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Development of Low-Cost Current Controlled Stimulator for Paraplegics

Aizan Masdar[1, 3], B. S. K. K. Ibrahim[1, 3] and M. Mahadi Abdul Jamil[2, 3]

Department of Mechatronic and Robotic Engineering[1], Department of Electronic Engineering[2], Modeling and Simulation Research Laboratory[3], Faculty of Electrical and Electronic Engineering, Universiti Tun Hussein Onn Malaysia, Parit Raja, Batu Pahat, 86400 Johor, Malaysia

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Abstract: A spinal cord injury (SCI) has a severe impact on human life in general as well as on the physical status and condition. The use of electrical signals to restore the function of paralyzed muscles is called functional electrical stimulation (FES). FES is a promising way to restore mobility to SCI by applying low-level electrical current to the paralyzed muscles so as to enhance that person's ability to function and live independently. However, due to the limited number of commercially available FES assisted exerciser systems and their rather high cost, the conventional devices are unaffordable for most peoples. It is also inconvenient because of wired based system that creates a limitation in performing exercise. Thus, this project is concerned with the development of low-cost current controlled stimulator mainly for the paraplegic subjects. The developed device is based on a microcontroller, wireless based system using Zigbee module, voltage-to-current converter circuit and should produce proper monopolar and bipolar current pulses, pulse trains, arbitrary current waveforms, and a trigger output for FES applications. This device has been developed as in the new technique of the stimulator development with low cost and one of the contributing factors in Rehabilitation Engineering for patients with SCI.

Keywords: Functional electrical stimulation (FES), voltage current converter, wireless, low cost

1. Introduction

The brain, spinal cord and peripheral nerves make up a complex, integrated information-processing and control system known as central nervous system. It is vital to our existence, controlling voluntary movements and regulates involuntary activities such as breathing and allowing us to function in daily life. As a part of the central nervous system, the spinal cord extends from the base of the brain down the midline of the back and ends at the bottom of the spine. The spinal cord is the pathway to send signal to the body and serves as a communicator between the body and the brain. These peripheral nerves carry impulse that causes such as muscles to contract and also carry signals up through the spinal cord towards the brain that enable us to experience sensations such as pain and touch to name a few.

However, damage to the spinal cord results in loss of motor or sensory function. A spinal cord injury (SCI) has a severe impact on human life in general as well as on the physical status and condition. Spinal cord injuries (SCI) can be separated into two major categories; complete or partial. A complete injury is defined by complete loss of motor function and sensation below the area of injury. In partial injury, there can be a sparing of motor or sensation below the level of the injury. Injury to the spinal cord can be the result of traumatic (road traffic accidents and falls) or non-traumatic (disease such as polio) events. Road traffic accidents account for the largest cause of SCIs worldwide [1].

Individuals with SCI do not easily regain their function without the help from an assistive device. SCI also leads to susceptibility to the inactivity related diseases such as obesity, insulin resistance, type II diabetes, and coronary heart disease increases [2]. The improvement or restoration of lost function is one of the major issues in the rehabilitation of people with neurological disorder such as those caused by SCI [3]. One technique is called functional electrical stimulation (FES), and can be used in rehabilitation by producing controlled contractions in the paralyzed muscle. The first developed FES was used as an orthotic system to prevent "foot drop" during hemiplegic walking [4]. FES is one of the techniques to restore mobility to paralyzed muscles and can be used in rehabilitation by producing controlled contractions in the paralyzed muscle [5].

FES is a promising way to restore mobility to SCI by sending electrical signals to restore the function of paralyzed muscles. In this technique, low-level electrical current is applied to an individual with disability so as to enhance that person's ability to function and live independently [6]. It is important to understand that FES is not a cure for SCI, but it is an assistive device [7]. For SCI, the damage is only to the central nervous system, the muscle and its nerve supply remain healthy.

**Corresponding author: snazia07@yahoo.com*

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By using FES, the paralyzed muscle is possible to contract due to the reaction of the artificial electrical stimuli. FES system mainly consists of electrodes and a stimulator unit. Current pulses will be generated from the stimulator unit through the electrodes and these cause the paralyzed muscles to make contraction. The main objective of FES in injuries to the central nervous system is the substitution of the absent bioelectric activity with an appropriately formed series of electric pulses, generated by a stimulator, or the elimination of the hyperactivity in paralysis and spastic paresis [8]. Basically, two electrodes are essential to close the current circuit of the stimulation system as shown in Fig.1.

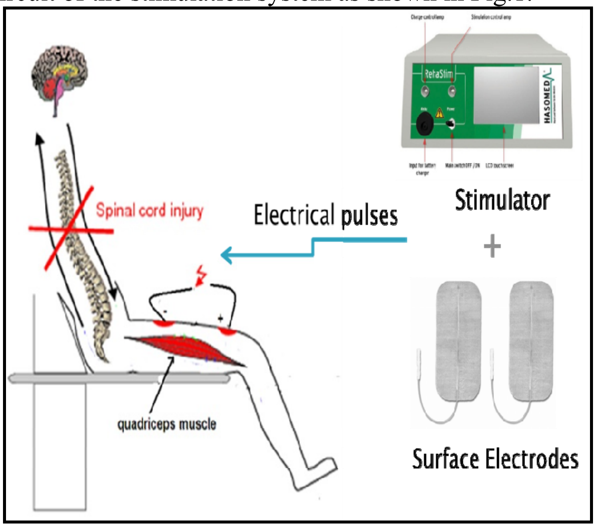

Fig.1: A basic electrical stimulation system

In many years, FES has been applied to restore or maintain muscle activities of paralyzed patients who suffer from spinal cord injuries and related neural impairments [9]. However, due to the limited number of commercially available FES assisted exerciser systems and their rather high cost, the conventional devices are unaffordable for most peoples. Moreover, it also inconvenient because of wired based system that creates a limitation in performing exercise. Thus, this project is concerned with the development of low-cost current controlled stimulator mainly for the paraplegic subjects. A paraplegic is a patient who has lost some or all of the neurological function in their lower body.

2. Functional electrical stimulation (FES)

A controlled electrical stimulus is applied in FES to motor units/nerves to elicit a muscle contraction in an attempt to restore functional movements of a paralyzed musculoskeletal system. Several FES stimulators with microprocessor or microcontroller have been developed to improve lower and upper limb functions in subjects after SCI or stroke [10]. Most of the proposed systems have a more or less fixed design and lack of an open architecture. They generally operate with pre-programmed stimulation patterns that are stored in a look-up table. Often, a single sensor combined with a control algorithm either triggers pre-programmed stimulation sequences or scales and reads the stimulation parameters out of a look-up table [11]. Besides that, the stimulus mode, stimulus pattern, safety features and output stage of the stimulator need to be concerned as well in developing an electrical stimulator.

2.1 Stimulus mode

There are two distinct modes for stimulation which are current-mode and voltage-mode [12]. The current-mode stimulation is widely used in surface as well as implantable stimulator for FES applications. The current amplitude is directly controlled by a digital-to-analog converter (DAC) and is not affected by changes in the tissue load. Therefore, the quantity of charge delivered per stimulus pulse is easily controlled. In the voltage-mode stimulation, the stimulator output is a voltage, and therefore the magnitude of the current delivered to the tissue is dependent on the inter-electrode impedance (Ohm's law). Thus, it is difficult to control the exact amount of charge supplied to the electrode and tissue because of the impedance variation.

2.2 Stimulus pattern

Stimulus waveforms are generally either monophasic or biphasic in shape. A monophasic stimulus consists of a repeating unidirectional (usually cathodic) pulse which is more common in surface electrode stimulation. Biphasic waveform consists of a repeating current pulse that has a cathodic (negative) phase followed by an anodic (positive) phase. The cathodic phase depolarizes nearby axons and initiates the action potential which elicits the muscle response. The succeeding anodic phase reverses the potentially damaging electrochemical processes that can occur at the electrode-tissue interphase during the cathodic phase by neutralizing the charge accumulated in the primary phase. The use of charge-balanced waveforms is especially important when the stimulating electrode is implanted rather than placed on the surface of the skin. Usually, the stimulus for the cathodic phase is in square-shape, supplied by active circuits, while the stimulus for the anodic phase could be either square or exponentially decaying. The square secondary phase is also known as active discharging and the exponentially decaying phase is known as passive discharging. The passive discharging is achieved by shorting the tissue load with the discharging driver, in series with either a blocking capacitor or a capacitive electrode for safety reasons [12].

Pulse shaped waveforms have contributed to the effectiveness of today's practical FES applications such as transcutaneous electrical nerve stimulation (TENS) for pain management and neuromuscular electrical stimulation (NMES) programs for muscle strengthening. These pulsed current waveforms can be defined as providing discrete electrical pulses of known waveform, frequency, amplitude and pulsewidth. Most of today's FES is done using pulsed stimulation waveforms. Pulse shapes commonly used are rectangular, which rise abruptly (eliminating any concern of nerve accommodation), stays at constant amplitude for a determined period of time and then falls abruptly.

As been discussed before, stimulus waveforms are generally either monophasic or biphasic in shape. Monophasic pulses move current only in one direction. When these pulses are used for TENS or NMES applications, they have the likelihood of causing electrode deterioration and tissue damage (skin irritation or rash when surface stimulation is used) when used for prolonged periods of time (over an hour) [13]. This effect is due to the altering of ionic distributions and causing polarization which leads to tissue breakdown and burns. Although the effect of ionic distribution is not desirable, monophasic waveforms are still used in some short-term therapeutic TENS applications. The unequal ion transfer can be reduced by using biphasic (symmetrical or asymmetrical) stimulation pulses. In the case of asymmetric biphasic waveforms (as shown in Fig.2), one direction of current is enough to cause excitable tissue to depolarize, while the opposite direction is lower in amplitude but proportionally longer in duration minimizing neural excitation. The overall effect of the stimulation is similar to the monophasic waveform, but with a reduction of ion redistribution. The area under these pulses indicates the amount of charge that is delivered to the tissue. These waveforms can be either balanced or unbalanced in terms of the area under each pulse within the period. The most common and desirable biphasic waveform is the balanced charge pulse waveform, which further reduces issues of ion build-up. The symmetric biphasic waveform shown in Fig.4 has equal amplitude and duration in both directions. Since both the positive and negative pulses are equal, they both are effective in causing depolarization in the excitable tissue and are usually used for the activation of large muscles [13]. Overall most FES applications desire the use of biphasic pulse waveforms, especially when they are used for prolonged periods of time.

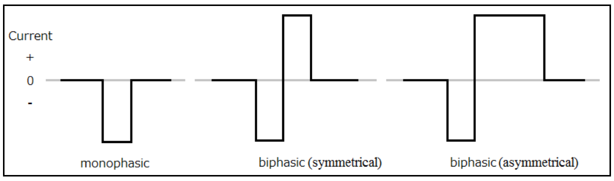

Fig.2: Pulse-shaped stimulation waveform configurations

2.3 Safety features

Safety is one of the prime concerns for stimulator output stage design. A failure in the stimulator output stage could pass prolonged DC current through the electrode-nerve interface, causing serious injury to the tissue. There are three commonly used protection methods against electrolysis caused by direct current. The first approach employs continuous monitoring of the electrode-tissue impedance [14], electrode voltage [15] or the stimulus current level [16].

2.4 Output stage

In general, complicated circuitry and control method are needed for this application which, in turn, imposes designs that are bulky, expensive, and high-power consumption [17]. The required components are small and the required input voltage is low. The circuits have three degrees of controllability which are amplitude, pulsewidth, and frequency and are ideal candidates for improvement of the FES circuit.

Conventionally, FES circuit is designed by using an oscillator which generates necessary pulse by using analogue electronics. The output waveforms including amplitude, frequency, and pulsewidth can be regulated. The output is then stepped up to the required voltage by a step-up transformer as shown in Fig.3. The drawback of using transformer is that this increases the device size and cost, and electromagnetic interference due to the transformer. The design of the transformer is also needed to handle the small mark-space ratio of the pulse. The wide range of amplitude is also restricted because of the fixed transformer turns-ratio. Various control strategies and circuit design have been developed to provide enhanced functionality, repeatability, and a wide range of stimulation parameters for FES stimulator [18] in order to provide predictability of muscle responses. The transformer is used to further step up the output voltage. The function of this part is to transfer the output pulses of the multivibrator into a series of current pulses and a current feedback loop is included to ensure the current amplitude.

Fig.4 shows the schematic diagram of the switching resonant circuit. The circuit is based on resonant converter [19] which has been used in power conversion but rarely used in medical electronics. It consists of two transistors and a set of resonant components and amplitude regulating components.

The performance of two circuits is very similar and both can provide the required pulse pattern for use as an FES. The first circuit is an analogue electronic circuit, which requires a transformer to step up the voltage. The transformer is also the most bulky and expensive component in the circuit. The component count is also high, therefore, in practice; surface-mount devices are needed. The second circuit is based on a zero-voltage switching resonant techniques. The main feature of the circuit is that no transformer is needed. Therefore, it obviously has an advantage of no large magnetic components. The component is also small in size. The resonant circuit proposed has a preferred feature and require less component and do not need to install a bulky transformer. It also required minimal components in quantity.

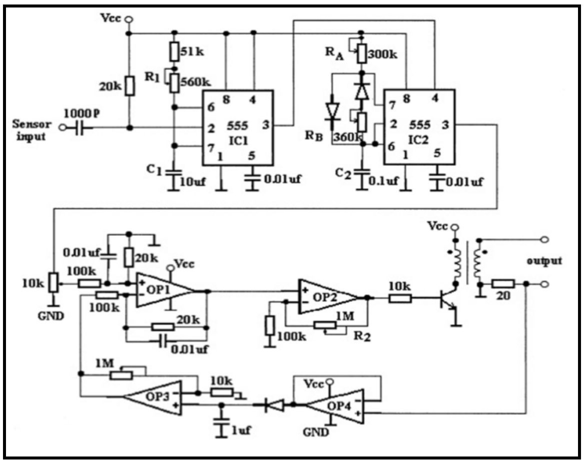

Fig.3: Typical circuit of a transformer-based FES [17].

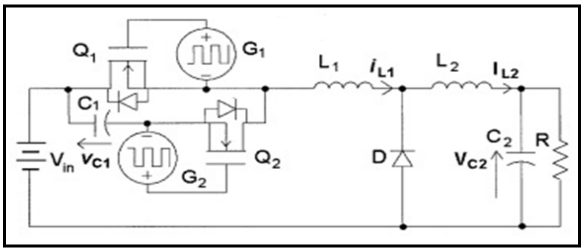

Fig.4: Switching resonant circuit FES [17].

2.5 Wireless module

The Wireless Sensor Network (WSN) has a very broad application prospects,and has been considered as one of the most important technologies that can change the future. The main features of this network are real-time transmission, accuracy and comprehensiveness. ZigBee is one of the most popular wireless network technologies in the world [20]. Currently, ZigBee technologies are widely used in various fields such as biological research, control, disaster monitoring and environmental science to name a few. Moreover, ZigBee have many advantages, which determines the tremendous potential of use in medical field [21]. A kind of dynamic and strong integration of ZigBee hybrid system was developed, under wide coverage, low cost and high reliability [22]. In order to provide more conveniences to patients, people developed ZigBee wireless sensor system, whose purpose is to collect the patient's physiological information, such as pulse, temperature, etc. The system not only ensures accurate measurements, but also saves the patient from the time between hospital and home [23]. ZigBee is a new wireless communication technology based on wireless standard 802.15.4. It is an extension of the WPAN. This technology has a number of significant features. The first is short range; ZigBee transmission range is between 10-100m, good enough to meet the needs of mobility equipment. The second is low-power, when data exchange is not needed, the node will enter a very low power consumption sleep mode. Compared to Bluetooth devices, two common batteries can support ZigBee devices from several months to several years. The third is the low transmission rate; ZigBee work in the 2.4GHz (global GM), 915MHz (USA) and 868MHz, with transmission rates 250KB/s, 40KB/s and 20KB/s. The fourth is less complexity, ZigBee network layer structure uses star, tree and mesh structure. A ZigBee node can connect up to 254 nodes and the whole network can support a maximum of 65535 nodes. That has greatly enhanced network scalability. Also, the network is very strong in self-grouping; the join and disconnect of nodes are very fast. Compared to Bluetooth and WI-FI, ZigBee technology has the following advantages such as good security, low cost, low power consumption, flexible working bandwidth, short delay, low data transmission rate, large network capacity and small effective range [20].

3. Development of low cost current controlled stimulator

3.1 Procedures

In order to achieve the objectives of this research, the following procedures and the research flow chart (Fig.5) have to be considered:

1. Understanding an established conventional stimulator specification to be compared in developing the new low cost stimulator.
2. Understanding the wireless module (i.e Zigbee) function and specification to utilize in the new system of stimulator control and data transmission.
3. Designing the electronic circuit for current controlled signal generator, microcontroller and wireless module.
4. Developing the software of the stimulator.
5. Designing the chassis of the portable stimulator and come out with the prototype.
6. Validating the stimulator in the real environment.

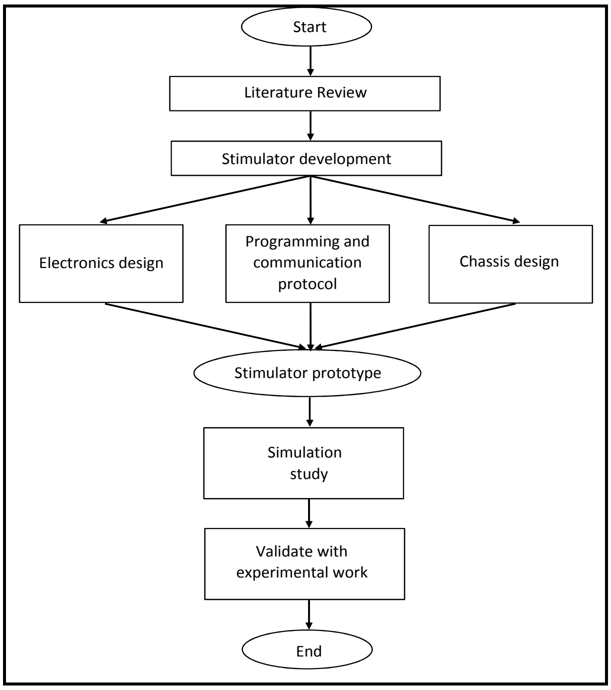

Fig.5: Research flow chart

3.2 Proposed device

The developed device consists of microcontroller, surface electrodes and WPAN (Zigbee module) for system control and data transmission. Validation data will be analysed quantitatively using the appropriate descriptive and inferential statistical of at least one SCI patient. A development of the FES stimulator with a new technique which is low cost is the aim of this research. Fig.6 and 7 are the overall description of the proposed electrical stimulator development. The proposed electrical stimulator can be divided into two units which are controller unit and stimulator unit. The controller unit consists of microcontroller, input interface such as switch and LCD display as an output interface. The stimulator unit will be in the construction of microcontroller, output stage circuit and surface electrodes. Both units will be connected to Zigbee wireless network. The controller will generate signal to the stimulator unit via this wireless network in order to make the stimulator generate stimulus for the paralyzed muscle to contract. In safety point of view, the stimulator unit will monitor the output current level as well as the electrode-tissue impedance and transmit the data via this wireless network to the controller unit as a feedback. Fig.7 shows that the controller unit will be worn at the arm of the paraplegic subject and the stimulator unit will be fixed at a part of the paralyzed leg. Without any wiring interference between the controller and stimulator unit, the movement of the paralyzed lower limbs can be easily generated.

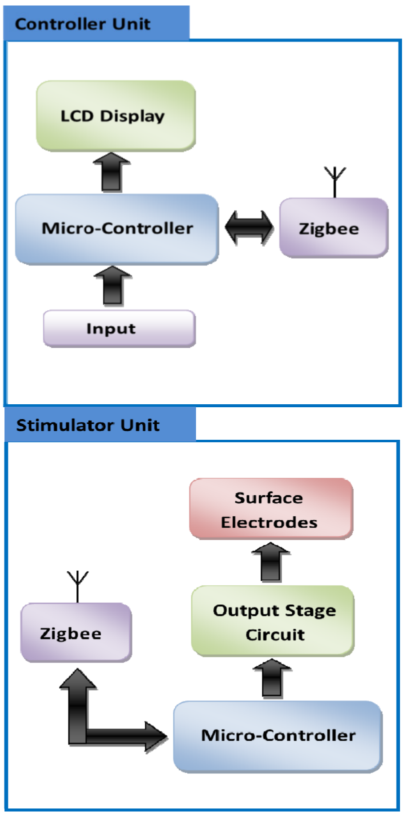

Fig.6: The block diagram of the proposed stimulator system

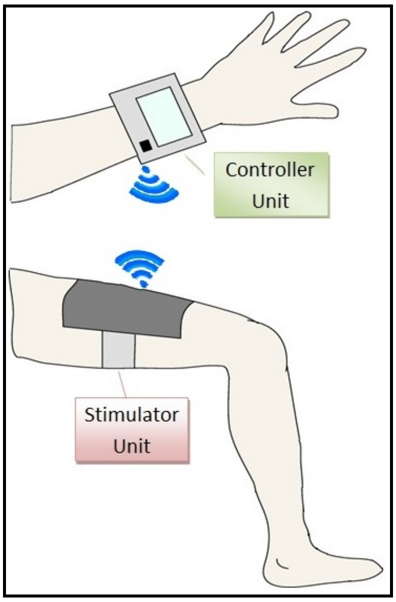

Fig.7: The illustration of the proposed stimulator system

3.3 Hardware design

3.3.1 Microcontroller

A microcontroller is a kind of miniature computer. Unlike a general-purpose computer, the microcontroller is a single integrated circuit which is designed for a very specific task to control a particular system. As a result, it can be simplified to become a low cost and a compact-size that can reduce the power consumption. Although microcontrollers typically have a frequency (speed) less than 20 MHz in the system clock, the frequency is not slow but adequate for typical applications in controlling industrial and home electronic and/or mechanical devices.

Basically, microcontroller contains all of the components which are required to function as a general-purpose computer. The components include a central processing unit (CPU), read only memory (ROM), random access memory (RAM) for data storage, input and output (I/O) ports such as serial and parallel ports, serial communications interfaces, and timers. In some of the microcontrollers, an analog-to-digital (A/D) converter is equipped. Indeed, there are many kinds of microcontrollers which are developed and produced for many specific applications throughout the world. Each of them has its own specific aspect to fit the specific application, for example, in the peripheral functions, the number of bits that can be processed at one time, the speed and the memory size.

In the present study, H8/3694F microcontroller (H8/300H Tiny series) from Renesas Technology was used. The H8/3694F microcontroller is a small-size and low-cost microcontroller that features a high-speed central processing unit compared to other microcontrollers. It has sixteen 16-bit general registers and outstanding peripheral functions required to configure a system such as a 10-bit A/D converter, a serial communication interface, an I2C bus interface and timers which are ideal for real-time control. The H8/3694F microcontroller is driven by 5V power supply and has a maximum system clock frequency of 20 MHz. The memory includes 32K byte ROM and 2K byte RAM. In addition to these, it has a serial programming capability which is re-programmable on flash memory and a free development tool for programming. The program developed at the host PC was transferred and implemented to ROM of the H8/3694F microcontroller through EIA-232 serial communication interface circuit.

3.3.2 Sub-system

The proposed stimulator system consists of three main sub-systems which are output stage interface, safety monitoring system and wireless module interface.

3.3.2.1 Output stage interface

In this research, voltage-current converter has been used as an output stage interface of the stimulator. In this research project, power operational amplifier (LM675) is used which can produce the current output with 3A as the maximum value. As shown in Fig.8, V1 and V2 are the power voltages of the circuit which produces polarity voltage. The V3 is the voltage control of the circuit in producing rated current as an output. V3 is actually controlled by microcontroller through Digital Analog Converter (DAC). Compared to the conventional transformer-based analog circuit, this circuit consists of only basic electronic components which has low development cost and has no bulky and expensive transformer.

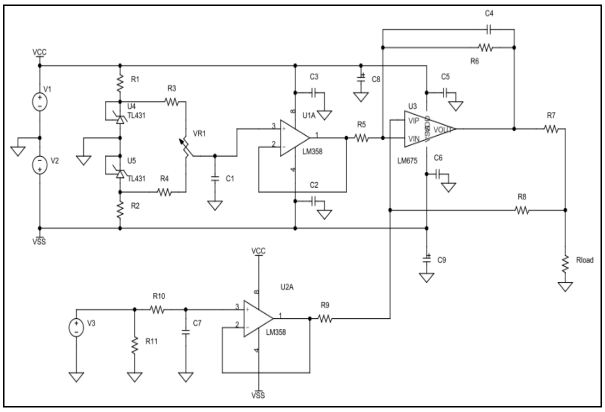

Fig.8: Output stage circuit using voltage-current converter

3.3.2.2 Safety monitoring system

Using the current monitoring circuit with safety relay (as shown in Fig.9), the measured result is compared with a pre-defined reference value and if the measured result exceeds the reference, the stimulator output stage is immediately disabled to prevent nerve damage. The advantage of this approach is volume saving since the monitoring circuit can be integrated with the stimulator output stage circuit. However, the monitoring circuit increases the stimulator complexity which itself increases the probability of semiconductor failure.

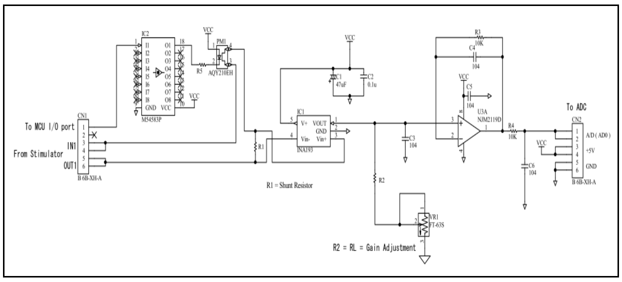

Fig.9: Current monitoring circuit with safety relay

3.3.2.3 Wireless module interface

As shown in Fig.10, wireless Zigbee module has been connected with RS232 serial communication in order to make data transmission between microcontroller in controller unit and stimulator unit of the system.

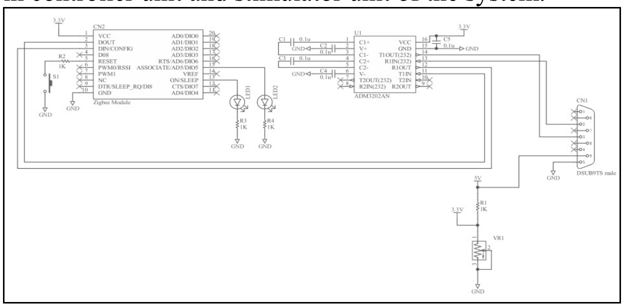

Fig.10: Wireless Zigbee module circuit.

3.4 Software design

In order to develop software programs for the H8/3694F, it is important to have software developing tools such as High-performance Embedded Workshop (HEW) and FDT4.05 which work on a host PC. HEW is used in developing a software program in H8/300H Tiny series microcontrollers such as the H8/3694F. This low cost and free software developing tool provided by Renesas Technology consists of a compiler for C language, an assembler and a linker. The compiler compiles a program that is written in C language into an assembly language program, and then the assembler assembles the assembly language program to several object files. Finally, these files and utility programs are united by the linker, resulting in a machine language program that can be understandable and executable by the H8/3694F microcontroller. Another program developing tool for the ROM (flash memory), FDT4.05, was also provided by Renesas Technology, and used to transfer the program developed on the host PC to the ROM of the H8/3694F microcontroller through the serial communication interface.

3.5 Stimulator Output

Experimental works have been done to evaluate the output stimulus characteristics of the stimulator. In this experiment, 1kΩ of Rload has been selected and it is assumed as an external load of skin surface. Fig.11 and 12 show that the amplitude of the current stimulus can be produced from 10mA to 120mA in range with a step of 2mA and the pulse width of the stimulus can be produced from 10us to 500us in range with a step of 10us. Fig.13

shows the output stage features comparison between the newly developed device and the various type of currently available FES stimulator.

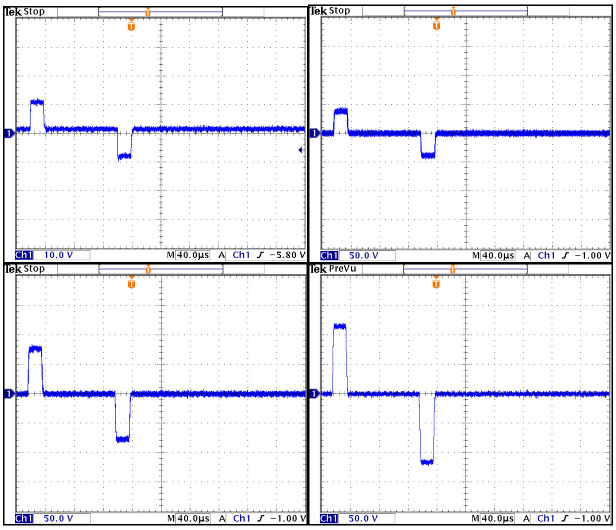

Fig.11: Experimental result of various current amplitude

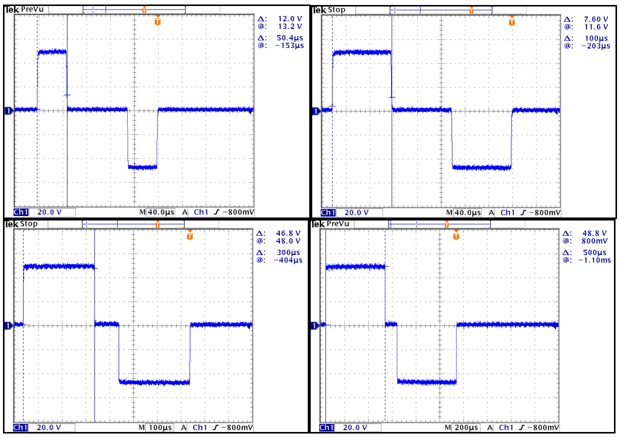

Fig.12: Experimental result of various current pulse width

Table.1: A output stage features comparison between the newly developed device and the various type of currently available FES stimulator

Stimulator	Channel	Amplitude [mA]	Pulse-width(us)	Frequency [Hz]	Waveform type
Parastep	6	0-300	150	24-25	• Constant current • Biphasic/asymmetric
Motionstim8	8	0-125	10-500	1-99	• Constant current • Rectangular • Biphasic/symmetric
Newly developed device	1	0-120	10-500	1-50	• Constant current • Biphasic
HasoMed	8	0-130	20-500	1-50	• Constant current • Biphasic
Compex3	4	0-120	30-400	1-150	• Constant current • Rectangular • Biphasic/symmetric
NueRX DPS RA/4	5	5-25	50-200	5-20	• Constant current • Biphasic

4. Conclusion

In sum, a lot of criteria need to be concerned in developing a safety, accurate, effective and convenient stimulator for patient with SCI. The output stage of the stimulator is the prime criteria which directly affects the safety point of view. The electrode-tissue impedance and the level of the stimulus current are compelled to be monitored. The circuit design of the stimulus generator is the major contributing factor to a high development cost if a transformer or DC-DC converter based circuit are used. In this paper, a simple low cost current adjustable circuit for electrical stimulator was designed and developed whose output consists of current pulses with a wide range of rectangular waveforms (monophasic/biphasic), ranging from 10-120mA with a step of 2mA and a time resolution of 10μs. The circuit also capable of adjusting the current amplitude, frequency and pulse width of the output signals. The advantages of the device are the high level of output current amplitude controlled by low level of control voltage, the capability of fine time and amplitude tuning, the vast range of output waveforms, wireless based system using zigbee module and the use of low cost electronics components in its structure which make it economically efficient for being used in various FES research studies as well. This newly developed device will be a new technique of the stimulator development with low cost for patients with SCI especially paralegic.

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