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«КИЇВСЬКИЙ ПОЛІТЕХНІЧНИЙ ІНСТИТУТ
імені ІГОРЯ СІКОРСЬКОГО»
ФАКУЛЬТЕТ БІОМЕДИЧНОЇ ІНЖЕНЕРІЇ
(повна назва інституту/факультету)

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Дипломна робота
на здобуття ступеня бакалавра

зі спеціальності 163 «Біомедична інженерія»
(код і назва)

на тему: Моделювання впливу електростимуляції на тканини нервової системи

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“ ____ ” ______________2021

Diploma thesis

for a bachelor's degree

in the specialty 163 « Biomedical engineering »
(code and name)

topic: Nervous system behavior simulation under electrostimulation

Completed: 4th year student, group BM-73i
(group code)

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“ ____ ” ________________2021

TASK
For student`s bachelor thesis

Stefany Pineda
(Full Name)

1. topic Nervous system behavior simulation under electrostimulation

scientific supervisor of the dissertation Ass. dep. BMI M. Kozii
(last name, first name, patronymic, academic degree, academic title)

approved by the order of the university №257 / 19-si from 11/18/2021

2. The deadline for students to submit a dissertation 05.12.2021

3. The object of study is Nervous system

4. the subject of research is simulation under electrostimulation

5. List of tasks to be developed An analytical review was carried out, on the basis of which medical requirements were formulated and a structural scheme was developed. The electric principled scheme was assembled and the accuracy of its work in the MC 9 environment was checked. A printed circuit board was designed and a prototype of

the device for neurostimulation was manufactured. Technical and medical tests have been performed.

6. Approximate list of graphic material 16 tables, 18 figures

7. Approximate list of publications: the bachelor thesis protection

8. Final deadline ______07.06.2021______

SCHEDULE

№ з/п	Name of stages of execution diploma thesis	Deadline for stages diploma thesis	Note
1	Review of existing patents and how tDCS works and possible brain stimulation zones.	10.11.2020	
2	Modeling of biological objects and current generator in Micro-CAP software	26.02.2021	
3	Development of a prototype of the device and checking it for compliance with the technical task.	12.03.2021	
4	Safety and precautions	24.05.2021	
5	Registration of bachelor thesis	01.06.2021	
6	Getting a review and feedback	04.06.2021	
7	Passing norm control	07.06.2021	
8	The bachelor thesis protection		

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Supervisor of the dissertation ____________________ Mykola Kozii
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РЕФЕРАТ

Тема дипломної роботи: «Моделювання впливу електростимуляції на тканини нервової системи».

Обсяг роботи становить 63 сторінки, міститься 28 ілюстрацій, 22 формули, 16 таблиць. Загалом опрацьовано 43 джерела.

Актуальність**:** відсутність вітчизняної обґрунтованої теоретичної бази впливу tDCS на мозок людини. та відповідних приладів.

Мета**:** створити та випробувати пристрій для tDCS, який буде відповідати сучасним вимогам, враховуючи економічний аспект.

Завдання:

1. Здійснити огляд літератури за темою роботи.
2. Сформулювати медико-технічні вимоги.
3. Розробити структурну та електричну принципову схеми приладу.
4. Створити еквівалентну модель досліджуваного об’єкту.
5. Спроектувати схему в DipTrace.
6. Виготовити схему на друкованій платі.
7. Створити та випробувати прототип.
8. Порівняти результати випробувань і моделювання.

Основні результати: було здійснено аналітичний огляд, на його основі сформульовано медико технічні вимоги та розроблено структурну схему нейростимулятора. Проведено комп’ютерне моделювання електростимуляції. Розроблено електричну принципову схему і перевірено правильність її роботи у середовищі MC 9. Спроектовано друковану плату та виготовлено прототип пристрою для нейростимуляції. Проведено технічні та медичні випробування.

Ключові слова: нейростимуляція, транскраніальна стимуляція, прецизійне джерело струму, трасування схеми, схема електрична принципіальна, електромагнітна сумісність, метод Монте-Карло.

ABSTRACT

Theme of the thesis: “Nervous system behavior simulation under electrostimulation”.

The size of the report is 58 pages, contains 29 illustrations, 22 formulas, 16 tables. In total, there have been processed 43 sources.

The relevance is: the absence of a national substantiated theoretical basis for the influence of tDCS on the human brain and appropriate devices.

The objective is: to create and test a tDCS device that meets modern requirements, taking into account the economic aspect.

Task:

1. To review the literature on the topic of work.
2. To formulate medical and technical requirements.
3. To develop a structural and electrical principle diagram of the device.
4. To create an equivalent model of the object under study.
5. To design the schematics in DipTrace.
6. Make a circuit diagram on a circuit board.
7. Create and test the prototype.
8. Compare test results and modeling.

Main results: An analytical review was carried out, on the basis of which medical requirements were formulated and a structural scheme was developed. The electric principled scheme was assembled and the accuracy of its work in the MC 9 environment was checked. A printed circuit board was designed and a prototype of the device for neurostimulation was manufactured. Technical and medical tests have been performed.

Key words: neurostimulation, transcranial stimulation, precision current source, tracing of the circuit of electrical principle, electromagnetic compatibility, Monte Carlo method.

CONTENT

LIST OF CONDITIONAL ABBREVIATIONS

EOP - Endogenous opioid peptides

MC9 – Micro-Cap 9 software

tES (tDCS) - Transcranial direct current stimulation

INTRODUCTION

Electrotherapeutic procedures based on the action of current are often used for the treatment and prevention of diseases. Despite the spread of electrotherapy, the mechanisms of action and characteristics of stimuli in various biological structures have been insufficiently studied. The development of technology has created the conditions for a new vision of the method of stimulation, and the development of the theory of bioelectric impedance of living tissues opens up new possibilities in describing the processes of life of the human body.

Recent scientific studies [1,2,3] show that transcranial direct-current stimulation (tDCS) can improve cognitive abilities not only in the treatment of diseases, but also in completely healthy people.

Scope of tDCS - patients with diseases: central nervous system (cerebral palsy, mental retardation, the consequences of infectious and traumatic injury to the brain and spinal cord); peripheral nervous system; disorders of speech, visual, auditory functions; neuroses and neurosis-like states; degenerative-dystrophic processes; for disease prevention, healthy lifestyle; general recovery of the body, etc.

Relevance: the absence of a domestic substantiated theoretical basis for the effect of transcranial stimulation with direct current on the human brain, and appropriate devices for its implementation.

The aim of the thesis is to create and test a device for tDCS, which will meet modern requirements, taking into account the economic aspect.

To achieve this goal, it is necessary to solve the following tasks:

1. Review the literature on the topic of the work.
2. Formulate medical and technical requirements.
3. Develop a structural and electrical schematic diagram of the device.
4. Create an equivalent model of the object under study.
5. Design a circuit in DipTrace.

6. Make a diagram on a printed circuit board.
7. Create and test a prototype.
8. Compare test and simulation results.

CHAPTER 1
ANALYTICAL INSPECTION

1.1 Neurostimulation and its development

Neurostimulation is a method of influencing the nervous system through electrical signals. Applications:

- electrical stimulation of peripheral nerves;
- neurostimulation of the spinal cord;
- stimulation of deep structures or cerebral cortex. [4]

The tDCS method was originally considered as a purely medical technology and has been used successfully for the treatment of depression, chronic pain, and stroke recovery. Gradually, scientists have found that tDCS can be used to improve the cognitive abilities of perfectly healthy people (see table 1.1). [5]

Table 1.1 - Development of neurostimulation

Period	Events
End of the 18th century.	Luigi Galvani studied the effect of electrical energy on living tissues [6].
Early 1800s	Giovanni Aldini passed electricity through the heads of dead people, resulting in muscle contraction and even eye opening [6].
In 1964	Joe Redfirn discovered that by passing a weak (50-250 mA) current through electrodes placed at specific points on the scalp, he could achieve a variety of effects. Depending on the direction of the current, those who wish to become sociable and talkative, or silent and withdrawn, can use it. However, because colleagues were unable to replicate these experiments, the research data was quickly forgotten [6].
In the 1990s	The introduction of transcranial magnetic stimulation (the exposure of the brain to a low-frequency magnetic field) reignited interest in this type of research [6].
In 1993	Alberto Priori demonstrated that tES improves the efficacy of subsequent transcranial magnetic stimulation, but his colleagues simply did not believe him - they questioned the ability of the electric current to penetrate the skull [6].
In 1998	Priori managed to convince the scientific community of his rightness [6].
In 2008	DARPA, the US military's research arm, conducted a study that found that using tDCS in military training doubles the effectiveness of volunteer training [3].

Continuation of table 1.1

In 2010	Roy Cohen Kadosh, a professor at Oxford University, has shown that tDCS improves math skills. Volunteers memorized invented symbols denoting numbers from 1 to 9 and performed mathematical operations with them [3].
In 2011 and 2012	A team of scientists led by Alan Snyder established that tDCS improves thinking creativity. Volunteers who received transcranial temporal lobe stimulation completed tasks three times faster than those in the control group [3].
In 2013 and 2014	According to research conducted by a group of Dutch scientists led by Anna Goodrian, tDCS reduces addiction to nicotine, alcohol, and even cocaine. German scientists led by Kerstin Altmans discovered that after a one-day effect of tDCS on healthy volunteers, the number of calories consumed decreased by 14% [3].
In 2015	A team of American scientists led by Roy Hamilton published a meta-analysis demonstrating that tDCS improves language ability. Specifically, the ability to memorize new words and the speed of speech [3].

A large number of scientific studies have demonstrated that neurostimulation has significant potential, is developing at a fairly rapid pace, and is of great interest to scientists around the world.

1.2 Analogs of neurostimulation

After conducting a patent search of existing devices, a comparative table of analogues was created - table 1.2.

Table 1.2 - Comparison of the created device with foreign analogues

Name of parameters	Our prototype Ukraine	"Polaris" RF [7]	tDCS with Limited Total Energy (1x1 tDCS-LTE) US[8]	Transcranial Alternating Current Stimulation (1x1 tACS) US[9]	Transcranial Electrical Stimulation (1x1 tES) US[9]
1. Range of stimulating currents, tDCS, mA	0.01-1.0	0.01-5.0	0.5; 1; 1.25; 1.5	-	1, 1.5, 1.75, 2
2. Current reference step, mA	0.05	1μA to 1mA 10 mA from 1-5 mA	-	-	-

Continuation of table 1.2

3. Setting of the session duration range, min.	5-40	10-50	5-20	10-40	10-40
4. Setting of the session duration time, min.	5	5	5	10	10
5. Stimulation scheme (number of anodes× number of cathodes)	1×1	1×1 2×1	1×1	1×1	1×1
6. Number of channels	1	2	1	1	1
7. Indication of contact quality	-	-	+	+	+
8. Termination of the session in case of electrodes-skin contact interruption	-	+	-	-	-
9. Energy injection rate stabilization mode	+	-	+	-	-
10. Time of continuous work from the accumulator, h	20	4	3	3	3

Notes:

1. tDCS - Transcranial Direct Current Stimulation;
2. tACS - Transcranial Alternating Current Stimulation;
3. tES - Transcranial Electrical Stimulation: tDCS (direct current stimulation), tACS (alternating current stimulation);
4. Plots of these currents (Fig. 1.1)

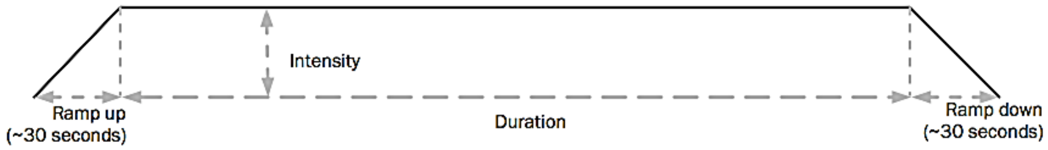


Figure 1: Active tDCS waveform

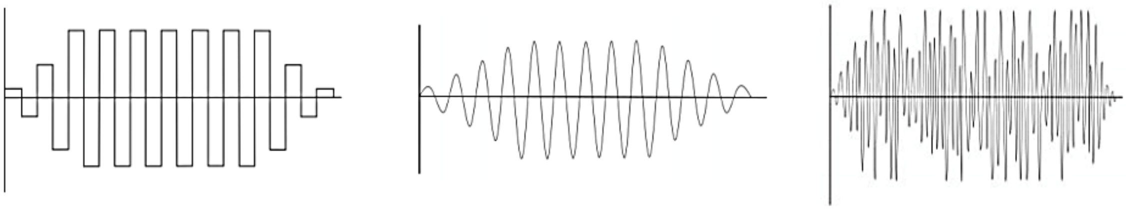


Figure 2: Active tPCS waveform (left). Active tACS waveform (middle). Active tRNS waveform (right). All waveforms depicted are bipolar.

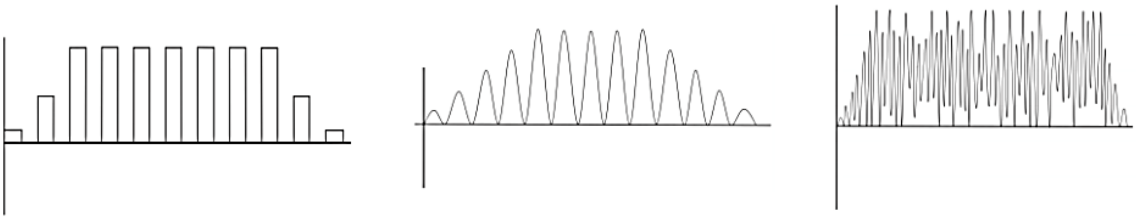


Figure 3: Active tODCS waveforms. tODCS is generated from unipolar versions of Figure 2: Pulsed (left), Sine (middle), and Random Noise (right).

Figure 1.1 - Signal forms for neurostimulation [9]

The shape and parameters of the stimuli are important factors in current stimulation, they also determine the effectiveness of the procedure.

1.3 Transcranial stimulation

tDCS (tES) is a non-invasive effect of a weak current on the brain to change its functioning. [10].

tES therapy is one of the first methods that has been shown to non-invasively, selectively, and loosely activate the work of structures that produce endogenous opioid peptides. EOP is the most important system of the body that regulates the neuro-immune-endocrine function. tES selectively activates the EOP structures of the brain, producing β-endorphin, using a pulsed electrical effect supplied through the main skin electrodes.[11]

An increase of β-endorphin in the blood leads to increased immunity, accelerated healing processes in the body and slow the growth of tumors. At the same time there is an increase in the same hormone in the brain, which has a positive effect on blood pressure, reducing drug and alcohol dependence, as well as gives the effect of analgesia.[12]

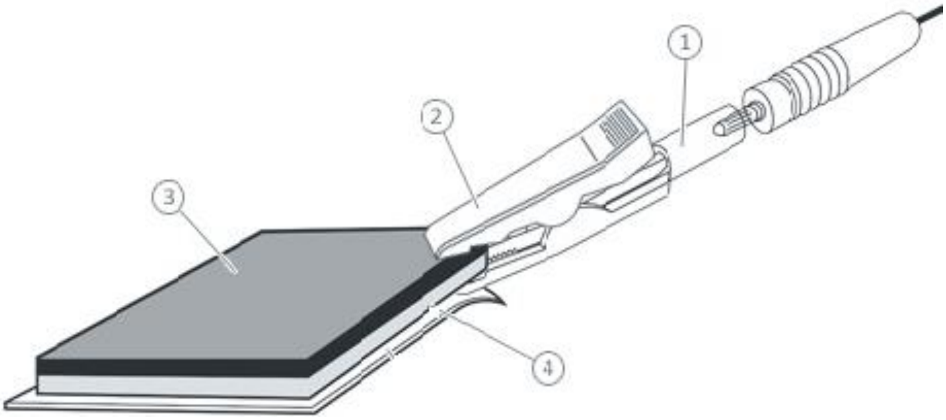
tES-therapy is based on long-term studies that revealed the relationship between the degree of activation of the image intensifier and the main characteristics of the applied pulse current (the shape of the pulses, their repetition rate, and duration). It has been established that the EOP system can be activated selectively and reproducibly only in a very narrow range of pulse current characteristics. [11]

1.4 Use of electrodes during stimulation

In the created device for transcranial stimulation, the electrodes are an important functional part of the device-patient system. A review of the patent and technical literature showed that various electrically conductive materials are used in the construction of electrodes.

The neurostimulation technique is quite simple, consisting of supplying a direct current through two electrodes connected to opposite poles of the device. In their composition, the electrodes include a metal or any other material that conducts current, a plate, and a so-called hydrophilic gasket. As an electrode, lead plates with thicknesses ranging from 0.3 to 1 mm are most commonly used. Other metals that can be used include aluminum, foil and platinum. Sheet lead electrodes are useful because they can easily conform to the shape of the body surface to which they are applied, they can be of any configuration, also they conduct electric current well. [13]

To prevent the damaging effect of electrolysis products on the tissue, a hydrophilic gasket is placed between the human body and the electrode (Fig. 1.2).



1 - conductive system, 2 - contact plate, 3 - electrical distribution layer, 4 - hydrophilic gasket

Figure 1.2 - Electrode with hydrophilic gasket [14]

It is made of light materials that easily absorb water (gauze, flannel, calico, fleece, bombazine). It cannot be made of woolen or colored fabrics. The hydrophilic gasket should have the same shape as the electrode and should protrude 1-2 cm^2 beyond the electrode's edges. The shape and size are designed to contribute to the uniform distribution of current over the area of stimulation, reducing the risk of skin burns caused by the concentration of electricity in the areas of skin contact. The thickness of the gasket should be more than 1 cm. The cathode and anode must be separated by hydrophilic gaskets. After completing the work, the gaskets must be rinsed with running water, sterilized, boiled, and dried. Separately, the anode and cathode gaskets should be washed and boiled. The uniformity of the electrode and the gasket to the body plays an important role. If the contact is uneven, the current density will not be consistent throughout, which can result in burns. Considering this, the pads should not have wrinkles, therefore, they must be well smoothed before use.

The intensity of exposure is determined by the strength of the current, which is expressed in milliamperes (mA). The maximum permissible current is calculated by the current density indicator, the current per 1 cm^2 of the active electrode area (mA / cm^2). To calculate the maximum current strength, multiply the density value by the electrode area, which is the size of the gasket surface. The area of the active electrode, the location of exposure, individual sensitivity to current, age, and gender of the patient all influence the current density value. The current density decreases as the area of the electrode increases. When using electrodes with different areas, the area of the smaller electrode is used to calculate the amperage. When the cathode or anode is doubled, the total area of these electrodes is used for calculation. [15]

1.5 tDCS operation principle

During stimulation, two electrodes are applied to the head (Fig. 1.3): the anode (positively charged) and the cathode (negatively charged). The first reduces the potential difference on the membranes of nerve cells and increases their excitability. The second, on the contrary, reduces the difference so that the neurons are less excited when receiving an external signal. The anode and cathode are attached to different parts of the head depending on what cognitive function you want to develop. Sometimes the anode is enough, then the cathode is attached to the shoulder. [16]

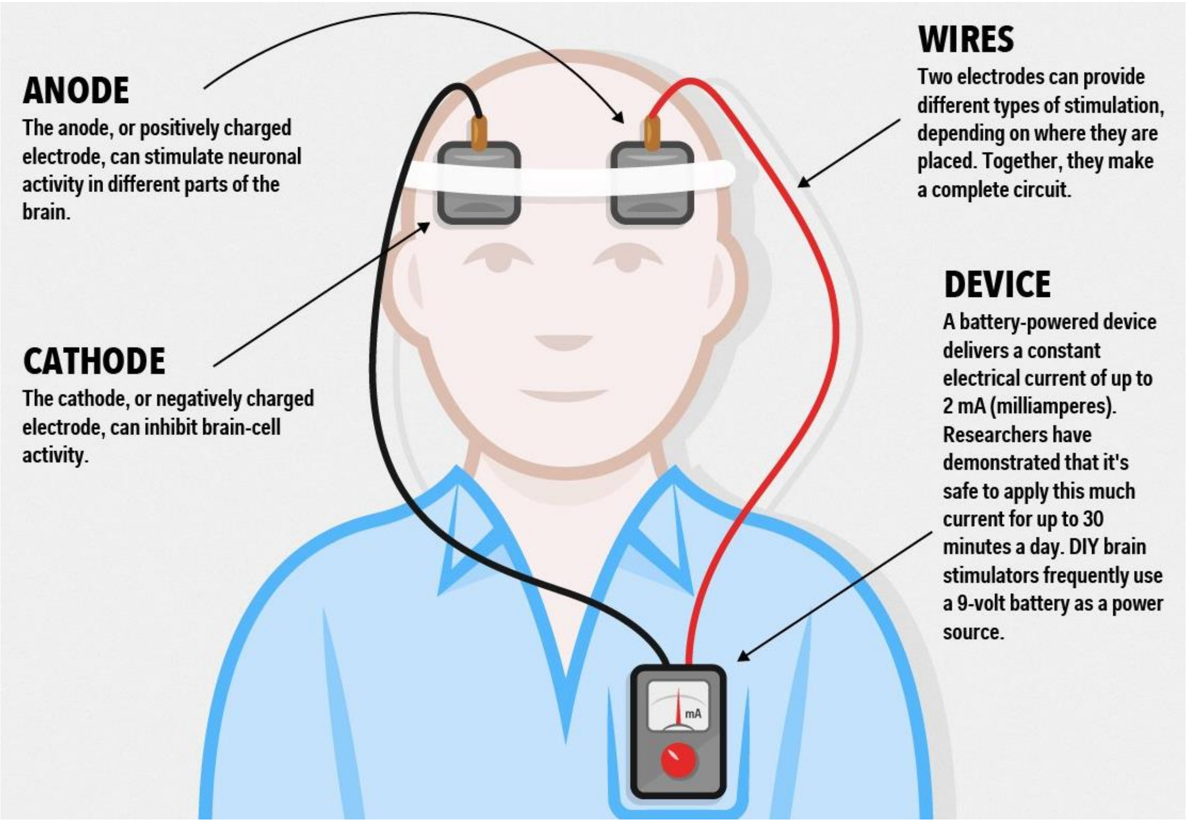


Figure 1.3 – The principle of transcranial stimulation [10]

By placing the anode and cathode on specific areas of the head, the user can stimulate the corresponding brain functions. tDCS is performed once a day for 40 consecutive minutes. It is necessary to start stimulation with a current of 0.6 mA and gradually increase it to 2 mA. There may be tingling and burning in the area of attachment of the electrodes, as well as flashes of light in the eyes. In case of discomfort, it is recommended to reduce the current strength to a comfortable level.

Sometimes the effect of tDCS is observed after one session, but in most studies it was necessary to undergo stimulation for 5-10 consecutive days. The effect of tDCS can last from 1 hour to several hours, days and even months, depending on the area being stimulated and the type of effect. After completing a 5-10-day course, a break of 2-3 months should be taken before the next course. In order to improve a certain cognitive function, it is recommended to perform tDCS while doing this activity (for example, to improve mathematical abilities during tDCS solve mathematical problems). [10]

1.6 Functional areas of the cerebral cortex

Each hemisphere of our brain is divided into four parts: frontal, parietal, occipital and temporal. But, in addition to the topographic division, the cerebral cortex is also differentiated on a functional basis. It is divided into:

- sensory (area through the ascending nerve pathways receives sensory information from most of the body's receptors);
- motor (area associated with the organization, management, and execution of voluntary movements);
- associative (area responsible for memory, thinking, speech and language).[17]

Therefore, with tDCS, it is very important to choose the right areas of the head to which electrodes should be applied, since different areas of the brain are responsible for different functions (Fig. 1.4) [10]:

Prefrontal cortex	Attention, memory, thinking
Motor cortex	Control over the muscles
Temporal lobe	Auditory and visual processing
Broca's area	Language production
Wernicke's area	Language comprehension
Parietal lobe	Sensory perception
Somatosensory cortex	Touch
Occipital lobe	Receives visual information

Figure 1.4 – Brain areas [10]

In the graphic above (Fig. 1.4) shows only large areas of the brain. In fact, each of them is subdivided into much smaller sections responsible for their own specific functions. [10]

1.7 Signal transmission mechanism

Each nerve fiber ends with terminal apparatus - nerve endings, they are able to come into contact with neurons or organ tissues. The places where excitation is transmitted from one nerve cell to another are called synapses. (Fig. 1.5)

According to the method of excitation transmission, synapses are divided into:

- electrical (excitation is transmitted by electric current);
- chemical (excitation is transmitted by a chemical substance). [18]

It is the signal transmitted through the central nervous system mainly in the form of action potentials (AP), simply called nerve impulses, through a succession of neurons, one after the other. However, you can follow three ways,

1) get blocked in the transmission between one neuron and another,

2) become a repeating string

3) integrate with stimuli from other cells to originate specific patterns

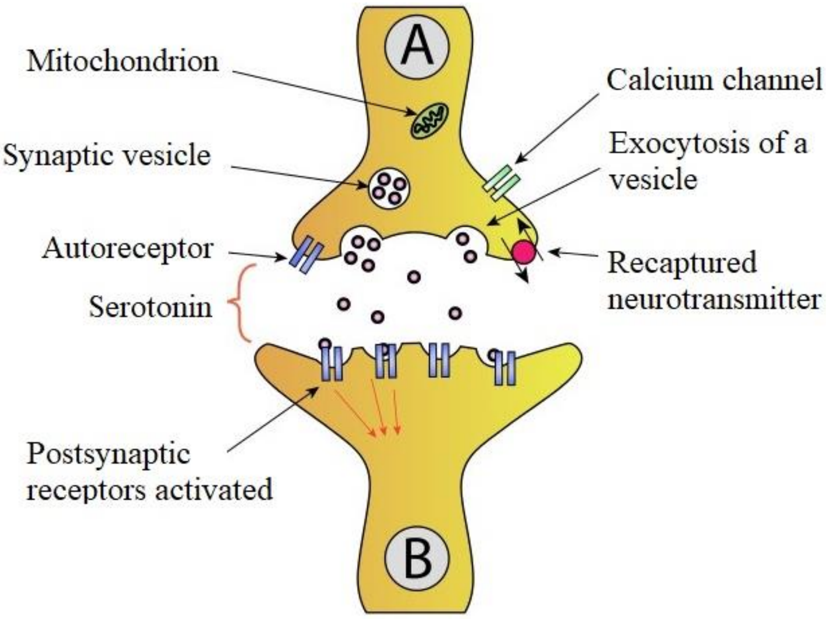


Figure 1.5 - Physiological anatomy of a synapse [11]

The majority of synapses used are chemical, in this case, the first neuron secretes a transmitter substance or neurotransmitter at the nerve ending level. This acts on the next membrane's receptor proteins to excite, inhibit, or even modify their sensitivity. More than 40 important neurotransmitters have been discovered, the most well-known of these are acetylcholine, noradrenaline, adrenaline, histamine, glycine, serotonin, glutamate, among others. The chemical synapse typically transmits information in one direction, from the endfoot, or presynaptic element, across the synaptic cleft, to the receiving membrane, or postsynaptic element of the synapse. The presence of vesicles, tiny spheres of membrane containing neurotransmitter substances, is perhaps the most striking anatomical feature of the endfoot at a chemical synapse. The highly active neurotransmitter substance, packaged within a vesicle, can be transported to and stored within the endfoot. Endfeet contain a lot of mitochondria. This is an anatomical indication that the endfoot's biochemical machinery requires a constant supply of high-energy materials. In fact, a variety of complex, energy-consuming biochemical processes occur within the presynaptic component of the synapse. The synaptic cleft is the space between the presynaptic and postsynaptic membranes. This gap is approximately 20-30 nm wide and contains a significant fluid component.[19]

Electrical scheme of the quanta action of potential neuronal mediator (Fig. 1.6) is as follows: classical neurotransmitter agents change the membrane potential of the postsynaptic neuron very rapidly by regulating chemically gated ion channels. Furthermore, these effects disappear fast.

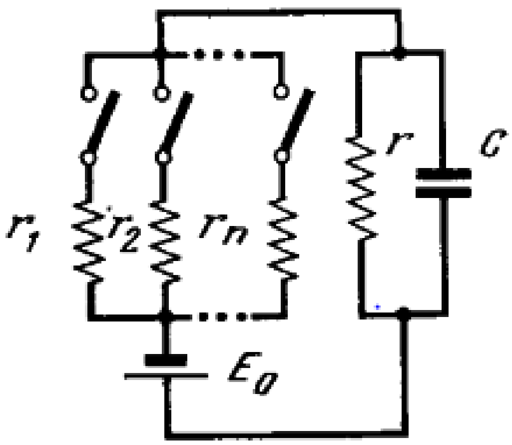


Figure 1.6 - Electrical diagram of mediator selection quanta from the synaptic ending [20]

According to this circuit, the action of a single quantum of the mediator is equivalent to the inclusion of additional conductivity r_0^{-1}, so the simultaneous action of k quanta creates the potential:

$$u_k = \frac{E_r}{(r + r_0/k)}. \quad (1.1)$$

The number of many synaptic terminal effects located on the body of a single neuron is also electrically represented. Scheme (Fig. 1.6), where the individual conductivities $1/r_0$ make a joint contribution to the change in the conductivity of a single synapse. [20]

Conclusions to chapter 1

Neurostimulation enhances cognitive functions in healthy volunteers, including memory, attention, learning, the ability to solve complex problems, and even mathematical and language skills. However, due to a lack of theoretical knowledge on the topic, the use of neurostimulation in medical practice is not gaining traction.

To date, nerve electrostimulation with tDCS is in an early stage of development, so there is not enough literature available to verify the effectiveness of the proposed techniques.

CHAPTER 2

DEVELOPMENT AND SIMULATION

2.1 Software and hardware

To achieve these objectives, we used the software:

- Micro-Cap 9 - for circuit modeling,
- DipTrace - for the development and design of analog circuits

For hardware:

- PCSGU250 - where the device was tested.

2.1.1 Micro-Cap 9

The neurostimulator prototype was designed using both software and hardware.

The Micro-Cap circuit analysis program has an easy-to-use interface and has very modest requirements for personal computer hardware and software. However, the opportunities that are provided are quite great. With the help of Micro-Cap, you can analyze analog, digital and mixed (analog-digital) devices, as well as synthesize active and passive filters. An experienced user can create their own macro models in non-standard situations, which makes simulation easier without losing essential information about the behavior of the system. [21]

In the component's menu, in passive components, the transmission lines are enabled. An equivalent circuit for a long lossless and lossy line is shown. (Fig. 2.1.)

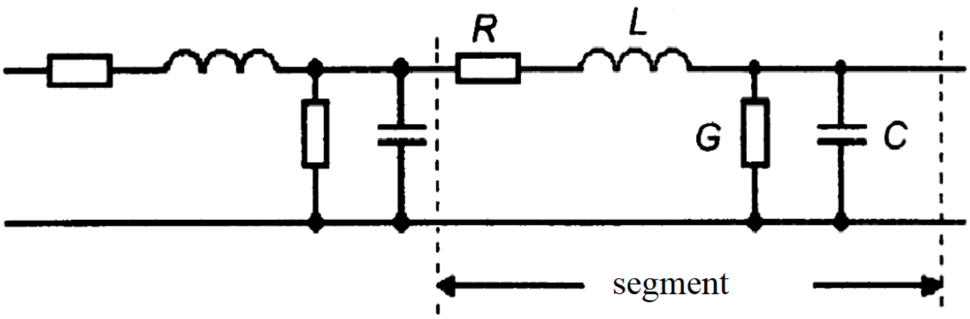


Figure 2.1 - Transmission line equivalent circuit [22]

The lossless transmission line in the calculation of transient processes plays the role of a delay line, in the calculation of the frequency characteristics it is a link without inertia.

For a lossy transmission line, the complex transmission ratio of the line is calculated analytically. Transient analysis is performed using a convolution integral with the impulse response of the line, which is calculated as the Fourier transform of the transmission coefficient (which takes a long time). [22]

We demonstrate the use of this element in MC9 (Fig.2.2)

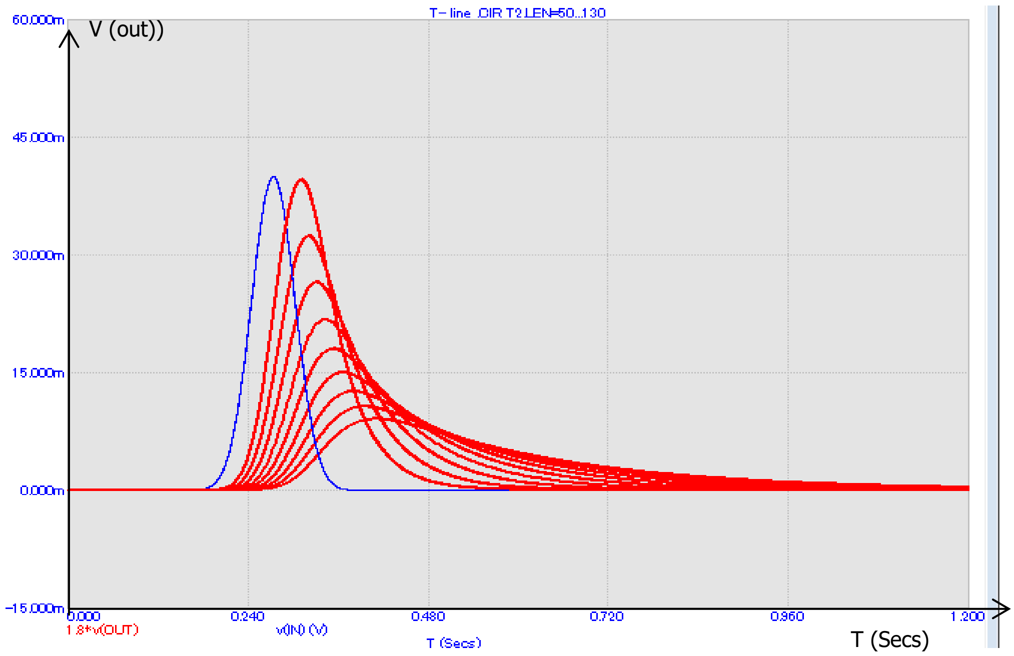


Figure 2.2 - Propagation of the action potential through the cell sequence

The result of modeling the excitation propagation through cells with losses.

2.1.2 DipTrace

The DipTrace software was used to produce a printed circuit board in this project. It automatically designs the printed and circuit board of the device based on the electrical circuit. DipTrace has a wide number of elements (about 40,000), the ability to edit elements and patterns, saving time and money. You can easily generate some schematics and then convert them to different formats.

It has four modules:

1. Schematic Capture - enables the user to connect the pins visually, without wires, logically, or using the embedded net ports on the circuit board.

2. PCB Layout - high-quality board-level design tool that features smart placement and routing tools, shape-based autoroute, copying hierarchical blocks, smart project structure, and verification features that ensure accuracy even for the most complex projects with high-speed signals.

3. Library Creation - is also being divided into two major sections, namely, component and pattern editor. When it comes to the component editor, it helps the user in managing libraries and creating single or multi-bit components by choosing an optimized template.

4. 3D Modeling - Works as a part of the PCB Layout and Pattern Editor. The 3D module allows the designer to preview the board with installed components on any design stage, rotate and move it in real-time with hardware acceleration. [23]

2.1.3 PCSGU250

PCSGU250 is a complete USB powered lab in one device. Software for two channel oscilloscope, spectrum analyzer, recorder, functional generator and Bode plotter. Using the generator, the user can create individual signals using a special signal editor. Integrated automated sequence generator, using file or external input.

General characteristics:

- markers for amplitude / voltage and frequency / time;
- input coupling: DC, AC and ground;
- 8-bit resolution;
- power supply from USB port (500mA).

Spectrum analyzer

- frequency range 0 ... 120 Hz to 12 MHz;
- linear or logarithmic timescale;
- working principle: Fast Fourier Transform;
- spectrum analyzer resolution: 2048 lines;
- resolution: 2048 lines;
- input channels 1 or 2;
- zoom function.

Recorder

- timescale: 20 ms / division to 2000s / division;
- maximum record time: 9.4 hours / screen;
- automatic data storage;
- automatic recording for more than 1 year;
- maximum number of samples: 100 / s;
- minimum number of samples: 1/20 s.

Functional generator

- frequency range: sine 0.005 Hz to 1000kHz;
- frequency range: square and triangle 0.005 Hz to 500 kHz;
- extended signal library;
- amplitude range: 0.1 - 10 V (1 kHz, 600 Ω), output impedance: 50 Ω.

Oscilloscope

- bandwidth: two channels from DC to 12 MHz ± 3 dB;
- input impedance: 1 MΩ / 30 pF;
- maximum input voltage: 30 V (AC + DC);
- time base: 0.1 μs to 500 ms per division;
- input range: 10 mV to 3 V / division;
- indications: True RMS, dBV, dBm, duty cycle, frequency, etc.;
- record length: 4 K simples / channel;
- sampling frequency: 250 Hz to 25 MHz

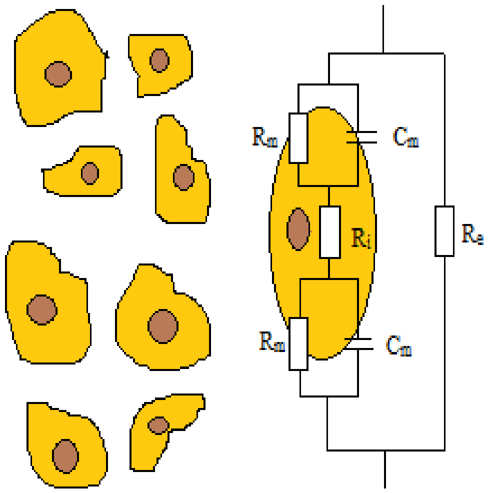
Bode plotter

- automatic synchronization of the oscilloscope and generator;
- frequency range: 1 kHz, 10 kHz, 100 kHz, 500 kHz;
- initial frequency: 10 Hz, 100 Hz, 1 kHz, 10 kHz. [24]

2.2 Modeling of biological objects

The modeling of biological artifacts is attributed to the complex dynamics of the processes that exist in biological systems, which are correlated with the structural and functional diversity involved in the creation of their behavior mechanisms.

The action of biological structures can be characterized by an analogous electrical circuit, in which the resistors and capacitors correspond to the membrane and intercellular fluid resistance and capacitance (Fig. 2.3):



Cm is the capacity of the membranes, Re is the external resistance of cells, Rm is the resistance of the membranes, Ri is the internal resistance of the cells

Figure 2.3 - Equivalent structural diagram of a cell

For a biological object, the impedance has a composite character Z = (R, X). R is the active resistive component, and it is primarily associated with the conductivity of internal liquid media, which are electrolytes. Various processes in tissues, which are followed by irreversible energy loss, often lead to the value of the impedance's active component.

X is the reactive capacitive component of the system, which is determined by the capacitive properties of the studied tissue, specifically the ability of biological membranes. Furthermore, the capacitive portion of impedance refers to the area of contact between the stimulating electrodes and biological tissues. Expression (2.1) - for the absolute value (modulus) of electrical impedance [25]:

$$|Z| = \sqrt{R^2 + X^2} \tag{2.1}$$

As a result, the basic composition of biological tissue (for example, lipids, water, electrolytes in extracellular fluid) determines the impedance value and its characteristics.

Consider a primitive model of a neuron in the form of a spherical cell without processes. The specific shape of the cell is not significant if the condition of cytoplasmic equipotentiality is satisfied. A microelectrode (Fig. 2.4, a) is introduced into the cell, through which a current j is passed.

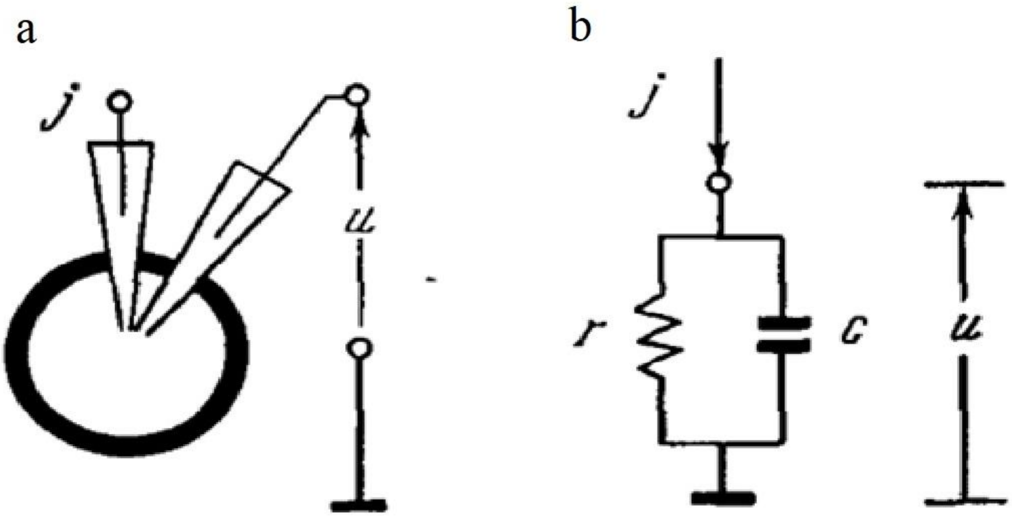


Figure 2.4 - Experimental (a) and electrical (b) schemes for measuring the electrical parameters of a spherical cell with a single microelectrode source. [20]

At rest, there is a potential difference between the external environment and the cytoplasm, which is the membrane resting potential due to the stationary ion gradient. Denote by u the potential difference between the external and internal environment of the cell, measured relative to the level of resting potential. Since the equivalent electrical circuit of a spherical cell is the parallel resistance r and capacitance c (Fig. 2.4, b), the relationship of the potential u with the current j passed through the cell is described in the general case by a differential equation of the 1st order:

$$c\frac{du}{dt} + \frac{u}{r} = j, \qquad (2.2)$$

where r is the input resistance of the cell, which is determined by:

$$r = \frac{R_m}{S}, \qquad (2.3)$$

where Rm - resistivity of the membrane, which is measured in units of Ohm • cm2, S - area of the membrane.

The capacity is similarly defined:

$$c = C_m S, \tag{2.4}$$

where Cm - specific capacity of the membrane, which is measured in units of μF / cm2.

The product r · c = Rm · Cm has a time dimension (cm · μF = ms) and is called the membrane time constant.

The value of the membrane time constant τ_m is a scale unit of time, and the input resistance of the cell r - unit of resistance.

Then the equation can be rewritten with unit coefficients:

$$\frac{du}{dt} + u = j, \tag{2.5}$$

now t ~ t / τ_m is a dimensionless quantity, and j ~ rj - has a potential dimension.

A fundamental solution to a linear differential equation is a solution that corresponds to an influence in the form of a delta function. For the simplest differential equation (2.5), the case j = δ (t) corresponds to the solution:

$$u(t) \equiv \varphi(t) = e^{-t}\varepsilon(t). \tag{2.6}$$

The potential change in response to an effect, representing the inclusion of a constant effect j = ε (t) is called the transient process u (t) = h (t). For equation (2.5)

$$h(t) = (1 - e^{-t})\varepsilon(t). \tag{2.7}$$

That is, selecting function φ (t) in the form of function (2.6) is equal to employing the neuron's spherical model. [20]

2.3 Simulation of current source and object under study in MC9

The device creation process is divided into several phases. One of them is the development of a precision current source in Micro-Cap 9 software. A simulation was done using formulas 2.9-2.13. (Fig.2.5).

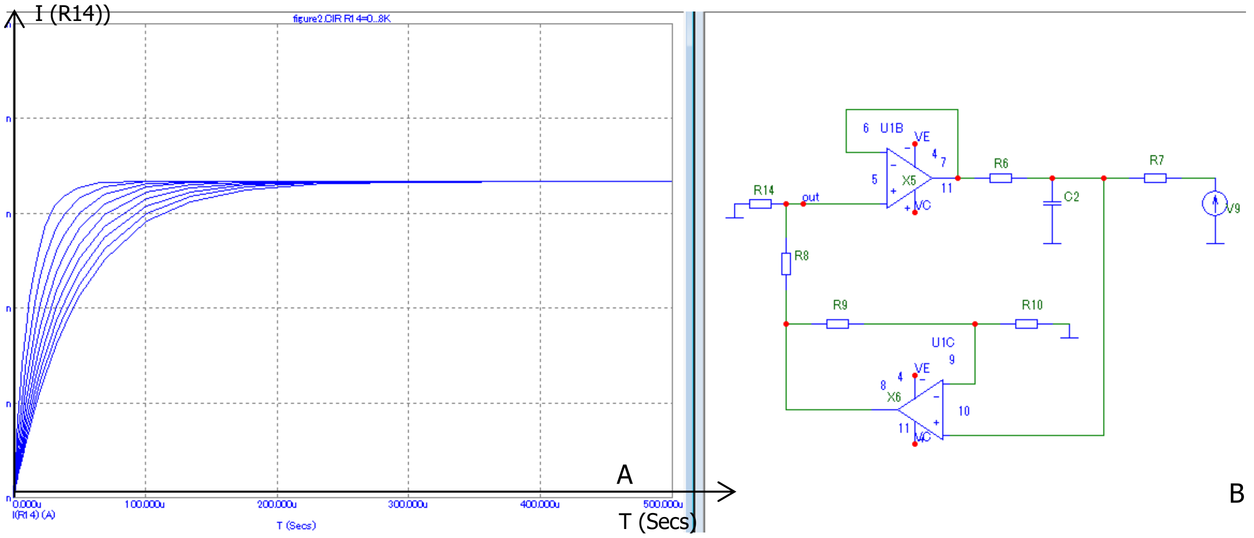


Figure 2.5 - Precision current source (B) and simulation of the performance (A) in Micro-Cap 9

Fig. 2.5 (A) shows that when the patient's resistance varies from 0 to 8 kΩ, the circuit provides a current of 1mA, indicating that the current source is working properly.

Fig. 2.5 (B) U1B and U1C are the current source, the output current of which is calculated by the formula:

$$I = \frac{V_{ref}}{R_8}, \tag{2.8}$$

where I - output current;

V_{ref} - voltage;

R_8 - resistor that sets the output current.

Since the input impedance U1C is quite high, the current flowing through R_6 is approximately equal to the current flowing through R_7, so:

$$V_{in}U1C = \frac{V_{ref} - V_{out}U1B}{2} + V_{out}U1B = \frac{V_{ref} + V_{out}U1B}{2} \quad (2.9)$$

$$V_{out}U1C = 2\left[\frac{V_{ref} + V_{out}U1B}{2}\right] = V_{ref} + V_{out}U1B \quad (2.10)$$

$$V_{out}U1B = V_{in}U1B \quad (2.11)$$

$$V_{R8} = V_{out}U1C - V_{in}U1B \quad (2.12)$$

$$V_{R8} = V_{ref} + V_{out}U1B - V_{in}U1B, \quad (2.13)$$

where $V_{in(out)}$ U1C– voltage at the input (output) U1C;

$V_{in(out)}$ U1B - voltage at the input (output) U1B;

V_{R8} - voltage in R_8 [26].

Another stage in the development process is the equivalent circuit simulation of the object under study.

The electrical interaction of cells occurs through intercellular contacts. To analyze the factors that determine the conditions of excitation transmission from cell to cell, it is necessary to consider an equivalent electrical circuit of the contact area, which takes into account all its main elements that affect the transmission of electrical signals through this area. Contacts of different morphological structure correspond to different electrical circuits (Fig. 2.6). [27]

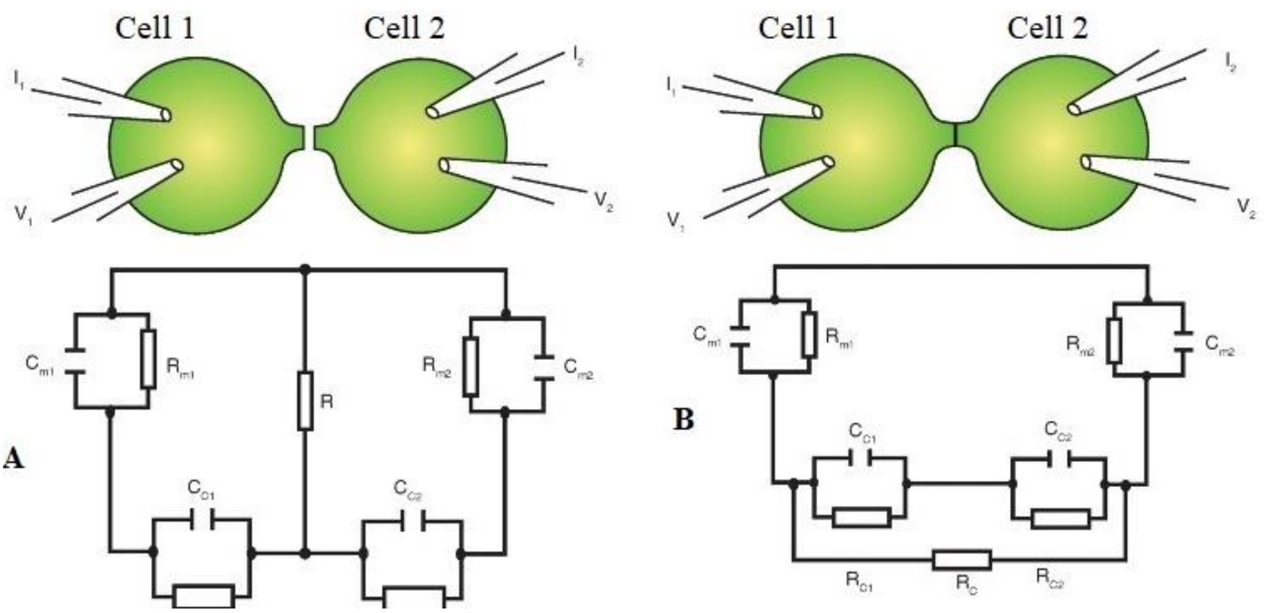
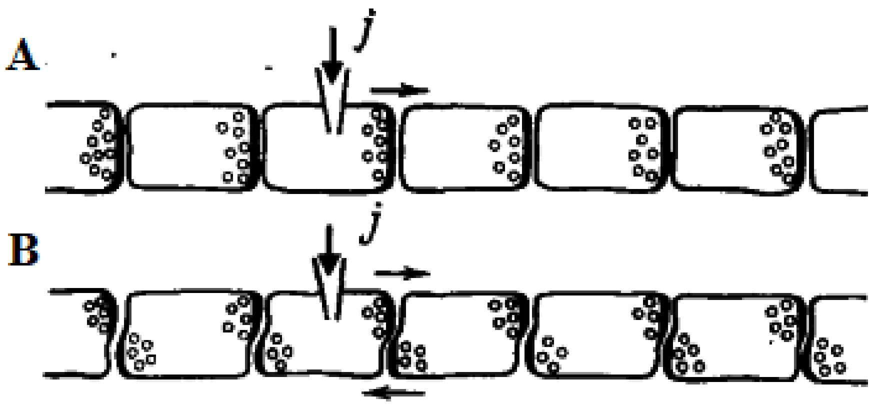


Figure 2.6 - Equivalent electrical circuits of cell contacts: A - intercellular gap without connexons, B - slit contact with connexons [27]

The specificity of cell interaction via chemical synapses is most evident in the simplest model of nervous tissue - when cells lack axons and communicate via somatic contacts (Fig. 2.7, A). If in such a "hypothetical" column, each cell forms only one chemical synapse, for example with the right neighbor, the transfer of effects is possible only in one (positive) direction. Bilateral transmission is possible with a special organization of synaptic contacts (Fig. 2.7, B).



A is a column of cells with unilateral synaptic interaction, j is the current of the stimulating electrode, the arrow indicates the direction of transmission, B is a column of cells with bilateral interaction

Figure 2.7 - Schemes of biological neuron model [20]

According to the electric model (Fig. 1.6), each cell in the considered columns is represented by an rc-element and the whole column is a series of such elements directly connected by one pole simulating the external conducting environment, and the sources are included in the second poles current, representing the synaptic effect (Fig. 2.8). [20]

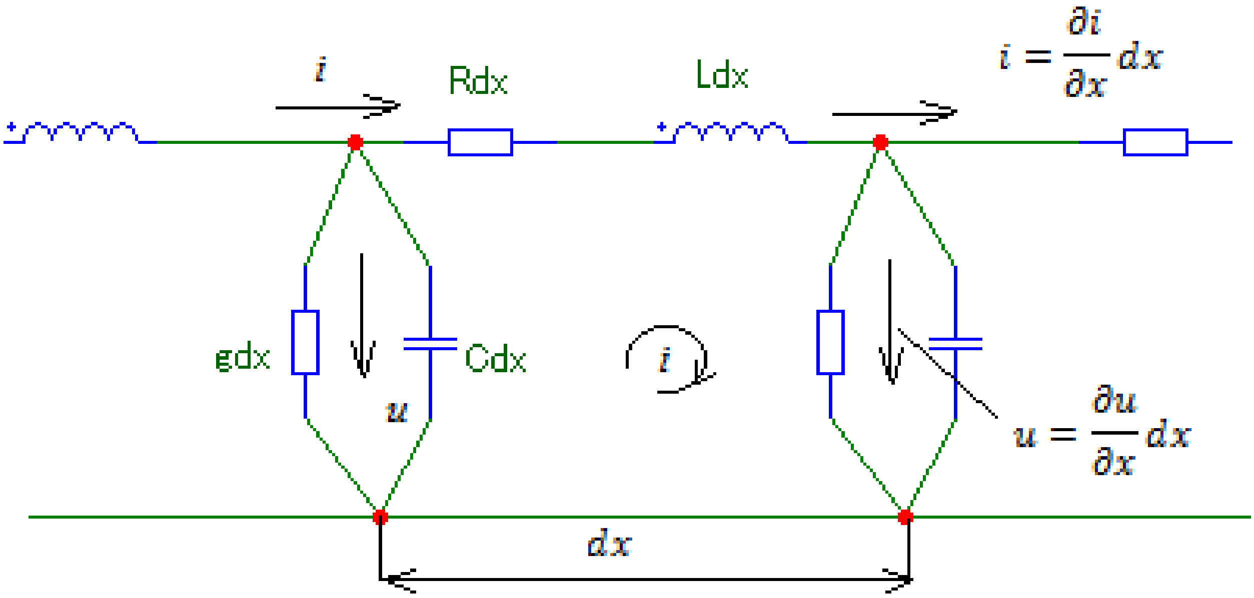


Figure 2.8 - Equivalent electrical circuit of nerve tissue with equipotential cells

From the theoretical foundations of electrical engineering, it is known that the line with distributed parameters is described by equations [20]:

$$\begin{cases} -\dfrac{\partial u}{\partial x} = iR + L\dfrac{\partial i}{\partial t} \\ -\dfrac{\partial i}{\partial x} = gu + C\dfrac{\partial u}{\partial t} \end{cases} \tag{2.14}$$

Based on the above-described theoretical data on the equivalent section of the object, the diagram shown in Fig. 2.9 (B) and simulated work.

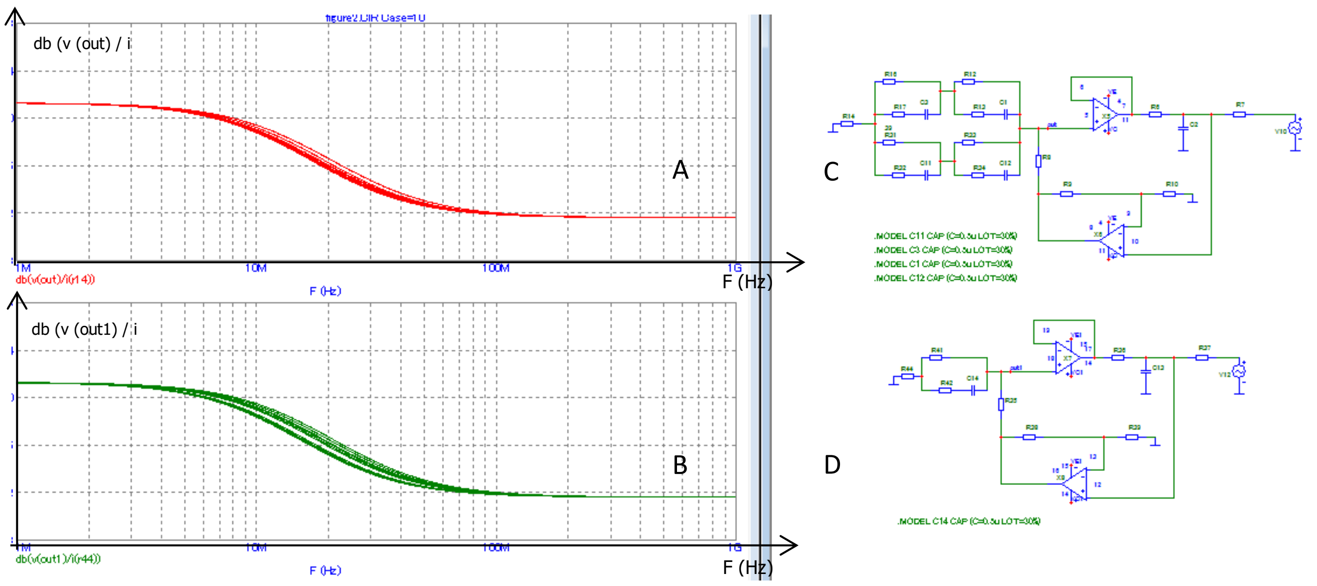


Figure 2.9 - Simulation of the impedance curve by the Monte Carlo method in Micro Cap 9

From Fig. 2.9. we see that if the equivalent part of the object is taken 4 (C) and 1 (D) cells, the nature of the impedance curve A and B, respectively, does not change, and only disperse when changing denominations. As a result, we can conclude that the analysis of a group of cells can be replaced by an equivalent scheme of one cell. This conclusion was reached using the simulation method - Monte Carlo.

2.3.1 Monte Carlo method

Monte Carlo Simulation, also known as the Monte Carlo Method or a multiple probability simulation, is a mathematical technique, which is used to measure the possible outcomes of an unexpected event.

Suppose we need to calculate some unknown quantity m. Let's try to come up with such a random value ξ that Mξ = m. Let Dξ = b^2.

Consider N independent random variables $\xi^1, \xi^2, \ldots, \xi^N$ (realizations), whose distributions coincide with the distribution ξ. If N is large enough, then according to the central limit theorem, the distribution sum $\rho_N = \sum i\ \xi i$ will be approximately normal to $M\rho_N = Nm$, $D\ \rho_N = Nb^2$.

Known as the Central limit theorem (or Moivre-Laplace limit theorem) we obtain the relation:

$$P\left(\left|\frac{\rho_N}{N} - m\right| \leq k\frac{b}{\sqrt{N}}\right) = P\left(\left|\frac{1}{N}\sum_i \xi_i - m\right| \leq k\frac{b}{\sqrt{N}}\right) \to 2\Phi(k) - 1, \qquad (2.15)$$

where Φ (x) - distribution function of the standard normal distribution.

This is an extremely important relationship for the Monte Carlo method. It gives both a calculation method m and an error estimate.

Find N values of the random variable ξ. From this ratio it is seen that the arithmetic mean of these values will be approximately equal to m. With a probability close to (2 Φ (k) -1), the error of this approximation does not exceed the value of kb / √N. Clearly, as N increases, this error tends to zero. [28]

This algorithm is included in the Micro-Cap 9 software package as an additional type of electronic circuit analysis.

Monte Carlo is a type of analysis in which a series of calculations are performed to statically process the results. In this case, the parameters of the circuit components change by random law within a given tolerance. Thus, the distribution of parameters, which always exists in real components, on the characteristics of the circuit is investigated. In addition, the Monte Carlo analysis is designed to identify combinations of parameters of the components of the circuit, in which the characteristics of the circuit go beyond the specified limits. All such combinations of parameters are written to a numerical output file and can then be analyzed in detail, recalculating the results several times, each time using a different set of random numbers between the minimum and maximum values. Since Monte Carlo analysis necessitates a large number of calculation choices with various parameter combinations, it takes a long time. [21][22]

2.4 Electromagnetic compatibility

For the correct functioning of the created device, it is necessary to observe certain conditions. One of which is the provision of electromagnetic compatibility (EMC).

Electromagnetic compatibility is now a major concern on any project that involves the design, development, manufacture, and installation of electrical and electronic equipment and systems. Is the ability of a device, equipment or system to function satisfactorily in its electromagnetic environment without creating unacceptable electromagnetic interference to other equipment in their operating location. [29]

The need for electromagnetic compatibility comes from the fact that there is a significant amount of different radiation types in actual situation, and the correct and reliable operation of the devices is impossible without the provision of EMC. It can be achieved using a variety of techniques. Techniques for avoiding disturbances call for the elimination of the source of disturbance or a reduction in the level of emission.

Technical failure or improper work can lead to an accident. Furthermore, violations can be both reversible and irreversible. [30]

To ensure the electromagnetic compatibility use the following technical methods:

- shielding - the practice of reducing an electromagnetic field in a space by blocking it with conductive or magnetic barriers. Shielding is commonly used to separate electrical devices from their surroundings, and it is also used to distinguish wires from the area in which the cable passes;

- filtering - commonly used on lines into and out of a circuit with cables and connectors, and some special connectors may have built-in low-pass filters whose main task is to soften digital waveforms to increase rise and fall times and minimize harmonic generation;

- grounding - establishing an electrically conductive path between an electrical or electronic element of a device and a ground-referenced. point or plane. [31]

Norms of conductive interference are established by the following international standards (fig. 2.10):

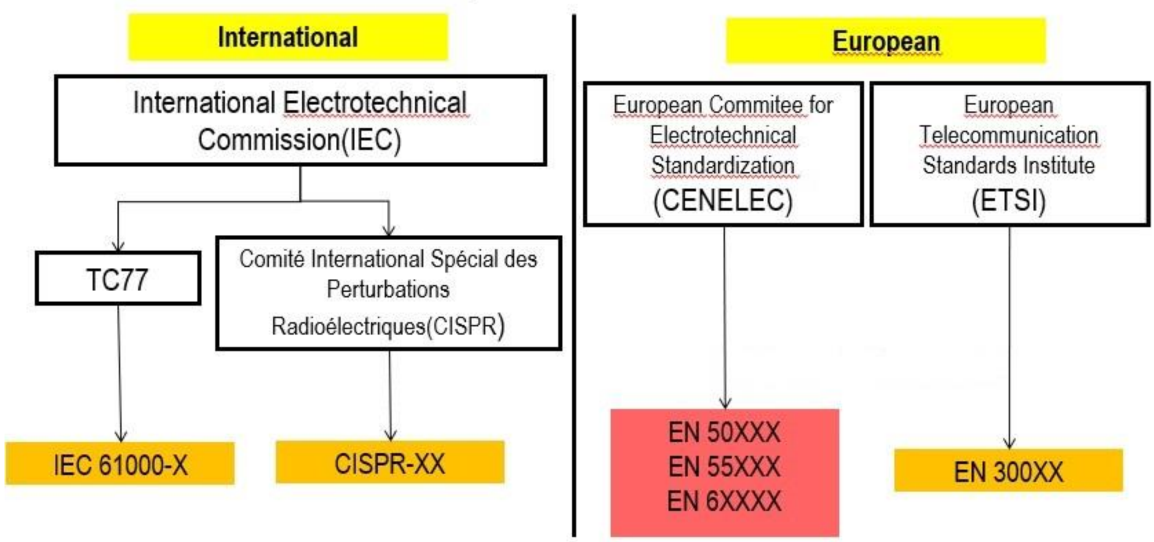
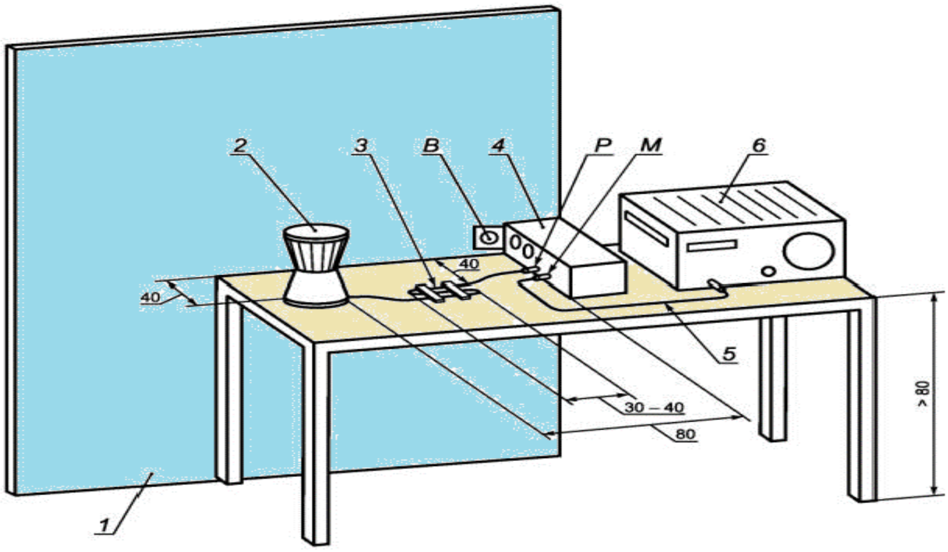


Figure 2.10 International standards

Basic standard (general and fundamental rules)	*EN 61000-4-x (IEC61000-4-x)*	EMC – Testing and measurement techniques
Generic standard (for equipments in a specific environment)	EN 61000-6-3 *(IEC61000-6-3)*	Generic Emission Standard, for residential, commercial and light industrial environment
	EN 61000-6-1 *(IEC61000-6-1)*	Generic Immunity Standard, for residential, commercial and industrial environment
Product standard (for a specific product family)	EN 55022 *(CISPR22)*	Information technology equipment (ITE)
	EN 55014 *(CISPR14)*	Household appliances, electric tools and similar apparatus
	EN 55012 (CISPR12)	Vehicles, boats and internal combustion engines
	EN 330220 *(ETSI 330 220)*	Electromagnetic compatibility and radio spectrum matters (ERM); Short Range Devices (SRD); Radio equipment to be used in the 25 MHz to 1 000 MHz frequency range with power levels ranging up to 500 mW;
	EN 330330 *(ETSI 300330-1)*	Electromagnetic compatibility and radio spectrum matters (ERM); Short Range devices (SRD); Radio equipment to be used in the frequency range 9 KHz to 25 MHz and inductive loop systems in the frequency range 9 KHz to 30 MHz

Figure 2.11 – EMC Commercial standard [32]

Method to measure conductive interference (Fig.2.12):



1 - metal wall 2 x 2 m; 2 - experiment; 3 - power cord sheathed with 3 x 40 cm flat loops; 4 - V-shaped network equivalent; 5 - coaxial cable; 6 - measuring receiver; B - support grounding connection; M - input of the measuring receiver; P- experiment power supply

Figure 2.12 - Example of a test configuration for a desktop with a built-in power cord [33]

Example of measuring conductive interference in real conditions (Fig. 2.13)

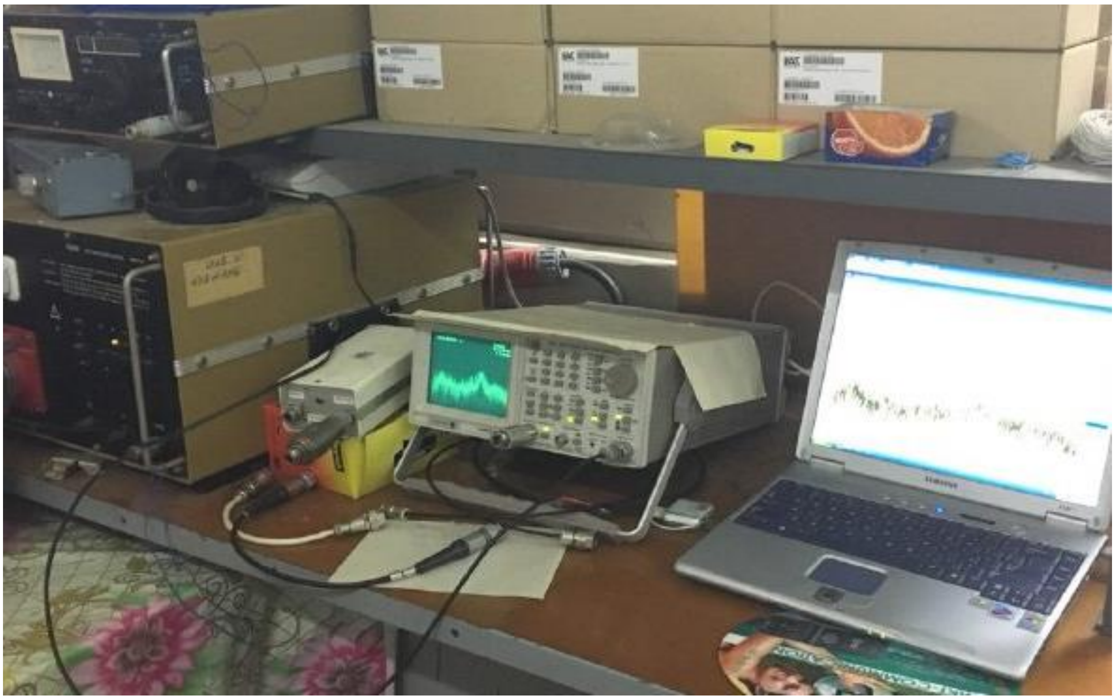


Figure 2.13 - Measuring conductive interference installation

2.5 Technical requirements for the developed device

The construction of electrical stimulators must ensure the formation of an adequate signal of impact, meet the requirements for the implementation of the necessary modes of operation, as well as meet the general requirements for medical equipment. Based on the developed literature and practical research in the MC 9 software, the technical requirements for the developed device were determined (Table 2.1).

Table 2.1– Technical requirements for the developed device

Features	Value
Output current, mA	0.01-1.0 ± 5%
Maximum patient electrical impedance, kΩ	8
Stimulation time, min	5-40
Supply voltage, V	9
Device parameters must be saved at	30% battery discharge
Climatic performance of the product according to GOST 15150-69 [34]	NF 4.2

Operating humidity values at 25 °C according to GOST 15150-69,%	80
Operating temperature range according to GOST 20790-93, °C [35]	+ 10… + 35
Depending on the possible failure consequences in the process according to GOST 20790-93, class	G
resistance to mechanical influences according to GOST 20790-93, group	2
Electrical safety according to DSTU 3798 [36]	class II, type BF
Weight, kg	0.35
Overall dimensions, mm	110x65x28

The device must meet the requirements of DSTU 3798, GOST 20790, technical conditions (TC) and a set of construction design (CD).

The external surfaces of the device must be resistant to repeated disinfection in accordance with GOST 42-21-2, GOST 177 and DSTU 2972.

The electrodes contact surfaces that are in contact with the patient's body must be resistant to repeated disinfection by means that are intended for disinfection of non-invasive medical devices and are allowed to be used by the Ministry of Health of Ukraine in prescribed manner.

The technical conditions for the device must be suitable for certification in accordance with the requirements of the state certification system.

Conclusions to chapter 2

As a result of computer simulation, the maximum resistance of the object under study was determined, at which the circuit provides 1 mA of current, was found that:

1) the nature of the obtained impedance curve does not change, but only the scatter of frequency characteristics changes when the denominations change;

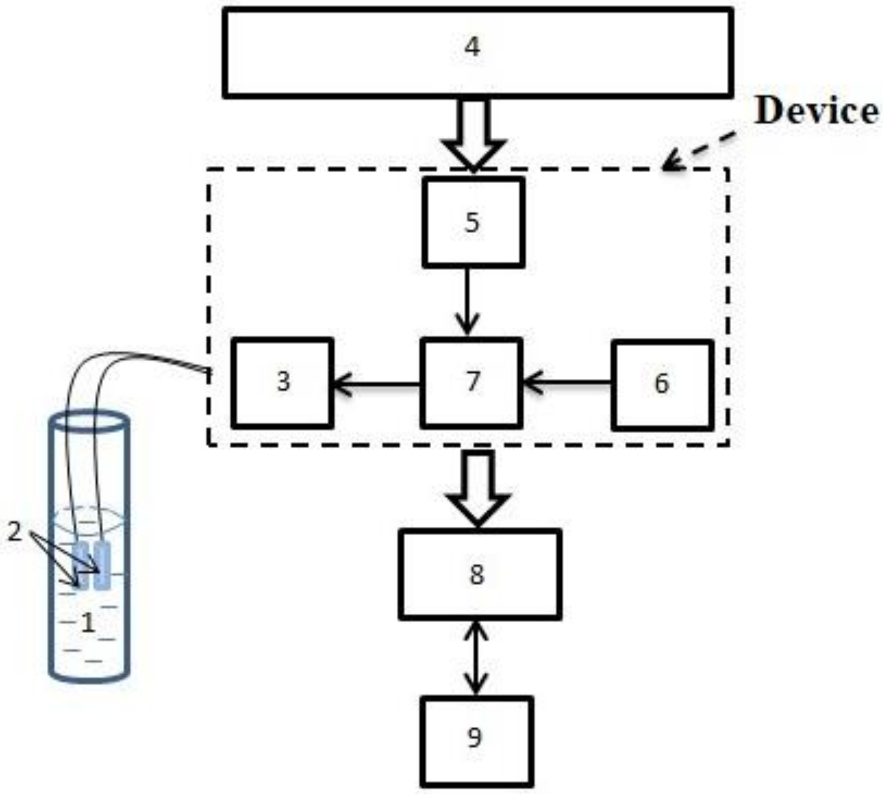
2) a conglomerate of cells in an equivalent scheme can be replaced by an equivalent scheme of one cell.

Based on the obtained results and the processed literature the medical and technical requirements to the developed device were formed.

CHAPTER 3
CREATING A PROTOTYPE

3.1 Block diagram of the device

The design of a block diagram is required for the development of any device. The block diagram of the device which is planned to be made is presented on fig.3.1.



1 - the studied object, 2 - electrodes, 3 - current source, 4 - power supply, 5 - filter, 6 - reference voltage source, 7 - current reference, 8 - PCSGU-250 analyzer, 9 - personal computer (PC)

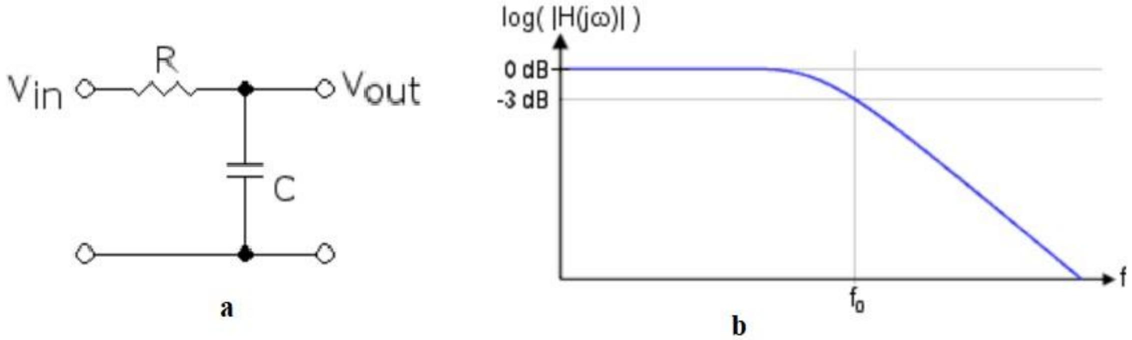
Figure 3.1 - Block diagram of the device

The power supply consists of a Nine-volt battery and a DC-DC converter. The PCSGU-250 analyzer records the cell impedance module in a test tube and transmits the data to a PC, which is also controlled by it.

3.2 Filter calculation

A low-pass filter was used to ensure the technical task and the correct operation of the device. Since the signal is constant, using this filter is sufficient to suppress high-frequency components.

In fig. 3.2 shows a diagram of a simple RC-filter of low-pass filter and its frequency response.



a b

Figure 3.2 - LPF (a) and its frequency response (b) [37]

The transmission ratio in complex form can be expressed by formula (3.1):

$$K(j\omega) = \frac{U_{\text{вих}}(j\omega)}{U_{\text{вх}}(j\omega)} = \frac{1/j\omega C}{R + 1/j\omega C} = \frac{1}{1 + j\omega RC} \qquad (3.1)$$

From here we get the formulas for frequency response and phase response:

$$|K| = 1/\sqrt{1 + (\omega RC)^2},, \qquad (3.2)$$

$$\varphi = -arctg(\omega RC) \qquad (3.3)$$

Having accepted

$$K(j\omega) = 1/\sqrt{2} = 1/\sqrt{1 + (\omega_{CP}RC)^2} \quad (3.4)$$

We obtain the expression for the cutoff frequency ωCP

$$\omega_{CP} = \frac{1}{RC}, \quad (3.5)$$

$$f_{cp} = \frac{1}{2\pi RC} \quad (3.6)$$

The phase shift at this frequency is -450.

| K | = 1 = 0 dB at low frequencies f≪fCP.

At high frequencies f≫fCP according to formula (3.2), | K | ≈1 / (ωRC)), i.e., the transmission coefficient is inversely proportional to the frequency. When the frequency is increased 10 times, the gain decreases 10 times, i.e., it decreases by 20 dB per decade or 6 dB per octave. | K | = 1⁄√2 = -3dB at f = fCP. [38]

3.3 Prototype development

3.3.1 Selection of base elements

For conversion from 5 V direct current to 12 V direct current, the converter P6AU-0512ELF from PEAK was chosen (Fig. 3.3) [39].

Figure 3.3 - Actual view of the viewconverter P6AU-0512ELF[39]

As a precision operational amplifier (OP) in the scheme was used - OP284 manufactured by Analog Devices (Fig. 3.4).

Figure 3.4 - Actual view of the operational amplifier OP284[40]

These high-speed OPs with low distortion (1 nA or less) and low noise allow system developers to obtain higher signal quality in the most difficult conditions and achieve less system noise at high source impedances. They also have a wide range of supply voltages ± 18 V and low power consumption.[40]

During the development of the model, the appropriate passive elements were selected using standard series according to IEC-63 for resistors and capacitors [41].

The values for resistors R_6, R_7, R_9 and R_{10} were selected from the series E48, and for the resistor R_8 - from the series E96, the value for the capacitor C2 was selected from the E3 series using simulation in the MC9 software (Fig. 3.5).

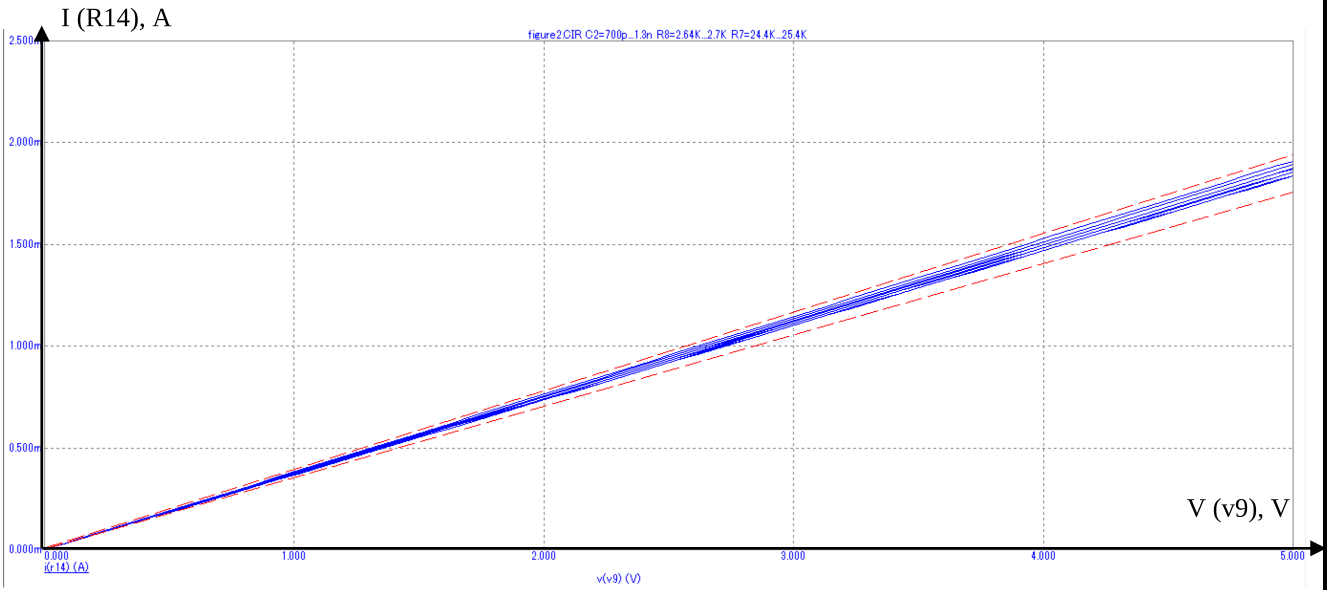


Figure 3.5 - Simulation in MC9

In fig. 3.5 shows that the selected values for resistors and capacitors will fall within the specified limits.

3.3.2 Development of a printed circuit board

A printed circuit board was developed in the DipTrace software. The pre-assembled circuit (Fig. 3.6) is transferred to the DipTrace Schematics module, adding the necessary structural elements, such as connectors, junctions, etc. [23].

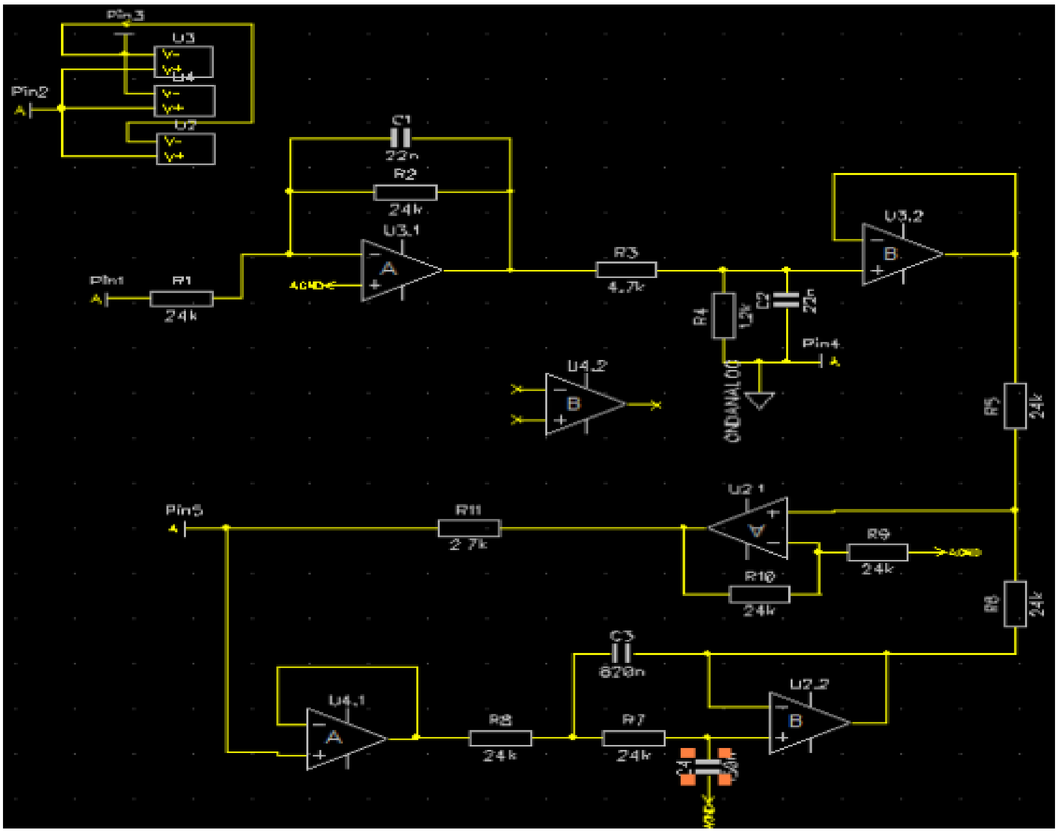


Figure 3.6 - Schematic electrical diagram

After that, switch to PCB Layout mode, which allows you to develop a printed circuit board and trace it (Fig. 3.7).

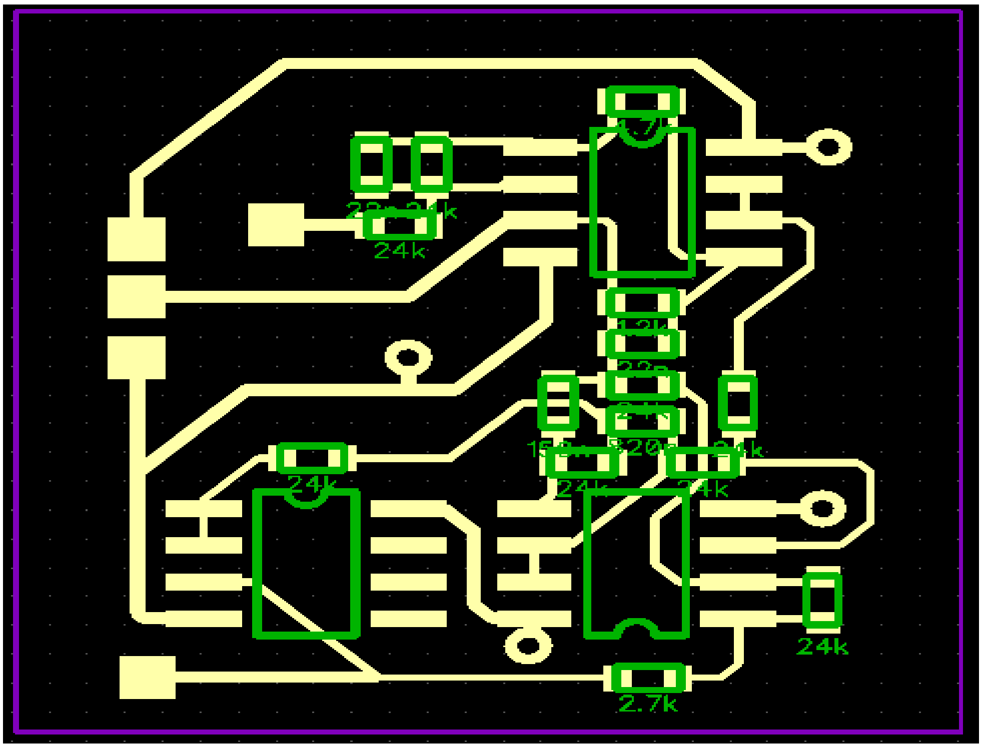


Figure 3.7 - PCB tracing

The circuit, traced using DipTrace, became the basis for the manufacture of the printed circuit board shown in Fig. 3.8.

Figure 3.8 - Finished board appearance

The designed printed circuit board was tested in the laboratory.

3.3.3 Created a prototype

The created prototype in addition to the printed circuit board contained some other components, such as DC-DC converter, potentiometer, battery, etc .. Then all these elements were placed in the case (Fig. 3.9).

Figure 3.9 - Developed a prototype

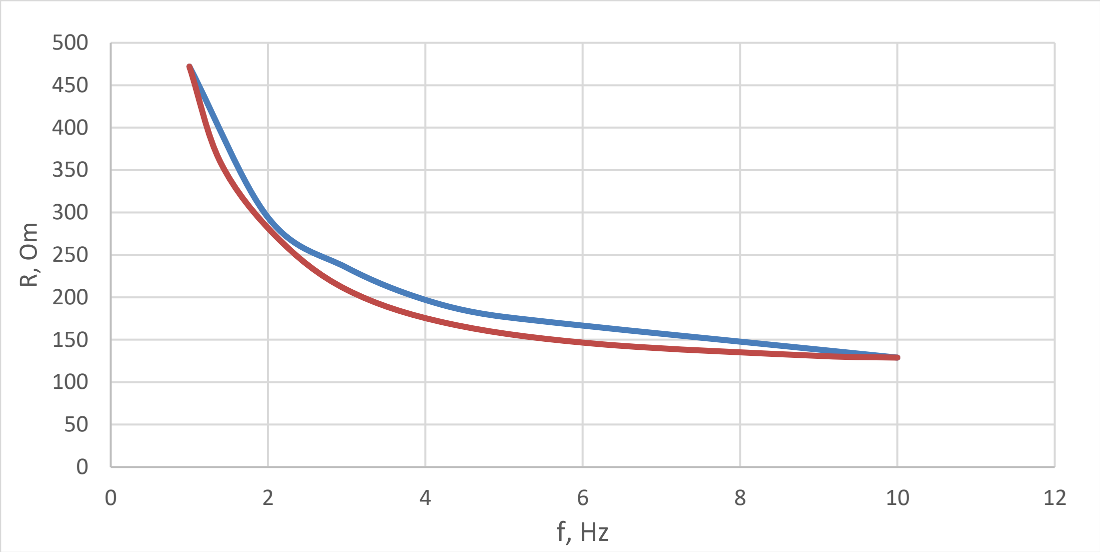
To perform the study, the source of the stimulation signal must generate a current with parameters that depends on the magnitude of the load resistance, i.e., the suspension of nerve cells. The frequency range is determined by the characteristics of the nervous tissue and is set through the characteristics of the stimulating effect.

An experiment was performed which showed that when we increase frequency the resistance decreases, this is due to the fact that the suspension has resistive and capacitive bonds. Since direct current does not flow through the capacitor, but as frequency increases, the equivalent resistance decreases, some current may flow through the capacitor, allowing the impedance to decrease (Table 3.1).

Table 3.1 – Experiment results

lg · f, Hz	Vpp, mV	R, Om	f, Hz	Vpp, mV	R, Om
1	646	472	200	50	37
2	402	294	250	47	34
3	322	235	300	45	33
4	270	197	350	44	32
5	242	177	400	42	31
10	176	129	450	41	30
15	150	110	500	40	29
20	136	99	1000	34	25
25	124	91	1500	32	23
50	90	66	2000	30	22
75	80	58	2500	26	19
100	70	51	3000	26	19
125	65	47	4000	26	19
150	60	44	5000	26	19

Let's construct the schedule of impedance change depending on frequency change (fig. 3.10).



blue curve - experimental results, red curve - simulation results

Figure 3.10 - Graph of impedance change from frequency

Figure 3.10 shows that the experimental results (blue curve) validated the simulation results (red curve). As a result, we can conclude that the prototype created meets the technical requirements.

Conclusions to chapter 3

Based on the technical task, a block diagram and an electrical circuit diagram were developed for the device.

The choice of real components was made taking into account their technical characteristics, price and availability. Passive circuit elements were selected using standard IEC-63 series for resistors and capacitors and by simulation in MC9 software.

In addition, the printed circuit board was designed and traced, and a prototype was made. Laboratory test showed that the device's designed sample meets the specified technical requirements.

CHAPTER 4
LABOR PROTECTION

4.1 Device characteristics

The block diagram of the developed device for neurostimulation is presented in Fig. 3.1.

The construction of electrical stimulators must ensure the formation of an adequate impact signal, meet the general requirements for medical equipment. Therefore, it is necessary to determine the technical requirements for the developed device (table 2.1).

4.2 Analysis of potential hazards and measures to prevent them

Table 4.1 shows the analysis of dangerous and harmful factors that occur during the operation of the DC stimulation device.

Table 4.1 - Dangerous and harmful factors

Types of factors	Effects
Physical factors	Electrical and fire safety
Biological factors	Electrode with hydrophilic gasket
Chemical factors	Battery leakage
Thermal factors	Electrode overheating

Consider the impact of each factor on the human body, the effect results, and the steps that can be taken to prevent them.

4.2.1 Electrical safety

Table 4.2 shows the possible sources and consequences of damage from an electric device.

Table 4.2 - Source and consequences of exposure to dangerous physical factors

Source	Effects
Amperage	Electric burn

Table 4.3 - Comparison of actual and normalized current values

Factor	Actual	Normalized
Current strength, mA	0.01 - 1.0	0.6 - 2.0

From the table we see that the actual current does not exceed the norm.

Table 4.4 provides safety precautions to prevent electrical accidents.

Table 4.4 - Security measures

Type of measures	Means of overcoming danger
Technical	Installing the current control knob. Installing the battery discharge indicator. Correct selection of scheme denominations Electrical safety class of the device - II Type of electrical safety of the device - BF
Organizational arrangements	Conducting briefings with doctors and patients. Acquaintance with the operation manual.

When designing the device, it is necessary to install battery discharge indicator. Other measures were taken.

4.2.2 Biological factors

Table 4.5 lists the possible sources and effects of hazardous biological factors on human health.

Table 4.5 - Sources and consequences of the impact

Source	Effects
Electrode with hydrophilic gasket	Transmission of diseases and infections

Table 4.6 lists the safety measures that must be taken to eliminate the risk of harm to health.

Table 4.6 - Security measures

Type of measures	Means of overcoming danger
Technical	Choose an antibacterial material for the hydrophilic gasket
Organizational arrangements	Thoroughly rinse under running water. Sterilization by boiling Use of disposable hydrophilic gaskets Acquaintance with the operation manual

Both precautions were taken during the final prototype's testing.

4.2.3 Chemical factors

The developed device contains the battery "nine-volt" with the following technical characteristics:

- Voltage- 9 V.
- Capacity of normal alkaline battery is 625mA • year.

After a breakdown of chemical processes in the battery, the electrolyte flows and the oxide will be formed on the contacts. Therefore, when replacing a leaking battery, there may be a risk of exposure to a chemical hazard (Table 4.7).

Table 4.7 - Danger of chemical factor

Source	Effects
Alkali	Mucous membranes burns and skin.

Here are the protection measures that will help to avoid the chemical dangerous effects on human health (Table 4.8).

Table 4.8 - Protective measures against the effects of chemical influences

Organizational	Check the battery charge. Observe the storage conditions of the device. Do not subject the device to mechanical damage.
Personal protection measures	Gloves

All measures must be taken during the device operation.

4.2.4 Thermal factors

The device stimulates the human nervous system with direct current due to a pair of electrodes. Since the electrodes can overheat, they can cause a dangerous thermal effect on the skin (Table 4.9).

Table 4.9 - Thermal factor risk

Source	Effects
Electrode overheating	Thermal burns

Here are the protective measures (Table 4.10), which will help to prevent the dangerous effects of electrodes overheating on human health.

Table 4.10 - Protective measures against thermal factors

Technical	Electrode’s isolation
Organizational	Training on how to work with electrodes.

During this process, the operational instructions were followed and electrode’s isolation were used.

4.2.5 Fire safety

The device components are stored in a plastic case; this material belongs to a specific category of flammability and shows the equipment's fire danger (table 4.11).

Table 4.11 - Parameters of a possible fire

Device name	Combustible substance (integral part of the equipment)	Substances that are combustible	Fire's possible cause
tDCS device	Plastic	Fuel	Human factor: violation of fire safety rules. Technological factor: device overheating, electric sparks, alkali.

Table 4.12 Safety measures that must be taken to eliminate the risk of harm to health.

Table 4.12 - Protection measures

Technical	Protection from nonflammable material
Organizational	Training in physiotherapy field Observance of safety rules

All measures must be taken during the device operation.[42]

4.3 Operating instructions

1. Preparing the device for work

Before starting, make an external inspection of the device and check: integrity, completeness, absence of visible mechanical damage to the device and electrodes. Make sure a battery is connected in its compartment or connect the battery to the corresponding terminals.

2. Preparation of electrodes

Unpack the contact wires and electrodes. Connect the contact wire plugs to the electrode sockets, those should be placed on patches soaked in saline to promote electrical conduction. Then connect the plug of the common part of the contact wires to the socket on the body of the device. The electrode system is ready for operation.

3. Preparation for the procedure

Make sure the skin where the electrodes are applied is clean, without cosmetics, there are no rashes and damage. It is recommended to wipe the skin with a lotion or a weak alcohol solution before the session. Then secure the electrodes to the appropriate areas of the head or shoulder.

4. Conducting tDCS

During the operation, the patient should be calm, comfortable, and awake. Some patients may experience discomfort during the initial period of tDCS. In these cases, the current can be reduced progressively over a short period of time, for example, by 50%, as the subject adapts, and then gradually increased to the desired amount. The duration of the session should not exceed 10-15 minutes.

It is possible to recommend stimulating at a lower intensity, such as 0.5-1.0 mA, but this does not guarantee that skin irritations or accidents can be avoided. As a result, before and after tDCS, the skin under the electrodes should be examined.

After the procedure - turn off the device by turning the knob counterclockwise. Remove the electrodes from the head and/or shoulder.

Recommended mode of exposure: 40 minutes per day, 5-10 days in a row, between sessions, you need to take a break of 2 months.[43]

Conclusions to chapter 4

In this section of the thesis, the potential dangers that arise during stimulation of human nervous tissue with direct current were identified and analyzed. In particular, physical, biological, chemical and thermal hazards were analyzed.

For each type of hazard, measures have been developed to improve neurostimulator safety. For the device under development, an operation manual was established, which describes recommendations and rules to carry out the procedure.

The developed device is safe to use and generally complies with labor protection standards, but certain measures have been proposed to reduce the physical risk.

CONCLUSIONS

As a result of processing the theoretical material, construction of a precision current source and an equivalent model of the object under study, modeling in the Micro-Cap 9 software, testing a sample of the device, it was found that:

- by influencing brain activity, it is possible to positively influence most of the body's processes (improvement of cognitive function, treatment and prevention of diseases);
- the maximum resistance of the object under study (8 Ohms), at which the circuit provides a current of 1.0 mA;
- the conglomerate of cells in the equivalent scheme can be replaced by the equivalent scheme of one cell.

The choice of real components was made taking into account their technical characteristics, price and availability. Passive circuit elements were selected using standard IEC-63 series for resistors and capacitors and by simulation in MC9 software.

Technical specifications for the unit, as well as structural and electrical schematic diagrams, were also created. A prototype was created after the printed circuit board was designed and traced. Laboratory tests showed that the designed sample of the device meets the specified technical requirements. The results of the experiment confirmed the results of computer simulation.

The developed device is safe to use and mostly meets the standards of labor protection, but certain measures have been proposed to reduce the physical danger.

BIBLIOGRAPHY

1. What is transcranial direct current stimulation? [Electronic resource]. (2016). Retrieved from: https://neuromodec.com/what-is-transcranial-direct-current-stimulation-tdcs/
2. Immediate neurophysiological effects of transcranial electrical stimulation [Electronic resource]. (2018). Retrieved from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6269428/
3. Shubina N., Glinin T. (2016) Neuroscience for medicine and phychology. Scientific research of tDCS.
4. Krames E. P. About Neuromodulation [Electronic resource]. (2018). Retrieved from: https://www.neuromodulation.com/about-neuromodulation
5. Neurostimulator Brainstorm [Electronic resource]. (2018). Retrieved from: http://boomstarter.ru/projects/517741/neyrostimulyator_brainstorm
6. Bulgakov N. Turbo brain [Electronic resource]. (2015). Retrieved from: https://www.ranibu.ru/turborezhim-mozga.html
7. Apparatus for micropolarization of the brain [Electronic resource]. (2016). Retrieved from: http://medilife.com.ua/index.php?route=product/product&path=250_225&product_id=2600.
8. A Professional tDCS System [Electronic resource]. (2018). Retrieved from: https://thebraindriver.com/pages/what-is-tdcs
9. Empowering neuromodulation [Electronic resource] // Soterix Medical. (2018). Retrieved from: https://soterixmedical.com/
10. On the method of transcranial electrical stimulation [Electronic resource] // Neurostimulator Brainstorm. (2016). Retrieved from: https://mybrainstorm.ru/wp-content/uploads/2017/01/BRAINSTORM_Method.pdf.

11. Hall. J. E., Guyton. A. C. (2015) Guyton Physiology (13th Ed.). Mississippi, USA: Saunders.

12. tES therapy (Transcranial Electrical Stimulation) [Electronic resource]. (2014). Retrieved from: http://medrakurs.ru/metod_rakurs/metody_lechebnogo_vozdejstviya/tes_terapiya/.

13. Vishnyakov L. R., Kokhana I. M., Andrienko O. M., Electrodes for physiotherapeutic methods of treatmen. // Science and innovation. (2007). p. 23–26.

14. Surface electrodes [Electronic resource]. (2018). Retrieved from: http://xn--d1abiaue3aa.xn--p1ai/surface-electrodes.html.

15. Direct currents [Electronic resource] – Retrieved from: http://intranet.tdmu.edu.ua/data/kafedra/internal/sport_medic/lectures_stud

16. Ovchinnikov N. Acceleration for the brain [Electronic resource]. (2017). Retrieved from :https://apparat.cc/world/brainhacking/

17. Khalid. H. J., Sandeep. S., Physiology, Cerebral Cortex [Electronic resource]. (2021). Retrieved from: https://www.ncbi.nlm.nih.gov/books/NBK538496/

18. The mechanism of excitation transmission in the neuromuscular synapse [Electronic resource]. (2017). Retrieved from :http://radio-angusht.ru/mehanizm-peredachi-vozbuzhdeniya-v-nervno-mishechnom-sinapse/.

19. Synaptic activity [Electronic resource]. Retrieved from: https://www.albany.edu/faculty/cafrye/apsy601/Ch.04feb10,psychopharmacology.html

20. Smolyaninov V. V. Mathematical models of biological tissues. (1980).

21. Models of analog passive components of the MicroCAP [Electronic resource]. Retrieved from: https://xreferat.com/33/336-1-modeli-analogovyh-passivnyh-komponentov-programmnogo-paketa-microcap-7.html

22. Monte Carlo Simulation [Electronic resource] // IBM Cloud Education. (2020). Retrieved from: https://www.ibm.com/cloud/learn/monte-carlo-simulation

23. DipTrace [Electronic resource] // Novarm Limited. (2021). Retrieved from: https://diptrace.com/diptrace-software/

24. PCSGU250 Description [Electronic resource]. (2021). Retrieved from: https://www.velleman.eu/products/view/?id=377622

25. Andanchenko M. V., Milikh M. M. Measurement of impedance of biological tissues [Electronic resource]. Retrieved from: http://www.rusnauka.com/14_ENXXI_2014/Tecnic/6_169534.doc.htm.

26. Practical RTD Interface Solutions [Electronic resource]. // Texas Instruments Incorporated. Retrieved from: http://www.ti.com/lit/an/snoa481b/snoa481b.pdf.

27. Kamkin A. G., Kiseleva I. S. Synapses // Atlas of Physiology. p. 408.

28. Monte Carlo method and its accuracy [Electronic resource]. (2016). Retrieved from: https://habr.com/post/274975/

29. Electromagnetic Compatibility [Electronic resource]. // Science Direct. (2019). Retrieved from: https://www.sciencedirect.com/topics/engineering/electromagnetic-compatibility

30. Electromagnetic compatibility [Electronic resource]. (2021). Retrieved from: https://www.iec.ch/emc

31. How to prevent electromagnetic interference [Electronic resource]. (2021). Retrieved from: https://blog.ttelectronics.com/electromagnetic-interference#3

32. Kerr. R. EMC measurements of components [Electronic resource]. Retrieved from: https://slideplayer.com/slide/1327616/

33. Methods for measuring the parameters of industrial radio interference and noise immunity [Electronic resource]. (2009). Retrieved from: https://www.derev-grad.ru/gradostroitelstvo-i-arhitektura

34. Machines, devices and other technical products: GOST 15150-69. p. 58.

35. Devices and medical equipment: GOST 20790-93. p. 26.

36. Medical electrical products: DSTU 3798-98. p. 176.

37. Petrov V. RC-filters [Electronic resource]. (2016). Retrieved from: https://vt-tech.eu/articles/calculators/165-simple-rc-filters.html.

38. Passive Low Pass RC Filters [Electronic resource]. (2019). Retrieved from: https://www.electronicshub.org/passive-low-pass-rc-filters/

39. P6AU-0512ELF Datasheet [Electronic resource]. Retrieved from: http://initiativa.com.ua/sites/initiative/upload/files_colection/p6au-0512elf.pdf.

40. OP284 Datasheet [Electronic resource]. Retrieved from: http://www.analog.com/media/en/technicaldocumentation/datasheets/OP184_284_484.pdf.

41. Standard series on IEC-63 [Electronic resource]. (2018). Retrieved from: http://signalizacia.in.ua/index.files/mezhdunarodnye_standartnie_rjady_dlja_rezistorov_i_kondensatorov

42. Demchuk, G., Demych, N. V., Kachynska, N. P. Methodical instructions for the implementation of the section "Labor protection" in diploma projects for students of the Faculty of Biomedical Engineering. (2017). Kyiv, UA. p. 38

43. Electrode Positioning and Montage in Transcranial Direct Current Stimulation [Electronic resource] // NCBI. (2016). – Retrieved from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3339846/