LINarm++

Affordable and Advanced LINear device for ARM rehabilitation

Deliverable D5.1

NMES-based system design

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Table of contents

Executive summary

This document is aimed at describing the design of the NMES system to be used in Linarm++. Economical, technological readiness, physiological and clinical rationale that affect the design choices are included in the introduction and in the specific sections of this document. The described system thus derives strictly from those choices. In the following sections it will be detailed first the clinical rationale, with data updated to years 2014 and 2015, then we proceed with the NMES intended use and the targeted body parts. Then follows the choice of the stimulator, its control modality, and the description of the GUIs that are in use for evaluation of the biomimetic and model based control schemes. 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 in 2014 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.

In this perspective to both offer multimodal and simple to use motor support and sensory feedback, we will focus on a 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 FES. Graphical User Interfaces will be moreover developed to allow an easy optimization of the electrode selection in the different matrixes and to facilitate the control of the different electrodes by clinicians and therapists in a simple and effective way.

[1] Evidence Based Review of Stroke Rehabilitation, http://www.ebrsr.com/

[2] Kwakkel et al. APMR, June 2015 Volume 96, Issue 6, Pages 991–993

4. Uses of NMES

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. Differently from iontophoresis, 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.

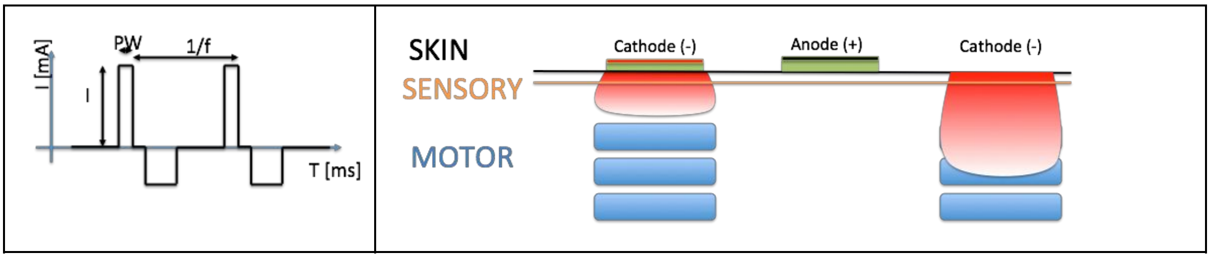


Table 1: Electrical Stimulation pulses and Field of activation. Depth and breadth of field are a complex function of the stimulation profile and of the underlying tissues properties. Low intensity pulses trigger only superficial responses, whereas higher intensity pulses trigger deeper neurons. Sensor 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.

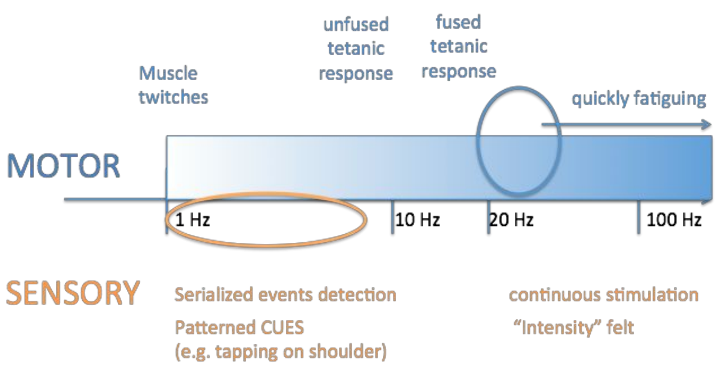


Figure 1: Motor and sensor responses can be triggered at different frequencies with different effect, but sensation during stimulation is always evoked.

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. In particular to efficiently provide muscle contraction the location and intensity of the stimulation has to be optimized to provide the necessary selectivity and not to cause unpleasant sensations.

5. Tasks and Targeted Muscles

The tasks envisioned for the Linarm++ platform are standard functional movements that greatly affect the patient independence. 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 both to 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.

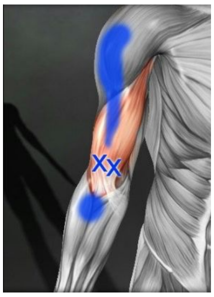
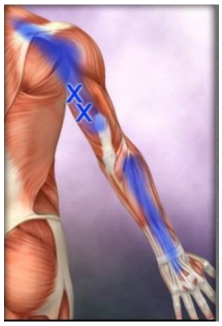
Task	**Muscles**	
	Proximal Dominant	**Distal Dominant**
Hand to Mouth	 Biceps Brachii	 Brachioradialis
Reaching	 Deltoid Anterior	 Triceps

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

6. Hardware Choices

The Rehastim One (Hasomed GmbH, Magdeburg, DE) is a programmable eight channels electrical stimulator for clinical and research purposes. Examples of interfacing are provided by Schauer et al[3]. Hasomed also has developed special hardware version of the RehaStim One[4] 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 2: Hasomed RehaStim One

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 [us] for all the initialised channels. These stimulation parameters will be repeated indefinitely until a new Update or Stop command is received.

[3] ScienceStim communication protocol, http://sciencestim.sourceforge.net/dokuwiki/doku.php?id=rehastim1
[4] MUNDUS Project, http://www.mundus-project.eu/

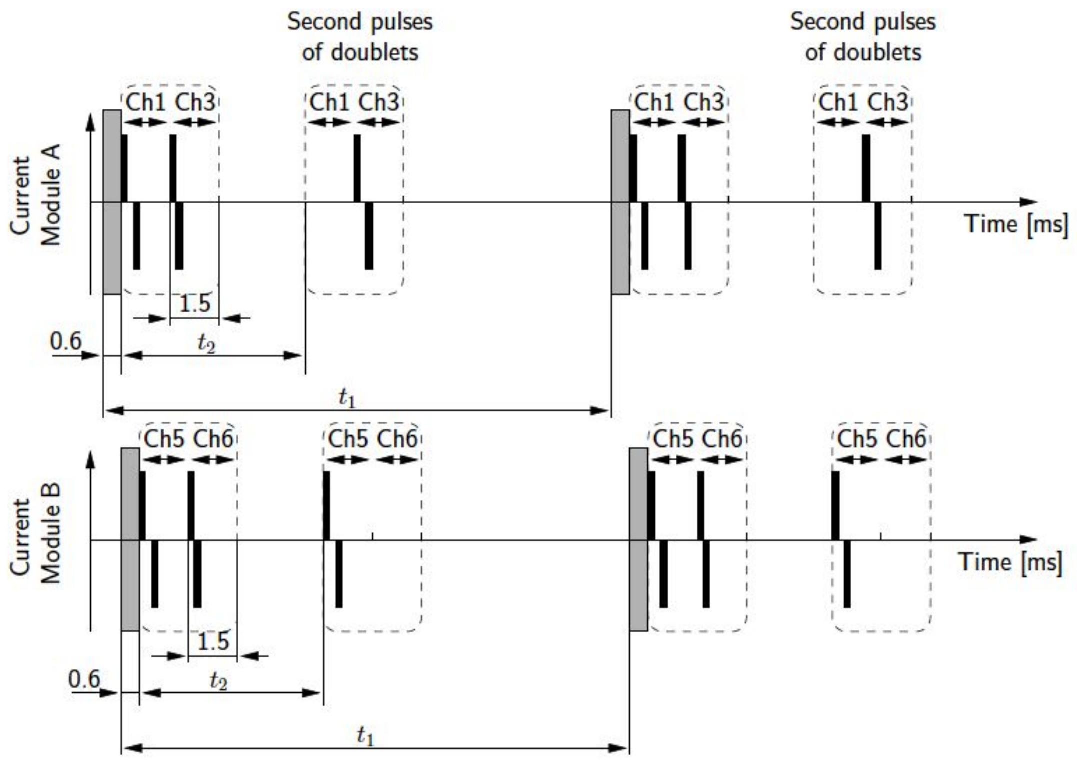


Figure 3: Example of the CCL mode patterning from the ScienceMode manual.

A simple event based communication from the PC would reliably allow to control three indepedent 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 A in different locations, and that channels 5-8 stimulate Muscle B. Channels 1, 3 and 7 are Initialized. Muscles A and B 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 3 x 3 cm2 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.

7. 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. 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 4, 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.

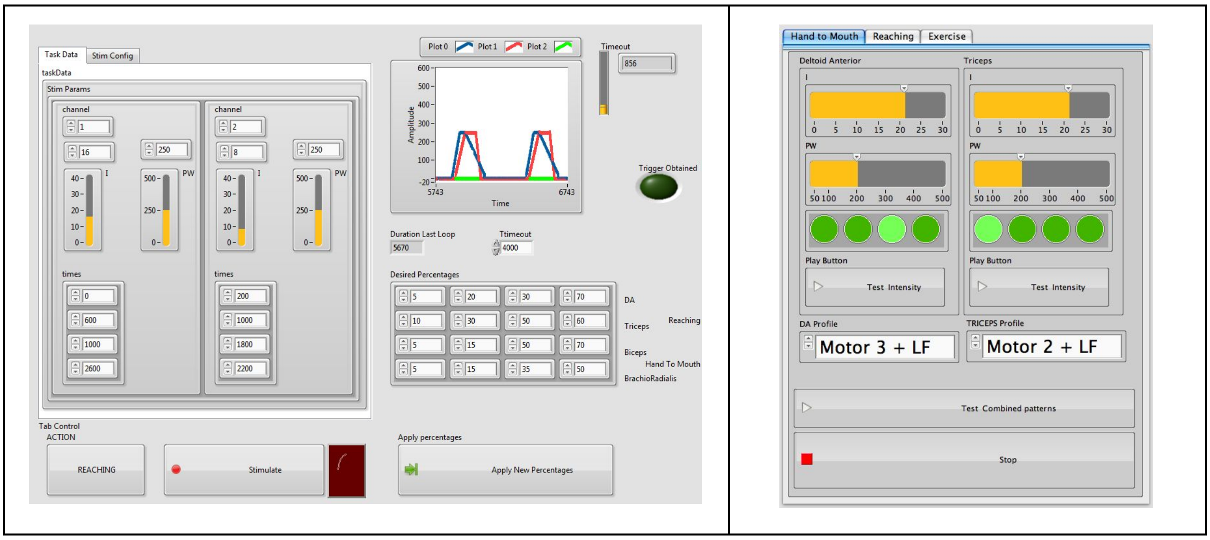


Figure 4. Left: a simple GUI that allows in "engineering mode" to quickly prototype and test different activation profiles. Right: a simplified GUI that allows choosing stimulation intensity, location of stimulation, and preset patterns, and then testing the overall pattern.

Once all the motor stimulation strategies will be defined, simplified GUIs for RIF and clinical testing will be optimized. Figure 4, on the right, exemplifies a quick configuration muscle setup where preset muscle activations can be tested before the beginning of the exercise.

8. Wearables

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. The overall cabling from the stimulator is implemented by means of two sets of PCBs: 1) an adaptor PCB with switches that allows selecting the subset of electrodes, and 2) a small PCB that fits inside the fabric support of the electrodes. The electrodes patches, as visible in Figure 5, are are covered with velcro hooks, and are hosted on fabric covered with corresponding velcro straps.

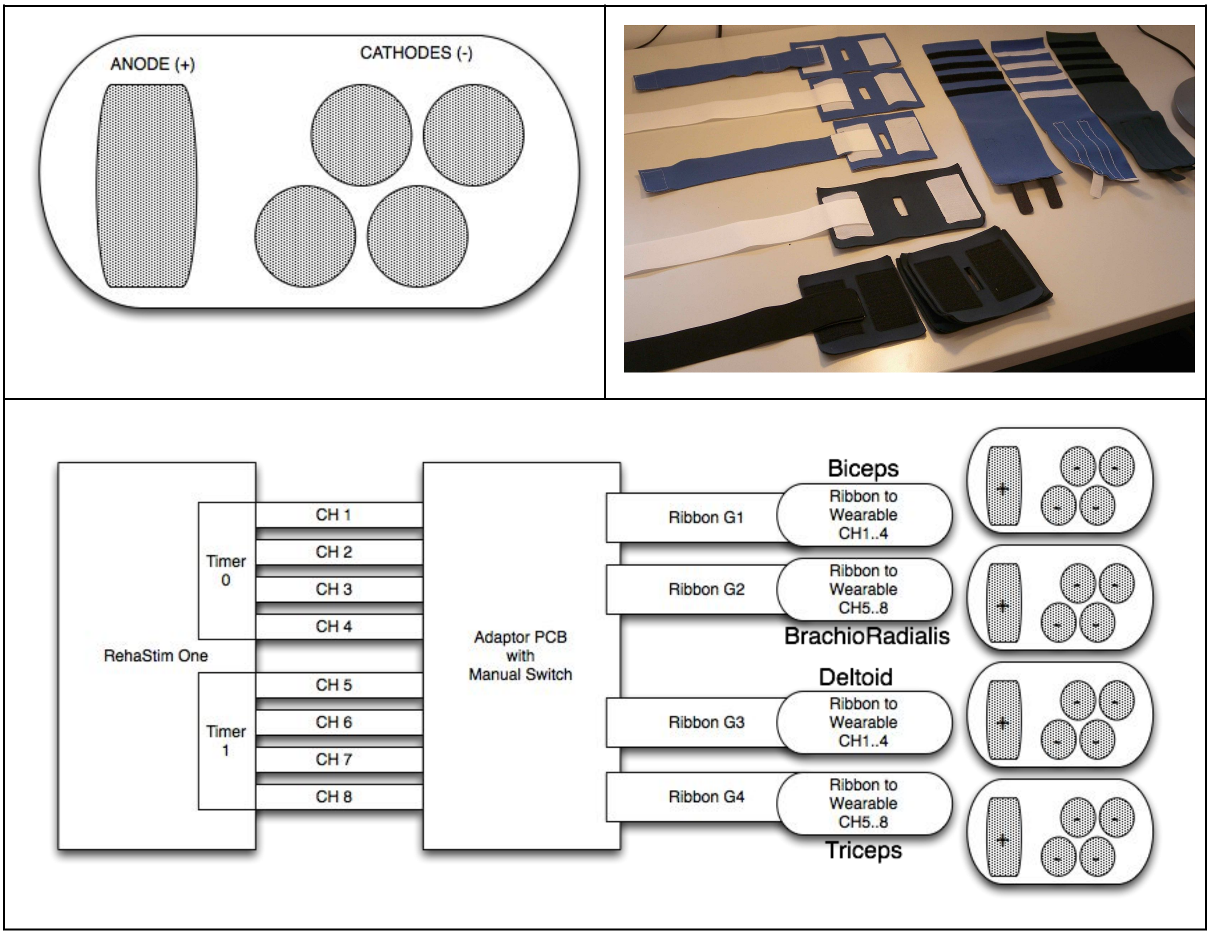


Figure 5. Top Left: a simple 4 electrodes matrix that allows non-experts to don the device on the targeted part. Top Right: examples of stretchable wearables able to host the electrode matrices. Bottom: a blocks scheme that shows the overall NMES-system.