

Implantable neurostimulator for bladder rehabilitation in paraplegics.

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Abstract

Following a spinal cord-injury, paraplegics suffer from bladder dysfunctions due to partial or complete rupture of sensitive and motor innervations. Stimulation of the sacral nerve root seems to be one of the most promising techniques for bladder rehabilitation as it does not require any neurotomy or rhizotomy. A new implantable neurostimulator system is reported. The implant prototype offers Selective Stimulation to recover voluntary control of the micturition reflex and Permanent Stimulation to reduce, or eliminate the undesirable hyperreflexia of the detrusor. This paper gives an overview of the neurostimulator design evolution through a review of the main architectures that led to this new system.

1. INTRODUCTION

The spinal cord is the unique neural pathway between the brain and all physiological and anatomical systems. A normal individual feels the need to urinate as soon as the bladder is full. The brain commands a voluntary micturition by contracting the bladder muscle, the detrusor, and relaxing the sphincter [1, 2]. In addition, the brain inhibits autonomously any reflex contractions of the detrusor that may occur during the filling process. Following a spinal cord-injury, paraplegics suffer from bladder dysfunctions due to partial or complete rupture of sensitive and motor innervations [3]. Many attempts have been made to recover voluntary control of the micturition reflex by means of electrical stimulation at different sites of the urinary system [4]. Selective Stimulation of the sacral nerve root seems to be one of the most promising techniques to induce voiding without neurotomy or rhizotomy [5].

This paper reports a new urinary implant prototype named Mixture Neurostimulator (MNS) for the urinary system rehabilitation by means of electrical stimulation of sacral nerves.

It has been designed by the Urostim team within the Polystim lab in partnership with Victhom Human Bionics. In order to undertake a new phase of animal experiments, previous designs have been reviewed, modified and improved taking into account all past experiments.

2. SYSTEM DESCRIPTION

The electronic device, as shown in Fig.1, consists of a small implantable neurostimulator and an external controller to communicate instructions and stimulation parameters to the implant. In addition, the controller sends energy via a wireless inductive link to provide enough power for high current stimulations.

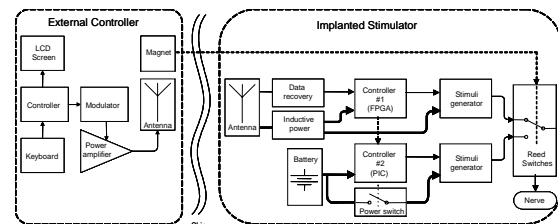


Fig. 1 - Stimulation system block diagram

The neurostimulator combines two types of functions. The first one, called Selective Stimulation and illustrated in Fig.2, aims for voluntary voiding. It is a bi-frequency, high amplitude stimulation that is launched on a time limited basis by the external controller. This stimulation uses the inductive power and will stop as soon as the controller is removed.

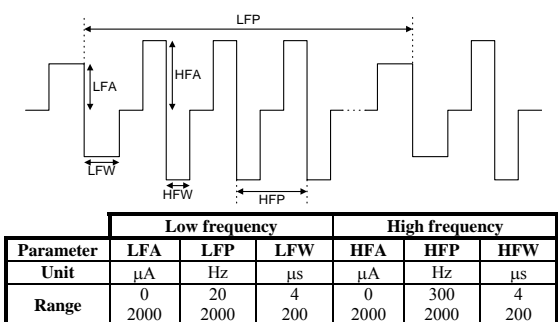
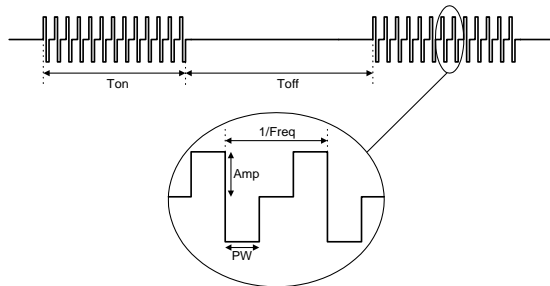


Fig. 2 - Selective Stimulation waveform

The second one, called Permanent Stimulation and illustrated in Fig.3, aims for hyperreflexia suppression. It is a low frequency, low amplitude pulse train that, once launched, runs on a continuous time basis and in an autonomous mode. This stimulation uses a long life embedded battery and may be stopped at anytime by the controller.



Parameter	Amp	Freq	PW	Ton	Toff
Unit	μA	Hz	μs	sec	sec
Range	0 1000	5 100	10 300	1 60	1 60

Fig. 3 - Permanent Stimulation waveform

The Selective and Permanent Neurostimulator (SPN) was patented by the Polystim neurotechnologies laboratory in 2002 [6,8]. Three years of chronic animal experiments demonstrated the efficiency of micturition by means of selective stimulation [6,7]. The MNS is an advanced version of the SPN and offers the choice of running the Permanent Stimulation either from the embedded battery or from the inductive power. The external controller has been improved as well to provide ease of handling and complete flexibility over the stimulation parameters.

3. ARCHITECTURE REVIEW

This section gives an overview of the neurostimulator design evolution through a review of the main architectures [9] that led to the SPN and MNS systems.

The first architecture (Fig.4) uses an FPGA (Field Programmable Gate Array) as the unique controller for both Selective and Permanent Stimulations. With a multiplexer, the FPGA and the stimuli generator are powered either from the inductive power or the embedded battery power. This is required for the Permanent Stimulation that must run autonomously when the inductive power is removed. It is, however, difficult to guaranty a continuous transition of power, therefore, the risk of losing power and memorised data makes this solution inconvenient.

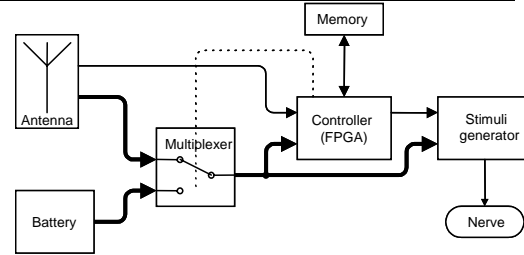


Fig. 4 - Architecture I

The second architecture (Fig.5) solves this power discontinuity risk by powering the FPGA permanently by the embedded battery. Power multiplexing is applied to the stimuli generator only; that way Permanent Stimulation could run on the battery power. Unfortunately, the energetic performance of the (less recent technology) FPGA was not suitable for this neurostimulator since low power consumption is of crucial importance for the battery life.

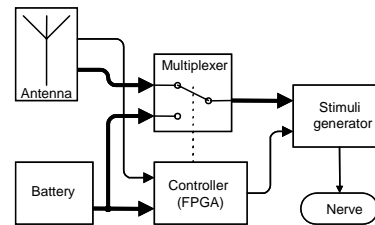


Fig. 5 - Architecture II

In the third architecture (Fig.6), the FPGA is replaced by a microcontroller (PIC) that has the advantage of offering low power consumption modes as well as a non-volatile memory. However, to achieve the same performance as the FPGA in selective stimulation, the clock frequency of the PIC has to be increased. Thus, the low power advantage will not be as expected. In addition, decoding data and extracting the clock from the signal emitted by the external controller is complex to implement with the PIC.

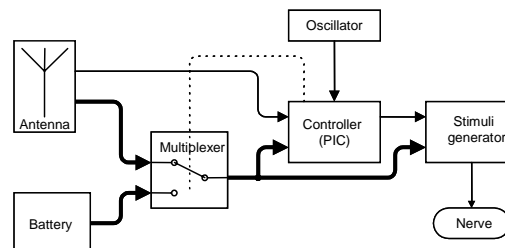


Fig. 6 - Architecture III

The final architecture of the SPN (Fig.7) combines both types of controllers to benefit from the advantages of each one. The FPGA is used for the Selective Stimulation with the inductive power and the PIC is used for the

Permanent Stimulation with the battery power. Control signals and power multiplexing is applied to the stimuli generator as it is shared by both controllers.

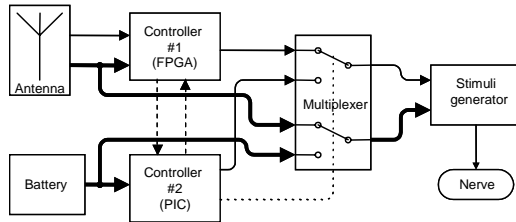


Fig. 7 - Architecture IV

One of the main concerns discovered throughout chronic animal experiments has been the complete interruption of all neurostimulator functions when the battery runs down. It was desirable that the selective stimulation stays functional. This is due to the fact that the PIC has the control of the power multiplexer of the stimuli generator. Once the battery runs down, the stimuli generator is no longer powered.

Moreover, previous animal experiments proved that the impedance of the cuff-electrode/nerve interface may be as high as 2KΩ. Hence, the stimuli generator, and specifically the current source, needs a voltage supply of 5V at least to provide a selective stimulation current as high as 2mA.

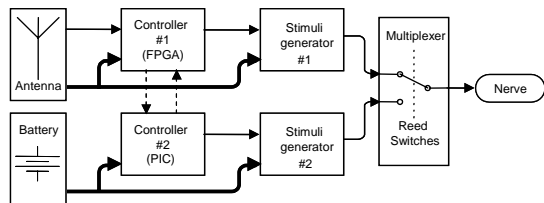


Fig. 8 - Architecture V

The chosen approach (Fig.8) to solve these issues is to use separate stimuli generators for each controller. This way, the FPGA stimuli generator may be powered at 5V (or more depending on the available inductive power) whereas the PIC stimuli generator will stay battery powered at 3.3V. Selection of one of them is achieved using Single Pole Double Throw (SPDT) Reed Switches mounted as a multiplexer. The Reed Switches are activated externally using a magnet. The MNS is based on this new architecture and made with commercially available electronic devices on a printed circuit board (PCB). Even though it requires more components, the small scale factor of recent technologies has made it possible.

5. CONCLUSION

A new implantable neurostimulator prototype has been elaborated with an architecture review of previous designs. At the time it was written, several prototypes were being assembled and tested before starting in-vivo animal experiments.

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