PRODUCT REPORT
MsC04, Industrial Design
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Title page

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Projectmodule: Master's thesis Industrial Design 2018
Theme: A life after stroke
Titel: Product report
Project period: 01/02/2018 - 08/10/2018
Main Supervisor: Thomas Arvid Jaeger.
Technical Supervisor: Ewa Kristiansen.

Number of pages: 13
Appendix pages: 95

Allan Lu

Introduction

A stroke affects a person's mobility, motor skills, speech, perception of things, memory and thinking. It is caused by suffocation, which kills one area or several areas in the brain. Thereby the five skills are affected: mobility, motor skills, speech/ communication, perception, memory/ thinking. By affecting the five skills, the patient's suffer cognitive and physical impairment which decreases their living standard. The damage of a stroke in each of the skills can vary a lot from patient to patient, but all stroke victims go through changes that affect their standard daily life. But through rehabilitation there is hope to recover the lost lifestyle the person once had. The stroke recovery is divided into four stages 1. Acute treatment, 2. Rehabilitation during hospitalization 3. Rehabilitation after discharge 4. Stabilized maintenance. The number of strokes in Denmark alone is around 15.000 a year, and it costs the government 2.030 mio. kr. in treatment and nursing.

The project theme is "a life after stroke", how to live after a stroke and become independent again. A person's life can be changed a lot after a stroke incident, the damage a stroke causes can vary a lot, but all stroke victims go through changes that affect their daily life. These changes can be hard for the patient, especially in the early stage, because the symptoms are most severe immediately after a stroke.

According to the National Stroke Association 9 out of 10 stroke patients have paralysis to some degree in the acute stage. The solution is to focus on a physical problem of regaining mobility from paralysis of one side of the body. The solution is to focus on a physical problem of regaining mobility from paralysis of one side of the body. One-sided paralysis can be characterized as either hemiparesis, which is moderate to severe nerve or brain damage, or hemiplegia, which is mild to moderate nerve or brain damage. Both are nervous system disorders that interfere with the signal sent by the brain to the areas of the body that are affected. This is why the paretic limb which is affected by the stroke has weakened its ability to receive and send back signal to perform actions of mobility and motor skill movement.

The project resulted BOSI, which refers to Body Situation. BOSI creates value for users, therapists and the rehabilitation process. It creates value by giving the users more independency throughout the day when admitted. When the users are taking better care of themselves, it will impact the therapists and the training sessions because problems that influence the trainings sessions will be reduced. This makes the rehabilitation result of each training session more persistent, and it may result in the user being discharged sooner and being more prepared to return home.

Content

The mission of the project is to create a solution to help people who suffered a stroke regain independency by making them pay more attention to their paretic side, thereby decreasing the rehabilitation and hospitalization period by helping users avoid problems that can affect the training session. The solution is a daily aid for the patients, a solution that constantly monitors their health during daily activities before, during and after training sessions, and helps the patient correct body posture and be more active with the paretic arm.

The solution is to be implemented in the early second stage of rehabilitation, because this is when the users are able to start their rehabilitation training with their therapists. The product would need to be used together with therapists to begin with during training sessions to create a routine and understanding, so the users learn to know how to use and interact with the product independently afterwards.

Mission

User problems

POSTURE

Irregular posture position & Kyphotic back:
After a stroke, users who suffer from paralysis have difficulties to withhold an aligned shoulder position and to sit in an upright position, because their mobility and perception skills are affected.

NEGLECT

Perception of their own body:
Users can suffer from neglect after a stroke, which makes them "ignore" the existence of the paretic side. Stroke also causes perception problems, making the users unable to use and understand their five senses normally, to know of and realize what they are sensing. (Sight, hearing, touch, smell and taste)

Inactivity of the paratic side:
Users with or without neglect tend to use their stronger side more often, because it is just easier to use what works. However, favoring their stronger side during activities of daily living (ADL) and using the paretic side less, lead users to start seeing the paretic limb only as a burden, and this makes it more unmotivating and harder to integrate it in ADL.

Prevented long term problems

ABNORMAL SCOLIOSIS & KYPHOSIS

Continuous irregular body posture will lead to sideward abnormal spinal curvature, an S-shaped spine. Continuous forward-bent posture, will eventually lead to abnormal kyphosis.

WRONG PERCEPTION

Continuous wrong interpretation of their perception and the longer period that passes, the harder and more difficult it becomes to resolve.

POST-PONING REHABILITATION PROCESS

The rehabilitation can be postponed due to several problems such as oedema which influences the training sessions because it is too painful to do anything with the hand/arm. In worst case scenario, longer periods of inactivity of the paretic arm weaken the muscles so much they cannot hold the arm up, and the humeral head will start to keep dislocating from the shoulder joint because the shoulder ligaments have become too stretched.

Value

USER

- **Independency**
- **Awareness**
- **Insureance**
- **Less worries**
- **Improved health**

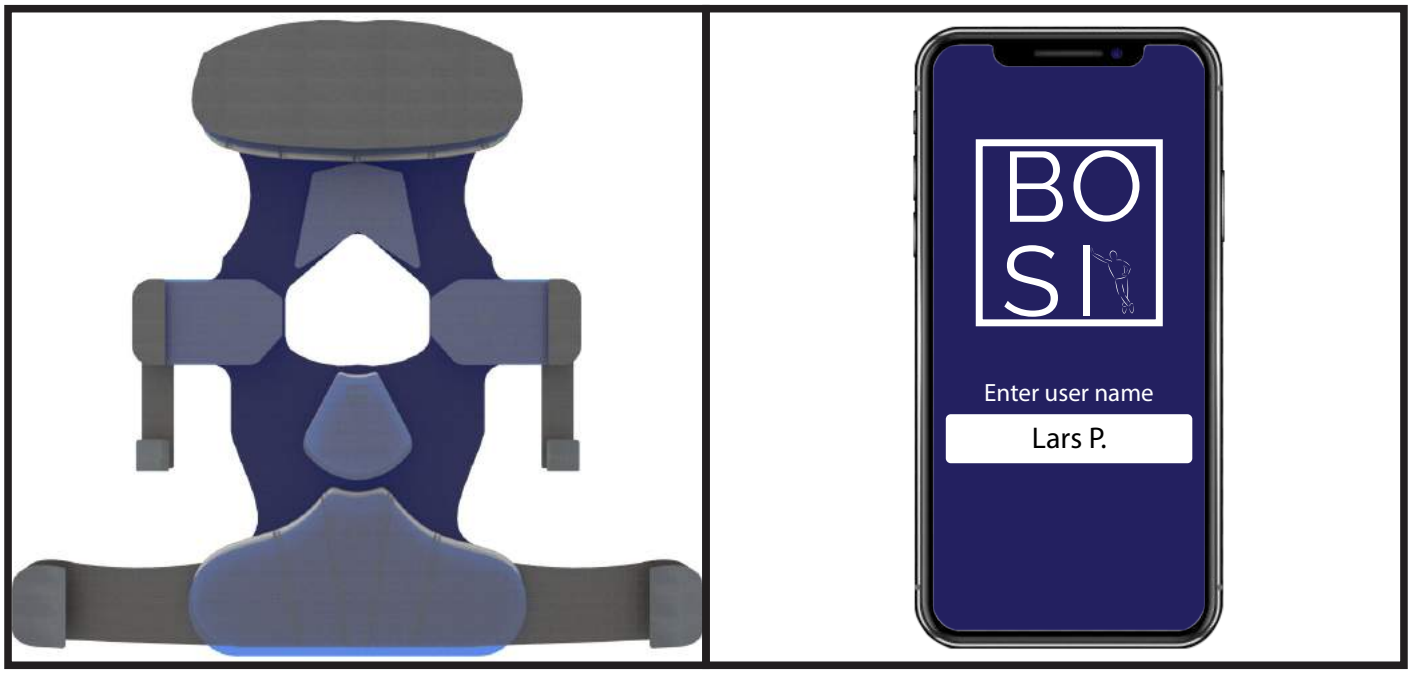
When users correct their body posture and are more active with their body and paretic arm, it will improve their perception of their own body which also increases their independence, as they are taking more care of themselves. By being more active with their paretic arm, the users worry less about occurring problems, which can influence the training session, because these are less likely to occur when users are active.

THERAPIST

- **Insurance & less worries about user**
- **Higher success rate of training result of training sessions in general**

The solution gives therapists less worries about patients, knowing they are active with the paretic arm outside trainings sessions, so no complications occur that prevent them from training during the training sessions. By users being more aware of and active as regards their body and health, users will attend training sessions with a higher performance capability, which makes it easier for therapists to train them.

Concept



BOSI - Vest

The BOSI vest is a rehabilitation product worn in the daily life during hospitalization. Its design and material selection are inspired from ice hockey protection equipment, which is easy to slip onto the body, is made from lightweight and breathable materials, is ergonomically shaped and constructed, so it is comfortable to wear and flexible so that the users can move and wear it for longer period of time. The vest can measure an irregular shoulder position, forward-bent back and activity detection of the paretic arm by using sixth motion tracking sensors.

BOSI - Application

The BOSI-application is mainly to be used by therapists, who are to program the BOSI-vest feedback settings for each individual user's paralysis issues. The application has additional features such as data storing of the user's daily performance and activity levels, this feature can be provided to a user, so they are able to see the information about their daily achievements. Therapists can use this feature to help create users weekly training goals more accurately and according to what a user's current capability is.

Arm movement detection

Motion tracking of selective arm movement exercises during training sessions was meant to be a part of the solution features. Therapists need to supervise and observe between 3 to 5 patients at once during training sessions. This can be difficult to keep track on how many repetitions patients perform per training session. Feedback can be used during training sessions to call upon the therapist, so that only the patients that need it get the support. This makes the training session more dynamic and the flow more fluent.

How is it used?

The vest is equipped every morning, by the help of a nurse. It would then be worn during a whole day, which is usually from 7 AM to 16 PM. During this period the user will spend around 2 hours with the therapist in training sessions, the time period before, between and after training sessions users train by themselves.

During training sessions, the vest is used as an assistive device to notify the user and therapist that a user is performing an exercise with the proper body posture, if not it gives feedback by a sound signaling that an irregular posture is being assumed, which therapists can respond to and thus help the user.

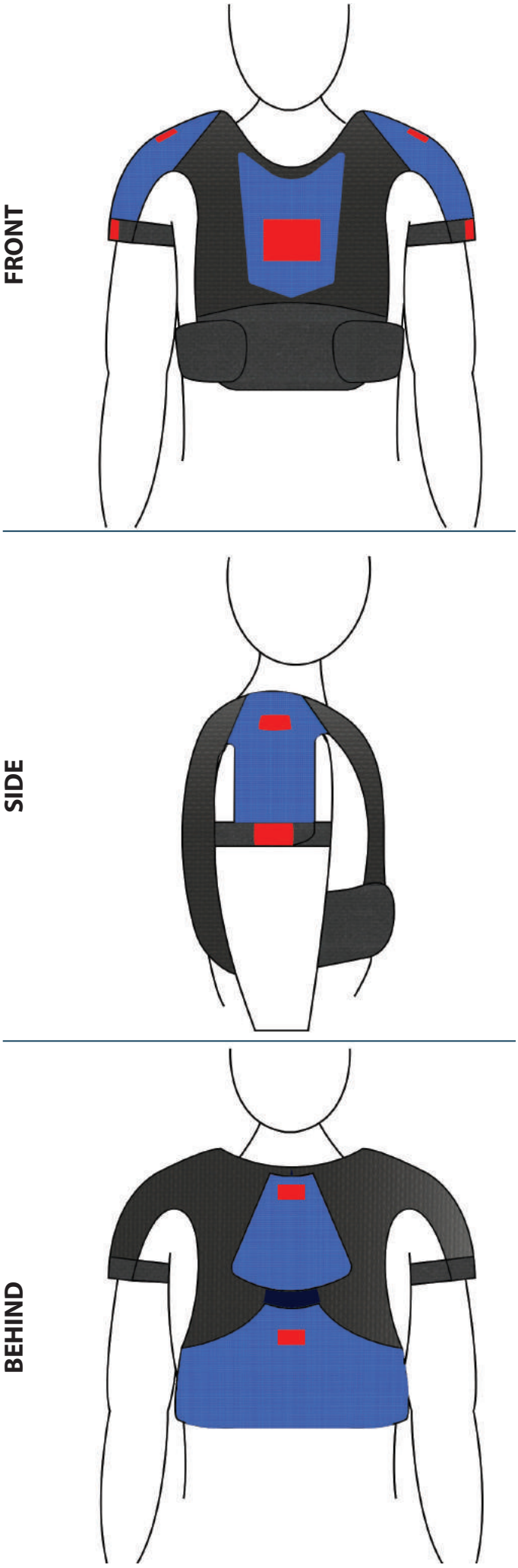
During daily living before, between and after training sessions, the user uses the vest independently. Feedback is given when users are sitting; their posture and activity level of the paretic arm are constantly monitored, and feedback is given when they take an irregular and forward-bent posture, and when too little motion is detected, activity detection will perceive the paretic arm as being to inactive and feedback is given.

- 7:00 AM - 9:00 AM (Independent)
- 9:00 AM - 10:00 AM (Training session)
- 10:00 AM - 10:30 PM (Independent)
- 10:30 AM - 11:30 AM (Training session)
- 11:30 AM - 16:00 PM (Independent)

How does it work?

The vest uses sixth motion tracking sensors to monitor a user's body posture and activity level. A sensor uses and consists of a digital gyroscope, an accelerometer and a magnetometer to create an "inertial measurement unit". Using sixth of these sensors placed on different parts of the body will give value to 3D monitor the user's body posture and movement, two sensors on each upper arm, two sensors on each of the shoulders and two sensors on the back, one place in the upper part and one in the lower. The two sensors used for each monitored body condition, is sending values to a pre-programmed Arduino board, which will process the register data values and feedback, feedback is only given when the Arduino board receive the data values that are outside the programmed threshold settings.

The placement of the sensors and the Arduino board on the vest is displayed in three illustrations on the right as red squares. The sensors and the Arduino board are secured and fixed by being sewed in and placed between two layers of fabric.



Application settings

The application allows therapists to see a patient's daily and weekly posture performance and activity level of both arms by the built-in activity log. The vest uploads data to a smartphone through Bluetooth, during the patrolling and routine checks of every patient, when nurses are visiting every patient room. It uploads the information by automatically connecting to the nurse's smartphone, when the nurse is inside the patient room and is nearby the vest. 'Automatic upload' is a programmed feature that turns the Bluetooth module on automatically at 15 PM, and between 15 PM – 16PM, the Bluetooth will every 10 mins try to detect a nearby smartphone.

The app is mainly to be used by therapists to see a user's 'Activity log' for determining if any change is needed within the feedback settings. The application's front page is divided in three sections of choices when entering the app, 'Feedback', 'Activity log' and 'Settings'.

Feedback:
consists of programming each scenario of feedback that is to be given to a user. These scenarios are shoulder posture, spine posture and activity detection. Figure 4, 5 and 6, illustrate the three programmable scenarios (Mainly illustrative dissemination). Therapists will need to be consulted for creating the proper and more intuitive way of adjusting the feedback scenario settings.

Activity log:
has three sections for each of the three scenarios of feedback, each section has two options: to display either the daily or weekly activity performance.

Settings:
has three sections as well, one for pairing with a smartphone, an optional 'Alert mode' to notify the nearest nurse or therapist by giving them a notification on their smartphone if too high inactivity is detected with the paretic arm and chance of oedema occurring is high. The third section is the automatic upload function.

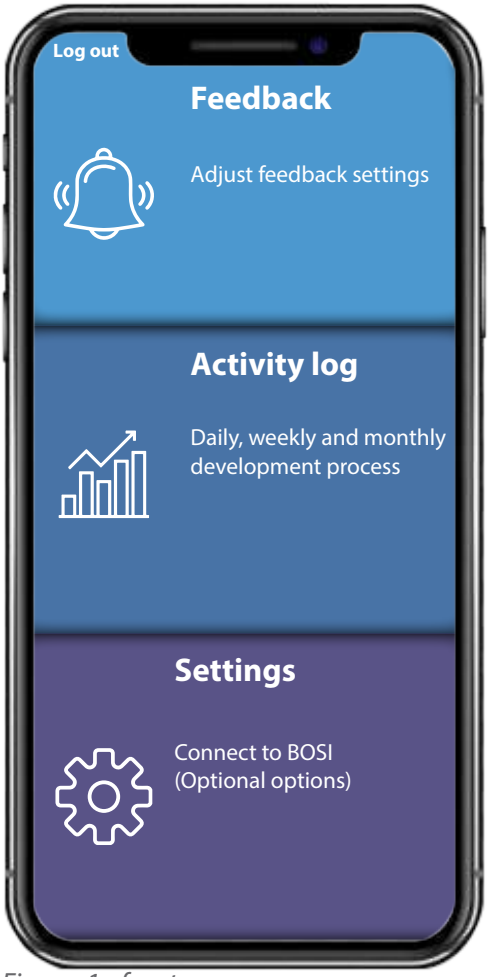


Figure. 1 - front page

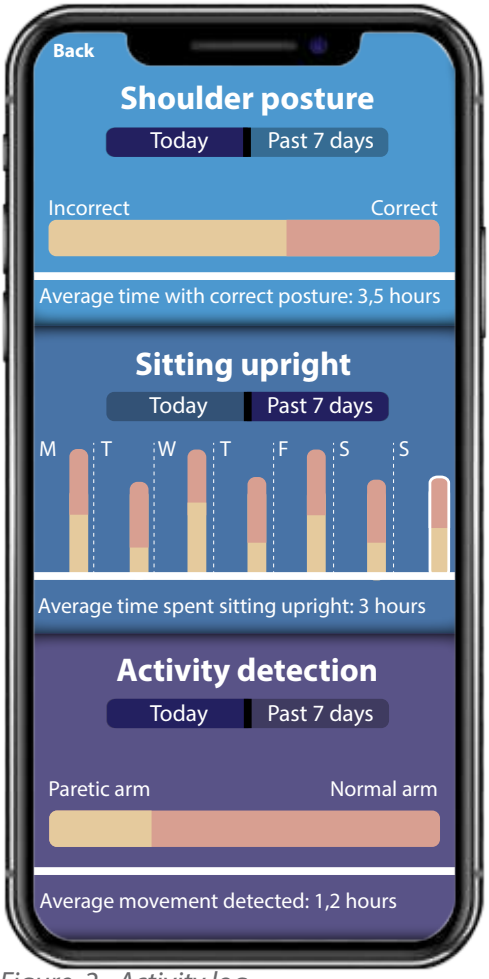


Figure. 2 - Activity log

BOSI introduction - step by step

The first time the vest is programmed, the therapist and the user are guided through a step by step tutorial process, as demonstrated below.

Figure. 3 - Log in - Step 1

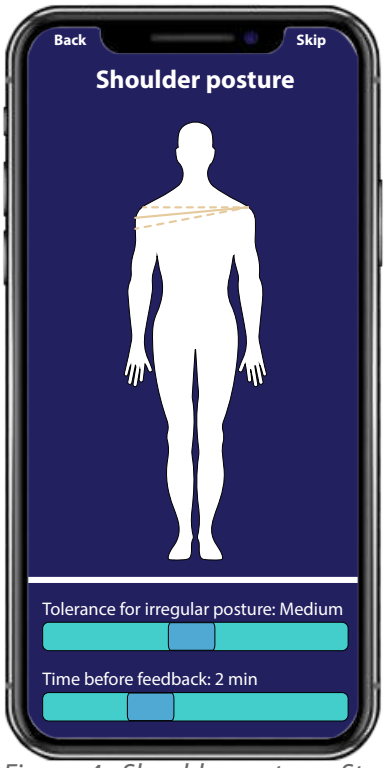


Figure. 4 - Shoulder posture - Step 2

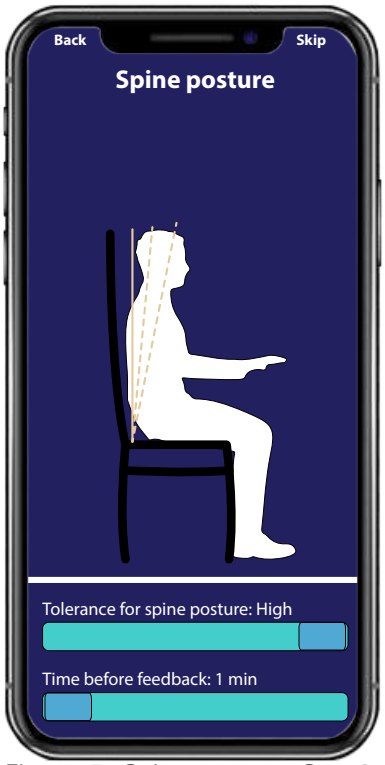


Figure. 5 - Spine posture - Step 3

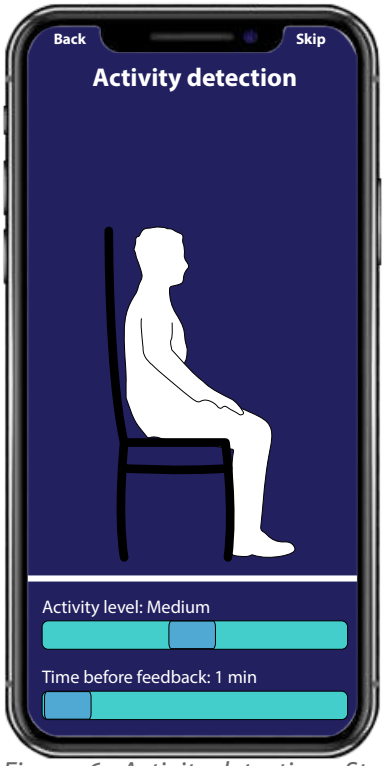


Figure. 6 - Activity detection - Step 4

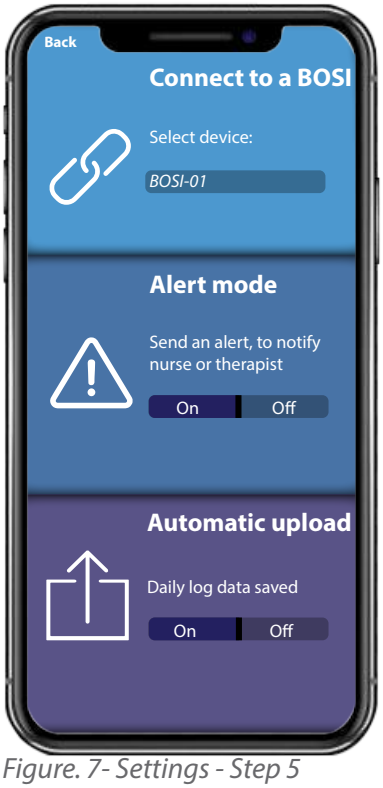
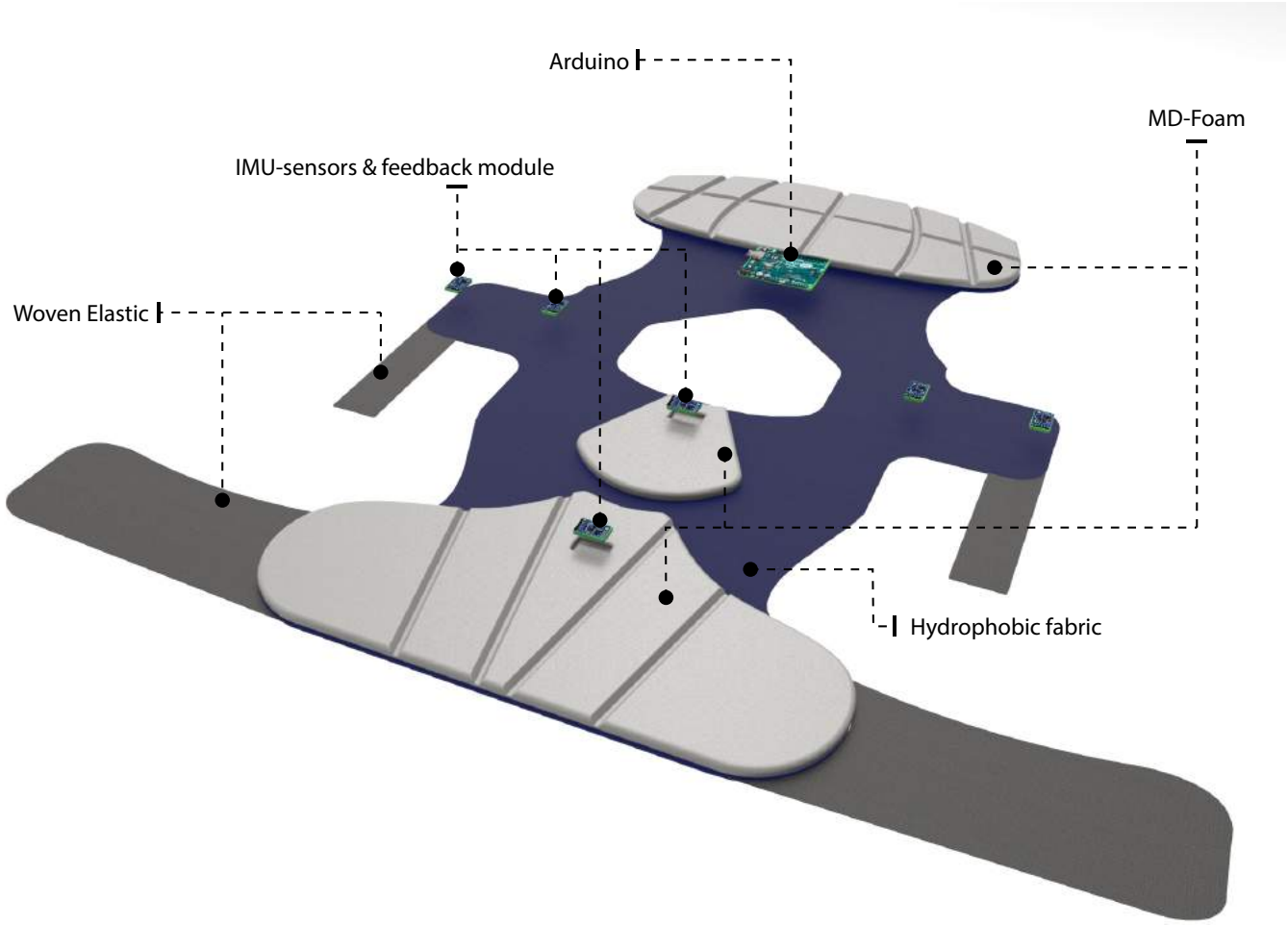
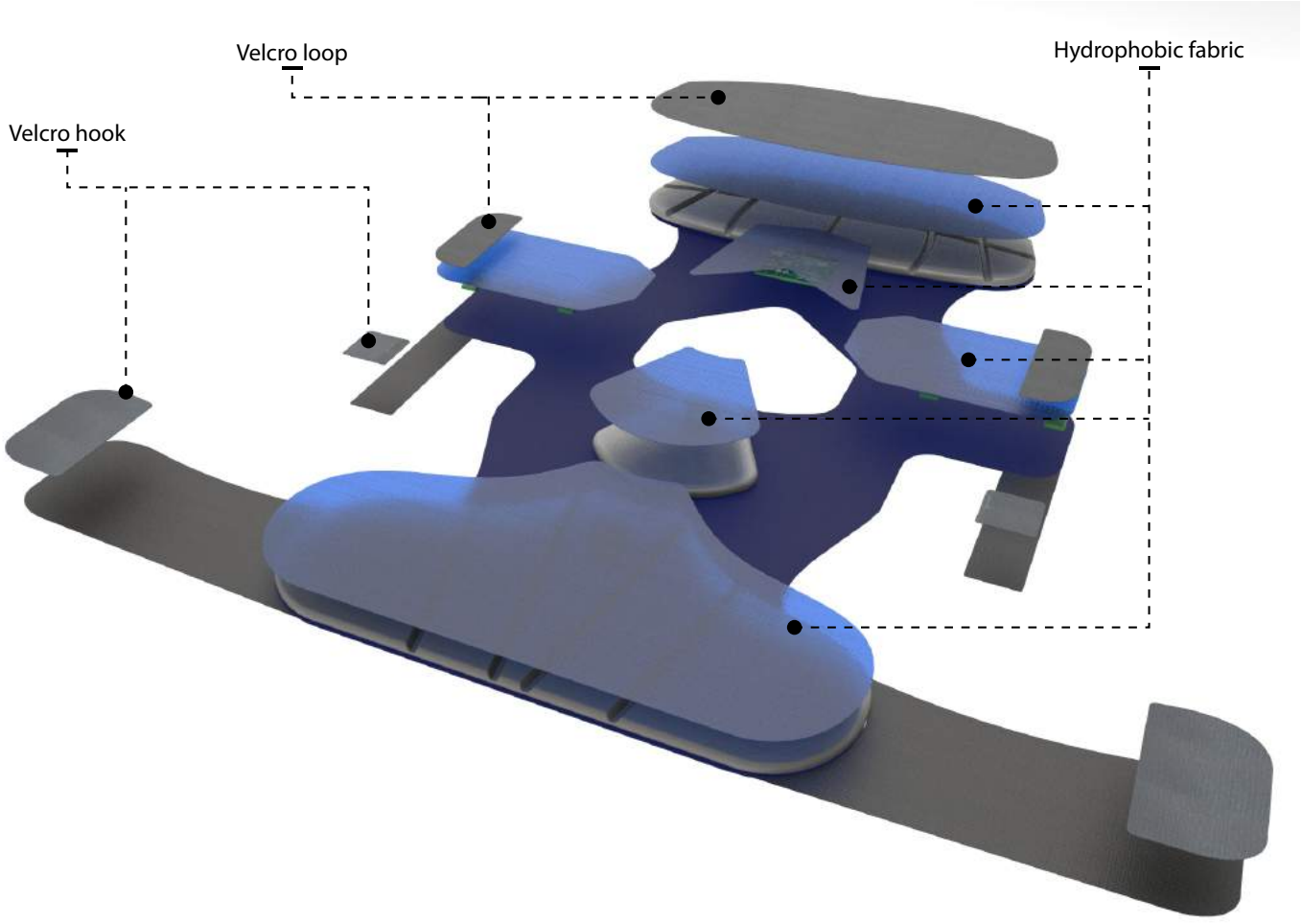
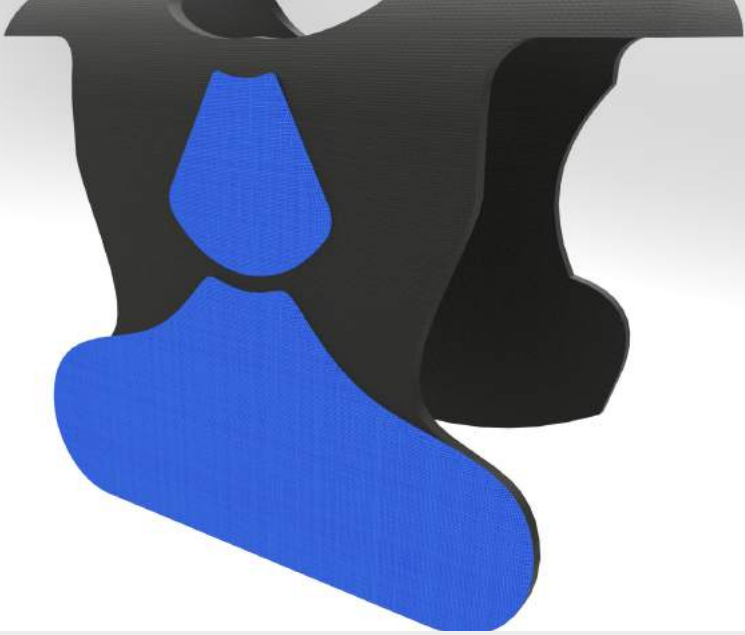


Figure. 7- Settings - Step 5

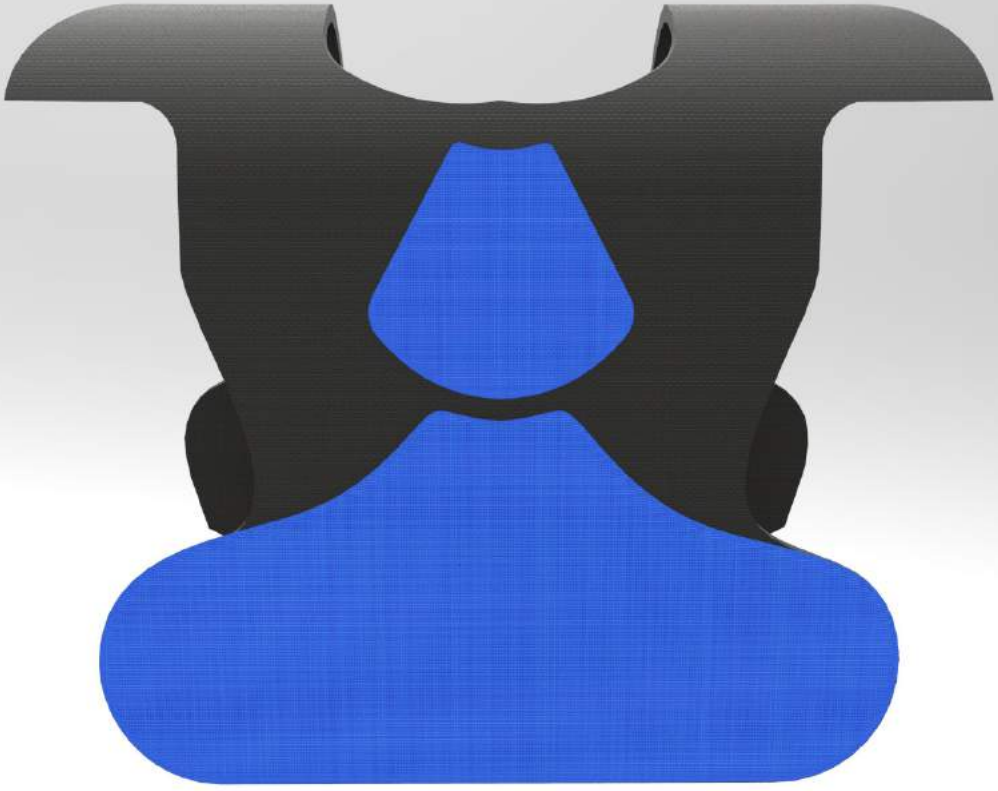
Construction - Bill of materials (BOM)







FRONT

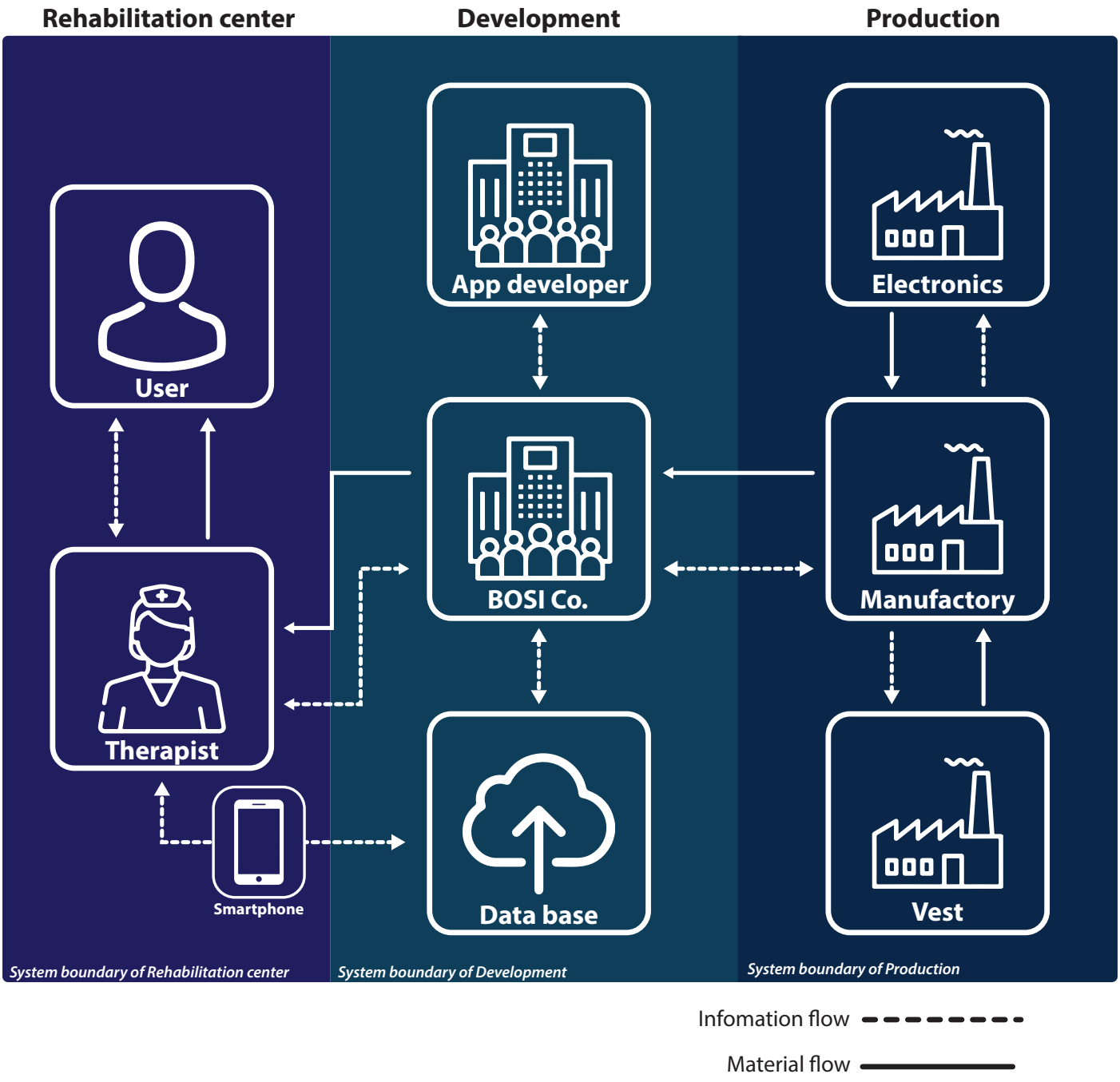


BEHIND

System Model

The illustrated system map shows the flows between the stakeholders before the product reaches a user, it also shows the material-flow and information-flow. The system map also shows system boundaries of what each stakeholder is controlling. Starting from the left, the information-flow between user and therapist is used for better structuring user training programs and weekly schedules, which could improve the rehabilitation process in general.

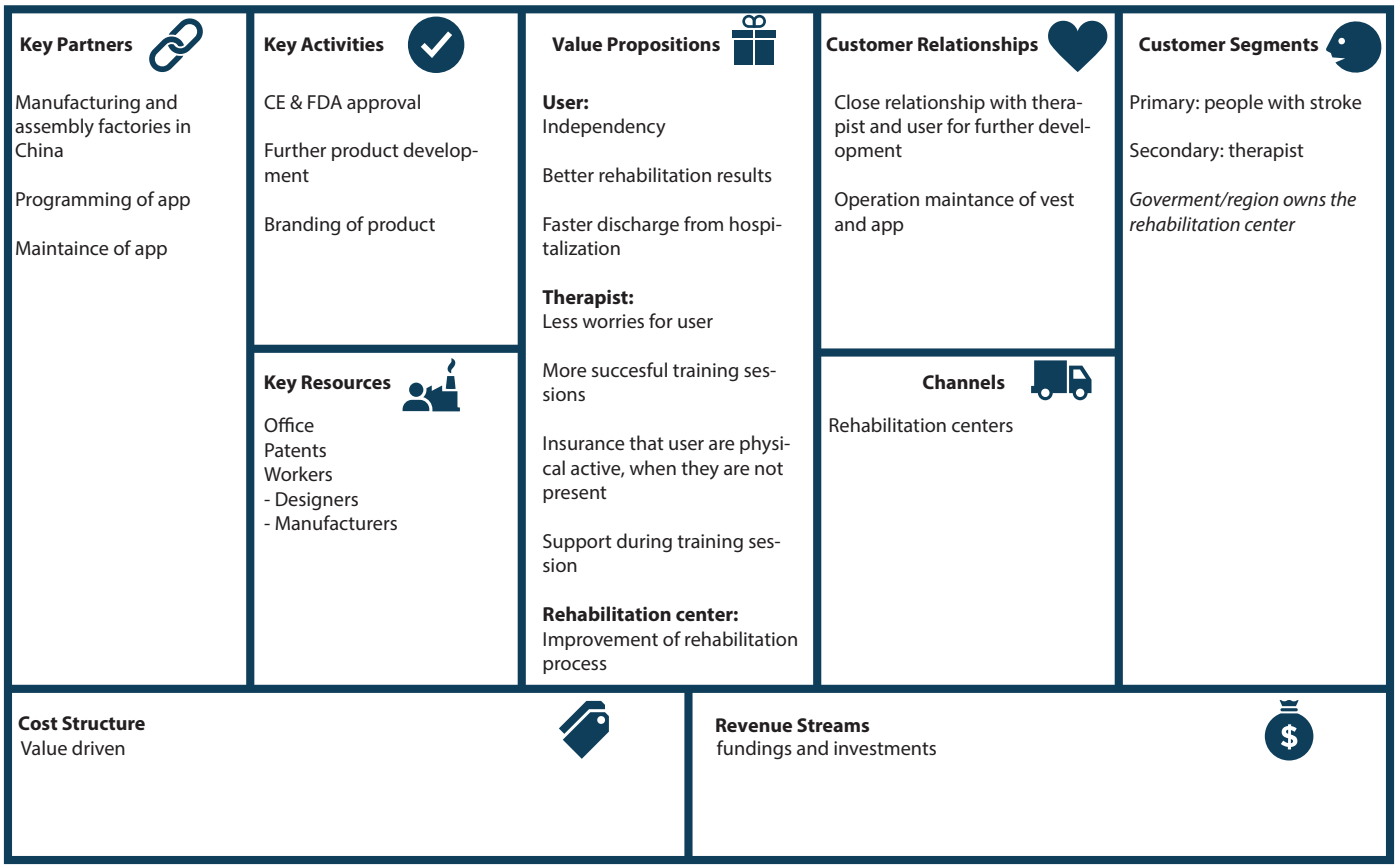
The information-flow between the system of the Rehabilitation center and system of Development, is used to improve and develop further upon the product solution of BOSI. The information-flow between the system of Development and Production, is information given by BOSI co., which could be changes or improvements of either sensors, feedback module or the vest. The material-flow shows the journey of the BOSI-vest from production to end-user.



Business Model

The product is sold to the government of Denmark and distributed through the regions in Denmark, which then will provide the product to each regional rehabilitation center and then it is the therapists' role to evaluate a user fit for using the product. Before the product is fit to be used by patients, it would require three things.
1. If the product is classified as a medical device, 2. If the product is a medical device, it will get a medical product classification, 3. If it is a medical device then CE/FDA approval is required. For the government to consider buying the product, the product would need to show results of improving the rehabilitation process, by making therapists' job more efficient, by being able to treat more people in shorter time.

The value propositions are shown on page 5. The product is most likely going to be more expensive than a regular rehabilitation device, so it needs to provide much greater value to the user, therapist and rehabilitation process, which makes the cost structure of the product value driven. In relation to the choice of key partners, in order to make it an affordable price, the manufacturing and assembly of the product will be executed by a Chinese manufactory. The key activities are developing the product further to make it ready for launching, such as having the programmer creating the application for service, finding investors, achieving CE/FDA approval and branding the product in order to get it out to rehabilitation centers and to a user. The key resources relate mostly to the expenses of running the business, i.e., paying the workers, renting of office facilities, and having a good distribution network.

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PROCESS REPORT
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Title page

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Main Supervisor: Thomas Arvid Jaeger.
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Number of pages: 55
Appendix pages: 95

Allan Lu

Abstract

The objective of the project was to create a product that could impact and improve upon the rehabilitation process for stroke survivors (SV). The focus is to improve stroke SVs' rehabilitation results by making them more independent as they are discharged to their home. The aim was to help patients recover their mobility of the upper extremity. The main problems are that they have neglect, are too inactive with their paretic side, and need posture correction. All problems – if not treated or addressed during rehabilitation – cause new problems that influence the most crucial part of the rehabilitation process, which is being able to train with therapists during training sessions.

The finale product proposition consists of: A vest that can be easily equipped onto the patient by a therapist or a nurse. The vest consists of 6 sensors and 6 feedback modules with vibration and audio and an Arduino board with a Bluetooth module. The therapist programs the vest through an application according to each individual paralyzed patients training needs. The product increases the awareness and activity level of the paretic side for patients, by monitoring their body posture and arm movement, which decreases therapists' worries about patients attending training sessions with complications. Hence, the vests name BOSI, which refers to body situation.

Preface

The project first consisted of two group members from the period from 1st of February until 30th of May 2018. This period of process was development by the group-12 at the time. The project that is showcased in these reports was made by a single person, from MSc-04 ID group-12-a, at Aalborg University over a four-month working period from June to October 2018. The project consists of re-evaluated old tasks and new ones, to construct a process report, product report, and appendix.

The project started with a general and broad approach of finding a problem to solve, within problems SVs suffer from. A problem was introduced to the project of patients with upper extremity problems, of having a paretic arm as it is commonly a burden for stroke patients, in all stages of the rehabilitation process.

In order to locate and verify the problems a collaboration with different stakeholders in the rehabilitation process and other experts was conducted to gain knowledge and feedback on ideas. This report describes the process of the project, which is divided into overall phases each containing the research, analysis, investigations, and tests performed along with the methods used, to move the project one step closer to a final product. The report may seem to be setup in a sequential order, the design process and information used to define project focus has been iterative, meaning it has been moved between phases in order to link all the aspects of the project together.

I would like to thank supervisor Thomas Arvid Jaeger and Ewa Kristiansen for both their guidance, support ,and supervision. A big thank you to all the people whom have been involved and provided insightful knowledge and feedback throughout the project. For the information provided for rehabilitation of stroke survivors, a big thanks goes to Tine Steenholt Rasmussen, Helle R.M. Jørgensen, Carina Lykke Wested, Dorte Jelsbak, Julie Haslund, and Johanne Vestby. For additional information provided for other aspects of the project, a thank you goes to Daniel J. R. Christensen, Troels Johansen, Jakob Mulbjerg Gravers, Daniel Lassen, Laila Bøssbak, Simon Christensen, and John Rasmussen.

Table of content

Reading guide

This is the process report, which describes the process of the project from ongoing infomation gathered throughout the project, used to define the frame and the development of the final product solution. In the product report is a description of the final product.

The appendix will be referred to during the report. The referencing method used in the report is the Harvard method. The content of the process report is in a thematic order and consists of five phases: Project focus, Concept development, Frame, Product development, and Finalizing.

In the beginning of each phase the methods used throughout the phase is presented. Each phase consists of different sections. Each section is concluded using a blue box containing the main points that were taken and used further on in the process.

Throughout the report some phrases with a specific meaning are used:

- User = Stroke patient
- Therapists = Physiotherapist & occupational therapists
- Therapist = Physiotherapist
- ADL = Activities of daily living

The final concept will be referred to in four parts:

- vest = the clothing equipped onto the user, consisting of a vest with extended fabric down to upper arm.
- Feedback module = Sound & vibration module
- Sensor = IMU-sensor
- Circuit board = Arduino UNO, including battery and bluetooth module.

Introduction

A stroke affects a person's mobility, motor skills, speech, perception of things, memory and thinking. It is caused by suffocation which damages one area or several areas in the brain. The damage of a stroke in each of the skills can vary a lot from patient to patient, but all stroke victims go through changes that affect their daily standard of life. However, there is hope to recover the lost skills the person once had through rehabilitation. The stroke recovery is divided into four stages 1. Acute treatment, 2. Rehabilitation during hospitalization 3. Rehabilitation after discharge 4. Stable maintenance. The number of strokes in Denmark alone is around 15.000 a year, and SVs cost the government 2.030 mio. kr. in treatment and nursing.
The project theme is "a life after stroke". That is to say how to live after a stroke and become independent again. A person's life can be changed a lot after a stroke incident, the damage a stroke can cause varies, but all SV go through changes that affect their daily life. These changes can be hard for the patient, especially in the early stages because the symptoms are most severe right after a stroke. This makes it very hard for the patient to see a future living with these changes right away. But there is hope to recover a lot of the lost skills and regain the lifestyle the person once had through rehabilitation. After stroke, not only the patient is affected but also family and friends can feel misplaced and unsure how they can help, as they become the stakeholders in the later phase of the rehabilitation process.

Rehabilitation improvement

Stroke survivors struggle with everything after a stroke: to regain physical function, such as walking or being able to drink and eat by themselves. It is very crucial for these victims to be able to become independent again.

According to the National Stroke Association 9 out of 10 stroke patients have paralysis to some degree in the acute stage. The solution is focus on a physical problem of regaining mobility from paralysis of one side of the body. Improvement of rehabilitation in stage 2 is chosen because it is the stage in which a product has the largest impact of a SVs' rehabilitation results.
The project resulted in a product, which creates value that has an impact on users, therapists and the rehabilitation process. It creates value by giving the user more independency throughout the day when admitted to the rehabilitaiton center. When the users are taking better care of themselves, it will impact the therapists and the training sessions because problems that influence the trainings sessions will be reduced. This makes the rehabilitation result of each training session more persistent, and it may result in the user being more prepared when discharged to their home.

PROJECT FOCUS

Project focus describes the project process, Stroke in general, the users with paralysis and their needs. This chapter will showcase the infomation which the project has been using, from interviews and desktop research to create the projects direction of focus.

RESEARCH

The process of gathering the information in different ways from trustworthy sources. This involves desktop research or field studies. Then the results are documented and refined.

INTERVIEW

Interviews are used to gather the information from different sources that are related to the topic. It may include users, stakeholders or academic professionals.

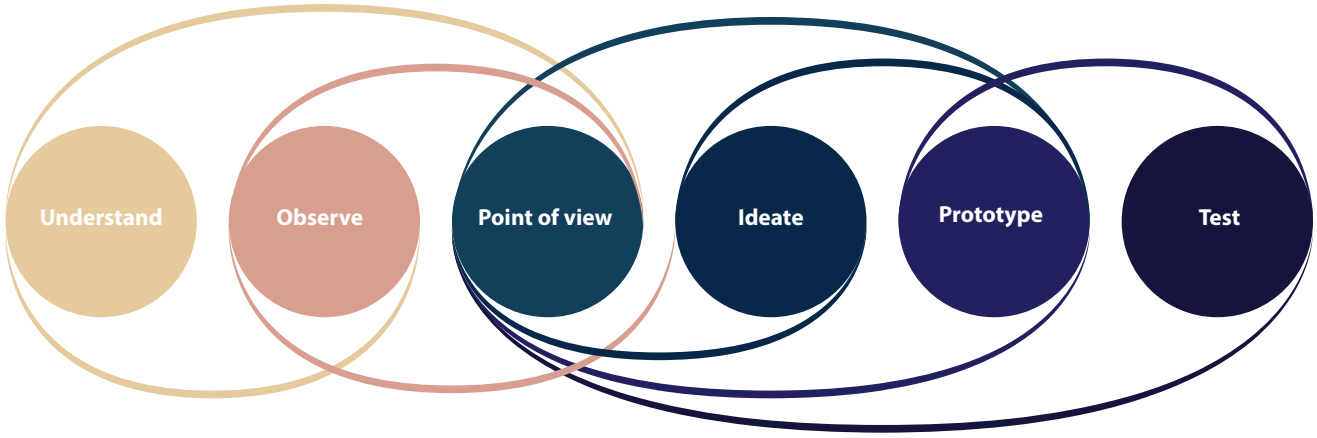
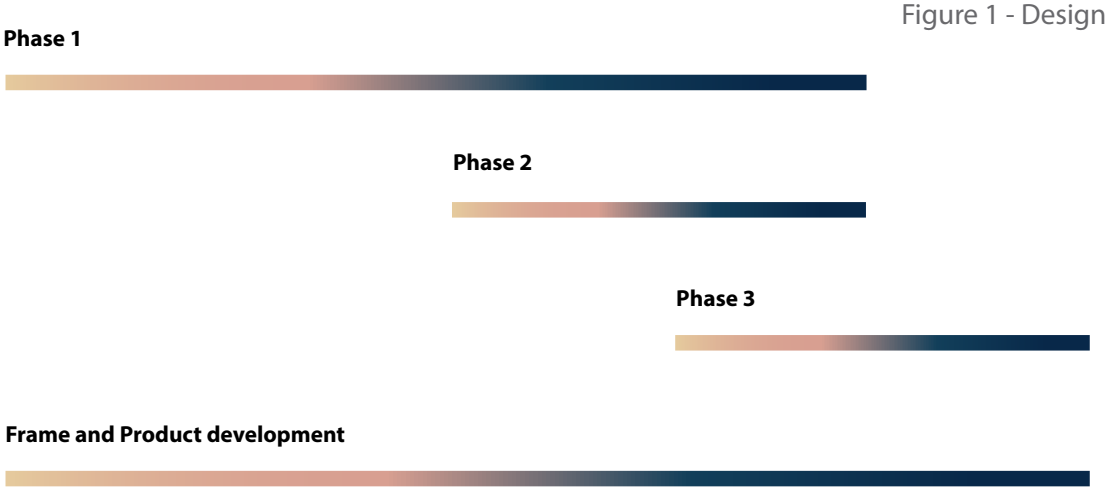


Figure 1 - Design Thinking Process.



Process of the project

Specifying the focus area within mobility can be divided into three phases, that specifies more and a focus area within rehablilitating mobility for user when they are hospitalized. Until the project needed reframe to adjust the scope towards a more specific users segment, used for a fourth phase.

Phase 1
The first phase works further on from a brainstorm on the connection between mobility and motor skills. This brainstorm gave an overview of how these two skills control the body and an understanding of how they are entangled together to make the body perform ADLs. The result and conclusion was that mobility is used for movement of the limbs and also for the body to balance, motor skills were seen as the ability to control hands, fingers, feet and toes to perform fine action after movement of the limbs. Ideation 1 can be seen in Appendix 12.

Phase 2
The second phase was defining the user problems during training sessions to regain movement in their paretic arm. This involves research to understand how users are trained to regain mobility movement of the arm and to perform ADLs. This led to exploring the solution space of creating a product that has an impact on helping users during the rehabilitation training process.

Phase 3
In the third phase therapists and experts within the solution space were consulted. This was a crucial point in the project because it became clear that a reframe was required to adjust the perspective on how to rehabilitate users and to make a proper adjustment of requirements.

Phase 4
The last phase consists of a frame and detailing of a product solution. In this phase the product specifications were determined, in regard to how it addresses and solves selected user problems described in the frame, this includes choosing of specific technology, materials, and design.

Stroke

Figure. 2 - four stage of rehablitation

A stroke in general

A stroke is an acquired brain injury. It is the third most frequent cause of death in Denmark and is the most common cause of severe disability in adults [Sundhedsstyrelsen, 2018].

A stroke is a disease that concerns the arteries leading towards the brain. There are two types of stroke: ischemic and hemorrhagic. Ischemic strokes happen when a blood clot blocks the flow in the vessel, thereby the blood flow is restricted, and a particular area of the brain is deprived of oxygen. Hemorrhagic stroke happens when a vessel wall is disrupted, and bleeding in the brain occurs [National Stroke Association, 2018]. A stroke can damage several areas of the brain depending on where the stroke is situated in the brain. Thereby the five skills are affected: mobility, motor skills, speech/ communication, perception, memory/ thinking. By affecting the five skills, the patient's suffer cognitive and physical impairment which decreases their standard of living. This can also cause personality changes, which leads to huge problems for relatives as well.

Stages and diagnosis of the stroke

The project will be using the Danish healthcare system method of diagnosing a stroke and its definition of stages for stroke rehabilitation. [Sundhedsstyrelsen, 2018].
Doctors examine the patient mentally and physically to determine a diagnosis of the level of functionality a patient is left with after the stroke, which is divided into three levels: 1. main functional level, 2. regional functional level or 3. highly specialized level. For more specific details of functional level characteristics see [Appendix 1].
Stroke recovery is divided into four stages: 1. acute treatment, 2. rehabilitation during hospitalization 3. rehabilitation after discharge and 4. the stable maintenance phase.

1. Stage - Acute treatment
In this stage the patient gets treatment immediately when they are brought to the hospital after the stroke accident. Doctors examine the patient and diagnose the severeness of the stroke damage. The first stage is controlled by the hospital that will make a proper rehabilitation plan based on the diagnosis. Patients spend between 2,3 - 2,9 days in this stage before getting either discharged or transferred to the second stage [Tine, section chief nurse at Neurological stroke section, Aalborg Universitetshospital]. If the patient needs rehabilitation, the hospital will, depending on the needs of the person, rehabilitate at the main functional level, regional functional level, or highly specialized level.

2. Stage - Rehabilitation during hospitalization
The second stage is controlled by a Regional hospital center. In this stage the patients' cognitive and primary physical problems are assessed. Together with their personal therapists, goals are set for the patient to achieve, which is used to structure their training.
Therapists work with patients to enable them to do activities of daily living (ADL), i.e., relearning the ability to perform certain actions such as drinking, walking etc.. The relearning of these movement patterns are achieved by neuroplasticity. *Neuroplasticity will be elaborated on page 11 under rehabilitation training*.

3. Stage - Rehabilitation after discharge
The patient lives at home and participates in the rehabilitation sessions in the municipality, and a therapist from the municipality is assigned to train with the patient in his own home a few times a week. In this stage the patient is monitored less and more dependent on his relatives and himself.

4. Stage - Stable maintenance phase
In the last stage the patient is in a stable state and is independent or as much as he can be. Relatives and friends represent a major role for the patient.

Figure. 3 - Five skills

5 skills:

MOTOR SKILLS

The brain is like a storage deposit of boxes, and the activation of muscles specifically used for motor skills such as grasping has a box for itself. After a stroke, a person forgets which box belongs where and thereby are weakened in the motor skills. It is a necessity to practice every day to fill up a new box in the brain so he or she can use the motor skills again. Task-specific training is better than just a general exercise - such as braid collection or trying to pick up pennies from the ground, playing the piano or doing puzzles.

MOBILITY

As a result of a stroke many survivors have mobility problems as for example paralysis and/or balance problems. Paralysis is the inability of a muscle or group of muscles to move on their own. After a stroke, signals from the brain to the muscles often do not work properly. This is due to stroke damage to the brain. This damage can cause an arm or leg to become paralyzed and/or to develop spasticity. Spasticity is a condition where the muscles are tight and stiff and resist being stretched. It primarily affects the arms, fingers, or legs. It can result in an arm being pressed against the chest, a stiff knee or a pointed foot that interferes with walking. It can also be accompanied by painful muscle spasms.

SPEECH & COMMUNICATION

After a stroke it is very common to have communication problems as the inability to express yourself either verbally, by pointing, or by signs. This condition known as Aphasia can affect your ability to find the right words, to understand what others are saying and/or reading and writing.

MEMORY & THINKING

Memory is the ability to take in, store and retrieve information. Memory is not one single system. A person may remember people or things they have seen, like what their physiotherapist looks like, or what they ate for breakfast. This is called visual or spatial memory. They might also remember things that have been said, like what a doctor's name or a conversation they had with a family member. This is called verbal memory. Short-term memory recalls information from the recent past, and long-term memory can recollect information from years ago.

PERCEPTION

Perception is the ability to process and interpret the sensory impressions so that you not only see, but also know of and realize what you are sensing. Perception means making sense of the surrounding world. Your brain receives information from each of your five senses: sight, hearing, touch, smell, and taste.
[National Stroke Association, 2018]

Interview 1

To get a better understanding of SV in the aftermath of a stroke, interviews with therapists have been conducted. Several therapists have taken part in interviews during the project, five therapists from Brønderslev Rehabilitation center, three of whom participated in interviews in the original project period from 1st of January until 30th of May. Two therapists from Hobro Rehabilitation center have been contacted on the 4th of June and have participated for further development.

The interviews had the objective of identifying the problems and challenges stroke patients go through during rehabilitation, both in training sessions and in activities performed outside of training sessions. Some of the knowledge collected through these interviews was translated into user needs, which can be seen on page (31)

Therapists

Helle R.M. Jørgensen (HJ) is a developmental therapist at Brønderslev Rehabilitation center. During the project HJ was interviewed twice. The meetings with HJ provided a general understanding of the process of rehabilitation for stroke patients and a definition of insight into the 5 skills and how the therapists rehabilitate during hospitalization. The interview with HJ can be seen in Appendix 6 and is transcribed as quotes only.
Carina Lykke Wested (CW) and Dorte Jelsbak (DJ) are both physiotherapists at Brønderslev Rehabilitation center. CW was the main physiotherapist and contact person during framing and concept development, but together with DJ she gave input during interviews. CW was interviewed three times, and DJ was present in two of them. The interviews with CW concerned the problems users have both during and after training. During the project CW introduced some users, which we were allowed to observe, interview, and video record during training.

Julie Haslund (JH) and Johanne Vestby (JV) are both physiotherapists at Hobro Rehabilitation center where some users can be referred to if they need further rehabilitation after Brønderslev. Thus, it can be seen as a later point in the process during stage 2 of rehabilitation than Brønderslev Rehabilitation center. However, patients with milder stroke symptoms can also be referred directly to Hobro. The interview with them was a continuation of what we have done at Brønderslev, which made the interview information gathered more specific such as a more detailed definition of target groups, types of paralysis, and validation of needs which are the same as at Brønderslev.

VR-Rehab

Daniel J. R. Christensen is a physiotherapist and the founder & CEO of VR-Rehab. Daniel and his team work with developing virtual reality games that simulate the ADL environment of the kitchen and bathroom for stroke rehabilitation training.

VR-rehab focuses on rehabilitating the cognitive problems of the users through a virtual reality game. They create the software for a virtual environment of the kitchen used for training, such as training the steps of making coffee, putting a plate back on the shelf, etc.. These processes can be difficult for users that have difficulties with their memory, thinking, and perception. VR-rehab have great success in training cognitive disabilities. It works by sensing infrared light sent by the two controllers in the hands of the user, using two camera sensors installed in the room.

Output:

Speaking with several therapists gave a wide range of information. SVs are usually to some extent affected in all 5 skills and it varies from individual to individual. However, it is very common among all SVs to have some degree of paralysis. The sooner the Rehabilitation training begins the better, because the longer time goes by the lesser are the chances of regaining any functions of the paretic side.

Daily life during rehablitation

Users interact with their therapists and the nursing staff during the daily ADLs. Therapists at Brønderslev have working hours ranging from 8 AM until 4 PM. The nursing staff meet in the morning at around 6-7 AM to help users with their daily morning routines/ADLs. the nursing staff also works after-hours which is work taking place after 4 PM. They also do night shifts, during which a few nurses need to patrol and take care of the more disable users.

Therapists and users:

Depending on the weekly training goal of each individual user, they go to different daily training session rooms from 9 AM to 10 AM with a team of therapist. Afterwards, some users have an additional training session spanning from 10:30 AM to 11:30 AM, which can be with their personal therapist or another training session room with a therapist team.
After the second training session they rest until 1:30 PM, where they can train again at what we call open gym "Åben gymnastiksal" until 1:30-4 PM. A physiotherapist and an occupational therapist are present during open gym to train/teach more individual development, hence the equipment applied in the morning training session rooms will not be used.
During rehabilitation therapists can give users orthosis, arm slings, support walkers and other equipments/tools/products to help them with their paretic problems or to assist them in performing exercises and ADLs. These products are only used in certain periods of time in the rehabilitation or until the patient does no longer need the support from the product.

Nurses and users:

Patient groups consist of around 7 patients who are taken care of by nurses, but the time used to take care of the patients by the nurses is not equally divided between patients. Patients with the highest dependency are given most care such as patients who need lifting from the bed to the toilet, feeding when eating etc. because they are unable to do things by themselves. So, if a patient group consists of 7 patients, and 5 of them have high dependency, the remaining two patients receive very little attention. Nevertheless, every patient is visited by nurses in the morning.

Rehabilitation training

The rehabilitation training goal is to rehabilitate the users to a state where they can carry out ADLs independently. This means that therapists need to train and rehabilitate on all 5 skills, therefore the training needs to consider every aspect of the decreased level of function both mentally and physically. During rehabilitation in stage 2 at Brønderslev, each user has his own personal therapists, a physiotherapist, and an occupational therapist. In the beginning when hospitalized, users set goals to achieve together with their personal therapists. These goals are used to structure their training sessions and ADL training.

When rehabilitating paralyzed users, they will need to relearn movement patterns of controlling their paretic limbs. To do so – whether it is to use their legs to walk, use the hand to grasp a glass to drink – maintaining a correct and aligned body posture is important, because performing the movement while maintaining posture ensures that the user is activating all necessary muscles for exercises or ADL. To be able to do this the user constantly is given feedback from a therapist to ensure correct posture and movement.
Rehabilitating paretic limbs is a long and progressive process which requires what is mentioned above and correcting posture must be repeated a lot of times, this is known as neuroplasticity.
Neuroplasticity is the capibility of the brain to rewire the still active brain and regain lost functions after a stroke: Neuroplasticity training consists of three important points: 1. Highly intensive training 2. Between 200-400 repetitions a day 3. must be goal oriented.

Self-training exercises are given to a user by their personal therapists. If the user has the cognitive abilities and motivational aspect of wanting to be independent and to do more exercises to get better, therapists can give them exercises and tools to use fit for their current state to train by themselves.

Output:
During the working hours 7 AM - 4 PM therapists and nursing staff are present and attend to every user at some point during the day, but after 4 PM only the nursing staff remains. This leads to the fact that users do not get the same care because less people are available, and the users do not get the help/feedback from their therapists necessary to ensure that exercises are executed correctly.

Users at some point want to be able to become independent again without the need for products and tools such as orthosis, arm sling etc. which means that they are able to perform their ADLs by themselves after being discharged to their home. For this to be achieved patients need to relearn the lost abilities of their paretic limbs through training and through meeting the demands of the three points of neuroplasticity training in the hours where therapists are not available.

Figure. 4 - Paralysis

Paralysis and needs

According to the National Stroke Association 9 out of 10 stroke patients have paralysis to some degree in the acute stage. This project will be looking into two types of paralysis: hemiparesis and hemiplegia.

The following description is of the two types of nervous system disorders from which stroke patients suffer and the needs of each disorder during the daily life of the patients throughout the rehabilitation. Mild to moderate brain injuries cause hemiparesis, moderate to severe brain injuries cause hemiplegia. The two disorders are very similar, they are both part of the same continuum of central nervous system injuries that interfere with the brains ability to send and receive signals that produce movement and sensation. It is the degree of paralysis and needs that differentiate the two. In the acute stage it is impossible to diagnose whether the patient will end up having hemiparesis or hemiplegia.

The needs presented on the right are based on an analysis of 'pains and needs' identified through desktop research, interviews with therapists and users, observation of stroke patients during training session. After the second visit at Brønderslev, the pains are specified in more detail within a selected focus area on page 30. All identified 'pains and needs' used for this section can be seen in Appendix 2.

Hemiparesis

Mild to moderate - paralysis:
Weakness/partly paralysis of one side of the body

Need:
- Needs part time care/supervising
- Needs guidance to ensure that repetitions are being executed correctly during exercises
- Needs reminder to correct posture positions & movement of the arm/leg

Hemiplegia

Moderate to severe - paralysis:
Paralysis of one side of the body

Need:
- Need for full time care
- Need for high levels of assistance with ADL and personal care
- Needs individual training with therapist to help build up muscle functions again

Output:
Hemiparesis: The main problem is to perform certain ADL/exercises correctly. There are two core problems: one is the physical problem of being partly paralyzed, the other is being unaware of or know what is the correct way to perform an exercise, from an incorrect execution.
Hemiplegia: The main problem is to activate and rebuild nerve-muscle function, because the nerve connections from the brain to the paretic limbs are highly impaired. So, users need therapist to move their limbs for them, to try and rebuild some kind of sensation of the movement pattern. This is done during training sessions and require a therapists full attention and time.

Implementation table

Based on interviews with therapists, implementing a product early in the second stage of rehabilitation would be most reasonable, because this is when the users are able to start their rehabilitation training with their therapists. The product would need to be used together with therapists to begin with during training sessions to create a routine and understanding, so the user learns to use and interact with the product independently afterwards.

Implementation tables for mild, moderate, and severe paralyzed users was thought through, before making the figure 5 shown below. The tables can be seen in the appendix (20)

1. Starting training with therapist
2. Capable of learning to use the product
3. Capable of using it independently
4. Continue using it independently at home, if needed
5. No need for the product anymore

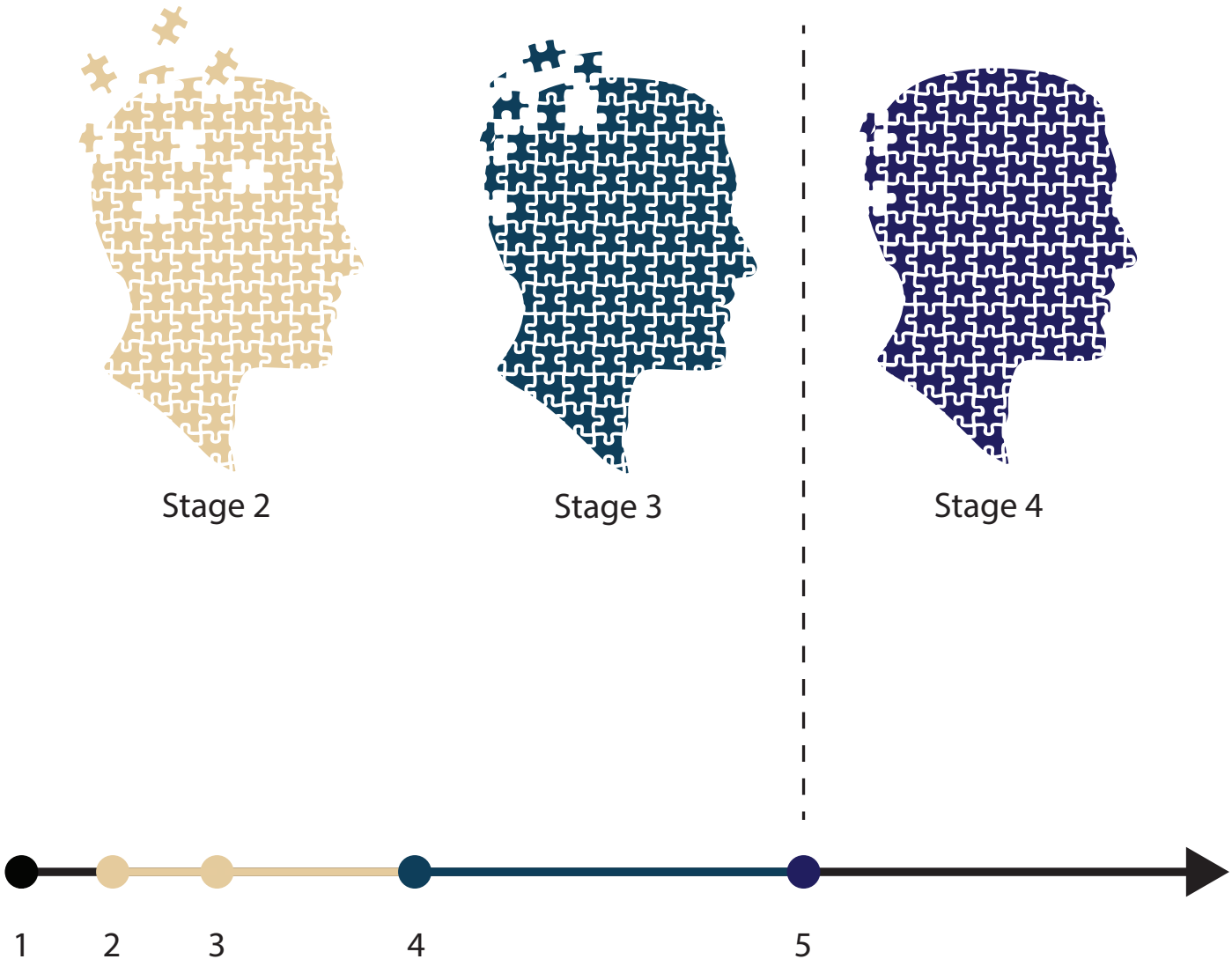


Figure. 5 - Implementation table

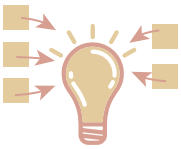
CONCEPT DEVELOPMENT

The chapter of Concept Development is an ideation and research process that the Frame chapter is constructed from. The chapter consist of ideations, analysis, interviews and observations, which have been used to form the frame and requirements for the solution to solve.

SKETCHING

Sketching serves as a tool for visualisation of ideas and helps in the communication when working witin the ideation process. It also provides a wider range of different ideas that can be thought upon.

STIMULI



Pictures, photos and objects stimulate the creative process to help cover the framing area. It is used to create more solutions for a concrete problem scope.

SYSTEMATIC SKETCHING

A sketching method where different ideas overlap and combine various solutions. Sketching is systematic and provides a better overview of the possibilities for the concept.

MOCK-UPS

Mock-ups are 3D physical representations of the 2D ideas. It helps to understand the dimensions and shapes. They are used to verify how the further development should be designed and executed.

Act-it-out

Act it out is a phenomenological process where acting and simulation of specific situation gives an insight into the aspects of what the user would do or feel. This includes usage of mock ups and models.

FRAMING

Framing is a continuous process throughout the whole project. It serves to corrdinate the coming information and data gathered during the research and development phase. This method helps in overall understanding of the problem scope and the focus area.

RESEARCH

The process of gathering the information in different ways from trustworthy sources. This involves desktop research or field studies. Then the results are documented and refined.

INTERVIEW

Interviews are used to gather the information from different sources that are related to the topic. It may include users, stakeholders or academic profesionals.

Technology insight

The objective is to find inspiration to begin the ideation process. There exists a wide range of products which all apply to different types of physical disability. Technology insight is divided into three categories of products. Products are evaluated based on pricing and purpose of the product. See full list of products in appendix 11.

Figure. 6 - Technology insight

Category 1

Products used for taking better care of the paretic limbs such as help to hold the paretic limb in a better and more natural position to prevent spasticity of the hand.
These are typically the products available in the rehabilitation center that therapists can give to the user.

Products: Arm-sling, shoulder orthosis, edema gloves, hand brace, etc...
Price range: 20 USD - 100 USD

Category 2

Products used to ease/support of the weakened paretic limbs, so it is easier for the user to move their paretic limb or body for actions such as using the paretic arm for eating, walking, and training.
The problem is that the arm support device is not portable and is attached to a table, which mean users cannot bring it with them though it can be attached to a wheelchair if a user is using one.

Products: Walking support, wheelchair, arm support
Price range: 50 USD to 3500 USD

Category 3

Products that strengthen or control the paretic limbs, so the user can move their paretic limb or body.
Strengthening body by applying force through a motor to run it and a sensor to control it properly.

Product: Exo-skeleton
Price range: 40.000 USD to 100.000 USD

Output:

The many products found gave the conclusion of a very vast market of products that help users in many ways from easing the problems of care taken to a paretic arm or hand, or to help users do ADLs and more sophisticated technology of moving a severely impaired arm. Hence, the solution space that the project is working on, would have many angles of approaches towards helping users with paralysis. To narrow the many approaches, a specific ADL is to be chosen to begin the ideation process. The many products found were printed and put on the walls in the group room, to work as inspiration and stimulate a creative process of solutions in ideations.

Ideation 2

Stimuli from technological insight, rehabilitation products and moodboard of forms was used during the ideation to stimulate the ideation process. The pictures of forms used can be seen in Appendix 13. Ideation 2 focused on mobility. The cases presented by HJ with users that struggle with shoulder problems that lead to arm drop issues influenced the decision of which mobility was chosen.

The objective is to find the functionality of the mechanism to help users in performing ADL. The chosen focus activity was drinking. The ideas resulted in a combination of technologies and mechanisms integrated into a wearable vest/suit/arm orthosis for the user to wear.

Mechanism:

- Movement and posture correction
- Adjustable fixation of limb for different situations and use
- Direction of strings, strings in tension to restrict bad compensating positions of the paretic limb.
- Flexible and stiff materials - for restricting movement in one direction and allowing movement in another (Fiberglass Fabric)

The mechanism would sustain the body posture and certain cables would be in tension that would make it easier for the user to, for example, extend the arm forward. The ideas are to make a wearable suit so it is less difficult to perform upper extremity movement in certain situations for the user.

Sensors:

- Infrared sensor to be used together with VR-rehab, to motion track arm movement
- Sensors to activate FES stimulation for users that need muscle stimulation to activate muscles.

For more sketches, see appendix (13)

Output

It is difficult to make any conclusion on the ideas without any criteria to hold them up against. The next objective was to interview CW, the physiotherapist from Brønderslev rehabilitation center to learn about rehabilitation training, to define more specific user needs during their rehabilitation training in stage 2 to focus on and have requirements for ideas to fulfill.

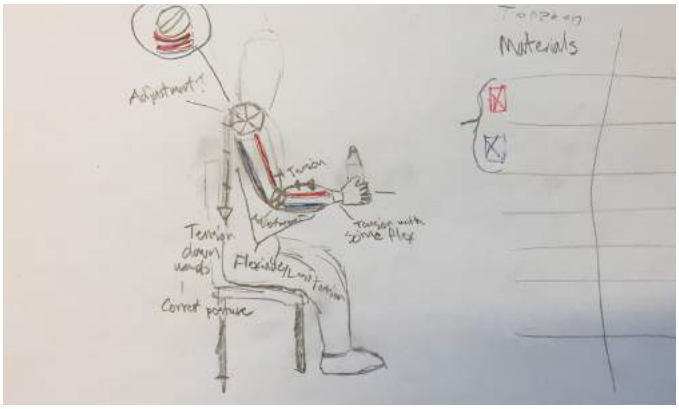


Figure. 8 - Wires attached on the upper extremity

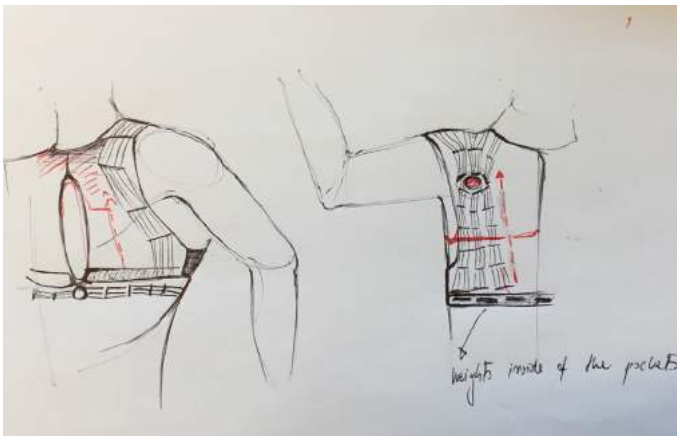


Figure. 9 - Wires/cables to correct posture

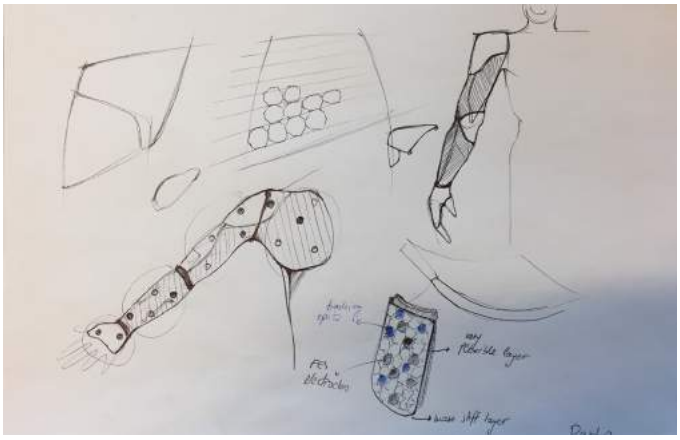


Figure. 10 - Sensor tracking and electrical stimulation

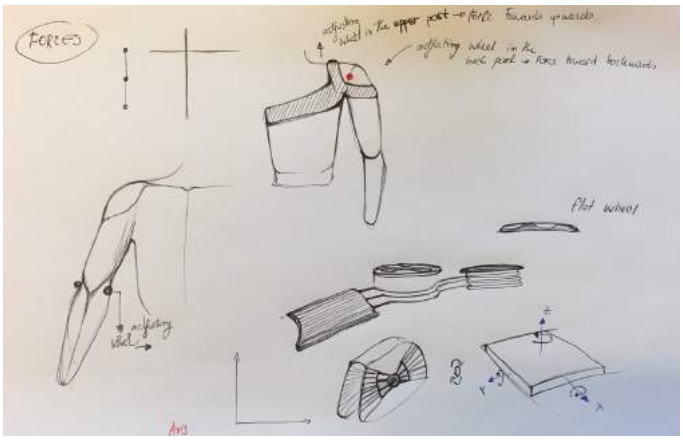


Figure. 11 - Axis mapping for wire directions

First visit at Brønderslev Rehablitation center

Figure. 12 - interview with Carina

Interview with CW

CW is one of seven physiotherapists at Brønderslev rehabilitation center. She creates schedules and goals for the users assigned in her care when they arrive at the center. Beside planning schedules she also carries out the training during training sessions.

The objective of the first interview with CW was to learn more about the upper extremities. To understand how the rehabilitation procedure works from a physiotherapists point of view. Also, how arm movement is regained to perform ADLs.

A variation of topics was discussed:

- Basic movement and training exercise to regain movement
- Problems users have when training to regain movement
- Anatomy of muscles involved for this training
- Rehabilitation process for users throughout the four stages of rehabilitation
- Stakeholders involved in each stage of rehabilitation
- Product available and how they are used by users
- Therapists' roles in rehabilitation

Ideation 2 was explained to CW, which led to an introduction of how paralyzed users are trained in rehabilitation training sessions that focused on drinking, and how the procedure is for this specific ADL. Drinking is within the training theme called reaching, whose end goal is to train user's paretic arms, so they are able to reach out and grasp an object.

Output - interview with CW

CW suggested to focus on reaching training, which is the term for training to move the arm and interact with an object. This is analyzed in more detail on page 19 after having seen a user train this specific action during a training session.
CW said this is a good focus, because reaching training works on the basic movement of the upper extremity to perform any kind of ADL that requires using the arm for doing things.

After the interview, we went to the arm training session room to observe how a training session is carried out. This would give a better insight and understanding of what problems users have so the next ideation would be based on the criteria deduced from these user problems.

Figure. 13 - Observing users during training

Observing users

Three users participated in the arm training which was observed, only two were closely observed. Each user suffers from paralysis after a stroke, the degree of the paralysis and the physical and mental aspects differed among them, thus each had their own training routine specified as to regards of the pains and needs of each individual user.

User 1:
The user above is performing exercises with wooden sticks and cutlery, he is training fine motor skills and perception. In the cutlery training the fork is taped onto his index finger because he has difficulties with grasping the fork and keeping it still on the butter while cutting it. The user also suffers from decreased sensibility, which makes him unable to feel anything with his paretic arm. This disability makes it hard for him to control how much force is put into holding the fork in place on the butter.

User 2 (Per) :
Per suffered from a more severe paralysis and performed more selective training exercises as described by Carina. Selective training is explained to be exercises that focus on a simple movement for activation of specific muscles. An example is shown in figure 13 on the bottom right picture where he places the arm on a table and pushes the arm back and forward holding a wood sliding frame. This action uses flexion and extension that activates and strengthens the muscles used to lift the arm. The user needs to strengthen and to rebuild muscle memory of controlling the arm. A crucial point for the training is for the user to have a correct position of the body and maintaining it as best as possible during the exercise because this ensures that the correct muscles are used. Otherwise he would be performing flexion and extension incorrectly.

Per was more closely observed due to his case resembling the project topic the most at the time. He had a major arm immobility. He had difficulties with moving his arm when he was to sustain the full weight of the arm, therefore he trains the arm on a table for it to support the arm's weight so he can focus on correct flexion and extension.
Another aspect that affected Per's training performances was oedema in his paretic arm and hand, which made it painful and immobilized him even further because of the high amount of fluid. This is caused by inactivity of the paretic limb. Activating muscles in the hand and arm makes the blood circulate better in and out of the limb. This problem occurred in the time period from 7 AM when Per woke up and until 9 AM which the training session begins.

Output

The observation of the users gave an understanding of how difficult it for therapists to rehabilitate users. The problems during training are to perform the exercises accurately according to the therapist's instructions. Furthermore, users have problems daily when taking care of and using the paretic arm frequently to prevent problems such as oedema that can make it painful for the user to do any movement at all and not being able to train.

What is reaching?

Reaching training consists of three phases, 1. Transport, 2. Pre-shaping, 3. Grasping. The project will address the details of the transport phase because this phase involves the motor control of moving the arm whereas pre-shaping and grasping is the motor control of the hand and fingers.

Transport is referred to as the movement of the arm and hand moving towards an object. The essential components to perform transport involve shoulder flexion, protraction, external rotation of the arm, elbow flexion and extension to move the arm toward an object and back again. When reaching out to an object that is in close range, minimal hip flexion and trunk movement are also performed. When reaching to an object further away than the user length of arm, the hip flexes to move the trunk and arm in ordre to reach the object. The elbow may not fully extend at the end of reach unless that is the only way the object can be reached. Annie McCluskey & Karl Schurr (2018). For full analysis for transport phase, see appendix (14)

During the observation of Per, a dialog with CW helped understand what "wrong doings" Per did in the action of movement with his paretic arm during daily life and during exercise in the training session.
This is illustrated in the below flowchart, in figure 14.

Requirements were made based on interviews and the observation of users. A few of the requirements are listed on the right. The requirement list is used for ideation 3 and 4. The full list can be found in Appendix (15)

Requirements:

- The solution should ease and decrease the assistance the therapist provides for the patient during the training sessions.
- The solution needs to regulate specific movements in the transport movement exercises- according to therapist instruction.
- The solution should prevent, restrict or limit the compensating movements.
- The solution should give the patient feedback: to signal when an incorrect movement is performed during ADLs and exercises.
- The solution should save time for the therapist during the training sessions.
- The solution should give the patients a feeling of being more responsible for themselves.

Transport phase movement:

Desired "correct" movement with an upright posture:
Shoulder flexion, shoulder protraction, elbow flexion and elbow extension.

"Incorrect"/compensating movement typically performed by users with a paretic arm:
Elevation & too much abduction, inner rotation and too much abduction, trunk rotation and inner rotation and abduction.

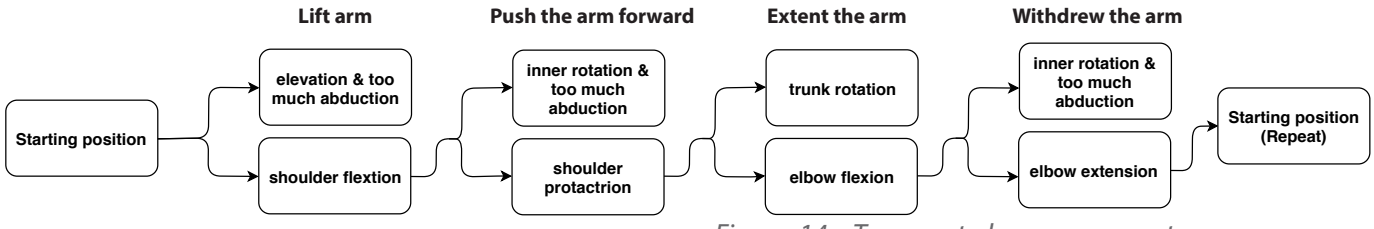


Figure. 14 - Transport phase movement

Output

The information gathered through interviews, observations and analysis of the transport phase led to the decision to focus on working with restricting the movement of abduction during training, on giving feedback for compensating movement and adjusting the user posture upright so they did not need to focus on it when training to relearn movement easier.

Focus area:
How can the solution ensure that the user with paralysis is performing correct movements with the paretic arm. So that all movements are performed correctly to ensure activation of the specific muscles intended by the therapist? The intention is for them to recover faster. How can the solution help with upright posture maintenance and at the same time also prevent the compensating movement?

Ideation 3

The aim of ideation 3 was to ideate on solutions to help users with physical upright posture corrections and movement corrections required to perform within the transport phase.
Figure 15 shows the mechanics of cables or elastic bands placed on top of a body to hold a protracted shoulder position, lifting of the arm. Figure 16 shows the flexible structure inspired by the muscle texture.

Figure 17 & 18 show an arm orthosis that has a modular part that can be clicked on and off, which can limit the degree of abduction that is allowed to be performed.
For more sketches, see appendix (15)

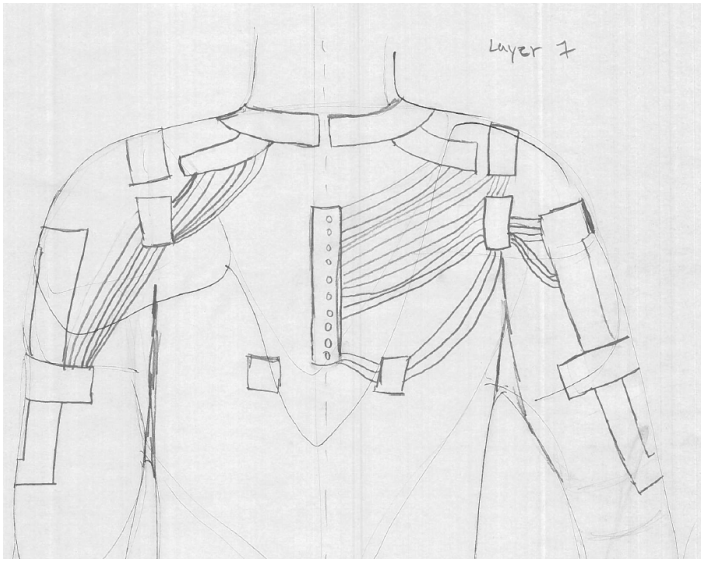


Figure. 15 - cables or elastic band micking muscles to stimulate natural posture

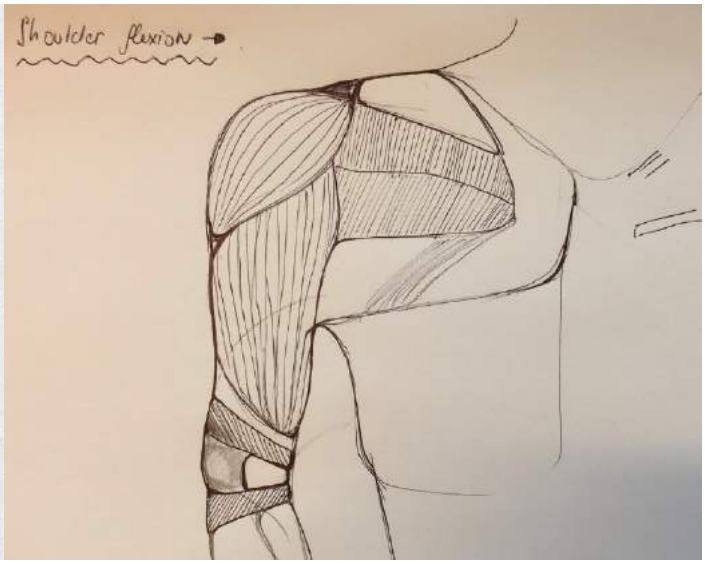


Figure. 16 - cables woven into a suit

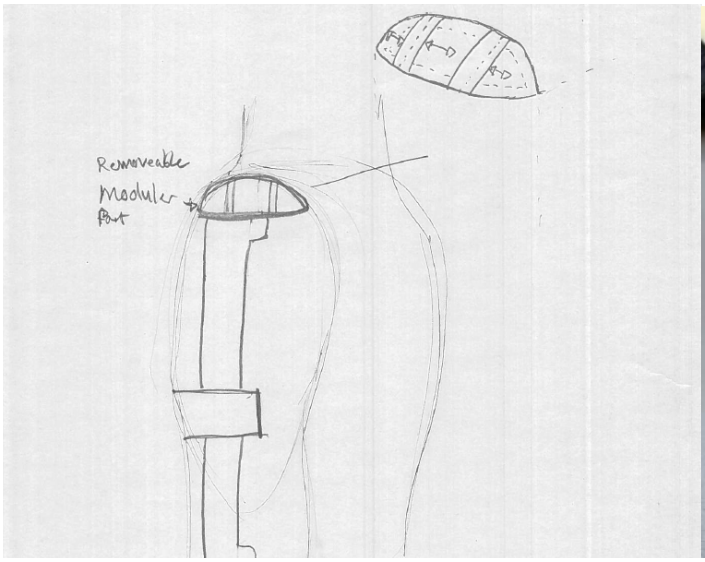


Figure. 17- Attach/removable modular that restrict different degrees of abduction during training

Figure. 18 - 3D printed modular part

Output

Upright posture correction solution was concluded to be solved by pulling the shoulder in a protracted position, and stimulate the correct posture at first, so the user could focus on the movement instead. The ideation for correcting movement was very dominated by the mechanism to be place around the shoulder, to prevent, restrict or limit compensating movement of abduction.

These mechanisms would require a stiff frame of some kind that can be equipped on the body and upper arm, like an exo-skeleton or arm orthosis. To be able to control the abduction.

Ideation 4

The ideation 4 focused on different types of feedback within sound, vibration and light. That would work as a guide to signal the user that the incorrect or correct movement are being performed, so they know to either continue doing the movement, or that they need to avoid a compensating movement.
This feedback would work by sensors which can motion track the arm movement, and then give feedback according to a correct or incorrect movement. Motion tracking sensors would require to be adjustable, because as a user progressively improves in avoiding compensating movement, the motion needs to adjust according to that improvement and to give the correct feedback. So, interfaces were ideated on for therapist control.
More sketches can be seen in appendix (18)

Figure 19 & 20 show illustrations of motion tracking sensors, that are attached to the shoulder and the arm to register movement which then makes a sound, light up green for correct movement or red for incorrect movement.
Figure 21 & 22 show illustrations of interfaces, where therapists can push a button or turn a wheel, to set the variables for correct movement and incorrect movement.

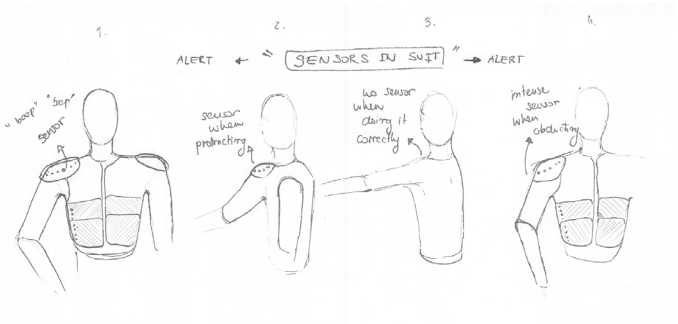


Figure. 19 - A sensor that registers movements and with a "beeping" sound feedback given to the user

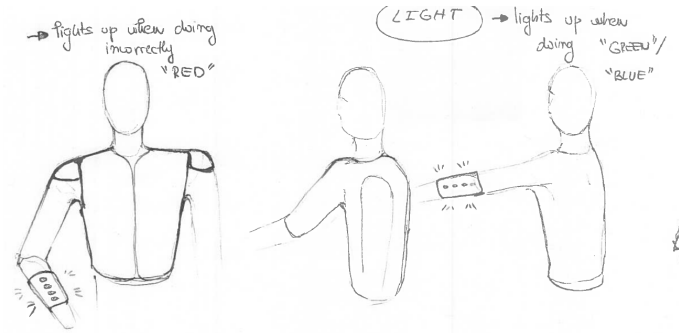


Figure. 20 - A sensor registers movement and feedback is given with green or red light to signal when correct and incorrect movement is performed.

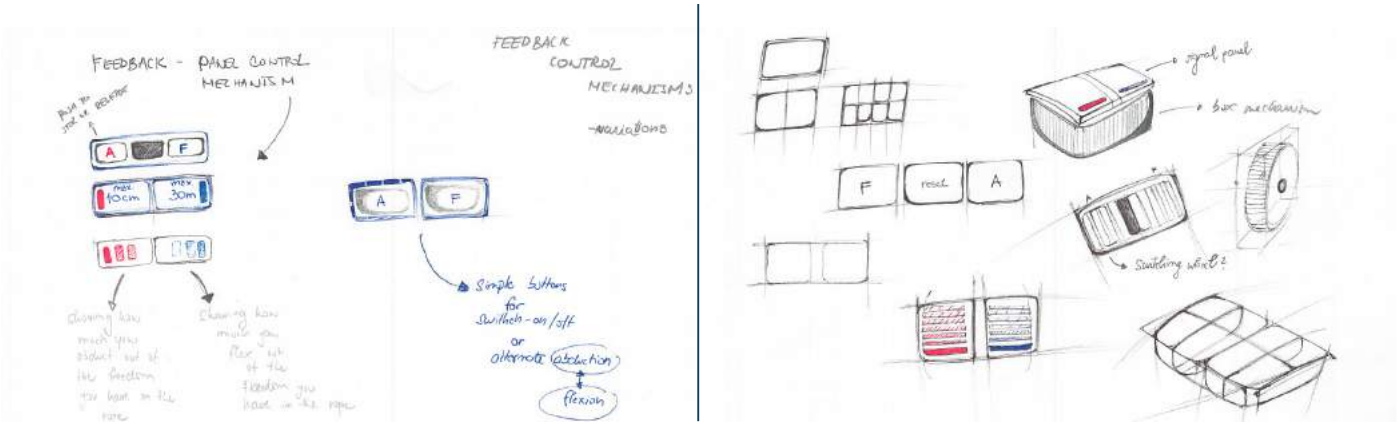


Figure. 21 & 22- Switch detail of adjusting flexion and abduction length limit allowed

Output

The conclusion of the feedback is that it gives the aspect of the therapists in guiding and helping users by informing them if they are doing incorrect or correct movements. Unlike ideation 3 that puts limit to how much physically compensating movement is allowed and does not to give a understanding or informs users on what they should do instead.

Evaluation of ideation 3 & 4

The solutions from ideation 3 resulted in a wearable, that a user needs to equip on to the upper arm, shoulder and body, so it can "control" the compensating movement allowed, but it needs the feedback from ideation 4 to help users to be guided in the next step of movement in the transport phase.

Figure. 23 - Suit act-it-out and analysis

Creating a wearable

The objective is to get a physical representation. To help understand which requirements are needed to make a wearable, which needs to be flexible to move in, but also to have a stiff part which can be equipped on the upper arm, shoulder and body to prevent the unwanted abduction. The analysis of these armor suits was performed in an act it out. When wearing the shoulder pads protection gear from American football and ice hockey, it was possible to understand the effects the suits had on the body while performing the transport phase.
The top pictures in figure 23, show the suit worn and analyzed by the group. The bottom pictures in figure 23, show the suit worn by other students to get a more reliable analysis using people in different sizes for understanding the comfort of the suits. Below are a few quotes from the analysis with other students, full details of the analysis performed and interviews can be found in appendix 17.

American football:
"It feels better when it is tighter (around the chest), because then it is not laying on top of the shoulder, but the whole body is carrying it. The suit makes me want to stand straight more with my back, because leaning forward makes it uncomfortable"
-Person D, male (size: XL, chest length: 102 cm)

Ice hockey:
"It feels like it is stretching my back out, so I have better posture. When I do elevation, the suit follows and I have to pull it down again"
- Person F, male (size: M, chest length: 92 cm)

"I feel like pulling it down, it's too small in the length but too wide over the shoulders. So, I feel like pulling it downwards. It feels a little tight above the chest area, below at the velcro it feels quite nice. I think it feels very flexible for movement, it doesn't lock me"
- Person G, female (S, 77 cm)

"There's a little resistance when I elevate my shoulders. It doesn't fit me accurately; it's too loose around my shoulders. When it's too big, it makes me feel locked, I would like it to fit more like a shirt, and if it's tighter, it could correct my posture" -Person H, female (S, 77 cm)

Output:

The stiff plastic on the football pads made the suit more rigid making the person wearing it maintain an upright posture because the plastic edges would push against the body if the person leaned forward. But the rigid part could work as fixations for the mechanics in ideation 3. The hockey pads have a layer of foam underneath the suit worn on the body, which is cut in a specific structure that follows the movement of the trunk. This makes it a lot more flexible and ergonomically tailored to be worn. It is light weight and easy to equip on the body with the Velcro straps. The ergonomically shaped foam layers seem to be a good structure to mimic and take inspiration from for making a suit which is flexible for the user to wear and perform movements in.

Experts

Experts within bio-mechanics was consulted for the concept development of the suit, to gain expert knowledge and insight.

Simon Christensen, a PhD student at the biomechanical department was consulted in the matter of the mechanical suit, because of his own development of an exo-skeleton. The concept at the time was imagined to be a suit with wires that could be adjusted in length and tension to help the upper extremity in certain actions. He explained that: this product area is also known as a cable exo-skeleton, furthermore it was explained that within exo-skeletons there exists passive and dynamic devices.
Simon has developed a motordriven dynamic exo-skeleton device whose motor adds energy to strengthen the body. Passive devices are static driven and do not involve any component that can generate energy by itself.

John Rasmussen is a Ph. D Professor at Biomechanical department and CEO of Anybody. He was consulted because of his expertise in making simulations of human motions to help design products to be optimized for human use.
The solution from ideation 3 was presented to John, which he suggests would be a job for a bandagist to make, because these professionals specialize in creating orthotics that are made to specifically fit a certain individual user.
John emphasizes that these orthotic devices which physically correct posture and restrict movement are very difficult to make. Because unlike the human body, which has muscles that use several thousand newton of force anchored on the bones. To pull up an arm or to keep the shoulder in a correct position, the orthosis needs to mimic the muscles. It can only be placed/ anchored on the surfaces of the human body and needs to transform the same newton of forces as muscles through the cables or elastic band, as shown in ideation 3, to do the same.

He also commented on the idea of making restrictions of movement, upon which he commented:

"The compensating movement is the only motion the patient can do right now, and creating some restriction does not motivate the user, it only makes it harder, because by restricting the user they cannot do the compensating movements. They do the compensating movement because it is the only movement they are able to do at this time, if it is during training they need to perform the correct movement, then it could be a good idea because they have therapists helping them"

Figure. 24 - Simon's exo-skeleton

In his third comment John addressed the design issue concerning the shoulder, because it consists of many joints and has at least 3 degrees of freedom. This makes the shoulder able to move in many directions of motions. This makes creating an orthosis to be placed on the shoulder very difficult, and orthoses in general are very complicated devices.

Output:

Both experts gave new insight to reflect on. Simon gave an understanding of which product category our solution belonged to, which is passive devices. John provided a deeper insight and understanding of the project itself. First, creating a suit like the ideas from ideation 3 may require that each individual user gets a tailor made suit so it would fit them specifically for the cables or elastic band to correct the posture.
The restrictions for compensating movement were seen to prevent the rehabilitation training further rather than helping it because it just immobilizes and makes it more difficult for the user. It may help during training to assist the therapist in training the user somehow. Thus, it should not be a device which the users should wear or use by themselves. John had concerns about making an orthosis that needs to fit on the shoulder and also perform the movement restriction in one direction while also having the flexibility to do other movements than the restricted direction.
Next step is to present the concept to therapists, and an evaluation will be made for both experts and therapists on page 25.

Figure. 25 - A box used to give abduction feedback

Figure. 26- mock-up of an idea feedback.

Second visit at Brønderslev Rehablitation center

The concept from ideation 3 and 4 was presented to therapists. Three physiotherapist therapists were present during the interview, the ice hockey and football protection gear were used as mock-ups to illustrate the ideas to give the therapist a physical representation while presenting them.

Their feedback encouraged the scope and expressed a need for a solution in the arm training session which was presented to them. They thought that the upright posture correction and movement restriction may help improve the current way of training by making training sessions more consistent from day to day. Because currently it is a therapist's job to ensure that those corrections are given to users during training, and it is not always the same therapist that is present during each training session. So, the problem was explained to be a fluctuation of approaches that different therapists have when preparing the training session environment and the execution of exercises in training sessions, and this makes the training sessions inconsistent with each other.

Some examples: Different placements of a wooden tool on the table as mentioned on page 18. And the placement of a foam box tool used to give the user abduction feedback, which is shown in picture 25. These tools are being placed in an inconsistent distance from the user, and the result of this inconsistency is that therapists cannot make sure to give a user the same high intensive training in each training session, day by day.

What also was expressed is the wish for a suit to be used outside training because therapists thought that the idea of being able to give feedback to a user from when he wakes up until the end of a day would be great. It would make sure that users are also correcting their posture and movements according to the same instructions as those during training session throughout a whole day as therapists can only be present between 1-2 hours a day for each user.

Therapists also commented on the movement restriction. The following quotes are condensations from all three therapists:

"When training different users, it is required to prepare the training session environment and the execution of exercise according to each individual user because each user does not have the exact same paralysis symptoms, and the paralysis which physically limits their movements varies from patient to patient."

Then they explained it in a similar manner as John also pointed out during his interview:

"We do restrict any movement because you have to understand that the training to relearn how to use an arm, such as for drinking, is a longer progressive process, which a user needs to slowly learn. He needs to become better and better in controlling his paretic arm, which goes along with him becoming stronger, and more nerve connections are established day by day for each training session. This is done by letting them do the compensating movement during the exercise, but then guide them to understand and correct it little by little, and then allow less compensating movement as they get stronger through each training."

Output:

Therapists' main outputs:

- Make each training session more consistent
- Give feedback to users daily, with the same instructions as the therapist gives during training.
- Guide the user to the correct posture and movement, instead of restricting the incorrect ones.

Suggested requirements for the suit:

- It needs to be lightweight to be worn daily
- Easy to equip on a user, otherwise therapists will not use it and neither will nurses or patients themselves. *(They liked the ice hockey vest, because it was lightweight and very easy to slip on to the body)*

Evaluation of focus area

After consulting both therapists and experts within bio-mechanics, an obvious refinement to the project focus is needed before engaging in any further development.

The main points, which need to be re-evaluated are:
- What specific problems are in focus to be resolved for further development of the product?
- Which parameters should the requirements be built around?
- How and in which ways should the product impact the rehabilitation results for a user?

To help make the evaluation, theory from [Dorst, K. 2011] is used to understand and create the frame of the project. This is the content of the next chapter.
The objective is to define the aspired values and how they could be achieved.

By performing following methods:
Abduction-2 within the area of interest
Design reasoning
Area of interest:
Is to improve the user's ability to perform basic movements, and this is done in the rehabilitation training through training the user in performing the transport phase.

Abduction-2:
Abduction-2 is a productive reasoning method.
The method gives an overview and a reflective perspective upon the following:

What + How = value (aspired values)

What: is a thing, in this case the vest that a user puts on.

How: is working principles, the methods that are used to achieve the aspired values.
These working principles need to be created from the therapists' points of view because they are the main stakeholders who have the largest influence on the rehabilitation results due to the fact that they are the ones who train the users.

The aspired values are:
Better and more independent rehabilitation results when users are discharged from stage 2.
Decrease of the hospitalization time period for a user by reaching the desired training results sooner
Make the training sessions more consistent (could also be a "how")
Help users to be more aware and active with their paretic arm (could also be a "how")

Design reasoning:
Design reasoning is used to reflect upon the current suit solution in relation to the new information provided from therapists and experts, which is used to make the aspired values, as shown in abduction-2.
Design reasoning has the purpose of creating the project frame, a frame is determined by (how = value).

For now, the current solution of movement restriction does not belong within the working principles of "how" the aspired values are achieved. This movement restriction needs to be removed. The motion sensors and feedback on the other hand align much better with the working principles to achieve the aspired values.
But some parameters within how the working principles should be implemented in the solution are yet to be fully described.

What is left to be determined for further development?
- Find out what are the main problems in focus
- Who is the target group within users with paralysis?
- Create requirements more accordingly to the frame

This will be unfolded in the next chapter.

FRAME

Framing specifies the users and their problems and needs. To make the frame, new interviews were conducted, that focused on the daily care of paretic body parts. For this, interviews with Henning, a user, a third visit at Brønderslev Rehabilitation center and a visit at Hobro Rehabilitation center, have provided further information to proceed the analysis used to make a frame. This information will be explored in this chapter with the purpose to narrow down which values are created to the various stakeholders and consequently to make a list of the requirements that the product has to meet.

RESEARCH

The process of gathering the information in different ways from trustworthy sources. This involves desktop research or field studies. Then the results are documented and refined.

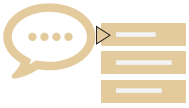
INTERVIEW

Interviews are used to gather the information from different sources that are related to the topic. It may include users, stakeholders or academic profesionals.

FRAMING

Framing is a continuous process throughout the whole project. It serves to corrdinate the coming information and data gathered during the research and development phase. This method helps in overall understanding of the problem scope and the focus area.

INTERPRETED CUSTOMER NEED



This method serves to identify and specify the needs and requirements collected during the interviews and analysis of the data. These are dicussed and selected based on the frame of the problem.

Figure. 27 - Rehablilitation products

Interview 2

Brønderslev Rehabilitation center:
The objective for the third visit at Brønderslev was to clarify any missing information about the rehabilitation process and discuss it. The interview is translated from Danish to English and can be seen in appendix 4.

The output of the interview, gave the following:

1. A list of problems users have in their daily life and during training sessions
2. The consequences of these problems.
3. Current methods, tools and products in the rehabilitation that are available and can help prevent or solve their problems.
4. Problems within the method, tools and products.
5. Functional electrical stimulation (FES):
   FES was experienced firsthand. The use of FES requires a therapist to be present because the electric pad needs to be placed accurately and adjusted during the training, not something to be used independently. A full worksheet of electrical stimulation has been made and can be seen in appendix 10.

This information has been analyzed in appendix 3 and is used to determine the main problems in focus, which is illustrated on page 30.

Hobro Rehablilitaion center:
The visit at Hobro Rehabilitation center had the objective to find out if user problems and needs are the same as at Brønderslev. Ideation 4 was presented in the matter of giving feedback to the user, this is used for the next chapter, Product Development. The discussing about feedback gave an insightful conversation about to whom specifically it could be applied within users that suffer from paralysis. This information is used to describe the target group on page 30.
The interview is translated from Danish to English and can be seen in appendix 8.

Henning user:
Henning suffers from right-side paralysis and was interviewed to understand problems better from his perspective, to understand which values he prioritizes the most. This information is used as quotes to describe the target group on page 30. The interview is translated from Danish to English and can be seen in appendix 7.

Figure. 28 - Target group

Target group

- **Age, 55+**
- **Men and women**
- **Aware of their condition**
- **Want to be indenpendent again**

The target group who is to use the product is mainly people diagnosed within the main/regional functional level are hospitalized up to 59 days in the second stage of rehabilitation. In general, the target group of users suffer from hemiparesis and have perception problems of not being able to know that they have an unaligned body posture if they are not corrected. The severity of perception problem can be divided into two groups: The first group of users have neglect. The second group are not using the paretic side enough because it is easier to use the one that works properly.

The target group is typically aged above 55 and has a social life/family awaiting them after discharge. During their stay at the rehabilitation center in the second stage, they have ADLs and exercises that require aligned body posture during the whole day. The target group is dependent on the therapist's feedback during training session to ensure proper execution of ADLs and exercises. They have an appreciation of their own condition, which makes them aware of their problems and the consequences that follow if no action is taken, but they are unable to – or it is very difficult to – correct their "wrong doings" without the therapist. This means they are self-motivated to perform more exercises and ADLs using their paretic side, but should not overdo it because they perform them incorrectly without feedback from the therapist or forgets.

"When using my support walker for walking, I devote a lot of my attention at walking with my shoulders evenly aligned. Were it not so, I would be walking unevenly"

"But I am not aware of this when walking, only when my therapists' tells me to adjust my body posture"

"It is not very often a person has the time to walk with me in my wheelchair, so I would really like to walk again. This would make me much more independent"
-Translated, Henning, stroke survivor

User types

When a person suffers from a stroke and needs rehabilitation training, the rehabilitation training covers all of the persons disabilities within the five skills. In this project, the solution will be adressing mobility (paralysis) and perception issues mainly. This section will be giving some user types example, to try and showcase how diffrent patient with mobility and perception, is influenced by the other 3 skills.

Based on the interviews with therapists, Henning and observation of users during training session.
4 user types with different degree of paralysis and perception have been established, for the purpose of having some more understandable and concrete user cases, so it is more relatable to reflect upon how paralysis can affect the body, and cause different kind of user problems during ADL.

User A:

User A has decreased sensibility of the paretic arm/hand and weakened motor skills, but has "good" mobility of upper extremity. User A tends to use her functional arm more. Because with her paretic arm she cannot feel cold/warmth or control the force when grasping due to the decreased sensibility. This makes it difficult or even harmful when performing an ADL. For instance, she is not able to use a fork and a knife properly or feeling that a hot coffee is burning her hand.

Problem:
As she tends to use the normal arm/hand more during ADL. Because she sees the paretic side as a burden, so she does not physically stimulate her arm/hand enough.
Need:
She would need to regain sensibility for doing ADL. This requires constant physical stimulation, such as, touch, vibration, heat, cold etc. Thus, the more sensibility she regains, the less of a burden the paretic side becomes, because her ability to use the paretic side increases.

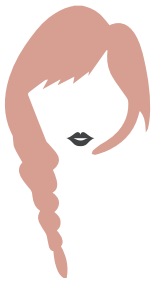
User B:

User B suffers from neglect and partial paralysis. He struggles with oedema that influences his abilities to properly perform exercises during a training session. This is caused from inactivity of the paretic arm/hand throughout a day. His neglect makes it difficult and unable to properly include it in his ADL routines. It is crucial for him to be active with his paretic side.

Problem:
He is unable to use his paretic side, not because he physically cannot, but his neglect make him unable to include it during the day.

Need:
He needs a reminder that regularly draws his attention to counter neglect to be more active with the paretic side.

User C :



User C has perception issues and partial paralysis that influences her posture and arm mobility. She has difficulty performing basic arm movements while maintaining proper posture during ADL.
Training with poor body posture decreases the efficiency of the training outcome, this led to her rehabilitation process being prolonged, because she can only achieve her rehabilitation results by attending the training sessions.

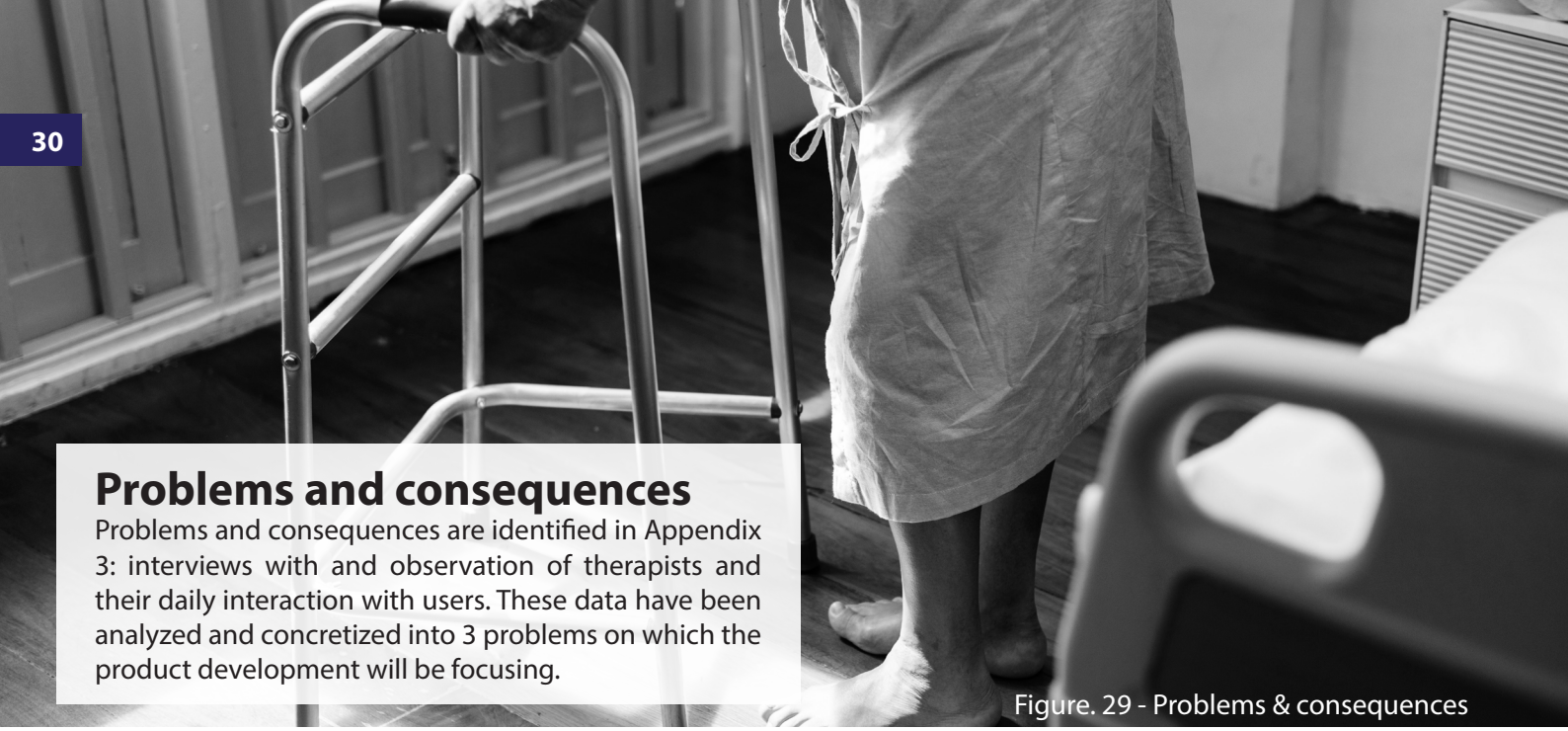
Problem:
She is not able to correct her posture herself during the day, and therapists lack in staff and time to be present for her.
Need:
User C needs live feedback information about her posture status so that she can regulate her posture independently. If she becomes able to do that, her rehabilitation result would be less dependent on only the training sessions, and her rehabilitation process would be more cohesive.

User D:

User D has short time memory and had a severe paralysis that immobilized his mobility and motor skills, but after only 2 weeks he was able to regain function in his fingers, mobility to lift his arm and sit upright briefly. He is very motivated to train constantly but is very dependent on therapists. He is not able to be more active and uses a lot of rehabilitation products to prevent problems such as oedema and muscle spasms.

Problem:
His short time memory makes it hard for him to be more active, because he forgets to use his paretic arm more or to take care of it by using his rehabilitation products.

Need:
He needs to be regularly reminded to be active and use his products to prevent problems that can influence his training sessions, which is very crucial for him.



Problems and consequences

Problems and consequences are identified in Appendix 3: interviews with and observation of therapists and their daily interaction with users. These data have been analyzed and concretized into 3 problems on which the product development will be focusing.

Figure. 29 - Problems & consequences

	PROBLEM	CONSEQUENCES
1	**Neglect** Users can suffer from neglect which makes them "ignore" the existence of the paretic side. They can "forget" or are unaware of their paretic side and do not use it [5]. *Neglect is a neuropsychological condition that can occur after a brain injury.*	Neglect causes very little muscle activation of the paretic limbs. This leads to poor-blood flow in the paretic limbs and causing oedema. This causes pain and immobilizes the limbs even further. Longer periods of high inactivity of the arm will weaken the muscles used to hold the arm up, this might lead the humeral head to keep dislocating from the shoulder joint because the shoulder ligaments have become too stretched.
2	**Inactivity of paretic limbs** The users tend to favor their stronger side during ADL and use the paretic side less. This can lead the users to start seeing the paretic limb only as a burden, and this makes it demotivating and harder to integrate in ADL. *(Neglect differs from inactivity by being a condition the user did not choose).*	Users who tend to use their stronger side more often see their weakened limbs as a burden because they are in the way when performing ADL. This led users to use arm slings to hold the paretic arm in a locked position, which causes stiff ligaments that make it hard and painful to extend the arm when needed. *"If the user has too much pain, it influences the training with therapists, because they will be unable to perform exercises"* - Dorte Jelsbak, physiotherapist
3	**Movement and posture** Paralysis makes it hard for users to maintain proper posture and move their paretic limbs. This is very important to successfully relearn lost functional abilities through neuroplasticity training.	Bad posture makes it hard to perform correct movements. Any exercise starting with a bad posture means that the user will perform a compensating movement, which is undesirable. If a user performs an incorrect movement with bad posture, it does not activate all necessary muscles. If not corrected immediately, they may keep doing the compensating movement and believe it is correct.

Interpretation of customer needs

Interpretation of customer needs - is a list of statements which have been converted to needs that is used to form the base for the product requirements. The full requirement list is shown on the last page in this chapter.

The objective of the analysis is to identify the customer needs by translating relevant customer statements from stakeholders (Eppinger, 2012, page 73). The statements are taken from relevant interviews with therapist and users about stroke patients with paralysis, see full interviews in Appendix 4 to 7. More detailed information of the chosen statements below can be seen in Appendix nr. (19).

STATEMENT	INTERPRET NEED
"if patients are not paying attention to training correctly by performing the exercises properly, then all the hours spent on self-training become in vain, because they compensate and do not activate the correct muscles"	The solution should give feedback to the users, so they can perform exercises correctly and intendedly.
"The patient is not aware of the placement of the paretic limb when sitting. Example: The limb is placed on the lap and is locking the wrist, which stops the blood circulation in the arm. That is when we use hand splint and edema gloves on the patient."	The solution should register inactivity and give feedback to the users to move their paretic limb when it has been inactive for too long to make the blood flow circulate in the limb.
"When I use the support walker, I rest my elbows on it which pushes my shoulder upwards, I lean and put more force on my right side, which makes me walk unbalanced so I need to pay a lot of attention to walking with even/ natural shoulders, otherwise I will subsequently keep walking unevenly"	The solution should inform users about aligning their body/shoulder posture, so they can perform exercises/ ADLs with an even posture.
"Regardless if the patient can stand or sit in a wheelchair it is important to align the shoulders in a correct and neutral position during involvement of activities if the patient is to ever get function over his hands"	The solution should be made for paralyzed users able to stand, sit in a wheelchair or walk.
"We remind and help patients by telling them that they need to pay attention to correcting their shoulder posture themselves and some need physical correction"	Physical feedback must be placed at the area of the paretic side which needs adjustment, so the users know which location requires adjustment.
"Help is given to the patient softly spread out over a day, so it is not a continuous help they get all the time, such as when they are alone by themselves"	The solution should give feedback when the therapist is not present with the user

Framing

Problem Description

People with stroke can suffer from loss of perception and mobility after a stroke. The combined suffering in both these areas can lead to difficulty in balancing and muscle control in adjusting/moving one's own posture, arm and legs due to a weakened muscle function to control and activate certain muscles. Moreover, problems with perception can cause the user to not be able to know they have a bad posture and are tilting towards one side. Unawareness of and living with bad posture every day makes the users accustomed to this, and they are unable to do anything about it themselves. Not solving this issue during the rehabilitation in stage 2 can cause long term problems and physical pain for the patient. This has influence on the rehabilitation training itself and can lead to delaying the rehabilitation process.

Mission

The mission of the project is to create a solution to help people who suffered a stroke regain independency. By making them pay more attention to their paretic limb, and thereby decreasing the rehabilitation hospitalization time by helping users avoid consequences that can affect the training session. Problems occur from 7 AM - 9 AM right before training sessions begin.
The focus is on patients with partial paralysis. The main aspects to be solved during rehabilitation are the body posture, inactivity of paretic arm and neglect. The correct movement should be regained through training sessions together with therapists. Training equipment used for selective training exercises are not very portable and a therapist is needed to give assistance, guidance and motivation to the patient for the wholesome performance to be achieved.

The solution must bring an aid for the patient to constantly monitor their health during daily activities before, during and after training sessions and must help the patient to correct body posture and to be more active with the paretic arm.

The primary patient users are in stage 2 of rehabilitation. They need to have been through rehabilitation training, so they are cognitively able to understand and perceive information, and physically strong enough to be able to sit up straight. The solution will be to help the users first to sit up straight by themselves and later in performing ADL/exercises more intendedly, such as walking straight and moving the paretic arm "more correctly" without the help from a therapist.

Values

The solution would create value that has an impact on users, therapists and the rehabilitation process. It creates value by giving the user more independency throughout the day when admitted. When a user takes better care of themselves it will impact the therapists and the training sessions because problems that influence the training sessions will be reduced. This makes the rehabilitation result of each training session more persistent, and it may result in the user being discharged sooner and be more prepared in returning home.

User

Users would not have to worry and wonder, if they have corrected their body posture or are too inactive with the paretic arm. Daily adjustment on posture by themselves would improve their perception of their own body which also increases their independence because they are taking more care of themselves. By being more active with their paretic limb, they are less likely to have problems, which can influence the training session.

Therapist

The solution can act as an assistance during training sessions for therapists by, for example, monitoring the user posture, and make it one less thing therapists need to observe when training with their patients. The solution also gives less worry of user inactivity with the paretic limb for the therapist. Thus, problems that can influence the training session will be less likely to occur.

Requirements

Needs - Quantitative

1. The solution should be easy to equip onto the user by the therapist, nursing staff or the user themselves
2. The solution should remind the user to activate his arm, for circulating the blood-flow in the paretic arm
3. The solution must inform user about their body posture status whilst sitting
4. The solution should inform the user by giving feedback to draw their attention towards their paretic side in ordre to counter their neglect
5. The solution must be portable, so the user can bring it with them when moving around the rehabilitation center
6. The solution must be lightweight and of breathable material, if it is to be worn a whole day
7. The solution should monitor posture and movement activity level of the paretic limb, to show the process

Needs - Qualitative

8. The solution should motivate the patient to engage in more use of the paretic arm in daily activities
9. The solution should give the user a feeling of being more independent, by using the solution without therapists present
10. The solution should give the user a feeling of having more responsibility for their own health

Wishes - Quantitative

11. The solution must inform the user about their body posture status whilst walking
12. The solution must inform the user whether correct movement patterns are performed during training session exercises
13. The solution should inform nursing staff if the user falls
14. The solution should physically stimulate the paralysed side to increase sensibility
15. The solution should assist the therapist during training session with the user

Source for requirements:

1. (Interview: Physiotherapist,Carina & Dorte Brønderslev rehabilitation center , Julie and Johanne Hobro rehabilitation center

2. (Interview: Physiotherapist - Carina & Dorte)

3. (Interview: Henning, user - Interview: Physiotherapist - Dorte, Carina, Julie and Johanne). Training session observation - Per, user)

4. (Interview: Julie and Johanne, Physiotherapist -)

5. (Interview: Physiotherapist - Physiotherapist, Carina & Dorte)

6. (Interview: Physiotherapist - Carina & Dorte)

7. User value - motivation of seeing progress

8. (Interview: Physiotherapist - Carina & Dorte, Julie and Johanne)

9. (Interview: Physiotherapist - Carina & Dorte)

10. (Interview: Physiotherapist - Carina & Dorte.)

11. (Interview: Henning, user - Interview: Physiotherapist - Dorte, Carina, Julie and Johanne). Training session observation - Per, user)

12. (Interview: Physiotherapist - Dorte, Carina).(Training session observation - Per, user)

13. (Interview - Henning, user)

14. (Interview: Physiotherapist - Julie and Johanne)

15. (Interview: Physiotherapist - Julie and Johanne)

PRODUCT DEVELOPMENT

Product development, specifies the selected chosen functional aspect of the product solution, this process goes through a variation of analysis, testing and ideation to make a solution proportion by implementing technology, materials and prototyping.

SKETCHING

Sketching serves as a tool for visualisation of ideas and helps in the communication when working witin the ideation process. It also provides a wider range of diferent ideas that can be thought upon.

SYSTEMATIC SKETCHING

A sketching method where different ideas overlap and combine various solutions. Sketching is systematic and provides a better overview of the possibilities for the concept.

MOCK-UPS

Mock-ups are 3D physical representations of the 2D ideas. It helps to understand the dimensions and shapes. They are used to verify how the further development should be designed and executed.

ACT-IT-OUT

Act it out is a phenomenological process where acting and simulation of specific situation gives an insight into the aspects of what the user would do or feel. This includes usage of mock ups and models.

RESEARCH

The process of gathering the information in different ways from trustworthy sources. This involves desktop research or field studies. Then the results are documented and refined.

TECHNOLOGY ANALYSIS

Technology analysis divides a product/ technology within *Technique, Knowledge, Organization* and *The product*. These four aspects are analyzed, to understand a company use of different internal and external resources to create a product/ technology.

Chosen areas of specifications

Based on feedback from the second visit at Brønderslev and research within motion track sensor, some aspects have been chosen to focus on to make the development less comprehensive and initiate it more quickly.

1. **The interval for when the solution is used, which will be as such:**

- 7:00 AM - 9:00 AM (Independent)
- 9:00 AM - 10:00 AM (During training session)
- 10:00 AM - 10:30 PM (Independent)
- 10:30 AM - 11:30 AM (During training session)
- 11:30 AM - 16:00 PM (Independent)

This interval of time is chosen because it is when the therapist is available during the day, and it is also the hours in which the training sessions is held. By using the solution independently before, in-between and after training sessions, it is the hypothesis that it would make the user's training throughout a day more intense. By helping users to become active and aware outside training sessions in taking care of using the paretic arm, this might prevent complications such as oedema and the ligaments becoming stiff.

2. **Starting on posture correction and inactivity of the arm in the development at first.**

The reason for choosing to start with working on posture are:

- Correcting movement is a progressive training process and is mainly achieved through many weeks of training sessions. Training sessions have the necessary environment equipment and different tools that are used from week to week. The reasons for using different tools each week are that they each have a specific training purpose which trains a user according to his current paralyzed condition. This means the training session is structured in different steps that uses tools which make the training exercise less and less “selective” and gives the user more control, as a user becomes stronger and builds up better motor control. Thus, the movement correction feedback needs to be adjusted according to each step throughout the training sessions.
- Before a user can or should start performing any arm movement training, they need to have established the foundation of muscle strength, motor control and perception of their own body posture. This is required to be able to correctly begin a selective training exercise.

3. **Use of IMU-sensors to monitor the user posture, inacivity and motion tracking of the paretic arm.**

The sensor is chosen based on the knowledge used in relation to drones to navigate them, by knowing they angular position and orientation. It is relatively inexpensive and easy to use for prototyping.

4. **Use of ice hockey vest as the main inspiration to perform a redesign for the solution.**

The ice hockey vest is chosen, because it is easy to equip, is lightweight and ergonomically made to fit and adapt to the human body movement. All this makes it more convenient to be used.

IMU-sensor

The sensor is connected to an Arduino Uno board, which is one of the most common microcontroller boards used for small electronic applications.

How does an IMU-sensor work?
The IMU-sensor used for this project has 9 degrees of freedom, it has a 3-axis gyroscope, 3-axis accelerometer and 3-axis magnetometer. The IMU-sensor can combine all three sensors to give a 3D representation of position and orientation in space. By knowing the angular velocity/rate, detecting linear acceleration and orientational direction based on the earths magnetic field, an "inertial measurement unit" can be calculated to give a position and orientation. Thus, when placing an IMU-sensor on a certain position, such as on the shoulder, the IMU can calculate the shoulder's position and orientation values. These values can then be processed through an Arduino to give feedback, such as, when these values are outside a certain pre-set threshold, to light up a LED, make a sound or vibrate.

The presented equipment is currently used for prototyping purposes, it is to be mentioned that there exist more compact Arduino boards and accurate IMUs on the market, which could be more suitable for a final product.t

IMU-sensor specification
Accuracy:
Gyroscope range: ± 250 500 1000 2000 °/s
Acceleration range: ± 2 ± 4 ± 8 ± 16g
Field range: ± 1.3 ± 8.1 gauss magnetic field
Communication:
Standard IIC / SPI communication protocol
Size:
Width:23.00 mm, length: 38.00 mm, thickness: 2.54 mm
Price:
4.00 USD

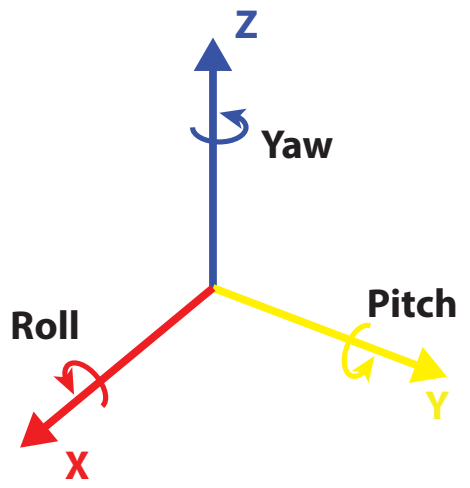


Figure. 30 - Pitch, Yaw & Roll

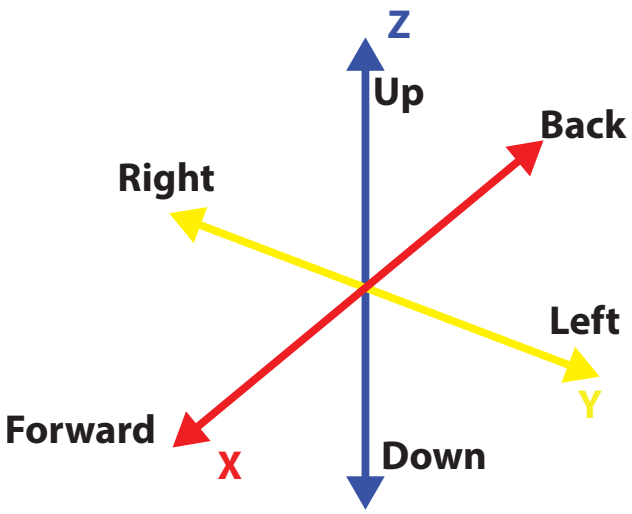


Figure. 31 - Linear acceleration along axis

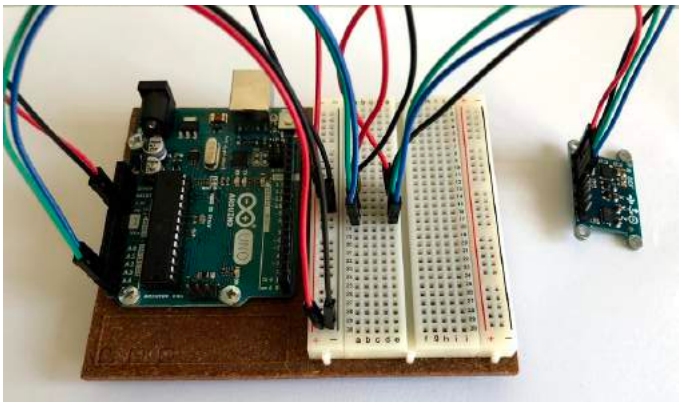


Figure. 32 - IMU-sensor and Arduino

Pros of IMU
The advantages of using and prototyping with IMU sensors is that they are designed to operate under harsh conditions, potentially prolonging the lifespan of the solution, despite how rough it is treated. They are widely used in smartphones and tablets for convenient interaction of knowing how it is held, such as to turn the screen on landscape mode when tilted on the side. They are also inexpensive.

Cons of IMU:
IMUs typically suffer from accumulated error. Because of the measurement of analogue values in relation to each other, which means when small errors occur they accumulate over time. This leads to an ever-increasing difference between the measured location and the actual location. Hence, when applying them, the errors need to be considered and compensated for.

Front view

Back view

Placement of IMU sensors

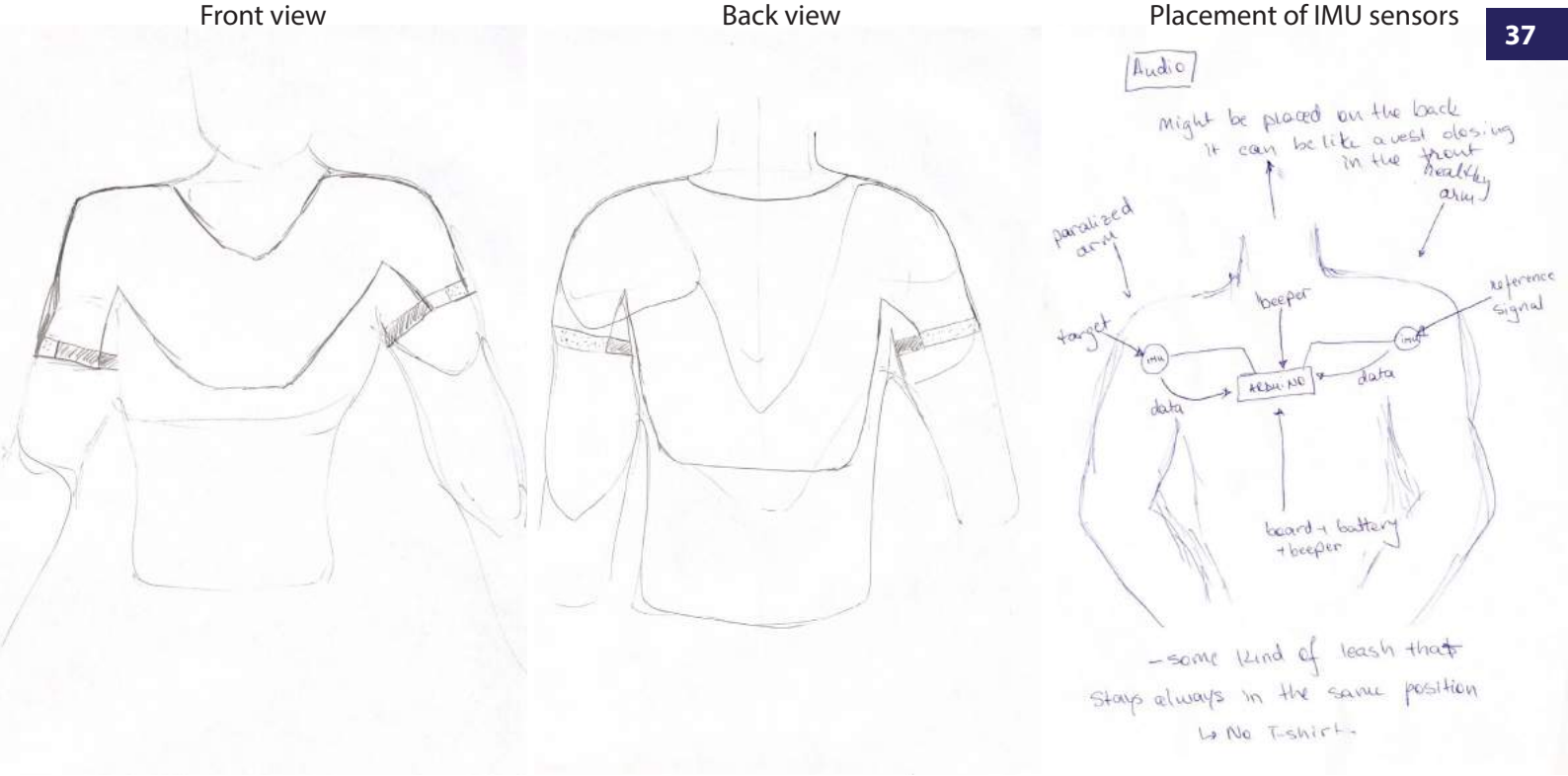


Figure. 33 - Ideation 5

Ideation 5

The objective of ideation 5 is to initiate an ideation to get a first thought of a redesign for a vest and the implementation of IMUs.

Sketches of the vest front and back of the vest illustrate how the vest is imagined. It has the same properties as the ice hockey gear but has extended fabric on shoulder and down to the upper arm, with velcro scrap to secure around the upper arm. A sensor needs to be placed on the arm to register movement of the paretic arm.

The sketch on the right, with placement of IMU-sensors, illustrates an example of registering irregular shoulder posture by placing an IMU on both shoulders. The text on the sketch explains how the IMU on the normal shoulder could be placed in the area of the chest instead, because it is a more stable position. This sketch gave rise to a speculation that there are multiple solutions to how the IMU is used, and how the data the IMU register should be processed.

More sketches can be seen in Appendix (21)

Output

The next step is to set scenarios to understand different solutions with body and inactivity to be registered by IMU, analysis and determine how the data from IMU should be processed in the Arduino, to find out which data processing method would be most appropriate to use.

Scenarios of feedback

The solution needs to give feedback in four scenarios during a day. In this section, the four scenarios will be analyzed in relation to what the IMU sensors need to register as input to generate a certain output/outputs. This will give an understanding of the circumstances of the different situations of a scenario.

Shoulder posture

- Shoulder posture needs to be detected, when the shoulder has been in an irregular position for a certain period of time.
- The irregular position can be detected by two sensors not being in alignment to one another. Such as, should the paretic shoulder drop, hence becoming out of level. Or it can also be detected by a pre-fix range of angle and orientation.

Spine posture

- Spine posture needs to be detected, when the user is bended forwards within a certain time interval.
- The IMU need to detect, when the user's spine is outside a pre-fixed angular orientation relative to another point of reference. such as, on the lower back, so the correct spine position should be close to the other references point in angular and orientation position.

Activity detecting of movement

How often the paretic limb should be active, is very individual from user to user. But what is the most important, is to be active before training sessions, to avoid any problems that could influences or prevent the user ability to perform exercises.

- Using two IMU sensors on both arms to register how often each arm is being used, by detecting the acceleration, after a certain time period, such as every minute the acceleration data from both arms is compared to one and another, if the paretic arm is a certain percentage low than the normal arm, feedback should be giving, to remind the user they should be engaging more the paretic arm.

Neglect

Neglect does not necessarily need to be detected by any sensor. it is more a regular time reminder that gives feedback every minute or so to the user to help them improve their awareness of their paretic and neglected side.

- Nevertheless, it shows resemblance to the inactivity of a paretic arm, using two sensors, one on each arm, the activity level can be detected. So, the data processing can give feedback based on how often the users are using their paretic side compared to the normal.

Figure. 34 - Scenario of body posture

Figure. 35 - sensor placement

Output

Detecting shoulder posture, inactivity and neglect with one sensor solves the problem by increasing the use of the paretic side. However, the user would need to have used the product for a certain time limit before a therapist would know what their current state of activity is to be able to start setting different goals. Using two sensors for each scenario may make the process faster because it would not depend only on registering the activity level for the paretic side, but can compare it directly to the normal side after a day of using the product. For example, the normal side has been registering movement 900 times an hour compared to the paretic side which only has registered movement 100 times within an hour.
Using one sensor to detect spine posture would not provide reliable data, because it cannot distinguish between if the user is sitting or lying down. Using two sensors would give a reference point, to know when the user is in a forward bended position or aligned.

To properly determine the sensors placement, it would require testing. By placing two sensors on the body, for each scenario multiple times, to get data analysis and then determine which placement or placements gives the most reliable results.

Data processing

The prototyping of the solution can only be demonstrated through the use of one IMU to make a feedback. Figure. 35 shows the placement of sensors. The use of sensors is illustrated in examples for shoulder posture, spine posture and activity detection. Activity detection is for both inactivity and neglect. Each scenario of data processing has two examples, for prototyping the project will be using SISO (Single-Input Single Output) as shown on the left side, because the Arduino used can only connect to one IMU-sensor at a time. However, for future implementation two IMU-sensors are used, thus the final product can use MISO (Multiple-Input - Single-output) as shown on the right side, because this gives a more reliable source of data input by having reference points for the sensors.

SISO	MISO
	
Shoulder posture: 1. If. Sensor-2 ≥ 10° roll, after 100 readings. Then. Feedback	2. If. Sensor-2/Sensor-3 ≤ 1 roll, after 100 readings. Then. Feedback *Sensor-3 is the reference point*
Spine posture: 1. If. Sensor-5 ≤ 60° pitch, after 100 readings. Then. Feedback	2. If. Sensor-5/Sensor- 6 ≤ 1 pitch, after 100 reading Then. Feedback *Sensor-6 is the reference point*
Activity detection *(inactivity & neglect)*: 1. If. Sensor-1 < 0,5 m/s, after 100 readings. Then. Feedback	2. If. Sensor-1 < Sensor 4 in acceleration, after 100 readings. Then. Feedback *Sensor-4 is the reference point*

Figure. 35 - data processing

Output

The processing of each reading is set to be approximate 1 reading per. second, meaning 100 readings, equals 1 min and 40 sec. This is just used as an example, in real scenario use, different users would require different intervals and thresholds of the amount of the reading register and time interval, before feedback is given. Registering readings with certain time interval and threshold before giving feedback, would need to be adjustable for each individual user. Because for every week or month a user would have gone through training and would have become stronger. So the feedback needs to adjusts according to a user's progression.

This function needs to be available for the therapist to interact with and adjust, because they are the stakeholders that structure users daily, weekly and monthly plans, and have an intricate understanding of the users training. This adjustment feature is imagined to be done through application.

- Body posture correction for the shoulder and spine, is based on the angular orientation and position. By using two sensors. Feedback is given when a sensor data is below a select threshold compared to the reference point sensor.
- IMU registers all velocity, whether it is small or big, so a threshold is needed to know what movement should be registered as movement and which movement are not, to distinguish between an arm swaying and one actually in motion.
- Using IMU may not be the most efficient measurement for activity level of how much an arm is being used, or at least by itself. The consequences of inactivity can cause stiff ligaments and oedema, stiff ligaments come from a user holding the paretic arm in a locked position and being inactive for a certain time aspect, this may also cause oedema. So, the problem and consequences of inactivity and neglect, is when a user is not using the arm enough which then lead to poor blood circulation. To proper prevent and solve this problem, the data for both activity level and blood pressure measurement are needed. Therefore, an IMU combined with perhaps a blood pressure sensor could provide more useful information to give feedback based on detecting blood circulation to prevent the consequences of inactivity.

Technology Analysis

Technology analysis has the objective to unfold and understand the process of how Bauer manufacture their shoulder pad. Disassembling of the shoulder pad is shown in figure 36, this is done to understand which components it consists and made of. Desktop research is conducted for further information about the company Bauer itself to define the aspects in the analysis better. Also, an interview with a hockey equipment retailer gave the insight of how a hockey shoulder pad is designed to meet the virtue use value for players. The more specific details of technology analysis can be seen in appendix 22.

Bauer has 8 shoulder pad series. All shoulder pad series consist of the five same components: two upper arm parts, two shoulder parts and one vest. Each shoulder pad series belongs in a category that defines its quality. There are three categories of qualities: recreational, performance and elite. Each series has a category for senior, junior and youth, and each of these categories is divided into four sizes (S, M, L, and XL). Each series consists of a different quality and quantity of foam and fabric material used; these two materials of foam and fabric have an impact on how much an ice hockey player is protected, and how well the body heat is evaporated. The analysis will be addressing the shoulder pad vest shown in figure. 36. The west is a size (S) in the recreational category.

Technique:

Producing a shoulder pad requires fabric to be cut out and molding of foam, the fabric is tailored and foam is inserted inside during assembly of the shoulder pad.

The shoulder pad is manufactured in China, and uses only Chinese labor for the whole manufacturing process, from getting an injection mold made, managing injection molding machines, use of Chinese workers for cutting, sewing, and assembly of the final product. The fabric used for the vest is hydrophobic; this fabric allows air to pass through but stops water. The foam is two layers both of (MD)-Foam, the inner layer covers the entire vest, while the second layer part is cut and glued on top of the inner layer.

Knowledge:

Bauer has 91 years of know-how experience and works closely with professional ice hockey athletes to get the know-why insight to create innovative hockey equipment directed towards player needs. This insight is used to choose the specific fabric and foam, as well as how to cut and assembly the shoulder pad ergonomically to maximize protection and preserve the agile movement aspect players need for skating and shooting.

Organization:

Bauer themselves have a horizontal division of labor within the company that develops and innovates on their products. They have a vertical division of labor for the manufacturing and assembly line for the shoulder pad.

The product:

The end result is a shoulder pad, whose components and materials are chosen based of the virtue of their use values for an ice hockey player. The components of the shoulder pad are modular, this makes it easy for Bauer to scale up and down on quality and size, so Bauer can cover multiple user segments within the market.

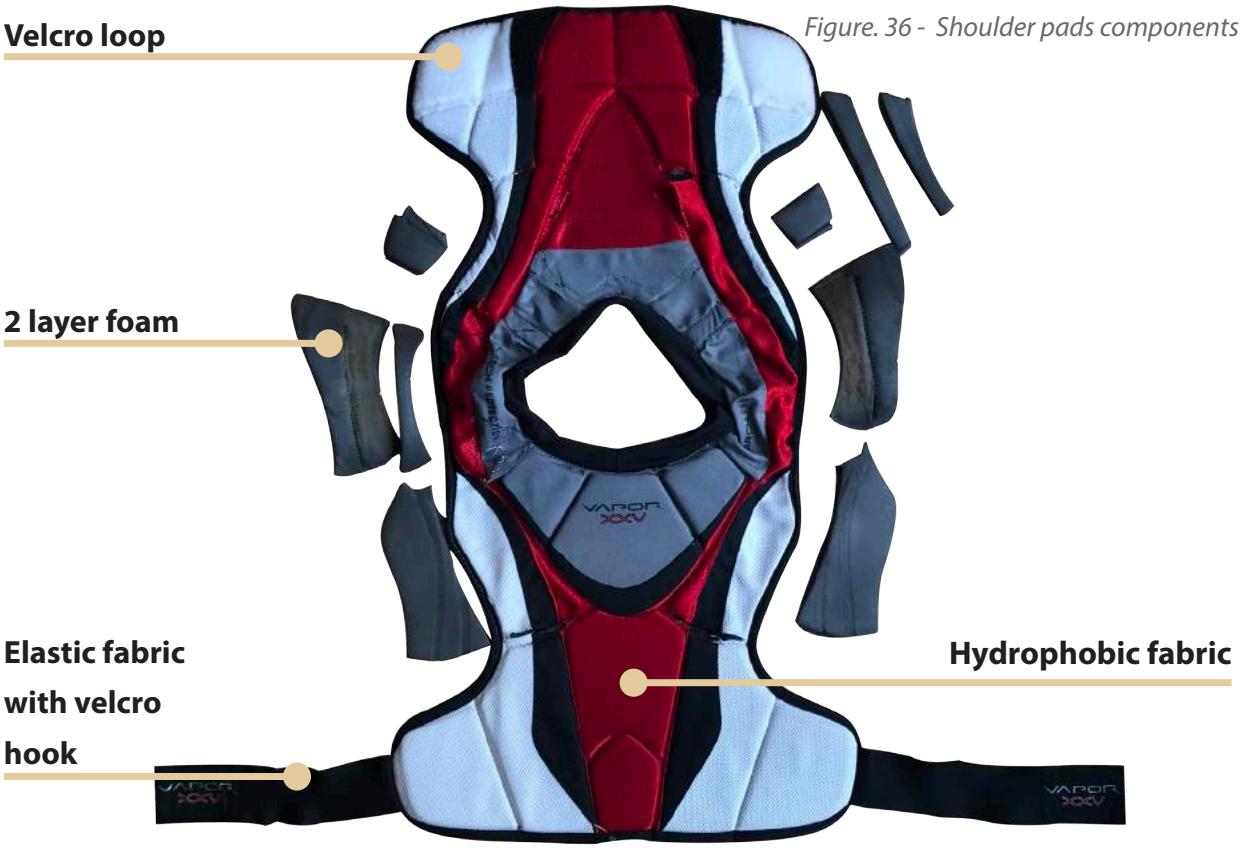


Figure. 36 - Shoulder pads components

Mock-up of redesigned vest

A mock-up is made based on ideation 5 and insight from the technology analysis. The act it out was carried out by wearing both the hockey and mock-up vest to understand the pros and cons of the components, and what is beneficial according to fulfilling the requirements for the product.

- The mock-up has pockets in the front and back to insert cardboard to create some stiffness. This made it easier to slip on, secure and close the vest with velcro scraps. When no cardboard was inserted, the mock-up collapsed upon itself, which made it more difficult to put on.

- The extended upper arm part was easy to secure by closing it with velcro scraps. Using only one hand simulated the act it out as a user with a paretic arm. It was not possible to secure both upper arm parts, thus, the user would still require assistance from a nurse to equip it in the morning.

- The mock-up is more flexible than the hockey vest because it has less material in the back and front. But the hockey vest is easier to put on and is more secure with the foam material. However, the cardboard in front of the mock-up collapsed after a short time because the elastic fabric with Velcro pulled the front backwards with more force than the ability of cardboard to maintain stiff.

Figure. 37 - cardboard inside mock-up

Figure. 38 - Act-it-out with mock-up

Figure. 39 - vest mock-up

Redesign of vest

The design and construct of the vest is a combination (1) IMU-sensor placement, (2) Technology Analysis, (3) Mock-up as previous desribed.

The vest will be addressed in two layers (inner layer and outer layer) and three sections (front, top, and back).

It is considered that the vest will be used independently by a user during the hours before, between and after training sessions, and as an assistive device during the training session. The vest is worn on top of the user's own clothing.

Inner layer: (Figure. 40)
The inner layer consists mainly of hydrophobic fabric and woven elastic. The six sensors is also equipped with a feedback module. They are placed on the top and back sections of the vest according to the scenarios which the sensors need to register and give feedback for. The circuit board is placed on the front, to which all sensors are connected through cables underneath the fabric. The circuit board is placed on the front because wearing the vest throughout a whole day, a user is required to sit and maybe lay down, and if the circuit board was placed in the back, it would press it against the users body.

Outer layer: (Figure. 41 on next page)
The outer layer front section consists of 3 layers of materials. The top section consists of 4 layers of materials. The back section consist between 2-3 layers of materials. This is hard to illustrate in 2D, and will be better illustrated in the product report in a bill of material.

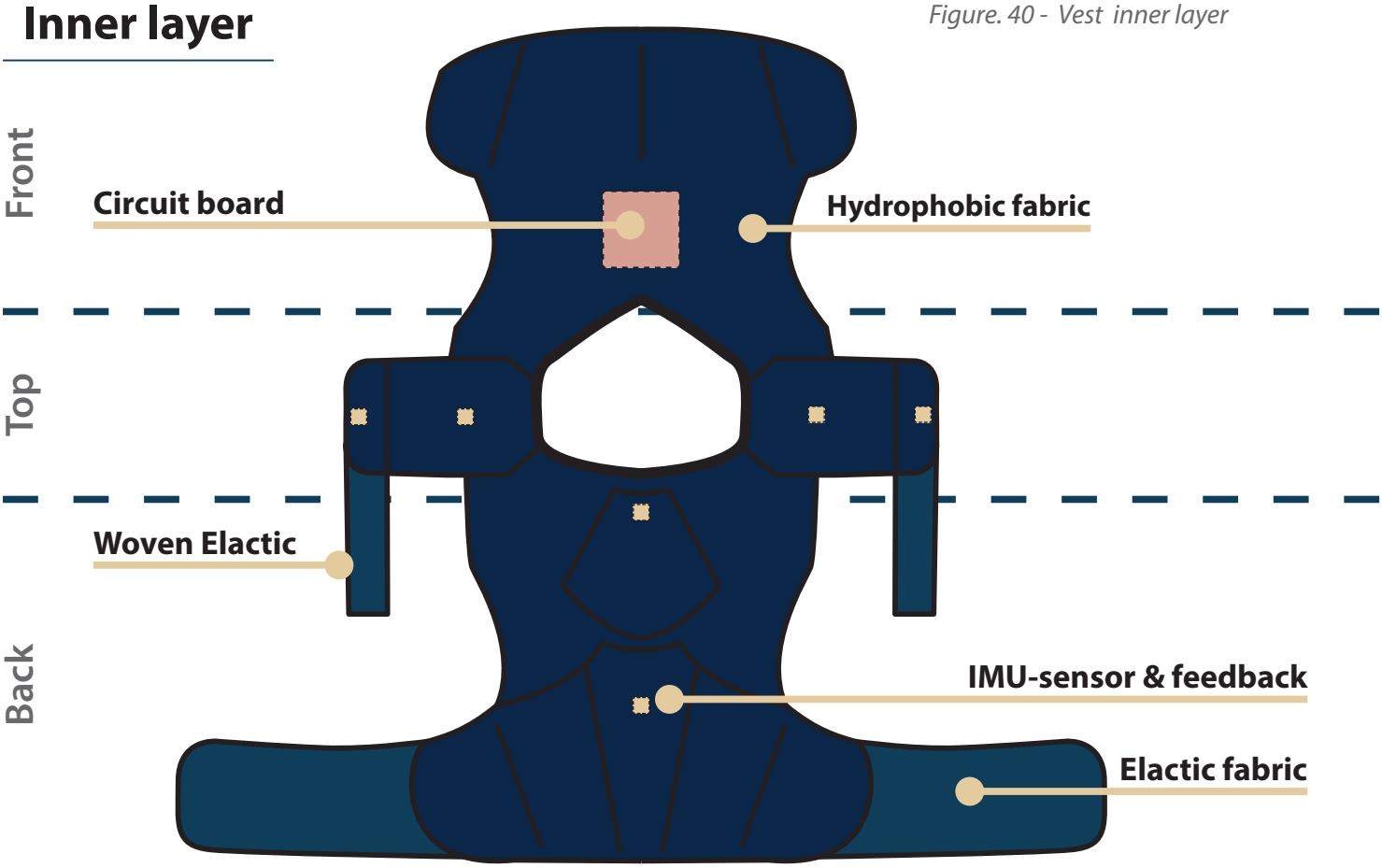
Front:
The first layer on top of the inner layer is MD-foam, the placement and amount of foam used is chosen for keeping vest partially stiff to make it easier to slip on and more secure when worn. Keeping the amount of foam at a minimum allows the vest to be more breathable. On top of the foam another hydrophobic fabric is used to secure the foam, a layer of velcro loop is place on the fabric used for closing the front and back of the vest. Hydrophobic fabric is used to cover the circuit board.

Top:
A layer of hydrophobic fabric is used to cover the sensors, and at the end of the upper arm part a layer of Velcro loop is sewed on of the fabric.

Back:
The back consists of the same foam and fabric layers as the front but does not have a layer of velcro loop. At the end of the woven elastic, velcro hook is sewed on top of the woven elastic to be used for securing the vest in the front section of the best, to give a secured fit onto the body.

Inner layer

Figure. 40 - Vest inner layer



Components:

The whole product consists of 8 components, and some components are used multiple times, this is written as piece/pieces after each component.

Vest: 1 piece
The vest is one whole piece of fabric, made out of hydrophobic fabric, that is cut out in different size (S, M, L, XL).

Woven elastic: 4 pieces
The woven elastic is made from a roll that is several meters, from which the desired length and shape is cut out.

Velcro loop: 2 pieces stanard size / 1 custom piece
The Velcro loop on the top section is a standard size, which comes in a roll that is cut in the desired length. The Velcro loop on the front consists of two-three standard size rolls (depending of the size), the rolls are sewed together before getting sewed onto the vest.

Velcro hook: 4 pieces
All Velcro hooks come in a standard size roll, which is cut in the desired length and shape.

MD-foam: 3 pieces
MD-foam is injection molded, this requires 3 molds for each foam part.

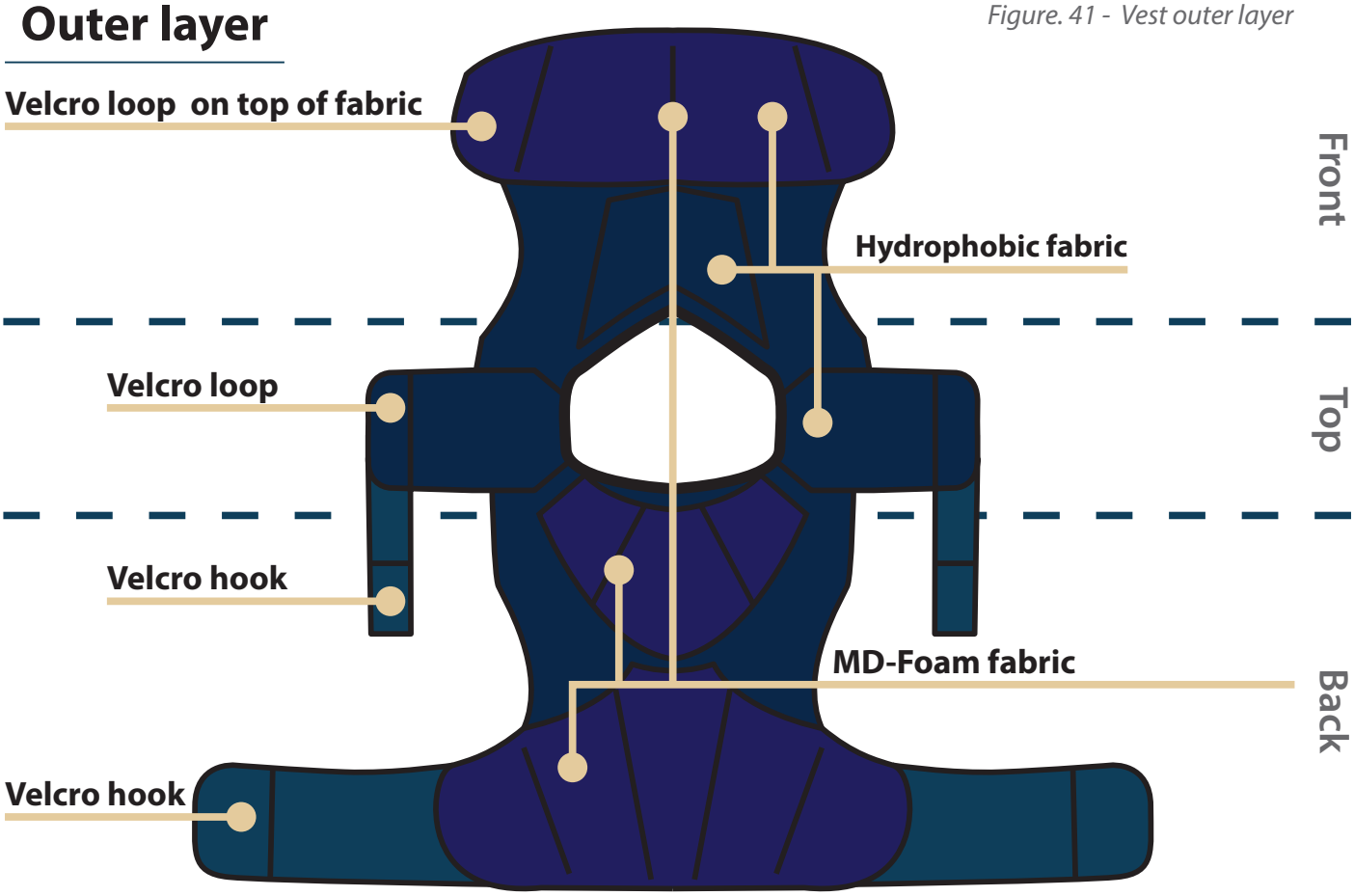
IMU-sensor: 6 pieces
The current IMU-sensor used for prototyping will be replaced with a MTi-7 GNSS/INS module, this module has the same sensor as the IMU and includes a GNSS receiver that has advanced sensor fusion algorithms to motion tracking module.

Feedback module: 6 pieces
The feedback module consists of a sound and vibration unit and is right next to each sensor.

Circuit board:
The circuit board is inside a shell to protect it. The shell is made from ABS plastic because of its relatively low cost material, hard and scratch resistance, excellent stiffness and extreme toughness with good impact resistance. [The material list for the shell can be found in appendix 23]. The circuit board will be using a Bluetooth module for therapists to connect to the device wirelessly through their smartphone. An A9 battery is used to power the electronical components. The final product will be using an Arduino Mega because the 54 connection pins makes it easier to connect all the sensors/feedback module, Bluetooth module and battery.

Outer layer

Figure. 41 - Vest outer layer



Application

On page 39 (Data processing) it is mentioned that therapists would require adjusting features for each scenario. In the previous section of Components under Circuit board, it is mentioned that a Bluetooth module will be connected to it. Hence, it was chosen to create an application, so that therapists can easily connect to the product through their smartphone. This section will describe needed features and the interface of the application.

Features

As the circuit board needs to be programmed, the first solution that fell in mind is to use an application. Based on the data processing, implementation table and interview with therapist and user, the application has the following requirements.

1. First-time use (introduction) for easy setup.
2. Adjustable feedback settings for the three scenarios (shoulder posture, spine posture and activity detection).
3. Diagram feature to display a user progression. That also can help the therapist to determine a users next training goals.
4. An alarm feature to call upon therapist/nurse after a certain time aspect, such as if a user is too inactive right before training sessions, or an error has occurred in the vest.

Output

The application features:

- Easy first-time setup feature
- Choose interval of how many readings for each scenario, before a feedback is given.
- Choose of how the threshold is for a reading to be considered a “incorrect” or “correct” reading in each scenario, before a feedback is given.
- Adjust sound volume and vibration intensity
- Upload daily posture and activity improvement
- Choose to alarm therapist/nurses

Interface

The application interface will mainly be used by therapists, and the application design will have ‘easy interaction’ as its focus to make it intuitive for therapists to navigate in the application and to adjust features.
Most users are above the age of 55, which often means poor eyesight, hence the diagram features should be easily readable for the user, as well.

The application is presented in the product report.

Business model

The business model for the product is created by using the Business Model Canvas, shown on figure. 42. The more thorough Business Model Canvas document can be seen Appendix 27. Data is used from an interview with welfare technology and Troels who is a biomedical engineer and who is also co-founded BalancAir a medtech company, WHO's definition of medical device include for creating the business model. The documents can be seen in appendix 24 – 26.

The product is sold to the government of Denmark and distributed through the regions of Denmark, which will provide the product to each regional rehabilitation center and then it is the therapists' role to evaluate a user fit for using the product. For the government to even consider the product fit for use by patients, it would require three things. Firstly find out if the product is classified as a medical device (Definition 1). If the product is a medical device, it will get a medical product classification within three classes (Definition 2). If it is a medical device then a CE/FDA approval is required (Definition 3). For the government to consider buying the product, the product would need to show results of improving the rehabilitation process, by making therapists' job more efficient, such as being able to treat more people in shorter time, (Example 1). An app can be a medical device if it takes a role in any medical way.

The value propositions are the same as seen in the framing on page 32. The product is most likely going to be more expensive than a regular rehabilitation device, so it needs to provide much greater value to the user, therapist and rehabilitation process, which makes the cost structure of the product value driven.
In relation to the key partners the most important are the manufacturing and assembly of the product, which will be executed by Chinese manufacturers to make it affordable. The key activities are developing the product further to make it ready for launching, such as having the programmer creating the application for service, finding investors, get a CE/FDA approval and branding the product in order to get it out to rehabilitation centers and to a user. The key resources relate mostly to the expenses of running the business and paying the workers, along with paying the rent of office facilities, as well as having a good distribution network.

Figure. 42 - Business model canvas

WHO's definition:

1. Medical device:
'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception
- disinfection of medical devices
- providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Note: Products which may be considered to be medical devices in some jurisdictions but not in others include:

- disinfection substances,
- aids for persons with disabilities,
- devices incorporating animal and/or human tissues,
- devices for.in-vitro fertilization or assisted reproduction technologies

2. Medical product class: There are three medical classes.- the classes represents the potential risk the product present to a user. Products with the 3. class of medical device present the highest risk, so they need more regulation.

3. CE/FDA approval:
CE marking is a certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA).[1] The CE marking is also found on products sold outside the EEA that are manufactured in, or designed to be sold in, the EEA. This makes the CE marking recognizable worldwide even to people who are not familiar with the European Economic Area.
The FDA approval process requires the manufacturer to work with the FDA during human trials of drugs and other devices to ensure trials meet rigorous scientific standards and that human subjects are protected from unnecessary risks. The FDA uses its own statisticians, biologists, chemists, physicians, and other experts to analyze the data from the manufacturer's clinical trials and other research. Based on this analysis, the agency decides whether or not to approve a drug or medical device for a particular use. To get the FDA approval, the medical device or drug must be considered as effective and safe.

Example:

Example 1- A physiotherapist earns on average between 320-390.000 DKK a year (not including pension and statutory sick pay) and spends around 37 hours a week working with the patients. If the therapist spends 2 hours on a patient, then she can handle 18,5 patient a week. If the product can reduce this to 1.5 hours per patient and save half an hour per patient, the therapist would be able to handle 24,6 patients per week, that is 6 patients more a week.

FINALIZING

Process reflection

The process of the project could have been optimized a lot, both in the beginning in the first three weeks and especially afterwards. Starting with the beginning of the project, choosing stroke without any knowledge of which problems specifically should be in the project focus, made it very difficult to do any delimitation, because stroke patients suffer from literally everything. Everything was considered equally important, which is true for rehabilitating stroke patients, and therapists need consider every aspect cognitively and physically, but this not very effective when creating a useable content for the report. In the three first weeks of research conducted to find problems within all five skills, everything was so general and no specific deep understanding was reached, that could be used to define what users' actual problems and needs are.

What is quite silly is the time spent to determine a focus area when, in hindsight, we already in week 5 conducted the interview with HJ, and problems with patients with mobility, motor skills and indirectly paralysis problems were explained from a therapist's point of view. This was in the beginning of the project. And still the first three weeks were spent researching and analyzing to try to choose a focus area that somehow could include all the five skills, but ended with choosing mobility and motor skills because based on HJ's input, this was the only concrete and patient problem that we could relate to.
When all five skills were prioritized equally in the three first weeks of the project, week 5-7, it made a lot of the analysis done irrelevant and actually unusable for the report. So, the first three weeks of the problem were basically spent on analyzing all five skills to understand them and to try to reflect on how a product could be made to impact as many of the five skills as possible, and this process just gave very abstract ideas, only the mobility and motor skills ideas from ideation 1 were a little useable, became real user problems was introduced to us by HJ, which just led to quite a lot of time being wasted.

To prioritize the tasks could have been done a lot better in the beginning, but was held back because of the too broad focus of considering all five skills. Reading about [Forløbsprogram for rehabilitering af voksne med erhvervet hjerneskade,] the document that describes every detail of stroke rehabilitation process in Denmark, was not conducted until week 8... this information was needed to understand how the rehabilitation process functioned within the four stages of stroke, and how stroke patients are rehabilitated concerning their cognitive and physical disabilities during hospitalization. The stroke rehabilitation document was actually introduced on the 12th of January by Tine, section chief nurse at Neurological stroke section, Aalborg Universitetshospital, but was first prioritized to be read after 3 weeks, which were spent analyzing, ideating and defining general patient problems within all five skills.

On the first page of appendix a list of all worksheets is shown. The first three weeks of the project may had felt like going in circles, but the worksheets that were accomplished during this period was done very well and thorough, which cannot be said to the rest of the worksheets from week 9 and afterwards. Worksheets got postponed a lot, were not proper evaluated upon and not fully finished, this meant that a lot of the interviews were poorly documented and were only translated in few quotes and not structured. When the worksheets were so poorly made, it became a very a difficult task later on when inserting documents into the report, because everything needed to be rewritten.

Visiting Brønderslev rehabilitation center for user observation and interviewing with physiotherapist CW was not arranged until week 10, so six weeks after the project had begun, which was very late in the project to see concrete cases about rehabilitating users through ADL and training sessions in stage 2.
The incorrect Interpretation of how to solve compensating movement by restricting it, also did not help the project course of direction, this wrong interpretation of a need caused many of the first requirements on page 19 or in appendix 15 to become incorrectly used for ideations for the project, which a lot of ideas, the mock-up from ideation 3, 4 and the American football/ice hockey shoulder pads investigation focused on solving.
First after talking to the experts (Simon and John) and therapists during the second visit at the rehabilitation center, it was realized that this need was wrongly interpreted, and this was at a very late point in the project... This is what the illustrated figure on page 7 shows with the use of design thinking process.
Daily life during rehabilitation on page 11 gives a comprehensive understanding of how a day is structured in the rehabilitation process for a user and the relationship between therapist, nurse and a user. This information was first conducted in interview 3, on the 30th of April, hence, a very important fact of understanding users' daily life during the rehabilitation process was first asked about specifically in an interview after three months had passed since the project began.

Group disunity:
The worksheets mentioned above made in week 9 and forward were very difficult to manage and put into the report, which at the time was Andrea's responsibility, as the group then consisted of two persons. There were many factors which led to the group disunity, which was not anyone's fault. The project had an overall good plan in the beginning when it was established together, but

as the project progressed, a project manager was chosen for different aspects of the project and task, such as who would be taking care of the report, weekly schedule and planning in general. It is unknown when complications specifically occurred, but it can be assumed that Andrea and I had different approaches when it comes to being project manager, which may have led to a lot of disagreements, such as worksheets not being properly done, how to be prioritize tasks and workload. I may have taken too much charge by thinking too much ahead, which may have led the project to become a little by little too one-sided.

Product development:
After the group disunity, I visited Brønderslev rehabilitation center two times more afterwards, once for the interview with therapists and then a fourth time to meet privately with Henning, and then I visited Hobro rehabilitation center, to ask more specific questions and to get concrete information, which is shown on page 27 and used for the frame chapter.

As mentioned above almost every worksheet made needed to be rewritten, so much time was spent both on making sense of and rewriting the old worksheets, but also on carrying out new tasks and making the new tasks and collecting new information after group disunity. Short time was spent on detailing the product, and working alone came with challenges, from choosing some specific element of specifications for the product development shown on page 35, mainly posture correction, IMU-sensor and redesigning the ice hockey vest, and evaluating ideas was very biased. But everything has its pros and cons, by having established these chosen specifications and requirements, the WHAT + HOW just needed to be specified to reach the aspired values, so the product development process became a lot more dynamic, as the tasks became concrete and could be initiated quickly. Now, after the solution is done, deduction can be used to evaluate upon how well the product solution is either partly or entirely meeting each requirement [Dorst, K. 2011].

Some details did not get the attended attention during the product development, because it was thought to be more ideal to ensure that the functional aspect of sensor and feedback works.What the solution did not address, which could improve the product were as follows: Specific user interaction investigation, including posture brace to physical help stimulating protracted shoulder position, aesthetics investigation, another solution for the inactivity problem that prevents or detects oedema before it occurs, motion tracking when performing the transport phase during training, battery life and price estimation of the product.

Product reflection

There is a range of elements, which was not directly addressed, that could be valuable to address for improving the current product proposition.
The solution solves a lot of problems for the users, but it may also cause as many complications, the feedback that a user receives to correct their posture could, e.g., confuse them even more. , The interview feedback from physiotherapist JW and JH during the first visit at Hobro rehabilitation center was that it seemed sensible that the user would able to use the product and feedback, if they are able to communicate with the patient and the patient can understand what they say.

Feedback in form of vibration was expressed to be a good choice to gain better sensibility in the paretic arm, and sound would help user conquer or decrease their neglect, but the sound feedback does have a downside when it comes to shoulder posture correction: how should the sound feedback be given to indicate when the arm was raised too high and when too low. Another thing is how often should feedback be given, in data processing "readings" was used as a unit for the therapist to adjust, but how precise would the feedback work within all of the scenarios, when using IMU-sensors or MTi-7 GNSS/INS module. This would require time to test it together with therapists to be able to determine how efficient it is to use motion tracking sensors.

The placement and numbers of sensors used for current solution may not be the most optimal, either because the conducted task was executed quickly without proper testing, but it rather works as a starting point to place the sensor where it seemed to make most sense, and then it was thought a little more through how many sensors would be required for each scenario to get proper data input needed for most efficient or reliable output to be given.

Is using motion tracking sensor technology the best choice? Hard to say with a biased opinion. As the current product proposition is right now, I think it would partly work, though other sensors would be needed and required to fully accomplish the solution. The IMU-sensor is not ideal for preventing oedema and inactivity for more severely paralyzed patients, but it does not make sense to give feedback to remind them to activate their paretic arm, when they cannot. Preventing or detecting blood pressure for example could, combined with motion tracking, give more valuable and reliable data for not just the patient but could also inform the therapist through the smartphone application to alert them before oedema occurs in the patient's paretic arm.
Aesthetics wise, nothing really has been done. It may have a sporty look and feel to it, and by using the functionality and material properties of an ice hockey protection, it is given a training vibe in my biased opinion.
But an aesthetics investigation would definitely be able to improve upon the solution's aesthetic design and form expression.
Bluetooth is chosen to connect with the vest to program it. It does not make sense to make a separate device to program the vest as most people today own and carry a smartphone on them.
Sadly, not enough time was spent on 3D modelling the solution, also, I did lack the proper 3D capabilities to construct the product solution, I gave it a try and only partly made the solution, which can be seen in a bill of materials (BOM) and a vest without the extended fabric down to the upper arm. This is presented in the product report.

Further development of the product proposition could be: improving the motion-tracking for arm movement during training sessions such as counting every correct repetition and include counting incorrect repetitions, because every user needs to start from somewhere: The rehabilitation training is an individual progressive process of development, so every kind of movement should be counted. Therefore, data from "every" paralyzed user would be fit to use during training sessions, this could provide a beneficial service for therapists when training patients to more accurately know how many repetitions a day every patient in the arm training have executed.

Battery life is currently unknown and may not be a problem because the programming of the Arduino board only needs to connect to a smartphone through Bluetooth once every week or month to change settings, and once a day to upload the daily monitored (posture and activity) training status. Consequently, battery life and consumption were not considered important to focus on for the current solution.
Pricing is also not calculated, a calculation could be estimated for the exam, with the detailing of knowing the material of every component and the manufacturing process the current product proposition consists of.

Technical drawing was not made, it was discussed with main supervisor Thomas that this was not the most crucial aspect of the product proposition, that was needed to be made.

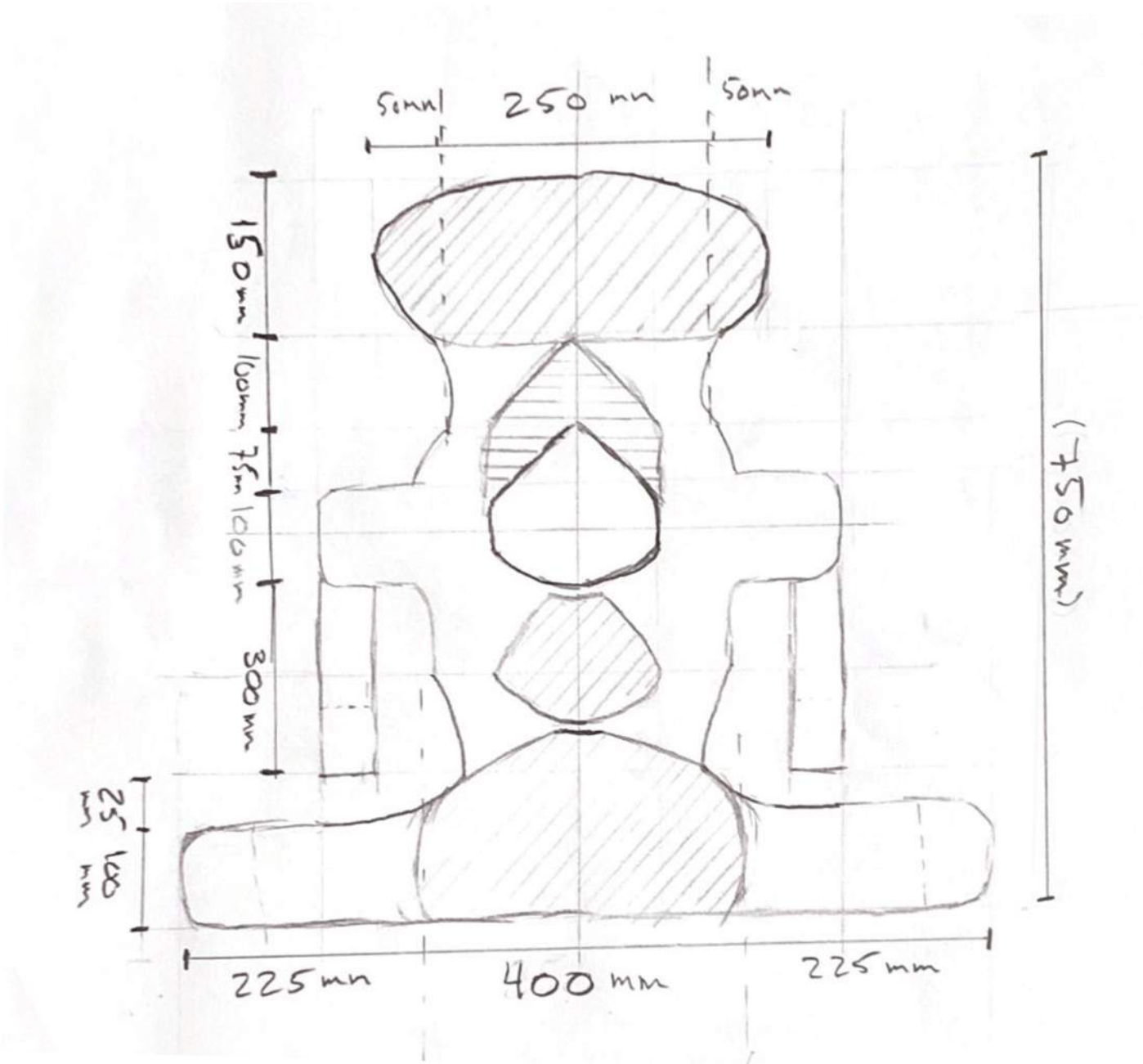


Figure. 43 - Sketch of vest with dimensions

Requirement evaluation

Requirements achieved:

3: The requirement to inform users about their body posture is achieved. However, it may be considered more as partly achieved because of the missing investigation of how to distinguish between the sound feedback of whether the shoulder r position is too high or too low. informing the shoulder posture requires some finer details of how to make the feedback understandable

4: To counter a user's neglect is quite straight forward. Neglect is a condition that makes the user "ignore" or "forget" that the paretic side exists. By watching a few videos of neurological doctors and talking with therapists about neglect, they explain that to regain awareness of the paretic side, continuously reminding and cognitive training helps a user regain more awareness of the paretic side.

6: The choice to redesign an ice hockey vest was a good choice to keep the wear a lightweight and breathable equipment to be worn. Removing a lot of the original quantity of foam used for the ice hockey vest would make it feel more like wearing normal clothing.

9. Helping user to be more aware of their own body would be considered as successful in giving users more independence, even though the solution only partly solves some of the requirements of feedback.

10. By wearing the vest users are more independent without a need for the presence of a therapist. Hereby, the users are given certain amount of responsibility that enables them to act in taking care of their own health.

Requirements partly achieved:

1: Making the product as a vest to be worn makes it very easy for therapists and nurses to slip onto a user. But, when performing the act-it-out of the mock-up vest with using a "partial" paretic arm, it was not possible to close the normal arms upper-arm fabric part with the Velcro.

5: The solution is only seen to be partly fulfilling the portability perspective. The reason is not the vest, but rather battery life and power consumption of the device. It is not calculated whether the device would last throughout a whole day, only assumed.

7: Making an application would make the solution able to register the posture data and display it. But it is only partly achieved because the registering of movement activity with motion tracking (IMU) or the MTi-7 GNSS/INS module may still be too inaccurate.

8: Motivating users to use the paretic arm more would be achieved by some users. It all depends on the user's paralysis, a less paralyzed user may be motivated and is able to engage in ADL, but for others with more difficulties it would only help to give them more awareness. (This requirement could be evaluated to be both achieved and partly achieved)

13: This requirement was made from interviewing Henning as one of his fears was falling and getting hurt. It is set to be partly achieved, because by using two motion sensors it could be programmed to register if a use is in a flat/laying position, and then inform nurses through the application.

14: Stimulating the paretic side to increase sensibility is partly achieved because the vibration needs to be quite strong and may require to touch the user's skin for best sensible stimulation. As it is now, it would be worn on top of a user's daily clothes.

15. The solution could prove to be an assistance during training as it is registering and informing about spine posture, but it is set to be partly achieved, because the value would increase if the solution could register every arm motion movement and provide a repetition counter, so therapists with better certainty can know how many repetitions users are actually performing.

Requirements not fulfilled:

2: Activation of paretic arm for circulating blood-flow is seen as not achieved. When reevaluating the prevention of oedema that occurs from inactivity or neglect by not using the paretic arm, the detecting of the activity level to prevent oedema would not be useful by reminding them only. It needs to be considered what if a user has difficulties activating the arm, then that specific user would not be considered as a fit user to use the product. But he could be a user with another method, because the problem with oedema is poor blood-flow circulation, which could be detected better with a blood pressure sensor, and together with a motion tracking sensor could provide a proper registration of inactivity and prevent oedema before it happens. (just an idea). But for this reason, this is seen as not fulfilled.

11 and **12:** was not focused on.

Requirements

Needs - Quantitative

1. The solution should be easy to equip onto the user by the therapist, nursing staff or the user themselves
2. The solution should remind the user to activate his arm, for circulating the blood-flow in the paretic arm
3. The solution must inform user about their body posture status whilst sitting
4. The solution should inform the user by giving feedback to draw their attention towards their paretic side in ordre to counter their neglect
5. The solution must be portable, so the user can bring it with them when moving around the rehabilitation center
6. The solution must be lightweight and of breathable material, if it is to be worn a whole day
7. The solution should monitor posture and movement activity level of the paretic limb, to show the process

Needs - Qualitative

8. The solution should motivate the patient to engage in more use of the paretic arm in daily activities
9. The solution should give the user a feeling of being more independent, by using the solution without therapists present
10. The solution should give the user a feeling of having more responsibility for their own health

Wishes - Quantitative

11. The solution must inform the user about their body posture status whilst walking
12. The solution must inform the user whether correct movement patterns are performed during training session exercises
13. The solution should inform nursing staff if the user falls
14. The solution should physically stimulate the paralysed side to increase sensibility
15. The solution should assist the therapist during training session with the user

Evaluated status

1. Partly achieved
2. Not fulfilled
3. Achieved
4. Achived
5. Partly achieved
6. Achived
7. Partly achieved
8. Partly achieved
9. Achived
10. Achived
11. Not fulfilled
12. Not fulfilled
13. Partly achieved
14. Partly achieved
15. Partly achieved

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Illustration list

Figure. 1 - 2 : own illustration

Figure. 3 :
https://www.pexels.com/photo/man-hands-waiting-senior-33786/
https://www.pexels.com/photo/two-person-pushing-yellow-wall-233227/
https://www.pexels.com/photo/administration-agreement-banking-blur-618158/
https://senior.com/wp-content/uploads/2016/04/Senior-Flower-764x352.jpg

Figure. 4 : https://www.pexels.com/photo/action-adult-affection-eldery-339620/

Figure. 5 : own illustration

Figure. 6 :
https://www.physioroom.com/product/Neo_G_Shoulder_Support/3069/40725.html
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Figure. 7 - 23 : own illustration

Figure. 24 : https://newatlas.com/axo-suit-exoskeleton-seniors/39852/

Figure. 25 -27 : own illustration

Figure. 28 :
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https://pixabay.com/da/%C3%A6ldste-midtergang-l%C3%A6ge-1461424/

Figure. 29 :
https://www.pexels.com/photo/person-holding-medical-walker-beside-white-hospital-bed-886464/

Figure. 30 - 43 : own illustration


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