Design of an implantable multichannel neurostimulator for restoring impaired gastrointestinal motility

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Abstract

Neural gastrointestinal electrical stimulation (NGES) has been suggested as an avenue for treating a variety of gastrointestinal motility disorders. In this paper, design and development of an implantable microcontroller-based stimulator is discussed. Particular attention is paid to design versatility, minimization of power consumption and size, as well as wireless control. The stimulator utilizes voltage-based functional electrical stimulation to restore impaired motility in the colon and the stomach. Stimulation parameters, such as voltage amplitude, duty cycle, time length and the overlap between successive stimulating channels can be changed after implantation via a wireless link. The stimulator modules have been completely designed and tested. Following the integration of these modules, the implantable stimulator will be tested in animal studies.

1 Introduction

A variety of gastrointestinal (GI) disorders, including gastroparesis, colonic pseudo-obstruction and chronic constipation, are related to impaired GI motility and transport. These disorders are chronic and affect the lifestyle of millions of sufferers [1]. In addition, control of gastrointestinal motility might be extremely beneficial in treating morbid obesity [2], and for shortening postoperative ileus. Various technological methods have been implemented in order to control, facilitate or recreate GI motility. Sequential neural electrical stimulation is considered the most promising technique for restoring impaired GI motility under microprocessor control [3]. Recently, Lin et al. reported on the successful design and chronic animal testing of a portable GI stimulator [4]. Immediate colonic emptying due to functional electrical stimulation was observed in chronic constipation models of large dogs.

The optimal stimulating parameters required for long-term colonic stimulation derived from these chronic animal tests [4] are listed in Table 1.

Parameter	Optimal Value
Stimulation pattern	sequential overlapping
Amplitude [V]	6
Frequency [Hz]	50
Duty cycle [%]	100
Duration per channel [s]	6
Phase lag between channels [s]	3
Pause between sessions [s]	60

Table 1: *Chronic colonic stimulation requirements*

Figure 1 depicts the electrode placements used in colonic and gastric stimulation. Four subserosally-implanted electrode sets are positioned longitudinally (in the case of colonic stimulation) or circumferentially (for gastric stimulation) along the axes of the organs.

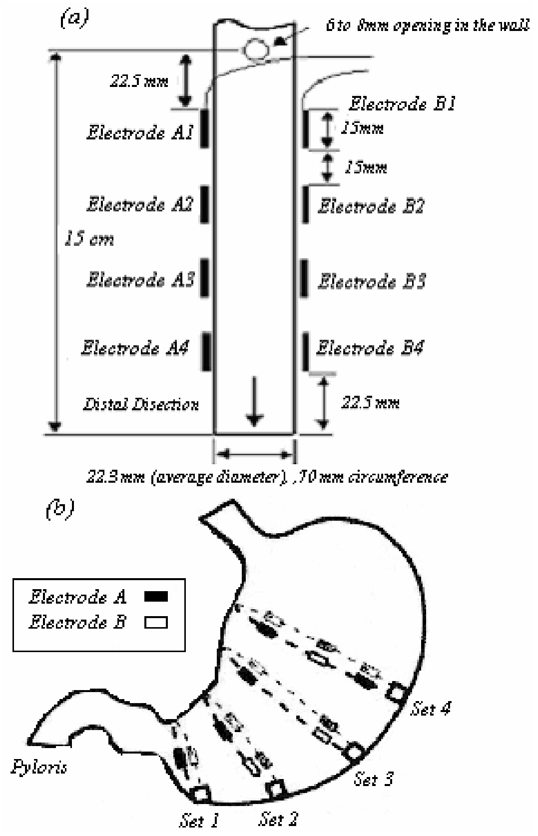

Figure 1: *Electrode placement for colonic (a) and gastric (b) neurostimulation.*

2 Methods

The stimulator is built on a miniature printed circuit board (PCB) and is powered by a 3V battery. The device is turned on and off by an abdominal electronic belt using a magnetic reed switch. Figure 2 shows the block diagram of the system.

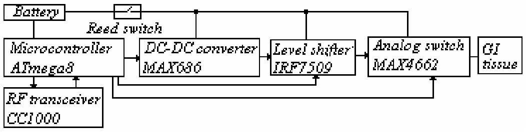

Figure 2: *Block diagram of the implantable system*

2.1 Timing and Control

Biphasic stimulation must be utilized to ensure that the net ion flow between the electrodes of each channel is zero, thus avoiding tissue damage or electrode corrosion [5, 6]. This can be achieved by applying two monopolar waveforms of opposite phases to a set of electrodes, for example A1 and B1 in Fig.1. The microcontroller Atmega8L (Atmel, San Jose, CA) generates two digital pulse trains with the same frequency and duty cycle but in opposite phases. The microcontroller controls the stimulating voltage levels, the overlap between successive channels, and the wireless communication as well.

2.2 Power Source and DC-DC Conversion

Gastric and colonic electrical stimulation require high voltage and current levels (up to 10V and 10mA per channel) to be delivered to the tissue at high duty cycles [7]. Since most implantable batteries deliver output voltages below 5V, a step-up DC-DC converter must be used to generate the voltage levels required for stimulation.

A switching regulator MAX686 (Maxim, Sunnyvale, CA) generates a DC output voltage between 4V and 10V (V_{stim}) from input voltages as low as 0.8V. This integrated circuit has a built-in Digital-to-Analog Converter (DAC). The microcontroller changes the output voltage (V_{stim}) by modifying the input voltage of the DAC. The output voltage resolution of the DC-DC converter is 100mV. WG9424 (Wilson Greatbatch, Clarence, NY) is a 3V, 1.323A.hr implantable battery used as the source of power to the DC-DC converter. A 3V, 1000mA.h lithium coin battery BR2477 (Panasonic, Secaucus, NJ) provides power to the digital components in the system.

2.3 Level Shifting and Output Distribution

Microcontroller-generated digital waveforms are level-shifted by power MOSFETs IRF7509 (IRF, El Segundo, CA) to the appropriate stimulating amplitude (V_{stim}). A similar approach has been suggested before [6]. Analog switches MAX4662 (Maxim) are utilized to distribute the stimulating waveforms produced by the level-shifters to the four electrode sets. The stimulation duration T during which a channel is active and the overlap between successive channels are determined by the microcontroller. Analog switches implement the desired overlap between successive channels and minimize the crosstalk between channels by electrically separating them from each other. Figure 3 shows the schematic diagram of the level shifting and the output distribution stage.

2.4 Wireless Control and Reprogrammability

The stimulation parameters can be reprogrammed after implantation via a wireless link provided by an implanted transceiver CC1000 (Chipcon, Oslo, Norway) and an external transceiver, located in the abdominal electronic belt, which is connectable to a PC. The implanted transceiver is used to transmit a signal confirming the end of each stimulation session as well.

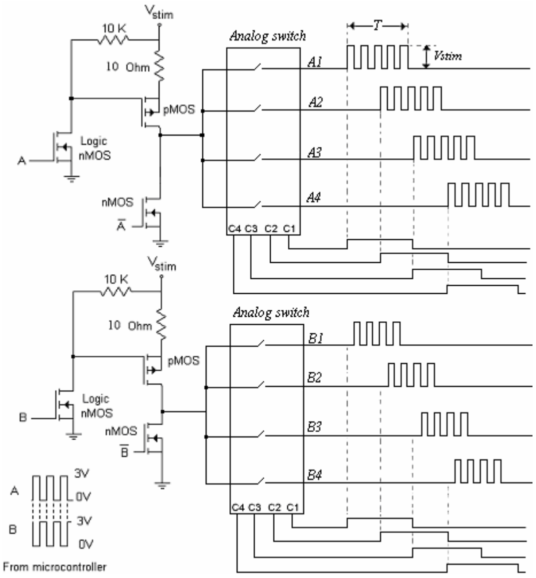

Figure 3: *Level shifter and output distribution stage.*

A and B are digital pulse trains of opposite phases, generated by the microcontroller. C1-C4 are produced by the microcontroller and control the different channels of the analog switches. Output signals A1-B1 to A4-B4 represent the analog stimulating voltages sent to the stimulating electrodes. T is the stimulation duration for each channel per session.

3 Results

All system modules have been developed and laboratory-tested. Loads ranging from 200Ω to 1kΩ were used to simulate the tissue. Multiple sessions with adjustable pause periods were performed and the stimulation parameters were easily modifiable from the software. The operation of the wireless transceiver has been successfully tested as well.

Laboratory testing shows that the device is capable of withstanding the equivalent of at least 1000 chronic colonic stimulation sessions, indicating a minimum device longevity of 1.3 years if the stimulator is used twice daily.

Device dimensions before packaging are 5.8 × 2.8 × 1.2 cm, making it easily implantable in large animals and humans.

4 Conclusion

An implantable multi-channel functional electrical neurostimulator for the GI tract has been designed and developed. Following the integration of the system modules and encasing in a biocompatible package, the stimulator will be used in animal studies, paving the way for future clinical trials of NGES.

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