NEW INTEGRATED MINIATURIZED NEUROMUSCULAR STIMULATOR TO ENHANCE BLADDER VOIDING

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ABSTRACT
Electrical stimulation of the sacral roots can be used for bladder emptying but it induces simultaneous contraction of the external urethral sphincter and the bladder muscles. A new selective stimulation technique shows promising results to inhibit sphincter contraction by high-frequency blockage during stimulation and has many advantages over other methods. This paper describes new neuromuscular stimulator dedicated to generate the needed stimuli and perform precise excitation of the sacral roots. The proposed device receives the command words and the energy transcutaneously and allows the generation of a wide range of parameters as well as high frequency capabilities. The stimulator is integrated in one chip using the 0.35 µm technology. This miniaturized device replaces a previous version realized with commercially available components and programmable devices.

Keywords: selective electrical stimulation, urinary bladder, sacral roots, implantable stimulator, integrated circuit.

INTRODUCTION
Urinary bladder functions can be lost after spinal cord injury at the T12 level or higher. In order to regain partial bladder control, functional electrical stimulation has been performed at various sites including the spinal cord, the pelvic nerves, the bladder wall and the sacral roots. It is well established that sacral roots stimulation shows the most promising results but it induces a simultaneous contraction of both the detrusor muscles and the external urethral sphincter.¹) Somatic fibers supplying the bladder sphincter are more sensitive to electrostimulation than autonomic fibers innervating the detrusor muscle. A stimulus large enough to provoke detrusor contraction will inevitably induce external urethral sphincter activation and prevent micturition. Recently, selective electrical stimulation of the detrusor muscles was achieved by using a signal composed of two distinctive trains of bipolar-current pulses. A high-amplitude, low-frequency train provokes detrusor contraction while a low-amplitude, high-frequency train relaxes the external urethral sphincter for complete voiding of the bladder.

To perform electrostimulation, many devices are now available but they lack important features such as a wide range for programmable parameters, a high efficiency in energy transfer and data transmission, a user-friendly interface, high-frequency stimulus generation and waveform flexibility.²) Several implantable multichannel stimulators and their external controllers have already been proposed by members of our team to fill the gaps and carry out functional electrical sacral roots excitation. We propose in this paper a new miniaturized integrated implantable stimulator which is based on a prototype currently used for chronic experiments and realized with commercially available components. This paper describes methods an materials, gives simulation and experimental results and main conclusions.
METHODS
In order to perform selective neuromuscular stimulation of the bladder through sacral roots, a new integrated stimulator was designed to meet the needed parameters and precision. This device is a component of a complete system which includes three parts:
- The external controller providing the parameters and the energy transcutaneously to the stimulator;
- The implantable stimulator receiving the information and generating the current pulses necessary for bladder emptying;
- The bipolar cuff electrode wrapped around the nerve.

Two complementary models of the external controller have been realized. The first one, attached to a personal computer (PC), offers the generation of a large sets of parameters. Through dedicated software, each stimulation parameter can be easily changed. The current set of parameters can also be saved and retrieved from disk or exported to a binary file for subsequent use with the portable controller. The second model is a hand-held device dedicated to moving individuals. This memory based unit allows the generation of eight preprogrammed sets of parameters. The user-friendly interface enables to view and choose from the set of parameter's description displayed on a liquid crystal display (LCD). Both models include an amplitude modulation (AM) emitter to send the Manchester encoded bit stream and the necessary energy to the implantable part of the system.

The new miniaturized stimulator is composed of two main modules (figure 1): 1) RF electronics part, and 2) a mixed signal (analog – digital) integrated circuit which is the subject of this paper and identified by the gray box on the block diagram. The implant receives the data and the energy through an inductive coupling link. The received 20 MHz AM waveform is rectified to power up the implant while the 300 kHz clock signal and data are extracted from the Manchester encoded signal.

The digital modules of the implant completed with very high speed integrated circuit hardware description language (VHDL) where synthesized with Synopsys tool. The resulting circuit was simulated and merged with the full-custom current source under Cadence design environment.
The complete design (control logic as well as the current source) has been realized with complementary metal-oxide semiconductor (CMOS) 0.35 µm technology on a 1.8 mm x 2.2 mm silicon die. The integrated digital part of the implant receives the data serially and detects the header of the bit stream. There are two valid 10-bits command words to be interpreted by the control logic. The first one forces the stimulator to test mode in which it generates a bipolar ramp. This mode facilitates the current source validation and characterization. The second header shifts the system in stimulation mode (normal mode). Received parameters are then transferred to the stimulus generation and control modules to produce the selective stimulation waveform. The generated 5-bits control commands are interpreted by the bipolar current source to transform the digital signals into a current waveform.

The current source uses identical p-channel transistors placed in parallel or in series to deliver a preprogrammed binary weighted current level. This architecture as a low sensitivity to fabrication process errors. Bipolar signal generation is achieve through an H output architecture (figure 2). The current mirror is used for both polarity creating well-balanced stimuli and reducing the possibility of nerve polarization by charge induction. Figure 2 depicts the typical selective stimulation current waveform where all parameters can be adjusted within the ranges shown in table 1.

![Typical Selective Stimulation Waveform](image)

**Figure 3: Typical selective stimulation waveform (meaning of abbreviations are given in table 1)**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Abbreviations</th>
<th>Maximum range</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amplitudes</td>
<td>HFA, LFA</td>
<td>0 - 5 mA</td>
<td>0.1 mA</td>
</tr>
<tr>
<td>Frequencies</td>
<td>HFP, LFP</td>
<td>1 - 5000 Hz</td>
<td>1 Hz</td>
</tr>
<tr>
<td>Pulses width</td>
<td>HFW, LFW</td>
<td>0 - 1000 us</td>
<td>3.3 us</td>
</tr>
</tbody>
</table>

The last part of the stimulation system is the dedicated cuff electrode which connects the implant to the sacral root. The electrode consists of two stainless-steel leads covered with polytetrafluoroethylene (Teflon®) and soldered to 25 µm platinum foil forming the contact surface to the nerve inside the cuff of the electrode.

**RESULTS**

The external controller have been used twice a day for chronic experiments stimulation for more than 2 years showing expected performance and good reliability. Following a previous
version of the stimulator based on a FPGA (field programmable gate array) which has been completed to prototype the stimulator and start validation of the selective stimulation technique, the central part of the implant, which is the integrated mixed-signal circuit, has been processed in 0.35 µm CMOS technology. The control part of the integrated circuit was validated through a series of functional tests. Various internal signals where externally connected allowing simplified testing by reading intermediate signal and applying the desired value. The remaining part which is the current-source block proved good functionality using the ramp generation built-in test routine.

DISCUSSION
Reducing the dimensions of the whole implant is an important issue to validate the stimulation technique in small animals like rats. Miniaturizing the implant is mainly based on the integration of mixed-signal functions on an application specific integrated circuit (ASIC). A completely integrated implantable stimulator will also reduce the power consumption allowing to decrease the emitting signal amplitude, therefore extending battery life in the portable controller. The design of a custom version of the whole implant (RF and stimulator parts) that will incorporate all features on the same silicon die is undertaken in our team to obtain a minimal power consumption, to decrease the whole implant dimensions and to continue the selective stimulation validation. The realization of the digital part of the design with a high-level hardware description language will allow to rapid modification for the implementation of new functions like telemetry. The full-custom current source allows a large maximum current output and a precise and well-balanced stimulation.

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REFERENCES