An Implantable Selective Nerve Stimulator

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Abstract – *An implantable stimulator system, suitable for selective stimulation of nerves, has being developed at University College London. This device should be capable of selectively stimulating nerve either by fibre position, fibre size or to send action potentials in one direction only, using implanted nerve cuff electrodes.*

The stimulator produces either quasi-trapezoidal current pulses, to allow anodal blocking, or conventional rectangular-shaped current pulses, of amplitude 20μA to 5mA (in 20μA steps) with duration of 16μs to 1ms (in 8μs steps). For safety, both active and passive charge balancing is used. The amplitude of the active charge-balancing phase can be varied between 1/7 and 1/47 of the pulse amplitude. During manufacture, each implant is customised so as to drive either 4 tripolar or 2 pentapolar electrode cuffs.

The implant comprises two custom-integrated circuits, a stimulator circuit and a digital control circuit, and other components. At present, stimulator-command signals are generated by a microprocessor, with a PC interface.

The system is currently being evaluated in acute animal experiments and the implant should be ready for chronic experiments later this year.

Keywords: stimulator, implant, electrical stimulation, anodal blocking

1. Introduction

Many workers have demonstrated methods of selective stimulation either by fibre size [1,4,8], fibre position [5,7,10] or production of unidirectionally-propagating action potentials [9] using nerve cuff electrodes. However, although the first of these papers appeared in 1979, practical stimulators for the chronic application of these methods have not come into use. This paper describes a stimulator system, suitable for use with all three of these methods, which has being developed at University College London.

The implant includes two custom-integrated circuits, a *stimulator unit* (SU), previously described [2] and a *digital control unit* (DCU) [6]. At present, for acute experiments, stimulator-command signals are generated by a microprocessor, controlled via a PC interface (Figure 1).

The stimulator can produce quasi-trapezoidal current pulses, to allow anodal blocking and rectangular-shaped current pulses, for conventional stimulation. Current amplitude, duration, and the active charge balancing current are adjustable. The implant is capable of driving either 4 tripolar cuffs, for anodal blocking, or 2 pentapolar cuffs [2], for spatial selectivity (fascicle-selection). The pentapolar electrode cuff consists of four 'dot' cathodes spaced round the central circumference between two internally-connected ring anodes**.**

Proposed applications (i) In the very successful Brindley implant for bladder emptying, only 50% of

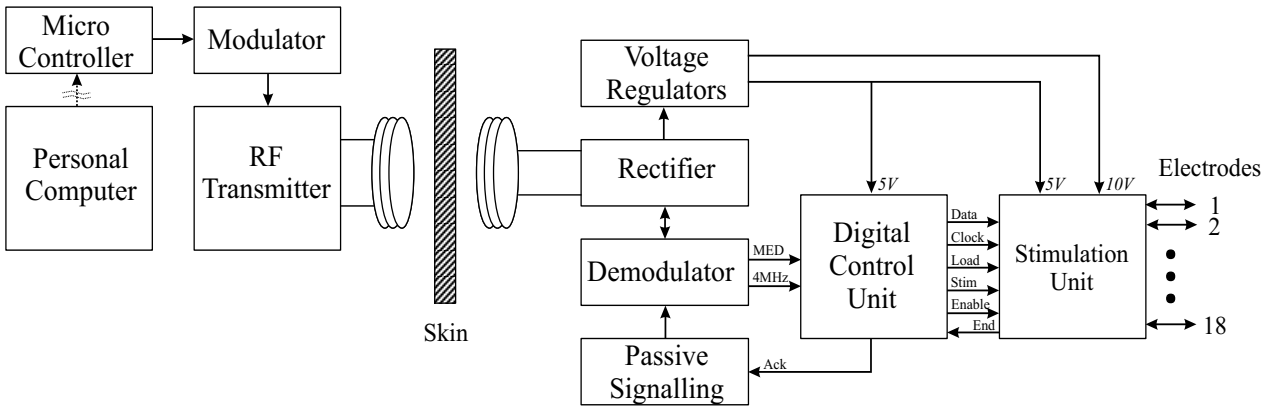

Figure 1. Overview of the selective nerve stimulator system

patients are able to defecate using the implant alone, due, probably, to unwanted contraction of the external anal sphincter which is innervated by large motor nerve fibres from the same roots. Our device should allow activation of only the small nerve fibres innervating the rectum, and, therefore, allow a larger proportion of the patients to defaecate using the stimulator [3]. (ii) Placing a pentapolar cuff on the common peroneal nerve can produce dorsiflexion of the ankle while balancing concomitant inversion/eversion of the foot [7,10]

A bench version of the stimulator system is currently undergoing evaluation in acute animal experiments, while the final device is being manufactured by MCE Newmarket Ltd and the Implanted Devices Group at University College London

2. *Stimulation Unit* Specification

The *Stimulation Unit* produces charge-balanced stimulation waveforms whether quasi-trapezoidal or rectangular. The pulse definitions used in the specification are shown in Figure 2 (anodal current waveforms shown).

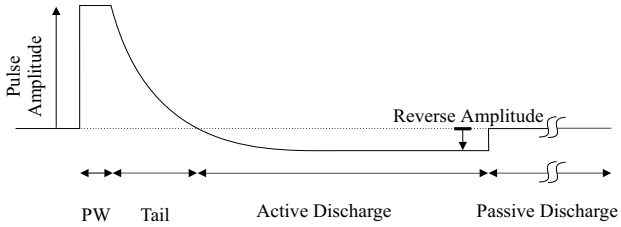

Figure 2. Stimulator waveform definitions

The stimulation has three main phases. Phase 1 (stimulation) comprises a rectangular pulse, possibly followed by an exponential "tail". Phase 2 is active discharge of the electrodes. Phase 3 is passive discharge, when any remaining charge on the blocking capacitor can flow through a resistive pathway.

Parameter	Range	Resolution
Pulse Width	0µs – 1016µs	8µs
Reference Amplitude	0µA – 4896µA	19.2µA
Attenuation Factor	0:1 – 1:1	1/15
Reverse Amplitude (1)	1.4% - 10%	7 Amplitudes: 10%, 5%, 3.3%, 2.5%, 2%, 1.7%, 1.4%
Tail	<10µs, 350µs (2)	ON / OFF
Cuff Number	Dipolar 1 – 9 Tripolar 1 – 6 Pentapolar 1 – 3	

(1)Percentage of Reference Amplitude (2) Fixed at time of manufacture

Table 1. Stimulator Parameters

Table 1 shows the stimulator parameters and their resolutions. The stimulation amplitude is controlled by defining a reference amplitude and then an attenuation factor for each output channel in the cuff which is being addressed. The S*timulation Unit* is capable of controlling three types of nerve cuffs, 9 dipolar , 6 tripolar, or 3 pentapolar.

It should be noted that although the reference amplitude has a resolution of 19.2µA, in tripolar mode (and pentapolar mode to a smaller degree) at certain output current ratios (1:1, 1:1.25, 1:1.33, 1:1.5, 1:1.66, 1:2, 1:2.5, 1:3, 1:4, 1:5) the resolution obtainable is much higher. This is due to the ability to vary both the reference current and the output ratio to define the output currents (at 1:1, there are 1842 output current levels; at 5:1, 512 output current levels).

The maximum stimulation frequency will depend on the pulse parameters (duration, tail and reverse phase) and the number of cuffs in use. If 1mA, 500µs rectangular stimulation pulses with a reverse amplitude of 5% are used, then each pulse will take 11.22ms (1ms PW, 20ms active discharge and 720µs data transmission). In that case, the maximum frequency for one cuff will be 90Hz, but for three cuffs this falls to 30Hz per cuff. There is a compromise between the number of cuffs and the pulse frequency. Note that the second phase at one cuff must be completed before the first phase at the next cuff begins, in order to prevent current flowing between cuffs.

3. Custom Integrated Circuits

The implant receives a 100%-amplitude modulated (@83.3kHz) 4MHz RF signal from which both data and power are recovered by the stimulator electronics.

The DCU has three main functions:

i) Decoding of the received data and error detection;
ii) Generation of timing waveforms and data for the SU;
iii) Communication with the external controller (via passive signalling).

For every stimulation pulse, the DCU has to receive a correct data set from the external controller. Every data set consists of 44 data bits and 16 parity bits (Manchester Encoded) for error detection. The total time required for each data transmission is 720µs.

The DCU was produced using a 5V Mask Programmable Gate (MPGA) array technology and is approximately 6.5mm x 6mm in size.

The SU has five main functions:

i) Production of the stimulation waveforms;
ii) Active and passive charge balancing;
iii) Selection of the active nerve cuff;
iv) Wired for Tripolar / Pentapolar Operation;
v) To inform the DCU when stimulation has finished.

The length of the exponential tail is defined during manufacture with a small external capacitor, at present giving nominally 350µs.

The SU was produced using a 10V full-custom CMOS technology and is approximately 5mm x 5mm in size. The use of a 10V process means that the output current specification is only valid while the voltage between the anode and cathode is lower than 7V. Above 7V, the output saturates which means a 5 mA pulse is only possible if the load impedance is below 1.4 kohm.

There are two reasons why the SU uses both active and passive charge-balancing. (i) Any error in the active charge balancing will accumulate charge on the blocking capacitors (in series with the electrodes) and cause the outputs to saturate. (ii) If the impedance of the electrode becomes larger than expected over time (due to encapsulation or lead breakage) the output of the stimulator may saturate during stimulation and will therefore no longer be charge-balanced. Passive charge balancing is therefore a safety precaution.

3. Prototype Implant

A prototype of the stimulator is currently being manufactured by MCE Newmarket Ltd and University College London and will be available for chronic animal experiments later this year.

During Manufacture both the stimulator mode (Tripolar / Pentapolar / Dipolar) and the polarity of the output currents are defined by wiring dedicated control pins. For tripolar cuffs, positive (anodal) currents, and for pentapolar cuffs, negative (cathodal) currents are generated, relative to the reference electrode(s) (Figure 3).

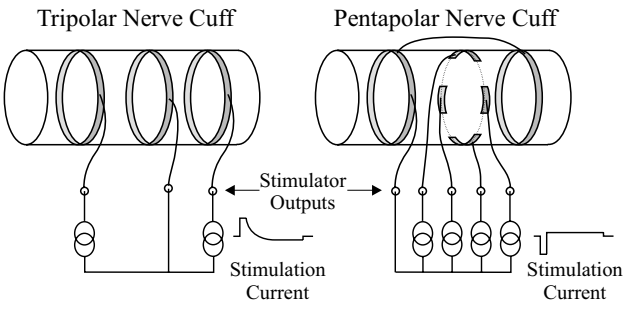

Figure 3. Cuff configurations in use with the prototype implant

The stimulator electronics consist of a hybrid circuit enclosed inside a ceramic hermetic lid. The RF receiver coil is placed outside the ceramic lid and the electrode cables are connected on the back of the substrate (Figure 4).

The prototype implant can drive either 4 tripoles or 2 pentapoles. For safety, blocking capacitor (10µF) are connected in series with each output to prevent electrochemical damage in the event of a failure in the implant (e.g. stimulator goes short-circuit).

The dimensions of the prototype implant are shown in Figure 4. After encapsulation in silicone elastomer the device will be approximately 47mm x 28mm x 7mm.

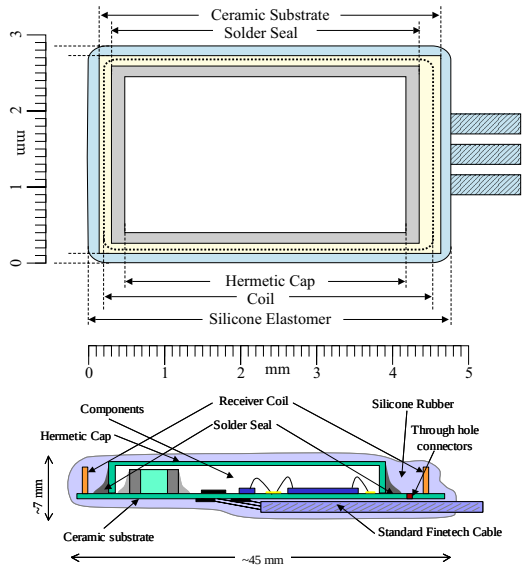

Figure 4. Implant dimensions and cross sectional view

4. Electrical Testing

The bench version of the stimulator has undergone extensive electrical testing. The performance of the device shows good agreement with the simulated performance. Figure 6 shows the output of the stimulator: the upper graph displays the output currents when driving 1 kohm resistive loads. The lower graph shows the voltage observed when driving a 1.5 mm diameter tripolar nerve cuff (contact width 0.5mm, contact spacing 3mm) submersed in 0.9% normal saline.

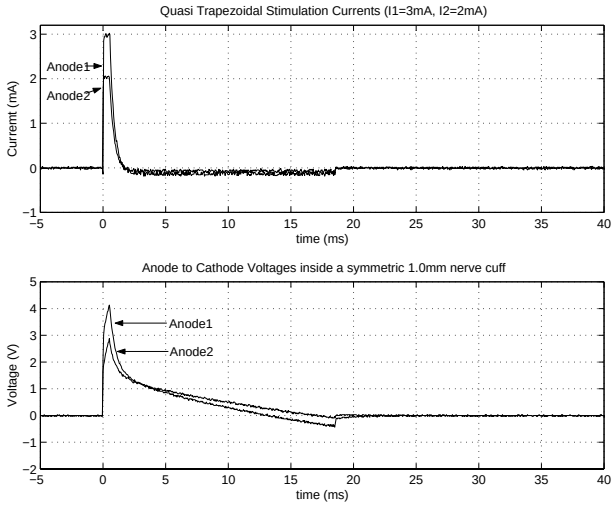

Figure 5. Tripolar stimulator waveforms (I1=3mA, I2=2mA, pw=560µs, reverse amplitude=3.3%)

A bench version of the stimulator is currently been evaluated in acute animal experiment at Aalborg University.

5. Computer Interface

The digital words, which define the stimulation, are produced by a microcontroller with a PC interface. The

interface allows control of all the parameters described in this paper. Figure 6 shows the stimulator interface for a pentapolar cuff stimulator. The window in the upper right allows the stimulator mode to be selected. The window in the upper left sets the pulse parameters and the window at the bottom sets the frequency/duration/cuff number and starts and stops the stimulator.

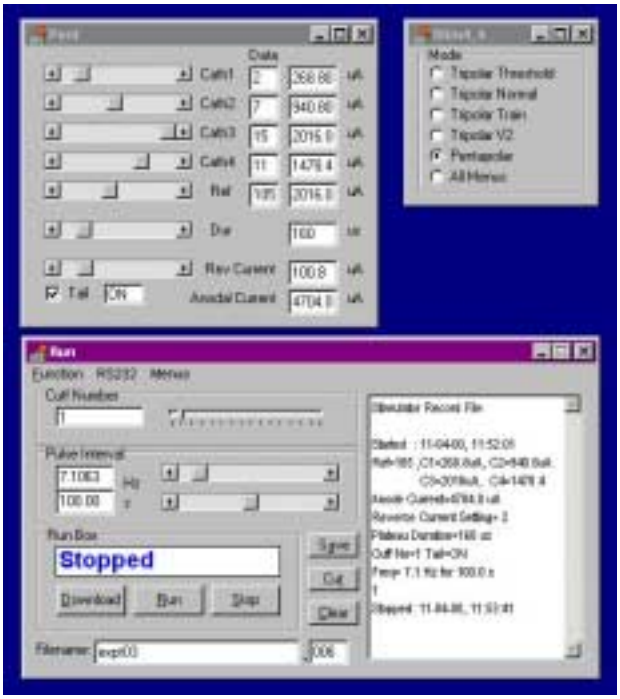

Figure 6. Stimulator software interface (pentapolar mode)

6. Conclusions

A stimulator has been developed that will allow the chronic investigation of selective stimulation by either fibre size (using anodal blocking) or fibres position (using multipolar nerve cuffs). The system is currently controlled via a PC and is suitable for chronic animal experiments. For use with patients, a "Control Box" for their use would be necessary, but the rest of the system would remain unchanged.

The prototype implant can drive up to four tripolar electrodes or two pentapolar electrodes. Using the existing chip set, these numbers could be increased to six and three respectively.

A bench version of the device is currently being evaluated in acute animal experiments at the Center for Sensory Motor Interaction (SMI), Aalborg University.

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