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An assistive device based on the detection of the user's intention from residual EMG to drive an upper limb neuroprosthesis.

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Sommario

1 Introduzione e obiettivo del lavoro

Al giorno d'oggi i dispositivi assistenziali di impronta medica sono sempre più di uso comune. Numerose ricerche sono infatti state condotte al fine di aiutare le persone con invalidità motoria: lo scopo è quello di fornire loro assistenza e migliorare la loro qualità di vita. In particolare, è possibile individuare tale obiettivo nella maggiore indipendenza acquisita dal paziente durante l'utilizzo di tali dispositivi. La più recente introduzione della robotica nell'area dei dispositivi assistenziali ha portato un netto miglioramento ai singoli apparecchi; dal suo avvento, infatti, sono stati compiuti numerosi passi avanti per esempio nell'ambito della deambulazione autonoma. Oggetto di studio più recente sono i dispositivi assistenziali modulari.

Il presente lavoro di tesi si inserisce all'interno del progetto europeo MUNDUS (MUltimodal Neuroprosthesis for Daily Upper limb Support), il cui obiettivo consiste nella realizzazione di un dispositivo assistenziale costituito da una neuroprotesi che permette il movimento dell'arto superiore. MUNDUS è un sistema modulare che sfrutta tutte le abilità motorie residue dell'utente. Presenta infatti la possibilità di essere adattato al paziente al fine di potenziarne le capacità e di permettergli di muovere il braccio nello spazio durante l'esecuzione di attività di vita quotidiana. Il target a cui il dispositivo si rivolge sono i portatori di malattie neurodegenerative e neuromuscolari genetiche quali Sclerosi Laterale Amiotrofica (SLA), atassia di Friedreich (FRDA) e Sclerosi Multipla (SM) oltre alle persone che riportano gravi lesioni alla colonna vertebrale (tetraplegia). Le patologie elencate sono nella maggior parte dei casi degenerative e causano al paziente una progressiva perdita delle capacità motorie. MUNDUS è pensato per adattarsi al livello di gravità che colpisce il soggetto. Attraverso la selezione di sensori, attuatori e soluzioni di controllo più adeguati, viene concesso a chi lo utilizza di dirigere il dispositivo personalmente con un approccio diretto (fig.1).

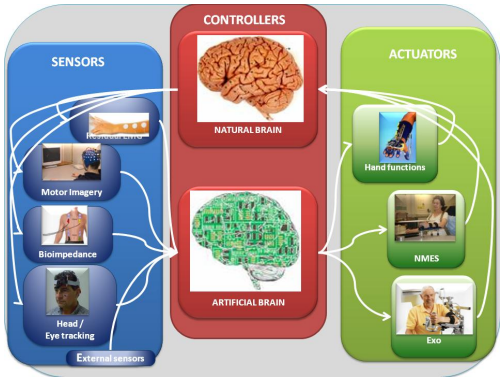


Fig.1:MUNDUS concept.

Nonostante sia data l'opportunità di adeguare continuamente il dispositivo all'utente tramite l'aggiunta e la sostituzione di moduli al suo interno, tre scenari sono stati individuati al fine di rispondere meglio alle necessità che la patologia presenta durante il proprio decorso. In Scenario 1 vengono inseriti quei pazienti che hanno ancora un residuo controllo funzionale del braccio e/o della mano ma che allo stesso tempo sono troppo deboli per portare a termine il movimento che desiderano effettuare. All'interno di Scenario 2 e Scenario 3, invece, il soggetto non presenta più alcuna residua attivazione funzionale volontaria dei muscoli del braccio e talvolta neanche di quelli della mano. Le persone che appartengono allo Scenario 2 sono quelle che hanno ancora la capacità di compiere movimenti oculari; pertanto possono far conoscere le proprie intenzioni a MUNDUS attraverso un sistema di "Eye Tracker". Quando anche questa capacità viene persa, i pazienti rientrano in Scenario 3 il quale dà la possibilità di guidare il dispositivo tramite segnali EEG (Brain Computer Interface).

Lo studio qui proposto si focalizza sulla finalizzazione e successiva validazione della piattaforma sviluppata per i pazienti di Scenario 1. In particolare, il lavoro si è concentrato sullo sviluppo di un algoritmo per la detezione della volontà dell'utente sulla base del segnale EMG residuo. L'obiettivo è quello di implementare una soluzione semplice da comprendere da parte del sistema e tale da identificare le intenzioni del paziente con ridotta probabilità di errore. Il codice implementato presenta inoltre la possibilità di adattarsi alle caratteristiche del soggetto che lo utilizza e un basso rischio di rilevare segnali che siano falsi positivi. Per verificare la robustezza dell'algoritmo e la sua corretta comunicazione con l'intero sistema MUNDUS, due sessioni di test sono in

seguito state condotte. La prima unicamente su soggetti sani mentre la seconda ha previsto la partecipazione sia di pazienti che di sani.

2 Metodi

Come esposto in precedenza, il lavoro qui descritto si inserisce in Scenario 1. Il principale modulo messo a disposizione del paziente è l'esoscheletro per il supporto del braccio durante i movimenti. A seconda delle necessità del soggetto, possono essere utilizzati anche altri componenti presenti nel "modulo braccio" e nel "modulo mano" di MUNDUS. Il primo prevede di supportare ed assecondare i movimenti del paziente tramite la stimolazione elettrica neuromuscolare (NMES) del bicipite e del deltoide mediale. Il secondo invece fornisce un sostegno nella chiusura e apertura della mano tramite stimolazione NMES o l'utilizzo di una protesi robotica. Per quanto riguarda il loro funzionamento, una macchina a stati (MUNDUS CC) garantisce un alto livello di comunicazione tra tutti i componenti che si è scelto di utilizzare all'interno del sistema. Quest'ultima è messa in comunicazione diretta con un PC (real-time control system, RTS), il quale lavora in tempo reale per generare e coordinare i singoli movimenti del dispositivo. La detezione della volontà del soggetto per il suo controllo del dispositivo può essere effettuato in due modi. Uno è rappresentato dal lavoro qui discusso e si basa sulla detezione del segnale EMG residuo dell'utente; la seconda modalità è invece rappresentata dall'utilizzo di un pulsante-USB.

Setup sperimentale

Il setup sperimentale utilizzato all'interno del presente lavoro prevede l'impiego di tre componenti: un personal computer per l'acquisizione ed analisi dei dati in tempo reale, un amplificatore di segnali elettromiografici (EMG) e un esoscheletro passivo per la movimentazione del braccio. La fig.2 di seguito illustra l'interazione dei diversi moduli sia tra di loro che con MUNDUS CC.

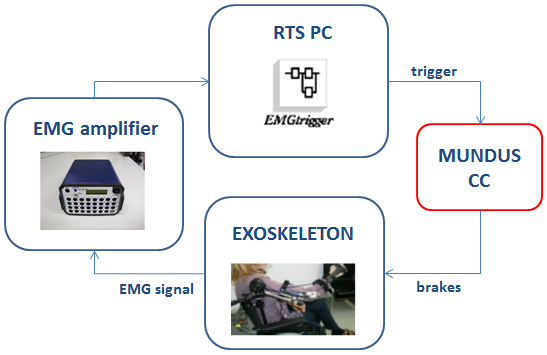


Fig.2: experimental setup.

Per prima cosa, il PC RTS è stato utilizzato per l'implemetazione dell'algoritmo oggetto di studio del presente lavoro. Si è infatti fatto uso dei software per l'acquisizione e l'elaborazione dei segnali in tempo reale di cui il PC è dotato (PC Linux_RTAI, Scilab/Scicos). Il secondo componente utilizzato è l'amplificatore di segnale EMG; la sua funzione è quella di rilevare la contrazione volontaria effettuata dal soggetto e comunicare tale evento direttamente all'ingresso del blocco contenuto nel pc RTS. Infine, l'esoscheletro è un dispositivo meccanico dotato di un sistema di molle e smorzatori che in parte supportano il peso del braccio di chi lo indossa. Tale esoscheletro, sviluppato all'interno del progetto MUNDUS è dotato di 3 gradi di libertà (elevazione e rotazione della spalla, flesso/estensione del gomito) e può essere montato direttamente sulla sedia a rotelle del paziente. Nelle tre direzioni in cui è concessa libertà di movimento, l'esoscheletro è munito di freni elettromagnetici controllabili da PC.

Algoritmo per individuare l'intenzione del soggetto sulla base del segnale EMG

All'interno di questo studio è stato sviluppato un algoritmo per permettere all'utente di Scenario 1 di scandire i movimenti che vuole eseguire con il supporto di MUNDUS. E' infatti lasciata la possibilità al paziente di attivare e/o disattivare autonomamente i freni al fine di mantenere una desiderata posizione e di aprire o chiudere la mano per afferrare o rilasciare oggetti qualora l'utente necessiti di utilizzare anche il modulo per il supporto delle funzioni della mano. Per interagire con il sistema è necessario che il soggetto invii un segnale per rispondere ad alcune domande che compaiono su uno schermo posizionato davanti a lui.

La soluzione implementata prevede l'elaborazione del segnale EMG acquisito su un muscolo del braccio controlaterale rispetto a quello supportato da MUNDUS.

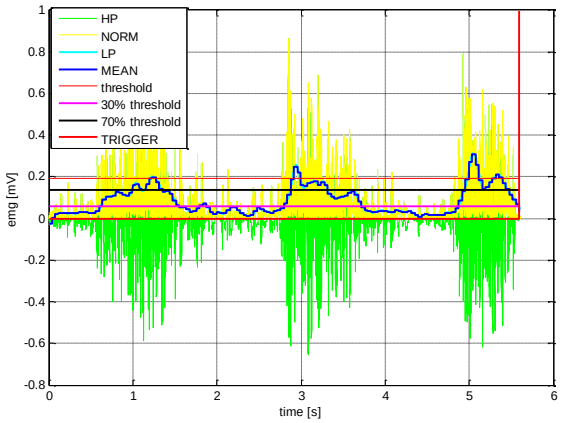


Fig. 4: example of EMG signals acquired from the brachioradialis muscle of one healthy subject.

Quando il paziente vuole comunicare la sua intenzione deve effettuare una semplice sequenza di tre contrazioni isometriche della durata ciascuna di un secondo circa. L'algoritmo è stato scritto appositamente per riconoscere tale successione di contrazioni e generare un segnale (trigger) da inviare a MUNDUS CC per comunicare la decisione del soggetto. La procedure implementata prevede che inizialmente il segnale ricevuto venga filtrato da un filtro passa alto (10 Hz), rettificato e nuovamente filtrato passa-basso a 5 Hz. Successivamente, ogni 40ms ne viene calcolato il valore medio e tale dato è poi confrontato con una soglia che è stata opportunamente identificata sul singolo soggetto in fase iniziale (fig.4). Quando il paziente effettua una contrazione, questa viene riconosciuta grazie al confronto del segnale con due differenti valori che corrispondono al 70% e 30% della soglia calibrata in partenza sul soggetto. Il superamento della soglia superiore sancisce l'inizio dell'attivazione del muscolo da parte dell'individuo monitorato; quando il segnale scende sotto quella inferiore (fine dell'attivazione) il contatore delle contrazioni viene incrementato. Una volta che quest'ultimo ha rilevato la conclusione della terza contrazione, un trigger viene inviato al sistema (fig.5).Attenzione è stata posta su alcuni aspetti all'interno del codice che limitino il più possibile l'insorgere di errori; un esempio è la possibilità di impostare il valore massimo di durata dell'intervallo tra due contrazioni successive. Qualora questo non venga rispettato, il contatore considera l'ultima contrazione rilevata come la prima di una serie successiva. Durante lo svolgimento di attività quotidiane da parte del

soggetto, c'è infatti il rischio di fraintendere contrazioni dovute ad un suo generico movimento con la volontà di questi di comunicare un comando al sistema.

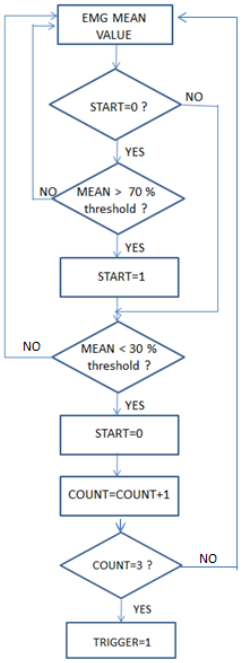


Fig. 5: Algorithm flow chart.

Validazione dell'algoritmo per la detezione dell'intenzione

Una prima serie di test è stata condotta per valutare la robustezza dell'algoritmo.

Per effettuare i test è stata richiesta la partecipazione di quattro soggetti sani e il setup sperimentale non includeva la presenza dell'esoscheletro. A ciascuno di loro è stato chiesto di trascorrere un'ora di attività a loro scelta tra quelle comunemente svolte stando seduti ad un tavolo. La scelta è ricaduta su studiare, leggere e scrivere, pranzare e intrattenersi con gli amici. Nel frattempo, è stato monitorato su di loro il segnale EMG di quattro muscoli (brachioradiale, trapezio, sternocleidomastoideo e frontale) al fine di rilevare il numero di volte che il soggetto attivava involontariamente il trigger (sequenza di tre contrazioni ravvicinate). All'inizio e alla fine della prova a ciascun soggetto è stato chiesto di effettuare una serie di contrazioni volontarie con lo scopo di valutare la facilità di comprensione della procedura di attivazione del trigger EMG. In particolare, si è valutato il tempo necessario affinché l'algoritmo riconoscesse il trigger a partire dall'instante in cui veniva richiesto al soggetto di inviarlo.

Validazione di MUNDUS – Scenario 1

La seconda serie di test è stata effettuata con lo scopo di validare lo Scenario 1 di MUNDUS svolgendo un'analisi complessiva del dispositivo assistenziale. Durante le sessioni è stato inoltre testato il corretto funzionamento dell'algoritmo sviluppato e la sua comunicazione con gli altri moduli all'interno del sistema. Per lo svolgimento delle sessioni di test è stata richiesta la presenza di tre pazienti e di cinque soggetti sani. La partecipazione di questi ultimi è servita a raccogliere dati per stimare i "range di normalità" da confrontare con le prestazioni eseguite successivamente. I tre pazienti che hanno effettuato i test appartengono a Scenario 1 e sono stati selezionati in quanto affetti da patologie tra quelle considerate all'interno del progetto MUNDUS. Il protocollo ha richiesto l'utilizzo dell'esoscheletro con la possibilità di attivarne i freni sfruttando l'algoritmo implementato all'interno di questo studio. Il test prevedeva l'esecuzione di dieci ripetizioni di quattro movimenti quali bere da una cannuccia, toccare la spalla sinistra, toccare la mano sinistra e schiacciare un bottone. I parametri che sono stati monitorati sono: il tempo di esecuzione, la velocità media, la capacità di eseguire una traiettoria rettilinea e la fluidità del movimento. Ai soggetti sani è stato richiesto di fare una sola eseguzione della prova mentre ai pazienti di ripetere tre volte la sessione in giorni separati.

3 Risultati

Prove di validazione dell'algoritmo

I risultati del test hanno confermato che l'algoritmo è in grado di rilevare l'intenzione del soggetto e che a sua volta quest'ultimo è in grado di eseguire facilmente la sequenza di contrazioni ravvicinate. Inoltre, è stato scelto il valore da assegnare ad alcuni parametri temporali fissi relativi al funzionamento del codice e contemporaneamente sono stati selezionati quelli che è preferibile calibrare sul singolo utente. Alcune osservazioni sono state fatte anche riguardo alla scelta del muscolo da utilizzare per rilevare l'intenzione del soggetto. Nonostante sia stato confermato dai test che il muscolo debba venir scelto in base alle caratteristiche e alle preferenze di ciascun individuo, alcuni tra quelli selezionati durante la procedura si sono rivelati inadeguati. Un esempio è il muscolo frontale: in quanto utilizzato per la mimica facciale, è stato spesso contratto involontariamente.

Prove di validazione di Scenario 1

Nella seconda sessione di test i soggetti sono stati capaci di eseguire autonomamente tutte le ripetizioni dei movimenti richiesti. Questo aspetto sottolinea che MUNDUS è in grado di far eseguire attività di vita quotidiana a pazienti che non ne sarebbero in grado autonomamente, soprattutto per l'insorgere di effetti quali la fatica in seguito a numerose ripetizioni. Durante la procedura il codice si è dimostrato robusto anche nel comunicare con gli altri moduli di MUNDUS. Durante ciascuna sessione, i pazienti sono riusciti ad attivare e disattivare i freni comunicando con il sistema attraverso il segnale EMG rilevato da un muscolo a loro scelta. Inoltre, nessun falso positivo è stato rilevato durantele sessioni. Infine, i dati raccolti durante le sessioni del test sono stati in seguito elaborati da un punto di vista statistico. Da tale analisi è stato riscontrato che nell'arco dei tre giorni due pazienti su tre hanno migliorato l'esecuzione dei movimenti richiesti dal protocollo. Tale fatto indica una certa rapidità di apprendimento nello sfruttare al meglio tutte le qualità del dispositivo assistenziale.

4 Conclusioni e sviluppi futuri

Sulla base di quanto riscontrato dai risultati dei test effettuati, è possibile concludere che l'algoritmo sviluppato nel presente studio è robusto e risponde alle richieste per le quali è stato implementato. Permette infatti di rilevare la volontà del soggetto e di comunicarla al sistema con cui egli deve interagire. Inoltre, si è dimostrato facilmente comprensibile da parte degli utenti, i quali hanno trovato semplice la sequenza di contrazioni da effettuare per comunicare la propria intenzione. Allo stesso tempo, anche l'utilizzo generale del dispositivo MUNDUS non ha portato complicazioni agli utenti.

Tra le due modalità messe a disposizione in Scenario1, i pazienti reclutati nei test hanno preferito comunicare tramite l'utilizzo del segnale EMG residuo di un loro muscolo piuttosto che premere un pulsante. Infatti, laddove il paziente non ha sensibilità al tatto, questi non riesce a dosare opportunamente la forza con cui schiacciare il pulsante. La modalità studiata all'interno del presente lavoro si è quindi rivelata la più utile per loro.

Miglioramenti possono essere apportati al modulo per fronteggiare l'insorgere della fatica durante l'esecuzione dei movimenti. Con il passare del tempo è infatti stato riscontrato che il paziente contrae meno intensamente il muscolo monitorato. Sarebbe

opportuno sviluppare un algoritmo che aggiorni la soglia di attivazione del trigger durante l'utilizzo del dispositivo. In conclusione poi, andrebbe effettuata una validazione più complessiva di Scenario 1 che richieda l'utilizzo dei moduli del braccio e della mano da parte dei pazienti.

Abstract

1 Introduction and objective of the work

Nowadays the medical assistive devices are more and more widespread. Many researches have been directed towards helping motor impaired people: the aim is to give assistance and improve the quality of their life. Especially, it is possible to identify this purpose in the fact that the patients are more independent while are using them. The recent introduction of the robotics in the area of assistivel devices took to a clear improvement to that instrumentation; from its introduction, indeed, a lot of steps forward were made, such as progresses regarding the independent ambulation. The modular assistive devices are more recently studied.

The present work takes part in the European project MUNDUS (MUltimodal Neuroprosthesis for Daily Upper limb Support), whose main aim is to realize a neuroprosthesis assistive device which allows the upper arm movements. MUNDUS is a modular system which makes use of all the residual motor capability of the user. In fact, it offers the possibility of being suited to the patients with the aims of empowering their abilities and of allowing them to move their arm during daily life activities. Targets of the device are people affected by neurodegenerative and genetic neuromuscular deseases, such as Lateral Amiotrophic Sclerosys (SLA), Friedreich ataxia (FRDA) and Multiple Sclerosis (SM), as well as people who suffer of serious lesions of the spinal cord (Spinal Cord Injury). Such drawn up pathologies are for the most degenerative, and they cause the patients a gradual loss of motor capability. MUNDUS has been conceived to be adapted to the pathology level. Through the selection of sensors, actuators and more adapted control solutions, it is possible for the user to personally supervise the device with a direct approach (fig.1).

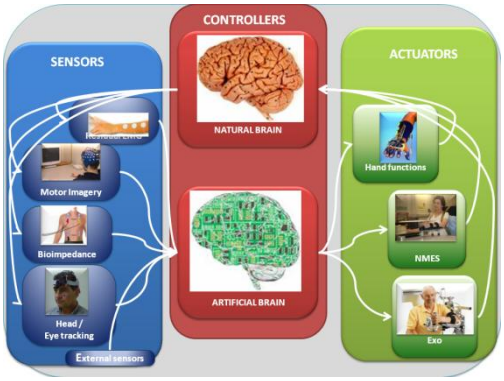


Fig.1:MUNDUS concept.

Although the possibility of keeping the device adapted to the patient is given by adding and substituting modules, three scenarios are considered in order to reply better to the pathology necessities. Scenario 1 gathers all the patients that have a residual functional control of the arm and muscles, but who are too weak to accomplish functional tasks. In Scenario 2 and 3 indeed, the subject does not show any residual voluntary functional activation neither of the arm nor of the hand muscles. People belonging to Scenario 2 can still control the head and gaze fixation; thus, they can use the "Eye tracker" system to show their intentions to MUNDUS. Finally, subjects that cannot interact by brain signals (EEG) are enlisted in Scenario 3.

The present study focuses on the conclusion and validation of the platform developed for Scenario 1 patients. More in details, the work is centered on the development of an algorithm to detect the user's intention based on the EMG signal. The aim is to implement a solution which is simple to be understood by the system and able to identify the user's will without errors. The code gives the possibility to be adapted on patient's characteristics together with a low probability of detecting false positive events. In order to check the algorithm robustness as well as its correct communication with the whole MUNDUS system, two test sessions were done. In the first one only healthy subjects were included while in the second both patients and healthy people were asked.

2 **Methods**

The work here presented is included in Scenario 1. The main MUNDUS module used by the patient is the exoskeleton which supports the arm during movements. With

respect to the needs of the user, other components could be used. They are the “arm module” which could help the person in doing actions by the use of the NMES stimulation on both the biceps and the medial deltoid. The second block is the “hand module”: it is composed by two different solutions which can aid the closure and opening of the hand during grasping movements. They are composed by either a glove with NMES stimulation or a robotic orthosis. The operating of all the modules is coordinated by a state machine (MUNDUS CC) that guarantees a high level of communication within the system. It is directly linked to a PC (real-time control system, RTS); it drives the system in real-time and allows the cooperation among all the blocks. The user’s intention detection could be accomplished by the use of two modalities: the first one is based on the EMG signal and it is the one here presented; the other one exploits the use of a USB-button.

Experimental setup

The experimental setup used within the current work consists of three main components: personal computer used to control the system and acquire the signals in real-time, an EMG amplifier and a light weight passive exoskeleton to support the arm weight during movements. In Fig. 2 it is clearly shown how they direct interact both with each other and with MUNDUS CC.

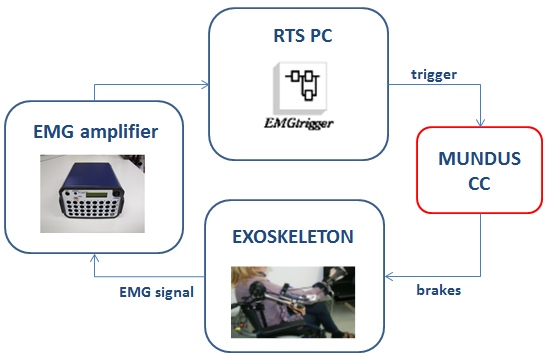


Fig.2: experimental setup.

First of all, the RTS PC has been used to implement the algorithm studied within this work. In fact, the PC is supported by software for the acquisition and elaboration of the EMG signals in real-time (PC Linux_RTAI, Scilab/Scicos). The second component is the EMG amplifier; its aim is to detect the voluntary contraction made by the subject

and to communicate it to the block in RTS PC. Finally, the exoskeleton is a mechanical device provided with dumping elements and elastic structures for supporting the arm weight giving gravity compensation. It has 3 degrees of freedom (shoulder elevation and rotation, elbow flexo-extension) and could be directly included in the patient's wheel chair. Three electromagnetic brakes are contained within the EXO to allow the control of the joints by the use of the PC.

Algorithm to detect the user's intention based on the EMG signal

Within the present studying an algorithm has been implemented; it allows the Scenario 1 user to trigger the movements he wants to make with the MUNDUS device. The patient could activate or deactivate the brakes by himself in order to keep a chosen position; in addition to this, he can decide to open or close his hand to accomplish grasping tasks whenever he needs to use the hand module as well. To interact with the system it is necessary that the subject sends a signal which shows his answers to questions that are plotted on a screen in front of him. In the implemented solution, the EMG signal is acquired from a muscle of the contralateral upper limb and then elaborated.

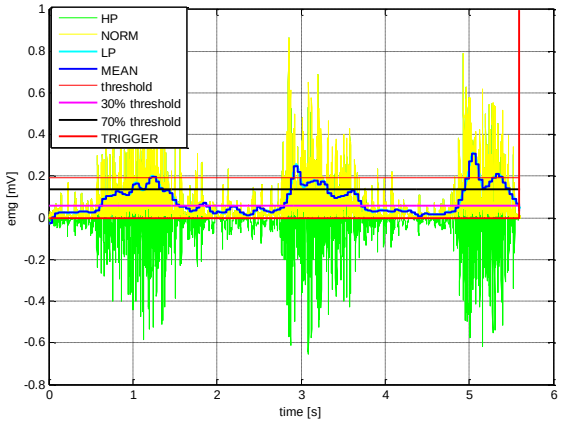


Fig. 4: example of EMG signals acquired from the brachioradialis muscle of one healthy subject.

When the user desires to communicate his will he is requested to do a simple series of three isometric contractions that last nearly one second each. The algorithm has been developed to detect that series and to generate a trigger to be sent to MUNDUS CC to transmit the decision of the subject to it. The signal acquired is first of all high-pass

filtered (10 Hz), rectified and filtered again by a low-pass filter (5 Hz). After that, signal mean value is calculated each 40 ms and its output value is compared to a threshold took from the patient during the initial calibration procedure (fig.4). Thanks to the comparison with the 70% and the 30% of the threshold value, contraction is detected. Whenever the patient activates his muscle, the signal values become higher than the activation threshold so the start of the activation is noticed by the system. After that, when the output data received goes under the deactivation threshold, the contraction counter increments its number. When three contractions are recognized, a trigger is sent to the system (fig.5). Attention has been paid on several code features that limit the possibility of mistaking false positive. One example is the possibility to select the maximal duration of the interval that separates two consecutive contractions. When time between two activations is longer than it, the counter considers the last contraction as the first of the following series. During daily life activities there is the risk of mistaking the muscle contractions of a common movement with the user's intention of communicating with the system.

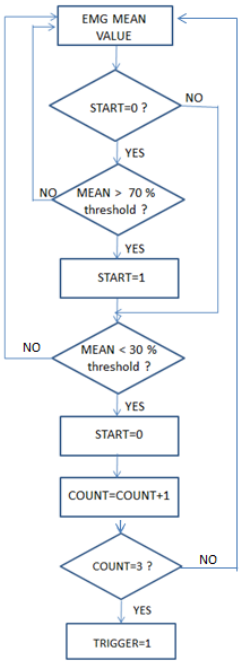


Fig. 5: Algorithm flow chart.

Experimental validation of the algorithm

A first series of tests has been done to check the algorithm robustness.

To do the trials four healthy subjects were recruited. The exoskeleton was not included in the experimental setup. The participants were asked to spend one hour in doing a common daily life activity around a table. They could have chosen among studying, reading and writing, having lunch and being with friends. During the whole hour EMG signals have been monitored from four muscles (brachioradialis, trapezius, sternocleidomastoid and frontalis) to detect the unwilled trigger activations caused by the subject. Both at the beginning and at the end of the session the people were asked to do a series of willed contractions to evaluate if the trigger activation procedure was easy to be learnt. In details, it has been evaluated the time spent between the moment in which the subject was asked to activate the trigger and the one in which it was detected by the system.

Validation of MUNDUS - Scenario1

The aim of the second series of trials was to validate MUNDUS Scenario 1 by doing a general analysis of the assistive device. During the sessions, the algorithm correct operating has been tested as well in particular it has been check it communication with the other MUNDUS modules. Three patients together with five healthy persons were asked to do the test. The participation of the second group has been useful to collect data to calculate the "normality ranges" to be compared to the following performances. The three patient recruited in the session belong to Scenario 1 and were selected due to their pathologies which are among the MUNDUS target ones. The exoskeleton has been used in the test and the subjects were supposed to activate the brakes with the help of the algorithm here studied. It has been asked to do ten repetitions of four movements: drinking with a straw, touching left shoulder, touching left hand and pressing a button. The monitored parameters are: time, mean speed, straightness and smoothness. The healthy subjects have to do only one repetition while the patients did three sessions during consequent days.

3 Results

Validation of the algorithm - test

Test results confirmed that the algorithm is proficient in detecting subject's intention and that the subject itself is allowed to perform easily the sequence of close

contractions. Moreover, it was chosen the value to assign to some fixed temporal parameters relative to the functioning of the code and at the same time were defined the parameters which should be calibrated on each subject. Some observations were also made regarding the choice of the muscle to be used to detect subject's intention. Even if tests confirmed that the muscle should be chosen based on the characteristics and on the preferences of each individual, some among the parameters selected during the procedure, showed to be inappropriate. An example is the frontal muscle: since it is used for facial mimics, it was often contracted unintentionally.

Validation of MUNDUS Scenario1 - test

In the second test session, subjects were capable of executing autonomously all the repetitions of required movement s. This aspect highlights the fact that MUNDUS makes patients perform daily-life activity, that otherwise would not be possible especially due to raising of effects, such as fatigue after numerous repetitions. During the procedure the code proved to be robust even in communicating with other MUNDUS modules. During each session, patients managed to activate and inactivate brakes, communicating with the system through the EMG signal detected from a muscle chosen by themselves. Furthermore, no false positive was detected during sessions. Lastly, collected data during test sessions were processed afterwards from a statistical point of view. Given the analysis, it was found that in the period of three days two patients out of three improved the execution of the movements required from the protocol. This fact shows a certain speed in the learning process in exploiting at the best all the qualities of the assistive device.

4 Conclusions and further developments

Based on what assessed from the tests, it is possible to conclude that the algorithm developed in the present study is robust and answers to the requirements for which it was implemented. It allows to detect subject's will and to communicate it to the system with which the patient needs to interact. Moreover, it proved to be easily understandable from the patients, who found simple the sequence of contractions to perform to communicate their intentions. At the same time, even the general use of MUNDUS device did not cause further complications for the users.

Between the two modalities presented in Scenario 1, patients selected for the test preferred to communicate through EMG residual signal of one of their muscle rather than pushing a button. This is because since patients do not have tactile sensibility, they cannot dose properly their pushing force. The modality studied in this work turned out to be more useful for them.

Improvements could be added to the module to face the onset of fatigue during movement execution. As a matter of fact, it was noticed that after some time the patient was contracting less intensively the monitored muscle. It would be appropriate to develop an algorithm that would update the threshold of trigger activation during the utilization of the device. In conclusion, a broader validation should be carried out of Scenario 1 that would require the patient to use arm and hand modules.

Chapter 1

Introduction

1.1 Assistive devices

All the systems created in order to enhance lives of persons with disabilities are called "assistive devices" (AD). Technologies gathered under this name could be very different one from the other, actually they space from manual wheelchairs to the motorized ones, to highly sophisticated robotics and augmentative communication devices [1]. Even if some of them seem to have nothing in common with the others, all ADs are focused on satisfying the needs of disabled users.

To cover all the consumers' requests is not easy, but in the last decades more and more studies have been directed towards improving patients' independence and quality of life. In particular, researches have been made in order to achieve many potential benefits as enhanced mobility, vocational tasks and improved communication with other people, aspects most wished by the users. At the same time, enhancements have been made in terms of a more widespread possibility to live at home instead of in long-term facilities and a lessened burden for the caregivers [2]. Over the years, large and complex assistive technologies have become more affordable in respect to aesthetical aspects because there is the need of an improved self-image of the person which has to meet the continuous attention towards safety advance.

At the same time, the possibility of making the patient more and more independent by using assistive devices could create some problems to him. Loss of human interaction and the consequent fear of social isolation are two of the main aspects on which attention should be paid while studying a new device [3]. A balance towards this direction has always to be taken into consideration, for example by helping him in being

more independent while he spends time with friends or doing all the other common daily activities. In addition to this, it is needed to remember here that the principal role of ADs is to cooperate together with the caregiver; indeed a complete substitution of human help is far to be achieved and –as explained before- it is neither requested by users.

Other types of ADs are aimed at preventing complications due to immobility, such as the outbreak of osteoporosis which occurs in elderly patients that have been used wheelchair for long [4]. The extended permanence in a bed could create problems in blood circulations [5] as well as bed sores. Due to this, ADs created to prevent the enlisted bad outcomes are more and more used both in hospitals and within patients' houses [6].

Nowadays many ADs are commercially available and they manage to cover lot of the users' requests. In order to find out the "ad hoc" system to each person, ADs are diverse and at the same time provided with own specific characteristics. Nevertheless there is still the risk to prescribe an improper device to the patient with the consequence of damaging him. In order to avoid this problem, many researches are now directed towards the setting-up of devices which could be customizable on each user.

1.1.1 Robotic and hybrid assistive devices

An important improvement in the field of patient assistance is the introduction of robotics. Due to this, nowadays the majority of ADs studied are the robotic ones (RD). Researches are directed towards more functional and aesthetically pleasing systems which may have an advantage in size, appearance and user control features [2]. Robotics allows patients to train independently of a therapist and to improve upon their own functional level. It is the case of the robotic-assisted body-weight-supported treadmill training (BWSTT) which is a device that enhances motor control and walking ability [7]. Furthermore, there is the strong evidence to increase treatment compliance by way of inducing incentives to the subject, such a game [8]. Devices gathered in this

group are often rehabilitative systems that enable the training of activities of daily living (ADL) with the support of an assistive robot empowered by a virtual environment [9].

Every day individuals living with impairments face barriers on many levels [3]. RDs work on the user capacity to independently mobilize so that he could be able to getting around the home and accomplish some tasks as both the daily hygiene and the possibility to eat by himself. In respect to self-feeding tasks, more and more devices commercially available aim at accomplish this necessity. They space from Mealtime Partner to DeVAR and from SECOM MySpoon to the MANUS arm [2]. The first one focuses only on the way of letting the user eat alone while the last is a complete robotic arm which can supply for lots of actions till opening cabinet door and putting on glasses. As well as RDs in general, they all embody sensors from all the categories. In respect to their specific functions, sensors could be enlisted here; the exteroceptive instruments are the one which register force, vibration and pressure; by the use of them the subject can avoid obstacles, monitor the area around him and calibrate the force to be used towards the objects. Another way to receive information from the environment is related to visual sensors (e.g. cameras) and to the auditory ones. They become relevant towards people that use such devices in their own houses where unintended obstructions could often be faced [10]. In conclusion, all sensors cooperate in coupling the person and the device in order to gain safe and effective interaction. In addition, RDs are composed by appropriate user interfaces (e.g. joystick, pc screen) and control systems. The second ones with both software and hardware, are getting more and more sophisticated by mimic natural upper limbs movement [2].

In parallel with the development of new singular device potentiated by robotics, studies are directed towards testing the advantages got from the union of some of them in a single "modular assistive devices". Nowadays only few kinds of electrical wheelchairs endowed with robotic arm are sold [11] but researches aim at enlarge this area of interest.

The combination of neuromuscular electrical stimulation (NMES) and an externally powered and controlled brace has become a promising technique able to blend together technologies, actuation, and rehabilitation principles that could overcome the

performances of each single approach [12]. This combined system is called hybrid assistive system (HAS) [13].

1.1.2 Assistive devices evaluation

From the user perspective, RDs can be divided into two groups: physically assistive robots (PAR) and socially assistive robots (SAR) [2]. The first one is composed by all RDs which give mechanical assistance to the user. On one hand they can execute different functions according to user's perspective, in particular fetch and carry tasks; on the other hand, there is an unwanted aspect related to them which is the slowness in doing actions. SAR are devices that give assistance and help in achieving measurable progresses. Their characteristic is the noncontact human-robot interaction which decreases risks and allows quicker execution of tasks.

The previous mentioned is one of the few existing way of categorizing ADs. In fact, the literature is deficient in this, there is no comprehensive analysis of the ultimate criteria by which such devices could be judged [1]. On the contrary, many studies aim at check whether a specific robotic device help user or not. An example are the overspread analysis on stroke patients [14] as well as the one affected by ataxia [15]. Nevertheless, the quantitative analysis obtained from them could not be enlarged to all the other RDs due to the fact that researches always focus only on a pathology kind supported by an exact device.

Nevertheless, the need of evaluate AD is urgent, especially now that they are becoming more and more widespread. The reason is that, by an exhaustive list of assessments, there could be the possibility to have a more careful improvement in assistive technologies.

A general principle is to evaluate whether the ADs satisfy the need of the disabled consumer. This criterion often comes useful to doctors as well, in order to do clinical evaluation and to prescribe the device itself. Unluckily, sometimes the patient, especially who is "newly-disabled", does not know exactly which are his own needs because he is not familiar with them yet. A device that does not result helpful for the user can provoke frustration and dissatisfaction. To face this problem, a series of

"assessment questions" are used by the clinician to guide the user in the selection of the most appropriate AD. The evaluation is based on the difficulty in learning to use the device, the discomfort that AD could cause, the danger associated to the utilization and the interference with the individuals lifestyle and social activities.

A.I. Batavia and colleagues [1] identified 17 general factors to describe 11 types of AD. Even if they do not express a strictly numerical evaluation, some of the elements taken in consideration (e.g. dependability, effectiveness, operability) need to be judge by the use of dynamic and kinematic variables registered during test sessions.

In conclusion people said that it is difficult to judge whether AD will meet the user's needs if the device has not been used for long time. The consumer who has used the device for an extended period of time is in the best position to offer factors to be considered in developing evaluation criteria for ADs.

1.2 MUltimodal Neuroprosthesis for Daily Upper limb Support – MUNDUS

The present work has been carried out within the European project MUNDUS[1].

MUNDUS is an assistive framework for recovering direct interaction capability of severely motor impaired people based on arm reaching and hand function. Nowadays most of the solutions provided by Assistive Technology for supporting independent life of severely impaired people completely substitute the natural interaction with the world, reducing their acceptance. Indeed, the majority of the available solutions assist or substitute the arm movements but either they could be gather into SAR category (noncontact human-robot interaction) or –whenever they directly couple with the user limb- they work starting from the "robot perspective" (e.g. paths are already planned).

People, coming from personal history of severe traumas or neuromuscular diseases that had led to a sudden or progressive loss of motor capabilities, attribute a high value to the maintaining of direct interaction with the objects of daily life [2].

1.http://www.mundus-project.eu

Simple gestures, such as taking autonomously a glass, bringing it to the mouth and drinking, are actions that contribute to a positive assessment of their own quality of life. Human dignity and self-esteem are more preserved when restoring missing functions with devices safeguarding self-perception and first hand interaction while guaranteeing independent living. MUNDUS provides an innovative solution offered by a customizable and modular system able to exploit any residual motor capability of the user and empower him allowing the natural motion of the arm in the space. Sensors, actuators and control solutions (fig.1.1) adapt to the level of severity or to the progression of the disease allowing the user to directly drive the system.

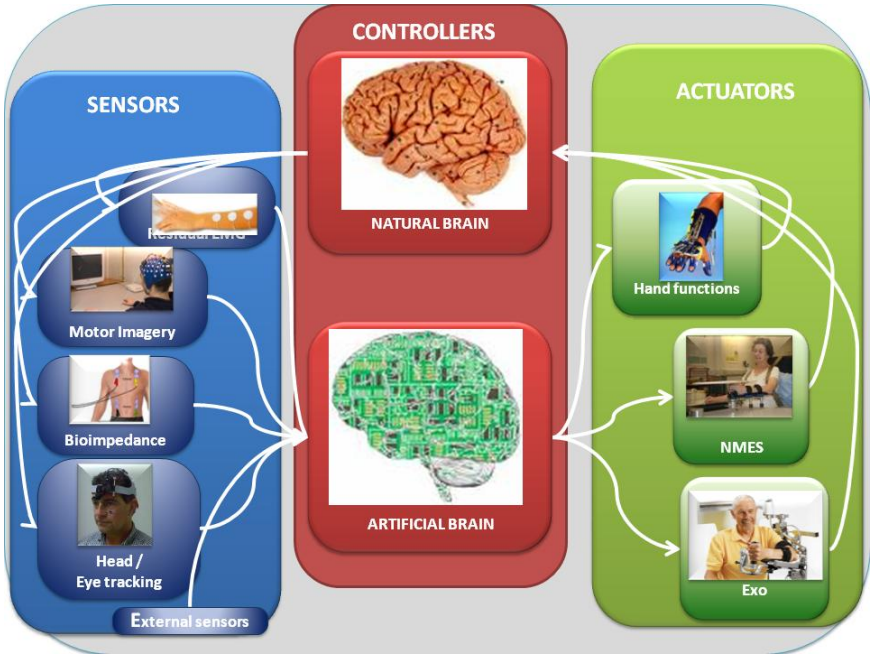


Fig.1.1: MUNDUS concept

MUNDUS implements a new concept of assistive Neural Prosthesis (NP) to support basic arm functions; it helps the subject to reach an object by positioning the arm in the space, to grasp it and to bring it to a target final destination (the mouth or other location in the user's own space).

The motion of the arm is supported by a light exoskeleton (EXO), powered by residual muscle functions, or muscular contractions artificially induced by Neuro Muscular Electrical Stimulation (NMES).When the user does not have any residual hand

functions, different solutions to support the gross grasping of cylindrical objects are also available: an actuated robotic hand orthosis and a NMES-based grasping system including a garment with embroided stimulation electrodes. The best solution can be selected according to the user's condition.

MUNDUS platform has the advantage of being adaptable towards degenerative diseases. Despite the majority of AD that have to be changed every time that the pathology enters a worse step, MUNDUS can keep on helping the patient at each stage by adding or substituting some modules. Due to this fundamental characteristic, problems related both to finding the best device for the patient and to coping with newly disabled people could be overcame. In addition, allowing immediate adjustment to the new situation it is possible to reduce training time. In severe neurodegenerative impairments, the possibility to manage the same AD device from the early phases of the disease to the latest ones is a key issue to increase acceptability of the system itself and to increase its usability.

On the control level, MUNDUS exploits any voluntary command that the user is able to send. In case of impairment of neuromuscular functions, there are few exploitable commanding strategies, to detect the willingness to move and the capability to decide "where to go": electromyography (EMG) signals, by taking advantage of residual local neuromuscular function, head motion and eyes motion, brain signals when muscular activities are no more available. MUNDUS pursues the modular implementation of both these possible strategies. It will depend on the MUNDUS user to decide which control to use accordingly to his capabilities.

On the execution level, MUNDUS allows the choice of actuators, again, accordingly to available personal resources. When it is possible, the motion of the exoskeleton is powered by user own muscles, facilitated by EXO gravity compensation. Alternatively, NMES is used to get the desired motion; on the other hand when this is not possible, a simple mechanism is used to support wrist and hand motions. The design of exoskeleton supporting the arm is tailored to a real light and non-cumbersome solution.

At the hand level, it is possible to use the own hand when, due to the spinal injury or disease progress, the proximal motor function is more impaired than the distal one, and,

consequently, the disabled person has an insufficient shoulder and elbow control to exploit the residual hand mobility. Alternatively, an NMES actuated grasping glove is available to assist the grasp of collaborative "functional objects" (e.g. a cup within a special handle).

1.2.1 MUNDUS - pathologies

The expected users of MUNDUS are people coping with neurogenerative and genetic neuromuscular diseases such as Amyotrophic Lateral Sclerosis (ALS), Friedreich Ataxia (FRDA) and Multiple Sclerosis (MS) plus persons affected by high level Spinal Cord Injury (SCI). Most of these pathologies are characterized by a progressive course of the impairment with a faster or slower continuous loss of motor capabilities.

ALS is a relatively rare disease with a reported population incidence of between 1.5 and 2.5 per 100000 per year [16].It is a rapidly progressive neurological disease that attacks the nerve cells (neurons) responsible for controlling voluntary muscles. Gradual degeneration and death of motor neurons characterize the pathology: they are nerve cells located in the brain, brainstem, and spinal cord that serve as controlling units and vital communication links between the nervous system and the voluntary muscles of the body. In ALS, both the upper motor neurons and the lower motor neurons degenerate or die, ceasing to send messages to the muscles. Due to disuse, the muscles gradually weaken, waste away (atrophy), and twitch (fasciculation). Eventually, the ability of the brain to start and control voluntary movement is lost. In addition the patient is affected by painless weakness and he feels only few or no sensory symptoms. Average survival time ranges from 3 to 5 years after onset of symptoms, although about 10 percent of ALS patients survive for 10 or more years.

FRDA is a genetic, progressive, neurologic movement disorder. Symptoms may include unsteady posture, frequent falling, and progressive difficulties walking due to an impaired ability to coordinate voluntary movements (ataxia). It results from a lack of function of the frataxin protein that turns out in degenerative changes of nerve fibers of the spinal cord as well as peripheral nerves, which are motor and sensory nerves and

groups of nerve cell bodies (ganglia) outside the brain and spinal cord. Generally, within 15 to 20 years after the appearance of the first symptoms, the person is confined on a wheelchair and in later stages of the disease individuals become completely incapacitated [17]. The incidence of FRDA has been estimated to 1 in 50000 in Europe.

MS is an autoimmune condition in which the immune system attacks the central nervous system, leading to damages to the myelin sheath. It affects the ability of nerve cells in the brain and spinal cord to communicate with each other effectively. The communication is based on sending electrical signals (action potentials) down axons, which are contained within an insulating substance called myelin. When myelin is lost, the axons can no longer effectively conduct signals. Among all the symptoms caused by MS, three of them are relevant to be underlined here: muscle weakness, trouble with coordination and balance and sensation such as numbness and prickling. MS has a prevalence that ranges between 2 and 150 per 100000 depending on the country or specific population [18]. Although the disability progression, in the latest years the life expectancy of people with MS, is nearly the same as that of unaffected people.

SCI usually begins with a blow that fractures or dislocates vertebrae, the bone disks that make up the spine. Most injuries don't sever the spinal cord. Instead, they cause damage when pieces of vertebrae tear into cord tissue or press down on the nerve parts that carry signals. In a complete spinal cord injury, the cord can't relay messages below the level of the injury. As a result, patient is paralyzed below the level of injury. In an incomplete injury, people can have some movements and sensation below the injury. SCI has an incidence that ranges between 35 and 85 per million by year depending on the country [19]. High level (cervical) SCI can induce tetraplegia.

1.2.2 MUNDUS - Scenarios

Depending on residual personal capabilities, specific scenarios are used to assess, subjectively and qualitatively, the usability of the system by real end-user in the living facility.

Although the MUNDUS system can theoretically be customized on each end-user, to simplify the implementation and the validation phases, three different scenarios, have been identified. Specifically, in scenario 1 subjects present residual functional control of the arm and/or hand muscles, but they are too weak to accomplish functional tasks. Within scenario 2, instead, subjects have no residual functional voluntary activation of arm and hand muscles but they can still control the head and gaze fixation. The eye tracker identifies the intention of the users. Finally, subjects belonging to scenario 3, even if not blind, lack the ability to move their eyes and, thus, they are not able to fix reliably different locations of the screen which is a prerequisite for the eye tracking module. The interaction with these subjects is performed only by brain signals through the use of brain computer interface module.

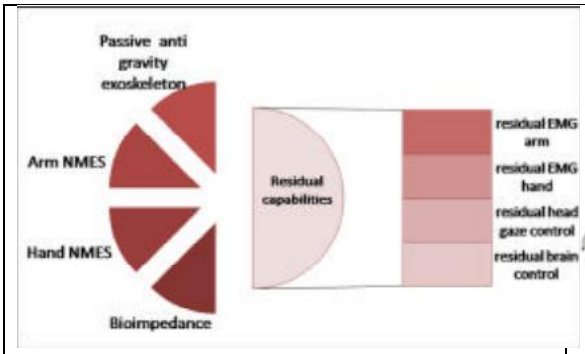
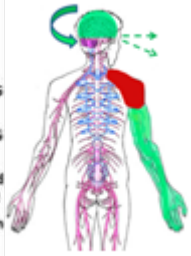
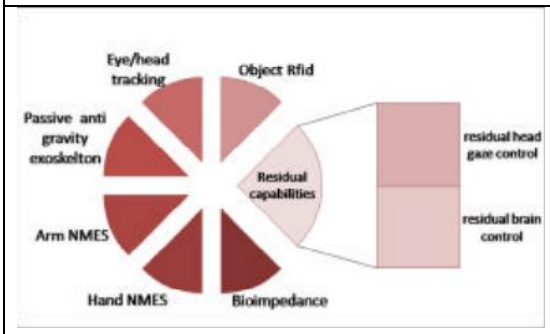
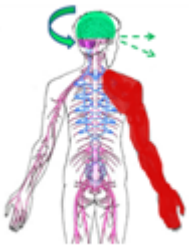
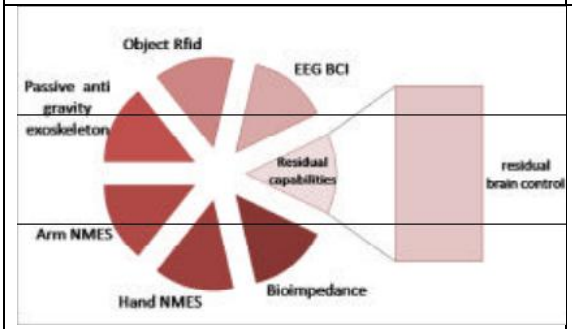
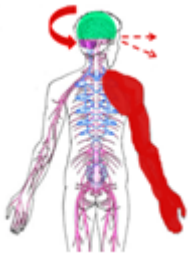
		**SCENARIO 1**: the subject has a residual functional control of the arm and hand muscles but he is too weak to accomplish functional tasks.
		**SCENARIO 2**: the subject has not residual functional voluntary activation of muscles in the arm and hand. He can still control the head and gaze fixation.
		**SCENARIO 3**: the subject can only interact by brain signals; the sight is preserved.

Fig.2: Scenarios description. (Red body districts are impaired, while green ones are still working)

1.3 Objective of the work

The present work is focused on the development and validation of MUNDUS platform to be used by subjects within Scenario 1 while they are helped by the exoskeleton and the hand module (NMES hand or robotic hand) if it is needed. The potential users of this setting are people having at least a residual weak functional control of their

muscles. Due to this, it is possible to detect the user's intentions from their EMG signals.

While he is wearing MUNDUS exoskeleton, the subject can decide to rest in chosen positions, controlling the brakes of the exo joints, and controlling either the NMES hand prosthesis or the robotic hand, whenever he wants to grasp an object. Two solutions are included within MUNDUS to allow the user to do it. He can have full control of the device by either simply pressing a button or regularly contracting one selected muscle of the contralateral upper limb. The latter solution has been studied and implemented within the present work.

An algorithm has been developed to detect the user's intention from his EMG signal. A solution easy to be recognized by the system was implemented. In particular, attention was paid on minimizing the possibility of errors: the detected EMG signal needs to be caused by a movement clearly different from the ones of common daily life activities. Another algorithm feature was its adaptability to the subject's characteristics in terms of muscle choice as well as time parameters. In conclusion, it was decided to ask the subject to do three regular contractions close in time in order to communicate his will to MUNDUS Central Controller.

Once the code has been concluded, firstly it was validated on healthy persons in order to check its robustness during daily life activities. A series of tests were done on five subjects to fulfill the research.

Subsequently the code was integrated inside the whole MUNDUS software of Scenario 1. In order to check the algorithm correctly operating during MUNDUS tasks, a second series of tests have been done. Three patients and five healthy people were asked to do the trials. It was possible to validate the system by comparing patients' data to normality indexes obtained from the tests on the healthy subjects. The system's usability and its functionality were taken into consideration as well.

Chapter 2

Structure of MUNDUS platform (Scenario 1)

The present thesis work is included in MUNDUS scenario 1; current chapter will describe the general structure of the platform, proving some details about all the modules it is composed by.

Scenario1 gathers all the persons who have a residual control of the arm and hand muscles but that are too weak to accomplish functional tasks. It is possible to say that individuals belonging to this group either are at the beginning of their disease or have a disorder which could be classified less severe than the one of the persons who belongs to the other two scenarios. Indeed, if the patient has not residual voluntary activation of muscles in the arm and hand, he cannot be included in scenario1 and he needs an additional specific module (ET or BCI) to interact with the system and communicate which task he wants to accomplish.

Within Scenario 1, MUNDUS can provide a different level of assistance tailored on the user's needs. In the less impaired patients, a passive exoskeleton will provide the weight compensation of the arm in order to reduce the effort required by the user to perform daily life activities. In more impaired patients, a higher level of support is provided by NeuroMuscular Electrical Stimulation (NMES) of the weaker muscle of the arm. A specific assistance for the grasping functions is also foreseen by MUNDUS if the user is not anymore capable to grasp and release objects voluntarily. In addition, the whole MUNDUS platform is composed by a series of environmental and angular sensors which allow the system to better help the user by recognizing his position in the workspace. At the same time, modules based on EMG signal detection have the utility of perceiving user intention by recording his voluntary movements. Finally, a state machine called MUNDUS Central Controller (CC) ensures high level communication

between all the modules. Here below a scheme of all modules included in Scenario 1 (fig.2.1).

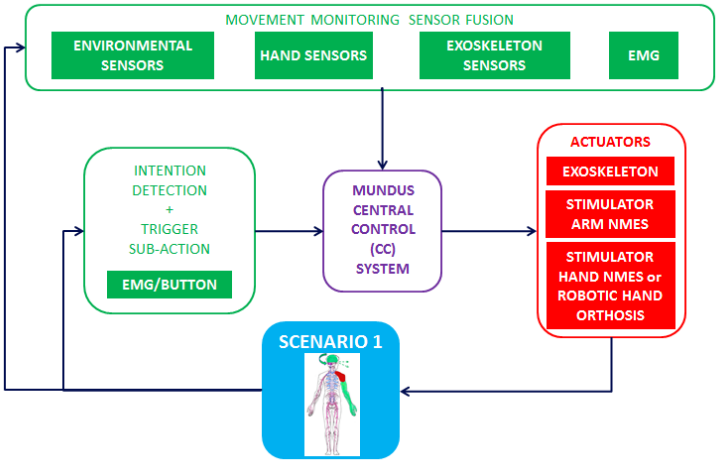


Fig.2.1: Scenarios concept.

In this scenario, the tasks should be controlled directly by the subject and the system needs to be comfortably wearable. Indeed, in this case the user does not need to communicate what he wants to do in advance; he has just to start the action by using his own muscles at the level he is able to. As soon as the system perceives the subject movement, it will keep on adapting in order to help him in doing the action at best. In respect to the number of components used, MUNDUS just bears the arm weight, allows arm movement or hand grasping.

First Scenario 1 user objective is to increase or at least to maintain autonomy. In order to give him the possibility to master the situation, an important aspect to be taken into account is to help him in reducing fatigue. In many cases the subject is still able to do the "base" movement by himself but he has not strength enough to conclude alone what he wants to. In addition to this, it would be very important for the patient to be able to reproduce movements as near as possible to the "natural" one, especially for the activities of daily living (ADL). In conclusion, starting from the patient need, it is possible to select which MUNDUS modules are better to be used in order to make the subject reaching his goals without overload him too much.

More in details, four different categories of users can be identified within Scenario 1:

a) Subjects with residual functional control of both the arm and the hand, but requiring weight compensation to accomplish upper limb motor tasks due to a general weakness. These persons use only the Exoskeleton (EXO) module, with the weight support properly fixed (fig.2.2).

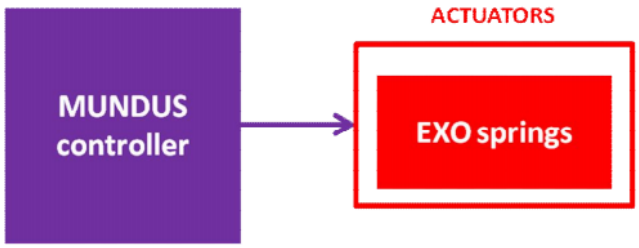


Fig.2.2: MUNDUS structure for Scenario 1 users, category A.

b) Subjects with a complete functional control of the wrist and hand but only a residual voluntary muscular control on the arm, not enough to accomplish functional motor tasks. These individuals use, in terms of actuators, both the exoskeleton with adjustable weight support and the arm NMES module. EXO sensors, environmental sensors and the EMG module are used to monitor the movement; the EMG signals will be used also for action selection and/or trigger (fig.2.3).

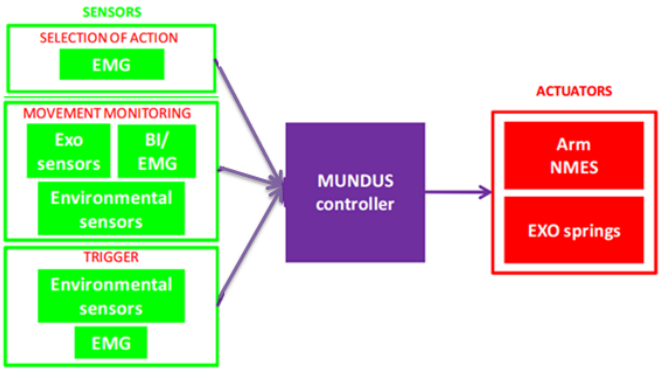


Fig.2.3: MUNDUS structure for Scenario 1 users, category B.

c) Subjects with a complete functional control of the arm but with no residual grasping ability and wrist control. These subjects use the exoskeleton with adjustable weight support and either the hand NMES module or the actuated

robotic hand orthosis. Hand sensors and environmental sensors are provided to monitor the movement .The EMG signals are used also for action selection and/or trigger (fig.2.4).

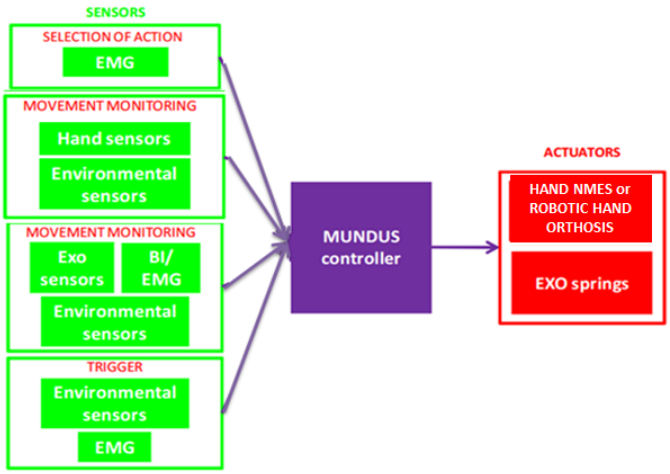


Fig.2.4: MUNDUS structure for Scenario 1 users, category C.

d) Subjects with only a residual voluntary EMG on the arm, not enough to accomplish functional motor tasks, and without residual grasping ability and wrist control as well. These users use all the modules together: the exoskeleton with adjustable weight support, the arm NMES module and either the hand NMES or the robotic hand orthosis. EXO sensors, hand sensors, environmental sensors and the EMG module are used to monitor the movement; the EMG signals are recorded also for action selection and/or trigger (fig.2.5).

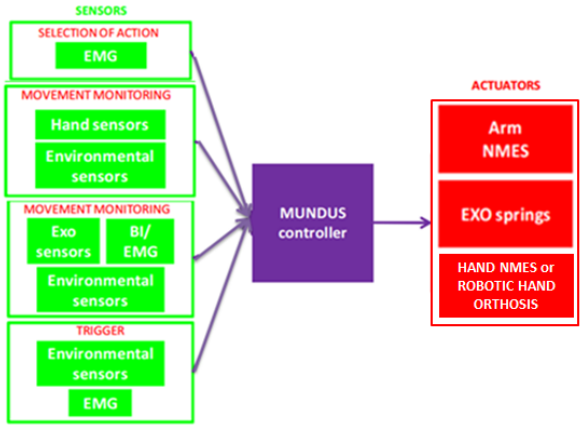


Fig.2.5: MUNDUS structure for Scenario 1 users, category D.

In what follows, the different modules that characterized MUNDUS Scenario 1 are briefly described.

2.1 Exoskeleton

The mechanical arm exoskeleton of MUNDUS is a completely passive lightweight device (fig.2.6), on purpose designed by the Vienna University of Technology. It was preferred to include no active elements in order to build a light and small system really usable in home environment.

Fig.2.6:MUNDUS exoskeleton

Two degrees of freedom at shoulder (θ_u , φ_u) are provided together with the one at elbow (θ_f). The third degree of freedom at the shoulder (φ_f, rotation of the humerus around its axis) is locked permanently because this movement cannot be induced by stimulation (fig.2.7). The available ranges of motion are 20-110° for shoulder elevation (θ_u), 10-110° for the shoulder flexion/extension (φ_u) and 0-140° for elbow flexion (θ_f). The humeral rotation (φ_f) can be fixed in any desired position between 0 and 90°.

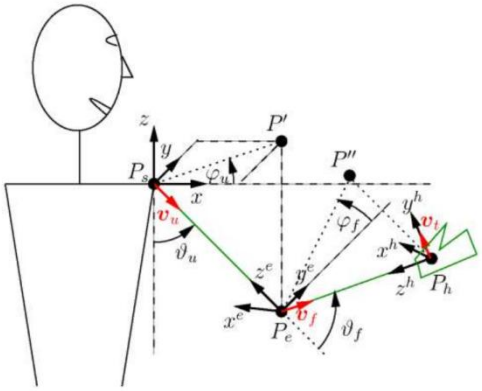


Fig.2.7: Kinematic of the human arm - definition of angles and coordinate systems.

The two degrees of freedom at the shoulder allow three different movements of the upper arm in three body planes:

1) flexion/ extension in the sagittal plane obtained through a rotation of the upper arm around the z-axis (fig.2.8);

2) flexion extension in the transverse plane obtained through a rotation of the upper arm around the x-axis (fig.2.8);

3) adduction /abduction in the coronal plane obtained as a combination of rotation in the transverse plane to +90° and shoulder flexion/extension in the sagittal plane.

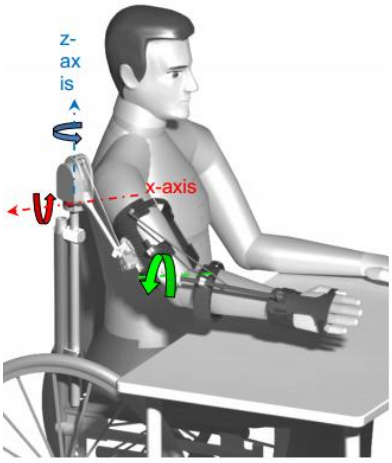


Fig.2.8:DoF of the exoskeleton at the shoulder and elbow joint.

The displacement of the mechanical and the anatomical joint of the shoulder is compensated for flexion and extension of the shoulder by the translation of the upper arm cuff on a linear guiding. In addition, dumpers are implemented as additional

controllable dumping elements and elastic structures for gravity compensation power transfer and to adjust the mechanical properties of the mechanical structure.

To monitor the user's position, the orthosis is equipped with angle encoders at the available degrees of freedom. Their output values are used both for optimum control and for recording voluntary movements of the subject.

The EXO accomplish two main functions; firstly it can block and release separately each degree of freedom in specific postures depending on the current action. Indeed, to decrease muscle work and fatigue a brake is implemented at each degrees of freedom. Brakes could be activated in order to help the user in keeping a chosen position. Secondly, the EXO provides gravity compensation depending on arm posture and joint current trajectory, especially towards antigravity movements (e.g. touching the contralateral shoulder). On the other hand, some limitations on the plane of movements can be caused by the gravity compensation which can hinder downward movements because of EXO stiffness. This limitation will depend on the subject strength and on the initial setting of weight compensation.

The continuous stream of the current angular data is acquired by the Real-Time control System (RTS) PC at a sample frequency of 60 Hz. At the same time, RTS communicates with the EXO in order to control the brakes for each degree of freedom that offers the locking property.

For the moment, the prototype could be worn on right arm only. It can be mounted on a wheelchair; it is made of compound materials and could be customized on each user by regulating the single segments length. The focus of the design has been put on wearability, lightweight construction comfort and durability.

2.2 Arm NMES

This module consists of the stimulator unit. An 8-channel current controlled stimulator (Rehastim™, Hasomed GmbH), delivering rectangular biphasic current pulses, is used. The RTS PC linked to it sends the commands to control the pulse generation. The

stimulation frequency is constant and fixed, whereas the pulse amplitude and the pulse width are set individually in respect to the user characteristics.

Within scenario 1, if the user needs help in arm movements, “arm module” has to be integrate in the system to help movements at shoulder and elbow joints. It is a neuroprosthesis driven by residual muscular activity of the user. Due to this, the starting point to make the block working properly is to detect the volitional user EMG signal. It is recorded by using Porti32™ amplifier (Twente Medical System International,TMSI, Nederlands). Signal is detected from medial deltoid and biceps muscles. On both of them surface electrodes are placed in a bipolar configuration, a stimulation frequency of 25 Hz is used and the EMG is acquired with a sampling frequency of 2 kHz.

The EMG recording electrodes are placed 1 cm apart on the belly of each muscle, within the two respective stimulation electrodes as indicated in SENIAM project [20]. The EMG electrodes are located perpendicular to the muscle fibers as is reported in Fig. 2.9.

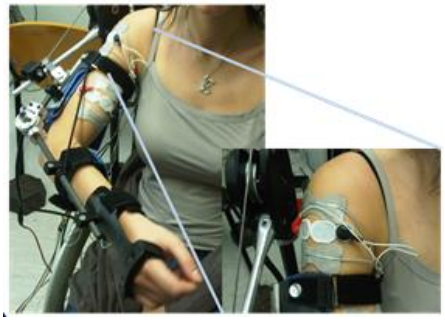


Fig.2.9: Electrodes placement.

In order to estimate the intensity of the muscle activity from the EMG data measured during each stimulation period, the recorded signal need to be filtered. In addition, artificial stimulation causes the occurrence of an artifact called “M-wave” which overlaps with the useful signal. Due to this, together with the filtering procedure, EMG volitional signal extraction has to be done. The output is then used to compute the root mean square (RMS) of the signal for each stimulation period, providing an estimate of the voluntary activity every 40 ms.

Afterwards, the voluntary activity estimation become the input of the EMG-controller for NMES that give as output the stimulation pulse width (PW) to be delivered to the

biceps. The controller has a piece-wise linear input-output relationship: when the input is below the inferior threshold calibrated on the user, RMS_{EMGv}^{MIN}, the controller maintain the PW at the minimal value, PW_{min}; when the input is above the superior threshold, RMS_{EMGv}^{MAX}, the controller provided a PW equal to the maximal value, PW_{max}; finally, when the volitional EMG is in-between the two thresholds, the input-output relationship is linear, and the output is included between PW_{min} and PW_{max} [21].

Fig. 2.10 shows the flow chart of the closed-loop control system which consisted of two main parts: the detection of the volitional EMG and the EMG-control system for NMES.

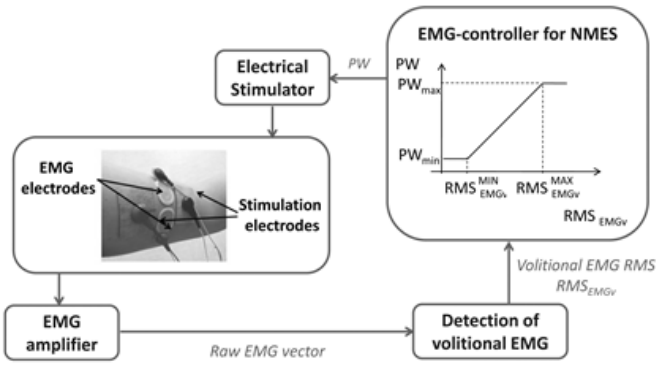


Fig.2.10: Flow chart of the ARM module closed-loop control system.

2.3 Hand module

The "hand modules" are used to restore grasping function in a different and flexible way according to the specific needs of the subjects. The two components main difference is based on either using NMES or wearing robotic orhosis.

The first solution is composed by a garment embedding multisite stimulation electrodes and a sensorized glove to measure the finger flexions and the forces at the finger tips (Fig.2.11). For the hand, the same stimulator model of the arm one is used (Rehastim™, Hasomed GmbH). This time, a stimulation frequency of 20 Hz is set for NMES and the device is provided by two demultiplexers (arrays) that can deliver stimulation pulse only to the selected electrodes.

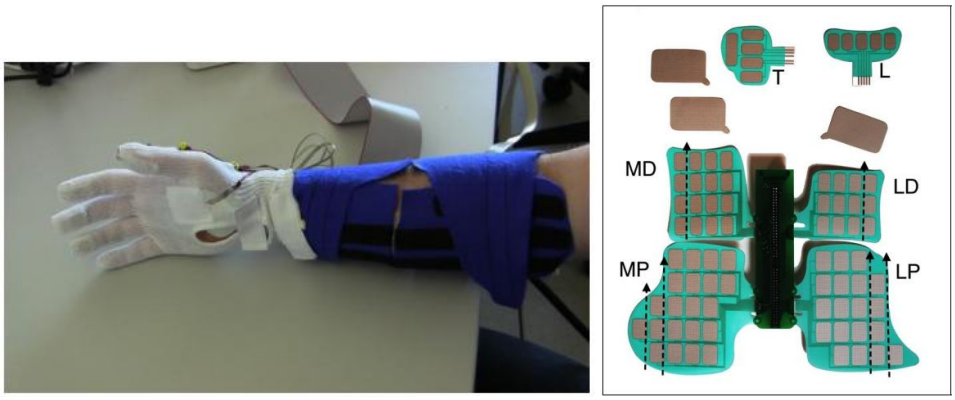


Fig.2.11: complete hand module (left) and the electrode arrays (right)

The garment is a customizable device meant to deliver electrical stimuli to the subject's hand and forearm. Six soft flexible printed circuit boards (PCB) are used to create bendable electrode arrays. The stimulation from the two lateral matrices of electrodes (Lateral Distal and Lateral Proximal) causes the hand closure; whereas the medial ones (medial Distal and Medial Proximal) together with the two put directly on the hand (Lumbrical and Thenar) allowed the grasping movement. Four of the six bendable arrays (MP, MD, LP, LD) are connected through small electric gates to a rigid PCB although the other two (T, L) are connected to it via wires.

Hand module calibration includes the identification of the stimulation electrodes in the garment and the calibration of the stimulation current for each identified electrode. The possibility to have multiple electrodes focused on the same gesture is twofold useful. First of all, during the calibration procedure, the selection of one electrode per each matrix increases the probability of finding out the best stimulation points which is the one that causes the best hand movement involving each finger. Secondly, the use of two matrices for opening and four ones for grasping gives the opportunity to augment the strength induced due to the fact that all the selected stimulations start together during the action execution.

Where the application of the hand NMES system is not suitable (e.g. due to a hypersensitivity to electrical stimulation or degenerated muscle functions), a robotic hand orthosis supporting the grasping and releasing actions is used (fig. 2.12). In contrast to an end-effector design approach, this allows for a physiologically correct

grasping movement even in the presence of a slight spasticity or abnormal finger muscle synergies. The orthosis has one actuated degree of freedom allowing the flexion and extension of the metacarpophalangeal (MCP) joint. The flexion and extension of the proximal interphalangeal joint is coupled with the MCP rotation by a fixed belt drive ratio. A customized soft thumb orthosis which is donned one step before the robotic orthosis keeps the thumb in opposition which is essential to achieve the grasping of cylindrical objects. Therefore, the current design does not have a thumb actuation mechanism. During the calibration phase of the MUNDUS system, the positions for the hand open and closed need to be calibrated. The caregiver moves the patient's fingers to the desired position to save the angles which are then used during the session.

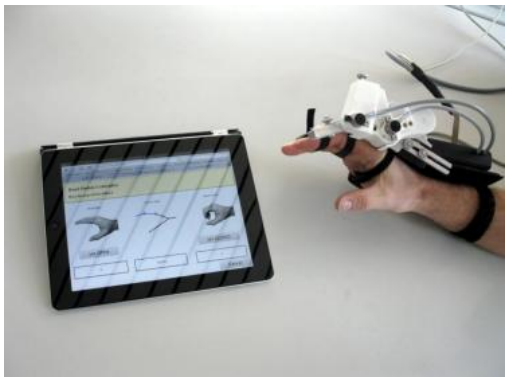


Fig.2.12: robotic hand orthosis during calibration procedure.

2.4 MUNDUS CC

The overall control of the modules will be set by the MUNDUS Central Controller (CC), a state machine which communicates with all components and generates synchronized input signals to achieve the task completion depending on the current status of each module. MUNDUS CC is the core of the integration of MUNDUS. In particular, a solution in which a dedicated system "real time system", separated but connected to MUNDUS CC, controls all real time critical components is adopted to simplify and make less risky the control of the whole system. In this case, MUNDUS

CC activates, deactivates and controls all the non-real time modules and it will only decide when to activate the real time system (fig.2.13).

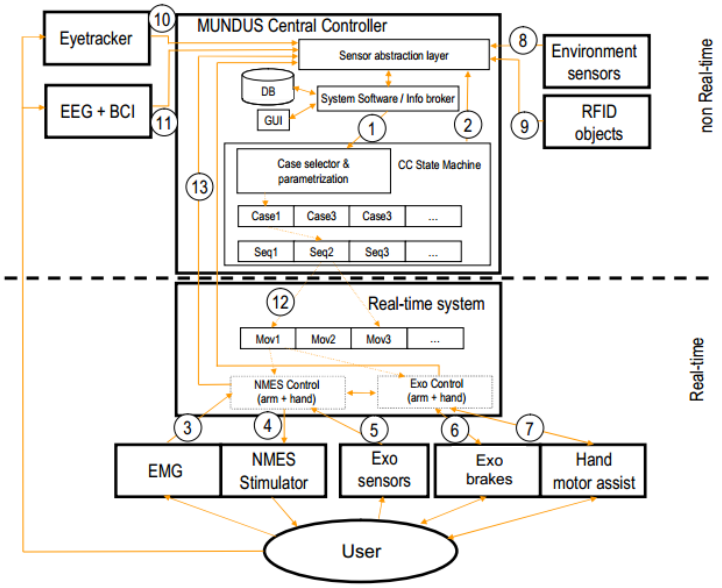


Fig.2.13:Overview of MUNDUS components connection through MUNDUS CC.

MUNDUS CC first manages the operational procedures to don and calibrate the system. Indeed, a simple interface has been developed within the project to help the caregiver in the calibration procedure.

Once all modules are donned by the subject, properly connected and switched on, the MUNDUS CC automatically recognizes which modules are connected and checks the correspondences between the user's registered data and the current setup (modules recognition phase). After that, single module initialization starts following a sequence predefined by MUNDUS CC (initialization of single modules phase). For each module, the GUI interface will be activated. Before the beginning of the session, for all the modules that need it, calibration is done by following a specific procedure for setting all the parameters of each of them (single module calibration phase).

At the end of all the previous steps, the session can start. MUNDUS CC controls all inputs to recognize the first time the user wish to interact with an object (e.g. by using EMG signal recordings). In respect to scenario 1, non-real time critical control is given for the environmental sensors only. On the other hand, real time control is provided by a PC running Scilab/Scicos under real time Linux-RTAI (RTS PC). It is activated directly

by MUNDUS CC and it is used to acquired data and control signals related to EMG, arm and hand NMES, exoskeleton sensors, exoskeleton actuators and hand motors. In addition, MUNDUS CC manages any emergency signals and consequent procedures.

MUNDUS CC keeps on controlling the communication with all the modules through XML broadcast messages in order to trigger the different phases of the workflow of the supported interaction tasks. Furthermore, during the execution of the task, it displays on the screen previously used by the caregiver some messages and questions that facilitate the interaction of the user with the system.

2.5 PC – Real time system

The Real-Time control System (RTS) is responsible to generate individual movements of the MUNDUS system. For development of the control system, a powerful PC system is required: a Dual Core Intel CPU has been chosen which runs at 1.6 GHz. The main memory is of 2 GB and for recording of data during clinical experiments, a hard drive of 160 GB is used. Due to the high communication load, when using multiple USB devices, at least two USB 2.0 controllers are needed in order to fulfill the required low latency of the RTS. Ten USB ports are needed for connecting external devices. In order to communicate with other computers like the "MUNDUS CC" one, two Ethernet ports are required (one for real-time communication and another one for generic internet access for data transmission). The used operating system is Ubuntu[1] 10.04 LTS with an on top installation of RTAI[2].

Sensor and actor systems can be accessed from the RTS via USB using different serial communication protocols. Among all of them, the PowerMate (Griffin Technology, Nashville, USA) has been used. It is a particular knob that could communicate by pushing or rotating it; e.g. it is very useful during calibration procedure when a signal interval has to be acquired. It is linked to the PC by a USB connection as well.

The Personal Computer that controls the instrumentation has to be able to manage the Hard Real Time (HRT) in order to execute all the operations within a fixed time,

without any exceptions. The RTS module is based on an i686 computer system equipped with the real-time operating system Linux/RTAI that is open source software and thus freely available. RTAI introduces a new kernel which executes the operating system as a task with lower priority and is not able to disable the interrupts. Doing this, it allows the computer to work in Hard Real Time modality. The controllers for different movements are implemented in C/C++. The software that manages the instrumentation is Scilab[3]/Scicos[4], an open source software for the numerical calculation. In particular Scicos has been used (fig.2.14); it is a continuous and discrete time dynamic systems simulator. By using it, it is possible to create block diagrams to manage, visualize, memorize and analyze data in real time. In particular, the RTAI-Lib is a palette of Scicos blocks that provides an interface to RTAI and signal acquisition hardware. Block diagrams that use RTAI-Lib can be compiled into RTAI executable software.

Finally, the HART (Hardware Access in Real-Time) Toolbox[5] is used to generate Scicos-blocks for hardware that have a C/C++ interface or, more in general, to develop any user-defined Scicos-Blocks (for signal processing, control, etc).

After the block creation in Scicos, it has been compiled to obtain an executable file. Furthermore, QRtaiLab[6] gives the possibility to visualize the acquired and processed signal in real time. It is a graphic interface created for RTAI. It works as a virtual oscilloscope and, at the same time, it allows the possibility to change the executed Scicos model parameters. In this way the interaction with the program is higher.

1. *Ubuntu: www.ubuntu.com (A popular Linux distribution)*
2. *RTAI: www.rtai.org (Hard real-time add-on for Linux)*
3. *Scilab: www.scilab.org (An open source MATLAB equivalent)*
4. *Scicos: Dynamic block simulator capable of generating C-Code; Similar to Simulink*
5. *HART Toolbox: http://hart.sourceforge.net (Collection of hardware drivers for use within RTAI)*
6. *QRtaiLab: http://qrtailab.sourceforge.net/ (An graphical user interface to RTAI)*

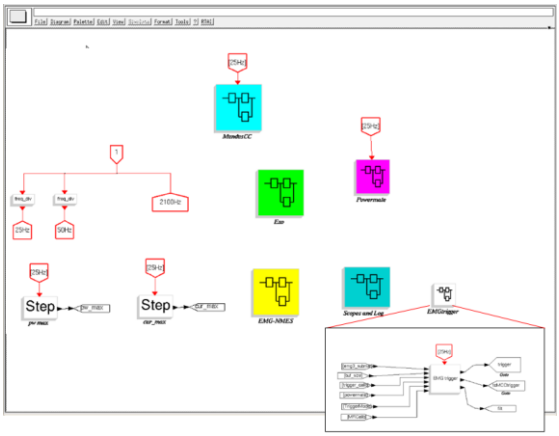


Fig.2.14: Scicos graphical interface-MUNDUS Scenario 1 blocks

2.6 Experimental setup

The experimental setup used within the current work consists of three main components: a polygraph for EMG recordings (Porti32™, Twente Medical System International,TMSI, Nederlands), a light weight passive exoskeleton to support the arm weight during movements and a personal computer used to control the system and acquire the signals with Scilab in Ubuntu Rtai. In Fig. 2.15 it is clearly shown how they direct interact both with the subject and with each other.

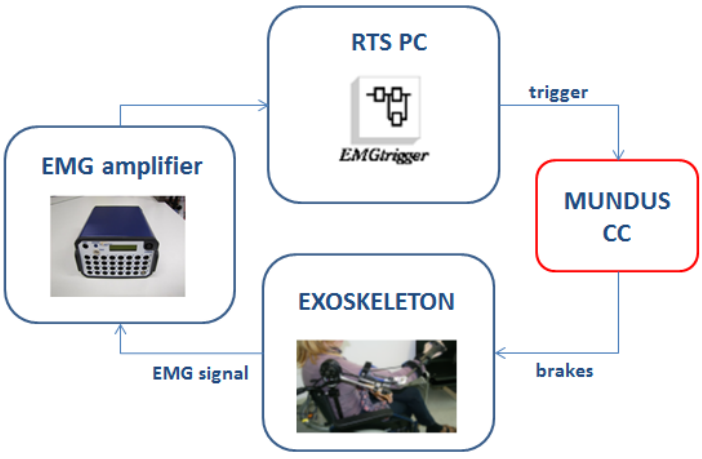


Fig.2.15:experimental setup

The exoskeleton and the PC used are the ones already described in par. 2.1 and par 2.5 respectively, while the EMG amplifier is presented below.

2.6.1 EMG amplifier

The electromyogram (EMG) represents a weak bio-signal caused by muscular fibers contraction. The less invasive way to acquire the EMG is to put a pair of surface electrodes attached to the skin and to amplify the signal through a differential instrumentation amplifier. Electrical activity related to muscle contractions generates the EMG signal. The EMG is precisely the measurable net effect of action potentials caused by firing motor units. From a frequency point of view, the EMG spectrum varies from very low frequencies (2 Hz) to 400 Hz. This is the reason why it is sampled at least at 1 kHz. Signal conditioning is made by the use of a high-pass filter with a cutoff frequency of 10-20 Hz. Even if some information could be enriched in the lower frequency values, many errors caused by movement artifacts are hidden among them. The main signal spectrum characteristics are based on many factors as muscle properties and its fibers, contraction speed, generated strength and fatigue level [22].

The EMG/EEG Amplifier Porti32™ (fig.2.16) is the polygraph used to record the EMG signals within MUNDUS. The model has 32 acquisition channels, among which 12 monopolar, 16 bipolar and 4 channels for auxiliary signals that allow the management of other external sensors.

Bipolar channels are the one here utilized, they show the following characteristics:

- Noise smaller than 2μVpp at 128 Hz;
- Gain: 20;
- Input impedance > 10^{12} Ω;
- Range of input common mode: -2V/+2V;
- CMMR > 100db.

Fig.2.16: Porti device (TMSI).

Signal sampling is made by a different ADC per each mono- and bipolar channel, with high resolution (22 bits). Real time data transmission at 2048 Hz to RTS PC is achieved via an USB connector. Within the ADC, the signal is low-pass filtered by a digital FIR filter with a cutoff frequency of 0,27*sample frequency in order to avoid aliasing. No high-pass filtering is done inside TMSI. The worst noise sources in measuring EMG are: movements artifacts between electrode and skin together with network interferences, present in the body as well as in wires. Both the high input impedance and the high CMRR remove the common interferences at the two electrodes while the cables used have an active shielding pilot by an amplifier which receives the signal from the electrode so to cancel the capacitive coupling between cable and external environment. In order to assure the noise to be minimal in the data transmission towards PC, it is transferred via optic fiber cable at a bit rate of 7.168 Mbit/s. The signal from optic fiber is converted into electrical signal to be connected to the PC through a USB port. The electrodes are disposable with gel Ag/AgCl Ambu® Blue Sensor N (Ambu A/S, Ballerup, Danimarca) for ECG and EMG recording.

2.7 Detection of the user's intention

The main aim of current studying is strictly related to the detection of the user's intention.

Within scenario 1 the subject can directly guide the movement he wants to accomplish. In addition to the possibility of amplifying the activities of the arm muscles he can still

control voluntarily by means of NMES, he can directly interacts with MUNDUS CC to trigger the different sub-actions of the supported tasks in two different ways. The first possibility is to press a USB-button with the hand that does not wear the MUNDUS device. The second implemented solution, in case of more impaired subject or if the user has lost all feelings in his contralateral hand, consists of the detection of the user's intention starting from his residual EMG (fig.2.17). Within this module, electromyogram signal is recorded by the Porti32™ amplifier. The current work deals with the development and testing of the second solution.

Fig.2.17:intention detection modalities.

The two methods mentioned above allow the user to answer a series of questions he reads on the screen in front of him. By doing this, first of all he has the possibility to activate/deactivate the brakes of the exoskeleton. This could be useful in doing tasks such as drinking: whenever the user reaches the mouth, he can keep the position as long as he wants by simply activating the brakes. Moreover, if the hand module is worn, the user has to communicate to MUNDUS system when he wants to grasp an object; the subject can ask either to open or to close the hand by pushing the USB-button or by regularly contract a muscle.

Chapter 3

Algorithm to detect the EMG trigger

To allow the user to trigger the different sub-actions of the task based on the residual EMG signal, an appropriate algorithm has been developed. The main requirements were that the solution implemented was easy to be understood by the user and characterized by the lowest possibility of error. In addition, the calibration phase needed to be simple in order to allow the caregiver not to waste time during the beginning procedure.

3.1 Algorithm implementation

The solution developed consists in acquiring the EMG activity of a muscle that the user is still able to control. Due to the fact that MUNDUS is donned on one arm and that in most cases the subject is no more able to move his legs on purpose, contralateral upper limb has been chosen as the area where look for the best muscle to detect the user's intention. The subject was instructed to contract three times the selected muscle within a pre-defined interval (each activation should last at about 1 s) when he/she wants to trigger a sub-action. When the algorithm detects the desired sequence of contractions an "EMG trigger" command is sent to MUNDUS CC. Attention has been put on find out a solution not mistakable with common daily actions, this is the reason why a repetition scanned over time has been selected. Moreover, in accordance with all the other MUNDUS modules, the algorithm can be tailored on user's needs. First of all, the choice of the muscle is subject-dependent with respect to the individual capability as well as to his comfort and habit. Furthermore, some parameters related to time and activation threshold are calibrated on the single user.

The algorithm has been written in C-code in order to directly drive the working of one block in Scilab/Scicos Software. Due to the fact that all the other MUNDUS modules are implemented in the same Software, in this way it has been possible to manage the communication and to integrate the work in the whole device system.The "EMGtrigger" block (as it has been called and saved inside a MUNDUS Scicos library) has six inputs and three outputs. The main input is the EMG signal: the amplifier send a vector of size 82 to the block at a frequency of 25 Hz.

Each time that one EMG vector is received, the algorithm filters it in real time. A standard procedure has been implemented to obtain the EMG envelope: high-pass filtering (3th order Butterworth, cut-off frequency of 10 Hz), rectification and low-pass filtering (3th order Butterworth, cut-off frequency of 5 Hz). Butterworth solution has been chosen for both the high-pass and the low-pass filter. The main reason is related to its flat frequency response within the passband. Indeed, it represents the linear continuous-time filter category with the most constant group delay from a frequency point of view. Secondly, the choice of filter order has been made to balance high accuracy and minimum time requested. Actually, the higher the filter order is, the higher the accuracy is but the longer the requested time to filter the signal is. Due to the fact that this is included in the first step of an algorithm which works in real time, it is not possible to waste too much time filtering signal.

Afterwards, each vector that has been processed enters a second step in which the average value is extracted. Each 40 ms one mean value is calculated and compared to a selected percentage of the threshold (in general, 70%). As soon as the processed EMG overcomes the threshold, the system noticed it and the input enters a different loop of comparison inside the code. From that moment, the mean EMG signal is compared with the 30% of the threshold: when the former decreases under the latter, the contraction counter is increased of one unit. At the same time the received processed EMG signal is back compared with the highest threshold percentage. The whole process is then repeated in order to find out the consecutive contraction. As soon as the counter notices three contractions, trigger value is put equal to 1 (see fig.3.1). Immediately MUNDUS CC recognizes the change in trigger value and it activates/deactivates the exoskeleton brakes or helps the subject in opening/closing his hand in accordance to the question

displayed on the screen in front of the user. If the time between two following contractions (“time interval”) is longer than the one selected in accordance to the user characteristics (e.g. 3 or 5 seconds), after the second contraction the counter is set back to 1. The “time interval” set as parameter accomplish another role as well: it is the time-limit the counter has to wait before detecting a new contraction once that the trigger has been activated.

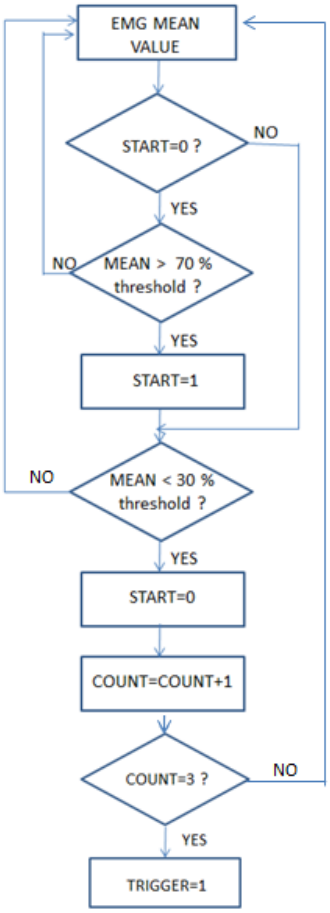


Fig.3.1: Algorithm flow chart.

In respect to threshold value selection, at the beginning of the session it is given the possibility to do the calibration procedure. If the assistant decides to skip this step, the digit calculated during the previous session is kept as threshold; otherwise, calibration could start. The operator has to select two points in time as the start and the end of an interval while the subject is contracting the chosen muscle. It is not request that the user executes a maximal voluntary contraction (MVC). It is only needed that he performs the movement he will do to communicate his intention to the system. At the same time, he

could be asked to keep the position for few seconds until the operator has selected the end of the EMG recording. Immediately after, all the signal vectors belonging to the interval are filtered and the mean value among all of them is taken as the threshold one. At this point, if the operator considers that some errors occur during this step (e.g. the subject has not kept on contracting the muscle for the whole interval selected or he has made some mistakes during it) he can repeat the procedure. Otherwise, the user can start to directly interact with the system in order to impart his intention.

3.2 Operation of the algorithm

In the current paragraph, the operation of the algorithm is described.

Fig.3.2 illustrates a representative example of EMG signal acquired from the brachioradialis muscle of a healthy subject. All the algorithm steps are shown in it. The raw EMG signal acquired is high-pass filtered (HP) to remove all the low frequency artifacts. It is then rectified (NORM) and low-pass filtered so to have a smoother trace. Mean values (MEAN) calculated each interval of 40 ms are plotted as well in order to be compared with the activation and deactivation threshold values (70% and 30% respectively). Trigger activation occurs after three consecutive contractions (TRIGGER).

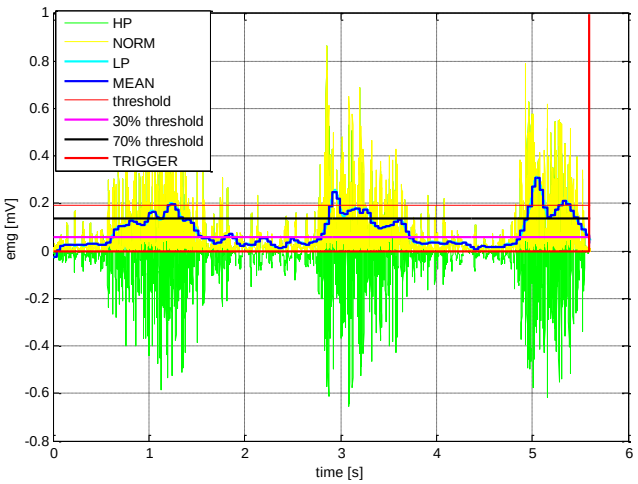


Fig.3.2: example of EMG signals acquired from the brachioradialis muscle of one healthy subject.

In fig.3.3 two consecutive trigger activations are illustrated. The plot helps in understanding an aspect of how the algorithm works. EMG signal - here expressed by its high-pass filtered trace (green) – shows that initially the subject contracted his muscle three times to induce the first trigger detection. After it, the algorithm waits for 5 seconds before looking for a new muscle contraction (time interval=5 seconds). As a consequence, no mean value is neither received nor compared with the threshold in that interval. This feature is twofold useful; first of all, it has been noticed that the user does not need to interact with the system immediately after trigger activation. In addition to this, it is given the possibility to the subject to maintain the requested position (e.g. brakes on or hand closed) and to keep on doing the action without minding about contraction/relaxation of the muscle whose signal is recorded (e.g. drinking or putting the object he is interacting with in another part of the table).

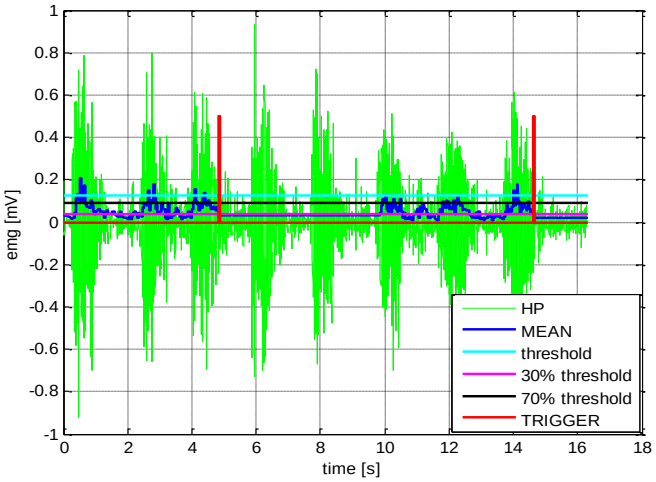


Fig.3.3: example of EMG signals recorded during muscle contractions to obtain two trigger activations.

Two more time-related features are shown in fig.3.4. On one hand, two following contractions could not be too far apart in time (in the example, more than 5 seconds due to the fact that "time interval" is here set equal to 5). In that case, the counter is reset to 0 and other three contractions are needed to activate the trigger. On the other hand, a minimum amount of time is imposed between two of them. When the mean value goes under the inferior threshold, for one second no contraction could be registered. The latter aspect is very important for people who have problems in executing isometric contractions.

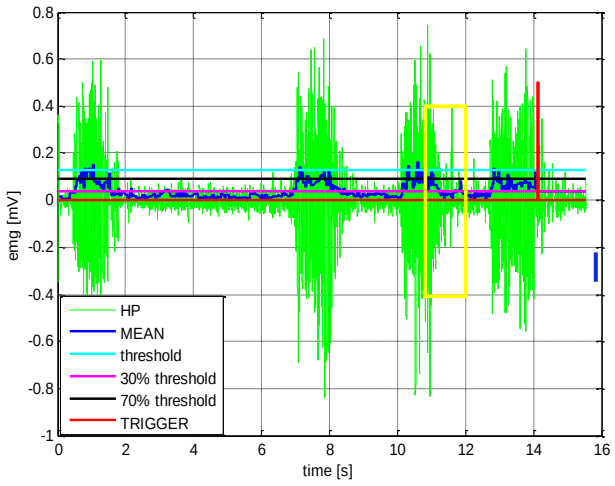


Fig.3.4: example of EMG signals recorded during muscle contractions to show min and max time-limits imposed.

3.3 Experimental validation of the algorithm

First step towards algorithm validation and optimization consisted of performing a set of trials on healthy subjects. The main goal of the first series of experiments was to check algorithm overall robustness. In addition, the second aim of these tests was to select the best muscle for detecting the user's intention and to fix some parameters such as the values of the activation threshold and the time interval between two consecutive contractions.

3.3.1 Experimental protocol & Subjects

Each subject was asked to do one hour of common daily life activities as studying, reading and writing, having lunch and being with friends. While he was sitting on a chair around a table the EMG signals were recorded from him. Four muscles were chosen from the left arm due to the fact that it is the contralateral limb not involved in MUNDUS device. The monitored muscles are listed here below and figure 3.5 shows electrodes placement on them.

1. brachioradialis muscle;
2. trapezius muscle;
3. sternocleidomastoid muscle;
4. frontalis muscle.

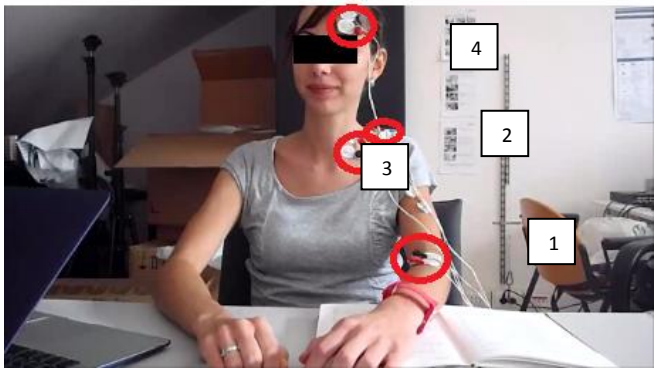


Fig.3.5: electrodes placement.

In order to check the stability of electrode-skin coupling over time, one last test was done on a healthy subject. EMG signals were recorded from the same four muscles previous mentioned. This time, the acquisitions of three consecutive trigger activations were done in two separated moments; the interval between them lasted three hours.

During all the tests exoskeleton was not used; the reason is that the aim of the trial was the evaluation of the algorithm alone. The experimental protocol consisted of the following steps. One single repetition was asked to each subject.

1. calibrate the thresholds for each muscle;
2. ask the subject to do 3 series of 3 contractions per each muscle (3 times trigger put equal to 1 by each muscle) in order to check the threshold value [START];
3. if some threshold values need to be changed, go back to point 3;
4. ask the subject to spend 1 hour in doing the daily life activity chosen in advance;
5. ask the subject to do 3 series of 3 contractions per each muscle (3 times trigger put equal to 1 by each muscle) [END];

Five healthy people were selected to do the tests. They were only requested to be neurologically and orthopedically intact.

3.3.2 Data analysis

At the end of every test, the number of trigger detected by the algorithm was counted. In particular, attention was paid on the unwilled trigger activations occurred during daily life activities. Furthermore, it has been calculated the mean amount of time that the subject spent in activating the trigger on purpose (three consecutive contractions). Each aspect has been evaluated focusing on every monitored muscle.

Observations are done on the movement that has caused the unintentional repeated contractions in short time. In addition, attention towards the duration of the START and END interval has been paid.

Moreover, an overall comparison among all the subjects is done in order to select the best muscle and the best algorithm parameters.

Finally, evaluations on the stability of electrodes-skin coupling are made as well.

Chapter 4

Validation of MUNDUS – Scenario 1

A second series of trials were performed on potential final end-users. The aim of the tests was to validate the algorithm together with the other modules of Scenario 1. In addition, an analysis of the whole system has been done; in order to have normality ranges, healthy people were recruited as well and asked to do the tests.

4.1 Assessment of patient at the baseline

Before the execution of the test, all patients received an information sheet and provided their written informed consent. The whole MUNDUS research protocol was approved by the medical ethics committee of the Valduce Hospital, the clinical partner of the project. Furthermore, the patients were requested to submit to a clinical evaluation together with some biomechanical tests in order to define their initial situation.

Clinical estimation is composed on several "evaluation scales"; only four of them are here taken into consideration due to their utility in respect to the present work. Indeed, they estimate scores that highlight the residual motor function ability of the arm.

- MODIFIED ASHWORT SCALE (MAS) which evaluates the degree of spasticity of the subject [23].
- MOTRICITY INDEX (MI), it assesses motor power of the upper extremities (0-100 score points)[24] .
- BARTHEL INDEX (BI) that checks the residual motor function ability of upper limb, it ranges from 0 to 20 [25].
- MEDICAL RESEARCH COUNCIL (MRC) which gives information about muscular contractility (score from 0 to 30).

Afterwards, during biomechanical tests the patients were asked to do ten repetitions of "mouth reaching" task (hand from the thigh to the mouth and back). The session was repeated two times, one after the other, but in different conditions. The first one was done by the subject without any assistive device ("free movements") while the second session of ten repetitions was done with the use of MUNDUS exoskeleton. The "free movements" has been monitored by SMART DX 7000-3D Optoelectronic movement analyzer system (BTS SpA Italy). For kinematic data acquisition a protocol with 5 markers on the subject (D5, C7, acromion, elbow, wrist) was used [26]. On the other hand, during the movement repetitions done with the EXO, angular data were collected by MUNDUS system. Dynamic EMG of pectoralis major, trapetius, medial and posterior deltoids, biceps and triceps were recorded during both the sessions by the use of PocketEMG 16 channels EMG system (BTS Spa Italy).

EMG signals collected during the biomechanical tests have been filtered twice (high-pass and low-pass filters) and rectified. After that, the ten signal intervals related to one repetition each were isolated and normalized in order to calculate both the mean and the standard deviation values from them. Root mean square (RMS) value was compute as well.

4.2 Experimental protocol & Subjects

The patients were asked to perform ten repetitions of four selected tasks. Due to the fact that in Scenario 1 the user can directly drive the action he wants to accomplish, there are not fixed tasks specified by MUNDUS CC as the ones for the other two scenarios. Nevertheless, within these series of tests, it has been decided to ask the subject to perform four tasks among the list of the MUNDUS ones. They are: drink with a straw, touch left shoulder, touch left hand and press the button. During the test, each subject has to wear MUNDUS exoskeleton and to control the brakes by using the EMG signal detection intention modality. Every person was asked to do three repetition of the whole session in three different days within a week.

The following protocol was used for the experiments.

1. Customize the EXO on each subject;
2. Select a good muscle to which detect the user's intention;
3. Calibrate the EMG threshold and fix algorithm parameters (threshold and max time between two following contractions);
4. Repeat 10 times: "drink with a straw" [hand in rest position-grasp the cup on table-go to mouth-activate brakes-keep position-deactivate brakes-leave the cup on table-hand in rest position];
5. Repeat 10 times: "touch left shoulder" [hand in rest position-touch left shoulder-activate brakes-keep position-deactivate brakes-hand in rest position];
6. Repeat 10 times: "touch left hand" [hand in rest position-touch left hand-activate brakes-keep position-deactivate brakes-hand in rest position];
7. Repeat 10 times: "press the button" [hand in rest position-hand on button-activate brakes-keep position-deactivate brakes- hand in rest position];
8. Don off the EXO.

Three patients were asked to take part in the trial session. Selection criteria were to be affected by one of the MUNDUS pathologies and to be eligible for Scenario 1. In addition, five neurologically and orthopedically healthy persons were asked to do the test. Each of them performed the test only once; data collected from them were elaborated to form normality ranges.

4.3 Data analysis

During the trials, the angles at the shoulder and elbow joints were collected and used to compute the following parameters for each single repetition:

- Time 1: duration from rest position to brake activation (target position);
- Time 2: duration from brake deactivation (target position) to rest position;
- Straightness 1: Shortest distance between the rest position and the target position divided by the trajectory length covered by the subject;
- Straightness 2: Shortest distance between the target position and the rest position divided by the trajectory length covered by the subject;

- Smoothness 1: Ratio of the average speed to top speed (from rest position to target)
- Smoothness 2: Ratio of the average speed to top speed (from target position to rest)
- Mean Speed 1: Average speed (from rest position to target)
- Mean Speed 2: Average speed (from target position to rest)

To compute these parameters, the MUNDUS Experimental Testing Platform (ETP) was used. This platform was developed by the Institute for Experimental Software Engineering of the FRAUNHOFER organization in Kaiserslautern, Germany, which is a partner of the MUNDUS project. In order to do the evaluation of the tests from a kinematic point of view, the software took all the data collected from the EXO angular sensors and combined them together with the anthropometric characteristics of each user (arm and forearm lengths).

4.4 Statistical analysis

The results of the tests computed by the use of ETP software were then statistically analyzed. Two statistic non-parametric tests were implemented; the median and the interquartile range were computed for the ten repetitions done within the same day with respect to each of the parameters examined. First of all the Kruskal-Wallis test was done to compare the sessions done by the same subject among the three days. Post-hoc analysis was done whenever a significant p-value was obtained. In addition, Mann-Whitney U test has been hold to do comparison between patient's repetitions of each day and normality ranges.

Chapter 5

Results and Discussions

5.1 Experimental validation of the algorithm

5.1.1 Results

Five students from the University *"Politecnico di Milano"* were recruited to be involved in the trials aimed at validating the operation of the algorithm for the EMG trigger detection (Table 3.1).

	age	**gender**	**1 hour activity**	**threshold activation**	**time interval**
Subject 1	24	Female	Studying (reading from a book, using laptop, handling mobile phone)	70 %	5 sec
Subject 2	21	Female	reading and writing (+ on purpose movements to check robustness)	70 %	5 sec
Subject 3	24	Female	having lunch, speaking with friends and using PC	50 %	5 sec
Subject 4	23	Male	being with friends	50 %	3 sec
Subject 5	24	Female	stability of electrode-skin coupling check (3 hours)	50%	3sec

Table 3.1:test subjects description and selected parameters

Here below a detailed analysis of the whole test. Separated tables show data recorded from each muscle. At the beginning (START) and at the end (END) of the trials the subjects were asked to provide a series of 3 intentional triggers. The time elapsed between the instant the subject was asked to provide the intentional trigger and the instant in which the algorithm registered the trigger was measured and is reported in the tables. Moreover, the number of non-intentional triggers registered during the monitored hour of daily activities is reported.

Brachioradialis (B)	**Time START phase [s]**	**Time END phase [s]**	**number of non-intentional trigger activations**
Sub1	17,3(9)	9(2,4)	0
Sub 2	26,5(26,6)	18(10,5)	22
Sub 3	7,2(2,4)	9,8(4,7)	11
Sub 4	4,6(1)	5,4(1,4)	26

Values:Mean(std) *Table 3.2: test results-brachioradialis muscle*

Table 3.2 shows all the data collected by monitoring the brachioradialis muscle. No trigger activations were recorded from brachioradialis of the first tested person; it did not happen neither while she was typing at the pc nor while she was using her mobile phone. On the other hand, it is possible to say that she became more confident in regularly contract the muscle on purpose at the end of the trial compared to the START phase, as shown by the time intervals reported in the table (17,3 s at the beginning compared to 9s at the end of the trials).

During the whole hour, subject 2 contracted the brachioradialis muscle 22 times. Indeed, at the beginning of the trial it was difficult to calibrate the best threshold for the person. The data in the table 3.2 (long time interval and long standard deviation values) show that the subject faced problems in activating the trigger. The EMG signals recorded (fig. 3.1) illustrate that the chosen threshold was too low: if the subject did not

perfectly relax the muscle after the contraction, the signal did not go under the inferior threshold value. In this way the trigger activation was prevented due to the fact that one contraction is not counted until the signal value becomes lower that the inferior threshold. It happened especially during the third interval in both phases: the subject needed to do many contractions to obtain the last trigger equal to 1.

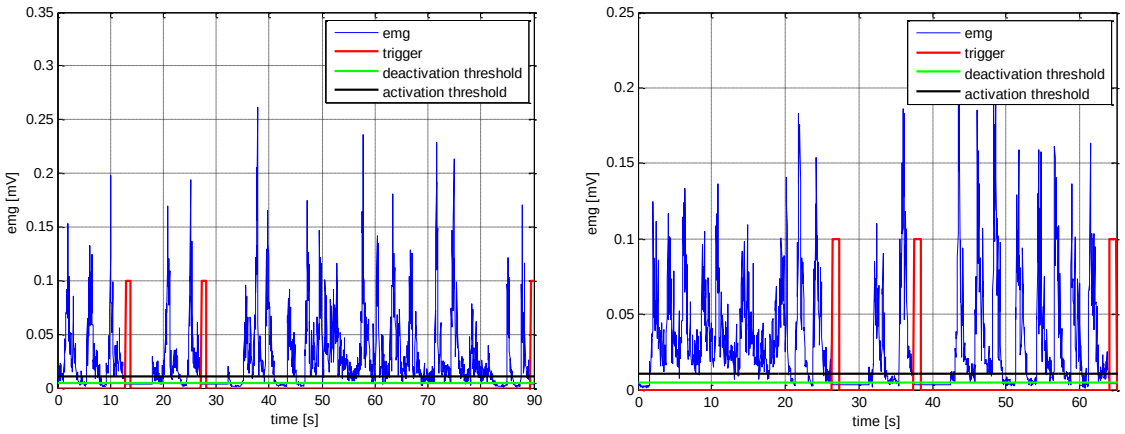


Fig.3.1:brachioradialis muscle ,subject 2-START (A) and END (B)

The third tested person activated the trigger for 11 times. To better understand the results, it is useful to remember that the subject has been monitored during lunch break: she used left hand to bring food to the mouth. After lunch, brachioradialis contractions were caused as well by moving the laptop from a side of the table to another, waving goodbye to a friend and putting lipsalve. On the contrary, typing, handling the mobile phone with touch screen and putting cream on hands did not give back any answer. The last subject generated 26 unwilled trigger activations. He chated to friends during the majority of the time; since he is used to gesture a lot while speaking, the brachioradialis muscle produced many trigger activations. Both subject 3 and subject 4 executed the END phase in an interval slightly longer than the START one. Unlike the first two persons, their first phases were already short, thus the difference in time intervals does not underline any problems.

Trapezius (T)	Time START phase [s]	Time END phase [s]	number of non-intentional trigger activations
Sub1	16,3(9,3)	7,1(1,1)	32
Sub 2	14(1,9)	7(1,3)	4
Sub 3	37,9(30,6)	8,3(5,8)	0
Sub 4	4,8(0,6)	4,9(0,8)	4

Values:Mean(std) *Table 3.3: test results-trapezius muscle*

Among all the muscle monitored for one hour, trapezius was the only one that was unintentionally contracted by subject 1. She activated the trigger 32 times in total while turning over the book pages, changing position on the chair by lifting herself with the arms and moving the chair closer to the table. Even when the subject laughed, trapezius muscle was contracted. At the end of the test, it has been noticed that the chosen threshold value was too low (fig. 3.2) and thus the muscle remained constantly activated. The subject probably did not contract the muscle maximally during the calibration; due to this, so many unintentional triggers were activated over the hour. On the other hand, during the END phase, she showed to have learned how to drive the trigger activations. Fig.3.2 (panel A) illustrates that she managed to completely relax the muscle between consecutive contractions: although the wrong calibration, trace signal goes under the deactivation threshold. Data reported in table 3.3 shows this improvement (the second time interval was shorter than the first one).

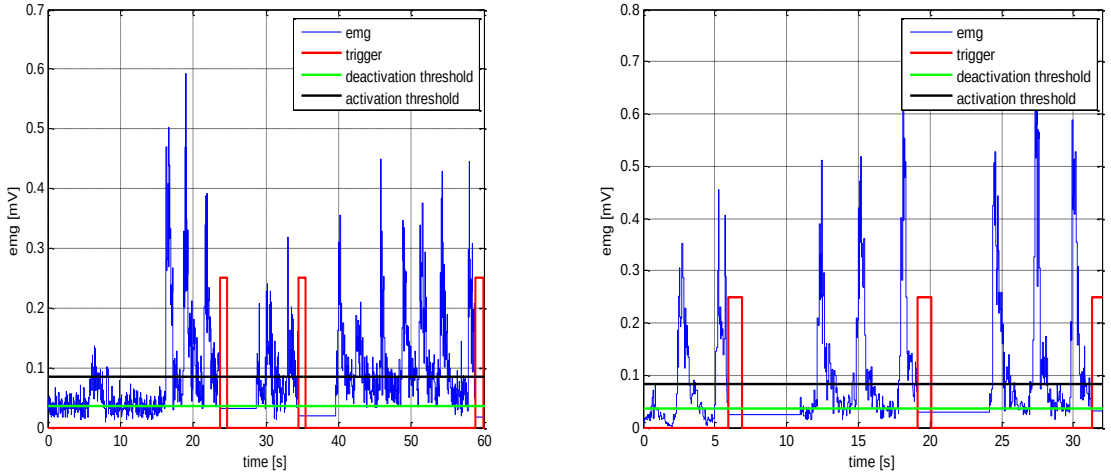


Fig.3.2: trapezius muscle, subject 1-START (A) and END (B)

Subject 2 produced only 4 unwilled trigger activations. She contracted the trapezius while moving on the chair in order to adjust herself and while stretching the arms. On the other hand, when she combed her hairs no activations were registered. At the end of the session, she became more confident in contracting the trapezius: the time spent in doing END phase is half the one of the START interval.

The third tested person never caused trigger activations at all during the hour of daily life activity. In respect to requested contractions, fig. 3.3 illustrates that while at the beginning the subject faced problems in triggering the trapezius (START), at the end of the test she managed to use it properly (END). Subject 4 instead, contracted the trapezius only 4 times during the non-intentional phase while he was stretching his arms and blowing his nose.

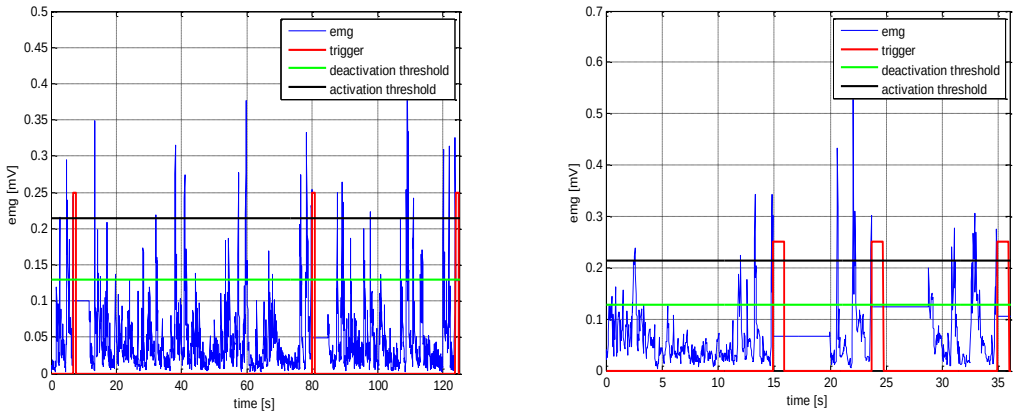


Fig.3.3: trapezius muscle, subject 3-START (A) and END (B)

Sternocleidomas. (S)	Time START phase [s]	Time END phase [s]	number of non-intentional trigger activations
Sub1	19,6(7)	9,4(4,7)	0
Sub 2	6,6(0,8)	6,4(1,3)	0
Sub 3	6,2(0,2)	6,2(2,3)	0
Sub 4	7,8(4,5)	7,6(5,7)	3

Values:Mean(std) *Table 3.4: test results-sternocleidomastoid muscle*

Table 3.4 shows that no sternocleidomastoid trigger activations were caused by the subjects except for the fourth one. He did 3 unwilled trigger activations; one of them happened at the conclusion of three sneezes. From the same subject nothing was recorded while yawning, drinking and eating a chewing gum.

Moreover, no differences could be noticed between the times spent in doing the START and END phase by each subject except for the first tested person. Data tabulated show a big improvement in controlling the action by subject 1 at the end of the test due to the fact that the time spent is half the START one.

Attention should be paid on signal recorded from subject 3 during the END phase.

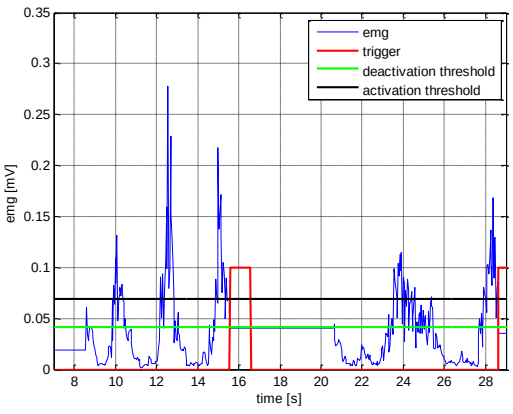


Fig.3.4: sternocleidomastoid muscle, subject 3- END

Fig. 3.4 displays that during the last sequence she forgot to relax completely the muscles after the first contraction. Indeed, three separate picks are not shown in the

second interval. It was caused by the fact that the contraction was not perfectly isometric and it lasted for more than one second. During that time, the EMG signal went under the lower threshold for a short time and make the counter to be incremented. This is the reason why it is needed to select a proper threshold on each user at the beginning.

Frontalis (F)	**Time START phase [s]**	**Time END phase [s]**	**number of non-intentional trigger activations**
Sub1	11,5(5)	7,9(0,3)	0
Sub 2	7,9(2,2)	5,6(0,6)	107
Sub 3	5,4(1,4)	7,7(4,7)	11
Sub 4	5,1(1,8)	5,1(0,8)	0

Values:Mean(std) *Table 3.5: test results-frontalis muscle*

As table 3.5 shows, subject 1 and subject 4 did not activate the trigger by the use of frontalis muscle during the monitored hour. In both cases, the trigger was never activated while the subject was speaking. With respect to them, no significant conclusions about time intervals could be done.

On the other hand, 107 trigger unwilled activations were done by the second person. Actually, it has been really difficult to take a good threshold value due to the fact that the subject was not able to control the muscle activation (fig.3.5). Over the whole hour, she inadvertently contracted the muscle by moving the head from up to down and backward (in the way to say “yes” with the head), by rotating the head rightward, looking at the ceiling, speaking, laughing, sneezing consistently, coughing and eating a biscuit. In addition to this, time requested in doing the END phase was longer than the one of the START interval.

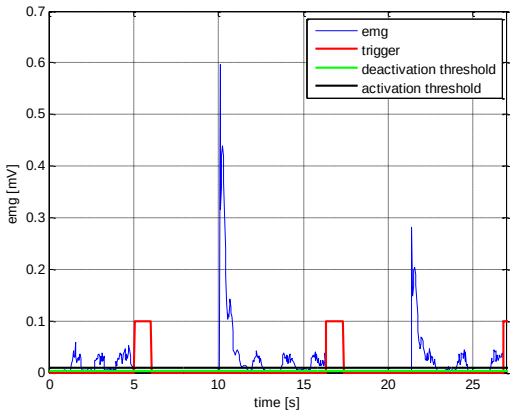


Fig.3.5: frontalis muscle, subject 2- END

Finally, subject 3 did 11 trigger activations especially while eating food hard to bite (chocolate and apple). It was noticed that neither drinking straight from the bottle nor sneezing produced any evident contraction.

In general, all the subjects faced difficulties in controlling frontalis muscle activation especially during calibration. Fig.3.6 is an example of the behavior shown by all the participants: a high first contraction value followed by two lower ones. Difficulties in balancing contraction intensity over the interval caused error in threshold selection. It could create problems during the session as happened to subject 2 (too many unwilled trigger activations). In that case, to fix a higher threshold was not useful: in that occasion the person never managed to activate the trigger at all.

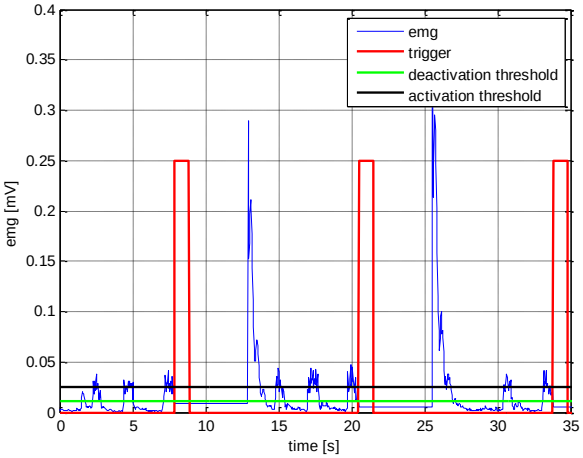


Fig.3.6: frontalis muscle, subject 1- END

Subject n°5 (stability of electrode-skin coupling)

After three hours, all the electrodes were still attached on subject skin and it has been possible to do the final recording for all the muscles with proper trigger activations. More in details, the two electrodes used to acquire signal from frontalis were no more perfectly stuck on the person's forehead. This is another reason not to use that muscle within the "EMG trigger modality" of Scenario 1: on the forehead the electrodes feel the effect of gravity force.

5.1.2 Conclusions

At the end of the whole trial it is possible to make some conclusions.

	Brachioradial. (B)	**Trapezius (T)**	**Sternocleidom. (S)**	**Frontalis (F)**	**best choice**
Sub1	0	32	0	0	B,S
Sub 2	22	4	0	107	S
Sub 3	11	0	0	11	T,S
Sub 4	26	4	3	0	T,S

Table 3.6: results of the tests

First of all, results together with comments related to the EMG signal recorded, highlight that both the muscle to be used and the parameters choice are user and operator dependent. On one hand the user could inadvertently activate one muscle more than another depending on the activity he wants to do. On the other hand, the operator has to be able in selecting the proper threshold value.

Nevertheless, among the 4 tested muscles, sternocleidomastoid is the one that best replay to code requests. Decision is based on results discussed above. It is the one that caused the lower number of unwilled trigger activations. In addition, no significant problems are highlighted by time spent in START and END phases. Furthermore, the brachioradialis and the trapezius could be good as well. On the contrary, frontalis

muscle created problems in contraction towards all the participants and, in general, it is preferable not to put electrodes on person's face.

In respect to time calculated for both the START and END phases, it is possible to make a general evaluation. It has been registered by the users an overall improvement in reducing the time requested to communicate their own intention. This highlights that it was easy for the subjects to become familiar with the system.

During the test, healthy persons have been done all the movements they need to by using both the left and the right arm. If they would have use just one arm, which is the one supported by the MUNDUS system, trigger activation number would have been even smaller.

Table 3.1 shows that tests have been done with a different selection of "threshold activation" and "time interval" parameters for each subject. The aim of it was to find the optimal set of parameters for healthy persons. Nevertheless, no relevant differences among subject were found. In particular, the activation threshold values used (50% and 70%) did not change the situation. On the other hand, according to the choice of "time interval" parameter, 3 seconds are considered enough to make the code robust.

Finally, by checking the stability of electrode-skin coupling, it comes out that only the placement on frontalis muscle could induce some problems.

The results yielded from these experiments represent an important starting point for the algorithm introduction in the whole MUNDUS system together with the possibility to let Scenario 1 subjects use the EMG signal as intention detection modality.

5.2 Validation of MUNDUS - Scenario 1

5.2.1 Results

Five healthy subjects (neurologically and orthopedically intact) have been involved in the trials for validating the MUNDUS platform (Scenario 1). The data acquired on healthy subjects were used to compute for each of the parameters listed in Par.2.5.3 a sort range of normality. Demographic and anthropometric characteristics of the control group are reported in Table 3.3.

Healthy subjects performed the trials according to the same protocol defined for the end-users: while being supported by the EXO, they were asked to execute 10 repetitions of the 4 tasks enlisted in the protocol reported in Par.2.5.2. During the trials, they used the EMG trigger modality in order to activate brakes. The best muscle to detect their intention was selected according to personal preferences; three of them used the abductor pollicis brevis muscle, while the other two used the brachioradialis muscle.

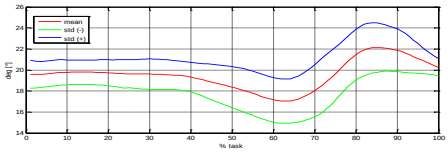
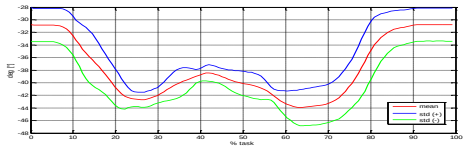
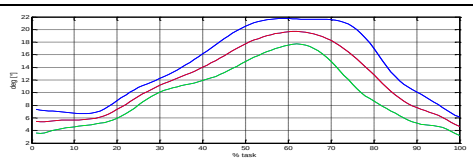
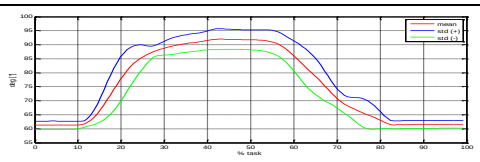
Three patients were involved in the trails for validating the MUNDUS platform – Scenario 1 on real end-users. Patients were asked to repeat the testing session three times on consecutive days. Table3.4 outlines the clinical and demographic details of the patients while Table 3.5, Table 3.6 and Table 3.7 show the results of the biomechanical analysis taken before the tests start. In what follows, the results are presented patient by patient. First of all, Table 3.4 shows that no one has residual spasticity in the arm (MAS). Moreover, MI index is characterized by low scores for the second and the third patients. In details, the main difference between them and the first one is based on the difficulty in fine grasping of the formers subject. On the other hand, problems in doing anti-gravitary movements were diagnosed to all the three subjects within the same clinical scale. The less independent patient is the third one (BI) but the other two are not completely self-sufficient as well. Finally, the last index describes the level of muscle contractility (MRC). Patient 2 took a high score in it, while the third one shows to have low residual strength in his right arm.

Healthy subject	Age	gender	Arm length [cm]	Forearm length [cm]
Subject 1	24	Female	29	28
Subject 2	23	Female	33	32
Subject 3	20	Male	38	35
Subject 4	21	Female	30	31
Subject 5	45	Male	29	31

Table 3.3: Demographic and anthropometric details of healthy subjects.

	Age	Gender	Pathology	Diagnosis date	MAS [0-24] right arm	MI [0-100] right arm	BI [0-20] right arm	MRC [0-30] right arm	Arm length [cm]	Forearm length [cm]
P1	30	Female	FRDA	1996	0	76	4	12	28	32
P2	51	Male	FRDA	1986	0	49	3	24	31	28
P3	71	Male	SCI (C3-C4)	2012	0	49	0	4	33	28

Table 3.4:Clinical, demographic and anthropometric details of the patients involved in the validation tests.

P1	FREE	EXO
Sh.rotat.		
		
Sh.elev.		
		
Elbow fl.		

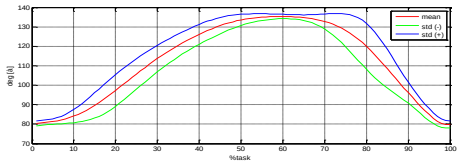
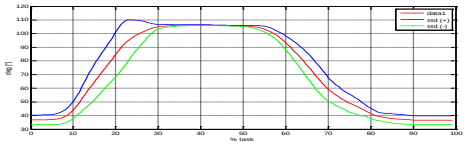
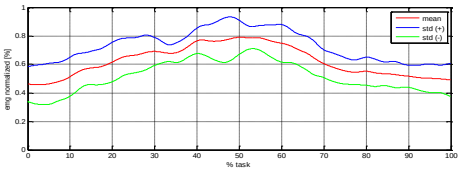
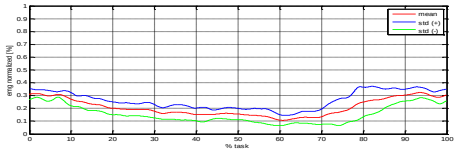
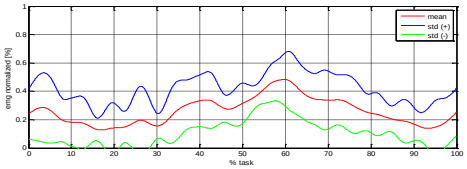
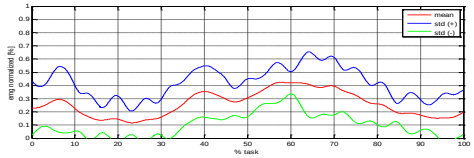
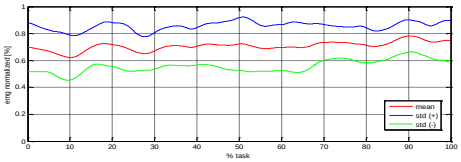
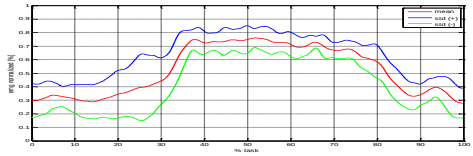
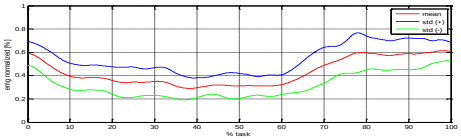
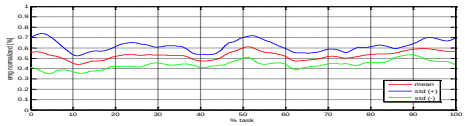
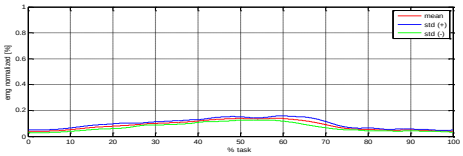
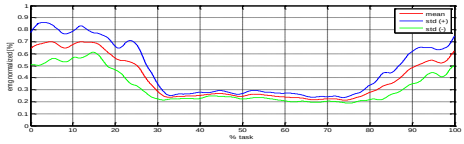
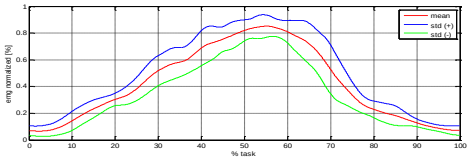
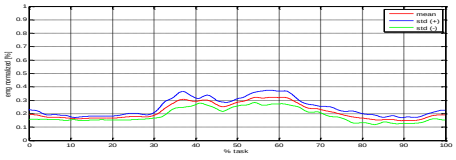
		
trapetius	RMS: 10,68	RMS: 3,53
		
Pectoralis	RMS:1,04	RMS:0,68
		
M. deltoid	RMS:4,78	RMS:9,71
		
P. deltoid	RMS:1,77	RMS:20,31
		
triceps	RMS:0,83	RMS:4,13
		
biceps	RMS:15,24	RMS:6,76
		

Table 3.5: biomechanical analysis of P1. Conditioned angular traces and EMG signals recorded during hand-to-mouth movement are plotted. Mean values (red line) and standard deviation (blue lines) of 10 repetitions are illustrated. Comparison is made between signals recorded during free movement and with the EXO support.

EMG traces in Table 3.5 highlight that P1 received big help from the EXO during the movements in the use of both trapezius and biceps muscles. Indeed, in the respective plots, the EMG signal reaches a maximum value which is the half of the corresponding free movement maximum data. RMS scores give a confirmation of it. Pectoralis major muscle is less used in the second case as well; in its second graph, it is shown that the EXO support makes the subject use the muscle in particular at the very beginning and at the end of the movement. It points out that the arm is supported when the patient reach the target position. On the contrary, the deltoid muscles and the triceps one are more used during the tasks execution with the EXO. Actually, going into details, when helped by the EXO, the triceps muscle is used as biceps antagonist, the role which it is supposed to have.

In respect to the angular analysis, the shoulder rotation value underlines that the subject completely change the trajectory while using the EXO support.

P1

On the first day, before starting the test, more than one muscle was monitored for ten minutes while the EXO was customized on the subject in order to select the best muscle to be used for the detection of the user's intention. The user was able to control different muscles of the contralateral arm but she preferred to use the trapezius for the EMG trigger detection. During the second session (day 2), the subject preferred to use the abductor pollicis brevis muscle but the many requested hand movements to contract the thumb caused low stability to the electrodes in this position. Due to this, on the third day, she used the brachioradialis muscle to control the system. At the end of the three sessions, the subject said to be more comfortable in driving the system by contracting the brachioradialis muscle than by contracting the other two muscles tested. From the software point of view, no relevant differences are noticed among the three muscles: in all cases the algorithm shows to be robust even when the person used the left arm to gesture while speaking.

In the following tables the results obtained by P1 on the three testing days are compared; in particular, Table 3.8 shows the results related to the "drinking with a straw

task"; Table 3.9 those related to the "touching the left shoulder task; Table 3.9 illustrated the "touching the left hand" task data and Table 3.10 the ones got from the "pressing a button" task. The values obtained by the healthy subjects group are also reported in the tables (normality ranges).

Table 3.8:results obtained on the 3 testing days by P1 while testing the "drinking with a straw" task.

P1-drink	Day 1	Day 2	Day 3	Normality range	P-value (among days) **	P (day1 vs day2) #	P (day2 vs day3) #	P (day1 vs day3) #
Time 1 [s]	*15,94 (5,24)	*13,82 (2,08)	*22,8 (19,64)	8,8 (2,76)	<0,001	0,266	0,001	0,062
Time 2 [s]	*10,02 (1,6)	*8,3 (2,24)	*8,66 (1,28)	4,32 (1,6)	0,134			
Straightness1 [0-1]	*0,48 (0,16)	*0,545 (0,1)	*0,365 (0,12)	0,75 (0,09)	0,03	0,363	<0,001	0,191
Straightness2 [0-1]	*0,635 (0,11)	0,71 (0,08)	0,7 (0,09)	0,735 (0,11)	0,038	0,033	0,791	0,464
Smoothness1 [0-1]	0,115 (0,05)	0,1 (0,03)	*0,04 (0,08)	0,115 (0,04)	0,015	0,875	0,226	0,014
Smoothness2 [0-1]	*0,18 (0,05)	*0,155 (0,07)	*0,16 (0,03)	0,28 (0,07)	0,356			
Mean speed1 [cm/s]	*5,892 (2,631)	6,6235 (2,41)	*4,7765 (2,217)	7,638 (3,461)	0,079			
Mean speed2 [cm/s]	*7,85 (2,056)	*8,353 (3,438)	*7,8885 (0,48)	14,939 (5,435)	0,991			

- Values: Median (interquartile range, IQR)
- ** Significant level of Kruskal-Wallis test ($p < 0.05$)
- # Significant level of Kruskal-Wallis post-hoc analysis ($p < 0.05$)
- *Significant level of Mann-Whitney U test ($p < 0.05$)

Table 3.9:results obtained on the 3 testing days by P1 while testing the "touching the left shoulder" task.

P1-shoulder	Day 1	Day 2	Day 3	Normality range	P-value (among days) **	P (day1 vs day2) #	P (day2 vs day3) #	P (day1 vs day3) #
Time 1 [s]	*10,04 (6,72)	7,7 (2,44)	*13,26 (5,7)	7,54 (2,52)	0,069			
Time 2 [s]	*7,5 (2,2)	*3,66 (1,16)	*4,9 (0,92)	2,9 (1,2)	<0,001	<0,001	0,252	0,022
Straightness1 [0-1]	*0,72 (0,1)	0,765 (0,1)	0,81 (0,12)	0,81 (0,11)	0,199			
Straightness2 [0-1]	0,71 (0,05)	0,74 (0,07)	0,795 (0,09)	0,785 (0,04)	0,003	0,612	0,115	0,002
Smoothness1 [0-1]	0,1 (0,07)	0,11 (0,03)	*0,03 (0,09)	0,12 (0,06)	0,120			
Smoothness2 [0-1]	0,28 (0,14)	*0,37 (0,08)	*0,02 (0,03)	0,28 (0,1)	<0,001	0,320	<0,001	0,064
Mean speed1 [cm/s]	11,23 (6,101)	14,929 (7,218)	7,199 (2,953)	13,052 (5,142)	0,003	1	0,003	0,058
Mean speed2 [cm/s]	*15,702 (3,4)	32,079 (5,77)	*18,151 (5,872)	32,26 (12,258)	<0,001	<0,001	0,001	1

- Values: Median (interquartile range, IQR)
- ** Significant level of Kruskal-Wallis test ($p < 0.05$)
- # Significant level of Kruskal-Wallis post-hoc analysis ($p < 0.05$)
- *Significant level of Mann-Whitney U test ($p < 0.05$)

Table 3.10:results obtained on the 3 testing days by P1 while testing the "touching the left hand" task.

P1-hand	Day 1	Day 2	Day 3	Normality range	P-value (among days) **	P (day1 vs day2) #	P (day2 vs day3) #	P (day1 vs day3) #
Time 1 [s]	*10,58 (3,2)	*9,5 (3,44)	*13,2 (2,72)	7,32 (2,56)	0,024	1	0,045	0,064
Time 2 [s]	*8,08 (1,44)	*4,06 (1,32)	*6,52 (2,44)	3,08 (0,76)	0,001	<0,001	0,115	0,296
Straightness1 [0-1]	*0,405 (0,1)	*0,425 (0,15)	*0,38 (0,12)	0,51 (0,08)	0,522			
Straightness2 [0-1]	0,455 (0,13)	0,51 (0,05)	0,465 (0,09)	0,535 (0,09)	0,433			
Smoothness1 [0-1]	0,105 (0,07)	*0,105 (0,03)	*0,015 (0,11)	0,14 (0,06)	0,034	1	0,185	0,039
Smoothness2 [0-1]	*0,245 (0,06)	0,235 (0,15)	*0,015 (0,01)	0,3 (0,08)	<0,001	1	<0,001	<0,001
Mean speed1 [cm/s]	10,328 (2,74)	12,082 (7,9)	*16,452 (8,32)	13,818 (5,26)	0,015	1	0,134	0,015
Mean speed2 [cm/s]	*11,37 (2,08)	*24,204 (5,51)	*16,452 (8,32)	29,646 (9,64)	<0,001	0,003	<0,001	1

- Values: Median (interquartile range, IQR)
- ** Significant level of Kruskal-Wallis test ($p < 0.05$)
- # Significant level of Kruskal-Wallis post-hoc analysis ($p < 0.05$)
- *Significant level of Mann-Whitney U test ($p < 0.05$)

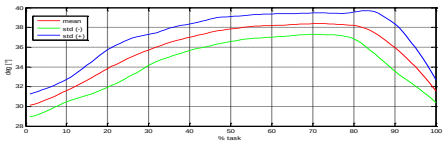
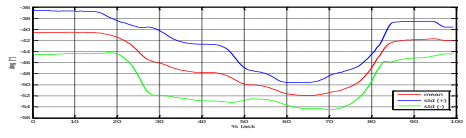
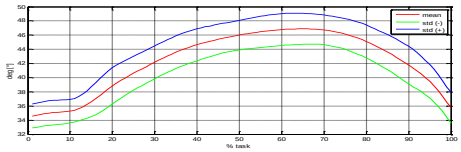
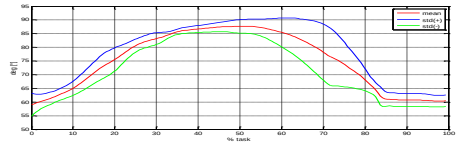
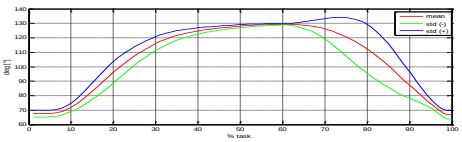
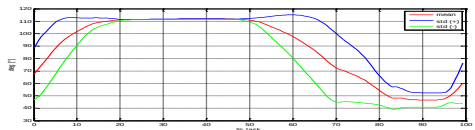
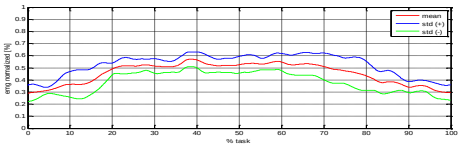
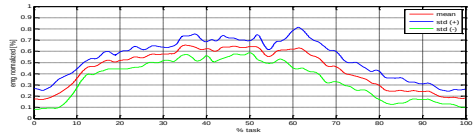
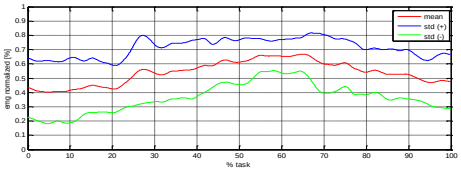
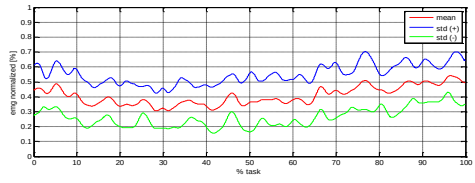
Table 3.11:results obtained on the 3 testing days by P1 while testing the "pressing a button" task.

P1-button	Day 1	Day 2	Day 3	Normality range	P-value (among days) **	P (day1 vs day2) #	P (day2 vs day3) #	P (day1 vs day3) #
Time 1 [s]	*10,46 (1,68)	*8,08 (2,44)	*11,98 (5,96)	6,86 (1,92)	0,003	0,1606	0,002	0,4872
Time 2 [s]	*8,24 (3,16)	*4,18 (1)	*4,38 (2,84)	2,5 (0,56)	0,015	0,024	1	0,056
Straightness1 [0-1]	0,435 (0,13)	*0,415 (0,08)	*0,285 (0,07)	0,485 (0,1)	<0,001	1	0,002	0,002
Straightness2 [0-1]	*0,785 (0,13)	0,51 (0,26)	*0,505 (0,12)	0,68 (0,15)	0,001	0,042	0,893	0,001
Smoothness1 [0-1]	0,13 (0,01)	0,11 (0,05)	0,115 (0,09)	0,12 (0,04)	0,2268			
Smoothness2 [0-1]	0,09 (0,05)	0,125 (0,12)	0,145 (0,03)	0,215 (0,09)	0,026	0,824	0,337	0,022
Mean speed1 [cm/s]	*8,9105 (4,74)	*8,025 (1,6)	6,385 (2,29)	5,975 (1,96)	0,112			
Mean speed2 [cm/s]	*6,36 (3,38)	*10,57 (3,09)	*10,63 (3,17)	14,795 (3,76)	0,064			

- Values: Median (interquartile range, IQR)
- ** Significant level of Kruskal-Wallis test ($p < 0.05$)
- # Significant level of Kruskal-Wallis post-hoc analysis ($p < 0.05$)
- *Significant level of Mann-Whitney U test ($p < 0.05$)

By looking at the results of the first patient, it is possible to underline both the similarities and the different aspects that came out during the tests. First of all, in general many parameters are significantly different from normality ranges (Mann-Whitney U test, $p < 0.05$). On the contrary, two exceptions have to be noticed. The first one is the straightness of the backward movement. Data show that the subject managed to do a shorter path by exploiting the gravity effect of the backward movement. The other exception is the forward smoothness which did not differ significantly from the normality range values in all the tasks. Between different testing days a differences were found: there was an overall worsening on day 3 after the improvement obtained on day 2. The worse performance during last day could be simply related to the global patient's

condition. The last movement performed by the first subject differs from the others in terms of workspace involved; indeed, the button was placed on the right of the patient and thus, to reach it, a movement of abduction was required (Table 3.11). For all button-task sessions, the smoothness of both forward and backward movements did not differ significantly to the normality ranges. Furthermore, in the last task forward mean speed is always higher than the one obtained for healthy subjects.

P2	**FREE**	**EXO**
Sh.rotat.		
		
Sh.elev.		
		
Elbow fl.		
		
trapetius	RMS: 23.64	RMS: 24.35
		
Pectoralis	RMS: 2.72	RMS: 1.64
		

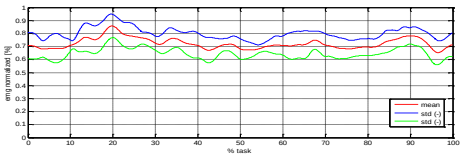
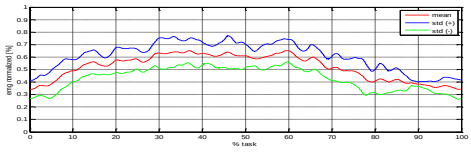
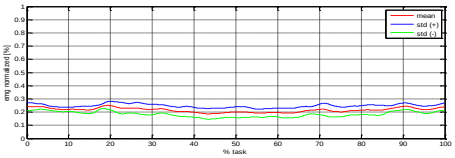
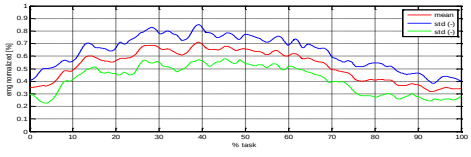
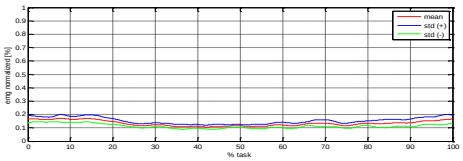
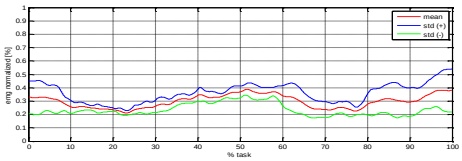
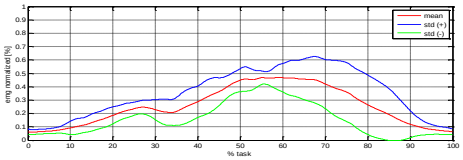
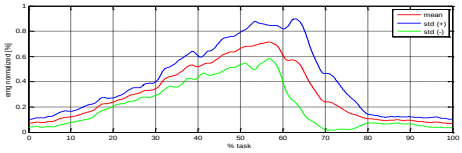
M. deltoid	RMS:12.31	RMS: 8.48
		
P. deltoid	RMS: 3.89	RMS: 9.76
		
triceps	RMS: 0.67	RMS: 1.51
		
biceps	RMS: 9.38	RMS: 12.11
		

Table 3.6: biomechanical analysis of P2. Conditioned angular traces and EMG signals recorded during hand-to-mouth movement are plotted. Mean values (red line) and standard deviation(blue lines) of 10 repetitions are illustrated. Comparison is made between signals recorded during free movement and with the EXO support.

No main differences are shown by the second patient in the use of the trapezius muscle with and without the EXO (Table 3.6). Furthermore, pectoralis major muscle highlights that the respective maximum and RMS values are similar in both the executions. On the other hand they show an opposite trace progression: with the EXO support, the muscle is contracted more while lifting and lowering the arm. These are indeed the phases in which the muscle should be used. During free movement, medial deltoid is always activated; on the contrary the EXO introduction allows the subject to use it in a better way. Low EMG values are reached in its second plot and it is more used while the hand is higher than the shoulder. The posterior deltoid indeed is used very little during free movement. On the contrary, the EXO make the patients to activate it more but, at the

same time, he can use it in a proper way. Finally, the subject is not able to take advance from the EXO in the use of both triceps and biceps muscle.

Shoulder rotation angular values confirms that the subject completely change the trajectory while using the EXO support.

P2

The subject preserved some residual motor ability that allowed him to execute all the tasks just with the help of the exoskeleton without the support of the arm NMES module. However, no many muscles on the contralateral arm could be selected to control the EMG trigger modality. During the first session, the brachioradialis muscle was selected to detect the user's intention. Due to the difficulties in the selection of a proper value of threshold together with problems in choice of the time interval between consecutive contractions, the muscle was changed in the following testing days. On patient's advice, the masseter muscle was selected and no complications during calibrations occurred. The EMG signal was not affected by subject's sneezes.

The tables below show all the results obtained by Patient 2 (P2).

Table 3.12:results obtained on the 3 testing days by P2 while testing the "drinking with a straw" task.

P2-drink	Day 1	Day 2	Day 3	Normality range	P-value (among days) **	P (day1 vs day2) #	P (day2 vs day3) #	P (day1 vs day3) #
Time 1 [s]	17,96 (7,88)	15,26 (2)	11,24 (2,76)	8,8 (2,76)	<0,001	0,382	0,022	<0,001
Time 2 [s]	*13,92 (12,44)	*14,18 (2,92)	*10,06 (3,92)	4,32 (1,6)	0,004	1	0,007	0,029
Straightness1 [0-1]	0,72 (0,21)	*0,645 (0,13)	0,74 (0,08)	0,75 (0,09)	0,100			
Straightness2 [0-1]	*0,66 (0,08)	*0,605 (0,08)	0,725 (0,1)	0,735 (0,11)	0,001	0,191	<0,001	0,245
Smoothness1 [0-1]	0,11 (0,02)	*0,135 (0,05)	*0,175 (0,04)	0,115 (0,04)	0,003	0,118	0,668	0,003
Smoothness2 [0-1]	*0,1 (0,05)	*0,1 (0,03)	*0,115 (0,05)	0,28 (0,07)	0,089			
Mean speed1 [cm/s]	*4,224 (1,785)	*4,784 (0,375)	*5,414 (1,201)	7,638 (3,461)	<0,001	<0,001	0,1966	0,1654
Mean speed2 [cm/s]	*5,821 (2,695)	*5,47 (1,144)	*5,361 (2,421)	14,939 (5,435)	0,561			

- Values: Median (interquartile range, IQR)
- ** Significant level of Kruskal-Wallis test ($p < 0.05$)
- # Significant level of Kruskal-Wallis post-hoc analysis ($p < 0.05$)
- *Significant level of Mann-Whitney U test ($p < 0.05$)

Table 3.13:results obtained on the 3 testing days by P2 while testing the "touching the left shoulder" task.

P2-shoulder	Day 1	Day 2	Day 3	Normality range	P-value (among days) **	P (day1 vs day2) #	P (day2 vs day3) #	P (day1 vs day3) #
Time 1 [s]	*14,06 (7,08)	*10,1 (2,6)	*11,64 (2,76)	7,54 (2,52)	0,1899			
Time 2 [s]	*9,28 (1,72)	*5,96 (0,64)	*6,16 (1,2)	2,9 (1,2)	<0,001	<0,001	1	0,003
Straightness1 [0-1]	*0,7 (0,09)	0,84 (0,02)	0,815 (0,03)	0,81 (0,11)	<0,001	<0,001	0,612	0,01
Straightness2 [0-1]	0,73 (0,05)	0,865 (0,09)	0,845 (0,07)	0,785 (0,04)	0,001	0,002	1	0,162
Smoothness1 [0-1]	0,125 (0,08)	0,12 (0,04)	0,13 (0,06)	0,12 (0,06)	0,6839			
Smoothness2 [0-1]	0,2 (0,08)	0,265 (0,14)	0,285 (0,12)	0,28 (0,1)	0,016	0,073	1	0,022
Mean speed1 [cm/s]	*8,782 (4,83)	*7,269 (1,63)	*8,385 (1,555)	13,052 (5,142)	0,453			
Mean speed2 [cm/s]	*12,146 (3,44)	*14,635 (2,2)	*14,041 (2,824)	32,26 (12,258)	0,034	0,033	1	0,252

- Values: Median (interquartile range, IQR)
- ** Significant level of Kruskal-Wallis test ($p < 0.05$)
- # Significant level of Kruskal-Wallis post-hoc analysis ($p < 0.05$)
- *Significant level of Mann-Whitney U test ($p < 0.05$)

Table 3.14:results obtained on the 3 testing days by P2 while testing the "touching the left hand" task.

P2-hand	Day 1	Day 2	Day 3	Normality range	P-value (among days) **	P (day1 vs day2) #	P (day2 vs day3) #	P (day1 vs day3) #
Time 1 [s]	*17,22 (8,84)	*12,68 (4,68)	*13,36 (1,68)	7,32 (2,56)	0,045	0,049	1	0,239
Time 2 [s]	6,96 (2,6)	8,5 (0,32)	6,54 (0,68)	3,08 (0,76)	0,019	0,432	0,015	0,534
Straightness1 [0-1]	0,5 (0,08)	0,52 (0,07)	0,52 (0,05)	0,51 (0,08)	0,120			
Straightness2 [0-1]	0,535 (0,08)	*0,605 (0,04)	*0,65 (0,05)	0,535 (0,09)	0,013	0,22	0,807	0,011
Smoothness1 [0-1]	*0,115 (0,05)	0,14 (0,08)	0,155 (0,02)	0,14 (0,06)	0,087			
Smoothness2 [0-1]	*0,195 (0,08)	0,32 (0,14)	*0,21 (0,05)	0,3 (0,08)	0,043	0,058	0,160	1
Mean speed1 [cm/s]	*7,205 (3,08)	*9,873 (2,59)	*8,272 (1,01)	13,818 (5,26)	0,031	0,026	0,345	0,893
Mean speed2 [cm/s]	*16,52 (4,39)	*16,5 (4,4)	*14,334 (1,37)	29,646 (9,64)	0,180			

- Values: Median (interquartile range, IQR)
- ** Significant level of Kruskal-Wallis test ($p < 0.05$)
- # Significant level of Kruskal-Wallis post-hoc analysis ($p < 0.05$)
- *Significant level of Mann-Whitney U test ($p < 0.05$)

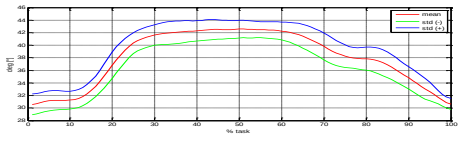
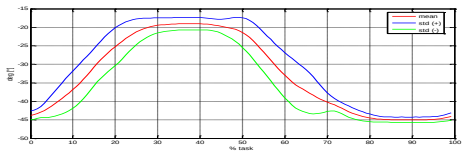
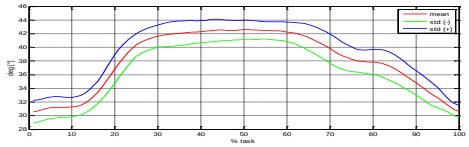
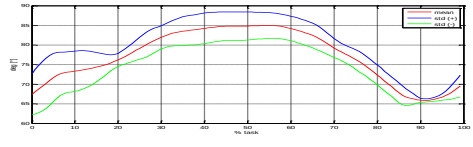
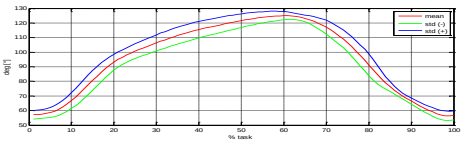
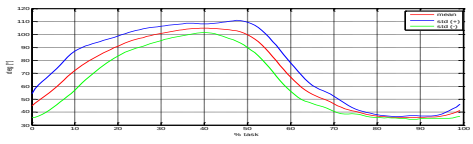
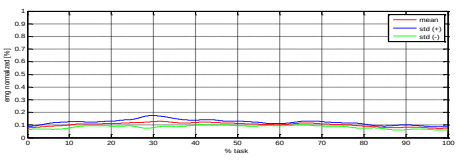
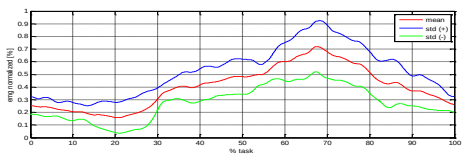
Table 3.15:results obtained on the 3 testing days by P2 while testing the "pressing a button" task.

P2-button	Day 1	Day 2	Day 3	Normality range	P-value (among days) **	P (day1 vs day2) #	P (day2 vs day3) #	P (day1 vs day3) #
Time 1 [s]	*11,98 (4,44)	*12,72 (3,2)	*12,76 (3,96)	6,86 (1,92)	0,755			
Time 2 [s]	*6,26 (2,48)	*7,46 (0,96)	*6,36 (1,8)	2,5 (0,56)	0,298			
Straightness1 [0-1]	0,415 (0,19)	*0,33 (0,15)	0,54 (0,13)	0,485 (0,1)	0,016	0,422	0,012	0,487
Straightness2 [0-1]	0,47 (0,18)	0,35 (0,14)	0,64 (0,18)	0,68 (0,15)	0,001	0,475	<0,001	0,073
Smoothness1 [0-1]	*0,16 (0,03)	0,125 (0,04)	0,125 (0,06)	0,12 (0,04)	0,037			
Smoothness2 [0-1]	*0,115 (0,06)	*0,09 (0,04)	*0,1 (0,02	0,215 (0,09)	0,220			
Mean speed1 [cm/s]	*3,947 (1,59)	*3,172 (0,45)	*3,776 (1,42)	5,975 (1,96)	0,092			
Mean speed2 [cm/s]	*5,54 (3,32)	*5,74 (2,23)	*5,87 (1,39)	14,795 (3,76)	0,950			

- Values: Median (interquartile range, IQR)
- ** Significant level of Kruskal-Wallis test ($p < 0.05$)
- # Significant level of Kruskal-Wallis post-hoc analysis ($p < 0.05$)
- *Significant level of Mann-Whitney U test ($p < 0.05$)

At the end of the tests, data collected highlights a general improvement of patient 2 over the days. Kruskal-Wallis post-hoc analysis underlines it by the presence of significant p-values ($p<0,05$) referred to day 3. In this way, it points out that the subject became familiar with the device during the three sessions. Moreover, time 1 and 2 together with mean speed 1 are completely different from the normality index values. On the contrary, attention is needed to be paid on straightness in performing "touching the left hand" action (Table 3.14): both forward and return show good values among the three days; whenever Mann-Whitney analysis gives back a significant p-value as output, it is related to a better execution performed by the patient. With respect to "pressing the

button" task (Table 3.15), statistical test underlines significant differences between consecutive days in terms of straightness of forward and backward movements. In both cases a worsening happens during day 2 with a following improvement during the third repetition. At the end of the last test day, the second user expressed his preference towards the "touching the left shoulder" task among all the ones he was asked to execute. He says that he have been helped at best by the EXO during the execution of that movement. As confirmation of it, both straightness and smoothness related to the two directions of the action are not statistically different from the control group values (Table 3.13).

P3	**FREE**	**EXO**
Sh.rotat.		
		
Sh.elev.		
		
Elbow fl.		
		
trapetius	RMS: 8.27	RMS: 34.24
		

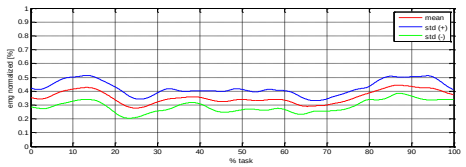
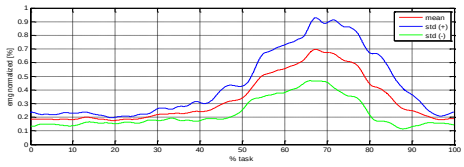
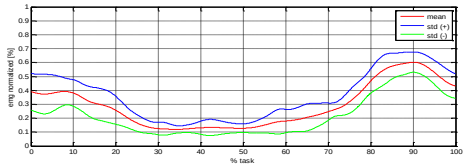
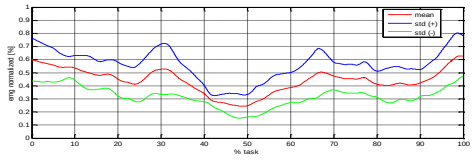
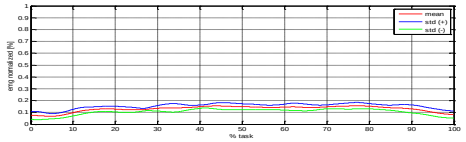
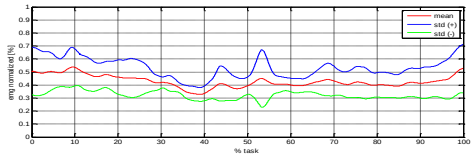
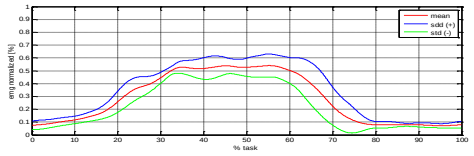
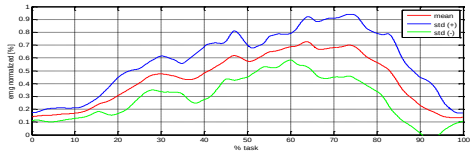
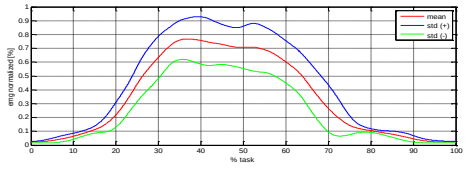
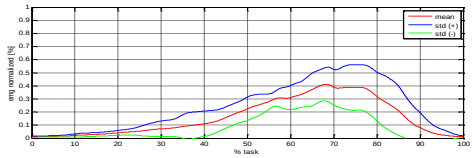
Pectoralis	RMS:8.28	RMS: 8.62
		
M. deltoid	RMS:10.88	RMS: 14.79
		
P. deltoid	RMS:2.64	RMS: 8,61
		
triceps	RMS:6.52	RMS:9.07
		
biceps	RMS:100	RMS:51
		

Table 3.7: biomechanical analysis of P3. Conditioned angular traces and EMG signals recorded during hand-to-mouth movement are plotted. Mean values (red line) and standard deviation(blue lines) of 10 repetitions are illustrated. Comparison is made between signals recorded during free movement and with the EXO support.

The EMG signal recorded and plotted in table 3.7 show an overall higher activation of the muscles during the movements done with the support of the EXO. On the contrary, exception is made by the biceps muscle which is much more used during free movements than during the following one. It could be conclude that during the biomechanical test done before the trials the patient did not manage to exploit the

exoskeleton characteristics. It is confirm as well by the fact that the subject did not change the way of bringing the hand to mouth while using the Exoskeleton as the other patients did.

P3

The third subject has difficulty in lifting his arms but arm NMES module is not recommended to him due to the fact that he can still do it by himself. On the other hand, due to fatigue, few muscles of the contralateral limb were suitable to show the person intention while using MUNDUS EMG trigger modality. The final solution was to record signals from the trapezius muscle: the subject managed to regularly contract it by sliding the forearm on the table so not to support total arm weight. During all the 3 days, tests were done by using the same muscle.

Tables below include a detailed analysis of tests carried out by Patient 3 (P3).

Table 3.16:results obtained on the 3 testing days by P3 while testing the "drinking with a straw" task.

P3-drink	Day 1	Day 2	Day 3	Normality range	P-value (among days) **	P (day1 vs day2) #	P (day2 vs day3) #	P (day1 vs day3) #
Time 1 [s]	*14,5 (6,92)	*13,12 (4,96)	9,84 (3,08)	8,8 (2,76)	0,007	1	0,021	0,019
Time 2 [s]	*8,3 (5,65)	*7,26 (2,52)	*6,06 (4,16)	4,32 (1,6)	0,105			
Straightness1 [0-1]	0,505 (0,12)	0,485 (0,08)	0,705 (0,13)	0,75 (0,09)	0,002	1	0,006	0,012
Straightness2 [0-1]	*0,5 (0,17)	*0,55 (0,05)	*0,6 (0,07)	0,735 (0,11)	0,081			
Smoothness1 [0-1]	0,125 (0,04)	0,14 (0,05)	0,115 (0,03)	0,115 (0,04)	0,16			
Smoothness2 [0-1]	*0,21 (0,05)	*0,20 (0,04)	*0,22 (0,07)	0,28 (0,07)	0,808			
Mean speed1 [cm/s]	5,759 (1,773)	6,848 (1,341)	8,87 (1,927)	7,638 (3,461)	<0,001	0,858	0,028	<0,001
Mean speed2 [cm/s]	*10,14 (3,878)	*11,11 (1,60)	16,869 (11,601)	14,939 (5,435)	0,138			

- Values: Median (interquartile range, IQR)
- ** Significant level of Kruskal-Wallis test ($p < 0.05$)
- # Significant level of Kruskal-Wallis post-hoc analysis ($p < 0.05$)
- *Significant level of Mann-Whitney U test ($p < 0.05$)

Table 3.17:results obtained on the 3 testing days by P3 while testing the "touching the left shoulder" task.

P3-shoulder	Day 1	Day 2	Day 3	Normality range	P-value (among days) **	P (day1 vs day2) #	P (day2 vs day3) #	P (day1 vs day3) #
Time 1 [s]	*8,7 (1,64)	*10,78 (3,6)	*10,64 (2,6)	7,54 (2,52)	0,317			
Time 2 [s]	*5,44 (1,08)	*5,52 (1,88)	*4,66 (0,96)	2,9 (1,2)	0,242			
Straightness1 [0-1]	*0,735 (0,07)	*0,685 (0,05)	*0,72 (0,04)	0,81 (0,11)	0,724			
Straightness2 [0-1]	0,73 (0,03)	0,66 (0,02)	0,69 (0,04)	0,785 (0,04)	<0,001	<0,001	<0,028	0,22
Smoothness1 [0-1]	*0,145 (0,04)	0,115 (0,03)	0,11 (0,03)	0,12 (0,06)	0,111			
Smoothness2 [0-1]	0,265 (0,01)	0,255 (0,06)	0,28 (0,05)	0,28 (0,1)	0,203			
Mean speed1 [cm/s]	*10,595 (1,505)	10,869 (2,67)	*9,608 (1,795)	13,052 (5,142)	0,089			
Mean speed2 [cm/s]	*19,284 (2,93)	21,175 (6,332)	*23,099 (4,93)	32,26 (12,258)	0,159			

- Values: Median (interquartile range, IQR)
- ** Significant level of Kruskal-Wallis test ($p < 0.05$)
- # Significant level of Kruskal-Wallis post-hoc analysis ($p < 0.05$)
- *Significant level of Mann-Whitney U test ($p < 0.05$)

Table 3.18:results obtained on the 3 testing days by P3 while testing the "touching the left hand" task.

P3-hand	Day 1	Day 2	Day 3	Normality range	P-value (among days) **	P (day1 vs day2) #	P (day2 vs day3) #	P (day1 vs day3) #
Time 1 [s]	*9,82 (5,04)	7,6 (2,72)	*10,34 (1,76)	7,32 (2,56)	0,133			
Time 2 [s]	*6,06 (1,04)	*4,28 (1,16)	*4,7 (0,72)	3,08 (0,76)	0,030	0,029	1	0,213
Straightness1 [0-1]	*0,46 (0,05)	0,47 (0,1)	*0,46 (0,06)	0,51 (0,08)	0,608			
Straightness2 [0-1]	0,56 (0,07)	0,485 (0,05)	0,485 (0,04)	0,535 (0,09)	<0,001	<0,001	1	0,003
Smoothness1 [0-1]	0,155 (0,05)	0,145 (0,03)	0,11 (0,01)	0,14 (0,06)	0,015	1	0,041	0,038
Smoothness2 [0-1]	0,25 (0,09)	0,3 (0,01)	0,275 (0,06)	0,3 (0,08)	0,204			
Mean speed1 [cm/s]	11,343 (3,51)	14,142 (2,75)	*10,213 (1,77)	13,818 (5,26)	<0,001	0,027	<0,001	0,791
Mean speed2 [cm/s]	*16,178 (4,33)	28,493 (5,15)	*22,394 (8,1)	29,646 (9,64)	0,002	0,001	0,076	0,639

- Values: Median (interquartile range, IQR)
- ** Significant level of Kruskal-Wallis test ($p < 0.05$)
- # Significant level of Kruskal-Wallis post-hoc analysis ($p < 0.05$)
- *Significant level of Mann-Whitney U test ($p < 0.05$)

Table 3.19:results obtained on the 3 testing days by P3 while testing the "pressing a button" task.

P3-button	Day 1	Day 2	Day 3	Normality range	P-value (among days) **	P (day1 vs day2) #	P (day2 vs day3) #	P (day1 vs day3) #
Time 1 [s]	*9,06 (2,6)	*7,74 (0,76)	*10,28 (2,96)	6,86 (1,92)	0,019	0,598	0,015	0,392
Time 2 [s]	*3,54 (0,52)	*4,58 (0,92)	*4,26 (1,48)	2,5 (0,56)	0,011	0,010	1	0,111
Straightness1 [0-1]	0,47 (0,11)	0,5 (0,06)	*0,27 (0,07)	0,485 (0,1)	<0,001	1	<0,001	0,004
Straightness2 [0-1]	*0,47 (0,05)	0,59 (0,06)	*0,386 (0,04)	0,68 (0,15)	<0,001	<0,001	<0,001	1
Smoothness1 [0-1]	*0,075 (0,02)	*0,095 (0,02)	*0,09 (0,02)	0,12 (0,04)	0,1819			
Smoothness2 [0-1]	*0,18 (0,04)	0,21 (0,03)	0,24 (0,06)	0,215 (0,09)	0,012	0,208	0,824	0,010
Mean speed1 [cm/s]	*4,647 (0,364)	*8,87 (3,1)	6,088 (1,36)	5,975 (1,96)	0,002	0,001	0,170	0,328
Mean speed2 [cm/s]	13,542 (3,74)	15,31 (2,01)	12,291 (3,96)	14,795 (3,76)	0,063			

- Values: Median (interquartile range, IQR)
- ** Significant level of Kruskal-Wallis test ($p < 0.05$)
- # Significant level of Kruskal-Wallis post-hoc analysis ($p < 0.05$)
- *Significant level of Mann-Whitney U test ($p < 0.05$)

No best performance within the three repetitions of the third user can be selected in respect to all the parameters analyzed during the four tasks. A general common behavior over the three days is not recognizable, neither a general improvement nor an overall worsening. At the same time, few similar aspects within the same task are here underlined. During "drinking with a straw" task, data (table 3.16) show an improvement in time1, straightness 1 and mean speed 1. The three parameters are indeed strictly related among them. On the contrary, data related to the backward movement differed significantly from the normality ranges. This aspect underlines that the patient did not

exploit the gravity effect in bring the cup back to the table. The data enlisted in Table 3.17 illustrate that straightness 1 and smoothness 1 are not statistically different from control group values. From the analysis of "pressing the button" task it is clear that many values are out of normality ranges (table 3.19). In particular, the same relation noticed between parameters in the first task is here repeated. This time, instead, while time 1 is nearly always equal, straightness 1 and mean speed 1 behave in the opposite way. By following the third subject during the whole test, it is needed to say that at the end of each session he was always tired. Even if he could rest whenever he wants and could do breaks of the duration he prefers when the brakes are on, he was not trained to perform many repetitions of movements.

5.2.2 Conclusions

The trials showed that the EMG trigger modality could be used to detect the user's intention; it worked within the MUNDUS system and managed to communicate with all the other modules. All the subjects involved in the tests - both patients and healthy persons - were able to activate and deactivate the brakes whenever they desired. Therefore, the robustness of the algorithm within the MUNDUS platform was verified.

In addition, from patients' performances some general considerations can be underlined.

It can be confirmed that MUNDUS, as an assistive device, is able to help the user of Scenario 1 in doing the tasks he wants. Indeed, all the three patients managed to conclude the whole sessions supported by the exoskeleton empowered by the brakes. The possibility to enable brakes during common daily life activities helped the users in reducing fatigue while keeping the arm in a suspended position. In particular, one of the patients would have used MUNDUS device to support her harm when she uses the hair dryer as well as when she put make up on her face.

At the end of the test results analysis, it is clear that two parameters are the most meaningful among the four described. They are the straightness and the smoothness. Their importance is related to the fact that straight and smooth movements are

considered rare among people affected by MUNDUS target pathologies. Indeed, they are characterized by a series of complications that impede the person in concluding the task without stopping before it is finished. From the results of each task done by subjects recruited in the test, it is possible to say that the calculated smoothness and straightness values are often similar to the ones of the normality indexes. On the contrary, the time spent and the mean speed are not significant by itself; they are not the main characteristic requested by auser which looks for autonomy.

Furthermore, two out of three patients showed general improvements after the first test day. This highlights the fact that it is possible for the user to became familiar with the device after few test repetitions. It is an important aspect towards assistive devices, especially for the ones that help people with degenerative pathologies. On the contrary, the third patient did not learn how to best use it. At the end of the trial it is possible to say that he should have done some more test repetitions in order to get acquainted with the device and really take all the advantages that MUNDUS could give him.

One last observation is referred to the loss of the humeral rotation degree of freedom. Even healthy people realized that it is much more comfortable to use the device by slightly changing the common trajectories. For example, while using the EXO, the subject is much more helped in taking a cup from the table by first lifting the arm and then moving down towards it. At the first execution it could seem strange from the user point of view, but during repetitions even the healthy people notice that the weight compensation works better in this way because the arm is partly lifted by the system. At the same time, the reduction of the number of degrees of freedom could be an aid towards patients; indeed they have to concentrate on a lower number of joint movements during the action execution.

Chapter 6

Discussions and future developments

The current work is included in the MUNDUS project, a European study focused on the development of an upper limb neuroprosthesis. The device is based on recovering direct interaction capability of severely motor impaired people based on arm reaching and hand function. The four main target pathologies addressed by the project are: ALS, FRDA, MS, SCI. They all share the common characteristic of being degenerative. Starting from it, the system is composed by several modules that can be added to the device or gradually substituted in order to follow the progression of the disease. At the same time, three different scenarios are considered within the project. Their role is to gather patients of similar impairment level in order to assist them at best. In particular, Scenario 1 users are the one who have a residual functional control of the arm and hand muscles but that are too weak to accomplish functional tasks. The work exposed here is one of the modules included into Scenario 1.

More in details, the present study focuses on the detection of the user's intention from residual EMG signal of one of the muscle he is still able to voluntarily contract. Firstly, an algorithm was implemented by using several software. Then, it was validated on healthy people in order to check its operating and robustness. In conclusion, an overall evaluation of MUNDUS Scenario 1 was made. Tests were done on both patients and healthy subjects by exploiting the module studied within this work.

During algorithm implementation attention was paid on user's contralateral upper limb to make him express his intention. At the beginning of the study decisions about the conditioning of the EMG signal were taken; it was chosen to have a mean value of the filtered signal as output every 40 ms. Data are then compared to a threshold which is identified on each user during an initial calibration procedure. In order to detect the

user's intention, it has been decided to find a brief sequence that the system could easily recognize. In respect to human common behaviors, three following contractions within a short interval are considered a good way to show the personal will. Indeed, they do not happen frequently during daily activities. The algorithm includes a series of features as well that minimize the possibility of mistaking signal for false positive.

Trials on healthy subjects were carried out to evaluate the robustness of the developed algorithm. EMG signals of four different muscles were monitored during an hour of common daily life activities, such as studying, reading and writing, having lunch and spending time with friends. The results of these trials showed that the algorithm is easy to be understood and it is able to detect the intention of the user. The tests were useful also to fix some parameters of the algorithm and to have some indications about the best muscle to be used for the detection of the trigger. Intentional contractions are strictly related to personal behavioral characteristics and depend on the executed activity. Nevertheless, some muscles are preferable than others in being involved in MUNDUS module. For example, all people showed difficulties in contracting the frontalis muscle in a repeatable way for activating the trigger. Furthermore, for two subjects a high number of non-intentional triggers were recorded during the execution of daily life activities. Actually, the muscles used for mimic functions are difficult to be controlled. Similarly to frontalis, brachioradialis muscle showed to be problematic if the user wants to do activities in which left upper limb is directly involved. On the other hand, both trapezius muscle and sternocleidomastoid are the one that people manages to better control. After the whole session of tests it is possible to say that subject-specific calibration of the parameters is needed for people affected by MUNDUS pathologies.

A second set of trials were then performed both on healthy subjects and on patients to provide an overall evaluation of the MUNDUS platform for patients belonging to Scenario1. These trials aimed also at validating the integration of the developed solution for intention detection within the MUNDUS system. Moreover, the feasibility of the proposed solution for EMG trigger detection on three neurological patients was investigated. They were affected by diseases which are included among the MUNDUS ones (two FRDA and one SCI patients). A set of parameters, such as time, straightness, smoothness and mean speed focused on forward and return movements were defined to

evaluate the capability of the users to take advantages from the MUNDUS system for carrying out daily life activities. Tests on five healthy subjects were performed to define normality ranges for these parameters. The trials consisted of ten repetitions of four different tasks: drinking with a straw, touching left shoulder, touching left hand and pressing a button. Healthy subjects executed a single session of trials, while patients were asked to repeat the trails on three consecutive days to evaluate whether they learned how to use the system at best.

From the results of the tests it is possible to conclude that the algorithm is still robust within MUNDUS system. Indeed, no errors in mistaking false positive occurred. The module showed to be easily integrated in the device whenever the patient needed it. During the tests all the users managed to communicate their intentions: they did not faced problems in learning the simple procedure to activate the trigger. Moreover, the patients controlled the activation and deactivation of the brakes autonomously. The initial calibration together with the choice of muscle and time parameters lasted few minutes and always succeeded in satisfying the user's requests. Thanks to it, all the patients managed to finish each session composed by ten repetitions of four movements by using the EXO empowered by brakes. In conclusion, the trial sessions underlined that MUNDUS permits the patient to execute common daily life activities alone. Even if the subjects showed to be able to do hand-to-mouth movement by themself (biomechanical initial tests), they all expressed positive opinions at the end of the trial. They were satisfied in terms of usability and benefit received by the use of MUNDUS device. In particular, they enjoyed the possibility of staying in a chosen position with the arm suspended over the table whenever they need it.

The parameters evaluated on patients during the test sessions are in general statistically different from the one expressed within the normality ranges. On one hand, time and mean speed always contrast to the healthy people values. On the other hand, straightness and smoothness data showed to became closer to the one of the normality indexes over the days. This clarified the utility of MUNDUS scenario 1 in assisting the patients in the execution of movements which are smoothed and coordinated. In addition, it underlined that the user needs to get used to the device before benefit from all the MUNDUS advantages. Another positive aspect shown by the test is that two over

three subjects becomes familiar to the EXO in few sessions. In particular, tests pointed out that the loss of the humeral rotation as degree of freedom (DoF) is a good aspect towards people affected by FRDA disease. Due to their difficulty in controlling arm trajectories, they are helped by the opportunity given by MUNDUS of paying attention only on three DoFs instead of four.

As explained in par. 2.1.4, the detection of the user intention within Scenario 1 can be done in two different ways; in this study it is presented the one based on the residual EMG signal while the second is the possibility to press a USB-button. The main selection criterion is based on the residual capabilities of the user's contralateral arm. In respect to the test done within the present study, it has been noticed that the patients preferred to communicate with the system by muscle contraction modality. Of course at the beginning they need to get used to it but when they do, they feel at their ease after few contraction repetitions. The reason is that due to their pathology, they do not perfectly feel all the things they touch. The consequent risk of it is that they could not be able to control the force given in pressing a button. In particular, the second and the third patient most highlighted this difficulty because of the progress of their diseases.

In a similar way to the algorithm here studied, accelerometers could have been used to detect the user's intentions. The preference towards EMG signals recording within this work is twofold. First of all it has been decided to exploit one component already involved in MUNDUS system. The EMG amplifier indeed was already used in Scenario 1 within the "arm module" (EMG-NEMS). Furthermore, it is mandatory for the patient to do a whole movement if accelerometers are used (e.g. rotating the forearm). On the contrary, the EMG trigger detection modality is based on user's capability of contracting muscle. People could even do a minimal isometric contraction and the system can still detect it. Indeed, there is the possibility to calibrate the system on each user according to the level of their pathology.

The module studied within the current work could be improved, here below some suggestions as future developments.

The only problems that have been faced within the tests' phase are related to the threshold selection. Single patient's session lasted at least half an hour. Due to this, at

the end of the repetitions, all the subjects showed to be tired. It has been seen that fatigue hit the intensity they managed to give in contracting the muscle with a consequent lowering of the EMG signal values. Even if people succeeded in concluding the session, an improvement could be made in that sense. It could be developed an algorithm which keeps on update threshold value by using the ten EMG peaks that have caused previous trigger activations. Anyway, attention needs to be paid on finding the proper features to prevent false positive detection.

In conclusion, some trials with the hand module need to be done. It is necessary to validate the algorithm on the user's capability of controlling the opening and closing of their hand by the help of either the NMES component or the robotic orthosis one. In particular, attention has to be put on checking if the patient gets tired. Actually, he has to contract the muscle selected on the contralateral upper limb to control both the brakes and the hand.

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