Use of an Electrical Stimulation Device in a Home-Therapy Setting

Are stroke survivors able to handle it?

Master Thesis

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by
Lisa Müllauer, BSc
1610756812

First advisor: FH-Prof. Romana Bichler, MAS

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Declaration

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Place, Date Signature

Preface

...

Thankyou

to

all my family,

friends,

workmates,

and FH staff

who have always supported me

...

Abstract

Subject	Purpose of this thesis is the evaluation of usability of an electrical stimulation device for stroke survivors at age of 65 or older in a home therapy setting.
Problem	Because electrical stimulation is recommended for stroke rehabilitation, it is important to evaluate if an electrical stimulation device is usable for stroke patients who are 65 or older. Especially if this rehabilitation approach is desired in a home-therapy setting, the ability to autonomously use of the device needs to be evaluated.
Research questions (**Q**)	**Q1:** Are stroke patients, at the age of 65 or older, able to use an electrical stimulation device correctly by themselves when they were instructed by a therapist? **Q2:** Is there a correlation between the ability to use and cognition?
Method	Usability testings with electrical stimulation device Stiwell med4 were performed with ten stroke survivors (N=10). Additionally, all subjects had to pass a cognitive examination called MOCA. The usability test results were interrelated with the results of MOCA. Furthermore, all failures as well as feedback of subjects have been documented and evaluated.
Results	No subject was able to use Stiwell med4 correctly after onetime instruction by a therapist and there was no correlation found between cognitive skills and the ability to use the device. Most subjects struggled with terminology and structure of the user interface of the device.
Discussion	As results show, visual abilities and technological terminology have a huge impact to usability performance. Therefore, further research should focus on these factors to gain more information about ability to use of elderly. A bigger sample size would also cause more detailed information.
Conclusion	To sum up, it can be said, that onetime instruction of Stiwell med4 is not sufficient to make sure that stroke survivors at age of 65 (or older) are able to use this device autonomously in a home-therapy setting. This result shows no correlation with

cognitive impairments which were collected by MOCA. Especially visual abilities and technical terminology still seem to be important factors for the ability to use the device.

Keywords Usability testing, electrical stimulation device, Stiwell med4, stroke survivors, home-therapy setting

Kurzfassung

Zielsetzung — Thema dieser Masterarbeit ist die Evaluation der Benutzerfreundlichkeit eines Elektrostimulationsgerätes, wenn dieses von SchlaganfallpatientInnen (65 Jahre oder älter) selbstständig, als Heimübungsprogramm, angewendet werden soll.

Problem — Da Elektrostimulation ein gängiger und empfohlener Therapieansatz in der Schlaganfallrehabilitation ist, ist es notwendig, die Benutzerfreundlichkeit dieser Geräte speziell für SchlaganfallpatientInnen zu evaluieren. Soll diese Therapiemethode als Heimübungsprogramm genutzt werden, ist die selbstständige Bedienung der Geräte essentiell. SchlaganfallpatientInnen sind oftmals höheren Alters, weshalb die Testgruppe mit dem Kriterium 65 Jahre oder älter gewählt wurde.

Forschungsfragen (**Q**) — **Q1:** Sind SchlaganfallpatientInnen, welche mindestens 65 Jahre alt sind, in der Lage ein Elektrostimulationsgerät selbstständig und richtig zu bedienen, wenn sie vorher ausführlich von einem/einer Therapeuten/Therapeutin eingeschult wurden? **Q2:** Besteht ein Zusammenhang zwischen den individuellen kognitiven Fähigkeiten und der Bedienung des Gerätes?

Methode — Benutzerfreundlichkeitstests wurden mit zehn ProbandInnen (N=10) anhand des Gerätes Stiwell med4 durchgeführt. Zusätzlich wurden die kognitiven Fähigkeiten mit dem kognitiven Test MOCA erhoben. Die Ergebnisse der Benutzerfreundlichkeitstests wurden mit den Ergebnissen der kognitiven Testungen auf Zusammenhänge (Korrelationen) überprüft. Außerdem wurden alle Probleme mit der Bedienung des Gerätes sowie das Feedback der ProbandInnen dokumentiert und ausgewertet.

Ergebnisse — Kein/e Proband/in konnte Stiwell med4 nach einer einmaligen, ausführlichen Einschulung richtig bedienen. Außerdem konnten keine Zusammenhänge zwischen den kognitiven Fähigkeiten und den Ergebnissen des Benutzerfreundlichkeitstests gefunden werden. Die größten Schwierigkeiten in der

Bedienung des Geräts ergaben sich aus der Fachterminologie und der Benutzeroberfläche von Stiwell med4. Alterentsprechende Sehverminderungen stellten eine große Hürde für die eigenständige Bedienung des Elektrostimulationsgerätes dar.

Diskussion Wie in den Ergebnissen erwähnt, scheinen visuelle Fähigkeiten und Fachterminologie einen großen Einfluss auf die Bedienung des Gerätes zu haben. Hierfür wären weitere Studien, welche sich auf diese Bereiche fokussieren, interessant. Zudem würde eine größere Stichprobenzahl genauere Ergebnisse liefern können.

Conclusio Zusammenfassend kann gesagt werden, dass eine einmalige, ausführliche Einschulung auf das Elektrostimulationsgerät Stiwell med4 nicht ausreicht, um eine selbstständige Nutzung im Heimtraining zu ermöglichen. Dieses Ergebnis kann nicht in Zusammenhang mit kognitiven Fähigkeiten, welche durch den MOCA überprüfbar sind, gesetzt werden. Vor allem die visuellen Fähigkeiten und die Fachterminologie scheinen jedoch einen großen Einfluss auf die Benutzerfreundlicheit zu haben.

Schlüssel-wörter Benutzerfreundlichkeit, Elektrostimulationsgerät, Stiwell med4, stroke survivors, Heimübungsprogramm, Heimtraining

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1 Introduction

Nobody can foresee a stroke. The human brain works silent and without any consciuos effort. People normally do not think about all their abilities and skills until something does not work anymore. After a stroke some survivors have to learn how to walk, to grasp, to read or to speak again. Things we all have learned when we were young.

1.1 Problem

In 2013 there were 25.7 million strokes worldwide, with 10.3 million people having their first stroke [1]. Strokes are worldwide a common cause for disabilities and thus often need to be treated by physiotherapy, occupational therapy and speech therapy. Lately more and more therapy devices have been developed for stroke survivors and especially electrical stimulation is recommended for extremities' rehabilitation after a stroke [2].

Furthermore, the amount of elderly people (over 65 years old) is predicted to increase by an amount of 9.9% until 2050 [3]. So, it is important to evaluate the usability of electrical stimulation devices especially for the use for elderly people.

Inglis et al. [4] pointed out that even healthy elderly (without cognitive impairments) are not familiar with the technological terminology and often struggle with interfaces or handbooks. They often need more time and more detailed explanations to understand medical devices or training programmes [5]. It is not only the age which can provoke cognitive impairements, but also strokes. Stroke survivors often suffer from cognitive impairments in memory, orientation, language and attention [6]. Due to these impairments a very simple user interface and a simple, adapted language are required to allow elderly people to participate in computerised rehabilitation [6]. Therefore, it is important to find out if electrical stimulation devices, which are recommended for stroke rehabilitation, are usable for stroke patients who are 65 or older.

1.2 Pivotal Question

The following two main questions of research (Q1 and Q2) have been created:

Q1: Are stroke patients, at the age of 65 or older, able to use an electrical stimulation device correctly by themselves when they were instructed by a therapist? **Q2:** Is there a correlation between the ability to use and cognition?

1.3 Goals

The aim of this thesis is to find out more about the usability of electrical stimulation devices in elderly stroke patients. Therefore, the electrical stimulation device Stiwell med4[1] is used exemplarily. Critical tasks just as improvement suggestions are described and discussed in this thesis.

1.4 Method

To ascertain individual problems and resources in use of electrical stimulation devices, usability tests were performed. Additionally, all subjects had to pass a cognitive examination called Montreal Cognitive Assessment (MOCA)[2]. The usability test results were interrelated with the results of MOCA with the aid of Pearson's correlation. Furthermore, reasons for failure in operating Stiwell med4 as well as subjects' improvement suggestions are described.

1.5 Structure

This thesis is structured in seven main chapters. Chapter one presents the problem, the pivotal question, the used method and the goals of this thesis. Chapter two is about theoretical background and the state of the art. The used method of investigation is described in chapter three.

[1] Stiwell med4 is an electrical stimulation device from MEDEL: https://stiwell.medel.com/de-at/

[2] MOCA is a short cognitive test. It gives an overview about visuospatial/executive functions, naming, memory, attention, language, abstraction, delayed recall and orientation.

Chapter four contains information about the implemented usability tests and the following chapter five is about the very results. The last two chapters (six and seven) present the discussion of results and the conclusion of the thesis.

2 Theoretical background

The following chapter deals with fundamental theoretical background like definitions of stroke and electrical stimulation devices. Moreover, it gives an overview of the usage of electrical stimulation in therapy after stroke.

2.1 Stroke

2.1.1 Definition

Strokes are worldwide the most common cause for disabilities. Strokes are brain injuries caused by cerebral infarction, intracerebral haemorrhage or subarachnoid haemorrhage [7].

Cerebral infarction is a neurological dysfunction caused by focal cell death in brain, spinal cord or retina conditioned by ischaemia, also referred to as ischaemic stroke [7].

Intracerebral haemorrhage is a neurological dysfunction caused by a focal collection of blood. It is located within the ventricular system or brain parenchyma and is developing rapidly [7].

Subarachnoid haemorrhage is a neurological dysfunction caused by bleeding in the subarachnoid space. It often involves headache and is developing rapidly [7].

Furthermore, it is important to distinguish strokes from transient ischemic attacks. The world health organisation introduced a definition of stroke in 1970 which is still used and describes stroke as

"…rapidly developed clinical signs of focal (or global) disturbance of cerebral function, lasting more than 24 hours or leading to death, with no apparent cause other than of vascular origin [7]."

As opposed to this, a transient ischemic attack is a local dysfunction which is temporary and variable in duration. It often lasts from two to fifteen minutes, but different from a stroke it does not last longer than twenty-four hours [7].

2.1.2 Diagnosis of Stroke

There are two common methods to diagnose a stroke: the clinical diagnosis and the radiographic diagnosis. Normally both methods are combined to find out where the brain injury is located and to identify the involved vessels.

Clinical diagnosis

For clinical diagnosis of a stroke and transient ischemic attacks knowledge of vascular anatomy and neuroanatomy is indispensable. Physicians use symptoms to find out if there is a vascular process, where it is located and if it is a haemorrhage or ischemia. Furthermore, it is important to exclude other causes like demyelination, infection, brain tumor, traumatic injury or metabolic disorder that simulates stroke [7].

More important information should be collected by an anamnesis. The patient, relatives or records can add information about past strokes, onset of the current stroke, current symptoms, progression of symptoms and concomitant features like vomiting, headache or confused or decreased consciousness. Additional to the anamnesis the physical examination provides further information about blood pressure, cardiac murmurs or enlargement [7].

State of the art is to merge the clinical diagnosis including the anamnesis and the physical examination with the radiographic diagnosis [7].

Radiographic diagnosis

The two important tools for brain imaging are the computed tomography (CT) and the magnetic resonance imaging (MRI). Ultrasound, computed-tomography-angiography, magnetic-resonance-angiography or catheter-angiography can be used for vascular imaging. Brain imaging with CT or MRI is able to differentiate between hemorrhage and ischaemia and to exclude causes that simulate a stroke [7].

2.1.3 Stroke prevalence

Results of Austrian Health Survey (ATHIS) 2006/2007 show a stroke prevalence of approximately 150,000 strokes in Austria which is two percent of the Austrian population. This data includes only people older than 15 years and does not distinguish between ischemic and hemorrhagic strokes. There is no difference in stroke rate between males and female but a difference in elder and younger people, in particular that elderly suffer from a stroke more often. Furthermore, they found a higher stroke prevalence in population with low level of education [8].

2.1.4 Stroke consequences

Depending on the part of the brain where the stroke is located, patients suffer from different symptoms like hemianopia, neglect, attentiveness disorder, memory disorder, aphasia, dysarthria, apraxia, sensory deficits, hemiparesis or hemiplegia [9]. This chapter does not describe all consequences of stroke, but it gives an overview about the common ones, people have to deal with in their daily lives.

Hemianopia: A visual field loss on one half of the visual field [10]. Patients are able to compensate the visual field loss by eye or head movements towards the impaired direction [11]. Rathore et al. found out that hemianopia is a common stroke sign on presentation [12].

Neglect: The patient is not able to pay attention to the contralateral side of the brain injury. Patients with severe neglect act like the whole contralateral side does not exist. Neglect can affect a single modality (vision, acoustic or sensorimotor function) or more than one [15]. Neglect phenomenons affect one half of the body or space, and do not result from sensory or motor impairments [10].

Attention disorder: A disability in paying attention. Patients often feel fatigued, stray thoughts, are distractible or are not able to concentrate on a given task [14].

Memory disorder: The memory is responsible for information storage, consolidation and retrieval. Brain injuries can cause massive impairments in any part of information processing [15].

Aphasia: Communication disorder caused by an injury of the speech center in the brain without injury of an organ of speech or mental retardation [10]. It often concerns to speech, comprehension, reading and writing [16].

Dysarthria: Speech disorder without disabilities in comprehension, reading and writing. Speech can be slurred, voice can be low or monotonous and speaking rate can be to fast or to slow. The cause for these disabilities are difficulties in breathing, voice and articulation due to brain injuries [17].

Apraxia: A group of disorders concerning the performance of single or complex movements and/or the correct use of objects due to a cerebral injury [18]. Patients struggle in planning and performing movements or activities [19].

Sensory deficits: Hypoesthesia means a decreased touch sensation. Paraesthesia is the abnormal sensation like tingling or numbness [10]. In the study of Rathore et al. 44.5% of people who had a stroke suffered from sensory deficits of one arm, leg or the face, most commonly on the left side of the body [12].

Hemiparesis: Incomplete or partial paralysis of one half of the body (arm, leg, face) due to a cerebral injury of the contralateral hemisphere of the brain [10].

Hemiplegia: Complete paralysis of one half of the body (arm, leg, face) due to a cerebral injury of the contralateral hemisphere of the brain [10]. More than 80% of stroke patients suffer from hemiparesis or hemiplegia. 75.5% present paresis of their arm, 68.6% of their leg and 54.6% of their face [12].

2.1.5 Stroke rehabilitation

The professional rehabilitation team for stroke patients should consist of physicians, occupational therapists, physical therapists, speech therapists, nurses and dieticians [2]. In Austria the rehabilitation phase starts at an early/acute state at the hospital. For optimum outcome stroke survivors are normally sent to a rehabilitation center after the acute phase. There, they continue with physiotherapy, occupational therapy, speech therapy and the neuropsychology training to get as independent as possible before they will be send back home again. Because this thesis addresses mainly physical rehabilitation of extremities, there are examples for typical rehabilitation approaches listed below.

Upper limb rehabilitation after stroke

Paresis or plegia of one arm is a huge limitation for performing daily living activities [2]. As it is mentioned in chapter 2.1.4, 75.5% of stroke survivors present paresis of their arm. Thus, there are recommendations for an optimum rehabilitation outcome in upper limb training after a stroke [2]. General principles are the improvement of motor control and sensorimotor function and the use of the affected limb during activities of daily living. The Stroke Rehabilitation Practice Guidelines [2] recommend a few therapeutic approaches (inter alia functional electrical stimulation), which are listed below.

- Range of movement exercises
- Mental imagery
- Functional electrical stimulation
- Constraint induced movement therapy
- Mirror therapy
- Virtual reality
- Strength training
- Bilateral arm training

This list shows the state of the art in stroke rehabilitation but not all approaches are suitable for all stroke patients. So, it is important to create an individualised rehabilitation plan based on patients' abilities and impairments.

Lower limb rehabilitation after stroke

The main goal for patients is to improve their mobility and transfer skills. Therefore, the Stroke Rehabilitation Practice Guidelines [2] recommend the following therapeutic approaches:

- Strength training
- Threadmill-based training
- Electromechanical assisted gait training
- Rhythmic auditory stimulation
- Mental practice
- Biofeedback balance training
- Aerobic training
- Gait aids
- Rhythmic auditory stimulation

This list is also only a recital of state-of-the-art approaches. An individual rehabilitation plan is necessary for every single stroke survivor.

2.2 Electrical stimulation devices

As shown in 2.1.5, electrical stimulation is a common approach in rehabilitation of extremities after stroke. This section describes definition, functional principle and field of use of electrical stimulation.

2.2.1 Definition

Electrical stimulation is a therapeutic intervention for improvement of voluntary motor function and thus an improvement of activities in daily living of patients. It is also known as functional electrostimulation (FES), functional neurostimulation (FNS), neuromuscular stimulation (NMS) or neuromuscular electrostimulation (NMES) [20].

2.2.2 Functional principle

Low frequent stimulation triggers an action potential in a peripheral nerve which leads to muscle contraction of the stimulated muscle. Therefore, surface electrodes can be used. The aim of this intervention is salvage or improvement of muscle function and movement [20].

Depending on the number of muscles or muscle groups either single-channel or multichannel stimulation is used. Single-channel electrostimulation is for improving a selective movement, for example a contraction of a single muscle like the musculus flexor pollicis longus which is responsible for bending the thumb. To perform complex movements, a few muscles need to be contracted and thus be

stimulated. Therefore, a multichannel-stimulation is necessary [20]. An example for a complex movement would be to grab and release something with one hand. For this activity three muscle groups (wrist extensors, finger flexors and thumb flexors) have to interoperate which requires at least three channels [21]. So, depending on the aim of the therapy as well as on the impairments of the stroke survivor, either single-channel or multichannel stimulation is required.

2.2.3 Functional electrical stimulation devices at a glance

Tevnan [22] found out that the most known and most used electrical stimulation device in Austria is Stiwell med4 from MedEL. For this reason, Stiwell med4 is the means of choice for this investigation. Other electrical stimulation devices which are available in Austria are listed below alphabetically:

- Automove/Neuromove – Zynex
- ®bentrofit – bentronik
- Fußheber Stimulator MyGait® - Ottobock
- Fußheber-Stimulator NESS L300 – Bioness
- Hand-Rehabilitationssystem NESS H200 – Bioness
- MOTOmed mit FES – Reck
- Stimulette – Schuhfried
- Stiwell med4 – MedEL

2.2.4 Electrical stimulation in stroke rehabilitation

Electrical stimulation for upper extremity is not only recommended in Stroke Rehabilitation Practice Guidelines [2] but also in AHA/ASA Guideline 2016 from American Heart Association/American Stroke Association [23]. Tevnan [22] evaluated the use of functional electrical stimulation in Austria and described an augmented implementation of functional electrical stimulation devices in rehabilitation of neurological patients, especially stroke survivors. Most interviewed therapists use electrical stimulation for movement imagination and target-oriented functional hand training. But they pointed out that there are some important conditions for use:

- a good general state of health of the patient
- individual therapy and a calm environment
- at least 30 minutes therapy time
- availability of functional electrical stimulation devices

The common fields of application are freelance therapeutic office, hospitals and outpatient and inpatient rehabilitation centers. Furthermore, some therapists recommend functional electrical stimulation as a training, which stroke survivors can do at home by themselves [22]. Especially the use of electrical stimulation devices in a home-therapy setting is the object of interest of this thesis.

3 Investigation

This chapter is about the implementation of the usability tests with Stiwell med4. The aim of this investigation, the research questions, the study set up, the usability testing, the MOCA, the data handling and the test group are described in detail.

3.1 Aim of investigation

The aim of this investigation is to ascertain critical tasks in operation just as improvement suggestions of Stiwell med4 in a home-therapy setting in stroke survivors. Furthermore, this examination works out if there is a correlation between the ability to use and individual cognitive abilities.

3.2 Research questions

Q1: Are stroke patients, at the age of 65 or older, able to use an electrical stimulation device correctly by themselves when they were instructed by a therapist? **Q2:** Is there a correlation between the ability to use and cognition?

3.3 Usability testing

"User testing with real users is the most fundamental usability method and is in some sense irreplaceable, since it provides direct information about how people use computers and what their exact problems are with the concrete interface being tested [24]*."*

Usability testing is one of the most known methods for evaluation of suitability for use. Usability experts observe users applying a system. They gain information by observation, user comments, measurements (for example duration of a task) or following interviews or questionnaires. This information can show problems and suggested improvement of the system. Thus, usability testing is an empirical method [25]. In this case the usability test consists of observation and a cognitive assessment. Following questionnaires were taken into account but due to stroke survivors cognitive and physical abilities it was determined that three parts of the testing could be too difficult and last too long.

3.4 Study setup

Stroke survivors have been tested between 5th and 25th of March 2018. To recruit subjects who are already in rehabilitation phase C (see definition of rehabilitation phase C in 3.9), stroke support groups were approached. All testings took place at patients' homes (in Lower Austria, Upper Austria and Vienna) to reconstruct a real user scenario for best possible validity. Furthermore, all testings took place in a separated room to prevent disturbance by other house residents. Care was taken that these separated rooms were calm and well-lighted and that they were equipped with a table and a chair. Single trails lasted 60-90 minutes because stroke survivors were allowed to have a break if required. All testings were implemented by the author to decrease bias due to different examiners. First, subjects had to do the usability testing with Stiwell med4, then they had to complete the MOCA. This chronology was chosen to make sure that subjects are rested and vigilant enough to follow the explanation of the electrical stimulation device. During usability testing the examiner used an observation protocol for documentation which is attached in the appendix (see appendix: A). The observation protocol contains all tasks subjects had to absolve and also allows the examiner to tick off if the subject did a task autonomous or by using the instruction manual (see instruction manual from MedEL in Appendix: D).

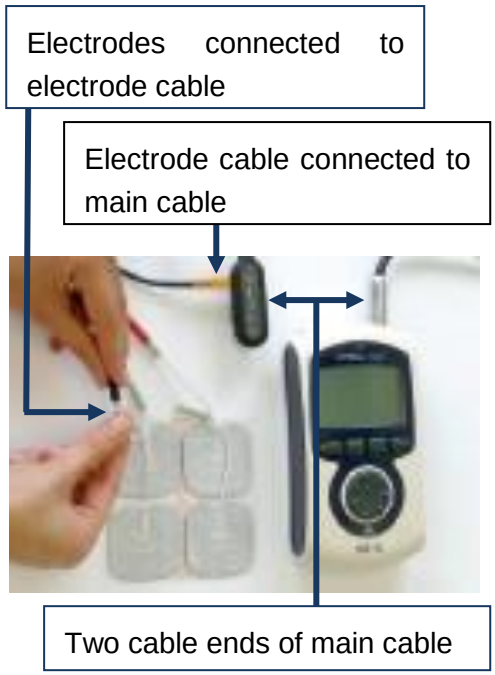
3.5 Hardware setup

Due to findings of Tevnan [22] Stiwell med4 was the means of choice for this investigation because of its mainstream fame in Austria at present. As shown in pictures below, the electrical stimulation decive Stiwell med4 consists of a console (picture 1), a main cable, electrode cables, a reference cable and electrodes. All components are packed in a portable plastic box.

Height: 175 mm
Width: 95 mm
Depth: 30 mm
Weight: 44g

Picture 1 - Stimulation device console

Picture 2 - Bottom view of console



Picture 3 - Console, main cable, electrode cable and electrodes

Picture 2 shows the bottom view of the device with the main cable and connection jack A. Picture 3 illustrates the connection of electrodes to one electrode cable (yellow), which is already connected to the main cable.

3.6 Usability test scenario

Stiwell med4 provides different training programs with different severity. For this usability testing the program “Greifen/Loslassen” was chosen. This program is one of the easier ones and is normally used for hand rehabilitation. Due to a high probability of hemiparesis or hemiplegia of one arm as a stroke consequence, it was obvious to choose an arm-rehabilitation-program for this examination. To create a real end user scenario, the program “Greifen/Loslassen” was defaulted. That means that subjects did not have the possibility to choose this program out of a list. When the device is plugged, only “Greifen/Loslassen” pops up. Therapists can do this simplification for an easier use of Stiwell med4. Another simplification was to only provide the three wire subjects needed for their training program and not all of them. This means that subjects only got the yellow, orange and green wire instead of getting these three plus the purple one. Furthermore, subjects got an original illustrated instruction manual from Stiwell

med4. In consequence of ethical principles subjects were not allowed to get electrical stimulation during the examination. Therefore, it was not possible to let subjects affix electrodes on the paretic or hemiplegic arm. In order to still verify if subjects can position the electrodes correctly on their arm, paper-stickers (equally big as electrodes) were used. Stickers had the same color like the electrode cables to simplify this task.

3.6.1 Introduction to subjects

Observed usability testings can cause stress, strain or anxiety in subjects. To decrease these feelings, subjects were undeceived about the aim of the testing and the execution. Furthermore, they were informed about the collected data, the use of data and that data is anonymized. It was emphasized that not the subject will be tested but the device and that their difficulties in usability are not their own failings but important information for the optimization of device.
All subjects were advised that they can abort the testing any time without giving a reason. Then they were asked if they want to start the usability testing and if so, they were asked to sign the declaration of consent which is attached in appendix (see appendix: C). Finally, subjects were questioned if there are any obscurities.

3.6.2 Instruction Stiwell med4

First, the illustrated instruction manual was handed over. Then subjects were instructed on the basis of this manual by the therapist. Therefore, the therapist used exactly the wording of the manual to make sure that all subjects get similar instructions. Each task was demonstrated by the therapist. To reduce varieties, it was considered to use a video-instruction. This possibility was scrapped due to a real end user scenario, though. A video-instruction would not be the means of choice when therapists explain a therapy device. Subjects were able to question at any time of instruction. One task which was not described in the manual was added to the examination. It was the possibility to pause and restart the training program. This task was added due to therapeutic experience. Sometimes patients have to pause an ongoing intervention for example because of uncomfortable sitting position. After general instruction, subjects were asked if they still have any questions. If not, the testing continued with autonomous use of the device.

3.6.3 Autonomous use of Stiwell med4

Subjects did not have to remember the chronology of single tasks. They were told which task they have to perform next. These directives were given via tape-recording-instruction to ensure that all subjects get exactly the same directives. Subjects were asked to have a try without the instruction manual first. If it was not possible to absolve a task without the manual, they were allowed to use it. Subjects did not get any help until they tried to complete a task without and with instruction manual. If both ways did not work, they got help from the examiner but therefore the task was reported as not performed autonomously. Reasons for failure and potential questions were documented on the observation protocol. An outline of tasks subjects had to perform is listed below:

Task 1	Unpack device, cables and electrodes
Task 2	Connect main cable to jack A
Task 3	Connect all electrode cables to main cable
Task 4	Connect white reference cable to main cable
Task 5	Plug in all electrodes
Task 6	Show positioning of electrodes on own arm with colored stickers
Task 7	Power up device
Task 8	Select program “Greifen/Loslassen”
Task 9	Start program “Greifen/Loslassen“
Task 10	Press control key I
Task 11	Select 5 mA as intensity
Task 12	Press control key II
Task 13	Select 3 mA as intensity
Task 14	Press control key III
Task 15	Select 2 mA as intensity
Task 16	Continue program
Task 17	Pause program
Task 18	Start program again

Task 19	Power off device
Task 20	Unplug all cables and electrodes
Task 21	Store device, cables and electrodes

3.6.4 Feedback

After examination, subjects were asked if they want to give feedback to the usability of the device and if they have any improvement suggestions. Feedback and suggestions were documented on the observation protocol.

3.7 MOCA

Second part of the examination was to pass the cognitive assessment MOCA. 1996 MOCA was developed by Dr. Ziad Nasreddine in Montreal/Quebec as a screening instrument for cognitive impairments. MOCA is not as detailed as other cognitive assessments like the MMSE[3], but it gives an overview about some important cognitive abilities. MOCA is structured in seven fields of cognition which are described in detail below.

1. Visuospatial and executive abilities

Visouspatial abilities include the correct perception of the main spatial axes – the visual vertical and horizontal, the correct bringing into line, the correct estimate of length, distance and shape and the correct perception of position. Executive abilities are structured in basic action control, urge and basic social behavior. Basic action control means abilities like: adaption capability, action planning, anticipation, control of action and in case of need adaption of action, solve a problem, distinguish between important and significant and unsignificant, inhibition as well as making decisions. The ability of urge includes start and maintain of action or behavior, initiative in social relationships and development of ideas. The third section of executive abilities consists of knowing and following rules of etiquette, self-awareness of own abilities and deficits, empathy, ability to take criticism and adaption of communication behavior depending on different situations and the collocutor [19].

[3] MMSE: Mini-Mental State Examination: is a common instrument to assess cognitive abilities or impaiments. http://www.gesundheitundalter.ch/Portals/3/media/geriatrische/PDF/MMT.pdf

2. Naming:

Naming is the ability to find the correct word for things humans can see. It is not an act of communication, it is about vision, recognition and knowledge of the correct word [19].

3. Attention:

Attention is the ability to focus upon something without feeling fatigued, stray thoughts or being distractible or not able to concentrate on something [14].

4. Language:

Important language skills are speech production and speech comprehension. For expression it is necessary to have knowledge about grammar and vocabulary. A sentence has to be planned before the motor system (lips, tongue, velum, larynx) is able to create the sentence. For speech comprehension it is important to be able to hear, to process words with the help of the auditory word pool and to know the word meaning [19].

5. Abstraction:

Abstraction is the ability to think in a generalizing and non-objective way and to select partial information out of the entirety [26].

6. Delayed recall:

Memory is responsible for information storage, consolidation and retrieval [15]. Delayed recall is therefore the activation of information which has been stored in memory [10].

7. Orientation:

The subarea orientation includes the knowledge of facts about the personal history (for example: name, age, date of birth), timely orientation (for example: date, season), local orientation (for example: actual whereabouts, place of residence, workplace) and situative orientation (for example: reason for hospitalization).

A maximum score of 30 points is possible, where a score of 26 or more points is considered as no appreciable disease. All subjects had to pass this assessment to gain information about their cognitive abilities and to ensure that subjects were able to follow instructions. This examination lasted about 10-15 minutes.

3.8 Data-handling

3.8.1 Collected data

All subjects had to absolve the usability testing as well as the MOCA at the same day. The anonymized collected data of both tests are described below.

The usability test was structured in 21 tasks subjects had to pass (see observation protocol in appendix). Subjects could attain between zero and two points for every task depending on if they did the task independently (two points), if they needed the instruction manual to perform a task (one point) or if they were not able to complete a task (zero points). Altogether a maximum score of 42 points is possible in this examination. For better data handling and analysis, the 21 tasks were devided into in two classes. Group one is called *"setup/disassembly"* and includes tasks 1-6 and tasks 20-21. These tasks contain all work stages concerning preparation of the device, electrode-handling and disassembly of device. Group two is called *"operation"* and includes tasks 7-19. These tasks are all about the handling of the device. Furthermore, the observation protocol made it possible to filter out subjects' most frequently asked questions as well as the commonest correctly and incorrectly completed tasks. Subjects' feedback to usability of device was recorded in writing on the observation protocol as well as the age and sex of subjects. Additionally, all persons were asked about other devices they use in their daily life, like a cellphone, a computer or others.

Data raised by MOCA are the maximum score of MOCA as well as the score of every subarea of the assessment.

3.8.2 Statistical analysis

All data were collected and rehashed in Excel before calculating with PSPP[4]. For calculating correlations, data were checked into normal distribution. All data was normally distributed and therefore the Pearson correlation was chosen for this study. Furthermore, the effect size was predefined based on Cohen's effect size [27] which is defined as follows in table 1:

[4] GNU PSPP is a free alternative for the statistical program SPSS. https://www.gnu.org/software/pspp/

Table 1 - Cohen's effect size

r=0.20	vague effect
r=0.50	medium effect
r=0.80	strong effect

3.9 Subjects

For the validity of usability testing it is essential to select subjects who represent the end users. Selection criteria are for example age, sex or in case of this investigation health condition. For usability testing it is also important that subjects do not have prior knowledge of the tested system [28]. To recruit subjects for this examination inclusion and exclusion criteria were prescribed and listed in table 2. It was necessary to include subjects who had a stroke and are within rehabilitation phase C. Phase C means that stroke survivors are conscious, at least partial oriented and able to participate in altogether three hours of therapy per day. Patients within phase C are able to perform some activities of daily living[5] autonomously, but still need lots of nursing help in their daily routine. Comorbidities do not impair or prohibit their therapy [29]. The precondition of unilateral hemiparesis is important since this is the field of application for electrical stimulation devices. Another important inclusion criterion is participants' age, subjects had to be 65 years or older to examine the ability to use for eldery stroke survivors. Furthermore, it was necessary to ensure that subjects are allowed and able to sign. This means that they are able to decide autonomously if they want to participate in this testing and that they are able to abandon the testing anytime without any reason. Subjects were not allowed to participate in testings if they still suffer from distinctive neglect for the simple reason that testings are not fitted to stroke survivors who act like one half of their body or space does not exist. Because speech comprehension is essential for the explanation and a safe use of the electrical stimulation device, stroke survivors with impaired speech comprehension or aphasia were not allowed to participate in this investigation. The last exclusion criterion was an acute injury or illness of potential subjects.

[5] Activities of daily living are for example: to brush one's teeth, to have a shower or to have a meal.

Table 2 - Inclusion and exclusion criteria

Inclusion criteria	*Exclusion criteria*
+ *Diagnosis of stroke*	– *Distinctive neglect*
+ *Rehabilitation phase C*	– *Acute injury or illness*
+ *Unilateral Hemiparesis of at least one extremity*	– *Impaired speech comprehension or aphasia*
+ *65 years or older*	
+ *Authority to sign*	
+ *No experience with electrical stimulation devices*	

Actual subjects

Actual subjects are shown in table 3. Ten subjects (N=10) who met inclusion and exclusion criteria were chosen to take part in this investigation. Four were female (f) and six were male (m). At the time of testing subjects were between 65 and 83 years old. The mean age of all participants was 73.7 years with a standard deviation (SD) of σ=7.2. The mean age of females was 72.3 years with SD of σ=5.1 and the mean age of males was 74.7 years with SD of σ=8.7. All subjects took part by choice.

Table 3 – Actual subjects

Subject	Age	Sex
1	78	f
2	82	m
3	83	m
4	75	f
5	65	m
6	71	m
7	65	m
8	67	f
9	69	f
10	82	m

4 Results

This chapter is about the findings of the investigation. Collected data is shown in section 4.1. Second section 4.2 describes results of autonomous use of the electrical stimulation device in detail. In 4.3 the calculation of correlation is shown and the following section 4.4 is about subjects' failures and questions subjects asked during the usability testing. In a final step (section 4.5) subjects' feedback about usability of the device is detailed.

4.1 Data at a glance

4.1.1 Usability testings

Table 4 shows scores of every subject in usability testing. Tasks 1-6 and 20-21 are colored in green and represent all tasks of group 1 *"setup/disassembly"*. Tasks 7-19 are colored in blue and represent all tasks of group 2 *"operation"*. These two groups are used later on for calculating correlations (see section 4.2).

Table 4 - Total data Usability testings

Subject	Task 1	Task 2	Task 3	Task 4	Task 5	Task 6	Task 7	Task 8	Task 9	Task 10	Task 11	Task 12	Task 13	Task 14	Task 15	Task 16	Task 17	Task 18	Task 19	Task 20	Task 21
1	2	2	0	2	2	0	2	1	1	1	1	2	2	2	2	1	2	2	2	2	2
2	2	0	1	2	0	2	2	2	1	2	0	2	0	2	0	0	2	2	2	2	2
3	0	0	0	0	0	1	2	2	1	2	0	2	0	2	0	2	0	2	2	0	0
4	2	1	2	2	2	2	2	0	2	0	0	2	0	2	0	0	0	0	2	2	2
5	2	0	1	2	2	1	2	2	1	1	1	1	1	1	1	0	2	2	2	2	0
6	2	0	2	0	2	0	2	2	2	1	1	1	1	2	2	0	2	2	0	2	2
7	2	0	1	0	0	0	2	2	2	2	2	2	2	2	2	1	2	2	0	0	2
8	2	2	2	2	2	0	0	2	2	1	1	1	1	1	1	0	2	2	0	0	0
9	2	2	1	2	1	0	2	0	2	1	1	2	2	2	2	0	2	2	0	2	2
10	2	2	0	0	2	2	0	2	2	2	0	2	0	2	0	2	0	2	2	0	2

Both groups, *"setup/disassembly"* and *"operation"* had to be checked into normal distribution to choose the correct method of calculating correlations later on. Therefore, the Kolmogorov Smirnov Test (K-S-Test) was chosen. Normal curves of the two groups showed a normal distribution of both.

Before usability testings have started, all subjects were asked if they use other technical devices regularly in their daily lives. As shown in table 5, 90% of test group claimed to use a cellphone, 50% claimed to use a computer.

Table 5 - Use of technical devices in daily life

Subject	Cellphone	Computer
1	yes	yes
2	yes	yes
3	-	-
4	yes	-
5	yes	-
6	yes	yes
7	yes	yes
8	yes	-
9	yes	yes
10	yes	-

4.1.2 Data MOCA

Table 6 shows total score as well as subscores of every subject in MOCA. A maximum score of 26 points could have been attained. If a subject had 12 years of education or less, he/she got an extra point. Maximum points of every subarea are listed below:

- Executive: 5 points
- Naming: 3 points
- Attention: 6 points
- Speech: 3 points
- Abstraction: 2 points
- Delayed recall: 5 points
- Orientation: 6 points
- Less than 12 years of education: 1 point

Three subjects attained a total score of 26 points or more in MOCA, which is considered as no appreciable disease. All other subjects attained a score of 21-25 points, which stands for a cognitive impairment. The mean total score of all subjects is μ=24.2 points with a SD of σ=2.52. Subjects attained the highest scores in subareas naming, abstraction and orientation (colored in green) and the lowest scores in speech and delayed recall (both colored in red). Two subjects had less than 12 years of education and therefore got an extra point.

Table 6 - Total data MOCA

Subject	Executive	Naming	Attention	Speech	Abstraction	Delayed recall	Orientation	Education	TOTAL
1	4	3	6	2	2	3	6	-	**26**
2	5	3	6	3	2	4	6	-	**29**
3	5	3	5	2	2	0	6	-	**23**
4	5	3	4	0	2	0	6	1	**21**
5	5	3	6	1	2	2	6	-	**25**
6	5	3	5	1	1	0	6	-	**21**
7	5	3	5	0	2	4	6	-	**25**
8	3	3	4	0	2	3	6	-	**21**
9	5	3	6	0	2	2	6	1	**25**
10	3	3	6	3	2	3	6	-	**26**

Check-up into normal distribution of total score of MOCA showed that data is normal distributed.

4.2 Results of autonomous use of device

Figure 1 shows results of every subject in usability testing. The best subject was able to perform 79% of tasks without any help except of using instruction manual, which was allowed. The subject with the lowest score in usability testing was able to perform 43% of tasks without any help. Overall, there was no subject able to do all tasks autonomously. Autonomy in using the electrical stimulation device was μ=64% on average.

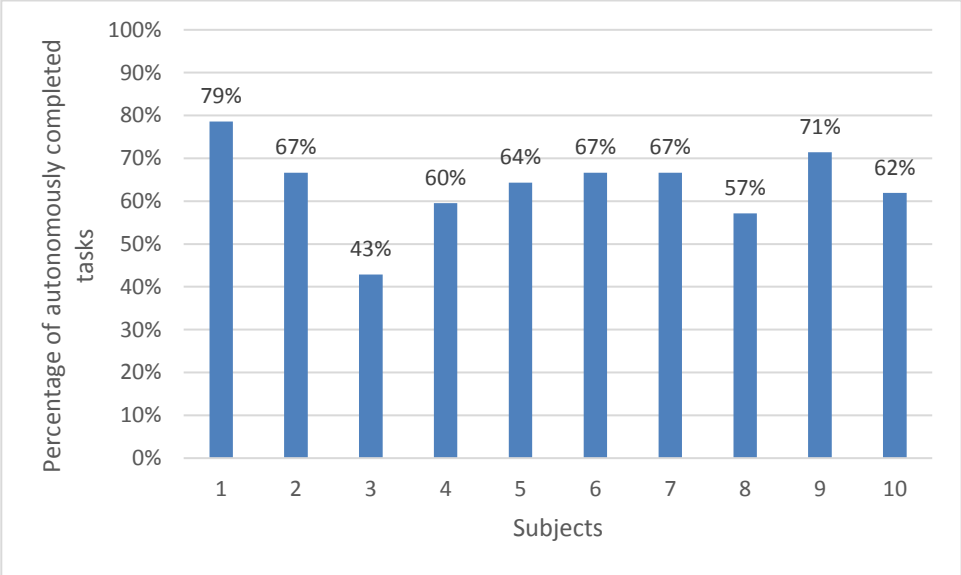


Figure 1 - Percentage of autonomously completed tasks per subject

Below there is a detailed listing of all tasks. It is described if subjects were able to complete a task autonomously (with or without instruction manual) or if subjects were not able to complete a task at all. After this listing, there is figure 2 which visualizes these results.

Task 1: Nine of ten subjects were able to unpack the device, cables and electrodes. One subject was not able to complete this task at all. There is no description of this task in the instruction manual.

Task 2: Four subjects were able to connect the main cable to connection jack A without instruction manual. One subject needed the instruction manual to complete this task and five subjects were not able to connect the main cable at all.

Task 3: Three subjects were able to connect all electrode cables to main cable without instruction manual. Four subjects needed instruction manual to complete this task and three subjects were not able to connect the electrode cables at all.

Task 4: Six subjects were able to connect the white reference cable to the main cable and four subjects were not able to complete this task at all.

Task 5: Six subjects were able to plug in all electrodes without instruction manual. One subject needed the instruction manual to complete this task and three subjects were not able to plug in all electrodes at all.

Task 6: Three subjects were able to show the positioning of electrodes on their own arm with colored stickers without instruction manual. Two subjects needed the instruction manual to complete this task and five subjects were not able to show the positioning of electrodes at all.

Task 7: Eight subjects were able to power up the device without instruction manual and two subjects were not able to complete this task at all.

Task 8: Seven subjects were able to select the program “Greifen/Loslassen” without instruction manual. One subject needed the instruction manual to complete this task and two subjects were not able to select the program at all.

Task 9: All subjects were able to start the program “Greifen/Loslassen“. Six subjects completed this task without instruction manual and four subjects needed the instruction manual to start the program.

Task 10: Four subjects were able to press control key I without instruction manual. Five subjects needed the instruction manual to complete this task and one subject was not able to press the control key I at all.

Task 11: One subject was able to select 5mA as intensity without instruction manual. Five subjects needed the instruction manual to complete this task and four subjects were not able to select 5mA at all.

Task 12: All subjects were able to press control key II. Seven subjects completed this task without instruction manual and three subjects needed the instruction manual to press control key II.

Task 13: Three subjects were able to select 3mA as intensity without instruction manual. Three subjects needed the instruction manual to complete this task and four subjects were not able to select 3mA at all.

Task 14: As in task 12, all subjects were able to press control key III. At this time only two subjects needed the instruction manual, all others were able to press control key III without instruction manual.

Task 15: As in task 13, six subjects were able to select 2mA as intensity. At this time, four of them did not use the instruction manual and two subjects needed the instruction manual. Four subjects were not able to select 2mA at all.

Task 16: Four subjects were able to continue the program “Greifen/Loslassen”. Two did not use instruction manual, two subjects did. Six subjects were not able to start the program at all.

Task 17: Because the task ‘pause program’ was added to the usability testing by the examiner, this task is not described in the instruction manual. Seven subjects were able to pause the program, three subjects were not.

Task 18: Nine subjects were able to start the program again without instruction manual. One subject was not able to complete this task.

Task 19: Six subjects were able to power off the device without instruction manual, four subjects were not able to power off the device at all. There is no description of this task in the instruction manual.

Task 20: Six subjects were able to unplug all cables and electrodes, four were not able to complete this task. There is no description of this task in the instruction manual.

Task 21: Seven subjects were able to store the device, cables and electrodes in the plastic box. Three subjects were not able to complete this task. There is no description of this task in the instruction manual.

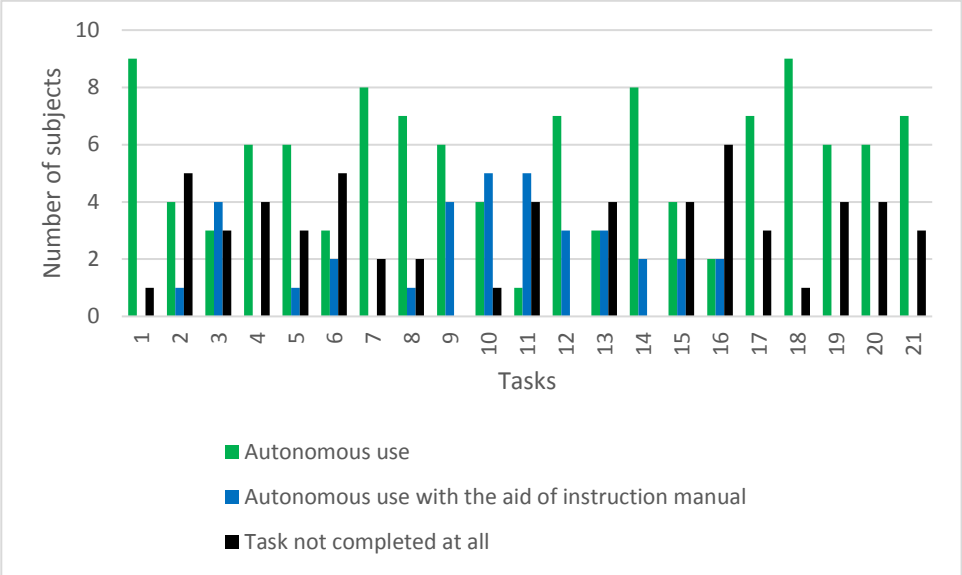


Figure 2 - Autonomy of completed tasks

4.3 Correlations

To make out if there is a connection between cognitive abilities and the ability to use a device, calculating correlations is the means of choice in this investigation. Because collected data is normal distributed, the Pearson's correlation has been chosen. The correlation coefficient (r) is the result of Pearson's computation and indicates the strength of the linear association of the variables. The correlation coefficient can be between -1 and +1. If the correlation coefficient is 0, there is absolutely no connection between the variables. A value close to -1 means that one variable decreases as the other one increases. As opposed to this, a value close to +1 means that one variable increases as the other one increases [30]. Apart from this, the value of correlation coefficient is only relevant if the result is significant.

For calculating correlations three groups of data were prepared. As described in 4.1.1, all data of usability testing was devided into classes *"setup/disassembly"* and *"operation"*. The third group which was necessary for correlations was group *"MOCA"*. This group includes total score of every subject in MOCA. To detect potential outliers, an exploratory data analysis was used. One outlier was found and excluded. That implies an attendance of N=9 for calculating correlations. For better overview, questions about correlations were written up and answered with the aid of visualization:

1. Is there a correlation between abilities in setup/dismounting of device and total score of MOCA?

There is no significant correlation between setup/dismounting of device and total score of MOCA. Correlation coefficient is r=-.115 with p= .769. Figure 3 shows coefficient of determination r^2=0.0132 which is not pertinent because of absent significance.

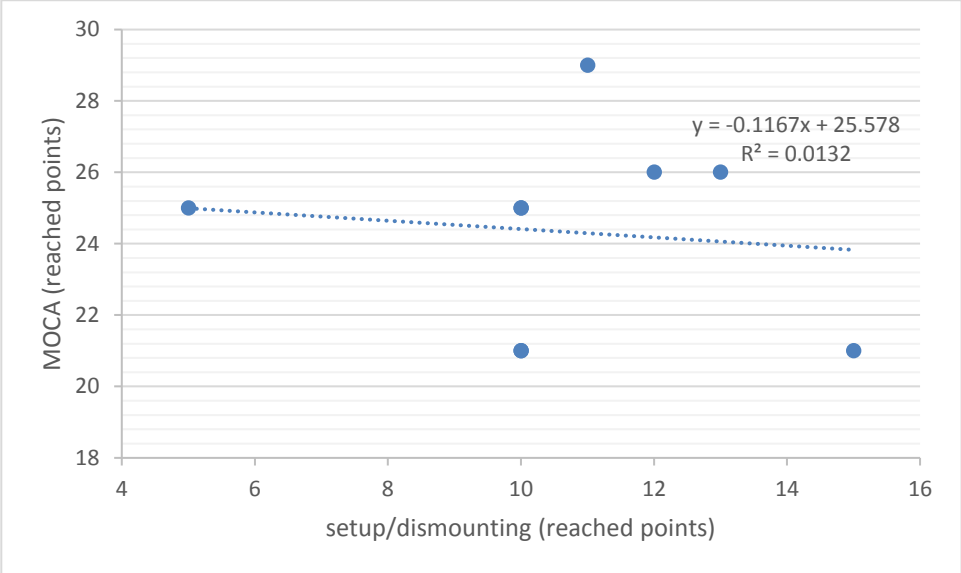


Figure 3 - Scatterplot: MOCA and setup/dismounting

2. Is there a correlation between abilities in operation of device and total score in MOCA?

There is no significant correlation between operation of device and total score of MOCA. Correlation coefficient is r= .498 with p= .172. Figure 4 shows coefficient of determination r^2=0.248 which is not pertinent because of absent significance.

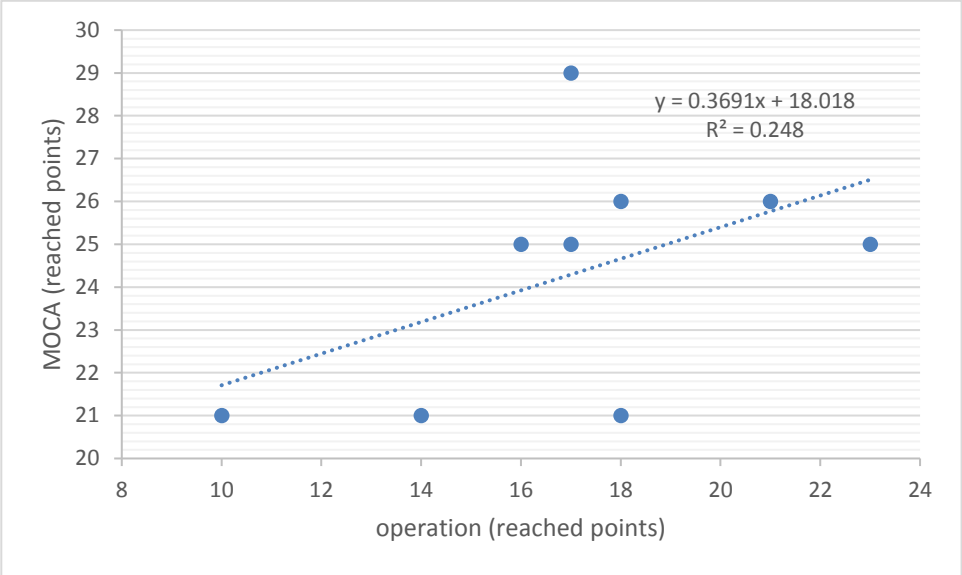


Figure 4 - Scatterplot: MOCA and operation

3. Is there a correlation between age of subjects and total score in MOCA?

There is no significant correlation between age of subjects and total score of MOCA. Correlation coefficient is r= .473 with p= .199. Figure 5 shows coefficient of determination r^2= 0.2236 which is not pertinent because of absent significance.

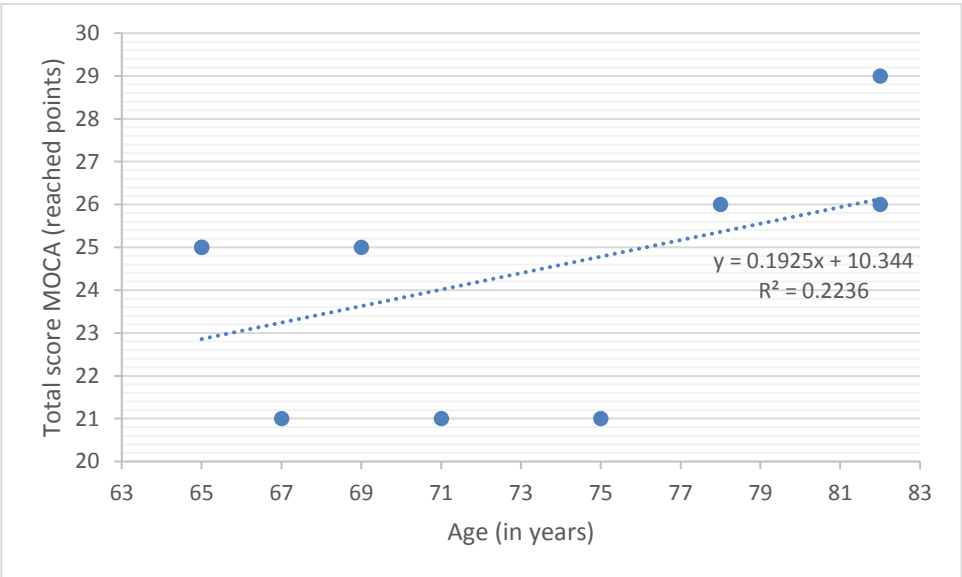


Figure 5 - Scatterplot: Total score MOCA and Age of subjects

4. Is there a correlation between age of subjects and total score in usability testing?

There is no significant correlation between age of subjects and total score of usability testing. Correlation coefficient is r= .162 with p= .675. Figure 6 shows coefficient of determination r²= 0.0266 which is not pertinent because of absent significance.

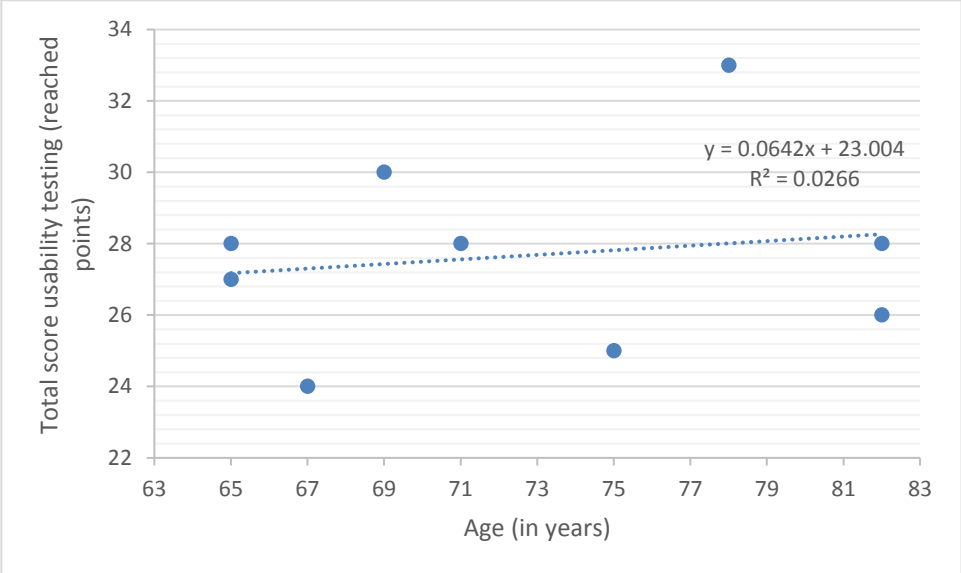


Figure 6 - Scatterplot: Total score usability testing and age of subjects

5. Is there a correlation between total score in MOCA and total score in usability testings?

There is no significant correlation between total score in MOCA and total score of usability testing. Correlation coefficient is r= .484 with p= .187. Figure 7 shows coefficient of determination r²= 0.2339 which is not pertinent because of absent significance.

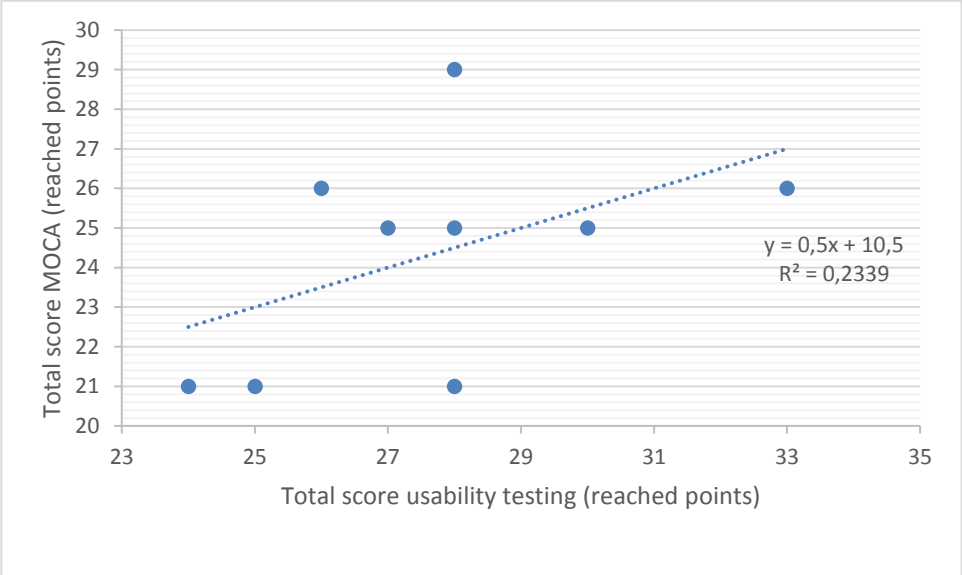


Figure 7 - Scatterplot: Total score MOCA and total score usability testing

What the results all amount to, is that there is no significant connection found. Either between cognitive abilities MOCA can examine and scores of usability testing or between age of subjects and MOCA or usability testing results.

4.4 Reasons for failure and subjects' questions

Subjects were able to ask questions at any time during usability testing. Questions during instruction were answered by the examiner immediately and were not protocolled. If subjects were not able to perform a task autonomously or with the aid of instruction manual and therefore asked a question, this task was documented as "not completed correctly" and reason for failure as well as subjects' questions have been written down at observation protocol. The following figure 8 shows the number of failures per task.

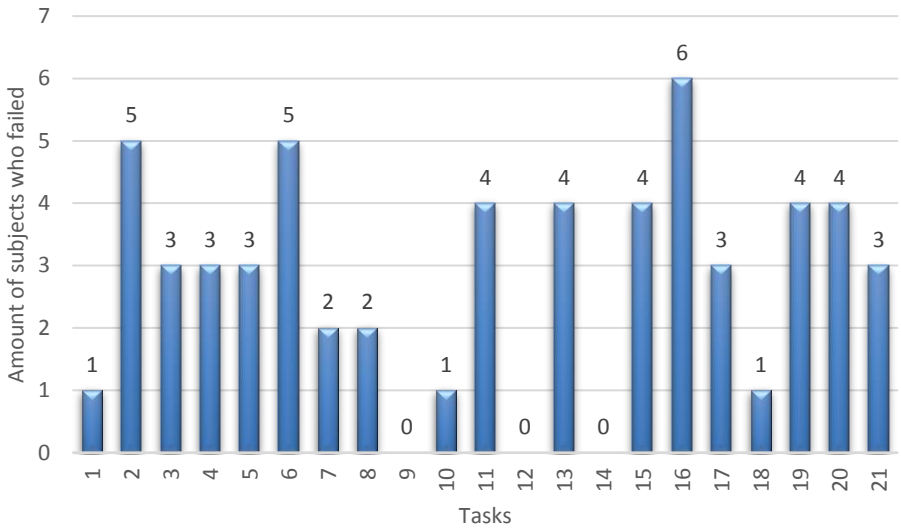


Figure 8 - Failures per task

Failures and asked questions are described in detail in descending succession below:

Most questions concerned task *16-continue program*. Five subjects tried to press the purple button which had to be used for task *9-start program "Greifen/Loslassen"*. They could not see the instruction on the display which commised them to use another button to start the training program. All subjects asked why the start button does not work that time.

Task 2 was another difficult task for some subjects. Five subjects struggled with connecting the main cable to connection jack A. After some tries, all of them asked if they are trying to connect the main cable to a wrong jack. The mistake of all subjects was a wrong mating direction.

Five subjects who had difficulties in task *6 - show positioning of electrodes* on their own arm could not see the position clearly on the instruction manual and were not able to remember the instruction of the examiner. The most asked question/statement concerning this task was *"…I cannot find this muscle, but I know it's gotta be around here somewhere…".*

Tasks 11, 13, and 15 relate to *selection of intensity of amperage*. In each task four subjects were not able to perform well because of small font size of amperage on the display. Most asked question was where they can see the amperage on the display.

Four subjects who were not able to *power off the device* (task *19*) used the purple start button which they had to use for task *9-start program "Greifen/Loslassen"* and asked why this button does not power off the device.

Four subjects asked for help in task *20-disconnecting cables and electrodes* because of impairment of fine motor skills.

All tasks concerning *connection of electrode cables, reference cable and electrodes* (task 4, 5 and 6) caused questions. Always, three subjects asked if they are connecting the right cables because they could not use information of the instruction manual due to small picture- or font size. Some of them asked for help because they were not able to connect the cables due to impaired fine motor skills.

Three subjects struggled with task *17-pausing the training program*. Because this task is not described in the instruction manual, subjects had to ask about it when they were not able to remember how to pause the program. All of the three struggling subjects asked where they can find the pause button.

Three subjects who had difficulties with task *21-store device, cables and electrodes*, asked if they have to disconnect all cables and where to put them away.

Only two subjects were not able to complete task *7-power up the device*. One tried to use the button for starting training program and the other one tried to use the button for starting program "Greifen/Loslassen". Both of them asked why the device does not power up.

Regarding reasons for failure, it can be said that most subjects had difficulties in vision and grasp. Directives on the display of device were often too small to read and some subjects did not understand directives due to terminology. Four subjects mentioned that they do not understand the difference between power up the device and start the program and five subjects said, that the instruction for positioning of electrodes is not self-explaining. The sixth picture of the instruction manual, which shows how to position the yellow electrodes, is called "Fingerbeuger" which does not make sense for half of the test group. All of them thought that "Faust" would describe positioning much better.

4.5 Feedback / Improvement suggestions

Altogether eight subjects wanted to give feedback to usability of the device. Feedback was given at the end of examination. All of them mentioned that they could hardly see information on the display of the device. Eight subjects said that the font size is too small and that contrast of the display is too low. Four subjects

added that the connection of cables is very difficult, especially with impaired fine motor skills. Six subjects mentioned that it is important to have an instruction manual, but they would require bigger pictures and bigger font size for easier usability. Four subjects also suggested bigger buttons which are lettered. They found it hard that the functionality of a button is described on the display and thought it would be easier if the button itself would be lettered.

5 Discussion

Aim of this thesis was to examine the usability of an electrical stimulation device and to consider individual cognitive abilities in this context. To assess practicality of electrical stimulation device for elderly stroke survivors in a home-therapy setting, it was important to find out if an autonomous use of the device is possible. Therefore, the questions of research are answered in this chapter and additional collected data is interpreted. All results are presented having regard to limitations. For better overview, this chapter is structured in the same order like the results.

5.1 Autonomous use

> **Q1:** Are stroke patients, at age of 65 or older, able to use an electrical stimulation device correctly by themselves when they were instructed by a therapist?

The results of usability testings show that no subject was able to use the device autonomously after onetime instruction by a therapist, but there is reason to believe that repeated instruction could lead to better results. A reason for this assumption is the improvement of subjects' ability-to-use skills when they had to perform a task more than once. This occured for example when subjects had to adjust amperage of device. They had to perform this task three times and got better results per try which shows that subjects were able to learn and improve. Considering that, it is not sufficient to instruct stroke survivers only once if an autonomous use in a home-therapy setting is desired. This result agrees with argue of Mykityshyn et al. [5] that elderly often need more time to understand medical devices or training programs.

Furthermore, this investigation pointed out that every subject had at least two questions (up to 11 questions) which needed to be answered for continuing the use of Stiwell med4. This outcome represents the importance of presence of a therapist, especially at the beginning of teaching stroke survivors how to use an electrical stimulation device.

5.2 Cognition and Usability

Q2: Is there a correlation between the ability to use and cognition?

All calculated correlations show no significant correlation between scores in MOCA and usability skills in operating Stiwell med4. Because of excluding one outlier, the number of subjects decreased to N=9 for these calculations, which is a very small sample group. Furthermore, the use of MOCA as a cognitive assessment could have been a limitation for this investigation. MOCA is a short screening which gives an overview about cognitive skills but it is not designed to detect cognitive impairments in detail. Because other available assessments, which are able to identify cognitive impairments in greater detail, often last longer than 20 minutes, MOCA has been chosen, though. Moreover, assumption can be made that a bigger sample size would show results more detailed and moreover increase the chance for manifestation of significance.

5.3 Reasons for failure

As results show, most subjects had difficulties in vision due to the small display of the device. All subjects do not suffer from severe visual impairments which means that they are not limited in their daily lives due to vision. Anyway, they struggled with operating Stiwell med4 which hints at the need of a bigger display, bigger font size or higher contrast for the use of the device in elderly.

Difficulties in understanding due to terminology was another reason for failure. In spite of the fact that 90% of the test group use a cellphone and 50% use a computer in their daily lives, it could have been assumed that terminology should not be a reason for failure. Anyway, subjects struggled with knowing the difference between directives “power up” and “start” and had difficulties with description of positioning electrodes.

5.4 Subjects‘ Improvement suggestions

Like Sarodnick & Brau [25] pointed out that usability testings are important to obtain information about problems and resources of use of devices and to deduce improvement suggestions. Subjects’ improvement suggestions were similar and most of them concerned the interface of the device. These findings agree with conception of Inglis at al. [4] who pointed out that even healthy elderly often struggle with interfaces. Subjects would require a bigger display, with bigger font

size and higher contrast, to see information clearly. They also mentioned that cable ends are too small to connect them, especially with impaired fine motor skills. Another improvement suggestion was to tailor the instruction manual to elderly. Therefore, bigger pictures and bigger font size would be necessary. Similar to findings of Patel et al. [6], some subjects would like to have an easier language in instruction manual, especially for the positioning of electrodes. Another suggestion was to create bigger buttons which are lettered.

5.5 Further limitations

As mentioned before, the small sample size of N=10 should be regarded as a limitation. To answer research question **Q1,** data of all subjects was used (N=10). For calculation correlations (**Q2),** only data of nine subjects (N=9) was used because of exclusion of one outlier.

The length of the whole examination subjects had to pass could also be seen as a limitation. The whole investigation lasted between 60-90 minutes which can be a long time for stroke survivors. Some subjects needed a break between the usability testing and MOCA.

Usability testing was structured in 21 tasks which have been used for the observation protocol. The oberservation protocol was not standardized because none of the already existing observation protocols was expedient for this examination.

The fact that the author of this thesis acted as the examiner of the investigation should be seen as a limitation too. To decrease bias, the examiner used standardized instruction for the cognitive assessment MOCA and used the instruction manual of Stiwell med4 for instruction. Furthermore, a tape-recorded-instruction has been used to tell subjects which task they have to perform next.

5.6 Prospect

This investigation could not find correlations between the ability to use and cognitive impairments of subjects. In spite of that, all subjects struggled with operation of Stiwell med4 because of age related visual impairments or because of fine motor skills or terminology related problems. Further investigation should therefore focus on visual skills of subjects and on the used terminology of the device. Furthermore, a bigger sample size would be more meaningful. Because elderly often need more explanation, the use of an instruction video can be another

valuable approach which should be evaluated in further trails. Subjects could use this video instead of an instruction manual. An instruction video instead of an instruction by a therapist is not recommendable due to a great number of questions subjects had during tuition. Also, the coaching of potential life partners should be considered. Especially when users suffer from impaired fine motor skills it is useful to include life partners in tuition of the device.

6 Conclusion

Aim of this investigation was to find out if a stroke survivor can operate Stiwell med4 autonomously and to detect potential correlations between cognitive abilities and their ability to use. Furthermore, failures in usability have been ascertained.

Results show that there is no significant correlation between reached score in MOCA and usability testings with Stiwell med4. In spite of that, no subject was able to operate Stiwell med4 after detailed instruction by a therapist. Most common reasons for failure were visual related or terminology related. These findings agree with conception of previous studies [4], [6].

To sum up, it can be said that onetime instruction of Stiwell med4 is not sufficient to make sure that stroke survivors at age of 65 (or older) are able to use this device autonomously in a home-therapy setting. In fact, there was no correlation found between cognition and ability-to-use skills, but subjects' failures and subjects' feedback pointed out that especially visual abilities and terminology of device are critical factors for usability of this device. A more detailed instruction manual or maybe an instruction-video, which stroke survivors can watch at home again, could be a facilitation for elderly. Furthermore, stroke survivors should have the possibility to receive several instructions by therapists.

Prospective studies should focus on age appropriate display and handling of electrical stimulation devices.

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List of Abbreviations

CT – Computed Tomography

f – Female

m – Male

mA - Milliampere

MOCA – Montreal cognitive Assessment

MMSE – Minimental state examination

MRI – Magnetic Resonance Imaging

r – Correlation coefficient

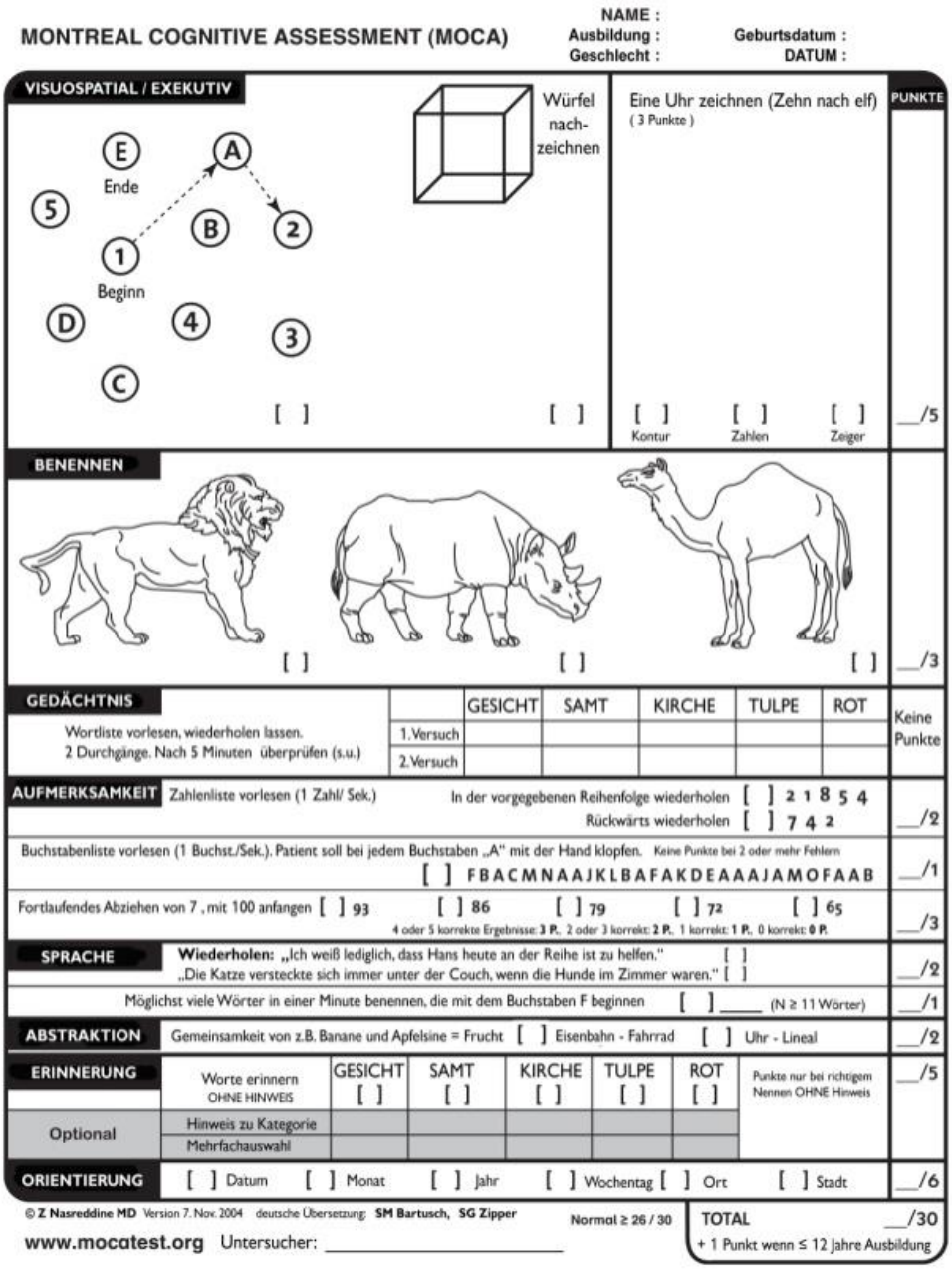
N – Sample size

SD – Standard deviation

Q – Research question

Appendix

A. MOCA



MONTREAL COGNITIVE ASSESSMENT (MOCA)

NAME :
Ausbildung :
Geschlecht :
Geburtsdatum :
DATUM :

VISUOSPATIAL / EXEKUTIV — PUNKTE

Würfel nachzeichnen

E Ende, A, 5, B, 2, 1 Beginn, D, 4, 3, C

[ ] [ ] — /5

Eine Uhr zeichnen (Zehn nach elf) (3 Punkte)

[ ] Kontur [ ] Zahlen [ ] Zeiger

BENENNEN

[ ] [ ] [ ] — /3

GEDÄCHTNIS — Keine Punkte

Wortliste vorlesen, wiederholen lassen. 2 Durchgänge. Nach 5 Minuten überprüfen (s.u.)

	GESICHT	SAMT	KIRCHE	TULPE	ROT
1. Versuch					
2. Versuch					

AUFMERKSAMKEIT Zahlenliste vorlesen (1 Zahl/ Sek.)

In der vorgegebenen Reihenfolge wiederholen [ ] 2 1 8 5 4

Rückwärts wiederholen [ ] 7 4 2 — /2

Buchstabenliste vorlesen (1 Buchst./Sek.). Patient soll bei jedem Buchstaben „A" mit der Hand klopfen. Keine Punkte bei 2 oder mehr Fehlern

[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B — /1

Fortlaufendes Abziehen von 7 , mit 100 anfangen [ ] 93 [ ] 86 [ ] 79 [ ] 72 [ ] 65

4 oder 5 korrekte Ergebnisse: **3 P.** 2 oder 3 korrekt: **2 P.** 1 korrekt: **1 P.** 0 korrekt: **0 P.** — /3

SPRACHE **Wiederholen:** „Ich weiß lediglich, dass Hans heute an der Reihe ist zu helfen." [ ]

„Die Katze versteckte sich immer unter der Couch, wenn die Hunde im Zimmer waren." [ ] — /2

Möglichst viele Wörter in einer Minute benennen, die mit dem Buchstaben F beginnen [ ] _____ (N ≥ 11 Wörter) — /1

ABSTRAKTION Gemeinsamkeit von z.B. Banane und Apfelsine = Frucht [ ] Eisenbahn - Fahrrad [ ] Uhr - Lineal — /2

ERINNERUNG

	Worte erinnern OHNE HINWEIS	GESICHT [ ]	SAMT [ ]	KIRCHE [ ]	TULPE [ ]	ROT [ ]
Optional	Hinweis zu Kategorie					
	Mehrfachauswahl					

Punkte nur bei richtigem Nennen OHNE Hinweis — /5

ORIENTIERUNG [ ] Datum [ ] Monat [ ] Jahr [ ] Wochentag [ ] Ort [ ] Stadt — /6

© **Z Nasreddine MD** Version 7. Nov. 2004 deutsche Übersetzung: **SM Bartusch, SG Zipper**

www.mocatest.org Untersucher: _____

Normal ≥ 26 / 30

TOTAL /30

+ 1 Punkt wenn ≤ 12 Jahre Ausbildung

B. Observation protocol

Date:	ID:
Age:	Sex: male ☐ female ☐
Time:	

G= Anweisung gehört und selbstständig, richtig durchgeführt
BA= Anweisung gehört, Umsetzung nicht selbstständig möglich, Bedienungsanleitung herangezogen
F= Anweisung gehört, Bedienungsanleitung herangezogen, Task trotzdem nicht selbstständig durchführbar

Nr.	Task	G	BA	F	
1	Gerät und alle Kabel sowie Elektroden auspacken	☐	☐	☐	
2	Hauptkabel an Buchse A anschließen	☐	☐	☐	
3	Alle Elektrodenkabel mit Hauptkabel verbinden	☐	☐	☐	
4	Weißes Referenzkabel mit Hauptkabel verbinden	☐	☐	☐	
5	Elektroden anschließen	☐	☐	☐	
6	Positionierung von Elektroden und Referenzkabel zeigen	☐	☐	☐	
7	Gerät einschalten	☐	☐	☐	
8	Programm „Greifen/Loslassen" auswählen	☐	☐	☐	
9	Programm starten	☐	☐	☐	

10	Funktionstaste I drücken	☐	☐	☐
11	Intensität I auf 5 mA einstellen	☐	☐	☐
12	Funktionstaste II drücken	☐	☐	☐
13	Intensität II auf 7 mA einstellen	☐	☐	☐
14	Funktionstaste III drücken	☐	☐	☐
15	Intensität III auf 2 mA einstellen	☐	☐	☐
16	Training starten	☐	☐	☐
17	Training pausieren	☐	☐	☐
18	Training wiederaufnehmen	☐	☐	☐
19	Gerät ausschalten	☐	☐	☐
20	Alle Kabel und Elektroden abstecken	☐	☐	☐
21	Kabel, Elektroden und Gerät im Koffer verstauen	☐	☐	☐

C. Declaration of consent

Einverständniserklärung
zur Teilnahme an einem Benutzerfreundlichkeitstest mit dem Gerät Stiwell med4 und zur Durchführung des kognitiven Assessments MOCA

Sehr geehrte Damen und Herren!

Im Zuge meiner Masterarbeit möchte ich Sie herzlich einladen an einem Benutzerfreundlichkeitstest teilzunehmen. Getestet wird die Handhabung eines Elektrostimulationsgerätes der Firma MedEL. Dieser Benutzerfreundlichkeitstest wird circa eine Stunde in Anspruch nehmen. Danach folgt ein kurzer Test der geistigen Fähigkeiten welcher in etwa 20 Minuten dauert.

Im Zuge des Benutzerfreundlichkeitstests mit dem Gerät Stiwell med4 werden Sie KEINE Elektrostimulation erhalten, die Testung beschäftigt sich rein mit der Bedienung des Geräts. Es erfolgt also KEINE Behandlung!

Ihre Teilnahme ist selbstverständlich freiwillig, das heißt, Sie haben zu jeder Zeit die Möglichkeit, ohne Angabe von Gründen, die Testung abzubrechen. Außerdem besteht die Möglichkeit Pausen zu machen. Bitte teilen Sie mir Ihre Bedürfnisse zu jeder Zeit mit!

Ihre Daten werden anonym und vertraulich behandelt und werden nicht an Dritte weitergegeben.

Sollten Sie mit der Durchführung des Benutzerfreundlichkeitstests sowie der Testung der geistigen Fähigkeiten einverstanden sein und stimmen Sie der Verwendung Ihrer Daten für diese Masterarbeit zu, so unterschreiben Sie bitte die folgende Einverständniserklärung:

Ich bin von Frau Müllauer ausführlich über den Zweck der Testung sowie die Verarbeitung meiner Daten aufgeklärt worden und nehme freiwillig, an den oben genannten Tests, teil.

Ich nehme zur Kenntnis, dass ich bei dieser Testung keine Behandlung (Elektrostimulation) erhalte. Zudem weiß ich, dass ich die Testung zu jeder Zeit ohne Angabe von Gründen abbrechen kann.

……

Name

……

Datum, Unterschrift TeilnehmerIn

D. Instruction Manual

MED EL

STIWELL med4 Programmanleitung „Greifen / Loslassen (EMG)“

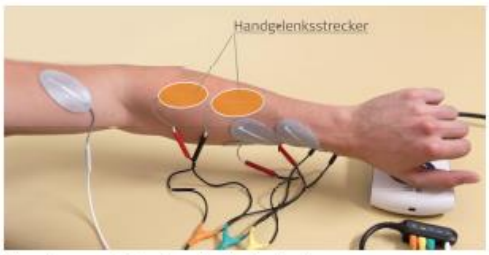
Hauptkabel an Buchse A anschließen

Oranges, gelbes und grünes Elektrodenkabel mit Hauptkabel verbinden

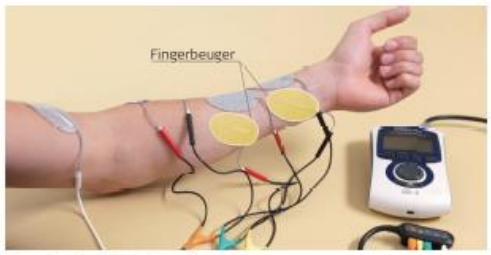
Weißes Referenzkabel mit Hauptkabel verbinden

Elektroden anschließen

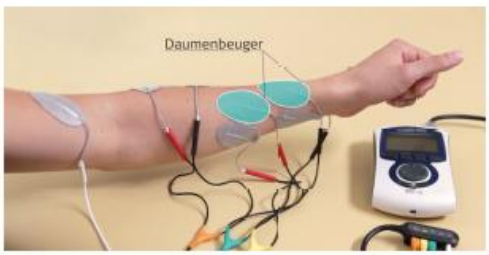
Elektroden wie vom Arzt/Therapeuten empfohlen aufkleben; Beispiel für die Elektrodenpositionierung:



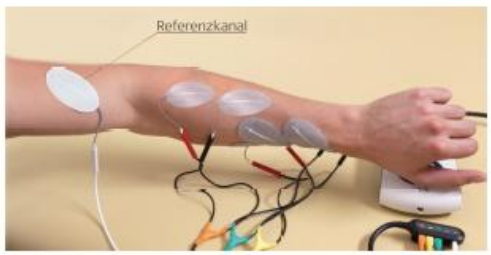
Kanal orange (1) – Handgelenksstrecker



Kanal gelb (2) - Fingerbeuger

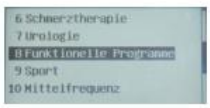


Kanal grün (3) - Daumenbeuger



Referenzkanal weiß - Arm

Gerät einschalten



Bei gesperrtem Programm (🔒) wird sofort „Greifen / Loslassen (EMG)“ angezeigt

oder

bei nicht gesperrtem Programm vorher „8. Funktionelle Programme“, anschließend „2. Greifen / Loslassen (EMG)“ wählen.

Jeweils mit OK ✓ auswählen (violett markierte Taste)

AW 107186 Rev. 2.0

1

Bei der Softwareversion 2.0 entfallen diese Schritte, da die Kalibrierung automatisch erfolgt.

Programm wird angezeigt - START drücken

Zuerst den Muskel entspannen und den Ruhetonus (Entspannungswert) mit OK bestätigen

Jetzt den Muskel anspannen und den maximalen Kontraktionswert (Anspannungswert) mit OK bestätigen

Die Trigger-Schwelle zum Auslösen des Stimulationsimpulses manuell mit + und – (oder Drehregler) einstellen und mit OK bestätigen

Zum Einstellen der Intensität die Funktionstasten 1x drücken – „0 mA" beginnt zu blinken

Während die „mA"-Anzeige blinkt, mit dem Drehregler die Intensität der Muskelstimulation einstellen

Nach Einstellung der Intensitäten die Behandlung durch Betätigung von ◁■▷ starten

Die Muskelaktivität wird als gefüllter Balken angezeigt. **Versuchen Sie, durch Anspannen des Muskels den Balken bis zum Pfeil zu füllen.**

Bei Erreichen des Pfeils beginnt die Stimulationsphase. Die Muskeln werden nun einige Sekunden lang mit den von Ihnen vorher eingestellten Intensitäten stimuliert. Kontrollieren Sie die Greiffunktion - ggf. können Sie die Stromstärke und Elektrodenposition anpassen.

Nach der Entspannungsphase muss zum Auslösen der Stimulation wieder der Pfeil erreicht werden. Dieser Ablauf (Anspannen – Stimulation – Entspannen) wiederholt sich bis zum Ende der Behandlungsdauer.

Nach dem Behandlungsende das Gerät ausschalten und Gerät sowie Zubehör bis zur nächsten Verwendung im Transportkoffer lagern. Die Elektroden im Elektrodenpäckchen verschließen, um Austrocknung zu vermeiden.

Das STIWELL Team wünscht Ihnen viel Erfolg bei der Behandlung!

Hinweis: Bitte beachten Sie, dass dieses Blatt eine Hilfestellung zur Verwendung des Programms „Greifen / Loslassen (EMG)" anhand eines Anwendungsbeispiels darstellt. Für produktspezifische Daten, Warnhinweise und detaillierte Informationen zur Handhabung lesen Sie bitte die dem Produkt beiliegende Bedienungsanleitung.

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