

AUTOMA 2.0: a Wearable Platform to Assess the Muscular Activity of Upper and Lower Limbs in Patients affected by Neuromuscular Disorders

Stefano Roccella, Andrea Vannini, Roberto Lazzarini
The BioRobotics Institute
Scuola Superiore Sant'Anna
 Livorno, Italy
 name.surname@santannapisa.it

Mario Milazzo
Department of Civil and Industrial Engineering
University of Pisa
 Pisa, Italy
The BioRobotics Institute
Scuola Superiore Sant'Anna
 Pontedera (PI), Italy
 mario.milazzo@unipi.it

Marco Calderisi, Francesca Giorgolo, Matteo Papi
Kode s.r.l.
 Pisa, Italy
 n.surname@kode-solutions.net

Giulia Ricci, Francesca Torri
Department of Clinical and Experimental Medicine
University of Pisa
 Pisa, Italy
 name.surname@unipi.it

Raffaele Conte
National Research Council of Italy
 Rome, Italy
 raffaele.conte@cnr.it

Alessandro Tonacci, Francesco Sansone
Institute of Clinical Physiology
National Research Council of Italy
 Pisa, Italy
 name.surname@cnr.it

Abstract—**Neuromuscular Disorders (NMDs) are conditions that affect a high percentage of the population, globally. The assessment of the muscular activity of the limbs is currently performed by means of bulky and costly pieces of equipment or based on the expertise of the operator. AUTOMA 2.0 builds on the results achieved within previous studies, being a wearable sensorized device with high flexibility, able to detect the main force/displacement information of the limbs, in order to define a objective framework related to the specific patient in view of a more correct diagnosis and treatment. A pilot study carried out on healthy patients was successfully performed with a interdisciplinary team to tests the components of AUTOMA 2.0 in view of its employment for NMD patients.**

Keywords—**Neuromuscular disorders, wearable devices, upper limb function, sensing, clinical monitoring, rehabilitation**

I. INTRODUCTION

Neuromuscular Disorders (NMDs) are often considered rare clinical conditions when considered singularly. However, as a group of diseases, they are not rare at all: most NMDs' prevalence is in the range between 1 and 10 per 100,000 individuals, except for some particular conditions, e.g., oculopharyngeal muscular dystrophy, and congenital muscular dystrophies (below this range), or post-polio syndrome and Charcot-Marie-Tooth (above the highest boundary) [1]. To give an idea about the societal impact of NMDs, it has been estimated that, globally, as a group, they are as prevalent as Parkinson's disease and twice more prevalent than Multiple Sclerosis in the European framework [2], [3]. In addition, their worldwide prevalence is increasing, also thanks to the development of new instruments for diagnosis, often relying on genetics, able to provide new insights on diagnostic methods and principles [4].

To date, a dedicated neurological exam has been widely considered the most accurate approach in diagnosing NMDs.

Such approach includes a variety of domains to be assessed, potentially fine-tuned according to the specificities of the patient, e.g., age, gender, genetic features. Nevertheless, the neurological exam possesses a number of issues that might affect the success of the examination. Among them, the expertise and the subjective evaluation of the operator might hinder a reliable diagnosis, and following treatment, of NMDs [5], [6]. In the specific case of the activity of the muscular activity of the upper limb, current approaches consist in assigning a score to the ability of a patient to perform selected exercises. This methodology cannot be employed on large scale to create an objective database in terms of diagnosis and follow-up throughout time since patients can be treated by different operators with different expertise.

A first step towards overcoming such issues was represented by the design of bulky pieces of equipment that require a dedicated training, are costly, and provide only a limited number of benchmarks, often highly dependent on the patient positioning, and with a limited flexibility [7], [8].

A different approach was recently developed by Milazzo et al., that designed and assessed in a pilot study a wearable device for evaluating the muscular functionality of the upper limb through embedded force and displacement sensors. Such device, called AUTOMA, was tested on a representative sample of patients with conditions ranging from the mild to medium severity, showing how it is possible to make reliable correlations between the NMD conditions qualitatively assessed, and quantitative benchmarks of the musculoskeletal activities [9].

In the present work, we aim at providing a further step towards the integration and correlation of quantitative sets of information relating to the muscular activity of patients, to genetic data in order to give clinicians and operators an integrated tool to better diagnose NMDs in view of the design of dedicated and efficient treatment protocols.

II. MATERIALS AND METHODS

A. AUTOMA 2.0

AUTOMA 2.0 improved the designed presented in [9], implementing new features for the characterization of upper and lower limbs musculoskeletal activities during the physical examination. In detail, AUTOMA 2.0 is provided of one 4-channels Bluetooth electronic module (Biosignalplux Explorer Kit - PLUX WIRELESS BIOSIGNALS S.A., Lisbon, Portugal) and another 6-channels Bluetooth module (BITalino - PLUX WIRELESS BIOSIGNALS S.A., Lisbon, Portugal) both able to acquire synchronized data at 1000 Hz. According to the application, multiple sensors can be connected to the main system: biaxial electro-goniometers SG150 (Biometrics Ltd, Newport, UK), Electromyography (EMG) sensors (Biosignalplux), Electrocardiography (ECG) sensors (Biosignalplux), Respiration sensors (Biosignalplux), Inertial sensors (Biosignalplux), Force sensors (Biosignalplux). These sensors can be fixed on the limb by means of adaptable cases carried by a harness to better adhere on the body over the clothes.

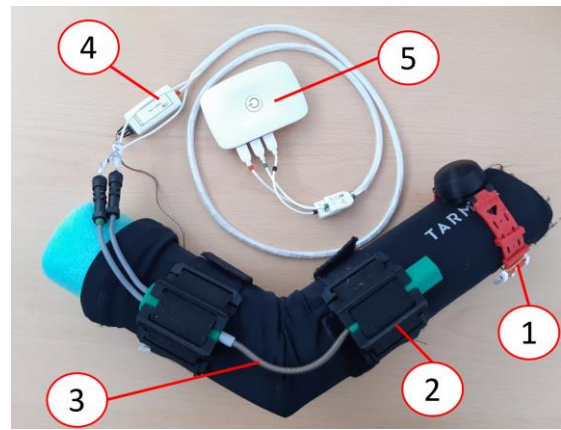


Fig. 1. AUTOMA 2.0 for the upper limb. (1) Bracelet with load cell; (2) new frame modules to host the electro-goniometer; (3) electro-goniometer; (4) electronic interface for the load cell; (5) wireless module.

In the specific case of upper limb measurements during Manual Muscle Tests (MMT) [9], AUTOMA 2.0 is composed of a biaxial electro-goniometer and an improved version of a customized force bracelet (Fig. 1).

Sensors signals are acquired and stored through a laptop and processed in real time by a dedicated App, properly developed to assign a score on the basis of artificial intelligence-based algorithms (details in Section B).

In the specific application for measurements on the shoulder during fatigue & endurance tests, same goniometer is carried by a case endowed with a passive hinge joint that allows to better align the goniometer with the principal axis of movement in order to reduce the cross-talk between channels. EMG electrodes are also placed on the deltoid muscle. An accelerometer is placed on the back of the hand to detect acceleration and upper limb inclination in quasi-static endurance tests.

Data from the electro-goniometers are recorded through the same 4-channel Bluetooth electronic module at 1000 Hz (As for data from the EMG electrodes and Accelerometer, the BITalino module is employed to log them. All data are eventually stored and post-processed in a laptop endowed with the OpenSignals software. The same system can be used also for the measurement of hip movement during fatigue tests. Fig. 2 depicts AUTOMA 2.0 for shoulder and hip measurements.

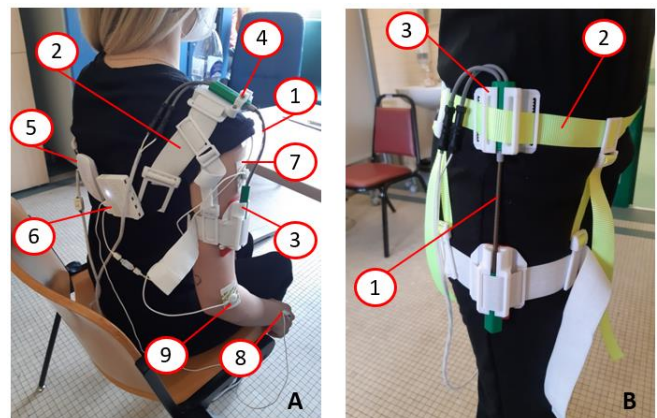


Fig. 2. AUTOMA 2.0 for the shoulder and the lower limb. Panel A: AUTOMA 2.0 for shoulder measurements; Panel B: AUTOMA 2.0 for hip measurements. (1) dual axes electro-goniometer Biometrics SG150 model; (2) Adjustable harness; (3) Goniometer end-block cases; (4) Adjustable

hinge joint; (5) Biosignalplux electronic module; (6) BITalino electronic module; (7) EMG electrodes for deltoid activity measurement; (8) Accelerometer; (9) EMG reference electrode.

B. Software user-interface to visualize and process data from AUTOMA 2.0

A software user-interface dedicated to process and post-process data from AUTOMA 2.0 was developed. In particular, the interface is structured in four sections: i) Calibration, ii) Real-time acquisition, iii) Last acquisition; iv) Documentation.

In the “Calibration” section, also shown in Fig.3A, the user can either check the current sensors calibration or set a new calibration for each sensor, associating to the raw sensor values the corresponding physical measure. This operation should be carried out in an equipped laboratory.

In the “Real-time acquisition” section, before the beginning of the motor tasks, the user can set the initial values of the acquisition by setting the initial position of the limb.

Once the acquisition has started, data from AUTOMA 2.0 are plotted up to the end of the task: at this point the system is able to log the entire session and the user is redirected to the “Last acquisition” section.. Here, data acquired is shown in both graphical and tabular format (Fig. 3B). This section also allows the estimation of the exercise score [9], and an evaluation of the execution quality of the exercise.

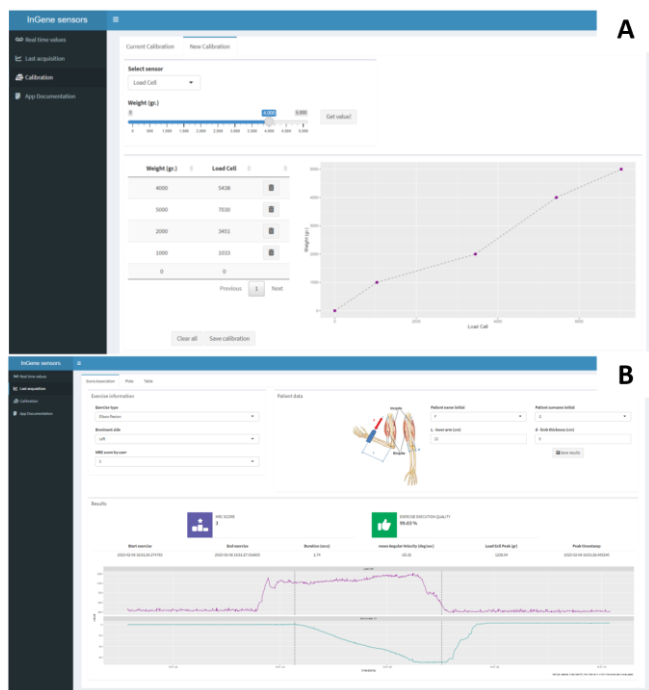


Fig. 3. Health360 for AUTOMA 2.0. Panel A. User interface for the calibration of the sensors. Panel B. Graphical interface for data acquisition in the specific case of angular displacement and forces on the upper limb.

C. Pilot study

A pilot study was designed and performed in Pisa, Italy, at the local hospital (Azienda Ospedaliera Pisana – AOUP), involving an interdisciplinary team composed of neurologists, physiotherapists, and engineers, in order to test the components of the system.

The motor tasks performed with AUTOMA 2.0 consisted in assessing the activity of 1) the shoulder; 2) the lower limb

upon walking/running tasks; 3) the upper limb of healthy patients in fatigue and endurance tests.

III. RESULTS AND DISCUSSION

The pilot study highlighted the reliability of AUTOMA 2.0 in assessing the musculoskeletal activity of patients. Fig. 4 reports the data acquisition from the electro-goniometers related to the position of the joints.

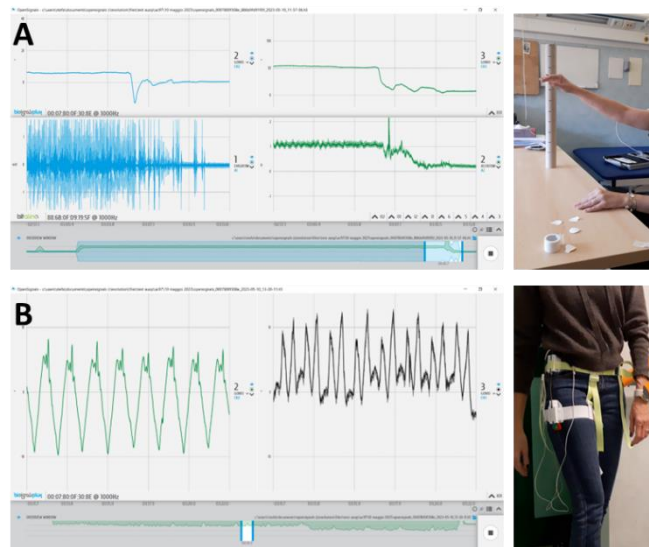


Fig. 4. Preliminary results from the application of AUTOMA 2.0 on measurements related to the shoulder (Panel A), and the hip (Panel B).

As for the upper limb, Fig. 5 reports the data acquired during the motor task, and the possibility to visualize in real-time the data from the endowed force/accelerometer/angular sensors, as well as to estimate an objective score associated to the NMD for the specific patient, based on the data acquired earlier by the team with the first version of AUTOMA [9], [10].



Fig. 5. AUTOMA 2.0 for the upper limb. Motor task performed with an operator (Panel A), and logging of the main displacement, acceleration, and force measurements (Panel B) for the estimation of an objective NMD score.

IV. CONCLUSIONS AND FUTURE DEVELOPMENTS

A. Conclusions

AUTOMA 2.0 is a wearable device that, properly integrated with the software interface might significantly contribute to the advancements in diagnosing and treating NMDs that overcome the limitations of the current protocols characterized by high subjectivity of the expert operator and/or the employment of bulky and costly pieces of equipment limited in flexibility and maneuverability.

B. Future steps: from AUTOMA 2.0 to AUTOMALink

The future works dealing with AUTOMA 2.0 include a two-step approach, working at the hardware and the software/communication levels. Concerning the hardware part, we seek to involve a broader amount of NMD patients to validate the protocols on a larger scale. This will be possible thanks to the activities already foreseen within the InGene 2.0 project, already involving four clinical centers in Tuscany Region, Italy. From the software and communication side, the AUTOMA 2.0 system is expected to communicate with Health360, a software tool, developed within the InGene 2.0 project [10], [11], for data collection and ready to also host Artificial Intelligence algorithms for supporting the study of genotype-phenotype relationships in NMDs. This step would be enabled through the conception and implementation of AUTOMALink, a communication means between the two sides, which will be based on RESTful Application Programming Interfaces (APIs), allowing a real-time or semi-real-time storage of the data collected during the neurologic examination in the data collection (and analysis) platform.

ACKNOWLEDGMENT

This work was supported by Regione Toscana, Bando Salute 2018 (project InGene 2.0).

REFERENCES

- [1] J. C. W. Deenen, C. G. C. Horlings, J. J. G. M. Verschuuren, A. L. M. Verbeek, and B. G. M. van Engelen, "The epidemiology of neuromuscular disorders: a comprehensive overview of the literature," *J. Neuromuscul. Dis.*, vol. 2, no. 1, pp. 73–85, 2015.
- [2] K. Wirdefeldt, H.-O. Adami, P. Cole, D. Trichopoulos, and J. Mandel, "Epidemiology and etiology of Parkinson's disease: a review of the evidence," *Eur. J. Epidemiol.*, vol. 26, pp. 1–58, 2011.
- [3] T. Dua and P. Rompani, "World Health Organization, Multiple Sclerosis International Federation: Atlas Multiple Sclerosis Resources in the World." World Health Organization, Geneva, Switzerland, 2008.
- [4] A. E. H. Emery, "Diagnostic criteria for neuromuscular disorders," *R. Soc. Med. Press*, 1997.
- [5] D. Fritz and M. K. Musial, "Neurological assessment," *Home Healthc. now*, vol. 34, no. 1, pp. 16–22, 2016.
- [6] M. Shahrokhi and R. M. D. Asuncion, "Neurologic exam," in *StatPearls [Internet]*, StatPearls Publishing, 2023.
- [7] D. C. Feiring, T. S. Ellenbecker, and G. L. Derscheid, "Test-Retest Reliability of the Biodex Isokinetic Dynamometer," *J. Orthop. Sport. Phys. Ther.*, vol. 11, no. 7, pp. 298–300, Jan. 1990, doi: 10.2519/jospt.1990.11.7.298.
- [8] H. Aramaki, M. Katoh, Y. Hiiiragi, T. Kawasaki, T. Kurihara, and Y. Ohmi, "Validity and reliability of isometric muscle strength measurements of hip abduction and abduction with external hip rotation in a bent-hip position using a handheld dynamometer with a belt," *J. Phys. Ther. Sci.*, vol. 28, no. 7, pp. 2123–2127, 2016, doi: 10.1589/jpts.28.2123.
- [9] M. Milazzo *et al.*, "AUTOMA: a wearable device to assess the upper limb muscular activity in patients with neuromuscular disorders," *Acta Myol.*, vol. 40, no. 4, p. 143, 2021.
- [10] R. Conte *et al.*, "InGene: A multimodal approach to the genotype-phenotype association in neuromuscular diseases," in *2018 IEEE 8th International Conference on Consumer Electronics-Berlin (ICCE-Berlin)*, 2018, pp. 1–4.
- [11] R. Conte, F. Sansone, A. Tonacci, and A. P. Pala, "Privacy-by-Design and Minimization within a Small Electronic Health Record: The Health360 Case Study," *Applied Sciences*, vol. 12, no. 17, pp. 8441, 2022.