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Nerve Stimulator with High Reliability for Assistance in Regional Anesthesia

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1 Introduction

Plexus blockade, or regional anesthesia, is the technique used in minor surgery to eliminate pain, such as in surgery of the hand, arm, elbows, feet, knees, legs and so on. Its preference over general anesthesia is due to a shorter stay in recovery room, minimized systemic adverse effects, decreased incidence of nausea and vomiting and eliminated need for intubation (Cangiani et al, 2006).

In the last decades, the use of nerve stimulators for identifying plexus in assisting regional anesthesia has been a technique of great importance for the identification of nerves, consolidating highly beneficial to the patient, because (Bollini et al, 2006, Regatieri, 2002):

- Reduces risk of injury to the nerve;
- Allows a precise identification of the nerve plexus;
- Possible reduction in the dose of anesthetic blockade for providing best quality;
- Reduction of collateral effects from excess anesthetic.

These benefits are possible due to the ability of the nerve stimulator to estimate the distance between the needle tip and the nerve. Therefore, one can identify the best place to infiltrate the local anesthetic solution (Dalrymple et al, 2006).

1.2 Use of the Nerve Stimulator to Aid Plexus Location

Nerve stimulation occurs only when current intensity is applied by the needle electrode and the tip is sufficiently close the nerve. Consequently, a muscle contraction becomes evident (Andrés et al, 2001).

The procedure for locating plexus and the correct placement of the needle by use of the nerve stimulator begins with a standard routine for regional anesthesia, followed by adjustment of the initial current stimulator for 1 to 2 mA and the duration of the stimulus for 100us, with a frequency of 2 Hz. The needle is inserted until a contraction or muscle spasm is identified visually. After identification of the contraction, current amplitude is decreased until the contraction disappears. Introduction of the needle continues until a new contraction appears. This procedure is repeated until the applied current is 0.3 mA and a muscle contraction is visible. At this point, the needle tip is from 1 to 2 mm distance from motor nerve and the injection of local anesthetic solution should provide a satisfactory blockade (Sardesai et al, 2009).

1.2 Features Standard Equipment

Much of the equipment that is available on the market designed to aid the regional anesthetic procedures does not have the minimum requirements recommended for a good neurostimulator (Hadzic et al, 2003; Jochum et al, 2006). This shortcoming in the equipment can increase the risk to the patient, since the minimum requirements ensure its use in the identification process of the nerve plexus with the precision necessary to achieve a satisfactory blockade.

Constant current: The ability of the neurostimulator to provide constant current is of critical importance for achieving plexus blockade. Tissue impedance may vary between different individuals. These variations may be caused by diseases like diabetes or renal problems, and also higher impedance obstacles such as bones. Thus, the equipment must be able to provide a constant current to a load variation between 1kΩ and 10kΩ (Barthram, 1997; Jochum et al, 2006).

Duration of pulses: The duration of the stimuli should correspond to chronaxy of motor neurons to ensure that Aα sensory neurons are not stimulated and hence muscle contraction occurs in the absence of pain. Thus, the stimulator should have the following options for stimulus duration: 50µs, 100µs, and 200µs (Barthram, 1997; Jochum et al, 2006).

Accuracy: Accurate control of stimulation parameters is mandatory for the correct placement of the needle. This means that the current delivered by the stimulator must be equal to the expected current, the morphology of the pulses must be rectangular, the pulse width variation should be less than five percent of the expected value, and rise and fall times should be less than 3µs (Hadizic et al, 2003; Jochum et al, 2006).

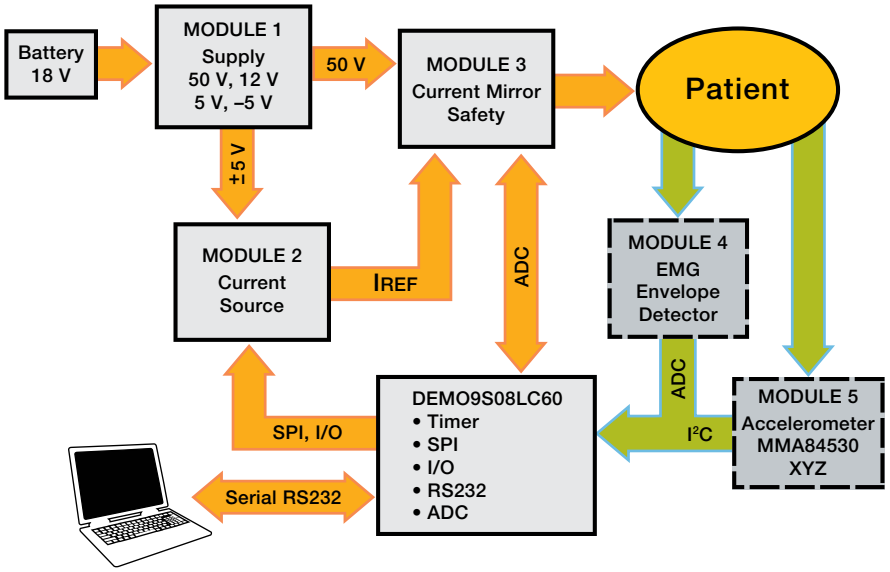
Frequency Stimulation: The frequency of stimulation allows control of the speed at which the nerve is located. The frequency should be selected to 1 Hz or 2 Hz, the most usual frequency of 2 Hz (Barthram, 1997; Jochum et al, 2006).

Functionality: The stimulator must provide maximum safety for the patient and provide the user with pertinent information about the operation of the system, such as visual and audible warning at the time of stimulation; battery information; high impedance warning; and indication of selected parameters (Regatieri, 2002; Jochum et al, 2006).

2 Method

The stimulator developed in this project can be summarized by the block diagram shown in Figure 1. The system is organized into modules to facilitate identification of possible sources of noise and failures. As central control processes, we opted to use the Freescale development board DEMO9S08LC60. This board is responsible for the communication interface between the stimulator and the PC (that is isolated from

Figure 1: Block Diagram of Operation of the Stimulator



the power grid, powered by battery), control of stimulation parameters and graphical user interface via an LCD display. Modules 4 and 5 will be added in the future as a feedback mechanism to the neurostimulator, allowing the current amplitude settings to be performed automatically. This control will give more autonomy to the anesthesiologist.

2.1 Module 1: Supply

This equipment has to be portable for convenience. Therefore, its power supply is derived from two 9V batteries in series, providing 18V. Whereas the maximum load impedance does not exceed 10kΩ, and stimulus current is never beyond 5 mA, the voltage compensation will be a maximum of 50V. We decided to use a charge pump converter, Dickson type.

The output voltage of this circuit can be calculated by the following formula:

(1)

$$V_{out} = (N+1)V_{DD} - N\frac{I_L}{C}$$

Where N is the number of stages, VDD is the supply voltage, IL is the current output to the load, C capacitance and Vout is the output voltage.

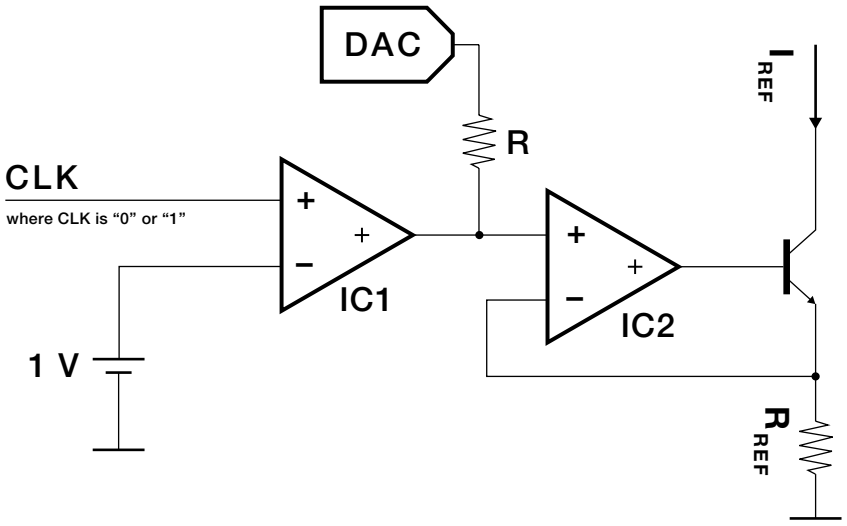
Considering the need for a voltage of 50V, and that the voltage supplied by the battery may vary between 18V and 15V during its useful life, the converter should have three stages (n = 3). Thus, there is a Vout ranging between 60V and 72V. A voltage regulator coupled to the output of the circuit ensures that the output voltage is stabilized at 50V. This regulator consists of a bipolar transistor biased by a zener diode (Vz = 52V) connected at its base. A negative voltage of -5V was obtained through an inverter to a charge pump stage with its output set to -5V by a bipolar regulator. The voltages of 5V and 12V were determined using bipolar regulators.

2.2 Module 2: Pulse Generator and Digital Controller

This module is aimed at controlling the duration of the stimulus and amplitude current digitally. An open-collector comparator was used to control the width of the pulses (CLK), which is enabled by the MCU. To control current amplitude, a DAC (digital-to-analog converter), connected to a pull-up resistor (R) which is connected to the output of the comparator controls the voltage level (VDAC) necessary for generating the current required. A constant current source is accomplished by a current voltage converter comprising the amplifier IC2, transistor Q1 and RREF (Figure 2). Thus, the current generated is given by:

$$I_{REF} = \frac{V_{DAC}}{R_{REF}} \times CLK$$

Figure 2: Schematic of Control and Generator Stimulus



2.3 Module 3: Current Mirror

As human body impedance may vary due to several factors, a system that provides a constant current independently of load change was implemented. The characteristic of a current mirror fits this application, allowing a constant current, invariant with the load. Thus, the current mirror must have high output impedance so that the current does not undergo changes with the load. Wilson type was chosen because it has a high output impedance and large output voltage excursion.

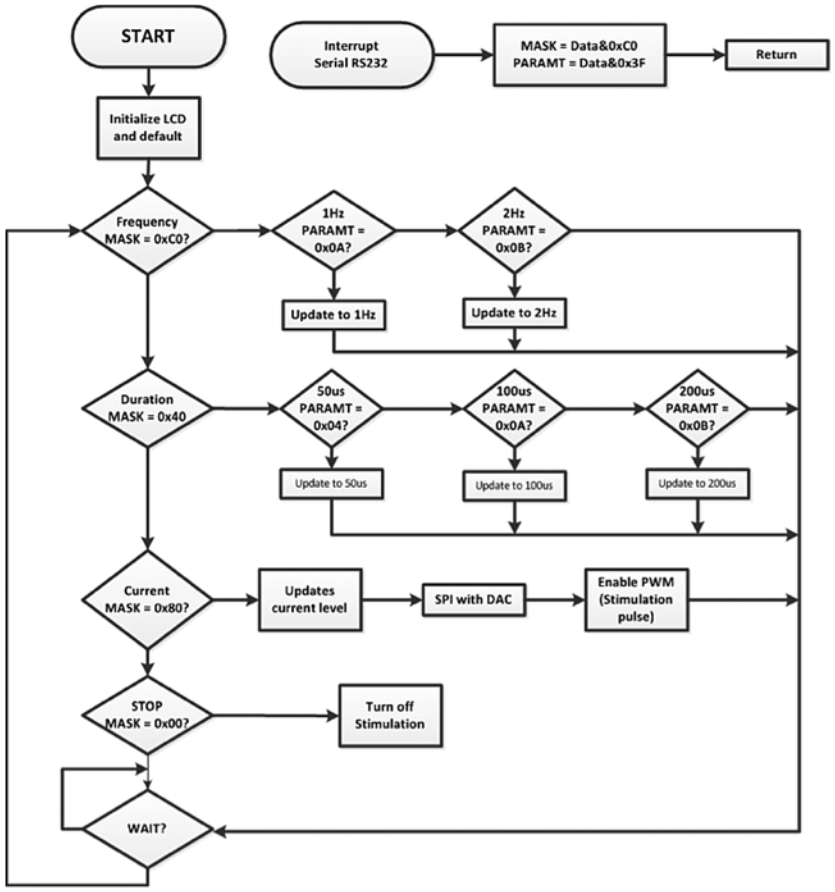
The current measurements to check the linearity of the circuit were made with a multimeter connected in series with output impedance.

2.4 Development Board

The DEMO9S08LC60 development system was used for digital control of the other modules. This board integrates the Freescale MCU MC9S08LC60, plus a built-in LCD display, RS232 interface and buzzer. This board provides all the tools needed to develop this nerve stimulator because it is able to control all stimulation parameters, such as frequency and duration of the stimuli by triggering timers, current amplitude by updating the DAC through SPI (serial peripheral interface), communication with PC through RS232 interface, plus visual and audible warnings through LCD and buzzer, respectively. The flow diagram shown in Figure 3 illustrates the sequence of work performed by the MCU.

Subsequently, the equipment will receive a module for capturing electromyographic signals (EMG), whose purpose is to provide a feedback for process automation of current level control. Thus, the AD converter of the MCU will be used. Complementary to this process, the use of a Freescale accelerometer (MMA84530) attached to a selected muscle enables data collection from a muscle contraction evoked by stimulation. These data enhance the feedback process in the automatic control of current levels.

Figure 3: Sequence of Work Performed by the MCU



2.5 PC Interface

All settings to the nerve stimulation and location are controlled through a graphical user interface developed for Windows® environment in Microsoft Visual Basic®. This interface allows the user to select stimulus duration, frequency and current amplitude with ASCII commands sent to the MCU through RS232 serial interface at a transmission rate of 115 kbps.

3 Results

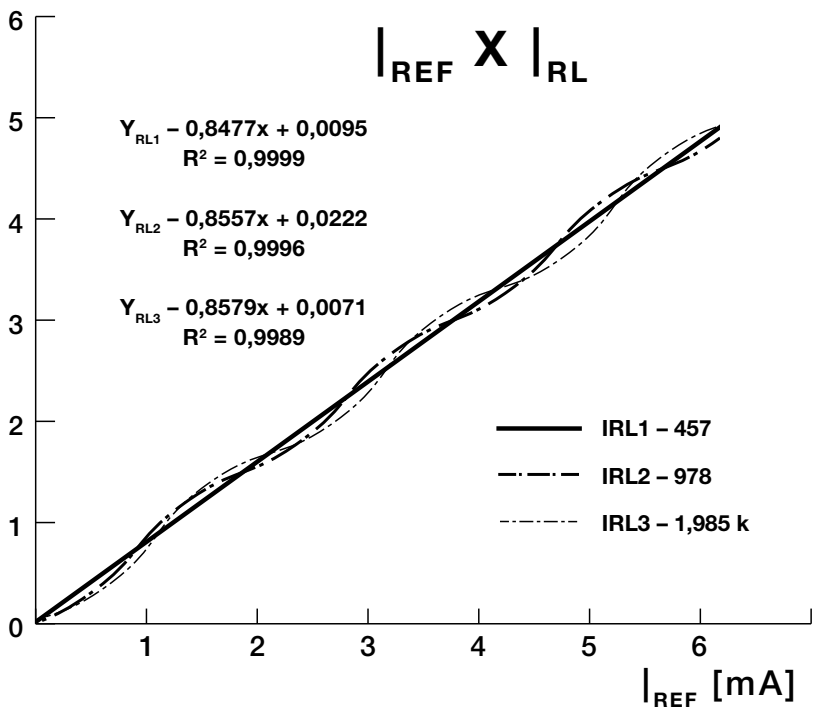
A very important factor for electrical stimulation with invasive electrodes is low-noise generation from electronics. The major source of noise in this system originates in voltage converters. Thus, we observed the noise generated at the outputs of the converters (Table 1).

Table 1: Noise Level in the System

	+5V	-5V	+12V	+50V
Noise (mV)	–	–	–	0,1

The output voltage of the Dickson topology remained constant until the output current was 4 mA, during which it suffered a significant decrease. This decline was expected, as seen in Equation 1. However, this variation in output voltage is not an issue to the system since the current pulses are of short duration (less than 200 µs), which causes a voltage drop lower than 200 mV when applying a current pulse of 5 mA with duration of 200 µs in a load of 8 kΩ. It also exhibited rapid recovery.

Figure 4: Linearity For the Wilson Model



The pulses of current generated by the system presented rise time of less than 0.4 µs, 0.25 µs for falling time; width of the pulses with variation of less than one percent.

The current mirror presented excellent results in maintaining a constant current, independent of the load, as seen in Figure 4. This means that the circuit is able to generate and maintain the actual current equal to the expected current within the load range. The output impedance of the current mirror was measured indirectly by means of voltage variation observed for two different loads when the same current is selected. Thus, the calculated output impedance is 1.7 MΩ.

4 Discussion

Electrical noise exceeding 10 mV may trigger undesired stimulation. The boost converter was chosen first for this system. However, this circuit showed high noise level, in the order of 100 mV, precluding its use. The charge pump converter and Dickson topology presented satisfactory results, although its efficiency is not high (75 percent), when compared to other conversion techniques, which have efficiency greater than 80 percent.

To make sure the reference current was linear with high accuracy, the DAC should provide excellent linearity. The converter used for this project was adequate, with a coefficient of linearity (R2) equal to 1. This provides assurance that the actual current is equal to the expected current.

The stimuli generator responded appropriately, with rise and fall times well below the maximum expected. This ensures that the stimulus format is closest to the rectangular, as desired.

The graph in Figure 4 reflects that the system has excellent linearity. Thus, the load current (i.e., the current in the patient) will be within the range of accuracy to the stimulation purpose of locating plexus.

5 Conclusion

The development equipment was of excellent quality, and all of the features needed for proper equipment were met. The low variation in stimulation parameters such as pulse width and morphology was analyzed with excellent correlation between the expected and the real current. These are critical factors for selective stimulation of motor fibers Aα. During induction, the patient submitted to the use of the equipment to avoid discomfort and pain. The accuracy in the parameters is what ensures an excellent plexus location.

The equipment works with a PC interface (in this case, a battery-powered notebook computer that was isolated from the power grid), which allows control of frequency, width and amplitude of the stimulation current. Moreover, this communication will allow storing the information obtained through EMG and 3-axial acceleration of muscle contraction to be evoked by electrical stimulation. This information will be used for automating the neurostimulator, and also for assessing the patient's motor response to local anesthetics, as well as a pre-test of the quality of regional blockade.

After field testing, we intend to change the MCU so the final equipment will be more portable ,with less power consumption. Our probable choice will be the Kinetis K53 MCU which has these embedded features: LCD controller, digital-to-analog converter, touch sensing interface and an op-amp that can be used as a PGA. With all of these features, the final prototype will demand less external components.

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