Principles of Organization and Control of the New Implementation of the “SYMPATHOCOR-01” Neuro-electrostimulation Device

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Keywords: Neuro-electrostimulation, Mobile Device, Device Control, Device Organization, “SYMPATHOCOR-01”

Abstract: The paper describes peculiarities of the organizational and control principles of the new implementation of the “SYMPATHOCOR-01” device. Necessity of the device division into two blocks, having different functions, was justified. The specifics of the schematic implementation were mentioned. Advantages of the wireless connection between two blocks were shown. Particular possibilities and actual implementation of the control block via Android application for mobile devices were presented. The potential targets for the neuro-electrostimulation that affect autonomic processes were considered.

1 INTRODUCTION

It is well known that combination of several kinds of stimulation, each of which provides different types of physiological reactions of damaged cognitive, autonomic, motor, sensory and vestibular functions, achieves the best efficiency in the process of neurorehabilitation. This is necessary for the specific attraction of new neuronal resources into the damaged neural network, which provides rehabilitated function (Enriquez-Geppert *et al.,* 2013). This principle has been used for a long time in the creation of the effective programs for the physical rehabilitation by means of the transcutaneous electrical muscle stimulation (Nagai *et al.,* 2016).

According to modern science concepts, addition of the physical and cognitive load to the process of neurorehabilitation can increase the production of neurotrophic factors and activate the mirror neuron system (Yuan *et al.*, 2015). The neurotrophic factors implement the neuroplasticity of the brain mechanisms. At the same time, mirror neurons are able to remodel lost functions (Reichardt, 2006).

Devices that are compact, portable and do not cause discomfort for patients during rehabilitation procedures are the most promising for the combination of several kinds of stimulation during treatment process. At present time, many neuro-electrostimulation devices that meet these requirements are designed.

Neuro-electrostimulation devices, which use low-frequency current pulses with single polarity, are among the perspectives types of the neuroelectrostimulation. The duration and frequency of such devices commensurate with the duration of nerve pulses and the frequency of their appearance in neural networks.

The number of corresponding devices decreases dramatically, if one exclude devices with implanted electrodes. Non-invasive neuro-electrostimulation devices, that include multi-electrode systems, have greater opportunities for activation of the brain neuroplasticity mechanisms, compared to other devices, due to the redundancy of the information generated by their spatially distributed current pulses fields.

Two original multi-channel portable systems for non-invasive stimulation of the tongue (PoNS device) (Danilov and Kublanov, 2014) and the neck area (“SYMPATHOCOR-01” device) (Kublanov 2008) are fully satisfied of these requirements.

The “SYMPATHOCOR-01” device is included in the register of medical equipment products of the Russian Federation and has the Certificate of correspondence to the requirements of the Safety. The Manual for its use was approved by the State Control of the quality, effectiveness and safety of the medicines and medical equipment Department of the Russian Ministry of Health.

This article discusses the features new technical

Kublanov V., Babich M. and Dolganov A.
Principles of Organization and Control of the New Implementation of the âĂIJSYMPATHOCOR-01âĂİ Neuro-electrostimulation Device.
DOI: 10.5220/0006175802760282

implementation of the compact and mobile “SYMPATHOCOR-01” device. The device is aimed for application in neurorehabilitation tasks that imply using of several kinds of stimulation.

2 NEURO-ELECTROSTIMULATION TARGETS

The basis of all human mental activity are the processes in the central nervous system. It should be noted that the role of the cerebral circulation: mental performance (attention, memory and perception, logical thinking) is reduced at the deterioration of blood supply to the brain. This feature determines the search for solutions to manage the blood supply of the brain. Therefore, those physiological mechanisms of the sympathetic nervous system are fundamental which allows to control the tone of the blood vessels of different caliber.

The most important formations that are involved in the organization of the neuro-electrostimulation are:

- glossopharyngeal nerve and its branches;
- vagus nerve and its branches;
- the accessory nerve;
- the nerve plexus around the carotid artery;
- the sympathetic trunk structures
  - upper cervical node;
  - middle cervical node;
  - vertebral ganglion;
  - stellate ganglion;
- spinal nerves C2-C4 forming the cervical plexus.

Figure 1 shows the conventional areas of the nerve structures location in the neck region.

Regulating centers of the vital functions are placed in the nuclei of the brain stem, midbrain, pons and the cerebellum, in the autonomic nuclei of the brain and spinal cord. Many of the mentioned pathways are located in the neck.

The nervous formations of neck area are closely associated with brainstem, which have two-side connections with midbrain, cerebellum, thalamus, hypothalamus and the large brain cortex. Presence of these connections provides participation of the neck nervous formations in analysis of sensory stimulation, regulation of the muscle tonus, autonomic and the highest integrative functions (Netter, 2010).

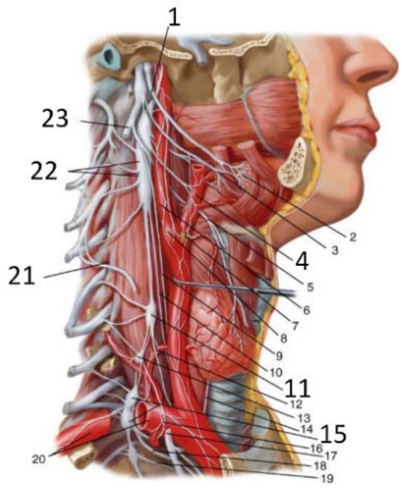

Figure 1: Conventional areas of the nerve structures location in the neck: 1 – n. glossopharyngeus; 4 – n. plexus caroticus externus; 11 – ganglion cervicale medium; 15 – ganglion stellatum; 21 – ramus communicans griseus; 22 – ganglion cervicale superius; 23 – n. vagus.

As a stimulation targets can be used:

- the superior cervical ganglia of the sympathetic nervous system;
- the stellate ganglion;
- other components of the sympathetic trunk;
- the afferent branches of the cervical plexus;
- cranial nerves and their branches (IX, X and XI pair).

These targets are the conductive paths of the brain stem nerve structures. Usage of them significantly extends the capabilities of the neuro-electrostimulation method (Kublanov and Babich, 2015).

The stimulation of neck nodes of the sympathetic trunk affects both the vascular tone of arteries of the brain, and autonomic spinal nucleus. Thus, neuro-electrostimulation device is able to fully modulate the autonomic processes and affect motor control and cognitive functions.

3 ORGANIZATION OF THE “SYMPATHOCOR-01” DEVICE

The “SYMPATHOCOR-01” is the non-invasive neuro-electrostimulation device that performs stimulation by the spatially distributed current pulses field using two multi-electrode (ME) systems. ME systems are placed symmetrically on the neck skin, in projections of the sympathetic nervous system neck ganglion.

Partial current pulses that flows from partial cathodes of one ME system to single anode of the other ME system carry out the stimulation process. Partial current pulses have the amplitude, ranging from 0 to 15 mA; the duration, ranging from 15 to 60 us; the modulation frequency from 5 to 150 Hz. For the neuro-electrostimulation process from 1 to 13 partial cathodes can be involved.

3.1 General Structure

The “SYMPATHOCOR-01” device consists of two blocks. First block has autonomous power source (built-in Li-ion battery) and forms the spatially distributed field of current pulses. The energy consumption of the first block reaches 47 mA. Time of the continuous operation reaches 22 hours.

Second block sets characteristics of the spatially distributed current pulses field, field’s configuration in the neck area, based on functional state of the autonomic and central nervous systems of the patient. Personal computer or mobile device can be used as the second block.

Fig. 2 presents the block-scheme of the “SYMPATHOCOR-01” device.

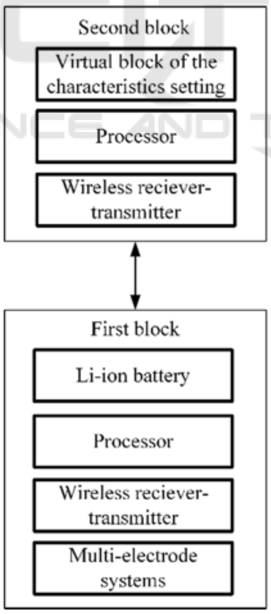

Figure 2: Block-scheme of the “SYMPATHOCOR-01” device.

The built-in processors control both blocks. The wireless communication channel provides connection between two blocks. Each block has a built-in receiver-transmitter. The Bluetooth Low Energy technology is used as the wireless communication channel. The second block implement virtual block of the characteristics setting as the graphical user interface accessible to the doctors.

The wireless communication channel between two blocks has possibility to perform the information transfer using unique addresses of the receiver-transmitters, placed in both blocks. Therefore, it is possible for one doctor to organize management of simultaneous neuro-electrostimulation for group of patients by means of single second block.

The block-scheme of the “SYMPATHOCOR-01” organization in case of simultaneous neuro-electrostimulation of two patients is shown on Fig. 3.

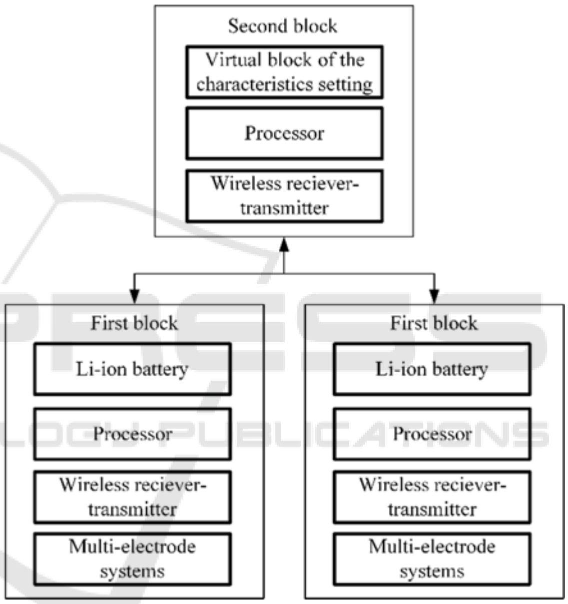

Figure 3: Block-scheme of the “SYMPATHOCOR-01” device organisation for two patients.

3.2 The First Block Structure

The division of the “SYMPATHOCOR-01” device into two blocks, in comparison with older releases, allowed to exclude user interface used by doctor, and to simplify the processor installed in the first block. Simplification of the first block processor arisen from shifting of particular functions to the second block. Because of that the first block was implemented as mobile and compact device with the following dimensions: 90.0 × 50.0 × 18.5 mm. The general view of the “SYMPATHOCOR-01” device first block is shown on Fig. 4. Fig. 5 shows general view of the main printed circuit board (PCB) in the “SYMPATHOCOR-01” device first block.

8-channel chips of the Analog Devices ADG5408 multiplexers are the basis for commutation of the partial cathodes and anodes. In the present implementation of the neuro-electrostimulation device, four chips are used. In this case, it is possible to use in the stimulation process up to 16 partial cathodes and 16 anodes.

Three bipolar transistors (two BC807 and one BC817) implement current source of the neuro-electrostimulation by means of the current mirror. The built-in 12-bit digital-to-analog converter generates control voltage of the current source. The resistor values of the current mirror were selected in a way that current source generates current with the amplitude in a range from 0 to 15 mA, with load in range from 0 to 2 kOhm.

The algorithm of the current pulses field formation, implemented in the first block processor is shown on Fig. 6.

Figure 4: General view of the first block.

Figure 5: General view of the first block printed circuit board.

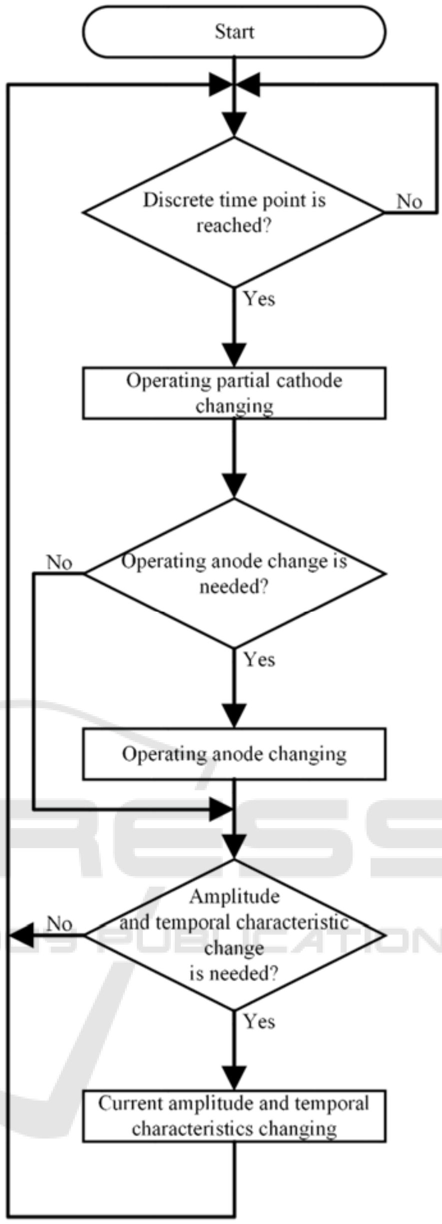

Figure 6: The algorithm of the field formation.

Change of the current pulses field state is possible only in certain discrete time points. These time points are defined by the equation

$$t = \frac{a}{\nu} + n * \tau, \quad (1)$$

where: $a \in N$, $n \in N$, $0 \leq n \leq K$, K – the number of the partial cathodes used in the neuro-electrostimulation, τ – the duration of the partial pulse, ν – the modulation frequency of the current pulse field.

The processor performs the following steps for i-th time point:

- Consequent turning off the previously connected cathode and turning on the following cathode in accordance with the neuro-electrostimulation program;
- Changing of the anodes, in case of the respective requirements of the neuro-electrostimulation program or by doctor command;
- In case of new target values of the amplitude, the duration, the modulation frequency of the partial current pulses, set by the second block of the device, changing of the respective characteristics in accordance with the following equations:

$$A_{\mathrm{i}} = \begin{cases} A_{\mathrm{target}}, \left|A_{\mathrm{i}-1} - A_{\mathrm{target}}\right| < \Delta_{\mathrm{A}} \\ A_{\mathrm{i}-1} + \Delta_{\mathrm{A}}, A_{\mathrm{i}-1} + \Delta_{\mathrm{A}} < A_{\mathrm{target}} \\ A_{\mathrm{i}-1} - \Delta_{\mathrm{A}}, A_{\mathrm{i}-1} - \Delta_{\mathrm{A}} > A_{\mathrm{target}} \end{cases} \tag{2}$$

$$T_{\mathrm{i}} = \begin{cases} T_{\mathrm{target}}, \left|T_{\mathrm{i}-1} - T_{\mathrm{target}}\right| < \Delta_{\mathrm{T}} \\ T_{\mathrm{i}-1} + \Delta_{\mathrm{T}}, T_{\mathrm{i}-1} + \Delta_{\mathrm{T}} < T_{\mathrm{target}} \\ T_{\mathrm{i}-1} - \Delta_{\mathrm{T}}, T_{\mathrm{i}-1} - \Delta_{\mathrm{T}} > T_{\mathrm{target}} \\ T = 1/\nu \end{cases} \tag{3}$$

$$\tau_{\mathrm{i}} = \begin{cases} \tau_{\mathrm{target}}, \left|\tau_{\mathrm{i}-1} - \tau_{\mathrm{target}}\right| < \Delta_{\tau} \\ \tau_{\mathrm{i}-1} + \Delta_{\tau}, \tau_{\mathrm{i}-1} + \Delta_{\tau} < \tau_{\mathrm{target}} \\ \tau_{\mathrm{i}-1} - \Delta_{\tau}, \tau_{\mathrm{i}-1} - \Delta_{\tau} > \tau_{\mathrm{target}}, \end{cases} \tag{4}$$

where: A – the amplitude of the partial current pulses, A_{target} – the target amplitude of the partial current pulses, Δ_{A} – the maximum amplitude increment, T_{target} – the target period of the current pulses, ΔT – the maximum period increment, τ_{target} – the target duration of the partial pulse, Δ_{τ} – the maximum duration increment.

Usage of the constraint to the rate of the characteristics change allowed preventing pain feelings during the neuro-electrostimuation process.

3.3 The Second Block Structure

Currently, the second block control program is implemented as the application for the mobile devices with the operational system Android 4.2.2 and higher. Fig. 7 shows general view of the graphical user interface for the application.

The application allows one to control and change the amplitude, duration and the modulation frequency of the partial current pulses, to switch the currently used anode and to change field direction in real time.

The characteristics of the partial current pulses can be set by either using the seek bar or through direct value setting in the corresponding fields, to the right of seek bar elements. For the amplitude changes buttons of coarse (‘+1’, ‘-1’) and fine (‘+0.1’, ‘-0.1’) change were additionally implemented. This addition allowed preventing pain feelings caused by unreasonable amplitude increase.

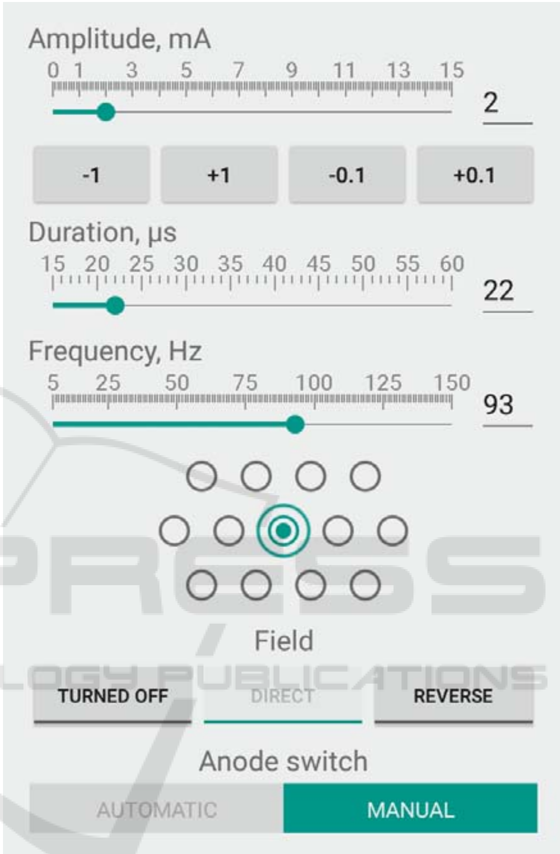

Figure 7: General view of the graphical user interface.

The group of radio buttons are used for switching of the current anode. The pattern of the radio buttons placement is similar to the pattern of the partial electrodes placement of the ME systems.

The filed state can be either ‘Turned off’, or ‘Direct’ or ‘Reverse’. Three corresponding buttons on the graphical user interface control the field state. The ‘Reverse’ state changes role of the ME systems.

In present time, two modes of the currently used anode switch are implemented: ‘Manual’ and ‘Automatic’. In case of manual mode, the doctor switch currently used anode based on functional state of the patient. In case of automatic mode, currently used anode switch in accordance with the specific neuro-electrostimulation algorithm.

4 RESULTS

In the present time, the efficacy of the "SYMPATHOCOR-01" device was proven both, for prenosological state of the pathology development and for patients treatment, suffering from the disorders of the cognitive, autonomic, motor, sensor and vestibular functions. The "SYMPATHOCOR-01" device is used in more than 200 Russian hospitals (Kublanov *et al.,* 2010). The device is applied for correction of the following pathologies:

- migraine;
- neurocirculatory dystonia;
- alcohol and narcotic abstinences;
- hypertonic diseases;
- obliterate atherosclerosis of the lower limbs;
- Raynaud's disease;
- trigeminal nerve inflammation;
- sensorineural deafness;
- degenerative diseases of vision;
- atrophy of the optical nerve;
- osteochondrosis of the back bone;
- neuropathies of various genesis;
- cephalalgia syndrome;
- hyperhidrosis syndrome;
- syndrome of the orthostatic hyposthenia;
- postural tachycardia;
- vestibular disease;
- vegetative deregulation syndrome;
- epilepsy;
- attention deficit hyperactivity disorder.

New mobile implementation of the "SYMPATHOCOR-01" device can be used for the neuro-electrostimulation in combination with different kinds of the stimulation. This extends the application of the device for the following directions:

- treatment of the cognitive disorders caused by the cranial injuries, strokes, neuroinfections during the athrophic diseases of the human brain;
- treatment of the depressive and anxiety disorders;
- improvement of the senso-motor coordination and recovery of the autonomic functions for patients with brain circulation disorders;
- rehabilitation of the military personnel;
- target transport of the drugs in the local areas of the organism;
- preventative medicine;
- recovery of the sportsmen in the training period and during the competitions in the sport medicine.

Table 1 presents comparison of electrical and ergonomic characteristics of the new and old technical implementations of the "SYMPATHOCOR-01" device. The standard laboratory equipment, which includes oscilloscopes and the power supply, were used for comparison of the characteristics. A system of resistors, that connects all cathodes and all anodes at the same point, was used as an equivalent to biological material.

Table 1: Comparison of characteristics of the new and old technical implementations of the "SYMPATHOCOR-01" device.

Characteristic	Old technical implementation	New technical implementation
Number of partial cathodes	12	13
Number of partial anodes	1	13
Weight	1.5 kg	200 g
Dimensions, mm	186x116x60	90x50x18,5
Amplitude of the partial pulses	0 - 25 V	0 - 15 mA
Frequency of the pulse field modulation, Hz	15 – 100	5 – 150
Length of the partial pulse, µs	35 – 50	15 – 60
Set of the field's parametres	Switchers on the panel of the device	Wireless channel by means of Bluetooth Low Energy

Also device with new technical implementation is capable of changing program of the neuro-electrostimulation and conducting procedures on multiple patients by single second block.

Comparative analysis of the data in table 1 shows the increase of the possibilities of the device in neuroreabilitation tasks due to decrease of weight and device proportions. New implementation of the device does not cause any discomfort to patient during the procedures. In addition to that, application of the wireless channel simplify combination of the neuro-electrostimulation with other kinds of stimulation used in the rehabilitation. The ability to change program of the neuro-electrostimulation as well as availability of the multiple partial anodes allows to involve in the stimulation process not only neck ganglia, but also influence on the stellate ganglion, the afferent branches of the cervical plexus, cranial nerves and their branches as well as other components of the sympathetic trunk. All in all, abovementioned improvements significantly enhance possibilities of the new technical implementations of the "SYMPATHOCOR-01" device in neurorehabilitation tasks.

5 CONCLUSIONS

The article describes new technical implementation of the "SYMPATHOCOR-01" device. Implementation of the device as the two block allowed to improve ergonomic characteristics, to make the device mobile and compact, to realize the simultaneous stimulation of the patients group by single doctor. Presented in the article analysis of the organizational and control principles of the "SYMPATHOCOR-01" device new implementation revealed the innovative possibilities in the neurorehabilitation tasks. Device mobility and wireless control allow doctors to combine several kind of stimulation including cognitive and motor loads and neuro-electrostimulation using "SYMPATHOCOR-01" device.

The next step of device implementation is automatic real-time recording of the functional changes in the central and autonomic nervous systems. This recording will allow us to improve informational control of the treatment management and to increase treatment efficiency.

ACKNOWLEDGMENTS

The work was supported by Act 211 Government of the Russian Federation, contract № 02.A03.21.0006.

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