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THE SOFTWARE INTERFACE OF A HYBRID FES AND MECHATRONIC EXOSKELETON SYSTEM FOR HAND REHABILITATION IN STROKE PEOPLE

BY

RADU IONAȘCU* and MARIAN-SILVIU POBORONIUC

“Gheorghe Asachi” Technical University of Iași,
Faculty of Electrical Engineering, Iași, Romania

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Abstract. This paper introduces novel contributions to the field of hand rehabilitation systems designed for stroke patients. The primary objective is to enhance voluntary movements in the paralyzed upper limbs, with a particular focus on hand functionality. The system, known as MANUTEX, comprises two main components: functional electrical stimulation (FES) implemented through a textile glove with embedded electrodes, connected to a programmable neurostimulator, and a mechatronic exoskeleton resembling a glove, powered by individual linear motors for each finger. These linear motors are controlled by a programmable microcontroller on a central board. MANUTEX delivers mirror therapy, a therapeutic approach requiring a sensory glove attached to the healthy hand. This sensory glove provides reference movements for the hybrid system located on the affected, impaired hand. An application installed on a computer serves as the control interface for the entire system. It reads movement data from the healthy hand and concurrently sends commands to both the FES and mechatronic exoskeleton glove, ensuring a balanced and synchronized therapeutic experience for the patient.

*Corresponding author; *e-mail*: radu.ionascu@gmail.com

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1. Introduction

Stroke is a cause of serious long-term disability, but even more than that a cause of mortality across the world as specified in the specialty literature. For instance, in Europe statistics mention that as close to year 2017, more than 1.5 million people were affected by a stroke. Also, around 9 million were living with stroke. Economically speaking, in EU countries the economical effort was around 60 billion euros in 2017 (Luengo-Fernandez *et al*., 2020).

Individuals who have experienced a stroke often suffer from motor impairment in their upper limbs, significantly impacting their daily lives. Ultimately, these patients aspire to regain their neuromotor abilities to the greatest extent possible, enabling them to perform even the most fundamental everyday tasks. (Post-Stroke Rehabilitation Fact Sheet, (ninds.nih.gov, 2020).

On the market there are many examples of devices available as an attempt to restore hand or/and upper limb functionality of the patients who encountered a stroke, by means of different wearable devices aiming for active motor training (Khan *et al*., 2020). The majority of the devices which aim towards upper limb rehabilitation rely on low weight robotic arm design with improved wearability (e.g. ALEx, MIT-MANUS, ARMin robot (Nef and Riener, 2012), HandMATE).

Functional Electrical Stimulation (FES) serves as a method to facilitate hand exercises for individuals impacted by strokes. This technique involves the placement of electrodes on the forearm, which, when activated by electrical currents, both stimulate the nerves and elicit movement in the paralyzed hand (Biasucci *et al*., 2018).

Using an exoskeleton-based device is another way to support stroke affected patients to perform hand exercises, for recovery. This type of mechatronic device is a passive one and in general uses linear motors (Randazzo *et al.*, 2018).

The two previously mentioned methods have been integrated into an innovative hand rehabilitation system known as MANUTEX, as outlined in studies (Poboroniuc *et al.*, 2021; Ionașcu *et al.*, 2021). This system is designed to aid stroke patients in their recovery process by achieving a harmonious balance between Functional Electrical Stimulation (FES) and a mechatronic exoskeleton. Furthermore, MANUTEX incorporates a monitoring feature that tracks any remaining voluntary movements in the patient's affected hand. Additionally, this novel device concept mimics the natural movements of a healthy hand and translates this data into coordinated motions for the affected hand (Ionașcu *et al*., 2021).

A software interface along with a control algorithm (developed in C++ on a computer and in embedded C on a microcontroller) has been developed to control the system and the hardware components (Ionașcu *et al*., 2021).

2. The MANUTEX System Hardware Design

The MANUTEX device consists of two main subsystems. One is the mechatronic glove (exoskeleton) which is aimed to mechanically support the patient in the process of recovering the affected hand movement abilities. The second is the FES component which consists of electrodes embedded into a textile glove connected to a programable stimulator. FES subsystem will stimulate hand movement via the muscular system and in parallel the exoskeleton will attempt to coordinate and control the hand motion. The healthy hand is a reference for the impaired hand and its movements are monitored by a sensorial glove. Practically the system will provide mirrored exercises by both hands for rehabilitation therapies (Ionașcu *et al*., 2021).

The overall hardware composition and components interconnections of the MANUTEX system are described in Fig. 1.

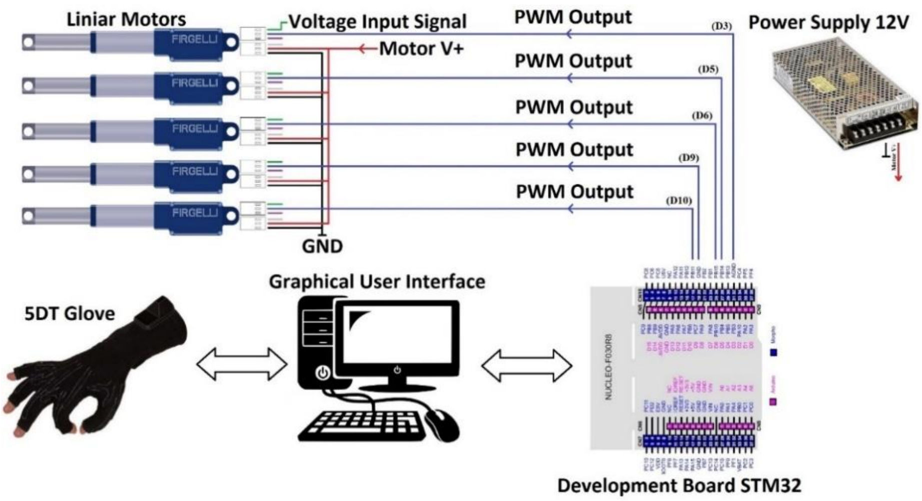

Fig. 1 – MANUTEX System Hardware Architecture.

Five Firgelli L12 linear motors are used as actuators to move each finger of the affected hand for flexion/extension. The linear motors are connected to some cables and are firmly attached to a special glove as shown in Fig. 2. Each linear motor may be initialized, calibrated and controlled independently by using PWM signals generated by an STM32 Nucleo-F030R8 board including an ARM Cortex M0 microcontroller.

Fig. 2 – Exoskeleton Mechatronic Glove.

An optical-based sensor glove (5DT) as in Fig. 3 is used for monitoring the fingers' positions of the healthy hand, which provides consistent digital information while maintaining a high level of comfort.

Fig. 3 – Optical-based Sensor Glove (5DT).

Below in Fig. 4 it may observed how the sensorial glove monitors the fingers' movement during a full closing and opening of the healthy hand on each finger individually (Ionașcu *et al.*, 2021).

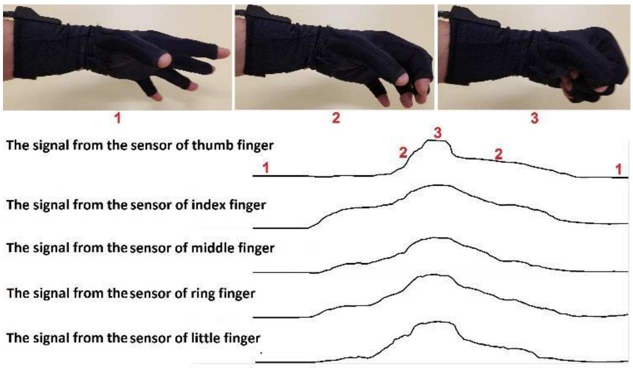

Fig. 4 – Closing and Opening the Fingers of the Healthy Hand.

The MotionStim8 neurostimulator serves as another crucial element of the MANUTEX system. This device is connected to a textile electrode glove, as illustrated in Fig. 6, and its primary purpose is to facilitate the restoration of lost muscle functions, as well as muscle strengthening and preservation. To operate MotionStim8, it can be configured and controlled via a PC or laptop using the RS-232 serial interface (Ionaşcu *et al.*, 2021).

Fig. 5 – MotionStim8 Neurostimulator.

Fig. 6 – Textile Electrodes Glove and MotionStim8.

Putting together: a Laptop, the exoskeleton glove with linear motors and development board (STM32 Nucleo-F030R8), the MotionStim8 connected to the textile electrodes glove and connecting them appropriately, a functional model is brought to life as it may be seen in Fig. 7.

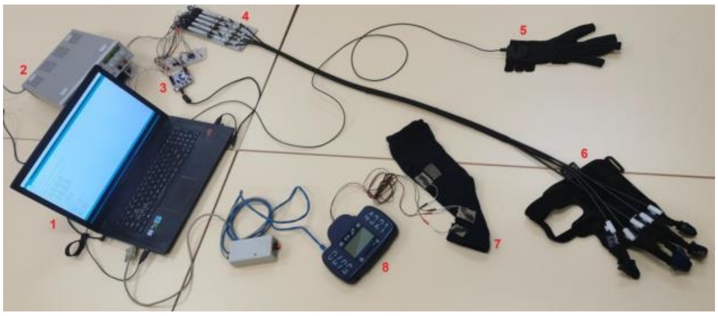

Fig. 7 – Functional Model of the entire MANUTEX System.

The whole system is powered up by a DC power Supply which is able to provide 12 Volts and maximum currents of 3 Amps.

While running tests on the MANUTEX system the mirror movement behaviour of both the healthy and the affected hand may be observer as in Fig. 8 (Ionașcu *et al.*, 2021).

Fig. 8 – MANUTEX System Testing.

3. The MANUTEX System's Software Applications

The software system responsible for managing the MANUTEX System consists of two key components. The first component, known as the Main Control and Data Conversion Component (Ionașcu *et al*., 2022), written in C++, is installed on a computer. This component plays a pivotal role in the system as it receives data from the sensor glove, interprets this data, and then converts it into commands. These commands are subsequently used to control both the mechatronic exoskeleton and the Functional Electrical Stimulation (FES) gloves (via MotionStim8). This coordinated control facilitates mirrored movements, aiding in the necessary exercises for the recovery of the patients' affected hand. Additionally, the implementation of this software includes a robust error tracking mechanism. This mechanism serves to detect and respond to unexpected behaviour, ensuring the system can be brought to a safe state when necessary (Ionașcu *et al*., 2021; Ionașcu *et al*., 2022).

The incoming data is transmitted to the STM32 Nucleo Board F030R8, where it undergoes processing through the Mechatronic Hand Software Control Software Component (developed in embedded C). This software component translates the data into PWM (Pulse Width Modulation) values, which are then utilized to control the linear motors within the mechatronic glove exoskeleton. These processes are iterated every 100 milliseconds, a suitable interval that grants the system ample time to process the commands and complete the required actions (Ionașcu *et al*., 2021; Ionașcu *et al*., 2022).

The main software application communicates with its peripherals via RS232 virtual ports emulated on USB, as shown in Fig. 9.

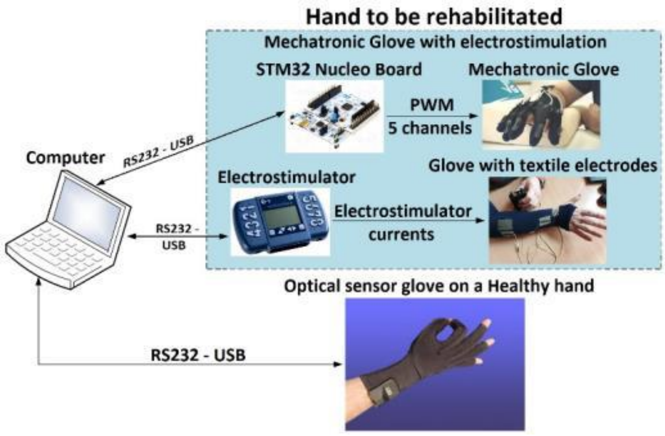

Fig. 9 – Communication Interfaces Between MANUTEX Components.

The Main Control and Data Conversion Component is depicted into three communication modules known as Mechatronic Hand (Exoskeleton) Command Unit, FES MotionStim8 Command Unit and Optical Sensors (5DT) Data Acquisition Unit which are practically using the RS232 interfaces. For a better view these blocks are emphasized in Fig. 10.

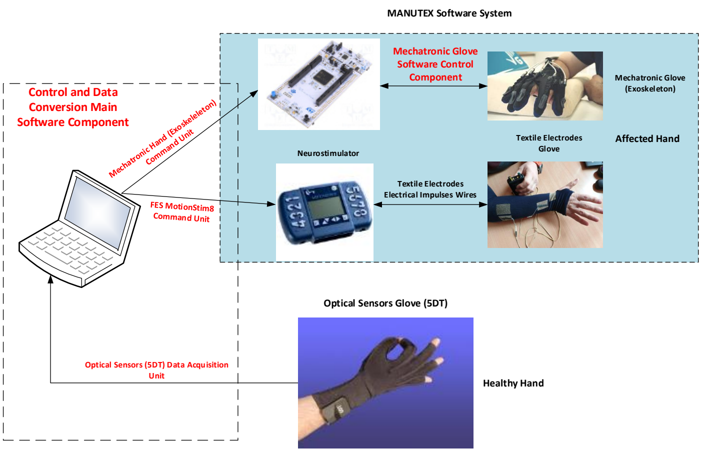

Fig. 10 – The Main Software Component Design.

In order to attain an efficient and adaptable implementation, the Main Control and Data Conversion Components have been divided into multiple software units, as depicted in Fig. 11. This approach brings the implementation closer to aligning with the standards established for the development of medical devices, specifically ISO 13485 for medical devices development and IEC 62304 for medical device software development.

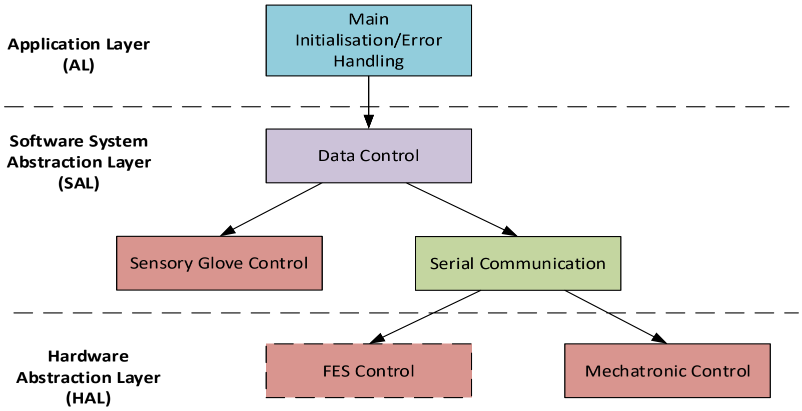

Fig. 11 – Main Control and Data Conversion Component Structure.

The control mechanism has been designed to actively identify potential software unit faults and is also capable of detecting any data inconsistencies during communication through interfaces. In the context of the FES subsystem, the manufacturer of MotionStim8 has furnished it with an error-checking mechanism. Conversely, for the mechatronic exoskeleton glove subsystem, a custom communication error-checking protocol has been developed from the ground up. The implementation hinges on a principle of mutual exclusive access when transferring data between the Control and Data Conversion Main Component and the Mechatronic Hand Software Control Component, with data validation as illustrated in Fig. 12 (Ionaşcu *et al*., 2022).

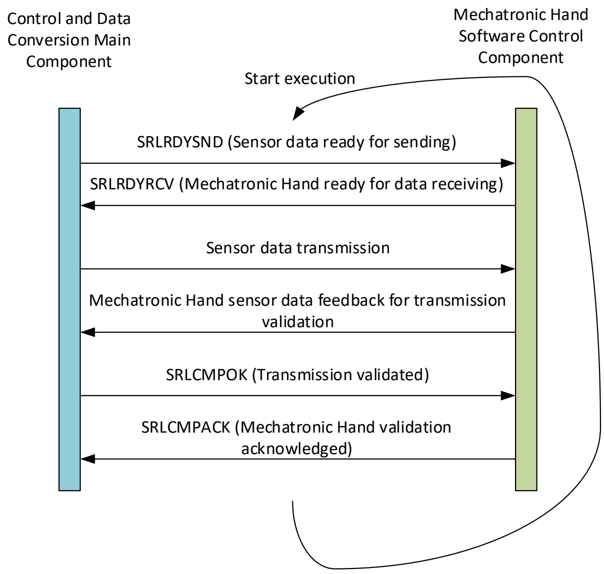

Fig. 12 – Communication Protocol Between Software Components.

In terms of data conversion, first of all it is necessary to know that the sensorial 5DT glove returns for each finger a normalized value, after calibration, each value being between 1.000 (finger extended) and 0.000 (finger flexion). These values are converted by software for the FES component using formulas (1) and (2).

$$averageGloveValue = \left. \begin{matrix} gloveValues[THUMB] + \\ gloveVales[INDEX] + \\ gloveValues[MIDDLE] + \\ gloveValues[RING] + \\ gloveValues[LITTLE] \end{matrix} \middle/ FINGERS\_NUMBER \right. \quad (1)$$

$$pulseCurrent = \begin{pmatrix} adjustedMaxPulseCurrent - \\ averageGloveValue * adjustedPulseCurrent \end{pmatrix} \quad (2)$$

(1) calculates the average of all fingers data received from the sensory glove and from (2) results the value of the pulse current in inverse proportion compared to the average value calculated in (1).

As a result, the FES feedback has a linear shape behavior and provides pulses with 300 μs fixed widths and with currents in the range of 0 – 127 mAmps as in Fig. 13 (Ionaşcu *et al*., 2022).

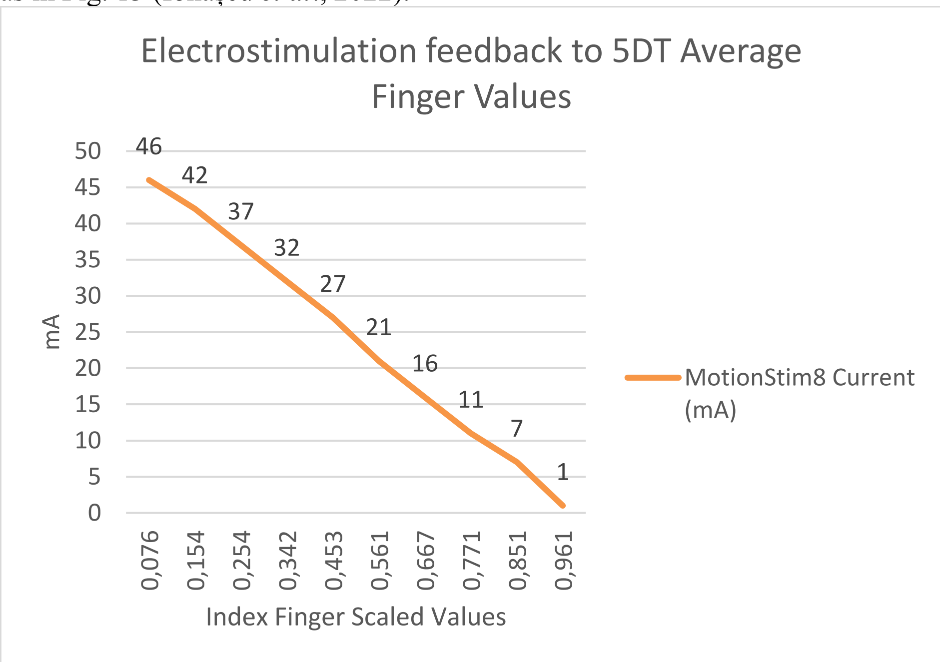

Fig. 13 – FES Feedback to Input Sensorial Glove.

In case of the linear motors of the mechatronic exoskeleton glove, the data read from the 5DT glove is converted, by software, to PWM duty cycles using formula (3).

$$motor < finger > DCycle = \left((motor < finger > MaxDCycle - motor < finger > MinDCycle) * 100 \right) / 100 \quad (3)$$

The output values for each affected hand finger are in range of 0% (finger extension) – 100% (finger flexion) PWM duty cycles, in a linear manner as in Fig. 14 (Ionaşcu *et al.*, 2022).

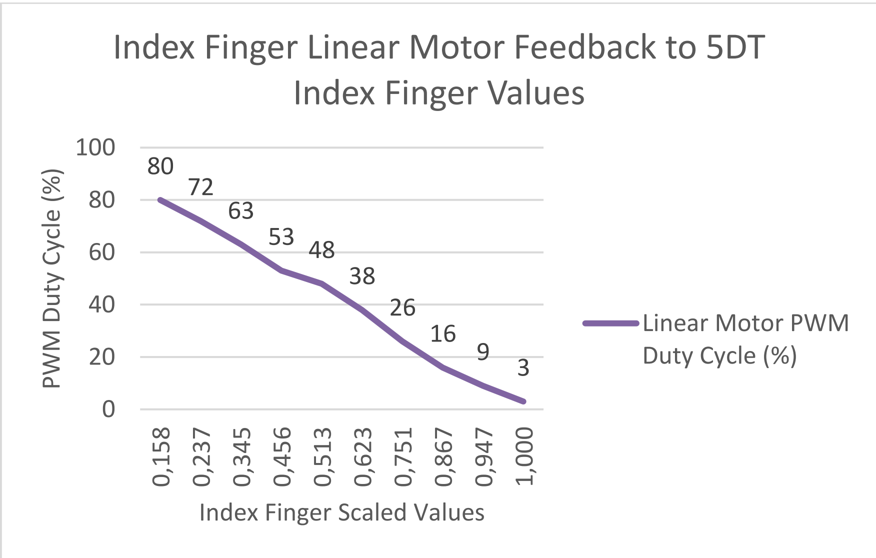

Fig. 14 – Mechatronic Exoskeleton Glove Finger Feedback to the Sensorial Glove Data.

4. Clinical Testing Results

The updated software implementation of the MANUTEX System has demonstrated greater efficiency when compared to its earlier functional models and concepts. A clinical assessment using the Fugl-Meyer evaluation was conducted with 21 patients in a clinical setting, revealing improvements in their independent movement capabilities and achieving higher scores compared to traditional rehabilitation therapies, as depicted in Fig. 15.

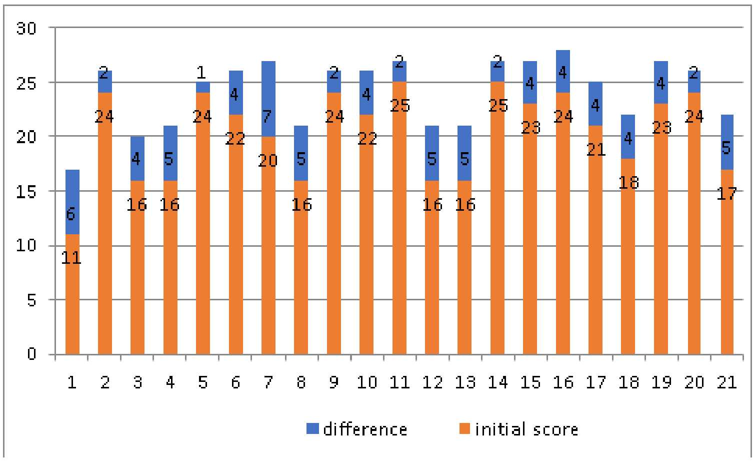

Fig. 15 – Fugl-Meyer scale A- Total score for all patients with MANUTEX used in therapies (yellow at the beginning and blue at the end, after 10 days).

The Fugl-Meyer scale A (FMA-UE) score has a maximum value of 30. In addition to their regular rehabilitation exercises, patients engaged in nine sessions with the MANUTEX System, each lasting approximately 60 minutes. The average FMA-UE scores from these sessions were approximately 24.19 ± 3.09 points, reflecting an increase of around 3.86 ± 1.53 points compared to their initial scores. This corresponds to a relative improvement of approximately 21.1% ± 12.24% relative to the initial values (Ionaşcu *et al.*, 2022; Piseru *et al.*, 2022).

5. Conclusions

The current iteration of the MANUTEX System achieves a more refined balance between Functional Electrical Stimulation (FES) and the mechatronic exoskeleton glove. Moreover, the software implementation offers the flexibility to assess and enhance therapy performance. The entire system demonstrates a swift processing time, typically taking around 3 to 4 milliseconds from data acquisition to command execution, ensuring a safe environment for the patient.

The therapy outcomes are further improved as the system can fully extend each finger within approximately 7 seconds, delivering a seamless and continuous movement experience. An important aspect to note is that both the MANUTEX System and its accompanying software applications have been developed in alignment with a medical device development approach. This strategic choice aligns the project with the primary requirements and standards of medical device development, such as ISO 13485, IEC 62304, and IEC 60601, bringing it one step closer to potential future CE certification.

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INTERFAȚA SOFTWARE A UNUI SISTEM HIBRID FES ŞI EXOSCHELET MECATRONIC PENTRU REABILITAREA MÂINILOR PERSOANELOR AFECTATE DE UN ACCIDENT VASCULAR CEREBRAL

(Rezumat)

Această lucrare își propune să prezinte noi contribuții, pentru componenta software, în cadrul unor sisteme de reabilitare a mâinii pentru persoanele afectate de AVC. Rezultatul important este cel legat de îmbunătățirea mișcărilor voluntare ale membrelor superioare paralizate, în acest caz particular la nivelul mâinii. Sistemul numit MANUTEX este compus din două componente fizice cheie, stimularea electrică funcțională (FES) și un exoschelet mecatronic. Subsistemul FES poate fi văzut ca o mănușă textilă cu electrozi încorporați conectați la un neurostimulator programabil. Exoscheletul este de fapt o mănușă, iar fiecare deget este antrenat de un motor liniar. Toate cele cinci motoare sunt controlate de o placă cu un microcontroler programabil. MANUTEX oferă posibilitatea realizării de terapii de tip oglindă care necesită o mănușă senzorială atașată la mâna sănătoasă, acționând ca referință de mişcare pentru sistemul hibrid plasat pe mâna afectată. Întregul echipament este controlat de o aplicație computerizată care citește datele de la mâna sănătoasă și controlează sistemul pentru a susține exercițiile mâinii afectate prin FES și mănușa exoschelet mecatronic simultan, într-un mod echilibrat.