

APPLICATION OF MICROPROCESSOR CONTROLLED MULTICHANNEL STIMULATOR TO THE REHABILITATION OF SCI SUBJECTS

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Abstract: This paper describes an enhanced surface electrical stimulation system for research and clinical applications, primarily intended for the restoration of walking in subjects with complete and incomplete spinal cord injuries. The main advantages of the system are its ease of use and extensive capabilities. The requirements for a modern stimulation system are discussed in this report and it is shown how these were implemented. The system is also described from the user's point of view and simple examples of a few stimulation patterns used in our clinical investigations are given to demonstrate some of the stimulator's capabilities.

Keywords: spinal cord injury, functional electrical stimulation, stimulators

Introduction

Partial restoration of lost locomotor functions is possible in a significant number of subjects with complete and incomplete spinal cord injuries (SCIs) through the application of functional electrical stimulation (FES) [1]. Approximately 10% of subjects with complete SCI at the mid to low thoracic levels are able to exercise crutch and FES assisted reciprocal gait after a few months of appropriate training. In such subjects FES has been proven to be an efficient means of rehabilitation. A typical FES rehabilitation process consists of the following:

- subject selection;
- atrophied paralysed muscle restrengthening;
- standing, standing-up, sitting-down;
- gait training.

Each FES application requires different stimulation sequences to recruit various muscles or elicit reflexes at different times. Even to excite the same functional activity, stimulation sequences depend heavily on the subject's tissue properties and current electrode placement.

The gait is one of the most complex locomotor activities. In cases of complete SCI at least four-channel surface FES is required. Such a stimulation pattern is also known as a minimal walking pattern. Both afferent and efferent stimulation are utilized. The swing phase is realized through afferent FES-provoked flexion reflex, resulting in the simultaneous flexion of the hip and knee and ankle dorsiflexion, providing clearance of the foot from the ground. The stance phase is achieved by stimulating the knee extensors. Gait is step-by-step triggered by a crutch built-in push-button that provokes a swing phase of the ipsilateral leg.

The stimulation patterns become more complex when doing research trials. In such cases it is not unusual to change the stimulation sequences for each trial. Stimulation channels may even be added or removed.

Many and various surface stimulation devices have been built [2, 3]. However, none of these systems fully met our requirements for clinical and research work. Based on the experience of the Ljubljana FES team in recent years with a large group of SCI subjects [4], we designed a clinical multichannel surface stimulation system that is specifically aimed at use in research and rehabilitation environments and enables both classic

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Fig. 1. Eight-channel functional electrical stimulator.

FES rehabilitation as well as fast adoption of new approaches. The result is a microprocessor-based eight-channel stimulator, shown in Figure 1. The properties of the multi-functional FES stimulator meet the requirements of both subject and medical personnel to the maximum possible extent.

Methods

Stimulator design

The sophisticated stimulation sequences, planned to be used, define the properties of the clinical eight-channel surface functional electrical stimulator. The design is based on three main objectives: stimulation, sensory data acquisition, and communication. However, regardless of the device complexity the control of the whole system still relies on the subject's voluntary commands to the largest possible extent. Our main objective, however, was to achieve a functional enhancement of the current multichannel stimulation systems.

Figure 2 shows the stimulator design concept. The input commands and/or data originate from different sources: push-buttons, sensors or even specific devices such as an ultrasound gait distance/velocity measuring system [5]. The output are not only stimulation pulses, but also digital signals which can be used in conjunction with stimulation patterns, for example to enable different types of feedback [6]. Control buttons and liquid crystal display (LCD) display are used for setting up the stimulator, choosing the stimulation pattern, and adjusting stimulation parameters, etc. A serial communication link is provided to enable simple interaction with a user-friendly environment on PCs for simple stimulation pattern creation/modification. The next sections discuss the design aspects in detail.

Stimulation

The main task of a FES rehabilitative system is the generation of stimulation sequences. Standard FES

sequences enable several considerably complex functional tasks, eg, standing with posture switching and walking with minimal four-channel gait pattern. Current research work and clinical applications require the introduction of additional stimulation channels. Eight stimulation channels were found to be appropriate. The stimulation parameters such as maximum pulse amplitude (0–150 V), pulse width (50–800 μ s) and pulse frequency (5–60 Hz) are selected independently for each channel. Stimulation pulses are monophasic and of rectangular shape. Because certain locomotor activities require modulated stimulation output [7], we used amplitude modulated pulses. The modulation signal is part of the stimulation pattern description. With variable stimulation frequency, one can achieve an appropriate compromise between fatigue and force [1]. Therefore, the frequency of each stimulation channel is set-up independently.

The safety measures are of utmost importance. The stimulation channels are voltage sources, thus reducing the possibility of skin burn in case of poor electrode–skin contact. But for the same reason, even a slight shift of electrodes results in changed muscle activation. A set of potentiometers on the stimulator's front panel can be used by the physiotherapist to promptly correct the stimulation amplitude to achieve the desired muscle action. All stimulation outputs are mutually double-electrically isolated to prevent leakage currents between the electrodes. Of course, each stimulation output is also protected against DC current. A third safety precaution is a battery monitor which buzzes in case the batteries are low.

FES research work and clinical practice require fast

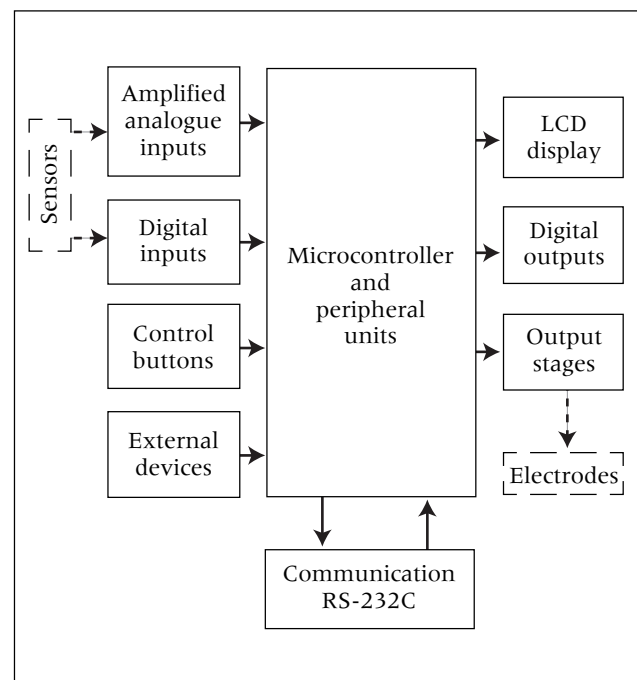


Fig. 2. Design concept of the eight-channel stimulator. LCD = liquid crystal display.

and simple changing of stimulation sequences. It can be expected that this task is conducted mainly by medical personnel, physicians, or physiotherapists. Designing and/or modifying the stimulation sequences should, therefore, be user-friendly.

Following that idea we separated the design from the generation of stimulation sequences; the latter is performed by the stimulator. The same program in the stimulator is used to generate all possible stimulation sequences. Thus, unlike the other stimulation systems, we have eliminated the need for reprogramming the entire stimulator software even when a complete stimulation pattern redesign is required. This was possible by implementing the concept of a modified finite state automaton theory, that provides necessary theoretical tools to describe a wide set of stimulation patterns [8]. Basically, a finite state automaton is a machine that is characterized by its history, present input and its current uniquely defined state from a finite set of possible states. Based on its definition, the automaton generates a preprogrammed output. In the case of an electrical stimulator used in gait synthesis, the output is of course a stimulation description for at least four stimulation channels. The input is the commands from the crutch built-in push-buttons and the state of the finite state automaton relates to the gait phase; left leg swing, right leg swing, or double support. In particular, we used a modified Moor's automaton approach [9, 10], where the system output, eg. stimulation, is directly related to the respective system state, eg. stance or swing phase in gait. The stimulator has a built-in software finite state automaton, which, based on selected stimulation patterns, determines what stimuli type are required in a given state. The transition from one state to another is triggered by time, sensory signals, voluntary commands, or by a combination of each. With such an approach we can define a wide spectra of stimulation patterns including fully preprogrammed, completely voluntarily controlled ones, and any combination of these.

The coding of a finite state automaton is a sophisticated task and can be performed only by highly trained technical personnel. In order to enable simple stimulator use we have been working on a graphical user-friendly interface for stimulation pattern design and modification. This PC-based software encompasses most of the stimulator technical details. The software also acts as a stimulation pattern manager and can down-load, delete or change stimulation patterns in the stimulator non-volatile memory.

In addition, the stimulator also offers a special server mode when it follows, in real-time, the stimuli generation commands initiated by a client, usually a PC computer. In this mode, the stimulator generates the pulses as instructed on-line by a remote computer, where complex pattern generation software may run. This mode is particularly useful for research work, because it offers

the on-the-fly modification of stimulation sequences, but at the expense of having to cope with many stimulator technical details.

Sensors, communication, and control

Multichannel stimulators for lower extremities have traditionally been open-loop devices. The only feedback information was the subject's vision. That fact leads an FES-assisted gait to an inappropriate posture resulting in fast arm fatiguing. Using a biofeedback loop, a subject's gait speed can be significantly increased [11]. This means, that the description of stimulation sequences must also include the specification of biofeedback signals. The stimulator should, therefore, also perform sensory data acquisition.

The majority of developed systems have so far realized the sensory feedback loop without directly involving the subject. In these systems the subject is just following the closed-loop induced FES movements. Our fundamental requirement was, however, that the subject himself must supervise and coordinate the FES-induced movements with his own voluntary actions. Sensory data, therefore, need to be delivered to the subject in an appropriate and condensed form. This processing needs to be realized by the stimulator. For this purpose our stimulator has several analogue and digital input ports, where different sensors can be connected. Simple data processing is done by a special programme running concurrently with the stimulation generating routines. The filtered data can be used in conjunction with voluntarily generated commands from SCI subjects as input data to the finite state automaton, which in turn yields different types of stimuli. The automaton also controls a set of digital outputs that can be used for triggering purposes or as indicators of the stimulation status. Additionally, acquired sensory data can also be used for simple gait evaluation, eg. counting steps or measuring instantaneous/average gait velocity [5].

As mentioned above, the stimulation sequences are designed on a PC computer. They are down-loaded to the stimulator through a serial link. The serial line is also used in a server/client mode where a PC and the stimulator exchange in real-time the stimuli generating commands and status information.

To accomplish all the listed tasks, we designed the stimulator on a four layer printed circuit board based on an MC68HC16 microcontroller (Motorola Inc, USA) with optimized power consumption and surface mount devices (SMDs) to minimize size. Software and stimulation patterns are kept in non-volatile electrically erasable programmable read-only memory (EEPROM). Batteries are used as a power source for both circuitry and stimulation. The stimulator software consists of a custom-developed multitasking real-time kernel enabling a dynamic time-sharing mechanism. The kernel controls

all other jobs: stimulation pulses generation, stimulation pulses calculation, finite state automaton control, sensory data acquisition, and communication control.

Results

User's point of view

The predefined technical properties as well as subject-stimulator interface specify the basic system design. The system management is conducted by three push-buttons on the stimulator placed nearby the LCD display. The user controls the stimulator through the hierarchical menu divided into three main branches: stimulation, sensory data acquisition, and stimulator maintenance. The settings are shown on the LCD display. Three push-buttons on the stimulator box with self explanatory meaning (←, ENTER, →) are used for moving through the menu tree as shown for example in Figure 3. The tree was carefully designed to have the most important functions available with as few key pressings as possible.

The stimulator is ready for operation 2 seconds after it has been turned on. The default power-on choice shown on the LCD screen is the root of the stimulation menu. It is intended for selecting the stimulation program, setting the stimulation parameters and starting/stopping the stimulation run. Figure 3 shows a detailed view of the stimulation menu. The boxed labels are displayed on the stimulator LCD screen. The arrows indicate possible transitions in the menu tree. In this menu we choose the appropriate stimulation sequence in the first level and we proceed to stimulation parameters set-up in the

second level. Here, pulse width and pulse frequency can be adjusted. Absolute amplitude is set-up for each stimulation channel independently using the potentiometers on the front panel. Thereafter, we move to 'start stimulation' where the stimulation run is actually initiated. Adding new stimulation sequences adds new options to the first 'Stimulation' menu level.

The 'Sensory data acquisition' menu is used for adjusting and testing the sensors as well as controlling the ultrasound distance meter and activation of the optional gait evaluation algorithm. Adjusting sensors actually results in tuning the input amplifiers and setting the simple software digital filters' properties. The latter process all the sensor input signals. We can also check whether all the connected sensors work properly. Perhaps the most useful and most frequently used evaluation program offered here is that which simply transfers all the stimulation and sensory information to the remote computer through the serial link. The remote computer logs the stimulation run and the data can be used later for off-line analysis of the experiment.

The menu 'Stimulator maintenance' is usually only used for changing the stimulation sequences. That task is performed in conjunction with a PC-based stimulation sequence design program. Another option offered by this menu is the server-client operating mode explained above.

Example of use

As a simple demonstration of some capabilities of the newly developed stimulator we offer the following example. In a recent study, we investigated the influence

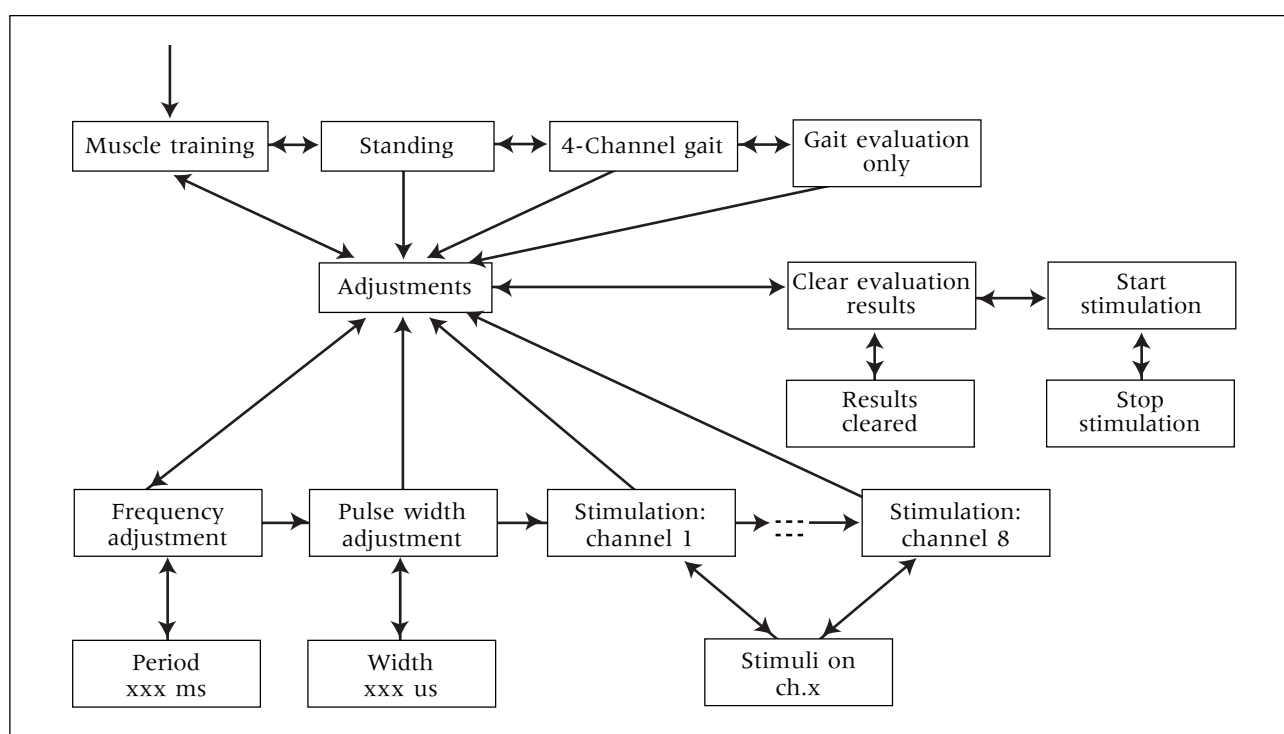


Fig. 3. 'Stimulation' menu used for selecting, tuning, and initiation of stimulation patterns.

of the stimulated ankle plantar flexors on the swinging leg during walking in subjects with incomplete SCI [12]. In such cases, a variety of stimulation patterns has to be used in order to find an adequate combination. Three stimulation channels were used; the first for the knee extensors enabling stance, the second triggered the flexion reflex for initiating the swing phase and the third channel delivered stimuli to the ankle plantar flexors. A subset of stimulation sequences used is shown in Figure 4. The selection shown demonstrates some key stimulator features.

The first important feature is stimulation with different frequencies. If a fast, impulsive, but time-limited response is required, higher frequencies are used. The second important stimulator capability is combining time- or sensory-based signals to trigger appropriate stimulation activity. In the first and the second case, only the subject's voluntary control is applied: when the crutch push-button is pressed the stimulation starts on the peroneal nerve or plantar flexors and shuts off the knee extensors. In the third case, there is a preprogrammed time delay included in the stimulation pattern. When the push-button is pressed the stimulation on the peroneal nerve is delayed for a selected amount of time. The stimulation of the ankle plantar flexors stops when the crutch push-button is released.

Figure 5 shows the knee goniograms as assessed with an OPTOTRAK Motion Analysis System (Northern Digital Inc, Waterloo, Ontario, Canada) during three consecutive steps of a tetraparetic SCI subject while walking with one of the three stimulation sequences shown in Figure 4. The maximal swings are increased for approximately 20° when the stimulation is applied to the ankle plantar flexors compared with the peroneal nerve alone. However, the most significant difference between the gait patterns is evident from the swing time reduction, which is decreased for more than 50% between the first and the second stimulation pattern. That is attributed to the FES of the calf muscles. This observation is particularly

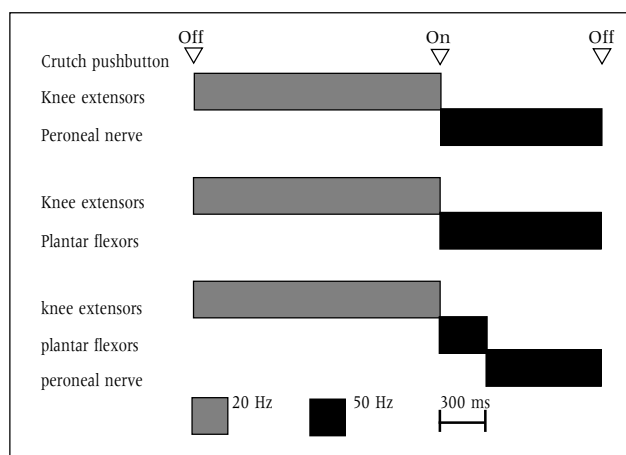


Fig. 4. Stimulation sequences delivered to the knee extensors, ankle plantar flexors, and peroneal nerve.

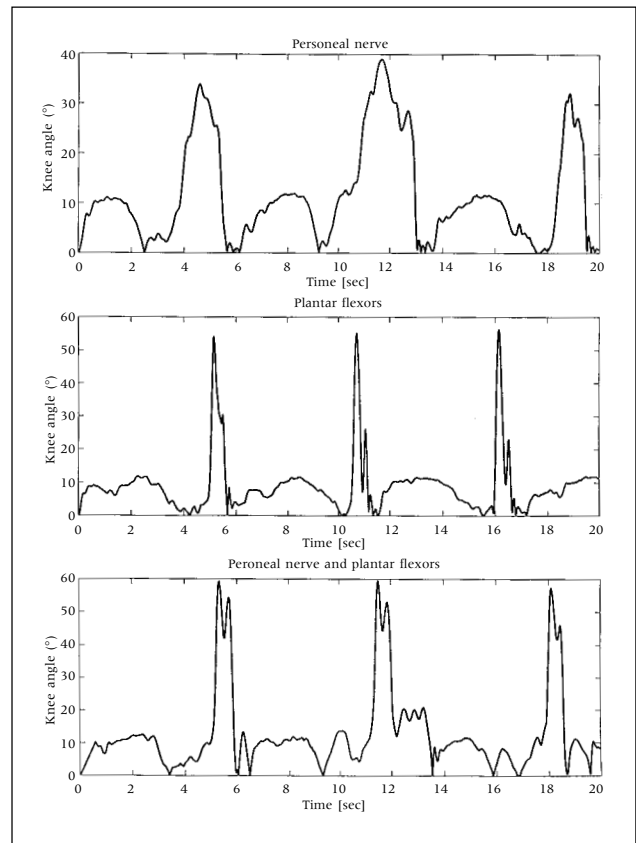


Fig. 5. Knee goniograms for three different stimulation patterns.

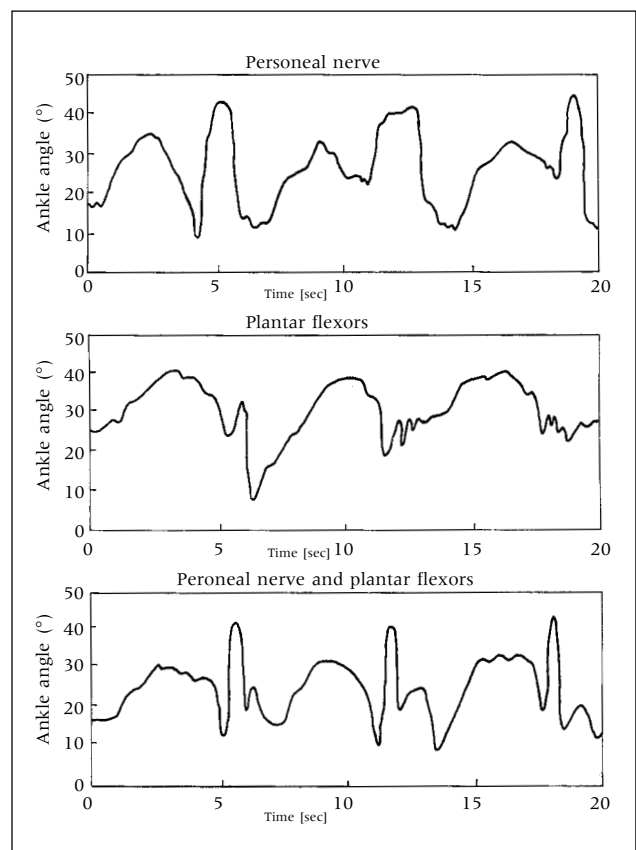


Fig. 6. Ankle goniograms for three different stimulation patterns.

important as a shorter swing phase may result in faster walking [13]. The problem with the second stimulation pattern is that the foot remained in the plantar flexion position throughout the swing phase, which is neither desired nor cosmetic. That is clearly demonstrated by the second diagram in Figure 6. This problem was removed by applying the third stimulation pattern from Figure 4. We added the stimulation of the peroneal nerve after only a short train of stimuli delivered to the calf muscles. The results are shown by the bottom traces in Figures 5 and 6. The appearance of the swinging leg was more cosmetic because of the adequate dorsiflexion of the foot. The effect was achieved at the expense of only about a 15% longer swing phase.

Conclusion

The main features of the newly designed stimulator can be summarized as follows:

- eight stimulation channels with rectangular monophasic voltage outputs;
- preprogrammed stimulation sequences cover standard and enhanced FES rehabilitation programme for subjects with SCI;
- sequences are added or modified through a standard serial link;
- stimulation sequences are voluntary-controlled, preprogrammed or combined;
- software adjustable stimulation pulse parameters for each channel independently: frequency (5–100 Hz), pulse width (0.050–0.800 ms) and amplitude (0–150 V)
- amplitude modulation of stimulation pulses with ramp and step functions;
- application of analogue, digital, active, passive, single, or differential output transducers connected to eight analogue and up to 14 digital inputs;
- software adjustable triggers for analogue signals;
- 19 digital outputs are used as an integral part of the stimulation sequence generation;
- sensory signal acquisition and processing for biofeedback, gait phase determination and/or gait evaluation;
- client-server functionality associated with a PC computer;
- simple system management through three control push-buttons, LCD screen and hierarchical menus;
- minimum two hours autonomy in the worst case.

Some of the above features were successfully implemented in a study addressing the role of calf muscle stimulation on the swing phase duration. We discovered that FES of the ankle plantar flexors results in a significantly shorter swing phase that may result in a higher walking speed in subjects with incomplete SCI. An additional improvement was the increased foot clearance from the ground, which is particularly important for walking on a rough, uneven terrain with obstacles.

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