Advancing Towards Clinical Validation of an Innovative System for Restoring Upper Limb Control in Individuals with Neurological Disorders

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***Abstract*—This paper describes the validation and improvements made to a mechatronic rehabilitation system, specifically an exoskeleton, through clinical trials involving patients with neurological disorders. Known as MANUTEX EMG, this system supports the development of motor control and enhances coordination of the distal components of the upper limb. It particularly focuses on improving fine movements, precision, dexterity, and hand coordination. The use of an exoskeleton-type system for passive mobilization of the fist and fingers, combined with electromyography (EMG) using surface electrodes, helps increase recruited motor units while reducing spasticity and joint stiffness associated with deficits. The functionality of MANUTEX EMG was comprehensively evaluated initially in a laboratory at the Technical University of Iasi, followed by tests conducted at the Neurology Department of the Clinical Rehabilitation Hospital in Iasi involving healthy subjects (doctors and physiotherapists). This article aims to present the validation tests conducted on the entire system.**

Keywords— hand rehabilitation, stroke, exoskeletons, EMG, mechatronic glove, neurological recovery.

I. INTRODUCTION

This article suggests using robotic technology to assist in the rehabilitation of patients recovering from stroke, with the main goal of providing enhanced support to healthcare providers, therapists, and patients. After experiencing a stroke, patients often face various symptoms, with spasticity being particularly severe and potentially causing complete loss of motion in the affected upper limb. Early intervention is vital for the recovery process, helping patients regain independence in their everyday tasks.

MANUTEX EMG is an integrated system consisting of a functional electrical system, a carefully tailored mechatronic hand system for the patient, and a sensory system that gathers data from the unaffected limb. This comprehensive method is known as mirror therapy. By utilizingEMG monitoring, communication is established between the stretching system and upper limb commands in post-stroke patients with spasticity. This feature makes MANUTEX EMG beneficial for individuals with varying degrees of upper limb limitations[1].

To fully understand the operation of the robotic glove, it is essential to break down its mechanism into distinct components and thoroughly explain each element. Surface EMG emerges as a crucial technology that provides valuable insights into examining and exploring physiological or pathophysiological processes within the neuromuscular system. This versatile technology has a wide range of potential applications, including capturing voluntary movements among agonist and antagonist muscles, as well as identifying and understanding neuromuscular disorders. The primary significance of this device lies in its ability to unravel the complexities of neuromotor action, thereby facilitating a deeper understanding of how action potentials function at the motor unit level.

EMG is widely used across various sectors, including biological research, medical facilities, rehabilitation, robotic prosthetics, and more. Since muscles are controlled by the neurological system, EMG systems collect data from muscles, providing insights into the corresponding electrical signals. The EMG signal represents the electrical activity at the motor unit level and can be obtained through invasive or non-invasive techniques. Currently, there are multiple methods in use, as detailed in the table provided (Table I).

TABLE I. EXISTING EMG TYPES.

1	Surface EMG System (sEMG)
2	Needle EMG System (nEMG)
3	Wire EMG System (wEMG)
4	High-Density EMG System (HD-EMG)
5	Telemetry EMG System
6	Surface and Needle EMG Combined Systems
7	Integrated EMG System
8	Single Fiber EMG (SFEMG)
9	Array EMG
10	Quantitative EMG (QEMG)
11	EMG Signal Decomposition
12	Wireless EMG

Surface electromyography uses electrodes to collect information in a non-invasive manner, which makes it well-suited for obtaining data from superficial muscles[2].

The signals obtained from EMG can be utilized to seamlessly control a variety of therapeutic devices. The MANUTEX EMG model incorporates an integrated surface

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EMG system that connects the mechanical component with the anatomical component represented by the muscles.

One limitation of the EMG signal arises from background noise generated by equipment and physiological factors. Surface EMG, which uses non-invasive surface electrodes, eliminates the need for anesthesia and ensures patient comfort. Electrodes made of silver or silver chloride with low impedance provide optimal reduction of background noise. [3].

In addition to background noise, other undesirable factors in EMG recordings include electromagnetic interference, crosstalk, internal noise, electrocardiographic (ECG) signals, and movement artifacts (Table II)[4, 5].

TABLE II. NEGATIVE ASPECTS OF THE EMG

ELECTROMAGNETIC NOISES	Electromagnetic signals from surroundings overlay or cancel the electrical signal captured from a muscle.
CROSSTALK	Collect unwanted EMG signals from a muscle area that is not usually examined.
INTERNAL NOISE	It relies on the number of muscle fibers per unit, the depth and position of active fibers, and the volume of tissue.
ELECTROCARDIOGRAPHIC ARTIFACTS	Cardiac activity usually affects EMG signals
MOVEMENT ARTIFACTS	The information can be affected by the cables that connect the electrodes to the amplifier, contraction of muscles, and skin density.
BACKGROUND SOUNDS	Caused by equipment and physiological parameters.

The earliest documentation of electrical activity in nerves and muscles dates back to the mid-nineteenth century, with the initial publications on this subject and the recognition of what we now understand as the action potential emerging toward the late nineteenth century[6].

The motor unit is a group of muscle fibers innervated by a single neuron, consisting of the alpha motor neuron, the neuromuscular junction, and the muscle fibers it activates. Within the motor unit, action potentials travel from the nervous system to the muscle, initiating contraction. The main goal of EMG is to study the motor unit. Surface electromyography is used to assess neuromuscular responses and can be applied in rehabilitation and to detect potential pathological changes [7].

Surface EMG is unable to directly detect the spontaneous activity of motor units through the skin. However, it can analyze the combined activity of individual motor units and the entire muscle over extended periods. The distance between the electrodes serves as a filter. A shorter distance between the electrodes leads to lower voltage measurements, which allows for the detection of small amplitudes and the filtering out of low frequencies[8, 9].

EMGis a versatile technology used for recording muscle activity during voluntary movements, aiding in the analysis of both agonist and antagonist muscle behavior. EMG is crucial for assessing various conditions including gait abnormalities, dystonia, tremors, and central fatigue.

At the peripheral nervous system level, EMG utilizes mono/bipolar channels to identify neurogenic patterns. Introducing a second channel allows for collecting data on the average conduction speed of motor unit potentials. EMG assessments also cover evoked activity, compound muscular action potential, amplitude, frequency, fatigue, end plate location, and muscle fiber conduction velocity.

Conduction velocity in EMG is measured by calculating the time impulses take to travel between two or more linearly placed bipolar electrodes. Surface electrodes typically exhibit velocities of 4–4.5 m/s, while needle electrodes demonstrate velocities of approximately 3.5 m/s for muscle fiber conduction.

Following EMG evaluation, waveform types such as F and M waves are analyzed. F waves are generated after applying an electrical stimulus to a neuron and depend on motoneuron excitability and functional axon quantity. Each motor unit presents distinct F wave patterns, leading to variations in forms and latency. Individuals with motor fiber injury and reduced motoneurons may exhibit F waves with consistent latency or recurrent patterns [10].

Persistent F waves are indicative of motoneuron excitability and the total number of motor units at the muscle level. These waves are important for detecting polyneuropathies and neuropathic conditions characterized by proximal conduction impairment[11].

The A wave is a distinctive waveform characterized by consistent form and latency, often observed in neurological disorders and influenced by processes like nerve regeneration or demyelination. EMG faces limitations related to factors affecting nerve impulse transmission, including mechanical properties of the device, electrode positioning, and individual characteristics such as age, height, limb position, muscle length, temperature, and nerve length[8].

This article aims to discuss the use of robotic technology in post-stroke rehabilitation, which is essential for improving support for patients, therapists, and healthcare providers. MANUTEX EMG integrates Electromyography (EMG) with a mechatronic hand system and sensory feedback, enabling therapy through reflection for post-stroke patients. EMG plays a crucial role in facilitating communication between the rehabilitation system and the patient's neuromuscular system.

The MANUTEX EMG hardware consists of a mechatronic glove and an EMG reading module interfaced with microcontrollers and linear actuators, using surface EMG signals to initiate assisted movements in response to muscular activity. The software operates on the ESP32 development board to manage rehabilitation phases with EMG-based exoskeletons, facilitating adaptive rehabilitation by responding to muscular activity and optimizing hand mobility recovery. EMG data from the modules are recorded in Excel, providing information on muscle contractions and relaxation periods, and real-time data visualization helps quantify recovery outcomes during therapy sessions.

Clinical trials evaluate the effectiveness and user-friendliness of MANUTEX EMG among post-stroke patients and healthy subjects, with positive feedback from healthy volunteers highlighting ease of use and potential impact on rehabilitation.

In conclusion, MANUTEX EMG demonstrates promising capabilities in restoring motor control and

improving coordination of upper limbs, with the potential to aid in post-stroke motor recovery.

II. HARDWARE & SOFTWARE

A. Hardware

The novel device MANUTEX EMG (Fig. 1) comprises two main components: a mechatronic glove facilitating movement of the affected hand, and an EMG reading module for signal measurement and transmission to the microcontroller. The analog signal undergoes digital conversion and is compared to a preset threshold; upon reaching it, the microcontroller commands linear actuators via PWM. The EMG value is transmitted to a graphical interface in real time and logged into Excel. Five micro-linear actuators support mechanical movement, each connected to a finger via iron wires. Software controls each actuator independently using PWM signals from an ESP32 WROOM32 board. The EMG signal is monitored by an H124SG module undergoing multiple stages of signal processing. The core of the system is the ESP32 WROOM 32 module, integrating WI-FI and Bluetooth. Linear actuators are powered by a LiPo battery to reduce EMG noise. The GUI, created in LabVIEW, displays EMG values graphically and saves data to Excel. Users input patient information and set task parameters. During tasks, EMG values are graphically represented, and the mechatronic glove maintains hand movement upon reaching the threshold. Data is recorded for analysis. Schematic and layout were created using Easy EDA, and the PCB was made using a CNC model WEGSTR.

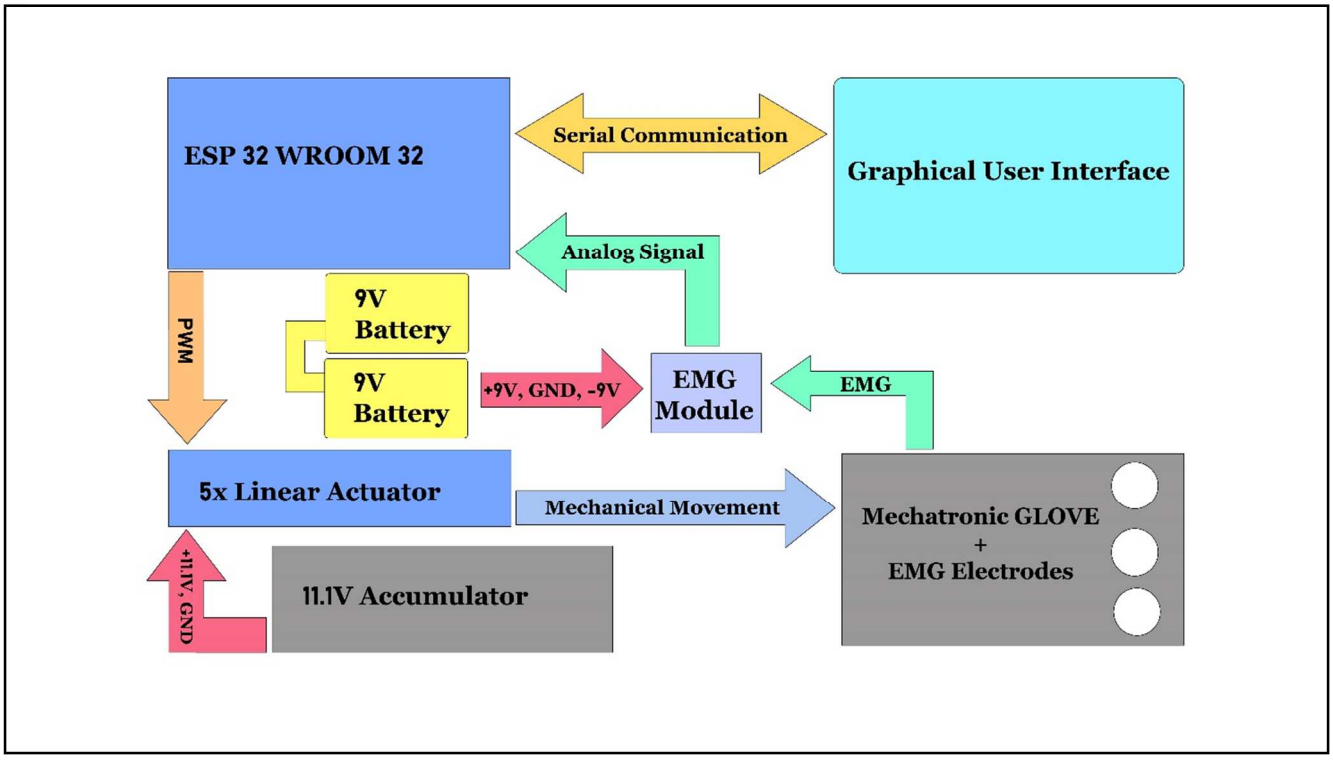

Fig. 1. The MANUTEX EMG block diagram. The MANUTEX system consists of a robotic glove equipped with linear motors, which is used on limbs affected by spasticity. It also includes an EMG system for collecting data from the upper limbs, as well as EMG electrodes that are applied distally on the upper limbs. Additionally, there is a graphic interface designed to collect and store the data, which can be used by healthcare professionals to facilitate future therapeutic planning for the patient.

Data communication between the Graphical User Interface and the ESP32 WROOM32 board is facilitated through a Serial Communication (RS232-USB) physical cable interface. This method is chosen to minimize potential interferences, which are more common with wireless solutions, and to align with safety protocols typical of medical devices.

B. Software

Operating on the ESP32 development board, the MANUTEX EMG system manages critical phases of hand exoskeleton rehabilitation. Utilizing EMGsignals triggers the exoskeleton to assist individuals with impaired hand mobility. The system's workflow includes several stages: initial setup, continuous loop operation, retrieval of EMG thresholds, sensor readings, condition-based actuation, and repetitive iteration. This integration of biomedical engineering with advanced mechatronics and sensor technology optimizes hand rehabilitation effectiveness by adapting to the patient's muscle activities. The seamless interaction among components ensures a responsive and efficient approach to rehabilitation, leading to improved recovery outcomes (Fig. 2).

The software control and data conversion application is divided into several steps. Initially, the setup routine manages the linear motors to set the mechatronic hand's fingers to a CLOSED position. The READ EMG routine then captures the threshold value set by the user manually via the RS232 serial communication interface from the Graphical User Interface application. Following this, the current EMG sensor value, which has been digitized through an ADC, is compared with the previously established EMG threshold. If the current EMG sensor value surpasses the threshold, a complete extension and flexion cycle of the mechatronic hand is triggered, with a four-second pause

between actions. Once the action of opening and closing the fingers is completed, the software resumes monitoring the EMG sensor value, continuing as long as it remains below the threshold.

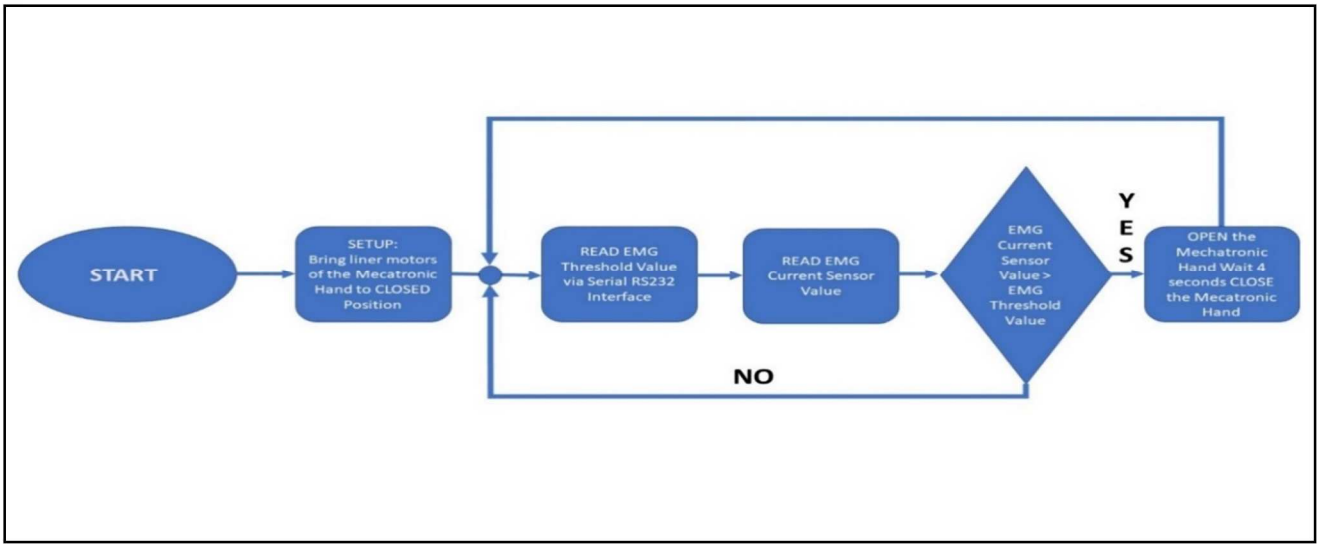

Fig. 2. The MANUTEX EMG main control & data conversion software component logical diagram

III. RECORDING AND DISPLAYING DATA

With the interface, all data is stored in Excel files for convenient analysis. Through this interface, real-time muscle contractions detected by the EMG module, any artifacts (noise), and the relaxation periods of the subjects under test (indicating lack of muscle electrical activity) can be observed. Furthermore, it allows the identification of contractions that have not reached the predetermined threshold to activate the mechatronic component of the system, those that have reached or exceeded the established threshold, and finally, the activation duration of the mechatronic glove via the linear motors (Fig. 3). These data are crucial for quantifying the outcomes of recovery and establishing a favorable setting to demonstrates enhancements in motor control during MANUTEX EMG sessions.

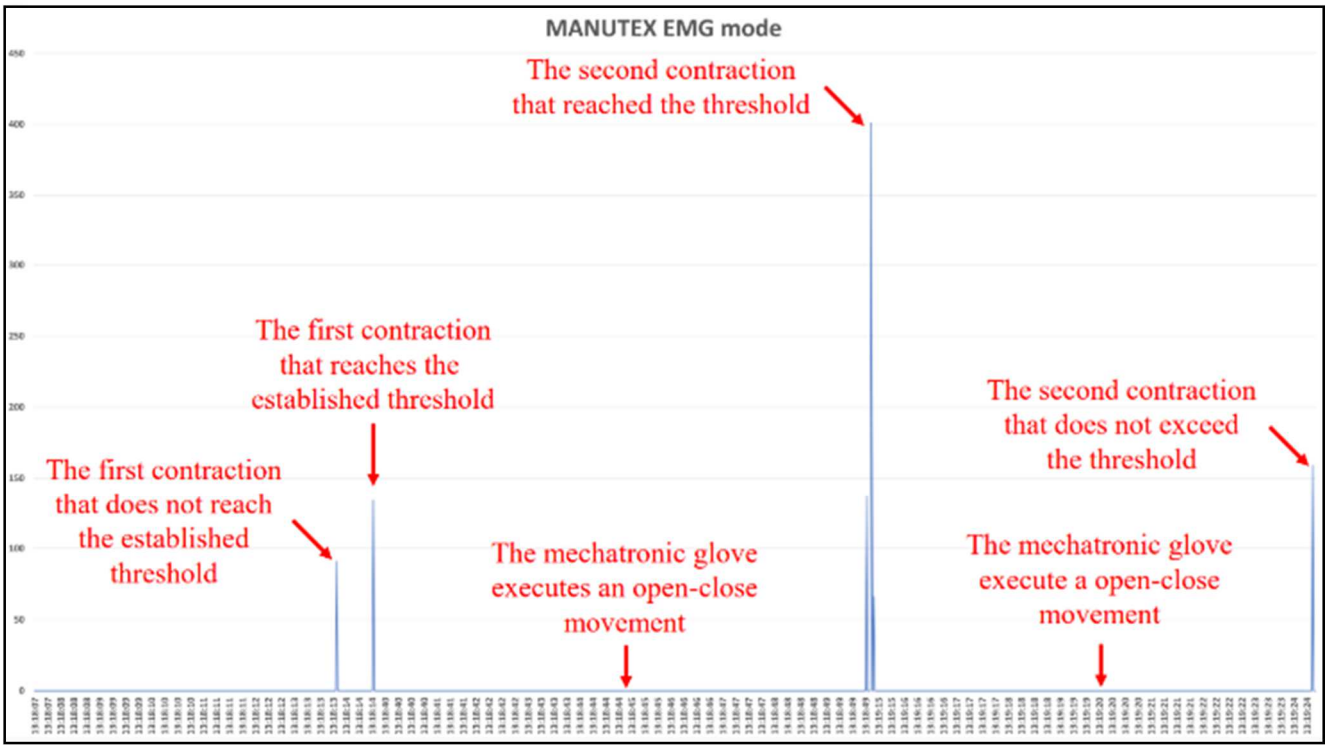

Fig. 3. MANUTEX EMG mode.

After the patient is positioned comfortably to ensure comfort during the MANUTEX EMG session, the therapist adjusts the glove on their hand and mounts the EMG electrodes with which we record the contractions. During the first encounter, we test and record the maximum value of the existing contraction. We refer to this contraction as a

threshold and it represents the maximum contraction that the patient can achieve in finger and wrist extension. For the therapy module, we will set the threshold between 60% and 80% of the recorded maximum value. Achieving this new threshold through a voluntary contraction activates the linear motors and the glove, which perform finger and wrist flexion. It was decided that this threshold should be set below 80% of the maximum value to prevent fatigue, increased blood pressure, or heart rate, in accordance with clinical practice.

IV. Clinical Testing Methods

Clinical testing is crucial for validating and refining the ManutexEMG system. This evaluation process provides valuable insights that lead to enhancements aimed at improving user-friendliness and optimizing rehabilitation outcomes. Initially, patients with post-stroke spasticity in their upper limbs were selected for enrollment in a clinical trial to demonstrate the efficacy of the system.

Due to a shortage of cases and a limited timeframe, an alternative approach was used. A preliminary test was conducted with a subset of medical staff as participants to analyze the system's advantages and identify potential drawbacks. This test took place in a controlled environment to observe the device's performance on healthy subjects and evaluate any limitations that could be challenging for patients with impaired upper limb mobility.

Implementing this active evaluation approach not only provides useful information on the operation and usability of the ManutexEMG system but also contributes to improving its design and functionality to maximize its effectiveness in rehabilitation settings. The ManutexEMG system (Fig. 4) was positioned in a neuromotor rehabilitation chamber within the Clinical Rehabilitation Hospital of Iasi to ensure convenient accessibility for the evaluated groups. The chamber provides ample ventilation and benefits from effective natural and artificial lighting. The system is placed on a worktable, accompanied by chairs for both the subject undergoing testing and the evaluator.

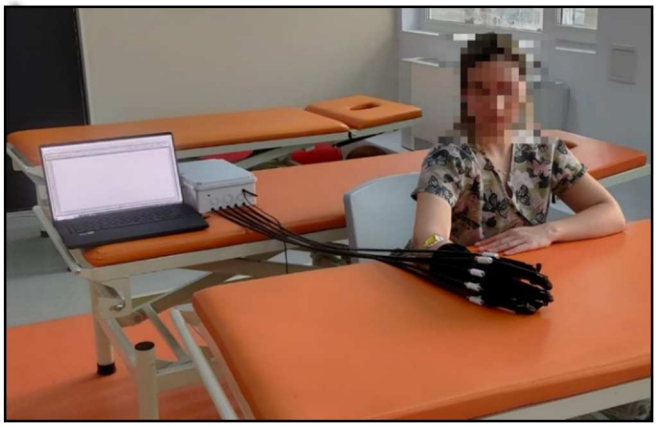

Fig. 4. The Manutex EMG system underwent testing on healthcare providers to observe any potential restrictions and errors in the device's operational mode

Before assembling the group of healthy subjects, they were provided with detailed information about the technology used and its operation. They then consented to participate in the study by signing the User Informed Consent form and completing a questionnaire detailing their impressions of the system. A similar procedure will be followed for the patients who will undergo testing with the equipment.

After developing the mechatronic rehabilitation device, we conducted an assessment to determine its efficacy in achieving the intended movements. A group of healthy volunteers was assembled, including 4 doctors, 9 physiotherapists, and 18 resident doctors from the Neurology and Neuromotor Rehabilitation department. The objective was to evaluate the system's effectiveness, assess the ease of wearing and removing the device, and identify any safety or performance concerns.

After using the device, participants completed a questionnaire with mostly closed, unique Likert scale-type responses, which included four main sections:

- Mechanically generated glove movement (efficiency, comfort);
- EMG (comfort, efficiency, detection of smallest contractions);
- Overall impression of the system (EMG + mechatronic glove);
- Efficiency in recovery in terms of the therapies used.

The group of healthy volunteers did not have any neurological, orthopedic, or rheumatologic conditions that could affect the mobility and functionality of the distal part of the upper limb or alter perception and response to possible adverse effects. During the assessment of the MANUTEX EMG device on healthy subjects, no difficulties were encountered in placing the EMG electrodes or detecting the smallest contractions.

Following the assessment of healthy subjects, a group of patients with post-stroke hemiparesis was assembled based on the study's inclusion criteria. Initially, these patients underwent testing using the Fugl-Meyer scale to assess the extent of impairment in the distal part of the upper limb. Subsequently, the same scale was used after 12 days of utilizing the system, with sessions lasting 30 minutes each day, to quantify the results by comparing them with the initial testing data. This approach aims to evaluate the effectiveness of the MANUTEX EMG system in improving motor function and rehabilitation outcomes for patients with post-stroke hemiparesis.

V. Results

The group of 31 healthy volunteers consists of doctors, physiotherapists, and resident doctors (see Fig. 5) working in the Neurological Recovery and Neuromotor Recovery departments of the Clinical Rehabilitation Hospital of Iași. They are aged between 25 and 35 years and are evenly distributed by gender.

After using the MANUTEX EMG device according to the protocol, the healthy volunteers were given a questionnaire consisting of 20 single-answer questions covering general and specific aspects of the device. These questions addressed topics such as ease of donning and doffing the device, ease of using the laptop interface, and a final comment/suggestion box. The questionnaire was created in Google Forms to facilitate data collection and analysis.

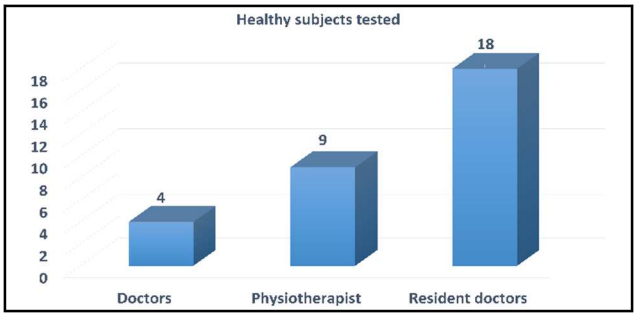

Fig. 5. The cohort of healthy participants that underwent testing using the MANUTEX system consisted of 4 doctors, 9 physiotherapists, and 18 resident doctors aged between 25 and 35 years, all of whom had no prior health issues

The overall impression of the healthy volunteers regarding the studied device was very positive, particularly in terms of ease of use and performance. They praised the intuitive interface design and the seamless integration of the device into their rehabilitation routines. The volunteers emphasized the potential of the device to significantly enhance patient outcomes and streamline clinical processes. This positive feedback highlights the effectiveness and user-friendly nature of the MANUTEX EMG system (Fig. 6).

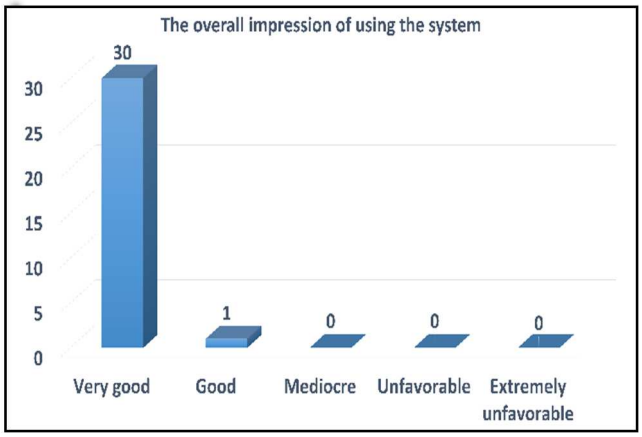

Fig. 6. The MANUTEX EMG system received an overall feedback ratio of 30:1, with the majority of users expressing high satisfaction with its performance.

The feedback received regarding the separate EMG components and the mechatronic glove was overwhelmingly positive. All volunteers found the detection of contractions using the EMG module to be highly efficient (Fig. 7).

Overall, 85% of the participants in the healthy volunteers group described the use of MANUTEX EMG as very good. Regarding the efficiency of the hand segment movements generated by the glove, 29 volunteers felt that the device accurately imprints the intended movements (finger and wrist extension). In comparison, 2 volunteers noted that the glove imprints a significant portion of the intended movements on the wrist and fingers but not at maximum amplitude.

Additionally, all participants agreed that the mechatronic glove did not cause any discomfort during testing. Lastly, all healthy volunteers believed that the MANUTEX EMG system could provide real benefits to patients with hand paralysis. They noted that the system incorporates techniques used in classical rehabilitation, such as repeated contractions, segment mobilization, and muscle stretching, which are deemed valuable for improving patient outcomes (Fig. 8). This positive feedback underscores the potential effectiveness and suitability of the MANUTEX EMG system for enhancing rehabilitation efforts in patients with hand paralysis.

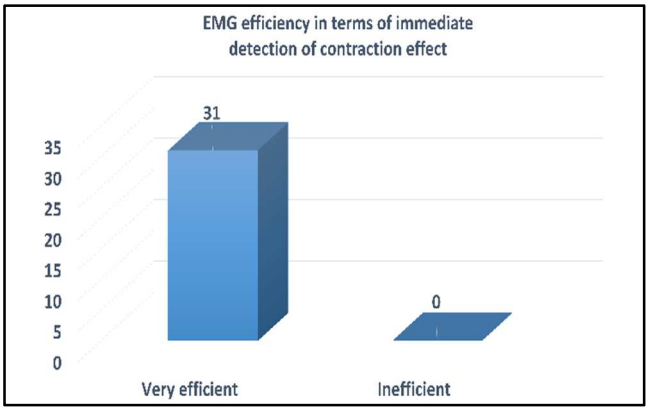

Fig. 7. The EMG accuracy of recognizing subtle contractions was extremely precise, as the system was able to record all contractions.

In summary, there was unanimity among the participants that the use of the MANUTEX EMG system from the patient's perspective can be considered interesting and a real help for motor deficit recovery after a stroke. This feedback highlights the positive impact and potential effectiveness of the system in aiding motor recovery in stroke patients.

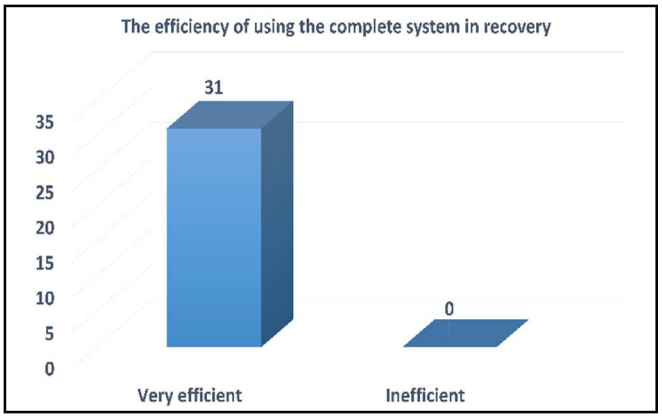

Fig. 8. Every test participant unanimously acknowledged that the technology could offer tangible advantages to people suffering from upper limb spasticity

In the second stage of the study, we will analyze the effectiveness of the MANUTEX EMG system in a cohort of 20 patients with paralysis due to central nervous system disorders. Up to this point, the system has not been tested on a sufficient number of patients to analyze the results comprehensively. This stage of the study will provide valuable insights into the system's performance and efficacy in a clinical setting with patients who have paralysis caused by central nervous system disorders.

VI. DISCUSSION

The study aimed to demonstrate the efficacy of the MANUTEX EMG system in enhancing motor control, coordination, and fine movements in patients with upper limb deficiencies, particularly those with post-stroke spasticity. The evaluation of the MANUTEX EMG system was initially conducted in a controlled laboratory environment at the Technical University of Iasi and later at

the Neurology Department of the Clinical Rehabilitation Hospital in Iasi. Tests were performed on medically certified individuals in good health to assess the system's functionality, ease of use, and performance. The study also focused on identifying any potential limitations or disadvantages of the MANUTEX EMG system, crucial for enhancing its design and functionality.

Monitoring the system's performance on individuals without health issues allowed for the analysis of potential challenges that may arise for individuals with restricted motion in their upper limbs. While the study demonstrated potential advantages for stroke survivors, there is a need for a controlled trial involving a longer evaluation period and a larger sample size of subjects with distal upper limb spasticity.

One challenge identified is recruiting a sufficient number of patients with upper limb spasticity for a clinical trial. This trial aims to assess the system's effectiveness and limitations in real-world settings, monitoring its benefits for successful rehabilitation. Conducting such trials is essential for fully understanding the impact and potential of the MANUTEX EMG system in improving outcomes for patients with upper limb deficiencies, particularly those with post-stroke spasticity.

VII. Conclusion

This article presents the validation and enhancements of a mechatronic rehabilitation system, specifically an exoskeleton type, through clinical trials involving patients with neurological disorders. The MANUTEX EMG system demonstrates promising capabilities in fostering motor control development and enhancing coordination of the distal components of the upper limb, ultimately improving fine movements, precision, dexterity, and hand coordination. By integrating functional electrical stimulation and surface EMG. MANUTEX EMG aids in recruiting motor units, reducing spasticity, and relieving joint stiffness associated with deficits.

Comprehensive testing of MANUTEX EMG functionality was conducted in a university technical laboratory and at the Neurology Department of the Clinical Rehabilitation Hospital in Iasi, involving healthy subjects from medical backgrounds. Feedback from the healthy volunteers reflects a highly positive impression regarding the system's ease of use and performance. Specifically, the individual EMG components and the mechatronic glove received favorable feedback, with all volunteers recognizing efficient contraction detection and the absence of discomfort during testing.

Overall, MANUTEX EMG shows promise in delivering tangible benefits to patients with hand paralysis, leveraging classical rehabilitation techniques incorporated within the system. The unanimous agreement among participants underscores the potential of the MANUTEX EMG system as an engaging and valuable tool for motor deficit recovery post-stroke. Future studies will further analyze the effectiveness of MANUTEX EMG on patients with paralysis stemming from central nervous system disorders, aiming to provide deeper insights into its therapeutic efficacy.

Following the testing of the MANUTEX EMG system on the medical staff from the Neurological Recovery Department, we observe the following:

- Positive Reception Among Healthy Volunteers: The study's healthy volunteers, comprising doctors, physiotherapists, and resident doctors, overwhelmingly praised the MANUTEX EMG system for its ease of use and performance. Their feedback indicates that the device integrates seamlessly into rehabilitation routines and has the potential to significantly improve patient outcomes.
- Ease of Use and Performance: Volunteers appreciated the intuitive interface design and efficient EMG detection capabilities of the device. They found the system user-friendly, emphasizing its potential to enhance clinical processes and patient care.
- High Satisfaction Rate: The feedback ratio of 30:1 underscores the high level of satisfaction among users, highlighting the MANUTEX EMG system's positive impact on rehabilitation efforts.
- Accurate Detection of Contractions: The system's ability to recognize subtle contractions accurately was a key positive feature noted by all volunteers, indicating its precision in detecting and recording muscle activity.
- Efficient Hand Movement Imprinting: Most volunteers felt that the device accurately imprints intended hand movements, though some noted limitations in achieving maximum amplitude, particularly in wrist and finger extensions.
- Comfort and Suitability for Patients: Volunteers reported that the mechatronic glove component of the system caused no discomfort during testing. They unanimously believed in the system's potential to benefit patients with hand paralysis, citing its incorporation of valuable rehabilitation techniques.
- Potential for Motor Recovery in Stroke Patients: Participants unanimously agreed on the system's potential to aid in motor recovery for stroke patients, suggesting its ability to offer tangible advantages in managing upper limb spasticity.

In summary, the feedback from healthy volunteers indicates strong support for the MANUTEX EMG system's effectiveness and suitability for rehabilitation efforts, particularly in addressing motor deficits and aiding recovery in patients with hand paralysis and similar conditions. The upcoming clinical study with patients suffering from central nervous system disorders will further evaluate the system's performance and efficacy in a clinical setting, providing valuable insights for its broader application.

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