IMPLANTABLE ELECTRICAL STIMULATOR FOR BLADDER CONTROL

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SUMMARY

In the present paper we describe a circuit intended for electrical stimulation of the bladder in spinal cord injured patients. The system has been fully integrated with a commercial available CMOS technology. The stimulator is based on a eight bit digital to analogue converter and three independent current amplificators along with the correspondent discharge stage. A high performance inductive coupling is used to communicate data and energy to the implant.

INTRODUCTION

Continence and micturition depend on a set of peripheral nerves that are located in the spinal cord and regulate the activity of the detrusor muscle, which enervates the bladder. By means of electrical stimulation of the sacral nerve roots is possible to control the voiding of the bladder in medullar injured patients as has been widely reported /1-5/.

The objective of our work is to develop a fully integrated passive sacral roots stimulator that allows to program and control all the parameters which define the stimuli waveforms (i.e. current amplitude, pulse width, frequency...). The telemetry used through a high performance inductive coupling provides a medium of wireless, independent distance transmission of information, and allows an implanted stimulator which contains no power supply inside. In this paper only the stimulation block of the whole circuit is presented.

The stimuli produced by the system consist on charge balanced bipolar current pulses with an exponential negative discharge that allows easily to totally eliminate the charge injected during the positive pulse. The amplitudes of the pulses range between 300µA and 40mA with pulse widths between 30µs and 1ms. Tripolar symmetrical electrodes with two short circuit anodes and a cathode are used. To perform the simulation the electrodes has been electrochemically characterised given a parallel RC structure with values above 800kΩ for the resistance and above 3µF for the capacitor. Compliance voltage of 16 V has been used to provide 40mA current stimulation for a 400Ω resistance load (expected tissue resistance surrounding the electrodes). This fact forces us to use technologies with makes feasible the use of voltages higher than 5V.

The stimulator is able to generate three independent, consecutive signals that are usually applied over S2, S3 and S4 sacral roots by means of three tripolar electrodes. Its primary purpose are to improve bladder emptying along with to assist defecation and enable male patients to have erection when they want. The system is also able to measure the impedance of the stimulated nerve and as a consequence, test the performance of the implanted system.

CIRCUIT DESCRIPTION AND RESULTS

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The stimulator circuit is composed by a digital to analogue converter, a current amplifier along a recovery charge block and a channel selector as an analogue multiplexer. A block diagram of the circuit is shown on **Figure 1**.

Since our aim is to generate three independent and non consecutive stimulating current pulses, we have used an unique DAC and three current amplifiers with their recovery charge block. The DAC current is delivered to one or other channel by means of three channel selection switches that select the appropriate current amplifier. The I2T 0.7 CMOS Mietec technology has been used to design the integrated stimulator. The advantage to use this technology is that provides us with power transistors both MOS and bipolar transistors which are able to deal with voltages bigger than 5V. As we have explained above we need to work at least with 16V.

Digital to analogue converter: The DAC is composed of seven binary weighted current sources made with MOS transistors. This configuration allows that the current levels double at each successive stage, obtaining an intrinsic monotonic DAC /6/. Bit 8 controls the DAC activation, enabling the DAC only when stimulation is being done so, a low power consumption circuit is achieved. The DAC is able to deliver a maximum of 2.17 mA to a current amplifier formed by bipolar transistors. The transfer characteristic of the 7-bits DAC is shown in **figure 2**. The Differential and Integral Linearity evaluated from the simulation results are 0.8 LSB and 1.6 LSB respectively. Nevertheless the DAC presents a monotonic behaviour.

Current amplifier and recovery charge block: High voltage MOS transistors have very high channel resistance. Since currents of 40mA are required, high voltage drop takes place on these MOS transistors. On the other hand the voltage drop on bipolar transistors for the same level of current is lower, so we have decided to use bipolar transistors instead of MOS to design the amplifier eventhough the power consumption for these devices (due to the base current) is higher than for MOS transistors.

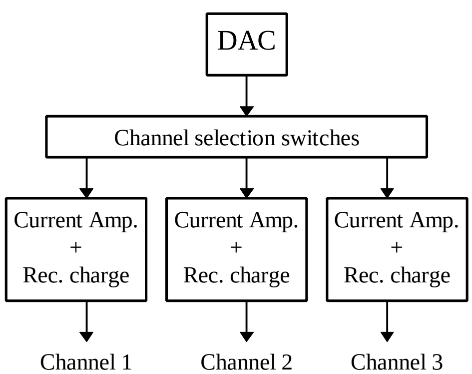

Figure 1: Block diagram of the stimulator circuit

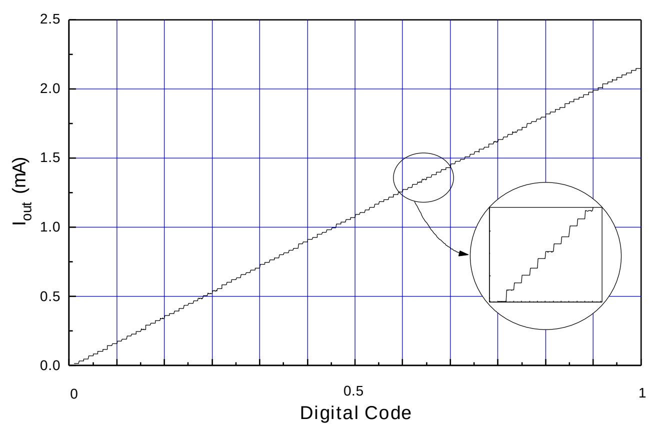

Figure 2: Transfer characteristic of the 7-bits DAC (Hspice simulated results). In the inset is shown a "zoom" of the characteristic.

Bipolar transistors available on I2T have a very poor current gain (close to 25). In order to improve it, we have used a Darlington current mirror structure. On the other hand, we have added a transistor to provide the necessary current to the Darlington structure /7/. The schematic is shown on **figure 3** and the simulation results are shown on **figure 4**.

In order to get a safe stimulation the recovery of all the charge injected into the tissue is needed. The architecture we propose consists of a power MOS transistor that acts as a simple switch and connects the current amplifier output and both anodes of each electrode as has been widely used /8/. Once stimulation pulse has been generated, the charge injected during the primary pulse is recovered by the activation of this transistor switch, obtaining a balanced bipolar stimulating current pulse. An specific circuit to provide the right voltages values to control this switch ($V_{control}$ on **Figure 3**) has been implemented.

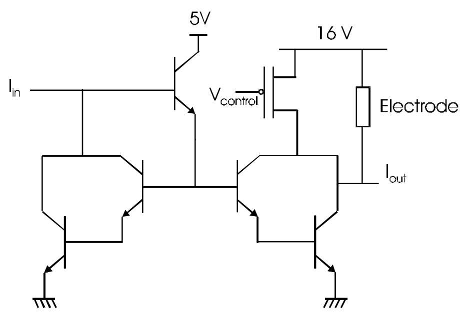

Figure 3: Current amplifier and recovery block. The MOS transistor acts as the recovery charge block, enabled when the DAC is off by $V_{control}$.

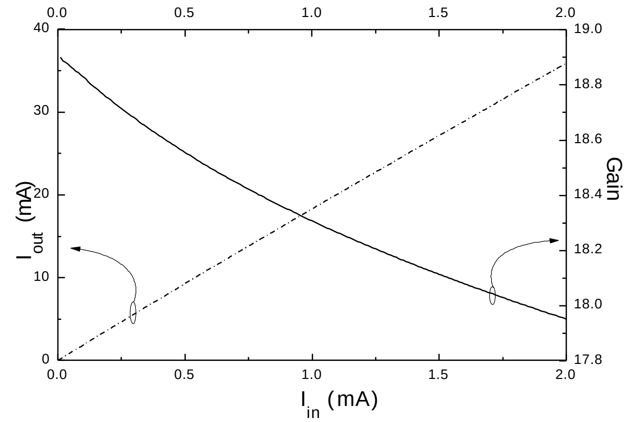

Figure 4: Current amplifier simulation. I_{out} and the amplifier gain versus I_{in} are shown. Note that the linearity error is less than 6%.

On **Figures 5** and **6** it is shown the simulated results for all the system using the measured model for the electrode. **Figure 5** shows the obtained signal for one channel. Note that the recovery of the charge is exponential with a very low time constant. In fact as the stimulating signals are at low frequency (the highest is around 50 Hz) we design the circuit to have a low time constant and thus to provide a very small negative peak. To obtain the results a 370 Ω resistance has been used as the tissue impedance and the equivalent model of the real tripolar electrodes. **Figure 6** shows the three stimulating channels with different amplitudes. With our stimulator the three channels can not be simultaneous but the delay between them is negligible.

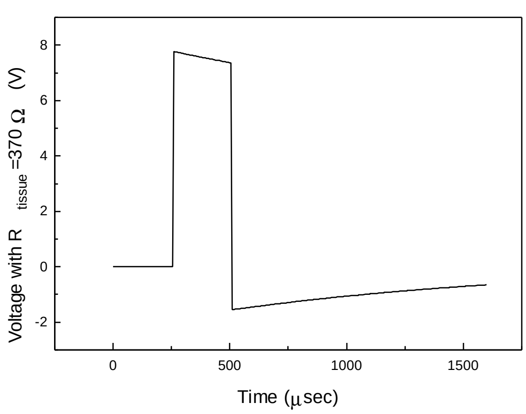

Figure 5: One channel stimulation waveform. The exponential recovery of the charge is shown.

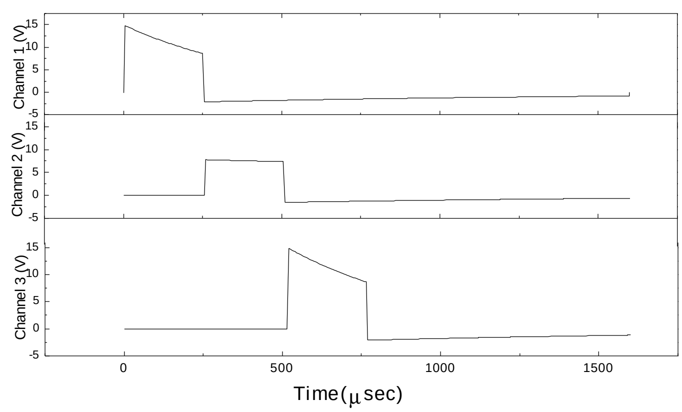

Figure 6: The three channels were programmed to stimulate with the same pulse width (250μs) an amplitudes of 40, 20 and 40 mA respectively.

CONCLUSIONS

A three channel bladder implantable electrical stimulation telemetric controlled circuit has been designed.

The full system allows the user to generate the necessary information to the implant (current amplitude, pulse width…) in order to get an independent distance stimulation. The versatility of the system allows the generation of different waveform shapes that can be very useful in the study of selective stimulation to control the bladder emptying avoiding the dissynergia between the sphincter and the detrusor.

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