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The design of an embedded spinal cord stimulator

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Abstract: Spinal cord stimulation is a physical therapy methodology utilizing electrical impulses, pulses, or a combination of various standard electrical waveforms to block pain. However, standard forms are not functioning effectively for each illness due to the unique conditions of the patient. Therefore, patient-specific waveforms (or user-defined waveforms) integrated with nondestructive, complete, or partially noninvasive and effective medical instruments to help relieve pain are required. In the literature, 2 different designs have been discussed: the bedside/portable and the implantable/surgical types. This work is introducing a new hybrid type: a portable touch-screen multichannel embedded spinal cord stimulator.

This work is made of 3 parts: the hardware and the software designs, and an embedded interface introducing the system to external medical systems or patients. The hardware and software designs are explained in detail. The S3C2440 microprocessor-based embedded spinal cord stimulator generates not only 6 standards types of signals, but also user defined waveform(s). This requires medical experts' close relation, consultation, and cooperation with biomedical engineers who are able to design and develop new instruments with new requirements. In this paper, a microprocessor-based spinal cord stimulator is developed in the Samsung S3C2440 environment and PIC18F452-based channel boards. The S3C2440 environment is the main controller unit and the therapy signal is produced by the channel boards as a signal generator. The software is prepared by MS Visual Studio 2008 and Hi-Tech C. The frequency, duty-cycle, and amplitudes of the pulses can be altered by software control. The architecture of the stimulators is designed to be modular; therefore, its different blocks can be reused as standard building blocks.

The designed and developed embedded spinal cord stimulator enables both home and bedside health care. The system is battery-operated, portable, user-friendly, and cost-effective.

Key words: Patient-specific waveform, user defined waveform, embedded, spinal cord stimulator, software control, multichannel, touch screen

1. Introduction

The reason for using electrical stimulation is to cause nerve cells or muscle fibers to be induced. Galvani achieved this realization with a most primitive experiment with frog legs in 1791 to show that stimulation of biological systems or organs is possible. Excitation by electrical pulses or inputs has widely been used in various clinical treatments and physiological research, with important examples from different areas, such as pain relieving, muscle strengthening, cardiac pacing, iontotherapy-based drug delivery, and functional electrical stimulation (FES) [1]. In 1965, it was Melzack and Wall's research group that was able to present the "gate control" stimulation theory for the first time in history [2], describing that the neural mechanism in the dorsal horn of the spinal cord is like a gate. When the gate is opened by a potentially higher voltage than a threshold voltage,

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neuron cells are excited in the dorsal horn to transmit pain signals through transmission cells (T cells) to the cerebrum [3]. In contrast, the pathway of pain signals from the neuron fibers is blocked when the gate is closed [4]. In 1965, Melzack and Wall provided a physiological rationale for electroanalgesic effects. They proposed that transmission of information could be inhibited by activity in large-diameter peripheral afferents or by activity in pain-inhibitory pathways descending from the brain. Since then, the use of electricity in medical equipment has grown significantly [5].

Moreover, gate control theory integrated with the spinal cord stimulation (SCS) method, with a proper new approach, has been used for chronic neuropathic pain treatment [6]. The principles governing the gate control theory use specific types of electrical pulses to charge up the somatosensory nerve fibers by an array of stimulating electrodes, such that the pain can be extenuated to an important degree. Therefore, the SCS method has been verified to be an effective medical-clinical application technique that reduces a patient's dependency on narcotic drugs, specifically when morphine is considered, in such a way that medicinal addiction is prevented [3].

A similar technique used in hospitals for several decades, FES, has also been used to regenerate or sustain the muscle activity of paralyzed patients. Therefore, the FES technique generates positive treatment results for people who suffer from spinal cord injuries and related nervous damages [7]. A new type of stimulator able to directly combine arbitrary waveforms in order to form new forms for multichannel FES applications has also been presented. A novel so-called element-envelope method is suggested, which is claimed to be able to generate flexible waveforms, and these waveforms can be implemented by digital signal processing or microcontroller-based systems. The designed hardware circuitry provides voltage-controlled biphasic constant-current outputs, but keeps high-voltage conformity and wide-signal bandwidth in parallel. This design claims to give the opportunity to synthesize not only high time resolution and arbitrary stimulating waveforms, but also achieve more flexible closed-loop feedback controllers [1].

The design and construction of a microprocessor-based multichannel stimulator, having great diversity and competence, for epidural SCS (ESCS) has been reported [7]. The design aims to use this homemade research instrument to examine the effect of ESCS on modulating spinal cord functions. Application areas are listed to be gait recovery and chronic pain management, with different therapeutic applications. This research instrument is made of 2 parts: a microprocessor-based controller and a power circuitry able to deliver sufficient stimulation power. The digital controller developed uses an 89S51 single-chip integrated circuit and connected peripheral hardware design. A multicontact electrode array is used with the stimulator to present arbitrarily specified sequences of electrical stimulus. The 3 main parameters of each pulse in the stimulus sequence, the width, amplitude, and interpulse interval, are chosen to be independently variable, and the 3 associated channels are independently programmable, as well, leading to the generation of a wide variety of stimulus patterns [7].

A higher version of a stimulator instrument for neuromuscular stimulation of spinal cord injury patients was also reported [6]. It is an externally controlled and powered instrument, by a single encoded radio frequency carrier, and has 4 independently controlled bipolar stimulation channels [6]. Therefore, widely speaking, 2 main research and application areas are present. Commercial SCS products are a well-established medical practice, although with many disadvantages. Chip-based spinal cord stimulators (implantable versions) are becoming more commonly used surgical components, although having a set of disadvantages, as well. A new approach could be the hybrid form of those 2 well-documented spinal cord stimulator versions. This paper focuses on that point and produces a new version of SCS to be used, preferably in underdeveloped and developed countries worldwide. A main disadvantage with the hybrid form of SCS is that it has only been tested with dead tissues and still needs to be tested on animals. However, tests on animals need medical and/or veterinary faculties' interference and cooperation, which needs required and authorized/certified laboratories and personnel.

2. Materials and methods

The human brain is able to receive disturbing stimulus detected by pain receptors developed within the body as urgent signals. The signal is then carried to the spinal cord as impulses, then transferred to the brain for evaluation and interpretation. There is a type of chronic pain that may not respond to drugs prescribed or other conventional therapies. One available alternative therapy for a subset of chronic pain is SCS-based therapy, which uses the gate control theory of pain [8]. This therapy uses electrical impulses triggering targeted nerve fibers along the spinal cord. The stimulation of these nerve fibers suppresses pain signals from being transmitted to the human brain. A reasonable amount of papers assessed SCS as a pain controlling method for a set of clinically accepted syndromes of pain. Research carried out by several groups accepts that SCS, if applied properly in accordance with medical practice, is a first-class means to handle, process, treat, and alleviate pain. Generally speaking, the stimulating pulses have stimulation modes, namely mono-, bi-, and tripolar, to respond to the various and different demands of clinical practice [3].

Although the exact pain control mechanism is not entirely understood due to its complexity, it is accepted the exact pain control mechanism is a result of direct or facilitated inhibition of pain transmission. Thus far, there are 5 mechanistic theories for SCS that have been explained in the literature [9]: 1) gate control theory, or segmental, antidromic activation of A beta efferents; 2) SCS blocks transmission in the spinothalamic tract; 3) SCS produces supraspinal pain inhibition; 4) SCS produces activation of central inhibitory mechanisms influencing sympathetic efferent neurons; and 5) SCS activates putative neurotransmitters or neuromodulators. Shealy et al. [10] concluded that if extended stimulation is applied to the dorsal columns, it would cause the gate to be held closed and provide continuous pain alleviation [9], whereas the theoretical model developed and suggested by Melzack and Wall has verified that the pain (gating) exists. Some researchers think that pain relief due to SCS instruments results from direct suppression of the pain nerve tract in the spinothalamic tracts and is not less important than selective large fiber stimulation. This approach has also been supported by Hoppenstein [11], who demonstrated that the posterolateral stimulation of the spinal cord supplied effective contralateral pain relief with significantly less current than later stimulations. Some research demonstrates that the changes in the blood flow pattern and skin temperature due to SCS may affect nociception at the peripheral level. This postulate is further supported partly by data from Marchand et al. [12], who investigated the effects of SCS on chronic pain using noxious thermal stimuli [12]. As SCS causes dilation of the blood vessels in animal studies, this modality has been used for the treatment of chronic pain by medical practices due to peripheral vascular disease. The precise action of pain modulation by SCS is still debatable. A deep and comprehensive understanding of the pain system will certainly lead to more effective stimulators and allow for even greater success in the near future [9].

Electrical stimulation can create impulse transmissions within the large fiber and stimulate enough positive excitation to subsequently inhibit pain impulses. The stimulation applied to the dorsal column, adjacent to the cord, can act in a similar fashion by exaggerating the number of descending modified impulses. These signals seem to jam the pain signals traveling along the nerve pathways before they can reach the brain. The result is analgesia, often for hours after the stimulation ends. Perhaps the stimulators perform an 'electronic massage', providing relief from pain [13,14].

Investigations indicate that the square wave and the spike wave are optimally suitable for pain relief and that both are equally effective. The step function is useful as a test signal since its initial instantaneous jump in amplitude reveals a great deal about a system's quickness to respond. The step function has a wide band of frequencies in its spectrum as a result of the jump discontinuity. Hence, as a test signal, it is equivalent to the application of numerous sinusoidal signals with a wide range of frequencies.

In contemporary times, some types of chronic pain do not respond to the conventional therapy methods developed and used; therefore, SCS is considered as a new and valuable therapeutic alternative in treatment of those types of chronic pain [7]. Until recently, it was thought that the nerve tissue in the central nervous system (CNS) was incapable of self-repair, leading to paralysis, whereas nerve tissue in the peripheral nervous system alone was capable of regeneration. It is now accepted that the CNS is also capable of rejuvenation. Spinal cord stimulators enable rejuvenation of nerve tissues in the CNS. Stimulation has been found to be beneficial in some patients with multiple sclerosis and other neurological disorders. It is expected that this technique will see increasing use in the near feature. For SCS, pulses for a duration of 0.2 ms minimize the energy requirement and are optimal in terms of safety. The current is of the order of 4 mA and the energies range from 2 μJ to 150 μJ. The electrical load is equivalent to an RC network whose impedance lies in the range of 400 Ω to 3000 Ω [15,16].

However, a few commercial systems do fully meet the clinical requirements and needs, or, more importantly, the patient expectations. In fact, real systems have capability and capacity limitations, or are not sufficiently miniaturized, which makes them heavy and unable to be carried by patients [17]. In that sense, a rechargeable and implantable SCS prototype system has been realized. A system on a chip design is realized and integrated on the prototype, which acts as a stimulating pulse controller [3].

ESCS has been used with various diseases, including chronic pain, spasticity, peripheral vascular disease, bladder dysfunction, and torticollis, with varying results [18]. Three critical ESCS parameters are electrode contact separation, pulse duration, and amplitude [11]. In animal experiments, low frequency, long pulse duration, and supramotor threshold intensity have been used as stimulus parameters. The results obtained proved to be compatible with those reported in human experiments with clinical complete spinal cord injury by Dimitrijevic [19]. On the other hand, Carhart et al. [20] applied lumbar ESCS to a tetraplegic incomplete spinal cord injury patient and observed mechanical and metabolic changes in gait performance [20]. These results show that ESCS has effects on motor function. The mechanism on which ESCS modulates motor function needs further research, and more complex stimulus patterns should be generated and tested [6].

2.1. Stimulator hardware design

Key parameter items and hardware capabilities of the spinal cord stimulator designed, developed, and tested are given below in the Table.

This embedded spinal cord stimulator consists of 2 separate parts; the first is a Samsung S3C2440 environment-based main board and the second is a microcontroller-based interface circuit for the interconnection of these modules, as shown in Figures 1a and 1b, respectively. The Samsung S3C2440 environment is used to input and store the data, do necessary data processing according to the software developed, send the data to the channel boards, and finally display messages regarding the online data transfer to the system output. The Samsung S3C2440 environment has a 64-MB SDRAM and a 1-GB NAND flash memory. It has 3 RS232 ports for connection with environmental devices. One of the RS232 ports is used to connect to the channel boards. The stimulator has a touch-screen display panel that is used to accept the input variables. It is user-friendly, both for the experts and the patients. The required waveform given to the system controller is defined by medical experts.

Table. The comparison table of the key parameters and hardware capabilities of different types of spinal cord stimulators.

Stimulation parameters	Embedded SCS V1.0 (presented in this paper)	Medtronic Itrel	One-time implantable SCS system prototype [2]
Number of independent channels	3	1	4
Signal types	Continuous saw-tooth Continuous impulse Continuous triangular Continuous square Discrete saw-tooth Discrete square	Impulse	Impulse
Pulse period	50–1000 ms (10 ms)	60–450 ms	6–500 ms
Amplitude	0.00–5 V (0.01 V)	0.0–10.5 V	0.0–10.5 V
Duty cycle	0%–100% (1%)	100%	0%–100%
Stimulator type	Bedside-portable	Implantable	Implantable
User defined waveforms/patient-specific waveforms	Yes	No	No
Modular structure-extendable design	Yes	No	No

For SCS, different pulses with variable widths are required. These pulses can be generated using a microcontroller such as, for example, a PIC18F452, which can be realized using a digital-to-analog converter (DAC) and an operational amplifier. The design of the spinal cord stimulator with multiple outputs makes the system quite complicated in all of these realizations. A DAC is used for each channel board. The DAC parallel interface is connected to a peripheral interface controller microcontroller. An operational amplifier is used to increase the signal amplitude. The printed circuit board (PCB) design is a prelude to the realization of the hardware and is made using a smart work program on a personal computer (PC).

The SCS channel board design is given in Figure 2.

2.2. Stimulator software design

The system software consists of the Samsung S3C2440 environment and channel boards, programs, and subprograms developed, and it implements the following features: the stimulus can be applied for 3 different subjects simultaneously; the frequency, the duty time, and the amplitude of the stimulus are also programmable and can be changed for different patients. The Samsung S3C2440 environment of the spinal cord stimulator needs to be interfaced with the program memories, data storage registers, and input/output devices for communicating with the environment. To do this, the processor must be capable of waiting for the interfaced device as long as is desired. When the Samsung S3C2440 environment addresses a nonexistent peripheral, it has to wait for a response that will never arrive. This interface connects the channels on 2 wires to the Samsung S3C2440 environment.

Two different software programs are stored in the spinal cord stimulator. The first is the Samsung S3C2440 environment software and the second is the channel-board software. The channel-board software is C language-based with the compiler Hi-Tech C18. The function of the compiler is to create a hex file according to the C code written, and the developed C code is then embedded into a 32-K flash memory in a PIC18F452 microcontroller with a programmer device.

The Samsung S3C2440 environment has a touch screen accepted to be one of the advantages of the

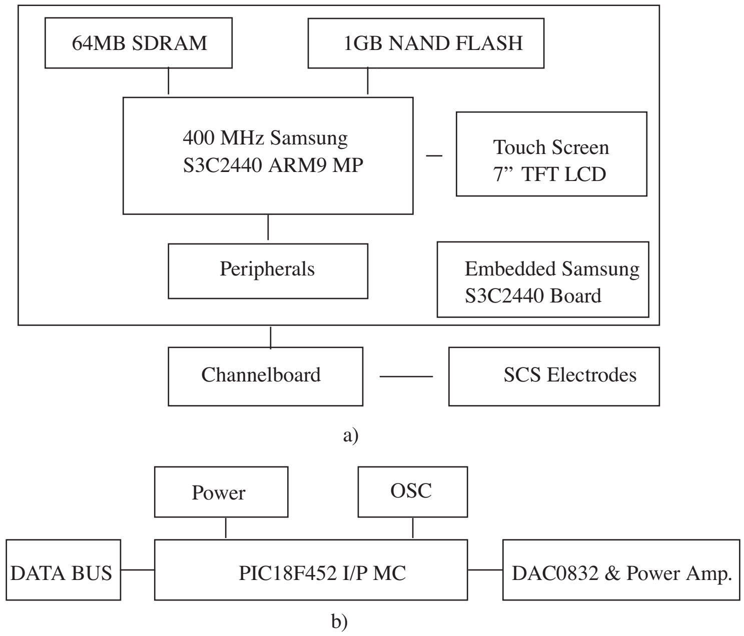


Figure 1. a) Portable touch-screen spinal cord stimulator in the Samsung S3C2440 environment. b) Portable touch-screen spinal cord stimulator channel boards.

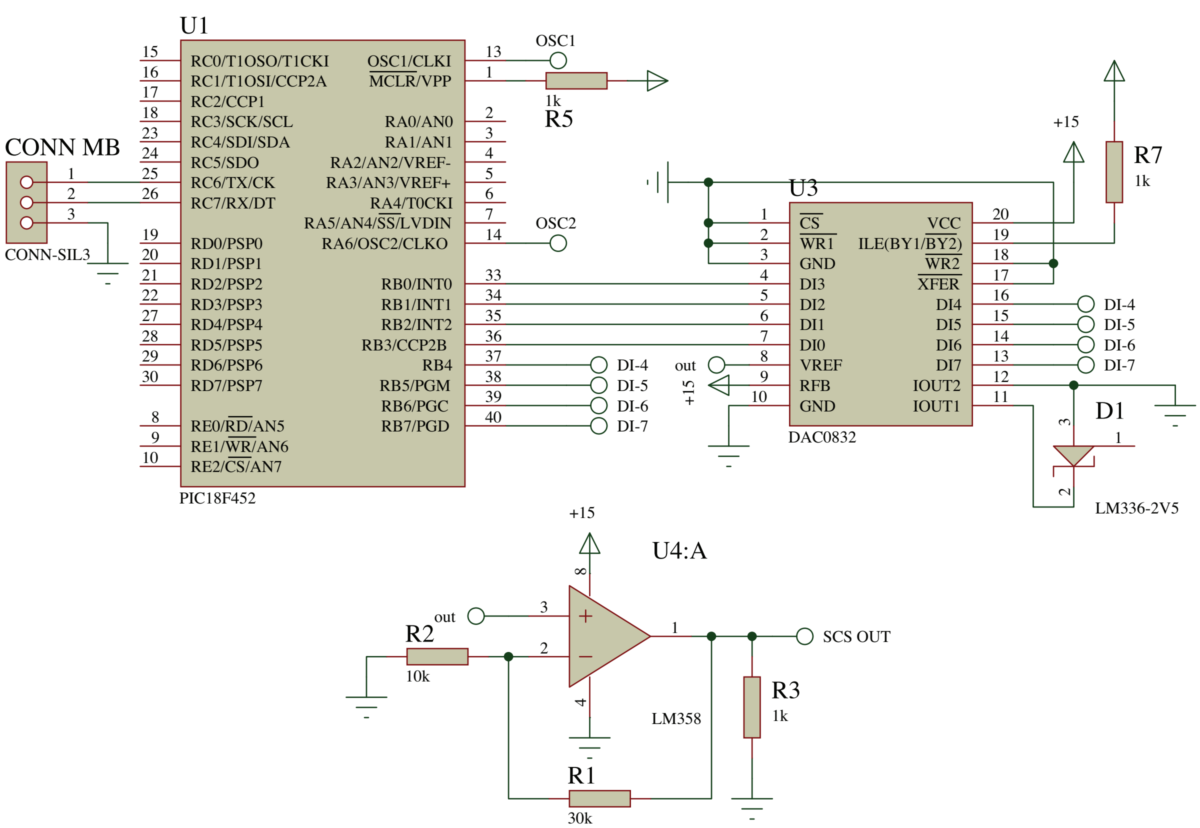


Figure 2. View of the SCS channel board design.

SCS unit developed. Before the software program is started, medical experts define the parameters of the stimulation signals, taking into account the requirements of the patient. Having chosen the input parameters (period, amplitude, and duty cycle), and setting their usable limits with a numeric on-screen keyboard, the data are then transmitted from the data bus to the channel board.

On the channel board, when the system is being powered or reset, the software starts working from the initialization routine. After the initialization routine completes its circle, the channel-board software starts realizing 2 functions. First, it scans the data bus. If the data are sent to its own channel, it reads the data; then the channel generates the signal or stops. Data transmission is being done between the microcontroller on the main board and the DAC on the channel board, as well as the real-time control on the ports of the microcontroller. The Samsung S3C2440 environment and the channel board communicate serially via the RS232 port. The data protocol is one-way from the main board to the channel boards. The flow charts developed to implement these features are shown in Figure 3.

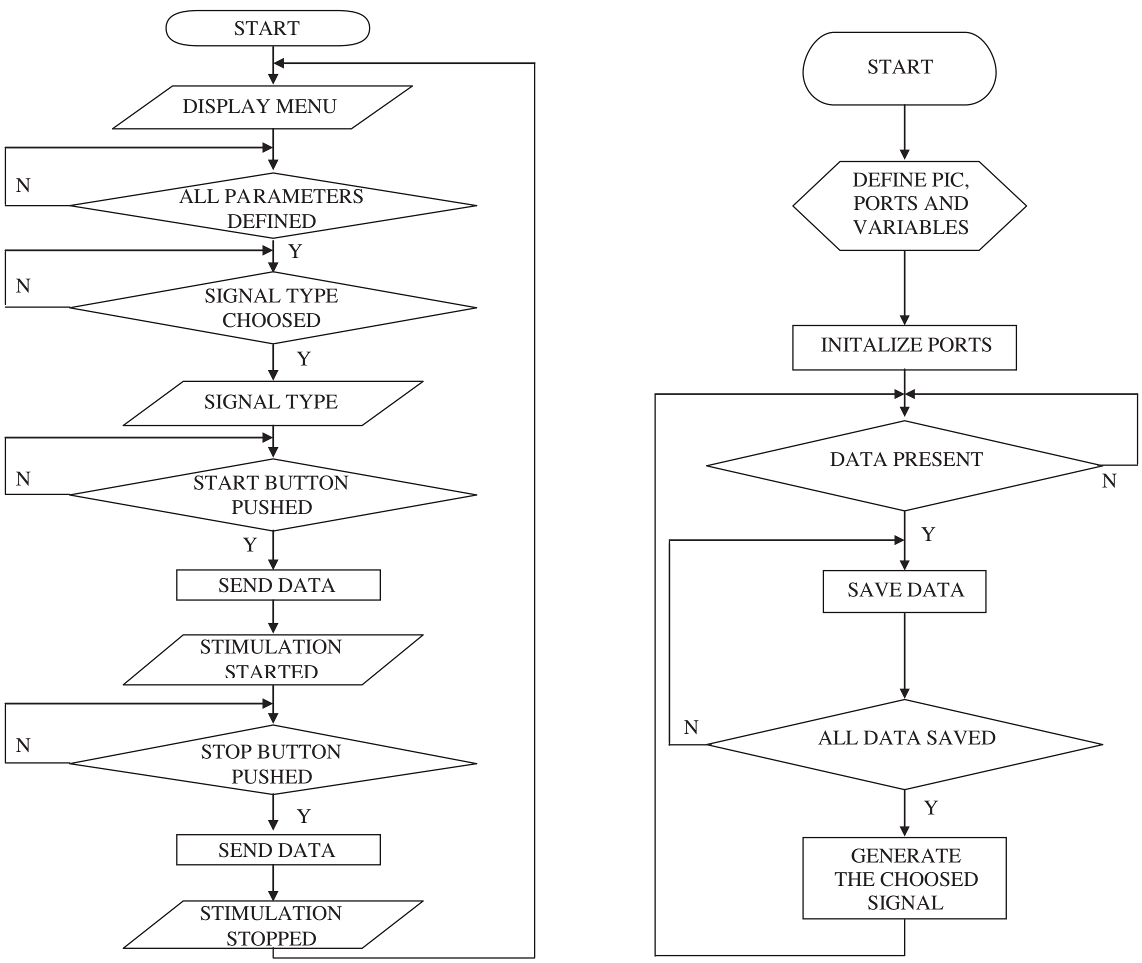


Figure 3. Flow chart for the Samsung S3C2440 environment and channel board.

3. Results and conclusions

When the human body functions improperly, although natural repair can occur, science is used and does not spare any effort to accelerate the pace of the repair. One such effort is called stimulation. Partially necrotized muscles can be rejuvenated by stimulating them with the appropriate electrical signals. This paper presents the design and development efforts put into building a Samsung S3C2440 environment-based portable touch-screen multichannel embedded spinal cord stimulator. The hardware and software designs are explained. The PCB layout is designed using a smart work package. This is a battery-operated light-weight device for long-term usage. Multiple outputs enable the treatment of a number of patients at a time, as in a modern physiotherapy department. In fact, this can be a general purpose stimulator. The Samsung S3C2440 environment-based portable touch-screen multichannel spinal cord stimulator generates not only 3 standards types of signals but also the user defines any waveform or patient-specific waveform. The 18-cm TFT LCD display of the spinal cord stimulator displays real-time signals, actual amplitudes, duty cycles, and pulse period widths of the 3 stimulation channels in Figure 4. For biostimulators, battery-operated systems are essential since the main operation systems might cause fibrillation of the heart, to the detriment of the patient's interest.

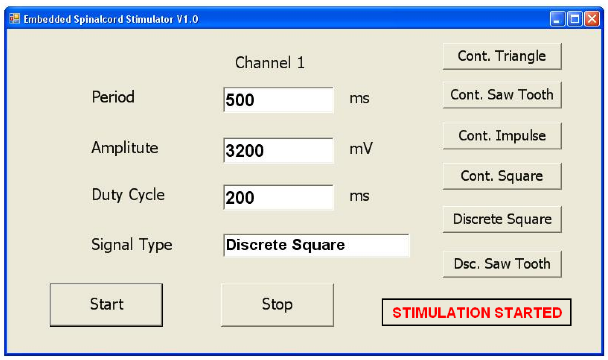


Figure 4. View of the display as Channel 1 is active.

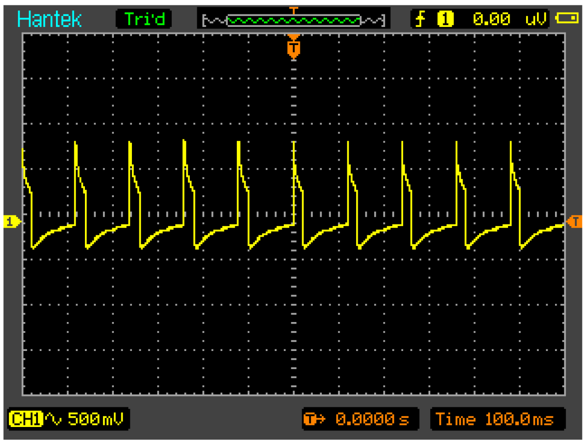
The design has 6 stimulation modes with preset treatment protocols. The protocols are designed to be flexible and medical experts could reprogram them to the need and requirements of the patients. Presently, a limited amount of patient data could be saved, but based on the memory capacity of the microcomputer used, this could be increased. The system is operated based on a constant current mode. The quality of the graphic display used needs to be improved. An ample display showing all of the output parameters is to be done.

Rehabilitation engineering is increasingly getting special attention due to the increase in the number of elderly people around the world. Therefore, multifunctional portable, handheld, and/or bedside medical instruments will be at the center of concern in the medical product industry. To be ready, within the scientific community of Turkey, this research intends to produce multifunctional medical therapy devices. As a future work, this developed embedded system will be integrated with 2 more features: the first is to integrate a data logger feature, so that the instrument will be able to record and save electromyography signals or even electrocardiography signals and transmit the signals via the Internet or global positioning system to the databases of medical centers. The second is to integrate a feature that will give the opportunity to medical experts or patients to use the system as an ultrasonic medical therapy device, as well.

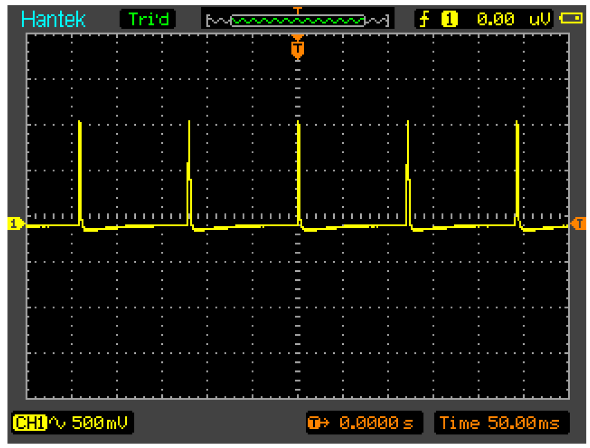
PC-based spinal cord stimulators are heavy, expensive, and have a limited number of features. There are 2 main categories of spinal cord stimulators: the first group is PC-based and is used only in hospitals or medical centers. The second group includes the implantable versions, which need microelectronics and micromechanical components integrated properly in an application-specific integrated circuit or chip mode. Implantable versions of spinal cord stimulators require a medical operation and use advanced technology with very high accuracy and sensitivity. This research intends to produce a new version of SCS, in such a way that the design will make home usage possible and it will not be expensive at all, even when creating more features within the stimulators.

The presented spinal cord stimulator is tested on dead tissue. The repeatability of the signal is observed with its characteristic features when the signal is transmitted on dead tissue. Due to the dead tissue, a voltage drop occurred on the nerve fiber.

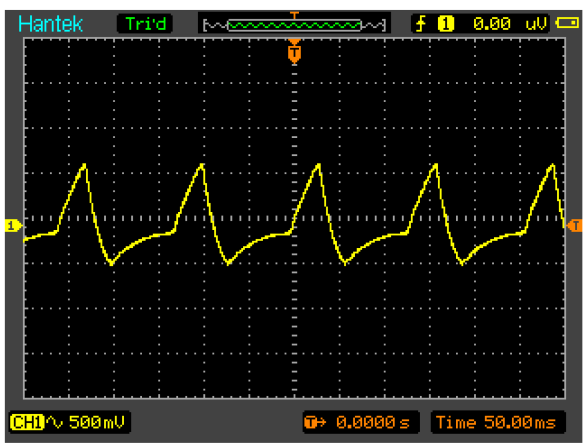
The 3-needle measuring system is inserted in the dead tissue on nerve fiber. The patient-specific waveforms defined by the medical literature are tested on the nerve fiber, and the applied signal response is measured by an oscilloscope. These measured signals are shown in Figures 5a–5c.



a)



b)



c)

Figure 5. The measured signals on nerve fiber (a, b, and c).

The main difficulty with conventional SCS systems is their general use without taking into account the patient-specific requirements. Therefore, a SCS system being able to produce patient-specific waveforms is a very crucial contribution to physical therapy. Figure 5 clearly indicates the variety of waveforms that this research is able to produce. To realize an efficient and effective medical-clinical instrumentation, it is necessary to determine all of the used signal types as well as might-be-used electrical signals. The waveforms given in Figure 5 are only a portion of all of the waveforms tested or planned to be tested. This needs close cooperation with medical-clinical experts. Theoretical or mathematical waveforms and clinically requested waveforms are different from each other to some extent. The future works of this research will mainly be focused on that practically and clinically critical issue with the help and consultation of medical-clinical experts.

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