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THE E-GLOVE: DESIGN, PRODUCTION AND VALIDATION OF A WEARABLE DEVICE FOR REHABILITATION OF THE NEUROLOGICAL HAND.

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DEDICATION

Con questo documento si concludono cinque anni di una splendida storia, un'avventura ricca di soddisfazioni, battaglie, vittorie, sconfitte, ma soprattutto un momento di crescita che va oltre il semplice progresso accademico. Vorrei dedicare questo manoscritto a tutte le persone che mi sono state vicine in questa avventura, quelle che mi hanno supportato sempre, quelle che hanno proposto un'idea, quelle che hanno sostituito un problema con la soluzione. Mi riferisco, in primis, alla mia famiglia, a voi Roberta e Marco che mi avete costantemente spronato a dare il meglio fin da quando sono in grado di ricordare. Nei vostri occhi ho letto la soddisfazione e l'orgoglio crescere e questo è stato carburante inesauribile per superare tutte quelle difficoltà che in questi cinque anni mi si sono parate davanti. Volevo ringraziare anche te, Riccardo, potrai sempre trovare in me un saldo supporto a qualunque decisione tu decida di prendere crescendo. Un ringraziamento speciale a te Beatrice, siamo cresciuti insieme in questi anni ed hai sempre saputo come aiutarmi a superare i momenti no con un semplice sorriso. Non ti sarò mai grato abbastanza. Volevo ringraziare le mie cugine, Bea e Franci, che sono più che sorelle per me, zio Marco e zia Paola con i loro inesauribili consigli ed anche i nonni, Beba, Carla, Toto e Giulio che con il loro sapere, con le loro storie e con la loro infinita conoscenza riguardo ai segreti delle cose hanno contribuito a stimolare costantemente la mia curiosità e la mia voglia di crescere.

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LIST OF ABBREVIATIONS

ICF	International Classification of Functioning
CVA	Cerebrovascular Accident
MS	Multiple Sclerosis
SCI	Spinal Cord Injury
CP	Cerebral Palsy
TBI	Traumatic Brain Injury
OA	Osteoarthritis
RA	Rheumatoid Arthritis
DM	Diabetes Mellitus
SSc	Systemic Sclerosis
FES	Functional Electrical Stimulation
CSCI	Cervical Spinal Cord Injury
MeCFES	Myoelectrically Controlled Functional Electrical Stimulation
EMG	Electromyography
ECRL	Extensor Carpi Radialis Longus
ECRB	Extensor Carpi Radialis Brevis
ECU	Extensor Carpi Ulnaris

LIST OF ABBREVIATIONS (Continued)

LSB	Least Significant Bit
BT	Bluetooth
GUI	Graphic User Interface
BLE	Bluetooth Low Energy
QUEST	Quebec User Evaluation of Satisfaction with Assistive Technology
IoT	Internet of Things

SOMMARIO (Italiano)

Disfunzioni della mano possono rappresentare un grave ostacolo allo svolgimento di attività di vita quotidiana (ADL), come mangiare, pulire, cucinare, guidare, lavorare, vestirsi, fare il bagno, ecc. Per le persone con disabilità agli arti superiori, queste attività possono risultare particolarmente difficili, se non addirittura impossibili.

Secondo quanto osservato dalla 7a edizione delle “Linee guida italiane sull'ictus cerebrale”, redatta dalla *Stroke Prevention and Educational Awareness Diffusion (SPREAD)*, l'ictus è la principale causa di disabilità degli arti superiori (1). In Italia, circa 196.000 persone ogni anno sono colpite da episodi di ictus ed il numero di soggetti attualmente residenti nel paese che hanno avuto un ictus e sono sopravvissuti, con esiti più o meno invalidanti, può essere calcolato in circa 930.000 individui.

A seguito di tale evento, si stima che circa il 20% dei soggetti non recuperi l'uso dell'arto superiore e che la maggior parte degli stessi (dal 65 all'85%) subisca un recupero solo parziale.

Il numero degli individui con disabilità agli arti superiori aumenta notevolmente se si considera che anche altre cause quali sclerosi multipla (SM), lesione del midollo spinale (SCI), artrite reumatoide (RA) ed incidenti traumatici possono portare a danni alla mano.

A seguito di alterazioni neurologiche, come nel caso dell'ictus, la riabilitazione motoria sensoriale si è rivelata essenziale per il recupero del controllo motorio. Nello specifico, la rieducazione sensoriale è una tecnica attualmente utilizzata nella moderna fisioterapia per riqualificare percorsi sensoriali o stimolare percorsi inutilizzati.

Questa terapia può essere combinata con esercizi in cui il paziente manipola oggetti diversi mentre identifica e valuta le prestazioni di presa. Sia il terapeuta che i pazienti possono valutare parametri di prestazione come la forza di presa e la velocità, valutando l'esecuzione dell’azione su oggetti di diversa consistenza e peso.

Tuttavia, la valutazione delle performance e dei progressi dei pazienti è solitamente soggettiva in quanto, ad oggi, sono disponibili pochi strumenti che consentano una valutazione oggettiva dei parametri di interesse. Nella pratica clinica, la valutazione della funzionalità della mano viene eseguita principalmente utilizzando scale qualitative compilate direttamente da medici e terapisti.

Ciò riduce l'efficienza della misurazione e del monitoraggio dei progressi mostrati dal paziente durante l'evoluzione del percorso riabilitativo, riducendo infine l'efficacia stessa del processo.

Questo progetto si concentra sulle esigenze dei pazienti affetti da mano neurologica, con l'obiettivo di dare a loro ed ai terapisti che ne supportano il processo riabilitativo, uno strumento in grado di monitorare in maniera oggettiva i risultati ottenuti, migliorando gli esiti riabilitativi.

In particolare, l'obiettivo principale di questo lavoro è la progettazione, implementazione e validazione di un sistema leggero, wireless e indossabile, denominato E-glove, dedicato al monitoraggio della forza esercitata durante un'azione di presa da un paziente affetto da Sclerosi Multipla (SM), Lesioni al midollo spinale (SCI), Artrite reumatoide (RA), ma anche pazienti post-ictus e soggetti che hanno subito un intervento chirurgico alla mano. Il dispositivo prodotto deve essere in grado di quantificare e condividere con i medici i valori di forza espressi dal paziente, consentendo così un monitoraggio obiettivo degli output riabilitativi durante il decorso clinico.

Questo documento raccoglie tutte le informazioni sui materiali utilizzati, il processo di realizzazione, i test eseguiti ed i risultati ottenuti al fine di realizzare il prototipo ultimo di E-glove.

Il risultato di questo progetto è stata la realizzazione di un prototipo perfettamente funzionante basato su ESP32, una scheda elettronica che integra un modulo IoT compatibile con Arduino, integrata all'interno di un guanto ai cui polpastrelli sono stati cuciti dei sensori di forza appositamente realizzati, in posizioni che sono state definite dalla letteratura come quelle maggiormente coinvolte all'azione di presa. Inoltre, sono stati configurati alcuni LED che consentono una visualizzazione intuitiva e in tempo reale dei valori di forza misurati dal dispositivo.

Per garantire una migliore indossabilità del dispositivo e per ridurre la possibile influenza dello stesso sui movimenti fisiologici del paziente, E-glove è stato dotato di un modulo Bluetooth (BLE) 4.0 a basso consumo energetico e di un modulo Wi-Fi che consentono una rapida ed efficace comunicazione senza fili.

Tutti i componenti sono stati testati per valutarne le prestazioni, l'influenza delle condizioni al contorno e per validare la riproducibilità del processo di realizzazione seguito, riportando tutti i risultati e la procedura di collaudo al fine di consentire a terzi di riprodurre la stessa attività.

Come illustrato nei capitoli successivi, alla realizzazione di E-glove, è stata accompagnata quella di un'applicazione web di supporto che permette all'utente di visualizzare e controllare l'attività dell'E-

glove ed alla quale si può accedere da qualsiasi dispositivo, ovunque si trovi entro 100m dall'ausilio riabilitativo.

Includendo la descrizione di tutte le caratteristiche principali del dispositivo, più una serie di spunti interessanti per sviluppare ulteriormente la piattaforma lasciando spazio alla telemedicina ed alla riabilitazione "domestica", questa applicazione web rappresenta un'impronta visibile del rilevanza di questo lavoro e di quanto ancora resta ancora da ultimare.

Il lavoro si conclude con una serie di pareri e impressioni sul dispositivo espresse da medici, terapisti e ingegneri del reparto spinale dell'ospedale Niguarda di Milano e della Fondazione Don Gnocchi di Milano, raccolte a seguito di una serie di presentazioni dimostrative del dispositivo proposte al pubblico. I risultati ottenuti hanno confermato la bontà del lavoro svolto, riaffermando la volontà dei partecipanti a testare le proprietà del dispositivo in una prova clinica che coinvolga direttamente i pazienti stessi. In aggiunta, è stata riscontrata una buona impressione relativamente al dispositivo che ha ottenuto un punteggio di 4,5/5 nel test QUEST (Quebec User Evaluation of Satisfaction with Assistive Technology), un test pre-validato che permette un confronto con ausili riabilitativi alternativi già in uso nel settore.

La raccolta di opinioni e dubbi da parte di esperti e potenziali utenti è stata utile anche per raccogliere informazioni, critiche e spunti che potrebbero essere d’aiuto nella definizione delle future aree di sviluppo del dispositivo.

Oltre ad un possibile utilizzo nel campo della valutazione funzionale e della validazione delle scale cliniche, lo sviluppo di E-glove ha aperto interessanti prospettive anche per quanto riguarda il possibile sfruttamento dei dati in un sistema ad anello chiuso per l'ottimizzazione dei parametri di stimolazione elettrica funzionale (FES) in un ausilio preesistente e dedicato alla riabilitazione della mano neurologica.

In particolare, i valori di forza misurati potrebbero essere utilizzati per modulare i parametri di stimolazione (intensità, durata, ecc.) del dispositivo preesistente MeCFES (Myoelectrically Controlled Functional Electrical Stimulation), valutando l'interazione tra la mano e gli oggetti target, durante un azione di presa. Analizzando il segnale biologico raccolto, sarà possibile regolare la forza all'interfaccia mano-oggetto aumentando o diminuendo la stimolazione muscolare con l’obiettivo di dare al paziente la possibilità di ottenere una forza di presa costante risultante in un’azione funzionale e simil-fisiologica. Il raggiungimento di una forza di presa costante potrebbe, quindi, essere utile per consentire al paziente di spostare correttamente l'oggetto di riferimento.

Molti aspetti meritano di essere ulteriormente approfonditi e sviluppati partendo dall'hardware di e-glove che potrebbe essere miniaturizzato ed incluso in un *e-watch* o similare, passando dalla piattaforma di telemedicina e concludendo con alcuni test clinici da eseguire sui pazienti prima di poter rilasciare il dispositivo.

La strada è stata definita, ora è il momento di esplorare, creare e andare oltre i limiti cercando di realizzare un dispositivo che abbia un impatto reale sulle abitudini cliniche e sugli esiti riabilitativi.

SUMMARY

Hand dysfunctions could represent a severe obstacle to accomplish activities of daily living (ADL), like eating, cleaning, cooking, driving, working, dressing, bathing, etc. For people with upper limb impairment, these tasks may result particularly difficult, if not impossible.

According to the 7th edition of the Italian Guidelines on Cerebral Stroke (2012) of the Stroke Prevention and Educational Awareness Diffusion (SPREAD), stroke is the leading cause of upper-limb disability (1). In Italy, about 196,000 people experience a stroke episode every year and the number of subjects who have had a stroke and survived it, with more or less disabling outcomes, can be calculated as about 930,000.

After a cerebrovascular accident (CVA), it is estimated that about 20% of subjects do not recover the use of the upper limb and that most of the subjects (from 65 to 85%) undergo a partial recovery.

This number dramatically increases when considering that also Multiple Sclerosis (MS), Spinal Cord Injury (SCI), Rheumatoid Arthritis (RA) and traumatic accidents may lead to hand impairment.

After neurological insults, such as stroke, motor-sensory rehabilitation has revealed to be essential for motor control recovery. Specifically, sensory re-education is a currently-used technique in modern physiotherapy to retrain sensory pathways or stimulate unused pathways.

Task-oriented therapy can be combined with exercises in which the patient is manipulating different objects while identifying and evaluating the grasping performances. Both therapists and patients may determine performance parameters like grasp force and speed by timing execution of manipulating objects with different textures and weights.

However, the evaluation of patients' performance and progress is usually subjective because few adequate objective measures are available. Hand functionality assessment is mainly performed by using qualitative scales directly compiled by doctors and therapists.

This reduces the efficiency of measuring and keeping track of patients' signs of progress and evolution during the rehabilitation course.

Therefore, this project focuses on the needs of patients with neurological hand, trying to provide them and the therapists that support their rehabilitation process, a powerful tool to increase rehabilitation outputs.

In particular, the main aim of this project is the design, implementation and validation of a lightweight, wireless and wearable system, called E-glove, dedicated to monitoring the force exerted during a gripping action by a patient suffering from Multiple Sclerosis (MS), Spinal Cord Injury (SCI), Rheumatoid Arthritis (RA), but also post-stroke patients and individuals who have had hand surgery. The produced device should be capable of quantifying and sharing with clinicians the force values expressed by the patient, thus allowing objective monitoring of the rehabilitative outputs during the clinical course.

This thesis manuscript group all the information about the used materials, the realization process, the processed tests and the obtained results that have been performed in order to get the final prototype of the e-glove.

The final result of this project was the creation of a functional prototype based on ESP32, an electronic board integrating an IoT module compatible with Arduino, mounted on a glove whose fingertips, in positions that have been defined by the literature as those most involved in the gripping action, were sewn some force sensors specially made for the application. In addition, some LEDs, which allow an intuitive and real-time visualization of force values measured by the device, have been integrated.

To guarantee freedom of operation of the device and to reduce the possible influence over the physiological movements of the patient, E-glove has been equipped with a low-energy Bluetooth (BLE) 4.0 module and a Wi-Fi module that allow rapid, effective and wireless communication.

All the components have been tested to evaluate their performances, the influence of boundary conditions and to prove the reproducibility of the performed realization process reporting all the results and the testing procedure in order to allow thirds to reproduce the same activity.

As illustrated in the next chapters, the E-glove was accompanied by a support web application that allows the user to view and control the activity of the aid, which can be accessed from any device, wherever it is within 100m from the rehabilitation aid. Including the description of all the main features of this device, plus a series of interesting ideas from which to start in order to develop the platform further and giving space to telemedicine and "at home" rehabilitation, this web application represents a visible imprint of the relevance of this work and how much still needs to be done.

The work is concluded by a series of opinions and impressions on the device expressed by doctors, therapists and engineers of the Niguarda hospital's spinal unit in Milan and the Don Gnocchi Foundation in Milan, collected on a series of demonstration presentations of the proposed device to the clinicians. The obtained results confirmed the goodness of the work carried out, reaffirming the desire of the participants to test the properties of the device in a practical test that also involves the patients themselves. In addition, the E-glove has raised an excellent general impression receiving a score of 4.5 /5 in the QUEST test (Quebec User Evaluation of Satisfaction with Assistive Technology). This pre-validated test allows a comparison with alternative aids in the sector.

Collecting opinions and doubts from experts and potential users were also useful to gather information, criticisms and ideas that could be of considerable help in defining the future areas of development of the device.

In addition to a possible use in the field of functional evaluation and validation of clinical scales, the development of E-glove has opened interesting perspectives regarding the potential use of data in a closed-loop control system for the optimization of functional electrical stimulation (FES) parameters in a pre-existing aid dedicated to the rehabilitation of the neurological hand.

In particular, measured force values might be used to modulate the stimulation parameters (intensity, duration, etc.) by the pre-existing MeCFES (Myoelectrically Controlled Functional Electrical Stimulation) device, evaluating the interaction between the hand and the target objects during a grasping action. By analyzing the grip force exerted, it will be possible to adjust the force at the hand-object interface by increasing or decreasing muscle stimulation to give the patient the possibility of obtaining a constant force resulting in a functional and physiological-like grip dependent on the characteristics of the targeted object. Achieving a continuous gripping force will then allow the patient to move the reference object correctly.

However, there is a lot that deserves to be further explored and developed, starting from e-glove hardware that could be miniaturized and included in an e-watch or similar, passing from the telemedicine platform and concluding with some real testing on patients before releasing the device.

A possible way to revolutionize hand impairment treatment has been defined, now is time to explore, create and go beyond limits trying to realize a device with a real impact on clinical habits and rehabilitation results.

CHAPTER 1

INTRODUCTION

Accomplishing daily tasks, like eating, cleaning, cooking, driving, working, dressing, bathing, etc., require the use of hands. However, for those individuals who show upper limb impairment, these tasks may result particularly difficult, if not impossible.

According to the 7th edition of the Italian Guidelines on Cerebral Stroke (2012) of the Stroke Prevention and Educational Awareness Diffusion (SPREAD), stroke is the primary cause of upper limb disability (1) and the third leading cause of death in Italy after cardiovascular disease and neoplasms, causing 10% -12% of all deaths per year. In Italy, about 196,000 people experience a stroke episode every year and the number of subjects who have had a stroke and survived it, with more or less disabling outcomes, can be calculated as about 930,000.

This high stroke incidence, combined with an aging population, implies future increases in incidence, greatly strains national healthcare services and related costs.

After a cerebrovascular accident (CVA), it is estimated that about 20% of subjects do not recover the use of the upper limb and that most of the subjects (from 65 to 85%) undergo a partial recovery.

This number dramatically increases when considering that also Multiple Sclerosis (MS), Spinal Cord Injury (SCI), Rheumatoid Arthritis (RA) and traumatic accidents may lead to hand impairment.

Loss of functionality in the use of the upper limb is one of the main factors affecting disability, an independent predictor of life quality. The impairment in the upper limb is one of the first obstacles to the recovery of competence in managing ADL activities.

High-intensity and task-specific upper-limb treatment consisting of active, highly repetitive movements is one of the most effective arm and hand function restoration (2). After neurological insults, motor-sensory rehabilitation has been recognized as essential for the recovery of motor control. Specifically, sensory re-education is a technique that is used in modern physiotherapy while retraining sensory pathways or to stimulate unused pathways.

Task-oriented therapies, such as mirror therapy, tactile stimulation, robotic-assisted therapy or Virtual reality (VR), can be combined with exercises in which the patient is manipulating different objects while

identifying and evaluating grasping performances. Both therapists and patients may determine performance parameters like grasp force and speed by timing execution of manipulation of objects with different textures and weights.

1.1 Clinical problems to solve

However, the evaluation of patients' performance and progress is usually subjective because few adequate objective measures are available (3,4). Hand functionality assessment is mainly performed using qualitative scales directly compiled by doctors and therapists (5).

One example is the Action Research Arm Test (ARAT), a 19 item observational measure used by physical therapists and other health care professionals to assess upper extremity performance (coordination, dexterity and functioning) in stroke recovery, brain injury and multiple sclerosis populations (6). Hand recovery and grasp force are indirectly measured by lifting items requiring various hand grasp forces.

Despite the effectiveness of this method and the efficacy of the used clinical scales, these techniques are still limited. In particular, the absence of objective measurements of the biological parameters of interest could cause an error while reducing the efficiency of rehabilitation progresses monitoring.

Moreover, the existing monitor devices dedicated to the monitoring of the biological signals of interest are limited by a series of issues.

First, they usually require physical cables to connect to the data-reading device, limiting the freedom of movement of the patient and disturbing the way the task is performed.

On the other hand, their configuration has revealed to be incompatible with hand deformities observable in patients suffering from neurologic hand.

1.2 Project Aims

This project focuses on the needs of patients suffering from neurological hand trying to give them and the therapists that support their rehabilitation process an effective tool to obtain the best possible recovery.

The *main objective* of this project is the design, implementation and validation of a wearable system, denominated E-glove, dedicated to monitoring the force exerted during a gripping action by a neurological patient during rehabilitation.

The E-glove design work includes force sensor production, characterization and integration into the device, circuit design, e-glove design, but also the implementation of the communication architecture that provides for BT module setting, Wi-Fi structure creation and the implementation of the User interfaces. The final device was projected to be wearable, performing and connected, minimizing the impact on the patient's daily life. At the same time, by including Internet of Things (IoT) technology and wireless connectivity in the realization of this project, E-glove could represent a further step towards the possibility for patients to carry out the rehabilitation process even outside the clinic visit hours, directly at home, thus significantly increasing the chances of functional recovery.

The project has been developed in four main phases: the first part of the work has been dedicated to the identification of a force sensor able to measure the grasping force exerted by the subject.

Secondly, the work has focused on the production of a versatile system hardware, choosing which elements have to be embedded in the proposed solution in order to maximize its efficacy.

In addition to the projected device, E-glove has to integrate support software applications that allow reading and visualizing data while controlling device functionalities. These applications have to be readily available, possibly avoiding app download and installation processes to simplify the clinician's operations.

In the fourth phase, the projected device has been presented to clinicians and therapists to collect some of their opinions that could define the way for future developments of E-glove.

To conclude, the produced device has been designed to be used jointly with a system for MeCFES (Myoelectrically Controlled Functional Electrical Stimulation) in order to implement a closed-loop structure that could help to optimize stimulation parameters of the EMG based FES performed by the existing device. These adaptive mechanisms will be done automatically by the device integrating data coming from the stimulator and data coming from the patient's fingers that will be collected using noninvasive force sensors.

To summarize, the result of this work will be the realization of a complete, non-invasive, lightweight, wearable rehabilitation device that may help patients to recover part of the function lost by their hand.

The created tool will be useful, when used alone, to monitor rehabilitation progress. A further possibility is to integrate it with the MeCFES device to optimize stimulation parameters of the device.

1.3 Materials and methodology

As most of the project has developed during COVID-19 pandemic of 2020, the project has been designed and implemented in a domestic environment, without access to laboratory equipment. As this project inserts itself within a context of co-designing assistive technologies, methods and materials that could be easily replicated have been chosen. If this may represent a limit, on one side, as it has influenced the professionality of the final prototype and its aspect, it is also a useful feature when thinking that many people could build the same project on their own, contributing to that knowledge share that is essential in science and that could help this project growing more and more.

E-glove electronics has been developed using Arduino-based ESP32 board, commercially available Lilypad LEDs and handcrafted force sensors made of Velostat^{TM} and conductive fabric. Its firmware has been implemented via Arduino IDE, a free-to-use software and the web apps, accessible to both the patient and the clinician, has also been realized using HTML, CSS and JavaScript languages.

Here, all the information coming from the devices is received, elaborate, and shown. In the future, they will be stored and sent to the clinician itself.

The last step of the project has been the testing of the new device and its presentation to clinicians and therapists in order to prove the efficiency of the obtained prototype and to collect some genuine opinion from potential uses of the device. The first idea was to complete the work by testing the device on clinical subjects, but due to the arising pandemic events linked with Covid-19 spreading, this has not been possible.

1.4 Results in brief

A device named the E-glove has been realized to measure and display force values recorded at the fingers by the textile handcrafted force sensors. The E-glove aid is wearable, weights ~70g, thin (thickness <6mm) and collected data are streamed in real-time and they can easily accessed via web browser. The collected force values may be useful to a clinician for keeping track of patients' progress

during rehabilitation, giving him/her an objective overview of patients' ability to exert force during grasp action.

Data collected from doctors and therapists have confirmed the potential efficiency of the device, also revealing a series of interesting ideas about future developments of the aid.

This device has also been prepared for integration with MeCFES to optimize stimulation parameters of the currently existing tool and it could be controlled by the implemented web apps that could be accessed by any device.

Prospective development of the E-glove may include but not limited to: revision of the circuit design, miniaturization, integration into an e-watch or similar and optimization of the glove physical structure. In addition, the v2.0 of the device will include an IMU that could be useful to evaluate other aspects of hand movement such as tremor, mediolateral movements and anteroposterior accelerations.

Even the web app could be furtherly upgraded, including the telemedicine platform that could allow patients and clinicians to remain in contact even when performing the rehabilitation at home.

One significant advantage over similar systems is the possibility to upgrade the software over the air (OTA) and its use of cloud technology makes it suitable for automatic updates, programmed generation of progress reports, statistical processing, tele rehabilitation and monitoring of compliance, simplifying the release of future updates

1.5 Thesis Structure

Chapter 1 has been mainly dedicated to the *introduction* of the main topic of this study, including also a brief description of the main aims of this work. Chapter 2 will be entirely dedicated to the description of the existing *state of the art*, including a definition of the biological origins of upper limb impairment and the currently leading technologies to recovery a functional use of the hand after a neurological injury. The chapter is concluded by an introduction to E-glove.

In order to follow the development process of the wearable device, Chapters 3, 4 and 5 have been respectively dedicated to "Materials", "Methods" and "Results" of the project.

Chapter 3 contains a complete description of the *materials* used to realize, test and compare with a commercially available alternative the utilized force sensors. In addition, it also collects a description of the instruments that were necessary to realize the hardware and software components of the E-glove.

Chapter 4 contains a description of the *methodologies* used to design and realize the final version of the augmented proprioception glove.

Chapter 5 collects all the obtained *results* of this work, in an in-depth description of the features of the realized rehabilitation aid.

Finally, Chapter 6 has been dedicated to a critical *discussion* and *conclusion* about the obtained result, a definition of its limits and some purposes for further developments of the device.

CHAPTER 2

STATE OF THE ART

Arm and hand motor impairment are one of the most common consequences of disturbed neural command generation in the sensorimotor cortex in post-stroke patients.

A stroke, or cerebrovascular accident (CVA), causes partial destruction of cortical tissue and results in the disturbed generation and integration of neural commands, leading to a reduced or even absent ability to selectively activate muscle tissue, affecting motor task performances (7) and commonly ending with upper-limb dysfunctions.

The annual incidence rate of stroke in the Netherlands is approximately 250 per 100,000 and in the US has been calculated in 219.4 stroke patients per 100,000 inhabitants, with an average recurrence of a CVA episode every 40 seconds (8). In Italy, the yearly absolute incidence is around 196,000 people per year (1).

However, the percentage of people suffering a stroke is strongly related to age, and, in combination with an aging population, this means an increasing requirement of economic and human resources to be invested in this field.

After a stroke event, it is estimated that about 20% of subjects do not recover the upper limb's use and that most of the subjects (from 65 to 85%) undergo a partial recovery only.

The number of people suffering from upper-limb impairment dramatically increases when considering that also Multiple Sclerosis (MS), Spinal Cord Injury (SCI), Rheumatoid Arthritis (RA) and traumatic accidents may lead to hand dysfunctions.

Repetitive and task-specific upper-limb treatment consisting of active, high-intensity movements is one of the most effective arm and hand function restoration Task-oriented therapies, such as mirror therapy, tactile stimulation, FES-aided retraining, robotic-assisted therapy or Virtual reality (VR), can be combined with exercises in which the patient is manipulating different objects while identifying and evaluating grasping performances.

However, performances parameters such as grasp force and speed are usually subjectively evaluated by the clinician or measured using clinical scales.

The introduction of a wearable device, which could objectively monitor performance parameters such as patient's exerted force during grip, could increase the efficiency of the rehabilitation procedure, helping the therapist to keep track of patients' progress.

This introductive chapter will firstly present the biological and anatomical principles at the base of upper limb dysfunctions, introducing an in-depth description of cerebrovascular accidents and CSI.

Along with this definition, a comprehensive review of the most relevant existing rehabilitation alternatives will be introduced, focusing on those, which rely on functional electrical stimulation (FES).

Particular attention has been reserved to the precise definition of what does FES means, which are the most important features to take under control, how functional electrical stimulation produces muscle activity and which are the main characteristics of the device that could be coupled to the aid developed in this work: MeCFES.

The conclusive section has been reserved for the description of some existing force evaluating sensor types, which have been analyzed in order to identify the best suitable solution to integrate into this project.

2.1 Upper limb motor impairment

Accordingly to the International Classification of Functioning, Disability and Health model (ICF), physical impairments may be defined as "disability of body function that leads to a significant deviation or loss in neuromusculoskeletal and movement-related functions that may affect joint movements, muscle power and tone, but also involuntary movements" (9).

The impairments are a constantly changing phenomenon and as motor recovery goes on, the characteristics and nature of the impairments may change due to neural plasticity.

In particular, upper-limb impairment is usually a consequence of pathological events such as Stroke (CVA), Multiple Sclerosis (MS) (10), incomplete Spinal Cord Injury, Cerebral Palsy (CP), Traumatic Brain Injury (TBI) or other injuries of the central nervous system (11). However, it may also be caused by chronic diseases that may affect the final ability to correctly control hand movements, such as osteoarthritis (OA), rheumatoid arthritis (RA), but also diabetes (DMII) and systemic sclerosis (SSc) (12).

Due to the high occurrence of these events, with nearly 1 million cases/year in Europe and America combined (13–15), and the possibility to use Functional Electrical Stimulation (FES) to obtain better results during the functional rehabilitation, this work will mainly focus on the rehabilitation of patients suffering from Spinal Cord Injuries (SCI) and Stroke (CVA). However, the proposed solution might be suitable for other pathologies involving hand impairment.

Multiple impairments may be present simultaneously, making it challenging to decide what to treat first and which procedures to follow (16).

Due to the strong impact on personal independence (17) and its psychological implications, hand rehabilitation is highly prioritized among those patients presenting this kind of upper limb motor impairments, contributing to give this work a more significant relevance even on the practical point of view as it could be able to optimize the therapy increasing its efficiency.

Cerebrovascular accident

Cerebrovascular accident (CVA) or Stroke is defined by the WHO, World Health Organization, as a syndrome characterized by the sudden onset of focal or global neurological deficits (coma), lasting more than 24 hours, or with a lethal outcome, not attributable to any other apparent cause except for cerebral vasculopathy (18).

The Italian Ministry of Health distinguishes three types of stroke:

- *Ischemic stroke* occurs when the cerebral arteries are blocked by the gradual formation of an atherosclerotic plaque and/or a blood clot, which comes from the heart or another vascular area (thrombo-embolic stroke). About 80% of all strokes are ischemic.

- *Hemorrhagic stroke* occurs when a brain artery ruptures, thus causing non-traumatic intracerebral hemorrhage (this form represents 15-20% of all strokes) or characterized by the presence of blood in the subarachnoid space (this form accounts for about 3% of all strokes). Hypertension is almost always the cause of this severe form of stroke.

- *Transient ischemic attack or TIA* differs from ischemic stroke due to the shorter duration of the symptoms (less than 24 hours, although in most cases the TIA lasts a few minutes, from 5 to 30 minutes)

According to the 7th edition of the Italian Guidelines on Cerebral Stroke (2012) of the Stroke Prevention and Educational Awareness Diffusion (SPREAD), stroke is the third leading cause of death in Italy after cardiovascular disease and neoplasms, causing 10% -12% of all deaths per year, and is the leading cause of disability (1).

A stroke causes the destruction of brain tissue in areas that are subjected to blood deprivation. This can result in a variety of sensory, motor, cognitive and psychological symptoms, such as sensory loss, hemispatial neglect, aphasia, muscle weakness, spasticity, limited movement coordination, attention and memory deficits, depression and behavioral changes (2).

Concerning the motor domain, a stroke leads to damage of nerve pathways between the brain and the spinal cord and to reduced integration of sensory and motor information during motor planning in the brain. Such impaired conduction of nerve signals from the cortex's motor areas to the spinal cord limits selective activation of muscle tissue.

Concerning the upper extremity, impaired arm and hand functions may cause severe limitations in daily living activities for the majority of stroke patients. Directly after stroke, upper extremity weakness is the most common impairment, occurring in 77% of patients with a first-ever stroke (19).

After a stroke episode, spontaneous neurological recovery of motor function occurs, but the extent varies largely depending on individuals (2). This process of spontaneous neurological recovery can involve several short-term and long-term physiological mechanisms in the brain. One of the mechanisms underlying neurological recovery after stroke is enhancement of active brain tissue surrounding the actual damaged area. Shortly after the stroke, edema in the tissue surrounding the infarct is reduced (both intracellular and extracellular), the ischemic penumbra is resolved (i.e., reperfusion of the blood deprived brain area) and diaschisis (i.e., malfunction of remote brain areas due to lack of neural input) is diminished so that that related brain areas can regain their neural communication (2). A longer-term mechanism involved in neurological recovery is neural plasticity (20), meaning that brain activity and cortical representations of motor actions change during recovery. This cortical reorganization can occur in areas adjacent to and remote from the infarcted site. Processes involved in cortical reorganization can include activation of previously inactive neurons (i.e., unmasking of latent synapses), facilitation of alternative networks, and collateral sprouting (i.e., growth of new axons). These processes allow for the development of new paths for neural communication to circumvent those damaged by the stroke.

In particular, motor-sensory rehabilitation has been recognized as essential for the recovery of motor control. Sensory re-education is a technique that is used in modern physiotherapy while retraining sensory pathways or to stimulate unused pathways.

In order to facilitate this recovering process task-specific upper-limb treatment consisting of active, highly repetitive movements is one of the most effective approaches to arm and hand function (2) and natural feedback restoration (2).

Cervical spinal cord injury

Another possible clinical application field of the projected aid is the treatment of patients suffering from Spinal Cord Injury (SCI).

Injuries like traffic accidents or pathologies like cancer may lead to a lesion of the spinal cord. About 30% of spinal cord lesions are in the cervical region, the cervical section of the spine comprising seven vertebrae (C1 - C7) in the neck (21).

This damage may be derived from the lesion of ligaments, intervertebral discs, vertebrae or directly to the spinal cord itself and it may be divided into traumatic Spinal Cord Injuries and non-traumatic ones. A traumatic spinal cord injury may derive from a sudden blow to the spine that fractures, dislocates, crushes or compresses one or more of the vertebrae, but also by external objects (e.g. gunshot or knife) that eventually damage the spinal cord.

On the other hand, a non-traumatic spinal cord injury may be caused by different pathologies such as arthritis, cancer, infections or disk degeneration of the spine (22).

If damage in the cervical area occurs, it results in tetraplegia/quadriplegia, leading to a severe motor impairment of the upper limb, the loss of sensory functions and many associated complications. High cervical spinal cord injury is often fatal because it may cause the collapse of the circulatory and/or respiratory system, as their control centers are located in this section of the spine (23–25). As described in the image shown in the next page (Figure 1), most cervical spinal cord injuries fall into the segment of C4–C7. This kind of lesion causes the loss of proximal control inducing a severe impairment of the hand functions leading to the necessity of rehabilitation.

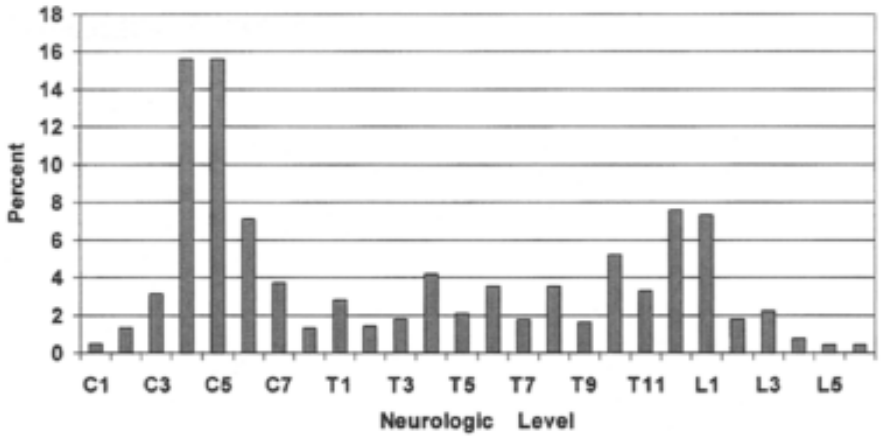


Figure 1: Distribution of neurological level of injury. – [12]

A scheme from the International standard classification for spinal cord injury (Figure 2) and an illustration about the biological correspondence between the neurological lesions and the consequently body district (Figure 3) have been reported in the following pages

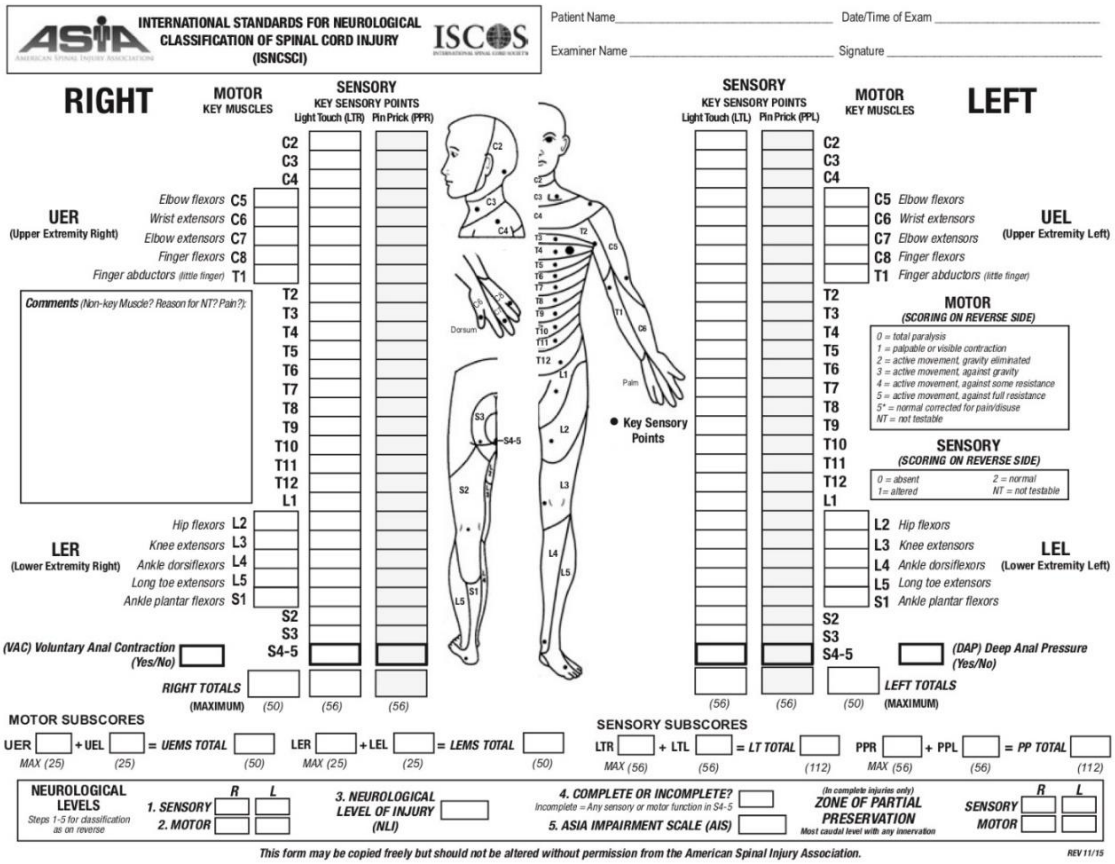


Figure 2: Official classification of spinal cord injury - [(27)]

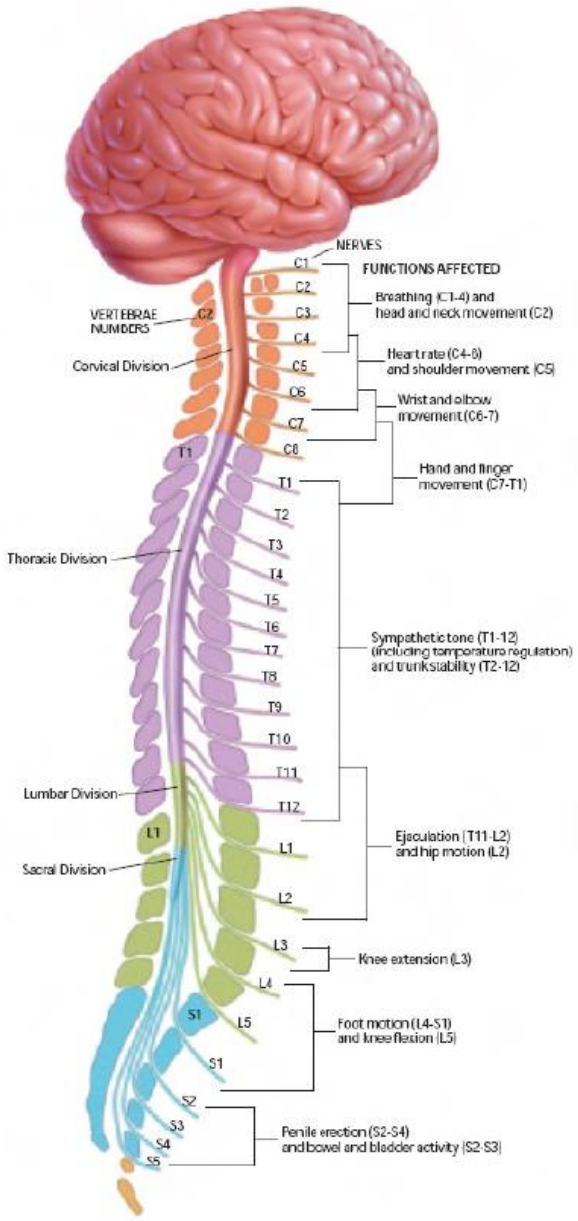


Figure 3: Spinal cord structure. – [13]

For these injuries, early after the damage, conservative management may promote the tenodesis grasp (29). The tenodesis grip is a grasping technique used by people with tetraplegia and others with innervated wrist extensor muscles, in particular extensor carpi radialis longus (ECRL), extensor carpi radialis brevis (ECRB), and extensor carpi ulnaris (ECU) (30), or denervated finger and thumb flexor muscles, known as Flexor Digitorum Profundus (FDP), Flexor Digitorum Superficialis (FDS) and Flexor Pollicis Longus (FPL) and innervated by Median Nerve, and Ulnar Nerve (31), to perform an efficient grasping task. The tenodesis grasp works as follows (Figure 4): the patient passively positions the fingers around the target object and then, when they are in the exact position, he/she actively extends the wrist to grasp the object. Wrist extension causes the fingers to flex and the thumb to approach the other fingers allowing the patient to hold the targeted item between the thumb and the index.

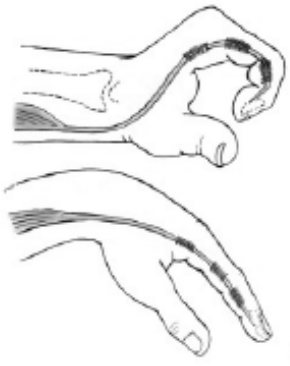


Figure 4: Tenodesis pattern. - [15]

However, the final effectiveness of the tenodesis in everyday life activities is strongly dependent on the resulting grasp force (29). To improve this force a wide variety of different approaches may be adopted. Firstly, reconstructive surgery may be performed, but also implanted functional electrical stimulation (FES) devices may help to increase the exerted grasp force (17). However, due to its invasiveness, but also to the difficulty of the surgical procedure, these techniques may be probably

replaced in the next years by a series of noninvasive, lightweight and wearable solutions that may give a significant improvement to the life of these patients, while reducing the drawbacks deriving from the previously cited alternatives. For rehabilitation purposes, any projected solution has to consider possible hand deformities or non-physiological acquired grasping techniques, demonstrating its versatility of use with any physiological alteration.

In particular, in chapter 2.5/2.7, some of the existing alternatives, based on robotics or FES, will be described starting from the surface stimulation device, MeCFES, to which this work is mainly directed. This type of equipment can be applied without invasiveness and safety issues and have demonstrated their validity as an assistive technology for daily use (33,34). However, they are still limited by some defects this project aims to solve.

2.2 Natural muscular contraction

As E-glove device will be dedicated to the measurement of the grasping force exerted by a patient, it might be important to have a brief overview of how skeletal muscle works, how they can express force and which are the main processes that are involved in muscle contraction.

The activity done by the wearable device is biologically achieved by the coupling of muscle spindles and Golgi tendon organs, those mechanoreceptors dedicated to monitor, respectively, muscle length and contraction speed and muscle exerted force (35).

Skeletal muscles are composed of a complex hierarchical structure made of multiple subparts, contributing to the global system's final work. A thin membrane, the epimysium, constituted by connective tissue, covers the muscle hiding different bundles of contractile cells, called *fascicles*.

As highlighted in the image reported below (Figure 5), each fascicle is enclosed into the second layer of connective tissue called *perimysium* and contains around 10-100 muscle fibers.

Each muscle fiber contains the contractile elements of the muscle, called *myofibrils*. These myofibrils are composed of different proteins (actin, myosin, tropomyosin, troponin, etc.) arranged into a repeated

sequence of a structure, called sarcomere. *Myosin* molecules, forming thick filament, have parallel tales, a neck and globular heads that bind with actin, thin filament.

Actin is a globular protein composed of two filaments forming a double helix structure. *Tropomyosin* and *troponin* (I, C or T) are responsible for the activation or the inactivation of the binding process that is responsible for muscle contraction. In fact, tropomyosin is, at rest, covering the binding sites on the actin filament. In contrast, troponin is a Ca^{2+} dependent protein that may alter its shape depending on the amount of calcium released in the environment surrounding the sarcomere, modifying the tropomyosin location.

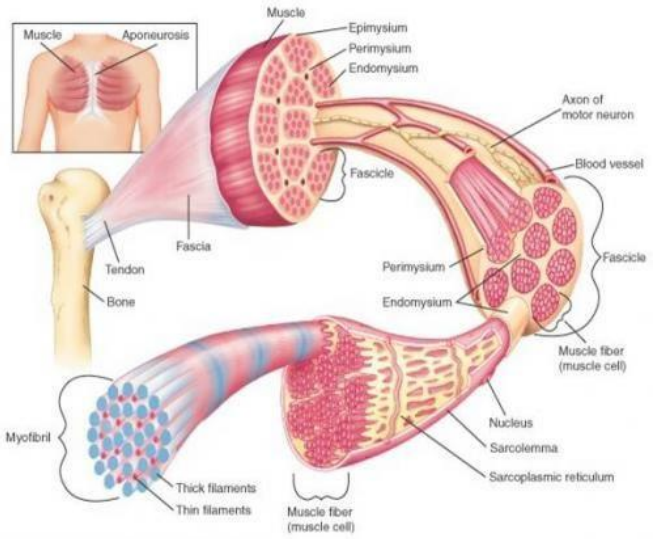


Figure 5: Muscle structure. - [(36)*]*

Despite its reduced dimensions, overall muscular contraction is caused by the sarcomere shortening, or better by the shortening of thousands of sarcomeres arranged in parallel and contracting following the *sliding filament theory*.

This adenosine triphosphate (ATP) dependent process caused the myosin heads to bind to the active sites of the actin and rotate about 45º in a process called “power stroke”, causing a relative movement

between the two filaments. This movement is not synchronized for all the heads: in every instant, about half of the heads are rotating so that there is a turnover and the shortening is continuous.

The mechanism, better described in Figure 6, is triggered by an arriving action potential from the motor plate, where the stimulus coming from the efferent moto neuron may start the contraction via synaptic input. The complex formed by muscle, moto neuron and its axon is called the *motor unit*.

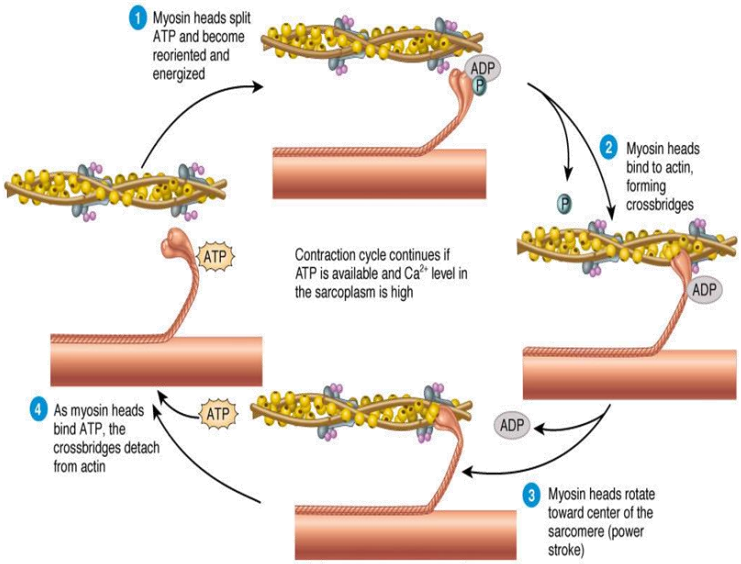


Figure 6: Sliding filament theory - [(37)*]*

When the action potential is transmitted from the moto neuron to the muscle membrane, a similar impulse is generated on the muscular fiber itself traveling from the endplate to the muscle's limits. If the induced depolarization is sufficiently high, this process may trigger a variation of the sarcoplasmic reticulum membrane permeability allowing the release of Ca^{2+} ions from the cisternae into the intracellular environment. Here, the released ions will bind to troponin C (TnC) causing a change in the protein that eventually led to a change in the location of tropomyosin, revealing the binding sites on the actin filament.

The contraction gradually stops because of an active ion pump, called SERCA, which is useful to bring Ca^{2+} ions inside the cisternae using ATP energy. When a low concentration of calcium ions in the sarcoplasm is reached again, the tropomyosin covers the binding sites on the actin filament and the contraction stops. This process has a determinant role in the fatigue phenomena that characterize the evolution of muscle activity.

Whenever one of these biological processes involved in muscle contraction is impaired, this may cause severe problems and limitations for the patient. For post-stroke and spinal cord injured individuals, alterations on the neuromuscular connection led to muscle-control impairment and inability to express muscle force. Therefore, one the possible solutions to these problems is represented by functional electrical stimulation (FES) working as an artificial substitute of neural control. This technique, coupled with task-specific, highly-repetitive exercises could help, for post-stroke individuals in particular, neural plasticity, increasing the clinical benefits of rehabilitation.

However, as demonstrated by researches (38) FES solutions are still limited by a variety of limits and a wearable device to monitor the output of the performed stimulation could be useful to quantify patient' performances, substituting or completing currently used clinical scales.

2.3 Function electrical stimulation

The E-glove indirectly measures muscle forces. A way of artificially control the force and a possible solution to upper limb motor impairment can be Functional electrical stimulation (FES).

When applied to the human body, electrical pulses applied can elicit action potentials. The stimulating electrode can generate an electric field in the area surrounding the application point that may perturb the resting potential of the neurons, typically around -65mV in the human body. If the depolarization reaches a critical threshold, an influx of sodium ions from the extracellular space to the intracellular space produces an action potential that propagates in both directions away from the point of stimulation.

Action potentials that propagate proximally in the efferent axons of a peripheral nerve will be annihilated at the cell body, whereas action potentials that move distally will be transmitted across the neuromuscular junction and cause muscle fibers contraction.

In general, large-diameter axons, which innervate the larger motor units, are more easily activated requiring less current than small axons.

FES applications over muscles essentially operate under the fundamental principle that electrical stimulation generally activates nerve terminations rather than muscle fibers. This is because the intensity threshold for direct excitation of muscle fibers is much greater than the threshold for producing action potentials in neurons, as shown on the next page.

Thus, for FES to be effective, the lower motor neurons have to be intact from the spinal cord's anterior horns to the neuromuscular junctions in the muscles. In addition, both the neuromuscular junction and muscle tissue must be healthy for electrical stimulation to work effectively.

This is why FES may be useful for spinal cord injury (SCI), stroke, head injuries, cerebral palsy, and multiple sclerosis, whereas it is not for muscular dystrophies or peripheral nerve injuries.

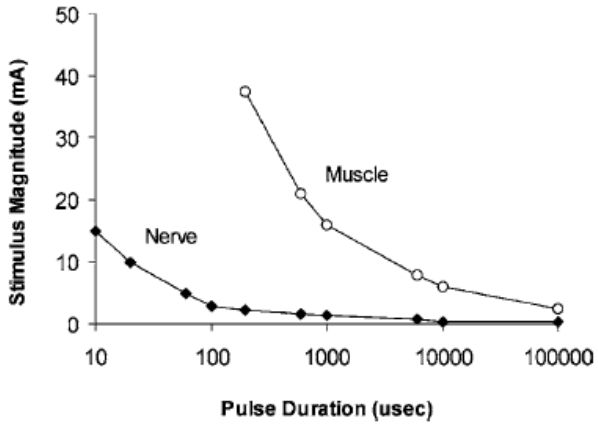


Figure 7: Strength-duration curve for nerve and muscle tissue. - [(39)*]*

To provoke electrical activation of the nerve at least two electrodes are required to produce a current flow. These electrodes are typically arranged in a monopolar or bipolar configuration with one electrode, generally referred to as the active electrode, placed near the peripheral nerve to be stimulated and the other one, named as reference electrode or return electrode, localized in different locations depending on the configurations.

The stimulus is given as a waveform of electrical current pulses, characterized by three parameters: *pulse frequency*, *amplitude*, and *duration*. By changing these parameters, it is possible to control the strength of muscle contraction.

Above a specific stimulation frequency, defined as the fusion frequency, the response becomes a smooth contraction. This process of summation of repeated stimuli within a brief period is known as temporal summation.

Typically, stimulus frequency rates of 12 to 15 Hz are the minimum required for temporal summation. Another way to increase muscle contraction strength is by increasing the number of motor units activated, a phenomenon known as spatial summation.

In order to perform this task, it is possible both to increase the stimulus pulse amplitude and pulse duration, which finally causes an increase of the effective electric charge injected.

Stimulus waveforms are generally either monophasic or biphasic in shape. A monophasic waveform consists of a repeating unidirectional (usually cathodic) pulse. Biphasic waveforms consist of a repeating current pulse with a cathodic (negative) phase followed by an anodic (positive) phase. The first, or primary, phase produces an action potential in nearby axons by injecting a quantity of electrical charge, and the secondary positive pulse balances the charge injection of the primary pulse. The purpose of the secondary pulse is to reverse the potentially damaging electrochemical processes that can occur at the electrode-tissue interface during the primary pulse, allowing neural stimulation without causing tissue damage.

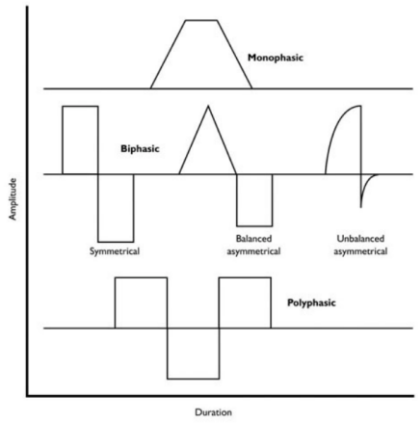


Figure 8: Typical stimulus waveforms. - [(40)*]*

One last important information to take into account is that, when using surface electrodes, the impedance at the electrode-skin interface might increase as the electrode dries or loses contact with the skin and this may eventually cause a severe reduction of the efficacy of the stimulation if it is controlled in tension, or skin lesions if it is handled in the current.

Functional electrical stimulation may be delivered toward superficial, percutaneous or implanted systems (39). This work will mainly focus on surface systems, also known as transcutaneous systems. These configurations utilize electrodes placed on the skin and connected toward flexible leads to a stimulus generator placed on the arm, waist, or leg. As we will see, the stimulation may be regulated using different sensors.

Electrodes must be placed over the nerves or, better, over the “motor points” of muscles to be activated. As seen, the motor point or motor plate is the stimulation site that produces the most vigorous and most isolated contraction of the muscle. On the contrary, of the other two methods, the main advantages of this technique are that this one is noninvasive and relatively technologically simple.

However, some of the problems that may derive from this kind of setting are electrode placement, difficulties in provoking the activation of a singular muscular group, painful sensations in sensate skin and the possibility to attract unwanted attention from other people if the device is particularly visible.

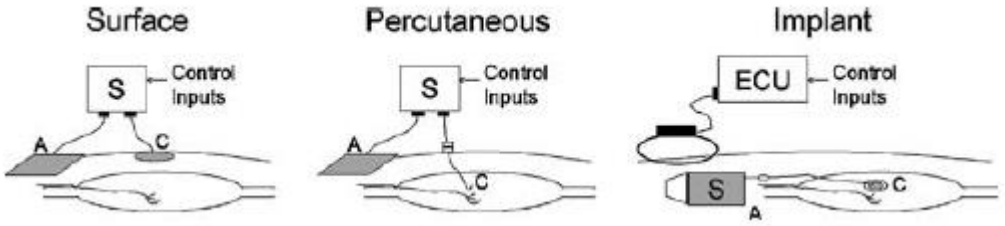


Figure 9: Neuroprosthetic system configurations [1]. - [(39)*]*

These are the main reasons why other configurations exist. In particular, percutaneous systems use intramuscular electrodes that pass through the skin and are implanted into the muscles to be activated, whereas implanted systems have both the electrodes and the stimulator implanted inside the human body. However, even if these configurations are more efficient in stimulating the exact muscular groups, even if small and profound, these kinds of implants are still quite invasive and the devices require a surgical operation to be implanted.

2.3.1 FES controllers

Decades of research and development of FES devices (41,42) have been responsible for creating a wide variety of different control systems with an associated diversity of effectiveness and complexity.

2.3.1.1 Open Loop controller

The simplest example of an FES controller is the *open-loop system*. This system is associated with an output that depends only on the user's action without any type of feedback instrument, except for patient visual control and perceptions.

[1] *S = stimulator, A = anode (reference electrode), C = cathode (active electrode), ECU = external control unit.*

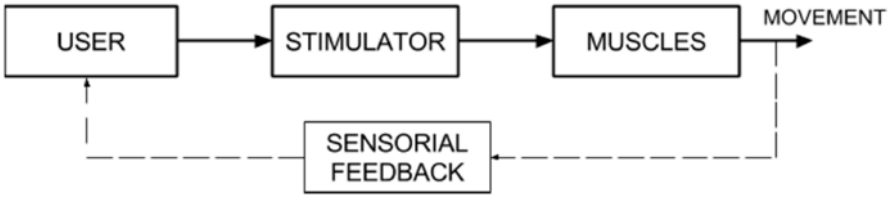


Figure 10: Open-Loop controller for FES. - [(43)*]*

The user entirely controls the resulting device via predefined stimulation patterns, but despite its simplicity, it does not allow any type of disturbances or unattended events compensation or adaptability to fatiguing muscles.

2.3.3.2 Closed Loop controller

On the other hand, *closed-loop systems* determine the stimulation pattern by continuously considering the error between the desired movement and the effective one. This action is usually performed using the *PID* (proportional-integral-derivative) *controller*, which is proportional to the current error, integrative with respect to the error history and derivative referring to error changes.

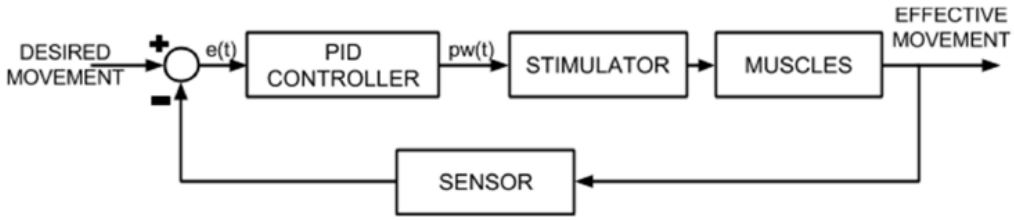


Figure 11: FES closed-loop controller example. - [(43)*]*

The following function describes the behavior of the PID controller:

$$pw(t) = K_p \cdot e(t) + K_d \cdot \frac{de(t)}{dt} + K_i \cdot \int e(t)\, dt$$

The evaluation and the computation of the parameters needed to use this non-linear system can be complicated, depending also on the kind of feedback variable adopted, making the PID controller used only in case of simple and slow movements.

For more complex movements, this type of controller needs an extended amount of time to adjust itself. A *feed-forward controller* based on the inverse model of the plant could be used to solve this issue, but this kind of system is usually complicated and highly approximate in the inverse modeling of the muscular behavior.

The *adaptive controller* may represent one possible solution to the problems of the previously seen controllers. In this case, an adaptive algorithm might be used to consider the changes in the external system parameters that can occur over time. The main drawback of this approach is represented by the fact that parameters are not fixed and the controller has to be continuously updated online.

Moreover, methods like *artificial neural network controllers* can be used (44). The main problem is to build a training set that can map muscle fatigue creating an effective and adaptable controller and reducing the fatigue problem.

2.3.3.3 FES controlled by afferent signals

Another way to control the FES is to use the signals from the peripheral receptors' afferent neurons (45). These signals can be used to trigger the FES activation, but to be detected they require an implantable system with special electrodes surrounding the nerve fibers. In the case of impaired hand, the signals, recorded with implanted electrodes from the tactile mechanoreceptors, can be used, for example, to control if there is slipping and to reinforce the hand grasp if needed automatically.

This approach may be particularly effective in SCI and tetraplegic patients, where the mechanoreceptors are not damaged, but the afferent signal cannot be transmitted to the central nervous system because of the injury. The main limitation of this technique is linked to the implant's invasiveness and the difficulties in controlling an implantable device. Moreover, the electrical noise affecting the signal during the collection and processing of the signal may reduce the effectiveness of the entire system.

2.3.3.4 EEG controlled stimulation

Another effective way to control FES uses brain signals to directly reproduce the same process that has been damaged from a spinal or a nerve injury. In particular, the EEG signal is collected, processed and used to trigger the activation of the stimulation system to allow the patient to directly control the action of the impaired structure by only training him/her mind to do it.

Recent researches have demonstrated that both alpha (8 - 12 Hz) and beta (13 - 30 Hz) waves may be used to trigger the movement by merely imagining voluntary activities (46). This EEG technique is particularly interesting because it is non-invasive, as the signal is acquired through electrodes outside the scalp, usually placed following the 10-20 standard configuration. However, other methods also exist to extract brain signals: an *invasive* way may be represented by the implantation of the recording electrodes inside the grey matter of the brain, whereas a *partially-invasive* alternative is represented by the implantation of the electrodes below the scalp, but outside the brain.

The higher the invasiveness, the better the recorded signal, but big invasiveness is also more critical from the surgical perspective and may cause severe damages for the patient

2.3.3.5 FES controlled by artificial sensors

FES may also be triggered and controlled by a wide variety of different artificial sensors trying to reproduce the biological sensing mechanisms that are present inside the muscle itself like muscle spindle and Golgi tendon organ (47).

First of all, *electrogoniometers* may be used to compare the reciprocal position of body segments in the space. In addition, recent researches have demonstrated the efficacy in the use of *inertial sensors*, like IMUs, in order to evaluate all the cinematic characteristics of the moving body component. Accelerometers, magnetometers and gyroscopes allow to tri-axially determine trajectory, acceleration, angular velocity and angle of body segments. These sensors are generally wearable, lightweight and small.

The last examples of artificial sensors used to control the work of an FES device are the *force sensors*. These sensors, which may be resistive or capacitive, are usually utilized in walking aid devices in order to monitor forces and pressures distribution under the feet. They are used to proportionally modulate FES stimulation depending on the force value measured by the sensors. With these sensors, the stimulation is activated and controlled by the sensors' values through the predefined threshold overcoming. This is the basic idea from which the E-glove-FES coupling has been projected.

2.3.3.6 EMG controlled stimulation

This technique uses the electromyographical (EMG) signal from an unimpaired muscular group to activate and control the functional electrical stimulation. This reference muscle may be located both in the activated group or in another one. If the interested muscle is not in the same group, there are two different possibilities: the reference muscle can be involved in the movement, or it can also be in another area, only needed for the activation of the stimulation.

Anyway, when an EMG signal from another muscular group is utilized, it reduces the noise coming from the electrical stimulation but obliges the patient to learn a specific movement to trigger and

modulate the stimulation. When the EMG signal belongs to the same muscular group, the controlling system does not require the patient to be trained, but some noise reduction systems have to be implemented to reduce the stimulation's disturbances. After the acquisition, the EMG is digitally processed to reduce the noise and then compared with predefined or manually settled thresholds defining the enabling condition for the stimulation.

The growth of this technique is mainly due to its versatility, non-invasiveness and simplicity of use. However, some drawbacks are linked to the definition of the stimulation pattern and the fixity of threshold that usually is not automatically adapted to different muscles or situations.

2.4 Introduction to the existing rehabilitation solutions

However, the main objective of upper extremity neuroprostheses or rehabilitation aids is to enable individuals with upper extremity dysfunctions to use their hands in activities of daily living (ADL), reducing the need to rely on assistance from others, the need for adaptive equipment, braces or other orthotic devices, and the time taken to perform tasks (48).

From the 1960s (42), when the first pioneering device integrating surface electrodes to open and close the hand has been accomplished, a lot has changed, leading to the introduction and testing of surface, percutaneous and implanted FES systems for hand grasp, but also the introduction of robotic gloves used to support and guide the grasping movement functionally.

Despite these significant improvements and some clinical results showing an overall good level of satisfaction by the patients and the clinicians (39), the sector is still interesting and many problems have yet to be solved.

Future developments in this sector may be directed toward the introduction of systems to quantify patient’ grasping performances, the designing of an automated systems that eliminate the need to start or stop processes manually, the expanded use of myoelectric control algorithms and the introduction of a

redundant system of control of the efficiency of the performed task to replicate at the best level what is done by the healthy body part (39,48).

The following paragraphs will be dedicated entirely to the description of the most interesting examples of these technologies, focusing on the ones that will be useful for this work.

2.5 FES-Based devices

2.5.1 MeCFES system

The MeCFES (Myoelectrically Controlled Functional Electrical Stimulation) is a device that uses the EMG control method applied to a surface neuroprosthesis.

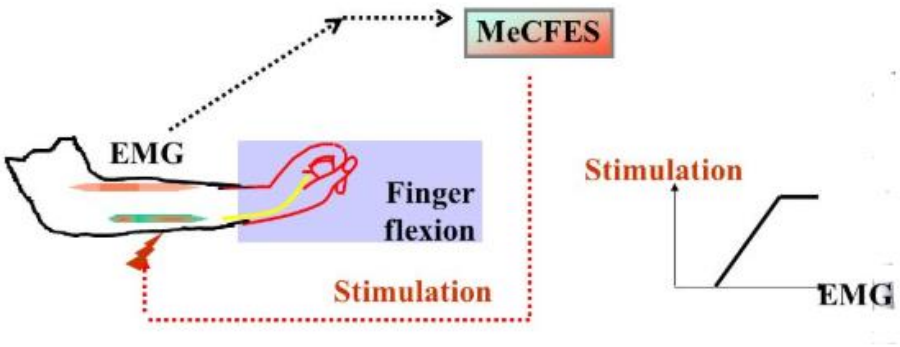


Figure 12: MyoElectrically Controlled FES (MeCFES) - [(49)*]*

The device is used for the rehabilitation of the hand, in particular for those subjects that had suffered a Cervical Spinal Cord Injury, but also for MS of post-stroke patients if the appropriate modifications are applied. One of the most interesting pros of the MeCFES system is the proportional EMG control. For this device, the muscle stimulation is proportionally activated by analyzing the EMG of the wrist extensors. Contrarily to the EMG based aids that are already present on the market, that use predefined

stimulation pathways, this device allows direct control over the stimulation parameters. This is very important as the patient may actively modulate and control the produced force so that he/she can adapt it to the different tasks and situations.

MeCFES takes advantage of the tenodesis function that has been described in the previous chapter. As seen, the extensor carpi radialis, that is the muscle directly involved in the extension of the wrist, when contracted causes the passive flexion of the fingers. This passive movement may be utilized to perform some tasks, but often the resulting grasp force is still not high enough to adequately perform them without any difficulties. MeCFES stimulation, triggered by wrist extension, could fill this gap leading to a grasp reinforcement.

However, one of the main problems associated with this kind of application are electrode placement and stimulation parameters optimization. There is a lot of muscle in the forearm controlling the hand movements and it can be challenging to choose the muscles to be recorded and stimulated. For example, wrist extension is managed by extensor carpi radialis longus (ECRL), extensor carpi radialis brevis (ECRB) and extensor carpi ulnaris (ECU), but only the ECRB provides a pure wrist extension. In contrast, the others are also linked to other hand movements.

The system is composed of two *surface electrodes* to acquire the EMG signal, two *surface stimulation electrodes* and the *electronic circuit* for signal acquisition, processing and sharing, but also for the stimulation waves generation.

The surface electrodes have been chosen in order to reduce the invasiveness of the device and the infection risk. Device parameters may be controlled and set by the mobile software that may be directly executed on a mobile phone or a tablet. The communication uses a Bluetooth module.

This device has two main advantages compared to the others: the EMG proportional control of the stimulation and the possibility to change and adapt the parameters through the software on the mobile device. These aspects result in smoother movements that help the subject to perform the needed tasks correctly.

2.5.2 Bionic Glove

Bionic Glove is a surface FES system, presented as one of the most important predecessors of MeCFES. Developed at the University of Alberta, the system consists of a fingerless glove with a forearm sleeve worn over three or four self-adhesive electrodes previously placed on the hand and forearm.

The stimulation is controlled with wrist movements, which are sensed by a displacement transducer on the wrist joint. Wrist extension beyond a certain angle triggers stimulation of grasp, and wrist flexion starts hand opening, thus enhancing the tenodesis grasp used by individuals with lower cervical SCI. The stimulation is essentially on or off, with an automatic ramping up and down. Because voluntary wrist extension is required, the system applies to patients with C6 level tetraplegia and lower.

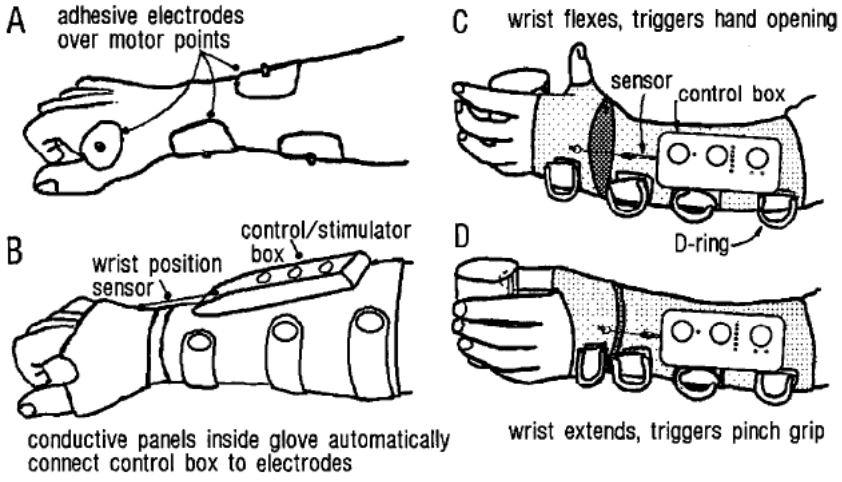


Figure 13: The Bionic glove[2]. – [(34)*]*

[2] *(A) Self-adhesive electrodes are placed over motor points of the muscles to be stimulated. (B) The glove is donned and tightened onto the electrodes, making electrical contact with them. (C) Voluntary flexion of the wrist to a preset trigger angle initiates stimulation of the muscles that open the hand. (D) Extending the wrist to another trigger angle directs stimulation to the muscles that produce grasp.*

Other drawbacks of this system are linked to donning and doffing the glove, achieving selective stimulation, and lack of sufficient wrist control for heavy objects. The Canadian company that was marketing the Bionic Glove is no longer active.

2.5.3 Fesia Grasp

The Fesia Grasp device is based on surface electrical stimulation of the forearm muscles to provide flexion and extension of the wrist and fingers. The main feature of this device is its multi-field electrode that allows better selectivity of movement and movements that are more natural.

Figure 14: Fesia-grasp. – [(11)*]*

The device consists of a stimulator, a multi-field electrode, a textile garment and a software application. The stimulator generates electrical pulses, which are transmitted to the skin through the multi-field electrode. It is a matrix electrode designed to cover both the posterior and lateral areas of the

forearm and thus stimulate the muscles of the flexion function and extension of the wrist and fingers. It consists of 32 cathodes (output fields) and eight anodes (return fields) that can be activated independently or combined, thus allowing adaptation to the different patient physiology. The multi-field electrode is personal and disposable, with an estimated life of two weeks of daily use. The textile garment ensures proper electrode-skin contact and, on the other hand, serves as a support for both the stimulator and electrode. Finally, Fesia Grasp has a software application that allows, on one hand, to control and configure the stimulation parameters and, on the other, to monitor the evolution of the different patients/users easily and intuitively.

The main positive aspects of this equipment are that the hand is free to move and the matrix of sensors allow to obtain a more precise stimulation over the exact targeted muscle, whereas one of the most significant drawbacks is the fact that stimulation is manually activated and performed following standard pathways.

2.5.4 Other examples

FESMate is a percutaneous system that is commercially available in Japan and uses up to 30 percutaneous electrodes. Stimulus patterns for several hand grasp and upper extremity motions are based on templates of natural muscle activation previously recorded from able-bodied subjects, which are customized with user-specific stimulus thresholds and maximums. Several different command sources have been implemented, including head switches, voice, sip and puff, and shoulder motion (39).

Freehand is an implanted system, developed at Case Western Reserve University (CWRU) and the Cleveland VA Medical Center, to provide lateral and palmar grasp to persons with C5 or C6 tetraplegia. It consists of a stimulator/ receiver implanted in the chest and eight epimysial or intramuscular electrodes implanted at the motor points of hand and forearm muscles. The movement of the shoulder is used to control the degree of hand opening and closing proportionally. A second-generation of Freehand system has been recently developed, including a system for the evaluation of the wrist movements via

implantable joint angle transducer, but also systems for the assessment of the EMG signal, usable to trigger muscle stimulation (50).

2.6 Robotic gloves

The robotic gloves represent an interesting alternative to the FES devices. This equipment can actively guide the hand during the grasping action.

These gloves may be classified into two main categories: the first one, and the older one in terms of the performed research, is the exoskeletal version of the gloves, whereas the soft gloves represent the more innovative ones.

Figure 15: MirrorHand device. – [(51)*]*

MirrorHand device (51) is a robotic exoskeleton projected to improve the outcomes of hand rehabilitation achieved for post-stroke patients by mechanically reproducing the action performed by the contralateral hand correctly.

Moreover, another interesting device is *SAFE* (52), which has been designed and realized by the Robotics and Mechatronics Lab of the Washington University and integrated a sensing feedback system to provide the best grasping force possible with respect to the performed task. In particular, this product uses a specific force sensor based on the finger's dimension variation as a feedback system for the evaluation of the force at the interface between the hand and the targeted object.

However, the main drawback of these devices is represented by their encumbrance and weight, as they fatigue patients' hands while attracting unwanted attention, with potential induced psychological consequences on the patient.

The use of soft gloves may solve this issue. These kinds of robotic gloves used pneumatic actuators in order to guide the finger flexion while reducing the overall impact of the glove in terms of encumbrance, weight and portability.

The most interesting example of this technology is represented by *Gloreha Sinfonia* (53,54), a pneumatic driven glove developed series of interactive task-oriented activities that may help to improve the neuroplasticity for patients with upper limb motor impairment. In this case, the movement pathways of the finger are predefined.

Another interesting example is represented by the *Wevolver Soft Robotic Glove* by Harvard Biodesign Laboratory (Figure 16). In this glove, the movement of the finger is manually activated toward a controlling device that may be held on the waist. The action is executed thanks to the presence of pneumatic actuators located on the upper part of the fingers.

Last example of these soft gloves is represented by the soft glove designed and realized by the University of Singapore that uses inflatable plastic actuators to perform the grasping task (55) while reducing the weight and the encumbrance of the device.

Figure 16:Wevolver Soft Robotic Glove –[(56)*]*

Summary of the existing rehabilitation solution

The following table summarizes the existing rehabilitation solution for hand rehabilitation, specifying pros and cons of each alternative.

TABLE I: SUMMARY OF THE EXISTING REHABILITATION SOLUTIONS.

Device Name	Working principle	Pros	Cons	Reference
MeCFES	FES	• EMG-controlled stimulation; • Direct control of the force via wrist extension.	• Correct electrodes placement; • Force stability control.	(32)

Bionic glove	FES	• EMG-controlled stimulation.	• ON/OFF stimulation; • Glove donning and doffing.	(22)
Fesia Grasp	FES	• Free-to-move hand; • Matrix of electrodes to provide precise stimulation	• Only predefined stimulation pattern; • Manually activated.	(3)
FESmate	FES	• Precise movements and challenging tasks;	• Invasivity	(25)
Freehand	FES	• Shoulder movement-guided stimulation;	• Invasivity	(33)
Mirrorhand device	Exoskeleton	• Active mechanical movement support; • High execrable forces.	• High visual/social impact;	(34)
SAFE	Exoskeleton	• Active mechanical support; • Force balanced on target characteristics.	• Size, encumbrance	(35)

Gloreha sinfonia	Soft exoskeleton	• Reduced encumbrance; • Active pneumatic support.	• Predefined finger movements.	(36,37)
Wevolver soft robotic glove	Soft exoskeleton	• Active movement support; • Reduced encumbrance.	• Manual activation and regulation.	(38)

2.7 Force evaluation sensors

Particular attention has been reserved to the identification of the best sensors to evaluate the gripping force monitored by the E-glove. Project constraints require it to be soft, small, flexible, lightweight and embedded inside a glove.

The first analyzed class of sensors has been *flexible force sensors*, commonly used for the creation of wearable devices where the measurement of the exerted force by a specific body district is required, for example, sensitized shoe insoles. The main drawbacks are the sensor's dimension, material rigidity and difficulty of integration within the E-glove.

Figure 17: Flexible force sensor. - [(57)*]*

Another type of force sensor is based upon the *conductive fabric* used to realize textile transducers. This approach guarantees flexibility cost reduction and efficiency if compared with the alternatives

Figure 18: Sensorized glove with fabric-made sensors. - [(58)*]*

As shown in image 18, this technique has been positively exploited to create sensorized gloves to evaluate the subject's tactile interactions (58).

Additional innovative alternatives have been investigated, starting from *smart tattoos*. Recent researches have demonstrated the possibility to design and realize wearable sensors directly printed on the skin of the patient (59–61) as shown in the image below.

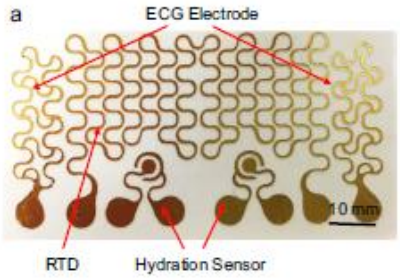


Figure 19: Skin printed sensors. - [(59)*]*

However, despite the innovation introduced by this technique and the non-invasiveness of this application method, the studies are only at their early-stages and the realized devices appear to be challenging and expensive relative to time, project design and required machinery to get an optimal result in terms of device' lifetime and performances.

Moreover, *conductive 3D-printed ink* has demonstrated its effectiveness as a possible inexpensive alternative to the previously analyzed methods (62). This material allows to directly printing the device on a suitable surface by using a hybrid 3D printing technique.

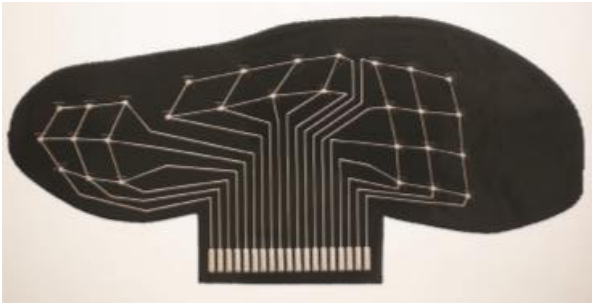


Figure 20: Conductive ink made pressure sensors. - [(63)*]*

Also in this case, the proposed technology is still under development and so are the tests on the conductive fluid. Biocompatibility has not been proven yet and a special 3D printer is needed to work with this material. In fact, the melting temperature of metal ions, which makes this material conductive, is known to be higher than the one of plastic polymers requiring a different printer to be used for the deposition and modeling of the sensor topography (64).

One last possible alternative is represented by *flexible microfluidic force sensors* (61,65,66). These sensors are built using knowledge coming from the microfluidic field and , due to their miniaturized dimensions and their reduced costs of fabrication, may represent the future of this field. Particularly interesting is the device that has been created by the wearable robotic laboratory of Harvard University, USA.

This microfluidic device can detect both the strain and the force applied to the sensor. The existing principal limit of this versatile device is linked with the fabrication process. The fabrication procedure of a microfluidic device requires a series of different machines, techniques such as replica and injection molding, embossing, and laser ablation and a dedicated “clean room” that are not always available in research laboratories. This is the main reason why these solutions are not diffuse yet.

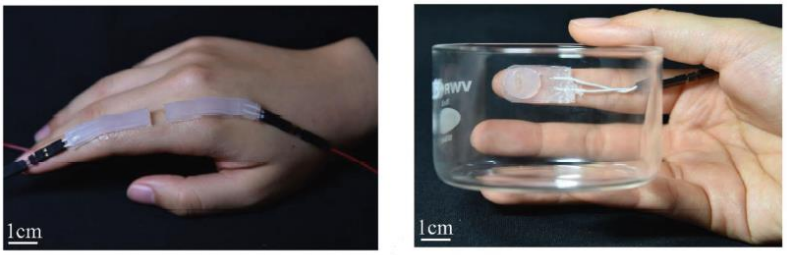


Figure 21: Soft microfluidic strain and force sensor. - [(65)*]*

Summary of the existing force evaluating sensors

Similarly to the current clinical solution, also in this case, it has been decided to dedicate a conclusive chapter to a comprehensive overview of the collected results about the existing force evaluating sensors suitable for wearable applications.

TABLE II: SUMMARY OF THE EXISTING FORCE EVALUATING SENSORS

Sensor name	Commercial availability	Pros	Cons	Reference
FSR (Force Sensitive Resistor)	Yes (5-10 €)	• Commercial availability; • Standardize and tested properties (reproducibility and predictable results);.	• Material rigidity; • Sensor size and influence on finger sensibility.	(40)

Textile force sensors	/	• Flexibility; • Integration inside fabric-based device; • Washable.	• Non-commercially available; • Results variability.	(41)
Smart tattoos	/	• No encumbrance (on-skin device); • Low psychological impact.	• Security for patients; • Non-commercial availability; • Durability.	(42,43,44)
Conductive ink force sensors	/ (ink 10€ -10ml)	• Fully integrated; • Reduced impact on hand movements.	• Early-stage studies; • Unknown biocompatibility properties; • Custom made 3D printers.	(45,46)
Flexible microfluidic force sensors	/	• Flexibility and reduced size; • Force and strain sensors;	• High-cost machinery; • Non-commercially available	(44,48,49)

2.8 The E-glove

The reviewed State of the Art has confirmed the clinical necessity of a rehabilitation aid dedicated to grasping force monitoring for patients suffering from neurologic hand.

Some common limits of the currently offered rehabilitation solutions have been identified (TABLE I). The main drawbacks of FES systems have been defined in electrode placement and in the absence of an autonomous system for force monitoring and stimulation parameters regulation.

On the other hand, mechanical exoskeletons have been demonstrated to be limited by their size, encumbrance and by the psychological drawbacks they can leave in patients.

Soft exoskeletons may represent a significant innovation in this field, but these technologies are still in progress, and lots of developments have to be made on finger motion control and automatic activation of the desired movements.

All these findings suggest that supervised task-specific activities have still to be considered as the Gold standard for successful hand rehabilitation. The E-glove could help to determine and monitor the evolution of performance parameters such as the exerted grasping force, in order to optimize the rehabilitation course, increasing its clinical efficacy.

E-glove device features directly arise from the existing alternatives on the market, trying to get the best out of each analyzed option. While developing this system, integration with the existing MeCFES device has been projected in order to solve its parameter optimization issue.

2.8.1 Force Sensors

After comparing all the existing alternatives (TABLE II), some specifically made textile force sensors, made of conductive fabric and force-sensible Velostat, have been handcrafted for this application. These transducers could guarantee a *small*, *lightweight*, *flexible*, *lasting* and *customizable* solution that could be directly integrated inside the realized glove, *minimizing the interference with finger movements*.

Commercially-available FSRs have been discarded because of their size and the rigidity of the plastic material they are made of, which could influence fingers' grip and patients' ability to grasp. Conductive ink, microfluidic and on-skin solutions have been discarded because they require expensive machines that were not available during project development, but they still represent interesting hints for the future upgrades of the device.

2.8.1.1 Realization

Leaving those sensors as a future possibility, fabric-made transducers have been produced.

These particular sensors are not commercially available, so it was decided to design and handcraft small, inexpensive, lightweight fabric force transducers made from cotton fabric, 3M Veloster layer and conductive medical-grade fabric chosen to avoid allergies while maintaining high biocompatibility.

All the information about realization instruments and methods has been directly derived from previous literature experiences (67–70) and have been selected because of material availability and test reproducibility.

2.8.1.2 Sewing on the E-glove

The produced sensors have been directly sewed to the glove. As all the different procedures described in this manuscript, also this one has been hand-made and personally carried out.

Four of the six realized sensors have been placed on the glove, as shown in Figure 22 in position s1, s2, s3 and s6. These positions have been chosen because they represent the points with the most significant involvement during the grasping procedure, according to various researches (71,72).

Studies demonstrate that thumb, index and middle finger are those with a greater influence and a greater involvement in a successful grasping task.

More precisely, the following positions have been identified as the most important:

- THUMB: the tip of the distal phalanx of the thumb and the distal thumb pad (s1);

- INDEX: the tip of the distal phalanx of the index finger, the distal index finger pad (s2) and the radial aspect of the distal phalanx of the index finger;
- MIDDLE FINGER: the tip of the distal phalanx of the middle finger, the distal pad of the middle finger (s3) and the radial aspect of the distal phalanx of the middle finger;
- ARCH: the arch between the thumb and the index (s6).

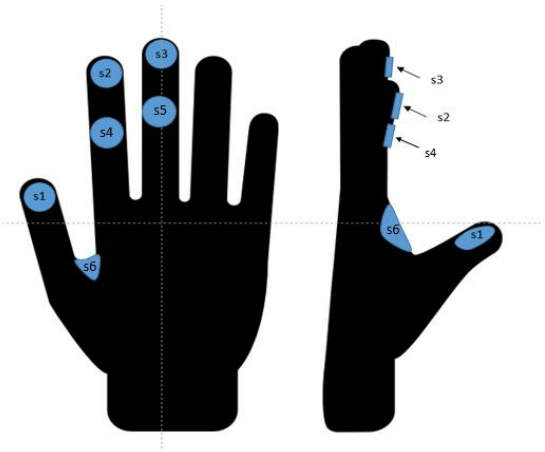


Figure 22: Scheme of sensors placement positions on the hand.

2.8.1.3 Testing

After concluding the design and sewing phases of the sensors, the next steps of the work have been dedicated to a testing session. The most critical sensors characteristics have been tested using a prototype setup built up with an ELEGOO UNO R3 board, a 100Ω resistor and one of the fabricated sensors in order to determine handcrafted sensors' performances, limits and reproducibility of the performed realization process. In particular, the following properties have been tested:

- LINEARITY AND CALIBRATION CURVE

  Linearity has been defined by the National Instrument (NI) as “an expression of the extent to which the actual measured curve of a sensor departs from the ideal linear curve” (73). In other words, the linearity expresses how directly proportional the value measured by a sensor is to the corresponding applied stimulus. Signal offset is not accounted when evaluating linearity and the sensor can still behave linearly even if there is an offset in the signal.

  To give a comprehensive characterization of the transducer, the fitting function of the Output Signal (OS)-weight (w) collected data points that describe the physical behavior of the tested system has been determined.

  In addition, the relation between the Output Signal (OS) and the applied stimulus (applied mass (w) or force) has been investigated. This test has been performed in order to verify the possibility of using a linear function to approximate the Resistance-Force relationship, as evidenced by literature (74). A rejection R^2 of 0.85 has been settled as a limit to refuse the proposed hypothesis.

  The obtained results could be particularly significant to facilitate a closed-loop control for the electrical stimulator. The sensors’ characteristics should be linear in order to simplify analog-to-force data conversion.

- HYSTERESIS

  Hysteresis has been defined by the National Instrument (NI) as “the measure of the sensor capability of following the changes of the input parameter regardless of which direction the change is made” (94). In words, it describes the dependence of the state on its history; it is often seen in materials having a “memory”. For force sensors with a visible hysteresis error, the transducer will not give the same reading for increasing force as for decreasing force.

  In particular, this test is relevant for force sensors because these transducers have been revealed to be particularly prone to hysteresis error (97–100), usually linked with the

physical/chemical characteristics of the materials they are made of. The main aim of this test is to verify the sensor's reading reproducibility and the ability to correctly evaluate force values independently from measurement history.

- SIGNAL DRIFT

  Signal time drift, also known as the loss of signal stability over time, could be defined as the low-frequency change in a signal with time. It is often associated with the electronic aging of components and tends to decrease with the age of a sensor as the parts mature. Sometimes this is expressed as guaranteed accuracy over a certain time.

  This feature has been tested as literature report several drift issues under high applied pressure (75).

  In order to evaluate the time dependency of the signal, continuous analysis of the output has been performed. An initial weight has been applied to the sensor and the Output signal has been evaluated every 30 seconds for a total of 990 seconds (around 16.5 minutes).

- RANGE AND SATURATION VALUE

  Another problem to solve was the risk of sensor saturation leading to the inability to distinguish between applied force stimuli above the sensor's limit. To evaluate the complete range of value measurable from the force sensors, the saturation threshold has been determined and compared with the needs of the rehabilitation aid.

- THERMAL STABILITY

  In order to complete the characterization of the handcrafted force sensors, their performances have been tested at different temperatures. In particular, by analyzing the thermal stability of the designed sensors, the independence between the measured output and the thermal condition of the environment surrounding the sensor itself could be assessed.

The glove would be used within a physiologically safe temperature range of 2 to 32 degrees Celsius. Therefore, five different conditions have been chosen to perform the test.

- 2 ºC has been considered as the lower bound of the evaluation scale (FSR sensors are evaluated between the industrial range of -40 ºC/85 ºC (76), but this has been the lowest reachable limit with the utilized materials).
- 18 ºC could be considered as the lower standard air temperature that could be recorded indoor (rehabilitation studio, or at home).
- 25 ºC is the standard ambient temperature of the air, defined at Standard Temperature and Pressure condition (STP) by the scientific community (77) and it could be used as a reference.
- 28 ºC has been chosen, as it could be an intermediate air temperature between the standard and the body temperature, considered as the upper limit of this test.
- 32 ºC is closed to the surface temperature of the skin of an adult human being.

Due to the experimental conditions, some of the obtained results might find no direct application in the daily rehabilitation activities that are mainly carried out inside, whereas they could be extremely relevant in the future if the glove will be used in a different application or as an everyday tool used to monitor hand activities and performances.

- SENSORS MEASUREMENTS' REPEATABILITY

The last analyzed property has been sensor reproducibility. This property is particularly critical for these transducers because they are handcrafted, thus a certain level of inter-sensors variability must be taken into consideration. In the performed analysis, all the sensor's performances have been recorded with the same conditions (same applied weight, same temperature, etc.) to highlight any major difference from the average behavior.

2.8.1.4 Comparison with commercially available FSR

To complete the analysis, the identified properties of the hand-made force sensors have been compared with an existing, commercially available, alternative: FSR 402 by Interlink electronics.

FSR 402 is a force-sensitive transducer, part of the Force Sensing Resistors™ family, specifically built to detect human touch and just applied in several wearable technologies such as sensorized shoe insoles (78). It is relevant to remind that this solution has been discarded because of its size and rigidity, to minimize the impact on natural patient movements.

Feature	Condition	Value*	Notes
Actuation Force		0.1 Newtons	
Force Sensitivity Range		0.1 - 10.0[2] Newtons	
Force Repeatability[3]	(Single part)	± 2%	
Force Resolution[3]		continuous	
Force Repeatability[3]	(Part to Part)	±6%	
Non-Actuated Resistance		10M W	
Size		18.28mm diameter	
Thickness Range		0.2 - 1.25 mm	
Stand-Off Resistance		>10M ohms	Unloaded, unbent
Switch Travel	(Typical)	0.05 mm	Depends on design
Hysteresis[3]		+10%	$(R_{F+} - R_{F-})/R_{F+}$
Device Rise Time		<3 microseconds	measured w/steel ball
Long Term Drift		<5% per $\log_{10}$(time)	35 days test, 1kg load
Temp Operating Range	(Recommended)	-30 - +70 °C	
Number of Actuations	(Life time)	10 Million tested	Without failure

Figure 23: FSR 402 Datasheet.

Figure 23 shows the main characteristics of FSR 402, reported in its official datasheet (78). In order to compare the FSR properties with one of the textile force sensors, FSR properties have been furtherly tested at the same conditions presented in the preceding chapters for the hand-made sensors.

This analysis aimed to test the two transducers at the same working condition to compare the obtained results.

2.8.2 Hardware

2.8.2.1 Prototypal version of E-glove

A first, prototypal version of the E-glove has been created. The main aim of this phase has been to realize a support hardware architecture able to read, elaborate and share force signals read by the analog sensors while minimizing the size and the weight of the obtained electronics board. In addition, a wireless architecture has been created by integrating the HM-10 Bluetooth (BT) module in the used ELEGOO R3 board and creating a web application to visualize the collected data.

2.8.2.1 Final version of E-glove

After completing and testing the prototypal version of the E-glove, an additional improvement of the hardware characteristics has been implemented to guarantee upgraded features and prepare the device for clinical applications. Firstly, the *glove shape* has been modified. Patients suffering from neurologic hand usually show rigidity or reduced motility of fingers. Therefore, it could result difficult for them to wear a classic glove like the one used for the prototype. On the other hand, the ELEGOO board and HM-10 module dimensions could be cumbersome and they could reduce patient freedom because of their weight. Thus, a *lightweight* and *smaller* ESP32 board integrating a BLE module has been used.

In addition, the LEDs have been moved from the board to the corresponding position on the glove to make more *visible* the correlation between the recorded force and the LED brightness.

To conclude, the prototypal version of the E-glove required Internet access in order to read the recorded signal from the sensors itself. This feature could be a limit whenever internet access is not suitable or if the connection is not stable or fast enough.

The newly implemented version of the glove has been designed to guarantee the *full availability of the measurements even without internet availability.* An additional *protective case* has been created to keep the hardware safe and allocate the needed batteries.

2.8.3 Software

2.8.3.1 Board software

The software code for the board has been written in order to control data acquisition, filtering, manipulation, formatting and sharing.

Developed code has been built to include the following essential features:

- The first section has to focus on DATA ACQUISITION and it has been performed by programming analog ports to read and convert to digital the analog voltage value measured by the textile force;
- In addition, a system for SIGNAL FILTERING and OFFSET COMPENSATION must be implemented;
- Moreover, a DATA MANIPULATION code is needed to convert the digital output from the ADC into a meaningful force value;
- The four LEDs have to be programmed in order to tune their light brightness with respect to the applied force on the corresponding textile force sensor.
- The board has to be programmed in order to CREATE A CUSTOM BLE service including a custom characteristic, used to share force values measured by the force sensors and pre-

processed to reduce noise and to obtain a formatting scheme compatible with BT communication;

- In conclusion, the ESP32 board has to be configured in soft Access Point (soft-AP) mode to make a personal Wi-Fi access point accessible from up to four devices at the same time. An additional web page where the collected data could be shown has to be created and uploaded on the board. Its compatibility with the most significant web browser (Chrome, Edge, Firefox, Safari, Opera, etc.) has been tested to assure therapists full availability of data.

2.8.3.2 Desktop GUI

A desktop GUI has been created to visualize data coming from the E-glove. The purpose of the GUI (Graphical User Interface) is to provide a simple, user-friendly interface collecting all the main information that may be significant when using the E-glove. The developed interface has been implemented via Processing Software following modern UX/UI (User eXperience/Interface) guidelines (79–82) and it has also been replicated in the web application for e-glove control.

2.8.3.3 Web application

Thanks to the BT connection provided to the e-glove and described in the figure below (Figure 24), both MeCFES and the E-glove could communicate with the preferable third device, computer/tablet/smartphone, without requiring a cabled connection.

The main reason behind the idea of building up a web application has been the necessity to define an easily-accessible, efficient, interactive, user-friendly interface between the devices and the therapist or the patient him/herself without the need to download and install a mobile/desktop app. These constraints directly arise from the acquired experience with the MeCFES device, which has had several issues with mobile app compatibility and the necessity of constant offline updates.

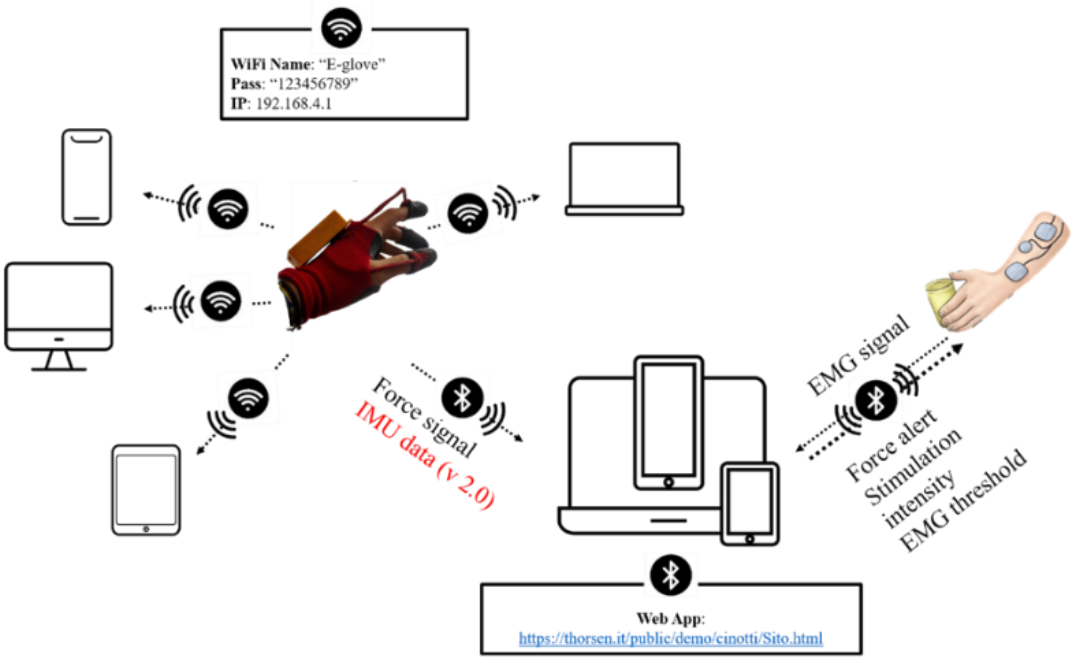


Figure 24: System communication architecture.

2.8.4 Clinical applicability

In order to test the potential interest of doctors, therapists and engineers in the designed device, some opinions, critics and ideas about the clinical applicability of the obtained device and possible way to upgrade the obtained features have been collected. This section has been first thought of as a possibility to make the patients trying the obtained device, completing a clinical validation of the tool.

Unfortunately, data collection from actual patients was not allowed and the only impression from the just cited professionals will be reported in the results.

Therefore, after concluding the E-glove design, setup and testing, it has been purposed to clinicians and engineers by organizing a presentation (83) (https://my.visme.co/projects/010q9041-e-glove-2#s1)

of the main features and characteristics of the device, asking the public to fill a form (84) collecting a series of answers that could be useful to investigate clinical applicability of the device.

When creating the questionnaire, a just validated section called “QUEST” (Quebec User Evaluation of Satisfaction with Assistive Technology) (85) that is used in clinical application to judge rehabilitation aid performances in terms of aid’ size, weight, durability, comfort, efficiency, simplicity of usage and stability has been integrated. These properties are evaluated on a scale from 0 to 5, where 0 represents dissatisfaction and 5 express satisfaction.

This choice has been taken to simulate a protocol that has just been used by the therapists themselves, helping to compare E-glove with some existing alternatives.

CHAPTER 3

MATERIALS

E-glove production has started from the choice of the right materials and instruments to realize the electronic aid. The first two sections are entitled to *"Force sensors"*, containing an in-depth explanation of the materials used of force sensors' realization, sewing, testing and comparison with commercially-available alternatives, and *"Hardware"*, including a complete definition of E-glove hardware characteristics and necessary instruments to replicate the same process. The last two chapters are dedicated to *"Software"*, describing the utilized software to build the app architecture and *"Clinical applicability"*, grouping all the technical information about the collected questionnaires from doctors, therapists and engineers.

3.1 Force sensors

3.1.1 Realization

To realize the stretchy fabric-made force sensors, the reported materials have been used.

- *Cotton jersey;*
- *Stretch conductive fabric by Holland shielding systems;*
- *Vinyl glue by Vinavil;*
- *Velostat by 3M;*
- *Paper;*
- *Conductive wires and scissor;*
- *Caliber (Range: 0-150mm, Sens:0,02mm).*

These materials have been chosen to build an easily replicable, thermally stable, flexible sensor using materials that are commercially available and requiring a designing, realization and testing time compatible with thesis timespan.

Stretch conductive fabric by Holland shielding systems

This stretch conductive fabric (86) is covered with a medical-grade silver coating that makes it a conductive material. Its properties are suitable for the realization of the E-glove. Thickness is equal to 0.4 mm, electrical properties are stable from -30ºC to 90vC, and the material is flexible. It could be stretched in both directions reaching up to 100% more of its original dimensions. In particular, it reaches up to two times its actual length on fibers direction (*Lengthwise stretch*) and up to 1.6 times its width orthogonally to fibers direction (*Crosswise stretch*).

Due to its electrical properties, this fabric can be used for electrode contact clothing, sensors building clothing, or other wearable applications. Moreover, the material's conductivity increases up to 25% as it stretches, which is convenient for smart textile applications, but it could be inconvenient for the E-glove design as signal changes may also be linked to sensor stretch. The silver coating is 99,9% pure

TABLE III: STRETCH CONDUCTIVE FABRIC SPECIFICATIONS - [(87)*]*

Property	***Test value***
Thickness	0.40 mm
Temperature range	-30 to 90ºC
Lengthwise stretch	~100% x length
Crosswise stretch	~60% x width
Surface resistivity	< 0.5 Ohm/sq. (unstretched)

Vinyl glue by Vinavil

Polyvinyl acetate is an adhesive commonly used for wood, paper, canvas and porous materials (88).

It is a dispersion of water-based polyvinyl acetate resins and it has the appearance of a milky white liquid. It is an electrically insulating material with low electrical conductivity (10^{-7} -10^{-5} to 0.239-1.623 $S.cm^{-1}$) (89).

Velostat by 3M

Velostat, also known as Linqstat, is polymeric material impregnated with carbon black to make it electrically conductive. This material is commonly used for the protection of devices that are susceptible to damage from electrostatic discharge. It was firstly developed by Custom Materials, now part of 3M. In 2015, it was acquired as a U.S. registered trademark by Desco Industries Inc (90).

Due to its properties of changing its resistance with either flexing or pressure, it has just been used in several experimental applications in order to realize inexpensive sensors for microcontroller experiments. Since the circuit's resistance is reduced when pressure is applied, this reading can indicate when weight is applied or removed. For instance, it has been used to realize a matrix of sensors for foot insoles to evaluate pathological alterations during walking tasks (91), but also to create tactile sensors for the electronic skin of robots (92) and gait-analysis applications (93).

3.1.2 Sewing on the e-glove

To sew the created sensors on the prototypal glove, the following materials have been used:

- *Elastic glove (13 gauge polyester);*
- *Sewing thread (4 different colors);*
- *Sewing needle;*

- 4 Textile handcrafted force sensors (only four textile sensors have been implemented for this study corresponding to the position, for each finger, with the highest involvement in the gripping action).

3.1.3 Testing

In order to test the main characteristics of the sensors, the following instruments have been employed.

- *ELEGOO R3 Board ATmega328P ATMEGA16U2 microcontroller;*
- *Stopwatch (Range: 0.00-86400.00s Sens: 0.01s);*
- *100Ω resistor;*
- *Wires and Breadboard;*
- *1 Textile handcrafted force sensor;*
- *Weighting scale Tefal BC5004 Optiss (Range: 0-5000g Sens: 1g);*
- *Scale (Range: 0-200kg Sens: 0,1kg);*
- *Arduino IDE;*
- *Microsoft Excel/OriginLab;*
- *Lilypad temperature sensor (Range: -40-125ºC Sens: 0,1ºC);*
- *Different heat sources (ice block, warm water bottle, air-conditioned room).*

ELEGOO R3 Board ATmega328P ATMEGA16U2 microcontroller

The ELEGOO R3 BOARD is a commercially sold microcontroller mounting an ATMega16U2 chip. This product directly derives from Arduino UNO and may be directly programmed using Arduino IDE software.

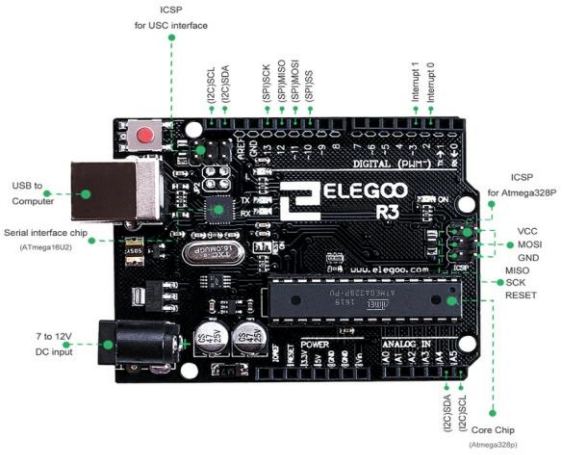


Figure 25: ELEGOO R3 Board ATmega328P scheme.

Main features (94)

- ATmega328P microcontroller
- Input voltage between 7-12V
- 5V Electric current: 500MA
- 3.3V Electric current: 50MA
- 14 Digital I/O Pins (6 PWM outputs)
- 6 Analog Inputs
- 32k Flash Memory
- 16 MHz Clock Speed

Lilypad temperature sensor

The MCP9700 is a small, washable, thermistor temperature sensor. This sensor will output 0.5V at 0 degrees C, 0.75V at 25 C, and 10mV per Celsius degree (95).

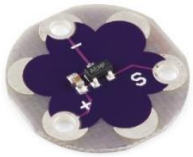


Figure 26: Lilypad temperature sensor

Lilypad temperature sensor could be employed to detect local ambient temperature, but also the temperature of the body is in contact with. LilyPad is a wearable e-textile technology developed by Leah Buechley and SparkFun creatively designed to have large connecting pads to allow them to be sewn into clothing.

Arduino IDE

For the board firmware, the free-to-use Arduino Software (IDE) has been used. This software has been built explicitly for Arduino electronic boards, making it easier to write code and upload it to the board.

It runs on Windows, Mac OS X, and Linux. The environment is based on Processing and other open-source software; thus, it is also compatible with GUI-design software (96). The programming language used for Arduino is the C / C ++.

OriginLab

OriginLab is a proprietary computer program for interactive scientific graphing and data analysis. It is produced by OriginLab Corporation and runs on Microsoft Windows. Data analyses in Origin include statistics, signal processing, curve fitting and peak analysis. Origin's curve fitting is performed by a nonlinear least-squares fitter, which is based on the Levenberg–Marquardt algorithm (97), also known as the damped least-squares (DLS).

3.1.4 Comparison with commercially available FSR

The same materials of the tests performed with textile-made sensors have also been utilized for these analyses. The only difference was that the handcrafted force sensors had been substituted by a commercially available FSR 402 by Interlink.

3.2 Hardware

3.2.1 Prototypal version of the E-glove

To realize the hardware of the prototypal version of the e-glove, the following materials have been used:

- *ELEGOO R3 Board ATmega328P ATMEGA16U2 microcontroller;*
- *8 x 100Ω resistors;*
- *Wires;*
- *4 x LEDs (Green, Yellow, Blue and Red);*
- *HM-10 Bluetooth module (BLE 4.1);*
- *Glove with 4 x Textile handcrafted force sensors;*
- *Elegoo Double Sided PCB Board Prototype kit;*
- *Soldering kit with soldering iron;*
- *Multimeter;*
- *9V battery with an ELEGOO board connector.*

HM-10 Bluetooth module (BLE 4.1)

The HM-10 is a readily available, less than 10€ expensive, high-performance BT 4.0 module commonly used to establish robust communication between devices (98). The module is designed using the CC2540 Bluetooth low energy (BLE) system on a chip by Texas Instruments and might work both as a master or slave in direct communication between different electronics boards. It is programmable and all its features such as working mode, name and transmission speed might be straightforward tuned via AT commands or using the official software.

Figure 27: HM-10 BT module

3.2.2 Final version of the E-glove

To produce the final version of the rehabilitation aid, the following materials were necessary:

- *ESP32 NodeMCU Wi-Fi microcontroller by AZ-Delivery;*
- *4 x 100Ω resistor;*
- *4 x Lilypad LEDs;*
- *Glove with 4 x Textile handcrafted force sensors;*
- *Elegoo Double Sided PCB Board Prototype kit;*
- *Soldering kit with soldering iron;*
- *Multimeter;*

- *Ultimaker 5 3D printer (0.4mm nozzle and PLA filament).*

ESP32 NodeMCU Wi-Fi microcontroller by AZ-Delivery

Figure 28: ESP32 NodeMCU WiFI

The ESP32 board is readily available, less than 10€, high-performance microcontroller integrating both BLE 4.0 and Wi-Fi modules that could be used to establish robust communication between devices (99). The ESP32 NodeMCU Wi-Fi Development Board with CP2102 is a Dev Kit C designed by Espressif to facilitate the programming of the new ESP32 Dual-Core processor. The WLAN (Wireless Local Area Network) functionality is implemented directly in the SoC with the additional Bluetooth Low Energy function (BLE). The ESP32 processor combines a two core Tensilica LX6 CPU on a single microcontroller chip, clocked up to 240 MHz, and 512 kilobytes SRAM.

The 32 pins provide UART, I2C, SPI, DAC, ADC (12 bit), and all GPIO pins can be used as input or output.

3.3 Software

3.3.1 Board software

The board software controlling data acquisition, filtering, processing and sharing via Wi-Fi and BLE has been implemented using Arduino IDE, compatible with the ELEGOO board and ESP32 IoT module used to produce the final version of the e-glove.

To conclude, the compatibility of the Wi-Fi app integrated into the software has been tested with Chrome, Opera, Edge, Firefox, Safari and Huawei web browsers in their latest available version.

3.3.2 Desktop GUI

The desktop GUI (Graphical User Interface) has been implemented using *Processing* software (100).

This open-source and free-to-use solution has been chosen because it is commonly employed to implement user interfaces (UI), rich in graphical libraries and time effective with respect to the other alternatives. Besides, it is compatible with Arduino, simplifying data sharing between the two platforms.

Processing.org software

Processing® has been firstly implemented by Ben Fry and Casey Reas in the spring of 2001 and has promoted software literacy, particularly within the visual arts and visual literacy within technology. It has been initially created as a software sketchbook to teach programming fundamentals within a visual context, but it has quickly evolved into a development tool for professionals like Google, Intel, General Electric, Nokia, and Yahoo. The Processing software is free and open-source and runs on the Mac, Windows, and GNU/Linux platforms.

The software is distributed today in various forms, including Processing (Java), p5.js (JavaScript), Processing.py (Python) and a recent Android version (58).

3.3.3 Web application

Web app structure has been articulated into five main pages and it has been implemented using HTML 5, CSS and JavaScript languages.

In particular, the Processing® software P5.js (101), using JavaScript as language, has been used to design the “E-glove” section in order to create and handle BT connection and data streaming with one or more devices.

P5.js is a free and open-source JavaScript library for creative coding, with a focus on making coding accessible and inclusive for everyone. Thus, it has been chosen and used to show the data received from the devices. P5.js and, in particular, p5.ble.js library (102), has been particularly useful in the definition of the connections with the HM-10 Bluetooth module of the device.

Similarly to the Wi-Fi App, the most significant web browsers (Chrome, Opera, Edge, Safari and Huawei WB), in their latest available version, have been used to test web BT app compatibility.

3.4 Clinical applicability

The presentation of the device has been created using Visme (103), whereas all the data coming from therapists, engineers and doctors have been collected on a form made with free-to-use Google Form software (104). “QUEST” (Quebec User Evaluation of Satisfaction with Assistive Technology) (85) questionnaire has been integrated into the form to have a previously validated standard set of questions that could help to compare E-glove with some existing alternatives.

CHAPTER 4

METHODS

The materials described in the previous section have been used for E-glove production and testing phases. This chapter has been entirely dedicated to the description of the procedures that have been performed in order to complete the realization of the E-glove device.

Coherently with what is illustrated in the previous chapters, this section has been divided into four main parts: *"Force sensors"*, *"Hardware"*, *"Software"* and *"Clinical applicability"*, defining the specific methodology adopted for each phase of this project.

4.1 Force sensors

4.1.1 Realization

The first step of the sensor design has been devoted to the definition of the geometry of the sensor. To create a unique reference model useful to obtain identical sensors, some paper stencils have been created.

The defined geometries have been reported on a paper sheet by measuring all the dimensions with the caliber and the obtained stencils have been used to draw a guide onto the fabrics and to cut out the correct number of components from the raw materials.

For each sensor, two cotton-fabric parts, one Velostat™ component and two Conductive fabric layers have been cut in order to realize the sensor. The layers have been assembled following the order shown in Figure 29. The first layer is the cotton fabric, followed by the conductive fabric, the Velostat™ layer, conductive fabric, and the cotton fabric layer.

Some insulating vinyl glue has been applied between the cotton fabric layers and the conductive fabric ones to increase the sensor's durability. Before concluding the procedure, the conductive wires have been integrated with the conductive fabric tabs knotting them together.

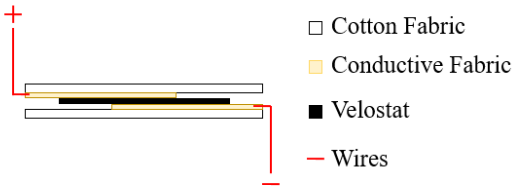


Figure 29: Sensor layers sequence scheme.

The process has been repeated six times to realize a sufficient number of sensors for testing and prototype realization.

4.1.2 Sewing on the e-glove

Textile sensors have been sewn on the perimeter borders to create a stable link on the lateral sides, where the wire-conductive fabric link is placed, in order to stabilize their connection. Different colors have been used to help recognize sensors and a path for the wires has been created, on the dorsal part of the glove, by sewing them to the fabric avoiding wire movements and breakage risks.

For the final version of the E-glove, only four textile sensors have been implemented, but the same procedure could be repeated, including either s4 and s5 sensors or extending their number up to eight force-measuring sensors in order to evaluate the force measured at the distal pad of the 3rd and 4th fingers.

4.1.3 Testing

For the testing sessions, the created testing setup was straightforward. A voltage divider has been built using the sensor, which works as a variable resistance and the 100Ω resistor (Figure 30).

This circuit topology has been preferred to the more accurate Wheatstone bridge topology because of its minimal size. By experimentally comparing the value obtained with the voltage divider setup and the Wheatstone setup, only a minimal difference in stability of the measured values has been noticed.

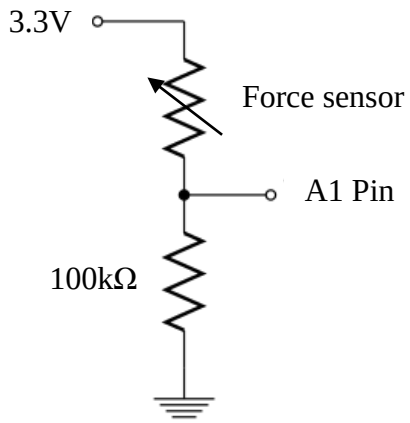


Figure 30: Setup schematic.

. In particular, offset was minimal even on voltage divider setup and even time/temperature drift has been demonstrated to be sufficiently small to be neglected with respect to the impact of a smaller-size acquisition circuit on the projected hardware

In addition, the 100Ω resistor has been chosen in order to minimize the joule effect of DC heating. In fact, by increasing the overall resistance, it has been possible to decrease the current intensity[3], thus reducing the heat dissipated by the two resistors[4]. This precaution results in the device not to heat up during the whole process. In conclusion, before introducing the obtained results, it is essential to observe

[3] *Ohm law – V=Ri – Voltage across a resistor is described as the product between the resistance and the current intensity.*
[4] *Joule effect – $P=Ri^2$ – Heat dissipated by a resistor because of Joule effect is directly proportional to resistance multiplied for the squared current intensity*

that the measured signal, defined as "*Digital output*", has been expressed in LSB (Least Significant Bit, see in appendix E for more information). As described, for this application, it has been considered:

$$LSB = \frac{5\ V}{2^{10}} = 4.88\ mV$$

Linearity and calibration curve

The breadboard has been set up as shown in Figure 31: the green wire has been connected to the 3.3V pin of the ELEGOO Board, a *100Ω* resistor has been placed in series with the force sensor and the black wire has been linked to the board ground (GND) pin. The yellow wire has been connected to the A1 pin of the board to measure the signal.

The firmware ("Testing_Lin_Hy.ino", see appendix A, in the dedicated document) has been uploaded on the board.

Progressively increasing weight has been applied to the sensor. From the Arduino IDE serial monitor, the evaluated analog signal has been recorded and noted down for further elaborations. The weighing scale has been used to assess the weight of the objects applied on the sensor, noting the overall applied weight and the recorded digital response readable from the serial monitor.

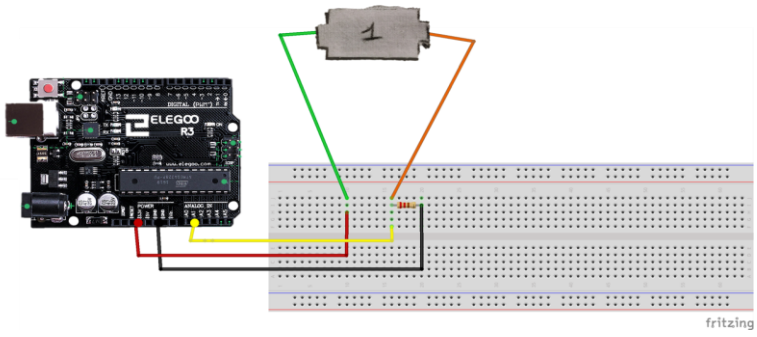


Figure 31: Testing Setup realized with Fritzing.

The obtained data have been elaborated using the OriginLab spreadsheet. First-order, second-order and third-order interpolating polynomials have been compared in order to identify the solution with the best fitting on the collected experimental data minimizing R-squared (R^2).
General equations of the polynomials have been reported:

$$\textit{Third-order polynomials:} \quad y = ax^3+bx^2+cx+d$$

$$\textit{Second-order polynomial:} \quad y = ax^2+bx+c$$

$$\textit{Linear:} \quad y = ax+b$$

The Textile sensor resistance-Force has been investigated to prove the consistency of the results coming from literature and to determine the conversion function.

Hysteresis

Likewise the previous experiment, the circuit has been organized as shown in Figure 31.

Again, the firmware "Testing_Lin_Hy.ino" (available in Appendix A) has been uploaded to the board and, using the weighing scale, the weight of the objects applied on the sensor has been measured. The operation has been repeated, both adding and subtracting weight to the sensor to test signal hysteresis. The overall weight has been noted down with the measured signal value readable from the serial monitor opened on Arduino IDE. All the collected information has been elaborated using OriginLab.

Time drift and signal stability

Also for signal stability evaluation, the same electronic settings (Figure 31) and the same script have been used. For this specific application, the serial monitor of Arduino IDE software has been used to continuously collect the observed values measured by the sensor when a 32g weight is applied to it.

In particular, the recorded values have been noted down every 30s, measured with a stopwatch, elaborating the results within the OriginLab environment.

Range and saturation value

The breadboard has been organized, as shown in Figure 33. “Testing_Lin_Hy.ino” script has been uploaded to the board and the serial monitor of Arduino IDE has been used to evaluate the saturation value of the sensor. A different weighing scale (Range: 0-200kg Sens: 0,1kg) has been used to assess the weight of the objects applied on the sensor and progressively increasing weights have been applied to the sensor until it reached its upper limit.

Thermal stability

The testing set up for evaluating sensors’ thermal stability has been organized as illustrated in Figure 32 and “Testing_temp.ino” script has been uploaded to the board using the serial monitor of Arduino IDE to read the collected analog signal. Sensor’ behavior at different temperatures has been investigated.

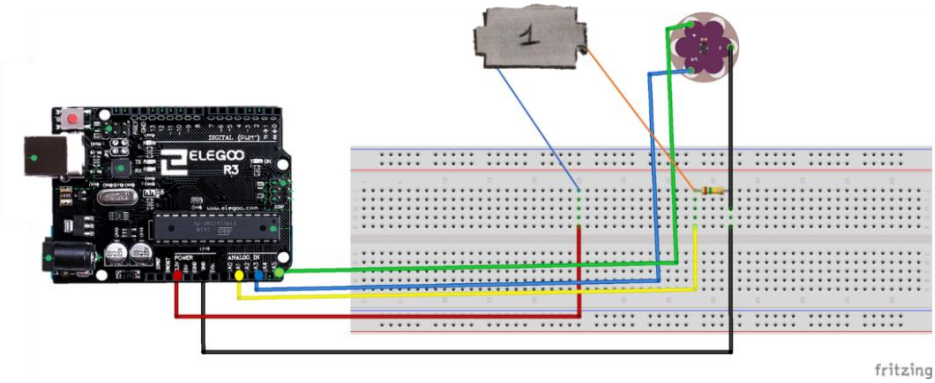


Figure 32: Thermal stability test setup

2ºC

The sensor has been placed on an ice block (T ~ 0 ºC) and the Lilypad sensor as close as possible to the force sensor. The weighing scale has been used to evaluate the weight of the objects applied to the sensor. The overall applied weight, the Lilypad sensor's temperature and the measured value of force readable from the serial monitor opened on Arduino IDE has been collected.

18 ºC

The sensor has been placed in an air-conditioned room that has been previously cooled down to ~ 18 ºC as close as possible to the Lilypad sensor. The same operations seen in the previous test have been repeated.

25 ºC

For this session, the sensor has been placed in a room at ambient temperature (T ~ 25 ºC), repeating the same procedures seen for the tests performed at 2ºC and 18ºC.

28 ºC

Another series of measurements have been performed keeping the sensor in an indoor room during the warmer hours of a summer day (T ~ 28 ºC). The same procedures seen before have been replicated.

32 ºC

In conclusion, the force sensor and the temperature one have been placed on an impermeable plastic bag filled with warm water (T ~ 32/35 ºC), repeating all the operations seen before.

All the obtained results have been processed using OriginLab.

Sensor measurements' repeatability

All the information about the testing setup has just been presented in the "*Linearity*" section. To avoid repetitions, they have not been reported here. The linearity experiment has been repeated six times, each one with a different sensor, working at the same external conditions.

4.1.4 Comparison with commercially available FSR

The same tests (linearity, hysteresis and thermal stability) performed for the textile-handcrafted sensors have been repeated by substituting the hand-made FSR with a commercially available FSR alternative by Interlink.

4.2 Hardware

4.2.1 Prototypal version of the E-glove

The hardware electronics have been mounted, soldering all the components to the ELEGOO PCB board and checking connection reliability.

After adding all the elements on the board and connecting the textile force sensors, the holes present on the ELEGOO board have been used to integrate the board to the upper surface of the e-glove, guaranteeing solidity and stability of the electronic circuit.

4.2.2 Final version of the E-glove

An upgraded version of the glove has been realized in order to increase connectivity and wearability of the device, integrating both the force sensors and the mini Lilypad LEDs on the fingers, and placing all the other electronics in the E-glove box, a protective case located on the upper part of the glove.

The resistors have been soldered on the ELEGOO PCB board using the soldering iron and each component has been checked for its functionality.

A protective box has been designed Onshape (105) CAD software, a free-to-use, online tool that allows projecting 3D structures via a user-friendly interface (the complete project has been reported in Appendix document) and printed using a 3D Ultimaker 5 printer with a 0.4mm nozzle supplied with a PLA filament. By using the holes present at the corners of the bottom plate of the case, the board itself has been sewn to the upper surface of the e-glove.

Some parameters like E-glove weigh, maximum fabric thickness, data-transfer rate (via Wi-Fi and BT) and battery consumption have been evaluated to complete E-glove hardware characterization. In particular, data transfer has been measured counting the number of string transferred per unit time and the power consumption has been measured using an amperemeter, placed in series with the power supply.

4.3 Software

4.3.1 Board software

The script reported in the Appendix document (App. B) has been uploaded to the device. Each textile sensor has been singularly tested by launching the "Serial plotter" tab on Arduino IDE. To conclude, the entire glove together has been tested during a grasping task. In particular, a bottle grasping and holding action have been performed, analyzing sensor recruitment sequence and force stability.
To conclude the testing phase, the Wi-Fi app compatibility with the most significant web browsers have been checked.

4.3.2 Desktop GUI

The code for the GUI has been designed using Processing software and all raw produced code has been reported in the appendix document (App. C).

4.3.3 Web application

All the raw code used to program the web app has been reported in the appendix document (App. D) and it has been realized using JavaScript, CSS and HTML code.

The following list describes the correspondence between the Web app sections and the corresponding references.

- Homepage: “Sito.html”
- E-glove app: “Webbluetooth.html”
- MeCFES app: “MeCFES.html”

Web app compatibility with the most common Web Browsers has been checked by verifying the ability to use the app on the chosen browser, leaving the clinician the possibility to chose his/her favorite one. In fact, web BT is not supported on all the main browsers and this may cause issues with E-glove control.

4.4 Clinical applicability

A presentation illustrating the main features of the device has been created using Visme software and then shown to the public in a 15 minutes long presentation.

After the end of the exhibition, clinicians and engineers have been invited to compile the designed form to acquire their opinion. The questionnaire has been subdivided into three sections:

- SECTION 1

The first section comprehends a series of preliminary questions about the visitor’s profession (therapist/doctor or engineer) and some general inquiries about interest in the device and some pros and cons that have been highlighted when discovering device features. A conclusive question requires a synthetic preliminary judgment about the device on a scale from 0 to 5, where 0 is considered as the negative extreme and 5 is representative of satisfaction.

- SECTION 2

Section two comprehends all the questions of “QUEST” (Quebec User Evaluation of Satisfaction with Assistive Technology). People are invited to judge each property giving it a mark between 0 and 5, where 0 represents dissatisfaction and 5 express satisfaction.

- SECTION 3 (not compulsory)

The last section of the designed questionnaire is not compulsory and it has been made in order to acquire some in-depth information about the impression generated in the audience. Some questions about versatility, connectivity and wireless applications are included as well as some additional questions about possible application field, general appearance and the economic predicted value of the device. This information contributes to obtain a more detailed picture of impressions and expectations of the tested audience, helping to highlight critical features and possible features to which dedicate future developments of the device.

A complete list of all the questions present in the questionnaire has been reported in the Appendix document (App. H).

CHAPTER 5

RESULTS

This section of the manuscript will be entirely dedicated to the illustration of the result obtained in the different stages of the experiment.

These outcomes will be treated one by one, following the same order presented in the “Materials” and “Methods” chapters of this document.

All the results, singularly presented in this section will be useful in the conclusive “Conclusion” and “Discussion” section in which the final collective outcomes of the work and a brief comment about limits and future developments will be presented to the reader.

5.1 Force sensors

5.1.1 Realization

All the produced sensors have been realized by alternating the different material layers, as shown in the “Method” section 4.1.1. Figure 34 illustrates the geometry of the obtained layers.

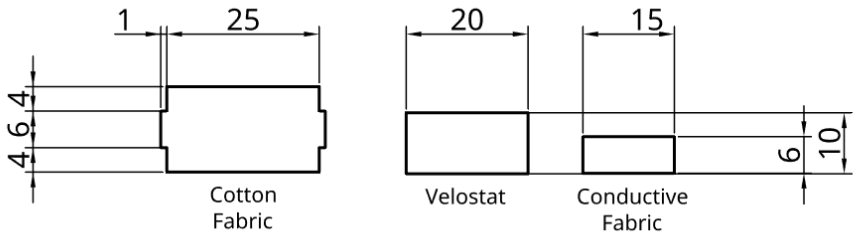


Figure 33: Stencil's geometrical characteristics (measures expressed in mm)

Figure 34 describes how the different layers are organized, revealing the alternation of the layers described in the dedicated paragraphs dedicated. The same scheme has been reproduced for all the six realized sensors that are shown in Figure 35.

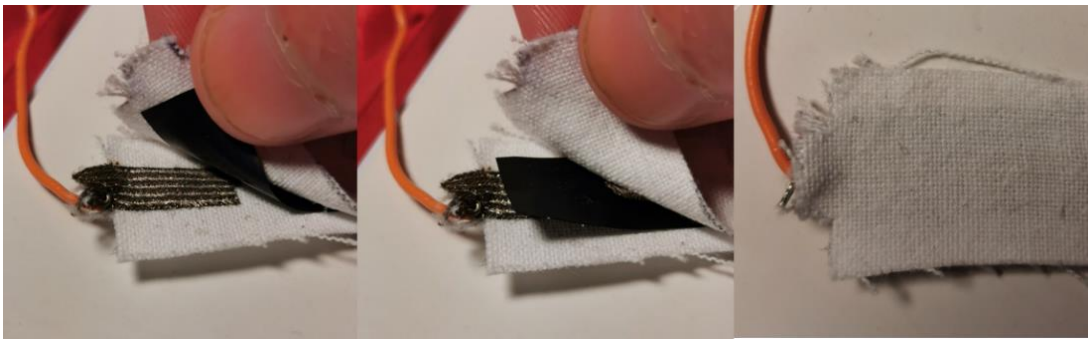


Figure 34: Sensor layers sequence during the assembling procedure.

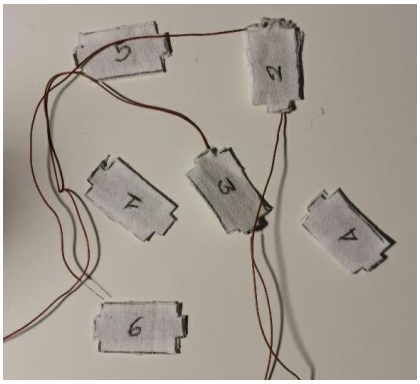


Figure 35: Set of six (n=6) labeled sensors.

As shown in Figure 36, the obtained sensors work as Force-Sensing resistors (FSRs) and they are able to detect any force applied to its surface thanks to the presence of the Velostat™ layer. The signal is stable and the read data are shown with null delay.

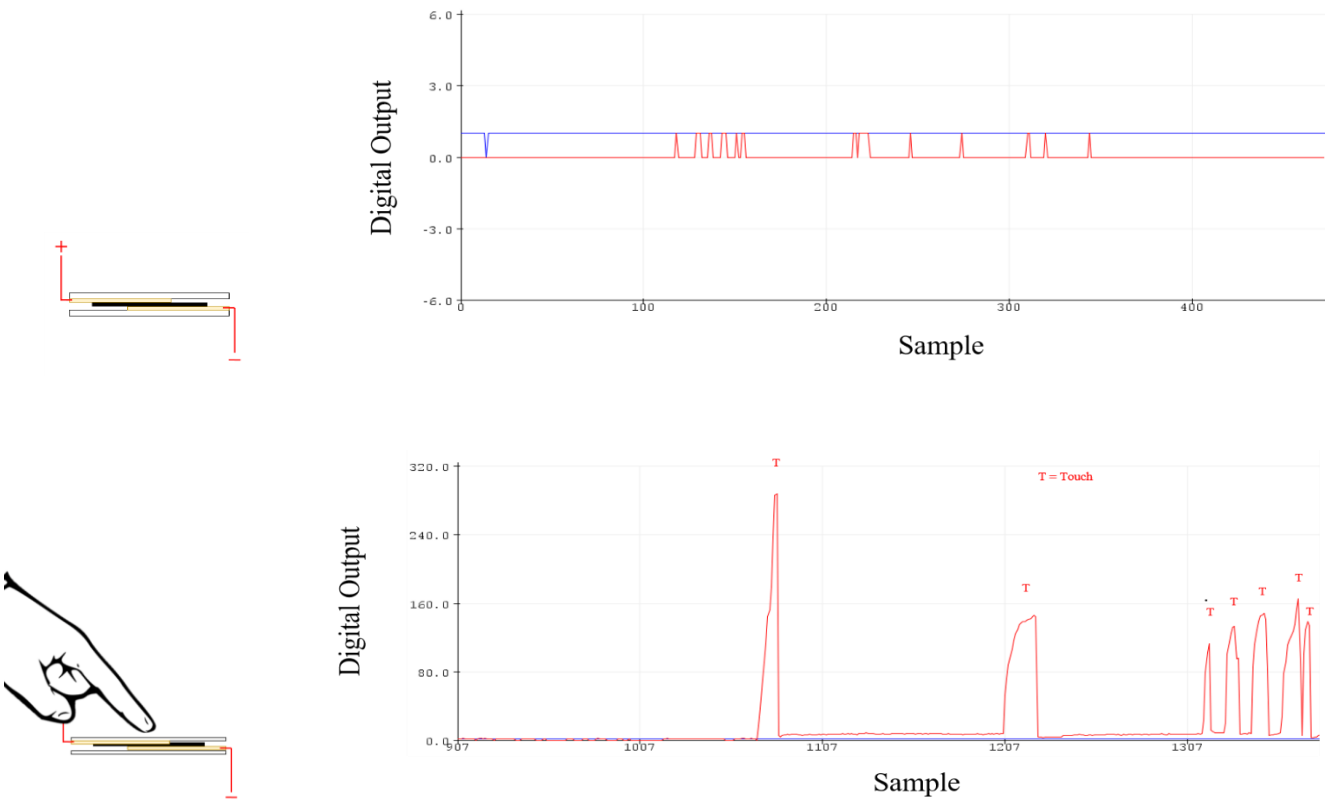


Figure 36: Read signal. No-pressure applied versus pressure applied (T)

A sequentially increasing series of n=17 resistance samples collected under growing force stimulus could be observed in Figure 37. It illustrates the relationship between the external force stimulus and the sensor resistance that could be analytically described as:

$$R = A/F$$

Where:

F=Applied force (N)

R=Textile force sensor resistance (Ω)

A=constant term (N/Ω)

Using OriginLab and Levenberg–Marquardt algorithm for least square fitting, *A* term and R^2 have been determined as equals to:

$$A = 476.46 \text{ N}/\Omega$$

$$R^2 = 0.89$$

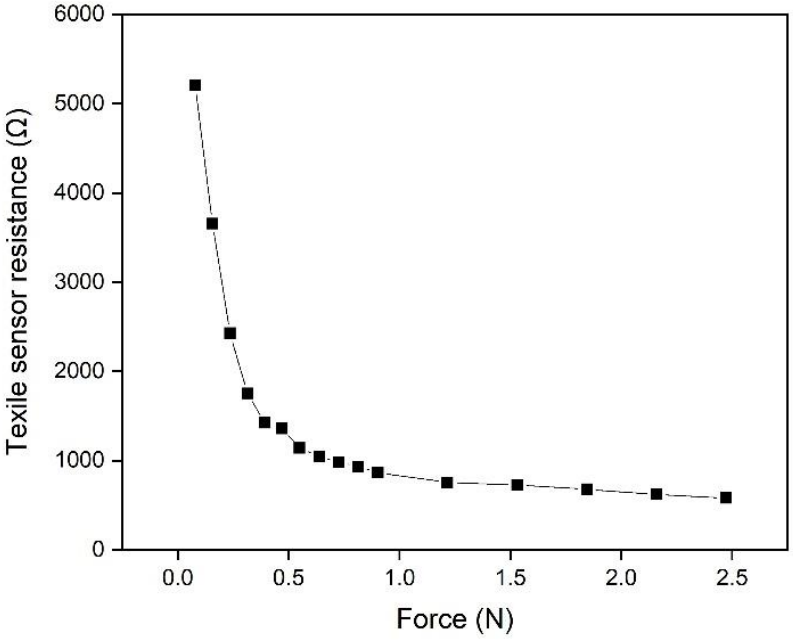


Figure 37: Textile sensor resistance on applied force stimulus
(n=16 samples calculated on a single testing session with progressively increasing applied force).

As observable, Velostat(™) polymer modifies its conductive carbon particle distance when an external force is applied, increasing the current passing toward it and this property can be exploited to evaluate the exerted force. All these characteristics have been favorably exploited in several applications, mainly directed to the creation of a matrix of sensors for foot insoles (91,106).

5.1.2 Sewing on the e-glove

The obtained e-glove is shown in Figure 38. Sensors have been sewed on their perimeter edges with different colors and have been labeled in order to recognize them during hardware prototyping and testing phases. Sensors are stable on the glove surface.

Figure 38: Sewed sensors on position s1,s2,s3 and s6.

5.1.3 Testing

Linearity and calibration curve

Figure 39 collects the samples (n=65) resulted from the two repetitions (n=2) performed to evaluate sensor behavior between 0 and 10N.

In order to identify a suitable function able to explain the relationship between the applied weight and the obtained digital output, the data have been interpolated with a 3rd order polynomial curve analytically described in the methods section. This curve is the one with the smallest order that is sufficiently reliable as a predictive model that can be used to describe and predict the sensor's behavior.

In fact, the defined R^2 value is high and well above 0.9, which might be considered as a good fitting for an experimentally determined calibration curve (107).

This is the equation of the third-order polynomial that has been obtained as descriptive of the sensor behavior:

$$OS = -9*10^{-8}\, w^3 - 4*10^{-5}\, w^2 + 0.396w + 21.6$$

$$R^2 = 0.9423 \ ^{(5)}$$

Where:

OS = Output signal (LSB)

w = Applied weight (g)

R^2 = Determination coefficient

The obtained results for the determination coefficient is close to 1. Thus the obtained 3rd order model can correctly represent the collected data and might be used to predict the missing ones, revealing that sensor behavior is not linear.

[5] ***Equation number 1***. *This equation has been experimentally defined.*

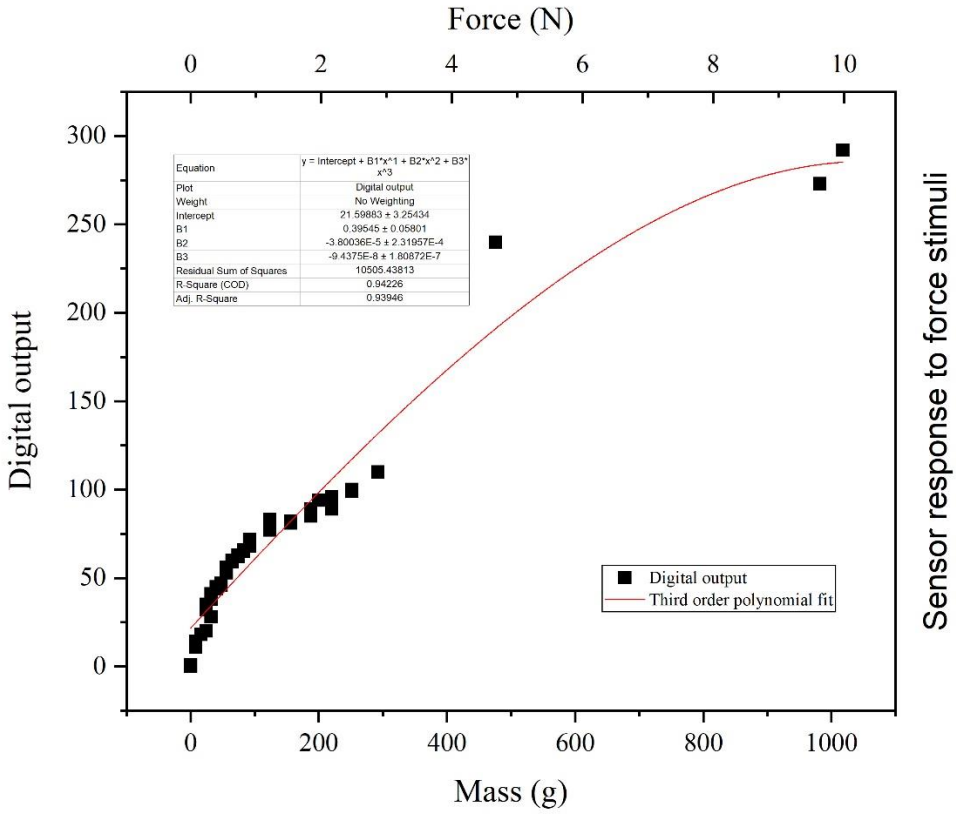


Figure 39: Linearity analysis graph between 0 and 10N.

On the other hand, Figure 40 report from six different repetitions (n=6) of the test with applied weight between 0 and 300g (0-2.5N), thus, more appropriate for the E-glove field of application. For each repetition, seventeen (n=17) increasing values have been collected.

For the third-grade polynomial interpolation, the obtained equation is equal to:

$$OS = 1.33*10^{-5}\, w^3 - 0.0068w^2 + 1.2704w + 1.044$$

$$R^2 = 0.9934 \ (6)$$

[6] ***Equation number 2***. *This equation has been experimentally defined.*

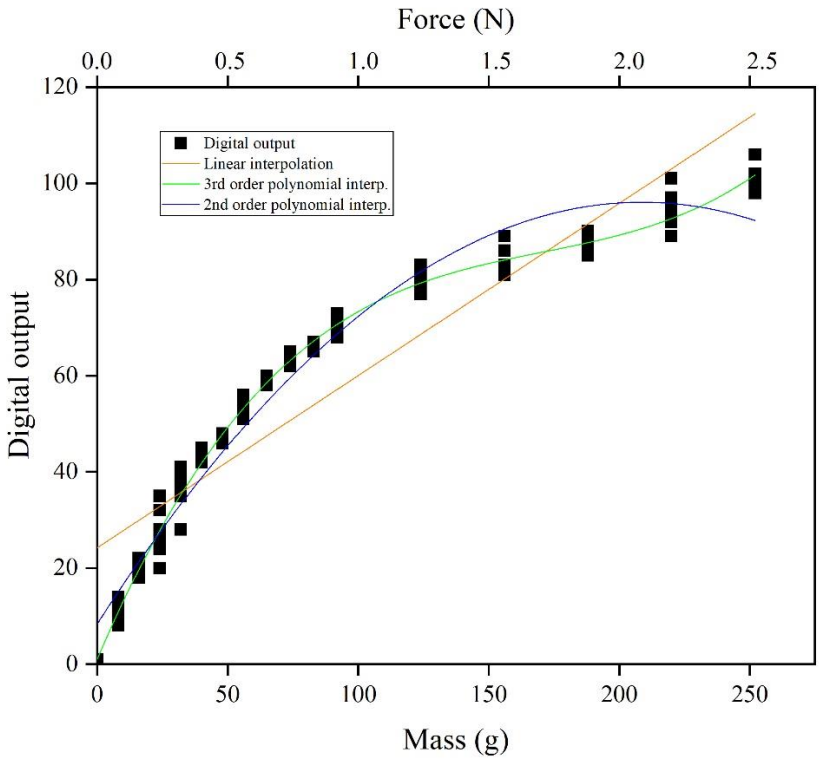


Figure 40: Linearity analysis graph between 0 and 2.5N.

On the other hand, also the second-order interpolation and the linear interpolation have been investigated, obtaining:

$$OS = - 0.0020w^2 + 0.8407w + 8.38$$

$$R^2 = 0.968 \ (7)$$

$$OS = 0.3418w + 25.161$$

$$R^2 = 0.8522 \ (8)$$

[7] ***Equation number 3***. *This equation has been experimentally defined.*

[8] ***Equation number 4***. *This equation has been experimentally defined.*

The non-linearity of the sensor has been demonstrated and system behavior has been “correctly” described by a third-order polynomial.

However, collected results between 0 and 2.5N are more similar to those shown by literature (74), where Velostat-made force sensors have been described as linearly behaving transducers.

The settled threshold R^2 of 0.85 has been outweighed by the obtained linear equation, thus, this option cannot be neglected and the force-conductance relationship (Figure 41) could still be interpreted as directly proportional. These observations may pay the way for a series of additional investigations and tests about sensors behavior to verify the error introduced by a linear approximation of the sensor behavior and how the testing conditions may have influenced the highlighted behavior.

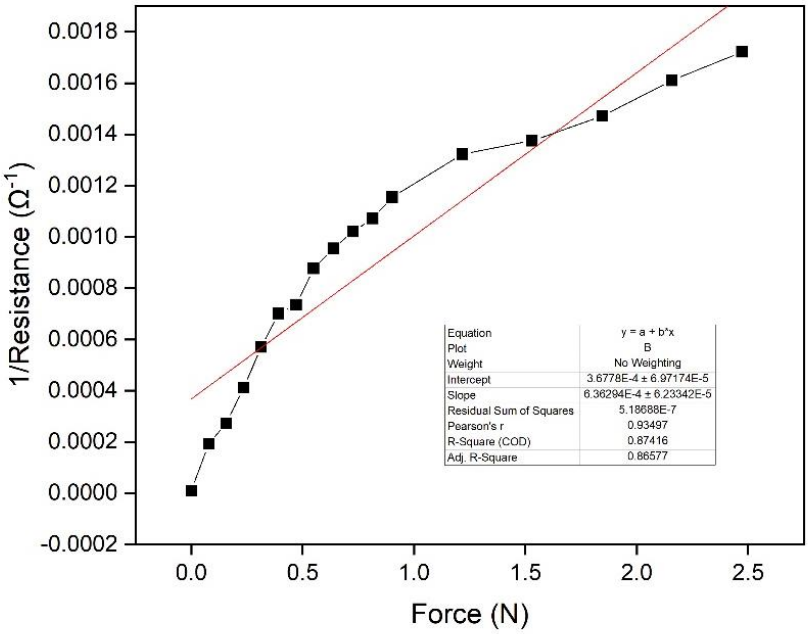


Figure 41: Textile sensor conductance on applied force stimulus.

Hysteresis

As noticeable from Figure 42, sensor behavior was independent of stimulus history and the most significant calculated error is equal to 3.14% (13.5 LSB) and it has been calculated for mass=24g. 34 averaged samples (n=17 for increasing force stimulation and n=17 for decreasing force stimulation) from two (n=2) repetitions have been collected during this test.

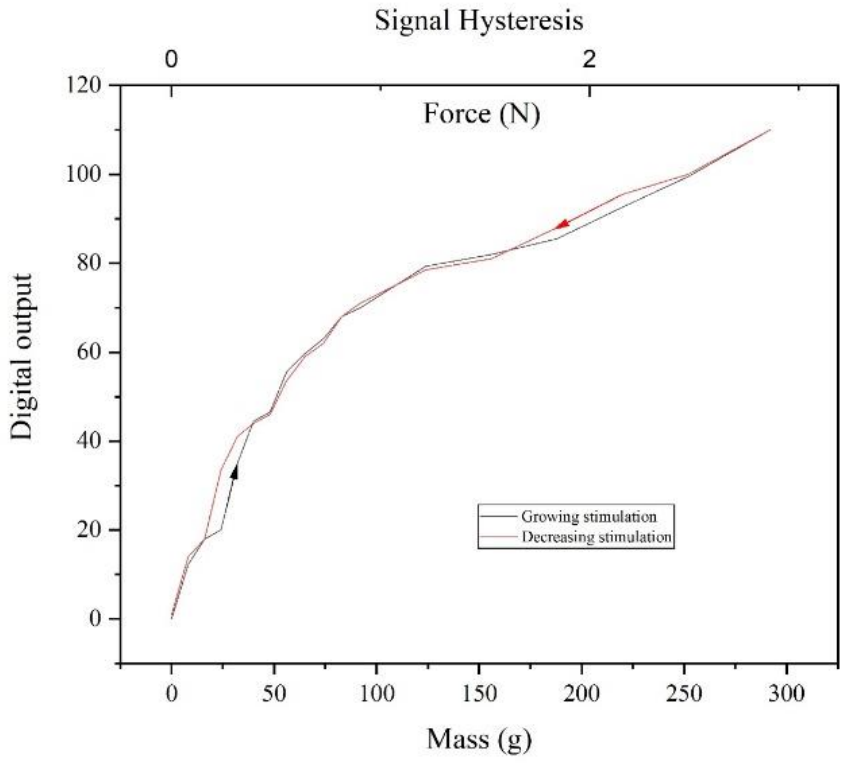


Figure 42: Hysteresis analysis graph

Time drift and signal stability

As noticeable from the images shown below (Figure 43), the digital output signal given by the sensor with an applied constant stimulus is almost constant over time. The variation of the signal that can be

noticed from Fig. 44 (~ 3 units in terms of signal output that corresponds to 14.64 mV) has happened in a time period of 990s (~16 min).

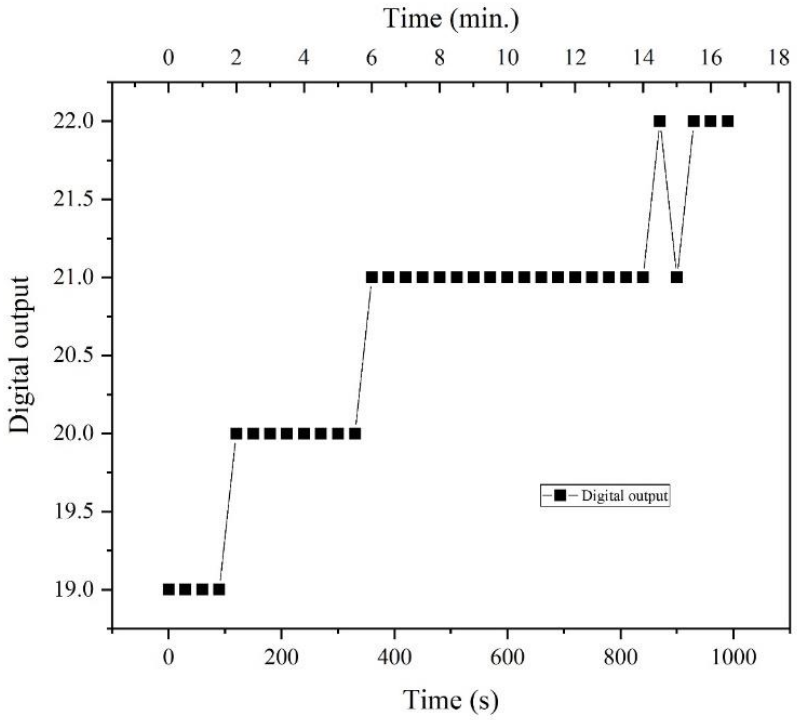


Figure 43: Signal drift analysis.
Digital output data (n=33) collected on an applied weight of 32g.

When compared to the full scale (0 – 430 LSB) of values that could be assumed by the sensor, it might be observed that the error is small, about 0,69%, and happened on a very long time window (~16 min). This error type represents only a minor issue in the quick actions this project aims to measure.

Signal drift could be defined as equal to 0.2 LSB/min. This phenomenon might be associated with the fact that a permanently applied stimulus may cause the carbon particles embedded in the Velostat™ layer of the sensor to get closer and closer, thus reducing the electrical resistance of the sensor itself.

This hypothesis that must be confirmed with experimental pieces of evidence will explain why the signal progressively increase in intensity over time

Range and saturation value

It has been measured a saturation value of:

$$OS_{saturation} = 430 \text{ LSB}$$

$$\text{for } w = 18000g = 18kg$$

Thus, the sensor will saturate for applied forces higher than 176N. This value is well above the needs of this application, so it is possible to conclude that the sensor will never reach saturation.

However, to better evaluate the behavior around the saturation limit of the sensor, it would be advisable to perform additional analysis using instruments that are more appropriate in terms of sensibility and accuracy.

The final measurement range has been defined between 0 and 430 LSB (0-176N).

Thermal stability

As shown in Figure 44, a maximum relative difference of -13/+8% (-5/+3 LSB) have been identified when comparing the ambient condition (T = 25.0 ºC) with the other testing temperatures. Only minor changes have been identified for extremely low temperatures. As observable from the following bar chart (Figure 46), obtained by collecting n=17 samples from the same sensor in 5 different temperature conditions, the relative error in respect to the measured force value at T_{amb} is more prominent for smaller amounts of the applied force, whereas it tends to decrease with the increasingly growing force stimulus

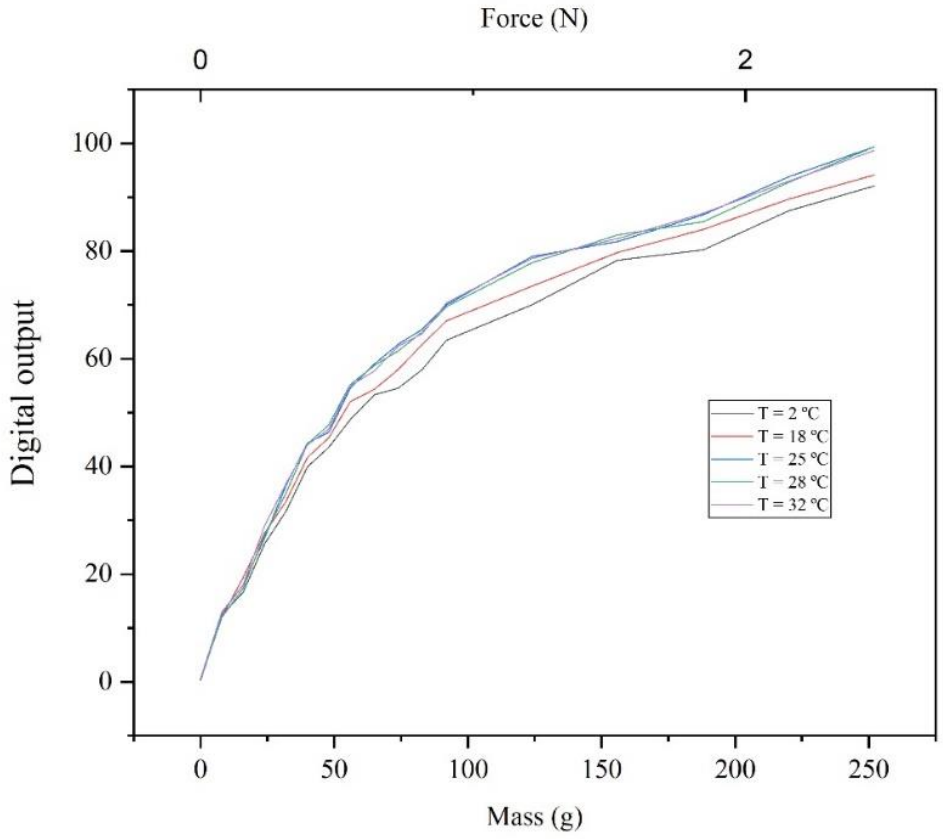


Figure 44: Temperature dependency of sensor performances.
17 samples collected at 2.0 ºC, 18.0 ºC, 25.0 ºC, 28.0 ºC and 32.0 ºC.

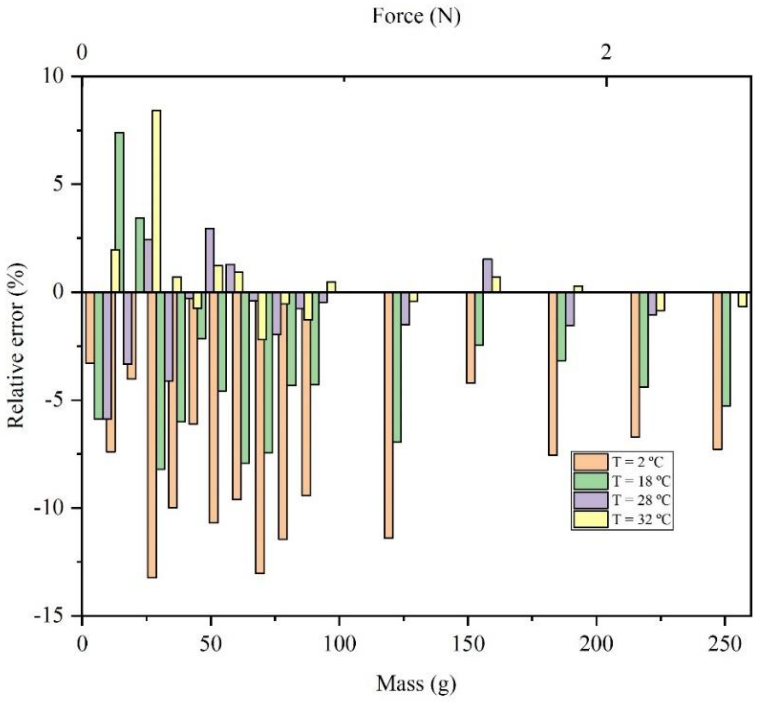


Figure 45: Relative error with respect to Tamb (25 ºC)

The relative error with respect to the standard condition (T = 25.0 ºC) has been calculated, noticing that the most significant error is the one obtained at the temperature of 2.0 ºC and tends to underestimate the Analog signal with respect to the one evaluated at standard condition. For all the other cases, the measured error is negligible.

TABLE IV: AVERAGE RELATIVE ERROR

T = 2.0 ºC	T = 18.0 ºC	T = 28.0 ºC	T = 32.0 ºC
-8%	-4%	-1%	0%

Sensor measurements' repeatability

The following graph (Figure 46) illustrates the obtained reproducibility results. Six different sensors have been tested at the same conditions collecting 20 measurements (n=20) for each sensor. This operation has been repeated twice and results have been averaged. Despite the expectable variability characteristic of a handcrafted sensor, the difference between the analog signals recorded by the six designed sensors is minimal.

The maximum recorded difference is equal to 8 LSB and it has been measured for an applied weight of 250g. The percentage on the maximum measurable value is 1.86%, whereas the calculated average error is equal to ±0.86%. In addition, it is also possible to observe that the difference grows with the growth of the applied force stimulus.

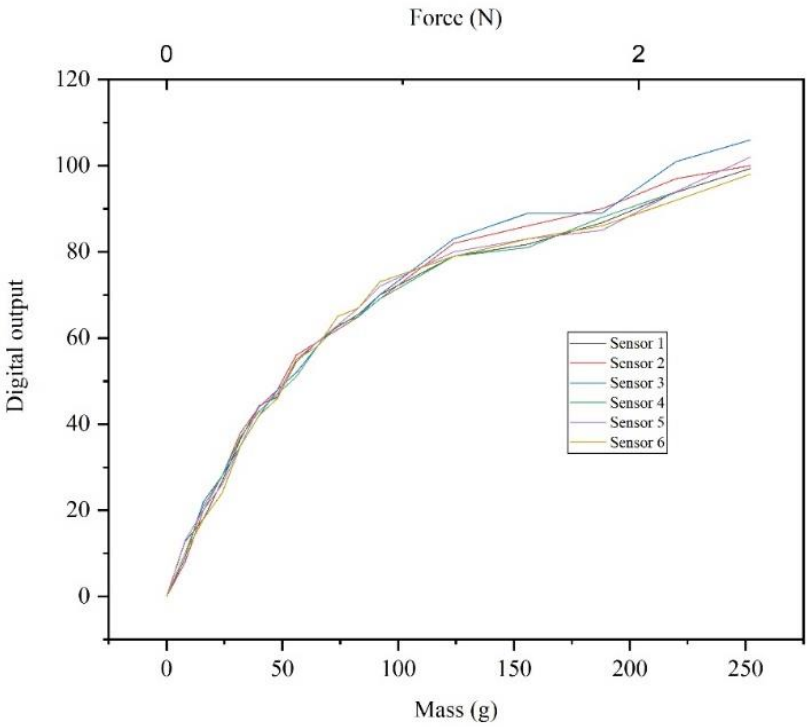
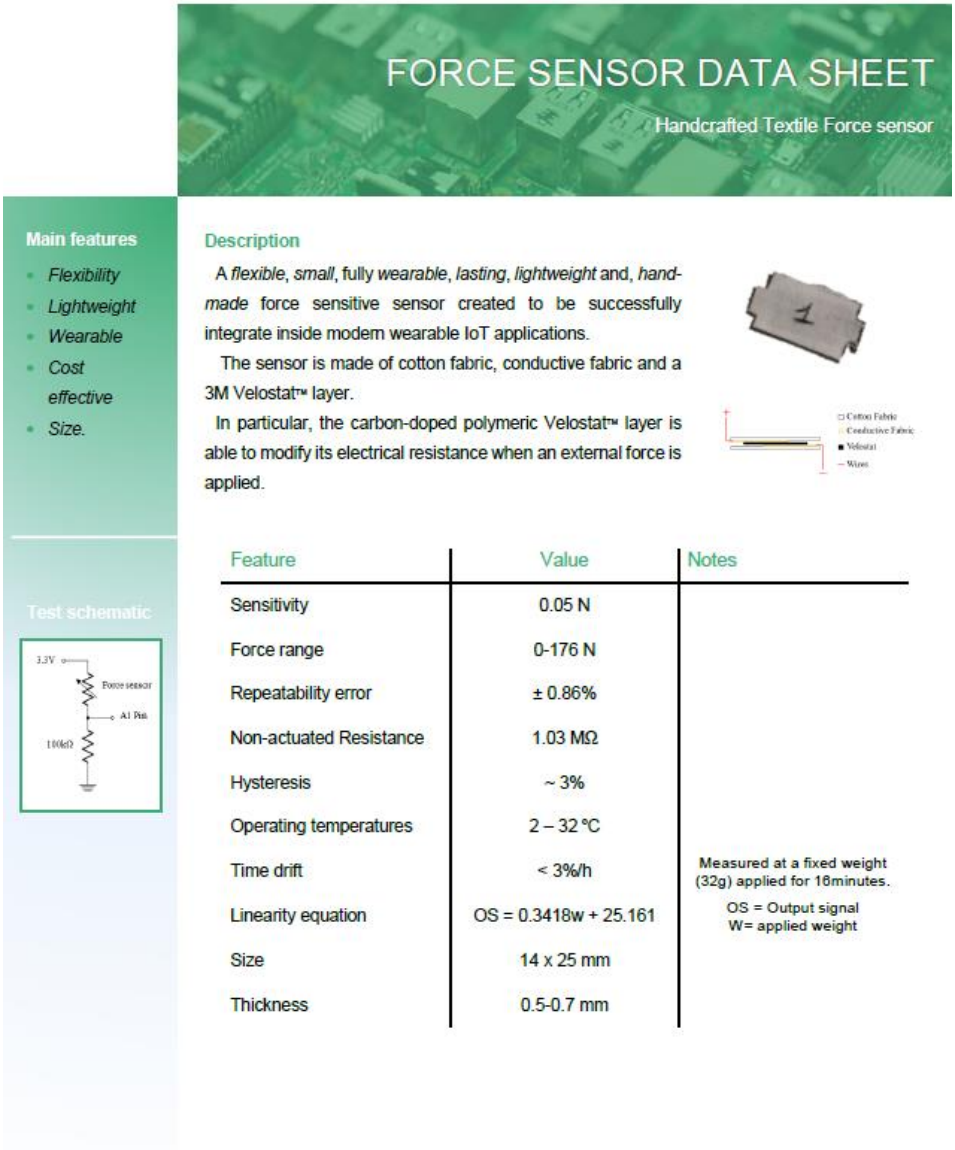


Figure 46: Sensors comparison (0-300g)

Summary

The specifications of the force sensors have been reported in the following summarizing schemes (Figure 47 and Figure 48), trying to replicate the datasheet of a commercially available sensor.



FORCE SENSOR DATA SHEET

Handcrafted Textile Force sensor

Main features

- *Flexibility*
- *Lightweight*
- *Wearable*
- *Cost effective*
- *Size.*

Description

A *flexible*, *small*, fully *wearable*, *lasting*, *lightweight* and, *hand-made* force sensitive sensor created to be successfully integrate inside modern wearable IoT applications.

The sensor is made of cotton fabric, conductive fabric and a 3M Velostat™ layer.

In particular, the carbon-doped polymeric Velostat™ layer is able to modify its electrical resistance when an external force is applied.

Test schematic

Feature	Value	Notes
Sensitivity	0.05 N	
Force range	0-176 N	
Repeatability error	± 0.86%	
Non-actuated Resistance	1.03 MΩ	
Hysteresis	~ 3%	
Operating temperatures	2 – 32 °C	
Time drift	< 3%/h	Measured at a fixed weight (32g) applied for 16minutes.
Linearity equation	OS = 0.3418w + 25.161	OS = Output signal W= applied weight
Size	14 x 25 mm	
Thickness	0.5-0.7 mm	

Figure 47: Page 1 sensor datasheet

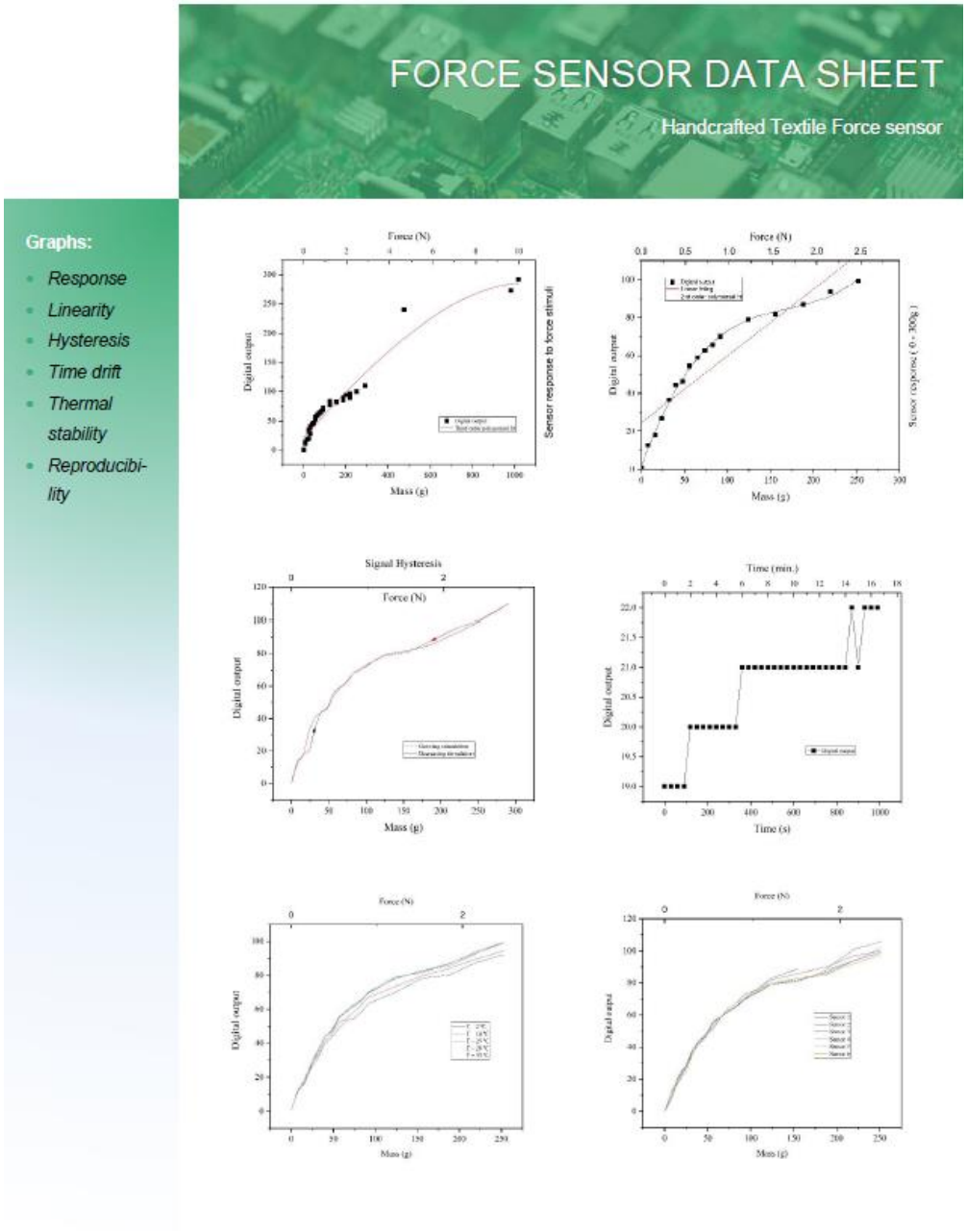


Figure 48: Page 2 sensor datasheet

5.1.4 Comparison with commercially available FSR

By repeating the testing procedures on the FSR 402 by Interlink electronics, the following results have been determined.

TABLE V: FSR 420 SPECIFICATIONS

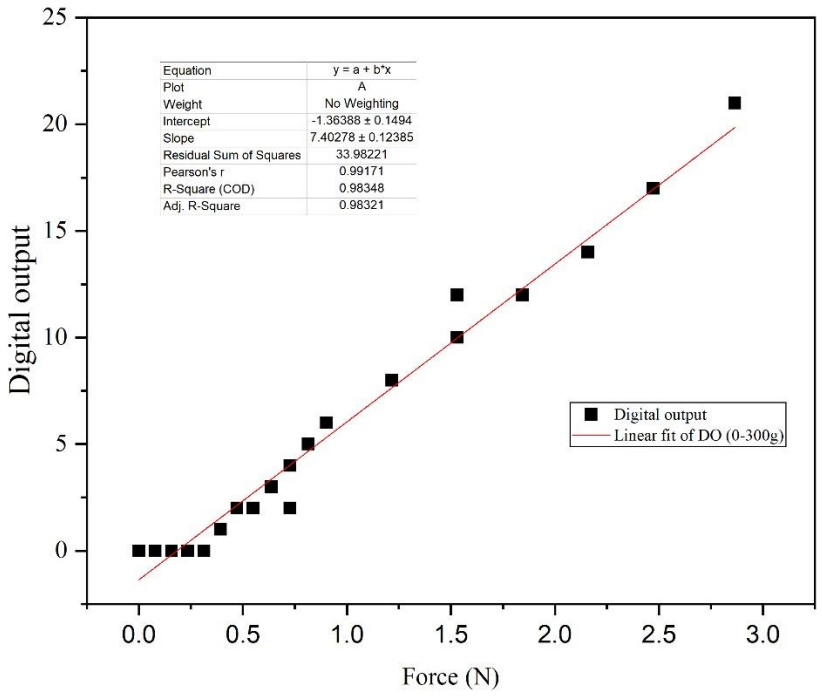
Feature	Value
Sensitivity	0.4 N
Force range	0-100 N
Non-actuated Resistance	10 MΩ
Hysteresis	~ 1.6%
Time drift	< 0.88%/h
Linearity equation	OS = 7.402w – 1.363[9]

Linearity has been assessed between 0.4 and 3 N, whereas under 0.4 N the sensor was not able to discriminate between applied force stimuli. On the other hand, Hysteresis has been calculated in a maximum relative error of 1.6% and time drift has been calculated below 8 LSB/h.

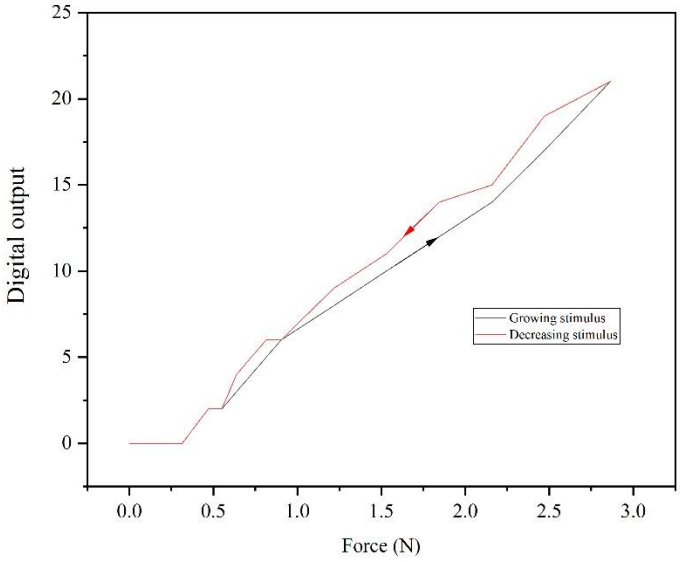
[9] *OS = Output signal W= applied weight*

Graphs

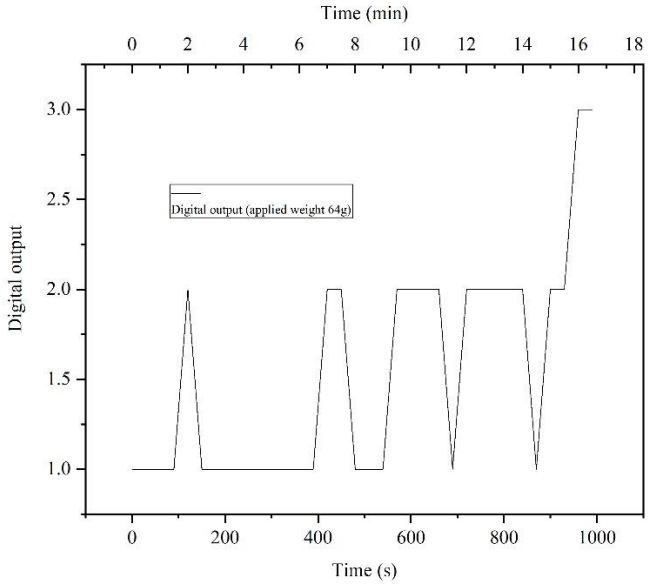
Sensor linearity



Hysteresis



Signal time drift



5.2 Hardware

5.2.1 Prototypal version of the E-glove

The electrical components have been assembled following the schematic shown in Figure 49 and realized with Autodesk EAGLE(™) software.

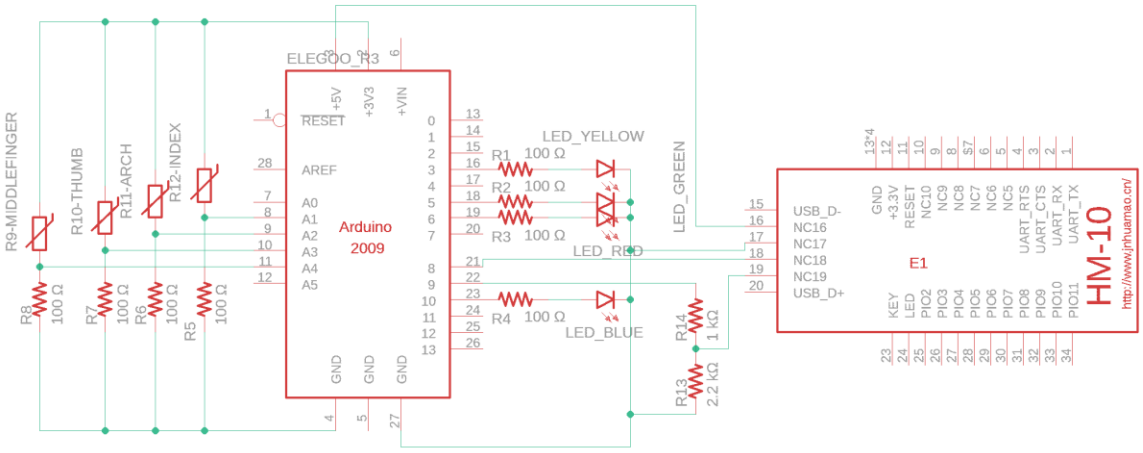


Figure 49: Circuit schematic realized with EAGLE(™) software

Figure 50 shows the result of the hardware production procedure, the first realized e-glove prototype.

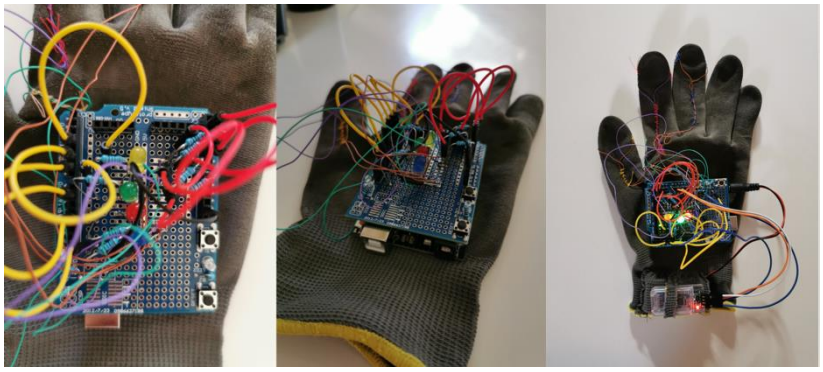


Figure 50: Assembled prototype

This prototypal version was equipped with an HM-10 Bluetooth Low Energy (BLE), allowing data collected from the E-glove to be wirelessly shared with the therapists and the patients, leaving more freedom of movement to the patient and reducing the impact on his/her actions. Moreover, it could be proactively used to optimize the stimulation parameters at the MeCFES device, creating a bidirectional communication with the FES device. MecFES sends information about the EMG activity receiving back manually adapted stimulation parameters defined by the doctor. E-Glove contributes by sending information about the exerted force (and movement in the 2.0 version), which could be used to automatically adapt the stimulation parameters, as shown in the image below (Figure 51).

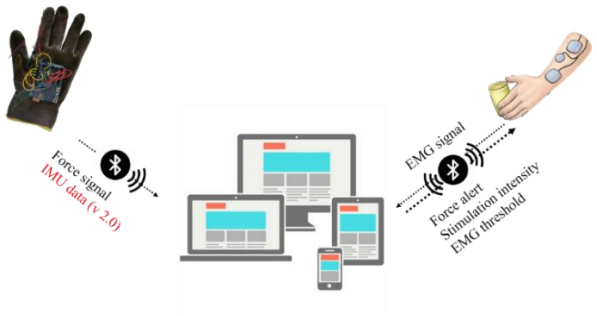


Figure 51: System communication architecture.

5.2.2 Final version of the E-glove

An upgraded version of the glove (Figure 52) has been realized in order to increase connectivity and wearability of the device, integrating both the force sensors and the mini Lilypad LEDs on the fingers, and placing all the other electronics in the E-glove box, located on the upper part of the glove.

Figure 52: New version of the E-glove

The hardware electronics have been mounted following the schematic shown in Figure 53 and realized with Autodesk EAGLE(TM) software.

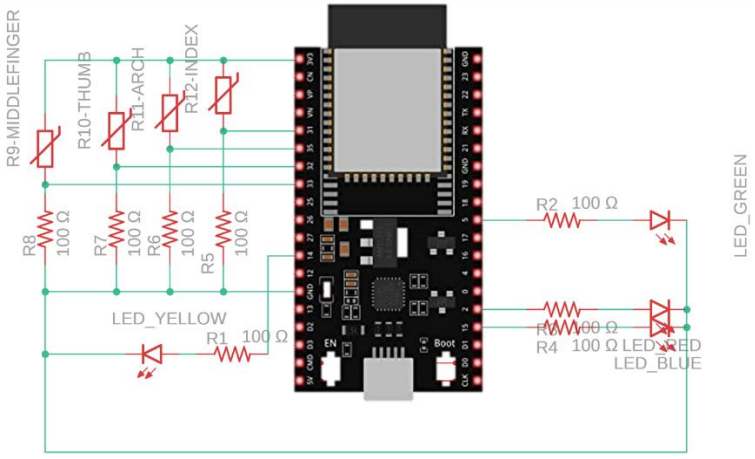


Figure 53: Circuit schematic realized with EAGLE(™) software

A protective box has been designed and 3D manufactured to host all the electronic components keeping them safer. The case has been designed (Figure 54) in order to host the board while allowing its activation via the button present on the frontal plate and charging via the micro-USB port.

By using the holes present at the corners of the bottom plate of the case, the board itself has been sewn to the upper surface of the e-glove.

Figure 54: Electronic components case

The resulting device is shown in Figure 55. The upgraded glove shape guarantees a more straightforward wearing procedure with a minor impact on natural hand movements and reduced weight (~70g) applied to the hand itself. All this progress contributes to creating a thin, lightweight and wearable device.

TABLE VI: E-GLOVE SPECIFICATIONS

Name	E-glove
Weight	72g
Max Thickness Fabric	6 mm
ADC frequency*	115 ksps [10]
BT transfer rate	1kB/s [11]
BT range*	Up to 100m
Wi-Fi transfer rate	1kB/s [11]
Wi-Fi range*	Up to 150m
Power consumption	ACTIVE MODE: ~100mA DEEP-SLEEP: ~10mA DEEP-SLEEP only ESP32 module: ~10uA
Over The Air (OTA) update*	Available

*From ESP32 board specifications

LEDs have been placed directly over the corresponding force sensor, making it simpler to comprehend the correspondence between the measured force and the light's brightness. The new protective case, hosting the electronic board and all the electronic components that make this device working, is compact and integrated with the glove, as noticeable from the images below.

[10] *kilosamplepersecond*
[11] *kiloBytepersecond*

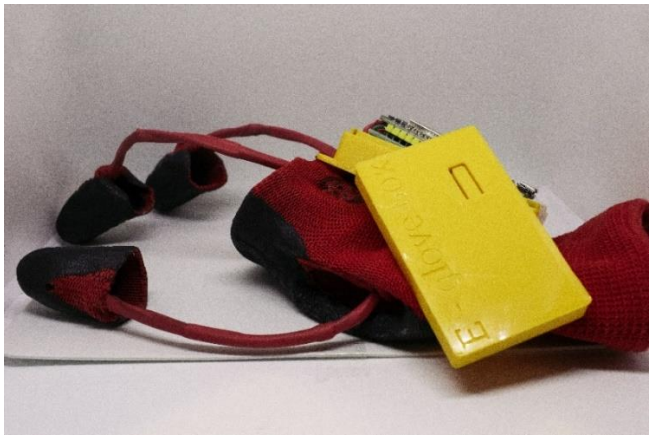


Figure 55: Assembled final version

The final version of the E-glove integrates a BLE system for communication via BT with the web app that is used to collect, elaborate and shows all the data from the glove, but also a new Wi-Fi system that guarantees full accessibility of the data from any type of reading device through a simple connection to the Access Point (AP) created by the glove itself. Up to five different devices (one via BT and four via Wi-Fi) could be connected to the E-glove simultaneously, guaranteeing a maintained functionality of the device even with adverse external conditions.

BLE could be used whenever an internet connection is available, whereas Wi-Fi access could be useful in poor connectivity conditions or whenever the Internet connection is absent.

As just seen for the prototypal version of the glove, BLE connection allows data collected from the E-glove to be proactively used to modify the stimulation parameters at the MeCFES device, creating a bidirectional communication on the MeCFES side, from where information about the EMG activity is received while modulating the electrical stimulation, and a unidirectional communication on the E-Glove side, from which only details on the exerted force are received (Figure 57).

On the other hand, the added Wi-Fi access guarantees the possibility to read the data collected from the E-glove using up to four additional devices. In a world where connection is everything, this solution

represents an interesting innovation and a potential benefit allowing to keep an objective track of the patients' progress during the rehabilitation path.

Interoperability is one of the keys to success. Full functionalities are guaranteed for laptops, mobile phones and tablets, leaving the device's choice a personal decision of the clinician or the patient itself.

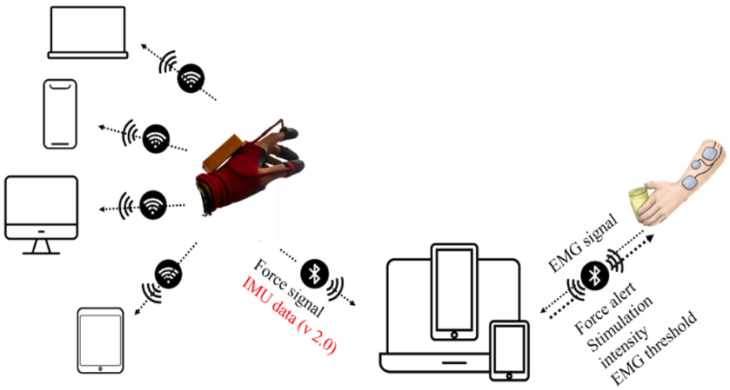


Figure 56: System communication physical architecture.

5.3 Software

5.3.1 Board software

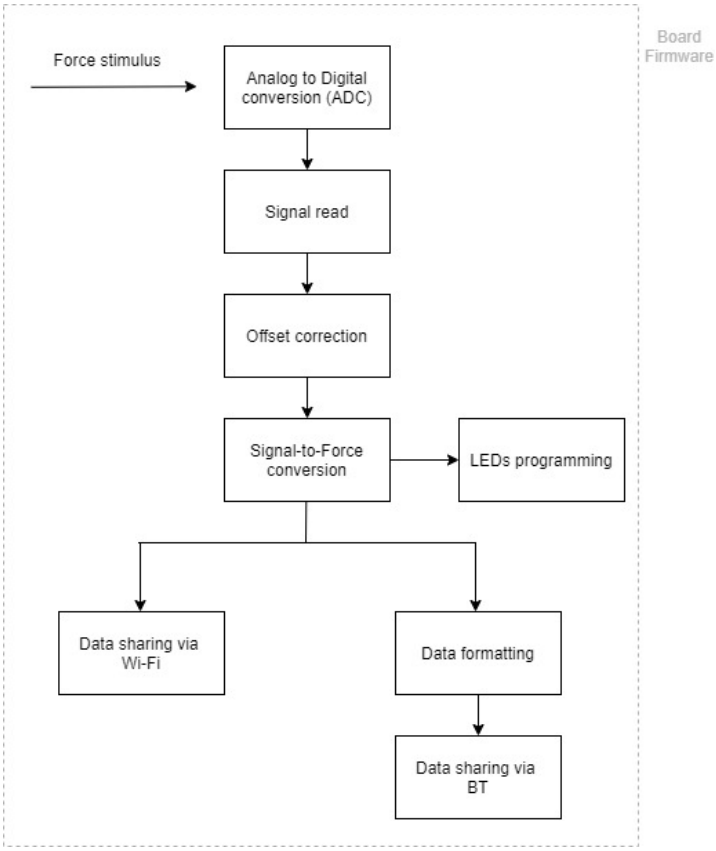


Figure 57: Firmware structure

The scheme defined above has been followed to implement board firmware. After declaring all the needed variables, setting up the board and collecting the analog data coming from the textile force sensors, a script has been implemented to correct input signal offset.

In order to correct this phenomenon, a “sensors calibration period” has been inserted during the first two seconds after the glove is worn and the program starts. During this period, the sum of the value

assumed by the sensors is collected and divided by the number of collected samples to determine the mean value at rest.

```
// Calibration of the sensors for the first two seconds after turning ON (to correct OFFSET)
if (millis() < caltime)
{
    indicetot = indicetot + indice;
    mediotot = medio + mediotot;
    pollicetot = pollice + pollicetot;
    arcotot= arco + arcotot;
    cont++;
}
else {

//Correction of the values
indice = indice - indicetot / cont;
if (indice < 0)
{
  indice = 0;
}
medio = medio - mediotot / cont;
if (medio < 0)
{
  medio = 0;
}
pollice = pollice - pollicetot / cont;
if (pollice < 0)
{
  pollice = 0;
}
arco = arco - arcotot / cont;
if (arco < 0)
{
  arco = 0;
}
```

Figure 58: Offset correction code.

This operation has to be performed to correct the offset that may be induced by the sensor stretch or by any movement that may affect the sensor when the hand is inside the glove. However, this is still not the optimized version of the code and limits such overflow and dynamical-correction still have to be solved. This could result in an error in the shown data, which could assume negative values, because the algorithm does not account for dynamical offset changes during the task.

```
//Force calculation for the different sensors

forzaindice = ((indice*invslope)+inter)*(gtoN);
forzapollice = ((pollice*invslope)+inter)*(gtoN);
forzamedio = ((medio*invslope)+inter)*(gtoN);
forzaarco = ((arco*invslope)+inter)*(gtoN);
```

Figure 59: Force calculation code

All the collected and corrected analog values have been converted into force measurement using experimental equation number 4. Here above (Figure 59), the code used to perform this operation has been shown.

From:

$$OS = 0.3418w + 25.161 \quad \text{(eq. 4)}$$

It is possible to derive:

$$F = \left(\frac{OS - 25.161}{0.3418}\right) * \frac{9.81}{1000}$$

Where:

- OS = Output signal
- w = weight (g)
- F = Force (N)

In addition, the connected mini LEDs have been programmed to modulate light brightness proportionally to the force value measured by the corresponding textile sensor. In order to do that, a PWM signal has been configured, following the code shown below. The ESP32 has a LED PWM controller with 16 independent channels that can be configured to generate PWM signals with different

properties. Here are the steps that have been followed to dim an LED with PWM using the Arduino IDE:

1. First, the PWM channel has been chosen. There are 16 channels from 0 to 15.
2. Then, the PWM signal frequency has been set. For an LED, a frequency of 5000 Hz is adequate to use.
3. In conclusion, the signal's duty cycle resolution has been set: it is possible to choose resolutions from 1 to 16 bits. For our application, 8-bit resolution has been used, which means that it is possible to control the LED brightness using a value from 0 to 255.

```
// setting PWM properties
const int freq = 5000;
const int ledChannel = 0;
const int resolution = 8;
const int ledChannel2 = 1;
const int ledChannel3 = 2;
const int ledChannel4 = 3;
```

Figure 60: PWM setup.

After matching the PWM channel with a corresponding GPIO, the portion of the code used to control LED light brightness has been implemented. As noticeable, brightness is modulated over 256 different levels of intensity (0-255), thus the force value has been mapped over these values too.

```
int pmap=map(valueP,0,350,0,255);
int imap=map(valueI,0,350,0,255);
int mmap=map(valueM,0,350,0,255);
int amap=map(valueA,0,350,0,255);
// changing the LED brightness with PWM
ledcWrite(ledChannel, pmap);
ledcWrite(ledChannel2, imap);
ledcWrite(ledChannel3, mmap);
ledcWrite(ledChannel4, amap);
```

Figure 61: LEDs control via PWM.

After completing the data collection, manipulation and filtering, the code to control the wireless communication while formatting the data to be sent from the E-glove to the receiving device has been added.

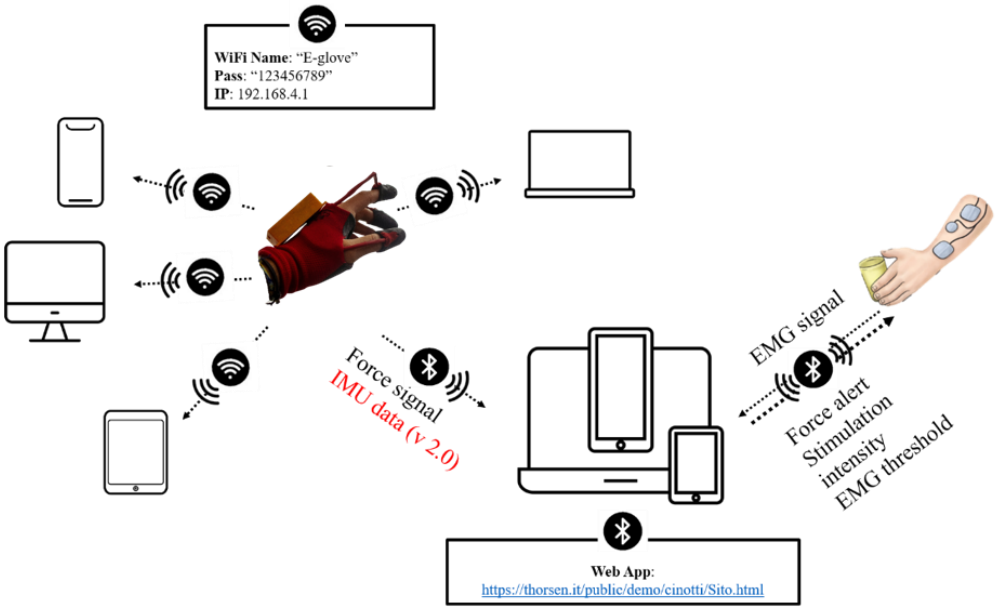


Figure 62: Communication architecture.

To correctly set up a BLE connection, it is first necessary to create a BLE server, generate a BLE Service and create one or more characteristics where the information to share could be written, read and notified, as shown in the image reported on the following page (Figure 63).

The top-level of the hierarchy is a profile, which is composed of one or more services. Usually, a BLE device contains more than one service. Every service includes at least one characteristic or can also reference other services. A service is simply a collection of information, like sensor readings, for example. There are predefined services for several types of data defined by the SIG (Bluetooth Special Interest Group) like Battery Level, Blood Pressure, Heart Rate, Weight Scale, etc.

At the bottom level of the hierarchy, there are characteristics. Here is where actual data is contained in the hierarchy (value). The characteristic always has two attributes: characteristic declaration (that provides metadata about the information) and the characteristic value. Additionally, the characteristic value can be followed by descriptors, which further expand on the characteristic declaration's metadata.

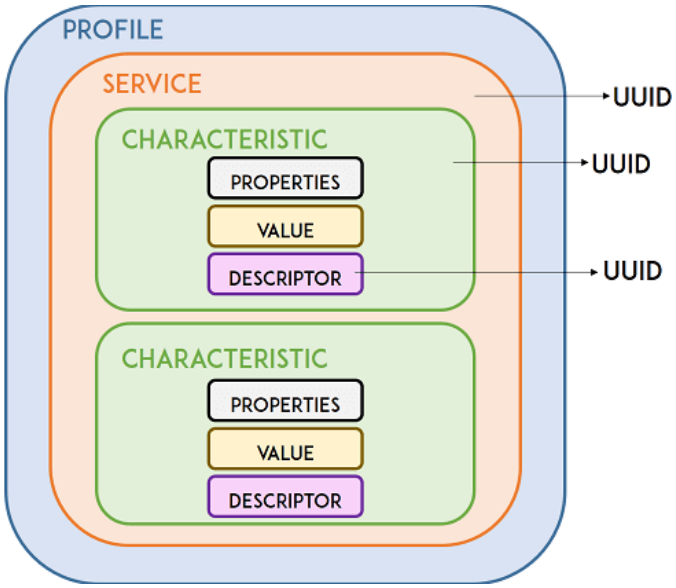


Figure 63: BLE Service structure

The properties contain the operations and procedures that can be used with the characteristic:

- Broadcast
- Read
- Write without response
- Write
- Notify
- Indicate

- Authenticated Signed Writes
- Extended Properties

Both Service, characteristic and descriptor is identified by a UUID (Universally Unique Identifier). A UUID is a unique 128-bit (16 bytes) number.

Thus, the UUIDs have firstly been declared in the board code, as shown in the image below.

```
#define ForceMeasurement BLEUUID("783b26f8-740d-4187-9603-82281d6d7e4f")
BLECharacteristic FICharacteristic(BLEUUID("1bfd9f18-ae1f-4bba-9fe9-0df611340195"),
BLECharacteristic::PROPERTY_READ  | BLECharacteristic::PROPERTY_WRITE  | BLECharacteristic::PROPERTY_NOTIFY);
BLEDescriptor FIDescriptor(BLEUUID("2f562183-0ca1-46be-abd6-48d0be28f83d"));
```

Figure 64: UUIDs declaration.

After that, the BLE service has been initialized, a new service dedicated to Force values measurement has been implemented and a characteristic has been added to the BLE server. This characteristic is write-only because the ESP32 board could only write it and no messages will be received on this characteristic.

After setting up all the components, coupling them with the correct UUID and adding the descriptor, the BLE service has been started and added to the other service composing the BLE profile of the board.

In addition, the BT device name has been changed into “E-glove” in order to make it easily recognizable by the clients (Figure 65).

```
void InitBLE() {
  BLEDevice::init("E-glove");
  // Create the BLE Server
  BLEServer *pServer = BLEDevice::createServer();
  pServer->setCallbacks(new MyServerCallbacks());

  // Create the BLE Service
  BLEService *pForce = pServer->createService(ForceMeasurement);


  pForce->addCharacteristic(&FICharacteristic);
  FIDescriptor.setValue("Valore Forza");
  FICharacteristic.addDescriptor(&FIDescriptor);
  FICharacteristic.addDescriptor(new BLE2902());


  /* ##################################################################  define callback */
  BLECharacteristic *pWriteCharacteristic = pForce->createCharacteristic(
                                        CHARACTERISTIC_UUID_RX_I,
                                        BLECharacteristic::PROPERTY_WRITE
                                      );

  pWriteCharacteristic->setCallbacks(new MyCallbacks());
  /* ################################################################## */



  pServer->getAdvertising()->addServiceUUID(ForceMeasurement);

  pForce->start();
  // Start advertising
  pServer->getAdvertising()->start();
}
```

Figure 65: BLE initialization.

After initializing BLE communication, a portion of the code dedicated to data formatting and characteristic value update has been implemented to guarantee a continuous exchange of information whenever a client gets connected to the BLE.

To guarantee the correct deliverability of the message, the information has been stored on a string of 20 characters, separated by commas.

Thus, data has been formatted to create a string of 20 characters to be sent to the connected device. In order to furtherly reduce the number of characters, the float force values have been transformed into

integer values by multiplying them by one hundred. Hereunder has been reported the code (Figure 66) and the data scheme (TABLE VII) that has been used to codify the information.

```
int fpint= fp*100;
int fiint= fi*100;
int faint= fa*100;
int fmint= fm*100;

char invio[20];
sprintf( invio, "%d,%d,%d,%d\n", fpint, fiint, faint, fmint );
```

Figure 66: Arduino code for data formatting

Data have been formatted using a CSV structured in order to simplify data splicing on the web app.

Whenever the web application collects data, they are comma-split and brought back to their original shape.

TABLE VII: STRING FORMATTING[12]

Fi	Fi	Fi	Fi	,	Fp	Fp	Fp	Fp	,	Fm	Fm	Fm	Fm	,	Fa	Fa	Fa	Fa	/

After concluding the data-formatting phase, the characteristic value is updated and the string is sent to the client by notifying him of a change in the value of the characteristic itself. The result is reached by using the code shown in the next figure (Figure 67).

In order to reduce energy consumption, data are sent only when an active client is connected to the BT terminal. A 20ms delay has been added between consecutive communications because this delay has revealed to be the smallest compatible with the refreshing speed on the different web browsers guaranteeing a smoother communication between the connected devices.

[12] *Fi = "Forza indice", Index force – Fp = "Forza pollice", Thumb force – Fm = "Forza medio", Middle finger force – Fa = "Forza arco", Arch force.*

```
if (_BLEClientConnected){
  char invio[20];
  sprintf( invio, "%d,%d,%d,%d\n", fpint, fiint, faint, fmint );
  FICharacteristic.setValue(invio);
  FICharacteristic.notify();
  delay(20);
}
```

Figure 67: Data transfer via BLE.

On the other hand, the final version of the E-glove also supports a Wi-fi connection to guarantee full accessibility of the results, even with the absence of an internet connection. The ESP32 board has been programmed in order to work as a soft access point (hotspot) to be able to set up its Wi-Fi and to communicate the data of interest with the connected clients.

By setting the ESP32 as an access point (hotspot), you can be connected to the ESP32 using any device with Wi-Fi capabilities without the need to connect to your router.

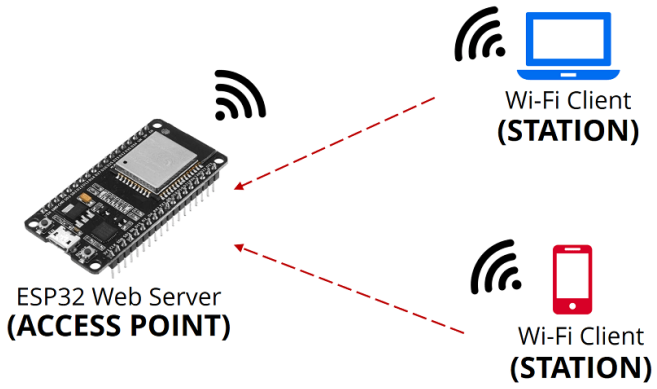


Figure 68: Soft-AP mode.

In simple words, when ESP32 is settled as an access point, it creates its Wi-Fi network and nearby Wi-Fi devices (stations) can connect to it.

To configure the E-glove to support this feature, additional code has been added to the board. First of all, the SSID name and password to access the ESP32 have been settled as shown in Figure 69.

```
// Network credentials
const char* ssid     = "E-glove";
const char* password = "123456789";
```

Figure 69: Network credentials.

After this, the ESP32 board has been configured in SoftAP mode by inserting the following code in the setup () section of the uploaded sketch. Network credentials have been defined, IP address has been determined and communication has been initiated.

```
Serial.print("Setting AP (Access Point)…");
// Remove the password parameter, if you want the AP (Access Point) to be open
WiFi.softAP(ssid, password);

IPAddress IP = WiFi.softAPIP();
Serial.print("AP IP address: ");
Serial.println(IP);

Serial.println(WiFi.localIP());
```

Figure 70: Soft-AP setup.

```
// Route for root / web page
server.on("/", HTTP_GET, [](AsyncWebServerRequest *request){
  request->send_P(200, "text/html", index_html, processor);
});

server.on("/thumb", HTTP_GET, [](AsyncWebServerRequest *request){
  request->send_P(200, "text/plain", String(fp).c_str());
});
server.on("/index", HTTP_GET, [](AsyncWebServerRequest *request){
  request->send_P(200, "text/plain", String(fi).c_str());
});
server.on("/middle", HTTP_GET, [](AsyncWebServerRequest *request){
  request->send_P(200, "text/plain", String(fa).c_str());
});
server.on("/arch", HTTP_GET, [](AsyncWebServerRequest *request){
  request->send_P(200, "text/plain", String(fm).c_str());
});
// Start server
server.begin();
```

Figure 71: Route for web page.

To complete the communication architecture, data-sharing via Wi-Fi has been set up by associating the received request from the webserver to the delivered data response as in Figure 71.

Whenever a client connects to the created Wi-Fi, by visiting the page http://192.168.4.1/, it is allowed to visualize the force sensor values measured finger by finger (Figure 72).

No internet connection is required to access and visualize data, configuring the device to a wide variety of different applications. The web page where data are visualized is hosted on the board itself, embedded in the Arduino code. Data are refreshed every 50ms, a time delay chosen in order to guarantee compatibility and fluidity of data sharing on the most common web browser (Chrome, Firefox, Safari, etc.).

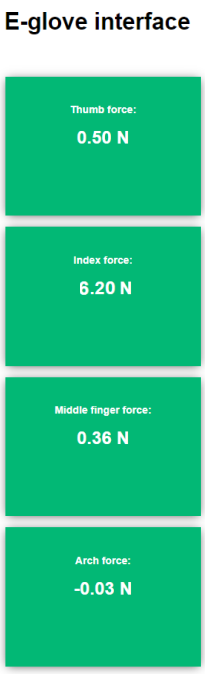


Figure 72: Wi-Fi accessible web page

(Arch force value negative because offset algorithm does not account for dynamical offset changes).

TABLE VIII: WIFI APPLICATION COMPATIBILITY

Wi-Fi application

(http://192.168.4.1)

Operative system	Web browser	Version	Compatibility	Devices
Windows 10	Chrome	86.0.4240.75 (64-bit)	✓	Desktop
	Microsoft Edge	44.18362.449.0	✓	Desktop
	Firefox	81.0.2 (64 bit)	✓	Desktop
	Opera	68	✓	Desktop
Linux	Chrome	85	✓	Desktop
iOS	Safari	13.6.1	✓	Desktop, Tablet, Mobile
Android 10	Chrome	86.0.4240.99	✓	Tablet, Mobile
	Firefox	81.1.4	✓	Tablet, Mobile
	Huawei Browser	11.0.2.303	✓	Tablet, Mobile
	Opera	60.2.3004.55409	✓	Tablet, Mobile

In conclusion, as described in the “Methods” section, the read signal by each sensor has been tested. Firstly, each force sensor signal has been analyzed singularly (Figure 73). The obtained signal is clear and timely in detecting interaction events and the force of interaction for each sensor position without remarkable delays, confirming the literature results (74,108). As noticeable, force spikes are recognizable, force is stable when the stimulus is maintained over time, and the recorded measurements are not affected by noise. Cross-talk events can not be observed.

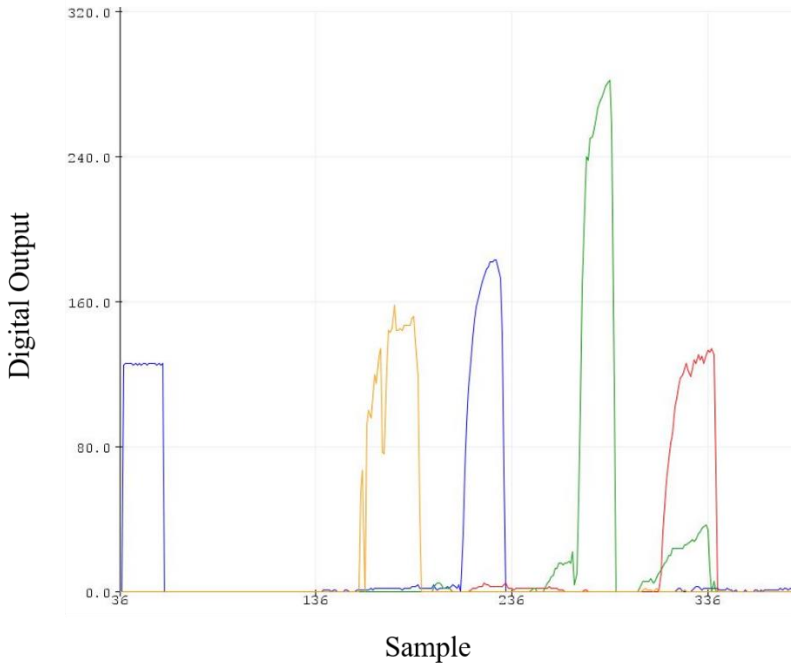


Figure 73: Measured signal for singular interactions[13]

In the second image (Figure 74), it is possible to observe the recorded signal during the grasping and holding task of a bottle. This test has been performed to evaluate sensors' behavior when working together on a life-situation job. The correctness of sensor recruitment during grasping tasks and the independence between the different measurements have been investigated.

As noticeable from the graph, after the approaching phase, the targeted bottle is firstly touched by the arch, in green, followed by the index and the thumb that contribute to sustain the weight of the bottle, guiding it in the desired movement. During this second phase, the arch is not in contact with the bottle and so its contribution is negligible and the applied force on the sensor is null. Index and Thumb are highly involved during the task and after the grasping action is completed, forces expressed by these two fingers and the middle finger remain stable during the holding phase.

[13] *Yellow = Thumb, Blue = Index, Green = Arch, Red = Middle finger*

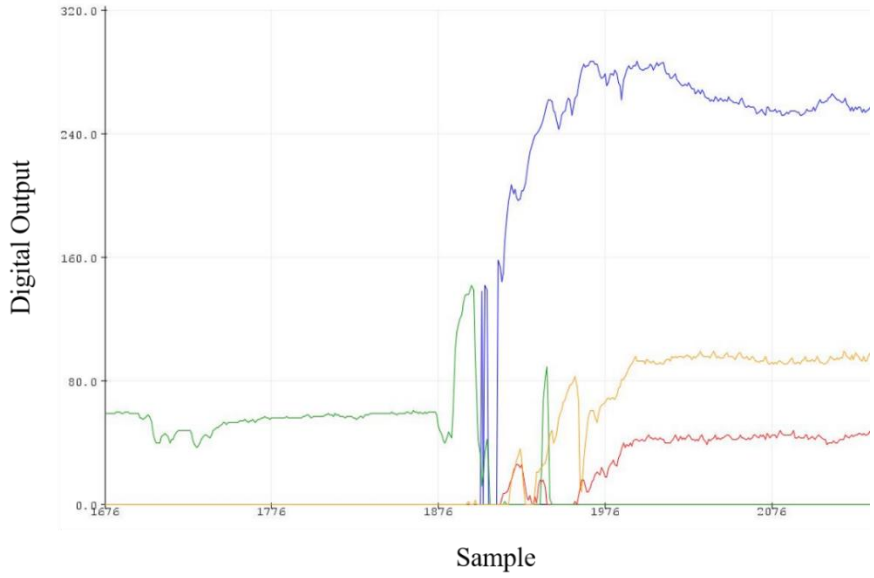


Figure 74: Measured signal during bottle grasp task[14]

5.3.2 Desktop GUI

The reported screenshot (Figure 75) illustrates the desktop application interface as would be presented to the therapist.

As UX guidelines suggest (80), the user interface has been taken as simple as possible but useful in showing the primary information of interest to the user is provided. On the center-left of the screen, the glove has been shown with a visual representation of the sensor collocation. In particular, some signal-responsive icons that can tune their color and dimension depending on the value of the force recorded by the corresponding sensor on the hand have been inserted, thus making a stronger impression on the clinician than a simple number that indicates the applied force.

On the right-hand side, the more technical data have been reported and the interface reveals the values that have been collected for the applied force. In particular, all these force values are expressed in Newton

[14] *Yellow = Thumb, Blue = Index, Green = Arch, Red = Middle finger*

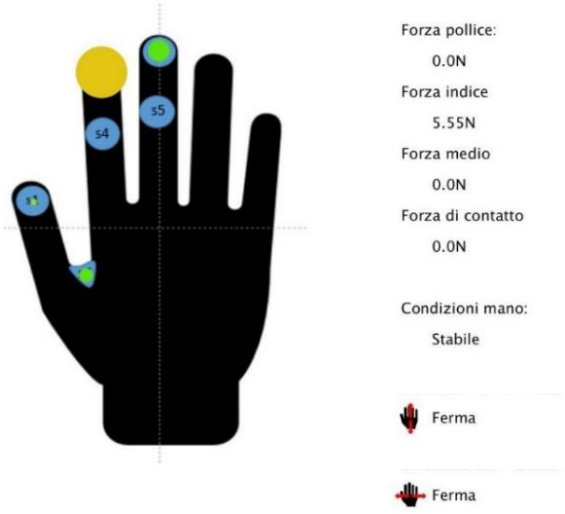


Figure 75: Processing GUI.

In conclusion, some additional functionalities that could become interesting whenever an IMU will be integrated into the e-glove hardware to track hand movement during the task have been integrated.

In particular, "*Condizioni mano*" will be used to indicate it the hand is stable, shaking or moving toward the target, whereas the icons may help to track the movement of the hand during the task, defining the anteroposterior (AP) and mediolateral (ML) accelerations, to evaluate the ability to address the target and reach it performing a complete and correct approach movement.

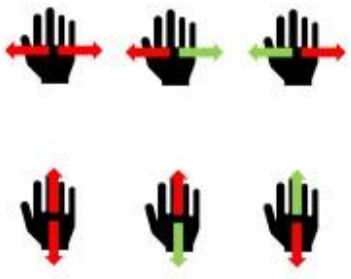


Figure 76: Icons from the GUI.

5.3.3 Web application

The created web application is hosted on a web server (https://thorsen.it/public/demo/cinotti/Sito.html), readily accessible by connecting via browser (Chrome, Opera) and it could be modified quicker and remotely if updates are needed.

The website structure includes the code for the GUI and communication with the device, but also a more didactic section with an explanation of the working principles at the basis of MeCFES and E-gloves and some advice about the correct way to use them.

Web application: Our mission

The opening section of the website is dedicated to the definition of the main goals of the devices and it has been divided into two main parts. In the first part, it might be noticed an in-depth description of the devices' aims, whereas, in the second part, these tools' characteristics are shown in four main points.

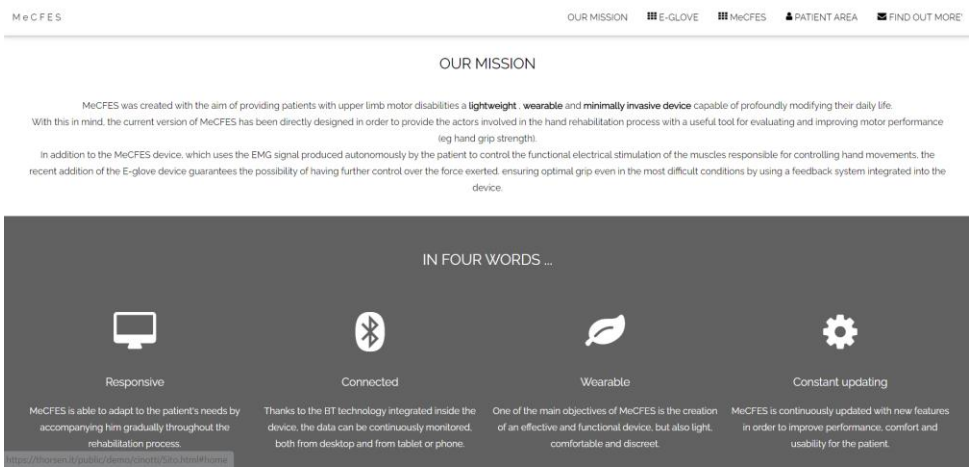


Figure 77: "Our mission" section website

The main goal of this section is to transmit the idea of easy-to-use, wearable, efficient tools that could help patients improving their rehabilitation results while minimizing the impact on their freedom and their everyday life.

Web application: E-glove

The front page of the website also gives access to the web-app that has been built for the E-glove devices.

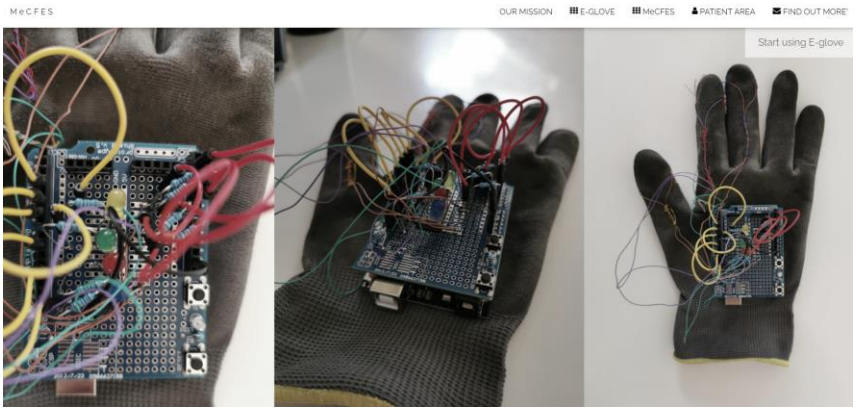


Figure 78: "E-glove" section website

As noticeable from Figure 79, the E-glove web BT app has been implemented following the same model of the desktop GUI. The force exerted by the fingers is shown both in numbers and in their graphical representation. Moreover, to prepare the device for its 2.0 version, the IMU information is ready to be shown, describing hand stability during the task and quantifying the mediolateral (ML) and anteroposterior (AP) acceleration during the grasping activity.

The connection button has been added to the page in order to guarantee the possibility to connect the E-glove to the personal device the clinician is using. As observable, the device is recognizable from the given name “E-glove” during pairing.

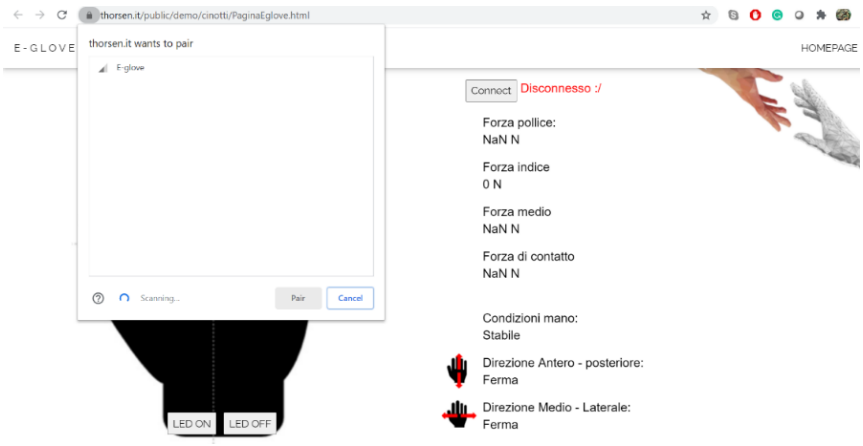


Figure 79: E-glove control section website

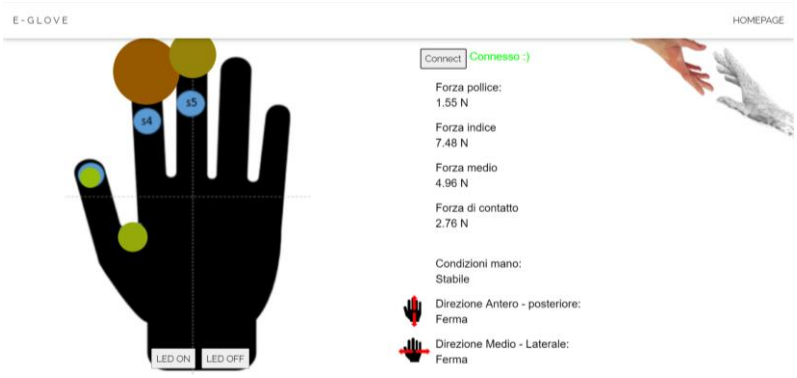


Figure 80: E-glove control section during use

As highlighted in the image above (Figure 80), when active, the E-glove can show all the patient's performance features, used for rehabilitation purposes.

In particular, this tool might be employed to highlight the force of contact and the stability of the contact, but also the presence of the contact itself, replicating what it has just been done with other cable-needing gloves (109,110) used for functional evaluation and rehabilitation purposes.

Web application: Discover E-glove

To guarantee the continuous development of this platform and the E-glove device, all the project information has been decided shared: codes, electronic topographies and a series of detailed guides about the exact steps to replicate the same device have been shared with the public. Public knowledge could stimulate a more significant change and a more leisurely development of the project itself.

Figure 81: Discover E-glove.

By creating an active community working on this project, sharing their developments and upgrades, refining some of the device's features and upgrading code efficiency, it could be possible to project a obtain a better device over any aspect. Sharing is the key because a shared idea could be the scum that leads to a technological revolution

Web application: MeCFES

Similar to what has been presented for the E-glove app, a web interface has been realized for the MeCFES tool . This section has been dedicated to the description of the working principle of MeCFES and its main advantages with respect to other techniques, as shown in Figure 84.

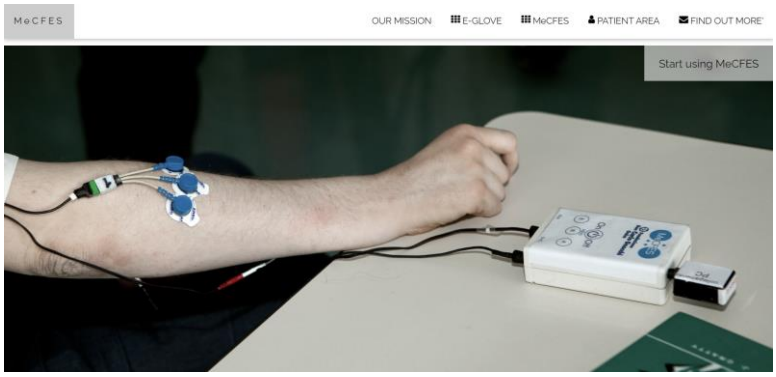


Figure 82: "MeCFES" section website.

It groups all the information that has been collected in the past years working on the MeCFES device, comprehending all the publications that could be significant to understand its working principles.

Moreover, a descriptive division about electrodes choice and placement has been inserted, describing how electrodes work and how they have to be placed in order to let MeCFES performing at its best.

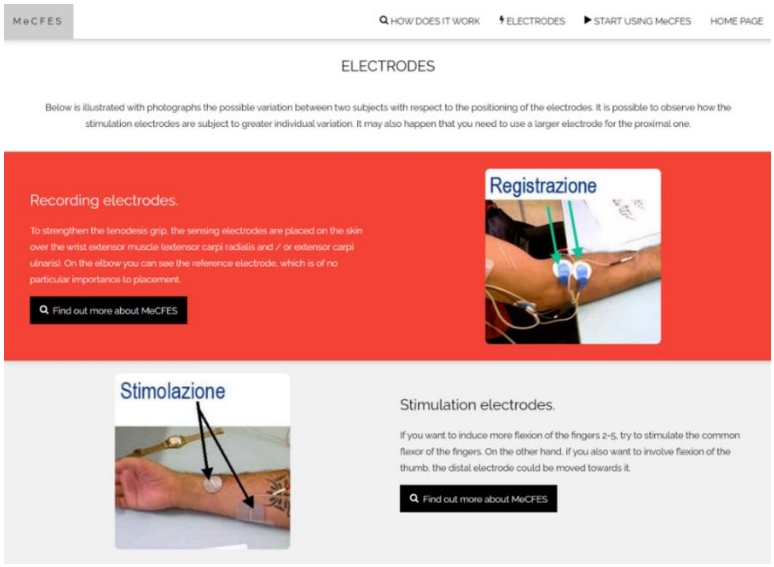


Figure 83: "Electrodes" section MeCFES website

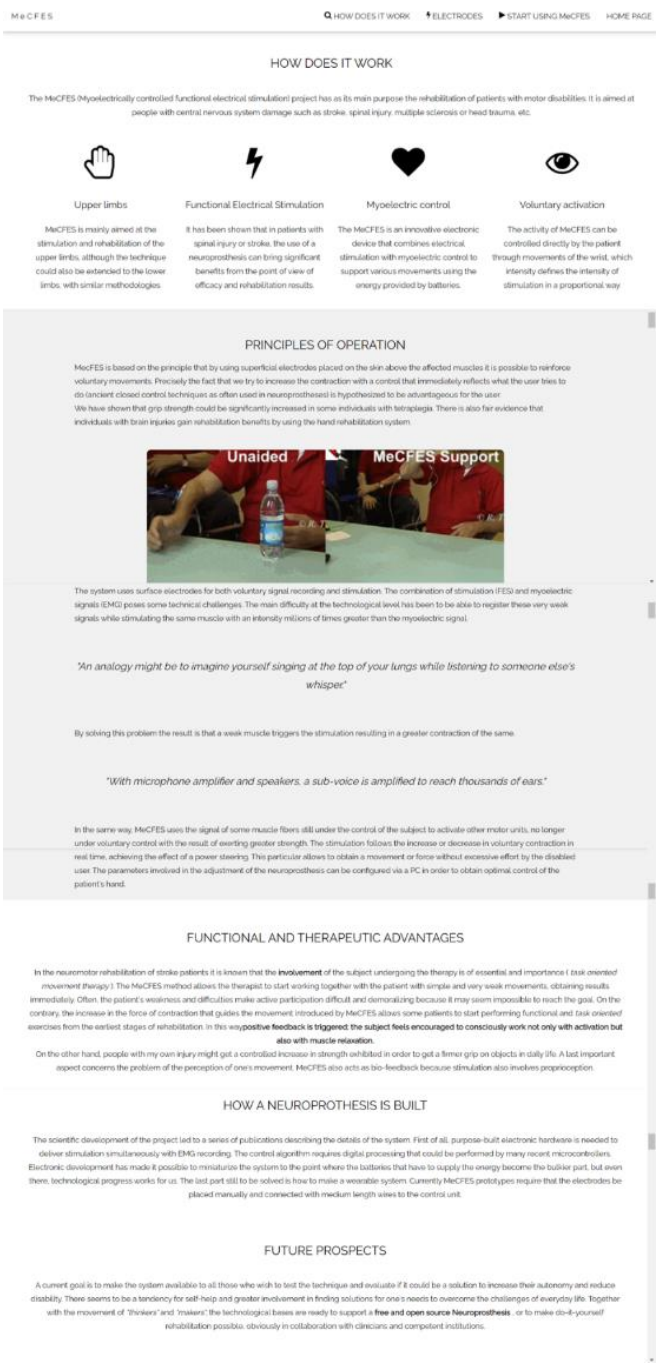


Figure 84: "How does it work" section MeCFES website

The MeCFES page is closed by the access panel to the device-controlling software that will be used to read data and control the system. This application is still under development. It will be able to read and show the EMG data coming from the arm, allowing the user to customize some parameters of the stimulation, such as stimulation intensity and power threshold for the automatic regulation via EMG activity.

Web application: Patient area

In addition, a section dedicated to telemedicine and communication between clinicians and patients has been inserted. This part has not been developed yet.

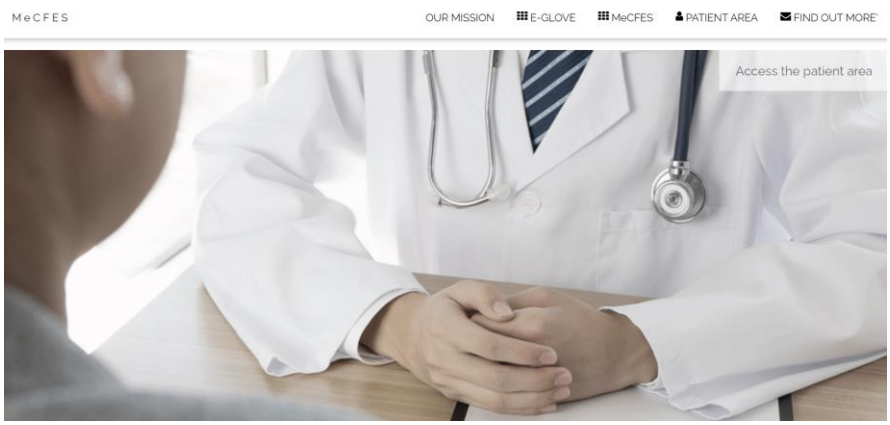


Figure 85: "Patient area" section website

This support platform has been thought to support patient domestic rehabilitation, allowing direct sharing of rehabilitation performance parameters with the clinician. Patients can directly update and share their daily results and improvements, tracking their progress and exchanging additional comments/opinions/material with the clinician itself. On the other hand, this system could also be used during rehabilitations session physically held by the therapists as it might allow the clinician to save

patient preferences on stimulation parameters, keep a record of previous session activities and results and even provide an automatic highlight of potentially significant elements using AI.

Web application: Find out more

The “Find out more” section closed the front page with additional information about the project, publications, participants and development history of the devices, including photos and videos of their performances.

A contact section with all the communication information, the lab location, and a contact form has been inserted to allow potentially interested people to contact the research group with doubts or purposes.

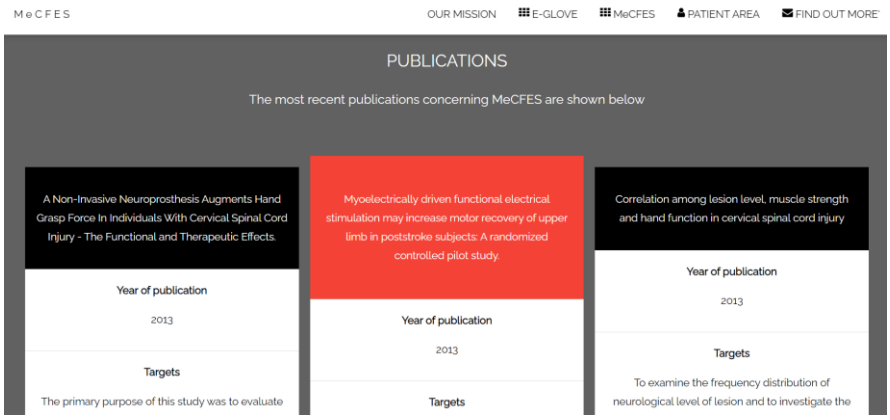


Figure 86: "Find out more" section website

Web application: Compatibility

Web BT app compatibility with the most common web browser has been checked, obtaining the following results (TABLE IX).

TABLE IX: WEB BT APPLICATION COMPATIBILITY

Web BT application

(https://thorsen.it/public/demo/egloveweb/webbluetooth.html)

Operative system	Web browser	Version	Compatibility	Devices
Windows 10	Chrome	86.0.4240.75 (64-bit)	✓	Desktop
	Microsoft Edge	44.18362.449.0	×	Desktop
	Firefox	81.0.2 (64 bit)	×	Desktop
	Opera	68	×	Desktop
Linux	Chrome	85	✓*	Desktop
iOS	Safari	13.6.1	×	Desktop, Tablet, Mobile
Android 10	Chrome	86.0.4240.99	✓	Tablet, Mobile
	Firefox	81.1.4	×	Tablet, Mobile
	Huawei Browser	11.0.2.303	×	Tablet, Mobile
	Opera	60.2.3004.55409	✓	Tablet, Mobile

*Require developer mode activation

5.4 Clinical applicability

A total of 12 people have completed the questionnaire, 9 engineers, 2 therapists and 1 doctor.

Considering the twelve submitted the questionnaire, the obtained results and the collected oral opinions have been positive and both therapists (n=2) and doctors (n=1) from Don Gnocchi hospital (n=1) and Niguarda spinal unit (n=2) have expressed their interest in clinical validation of the device.

In addition, collected results and oral opinions have helped to highlight the main pros and cons of the device: stability, safety, comfort and durability of the device have been defined as the most critical aspects with a grade slightly under 4/5, while all the other investigated features of the E-glove have registered a mean mark above 4/5, with an overall index of satisfaction of 4.5/5.

In particular, some of the glove features have impressed the clinicians: LEDs presence and automatic light adjusting, wireless connectivity, user-friendly application and ease of use have been defined from the interviewed population as the most interesting features of the implemented E-glove and one of the main factors that could induce them to choose the implemented solution instead of a commercially-available alternative.

Doctors and therapists have also suggested a series of modifications and further developments of the device that have to be considered when looking at the next updates of E-glove.

In their opinion, the device structure could be modified to make it more feasible also for patients showing hand deformation. However, a series of visual games that use E-glove data to trigger game action to increase patient psychological involvement in therapy should also be implemented. All these suggestions might be a good starting point in order to define the next steps of project development.

The complete results obtained in the submitted questionnaires have been reported in the following table (TABLE X).

TABLE X: QUESTIONNAIRE ANSWERS

Question	Answer
Did the presentation arouse interest in the device?	YES (100%)
Would you be interested in testing the device?	YES (100%)
What are the aspects that interest you most?	Ease of use, connectivity, integration with MeCFES, LEDs function, Applications
What are the elements that should be further improved?	E-glove box positioning, Visual game implementation.
Overall opinion on the device	4.5/5
QUEST: Dimensions (height, length, width, etc ...) of the aid	4.1/5
QUEST: Ease of adjustment (assembly, fixing, etc.) of the aid	3.8/5
QUEST: Stability and safety of the aid	3.6/5
QUEST: Durability (solidity, resistance, etc.) of the aid	3.7/5
QUEST: Ease of use of the aid	3.9/5
QUEST: Convenience (comfort) of the aid	3.7/5
QUEST: Effectiveness of your aid (how much it meets your needs)	3.9/5
Overall opinion on the features offered by the device	4.2/5
OPTIONAL: Aid evaluation: Connectivity	4.4/5
OPTIONAL:	4.6/5

Aid evaluation: Web applications	
OPTIONAL: Aid evaluation: Versatility	4.4/5
OPTIONAL: How important is the possibility of using a wireless device for you?	4.7/5
OPTIONAL: How important do you think the small footprint can be in ensuring greater patient comfort?	4.4/5
OPTIONAL: How important is the possibility for you to be able to access data from your device directly without the need to download specific apps or programs?	4.2/5
OPTIONAL: Do you think the device could be useful for the purposes for which it was designed?	YES (100%)
OPTIONAL: If E-glove were currently available, would you recommend it to other therapists?	YES (100%)
OPTIONAL: In what applications of functional assessment and motor rehabilitation could it be useful?	Functional test, Validation of clinical scales. Learning work - Perfetti method. Stroke, MS, SCI
OPTIONAL: Indicatively for how many patients could it be used?	5-10yr, thousands, post-stroke, SCI, rheumatoid arthritis, post-surgery rehabilitation after fracture
OPTIONAL: What could be, in your opinion, the economic value of a device like E-glove?	150€, in-depth use needed

CHAPTER 6

DISCUSSION AND CONCLUSION

As specified in the Introduction to this work, the main aim of the experiment was to perform a feasibility study about a rehabilitation aid able to monitor the exerted force during a grasping task with possible clinical application in the rehabilitation of patients suffering from neurologic hand. In particular, the projected solution was required to be a lightweight, wearable and wireless device that could be worn by the clinical subjects without affecting their freedom of movement.

In addition, the designed solution has to be compatible with a pre-existing functional electrical stimulation (FES) device helping to optimize stimulation parameters in order to achieve constant force values depending on the interaction between hand and the targeted object.

Figure 87: E-glove

The proposed work has investigated the feasibility, features and potential critical aspects of this application. The produced device has confirmed the potential efficacy of a wearable device designed for hand force monitoring dedicated to rehabilitation, also attracting a consistent interest from potential users from Fondazione Don Gnocchi and Niguarda Hospital in Milan.

The handcrafted *textile force sensors* have demonstrated their consistency and their ability to substitute commercially available FSR. They have shown similar technical properties, 3% hysteresis and <3%/h signal drift, good thermal stability in a typical human working environment (2-32ºC) and an optimal sensibility of 0.05N, eight-time smaller than commercially available FSR and better for our applications where forces are minimal.

Moreover, in-spite of the non-linearity of the analyzed system, a linear model to describe sensor force-conductance has been proven not negligible. The observed nonlinearity is probably linked with the non-linear behavior of the stretchy conductive fabric and it deserves to be further explored in the future.

Bottle grasping test (Figure 74) has demonstrated the practical ability of the e-glove to measure the force developed during a real life-experienced action. When integrated inside the E-glove, all the sensors' contributions are correctly read during the task and the correctness of the grasping pathway can be assessed by retrieving the signal measured by this glove.

On the other hand, the integrated *mini LEDs* have been appreciated by clinicians because of their efficiency for a qualitative, real-time and intuitive visualization of the force measured by the sensors. On one side, their presence could be helpful for therapists to identify hand areas recruited during grasp and their influence on the final action. On the other side, they could help the patient to visualize the force physically he/she is able to exert and to track his/her improvements during the rehabilitation process. This could induce positive psychological responses in the subject triggering an increased desire to achieve the wished objective, thus, increasing rehabilitation outputs

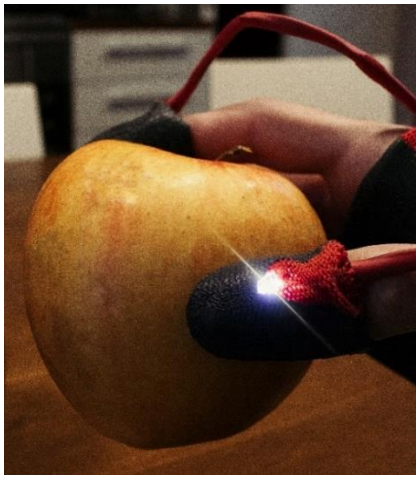


Figure 88: E-glove integrated LEDs.

In addition, the support *E-glove box* has demonstrated its efficacy in preserving electronics components, but it has also been criticized because of its dimensions and position on the superior part of the hand. However, the structure of the element could be easily modified and a new solution could be implemented quickly in order to satisfy clinicians' needs.

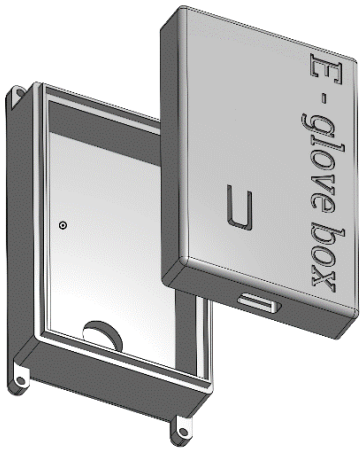


Figure 89: E-glove box.

To conclude, the E-glove *connection architecture* has proven its ability to respond to doctors' and therapists' needs, allowing them to visualize data in almost any condition.

On one hand, the implemented web BT solution will enable users to access measured data via BT, read force values, visualize their graphical representation and connect E-glove with other BT-equipped devices such as MeCFES. On the other hand, the Wi-Fi app allows E-glove to create an accessible Wi-Fi hotspot, hosting up to four connected devices simultaneously, where real-time force values measured by the sensors are readily available and no internet connection is needed to visualize them. In addition, this solution guarantees full compatibility with any portable device or desktop web browser contributing to compensate the limits of the web Bluetooth application, only available on Chrome and Opera web browsers.

In parallel, the created *website* has helped to spread knowledge about the technical basis and operating principles of the implemented device also involving therapists and patients in the comprehension of the characteristics of the tool they are using. It has also been decided to implement a web repository where all the information about product realization, utilized code sketches, 3D CAD projects and useful libraries along with some Italian and English complete guides describing how the device could be successfully replicated have been reported to allow anyone to contribute to future developments of the project.

In conclusion, interviewed doctors and therapists from Fondazione Don Gnocchi and Niguarda Hospital in Milan have confirmed the *clinical applicability* of the device revealing a genuine interest in the device, its future developments and its possible clinical applications. In particular, E-glove, which has obtained an overall mark of 4.2/5 on the QUEST scale, has been indicated by clinicians as an interesting tool also for application in the functional evaluation field, for validation of clinical scales, but also "Perfetti" method and applications in combination with MeCFES. These suggestions have revealed a series of additional areas of interest of the device not considered as primary applications in the

embryonal stages of the project, confirming the extreme versatility and the potential efficacy of this device.

8.1 Main limits and future developments

8.1.1 Force sensors

Despite the shown technical performances, the textile force sensors are still limited by a series of drawbacks like a difficulty to replicate the same procedure serially and the absence of in-depth analysis regarding durability, responsivity and force resolution. Starting from these limits, it could be possible, in future studies, to furtherly *assess sensor properties* to complete their characterization.

In addition, it could also be interesting to investigate the possibility to *miniaturize* the sensor or to modify its shape in order to adapt them to the finger pad. In conclusion, in Ch. 2, several innovative alternatives have been present. It could be interesting to analyze the possibility of using them to *substitute the textile force sensors*.

8.1.2 Hardware

Like the textile force sensors, also the hardware of the e-glove could be further improved in the future. For example, it will be possible to *integrate an IMU* on the board to track cinematic of hand movement and evaluate grasp stability or the presence of tremors. In addition, in order to improve the comfort of the device and its functionality, it might be interesting to *reduce its size* furtherly and to *change the glove shape*. People with neurologic hand usually find it difficult to wear a standard glove because of joint rigidity, thus it could be useful to implement a customizable “open” version of the glove that minimize the glove fabric, allowing to wear each single finger sensor separately and keeping all the electronics on a bracelet fixed on the wrist. Figure 90 shows a possible version of the final glove design.

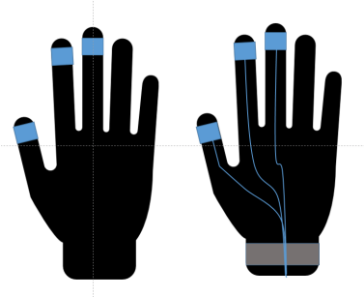


Figure 90: Possible final glove design

8.1.3 Software

Despite the excellent results in terms of software properties, there still exist a series of limits and defects in the used sketches. These limits are linked to the fact that the main aim of this project was to realize a feasibility study and, therefore, all the user codes have to be optimized to guarantee the best properties possible.

Starting from the *code running on the ESP32 board*, the implemented code's primary limits are linked with high power consumption, mainly related to ESP32 board characteristics and LEDs brightness control, and a reducible ADC error. An architecture for IMU signal reading and processing has to be created to guarantee the development of version 2.0 of the E-glove.

In addition, it would be preferable to realize a single characteristic for each force value to avoid value saturation problems that could happen if using the single characteristic technique presented in the previous sections.

When looking at further development of the E-glove User interface, it may be interesting to add multiple windows where it is possible to singularly observe the behavior, in terms of perceived force and analog-recorded signal, of every single finger. Moreover, to study the frequency of contact of each finger and its correlation with the FES pads placement, it could be interesting to do and show some statistical analysis of the obtained result, both dynamically and after the end of the rehabilitation session.

Moreover, also the *web BT* application could be further developed in order to guarantee the possibility to read multiple characteristics and to handle multiple notifications at the same client.

Unfortunately, web Bluetooth applications are rare and this field is still under development, but an additional effort could guarantee even better results and the design of a more performant solution could be implemented.

In particular, as shown in TABLE X, web Bluetooth is today compatible only with a reduced number of web browsers, Chrome and Opera in particular, and this could reduce the usability of the device itself.

However, the implemented Wi-Fi application could represent a valuable alternative to solve this compatibility issue, but it is not the final solution because part of the app functionalities is only available on the BT app.

Even when looking at the created website, there are still some sections that have to be completed: "*Patient area*" is an interesting idea, but it has to be further developed in order to bring telemedicine inside a field, like the rehabilitation one, where physical contact between therapist and patient is everything. However, this solution could still be valid and successful to extend the rehabilitation exercises period over the once-a-week routine appointment between patients and clinicians.

By bringing home the device, the patient could exercise at home extending rehabilitation potentialities and the patient area platform could offer additional contact between the patient and the therapist to exchange opinions and data about the obtained results.

Rehabilitation is based on the repetition of movement and this is the main reason why a full development of this solution could positively revolutionize rehabilitation output.

Moreover, the page dedicated to *MeCFES control* has to be completed, in order to create a user-friendly, customizable, complete and straightforward application, giving the therapist all the needed instruments to optimize the therapeutic process and creating a communication platform that could be an inspiration to future wireless devices.

8.1.4 Additional developments

An additional upgrade could come from a more *"technical" analysis and design* of all the device aspects. In fact, due to the pandemic events, the device has been created at home using an instrument that could be easily substituted by better performing alternatives when working in a dedicated environment. Therefore, all the tests on force sensors, the chosen electronic components, the fabric used to create the current version of E-glove could be furtherly developed in order to obtain a more "commercial-like" device.

To conclude, it could be interesting to evaluate the possibility of integrating MeCFES and E-glove abilities with a third instrument, a *wearable matrix of electrodes* programmed to automatically determine the correct stimulation areas based on the "observed" output that could be objectively measured thanks to the integrated E-glove.

The developed tool will be similar to the Fesia Grasp device (11). However, it will not run an automatic stimulation path as happens in the actual version of the cited device, but only a patient-based stimulation path that will automatically adapt to patient anatomy, solving one of the main problems of the existing version of MeCFES: electrode placements.

Nevertheless, the obtained results are a good starting point in order to create a clinically useful device that could help to increase the output of the rehabilitation process of the neurologic hand.

The obtained feasibility results, the created communication architecture and the collected therapist opinions are consistent proofs that the chosen direction could pay the way for a series of significant clinical applications of this work, improving the final efficacy of hand rehabilitation.

There is still a lot to do, think and create, but the traced road has demonstrated to be the right one.

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