Second generation stimulation equipment for Denervated Muscles in the scope of the EU project RISE

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Abstract

In the scope of the European Union (EU) Commission Shared Cost Project RISE the influence of electrical stimulation on long term denervated degenerated muscles (DDM) was investigated. As one of the major outcomes it could be demonstrated, that even long term DDM can recover to nearly normal status if electrical stimulation is consequently applied in a up to years lasting special trainings regime. In the beginning of the training muscle fibers have to be depolarized with pulse widths of up to 200ms and voltage levels up to ±100V. Custom built table top stimulators with huge battery packs provide those unusual stimulation sequences. As the training progresses less powerful stimulation parameters can be used to elicit tetanic contractions in DDM (40ms, 20Hz, ±100V). At this stage of the rehabilitation standing up and stepping training is desirable, requiring a light weighted and wearable stimulation equipment. Additionally, complex stimulation sequences must be programmable. The second generation stimulation equipment fulfills all this requirements. It is battery powered, has four very efficient DC free output stages and can be worn on a belt. A Pocket PC allows the patient to select among pre programmed stimulation patterns for training, standing up, stepping, sitting down and offers parameter adjustment in a limited range. The wireless communication between Pocket PC and stimulator is established via a Bluetooth link. If required the stimulator can be directly controlled from a PC via Bluetooth connection, alternatively through the Pocket PC via wireless LAN. The related PC software, intended for use in the rehabilitation center, offers a lot of possibilities for parameter optimization and setup of various stimulation sequences. The described device has an output amplitude range of 0... ±60V (up to 180mA), pulse width in the range of 100µs up to 100ms with a power efficiency of at least 50%.

1 Introduction

Restoration of lower limb function with the aid of Functional Electrical Stimulation (FES) is well known through decades. Lots of electrical stimulators, starting from simple one channel stimulators up to very complex PC controlled multi channel stimulators have been developed and applied to paraplegic patients with intact lower motor neuron [1,2]. Those patients require typically stimulation parameters in the range of 10µs ... 2ms width of biphasic rectangular pulses, 20-70Hz stimulation frequency and peak to peak voltage of ±60V, not conflicting with safety regulations.

Rehabilitation of patients with long term denervated degenerated muscles (DDM) is addressed in the European Union (EU) Commission Shared Cost Project RISE. The goal was to create a systematic body of basic scientific knowledge about the restorative effects of FES and related topics [3-5].

It was shown that recovering and strengthening of DDM is possible but requires stimulation parameters far beyond the limits of current safety regulations [6]. So a special allowance was given and a stimulator for DDM had to be developed.

Recovering and strengthening of DDM starts with a single twitch training with stimulation pulses of up to 200ms at 2Hz with an amplitude of up to ±100V (±200mA), resulting in an energy of 4J per pulse delivered to the tissue (EC-standards: max. 300mJ). Following the training muscle excitability decreases and pulse duration can be shortened to 80-100ms. Finally burst stimulation can be performed with 40ms pulse width and at a frequency of 20Hz. Stimulation during the stationary muscle strengthening training is provided by a custom built table top device [6].

After a quadriceps strengthening program the patient can start with a standing and stepping training in a similar way like in patients with spastic paraplegia [6]. Major difference is that patients with low lesion level cannot benefit from an electrically evoked flexion reflex. During the swing phase the leg has to
be lifted by moving the hip, mainly using the intact
lattisimus dorsi muscle.
The standing and stepping program requires
stimulation equipment strong enough to deliver the
described pulses, small enough to be easily worn and
flexible enough to preprogram various stimulation
sequences. Four stimulation channels are required to
activate quadriceps and gluteus muscles.

2 Material and Methods

The portable stimulator generation is designed to
fulfill the needs to stimulate DDM as well as to serve
as a multipurpose experimental stimulator that is also
suitable for stimulating muscles with intact lower
motor neuron. A constant voltage design for the
output stage is chosen for safety reasons. Drying and
peeling away of the electrodes results in a decreased
conducting electrode area leading to an increase in
current density when using constant current stimulus.
With a constant voltage output stage the current
decreases due to the raising ohmic resistance and
counteracts the hazardous surge of current density.
The whole stimulation system is packed into 3 cases,
one holding the batteries and the two others the
miniaturized electronic components for two
independent stimulation channels.

Figure 1 shows the block diagram of one stimulation
channel, power supply and the Bluetooth connection.
Battery and microprocessor section of the device are
consequently galvanically decoupled from the output
section by DC/DC converters, analog and digital
isolators. The stimulation voltage is produced by a at
500 kHz operating DC/DC converter. A feedback loop
takes care that the output voltage follows the
microcontroller specified value. Since the voltage
controller is designed to act fast the pulse shape of a
single stimulation impulse can be altered in real time
giving the opportunity to deliver pulses of any shape.
For safety reasons huge output capacitors are used to
keep the output signal DC free.

Each channel has its own microprocessor 18F4520
(Microchip, Chandler, AZ, USA). The firmware
was written in C and compiled with the Hi-Tech Picc 18
Compiler, (Hi-Tech Software Acacia Ridge,Australia).
Each channel processor can buffer several stimulation
sequences as shown in figure 2. The envelope of a
stimulation burst is built of n markers whereas n is
only limited by the internal memory of the
microprocessor. For each of the resulting n-1 parts of
the sequence, pulse width, pulse shape and frequency
can be set individually. Moreover, if required each
single pulse can be replaced by several biphasic
rectangular pulses, so called nlets [7] (figure 3). The
duration of the positive and negative part of the nlet
pulse can be independently set, a zero amplitude time
during polarity change can be chosen and finally
alternation of the pulse polarity is possible.

All processors are communicating via I2C bus through a RS232 / I2C interface with either a Pocket
PC (iPaq hx2490, Hewlett Packard, Houston, TX,
USA) or PC. The cable connection is replaced by a
Bluetooth link.

In the stimulator the CE certified Bluetooth
component WRAP THOR 2022-1 (Bluegiga, Espoo,
Finland) is used. It completely implements all the
Bluetooth requirements and offers a standard RS232
port to interact with the microprocessor. The iPaq
hx2490 has built in Bluetooth; the PC uses the USB /
Bluetooth adapter DB-20 (D-Link, Mt. Herrmann,
CA, USA).

A software library to control the stimulator was
written in Microsoft Visual Studio 2005 C# and is
suitable with very few modifications for PocketPC
and PC.
3 Results

The portable four channel stimulator is an agreement between size, weight and flexibility (figure 4). The output amplitude is in the range of 0...±60V (up to 180mA), the pulse width covers the range of 100µs up to 100ms with a power efficiency of at least 50%. Preprogrammed pulse shapes are biphasic rectangular, two kinds of saw tooth and triangular. Rectangular is available for all pulse widths while the other pulse shapes and a free definable pulse shape made of up to 255 single values are only available above 10ms. Nets can be built of max. 5 biphasic rectangular pulses with a positive and negative pulse width, independent in the range of 100µs up to 10ms. The zero plateau during polarity change is in the range of 0 to 2ms. The distance between nlet pulses can be set from 500µs up to 3 ms.

Fig. 4 4 channel stimulation system with Pocket PC, stimulation modules and special safety electrodes

3 Discussion

The major limiter to the useable output parameter range is the output stage. While the microprocessor is able to produce pulses from microseconds up to seconds the output stage has to be optimized according to maximum voltage output, pulse width, slew rate and power efficiency. All requirements can be easily fulfilled from the point of software engineering because latest microprocessors have enough memory capacity and are fast enough. The bottle necks are the batteries, the output capacitors and the used optimization strategy the output stage. The available parameter ranges proofed to be suitable for most applications in patients with spastic paraplegia and those with denervated muscles involved in the RISE project. Only RISE patients in the early rehabilitation phase, where single pulses with up to 4J have to be delivered to the tissue cannot benefit from the introduced device. The modular concept of the stimulation equipment makes it easy to further adapt the system to special applications. If required, the output stage can be changed while the microprocessor and its software as well as PC and Pocket PC software require no changes. Only the Graphical User Interface must be adapted to the proposed application and its specific parameter range.

3 Literature


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