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Research Article

Mobile Hardware-Information System for Neuro-Electrostimulation

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The article describes organizational principles of the mobile hardware-informational system based on the multifactorial neuro-electrostimulation device. The system is implemented with two blocks: the first block forms the spatially distributed field of low-frequency monopolar current pulses between two multielement electrodes in the neck region. Functions of the second block, specialized control interface, are performed by a smartphone. Information is exchanged between two blocks through a telemetric channel. The mobile hardware-informational system allows to remotely change the structure of the current pulses field, to control its biotropic characteristics and to change the targets of the stimulation. Moreover, it provides patient data collection and processing, as well as access to the specialized databases. The basic circuit solutions for the neuro-electrostimulation device, implemented by means of microcontroller and elements of high-level hardware integration, are described. The prospects of artificial intelligence and machine learning application for treatment process management are discussed.

1. Introduction

What has the twenty-first century brought to the humanity? Scientific and technological progress in modern society has led to an increase in the duration and improvement of the quality of human life, as well as maintenance of high efficiency and intellectual activity. These processes are taking place at a time of growing mental stress caused by unstable economic development and unpredictable crisis situations, local wars, interethnic conflicts, and natural disasters. The health of the population, which is the basis of the well-being and harmony of human civilization, is deteriorating. The most disturbing is the growth of chronic stress and mental disorders, personality disorders. As a result, a person is losing the ability of efficient information processing, cognitive control, and decision-making, the basic mechanisms of the social version are violated. In the field of neurology and psychiatry, there has been a catastrophic increase in the number of lost years due to movement, coordination, sensitivity, speech, intelligence, and memory disorders [1].

As noted by World Health Organization, among 56.9 million deaths worldwide in 2016, ischemic heart disease and stroke are the world's biggest killers, accounting for a combined 15.2 million deaths. These diseases have remained the leading causes of death globally in the last 15 years. Deaths due to dementias more than doubled between 2000 and 2016, making it the 5th leading cause of global deaths in 2016 compared to 14th in 2000 [2].

Every year, more than 795,000 people in the United States have a stroke. About 87% of all strokes are ischemic strokes, in which blood flow to the brain is blocked. Stroke is a leading cause of serious long-term disability. Stroke reduces mobility in more than half of stroke survivors age 65 and over. Stroke costs the United States an estimated $34 billion each year. This total includes the cost of health care services, medicines to treat stroke, and missed days of work [3].

The most common approach for treating such diseases is a neuroprotective therapy, which helps normalize and strengthen the physiological activity of brain tissue. During neuroprotective therapy, medicines are predominantly used. But physiotherapeutic methods of restorative medicine can be also applied [4].

Of all the variety of physical fields and methods, the most promising are spatially distributed fields of monopolar low-frequency current pulses whose structure and characteristics are adequate to endogenous processes in the human body [5–8].

2. Materials and Methods: Multifactorial Neuro-Electrostimulation of Neck Nervous Structures and Organization of Control Process

Personalized multidisciplinary approach to the organization of the patient's treatment process is promising for increase of the neuro-electrostimulation effectiveness. It implies to actively use neuro-electrostimulation in addition to various procedures of neurorehabilitation for triggering mechanisms of neuroplasticity in management of the brain functional processes [9].

The choice of the neck as a target for neuro-electrostimulation is determined by the location in it: centers of segmental control for vital functions (*cervical sympathetic ganglia*) and the conducting pathways of the suprasegmental centers of the homeostasis regulation (*glossopharyngeal* and *vagus nerves* and their branches, as well as the *cervical plexus* of the spinal nerves) [10]. In the deep muscles of the neck there are nodes of the *sympathetic trunk*, formed by the nervous processes of the *autonomic nuclei* of the spinal cord. The *upper*, *middle*, and *lower* (*stellate*) *sympathetic nodes* have numerous branches that enable sympathetic innervation of glands, meninges, vessels of the head, neck, and spine. The afferent fibers of the *spinal plexus* located on the posterior surface of the neck pass through the *posterior horns* of the spinal cord and end in the sensitive nuclei of the brainstem and the reticular formation. Near the main arteries of the neck lies the *vagus nerve*. The nuclei of the *vagus nerve* are located in the brainstem and are common to the *glossopharyngeal nerve*. They have extensive connections with the *hypothalamus*, olfactory system, and reticular formation. Together, the *glossopharyngeal* and *vagus nerves* activate parasympathetic innervation of most organs. Nerve formations in the neck are closely related to the *brainstem*, through which they have two-way links to the *pons*, *middle brain*, *cerebellum*, *thalamus*, *hypothalamus*, and *cerebral cortex*. The presence of these relations ensures the involvement of the neck nervous structures in the analysis of sensory stimuli, the regulation of the muscle tone, and autonomic and higher integrative functions [11].

With electrostimulation of the *cervical spinal plexus*, branches of the *vagus nerve*, *nervus accessorius*, and *glossopharyngeal nerve*, the gray matter of the brainstem can be stimulated along the afferent pathways. Through the reticular formation, the effect in this case extends to the *thalamic structures* and the *cerebral cortex*. The stimulation of the nodes of the *sympathetic trunk* makes it possible to influence both the vascular tone of the cerebral arteries and the autonomic nuclei of the spinal cord. As a result of these actions, it is possible to influence various functional processes in the brain tissues, modulate autonomic processes, and influence motor control and cognitive functions.

The next step in creating a promising neuro-electrostimulator suitable for providing comprehensive rehabilitation is the selection of the best solutions for organizing the architecture of the neuro-electrostimulator, taking into account the characteristics of the conducting pathways of the neck nervous formations.

3. Results: Selection of Basic Circuit, Engineering, Hardware, and Software Solutions

The analysis of tasks that are implemented in modern physiotherapy devices for recovery medicine shows that, as a rule, two tasks are performed in them:

(1) Formation of a physical field in the problem area of the body

(2) Regulation of characteristics of the physical field, which form a biological effect

Generally, such devices are constructed as the single block units and tend to have relatively high mass-dimensional characteristics [12–15].

Let us note that operationally, the first task is functionally "tied" to the patient and the second to the physician. In our case, we divide the neuroelectrostimulation device into two blocks, one of which will solve only the first task; the second block will only solve the second task. The information exchange between them will be provided by a telemetric communication channel, like Bluetooth. Then, according to this principle, a new architecture of the promising neuro-electrostimulator can be organized, which will make it compact and mobile [16]. This applies equally to the first block and to the second.

The implementation of the first block as compact and mobile one is quite realistic, as only the following components are mandatory:

(i) Two multielement electrodes, between which a spatially distributed field of current pulses is formed

(ii) Multichannel impulse current source, whose functions are performed by two multiplexers and a controlled current source

(iii) Accumulator

(iv) Bluetooth transmitter

(v) Flash memory

(vi) Microcontroller unit

Core features of the first block:

(a) Number of partial cathodes: 13

(b) Number of anodes: 13

(c) Mass, 200 g

(d) Dimensions, $90 \times 50 \times 18.5$ mm
(e) Current pulse amplitude, 0–15 mA
(f) Partial pulse duration, 15–60 μs
(g) Modulation frequency, 5–150 Hz
(h) Minimal time of autonomic work, 24 h
(i) Accumulator charging socket, USB Mini B

Diagram of the neuro-electrostimulator is presented on Figure 1, photo of the first block on Figure 2, and photo of the first block's printed circuit board on Figure 3.

The flowchart of the first block functioning algorithm is shown on Figure 4.

The program of the algorithm application is implemented as a set of tasks. Tasks that are not critical to the launch period are performed in the main program loop. Such tasks include first block unit testing, synchronizing cathodes pattern, and stimulation targets between first and second blocks, calculating amplitude for each cathode.

The tasks that are critical to the launch period include starting a new pulse packet and starting a new partial pulse inside pulse packet. This tasks forms current pulses field structure, sets up biotropic parameters, and determines stimulation targets. The critical to the launch period tasks has a higher priority and their starts are initiated by interrupt signals from the built-in microcontroller peripherals.

The current pulses field structure changing is possible only in a determined time points.

$$t = \frac{a}{\nu} + n * \tau, \tag{1}$$

where $a \in N$, $n \in N, 0 \leq n \leq K$, K is the number of partial cathodes participating in field structure, τ is the partial pulse duration, and $T = 1/\nu$ is the current pulses field structure modulating period.

When the current pulses field structure changing time point t occurs, microcontroller in the first block performs the following steps:

(1) Switching off the current partial cathode and switching on the new one according to neuro-electrostimulation program. If the current partial cathode is the last one in accordance with neuro-electrostimulation program, then a new partial cathode will not be connected.

(2) If the anode needs to be changed according to the neuro-electrostimulation program or by the physician's command from the second block, the current connected anode will be disconnected and a new anode will be connected.

(3) If current amplitude and time characteristics of current pulses field structure (such as modulating period T, partial impulse duration τ, and partial impulse amplitude A) differ from the target ones, then the characteristics is changing according to following equations:

$$\begin{aligned}
A_{i+1} &= \begin{cases} A_{\text{target}}, & \left|A_i - A_{\text{target}}\right| < \Delta_A, \\ A_i + \Delta_A, & A_i + \Delta_A < A_{\text{target}}, \\ A_i - \Delta_A, & A_i - \Delta_A > A_{\text{target}}, \end{cases} \\
T_{i+1} &= \begin{cases} T_{\text{target}}, & \left|T_i - T_{\text{target}}\right| < \Delta_T, \\ T_i + \Delta_T, & T_i + \Delta_T < T_{\text{target}}, \\ T_i - \Delta_T, & T_i - \Delta_T > T_{\text{target}}, \end{cases} \\
\tau_{i+1} &= \begin{cases} \tau_{\text{target}}, & \left|\tau_i - \tau_{\text{target}}\right| < \Delta_\tau, \\ \tau_i + \Delta_\tau, & \tau_i + \Delta_\tau < \tau_{\text{target}}, \\ \tau_i - \Delta_\tau, & \tau_i - \Delta_\tau > \tau_{\text{target.}} \end{cases}
\end{aligned} \tag{2}$$

The use of restrictions on the growth rate of the current pulses field structure parameters of neuro-electrostimulation avoids the appearance of patient's painful sensations during treatment procedure. The application for control of the field structure of current pulses and its characteristics of a microcontroller makes it possible to implement a large number of programs for neuro-electrostimulation.

Aforementioned computational procedures are required to implement the functions of the second block: when specifying the structure of the spatially distributed field of current pulses and the characteristics of this field, as well as the formation of various commands. These tasks can be handled on the basis of a computer or any specialized computation units that, in essence, will perform the functions of a specialized interface of the neuro-electrostimulator. To ensure the compactness and mobility of this specialized interface, we have chosen a smartphone.

The second unit of the neuro-electrostimulator is implemented in the form of an original cross-platform application for mobile devices based on Android, iOs, and Windows Phone. The application is structurally implemented in the form of two activities: the search for the first block and the control of the stimulation process. To organize the operation of the telemetric communication channel, the Bluetooth low energy API is used. In this case, a virtual control panel for the medical process is formed, which allows the physician to monitor the battery charge level in real time, the telemetry communication channel serviceability, the current pulse field structure, their biotropic parameters, and the position of the stimulation targets. Figure 5 shows a picture of specialized neuro-electrostimulator interface display in the virtual control panel mode of the treatment process.

Thus, the implementation of a neuro-electrostimulator in the form of two blocks will allow for the performance of the functions of restorative medicine:

(1) For a patient to form a spatially distributed field of current pulses for the organization of a multifactorial neuro-electrostimulation of the neck nervous

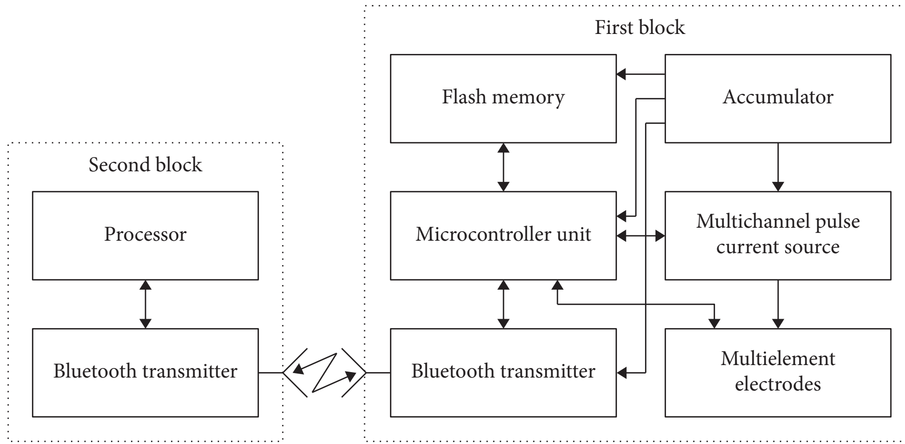

Figure 1: Diagram of the neuro-electrostimulator.

Figure 2: The first block of the neuro-electrostimulator

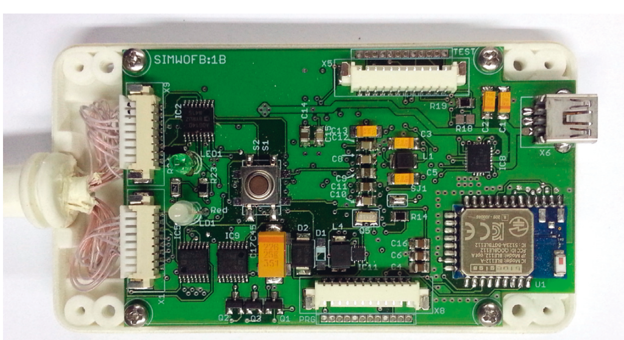

Figure 3: Printed circuit board of the first block.

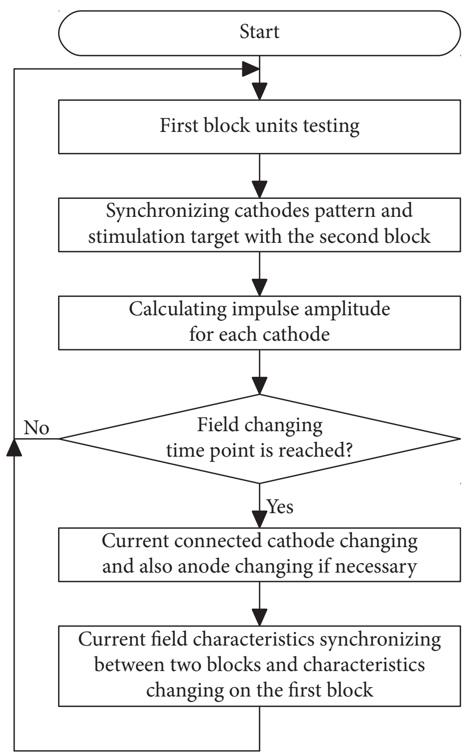

Figure 4: The first block functioning algorithm.

(2) For the physician to obtain wide opportunities for virtual management and control of the medical process, including the following:

(a) In real time to monitor the operation of the first block of the neuro-electrostimulator, including monitoring the level of charge of its battery
(b) Change the structure of the spatially distributed field of current pulses in the neck region, their parameters (amplitude, frequency, and duration)
(c) Choose targets for the impact in the projection of the *sympathetic trunk*, *carotid plexus*, *cervical spinal plexus*, *vagus nerve*, *nervus accessories* and branches of the *glossopharyngeal nerve* by selecting respectable functioning anodes
(d) Change the number of partial cathodes participating in the formation of the field
(e) Control the formation of a spatially distributed field of current pulses in the neck region in several patients (up to 10) via a telemetry channel using a single smartphone
(f) Use the potential of telemedicine technology through the organization of remote monitoring of the rehabilitation process by highly qualified medical personnel

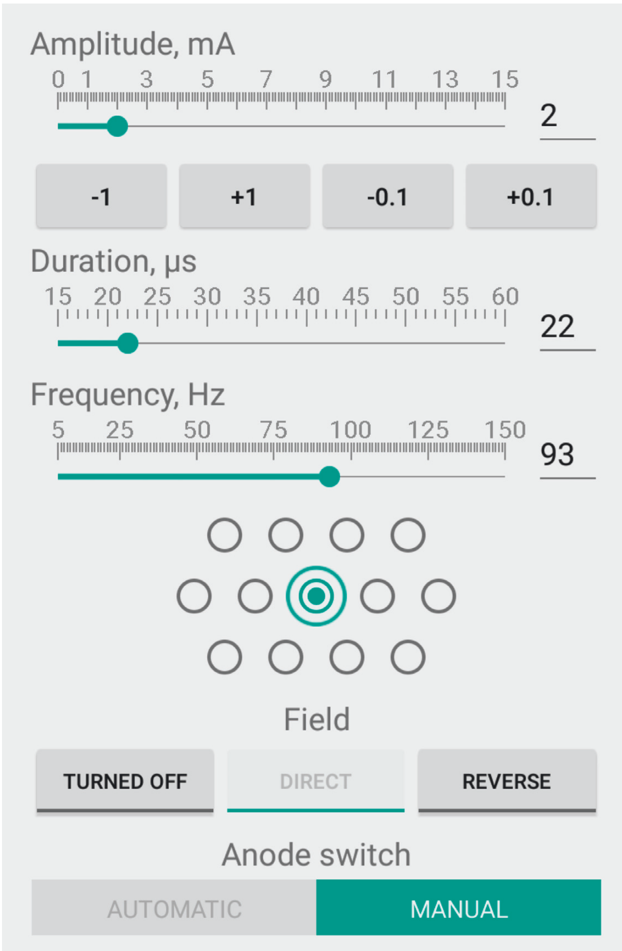

Figure 5: Specialized neuro-electrostimulator interface display.

(g) Ensure the collection and processing of data on changes in the functional status of patients with an option to monitor the treatment process

(h) Access to specialized databases of neuro-rehabilitation, storing personalized information about the course of the treatment process

The structure of such specialized database, named the neuro-electrostimulation service, implemented as a database model in the notation "Entity-Relationship" is shown in Figure 6.

Core elements of the database are entities (tables):

(i) «Physician», having lines physician_id; Name, Surname

(ii) «Patient», having lines patient_id; Name, Surname; Age; Sex; physician_id

(iii) «Procedure», having lines procedure_id, physician_id, patient_id, Date, procedure type (examination, neuro-electrostimulation procedure, functional load), device_id

(iv) «Device», having lines device_id, physician_id, patient_id, Stimulation features

(v) «Data», having lines data_id, physician_id, patient_id, procedure_id, Data type (arterial pressure, electrocardiography signal, biochemical tests, psychological tests), Content

The proposed structure provides quick access to information on the treatment process available for a particular patient, allows storing and systematizing registered data, and making decisions for management of treatment based on this data. The use of such a database allows the formation of complex search queries that can be used for further analysis and processing.

4. Discussion: Prospects of Artificial Intelligence Application for Neurorehabilitation Management

At present, high hopes are placed on the use of artificial intelligence and machine learning for use in the diagnosis and control of the therapeutic process [17–19]. Thus, in our early work on the clinical example of arterial hypertension, it was shown that the application of quadratic discriminant analysis and methods for selecting diagnostic features of heart rate variability signals allows not only to perform express diagnostics of arterial hypertension, but also to evaluate the effectiveness of the therapeutic process with the use of neuro-electrostimulation [20]. Thus, it is possible to create an information decision support system for a physician.

The use of artificial intelligence in determining the paradigm of rehabilitation personally for each patient is made possible by taking into account the opportunities of telemedicine. As noted earlier, the specialized interface of the neuro-electroimulator control is implemented as an application for a smartphone. A smartphone can interact with a global computer network. This allows not only to transmit the information generated in the neuro-electrostimulator, but also to obtain information from the specialized databases, to support the decision-making of the physician in treatment. Thus, the aforementioned information decision support system can be integrated with the neuro-electrostimulation service for the purpose of information exchange. The interaction of the neuro-electrostimulation service with the information decision support system provides express diagnostics of the cardiovascular system regulation disorders.

Creation of the neuro-electrostimulation service allows to close the contour of the physician and patient interaction and implements the functions of the biotechnical system for neurorehabilitation. The structural diagram of the biotechnical system is shown in Figure 7.

Such biotechnical system implements a number of principles of the patient-oriented approach in health care, such as personalized medicine and active involvement of the patient in the medical process. The presence of the neuro-electrostimulation service solves the problem of storing registered diagnostic data centrally on the server of the medical institution, simultaneous work with several patients

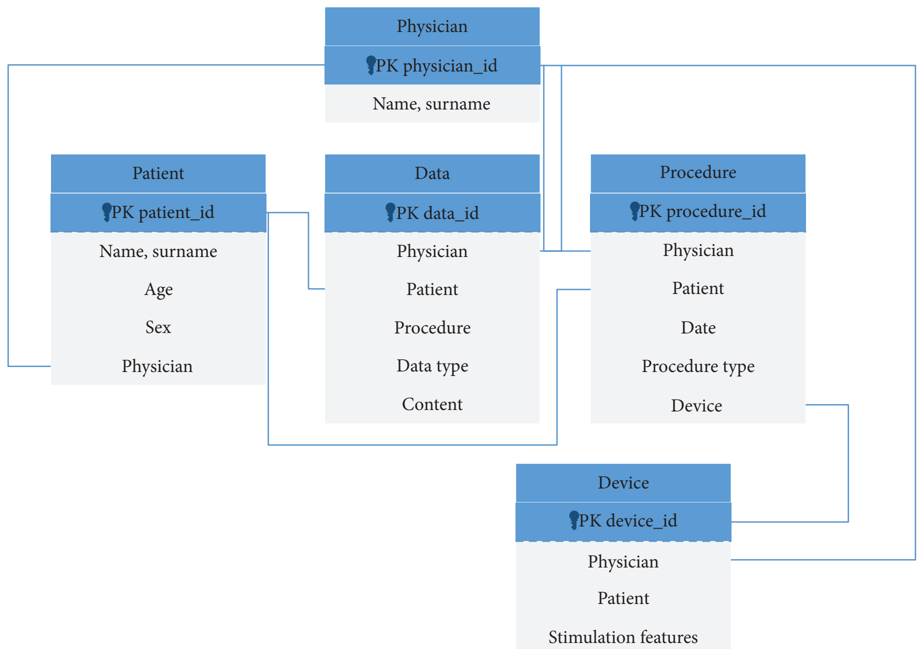

Figure 6: The neuro-electrostimulation service.

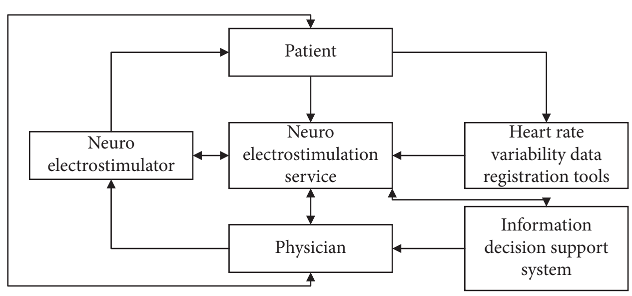

Figure 7: Biotechnical system for neurorehabilitation.

and effective use of the resources of the medical institution, and protection of patients' personal data from unauthorized access. The result of the interaction between the neuro-electrostimulation service and the information decision support system is the processing and automated analysis of the patient's data by means of machine learning to obtain express assessments for the diagnosis of arterial hypertension and the effectiveness of the therapeutic process, tracking the dynamics of changes in patient data, and information support by means of artificial intelligence for a physician.

5. Conclusion

As suggested in the article, principles of organization, circuit, and engineering solutions allowed to create mobile and compact hardware-information system for neurorehabilitation. Application of artificial intelligence and machine learning opens possibilities for treatment process management in accordance with the personalized medicine principles.

At present, the neuro-electrostimulation device has undergone clinical approbation in the treatment of depressive anxiety disorders, children with attention deficit disorder, and rehabilitation of patients after traumatic brain injuries. Clinical studies have shown that in comparison with known methods, a higher effectiveness of treatment is achieved through involvement in the regulatory process in addition to the autonomic nervous system and brain structures responsible for cognitive, motor, visual, auditory, vestibular, and other brain functions. These results are presented in more detail in the specialized publications of our physician co-authors [21, 22].

Data Availability

The data used to support the findings of this study are available from the corresponding author upon request.

Conflicts of Interest

The authors declare that they have intellectual property rights in the field of use reported in this article.

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