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A graphical user interface for a hybrid FES robotic exoskeleton for walking: design and usability evaluation

Tesi di Laurea Magistrale in
Biomedical Engineering - Ingegneria Biomedica

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Abstract: According to a report published by the World Health Organisation (WHO) [23] in 2013, each year between 250 and 500 thousand people suffer a Spinal Cord Injury (SCI). This pathology causes a loss of sensation and/or muscle function below the injury level, leading then to everyday social problems. This results in the necessity to develop rehabilitation treatments that aim to restore the lost functionalities, especially related to deambulation. Currently, standard treatments for SCI people are based on exercises for maintaining limbs mobility carried out by therapists or caregivers. However, the patient plays a passive role throughout the whole exercise execution, which makes the rehabilitation less effective. For this reason, alternative rehabilitation techniques to conventional ones have been proposed: Robotic Rehabilitation and Functional Electrical Stimulation (FES). The former uses robotic devices to assist therapists during rehabilitation sessions and to enable an intense and repetitive training. The latter induces artificial muscular contraction by delivering electrical pulses. In particular, what has gained interest in recent years is the possibility to integrate these two technologies is a single device, thus called hybrid. The advantages of these systems are the active role of the patient enabled by the electrical stimulation of his muscles and the possibility to prolong rehabilitative sessions thanks to the support provided by the exoskeleton. The main focus of this thesis work concerns the development of a Graphical User Interface (GUI) to assist therapists for a correct execution and assessment of rehabilitation treatments with an hybrid device. Indeed, hybrid systems are complex devices that handle a huge amount of data and set different parameters; then, the development of a user-friendly, intuitive and effortless GUI plays a crucial role for the correct delivery of the therapy. Several requirements for the GUI has been defined and empirically tested. Moreover, application's usability has been evaluated on 10 biomedical engineers and 7 therapists using SUS and *ad hoc* questionnaires. The analysis demonstrated that the user-friendly purpose was properly satisfied, both for engineers and therapists.

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1. Introduction

A Spinal Cord Injury (SCI) is a damage to the spinal cord, usually due to a trauma (e.g. fall) or a disease (e.g. cancer), causing a loss of sensations and/or muscle functions below the injury level. Thus, the SCI severity depends on the level of the spinal cord affected by the traumatic event: the higher the level, the larger the impairment of the patient. If the lesion occurs at the cervical vertebrae, the consequence is the tetraplegia (paralysis of both upper and lower limbs); if the lesion occurs at the thorax vertebrae, the consequence is the paraplegia (paralysis of the lower limbs). A method to quantify qualitatively the severity of the lesion is to use the Ashworth Scale, which is a clinical scale that evaluates muscular spasticity with a grade from 0 (low severity) to 4 (high severity) according to the resistance that muscle actuates as result to passive mobility. Furthermore, secondary debilitating conditions due to the immobility of the patient can develop, such as vein thrombosis, muscle spasticity, muscle atrophy and respiratory complications. As consequence, SCI people are 2 to 5 times more likely to die prematurely than healthy people. Beyond the physical impairments, another aspect to be consider is the involvement of the SCI person in the society, which is limited due to negative attitudes, indeed many SCI patients suffer from depression, and physical barriers. The World Health Organisation (WHO) estimates that each year between 250000 and 500000 people suffer a Spinal Cord Injury [23]. Among them, the 80% has an age in between 10-40 years old and thus it is crucial to find strategies to improve their quality of life. In this frame, acute care and rehabilitation treatments are essential to prevent the appearance of secondary conditions and to support the daily life of the patient.
Nowadays, standard therapies are divided in two phases: the first one, carried out immediately after the trauma, aims at avoiding long-term complications primarily related to essential life functions, like bowel and urinary activities; the second one aims at restoring lost functionalities, such as limbs mobility. These tasks are carried out by physical therapists that teach specific exercises, both to the patient and to his caregiver, calibrated on the cognitive deficit and focused on maintaining the joints range of motion and the muscles mass. The main advantage of these treatments is the non-invasive procedure, since the patient does not have to wear external devices. However, many limitations are related to these techniques: first, the patient is passive during the exercises execution as the movement is performed by the therapist or the caregiver. Then, the variety of used rehabilitation treatments strongly depends on the experience of the therapist. Also the evaluation of these treatments' effectiveness is limited as it is only qualitative and expressed by the sole therapist. As an alternative to the standard physical therapy, technological rehabilitative and assistive approaches that directly involve the patient have been investigated: namely Functional Electrical Stimulation (FES) and active orthosis or exoskeletons. In particular, a novel interesting research in this field is the optimal combination of these two technologies in a single structure, called hybrid system.

1.1. Robotic Rehabilitation

The robotic rehabilitation refers to a scientific field that develops robotic devices to assist a therapist or a caregiver during the rehabilitation of patients affected by movement impairments. These devices can be either passive (without motors) or active (with motors): the former are intended for only supporting the movement of one or more limbs; the latter, instead, using motors in correspondence of one or more joints, generate their movement.
Robotic devices can be divided in two categories: end-effectors and exoskeletons (see *Figure* 1).
The term end-effector is referred to systems that only perform the movement of the distal segment, without correspondence between the robotic arm and the anatomical segment that has to be moved. On the contrary, exoskeletons' structure is consistent with anatomical segments, allowing a physiological movement but increasing, at the same time, the complexity of the control system. Focusing on exoskeletons, they can be either grounded to an external structure, which goal is to bear the patient's weight and prevent possible falls, or have a wearable structure. In the latter case, the patient is required to have enough strength in the upper limbs to bear himself and the exoskeleton's structure, since patient movement (i.e. walking) is assisted by crutches. Exoskeletons' advantages include the possibility to treat the patient for longer session than conventional therapies, facilitating the re-organization of nerves connection, known as neural plasticity. It is an intrinsic mechanism that the nervous system actuates to induce modifications in the neural structure and functionality, according to intrinsic and extrinsic stimuli received. Furthermore, robotic devices provide a wide range of exercises with high repeatability between sessions and the possibility to modulate the level of assistance given by the robot, according to the actual condition of the patient. Considering the evaluation of patients' performances, rehabilitation robots allow a more quantitative and reliable assessment with respect to conventional therapies; in fact, they record kinetic and dynamic measures with sensors embedded in the structure, such as joints angular position or forces exchanged between the device and the patient, offering reliable data on which rating the efficiency of the therapy. In the last years, Virtual Reality (VR) was combined with robotic rehabilitation devices to increase the involvement of the patient during the treatment, making his experience more immersive and interactive. As

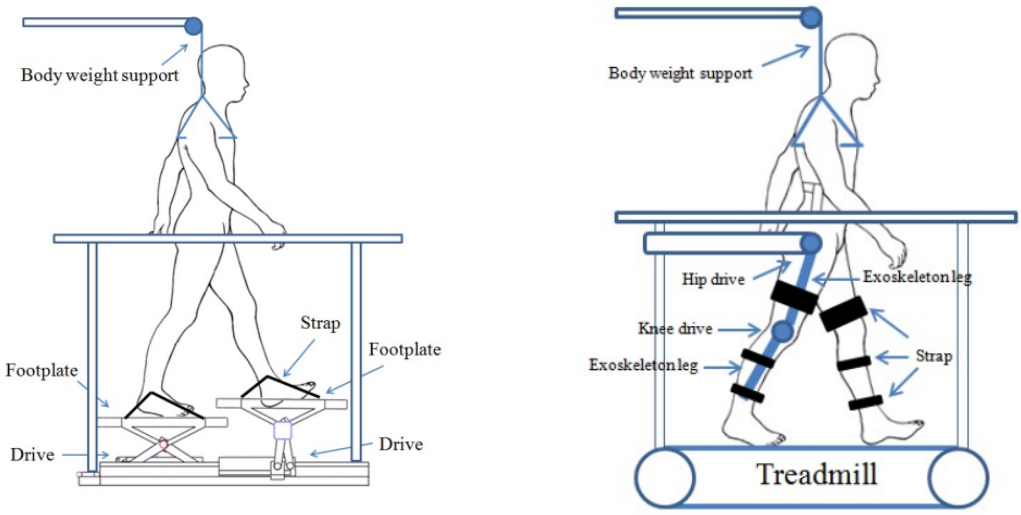

Figure 1: Examples of End-Effector and Exoskeleton [7]

drawbacks, exoskeletons usually have an heavy and bulky structure which limits their wearability and discourages patients from using them. Furthermore, the risk of doing a rehabilitative treatment with exoskeletons is to induce the slacking effect, namely the fact that the patient is completely moved by the device and thus passive during the movement, reducing the benefits of the therapy.

1.2. Functional Electrical Stimulation

Functional Electrical Stimulation (FES) consists in delivering low-energy short electrical pulses to peripheral nerves that innervate paralyzed muscles, to trigger the action potential in the motor neuron and induce a contraction, otherwise impossible since the damage that occurred at the spinal cord impedes the transmission of efferent signals. Electrical pulses are delivered by electrodes that can be applied to the skin or implanted near the muscle. Theoretically, the best choice is to use implanted electrodes (cuff or intramuscular ones) since, being closer to motor neurons, they are more selective; however, their positioning is critical and highly invasive. For this reason, in rehabilitation, surface electrodes are preferred, even if they do not allow to access some inner muscles and the electrical pulses can be weakened by the soft tissue interposed between the electrode and the muscle. Surface electrodes can be positioned in two different configurations:

- Monopolar Configuration: only one electrode is placed on the muscle belly and another one is placed on an electrically-neutral area such as bone prominence;
- Bipolar configuration: both electrodes, one anode and one cathode, are placed on muscle belly, letting the current flows from anode to cathode.

Another aspect to take into account is the activation threshold of the nerve to be stimulated, which mainly depends on its size. The stimulation should reach this threshold by modifying three parameters: Amplitude (current intensity of the pulse), Pulse width (duration of the pulse) and Frequency (time distance between pulses).
It has been demonstrated that, besides having a functional contraction of muscles, patients gain multiple benefits from using FES. Primarily, it induces central benefits by enhancing processes that lead to neural plasticity. Secondly, various physiological advantages are caused by this stimulation; in particular, muscular spasticity and atrophy are delayed, the general cardiovascular fitness is improved, reducing the risk of thrombosis, the incidence of pressure sores is reduced as well as the risk of osteoporosis. Nevertheless, two main problems are related to the use of FES. The former is the non-linear relation between the injected current and the induced muscle contraction, which makes it difficult to control the overall movement. The latter, instead, is the early appearance of muscle fatigue due to the non physiological motor units recruitment and activation of the FES-induced contraction. In the voluntary contraction, the Central Nervous System (CNS) recruits fibers with a frequency of 5Hz and exploits a turn-over in between fibers that varies both spatially and temporally the motor units involved in the contraction. Moreover, also the type of activated motor units changes over time: the first recruited fibers are the slow oxidative ones (type I), followed by the fast oxidative-glycolytic ones (type IIa) and then the fast-glycolytic muscolar ones (type IIb). On the other hand, FES recruits motor units with a frequency of 20Hz corresponding to a titanic contraction and using a non-selective, spatially fixed and

temporally synchronous pattern. As a consequence, the stimulation is always delivered to the same fibers and this causes a premature appearance of muscular fatigue.
In literature, attempts to limit these phenomena focused on two main aspects: on one hand, the implementation of closed-loop control strategies to regulate stimulation parameters and reduce the total injected charge; on the other one, the use of advanced electrodes arrays that, by alternating the activation of multiple electrodes, simulate the physiological fibers turn-over.
Although FES is one of the most exploited strategies in rehabilitation of SCI people, the amount of muscular force generated is lower in SCI person compared with healthy subjects. In this scenario, new treatment based on hybrid system are under study. The aim of these systems is to compensate the missing force by superimposing to FES stimulation the contribute given by the joint motor, allowing a better tracking of the trajectory.

1.3. Hybrid Systems

Taking into account the advantages and disadvantages of FES and exoskeletons, research in this field has recently focused on the combination of these two technologies in single structures, called *Hybrid systems*, with the aim of enhancing their advantages and limiting their disadvantages. In particular, on one side the addition of the exoskeleton supports the FES-induced movement and thus delays the appearance of muscle fatigue, prolonging the FES training session; on the other side, the addition of FES enables to reduce the power (and thus the weight) of motors and, consequently, increases the wearability of the structure. The objective of these hybrid structures is to provide stability and motor assistance to the users, unable to maintain balance and walk on their own. As the input for the movement comes both from motors and from FES, by appropriately adjusting their contribution to the movement, it is possible to implement a personalized therapy, adapted to the injury level of the specific patient. For example, by reducing the motor support to the movement, we can induce a higher patient participation and vice-versa. The level of assistance can also be varied for the same patient along the training session, depending on the level of fatigue over time: the higher the fatigue, the larger will be the needed motor contribution.
A fundamental feature for the motors of a hybrid system needs is the backdrivability; it indicates the possibility of the patient to apply torque to the robotic motors and these ones allow alteration from the equilibrium point, namely a change in their angular position. This feature is important in order to establish a cooperative mechanism between the human and the robot.
Hybrid exoskeletons can be divided in two main categories:

1. Semi-active hybrid exoskeletons: these ones can only dissipate energy by using brakes and clutches and apply FES only during specific phase of the step. Their main advantages are the low weight and the energy efficiency since they do not require batteries;
2. Fully-active hybrid exoskeleton: these ones can both dissipate and deliver energy to the joints. In this case, an external power source (batteries) and joint actuators are used to generate legs movements. Moreover, these systems can compensate the appearance of FES-induced muscle fatigue but they are energetically inefficient.

The aims of a cooperative controller are to ensure repeatable gait motions despite of the time-varying muscle response and to maximize the muscle force generated by the user during the movement. To pursue this objective, it is fundamental to find an adequate control strategy both for motors and FES.

1.3.1. Motors Control

Considering motors control, according to Gasperina et al. [14], hybrid systems should allow a compliant control of the robotic device to enhance the subject participation in the movement. In fact, a compliant control permits robotic motors both to generate movement and not to oppose to the torque or force generated by the patient's muscles during their contractions. To achieve this goal, the 2 available options are impedance and admittance controls.
Impedance Controller An impedance controller receives position data (i.e. the pre-defined target trajectory) as input and it produces force (or torque) values as output, to be sent to the motor. Differently from a position control, this controller does not rigidly force motors to follow a pre-defined trajectory but it allows to have some slightly variance from it.
The impedance controller architecture (see *Figure 2*) is based on two loops:

- an inner torque-feedback loop that compensates for the mechanical friction, promoting a transparency behaviour;
- an outer position-feedback loop that avoids excessive variances from the reference trajectory.

In general, the output torque of an impedance controller is expressed as:

$$\tau = I(s) * (\theta_{target} - \theta_{actual}) \tag{1}$$

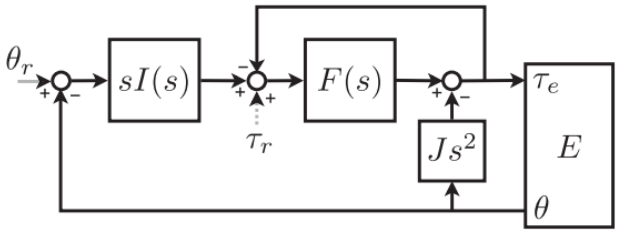

Figure 2: Impedance Controller Scheme [5]

where *I(s)* is the mechanical impedance model and θ_{target} and θ_{actual} are the target and actual trajectory of the joint, respectively.
The order of the impedance control depends on the order of the polynomial *I(s)*.
An example of impedance controller is the Proportional-Integrative-Derivative (PID) controller, which corresponds to a 2^{nd} order impedance controller. In PID controllers, the mechanical impedance model assumes the general form as:

$$I(s) = K_s + sK_d + s^2K_i \tag{2}$$

In this equation, K_s is the stiffness coefficient and it corrects the joint trajectories, K_d is the damping coefficient and it stabilizes the movement by limiting velocity errors, whereas K_i is the integrative coefficient and it allows to control the mass/inertia of the system. According to del Ama et al. [11], the stiffness parameter K_s can be modulated depending on the gait phase detected. For example, K_s will assume higher values when the reference trajectory has to be rigidly followed (i.e. stance phase) whereas it will assume lower values when the movement can be performed more freely (i.e. swing phase) giving the priority to the voluntary movement instead of the motor-induced movement.
The advantage of this controller is its compliance that allows to deviate from the reference trajectory, giving the priority to the voluntary or FES-induced movement. However, the non-linearity nature of impedance controllers can lead to instabilities in the human-robot system.
Impedance control can be either implicit or explicit. In the former case, torque is controlled by an open loop, which requires robotic motors to be highly backdrivable. In the latter case, instead, the torque is controlled with a closed loop, thanks to force/torque sensors that measure the actual torque generated by the motor.
Admittance Controller As dual of the impedance controller, the admittance controller switches the inner and outer control loops and thus it is position-driven instead of force-driven. The main advantage of this controller is that it does not require back-drivable motors but, as consequence, the drawback is that it limits the possibility of the patient to deviate from the reference trajectory.

1.3.2. FES Control

As illustrated in del Ama et al. [11], the control of the electrical stimulation can be performed either with an open-loop strategy or a closed-loop one.
The former stimulates muscles with pre-programmed patterns that are activated sequentially on detection of specific gait events (i.e. heel strike). The advantage of this approach is the low computational cost but, on the other hand, it is not able to adapt the stimulation with respect to changes in muscular performance. Hence, in hybrid systems, an open-loop strategy does not optimize the balance between the input given by the excited muscle and the one given by motors for achieving the movement. The latter, instead, takes into account the feedback of indirect measurements of muscle performances. They can be also embedded with techniques of muscle fatigue recognition, allowing to modulate FES parameters (pulse width, amplitude and frequency) with the aim of compensating for muscle fatigue. Despite of the great advantage of adapting stimulation parameters over time, some critical issues have to be managed when using FES, such as: the detection of muscle fatigue during the execution of a task, the control of joint trajectories and, when combined with a robotic device, the balance between muscular and motor actuation.
One example of a closed-loop FES control is the Iterative Learning Controller (ILC). According to Bristow et al. [3] and Müller et al. [21], the goal of ILC is to improve the muscular performance by embedding the information about the error of the previous iteration into the FES control for the following iteration. Thus, ILC adjusts FES parameters trying to reduce the performed error with a one-interation delay. Consequently, this strategy is not able to promptly react to disturbances as it does not include a direct feedback loop, but it is able to reject repeated disturbances by learning from previous iterations. In fact, using data from previous iterations, known in advance, ILC applies a non-causal learning algorithm, particularly effective in repetitive tasks such as walking. This feature allows the algorithm to anticipate the disturbances and compensate them with the

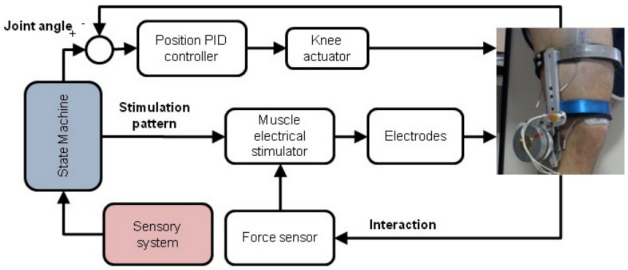

Figure 3: Control Architecture of Kinesis Exoskeleton [9].

current control: its amplitude will be increased in case of a huge error, decreased otherwise.
The generic expression for ILC in FES is given by del Ama et al. [11]:

$$\{u_{n,j+1}\} = [F] * [\{u_{n,j}\} + [L] * \{e_{n,j}\}] \tag{3}$$

where $\{u_{n,j+1}\}$ is the FES control vector that has to be applied to the next step (j+1) during the swing phase, which is divided in n frame. $\{u_{n,j+1}\}$ is computed by using the control vector of the previous step $\{u_{n,j}\}$, the Learning Constant Matrix $[L]$ and the error that was produced in the previous step $\{e_{n,j}\}$. All these elements are affected by the Forgetting Constant Matrix [F], which is a low-pass filter that can improve the learning behaviour and robustness during transients.

1.4. Examples of Hybrid Systems

In literature, many examples of hybrid systems under study are present.

Kinesis

One of them is the exoskeleton Kinesis ([2, 9, 10]). Kinesis is a KAFO orthosis with an active knee joint and a passive ankle joint. This system is embedded with force sensing resistors to detect floor contact, potentiometers for measuring knee position and a full wheatstone bridge to measure the torque generated at the knee level. The control architecture (see *Figure 3*) is mainly based on the knee controller and the FES controller.
The former exploits a PD controller, which allows a compliant actuation of the knee. The knee torque is controlled during swing and stance phases and it is given by:

$$\tau = K_k(\theta_{pattern} - \theta_{actual}) + C_k \frac{\Delta(\theta_{pattern} - \theta_{actual})}{\Delta t} \tag{4}$$

where $\theta_{pattern}$ is the reference trajectory and θ_{actual} is the actual position of the knee. The K_k parameter regulates the knee stiffness, assuming a value equal to 6 Nm during stance phase whereas it is set to 0 Nm during swing phase. This is done to have a rigid knee control in stance, where a higher support is needed, while allowing a free movement in swing. Instead, the C_k parameter is tuned by trial and error to improve controller stability. For the swing phase, the kinematic pattern was extracted by biomechanical data of walking healthy subjects, while for the stance phase the kinematic pattern has been reduced to a constant value. This strategy optimizes the movement induced by muscles, facilitating the cooperative behaviour between joint motors and muscle torque.
Instead, the FES controller aims to minimize the interaction torque by changing the stimulation pulsewidth whereas pulse amplitude and frequency are held constant. To achieve this goal, FES controller has a dual-closed loop structure in which knee extensors are controlled by a PID controller and the flexor muscles are controlled by an error-based ILC. PID controller manages the double support and the stance phases whereas ILC achieves the swing phase due to the cyclical movement.
Both controllers are fed-back with information about the interaction between the limb and the exoskeleton, measured with the force sensor.
As result, the cooperative behaviour of Kinesis allows to obtain adequate and personalized stimulation patterns delaying the appearance of muscle fatigue and giving priority to the movement produced by the stimulated muscles.

Vanderbilt

Another interesting hybrid system is Vanderbilt [13, 15, 16]. Vanderbilt is a powered exoskeleton including electric motors at both hip and knee joints. It does not have a foot ankle section then it is integrated with a

passive Ankle-Foot Orthosis (AFO). The embedded sensors are potentiometers in both hip and knee joints and accelerometers at the thigh link.
In this case, control architecture is more complicated. For what concerns joint controllers, their inputs are managed by a Finite-State Machine (FSM), described by four state: right step, double-support with right foot forward, left step and double-support with left foot forward. Hence, during walking the FSM moves sequentially through the different states and, according to actual state, the angular position profiles are given as input to joint controllers of hips and knees.
The joint controllers consist of two loops: a motor control loop and a muscle control loop. The motor control loop is a PD controller that exploits the feedback of joints angles to control the motor torque in order to follow the reference trajectory. Instead, the muscle control loop aims to minimize the contribution given by the motors. To achieve this goal, it utilises the motor torque profiles from previous step to properly shape the muscle stimulation profile.
For what concerns FES, it is delivered by a 4 channels stimulator to quadriceps and hamstrings. FES has a rectangular pulse profile, defined by three parameters: pulse start time t_s, pulse duration t_d and pulse amplitude i_s. These parameters are adapted according to the difference between the reference torque τ_r and the estimated muscular torque τ_m. Specifically, feature differences are described by the muscle torque lag time t_l, which is the time interval by which τ_m lags τ_r.
Hence, the stimulation profile parameters are updated at each step as follows:

- Pulse start for the next step is computed as:

$$t_{s(k)} = t_{s(k-1)} - t_{l(k-1)} \tag{5}$$

  where k is the step index and $t_{l(k-1)}$ is the measured muscle torque lag time of the previous step;
- Pulse duration of the next step is given by:

$$t_{d(k)} = t_{d(k-1)} + Dsgn(\Delta t_{w(k-1)}) \tag{6}$$

  where D is a predetermined increment and Δt_w is the pulsewidth difference between reference torque and muscle torque.
- Amplitude of stimulation profile is:

$$i_{s(k)} = i_{s(k-1)} + Isgn(\Delta T_{(k-1)}) \tag{7}$$

  where I is a predetermined increment and ΔT is given by the difference between the reference and the estimated muscle torque amplitude.

FEXO Knee

The last example of hybrid systems that is reported in this work is FEXO knee ([25, 27]). FEXO knee is composed by two components: a single-joint knee exoskeleton and a FES device. It is embedded with two different sensors: one encoder to measure knee angles and two force sensors to measure the force exchanged between the shank and the exoskeleton. The cooperative control aims to balance the contribution given by the motor and muscle contractions during the movement.
FES is delivered to quadriceps and hamstring and it is controlled by a feedforward controller:

1. Inverse Dynamics computes the desired actuation torque of the knee by receiving as input the reference trajectory, as follows:

$$\tau_k^d(t) = I\ddot{\theta}(t) + B\dot{\theta}(t) + K\theta(t) + mgl_c sin(t) \tag{8}$$

   where I [Nms^2/rad], m [kg] and l_c [m] are the segment inertia, mass and length, respectively; B [Nm/rad] and K [Nm/rad] are the knee viscous damping and stiffness coefficient; $\theta(t)$ [rad], $\dot{\theta}(t)$ [$rad/$] and $\ddot{\theta}(t)$ [rad/s^2] denote the knee angular position, velocity and acceleration; $\tau(t)$ [Nm] denotes the knee torque.
2. Finally, the desired torque that FES has to provide is given by:

$$\tau_{FES}^d = \delta_{FES}\tau_k^d$$

   where δ_{FES} is the FES distribution gain.

Since the muscle contractions induced by FES are not able to completely generate all the torque needed for the movement, a feedback controller is necessary to generate the missing torque. This missing torque that the motor has to produce is composed by two components. The first one compensates for the dynamics of the exoskeleton itself and it is computed by using a PID controller:

$$\tau_{exo1} = k_p\theta_{ref} + k_d\dot{\theta}_{ref} + k_i\ddot{\theta}_{ref} \tag{9}$$

in which, $\theta_{ref}, \dot{\theta}_{ref}, \ddot{\theta}_{ref}$ are the position, velocity and acceleration of the reference trajectory.
The second one, instead, has to provide torque for the assistive movement to the knee and it is computed as:

$$\tau_{exo2} = \delta_{exo}\tau_k^d(t) \tag{10}$$

where δ_{exo} is the exoskeleton distribution gain. δ_{FES} and δ_{exo} are chosen such as $\delta_{exo} + \delta_{FES} = 1$. However, δ_{FES} is a fixed parameter, while δ_{exo} is a flexible parameter.
The main advantage of this cooperative control is the tunable percentage of torque that FES has to produce, allowing an easy method to manage torque distribution between FES and the exoskeleton.

1.5. Graphical User Interface

As explained in section 1.3, hybrid systems are complex device that manage a huge amount of data and, considering their clinical applications, the development of Graphical User Interfaces (GUIs) allowing an effortless and clear control of the device plays a crucial role. In particular, it aims at guaranteeing a correct and safe running of rehabilitative sessions.
In particular, GUIs have to be intuitive and user-friendly to simplify the achievement of tasks, making the preparation of the rehabilitative session and the session itself shorter and more efficient. Thus, it is intended for avoiding inconveniences and errors for therapists and for reducing the frustration of patients that, in case of problems during the ongoing of the therapy, may be unlikely to prolong it or repeat it over time.
Furthermore, GUIs should fasten the learning process for therapists, thus the app should be easy to use so that therapists understand and remember how to properly use it between different treatments over the time.
Another goal that GUIs have to achieve is to guide therapists through the accomplishment of different purposes of the rehabilitation session. This feature could be pursued by visualization of messages that express clearly and concisely what are the duties that need to be done.
In addition, the system has to report to the user if any action is missing, limiting the possible human-related errors. Indeed, most of the times, the user does not have a technical background about the working principles of the hybrid system and the managing of related problems. Then, this feature is essential for avoiding potential harms to the patient. One way to fulfil this purpose is to guide the user through the control flow of the application, for example enabling/disabling button presses according to the actions that have to be performed, so that no undesired movement are enabled.
Finally, the possibility to store patient data for each rehabilitation session provides a feedback to the therapist about the on-going rehabilitation. These information can guide the therapists in the therapy-related decision making.

1.6. Aim of the Work

The purpose of this work is to update the old user interface of Twin to be suitable for the control of the novel implemented exoskeleton integrating Twin and FES. This new system offers new functionalities and control modalities and so, the user interface has been integrated with new components in order to help the therapist in handling different types of sessions. In particular, the main added features, not present in the previous version of the application, regard the possibility to manage a session with the hybrid modality and an automatic procedure to carry out the FES calibration. Moreover, additional functions were included, not directly related with the control of the device, but with the aim of improving the user experience for the therapist and easing the execution of a training. Among them, the possibility of storing both session's data (used modality, number of steps, ...) and FES calibration data (current parameters for each channel), with the chance of loading a pre-defined calibration set.
Overall, the application aims at simplifying the rehabilitation sessions for therapists, providing them with a single device able to manage both components of the hybrid system in an easy and intuitive way.

2. Materials and Methods

2.1. Twin-FES

2.1.1. Twin

Twin is an active lower-limb exoskeleton developed by the Italian Institute of Technology (IIT) of Genova. Its purpose is to assist patients affected by Spinal Cord Injury (SCI) or stroke during rehabilitation treatments performed within a clinical context. In particular, the patient should meet the following requirements: the

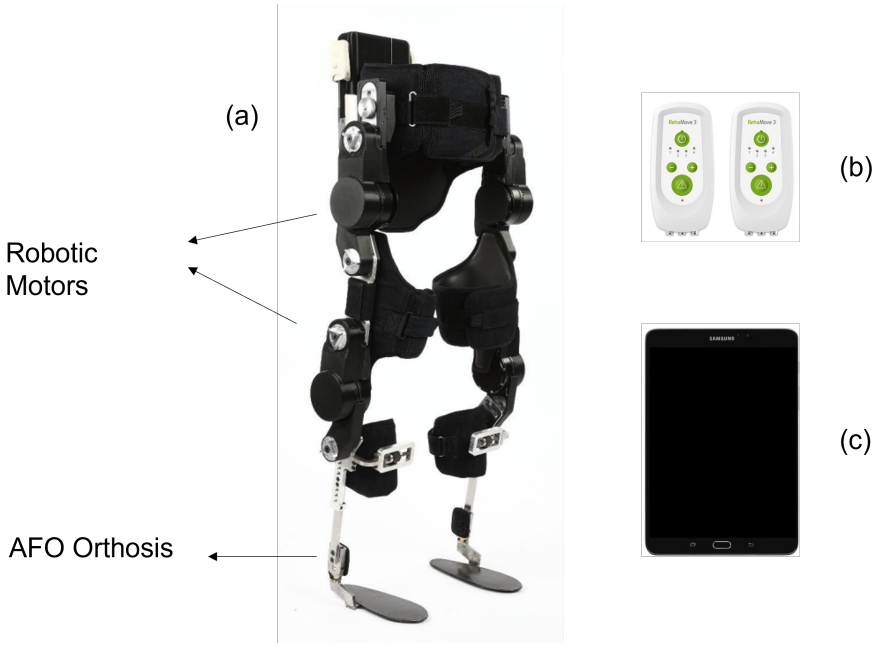

Figure 4: Figure depicts the elements that compose the system Twin + FES, namely exoskeleton Twin (a), stimulation devices (b) and tablet (c).

spinal lesion should be below the fourth thoracic vertebra (T4), the level of spasticity has to be less or equal to two in the modified Ashworth scale and the strength of the upper limbs needs to be enough to use crutches. The rehabilitation session has to be supervised by at least two operators, adequately instructed for the use of Twin.
All the components that play a role in Twin control are presented in *Figure 4* and they are illustrated below.
Twin's structure is composed by three joints for each leg and three modular links. The joints consist of two active junctions, hip and knee, and a passive Ankle - Foot Orthosis (AFO), which stiffness can be manually adjusted by loosening the spring in correspondence of the AFO. This stiffness determines the maximum plantar-flexion and the maximum dorsi-flexion allowed during the training and these two movements can be tuned independently. The modular components, instead, represent pelvis, femur and tibia and they are available in different sizes to adapt to the patient's anthropology. The movement is permitted only along the sagittal plane (i.e flexion-extension movements) and it is transmitted from the exoskeleton's structure to the patient by fabric braces fixed at the level of the hip, thigh and shank of both legs. To guarantee a correct transmission of the movement, it is necessary to take anthropometric measures of the patient and choose the correct link size.
For safety reason, Twin has an emergency button in case of malfunctioning or patient's illness. When the button is pressed, the motors are slowly released, exploiting their embedded friction, allowing the operator to sit Twin in a safety position.
Each motor has two position sensors:

1. Hall effect sensor: gives the absolute angular position of the rotor of the motor;
2. incremental inductive encoder: measures the relative angular position, since it takes as zero the starting position

2.1.2. FES

Twin's structure has been embedded with two stimulator devices in order to integrate FES, which is delivered to four muscles, namely quadriceps, hamstrings, femural biceps and gastrocnemius, for both left and right side. The stimulators are RehaMove3 devices and they are classified as medical devices of class IIa. Each stimulator has four channels, one for each muscle, to deliver current pulses through surface electrodes. In this work, the electrodes configuration is bipolar then both of them are placed over the muscle belly and the electrical pulses are delivered with a biphasic rectangular waveform.
In order to use FES during rehabilitation sessions, a calibration phase is required in order to adapt the current intensity to the specific patient and muscle. At the beginning, the following parameters are set: pulsewidth, frequency, current range, namely minimum and maximum values that current can assume, the starting value of the current and its increment.
Then, when the actual calibration procedure starts and muscles are tested one at a time. It consists in delivering a ramp of increasing current using surface electrodes and three current thresholds have to be defined. The first

one corresponds to the 'sensibility threshold', which is the current that is perceived by the person or, in the case of a patient with no residual sensibility (i.e. SCI people), it is set to a general low value (e.g. 4mA). The second (Level 1) is the motor threshold, corresponding to the current value that makes the body segment (the one actuate by the muscle) moving. The last one (Level 2) is the current value producing a complete movement of the segment or the maximum current that can be tolerated by the patient.
A more accurate description on how the calibration phase is achieved is reported in section 2.2.2.

2.1.3. Control Modalities

Twin has two different control modalities: proprioceptive and hybrid modality.
In the proprioceptive mode, the control is position-driven. It means that a reference trajectory is computed for each joint according to the walking parameters (i.e. clearance, step time...) and is rigidly followed over the steps. The patient plays a passive since the movement is completely performed by the motors and thus any participation or deviation form the predefined trajectory is not possible. Nevertheless, the muscle stimulation is present also in this modality but only with an afferent role, meaning that the aim is to exploit its physiological benefits rather than eliciting a functional muscle contraction. In this case, in fact, the amplitude is defined as *proprioceptive*, meaning that is stays below the motor threshold (i.e. Level 1).
For what concerns the hybrid mode, it implements a first order impedance control allowing a more compliant tracking of trajectory. Thus, it permits deviations from the reference trajectory and so allows the patient to take part to the movement. This participation can consist either in a voluntary or a FES-induced movement. The impedance mechanical model assumes the following form:

$$I(s) = K_s + sK_d \tag{11}$$

In this equation, K_s is the stiffness gain that, multiplied by the position error, corrects the joint trajectories towards the desired one. K_d, instead, is the damping component that, multiplying velocity errors, avoids significant velocity variations and thus stabilizes the movement.
Thanks to the 'functional' muscular contractions enabled by FES, the patient actively performs movements. In particular, this hybrid control is implemented for the flexion/extension of the swing knee. All other joints are controlled in the same way as in the proprioceptive mode. The stimulation pattern is tuned by an ILC which updates FES parameters step by step. In particular, the implemented ILC maintains constant frequency and pulsewidth while it varies amplitude according to the position error between the reference trajectory and the actual one. Hence, if the error is positive, meaning that the performed trajectory is below the target one, the amplitude will be increased whereas it will be decreased if the opposite condition occurs. As drawback, ILC fails when non-repetitive disturbances are present. The maximum amplitude that the stimulation current can reach is a value equal to 'Level 2', corresponding to a maximal flexion/extension. Moreover, the motor contribution totally compensates the exoskeleton's weight while the compensation of the patient's weight can be tuned between 0% and 100%.

2.2. Application

The remote control of Twin is performed with a Tablet through an Android app, called *TwinFes* and compatible with Android system 7.0 or previous, enabling to handle the overall execution of a therapeutic session. In particular, it allows the definition of training parameters and users data and the selection of the control modality. The communication between Twin and app uses the Bluetooth 4.1 protocol. The application has been developed in Java, which is a object-oriented programming language.

2.2.1. App Requirements

Since this application assists the execution of a therapeutic session with patients, it should fulfill some requirements in order to guarantee a correct and safe use of the hybrid device. This is a crucial point considering that the device is used for the walking activity of patients with disability and thus deals with their stability and safety. In this work, the requirements have been divided in three categories:

- **Always On Functions**: essential conditions to guarantee a safe therapy. The requirements are described in the *Table 1*.
- **Assistance throughout the therapy**: important features with the aim of limiting possible errors that the therapist can commit. Some possible errors are: clicking buttons in the wrong sequence or stimulating muscles that have not been calibrated yet. *Table 2* sums up all the requirements related to the assistance given to the therapist.
- **Data Management**: control over the data regarding both the single patient and the rehabilitation sessions. These data are important for the therapist in order to define a longitudinal training program for

Requirements	Description
Check Twin Connections	The application keeps a stable connection between Twin and app throughout the rehabilitation session. In case of connection lost, it warns the user.
App Communication	The application has to receive and send messages to Twin correctly.
Feedback to the user	User must be aware of the actions that are performed by the system through dialog window.

Table 1: Always On Functions.

Requirements	Description
Control the flow of the therapy	Application has to control the flow of the therapy by enabling/disabling buttons
Limit Human Error	Application has to aware the therapist if some actions are missing (i.e missing calibration). Dialog windows are used to indicate which actions are missing.

Table 2: Requirements regarding assistance throughout the therapy.

the patient and also to speed up some repetitive steps (such as the FES calibration) by using pre-defined values. As shown in *Table 3*, data concern FES calibration and previous therapy sessions.

2.2.2. Guidelines for a correct application use

When the application is launched, the Bluetooth connection between Twin and app is set automatically. Firstly, the users screen appears, from which it is possible to create a new patient, to modify or delete an existing one, or select an existing one. Once the user is selected and the button 'Start Session' is pressed, the main control panel appears.
The user navigates the application with a lateral menu (see *Figure 5*).

FES Panel

As first step, FES calibration has to be performed through the FES calibration panel, shown in *Figure 8*.
Once opened, the user can set FES constant values (i.e. the pulsewidth and the frequency) and the range of possible values for the current amplitude, in between a minimum and a maximum value and the increment (in mA per second) of the stimulation current ramp. Then, there is the selection of all the muscles that will be used in the session and thus need to be calibrated. To facilitate the electrodes positioning, the dot associated to the

Requirements	Description
Saving FES Calibration	The application has to save FES calibration parameters correctly.
Loading Existing FES Calibration	If a FES calibration already exists, it must be correctly loaded and showed to the user correctly.
Saving Training	At the term of each session, user should have the possibility to save the training data.
Loading Previous Trainings	All the previous trainings performed by the selected user should be loaded and visualize correctly.

Table 3: Data Management Functions.

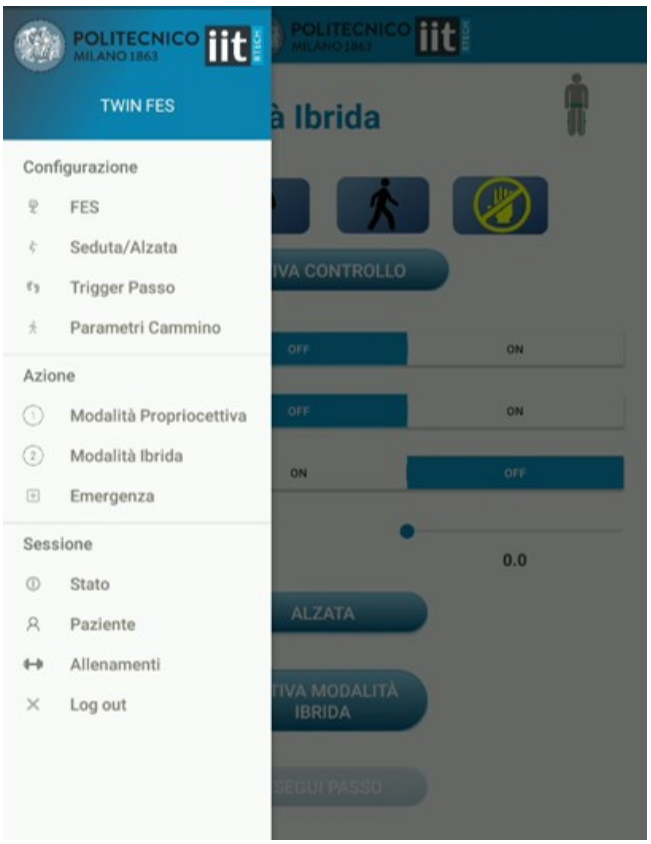

Figure 5: Navigation Menu.

Figure 6: Displaying of real-time calibration values within the FES calibration panel

muscle is coloured with the associated cable's color (i.e. Quadriceps have a red dot, meaning that the red cable has to be placed on them).The second part of the panel, instead, handles the real calibration procedure: the user selects the specific muscle to be calibrated (only one muscle at a time can be selected) and, as a consequence, the corresponding channel is activated. In this step a current ramp is delivered to the muscle with the aim of setting its specific thresholds: the movement one (i.e. when the limb starts to move) and the tolerated limit (i.e. when the stimulation becomes uncomfortable). From this same panel the user can also define the amplitude value (in mA) from which the ramp starts and the amplitude increment over time (in mA/s). While the FES ramp increases, the real-time value of the delivered current is displayed on the screen, as well as the selected values for levels one and two, once their respective buttons are pressed (see *Figure 6*).
If during the calibration, the user selects a muscle not previously marked as to be calibrated, a warning message on the tablet screen appears, indicating that the muscle selected does not have to be calibrated (see *Figure 7*). Each time the 'Confirm' button is pressed , current levels of the calibrated muscle are saved in a patient-specific file. A green tick appears beside the muscle just calibrated as user's feedback of the correct saving of the data (*Figure 7*). In case different data were previously saved for the same muscle, these new data will overwrite them. The patient-specific file can be loaded in further rehabilitation sessions with the same patient, allowing to save up some time during the training preparation. In fact, when a previous calibration set is present, a pop-up appears asking whether the therapist wants to use the existing data or to overwrite them by performing a new calibration. Moreover, the previously saved calibration data are accessible at any time from the related section in the 'Patient Panel' (*Figure 9*).

Figure 7: Advice of wrong muscle selection and visualization of muscles that are already calibrated.

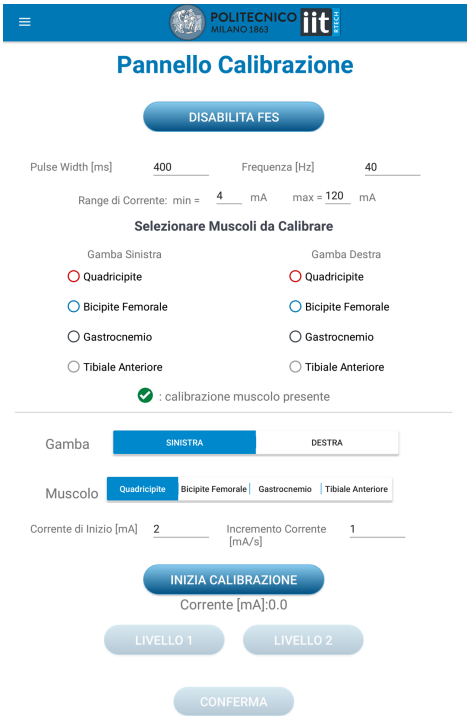

Figure 8: Calibration Panel

Figure 9: Calibration Stored Data

Walking Parameters Panel

Secondly, the therapist configures the gait parameters in the walking panel (see *Figure 10*).

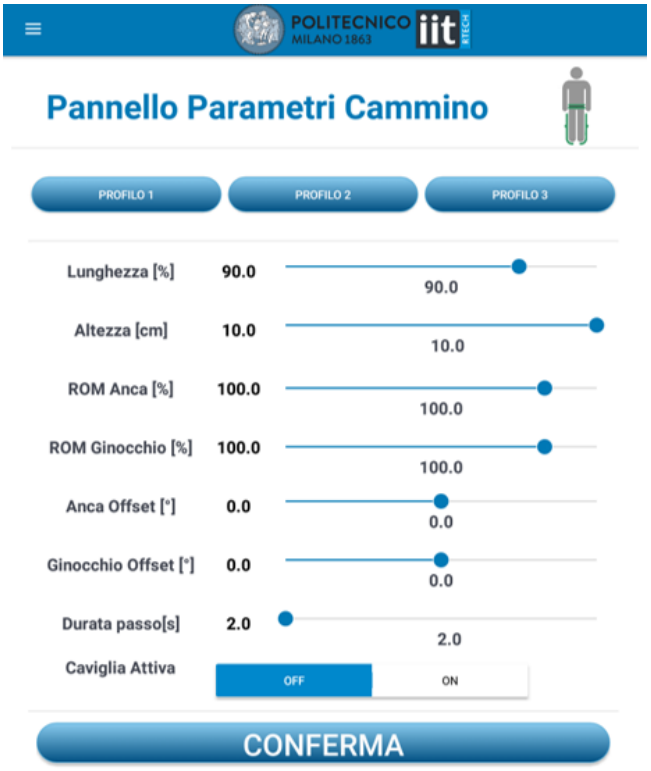

Figure 10: Walking Parameters Panel

The variables that can be modified are: step length, clearance, range of motion (ROM) and offset of hip and knee, duration of the step and active or passive ankle. The hip and knee offsets are the angular values for which the two joints are considered at rest. The selection of ankle either active or passive refers to the possibility to unlock or lock the AFO, according to the walking ability of the patient. If the ankle is set as active, a warning appears on the screen, reminding to reduce the stiffness of the AFO's spring, loosening the connected screw.

Control Panels

Once all the parameters are set, the actual therapeutic session can start. As first step, the therapist decides the Twin modality he wants to use, either **Proprioceptive** or **Hybrid**, and opens the relative panel by the side menu. The screens of the two modalities have common features. First, there is a miniature of the patient (on top right corner) wearing the exoskeleton (see *Figure 11*), which color changes according to the charge of the batteries and the connection's status of joints. The icon can be:

- green: if the batteries' level is above 30% and the joints are correctly connected;
- orange with a rectangular shape: if the batteries' level is below 30%;
- orange with triangular shape: if one or more joints are not connected correctly or the emergency mode is active;
- red: if the connection between Twin and app is lost.

Furthermore, four icons (see *Figure 12*), placed below the name of the modality, define the state in which the exoskeleton is. Possible states are: seated, standing, walking or no control.
The control mode is activated by pressing the button 'Activate Control', which light up the seated icon as Twin's position is recognized as seated. Then, if the patient already has a FES calibration, a dialog window appears, indicating for which muscles a previously saved calibration is available (*Figure 13*).
From this window, the user can either use these values and go on with the session or jump to the FES calibration panel, where he can update the existing calibration values or create new ones, with the procedure previously described in the Calibration Panel section.
If the user keeps the saved values, the session goes on and, by pressing 'Standing', Twin passes from the seated to the standing position. Afterwards, the therapist can select which muscles he wants to stimulate during the session and start it by pressing 'Activate Modality'. The icon passes to the 'walking' state and the app double checks if a calibration is available for every muscle that will be used during the following session. If the user had selected muscles for which a calibration for both the left and the right side is missing, a pop-up appears,

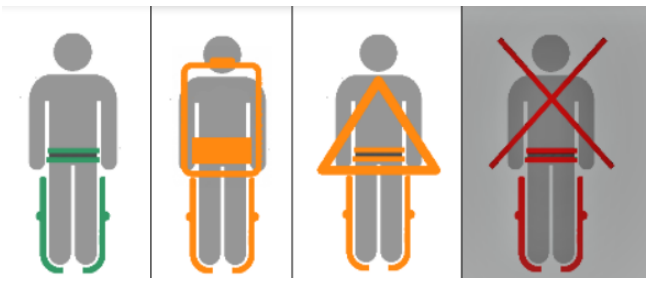

Figure 11: Twin State Icons

Figure 12: Twin Control State Icons

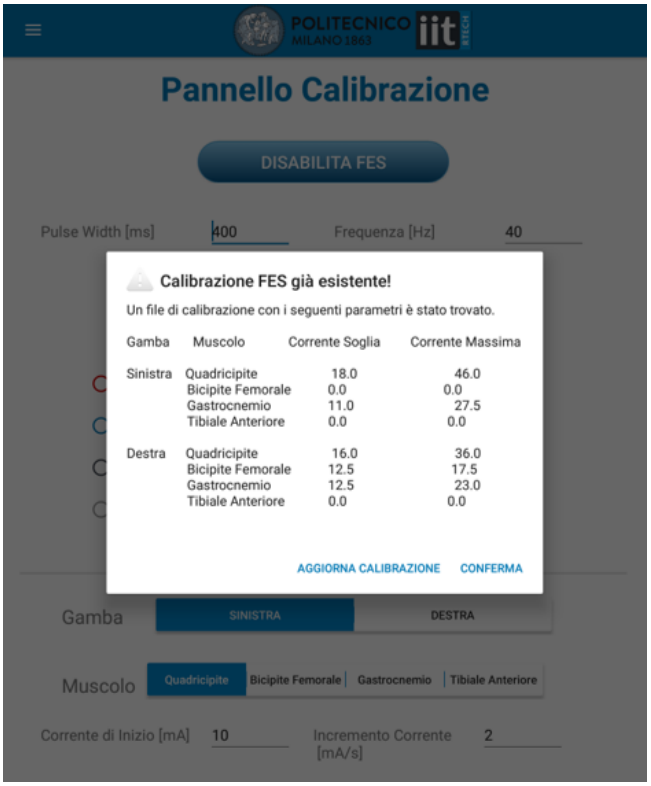

Figure 13: Dialog window that shows which muscles already have a calibration. In this case, quadriceps and gastrocnemius have the calibration for both sides while hamstrings only for the right side.

indicating the lack of calibration values. To solve this issue, the user can either add the calibration of these muscles or deselect them from the panel in order not to use them. Otherwise, if everything was set correctly, it is possible to start the walking activity by triggering each step with the button 'Perform Step'.
Once the rehabilitation treatment is finished, the control is disabled and a summary of the training is showed in *Figure 14*. In this summary, the stimulated muscles with the respective parameters and the number of steps performed during the rehabilitation are shown. The user can decide either to save or to discard these training data.

Training Panel

The saved training can be visualized in the Training panel. As shown in *Figure 15*, the list of all past training for the patient is displayed and each one can be selected and visualized in detail. For each training the following data are stored (*Figure 16*): the date in which it was performed, the used modality, the number of steps taken and the FES parameters, in particular the pulsewidth, the frequency and the current levels for the stimulated muscles. A level zero is displayed otherwise.

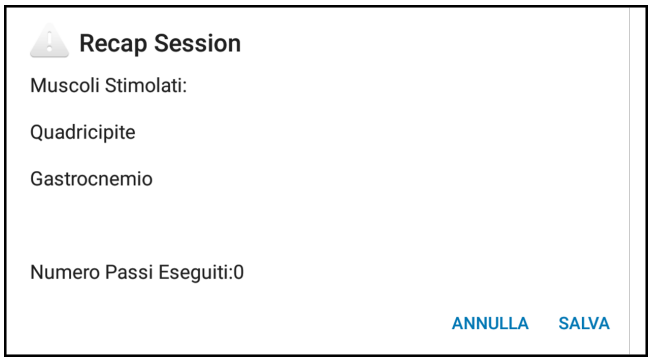

Figure 14: Dialog Window with Training Summary and possibility to save the session.

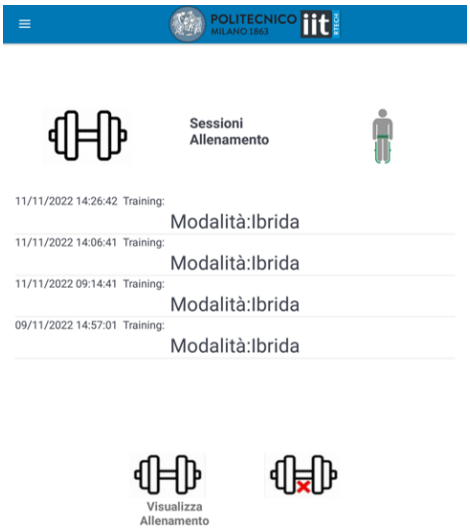

Figure 15: Visualization of Trainings

Figure 16: Stored data for each training

2.2.3. Usability Evaluation

For the validation of the implemented app, its usability was adopted as evaluation parameter. The term usability defines how much a system is appropriate for carrying out a precise purpose. Its definition and evaluation have to be adapted according to who will be the users of the system, the tasks that have to be pursued and the context in which the system will be utilised. In this work, the study was conducted on biomedical engineers (both master students and PhD candidates) and therapists working in a rehabilitation clinic. During the tests, participants were asked to use the device and then assess its usability by completing two questionnaires. The testing of the device included a training session in which the participant was instructed on the app functioning; in particular, on all the steps needed to conduct a rehabilitative session. Once acquired the necessary knowledge, the participant was invited to simulate a session on a voluntary participant. Thus, he was asked to replicate all the task that were shown to him. In particular, he was asked to create a new patient, carry out the calibration process and set up the parameters needed for the walking session. Moreover, all the additional functionalities were illustrated to the participant, in order to allow a complete and authentic evaluation of the application from its side. These include the possibility of saving training and FES data and the warning messages that appear whenever the user does something in the wrong way, aiming at preventing errors. Once completed, participants passed to the evaluation part, where they were asked to fill two different questionnaires: System Usability Scale (SUS) and *ad hoc* Questionnaire.

System Usability Scale

System Usability Scale (SUS) is a ten-item questionnaire related to the usability of a system. According to Brooke [4], SUS has been created as a tool that allows the direct comparison between different systems. SUS is compiled by the user soon after he has used the system by responding to the question with a score from 1 to 5. The score that each item gives to the total score is related to its position. The score of items that occupy odd positions (i.e question number: 1, 3, 5, 7, 9) is given by the scale position minus 1, while items in even position (i.e question number: 2, 4, 6, 8, 10) gives a score equal to 5 minus the value of the scale position. This inverted scale between questions aims at avoiding random or identical answers from participants, that can be immediately noticed. Moreover, it requires a careful reading of all questions. With this approach, each question assigns a score between 0 and 4 (subtracting 1 from the actual score). The overall score is given by summing up all the points of the questions and multiply it for 2.5. Doing this, the overall score will vary between 0 and 100. Overall, a total score above of 68 is considered as above average [1]. A template of SUS questionnaire is shown in *Figure 17*.
Since SUS purpose is to provide a tool that allows the usability evaluation of a wide range of system, it has the drawback to get general results. Then, the elaboration of a *ad hoc* questionnaire focused on the real use of the system is required.

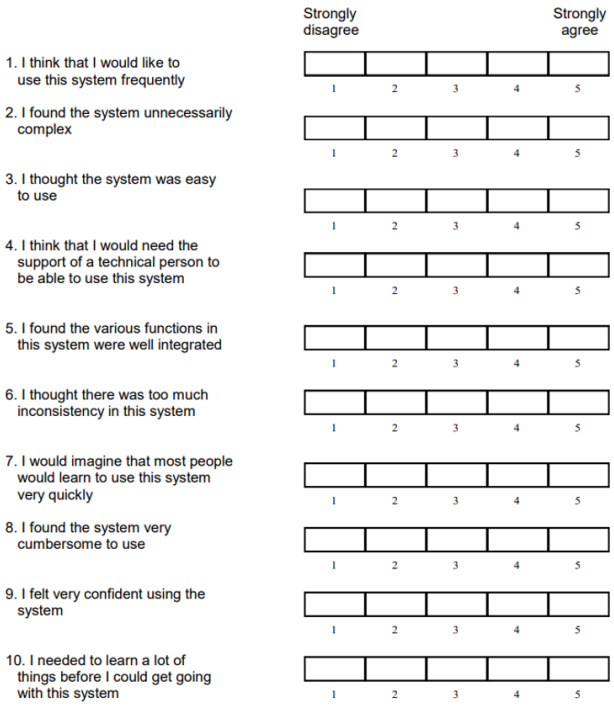

Figure 17: System Usability Scale Template

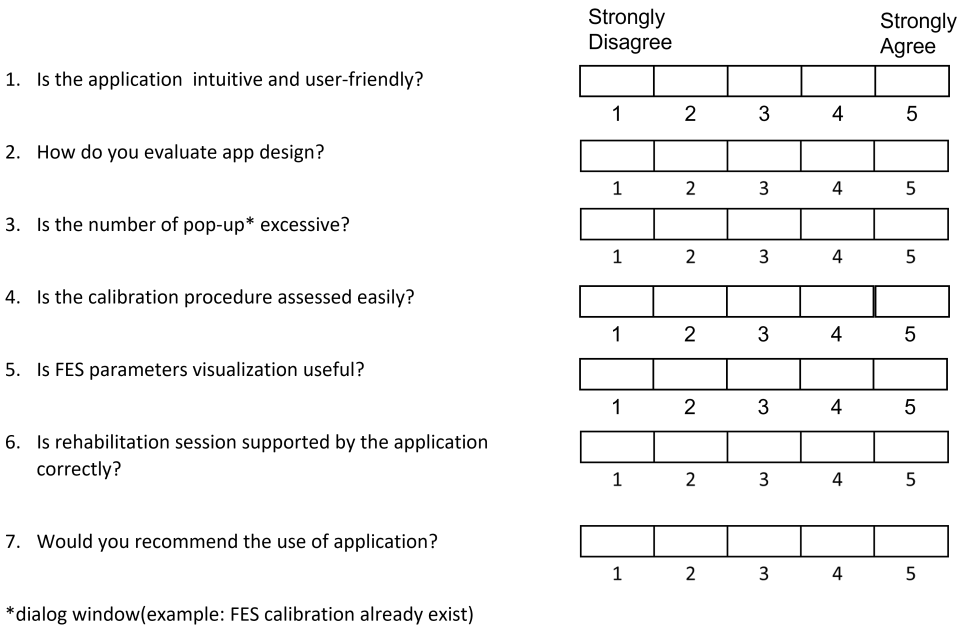

Figure 18: *ad hoc* Questionnaire Template.

Ad Hoc Questionnaire

As previously said, usability evaluation depends on three features: the user, the task and the context. To evaluate the usability of the application by considering its real utilisation, it has been proposed an *ad hoc* questionnaire. This questionnaire is composed by seven closed questions, three open questions related to positive, negative and general notes and three images of app panels, in which the user can indicate some improvements for the app design by directly annotating them on the image. The total score is calculated similarly to SUS. Each question assigns a score equal to the scale position minus 1 except for the third question that gives a score equal to 5 minus the scale position. Then, all the scores are summed up and the result is multiplied by 3,5 thus the total score can vary between 0 and 100. A template of the closed question of the *ad hoc* questionnaire is shown in *Figure 18*.

3. Results

In this section, the results are reported. In the first part requirements validation is addresses, while in the second part the usability of the application is taken into account by analysing the questionnaires filled out by therapists and engineers.

3.1. Requirements validation

The validation of the requirements, presented in 2.2.1, has been assessed empirically through laboratory tests. Regarding the Always on Functions, the following requirements have been verified:

- Check Twin Connections: application and Twin maintain the connection for the whole therapeutic session. However, it has to reported that the connection can be lost when a large amount of data is exchanged between the two devices, due to limits of the Bluetooth technology. In case it happens, the application reports it to the user;
- App Communication: the messages that one system sends to another are correctly collected and interpreted by the receiver that produces the required action;
- Feedback to the user: the user is constantly updated on the system state and on the performed actions. All updates are managed with both graphical tools (i.e Figure 12) and dialog windows (i.e. Figure 13).

For what concerns the requirements for assisting the therapy, the following ones have been validated:

- Control Flow of the Therapy: the application guides correctly the user through the rehabilitative session by enabling/disabling buttons functionalities;
- Limit Human Error: the application reports through dialog windows if any inconsistency is present. An example is that the app does not allow to start the control modality in case the calibration for a muscle that has to be stimulated is not present (*Figure 19*).

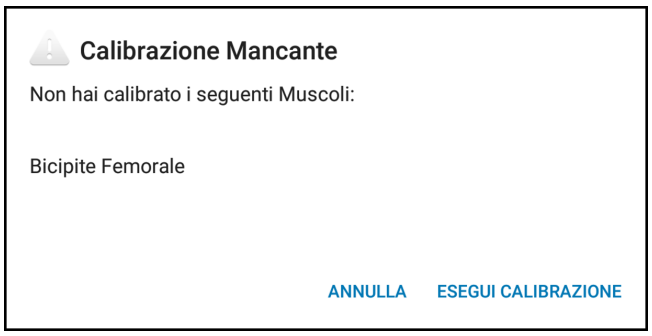

Figure 19: Example of dialog window that aims to limit human errors.

Finally, the data management has been verified:

- Saving FES Calibration: the system correctly stores and saves data for each muscle that has been calibrated. FES calibration data are memorized in a *.cfg* file located on Twin's motherboard;
- Loading existing FES calibration: if an FES calibration is already associated to the patient, it is correctly loaded and visualized through a dialog window (i.e. *Figure 13*) or in the section 'Visualize Calibration' within the 'Patient Panel' (*Figure 9*);
- Saving Training: at the end of each rehabilitative session, the user can save training data in order to track the patient's progress;
- Displaying Previous Training: if previous training are present for the selected patient, they can be correctly visualized within the Training Panel (*Figure 15*).

3.2. Usability Evaluation

This section reports usability results of the application *TwinFes*, intended for the control of the homonym hybrid exoskeleton. Data collected for the usability evaluation consist in the scores of two questionnaires, the SUS one and *ad hoc* one, presented in the previous section (2.2.3). Both questionnaires were filled out by 10 biomedical engineers and 7 therapists, after a practical test of the application with the hybrid device. In particular, participants received a general introduction to the application functioning, showing all the features and errors management offered by the interface. Then, they were asked to perform all steps needed to prepare a therapeutic session: the creation of a new patient, the execution of a calibration procedure and the setting of gait parameters. The calibration procedure was performed on a healthy subject who voluntarily accepted to take part to the acquisition after signing an informed consent.
The report of results can be divided in 2 parts:

- Response Frequencies
- Total Scores

Both parts are analysed by considering firstly therapists and engineers together then considering them separately. Moreover, in order to define what are the best and the worst aspects of the application, the median for each question was taken into account. If two or more questions had the same median, the average of the scores for each question has been considered to define the highest-rated and lowest-rated questions.

3.2.1. Response Frequency

At first, the overall frequency of response for each question has been analysed considering the two groups together. In *Figure 20* and *Figure 21* the scores frequency for the SUS and the *ad hoc* questionnaire respectively are represented.
Regarding SUS, the question that obtained the lowest score is #4 (i.e. 'I think that I would need the support of a technical person to be able to use this system') with a median of 2 (mean 1.9). Whereas, the maximum score has been noticed for question #7 (i.e.'I would imagine that most people would learn to use this system very quickly') with a median of 4 (mean 3.5).
On the other hand, considering the *ad hoc* questionnaire, it presents a less significant difference between the median of the lowest-rated question and the one of the best-rated question, with respect to the SUS. Indeed, the median of the lowest-rated question (i.e. Question #3) is 3 (mean 3) whereas the median of the best-rated question (i.e. Question #4) is 4 (mean 3.6).
The medians and average scores for each item of the two questionnaires are reported in *Table 4*.
In order to investigate if any relevant difference in the opinions of therapists and engineers is present, the response frequency of the two groups has been analysed separately.

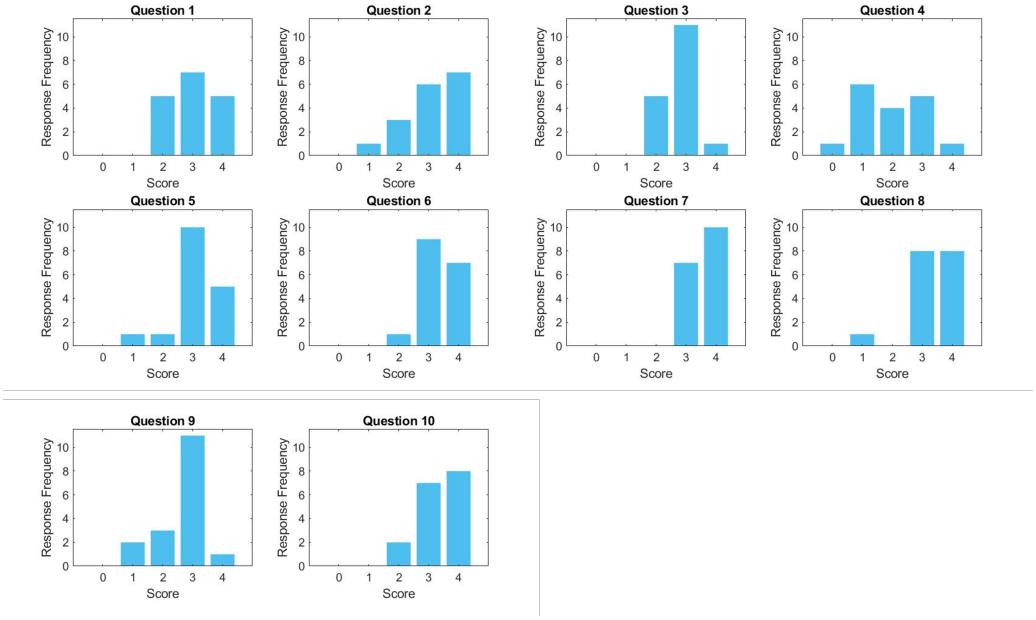

Figure 20: Response Frequencies of each question for SUS.

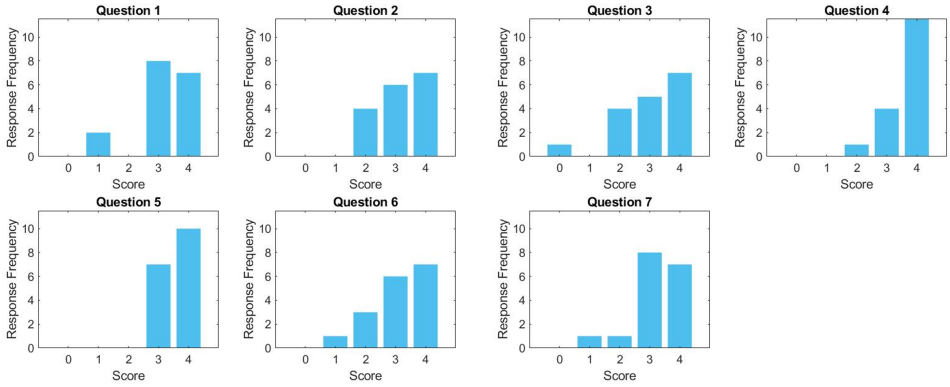

Figure 21: Response Frequencies of each question for *ad hoc* questionnaire.

Question	Median	Average Score
#1	3	3.0
#2	3	3.1
#3	3	2.7
#4	2	1.9
#5	3	3.1
#6	3	3.3
#7	4	3.5
#8	3	3.3
#9	3	2.6
#10	3	3.3

(a)

Question	Median	Average Score
#1	3	3.1
#2	3	3.1
#3	3	3.0
#4	4	3.6
#5	4	3.5
#6	3	3.1
#7	3	3.2

(b)

Table 4: Average Score of each question for SUS (*a*) and *ad hoc* (*b*) questionnaire considering all the participants.

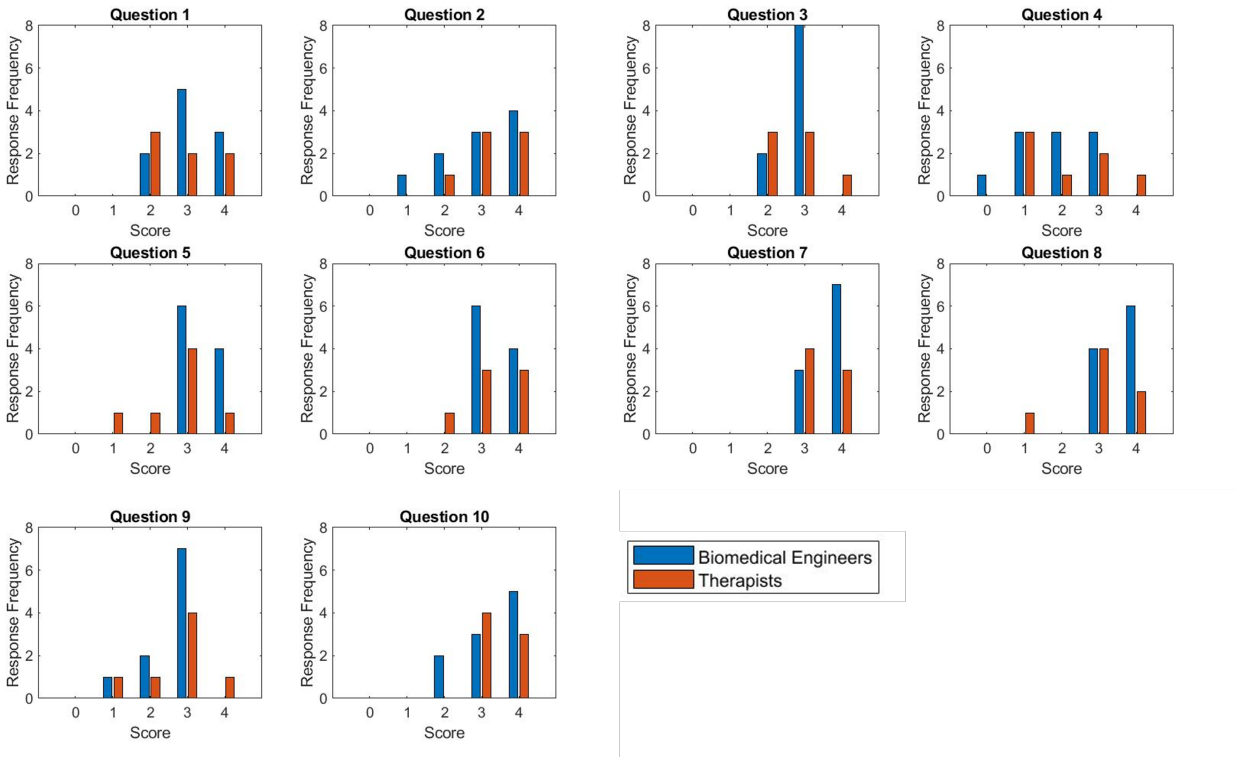

Figure 22: SUS questionnaire response frequencies divided in groups.

Considering SUS, both groups had given the lowest rate to question #4 ('i.e. 'I think that I would need the support of a technical person to be able to use this system': median for engineers: 2 (mean 1.8), median for therapists: 2 (mean 2.1)) and the higher rate to question #7 (i.e.'I would imagine that most people would learn to use this system very quickly': median for engineers: 4 (mean 3.7), median for therapist: 3 (mean 3.7)). The response frequencies for each question are represented in *Figure 22*.
For what concerns *ad hoc* questionnaire, the first disagreement between the two groups has been encountered. Indeed, question #2 (i.e. 'How do you evaluate app design?') has obtained the minimum rate, median of 3 (mean 3), from the point of view of engineers whereas therapists perceived the app not really intuitive and user-friendly since question #1 (i.e. Is the application sufficiently intuitive and user-friendly?') has scored the lowest score, median of 3 (mean 2.5).
Another difference of opinions regards the aspect that mostly satisfied the two categories. Therapists were more impressed by the fast calibration enabled by the application, in fact, they gave to question #4 (i.e. 'The application allows a fast FES calibration phase') a median of 4 (mean 4). On the other hand, biomedical engineers particularly appreciated the app design, scoring question #1 (i.e. Is the application sufficiently intuitive and user-friendly?') with a median 4 of (mean 3.6). All the response frequencies are depicted in *Figure 23*.
The medians and average scores of SUS and *ad hoc* questionnaire for each question are presented in *Table 5* and *Table 6* respectively.

3.2.2. Total Scores

The recorded total scores are graphically depicted in *Figure 24* and *Figure 25* for the SUS and *ad hoc* questionnaire respectively. Instead, the statistical parameters are listed in *Table 7* for the former and *Table 8* for the latter questionnaire.
The total scores of the two groups have been analysed by looking at how the data were distributed. For SUS, data distribution is depicted in *Figure 26* and listed in *Table 9*. Whereas statistical data of *ad hoc* questionnaire are depicted in *Figure 27* and listed in *Table 10* .
In order to see if any statistical difference was presented between the engineers and therapists opinions, a Mann-Whitney U test has been performed on the total scores of the two questionnaires. The statistical test did not arise any difference in both cases, in particular the null hypotesis (no statistical difference) has been accepted with a p-value of 0.94 and 0.93, respectively for SUS and *ad hoc* questionnaires.

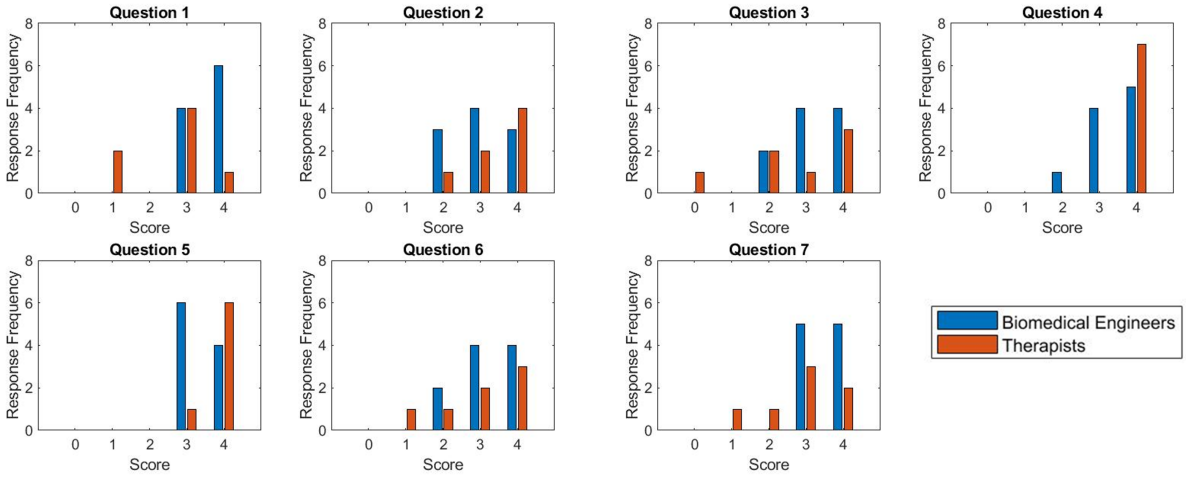

Figure 23: *ad hoc* questionnaire response frequencies divided in groups.

Question	Median	Average Score
#1	3	3.1
#2	3	3.0
#3	3	2.8
#4	2	1.8
#5	3	3.4
#6	3	3.4
#7	4	3.7
#8	4	3.6
#9	3	2.6
#10	3.5	3.3

(a)

Question	Median	Average Score
#1	3	2.8
#2	3	3.2
#3	3	2.7
#4	2	2.1
#5	3	2.7
#6	3	3.2
#7	3	3.4
#8	3	3.0
#9	3	2.7
#10	3	3.4

(b)

Table 5: Average Score of SUS for each question for Biomedical Engineers (a) and therapists (b).

Question	Median	Average Score
#1	4	3.6
#2	3	3.0
#3	3	3.2
#4	3.5	3.4
#5	3	3.4
#6	3	3.2
#7	3.5	3.5

(a)

Question	Median	Average Score
#1	3	2.5
#2	4	3.4
#3	3	2.7
#4	4	4.0
#5	4	3.8
#6	3	3.0
#7	3	2.8

(b)

Table 6: Average Score of *ad hoc* questionnaire for each question for Biomedical Engineers (a) and therapists (b).

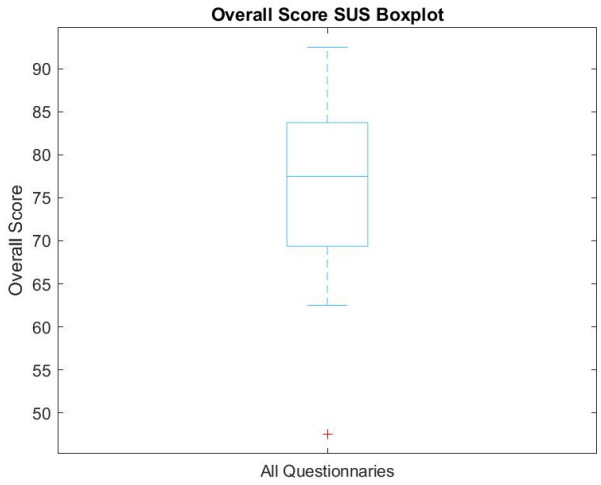

Figure 24: Boxplot of SUS scores.

Parameter	Value
Mean	75.5
Median	77.5
25^{th} Quantiles	69.3
75^{th} Quantiles	83.7

Table 7: Statistical Parameters for the SUS scores.

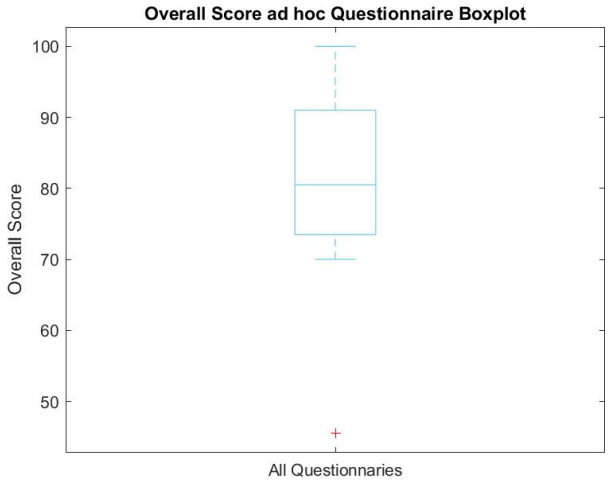

Figure 25: Boxplot of *ad hoc* questionnaire scores.

Parameter	Value
Mean	80.4
Median	80.5
25^{th} Quantiles	73.5
75^{th} Quantiles	91

Table 8: Statistical Parameters for *ad hoc* questionnaire scores.

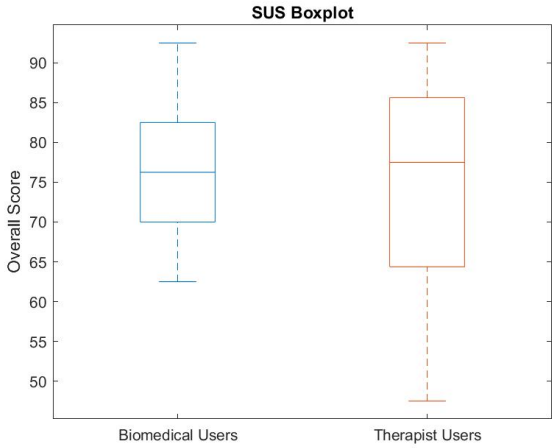

Figure 26: Boxplot of SUS scores divided in groups.

Parameter	Value
Mean	76.7
Median	76.2
$25^{th}Quantile$	70
$75^{th}Quantile$	82.5

(a)

Parameter	Value
Mean	73.9
Median	77.5
$25^{th}Quantile$	64.3
$75^{th}Quantile$	85.6

(b)

Table 9: Statistical Parameters for SUS considering biomedical engineers (a) and therapists (b).

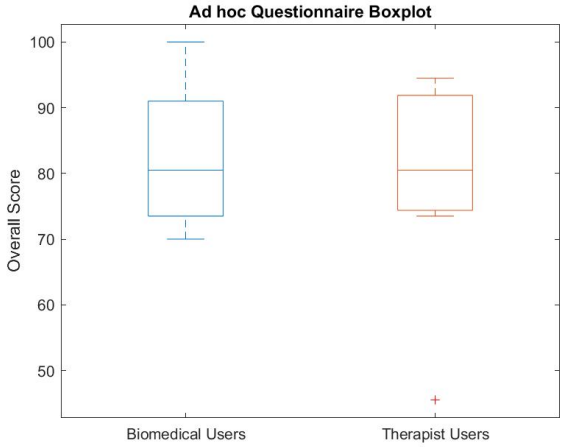

Figure 27: Boxplot of *ad hoc* questionnaire scores divided in groups.

Parameter	Value
Mean	81.7
Median	80.5
$25^{th}Quantile$	73.5
$75^{th}Quantile$	91.0

(a)

Parameter	Value
Mean	78.5
Median	80.5
$25^{th}Quantile$	74.3
$75^{th}Quantile$	91.8

(b)

Table 10: Statistical Parameters for *ad hoc* questionnaire considering biomedical engineers (a) and therapists (b).

3.2.3. Participants Opinions

In this section, the collection of the participants' opinion is presented. The opinions regard the positive, negative and general aspects that participants noted.
Some positive aspects that participants found regard usability. In particular, they declared that application was intuitive, well-organised and clear. Moreover, the visualization of FES parameters and the correspondence between dots' colours of the stimulated muscles and the cables connected to the stimulator have collected the approval of participants.
On the other hand, the negative aspect reported concerns the order of the buttons within the 'Hybrid Mode Panel'. Participants suggested to move the 'Enable Control' Button on top of the others.
As general notes, the following hints have been suggested. First of all, when the session starts, the user should have the possibility to choice if he wants to use FES or not. Other suggestions focus on the legibility of the screens. Especially, characters' size increasing and horizontal lines insertion to facilitate the reading of the parameters within FES parameters and training visualizations have been advanced.

4. Discussions

The results presented in the previous section can be considered as satisfactory since both questionnaires registered good results. Moreover, no statistically significant difference between therapists and biomedical engineers resulted from the analyzed data. Consequently, it can be concluded that the application results sufficiently user-friendly to correctly guide a rehabilitation treatment.
However, two main points arose from the results analysis. The first one is relative to the disagreement recorded between the two groups in the identification of the worst and best aspects in the *ad hoc* questionnaire. As highlighted in section 3.2.1, the worst aspect for engineers was the app design (Question #2) while for therapists the major disadvantage is the fact that the application is not enough user-friendly (Question #1). On the other hand, engineers particularly appreciated the intuitive design and the facility in learning it, whilst therapists were positively impressed by the fast FES calibration phase (Question #4). The cause of these disagreements can be identified both in the difference of average age and in the clinical experience of the users. In fact, the age range of the two groups is very different: biomedical engineers range between 21 and 30 years old, whereas therapists between 30 and 60 years old. Hence, this could explain why therapists found the system more complicated. Nevertheless, therapists had a more practical vision of how the robotic rehabilitation is carried out, indeed, they rewarded the functional aspect of the application such as the reduced time-consuming for FES calibration.
The second point regards the results obtained in SUS about the question with the minimum and the maximum score. Indeed, many users felt the need to have a technical person beside them to guide the rehabilitation treatment but, at the same time, they found the application very easy to use. This contradiction lets hypothesize that initially people are not very confident on how to use the application but think that they could handle it easily with more practice. Probably, multiple training sessions on how to use application are to be considered, to accelerate the learning process and increase the confidence of the user.
Overall, the obtained usability results are satisfactory as the mean scores of both questionnaires are above 75. In particular, if the SUS mean score results to be over 68 points, according to [1], the application is considered above average.
Concerning negative and general aspects reported by the participants, some considerations are required.
The confounding buttons position within the hybrid mode has been declared by 2 participants out of 17. This problem can be easily achieved by changing button disposition. However, the actual application already manages errors about pushing button in the wrong sequence. Indeed, all the buttons are disabled till the 'Enable Control' button is clicked, overcoming less intuitive displacement of buttons. When further usability investigation will be assessed and more opinions will be collected, if this issue will be reported more frequently, then adequate measures will be taken.
Furthermore, the possibility to choice if use FES or not at the beginning will be develop. One way to achieve it is through a dialog window appearing when session starts, which gives the chance to choice between two options: Twin+FES and Twin. If the user choices Twin+FES, he will be re-directed to 'FES Panel' otherwise, user goes directly to one of the control modalities, proprioceptive or hybrid.
Finally, increasing characters' size and introducing horizontal line to make parameters reading easier will be taken into account.
Despite these results, a more accurate usability analysis has to be performed by widening the number of participants involved during the test and collecting their opinions. Moreover, the application has to be tested during a complete rehabilitation session, not only performing FES calibration, to reveal possible malfunctioning not already detected.
Further works should focus on testing the real efficiency and functioning of Twin-Fes within a clinical contexts to guide rehabilitation sessions.

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