

Ergonomic and Electronic Designing of Muscle Stimulator

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The paper proposes a new ergonomic and electronic solution for the muscle stimulator. The device is programmable. It can be easily adjusted by the doctor, as well as by the patient. The design solution of this muscle stimulator has the improved interface. The device is safe to use and has determined ergonomic improvements. This muscle stimulator has small dimensions and light weight. The proposal includes a hardware solution using one of the most advanced electronic components MOSFET created on the basis of silicon carbide. The device has a low consumption. The stimulator has excellent electronic properties, while at the same time it is more suitable for handling and use in relation to existing ones. Presented design solutions also have a positive impact on the economic justification for the application of this device.

Keywords: SiC MOSFET, ergonomic design, electronic muscle stimulator.

1. INTRODUCTION

As a result of injury or illness, a certain number of patients are not able to carry out independently muscle activation of some body segment. Due to lesions to motoneurons in either the central command pathway or the spinal cord, or as a result of their combination, loss of muscle mass may occur in these patients. Damage to the central command pathway may result in disuse atrophy. For injuries to spinal motoneurons, on the other hand, muscle fibers undergo denervation atrophy. As a result, one of the tasks of the therapist is to prevent muscle atrophy in such patients, or to return the muscle tone if muscle atrophy occurred to a certain degree.

Discovery and development of electronic components and devices greatly affected the improvement of life quality. Today that impact is more pronounced. Electronic devices have penetrated all segments of man's environment. In this regard, medicine is no exception. Revolutionary change in the diagnosis and treatment was the beginning of electronic biomedical equipment use. Different therapeutic options that provide the electronic biomedical equipment were previously unimaginable. The electronic muscle stimulator is a device used in the treatment of patients with muscular dysfunction. The subject of this paper are certain ergonomic and electronic design improvements of the electronic muscle stimulator model, which was produced in 1994 [1].

2. ELECTRICAL STIMULATION OF MUSCLES

Electrical muscle stimulation (EMS) consists in the induction of muscle contraction using electric impulses. The impulses are generated by the electronic muscle stimulator and delivered through electrodes on the skin in direct proximity to the muscles to be stimulated. The

task of such impulses is to generate a simulation of the action potential coming from the central nervous system, causing the muscles to contract. The electrodes are generally pads attached to the skin.

Electrical stimulation of muscles and nerves to improve recovery of function is successfully used in the following medical conditions [2]:

- After injury to the joints or muscles.

It appears that in these cases electrical stimulation can return motor functions more completely and more quickly than in the absence of this intervention or following voluntary exercise.

- Damage to the central or peripheral nervous system or in the case of muscle diseases.

Motor functions can be improved by electrical stimulation of nerves or muscles. Electrical stimulation has been most widely utilized after spinal cord injury. In addition, particularly designed methods of stimulation of the muscles of spinal cord injury patients are able to initiate and control the movements lost. In patients with head injuries and stroke, electrical stimulation can also help to restore the function.

- Inactivity as a result of long lasting bed rest.

The consequences of such inactivity are also successfully treated by electrical stimulation of muscles. In addition, lack of gravity, such as during space flight, leads to changes of the neuromuscular system that are similar to those during bed rest, and these too can be successfully treated by electrical stimulation.

Determination of the necessary muscle stimulator electronic characteristics requires understanding of the properties of nerves and muscles activation. Three characteristics of electric impulses influence nerve fibers stimulation. These are [3]:

- The value or amplitude of the pulse,
- The rate of change (or rise) of the pulse, and
- The width or duration of the pulse.

The pulse amplitude is important in that the larger the pulse, the nerve fiber more rapidly reaches the threshold (the minimal level necessary for the activation). The rate of pulse change is important because a stimulus pulse that rises slowly to its

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maximum value is less effective than a sharp pulse. If a slow rising pulse is used, then the minimum amplitude that is necessary to elicit an action potential will be greater. The duration of the pulse is also important in that the longer the pulse duration, the fiber has more time to reach the threshold.

When the electronic muscle stimulator is used for therapeutic purposes, two global cases should be distinguished. The first relates to the stimulation of normally innervated muscle, while the second refers to the stimulation of denervated muscle. Depending on that, which of the two previously mentioned cases is subject of the treatment, currents of different characteristics are applied for muscle activation.

Stimulation of normally innervated muscle we have in the case when the nerve supply to the muscle is intact. In that case, transcutaneous electrical stimulation will evoke a motor response, not by the direct effect on the muscle fibers, but indirectly by excitation of the motor nerve fibers. Whatever intensity is applied, the muscle response to transcutaneous electrical nerve stimulation is dependent on the frequency of the stimulus. When a normally innervated muscle is stimulated at low frequencies (5 Hz or less), there is the time for the muscle to relax before the next contraction. It becomes more difficult to distinguish the effects of individual stimulus with a further increase in the frequency. At a stimulus frequency of about 20 Hz, only small wave formation can be seen on the force record. This effect is described as partial tetany. Between 20 and 50 Hz waves completely disappear, the contractile force reaches the plateau. This contraction is described as tetanic [3]. Summative effects of contraction can be obtained by using higher frequencies.

If the stimulus amplitude is high (for example, over 80 V), a very short duration of the stimulus (below 0.05 ms) is necessary to produce minimal muscle contraction. If the stimulus amplitude is smaller, longer time is needed to obtain minimal muscle contraction of the normally innervated muscle.

It was found that by using the electrical stimulation method, muscle strength can be restored even in long-term enervated human muscles. Also, joints can be treated after injury or surgery by using electronic stimulator. Furthermore, by using stimulation of muscle stimulator the mobility of paraplegics and assistance in decubitus prevention can be significantly improved. This can be achieved by applying direct stimulation of muscles. In order to elicit contractions of denervated muscles, the longer duration and higher amplitude stimulus need to be used [2]. However, electrical pulses that take a long time to reach peak amplitude are more effective, unlike stimulation of an innervated muscle, where pulses that rapidly reach peak amplitude are preferred. If the stimulus amplitude is high (for example 80 V), longer duration of the stimulus is necessary (about 4 ms) to produce minimal muscle contraction.

3. ERGONOMIC DESIGN REQUIREMENTS AND IMPROVEMENTS OF MUSCLE STIMULATOR

From the aspect of ergonomics, muscle stimulator should be safe, reliable, anthropometrically shaped and

comfortable, easy to use and suitable for control. In addition, manuals and warnings should be designed according to the ergonomic recommendations. Achieving coherence between the ergonomic demands and the price of product is also a priority.

First of all, muscle stimulator should be safe for the user. Today, at the market a large number of muscle stimulator can be found. The vast majority of these muscle stimulators are not intended for the therapy of injured and ill persons. Their primary purpose is to preserve muscle tone, increase muscle mass and decrease body weight in healthy adults. However, although this type of muscle stimulator is primarily used by the healthy adults, it is shown that its use is not completely safe. A certain number of accidents is recorded in which users suffered burns, bruises and skin irritation. As a result of muscle stimulator use, the muscle pains are not a rare phenomenon. In addition, the cases in which users were exposed to the electric shock are recorded. This situation has influenced the special act regulation of the sale of muscle stimulator in the U.S., which is issued by the U.S. FDA (Food and Drug Administration).

Bearing in mind the hazards that may arise as a result of inadequate muscle stimulator design, special attention was devoted to improving the safety of this device. In this regard, it is necessary to emphasize that this design solution of muscle stimulator meets the requirements prescribed by the U.S. National Electrical Code [4]. In accordance with these requirements, special attention was devoted to the solving of several important details relating to the safety of using this device.

In order to prevent electric shock in a patient, arising as a consequence of the use of devices powered from the electrical network by using the electronic solution it has been achieved the electric power supply of the device with a battery of 9 V. In this way, potential electric shock is avoided, due to the use of high voltage for supply. Also, this independent supply of electrical power contributes to the mobility of the patient, as opposed to devices powered from the electrical network, whose usage depends on the location of a socket.

In order to prevent muscle overload that arises as a consequence of prolonging the time of therapy, the additional software solution is provided (compared to the original version of this device from the 1994). If a patient fails to turn off the device at the time, or fall asleep during treatment, serious injury can occur. However, by using this software solution, the time of the cycle that applies to each individual therapeutic treatment is limited. Predicted duration of one cycle is such that it can not endanger the safety of the patient. The total therapy can contain a greater number of such cycles. In this way, the injuries are prevented that may occur as a result of using an independent device for measuring the time of treatment.

Treatment with the muscle stimulator sometimes involves changing of amplitude and/or frequency of stimulation over the course of a treatment. Treatment, almost without exception, does not start with the maximum values of the stimulation parameters. However, it can happen that a treatment ends with high values of the stimulation parameters. As a result, re-

activating the device can cause difficulty and pain in a patient if the values of parameters were not returned to the initial level prior inclusion. In order to prevent occurrence of such situations, the software solution provides that immediately after inclusion of the device, values of the parameters of stimulation return to the lowest level. Then the parameters' values gradually increase to the ones determined by using the position of the controls. In this way, the maximum load of the muscle is avoided immediately after turning on the device.

Successively bringing of the positive and negative charge to the muscle, an alternate convulsion and muscle relaxation is ensured. However, there is a certain probability that a denervated muscle remains loaded, due to the appearance of certain circumstances (for example, due to the sudden shutdown of device, discharge of the battery, etc.). Unloading of a muscle in such situations is provided in two different ways. First, by using software subroutine, it is regulated that the device may cease to operate only when the muscle is unloaded, i.e. only if the muscle received an equal amount of positive and negative charge. Physically, it is enabled by the appropriate electronic solution, which relates to the component of power electronics of this device.

This device is primarily intended for use in therapeutic purposes. It is envisaged that this device can be purchased in specialized shops. In other words, this device is partly intended for independent use. In order to prevent the possibility of inadequate use of the device and possibility of injury appearance in the patients, the two solutions are foreseen. First of all, in a visible place of the packaging of the device and its manual, the warning is pointed out that the device may not be used, prior the consultation with the doctor. After reviewing the patient, the doctor prescribes the therapy that relates to the use of this device. In other words, the doctor determines parameters of stimulation, within which the patient himself can change the levels of stimulation (in home conditions of treatment). If it happens that the patient inadequately utilizes the device beside the described procedure of use, its momentarily turning off is enabled by using a special switch designed for turning off (turning on) the device. Turning off is accompanied by a previously described procedure of muscle unloading.

In order to assess the consumer product safety, the European Commission has prescribed that the

assessment of risk is performed by using the RAPEX method. Having this in mind, as well as the fact that some products of this type had an impact on the occurrence of accidents, it is necessary to verify the safety of use of this device by applying the aforementioned method. Given that the users of this product are vulnerable persons (injured and ill persons) and likely healthy adult persons (if this device is used for recreation and exercise), the risk assessment will be performed for both of these groups.

First, the assessment for patients with a muscle damage will be done. Bearing in mind all the security measures which are undertaken, the only possible scenario of user injuring is the device use in a manner that is not in accordance with the instruction manual and the doctor recommendations. In this case, the possible types of injuries are burns and muscle overload. In this way, less than 2 % of damage can occur. Such a damage is not permanent and usually does not require hospital treatment. According to RAPEX method, the severity of damage that occurs in this way is classified as "slight".

Taken into account the quality of components that are built into the product and its reliability, the probability of hazardous product is less than 1 %. Having this in mind, and the fact that the hazard may occur under one improbable or two possible conditions, from the table for determination of the overall probability of health/safety damage, we accept the value "low" for the probability of harm.

The final risk assessment of using the muscle stimulator for vulnerable people is performed on the basis of the application of Table 1.

From Table 1 it can be seen that the overall gravity of outcome has a value "very low". With the respect to the value from the table, and the fact that the product is used by the vulnerable persons, the final risk assessment is "moderate risk". This is also the smallest possible value of the risk that can be achieved on the basis of the application of this method, when the assessment for vulnerable persons is done. It can be noted that the risk assessment will not change, even if the product is used by a very vulnerable person. In order to increase the safety, from the additional measures for the risk reduction, it can be recommended usage of the muscle stimulator by the vulnerable persons under the supervision of another person.

Table 1. Assessment of the risk of using the muscle stimulator for vulnerable persons by applying the RAPEX method

	Severity of health/safety damage			Overall gravity of outcome	Vulnerable people	
	Slight	Serious	Very serious		Very vulnerable	Vulnerable
Probability of health/safety damage		Very high	High	Very high	SERIOUS RISK	
	Very high	High	Medium	High		
	High	Medium	Low	Moderate		
	Medium	Low	Very low	Low		
	Low	Very low		Very low		

When the muscle stimulator is used by healthy adults, the scenario of risk occurrence is identical to that which relates to the vulnerable people. Procedure for the assessment of risk also remains unchanged, till the implementation of Table 2, which in this case is used for the final assessment of the risk.

From Table 2 it can be seen that the value overall gravity of outcome has the value of "very low". Bearing in mind that on the packaging of the product and in the manual adequate warnings are given, as well as from the standpoint of electronics all necessary protective measures are taken, and regarding the fact that this device has no hidden hazards, according to Table 2 we get the final assessment of the risk "low risk". Since the lowest possible values for the assessment of risk in both cases are obtained (when the device is used by the vulnerable persons as well as by healthy adults) by the application of RAPEX method, the new design solution of muscle stimulator can be considered as safe for usage.

Special attention is dedicated to design the muscle stimulator controls. The vast majority of muscle stimulators that can be found on the market use some kind of push buttons (keys) to increase or decrease controlled parameters. This type of controls has several shortcomings regarding the application of the device for muscle stimulation. First of all, from the ergonomic aspect, this type of controls is applied only for the discrete control [5]. However, in some cases the therapy may require continuous control of parameters. In addition, the application of these controls for the parameter regulation requires a mandatory application of the analogue or digital display. On the other hand, installation of a display additionally increases the price of the device. Additional aggravating condition is the fact that the application of this type of controls requires fine finger movements and the increased demands of the precision for the regulating, which can pose additional difficulties for some patients.

In order to eliminate these shortcomings, advanced muscle stimulator design solution uses a special modification of pointer knob for regulating the changes of parameters of stimulation. Such controls can be used for discrete control and continuous control. In visual

terms, this control looks like the pointer knob. However, it has the possibility of moving as the round knob, so in addition to discrete control functions, it is suitable for the continuous control of parameters of stimulation. This control does not require a display, thus the device is cheaper. On the device housing, there is the ergonomically designed scale of circular shape, with numerical values of the parameters of stimulation. This scale has a function of analogue visual display and it is designed in accordance with the ergonomic recommendations [6,7]. In this way, the patient is able to easily and precisely regulate the parameters of stimulation. In addition, the dimensions of the pointer knob are specified in accordance with the anthropometric characteristics of man and the ergonomic recommendations. The force necessary for this control activation is analogous to the force for the activation of the round knob. Accordingly, simple and precise regulation of the parameters of stimulation is provided.

The device has one more benefit for the users. The muscle stimulator has a special device which during stimulation intensity adjusting gives the sound signals of different heights. With increasing intensity of stimulation the pitch of sound increases. In this way, the user based on the subjective feeling of the stimulation intensity (by the way of muscle receptors) and the height of the sound, gets the information about the applied stimulation. Sound signals can be excluded if necessary. The application of this acoustic warning signal is particularly suitable for the patients who do not possess the feeling of muscle stimulation, due to the injury.

The device is designed from the anthropometric aspect. This means that the basic dimensions of the device correspond to the anthropometric characteristics of the hand. The device is suitable for operating with one hand only. Small weight of the device also contributes to this. The device has no sharp edges. In order to increase comfort, this muscle stimulator possesses the strip that can be put around the arm or neck of users, so the device can not drop during use. Dimensions of all controls were determined in accordance with ergonomic recommendations.

Table 2. Assessment of the risk of using the muscle stimulator for healthy adults by applying RAPEX method

		Severity of health/safety damage			Overall gravity of outcome	Normal adults				
		Slight	Serious	Very serious		No	Yes	No	Yes	Adequate warnings and safeguards?
Probability of health/safety damage	Very high		Very high	High	Very high					
	High	Very high	High	Medium	High					
	Medium	High	Medium	Low	Moderate					
	Low	Medium	Low	Very low	Low					
	Very low	Low	Very low		Very low					
						No	No	Yes	Yes	Obvious hazard?

One of the main goals in muscle stimulator designing was related to the simplicity of its use. The device has a minimum number of controls that are necessary for the device usage. Each of the controls has only one function, which is realized by using two alternative steps: turn on – turn off, or increase – decrease. The device has two modes, manual and automatic. Manual mode enables that patient manually regulates the change of the parameters of stimulation, according to the limits that are prescribed by the therapy. Automatic mode allows the implementation of therapies based only on pre-programmed therapy by a doctor. In other words, the doctor sets all the software parameters of stimulation, which can not be changed during the treatment in this mode. This mode is suitable for patients with severe damage of muscle – skeletal functions. Activity of a patient, in relation to the controls use, in the automatic regime is based only on the turning on and off the device. It should be mentioned that this device has a special regime, which is solely used for device programming by a doctor (or programmers as needed).

Programming the therapy for the automatic mode performs a doctor. A direct connection to external computer device is enabled. The user-friendly software was designed for placing parameters of stimulation. The software is easy to use. In the most cases, its use requires no special instructions. However, the manner of the device use and the software are presented in detail in the ergonomically designed instructions for use for this muscle stimulator.

4. STRUCTURE OF THE DEVICE

As a control system, early muscle stimulators used standard desktop computers with larger dimensions, for generating the necessary signals. Large dimensions and weight of the device were the significant drawback of these devices, so that the patient was connected to the one place. Later, alternative solutions have been made. Electronic devices became lighter and smaller, but they did not have option of parameters settings, or even programming. The main problems that have occurred during the use of these devices were related to the lack of programmability. The absence of possibilities of the device programming might caused too low intensity of excitation, when desired therapeutic effect cannot be achieved, or on the other hand too high intensity of excitation, when the health and safety of the users can be endangered. Particularly, a big problem was the sudden start of excitation when the device turns on, and the sudden cessation of muscle activation when the stimulator turns off.

With the advent of microcontrollers, it is enabled to create a small programmable muscle stimulator. One such device is developed for international market in 1994 [1]. The controller of the muscle stimulator consists of two units. The first unit is the control part, which basic component is the integrated microcontroller component MC68HC811E2 with internal memory. The second unit is the power electronics unit, which was realized using the analog discrete components. Block diagram of the muscle stimulator is shown in Figure 1.

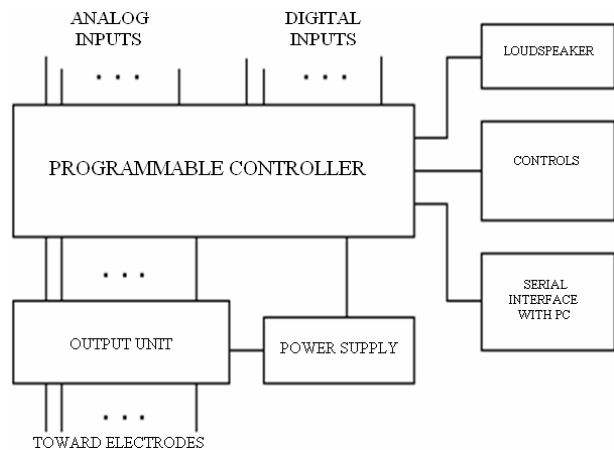


Figure 1. Block diagram of electronic programmable muscle stimulator

5. PROPOSAL FOR FURTHER IMPROVEMENT OF MUSCLE STIMULATOR BY USING THE SiC MOSFET

Owing to its good characteristics, silicon carbide (SiC) based MOSFET (metal oxide semiconductor field effect transistor) [8-15] can be used in output unit of electronic ergonomic muscle stimulator. Energetic converters based on SiC technology can work with much greater switch frequency and with a higher degree of efficiency compared to the standard silicon (Si) based transistors. High switch frequency is very suitable, because the converters then require less capacitance, inductance and the dimensions of the transformer, which reflects in smaller dimensions and weight of the device, as well as lower costs.

Since the SiC MOSFET can operate at high temperatures, there is no need for the incorporation of an additional cooler. This also has direct impact on reducing the size, weight and cost of the device.

It should be borne in mind that SiC MOSFET has less energy losses compared with Si transistors used in other muscle stimulators. Consumption of the device with the proposed type of transistor is thus lower, whereas the life of the battery is longer.

6. CONCLUSION

Researchers and designers are faced all the time with new demands for the Advancement and improvement of existing solutions, or seeking new ones. Development of electronic devices was conditioned by the development of electronic components. Electronic components more and more have better performances and meet increasingly complex demands. These demands are related to the reduction of device dimensions, work in extreme conditions, etc.

In this paper, the electronic muscle stimulator is presented, which is designed with special emphasis on the realization of better and more practical interface between man (user) and the device. The device is also easy to use. The muscle stimulator is also programmable. It is realized modularly. It possesses two basic hardware units and within them several sub-assemblies, so that they can be easily examined and tested, and if necessary,

expanded, or possibly changed. The device has its own power supply from the standard battery. It possesses a long life battery and low consumption, which significantly affects the quality of device. Particularly, it is proposed that the output level of the muscle stimulator, as well as the power level, should contain MOSFET based on silicon carbide, instead of standard silicon transistor. SiC MOSFET belongs to the most advanced electronic components. Improving the quality of muscle stimulator reflects in 1) improving the global performances of the electronic device, which enables full implementation of any prescribed treatment regime of muscle stimulation 2) improving the interface man – muscle stimulator as well as improving the other ergonomic properties of device and 3) reduction of the consumption and the price of the device by application of SiC MOSFET, and by application of ergonomic solutions to the controls of this device.

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ЕРГОНОМСКО И ЕЛЕКТРОНСКО ДИЗАЈНИРАЊЕ МИШИЊНОГ СТИМУЛАТОРА

Петар Лукић, Александар Жуњић

У раду је предложено једно ново решење за мишићни стимулатор. Уређај је програмабилан, може се једноставно подешавати од стране лекара, као и од стране пацијента. Дизајнерско решење овог мишићног стимулатора поседује унапређени интерфејс. Уређај је безбедан за употребу и поседује одређена ергономска побољшања. Овај мишићни стимулатор је малих димензија и мале тежине. Предлог хардверског решења укључује коришћење једне од најсавременијих електронских компоненти *МОСФЕТ*-а, израђеног на бази силицијум-карбида. Уређај има малу потрошњу. Стимулатор има одличне електронске карактеристике, а у исто време је погоднији за руковање и употребу од постојећих. Презентована дизајнерска решења такође имају позитиван утицај на економску оправданост примене овог уређаја.