Multimedia **A**uthoring and **M**anagement using your **E**yes and **M**ind

H2020-ICT-2014 - 644780

D6.1

Clinical requirements for the MAMEM platform for each of the patient cohort

Dissemination level:	Public (PU)
Contractual date of delivery:	Month 4, 31/8/15
Actual date of delivery:	31/08/15
Workpackage:	WP6 Clinical requirements analysis and pilot trials with patients
Task:	T6.1 Clinical requirements definition and usage scenarios specification
Type:	Report
Approval Status:	Final
Version:	0.4
Number of pages:	168
Filename:	D6.1 Clinical requirements_Final.docx

Abstract

According toT6.1 of MAMEM project, this report will describe the requirements for wearing and operation of the platform for each cohort of subjects, based on (1) literature surveys done by each clinical site; (2) analyses of focus groups conducted in each clinical site. This report contains the questionnaires, the protocol and the ethical approvals obtained for conducting these interviews. The requirements are summarized and prioritized. In next step we will extract similar information from interviews with patients and caregivers.

THE FRAMEWORK PROGRAMME FOR RESEARCH AND INNOVATION
HORIZON 2020

Co-funded by the European Union

Copyright

1. ETHNIKO KENTRO EREVNAS KAI TECHNOLOGIKIS ANAPTYXIS (CERTH)
2. UNIVERSITAT KOBLENZ-LANDAU (UNI KO-LD)
3. EB NEURO SPA (EBNeuro)
4. SENSOMOTORIC INSTRUMENTS GESELLSCHAFT FUR INNOVATIVE SENSORIK MBH (SMI)
5. TECHNISCHE UNIVERSITEIT EINDHOVEN (TU/e),
6. MDA ELLAS SOMATEIO GIA TI FRONTIDATON ATOMON ME NEVROMYIKES PATHISEIS (MDA HELLAS)
7. ARISTOTELIO PANEPISTIMIO THESSALONIKIS (AUTH)
8. MEDICAL RESEARCH INFRASTRUCTURE DEVELOPMENT AND HEALTH SERVICES FUND BY THE SHEBA MEDICAL CENTER (SHEBA)

History

Version	Date	Reason	Revised by
v0.1 (alpha)	June 30th, 2015	Table of contents to be checked and revised by the consortium and coordinator	Dr. Meir Plotnik Mr. Amihai Gottlieb
V0.2 (Beta)	August 10th, 2015	Refinements across all sections	Dr. Meir Plotnik Mr. Amihai Gottlieb Dr. Gabi Zeilig Dr. Rachel Kizony Ms. Lotem Kribus Dr. Zoe Katsarou Dr. Sevasti Bostantzopoulou Ms. Ariana Nichogiannopoulou Ms. Sissy Chlomissiou Dr. Vasilik Kosmidou
V0.3 (Pre-Final)	August 25st, 2015	Address comments from internal review	Dr. Meir Plotnik Mr. Amihai Gottlieb Dr. Gabi Zeilig Dr. Rachel Kizony Ms. Lotem Kribus Dr. Zoe Katsarou Dr. Sevasti Bostantzopoulou Ms. Ariana Nichogiannopoulou Ms. Sissy Chlomissiou Dr. Vasilik Kosmidou
V0.4 (Final)	August 31st, 2015	Address reviewer's remarks in verifying their comments	Dr. Meir Plotnik Mr. Amihai Gottlieb Dr. Gabi Zeilig Dr. Rachel Kizony Ms. Lotem Kribus Dr. Zoe Katsarou Dr. Sevasti Bostantzopoulou

			Ms. Ariana Nichogiannopoulou Ms. Sissy Chlomissiou Dr. Vasilik Kosmidou

Author list

Organization	Name	Contact Information
Sheba	Mr. Amihai Gottlieb	Amihai.gottlieb@gmail.com
Sheba	Dr. Meir Plotnik	Meir.PlotnikPeleg@sheba.health.gov.il
Sheba	Dr. Rachel Kizony	racheli.kizony@gmail.com
Sheba	Dr. Gabi Zeilig	Gabi.Zeilig@sheba.health.gov.il
Sheba	Ms. Lotem Kribus	lotem249@gmail.com
AUTH	Dr. Zoe Katsarou	katsarouzoe@gmail.com
AUTH	Dr. Sevasti Bostantzopoulou	bostkamb@otenet.gr
MDA Hellas	Ms. Ariana Nichogiannopoulou,	ArianaNichogiannopoulou@mdahellas.gr
MDA Hellas	Ms. Sissy Chlomissiou	sissychlomisiou@mdahellas.gr
CERTH	Dr. Vasilik Kosmidou	kosmidou@iti.gr

Executive Summary

In order to layout the *system definitions* for the MAMEM platform, the clinical partners of the consortium should provide the technology developing partners (TDP) with specific requirements derived from the fact that the end users will be subjects with disabilities (i.e., '*clinical requirements*') for the following cohorts: 1: Spinal Cord Injury (SCI); 2. Parkinson's disease (PD) and 3. Neuromuscular Disorder (NMD). The rationale behind this deliverable is to describe the process and its outcomes.

We worked in parallel, i.e., executed the same processes for each patient cohort:

(1) **Literature review:** We summarized clinical requirements including the special physical requirements for wearing and operating the platform and additional requirements derived from mental and regular clinical treatment aspects (2) **Focus group**: There were three different, medical condition - specific, focus groups. The requirements of the health professionals have been recorded and summarized. (3) **Questionnaires** for interviewing end users and care givers. The analysis of the questionnaires is not part of this deliverable. However, the final versions of the questionnaires are included in this document as an appendix, along with the ethical approvals for conducting the questionnaire trials with the participation of human beings from the Institutional Review Boards (IRB).

The core of the present document is a summary of the clinical requirements for each patient group, SCI, PD and PMD. Briefly, the common denominator of all the (three groups) participants is the difficulty/impossibility/impracticability to perform gentle upper limbs movements in an accurate, effective and time sparing way that allows them to activate existing (and future) technologies and so to participate in an active "e-life". It should also be considered that due to cognitive deficits that might exist in these patients, the system's learnability should be as easy as possible. We foresee that such a platform will improve the patient's ability to be engaged in multimedia authoring and as a consequence will enhance social involvement.

We anticipate that further complementary requirements will arise from the analysis of the questionnaires.

Abbreviations and Acronyms

AD	Autonomic Dysfunction
AIS	Asia Impairment Scale
ALS	Amyotrophic lateral sclerosis
ASIA	American Spinal Injury Association
BCI	Brain Computer Interface
DMD	Duchenne Muscular Dystrophy
EEG	Electroencephalogram
FG	Focus Group
HTPL	High Tetraplegia
ICF	International Classification of Functioning
ISNCSCI	International Standards for Neurological Classification of Spinal Cord Injury
IRB	Institutional Review Board
LMN	Lower Motor Neuron
MCI	Mild Cognitive Impairment
NLI	Neurological Level of Injury
NMD	Neuro Muscular Disorders
PD	Parkinson Disease
QOL	Quality Of Life
SCI	Spinal Cord Injury
SMA	Spinal muscular atrophy
SNP	Sip-And-Puff
TDP	Technology Developing Partners
UMN	Upper Motor Neuron

*** Additional abbreviations are spelled out within the document**

Table of Contents

1 INTRODUCTION 11

2 SPINAL CORD INJURY - CLINICALLY DRIVEN, DISEASE-SPECIFIC PHYSICAL AND TECHNICAL REQUIREMENTS 13

2.1 Literature review 13
- 2.1.1 Clinical background 13
- 2.1.2 Psychology and quality of life 16
- 2.1.3 Computer and internet use 16
- 2.1.4 Factors limiting the clinical application of brain-computer interfaces for SCI patients 18

2.2 Focus group 20
- 2.2.1 Background and methodological notes 20
- 2.2.2 Findings 21
- 2.2.3 Summary of SCI patients’ computer use habits and difficulties 30

2.3 Summary of requirements 32
- 2.3.1 Summary of SCI requirements based on a literature review 32
- 2.3.2 Summary of SCI requirements based on a focus group 34

2.4 SCI MAMEM Contraindication 37

2.5 An example of a user scenario 37

3 PARKINSON’S DISEASE - CLINICALLY DRIVEN, DISEASE-SPECIFIC PHYSICAL AND TECHNICAL REQUIREMENTS 39

3.1 Literature review 39
- 3.1.1 Clinical background 39
- 3.1.2 Factors affecting the ability to use computer for patients with Parkinson's disease 40
- 3.1.3 Patients with Parkinson's disease and use of computer 44

3.2 Focus group 46
- 3.2.1 Arranging the focus group 46
- 3.2.2 Methodology and Findings 47
- 3.2.3 Summary of PD patient’s’ computer use habits and difficulties 51

3.3 Summary of requirements 52
- 3.3.1 Summary of PD requirements based on a literature review 52
- 3.3.2 Summary of PD requirements based on a focus group 58

3.4 PD MAMEM Contraindication 59

3.5 An example of a user scenario 60

4 NEURO-MUSCULAR DISORDERS - CLINICALLY DRIVEN, DISEASE-SPECIFIC PHYSICAL AND TECHNICAL REQUIREMENTS 62

4.1 Literature review 62
  4.1.1 Clinical background 62
  4.1.2 Psychology and quality of life 65
  4.1.3 Computer and internet use........ 66
  4.1.4 Factors limiting the clinical application of brain-computer interface for NMD patients 67

4.2 Focus group 69
  4.2.1 Background and methodological notes 69
  4.2.2 Findings 70
  4.2.3 Summary of NMD patients’ computer use habits and difficulties........ 76

4.3 Summary of requirements 77
  4.3.1 Summary of NMD requirements based on a literature review 78
  4.3.2 Summary of NMD requirements based on a focus group 79

4.4 NMD MAMEM Contraindication 82

4.5 An example of a user scenario 83

5 SUMMARY OF REQUIREMENTS – CROSS-DISEASE AND CROSS-METHODS INTEGRATION 85

6 DESCRIPTION OF ADDITIONAL INPUT TO FOLLOW UP 88

6.1 Construction of questionnaires 88

6.2 Activities taken in order to obtain the ethical approvals........ 89

7 CONCLUSIONS 91

8 REFERENCES 92

9 APPENDIX A - QUESTIONNAIRES FOR PATIENTS AND FOR CARE GIVERS 100

9.1 SCI patients Questionnaire in English 100

9.2 SCI patients caregivers Questionnaire in English........126

9.3 Differences between the SCI, PD and NMD versions of the questionnaires 153
9.3.1 NMD Clinical information 153
9.3.2 PD Clinical information 154
9.3.3 PD extra mini difficulties questionnaire..... 155

10 APPENDIX B - ETHICAL APPROVALS FOR THE QUESTIONNAIRES STUDIES................156

10.1 Unified protocol outline (English)..........156

10.2 Copy of IRB approvals..........159
10.2.1 Copy of IRB approvals In AUTH..... 159
10.2.2 Copy of IRB approvals In MDA Hellas 162
10.2.3 Copy of IRB approvals In Sheba 165

List of Tables

Table 1: Summary of SCI patients’ computer use habits and difficulties according to a focus group 30

Table 2: Summary of SCI requirements based on a literature review 32

Table 3: Summary of SCI requirements based on a focus group 34

Table 4: Summary of PD patients’ computer use habits and difficulties according to a focus group 52

Table 5: Summary of PD requirements based on a literature review 54

Table 6: Summary of PD requirements based on a focus group 58

Table 7: Clinical classification criteria for spinal muscular atrophy 63

Table 8: Summary of NMD patients’ computer use habits and difficulties according to a focus group 76

Table 9: Summary of NMD requirements based on a literature review 78

Table 10: Summary of NMD requirements based on a focus group 80

Table 11: Summary of clinically driven requirements for the MAMEM platform 85

1 Introduction

Individuals who suffer from Loss of the voluntary muscular control while preserving cognitive functions are marginalized and unable to keep up with the rest of the society in a digitized world. MAMEM's goal is to integrate these people back into society by increasing their potential for communication. In this direction, MAMEM will deliver the technology to enable interface channels that can be controlled through eye-movements and mental commands. MAMEM, for demonstrating enablement, will engage three different cohorts of patients: subjects with spinal cord injury (SCI), Parkinson's disease (PD) and neuromuscular disorders (NMD

In the process of laying out the system's definitions, one should take into account the requirements that arise from the clinical condition of each patient cohort of users. Thus to counter the 'temptation' to leave the overall usage definitions to the technological perspective, which might be suitable for the general population (e.g., apple's approach when developing smart phones), but potentially not fit when users with special needs are involved.

To obtain clinically driven requirements for MAMEM we adopted the following approach: We conducted three **focus groups**, each one centred on each patients' cohort, in which clinicians and para-clinicians from different disciplines, 'brain stormed' about the current difficulties, current solutions and the requirements to the add-ons that MAMEN can provide. The common dominator to all clinicians in each one of the focus group is having specific expertise to the specific patient cohort. E.g. medical doctors for the Parkinson's groups were expert movement disorders neurologist, while in the group of SCI, neurological rehabilitation physician participated. The second pillar of our approach was to conduct thorough **literature survey** to extract the needs for each patient cohort. Finally we defined users' and care givers' **questionnaires** in order to extract clinically driven requirements from the point of view of the end user. Further we obtained **ethical approvals** in order to approach and interview patients and care givers with these questionnaires.

The main purpose of this document is to present the results what we have reached employing this approach leading the definition of clinically driven requirements for wearing and operation of the MAMEM platform for each cohort of subjects. We have not completed conducting all the interviews with the end users thus we include in this deliverable the questionnaires versions (i.e., for patients and care givers) and pointing out the differences between the questionnaires for each cohort. The main result of this deliverable is a set of requirements that are related to all three cohorts regarding the designing of the MAMEM platform. In order to assist the designers, we asked all of the clinical experts to assess their importance, thus creating a priority index. These requirements are to be translated into engineering aspects by the technological partners of the projects in later parts of the projects.

The document is divided into chapters. Chapter 2-4 describes the outcomes regarding each one of the clinical cohorts, and chapter 5 describes a cross-disease and cross-methods summarization of the requirements. Chapter 6 and the appendixes questionnaires preparation and approval related activities. .

2 Spinal Cord Injury - Clinically driven, disease-specific physical and technical requirements

2.1 Literature review

2.1.1 Clinical background

A spinal cord injury is defined as damage to any part of the spinal cord or nerves at the end of the spinal canal. Reasons for a SCI vary and can be divided into two main categories: traumatic and non-traumatic. In the traumatic category the main causes include: sports and recreation injuries, traffic accidents, acts of violence, falls and alcohol abuse. The non-traumatic category mainly includes medical conditions such as vascular, neoplastic, degenerative or infectious. SCI patients have impaired or lost motor, sensory and autonomic functions. The impairments correlate with the level of injury.

Epidemiology: About 330,000 people with SCI are living in Europe, with 11,000 new injuries occurring per year [1, 2]. These numbers (people suffering from SCI) are in the same range for United States as well.

About half of all individuals with an SCI are tetraplegics; half of them have a C4 and C5 lesion (see below for an overview) at the time of discharge from acute care to rehabilitation facilities. In lesions at the level of C5, finger's function is impaired, while in most C4 lesions, hand function and elbow flexion are additionally limited. About 8% of the patients have a neurological level rostral to C4 resulting in the loss of motor function of both upper extremities including shoulder, elbow, and hand movements. These individuals lose their independence and privacy almost completely, which results in a tremendous decrease in quality of life [3].

Severity of SCI: The severity of the SCI is dictated by the completeness and level of injury.

A brief summary of the anatomy and functioning of the spinal cord is available below (from Christopher and Dana Reeve Foundation website[1].

"The spinal cord is organized into segments along its length. Nerves from each segment connect to specific regions of the body. The segments in the neck, or cervical region, referred to as C1 through C8, control signals to the neck, arms, and hands.

---

[1] See website URL at the end of the reference list.

Those in the thoracic or upper back region (T1 through T12) relay signals to the torso and to some parts of the arms. Those in the lumbar or mid-back region just below the ribs (L1 through L5) control signals to the hips and legs.

Finally, the sacral segments (S1 through S5) lie just below the lumbar segments in the mid-back and control signals to the groin, toes, and some parts of the legs.

After injury, nerve cells, or neurons, of the peripheral nervous system (PNS), which carry signals to the limbs, torso, and other parts of the body, are able to repair themselves. Injured nerves in the CNS, however, are not able to regenerate."

The standard classification of the severity of the SCI today is based on the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI): 1) the Neurological Level of Injury (NLI), which is the last level with normal motor and sensory functions, and 2) the completeness or in-completeness of the injury as described by the ASIA Impairment Scale (AIS) grades: A, B, C, D or E. Subjects with grades A and B have motor complete injuries while individuals with grades C and D have some levels of motor function. Those with grade E have normal motor and sensory functions. This classification describes a person's neurological impairment as a result of their spinal cord injury. In the MAMEM project, the targeted SCI patients are those with the most severe impairments; those who have lesions at C4 level and above and a complete or incomplete injury. These patients can be classified as ASIA A, B or C.

The International Classification of Functioning, Disability and Health (ICF) is a framework for describing and organizing information on functioning and disability. It provides a standard language and a conceptual basis for the definition and measurement of health and disability. The ICF consists of four dimensions: body functions and structures (including impairments), activities, participation, personal and environmental factors. In the context of the ICF, the final product of the MAMEM project will provide enhanced functioning despite the severe neurological impairment in the body function dimension. This solution will allow better participation, and thus, better quality of life.

The clinical course of SCI: The clinical course of SCI can be roughly divided into two stages: the acute stage and the chronic stage. The chronic phase begins ~6 months following injury and continues throughout the lifetime of the patient with SCI. Since the MAMEM project's objective is to produce a relatively long-term solution for the patients, the targeted cohort will be those patients who are currently in the chronic stage in which their status is relatively static. In light of this, the rest of this document will describe aspects that are relevant to SCI patients in the chronic stage.

Pain and spasticity: Spasticity is one of the side effects of the spinal cord injury. It is an increased, involuntary, velocity dependent, movement disorder characterized by high muscle tone. Spasticity may occur during sudden movements or during SCI related/non related medical conditions, while the patient is sitting in wheelchair or lying in bed. Roughly two thirds of patients with spinal cord injury suffer from spasticity [4].

Chronic neuropathic pain and musculoskeletal pain are also severe side effects of SCI. Between 30-50 percent of the SCI population have neuropathic pain. Unfortunately, there are no treatments that may definitely resolve these two conditions. This pain is often described as tingling, lancinating, burning or electricity-like sensations that may suddenly appear and greatly interfere with functionality and quality of life [5].

Pain leads to deficits in concentration and attention – both having negative impact on the BCI performance. A recent study [6] showed that the EEG activity of spinal cord injured patients with chronic neuropathic pain differs from that of spinal cord injured patients with no pain and also from that of able-bodied people. Frequency-specific EEG signatures were identified that may be used to monitor the development of neuropathic pain. However, it is not clear if the involvement of these EEG patterns have a detrimental effect on BCI control. Moreover, some of the medications used for treating these conditions have severe side effects of their own, such as: somnolence, blurred visions, dizziness and weakness. Anticholinergics lead to significant lower spectral power in all relevant frequency bands in the EEG .Baclofen, an agonist to GABA-β receptors, has an influence on the EEG spectral power distribution leading to an increase of slow brain signals [3].

Autonomic dysfunction (a malfunction of the autonomous nervous system) (AD): AD is another consequence of SCI that often interferes with the person's functionality. In high tetraplegia, orthostatic hypotension is a common condition in which blood pressure suddenly falls [7]. This may lead SCI patients to change their wheelchair position from an upright position to a semi-upright sitting position or to a lying position.

Respiratory and breathing issues: Patients with high cervical lesions above C4 have serious respiratory problems and they are in a real need for a BCI. 3.5% of the total SCI population have permanent dysfunction of the respiratory function and need artificial ventilation. Electrical artifacts generated by the artificial ventilator or muscular artifacts caused by shoulder elevation for voluntary ventilation support, substantially decrease the quality of the EEG signals [3].

Fatigue: Fatigue is a common problem in persons living with SCI. About 25% of SCI report fatigue severe enough to affect their function or qualify of life, especially in persons aging with SCI [13].

2.1.2 Psychology and quality of life

On average, SCI people have reduced quality of life (QOL), as argued in [8], lower life satisfaction [9], and elevations in depression and anxiety [10-12]. On the other hand, QOL of people with SCI is positively affected by several factors, such as higher education, increased mobility, better perceived physical health, more social support, and better psychological functioning, such as higher levels of self-efficacy and lower levels of neuroticism.

Depression: Depression is more common in the SCI population compared with the general population. Estimated rates of depression among people with SCI range from 11 to 37%. Reduced energy leading to fatigue, diminished activity, and reduced concentration are among the most common consequences of these conditions and may result in an unwillingness to participate in any kind of rehabilitative training, including BCI therapy. Patients suffering from major depression refuse to be provided with assistive technology in general.

The P300 amplitude is decreased in individuals with major depression [13], which might contribute to the inability to achieve a sufficient level of BCI performance. The inability of BCI control might in turn contribute to an increase in the symptoms of depression.

2.1.3 Computer and internet use

Assistive devices are used for enabling environmental control and computer, internet, and social media access to compensate for the loss of motor function and to allow individuals with severe disabilities to participate in society. The social media access is extremely important for end users with severe motor impairments, because in the virtual world, persons with handicaps are on the same level than non-impaired people. Joysticks for the hand or the chin, suck-and-puff control, voice control, or eye-tracking systems are among these assistive devices. In high SCI lesions, and particularly those depending on artificial ventilation, the input devices for setup of an electronic user interface are in general very limited and may not work with a sufficient level of performance over an extended period of time. Computer technology allows people to access information on the Internet, offers an alternative or additional means to communicate, and enables participation in education, work and leisure. Therefore, over the last decade Brain Computer Interfaces became an interesting option for end users who achieve only a moderate level of control with traditional input devices [3]. Thus, patients in the chronic stage will rely on assistive devices to overcome their disabilities.

Computer and internet use levels: According to Goodman et al. [15], the majority of SCI patients use computers and within this population, almost all of them use the internet:

"Over two thirds of these participants (69.2%) had access to a computer, and of those with computer access, 94.2% had accessed the internet, with a majority of internet users (68.6%) going online daily. Computer use and internet use did not vary significantly by level of injury. Over 60% of those with paraplegia and tetraplegia used a computer; among those with computer access, 93.8% of those with tetraplegia and 94.6% of those with paraplegia used the internet. People with higher levels of injury were more likely to use the internet daily than those with lower injury levels: 71.2% of subjects with tetraplegia compared with 66.3% of subjects with paraplegia".

In addition, Goodman et al. add that:

"*The internet has considerable potential as a viable modality for prevention and treatment of secondary complications for persons who have sustained a traumatic SCI*".

As reported by Caltenco, et al. [16], who did a comprehensive online survey regarding the current computer use of patients with SCI, almost all SCI patients used Microsoft windows.

User interface requirements derived from a clinical point of view: Regarding the user interface of the assistive device software, almost no information was found in the literature. Caltenco et al. [16] stated that the system should not try to be as simple as possible since a trade-off exists between simplicity and functionality. In addition, although complex systems rate lower on learnability, eventually, after the subjects learn to use them, they reach higher levels of functionality with the system and report having better usability.

"The more sophisticated and complex a system is, the more functionality can be obtained from it, but the more difficult it is to use. On the other hand, if the device is too simple and general, computer interaction becomes slow and tedious. Some of these aspects are reflected by the evaluation of computer interfaces on this study. The fact that system learnability was rated higher for simpler interfaces (typing sticks, mouthsticks, and mouth joystick) than for more complex interfaces (trackers and speech recognition systems) was expected, as joysticks and typing sticks are easier to use than trackers, and speech recognition systems take time to learn to operate them correctly. On the other hand, systems that were rated with high learnability were also rated with lower usability, such as mouthsticks and typing sticks, whereas trackers had the highest usability ratings.

There were also considerable differences between the usability within interfaces: for example, gaze trackers have very good ratings for most usability questions (system speed, discretion and ease of operation) but very bad ratings for reliability and ease of correcting *mistakes. All usability factors are important aspects for the success of any computer interface. Balance between functionality, performance, and easiness of use must be found for the design of a good computer interface".*

Also, according to Caltenco et al. [16], it seems that the system should have a low number of calibration points as possible for the gaze trackers:

"*The fact that the system setup for gaze trackers was evaluated worse than other interfaces may be due to a trade-off between system setup time and system performance and accuracy of gaze trackers. From the point of view of the users, a low number of calibration points is preferred, as calibration can be considered a tedious procedure".*

Lastly, it was found that an interface able to interact with other devices is preferred*:*

"...But having an interface that is able to interact with other common operative systems would be advantageous. Moreover, the interface should be able to control alternative electronic devices, in addition to a personal computer, or at least it should be able to interface with other assistive devices that can control alternative electronic equipment and smart house controllers".

2.1.4 Factors limiting the clinical application of brain-computer interfaces for SCI patients

The paper of Rupp [3]: "Challenges in clinical applications of brain computer interfaces in individuals with spinal cord injury", addresses the exact objective of our document. In light of this, we included relevant parts from his paper regarding factors limiting the use of BCI interface with SCI patients. These factors are also later translated into direct requirements for a future system.

Hardware and technology related factors: *"…Commercial BCI systems are mainly based on gel electrodes placed inside an EEG cap. The correct montage of the cap and the electrode on the skull under the premise of a proper electrode contact are very time-consuming procedures taking in the case of eight electrodes an experienced therapist up to 15–20 min. With the use of more expensive active electrodes, which integrate the amplifier in the electrode, the montage time can be substantially reduced. However, if electrode gel is used, the hair of the end user needs to be washed afterward. This puts additional burden on the caregivers and the patient. Therefore, a substantial effort needs to be taken to improve the practical applicability of BCIs in clinical routine. This is related in particular to the availability of dry electrodes, which can be quickly mounted and adapted to the individual needs of a patient. Although the first technical implementations of dry or at least "one drop," gel-less electrodes were introduced recently, it needs to be shown that they achieve the same level of signal acquisition quality in particular in an electrically noisy environment and that they do not cause any discomfort to the user.*

For most effective use of time and personal resources, the necessary action of the therapist should be limited to turning the system on and off. Efforts toward this goal have recently started by implementation of a "push-button" user interface without the need for technical experts to setup and calibrate the BCI system manually. Further improvements in terms of a higher reliability can be expected from machine learning research in BCIs, as e.g., the transfer of classifiers between individuals bears the chance to circumvent the time-consuming calibration recordings for novel users, and novel algorithmic counter-measures have recently been published to adaptively cope with the non-stationarity omnipresent in brain signals."

Personal factors: There is an ongoing trend toward more patients above the age of 65. There is some evidence that the spatio-temporal brain activation patterns alter during aging and that the aging process appears to more substantively alter thalamocortical interactions leading to an increase in cortical inefficiency therefore it can be assumed that general cognitive problems of the older population such as attention and concentration deficits might negatively influence the ability to control or to learn how to operate a BCI (Rupp 2014).

Inability for BCI control: *"...Both tetraplegic and paraplegic patients have some significant differences in event-related desynchronization strengths, exhibit significant increases in synchronization and reach significantly lower mean accuracies (66.1%) than the group of non-impaired subjects (85.1%)."*

"…Furthermore, online experiments are more demanding, which may also affect the performance. One of the study subjects fell asleep during the training, which indicates a high physical and mental workload during the operation of the BCI."

"...In the framework of a single case study, in which an individual with a lesion of the upper cervical spinal cord was provided with a BCI-controlled upper extremity neuroprosthesis, no training effects occurred over a training time of more than 6 months. Even after 415 MI-BCI runs, the end user's average performance did not show any trend toward improvement, but remained at about 70% with large day-to-day variances."

"…This supports the view that in high-level tetraplegic subjects, an extensive BCI training period does not necessarily lead to superior results."

2.2 Focus group

2.2.1 Background and methodological notes

As part of the development process of a computer use supporting system for SCI patients, one focus group was carried out amongst a variety of professional stakeholders. The following is a list of the professional participants:

- Medical Doctor
- Rehabilitation nurse
- Social worker
- Health psychologist
- Occupational therapist
- Physiotherapist
- Speech therapist (participated in the first half hour of the discussion only)

There were consistent differences in the issues raised by the different professionals. The psychologist and social worker, and to some extent the nurse, referred mostly to emotional, social and motivational aspects, whilst the other medical professionals used the physical aspects of SCI as their baseline for discussion.

The focus group took place at the rehabilitation center, in Tel-Hashomer on June 22nd, 2015 and was transcribed online.

In order to set the focus group, the health professionals had been identified, and contacted and a comfortable date and place for the focus group was set (~2 hours allocated). Then, a commercial company (TNS), specializing in conducting focus groups was contacted. They provided a professional focus group guide and a professional transcriber. The focus group itself took place in a quiet seminar room during work hours, was recorded with a digital recorder and was filmed with a video recorder. During the focus group, the guide introduced a subject or a question and asked the participants to freely discuss it. If the discussion got “stuck” or drifted to unwanted places, the guide quickly fixed this by commenting or adding more focused questions.

In the following part (2.2.2), the main ideas that were raised during the focus group are presented. Each of these is followed by supporting accurate quotes from the groups’ discussion (texts marked with italics).

2.2.2 Findings

Characteristics of SCI and the role of computers in rehabilitation

The location of the injury determines its extent. Initially, professionals divide injuries into "4 limbs affected" vs. "2 limbs affected", with a further division, namely, whether there is complete or incomplete loss of sensation.

It appears that amongst those who experience incomplete loss of sensation, there is ongoing non-realistic hope that one day their condition will significantly improve. Paradoxically, this hope might hinder rehabilitation. There is danger that it might make these patients delay the search for supporting solutions or commence a rehabilitation process due to the hope that one day they will not need it.

"The patients with complete loss of sensation deal with a very drastic and dramatic loss, which forces them to undergo a relatively brief grieving process during which they need to adjust to a different life. The less drastic patients are busy with getting rehabilitated; the experience of 'the big change is just around the corner' keeps them going"

It appears that the incomplete loss of sensation population is very difficult to characterize, as the range of injuries and their level of severity is wide and highly diverse.

Participants mentioned that SCI patients, especially those with High Tetraplegia (HTPL), have a common denominator, e.g. **loss of independence**. There is an indication that the staff involved in the care of HTPL share frustration due to the gap between the severe consequences of the injury, and the minimal functionality the therapists may offer them.

"The amount of loss for the families is huge. Loss on top of loss. Patients speak of the physical ability of walking, but also about the loss of ability to control their sphincters, the loss of sexual function, even not being able to scratch their own nose. The losses are incomprehensible; I have tetraplegia patients that wanted to kill themselves".

"It's important to mention that there are very little functions to work on with these patients, even as a 'therapist-patient' team you are left very frustrated, you show up with high motivation and there is so little you can do".

The role of computer in the rehabilitation process is central and highly important, as described by one of the participants:

"Because our life is one big computer, the meeting with the computer is the initial stage"

During hospitalization, the computer enables injured individuals to make contact with those who were part of their pre-injury life: family, friends, and colleagues.

"This is a stage in rehabilitation… if in the past we had a computer room, nowadays everybody's got their own smartphone and tablet, availability is very high. Also the initial role it plays in the rehabilitation process is important"

After returning home the computer enables SCI patients to regain control and independently manage a part of their life. **The computer becomes an anchor for functional independence** for injured individuals. By doing so it touches upon a key difficulty of 'loss of selfhood' and hence provides a very significant rehabilitative tool.

It is important to notice the central role of various mobile devices: Smartphones, tablets etc., as they are generally very common and enable SCI patients, computer- dependent activity.

The participants raised the importance of the computer as a tool for maintaining communication and social interaction for SCI patients. The computer is a central tool in getting SCI patients back into social participation and that social communication is probably the computer's most central and important function.

Methodological remark: From now on the discussion of the focus group centered on SCI patients with C4 and above levels, both complete and incomplete

SCI patients' computer use

SCI patients use a variety of computer types and it was impossible to point to any single type. The type of supportive system for computer use SCI patient will require, mainly depends on the specific characteristics of the SCI patient (e.g. which muscles he can move voluntarily, other health issues, respiration, vocal control, the nature of desired activity, the level of knowledge and computer literacy pre-injury, age, type of computer used in the past, etc.)

Participants stressed that it is very difficult to give general responses regarding systems' compatibility to SCI patients; rather it should be examined specifically per user.

"Which system is preferable for a C4, This is a question that needs to be referred to patients, I don't know"

- There is an indication that patients with partially preserved sensation and capability to type, do not need a replacement system for the keyboard and the mouse, yet they may experience problems while typing.
- There is an indication that the most common position for computer use is while sitting in a wheelchair.

"Most computer use is done sitting down, when you lie down it limits the movement, most function is done whilst sitting in a wheelchair. That's in terms of positioning, but it really depends…"

HTPL lost their ability to type, and to activate the cursor using standard keyboards and mouse, touchpad or trackball, hence different other system interfaces are required, such as:

- Gaze focus system (replaces both keyboard and mouse)
- Upside down mouse, head mouse, hand or leg mouse, mouse positioned on the chin, different types of joysticks.
- Systems based on giving orders through Sip-and-Puff (SNP) systems for wheelchair moving
- Systems based on vocal control (most of the participants did not witness such systems in practice)
- Participants look at the issue of **computer use support systems from a broad perspective**, taking into account everything it takes to achieve computer use experiences similar to those of healthy people. They state that in order to enable computer use in this population there is a need to adapt the work environment as well as provide accessibility for everything needed to use a computer. Namely, it's not just about elements directly related with operating the computer. Considering computer use, it's about everything that enables a person to get into the position where they can operate a computer; starting with changing their body position – to sitting, proper holding of body parts (related to a sitting system), suitable motivation, the ability to turn a computer on and off, use additional accessories etc.

"Sitting down for a HTPL is not simple; they need a sitting support system. If it's a motorized wheelchair, the chair and back need to be able to lean back. Getting to a position of 90^{o} sitting down is not easy, to sit a HTPL patient down steadily you need to tilt him back a bit"

- Working positioning: difficulty in achieving a suitable working position – even before they start to work, both the user and his/her care-giver need to exert effort into getting into the right working position.
- Screen positioning – the position that enables body stability and movement control requires tilting the head slightly backwards and upwards, which requires adjusting the position of the screen.
- Low level of accuracy – because computer activation is based on gross movement such as that of neck or mouth muscles. With incomplete patients who have sensation in their fingers, movement is still less accurate compared to their pre-injury performance.
- Slow work – working on the computer is slower in comparison to that of a healthy person or pre-injury. Typing using a support system is typically very slow – letter by letter (for example using a virtual keyboard), compared to more fluent typing pre-injury. The use of the mouse curser is slower as well.
- Fatigue, efforts and pain – due to the need to activate neck muscles and due to the constant need to refine and correct gross movement, computer use for SCI patients much focus and straining one's eyesight.
- Limited computer work time– due to the effort required. It was estimated that most SCI patients can work up to 2 hours.
- Spasticity – might cause the hand to "lock" on instruments (e.g. gripping the mouse without the ability to let go).
- Significant motivational difficulty – a high level of motivation is required, both to re-learn how to use the computer and also how to use the computer fluently
- Lack of spontaneity – there is a need for preparation and planning the task to be completed.
- Need for constant assistance while activating the computer, for example: when using a credit card, taking smartphone pictures and transferring them to the computer, and even when turning the computer off and on.
- Need for training of the care givers with preparing and adjusting the work environment
- Funding difficulties (not everyone can't afford assistive devices for computer use)

“There is a need for accuracy using the muscles, the gentle movements are much more vulnerable than the gross muscles, and they need to make delicate movements for operating the computer”

“Everything that seems trivial to us, for them is a huge effort, if I think of a person that works with a head curser and has to lean back and move his head, and these are the only muscles at work this is quite a big effort for him. He might be limited in in terms of range of movement; these movements might cause him pain”

“The significant difficulty in typing is switching from fluent typing to letter-by-letter typing”

“You need to type letter after letter with your mouth, I keep imagining it… I have a patient that types with his eyes letter after letter, also virtuals [using a virtual keyboard] type letter-by-letter”

“A C4 patient and certainly a C3 patient have rather short sitting time- the amount time they can sit in front of the computer. You can’t leave them sitting for 4 hours. If you’ve arranged a sitting-down work environment it’s time-limited”

Unsatisfied needs of SCI patients regarding computer use and ideas for improvements

Lack of solutions for situations where there is a need to operate additional instruments accompanying computer use: Today, vast parts of computer use are interactive, namely involving the creation and uploading of user content. These activities are especially relevant for social uses. Many social applications involve using videos / photos taken with equipment external to the computer. There is a need to take the photos, then transfer them to the computer and upload to the website or application. Most websites have a “share” or “like” button etc.

“Someone to put credit card details for me, to open a photo in a dating website, I want to take a photo of myself, a flattering photo, social activity on the net should be more interactive”

Lack of ability to secure privacy: When using websites where privacy is of high importance and there is a need to type in passwords or credit card details, SCI patients must use an assistant. So, for example, to type in credit card details there is a need for someone to get the credit card out of the wallet and type in the details. Websites like National Insurance or Banks require password use. The lack of privacy hinders the SCI patient’s ability to use these sites freely and comfortably.

The demand: A personal identification system that will not require external assistance – such as biometric means of identification (retina, voice, facial features etc.)

"I have a patient that when she wants to check the status of her bank account, her care-giver is automatically exposed to her code. It's not just the care-giver; there is something very public about it"

Specificity /lack of versatility of supportive solutions: today there is a need to make adaptations to different software and different types of computers. It appears that all existing solutions require a specific adaptation both to the type of computer and the different software. Hence, switching computers or starting to use a new software (e.g. for study purposes) requires making adaptations involving effort on the part of both user and his care-giver.

The demand: Versatile systems that are compatible with a wide range of computers (including tablets and smartphones) and software, without needing to make a specific adaptation every time something changes in the nature of the user's activities.

"If you use a gaze focus system, you can't just go to any computer and operate it, no, every adaptation requires someone else's assistance, if you compare systems this should be one of the advantages"

"Say I took a selfie and I want to open it in Photoshop using a voice command. Can I do that?" "No"… "It appears to be possible only in the movies"

"I want to study fashion design, I want to use graphic software"

Difficulty carrying out a number of actions simultaneously: It is difficult to carry out several actions simultaneously using a supporting system. For example, "dragging" and pressing a button simultaneously is difficult to accomplish.

"Everything that requires two hands [is difficult to do]"

"Dragging for instance…"

"[an additional participant] If I want to drag an object I use the shift key, but try to think how a person with tetraplegia would do that.."

"Press CTRL and highlight a few objects"

"Pressing CTRL+ALT+DLT"

Slowness of work and lack of accuracy: It appears that the problems of slowness of work and the difficulty to type precisely – choosing letters, or picking commands or buttons, do not currently have good enough solutions.

The demand: Systems that will enable fast and accurate performance, that will either make up for or bypass the need to use gross muscles.

In relation to this point most participants perceive a vocal-operated system as having a significant advantage

“Vocal operation requires the least amount of effort” “It's the least cumbersome, seems less restrictive”

Need to change body position with relative ease in order to prolong the limited work time

The demand: Solutions that will enable using a computer in a variety of different body positions as well allowing for easy change of position.

Difficulty doing collaborative computer work: The key example that came up was the lack of ability to play computer games and other joint activities with children or friends. In relation to that, speed is a limitation as well.

“Joint activity, if someone has a kid and they want to play together they can’t”

“I want to play game consuls”

“If I want to play with someone or watch something with someone I can’. Someone needs to share the screen with me. I can’t play with someone”

Oversensitivity of supporting systems: Due to the relative coarse movement of SCI patients, the supporting systems are sometimes over sensitive, translating an unintentional movement into a command.

The demand: A system that can distinguish between a movement that is “background noise” and a movement that is aimed at an intentional command.

Eye movement and brain signal control system: Comments, ideas and demands:

Participants were presented with a general outline of a supporting system for computer use based on gaze control and brain signals:

- Participants raised a concern that such a system might suffer from over sensitivity due to a difficulty in distinguishing between a brain signal aimed at carrying out a certain command on the computer and other unrelated thoughts / emotions that are manifested as brain signals. The sensitivity problem exists in current systems; however it appears that the greatest concern here is that with this type of equipment there will be even greater difficulty in distinguishing between giving a command and "noise", the reason being that content such as films, photos etc. involves much thought and emotional responses. And more generally, it is feared that the system will be sensitive to brain signals produced by the mental and emotional state of the user.

"Is it influenced by an emotional state, like if I watch a film and get emotional or angry?"

"If I have a million thoughts in my head and the computer starts writing down the thoughts"

"Precision, be precise"

"The system needs to know how to filter what is meant for computer operation from emotional factors"

- An additional concern relates to the need to break down a desired action into small multiple stages that need to be carried out in order to complete it. The need to break everything down into stages might make working on the computer laborious and strain full.
- Participants wished that the system be able to "translate" the thought of an action into its required stages. For example, the user will think about opening a new folder and the system will translate this thought to the required steps.

"I'm thinking about the first, second and third steps, that can be confusing if I have a complex thought. If the system can break down that thought [into stages] that would be helpful"

"I think about the action and the system needs to break it down into processes, for example if I want to open a file I would think about it and the system will do it"

The system that participants envision needs to bridge the gaps discussed earlier, therefore:

- Continuing on from the idea that the system will be able to break a thought about a computer operation into stages, participants wish the system could overcome the slow typing problem, by having the user think of a word and the system would know which letters are required to put it together.

"If I want to write something ... I don't want to have to break the word down in my head into letters but rather have a word completion function"

- In order to avoid typing errors, participants had additional ideas for improvement: A system that familiarizes itself with the characteristics of the individual user, the option to choose between different templates according to the type of text the user wishes to create, having an editing option in case the system is not sure of the user's intent, presenting spelling options for the user to choose from.

"A system that will learn my style of writing"

"In order to improve the speed of work there is a need to establish templates, like WhatsApp that completes words for the user, or like I have a fixed shopping list or like Google which learns the way we use the internet. Just like Google learns our pattern of activity – that would make working on the computer easier and faster"

- Participants wish the system would enable carrying out two actions simultaneously such as watching a content and responding to it

"Like working with two windows open"

"I want to watch MasterChef and vote for my candidate"

- Participants would like the system to be versatile and enable working with new software or visit a website the user has not visited before, without having to make adaptations. A system that is adapted to a variety of operating systems and types of computers.
- The system needs to be usable in both sitting and lying down positions.
- Participants wish the system to look as "normal" as possible

"The closest to normal as possible, even in terms of operation, that I would have to do as little adaptation as possible, like in terms of what the curser looks like, and in terms of the different commands"

"It needs to look nice, be light-weight, suitable for sitting and lying down. Have a normative appearance, like the headphones young people wear these days".

The issue of lack of appropriate sensitivity and more generally the ability to enable better control of the system came up in discussion repeatedly.

- Some participants initially thought that the eye gaze system would be used to move the cursor (replacing the mouse), while the brain signal system would be used to give commands such as "open". As the discussion unfolded, the group suggested that the question as to which system is used for which operation depends on the type of activity the user is carrying out at the time. The decision will depend on the conditions under which there is a better distinction between a response (of eye gaze or brain signals) that is "noise" and a response that is intended for carrying out a command on the computer, as well as which system would interfere less in carrying out the key operation. For example, in operations where eye gaze is the main function- like watching a video, it might be better that computer control would be carried out using brain signals, whereas with operations where there is much thought and emotional response it might be preferable that operations would be done via eye gaze.

- Based on participants' comments it can be concluded that there is a need to establish which system would provide a better level of sensitivity and accuracy and prevent interference with the main activity - per use.

Additional comments:

Some of the issues raised in the discussion require further expansion and in-depth exploration through direct testing with users, for quantification and validation purposes.

Social legitimacy – one of the needs raised – especially by the health psychologist – is the use of computer, which minimizes as much as possible the SCI patient's difference. For example, the possibility of sitting at a café with a laptop, without having to use a system that attracts too much attention or looks strange to people. The system should have a good appearance which creates a sense of normality.

2.2.3 Summary of SCI patients' computer use habits and difficulties

The following table summarizes the most important points regarding SCI patients' computer use habits and difficulties raised during the focus group and their implications toward designing assistive devices for these patients. Note that these are not direct requirements from the MAMEM platform but general considerations.

Table 1: Summary of SCI patients' computer use habits and difficulties according to a focus group

General group points	Implication
The group has risen, unaided, the importance of the computer as a tool for maintaining communication and social interaction for SCI patients	The computer is a central tool in getting SCI patients back into social participation. The group reported that even for the patients themselves, social communication is probably the computer's most central and important function

Discussion revealed that SCI patients use a variety of computer types and it was impossible to point to any single type standing out	it is difficult to characterize types of computers and systems at use with this population
	The type of supportive system for computer use the SCI patient will require mainly depends on his specific type of injury: which muscles he can move voluntarily, other health issues – respiration, vocal control and other variables such as the nature of desired activity, the level of knowledge and computer literacy pre-injury, age, type of computer used etc.
Participants stressed that it is very difficult to give general responses regarding systems' compatibility to SCI patients.	Systems' compatibility should be examined specifically per condition and per user.
	There is an indication that the most common position for computer use is sitting down
	A need for adjusting the screen position – the position that enables body stability and movement control requires tilting the head slightly backwards and upwards, which requires adjusting the position of the screen
	Limited computer work time– due to the effort required. It was estimated that most SCI patients can work up to 2 hours
	Significant motivational difficulty – a high level of motivation is required, both to re-learn how to use the computer and also how to use the computer fluently, due to the effort, fatigue and relative slowness of work
	There is a need for training for care-givers assisting the SCI patient with preparing and adjusting the work environment

2.3 Summary of requirements

The following is a summary of the requirements from the literature survey and from the conducted focus group regarding SCI patients. It is arranged in two separate tables, one for the literature survey (based on chapter 2.1) and one for the focus group (based on chapter 2.2). Both of the tables consist of two columns: the rational, and the requirement that derives from it. In addition, the requirements were arranged into several relevant dimensions. These tables, along with the matching tables from chapter 3 and 4 are consolidated to one table in chapter 5 and the requirements in that table are prioritized.

Note that the following are mainly clinically described requirements, and they should be translated to engineering requirements based on the technological knowledge of human machine interfaces expertise. For example, the fact that the age of SCI patients varies and the average age is rising in the last few years requires engineering solutions that will cover the different ages of the users and the mentioned age trend. The definitions of these solutions are based on expert engineering knowledge.

2.3.1 Summary of SCI requirements based on a literature review

Table 2: Summary of SCI requirements based on a literature review

Rational	Requirement
Personalization/Adaption	
There is an ongoing trend toward more SCI patients above the age of 65, who demonstrate general cognitive problems such as attention and concentration deficits	A system that is adapted for subjects who demonstrate these problems or a system that is compatible with different age or cognitive profiles
Performance	
Orthostatic hypotension may cause the SCI patients to change their wheelchair potions often	Enable using a computer in a variety of different body positions as well as allowing for easy change of position
There is evidence that in high-level tetraplegic subjects, an extensive BCI training period does not necessarily lead to superior results	During training, this point should be taken into account

Interoperability	
	An interface that is able to interact with other common operative systems or able to control alternative electronic devices would be advantageous (e.g., TV remote, electrical wheel chair)
	The system should work with Microsoft windows
Usability	
Setup time for the EEG device should be as short as possible	The system should use dry or at least “one drop,” gel-less electrodes and a “push-button” user interface without the need for technical experts to setup and calibrate the BCI system manually
	The system designers should consider the trade-off between the simplicity of operation and the diversity of functional options
Depression is more common in the SCI population compared the general population. This may result in an unwillingness to participate in any kind of rehabilitative training	System learnability should be as easy as possible
	A low number of calibration points is preferred
Physiology	
Poor trunk and neck balance and movement disorders such as spasticity of SCI patients may cause tremors, imbalance and sudden movements	The device should include an error-correction mechanism or algorithm
Depression is more common in the SCI population compared the general population. P300 amplitude is decreased in individuals with major depression.	The system sensitivity should take this into account

6.5% of all patients are respirators dependent at least for some hours a day and 3.5% have permanent dysfunction of the respiratory function and need artificial ventilation. While these patients are the in most need for the system, electrical and muscular artifacts could substantially decrease the quality of the EEG signals.	The EEG based operating system should be able to provide a solution for subjects with potential different EEG inherent characteristics, and also accommodate varying EEG characteristics due to mood, medication and pain. In other words the system should probably be customized to each patient personally and take into account the above points
Some medication the SCI patients may be taking is known to affect EEG signals.	
Usually within the first year after the injury neuropathic pain develops in about 40–50% of the patients and tends to become chronic. Pain can lead to deficits in concentration and attention. Also, a recent study showed that the EEG activity of spinal cord injured patients with chronic neuropathic pain differs to that of spinal cord injured patients with no pain and also to that of able-bodied people	

2.3.2 Summary of SCI requirements based on a focus group

Table 3: Summary of SCI requirements based on a focus group

Rational	Requirement
Interoperability	
Many social applications involve using videos / photos taken with equipment external to the computer	A system that will enable to take photos/videos, then transfer them to the computer and upload to the website or application

It appears that all existing solutions require a specific adaptation both to the type of computer and different software. Hence, switching computers o starting to use a new software (e.g. for study purposes) requires making adaptations involving effort on the part of both user and his care-giver	A versatile system that will be compatible with a wide range of computers (including tablets and smartphones) and software
	A versatile system that will enable working with new software or visit a website the user has not visited before, without having to make adaptations
Personalization/Adaption	
When using websites where privacy is of high importance and there is a need to type in passwords or credit card details, SCI patients must use an assistant	A personal identification system that will not require external assistance – such as biometric means of identification (retina, voice, facial features etc.)
	A system that familiarizes itself with the characteristics of the individual user
Performance	
There is a difficulty carrying out a number of actions simultaneously using a supporting system. For example, “dragging” and pressing a button simultaneously is difficult to accomplish	A system that could allow carrying out a number of actions simultaneously
Slowness of work and lack of accuracy. It appears that the problems of slowness of work and the difficulty to type precisely – choosing letters, or picking commands or buttons, do not currently have good enough solutions	A system that will enable fast and accurate performance, that will either make up for or bypass the need to use group muscles
Need to change body position with relative ease in order to prolong the limited work time	A system that will enable using a computer in a variety of different body positions as well allowing for easy change of position

Oversensitivity of supporting systems. Due to the relative coarse movement of SCI patients, the supporting systems are sometimes over sensitive, translating an unintentional movement into a command	A system that can distinguish between a movement that is “background noise” and a movement that is aimed at an intentional command
Participants wished that the system be able to “translate” the thought of an action into its required stages. For example, the user will think about opening a new folder and the system will translate this thought to the required steps	A system that is able to “translate” the thought of an action into its required stages
Participants wish the system could overcome the slow typing problem	A system that is able to have the user think of a word and the system would know which letters are required to put it together
	A system that will enable carrying out two actions simultaneously such as watching content and responding to it
	A system that will be usable in both sitting and lying down positions
The group suggested that the question as to which system is used for which operation will depend on the type of activity the user is carrying out at the time	A system that will enable to distinct between a response (of eye gaze or brain signals) that is “noise” and a response that is intended for carrying out a command on the computer, as well as which system would interfere less in carrying out the key operation

Usability	
	A system that looks as "normal" as possible

2.4 SCI MAMEM Contraindication

In light of the literature review and the conducted focus group, several contraindications were raised regarding the use of a platform based on reading eye movements and brain signals, related to the clinical condition of SCI patients. These are clinical features that we believe prevent a subject to use the platform. The rational for naming those is to limit the challenges both on technology and on the users. For example, subject with involuntary eye movements will most likely encounter frustration when trying to use an eye tracking based device. Similarly, real-time reading of EEG signals in the presence of deep brain electrical stimulation (sometimes seen in PD patients) is an extreme technological challenge. The contraindications were laid out by clinicians and health professionals from the clinical sites.

1. Involuntary eye movements
2. Implanted devices that may interfere with the brain electrical activity recording by the - EEG
3. Medical conditions that may induce seizures.
4. Brain conditions such as brain trauma, brain surgery, stroke that may interfere with the brain electrical activity recording by the - EEG
5. Any psychiatric or cognitive conditions that may interfere with understanding the instructions or with user cooperation

2.5 An example of a user scenario

We describe for SCI patients a foreseen typical scenario for the use of the MAMEM platform that was scripted based on the results of the focus groups and the literature survey.

Ms. Cohen is a 45 years-old woman with C4, AIS C chronic tetraplegia following a road traffic accident five years ago. She has very limited movements and sensations in her upper limbs. She lives with her husband and has two children. She spends most of her day in a motorized wheelchair, controlling it by moving a joystick with her wrist. Her caregiver assists her in her basic activities of daily living. Her caregiver together with her husband and two kids are taking care of the household management (e.g., cooking; laundry etc.) Her participation in outdoor activities is limited and she spends most of her time home. She receives social security support and currently is looking for a job she can do from her house.

Ms. Cohen wants to use the computer to check her Facebook page wall. She moves to the computer work station and asks her care-giver to assist her with the placement of the MAMEM cap and glasses. Next, Ms. Cohen asks her caregiver to turn on the computer. Once turned on, the MAMEM software automatically starts and asks Ms. Cohen to begin the calibration routine. In this process the software loads the profile of Ms. Cohen. This profile already has been calibrated to Ms. Cohen's EEG patterns, eye movement patterns and personal preferences. Although Ms. Cohen approves it, the program instructs Ms. Cohen to perform visual calibration by moving her gaze to the four corners of the screen for a few seconds. Later, the software instructs her to perform EEG calibration by mental reading the words from a predefined list that appear on the screen and then disappear.

After settling in, Ms. Cohen moves the cursor using her gaze to open the internet browser and then selects "Facebook" from the bookmarks drop menu. Next, by moving the cursor with her gaze, she selects the password placeholder and a virtual keyboard appears. Then, she point on the letters comprising her password using her gaze and selects them using her thought. Once finished, she points and selects "Enter" and her Facebook page appears. She reads the posts on her wall and scrolls down with her gaze while reading. When she sees an old friend's exciting new post, she starts posting a comment on it. Suddenly, she receives a video call request from her son in the Facebook messenger. She thinks "answer", and has a short video chat with him using the webcam. Her son tells her about a home job opening and gives her the details. Later, she will call them and try to apply for the job.

3 PARKINSON’S DISEASE - CLINICALLY DRIVEN, DISEASE-SPECIFIC PHYSICAL AND TECHNICAL REQUIREMENTS

3.1 Literature review

3.1.1 Clinical background

Parkinson’s disease (PD) is a common neurodegenerative disorder affecting approximately 1% of the population over the age of 60 years [17, 18]. It has an age-adjusted frequency of 1.3 cases per 100.000 people younger than 45 years of age and 3100 cases per 100.00 in those aged 75-85 years [18]. The median age of onset is 60 years although 15% of cases present before the age of 45 year [17]. PD is characterized by motor symptoms that are bradykinesia (akinesia), tremor at rest, rigidity, postural instability, flexed posture and freezing [19]. However the clinical spectrum of PD is more extensive covering a wide range of non-motor symptoms including neuropsychiatric manifestations (cognitive impairment, depression, anxiety, psychosis, apathy, compulsive disorders), sleep disorders, autonomic dysfunction (constipation, urinary and sexual dysfunction), sensory symptoms and fatigue [18]. The pathological hallmarks of the disease are the loss of the dopaminergic neurons in the substantia nigra, causing dopamine depletion in the striatum, and the presence of Lewybodies in the surviving neurons. However a-synuclein deposition, neuronal loss and Lewy bodies are found not only in substantia nigra but also in other brain regions (locus coeruleus, raphe nucleus, pedunculopontine nucleus, olfactory bulb, dorsal motor nucleus of the vagal nerve, nucleus of Meynert and cerebral cortex) and as well as in the parasympathetic and sympathetic post-ganglionic neurons [19]. Levodopa is the most effective treatment for motor symptoms of PD. Other treatment options include dopaminergic agonists, COMT inhibitors, MAO-B inhibitors, amantadine, anticholinergics and deep brain stimulation [20].

Psycho-social factors: Motor and non- motor symptoms in PD patients have substantial implications for their social life. A hypophonic monotonous speech or a fixed facial expression can be embarrassing and are potentially ostracizing symptoms. Leisure activities that involve going out or relies on physical dexterity, can become difficult to maintain and lead to social isolation. Feelings of shame or stigma can result where a lack of social competence is perceived. Health related quality of life is severely compromised in PD patients in multiple domains and although disease specific disabilities are cardinal factors emotional and social aspects play an important role, too [21-23].

3.1.2 Factors affecting the ability to use computer for patients with Parkinson's disease

Bradykinesia: defined by slowness of movement, it is the main symptom of the disease and it encompasses difficulties with planning, initiating and executing movements and with performing sequential and simultaneous tasks [28]. The pathophysiology of bradykinesia is not fully understood. According to Wu et al [29] *defective motor automaticity is likely an important reason contributing to bradykinesia in PD; the impaired striatum plays a key role in supporting automatized motor programs and helping to acquire new automatic skills and restoring lost motor skills.* The initial manifestation is slowness and difficulties in performing activities of daily living, especially with tasks requiring fine motor control (deterioration in handwriting, buttoning, using utensils). Patients perform increased number of typing errors, repeating typed character or constant missing of the intended character in the computer keyboard and have difficulties using mouse.

Tremor: Almost 90% of the patients show tremor at rest at some stage of the disease [frequency 3-7 Hz, most commonly 4-6Hz] and 10% also had a postural/kinetic tremor with equal or higher frequency [19]. Tremor affects various body parts e.g. hands, feet, jaw, feet. Head tremor is rare and it is not a characteristic of PD. Tremor can be very mild but in some patients it can be severe and continuous producing significant disability [30].

Postural impairment: appears as the disease progresses to more advanced stages. The classic stooped posture is the most common postural deformity observed in individuals with PD. However in addition to the characteristic flexed posture, up to one third of PD patients have deformities of their neck or trunk that may include camptocormia, anterocollis, Pisa syndrome and scoliosis [31-32].

Disease progression: PD is a chronic neurodegenerative disorder with a relentlessly progressive course. The progression is driven both by progressive nigrostriatal degeneration and degeneration of other multiple brain areas. On a clinical level, disease progression is reflected by the increasing severity of motor symptoms as well as by the evolution of poorly levodopa responding symptoms and the development of non-motor symptoms. While in the early stages of the disease patients are completely autonomous as the disease progresses patients become severely disabled needing assistance in almost all activities of daily living. The Hoehn and Yahr scale is used to assess clinical disease staging [33].

Levodopa – induced complications: Levodopa is the most effective antiparkinsonian agent and almost all patients will receive the drug at some stage of the disease. However, with disease progression, patients start to experience levodopa-induced complications such as periods of reduced benefit (levodopa-induced fluctuations), periods of motor improvement but with hyperkinesias and fluctuations in non-motor symptoms [34]. Overall, 10% of patients per year develop motor fluctuations after the initiation of levodopa. Predictable wearing off (gradual re-emergence of parkinsonian symptoms at the end of a levodopa dose) is the most common fluctuation. Other types of motor fluctuations are unpredictable-sudden offs, dose failure, delayed or partial response and on-off fluctuations. In advanced disease the fluctuating response is the most prevalent complaint causing severe disability. In association with motor fluctuations patients develop involuntary, hyperkinetic movements such as peak dose dyskinesia, diphasic dyskinesia and off period dystonia that are troublesome in only 40% of patients. Furthermore many non-motor symptoms (neuropsychiatric, autonomic, sensory/pain) can fluctuate in response to levodopa [35].

Mild cognitive impairment – Dementia: In PD there is a wide spectrum of cognitive dysfunction, ranging from mild cognitive impairment (MCI) to dementia). Mild cognitive impairment is defined as cognitive decline that is not normal for age but with essentially normal functional activities. The prevalence of MCI using the MDS PD-MCI criteria ranges from 20% - 60%. It is found early at disease course even at the time of diagnosis and prior to initiation of dopaminergic therapy. Executive function is the most common cognitive domain affected in PD, early on as well as later on. Executive impairment can be disabling because it interferes with social and occupational functioning; patients report impaired concentration, problems with retaining information while undertaking daily tasks and reduced organization skills. Other cognitive domains affected are attention, explicit memory and visuospatial function. Visuospatial deficits (assessed by line orientation test, memory for spatial location, 3D mental rotation) and visuoperceptual impairment (assessed by object detection, categorization of visual stimuli, face recognition) are common in PD. Dementia, which can occur in up to 80% of patients over the long term, is a troublesome complication in advanced disease and affects quality of life, caregiving and socioeconomics [36-38].

Apathy: Apathy is a frequent neuropsychiatric disturbance that can precede the onset of the first motor symptoms of Parkinson’s disease. Depending on the diagnostic methods used, apathy is diagnosed in 20–36% of new-onset patients who have not been treated with drugs. In early-stage Parkinson’s disease, apathy seems to decrease after introduction of dopaminergic treatment, but its frequency increases again to 40% inpatients without dementia and to 60% in patients with dementia after 5–10 years of disease. Apathy is a key symptom of the worsening of Parkinson’s disease as the disease progresses, predictive of decreased functioning in activities of daily living, decreased response to treatment, poor outcome, and diminished quality of life and it is a major contributor to caregiver emotional distress [39].

Depression – Anxiety – Fatigue – Pain: ***Depression:*** The prevalence of clinically relevant depression in patients with PD is 30-40% [40]. Major depression is found in 17% of the patients, minor depression in 22%, dysthymia in 13% and subthreshold depression in 8%-28%. Depression occurs early in PD in around 10%-15% of patients. Although the exact etiology of depression is still unknown numerous factors contribute to depression in patients with PD, such as psychosocial stress, changes in neurotransmitters availability and function, cortical and limbic Lewy bodies, pain, etc. ***Anxiety:*** The prevalence of anxiety in PD ranges from 24% - 75%. Different types of anxiety disorders have been described in parkinsonian patients, such as panic attacks, generalized anxiety disorder, obsessive-compulsive disorder and social phobia [41]. ***Fatigue:*** Fatigue affects approximately 58% of patients with PD. It is a major cause of disability and reduced quality of life. The pathophysiology of fatigue is unclear and treatment effects is limited [42]. ***Pain:*** Pain is a common nonmotor symptom in PD with a prevalence ranging from 30%-83% [35]. Pain has a multifactorial origin (musculoskeletal, chronic pain, fluctuation-related pain, nocturnal pain, oro-facial pain, radicular pain etc.) and reduces quality of life.

Oculomotor function: PD has significant effects on the ocular motor system. Some abnormalities can be detected in the clinical examination but others are evident in laboratory testing. A broad variety of oculomotor alterations have been found in PD, such as impaired smooth pursuit, increased latency of visually guided reactive saccades, reduced saccadic gain and difficulties to inhibit unwarranted reactions [43]. Anderson and MacAskill [43] in a review article reported that patients with PD in the clinical examination show mild hypometria of upwards voluntary saccades and mildly impaired smooth pursuit. These patients in the laboratory investigation show reduced gain (hypometria) of voluntary saccades and in the presence of dementia increased latency and reduced gain of reflexive voluntary saccades, together with antisaccades errors. Pinkhardt et al [43] found in PD patients treated with oral medication or DBS increased saccade latency, reduced smooth pursuit eye movement gain and reduced frequency and amplitude of self-paced rapidly left-right alteration voluntary gaze shifts. None of the oculomotor parameters correlated with the UPDRS scale. Terao et al [45] reported *hypometria in all saccade paradigms and impaired initiation of internally triggered saccades such as memory guided saccades (MGS), whereas visually guided saccades (VGS) are relatively spared, although they are also mildly affected. The ability to inhibit unwanted saccades is also impaired. Saccade abnormalities in PD may be caused by the excessive inhibition of the superior colliculus (SC) due to the increased BG output and decreased activity of the frontal cortex-BG circuit, as well as impaired suppression of reflexive saccades that may be explained by the ''leaky'' suppression of the SC. Treatment of PD, such as L-dopa therapy and deep brain stimulation, works by normalizing these abnormal BG functions, but in different ways.* Linder et al [46] found correlations between total axial motor scores and vertical saccade velocity and precision and smooth pursuit gain at 20 and 30 degrees per second.

Ophthalmological features: Many complaints and deficits have been reported in patients with PD, ranging from blurred vision and diplopia to impairments of contrast and color discrimination, reduced recognition of facial expression and impaired motor detection. Nowacka et al [47] reported significantly reduced distance and near best corrected visual acuity, contrast sensitivity and color discrimination and increased frequency of convergence insufficiency. Concerning contrast sensitivity they found that *the photopic contrast sensitivity without glare was significantly decreased in PD patients compared to controls in all 4 examined spatial frequencies when analyzed by number of correct localized gratings. The photopic contrast sensitivity with high glare was significantly more reduced in the PD group only for 2 spatial frequencies: 3 cyc/deg and 12 cyc/deg. Results of 6 cyc/deg were of borderline statistical significance (p=0.055), while 18 cyc/deg were statistically irrelevant.* Finally Hanuska et al [48] reported the latency of convergence and divergence was significantly increased in PD subjects. Additionally, divergence was slow and hypometric, while other convergence metrics were similar to controls.

Electroencephalographic findings: Severe PD may produce diffuse changes in the EEG that is diffuse theta and delta slowing. Using quantitative EEGs Serizawa et al. [49] found diffuse slowing in the qEEG in parkinsonian patients compared to controls. The slowing of the EEGs becomes more obvious with disease progression [50]. Furthermore the slowing was more frequent with serious cognitive impairment [51]. Mostile et al [52] applying a Welch's periodogram to electroencephalographic signal epochs recorded from homologous pairs of electrodes over each hemisphere reported that *in mid/lateral frontal regions higher index of lateralization for the beta band (p = 0.015) and lower index of lateralization for the theta band (p =0.036) were found in PD subjects as compared to controls. Both parameters correlated with Hoehn-Yahr staging (beta: r = 0.428, p = 0.012; theta: r = -0.464, p =0.006). In occipital region lower index of lateralization for the alpha band was found in PD correlating with L-dopa short-duration response magnitude (r = 0.456; p =0.007).* Beudel et al [53] found that bradykinesia in Parkinson's disease correlates with EEG background frequency and perceptual forward projection. Furthermore according to Berendse & Stam [54] cross-sectional EEG and MEG studies showed that Parkinson's disease is characterized by changing patterns of disturbed neural synchrony that appear to be dependent on the stage of disease. Some of these alterations in neural synchrony may directly account for a number of disease-related impairments in motor and cognitive functions.

Event related potentials: particularly P300 provide a means of measuring cognitive processing. P300 latency is significantly prolonged in PD patients and is correlated with disease severity and cognitive impairment [55-56].

Bereitschaftspotential: Various components of pre-movement related potentials particularly readiness potentials (bereitschafts potential) have been reported abnormal in PD. The most pertinent findings are amplitude reduction over the precentral areas and deformity or disorganization of the wave form. However there is a lot of controversy concerning the magnitude of this neurophysiological impairment since there is a lot of heterogeneity between the PD patients studied and conditions of measurement [57].

3.1.3 Patients with Parkinson's disease and use of computer

There are very few studies concerning computer use of patients with PD. Begnum [24] in a survey of 794 individuals with PD in Norway found that computers are used frequently by patients (75% use computer - 55% on a daily basis and 20% on weekly basis), although older patients (>65 years) reported not to use a computer. Overall 79% of the patients consider computer use an important part of their everyday life. 77% of the patients reported significant and severe troubles using computers. The most common problem areas were inertia, muscle stiffness, tremor, using a standard computer mouse and using a standard keyboard. Most of them did not have any acquaintance with alternative PC peripherals. Keates & Trewin [25] observed that users with PD tend to show a lower peak velocity when moving the mouse cursor and spend more time pausing and aligning the cursor before clicking, compared to able-bodied users. Begnum & Begnum [26] more recently described usability tests of standard peripherals for use by people with PD in order to identify optimal combinations with respect to the needs of this user group. Different peripherals' suitabilities were determined based on their documented effect upon inertia, muscle stiffness, tremor, pain, strain and coordination. In a group of 8 patients with Parkinson's disease they tested the usefulness of 19 mouse adaptations, 10 keyboard adaptations and 4 ergonomic adaptations. Using a computer mouse poses two problems for the parkinsonian patients: controlling the mouse pointer and clicking the mouse buttons. The tests show that improving one of these issues unfortunately often further complicates the other. Trackball mice were found appropriate for improving control of the mouse pointer, especially when tremor is the main problem. Furthermore the IBM Assistive Mouse Adapter filter for tremor was useful in some cases. No general solution was found to improve mouse clicking. The results of the study showed that touched based computer interaction could prove a solution to both challenges related to mouse usage. Concerning keyboards ergonomic/split keyboards were beneficial mostly reducing stress, but not necessarily resolve any specific challenges related to the use of keyboards. Finally, different arm rests were found beneficial and well suited to ease ergonomic issues, tremor, fatigue and pain.

Lastly, Burns et al. [27] reported in their review paper that brain-computer interface in PD has been applied only for research purposes.

3.2 Focus group

3.2.1 Arranging the focus group

As part of the development process of a computer use supporting system for patients with Parkinson’s disease (PD), one focus group was carried out amongst a variety of professional stakeholders.

- Neurologists - 2
- Psychiatrist
- Physiotherapists – 2
- Social worker
- Occupational therapist

The 2 neurologists are specialized on Parkinson’s disease and movement disorders and they are in charge for an outpatient clinic for movement disorders which is the busiest in Northern Greece.

The psychiatrist has a long term experience working with patients with Parkinson’s disease and her PhD study was about mood disorders in Parkinson’s disease.

One physiotherapist is doing research on patients with Parkinson’s disease. Her Master was about ‘’Exercise in Parkinson’s disease” and now she is working on her PhD in the field of computer assisted physiotherapy in Parkinson disease.

The second physiotherapist is working with groups of PD patients and has developed a comprehensive program of physiotherapy adapted for those patients, according to their special needs and their disabilities.

The social worker is focusing on persons with motor disabilities and their social integration and she is interested in issues concerning computer use for people with stroke, cerebral palsy and Parkinson’s disease.

The occupational therapist is specializing on occupational therapy for persons with various neurological disorders in general and training for the use of a computer with assistive devices or environmental adaptation, in particular.

Coordinator of the focus group was Sevasti Bostantjopoulou.

The focus group took place at the premises of the Northern Greece Parkinson's Disease Association on July 2nd 2015. It lasted two hours and the whole discussion has been recorded.

3.2.2 Methodology and Findings

Scope of the focus group

Introduction about MAMEM: The members of the focus group were briefly informed about the MAMEM project: The purpose of MAMEM is to help patients with Parkinson's disease to use a computer, providing them with specialized assistive devices that will enable them to overcome their motor disability and operate the computer using eye movements and mental commands.

Goal for the members of the focus group: The members will discuss and provide information and suggestions about the usage of computer by PD patients and the problems and difficulties arising from this computer use.

Background about PD symptoms and problems for a successful life with disability

Neurologist introduction: PD is a common neurodegenerative disorder affecting also patients who are still active in the workforce. PD is characterized by a progressive decline in speed of fine and gross motor function throughout the body, including the extremities, trunk, face, and muscles of the voice and also with inability to carry two actions simultaneously. Other motor symptoms of the disease are tremor at rest, rigidity and postural instability. Also patients present with a variety of non-motor symptoms, especially apathy, depression, anxiety, cognitive defects etc. Fatigue is a common and disabling symptom.

Question: Do you think that motor symptoms affect activities of daily living and quality of life?

All participants agreed that living with Parkinson's disease is a challenge and motor symptoms interfere with basic activities of daily life. Furthermore in patients that continue full employment symptoms may interfere with the ability to carry out their occupational obligations. Activity limitations occur early in the disease and progress over time, necessitating increasing need for support and compromising participation in valued activities and roles. Quality of life is affected by physical disability too.

Question: What is the effect of treatment on motor symptoms?

The neurologists explained that the antiparkinsonian medications, especially dopamine, provide optimal control of movements. However after several years of treatment patients experience a gradual decline in duration of optimal symptom control and motor symptoms appear before the next dose of dopamine (off periods). These off periods can be very severe, causing significant disability. Furthermore patients may experience troublesome involuntary movements (dyskinesias) when the medication is having its peak effect. The physiotherapists and the occupational therapist added that this is a very significant problem that unables the patients to complete a rehabilitation program (the patient starts the rehabilitation program in good motility and then as the effect of the drug fades away the patient in incapable to continue).

Question: Do you think that non-motor symptoms interfere with daily activities?

Neurologists pointed out that PD is associated with symptoms that do not only affect the physical domain with motor disability but also with impairments and restrictions in emotional, cognitive, social functioning and quality of life. Apathy and depression are important non-motor symptom of Parkinson's disease. Apathy is a significant factor in social isolation and physical therapy compliance. According to the psychiatrist behavioral approaches such as constant encouragement and prompting, continuous presentation of new stimuli, activities that catch the patient's interest but do not require much effort, can make a difference. Computer use can open a window to the world for these patients within their home environment. Interaction with other people, particularly friends may function as a volitional "booster", prompting them to action.

The psychiatrist also pointed out that another problem is the aggravation of symptoms during stress *(for example, having houseguests or going out with friends may be a happy occasion but it may also be stressful, and patients frequently describe worsening of their symptoms during these times, going to the doctor also is a stressful event aggravating the symptoms).* So depression, anxiety and stress lead to social phobia and isolation of the patient.

Furthermore "*As the physiotherapist pointed out fatigue and pain discourage some patients from completing a rehabilitation program.*"

Question: Is social life affected by the motor and non-motor symptoms of the disease?

According to the social worker the physical aspects of the disease (e.g., a reduction in the ability to perform activities) combined with stress, anxiety, depression and communication difficulties decrease an individual's social activities increasing isolation. Patients with

Parkinson's disease can feel imprisoned in their unresponsive bodies and incapable of meeting minimal social norms of interpersonal behavior important for creating and sustaining relationships with family, friends, co-workers and others in their social environment.

The psychiatrist pointed out that psychosocial difficulties can be extremely challenging for individuals with Parkinson's disease, for instance, restriction in participation of activities, reduced social contact, or the inability to retain a job.

Withdrawal from social interactions and loss of leisure activities leads to isolation, despair and depression. It can make living with PD utterly unbearable for both patient and caregiver.

Question: Do you think that the use of a computer by patients with Parkinson' disease is really important?

All the participants agreed the major concern about patients with Parkinson's disease is how to maintain usual life status combining physical activity, working capacity and social interactions. So being able to use a computer opens lots of opportunities for the patient with PD, increase potentials for communication and leisure (keep in touch with friends and family, handle correspondence, share experiences with other patients, manage online banking and shopping, search subjects of interest on the internet) and for working capabilities. Furthermore many patients want to know about the research relevant to their disease, new drug developments etc., so by using a computer they can have access to up-to-date information.

Difficulties with computer use for patients with PD

Question: Are parkinsonian patients familiar with the use of a computer?

The general opinion was that Greek aged people are not very familiar with computer use and this also applies for aged parkinsonian patients, especially women. However young patients use computer for communication, leisure and work although they have significant difficulties.

Discussion revealed that patients usually use desk computer, laptops and few of them smartphones. Patients usually use a mouse and a keyboard and they are not familiar with other assistive devices.

Question: Have you noticed that parkinsonian patients experience certain difficulties using a computer?

All participants agreed that due to the tremor and bradykinesia patients are slow in typing and in using the mouse cursor, they make many mistakes and they have problems double clicking the cursor, open a file on the computer, selecting and dragging and using two keys at the same time. Touch screens also are very difficult to handle. They prefer to create a text by dictating than by typing on the keyboard or by touch. However hypophonia and dysarthria may be an extra problem. The neurologists referred also to another problem, the heterogeneity concerning the predominant symptom. In some patients tremor predominates and in others bradykinsesia, so we need to consider each patient separately. Anyhow all motor symptoms produce difficulties in computer use. Main issue that came up is the concern for the periods of severe disability – off periods. Patients who develop severe bradykinesia or tremor during this time will need the help of the caregiver in order to adjust the assistive device for them. Another issue is the dyskinesias during on-time. That means that abnormal involuntary movements could interfere with the assistive device function.

Furthermore they have also a great difficulty in uploading files from external sources e.g. videos/photos from cameras or smartphones to their computers and further processing them. Sometimes besides socializing, according to neurologists point of view, videos of the patient in specific situation may be important to their physician and help the diagnosis of a specific problem without the need of an extra visit. For these reasons Parkinsonian patients need assistive devices or applications and will simplify this process.

Question: Do you think that non-motor symptoms interfere with the use of computer?

Although they are slow in motion and reaction time PD patients do not like a slow computer system. The psychiatrist pointed out that Parkinsonian patients have a narrow attention span and they get easily bored and frustrated when facing difficulties with computer operation and they tend to abort tasks that are complicated. They would prefer assisted devices that enable them to type quickly if not letter by letter but by whole words if possible.

The occupational therapist, the psychiatrist and the neurologists referred to an increasing number of patients with PD show an enhanced artistic creativity particularly in the visual arts and have produced remarkable paintings, ceramics and mosaics despite their motor disability. However there are motor obstacles (e.g. finger stiffness, tremor) that they cannot overcome and they think that computer generated art could be a promising field for them to explore.

All professional stakeholders realize that two other main problems in using the computer are fatigue and pain that enable them to use the computer for a couple of hours only. The physiotherapists pointed out that small periods of rest are extremely helpful in restoring energy and enable the patient to carry on.

Finally the focus group believes that patients have also difficulties in identifying words on the computer screen which are in small print or in low contrast.

The role of the caregiver

The psychiatrist and the occupational therapist discussed the significant role of the caregiver for the well-being of the patient. Occupational therapist PD patients do not need a full time caregiver until the advanced stages of the disease. Mostly these caregivers are members of the patient's family. However even at the beginning of the disease the role of the caregiver is minor, but valuable since his or her support is circumstantially needed to help the patient overcome simple everyday problems, such as buttoning, shaving or performing other delicate tasks. The psychiatrist emphasized on the psychological support provided by the caregiver, even when the motor impairment of the patient is not debilitating. At less advanced stages of the disease the most important role of the caregiver is that of the "cheerleader", motivating the patient to overcome depression and apathy and participate in physical and social activities. Taking into consideration this fact, it seems reasonable that a PD patient's caregiver should be involved in the training of the patient for the MAMEM system and be able to provide assistance with the device adjustment and positioning in front of the computer.

3.2.3 Summary of PD patient's' computer use habits and difficulties

The following table summarizes the most important point regarding PD patients' computer use habits and difficulties raised during the focus group and their implications toward designing assistive devices for these patients. Note that these are not direct requirements from the MAMEM platform but general considerations.

Table 4: Summary of PD patients' computer use habits and difficulties according to a focus group

General group points
The group emphasizes the importance of the computer as a tool for maintaining communication (with friends, relatives and physicians), social interaction and artistic achievements in patients with Parkinson's disease
Parkinsonian patients, especially the young ones, usually use computer (desk computers or laptops) but they have difficulties which do not permit them to use the computer properly
Due to the heterogeneity of symptoms and the variety of non-motor symptoms the needs and difficulties of the patients should be examined specifically per condition and per user
Fatigue and pain are problems that limited computer working time
Apathy and depression decrease patients motivation, the use of a computer will prompt them to action. High level of motivation is required, both to relearn how to use the computer and also how to use the computer fluently
The impact of treatment is also a matter of concern, since patients during off period or with dyskinesias will need external help to adjust the assistive device
The role of the caregiver is important for emotional support and motivation at the early stages and full assistance at more advanced stages, off periods and in case of severe dyskinesias. Caregiver's participation in the training period should be considered as useful

3.3 Summary of requirements

3.3.1 Summary of PD requirements based on a literature review

There are very few literature data addressing directly the problem of assistive devices for computer use by patients with Parkinson's disease (PD). Nevertheless, taking into consideration already known clinical and neurophysiological characteristics of PD patients we can translate this information into specific requirements for the design of brain activity and eye gaze based assistive devices. The following is a summary of the most specific issues of PD that may affect the design of such systems.

Important notice: Patients with PD had a great heterogeneity concerning motor symptom severity, presence of non-motor symptoms (depression, cognitive impairment, apathy etc.), drug treatment response and EEG findings. So the system should be flexible in order to adjust to each patient's specific needs.

Hereafter the summary of the requirements from the literature survey and from the conducted focus group is arranged in two separate tables, one for the literature survey (based on chapter 3.1) and one for the focus group (based on chapter 3.2). Both of the tables consist of two columns: the rational, and the requirement that derives from it. In addition, the requirements were arranged into several relevant dimensions. These tables, along with the matching tables from chapter 2 and 4 are consolidated to one table in chapter 5 and the requirements in that table are prioritized.

Note that the following are mainly clinically described requirements, and they should be translated to engineering requirements based on the technological knowledge of human machine interfaces expertise.

Table 5: Summary of PD requirements based on a literature review

Rational	Requirement
Personalization/Adaption	
The system should be flexible in order to adjust to each patient's specific needs. Patients with PD had a great heterogeneity concerning motor symptom severity, presence of non-motor symptoms (depression, cognitive impairment, apathy etc.), drug treatment response and EEG findings. Patients with Parkinson's disease are in different stages according to disease severity. Also their clinical symptomatology depends on the response of levodopa ("on" phase: good motility, "off phase": impaired motility and presence of disability) so the system should be adapted for some subjects who demonstrate these problems. This is important also during training periods, since some patients should be trained both in "on" and ''off" phases. Adjustment of the assistive device may be more difficult during "off" phase. Impairment of posture even when sitting may be a problem in some PD patients, e.g. abnormal neck flexion, a tendency to lean forward or sideways; these are problems that we must have in mind.	PD patients are a heterogenous group regarding symptoms and posture. The system should be flexible in order to adjust to each patient's specific needs. PD patients respond differently to treatment and tend to fluctuate during the day having "on" and "off" periods. This should be kept in mind during training and at the adjustment of the assistive device

Performance	
The system should be fast and accurate, translate the thought of an action and able to respond to non-muscle commands since Parkinsonian patients show a lower peak velocity when moving the mouse cursor and spend more time pausing. Furthermore patients have difficulties performing sequential and simultaneous tasks, so the system could allow patients to carry two actions simultaneously. Finally Impairment of posture even when sitting may be a problem in some PD patients e.g. abnormal neck flexion, a tendency to lean forward or sideways; these are problems that we must have in mind when designing an assistive device taking into consideration each patient's postural status and the need of individual adjustments of the assistive device according to patients positioning in front of the computer.	PD patients show a lower peak velocity when moving the mouse cursor and spend more time pausing. The system should translate the thought of an action and able to respond to non-muscle commands. PD patients have difficulties performing sequential and simultaneous tasks, so the system could allow patients to carry two actions simultaneously Abnormal neck flexion in some PD patients may create the need for special individual adjustments
Interoperability	
An interface that is able to interact with other common operative systems or able to control alternative electronic devices would be advantageous (e.g., TV remote, electrical wheel chair).Most PD patients use Microsoft windows, so the assistive device must be compatible.	An interface that is able to interact with other common operative systems or able to control alternative electronic devices would be advantageous (e.g., TV remote, electrical wheel chair). Should work with Microsoft windows

Usability	
The system should try to be not very complicated for two reasons: patients with Parkinson’s disease are usually not young (usually above the age of 50 years) having little experience with computer uses. Second, even at the early stages of the disease there is some mild cognitive decline with impaired executive function and visuospatial disturbance. Setup time for the EEG device should be as short without the need for technical experts to setup and calibrate the BCI system manually. Regarding the gaze tracker system, a low number of calibration points is preferred, as calibration can be considered a tedious procedure.	The system should be as simple to operate as possible Possible mild cognitive dysfunction should be taken into consideration Setup time for the EEG device should be as short without the need for technical experts to setup and calibrate the BCI system manually. Regarding the gaze tracker system, a low number of calibration points is preferred. The system should be as simple to operate as possible
Emotion/motivation	
System learnability and use should be as attractive as possible. Depression and apathy are common in patients with Parkinson’s disease. This may result in an unwillingness to participate in any kind of rehabilitative training.. Pain also can lead to impaired concentration and attention. Fatigue which is also common in these patients will prevent them from continuing the training. PD patients need continuous encouragement and positive learning reinforcement during training periods	System learnability and use should be as attractive as possible. Training should include constant encouragement and positive learning reinforcement

Physiology	
Regarding EEG based operating device, the following should be accounted for: •Severe Parkinson disease show generalized theta and delta slowing therefore, an EEG based operating system should be able to provide a solution for subjects with potential different EEG inherent characteristics. •During on phase patients may have dyskinesias involuntary movements of the head, body or extremities producing muscular artefacts that decrease the quality of EEG signals. •Tremor and EEG artifacts. PD tremor is mostly a rest tremor of the extremities or/and chin and lips with a frequency of 4-6 Hz. This tremor can create EEG artefacts and should be taken into consideration. •The designer must consider the fact that eye movements in patients with Parkinson's disease are mildly disturbed with impaired smooth pursuit, increased latency of visually guided reactive saccades and reduced saccadic gain. •Various neurophysiological parameters related to brain activity may appear abnormal in PD patients: •Event-related potentials e.g. P300 latency is prolonged and this prolongation correlates with disease severity and cognitive impairment so designers of the system sensitivity should take this into account.	EEG slowing in some PD patients may interfere with the EEG modality of the system A 4-6 Hz rest tremor may create artifacts Dyskinesias may create artifacts Eye movements in patients with Parkinson's disease are mildly disturbed (impaired smooth pursuit, increased latency of visually guided reactive saccades and reduced saccadic gain),this should be taken into account

•Various aspects of movement related potentials particularly readiness potentials (bereitschaftspotential) with reductions over the precentral areas have been reported, although there is a lot of heterogeneity between patients and conditions of measurement.	

3.3.2 Summary of PD requirements based on a focus group

Table 6: Summary of PD requirements based on a focus group

Rational	Requirement
Interoperability	
	Parkinsonian patients would greatly benefit from assisted devices or applications that will facilitate the transfer of data from other devises such as cameras, smartphones (photos, videos) to their computers in order to upload to social media or send by e-mail to others (physicians included).
Personalization/Adaption	
Adjustment of the screen or working station according to the patient's needs.	There is a need to adjusting the screen to have good contrast and large letters
	The system should be flexible in order to adjust to each patient's specific needs

Performance	
	A system that can distinguish between a movement that is “background noise” (tremor, dyskinesia) and a movement that is aimed at an intentional command
A slow typing system could be a problem and may discourage the patient from using it	Parkinsonian patients would prefer assisted devices that enable them to type quickly if not letter by letter but by whole words if possible
Usability	
	The system should be easily applicable and comprehensive in order not to discourage the patients from using it

3.4 PD MAMEM Contraindication

In light of the literature review and the conducted focus group, several contraindications were raised regarding the use of a platform based on reading eye movements and brain signals, related to the clinical condition of PD patients. These are clinical features that we believe prevent a subject to use the platform. The rational for naming those is to limit the challenges both on technology and on the users.

1. Patients with dementia.
2. Any psychiatric or cognitive conditions that may interfere with understanding the instructions or with user cooperation
3. Implanted deep brain stimulator (DBS) or other electrical medical device.
4. Abnormal involuntary eye movements (Nystagmus)
5. Very severe body involuntary movements/dyskinesias.
6. Diminished visual acuity.
7. Prominent EEG abnormalities e.g. continuous slowing, epileptiform discharges

3.5 An example of a user scenario

We describe for PD patients a foreseen typical scenario for the use of the MAMEM platform that was scripted based on the results of the focus groups and the literature survey.

Mr. Panos is a 55 yrs. old patient with Parkinson’s disease (PD). He has been diagnosed since his mid-forties and now is at stage 3 of the disease. Mr. Panos was a high school teacher but he was forced to early retirement because of Parkinson’s disease at the age of 50 yrs. He lives with his wife who is his informal caregiver and also the “head” of the household, taking care of everything from domestic chores to financial matters. Mr. Panos has moderate to severe tremor of his hands, moderate generalized rigidity and bradykinesia with postural and balance impairment, too. He responds well to medication but for the last two years he has problems with smooth efficacy throughout the day and he has a few off periods lasting 1 hour each, when his manual dexterity is severely compromised and independent walking is difficult. During off periods he depends upon his wife for even his basic needs. During on periods he can move more freely and do most of his everyday chores with little help, but he is concerned about safety issues due to instability which is amenable to treatment. For this reason he is reluctant to go outdoors alone and remains home most of the day reading or watching TV. Before his illness he was very active having a lot of outdoors activities and participated in various professional and social events

After his symptoms become prominent he gradually withdrew from most of his former activities and kept contact only with family and very close friends only. When he was younger he had acquired basic computer skills and he used the computer a lot for his work, pleasure and socializing. While his disease progressed over the years, he had difficulties with computer operation being unable to control the mouse and the keyboard. He kept asking his caregiver to operate the computer for him. The last year after joining the local PD patients’ support group he decided to become more social and started to communicate with other patients through e-mail and Facebook. Initially his wife had to do everything for him but she was not very enthusiastic about this extra burden. Recently using MAMEM assistive system he manages to operate the computer by himself and has increased his operational skills since he can do most of his tasks alone with minimal help from his wife for putting the MAMEM cap and glasses on. He uses a regular desk computer, but he has a special armchair which helps him to sit more upright and facilitates his independent siting and standing. Today he has decided to check his Facebook page wall. He sits comfortably in his arm chair. He adjusts the MAMEM cap and glasses with a little help from his wife and turns his computer on. Once turned on, the MAMEM software automatically starts and asks Mr. Panos to begin the calibration routine. In this process the software begins by assuming the last user in also the current one and loads the profile of Mr. Panos. This profile already has been calibrated to Mr. Panos's EEG patterns, eye movement patterns and personal preferences. Although Mr. Panos approves this, the program still asks that he will do a short calibration by moving his gaze to the four corners of the screen for a few seconds. Later, words from a predefined list appear and after Mr. Panos thinks about them, they disappear.

Once the calibration stage ends, Mr. Panos moves the cursor with his gaze to open the internet browser and then selects "Youtube" from the bookmarks drop menu. Next, the YouTube homepage appears and Mr. Panos examines the newly added videos and the views of his channel. He sees that a video regarding elections in the local PD support group got many views and comments and after watching it, He starts writing a comment himself using his thought and eyes. At this moment his wife enters the room and when she hears about the elections, she prompts him to be more active with the support group and run for the post of the vice president. After a while he closes his comment informing the support group about his active participation in the elections.

4 Neuro-muscular disorders - Clinically driven, disease-specific physical and technical requirements

4.1 Literature review

4.1.1 Clinical background

Neuromuscular disease (or disorder) (NMD) is a very broad term that encompasses many diseases and ailments that impair the functioning of the muscles, either directly, being pathologies of the muscle, or indirectly, being pathologies of nerves or neuromuscular junctions. In general, problems with central (or upper motor neuron) nervous control can cause either spasticity (from upper motor neuron conditions) or some degree of paralysis, depending on the location and the nature of the problem.

Spinal muscular atrophies are disorders of lower motor neuron while amyotrophic lateral sclerosis is a mixed upper and lower motor neuron condition. Muscular dystrophies and inflammatory myopathies are examples of primary muscular (myopathic) disorders. It is obvious and well understood nowadays that the epidemiology and etiology of these diseases is very widebroad and new entities are published and described.

In the following text we will focus on Duchenne Muscular Dystrophy, Spinal Muscle Atrophy, Amyotrophic Lateral Sclerosis and Arthrogryposis as these are the most common diseases among our group of patients.

Duchenne Muscular Dystrophy (DMD): Duchenne Muscular Dystrophy (DMD) is an inherited X chromosome-linked recessive myopathy which affects approximately 1/4200 live-born boys [58]. DMD is characterized by a total, or near-total (<3%) absence of the cell membrane protein dystrophin. The absence of dystrophin results in a steady degradation of muscle fibers that causes progressive loss of muscle strength and functional abilities [59, 60].

Boys with DMD are usually confined to a wheelchair at the age of ten years [61] and have a median life expectancy of thirty years with spinal surgery and assisted ventilation [62]. Although ongoing studies show promising therapies that target the disease cause, there is still no curative pharmacotherapy available and, thus, treatment remains symptomatic. An important aim in the management of boys with DMD is to preserve functional abilities for as long as possible [63]. Delaying the loss of functional abilities is relevant for all activities in daily life and may optimize independence in boys with DMD.

The loss of functional abilities is primarily the result of a progressive decrease in muscle strength and muscle endurance during the course of the disease [61, 64]. However, increasingly limited physical and social possibilities gradually cause a secondary reduction of physical activity. Indeed, the increasing amount of energy a certain activity costs, the increasing frequency of falling (with the need for help to stand up), and the developing fear of falling further reduce leg and arm activities, resulting in disuse of the musculoskeletal and cardiorespiratory systems [65]. The use of an electrical wheelchair limits arm functions (like reaching and lifting) even more, since a top blade and a central operating joy stick force boys to function within the confines of the wheelchair. As the increased sedentary lifestyle results in progressive disuse, secondary physical deterioration will occur in all boys with DMD. Disuse in DMD thus can be defined as the discrepancy between a boy's potential capacity and his actual performance. To emphasize the importance of disuse, previous studies have shown that the presence of hip, knee and elbow flexion contractures is strongly related to the onset of wheelchair dependence [60]. Another example is that boys with DMD have a higher risk of bone fractures due to osteoporosis caused by unloading [66]. Fractures as a result of falling are followed by a loss of ambulation in 20-40 percent of the cases [67, 68]. In these aspects, the well-known saying "use it or lose it" is certainly applicable to boys with DMD.

Spinal Muscle Atrophy: Spinal muscular atrophy (SMA) is a severe neuromuscular disease characterized by degeneration of alpha motor neurons in the spinal cord, resulting in progressive proximal muscle weakness and paralysis. The disease was first described in the 1890s by Werdnig [69] and by Hoffmann [70]. The genetic defect was localized to 5q11.2-q13.3 a century later [71] with the identification of the survival motor neuron gene (SMN) as the disease-causing gene in 1995 [72]. SMA is the second most common fatal autosomal recessive disorder after cystic fibrosis, with an estimated incidence of 1 in 6,000 to 1 in 10,000 live births, with a carrier frequency of 1/40-1/60 [73, 74]. SMA is clinical classified into four phenotypes on the basis of age of onset and motor function achieved [75] (Table 1).

Table 7: Clinical classification criteria for spinal muscular atrophy

	Age of onset	Highest function achieved
Type I (Werding-Hoffman disease)	0-6 months	Never sit
Type II (intermediate)	7-18 months	Sit never stand
Type III (mild, Kugelberg-Welander disease) in adulthood	>18 months	Stand and walk during adulthood
Type IV (adult)	2-3 decade	Walk unaided

Clinical features are highly suggestive for the diagnosis of SMA particularly in the severe variant of a floppy baby or weak child. The attentiveness and intellect is always good. The weakness is usually symmetrical and more proximal than distal; generally it is greater in the legs than in the arms. The severity of weakness correlates with the age of onset with delayed motor milestones according to clinical classification. Sensitivity is preserved and deep tendon reflexes are more or less involved depending on age at onset and duration of the disease. In the most severe form moreover other clinical features include: impaired head control, weak cry and cough, swallowing and feeding difficulty, atrophy and fasciculation of the tongue and the infant relies on the diaphragm for breathing and abdominal breathing.

Amyotrophic Lateral Sclerosis: Amyotrophic lateral sclerosis (ALS) is a motor neuron disease. The clinical features of ALS are those of progressive neurological deterioration involving the corticospinal tract, brainstem and anterior horn cells of the spinal cord [76, 77]. Clinical, pathological and genetic advances indicate heterogeneity in phenotype, pathological substrate and genetic predisposition, suggesting that ALS should be considered a syndrome rather than a single disease entity [78–80]. The clinical presentation and progression of ALS varies considerably. The course is inexorably progressive and over 60% of patients die within 3 years of presentation. Of the remaining patients, up to 10% survive for more than 8 years [77]. ALS is familial in 5% of cases, and shows a Mendelian pattern of inheritance [81]. At least 15 genes have been associated with the various types of familial ALS, and variants in these genes account for 30% of these cases [78]. Sporadic ALS is considered to be a complex disease, in which genetic and environmental factors combine to increase the risk of developing the condition. The establishment of multidisciplinary ALS clinics has begun to present rich clinical, genotype and epidemiological data that can help to provide insights into this heterogeneous disease [82]. In populations of European extraction, ALS is more common in men than in women by a ratio of 1.2–1.5:1 [82, 83]. Careful evaluation of populations over a period of more than 10 years has indicated that the adjusted age-specific incidence of the disease is not increasing [84]. The incidence of ALS in Europe is 2–3 people per 100,000 of the general population, and the overall lifetime risk of developing the condition is 1:400 [85–87] and reduced in populations of non-European or mixed ethnicity [87, 88] and that genetic admixture might be protective [71]. The varied presentations of ALS [89] are also crucial to the understanding and development of measures of disease progression [90]. The identification of specific phenotypes has important implications for patients, particularly with regards to prognosis and survival, but also for their enrolment in clinical trials. Because no therapeutic drug is available, treatment is primarily symptomatic.

Arthrogryposis: Congenital contractures can be divided into two groups: isolated contractures (affect only a single area of the body) and multiple contractures (affect two or more different areas of the body). The term Arthrogryposis is often used as shorthand to describe multiple congenital contractures. Arthrogryposis is not a specific diagnosis, but rather a clinical finding, and it is a characteristic of more than 300 different disorders [93-95]. The overall prevalence of arthrogryposis is one in 3000 live births [96]. The inheritance, natural history, treatment guidelines, and outcomes of arthrogryposis vary among disorders, indicating the importance of making a specific diagnosis in each child [93, 97-103]. To establish a differential diagnosis, it is important to first decide whether a child has normal neurological function. A normal neurological examination suggests that arthrogryposis is due to amyoplasia, a distal arthrogryposis, a generalized connective tissue disorder, or fetal crowding. In contrast, an abnormal neurological examination indicates that movement in utero was diminished as a result of an abnormality of the central or peripheral nervous system, the motor end plate, or muscle. Amyoplasia is a distinct form of arthrogryposis with characteristic clinical features: the shoulders are usually internally rotated and adducted, the elbows are extended, the wrists are flexed and ulnarly deviated, the fingers are stiff, and the thumbs are positioned in the palm. In the lower limbs, the hips may be dislocated, the knees are usually extended, and the feet have severe equinovarus contractures. Most patients have normal intelligence. Clinical series [102] have shown that 84% of the children have symmetric involvement of the upper and lower limbs; other variations of presentation include upper limb only, lower limb only, or asymmetric patterns of involvement. The goals of initial treatment are to mobilize the joints, apply splints for improved position and function, and to provide physical and occupational therapy as well as instructions to the child's caregivers so that they may provide home therapy. With multiple orthopaedic and rehabilitation interventions, the ability to walk and perform activities of daily living has been reported to be as high as 85%. Characterization of the genetic and molecular basis of the arthrogryposis syndromes has served as a valuable framework to identify genetic risk factors for congenital contractures.

4.1.2 Psychology and quality of life

Having a neuromuscular disorder negatively influences the quality of life in several domains: gross and fine motor functioning, daily activities, vitality, and depressive moods. There are also reported problems in the areas of pain, aggressiveness, sleeping and social functioning with some differences between males and females patients. Adaptation to NMDs requires major changes in physical and functional independence, as well as an extended period of rehabilitation and readjustment. On average, NMDs have been associated with reduced quality of life, lower life satisfaction and increased frequency of depression and anxiety.

These disorders have a direct impact on thinking and behavior [104-106]. The most important impacts are:

- Behavior becomes embarrassing, childlike, inappropriate, or uncharacteristic
- Loss of judgment with regards to making decisions or making a decision that reflects a strong departure from views the person expressed in the past
- Inability to concentrate or to shift focus from one activity to another
- Fixation on a single idea or activity with a need to repeat the concern or repeat the activity
- Loss of spelling or loss of word meaning. Says sentences that convey little meaning
- Cannot follow instructions to complete physical therapy/occupational therapy/speech therapy exercises, stretches, or guidelines such as swallowing precautions
- Difficulty remembering what he/she intends to do

4.1.3 Computer and internet use

Persons with motor-related disabilities are often unable to use a standard keyboard. And so, alternatives have been developed. However, for an individual with motor and speech impairments these solutions are problematic because they lack efficiency. For example, scanning solutions are typically very slow although they require only a single input in the form of a switch activation. Another limited option is speech recognition. Text entry using speech can be fast, but speech recognition requires the ability to enunciate clearly. Such a model is not an option for a user with a neuromuscular disease because of dysarthria. Questions therefore arise on how to support users with motor and speech impairments who are forced to invest considerable effort and time to work with a standard keyboard because other options are unacceptably slow or inaccessible? All these parameters should be taken into account when working with NMDs patients.

Like any communication or control system, a BCI has the following parts: a) Signal acquisition, b) Signal processing: feature extraction, c) Signal processing: the translation algorithm, d) The output device, and e) The operating protocol.

All the above should be taken into account when designing a BCI system. In general all the patients express a strong interest to obtain a BCI system. For the majority of the patients an electrode cap is much more accepted than an outpatient surgery or a surgery with a short hospital stay in order to obtain a BCI. It is widely accepted that assistive technologies can ameliorate the effects of progressive declining motor function. However there are a number of factors that seriously limit the use of such technologies.

In a survey done by Huggins et al. [107] with ALS patients regarding the desired BCI features priorities, it was found that 63% of the subjects currently use a computer while the rest have stopped. Of those using a computer, 48% use them daily and 87% are connected to internet. No information was supplied regarding the preferred computer type or the operating system. To the best of our knowledge, no similar survey was done regarding other NMD patients' group and BCI use (e.g. for DMD, SMA).

4.1.4 Factors limiting the clinical application of brain-computer interface for NMD patients

NMDs disrupt the neuromuscular channels through which the brain communicates with and controls its external environment. These diseases impair the neural pathways that control muscles or impair the muscles themselves. Those most severely affected may lose all voluntary muscle control, including eye movement and respiratory motion, and may be completely locked into their bodies, unable to communicate in any way. Modern life-support technology can allow most individuals, even those who are locked-in, to live long lives, so that the personal, social, and economic burdens of their disabilities are prolonged and severe.

Progress in computer technology also includes the development of new methods to help individuals with disabilities enter text through a keyboard alternative. Earlier systems use basic techniques such as word prediction to facilitate input. Although operating a word prediction utility in the simplest form still relies on keyboard input, such an alternative is, in some sense, just an enhancement of the standard device. Growing computational power makes it possible to analyze spoken words and even video recordings online. Thus, speech recognition or eye tracking have emerged as alternatives. Eye tracking for text entry amounts to moving a mouse pointer across an on-screen keyboard. Thus, eye tracking is simply a pointing device alternative. To date, there are methods that use an input device different from the standard keyboard without requiring extensive computational power.

The adoption of BCI devices from laboratory to clinic, especially when dealing with NMDs patients holds several implications. It is likely that introducing the use of a BCI device to a patient will occur within a team setting. As with more conventional augmentative alternative communication devices, the BCI device may be introduced, demonstrated, and implemented by a team of professionals. A number of studies have been performed in order to evaluate the patients’ needs, to register their opinions and their priorities. According to J. Huggins et al [106] people with ALS have a great interest in BCIs for many tasks. When designing a BCI, accuracy, setup, simplicity, stand-by mode reliability and many available functions should be taken under consideration. People with advanced ALS can decide whether the effort of a specific technological solution is worth the functional gain. A willingness to accept less performance as impairment increases is demonstrated by significantly lower ratings of feature importance when tested with the response relay groups. Desired performance levels, however, did not vary by response group. Survey respondents [107] reported desired BCI performance as providing at least 90% accuracy, accidental standby mode exits only once every 2-4 hours, and speed of at least 15-19 letters-per-minute. The common co-incident occurrence of visual and auditory impairments and the prevalence of impaired gaze control should be considered during BCI design.

During another study, Nijboer et al [108] demonstrated that BCI technology can be moved out of the laboratory and into a home environment. The participants in this study received a great deal of support from highly trained laboratory members. For BCI to become a practical technology embraced by many, the required amount of expert supervision and the time required for setup and cleanup must be reduced; improvements in the comfort level and robustness of the equipment are also required [109]. Moreover, at present, the speed of online BCI systems is slow and requires patience from the user to effectively operate the system. It may be possible to significantly reduce this amount of time and increase the number of selection per minute without a reduction in classification accuracy.

4.2 Focus group

4.2.1 Background and methodological notes

- Loss of the voluntary muscular control while preserving cognitive functions is a common symptom of neuromuscular disorders leading to a variety of functional deficits, including the ability to operate software tools that require the use of conventional interfaces like mouse, key-board, or touch-screens.
- As a result, the affected individuals may be marginalized and unable to keep up with the rest of the society in a digitized world.
- Promising advanced technologies, like multimedia authoring using the eyes and mind may give back such individuals their freedom and autonomy, as well as the ability to be integrated socially, more functional and more productive for themselves

MAMEM's goal is to integrate people with disabilities back into society by increasing their potential for communication and exchange in leisure (e.g. social networks) and non-leisure context (e.g. workplace).

As part of the development process of a computer use supporting system for NMD patients, three focus groups were carried out amongst a variety of professional stakeholders. The composition of professional participants:

- Doctor
- Nurse
- Social worker
- Health psychologist
- Occupational therapist
- Physiotherapist

The focus groups took place in MindSearch facilities and in Iatriki Askisi facilities on the 3rd , 4th and 5th of July 2015. The participants were sought out of MDA Hellas resources of professionals associated with NMD’s. One of the largest Rehabilitation Centers in Athens (Iatriki Askisi) also provided their list of candidates. All participants had experience with the specific diseases. All volunteered to participate and were on time and very eager to discuss the MAMEM project and the requirements needed for its implementation. They were divided in three groups , one specialist of every profession in each group.

4.2.2 Findings

Characteristics of NMD and the role of computer in rehabilitation

The issue of the immobility degree and its impact on the NMD patient’s ability for an autonomous existence was referenced by all participants. The participants outlined that there are three major levels of mobility impairment in NMD patients that determine to a large extent:

Muscular impairment without the use of a wheelchair: The experts view this is the milder case, which allows for very wide use of the computer. They express that these patients can be very dependent on the use of the computer for fun and for a social life.

Muscular impairment with the use of a wheelchair: The experts note that it takes a while for the patients to get used to the reality of a wheelchair, and often the use of the computer becomes challenging.

Muscular impairment with the patient bedridden: The biggest challenge here is that patients may be overwhelmed by their dependency on their care givers. Often they are both depressed and passive about using a computer, especially since they have to depend on their care taker extensively in order to use it.

“The toughest situation is with patients who have progressive, degenerative diseases, and who understand that things could get dramatically worse… they are willing to grasp and work on anything that will promise to delay the progressive, expected worsening of symptoms”

“Preserving the positive morale of these patients is a priority”

“What is extremely tough for all patients with motor disabilities is their dependency on care takers, who are often overtired and overburdened… it is clear that the quality of care these patients have at home, and the kind of social life they do still have has a major impact on their ability to keep going, preserve a positive attitude and do their best in rehabilitation”

“Tetraplegic patients are not only suffering extremely, themselves, it is also their families that have the toughest time… it can happen that a care giver drops in on the patient every few minutes, to make sure they are fine. This can be exhausting for the patient, who has no privacy, and it can be exhausting for the care takers, who are exhausted and consistently over tired.”

The role of computer in the life of NMD patients is central and highly important, and more so among the younger patients, who have never known their life without a computer. The expert participants in the focus groups mentioned that the patients with fair mobility tend to be fairly intensive users of computers:

"… I have often seen people on the computer for hours on end; there is nothing better for them to do…"

"… Young people spend a lot of time playing games on the computer; it is their own way of having more fun."

"… These are lonely people, the young ones all have Facebook, they meet online, they belong to the same groups, it is their salvation… very important for them"

"… there are people who work online too… we have a graphics designer… she uses head gear to operate the computer and it takes her very long to complete each job, but I am convinced that this work keeps her optimistic and fulfilled, though at the end of each day she is particularly exhausted, and physically and mentally tired."

The current role of the computer in the life of NMD patients

- **Provides a sense of control** over their circumstances, and allows them to still do things for themselves (keep connected, maintain friendships, choose activities, pass the time, have fun)
- **Provides a sense of empowerment**, since with the computer patients can interact with others, make choices, and even earn an income (true of a minority of patients, according to the participants)
- **Helps maintain the social canvas** for the NMD patient: one of the more fulfilling activities for NMD patients was their ability to maintain a Facebook account, and to also participate in groups and fora alongside other patients, creating their own community
- **Provides entertainment** without the engagement of caretakers: It was mentioned that many patients, especially the younger ones can spend time on the computer playing games, watching films, participating in social media, in a way that provides rewarding entertainment without having to engage a care giver (depending of course on the degree of mobility of the patient).

NMD patients' modes of computer use

The participants described that the wide majority of patients use a standard computer (desktop or laptop)

- They use the computer in a sitting position
- A small minority with heavier immobility may be using special devices replacing a conventional mouse. It seems that more sophisticated devices replacing the mouse have minimal penetration in Greece, among NMD patients. The respondents mentioned a head mouse, hand or leg mouse, different kinds of joysticks.
- Some use of computer using phonetic/voice commands (mentioned as being there, but not currently extensively used). Respondents also mentioned that phonetic commands were also used on some occasions to make the use of a mobile phone easier and more effective for the patient.

However, no incidences were mentioned where any of the following were used:

- Gaze focus system (replaces both keyboard and mouse)
- Systems based on giving orders through inhaling and exhaling
- Systems based on vocal control (most participants did not witness such systems in practice)

What respondents emphasized was that the use of a computer does not have to do just with the computer itself, but the major challenge remains having to maintain the posture and position required to use it.

Characterizing difficulties with computer use

The respondents were in agreement, across all of the three focus groups, in relation to the following major challenges in the use of computers:

- **Sitting position**: The sitting position can be a challenge, especially as a disease progresses. Often, the patient has to be strapped to a particular position, which can quickly cause stiffness or numbness, and therefore causes the patient to terminate a computer session. The sitting position is fine with milder cases, but it can be a challenge for patients with more intense mobility issues.

- **Loss of posture while sitting in front of a computer**: When a patient is using a wheelchair, they often lose the correct posture in front of the computer monitor, they slide to the side, or their hand loses contact with the mouse. As a result, the care taker has to be on call to reposition the patient into the correct posture, in order to use the computer
- **Use of the computer while lying down**: A few patients were able to adjust the screen and use the computer while lying down. Most of the time they had created their own "mechanical solutions" allowing them to have an adjustable screen and mouse, using it while lying down. However, this was true of a minority of patients only.
- **Slow work due to spasticity or impaired movement**: It was mentioned that sometimes there are involuntary movements and twitches that cause too many mistakes in operating the computer, and it can be tiring and even exhausting to complete a task
- **Fatigue**: There are many reasons that can cause fatigue, causing a patient to terminate a computer session: the sitting position has caused stiffness, the slow work progress can be tiring, intense concentration during computer use can also be tiring.
- **Duration of each computer session**: Most sessions of computer use seem to last from half an hour to two hours. Those patients who are younger and with fewer mobility problems can spend more hours in front of the computer at a time. Overall, it is mentioned that patients wish they could spend more time on the computer without feeling exhausted. Those with progressive diseases feel increasingly frustrated by their inability to use the computer for longer, as they did in the past.
- **No privacy:** The care taker has to stand nearby or to be on call, to help. This can be especially frustrating when it comes to using the computer for conversations or for browsing material that the patients would desire privacy for.
- **Burden on care takers:** The use of the computer can be a relief for the care taker, in the earlier stages of a degenerative disease, BUT, as the disease progresses, and the care taker has to be there to make the use of the computer possible, then it can be a strain on both the patient and the care giver.
- **Decreasing morale and motivation:** As time goes on, and especially if the disease progresses, the patient loses morale and motivation about keeping using the computer. Increasingly they find that the effort involved is not worth the pleasure and rewards of its use.

Unsatisfied needs of NMD patients regarding computer use and ideas for improvements

Using the keyboard: Using the keyboard letter by letter can be taxing, time consuming and very tiring.

“I wish the keyboard could read my mind”

“I wish I could use the keyboard with my voice”

Accuracy while using the keyboard is a big issue. Those with involuntary twitches and micro movements mention that it can be very challenging to keep writing, correcting mistakes and keep writing.

“I wish there were a way to auto correct my keyboarding mistakes, without all of the effort that I do now”

Using the mouse: Using a mouse can be a real challenge, especially for those with severe motor disabilities. It can be time consuming, effortful, and still there can be lots of mistakes.

“I wish I could operate a mouse with another part of my body that I can control better.”

“I wish there could be a mouse that responds to tiny movements that do not tire me, and this mouse could understand and diagnose if it is an intentional or unintentional movement on my part, so that I end up doing fewer mistakes”

Using the screen: The patients desire to have a screen that can be adjusted to any position. At the moment they use the computer at a sitting position and that creates issues of posture over time.

“I wish there were a screen that would follow the movements of my body, which would stay upright when I am upright, or go sideways, or even upside down, when I am lying on the bed”

Achieving speed: For many, and especially as the disease progresses, there are issues of speed. The use of the computer can be painstakingly slow. Some remember the speed they used to have on a computer when they were healthier, and this can be very frustrating.

“When you take ages to complete a task on the computer… you keep to it, and keep to it… and eventually, there comes a point where you give up.”

Multi-tasking: It is widely mentioned that it is easy to do simple things on the computer, but it can be a challenge to do more sophisticated work, and multiple tasks at a time, for example:

- Select and re touch a picture
- Upload a video and write comments on it

- Search and download at the same time

Use sophisticated software: Using sophisticated software like Photoshop, Illustrator can be insurmountable. There was one case where a patient was mentioned who is a company owner, and seeks to manage their company and their business through the computer. Using accounting, e-banking software, as well as Excel or other software that demands multi-tasking can be a real challenge.

"I wish my frequent activities were coded, so that I might press a specific code key once, and a series of activities would be executed, right away, rather than getting through them one by one…"

Using multiple inter connected devices: Using a camera or a mobile phone or an ipod with the computer can be a challenge in sorting through the movements to do this smoothly.

"If I have to use more devices I have to ask another person to help me do it… I wish I could do more things with just one hand"

Usage speed: Respondents mention that as a disease progresses, even the more devoted participants tend to become frustrated with how tough and tiring and slow the use of the computer becomes, and eventually start to use it progressively less and less, and may eventually altogether give up on it.

"If it is only about pressing Likes on Facebook, life would be easy… but I want to attend e-learning courses, to be able to drag down on a test and press my answers on it, without it being a nightmare and taking forever."

Lack of privacy: A big issue is that of privacy, in that care takers are there and have access to the computer or online activity of patients. Often that frustrates them very much.

"Sometimes I want to visit specific sites… blue sites… I am a normal human being after all, and I do not want my mother to keep track of what I am doing, or to be there, while I am browsing, and it is frustrating that this is unavoidable from some point onward."

Eye movement and brain signal control system: Comments, ideas and demands:

- **Eye strain:** Will it be possible to keep using the eyes to operate the computer, without creating eye strain? How tiring will it be?
- **Learning and adjustment:** How easy will the system be to learn and to adjust to it?

“Is it like I will need to learn HOW to use my eyes to operate this… will it take a long trial and error period, will it frustrate me to actually learn to use this technology?”

- **Concentration fatigue:** Many respondents fear that the use of eyes to operate a computer may result in fatigue even faster than the use of hands.

“Will this cause eye strain?”

“When people concentrate, they squint their forehead, their eyes… will the use of eyes to operate the computer tire them more, mentally?”

- **Sensitivity:** Will the system be sensitive enough to the use of eyes? Participants fear that the system will be oversensitive, and translate even random eye movements into commands, thus creating higher needs to correct and proceed.
- **Accuracy:** Participants mention that an important draw back in the use of a computer is the fact that users eventually lose the accuracy of computer operation due to random, automatic, involuntary movements. They wonder to what extent this will be a problem with the use of an eye/brain operated computer.

4.2.3 Summary of NMD patients’ computer use habits and difficulties

The following table summarizes the most important point regarding NMD patients’ computer use habits and difficulties raised during the focus group.

Table 8: Summary of NMD patients’ computer use habits and difficulties according to a focus group

NMD computer use
One of the major elements that patients’ desire is a sense of self sufficiency and personal independence from their care takers. The chance to take care of themselves a bit better. On many occasions there is strain in the relationship with care takers (especially if they are partners rather than parents). The patients are very self-conscious about having to call on them for everything. The ability to use a computer provides a sense of normalcy, a sense of hanging on to a regular life. This greatly boosts morale. The experts who participated in the research did emphasize that the patients with muscular disabilities often worry whether as their disease progresses; they “might lose one’s mind”. The use of the computer validates their ability to think, respond and function well.

The use of the computer keeps the patients alert and optimistic about getting on, keeping up with life and being active. Last but not least, many of the patients meet fellow patients on line, and also find answers in their more pressing questions about their disease online.
NMD Challenges
Many NMD patients find it very challenging to stay in a comfortable position long enough to use the computer for as long as they would like. Their body slides to the side, and their hand may slide off the mouse. NMD diseases can be progressive, and eventually, progressively, the use of a computer becomes ever more challenging, as the patient becomes easily tired, has many involuntary twitches that slow down the use of the computer and create frustration and tiredness, so that eventually, as the disease progresses, many patients just give up using the computer, or use it less and less. For patients who are bedridden, or in a wheelchair, with severe motor impairments, the usage of the computer can be painstakingly slow. Use of the computer becomes an impossibility, unless the screen can be positioned in a comfortable way, and unless non muscle technologies are used to issue computer commands.
NMD expectations and demands
Patients want and need private moments (especially those taken care of by their parents). Very often they need to express their sexuality online, and this cannot be done with their parents overseeing their activity. They are susceptible to getting tired easily. The chance to handle a computer with speed and fast reactivity is fundamental. Being easily tired, these individuals need technologies that make it easy for them to use technology and do not tax their limited physical and energy resources.

4.3 Summary of requirements

The following is a summary of the requirements from the literature survey and from the conducted focus group regarding NMD patients. It is arranged in two separate tables, one for the literature survey (based on chapter 4.1) and one for the focus group (based on chapter 4.2). Both of the tables consist of two columns: the rational, and the requirement that derives from it. In addition, the requirements were arranged into several relevant dimensions. These tables, along with the matching tables from chapter 2 and 3 are consolidated to one table in chapter 5 and the requirements in that table are prioritized.

Note that the following are mainly clinically described requirements, and they should be translated to engineering requirements based on the technological knowledge of human machine interfaces expertise.

4.3.1 Summary of NMD requirements based on a literature review

Table 9: Summary of NMD requirements based on a literature review

Rational	Requirement
Personalization/Adaption	
The patients' profiles are heterogeneous concerning levels of mobility, symptoms and backgrounds. The system must be flexible and adjustable.	Gather information about the patient's previous interests, technological savvy, literacy level, personality and general mood and motivation.
Performance	
Patients have difficulties performing complicated tasks, and more-or-less unable to take quick decisions. The system must be fast and accurate, taking into consideration each patient's disease status and the need of individual adjustments.	Consider the patients' safety and be careful to guarantee the durability of the BCI. Make it accurate. The naturalness and quality of communication, the client's ability to independently operate it, and client satisfaction are vital.

Usability	
NMD patients are generally young and knowledgeable about computer use and WWW media. However, due to their mobility limitations they need assistance from relatives or nurses that are often older than them and less knowledgeable in computer use aspects. Thus operational simplicity is needed.	Perform initial training. Make it engaging and provide more fun for the user. Increase motivation by providing personal future to the patient. Take into consideration office assistants for specific tasks, accessible office locations, adjustable tables, equipment located within reach, work-related materials available in electronic format, and access to job-related resources on the Internet. Consider accessibility of the working area. It may take longer for individuals with mobility impairments to get from one worksite to another. Avoid any misunderstanding by employing the same (technical) vocabulary and common mother tongues. The instructions to the patients have to be given in his/her mother tongue.

4.3.2 Summary of NMD requirements based on a focus group

Here follows a list of the core expectations of participants, of an eye/brain operated computer usage technology. According to the practitioners who participated in the focus groups, the following areas would provide a significant improvement in the use of computers, in patients’ lives:

Table 10: Summary of NMD requirements based on a focus group

Rational	Requirement
Interoperability	
Multi-tasking is a problem, connecting more devices, like a mobile phone, to a computer, can be a problem.	Easy connectivity of multiple devices, and, in addition, ensure that once connected, the usage of additional devices in the computer becomes “automatic”, through menus of choices that simplify the usage and the required commands.
The steeper the motor impairment, the higher the dependence on care takers. This is a huge blow to morale, to a sense of personal autonomy and control. One of the major requirements of the patients is for “computerized autonomy”. That is, the ability to maximize their ability for autonomy, to stretch as far as possible their ability to take care of themselves.	1. Smart computer posture: the computer enables them to handle their wheelchair and/or bed, that is, to handle the angle and height of their posture, for ultimate comfort while using the computer. In this way, they will be able to use the computer longer, just by virtue of being able to control their physical comfort. 2 simply and swiftly able to handle basic operations in the house via the computer, like: turn lights on and off in their room, turn air conditioner or heat on and off. 3. Media center: they wish for the computer to offer them the simplest possible media operations: turn on and off the TV, the radio, the ipod; choose internet radio stations, browse TV channels. 4. Safety alerts: possibility to view the other rooms in the house, especially if and when the patients are alone at home. 5. Care taker alerts: Signal to care taker that their presence is required. Additionally, opportunity to signal to the care taker that the patient can now (or wishes to) stay alone.

	6. A swift “language-ing” medium: for patients with severe NMD, who have difficulty speaking. They want to be able to have a choice over a library of basic needs that they want to communicate to care takers (I am hungry, thirsty, I need to be turned, I am cold/hot, read to me, etc.) They want to be able to activate their selected command with a single move. 7. Yes – No communication signals: Ability to save their care takers of the need to have to guess on their needs. 8. Reader - The computer either turns the pages of an electronic book, or reads to them at required speed and required intervals.
Personalization/Adaption	
The patient may have a lot of involuntary movements that may disorient the operation and may be mistaken for commands.	There can be a calibration period, in which the system becomes familiarized with the user and is able to create a blueprint of their typical way of intentional commands.
Generally conceived simple actions (for healthy subjects), can be tiring, painful and taking a long time to complete, for an NMD patient. This can be true even for very simple computer commands and operations.	1. It may contextualize what their intention is, and creates shortcuts to different commands and operations, that make it easy and fast to use, as well as particularly time efficient. 2. It may “code” frequent activity and operations and create shortcuts. 3. It offers a library of shortcuts to choose from.

Performance	
The patient may have a lot of involuntary movements that may disorient the operation and may be mistaken for commands.	The computer is desired to be able to calibrate which movements are intentional and which ones are involuntary.
Patients often take way too long to execute even simple tasks, because of their motor and muscle use impairments.	Patients wish for the computer to be able to respond to non – muscle commands. For example: using voice, using blinking, etc.
Using a browser, using a keyboard can be very taxing for patients.	1. Intelligent keyboarding helper: once the intended task is indicated, the intelligent helper provides suggested texts to edit, thus cutting down greatly on time required to type longer text. 2. Intelligent keyboard: can be activated through non muscle operations.
Usability	
The patient often does not want the care taker to be present to some of their computer activity, or to see sensitive content that they use or create.	1. Simple computer "do not disturb" alert commands that signal to care takers when the patient's use of the computer is off or on limits (it can be a sound, or visual signal on the computer, intended for the care taker, signifying start and end times, during which the patient wants to be alone). 2. Passwords using phonetic, eye, finger print identification, bypassing muscle use.

4.4 NMD MAMEM Contraindication

In light of the literature review and the conducted focus group, several contraindications were raised regarding the use of a platform based on reading eye movements and brain signals, related to the clinical condition of NMD patients. These are clinical features that we believe prevent a subject to use the platform. The rational for naming those is to limit the challenges both on technology and on the users.

1. Involuntary eye movements and twitches
2. Implanted devices (pacemaker) that may interfere with the absorption of EEG signals
3. Medical conditions that can cause seizures, such as epilepsy
4. Brain conditions that may affect EEG signals
5. Any psychiatric or cognitive conditions that may interfere with understanding instructions or with cooperation

4.5 An example of a user scenario

We describe for NMD patients a foreseen typical scenario for the use of the MAMEM platform that was scripted based on the results of the focus groups and the literature survey.

Nikos G. is a 26 years old Duchene patient. He has very limited movement in his fingers. He spends his day in a wheelchair specially designed to accommodate his spine but which he can’t control. He lives with his mother and his younger sister who are his caregivers. He requires 24 hour care. Besides the occasional “walk” on the street which is very hard for the mother to navigate, he spends most of his time at home. His financial means are his mother's pension, social security and welfare.

Nikos is a bright cheerful young man. He and his sister share a hobby for photography. He asks his sister to go with him in the living room and to position him in front of the computer, help him with the MAMEM cap and glasses and turn it on.

The MAMEM software starts by asking for a password to verify the settings and preferences already calibrated by Nikos with the help of his sister previously. The screen presents a keyboard with letters and Nikos moves the cursor with his gaze to select three letters that he has chosen to start the program with. The program starts by opening a folder where Nikos sister stores pictures taken by her. The newest pictures appear on top. Nikos gazes at one particular one, selects it and opens the photo editing application. He then goes on selecting filters, cropping it, enhancing the contrast and so on until he is satisfied with the result.

Using his gaze and his concentrated thinking he selects “save picture”. He then proceeds to open his Pinterest account where he uploads the edited picture. He has a very colourful selection and many likes (hearts) and shares and that gives him immense pleasure. After he finishes with that he asks his sister for a little privacy and he uses his gaze to place a video call to an old neighbour of his who is currently living abroad. It has been awhile and they have a lot to talk about, besides Nikos is ready to open a Facebook account now that he can use MAMEM and wants more information about that. This will keep him busy and content for a long time.

5 Summary of requirements – cross-disease and cross-methods integration

In this chapter, we amalgamate all the data gathered from the various processes into a summary table portraying the cross-disease and cross-methods requirements. The following table is a summary of the requirements from the literature surveys and the conducted focus group from all three clinical sites. In The case that there were overlaps of requirements (although not complete overlaps), new requirements were drafted that include the meaning of the overlapping ones. The final list was arranged in a table and divided into the same dimensions that were created in the previous tables. Lastly, the list of requirements was circulated to all of the clinical experts of each site who were asked to code them by priority importance, with numbers ranging between 1 and 7. The scores for each requirement were later averaged. These average scores appear in the priority column and state the relevant importance of the requirement in regards to all of the MAMEM project cohorts.

Table 11: Summary of clinically driven requirements for the MAMEM platform

Clinically driven requirements for the MAMEM platform		
#	Personalization/Adaption	Priority*
1	Familiarizes itself with the characteristics of the individual user and flexible in order to adjust to each patient's specific needs	6.4
2	Compatible with different age or cognitive profiles	5.6
3	A personal identification system that will not require external assistance – such as biometric means of identification	5.2
4	Compatible with different work spaces (e.g., office desk, wheelchair tray)	5
	Performance	
5	System should be safety and durable for each and every type of end user.	7
6	Enable using a computer in a variety of different body positions as well allowing for easy change of position	6.2
7	Enable to transfer photos/videos to the computer and upload to the website or application	6
8	Enable to perform actions that require holding 2 keys on the keyboard or dragging	5.8

9	"Translate" the thought of an action into its required stages	5.6
10	That the question as to which system is used (EEG, Gaze) for which operation, depends on the type of activity the user is carrying out at the time	5.5
11	Carrying out two actions simultaneously such as watching content and responding to it	5.2
12	Fast and accurate performance, that will either make up for or bypass the need to use gross muscles.	5.25
13	To be able to respond to non–muscle commands. For example: using voice, using blinking, etc.	5
	Emotions/Motivation	
14	The training phase could be made more engaging and should provide more fun for the user. Highest motivation is achieved, if the patient is seeing a personal future need in the BCI	5.2
	Interoperability	
15	Should work with Microsoft windows	6.6
16	An interface that is able to interact with other common operative systems or able to control alternative electronic devices would be advantageous (e.g., TV remote, electrical wheel chair)	5.8
17	Be versatile and enable working with new software or visit a website the user has not visited before, without having to make adaptations	5.8
	Usability	
18	To distinguish between a movement that is "background noise" and a movement that is aimed at an intentional command, e.g. To be able to calibrate which eye movements are intentional and which ones are involuntary	6.8
19	Dry or at least "one drop," gel-less electrodes and a "push-button" user interface without the need for technical experts to setup and calibrate the BCI system manually	6
20	Overcome the slow typing problem, by having the user think of a word and the system would know which letters are required to put it together	5.8

21	System learnability should be as easy as possible	5.6
22	The instructions to the patients have to be given in his/her mother tongue	5.6
23	A low number of calibration points is preferred	5.2
24	Appearance - The system should Look as “normal” as possible	5
25	Consider the trade-off between the simplicity of operation and the diversity of functional options	4
	Physiology	
26	EEG/Eye movements error-correction mechanism or algorithm	6.6
27	Tremor generated artefacts (4-6 Hz) and dyskinesia generated artefacts in PD patients should be taken into consideration	5.75
28	Slowing of saccades in PD patients should be taken into consideration	5.5
29	P300 amplitude is decreased in individuals with major depression and P300 latency is prolonged in PD - system sensitivity should take this into account	4.5
* Priority was defined by members of the clinical partners. Each requirement was rated on a scale from 1 (low) to 7 (high). Averaged results are presented suggesting which requirement has high (H: >=6); medium (M: >=5-6) and low (L: <5) priority.		

6 Description of additional input to follow up

The information provided in this deliverable will be complemented by results of serial interviews which are being performed with subjects from the three patient cohorts and their care givers. Here we explain how these questionnaires were constructed and the appendix appearing immediately after presents the questionnaires themselves.

6.1 Construction of questionnaires

The purpose of constructing the questionnaires was to provide a tool to gather information regarding the computer use habits, difficulties and needs of the MAMEM project cohorts, to be able to develop a better assistive device in the future. The target populations to be interviewed are the three patient cohorts and their immediate care givers.

The first stage of building the questionnaires was conducted by searching for already existing questionnaires in the literature. Several suitable questionnaires have been taken in consideration. However, after a closer examination, none of them seemed to fit the exact objectives of the study. In light of this, it was decided that suitable parts will be taken from them and new questionnaires will be developed.

All consortium members were involved in the process of developing the questionnaires, in order to use their experience and knowledge. In particular, we involved the 'technological' partners who later on will be in charge of designing and constructing the platform. In addition, since there are three clinical cohorts in the project, and the questionnaires have to be addressed to all of them, each clinical site was asked to contribute and to suggest questions addressing its own specific cohort.

A first draft of the questionnaires was built and circulated for the first time, for further suggestions and comments. Once feedback was received, the questionnaires were amended in light of it and later a second close-to-final version was circulated. After additional feedback to this version was received, the last version was amended and circulated to the consortium and translated to the local language of the clinical sites (Hebrew and Greek). Then, each clinical site performed a short pilot study by interviewing two subjects, and minor modifications were added based on the experience gathered from these six subjects. Thus a final version was defined (see Appendix A).

Questionnaire structure: Both versions of the questionnaires have three parts. The first one includes demographic and clinical information. The second assess the computer related habits, environment and difficulties. The last part consists of open questions targeted to collect data regarding the needs, missing functions and demands of improvements that the subjects have from the current system and/or assistive device they are using.

Administering the questionnaires: Allowing subjects to self-fill questionnaires has its advantages and disadvantages, yet in the current case, to avoid potential misunderstandings, it was decided that an interviewer will administer the questionnaires. In light of this, specific instructions for the interviewer were added in necessary places and these were written in italics for highlighting purposes.

The difference between the versions of the questionnaires: There were two different versions of the basic questionnaire; one applies to the patient and the other to the patient's care-giver. This was done in order to obtain additional information from a person well familiarized with the daily life of the patient. Initially, we intended to include a third group of interviewees, relatives, yet since in many cases, relatives are also primary caregivers, and different relatives may have different level of exposure to the actual daily life of the patient, it was decided to omit this group.

The two versions of the questionnaires were quite similar with the appropriate differences: the care-giver version contained a few less questions regarding the clinical state of his patient, since it cannot be ascertained that the caregiver will be able to provide this information. This is also the reason the interviewer was instructed to mark 'uncertain' or 'unknown' where applicable in the care-giver version.

In addition to the first two different versions of the questionnaires, there were also three different paired versions of the questionnaires which applied to the three different cohorts of the MAMEM project: Spinal cord injury patients (SCI), Parkinson's disease patients (PD) and neuromuscular disease patients (NMD). Again, although an effort was made to make the three versions as similar as possible for the reason mentioned above, these three paired versions also eventually differed from each other in two points: first, the questions in the clinical information part were different for the three cohorts for obvious reasons. These questions were created by each clinical site members, based on their specific knowledge and experience during the input circulations mentioned above. Second, the PD version contained an extra difficulties mini-questionnaire (see appendix A.2).

6.2 Activities taken in order to obtain the ethical approvals

To obtain the ethical approvals for the questionnaires study, first, unified protocols and consent forms were prepared, according to the Helsinki Declaration guidelines (see appendix B for the protocol). The assumption was that the protocol and consent form will be applied to each cohort and therefore they were made general with options for the investigators to insert the relevant information of their respective cohort. Next, the protocol and consent form were circulated to all clinical sites and translated to the local language. Finally, the protocols and consent forms were submitted to – and approved by - the respective institutional ethical committees. Please see approvals for the study that were issued in appendix B.

7 Conclusions

In this document we completed two processes that allowed us to present clinically driven requirements for wearing and operation of the MAMEM platform by SCI, PD and NMD subjects. The first was a literature survey done by the clinical experts. The second effort was the conduction of three parallel focus groups that took place in each of the clinical centres.

The literature varies with respect to the ability to directly extract clinically driven requirements for a BCI device which encompasses both EEG and eye movement signals. For example in the case of SCI subjects concise recommendations could be found. This is probably related to a clear symptom generally common for this cohort, i.e., full or partial paralysis. On the other hand, in the cases of PD and NMD, where larger heterogeneity both in symptomatically and in pathogeneses, the literature may be too general in terms of recommendations.

The three focus groups, having inter-disciplinary composition of members of clinicians with expertise in the three patients' cohorts, were an effective tool to extract clinically driven requirements. These covered all roundly various disease aspects, including motor, cognitive, mental and social elements.

The two processes lead to the main outcome of this document which is depicted in table 10 that is presented in chapter 5. This table summarizes and prioritizes the requirements.

Contraindications were also identified, i.e., clinical features that: a) addressing them might be and excessive technological challenge; and b) Subjects with these clinical features are likely to become frustrated if try to be using platform.

Examples of hypothetic user scenarios foresee how the MAMEM platform, after incorporating technological solutions that are based on the clinically driven requirements, can be used by a typical patient from each cohort. Taking account the clinically driven requirements can facilitate multimedia authoring by SCI, PD and NMD patients. These examples are aimed to assist the technological partners in imagining the future users of the platform and their use of it while working on its design.

In the next steps we will complement the data obtained from experts (i.e., literature survey and focus groups) with data that will be gathered from the actual potential users and their care givers. This will be achieved by using questionnaires that are also presented here.

8 References

1. Ouzký, M. (2002). Towards concerted efforts for treating and curing spinal cord injury. Concil Eur Doc, 9401, 27.
2. Van den Berg, M. E. L., Castellote, J. M., Mahillo-Fernandez, I., & de Pedro-Cuesta, J. (2010). Incidence of spinal cord injury worldwide: a systematic review. Neuroepidemiology, 34(3), 184-192.
3. Rupp, R. (2014). Challenges in clinical applications of brain computer interfaces in individuals with spinal cord injury. Frontiers in neuroengineering, 7.
4. Maynard, F. M., Karunas, R. S., & Waring 3rd, W. P. (1990). Epidemiology of spasticity following traumatic spinal cord injury. Archives of physical medicine and rehabilitation, 71(8), 566-569.
5. Siddall, P. J., & Loeser, J. D. (2001). Pain following spinal cord injury. Spinal cord, 39(2), 63-73.
6. Vuckovic, A., Hasan, M. A., Fraser, M., Conway, B. A., Nasseroleslami, B., & Allan, D. B. (2014). Dynamic oscillatory signatures of central neuropathic pain in spinal cord injury. The Journal of Pain, 15(6), 645-655.
7. Krassioukov, A. V., Karlsson, A. K., Wecht, J. M., & Wuermser, L. A. (2007). Assessment of autonomic dysfunction following spinal cord injury: rationale for additions to International Standards for Neurological Assessment. Journal of rehabilitation research and development, 44(1), 103.
8. Martz, E., Livneh, H., Priebe, M., Wuermser, L. A., & Ottomanelli, L. (2005). Predictors of psychosocial adaptation among people with spinal cord injury or disorder. Archives of Physical Medicine and Rehabilitation, 86(6), 1182-1192.
9. J. Kemp, J. Stuart Krause, B. (1999). Depression and life satisfaction among people ageing with post-polio and spinal cord injury. Disability & rehabilitation, 21(5-6), 241-249.
10. Craig, A. R., Hancock, K. M., & Dickson, H. G. (1994). A longitudinal investigation into anxiety and depression in the first 2 years following a spinal cord injury. Spinal Cord, 32(10), 675-679.
11. Kennedy, P., & Rogers, B. A. (2000). Anxiety and depression after spinal cord injury: a longitudinal analysis. Archives of physical medicine and rehabilitation, 81(7), 932-937.
12. Bonanno, G. A., Kennedy, P., Galatzer-Levy, I. R., Lude, P., & Elfström, M. L. (2012). Trajectories of resilience, depression, and anxiety following spinal cord injury. Rehabilitation Psychology, 57(3), 236.
13. Diner, B. C., Holcomb, P. J., & Dykman, R. A. (1985). P 300 in major depressive disorder. Psychiatry Research, 15(3), 175-184.
14. Anton, H. A., Miller, W. C., & Townson, A. F. (2008). Measuring fatigue in persons with spinal cord injury. Archives of physical medicine and rehabilitation, 89(3), 538-542.
15. Goodman, N., Jette, A. M., Houlihan, B., & Williams, S. (2008). Computer and internet use by persons after traumatic spinal cord injury. Archives of physical medicine and rehabilitation, 89(8), 1492-1498.

16. Caltenco, H. A., Breidegard, B., Jönsson, B., & Andreasen Struijk, L. N. (2012). Understanding computer users with tetraplegia: Survey of assistive technology users. International Journal of Human-Computer Interaction, 28(4), 258-268.
17. Lees, A. (2010). The bare essentials: Parkinson's disease. Practical neurology, 10(4), 240-246.
18. de Lau, L. M., & Breteler, M. M. (2006). Epidemiology of Parkinson's disease. The Lancet Neurology, 5(6), 525-535.
19. Fahn, S., Jankovic, J., & Hallett, M. (2011). Principles and practice of movement disorders. Elsevier Health Sciences.
20. Connolly, B. S., & Lang, A. E. (2014). Pharmacological treatment of Parkinson disease: a review. Jama, 311(16), 1670-1683.
21. Schrag, A., Jahanshahi, M., & Quinn, N. (2000). What contributes to quality of life in patients with Parkinson's disease?. Journal of Neurology, Neurosurgery & Psychiatry, 69(3), 308-312.
22. Fereshtehnejad, S. M., Hadizadeh, H., Farhadi, F., Shahidi, G. A., Delbari, A., & Lökk, J. (2014). Comparison of the Psychological Symptoms and Disease-Specific Quality of Life between Early-and Typical-Onset Parkinson's Disease Patients. Parkinson's Disease, 2014.
23. Katsarou, Z., Bostantjopoulou, S., Peto, V., Alevriadou, A., & Kiosseoglou, G. (2001). Quality of life in Parkinson's disease: Greek translation and validation of the Parkinson's disease questionnaire (PDQ-39). Quality of Life Research, 10(2), 159-163.
24. Begnum, M. E. N. (2010). Challenges for Norwegian PC-Users with Parkinson's Disease–A Survey. In Computers Helping People with Special Needs (pp. 292-299). Springer Berlin Heidelberg.
25. Keates, S., & Trewin, S. (2005, October). Effect of age and Parkinson's disease on cursor positioning using a mouse. In Proceedings of the 7th international ACM SIGACCESS conference on Computers and accessibility (pp. 68-75). ACM.
26. Begnum, M. E. N., & Begnum, K. M. (2012). On the usefulness of off-the-shelf computer peripherals for people with Parkinson's disease. Universal Access in the Information Society, 11(4), 347-357.
27. Burns, A., Adeli, H., & Buford, J. A. (2014). Brain–Computer Interface after Nervous System Injury. The Neuroscientist, 1073858414549015.
28. Jankovic, J. (2008). Parkinson's disease: clinical features and diagnosis. Journal of Neurology, Neurosurgery & Psychiatry, 79(4), 368-376.
29. Wu, T., Hallett, M., & Chan, P. (2015). Motor automaticity in Parkinson's disease. Neurobiology of disease, 82, 226-234.
30. Williams, D. R., & Litvan, I. (2013). Parkinsonian syndromes. Continuum (Minneapolis, Minn.), 19(5 Movement Disorders), 1189-1212.
31. Doherty, K. M., van de Warrenburg, B. P., Peralta, M. C., Silveira-Moriyama, L., Azulay, J. P., Gershanik, O. S., & Bloem, B. R. (2011). Postural deformities in Parkinson's disease. The Lancet Neurology, 10(6), 538-549.

32. Schoneburg, B., Mancini, M., Horak, F., & Nutt, J. G. (2013). Framework for understanding balance dysfunction in Parkinson's disease. Movement Disorders, 28(11), 1474-1482.
33. Hoehn, M. M., & Yahr, M. D. (1998). Parkinsonism: onset, progression, and mortality. Neurology, 50(2), 318-318.
34. Aquino, C. C., & Fox, S. H. (2015). Clinical spectrum of levodopa-induced complications. Movement Disorders, 30(1), 80-89.
35. Chaudhuri, K. R., Rizos, A., & Sethi, K. D. (2013). Motor and nonmotor complications in Parkinson's disease: an argument for continuous drug delivery?. Journal of neural transmission, 120(9), 1305-1320.
36. Litvan, I., Goldman, J. G., Tröster, A. I., Schmand, B. A., Weintraub, D., Petersen, R. C., ... & Emre, M. (2012). Diagnostic criteria for mild cognitive impairment in Parkinson's disease: Movement Disorder Society Task Force guidelines. Movement Disorders, 27(3), 349-356.
37. Goldman, J. G., Williams-Gray, C., Barker, R. A., Duda, J. E., & Galvin, J. E. (2014). The spectrum of cognitive impairment in Lewy body diseases. Movement Disorders, 29(5), 608-621.
38. Pereira, J. B., Junqué, C., Martí, M. J., Ramirez-Ruiz, B., Bargalló, N., & Tolosa, E. (2009). Neuroanatomical substrate of visuospatial and visuoperceptual impairment in Parkinson's disease. Movement Disorders, 24(8), 1193-1199.
39. Pagonabarraga, J., Kulisevsky, J., Strafella, A. P., & Krack, P. (2015). Apathy in Parkinson's disease: clinical features, neural substrates, diagnosis, and treatment. The Lancet Neurology, 14(5), 518-531.
40. Aarsland, D., Påhlhagen, S., Ballard, C. G., Ehrt, U., & Svenningsson, P. (2012). Depression in Parkinson disease—epidemiology, mechanisms and management. Nature Reviews Neurology, 8(1), 35-47.
41. Dissanayaka, N. N., White, E., O'Sullivan, J. D., Marsh, R., Pachana, N. A., & Byrne, G. J. (2014). The clinical spectrum of anxiety in Parkinson's disease. Movement Disorders, 29(8), 967-975.
42. Franssen, M., Winward, C., Collett, J., Wade, D., & Dawes, H. (2014). Interventions for fatigue in Parkinson's disease: A systematic review and meta-analysis. Movement Disorders, 29(13), 1675-1678.
43. Pinkhardt, E. H., Jürgens, R., Lulé, D., Heimrath, J., Ludolph, A. C., Becker, W., & Kassubek, J. (2012). Eye movement impairments in Parkinson's disease: possible role of extradopaminergic mechanisms. BMC neurology, 12(1), 5.
44. Anderson, T. J., & MacAskill, M. R. (2013). Eye movements in patients with neurodegenerative disorders. Nature Reviews Neurology, 9(2), 74-85.
45. Terao, Y., Fukuda, H., Ugawa, Y., & Hikosaka, O. (2013). New perspectives on the pathophysiology of Parkinson's disease as assessed by saccade performance: a clinical review. Clinical Neurophysiology, 124(8), 1491-1506.
46. Linder, J., Wenngren, B. I., Stenlund, H., & Forsgren, L. (2012). Impaired oculomotor function in a community-based patient population with newly diagnosed idiopathic parkinsonism. Journal of neurology, 259(6), 1206-1214.

47. Nowacka, B., Lubiński, W., Honczarenko, K., Potemkowski, A., & Safranow, K. (2014). Ophthalmological Features of Parkinson Disease. Medical science monitor: international medical journal of experimental and clinical research, 20, 2243.
48. Hanuška, J., Bonnet, C., Rusz, J., Sieger, T., Jech, R., Rivaud-Péchoux, S., ... & Růžička, E. (2015). Fast vergence eye movements are disrupted in Parkinson's disease: A video-oculography study. Parkinsonism & related disorders.
49. Serizawa, K., Kamei, S., Morita, A., Hara, M., Mizutani, T., Yoshihashi, H., ... & Hirayanagi, K. (2008). Comparison of quantitative EEGs between Parkinson disease and age-adjusted normal controls. Journal of Clinical Neurophysiology, 25(6), 361-366.
50. Morita, A., Kamei, S., Serizawa, K., & Mizutani, T. (2009). The relationship between slowing EEGs and the progression of Parkinson's disease. Journal of Clinical Neurophysiology, 26(6), 426-429.
51. Morita, A., Kamei, S., & Mizutani, T. (2011). Relationship between slowing of the EEG and cognitive impairment in Parkinson disease. Journal of Clinical Neurophysiology, 28(4), 384-387.
52. Mostile, G., Nicoletti, A., Dibilio, V., Luca, A., Pappalardo, I., Giuliano, L., ... & Zappia, M. (2015). Electroencephalographic lateralization, clinical correlates and pharmacological response in untreated Parkinson's disease. Parkinsonism & related disorders, 21(8), 948-953.
53. Beudel, M., Roosma, E., Manzanera, O. M., van Laar, T., Maurits, N. M., & de Jong, B. M. (2015). Parkinson bradykinesia correlates with EEG background frequency and perceptual forward projection. Parkinsonism & related disorders.
54. Berendse, H. W., & Stam, C. J. (2007). Stage-dependent patterns of disturbed neural synchrony in Parkinson's disease. Parkinsonism & related disorders, 13, S440-S445.
55. Katsarou, Z., Bostantjopoulou, S., Kimiskidis, V., Rossopoulos, E., & Kazis, A. (2004). Auditory event-related potentials in parkinson's disease in relation to cognitive ability. Perceptual and motor skills, 98(3c), 1441-1448.
56. Lopes, M. D. S., Melo, A. D. S., & Nóbrega, A. C. (2014). Delayed latencies of auditory evoked potential P300 are associated with the severity of Parkinson's disease in older patients. Arquivos de neuro-psiquiatria, 72(4), 296-300.
57. Colebatch, J. G. (2007). Bereitschaftspotential and movement-related potentials: Origin, significance, and application in disorders of human movement. Movement Disorders, 22(5), 601-610.
58. van Essen, A. J., Busch, H. F. M., te Meerman, G. J., & Leo, P. (1992). Birth and population prevalence of Duchenne muscular dystrophy in The Netherlands. Human genetics, 88(3), 258-266.
59. Hoffman, E. P., Brown, R. H., & Kunkel, L. M. (1987). Dystrophin: the protein product of the Duchenne muscular dystrophy locus. Cell, 51(6), 919-928.
60. Kanagawa, M., & Toda, T. (2006). The genetic and molecular basis of muscular dystrophy: roles of cell–matrix linkage in the pathogenesis. Journal of human genetics, 51(11), 915-926.

61. McDonald, C. M., Abresch, R. T., Carter, G. T., Fowler Jr, W. M., Johnson, E. R., Kilmer, D. D., & Sigford, B. J. (1995). Profiles of neuromuscular diseases: Duchenne muscular dystrophy. American journal of physical medicine & rehabilitation, 74(5), S93.
62. Eagle, M., Bourke, J., Bullock, R., Gibson, M., Mehta, J., Giddings, D., ... & Bushby, K. (2007). Managing Duchenne muscular dystrophy–the additive effect of spinal surgery and home nocturnal ventilation in improving survival. Neuromuscular disorders, 17(6), 470-475.
63. Eagle, M. (2002). Report on the muscular dystrophy campaign workshop: exercise in neuromuscular diseases Newcastle, January 2002. Neuromuscular Disorders, 12(10), 975-983.
64. Bar-Or, O., & Rowland, T. W. (2004). Pediatric exercise medicine: from physiologic principles to health care application. Human Kinetics.
65. McDonald, C. M. (2002). Physical activity, health impairments, and disability in neuromuscular disease. American journal of physical medicine & rehabilitation, 81(11), S108-S120.
66. Quinlivan, R., Roper, H., Davie, M., Shaw, N. J., McDonagh, J., & Bushby, K. (2005). Report of a Muscular Dystrophy Campaign funded workshop Birmingham, UK, January 16th 2004. Osteoporosis in Duchenne muscular dystrophy; its prevalence, treatment and prevention. Neuromuscular Disorders, 15(1), 72-79.
67. McDonald, D. G., Kinali, M., Gallagher, A. C., Mercuri, E., Muntoni, F., Roper, H., ... & Pike, M. G. (2002). Fracture prevalence in Duchenne muscular dystrophy. Developmental Medicine & Child Neurology, 44(10), 695-698.
68. Vestergaard, P., Glerup, H., Steffensen, B. F., Rejnmark, L., Rahbek, J., & Mosekilde, L. (2001). Fracture risk in patients with muscular dystrophy and spinal muscular atrophy. Journal of rehabilitation medicine, 33(4), 150-155.
69. Werdnig, G. (1891). Zwei frühinfantile hereditäre Fälle von progressiver Muskelatrophie unter dem Bilde der Dystrophie, aber anf neurotischer Grundlage. European Archives of Psychiatry and Clinical Neuroscience, 22(2), 437-480.
70. Hoffmann, J. (1893). Ueber chronische spinale Muskelatrophie im Kindesalter, auf familiärer Basis. Journal of Neurology, 3(6), 427-470.
71. Brzustowicz, L. M., Lehner, T., Castilla, L. H., Penchaszadeh, G. K., Wilhelmsen, K. C., Daniels, R., ... & Gilliam, T. C. (1990). Genetic mapping of chronic childhood-onset spinal muscular atrophy to chromosome 5q1 1.2 13.3. Nature, 344(6266), 540-541.
72. Lefebvre, S., Bürglen, L., Reboullet, S., Clermont, O., Burlet, P., Viollet, L., ... & Melki, J. (1995). Identification and characterization of a spinal muscular atrophy-determining gene. Cell, 80(1), 155-165.
73. Ogino, S., Leonard, D. G., Rennert, H., Ewens, W. J., & Wilson, R. B. (2002). Genetic risk assessment in carrier testing for spinal muscular atrophy. American journal of medical genetics, 110(4), 301-307.
74. Prior, T. W., Snyder, P. J., Rink, B. D., Pearl, D. K., Pyatt, R. E., Mihal, D. C., ... & Garner, S. (2010). Newborn and carrier screening for spinal muscular atrophy. American Journal of Medical Genetics Part A, 152(7), 1608-1616.

75. Munsat, T. L. (1992). Meeting report: International SMA consortium meeting. Neuromusc Disord, 2, 423-428.
76. Charcot, J. M. (1874). De la sclérose latérale amyotrophique. Prog Med, 2(325), 341-453.
77. Kiernan, M. C., Vucic, S., Cheah, B. C., Turner, M. R., Eisen, A., Hardiman, O., ... & Zoing, M. C. (2011). Amyotrophic lateral sclerosis. The Lancet, 377(9769), 942-955.
78. Deng, H. X., Zhai, H., Bigio, E. H., Yan, J., Fecto, F., Ajroud, K., ... & Siddique, T. (2010). FUS-immunoreactive inclusions are a common feature in sporadic and non-SOD1 familial amyotrophic lateral sclerosis. Annals of neurology, 67(6), 739-748.
79. Beleza-Meireles, A., & Al-Chalabi, A. (2009). Genetic studies of amyotrophic lateral sclerosis: controversies and perspectives. Amyotrophic Lateral Sclerosis, 10(1), 1-14.
80. Beghi, E., Chiò, A., Couratier, P., Esteban, J., Hardiman, O., Logroscino, G., ... & Zoccolella, S. (2011). The epidemiology and treatment of ALS: focus on the heterogeneity of the disease and critical appraisal of therapeutic trials. Amyotrophic Lateral Sclerosis, 12(1), 1-10.
81. Byrne, S., Walsh, C., Lynch, C., Bede, P., Elamin, M., Kenna, K., ... & Hardiman, O. (2011). Rate of familial amyotrophic lateral sclerosis: a systematic review and meta-analysis. Journal of Neurology, Neurosurgery & Psychiatry, 82(6), 623-627.
82. Logroscino, G., Traynor, B. J., Hardiman, O., Chiò, A., Mitchell, D., Swingler, R. J., ... & Beghi, E. (2010). Incidence of amyotrophic lateral sclerosis in Europe. Journal of Neurology, Neurosurgery & Psychiatry, 81(4), 385-390.
83. Kuzuhara, S. (2011). [Muro disease: amyotrophic lateral sclerosis/parkinsonism-dementia complex in Kii peninsula of Japan]. Brain and nerve= Shinkei kenkyu no shinpo, 63(2), 119-129.
84. Chiò, A., Mora, G., Calvo, A., Mazzini, L., Bottacchi, E., & Mutani, R. (2009). Epidemiology of ALS in Italy A 10-year prospective population-based study. Neurology, 72(8), 725-731.
85. O'Toole, O., Traynor, B. J., Brennan, P., Sheehan, C., Frost, E., Corr, B., & Hardiman, O. (2007). Epidemiology and clinical features of amyotrophic lateral sclerosis in Ireland between 1995 and 2004. Journal of Neurology, Neurosurgery & Psychiatry.
86. Johnston, C. A., Stanton, B. R., Turner, M. R., Gray, R., Blunt, A. H. M., Butt, D., ... & Al-Chalabi, A. (2006). Amyotrophic lateral sclerosis in an urban setting. Journal of neurology, 253(12), 1642-1643.
87. Alonso, A., Logroscino, G., Jick, S. S., & Hernán, M. A. (2009). Incidence and lifetime risk of motor neuron disease in the United Kingdom: a population-based study. European Journal of Neurology, 16(6), 745-751.
88. Cronin, S., Hardiman, O., & Traynor, B. J. (2007). Ethnic variation in the incidence of ALS A systematic review. Neurology, 68(13), 1002-1007.
89. Zaldivar, T., Gutierrez, J., Lara, G., Carbonara, M., Logroscino, G., & Hardiman, O. (2009). Reduced frequency of ALS in an ethnically mixed population A population-based mortality study. Neurology, 72(19), 1640-1645.
90. Davenport, R. J., Swingler, R. J., Chancellor, A. M., & Warlow, C. P. (1996). Avoiding false positive diagnoses of motor neuron disease: lessons from the Scottish Motor Neuron Disease Register. Journal of Neurology, Neurosurgery & Psychiatry, 60(2), 147-151.

91. Ringel, S. P., Murphy, J. R., Alderson, M. K., Bryan, W., England, J. D., Miller, R. G., ... & Yu, P. (1993). The natural history of amyotrophic lateral sclerosis. Neurology, 43(7), 1316-1316.
92. Kuwabara, S., Sonoo, M., Komori, T., Shimizu, T., Hirashima, F., Inaba, A., ... & Hatanaka, Y. (2008). Dissociated small hand muscle atrophy in amyotrophic lateral sclerosis: frequency, extent, and specificity. Muscle & nerve, 37(4), 426-430.
93. van Cutsem, P., Dewil, M., Robberecht, W., & Van Den Bosch, L. (2005). Excitotoxicity and amyotrophic lateral sclerosis. Neurodegenerative diseases, 2(3-4), 147-159.
94. Hall, J. G. (1997). Arthrogryposis multiplex congenita: etiology, genetics, classification, diagnostic approach, and general aspects. Journal of Pediatric Orthopaedics B, 6(3), 159-166.
95. Hall, J. G., Reed, S. D., & Greene, G. (1982). The distal arthrogryposes: delineation of new entities–review and nosologic discussion. American journal of medical genetics, 11(2), 185-239.
96. Johns Hopkins University. OMIM. Online Mendelian inheritance in man. **http://www.ncbi.nlm.nih.gov/sites/entrez?db=omim**. Accessed 2009 Mar 11.
97. Fahy, M. J., & Hall, J. G. (1989). A retrospective study of pregnancy complications among 828 cases of arthrogryposis. Genetic counseling (Geneva, Switzerland), 1(1), 3-11.
98. Vanpaemel, L., Schoenmakers, M., van Nesselrooij, B., Pruijs, H., & Helders, P. (1997). Multiple congenital contractures. Journal of Pediatric Orthopaedics B, 6(3), 172-178.
99. Bevan, W. P., Hall, J. G., Bamshad, M., Staheli, L. T., Jaffe, K. M., & Song, K. (2007). Arthrogryposis multiplex congenita (amyoplasia): an orthopaedic perspective. Journal of Pediatric Orthopaedics, 27(5), 594-600.
100. Bernstein, R. M. (2002). Arthrogryposis and amyoplasia. Journal of the American Academy of Orthopaedic Surgeons, 10(6), 417-424.
101. Hall, J. G. (2002). Don't use the term “amyoplasia” loosely. American journal of medical genetics, 111(3), 344-344. 44. Sarwark JF, MacEwen GD, Scott CI Jr. Amyoplasia (a common form of arthrogryposis). J Bone Joint Surg Am. 1990;72:465-9.
102. Sells, J. M., Jaffe, K. M., & Hall, J. G. (1996). Amyoplasia, the most common type of arthrogryposis: the potential for good outcome. Pediatrics, 97(2), 225-231.
103. Hall, J. G., Reed, S. D., McGillivray, B. C., Herrmann, J., Partington, M. W., Schinzel, A., ... & Opitz, J. M. (1983). Part II. Amyoplasia: twinning in amyoplasia—a specific type of arthrogryposis with an apparent excess of discordantly affected identical twins. American journal of medical genetics, 15(4), 591-599.
104. Niven, E., Newton, J., Foley, J., Colville, S., Swingler, R., Chandran, S., ... & Abrahams, S. (2015). Validation of the Edinburgh Cognitive and Behavioural Amyotrophic Lateral Sclerosis Screen (ECAS): A cognitive tool for motor disorders. Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration, (ahead-of-print), 1-8.
105. Abrahams, S., Newton, J., Niven, E., Foley, J., & Bak, T. H. (2014). Screening for cognition and behaviour changes in ALS. Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration, 15(1-2), 9-14.

106. Poysky, J. (2007). Behavior patterns in Duchenne muscular dystrophy: report on the Parent Project Muscular Dystrophy behavior workshop 8–9 of December 2006, Philadelphia, USA. Neuromuscular Disorders, 17(11), 986-994.
107. Huggins, J. E., Wren, P. A., & Gruis, K. L. (2011). What would brain-computer interface users want? Opinions and priorities of potential users with amyotrophic lateral sclerosis. Amyotrophic Lateral Sclerosis, 12(5), 318-324.
108. Nijboer, F., Sellers, E. W., Mellinger, J., Jordan, M. A., Matuz, T., Furdea, A., ... & Kübler, A. (2008). A P300-based brain–computer interface for people with amyotrophic lateral sclerosis. Clinical neurophysiology, 119(8), 1909-1916.
109. Vaughan, T. M., McFarland, D. J., Schalk, G., Sarnacki, W., Krusienski, D. J., Sellers, E. W., & Wolpaw, J. R. (2006). The wadsworth BCI research and development program: at home with BCI. Neural Systems and Rehabilitation Engineering, IEEE Transactions on, 14(2), 229-233.

Websites:

http://www.christopherreeve.org/site/c.mtKZKgMWKwG/b.4453403/k.CDCA/Spinal_Cord_Injury.htm#

9 Appendix A - Questionnaires for patients and for care givers

9.1 SCI patients Questionnaire in English

Multimedia **A**uthoring and **M**anagement
using your **E**yes and **M**ind

H2020-ICT-2014 - 644780

THE FRAMEWORK PROGRAMME FOR RESEARCH AND INNOVATION
HORIZON 2020

Computer use habits, difficulties and needs questionnaire

Table of content

Rational for questionnaire…………………………………………………………………………………………...3
Questionnaire structure..3
Instructions for passing the questionnaire ……………………………………………………………………….3
Chapter I - Demographic and clinical information……………………………………………………………..4
    a. Demographic information…..5
    b. Clinical information…...5
Chapter II - Computer working environment, habits and difficulties ……………………….…………….7
    a. Computer use habits………………………………………………………………………………….........8
    b. Difficulties……………………………………………………………………………………………………....10
    c. Description and evaluation of the current working environment……………………..…….12
    d. Description and evaluation of Assistive device/s …………………………………………….…..14
Chapter III - Needs, missing functions and demands of improvements……………………….……..22

Rational for questionnaire:

The purpose of this questionnaire is to assess the computer use habits, difficulties and needs of subjects with spinal cord injury (SCI) under the demand of the first milestones of the MAMEM project.

Another issue regarding the questionnaires is the need for open and closed questions. The closed questions are designed to collect data appropriate for quantification and statistical analysis and the open questions are designed not to limit the subjects with their answers.

Since an appropriate questionnaire design to answer the specific study questions does not exist in the literature, some parts of the questionnaire were obtained from existing questionnaires and some were created specifically for the MAMEM project objectives.

Questionnaire structure:

The questionnaire is based on three parts. First is the demographic & clinical information section. The second is designed to assess the computer related habits, environment and difficulties. The last part consists of open questions targeted to collect data regarding the needs, missing functions and demands of improvements that the subjects have from the current system and/or assistive device they are using.

Instructions for the interview:

The questionnaire should be filled by a research assistant interviewing the subject. All questions should be answered according to the order of their appearance. Some questions have specific instructions for the interviewer. These are italicized and appear in parenthesis below the question. When answering an open question, the interviewer should try to recap the subjects' remarks and summarize them in a few words.

IMORTANT – an interview can start only after an informed consent form has been signed by the interviewee.

Chapter I

Demographic and clinical information

a. Demographic information

Subject code: ____________________

(*Instructions to interviewer: create the code like this: SCI -#- XX.*

 # - according to participation order, XX – according to the first letters of the subject's first and last name. Make sure you match the subject's code to his/hers real name in a separate coding form. Subject's real name will be kept in the coded list together with the informed consent by the PI of each site according to privacy regulations)

Date: _________________	Age: __________________	Gender: Male \ female
Single \ married \ Divorced \ widower	Number of children: __________________	Ages of children: ____________________ ____________________
Educational years: _____________	Occupation: __________________	If employed: Full time \ partial
Hours employed per week: ________		

b. Clinical information

1. Diagnosis: (Neurological level of injury (NLI) & American Spinal Cord Injury association – (ASIA) impairment scale (AIS) (International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI).
   (Instructions to interviewer: consult with MD/medical records)
   ____

2. Reason of SCI:

Traumatic:

- ☐ Sport
- ☐ Assault
- ☐ Transport
- ☐ Fall
- ☐ Other:____

Non-traumatic:

- ☐ ____

3. Years with SCI: ____

4. Are you in a motorized wheelchair? Yes / No

5. How many hours per day (approximately) do you spend in bed?

6. For how long have you been in a rehabilitation ward / day care ward, if any?

____

7. Please specify the financial support (e.g. medical insurance) you are provided with, in order to address your disease).

(Instructions to interviewer: only name the major sources of income)

____

8. In which of the following parts of the body do you present partial or complete immobility/numbness?

	Tongue	Jaw	Neck	Shoulders	Arms	Elbows	Wrists	Fingers
Complete								
Incomplete								

9. **If you own and use a PC, can we take pictures or short videos of your computer workspace while you are using it? (This will be shared only with the research team. In case the pictures or videos will be shared beyond the research team, your face will be blurred out.) Yes / No**

Chapter II

Computer habits, working environment and difficulties

a. Computer use habits

1. How is your social life affected by your disability?
   - ☐ My social life is normal.
   - ☐ There is no significant effect on my social life apart from limiting energetic aspects, such as dancing.
   - ☐ My social life is restricted and I do not go out as often.
   - ☐ My social life is restricted to my home.
   - ☐ I have no social life and feel lonely.

2. Have you any kind of hobby or recreational activity? Yes /No

3. If yes, please specify: ___________________________________

4. How is your mobility outdoors affected by your disability?
   - ☐ I travel frequently for needs / pleasure.
   - ☐ I travel sometimes.
   - ☐ I travel very rarely and only when there is an absolute need.
   - ☐ I cannot travel and must stay home.

5. Of the following systems, which do you own?
   - ☐ Desktop computer
   - ☐ Laptop computer
   - ☐ Tablet
   - ☐ Smartphone

6. If you own more than one, which one do you use the most?
   ____

7. Do you use a PC? Yes / No
   (Instructions to interviewer: if the subject does not use a PC – even if he/she owns one - go straight to chapter III.)

8. If so, how many hours (approximately) a day do you use it?
   ____

9. How many years of experience do you have using a computer?
   ____

10. Please indicate your main uses of your computer system and the three most important ones: *Instructions to interviewer: can choose more than one; mark an x next to the important three uses*)

☐ Social participation (Facebook, forums, etc.)	
☐ Productive activities (writing, editing, etc.)	
☐ Study (on-line courses, articles, etc.)	
☐ Games	
☐ Recreation (movies, music, crossword puzzles, blogs, etc.)	
☐ Communication (email, Skype, etc.)	
☐ Activities of daily living (purchases, payments, bank, etc.)	
☐ Information (Wikipedia, governmental sites, news, maps, etc.)	
☐ Other: ____ ____	

11. Please indicate the main applications you use and the three most important ones: *Instructions to interviewer: can choose more than one; if chosen, name the main application the subject use; mark an x next to the important three)*

☐ Internet browser: ________________________________	
☐ Email client:__________________________________	
☐ Word processor:_______________________________	
☐ Audio/video/image applications:______________________	
☐ Spreadsheets (e.g. excel):_________________________	
☐ Computer games:_______________________________	
☐ Presentation software:___________________________	
☐ Programming/database:___________________________	
☐ Media editing applications:________________________	
☐ Other: ____ ____	

12. Which operating systems do you work with?
    - ☐ Microsoft Windows
    - ☐ Unix / Linux
    - ☐ Apple MacOS

13. How does computer use contribute to you in the following aspects?

	1- not important at all, 5- very important)	Please indicate the three most important aspects (*mark an x next to the aspects*)
Interpersonal interactions and relationships	1 2 3 4 5	
Close, intimate relationships	1 2 3 4 5	
Educational attainment	1 2 3 4 5	
Work and employment status/potential	1 2 3 4 5	
Participation in desired community, social and civic activities	1 2 3 4 5	
Autonomy and self-determination (making decisions)	1 2 3 4 5	
Fitting in, belonging, feeling connected	1 2 3 4 5	
Emotional well-being	1 2 3 4 5	
Overall health	1 2 3 4 5	

b. Difficulties

1. Do you have difficulties performing the following on the computer system which you are using?
(*Instructions for interviewer: If a category is chosen, ask the subject to briefly specify what kind of difficulties*):

☐ Identifying the cursor on the screen
____

☐ Moving the cursor on the screen
____

☐ "Clicking" with the cursor
____

☐ "Double clicking" with the cursor
____

☐ Selecting and dragging, resizing windows
____

☐ Zooming / Panning
____

☐ Using the keyboard
____

☐ Identifying the letters on the keyboard
____

☐ Typing with the keyboard
____

☐ Using two keys at the same time
____

☐ Reading the words on the screen
____

☐ Understanding how to use the assistive device software
____

☐ Opening a file on the computer
____

☐ Picking an item from a list or menu
____

☐ Navigating the directory structure
____

☐ Perform a search on the computer or on the Web
____

☐ Browsing/Navigating the internet
____

☐ Other: ____

2. Fill up the following table:

		How difficult is it for you? (1- very difficult, 5- very easy)
How do you create a text on the computer and how easy it is? (*More than one option can be chosen*).	☐ Keyboard	1 2 3 4 5
	☐ By vocal dictating (a machine or a person)	1 2 3 4 5
	☐ By touch	1 2 3 4 5
	☐ Pointer and virtual keyboard	1 2 3 4 5
	☐ Other : ______________________________	1 2 3 4 5
How do you point on the screen and how easy it is? (*More than one option can be chosen*).	☐ Mouse	1 2 3 4 5
	☐ Keyboard	1 2 3 4 5
	☐ By touch	1 2 3 4 5
	☐ Assistive device: ______________________________	1 2 3 4 5
	☐ Other ______________________________	1 2 3 4 5

c. Description and evaluation of the current working environment:

1. Computer type:

☐ Stationary
☐ Portable

2. Computer location:

☐ On a desk
☐ Mounted on an arm
☐ Wheelchair tray
☐ Other: ____

3. Positioning while using the computer:

☐ Sitting on an armchair
☐ Sitting on special armchair
☐ Sitting on wheelchair
☐ Sitting on motorized wheelchair
☐ Standing
☐ Laying
☐ Other:____

4. Common operating location/s:

☐ Home
☐ Work
☐ Coffee shops
☐ Other: ____

5. How does the current physical condition affect the following computer use aspects? (*Instructions for interviewer: This question inspects the effect of the specific working environment in which the computer is operated, i.e. armchair/wheelchair/bed, desk, etc.)*:

	No effect	Mildly	Moderately	Substantially	Completely	Not relevant
Comfort	1	2	3	4	5	
Independence	1	2	3	4	5	
Satisfaction	1	2	3	4	5	
Pain	1	2	3	4	5	
Speed of operation	1	2	3	4	5	
Fatigue	1	2	3	4	5	
Accuracy of operation	1	2	3	4	5	
Endurance	1	2	3	4	5	
Effectiveness	1	2	3	4	5	
Ease of use	1	2	3	4	5	
Enabling privacy	1	2	3	4	5	

d. Description and evaluation of assistive device/s

1. Do you use any assistive device for computer access (apart or instead from a standard keyboard and mouse)? Yes / No
   (*Instructions for interviewer: if the subject does not use an assistive device, skip to chapter III*)

2. If so, what device/s?
   (*Instructions for interviewer: can choose more than one, please specify brand*)

   ☐ Typing Stick:____
   ☐ Mouthstick:____
   ☐ Chin joystick:____
   ☐ Mouth joystick:____
   ☐ Gaze tracker: ____
   ☐ Head tracker :____
   ☐ Speech recognition:____
   ☐ Mounting system (arms and support):_______________________________
   ☐ Other:
   ____
   ____

3. How long have you been using this device/ these devices (*months/years*)?
   ____

4. Where was this assistive device fitted for you?

   ☐ During rehabilitation
   ☐ Vocational/assistive-device counseling center
   ☐ Private/commercial company
   ☐ Other:
   ____

5. Have you used a different assistive device in the past? Yes / No

6. If so, what kind of assistive device and why did you stop using it?
   ____
   ____

7. Please indicate which body parts do you use to operate the assistive device, and try to assess the pain and/or fatigue it causes after prolong use, if any:
(*Instructions for interviewer: can choose more than one*)

	Pain level after prolonged use (1 – no pain at all, 5 – extreme pain)	fatigue level after prolonged use (1 – no fatigue at all, 5 – extreme fatigue)
☐ Tongue	1 2 3 4 5	1 2 3 4 5
☐ Eyes	1 2 3 4 5	1 2 3 4 5
☐ Jaw	1 2 3 4 5	1 2 3 4 5
☐ Neck	1 2 3 4 5	1 2 3 4 5
☐ Shoulders	1 2 3 4 5	1 2 3 4 5
☐ Arm	1 2 3 4 5	1 2 3 4 5
☐ Elbows	1 2 3 4 5	1 2 3 4 5
☐ Wrists	1 2 3 4 5	1 2 3 4 5
☐ Fingers	1 2 3 4 5	1 2 3 4 5

Instructions for interviewer:

Sections 7, 8, 9 and 10 are 'borrowed' from widely used questionnaires and their structure was kept.

Please fill out the following questionnaires regarding the assistive device the subject uses.

If the subject uses more than one assistive device, the following questionnaires refer to all of them as one 'system' which is actually the combination of all of them.

However, in case some questions in the questionnaires are answered in regards to a specific assistive device, please add in writing which device, next to the answer.

8. Quebec User Evaluation of Satisfaction with assistive Technology

QUEST
(Version 2.0)

Technology device: ______________________________________

Date of assessment: _____________________________

The purpose of the **QUEST** questionnaire is to evaluate how satisfied you are with your assistive device and the related services you experienced. The questionnaire consists of 12 satisfaction items.

- For each of the 12 items, rate your satisfaction with your assistive device and the related services you experienced by using the following scale of 1 to 5.

- Please circle or mark the **one number** that best describes your degree of satisfaction with each of the 12 items.

- D**o not** leave any question unanswered.

- For any item that you were not "very satisfied", please comment in the section ***comments***.

Thank you for completing the QUEST questionnaire.

ASSISTIVE DEVICE

How satisfied are you with,

1. The **dimensions** (size, height, length, width) of your assistive device?	1 2 3 4 5
2. The **weight** of your assistive device?	1 2 3 4 5
3. The **ease in adjusting** (fixing, fastening) the parts of your assistive device?	1 2 3 4 5
4. How **safe and secure** your assistive device is?	1 2 3 4 5
5. The **durability** (endurance, resistance to wear) of your assistive device?	1 2 3 4 5
6. How **easy** it is to use your assistive device?	1 2 3 4 5
7. How **comfortable** your assistive device is?	1 2 3 4 5
8. How **effective** your assistive device is (the degree to which your device meets your needs)?	1 2 3 4 5

SERVICES

How satisfied are you with,

9. The **service delivery** program (procedures, length of time) in which you obtained your assistive device?	1 2 3 4 5
10. The **repairs and servicing** (maintenance) provided for your assistive device?	1 2 3 4 5
11. The quality of the **professional services** (information, attention) you received for using your assistive device?	1 2 3 4 5
12. The **follow-up services** (continuing support services) received for your assistive device?	1 2 3 4 5

- Below is the list of the same 12 satisfaction items. PLEASE **SELECT THE THREE ITEMS** that you consider to be **the most important to you**. Please put an X in the **3 boxes** of your choice.

☐ Dimensions
☐ Comfort
☐ Weight
☐ Effectiveness
☐ Adjustments
☐ Service delivery
☐ Safety
☐ Repairs/servicing
☐ Durability
☐ Professional service
☐ Easy to use
☐ Follow-up services

9. How important are the following attributes of the assistive device for you?

	1- not important at all 5 - very important	Please indicate the three most important attributes (*mark an x next to the attribute*)
noninvasiveness	1 2 3 4 5	
setup time	1 2 3 4 5	
independent operation	1 2 3 4 5	
training time	1 2 3 4 5	
cost	1 2 3 4 5	
number of functions provided	1 2 3 4 5	
response time	1 2 3 4 5	
productivity	1 2 3 4 5	
Ease of use	1 2 3 4 5	
Aesthetics	1 2 3 4 5	
Enabling privacy	1 2 3 4 5	

10. Assessment of Comfort

	1- Extremely uncomfortable 7- very comfortable
Force required for actuation	1 2 3 4 5 6 7
Smoothness during operation	1 2 3 4 5 6 7
Effort required for operation	1 2 3 4 5 6 7
Accuracy	1 2 3 4 5 6 7
Operation speed	1 2 3 4 5 6 7
General comfort	1 2 3 4 5 6 7
Overall operation of input device	1 2 3 4 5 6 7

Chapter III

Needs, missing functions and demands of improvements

1. Why don't you use a computer?
   (*Instructions to interviewer: apply only to those who answered NO on question a.6 in chapter II*)

   ☐ I don't need to use a computer
   ☐ I don’t know how to use a computer
   ☐ I don't have a computer
   ☐ I cannot find a good assistive device
   ☐ It is too difficult in my condition
   ☐ I don’t like computers
   ☐ Other : ____

2. If you could design your own assistive device for computer use or improve an existing one, what would it look like? What features would it have? If you chose to improve an existing one – how would you improve it?

   Please detail:
   ____

   ____

   ____

3. What operation of the computer you used to do prior to the disease, that you can't do now, you miss the most, if any?
   (Instructions to interviewer: ask this question only those who still use a computer or stopped using the computer due to disease. examples of operations: using the mouse, the keyboard, etc.)

   Please detail:
   ____

   ____

   ____

4. What computer applications were you using prior to your disease that you now can't operate (or find very hard to operate) and miss the most, if any?
   (*Instructions to interviewer: ask this question only those who still use a computer or stopped using the computer due to disease. if the subject hesitates, explain what is an application, e.g., Facebook, Word etc.*).

Please detail:

____

____

____

5. Would you use an assistive device system based on mental commands? Yes/ No (*Instructions to interviewer: if the subject hesitates, explain how such a system could function*).

   Please detail:

   ____

   ____

6. What type of computer interaction do you think you could perform with an interface based on mental commands?

   Please detail:

   ____

   ____

7. Would you use an assistive device system based on eye movements? Yes/ No (*Instructions to interviewer: if the subject hesitates, explain how such a system could function*).

   Please detail:

   ____

   ____

8. What type of computer interaction do you think you could perform with an interface based on eye-tracking?

   Please detail:

   ____

   ____

9. Would you wear on your head an EEG recording device to facilitate controlling the computer with your thinking/mind? Yes/ No
   (*Instructions to interviewer: if the subject hesitates, explain what a wearable EEG recorder looks like, e.g. how light it is*).

   Please detail:
   ____

   ____

   ____

10. Would you wear on your head special glasses designed to facilitate controlling the computer with your eyes? Yes/ No
    (*Instructions to interviewer: if the subject hesitates, explain how these glasses would look and feel like*).

    Please detail:
    ____

    ____

    ____

9.2 SCI patients caregivers Questionnaire in English

Multimedia **A**uthoring and **M**anagement using your **E**yes and **M**ind

H2020-ICT-2014 - 644780

Computer use habits, difficulties and needs questionnaire

Table of content

Rational for questionnaire……………………………………………………………………………………………..3
Questionnaire structure…………………………………………………………………………………………….3
Instructions for passing the questionnaire ………………………………………………………………………..3
Chapter I - Demographic and clinical information…………………………………………………………………4
  a. Demographic information……………………………………………………………………………………5
  b. Clinical information……………………………………………………………………………………………7
Chapter II - Computer working environment, habits and difficulties …………………………………………8
  e. Computer use habits……………………………………………………………………………………………9
  f. Difficulties……12
  g. Description and evaluation of the current working environment……………………………………14
  h. Description and evaluation of Assistive device/s ……………………………………………………16
Chapter III - Needs, missing functions and demands of improvements……………………………………23

Rational for questionnaire:

The purpose of this questionnaire is to assess the computer use habits, difficulties and needs of subjects with spinal cord injury (SCI) under the demand of the first milestones of the MAMEM project. Here, the information will be provided from interviews with caregivers of SCI subjects.

Another issue regarding the questionnaires is the need for open and closed questions. The closed questions are designed to collect data appropriate for quantification and statistical analysis and the open questions are designed not to limit the subjects with their answers.

Since an appropriate questionnaire design to answer the specific study questions does not exist in the literature, some parts of the questionnaire were obtained from existing questionnaires and some were created specifically for the MAMEM project objectives.

Questionnaire structure:

The questionnaire is based on three parts. First is the demographic & clinical information section. The second is designed to assess the computer related habits, environment and difficulties. The last part consists of open questions targeted to collect data regarding the needs, missing functions and demands of improvements that the subjects have from the current system and/or assistive device their patients are using.

Instructions for the interview:

The questionnaire should be filled by a research assistant interviewing the subject. All questions should be answered according to the order of their appearance. Some questions have specific instructions for the interviewer. These are italicized and appear in parenthesis below the question. When answering an open question, the interviewer should try to recap the subjects' remarks and summarize them in a few words.

IMPORTANT – an interview can start only after an informed consent has been signed by the interviewee.

Chapter I

Demographic and clinical information

a. Demographic information

(Please note that the demographics of the interviewed person and subject he/she cares for are recorded separately in the following pages).

Subject code: ____________________

(*Instructions to interviewer: create the code like this: SCICG -#- XX.*

 # - according to participation order, XX – according to the first letters of the subject's first and last name. Make sure you match the subject's code to his/hers real name in a separate coding form. Subject's real name will be kept in the coded list together with the informed consent by the PI of each side according to privacy regulations)

1. Subject's demographics:

Date:	Age:	Gender:
_________________	__________________	Male \ female
Single \ married \ Divorced \ widower	Number of children: __________________	
Educational years:	Occupation:	If employed:
_____________	__________________	Full time \ partial

a. You are: (please check the box)

☐ Professional Caregiver (i.e. nurse)
☐ Family member of the SCI patient

b. In average, how many hours per day do you take care of your patient?

____

c. For how long have you been taking care of your patient (months):

____

d. Besides taking care of the patient, do you have another occupation? Yes / no

e. If so, what is it, and how many hours per week are you engaged with this activity?

____

____

2. Subject's patient demographics:

(Instructions for interviewer: (1) in case the patient taken care by this subject also participated in this study – insert his/her code instead of the initials of the patient; (2) in case the subject is not certain on a particular item please indicate this)

Initials of patient *(first letters of the subject's first and last name)* ____________________	Age of patient: __________________	Patient's Gender: Male \ female
Single \ married \ Divorced \ widower	Number of children: __________________	Ages of children: ____________________ ____________________
Educational years: _____________	Occupation: __________________	If employed: Full time \ partial
Hours employed per week: ________		

b. Clinical information of the patient

(Instructions for the interviewer: in case the subject is not certain on a particular item please indicate this; if unknown, indicate "unknown")

1. Diagnosis: (*Neurological level of injury (NLI) & American Spinal Cord Injury association – (ASIA*) impairment scale (AIS) (International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI):

   ____

2. Reason of SCI:

   Traumatic:

   ☐ Sport
   ☐ Assault
   ☐ Transport
   ☐ Fall
   ☐ Other:____

   Non-traumatic:

   ☐ ____

3. Years with SCI: ____

4. Is your patient in a motorized wheelchair? <u>Yes / No</u>

5. How many hours per day (approximately) does your patient spend in bed?

6. For how long was your patient in a rehabilitation ward / day care ward, if any?

   ____

7. Please specify the financial support (e.g. medical insurance) your patient is provided with, in order to address his/her disease).

   (Instructions to interviewer: only name the major sources of income)

   ____

8. In which of the following parts of the body does your patient present partial or complete immobility/ numbness?

	Tongue	Jaw	Neck	Shoulders	Arms	Elbows	Wrists	Fingers
Complete								
Incomplete								

Chapter II

Computer habits, working environment and difficulties

e. Computer use habits

14. How your patient's social life is affected by his/her disability?

    - ☐ Social life is normal.
    - ☐ There is no significant effect on social life apart from limiting energetic aspects, such as dancing.
    - ☐ Social life is restricted and he/she does not go out as often.
    - ☐ Social life is restricted to the home.
    - ☐ He/she has no social life and he/she feels lonely.

15. Does he/she have any kind of hobby or recreational activity? Yes /no

16. If yes, please specify: ____

17. How your patient's mobility outdoors is affected by his/her disability?
    - ☐ My patient can travel frequently for needs / pleasure.
    - ☐ My patient can travel sometimes.
    - ☐ My patient can travel very rarely and only when there is an absolute need.
    - ☐ My patient cannot travel and must stay home.

18. Of the following systems, which does your patient own?
    - ☐ Desktop computer
    - ☐ Laptop computer
    - ☐ Tablet
    - ☐ Smartphone

19. If he/she owns more than one, which one does he/she use the most?

    ____

20. Does your patient use a PC? Yes / No
    (Instruction to interviewer: if the subject's patient does not use a PC – even if he/she owns one - go straight to chapter III.)

21. If so, how many hours (approximately) a day does your patient use it?

    ____

22. How many years of experience (approximately) does your patient have using a computer?

____

23. Please indicate your patient's main uses of his/her computer system and the three most important ones:
(*Instruction to interviewer: can choose more than one, mark an x next to the important uses*)

☐ Social participation (Facebook, forums, etc.)	
☐ Productive activities (writing, editing, etc.)	
☐ Study (on-line courses, articles, etc.)	
☐ Games	
☐ Recreation (movies, music, crossword puzzles, blogs, etc.)	
☐ Communication (email, Skype, etc.)	
☐ Activities of daily living (purchases, payments, bank, etc.)	
☐ Information (Wikipedia, governmental sites, news, maps, etc.)	
☐ Other: ____ ____	

24. Please indicate the main applications your patient use and the three most important ones:
(Instruction to interviewer: can choose more than one, if chosen, name the main application the subject's patient uses, mark an x next to the important ones)

☐ Internet browser: ____	
☐ Email client:____	
☐ Word processor:____	
☐ Audio/video/image applications:___________________________	
☐ Spreadsheets:____	
☐ Computer games:_______________________________________	
☐ Presentation software:___________________________________	
☐ Programming/database:___________________________________	
☐ Media editing applications:_______________________________	
☐ Other: ____ ____	

25. Which operating systems does your patient work with?
☐ Microsoft Windows
☐ Unix / Linux
☐ Apple MacOS

26. How does computer use contribute to your patient in the following aspects?

	1- not important at all, 5- very important)	Please indicate the three most important aspects (*mark an x next to the aspects*)
Interpersonal interactions and relationships	1 2 3 4 5	
Close, intimate relationships	1 2 3 4 5	
Educational attainment	1 2 3 4 5	
Work and employment status/potential	1 2 3 4 5	
Participation in desired community, social and civic activities	1 2 3 4 5	
Autonomy and self-determination (making decisions)	1 2 3 4 5	
Fitting in, belonging, feeling connected	1 2 3 4 5	
Emotional well-being	1 2 3 4 5	
Overall health	1 2 3 4 5	

f. Difficulties

3. Does your patient have difficulties performing the following on the computer system which he/she is using?
(*Instruction for interviewer: If a category is chosen, ask the subject to briefly specify what kind of difficulties*):

☐ Identifying the cursor on the screen
____

☐ Moving the cursor on the screen
____

☐ "Clicking" with the cursor
____

☐ "Double clicking" with the cursor
____

☐ Selecting and dragging, resizing windows
____

☐ Zooming / Panning
____

☐ Using the keyboard
____

☐ Identifying the letters on the keyboard
____

☐ Typing with the keyboard
____

☐ Using two keys at the same time
____

☐ Reading the words on the screen
____

☐ Understanding how to use the assistive device software
____

☐ Opening a file on the computer
____

☐ Picking an item from a list or menu
____

☐ Navigating the directory structure
____

☐ Perform a search on the computer or on the Web
____

☐ Browsing/Navigating the internet
____

☐ Other: ____

4. Fill up the following table:

		How difficult is it for him/her? (1- very difficult, 5- very easy)
How does your patient create a text on the computer and how easy it is? (*More than one option can be chosen*).	☐ Keyboard	1 2 3 4 5
	☐ By dictating (a machine or a person)	1 2 3 4 5
	☐ By touch	1 2 3 4 5
	☐ Pointer and virtual keyboard	1 2 3 4 5
	☐ Other : ____________________________	1 2 3 4 5
How does your patient point on the screen and how easy it is? (*More than one option can be chosen*).	☐ Mouse	1 2 3 4 5
	☐ Keyboard	1 2 3 4 5
	☐ By touch	1 2 3 4 5
	☐ Assistive device: ____________________________	1 2 3 4 5
	☐ Other _________________	1 2 3 4 5

g. Description and evaluation of the current working environment:

6. Patient's computer type:
   - ☐ Stationary
   - ☐ Portable

7. Patient's computer location:
   - ☐ On a desk
   - ☐ Mounted on an arm
   - ☐ Wheelchair tray

☐ Other: ____

8. Positioning of the patient while using the computer:
   ☐ Sitting on an armchair
   ☐ Sitting on special armchair
   ☐ Sitting on wheelchair
   ☐ Sitting on motorized wheelchair
   ☐ Standing
   ☐ Laying
   ☐ Other:____

9. Common operating location/s:
   ☐ Home
   ☐ Work
   ☐ Coffee shops
   ☐ Other: ____

10. How does the current environment affect the patients' following computer use aspects? (*Instruction for interviewer: Answer this part regarding the working environment in which the computer is operated, i.e. armchair/wheelchair/bed, desk, etc.)*:

	No effect	Mildly	Moderately	Substantially	Completely	Not relevant
Comfort	1	2	3	4	5	
Independence	1	2	3	4	5	
Satisfaction	1	2	3	4	5	
Pain	1	2	3	4	5	
Speed of operation	1	2	3	4	5	
Fatigue	1	2	3	4	5	
Accuracy of operation	1	2	3	4	5	
Endurance	1	2	3	4	5	
Effectiveness	1	2	3	4	5	

Ease of use	1	2	3	4	5	
Enabling privacy	1	2	3	4	5	

h. Description and evaluation of assistive device/s

11. Does your patient use any assistive device for computer access (apart or instead from a standard keyboard and mouse)? Yes / No
(*Instructions for interviewer: if the subject's patient does not use an assistive device, skip to chapter III*)

12. If so, what device/s?
(*Instructions for interviewer: can choose more than one, please specify brand*)

☐ Typing Stick:____
☐ Mouthstick:____
☐ Chin joystick:____
☐ Mouth joystick:____
☐ Gaze tracker: ____
☐ Head tracker :____
☐ Speech recognition:____
☐ Mounting system (arms and support):__________________________________
☐ Other:

____
____

13. How long has your patient been using this device/ these devices (*months/years*)?
____

14. Where was this assistive device fitted for your patient?

☐ During rehabilitation
☐ Vocational/assistive-device counseling center
☐ Private/commercial company
☐ Other:

____

15. Has your patient used a different assistive device in the past? Yes / No

16. If so, what kind of assistive device and why did he/she stop using it?
____

____

17. Please indicate which body parts does your patient use to operate the assistive device, and try to assess the pain and/or fatigue it causes him/her after prolong use, if any:
    (*Instructions for interviewer: can choose more than one*)

	Pain level after prolonged use (1 – no pain at all, 5 – extreme pain)	fatigue level after prolonged use(1 – no fatigue at all, 5 – extreme fatigue)
☐ Tongue	1 2 3 4 5	1 2 3 4 5
☐ Eyes	1 2 3 4 5	1 2 3 4 5
☐ Jaw	1 2 3 4 5	1 2 3 4 5
☐ Neck	1 2 3 4 5	1 2 3 4 5
☐ Shoulders	1 2 3 4 5	1 2 3 4 5
☐ Arm	1 2 3 4 5	1 2 3 4 5
☐ Elbows	1 2 3 4 5	1 2 3 4 5
☐ Wrists	1 2 3 4 5	1 2 3 4 5
☐ Fingers	1 2 3 4 5	1 2 3 4 5

Instructions for interviewer:

Questions 7, 8 and 9 are 'borrowed' from widely used questionnaires and their structure was kept.

Please fill out the following questionnaires regarding the assistive device the subject's patient uses.

If the subject's patient uses more than one assistive device, the following questionnaires refer to all of them as one 'system' which is actually the <u>combination</u> of all of them.

However, in case some questions in the questionnaires are answered in regards to a specific assistive device, please add in writing which device, next to the answer.

18. Quebec User Evaluation of Satisfaction with assistive Technology

QUEST
(Version 2.0)

Technology device: _______________________________________

Date of assessment: ______________________________

The purpose of the **QUEST** questionnaire is to evaluate how satisfied you are with your assistive device and the related services you experienced. The questionnaire consists of 12 satisfaction items.

- For each of the 12 items, rate your satisfaction with your assistive device and the related services you experienced by using the following scale of 1 to 5.

- Please circle or mark the **one number** that best describes your degree of satisfaction with each of the 12 items.

- D**o not** leave any question unanswered.

- For any item that you were not "very satisfied", please comment in the section ***comments***.

Thank you for completing the QUEST questionnaire.

ASSISTIVE DEVICE

How satisfied is your patient with,

1. The **dimensions** (size, height, length, width) of the assistive device?	1 2 3 4 5
2. The **weight** of the assistive device?	1 2 3 4 5
3. The **ease in adjusting** (fixing, fastening) the parts of the assistive device?	1 2 3 4 5
4. How **safe and secure** the assistive device is?	1 2 3 4 5
5. The **durability** (endurance, resistance to wear) of the assistive device?	1 2 3 4 5
6. How **easy** it is to use the assistive device?	1 2 3 4 5
7. How **comfortable** the assistive device is?	1 2 3 4 5
8. How **effective** the assistive device is (the degree to which the device meets the patient's needs)?	1 2 3 4 5

SERVICES

How satisfied is your patient with,

9. The **service delivery** program (procedures, length of time) in which your patient obtained the assistive device?	1 2 3 4 5
10. The **repairs and servicing** (maintenance) provided for the assistive device?	1 2 3 4 5
11. The quality of the **professional services** (information, attention) your patient received for using the assistive device?	1 2 3 4 5

12. The **follow-up services** (continuing support services) received for the assistive device?	1 2 3 4 5

- Below is the list of the same 12 satisfaction items. Please **select the three items** that you consider to be **the most important to your patient**. Please put an X in the **3 boxes** of your choice.

☐ Dimensions
☐ Comfort
☐ Weight
☐ Effectiveness
☐ Adjustments
☐ Service delivery
☐ Safety
☐ Repairs/servicing
☐ Durability
☐ Professional service
☐ Easy to use
☐ Follow-up services

19. How important are the following attributes of the assistive device for your patient?

	1- not important at all 5 - very important	Please indicate the three most important attributes (*mark an x next to the attribute*)
noninvasiveness	1 2 3 4 5	
setup time	1 2 3 4 5	
independent operation	1 2 3 4 5	
training time	1 2 3 4 5	
cost	1 2 3 4 5	
number of functions provided	1 2 3 4 5	
response time	1 2 3 4 5	
productivity	1 2 3 4 5	
Ease of use	1 2 3 4 5	
Aesthetics	1 2 3 4 5	
Enabling privacy	1 2 3 4 5	

20. Assessment of Comfort

	1- Extremely uncomfortable 7- very comfortable
Force required for actuation	1 2 3 4 5 6 7
Smoothness during operation	1 2 3 4 5 6 7
Effort required for operation	1 2 3 4 5 6 7
Accuracy	1 2 3 4 5 6 7
Operation speed	1 2 3 4 5 6 7
General comfort	1 2 3 4 5 6 7
Overall operation of input device	1 2 3 4 5 6 7

Chapter III

Needs, missing functions and demands of improvements

1. Why doesn't your patient use a computer?
   (*Instruction to interviewer: apply only to those who answered NO on question a.6 in chapter II*)
   ☐ He/she doesn't need to use a computer
   ☐ He/she doesn't know how to use a computer
   ☐ He/she doesn't have a computer
   ☐ He/she cannot find a good assistive device
   ☐ It is too difficult in my patient condition
   ☐ He/she doesn't like computers
   ☐ Other : ____

2. If you could design your own assistive device for computer use or improve an existing one, what would it look like? What features would it have? If you chose to improve an existing one – how would you improve it?

   Please detail:
   ____

   ____

   ____

3. What operation of the computer did your patient use to do prior to his/her disease, that he/she can't do now, you believe he/she miss the most, if any?
   (Instruction to interviewer: apply only to those who still use a computer or stopped using the computer due to disease. examples of operations: using the mouse, the keyboard, etc.)

   Please detail:
   ____

   ____

   ____

4. What computer applications was your patient using prior to his/her disease that he/she now can't operate (or find very hard to operate) and miss the most, if any?
   (*Instruction to interviewer: apply only to those who still use a computer or stopped using the computer due to disease. if the subject hesitate, explain what is an application, e.g., Facebook, Word etc.*).

   Please detail:
   ____

____

____

5. Do you think your patient would use an assistive device system based on mental commands? Yes / No
   (*Instructions to interviewer: if the subject hesitates, explain how such a system could function*).

   Please detail:
   ____

   ____

6. What type of computer interaction do you think your patient could perform with an interface based on mental commands?

   Please detail:
   ____

   ____

7. Do you think your patient would use an assistive device system based on eye movements? Yes / No
   (*Instructions to interviewer: if the subject hesitates, explain how such a system could function*).

   Please detail:
   ____

   ____

8. What type of computer interaction do you think your patient could perform with an interface based on eye-tracking?

   Please detail:
   ____

   ____

9. Do you think your patient would wear on his/her head an EEG recording device to facilitate controlling the computer with his/her thinking/mind? Yes/ No

(*Instructions to interviewer: if the subject hesitates, explain what a wearable EEG recorder looks like, e.g. how light it is*).

Please detail:

____

____

____

10. Do you think your patient would wear on his/her head special glasses designed to facilitate controlling the computer with his/her eyes? Yes/ No

    (*Instructions to interviewer: if the subject hesitates, explain how these glasses would look and feel like*).

    Please detail:

    ____

    ____

    ____

9.3 Differences between the SCI, PD and NMD versions of the questionnaires

Although an effort was made to make the three versions as similar as possible, these three paired versions eventually differed from each other in two points: first, the questions in the clinical information part were different for the three cohorts for obvious reasons. These questions were created by each clinical site members, based on their specific knowledge and experience during the input circulations. Second, the PD version contained an extra difficulties mini-questionnaire added by the request of the PD clinical site members.

9.3.1 NMD Clinical information

1. Diagnosis (*which kind of NMD your diagnosis is related to*): ____________________
   (Instructions to interviewer: if needed, consult with MD/medical records)

1. Years since first diagnosis: ____

2. Have you had any spinal surgery because of your disease? Yes / No

3. Are you in a wheelchair? Yes / No

4. Are you in bedridden? Yes / No
5. Have you been in a Vocational Rehabilitation Center or program? Yes \ No

6. If so, please specify what center/program and for how long:

____

7. Please specify the financial support (e.g. Medical insurance) you are provided with, in order to address your disease).
   (Instructions to interviewer: only name the major sources of income)
   ____
8. In which of the following parts of the body do you present partial or complete immobility?

	Tongue	Jaw	Neck	Shoulders	Arms	Elbows	Wrists	Hands	Fingers
Complete									
Incomplete									

9.3.2 PD Clinical information

1. Age at diagnosis ____
2. Disease duration: ____
3. H&Y scale ____
   (Instructions to interviewer: if needed, consult with MD/medical records)
4. Are you in a wheelchair? Yes / No
5. Are you in bedridden? Yes / No
6. Have you been in a Vocational rehabilitation Centre or program? Yes \ no
7. If so, please specify what centre/program and for how long:

____

8. Please specify the financial support (e.g. Medical insurance) you are provided with, in order to address your disease).
   (Instructions to interviewer: only name the major sources of income)

   ____
9. In which of the following parts of the body do you present partial or complete immobility?

	Tongue	Jaw	Neck	Shoulders	Arms	Elbows	Wrists	Hands	Fingers
Complete									
Incomplete									

10. In which of the following parts of your body do you have tremor?

	Tongue	Jaw	Neck	Shoulders	Arms	Elbows	Wrists	Hands	Fingers
Severe									
Mild/moderate									

11. In which of the following parts of your body do you have dyskinesias (*involuntary movements due to medications)*

	Tongue	Jaw	Neck	Shoulders	Arms	Elbows	Wrists	Hands	Fingers
Severe									
Mild/moderate									

9.3.3 PD extra mini difficulties questionnaire

1. How do the following symptoms of Parkinson’s disease affect your computer performance?

	1=not at all // 5=very much
Tremor	1 2 3 4 5
Rigidity	1 2 3 4 5
Bradykinesia	1 2 3 4 5
Balance impairment	1 2 3 4 5
Other:_________________	1 2 3 4 5

10 Appendix B - Ethical approvals for the questionnaires studies

10.1 Unified protocol outline (English)

Here we bring an English version of the protocol for SCI subjects (Submitted at Sheba), which fully transpires the Hebrew translation. Based on this English version, protocols in Greek were submitted by MDA Hellas and AUTH.

Important remark- the following protocol was designed only for the questionnaires stage. Protocols for the pilot clinical trials will be submitted with reference to task T6.2 and T6.3.

Title of Study:

MAMEM - The rehabilitation of the participation in the management of multi-media computer interfaces by monitoring eye movements and brain signals - **questionnaires to identify needs, problems and applications.**

The purpose of the study:

The main objective of this study is to review the habits, difficulties and needs of subjects with spinal cord injury (Tetraplegia) who use desktop and laptop computers for surfing the web and participating in social networks. This study is a preliminary study for future research aimed to develop and test better solutions for subjects of this population that will be designed according to the results of the current study (see appendix 1). To achieve the purpose of the current study, subjects with spinal cord injury, their relatives and caregivers will be asked to fill questionnaires designed to assess the needs, difficulties and habits regarding computer use. These questionnaires will be based on the following questionnaires: SUS (System Usability Scale) (Brooke,1986), QUEST II (Quebec User Evaluation of Satisfaction with assistive Technology) (Demers, Ska, Giroux & Weiss-Lambrou, 1999), and the Survey of the Use of Technology from the MPT (Matching Person and Technology) questionnaire battery Scherer & Craddock, 2002).

Method:

The relevant populations for the study will be identified through the hospital clinics and records. In addition, an ad will be posted online advertising the study. Later, we will contact potential subjects to make sure that they are suitable for the study and to suggest them to participate. If they agree, they may be invited to the hospital for a one time session. In some cases, if not able to arrive to the hospital, we will perform the study at the subject's residence. If the participants will be invited to come to the hospital, they will be asked to bring a family member and their caregiver. Upon meeting with the research assistant, the subjects, their family members and caregivers will be debriefed on the study in more detail and will be asked to fill and sign an informed consent form. Then, they will be given the study questionnaires to fill. If there will be any questions, the research assistant will answer them as best he can. In case the study will be performed at the residence of the subjects, we may ask them to video of take stills of the way they use computers in their home environment in regard to the questions in the study questionnaires.

The subjects will be compensated for their travel and parking expenses.

After completing recruitment of all subjects, data from the questionnaires will be collected and analyzed.

The study period will be approximately one year.

Number of participants: 20 from every Group (Subjects with SCI, family members of Subjects with SCI and caregivers of Subjects with SCI)

Inclusion Criteria:

For the SCI Population:

1. Men and women aged 18-80
2. Suffering from a complete or incomplete spinal cord injury to the C5 vertebra and above

For the SCI family members population: [2]

1. Men and women aged 18-80
2. Family members of subjects suffering from a complete or incomplete spinal cord injury to the C5 vertebra and above
3. In a daily or weekly contact with the SCI family member

For the SCI caregivers population:

1. Men and women aged 18-80
2. Caregivers of subjects suffering from a complete or incomplete spinal cord injury to the C5 vertebra and above

---

[2] Pending amendment to the protocol requires the omission of this part. See section 8.1

Exclusion criteria:

For the SCI Population:

3. have involuntary eye movements
4. Have implanted devices that may interfere with the absorption of EEG signals

For the SCI family members population:[3]

1. Their SCI family member has involuntary eye movements
2. Their SCI family member has implanted devices that may interfere with the absorption of EEG signals

For the SCI caregivers population:

1. Their SCI patient has involuntary eye movements
2. Their SCI patient has implanted devices that may interfere with the absorption of EEG signals

Removal from study criteria:

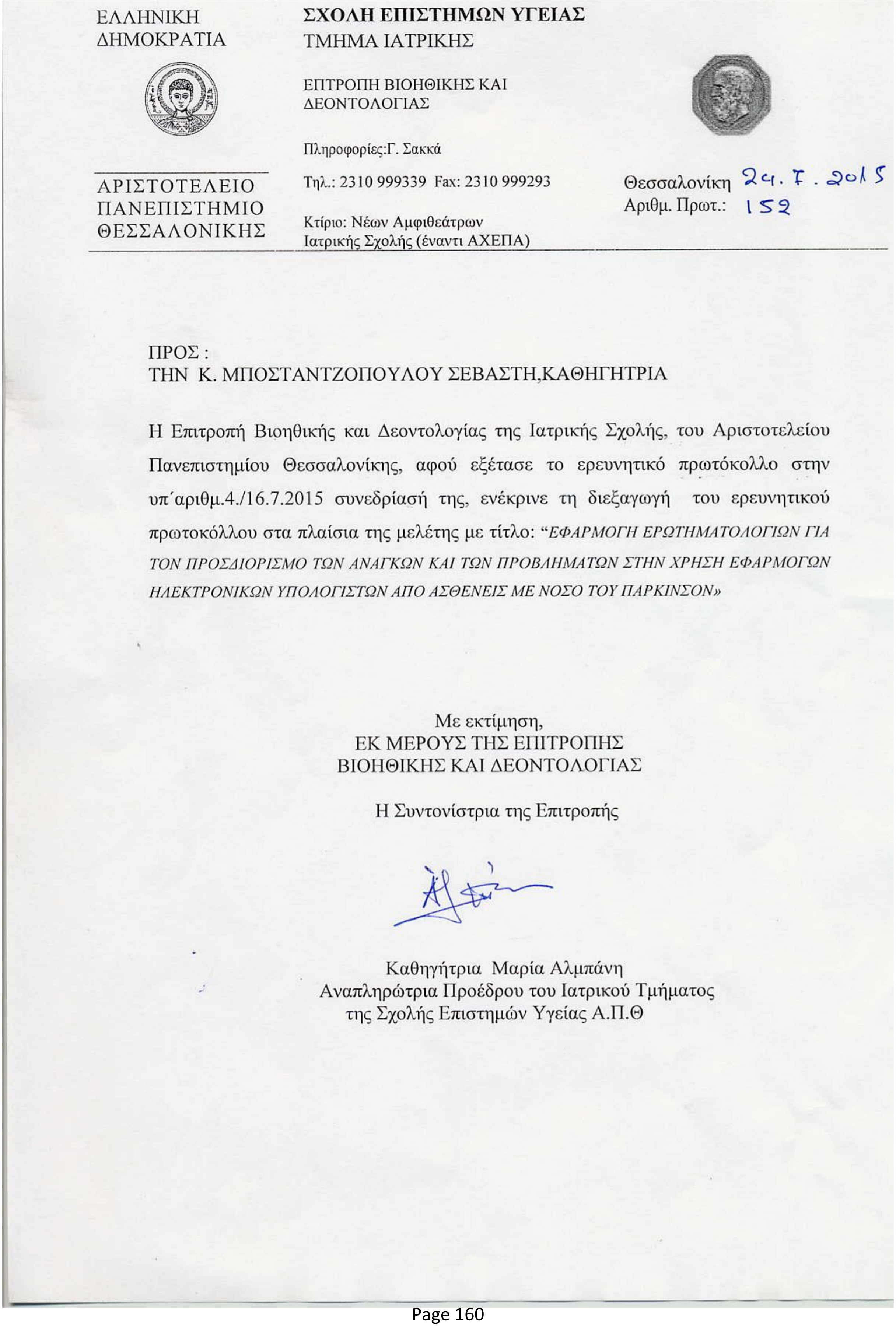
1. Do not understand or able to fill the questionnaire or able to complete filling out the questionnaires

---

[3] Pending amendment to the protocol requires the omission of this part. See section 8.1

10.2 Copy of IRB approvals

10.2.1 Copy of IRB approvals In AUTH



ΕΛΛΗΝΙΚΗ
ΔΗΜΟΚΡΑΤΙΑ

ΑΡΙΣΤΟΤΕΛΕΙΟ
ΠΑΝΕΠΙΣΤΗΜΙΟ
ΘΕΣΣΑΛΟΝΙΚΗΣ

ΣΧΟΛΗ ΕΠΙΣΤΗΜΩΝ ΥΓΕΙΑΣ
ΤΜΗΜΑ ΙΑΤΡΙΚΗΣ

ΕΠΙΤΡΟΠΗ ΒΙΟΗΘΙΚΗΣ ΚΑΙ
ΔΕΟΝΤΟΛΟΓΙΑΣ

Πληροφορίες:Γ. Σακκά

Τηλ.: 2310 999339 Fax: 2310 999293

Κτίριο: Νέων Αμφιθεάτρων
Ιατρικής Σχολής (έναντι ΑΧΕΠΑ)

Θεσσαλονίκη 24.7.2015
Αριθμ. Πρωτ.: 152

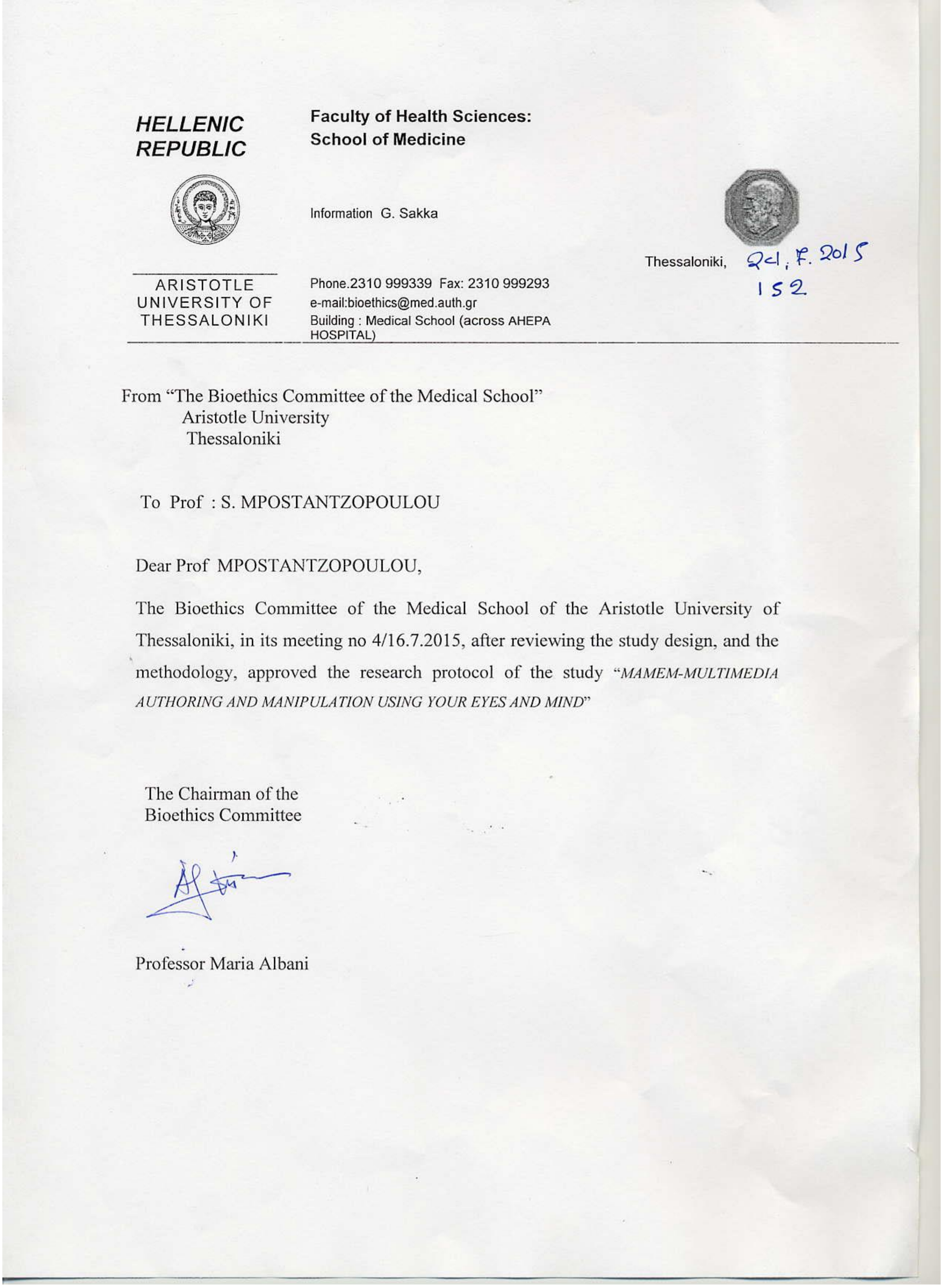
ΠΡΟΣ :
ΤΗΝ Κ. ΜΠΟΣΤΑΝΤΖΟΠΟΥΛΟΥ ΣΕΒΑΣΤΗ,ΚΑΘΗΓΗΤΡΙΑ

Η Επιτροπή Βιοηθικής και Δεοντολογίας της Ιατρικής Σχολής, του Αριστοτελείου Πανεπιστημίου Θεσσαλονίκης, αφού εξέτασε το ερευνητικό πρωτόκολλο στην υπ΄αριθμ.4./16.7.2015 συνεδρίασή της, ενέκρινε τη διεξαγωγή του ερευνητικού πρωτοκόλλου στα πλαίσια της μελέτης με τίτλο: “*ΕΦΑΡΜΟΓΗ ΕΡΩΤΗΜΑΤΟΛΟΓΙΩΝ ΓΙΑ ΤΟΝ ΠΡΟΣΔΙΟΡΙΣΜΟ ΤΩΝ ΑΝΑΓΚΩΝ ΚΑΙ ΤΩΝ ΠΡΟΒΛΗΜΑΤΩΝ ΣΤΗΝ ΧΡΗΣΗ ΕΦΑΡΜΟΓΩΝ ΗΛΕΚΤΡΟΝΙΚΩΝ ΥΠΟΛΟΓΙΣΤΩΝ ΑΠΟ ΑΣΘΕΝΕΙΣ ΜΕ ΝΟΣΟ ΤΟΥ ΠΑΡΚΙΝΣΟΝ»*

Με εκτίμηση,
ΕΚ ΜΕΡΟΥΣ ΤΗΣ ΕΠΙΤΡΟΠΗΣ
ΒΙΟΗΘΙΚΗΣ ΚΑΙ ΔΕΟΝΤΟΛΟΓΙΑΣ

Η Συντονίστρια της Επιτροπής

Καθηγήτρια Μαρία Αλμπάνη
Αναπληρώτρια Προέδρου του Ιατρικού Τμήματος
της Σχολής Επιστημών Υγείας Α.Π.Θ



HELLENIC REPUBLIC

ARISTOTLE
UNIVERSITY OF
THESSALONIKI

**Faculty of Health Sciences:
School of Medicine**

Information G. Sakka

Phone.2310 999339 Fax: 2310 999293
e-mail:bioethics@med.auth.gr
Building : Medical School (across AHEPA HOSPITAL)

Thessaloniki, 21. 7. 2015
152

From "The Bioethics Committee of the Medical School"
Aristotle University
Thessaloniki

To Prof : S. MPOSTANTZOPOULOU

Dear Prof MPOSTANTZOPOULOU,

The Bioethics Committee of the Medical School of the Aristotle University of Thessaloniki, in its meeting no 4/16.7.2015, after reviewing the study design, and the methodology, approved the research protocol of the study "*MAMEM-MULTIMEDIA AUTHORING AND MANIPULATION USING YOUR EYES AND MIND*"

The Chairman of the
Bioethics Committee

Professor Maria Albani

10.2.2 Copy of IRB approvals In MDA Hellas

ΑΙΤΗΣΗ

Προς : Επιτροπή Ηθικής και Δεοντολογίας (ΕΗΔ) Του Εθνικού Κέντρου Έρευνας & Τεχνολογικής Ανάπτυξης

Τίτλος έργου: « **MAMEM** - Multimedia Authoring and Management using your Eyes and Mind »

Κωδικός έργου: H2020-ICT-2014 - 644780

Ινστιτούτο ΕΚΕΤΑ: ΙΠΤΗΛ
Υπεύθυνος Ερευνητής: Ιωάννης Κομπατσιάρης

Ενημερώθηκα προφορικά για το σκοπό, τα πιθανά οφέλη, την αναμενόμενη διάρκεια και τις αναλυτικές διαδικασίες διεξαγωγής της μελέτης από τον/την υπεύθυνο της μελέτης και εγκρίνω τη διεξαγωγή των πειραμάτων όπως αναφέρονται στο πειραματικό πρωτόκολλο που κατατίθεται.

Τα μέλη της Επιτροπής:

Όλγα Καμμιώνα 02.07.2015

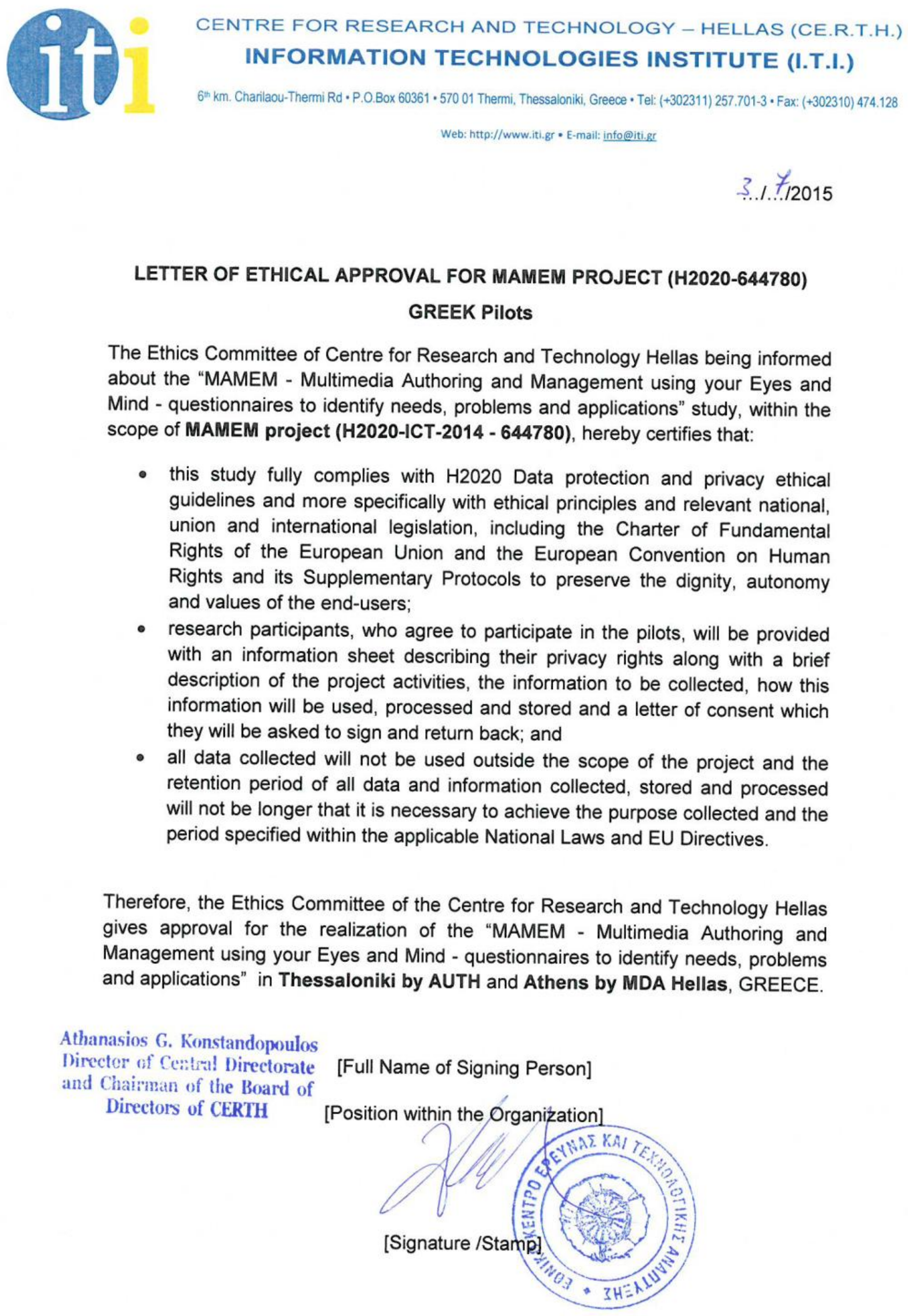
Γεωργία Αϋφαντοπούλου 02.07.2015

Αναγνώστη Αργυρία 03.07.15

____

Ο πρόεδρος της Επιτροπής:

ΑΘΑΝΑΣΙΟΣ ΚΩΝΣΤΑΝΤΟΠΟΥΛΟΣ



CENTRE FOR RESEARCH AND TECHNOLOGY – HELLAS (CE.R.T.H.)
INFORMATION TECHNOLOGIES INSTITUTE (I.T.I.)
6th km. Charilaou-Thermi Rd • P.O.Box 60361 • 570 01 Thermi, Thessaloniki, Greece • Tel: (+302311) 257.701-3 • Fax: (+302310) 474.128
Web: http://www.iti.gr • E-mail: info@iti.gr

3../..7../2015

LETTER OF ETHICAL APPROVAL FOR MAMEM PROJECT (H2020-644780)

GREEK Pilots

The Ethics Committee of Centre for Research and Technology Hellas being informed about the "MAMEM - Multimedia Authoring and Management using your Eyes and Mind - questionnaires to identify needs, problems and applications" study, within the scope of **MAMEM project (H2020-ICT-2014 - 644780)**, hereby certifies that:

- this study fully complies with H2020 Data protection and privacy ethical guidelines and more specifically with ethical principles and relevant national, union and international legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols to preserve the dignity, autonomy and values of the end-users;
- research participants, who agree to participate in the pilots, will be provided with an information sheet describing their privacy rights along with a brief description of the project activities, the information to be collected, how this information will be used, processed and stored and a letter of consent which they will be asked to sign and return back; and
- all data collected will not be used outside the scope of the project and the retention period of all data and information collected, stored and processed will not be longer that it is necessary to achieve the purpose collected and the period specified within the applicable National Laws and EU Directives.

Therefore, the Ethics Committee of the Centre for Research and Technology Hellas gives approval for the realization of the "MAMEM - Multimedia Authoring and Management using your Eyes and Mind - questionnaires to identify needs, problems and applications" in **Thessaloniki by AUTH** and **Athens by MDA Hellas**, GREECE.

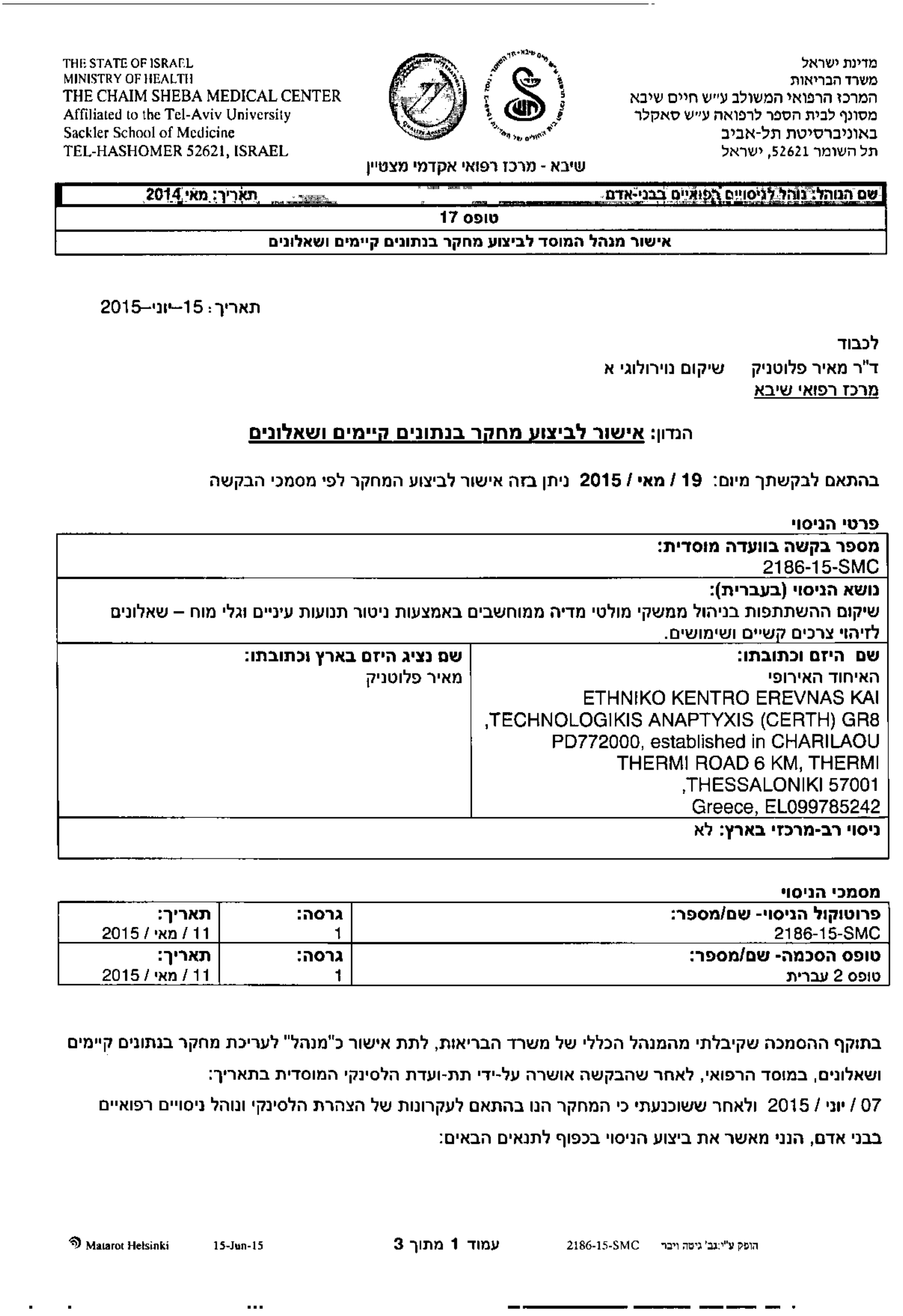
Athanasios G. Konstandopoulos
Director of Central Directorate
and Chairman of the Board of
Directors of CERTH

[Full Name of Signing Person]

[Position within the Organization]

[Signature /Stamp]

10.2.3 Copy of IRB approvals In Sheba



THE STATE OF ISRAEL
MINISTRY OF HEALTH
THE CHAIM SHEBA MEDICAL CENTER
Affiliated to the Tel-Aviv University
Sackler School of Medicine
TEL-HASHOMER 52621, ISRAEL

מדינת ישראל
משרד הבריאות
המרכז הרפואי המשולב ע״ש חיים שיבא
מסונף לבית הספר לרפואה ע״ש סאקלר
באוניברסיטת תל-אביב
תל השומר 52621, ישראל

שיבא - מרכז רפואי אקדמי מצטיין

שם הנוהל: נוהל לניסויים רפואיים בבני-אדם	**תאריך: מאי 2014**
טופס 17	
אישור מנהל המוסד לביצוע מחקר בנתונים קיימים ושאלונים	

תאריך: 15–יוני–2015

לכבוד
ד"ר מאיר פלוטניק שיקום נוירולוגי א
מרכז רפואי שיבא

הנדון: **אישור לביצוע מחקר בנתונים קיימים ושאלונים**

בהתאם לבקשתך מיום: **19 / מאי / 2015** ניתן בזה אישור לביצוע המחקר לפי מסמכי הבקשה

פרטי הניסוי

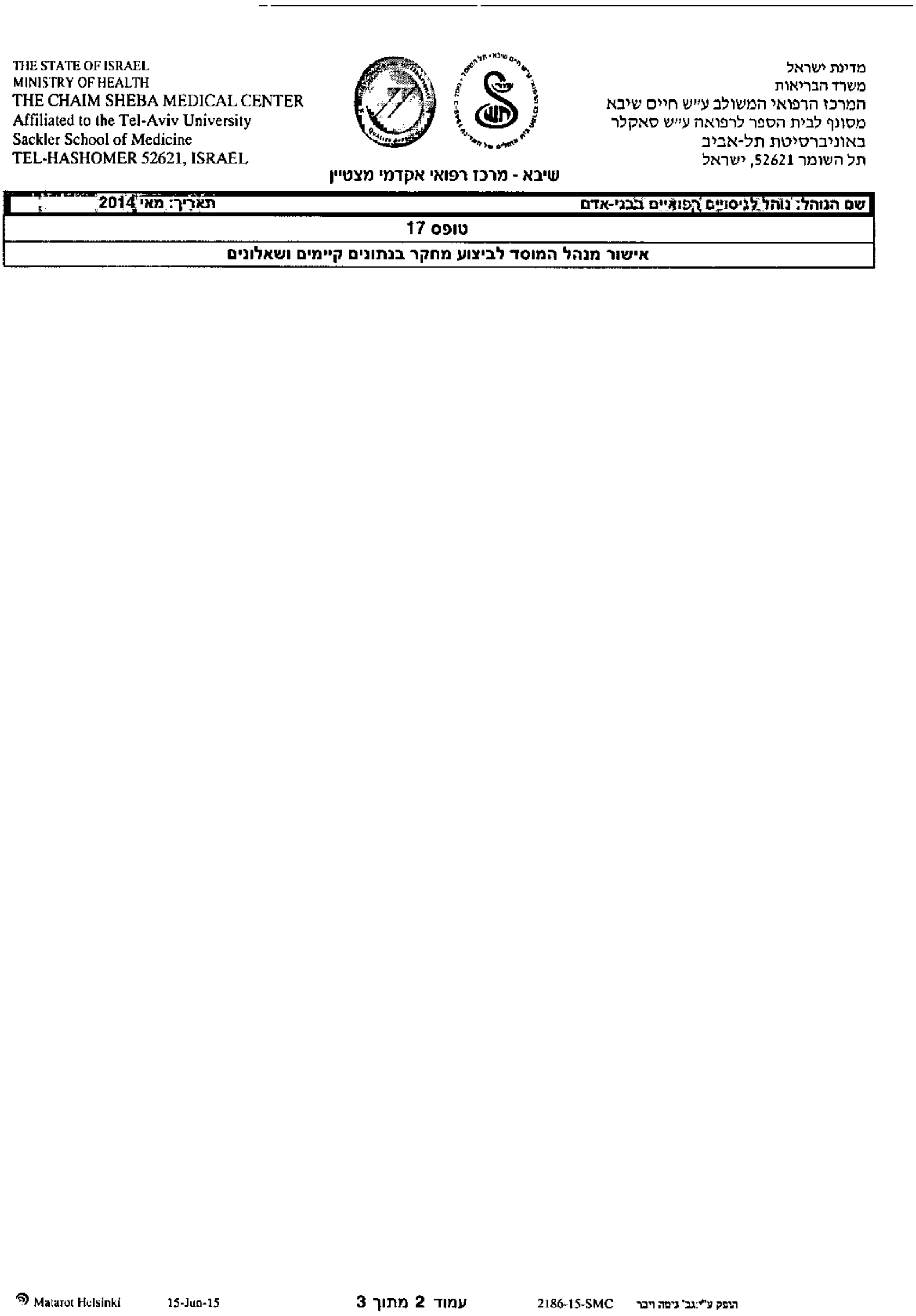
מספר בקשה בוועדה מוסדית: 2186-15-SMC	
נושא הניסוי (בעברית): שיקום ההשתתפות בניהול ממשקי מולטי מדיה ממוחשבים באמצעות ניטור תנועות עיניים וגלי מוח – שאלונים לזיהוי צרכים קשיים ושימושים.	
שם היזם וכתובתו: האיחוד האירופי ETHNIKO KENTRO EREVNAS KAI TECHNOLOGIKIS ANAPTYXIS (CERTH) GR8, PD772000, established in CHARILAOU THERMI ROAD 6 KM, THERMI THESSALONIKI 57001, Greece, EL099785242	**שם נציג היזם בארץ וכתובתו:** מאיר פלוטניק
ניסוי רב-מרכזי בארץ: לא	

מסמכי הניסוי

פרוטוקול הניסוי- שם/מספר: 2186-15-SMC	**גרסה:** 1	**תאריך:** 11 / מאי / 2015
טופס הסכמה- שם/מספר: טופס 2 עברית	**גרסה:** 1	**תאריך:** 11 / מאי / 2015

בתוקף ההסמכה שקיבלתי מהמנהל הכללי של משרד הבריאות, לתת אישור כ"מנהל" לעריכת מחקר בנתונים קיימים ושאלונים, במוסד הרפואי, לאחר שהבקשה אושרה על-ידי תת-ועדת הלסינקי המוסדית בתאריך:
07 / יוני / 2015 ולאחר ששוכנעתי כי המחקר הנו בהתאם לעקרונות של הצהרת הלסינקי ונוהל ניסויים רפואיים בבני אדם, הנני מאשר את ביצוע הניסוי בכפוף לתנאים הבאים:

Matarot Helsinki 15-Jun-15 עמוד **1** מתוך **3** 2186-15-SMC הופק ע"י:גב' גיטה ויבר



THE STATE OF ISRAEL
MINISTRY OF HEALTH
THE CHAIM SHEBA MEDICAL CENTER
Affiliated to the Tel-Aviv University
Sackler School of Medicine
TEL-HASHOMER 52621, ISRAEL

מדינת ישראל
משרד הבריאות
המרכז הרפואי המשולב ע״ש חיים שיבא
מסונף לבית הספר לרפואה ע״ש סאקלר
באוניברסיטת תל-אביב
תל השומר 52621, ישראל

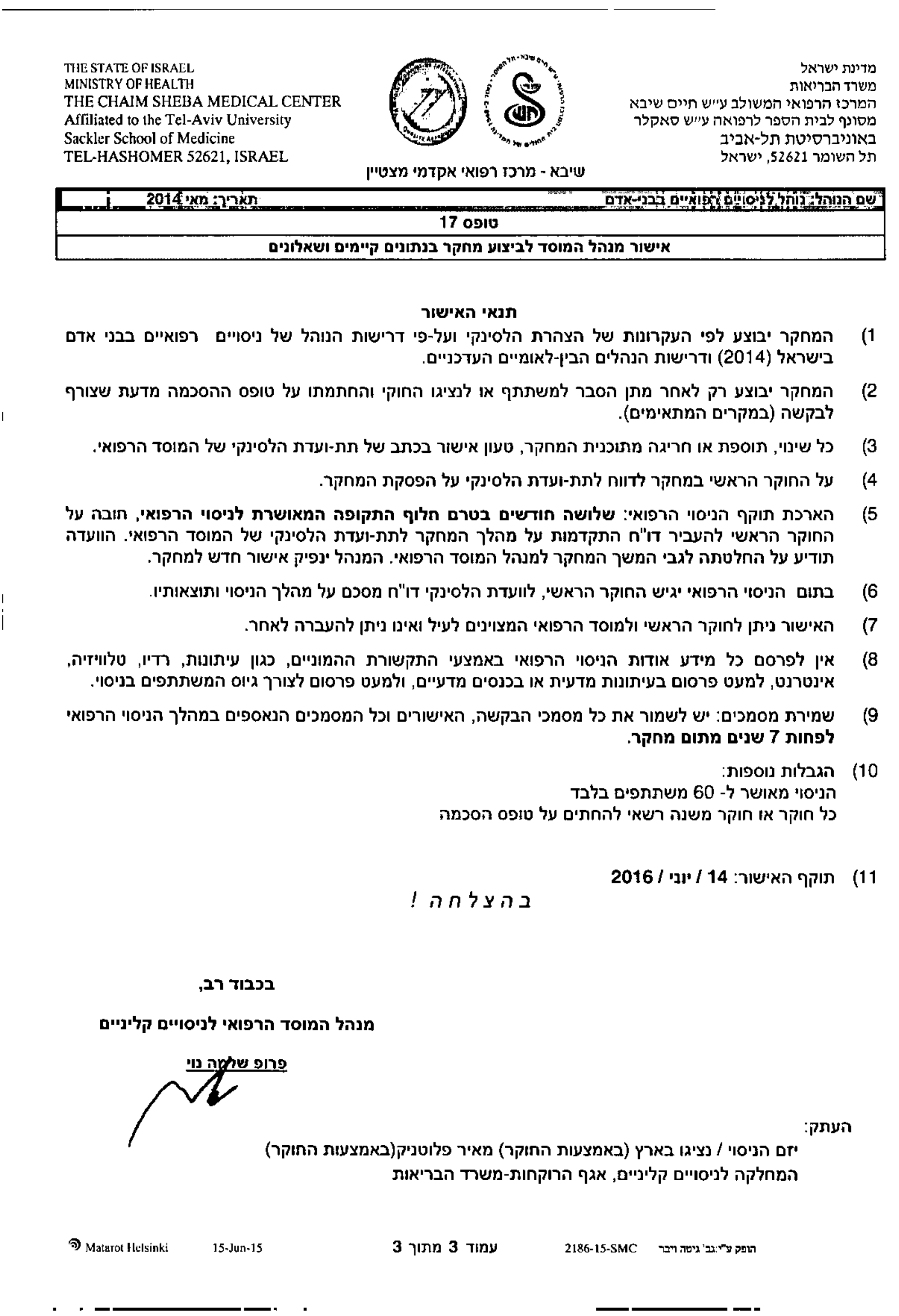
שיבא - מרכז רפואי אקדמי מצטיין

שם הנוהל: נוהל לניסויים רפואיים בבני-אדם | **תאריך: מאי 2014**

טופס 17

אישור מנהל המוסד לביצוע מחקר בנתונים קיימים ושאלונים

Matarot Helsinki 15-Jun-15 **עמוד 2 מתוך 3** 2186-15-SMC הנפק ע"י:גב' גיטה ויבר



THE STATE OF ISRAEL
MINISTRY OF HEALTH
THE CHAIM SHEBA MEDICAL CENTER
Affiliated to the Tel-Aviv University
Sackler School of Medicine
TEL-HASHOMER 52621, ISRAEL

מדינת ישראל
משרד הבריאות
המרכז הרפואי המשולב ע״ש חיים שיבא
מסונף לבית הספר לרפואה ע״ש סאקלר
באוניברסיטת תל-אביב
תל השומר 52621, ישראל

שיבא - מרכז רפואי אקדמי מצטיין

שם הנוהל: נוהל לניסויים רפואיים בבני-אדם
תאריך: מאי 2014

טופס 17

אישור מנהל המוסד לביצוע מחקר בנתונים קיימים ושאלונים

תנאי האישור

1) המחקר יבוצע לפי העקרונות של הצהרת הלסינקי ועל-פי דרישות הנוהל של ניסויים רפואיים בבני אדם בישראל (2014) ודרישות הנהלים הבין-לאומיים העדכניים.

2) המחקר יבוצע רק לאחר מתן הסבר למשתתף או לנציגו החוקי והחתמתו על טופס ההסכמה מדעת שצורף לבקשה (במקרים המתאימים).

3) כל שינוי, תוספת או חריגה מתוכנית המחקר, טעון אישור בכתב של תת-ועדת הלסינקי של המוסד הרפואי.

4) על החוקר הראשי במחקר לדווח לתת-ועדת הלסינקי על הפסקת המחקר.

5) הארכת תוקף הניסוי הרפואי: **שלושה חודשים בטרם חלוף התקופה המאושרת לניסוי הרפואי**, חובה על החוקר הראשי להעביר דו"ח התקדמות על מהלך המחקר לתת-ועדת הלסינקי של המוסד הרפואי. הוועדה תודיע על החלטתה לגבי המשך המחקר למנהל המוסד הרפואי. המנהל ינפיק אישור חדש למחקר.

6) בתום הניסוי הרפואי יגיש החוקר הראשי, לוועדת הלסינקי דו"ח מסכם על מהלך הניסוי ותוצאותיו.

7) האישור ניתן לחוקר הראשי ולמוסד הרפואי המצוינים לעיל ואינו ניתן להעברה לאחר.

8) אין לפרסם כל מידע אודות הניסוי הרפואי באמצעי התקשורת ההמוניים, כגון עיתונות, רדיו, טלוויזיה, אינטרנט, למעט פרסום בעיתונות מדעית או בכנסים מדעיים, ולמעט פרסום לצורך גיוס המשתתפים בניסוי.

9) שמירת מסמכים: יש לשמור את כל מסמכי הבקשה, האישורים וכל המסמכים הנאספים במהלך הניסוי הרפואי **לפחות 7 שנים מתום מחקר.**

10) הגבלות נוספות:
הניסוי מאושר ל- 60 משתתפים בלבד
כל חוקר או חוקר משנה רשאי להחתים על טופס הסכמה

11) תוקף האישור: **14 / יוני / 2016**

בהצלחה!

בכבוד רב,

מנהל המוסד הרפואי לניסויים קליניים

פרופ שלמה נוי

העתק:
יזם הניסוי / נציגו בארץ (באמצעות החוקר) מאיר פלוטניק(באמצעות החוקר)
המחלקה לניסויים קליניים, אגף הרוקחות-משרד הבריאות

Matarot Helsinki 15-Jun-15 עמוד 3 מתוך 3 2186-15-SMC הופק ע"י:גב' גיטה ריבר