for example, be of interest to competitors)		x				
21. Has your study been identified by the TU Delft Privacy Team as requiring a Data Processing Impact Assessment (DPIA)? <i>If yes please attach the advice/ approval from the Privacy Team to this application</i>	x					
22. Does your research investigate causes or areas of conflict? <i>If yes please confirm that your fieldwork has been discussed with the appropriate safety/security advisors and approved by your Department/Faculty.</i>		x				

If YES please complete the Risk Assessment and Mitigation Plan columns below.					Please provide the relevant reference #	
ISSUE	Yes	No	RISK ASSESSMENT – what risks could arise? <i>Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!</i>	MITIGATION PLAN – what mitigating steps will you take? <i>Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.</i>	DMP	ICF
23. Does your research involve observing illegal activities or data processed or provided by authorities responsible for preventing, investigating, detecting or prosecuting criminal offences <i>If so please confirm that your work has been discussed with the appropriate legal advisors and approved by your Department/Faculty.</i>		x				
F: Research Methods						
24. Will it be necessary for participants to take part in the study without their knowledge and consent at the time? (e.g., covert observation of people in non-public places).		x				
25. Will the study involve actively deceiving the participants? (For example, will participants be deliberately falsely informed, will information be withheld from them or will they be misled in such a way that they are likely to object or show unease when debriefed about the study).		x				
26. Is pain or more than mild discomfort likely to result from the study? And/or could your research activity cause an accident involving (non-) participants?		x				
27. Will the experiment involve the use of devices that are not 'CE' certified? <i>Only, if 'yes': continue with the following questions:</i>	x					
- Was the device built in-house? - Was it inspected by a safety expert at TU Delft? <i>If yes, please provide a signed device report</i> - If it was not built in-house and not CE-certified, was it inspected by some other, qualified authority in safety and approved? <i>If yes, please provide records of the inspection</i> 28. Will your research involve face-to-face encounters with your participants and if so how will you assess and address Covid considerations?	x		The device was built in-house. The device is not CE-certified and its use could therefore potentially pose a risk. The device will be augmented during the course of the study, based of the feedback from the stakeholder group.	An extensive risk analysis was performed and appropriate safety measures and maintenance procedures were defined. An operations manual is provided to ensure the correct use of the device. Changes in the device's design are tracked in a changelog and the device's risk analysis is updated. Before each evaluation round, the augmented device report and the chagelog are evaluated by the safety officer for approval.		
	x					
		x	Covid could be transmitted via the surfaces of the device or the surrounding equipment (e.g. table, chair, pen, computer mouse) that are in contact with the hands of the participants and/or experimenters.	The device and surrounding equipment will be disinfected before and after each session and between participants and/or experimenters.		

If YES please complete the Risk Assessment and Mitigation Plan columns below.					Please provide the relevant reference #	
ISSUE	Yes	No	RISK ASSESSMENT – what risks could arise? <i>Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!</i>	MITIGATION PLAN – what mitigating steps will you take? <i>Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.</i>	DMP	ICF
				We will comply with the recommendations and regulations of the Dutch government at the time of the experiments.		
29. Will your research involve either: a) "big data", combined datasets, new data-gathering or new data-merging techniques which might lead to re-identification of your participants and/or b) artificial intelligence or algorithm training where, for example biased datasets could lead to biased outcomes?		x				
G: Data Processing and Privacy						
30. Will the research involve collecting, processing and/or storing any directly identifiable PII (Personally Identifiable Information) including name or email address that will be used for administrative purposes only? (eg: obtaining Informed Consent or disbursing remuneration)	x		The identity of the participants could be revealed. The participants will fill out an informed consent sheet with directly identifiable PII. They will receive a unique identifier.	The informed consent sheet will be stored in a locked cabinet in a locked office according to the DMP.	119703	
31. Will the research involve collecting, processing and/or storing any directly or indirectly identifiable PIRD (Personally Identifiable Research Data) including videos, pictures, IP address, gender, age etc and what other Personal Research Data (including personal or professional views) will you be collecting?			The identity of the participants could be revealed. The following PIRD will be collected: Audio recordings of tasks - Audio recordings of semi-structured interviews - Age - Gender - Profession (only expert group)	Audio recordings will be stored in a password-protected folder. Each participant will receive a unique identifier of which the key is stored on a separate drive.	119703	
32. Will this research involve collecting data from the internet, social media and/or publicly available datasets which have been originally contributed by human participants		x				
33. Will your research findings be published in one or more forms in the public domain, as e.g., Masters thesis, journal publication, conference presentation or wider public dissemination?	x		The privacy of participants could be violated through the publication of identifiable data (e.g., profession).	This can be mitigated with strict adherence to the Data Management Plan.		
34. Will your research data be archived for re-use and/or teaching in an open, private or semi-open archive?	x		The privacy of participants could be violated through the publication of identifiable data (e.g., profession).	All data will be pseudonymized except audio recordings as this is not possible due to the required analysis. No data that allows the identification of participants no audio recordings will be archived in an open or semi-open archive. The participants have the option to explicitly give consent to the use of audio recordings in public presentation. It is clearly communicated in the informed consent that this is not mandatory for the	119703	

ISSUE	Yes	No	If YES please complete the Risk Assessment and Mitigation Plan columns below.	Please provide the relevant reference #	
				DMP	ICF
			MITIGATION PLAN – what mitigating steps will you take? Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!		
			RISK ASSESSMENT – what risks could arise? Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!		

H: More on Informed Consent and Data Management

NOTE: You can find guidance and templates for preparing your Informed Consent materials [here](#)

Your research involves human participants as Research Subjects if you are recruiting them or actively involving or influencing, manipulating or directing them in any way in your research activities. This means you must seek informed consent and agree/ implement appropriate safeguards regardless of whether you are collecting any PIRD.

Where you are also collecting PIRD, and using Informed Consent as the legal basis for your research, you need to also make sure that your IC materials are clear on any related risks and the mitigating measures you will take – including through responsible data management.

Got a comment on this checklist or the HREC process? You can leave your comments [here](#)

IV. Signature/s

Please note that by signing this checklist list as the sole, or Responsible, researcher you are providing approval of the completeness and quality of the submission, as well as confirming alignment between GDPR, Data Management and Informed Consent requirements.

Name of Corresponding Researcher (if different from the Responsible Researcher) (print)

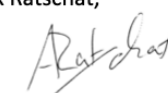
Signature of Corresponding Researcher:
Eline van der Stoep,



Date:
March 15th, 2023

Name of Responsible Researcher (print)

Signature (or upload consent by mail) Responsible Researcher:
Alex Ratschat,



Date:
March 15th, 2023

V. Completing your HREC application

Please use the following list to check that you have provided all relevant documentation

Required:

- **Always:** This completed HREC checklist
- **Always:** A data management plan (reviewed, where necessary, by a data-steward)
- **Usually:** A complete Informed Consent form (including Participant Information) and/or Opening Statement (for online consent)

Please also attach any of the following, if relevant to your research:

Document or approval	Contact/s
Full Research Ethics Application	After the assessment of your initial application HREC will let you know if and when you need to submit additional information
Signed, valid Device Report	Your Faculty HSE advisor
Ethics approval from an external Medical Committee	TU Delft Policy Advisor, Medical (Devices) Research
Ethics approval from an external Research Ethics Committee	Please append, if possible, with your submission
Approved Data Transfer or Data Processing Agreement	Your Faculty Data Steward and/or TU Delft Privacy Team
Approved Graduation Agreement	Your Master’s thesis supervisor
Data Processing Impact Assessment (DPIA)	TU Delft Privacy Team
Other specific requirement	Please reference/explain in your checklist and append with your submission

The HREC approval consists of the following documents:

1. HREC checklist
2. **Device report**
3. Data management plan

Delft University of Technology
INSPECTION REPORT FOR DEVICES TO BE USED IN CONNECTION
WITH HUMAN SUBJECT RESEARCH

This report should be completed for every experimental device that is to be used in interaction with humans and that is not CE certified or used in a setting where the CE certification no longer applies¹. The first part of the report has to be completed by the researcher and/or a responsible technician. Then, the safety officer (AMA – Arbo en milieu adviseur) of the corresponding faculty has to inspect the device and fill in the second part of this form. Please visit <https://intranet.tudelft.nl/arbeidsomstandigheden/arbeidsomstandigheden/overzicht-amas/> for more information.

Note that in addition to this, all experiments that involve human subjects have to be approved by the Human Research Ethics Committee of TU Delft. You can find more information on the procedures at <http://www.hrec.tudelft.nl/>

Device identification (name, location): Portable hand trainer

Configurations inspected²: NA

Type of experiment to be carried out on the device:³ Usability for unsupervised hand training

Name(s) of applicants(s): Alexandre Ratschat, Raphael Rätz, Laura Marchal-Crespo

Job title(s) of applicants(s): PhD student, External PhD student, Associate Professor

(Please note that the inspection report should be filled in by a TU Delft employee. In case of a BSc/MSc thesis project, the responsible supervisor has to fill in and sign the inspection report.)

Date: 21-04-2022

Signature(s): 

¹ Modified, altered, used for a purpose not reasonably foreseen in the CE certification
² If the devices can be used in multiple configurations, otherwise insert NA
³ e.g. driving, flying, VR navigation, physical exercise, ...

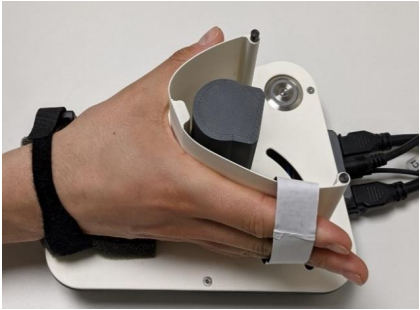
Setup summary

Please provide a brief description of the experimental device (functions and components) and the setup in which context it supposed to be used. Please document with pictures where necessary.

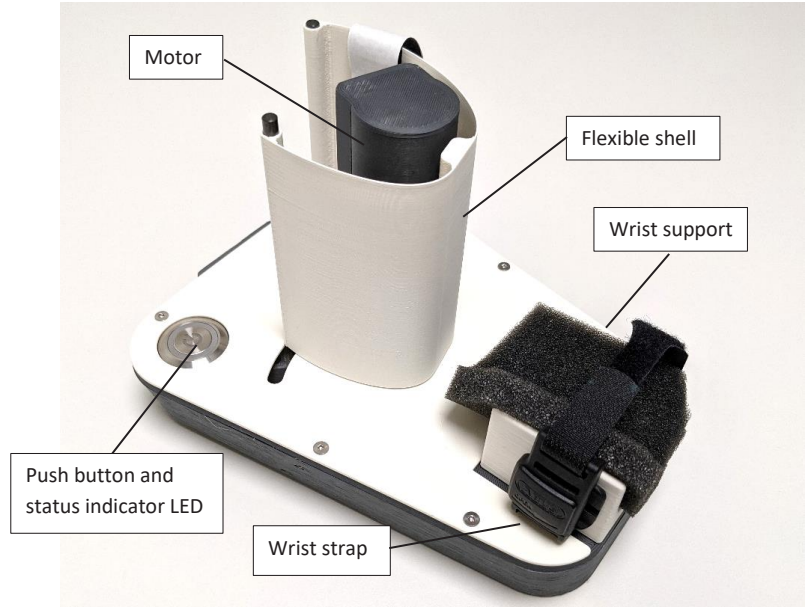
More elaborate descriptions should be added as an appendix (see below).

The experimental device is developed for sensorimotor training of hand and wrist functions. It consists of a flexible shell that can be grasped and a platform which is rounded at the bottom. The shell allows to perform grasping movements of the hand, while the entire device can be tilted to perform pronosupination movements. An electric motor is used to actuate the shell and to generate haptic feedback and to provide resistance or assistance during grasping movements. Exercises with the device can be performed using a computer and a monitor. The device is equipped with two independent emergency stop buttons – one for the participant and one for the experimenter.

The functionalities of the device are as follows:

	
Grasping (closed hand)	Grasping (open hand)
	
Tilting the device for pronosupination movements	

The setup consists of the parts listed below:

	
1 x Portable hand training device (see A1_OperationsManual for details)	
	
2 x Emergency stop button	1 x Power supply
	
1 x Host computer (exemplary)	1 x Monitor (exemplary)

Risk checklist

Please fill in the following checklist and consider these hazards that are typically present in many research setups. If a hazard is present, please describe how it is dealt with.

Also, mention any other hazards that are present.

Hazard type	Present	Hazard source	Mitigation measures
Mechanical (sharp edges, moving equipment, etc.)	x	The device is actuated by an electric motor.	The force produced by the motor does not exceed 20N. The participant and the experimenter each have an independent emergency button that immediately powers off the device.
Electrical	x	The device is powered by electricity.	An external, certified power supply provides 12V DC to the device. The voltage present in the device is not harmful. All cables and connectors are regularly checked.
Structural failure	x	Mechanical parts could fatigue and break.	The device is inspected prior to each use. It is designed such that any mechanical failure is not harmful.
Touch Temperature	x	The motor or the motor driver may get warm during use.	The motor driver is not accessible to the user. The motor must not be touched during use. This is indicated in the appendix A1_OperationsManual. See A2_RiskAnalysis for more details.
Electromagnetic radiation			
Ionizing radiation			
(Near-)Optical radiation (lasers, IR-, UV-, bright visible light sources)			
Noise exposure			
Materials (flammability, offgassing, etc.)			
Chemical processes			
Fall risk			
Other:	x		An in-depth risk analysis can be found in the appendix A2_RiskAnalysis.
Other:			
Other:			

Appendices

Here, you may add one or more appendices describing more detailed aspects of your setup or the research procedures.

- A1: Operations Manual
- A2: Risk Analysis
- A3: Data Sheets

Device inspection

(to be filled in by the AMA advisor of the corresponding faculty)

Name: Peter Kohne

Faculty: 3mE/IO

The device and its surroundings described above have been inspected. During this inspection I could not detect any extraordinary risks.

(Briefly describe what components have been inspected and to what extent (i.e. visually, mechanical testing, measurements for electrical safety etc.)

Date: 25-04-2022

Signature: 

Inspection valid until⁴:

Note: changes to the device or set-up, or use of the device for an experiment type that it was not inspected for require a renewed inspection

⁴ Indicate validity of the inspection, with a maximum of 3 years

The HREC approval consists of the following documents:

1. HREC checklist
2. Device report
3. Data management plan

Plan Overview

A Data Management Plan created using DMPonline

Title: Usability study on device for upper limb rehabilitation

Creator:Eline Van der Stoep

Affiliation: Delft University of Technology

Funder: Netherlands Organisation for Scientific Research (NWO)

Template: TU Delft Data Management Plan template (2021)

Project abstract:

High-intensity and repetitive hand training is essential to improve the hand function of people after stroke, leading to better performance of Activities of Daily Living (ADL) and improving the quality of life. Easy-to-use devices for unsupervised training are crucial to increase the availability of training opportunities and, thus, the training frequency. However, such devices often fail the transfer to commercialize due to limited usability and, thus, low acceptance by the target users, stroke patients. In this work, a portable hand rehabilitation device, designed for unsupervised sensorimotor hand training will be presented. The feasibility of unsupervised training and device usability will be evaluated in a study with two groups. One group of healthy participants will join a single-session study. Another group (called the 'stakeholder group'), consisting of experts, will join a multi-session study. The healthy participants are involved to identify general feasibility and usability issues, while experts provide additional feedback for the device development.

ID: 119703

Start date: 20-03-2023

End date: 31-03-2024

Last modified: 16-03-2023

Grant number / URL: P80461

Usability study on device for upper limb rehabilitation

0. Administrative questions

1. Name of data management support staff consulted during the preparation of this plan.

My faculty data steward, Bjørn Bartholdy, has received this DMP for review.

2. Date of consultation with support staff.

I. Data description and collection or re-use of existing data

3. Provide a general description of the type of data you will be working with, including any re-used data:

Type of data	File format(s)	How will data be collected (for re-used data: source and terms of use)?	Purpose of processing	Storage location	Who will have access to the data
Informed Consent Form (Names, email address, age, gender, profession (only expert group))	Paper	In person	To ask for consent and demographics from participants	Locked cabinet in a locked office	Research team of Laura Marchal-Crespo (MLN Lab)
Questionnaires (usability, mental effort, physical effort, motivation)	Digital (.csv)	In person, Microsoft Forms	To assess the usability, mental effort, physical effort and motivation of the device	Project Drive A with limited access, on TU Delft Servers	Research team of Laura Marchal-Crespo (MLN Lab)
Unique Identifiers relating to names	Digital (.csv)	Recruitment	To pseudonymize data	Project Drive B with limited access, on TU Delft Servers	Research team of Laura Marchal-Crespo (MLN Lab)
Task Metrics (Time, Score, Issues, Buttons presses)	Digital (.csv)	Post-evaluation using log files and notes	To assess usability and feasibility of the device	Project Drive A with limited access, on TU Delft Servers	Research team of Laura Marchal-Crespo (MLN Lab)
Semi-formal interview (participant feedback on device, procedure and usability)	Digital (.docx; .mp3)	Post-evaluation using audio recordings and notes during interview	To assess usability and feasibility of the device	Project Drive A with limited access, on TU Delft Servers	Research team of Laura Marchal-Crespo (MLN Lab)

4. How much data storage will you require during the project lifetime?

- < 250 GB

II. Documentation and data quality

5. What documentation will accompany data?

- README file or other documentation explaining how data is organised
- Data dictionary explaining the variables used

III. Storage and backup during research process

6. Where will the data (and code, if applicable) be stored and backed-up during the project lifetime?

- Git(lab)/subversion repository at TU Delft
- Project Storage at TU Delft

IV. Legal and ethical requirements, codes of conduct

7. Does your research involve human subjects or 3rd party datasets collected from human participants?

- Yes

8A. Will you work with personal data? (information about an identified or identifiable natural person)

If you are not sure which option to select, ask your [Faculty Data Steward](#) for advice. You can also check with the [privacy website](#) or contact the privacy team: privacy-tud@tudelft.nl

- Yes

We will collect data such as age, gender, profession, years of expertise, and audio recordings of interviews.

8B. Will you work with any other types of confidential or classified data or code as listed below? (tick all that apply)

If you are not sure which option to select, ask your [Faculty Data Steward](#) for advice.

- No, I will not work with any confidential or classified data/code

9. How will ownership of the data and intellectual property rights to the data be managed?

For projects involving commercially-sensitive research or research involving third parties, seek advice of your [Faculty Contract Manager](#) when answering this question. If this is not the case, you can use the example below.

The datasets underlying the published papers will be publicly released following the TUDelft Research Data Framework Policy. During the active phase of research, the projectleader from TU Delft will oversee the access rights to data (and other outputs), as well as any requests for access from external parties. They will be released publicly no later than at the time of publication of corresponding research papers. Relevant NWO policies will be respected in decisions about data ownership and intellectual property rights.

10. Which personal data will you process? Tick all that apply

- Data collected in Informed Consent form (names and email addresses)
- Gender, date of birth and/or age

- Signed consent forms

11. Please list the categories of data subjects

Participants in the single-session group include healthy subjects. Participants in the stakeholder group include physiotherapists, occupational therapists, clinicians, and engineers. All participants will be adults.

12. Will you be sharing personal data with individuals/organisations outside of the EEA (European Economic Area)?

- No

15. What is the legal ground for personal data processing?

- Informed consent

16. Please describe the informed consent procedure you will follow:

All study participants will be asked for their written consent for taking part in the study and for data processing before the start of the experiment.

17. Where will you store the signed consent forms?

- Other - please explain below

Explained in question 3, locked cabinet in locked office.

18. Does the processing of the personal data result in a high risk to the data subjects?

If the processing of the personal data results in a high risk to the data subjects, it is required to perform [Data Protection Impact Assessment \(DPIA\)](#). In order to determine if there is a high risk for the data subjects, please check if any of the options below that are applicable to the processing of the personal data during your research (check all that apply).

If two or more of the options listed below apply, you will have to [complete the DPIA](#). Please get in touch with the privacy team: privacy-tud@tudelft.nl to receive support with DPIA.

If only one of the options listed below applies, your project might need a DPIA. Please get in touch with the privacy team: privacy-tud@tudelft.nl to get advice as to whether DPIA is necessary.

If you have any additional comments, please add them in the box below.

- None of the above applies

22. What will happen with personal research data after the end of the research project?

- Personal data will be shared with others - please explain which personal data will be shared, with whom, how and whether you have specified this in the informed consent form
- Anonymised or aggregated data will be shared with others

The gender, age, years of experience, and profession of the expert group will be pseudonymized and published with explicit consent.

23. How long will (pseudonymised) personal data be stored for?

- 10 years or more, in accordance with the TU Delft Research Data Framework Policy

24. What is the purpose of sharing personal data?

- For research purposes, which are in-line with the original research purpose for which data have been collected

25. Will your study participants be asked for their consent for data sharing?

- Yes, in consent form - please explain below what you will do with data from participants who did not consent to data sharing

If participants do not consent to share personal data (age, gender, profession), they will be excluded from the experiment.

V. Data sharing and long-term preservation

27. Apart from personal data mentioned in question 22, will any other data be publicly shared?

- All other non-personal data (and code) underlying published articles / reports / theses

29. How will you share research data (and code), including the one mentioned in question 22?

- I will upload the data to another data repository (please provide details below)

Zenodo

31. When will the data (or code) be shared?

- As soon as corresponding results (papers, theses, reports) are published

VI. Data management responsibilities and resources

33. Is TU Delft the lead institution for this project?

- Yes, the only institution involved

34. If you leave TU Delft (or are unavailable), who is going to be responsible for the data resulting from this project?

Laura Marchal-Crespo, L.MarchalCrespo@tudelft.nl

35. What resources (for example financial and time) will be dedicated to data management and ensuring that data will be FAIR (Findable, Accessible, Interoperable, Re-usable)?

Zenodo is able to archive 50 GB of data per dataset free of charge. We do not expect to exceed this and therefore there are no additional costs of long-term preservation.

-

C. Informed Consent form

Delft University of Technology
HUMAN RESEARCH ETHICS
INFORMED CONSENT

16-03-2023

Usability study for the development of a device for unsupervised hand and forearm training

Participant Information

You are being invited to participate in a research study titled “Usability study for the development of a device for unsupervised hand and forearm training”. This study is performed by the Motor Learning and Neurorehabilitation laboratory from the TU Delft.

The purpose of this research study is to evaluate the usability of a hand and forearm training device. The study will include 2 groups of participants. The first group will participate for only one session of approximately 60 minutes. The second group, called the ‘stakeholder group’, will participate in approx. three sessions, divided over a period of twelve weeks, of approximately 60-90 minutes.

You are in the (single-session / stakeholder) group (to be filled in by the researcher).

Single-Session Group: We will be asking you to use the device in a simulated unsupervised scenario (an experimenter will always be present), to turn it on and to perform tasks in a game which is displayed on a computer monitor. You will receive instructions prior to the experiment. After the experiment, you will be asked to complete a questionnaire and to share your feedback in an interview. During the experiment, audio will be recorded. Furthermore, metrics related to the task will be recorded. The gathered data will help to evaluate the usability and identify areas of improvement of the device. The data will be used for further development of the device, reports, publications, presentations, and teaching.

Stakeholder Group: During multiple sessions, we will ask you to share your opinion about the device and potential improvements. You will receive instructions about the sessions beforehand. During the sessions, audio will be recorded. The gathered data will help to evaluate the proposed improvements. The data will be used for further development of the device, reports, publications, presentations, and teaching.

Risks Involved: Because the device that you will test is a prototype, it cannot be excluded that a failure or malfunction occurs, which could potentially result in mild discomfort. Otherwise, no physical, emotional or reputational risks are expected. Although the haptic forces that you will experience during the experiment are low, the device is equipped with appropriate safety features. The device’s appearance and function will change during the development stage according to identified areas of improvement, potentially resulting in new risks. Every device iteration will be assessed by the safety officer of the faculty.

Your participation in this study is entirely voluntary and you can withdraw at any time during the experiment. You are free to omit any questions. You have the right to request access to and/or deletion of your collected data until one month after your participation, before the publication of the study. In case of any questions or requests, contact:

Eline van der Stoep
Motor Learning and Neurorehabilitation Laboratory
Department of Mechanical and Maritime Engineering
Delft University of Technology
Building 34, Mekelweg 2
2628 CD Delft, Netherlands
e.n.vanderstoep@student.tudelft.nl

Explicit Consent Points

PLEASE TICK THE APPROPRIATE BOXES	Yes	No
A: GENERAL AGREEMENT – RESEARCH GOALS, PARTICPANT TASKS AND VOLUNTARY PARTICIPATION		
1. I have read and understood the study information dated 16.03.2023, or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction.	☐	☐
2. I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason.	☐	☐
3. I understand that taking part in the study involves: - I will receive instructions about the tasks and the device that I will test and evaluate. (single-session group) I will perform tasks with the device in a simulated unsupervised scenario. This means that the experimenter will be close enough to help in case of emergency, but I will be asked to perform the tasks by myself. (single-session group) I will be setting up a research prototype device for hand and forearm training and I will be performing different tasks with this device. Task metrics (e.g., time, completeness, issues) will be recorded. - The device is capable of haptic rendering. This means that it will simulate interaction forces with tangible objects that are displayed on the computer monitor. When I touch an object in the specific task, I will feel the interaction forces through the device. - During the study sessions audio recordings of me will be recorded. - I will have to complete a set of questionnaires. - I will be interviewed by the experimenter. The audio of the interview will be recorded. (stakeholder group) I will participate in activities, e.g., brainstorming, with others.	☐	☐
5. (single-session group) I understand that the study will take approximately 60 minutes. (stakeholder group) I understand that each session will take approximately 60-90 minutes, total 3-5h.	☐	☐
B: POTENTIAL RISKS OF PARTICIPATING (INCLUDING DATA PROTECTION)		
6. I understand that taking part in the study involves the following risks: - The device that will be evaluated is a research prototype and not a CE-certified device. It can therefore not be excluded that a mechanical or electrical failure or a software malfunction occurs. - If such a failure occurs (e.g., the handle of the device breaks or a strap becomes loose), I might experience discomfort. - The device will change throughout the study. I understand that these will be mitigated by: - The device is equipped with an emergency stop button. Pushing the emergency stop button will immediately power off the device. I am allowed to press the emergency stop button at any time without justification. - An in-depth risk analysis was performed by the developers. The risk of a harmful incident was mitigated by design.	☐	☐

PLEASE TICK THE APPROPRIATE BOXES	Yes	No
Safety of the device will be evaluated before every session by the developers and the security officer.		
7. I understand that taking part in the study also involves collecting specific personally identifiable information (PII) such as my name, age, profession and contact details and associated personally identifiable research data (PIRD) such as audio recordings with the potential risk of my identity being revealed to all researchers involved in this study. No PII or PIRD will be made publicly available unless explicit consent is given (see questions 12 – 13).	☐	☐
9. I understand that the following steps will be taken to minimise the threat of a data breach, and protect my identity in the event of such a breach: - All data will be stored according to a data management plan that was developed and approved by an expert at TU Delft. - The data will be stored on a server located at the TU Delft. - The data will be pseudonymized. Every participant will receive a unique identifier. - The keys for the unique identifier – participant allocation will be stored on a separate drive. - The informed consent sheet will be stored in a locked cabinet in a locked office. - Audio recordings will be stored in a password-protected folder.	☐	☐
10. I understand that personal information collected about me that can identify me, such as my name, my age, my gender and my profession will not be shared beyond the study team.	☐	☐
11. I understand that the (identifiable) personal data I provide will be destroyed after publication of the study results.	☐	☐
C: RESEARCH PUBLICATION, DISSEMINATION AND APPLICATION		
12. I understand that after the research study the de-identified information I provide will be used for further development of the device, reports, publications, presentations, and teaching.	☐	☐
13. I agree that my responses, views or other input can be quoted anonymously in research outputs.	☐	☐
14. Optional: I give explicit permission that my audio recordings do not have to be deleted after publication of the study results (see questions 10, 11). This is not mandatory for the participation in the experiment. There will be no disadvantages if this is answered with “No”.	☐	☐
D: (LONGTERM) DATA STORAGE, ACCESS AND REUSE		
15. I give permission for the de-identified research data (task metrics, transcribed audio recordings, questionnaire results, age, gender, profession) that I provide to be archived the Zenodo repository so it can be used for future research and learning.	☐	☐
16. I understand that access to this repository is open.	☐	☐

Signatures

Name of participant [printed]

Signature

Date

I, as researcher, have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting.

Eline van der Stoep

Researcher name [printed]

Signature

Date

Study contact details for further information:

Eline van der Stoep
Motor Learning and Neurorehabilitation Laboratory
Department of Mechanical and Maritime Engineering
Delft University of Technology
Building 34, Mekelweg 2
2628 CD Delft, Netherlands
e.n.vanderstoep@student.tudelft.nl

D1. Peer test protocol

Usability test with PEERS – PROCEDURE

Week 6: April 3rd – 7th

INTRODUCTION & TRAINING SESSION (15')

1. Welcome and introduction
2. Sign consent form
3. Explain experiment setting
 1. Where to sit
 2. Prepare table and chair, adjust height
 3. Audio is recorded
 4. Asking questions is possible
 5. Thinking out loud!
 6. Explain game instructions >> do it yourself
 7. Remind that the experiment simulates an “unsupervised training”
4. Run test
 1. Setting up/intro 5'
 2. Start the game 5'
 3. Stop game 2'

SEMI-STRUCTURED INTERVIEW (15')

Ask the following questions:

- Regarding the full system:
 - i. How simple was it to use for you?
 - ii. Did you feel comfortable using the system?
 - iii. Did you think the functions of the system are well integrated?
- How did you experience setting up the device using **the instructions manual** provided?
 - i. Were the instructions clear enough?
 - ii. Was it easy to find the information that you needed?
 - iii. What did you like the most?
 - iv. What did you like the least?
- How did you experience **performing the two different movements** to complete the task?
 - i. Was everything clear?
 - ii. How physically and mentally demanding did you find the tasks you had to perform?
- (How did you experience the **haptic feedback**?)
- What do you think of the **serious game** used for training?
 - i. To what extent did you experience the different liquids differently?
 - ii. How did you experience the UI of the game?
- If you could **change** anything to the design, what would it be and how?
 - i. Ergonomics
 - ii. Usability
 - iii. UI
- Any other **comments**/tips/recommendations?

CLOSURE (2')

Checklist of required items:

- Prototype device + 2 emergency buttons + shells
- 1x laptop HP
- Mobile phone for audio recording
- Consent forms
- Interview questions

Set-up before experiment:

- Prepare the experimental room (IO-K5).
- Turn on Windows Laptop and connect to the prototype device via USB cable.
- Check that emergency buttons are unlocked and correctly placed.
- Start the correct game, size S/M/L (try any shell size).
- Test the device functionality:
 - Computer screen is working, and the resolution is correct.
 - Calibration of device is working.
 - Red LED during operation.
 - Device button works (try to navigate through instructions).
 - Haptics work (different sensations for each dispenser).
 - The shell compensation works (movements require almost no force).
 - Pronosupination results in left/right movement.
 - The timer is displayed and shows 5:00.
- Exit the game.

D2. Peer test transcripts

Peer test 1

Subject: Peer test 1

Location: Industrial Design Engineering faculty TU Delft, studio K5

Date: April 4th, 2023

P=healthy participant (student)

E=Eline

P: “Ik mag hem niet aanraken in ieder geval”.

P: “1,2,3. Ah, oké.”

E: “Oh wacht, hij moet nog een keer, want hij moet kalibreren.”

P: “Ja, dat staat er, ja”

E: “Hij heeft vandaag wat kuurtjes want de vorige keren deed hij het gewoon altijd.

Misschien ben ik hem aan het overbelasten. Nou.”

P: “Ik weet dat alles erin en eruit altijd de oplossing is.”

E: “Ja, echt he. Nou. Ja, nu doet hij dit. Ach. Oké, misschien als ik het spel opnieuw opstart.

Sorry voor de onderbreking.”

E: “Best wel leuk bedacht he?”

P: “Ja.”

E: “Ja, hij doet het.”

P: “Oke, en wat is het spel?”

P: “Hold back the locking mechanism of the wrist to strap it open. Ja, oke naar achteren.

Place your hand around the outer shell. You can adjust finger strap if needed. AHA. Close

the wrist strap and adjust if necessary. The wrist strap locking mechanism is magnetic so will

hear a click sound when it locks. AHA.”

P: “Squeeze all the bottles to fill the glasses. Try not to spill liquid. Oké.”

P: “To the other hand. Oké, spannend. Press the emergency stop button. This is

unsupervised environment. Try to solve all the questions you have on your own. If you are

absolutely certain you can’t resolve the question on your own, ask the researcher. Press the

device button once quickly to start the game. OH!”

E: “Ah, hij doet het niet.”

E: “Hij heeft het nog nooit zo slecht gedaan. Ik denk dat het door die kabel kwam die kwijt

was.”

P: “Je kent hem ook goed genoeg om te weten wanneer die het niet doet.”

E: “Ja.. Echt zonde.”

P: “We hebben alle tijd.”

E: “Gelukkig.”

P: “Aha, gaat veel naast. Weet niet of dat. Oh dit gaat wel van m’n levens af, ik moet iets

anders doen. Ahaaaaa.”

E: “zo grappig hoe je reageert.

P: “Oeh, ik vind het spannend. Aha.”

P: “Hij kan wel harder.”

E: “Voel je verschil tussen de viscositeit van de verschillende units?”

P: “uuuh, naja ik moest harder knijpen. Nu moet ik heel hard knijpen. Oh m’n levens gaan

heel snel. Oh, heh. Dit gaat mij te langzaam. Ik moet hier echt heel voorzichtig mee doen,

ho! Ho! Ho! Oh, ik krijg een nieuw glas erbij.”

E: “Dat is inderdaad niet uitgelegd.”

P: “Ah, dit keer is het goed gegaan. Nu komt de moeilijke weer.”

P: “Oke, ik mag hem niet meer.”

E: “oeh oke. Je snapt wel het idee toch?”

P: “Ja.”

E: “Oke, nu heb ik nog wat vragen.”

P: “Yes.”

E: “Oke, eerst over het hele product. Vond je het simpel om te gebruiken?”

P: “Uh, opzich wel, want er stond heel duidelijk dat die naar achteren moest. Oh, oeps.”

E: “Oh, ik doe hem wel even uit.”

P: “Wat ik wilde illustreren was dat er stond dat je hem naar achteren moest doen en het

ziet eruit als **een magneet dus je denkt dat je hem zo moet doen**. Umm, ja was makkelijk te

gebruiken.”

E: “En het spel, de instructies enzo?”

P: “Ja, dat was ook wel redelijk duidelijk. **Enige wat ik niet helemaal begreep, omdat je ook**

naar links en rechts kan, dat je ook naar voren en naar achteren kan, hahaha. En dat je dus

niet moet gaan knijpen om daarheen te gaan. Want dat is ook wel een beetje raar.

E: “Ja, dat is een gekke beweging.”

P: “Ja, **om te knijpen om erheen te gaan** en dan moet je vervolgens gaan voelen hoe sterk je

moet knijpen.”

E: “Was het comfortabel om het product te gebruiken? Of viel je iets op dat iets niet lekker

lag ofzo?”

P: “uuuuu, voor 3 min was het echt prima. Het is allemaal best zacht. Misschien is het juist

wel RSI beter, **maar het is wel een gelifte arm dus ik weet niet hoelang je dat volhoudt**.”

E: “Ja vanaf hier bedoel je dan?”

P: “Ja, het zit wel echt net een stukje hoger.”

E: “Oke. Had je door de instructies het idee dat je alle informatie nodig had die je moest

hebben om het spel te kunnen spelen? Je noemde net al dat je het idee had dat je dit moest

doen.”

P: “Uhhh, maar ik vond het ook wel een beetje een **overload aan informatie**. Ik denk dat je

mensen ook wel eens gewoon kan laten ervaren.”

E: “Dat komt een beetje terug in de volgende vraag. Was het fysiek of mentaal demanding?”

P: “Dit? Nee.”

E: “En mentaal?”

P: “Nou, toen je vroeg van. Nadat ik voor het eerst doorhad dat je niet moest spetteren,

moet ik wel een stukje beter concentreren hoe hard ik moest knijpen.”

E: “Nice. Dat wordt niet in de instructie genoemd toch dat ze verschillende viscositeiten

hebben toch?”

P: “Nee. Tenminste dat heb ik niet gelezen.”

E: “Dit had ik al gevraagd. Voelde je verschil in viscositeit. Dus dat je bij de ene harder moest

knijpen dan bij de ander? Haptic feedback.”

P: “uhhh, nee. Voor mn gevoel niet. Ik had het idee dat ik helemaal kon knijpen of niet. Ik

voel niet echt druk terug, dat het heel zwaar was.”

E: “Dit is een hele open vraag, maar als je iets nu in je opkomt wat je eraan zou veranderen,

wat zou je dan veranderen? Dat kan op ergonomie, usability of interface, etc. Als ik iets

meer context uitleg. Het is voor mensen die hun hand en onderarm moeten revalideren.

Dus ze kunnen deze hand wel gebruiken en deze niet. En dit doen ze dan naast de therapie

die ze al hebben. Dus in hun bed of aan een tafel in hun kamertje. Je hoeft ook niks te zeggen hoor.

P: “Ik zat te denken, want ik zou **persoonlijk meer feedback willen krijgen**, van oké je hebt nu heel hard aan het drukken of niet, want ik had het gevoel dat ik eigenlijk elke keer naar de max ging en dan kijken hoe je eruit kan. Uhm.”

E: “Van het interface of van het device?”

P: “Nou, ik speelde hiermee en dan dacht ik dat ik heel hard kneep en dan losliet. Naja, ik had niet per se het gevoel dat. Ik deed zeg maar aan het begin zat ik te knijpen en keek ik hoever ik terug moest gaan en op het oog goed ging. **Daarvoor zou ik meer feedback willen hebben, dat ik eigenlijk al op de max hoor te zitten.** Dat je bij de ene zo knijpt en bij de andere zo moet knijpen soort van. Maar ik begrijp wel dat als je dit aan het trainen bent met je arm dat de beweging überhaupt al zwaarder is, waardoor ik te hard aan het knijpen ben.”

E: “En wil je dan die feedback van het device of van de computer?”

P: “Uh, **via de device** eigenlijk het liefst.”

E: “Oké dankjewel dat was het. Dankjewel voor het meedoen, ondanks de hakkelige bedoeling.”

Peer test 2

Subject: Peer test 2
Location: Industrial Design Engineering faculty TU Delft, studio K5
Date: April 4th, 2023

P=healthy participant (student)
E=Eline

E: “Ongeveer 5 slides en dan begint het spel.”

P: “Hoelang duurt het ongeveer?”

E: “Het spel iets van 2 minuten, en dit duurt 5 minuten. En dan nog wat vraagjes. En als je dingen bedenkt, dan lekker hardop denken.”

P: “**Hij moet een kleur geven?**”

E: “Nee je kan gewoon loslaten. Dat is ook al een issue die ik heb ontdekt.”

P: “At least three seconds, yes, okay.”

P: “Ik zou hier bijvoorbeeld ‘**once quickly**’ dat betekent meestal van, ja meestal leg je dat niet zo uit. Maar het is een beetje meer van taalgebruik. Weet ik niet, maakt niet uit.”

P: “Ik denk dat het in ieder geval **nice is om visuals te hebben**, van hoe gaat je hand erin, doe dit zo aan ofzo, want ik vind dit best wel, ja, ik heb het idee dat ik dit moet doen, maar met woorden word ik altijd een beetje in de war.

E: “Ja zeker.”

P: “Net zoals de gebruiksaanwijzing van ikea, gewoon chill.”

P: “**Hij zit ook best hoog**, maar nee dat kan niet anders.”

E: “Ja, goeie.”

P: “En misschien is dit comfortabeler dan zo. Als hier ofzo iets zit. Ik gooi echt alles wat ik denk he.”

E: “Ja goeie, doe maar gewoon.”

P: “**Ik vind hier ook heel veel gaande.** Ik denk dat glass niet per se uitgelegd hoeft te worden. Bottle, liquid. Deze is best wel veel dingen, en voel score hand dit ik weet het niet zo goed.”

P: “Mag ik het al proberen?”

P: “Oh leuk!”

P: “Oh je moet het ook echt bewegen zo.”

P: “Hooo.”

E: “Doe is zo en dan nog een keer proberen?”

E: “Mmh, oh nee, hij moet ook echt, wacht opnieuw proberen.”

P: “Wel echt een vet apparaat.”

E: “Ja wel echt goed ontworpen, in ieder geval functioneel heel goed.”

-Personal conversation with participant, no relation to test-

E: “Oke, het werkt, nice.”

P: “Oh, het werkt vanzelf.”

E: “Oh nee toch niet.”

E: “Ja, het is wel leuk dat ik alvast dingetjes kan testen.”

E: “Had je het idee dat je goed snapte wat je moest doen?”

P: “Ja, het spreekt best voor zich. Maar ik denk dat het best wel veel tekstueel is en dan is het moeilijker is om voor me te zien, maar ik weet niet of dat bij iedereen is maar ik ben echt een visueel persoon.”

E: “Ik ga het nog een keer proberen. Oh, dit is al niet goed.”

P: “Dit is ook lekker flexibel.”

E: “Ja dit is inderdaad goed geprint.”

E: “Ja zo, ja, kijk!”

P: “Zooo, het maakt ook echt uit hoeveel je knijpt.”

P: “**Hij moet gewoon vol denk ik he?**”

E: “Ik zeg niks.”

P: “oh oh oh.”

E: “Echt grappig.”

P: “Echt leuk!”

E: “Ja?”

P: “Ja dit gaat ook meer om de precisie van hoe hard je knijpt en.”

P: “oh, oeh, o ja, oh leuk! Ik snap niet helemaal wat dit hartje betekent.”

P: “Oh misschien als ik te veel mors ofzo.”

E: “Ja dit is je leven soort van.”

P: “**Oh nog een keer? Ik had deze al vol?**”

E: “Hij doet gewoon nieuwe glazen tot de tijd stop is.”

P: “Oh ja, mijn tante is revalidatiearts trouwens. Ze is nu met pensioen. Voor mensen die ernstige ongelukken hebben gehad. Ik weet niet precies wat haar specialisatie was. Ze was altijd heel erg panisch over bepaalde dingen.”

P: “Oh hij doet het niet meer. Naja ik snap wel hoe het werkt.”

E: “Ik was bij Rijndam geweest, en het lijkt mij zo’n pittige baan. Ik mocht even meelopen met iemand die een testje moest doen hoe goed haar handen nog werken want zij heeft MS. Maar het is gewoon een super jonge meid, even oud als ik. En die loopt daar dan. Die is

daar dan 50 dagen intern en daarna gaat ze wel naar huis denk ik. Maar dat je daar dan elke dag zit. En de negativiteit van die mensen.”

P: “Het is hard om dit te zien. Dat die mensen zo strugglen en dat er echt iets ernstigs gebeurd is. Mijn tante was altijd heel erg van voorzichtig doen. Niet heel leip maar wel altijd heel duidelijk van voorzichtig rijden. Terwijl haar man rijdt als een gek. Die rijdt zo assertief niet normaal haha.

E: “Oke, nog een paar vragen.”

P: “ja.”

E: “Eerst over het hele systeem, dus de hele combinatie tussen de interface en product.

Vind het je het makkelijk te gebruiken?”

P: “Ja, eigenlijk wel. Ik denk inderdaad **qua comfort hier verlengde is gewoon zit fijner**. Dan is het iets meer alsof je een joystick hebt.”

E: “Ja, heb je een referentie? Wat bedoel je met joystick?”

P: “Ja vroeger had je zo’n game met zo’n joystick alleen dan zit het hoger, maar dan houd je hem in je hand. En ik denk dit werkt heel soepel en hij crasht af en toe ja dat kan gebeuren. Dit is ook wel heel comfortabel. En dit zit ook prima denk ik.”

E: “Het was eerst niet helemaal duidelijk hoe je deze moest gebruiken toch?”

P: “Nee, dit niet, zeker, ik heb geen idee. Maar dat stond ook niet. Ik dacht gewoon ik doe dit open en dan zo doorheen. Ik ga hier meer op af. **Ik ben zo’n sluiting ook niet gewend**. En ik denk dat als er een foto staat van dit kan open, dan zou ik het wel gebruiken.”

E: “Die was er trouwens wel.”

P: “oh ja ik heb heel slecht gekeken dan.”

E: “die pijl is ook oranje in een donkere foto.”

P: “Ik vind het niet heel duidelijk en omdat, dan zou ik het misschien opsplitsen want hier staat ook dit en dan heb ik hiernaar aan het kijken en ja dat is ook wat hier staat. Ik ben niet zo heel erg bezig van dit klopt met dat locking mechanism want dit staat hier en dit staat hier.”

E: “Nee, er is geen connectie.”

P: “Je kan misschien inderdaad gewoon **een foto met daaronder de instructie** van doe dit met dit. Want hier is nu gewoon zo van alles. Dat leidt mij wat minder logisch door de instructies heen. En ik denk dat als je naar het spel zelf kijkt, dat is, ja, ik weet niet hoe passend ze het willen hebben. Dat dit daar een beetje op lijkt en andersom. Want dat zou nog wel leuk zijn.”

E: “Daar is echt totaal niet naar gekeken denk ik. Ja goeie.”

P: “**Ja dat het ook als een geheel gebruikt en verkocht kan worden**. Maar het leuke hiervan is wel dat je dan het wel open houdt om andere spellen te maken. Dus dan zou ik het ook niet per se aanpassen. Licht eraan wat ze willen. Want ik kan me voorstellen dat je heel veel verschillende spellen kan maken.”

E: “Ja je zit wel vast aan die twee bewegingen dus zoveel bewegingsvrijheid heb je ook weer niet.”

P: “Ja je hebt ook van die vangspelletjes, met een mandje, dus hoe verder je knijpt hoe hoger of lager die gaat en dit is van links naar rechts.”

E: “En dan komen er ballen.”

P: “Ik zie het al helemaal voor me. Wel leuk!”

E: “Um, even kijken, hier hadden we het eigenlijk al over gehad. Had je het idee dat je toen je door alle slides was dat je alles snapte voordat je het spel begon?”

P: “Nou, ik kwam erachter bij het spel dat het uitmaakte hoe hard je knijpt of ik heb niet goed gelezen. Dat dat uitmaakt. Maar dat is ook weer niet heel erg om het niet te weten. Misschien toch **wel chill omdat je anders had van oh ik doe iets verkeerts**, en dan zit je al van je levens af en dan kan je geen topscore meer maken. Um even denken, en dat **hartje**. Ik weet niet hoe dat hier uitgelegd stond. Niet heel duidelijk als je speelt of morst dat dat dan uitmaakt. Want wat gebeurt er als deze helemaal leeg is?

E: “Ja dat weet ik niet, dat is nog nooit gebeurd.”

P: “Ik wist niet of er nog steeds glazen meer kwamen. Ik was klaar en toen kwam er ineens nog een keer een glas. En toen dacht ik oh ik moet door.”

P: “Dus bijvoorbeeld dat er staat van ‘je moet zoveel mogelijk glazen afronden in een bepaalde tijd’.”

E: “Het doel van het spel bedoel je dan?”

P: “Ja precies.”

P: “En wat betekent de score? Is dat hoeveel glazen je gevuld had?

E: “Oke. Vond je het fysiek of mentaal veeleisend?”

P: “Nee, valt mee. Nee ik vond het wel een leuke hoeveelheid. Maar ik kan me voorstellen dat als je dit voor een uur gaat doen dat je dan niet meer dit spel hoeft te doen.”

E: “Haha, ja dat snap ik.”

P: “Maar dat geeft wel vrijheid om andere spellen te maken of andere interfaces.”

E: “Heb je verschil gevoeld in verschillende viscositeit van de vloeistoffen?”

P: “Ja, want je moest de ene harder knijpen. Deze moest je heel hard knijpen en deze heel weinig.”

E: “Heb je iets van haptic feedback gevoeld vanuit het device? Iets van een soort trillinkje.

Alsof er liquid doorheen stroomt”

P: “Dat is mij niet opgevallen.”

E: “Ja dat is bij heel weinig mensen.”

P: “**Dat kan wel echt meer denk ik, gewoon veel duidelijker**. Is dat een vibratie wat erin zit?”

E: “Ja een hele lichte.”

P: “Ja ik denk dat die harder kan, want het maakt niet uit of het een vibratie is of niet. Want als er iets stroomt en er vibreert is dat is altijd leuk als extra dementie. Dat heb je ook met XBOX. Daar zit een radartje in en als je dan gaat schieten dan gaat hij bbbzzt. Of als je moet opletten of als je aan het rijden bent en je gaat van de weg dan gaat hij ook zo brrrrzt. Of meer weerstand. Dat kan denk nog wel duidelijker.”

E: “Oke goeie. Laatste. Beetje open vraag, maar als je iets zou kunnen veranderen eraan, op ergonomie comfortability of user interface?”

P: “Moet ik meerdere dingen zeggen of een ding?”

E: “Gewoon alles wat in je opkomt.”

P: “Dit inderdaad. Gewoon comfortabel. Verder dit is denk ik ook nodig voor mensen?”

E: “Ja een fixatie punt is wel handig voor mensen. Want was het niet fijn om daar vast te zitten?”

P: “Als ik nu zo denk, dit kan ik wel maar misschien die mensen wel. Dit turnen zonder lukt mij wel, maar ik heb het idee dat dit ook al wel een soort fixatiepunt is. Maar ik snap het wel, dit heeft dan gelijk invloed op je hand, bedoel ik. Ja ik weet niet, het is niet erg, het is het chillst. En de **kleuren zijn kinderlijke** mickey mouse spel. Ik weet niet wat voor doelgroep het per se is. Als je dit een soort james bond thema geeft dan weet ik het wel. Of

je zet er een soort **thema aan vooraf**. Dit is **jouw missie**. Dat je elke keer een andere missie hebt. Zelfde uitvoering, maar dat maakt het spannender om te doen. Maar verder nice.
E: “Thanks voor al jouw feedback. Heel veel dingen. Ook weer nieuwe dingen, dat is wel leuk.”
P: “Nou gelukkig, haha. Dat is waar we het voor doen.”

Peer test 3

Subject: Peer test
Location: Industrial Design Engineering faculty TU Delft, studio K5
Date: April 4th, 2023

P=healthy participant (student)
E=Eline

E: Ja dat is omdat die ging kalibreren maar dat heeft hij al gedaan.
P: Dus dit is allemaal al klaar.
E: Ja, eigenlijk is dit klaar.
P: Device, calibrations, subject, oke, volgende.
P: oke, pull back the locking mechanism. Open. **Toevallig weet ik dit, dat komt van een motor. En skihelmen hebben dit tegenwoordig.**
E: echt? Oh. Niemand heeft dit door, je bent de eerste.
P: En dit kwam omdat er OPEN op staat. Dus het staat er heel duidelijk op hoe het open moet (sarcastisch). Place your hand around the outside of the shell. Oke, dit is de shell. Close the wrist strap.
P: Prima.
P: Game instructions. Squeeze all the bottles to fill the glasses. Try not to spill the liquid. Health bar. Oke, het zal wel. Ik ga het gewoon een keer proberen.
E: Moet je nu veel moeite doen om hem terug te krijgen.
P: Nee.
E: Oke, ik denk dat het nu goed gaat.
P: To move a bottle, oke dus als je beweegt dan pak je de andere. En je ziet echt een handje.
E: yes. Dus als je opeens een gekke beweging voelt, dan kan je erop drukken. Maar dat is niet waarschijnlijk.
P: Ja, kan ik erop drukken?
E: Ja
P: Vet!
P: **Wat moet ik doen? Hoeveel moet erin?**
E: Kan je eens zo doen en dan nog een keer knippen?
E: Ik moet hem opnieuw starten.
P: (Shell klap open) Klak! Zo dat klinkt best wel lomp.
E: Dit is echt de eerste dag dat die dit soort kuren heeft.
P: Cocktailbar, wel een leuk spelletje!
E: Alles weer erin.
P: (Ziet ‘Unity staan’) **Het lijkt bijna PowerPoint, maar het is gewoon onderdeel van het spelletje.**

E: Ja, oke, nog een keer.
P: Ja, kijk is.
E: Oke top, met een kleine onderbreking.
P: Oh ja oke hij moet helemaal vol tot het einde.
P: Haha
P: Oh, nee. Volgens mij is de blauwe gewoon iets mis mee.
E: Probeer dit is nog een keer? Nee.
E: Nee, hij doet het niet meer.
P: Wat zonde! Nou ja het is niet jouw ontwerp. Hoe kan dat nou?
E: Ik weet het ook niet, ze hebben dat vaker gehad.
P: Doe jij wat verkeerd?
E: Nee, ze hadden me al gezegd dat dit soms gebeurt. Maar de testjes die ik vorige week had gedaan, die gingen allemaal goed. Oh nu gaat hij ineens niet meer kalibreren.
P: Oh je hebt twee noodstoppen, eentje voor jezelf en eentje voor iemand anders. Ah oke.
E: Je hebt in ieder geval al een beetje een idee gekregen.
P: Het is mooi. Oh nu is die rood.
E: Ja maar hij moet kalibreren en dat heeft hij niet gedaan.
P: Ding gemold.
E: Misschien als ik ze een keer omwissel.
E: Oke hij is ermee gekapt.
P: Ik heb hem gesloopt.
E: Nee nee!
E: Je hebt een beetje een indicatie gehad toch?
P: Ja
E: Oke. Nog wat vraagjes. Vond je het makkelijk te gebruiken? Het hele systeem dan? Dus met de instructies en dan in combinatie met het product.
P: Ja en nee. Het is voor de eerste keer wel fijn om het zo te doen. Maar als ik het vaker wil spelen, dat is net als bij wii controller, dat je dan een knop hebt op de machine waardoor je niet allemaal dingen op de computer hoeft te doen. **Dus als je daar op de knop drukt, gaat alles gelijk aan.**
E: Dus als je al weet hoe het werkt?
P: JA als ik al weet hoe het werkt. Dan is die uitleg ook niet meer nodig. En dan als je dan hier ergens op een knop drukt, gaat het spelletje gelijk aan. Dat lijkt me nice, misschien sommige mensen niet hoor.
P: En ja die armband. Ziet er niet helemaal 100% fantastisch uit, maar dat maakt niet uit. Ik vind het wel nice dat het magnetisch is. Ook als je oud bent. Waarom is het uberhaupt nodig? Om het een beetje op z’n plek te houden?
E: Ja, om een fixatiepunt te hebben, dat je makkelijker die rotatie kan maken.
P: Ja, op zich als ik dat...
E: Ja eventueel als je hier ook een soort ding plaatst.
P: **Je kan ook aan die kant een schotje plaatsen**, dus iets symmetrischer. Maar dan wordt het weer moeilijker verstelbaar. Aan de andere kant werkt het ook wel weer oke. Nee, maar dat werkt wel lekker.
P: Uh, **ik zou wel ronder maken, de onderkant.**
E: Dat je makkelijker deze beweging kan maken?
P: Ja. Ik weet niet hoe makkelijk het is voor mensen die daar meer moeite mee hebben. Dat die gewoon goed gebalanceerd is en dat je dit makkelijker gaat. Dat komt ook deels door de

kabels die aan de achterkant hangen. Er is een beetje over na gedacht. Ja, dus dat is echt in gebruik. De shell houdt prima vast, dat is leuk gedaan. Dat is prima.

E: En qua comfort?

P: Mmh, ja het gaat hier net wel net niet goed. Dus het is lekker dat het wat zachter is. Het is net wel een gevoelig plekje van je pols waar je alle kracht op krijgt. **Misschien is het toch wel nice als je hier in ieder geval ietsje meer mee loopt.** Niet dat het hier gewoon stopt en dat alles door die strap wordt opgevangen. Misschien zachter schuim, zou ook nog kunnen. Het is best hard, niet super hard, maar het is geen open schuim.

E: Ja, dit is van dat medical approved schuim. Goed schoonmaakbaar.

P: Je hebt gesloten cellen en open cellen. Gesloten is vaak wat harder, maar open cellen gaat zooi in.

E: Dus dat is niet heel hygienisch.

P: Het is best wel zwaar aan de onderkant. Dat zou misschien wel moeten. Als het buigen minder kracht zou kunnen kosten. Het is niet super veel maar als je het langdurig moet gaan oefenen. Dan heb je best wel een lamme arm aan het eind van de training. **Of dat het rollen makkelijker gaat, dat die iets meer daarbij helpt.** Ja.

E: Oke. En had je het idee dat je door alle instructies die je had gekregen wist hoe het spel werkte? Of had je nog vragen in je hoofd.

P: Ik snapte niet wat ik aan het doen ben.

E: Nee?

P: Nee. Ik ben glazen aan het vullen, maar je bent niet aan het mixen ofzo. Het is een cocktailbar, maar je knijpt in een dik en er loopt liquid uit. Het zou leuker zijn, als je een **beetje blauw erin moet doen en dan een beetje groen** er bovenop moet gooien.

E: dat je echt specifiek moet kijken tot hoever je moet vullen.

P: Ja, specifiek moet kijken tot hoever je moet vullen, en dat je dus bijvoorbeeld het glas moet meenemen naar de overkant. Dat je het glas moet pakken, die op een andere plek neer moet zetten. Maar misschien wordt dat te moeilijk. Dat je het idee hebt dat je een drankje aan het maken bent. Nu is het een beetje van ‘oh er moet zoveel in’, gooi dat glas vol en dat is het. Iets minder.

E: Niet zo spannend.

P: Nee. Wel nice dat je de hand kan zien. Dat is wel duidelijk.

E: Was het gelijk duidelijk welke beweging je met je hand moest maken voor welke functie in het spel?

P: JA dit was wel duidelijk. Ja jawel. Ik snapte alleen de score niet.

E: Ja de score is hoeveel glazen je hebt gevuld. Dus waarschijnlijk stopte die heel snel.

P: Uh ja joh. Ik weet niet of het voor mensen met een beroerte..., ja het is wel grappig.

Sommige maken vast cocktails, anderen niet. Waar moet je ergens anders in kunnen knijpen. Een kind gelooft ook wel hoe dit werkt.

E: Voelde je verschil in verschillende viscositeit van de spuiten. Je hebt er niet heel veel gedaan denk ik.

E: En had je door dat er een beetje haptic feedback in het device zat?

P: Nee

E: Dat heeft niemand door.

E: Oke. Vond je het fysiek of mentaal veeleisend.

P: Nee.

P: Ik heb wel gevoeld hoe zwaar zo’n ding kan zijn. Dat lukt mij haast niet, moet je nagaan iemand in revalidatie. De vraag is of dat nodig is. Ik zou het eerder andersom willen zien.

E: Hoe bedoel je andersom?

P: Ja, dat het gewoon wat slapper is. Dat je er makkelijker doorheen duwt. Dus of dat de motor veel vermogen kan leveren als het nodig is, maar dat als het echt te veel wordt dat het dan los schiet. Dat je het kan ontkoppelen als het nodig is. Het was wel echt lomp. Best wel zwaar.

E: En heb je het dan alleen over deze beweging?

P: Nee. De terugslag van dat ding.

E: oh ja klopt. Toen het mis ging.

P: Niet dat ik denk dat het mij verwond, maar ik snap de noodstoppen wel maar dat is niet echt nodig. Niet echt. Het is wel beter om het te hebben.

E: Ja volgens mij willen ze sowieso dat ik dat eruit haal en dat ik het op een andere manier integreer. Het is heel lomp. Het ziet er ook uit alsof het mis kan gaan door die twee knoppen.

P: Je zou bijna denken, **kan ik niet gewoon dit ding de stop maken (wijst naar wrist strap).**

Maar als je met een harder ruk dit eraf ruikt dat het dan stopt. Dan is en je hand weg, dus die kan geen pijn meer krijgen, en dan stopt die ook gewoon. Met die magneetjes werkt wel goed. Dan was het ook logisch geweest dat er geen stopknop lag. Dan kan je gelijk weg als het nodig is. Of dat je zo kan terugtrekken. Hoeft niet per se naar boven, kan ook naar de zijkant. Net als met wielrennen. **Die klikpedalen.** Als je op een specifieke manier gek draait, kan je eruit en er weer in. Maar tijdens het fietsen zit het altijd vast. Alle bewegingen die er tijdens het fietsen op komen, blijft die zitten. Je hebt een heel vage draai, die je even moet leren. Dus als dat makkelijker zou kunnen. **En dan de meest natuurlijke beweging,** die zou je mogelijk moeten maken. En dan als je er vanaf wil, dan zou ik niet weten waarom je nog een stopknop nodig hebt. Als je het allemaal super veilig wil doen.

E: Uh. Dan wel ja.

P: Dan vind ik het wel logisch dat die hier staat. Dat misschien zelfs die eerst hierheen gaat en daarna hierheen. Dat je bijna soort van. Dat dit eigenlijk een soort extra kastje is. Dat is echt alleen aansturing zou zijn. Nu zit alles in die ene kast voor m’n gevoel. Moet je bijna omdraaien. **Dat je alles in de stopknop doet. Dat dit echt alleen maar het stukje wordt wat iets helpt te doen.** Maar goed.

E: Dan zou je het wel veel compacter kunnen maken.

P: Ja veel compacter kunnen maken. Als je hier alleen de bewegingen in doet. Tenzij het echt een product moet worden. Dat ligt er een beetje aan.

P: Zo lomp en stom als je twee dingen hebt.

E: Dat is dan niet heel erg portabel, dat is dan wel jammer.

P: Ik weet niet of het vanuit certificering is dat het moet stoppen.

E: Ja voor de veiligheid. Maar dat is denk ik meer voor het testproduct. Het uiteindelijke product niet. Dus voor het prototype wat ik ga maken, zal dat ook wel moeten. Maar als het ook met zoiets kan werken, is het ook prima. Zal ik achterna moeten gaan!

E: Als laatste vraag, maar dat heb je eigenlijk een beetje beantwoord, maar of je iets zou veranderen, iets wat in je opkomt. Kan iets van usability, UI zijn of ergonomie?

P: Op deze manier, voor m’n gevoel wel minder, het is nice, gaat makkelijk, zit lekker om mijn hand heen, **maar ik heb het gevoel dat bepaalde vingers meer werk doen dan anderen.** Ik weet niet of dat erg is of dat dat de bedoeling is. Maar als ik iets pak. Ik weet niet wat ik aan het pakken ben. Ben ik in zo’n slurf aan het knijpen? Want dan gaat dat anders. Dat maakt verder niet uit, dat dat niet hetzelfde is, maar ik heb het idee dat de onderste twee vingers meer willen doen.

E: Ja dat het een beetje onevenredig verdeeld, bedoel je?

P: Ja

P: Maar misschien als er echt kracht achter zit dat het dan weer anders is. Nee, dan ook.

P: Maar ik vind het niet oncomfortabel, dat is wel vet! Maar het is meer een ding van dat als het echt zwaar wordt, dan ben ik 2/3 vingers meer aan het belasten dan de rest.

E: Ja, ik heb ook het idee dat als je deze beweging maakt dat je duim doet niet zo heel erg mee. Die hangt daar maar. Want dit zorgt ervoor dat...

P: Zit dat aan elkaar vast? Ja. Het is zit ook aan elkaar vast. Oh ja, ja.

E: Nou dat was het, dankjewel!

P: Ik vind het wel leuk!

E1. Decision matrix changes

		1 t/m 5	5=veel	5=hoog	5=veel	5=positive	Score
		Weight of importance	Effort	Costs	Added Value	Sustainable impact	
device	Adjustable wrist holder		3	2	4	3	43
device	Improve ergonomics of wrist holder + strap		2	2	4	3	47
device	Improve ease of use of wrist holder + strap		1	1	3	3	49
device	Improve effectiveness pronosupination movement		2	1	5	3	55
device	Improve effectiveness flexion/extension movement		3	2	5	3	48
device	Include left hand usage		5	4	5	2	32
device	Improve ergonomics of shell + strap		3	2	4	3	43
device	Include independent movement of fingers		4	3	4	2	34
device	Redesign emergency buttons functionality		2	2	2	4	39
device	Redesign on/off button functionality		1	1	3	3	49
device	Improve connection of cables		1	1	3	4	51
device	Redesign Don Doff on embodiment		3	2	5	3	48
game	Increase short-term engagement (extrinsic motivation)						35
game	Increase long-term engagement						35
game	Improve haptic feedback						35
game	Improve engagement with clinic therapy						35
game	Improve visual/audio feedback during game						35
UI	Redesign instructions visuals that take the lead over text						35
UI	Improve order of steps to take						35
combi	Usage without prior instructions from therapist		1	1	2	3	44
combi	Wirelessness of device		3	2	5	4	50
combi	Improve sustainability		3	2	4	5	47
combi	Improve cleanability		2	1	4	4	52
combi	Improve coherency between design of software and embodiment		3	3	2	3	30

effort = time and complexity

Decision matrix 1 (top) is rated by the researcher herself. Afterwards, the ratings were discussed with a physical and occupational therapist from Rijndam. This resulted in matrix 2 (bottom). Note that only changes were made in the column 'added value'.

		1 t/m 5	5=veel	5=hoog	5=veel	5=positive	Score
		Weight of importance	Effort	Costs	Added Value	Sustainable impact	
device	Adjustable wrist holder		3	2	5	3	48
device	Improve ergonomics of wrist holder + strap		2	2	4	3	47
device	Improve ease of use of wrist holder + strap		1	1	4	3	54
device	Improve effectiveness pronosupination movement		2	1	5	3	55
device	Improve effectiveness flexion/extension movement		3	2	5	3	48
device	Include left hand usage		5	4	5	2	32
device	Improve ergonomics of shell + strap		3	2	4	3	43
device	Include independent movement of fingers		4	3	4	2	34
device	Redesign emergency buttons functionality		2	2	2	4	39
device	Redesign on/off button functionality		1	1	2	3	44
device	Improve connection of cables		1	1	2	4	46
device	Redesign Don Doff on embodiment		3	2	5	3	48
game	Increase short-term engagement (extrinsic motivation)						35
game	Increase long-term engagement						35
game	Improve haptic feedback						35
game	Improve engagement with clinic therapy						35
game	Improve visual/audio feedback during game						35
UI	Redesign instructions visuals that take the lead over text						35
UI	Improve order of steps to take						35
combi	Usage without prior instructions from therapist		1	1	2	3	44
combi	Wirelessness of device		3	2	5	4	50
combi	Improve sustainability		3	2	4	5	47
combi	Improve cleanability		2	1	4	4	52
combi	Improve coherency between design of software and embodiment		3	3	2	3	30

effort = time and complexity

		1 t/m5	5=veel	5=hoog	5=veel	5=positive	Score
		Factor	Effort	Costs	Added value	Sustainable impact	
		Weight of importance	4	3	5	2	
device	Adjustable wrist holder		3	2	5	3	48
device	Improve ergonomics of wrist holder + strap		2	2	4	3	47
device	Improve ease of use of wrist holder + strap		1	1	4	3	54
device	Improve effectiveness pronosupination movement		2	1	5	3	55
device	Improve effectiveness flexion/extension movement		3	2	5	3	48
device	Include left hand usage		5	3	5	2	35
device	Improve ergonomics of shell + strap		3	2	4	3	43
device	Include independent movement of fingers		4	3	4	2	34
device	Redesign emergency buttons functionality		2	2	2	4	39
device	Redesign on/off button functionality		1	1	2	3	44
device	Improve connection of cables		1	1	2	4	46
device	Redesign Don Doff on embodiment		3	2	5	3	48
game	Increase short-term engagement (extrinsic motivation)		2	2	4	3	55
game	Increase long-term engagement		4	3	5	3	41
game	Improve haptic feedback		4	1	4	3	42
game	Improve engagement with clinic therapy		2	1	2	3	40
game	Improve visual/audio feedback during game		2	1	3	3	45
user interface	Redesign instructions visuals that take the lead over text		3	1	4	3	46
user interface	Improve order of steps to take		2	1	5	3	55
combi	Usage without prior instructions from therapist		1	1	2	3	44
combi	Wirelessness of device		3	2	5	4	50
combi	Improve sustainability		3	2	4	5	47
combi	Improve cleanability		2	1	4	4	52
combi	Improve coherency between design of software and embodiment		3	3	2	3	30

Effort = time and complexity of implementing improvement
Costs = costs of implementing improvement
Added value = how much more valuable the end-product would be with the improv.
Sust. Impact = an increase or decrease in sustainability of the end-product by implementing improvement

Critical
NICE-to-HAVEs
no attention

The results from the matrix 2 were divided into three groups and color-coded accordingly. This can be seen in matrix 3 (top). The ratings and priority division were discussed with the daily supervisor of the project, a pdh student at the MLN Lab. The outcome of this discussion can be seen in matrix 4 (bottom).

		1 t/m5	5=veel	5=hoog	5=veel	5=positive	Score
		Factor	Effort	Costs	Added value	Sustainable impact	
		Weight of importance	4	3	5	2	
device	Adjustable wrist holder		3	2	5	3	48
device	Improve ergonomics of wrist holder + strap		2	2	4	3	47
device	Improve ease of use of wrist holder + strap		1	1	4	3	54
device	Improve effectiveness pronosupination movement		2	1	5	3	55
device	Improve effectiveness flexion/extension movement		3	2	5	3	48
device	Include left hand usage		5	3	5	2	35
device	Improve ergonomics of shell + strap		3	2	4	3	43
device	Include independent movement of fingers		4	3	4	2	34
device	Redesign emergency buttons functionality		2	2	2	4	39
device	Redesign on/off button functionality		1	1	2	3	44
device	Improve connection of cables		1	1	2	4	46
device	Redesign Don Doff of the physical device		3	2	5	3	48
game	Increase short-term engagement (extrinsic motivation)		2	2	4	3	55
game	Increase long-term engagement		4	3	5	3	41
game	Improve haptic feedback		4	1	4	3	42
game	Improve engagement with clinic therapy		2	1	2	3	40
game	Improve visual/audio feedback during game		2	1	3	3	45
user interface	Redesign instructions visuals that take the lead over text		3	1	4	3	46
user interface	Improve order of steps to take		2	1	5	3	55
combi	Usage without prior instructions from therapist		1	1	2	3	44
combi	Wirelessness of device		3	2	5	4	50
combi	Improve sustainability		3	2	4	5	47
combi	Improve cleanability		2	1	4	4	52
combi	Improve coherency between design of software and embodiment		3	3	2	3	30

Effort = time and complexity of implementing improvement
Costs = costs of implementing improvement
Added value = how much more valuable the end-product would be with the improv.
Sust. Impact = an increase or decrease in sustainability of the end-product by implementing improvement

Critical
NICE-to-HAVEs
no attention

		1 t/m5	5=much	5=high	5=much	5=positive	Score
		Factor	Effort	Costs	Added value	Sustainable impact	
Weight of importance			4	3	5	2	
device	Improve effectiveness pronosupination movement		2	1	5	3	55
device	Improve ease of use of wrist holder + strap		1	1	4	3	54
device	Adjustable wrist holder		3	2	5	3	48
device	Redesign the DOn/DOff element of the physical device		3	2	5	3	48
device	Improve ergonomics of wrist holder + strap		2	2	4	3	47
device	Improve effectiveness flexion/extension movement		3	2	4	3	43
device	Redesign emergency buttons functionality		2	2	2	4	39
device	Improve ergonomics of shell + strap		3	2	3	3	38
device	Include left hand usage		5	3	5	2	35
device	Include independent movement of fingers		4	3	4	2	34
device	Improve connection of cables		1	1	2	4	46
device	Redesign on/off button functionality		1	1	2	3	44
game	Increase short-term engagement (extrinsic motivation)		2	2	4	3	47
game	Improve visual/audio feedback during game		2	1	3	3	45
game	Improve haptic feedback		4	1	4	3	42
game	Increase long-term engagement		4	3	5	3	41
game	Improve engagement with clinic therapy		2	1	2	3	40
user interface	Improve order of steps to take		2	1	5	3	55
user interface	Redesign instructions visuals that take the lead over text		3	1	4	3	46
combi	Improve cleanability		2	1	4	4	52
combi	Improve sustainability		2	2	4	5	51
combi	Wirelessness of device		4	2	5	4	46
combi	Usage without prior instructions from therapist		1	1	2	3	44
combi	Improve coherency between design of software and embodiment		3	3	2	3	30

Effort = time and complexity of implementing improvement
Costs = costs of implementing improvement
Added value = how much more valuable the end-product would be with the improv.
Sust. Impact = an increase or decrease in sustainability of the end-product by implementing improvement

Critical
NICE-to-HAVEs
no attention

Matrix 5 (top) shows the adjustments on the matrix after the discussion with the daily supervisor.

Matrix 6 (bottom) shows the final list of improvements for the project. The final adjustments are based on discussions with the daily supervisor regarding the scope and goal of the project.

		1 t/m5	5=much	5=high	5=much	5=positive	Score
		Factor	Effort	Costs	Added value	Sustainable impact	
Weight factor			4	3	5	2	
device	Improve unnatural pronosupination movement		2	1	5	3	55
device	Improve ease of use of wrist support & wrist strap		1	1	4	3	54
device	Improve danning/doffing of the shell and straps		3	2	5	3	48
device	Improve ergonomics of wrist support & wrist strap		2	2	4	3	47
device	Improve on/off button functionality		1	1	2	3	44
device	Redesign emergency buttons functionality		2	2	2	4	39
device	Improve finger placement and ergonomics of the shell		3	2	3	3	38
device	Improve connection of cables		4	1	2	4	34
device	Accommodate adjustable positioning of the wrist support		3	2	2	3	33
device	Include left hand usage		5	4	5	2	32
device	Include independent movement of fingers		4	3	3	2	29
game	Increase short-term engagement (extrinsic motivation)		2	2	4	3	47
game	Improve visual/audio feedback during game		2	1	3	3	45
game	Improve haptic feedback		4	1	4	3	42
game	Increase long-term engagement		4	3	5	3	41
game	Improve engagement with clinic therapy		2	1	2	3	40
GUI	Improve order of steps to take		2	1	5	3	55
GUI	Redesign instructions visuals that take the lead over text		3	1	4	3	46
combi	Improve cleanability		2	1	4	4	52
combi	Improve sustainability		2	2	4	5	51
combi	Wirelessness of device		4	2	5	4	46
combi	Usage without prior instructions from therapist		1	1	2	3	44
combi	Improve coherency between design of software and embodiment		3	3	2	3	30

Effort = time and complexity of implementing improvement
Costs = costs of implementing improvement
Added value = how much more valuable the end-product would be with the improv.
Sust. Impact = an increase or decrease in sustainability of the end-product by implementing improvement

High-priority
Medium-priority
Low-priority

E2. Explanation of improvements

List of potential improvements (device) - explanation

Improve effectiveness of the pronosupination movement:

Pronosupination is done by turning the device to the left and right. This does not go smoothly. The pronosupination movement must be done along the longitudinal axis of the forearm, which is currently not the case.

Improve ease of use wrist support & wrist strap:

The wrist support is currently not easy to use, because of the unfamiliar locking mechanism and the misleading red lip on the Velcro.

Improve ergonomics of wrist support & wrist strap:

Comfort may be increased when the wrist support's ergonomics are improved. Ergonomics includes a design that is based on anthropometric data, more effective support at the wrist, towards the hand, and towards the elbow.

Improve the donning and doffing of the shell and straps:

The hand cannot be placed easily around the shell, because the donning steps do not support people with spasticity.

Improve on/off button functionality:

The on/off button has two functions: turning the physical device on and off and navigating through the game. The on/off icon is therefore confusing. Moreover, the blinking red light does not communicate effectively.

Redesign emergency buttons functionality:

The current two emergency buttons are necessary for safety reasons but are bulky and scare users. The main function is for the user to be able to stop whenever preferred, which can be designed in a subtler way.

Improve finger placement and ergonomics of the shell:

The strap fixates the fingers to the shell, the thumb is currently free to move. The thumb and lateral side of the fingers are not supported enough to optimise comfort. The shell is based on the anthropometrics of the human hand and makes sure the shell movement is following the same pattern as the natural hand movement while performing flexion/extension. There are currently little use cues on how to place the fingers and thumb around the shell.

Improve connection of cables:

The connection of cables is not good, since the connection is lost sometimes while the cables are still connected.

Adjustable wrist holder:

~~The wrist holder is fixed on the base. Comfort may increase when the wrist holder is adjustable in distance to the shell, height to the base, width, and angle to the base.~~

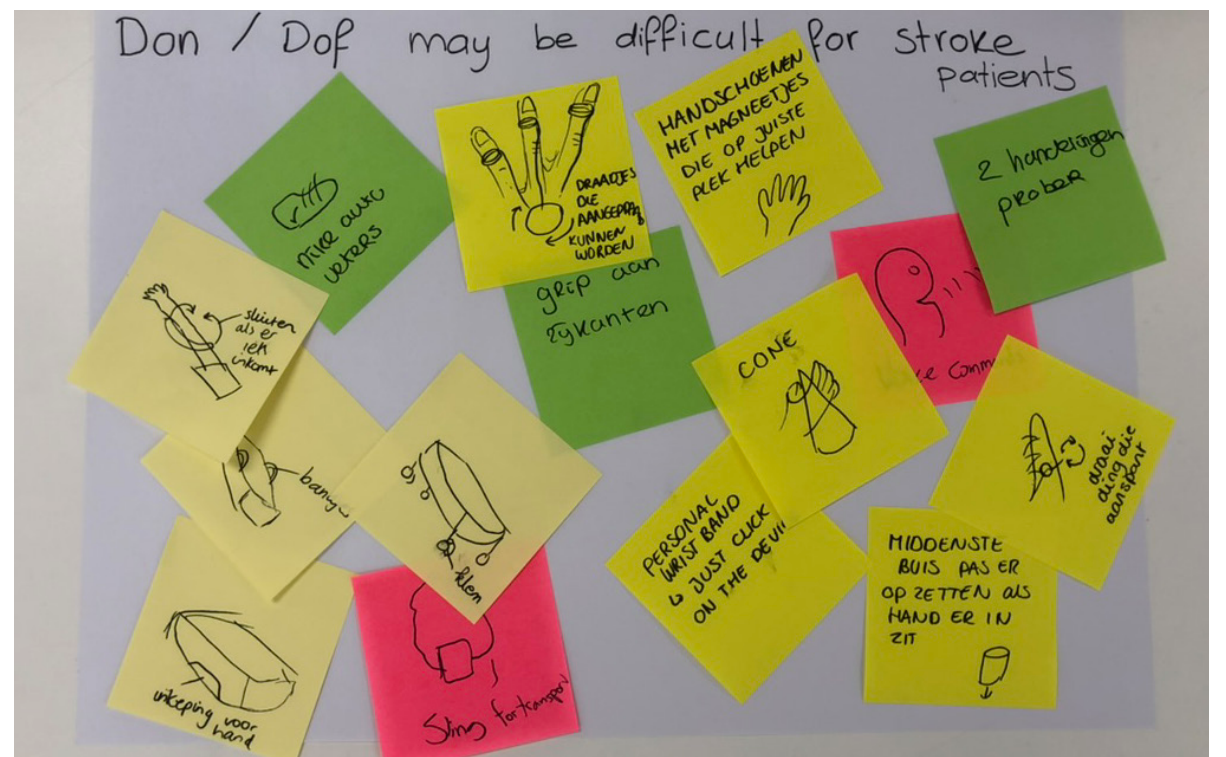
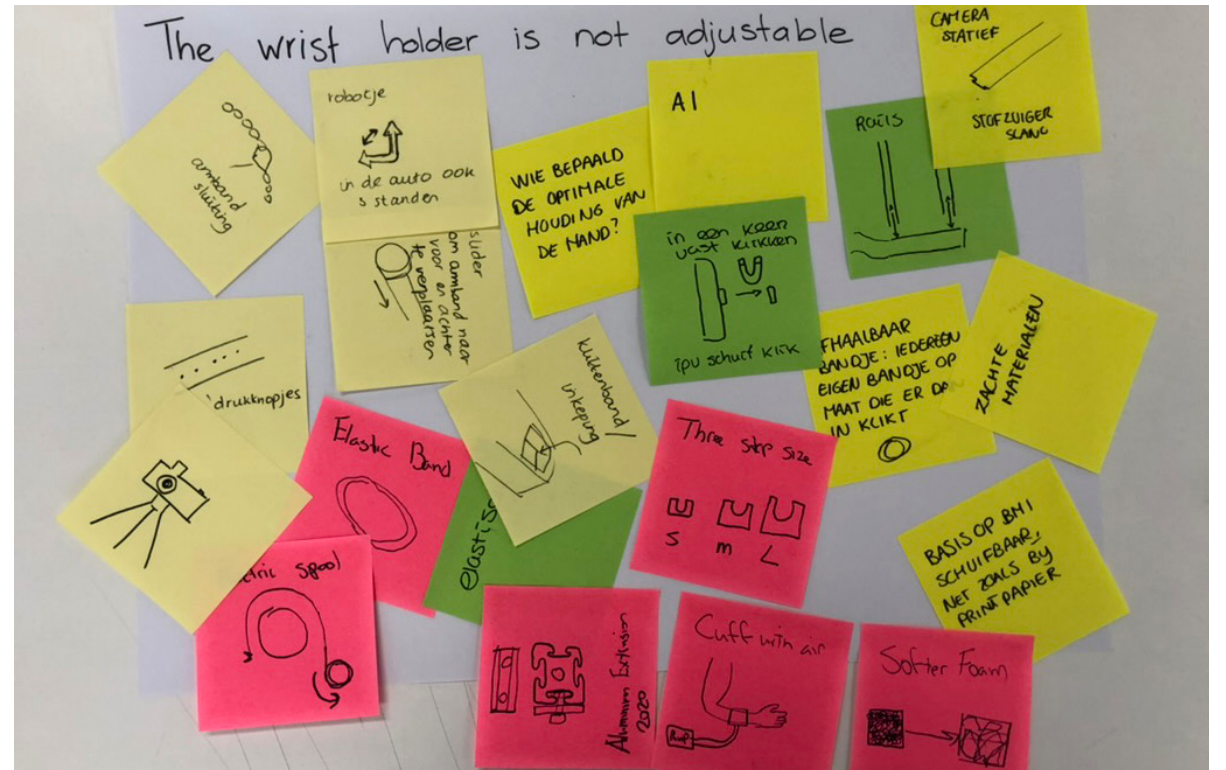
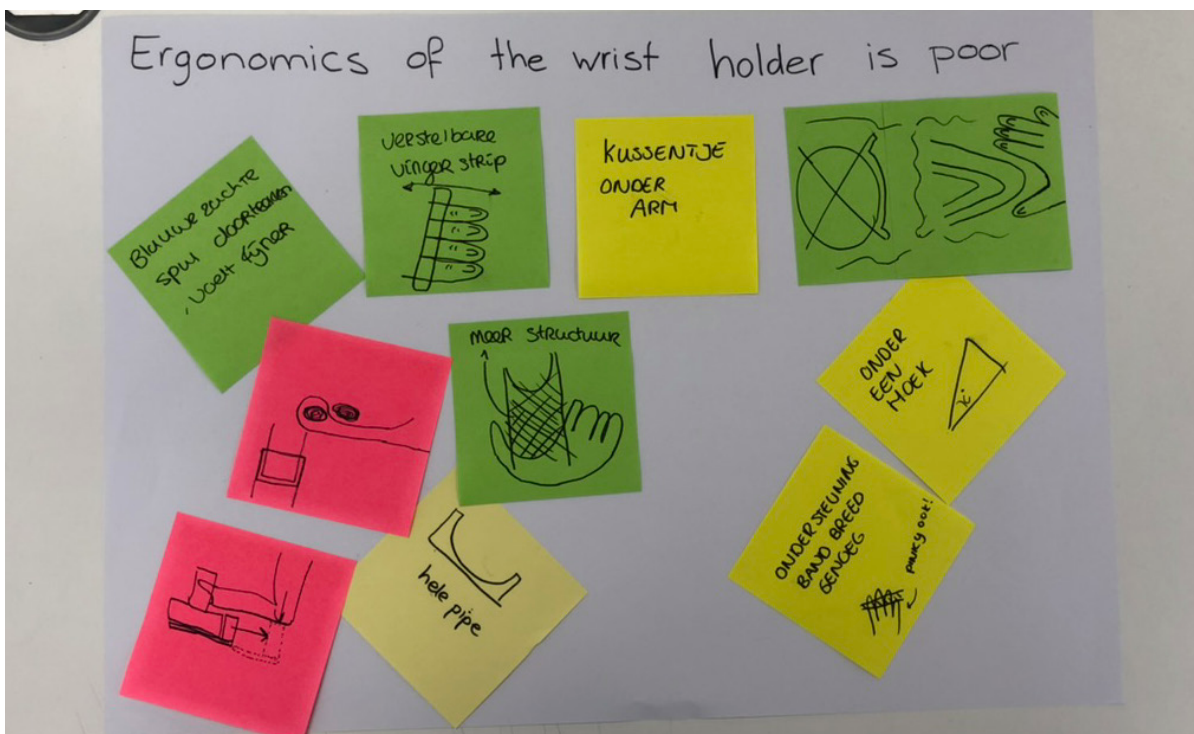
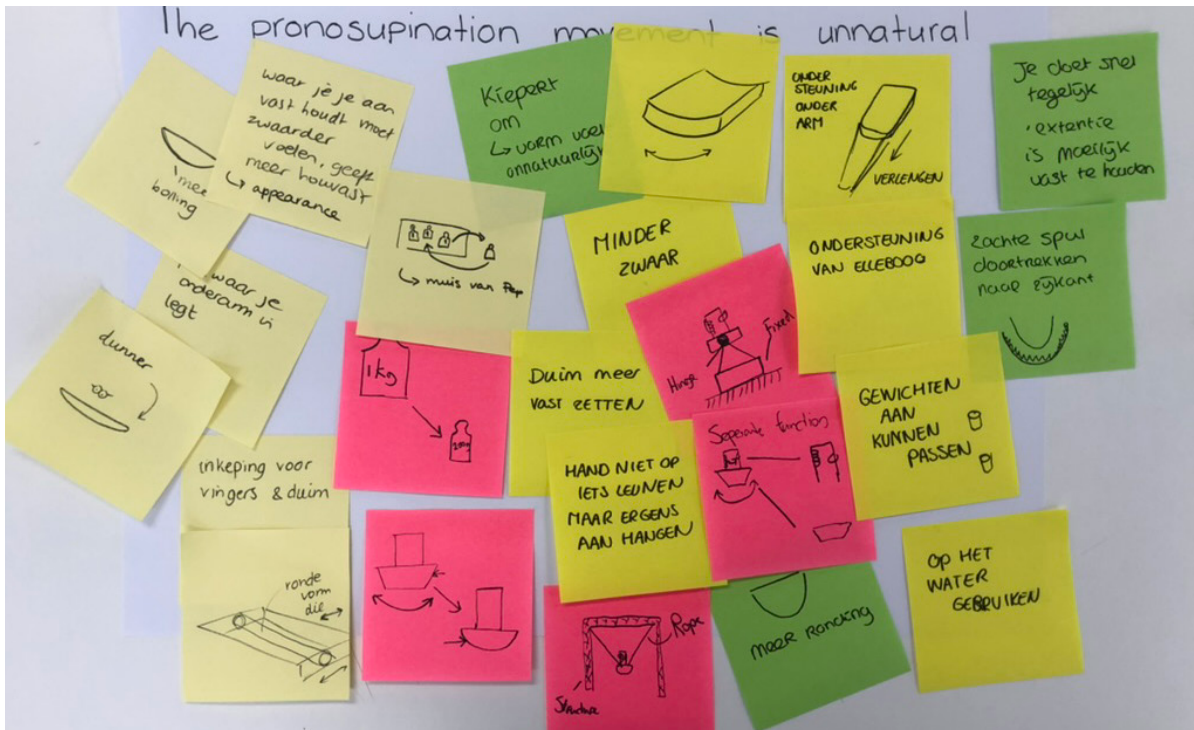
Include left-hand usage:

The device can currently only be used with the right hand. People that had a stroke incident, can be paralysed on either side of the body. There is no definite ratio for right/left-sided paralysis.

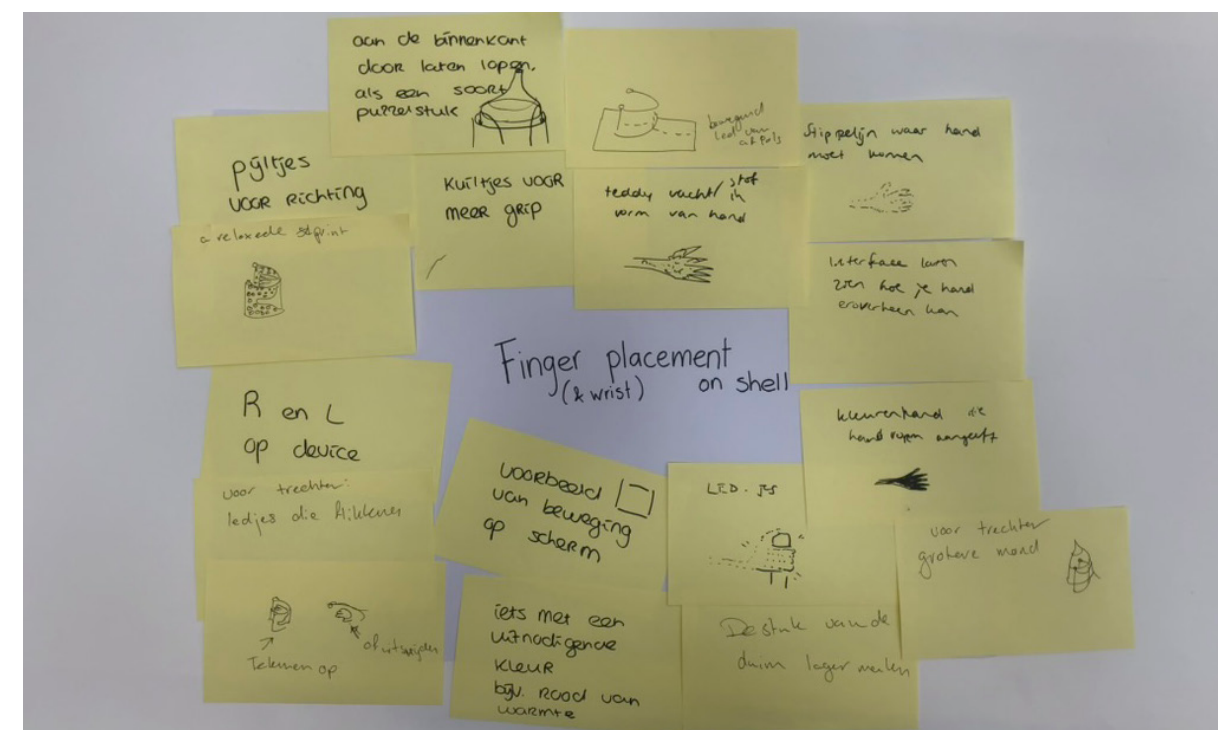
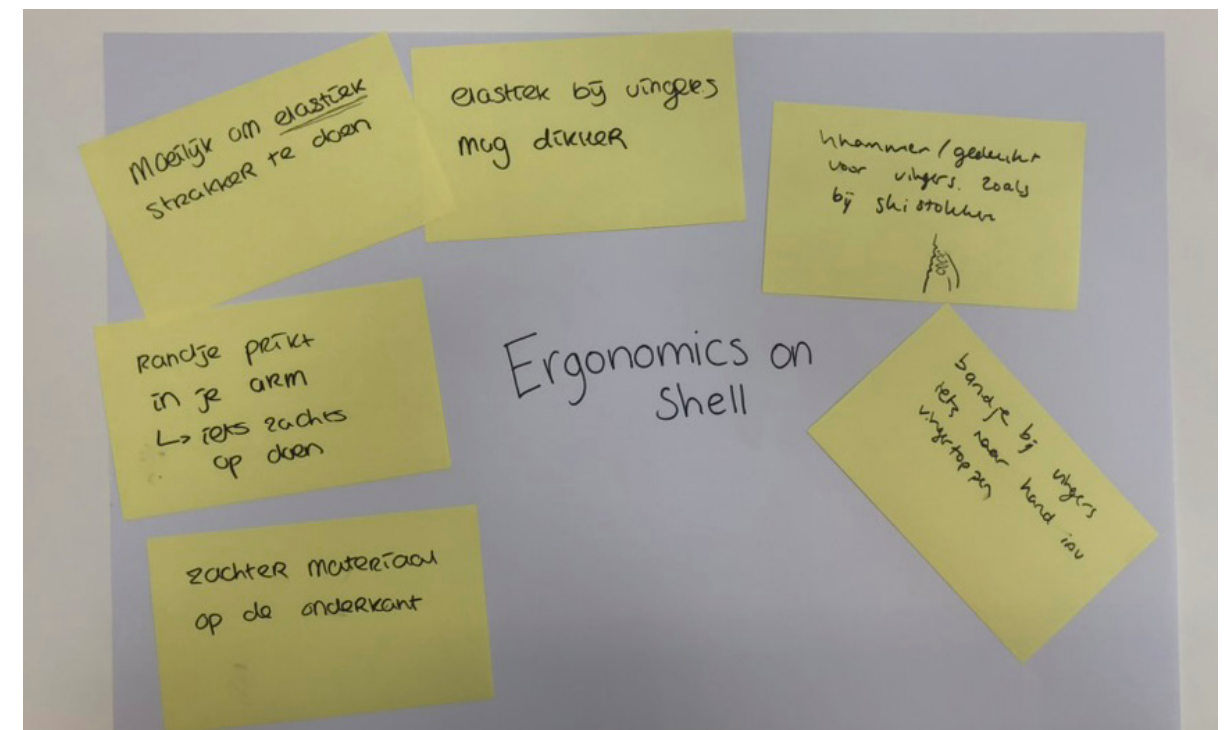
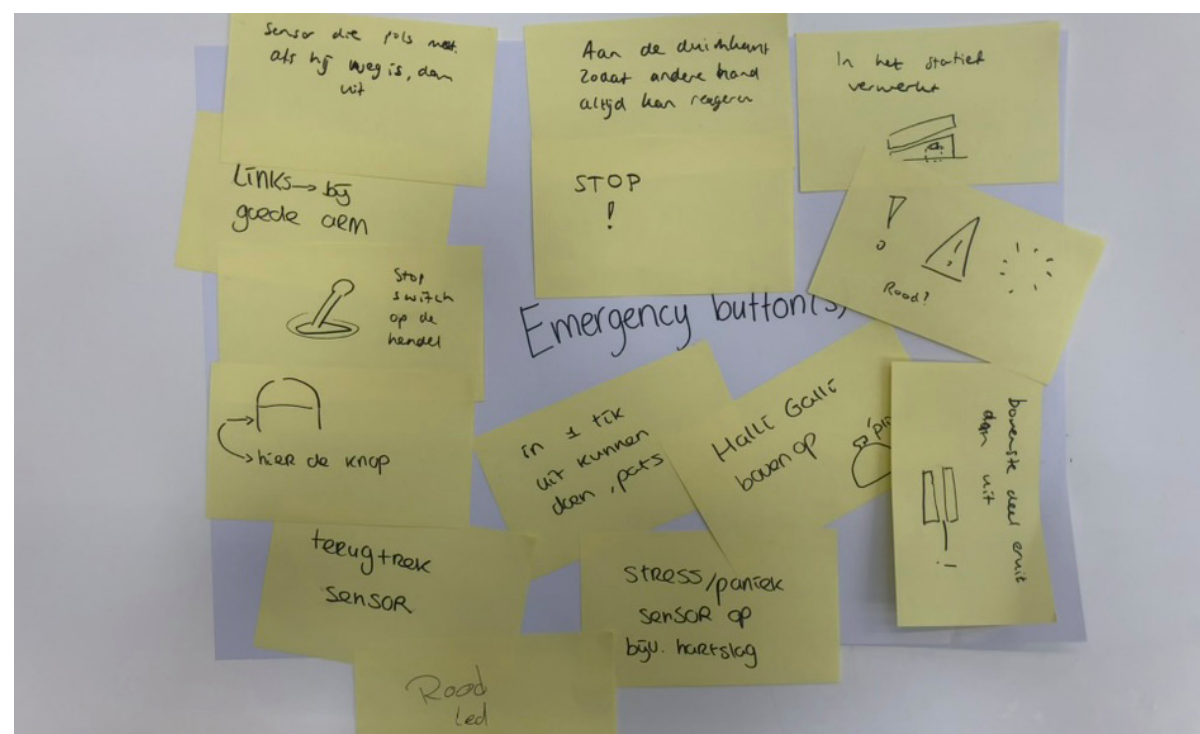
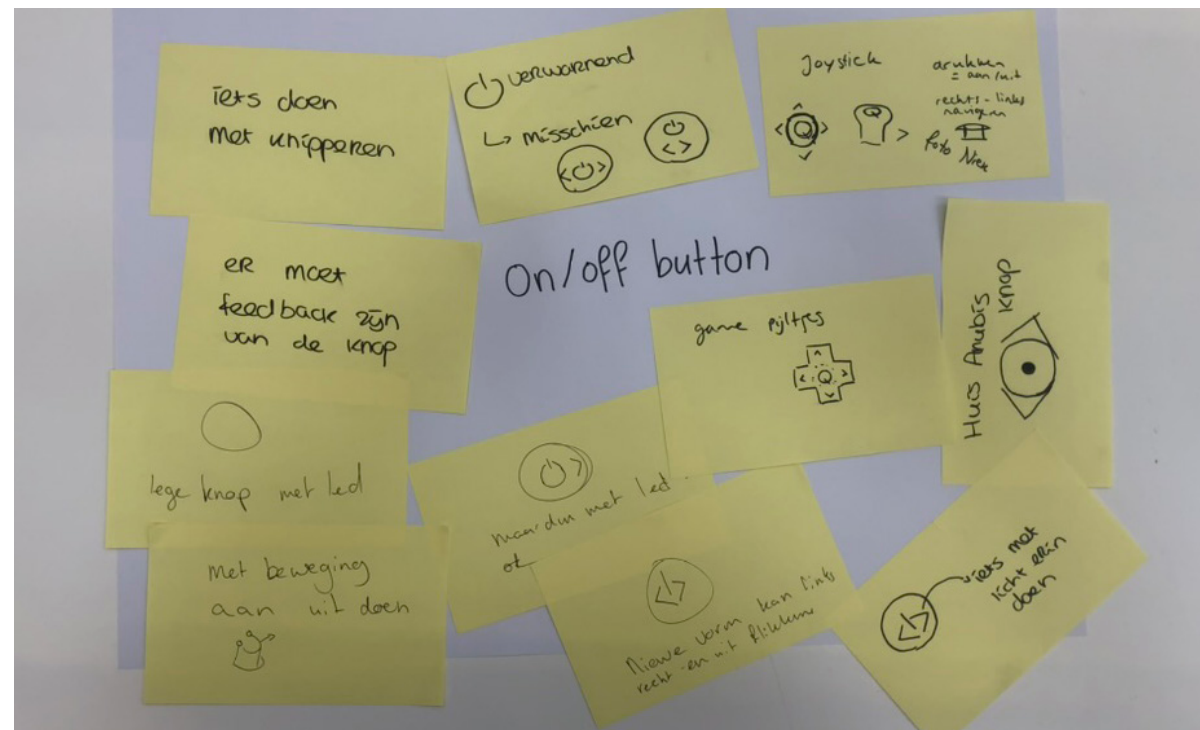
Include independent movement of fingers:

The two mechanisms that control the endpoints of the shell (the metal rods) are connected, so the thumb and fingers cannot move separately from each other. The pincer movement/key grasp (=individual movement of index finger and thumb) is important during rehabilitation, so it could be good to integrate.

F1. Ideation on high-priority improvements



F2. Ideation on medium-priority improvements



G.1 FGBS - protocol

FGBS = Focus Group Brainstorming Session

Stakeholder Brainstorming Session (SBS) – PROTOCOL

Date: May 2nd 11.00-12.00u

Location: Hybrid/ Rijndam Rotterdam

Attendees: PT, OT, C, E1, Salvo (hybrid), E2 (hybrid), Alex (hybrid), Eline

INTRODUCTION (10')

1. Welcome and introduction
2. **START RECORDING**
3. Sign consent forms
4. Switch to Zoom whiteboard!
5. Introduction to the project
 - Experts can ask questions -> using post-its.
 - *Only general questions, pick out the most relevant ones for this session.*
6. Introduction SCAMPER

BRAINSTORMING SESSION (50')

1. Introduction to the method SCAMPER
 - i. **S = substitute, what can be substituted/replaced in the idea to improve it? What materials or resources can you substitute or swap?**
 - ii. **C = combine, what (features) can be combined to improve the idea?**
 - iii. **A = adapt -> add, what aspects of the idea can you adapt/add to improve it?**
 - iv. **M = modify, how could you modify your idea to improve it? How could you change the shape, look or feel of the idea?**
 - v. **P = put to another use, can you use the idea somewhere else, how would the idea behave differently in another setting?**
 - vi. **E = eliminate, what aspects of the idea can be eliminated? How could you streamline or simplify the idea?**
 - vii. **R = reverse, what would happen if you reversed the use process? Or change the sequence of use?**
2. 10' Execute **SCAMPER** for critical improvement (1)
 - Explain ideas quickly.
 - Give some tips.
 - Let them use post-its on the whiteboard.
3. 10' Execute **SCAMPER** for critical improvement (2)
 - Explain ideas quickly.
 - Give some tips.
 - Let them use post-its on the whiteboard.
4. 10' Execute **SCAMPER** for critical improvement (3)
 - Explain ideas quickly.
 - Give some tips.
 - Let them use post-its on the whiteboard.
5. 10' Execute **SCAMPER** for critical improvement (4)
 - Explain ideas quickly.
 - Give some tips.

- Let them use post-its on the whiteboard.
6. 10' Execute **SCAMPER** for critical improvement (5)
 - Explain ideas quickly.
 - Give some tips.
 - Let them use post-its on the whiteboard.

CLOSURE (2')

1. Thank you!

Checklist of required items

- 1x Laptop with Teams/Zoom
- 1x screen to use Teams/Zoom
- 1x external speaker/microphone/camera
- 6x BIG paper
- 6x Pencils and colors
- Post-it's in 4 colors
- Hand trainer prototype
- LAPTOPS OF PARTICIPANTS!
- Coffee/tea
- Cookies

Set-up before the experiment

- Put all materials on the table:
 - White BIG paper
 - Post-its
 - Pencils and colors
 - Hand trainer
- Put cookies on the table.
- Connect the laptop to the external speaker.
- Connect the laptop with Teams/Zoom and start the meeting.
- Open the Zoom whiteboard and share it with others.
- Put my mobile phone on the table to:
 - Make recordings.
 - Make photos.
 - Use timer.

G.2 FGBS - introduction

FGBS = Focus Group Brainstorming Session

Stakeholder Brainstorming Session—Introduction

Date: May 2nd, 11:00-12:00 (one hour)

Location: Hybrid: online & Rijndam Rotterdam

Attendees: Rijndam: Marc, Sam, Eric, Bram; TU Delft: Salvo (online), Laura (online), Alex (online), Eline

1. Introduction to the project

High-intensity and repetitive hand training are essential to improve people's hand function after a stroke incident. It leads to better performance of Activities of Daily Living (ADL) and improves the quality of life. Currently, the therapeutic potential is not fully exploited due to missing resources, such as limited therapist availability.

In this study, we continue developing and evaluating the third design iteration of a portable hand and forearm trainer designed for minimally supervised use, such as training at home or in the clinic. It facilitates flexion/extension of the hand and pronosupination of the forearm. We will improve the device based on the findings of our previous usability study, by involving three industrial design students in peer reviews, stakeholder group sessions, and a final usability study.



2. The goal for this session

In preparation for the session, we have identified several usability and functional issues of the device. Together with the development team and with feedback from a physical therapist, we categorized and ranked these issues based on four parameters: effort, cost, added value, and sustainability. Based on this ranking, we have identified five critical problems of the hand trainer. We have worked on a promising solution for each issue, which we would like to present.

In this session, we want to gather feedback from the stakeholders on the five solutions using a modified SCAMPER method. We plan to iterate the device's design based on the input of the stakeholders to elevate the solutions into feasible and viable concepts.

2.1 Important things to consider for you as a participant:

- Since the meeting will be hosted in a hybrid environment, it is important to bring your own laptop.
- After a short introduction, we have dedicated 2-3 minutes to answer your questions regarding the project.

3. The method: SCAMPER

In this session, we will work with the SCAMPER method. Here's a short overview of the method:

The SCAMPER method can be used in the late stage of idea generation when initial ideas or concepts already exist. SCAMPER is often used as part of a Brainstorming session when it can elicit a new range of

ideas based on what is already on the table. It creates ideas through the application of seven heuristics: Substitute, Combine, Adapt, Modify, Put to another use, Eliminate, and Reverse [1].

When using the SCAMPER method, each idea is confronted with the seven heuristics by asking several questions:

S: Substitute. What can be substituted/replaced in the idea to improve it? What materials or resources can you substitute or swap?

C: Combine. What (features) can be combined to improve the idea?

A: Adapt. What aspects of the idea can you adapt to improve it?

M: Modify. How could you modify your idea to improve it? How could you change the shape, look or feel of the idea?

P: Put to another use. How can the idea be put to another use? Can you use the idea somewhere else and how would the idea behave differently in another setting?

E: Eliminate. What aspects of the idea can be eliminated? How could you streamline or simplify the idea?

R: Reverse. What would happen if you reversed the use process? Or change the sequence of use?

3.1 Using SCAMPER during the session

We will reflect on the five problem and solution combinations during the one-hour session.

Due to time limitations, we adjusted the method to be more time effective. We will not discuss all heuristics but focus on three: Add (A), Modify (M), and Eliminate (E). We will discuss AME and conclude with concrete iterations for each problem and solution combination.

4. Identified problems of the hand trainer

In this paragraph, we introduce the five identified problems. During the session itself, the ideas for each improvement will be presented.

4.1 The pronosupination movement feels unnatural.

The pronosupination movement is performed by rotating the device along the longitudinal axis. Currently, the movement feels unnatural and not smooth to the user. The forearm should be able to rotate freely and must not be restricted by the device. There is no maximum or minimum rotating angle yet defined.



4.2 The wrist support and attachment strap are not intuitive to use.

The wrist holder and strap lack ease of use for multiple reasons. The color coding of the strap suggests that the Velcro should be adjusted instead of using the magnetic closing mechanism. Despite its ease of use for regular users, the magnetic closing mechanism itself is not intuitive for

new users. Closing, opening, and adjusting the wrist fixation of the device should be as straightforward as possible.

4.3 The wrist support is not adjustable.

The wrist holder is currently fixed on the device's base, potentially leading to discomfort for people with different wrist sizes.

4.4 The ergonomics of the wrist support and attachment strap may be poor.

Comfort could be increased when the wrist holder's ergonomics are improved. Ergonomics includes more effective support at (1) the wrist, (2) toward the fingers, and (3) toward the elbow.



4.5 Donning and doffing the device for people after stroke may be difficult.

There are no instructions on how to position the hand and forearm on the device. We expect that the user's hand cannot be placed easily around the shell because of the spasticity of the forearm muscles.



References

[1] van Boeijen, A., Daalhuizen, J., van der Schoor, R., & Zijlstra, J. (2014). *Delft Design Guide: Design Strategies and Methods*.

G.3 FGBS - Zoom whiteboard

FGBS = Focus Group Brainstorming Session

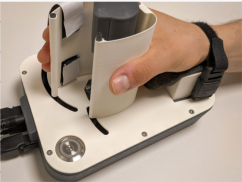
Whiteboards

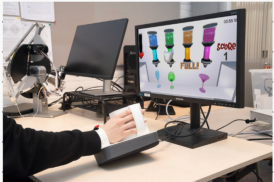
Stakeholder Brainstorm Session - 02/05/23

Share

Identified problems

Problem 1 - The pronosupination movement





Start recording!

Set whiteboard to 120% zoom

- Goal: collect feedback from stakeholders on ideas for five identified problems
- Method: modified SCAMPER
- Question round - 3'
- Short demonstration

Whiteboards

Stakeholder Brainstorm Session - 02/05/23

Share

SCAMPER method - modified

A = add

What aspects would you **add** to the idea to improve it?

M = modify

How would you **modify** the idea to improve it?

What aspects of the idea would you modify to improve it?

How would you change the shape, look or feel of the idea?

E = eliminate

What aspects of the idea can be **eliminated**?

How would you streamline or simplify the idea?

Whiteboards

Stakeholder Brainstorm Session - 02/05/23

Share

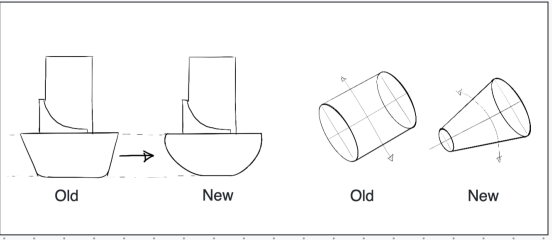
Identified problems

Problem 1 - The pronosupination movement



Where should the rotation point be?

What is the angle minimal and maximum angle at which pronosupination must be performed?



Old

New

Old

New

Whiteboards

Stakeholder Brainstorm Session - 02/05/23

Share

Feedback

add part on the bottom of the device to facilitate rotation movement

Personalized set of range of motion - patient-dependant

locking system that regulate the range of motion

add shoulder function?

adding a system that allows for rotation of the shoulder

Maybe a deformable material that stable each position

Could we add a moving weight over a linear guide inside the base that helps in the movement?

Different interchangeable shapes that can be easily changed

Internally rotating axle instead of Cone shape

Old

New

Old

New

187

Whiteboards

Stakeholder Brainstorm Session - 02/05/23

ES

Share

Problem 2 - Donning and doffing of the shell



step 1 hand around shell

step 2 wrist on wrist support

Love it :)

Whiteboards

Stakeholder Brainstorm Session - 02/05/23

ES

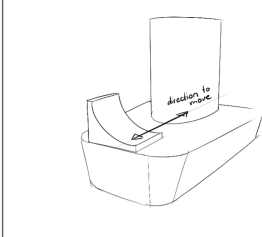
Share

Problem 3 - The wrist support



Is a wrist support needed?

If yes: does it need to be personalised?



Must we include more DOFs other than longitudinal?

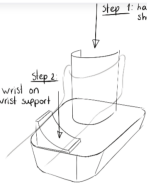


Whiteboards

Stakeholder Brainstorm Session - 02/05/23

ES

Share



step 1 hand around shell

step 2 wrist on wrist support

Love it :)

Feedback

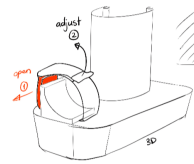
Add	Modify	Eliminate
How to fix the cone? remove the cone after	Integrate "Cone" into shell (one part) How do you get the fingers under the strap? Strap should be more intuitive to access Add "vibrations" to make tasks more difficult	

Whiteboards

Stakeholder Brainstorm Session - 02/05/23

ES

Share

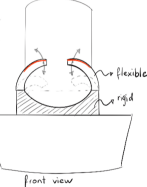


adjust

open



side view



flexible

rigid

front view

Feedback

Add	Modify	Eliminate
Adapter = remove/add /adjust the wrist quick release is a must	symmetric part with strap on top bottom part (rigid part) = should be smaller to Wrist should be able to be fixated for all sizes	I would not add more degrees of freedom, you are adding complexity to a device that should be as simple as possible to be used at home without supervision Remove longitudinal DoF

G.4 FGBS - transcript

FGBS = Focus Group Brainstorming Session

Focus Group Brainstorming Session – transcript

Subject: Focus Group Brainstorming Session

Location: Hybrid, location: Rijndam Rehabilitation Center in Rotterdam

Date: May 2nd, 2023

E=Eline

A=Alex

PT=physical therapist from Rijndam

OT=occupational therapist from Rijndam

D=doctor from Rijndam

ER=engineer from Rijndam

EM1=engineer from MLN Lab

ID=industrial designer from MLN Lab

E: Okay, I will just start with the introduction while you sign the consent forms.

E: Welcome to the stakeholder brainstorming session, about the portable hand trainer, the device I am working on for my graduation project.

E: oh, start recording. Oh, it is already started.

A: yes, I started it.

E: um, are you in Zoom actually?

OT: No, should we be in Zoom?

E: yes, can you be in the Zoom? Via de link.

PT+OT+ER: (undefinable sentences about setting up Zoom)

E: Er hoeft geen geluid, maar dat is zodat je het whiteboard kan veranderen, kan aanpassen.

PT+OT+ER: (undefinable sentences about setting up Zoom)

E: ja top

PT: ik ben niet zo snel

E: If you set the whiteboard to 120%, it is perfect, all the presentation slides. So you don't have to zoom in and out all the time.

E: so, the goal of this session is to collect your feedback on the ideas that I propose. Does it work?

ER: hij gaat in een keer naar 150%. Hij heeft geen tussen modus.

E: Je kan scrollen met je vingers. Ja?

E: Okay, the goal is to get your feedback on the ideas that I propose for the identified problems. And those problems have been categorized with your feedback and based on the interviews and the tests I did. In this session, we use the scamper method. Are you familiar with it?

PT+OT+ER: No.

E: Okay. We modified it a bit because of the time we have. Each letter in the word SCAMPER stands for a certain activity in the brainstorming session. But we only use the letters A, M, and E. A stands for Add. If you look at the idea that I propose, what would you add to the idea to improve it, to make it better? M stands for modify, so what would you modify to the idea to improve it. And E stands for Eliminate, so what would you eliminate? And if you scroll to the right, it quickly shows you again what each Letter asks you. So, for all the ideas I will go over these three letters and gain your feedback.

E: Yeah. Do you have any questions regarding the method or the section?

E: No? Everything is clear. Great.

E: Okay, [name of ER] I am not sure if you have already seen the device.

E+PT+OT+ER: (undefinable sentences about the explanation of the device)

E: um, so I have clustered the problems into three problems, which we go over now.

E: so, the first problem is about the pronosupination movement, exactly, turning it left and right. So, the problem is that currently, it does not go smoothly/naturally. And uh, the two things that we propose to adjust is, you can see it here. So, you have the old situation, which is blocky and does not have round edges. And the new shape will have a round bottom but also changed into a conical shape. Yes exactly.

E: Another one, that we were thinking about. A bit more related to ergonomics is that the whole device is a bit tilted. So indeed. You finger until your elbow is in one straight line. So you can decide yourself around what point you want to rotate.

PT: we are getting a new prototype so you can break it.

E: No.

E: Um, so the first question that popped up when we were brainstorming was 'Around what point do you actually want to perform pronosupination around'? Because now, it was a bit unclear for me, about what point it rotates. And if you have your hand and elbow in one straight line, it feels like you can either choose if you want to rotate from your wrist or from your whole elbow.

ER: de vraag is, wil je je pols of wil je je hele arm bewegen? **In theorie is pronosupination een beweging om je hele bovenarm, dus dat zou dan rotatie om je hele arm zijn i.p.v. alleen de pols.**

E: the forearm?

A: we cannot hear you very well and it would be nice if you can speak English. Please speak English.

EM: So, it did not get it with respect to the wrist. How can we rotate the wrist if the wrist is fixed? Maybe I must look at it. Okay.

E: What was the question, [name of EM]?

EM: So, you said, depending on which point you want to rotate.

E: so, the question was, around what point do we want to have the rotation?

EM: can you do the movements in front of the camera? So, I can understand you, please.

E: Can you see me?

E: so, it is either only this or your whole forearm.

ER: if you do it here, the rotation is the same only the wrist is fixed.

ER: I think the question is, do you want to rotate like this or like this? So, rotation is like this, the device stays in one spot. Or your arm rotates on this.

ER: This is of course dependent on where the device is located. So, it was first intended to also be used on top of the body of the patient. So, you would need a table. I need to have more information to answer this question. What is the place you want to use the device?

E: yeah. We were thinking about it yesterday as well. If we want to change it into this idea, the device tilted under an angle, it must be placed on a table, so you elbow can rest on the table. So, the scenario would change a bit, you will not use it on the bed anymore, because that is going to be uncomfortable, I think. So, you must sit next to a table and place the device on a table and use it in this way.

ER: [Name of EM], I think when it is fixed to the hand you also need a robot because it is quite heavy.

EM: The idea is that if you are lying on the bed, you can use it in your lab. Or put it on top of the legs.

A: they cannot do pronosupination when it is on the legs either way because it is not a stable surface.

EM: in the form it is now, it is stable enough.

A: but not effective

PT: but the question was, where should the rotation be? You can decide, do you keep it liket this for the rotation. **Or do you make a cuff in the frame where the frame is in one position and the cuff slides over the frame?** And you can rotate in one position. And you must add a moving part on it.

E: you think it would not work in a cone shape.

PT: you keep the same movement as before. Not as much as the fully round (tubular) shape, but you still move a bit. The question is, is that a problem?

ER: what do you think? Because it could be good for watering the plants, because then you are moving in that way. But do the physical therapists want to train. Do you want to do it like this or like this?

PT: **um, I think, the cone shape would be best because otherwise you have to add a moving part to it and you have to completely redesign the device.**

D enters the brainstorming session.

PT: we waren nu bij de pronosupinatie bezig. Dat draait nog niet helemaal lekker. Je kan hem rondler maken aan de onderkant of je kan het platte deel aan de onderkant vastzetten en een extra bewegend onderdeel maken die erover beweegt.

ER: that is not an option. You can choose between the cone shape and tubular shape.

PT: I would choose the cone.

PT: even in het Nederlands hoor, dat is iets makkelijker. Jij bent de natuurkundige onder ons he. Ik denk wel als je die cone maakt, **als je naar de straal kijkt dat die dan wel als ondersteuning bij de elleboog uit moet komen.** Anders is dat een andere beweging.

A: so, the new idea is a two-part device in which the top part rotates on top of the bottom part? If I understood correctly?

ER: yes, that is one of the ideas. And what [name of PT] also said is that if you choose for the cone, the rotation point needs to end up in the elbow.

A: as long as your wrist is straight to the ulnar radial direction, the radius always goes through the arm.

ER: if you make the bottom in a cone shape, you need to make sure the cone is not too narrow. **The rotation point is at the elbow.**

A: ah okay.

E: what was the question.

PT: pincet greep.

E: well, spoiler, we are not going to talk about it.

E: okay, and one other small question. If you do the pronosupination, is there a guideline until where you must do the pronosupination. **Is there a max and a minimum of rotation.**

PT+ER: **what is possible for the patient.**

E: okay, as much as possible and patient can do how much they can.

PT: **it would be ideal if you can set the range of motion.** So patients do a small assessment/calibration that sets the range of motion. And then try to increase it.

E: okay, so to specifically.

E: So, I will explain the method again to the [name of D]. For each of the ideas I show you on the board, I want to ask three questions. What would you add to the idea to improve it? What would you modify to improve? What would you eliminate? And now it is specifically on the bottom shape. So, for now, we have discussed that the bottom shape will transform into a cone and will be tilted, so your hand and forearm are in one straight line.

E: so, for the first one, just throw everything you can. So, what would you add to the idea to improve it? So, you for example said, make a slider. What would other things be?

PT: so that would be a possibility.

ER: you already wrote down some things.

ID: we wrote about specific ranges of motion for specific patients. Calibration. And the moving part on the bottom. Movement of the arm. Laura is writing interchangeable shapes.

E: Or what would you eliminate?

ER: **a locking system where you can set the range of motion.**

ER: even if you make a cylinder or a cone shape. I you don't want the patients to do that, you can stop them.

E: yeah.

D: So, you are now focusing on the hand and wrist, but you also need a good shoulder function as well. Do you take that into account?

E: good point

D: some patients have limited shoulder function. Then it is hard to manipulate.

ER: if you put your elbow on the table, you kind of fixate on it.

PT: it would be maybe nice, to add that you can make a rotation.

E: oh, so you can slide the device.

D: depends on what you want to train.

ER: that is what makes it difficult for us to add or eliminate things. So it is not fully clear what the context of the device is. So, you are now focusing on pronosupination, but is it a grip trainer? So, you must train the grip.

ER: You must discuss a bit what you want it to do, what you are designing for.

D: If I could say something. Adding the key grip would be nice.

E: The key grip.

D: that is a big function.

E: the key grip. If you hold your hand like this.

EM: so, we are moving to another subject?

ER: that is what I wanted to discuss. So, what is the functionality that we are focusing on right now? I think we can all add different things to the device.

We are focusing now on pronosupination, but my question is why?

E: Indeed, it is for flexion-extension and pronosupination and in the research I did the last couple of weeks I found out that a lot of problems, and a lot of things to add. I prioritized them and rated them on effort, time, costs and sustainability. And this resulted in five points. And that when we decided to keep it to just these two movements. And improve on the pronosupination because it does not go smoothly. Improve on the ergonomics and the wrist support. That is the scope.

ER: Is this the scope of the project of the envisioned product?

E: no, my project.

E: so, indeed the list of improvements is quite long, after my project, the other improvements can also be added. Just as the key grip. That could be good to add.

EM: for that we have another device, we really do not need to change this device in order to be able to do that. Because that is the other device that we develop.

A: we should be moving forward.

E: yes, we will move forward. We leave the base shape behind.

E: we go the problem 2. The donning and doffing of the device. We did not consider that patients after a stroke are often cramped, through spasm.

E: they first put their wrist on the wrist holder and must open their hand and we can foresee that does not really work.

E: The idea that we have now is, instead of step 1 and step 2, we do step 2, step 1. We go on to the idea. Based on your tip. We can do a cone shape on top. This is a fast mock-up. If they have their hand like this, they can slide around the shell. And motivate you to place your hand like this and then the wrist support becomes step 2. So, switching around the steps.

A: can you also show it for the camera Eline?

E: yes

E: so, instead of first placing your wrist on the wrist holder and open your hand and form it around the shell. We now propose to have a cone on top, or some form of shape, that guides your hand around the cone and then into the shell shape. So, the shell becomes step 1, and the wrist becomes step 2.

E: um, so, I think it is good to directly go to the whiteboard.

ER: [name of EM] love it.

E: Haha, thank you [name of EM].

E: so, quickly go into the add/modify/eliminate. What do you think of the idea? Would you add, modify or eliminate something? So, we are now only focusing on the shell, not the wrist support yet.

D: with the shell you mean.

E: yes, this part.

D: and the part underneath, do you need that for technology?

E: the base?

E: good question, you could also think you only have the embodiment. And have the electronics in another part of the design.

ER: yes good question. I think if you skip the pronosupination, you still need the device. How much is in there? How many electronics are in the bottom?

E: also, for connection with the laptop. And, for the flexion/extension. Motor etcetera.

E: focus on the shell, what do you think.

PT: **I like the cone, but I was wondering, if the patients put their hand around the cone, how does he get his fingers under the strap.**

E: good point, can be changed. A bit more intuitive yes.

D: yes, I like the idea, **we have to see how it practically works.** Will it be fixated, the cone?

E: that is an option. Yes, it would be nice to have it fixated. But it would make it bigger.

ER: yes, I think it must be separate, because otherwise you are also limiting your range of motion. So. you have to be able to take it off.

A: If you design it in a smart way, e.g., with fins, **I think you can integrate it into the design without limiting the functions.**

EM: I agree, it think it is possible.

ER: but why not take it off?

A: one part is always easier, it is cheaper, a not mount it on? And if it does not limit its functions why not?

EM: it also covers the motor, which I like.

A: it is both things that are possible. But we should think about what makes more sense.

E: yes exactly, a trade-off. So, would you see this work?

PT: We have to ask patients. I think it would work

ER: you should make this shape and try to slide it into patients' hands. **Their hands are quite forceful.**

PT: **patients with high spasm, you will not be able to use this device in the first place.**

D: with high spasm, their hands are really tightened, and they cannot open it again.

E: So, it would be used for a specific level of spasm. Any other random thoughts?

E: you can always shout.

PT: you haven't asked the patients yet.

D: you are now focusing on quite a difficult patient who also has spasticity in the hand or arm. When you focus more on patients who have limited muscle function and no spasticity. Could you make something that would make the movement more difficult.

E: yes there is a motor inside, so you can adjust the resistance. Also with the game, you can give them other exercises.

E: what do you mean with trembling?

D: if you add that, you can make the task more difficult.

E: to keep it still you mean?

D: might it be useful to add this kind of difficulty or maybe it requires too much technology.

ER: the question is what is the added value?

D: that the tasks becomes more difficult.

ER: you can also increase the force

D: **but for patients with spasticity that they get a little bit more loose and relaxation. You can try it out in a setting.**

D: one idea would be to make the task more difficult or do something with relaxation.

A: I think we have to move on again. Sorry for bumping in the discussion.

E: That's okay. I think it is time.

E: So the last problem. Um. Is the wrist support in general? It is right now, for the first time, not intuitive to use because the red lip indicates that you have to do that first and then squeeze your hand in. But this is a magnet, so it is not necessary at all. And it is not adjustable. It is a fixed wrist support. You cannot change the length to the shell. Or tilt it. Or to left or right. I cannot be personalized to conclude. Two questions we directly have: **do you think a wrist support is necessary on this device at all?**

ER: **if you want to have the pronosupination, then yes.**

PT: we already had a discussion about it.

A: don't you think, if you hold the shell by itself regardless of how much strength you have left, if you do the pronosupination, this is already enough?

OT: it is also good for patients to remember to put their hand in the same place. So, it is not functional, also good for memory.

E: so, Alex said it might already be enough to only hold the shell. Can you explain it again.

A: the shell is already like grabbing a stick. Although you do not have much force yet, it is a big lever, so if you pronate and supinate, then depending on your ability, should it not always be enough to pronosupinate with the need to fixate the wrist.

EM: **That would be only the case the patient is able to reach the natural position, straight. In the moment it is like this, it is a problem.**

ER: if you have it loose, **you also might have some flexion and extension of the wrist and not isolate the pronation supination.**

ER: I think for healthy people, you can do it, but **patients will compensate, so if they think this is easier than this, they will do that.**

A: Okay.

PT: maybe you can make an adapter. So it is like. You can add stuff on it. You can take it off and put it back on.

E: for personalization?

ER: yes, and also if you don't want to use it.

E: would it be beneficial to take it off when a person can do it without wrist support?

PT: No

EM: from my point of view, I think we should have as little moving parts as possible. Because things get lost.

ER: I agree. This moving part is more a constraining part than a moving part. I think it is good to ensure the patient is doing the right thing.

EM: if you remove the wrist support, would this not be a hazard because we are motivating the patient to do a movement that is physiologically not possible?

ER: Yes, if you take it off, the patients are also doing flexion extension of their wrist. **And if you take it off and people pronate and supinate, they will try to compensate it by introducing some wrist flexion and extension.**

ID: there is another problem popping up. Without stopping the wrist, the shell comes more open than without stopping the wrist.

ER: But I think you can personalize it, by making two circles that you can to connect to each other. So, if you make it two sides with a strap on top, you have two shells combining. You can tighten it.

ID: this is your idea right?

ER: Okay, then I love it.

E: Okay, so the first drawing is about being able to move it towards the shell and from the shell with a mechanism with for example like used in a camera tripod. So something slides in something else. You can see it.

ER: so underneath the wrist support so you can move it to any point.

E: so, is that what we want, and is this the right mechanism to use for it?

ER: I think if you take the second option, you can also grip it down at different places. If you make it fixed on one spot, you can adjust by gripping it somewhere else. In a range.

A: can we discuss first, do we need the longitudinal displacement?

ER: that is what I said, so I think if you make the fixation adjustable enough. If you think about where you must place it and then make the bands adjustable it would work. To grip at different places.

EM: **I really would oppose adding more DOFs in this, this level of difficulty.** For me, it is not needed at all. It would be nice but is adds much more complexity to a device that should be easy and intuitive. And I don't see the value by listening to other people in this meeting.

ER: the wrist is always in front of the device, so it does not make sense.

A: can you maybe show the idea with the flexible things.

E: **so, the conclusion is it can be fixed.**

E: here you see it is lower than this support, so e.g., half the length. This will be rigid and this will be hard flexible. And then keeping the idea of the cone on the shell in mind. So if you are sliding your hand around the shell and then sliding in the wrist by dropping in there.

D: so they can open up.

E: it is flexible so they can bend inwards to get your hand in and bend outwards again to form around the wrist. That the wrist is kind of trapped.

ER: do you want to make it flexible or make two rotation points?

E: also, possible yes. Or both.

E: if you make it flexible, it adjusts to your wrist ergonomics.

ER: if you make it flexible, people can still move it. If you make it rigid and you have two connection points and make it tight you are fixed on many points.

E: but if you make it rigid enough above the bones, you still have enough support and then the flexible parts on top.

ER: I would suggest the bottom part rigid as small as possible and two rotation points. Three points to fixate. You can adjust so you can fit many types of wrists.

EM: what is the variability of the wrist size that we are talking about here?

ER: can also depend on age groups. Do you also want to design it for children?

E: no

ER: why not?

E: you cannot design for all

ER: if you design for elderly, the sizes can also vary a lot.

E: I did not yet look into the anthropometric data for wrists.

EM: **it would be good to know what we are talking about here, otherwise it is hard to make a decision.** It is not the same as height. It is not the length of an arm. Did you look at this Alex at some point.

A: no I did not.

ID: at industrial design there is a database on anthropometrics.

E: yes **DINED.**

ID: yes, do you know it? It is at least for the Dutch population. A range.

A: there is also this system with some rubbers and a strap in the middle to fix cable. You put the cable in and then it punches down, and there is a rubber ring at the bottom.

EM: you have to have enough force.

ER: I do like the idea, but I think for many people, if you have the top of the cone and push your hand down and also use force to push your wrist in, you always need a therapist when setting up.

EM: **it has to be a system with quick release, for safety.** So if something happens, we should be able to remove the wrist of the patient very quickly.

E: yes

EM: because they have to disconnect the cables

ER: I think that you cannot really destroy something, so the wrist strap is a valid idea. If you wrist is like this and the device is like this, it is easy to come up and not break it.

ER: I think we don't need to be too careful. We always have the two emergency stops.

A: I think it is time.

E: I think we have a lot of valuable feedback, so thank you for that.



Calculation wrist width and depth

book

TextNonexecutable MathMathC 2D InputTimes New Roman12B I U

> restart;

> circumference := 2·Pi· $\sqrt{\frac{(r1^2 + r2^2)}{2}}$ = 185.5;

> r2 := alpha·r1;

> alpha := 0.68 ;

> r1 := solve(circumference, r1);

> r1 := r1[1];

> r2 := r2;

> wristwidth := r1·2 mm

> wristdepth := r2·2 mm

> wristbandheight := r1·0.75;

>]

$circumference := \pi \sqrt{2 r1^2 + 2 r2^2} = 185.5$

$r2 := \alpha r1$

$r1 := 34.52597519, -34.52597519$

$r1 := 34.52597519$

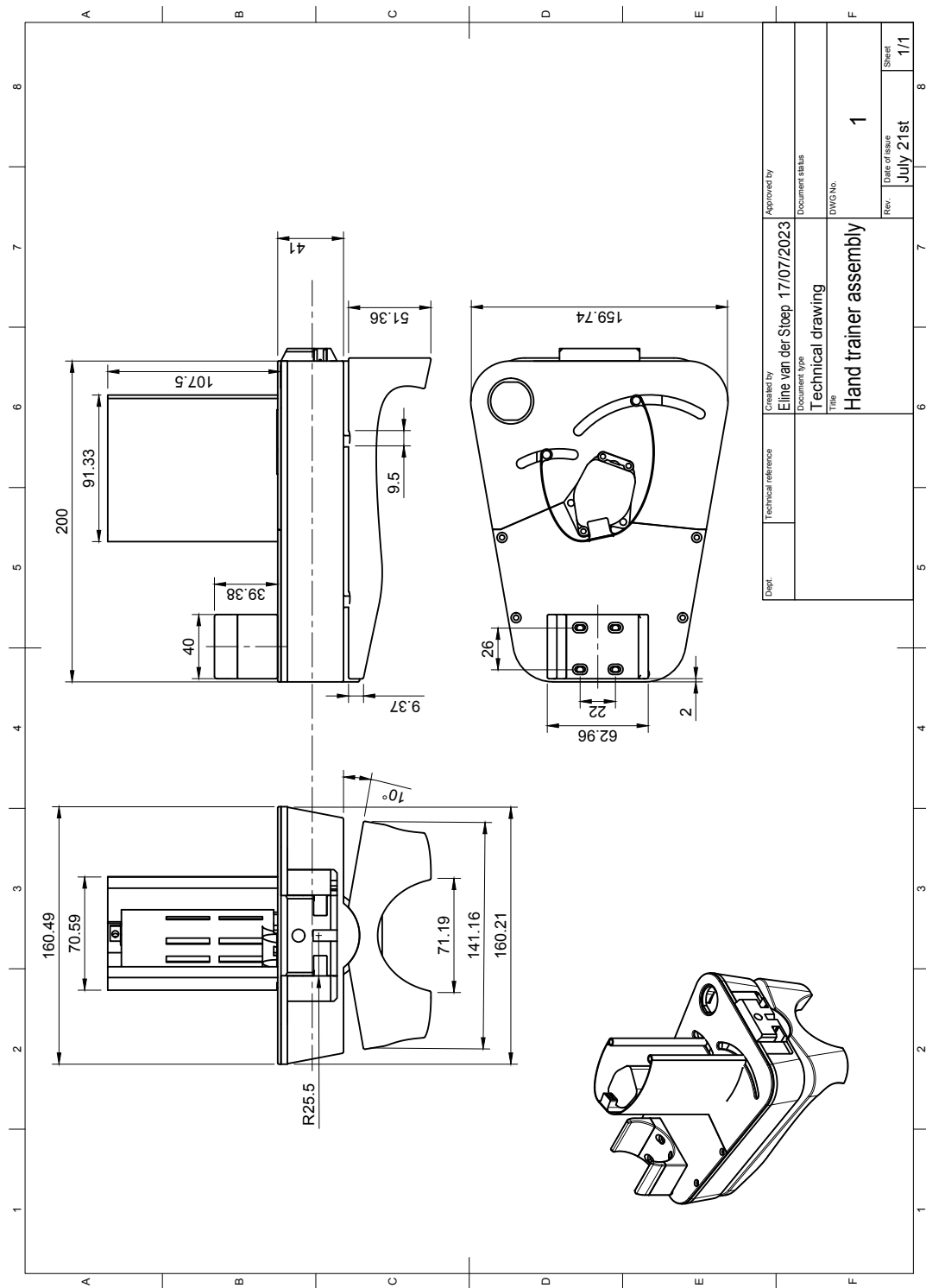
$r2 := 23.47766313$

$wristwidth := 69.05195038\text{ mm}$

$wristdepth := 46.95532626\text{ mm}$

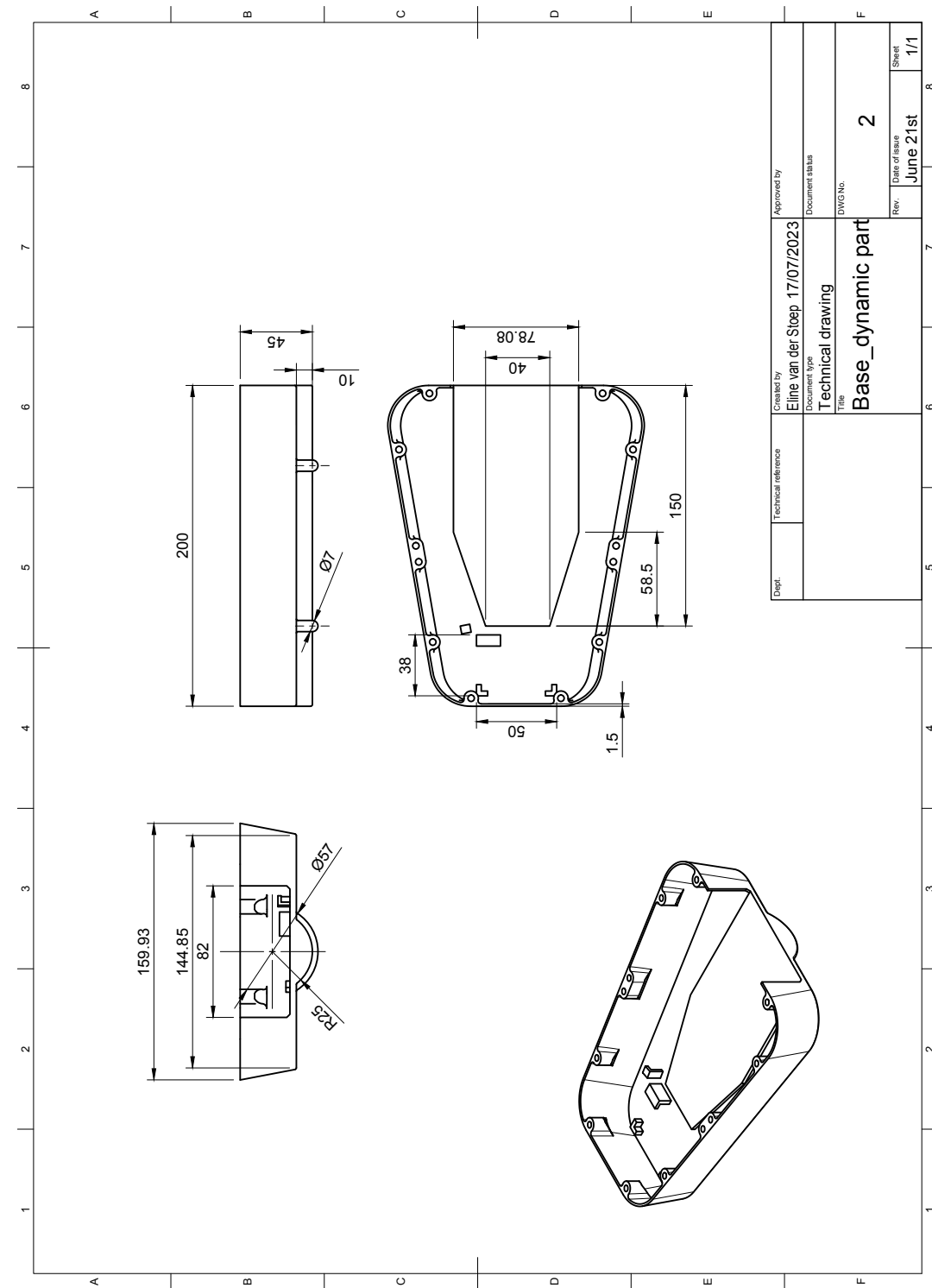
$wristbandheight := 25.89448139$

1. Technical drawing - hand trainer



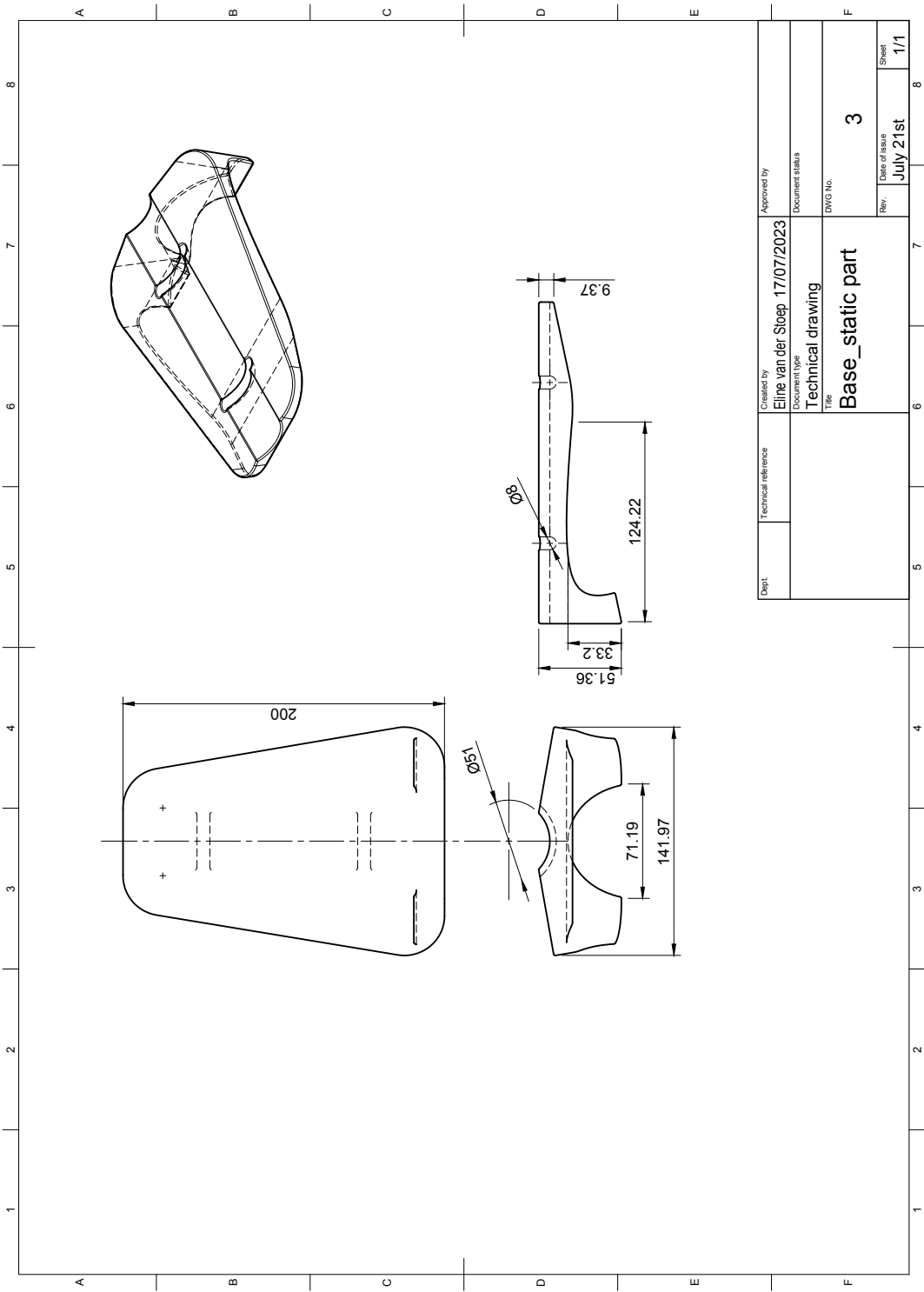
Scale = 1:2 (A3), in mm

12. Technical drawing - dynamic part



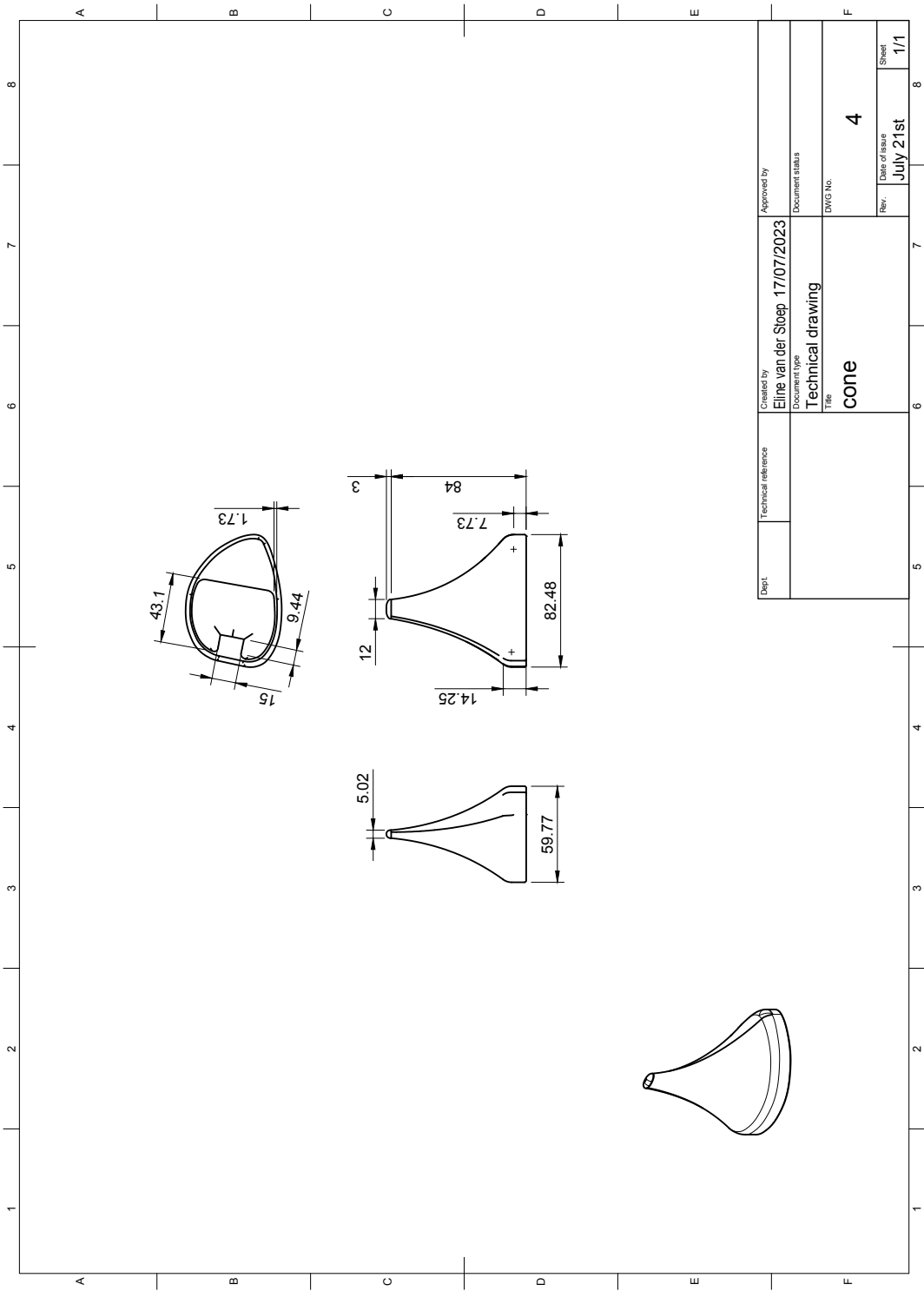
Scale = 1:2 (A3), in mm

13. Technical drawing - static part



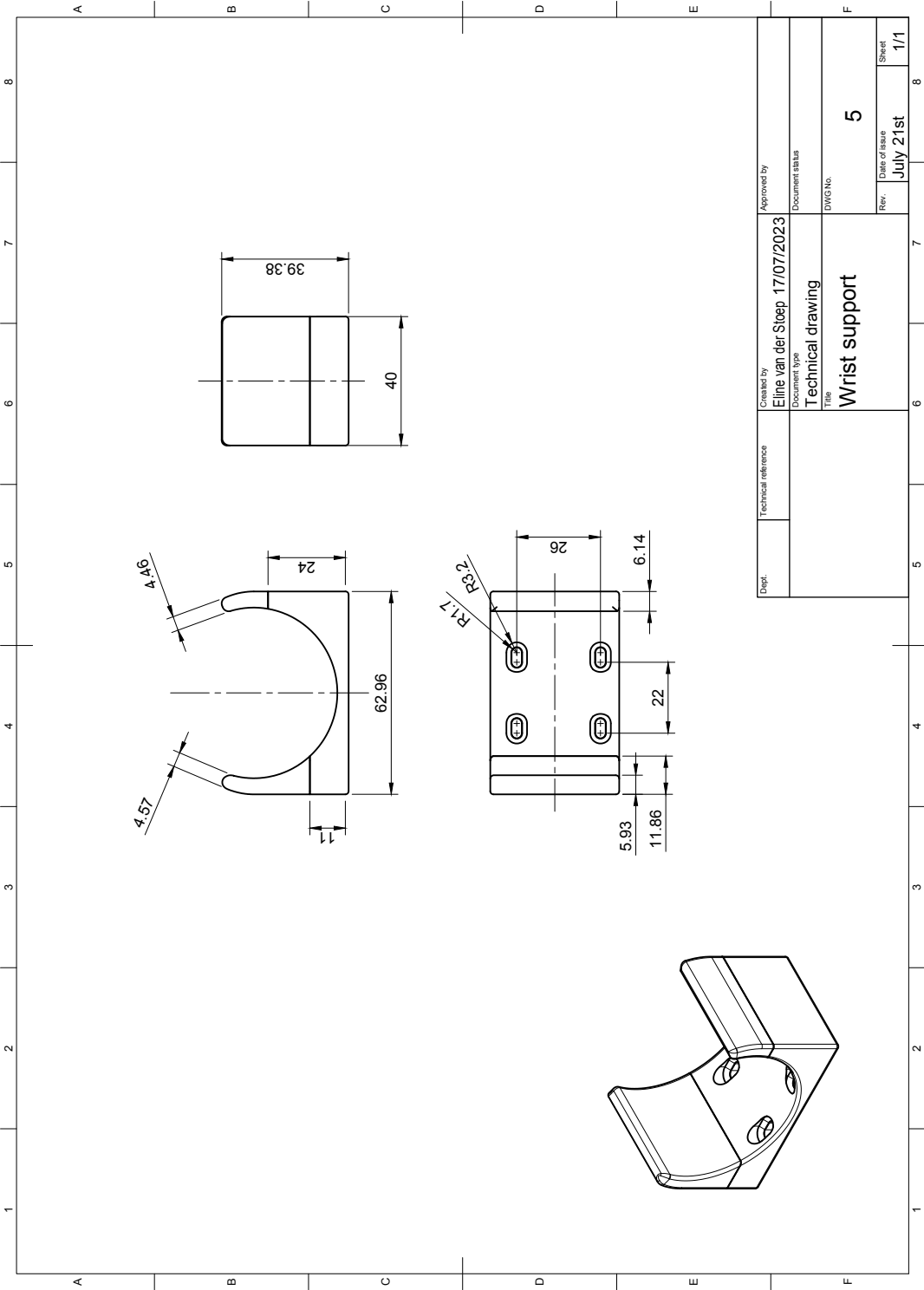
Scale = 1:2 (A3), in mm

14. Technical drawing - cone



Scale = 1:2 (A3), in mm

15. Technical drawing - wrist support



Scale = 1:1 (A3), in mm

J1. Evaluation 1

Evaluatie – herontwerp van de Portable Hand Trainer

Expert in Biomechatronics – 5 juli 12:00

1. Introductie:

- a. Doel van het product:
 - Revalidatie van hand en onderarm, specifiek **flexie/extensie** en **pronosupinatie**
 - Doelgroep:
 - o Volwassenen die een beroerte hebben gehad
 - o Aanzienlijke spierafname of volledige verlamming aan een kant van het lichaam
 - o Vroeg stadium van revalidatie
 - o Spasticiteitslevel 0,1 of 2 (exclusie = 3 en 4)
 - o Revalidatiestadium II-IV (exclusie = I, V en VI)
 - Met behulp van: een virtual reality spel op laptop die de bewegingen stimuleert
- b. Herontwerp op het volgende gebied:
 - Hardware-ready 3D prototype voor usability testing
 - Advies op de GUI en game design
- c. 3 focusgebieden
 - i. Geïdentificeerd probleem: **pronosupinatie** is onnatuurlijk en wordt niet correct uitgevoerd.
 - ii. Geïdentificeerd probleem: **donning** en **doffing** van de shell vanuit het oogpunt van patiënten na een beroerte wordt niet (genoeg) ondersteund.
 - iii. Geïdentificeerd probleem: de **pols support** is niet makkelijk in gebruik en ondersteunt simpel donning/doffing van de shell niet (genoeg).

2. Herontwerpen:

I. Pronosupinatie

3 belangrijke inzichten tijdens het ontwerpproces:

- a. Rotatie moet om eigen as van product -> longitudinale as van de onderarm
 - i. Uitsluitel dat er geen andere beweging wordt uitgevoerd
- b. Rotatiepunt moet zo dicht mogelijk bij de longitudinale as liggen
 - i. Pure vorm van pronosupinatie
- c. Product onder een hoek zodat het midden van de hand en de elleboog op een lijn liggen tijdens pronosupinatie
 - i. Rotatie om de longitudinale as

- Vragen

- o Wat vindt u van de mechaniek? Werkt het natuurlijk en soepel?
Specifiek vragen naar de 10 graden rotatie en rotatie om onderarm as.
- o Is het doel bereikt volgens u? Is het een verbetering t.o.v. het oude ontwerp?
- o Ziet u verdere verbeterpunten voor de pronosupinatie beweging?
Welke problemen voorziet u bij het gebruik van dit herontwerp?

Mechaniek: werkt goed. De bovenkant lijkt er af en toe af te glijden bij grof gebruik. Idealiter inderdaad rotatie om de onderarm, maar klopt ook dat er meer kracht gezet moet worden om de pronosupinatie beweging te kunnen maken.

Hoek: omdat het product nu onder een hoek gebruikt wordt, liggen je pols en hand in een lijn met je onderarm. Is dit de meest prettige/rust houding of zou je pols eigenlijk een stukje moeten hangen naar beneden?

Verbetering: het ontwerp heeft voordelen maar ook weer nadelen. Hij is wat groter, maar wat instabieler, je kan zo een kant op vallen. Hierdoor wordt er tijdens flexie/extensie ook focus gelegd op de pronosupinatie beweging i.p.v. alleen flexie extensie. Is dat een nadeel? Wat is het einddoel van het product? Is het bijvoorbeeld ook handig om de optie toe te voegen dat je het product over de tafel kan laten glijden en je schouder ook daarmee traint.

II. Donning/doffing

3 belangrijke inzichten tijdens het ontwerpproces:

- a. Patiënten hebben last van spasticiteit, waardoor de hand en onderarm in verkrampte positie zitten
- b. Extensie is (vrijwel) onmogelijk zonder hulp van iets externs
- c. Coördinatie van de hand en onderarm is verminderd

- Vragen

- o Wat vindt u van de vorm en mechaniek? Werkt het natuurlijk en soepel?
Specifiek wijzen op draaiing van de arm om in een lijn te komen met de pols support.
- o Is het doel bereikt volgens u? Is het een verbetering t.o.v. het oude ontwerp?
- o Ziet u verdere verbeterpunten voor het donning/doffing?
Bijvoorbeeld de bevestiging van de cone aan de shell en het helix-idee.
Welke problemen voorziet u bij het gebruik van dit herontwerp?

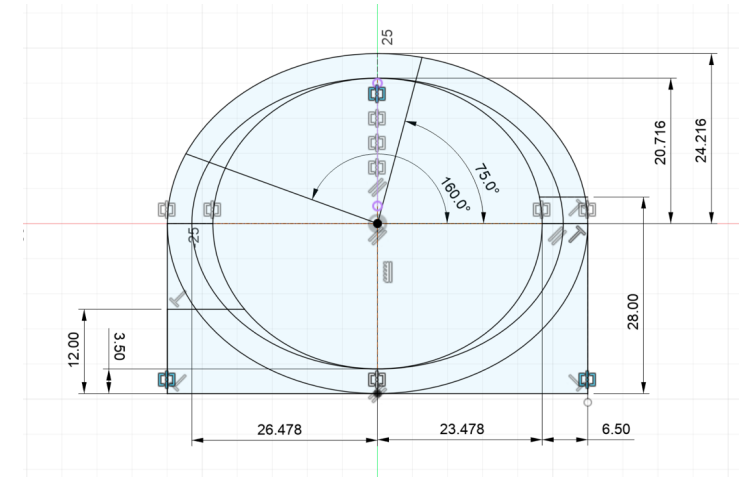
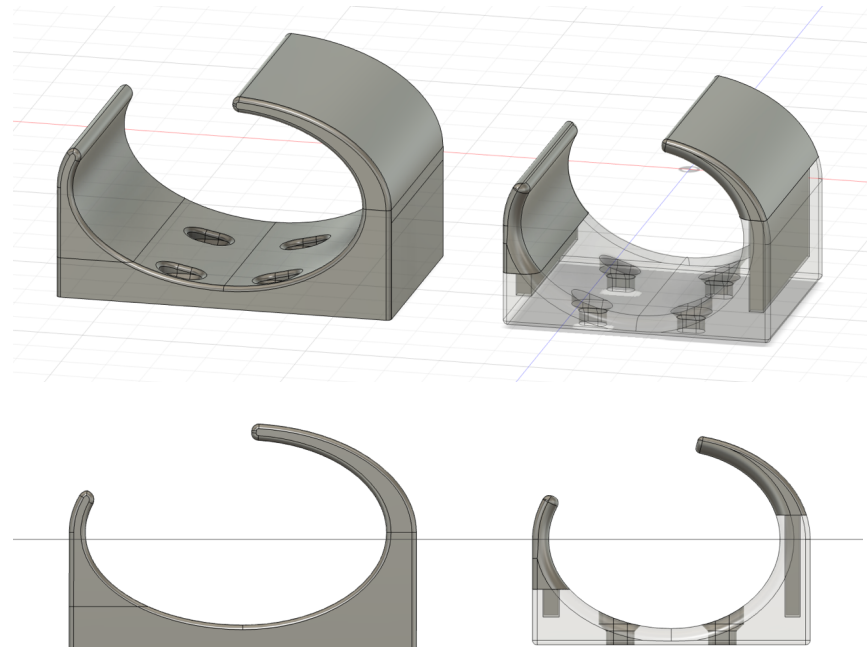
Mechaniek: de kegel werkt goed, je hand wordt er goed door naar beneden geleid. Echter is het tegenstrijdig dat een patiënt niet makkelijk zelf de kegel erop kan zetten. Het feit dat de shell flexibel is en met een veer werkt, kan je goed gebruiken. Gebruik het puntje van de rod om de shell kleiner te maken en zorg ervoor dat het vierkantje blokje bij de batterij makkelijker te centreren is door bijvoorbeeld een kegelvormpje toe te voegen. (zie tekening) Verbetering/verbeterpunten: ja, goede toevoeging. Wel dus tegenstrijdig dat het niet makkelijk erop te zetten is. Helix werkt niet. Misschien niet per se iets toevoegen maar de kegel iets anders vormgeven. Als je de rechter- en linkerkant sneller breder maakt, heeft de hand minder de neiging om naar de boven-en onderkant te glijden en daar de handpalm uit elkaar te halen. (zie tekening)

III. Pols support

Belangrijke inzichten tijdens het ontwerpproces

- Patiënten die een beroerte hebben gehad zijn vaak fysiek én cognitief verzwakt.
- Het aan-en uitdoen van de polsband is niet intuïtief en/of simpel in gebruik en kan daardoor veel cognitieve activiteit vereisen.
- Tijdens donning: heeft de pols de neiging naar de buitenkant (rechterkant) te draaien vanwege spasticiteit.
 - Support aan de buitenkant van de pols (rechts) heeft daardoor meer prioriteit dan de binnenkant (links).
 - De onderarm zal naast van boven naar beneden te bewegen, ook van links naar rechts moeten bewegen om in de pols support te komen.

Laatste iteratie:



*afmetingen gebaseerd op DINED Decathlon

- Vragen

- Wat vindt u van de mechaniek en het materiaal? Werkt het natuurlijk en soepel?
Specifiek wijzen op support aan de rechterkant en donning vanaf linksboven. Specifiek wijzen op de laatste iteratie en het blauwe foam wat nog toegevoegd zal worden.
- Is het doel bereikt volgens u? Is het een verbetering t.o.v. het oude ontwerp?
- Ziet u verdere verbeterpunten voor de pols support?
Bijvoorbeeld de afmetingen (ook t.o.v. de shell) en het materiaal? Welke problemen voorziet u bij het gebruik van dit herontwerp?

Mechaniek: werkt nog niet lekker. Waarom zit dat daar vraag je je af, en wat zou het moeten doen. Maar het is wel redelijk comfortabel. Kan niet gebruikt worden enkel met de aangedane hand.

Einddoel van dit onderdeel? /verbeterpunten: is het om alleen de zijkanten van de pols ondersteuning te geven of is er ook support nodig aan de bovenkant (vragen aan therapeuten)? Anders zou je ook een V-vorm kunnen gebruiken en als men een grotere pols heeft, ligt die gewoon wat hoger maar nog wel genoeg support. Je zou die V helemaal van dat resin materiaal kunnen maken. (zie tekening)

J2. Evaluation 2

Evaluatie – herontwerp van de Portable Hand Trainer

Ergo- en fysiotherapeut (OT en PT)

1. Introductie:

- a. Doel van het product:
 - Revalidatie van hand en onderarm, specifiek **flexie/extensie** en **pronosupinatie**
 - Doelgroep:
 - o Volwassenen die een beroerte hebben gehad
 - o Aanzienlijke spieraftname of volledige verlamming aan een kant van het lichaam
 - o Vroeg stadium van revalidatie
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2. Herontwerpen:

I. Pronosupinatie

3 belangrijke inzichten tijdens het ontwerpproces:

- a. Rotatie moet om eigen as van product -> longitudinale as van de onderarm
 - i. Uitsluitel dat er geen andere beweging wordt uitgevoerd
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 - i. Pure vorm van pronosupinatie
- c. Product onder een hoek zodat het midden van de hand en de elleboog op een lijn liggen tijdens pronosupinatie
 - i. Rotatie om de longitudinale as

- Vragen

- o Wat vindt u van de mechaniek? Werkt het natuurlijk en soepel?
Specifiek vragen naar de 10 graden rotatie en rotatie om onderarm as.
- o Is het doel bereikt volgens u? Is het een verbetering t.o.v. het oude ontwerp?
- o Ziet u verdere verbeterpunten voor de pronosupinatie beweging?

Welke problemen voorziet u bij het gebruik van dit herontwerp?

S: De 10 graden beperkt uiterste draaiing die een patiënt kan maken. Het heeft voor-en nadelen. Maar ik zie er nu vooral voordeel in.

S: Dan voorkom je dat ze bewegingen fout gaan maken. **Het is goed dat er een beperking is, dan gaan ze niet over hun grenzen heen.**

S: De draaiing om de as is goed, **voelt wat meer geïsoleerd**, dat het minder foutieve beweging stimuleert.

S: Over het uiteindelijke ontwerp: er is niet iets waarvan het niet logisch voelt of gek.

M: die 10 graden is goed genoeg als patiënten nog bijna geen supinatie kunnen uitvoeren. Als patiënten dat al wel kunnen, dan is dit product al niet meer nodig (buiten de doelgroep). **Maar voor die eerste stapjes is de 10 graden echt goed genoeg.**

M & S: Eigenlijk ideaal als het product in lengte nog ietsje meer onder de onderarm steun geeft, zodat de pols ondersteuning iets meer naar achteren geschoven kan worden op de bovenkant van het product.

II. Donning/doffing

3 belangrijke inzichten tijdens het ontwerpproces:

- a. Patiënten hebben last van spasticiteit, waardoor de hand en onderarm in verkrampte positie zitten
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- Vragen

- o Wat vindt u van de vorm en mechaniek? Werkt het natuurlijk en soepel?
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Bijvoorbeeld de bevestiging van de cone aan de shell en het helix-idee.
Welke problemen voorziet u bij het gebruik van dit herontwerp?

S: Er mag best geholpen worden met de andere hand, dat is niet erg.

M: **Je komt wel aan de rechterkant van het support uit**, dus hoe de pols ondersteuning nu is uitgedacht is niet goed (genoeg). Het zit eerder in de weg.

M: Het moet nog wel **handiger gemaakt worden om de cone erop te zetten** door een patiënt met een hand. Dat is natuurlijk geen eis, maar wel wenselijk om het zo simpel mogelijk te houden.

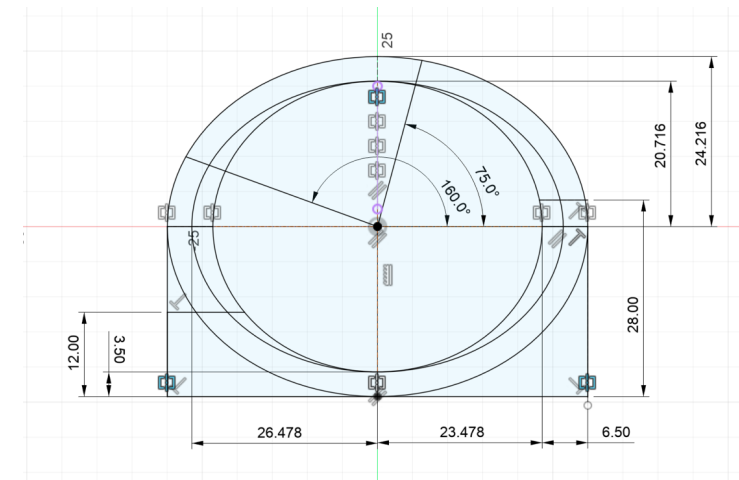
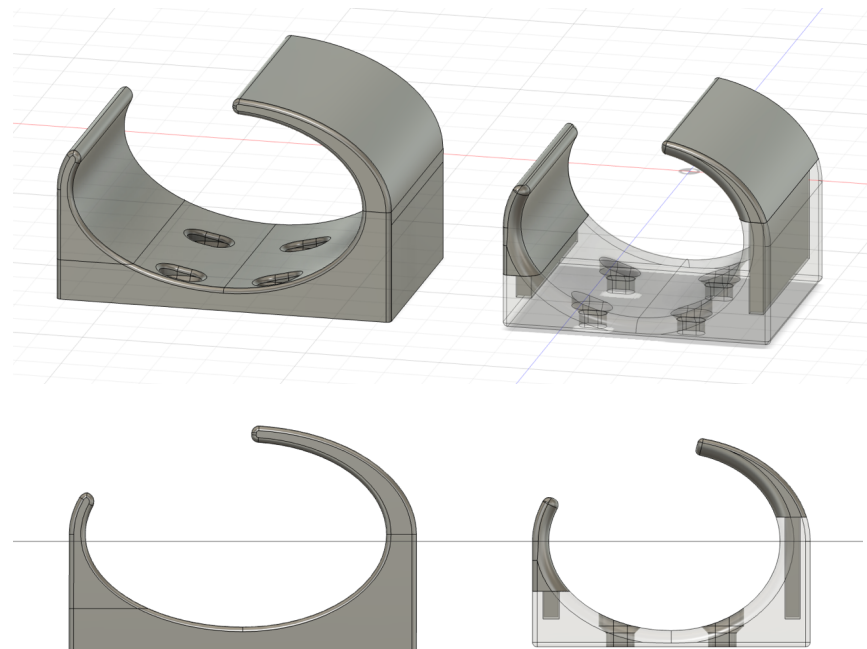
Misschien is een referentie streepje al wel genoeg. Alleen de duim is nog wel een lastig puntje, maar alsnog is het niet erg om de andere hand een beetje te laten helpen.

III. Pols support

Belangrijke inzichten tijdens het ontwerpproces

- Patiënten die een beroerte hebben gehad zijn vaak fysiek én cognitief verzwakt.
- Het aan-en uitdoen van de polsband is niet intuïtief en/of simpel in gebruik en kan daardoor veel cognitieve activiteit vereisen.
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Laatste iteratie:



*afmetingen gebaseerd op DINED Decathlon

- Vragen

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- Is het doel bereikt volgens u? Is het een verbetering t.o.v. het oude ontwerp?
- Ziet u verdere verbeterpunten voor de pols support?
Bijvoorbeeld de afmetingen (ook t.o.v. de shell) en het materiaal? Welke problemen voorziet u bij het gebruik van dit herontwerp?

M: Het werkt nog niet lekker. De breedte van het nieuwste model is goed, **die zal wel passen voor de meeste patiënten.**

M: Wel meer steun aan de rechterkant van de pols, dus dat is goed, maar **de flap die over de pols heen zit is te lang.** Dat is niet nodig en werkt echt niet goed. Eigenlijk zou je **dezelfde hoogte als de andere kant willen, misschien nog iets hoger.**

M: Je zou bijvoorbeeld, net als de cone, iets erop moeten kunnen zetten waardoor het makkelijker wordt om erin te komen en die daarna er weer af kan halen tijdens productgebruik. Voor patiënten die dat nodig hebben.

S: **Er is voornamelijk support aan de zijkant nodig.** Als er geen incentive is om de pols omhoog te bewegen in het spel, dan is support aan de bovenkant niet nodig. Voor de pure oefeningen die hiermee getraind worden, is namelijk die support aan de bovenkant niet nodig.

S: Het kan ook minder diep zijn, **dat is wel comfortabeler. Er kan echt 10-15mm af.**

S: Het is wel echt een verbetering t.o.v. de bandjes, dat vergt te veel cognitieve aandacht. Dus in een keer erin glijden is wel een goede verbetering.

(medisch gecertificeerd) M: 3D-geprinte producten mogen überhaupt niet op de markt gebracht worden omdat het te poreus is en daardoor te snel bacteriën opvangt.