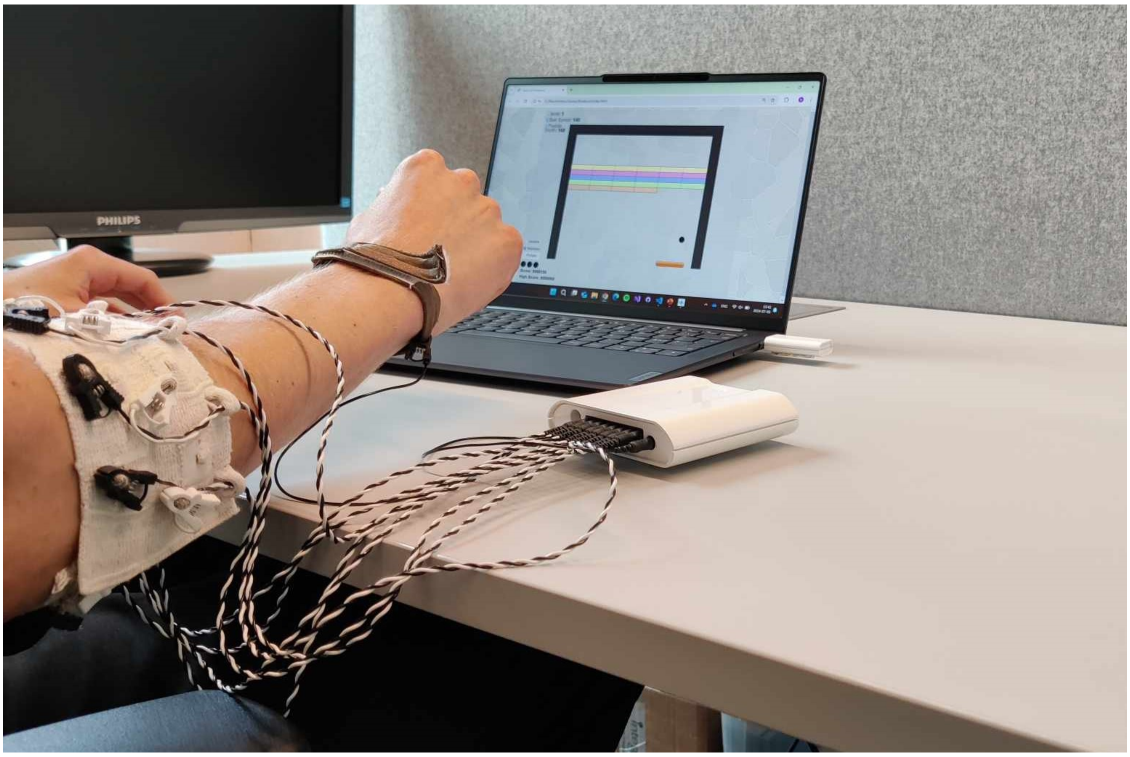

Enhancing Phantom Limb Pain Rehabilitation Technology with User-Centered Improvements

Improving a CE-Marked Medical Device in Collaboration with Integrum AB

Master's thesis in Biomedical Engineering

OLIVER MOBERG

DEPARTMENT OF ELECTRICAL ENGINEERING
CHALMERS UNIVERSITY OF TECHNOLOGY
Gothenburg, Sweden 2024
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Master's Thesis 2024
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Cover: Neuromotus device used with the textrode band, playing the improved Breakout game in joystick mode.

Typeset in LaTeX
Printed by Chalmers Reproservice
Gothenburg, Sweden 2024

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Abstract

Phantom limb pain (PLP) is a common and distressing sensation experienced by $50-85\%$ of individuals with limb loss, often manifesting as pain in the removed body part without any physical cause. Rehabilitation methods such as mirror therapy, motor imagery, and phantom motor execution (PME) are used to alleviate this pain. PME, in particular, engages the central and peripheral nervous systems to activate muscles in the residual limb. Integrum AB has developed Neuromotus, a medical device for PLP rehabilitation that leverages PME principles through virtual reality (VR), augmented reality (AR), and serious gaming. This project aims to identify and implement user-centered improvements to Neuromotus.

The project began with a qualitative pre-study involving semi-structured interviews with experienced therapists who have used Neuromotus in clinical practice. Based on their feedback, several improvements were identified and implemented. Including two new open-source games, enhanced functionalities in existing games, the addition of a proportional controller, and the ability to customize the AR limb skin tone. Stakeholders subsequently tested these enhancements and validation tests were made for all then new functionalities.

The results indicate that the proportional controller significantly enhanced gameplay, while the customizable limb color in the AR environment promoted inclusiveness and ensured alignment with ethical standards. These improvements could collectively contribute to a more effective and user-friendly PLP rehabilitation experience.

Keywords: Phantom Limb Pain, Phantom Motor Execution, Neuromotus, Augmented Reality, Serious Gaming.

Acknowledgements

I would like to express my sincere gratitude to Integrum AB for granting me the opportunity to be part of this enriching experience. I am deeply thankful to my examiner, professor Petter Falkman, and my supervisor, Morten B. Kristoffersen, for their invaluable guidance and continuous support. I am also grateful to the physiotherapists who agreed to be interviewed and provided feedback and information that guided this project forward. Additionally, I extend my appreciation to the representatives from the HOPE study for their valuable insights and contributions to this project.

I am appreciative of all my peers and colleagues at Integrum for their support, collaboration, and shared experiences throughout my academic journey. In particular, I am grateful to, Magnus Lindholm, Elin Sjöqvist, and Björn Davidsson, whose expertise, support, and camaraderie have been invaluable throughout my thesis project.

Oliver Moberg, Gothenburg, 07 2024

List of Acronyms

Below is the list of acronyms that have been used throughout this thesis listed in alphabetical order:

AR	Augmented Reality
HID	Human Interface Device
MDCG	Medical Device Coordination Group
MDD	Medical Device Directive
MDR	Medical Device Regulation
MPR	Myoelectric Pattern Recognition
PLP	Phantom Limb Pain
PME	Phantom Motor Execution
RMS	Root Mean Square
sEMG	surface Electromyography
TAC	Target Achievement Control
VR	Virtual Reality

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1
Introduction

The human body perceives information about the surroundings by using receptors that sense vibration, temperature, touch, and noxious stimuli [1]. A part of the neurological system that processes this information is called the somatosensory system, which facilitates feedback from the surroundings through the stimulated receptors. It has several purposes including working as a warning system, alerting our body of harmful situations perceived as pain.

Amputation can inflict a sensation of pain without any physical strain, called neuropathic pain [2]. The origin of this pain is yet to be conclusively determined. A different type of pain that can emerge after amputation is nociceptive pain which is associated with physical pain receptors producing afferent discharges, sometimes resulting in neuroma pain. A pain inflicted from the growth of nerve tissue that occurs due to nerve injury, often presenting as a painful, disorganized mass of nerve fibers [3]. Both of these two mechanisms inflict pain with varying sensations and are referred to as phantom limb pain (PLP). They are different and it is therefore important to make a distinction between these, Professor Ortiz Catalan defined it as [2]:

"Neuropathic Phantom Limb Pain is pain perceived as arising from the missing limb due to sources other than stimulation of nociceptive fibers that used to innervate the missing limb."

"Nociceptive Phantom Limb Pain is pain perceived as arising from the missing limb deterministically by stimulation of nociceptive fibers."

This distinction is important for the treatment being adapted to fit the appropriate pain profile such that the clinicians can offer personalized therapy to reduce PLP [4]. Bacterial or viral infections could stimulate the nociceptive receivers and cause nociceptive PLP[[5], [6]]. Treating this as neuropathic PLP with cognitive therapy would be unsuccessful, finding the correct cause is therefore of significant importance.

The phenomenon of PLP has been recognized for centuries. The term "phantom limb" was first coined by American neurologist Silas Weir Mitchell in the late 19th century [7]. In his observations of Civil War persons with limb loss, Mitchell described expressive sensations of lost limbs, including severe pain. Prior to Mitchell's work, French military surgeon Ambroise Paré, in the 16th century, documented cases of persons with limb loss who felt pain in their absent limbs [8]. These historical accounts laid the foundation for understanding PLP, which has since evolved significantly with advancements in medical science.

The relevance of studying PLP and its underlying causes is emphasized by the increasing number of amputations due to diabetes, vascular diseases, trauma, and cancer [9]. The perception of a phantom limb can result in sensations such as numbness, tickling, and cramps. When these sensations become painful, they are defined as PLP [10]. This painful sensation appears in 50-85 % of all persons with limb loss, making it the most common condition after amputation. It affects daily life during work, sleep, and exercise which reduces enjoyment and life quality [11].

In 2017, 57,7 million people worldwide were living with limb loss due to traumatic causes [12]. With advancements in surgical techniques and prosthetic technology, amputations are becoming more common, making PLP a growing concern in both civilian and military populations [13]. Addressing PLP effectively requires a multifaceted approach, incorporating medical, psychological, and rehabilitative strategies to improve patient outcomes [14].

1.1 Background

The company Integrum AB will in collaboration with University of Borås participate in a new study, HOPE, founded by the KK-stiftelsen (Stiftelsen för kunskaps- och kompetensutveckling). The study will focus on how textile-based electrodes can be combined with Neuromotus, a medical device for treating PLP, to improve adherence to home-based rehabilitation. The clinicians and therapists included in the study will use Neuromotus for the PLP rehabilitation treatment. Leading up to this project, two research projects have been conducted.

The first study was conducted from 2016 to 2019 to introduce the textrode-band for Surface Electromyography (sEMG) recording using advanced flat knitting technology [15]. This band integrates electrodes and connectors into the fabric, providing a flexible, wearable, and washable alternative to conventional single-use electrodes. The study evaluated the band's feasibility in a myoelectric pattern recognition (MPR) task involving decoding movements of the lower limb. Results showed promising signal-to-noise ratio, offline MPR accuracy, and real-time performance metrics, particularly for proximal limb movements like knee flexion/extension.

The second study was conducted from 2020 to 2023 and focused on advancing smart textile technology to improve healthcare, particularly in neuromuscular rehabilitation [16]. By embedding sensors in textiles, patients can monitor their health easily by wearing sensor-equipped clothing and using a smartphone app. The project aims to develop NeuRehab@home, a smart textile platform for neuromuscular rehab at home. It utilizes sEMG for biofeedback-based therapy, including treating PLP using sEMG signals to control VR hands. Traditional sEMG methods with disposable electrodes have limitations, so the project explores smart textile solutions with improved comfort and usability.

1.2 Theory

This chapter presents the theory behind PLP and the current therapy methods used for rehabilitation. It also provides a detailed description of Neuromotus, including its key features and previous studies related to the device. Furthermore, an overview of the regulatory framework for medical devices and the process of changing these devices is included.

1.2.1 Cortical mapping

Understanding the neural mechanisms underlying PLP is crucial for developing effective therapeutic interventions. One key aspect of this understanding lies in cortical mapping and cortical reorganization [17].

Cortical mapping refers to the organization of the somatosensory cortex, the area of the brain responsible for processing sensory information, including touch and proprioception [18]. Figure 1.1 illustrates how different parts of the somatosensory cortex are linked to specific body parts. In individuals with intact limbs, cortical mapping is highly organized, with specific regions dedicated to different body parts. However, following amputation, the cortical mapping can experience significant changes [17]. This phenomenon is called cortical reorganization, occurring due to the brain's ability to reorganize its structure and function in response to sensory input or damage. In the context of PLP, cortical reorganization involves remapping the somatosensory cortex as the brain attempts to repurpose areas previously used by the now-missing limb. This can become maladaptive if it begins to contribute to the development and persistence of PLP.

The therapeutic methods of managing PLP are closely linked to cortical reorganization [19]. The methods can promote neuroplasticity and facilitate the reorganization of cortical maps by engaging the brain's motor and sensory networks. Studies have shown that the therapy method mental imagery, can modulate neural activity in the sensorimotor cortex and reduce PLP intensity [18]. This therapeutic effect may be attributed to the restoration of cortical organization, where the brain learns to adapt to the absence of the limb and alleviate pain sensations.

1.2.2 Current therapy methods

There is currently no therapeutic method that is effective for all patients in reducing PLP. Attempts to reduce this pain have therefore been researched to find the underlying cause for both the neuropathic and nociceptive pain as well as find effective rehabilitation therapy methods. Clinical trials and studies have found potential treatments that work for some but not all patients by using mirror therapy, virtual mirror therapy, motor imagery, or motor execution [[10], [20]]. Mental imagery is

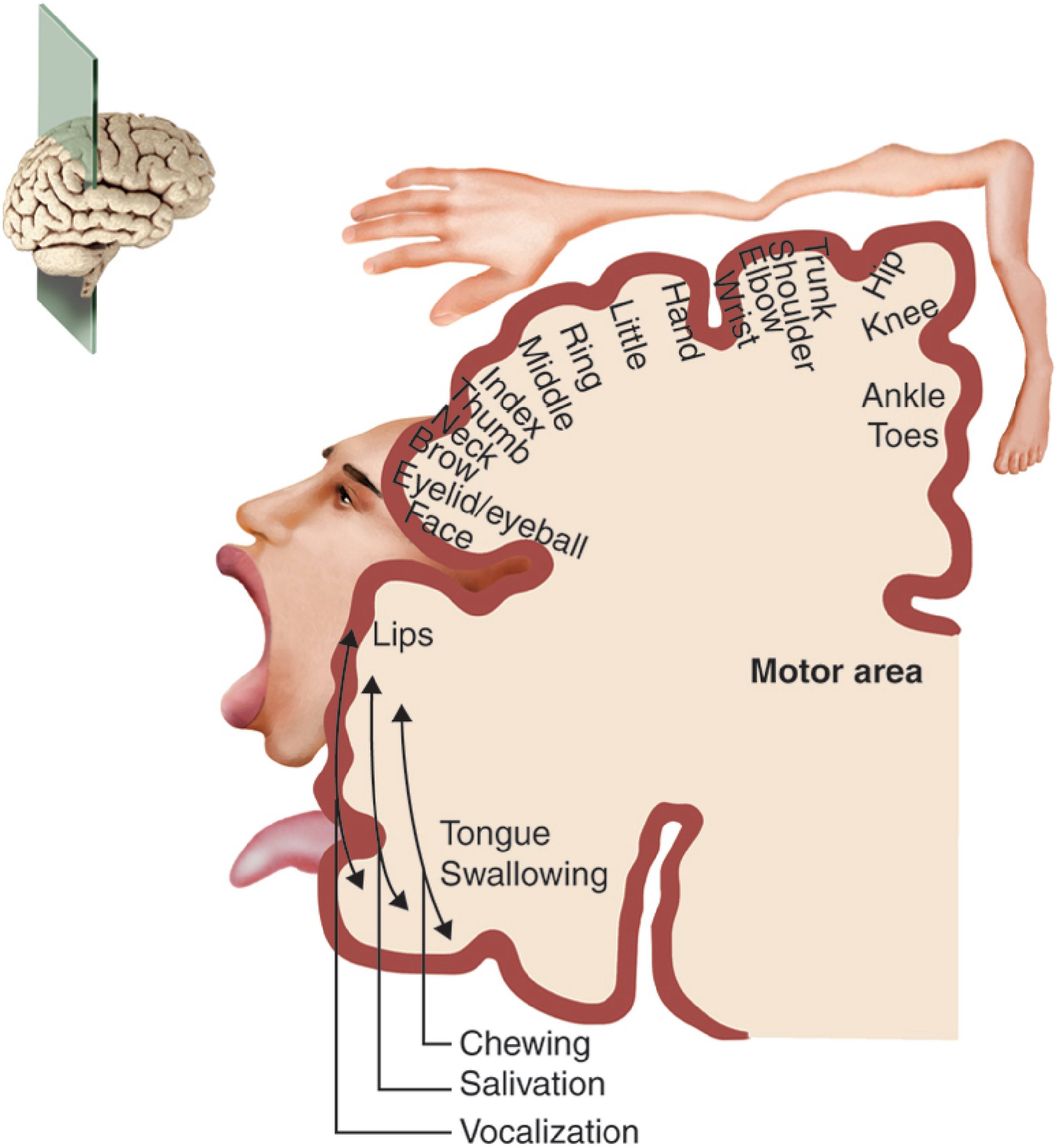


Figure 1.1: The cortical mapping of the somatosensory cortex, highlighting how different regions of the cortex are linked to specific body parts. The image was adapted from Nursing Hero and licensed under CC BY 3.0 US.

included in these methods and has been established to facilitate cortical reorganization, alleviating PLP [[18], [21]].

Mirror therapy was introduced in the 1990s as a therapy treatment to reduce PLP [10]. It works by having the amputated limb concealed with a mirror which displays the healthy limb in the visual space of the phantom limb. The patient then performs the intended movements with the phantom limb while simultaneously moving the healthy limb with the equivalent movement. This provides visual feedback through the mirror that the phantom limb is moving as intended and is thought to result in changes in the somatosensory and primary motor cortex, relieving pain [11].

Motor imagery involves mentally simulating a movement without physically performing it, engaging areas in the brain similar to those activated during actual movement [22]. There are two types of motor imagery, implicit and explicit. The implicit motor imagery, also called laterality recognition, is a therapy form where the patient must differentiate between images of the left or right side of the body. Persons with limb loss are generally slower and less accurate at determining whether the body part is on the left or right side, especially if their loss was on their predominant side [23]. This therapy improves performance in lateral recognition tasks and activates somatosensory and motor areas opposite to the phantom limb [24]. The explicit part of the motor imagery involves the patient actively thinking about a movement that is being displayed on a screen and performing this movement with the phantom limb [22].

Combining therapy methods and performing them in series can reduce the intensity of PLP [11]. The Graded Motor Imagery is a method that includes implicit and explicit motor imagery together with mirror therapy. Contradicting conclusions have been made about the effectiveness of this sequential therapy method and a study including a larger sample of people is needed [22].

Phantom Motor Execution (PME) involves generating phantom movements by engaging both central and peripheral circuits, leading to muscular activation at the residual limb [2]. While mirror therapy is a common approach to facilitate PME, it lacks the ability to measure actual motor output. This introduces uncertainty, as individuals may focus solely on visual feedback from the contralateral limb, neglecting physical execution in the residual limb which might play a role in pain relief. However, employing myoelectric decoding of motor volition at the residual limb verifies movement execution. This approach relies on detecting muscular contractions as a reliable physiological response to motor execution. Obtaining phantom motor intention from the muscular activity at the residual limb confirms the activation of the relevant parts of the central and peripheral nervous system. This phantom motor intention can then be utilized to provide feedback to the user through various media such as Virtual Reality (VR), Augmented Reality (AR), and serious gaming by incorporating these elements into the therapy.

1.3 Neuromotus

Integrum AB developed Neuromotus, a CE-marked and medical device directive (MDD) Class 1 medical device, used in rehabilitation to reduce PLP for people with limb loss effectively. It uses VR, AR, and serious gaming focused on PME with the help of pattern recognition.

1.3.1 Hardware

The Neuromotus kit consists of six components illustrated in Figure 1.2. Their function is the following:

- **1:** The Neuromotus main device with the function of sending the electrode signals to the dongle.
- **2:** The dongle connects the main device to a computer.
- **3:** Electric leads with eight channels connecting the main device to the electrodes.
- **4:** Fiducial marker used for the AR function to detect the residual limb location.
- **5:** Charger for the main device.
- **6:** Leg band with belt clip.

Figure 1.2: Neuromotus user kit.

1.3.2 Software

When starting up the Neuromotus program, a user profile must either be created or selected, providing the program with the patient's personal information. The user interface is then divided into three segments illustrated in Figure 1.3. It starts with a signal check, followed by a movement selection and recording phase, and limb control can then be used with the built-in functionalities.

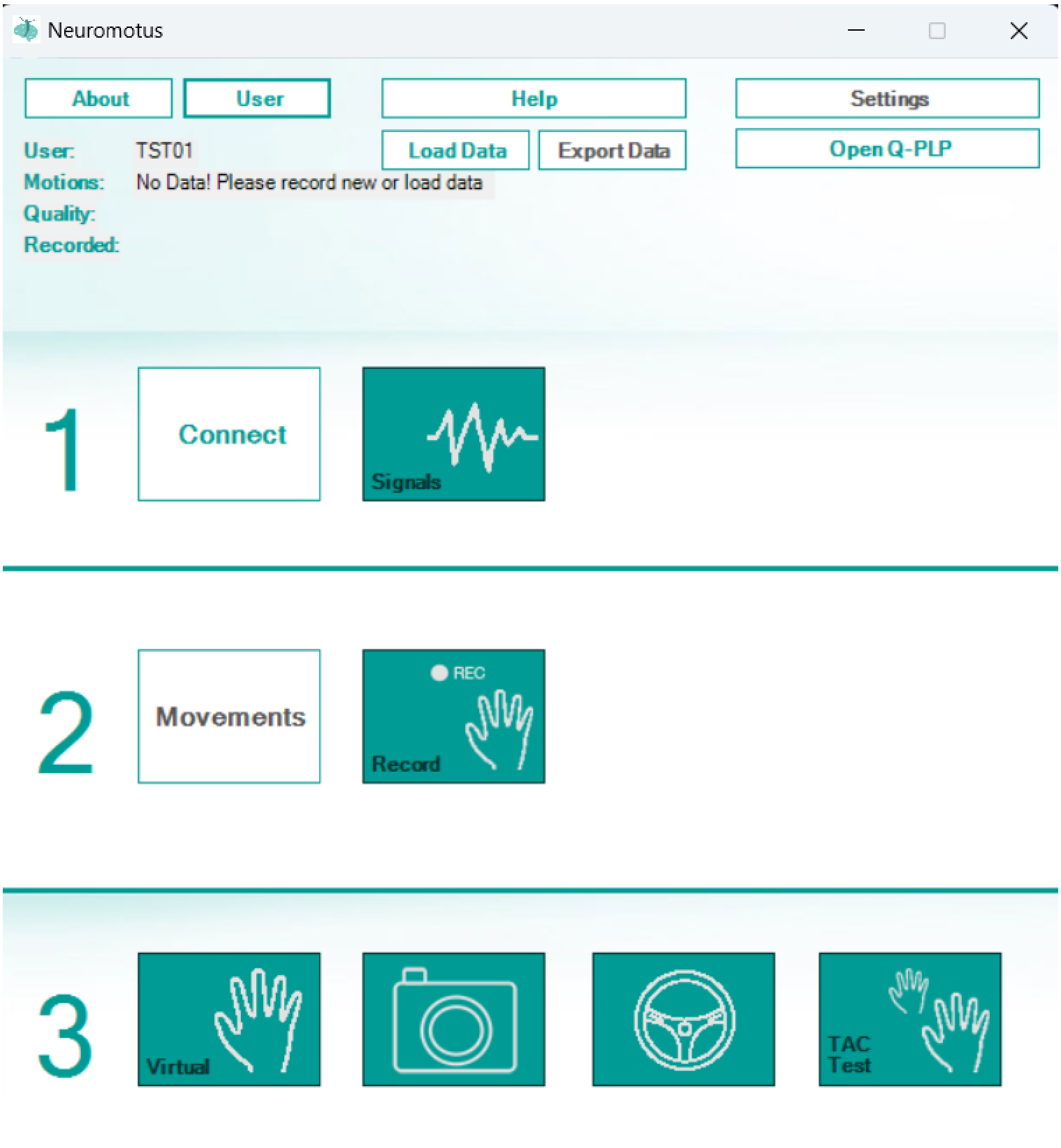


Figure 1.3: Neuromotus user interface.

Before entering any of these sections, the settings tab can be opened and the layout is illustrated in Figure 1.4. Here you can define the movements to record, the left or right limb, which movements are used for the game control, and advanced settings for more control over the calibration sequence. The user can then move on to the first section.

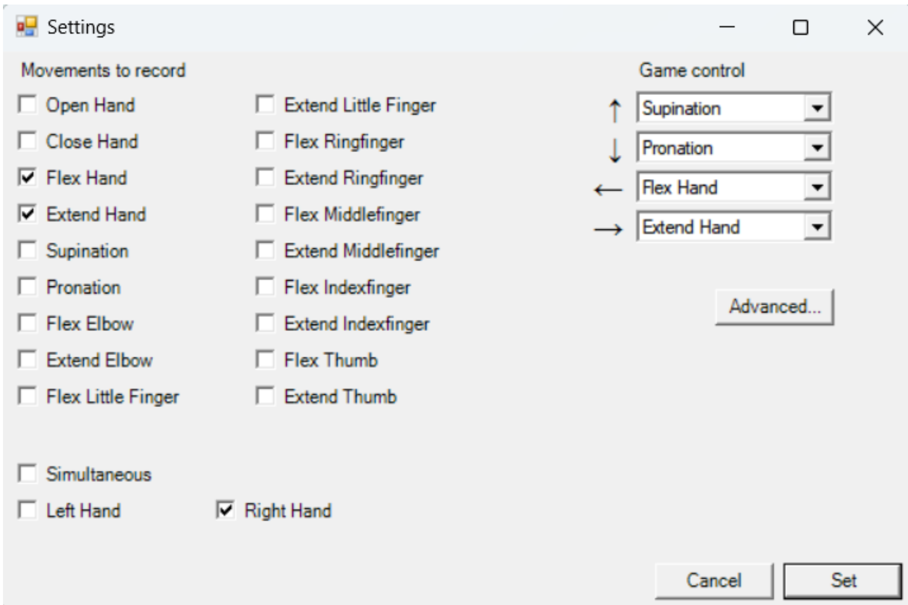


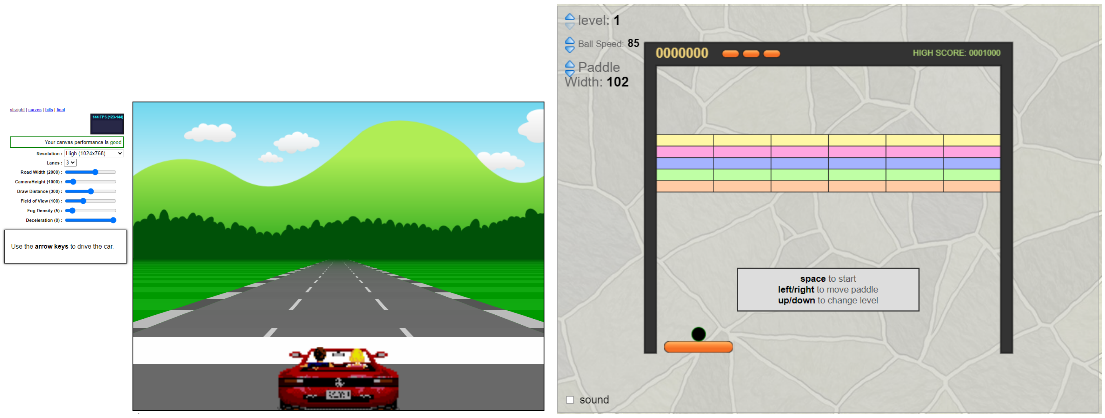
Figure 1.4: Neuromotus settings for a user with upper limb loss.

The first section is the connection part where the system ensures the dongle has established a connection with the main device before the user can move on to the next step. All of the electrode channels can be viewed in the *signals* window to confirm that all channels produce the expected output.

Secondly, in the recording sequence, the user selects the desired movements such as open/close hand, flex/extend hand, and supination/pronation, from the *Movements* button if not previously selected in the settings tab. Subsequently, the user initiates a *Record* session and performs the selected movements. The therapist or user can select a movement duration and rest time which is three seconds by default. The contraction/rest sequence is performed three times and the resulting data is fed to a pattern recognition algorithm capable of classifying phantom limb movements.

Thirdly, the main functions of the treatment, consist of VR, AR, serious gaming, and Target Achievement Control (TAC) test that can be initialized. They are all based on pattern recognition for control and provide different objectives for the user. In VR, the user controls a virtual arm for easy visualization with the freedom to perform the selected movements at their own pace and desired order. In AR, a fiducial marker is placed on the user's residual limb to display an AR limb in its original place in the AR space. The AR limb will then follow the user's position through the marker allowing back/forth and rotational positional changes while still performing the selected movements. Another function is the TAC test which measures how well the user can match defined limb positions and receives feedback on how well it matched.

For the serious gaming function, specific phantom limb movements, such as opening and closing the hand, are translated into keyboard inputs for controlling a racing game and Breakout, as illustrated in Figures 1.5a and 1.5b, respectively. The racing game features four maps of varying difficulty and user-changeable driving parameters, while Breakout includes features such as a score, a high score, and user-changeable ball and paddle parameters.



(a) Racing game. **(b)** Breakout.

Figure 1.5: Current games included in the Neuromotus package.

A Questionnaire for PLP (Q-PLP) tracking can be filled in after a session to track recent progress and pain development over time, illustrated in Figure 1.6. It contains a questionnaire regarding pain intensity, location, type of pain, and change over time. It is possible to only use the visual analogue scale for a quicker evaluation, this is also included in the questionnaire. The pain distribution is used to evaluate how the pain differs throughout the day. The results are then displayed in the *Results* section. This is used as a metric for the therapist, user, and researchers to track progress and evaluate the result of the treatment.

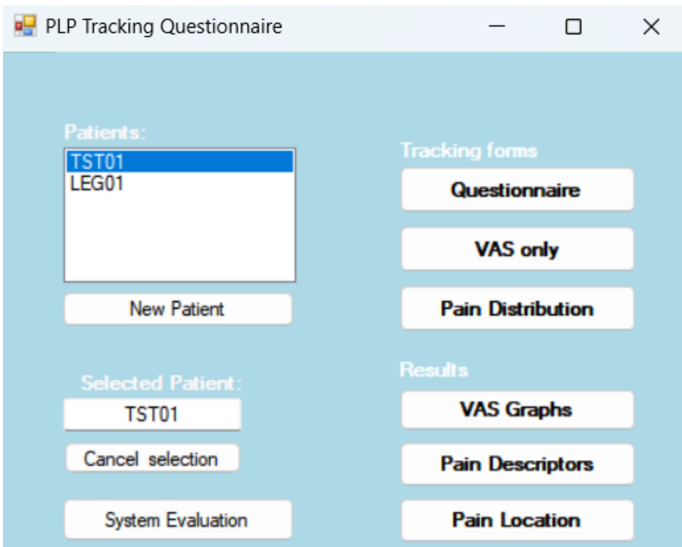


Figure 1.6: Neuromotus Questionnaire interface.

1.4 Previous related Neuromotus studies

Studies have examined the effects of using PME while utilizing pattern recognition, VR, AR, and serious gaming [26]. Three main studies have been completed, the first was a case study that used the principles of PME, but the actual Neuromotus device was not yet created. The second and third studies were clinical trials that used Neuromotus for the PLP treatment.

1.4.1 The first case study

The first study was published in 2014 and introduces a system that combines myoelectric signals from the patient's residual limb with AR, allowing direct volitional control of a virtual limb [26]. The case study involved a 72-year-old male person with limb loss who experienced PLP for 49 years and has unsuccessfully tried various treatments, including mirror therapy, drugs, acupuncture, and self-hypnosis. The intervention utilizes BioPatRec, an open-source myoelectric control platform, to predict the patient's intended movements. The AR environment is created using a webcam capturing the patient's surroundings.

Pain levels were monitored using the short-form McGill pain questionnaire, revealing a gradual reduction in pain intensity and the emergence of pain-free periods after multiple sessions. The patient gained the ability to voluntarily control the virtual limb, even outside the laboratory. Changes in phantom limb perception were also observed, with the patient transitioning from a closed fist position to a mid-open hand position.

The article suggests that the combination of myoelectric control, AR, and gaming holds promise for PLP treatment. The improved quality of life and pain reduction in the patient indicate the effectiveness of the proposed system, calling for further exploration in a broader PLP population. The study underscores the non-invasive, portable, and open-source nature of this innovative technology.

1.4.2 The second study

The researchers of this clinical trial introduced a novel therapy for chronic PLP, focusing on promoting PME [20]. This non-invasive approach, grounded in principles of brain plasticity, aimed to address the limitations of existing treatments for patients who had experienced upper limb amputations. The clinical trial highlighted the potential efficacy of the therapy and its application in cases where conventional methods had previously failed.

Over a period from September 2014 to April 2015, 14 patients with refractory chronic PLP participated. The average age was 50.3 years, with a mean PLP duration of 10.3 years. Previous treatments had been unsuccessful for an average of 5.6 years before enrollment. The outcomes demonstrated a consistent reduction in PLP across various metrics, with sustained improvements noted in pain intensity, quality, and interference with daily activities and sleep. The proposed technology, requiring volitional control of musculature at the residual limb, exhibited potential benefits but acknowledged limitations for certain patient groups.

While the clinical trial revealed promising results, including a 50% reduction in PLP for many participants, it underscored the need for further research. Limitations, such as the absence of a control group and potential bias in follow-up interviews, were acknowledged. Technological feasibility and future applications of the proposed therapy beyond PLP were discussed, emphasizing its integration into a treatment–evaluation system. Overall, the findings suggested a novel and potentially effective avenue for addressing chronic PLP, though additional clinical evidence and exploration of underlying mechanisms are warranted.

1.4.3 The third study

This clinical trial explores the process of identifying user types for a technological therapy PME, designed to address PLP [27]. The methodology involves conducting ethnographic unstructured interviews and employing the KJ methodology for analysis. The information gathered from interviews is categorized into themes, leading to the recognition of two distinct user types: Goal-Oriented Users and Experiential Users.

The Goal-Oriented Users, categorized as User Type I, are individuals who measure their progress based on the completion of specific goals. They exhibit a preference for goal-oriented activities, such as the TAC test, and seek feedback related to goal achievement.

On the other hand, the Experiential Users, identified as User Type II, perceive the therapy through the AR experience. They prioritize the realistic qualities of the virtual limb and tend to base their practice on time markers rather than specific movement goals.

The discussion highlights the adaptability of PME for PLP treatment at home. Adherence to the therapy is dynamic and influenced by factors such as pain levels, patient needs, motivations, and daily life contexts. The clinical trial emphasizes that the collected pain data may not solely reflect the effectiveness of the treatment but rather how pain influences therapy usage patterns.

Barriers to adherence are identified, including the time demands of the therapy sessions and the necessity for reusable electrodes. It suggests recommendations for designing a device compatible with both user types, such as incorporating a time display for Experiential Users and providing feedback on results for Goal-Oriented Users. Additionally, enhancements in AR realism and compatibility with diverse user populations are proposed.

The clinical trial acknowledges limitations, such as a small sample size (n=4), affecting generalizability. Future research is encouraged to conduct a more systematic investigation over an extended period. In conclusion, the methodological relevance of the clinical trial extends beyond PLP, offering insights into the home use of health technologies. The combined expertise of medical anthropology and human-machine interface design provides a holistic understanding of patient-led in-home care, informing the design of interventions that enhance technology's capacity and relevance.

1.5 Medical device regulations

The MDD, formally known as Council Directive 93/42/EEC, was the foundational regulatory framework established by the European Union to ensure the safety, efficacy, and quality of medical devices within the EU market [28]. This directive required devices to meet essential safety and performance requirements, undergo conformity assessments by notified bodies, and be classified into risk categories with corresponding regulatory obligations. The MDD required CE marking, which signified a device's compliance with EU regulations and allowed its free movement within the European Economic Area.

However, the MDD had limitations that necessitated a more robust framework. The Medical Device Regulation (MDR), which came into effect as EU Regulation 2017/745, replaced the MDD to address these limitations [29]. The transition from MDD to MDR was driven by the need for stricter controls, prioritizing the safety and performance of medical devices, prompted by incidents involving faulty devices that underscored the shortcomings of the MDD [30]. The MDR introduced enhanced transparency and traceability measures, including the Eudamed database and Unique Device Identification system, to ensure better oversight. Additionally, the MDR placed greater emphasis on clinical evidence and post-market surveillance, requiring continuous monitoring of device safety and performance. The scope of the MDR was expanded to cover a broader range of products, including certain software and devices with non-medical purposes, and aimed to harmonize regulatory requirements across the EU, improving compliance and enforcement mechanisms.

1.5.1 Regulatory implications of changing a MDD classed medical device

Article 120 of the MDR addresses the transitional provisions for devices that were already on the market under the MDD or the Active Implantable Medical Devices Directive 90/385/EEC [29]. This article ensures a smooth transition from the old directives to the new regulation, providing clarity and continuity for manufacturers and other stakeholders.

When a change is made to a medical device, it can be regarded as either significant or non-significant. According to MDR Article 120(3c), point (b), there can be no significant changes in the design and intended purpose [29]. To determine whether a change is significant or not, the Medical Device Coordination Group (MDCG) has created a document providing guidance on significant changes related to Article 120 of the MDR [31]. A flow chart, as illustrated in Figure 1.7, is used to guide the classification process. Additionally, connecting child flowcharts (A-E) are provided in Appendix C.

1.6 Purpose

This study aims to identify and define specific improvements to the Neuromotus system, focusing on improving usability and functionality. A qualitative pre-study aims to address and define existing challenges and limitations. The insights gained will guide the selection of targeted improvements which will be implemented and validated in preparation for the clinical study HOPE, to advance the quality of the treatment.

1.7 Delimitations

To narrow the scope of this project and maintain conciseness, several delimitations were established. These limitations were crucial for shaping the design and methodology of the study, ensuring focused research. The specific delimitations are outlined below:

- **Pre-study:** The pre-study will only involve therapists.
- **Neuromotus:** The improvements on Neuromotus will solely focus on the software.
- **Regulatory:** From a regulatory standpoint, the changes made to the system will be non-significant.
- **Testing:** User tests will not be performed.

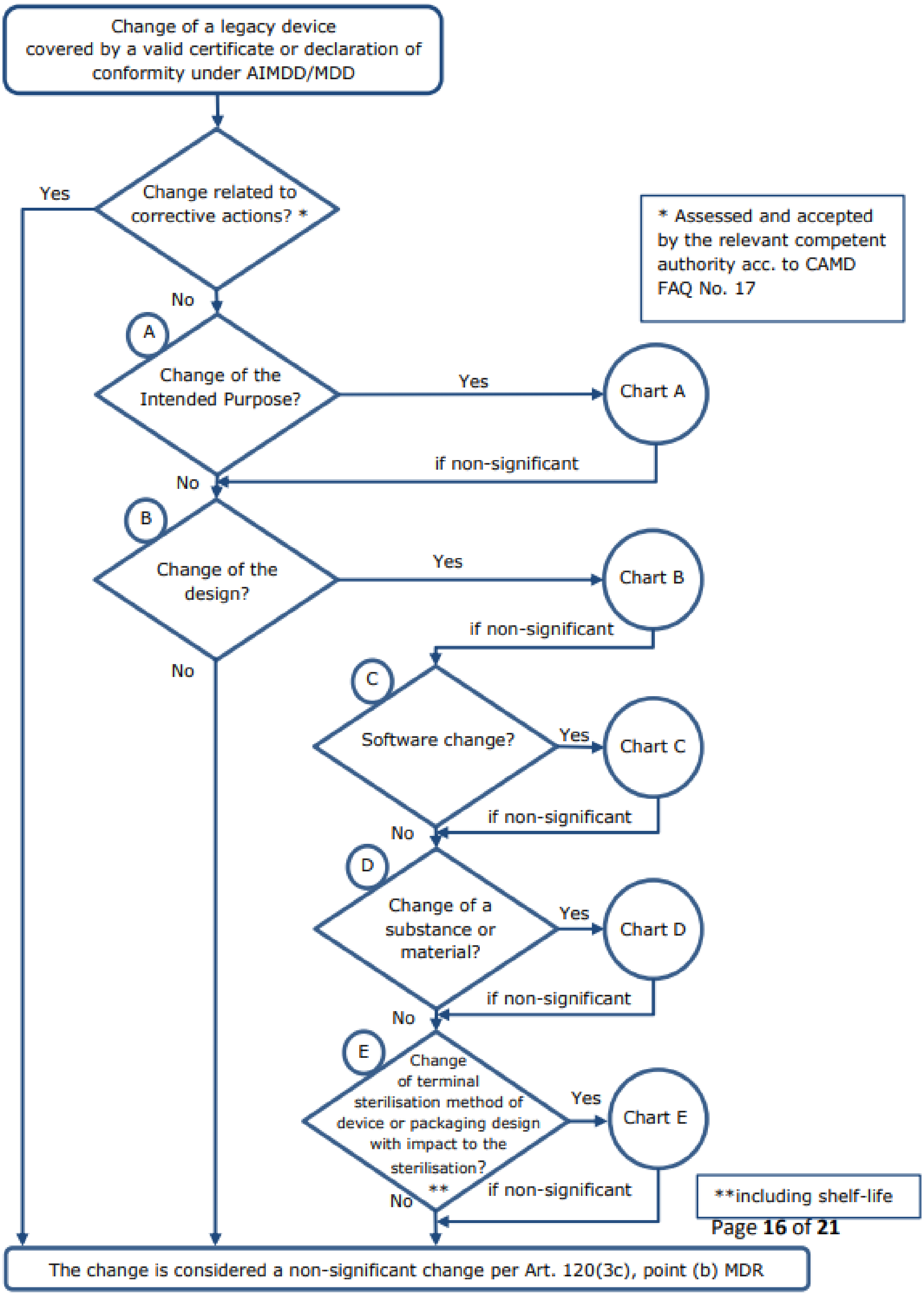


Figure 1.7: Significant changes regarding the transitional provision under Article 120 of the MDR (Source: MDCG 2020-3 Rev.1) [31].

2

Pre-Study

This chapter introduces the pre-study conducted through meetings and semi-structured interviews with a focus on data acquisition and feedback collection. The results from this pre-study will guide the remainder of the project.

2.1 Introduction

The Neuromotus device is utilized in clinics across Europe. Due to the stringent laws governing the handling of personal information, patients were excluded from being contacted. Therefore, the focus is placed on reaching out to physiotherapists.

Semi-structured interviews were chosen as the primary method for gathering information. This approach is advantageous because it combines the flexibility of open-ended questions with the focus of structured interviews, allowing for in-depth exploration of specific topics while still providing room for respondents to express their thoughts and experiences freely. This method is particularly effective for obtaining detailed and nuanced insights from experts, such as physiotherapists, who can provide valuable information about the practical use and impact of the Neuromotus device in clinical settings.

2.2 Methods

The pre-study was divided into two parts, the first one was a meeting together with representatives from the upcoming HOPE study where they presented feedback from previous patients using the Neuromotus device. The second part was semi-structured interviews where the interview questionnaire found in Appendix A, acted as a guideline for the interviews. The interviews were conducted with two physiotherapists having worked with Neuromotous to alleviate PLP for amputees. Transcribed interviews are found in Appendix B.

From the meeting, the following feedback was provided by the HOPE representatives regarding patient experiences:

- **Games**
  - ▶ The games are not intuitive for people with lower limb amputations. Allowing games to be controlled up/down instead of left/right would be

more suitable for knee/foot movements since they inherently move along that axis.
  - The games are too monotonous, leading to decreased adherence over time.
  - Patients desire more advanced features and progress tracking.
- **VR**
  - Generally enjoyed by patients.
- **AR**
  - The limb in the Augmented Reality environment appears unnatural and the skin color is not adjustable.
  - The camera position is difficult to adjust for lower limb amputees.
- **TAC Test**
  - The TAC Test and its feedback features were well-received.
- **Hardware**
  - The lanyard around the neck does not fit all body types.
- **General**
  - It should be communicated that pain levels will likely increase at the beginning of therapy.

The questions in the semi-structured interviews were divided into two parts. The first part focused on patient feedback, where therapists provided insights from treating and conversing with patients during rehabilitation sessions. The second part focused on therapist feedback, where the therapists described their own experiences with the Neuromotus device.

Data from these two parts were then combined and categorized into sections covering various aspects, including games, VR, AR, TAC tests, hardware, and general feedback. Below is a compilation of the combined feedback from both sets of interviews.

- **Games**
  - The car game lacks a defined objective, resulting in a sense of aimlessness and diminished engagement.
  - Breakout proved more enjoyable when a clear objective was established.
  - The games provided a refreshing and engaging alternative to other conventional treatment methods.
  - The synchronization between the contractions and movements of the bar or car was suboptimal for certain participants, leading to frustration. This issue primarily stemmed from patients becoming overly excited and inadvertently disrupting the cables causing movement artefacts which lowered the precision of the movement decoding.
  - Incorporating more engaging games could enhance patient involvement, as some found the current selection to become monotonous over time.
  - Including additional goal-oriented games with feedback mechanisms could enhance patient engagement and satisfaction.
  - The current design appears outdated, lacking the desired level of excitement and engagement. Additional fun and interactive games are desired.

- **VR**
  - The inclusion of a more realistic limb would enhance the overall experience.
  - Some movements extend beyond the screen, rendering them invisible to the patients. This poses a challenge as it becomes difficult for them to discern their actions, particularly with regard to finger and foot movements.
  - Some movements appear anatomically implausible, resulting in a visually awkward appearance.
  - Improving the graphics for a more realistic representation would enhance the overall experience.
- **AR**
  - The skin tone representation on the AR limb appeared unnatural and did not accurately match the diverse skin tones of some users, causing a sense of discomfort or disconnect.
  - The graphics appeared outdated.
  - A more realistic AR limb would enhance the experience.
  - A portion of the patients expressed positive feedback, perceiving it as a valuable tool.
  - Some therapists, particularly those who are older, may find it challenging to accurately position the limb.
  - This was a popular and highly useful tool for treatment purposes.
- **TAC Test**
  - The guidance on movements and the feedback offered were helpful and appreciated.
  - The patients frequently expressed appreciation for and enjoyment of the experience.
  - The effectiveness stemmed from its goal-oriented nature.
  - Incorporating features to display the number of repetitions, range, and time would be beneficial.
  - This was a popular and highly useful tool for treatment purposes.
- **Hardware**
  - Generally, the experience was satisfactory, though occasional challenges were encountered regarding the placement of the main device
  - The connection between the main device and the dongle occasionally became unstable or disappeared.
  - Improved guidelines for electrode placement would be beneficial.
- **General**
  - A minor delay between contraction and the corresponding movement on the screen was noted.
  - The addition of VR glasses could enhance the enjoyment of the experience.
  - The arm's mirrored presentation at times reduced intuitiveness for patients. Adjusting the perspective could improve user experience.
  - Simplifying medical terminology and providing illustrated guides for patients could improve comprehension and usage.

- ▶ Including sound cues as auditory feedback upon task completion.
- ▶ Providing a final report detailing the number of sessions, session lengths, utilized movements, and progress over time.
- ▶ Ensure clarity regarding potential initial pain increases at the beginning of treatment, possibly by including this information in the manual.
- ▶ Enhancing the range of thumb movements.

From the data acquisition, potential improvements to the system were identified from both the therapists' and indirectly the patients' perspectives. A list of criteria was established, including aspects about regulatory implications, project feasibility, and stakeholder priorities, to determine what to implement and improve in Neuromotus. The following list of criteria was used indiscriminately to guide the decision-making.

- **User Feedback:** The indirect input provided by previous users will be of great importance, as their experiences are invaluable in pinpointing areas for enhancement.
- **Therapist feedback:** The potential impact of suggested improvements on patient outcomes and clinical workflows will be assessed to prioritize changes that yield the greatest benefits.
- **Regulatory Implications:** Consideration will be given to any new regulatory requirements introduced by the proposed modifications, ensuring compliance with relevant standards. This will minimize potential complications in device deployment and ensure that the changes are classified as non-significant.
- **Project Feasibility:** The feasibility of implementing each improvement within the allocated time frame and resource constraints will be evaluated to ensure realistic project planning and execution.
- **Stakeholder Priorities:** The viewpoints of Integrum, as well as other key stakeholders connected to the HOPE study, will be solicited to ascertain their perspectives on prioritizing improvement initiatives.

2.3 Results

The information acquired from the meeting with the HOPE representatives and interview feedback was compiled into concrete improvement suggestions presented below:

1. **Make changes for the serious gaming function**
   - i Conduct a thorough investigation of other open-source games, comparing them to previous findings to identify any recent developments or improvements. This exploration aims to discover games that offer enhanced features or gameplay experiences, which could be considered for inclusion in Neuromotus.
   - ii Enhance the existing games by incorporating user feedback mechanisms to provide real-time feedback and increase user engagement. Introduce competitive elements to foster a sense of competition among users and

make the experience more dynamic. Additionally, implement progress tracking features to allow users to monitor their improvement over time.

iii Incorporate a proportional controller to provide users with more control over their interactions.

2. **Enhance the augmented reality environment**
   i Implement the ability to customize colors based on the patient's skin tone to enhance inclusivity and personalization of the experience.
   ii Improve the tracking system of the fiducial marker in the AR environment.
   iii Identify movements that extend beyond the screen boundaries or exhibit anatomical inaccuracies.
3. **Create a final report detailing the number of sessions, session lengths, utilized movements, and progress over time.**

2.4 Final improvements of Neuromotus

The improvement suggestions presented in the results were discussed with stakeholders to create a prioritization list. Five main improvements were defined, the first two (1.(i), 1.(ii)) being mandatory and the remaining three to be addressed in accordance with the list as time permits. The first three are related to the serious gaming functionality, the fourth is related to the AR environment, and the last one is an extension of the Q-PLP result section:

1. (i) Conduct a thorough investigation of other open-source games, comparing them to previous findings to identify any recent developments or improvements. This exploration aims to discover games that offer enhanced features or gameplay experiences, which could be considered for inclusion in Neuromotus.

1. (ii) Enhance the existing games by incorporating user feedback mechanisms to provide real-time feedback and increase user engagement. Introduce competitive elements to foster a sense of competition among users and make the experience more dynamic. Additionally, implement progress tracking features to allow users to monitor their improvement over time.

1. (iii) Integrate proportional control to offer users an alternative controller that enhances precision during gameplay and simultaneously trains muscle contraction strength.

2. (i) Implement the ability to customize colors based on the patient's skin tone to enhance inclusivity and personalization of the experience.

3. Create a final report detailing the number of sessions, session lengths, utilized movements, and progress over time.

3
Methodology

This chapter describes the methodological approach employed to implement and validate the improvements to the Neuromotus device defined in the pre-study.

3.1 Improvements

Based on the results from the pre-study, an improvement prioritization list was created. The first four items on that list were implemented, while the fifth item, which involved creating a final report, was not implemented due to lack of time.

3.1.1 Improvement 1.(i) Finding suitable open-source games

The two games accompanying Neuromotus were found and implemented before the second clinical trial in 2014. It was considered likely that now there would be new or updated open-source games available. To find suitable games, selection criteria had to be defined. The criteria were composed of both objective and subjective criteria defined as:

1. Appropriate difficulty level for myoelectric control
   - i Games without mouse movements
   - ii six or fewer controlling keys
   - iii Easy to control
2. Have a license allowing use, modification, publishing and distribution rights, and software selling, such as the MIT and GNU General Public License.
3. Compatible with modern operating systems
4. Improved graphical interface or new features compared to the current Neuromotus games
5. Ability to play as a single-player

The open-source games market was investigated by using the search terms *Open-source games*, and *Open-source racing games* in Google. This produced four primary sources of information to explore the available games. The first one was *Wikipedia* which provided a list of 106 notable open-source games with open engine and free data [32]. The second one was *SourceForge* and provided 9701 open-source games [33]. The third and fourth were two Github profiles providing lists with 144 and 77 open-source games respectively [[34], [35]].

From this, seven games fit the criteria enough to be further examined by playing the games and exploring features. A short description of each game is presented in Table 3.1.

Table 3.1: Game Information

Game	**Description**	**Genre**	**License**
Stepmania	Stepmania is a rhythm-based music game where the goal is to match arrows in rhythm with a song with the aid of the arrow keys.	Music	MIT License
Speed Dreams	Speed Dreams is a racing car simulator with accurate driving behavior, multiple physics engines, and high adaptability.	Racing	GNU General Public License version 3.0 (GPLv3)
HexGL	HexGL is a futuristic racing game where the vehicle is a spaceship.	Racing	MIT License
2048	2048 is a puzzle game where you move numbered tiles to match and merge them into higher numbers with the help of the arrow keys. The numbers are powers of two and the goal is to reach 2048.	Puzzle	MIT License
Pong	Pong is an old game featuring two paddles and a ball with the objective of getting the ball past the opponent's paddle. The paddle is controlled with the up/down keys.	Arcade	MIT License
Fluid Table Tennis	Fluid Table Tennis is a game based on the traditional pong game with the addition of fluid dynamics where each player can shoot plasma to steer the ball without it having to touch a paddle. It is controlled by the up/down arrow keys to steer the paddle and the right/left arrow keys to control the fluid plasma.	Arcade	MIT License
Snake	Snake is a game where a growing snake is controlled within a confined space without steering it into a wall or itself. The snake grows when it eats a fruit that is spawning in a random location on the map.	Arcade	MIT License

3.1.1.1 Game evaluation and elimination

After further examination, the games were reevaluated against the criteria to determine their suitability for Neuromotus. The seven games and their alignment with the five criteria are shown in Table 3.2. If a game fulfills all the criteria, it should proceed to the next stage and be highly considered for inclusion in the Neuromotus package.

Table 3.2: Game evaluation

Criterion	Stepmania	Speed Dreams	HexGL	2048	Pong	Fluid Table Tennis	Snake
1	✓	X	X	✓	✓	X	✓
2	X	✓	✓	✓	✓	✓	✓
3	✓	✓	✓	✓	✓	✓	✓
4	✓	X	X	✓	✓	X	✓
5	✓	✓	✓	✓	X	✓	✓

Below is a summary of the games under consideration, along with an explanation of how each game meets the specified criteria:

- **Stepmania:** The Stepmania music game's objective is to match key presses to keys appearing on the screen in rhythm with the music. There are adaptability features, multiple game modes, and difficulty levels for the user to choose from. However, the three songs that were included in the download did not fall under the same MIT License. This meant new songs had to be created or imported with all keys manually inserted. Hence, it does not meet the 2nd criterion and is thus excluded from the list.
- **Speed Dreams:** The Speed Dreams racing game provides realistic driving behavior and has high adaptability regarding the physics engine, controller, and game modes. There are four track categories with multiple tracks in each category, as well as a variety of cars. When driving, multiple angles can be chosen to get the user's preferred point of view. The steering of the car can be too realistic which makes it difficult to stay on track and control the car with myoelectric control. It is therefore eliminated from the list for being too difficult to control and does not fulfill the 1st criterion.
- **HexGL:** The HexGl racing game is a fast-paced game where the objective is to drive three laps around a track. It has few features and adaptability possibilities regarding handling and speed control which makes it challenging to adjust the difficulty level. There is also only one track which can make it monotonous and less motivating over time. It does not fulfill the 1st and 4th criteria because of the difficulty level and lack of features resulting in elimination from the list.
- **2048:** 2048 is a turn-based puzzle game where the player each turn has the possibility of sliding numbered tiles to match and merge the numbers increas-

ing them as powers of two. E.g. when a four slides into a four it merges and becomes an eighth and when a 1024 slides into a 1024 it merges and becomes a 2048 which makes you win the game. The game is easy to understand yet requires strategy. It displays scores and high scores to keep track of your progress. It fulfills all of the criteria and remains on the list.

- **Pong:** In Pong, the objective is to bounce the ball from your paddle such that the opponent misses the ball with their paddle. It keeps the score from the ongoing round but not after the game has ended. This version of Pong requires a second player as the opponent and playing against the "computer" is not an option, this was the case for all of the open-source Pong games found during the game searching phase. It does not fulfill the 5th criterion and is therefore eliminated from the list.
- **Fluid Table Tennis:** The Fluid Table Tennis arcade game is a more advanced version of Pong where the objective is the same, get the ball past the opponent's paddle. However, a new element is now introduced, a plasma cannon that both players shoot out from their paddle that interacts with the ball and the other player's plasma according to fluid dynamics laws. It creates a high difficulty level and makes it difficult to control. It does therefore not fulfill the 1st criterion and is eliminated from the list.
- **Snake:** In the arcade game Snake, the objective is to control the head of a snake-like object and prevent it from colliding with itself or the walls. Points are rewarded by gathering fruits located in a confined space, when fruits are gathered, the snake grows one block longer. It has score and high score display features in combination with easy control and a modern graphical interface. All of the criteria are fulfilled and it remains on the list.

From Table 3.2, it's evident that five games have been eliminated due to their inability to meet all criteria outlined for inclusion. However, the puzzle game 2048 and the arcade game Snake have successfully navigated this evaluation process, as demonstrated in Table 3.3. These two games are now considered to be included in Neuromotus. It's worth noting that they may undergo further modifications to align them more closely with the requirements of the PLP rehabilitation process facilitated by Neuromotus.

Table 3.3: Game elimination

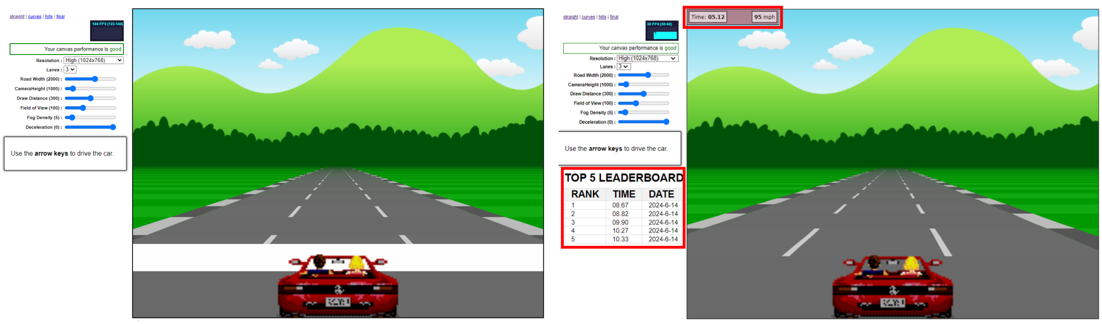
Criterion	Stepmania	Speed Dreams	HexGL	2048	Pong	Fluid Table Tennis	Snake
1	✓	X	X	✓	✓	X	✓
2	X	✓	✓	✓	✓	✓	✓
3	✓	✓	✓	✓	✓	✓	✓
4	✓	X	X	✓	✓	X	✓
5	✓	✓	✓	✓	X	✓	✓

3.1.2 Improvement 1.(ii) Improving the games

Improvement number two could then commence, and in-game implementations such as speedometers, leaderboards, and the possibility of adjusting the difficulty were implemented. This was done by accessing the games' source code written in HTML for the structure and content, CSS for the control and styling of the HTLM element, and JavaScript for adding interactivity and dynamic behavior to the game.

3.1.2.1 Racing game

The racing game, one of the previously included games in the Neuromotus package, needed updates to make it more interactive and engaging to increase user adherence. The game currently features four different maps with varying levels of difficulty. Three key changes were made to enhance the game, first, a top 5 leaderboard was added for all four maps, displaying rank, time, and date. Second, a speedometer was introduced to track the car's speed, allowing for easier adjustments to the difficulty level. Lastly, a lap timer to observe how well the lap is going. A comparison of the improvements before and after implementation is illustrated in Figure 3.1.



(a) Old racing game version **(b)** New racing game version

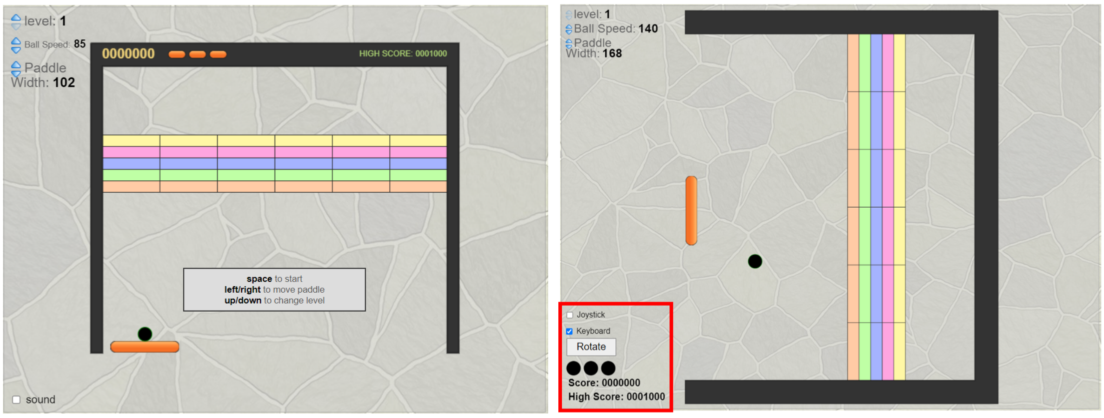
Figure 3.1: Comparison of the old and new version of the racing game.

3.1.2.2 Breakout

Breakout is another game included in the Neuromotus package that required updates to make it more intuitive for lower-limb amputees to move the paddle. This was achieved by adding a rotate button, allowing the user to rotate the playing field by 90 degrees. Consequently, the controller was updated so that the up and down arrow keys were used instead of using the left and right arrow keys. The comparison between the old and new versions of Breakout is illustrated in Figure 3.2

In preparation for improvement number 1(iii) (Integrate a proportional controller), two new checkboxes were created to choose the controller mode. The *Joystick* option is a proportional controller that allows the user to move the paddle with higher precision.

Smaller improvements were also made, such as changing the location of the score and lives and updating the icon representing lives from a paddle to a ball.



(a) Old Breakout version **(b)** New Breakout version

Figure 3.2: Comparison of the old and new version of Breakout.

3.1.2.3 2048

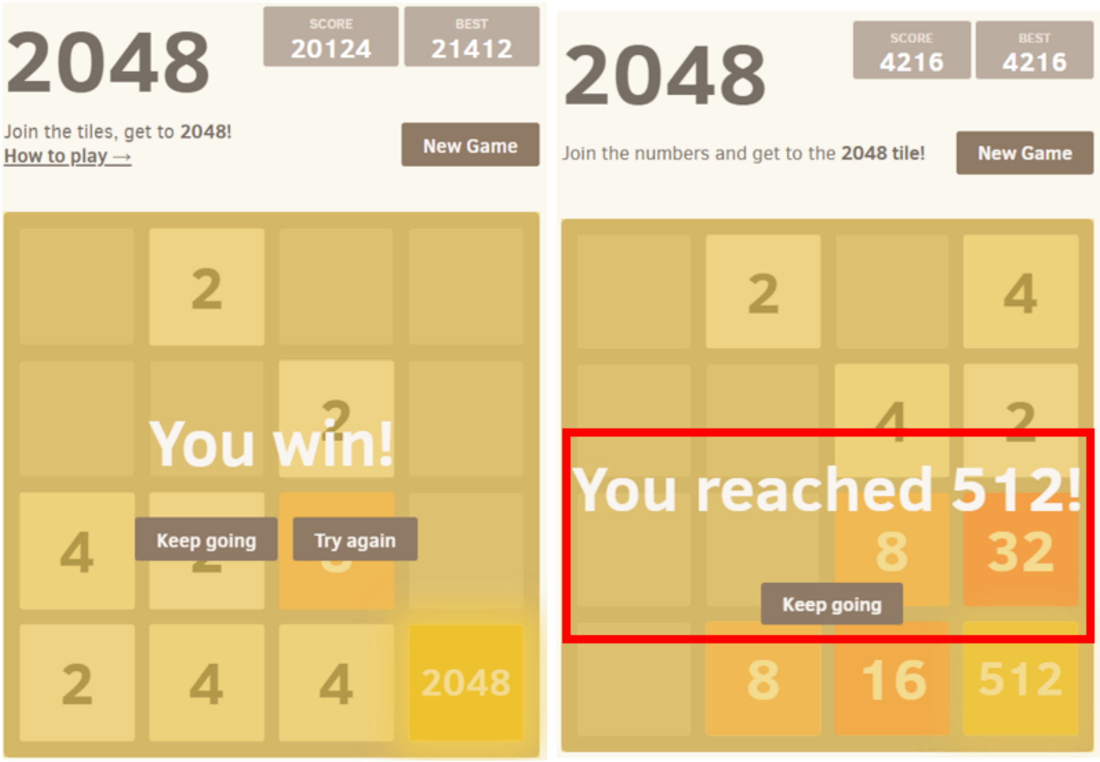
2048 is one of the new games in the Neuromotus package and already includes desirable features for increasing adherence, necessitating only two minor changes. First, the *Try again* button illustrated in Figure 3.3a that appears when the player reaches 2048 on a tile was removed. Second, feedback timing was adjusted to accommodate the longer time estimated for users to reach 2048 using myoelectric control compared to manual control. It was decided that positive feedback should be given for every new power of 2 starting from 2^8, as illustrated in Figure 3.3b where feedback is given upon reaching 512 on a tile.

3.1.2.4 Snake

The second new game introduced was Snake, which held promise due to its simplicity and high recognizability. However, several adjustments were necessary to enhance its adaptability and competitiveness, with the aim of increasing user adherence. A comparison of the old and new versions of Snake is Illustrated in Figure 3.4

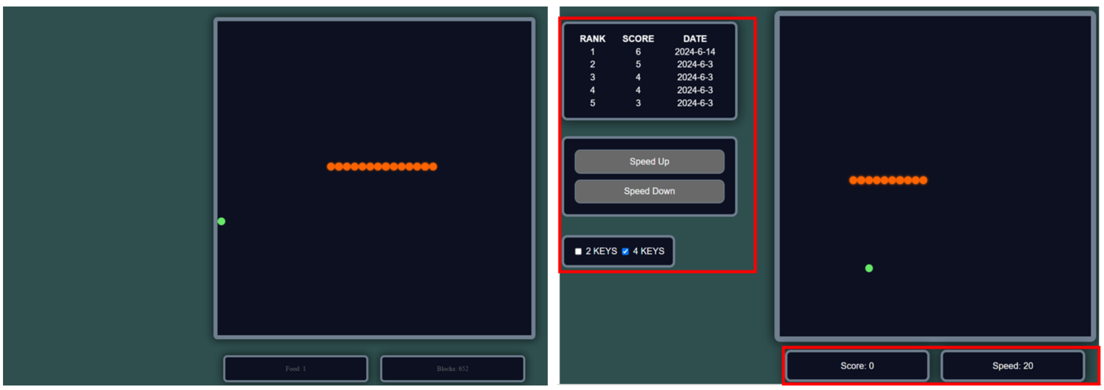
The first change involved adding a top 5 leaderboard displaying rank, score, and date, akin to the racing game. The second change was the inclusion of a speed controller, allowing users to adjust the snake's speed and thereby tailor the game's difficulty.

Snake is traditionally played using four arrow keys, and the user is then required to accurately generate four movements for Neuromotus to classify. The new version offers an alternative control scheme. Since the snake continually turns left or right, users can effectively navigate with two keys, requiring only two movements. Buttons enabling this simplified control were integrated into the game interface.



(a) Old 2048 version (b) New 2048 version

Figure 3.3: Comparison of the old and new version of 2048.



(a) Old Snake version (b) New Snake version

Figure 3.4: Comparison of the old and new version of Snake.

3.1.3 Improvement 1.(iii) Integrate a proportional controller

The third improvement involved integrating a human interface device (HID), such as a joystick, to serve as a proportional controller. This allows users to exert finer control over games by modulating the force with which they contract their muscles. This functionality was implemented using vJoy, an open-source virtual joystick device licensed under the MIT license. vJoy is recognized by the operating system as a physical joystick, with state information about its axes and buttons being provided by a feeder application. By manipulating this feeder application, users can play games that support joystick input, thus increasing the versatility and compatibility with third-party games.

Unlike binary key presses, the system transmits an amplitude value derived from the root mean square (RMS) of the EMG signals for the movements. Each movement undergoes a calibration phase, during which the user performs the movement repeatedly for r iterations. Post-calibration, the system enters a pre-processing phase, where the RMS is computed for n window samples across all electrode channels ($C_i = \{c_{1i}, c_{2i}, \ldots, c_{ni}\}$). To mitigate the influence of noise and artifacts, the 75th percentile RMS is calculated for each channel. The channel with the maximum 75th percentile RMS is then identified, and this value serves as a reference in the real-time session. The relevant equations are presented below:

$$
\begin{aligned}
C_i &= \{c_{1i}, c_{2i}, \ldots, c_{ni}\} && \text{(Channel i with n windows)}\\
P_{75i} &= c_{ki}, \quad \text{where } k = \lceil 0.75 \cdot n \rceil && \text{(75th percentile RMS)}\\
i_{\max} &= \arg\max_i P_{75i} && \text{(Channel index)}\\
P_{75\,\max} &= P_{75i_{\max}} && \text{(Max 75th percentile RMS)}
\end{aligned}
$$

This reference value is then used to calculate the ratio between the reference RMS and the real-time RMS value derived from m window samples, representing the amplitude of the muscle contraction. The resulting amplitude is normalized to a range of 0 to 1 where 0 is the floor noise threshold. Any values exceeding 1 (i.e. exceeding the maximum 75th percentile) are being capped at 1, as described by the following equations:

$$
\begin{aligned}
\mathrm{RMS}_{i_{\text{now}}} &= \sqrt{\frac{1}{m}\sum_{j=1}^{m} c_{ji_{\text{now}}}^2}\\
P_{75i_{\text{now}}} &= \mathrm{RMS}_{i_{\text{now}}}\\
A &= \frac{P_{75i_{\max}}}{P_{75i_{\text{now}}}}, \quad \text{where} \begin{cases} A \in [0,1] & \text{if } P_{75i_{\text{now}}} \le P_{75i_{\max}} \\ A = 1 & \text{if } P_{75i_{\text{now}}} > P_{75i_{\max}} \end{cases}
\end{aligned}
$$

In addition to allowing users to play more third-party games, this functionality was also implemented to work with Breakout. This was achieved by creating a web socket as the communication channel, enabling the Neuromotus application to send amplitude data that would otherwise be sent to the joystick feeder. Since the web-based game cannot receive real joystick data from an HID, this method provided a straightforward implementation

The proportional controller was extended to support simultaneous movements which is a feature allowing combinations of movements to be classified as one. These simultaneous movements are classified in the same way as individual movements, rather than as combinations of two classified movements. Consequently, it is impossible to differentiate between the amplitudes of the two movements in a simultaneous action. Instead, it is assumed that the movements have equal amplitude.

This assumption is illustrated in Figure 3.5, which shows the four movements: *Flex hand*, *Extend hand*, *Open hand*, and *Close hand*. When contradictory movement combinations, such as *Open hand + Close hand*, are excluded, four possible combinations of simultaneous movements remain. Contradictory movements are represented in opposite directions along an axis. The allowed simultaneous movements fall along the lines defined by the linear functions $f(x) = x$ and $f(x) = -x$, causing the two movements in any simultaneous action to have the same amplitude. The empty square in the middle represents the area where the amplitude is too low for the algorithm to classify the movement as anything other than rest.

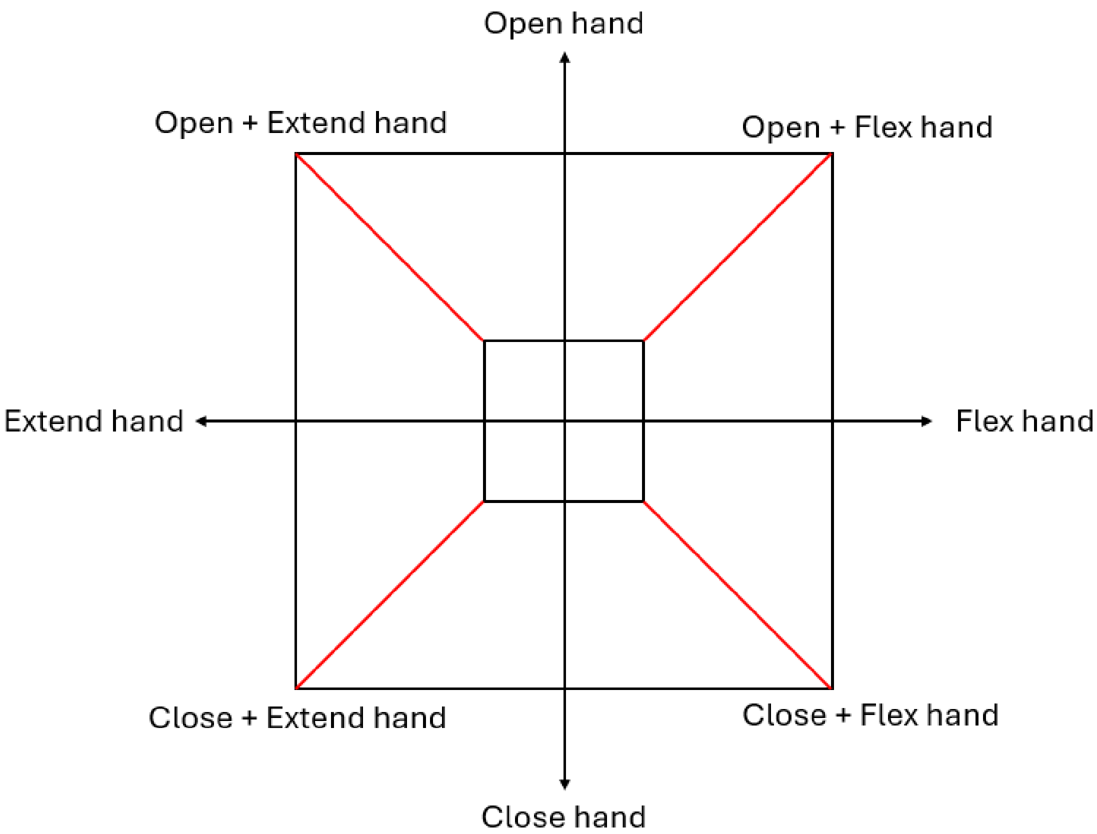


Figure 3.5: Illustration of simultaneous movement limitations.

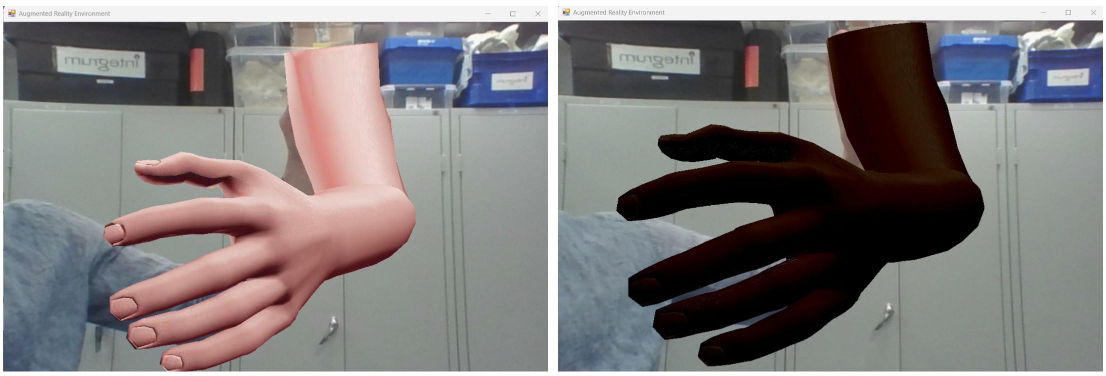
3.1.4 Improvement 2.(i) Customize AR limb color

The fourth improvement involved adding different colored limbs in the AR environment for the user to choose from. The monk skin tone scale consists of 10 skin tones and claims to balance diversity with ease of use, the scale is illustrated in Figure 3.6 [36]. It was developed to be used in the field of computer vision to reduce skin tone bias in machine learning.

Figure 3.6: Monk skin tone scale.

The AR environment is built using the Ogre3D 3D graphics engine and employs material files to define the texture of the limb. New materials were created programmatically using Matlab, streamlining the process and allowing for easy adjustments. This method enables the creation of new textures for both the arm and leg. Users can then select the desired limb color through the Neuromotus settings interface.

It is also possible to change the color of the limb using keyboard keys 1-10, where each key number corresponds to a skin tone number on the Monk skin tone scale. Figure 3.7 illustrates the difference between skin tone 1 and skin tone 10.



(a) Skin tone 1 on the Monk skin tone scale.

(b) Skin tone 10 on the Monk skin tone scale.

Figure 3.7: Comparison between the 1st and 10th skin tone on the Monk skin tone scale.

3.2 Tests of the new improvements

The tests consisted of two parts, the stakeholder feedback phase and the validation tests.

3.2.1 Stakeholder feedback

The stakeholders included representatives from the HOPE study and employees at Integrum who were previously familiar with Neuromotus. They used the upper arm textrode band, developed for the HOPE study, to test the new improvements. Feedback from the HOPE representatives was obtained by asking their opinions on the changes and whether these could improve user compliance. At the time of the meeting with them, the ability to change the skin tone of the AR limb was not yet implemented.

Participants from Integrum also used the textrode band and tested the new functionalities and changes. The evaluation did not follow a strict protocol, and some participants did not have the time to test all the improvements. During this test, two sizes of the textrode band were available: one smaller and one larger. Given the larger size of the group, participants were asked to fill out an online form consisting of multiple-choice questions after their interaction with Neuromotus. This form aimed to gather their opinions on how the changes impacted the device, if they had any preferences among the functionalities, and if they were satisfied with the changes. Since this was the first time most participants had used the device, and there was a learning curve associated with myoelectric control, only features requiring 1 DOF were tested. Consequently, the 2048 game and the four-key control scheme in Snake were excluded from testing. However, participants were shown the 2048 game and how it works. Appendix D presents the questions asked in the form.

3.2.2 Validation tests

To validate the changes and ensure that the final release of the updated Neuromotus device works as intended, a test protocol was created with requirements for the device to meet. The following requirements had to be validated during the test phase:

- **General**
  - ☐ Neuromotus shall launch.
  - ☐ All Neuromotus functionalities shall work with the keyboard or joystick controller selected.
- **Augmented Reality**
  - ☐ It shall change the AR limb color according to what's chosen in the settings.
  - ☐ It shall be possible to change the AR limb color in the AR environment by using key presses from 1-10.
  - ☐ It shall work for both the left and right limbs.
  - ☐ It shall work for both the arm and leg.

- **Serious Gaming**
  - ☐ The racing game shall have a top 5 leaderboard and a speedometer that updates correctly for all four maps.
  - ☐ Breakout shall have a button to rotate the playing field and change the control from left/right to up/down.
  - ☐ Breakout shall be able to accept joystick input for proportional control of the game.
  - ☐ It shall be possible to open and close the game mode in the Neuromotus interface and still connect and send information to games through the web socket.
  - ☐ The 2048 game shall give positive feedback for every new power of 2 from 2^8 and the restart button shall be removed.
  - ☐ The Snake game shall have a top 5 leaderboard, speed controller, and the possibility to choose between a controller with one or two DOFs.

4

Results

This chapter presents the results from the feedback collected from HOPE representatives and Integrum employees, along with the validation tests of the new improvements.

4.1 Feedback from stakeholders

Feedback from HOPE representatives was gathered by asking for their opinions and taking notes, while Integrum employees provided their feedback by filling out an online form.

4.1.1 HOPE representatives

Feedback from HOPE representatives is presented in the bullet points below where they gave their thoughts on the improvements. They only tried the joystick with Breakout and changing the skin tone of the AR limb was not yet implemented. Therefore, they only provided feedback on the four games.

- **Racing game:** The addition of a leaderboard made the game more competitive. The lap time feature provided immediate performance feedback, allowing players to see their progress in real-time.
- **Breakout:** They enjoyed playing Breakout with joystick control, finding it easier to maneuver the paddle. This also challenged users to be more conscious of the strength of their muscle contractions.
- **Snake:** The ability to switch between 1 and 2 DOF and adjust the snake's speed was well-received. However, it was somewhat easy to run into oneself and lose when using the 1 DOF. The leaderboard provided good motivation for improving and achieving a high score.
- **2048:** They enjoyed the 2048 game, which introduced a different type of gameplay where users could take their time and make strategic moves. This allowed users to rest their muscles between turns, enabling longer play sessions without fatigue.

4.1.2 Integrum employees

Thirteen participants from Integrum took part in the testing and subsequently answered a form. The form consisted of five mandatory questions and one optional question, covering the changes that were made.

Question one asked the participants which games they played. Breakout and the Racing game were played the most with twelve and eleven participants respectively. Snake was played by three and 2048 by zero. 2048 requires a control scheme using 2 DOF and was therefore not tested since the participants only used 1 DOF.

Question two, illustrated in Figure 4.1, a follow-up to the first, inquired about their game preference. Resulting in 69.2% (nine people) preferring Breakout and 30, 8% (four people) preferring the Racing game.

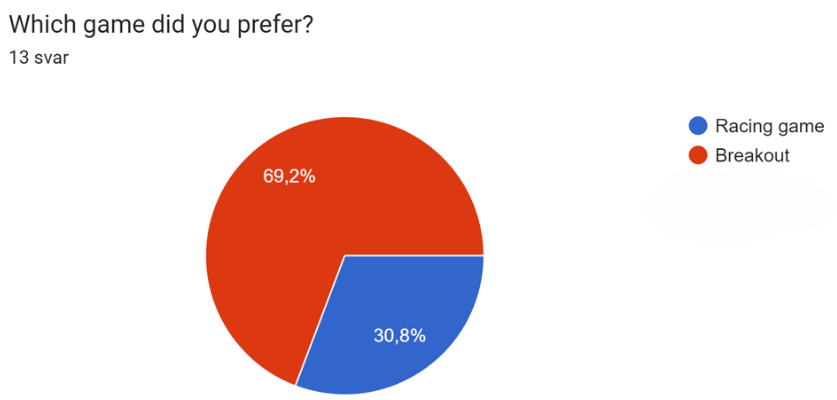


Figure 4.1: Feedback form, question two.

Question three, illustrated in Figure 4.2, is concerned with the customization of the skin tone of the AR environment limb and how well it matched the users' actual skin tone. It ranges from "not even close" (1) to a "perfect match" (5). The responses were as follows: 30.8% thought it looked okay, 30.8% thought it looked good, and 38.5% thought it was a perfect match.

Question four asked about controller preference when playing Breakout, specifically whether users preferred the joystick or keyboard controller. Among the respondents, 30.8% (four people) did not play with both controllers due to lack of time. Out of the remaining 69.2% (nine people) who tried both the joystick and keyboard controller, all preferred using the joystick controller.

The fifth question, illustrated in Figure 4.3, was about their general experience with Neuromotus, ranging from "I strongly dislike it" (1) to "I strongly like it" (5). The results were 38.5% liked it and 61.5% strongly liked Neuromotus.

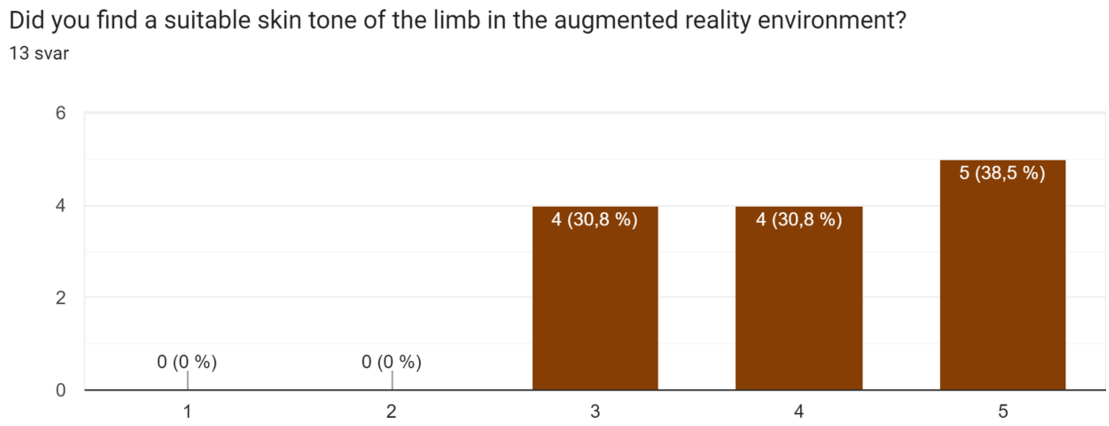


Figure 4.2: Feedback form, question three.

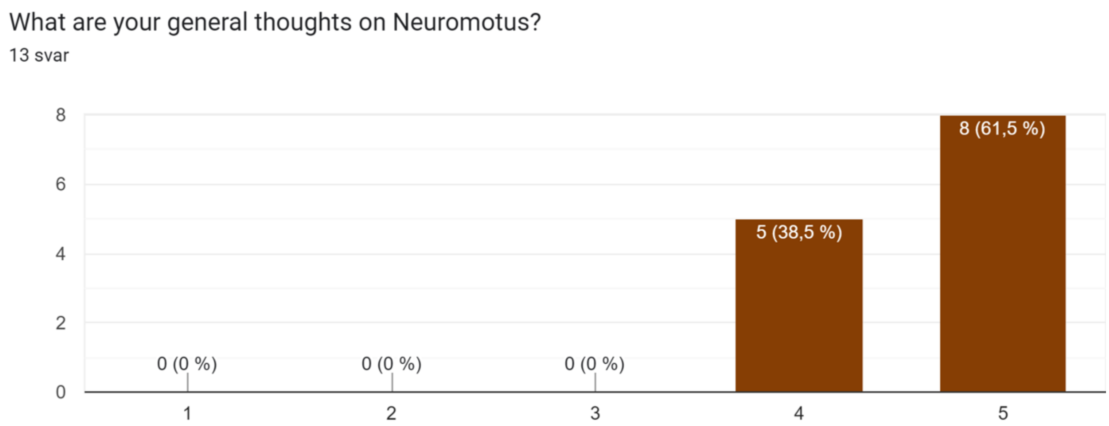


Figure 4.3: Feedback form, question five.

The final question was an optional open-ended question where participants could express their specific preferences or dislikes. Seven people responded, with summarized feedback indicating that the size of the textrode bands was not optimal for all body types, the device felt natural surprisingly quickly, and it was easy to run into oneself in Snake.

4.2 Tests

The validation tests are divided into three categories based on the functionality being tested. Each test consists of a requirement and a qualification method, resulting in a YES/NO outcome depending on the test's result.

4.2.1 General

General tests focus on ensuring that Neuromotus functions without any errors and assess the overall system performance. These tests also cover all the different functionalities within Neuromotus with no specific change being tested.

Table 4.1: Tests of improvements for general use.

Requirement	**Qualification method**	**Approved YES/NO**
Neuromotus shall launch without any errors.	Launch the new Neuromotus version.	YES
All Neuromotus functionalities shall work with the keyboard or joystick controller selected.	Test all functionalities with both controllers.	YES

4.2.2 AR environment limb color customization

These tests focus on the AR environment and the option of limb color customization, ensuring that users can choose colors both in the settings and within the AR environment, with the correct outcome.

Table 4.2: Tests of improvements in the AR environment

Requirement	**Qualification method**	**Approved YES/NO**
It shall change the AR limb color according to what's chosen in the settings.	Launch the AR environment.	YES
It shall be possible to change the AR limb color in the AR environment by using key presses from 1-10.	Launch the AR environment and press the keys 1-10.	YES
Changing the AR limb color shall work for both the left and right limbs.	Launch the AR environment with the left and then the right limb selected.	YES
Changing the AR limb color shall work for both the arm and leg.	Launch the AR environment from lower and upper limb Neuromotus applications.	YES

4.2.3 Games

Game tests focus on evaluating all the newly implemented features in the games, ensuring they work without any bugs and perform as intended.

Table 4.3: Tests of improvements of the games.

Requirement	**Qualification method**	**Approved YES/NO**
It shall work to play third-party, joystick-compatible games with the joystick controller selected.	Select joystick control and test to play Trackmania in joystick mode.	YES
The racing game shall have a top 5 leaderboard and a speedometer that updates correctly for all four maps.	Launch the racing game and test drive the four maps.	YES
Breakout shall have a button to rotate the playing field and change the control from left/right to up/down.	Launch Breakout and rotate the field.	YES
Breakout shall be able to accept joystick input for proportional control of the game.	Select the joystick control and play Breakout.	YES
It shall be possible to open and close the game mode in the Neuromotus interface and still connect and send information to games through the web socket.	Repeatedly open and close the game mode.	YES
The 2048 game shall give positive feedback for every new power of 2 from 2^8 and the restart button shall be removed.	Launch 2048 and observe feedback.	YES
The Snake game shall have a top 5 leaderboard, speed controller, and the possibility to choose between a controller with one or two DOFs.	Launch Snake and test functionalities.	YES
It shall be possible to have the simultaneous setting active and use it in the game mode.	Activate the simultaneous setting and test the games.	YES

4.3 Regulatory aspects

Neuromotus is a class 1 medical device according to the MDD. The significance of the change has therefore been assessed in accordance with MDCG 2020-3, using the guide charts found in Appendix C. It is important to note that these changes are limited to software enhancements and do not affect the core aspects of the Neuromotus device. It does not affect:

- **Main Functionalities:** The primary functionalities of the Neuromotus device remain unchanged. The device will continue to perform its core functions as intended, ensuring consistent operation and reliability.
- **Intended Use:** The intended use of the Neuromotus device remains the same. It will be utilized as a tool to facilitate rehabilitation by providing interactive feedback and engagement for users, without altering its original purpose or application.
- **Hardware:** No modifications will be made to the hardware components of the Neuromotus device. The physical design, structure, and technical specifications of the hardware will remain identical to the existing configuration.
- **User Interface** The user interface of the Neuromotus device will not undergo any major changes. Users will interact with the device in the same manner as before, ensuring a familiar and consistent user experience.

This information helped guide the answers to the charts as illustrated in Figure 4.4, resulting in the determination that the changes are considered non-significant according to MDCG 2020-3.

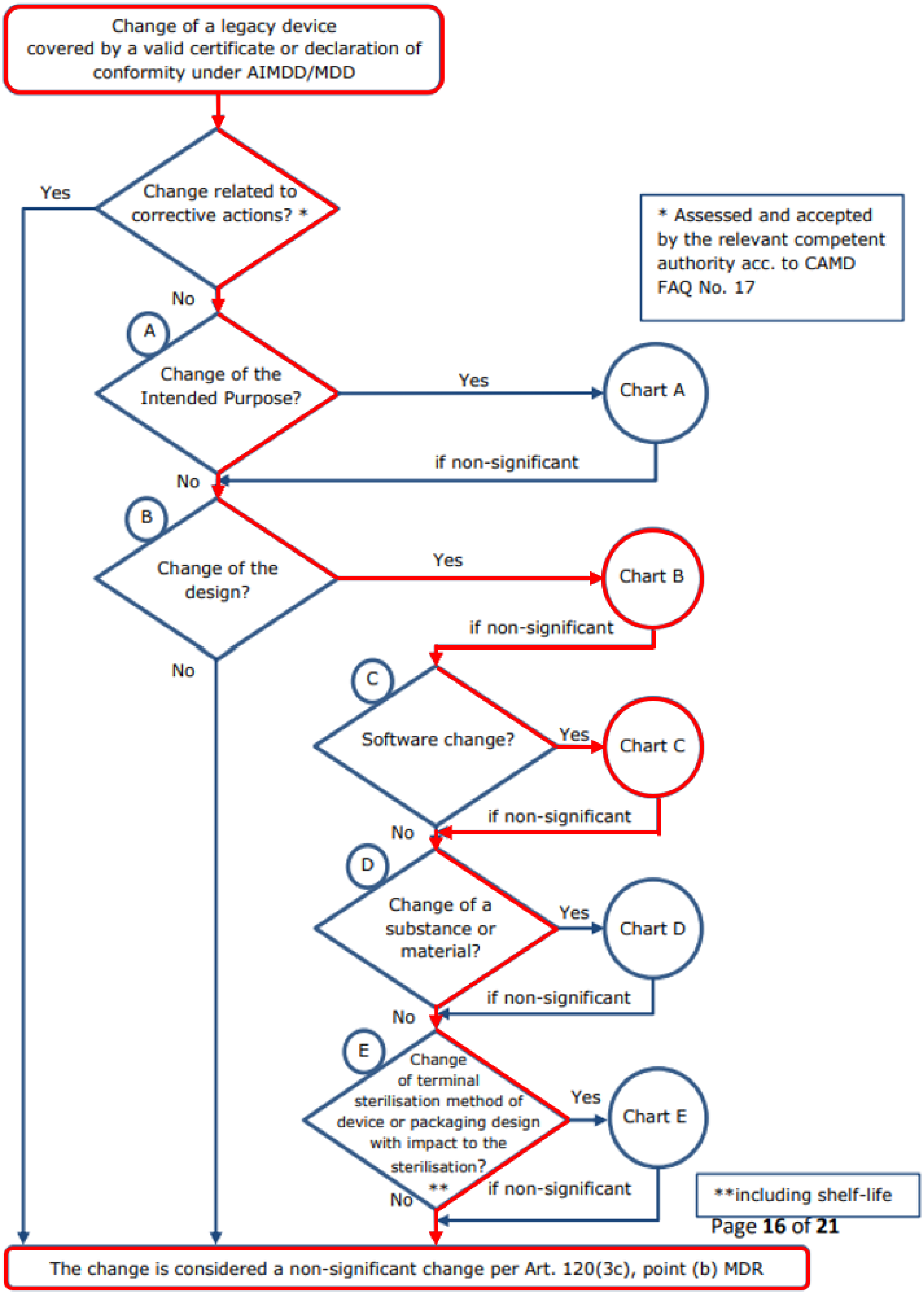


Figure 4.4: Decision route for significant changes regarding the transitional provision under Article 120 of the MDR (Modified version from the source: MDCG 2020-3 Rev.1) [31].

5

Discussion

During the data acquisition phase, two interviews were conducted with physiotherapists who have used Neuromotus in practice. The information accumulated over these interviews was pivotal for guiding the direction of the improvements. While the interviews provided cohesive feedback in some areas, there were some discrepancies in others. The limited availability of therapists with appropriate knowledge made finding suitable candidates and conducting the interviews a time-consuming process.

Conducting additional interviews could have offered a more comprehensive understanding of both therapists' and patients' opinions on the device. However, this would have resulted in a delay in the improvement process and consequently a reduced number of improvements. It therefore became a question of either implementing more improvements even though they might not be the most critical ones or fewer with higher certainty that these improvements are the most critical ones. Given these options, and considering that the interviews were conducted with highly experienced therapists, it was concluded that two interviews would provide sufficient information.

Feedback from the HOPE representatives provided valuable insights into the games, indicating that Breakout was the most enjoyable and that the joystick controller was a beneficial change. However, despite their familiarity with the system, the HOPE representatives still found the Snake game difficult and too easy to run into oneself and lose. It was therefore decided that Integrum employees would not be required to test Snake unless they specifically wanted to. This led to only three out of thirteen Integrum employees testing Snake during the second part of the stakeholder feedback.

In response to feedback indicating that it was too easy for the snake to run into itself and lose, a small delay was implemented to prevent this behavior. This delay ensures the snake cannot make two consecutive turns too quickly, resolving the issue. However, this modification also removes the option of making rapid turns. Given that the snake moves relatively slowly, it is believed that this change will not negatively impact performance while still removing the problem of the snake running into itself.

The Integrum employees never tested the game 2048 because it requires 2 DOFs, and it was decided that keeping it simple with only 1 DOF would facilitate their learning and operation of the functions. This is unfortunate, as feedback on 2048 would have been valuable to understand its reception and identify any necessary future modifications. Nevertheless, the HOPE representatives provided positive feedback on 2048.

Breakout was the most played game among Integrum employees, with twelve participants, closely followed by the Racing game, with eleven participants. Despite this, Breakout was significantly preferred, with 69.2% favoring it. This preference can be partly attributed to the new feature of playing with either a keyboard or joystick controller, with 100% of the users who tried both preferring the joystick controller.

The implemented changes were evaluated through a series of validation tests and by gathering feedback from stakeholders who interacted with the modified system. The results from these validation tests indicated that all changes were successfully approved and passed without any detected bugs, confirming that the modifications functioned as intended.

Among the various changes, the updates to the Breakout feature and the introduction of customizable limb skin tones in the AR environment were particularly well-received by the stakeholders. These modifications were praised for their potential to enhance user experience and satisfaction.

Despite these positive responses, determining whether these changes significantly improve user compliance and enhance the overall treatment of Neuromotus remains challenging. Comprehensive user testing is necessary to draw more definitive conclusions about the practical benefits and effectiveness of these changes in a real-world setting. Unfortunately, conducting user tests was beyond this project's scope due to the ethical procedures required to obtain approval for user testing.

The stakeholders only tried the new improvements with the upper limb textrode band, not the lower limb, due to practical reasons when placing the band. The games function the same regardless of whether the lower limb is used for myoelectric control. However, Breakout's new feature of rotating the playing field 90 degrees allows for more intuitive control when using the lower limb with the up and down movements instead of left and right. In the AR environment, the same skin color customization is available for the lower limb as for the upper limb. Therefore, even though the stakeholders did not use the lower limb control, the potential for its use was evident through their experiences with the upper limb, given the similarities between the two.

The racing game received the updates: the addition of a top 5 leaderboard displaying rank, time, and date, a speedometer, and a lap timer. These changes could enhance user compliance by making the game more competitive and engaging, provided there are no fundamental issues with the graphics or similar elements. Additionally, the integration of joystick functionality allows users to play more modern games that require a joystick, giving them the freedom to choose their preferred games. This increased personalization option is believed to boost engagement and result in an improved user experience.

Simultaneous movements are currently classified as a single discrete movement, and the system is trained to recognize that specific combination. This approach has limitations, as the two movements must be contracted with similar strength during both the calibration phase and real-time use to produce the correct combination of signals for the classifying algorithm. This makes using the joystick mode with simultaneous movements impractical, as the two movements would always have the same amplitude, which is not ideal for gaming scenarios.

If the algorithm could detect and separate simultaneous movements, identifying their individual signal strengths, it would simplify the calibration phase by eliminating the need to calibrate each movement combination. Additionally, this would make the joystick mode more beneficial by allowing greater flexibility in the signal strength of combined movements. However, this approach would increase the computational complexity of the classification system and introduce greater latency. This tradeoff should be considered in the future development of the system.

There is no universal scale for defining skin tone due to the high variation of people's skin tones worldwide. To address this diversity, the Monk Skin Tone Scale, created by Ellis Monk in collaboration with Google, was adopted in this project. Originally designed for the computer vision field, this scale aims to capture demographic representation with high precision while ensuring that the selection process remains user-friendly and straightforward. Its applicability extends to both VR and AR environments, where it can be used to model bodies or body parts accurately.

From an ethical standpoint, the inclusion of a diverse range of skin tones in the AR limb model is crucial. It recognizes and respects the wide spectrum of human diversity, promoting inclusiveness and ensuring that users of various backgrounds feel represented. This inclusivity helps to avoid continuing biases and stereotypes that can arise from the underrepresentation or misrepresentation of different skin tones in digital environments.

Moreover, incorporating the Monk Skin Tone Scale aligns with ethical principles of equality and fairness. It supports the creation of technology that serves all users equitably, which is particularly important in healthcare applications. By enabling users to choose skin tones that closely match their own, we enhance the psychological comfort and acceptance of the AR limb, which can positively impact the user experience and therapeutic outcomes.

In terms of regulatory standards, the use of a comprehensive skin tone scale can be connected to the principles outlined in various guidelines and frameworks that advocate for diversity and inclusivity in technology. For instance, the World Health Organization (WHO) emphasizes the importance of cultural sensitivity and appropriateness in health technology design. Similarly, the ISO 9241-171:2008 standard on ergonomics of human-system interaction, particularly in software accessibility, underscores the need for inclusive design that accommodates a wide range of human characteristics and preferences.

The result of question three in the form showed that 30.8% thought the skin tone of the limb looked okay, 30.8% thought it looked good, and 38.5% thought it was a perfect match. This indicates that people are generally satisfied with the ability to select a skin tone resembling their own. However, even with the introduction of new skin tones, there remains room for improvement in the realism of the AR limbs. Enhancing the realism of the arms would create a more convincing illusion of the AR limb being part of the user's own body. Specifically, the shading and contrast of the limbs could be improved, particularly for darker skin tones. The contrast and shading of the skin appear less realistic for the darkest skin tones because there is, for example, a greater difference in the nuances between the forearm skin tone and the hand palm for darker-skinned compared to lighter-skinned individuals. This variation was not fully considered during the development of the new skin tone textures and represents an area for future improvement in the AR environment.

Improvement number five involves creating a final report that details the number of sessions, session lengths, utilized movements, and progress over time. Due to time constraints, this improvement was not implemented during this project. However, it represents a valuable future enhancement that could provide therapists and users with comprehensive information about their rehabilitation progress. Such a report could offer a better overview of their rehabilitation journey and serve as motivation to continue using the Neuromotus device, potentially improving adherence and outcomes.

Modifying an MDD-certified medical device requires a thorough understanding of the regulatory framework governing such changes. According to Article 120 of the MDR, significant modifications to devices under the MDD are restricted. Therefore, it was crucial to navigate the project in compliance with these regulations.

To ensure adherence, the project utilized the MDCG 2020-3 decision tree, which is designed to assess the significance of changes made to medical devices. This assessment confirmed that the changes implemented were classified as non-significant. As a result, the modifications did not require a new conformity assessment or recertification under the MDR, thus maintaining regulatory compliance and ensuring that the device continued to meet all required standards.

6
Conclusion

The implementation of a user-centered design approach was highly effective in identifying and addressing the needs of therapists using the device. However, incorporating feedback from amputated patients would have further enriched the development process and ensured that the device meets the needs of all end-users.

Identifying a suitable open-source game for myoelectric control with high-quality graphics and single-player capability presented significant challenges. Even the games selected for the Neuromotus package required adjustments to ensure that the game was on an appropriate level. Feedback from users indicates that these improvements were beneficial and introduced valuable enhancements to the device, potentially leading to higher user compliance. The joystick controller for playing Breakout was particularly appreciated, with all users preferring it over the keyboard controller. Nonetheless, definitive conclusions regarding the impact of these improvements on compliance and long-term adherence can not yet be drawn due to the limited scope of user testing.

Furthermore, the ability to customize the skin tone of the limb in the AR environment carries significant ethical considerations. By utilizing the Monk skin tone scale, the device promotes inclusivity and ensures that users from diverse backgrounds feel represented. This feature not only enhances user experience but also aligns with ethical standards in medical settings.

Overall, while the advancements made through this project show promise, further research, and extensive user testing are required to validate the long-term benefits and ensure the device meets the needs of all potential users.

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A
Interview Questionnaire

Semi-structured interview questionnaire

Introduction

1. Please tell us a bit about yourself and your background as a clinician.
2. For how long have you been working with phantom limb pain treatment?
3. Approximately how many patients have you treated using Neuromotus?
4. Please share a bit about your overall experience using Neuromotus.

Patient Feedback

5. In your discussions with patients, have they provided suggestions or feedback on how the device could be enhanced to better address their needs?
6. What aspects of the device do patients appreciate the most, and where do they see room for improvement?
7. Have the patients expressed any specific feedback regarding the hardware?
8. Have the patients expressed any specific feedback regarding the user interface?

Clinician's Perspective

9. From your professional standpoint, what improvements or additional features would you like to see in the device to make it more user-friendly?
10. Are there any specific functionalities that could better support clinicians in treating the patient's phantom limb pain?
11. What parts of the device do you think are difficult to handle?
12. What parts of the device do you think are easy to handle?
13. What challenges or limitations have you observed while using the device?
14. Are there specific metrics or indicators that you find particularly useful in evaluating the ongoing progress of the treatment?
15. How do you address cases where the treatment may not provide the expected relief?
16. Have you encountered any patient adherence issues to the device, and how have you addressed them?
17. Have you observed any patterns or preferences among patients regarding certain features or functionalities of Neuronotus? How do you accommodate individual preferences in your approach?

B

Interviews

B.1 Interview 1

Speaker 1 (Interviewer)

Please tell me a bit about yourself and your background as a clinician.

Speaker 2 (Therapist)

Yeah, so I have a background as a physiotherapist, and I arrived in Sweden in 2018 and I started working at Integrum as a consultant because I was trying Neuromotus in Chile. I'm originally from Chile, and I was completely lost. Because I didn't have kind of a protocol or anything. So I asked if I could come here to learn a little. I came to Sweden and then I started learning about Neuromotus and then I started helping develop the training protocol of Neuromotus. And then I was hired to be kind of the clinical representative, meaning that I was helping to train therapies in different parts of the world on how to use the device. And also I was helping in doing kind of all the material for therapies and patients. And then I started doing research with Chalmers at CBPR. And then I started my PhD. So now I'm currently doing my PhD with CBPR and Gothenburg University. I moved my projects to stroke, but I'm working still with surface electromyography to promote function in this type instead of treating pain.

Speaker 1

For how long have you been working with phantom limb pain treatment using Neuromotus?

Speaker 2

It has been now more than five years. So I was doing a lot of testing and a lot of training. The first two years were quite a lot. And then I was just a consultant. And then I just stopped working for them because also, as you might see, things kind of stopped happening for a while. So I think since me and my colleagues worked on them, I mean not much has happened. So yeah.

Speaker 1

Yeah. So approximately how many people have you been treating with the Neuromotus this device?

Speaker 2

Yeah, I think maybe around 20-25, I don't know. Yeah.

Speaker 1

So First off, I would like to ask you in your discussion with patients, have they provided suggestions or feedback on how the device could be enhanced to better address their needs?

Speaker 2

Yes, I have received different types of feedback, so one that was very straightforward is that uh, for example, some patients that have darker skin. They feel sometimes kind of uncomfortable with their augmented reality because the arm was white, so they were kind of this. It didn't make much sense to them. For some people, this augmented reality makes it feel like it is a part of my body and they get all excited, but also I have patients who were kind of this feels so awkward, you know, kind of I don't want to do this step so that that was kind of different opinions. Then in general I have several younger patients who thought that it looked very old, kind of graphic, and all this type of thing. They were kind of these look kind of from the 2000 kind of or like I don't know 1990 or whatever. Yeah, it's like kind of OK but that was some feedback that some people referred to me.

Several people enjoy a lot the TAC test, you know this one that has. That was one of the kind of a very good step usually patients enjoy it quite a lot because you have the chance to actually kind of challenge themselves. I think usually people enjoy that.

Speaker 2

The games, I also have mixed feelings about the games, so usually because we have the car game and the bar game, the bar game was much more successful than the car game that is incorporated into the software because the car game. I don't know if you have seen it, but. You'll have no goal. You can't change or whatever, so you can so in the beginning it's fun and you're together with the patient and you scream and well, but then you can you can be kind of whatever because there's no end point of that thing. So I have also kind of this feeling, but from the patient what kind of how long do we need to do this? While the blocks were kind of OK, we kind of killed X amount of blocks or colors. So I think it was more dynamic but sometimes what happened is that kind of the synchronization between kind of the contraction and the bar was not so good, for example, and the same with the car. So then that generates quite some frustration. So that sometimes it was. Not so good for some patients. So some of them didn't enjoy it because. Sometimes the bar moves kind of too fast because for example, if the cables make some noise then the bar isn't moving, so they think is it me or is the cables you know? So in the other moments, they are not accelerating so much. But in the game, they get too excited. So that's why I have that sometimes happen.

Speaker 2

What else? In the visualization of the hand sometimes, for example, and flex extension of the fingers or stuff, the finger sometimes disappears in the software. There are some moments that kind of disappear or some moments that look kind of contortionist. You know, a movement that is not anatomically correct. So that's something that some patients have. I don't recall all the movements but some were quite awkward. It looks anatomically weird and I have had this comment for sure from the therapist right away. But Morten helped at the time, for example, with the leg in the beginning, there were quite some moments that were kind of that, he helped to make it so there were some moments that were kind of awkward still work, but it was some awkward. And the fingers disappear and also the toes. Sometimes there were some moments when you stopped seeing the finger. That is all I can remember for now.

Speaker 1

I can ask you something like have they expressed anything regarding the hardware?

Speaker 2

No, in general, was quite OK I think. For them was kind of fine. It was light. It was convenient to put it here or to put it in the leg. So I think usually it was not something but sometimes if some patients wanted to put their cable or by themselves, that was sometimes a little bit tricky, especially if they were old people or if they were amputated from the arm. That could be more tricky, you know. But apart from that, I think was quite OK, that is I think it worked and like having the dongle, it was quite OK.

Speaker 1

But yeah, no problems with batteries, battery life, or anything like that?

Speaker 2

No, not there. We have some customers that have some issues with the batteries, but they were because the batteries were kind of old, but then we replaced them and then it was fine. So there was nothing else there. No, it was fine, I think.

Speaker 1

Have the patients expressed any specific feedback regarding the user interface?

Speaker 2

Yeah, I have some feedback about that in the sense that some patients thought because, uh, the arm for example, in the TAC test and all these types of things you look normal but in the augmented reality is like a mirror. The point of view was changing sometimes. So for example some patients also referred that. There sometimes it was weird that you have a different perspective and one patient also told me to ask me if we could change the perspective and we couldn't. That with perspective is also a topic because for example, when we were doing with the leg dorsal and palatial flection, Sometimes you could not see because their feet disappeared. So for example, lateral it's much easier, but they didn't know how much flexion they were doing. So that was also something awkward.

Speaker 1

Was it mainly the lower-body amputees that had these kinds of problems?

Speaker 2

No, the upper as well. But I think the upper was better designed, I think also the upper limb was first designed. So I think it was more time invested I think. So I think some of the lower limb was less invested in, to be honest. Well, that's my feeling, but I don't recall exactly the times and such.

Speaker 1

From your professional standpoint, what improvements or additional features would you like to see in the device to make it more user-friendly?

Speaker 2

Yeah. Uh, well, from therapies, I get quite some feedback, because many of them were asking me also things. For example, these things about the position or having more interactive games that also many people ask me, we can have more fun games in the sense that the patient can engage more. Because after a while it's kind of you're doing all the time the same. So that's something that a lot of therapists kind of ask if that is possible. I also consider that it would be nicer to have more fun games. Like goal-oriented task games. Yeah, I think like in general.

I think also selecting the movement and those parts were quite easy in the beginning, but for example, there were some words that we wanted to use for home, for example, that were hard to understand for a patient, so for example they say a supination or dorsal and plantar flexion and all these types of things. I think the language is not quite the best thing if you give it to someone for home. So we did some study for people at home and we needed to clarify and show them what is it. So in the future, we'll be I think cool to maybe show what we are looking for you know kind of.

And then I think in the part of the recording. I think it was quite OK. It was nice and I got the comment also from other therapists that you can change the times kind of. So that was quite nice. Then in the TAC test, therapists enjoyed it, but it's also because it's very target-oriented and such. But also here I ask Morten at a certain point if we could modify a little bit more kind of the parameters of the TAC test, meaning like how many repetitions or how is the range. When someone reaches or does not reach, you know how much time it takes. So, then Morten told me that you can go to the code in and change it. But I mean, when you're in a normal therapist, will not go to like the code. It won't change anything, you know. I think it will be nice to have this freedom to kind of play around with those parameters, and a therapist told me like, hey, because some people were almost there for example. And then it goes to the next task. So then it's quite frustrating again.

Something else that we were talking about is that it would be nice maybe to add some sound. For example when you're achieving something in the TAC test for example. So then it's also kind of more, more fun to do.

Then we have in the augmented reality. Usually, therapies also like it because it's quite impressive when you are there like once I have a patient that start crying because it was. Because it was very strong for him. He kind of said I can see my arm and I can move it. So, it's quite something. There, the therapists have challenges sometimes to put the arm and the leg in the correct position. Because you have this marker that you need to kind of put in the position and then you click some buttons and stuff. So many therapists were kind of kind of afraid, you know how to operate that. So, of course, people learn. But I have more older therapies that had trouble doing it.

Speaker 1

Would it be better with some better instruction on how to place and perform the augmented reality with the marker?

Speaker 2

Yeah, exactly. Or find an easier way, because I think for some, it was not critical, but I get the comment that it is not so nice.

And then the game. I think everyone wanted to kind of have more fun stuff. I think everyone thought that it was very old school. So many times they asked me if we could do more fun stuff and improve. Also the visualization of the arm, the color of the arm, as I told you, as well as something that I have a colleague in South Africa and she was awkward about it and thought it was weird.

Speaker 1

Were there any parts of the system that were easy to handle if you enjoyed and think we're good for the patients?

Speaker 2

I enjoy the TAC test and the bar game. Those were my favorites for sure.

Speaker 1

Are there specific metrics or indicators that you find particularly useful in evaluating the ongoing progress of the treatment?

Speaker 2

Something that I was missing and I talked with other therapists and we were planning to implement it, but then life happened. It is a final report of what you did in the training with your patient because you don't have that, you know, you know, kind of how many sessions you did, how long were the sessions, what movements? To tell, well, how was it? You have this questionnaire, which is very good at the end. And that was kind of the reference point that we were always using to see the progress of the patient and such. But it's also good to see what have you done. And then also the therapist can show them to their employers. So we're like, hey, with this patient, we did x amounts of sessions and they did this. Also, it would be nice to see, that last week I trained this and that. So then you and the patient see, OK, there was training or, you know kind of have more track or what was happening.

Speaker 1

Yeah, some sort of tracking the summarize previous sessions.

Speaker 2

Exactly. So then you get a score, and so then it's easy for us to progress and the patient to see us. So how things have been happening because for them it's quite demanding you know? So then it's better to see kind of hey, things are happening. Look how far we have gotten. And all this type of thing. So I think that's a big feature that the software is missing.

Speaker 1

Have you encountered any patient adherence issues to the device, and how have you addressed them?

Speaker 2

So it had been different. So one thing is that for some patients in the beginning like because we were doing a protocol kind of 15 to 20 sessions and for some patients in the beginning and the three first sessions the pain might increase. And it's quite expected, because imagine people have amputation for several years, they haven't used their muscles. If they don't have a prosthesis and such. So you're kind of waking up everything. So we saw that some patients have this behavior of pain. It goes up and then it goes down. So some people were kind of, no, I don't want to do this anymore, which I understand.

Understand that educating the patient is important but that's not mostly with Neuromotus, but it's I think maybe we need some education, maybe improving the manual. Another thing, that we have in the home trial. As I recall, for some patients it still took time to set up everything with the electrodes. So the setup also takes time. Of course, the first session takes longer, the second less and less over time. That's also something that might be useful for therapies as well, to know where to place them, and maybe if the device has also some guidelines or something. Because of course, we know anatomy or we think that we know but still, it's quite challenging. You can follow anatomic lanyards. But it would be nice with some more guidelines.

Speaker 1

As you mentioned, some people like the TAC test more, and some people may like augmented reality more than others. How do you accommodate individual preferences in your treatment approach?

Speaker 2

Several of the patients that I treated were part of the clinical trial and then we needed to follow the protocol. But after that or before that I just did depending on what they liked and the most important thing is that I keep them challenged. We start with, for example, we do it 1-DOF in all the steps, and then we do a new recording and we do 2-DOF to keep them challenged in a session. So in a session, I usually do three pairs of movements or more. And over the sessions, I also progressed.

So you have this simultaneous option. That's also very interesting if you see the different combinations that don't make sense. Many therapists commented to me that there are impossible combinations. You can play around with them, but then there are things that you don't do or that look kind of weird. So maybe more functional movements are better. Rather than do these kinds of weird combinations.

Speaker 1

Yeah. When you say functional movements, could you elaborate a bit more?

Speaker 2

For example grip. This is a very important movement, like a grasping, you know, kind of all these things that you sometimes use with the prosthesis grip, like a tripod, like this type of function for example in the hand. Of course, the lower limb is harder but in the hand, you have some moments that are more important than others. I don't remember, but there were some things that you had no function with it. So more intuitive movements are better, I mean you grasp a phone, you grip sometimes to eat or so this type that what I refer to as functional.

B.2 Interview 2

Speaker 1 (Interviewer)

So I can start by asking if you could please tell me a bit about yourself and your background as a therapist.

Speaker 2 (Therapist)

I have been working as a hand therapist for quite some years at the University Medical Hospital in a city in the Netherlands. Together with a rehabilitation specialist, I worked with the treatment of the Neuromotos system for patients with phantom limb pain. I'm a physiotherapist from my background. Usually, I was working with upper limb problems, but for the Neuromotos system, of course, it can be lower limb as well.

Speaker 1

Approximately how many patients have you treated using Neuromotus?

Speaker 2

Maybe 20?

Speaker 1

Please share a bit about your general experience using Neuromotus.

Speaker 2

I think it's a very nice tool to have to treat phantom limb pain. Especially in patients who already had multiple pain treatments or long-term complaints. And in some cases, it does help and in some cases, it helps a just little bit. But in most patients, they at least get some sort of sense of their phantom limb pain and also sometimes a bit more control. But also, I have had some cases in which I was thinking, hmm, what am I doing? Does it make any difference? So yeah, it can be a bit of both.

Speaker 1

Yeah. So in your discussions with patients, have they provided suggestions or feedback on how the device could be enhanced to better address their needs?

Speaker 2

Yes, they did. What I heard many times is that the limp should be more realistic. For example, can the color of the limb be adjusted to the patient?

Speaker 1

Mainly in the augmented reality part?

Speaker 2

Yeah. In the augmented reality. But maybe also in the virtual reality because, then it doesn't look like their limp at all. Well, considering the colors and stuff. But I think augmented reality is even more important for them. I also often hear that the movement of the limp which can be virtual and augmented is sort of a small delay in their own contraction and the movement that they see on the screen. And it is sort of bothering for them to feel like it's their own movement.

Speaker 1

Did any of the patients mention anything regarding the games?

Speaker 2

Well, they sort of felt it was quite fun to do. For some of them, it was a bit difficult, but usually, they felt it was quite fun because it was something different than the other exercise. Some felt like now we stop exercising and we're doing something fun and then we're going back to the exercise later. And there was this one guy who was asking me why don't we just use some VR glasses, maybe it feels more realistic to be in some kind of VR environment.

Speaker 1

What aspects of the device do patients appreciate the most, and where do they see room for improvement?

Speaker 2

I think for most of them augmented reality is most helpful because, obviously they see themselves with their limp again if it feels realistic enough. For some that was difficult to help to restore the image of their own body.

Yeah, I think that's still the most important, but some felt the TAC test was helpful because they had some kind of guide for their movements. But, there is a point in the TAC test that I can remember with some of the movements, for example, you want to straighten your elbow. I'm not sure if this is the right example, but you want to straighten your elbow, and then at some point, the image always stops. So even if you want, you cannot straighten it.
But then there are other movements where the joints in the screen can move even further than is realistic. So that was sometimes a bit bothering because then the patient actively has to correct that movement in the screen, while it's not really their own movements.

Speaker 1

Have they expressed anything specific regarding the hardware part?

Speaker 2

Well. Sometimes we had to be creative about where to put the Neuromotus system, for example. Do you attach it to a chair? Do you put it around the neck? Sometimes that was a bit like a search where to the system. Especially when they had to make movements.

Speaker 1

From your professional standpoint, what improvements or additional features would you like to see in the device to make it more user-friendly?

Speaker 2

Well, it could be helpful if it would be more realistic, the visuals. I mean, we see so many movies, and a lot of VR stuff is going on, we know it can be really professional in games and stuff like this. And sometimes in the Neuromotus system, it feels like not smooth. I think that it could be improved. And to help with the feeling that it's really them making the movement.

Speaker 1

Do you as a professional think it's easy to use the device?

Speaker 2

I think the device itself and the software as well is it was quite intuitive. But I also remember that. In quite some cases I had the problem that then suddenly the connection was gone for example and then if you already was doing an exercise based on. Well, if you already have a recording, you can just open the file, but if you are in the middle of a recording for example, you have to start over again. And if the patient gets tired easily, that can be bothering.
And we had a lot of contact with Morton and Maria and other guys and it couldn't really be solved. What was the problem in the end, maybe the suggestion was it's getting too old or something. But yeah, that's kind of bothering if that happens. And then you see the patient is thinking, uh, what is this kind of system? I thought I was using professional stuff and then two or three times it just stopped. So, I discussed it with Maria for example, she said, well, it should be just OK if you are still in one room with the system and she told me well I sometimes have patients that go to the toilet and come back and they still have the connection. Yeah, I'm not sure what was the reason but it was frustrating.

Speaker 1

Are there any specific functionalities that could better support clinicians in treating the patient's phantom limb pain?

Speaker 2

Maybe if we are talking about the games. For some patients, it felt a bit like why is this really contributing to the treatment? And I was thinking maybe if you sort of integrate like a TAC test and the game a bit more that you can sort of use the game to reach a goal or get a a certain amount of contractions or stuff like that.

Speaker 1

Were there any parts of the device that you thought were especially difficult to handle?

Speaker 2

No, not really difficult to handle.

I was thinking about something different. When you were talking about movements of the hand and the thumb, for example. Well, you cannot exercise by joint. But it could be the case in partial hand problems maybe? And the thump? I'm not sure if you can exercise all movements or if it's only bending and extending. Because for some patients specifically, if they have a lot of pain in the thumb. It could be interesting to make all the movements in all directions.

Speaker 1

What parts of the device do you think are easy to handle?

Speaker 2

Well, in the beginning, everything is difficult because you're not used to it. And then at some point, you're used to it so it's not really that difficult anymore. Well, sometimes, for example, one of the signals wasn't that well or was giving some kind of distortion, you can always check if the cable is in good condition or if it's what is it crossed or something like that. But sometimes there were these kinds of distortions that couldn't be located. But I'm not sure if you can improve that in the device itself. I mean you can always have some kind of disturbance.

Speaker 1

Are there specific metrics or indicators that you find particularly useful in evaluating the ongoing progress of the treatment?

Speaker 2

I think that the overview of the amount and kind of pain that a patient gives in the last 24 hours, for example, can be interesting to see if there is any kind of change. Yeah, I must say I wasn't really using the questionnaire that much. Yeah, I wasn't always actually using that. I mean, you have your own evaluation with the patient. Like, is it getting any better, or what's the difference because you're always checking with the patient. However, I wasn't really using the visual feedback from the system itself with the patient. Maybe that can be upgraded or be easier or lower level for the therapist to just check and use during the treatment.

Speaker 1

Then would it be better to have easier ways to put in the data on how the patients are feeling and their progress?

Speaker 2

Yeah, yeah.

Speaker 1

How do you address cases where the treatment may not provide the expected relief for the patient?

Speaker 1

In the beginning, you try to, you're trying to find what's most helpful and useful for the patients. So for example, if one of the functions is doing more for the patient or that they are feeling a sort of connecting with the limp with VR or augmented reality or TAC test. Then I didn't have the feeling at the end I had to use all of them all the time. I was sort of trying to find what was most helpful.

Speaker 1

You previously mentioned that some of them like augmented reality and some like the TAC test. And did you observe any specific pattern on what people liked the most?

Speaker 2

I think augmented reality. I think if you would provide this treatment without augmented reality. I think it would be less useful or helpful to the patient.

Speaker 1

And when you're doing the treatments, do you usually follow a protocol of we're doing these exercises in this order or do you have some individual preferences on how you can do the treatments?

Speaker 2

In the beginning, I usually have a protocol I follow. I guess I always start with virtual reality just to let the patient try the movements. For example, if a patient has already done a few exercises and then we decide, OK, we try one more movement for example. In motor execution, if the patient is already tired. I start with VR and then I discuss with the patient if he wants to do some exercise in augmented reality or if he prefers to do a TAC test.
And I feel that if the patients are already tired, I tend to not do the games.

Speaker 1

Speaking of the games, did they have any preference between the games?

Speaker 2

A lot of them like the racing game. And I mean the car racing you have the Track mania. Some elderly patients, they really like to do that game and then they were like, OK, now I can play this game with my grandson.

Speaker 1

Those were all the questions I had for you. Thank you for participating in this interview.

C

Charts guiding the assessment whether changes are significant

C.1 Chart A

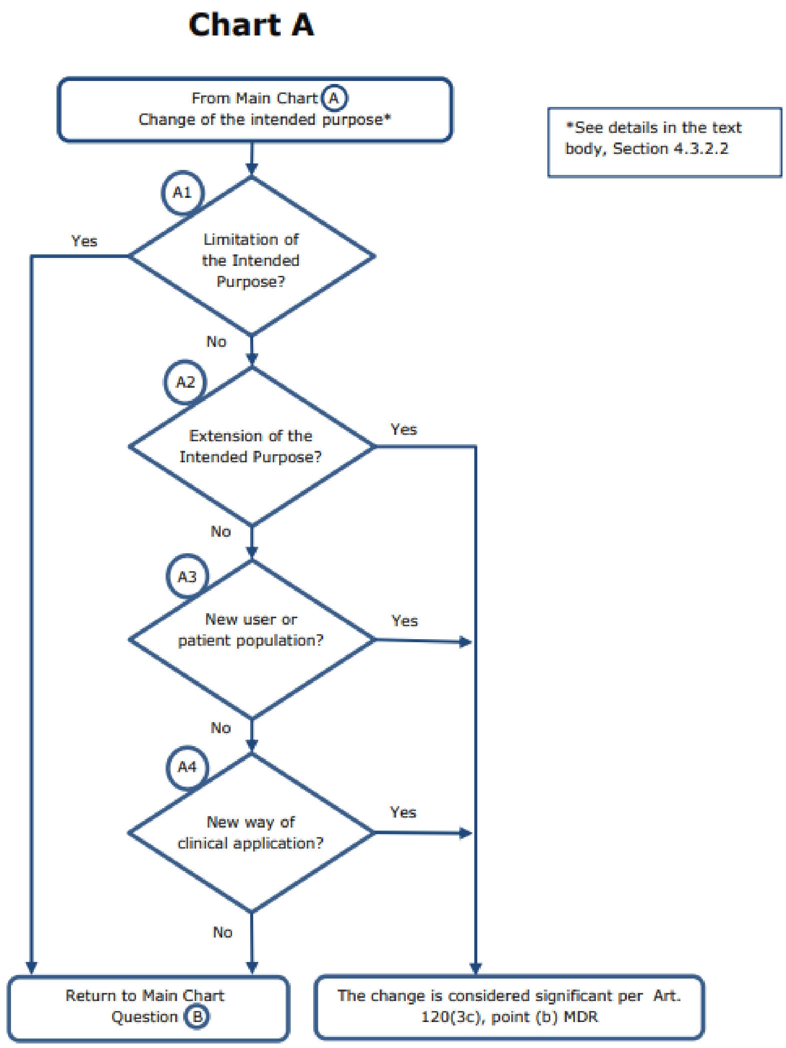


Figure C.1: Guiding changes related to the intended purpose. Source: MDCG 2020-3 Rev.1 [31].

C.2 Chart B

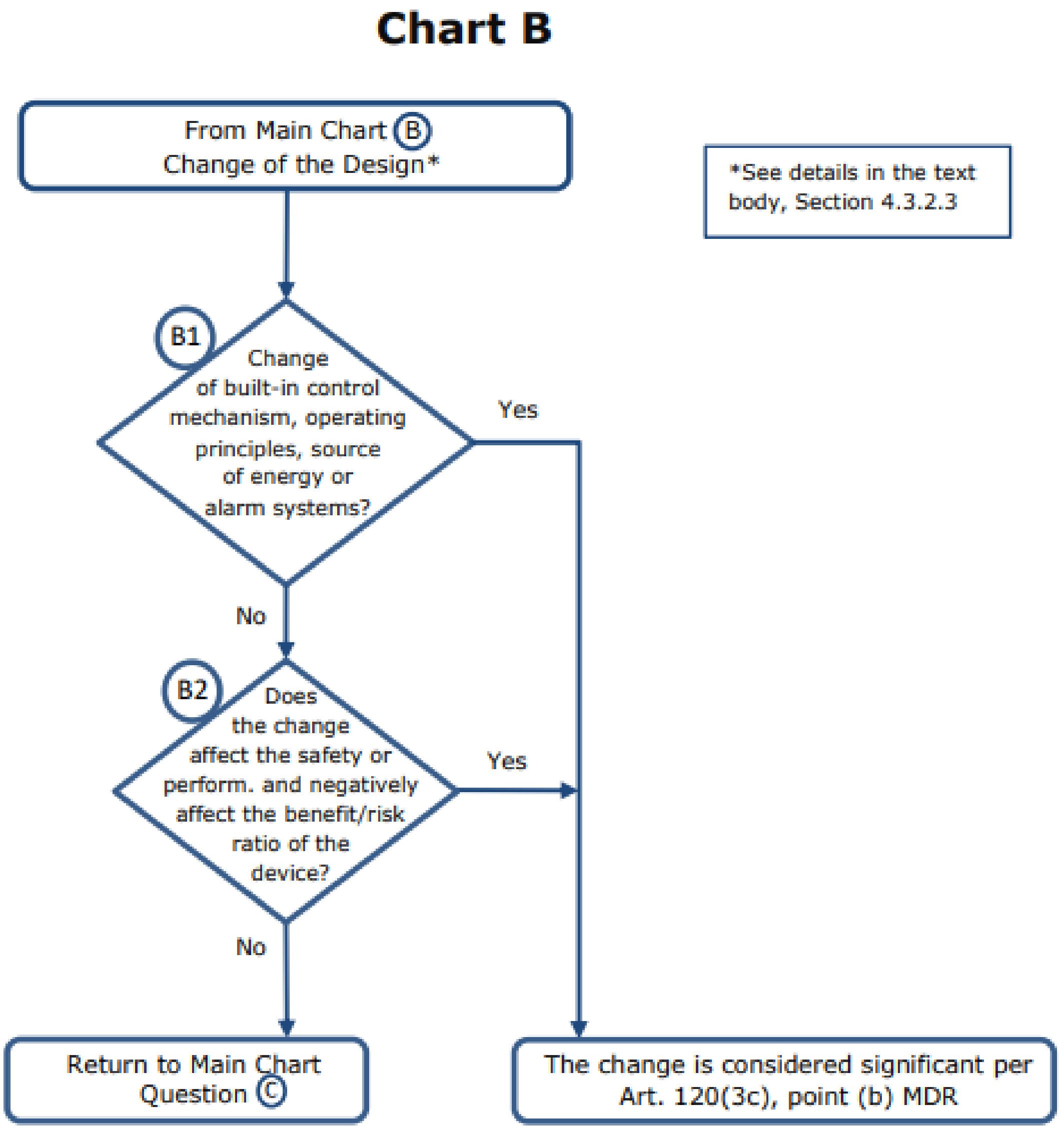


Figure C.2: Guiding changes related to the design where the following principles should apply. Source: MDCG 2020-3 Rev.1 [31].

C.3 Chart C

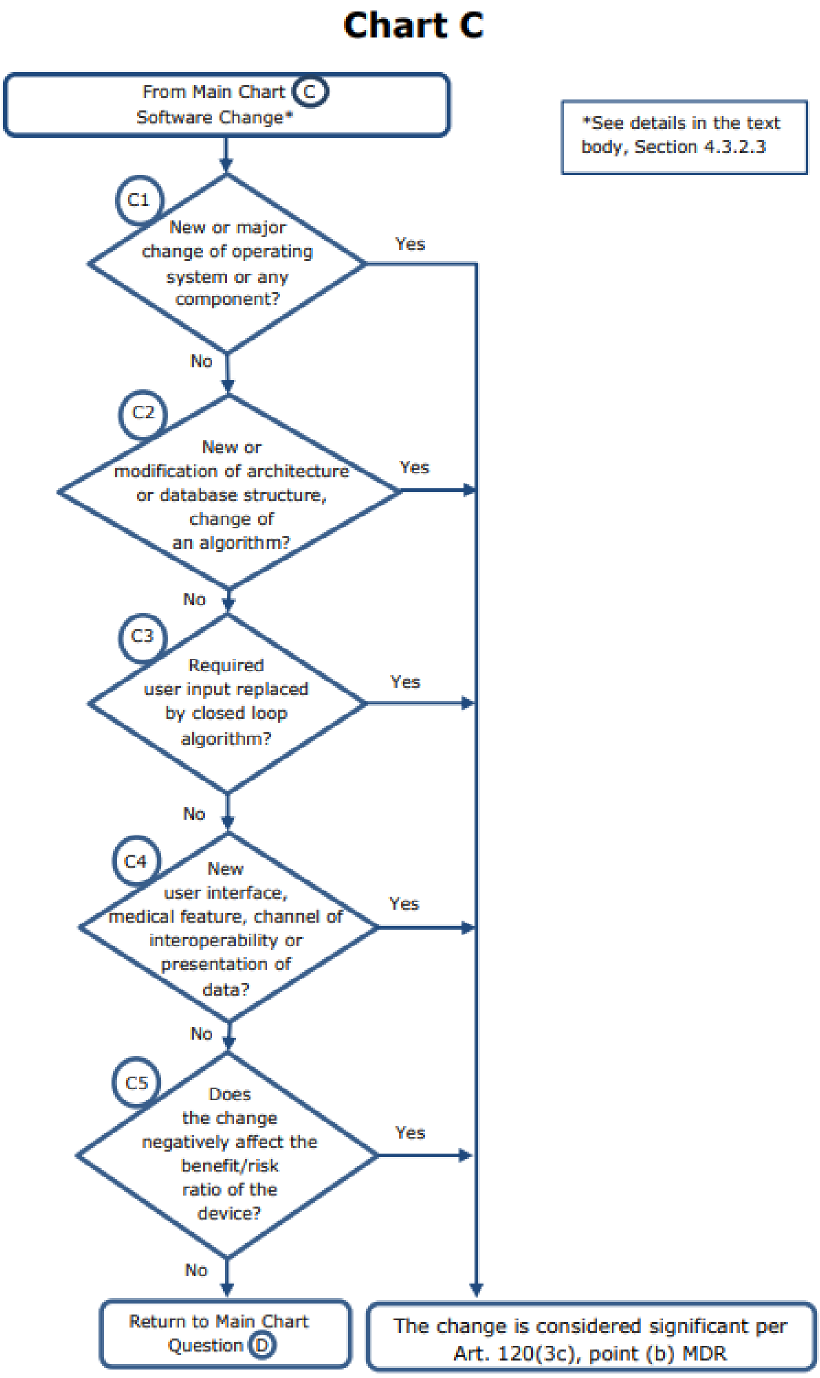


Figure C.3: Guiding changes related to software. Source: MDCG 2020-3 Rev.1 [31].

C.4 Chart D

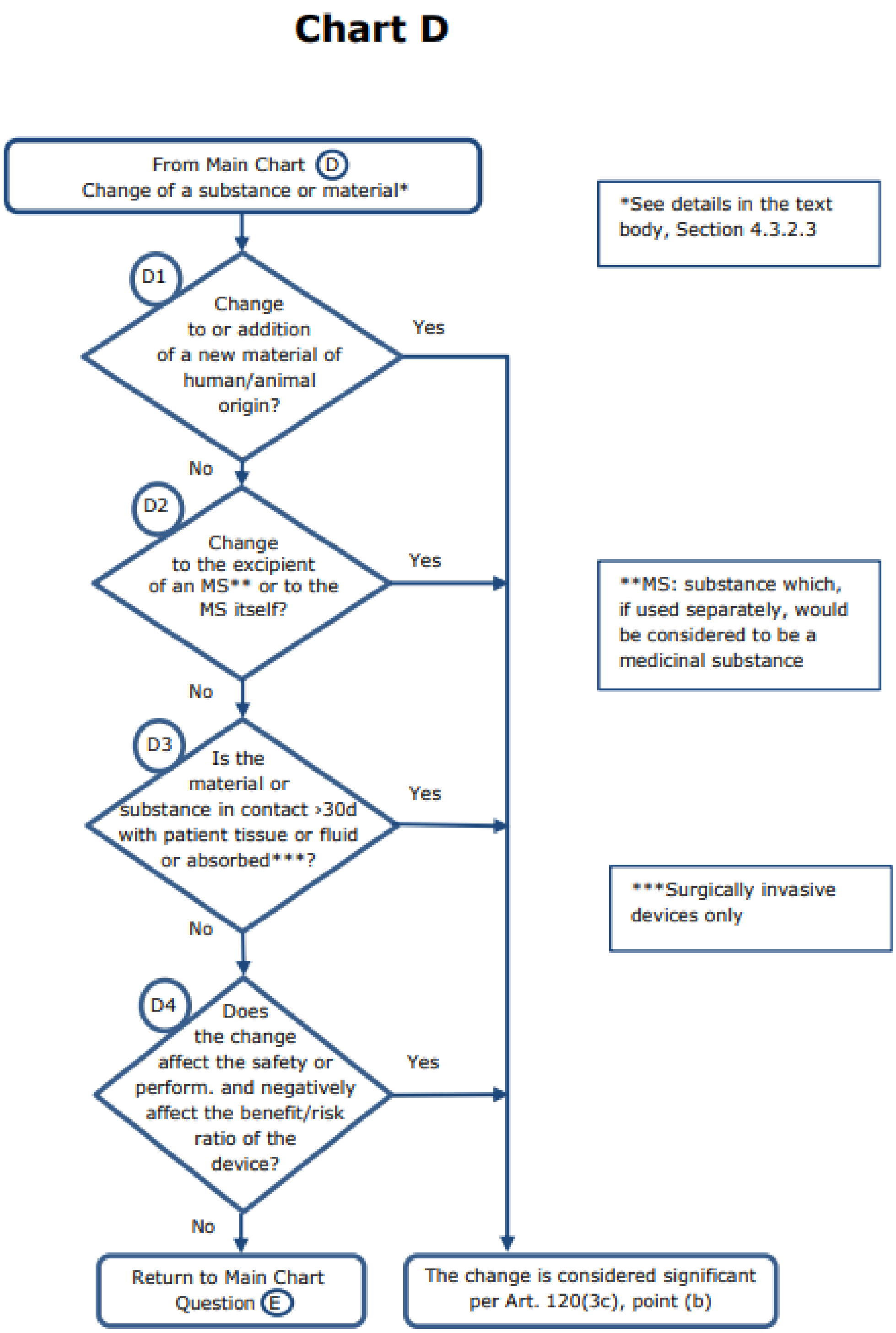


Figure C.4: Guiding changes related to a substance or material. Source: MDCG 2020-3 Rev.1 [31].

C.5 Chart E

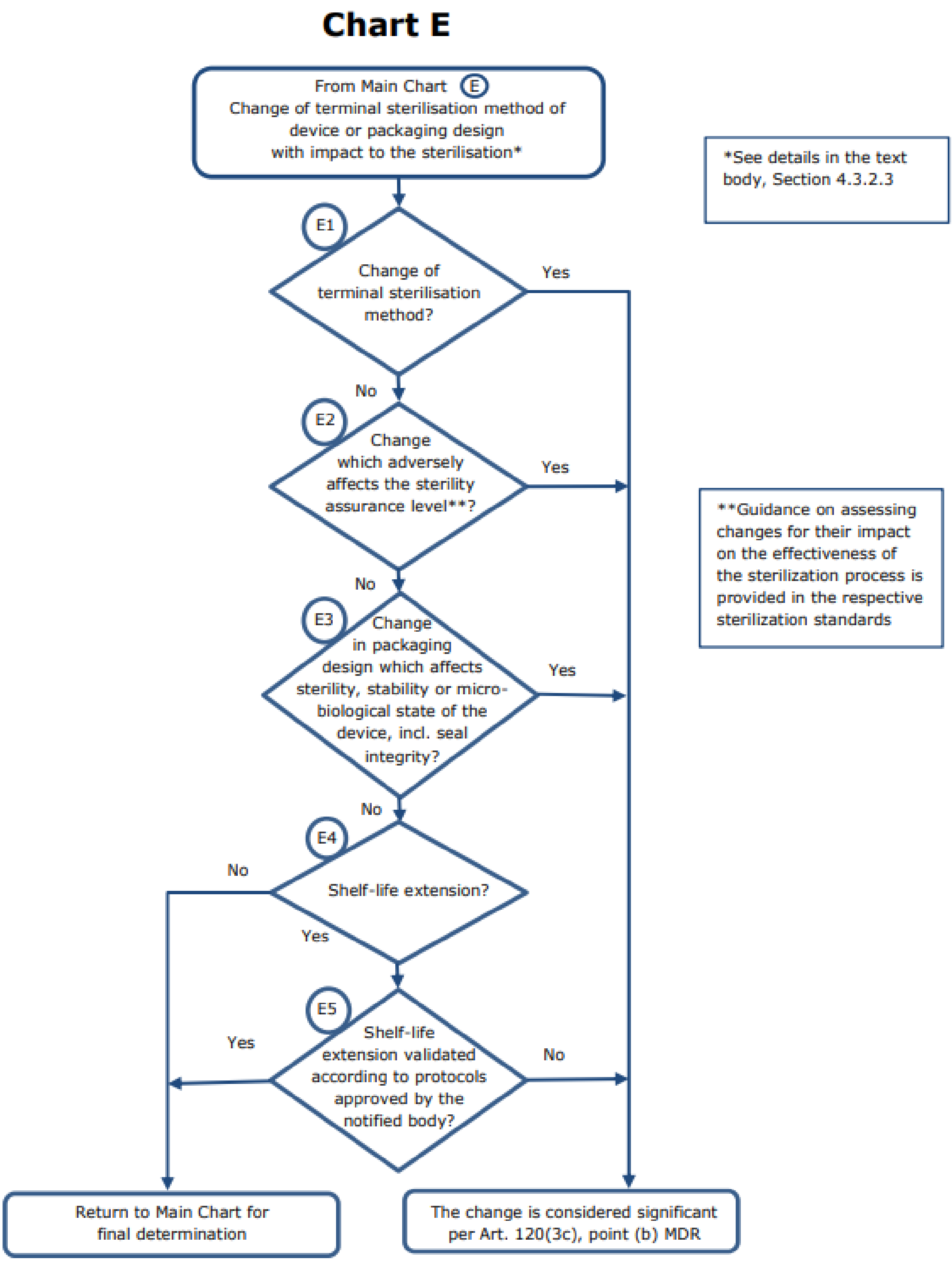
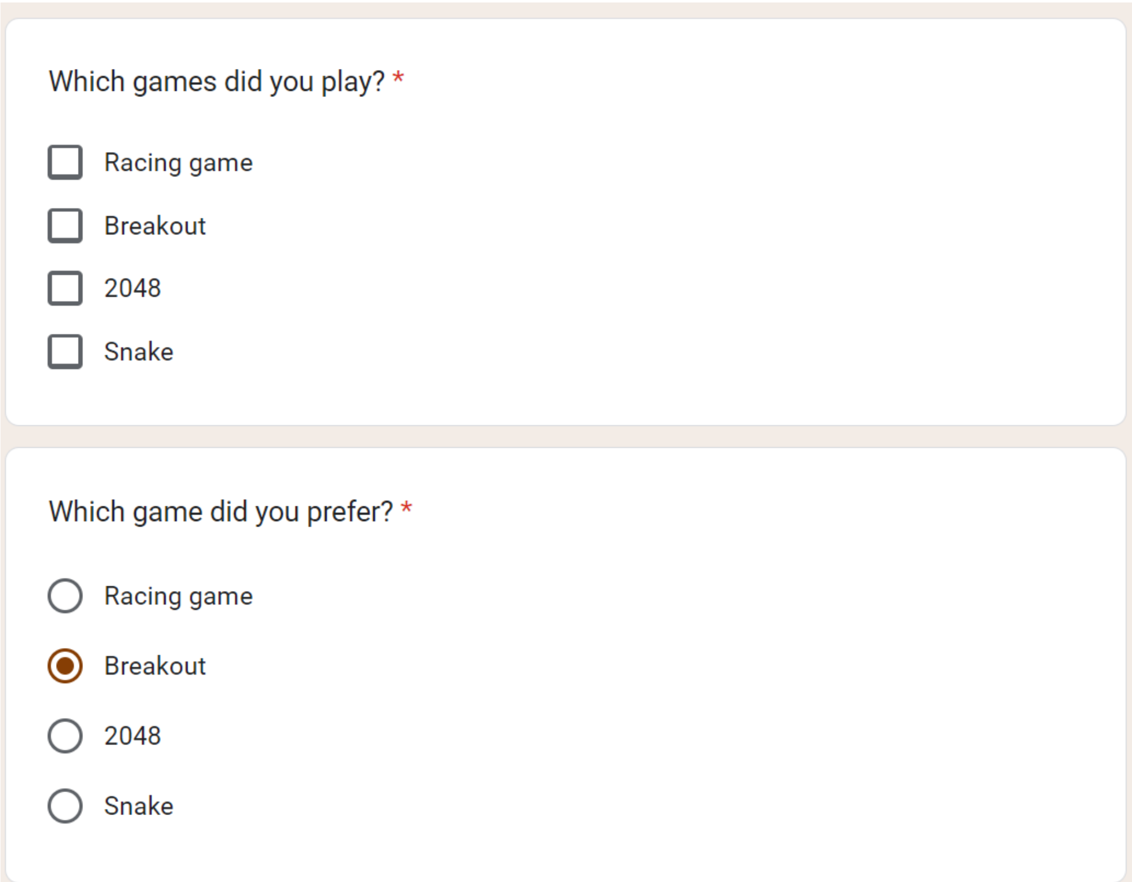


Figure C.5: Guiding changes related to sterilisation. Source: MDCG 2020-3 Rev.1 [31].

D

Question form for stakeholders



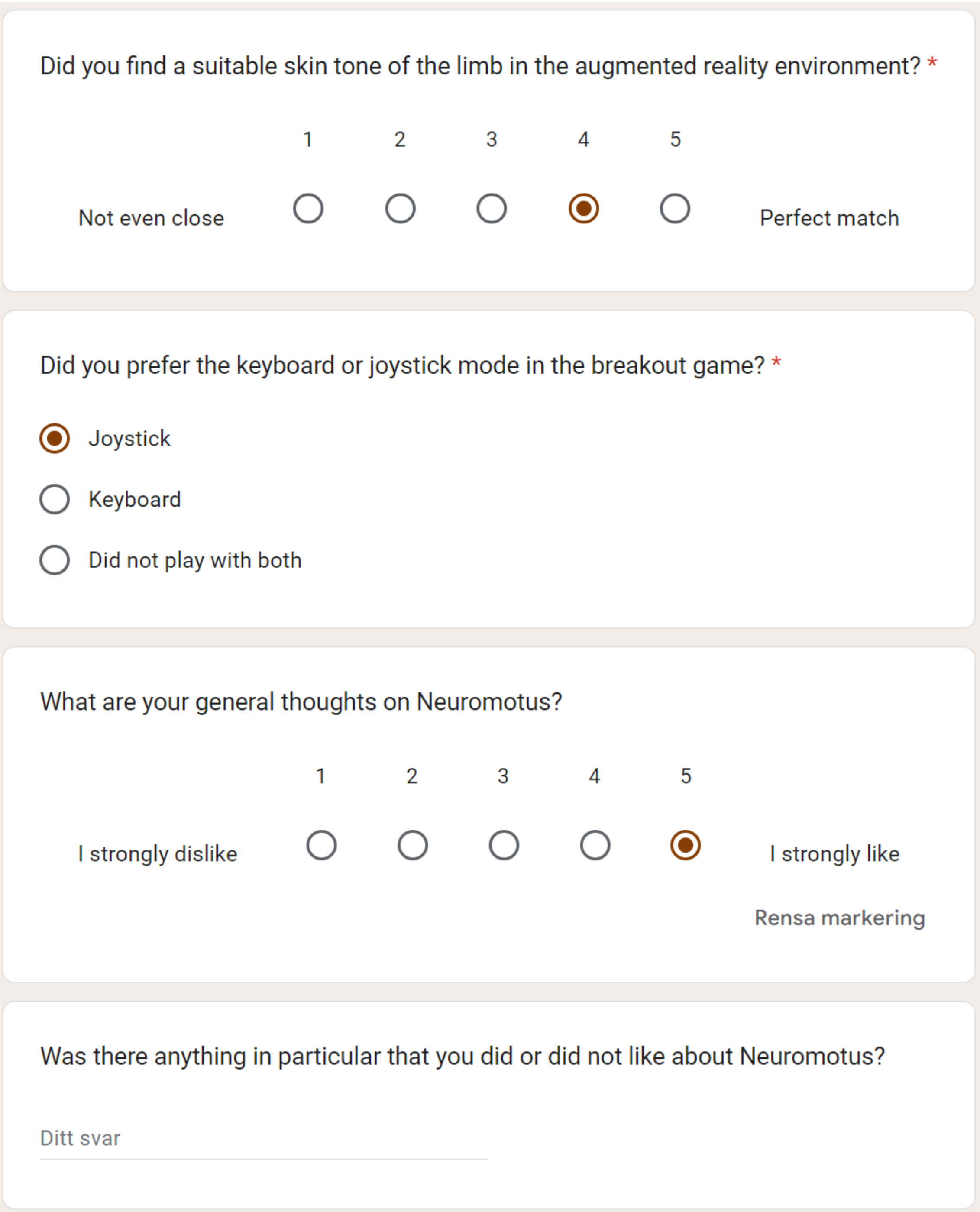
Which games did you play? *

- [ ] Racing game
- [ ] Breakout
- [ ] 2048
- [ ] Snake

Which game did you prefer? *

- ( ) Racing game
- (•) Breakout
- ( ) 2048
- ( ) Snake

Figure D.1: First two questions of the form.



Did you find a suitable skin tone of the limb in the augmented reality environment? *

	1	2	3	4	5	
Not even close	○	○	○	◉	○	Perfect match

Did you prefer the keyboard or joystick mode in the breakout game? *

- ◉ Joystick
- ○ Keyboard
- ○ Did not play with both

What are your general thoughts on Neuromotus?

	1	2	3	4	5	
I strongly dislike	○	○	○	○	◉	I strongly like

Rensa markering

Was there anything in particular that you did or did not like about Neuromotus?

Ditt svar

Figure D.2: Last four questions of the form.

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