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HEURISTIC EVALUATION OF A MEDICAL DEVICE PROTOTYPE

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ABSTRACT

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Usability principles are often secondary to clinical effectiveness when assessing medical devices. However, the majority of medical device incidents are linked to user error. Greater attention to usability evaluation during the development of a medical device can prevent patient-endangering errors. In this study, the usability of a medical device prototype is assessed through heuristic evaluation. The aim was to carry out an evaluation and to assess heuristic evaluation as a method to improve medical device usability.

The evaluated prototype is a mobile eye blink pacemaker aimed at patients with unilateral facial palsy. Facial palsy impairs the muscles responsible for producing the eye blink. Lack of blinking can result in complications such as dry eye disease and corneal ulceration. The purpose of the studied prototype is to evoke the eye blink with electrical stimulation. The device could be a simple and cost-effective alternative for more invasive methods.

Heuristics targeted particularly for medical devices are yet to be developed. Heuristic applied in this study are a combination of heuristics formerly used in other studies analyzing medical devices. The majority of usability problems detected concerned the user's control and physical effort. The most severe problems were related to error situations. Most of the heuristic violations were rated as minor problems; no catastrophic problems were found. The most problematic part of the prototype was the adjustment of the stimulation level.

The heuristic evaluation is a quick and resource-efficient method to identify usability problems and their severities in medical devices. However, more research is needed to create a standard set of heuristics aimed especially at medical devices.

Keywords: heuristics, medical device, facial palsy

Contents

1 Introduction

1.1 Essential Eye Blink

Eye blink is a semi-autonomic bodily function that a healthy person rarely stops to think about. Its importance becomes evident when the ability of blinking is impaired. Blinking protects, lubricates and cleanses the eye. The lack of blink often results in ocular complications such as dry eye disease and corneal ulceration (Craig et al., 2017; Twoon, Saeed, Fong, & Hallam, 2016). Symptoms related to the lack of blinking are usually treated with eye lubricants and ointments. If the condition is permanent or chronic, surgical treatment is required. (Twoon et al., 2016.)

Facial palsy is a common cause of the lack of blinking. The paralysis is typically unilateral affecting only one side of the face. The most prevailing form of acute facial paralysis is Bell's palsy (Peitersen, 2002). Facial palsy impairs the function of muscles essential for basic functions including blinking, speech, eating, drinking, and facial expressions. In addition to functional problems, a significant number of patients suffer from social isolation, depression and physical pain. (Wax & Cannady, 2015.)

Methods to treat the various symptoms of facial paralysis are available. Surgical intervention is common when the paralysis is known to be permanent. (Peck & Wax, 2015.) However, in the case of Bell's palsy, 70% of patients will fully recover within three months (Sánchez-Chapul et al., 2011). Alternatives for invasive and risky surgery are needed when the potential for recovery exists. To reclaim the facial functions related to the paralysis, methods to electrically trigger the facial muscles have been studied (Lylykangas et al., 2017; McDonnall, Guillory, & Gossman, 2009).

An electrical stimulator method to evoke eye blink is developed in Tampere University. The method could possibly prevent the symptoms related to the lack of blink on patients with facial paralysis. This thesis focuses on a mobile prototype based on the aforementioned method.

1.2 Research Aims

Nowadays the importance of usability and user experience is recognized in various domains. Usability standards and goals are regularly applied in the design process of products and systems involving interaction between humans and technology. However, in the medical field usability principles are still under-used. Little published work exists concerning the usability inspection of medical devices (Martin, Norris, Murphy, & Crowe, 2008).

In this thesis the aim is 1) to carry out a heuristic evaluation of a medical device prototype designed to electrical stimulation of eye blink, and 2) to assess heuristic evaluation as a tool to improve medical device usability.

Heuristic evaluation is a frequently used method to inspect usability violations throughout the design process. In this study heuristic evaluation is applied to identify possible usability problems with the prototype before more comprehensive usability tests with participants. Heuristic analysis has been used to evaluate the usability of medical devices before (see e.g. Cifter, 2017; Graham et al., 2004; Tang, Johnson, Tindall, & Zhang, 2006), but no standard set of heuristics for medical device design has been developed yet. Hence, the secondary aim of this study is to weigh the possibilities and limitations of heuristic evaluation as a method for usability inspection in the medical field.

2 Usability in the Medical Field

2.1 Defining Usability

In the field of human-technology interaction, the term *usability* often refers to a quality feature measuring how easy user interfaces are to use (Nielsen, 1994). However, while usability has been a key issue in the field of computer science since the early 1990s (Hollingsed & Novick, 2007), it can be argued that a clear, generally accepted definition for the term still does not exist (Lewis, 2014).

Nowadays usability is regularly seen as a part of the broader term *user experience*. The concept of user experience is a broad and complex one. According to one definition usability is associated with the methods for enhancing ease of use during the design process while user experience refers to all forms of the user's interaction with the company, its services, and its products (Nielsen, 1994; Norman, 2013). Another definition describes user experience as a consequence of a user's internal state, the characteristics of the designed system or product and the context or the environment of the interaction (Hassenzahl & Tractinsky, 2006).

The official ISO 9241-11 definition of usability is: "the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use." In the same standard user experience is defined as "a person's perceptions and responses that result from the use or anticipated use of a product, system or service". The standard introduces the usability terms of *user* (person who interacts with the product), *goal* (intended outcome), *effectiveness* (accuracy and completeness in achieving of the goals), *efficiency* (resources spent in relation to the accuracy and completeness in achieving goals), *satisfaction* (user's freedom from discomfort and positive attitudes towards the user of the product) and *context of use* (users, tasks, equipment and the environment in which a product is used). (ISO 9241-11.)

Definitions of usability can be split into two major conceptions, summative and formative. Summative concepts focus on metrics related to meeting product goals while formative concepts focus on usability problem inspection and associated design solutions. The concept of summative usability emphasizes the importance of effectiveness, efficiency, and satisfaction in the context of use. Research focused on these metrics has led to the aforementioned ISO usability standard. The formative usability concept focuses on the iterative design process and it has led to the development of usability evaluation methods such as empirical usability testing and experts-based inspection methods. (Lewis, 2014.)

2.2 Usability Goals

Another way to approach to the concepts of usability is by scrutinizing the usability goals. Nielsen (1994) defines usability by the following five goals:

- **Learnability**: The system should be easy to learn.
- **Efficiency**: The system should be efficient so that a high level of productivity can be achieved after the user has learned the system.
- **Memorability**: The system and its functions should be easy enough to remember so that the user can return to the system after some period of not having used it without the need to learn everything from the start again.
- **Errors**: The system should have a low error rate and users should be able to easily recover from the errors. Catastrophic errors must not happen.
- **Satisfaction**: Users should find the use of the system pleasant.

Nielsen's goals fall under the summative usability concept where a product is considered usable when people can use it effectively, efficiently and with a feeling of satisfaction. In the formative usability conception, the usability goals are related to the absence of usability problems found on empirical usability testing. (Lewis, 2014.)

Hassenzahl (2010) presents goals on a simplified three-level hierarchy in which goals are divided into so-called motor-goals (how?), do-goals (what?) and be-goals (why?). A do-

goal is a concrete outcome such as “making a telephone call”. Below the level of do-goals are motor-goals that are deliberately designed parts of the interaction, such as a single press of a button when making a phone call. Usability testing and usability goals mainly focuses on models and methods of do-goal accomplishment. Most of Nielsen’s usability goals are essentially do-goals. Be-goals are on the top level of the hierarchy, and they are the goals that motivate action. For example, in the context of a phone call, a be-goal – the motivation behind the action - can be to ease loneliness. Be-goals are related to human feelings and thus they are related to user experience, unlike the do-goals that are in the focus of usability. (Hassenzahl, 2010.)

User experience goals define what kind of positive experiences the product or system should invoke in the user (Karvonen, Koskinen, & Haggrén, 2012). Possible use experience goals are for example “feeling of control” and “feeling of safety”. One of Nielsen’s five usability goals, satisfaction, can also be seen as a user experience goal. In this study, the main focus is on usability and usability goals.

2.3 Usability of Medical Devices

In the medical field, the usability and user experience of devices is directly linked to patient safety. Errors while using medical devices are a common cause of patient injury and even death (Zhang, Johnson, Patel, Paige, & Kubose, 2003.). According to McConnell et al. (as cited in Graham et al., 2004), reported errors regarding medical devices are often user errors rather than technical issues (McConnell et al. as cited in Graham et al., 2004).

Despite the growing understanding of the importance of the user in other design domains, in medical device development usability principles are still under-used. In the medical field, a typical challenge is that developers fail to appreciate user experience requirements beyond clinical effectiveness. Another characteristic of the field is that devices are often used by different kinds of people from clinical experts to patients and thus the needs of several types of users must be understood. (Martin et al., 2008.)

A significant number of medical and health care devices are intended for home-use. Home healthcare technology is mainly used by laypeople without or experience or training in health care. It also needs to be taken into account that users of home healthcare devices might have declined capabilities and chronic illnesses. Despite this, usability is often overlooked in the design of home-used medical devices. (Cifter, 2017.)

Besides reduced errors and increased patient safety, carefully designed, easy-to-use devices can also lead to improved productivity, reduced need for user training and improved user acceptance (Jaspers, 2009). While safety concerns alone are a critical reason to carefully assess new medical devices before releasing them to market, human factors analyses bring also financial and legal benefits in medical device development. Human factors analyses can improve the use of the equipment, lower the likelihood of legal exposure and possible judicial or regulatory action. Furthermore, while usability and user experience analyses add expenses to the development of equipment, they can help lower the overall costs by reducing the need for hardware changes and software updates. Good user experience is also likely to have a positive impact on sales. (Bezerra et al., 2014)

2.4 Regulation

When designing and developing medical devices, certain procedures concerning human factors must be undertaken. International standards help to ensure the development of safe, effective and usable medical and health care devices. Several standards and regulations are set in place to reduce risk and improve patient safety. (Privitera, Evans, & Southee, 2017.) However, these regulations vary significantly across the world (Martin et al., 2008).

The most important standards and regulations concerning medical device development are standards by the International Organization for Standardization (ISO), International Electrotechnical Commission (IEC) and on the US market the American National Standard Institute (ANSI).

Usability, in general, is defined, as mentioned earlier in this chapter, in ISO 9241 Ergonomics of the human-system interaction. Other ISO standards concerning usability, are ISO 13407 Human-centered design processes for interactive systems and ISO 9126 Software engineering – Product quality.

For medical device development, the IEC 62366 Medical devices - application of usability engineering to medical devices defines a process to analyze, specify, develop and evaluate the usability of a medical device as it relates to safety. The process permits the manufacturer to assess and reduce risks related to the correct use and user errors. (IEC 62366, 2015.) General requirements for the safety of electrical medical equipment are guided by IEC 60601-1 Medical electrical equipment. IEC 60601-2-10 is a specific standard giving requirements for the basic safety and essential performance of nerve and muscle stimulators.

In the European Union, medical device regulation is currently undergoing a major reform. Two new regulations on medical devices were adopted on 5 April 2017. The new regulation for medical devices will be fully applicable in May 2020. The new regulations bring for instance stricter control for high-risk devices, more transparency through a comprehensive EU database on medical devices, improved coordination mechanisms between EU countries and new rules to ensure the safety of medical devices. (European Commission, 2019.)

Privitera et al. (2017) have identified challenges concerning the application of human factors' standards. These challenges are related to the connection with the users and developers. Firstly, direct access to users for the purpose of device development can be limited in the medical and health care field. Secondly, users often lack the understanding of the importance of their role in the development process because it is not defined clearly enough by the developers. Thirdly, the contract formalities may limit user involvement. Lastly, users may expect compensation to collaborate with the device industry and that can affect their attitude towards the development process.

To tackle these challenges, the researches give recommendations such as enabling access to users, effectively collaborating with users and ensuring consistent user input throughout the development process. Despite the challenges, the understanding of user-centered design is getting recognized in the medical and health care industry. (Privitera et al., 2017.)

3 Facial Paralysis and Artificial Eye Blink

3.1 Facial Paralysis

Peripheral facial paralysis is a condition where the facial muscles of a patient are impaired due to facial nerve injury. Facial paralysis can be congenital, neurologic, infectious, traumatic or it can be caused by a chronical illness or tumor (Wax & Cannady, 2015.)

The most common cause of facial nerve injury is idiopathic facial palsy named Bell's Palsy. It represents about half the cases of facial nerve palsy. Bell's Palsy is an acute, unilateral facial paresis without any known cause. The annual incidence of Bell's Palsy is about 10-40 cases per 100 000 population. (Twoon et al., 2016) According to one source, approximately 70% of patients fully recover within three months (Sánchez-Chapul et al., 2011). In another study, 83 % of the patients recovered with a fair result within 3-5 months. The rest remained with facial dysfunctionalities of various degrees. (Peitersen, 2002.)

Facial nerve injury may result in the inability to produce voluntary facial expression, glandular secretions and loss of protective eyelid closure causing patients serious problems that impact their general health and quality of life (Twoon et al., 2016). Facial nerve is responsible for normal functioning of the forehead, upper and lower eyelid complex, nasal passage, midface, and lower face. Thus, facial paralysis is not only a functional issue but it also affects the patient's ability to communicate with other people by facial expressions. Consequently, it reflects the patient's self-image. The cosmetic and psychological impaction of facial palsy can be as devastating as the functional impairment. (Wax & Cannady, 2015.)

In chronical facial paralysis, the primary rehabilitation method is surgical intervention. However, more than two of three patients of acute facial paralysis will recover fully within three months. The patients who have the possibility of return of facial nerve function need other rehabilitation methods than surgical intervention. (Peck & Wax, 2015.)

This study concentrates on the possible aid and rehabilitation of eye blink with the help of a medical device prototype for artificial blinking. Blinking is an essential function for a healthy eye. The lack of blinking can cause severe conditions from conjunctivitis and corneal ulceration to loss of vision (McDonnall et al., 2009). For now, there isn't an effective treatment for loss of eye blink due to facial paralysis (McDonnall, Askin, Smith, & Guillory, 2013). The non-blinking eye needs constant care: to protect the cornea from excessive dehydration and abrasions patients are advised to apply lubricating artificial tears and eye ointments (Zandian et al., 2014). The eye drops must be used as often as every one or two hours during the day and ointment and permeable synthetic tape must be used at night (Masterson, Vallis, Quinlivan, & Prinsley, 2015). However, the lack of effective therapies still causes patients disruptive complications related to loss of eye blink and vision (McDonnall. et al., 2009). Furthermore, the benefit of surgery in the treatment of Bell's palsy is controversial. Potential risks of surgery include seizures, unilateral hearing loss, and facial injury. (Zandian et al., 2014.)

3.2 Electrical Stimulation to Evoke Eye Blink

Electrical nerve stimulation through invoked muscle stimulation is a proposed method of helping the progress of recovery in Bell's Palsy (Zandian et al., 2014). The application of electric stimulation to evoke blink in paretic eyelid has been researched in several studies with different methods. Some of the suggested stimulation methods are invasive and percutaneous (see e.g. Frigerio & Cavallari, 2012; Frigerio, Brenna, & Cavallari, 2013; McDonnall et al., 2009) while some are transcutaneous (see e.g. Frigerio, Hadlock, Murray, & Heaton, 2014; see e.g. Ilves et al., 2019; Marcelli et al., 2013).

To regain lost facial functions, a method called facial pacing has been studied (Frigerio et al., 2015; Ilves et al., 2019; McDonnall et al., 2009). The idea of facial pacing is to detect signals of facial activity on the healthy side of the face and to use this measurement to evoke muscle activity via electrical stimulation on the paralyzed side of the face. The facial pacing technology could possibly be applied to both transcutaneous and percutaneous methods for evoking the eye blink.

McDonnall et. al (2009; 2013) are developing an implantable functional electrical stimulation (FES) system to restore eye blink activity in patients with unilateral paralysis. They aim to record blink from the functional eyelid to use as a timing signal for electrical stimulation of the paretic eyelid. In this method stimulation electrodes are placed on the paralyzed eyelid and recording electrodes are located underneath the healthy eye to track spontaneous eye blink. (McDonnall et al., 2009; McDonnall et al., 2013.)

Frigerio et al. (2013) have tested a similar idea where the focus is also on the tracking of the spontaneous blink. They are designing a closed-loop implantable device that electrically stimulates a paretic eyelid when detecting a spontaneous blink activity on the healthy eyelid.

As a non-invasive method infrared-based blink-detecting glasses have been tested by Frigerio et al. (2014). The idea is to attach a blink detection to standard eyeglasses and use it as a part of a closed-loop facial pacing system. With the glasses, a challenge is to minimize the detection errors caused by facial expressions and the shifting of the sensors.

For rehabilitation purposes, electrical stimulation has been tested for facial nerve paralysis patients since the 1950s (Mosforth & Taverner, 1958) with the goal to encourage nerve regeneration (Kim & Choi, 2015). In some cases, it has been beneficial (Quinn & Cramp, 2003). Low-level evidence to support the use of electrical stimulation for patients with chronic facial nerve paralysis exists. In the acute phase electrical stimulation does not seem to alter the speed or rate of full recovery but in the chronic phase extensive electrical stimulation may improve facial functionality. (Fargher & Coulson, 2017.)

3.3 Electrical Eye Blink Stimulator: MobiStim1

Studies of facial pacing technology indicate that the reliable detection of eye blink can be challenging even in a controlled laboratory setting (Frigerio et al., 2013). Therefore, less complex methods have been studied. Lylykangas et al. (2017; 2019) have tested an

alternative to pacing method where the eye blink stimulation is triggered by a pre-programmed timer. The pace of stimulation is based on the average blinking parameters.

The pacing device prototype includes four amplifiers for EMG measurement and four amplifiers for stimulation, and it is controlled through Wi-Fi connection with a computer. (Rantanen et al., 2016). In the first user study, the timer-triggered blink stimulation method was tested with healthy participants. Researchers were interested in the first-hand information on longer periods of stimulation. The participants watched a movie for 78 minutes while the eye blinks were produced by stimulator. As a result, the timer-triggered stimulation method was found functional and the stimulation was experienced mainly positively. (Lylykangas et al., 2017.)

In the next study, the timer-triggered blink stimulator was tested with participants suffering from dry eye disease caused by facial palsy. In this test, the focus was again on longer period use (~120 minutes). The participants rated the experienced eye dryness significantly lower after the stimulation than before it. The stimulation was rated painless and fairly natural. (Lylykangas et al., 2019.)

As the test results with static pacing device have been promising, a mobile prototype with improved functionality was developed. *MobiStim1* (Figure *1*) is a prototype of a mobile eye blink pacemaker device developed. Primarily it is designed for patients with acute facial paralysis to protect the eye during monitor work and other similar everyday activities. In the future, it can be tested also for rehabilitation purposes. Prototype is accepted for clinical investigation by Valvira (National Supervisory Authority for Welfare and Health). In this thesis, the focus is on the usability of the prototype.

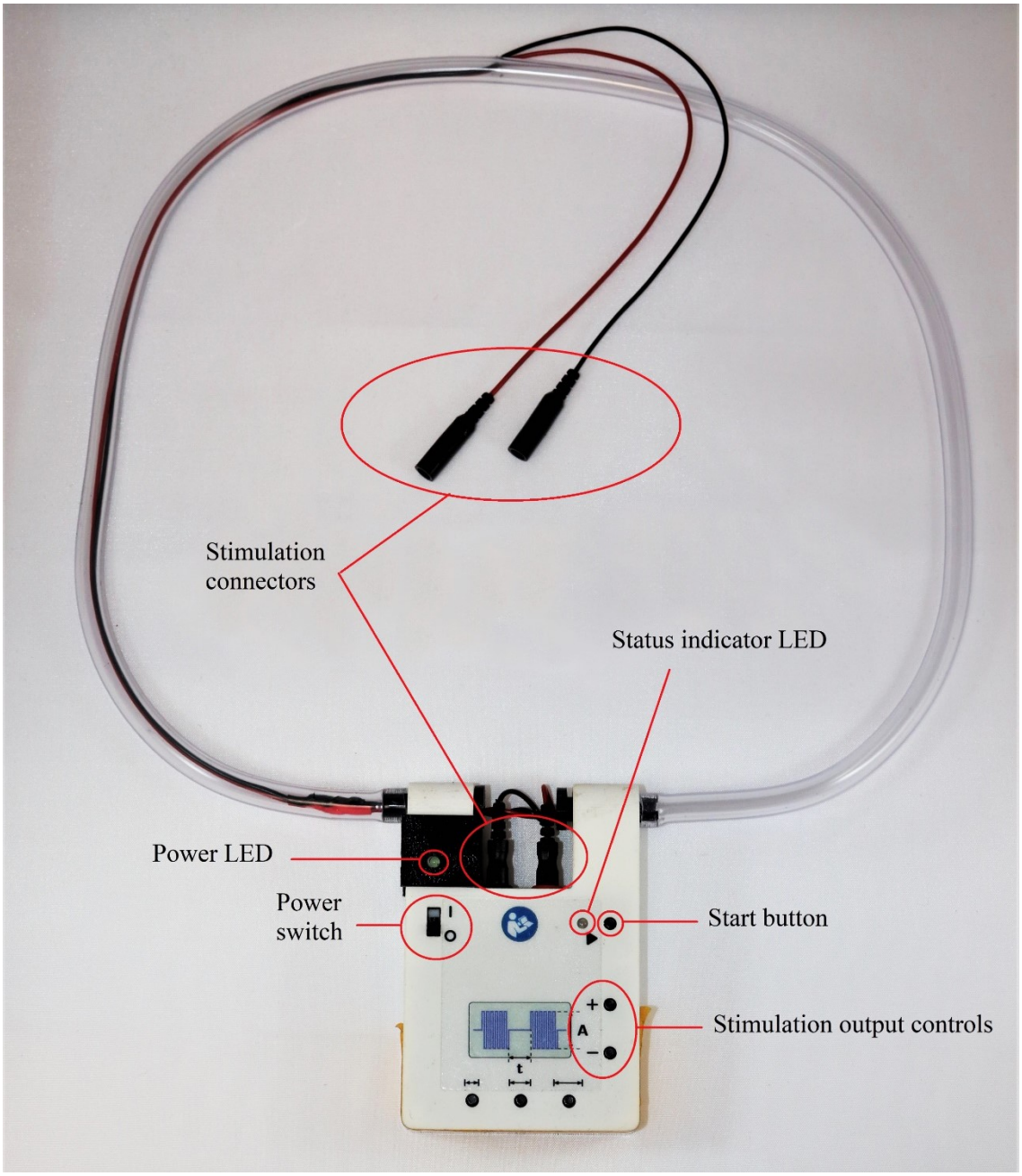

Figure 1. MobiStim1 prototype with main parts labeled.

4 Method: Heuristic Analysis

4.1 Heuristic Evaluation

Heuristic evaluation is an expert-based method for usability inspection. It is an approach in which evaluator(s) investigate an interface for usability issues. Its high benefit-cost ratio and efficiency makes it the most common and most popular method for assessing usability. Heuristic evaluation is normally conducted by a small group of expert evaluators who inspect a system and evaluate its interface against a list of recognized usability principles called heuristics. (Nielsen, 1992.) Typically, several heuristic-type analyses are conducted during the design process to evaluate the concept and to propose corrective measures for problems detected (Stanton, 2013).

Heuristic evaluation is an especially valuable method in situations where time and resources are limited as it does not involve the participation of end-users. According to Jaspers (2009), several studies have shown that a large number of usability problems can be found with heuristic evaluation. More problems can be detected than with other compared methods such as the cognitive walkthrough and think-aloud method. Furthermore, problems identified with heuristic evaluation are often not detected in the user testing phase. (Jaspers, 2009.)

However, the lack of end-user participation means that the quality of the results is dependent on the skills and experience of the experts. Many different sets of diverse heuristics and guidelines have been accumulated through the years to assist reviewers in heuristic evaluation. Thus, the evaluator must become knowledgeable and proficient in applying suitable guidelines for each specific context. Unified set of heuristics that can be applied in various contexts, lead to reliable results and provide additional design guidance do not yet exist although initiatives to develop such a set are in progress. (Kamper, 2002.) Another challenge with this method is that it often identifies many minor problems that are not significant for the users (Graham et al., 2004). Other downsides of the heuristic evaluation are related to ambiguity of the heuristics and the often strong subjective views and preferences of the experts (Jaspers, 2009).

According to Zhang, Patel, Johnson and Smith (2002), a comprehensive human factors engineering analysis for medical devices includes four major segments: user analysis, functional analysis, task analysis, and representational analysis. User analysis aims to identify the features of users. Functional analysis identifies the critical domain structures and goals. Task analysis identifies the system functions. Representational analysis aims for direct and transparent interaction between the users and the system by recognizing appropriate information display format for a given task performed by a specific type of user. The heuristic evaluation method is one of the major techniques at the representational level. (Zhang et al., 2002; Zhang et al., 2003.)

Heuristic evaluation is designed to be used alongside other usability inspection methods to identify a comprehensive list of usability problems in a product. While it can recognize possible usability and safety issues, it does not reveal the elements that correctly follow usability guidelines, nor is it a suitable method to inspect major missing functionalities (Graham et al., 2004). On the other hand, errors made by users during user tests can be better understood by the detailed information gathered in the heuristic evaluation phase (Ginsburg, 2005).

Heuristic analysis has proven to be a quick and useful method to identify problems and risks related to medical devices (Bezerra et al., 2014; Graham et al., 2004). Heuristic evaluation can be a useful tool as an initial usability test in the early stage of medical device development to identify and solve problems before performing extensive usability tests with users (Martin et al., 2008). It can be used to discover problems that can cause medical errors and it can be used to guide design changes and modifications of the device to enhance usability and safety (Ginsburg, 2005).

In this study heuristic evaluation is used to identify possible initial problems in a prototype before usability tests with target users. It should be noted that due to the nature of this study the evaluation is conducted by a single evaluator. While heuristic evaluation is usually conducted by several analysts, it can also be executed by a single evaluator. According to Nielsen (1992), it is expected that approximately 20 – 51 % of the usability

problems are found by one evaluator analysis. Thus, it is worth emphasizing that this evaluation is intended to be an initial part of a more extensive process of usability and user experience testing of MobiStim1 prototype.

4.2 Contextual Heuristics

Heuristic evaluation has long been leaning on Nielsen's general heuristics. Nowadays heuristics are used to analyze various kinds of products and systems. To provide better results, development of new heuristic sets for specific application domains is needed. Suggestions for methods to create contextual heuristics are made by various researchers.

Van Greunen, Yeratziotis and Pottas (2011) propose a three-phased method to develop new heuristics. The first phase is a literature-based planning phase, the second phase is expert-based validation and the third phase is the application of the heuristics. Jiménez, Rusu, Roncagliolo, Inostroza and Rusu (2012) propose an eight-step method to create heuristics. Compared to the method suggested by Van Greunen et al. (2011), the Jiménez et al. method has a descriptive, comparative and explaining steps after the literature step. After the validating step, there's a modifying step where the heuristics list is modified based on the results of validating tests.

In a review by Hermawati and Lawson (2016) 70 studies of domain-specific heuristics were inspected. The authors noticed that more than 80 % of the studies reviewed used similar heuristics as Nielsen's. It was inconclusive whether the domain-specific heuristics were better than the general ones. A possible problem with the efficiency of domain-based heuristics is the insufficient validation process of the chosen heuristics. (Hermawati & Lawson, 2016.)

4.3 Evaluation Process

Heuristic evaluation is not a strictly structured evaluation method and so the evaluation process may vary. This study follows the evaluation process suggested by Stanton (2013). Stanton divides the process into five different phases:

1) Phase one is to define a representative set of tasks for the device under analysis. The defined tasks are written down in a task list and the heuristic analysis is based on these tasks.

2) In phase two the heuristics list is defined. As discussed earlier in this chapter, the existing list of heuristics such as Nielsen's heuristics can be used, or the researches may define their own set of heuristics to apply on the specific device or system.

3) Phase three is the familiarization phase where the analyst(s) involved spend some time to familiarize themselves with the device or system in question. This phase can involve steps such as getting to know the instructions manual and watching a demonstration of the device being used.

4) The fourth phase is the phase where the analysis takes place. In this phase, the analyst performs each task from the previously formed task list and offers opinions concerning the design and the heuristic list applied. Good and bad points associated with the analyst's interactions with the device are documented.

5) In the fifth and last phase, the analyst(s) proposes remedies for any problems detected. (Stanton, 2013)

4.4 Heuristics for Medical Devices

In the lack of a standard set of heuristics to use for medical devices, the heuristics applied in this study are a modified collection of heuristics formerly applied by Zhang et al. (2003) and Cifter (2017). Zhang et al. have applied heuristics to evaluate and compare usability and safety features of infusion pumps. Cifter used hierarchical task analysis and heuristic evaluation to assess the usability of blood pressure monitors.

Zhang et al. (2003) combine Nielsen's heuristics to 8 golden rules by Shneiderman. The result is a list of 14 heuristics called Nielsen-Shneiderman heuristics. Nielsen's widely used usability heuristics include attributes concerning learnability, efficiency, memorability, errors, and satisfaction (Nielsen, 1992). Shneiderman's golden rules for user interface design focus on consistency, shortcuts, feedback, closure, error handling and reversal of actions (Shneiderman et al., 2016).

Cifter develops the combination further by adding principles of design considerations identified by Gardner-Bonneau (Weinger, Wiklund, & Gardner-Bonneau, 2010) to Nielsen-Shneiderman heuristics. Gardner-Bonneau's principles focus, especially on home health-care devices. Thus, they take into account issues such as users' possible physical limitations and challenges.

Heuristics applied in this thesis are mainly based on 14 Nielsen-Shneiderman heuristics. Two additional heuristics are loaned from Cifter to consider issues concerning home-used devices. The comprehensive list of heuristics is described in chapter 5.2.

5 Evaluation of the Eye Blink Pacemaker

MobiStim1 artificial eye-blink pace-maker prototype contains a hand-held size plastic controller (Figure *2*) and two stimulation connectors. The device weighs approximately 125 grams. The size of the controller is 6,5 cm x 10 cm. A charger and disposable electrodes are separate parts of the device. Stimulation connectors are located partly inside a plastic tube ring. The device contains two types of written manuals: one for the expert (e.g. doctor, researcher) and another one aimed for the patient. The manuals were not evaluated but they were used to support the test tasks when needed.

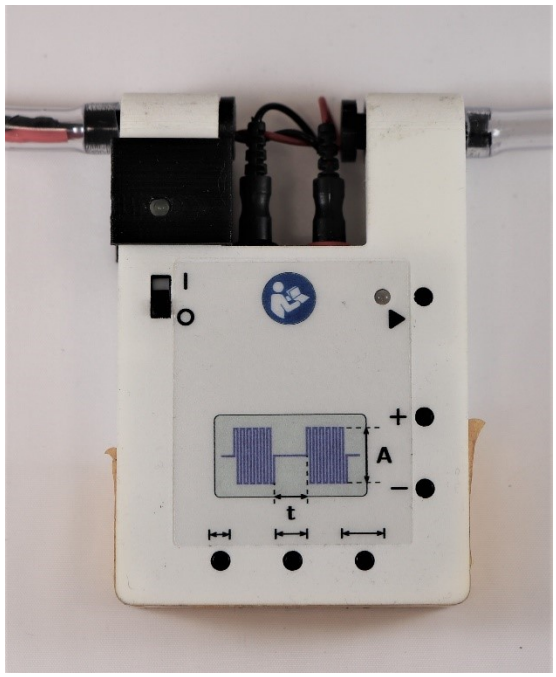

Figure 2. Controller.

When the device is in use, it hangs by the plastic tube ring on the user's neck. Stimulation connectors are attached to the controller on one end and to the electrodes on the other end. The electrodes are placed on the user's face. The device is controlled by using a switch and buttons on the controller. There are six different buttons on the controller. In the prototype, three of the buttons are aimed for the user while the other three are only used by the expert to preset the frequency of the stimulation. The expert buttons are excluded from the evaluation. Although the device is designed for home-use, guidance by

an expert is needed before the first time use. The expert advises the user with the right location of the electrodes and with the functionalities of the device.

There are two different LED-lights on the device. One is located above the power button and it indicates whether the device is turned on (yellow light on) or not (light off). Another LED-light is located next to the start button. The light flashes when the stimulus is produced. When the scheduled stimulation is on, this light is permanently on and the stimulus is indicated with a brighter flash.

The prototype has two main functions: it can produce a single stimulus, or it can produce a continuous, scheduled stimulation. A user can set the strength of the stimulus up and down portably. The length and frequency (on scheduled stimulation) of stimulus are preset by the expert and the user cannot change the setting. Besides the main functions, the device can be switched on and off and it can be charged. For safety reasons, on this prototype phase, the charging socket is hidden behind a separate lid that is screwed to the device and it is meant to be used only by the expert. Therefore, the easiness of charging is not assessed on this evaluation per se but the functionality of the charging process is tested.

5.1 Identified Tasks

At first, the operation of the prototype was divided into a set of tasks and functionalities. The following tasks were identified:

- attaching the stimulation electrodes
- turning the device on and off
- pressing the button(s)
- setting the suitable level of stimulation power
- producing the blink
- producing a singular stimulus
- setting the scheduled stimulation on and off

- increasing/decreasing the level of stimulation power while on scheduled stimulation
- charging the device

The evaluation was based on testing the functionality of this set of tasks. In addition, the analyst evaluated the physical feeling of the device such as the weight of the device when in use, the buttons and the level of freedom to do other things while using the device. Additionally, long term (60+ minutes) use was tested to assess the physical impact of the device on the user. Possible error situations, such as detaching one of the electrodes, was also tested.

5.2 List of Heuristics and Severity Scale

In the evaluation, a set of sixteen heuristics was applied. The chosen heuristics are based on former research (see Cifter, 2017; Nielsen, 1992; Shneiderman et al., 2016; Weinger et al., 2010; Zhang et al., 2002). The heuristics chosen are intended to assess especially medical devices used at home by the patients themselves. The process of identifying heuristics is described in chapter 4.4. The heuristics are named and described in Table *1*.

Identified usability problems were rated by their severity. The severity of a heuristic violation is a combination of the frequency of the detected problem, the impact of the problem if it occurs and the persistence of the problem (Nielsen, 1992). To scale the severity of usability problems, following severity scale by Nielsen (1992) was applied:

0 = not a usability problem at all
1 = cosmetic problem: need not be fixed unless extra time is available on project
2 = minor problem: fixing this should be given low priority
3 = major problem: important to fix, should be given high priority
4 = usability catastrophe: imperative to fix this before the product can be released

Table 1. Heuristic applied in the evaluation.

Heuristics	**Description**
1 Consistency and standards	Users should have no doubt about the actions, words or situations with a different meaning.
2 Visibility of system state	Users should be aware of the status of equipment in all situations. Users should be able to tell what can be done in the current status.
3 Match between system and world	The system and the perception of the user's world correspondence.
4 Minimalist design	Simple is efficient. Unnecessary extra information is distraction.
5 Minimize memory load	Minimize the amount of information that the user must remember to use the equipment.
6 Informative feedback	Users should receive immediate feedback about their actions.
7 Flexibility and efficiency	If possible, users should be given the possibility of user customization and creating shortcuts to optimize the use of equipment.
8 Good error messages	Error messages should be informative. Avoid generic messages with codes.
9 Prevent errors	The device must be capable to prevent error before it occurs.
10 Clear closure	It should be clear for the user that a task has been finished.
11 Reversible actions	Users should be able to recover from their mistakes through reversible actions.
12 Use user's language	The device should use a language corresponding to the technical field level expected by users and their perspective.
13 Users in control	Users should not get the impression that the equipment is controlling their actions. Users should be initiators of actions.
14 Help and documentation	Offer help always. The help must be present in support documents, labels and equipment identification.
15 Perceptive information	Consider different modes of information. Consider users' sensory limitations.
16 Low physical effort	User should be able to maintain a neutral body position while using the device. Required operating forces should be reasonable.

5.3 Heuristic Violations

This chapter describes the detected heuristic violations and usability problems. Problems are named and described. The heuristics violated and the rated severity of the violation are mentioned in brackets.

1. It is difficult to adjust the placement of electrodes if they are not attached to the right place on the first try. The glue on the electrodes is strong and durable which makes the electrodes stay in place well. However, if the electrodes are not placed correctly for the first time, it can be difficult to change their placement. The electrodes do not need to be on any exact position to produce the blink so this notion is not a usability problem at all but it highlights the importance of the guidance before the use of the device. With the proper guidance beforehand, unnecessary transferring of the electrodes can be avoided. [Help and documentation, Low physical effort][0]

2. The same level of stimulus may feel stronger or weaker depending on the exact location of the electrodes. This heuristic violation is more of an observation than a real usability problem. However, it is important that the proper guidance is given to the user before using the device at home so that the user knows how to put the electrodes in place. The user should be made aware that the closer the electrode is to the eye, the stronger the stimulus may feel. [Help and documentation, Users in control][0]

3. Disinfectant and the glue on the electrodes can be irritating on sensitive skin, especially on frequent use. Before attaching the electrodes, the skin needs to be wiped with disinfectant which most users' skin probably tolerates well but for some, the disinfectant can be irritating especially when used frequently. The glue used in electrodes can also be slightly irritating for the skin. This is not a remarkable problem and it cannot be easily avoided other than minimizing the need to re-attach the electrodes more than necessary. [Help and documentation, Low physical effort][1]

4. A suitable stimulation level needs to be tested and set again every time when the device is turned on. The device does not remember the level of stimulation the user set on the previous time of usage. When the device is turned on, the stimulus is on the minimum level. For safety reasons, this is wise but it adds the user's workload. This could be avoided for example if users could see the level of stimulus as a number on a screen and thus they could quickly re-set the desired level of stimulus when getting back to the device after a break of user.
[Visibility of system state, Minimize memory load, Flexibility and efficiency][1]

5. The user does not know the exact level of stimulus. User can set the stimulus higher or lower but they do not know the exact level of the stimulus. While the exact amount of mA may not be necessary information for the user, the user would feel more in control if the device would indicate the level of current stimulus somehow.
[Minimize memory load, Users in control][2]

6. The user does not know if and when the maximum and minimum level of stimulus is reached. The device does not indicate when the stimulus is at the lowest or at the highest level. Although this information is not crucial for the user, notifying the user of the minimum and maximum level would add the feeling of control.
[Informative feedback, Users in control][2]

7. The colors of light indicating the level of stimulus, bright yellow and bright green, are hard to distinguish. The color of the LED light indicates whether the level of stimulation is less than 10 mA (green light) or more than 10 mA (yellow light). However, the similarity of these colors makes this feature ineffectual. If possible, a change to more distinguishable colors is recommended.
[Visibility of system state, Perceptive information][2]

8. The stimulus status light communicating several different things can be confusing. The light indicating stimulus status is located next to the start button but it communicates things not only related to the start-button which can be confusing for the user. Adding another light or some other method to indicate the level of stimulus could diminish the possibility of confusion. Alternatively, locating this light further away from the start-button would make it clearer that its purpose is not only related to the start-button. [Consistency and standards, Visibility of system state, Perceptive information][2]

9. The image on the controller is not informative. In the middle of the controller is an image that is not understandable for the average user, hence it can be confusing. It is not recommended to have this image on the final design. [Minimalist design][2]

10. The symbols on the controller are not comprehensible for the user. The letter 'A' next to the stimulus level buttons is not clearly understandable for the user. It could be left out entirely in order to avoid confusion. Similarly, the purpose of the arrow symbol (Figure *3*) close to the start button is not clear for the user. The arrow should be moved next to the start-button or it could be replaced with text ("START" or "PLAY"). [Match between system and world, Use user's language][2]

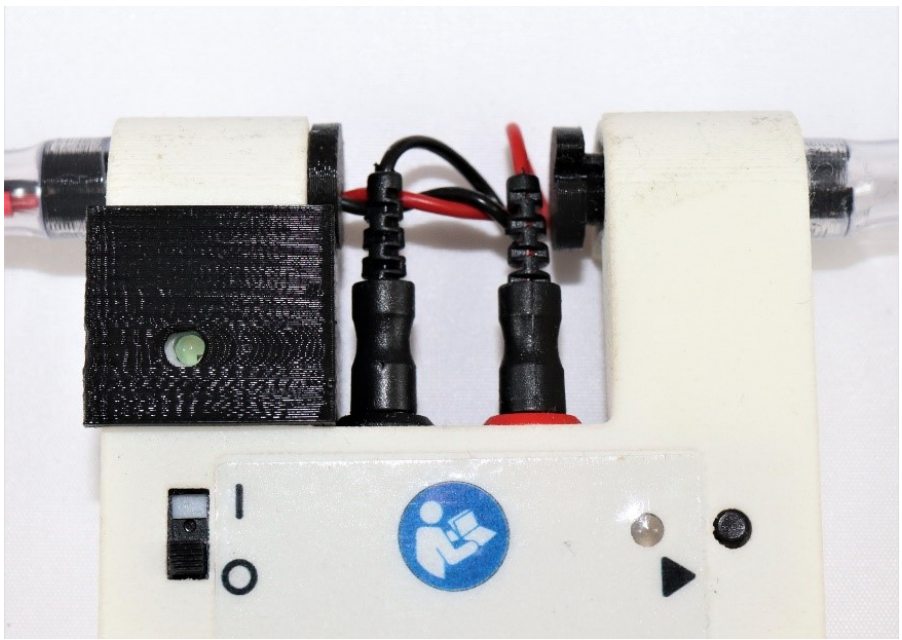

Figure 3. Close up of the upper part of the controller.

11. It is not clear to tell the difference between the buttons when using the device without looking at it. All three buttons on the device are similar and they are located close to each other. When the device is used without looking at it, it is not clear which button is which. Locating the buttons further apart from each other would make it easier to identify the buttons without looking at the controller. Alternatively, using symbol-shaped buttons (+, - and arrow) would make the identifying even easier.
[Flexibility and efficiency, Low physical effort][2]

12. Buttons are somewhat hard to press. The buttons are small and flat and therefore it is somewhat difficult to press them especially on the non-dominant hand. In order to avoid unintentional pressing, it is good that it takes some amount of pressure to press the buttons. However, the buttons could be made bigger or less flat to make them easier to use. [Low physical effort][2]

13. All buttons are located on the left-hand side and are difficult to operate with the right hand. For a healthy user, the buttons are relatively easy to find and press even with the non-dominant hand without looking at the controller. However, if the user's left hand is weakened, the use of the controller may become difficult. One possible solution could be to have two different versions of the controller: one where the buttons are designed to be pressed on the left hand and one where the buttons are designed to be pressed on the right hand. [Low physical effort][2]

14. The device does not turn itself off in any tested error situations. If a user error occurs, the device does not turn itself off. For example, if one of the electrodes is detached or if one of the stimulation connectors is detached, the device stops producing stimulation but the power stays on. It is recommended that the device would turn itself off to increase safety de facto but also to increase the user's feeling of safety. [Prevent errors][3]

15. For some users, the small size of the device can make its handling challenging. The device is relatively small which can make it difficult to operate for people with weakened muscle strength and/or muscle control. Making the device slightly bigger could make it more comfortable to use. [Low physical effort][2]

16. It is possible to set the level of stimulus painfully high. The maximum level of the stimulus is high enough to cause pain for the user. Although it is not easy to reach the maximum level unintentionally the user should not be able to set the stimulus painfully high. The maximum level of the stimulus should not be higher than the level needed to produce the blink. [Users in control, Prevent errors][3]

17. The device does not turn itself off when it is not in use. When the user wants to end the usage of the device, they should turn the device off before detaching the electrodes. Unfortunately, it is easy to forget the right order of actions and for the user, it feels natural to first take off the electrodes when quitting the usage. This can be a safety hazard. The device should always turn itself off if the electrodes or stimulator connectors are taken off. [Clear closure, Prevent errors][3]

6 Results

6.1 Usability Problems

In the evaluation process, the aforementioned tasks and situations were tested several times and the general feeling, appearance, and functionality of the prototype was assessed. The detected usability problems and heuristic violations were rated for their severity. Altogether 17 heuristic violations were identified. No catastrophic problems were detected. Most of the usability problems, 10 problems out of 17, were rated as minor problems. Three of the problems were rated as major problems that would be important to fix. One perceived problem was rated as a cosmetic problem. Two of the heuristic violations were rated as a not usability problem at all. Detected heuristic violations and usability problems are described in Table *2*. Problems are categorized based on the main situation or place of their occurrence. Two violations rated as not usability problems are not included in the table.

The majority of the problems were related to the stimulation. The main concern with the problems related to stimulation is that the user is not aware of the exact level of the stimulation. The exact level of the stimulation is not necessarily important information for the user but the user could benefit, for example, from a screen showing the level of stimulation on a designed scale. Problems with stimulation were most often violating heuristics *Users in control* and *Minimize memory load*. While most of the problems related to the stimulation process were not severe, fixing these problems could make the device easier and more pleasant to use, and consequently, users could feel more on control of the device.

Table 2. Detected usability problems.

Situation or place of occurrence	**Usability problem description**	**Heuristics violated**	**Severity rating**
Controller	The image on the controller not informative.	Minimalist	2
	The symbols on the controller not comprehensible.	Match, User's language	2
	The small size of the device can make its handling difficult.	Physical effort	2
Electrodes	Disinfectant and glue can be irritative for the skin.	Help, Physical effort	1
LED lights	The colors of low and high level stimulus hard to distinguish.	Visibility, Perceptivity	2
	Stimulus status light communicates different things.	Consistency, Visibility, Perceptivity	2
Buttons	The difference of the buttons not clear.	Flexibility, Physical effort	2
	Buttons somewhat hard to press.	Physical effort	2
	All buttons on the left hand side.	Physical effort	2
Stimulation	Desired stimulation level reset every time device is used.	Visibility, Memory, Flexibility	1
	User doesn't know the exact level of stimulus.	Memory, Control	2
	User doesn't know when the max and min level of stimulus reached.	Feedback, Control	2
	It's possible to set the level of stimulus painfully high.	Control, Errors	3
Power	Device doesn't turn itself off in error situations.	Errors	3
	Device doesn't turn itself off when not in use.	Closure, Errors	3

The more severe problems concerned the power source and the stimulation. The prototype does not seem to turn itself off in error situations or when it is not in use. This is problematic because errors such as detachment of the electrodes can fairly easily happen during the usage. Besides, it is not unlikely that the user accidentally, against the instructions, takes the electrodes off before switching the device off. In the prototype, there is a built-in method that quits the scheduled stimulation if one of the electrodes or stimulation connectors is taken off, but this does not completely eliminate the safety risk. Therefore it is highly recommendable that the device shuts itself down completely in a situation where an electrode or connector is detached.

The last major problem is that the user can set the stimulation level painfully high. On a healthy user, the blink reaction does not seem to require a high level of stimulation. It is possible that the paralysis patient needs stronger stimulation. Nevertheless, the maximum level of stimulation should not be set on a higher level than what is required to produce the blink. Unnecessarily high stimulation can be painful; users should not be able to hurt themselves while using the device.

Some usability problems detected are problems concerning the features of the prototype that are presumably not intended to be a part of the final design of the device. For example, the image on the controller can be confusing for the user and it is probably not meant to be in the actual device. Another confusing matter on the controller is the symbols. The symbols are not clearly comprehensible for the user. Symbols could be left out entirely or replaced with more well-known symbols or even with text.

Six of the usability problems violated the heuristics *Low physical effort*. This heuristic is especially significant in medical devices that are meant for users with (temporarily) weakened physical abilities. For instance, the buttons on the prototype are not very pleasant or easy to use. It is hard to identify the different buttons without looking at the controller. The buttons are also somewhat hard to press, depending on the user's position. All the buttons are located on the left-hand side. It is worth considering that the potential

user might have weakened muscle strength and control on one hand so it could be a good idea to provide devices with buttons on the other side of the controller, too.

Two problems concerning the device's LED lights were detected. It is hard to distinguish the color of low-level stimulation (bright green) of the color of high-level stimulation (bright yellow). The stimulus status light communicates several different things which can be confusing for the user. The use of different colors and possibly different locations for the LED lights could make their purpose clearer for the user.

In general, the prototype seems to function well. For the intact user, it was easy to find a suitable level of stimulation to produce the blink. The stimulation does not feel unpleasant and the user quickly gets used to it. No problems related to the long-term (60+ minutes) use were detected. The device is very light-weight, and apart from the initial setting of the stimulation, the user does not have to hold or look at the device while using it. Therefore, normal daily activities can be performed without distraction while using the device.

Not many violations of the minimalist design heuristic were detected while evaluating the device. Heuristics concerning feedback, error messages and reversible action proved irrelevant for this study as no violations against them were found on this type of user interface. The prototype is simple and efficient. The interaction between the user and the device occurs via the buttons, lights, and electrodes. The device does not give user feedback. It is not possible, nor intended, to use the device without former guidance from the expert and without the user manual. In a further development, it is worth considering whether some forms of feedback, such as audio or haptic feedback, could improve the usability of the device. However, possible additions to the device should not be made at the cost of simplicity.

6.2 Heuristic Evaluation as a Tool to Assess Medical Devices

Heuristic assessment is a quick and cost-effective way to approach usability testing. It is a simple method to help eliminate potential usability problems before user tests. Heuristic evaluation can be repeated throughout the design process. However, not all problems are

found through heuristic evaluation, and some problems found in heuristic assessment might not necessarily bother the end-user. Hence, the developers should consider whether modifications based on heuristic evaluation alone are worth implementing before the user testing phase – unless the recognized problems are directly linked to the safety of use.

A known weakness of heuristic analysis is that problems found through this method are often minor or cosmetic on the severity scale. In this study, most of the usability violations were minor problems. Other evaluation methods are needed to detect possibly more severe problems. However, minor problems should not still be overlooked as fixing them can improve user satisfaction and the lack of minor disturbances can be the element that separates a device from its competitors.

Contextual heuristics aimed specifically for evaluating medical devices do not yet exist. Commonly used Nielsen heuristics don't cover all the features and needs related to medical devices. For example, in the medical field, it is common that the end-users have declined capabilities. Another characteristic of the field is that devices are often used by different groups of people from patients to clinical experts. On the other hand, many different kinds of medical devices exist and users of different kinds of medical devices are heterogenous groups with possibly special needs. Therefore, creating a list of heuristics valid for all medical devices is not likely.

Heuristics applied in this study are a combination of Nielsen's, Shneiderman's and Gardner-Bonneuau's principles. The majority of the detected heuristic violations, 17 out of 27 mentions, concerned Nielsen's heuristics (one detected problem can violate several heuristics). Shneiderman's heuristics were violated 3 times and Gardner-Bonneau's principles 7 times. Major violations were related to Nielsen's and Shneiderman's heuristics. Based on this study only, it seems that while most usability problems are found with Nielsen's heuristics, more contextual heuristics can be a valuable addition. A more comprehensive and systematic assessment of heuristics in the medical field could provide useful information and improve the method.

The overall number of heuristic violations detected in this study was fairly low. This can partly be attributed to the relative simplicity of the evaluated device compared to more complex user interfaces. However, heuristic evaluation is a method where the expertise and skills of evaluators influence reflect the number of usability problems found. Usability experts find nearly two times, and application domain experts with usability experience almost three times more problems than the novices (Nielsen, 1992). Medical field is a high-skilled domain and the use of medical devices, depending on the purpose of use, may require medical expertise. Thus, having evaluators with both medical and usability experience may lead to more beneficial results when assessing medical devices.

Heuristic evaluation is always a subjective method and the findings depend on the experience, skills and even personal preferences of analysts. In this study, the heuristic assessment was done by one evaluator. Having just one evaluator is a quick and simple way to get a preliminary view of the usability and to detect possible problems and risks. Evaluation by one analyst can still be useful as long as it is taken into account that typically a maximum of 50 % problems can be found by one evaluator (Nielsen, 1992). Another limitation whit having just one analyst is related to the severity assessment. Typically, evaluators discuss the severity of the detected problems and the rating is decided together. When the severity is assessed by just one analyst, the rating is inevitably subjective. If possible, it is always recommendable to have several evaluators preferably with different backgrounds and variable sets of skills to provide more universalized results.

As discussed earlier in this thesis, in medical field usability and user experience are still often overlooked while clinical effectiveness is prioritized. User errors in medical devices are common and they can have severe consequences. Heuristic evaluation can be a practical tool to indirectly improve usability and safety in medical devices as long as its limitations are recognized.

7 Discussion and Conclusions

Impaired or lacking eye blink, often as a result of facial paralysis, is a risk of severe ocular complications. In this study, a prototype of an electrical eye blink stimulation device called MobiStim1 was tested and evaluated through heuristical evaluation. The aim of the device is to provide a noninvasive alternative for surgical methods to fix the lack of blinking. Methods to detect the blink from the healthy side of face to pace the stimulation have been studied before (Frigerio et al., 2015; McDonnall et al., 2009). The pre-programmed stimulation used in this prototype may provide a more simple and cost-effective method to produce the blink. The main target user group is patients with acute unilateral facial paralysis with the potential for recovery.

Medical field is a highly regulated domain but despite the regulation, errors while using medical devices are a common cause of patient injury (Zhang et al., 2003). In general, the valuation of usability in the medical field is insufficient but the comprehension of its significance is improving. Investing in usability and user experience may advance safety, productivity and user acceptance in the field. (Jaspers, 2009.) The development of medical devices is regulated by international standards. The new regulation for medical devices in the European Union may improve also usability and user safety by guiding the design of medical devices.

In this study, the usability of the prototype was evaluated against 16 heuristics based on former studies. Heuristics violated most often concerned user's physical effort and error situations. Most of the usability problems were minor which is a typical result of the heuristic evaluation (Graham et al., 2004). Three of the heuristics were not relevant for this study. Currently, a standard set of heuristics for evaluating medical devices does not yet exist. In this study, heuristics based on Gardner-Bonneau's design principles prove to be a valuable addition to most commonly used Nielsen's heuristics. The usability in the medical field could benefit from a specific set of heuristics aimed at medical and health care devices. More systematic studies of contextual heuristics and heuristic evaluation in the medical field are needed.

The most problematic parts of the prototype's usability were related to the safety of the stimulation connectors. Several problems related to the user's feeling of control and flexibility were found. A significant number of minor problems concerned the user's physical effort. The problems concerning safety should be taken into account before user testing. The less severe problems don't call for immediate action but the descriptions of the minor problems can help to design user tests. Despite the problems detected, the device is capable of producing a blink with no notable irritation or displeasure. The results encourage further development of the prototype. Based on the evaluation, the suggested user experience goals for further evaluation are feeling of control, feeling of (physical) effortlessness and feeling of safety.

Heuristic evaluation in this thesis was conducted by one novice-level analyst. Repeating the evaluation with a group of analysts could provide interesting results to compare. Medical devices are typically used by different kinds of people from experts to patients (Martin et al., 2008). Having an evaluator with a medical background in the group could further improve the results. However, the device is aimed at users with a specific condition and thus the general overview of the usability of the device can only be provided by user tests with patients.

In conclusion, the mobile blink stimulator is a promising alternative treatment for patients recovering from acute facial palsy. Facial paralysis affects the patient's life beyond the basic function of the facial muscles. In a longer-term perspective, the mobile blink stimulator could enhance the quality of patients' life by preventing ocular complications and giving patients more freedom in their everyday life.

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