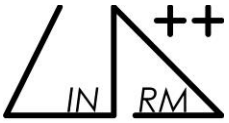

LINarm++

Affordable and Advanced LINear device for ARM rehabilitation

Deliverable D5.2

NMES wearable systems for shoulder and elbow

Contractual delivery date	31.07.2016 (month 15)
Actual delivery date	31.07.2016 (month 15)
Version	1.0
Dissemination level	PU
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Executive summary

This document describes the implementation of the NMES system used in Linarm++. Economical considerations, technological readiness factors, physiological and clinical rationale that affect the design choices are included in the introduction and in the specific sections of this document. In the following sections it will be detailed first the clinical rationale, with rehabilitation practice data. The NMES intended use and the targeted body parts are used offer insights on the choice of the stimulator and its control modality. Finally it's described the design of the wearable that complies the needs of simplicity and low cost.

1. Keywords

Evidence Based Rehabilitation
Motor Rehabilitation
Upper Limb
Stroke
NMES

2. List of Acronims

FES **F**unctional **E**lectrical **S**timulation
ML **M**otor **L**earning
NMES **N**euro **M**uscolar **E**lectrical **S**timulation
CCL **C**ontinuous **C**hannels **L**ist mode
OSCL **O**ne **S**hot **C**hannels **L**ist mode
SP **S**ingle **P**ulse mode

3. Introduction

The Stroke Rehabilitation Clinician Handbook [1], published by The Canadian Partnership for Stroke Recovery, provides evidence-based review of the state of the art of stroke rehabilitation. The main outcomes of the meta-review is assessing that intensity of therapy, number of repetitions, and task specific training are the main factors that determine the success of the upper limb rehabilitation in clinical environment. Specialization of treatments is required according to the sensorimotor and cognitive neurological damage the patient is subjected to.

Kwakkel [2] in 2015 in the "Invited Commentary on Comparison of Robotics, Functional Electrical Stimulation, and Motor Learning Methods for Treatment of Persistent Upper Extremity Dysfunction After Stroke" compares the effectiveness of the three rehabilitation techniques. In the dose matched clinical trial, 39 patients beyond 6 month post stroke, shown that motor learning (ML) physical therapy with Functional Electrical Stimulation (FES) shows groupwise the same results of physical therapy with exoskeletons, and that within-groups therapeutic gains of 10%-15% were measurable on the Arm Motor Ability Test and on the Fugl-Meyer test. It was also noticed that significant cost reductions per patient was achieved with the use ML with FES when compared with ML and shoulder-arm robotic. For such reason, Kwakkel in the final remarks suggests to those who aim to develop commercially viable multimodal robotic solutions to take costs into considerations.

At the moment of writing this document, there is no commercial NMES system for full electrode array compliance able to provide the needed flexibility for wearable applications, the reliability for use in clinical context, and a realistic cost. In this perspective to both offer multimodal and simple to use motor support and sensory feedback, we will focus on a simple NMES system fitting with Linarm++ budget and Technological Readiness requirements.

This document is intended to present the underlying choices for the specific wearable, multi-site and flexible NMES-based system with multiple arrays for NMES.

4. NMES rationale

A NMES stimulator is a voltage-limited current-controlled source that injects charge through the skin. The injected electrical current is converted by the hydrogel in the electrodes in ionic currents that diffuse in the underlying tissues. NMES stimulation is delivered in pulsed fashion, and pulses are charge compensated to cause an overall zero ionic flux in the tissues. Each pulse is constituted by a positive and a negative wave, which are described in terms of current intensity (I,[mA]) and pulsewidth(PW, [μs]), and whose product determines the injected charge. Pulses can be delivered with constant delays, thus having constant frequency (f,[Hz]). The tissues underlying the electrodes are elicited by the injected pulses, and the overall excitation effect depends on the compound effect of intensity of stimulation (I, PW, f) as well as the location of the stimulation and the properties of the underlying tissues. The intensity of the stimulation determines the depth of the activation field. On humans, sensory fibers are more superficial than motor fibers, and transcutaneous stimulation of low intensity elicits first sensory fibers. In order to induce also muscle contraction, higher intensity stimulation is required.

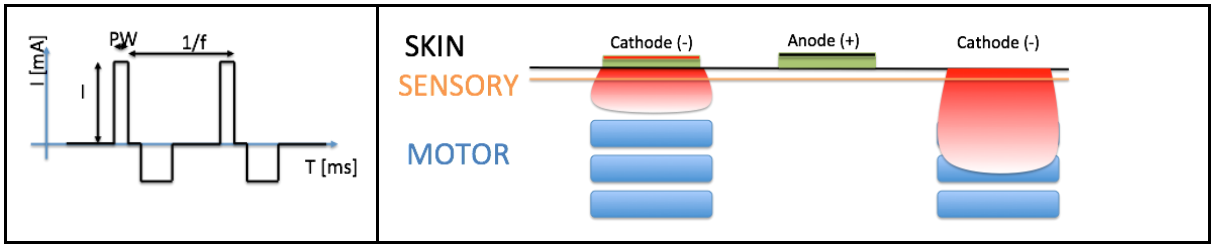


Table 1 Electrical Stimulation pulses and Field of activation. Depth and breadth of field are a function of the stimulation profile and of the underlying tissues properties. Low intensity pulses trigger only superficial responses, whereas higher intensity pulses trigger deeper neurons. Sensor receptors have more superficial afferent neuronal pathways, whereas efferent motor neurons lie deeper from the skin.

To have sustained muscle contraction (tetanic contraction) the stimulation frequency has to be higher than 20 Hz, but a high stimulation frequency causes a quick fatigue onset. A low stimulation frequency on the other side does cause single serialized contraction events that do not allow to sustain a movement.

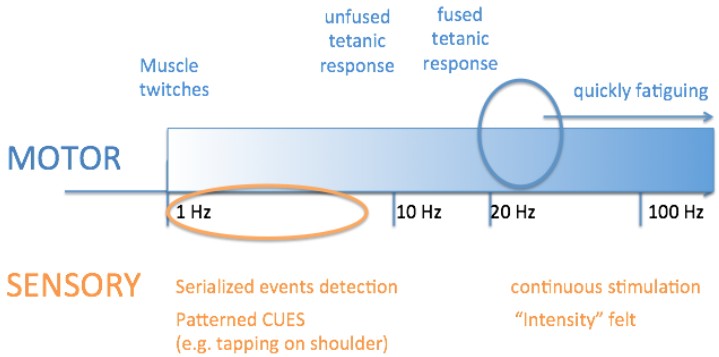


Figure 1: Motor and sensor responses can be triggered at different frequencies with different effect, but sensation during stimulation is always evoked

Low frequency stimulation, from the sensory viewpoint, allows easier detection of serialized events. If the stimulation frequency increases the sensation appears continuous with the possibility of pain onset. For such reasons NMES can be used at low frequencies/ low intensities to provide sub-liminal or supra-liminal sensations, and at higher intensities to provide both sensation and motion. For applications involving induced muscle contraction, electrode size, location and intensity of the stimulation are factors that affect stimulation efficacy and comfort. An optimization of the design is necessary to provide the necessary selectivity and not to cause unpleasant sensations. As reported by Kuhn [3], "small electrodes 0.8 x 0.8 cm^2 are more comfortable for thin fat layers (0.25 cm) and superficial nerves (0.1 cm) and larger electrodes (4.1 x 4.1 cm^2) are more comfortable for thicker fat layers (2 cm) and deeper nerves (1.1 cm) at a constant recruitment".

5. Tasks and Targeted Muscles

The tasks for the Linarm++ platform are standard functional movements that greatly affect the patient independence, and in particular focus on mimicking the main activities daily living. The simpler tasks that can be approximated with a linear actuator are the reaching of an object, and the bringing of a given object to the head (e.g. eating, drinking, wearing one earbud, combing, etc.). To sustain such movements with NMES, as mentioned in the previous section, it's needed to both be selective on superficial muscles and not to cause adverse sensation in particularly sensitive areas. For such reasons, the Hand to Mouth and for the Reaching tasks are sustained using the muscles shown in Table 2. Other potentially useful muscles, such as the pectoral muscle, have been excluded because of the high sensibility in part of the potential population.

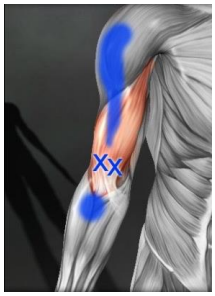
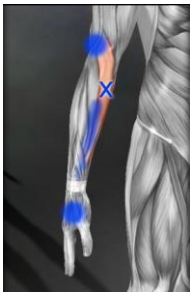
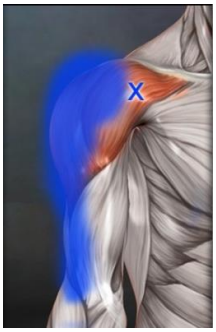
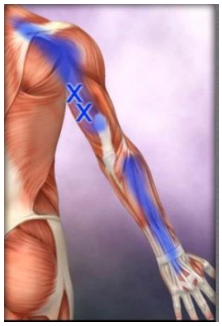
Exercise	Muscles	
	Proximal Dominant	**Distal Dominant**
A) Hand to Mouth	 Biceps Brachii	 Brachioradialis
B) Reaching	 Deltoid Anterior	 Triceps

Table 2 Muscle groups are divided depending on the chosen task, and the main targeted articulation

During the project, some simplifying approximations were made to ensure low cost and acceptable level of technological readiness:

- Each exercise is repeated for a prolonged time, and there is a limited number of commutations between exercise A and exercise B
- The electrode patches have to be commercially available from a standard supplier
- The chosen electrical stimulator has to be a commercial medical grade CE marked electrostimulator, with a kernel extension allowing external control.

6. Hardware Choices

Low-cost devices for upper-limb neuromotor rehabilitation are subject of intensive R&D, to enable rehabilitation at home, supporting remotely the function of the medical personnel and making the patient partially independent. Low-cost requirements and high technological readiness pose limitations to maneuvering with state of art NMES equipment, mostly relinquished to prototypes of universities or companies affected by high costs and/or uncertified behavior.

To maintain a reasonable tradeoff between stimulation controllability, available number of independent channels, reliability and low-cost, we selected a well-established stimulator, and built a switch box that can commutate the available channels to the needed electrode patches. The overall scheme is reported below in Figure 2. As different body districts are targeted by stimulation, each muscle group uses a patch containing four active electrodes and one ground. Since a maximum of two muscles are active a time, and

the exercises are limited to the two chosen movements, a stimulator with 8 independent channels and a custom switch box can drive the four patches with four independent channels each.

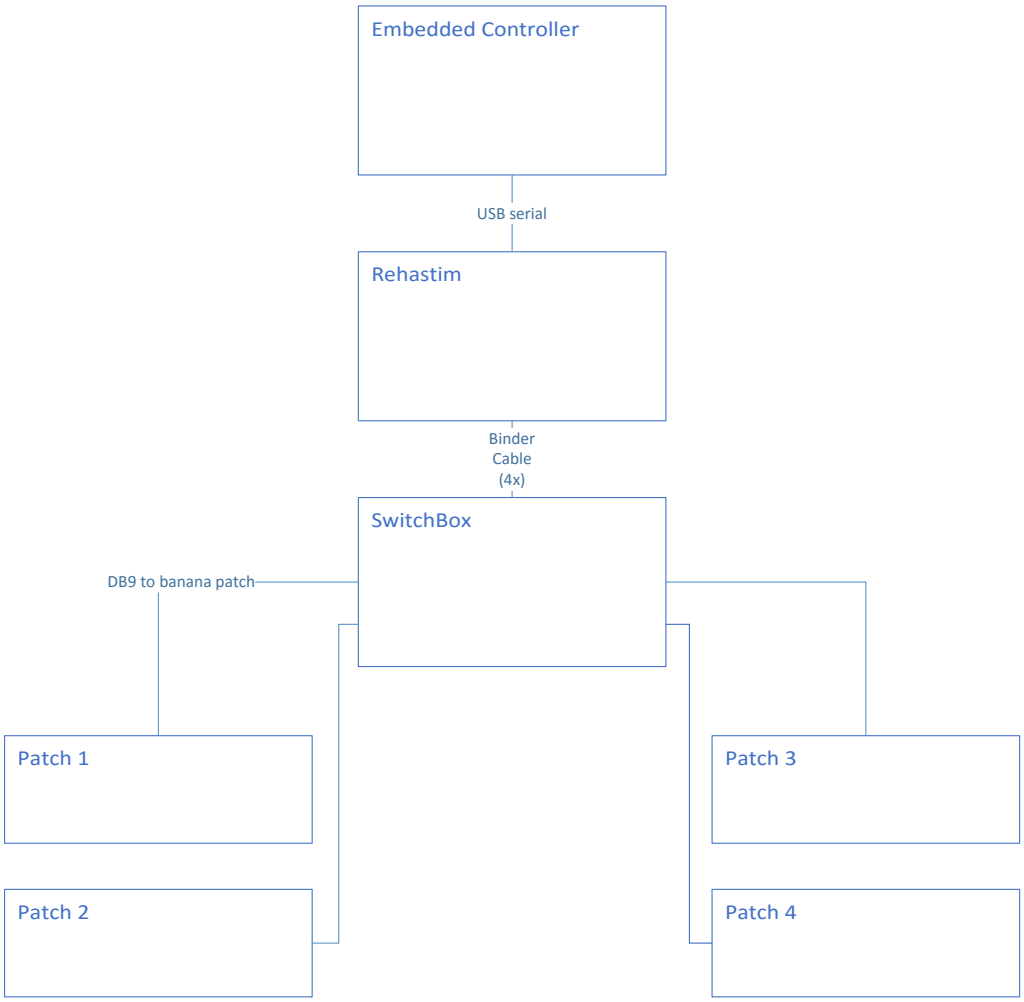


Figure 2 Connectivity schematic of the NMES module

6.1 Electrical Stimulator

The Rehastim One (Hasomed GmbH, Magdeburg, DE), visible in Figure 3, is a programmable eight channels electrical stimulator for clinical and research purposes. Examples of interfacing are provided by Schauer et al.[4]. Custom drivers for Labview and Python are available within the Linarm++ consortium. Hasomed also has developed special hardware versions of the RehaStim One and RehaStim Two that extend the stimulator number of channels, but such prototypes do not present the Technological Readiness needed for the current project, and thus are not considered.

The ScienceMode, provided by Hasomed as a firmware extension of the standard device, is a protocol for the interface between the RehaStim and an external PC, which allows external control of the RehaStim in order to generate stimulation pulses. The Science mode can be used for the generation of stimulation pulses of the RehaStim controlled by an external PC, the generation of a Single Pulse (SP mode) on a specific channel with desired pulsewidth and current amplitude, for the generation of stimulation patterns

as a Continuous Channels List (CCL mode) where the stimulator is responsible for controlling the stimulation timing (frequency of the stimulation pulses), and the generation of stimulation patterns where the external PC controls the stimulation timing (OSCL mode).

Figure 3: the Hasomed RehaStim one electrical stimulator

In CCL Mode the generation of complex patterns is greatly simplified. The stimulator itself ensures the pulse pattern generation by means of timer-interrupts. A list of stimulation channels has to be specified, on which pulses or even pulse groups (doublets or triplets) will repeatedly be generated. The CCL mode uses three different methods: Init, Stop, and Update. The CCL Init defines the stimulation frequency, which channels will be used, and in which order. The CCL Stop stops any ongoing stimulation. The CCL Update allows defining current intensity [mA] and pulsewidth [µs] for all the initialised channels. These stimulation parameters will be repeated indefinitely until a new Update or Stop command is received.

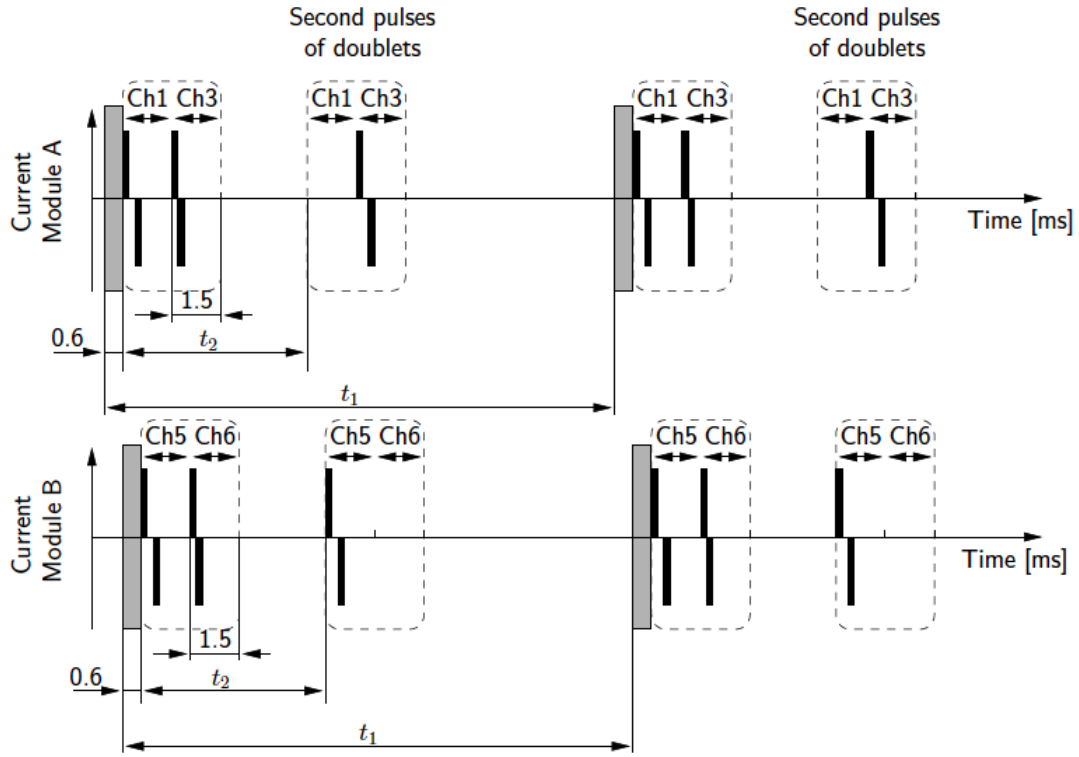


Figure 3: Example of the CCL mode patterning. Excerpt of the ScienceMode manual.

A simple event-based communication from the PC reliably allows to control three independent channels running at 30 Hz each, which can be dynamically updated. As an example, we can imagine that channels 1-4 are used to stimulate the Muscle α in different locations, and that channels 5-8 stimulate Muscle β. Channels 1, 3 and 7 are Initialized. Muscles α and β are agonists of a predefined task, but different stimulation intensities are required for the muscle recruitment. By using the Update call, the stimulation can be modulated according to the expected phase of the movement. Would be required a change of the stimulation location to channels 1,5 and 8, a simple queued sequence of Stop, Init and Update commands would define the new stimulation pattern.

From a practical viewpoint the maximum usable current intensity is limited by two factors 1) nociceptive sensations, which are varying from subject to subject, and 2) maximum skin current density of 2.5 mA per square cm. Using e.g. a square 3 by 3 cm^2 electrode, the maximum allowed current would be of 22.5 mA. The Rehastim allows current step increments of 2 mA, thus allowing only a current intensity modulation of 12 levels. The pulsewidth step increase is of 1 us, thus allowing a broader modulation range from 50 to 500 us. For such reasons, the maximum current presets will be controllable from the GUIs, and pulsewidth modulation will be used by the low level algorithms to allow finer motor control.

6.2 Switch Box and cables

The SwitchBox includes mechanical switches, rated for 2kV isolation, a custom PCB aimed at simplifying grounding and routing, and wall mounted connectors matching the chosen cables specifications. Standard Binder extension cables connect the stimulator with the switchbox.

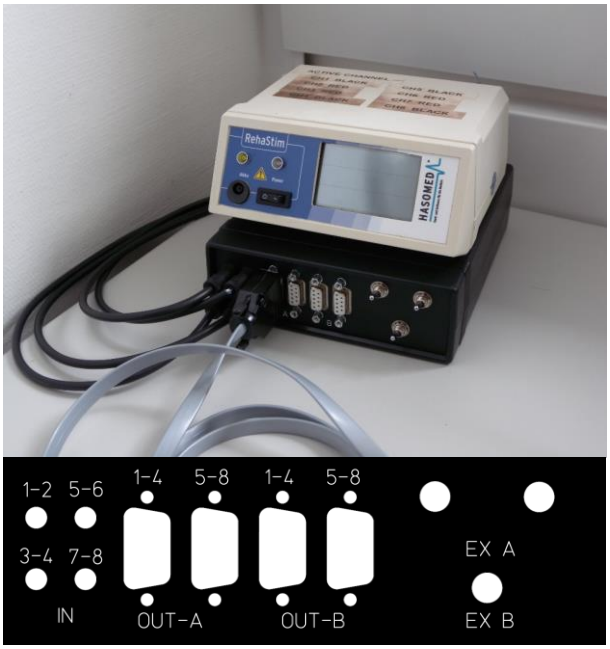


Figure 4: Front panel of the switch box. On the left, housing for binder wall mounted female connectors. At the center, housing for DB9 connectors for exercises A and B. On the right, switches for selecting the exercise.

As an output for the stimulation box, each DB9 connector is associated with one wearable patch. Standard 2mm banana connectors for medical applications ensure good connectivity with commercial, widely available, electrodes. The description of the patches is reported in the next section.

7. Wearables

Several factors affect the overall usefulness of a wearable for NMES. In clinical practice the overall number of used electrodes is reduced for two main issues: lower cost of consumables, reduction of clutter and misplacing errors, and ease of stimulation configuration. In a usual clinical scenario, a small number of channels with no shared grounds is positioned by a skilled therapist. The therapist tests a reasonable sets of stimulation intensities and, if unsatisfied with the stimulation outcome, repositions the electrodes with a trial and error process. Each attach-detach operation elides a thin superficial layer of gel between skin and electrode, thus progressively degrading the performances (mechanical tack with skin, electrical homogeneity of stimulation, perceptive stimulation comfort, etc.) of the electrode at each repositioning

We aim at simplify the aforementioned workflow, while maintaining the benefits of simplicity, and introducing a more powerful approach. With this wearable several electrodes are positioned at once, the stimulation location and intensity is then optimized via software.

As the different exercises are not executed in interleaved mode, four independent stimulation channels can be used per each muscle group, and thus allowing a quick sw-calibration without requiring electrodes repositioning.

7.1 Wearable Patch

The wearable is made partly of disposable and partly of reusable parts. The reusable parts can be cleaned in accordance with the standard clinical hygienic praxis and usage wearout. The electrodes have a shorter reusability, largely affected by the skin conditions, and of the storage conditions. The patches are visible in Figure 5.

A main support patch is made of ipoallergenic washable foam (Plastazote , Ottobock Health products). The foam patch is selectively cut to conform easily with the skin also during motion. Two different sizes of the patch (150 mm x 90 mm, and 180mm x 110mm) are currently produced to host the chosen electrodes, but size and shape can easily be adapted upon need. The top layer of the patch is laser-cut and engraved with wiring reference information and indications of the targeted muscle.

On the opposite side, velcros allow to have replaceable electrodes easily positioned and replaced. The standard counter electrode is squared 50mm wide. The active electrodes are in small, medium, and large size, measuring respectively 25mm, 32 mm and 50 mm. Small and medium round electrodes can be mounted on the 150mm x 90mm patch, whereas medium and large electrodes can be used on the 180 mm x 110mm patch. A counter-patch in PET (Mylar, Tekra. Inc) protects the electrodes after each usage session.

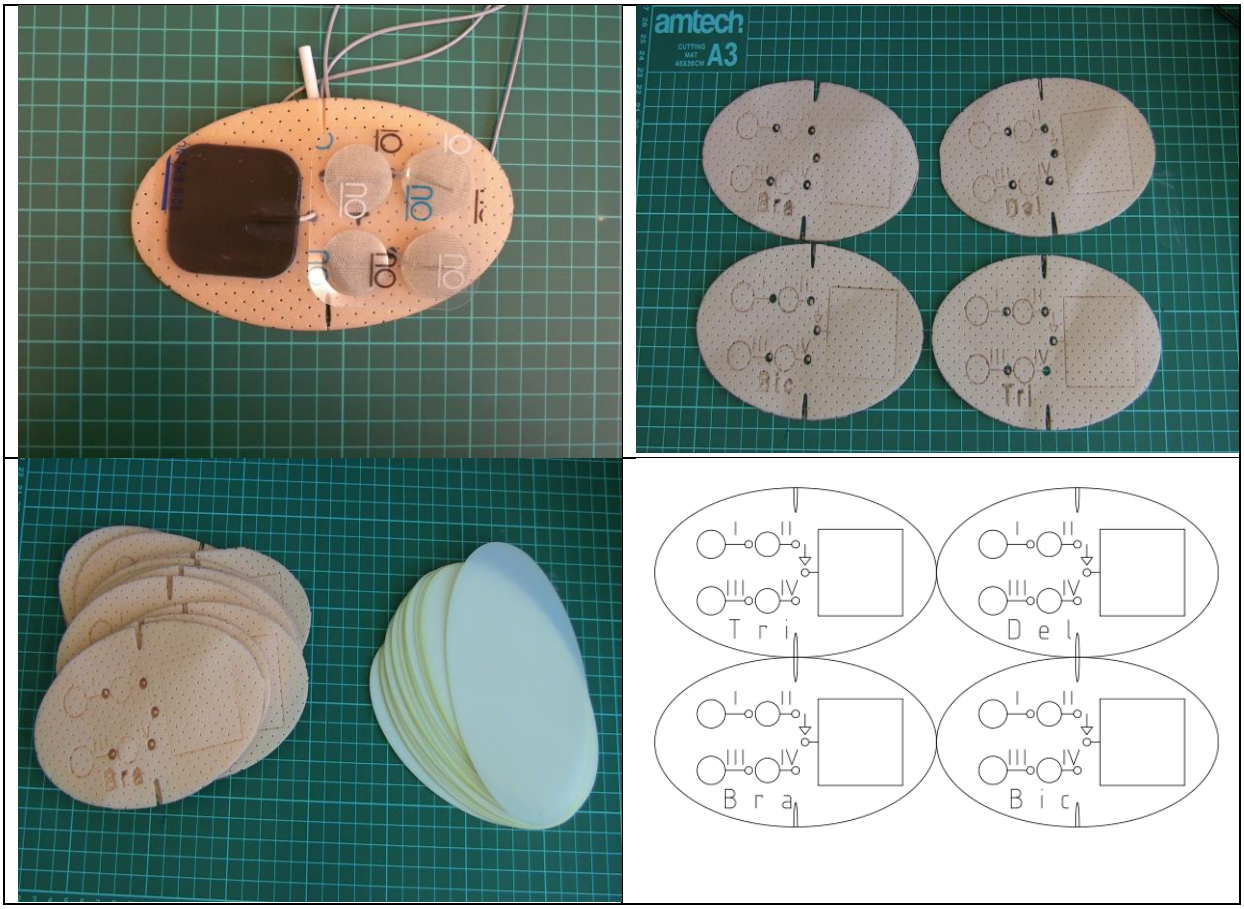


Figure 5: examples of custom pads for stimulation. Top left, the skin side of the patch. Bottom left, precut patches and covers for electrode protection. Right: example of custom cut and engraving for labelling purposes.

7.2 Electrode Choice

Standard electrodes are available from various producers. Here below is reported a quick selection guide with respect to the targeted muscle depth, fat layer thickness, optimal comfort, and allowed current ranges. What sets apart low cost electrodes to high cost electrodes is the overall quality of the skin-electrode interface and the distribution grid inside each electrode. Poor quality electrode can cause stimulation hotspots, with unpleasant sensations at relatively low stimulation intensities or with bear the risk of skin burns. For good quality electrodes, a rule of thumb for selecting the electrode size is reported in Table 3. Electrode size as well affects the depth of stimulation, with smaller electrodes targeting more superficial muscles.

Electrode Shape	*Electrode Width [cm]*	*Max Current [mA]*	*Application*	*Notes*
Square	5	62.5	Ground electrode	Trimmable upon need
Round	2.5	12.5	Active electrode	Small superficial muscles, skinny subject
Round	3.2	20	Active electrode	Intermediate depth muscles and skinny subject, or superficial muscles and intermediate fat

				thickness
Round	5	50	Active electrode	Deeper muscles, higher currents

Table 3: Quick electrode selection guide

8. Stimulation Strategies

As mentioned in the previous section, the CCL mode for the stimulator is the less computationally demanding control mode from the perspective of the Linarm++ general controller, and it's consequently the candidate for the final implementation of the platform.

While proceeding with the full system implementation, GUIs written in Labview and implementing the ScienceMode drivers backend for CCL, OSCL and SP modes are in use for evaluating the optimal tradeoff between standardized and personalized modulation strategies, and the final update rate that the Linam++ central controller will need to provide to through the CCL mode.
Stimulation can be modulated either to give sensory cues with low-intensity on-off bursts at 2-5 Hz, or at higher frequencies to cause muscle contraction in a coherent fashion with the task needs.
Because the exercises envisioned for Linarm++ are based on a cyclical repetition of the same task, and the percentage of the task is known from the the central controller, the stimulation profile can be discretized in normalized cyclical PW modulation profiles.

8.1 Standard Strategies

The pattern modulation can be based on biomimetic empirical strategies by using a priori known data such as EMG activation profiles of healthy subjects, or approximated with easy to adapt activation profiles. Figure 6, on the left, shows examples of trapezoidal activation profiles in preliminary testing GUIs. The activation profiles are designed to provide smoothed activation transitions that thus minimize the risks of spastic onsets.

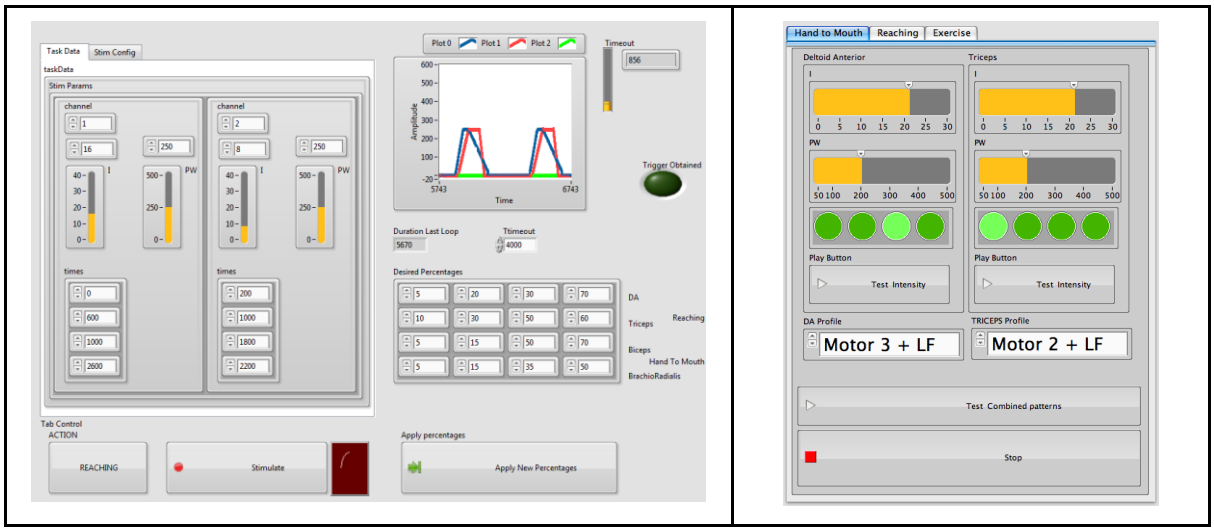


Figure 6: Left: a simple GUI that allows in "engineering mode" to quickly prototype and test different activation profiles. Right: a simplified GUI that allows choosing stimulation intensity, location of stimulation, and preset patterns, and then testing the overall pattern.

Once all the motor stimulation strategies will be defined, simplified GUIs for RIF and clinical testing will be optimized. Figure 6, on the right, exemplifies a quick configuration muscle setup where preset muscle activations can be tested before the beginning of the exercise.

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