



## Fundamentals of design and design of medical equipment

### Work program of the academic discipline (Syllabus)

#### Реквізити навчальної дисципліни

Level of higher education	<i>First (Bachelor's)</i>
Branch of knowledge	<i>16 Chemical and Bioengineering</i>
Specialty	<i>163 Biomedical Engineering</i>
Educational program	<i>Biomedical Engineering</i>
Discipline status	<i>Normative</i>
Form of study	<i>full-time (full-time)</i>
Year of preparation, semester	<i>3rd year, spring</i>
The scope of discipline	<i>120 hours</i>
Semester control / Control measures	<i>Essay, credit</i>
Lessons schedule	<i>36 hours of lectures, 36 hours of practice, abstract</i>
Language of instruction	<i>Ukrainian/English/</i>
Information about course leader / teachers	<i>Lecturer: Doctor of Technical Sciences, Prof. Lebedev Oleksiy Volodymyrovych, <a href="mailto:mmif@kpi.ua">mmif@kpi.ua</a>, vol. 0955901559<sup>1</sup> Practical: prof. Lebedev Oleksiy Vladimirovich</i>
Course placement	<i>Moodle <a href="https://do.ipo.kpi.ua">https://do.ipo.kpi.ua</a></i>

#### Program of the discipline

##### 1. Description of the academic discipline, its purpose, subject of study and learning outcomes

*The discipline "Fundamentals of Design and Design of Medical Equipment" (hereinafter referred to as OKP) is taught by a professor with 48 years of experience in scientific and practical work on the use of engineering and medical engineering tools and technologies.*

***The purpose of the discipline*** is to form students' abilities to analyze and design medical equipment using modern applied design packages, provide analysis and synthesis of design solutions.

*During the study of the discipline, the following professional competencies are formed.*

*The academic discipline belongs to the cycle of normative academic disciplines of professional training of bachelors. OKP is an important new discipline in engineering education. Many companies are developing high-tech products for the medicine of today and the future. In accordance with international educational programs, the theoretical content of disciplines includes the main problems at the intersection of engineering and medical. The practical part is aimed at solving the problems of analysis and design of electronic medical equipment.*

*To study the discipline, you need the following skills:*

1. Knowledge of a foreign language;
2. Knowledge of the basics of design and design of electronic equipment.
3. Knowledge of standards for medical equipment.
4. Knowledge of the basics of mechanics and theory of resistance of materials.
5. Knowledge of the theoretical foundations of electrical engineering.
6. Ability to search, process and analyze
7. Ability to analyze complex medical-engineering and bioengineering problems and formalize them to find quantitative solutions using modern mathematical methods and information technologies.
8. Ability to investigate biological and technical aspects of the functioning and interaction of artificial biological and biotechnical systems.

*General competencies (the OP was put into effect by the Order of the Rector NON/434/2024 of 10.06.2024):*

**ZC 2** - Knowledge and understanding of the subject area and understanding of professional activities.

**ZC 3** - Ability to communicate in the state language both orally and in writing.

**ZC 5** - Ability to conduct research at the appropriate level.

**ZC 10** - Skills in carrying out safe activities.

*Special (professional) competencies (OP put into effect by the Rector's Order NON/434/2024 of 10.06.2024):*

**FK 1** - Ability to apply engineering software packages to carry out research, analysis, processing and presentation of results, as well as for the computer-aided design of medical devices and systems.

**FK 2** - Ability to provide engineering expertise in the planning, development, evaluation and specification of medical equipment.

**FK 7** - Ability to plan, design, develop, install, operate, maintain, maintain, control and coordinate the repair of devices, equipment and systems for prevention, diagnosis, treatment and rehabilitation used in hospitals and research institutes.

**FK 12** - Ability to ensure and monitor compliance with safety and biomedical ethics when working with medical equipment.

*The program results of training after studying the discipline "Microprocessor Technology" are (OP put into effect by the Rector's Order NON/434/2024 of 10.06.2024).):*

**PRN 2** - Formulate logical conclusions and reasonable recommendations for the assessment, operation and implementation of biotechnical, medical-technical and bioengineering tools and methods.

**PRN 4** - Apply the provisions of regulatory and technical documents regulating the procedure for product certification, production certification.

**PRN 7** - To carry out engineering support, service and maintenance during the operation of laboratory and analytical equipment, medical diagnostic and therapeutic complexes and systems in accordance with the rules established by technical documentation and regulatory documents regulating the procedure for commissioning, use and repair of medical equipment, as well as to draw up standard documentation for types of work in accordance with the Technical Regulations on Medical Devices.

**PRN 12** - Provide recommendations on the selection of equipment to ensure diagnosis and treatment.

**PRN 18** - Understanding of fundamental-applied, medical-physical, physico-chemical regularities of the functioning of biological objects, and bioengineering foundations of technologies and equipment for the study of human body processes.

## **2. Pre-requisites and post-requisites of the discipline (place in the structural and logical scheme of training according to the relevant educational program)**

*Discipline "Fundamentals of Design and Design of Medical Equipment" belongs to the cycle of professional training and has an interdisciplinary character. For the successful study of the discipline "Fundamentals of Design and Design of Medical Equipment", it is necessary to first study the following disciplines: "Biomedical Mechanics", "Engineering Mechanics", "Biothermodynamics and Mass Transfer", "Diagnostic Technology". Discipline "Fundamentals of Design and Design of Medical Equipment" is basic for such educational components as "Pre-Diploma Practice", "Research Practice", "Master's Thesis".*

*The acquired practical skills and acquired theoretical knowledge during the study of the academic discipline "Fundamentals of Design and Design of Medical Equipment" can be used in the future during the mastering of academic disciplines:*

- from the cycle of professional training (educational and professional program "Medical Engineering"): "Biomedical devices, devices and complexes";*
- in elective disciplines (educational and professional program "Medical Engineering"): "Medical Medical Equipment", "Development and Operation of Physiotherapy Medical Devices", "Information Support of Diagnostic and Treatment Processes of Patients with Lost Limbs", "Design of Medical Information Systems".*

## **3. Content of the discipline**

*The main sections and topics that will be considered in the course of study:*

### **Section No. 1 General information on the design and design of medical equipment**

**Topic1.1.** Basic standards for the design of biomedical devices.

**Topic1.2.** Design stages.

**Topic1.3.** Requirements for the terms of reference for design

**Topic1.4.** Overview of 3D modeling programs.

**Topic1.5.** Basic information and techniques for working with programs: MIMIX, Compass, Autodesk Inventor, 3D MAX.

### **Section No. 2 3D modeling in SolidWorks and Fusion 360 environments.**

**Topic2.1.** Basic technologies for creating 3D models.

**Topic2.2.** Creation of animation and movement research.

**Topic 2.3.** Creating photorealistic images of 3D models.

**Topic 2.4.** Creating collections.

**Topic 2.5.** Converting 3D models into drawings.

### **Section No. 3 Solving problems of resistance of materials and mechanics and thermophysics in the COMSOL environment.**

**Topic 3.1.** Basic information and techniques for using the **COMSOL module**

**Topic 3.2.** Design of a prosthesis of the lower limbs.

**Topic 3.3.** Design of a hip prosthesis.

**Topic 3.4.** Preoperative prognosis of stenting surgery and treatment of aneurysm.

**Topic 3.5.** Design of a bulletproof vest and a protective helmet.

**Topic 3.6.** Design of equipment and technologies for pressotherapy (or lymphatic drainage, pneumomassage) and shock wave therapy.

**Topic 3.7.** Study of the frequency properties of the eardrum.

**Topic 3.8.** Optimization of the model to achieve certain goals: minimum weight, service life, strength.

**Topic 3.9.** Modeling of Thermophysics Problems.

### **Section No. 4 Solving problems of fluid and gas flow in COMSOL environments.**

**Topic 4.1.** Basic information and techniques for working with **COMSOL**

**Topic 4.2.** Examples of **COMSOL** applications for biomedical device research and design.

**Topic 4.3.** Study of blood movement in sclerosed vessels.

**Topic 4.4.** Solving problems of biothermodynamics and mass transfer in devices and the human body.

### **Section No. 5 Application of COMSOL for the study of electromagnetic processes in biomedical devices and technologies.**

**Topic 5.1.** Design of devices for darsonval and electrophoresis.

**Topic 5.2.** Design of devices for DC and AC treatment.

**Topic 5.3.** Design of devices for constant alternating magnetic field treatment.

**Topic 5.4.** Design of microwave devices for treatment in oncology.

## **4. Educational materials and resources.**

### **Basic resources.**

1. Lebedev Oleksiy Vladimirovich, Dubko Andriy Grigorovich. *Methodical Instructions for the Implementation of Practical Work on the Credit Module "Design of Biotechnical Systems" for the Direction of Training 6.051402 – "Biomedical Engineering" / KPI. Igor Sikorsky Electronic text data. – Kyiv: KPI. Igor Sikorsky, 2017.*
2. Lebedev Oleksiy Vladimirovich, Dubko Andriy Grigorovich. *Methodical instructions for the implementation of practical work on the credit module "Fundamentals of Design and Design" - on the discipline "Fundamentals of Clinical Engineering - 1" for the direction of training 6.051402 - "Biomedical Engineering" K.: NTUU "KPI", 2015.205p. Electronic edition <http://ela.kpi.ua/handle/123456789/11764>*
3. Lebedev Oleksiy Vladimirovich, Dubko Andriy Grigorovich. *Methodical*

*recommendations for independent work of students in the discipline "Expertise and engineering support of medical equipment" for the direction of training 6.051402 – "Biomedical engineering" [Electronic resource] / KPI. Igor Sikorsky Electronic text data. – Kyiv: KPI. Igor Sikorsky, 2017.*

4. Lydia Cline. *Fusion 360 for Makers*. Maker Media. San Francisco, 2019, p. 540.

### ***Auxiliary resources***

*V. V. Shevchenko, O. V. Osadchiy, M. O. Simuta. *Technology of Instrumentation: Textbook for Students of the Direction of Training 6.051003 "Instrumentation", specialty "Scientific, Analytical and Environmental Instruments and Systems" / Kyiv: NTUU "KPI", 2010. Electronic version**

### ***Educational content.***

#### **5. 5. Methods of mastering the academic discipline (educational component)**

<b>No. s/ n</b>	<b>Theme</b>	<b>Software Results Training</b>	<b>Main tasks</b>	
			<b>Control measure</b>	<b>Term Execution</b>
<b><i>Section No. 1 General information on the design and design of medical equipment</i></b>				
1	<i>Basic standards for design of biomedical devices. Design stages. Requirements for the terms of reference for design.</i>	PRN 1  PRN 2  PRN 3	Practical lesson No. 1	1 week
2	<i>Overview of 3D programs modeling. Basic information and techniques for working with programs: MIMIX, Compass, Autodesk Inventor, 3D MAX.</i>		Practical Lesson No. 1	Week 2

<b>Section No. 2 3D modeling in SolidWorks and Fusion 360 environments.</b>				
3	<i>Basic technologies for creating 3D models.</i>	PRN 3 PRN 40	<i>Practical lesson No2-6</i>	<i>3-6 weeks</i>
4	<i>Animation creation and movement research.</i>	PRN 2 PRN 3	<i>Practical lesson No7</i>	<i>Week 7</i>
5	<i>Creation of photorealistic images of 3D models.</i>	PRN 7	<i>Practical lesson No. 8</i>	<i>Week 8</i>
6	<i>Creating collections.</i>	PRN 8	<i>Practical lesson No9</i>	<i>Week 9</i>
7	<i>Перетворення 3Д моделей в креслення.</i>	PRN 9	<i>Practical lesson No9</i>	<i>Week 9</i>
<b>Section 3 Solving Material Resistance and Mechanics Problems in COMSOL Environments.</b>				
8	<i>Basic information and techniques for using the COMSOL module</i>	PRN 5 PRN 36	<i>Practical Lesson No10</i>	<i>Week 10</i>
9	<i>Applications of COMSOL for the design of biomedical devices, devices, and technologies.</i>	PRN 5 PRN 8	<i>Практичне заняття №10</i>	<i>Week 10</i>
10	<i>Design of a prosthesis of the lower limbs</i>	PRN 9	<i>Practical lesson No11</i>	<i>Week 11</i>
11	<i>Prosthesis design hip joint.</i>	PRN 8 PRN 9	<i>Practical lesson No11</i>	<i>Week 11</i>
12	<i>Preoperative Forecasting stenting operations and treatment of aneurysm.</i>	PRN 36	<i>Practical lesson No. 12</i>	<i>Week 12</i>

13	<i>Design of a bulletproof vest and a protective helmet.</i>	PRN 2 PRN 3	<i>Practical lesson No. 12</i>	<i>Week 12</i>
14	<i>Design of equipment and technologies for pressotherapy (or lymphatic drainage, pneumomassage) and shock wave therapy.</i>	PRN 5 PRN 8	<i>Practical lesson No. 12</i>	<i>Week 12</i>
15	<i>Study of the frequency properties of the eardrum.</i>	PRN 3 PRN 40	<i>Practical lesson No. 13</i>	<i>Week 13</i>
16	<i>Optimizing the model for achievement of certain goals: minimum weight, service life, strength.</i>	PRN 8	<i>Practical Lesson No13</i>	<i>Week 13</i>
17	<i>Problem modeling Thermophysics.</i>	PRN 9	<i>Practical lesson No. 13</i>	<i>Week 13</i>

***Section No. 4 Solving problems of fluid and gas flow in COMSOL environments.***

18	<i>Basic information and techniques for working with the add-on COMSOL</i>	PRN 40	<i>Practical lesson No14</i>	<i>Week 14</i>
19	<i>Examples of COMSOL Applications for Biomedical Device Research and Design.</i>	PRN 9	<i>Practical lesson No14</i>	<i>Week 14</i>
20	<i>Study of blood movement in sclerosed vessels.</i>	PRN 36	<i>Practical lesson No14</i>	<i>Week 14</i>

21	<i>Problem solving biothermodynamics and mass transfer in devices and the human body.</i>	PRN 10 PRN 5	<i>Practical lesson No14</i>	<i>Week 14</i>
<b><i>Section No. 5 Application of COMSOL for the study of electromagnetic processes in biomedical devices and technologies.</i></b>				
24	<i>Design of devices for darsonval and electrophoresis.</i>	PRN 8	<i>Practical lesson No15</i>	<i>Week 15</i>
25	<i>Design of devices for DC and AC treatment.</i>	PRN 36	<i>Practical lesson No15</i>	<i>Week 15</i>
26	<i>Design of Devices for Constant Alternating Magnetic Field Treatment.</i>	PRN 40	<i>Practical lesson No15</i>	<i>Week 16</i>
27	<i>Design of microwave devices for treatment in oncology.</i>	PRN 10 PRN 5	<i>Practical lesson No15</i>	<i>Week 16</i>

### **Practical classes**

The main tasks of the cycle of practical classes are to consolidate in practice the main provisions of the academic discipline "FUNDAMENTALS OF DESIGN AND DESIGN OF MEDICAL EQUIPMENT" by performing specially formulated tasks and real options for biomedical equipment. The practical lesson includes the control of knowledge, skills and abilities, solving problems of designing bioengineering systems with their discussion, solving control tasks, checking and evaluating them.

The grades received by the student for individual practical classes are entered into the journal of classes of the study group and are taken into account when determining the final grade (rating) in this academic discipline.

<b>No. s/p</b>	<i>Name of the topic of the lesson</i>	
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1	<i>Basic standards for the design of biomedical devices. Design stages. Requirements for the terms of reference for design. Overview of 3D modeling programs. Basic information and techniques for working with programs: MIMIX, Compass, Autodesk Inventor, 3D MAX.</i>	2
3	<i>Basic technologies for creating 3D models.</i>	6
4	<i>Animation creation and movement research.</i>	2
5	<i>Creation of photorealistic images of 3D models.</i>	2
6	<i>Creating collections. Converting 3D models into drawings.</i>	2
7	<i>Basic information and techniques for working with <b>the COMSOL</b> module. Application of <b>COMSOL</b> for the design of biomedical devices, devices and technologies.</i>	2
8	<i>Design of a prosthesis of the lower extremities. Design of a hip prosthesis.</i>	2
9	<i>Preoperative prognosis of stenting surgery and treatment of aneurysm. Design of equipment and technologies for pressotherapy (or lymphatic drainage, pneumomassage) and shock wave therapy.</i>	2
10	<i>Study of the frequency properties of the eardrum. Optimization of the model to achieve certain goals: minimum weight, service life, strength. Modeling of Thermophysics Problems.</i>	2
11	<i>Basic information and techniques for working with <b>COMSOL</b>.</i>	2
12	<i>. Study of blood movement in sclerosed vessels.</i>	2
14	<i>Design of devices for electrophoresis. Design of devices for DC and AC treatment.</i>	2

15	<i>Design of devices for constant alternating magnetic field treatment. Design of microwave devices for treatment in oncology.</i>	2
	<i>Total:</i>	30

### Policy and control

#### 6. Policy of academic discipline (educational component)

##### **Attending classes**

*Attendance at lectures is optional. Attending practical classes is desirable, as they are used to write express tests / tests, as well as to defend practical work.*

*The grading system is focused on obtaining points for student activity, as well as performing tasks that are able to develop practical skills and abilities.*

##### **Control measures missed**

*Missed control measures (defense of practical work) must be practiced in the next classes, provided that the task is scheduled for the current lesson, or in consultations.*

*Omissions of writing a module test and express test are not fulfilled.*

*Calculation and graphic work, which is submitted for inspection in violation of the deadline is evaluated with a decrease in the number of weight points.*

##### **Violation of deadlines and incentive points**

Encouragement points		Penalty points *	
Criterion	Weight points	Criterion	Weight points
<i>Improving practical work</i>	<i>1 points (for each practical work)</i>	<i>Untimely implementation and test of practical work</i>	<i>From -0.5 points to -5 points (depending on the delivery date)</i>
<i>Passing distance courses on topics that are agreed with teachers</i>	<i>5 points</i>	<i>Untimely execution and test of calculation and graphic work</i>	<i>From -2 points to -20 points (depending on the construction period)</i>
<i>Registration of scientific work for participation in the competition of student scientific works</i>	<i>10 points</i>		
<i>Writing abstracts, articles, participation in international, national and / or other events or competitions on the subject of the discipline</i>	<i>5 points</i>		

*\* if the control measure was missed for a good reason (illness, which is confirmed by a certificate of the established sample) - penalty points are not accrued.*

## **Academic integrity**

*The policy and principles of academic integrity are defined in Section 3 of the Code of Honor of the National Technical University of Ukraine "Igor Sikorsky Kyiv Polytechnic Institute". Read more: <https://kpi.ua/code>.*

## **Norms of ethical behavior**

*Normative principles of behavior of students and employees, defined in sections 2 of the Code of Honor of the National Technical University of Ukraine "Igor Sikorsky Kyiv Polytechnic Institute". Read more: <https://kpi.ua/code>.*

## **Procedure for appealing the results of control measures**

*Students have the opportunity to raise any issue related to the control procedure and expect it to be addressed according to predefined procedures.*

*The student has the right to appeal the results of the control measure according to the approved provision on appeals in the National Technical University of Ukraine "Igor Sikorsky Kyiv Polytechnic Institute" (approved by the order №NON/128/2021 from 20.05.2021) - <https://osvita.kpi.ua/index.php/node/182>*

## **Inclusive education**

*The discipline "Medical Microprocessor Systems" can be taught to most students with special educational needs, except for students with severe visual impairments who do not allow to perform tasks using personal computers, laptops and / or other technical means.*

## **Distance learning**

*Distance learning takes place through the Sikorsky Distance learning Platform «Sikorsky».*

*Distance learning through additional online courses on certain topics is allowed subject to agreement with students. If a small number of students wish to take an online course on a specific topic, studying the material with such courses is allowed, but students must complete all the tasks provided in the discipline.*

*The list of courses is offered by the teacher after the students have expressed a desire (because the bank of available courses is updated almost every month).*

*The student provides a document confirming the completion of the distance course (in the case of a full course) or provides practical tasks from the distance course and subject to an oral interview with the teacher on the topics can receive grades for control measures provided for the studied topics (express control / test tasks, practical work).*

*Performance of practical works, and also performance of settlement and graphic work, is carried out during independent work of students in a remote mode (with a possibility of consultation with the teacher through e-mail, social networks).*

## **Learning a foreign language**

*Teaching in English is carried out only for foreign students.*

*At the request of students, it is allowed to study the material with the help of English-language online courses on topics that correspond to the topics of specific classes.*

## **7. Monitor and evaluate the system of evaluation of learning outcomes (Rating System of Evaluation)**

### ***Evaluation system (current control):***

No s/n	Control measure	%	Weight points	Number	Total
1.	Express control works / test tasks	10	2	5	10
2.	Execution and test of practical works	24	2	12	24
3.	Execution and test of laboratory works	36	4	9	36
6.	Test work <sup>2</sup>	80	80	1	80
	<i>Total</i>				<b>100</b>

*Calendar control (CC) - is performed twice a semester as monitoring of the current state of compliance with syllabus requirements.*

*The purpose of calendar control is to improve the quality of student learning and monitor the implementation of the schedule of the educational process by students.*

Criterion		<i>The first CC</i>	<i>The second CC</i>
<i>Deadline of calendar controls</i>		<i>8th week</i>	<i>14th week</i>
<i>Conditions for obtaining a positive result from the calendar control</i>	<i>Current rating</i>	$\geq 24$ points	$\geq 42$ points
	<i>Execution practical work</i>	<i>PW № 1-5</i>	+
		<i>PW № 6-12</i>	-
	<i>Express control works / test tasks</i>	<i>At least 4 of any lectures</i>	+
		<i>At least 8 of any lectures</i>	-
	<i>Modular control work</i>	<i>Estimated MCW</i>	-
	<i>Calculation and graphic work</i>	<i>Estimated CGW</i>	-

*In case of detection of academic poor quality during training - the control measure is not credited.*

### *Semester certification of students*

<i>Mandatory condition for admission to the test</i>		<i>Criterion</i>
1	<i>Current rating</i>	<i>RD <math>\geq 42</math></i>
2	<i>Obtaining a positive assessment for the performed calculation and graphic work</i>	<i>More than 8 points</i>
3	<i>All practical works are tested</i>	<i>More than 14 points</i>
4	<i>Writing at least 6 express tests / tests</i>	<i>More than 6 points</i>

*The results are announced to each student separately in the presence or remotely (by e-mail). Also recorded in the system "Electronic Campus".*

*Optional conditions for admission to closure:*

1. *Activity in practical classes.*
2. *Activity in laboratory classes.*
3. *Positive result of the first attestation and the second attestation.*
4. *Attending 50% of lectures.*

*Table of translation of rating points to grades on a university scale:*

<sup>2</sup> *Taken into account in the amount of the rating together with the grade for CGW in case the student has not scored 60 points per semester or he wants to improve his grade.*

Number points	Assessment on the university scale
100-95	<i>Perfectly</i>
94-85	<i>Very good</i>
84-75	<i>Good</i>
74-65	<i>Satisfactorily</i>
64-60	<i>Enough</i>
Less 60	<i>Unsatisfactorily</i>
<i>Admission conditions are not met</i>	
<i>Not allowed</i>	

## 8. Additional information on the discipline (educational component)

### **Appendix 1. Program learning outcomes (extended form)**

*In accordance with the Order of the Ministry of Education and Science of Ukraine No. 1204 dated November 19, 2018 "On approval of the standard of higher education in the specialty 163 Biomedical Engineering" for the first bachelor's level of higher education", in Appendix 1 establishes the correspondence of learning outcomes to competencies in the discipline "Microprocessor Engineering".*

### **Appendix 2. The list of questions for preparation for module control work**

*The list of questions for preparation for modular control work, and also for preparation for credit is given in Appendix 2.*

*Distance learning through additional online courses on certain topics is allowed subject to agreement with students. If a small number of students wish to take an online course on a specific topic, studying the material with such courses is allowed, but students must complete all the tasks provided in the discipline.*

*The list of courses is offered by the teacher after the students have expressed a desire (because the bank of available courses is updated almost every month).*

*The student provides a document confirming the completion of the distance course (in the case of a full course) or provides practical tasks from the distance course and subject to an oral interview with the teacher on the topics can receive grades for control measures provided for the studied topics (express control / test tasks, practical work).*

### **Work program of the academic discipline (syllabus):**

**Compiled by** Professor of the Department of BMI, Doctor of Technical Sciences, **Lebedev Oleksiy Volodymyrovych**

**Approved** by the Department of Biomedical Engineering (Minutes No. 16 dated June 21, 2024)

**Approved** by the Methodological Commission of the Faculty of Biomedical Engineering (Minutes No. 9 dated June 26, 2024)