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Towards a User Friendly Home Training System for Neuromuscular Rehabilitation

Master's thesis in Industrial Design Engineering and Product Development

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Abstract

Phantom limb pain has long been a difficult affection to treat due to insufficient knowledge of its cause. In collaboration with Chalmers University of Technology and the Sahlgrenska University Hospital, Integrum AB have, as a world leading company in osseointegrated prosthetics, developed a method for neuromuscular rehabilitation of the phantom pain. Via EMG signals acquired from the residual limb, the user controls a virtual representation of the lost limb in an augmented reality environment. This gives the user visual feedback of the performed movements.

The objective of this master thesis was to make an existing system for phantom limb pain treatment available to more users, and the goal was to deliver a prototype which supports the transition from neuromuscular rehabilitation in a clinical setting to training in the user's home. Through literature studies, interviews and observations, data needed to establish user needs and a target specification was gathered. Partial solutions were generated for the functions of the product, combined and refined to create a final concept.

The final concept is a product system consisting of an electrode band, as well as a controller box compatible both with the band and with single use electrodes. The electrode band facilitates the placement of electrodes on the residual limb, and allows the user to keep them in the same position for every training session. Because of variations in the anatomy of the residual limb, the pattern of electrodes in the band can be customised for optimal signal reading. The band also allows for a certain range of size adjustment, and is easy to handle with only one hand. For improved signal acquisition, point pressure is applied over the electrodes.

The controller box houses the electronics for processing the EMG signals, and can be attached on the electrode band to reduce disturbances in the signals.

Sammanfattning

Eftersom orsaken bakom fantomsmärtor länge har varit okänd har det varit ett bekymmer att bota dem. Tillsammans med Chalmers tekniska högskola och Sahlgrenska universitetssjukhuset har Integrum, ett världsledande företag inom osseointegrerade proteser, utvecklat en metod för neuromuskulär behandling av fantomsmärta. Med hjälp av EMG-signaler från återstående muskelvävnad kan brukaren styra en virtuell avbild av den förlorade kroppsdelen i en augmented reality-miljö. Detta ger brukaren visuell feedback for de utförda rörelserna.

Syftet med detta examensarbete var att göra ett existerande system för behandling av fantomsmärtor tillgängligt för fler brukare, och målet var att leverera en prototyp som stöder övergången från neuromuskulär rehabilitering på klinik till hemmaträning. Genom litteraturstudier, intervjuer och observationer samlades relevant data för identifiering av brukarkrav och fastställande av produktkrav. Dellösningar togs fram för produktens funktioner, kombinerades och förfinades för att generera ett slutkoncept.

Slutkonceptet för produkten är ett system bestående av elektrodband och en controllerlåda, som kan användas antingen med elektrodbandet eller med engångselektroder. Elektrodbandet gör det lättare att placera ut elektroderna på stumpen, och hjälper användaren sätta elektroderna i samma position vid varje träningstillfälle. Eftersom stumpens anatomi skiljer sig åt hos olika användare kan mönstret av elektroder i bandet individanpassas för optimal signalmätning. Bandet kan också storleksjusteras, och är lätt att hantera med en hand. För förbättrad signalmätning har ett punkttryck lagts över varje elektrod.

Controllerlådan innehåller elektroniken som behövs för behandling av EMG-signalerna, och kan fästas på elektrodbandet för att minska störningar i signalerna.

Acknowledgements

This project would not have been possible without the help and support from so many people, and we wish to thank you all.

First of all we want to thank Integrum, especially the Neuromotus team and Max Ortiz Catalán for an exciting thesis project and supervision. We also wish to thank Kerstin and Peter at Armprotescentrum and Ortopedtekniskt centrum for sharing your knowledge about everything regarding amputation and rehabilitation, as well as Antal Boldizar, Siw Eriksson, Örjan Berlin and Leif Sandsjö for expertise and support. Our warmest thanks also go to our supervisor and examiner at Chalmers, Eva Simonsen and Pontus Wallgren.

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Table of content

01 Foreword

1.1 Introduction

This thesis is centred around a system named Neuromotus which is under development at Integrum AB in cooperation with Chalmers University of Technology and the Sahlgrenska University Hospital. Neuromotus is made for neuromuscular rehabilitation of phantom limb pain, and resembles conventional mirror treatment. With the help of EMG signals acquired at the surface of the residual limb, the user can control a virtual representation of the lost limb in the computer.

1.1.1 Integrum AB

Integrum (Figure 1) was founded in 1998 to help amputees towards an improved quality of life. The company is based in Mölndal in Sweden, and is world leading in osseointegrated (bone anchored) prostheses and carry out continuous research and development in the field.

Figure 1. Integrum AB:s logo.

1.1.2 The project Neuromotus

The signal recognition technology (BioPatRec) used in the Neuromotus (Figure 2) system was developed as part of a master thesis at Chalmers University of Technology on signal acquisition and pattern recognition for robotic prostheses in 2009. The project was carried out by Max Ortiz Catalán at the Biomedical Engineering Divisions of the Department of Signals and Systems. In 2012, Ortiz Catalán started research on phantom limb pain and started investigating the possibilities to apply the technology to phantom limb pain treatment in combination with augmented reality and gaming. The first results were published in 2014, after a patent had been filed. At present, a project group at Integrum,

Figure 2. The logo of Neuromotus.

Chalmers University of Technology and the Sahlgrenska University Hospital are working on further development of the technology.

1.1.3 Objective

The objective of the project is to make an existing system for phantom limb pain treatment available for more users by allowing a transition from sessions in a clinical setting to home training.

1.1.4 Goal

The goal is to systematically develop a user friendly and manufacturable prototype used in a system for neuromuscular rehabilitation of phantom limb pain that can be used at home. The product will be developed with focus on easy and effective handling and placement of EMG electrodes.

1.1.5 Delimitations

No direct changes are made to the computer software or to the electronic design, and design changes affecting the housing of the electronics have only been made after consultation with Integrum. While aiming to keep the costs for manufacturing and distribution at a minimum, no elaborate cost calculations will be made.

The product design will be detailed enough to produce a prototype. Detailed solutions for industrial manufacturing will not be presented.

1.2 Framework

This section presents the scope and delimitations of the thesis in terms of the product, intended user group and market.

1.2.1 Product system

This thesis work is focused around presenting the existing technology of a neuromuscular rehabilitation system in a functioning product that will allow for the training to take place in the user's home instead of in a clinical setting.

1.2.2 Intended user group

A future objective is to adapt the technology to also be usable for lower limb amputees. In this project, the development is focused around unilateral upper limb amputees. The user of the developed concept is assumed to have enough technological knowledge to handle a computer.

1.2.3 Market

The device is still in a prototype phase and under clinical study. Within Sweden, the technology is assumed to be distributed, in the initial phase, via occupational therapists at clinics and rehabilitation centres. For the first edition, the product is assumed to be produced in 10-50 units.

In the future, the goal is to present the technology to an international user group and distribute it via medical centres and possibly over the internet.

1.2.4 Technical solutions

The sensors used for EMG signal acquisition are electrodes placed on the skin. When developing concepts, Integrum were consulted for possibilities and restrictions in the software and electronic design.

1.3 Report disposition

The report starts with the section Background, which is an introduction to how this project has come to being. This is followed by Theory, for basic understanding of the factors affecting the technical requirements of the product. The next section, called Methodology, describes what methods have been used and how the project has been carried out. The Results chapter that follows contains the findings from observations, interviews and surveys about the current system. These results lay the foundation for needs and requirements elicited and presented in the chapter Analysis. In the Concept development chapter, the results of the analyses are used to develop different concepts, from which features are selected, refined and combined into one concept under Concept refinement. The final result of the process is presented and evaluated in the chapter Final concept. The report ends with chapters for Discussion and Conclusion.

02 THEORY

The purpose of this chapter is to present the reader with relevant theory about the cause and treatment of phantom limb pain, along with what anatomical changes can be expected after an amputation. Principles of electromyography are also described. The theories presented in this chapter have been gathered through literature studies as well as interviews with experts in relevant fields.

2.1 Phantom Limb Pain

Pain is usually defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (IASP, 2012). Phantom limb pain, however, is a kind of pain experienced in a missing limb as a result from amputation. A difference is made between phantom limb sensation, phantom limb pain and stump pain (Nikolajsen and Jensen, 2000).

Phantom limb sensation is described as a non-painful sensation referred to the missing limb, while stump pain is pain localised to the residual limb. (Nikolajsen and Jensen, 2000) Up to 80% of amputees experience phantom limb pain after amputation (Nikolajsen and Jensen, 2000) (Flor, 2002), which is severe in five to ten per cent of patients (Nikolajsen and Jensen, 2000). According to Flor (2002), it seems like a patient is more likely to experience phantom limb pain if the pain was chronic before the amputation, while it is less likely for phantom limb pain to occur if the amputation was done at a young age. Phantom limb pain is most common after amputation of an arm or a leg, but can also occur after removal of other body parts.

Phantom limb pain is usually intermittent and commonly more intense in distal parts (further away from the centre of the body or point of attachment) of the phantom (Nikolajsen and Jensen, 2000). The pain is often experienced as stabbing, throbbing, burning or cramping. (Flor, 2002) Many patients experience a phaenomenon referred to as "telescoping", where the phantom gradually retracts towards the residual

limb, and progressively loses detail in its distal end. (Sherman, et al. 1997) Patients with phantom limb pain can also feel sensations referred to the phantom when skin areas elsewhere on the body are stimulated. (Flor, 2002)

2.1.1 Cause

One result of an amputation is the formation of sprouting growths of nerve tissue called neuromas. One potential source for phantom limb pain is increased sensitivity of pain receptors in the peripheral nervous system due to the neuroma formation. (Nikolajsen and Jensen, 2000) The increased sensitivity also leads to permanent changes in the synaptic structure of the dorsal horn of the spinal cord (Flor, 2002).

Another theory is that the mapping of the cerebral cortex is commonly distorted in amputees - a phaenomenon known as cortical reorganisation. This means that the area of the cortex that used to receive input from the lost limb reorganises, and instead receives input from neighbouring regions. According to Flor and Diers (2009), these reorganisational changes have only been found in amputees who experience phantom limb pain. (Flor and Diers, 2009)

2.1.2 Treatment methods

Figure 3. Person using mirror at home for mirror training.

Treatment methods for phantom limb pain include pharmacological, surgical, anaesthetic and psychological methods, as well as alternative treatments such as acupuncture, physiotherapy and prosthesis training (Flor, 2002). Most of these methods have turned out to be ineffective, potentially because they do not take the true cause of the pain into account (Flor, 2002).

On the other hand, neuromuscular treatment methods - such as the use of prosthetic devices - have been found to reduce both phantom limb pain and reorganisational changes in the cerebral cortex. (Flor and Diers, 2009)

By viewing the intact limb in a mirror (Figure 3) to provide the amputee with the impression of using the amputated limb, so called mirror treatment, phantom limb pain can be reduced and phantom movement improved. Mirror treatment might also reverse reorganisational changes in the cortex. (Flor and Diers, 2009) Mirror treatment is done by placing the residual limb in a mirror box, which reflects

the intact arm. As the arm in front of the mirror performs a series of movements, an illusion of an intact limb is created on the opposing side. (Hommer, McCallin and Goff , 2014) The reversion of the cortical changes is connected to behaviourally relevant stimulation of the brain, so that the representation zone of the lost body part in the motor cortex can expand. (Flor, 2002)

2.1.3 Neuromuscular rehabilitation with Neuromotus

Neuromotus is a neuromuscular rehabilitation system developed to treat phantom limb pain. It was originally inspired by mirror treatment, but designed to overcome the need for a remaining limb. The system also allows for appropriate visual feedback and engaging rehabilitation tasks, which lacks in conventional mirror treatment, and is beneficial for the constant engagement of motor execution for reversion of cortical reorganisation.

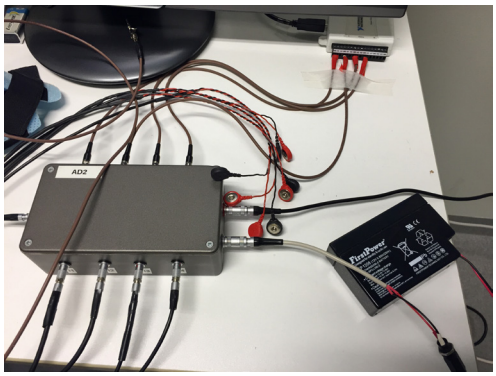

Figure 4. The different parts of Neuromotus today.

The system currently consists of four major parts: two hardware devices, EMG electrodes, a computer software and a fiducial marker (Figure 4). The system lets the user connect to the computer via the EMG electrodes, and once the system is calibrated different exercises can be performed.

EMG signals are acquired from the skin surface using single use adhesive electrodes on sites where muscle contraction has been detected. At least four electrode pairs are used for signal acquisition, and yet another electrode is used for common electrical ground for all the electrode pairs. The electrodes are usually placed as distally as possible where muscle movement is detected when performing a series of movements. The movements used to find the correct position for the electrodes are opening and closing of the hand, pronation (Figure 5) and supination (Figure 6) of the wrist, flexion (Figure 7) and extension (Figure 8) of the wrist, and flexion and extension of the elbow. An electrode for ground is placed over a bony prominence. The hardware devices amplify and process the signals, and send them on to the computer.

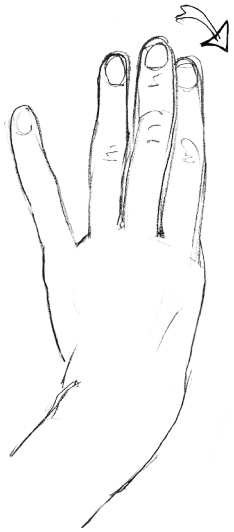

Figure 5. Wrist pronation.

Before the training starts, the user is asked to fill in a questionnaire (Guðmundsdóttir, 2014) to track the progress of the treatment. A reference recording is made of the EMG signal patterns for each movement that was performed for finding the position for the electrodes. This is done to

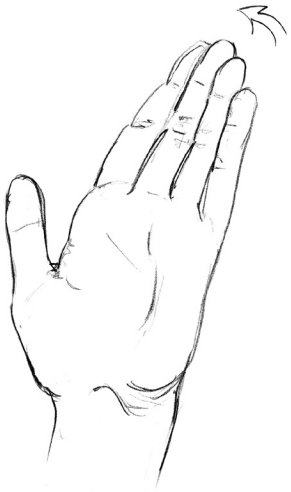

Figure 6. Wrist supination.

Figure 7. Wrist flexion.

Figure 8. Wrist extension.

inform the system which signal pattern is connected to what movement. The EMG signals help the user to perform different exercises with a visual representation of the phantom limb. This representation is used in an exercise called the Target Achievement Control test (TAC-test), to copy the movements of a dummy hand.

Another exercise uses augmented reality (AR) to project an image of the missing limb onto the picture of the user captured by a webcam. In the AR-environment, a conventional webcam captures the image of the environment surrounding the user and integrates it with the image of the lost limb. The projection is kept in the right position with the help of a fiducial marker that is placed on the residual limb. The fiducial marker is a (74 mm x 74 mm) picture with a simple shape and high contrasts. With the help of the marker, the computer can locate the position of the limb and track its movements. This allows the user to see themself with a visual representation of the lost limb.

The training session is commonly concluded by playing a car racing game where the user accelerates, brakes and steers the vehicle with help of the muscles connected to the phantom limb.

2.2 Armprotescentrum

The Rehabilitation Centre for Upper Limb Prosthetics (Armprotescentrum), is a national Swedish centre of knowledge and resources where both children and adults may get help and support if they have dysmelia (congenital absence of a body part) or if they have been amputated (Armprotescentrum, 2015). Armprotescentrum offers rehabilitation training and consultation meetings, and provides custom made prosthetics for both arm, fingers and legs in collaboration with the Orthopaedic Technology Centre (Ortopedtekniskt centrum). When a person is amputated, they are to be referred to Armprotescentrum for help, support and service.

Armprotescentrum is located in Gothenburg, while similar centres also exist in Örebro and Stockholm. Worldwide, comparable rehabilitation centres can be found in several countries, for example England, Italy, Holland, Belgium, Spain, Chile, Canada and USA (Caine-Winterberger, K., 2015 pers. comm 2015-03-31).

2.3 Electromyography

Electromyography (EMG) is a technology which uses electrodes to detect signals from muscular movement (Konrad, 2005). A muscle contracts or generates tension when it is properly stimulated. The signals originate in the motor cortex of the brain and are transported to the muscle fibres, or actuators, via nerves. The union of a muscle fibre and a nerve fibre are collectively called a motor unit. (Tortora and Derrickson, 2010)

The electrodes are placed in pairs over each muscle, and the voltage is measured as the difference in voltage between the two electrodes. In order to get a correct signal, an electrode for electrical ground is also used as a reference signal. The ground electrode is not placed over the muscles like the rest of the electrodes, but on the skin over a bony area or an area where a zero signal is obtained (Ortiz-Catalan, M., 2015, pers. comm., 2015-01-27). The measurement method relevant for this thesis is surface EMG, which means that skin mounted electrodes are used for acquiring the signals from the skin surface, rather than needle electrodes which pick up the signal from inside the muscle.

A strong, noise-free signal is essential for a good reading. The signal from the motor unit, is only a few millivolts on the skin surface (Konrad, 2005) which means that small perturbations have large effects on the signal readings. One factor that can affect the signal is the occurrence of scar tissue, which often has bad conductivity. Other factors are the contact between the skin and the electrodes, the size and shape of the electrode, the size of the motor unit's territory and location of the electrode in relation to the muscle innervation zone (Farina, Merletti and Enoka, 2004). To get a good signal, the skin should be as clean as possible, preferably without hair. Often the skin is cleaned with alcohol to get rid of dead skin and dirt. Even smooth sandpaper can be used for better signal acquisition. Conductive electrode gel can be applied under the electrodes to improve the connection. The latter efforts are serious practical drawbacks.

The size of the electrodes is of importance for the signal reading. An electrode with a small area of detection will give each motor unit a unique distance to the electrode. The small area will, however, be problematic when the skin is moving

- for example when the muscles in the limb contract. On the other hand, if the electrode has a large area, the distance from the detection area to each motor unit becomes less unique, which will make the signals more difficult to separate from each other. (Stashuk, Farina, Søgaard, 2004)

One factor that may or may not influence the quality of the signal reading is application of point pressure over the electrodes. This is thought to bring the electrode closer to the signal source by pushing skin, fat and scar tissue aside (Ortiz-Catalan, M., 2015 pers. comm., 2015-01-27) or it may simply help to ensure contact between the electrode and the rough skin surface that results from the production of scar tissue (cicatrisation) (Eriksson S., 2015 pers. comm. 2015-02-17). It is not certain that application of point pressure itself will improve the signal acquisition. On the other hand, the pressure will promote the production of heat and sweat - where the latter is an excellent electrolyte. (Sandsjö, L., 2015 pers. comm. 2015-02-16)

2.4 Anatomical changes after amputation

After an amputation is made, the remaining muscle tissue needs to be secured and stabilised at the distal end of the residual limb. This helps to retain the maximum amount of functioning muscle, to ensure strength and shape, and to prevent the progressive degeneration of the muscle called hypotrophy. Two common methods for securing the distal end of the muscle are myodesis and myoplasty. Myodesis means that radial stabilising sutures are made to attach the muscle to the periosteum (the outermost membrane of the bone). Myoplasty means that the muscles are sutured together and then folded over the end of the bone. This forms a cushion of muscular tissue around the distal end of the residual limb (Berlin, Ö., 2015, pers. comm 2015-04-20).

Because the attachment of the muscle is weakened, however, it is common for the cut muscles to undergo a certain degree of hypotrophy, meaning that amputees often have a decreased circumference around the residual limb. Atrophy is a decline in muscle size due to decreased employment of said muscle. (Berlin, Ö., 2015, pers. comm 2015-04-20) One estimation given by an occupational therapist working at Armprotescentrum (Caine-Winterberger, K., 2015 pers. comm. 2015-04-13) was that, although the variation in arm

size among amputees will be considerable for a time after the procedure, the majority of amputees end up with a residual limb circumference of 20 to 30 cm. If the users train their muscles, the fibres will grow. (Caine-Winterberger, K., 2015 pers. comm. 2015-04-13)

Amputees may also experience the formation of neuromas, which can be painful when wearing a prosthesis. Neuromas form as a mass of nerve tissue where the nerve endings have been severed (Berlin, Ö., 2015 pers. comm 2015-04-20).

Sometimes when an amputation is incorrectly made, the muscles are only attached to each other and not sutured to the periosteum. This can lead to displacement of the muscles and chafing against the bone. This can even cause the bone to penetrate the muscle and pierce through the skin (Berlin, Ö., 2015 pers. comm 2015-04-20). Scar tissue around the stump is also common, and complicates electrode placement for EMG measurement. (Ortiz-Catalan, M., 2015 pers. comm., 2015-04-13)

Choosing the level of amputation is one of the most important factors to determine after the decision to amputate has been made. Upper limb amputation may be transradial (between the elbow joint and the wrist joint) or trans-humeral (between the shoulder joint and the elbow joint), but can also take place at the wrist joint (wrist disarticulation) or elbow joint (elbow disarticulation). (ISO 8549-2:1989(en))

Each joint and muscle lost and replaced by a prosthesis will also cause greater cost and a greater degree of impairment for the amputee. (WHO, 2004) The best possible level for amputation is usually determined by the ability of soft tissues to heal themselves. The amputation must also be done with regard to the use of a prosthesis, as bony prominences, skin rubbing and sweating increase the friction between the skin and an artificial limb. (WHO, 2004)

03 METHODOLOGY

The following section describes the methods used in the development project, and how they were implemented.

3.1 Process overview

The project was initiated with a planning stage, where an outline for the development was established and visualised in a Gantt chart (Gantt chart, Appendix I). Data relevant for the product development was gathered through literature studies and user studies, and then analysed to draft a product specification.

When user needs and product requirements had been identified and a functional analysis had been established, the first ideation phase was initiated. The vast number of partial solutions that were generated was reduced through an initial screening phase. Remaining solutions were combined into four main concepts, from which desirable features were selected to form a final concept. The process was iterative throughout, especially in the design-build-test cycle where ideas were tested and evaluated with the help of prototypes. The different prototypes were made as simple as possible and aimed at investigating one problem at a time. Further on in the development phase, the prototypes became more detailed, and were also made modular to help evaluating different combinations of solutions. The process outline is illustrated in Figure 9.

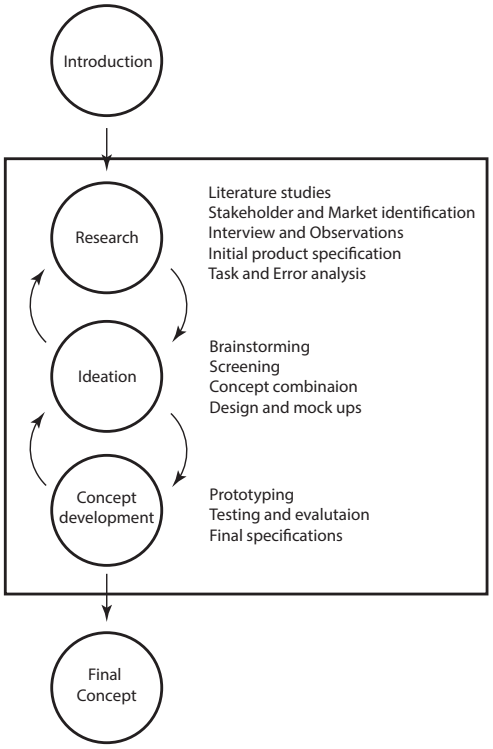

Figure 9. The outline for the project process, based on the product development process by Ulrich and Eppinger (2003).

3.2 Product planning

After the time plan for the project had been established, stakeholders for the product were identified to determine what groups of people should be contacted to identify relevant needs for the product. The product planning stage also included the study of competing products on the market, to verify the need for the rehabilitation system on the market.

3.2.1 Stakeholder identification

By explicitly listing all the groups of people who are affected by a product's success or failure, the needs of everyone who will be influenced by the product are kept in mind. (Ulrich and Eppinger, 2003) The stakeholder identification usually starts with the end user and the external customer who makes buying decisions about the product type. (Ulrich and Eppinger, 2003)

The stakeholders for the product developed in this project were identified starting with the primary and secondary users, as the use situation currently takes place in a clinical setting and in the presence of a professional trained in neuromuscular rehabilitation. As the conditions for acquiring good signal readings differ between users, a critical user for whom signal acquisition would be difficult was identified. Critical users may be expert users with special requirements, or they may be users with cognitive or physical impairments with special needs. (Bligård, 2015) By taking the critical user in account when developing a product, chances increase to also address the needs for the majority of primary users.

As Integrum have not developed a marketing plan for the product, alternatives for distribution were also discussed.

3.3 Data collection

In order to develop a product that fulfills the right functions and requirements, data was collected through interviews, observations and surveys. The interviews were made with both primary and secondary users, as well as with experts in different fields. This helped the project members gain better understanding of the users' experience of the product as well as the technical requirements affecting the design.

3.3.1 Interviews

Interviews are the most fundamental method for collecting information about people's opinions and thoughts. The raw data gathered is subjective, as the users express their personal opinions. The type of interview will affect what kind of data is obtained, where a structured interview will generate more quantitative data and a non-structured interview will provide qualitative data. A semi-structured interview is a half way

between a structured and a non-structured interview, where an outline for the topics covered has been established, but the order of the questions is of less importance and there is room for follow up questions. (Osvalder, Rose and Karlsson, 2008)

For this project, semi-structured in-depth interviews where used to retrieve information from users and secondary users. This gave the interviewer a better chance to pick up needs, ask the interviewee to elaborate a statement (probing), and ask follow up questions. Probing was used when the interviewees' statements were not elaborate enough, and follow up questions were asked when the user expressed something unexpected. The interviews were carried out with both project members present, one mainly asking questions and the other mainly taking down notes. Immediately after the interviews, the notes were compared and discussed to assure that both project members had the same picture of the findings. The notes were also typed for future reference.

The interview questions were focused around the user's experiences and opinions of the product system, the frequency and duration of the training sessions, and how the effect of the sessions on their pain and their mood. The interviews with the primary users were executed in connection with the neuromuscular training sessions, one interview taking place at Armprotescentrum and the other at Integrum. The secondary user was present during the interview taking place at Armprotescentrum. The product system that had just been used for training was present as a mediating object.

As the product system is still in a prototype phase and not yet commercially available, the number of interviewees with experience of using it was strictly limited. The user interviews were held with two primary users of the current product system, as well as with a secondary user working with the training sessions in a rehabilitation clinic. One of the primary users had already made the transition to home training, while the other had only participated in the clinical study of the product at Armprotescentrum in Gothenburg. Users who had already left the clinical study were not available for interviews.

For integrity reasons, potential future users were sought by contacting interest organisations for amputees rather than rehabilitation clinics. Koalition för amputerade (The Swedish

Amputee Coalition), Personskadeförbundet RTP (The Swedish Association for Survivors of Accident and Injury), and DHR - Delaktighet, Handlingskraft och Rörelsefrihet - förbundet för ett samhälle utan rörelsehinder were three of the contacted organisations. A forum thread on a forum for functionally impaired, funktionshinder.se, was also created to get in contact with potential future users.

In order to validate statements and theories and to gain further knowledge in fields where literature studies were not sufficient, semi-structured interviews were also held with an orthopaedic, an occupational therapist, and researchers with experience in measuring biosignals.

3.3.2 Observational studies

An observational study is an objective method for studying the behaviour of users in a certain use context. Observations are used to complement the subjective self-report data gathered through interviews. (Osvalder, Rose and Karlsson, 2008)

Two direct observational studies were performed in order to gain a better understanding for the use situation. One of the studies was made during a clinical study session led by an occupational therapist at Armprotescentrum, and the other took place during a control visit at Integrum where the primary user carried out all steps of the setup. During the observations, both project members were present. A protocol was used as an aid to systematically take down important data. Most of the data sought was qualitative, such as what tasks were problematic in the interaction with the system, while quantitative data of interest was time for setup of the system and total time required for the neuromuscular training session.

3.3.3 Surveys

Surveys, or questionnaires, are used for gathering subjective data in written form. As it is an indirect method, the respondents are anonymous.

A digital survey was sent out both to employees at Integrum and to people having used the product system under development during the clinical study. The survey was used to validate results from the interviews and observations by reaching a larger group of users. It consisted of a set of

statements about the product, which the respondents were to rate on a scale from one to five. The grading one was given to statements describing an undesirable product feature, while the grading five was given to statements describing critical features. The survey was made both in English and Swedish to reach a wider group of users.

3.3.4 Consultations

During the development process, consultations were held with experts with knowledge in areas relating to polymeric materials, textiles and foam materials. This was done to get input about feasibility and choice of materials, as well as cost-effective manufacturing.

3.4 Analysis

Various methods were used to systematically analyse the data gathered through interviews, observational studies and surveys. These are presented below.

3.4.1 Hierarchical Task Analysis

The purpose of a Hierarchical Task Analysis (HTA) is to describe what steps a user needs to perform in order to carry out a task leading to a certain goal. The analysis takes off in the identification of the overall goal, which is then decomposed into subordinate tasks needed to fulfill the goal. (Bligård, 2015) An HTA gives an overview of the different tasks that can be performed with the product as well as the relationship between different functions. Usually, physical and perceptible actions are described. (Osvalder, Rose and Karlsson, 2008)

In this project, an HTA was made for the steps in the use situation which require interaction with the hardware (the controller box, the electrodes, the cables and the fiducial marker). Due to the delimitations of the project, the questionnaire preceding the training session and the exercises in the training protocol were not included. Data from the observational studies served as input for the establishment of the HTA.

An HTA was also made for the final concept, to compare the number of steps required for setup.

3.4.2 Predictive Human Error Analysis

A Predictive Human Error Analysis (PHEA) is one way of investigating what use errors might occur in the human machine interaction, along with possible cause and effects of these errors (Bligård, 2015).

The PHEA for the neuromuscular training session was based on the established HTA. Use errors that had been observed or reported during the data collection phase were taken into account, along with other errors which could theoretically take place.

The setup of the final concept was also analysed using a PHEA to validate that the risks for and consequences of use errors had been minimised.

3.4.3 Personas

A persona is a description of a fictive user who is described with enough detail to feel like a real person. The use of a persona can help developers make the user more substantial and personal, to easier meet user needs and preferences (Bligård, 2015).

In this project, the use of personas has been highly motivated to compensate for the lack of users available for interviews and observations. Three different personas were created, with different personalities showing traits that may cause problems or serve as strengths when using the product system. The personas differ not only in age, personality and life experience, but also in experience of using technology, motor skills and motivation to train.

3.4.4 Scenario

A scenario is a narrative way of describing the use situation, describing the context, the mood and the feelings of the user. Just like personas, the method is used to make the use situation more vivid and easier for the project team to relate to (Bligård, 2015).

By writing scenarios in which the personas interacted with the product, potential use errors caused by certain personality traits could also be identified.

3.4.5 Needs list

The needs list is a set of written statements based on raw data from the customers. The data from the interviews and observations was sorted into categories depending on whether the statements expressed typical uses, likes, dislikes or suggested improvements of the current product. The statements were then interpreted in terms of needs which the product should satisfy. The needs were decomposed to describe as precise attributes as possible, before the relative importance of the needs was established. These needs, in turn, form the foundation for the target specification.

3.4.6 Functional analysis

By analysing the functions of the product in the needs identification stage, the general effects which the product should give are identified. At this stage, wanted effects and needed functions are of interest, as well as functions of value for the user and external customers. (Bligård, 2015)

The list of functions for the product resembles the list of needs. However, as user needs are generally expressed in "the language of the customer", they leave too much room for subjective interpretation. (Ulrich and Eppinger, 2003) Identified needs and technical requirements were translated into functions of the product, which can be implemented in different ways. Consistency was ensured by expressing the functions on the form verb + noun. The list of functions was later used as a foundation for idea generation.

3.4.7 Target specification

Product specifications represent an agreement on what must be delivered in the product design to satisfy user needs, rather than how the needs are to be addressed. The target specification for the hardware in the rehabilitation system was expressed in metrics and values based on the attributes described in the needs list. The purpose of the target specification is to help evaluate concepts, ensuring that technical requirements and user needs are fulfilled when choosing between different design solutions.

The target specification was continuously added to and refined as more decisions were taken in the design process.

3.5 Idea generation

This section goes through the process of developing concepts based on the results of the analysed data.

3.5.1 Brainstorming

Ideation was initiated by selecting a number of functions for the prototype, for which partial solutions were found. Ideas were generated through brainstorming (Figure 10) and looking at applicable existing solutions. The functions chosen as a foundation for the ideation were assumed to affect the design strongly.

Figure 10. Brainstorming with pen and paper.

Several brainstorming sessions were carried out in the ideation phase. The functions of the product were used to trigger the project members' imagination by asking the question "In what different ways can this function be achieved?". Ideas that came to mind were mainly communicated either through sketching or with words. All generated solutions were taken down without evaluation, screening or prioritisation, and further elaboration of each other's ideas was encouraged.

3.5.2 Initial Screening

The vast amount of ideas that were generated during the first ideation was reduced to a more manageable number in an initial screening phase. Partial solutions that were rejected at this stage were those that would result in doubtful feasibility, difficulties to integrate with existing technology and cost ineffective concepts. Discussing the solutions by taking on the roles of the personas also helped in this process.

3.6 Concept Generation

This section describes the methods used to combine partial solutions into concept combinations and to refine the combinations to create early product concepts.

3.6.1 Concept combination

In order to consider combinations of the remaining partial solutions systematically, a morphological matrix was used. A morphological matrix is a table where potential overall

solutions for the product are formed by combining partial solutions from different columns in the table, where each column represents different functions or requirements which the concept needs to provide for or fulfill (Ulrich and Eppinger, 2003).

The properties of the combined concepts for the electrode band created a foundation for the subsequent generation of concepts for the controller box. The ideas for attaching the controller box generated through brainstorming were compared to the properties of the electrode bands to combine ideas and create concepts for a controller box which could be firmly attached on the band and provide for good electrical contact.

3.6.2 Initial concept screening

A list of all possible combinations was created for the electrode band and controller box respectively, and concepts that contained any conflicting combinations were eliminated. One common type of conflict was when one partial solution called for a soft and supple electrode band, while another one required a stiff shell.

3.6.3 Development of early concepts

Four distinctly different concepts emerged for the electrode band and the controller box respectively, which best fulfilled the criteria for a user-friendly and effective home training system. For each of these concepts, however, new problems were pinpointed. Another round of sketching and discussion was thus carried out with focus on solving the identified problems. Once again, as many ideas as possible for solving the problems were generated. In the cases where these solutions in turn caused new problems, the idea generation was iterated until the biggest problems for all concepts were solved for, and the concepts were sufficiently defined to be presented in sketches. Simple mock-ups were also built for the concepts of the electrode band. In this way, the concepts ended up on a comparable level of refinement.

3.7 Concept evaluation

This section deals with the methods used to evaluate the combined concepts and choose features for the final concept.

3.7.1 Concept evaluation matrix

A simple concept evaluation matrix was used to compare the four obtained concepts. Since the concepts were still at an early stage of development and it would be too time consuming to build functional prototypes for physical testing, a theoretical estimation was made on how well each concept would fulfill general requirements.

The requirements chosen for the evaluation matrix were based on the importance of the requirements, as well as what requirements best displayed the differences between the concepts. The requirements were expressed in general terms in order to present an easy overview of the concepts' performance relative each other. The chosen requirements for this evaluation were handleability, size adjustment, comfort, durability, cleanability, possibility to apply point pressure, customisability of the electrode placement and manufacturability.

For an easy overview, the evaluation matrix was presented in a colour coded version, where a concept got "a red score" if it did not fulfill the requirement at all, "a yellow score" if it did not fulfill the requirement but had potential to do so, and "a green score" if it fulfilled the requirement well.

3.7.2 Evaluation using the personas

The concepts were also evaluated against the personas created, to see how they would suit a range of potential users. This was done by taking on the roles of the personas while discussing the concepts. The personas were also kept in mind during the development phase for continuous evaluation of ideas.

3.8 Concept selection

A meeting was held half-way through the project with representatives from Integrum along with the project supervisor and examiner. The aim of the meeting was to choose one concept for the electrode band and the controller box respectively to continue working with. Each concept was presented with sketches and simple mock-ups, along with a list of its strengths and challenges which remained

to be solved for. In addition, the colour coded evaluation matrix was shown to give the participants an idea of how well the concepts were believed to fulfill the requirements.

Following the presentation, everyone attending the meeting was encouraged to leave opinions on each presented concept and to discuss solutions for identified challenges.

3.9 Concept refinement

Once a concept had been selected, further decisions about the design were made starting with decisions that would affect the design the most. Decisions were then made about more detailed features that were dependent of earlier decisions and which could more easily be changed.

3.9.1 Concept scoring matrix

When choosing between different technical solutions in the concept refinement phase, a Kesselring matrix was used to compare how well the different alternatives fulfilled the requirements of the product. A Kesselring matrix, or a concept scoring matrix, is used to improve the resolution when choosing between alternative concepts. To refine the comparison between competing concepts, the relative importance of the selection criteria are weighted. The weighted sum of each concept's rating makes up the concept score. (Ulrich and Eppinger, 2003)

The concept scoring matrix was used to aid in making some of the decisions that remained after concept selection and the mid project discussion.

3.9.2 Design-build-test cycle

Figure 11. Building prototypes for the controller box.

Many decisions in the concept refinement phase were made in a design-build-test cycle, which was iterated when issues were identified when making or testing the prototypes.

A prototype is defined as "an approximation of the product along one or more dimensions of interest" (Ulrich and Eppinger, 2003). The prototypes (Figure 11) built for this project were mainly focused, meaning that they only implemented one or a few attributes of the product at a time (Ulrich and Eppinger, 2003) depending on what features were being evaluated. By building prototypes, problematic design features could be identified and redesigned faster.

While prototyping is a good way to test concept features to reduce the risk of costly changes later in time, some features could not be built without custom made components and had to be tested theoretically.

3.9.3 Design heuristics for medical products

The human-machine interaction was an important factor which affected many decisions in the concept refinement phase. Important guidelines for design of medical products were found in an article by Zhang et al. (2003), describing how Nielsen's usability heuristics can be applied. Out of the 14 guidelines called the Nielsen-Schneiderman Heuristics, the following were found applicable for the project.

Consistency means that standards and conventions should be followed. For example, sequences of actions should be consistent to make it possible for the user to improve in performing a task. Another case where consistency is of importance is when colour coding is used for organisation.

Visibility of system state means that the user should be informed about what is going on and what actions are available at the current state. One basic example is to give clear information about whether the product is on or off.

Minimalist means that any unnecessary information is distracting and slows the user down. The design should be kept as simple as possible, while providing the user with necessary information.

Prevent errors means that errors should be prevented from happening by making it impossible for the user to perform erroneous actions. (Zhang et al, 2003)

3.10 The Eco Strategy Wheel

The Eco Strategy Wheel (Figure 12) is a tool developed to stimulate new ideas for reducing a product's environmental impact through addressing the following eight main areas:

- Optimise the function
- Decrease the environmental impact during the use phase
- Reduce the amount of material
- Choose the right materials

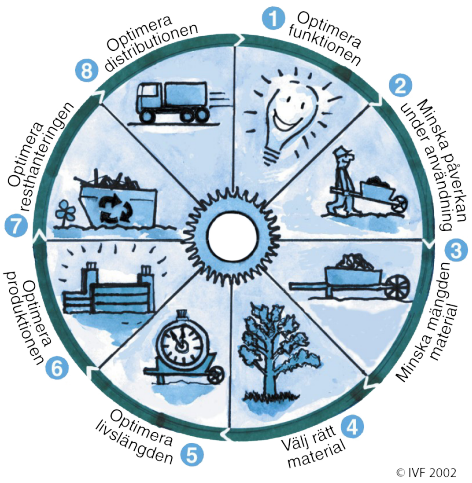

Figure 12. The Eco Strategy Wheel with its different parts.

- Optimise the durability
- Optimise the production
- Optimise the waste management
- Optimise the distribution (Hållbarhetsguiden (2015)

In this project, the Eco Strategy Wheel was mainly used as a means of continuous evaluation of ideas throughout the project, rather than a tool for idea generation. Important aims for the product development was to optimise the function of the product and reduce the use of single use adhesive electrodes. Aiming for easy separation of the components both optimises the durability and the waste management.

3.11 Usability test

A usability test was conducted to evaluate the process of customising the electrode placement. The aim of the test was to see what use errors may occur during the customisation process to see what improvements could be made. The test was also made to validate whether it would be reasonable to sell the product directly to primary users, who would then possibly need to customise the product without the help of a professional.

The task tested was to disassemble an electrode band with a default electrode array, map a desired electrode pattern marked on the skin surface onto the electrode band by placing the electrodes in the correct positions and then take the electrode band on. The desired positions of the electrodes were marked on the user's arm using stickers, placed pairwise in a random pattern.

Due to restricted possibilities to manufacture a realistic product representation, the prototype used for the test was considerably simplified. Only four electrode pairs were used in the usability test, and the electrodes were not connected to cables. The participants were allowed to use both hands for the task, as it had already been assumed that the task would be very difficult to perform with one hand and the participants were not used to managing chores with only one hand in the same way that amputees are. An amputee may also be able to perform the task if wearing a prosthesis.

Except for the product representation, the participants were given a sheer elastic nylon tube with an arrow marked along it. They were also given a pen, a pair of scissors, and instructions for mapping the desired positions for the electrodes from the arm onto the electrode band.

During the test, the participants were encouraged to think out loud for better understanding of their mental model of the product as well as what factors caused frustration or confusion. Other data taken down was the number of electrodes that ended up in the correct positions, as well as any discernable use errors made.

04 Results of data collection

4.1 Stakeholder identification

The identified stakeholders for this project are the primary and secondary users, as well as retailers or distributors of the product. The findings of the stakeholder identification are summarised in Table 1.

4.1.1 The primary user

The primary user is the one who performs the neuromuscular rehabilitation training using Neuromotus, and needs to be able to set up and use the developed concept on their own. Common for all primary users is that they have lost at least one limb and experienced phantom pain referred to that missing limb.

At present, the primary users' knowledge about the product is limited to the training procedure, which they have learnt after training under supervision of an occupational therapist at a rehabilitation centre – probably no more than twelve times at a weekly basis (Caine-Winterberger, K., 2015 pers. comm. 2015-01-27). The mental model of the Neuromotus will vary for different users - but regardless of how much they know about how the product works, it is essential that it helps relieve their phantom limb pain.

The main interaction with the product consists of connecting the residual limb to the system, following the training protocol, and ultimately disconnecting from the system. The goal with the training of the residual limb is to relieve phantom limb pain.

By taking the product home, the user will be in control of when and how often to train, although he or she will have been assigned with a training protocol to follow. Prior to starting training with the Neuromotus, the user is expected to have tried mirror treatment and might also have come in contact with other treatment methods.

After the transition to home training, the primary user will own and be responsible for taking care of the product, although he or she may not have paid for it. Furthermore, they will not have chosen the product themselves (other than their preferred method of pain treatment), so it might not feel very personal to them. The user's emotional relation to the product will be heavily influenced by how much the training helps relieve the phantom limb pain - but regardless of the effects, the users hope for a future without phantom limb pain.

The physical handling of the product will be impeded by the fact that the end user has lost part of at least one upper limb. Tasks that are more difficult to do with one hand include any interaction with objects requiring a second hand to keep it in place. Means of physical handling of the product that are not connected to the actual training sessions include cleaning, storage, transportation and charging the internal battery.

The cognitive interaction with the physical product includes figuring out where to place the electrodes and what cables go where. However, the main cognitive interaction is based around the computer software. How comfortable the user will be with the software depends on how experienced the user is with computers, and how easy the software is to handle.

The residual limbs of the users can vary both in level of amputation, occurrence of scar tissue and neuromas, and thus the chances of successful signal reading vary greatly among users. Common practise in amputation is to save as much of the limb as possible. Only what is necessary to remove is amputated, without any consideration for attachment of prosthetic limbs. (Caine-Winterberger, K., 2015 pers. comm. 2015-01-27) For example, a transradial amputee may want to attach some electrodes to the forearm to be able to train isolated finger movements, while a transhumeral amputee may need to experiment with the

electrode placement for optimal signal reading. Regardless of how the product is sold, it needs to be customisable to a certain extent.

The critical user identified for Neuromotus are amputees with a lot of scar tissue, or users who for some other reason have difficulties finding a favourable position for the electrodes - both in terms of location on the skin surface and closeness to the signal source. Other critical users may have impaired vision, decreased hand strength or little experience of technology.

4.1.2 Secondary users

Anyone who assists the primary user in training with the Neuromotus is considered a secondary user of the product. The secondary user may help out with placing the electrodes and attaching units for applying pressure, but they can also help the primary user with the computer software or pick up and put away the Neuromotus.

At present, the secondary user is typically an occupational therapist at a rehabilitation centre who has been trained in neuromuscular rehabilitation using mirrors as well as the Neuromotus system. After the transition to home training, the secondary user could also be an assistant or someone living with the primary user.

The secondary user probably does not know what it is like to have phantom limb pain, and might not understand how the product works. It is in their interest, whether it be professional or personal, that the training is effective as well as efficient.

4.1.3 Retailers

At present, it is not yet decided how the product will be distributed. For sales within Sweden, the Neuromotus can potentially be distributed by health care providers.

It is therefore possible that Neuromotus will be retailed in a similar manner to that of prosthetics, which are custom made in orthopaedic workshops in conjunction with institutions like Armprotescentrum after the residual limb has healed from amputation. Amputees do not pay for prostheses, but

need to undergo proper training before they can take them home (Caine-Winterberger, K., 2015 pers. comm. 2015-01-27).

The Swedish market for Neuromotus is very limited, seeing as only about 50 arm amputations take place in Sweden every year (RTP, 2015). To expand the market, customers will be sought internationally, where institutions such as Armprotescentrum may not exist. As a result, the product must be designed in a way that it does not require customisation made by a professional.

Type of user	User	Requirement areas of interest
Primary	End user	Effectiveness
		Easy to use with one hand
		Transportability
		Insensitivity to signal artefacts
		Comfort
		Easy to place electrodes
		Easy to clean
Secondary	Occupational therapist	Easy to learn (teach)
	Assistant	Easy to place electrodes
		Easy to adjust size for different users
		Easy to clean
Retailers		Durable
		Cost efficient

Table 1. Summary of areas of interests for different users of Neuromotus and what need they contributes with.

4.2 Interviews

No reply was received from the organisations which were thought to be able to help in getting in contact with potential users of the product system. The only reply was from DHR, which forwarded the matter to a facility center in Stockholm. The problem with institutions like these is that they cannot provide any contact information about their patients. A total of three interviews (Appendix II) were held with primary and secondary users. The information obtained through interviews is concluded below.

4.2.1 Primary users

Both primary users interviewed had experienced phantom limb pain for more than ten years, ever since the amputation. One described the pain as constant and pulsating, while the other reported intermittent pain arising every hour. One of the users expressed that the phantom limb pain made them less patient. One of the users was the first patient treated with the technology (Ortiz-Catalán et al, 2014), and had experienced a considerable improvement of the phantom limb pain and taken the training system home. The other user had a couple of sessions left within the clinical study, but had not yet felt any result of the neuromuscular rehabilitation. The clinical study consists of twelve training sessions at Armprotescentrum on a weekly basis.

The user who had not yet taken the system home saw the advantage of not having to travel to Armprotescentrum, but thought that one disadvantage would be to not have a therapist pushing them to try harder when performing the exercises. This user reported that the exercises were both mentally and physically exhausting. However, the user was interested in taking the system home, and would aim at training at least once a week. The training would probably take place in the user's home office. This user had never tried to place the electrodes on the residual stump, but assumed that with time, they would learn to locate the right positions by palpating the muscles. A concern expressed with placing the electrodes was to see and reach the triceps on the back of the arm.

The user who had already taken the system home saw the advantages of being able to train more often and whenever they wanted. Instead of coming to Armprotescentrum once a week, this user now aimed at training every other day and at least twice a week. A disadvantage expressed by this user was having to train by a computer with a smaller screen, and the risk of forgetting to train. The user reported the placement of one particular pair of electrodes as the most difficult part of the training. When using the system at home, the user often trains on their own by the kitchen table in the evening. The user stated that it is more difficult to train if anyone else is nearby, as the training requires full concentration. The user keeps the Neuromotus lying around, ready to use, and a training protocol from Integrum is followed.

Both primary users had a generally positive attitude to the product, especially the TAC-test exercise because of the direct feedback given. One user saw the Neuromotus sessions both as training and rehabilitation, but mainly as training. The other user called the Neuromotus "fun and intriguing", and something that helped them to live a better life.

One of the users expressed that it was harder to feel as a part of the AR-environment and to perform the exercises when the residual limb was within sight. The user's solution for this was to mount a piece of paper on the rim of their glasses, which would cover the view of the residual limb. The other user thought that the questions of the questionnaire preceding the training were difficult to understand.

Suggested improvements for the product were longer cables or a wireless product, and a way to keep the controller box out of the way. A sock or a prosthetic liner with marked holes for electrodes was suggested for facilitated electrode placement. Another jokingly suggested idea was to tattoo the residual limb as a reference for electrode placement.

4.2.2 Secondary user

One of the interviews was held with an occupational therapist at Armprotescentrum, who had carried out part of the clinical study of the product. The secondary user expressed that the Neuromotus works well and is easy to use.

Problems identified by the secondary user were insufficient time between the exercises for the user to relax, insufficient contact between the cables and the amplifier, as well as the amplifier moving around when inserting contacts. Another problem was the sensitivity to motion artefacts, which are disturbances in the signals caused by cables striking against each other.

The secondary user reported that even if the patients are in pain, they do not always do their rehabilitation exercises at home as they should. However, the pain was thought to definitely be a motivator for patients to use the system - especially for those who have already tried all other methods for phantom limb pain treatment. The importance of neuromuscular training to prevent hypotrophy of the muscles was also explained. For example, mirror treatment is compulsory for getting a prosthesis.

The secondary user expressed that it would be a good idea to be able to take the system home, but thought that the biggest disadvantages would be that it requires a computer and a webcam.The secondary user also mentioned that primary users do not always like seeing themselves with the virtual representation of the lost limb. However, they often like the TAC-test.

Suggested improvements for the product system were an adjustable strap for holding the fiducial marker, longer cables, and some sort of tube or prosthetic liner for easier electrode placement, and a velcro strap to tighten around the electrodes to push them closer to the signal source.

4.2.3 Experts

Results from the interviews with experts in biosignal acquisition and anatomical changes caused by amputation are incorporated in the related sections under the chapter Theory.

4.3 Observations

During the observations it was clearly seen that finding the position for the electrodes was a difficult step which was also important to get right. The secondary user solved this by using photos from the previous session as a reference, but sometimes had to reposition them anyway for better signal acquisition. The user who set up for the training themself used the fingers of the intact hand to feel the movement under the skin to find the correct position. Both users stated that they learnt with time how the electrodes should be placed.

The electrodes used were single use adhesive, but it was also stated by an attendant from Integrum, that one user used special electrodes due to sensitive skin and pain associated with the removal of the conventional adhesive electrodes. This was not one of the users that had been observed or interviewed during this thesis.

One of the users observed had problems acquiring good signal from the residual limb. An attempt at solving this problem was to place a velcro strap around the electrodes to push them closer to the signal source.

In both observational studies, problems arose with the cables that go from the controller box to the electrodes, because they are long and easily get tangled. They are also sensitive to motion artefacts when struck towards each other. Another observed problem was that the cables need to be connected to the electrodes after the fiducial marker has been placed on the residual limb, since the marker is placed on a closed elastic loop. The users were also constrained to sit close to the computers, as the cables between the electrodes and the amplifier are kept as short as possible. This resulted in one user not being able to see their own face in the AR-environment as it did not fit into the image captured by the webcam. This makes it harder for the user to feel as a part of the AR-environment.

At Armprotescentrum, Neuromotus is kept on the computer desk in the room intended for the training sessions. The user who had taken the system home stated that the training usually took place at the kitchen table, and that the product was kept lying around ready to use.

4.4 Survey

Seven answers were collected from the survey. The questions were about how they would weigh different properties they would wish for the new product (Appendix III). Three respondents had been using the Neuromotus as a primary or secondary user, and four worked for Integrum.

In general, employees at Integrum rated the importance of the product attributes higher than the users. The average score by company employees was at least half a point higher than the score given by the users for about two thirds of the questions, while the only attribute given a higher average score by the users was that the product should be usable anywhere in the home (Graph 1, Appendix IV).

The survey showed that the most desirable features for the product is that it should be safe to use, it should allow the user to perform the exercise (meaning that the training should not be impeded by any disturbances from the product system) and that the product allows for good signal reading (Graph 2, Appendix V).

Features that were less desirable was that the product should be unobtrusive during use, that the marker is out of the way and that the product should allow for a quick break.

05 Analysis

Results from the analysis of raw data are presented here. The foundation of the analysis is the results described in the Results section, for which different analysis methods have been applied.

5.1 Hierarchical Task Analysis

The HTA (Appendix VI) shows that the setup and closedown before and after the neuromuscular training sessions consists of a lot of steps that could be eliminated through the development of an electrode band. Tasks that could be eliminated mainly concerned the application and removal of electrodes and connecting and disconnecting the electrodes to the cables.

5.2 Predictive Human Error Analysis

The steps of the use scenario which had been identified as sources for use errors were gathered in a PHEA for analysis of their cause, effect and recovery. Probable use errors identified were mainly related to the placement of the electrodes (Appendix XII).

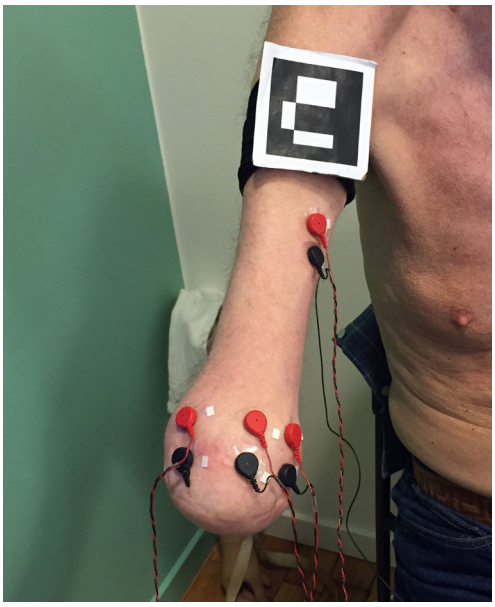

Figure 13. Picture of placed electrodes on residual limb.

5.2.1 Electrode placement

It is difficult to place the electrodes (Figure 13) so that they are in the right relation to the correct muscle, giving a collected signal from one muscle only. Potential errors when placing electrodes are misplacement of the electrode due to difficulties in finding muscle movements or mis-aiming when placing the electrode. Incorrect electrode placement will give erroneous signal readings and make it difficult for the user to perform the exercises during training. It is also easy to forget to place the electrode for electric ground after all the electrodes have been placed on the residual limb.

The risk of misplacing electrodes and the consequences of incorrect electrode placement supports the development of a way to facilitate the electrode placement. An electrode band will help the user to achieve correct electrode placement time after time as the electrodes in the solution will be kept at a set distance from each other.

An important need for the developed product is that it allows for electrode placement in the correct spots - by being customisable to optimise the signal acquisition. The product must also allow for correct placement along or around the residual limb, and stay in place without sliding down the limb or rotating while training. The fact that it is difficult to find the correct placement for the electrodes implies that the users will require assistance when customising the placement of electrodes in the band.

5.2.2 Connecting the electrodes to cables

Another source for use errors is the task of pairing the right electrode to the right cable. The cables in the current product are arranged in pairs - a red cable for positive signal pickup and a black cable for negative signal pickup - and each electrode pair should be matched by one pair of cables for correct signal readings. A potential use error would be to mis-match the electrodes and the cables.

By developing an electrode band in which the electrodes are already connected to the right cables, the risk for use errors concerning the connections are minimised. The risk for mis-matching the cables and the electrodes should be considered if the user is given the possibility to connect and disconnect the electrodes from the cables.

5.2.3 Application of pressure

Another issue observed was that the signals acquired from the skin surface were too weak. The solution for this observed at Armprotescentrum was to put a strap around the arm to apply extra pressure over the electrodes to push them closer to the signal source.

The strap used at Armprotescentrum consists of a stiff foam material and is tightened with velcro. If this band is tightened too hard, it would cause the user pain and discomfort. However, if too loosely tightened, the signal readings might

not be sufficient. The developed solution should allow for sufficient pressure over the electrodes without causing pain and discomfort.

5.2.4 The exercises

While performing the exercises, there is a risk that the cables strike against each other and cause problems with motion artefacts - a common result of the user making large or sudden movements. The restricted length of the cables could cause the controller box to fall off the surface on which it is placed, as the user accidentally pulls the cables when performing the exercises.

Signal transmission is needed between the electrodes and the controller box, as well as between the controller box and the computer. Conductors must be used between the electrodes and the controller box, and should be kept as short as possible to avoid signal noise before the signals are amplified. The connection between the controller box and the computer, however, could be replaced with a wireless connection.

A wireless connection between the controller box and the computer makes it possible to place the box closer to the user and reduce the noise in the signals. This will also make it easier for the user to train a little further from the computer to give more freedom of movement, and allows the webcam to capture more of the user and the use environment for the AR-exercise. The feeling of being "strapped to the computer" expressed during a user interview would also become less of a problem.

5.2.5 The fiducial marker

The handling of the fiducial marker may also cause problems, as it is easy to forget to take it on, or to place it in an angle making it hard for the webcam to recognise. This causes issues with the AR-environment exercise, as the marker is the software's reference for positioning of the virtual limb representation. If the user forgets to take on the marker before the electrodes are connected to the amplifier, the elastic loop on which the marker is attached needs to be pulled over all the cables and onto the stump.

The risk of forgetting the fiducial marker should either be minimised, or the consequences of forgetting it should be relieved by making it easier to put on once the user remembers it.

5.3 Personas

The creation of persona resulted in three user types represented in sections below. These are Agda, Karl and Karin - three users with different characteristics giving them different basic conditions for using the product.

5.3.1 Agda, 83

Agda (Figure 14) is 83 years old and has been living in her flat for the last 10 years, ever since her husband passed away. Despite her age, she is as good health, but she is wearing a pacemaker which she got 25 years ago. She can manage most daily chores by herself, but gets help with cleaning and laundry. One of her four children lives in the same town, while the rest live a couple of hours' drive away. Agda has a computer at home, but only her children and grandchildren have ever used it. Her children take care of her finances so she does not need to think about that. Agda spends most of her days reading books, watching TV or seeing her friends.

Figure 14. Agda, 83

Agda lost her left arm just at the elbow as a consequence of a cancer tumour. She mostly feels a tickling sensation in her fingertips, but at times she suffers from intense cramping pain, which she tries to hide so that no one should pity her or think that she has gone crazy. Agda finds her prosthetic arm rather cumbersome and only uses it when leaving her home.

5.3.2 Karl, 52

Karl (Figure 15) is married and lives happily with his husband Martin and their two children. Karl is interested in technical innovation and used to work in the local industry until one day 20 years ago, when he experienced the biggest change in his life. Karl had an accident in the factory and was hospitalised for two months. His dominant arm, the right, was in a too bad condition to be saved and was thus amputated 20 cm from the shoulder joint. As his work was hard to manage with only one arm, he studied to become a teacher. It took Karl a long time to adjust to his altered anatomy and to get used to new ways of carrying out ordinary tasks, such as typing or making dinner.

Figure 15. Karl, 52

Karl's phantom arm hurts several times an hour. Although the pain does not last for any longer periods, he often needs to take a break in writing on the blackboard - which also gives the students time to catch up. He use his prosthesis daily as it makes his life easier and he finds the looks from passers-by disturbing.

After a day at work, Karl sometimes takes some work home, to sit with the laptop on the sofa and grade student assignments. He also likes to cook, although many of the ordinary chores now take a little more time to do.

5.3.3 Karin, 9

Figure 16. Karin, 9

Karin (Figure 16) is nine years old and lives her mother in a small Swedish town. She is a happy girl doing the same things that her friends do, but there is a significant difference between Karin and her friends: Karin only has one arm. The accident happened a couple years ago when she got hit by a car when playing in the road. Given the circumstances, it all ended well as she come home from the hospital in good condition except that part of her left forearm had had to be amputated.

Nowadays, Karin does not have the energy to play with her friends just as much as before, as her phantom arm causes too much pain. This makes her angry and impatient, so she spends a lot of time in front of the computer by herself. Karin has got a prosthetic arm but it mostly lies on the floor, as she thinks it is too heavy and in the way. She almost only uses it when her mom tells her to, and that is not as often any more.

5.4 Scenarios

Fictive use scenarios were invented where two of the personas, Karl and Karin, interacted with the Neuromotus. This allowed for further identification of problems and strengths with the system that is used today, and shows how other users may experience the product. The full scenarios can be read in Appendix VIII and IX.

5.4.1 Karl

What can be seen from the first scenario is that even though Karl has done the training exercise several times, he is still not able to position the electrodes on himself. It can also be seen that when doing the neuromuscular training at Armprotescentrum, the questionnaire will take a lot of time from the actual exercise.

5.4.2 Karin

What can be seen from the second scenario is that although she has lot of pain, Karin does not do the training until she gets in a very bad mood. This suggests a solution that is easy to use and allows for quick setup. It is also hard for Karin to assemble the different parts of the system, as it is not made for being put together by a user with only one hand.

5.5 Needs list

The needs list, which is based on the interviews and observations, is a translation of raw data into elicited needs which the product needs to fulfill. The needs are based on comments, suggestions and observations from the data collection phase. The needs are presented in table 2.

5.6 Functional analysis

The overall function of the Neuromotus is to enable neuromuscular rehabilitation for phantom limb pain treatment. Only the functions of the physical product were considered in the function analysis as no changes were to be made to the software or electronic design.

The overall functionality of the product system will depend on the user's motivation to train. The motivation to train will mainly depend on how much pain the user is in and the effect of the neuromuscular training. The motivation to train is also supported by intuitive and efficient design of both the software and the physical product. Moreover, the product needs to retain its functionality for as long as possible, while being exposed to wear and tear.

The main function of the electrode band is to acquire EMG

Need number	Question/Prompt	By who	Customer statement	Interpreted need	Importance
1		U	"I train by the kitchen table"	The product is usable anywhere in the home*	4
2				The product is safe to use	5
3		U	"I have it lying around"	The product tolerates dust	4
4				The product is durable	4
5				The product withstands sun light	3
6				The product is unobtrusive when not in use	3
7				The product is cleanable	4
8		U	"It is easy to forget to train"	The product encourages the user to train	4
9		U	"The phantom pain makes me less patient"	The product prevents frustration	4
10	Likes-current	U	"It is fun and intriguing"	The product is intriguing	3
11		SU	"It is easy to use"	The product is intuitive	4
12				The product allows for good learnability	4
13	Dislikes-current	Integrum	"The snap-buttons have caused pain in patients with sensitive stump"	The product allows for pain-free use	4
14				The product feels safe	4
15				The product instills trust	4
16		Integrum,	Motion artefacts occur when cables strike against each other	The product can withstand "bumps"	5
17		U, SU	"It is hard to find the correct placement for the electrodes"	The product allows for intuitive electrode placement	3 or 4
18		U	"When I see my stump, I find it hard to feel as a part of the VR environment, which makes it difficult to perform the movement."	The product does not disturb the user during the VR excercise	3
19		U	"It would be nice with a bit more freedom of movement"	The product allows the user to perform the exercises	5
20				The product allows the user to easily disconnect for a quick break	3
21		SU	"The boxes move when you connect the cables one-handedly"	The product allows for use with one hand	5
22		SU	"Is it possible to make the marker smaller?"	The marker is out of the way	3
19		SU	"The cables are too short"	The product allows the user to perform the exercises	5
23				The product allows the user to easily disconnect for a quick break	3
24	Suggested improvement	U	"It should be easy to use whenever you want"	The product is easily ready to use	3
25				The product shows system status	4
26				The product is reliable	5
27		SU	"It could have a silicone prosthetic liner"	The product allows for application of pressure	4
28				The product continues to be pain free when pressure is applied	4
29				Is pinch-free	4
30		SU	"It could be tightened with velcro"	The product is adjustable to fit many different sizes	4
31				The product allows for different pressure on different places	3
32				The unit/units stays/stay in place during training	5
33			"If it had been wireless, I might want to hide it away somewhere (while training)"	The product is unobtrusive during use	3
34				The product enables user to focus on the training	4
27	Observation		A compressive band is used to get good EMG signals	The product allows for application of pressure	4
35			EMG signals are low due to scar tissue	The product allows for better signal reading in users with scar tissue	5
36			User forgot to place marker in time, and struggle with the cables to get it in place	The product helps the user to remember the marker	3

1. Feature is undesirable. I would not consider a product with this feature.
2. Feature is not important, but I would not mind having it.
3. Feature would be nice to have, but is not necessary.
4. Feature is highly desirable, but I would consider a product without it.
5. Feature is critical. I would not consider a product without this feature.

*wherever a computer can be used

Table 2. The needslist basted on interviews

signals from the surface of the residual limb. Two functions that are important in order for the electrode band to fit as many users as possible, are allowing for customisable electrode placement and allowing for application of pressure over the electrodes.

The main function of the controller box is to amplify and filter the EMG signals, suggesting that housing the circuit boards for this signal processing is the main function within the scope of this development project.

Four important functions which heavily affect the functionality of the electrode band are: placing the electrode band, tightening the band, customising the electrode placement and applying pressure over the electrodes. These functions laid the foundation for idea generation and will therefore be further described below. As it was already decided that the main function - to acquire EMG signals from the residual limb - would be solved for with surface electrodes, alternative solutions for this function were not investigated. The functional analysis is found in Appendix XI.

5.6.1 Placing the electrode band

The purpose of developing an electrode band is to reduce the time it takes to position the electrodes (Figure 17), as well as reducing the risk for erroneous electrode placement. Placing the band also requires that it is easy to place on the residual limb, as well as to tighten it without risk for the band to fall off the arm.

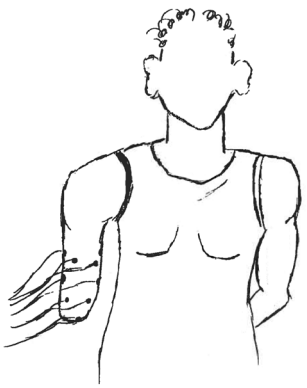

Figure 17. Example of how single use electrodes can be placed on the residual limb.

5.6.2 Tightening the band

To make sure that the band stays in the right place and does not move around or along the arm when training, the electrode band needs a tight fit around the residual limb without causing pain or discomfort. The solution for tightening the band must be operational with only one hand, and the band should not move in the circumferential direction while tightened.

5.6.3 Customising the electrode placement

All users are different in terms of amputation level, presence of scar tissue and muscle strength. To make a band that is able to acquire strong signals from a wide range of users, the

possibility to customise the placement of the electrodes is of importance. To ensure good signal acquisition, it is necessary to help the user repeat the same position of the electrode band, from session to session.

5.6.4 Application of pressure

Users with problems getting sufficiently strong signal readings may be helped by applying pressure over the electrodes. By pushing skin, scar tissue and fat aside, the distance between the electrode and the muscle fibre is minimised. Another advantage with applying pressure over the electrodes is that heat will be generated, causing sweat production. The sweat will help to transfer the signals better. (Sandsjö, L., 2015 pers. comm. 2015-02-16)

5.7 Target specification

The first target specification for the product is found in Appendix XI. The majority of the metrics are derived from identified user needs. Some are technical requirements which have not been expressed by users, but which need to be fulfilled in order for the product to function properly.

Requirements with the source specified as "Requests from Integrum" are not necessarily needed for the product to function, but have been desired by the company. One such requirement is that the electrode band should preferably be customisable - but the controller box must be compatible with standard single use electrodes as well as the electrode band.

Another request from Integrum is the possibility to apply point pressure over the electrodes. It had also been observed during the data collection phase that pressure was applied over the electrodes to acquire better EMG signals, but this compensating action probably derived from recommendations from company representatives. Integrum also requested an electrode band with 16 electrodes, plus one for electric ground used as a common zero reference for the electrode pairs. The electrode to ground can be placed either in the electrode band or on a bony prominence elsewhere on the body.

The target specification refers to the list of user needs as a source for many of the requirements to facilitate tracing of the metrics. Some user needs brought on several metrics, while some metrics can be derived from multiple needs.

Metrics derived from technical requirements are needed for the product to function properly. For instance, the electrodes in the band must be separated by insulators in order not to pick up each others' signals. Moreover, a reliable connection is needed between the electrode band and the controller box to avoid signal disturbances when the user performs the exercises.

Weighting of the requirements was done with regard to the weighting of the user needs from which they were derived. Technical requirements crucial for a functional product were given the highest importance weight, five.

Some requirements were given the unit "Subjective binary", meaning that it would not be possible or time efficient to make an objective measurement of the performance. Instead, it will simply be established whether a concept fulfills the requirement well enough or not.

A "Subjective scale" can be used to rate concepts as "bad", "acceptable" or "good". These ratings are colour coded as red, yellow and green. Subjective scales are used for requirements that are difficult to measure quantitatively.

The target specification for the developed product changed with time, as more decisions were made and the level of detail for the concept increased. The specification was continuously updated both by adding and removing metrics, as well as by tuning the target values for some metrics.

06 CONCEPT DEVELOPMENT

This chapter describes the generation of four early concepts for the electrode band and controller box respectively. First, some of the partial solutions generated in the ideation phase are presented, along with with those solutions that where eliminated in the initial screening phase. The combined concepts are then described before the chapter concludes in a concept evaluation and the selection of features to keep for the final concept.

6.1 Ideation

This section presents some of the partial solutions for basic functions for the electrode band and controller band, generated through brainstorming and identifying existing solutions.

6.1.1 The electrode band

Solutions generated for placing the electrode band, allowing for customisable electrode placement, tightening the band and application of pressure are the first to be presented.

6.1.1.1 Correct placement of the electrode band

The electrode band must be easy to place around the residual limb, in a way that it stays in position while the user tightens it. The easiest method identified was to slide a closed band over the the arm, which is already tightly fitted enough to prevent it from sliding off.

Another identified method was to wrap the band around the arm.

A relaxed position, with the residual limb hanging freely by the side could serve as a standard position of the arm, providing the user with directions to orient the electrode band. A default position could be to decide on a part of the electrode band (such as a print or the size adjustment device) which should point medially (towards the centre line of the body) while the user's arm is hanging loosely by the side.

One early idea was to use a prosthetic liner to place the electrodes in. Silicone prosthetic liners are worn on the residual limb to reduce friction inside the prosthesis, so most Neuromotus users should be familiar with and have access to liners in their size. As the liners are tubes with one closed end, the liners cannot be placed too high up on the residual limb. On the liner it would be possible to print a reference for the angle to place the liner in.

6.1.1.2 Allow for customisable electrode placement

The eight pairs of electrodes used to acquire EMG signals from the skin surface could be evenly distributed around the circumference of the band. This would not assure sufficient signal readings from all users, but the lack of customisability of the electrodes in the band could be compensated for by using so called "flying leads" - cables going directly from the controller box to single use adhesive electrodes that can be placed anywhere on the residual limb.

One idea discussed to provide for better signal acquisition was to make a matrix of abundant electrodes, which the user could choose between to obtain the optimal signal readings. Another thought was that the pattern recognition system might be able to handle all signals from the full grid of electrodes. However, as this requires a physical switch or relay in the circuit boards in the controller box, it would increase the size of the box considerably.

The alternative to using a grid of abundant electrodes was to make it possible to move the electrodes to optimal positions on the band. Three main solutions were found for this alternative.

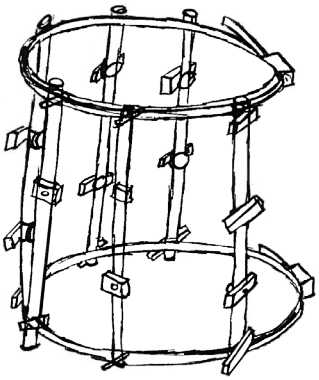

Figure 18. Concept with customisible placement electrodes in all directions.

One idea was to put the electrodes in tracks running along the axial direction of the band (Figure 18). This lets the user choose a suitable track to place electrodes in, slide the electrodes along the track, and secure them in the wanted position.

Another idea was to equip the electrodes with a pin, which can be positioned freely on a band made of a textile material.

The electrodes could also be placed in a grid of holes to obtain the desired configuration. This will give a more restricted placement of the electrodes but it is possible to give point pressure to the electrodes.

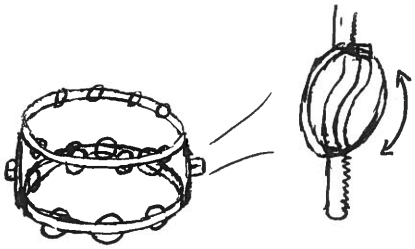

Figure 19. Concept with rings that can be set at different distances from each other.

Electrodes could also be placed on rings which could be placed at chosen distances and angles relative to each other to ensure a high level of customisability (Figure 19). However, this would require the user to find the right placement along and around the residual limb for each ring. This could be solved by connecting the rings with distancing sections, but this would result in a concept with a big amount of different parts.

6.1.1.3 Tightening the band

Tightening the band mainly serves as a way to fit it tightly around the residual limb to prevent it from sliding off or rotating around the arm. However, the solution for tightening the band will also affect the range of sizes that the electrode band will fit. Tightening the band also increases the pressure over the electrodes.

Figure 20. The ladder strap could be used to close and tighten the band.

One considered solution was to use a ladder strap buckle (Figure 20). The ribbed surface of the ladder straps makes the solution self-locking as the strap runs through the buckle. The ladder strap works both for flexible and stiff materials in the electrode band.

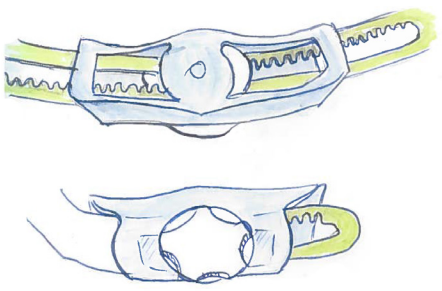

Figure 21. The buckle from a helmet, with rack and pinion mechanism.

Velcro is another solution that is easy to lock and works especially well with textile materials.

The size adjustment dial that is used in the neck of many bike helmets (Figure 21) is developed to adjust the circumference without having to apply force in the circumferential direction. In this way, the band will not rotate as the user adjusts the size of the product.

A pawl and hook mechanism, commonly used in ski boot buckles, works best in combination with a stiff electrode band. The buckle itself will be open between training sessions, meaning that it works best for applying additional firm pressure over the electrodes on a band that is already fitted around the residual limb.

Cords tightened with cord locks (Figure 22) is a solution commonly found in sleeves and legs of garments.

Figure 22. Two different cord tightening devices.

Designing the whole solution in an elastic material, or in sections joined by elastic material, helps the electrode band to automatically adjust to the arm of the user.

A compressible material, such as plastic foam, can be used in combination with any of the other size adjustment solutions. The material will follow the shape of the limb and provide better contact between the electrodes and the skin. The electrode band will also fit a bigger range of sizes the more compressible and the thicker the material is, as it allows for a change in the diameter of the band.

6.1.1.4 Apply point pressure over the electrodes

Point pressure is applied over the electrodes to move them closer to the signal source.

One way of applying point pressure would be to use a foam with an egg crate structure, and place the electrodes in the thick sections.

Each electrode could also be loaded with a compression spring with an adequate spring constant.

Using screws to apply point pressure over the electrodes allows the user to set a chosen value for the pressure over each electrode. To avoid screws sticking out through the band, an expandible bolt-and-nut assembly could be used.

Point pressure could also be achieved by a spring loaded button, allowing the user to set the pressure to on or off.

Another textile solution for application of pressure is to make a grid of pockets, into which pads can be inserted to gently push the electrodes closer to the signal source.

6.1.2 The controller box

Partial solutions for different functions of the controller box are presented below.

6.1.2.1 Where to place the box during training

The cables connecting the controller box to the electrodes needs to be kept as short as possible to minimise the noise from other electrical equipment affecting the signals. As users wished to sit further from the computer while training, this calls for a new place to keep the controller box during the neuromuscular rehabilitation sessions.

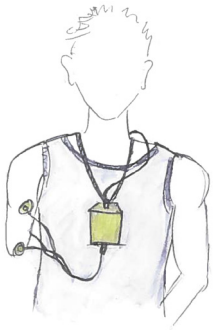

Figure 23. Shows how it can look with the box aound the neck.

To place the box next to the computer - like in the current solution - has the advantage that the dimensions and weight of the box are of less importance. Placing the box on the table may also facilitates physical interaction with it. However, keeping the controller box on the table requires long cables, unless the user sits very close to the computer.

If placed in the neckline or waistband of a garment, the box is always close to the user. However, the cables need to be quite long - especially if the box is worn in the waistband. This solution also requires the user to wear clothes with either a neckline or a waistband while training.

To wear the box around the neck in a necklace (Figure 23) is a way for the user to keep the box within reach, without having to wear any special type of garments. An issue could be that the box can start swinging when the user moves, which might cause frustration.

Figure 24. The box worn on the residual limb with ground electrode in the neck.

If the box is attached directly to the electrode band around the residual limb, the cables can be kept at a minimum length (Figure 24). Depending on the construction of the electrode band and how the box is attached to the band, however, electrodes might not be placed under the surface that is needed for attaching the controller box. The weight of the box might also cause the electrode band to slide down the residual limb if it does not fit very tightly.

6.1.2.2 Fasten the controller box

If the controller box is to be worn on the electrode band, it needs to be securely attached in order to avoid interruptions in the signal conduction and prevent the box from falling off during training.

The box could be attached using velcro, which is easy to use. However, an additional connector is needed for electrical contact to conduct the EMG signals. In order to assure this contact, and avoid misalignment of the box, a guide to show the right the position is necessary.

If the box is placed on the upper edge of the band or along a rail it is necessary to secure the box in some other way as well to ensure that the controller box will not fall of.

A plastic snap (Figure 25) could be used, but it will need a guide to hold the box in the right position.

Figure 25. Plastic snaps hold the box in place.

6.1.2.3 Transfer signals from electrode band to controller box.

To transfer the signals from the band to the controller box, an electrical connector with good contact is needed.

Plug and socket connectors consisting of a male and a female part are well known to users, but take up a lot of space in the box and on the band. They also need to be sufficiently tight to make a good electrical connection.

Snap buttons, which are a standard connector between cables and EMG electrodes, ensure good electrical connection. However, if all 16 contacts (plus one for ground) are to be connected to the box with snap buttons, the box will be too difficult to remove from the band. And it will take up lots of space, which will prevent the band from bending around the arm.

The use of compression contacts used in battery connectors will ensure good connections between the box and the band, as male connectors exert a force toward the female side.

6.1.3 Adapter

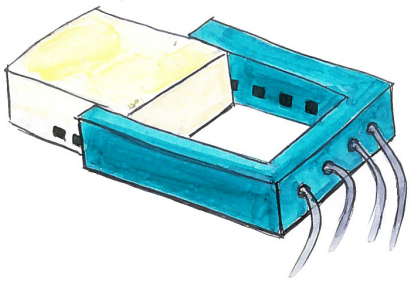

Figure 26. A concept for the adapter to connect flying leads.

Users having problems with signal acquisition due to bad scar tissue, or users with good signals at the most distal end of the residual limb, may benefit from using single use electrodes on so-called flying leads. They can be used either as a complement to the electrodes in the band, or on their own. To make the controller box compatible both with the electrode band and with flying leads, it should be possible to connect cables for extra electrodes in the box or to change the leads in the band. If extra connectors will be used, it is necessary to be able to switch between the ports using a physical switch in the controller box.

To facilitate the setup with single use electrodes only, they could be connected to the controller box via an adapter with pre-mounted cables (Figure 26). With one end of the adapter consisting of 17 cables with conventional press-button connectors, the other end is attached to the ports which the electrode band would otherwise be connected to. This option allows the product to be used like the current prototype, which is the only solution that allows for a fully customisable electrode placement.

6.1.4 The marker

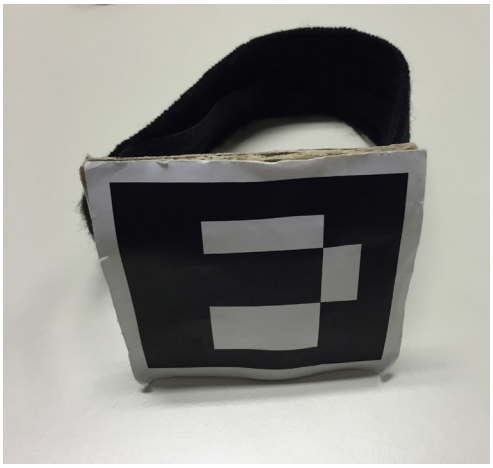

Figure 27. The marker as it is today, with an elastic.

To prevent errors by ensuring that the user does not forget to put on the fiducial marker (Figure 27), the marker could be integrated by printing it on either the controller box or the electrode band.

The fiducial marker currently used is easily damaged, as it is made of a printed image stiffened with a piece of cardboard. One suggestion for how to solve this was to mount or print the marker on the electrode band. In this way, it can always be in the right place and facing the right direction. This will work if the user wears the band on the upper arm, but if the amputation is transradial and the band is worn on the forearm, the fiducial marker will not be seen by the camera.

Depending on which arm the user has lost, different surfaces of the electrode band and controller box will face the webcam. The curvature of the band might also cause problems in recognising the marker. Moreover, if the marker

is printed on the box and it is worn around the neck, the necklace will be targeted as a reference point instead of the arm.

As the possibilities to integrate or attach the marker is depending on - and can easily be adapted to - the chosen concept, it was decided to leave decisions regarding the marker for when a product concept had been selected.

6.2 Initial screening

After the ideation phase, less advantageous partial solutions were eliminated. This also helped to minimise the number of possible concept combinations.

The idea to use prosthetic liners was eliminated, as they would be uncomfortable for transradial amputees and possibly be involuntarily displaced when flexing the elbow. The prosthetic liners could be beneficial for as long as the Neuromotus is distributed via Armprotescentrum, as the liners are individually fitted. However, an off-the-shelf solution must be adjustable to fit more users. Solutions for how to place the electrode band were not used in the morphological matrix, as they would depend on the rest of the design - especially the tightening device.

One eliminated solution for how to customise the electrode placement in the band was by using an abundant grid of electrodes. This concept was eliminated as it would either require physical switches in the controller box or result in too many signals for the system to process.

Putting the electrodes in tracks along the band was also eliminated, as the benefits of the tracks would not be big enough in relation to the number of customised components that the solution was assumed to require. It would also be difficult to apply point pressure over electrodes in tracks.

Using rings on which electrodes would be placed would give a high level of customisability, but the first setup - when the electrodes are put in the right positions - would be a cumbersome task as it would be difficult to map the right positions for the electrodes on the limb onto the modular electrode band.

Using hems with cords that are tightened and locked with a cord lock would only tighten the band right where the hems are. Due to the ineffectiveness of this solution, it was eliminated in the initial screening phase.

Solutions that were not expected to give sufficient point pressure over the electrodes were the egg-crate foam and pockets with pads. Although they may help the electrodes to follow the curvature of the skin on the residual limb, they were not considered to be very efficient. Spring loaded buttons were also eliminated, as they would require too many customised components. Although the expandible screws would also require customised parts, they remained in the morphological matrix as they also gave the benefit of setting the point pressure to an optimal value.

6.3 Concept generation

Combination of partial solutions using a morphological matrix (Appendix XII) resulted in four concepts for the electrode band. Based on these solutions, four concepts for the controller box were generated, with focus on how to attach the box to the electrode band and ensuring a good connection for signal.

At this stage, the different concepts had their own advantages and challenges, fulfilling different requirements to different extents.

6.3.1 Concepts for the electrode band

The concepts for the electrode band are combinations of partial solutions for tightening the band, customising the electrode placement and applying pressure over the electrodes. Combinations that were regarded as infeasible were eliminated in a subsequent screening phase, and a selection was made between combinations that were too alike to reduce the number of combinations. The remaining concepts were refined by identifying and solving for additional challenges.

6.3.1.1 NeuroScrew

NeuroScrew is a concept consisting of a plastic shell lined with an inner layer of foam.

The foam and the cover are perforated in a grid spanning the whole band. In this grid, expandible screw assemblies can be inserted to press the electrodes against the residual limb. The electrode placement is customised by inserting the screws in the best suited holes in the grid (Figure 28).

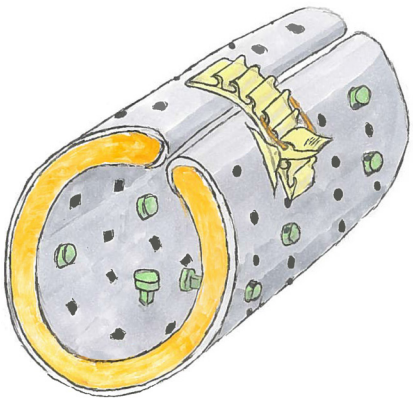

Figure 28. The NeuroScrew.

The assembly consists of a distance nut and a flanged screw (Figure 29). The nut is locked in rotation, and the screw is locked in radial translation so that the distance nut moves along the axis of the screw as the screw rotates. Caution must be taken so that the screws are not made too long, as this would cause them to stick out through the foam and give the electrode band a rough and painful expression. The screws have a flange to prevent the assembly from going through the hard shell of the electrode band. From the outside of the shell, a wing is mounted on the head of the screw for facilitated adjustment of pressure. The wings can be folded down to decrease protruding parts from the electrode band.

The electrodes are attached to the distance nut, and the cables from the electrodes are drawn through a neighboring hole to the one occupied by the screw assembly.

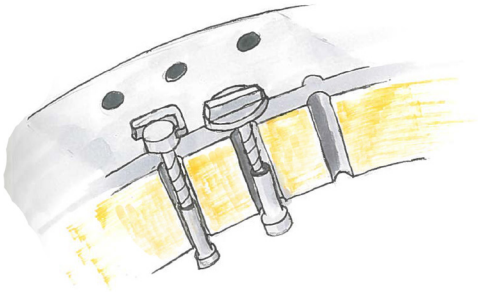

Figure 29. Shows different ways to interact with the screws.

To put on the band, it is slid onto the residual limb and tightened using a pawl and hook mechanism buckle. The buckle ensures a tight fit, but does not allow for a big range of sizes. All the cables from the electrodes are collected into a single place where the controller box will be placed.

6.3.1.2 NeuroFabric

The NeuroFabric concept consists of two layers of fabric padded with a thin layer of foam for comfort and stability (Figure 30).

On the inside surface, the electrodes are fastened using a pin solution (Figure 31). The fine mesh of the fabric makes the electrode placement fully customisable within the area of the band.

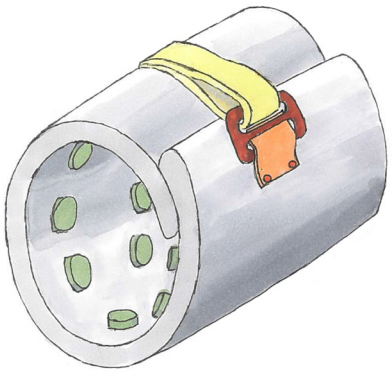

Figure 30. The NeuroFabric solution.

The pins are secured on the inside of the band, between the padding and the inner layer of fabric. From the pin, the cables lead the signals to a collecting point where the controller box is connected.

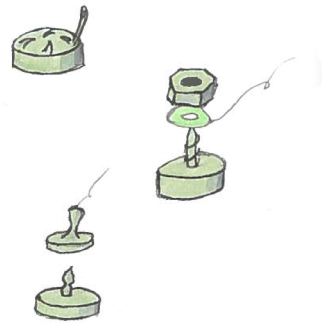

Figure 31. The pin solution for fastening the electrodes.

The band is tightened using velcro straps, allowing for easy manufacturing and intuitive use. One risk with using velcro is that the band can rotate when tightened around the limb, making it difficult to predict the position of the electrodes.

The inner surface of the band is laminated or wax coated so that it can be wiped off with a damp cloth, but due to the electronics inside the band, it still will not be washable.

6.3.1.3 NeuroGo

The NeuroGo is an electrode band with a stiff plastic shell lined with a layer of plastic foam (Figure 32).

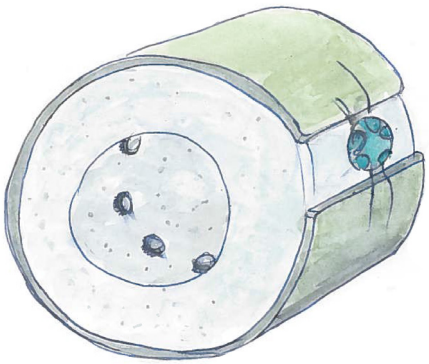

Figure 32. The NeuroGo.

Eight pairs of electrodes are evenly spread along the inner circumference of the band. The electrode placement is not customisable, but the standard array of electrodes will work for most users.

The electrodes are placed in holes in the foam layer, and loaded with compression springs so that the pressure over the electrodes will increase when the band is tightened. The springs allow for muscle contraction when the elbow is flexed and stretched without causing discomfort. Conductors are led through the springs (Fvigure 33), and then on to a gathering point via the interspace between the two layers.

Tightening the band is made easy for one-handed use with the help of a rack and pinion mechanism that can be seen in the neck of bike helmets. A dial is turned to increase or decrease the circumference of the band. When tightening the band, there might be a risk that the springs bend or misalign.

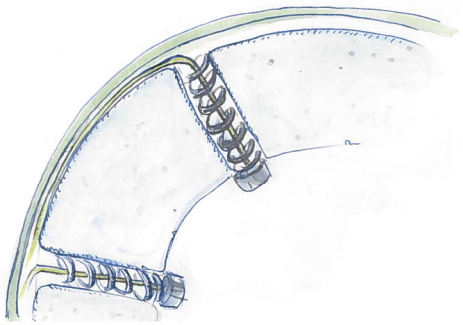

Figure 33. Shows how the cables are drawn through the springs.

The inner layer of foam is not fully covered by the plastic shell, so part of the foam layer will be exposed to the outside when the outer shell is not tightened. To prevent particles from entering the foam layer from the outside, the foam is waxed or laminated with a protective layer. This will also help the covering shell to glide along the foam layer. To fit as many users as possible, the band will need to be made in different sizes.

6.3.1.4 NeuroSpring

NeuroSpring is a concept consisting of sections organised around the circumference of the limb to form a closed band. The parts are interconnected with extension springs, ensuring an even distribution of electrodes as the

circumference of the band increases or decreases. The band can either be made of eight curved funnels (Figure 34), or it can be constructed like an expandible watch band (Figure 35) in order to prevent misalignment of the sections.

If the band is made of funnels, each section is placed in the wide gap of a neighbouring part, so that the segments can slide further into each other to adjust the electrode band to fit a smaller arm size. From the electrodes, placed pairwise on the inside surface of the band, conductors are led through the funnels to a common gathering point, where the controller box is to be attached.

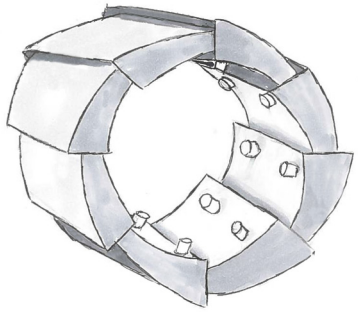

Figure 34. The NeuroSpring made by funnels.

To allow for better contact between the electrodes and the skin, a ladder strap can be added to tighten the band. One end of the strap is firmly attached to the narrowest part of one funnel, and led through the whole circumference of the band until it exits through a buckle on the exterior of the same cone. The electrode band is tightened by pulling the strap further through the buckle.

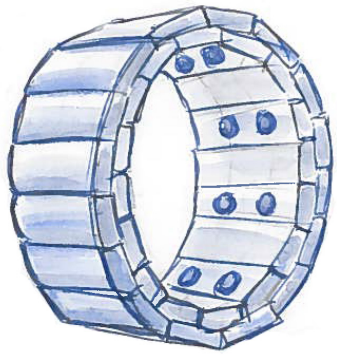

Figure 35. The NeuroSpring made like an expandible wrist watch band.

The band built like an expandible wrist watch band has an outer and an inner set of circumferential segments. The outer segments can slide along tracks in the inner components, on which the electrodes are placed two by two. The band is held tight by springs or spring loaded metal sheets in each and everyone of the segments. The electrodes are placed in pairs on eight of the inner segments, and the cables are led in a zigzag pattern between the outer and the inner segments (Figure 36) to where the controller box is placed on one of the outer segments.

6.3.2 Concepts for the controller box

The concepts for the controller box need to be compatible both with the electrode band and adhesive electrodes. Therefore, all the concepts have ports for connection of extra electrodes on the top surface in case additional electrodes need to be placed outside the reach of the electrode band. On this surface, there is also a port for the ground cable.

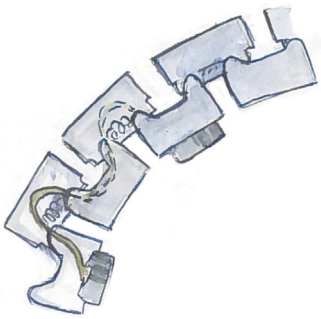

Figure 36. How the cables could go in the wrist watch band concept.

The controller box might also be used without using the electrode band at all, which means that it should be possible to detach the box from the band. Removing the box also facilitates charging and replacement of batteries, and makes it possible to replace either the box or the band in case one of the parts fail.

For use of the controller box without the electrode band, an adapter can be used. This adapter is further described after the four concepts for attachment of the controller box.

6.3.2.1 RecessMotus

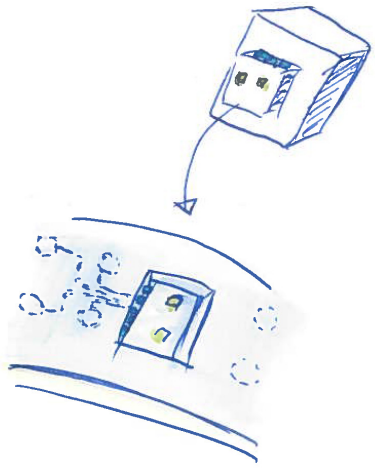

Figure 37. The RecessMotus.

RecessMotus is a concept for the controller box compatible with NeuroGo and NeuroSpring. A bulge on the back of the controller box matches a recess in the electrode band, in which it is placed (Figure 37). Spring loaded battery contacts will help to keep the box in place and transmit the signals from the electrode band to the controller box. An additional fastening mechanism, such as a plastic male-female fastener, may be needed to hold the weight of the controller box.

A wider contact surface will improve the ability to hold up the weight of the box, but it will also impede the curvature of the electrode band. A trade-off will need to be made between these two factors.

6.3.2.2 ClipMotus

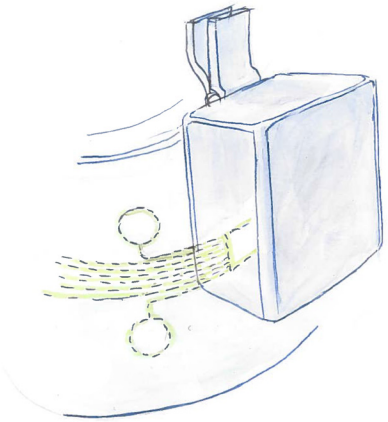

Figure 38. The ClipMotus.

ClipMotus follows the design of the NeuroScrew electrode band. Since the heads of the screws for applying point pressure over the electrodes stick through the outer shell of the band, the surface space for attaching the controller box is limited. The concept is also compatible with NeuroFabric and NeuroGo, as well as the expandible watch band version of NeuroSpring.

Attaching the controller box with a torsion spring clip mechanism is one way of minimising the required contact surface. The clip works like a clothes peg, where the controller box serves as one side of the clip, and the complementary back part is as thin as possible (Figure 38). If used without the electrode band, the box can be attached to the neckline of a vest or to the waistband of a skirt or a pair of trousers.

The back of the clip is slid into a track in the shell of the electrode band and pushes thin compression connectors on the electrode band against those of the controller box. To reduce the risk of incorrect placement of the clip, a bulge is assigned to the controller box and a matching recess to the electrode band.

6.3.2.3 SqueezeMotus

SqueezeMotus is a fastening concept where the electrode band is equipped with two hinged arms, which can snap into holes in the upper and lower edges of the controller box (Figure 39). This fastening minimises the interference with the curvature of the electrode band, as the back surface of the box will be tangent to it. As the concept requires a hard shell to attach to, it is compatible with all the concepts for the electrode band except for NeuroFabric.

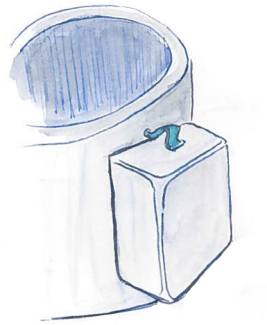

Figure 39. SqueezeMotus mounted on a band.

The fastening can be complemented with a plug and socket connector, which will help to hold up the weight of the controller box. Otherwise, compression connectors can be used in the contact surface to avoid building thickness on the band.

6.3.2.4 PermaMotus

PermaMotus is simply a concept where the controller box is mounted onto the electrode band with screws, allowing for secure attachment and good contact between the box and the band (Figure 40). As the box is difficult to attach and remove, this solution can only be used under the presumption that the user will rarely need to take it off the electrode band. The concept requires an electrode band with a flat surface for attachment, and is thus compatible with NeuroFabric and NeuroSpring.

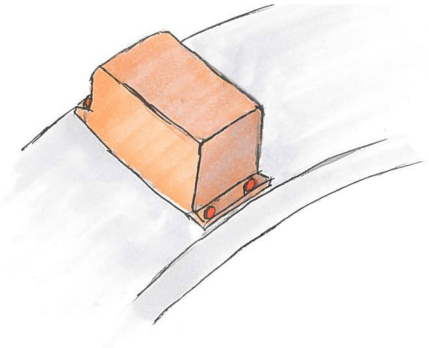

Figure 40. PermaMotus mounted on a band.

6.3.2.5 Adapter

If the electrode band cannot be used, or if some electrodes need to be placed outside the band, an adapter can be used for easy connection of so-called flying leads (Figure 41). The adapter is attached to the controller box with the same connectors used between the electrode band and the controller box. When using the adapter on the controller box, the box could be worn in a band around the neck, or in the neckline or a waistband of a garment.

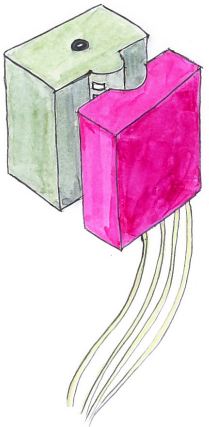

Figure 41. An adapter mounted on a controller box.

6.4 Concept evaluation matrix

Although simple, the colour coded evaluation matrix (Tabel 3) used to compare the different electrode bands was an effective way of illustrating their level of performance.

	NeuroGo	NeuroFabric	NeuroSpring	NeuroScrew
Handlability	Green	Yellow	Green	Yellow
Adjustable size	Red	Yellow	Green	Red
Comfort	Green	Green	Yellow	Red
Durability	Yellow	Green	Yellow	Yellow
Cleanability	Yellow	Yellow	Red	Yellow
Application of point pressure	Yellow	Red	Red	Green
Customisable electrode placement	Red	Green	Red	Green
Manufacturability	Yellow	Green	Red	Yellow

Table 3. Concept evautation matrix

6.4.1 Evaluation of the concepts for the band

Below follows the concept for the band with identified strengths and challenges.

6.4.1.1 NeuroScrew

Figure 42. The NeuroScrew mock-up is tested.

The greatest advantages of the NeuroScrew concept are the possibility to apply point pressure and to set its level, as well as the customisable electrode placement. On the other hand, the holes in which the screws were placed provided an entryway for dirt and made the electrode band difficult to clean. Durability, manufacturability and handleability were rated "yellow", as they were not particularly well solved for but still acceptable.

The biggest drawbacks of the concept was the small range of sizes it would fit and the discomfort it was believed to cause when pressure is applied (Figure 42).

6.4.1.2 NeuroFabric

Figure 43. The mock-up of NeuroFabric.

The number of green cells in the second column shows that the NeuroFabric concept has a lot of advantages over the other concepts - especially regarding comfort, manufacturability, durability and possibility to customise the electrode placement. The fabric follows the shape of the residual limb, and is soft against the skin. The fabric allows for good durability as it does not snap in the same way that hard plastic might when exposed to bending forces. Since the fabric itself is a fine mesh where electrodes can be pinned in place the electrode positioning is highly customisable.

As the signals are conducted to the controller box with the help of cables, the fabric cannot be washed, but needs to be waxed so that the surface can be wiped clean. The concept scored high in manufacturability as it requires no molds or special equipment to be manufactured. The exception is

the electrodes themselves, which have a custom pin design. These were, however, not believed to be very complicated, and they would also be manufactured in a relatively large quantity.

One of the weaker points of the NeuroFabric concept is the handleability. It is difficult to put it in the right position to close the band, and tightening the band with the velcro straps results in a rotation around the arm. The velcro also limitates the possibilities to adjust the band to different sizes.

The main drawback of the concept is the lack of point pressure. The NeuroFabric mock-up is pictured in figure 43.

6.4.1.3 NeuroGo

The greatest benefits of the NeuroGo concept (Figure 44) are the comfort and handleability of the electrode band. Although the springs provide point pressure, they also give way for the muscle belly when the muscle contracts. The point pressure is assumed to be sufficient for good signal acquisition, but there is need for validation.

Figure 44. NeuroGo is tested to se what it feels like to wear.

The product is easily ready to use thanks to the default electrode array. This also reduces the importance of placing the band in a certain position and makes it suitable for users with "strong signals". However, the handleability is achieved at the expense of customisability. There is a risk that users with a lot of scar tissue, for example, would need to use a number of additional single use electrodes in order to acquire the signals needed to perform the exercise.

The durability of the concept is assumed to be good enough for daily use, but its life time and manufacturability are estimated to be low compared to the NeuroFabric concept because of the plastic components which may fail. In order to wipe the foam layer clean, it would need to be laminated or sewn into a fabric pocket. There is a remaining risk, however, that dirt finds its way in behind the electrodes and into the springs.

The main drawback of the NeuroGo is that it only fits a small interval of sizes.

6.4.1.4 NeuroSpring

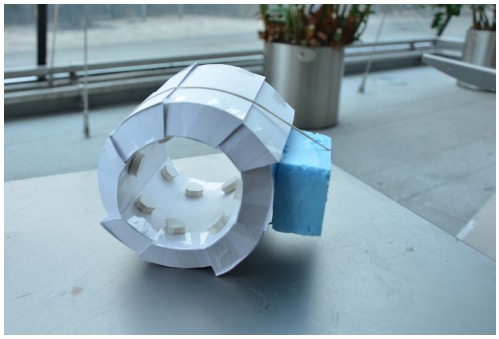

Figure 45. NeuroSpring with a box.

NeuroSpring (Figure 45) got high scores for handleability as it automatically adjusts to the size of the limb on which it is used. The eight pairs of electrodes will remain evenly spaced regardless of the size of the residual limb.

The division of the band into segments causes problems in terms of manufacturability and cleanability. The complex geometry requires a special mould and small tolerances, and dirt easily finds it way into the gaps between the sections. The comfort and durability of the concept are also affected by the segmented design. The spring connections between the sections also brought on a risk for pinching. The thin walls of the sections and the numerous springs were also a concern regarding durability, as there are many components that might break.

The lack of pressure over the electrodes and customisable electrode placement were two other drawbacks. All in all, the concept had many drawbacks compared to its advantages.

Another big challenge of the NeuroSpring concept is the risk for pinching and for dust getting inside the segments. However, the biggest challenge is the manufacturability.

6.4.2 Evaluation of the controller box concepts

The identified strengths and challenges of the concepts for the controller box are presented below.

6.4.2.1 RecessMotus

RecessMotus is an intuitive concept to use, and is easy to handle as the controller box can simply be pushed onto the electrode band for attachment. However, there are difficulties in making the box allow for the curvature of the electrode band while allowing for secure fastening.

6.4.2.2 ClipMotus

The biggest strength of the ClipMotus concept is that it requires little contact surface while giving good electrical connection. On the other hand, the clip must be placed in a precise position, and requires strong hands to be opened.

6.4.2.3 SqueezeMotus

The biggest strength of the SqueezeMotus concept is that it requires no protruding parts on the controller box. The challenges are to secure the fastening and to improve the handleability with one hand.

6.4.2.4 PermaMotus

The strengths of the PermaMotus concept are the secure fastening and the minimised need for interaction. The concept should only be used if it is assumed that the user would rarely need to detach and attach the controller box.

6.5 Concept selection

The concept selection was made with help from the the meeting held with Integrum and supervisors from Chalmers halfway through the project.

The general opinion from Integrum was that a combination of NeuroGo and NeuroScrew would yield the most suitable concept for the electrode band. Either screws or springs were suggested for applying pressure on the electrodes, and their placement was to be made customisable with a grid of holes. It was also suggested that adjacent holes in the grid would be interconnected in quadrants using conductive paint, where each quadrant could only be assigned with one electrode. The entire grid could be divided into colour coded sections for different muscles of the upper arm to help the user customise the electrode band. Another suggestion was that the electrode band would be delivered using a default electrode setup likely to suit as many users as possible, making customisation optional.

To mount the electrodes, the inner layer of foam and the outer plastic shell would need to be kept separable. To avoid bulging folds in the foam, foam-free sections were suggested. These need to match surfaces of the arm where no EMG signals are acquired. One concern expressed about the perforated foam was that electrode gel might find its way into the holes for the electrodes, and also into the pores of the foam. To minimise the risk for electrode gel entering the pores, the foam might be laminated or covered in a material that can be wiped off. Suggested advantages with the grid was that it might be used to attach the fiducial marker, and

that it would allow for good ventilation. Another opinion was that the grid gave the product a futuristic expression, resembling mesh material being used in sports equipment.

Screws were preferred to be used over springs since the pressure could be set to a chosen value. Countersunk or flat screw heads give a nicer surface to the electrode band, and make it possible to place the controller box over holes where electrodes are being used.

The use of springs for application of pressure would be supported if the obtained solution was not too complicated. To help users achieve the most adequate pressure over the electrodes, a suggested solution was to let users choose between different spring constants. Another idea was to use high density foam instead of springs.

The size adjustment dial was preferred for tightening the electrode band, since it is easy to use with one hand, and minimises the risk of the band gliding around the arm when being tightened. An important requirement given by Integrum was that the band must be closed so that it can easily be slid onto the arm and then tightened. It should, however, be possible to open the band fully to allow the user to customise the electrode pattern.

For the controller box magnetic connectors were requested, while a spring loaded mechanism (the RecessMotus concept) could be an alternative. The possibility to add an adapter with pre-mounted cables directly onto the controller box was a welcomed idea.

The two concepts NeuroFabric and NeuroSpring were both eliminated because of the lack of point pressure. This was mainly the issue for NeuroFabric, which was otherwise thought to be the best suited in terms of manufacturability and comfort. NeuroSpring was essentially excluded for the many issues that were left to solve, and because it would be both difficult and expensive to manufacture in small series.

6.5.1 Evaluation using the personas

After the mid project discussion, the concepts were also checked against the personas. An identified issue for Agda would be if the controller box contained magnets, as it could interfere with her pacemaker if worn around the neck. She might also think that NeuroScrew is too complicated to

handle, because of all the small tuning devices for adjusting point pressure. Agda also might not have strong enough hands to open the ClipMotus.

On the other hand, using magnets would be an intuitive way of attaching the controller box which Karin would like. Karin would not be particularly fond of the NeuroScrew concept, because of the uncomfortable feeling of the screws against the skin, and the time consuming tuning of the point pressure. She might like the NeuroGo, on the other hand, which is easily ready to use.

Karl would presumably like the NeuroSpring because of the technical solution. His attitude towards the NeuroScrew concept may not be as skeptical as Karin and Agda, but he would not like the idea of wearing it for a very long time.

07 CONCEPT REFINEMENT

After the mid project discussion, many decisions remained to be taken before a final concept emerged. After studying and refining partial solutions for the electrode band and the controller box one by one, they were evaluated against each other to aid the selection of features for the final concept. Important evaluation criteria were chosen from the target specification.

The concept refinement was done in an iterative design-build-test cycle, and the target specification has been updated and edited throughout the process. The final target specification is found in Appendix XIII, and the requirements for the electrode band and the controller box are summarised under their respective sections. The features of the concept were not developed in the order in which they are presented below. The first part of this section describes the concept refinement process for the electrode band, and the second part describes the selection of features for the controller box.

7.1 The electrode band

The purpose of developing an electrode band is to reduce the time for the electrode placement and allow for placement of electrodes in the same positions time after time. In order for the electrodes to be placed in the right positions, the electrode band should allow for a customisation of the array of electrodes in the band.

It is important that the electrode band allows for handling with only one hand, both when worn around the residual limb and when taken off. The electrode band should not be subjected to any involuntary displacement along or around

the residual limb during training or when tightened. While assuring a tight fit, the electrode band should also be made in a way so that it fits as many users as possible.

The chosen method to improve signal acquisition in users with scar tissue is to apply point pressure over the electrodes to push them closer to the signal source. This should be done without causing the user pain. The outer shell of the electrode band is also of importance, as it must withstand the pressure of the chosen solution for pressure application.

An important function of the electrode band is to house conductors from electrodes to the connector where the controller box is attached. The conductors need to be kept as short as possible to reduce the impact of noise on the signals.

On the electrode band, the controller box and the fiducial marker are also to be placed. The controller box needs to be detachable for facilitated battery charging, but needs to be tightly connected in order to retain sufficient contact during the training session. The fiducial marker also needs to be detachable, so that it can be moved to the desired position on the band, depending on which arm the product is used.

To optimise the durability of the product and reduce the use of materials by being able to replace one component at a time, one important requirement is that it should be easy to separate the components of the electrode band. This also allows for facilitated separation of materials at the product's end of life and enables recycling to optimise the waste management. Allowing the user to clean the product not only improves the durability, but also allows for better hygiene.

An important factor for keeping the costs for manufacturing the electrode band at a minimum is to minimise both the need for custom made components and the number of different components. This is especially important since the first batch will only consist of 10-50 units.

7.1.1 Optimising the size range

To minimise the number of sizes that need to be manufactured, the electrode band should span the biggest size range possible while still ensuring a tight fit. One important idea that needed to be investigated after the mid project discussion was to divide the band in sections, while

the size adjustment device and the lining are also important factors affecting the size range. The range of sizes that needs to be covered is estimated to 18-30 cm in circumference. (Caine-Winterberger, K., 2015 pers. comm. 2015-04-13).

7.1.2 Choosing between a modular or an undivided electrode band

After the mid project discussion, the request from Integrum was to create a modular concept, constructed in sections which could be added to or removed from the band to adjust the size. This would increase the size range of the band to avoid making it in different sizes.

7.1.2.1 Dividing the band in sections

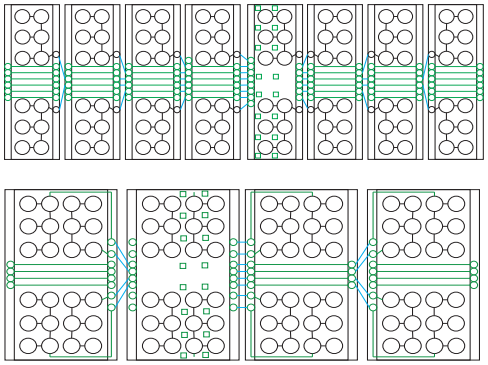

Figure 46. The two pictures show how much of the band can actually be used to place electrodes.

The idea of constructing the band in sections was tested through prototyping. The sections were connected to each other using hinges. One discovery from the prototyping phase was that much of the space that could be used for attaching electrodes was lost to the gaps and the connections between the sections (Figure 46).

If the signals from the electrodes to the controller box were to be conducted with a printed circuit, cables are needed anyway to transfer the signals over the gaps between the sections. In order to insert additional sections, the cables between the segments would need to be removable and able connect to the new ones.

An expert in polymer materials was consulted regarding the manufacturing possibilities for the different concepts. The hinged sections would need to be injection moulded, which implies that a large number of units need to be produced and sold to pay back the investment for the injection mould (Boldizar, A., 2015 pers. comm. 2015-03-26).

7.1.2.2 Making the band in different sizes

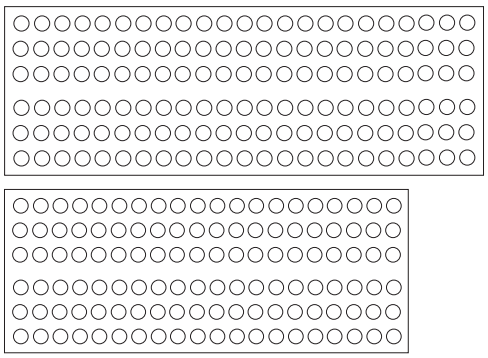

Figure 47. The grid of holes for two different sizes.

If made in one piece, the plastic shell could be extruded as a profile or cut from a sheet and thermoformed. Both these methods are considerably cheaper than injection moulding. Holes in the plastic shell could be either drilled or milled. These operations imply some additional costs, and they would also preferably be made on a flat surface - namely before the shell is thermoformed. Manufacturing the product in different sizes (Figure 47) also increases the total

manufacturing cost, but the sum is still expected to be less than for the injection moulded solution. (Boldizar, A., 2015 pers. comm. 2015-03-26)

7.1.2.3 Selected feature for the final concept

To back up the decision between the two different options, they were evaluated and compared relative each other using a Kesselring matrix, where the option of manufacturing the band in different sizes got the highest score. (Appendix XIV). The decision taken was to continue with this option, mainly due to lower manufacturing costs and better customisability of the electrode placement. The chosen concept leads to a decreased number of components which may fail, and allows for a minimalist expression.

As the electrode band is to be made in different sizes, the largest acceptable gap between the ends of the band had to be established. No electrodes can be placed in the gap, so a bigger gap decreases the possibilities of placing electrodes around the full circumference of the band. The largest acceptable gap was estimated to about 30 mm, if it is placed on the inside of the arm where no signals are acquired from the biceps or triceps.

7.1.3 Buckle and size adjustment

Two important product requirements affecting the solution for size adjustment and tightening of the band are that the device should be easy to use with one hand and that it should not cause any involuntary rotation around the arm (Figure 48). The only solution presented in the mid project discussion that fulfilled these requirements was the rack and pinion mechanism commonly used in bike helmets, where tightening and opening of the band is achieved by turning a dial to rotate the rack.

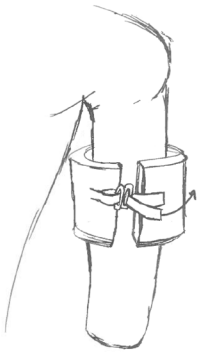

Figure 48. If the velcro is pulled to tighten the band, there is a risk that the band will rotate.

7.1.3.1 Size adjustment dial

In the design-build-test cycle it was found that the rack and pinion mechanism of the size adjustment device was too weak to withstand the circumferential pulling forces. After fully tightening the band, the forces would pull on the racks in each direction, causing the rack to skip teeth of the pinion.

7.1.3.2 Searching for a new solution

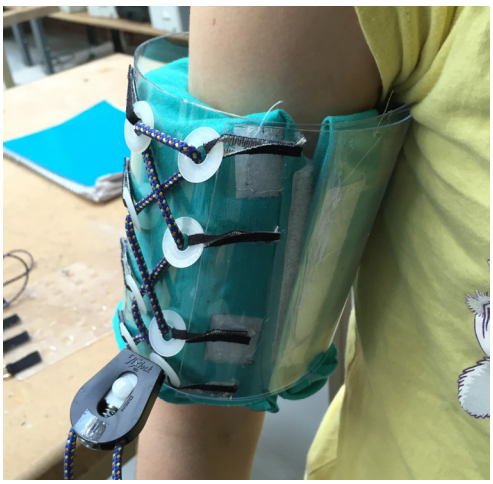

Figure 49. The string lacing in a prototype.

After the rack and pinion mechanism had been ruled out, a new idea generation cycle started, with brainstorming, sketching and searching for commercially available solutions.

The idea of using a string laced through rings on the edges of the band (Figure 49) came to mind, and cord locks were investigated as a possibility to keep the lacing tight. The idea with using lacing was to minimise rotational displacement of the electrode band while tightening it, as the laces can be pulled in any direction to decrease the circumference of the band.

The design-build-test cycle resulted in a concept where metal rings are attached to the ends of the electrode band. The rings are aligned (Figure 50) with their centre point on a common axis to minimise the contact surface and friction between the rings and the cord, allowing for facilitated tightening of the electrode band.

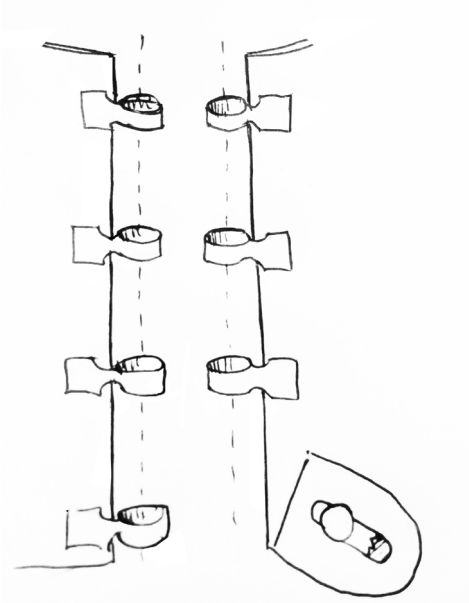

Figure 50. The orientaions of the holes to the cord.

A spring loaded cord lock (Figure 51) is used to make the lacing self-locking. The cord lock consists of a house, in which a toothed cord stopper is attached to one of the walls. The ends of the string go through the canal created between the inner walls of the house and the cord stopper, which provides friction and prevents the cord to pull up back through the canal. The cord lock is firmly attached to the plastic shell so that the user does not need to hold it in place when tightening the lacing.

7.1.3.3 Material selection for the final concept

Figure 51. 3D printed cord lock with a nylon string.

A nylon rope with a diameter of at least 4 mm is recommended so the user can easily grab it. The length of the string depends on the size of the residual limb.

The cord lock can either be bought from a supplier or 3D printed for the first batch, and the material selection will depend on what is available. Preferably, the cord lock is manufactured in the same plastic as the shell of the electrode band.

7.1.4 Compressible lining

Throughout the development process, a foam material had been considered for lining the electrode band. However, any compressible material could be used for this purpose, and so the search for a suitable material was widened. The purpose of the compressible lining is to allow the electrode band to follow the contours of the residual limb to allow for good contact between the electrodes and the skin, especially when placed over an area of the residual limb with a variable diameter. The compressible properties also allow for a certain extent of size adjustment as the inner radius of the band increases as the material is compressed. An important function of the lining is to provide space for screws or springs for applying point pressure on the electrodes, and therefore it needs to be perforated. The components for point pressure are placed in the holes and kept in place by the surrounding material.

7.1.4.1 Plastic foam

Lining the band with plastic foam gives the product the sought features, and as plastic foam is elastic to some extent it can be used within a somewhat larger size interval than a stiff material. Plastic foam can be cut and perforated using laser or waterjet cutting. (Boldizar, 2015) In a bare layer of foam, however, the pores are exposed to fluids and dirt - and with time, the material is expected to wear out by coming off in pieces. To protect against incoming particles and increase the durability of the lining, it would need to be covered in a layer of fabric that can easily be wiped off with a damp cloth.

One way to protect the foam would be to sew a pocket around it. In order for the foam to follow the elastic deformation of the fabric, they would need to be sewn together. This might cause the foam to rupture at the seam and also makes it difficult to separate the materials.

Laminating foam with fabric retains the elastic properties of the foam as long as the fabric laminated onto it is also elastic. However, only the front and back surfaces can be laminated in the same process. To protect the edges, they would need to be provided with a trim by sewing in the foam.

Additional issues were detected for using foam. One was that plastic foam dries very slowly after being washed, meaning that the rehabilitation system will not always be easily

ready to use. Another issue is that plastic foam is generally inflammable, and often treated with fire retardants. Plastic foam is not very breathable and hence not a pleasant material to wear while training. On the other hand, this promotes the production of sweat, which is an excellent electrolyte.

7.1.4.2 3D Spacer fabric

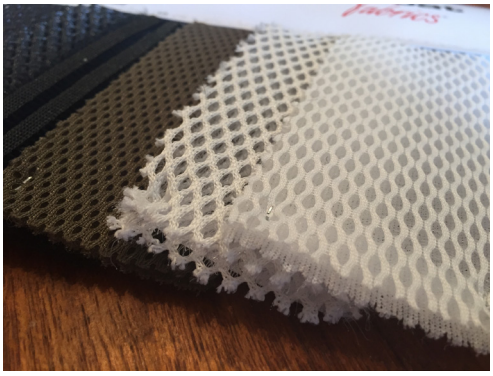

Figure 52. Some different 3D Spacer fabrics.

When consulting Siw Eriksson from The Swedish School of Textiles (Eriksson, S., 2015 pers. comm., 2015-04-27), the use of a polyester 3D spacer material (Figure 52) was recommended. This material is a structure with woven outer surfaces, joined by a compressible layer of spacing strands. Advantages of using the 3D spacer include improved breathability, short drying time and better comfort. There is also a range of possibilities for the outer surfaces of the material, allowing for properties such as elasticity and different densities of the woven mesh. The spacer fibres can also be made of other materials, such as polyamide (Baltex, 2015) and polypropylene (Culzean, 2015).

With a finely knit inner surface on the lining, better prevention from dirt is obtained. The spacer material is also better suited for sewing than plastic foam, and as the whole product can be made in one material, there is no need to separate the lining for recycling at the end-of-life. Laser cutting is commonly used to bond edges of most woven fabric to prevent fraying, (Steen and Kamalu, 1983) and can be used to create the grid of holes for the customisable electrode placement.

7.1.4.3 Material selection for the final concept

Due to the many advantages of the 3D spacer fabric, it was chosen for lining the electrode band. To allow for separation of the components in the electrode band, the lining must be easy to remove from the shell. It was decided to attach the lining with velcro, as it allows for secure fastening, easy removal and helps to keep the total thickness of the electrode band down.

To reduce the amount of material and optimise the waste management, it was decided to use a 3D spacer lining made in one material throughout. A material that can be used both for the woven surfaces and the spacing strands is polyester.

The density of the strands in the woven surfaces affects the comfort and hygiene aspects of the lining. A finer weave gives a nicer feeling against the skin, while a coarse polyester weave tends to itch. A fine weave also better prevents the entrance of dirt inside the lining.

Another important decision was to determine the thickness of the lining. Prototypes with plastic foam of varying thickness had been tested, leading to the conclusion that the thickest lining acceptable would be 20 mm. A thicker lining than 20 mm gives the product a bulky expression and can be uncomfortable to wear with the residual limb hanging relaxed by the side. On the one hand, a thicker lining will allow for more compression, and a bigger difference in limb circumference. 3D Spacer fabric thicker than 8 mm has not been tested, due to the materials available, but it is assumed that the lining needs to be thicker to better hold the electrodes in place.

When asking Integrum about colour preferences for the product, the obtained answer was black. Depending on the retailer, there may be a risk that the desired 3D Spacer fabric is only available in white unless it is custom made. A white lining may, however, can be of advantage for hygienic reasons as it allows for better detection of dirt. A white lining also makes it possible to draw marks in the grid of holes, which can facilitate the process of customising the electrode placement or make it possible to track earlier used electrode placements.

To give the product a more ready-made expression and avoid sharp edges, a trim can be sewn around the edges of the lining pad. A contrasting trim in the colour of the Neuromotus logotype refers back to the trade mark and adds a pop of colour to the product. In the hem, labels designating up and down on the lining can be sewn or added. Being able tell which side of the lining is up and down is of help when customising the electrode placement.

7.1.4.4 Further investigation of features for the lining

Further decisions needed to be made on how the lining would be placed inside the shell of the electrode band. One idea was to connect the ends of the lining to make a tube. A closed tube allows for placement of electrodes along the full circumference of the limb - but it also needs to allow

for a large elastic deformation to fit a wider range of sizes. Another problem with a closed tube is that it makes it harder to place electrodes in the grid of holes when customising the electrode placement.

Another idea was to equip the lining with a strap of velcro or with a fabric flap that can overlap the opposite edge to create a tube. The tube will thus have a variable circumference depending on the overlap. It is easier for the user to put the electrodes in the right positions in the grid if the lining can be flattened out, to minimise the risk of electrodes falling out before attaching the lining inside the shell.

However, the extra length gained by choosing a small overlap and a large circumference is not usable for electrode placement anyway. The excessive use of fabric and velcro also increases the number of manufacturing operations, builds thickness in the band and increases the risk of chafing the skin of the user.

A third investigated solution was to insert a plastic tongue under the lacing to close the gap between the ends of the electrode band. The idea of the tongue is to allow the user to fasten the ends of the lining to velcro on the inside of the tongue to create a tube of the desired size. This allows for a larger range of sizes, although the unlined distance of the tube will not be usable for electrode placement. The tongue makes it possible to place electrodes along the whole lining, and also protects the user from chafing and pinching caused by the lacing.

When prototyping the solution with the tongue, it was discovered that the outer shell could not glide along the tongue when tightening the band, as the lining needs to be attached with velcro to both parts. Instead, undesirable bulges formed in the lining. It was concluded that the gap between the ends of the electrode band is in evitable, and thus the range of sizes will mainly depend on the compressibility of the lining.

7.1.5 Allowing for customisable electrode placement

Customisable electrode placement was stated as a requirement from Integrum early on in the project, and a necessity to acquire sufficiently strong EMG signals from any user regardless of scarring and amputation level. However,

a default array of 16 electrodes (plus one for ground) placed pairwise in eight columns would work for most users (Ortiz-Catalan, M., 2015, pers. comm., 2015-01-27).

A drawback with a customisable electrode grid is that a much larger amount of holes for the electrodes must be made in the lining, out of which only 16 holes (plus one for ground) will be used. The empty holes provide an entryway for dirt and moist into the lining.

Problems may also arise when the electrode placement is done the first time. The user must, with or without the help of a professional, map the sites where muscle movement has been detected on the residual limb onto the grid of holes in the electrode band. The electrodes must then be positioned in the holes along with the springs and connected to the collecting site where the signals are conducted to the controller box. Ideally, this procedure would only need to be made once. The procedure may need to be repeated, however, since the muscle fibres grow as an effect of the training and it can be hard to find the correct electrode placement in the first attempt.

Using a fixed array would mean that critical users with problematic signal acquisition would need to use single use adhesive electrodes for locations of muscle signals outside the electrode grid. This would increase the setup time considerably for each training session, and could also require physical switches in the circuit boards. The consumption of single use electrodes also increases the product's environmental impact during the use phase.

Because of the importance of correct electrode placement for the signal acquisition, customisable electrode placement scored higher than fixed electrode placement in the Kesselring matrix used to support the decision (Appendix XV). When considering the users' motivation to train, it was also regarded a bigger drawback for critical users to spend time and single use electrodes before each session than to reorganise the electrode array when it is needed.

7.1.5.1 Organisation of the grid of holes

For larger amounts of holes in the grid, better resolution for customising the electrode placement is obtained. How closely spaced the electrodes could be was limited by the risk of signals from adjacent electrodes affecting each other (cross-

talk). After consulting Integrum the minimum distance between the centres of the electrodes was established to 20 mm. (Ortiz-Catalan, M., 2015, pers. comm., 2015-03-20)

The distance 20 mm was used both between each row and each column of the grid, to prevent use errors by making it impossible to place electrodes too close to each other even if two adjacent holes are used. Having decided on this distance, the circumference and width of the band determine the number of possible locations for the electrodes. Therefore, a larger size of the electrode band gives better resolution in the circumferential direction, and better possibilities to place an electrode in the ideal position. A wider band will increase the possibilities for placing an electrode in the band, but the width of the electrode band is also limited, as some amputees have a very short residual limb. It was estimated that six rows of holes would result in an electrode band that suits most users while giving an acceptable level of customisability.

7.1.6 Application of pressure over the electrodes

Two different concepts for application of point pressure remained after the mid project discussion meeting - one being the expandible screw assembly, and other one being the compression spring solution.

7.1.6.1 Screws or springs

Common for the two alternative solutions for application of point pressure is that they are inserted in the grid of holes in the lining material. While the screw assembly allows the user to set the pressure to a desired value, the compression springs adapt to the shape of the residual limb and gives moderate point pressure without causing pain.

7.1.6.2 Expandible screw assembly

The screw assembly (Figure 53) consists of two parts: one screw equipped with a flange under the head to prevent it from radial translation, and a distance nut (Figure 54) which needs to be custom made in order to fit the application. The bottom of the nut is dome shaped and works as the electrode. The idea of the dome shape is to eliminate any sharp edges, and can be added while the nut needs to be custom made in any case. This is not a required feature, however.

Figure 53. Mock-up of an expandible screw. The right part is the distance nut, which is locked in rotation.

The rest of the nut has a square section, making it possible to lock in rotation with the help of a matching hole in a stiff rib inserted in the lining. On the side of the nut, another flange is added to prevent the nut from passing through the rib locking it in rotation.

A threaded section needs to be added on the top of the nut for secure locking of a cable shoe. The full assembly is made of stainless steel to allow for easy signal transmission from the skin to the cable.

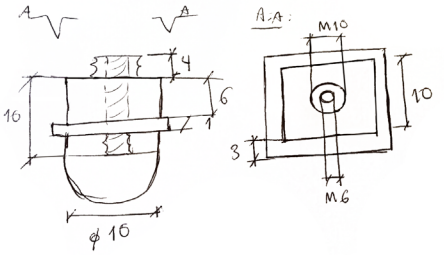

Figure 54. The nut that needed to be manufactured.

Needing to add a rib to each column of the grid of holes - regardless of whether the holes in the column are used or not - is a big disadvantage in terms of manufacturing and assembly of the product.

The expanding screw assembly cannot be screwed in place in the outer band, as the assembly could thus be turned loose when adjusting the pressure over the electrodes. One alternative would be to custom make a solution to snap the assembly in place in the shell. Another solution would be to let the assembly be kept in place by nothing else but the two layers of hard plastic and lining.

One issue detected for the screw solution is the need for a perforated outer shell. As the lining and the shell of the electrode band should follow the shape of the arm when worn, but need to be opened and separated for customisation of the electrode placement, it could be cumbersome to align the holes of the two layers when inserting the lining in the shell due to the difference in circumference between the lining and the shell.

The greatest advantage of expandible screws is the possibility to easily adjust the length of the screw assembly, and thus the level of point pressure over the electrodes. However, the constant point pressure over the electrodes causes great discomfort for users with sensitive skin or when the muscles of the residual limb contract.

7.1.6.3 Compression springs

The compression spring (Figure 55) was developed into a spring assembly working like a damper, where a telescoping tube assembly stabilises a compression spring coiled

Figure 55. A simple mock-up for the compression spring.

around it. This assembly requires small tolerances when manufacturing, as the space for the total spring assembly is limited to the size of the hole in the lining.

The electrode is soldered onto the free end of the thinnest tube, while the end of the assembly is equipped with threads so the spring assembly can be attached to shell of the electrode band. The signal can be conducted from the electrode through the walls of the tubes or the springs themselves, presuming that they are made in a conductive material. The signal could also be transferred using fine cables fitted into the thinnest tube.

The spring assembly can be mounted to the hard plastic shell by screwing the threaded end into a threaded hole in the shell, or it can be secured with a cap nut on the outside of the shell. Having holes in the outer shell causes the same alignment problem that was identified for the screw assembly.

Both the damper and the expandible screw will have a limited range of compressibility. The damper will very likely have a shorter range than the screw assembly, however.

7.1.6.4 Selected feature for the final concept

With theoretical reasoning as a background, a Kesselring matrix (Appendix XVI) was used to score the alternative concepts for application. Due to the complicated design of the screw assembly and the need to add rigid ribs inside the lining, it was decided to go for the spring solution.

Figure 56. Electrodes made for 8 mm liner.

The stabilising telescopic tubes were later eliminated to facilitate manufacturing, reduce the number of parts and amount of material, and increase the compression rate of the spring. It is also easier to customise the electrode placement if the springs do not need to be secured in the shell.

On the side (Figure 56) closest to the skin, the electrode is mounted. On the other end, a washer is attached to prevent the spring from passing through the hole in the lining when inserted. The risk for bending the springs is kept at a minimum by choosing a spring with a larger diameter which is not too long. The simplified solution also allows for the use of standard springs in the electrode band, which allows the user to choose the desired level of pressure over the electrodes by choosing between different spring constants.

7.1.7 Choice of material for the shell

The function of the shell is to stabilise the band and help pushing the electrodes in towards the signal source. To withstand the reaction forces on the electrodes, a stiff material is desirable. Until this point in the project, a stiff thermoplastic had been assumed, but after a request to widen the search for materials, two more options were added.

Three materials discussed for the shell were inelastic fabric, neoprene foam and a stiff thermoplastic.

7.1.7.1 Stiff fabric

Fabric is a suitable material for prototyping and cost efficient manufacturing. Despite its inelasticity, however, it will give away a bit to the reaction forces from the electrodes. This will cause the springs or screws to bulge out, giving a bubbly appearance and reducing the point pressure over the electrodes.

Using a fabric shell could also be problematic when attaching the controller box, as it is difficult to find a fabric that will not sag when attaching the controller box to it. The fabric shell could be equipped with a pocket in which the controller box is kept during training, but there would still be a limitation to how much weight the solution can handle without drooping. A pocket would also make it hard for the user to see when the box is properly connected to the band.

7.1.7.2 Neoprene foam

During a meeting at Integrum, a suggestion was given to use neoprene (Figure 57) or high density foam for the outer layer of the electrode band. As the neoprene foam is slightly elastic, it could also allow for an increased size interval. However, it is hard to find a material that is elastic enough to flex when putting it on, yet inelastic enough to retain its shape when subjected to the forces applied with screws or springs.

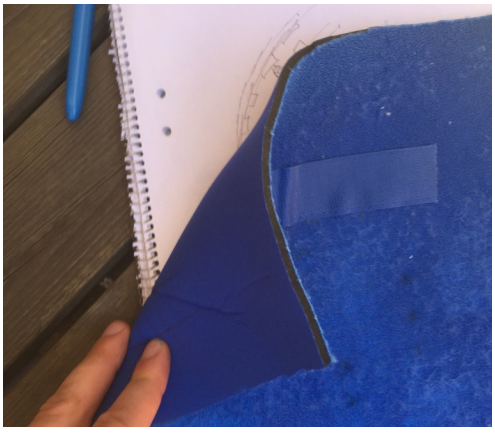

Figure 57. Neoprene foam.

7.1.7.3 Thermoplastic

A hard plastic shell will ensure efficient application of pressure over the electrodes, as the material will not undergo any discernible deformation. The simplest solution to obtain the desired shape of the shell is by cutting it out from a sheet and thermoforming it.

7.1.7.4 Selected feature for the final concept

To allow for efficient application of point pressure and secure attachment of the controller box, it was decided to use a thermoformed plastic shell. The shell can be made in black, and the up and down sides of the shell should be clearly labelled to facilitate the process of customising the electrode placement.

The shell of the electrode band needs to be thermoformed in order to keep its curvature and thus make it easier to wear and tighten the electrode band.

7.1.8 Transfer of signals from the electrodes to the controller box

At the mid project discussion, a printed conductive pattern was requested as an alternative to cables to lead the signals to the collecting point. Cables are an alternative to using a conductive print.

7.1.8.1 Conductive print

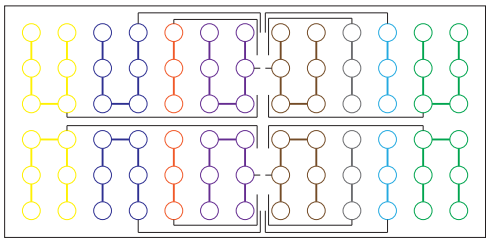

Figure 58. A pattern that could be used for drawing the paint from the electrodes to the box.

A plastic film with a printed circuit was also presented at a meeting with representatives from Integrum. The idea of the conductive pattern is to interconnect holes within sections of the grid of holes, where only one hole of each section can be used at a time. A common conductive track for all the holes within each section would then be used to transport the signals to the controller box.

Using a printed circuit would reduce the thickness and tangle that cables might cause. However, it would also decrease the customisability (Figure 58) of the electrode array and cause a risk for use errors by placing more than one electrode within a section.

7.1.8.2 Cables

The use of cables does not rule out the risk for use errors. As the EMG signals are processed as a difference in voltage between two electrodes paired together as a positive and a negative, it is important that the assigned pairs of cables for each electrode pair are not separated or mixed up. One way to minimise the risk for use errors is to colour code the cables, and designate whether the cable carries a positive or

negative signal with a red or black contact. One drawback of using cables is that they cause cumbersome troubleshooting if they break at some point.

Some strengths with the cables is that it is easy to use flying leads, by connecting them instead for the electrode, and then pull the cable out between the liner and the outer shell. It will also give bigger opportunity to customise the placement of the electrode, though the position is not bound to a printed grid. Cables are also easier to separate when the product has reached the end of its use.

7.1.8.3 Selected feature for the final concept

Cables were preferred over the conductive print supported by the Kesselring matrix (Appendix XVII) to retain a high level of customisability, as this allows the grid of holes to be used without being restricted to a certain section. By detaching the end of the cable that is attached to the electrode, and instead connect a cable with a press button connector, single use electrodes can be mounted on the skin outside the reach of the electrode band.

7.2 The controller box

A desired feature for the controller box is that it is kept as small and lightweight as possible, while housing circuit boards for signal processing as well as the battery. The controller box needs to allow for use both with and without the electrode band. Using the box without the electrode band is facilitated by an adapter with press-button cables which can be attached to single use electrodes.

The controller box can be switched on and off before and after the training sessions, so the user must be able to see when it is ready to use and when it is not. The box should also allow for indication of the battery level, so it is easy to see when it is time to connect the charger.

7.2.1 Outer dimensions

As the electronics inside the controller box are still under development, no detailed decisions could be taken about the design of the controller box. During a meeting at Integrum (2015-04-09), the current solution for the circuit boards and power supply were presented. The electronics consisted of

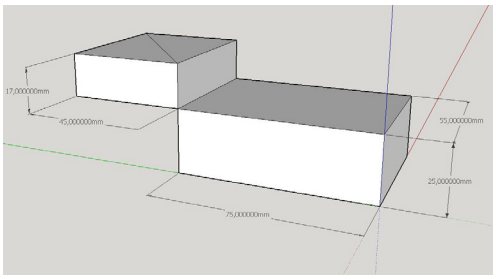

Figure 59. Information about how the circuit boards will be placed. Info from Integrum.

three circuit boards and one battery, which would need to be taken out of the box for charging. Altogether, the circuit boards and the battery would weigh 397g (57g + 340g). The circuit boards measure about 40 x 40 mm each and together build a height of 38 mm, and will be placed acordning to figuer 59. The project team at Integrum are currently working on finding a smaller and lighter battery which lasts for the whole training session. A way to charge the battery without having to take it out from the box is also under implementation.

If a smaller and lighter battery is found, two of the circuit boards could be stacked on top of each other with the third board placed over the battery. This allows for a thinner controller box with a centre of gravity close to the user, which keeps the moment from the box at a minimum.

Due to the uncertainties regarding the electronics of the controller box, two different cases have been investigated. The first case assumes a smaller controller box no bigger than 120 x 50 x 40 mm, and no heavier than 200 grams. The target dimensions for the circuit boards given by Integrum at the beginning of the project were 70 x 40 x 30 mm. The second case assumes a larger and heavier box, which cannot be worn on the electrode band, as it will both be uncomfortable to use and rotate around the arm through displacement of soft tissues.

7.2.1.1 Recommendations for a small controller box

If the controller box can be made small and lightweight, it can be used on the electrode band as planned, held in place by magnetic connectors. The connectors on the band are placed in the axial direction so that they do not interfere with the curvature of the band. The magnets on the electrode band attach to metallic surfaces on the back side of the controller box to avoid magnets placed over the heart when worn around the neck.

7.2.1.2 Recommendations for a larger controller box

If the box is too big or too heavy to be attached on the electrode band, it is recommended to let the user wear it around the neck. A multi signal shielded cable transfers the signals from the collecting site in the electrode band to a

port in the controller box. The cable can be connected to the electrode band using the same connector that would be used to attach a smaller box, so that when the box can be made small and light enough a new band does not need to be made.

7.2.2 Attachment of the controller box

At the mid project discussion meeting, magnetic connectors were requested to attach the controller box on the band. However, other possibilities were also investigated. Securing the box on the band using a track and placing the controller box in a pocket were two alternative solutions discussed. In order not to interfere with the curvature of the electrode band, the area of the surface that can be used to attach the controller box is restricted.

7.2.2.1 Magnetic contacts

Magnetic connectors are an effective way of keeping the controller box in place, and also help the user to align the box correctly when attaching it. If the controller box is heavy, magnetic plug and socket connectors can be used to help holding up the weight of the box. Otherwise, the magnets would need to be very strong, causing difficulties for the user to remove the box from the band. The magnets could also attract other metallic objects.

There is also a risk in using magnets for users with a pacemaker, if the magnets are placed right over the heart. Thus, magnets must only be placed on the electrode band, as they will be on a safe distance when placed on the arm. They must not be placed on the controller box, however, in case a user with a pacemaker should wear the box around the neck.

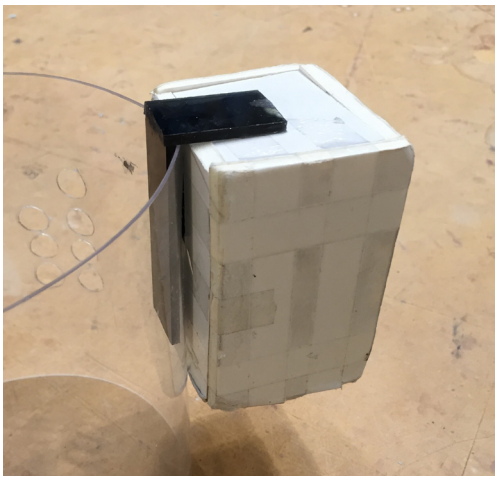

Figure 60. Shows a box mounted with a track

7.2.2.2 Track

The controller box can also be attached on the upper edge of the electrode band by mounting a hard clip on the controller box, which is inserted into a track (Figure 60 and 61) in the plastic shell of the band. With the help of gravity the box will be positioned in the right position in the track.

Compression contacts lined up vertically along the band, allow the box conductively connected in the same sliding movement that the clip is inserted in the track. There is a risk that the box might not be sufficiently secured, and could fall out of the track while the user performs the training.

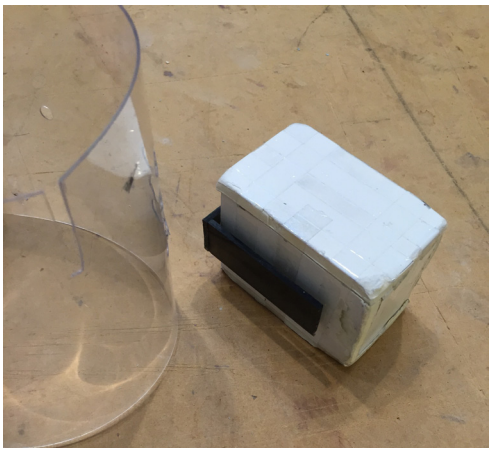

Figure 61. The track which the box is mounted on can be seen on the left.

7.2.2.3 Pocket

Figure 62. The pocket to put the controller box in.

If a fabric had been used as the outer shell of the electrode band, or if a layer of fabric is laminated onto the plastic shell, the controller box could be placed in a pocket (Figure 62) assigned with a lid to prevent the box from falling out. If the box is to be placed in a pocket, the easiest way to ensure electrical contact would be to connect cables from the band into the controller box prior to placing the box in the pocket.

7.2.2.4 Selected feature for the final concept

Even though there is a risk with using magnets if the user has a pacemaker, they will be chosen for the attachment of the controller box on the band, due to its easy-to-use self-aligning properties. Small surface connectors placed in two columns of eight connectors, plus one connector for the ground signal, gives a narrow contact surface between the electrode band and the controller box and does not interfere with the curvature of the band. To prevent use errors, alignment screws are added to constrain the controller box to upright direction.

If the magnets of the surface connectors are not enough to hold up the weight of the box, magnetic plug and socket connectors may help to keep the box in place.

7.2.3 User interaction with the controller box

Regardless of how the box is worn, the button for turning it on or off should be placed on the top surface where it will always be visible for the user. The button itself can be equipped with light emitting diodes to show the system state.

When the system is first turned on, a green diode starts flashing to show that the system has been turned on, but a steady connection with the computer has not yet been established. Once the connection is stabilised, the diode starts shining with a steady light. To turn the controller box off, the same button is pressed once more.

If the connection with the computer is not found or is lost, the button can be pressed again to reconnect.

A red diode lights up when it is time to recharge the battery. To charge the battery, the contact can be placed on the side of the box for easy access and connection to the battery. This diode should be placed close to the interaction surface for battery charging.

7.2.4 The fiducial marker

The fiducial marker is made of hard plastic, with a matte surface to prevent glare. It mainly consists of a simple print with high contrast, and has the dimensions 74x74 mm. A magnet keeps the marker in place on the electrode band, where it can be kept between training sessions. By attaching magnets on a number of selected spots in the electrode band, the user can choose the point of attachment to achieve the best angle possible for detection by the webcam.

The fiducial marker must also be usable without the electrode band, if the controller box is worn around the neck and single use electrodes are used. For this application, the marker can be attached to an elastic band, which can be opened and closed to avoid having to pull it over the cables that run from the electrodes to the controller box.

08 FINAL CONCEPT

In the beginning of this section, the features of the final concept are described and compared to the metrics in the target specification. The full comparison is found in Appendix XVIII, where the a column for the achieved values is added to the target specification for the final concept.

To evaluate the usability of the developed product, a theoretical evaluation was made for the setup and a usability test was conducted for the customisation process. The results from these analyses are found in the end of the chapter.

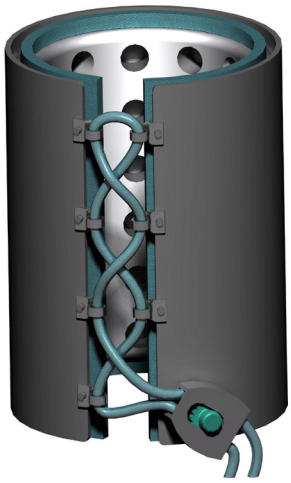

Figure 63. Shows the lacing and the cord lock.

8.1 The electrode band

The electrode band consists of two major parts: the outer thermoformed plastic shell and the inner 3D Spacer lining(Figure 63). Without the cables, the electrode band weighs 120 g, where the ideal weight for the electrode band was set to a maximum of 150 g. The electrode band would fit in a box with the dimensions 130 x 150 x 150 mm, which was the marginal value aimed for.

The shell is 2 mm thick, which is thin enough to adapt to the curvature of the residual limb, yet allows it to withstand the pressure from the compression springs attached to the electrodes.

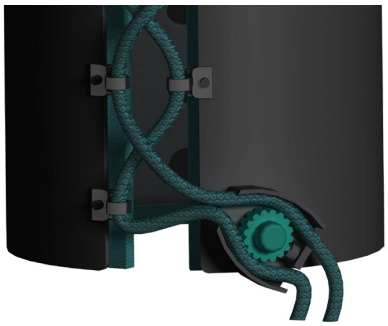

Figure 64. The self locking cord lock.

The shell is assigned with seven metal rings and a spring loaded cord lock for the lacing used to adjust the size of the band. As the string can be pulled out through the rings and removed, the electrode band can be fully opened for easier detachment of the lining and facilitated customisation of the electrode placement.

The string is laced like a shoe, with the ends running through a self locking cord lock (Figure 64). As the ends can be pulled in any direction, the band can be tightened without applying force in the circumferential direction. To loosen the band, the cord stopper is pulled to compress the spring and clear

the way for the string. This allows for easy size adjustment with one hand, and minimises the risk of involuntary displacement around the residual limb. The main drawback of the tightening device is that it may chafe or pinch the skin of the user. While the device is not expected to be very painful, it causes discomfort. It was therefore subjectively rated as being "acceptable", but calls for improvement.

A 20 mm thick 3D Spacer lining (Figure 65) is attached to the shell with velcro. A grid of laser cut holes is used for insertion of spring loaded electrodes in desired positions. The centres of the holes are spaced at an interval of 20 mm, resulting in a density of 25 possible electrode positions per square decimeter. This is far from the ideal value, which would be four times as high.

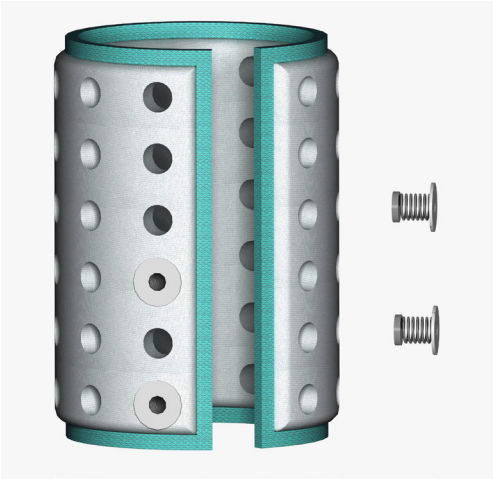

Figure 65. The 3D Specer lining of the band with two electrodes.

The compressible features of the lining, along with the spring-loaded electrodes, allow the electrode band to follow the shape of the limb so that all electrodes are in contact with the skin. The thickness is assumed to decrease by about 75%, and the circumference of the band can be expected to increase by at least 30 mm from the compression of the lining. In combination with an acceptable gap of approximately 30 mm between the ends of the band, the circumference of the band has a span of 60 mm in circumference. The electrode band does thus not need to be manufactured in more than three sizes to cover the size range 180-300 mm. The ideal size range was to cover the full range of 120 mm in one size, while the marginal value was set to 30 mm.

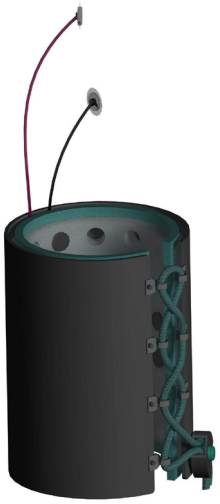

Figure 66. The external electrodes dran

In the interspace between the shell and the lining, shielded cables conduct the signal of each electrode to the connector on which the controller box is attached. The end of the cables, to which the electrodes are attached, can be exchanged with cables with a press button connector for use with single use electrodes. This allows the user to place single use electrodes on parts of the residual limb that are not covered by the band (Figure 66). For use with the electrodes in the band, the cables do not need to be longer than 160 mm for the smallest size of the electrode band.

Eight differently coloured cable pairs are made, and the polarity of each cable is shown with a red or white connector. The colour coding minimises the risk of mixing up the signals from the different electrode pairs. The colours of the cables should be easy to tell apart. Suggestions for the colours of the cables are given in Appendix XIX.

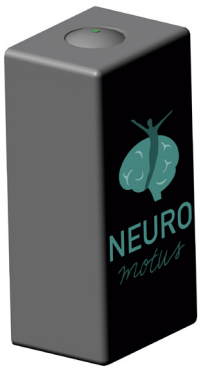

Figure 67. The controller box with the on and of button.

Figure 68. The contacts, which are magnetic to keep the box mounted on the band.

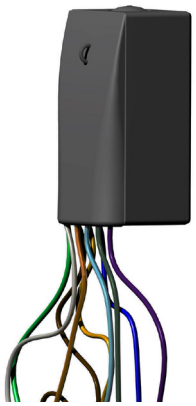

Figure 69. The controller box mounted on the adapter

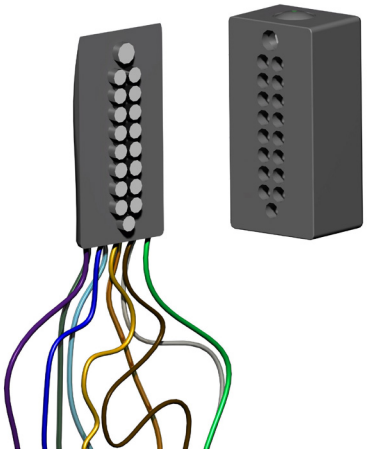

Figure 70. The controller box and the adapter showing the same contact that is on the band.

Each of the 17 electrodes is soldered to one end of a compression spring. The opposite end of the spring is soldered onto a washer, which prevents the electrode assembly to go through the lining by having a larger diameter than the holes in the grid. The spring pushes the electrodes toward the user's skin but gives away when a muscle is contracted, allowing for pain free application of pressure. The electrodes are 10 mm in diameter and can just pass through the holes in the lining. The springs have a slightly smaller outer diameter, and are 20 mm long to match the thickness of the lining. Any standard washer with an outer diameter of at least 15 mm can be used.

8.2 Controller box

If the controller (Figure 67) box can be made small enough, it is mounted on the band (Figure 68). Otherwise, it is worn around the neck in an adapter (Figure 69 and 70). Regardless of its size, it can also be worn around the neck for use with single use electrodes only. As long as the the controller box is only made in small batches, it can be 3D printed.

The controller box is attached to the electrode band with the help of magnetic connectors. Indication of system state and remaining battery level is ensured by light emitting diodes close to the power button and battery socket respectively.

8.3 The fiducial marker

The fiducial marker is made more durable by printing the pattern on a 74 x 74 mm square of matte plastic. The matte surface prevents glare to make it easier detectable by the webcam.

The marker is equipped with a piece of metal and can be attached on spots in the electrode band where magnets are inserted in the shell. This allows the marker to be placed in a suitable angle to the camera.

For use without the electrode band, the marker can be attached to an elastic band, which can be opened and closed with velcro. This allows the fiducial marker to be easily slid onto the residual limb, yet the band can be opened if the marker is forgotten and does not have to be pulled over the cables from the electrodes.

8.4 Evaluation of the final concept

The usability of the final concept was evaluated through an HTA and a PHEA of the setup procedure performed before each session. The customisation process was evaluated through a usability test.

8.4.1 HTA of the final concept

A new HTA (Appendix XX) was made to see how many steps of the setup procedure had been eliminated through the development of the product. The HTA covers the whole training process, but focuses on the setup and closedown, where the main tasks are preparing the skin, putting the electrode band on, attaching the controller box, removing the band and detaching the box.

What is seen directly when comparing the HTA of the final concept to the the analysis of the current product (Appendix VI) is that the total number of tasks for the setup before each training session has decreased. On the other hand, this has resulted in a more time consuming initial setup, when the electrodes are placed in the desired positions in the electrode band.

Some of the tasks of the setup are impossible to eliminate, such as removing any clothes covering the residual limb, and cleaning the skin where electrodes are to be placed. The only tasks added to the setup are to placing the band and tightening it around the residual limb.

8.4.2 PHEA of the final concept

The new PHEA (Appendix XXI) is based on the HTA made for the final concept. One finding of the PHEA is that many potential use errors identified for the current product (Appendix VII) have been eliminated through the development of the electrode band.

One example is the fiducial marker, which can be left on the electrode band between sessions, so that the user does not have to think about attaching it. If the marker has been detached, it is simply attached with a magnet in the electrode band. Hence, the consequences of the use error are much

smaller than for the marker attached to an elastic loop, which has to be pulled over the cables between the electrodes and the amplifier if forgotten.

Two use errors eliminated for the general setup procedure - placing electrodes in the wrong positions and mixing up the cables for the electrodes. There is still, however, a risk that these errors occur during the customisation of the electrode placement in the first setup. Recovering these use errors made during the first setup requires the user to disassemble the electrode band.

Just like the strap currently used to apply pressure over the electrodes, the electrode band can be tightened too tight or too loose, which may result in either discomfort, insufficient signal readings or that it moves. This error is difficult to eliminate, however, and easy to recover.

Another potential error is placing the electrode band in the wrong angle or too far medially or distally on the limb. This will result in all electrodes in the electrode band ending up in the wrong positions.

8.4.3 Usability test

The instructions given how the costumization should be done can be found in Appendix XXII.

One common problem discovered during the usability test was to keep track of up and down and inside and outside of the nylon tube, the lining and the plastic shell. Several participants did not note the labels on the lining and the shell, while other users spent a long time figuring out which side would be up and down, as well as what side would be turned inwards and outwards. Some users were also confused about the different components and mistook the lining for the nylon tube. These problems could have been avoided with the help of an illustrated manual or an instruction video showing the customisation process.

Some users had problems lacing the tightening device (Figure 71). The lacing could also be facilitated with an illustration in the instructions. The cord lock detached from the shell in the first test, and was not tested in the following four tests.

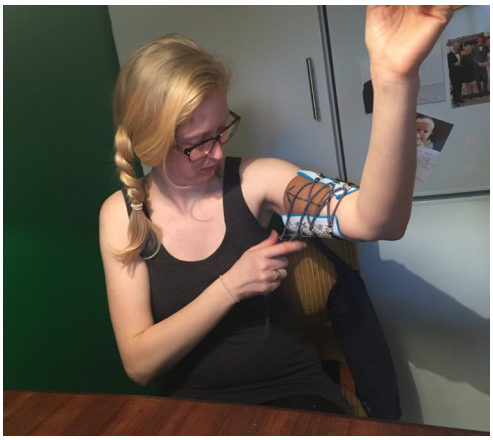

Figure 71. One user does the usability test, that hade some problem with the lacing and tightening.

Another problem was the use of an elastic tube. In order to correctly transfer the marks onto the lining, the nylon would need to be stretched out over the lining in exactly the same way that it was stretched around the arm. When the nylon contracted or was stretched out either insufficiently or too far, the electrodes ended up in the wrong relation to each other. The idea of using an elastic material was that it would hold itself in place on the arm. However, as it distorted the electrode pattern, it would be better to use an inelastic sheer fabric.

One user deliberately did not follow the instructions given, but tied the lining of the electrode band around the arm, marking the best suited holes for the electrodes with a pen directly on the lining. This user was also the only participant in the usability test who placed all the electrodes in the correct positions.

Another user, who confused the nylon tube with the lining, did almost the same thing - only it was done unintentionally. This user held the lining in place with one hand, and inserted electrodes in the holes with the other hand.

Only one user managed to put all electrodes in the correct positions of the grid. Three users placed six out of eight electrodes in the correct spots, and one user only managed to place two electrodes in the desired positions. It is believed that the elastic nylon tube may have caused distortion in the mapping of the electrode placement onto the grid in the lining. Another reason why the mapping went wrong was the difficulties to find the markings through the grid of holes in the lining pad, as well as keeping track of up and down and inside and outside of the nylon. The resolution of the grid may also have caused some electrodes to end up in the wrong position.

Because of design changes made to the electrode band shortly before the usability test, the lining was too big for the plastic shell. The incomplete prototype caused some problems listed separately in the protocol from the usability test. The notes taken down from the usability tests can be found in Appendix XXIII.

Figure 72. The final concept with electrodes placed afer customisation.

8.4.3.1 Customisation of the electrode placement

Finding the correct positions for the electrodes is a difficult task, and so the electrode band is delivered assembled with a default array of two rows with eight electrodes, plus one electrode for ground. In this way, the product will work for most users, and the customisation (Figure 72) only needs to be done if the user wishes to optimise the signal reading.

If the product is distributed via Armprotescentrum, an occupational therapist can help to perform the task of customising the electrode placement. If the product is sold directly to the primary user - via the internet for example - clear instructions must be given for the customisation process.

To facilitate the mapping of the positions on the skin where electrodes are wanted, the electrode band is delivered with a piece of thin fabric with velcro sewn on the edges. After the usability test, it was decided that an inelastic fabric would be used to avoid any distortion of the relation between the electrodes in the array. The velcro allows the fabric to be used multiple times, by marking out the electrode positions with different colours if repeating the customisation process. By connecting the velcro edges, a closed tube is obtained which matches the size of the electrode band. Indications for up and down - as well as inside and outside - of the tube are needed to avoid confusion.

The tube is placed around the residual limb so that the velcro runs along the inside of the limb when the arm hangs relaxed to the side of the body. The desired positions of the electrodes can be located through the thin fabric either through palpation or by first marking the positions with a pen. The positions for all eight electrode pairs are marked on the tube.

The tube is opened and the fabric laid flat with the outside facing upwards. The 3D spacer lining is laid flat on top of the thin fabric with the velcro side facing up. The spring loaded electrodes are placed in the holes of the grid that are closest to the markings on the thin fabric. The electrodes are paired so that the cables running from the electrodes in each pair have the same colour.

The cables from the electrodes are connected to the cables of matching colours running from the collecting point on the inside of the plastic shell. The shell is then attached to the lining, and the assembly is finished by lacing the string through the metal rings on the plastic shell and securing it with the cord lock.

If the desired positions of the electrodes are marked on the skin - either with stickers or by marking them with a pen - the lining can also be placed around the limb and held in place with elastic to allow the user to insert electrodes directly in the lining or marking the best suited holes on the lining pad. If inserting electrodes in the lining while it is worn around the residual limb, however, there is a risk that they fall out of the grid.

9 Discussion

This chapter discusses the process and outcome of the project, as well as recommendations for continued development of the product.

9.1 Process

This part discusses the conduction of the project work, and focuses on the data collection and concept development stages.

9.1.1 Data collection

The process took a quick start by conducting observational studies and by interviewing both primary and secondary users. Unfortunately, these observations and interviews were the only contact with the primary users. Integrum could not present more participants from the clinical studies, and no interest organisations for potential users answered the attempts to contact them. This made it a lot harder to understand what phantom limb pain is like and how it affects the daily life of the users and their motivation to train. The observations and the interviews were all conducted at either Integrum or Armprotescentrum, and there was always a third party present who may have affected the answers of the users.

To study a training session in the home of a user, where it is supposed to take place in the future, would have been rewarding. Due to the difficulties in finding users, especially primary users who had experience of training with the Neuromotus, the opinions of the interviewed users carry a lot of weight. As the product has only been used at home by one user, routines evolved around it could not be studied. Needs that arise in the transition to home training were largely based on guesses about where and how often the product would be used in the home. Furthermore, the participants in the study can be seen as early adopters of the product,

and may not have the same needs as users who embrace new technology later. To elicit more user needs for the product, more users would need to try the product at home.

The lack of users also affected the outcome of the survey, where only three replies were obtained from users. It was realised afterwards that some of the questions were hard to understand for users with little technical knowledge of the product. This may have affected their weighting of some functions.

The lack of primary users called for the invention of fictive personas and use scenarios. Although they gave new perspectives on using the Neuromotus as a child or a senior, the scenarios were inspired by what had been seen during the observational studies. The PHEA conducted for the current product was also influenced by errors observed during the user studies. If the Neuromotus hardware had been tested by the project members personally, a better understanding of the product, potential use errors and their consequences would have been gained.

The secondary user, who works as an occupational therapist at Armprotescentrum, has been an important source of information throughout the project. The secondary user has followed all the participants of the observational study conducted in Gothenburg, and has seen both strengths and weaknesses of the product and how they have affected different users.

Data regarding the sizes of residual limbs was a missing piece of information that would have been of use in the development process. Data on both amputation levels and residual limb circumference was needed for validation of the size interval that the product would need to cover. No anthropometric data regarding amputees was found in literature, and neither Integrum nor Armprotescentrum had any data to share. The most likely size range which the product needed to cover was established by looking at sizes available for prosthetic liners and asking the secondary user at Integrum for an estimation about the size range of her patients.

9.1.2 Concept development

The concept refinement phase was characterised by an iterative design-build-test cycle. Building and testing prototypes was limited by the possibilities to manufacture

custom made parts, and some ideas could not be tested in a physical prototype. Ideas that could have been used for the final concept may have been lost due to being difficult to prototype and validate.

Although physical prototypes were tested, they lacked important functionality by not being connected to the Neuromotus system. Requirements regarding the contact between the electrodes and the skin surface thus had to be tested by looking at marks left by the prototype on the skin, rather than measuring the strength of acquired EMG signals.

User involvement in the concept development phase would have been a good way to elicit more customer needs by meeting the users' response to the concepts under development. As the primary users were not available for meetings, the occupational therapist at Armprotescentrum was consulted to collect user feedback. Although the secondary user was able to make estimations about how suggested concepts would be received, it would have been beneficial to gather primary and secondary user for a focus group meeting to give them a chance to react to and discuss different product concepts. Users' opinions are also important for validation of subjective values such as comfort and expression.

The concept development phase would also have been favoured by conducting the work at Integrum as it was intended. This would have given the project team more time to get familiar with the Neuromotus system and allow for a more integrated design process. For example, decisions taken in the design process or in the development of the electronic components could have been reported and discussed directly, and better understanding for product requirements had been gained both by the thesis project members and Integrum.

9.2 Final concept

The final concept fulfills the most important requirements of the product, and facilitates the electrode placement before each training session. The developed electrode band does not only decrease the time required for the setup, but also reduces the number of steps. The biggest benefit is that the user only needs to locate the best positions for the electrodes in the initial customisation process, instead of having to detect sites for muscle movement before each training session.

It is hard to validate the fulfilment of some requirements, however, as a functioning prototype is needed for evaluation. The fulfilment of some requirements have been evaluated through theoretical reasoning.

One challenge in the project has been to create an electrode band that will fit as many users as possible, both in terms of size and electrode placement.

9.2.1 Size adjustment

As no data has been found about length and circumference of the residual limb, the required size range that needs to be covered has been estimated with the help of an occupational therapist at Armprotescentrum. Since it was requested that the product should be able to be distributed both via rehabilitation centres and via the internet, the product needs to be manufactured in three sizes to cover a range from 180 mm to 300 mm in circumference. Children's sizes are not covered by this interval. If the product had been distributed only via rehabilitation centres to start with, the product could be fitted for different sizes in orthopaedic workshops.

Little has been decided by Integrum about the intended number of units for the first batch, as well as the intended distribution channels for the product. As the aim has been changing, the development process has had to take new turns to make the product cost efficient for small scale manufacturing. The most cost efficient solution for producing 20 to 50 units, may be to adapt the design manufacturing and assembly in orthopaedic workshops. Taking distribution into account, this would also have been the most efficient solution for the Swedish market, as the product is assumed to be given to users at Armprotescentrum.

9.2.2 Customisation of the electrode placement

If sold without an intermediary trained in the customisation process, the default array of electrodes can be used by non-critical users. Users with difficulties acquiring sufficient signal readings with the standard array need to customise the electrode placement in the grid in the lining. This may be done as described earlier in the report, but if the product is sold for instance via the internet, clear instructions must be

given on how the customisation is carried out both via words and pictures or video. The customisation process could also be difficult to carry out using only one hand.

There is a large risk that many users will have to use a number of flying leads to place electrodes on the most distal end of the residual limb. Single use electrodes may also be needed to cover a longer section of the residual limb, as the width of the electrode band is limited to 130 mm. The width of the band is based on estimations for what width would give an acceptable number of holes in each column of the grid and how short the residual limb may be while it would still be considered worthwhile to use the electrode band. Since no data was found on amputees' arm lengths and amputation levels, however, there are no measurements that back up this decision.

The distance between the holes in the grid in the lining was established to prevent use errors by making it impossible to place electrodes too close to eachother. The resolution could be increased by reducing the distance between the holes, but placing electrodes in adjacent holes could lead to cross-talk. To decrease the distance between the holes, the diameter of each hole may also need to be smaller. This, in turn, requires a smaller electrode size for insertion of the electrodes in the holes, or else the electrodes would need to be attached to the compression springs by the user after both parts have been put in place.

9.2.3 Application of point pressure

Another important point for discussion is whether application of point pressure over the electrodes is the best solution for improved signal acquisition. Experts in the field of biosignal acquisition who were consulted agreed in part that point pressure may benefit by making the electrode better follow the shape of uneven skin, promote sweating or helping the electrode to stay in the same position by friction force. Another way to improve the contact between the electrode and the skin could be to use a textile electrode with a rugged surface. Sweating could also be promoted using alternative methods, or electrode gel could be applied as an electrolyte. Silicone rings around the electrodes could help them to stay in place when the skin of the residual limb and the electrode band move in relation to each other.

The compression springs attached to each electrode may prevent the electrode band from sliding around or along the residual limb, as well as promoting the production of sweat. The theory of pushing fat and skin aside to improve signal reading needs validation, however. It is therefore questionable whether the benefits of applying point pressure over the electrodes justify the discomfort it causes. Even if the signal readings are improved, any discomfort caused by wearing the band will decrease the user's motivation to train. In terms of relieving phantom limb pain, it may be better to develop a product that does not receive optimal signal reading, but which motivates the user to perform the training sessions.

The application of point pressure also calls for an electrode band with a hard shell that withstands the reaction forces in the outward direction. A stiff solution decreases the possibilities for the band to follow the curvature of the skin.

9.2.4 The controller box

As Integrum are still working on developing the hardware of the controller box and trying to decrease the size of the power source, the design of the controller box has also fallen behind schedule. The size for the controller box was still not known at the end of the project, which resulted in two design suggestions depending on the obtained dimensions and weight of the controller box.

A component of importance for the product's performance is the choice of a connector between the controller box and the electrode band. Due to restricted knowledge about the product's weight as well as the need to buy suggested connectors to test their ability to hold up the weight of the product, the selected connector is based on requirements for simple and intuitive attachment of the controller box on the electrode band. The chosen connector needs to be validated to see if the connection stays tight during training, and care should be taken to the choice of magnetic connectors, as they can interfere with some pacemakers.

9.2.5 Sustainability

The durability of the electrode band is a determinant of its environmental impact, as the product itself results in an increased amount of material compared to when single use electrodes are used for signal acquisition. By using the

electrode band, however, the consumption of single use electrodes can be decreased or eliminated. To really be able to say that the environmental impact during the use phase has been decreased, the product needs to be used for a certain amount of training sessions to "pay back" energy and material invested to manufacture the different parts of the electrode band.

The product is constructed for facilitated disassembly, which makes it possible to replace or service worn out parts to optimise the durability of the product. The possibility to separate different materials also facilitates recycling of materials.

The product's greatest contribution to sustainability is that it helps a large number of amputees suffering from phantom limb pain to a better life, while eliminating their consumption of ineffective analgesics.

9.3 Recommendations for further work

Some decisions remain to be taken about the product before it can be manufactured.

One decision that needs to be taken through testing the product together with the system is the force exerted on the electrodes by the springs. The spring force must be sufficient to allow for good signal acquisition, yet must not cause discomfort when the electrode band is worn for a full training session.

Once the dimension and size of the controller box have been established, and it is lightweight enough to be worn on the electrode band, the connector between the electrode band and the controller box needs to be validated. Although magnetic connectors are easy to align and connect, further investigations should be made on alternative solutions to ensure that the controller box can be worn around the neck by a user with a pacemaker.

Some parts of the product must be optimised for improved durability. One problem discovered with gluing velcro on the inside of the plastic shell is that the velcro comes loose after a couple of bend and stretch cycles. This may depend on the type of glue and the materials used for the prototype, and

can be discussed with the chosen supplier of the plastic shell. The velcro, as well a the rings for lacing and the cord lock, may need to be attached with rivets.

One requirement that was not met by the developed product was a pain free tightening device. Lace bite may be prevented by sewing a pad with channels through which the string is led, to avoid contact with the skin. A protective pad will make the lacing more cumbersome and there is a risk that it creases when pulling the string.

Manufacturing of the product can be discussed with prototyping workshops to find cost efficient methods suitable for small product series. Creating moulds for the controller box and the cord lock should be avoided until a larger market is confirmed. Self locking cord locks may be available for sales off-the-shelf. Syverket in Borås can be consulted for the final construction of the different sizes of the lining layer, as well as initial manufacturing.

One idea expressed by Integrum was that each participant from the clinical study would receive a Neuromotus system to thank them for their participation. This is also an excellent opportunity to study how the developed product is received as a home-training system and continue the identification of user needs.

One way of validating the transition to home training is to see how often the users train, and whether they follow the recommended training protocol. One of the users interviewed in this project expressed a concern that it would be harder to find the motivation to try their best if there was nobody there to keep them going.

The design of the product can be validated by studying how many of the users utilise the electrode band, and how many flying leads are used on average. If many flying leads are used, the electrode band may need to be made wider. On the other hand, due to the variable circumference of the arm, this may cause problems in obtaining the optimal fit. A reason for using flying leads can also be that electrodes are needed on the distal end of the residual limb.

It is also valuable for further improvements of the design to study the users' habits relating to the product, such as where the training takes place, how the equipment is stored, and if it is ever transported.

Another point for investigation is how well the electrode band stays in place while fully tightened. Edging the lining with silicone or adding silicone rings around the holes in the grid may prevent the band from displacing around or along the residual limb.

It is also of great importance that a decision is taken on how the product should be distributed. There are many advantages of distributing the product via Armprotescentrum within Sweden. Not only will this allow for introductory training sessions led by trained professionals, but it will also allow primary users to get help with the customisation of the electrode placement. As Armprotescentrum are in close collaboration with orthopaedic workshops, there will also be technicians who can make modifications to the product or custom make parts for optimal fit.

In contrast to the low number of upper limb amputations, about 2500 lower limb amputations take place in Sweden yearly (RTP, 2015), so once Neuromotus has been adapted to treat phantom limb pain in lower limbs, the national market may grow considerably. In future applications, the Neuromotus might also be used to treat pain caused by other disorders affecting control of muscular movement, such as stroke and incomplete spinal cord injuries, such as plexus injuries and hemiplegia. (Ortiz-Catalán et al, 2014)

It might also be used as a gesture control device for computers, where input from the EMG signals can be assigned to different commands in software for gaming or presentations. For the use of Neuromotus as a gesture control device, the only competitor on the market using EMG signals as input is Thalmic Labs Inc., developers of MyoBand. MyoBand is worn around the forearm, and uses EMG signals along with accelerometers, magnetometers and a gyroscope to track gestures and movements of the arm. MyoBand is both small and lightweight, something that should be aimed at in the development of Neuromotus.

Although the Neuromotus software is not a part of this project, it is an important factor for the users' motivation to train. The questionnaire preceding the training session should be made optional, as it impedes a quick setup. There is a risk that many users will start to invent values for the questionnaire in order to follow the training protocol sooner. Many of the users who have trained with the Neuromotus

like the TAC-test for its direct feedback, so one thing to work on in the exercises may be to let the software do some of the motivational work presently carried out by the occupational therapist. Some motivational features could be to display the time remaining for the current exercise or to track the user's progress. Making the exercises fun is, of course, another motivator. Integrum have already created a "fun factor" in the training by adapting a car racing game to be a part of the neuromuscular rehabilitation programme. With time, more such games may be added to the training protocol.

10 Conclusions

Figure 73. Neuromotus on a user.

The goal of this project was to systematically develop a prototype for the Neuromotus that will allow the neuromuscular rehabilitation training to take place in the user's home instead of in a clinical setting. Not only is this thought to make it available to make the treatment available for more users, but it would also allow them to train wherever and whenever they want.

The project was focused on facilitated electrode placement, but also included design work for improved signal acquisition by allowing for application of pressure over the electrodes and finding a way to attach the controller box on the electrode band to keep the conductors from the electrodes to the amplifier as short as possible.

The electrode band consists of a plastic shell lined with a layer of 3D spacer fabric, and is tightened with the help of a string laced like a shoe. Tightening the device is made simple by a self-locking cord lock.

The electrode band allows the user to place all the electrodes on the residual limb in one step and reduces the setup time before each training session considerably. While some users may be able to use the electrode band with the standard electrode pattern it is delivered with, other users may need to take time to customise the electrode band before the first training session. The electrode placement is customised by inserting electrodes in the desired positions in a grid of holes cut through the lining material.

The electrodes are spring loaded with compression springs to be pushed closer to the signal source and thus acquire stronger signal readings.

Due to uncertainties regarding the size and dimensions of the controller box, it cannot yet be validated that it is best placed on the electrode band. The length of the cables will, however, be reduced compared to the current prototype.

All in all, the design meets the goals set up for the project (Figure 73).

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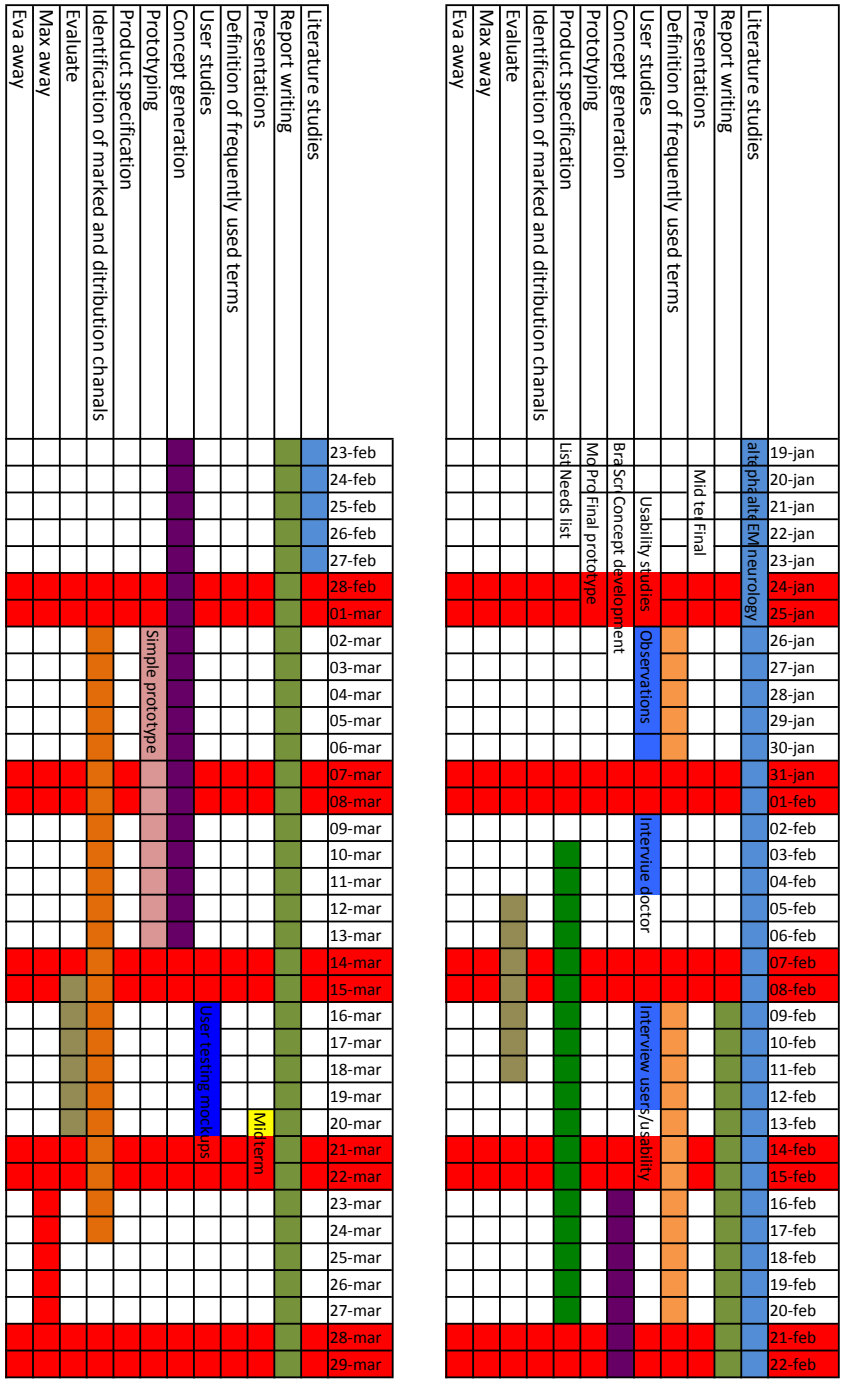
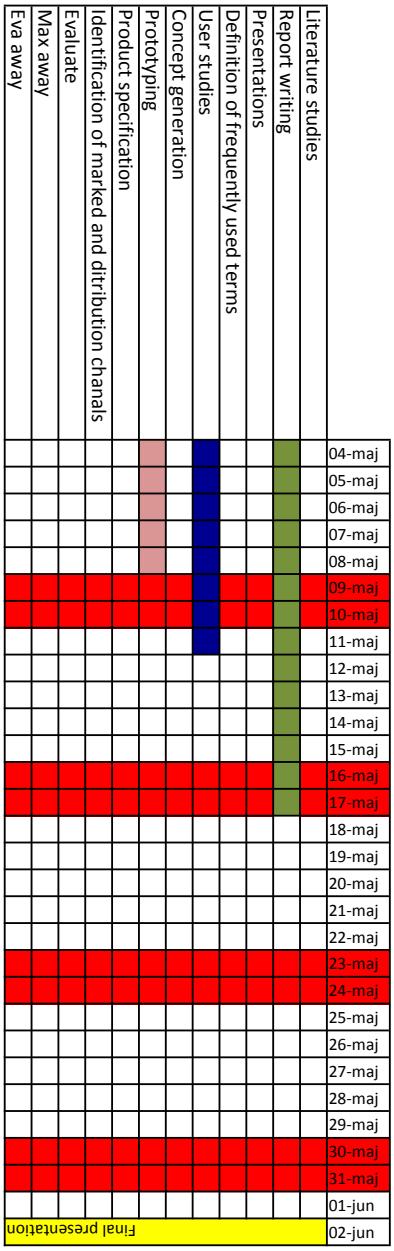
12 Appendix

Appendix I: Gantt chart

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Presentations
Definition of frequently used terms
User studies
Concept generation
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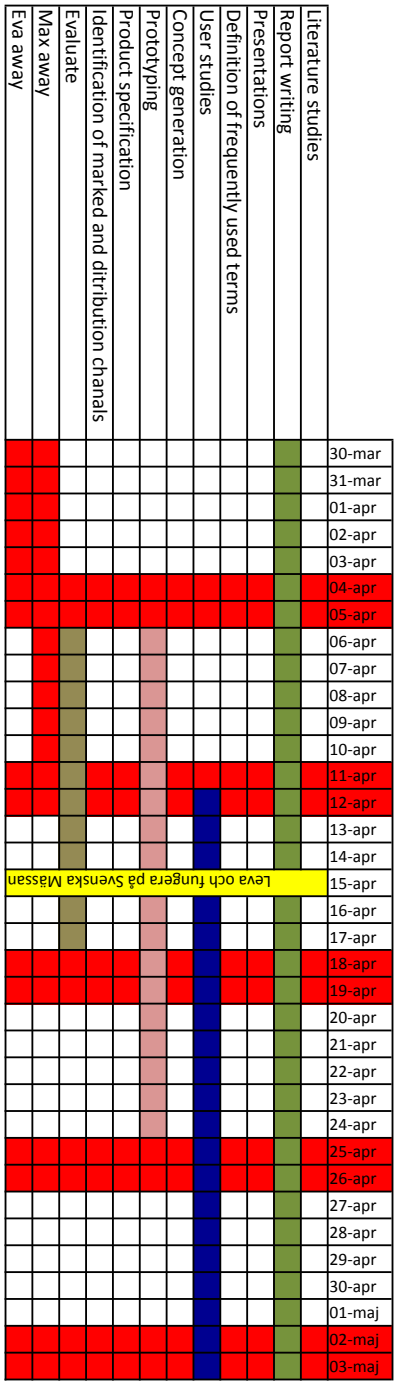
Final presentation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Appendix II: Interview question

Questionnaire

General

How do you see the product? Is it a tool for training / rehabilitation / aids..?

Pain

For how long have you had the phantom limb pain?

How often dose it occur

For how long at a time do you have the pain?

How dose the phantom pain effect you in your daily life? Mood / temper?

On how many treatment sessions has you to?

Would you want to use the system at home?

Do you see any advantage with training at home?

Do you see any disadvantage with training at home?

Has the training effect your pain? How?

How dose it feel between the sessions?

Dose the training make you tired?'

The sessions

If you should have the system at home...

When would you train (what time)?

Were in you home would you train?

Would you like to have a training protocol or do you want to plan the training by yourself?

Which step is the hardest when handling the units?

Can you find were to put the electrodes by your self? Have you tried to put the them on by your self?

Have you seen any changes in the signals during your sessions? (Have they getting stronger?)

Is it hard to see were the electrodes is to be placed? (strong signals, right electrode par in the right position)

Has there been any changes in the product during the time you have been using it?

The Computer

What do you think about the interface of the program?

Which exercise is the most fun?

Which exercise is the dullest?

Which exercise is the most giving?

Is there any exercise you miss or should want to do?

Wishes

Which changes du you think is necessary to be able to use the system at home?

Were would you prefer to have the controller box during the exercise?

How do you whished the electrodes would be fasten?

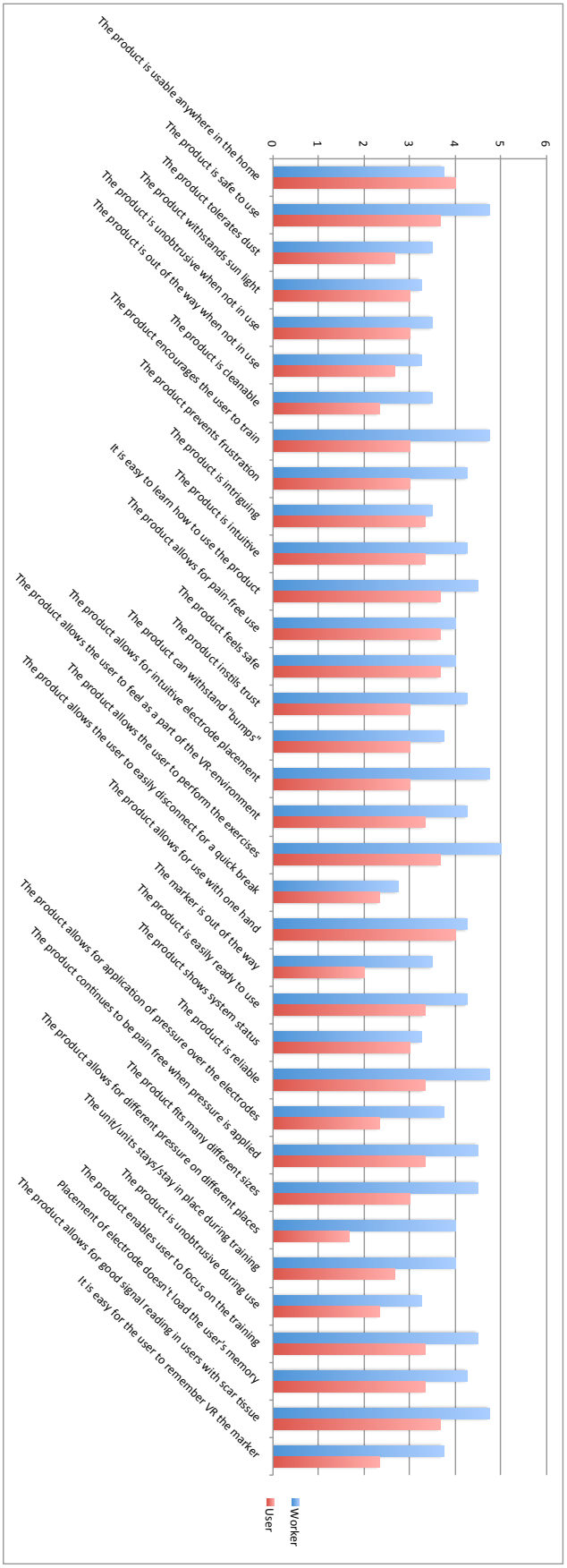
Do you see any other application for the system but training?

Do you have any more comments? Or anything to ad?

Appendix III: Survey questions

- How do you come in contact with Neuromotus?
- The product is usable anywhere in the home
- The product is safe to use
- The product tolerates dust
- The product withstands sun light
- The product is unobtrusive when not in use
- The product is out of the way when not in use
- The product is cleanable
- The product encourages the user to train
- The product prevents frustration
- The product is intriguing
- The product is intuitive
- It is easy to learn how to use the product
- The product allows for pain-free use
- The product feels safe
- The product instils trust
- The product can withstand "bumps"
- The product allows for intuitive electrode placement
- The product allows the user to feel as a part of the VR-environment
- The product allows the user to perform the exercises
- The product allows the user to easily disconnect for a quick break
- The product allows for use with one hand
- The marker is out of the way
- The product is easily ready to use
- The product shows system status
- The product is reliable
- The product allows for application of pressure over the electrodes
- The product continues to be pain free when pressure is applied
- The product fits many different sizes
- The product allows for different pressure on different places
- The unit/units stays/stay in place during training
- The product is unobtrusive during use
- The product enables user to focus on the training
- Placement of electrode doesn't load the user's memory
- The product allows for good signal reading in users with scar tissue
- It is easy for the user to remember VR the marker
- If you were to buy a Neuromotus, how much would you be willing to pay?
- What do you think is a reasonable price for a Neuromotus?

Appendix IV: Graph 1



Appendix V: Graph 2

Appendix VI: HTA

0	Perform Neuromotus training session
1	Bring the Neuromotus
1.1	Bring storage units
1.2	Open storage units
1.3	Take out the Neuromotus
2	Clean the skin
2.1	Undress
2.2	Clean the skin
2.2.1	Apply disinfectant on paper
2.2.2.	Apply disinfectant on residual limb
2.2.3	Apply disinfectant on skin for the ground electrode
3	Connect Neuromotus
3.1	Connect controller to the amplifier
3.2	Connect controller to the computer
3.3	Connect battery to the amplifier
3.4	Connect electrode cables to the amplifier
3.5	Apply electrodes on skin
3.5.1	Find the muscle
3.5.1.1	Perform movement with phantom limb
3.5.1.2	Palpate residual limb until muscle is found
3.5.2	Apply electrode
3.6	Apply ground to the bony area
3.7	Apply fiducial marker
3.8	Connect all electrode cables to the electrodes
3.9	Apply pressure
4	Follow training protocol
4.1	Fill out pain questionnaire
4.2	Test the signals
4.3	Do the training
4.3.1	Record the reference signal pattern for the movement
4.3.2	Do the exercises
5	Disconnect Neuromotus
5.1	Disconnect electrodes from the cables
5.2	Pull the electrodes off from the skin
5.3	Disconnect all cables
5.4	Put everything back in the storage units
6	Clean the skin
6.1	Clean the skin
6.2	Dress
7	Put Neuromotus aside

Appendix VII: PHEA

NR	Task	Use error	Cause	Consequence	Discovery	Recovery
3.5.1	Find the muscle	Muscle not found	Caution - palpation too gentle	User does not find the muscle	No muscle detected	Start searching again
		Two electrode pairs on the same muscle	Insufficient anatomical knowledge	Wrong input to software		
3.5.2	Apply electrode	Misplacement of the electrode	Mis-aim at correct position	Problem with signal readings	Bad signals	Move the electrode
		Electrode not in contact with skin	Electrode folded/garment in the way	Erroneous signals		
3.6	Apply ground to the user	Ground forgotten	Ground electrode out of sight	Erroneous signals		
		Ground placed on muscle	Difficulties placing ground electrode on back	Erroneous reference signal		
3.7	Apply fiducial marker	Fiducial marker forgotten	Lapse	User cannot perform training in VR environment	Problems with VR environment	Put on marker later
		Fiducial marker deformed	Carelessness	Might cause problems in VR environment	Programme might not know where the arm is located	Try to fix it
		Marker placed outside camera's range	Marker slips away	User cannot perform training in VR environment	Problems with VR environment	Pull marker in place
		Marker placed outside camera's range	Object covers the marker	User cannot perform training in VR environment	Problems with VR environment	Remove covering object
3.8	Connect all electrode cables to the electrodes	Cables paired black-black/red-red	Slip	Erroneous signal readings		
		Some cable forgotten	Hard to keep track of many cables	Erroneous signals		
		Wrong electrode pair on wrong muscle	Insufficient anatomical knowledge	Affects data for comparison	None	
3.9	Apply pressure	Strap too tight	Tightening device pulled too far	Discomfort	Discomfort	Loosen the strap
		Strap too loose	Tightening device not pulled far enough	Strap does not fulfil its purpose	Weak signals	Tighten the strap
		Cables constrained by strap	Too little of cables are on the right side of the strap	Decreased range of motion	Decreased range of motion	Loosen strap, pull out cables, and tighten strap again
4.3.2	Do the exercises	Movements too big	User too involved in the exercise	Cables disconnect	No response to movement in the software	Re-connect cables
		Movements too big	User too involved in the exercise	Boxes fall off the table	Visual and auditory feedback	Put boxes back on table
		Cables strike against eachother	Cables occupy space for movement	Motion artefacts	Disturbances in the programme	Artefacts decline with time
5.1	Disconnect the cables from electrodes	Cable breaks at contact	Pulling at the cable rather the contact	Cable broken	Cable broken	Replace
		Electrodes detach from skin	Weak adhesive or strong snap buttons	Fiddly removal of electrode from cable	Visual	Remove electrode from cable
5.2	Pull the electrodes off skin	User forgets to pull off electrodes	Lapse	Electrodes remain on skin until discovery	Visual	Pull off electrodes
		User pulls off electrodes in a way that hurts	Adhesive too strong	Pain	Sensory	

Other errors that might occur	
	Knocking a glass of liquid over
	Dropping things onto the floor

Appendix VIII: Scenario 1

At the Rehabilitation Centre for Upper Limb Prosthetics (Armprotescentrum)

Karl has just arrived at the rehabilitation centre for one of his weekly appointments. Ingrid, the occupational therapist, greets him and leads him into the training room where they both sit down by a desk. Connected to a desktop computer is a commercial webcam placed on top of the computer screen, and cluttering the desk is a prototype of Neuromotus - consisting of three hardware boxes (an amplifier, a battery and a controller), a bundle of electrode cables and a bunch of elastic and velcro straps.

Prior to the neuromuscular training, Ingrid and Karl fill out a questionnaire together to track the progress of his pain. Ingrid reads the questions from the screen, and Karl provides her with the information. They have done this once per week for a little more than one month now, so Ingrid almost knows Karl's standard answers by heart now: it has been 25 years since the amputation, he has tried to treat the phantom pain with mirror treatment and acupuncture, he wears a cosmetic prosthesis daily, and he suffers from severe stabbing pain at the palm of his phantom hand with short intervals.

There are also questions on how much he has slept the last night, as well as how much pain (time and intensity) he has experienced in the last 24 hours. Although the training has helped Karl a lot, he is still in a lot of pain and has barely been able to sleep.

After Karl has filled out the questionnaire, he takes off his shirt and his prosthesis. Ingrid gets the disinfectant and cleans her own hands, as well as Karl's residual limb. She then asks Karl to perform a number of movements, while palpating his muscles to find the right spots to place the EMG electrodes. Four pairs of electrodes are placed before the training session can begin. Karl has quite a lot of scar tissue, so Ingrid has made a velcro strap tighten over the electrodes to apply pressure. She wraps it around his arm, and then places an elastic band with a VR marker on top of it. Before proceeding to the training, she checks the EMG signals to make sure that no electrode is giving a zero input.

After Karl has filled out the questionnaire, he takes off his shirt and his right arm. Ingrid gets the disinfectant and cleans her own hands, as well as Karl's residual limb. She then asks Karl to perform a number of movements, while palpating his

muscles to find the right spots to place the EMG electrodes. Four pairs of electrodes are placed before the training session can begin. Karl has quite a lot of scar tissue, so Ingrid has made a velcro strap tighten over the electrodes to apply pressure. She wraps it around his arm, and then places an elastic band with a VR marker on top of it. Before proceeding to the training, she checks the EMG signals to make sure that no electrode is giving a zero input.

The training consists of a set of movements that are to be performed with the phantom limb. Ingrid knows what exercises are suitable for Karl. They begin with large isolated movements such as flexion and extension of the elbow, the training then shifts to smaller movements such as closing and opening the hand, flexion and extension of the wrist, and pronation and supination of the wrist. If these movements go well, the user might also attempt exercising small finger movements or combined movements.

For each movement that is trained, the EMG signal patterns are recorded to serve as a reference for performing the recorded movement in the subsequent exercises. If Karl should make any mistakes in the recording, he will also find it difficult to copy the same movement (i.e. producing the same EMG pattern).
Karl's favourite exercise is the Target Achievement Control (TAC) test, where he controls a virtual limb trying to copy the movements of a green limb performing each trained movement at a certain speed. Another exercise allows Karl to see himself with a virtual representation of his lost arm, which he can move as if it was his own.

After having recorded and trained all movements on the agenda, the training session is wrapped up by playing a car racing game. Karl controls the car by pronation and supination for steering left and right, and elbow flexion or extension for gas or break.

Appendix IX: Scenario 2

Karin's room

Karin was in a really bad mood yesterday, which - as her brother mockingly suggested – means that it is about time to train with the Neuromotus again. The sun shines through the window of her room decorated with posters of football players. The dream of becoming the world's best player is Karin's greatest motivation to train, and so she prefers using the Neuromotus in their company. It takes her two rounds to the home office to gather all the equipment; one for the laptop and another one, while the computer is starting, for the box in which they keep the stuff for the Neuromotus.

Now it is time to place the electrodes. Her parents used to help her with this after she first took the system home, but now she wants to manage on her own. Karin uses her hand to feel where her muscles move when performing the different movements for activating the right muscles - it's become a little choreography! Sometimes it is hard to feel where the electrode ought to be placed, but Karin has marked some of the tricky spots with a felt tip for memory… Once all the self-adhesive electrodes are in place, it is time to connect them to the cables into the controller box. This is a bit tricky with only one hand, as the box slides around on the bedside table as the cables are being tugged at. Since Karin has had problems with weak EMG signals before, her therapist has given her a compressive band to apply pressure over the electrodes. It is, however, not very easy to get in place with only one hand as it needs to be held in place while tightening the velcro straps – but Karin has learnt to jam the strap in between her arm and torso so it will stay in place while she tightens the velcro in.

Checking the signals to start training, Karin suddenly remembers: Ah, the marker! Lucky for her, her therapist has made a new marker with a velcro strap to make it easier to put on after connecting all the tables – it used to be the curse of the forgetful when the marker was attached to an elastic loop! Putting the velcro strap on with one hand is not very easy either, though…

Finally, the training can start! For each exercise, a recording is made before the actual training starts. It is lucky to have your own room, as it takes about two hours to complete the session, and Karin does not like being interrupted by her brother. Seeing herself with her lost arm is something Karin likes the idea of, although she thinks it looks a lot more like an earth worm than an arm. Once she has done all the compulsory items in the training protocol, it is finally time to play the car racing game.

Appendix X: Functional analysis

Functions system
Enables PLP treatment
Encourages user to train
Allows for quick set-up
Shows system status
Instills trust
Allows user to feel as a part of the VR-environment
Allows for total focus on the training
Allows for portability
Allows for compactability
Allows for safe use
Is injury-free
Durability/Reliability
Withstands daily use
Withstands at-home storage conditions
Allows for cleaning
Fits many users
Allows for customisable electrode placement

Functions electrode band
Acquires EMG signals
Provides space for conductors
Allows for application of pressure
Connects to controller box
Encourages user to train
Prevents frustration
Stays in place during training
Allows for pain-free use
Reduces time for electrode placement
Allows for repetition of electrode placement
Fits many users
Allows for size adjustment
Allows for sufficient signal reading in users with scar tissue

Functions controller box
Amplifies and filters signals
Provides space for circuit boards
Connects to electrode band
Transports signals to computer
Encourages user to train
Stays in place during training
Allows for intuitive use

Appendix XI: Target specification

Requirement Specification	Comments	By whom/source	Importance (1-5)	Units	Marginal value	Ideal Value
Overall						
Number of parts	Number of parts or subassemblies handled by the user during a normal training session	From needs no 1 and 33	3	number of parts	36	≤ 4*
Time for setup	Theoretical estimation	From needs no 9, 11 and 24	4	minutes	< 15	< 5
Time for close-down	Theoretical estimation	From needs no 9 and 11	4	minutes	< 15	< 5
Simplistic expression	Does not look complicated to use	From needs no 8, 11 and 18	3	Subjective scale**	Yellow	Green
Durable expression	Does not look fragile	From needs no 8, 11 and 14	3	Subjective scale**	Yellow	Green
Safe to use	Minimise the risk for self-inflicted injury	From needs no 2, 28, 29	5	Subjective scale**	Green	Green
Durability	Theoretical estimation: risk of breaking the equipment during a training session	From needs no 2, 4, 8, 15, 26 and 34	5	Subjective scale**	Yellow	Green
Few steps from start to finish	Tasks performed during setup. Does not include the training process.	From need no 12	3	Number of operations	≤ 8	≤ 4***
Allowed range from computer	Determines how far the user can move from the computer	From need no 19	4	m	> 2	> 4
Electrode device						
Weight	Estimation: weight of the band including electrodes	From needs no 1, 19 and 24	4	kg	≤ 200	≤ 150
Dimensions	Maximal outer dimensions for allowing storage and being comfortable wear	From needs no 1, 6, 18, 24 and 33	4	mm x mm x mm	≤ 130 x 150 x 150	≤ 130 x 130 x 130
Easy to open buckle with one hand		From need no 21	5	Subjective scale**	Yellow	Green
Easy to close buckle with one hand		From need no 21	5	Subjective scale**	Yellow	Green
Allowing the band to be placed with one hand		From need no 21	5	Subjective scale**	Yellow	Green
Allowing the band to be removed with one hand		From need no 21	5	Subjective scale**	Yellow	Green
Easy to adjust size with one hand		From need no 21	5	Subjective scale**	Yellow	Green
Number of electrodes		Request from Integrum	5	number of electrodes	16	16
Electrodes separated by insulators		Technical requirement	5	Binary	Yes	Yes
Application of point pressure over the electrodes		Request from Integrum/From need no 27	4	Subjective scale**	Yellow	Green
Pain free removal		From need no 2, 13 and 31	4	Subjective		
Pain free use	inte klämma sig, fastna i hår, riva sig, nypa sig	From need no 2, 13 and 31	4	Subjective scale**	Green	Green
Prevents entrance of particles	Theoretical estimation: electrode gel, sweat, dust or dirt does not enter the product	From need no 3	3	Binary	Yes	Yes
Withstand fall from height	Does not break if dropped or tipped from surface	From need no 4	4	m	> 1	< 2
Water resistance	Can be wiped off using a damp cloth, tolerates sweat and withstands spilled liquids	From need no 4	4	Binary	Yes	Yes
Involuntary displacement along arm	Tested using mockups	From need no 9 and 34	5	mm	≤ 5	0
Involuntary rotation around arm	Tested using mockups	From needs no 9 and 34	5	degrees	≤ 10	0
Time for electrode placement	Part of time for setup: time required to take on the electrode band	From need no 17	2	minutes	< 120	< 30
Electrode positioning for good signal reading	Electrodes are in the right position when placing the electrode band as intended.	From need no 26	5	Subjective scale**	Yellow	Green
Customisable electrode placement	Helps obtain correct electrode placement	Request from Integrum	3	Binary	No****	Yes
Importance for correct placement	Placing the band incorrectly does not affect the signal reading	From need 26	3	Binary	No	No
Adjustable size	Maximal difference in arm circumference covered by the band	From need no 30	3	mm	> 30	≥ 120
Size adjustment device stays tight		From needs no 9 and 34	5	Binary	Yes	Yes

Controller box						
Weight		From needs no 1, 19 and 24	4	kg	≤ 200	≤ 100
Dimensions	As small as possible while housing circuit boards of 70x40x30 mm, battery and cable connectors	From needs no 1, 6, 18, 24 and 33	4	mm x mm x mm	120 x 50 x 30	70 x 40 x 20
Electrode for electric ground		Technical requirement	5	Binary	Yes	Yes
Extra cable ports	The controller box is usable without the electrode band	Request from Integrum	5	Binary	Yes	Yes
Connection between electrode band and controller box	No interruptions in the transfer of signals	Technical requirement	5	Binary	Yes	Yes
Secure fastening on electrode band	Does not wobble when attached to the band	From needs no 9 and 34	4	Binary	Yes	Yes
Prevents entrance of particles	Theoretical estimation: electrode gel, sweat, dust or dirt does not enter the product	From need no 3	4	Binary	Yes	Yes
Alternative way of wearing	The box can be worn somewhere else than on the box for modular compatibility	Request from Integrum	3	Binary	Yes	Yes
Risk of box getting caught when worn in alternative way	Should not get caught in e.g. clothes, skin or hair	From needs no 2, 13, 14 and 29	3	Scale	No	No
Withstand fall from height	Does not break if dropped or tipped from surface	From need no 4	4	mm	> 1	< 2
Water resistance	Can be wiped off using a damp cloth, tolerates sweat and withstands spilled liquids	From need no 4	3	Binary	Yes	Yes
Possibility to attach controller box on electrode band with one hand		From need no 21	4	Binary	Yes	Yes

* Electrode band, controller box, fiducial marker, and separate electrode for ground

**The features evaluated are subjectively rated red-yellow-green, where red means "bad", yellow "acceptable" and green "good"

*** Take on electrode band, tighten band, attach controller box, and turn on controller box

****If the electrode placement is not made customisable, the controller box must be compatible with single

Appendix XII: Morphological matrix

Customise electrode placement	Tightening device/buckle	Application of point pressure
Textile fabric: pins	Ladder strap	Screws
Textile fabric: pins	Ladder strap	Springs
Textile fabric: pins	Ladder strap	No point pressure
Textile fabric: pins	Velcro	Screws
Textile fabric: pins	Velcro	Springs
Textile fabric: pins	Velcro	No point pressure
Textile fabric: pins	Helmet dial	Screws
Textile fabric: pins	Helmet dial	Springs
Textile fabric: pins	Helmet dial	No point pressure
Textile fabric: pins	Elastic band	Screws
Textile fabric: pins	Elastic band	Springs
Textile fabric: pins	Elastic band	No point pressure
Textile fabric: pins	Ski boot buckle	Screws
Textile fabric: pins	Ski boot buckle	Springs
Textile fabric: pins	Ski boot buckle	No point pressure
Grid of holes	Ladder strap	Screws
Grid of holes	Ladder strap	Springs
Grid of holes	Ladder strap	No point pressure
Grid of holes	Velcro	Screws
Grid of holes	Velcro	Springs
Grid of holes	Velcro	No point pressure
Grid of holes	Helmet dial	Screws
Grid of holes	Helmet dial	Springs
Grid of holes	Helmet dial	No point pressure
Grid of holes	Elastic band	Screws
Grid of holes	Elastic band	Springs
Grid of holes	Elastic band	No point pressure
Grid of holes	Ski boot buckle	Screws
Grid of holes	Ski boot buckle	Springs
Grid of holes	Ski boot buckle	No point pressure
No customisation	Ladder strap	Screws
No customisation	Ladder strap	Springs
No customisation	Ladder strap	No point pressure
No customisation	Velcro	Screws
No customisation	Velcro	Springs
No customisation	Velcro	No point pressure
No customisation	Helmet dial	Screws
No customisation	Helmet dial	Springs
No customisation	Helmet dial	No point pressure
No customisation	Elastic band	Screws
No customisation	Elastic band	Springs
No customisation	Elastic band	No point pressure
No customisation	Ski boot buckle	Screws
No customisation	Ski boot buckle	Springs
No customisation	Ski boot buckle	No point pressure

Appendix XIII: Target specification 2

Requirement Specification	Comments	By whom/source	Importance (1-5)	Units	Marginal value	Ideal Value
Overall: Product System						
Number of parts	Number of parts or subassemblies handled by the user during a normal training session	From needs no 1, 7, 24 and 33	3	number of parts	36	≤ 4*
Simplistic expression	Does not look complicated to use	From needs no 8, 11, 12 and 18	3	Subjective scale**	Yellow	Green
Durable expression	Does not look fragile	From needs no 8, 11 and 14	3	Subjective scale**	Yellow	Green
Conspicuous colour	The colour will not stand out	From needs no 6, 18 and 33	3	Subjective binary	No	No
General use - setup and training						
Few steps before training can start	Tasks performed during setup. Does not include the training process.	From need no 12, 24, 25 and 34	3	Number of operations	≤ 8	≤ 4***
Time for setup	Theoretical estimation	From needs no 9, 11, 12, 24 and 25	4	minutes	< 15	< 5
Time for close-down	Theoretical estimation	From needs no 9, 11, 12 and 25	4	minutes	< 15	< 5
Safe to use	Minimise the risk for self-inflicted injury	From needs no 2, 28, 29	5	Subjective scale**	Green	Green
Setup and close-down possible with one hand		From need no 17 and 21	5	Binary	Yes	Yes
Allowed range from computer	Determines how far the user can move from the computer	From need no 19	4	m	> 2	> 4
Durability						
Retains properties when exposed to sunlight	The material shouldn't bleach or turn brittle when exposed to sunlight	From needs no 1, 2, 4 and 5	4	Binary	Yes	Yes
Water resistance	All parts can be wiped off using a damp cloth, tolerates sweat and withstands spilled liquids	From need no 4	4	Binary	Yes	Yes
Tolerates mild detergents		From needs no 2 and 7	4	Binary	Yes	Yes
Shock resistance	Theoretical estimation: risk of breaking the equipment during a training session	From needs no 2, 4, 8, 15, 26 and 34	5	Subjective scale**	Yellow	Green
Manufacturability						
Number of different injection moulded parts	Kept to a minimum, as moulds for parts are expensive	Manufacturing cost	4	Number of injection moulded parts	≤ 5	≤ 2****
Electrode band						
General						
Weight	Total weight of electrode band including electrodes and springs	From need no 1, 19 and 24	4	g	≤ 250	≤ 150
Dimensions	Space occupied by the electrode band when assembled. (height, width, depth) Will depend on the size.	From need no 1, 6, 18, 24 and 33	4	mm x mm x mm	≤ 130 x 150 x 150	≤ 130 x 130 x 130
Usability						
Allows for positioning with one hand		From need no 21	5	Subjective binary	Yes	Yes
Allows for removal with one hand		From need no 21	5	Subjective binary	Yes	Yes
Involuntary displacement along arm	Tested using mockups	From need no 9, 19 and 34	5	mm	≤ 5	0
Involuntary rotation around arm	Tested using mockups	From needs no 9, 19 and 34	5	degrees	≤ 10	0
Time for electrode placement	Part of time for setup: time required to take on the electrode band	From needs no 11, 12 and 17	2	seconds	< 120	< 30
Reference marking	the electrode band as intended	From needs no 11 and 26		Binary	Yes	Yes
Pain free application		From need no 2 and 13	4	Subjective scale**	Green	Green
Pain free removal		From need no 2 and 13	4	Subjective scale**	Green	Green
Is separable	Allows for replacement, repair and cleaning of parts, as well as optimised waste management	From needs no 7 and 26, Eco Strategy Wheel	4	Scale	Yellow	Green

First time setup	Requirements regarding the customising of the electrode band					
Time required for customisation of electrode placement		From needs no 11, 24 and 26	3	minutes	≤ 60	≤ 15
Risk for use errors	Percentage of electrodes in incorrect position during usability test	From need no 11	5	percentage	12 %	0 %
Durability						
Withstand fall from height	Shock resistance	From needs no 4 and 16	4	m	> 1 m	< 2 m
Water resistance	Allow for cleaning with a damped cloth	From need no 4	4	Binary	Yes	Yes
Retains properties when exposed to sunlight		From needs no 1, 2, 4 and 5	4	Binary	Yes	Yes
Tolerates mild detergents	Allows for cleaning	From needs no 2 and 7	4	Binary	Yes	Yes
Shell						
Withstands pressure	Does not deform under the pressure of the springs on the electrodes	Technical requirement	5	Subjective Scale	Yellow	Green
Adapts to curvature of the residual limb	Improves comfort and reduces forces required to tighten the electrode band	Technical requirement	5	Subjective Scale	Yellow	Green
Lining						
Allows for insertion of 16 electrodes	To get as big resolution as possible	Request from Integrum and from need no 11 and 17	5	Binary	Yes	Yes
Allows for insertion of electrode for ground	Allows for placing electrode for ground in the band or on a flying lead	Request from Integrum and from need no 11	3	Binary	No	Yes
Customisable electrode placement	Possibility to change position of the electrodes time after time	Request from Integrum	3	Binary	Yes	Yes
Level of customisability	Helps obtain correct electrode placement	Request from Integrum	3	Holes per square decimetre	≥ 25	≥ 100
Electrodes separated by insulators		Technical requirement	5	Binary	Yes	Yes
Good electrode contection each time	Allways give suffisient pressure with the electrodes	From needs no 15 and 26	5	Scale	Yellow	Green
Compressible material	Adapts to the shape of the residual limb and allows for wider range of sizes	From needs no 2, 12, 19 and 27	4	Subjective Scale	Yellow	Green
Washable	To be able to clean	From need no 7	4	Scale	Yes	Yes
Springs						
Length	Must match the thickness of the lining to avoid scratching skin, and for simplistic expression	From needs no 13 and 26	4	mm	18 - 22	20
Outer diameter	Affects stability of springs	From needs no 2 and 13	4	mm	7 - 10	9
Inner diameter	Gives space for the cables	Technical requirement	3	mm	≤ 7	≤ 7
Spring constant	Estimated constant which gives pain free pressure allowing for sufficient signal readings.	Request from Integrum and from need no 12	4	N/m	Requires testing with Neuromotus system	Requires testing with Neuromotus system
Cables from electrodes to controller box						
Length	Kept as short as possible to avoid signal disturbances	Technical requirement	4	mm	< 300 mm	< 160 mm
Shielded conductors	Minimised signal disturbances	Technical requirement	4	Binary	Yes	Yes
Cables securely attached	Cables do not detach during training	From need no 32	4	Binary	Yes	Yes
Compatible with single use electrodes	To make it able to be used by users that need to have electrodes without the band.	Request from Integrum and from need no 35	5	Binary	Yes	Yes
Consistency	The colouring of the cables	From need no 12	3	Binary	Yes	Yes
Electrodes						
Number of electrodes		Request from Integrum	5	number of electrodes	16	16
Electrode for electric ground	Reference electrode	Technical requirement	5	Binary	Yes	Yes
Diameter		Technical requirement	5	mm	10	10
Conductivity		Technical requirement	4	Binary	Yes	Yes

Tightening device						
Does not require force in circumferential direction	May cause the band to rotate	Technical requirement and from need no 11, 12 and 21	4	Binary	No	Yes
Pain free	Does not pinch or cause lace bite	From needs no 2, 28 and 29	5	Subjective Scale	Yellow	Green
Size adjustment device stays tight		Needs no 9, 25 and 34	5	Binary	Yes	Yes
Easy to open buckle with one hand		From need no 21	5	Scale/Subjective	Yes	Yes
Easy to close buckle with one hand		From need no 21	5	Scale/Subjective	Yellow	Green
Easy to adjust size with one hand		From need no 21	5	Scale/Subjective	Yellow	Green
Adjustable size	Maximal difference in arm circumference covered by the band	From need no 30	3	mm	> 30	≥ 120
Controller box						
Weight		From needs no 1, 19 and 24	4	g	≤ 200	≤ 100
Centre of gravity close to surface of electrode band	Distance from shell to centre of gravity. Affects the moment when moving the arm.	From needs no 2, 9, 14, 19 and 33	5	mm	≤ 20	0
Dimensions	As small as possible while housing circuit boards of 70x40x30 mm, battery and cable connectors	From needs no 1, 6, 18, 24 and 33	4	mm x mm x mm	120 x 50 x 30	70 x 40 x 20
Battery charging	Should be possible without needing to take out the battery	From needs no 11, 12 and 26	3	Binary	Yes	Yes
Indication of system state	Shows if the controller is on or off	From needs no 25 and 26	4	Binary	Yes	Yes
Indication of battery level		From needs no 25 and 26	4	Binary	Yes	Yes
Secure fastening on electrode band		Technical requirement	5	Binary	Yes	Yes
Allows for alternative way of wearing	Required for compatibility with single use electrodes	Request from Integrum	3	Binary	Yes	Yes
Risk of box getting caught when worn in alternative way	Should not get caught in e.g. clothes, skin or hair	From needs no 2, 13, 14 and 29	3	Scale	No	No
Withstand fall from height		From need no 4	4	mm	> 1 m	≥ 2 m
Connection between controller box and band						
Good connection between electrode band and controller box	Electrical connection	From needs no 9, 26 and 34	4	Binary	Yes	Yes
Number of signals		Request from Integrum	5	Number of signals	≥ 17	17
Mate force	Force needed to attach controller box on band	From needs no 13, 21	4	N	Requires testing with Neuromotus system	Requires testing with Neuromotus system
Self-alignment	Little precision needed to attach controller box on band"Easy to connect"	From needs no 11, 12 and 26	3	Subjective scale	Yellow	Green
Secure attachment	Box does not disconnect while user performs exercises	From needs no 2, 26 and 34	4	Subjective scale	Green	Green
Width	Connection surface required must allow for curvature of the electrode band	Technical requirement and from need no 34	5	mm	4-15	4-6
Withstands mate and un-mate cycles		From need no 4	4	number of cycles	≥ 1300	≥ 1500
Possibility to attach controller box on electrode band with one hand		From need no 21	4	Binary	Yes	Yes
Separeatability	easy to change parts and reapare	From needs no 7 and 26	4	Scale	Yellow	Green
Marker						
Low risk of forgetting the marker		From needs nr 11 and 36	3	Subjective scale	Yellow	Green
Level of integration	Is the marker a loose part, part of the electrode band or the controller box?	From needs 11, 22, 24 and 36	3	Subjective scale	Yellow	Green
Readable by webcam	No glare	Technical requirement and from need no 11	4	Binary	Yes	Yes
Does not deform	Does not bend, causing recognition problems	From needs no 16 and 25	4	Binary	Yes	Yes
Can be worn without the electrode band		Request from Integrum	4	Binary	Yes	Yes
When worn without the electrode band, the marker allows for easy attachment.	Does not need to be pulled over the cables between controller box and electrodes.	From needs no 9 and 22	3	Binary	Yes	Yes

* Electrode band, controller box, fiducial marker, and separate electrode for ground

** The features evaluated are subjectively rated red-yellow-green, where red means "bad", yellow "acceptable" and green "good"

*** Take on electrode band, tighten band, attach controller box, and turn on controller box

**** Two halves for the controller box

Appendix XIV: Sections vs hole band

	SUM	Number of parts	Simplistic expression	Looks fragile	Risk to break it	Weight	Electrodes in correct spots	Easy to clean	Is protected from particles/electrode gel	Withstand fall from height	Water resistance	Adjustable size	SUM
Weight		**3**	3	3	5	4	5	4	3	4	4	3	
Sections	82	1	2	2	2	2	2	2	2	2	2	3	
		3	6	6	10	8	10	8	6	8	8	9	82
Not sections	116	3	3	3	3	2	3	3	3	3	3	2	
		9	9	9	15	8	15	12	9	12	12	6	116

Appendix XV: Customisable vs fixed electrode

	SUM	Weight	Electrodes in correct spots	Is protected from particles/electrode gel	Customisable electrode placement	SUM
Weight		4	5	3	3	
Customisable electrode placement	38	2	3	2	3	
		8	15	6	9	38
Fixed electrodes	30	2	2	3	1	
		8	10	9	3	30

Appendix XVI: Springs vs Screws

	SUM	Number of parts	Weight	Easy to clean	SUM
Weight		**3**	4	4	
Screws	22	2	2	2	
		6	8	8	22
Springs	18	2	2	1	
		6	8	4	18

Appendix XVII: Cables vs conductiv paint

	SUM	Weight	Electrodes in correct spots	Is protected from particles/electrode gel	Customisable electrode placement	SUM
Weight		4	5	3	3	
Cables	30		3	2	3	
		0	15	6	9	30
Conductive paint	30	2	2	3	1	
		8	10	9	3	30

Appendix XVIII: Target specification, result

Requirement Specification	Comments	By whom/source	Importance (1-5)	Units	Marginal value	Ideal Value	Achieved value
Overall: Product System							
Number of parts	Number of parts or subassemblies handled by the user during a normal training session	From needs no 1, 7, 24 and 33	3	number of parts	36	≤ 4*	2
Simplistic expression	Does not look complicated to use	From needs no 8, 11, 12 and 18	3	Subjective scale**	Yellow	Green	Yellow
Durable expression	Does not look fragile	From needs no 8, 11 and 14	3	Subjective scale**	Yellow	Green	Yellow
Conspicuous colour	The colour will not stand out	From needs no 6, 18 and 33	3	Subjective binary	No	No	No
General use - setup and training							
Few steps before training can start	Tasks performed during setup. Does not include the training process.	From need no 12, 24, 25 and 34	3	Number of operations	≤ 8	≤ 4***	5
Time for setup	Theoretical estimation	From needs no 9, 11, 12, 24 and 25	4	minutes	< 15	< 5	< 5
Time for close-down	Theoretical estimation	From needs no 9, 11, 12 and 25	4	minutes	< 15	< 5	< 5
Safe to use	Minimise the risk for self-inflicted injury	From needs no 2, 28, 29	5	Subjective scale**	Green	Green	Green
Setup and close-down possible with one hand		From need no 17 and 21	5	Binary	Yes	Yes	Yes
Allowed range from computer	Determines how far the user can move from the computer	From need no 19	4	m	> 2	> 4	> 4
Durability							
Retains properties when exposed to sunlight	The material shouldn't bleach or turn brittle when exposed to sunlight	From needs no 1, 2, 4 and 5	4	Binary	Yes	Yes	Can't be validated at this stage
Water resistance	All parts can be wiped off using a damp cloth, tolerates sweat and withstands spilled liquids	From need no 4	4	Binary	Yes	Yes	Can't be validated at this stage
Tolerates mild detergents		From needs no 2 and 7	4	Binary	Yes	Yes	Yes
Shock resistance	Theoretical estimation: risk of breaking the equipment during a training session	From needs no 2, 4, 8, 15, 26 and 34	5	Subjective scale**	Yellow	Green	Green
Manufacturability							
Number of different injection moulded parts	Kept to a minimum, as moulds for parts are expensive	Manufacturing cost	4	Number of injection moulded parts	≤ 5	≤ 2****	5 - 2
Electrode band							
General							
Weight	Total weight of electrode band including electrodes and springs	From need no 1, 19 and 24	4	g	≤ 250	≤ 150	120 + cables
Dimensions	Space occupied by the electrode band when assembled. (height, width, depth) Will depend on the size.	From need no 1, 6, 18, 24 and 33	4	mm x mm x mm	≤ 130 x 150 x 150	≤ 130 x 130 x 130	≤ 130 x 150 x 150
Usability							
Allows for positioning with one hand		From need no 21	5	Subjective binary	Yes	Yes	Yes
Allows for removal with one hand		From need no 21	5	Subjective binary	Yes	Yes	Yes
Involuntary displacement along arm	Tested using mockups	From need no 9, 19 and 34	5	mm	≤ 5	0	Can't be validated at this stage
Involuntary rotation around arm	Tested using mockups	From needs no 9, 19 and 34	5	degrees	≤ 10	0	Can't be validated at this stage
Time for electrode placement	Part of time for setup: time required to take on the electrode band	From needs no 11, 12 and 17	2	seconds	< 120	< 30	< 40
Reference marking	the electrode band as intended	From needs no 11 and 26		Binary	Yes	Yes	Yes
Pain free application		From need no 2 and 13	4	Subjective scale**	Green	Green	Green
Pain free removal		From need no 2 and 13	4	Subjective scale**	Green	Green	Green
Is separable	Allows for replacement, repair and cleaning of parts, as well as optimised waste management	From needs no 7 and 26, Eco Strategy Wheel	4	Scale	Yellow	Green	Green

First time setup	Requirements regarding the customising of the electrode band						
Time required for customisation of electrode placement		From needs no 11, 24 and 26	3	minutes	≤ 60	≤ 15	≤ 20
Risk for use errors	Percentage of electrodes in incorrect position during usability test	From need no 11	5	percentage	12 %	0 %	0,22
Durability							
Withstand fall from height	Shock resistance	From needs no 4 and 16	4	m	> 1 m	< 2 m	> 1
Water resistance	Allow for cleaning with a damped cloth	From need no 4	4	Binary	Yes	Yes	Yes
Retains properties when exposed to sunlight		From needs no 1, 2, 4 and 5	4	Binary	Yes	Yes	can't be validated at this stage
Tolerates mild detergents	Allows for cleaning	From needs no 2 and 7	4	Binary	Yes	Yes	Yes
Shell							
Withstands pressure	Does not deform under the pressure of the springs on the electrodes	Technical requirement	5	Subjective Scale	Yellow	Green	Green
Adapts to curvature of the residual limb	Improves comfort and reduces forces required to tighten the electrode band	Technical requirement	5	Subjective Scale	Yellow	Green	Green
Lining							
Allows for insertion of 16 electrodes	To get as big resolution as possible	Request from Integrum and from need no 11 and 17	5	Binary	Yes	Yes	Yes
Allows for insertion of electrode for ground	Allows for placing electrode for ground in the band or on a flying lead	Request from Integrum and from need no 11	3	Binary	No	Yes	Yes
Customisable electrode placement	Possibility to change position of the electrodes time after time	Request from Integrum	3	Binary	Yes	Yes	Yes
Level of customisability	Helps obtain correct electrode placement	Request from Integrum	3	Holes per square decimetre	≥ 25	≥ 100	≥ 25
Electrodes separated by insulators		Technical requirement	5	Binary	Yes	Yes	Yes
Good electrode contection each time	Allways give suffisient pressure with the electrodes	From needs no 15 and 26	5	Scale	Yellow	Green	Can't be validated at this stage
Compressible material	Adapts to the shape of the residual limb and allows for wider range of sizes	From needs no 2, 12, 19 and 27	4	Subjective Scale	Yellow	Green	Yellow
Washable	To be able to clean	From need no 7	4	Scale	Yes	Yes	Yes
Springs							
Length	Must match the thickness of the lining to avoid scratching skin, and for simplistic expression	From needs no 13 and 26	4	mm	18 - 22	20	18 - 22
Outer diameter	Affects stability of springs	From needs no 2 and 13	4	mm	7 - 10	9	7-10
Inner diameter	Gives space for the cables	Technical requirement	3	mm	≤ 7	≤ 7	≤ 7
Spring constant	Estimated constant which gives pain free pressure allowing for sufficient signal readings.	Request from Integrum and from need no 12	4	N/m	Requires testing with Neuromotus system	Requires testing with Neuromotus system	Can't be validated at this stage
Cables from electrodes to controller box							
Length	Kept as short as possible to avoid signal disturbances	Technical requirement	4	mm	< 300 mm	< 160 mm	< 160 mm
Shielded conductors	Minimised signal disturbances	Technical requirement	4	Binary	Yes	Yes	Yes
Cables securely attached	Cables do not detach during training	From need no 32	4	Binary	Yes	Yes	Yes
Compatible with single use electrodes	To make it able to be used by users that need to have electrodes without the band.	Request from Integrum and from need no 35	5	Binary	Yes	Yes	Yes
Consistency	The colouring of the cables	From need no 12	3	Binary	Yes	Yes	Yes
Electrodes							
Number of electrodes		Request from Integrum	5	number of electrodes	16	16	Yes
Electrode for electric ground	Reference electrode	Technical requirement	5	Binary	Yes	Yes	Yes
Diameter		Technical requirement	5	mm	10	10	10
Conductivity		Technical requirement	4	Binary	Yes	Yes	Yes

Tightening device							
Does not require force in circumferential direction	May cause the band to rotate	Technical requirement and from need no 11, 12 and 21	4	Binary	No	Yes	Yes
Pain free	Does not pinch or cause lace bite	From needs no 2, 28 and 29	5	Subjective Scale	Yellow	Green	Yellow
Size adjustment device stays tight		Needs no 9, 25 and 34	5	Binary	Yes	Yes	Yes
Easy to open buckle with one hand		From need no 21	5	Scale/Subjective	Yes	Yes	Yes
Easy to close buckle with one hand		From need no 21	5	Scale/Subjective	Yellow	Green	Green
Easy to adjust size with one hand		From need no 21	5	Scale/Subjective	Yellow	Green	Green
Adjustable size	Maximal difference in arm circumference covered by the band	From need no 30	3	mm	> 30	≥ 120	60
Controller box							
Weight		From needs no 1, 19 and 24	4	g	≤ 200	≤ 100	Can't be validated at this stage
Centre of gravity close to surface of electrode band	Distance from shell to centre of gravity. Affects the moment when moving the arm.	From needs no 2, 9, 14, 19 and 33	5	mm	≤ 20	0	Can't be validated at this stage
Dimensions	As small as possible while housing circuit boards of 70x40x30 mm, battery and cable connectors	From needs no 1, 6, 18, 24 and 33	4	mm x mm x mm	120 x 50 x 30	70 x 40 x 20	Can't be validated at this stage
Battery charging	Should be possible without needing to take out the battery	From needs no 11, 12 and 26	3	Binary	Yes	Yes	Can't be validated at this stage
Indication of system state	Shows if the controller is on or off	From needs no 25 and 26	4	Binary	Yes	Yes	Can't be validated at this stage
Indication of battery level		From needs no 25 and 26	4	Binary	Yes	Yes	Can't be validated at this stage
Secure fastening on electrode band		Technical requirement	5	Binary	Yes	Yes	Yes
Allows for alternative way of wearing	Required for compatibility with single use electrodes	Request from Integrum	3	Binary	Yes	Yes	Yes
Risk of box getting caught when worn in alternative way	Should not get caught in e.g. clothes, skin or hair	From needs no 2, 13, 14 and 29	3	Scale	No	No	No
Withstand fall from height		From need no 4	4	mm	> 1 m	≥ 2 m	Can't be validated at this stage
Connection between controller box and band							
Good connection between electrode band and controller box	Electrical connection	From needs no 9, 26 and 34	4	Binary	Yes	Yes	Yes
Number of signals		Request from Integrum	5	Number of signals	≥ 17	17	17
Mate force	Force needed to attach controller box on band	From needs no 13, 21	4	N	Requires testing with Neuromotus system	Requires testing with Neuromotus system	Can't be validated at this stage
Self-alignment	Little precision needed to attach controller box on band"Easy to connect"	From needs no 11, 12 and 26	3	Subjective scale	Yellow	Green	Yellow
Secure attachment	Box does not disconnect while user performs exercises	From needs no 2, 26 and 34	4	Subjective scale	Green	Green	Can't be validated at this stage
Width	Connection surface required must allow for curvature of the electrode band	Technical requirement and from need no 34	5	mm	4-15	4-6	Can't be validated at this stage
Withstands mate and un-mate cycles		From need no 4	4	number of cycles	≥ 1300	≥ 1500	Can't be validated at this stage
Possibility to attach controller box on electrode band with one hand		From need no 21	4	Binary	Yes	Yes	Yes
Separeatability	easy to change parts and reapare	From needs no 7 and 26	4	Scale	Yellow	Green	Can't be validated at this stage
Marker							
Low risk of forgetting the marker		From needs nr 11 and 36	3	Subjective scale	Yellow	Green	Yellow
Level of integration	Is the marker a loose part, part of the electrode band or the controller box?	From needs 11, 22, 24 and 36	3	Subjective scale	Yellow	Green	Yellow
Readable by webcam	No glare	Technical requirement and from need no 11	4	Binary	Yes	Yes	Yes
Does not deform	Does not bend, causing recognition problems	From needs no 16 and 25	4	Binary	Yes	Yes	Yes
Can be worn without the electrode band		Request from Integrum	4	Binary	Yes	Yes	Yes
When worn without the electrode band, the marker allows for easy attachment.	Does not need to be pulled over the cables between controller box and electrodes.	From needs no 9 and 22	3	Binary	Yes	Yes	Yes

** The features evaluated are **** Two

Appendix XIX: Cable colour

+	-
Yellow/Red	Yellow/Black
Blue/Red	Blue/Black
Green/Red	Green/Black
Orange/Red	Orange/Black
Purple/Red	Purple/Black
Brown/Red	Brown/Black
Grey/Red	Grey/Black
Turquoise/Red	Turquoise/Black

Ground: Yellow/Green

Appendix XX: HTA - Final Concept

0	Perform Neuromotus training session
1	Bring the Neuromotus
1.1	Bring storage units
1.2	Open storage units
1.3	Take out the Neuromotus
2	Clean the skin
2.1	Undress
2.2	Clean the skin
2.2.1	Apply disinfectant on paper
2.2.2.	Apply disinfectant on residual limb
3	Connect Neuromotus
3.1	Slide on the electrode band
3.2	Tighten the electrode band
3.3	Attach the controller box on the electrode band
3.4	Activate the controller box
4	Follow training protocol
4.1	Fill out pain questionnaire
4.2	Test the signals
4.3	Do the training
4.3.1	Record the reference signal pattern for the movement
4.3.2	Do the exercises
5	Disconnect Neuromotus
5.1	Deactivate the controller box
5.2	Detach the controller box from the electrode band
5.3	Loosen the lacing
5.4	Slide off the electrode band
6	Dress
7	Put Neuromotus aside

Appendix XXI: PHEA - Final Concept

NR	Task	Use error	Cause	Consequence	Discovery	Recovery
3.1	Slide on the electrode band	Sliding the electrode band too far or not far enough	Mis-aim at correct position	Problem with signal readings	Bad signals	Slide electrode up or down the limb
		Putting electrode band in wrong angle	Mis-aim at correct position	Problem with signal readings	Bad signals	Rotate the electrode band
		Putting on electrode band upside down	Little difference between up and down side of band	Problem with signal readings	Bad signals	Take electrode band off and repeat step
3.2	Tighten the electrode band	Band too tight	Tightening device pulled too far	Discomfort	Discomfort	Loosen the strap
		Band too loose	Tightening device not pulled far enough	Displacement of the electrode band	Bad signals or displacement of the electrode band	Put electrode band in place, and tighten the lace
4.3.2	Do the exercises	Movements too big	User too involved in the exercise	Impaired connection between box and band	Bad signals	Reconnect controller box
5.3	Loosen the lacing	Uncareful loosening of the lacing	Band not optimally fitted	Band slides off the limb too fast	Band falls off	Pick up band from where it fell

Other errors that might occur
Knocking a glass of liquid over
Dropping things onto the floor

Appendix XXII: Usability test, the tasks

Introduction:

This product is an electrode band developed to acquire EMG signals to control a virtual reality representation of your arm. As you can see, the electrodes are arranged in two rows of eight electrodes: an array you wish to modify to acquire better signal readings.

The dots on your arm are the places where you have found strong muscle movement, and where you wish to place the electrodes

Your task is to map these marks on your skin onto the electrode band, so that the electrodes will automatically end up in these positions when you take on the electrode band.

Feel welcome to think out loud!

Task 1:

Place the electrodes in the correct spots in the mesh and assemble the electrode band to fit around your arm.

Instructions:

1. Disassemble the electrode band by unlacing it, taking off the plastic shell, and taking the electrodes out.
2. Delivered with the box is a thin nylon tube with a blue line marked on it. Slide it onto your arm so that the blue line is directed inwards to the body when the arm hangs loosely on your side.
3. Locate the desired position of the electrodes, and mark them on the tube. Do this for all four pairs.
4. Open the tube by cutting along the line, and lay it out flat with the outside facing up. Place the lining material over the nylon sock.
5. Place the spring loaded electrodes in the holes nearest to the marks on the nylon.
6. Attach the lining to the hard plastic shell using the velcro. Lace the string through the D-rings, and secure it through the cord lock.

Task 2:

Take on the electrode band and tighten the laces by pulling the string

Observations:

Amount of electrodes ending up in the correct positions

Electrodes falling out

How well does the size fit?

User's circumference around arm

Appendix XXIII: Observations from usability test

Usability test 1 (25, teacher)

- It is hard to see what is up and down on the tube.
- Does not place the line on the tube in the recommended position.
- Has problem with stretching the tube over the lining.
- When translating the markings from the tube to where the electrodes should be, the user has problems knowing what is up and down on the tube.
- The electrodes end up in the wrong places because of the low resolution in the grid.
- The user lifts up the lining to place it in the plastic band and flips it in the air, which results in electrodes falling out of the holes.
- The user has problems with tightening the band.
- 2 out of 8 electrodes end up in the desired positions.
-
- The following problems also arose, which are a result of the product representation:
- The user has problem with that the spacer-material and the plastic band is in different sizes.
- The string for lacing gets caught in the velcro in the lining.
- The user wonders how the spacer should be placed in relation to the plastic shell.

Usability test 2 (25, student)

- The material of the tube is difficult both to make marks on and cut through.
- Markings for the placement of the electrodes end up under where the tube is supposed to be cut.
- The user stretches out the tube over the lining, taking time to figure out which side is up and down.
- The user has some problems in the beginning with placing the electrodes, because the tube is stretched over the lining.
- This is solved by stretching out a section of the tube at a time and placing the electrodes underneath the markings.
- The user asks for some pictures to help explaining both the instructions and the parts of the product.
- The string is tightened with the help of the mouth.

- 6 out of 8 electrodes end up in the desired positions.

Usability test 3 (25, student)

- It is not clear to the user what the tube is for, and immediately starts thinking of a more efficient way to adjust the electrode placement.
- The user begins by testing the band to se if it is possible to make the band fit without changing the electrode placement.
- It is difficult to cut through the tube.
- After a while, the user skips the tube, ties the lining around the arm with the help of the string, and mark the right holes in the lining with the pen.
- The user wants to cut new holes in the lining to increase the resolution.
- The user wishes for an explaining picture to describe how the string should be laced.
- 8 out of 8 electrodes end up in the desired positions.

The following problems arose, which are a result of the product representation:

- Electrodes end up outside the plastic shell.
- It is not clear what is up and down on the electrode.

Usability test 4 (25, student)

- It is difficult to cut through the tube.
- It is difficult to keep the tube stretched out when the liner is placed over it - it also is not clear whether the tube should be stretched out or not.
- It is difficult to see the markings made on the tube when they do not align with the holes in the grid. The user aligns the two layers to easier see the markings.
- The user places the liner upside down in the plastic shell.
- The lacing is done without problems.
- 6 out of 8 electrodes end up in the desired positions.

The following problems also arose, which are a result of the product representation:

- The string for lacing gets caught in the velcro in the lining.

Usability test 5 (27, baker)

- The user puts the lining around the arm to see where the electrodes should be placed.
- The electrodes that have already been placed in the lining fall out when the next is inserted.

- The user has problems keeping the lining around the arm when placing the electrodes.
- The user wishes for smaller holes to make the electrodes stay in place.
- The user notes which side is up and down on the lining and plastic band.
- The user only reads the instructions after the customisation is finished, does not understand it, but places the tube on the arm.
- After placing the tube on the arm, the band is taken on over the tube.
- The user has some problem how to place the electrode band on the arm in the right direction.
- The user puts the band on in the wrong direction.
- 6 out of 8 electrodes end up in the desired positions.

The following problems arose, which are a result of the product representation:

- The band is too small, and the string for lacing is too short.

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