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Abstract

This paper covers circuits and systems techniques for the construction of high reliability biosensing and neurostimulation smart medical devices. Such microsystems are dedicated for interconnections through the peripheral neural systems. Case study related to applications such as bladder control is discussed. Available electrical neurostimulation techniques for the rehabilitation of urinary bladder functions do not allow an adequate voiding due to dyssynergia between the bladder and the sphincter. A new implantable stimulator, built with commercially available electronic components, was designed to overcome these difficulties. The proposed system performs two types of stimulations: Selective Stimulation for bladder voiding and Permanent Stimulation to reduce the bladder overactivity symptoms. Also, a fully integrated extended version of the stimulator is achieved with the additional ability to monitor the electrodes-nerve contact impedance variations in order to detect electrodes faults or nerve physiology changes. The implemented full custom device provides a reliable stimulation technique and addresses the lack of features (programmable parameters, user-friendly interface and waveform flexibility) of the previous stimulation devices. Experimental results of the fabricated chip confirm its functionality. The microstimulator generates a wide range of stimuli waveforms with variable parameters and its modular architecture makes it an expandable multichannel stimulation system.

Key Words: *Medical device, Electronic implant, Electrical stimulation, Selective stimulation, Bladder controller, Detrusor-sphincter dyssynergia, Neurogenic detrusor overactivity, Hyper-reflexia.*

1. Introduction

Innovative circuits and systems techniques are required to build advanced smart medical devices (SMD). The high reliability and very low power consumption are among the main criteria that must be given priority to implement such implantable and wirelessly controlled microsystems. A typical SMD is composed of several integrated modules to be assembled on a thin substrate providing placement flexibility in the body [1–3]. Data recording, monitoring of electrodes-tissues interface condition for enhanced safety, and

for enabling troubleshooting after implantation are needed. In addition, in order to improve controllability and observability, bidirectional full-duplex communication canal between external controllers and implants is required. Regarding the spinal-cord injured patients at the T12 level or higher can lose the control of their urinary bladder. These patients become unable to voluntarily evacuate the urine from filled bladders and often suffer from many complications such as the neurogenic detrusor overactivity (NDO) or detrusor hyperreflexia which is an overactivity of the autonomic nervous system. The overfull bladder sends sensitive neural signals to the spinal cord where they travel upward until they are blocked by the lesion at the level of injury. Since these sensitive neural signals cannot reach the brain, the reflex arc stays activated, increases activity of the sympathetic portion of the autonomic nervous system and causes spasms. In most cases, incontinence occurs due to NDO or dysfunctions of the bladder neck (urethral insufficiency) [4].

1.1. Electrical stimulation to recover the micturition function.

Several types of Functional Electrical Stimulation (FES) have been introduced in order to recover the voluntary control of the micturition reflex at different sites of the urinary system. Four main stimulation sites have been investigated: the bladder muscle (detrusor), the pelvic nerves, the spinal cord and the sacral roots [5–10].

The electrical stimulation of the detrusor did not induce an adequate voiding and the required high amplitude of the stimulation current may cause damages [11, 12]. FES has been applied to the pelvic nerves, but their relation with the pudendal nerves generated a simultaneous excitation of the sphincter and the detrusor. This phenomenon, known as Detrusor Sphincter Dyssynergia (DSD), induces high detrusor pressure that may eventually lead to incontinence or kidney failure. An alternative solution implying neurotomy of the pudendal nerve has been proposed but the surgical approach makes this technique less popular [10, 13].

The stimulation of the spinal cord has been performed, but using penetrating electrodes may cause the double activation of the bladder and the striated sphincter muscles [14], [15]. The last stimulation site, the sacral roots, is one of the most promising methods, but early conventional stimulation of sacral nerves induces once again the DSD [11]. Recently, applying specific stimuli that allow overcoming the DSD attracted researchers attention. In fact, the detrusor and the external sphincter muscles share the sacral nerves as common innervation pathways. The autonomic afferent roots stimulate the sacral micturition reflex, while the somatic efferent pathways (controlled by the brain) are responsible for the contraction of the external sphincter [4]. This sacral roots stimulation method is the subject of the present work.

1.2. Sacral roots stimulation techniques

The intermittent stimulation of the sacral roots, also known as post-stimulus voiding, has been described and largely used in patients [16]. By stimulating the sacral nerves adequately, contractions can be induced in both the detrusor and the sphincter, but only the striated sphincter muscle is able to relax between the stimuli, thus allowing urine evacuation. The used stimulation pattern consists of intermittent pulse trains (typically, 3 to 6 seconds stimulation and 6 to 9 seconds stop). Good clinical results have been observed, but this intermittent stimulation method is characterized by a high intravesical pressure and high level of urine residue that are damageable for the kidneys. Also neurectomy of nerves may be required in most cases [17].

Another sacral nerve stimulation technique is the sphincteric fatigue. In this case, the pudendal nerves are stimulated with high-frequency signals until induction of the sphincteric fatigue. It is followed

by low frequency stimulation of the sacral nerves for voiding. This two-steps technique takes advantage of the difference between the contraction and the relaxation periods of the sphincter and the bladder. Even if this concept avoids neurectomy, it produces inefficient results comparable to those obtained with patients following pudendal neurectomy [18, 19].

More than a decade ago, a selective blockage method has been introduced. It is based on the blockage threshold (or excitation) difference of the A-delta and A-alpha fibers. Multiple types of blockage techniques have been tried: pudendal nerves collision [20], anodal block by sacral roots stimulation [21], [22], and pudendal nerves high-frequency blockage [23, 24]. Recently, authors introduced the selective activation technique of the small nerves fibers in the sacral roots by combining a cathodic excitation of all fibers and a selective anodic blockage of the large fibers [25, 26]. This technique achieves hyperpolarization of the nerve membrane between the excitation application point and the external urethral sphincter to prevent the propagation of nerve action potentials toward the sphincter. In fact, the large diameter fibers innervating the sphincter having a lower excitation threshold than those with small diameter; this blockage technique allows selective activation of the detrusor muscle thus inducing an efficient voiding. More recently, selective detrusor muscle activation has been obtained by performing stimulation of the sacral roots with a signal composed of two distinctive trains of bipolar-current pulses [27]. This stimulation technique is elaborated later in this paper.

1.3. Available implantable stimulators

Few implantable electronic devices were introduced for clinical purposes to address the bladder dysfunctions. Finetech presented in 1985 a triple transcutaneous stimulator generating monophasic stimuli [28]. In 1987, Physico-Med introduced a monochannel stimulator for urinary retention [29]. In 1997, Medtronic introduced devices for incontinence treatment and several versions followed. The Medtronic InterStim therapy is largely used worldwide for both purposes, incontinence and retention [30]. More recently, the Vocare bladder system introduced by NeuroControl, which is an updated version of the Finetech stimulator, has been approved for the North American market [31]. However, this device requires rhizotomies to achieve bladder voiding.

In the past years, several implantable stimulators and their external controllers have been proposed by our research team [32–34]. Multiple stimulation techniques were used for the rehabilitation of voluntary bladder voiding. Recently, we introduced an implantable device which is powered and controlled by a hand-held interface. The implant can deliver combined stimuli in order to selectively stimulate the bladder and the sphincter [33] as well as a battery powered Permanent stimulation with a long lasting life. Prototypes, made with commercially available electronic components, have been realized and used to conduct chronic studies on dogs during eight months. By means of selective stimulations using the high frequency blockage, DSD is reduced or even avoided. In addition, the Permanent stimulation demonstrated the feasibility to reduce the NDO [35]. These preliminary good results motivated us to improve our device and to address the lack of features such as a wide range of programmable parameters, a user-friendly interface, and the waveform flexibility. In addition, we proceeded to build a fully integrated version of our stimulation system, to which we added new required features such as the electrode-nerve impedance monitoring.

The remainder of this paper focuses on a description of the FES system which will be given in section II. In section III, we present the new miniaturized system, while Section IV describes the experimental results. We discuss the obtained results in section V and conclude this work.

2. Selective and Permanent Neurostimulator

A first version of the Selective and Permanent Neurostimulation System, which was built around off-the-shelf electronic components, is composed of an external controller, an electronic implant, and a bipolar cuff electrode to interface the implant with one of the sacral nerves.

2.1. The external controller

The external controller has three main features: 1) Power the implant by sending wireless inductive energy, 2) Select stimulation type (Permanent or Selective), and 3) Select the desired parameters (width, frequency and amplitude). When a Selective stimulation is requested, the implant generates current pulses as long as the inductive link is maintained. For the Permanent low-frequency stimulation, it automatically runs when the inductive link is interrupted. The external controller includes a user interface composed of few push buttons and a LCD. It is based on a finite state machine implemented in a commercially available microcontroller (Figure 1). A power amplifier is used to transcutaneously transfer the needed energy using an inductive coupling technique to power up the implant. Commands and data are Manchester encoded and sent to the implant with an Amplitude Shift Keying (ASK) modulation of a 20 MHz RF carrier.

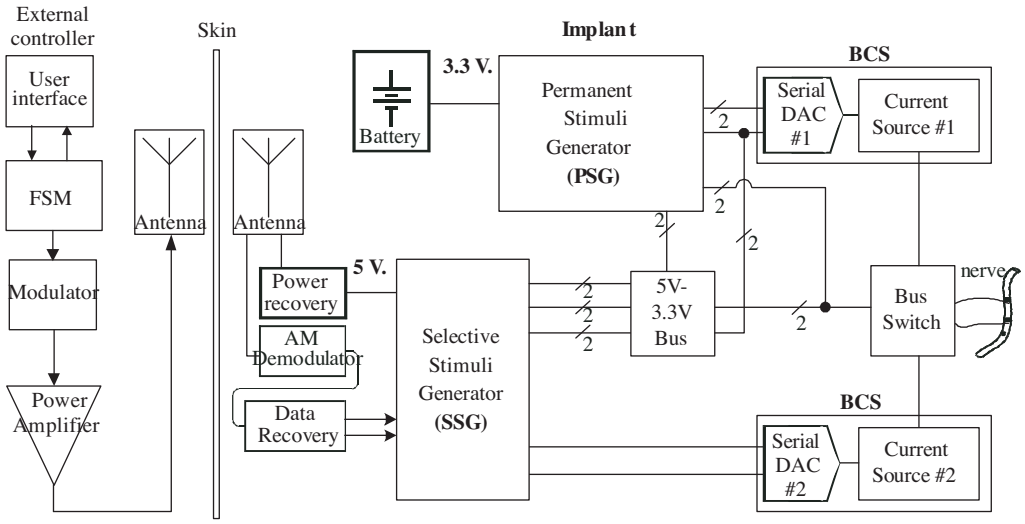

Figure 1. Block diagram of the stimulation system.

2.2. The implant

The system allows two operation modes for the implant: Selective or Permanent stimuli generation. Each mode is handled by an independent Stimuli Generator (SG). The block diagram of the implant, shown in Figure 1, is composed of a data and power recovery block, two SG's, two bipolar current sources (BCS) and a common switching stage to generate biphasic stimuli. The front-end block allows the demodulation of data sent by the external controller and the recovery of inductive energy to power up the selective stimulation block. On the other hand, the Permanent Stimuli Generator (PSG) is entirely powered by an embedded battery without any direct interaction with the external controller. The Selective Stimuli Generator (SSG), built within a FPGA (Field Programmable Gate Array), contains an internal controller which is in charge of data decoding and verification using a communication Cyclic Redundancy Check (CRC) technique.

Furthermore, it generates the adequate commands to produce selective stimulation waveforms or transfers to the PSG the required Permanent stimulation parameters. This PSG is built within a commercially available microcontroller. After reception and verification of the parameters, the PSG generates commands to produce low amplitude stimuli for the Permanent stimulation. Each SG controls its own BCS which contains a digital to analog converter and an operational amplifier based current source to deliver constant current pulses.

The Selective stimulation technique duplexes high and low frequency (HF & LF) stimuli alternately to respectively activate somatic A-alpha fibers, which innervate the sphincter and parasympathetic A-delta fibers innervating the detrusor muscle. Figure 2a shows a typical waveform of this technique. The Permanent stimulation is composed of a train of low-frequency pulses (Figure 2b). Also, biphasic stimuli are applied to avoid accumulation of charges at the electrode-nerve interface.

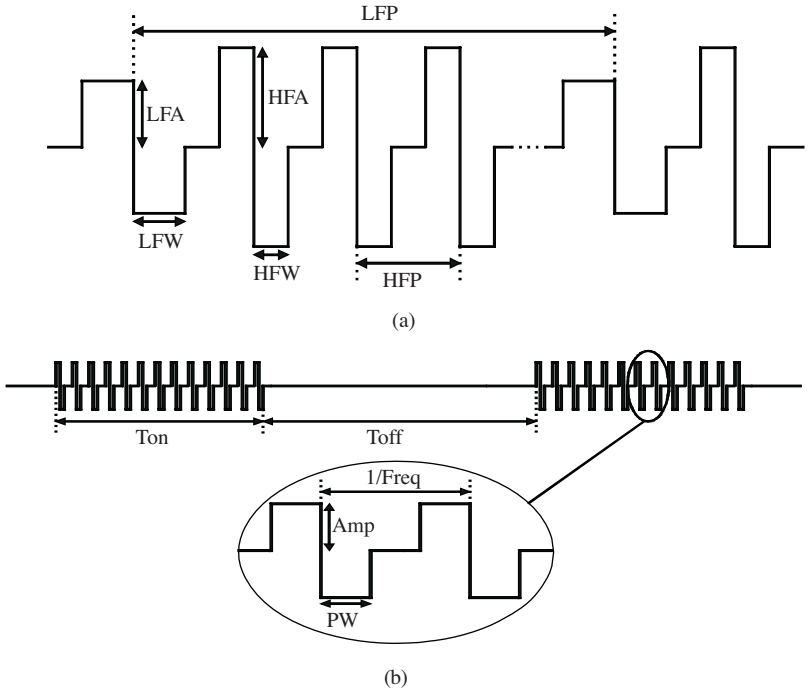

Figure 2. Stimulation waveforms: (a) Selective stimulation, (b) Permanent stimulation.

Selective stimulation may require high current amplitudes (up to 2 mA over a 1 kohm impedance). In order to avoid saturation of the current source with higher nerve impedance, a 5 V DC voltage is regulated from the received inductive energy carried at a frequency of 20 MHz. Special attention has been paid to isolate the battery from the inductive link to avoid any current leakage and consequent battery lifetime degradation. The dual SG architecture of the implant enrolls two independent stimulation pathways with independent power supplies. We thus have an implant that can be either a high amplitude bi-frequency Selective stimulator or a low power and low amplitude continuous stimulator.

A prototype of this new microstimulator was built on a printed circuit board (PCB) with commercial integrated circuits and discrete components. An Actel 40MX04 FPGA and a PIC16F84 Microchip microcontroller were used for the controllers. An 8-bit serial DAC (MAX550A) was selected to drive the current sources. This DAC occupies less space than equivalent parallel DAC used in previous versions of the implant. The remaining integrated circuits were chosen within the Texas Instruments family of CMOS circuits. They were mainly selected for small size factor and low power consumption requirements. Also, the battery is

a coin type Lithium battery (500 mAh), which should keep the implant operational for more than a year with nominal parameters. The inductive link receiving coil is a concentric 3-turn spiral of copper conductor integrated into the same PCB.

In-circuit programming function of the microcontroller is used to facilitate future updates of the microcontroller's code after final assembly of the implant. Connection jumpers were included in the PCB to connect a serial programmer. When assembled, the implant was placed in a test-bench which simulates intensive use of the microstimulator in all operating modes. Afterwards, the whole circuit was protected by a triple layer polyurethane coating. This coating is not adapted for medical applications and has to be perfectly dry and free from any solvent before being covered with a biocompatible material. The implant is again submitted to another test-bench in a bath of saline solution at +40 ^{o}C. Then it is coated with a biocompatible silicone. To ensure a uniform coating, the microstimulator is placed in a mould where liquid silicone is injected and then is heated at 65 ^{o}C for 6 hours. Figure 3 shows a photograph of the resulting implant.

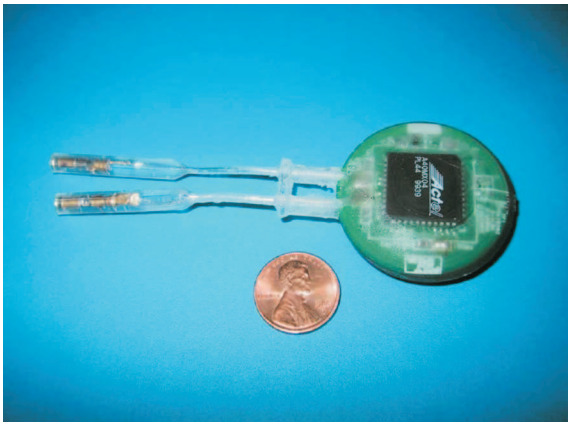

Figure 3. Photograph of the implantable stimulator.

2.3. The cuff electrodes

The proposed design is a split-cylinder cuff electrode with shape memory alloy (SMA) armature embedded inside the cuff wall (Figure 4). The electrode cuff is molded in a biocompatible silicone, and two electrode contacts are cut from a platinum foil of 25 μm thickness. The leads of electrodes are multi-strands stainless steel wires coated with Teflon. For the SMA armature, medical grade NiTi (50.7% Nickel, 49.3% Titanium) wires of 0.1 mm of diameter are used. This structure provides new mechanical properties to the whole electrode's cuff. It enables the electrode self-closing around the nerve during installation and its maintenance in place without requiring additional fixation means such as sutures. SMA electrodes are easy to wrap and to manipulate when kept at low temperature, but they automatically recover their original shape (cylindrical around the nerve) when heated at body temperature [36].

By applying selective electrical stimulation, the somatic fibers driving the sphincter can be stimulated without causing simultaneous contraction of the bladder; a high-amplitude, low frequency train provokes detrusor muscle contraction while a low-amplitude, high-frequency train inhibits the external urethral sphincter contraction to allow micturition. This type of blockage maintains the nerves and their motor ends in a refractory state to impede the external sphincter from contracting. This stimulation method allows bladder evacuation with a low-pressure voiding and low residual urine. It has been shown that the most

efficient blockage frequency was around 600 Hz [27]. Typical bladder (Pves) and urethra (Pura) pressures as well as electromyography (EMG) activity responses are shown in Figures 5a and 5b.

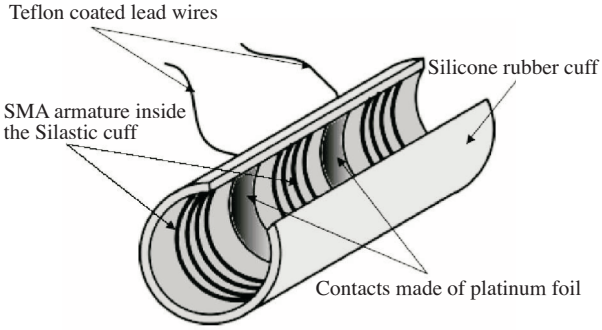

Figure 4. The shape memory alloy-based nerve cuff electrode.

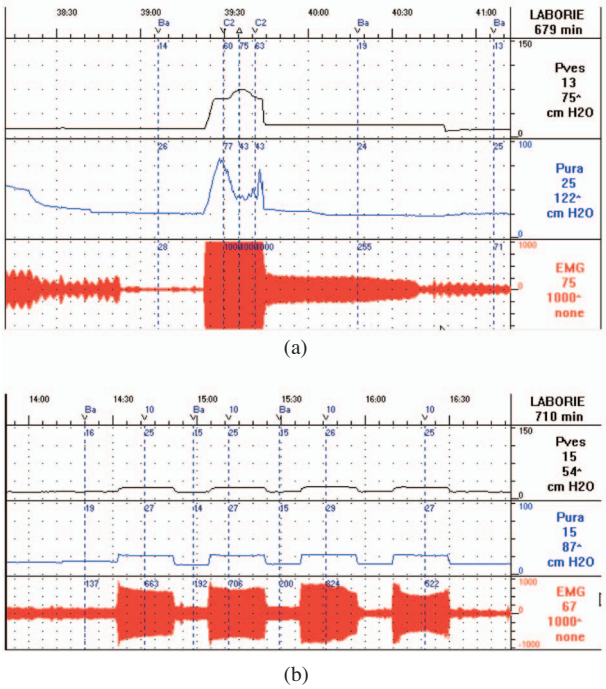

Figure 5. Typical CMG during: (a) Selective stimulation, (b) Permanent stimulation.

The dual stimulation technique has been validated by off-the-shelf electronic components built in a double face printed circuit board, but it does not allow monitoring of the electrode-tissues contact. Obtained results motivated us to build a fully integrated microstimulator on chip, together with the required measurement interface.

3. Fully Integrated On Chip Stimulator and Monitor

3.1. Overview of the device

The new fully integrated stimulator and monitor (ISAM) delivers both stimulation types: Selective and Permanent. It also allows generating flexible stimulation patterns, and characterizing the impedance of the

electrodes-nerve contact. Similar to the previous designed stimulator, the operation mode of the implant is selected by the external controller and the corresponding parameters are transmitted wirelessly. The Selective stimulation mode and the measurement technique require much more energy than continuous stimulation. Thus they are powered by the external controller. Waveforms generated for all modes are fully reprogrammable by the means of various parameters (amplitude, frequency, pulse widths, on and off times).

Selective stimulation requires biphasic and symmetric pulses of equal amplitudes and widths. However, asymmetric charge-balanced waveforms may allow better control of electrochemical reactions at the electrodes and may suppress undesired physiological reactions such as increase of excitation thresholds [37]. In order to increase such stimulation efficiency, we propose a new stimuli generator based on an arbitrary stimulation pattern to program and generate the stimulation waveforms (Figure 6). All stimulation parameters are prepared by the external controller, transmitted to the implant and then stored in an embedded Random Access Memory (RAM).

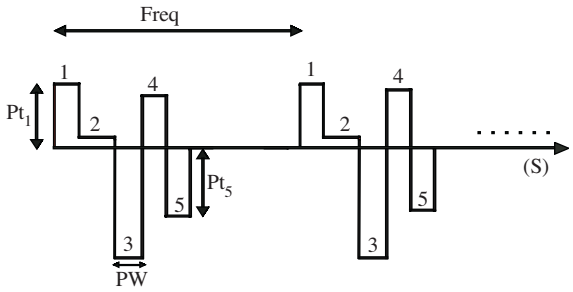

Figure 6. Flexible selective stimulation waveform. Parameters are described in Table 2.

Dysfunctions of the implant reduce the safety and reliability of the stimulation and lead to shorten the device lifetime. An efficient and safe method to monitor the different parts of the implant and to measure the impedance of the electrode-nerve interface (ENI) is required. A monitoring module has been integrated in the new microstimulator to detect any failure occurring at the ENI. This measurement technique requires to inject a current in the nerve and to measure the corresponding voltage developed between the two electrode contacts. This voltage is first converted into a frequency by a Voltage Controlled Oscillator (VCO) and the resulting frequency is converted to digital values and finally sent serially to the external controller using Load Shift Keying (LSK) technique. This measurement module can be set in idle mode when not used to reduce the power consumption [38].

3.2. Communication protocol

Wireless transmission of data from the external controller to the implant requires a robust communication protocol to avoid errors. The proposed protocol consists of transmitting frames of different lengths as follows: first a header (01111110) allows the Data Recovery (DR) module to detect the start command of every new frame, and then the selection command is transmitted to activate the specified stimulation channel. The command for the operation mode follows, and the stimulation parameters are sent with the CRC code calculated on all the bits of the frame except the header and the channel number.

3.3. Architecture of the implantable device

The integrated on chip ISAM is based on an expandable multichannel modular architecture (see Figure 7). This device includes four main blocks. The front-end block of the implant includes a Manchester decoder and a DR module. The Manchester decoder retrieves the binary digits received from the external controller. It recovers a 300 KHz global clock and transfers all remaining data to the DR module. The DR module detects the 8-bit header, identifies the channel and decodes the stimulation mode. This is followed by the transfer of the stimulation parameters to the specified channel. After activation of the channel, the front-end block remains in a wait state until the system is re-initialized.

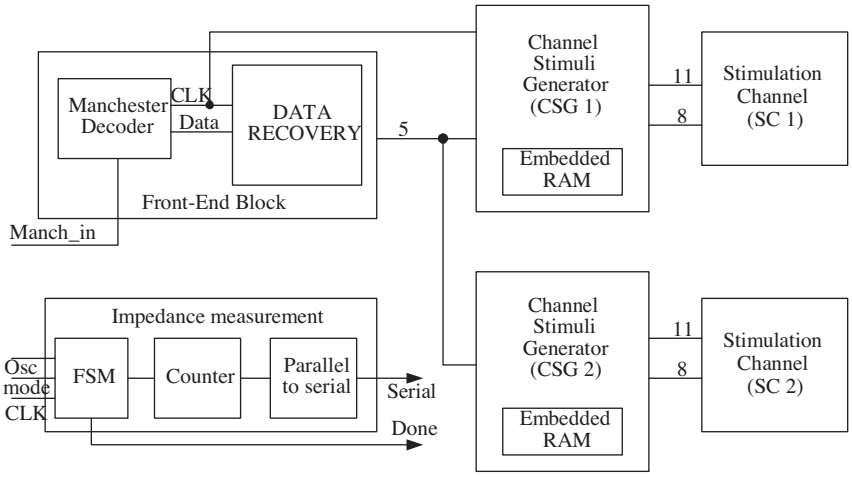

Figure 7. Block diagram of the integrated microstimulator.

One of the characteristics of the communication protocol is to introduce stuffing zeros into the frame to avoid six consecutive 1's other than those of the header. Thus, the system is stopped during a clock cycle following the detection of five consecutive 1's, but only after the detection of a valid header. A CRC block, based on a polynomial division technique, is used to guarantee the integrity of received parameters. If the rest of the polynomial division is equal to zero, the CRC is valid.

After the recovery of the stimulation parameters by the front-end block, the Channel Stimuli Generator (CSG) produces the signals which control the generation of the programmed stimuli. Our system integrates two Stimulation Channels (SC), which are connected to the front-end block by the same data bus and are activated selectively by a signal coming from the DR block. Each stimulation channel includes a data register to store the stimulation mode, the activation signal of the channel coming from the front-end block, and the number of points if flexible selective stimulation is used.

The RAM block in each CSG is divided into 32 eight-bit addresses to store all the stimulation parameters, and up to 30 points for the flexible stimulation. The writing operations are controlled by the front-end block while the reading operations depend exclusively on a Finite State Machine (FSM) which controls the CSG. After detecting the activation signal from the front-end block, the FSM gets the stimulation parameters from the RAM. The outputs are fed to a demultiplexer used as register and which sends the adequate stimulation parameters to the waveform generator block.

Following detection of the stimulation mode and storage of the parameters in the specified RAM, the Stimuli Waveform Generator (SWG) starts delivering the stimuli. This SWG, shown in Figure 8, includes several building blocks such as frequency dividers, counters, comparators and a FSM. The stimulation parameters are summarized in Table 1. The selective stimulation is composed of two combined bipolar

waveforms. A High Frequency pulse Width (HFW) and High Frequency Amplitude (HFA) characterize the first waveform. Each time the Low Frequency Period (LFP) is attained, a pulse is produced with a Low Frequency Amplitude (LFA) and Low Frequency Width (LFW). The LFP and High Frequency Period (HFP) are generated by counters. For the permanent stimulation, bipolar low frequency waveform is produced during the on time (Ton). A counter and a comparator are used for the frequency (FREQ) and the Pulse Width (PW). The stimuli amplitude is directly fed to the SG and during the off-time (Toff), the module is disabled.

Table 1. Stimulation parameters of the integrated microstimulator.

Type	Command	Parameters (bits)					
Permanent	10101010	LFP 8	LFW 8	AMP 8	Ton 4		Toff 4
Impedance measure	11001100	Freq 8	PW 8	AMP 8	Teval 4		Tsetup 4
Selective	00001110	LFP 8	HFP 8	LFW 8	HFW 8	LFA 8	HFA 8
Flexible	01110000	Nb_pt 4	Freq 8	PW 8	Pt_1 8	Pt_2 8	Pt_x 8

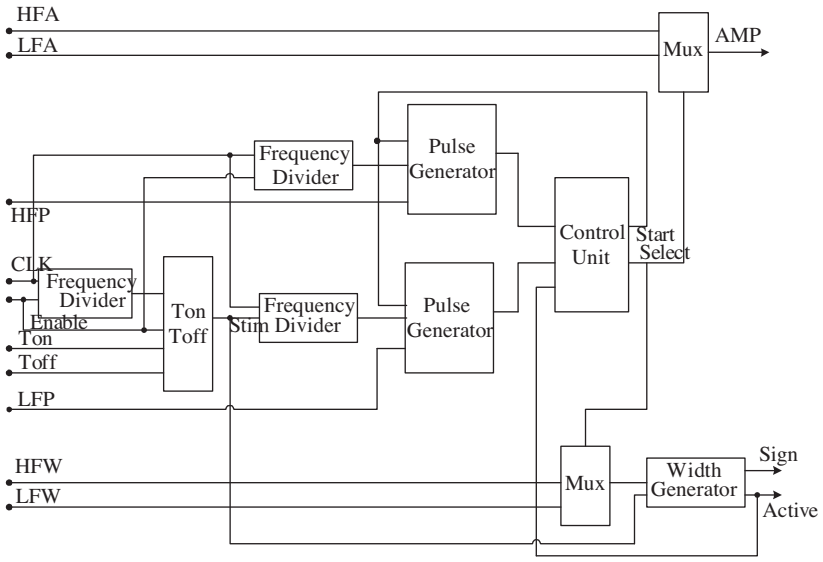

Figure 8. Block diagram of the Stimuli Waveform Generator.

For the flexible selective stimulation, a block is dedicated to the creation of the stimulation pattern. This module receives the eight-bit amplitude, the pulse duration, the stimulation pattern frequency and an activation signal, which indicates the beginning of stimulation.

When the desired pulse duration is reached, the generation of a new stimulation point is started. When all the points are produced, the block enters a waiting mode. The cycle restarts once the frequency pattern is reached.

A *receiving* signal allows the detection of RF power presence. The Selective stimulation and the impedance measurement modes are activated only with the presence of RF power. Thus, in these modes, the state of this signal is checked every clock cycle and the system is automatically re-initialized and awaits the stimulation frame if this signal is activated.

3.4. Output stage and measurement module

The output stage of each stimulation channel produces a constant current stimulus depending on the data received from the CSG (Figure 9). This output stage features an 8-bit programmable DAC and a wide swing, high output impedance voltage controlled current source. The DAC is based on identical PMOS transistors mounted in series or parallel to deliver to a current mirror the programmed current value; a stimulation switching circuit (SSC) dedicated to generate the bipolar stimuli via two pairs of NMOS and PMOS transistors forming an H structure; a calibration switching circuit (CSC) providing reliable stimulation by the reduction of mismatch errors related to the fabrication process, as well as those related to temperature variations.

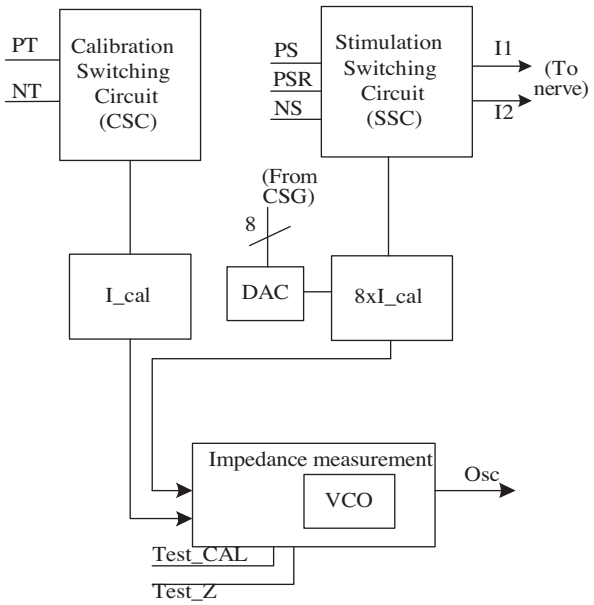

Figure 9. Block diagram of the analog Stimulation Channel.

The impedance measurement module is built around a VCO, a FSM, a counter and a parallel to serial converter. The VCO produces a signal frequency proportional to the monitored voltage from the ENI, and few cycles of this signal are counted during a period of times fixed by the FSM. The measurement process first calibrates the VCO during a setup time (T_setup). Next the impedance evaluation period (T_eval) starts where low frequency current stimuli are used, then a voltage is measured at the nerve contact. This voltage controls the VCO and the resulting signal is sent back to the front-end block where an impedance digital value is extracted. This digital value is then serialized and sent to the external controller.

4. Experimental Results

Characterization of the implant consisted of checking the precision of the real stimulation parameters compared to the programmed ones, but it also implied to check the reliability of the implant during commutation between the different operation modes. This guarantees the good management of power to allow a long lifetime of the battery. Tables 2 and 3 present the performances of the implant in Selective and Permanent stimulation modes respectively.

Table 2. Implant performances during selective stimulation.

	Low Frequency			High Frequency		
Parameter	Amplitude	Frequency	Pulse Width	Amplitude	Frequency	Pulse Width
Range	0 – 1.95 mA	18.3 – 1970 Hz	0 – 210 μs	0 – 1.95 mA	295 – 1970 Hz	0 – 210 μs
Resolution	9 μA	$<$ 80 mHz	3.7 μs	9 μA	1 Hz	3.7 μs
Precision	7.7%	0.6%	1.1%	6.2%	0.6%	3.0%

Table 3. Implant performances during permanent stimulation.

Parameter	Amplitude	Frequency	Pulse Pulse	On Time	Off Time
Range	0 – 0.95 mA	5.2 – 360 Hz	0 – 2120 μs	0.6 – 365 s	0.5 – 20 s
Resolution	9 μA	1 Hz	8.7 μs	4 s	$<$ 1 s
Precision	9%	1%	4.6%	1%	2%

Figure 10 depicts the post layout simulated results of the VCO during the evaluation of 4 different impedance values. In Figure 11, the output current and corresponding voltage of the digital to analog converter (DAC) used for the current source are presented. This figure depicts all possible 8-bit digital values (D7-0). A maximum stimulation current value of 2.25 mA is obtained. The constant current is applied to the output stage after being converted into a biphasic stimulus using the output stage switches. Figure 12 shows the reference current, the current at the output of the stimulation stage and the output voltage at the resistive load terminals.

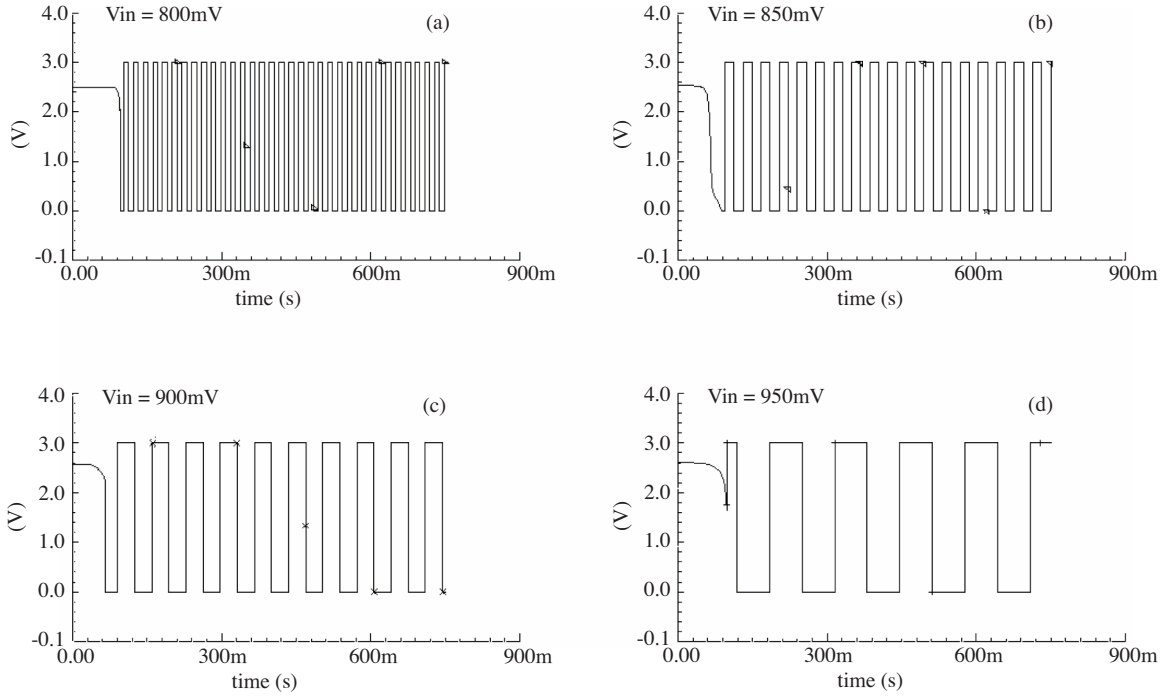

Figure 10. Simulation results of the impedance measurement's VCO : (a) Vin= 800 mV, (b) Vin= 850 mV, (c) Vin= 900 mV, (d) Vin=950 mV.

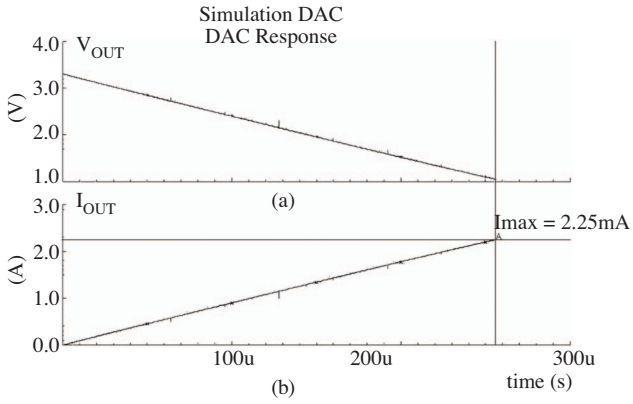

Figure 11. Simulation results of the DAC: (a) Output Voltage, (b) Output current after amplification.

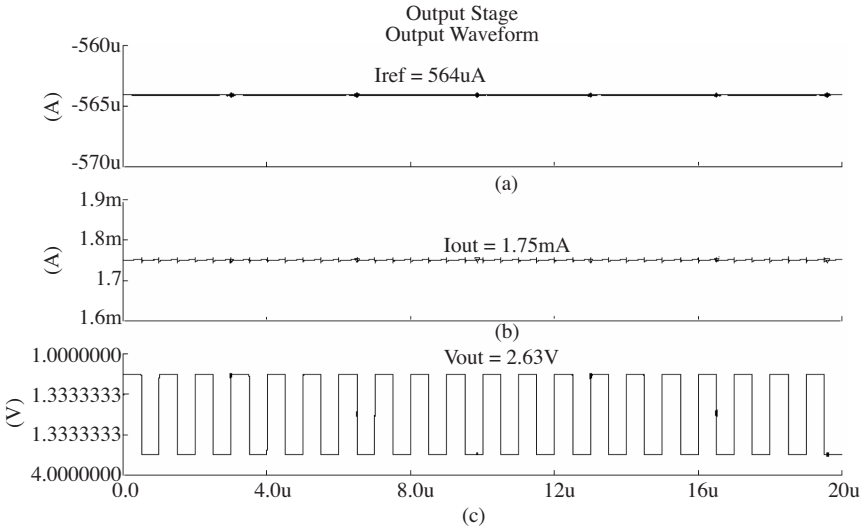

Figure 12. Simulation results of the output stage: (a) Reference current from DAC, (b) Output current after amplification, (c) Waveform of the applied stimulation voltage.

Figure 13 shows the fabricated chip in a CMOS 0.18 um process, which occupies 4 mm^2. The experimental results of the fabricated chip demonstrates its functionality, as shown in Figure 14. The microstimulator generates a wide range of stimuli with variable parameters. The high frequency waveforms range from 294 Hz to 75 KHz, while the low frequency ranges from 4.6 Hz to 1.2 KHz. The VCO frequency goes from 50 Hz to 300 KHz allowing the detection of short and open circuits. The pulse durations vary from 3 μs to 853 μs. Also, up to 32 8-bit values can be stored in the RAM, allowing the generation of flexible stimulation waveforms.

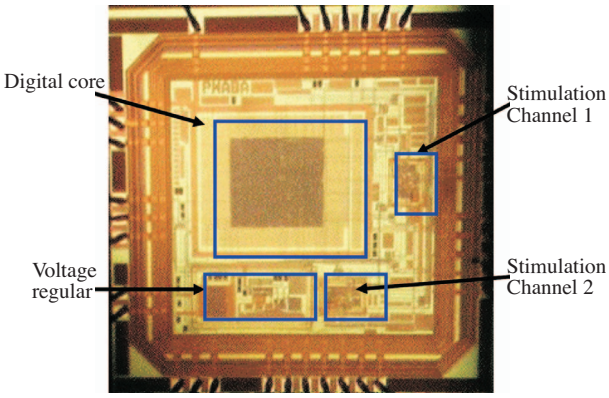

Figure 13. Chip microphotography of the integrated microstimulator.

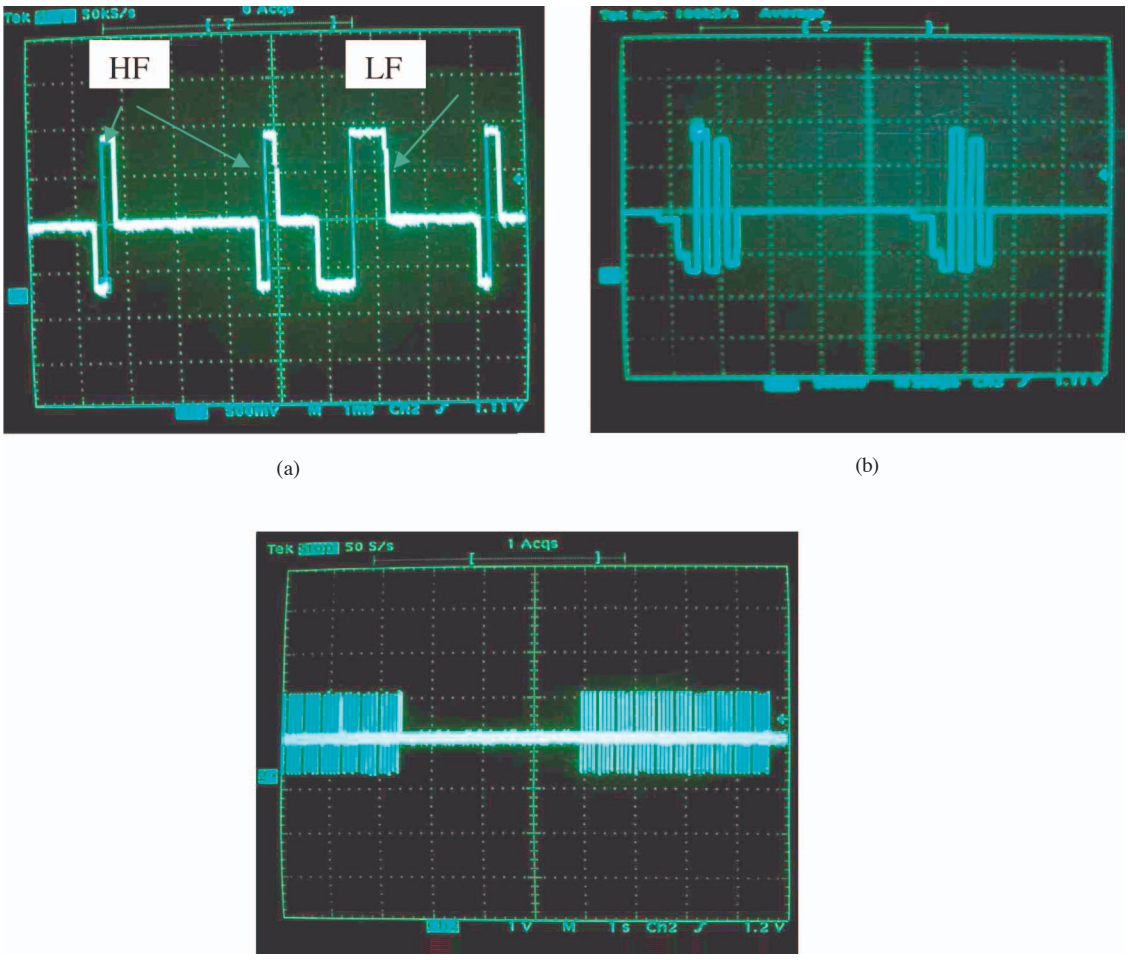

Figure 14. Measurement results from the integrated microstimulator (a) Selective high and low frequency stimulation, (b) Stimulation with arbitrary pattern, (c) Permanent stimulation with train of pulses.

4.1. Conclusion

We described in this paper functional stimulation systems dedicated to the rehabilitation of the urinary functions. An implant and a new integrated stimulator were described. We presented the experimental results

of the implantable stimulator. The reliability and the real lifetime of the battery of the implant were verified in the long run during in-vivo tests. These results were presented in previous works [35]. Experimental results of the stimulation strategies and dedicated implantable stimulators confirmed the reliability of the selective high frequency blockage stimulation for long term bladder voiding in paraplegics. Also, the neuromodulation technique, based on permanent low frequency and low amplitude current stimulation, appeared to be a promising solution to cure the neurogenic detrusor over activity with no drawback. On the other hand, the design and implementation of the integrated microstimulator, by combining multiple stimulation techniques with a proven efficiency, address at the same time the requirements that most stimulation systems lack such as flexibility, reliability and reprogrammability. This microstimulator needs to be validated in a real in-vivo environment to validate the results obtained with the previous versions and to confirm that the proposed techniques constitutes an adequate solution for a complete rehabilitation of the urinary bladder functions. More tests need to be performed regarding power consumption and management. Adequate packaging solutions will also be a priority.

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