National Technical University of Ukraine
"Igor Sikorsky Kyiv Polytechnic Institute"

Department
biomedical engineering

Biomedical Devices, Apparatus and Complexes

Working program of basic discipline (Silabus)

Requisites for basic discipline	
Level of higher education	*First (bachelor's)*
Branch of knowledge	*16 Chemical engineering and Bioengineering*
Specialty	*163 Biomedical Engineering*
Educational program	*Medical Engineering*
Discipline status	*Mandatory discipline*
Form of study	*full-time / day / mixed / remote*
Year of preparation, semester	*3th course, spring semester*
The scope of discipline	*5 ECTS credits / 150 hours*
Semester control / Control measures	*Exam, Modular Test Work, Calculation and Graphic Work*
Lessons schedule	*According to the schedule on the site http://rozklad.kpi.ua/*
Language of instruction	*English*
Information about course leader / teachers	***Lecturer:*** *D.Sc. (Medicine), Professor of the Department of Biomedical Engineering Vitalii Borysovych Maksymenko,* *e-mail - maksymenko.vitaliy@gmail.com, Telegram – Maksymenko Vitaliy, +380673005924* ***Practical:*** *PhD (Engineering), Associate Professor of the Department of Biomedical Engineering Maryna Mykhailivna Sychyk* *e-mail - sychykmm@gmail.com, Telegram – @Maryna_Sychyk, +380976898910*
Course placement	***Distance learning on the Moodle platform:*** *https://do.ipo.kpi.ua/course/view.php?id=5985* *— course " Biomedical Devices, Apparatus and Complexes "*

Distribution of hours			
Semester	**Lectures**	**Practical**	**Independent Work**
spring semester	*36*	*36*	*78*

Curriculum of the discipline

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

The academic discipline "Biomedical Devices, Apparatus and Complexes" *focuses on the application of methods and general principles for the design of medical devices related to the development and engineering maintenance of biological and medical instruments and systems.*

The ***main objective*** *of the discipline "****Biomedical Devices, Apparatus and Complexes****" is to develop students' ability to solve complex specialized problems, acquire knowledge of relevant software, standards, and technical characteristics of device components, and apply this knowledge in the design of medical devices.*

*Teaching of the discipline "****Biomedical Devices, Apparatus and Complexes****" is carried out based on a* ***student-centered approach*** *and a strategy of interaction between the instructor and students, aimed at mastering the course material and developing practical skills.*

Prerequisites for studying the discipline include:

Skills:

- *methods of systems analysis and simulation of technical and biological systems;*
- *methods of automatic control theory;*
- *basic knowledge of biophysics, biochemistry, and physiological parameters of interaction with the human body and biological tissues for mathematical and software modeling.*

Competencies:

As a result of studying the discipline, students will be able to:

- *understand and apply tools and methods for designing medical devices and equipment;*
- *search for, analyze, and synthesize information on medical devices and apply it within their professional competence;*
- *conduct research using modern software tools for simulation of life processes, including in technical and biological systems.*

Students will also be able to practically apply the acquired knowledge in:

- *methods for using industrial product models to simulate the operation of medical systems;*
- *development of basic models of human organs and body systems;*
- *general principles and trends in the development of modern medical systems;*
- *formulation and justification of technical requirements for medical systems;*
- *interpretation of biological objects as complexes of functional and dynamic components;*
- *application of modern theoretical methods and technical tools to determine parameters of technical and biological systems;*
- *analysis of processes occurring in medical devices, equipment, and biological objects and systems;*
- *repair and maintenance of various types of radio-electronic medical equipment.*

General competencies *(OPP was put into effect by the Rector's Order NON/434/2024 of 10.06.2024 p.):*

ZK 1 *- Ability to apply knowledge in practical situations.*

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

ZK 6 *- Ability to search, process, and analyze information from various sources.*

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

FK 3 *- Ability to study and apply new methods and tools for analysis, modeling, design, and optimization of medical devices and systems.*

FK 8 *- Ability to conduct research and observation on the interaction of biological, natural, and artificial systems (prostheses, artificial organs, etc.).*

FK 9 *- Ability to identify, formulate, and solve engineering problems related to the interaction between living and non-living systems.*

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

The program learning outcomes after studying the discipline "Biomedical Devices, Apparatus and Complexes" are *(OPP was put into effect by the Rector's Order NON/434/2024 of 10.06.2024 p.):*

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

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

PRN 8 *- Understand theoretical and practical approaches to the creation and management of medical equipment and medical technology.*

PRN 12 *- Provide recommendations for selecting equipment to facilitate diagnosis and treatment.*

PRN 13 *- Be able to analyze signals transmitted from organs to devices and process diagnostic information (signals and images).*

PRN 23 *- Development and implementation of modern diagnostic and therapeutic methods associated with the use of biotechnology, computer, and nanotechnology through the improvement of technical elements of medical devices and systems, as well as medical products, in the process of professional activity.*

2. Prerequisites and postrequisites of the discipline (place in the structural and logical scheme of education according to the relevant educational program)

The academic discipline "Biomedical Devices, Apparatus and Complexes" belongs to the cycle of professional training and has an interdisciplinary character. In accordance with its subject area, it integrates knowledge from other academic disciplines, including Quantitative Physiology, Human Anatomy and Physiology, Introduction to the Profession, Engineering and Computer Graphics, Physics, Higher Mathematics, Fundamentals of Computer Science, Biochemistry, and others.

According to the structural and logical scheme of the specialist training program, the discipline "Biomedical Devices, Apparatus and Complexes" is closely related to other disciplines of general and professional training, such as Methods of Modeling and Analysis of Biomedical Processes and Systems, Biophysics, and Mechanics and Biomechanics. It is directly preceded by the discipline “Analog and Digital Circuit Design”.

The practical skills acquired and theoretical knowledge gained during the study of the discipline "Biomedical Devices, Apparatus and Complexes" can be further applied in subsequent professional training disciplines within the educational and professional program “Medical Engineering”, including Microprocessor Technology, Expert Evaluation and Engineering Support of Medical Equipment, Pre-Diploma Practice, Diploma Project, and Design of Biomedical Systems. Interdisciplinary Course Project.

3. The content of the discipline

The main sections and topics that will be considered in the process of studying the course:

Section 1. Classification of Medical Devices

Subject 1.1. Classification of medical devices. Basics of metrology for medical instruments. Key standards for evaluation, operation, and implementation of biotechnical, medical-technical, and bioengineering tools and methods. Regulatory documents governing certification procedures.

Section 2. Non-Invasive Medical Devices

Subject 2.1. Devices in contact with damaged skin or mucous membranes. Dressings. Recommendations for selecting equipment to ensure therapeutic effects.

Subject 2.2. Devices that either do not contact the patient directly or only contact intact skin. Devices primarily intended for external support. Practical approaches to the development and management of rehabilitation devices.

Section 3. Invasive Medical Devices

Subject 3.1. Surgical invasive devices intended for temporary use. Recommendations for evaluating biocompatibility and operational techniques.

Subject 3.2. Surgical invasive medical devices for short-term use (<60 min) and surgical instruments/fixators (>60 min <30 days). Recommendations for equipment selection.

Subject 3.3. Endoprostheses and implants (>30 days). Artificial organs and materials for their construction. Implementation of biotechnical, medical-technical, and bioengineering tools and methods.

Subject 3.4. Devices inserted through body openings for diagnostic, therapeutic, or surgical purposes. Endoscopes for dental, ophthalmological, urological, gastroenterological, and ENT applications. Recommendations for equipment selection for diagnostics and treatment.

Subject 3.5. Cardiovascular catheters. Analysis of signals transmitted from organs to devices and processing of diagnostic information (signals and images).

Section 4. Active Medical Devices

Subject 4.1. Active therapeutic devices for energy management or exchange, including equipment for physiotherapy. Signals transmitted from organs to devices.

Subject 4.2. Active devices for diagnostics and monitoring, including diagnostic or therapeutic radiology. Analysis and processing of diagnostic information (signals and images). Equipment selection for ensuring diagnostic procedures.

Subject 4.2.1. Diagnostic ultrasound.

Subject 4.2.2. Electrocardiographs and electroencephalographs.

Subject 4.2.3. Optical devices and sensors for monitoring human physiological parameters (pulse oximetry, non-invasive and invasive measurement of pressure, temperature, blood coagulation, glucose monitoring).

Subject 4.3. Devices that alter the biological or chemical composition of human tissues, cells, blood, or other body fluids, intended for implantation or administration. Theoretical and practical approaches to the development and management of medical equipment.

Subject 4.3.1. Artificial circulation and oxygenators.

Subject 4.3.2. Hemodialysis. Devices for temporary storage or transport of organs for transplantation.

Subject 4.4. Active devices intended for administration or removal of drugs, body fluids, or other substances. Development and implementation of modern diagnostic and therapeutic methods. Improvement of technical components of medical devices.

Subject 4.4.1. Pumps and artificial hearts.

Subject 4.4.2. Artificial lung ventilation.

Subject 4.5. Other active devices, including equipment for disinfection, cleaning, irrigation, humidification, or sterilization. Regulatory and technical documentation governing procedures.

Subject 4.6. Devices made using human or animal tissues, cells, or derivatives. Biotechnology in biomedical engineering.

Subject 4.7. Devices containing or made from nanomaterials. Nanotechnology in biomedical engineering.

Section 5. Information Technologies in Medicine and Bioengineering

Subject 5.1. Software designed to provide information for decision-making in diagnostics or therapy, or software intended for monitoring physiological processes. Development and implementation of modern diagnostic and therapeutic methods.

4. Training materials and resources

Basic literature:

1. *Шликов, В. В. Інформаційно-діагностичні системи у медицині [Електронний ресурс] : навч. посіб. для здобувачів ступеня магістра і д-ра філософії за освіт. програмою «Біомедична інженерія» спец. 163 Біомедична інженерія / В. В. Шликов, В. Б. Максименко ; КПІ ім. Ігоря Сікорського. –Електрон. текст. дані (1 файл 5,83 Мбайт). – Київ : КПІ ім. Ігоря Сікорського, 2025. – 200 с.*
2. *Bogomolov, M. F. Biomedical devices, apparatus and complexes [Electronic resource] : Educational Tutorial for students for bachelor's degree in specialty 163 - Biomedical Engineering specialization "Medical Engineering" / M. F. Bogomolov, V. V. Shlykov, M. M. Sychyk ; Igor Sikorsky Kyiv Polytechnic Institute. – Electronic text data (1 file: 3.01 MB). – Kyiv : Igor Sikorsky Kyiv Polytechnic Institute, 2023. – 93 p.*
3. *Конспект лекцій з дисципліни «Лікувальна медична техніка» [Електронний ресурс] : навчальний посібник для здобувачів ступеня бакалавра за спеціальністю 163 Біомедична інженерія, спеціалізацією «Медична інженерія» / КПІ ім. Ігоря Сікорського ; уклад.: М. Ф. Богомолов, В. Б. Максименко. – Електронні текстові данні (1 файл 3,36 Мбайт). – Київ : КПІ ім. Ігоря Сікорського, 2021. – 78 с.*
4. *Методи та засоби діагностики. Сучасні оптоелектронні діагностичні прилади [Електронний ресурс] : навчальний посібник для здобувачів ступеня бакалавра за освітньою програмою «Медична інженерія» спеціальності 163 «Біомедична інженерія» / КПІ ім. Ігоря Сікорського ; уклад. М. Ф. Богомолов, В. Б. Максименко, В. В. Шликов ; КПІ ім. Ігоря Сікорського. – Електронні текстові данні (1 файл 4,3 Мбайт). – Київ : КПІ ім. Ігоря Сікорського», 2021. – 125 с.*
5. *Методи та засоби діагностики. Основи лазерних лабораторних методів біомедичних досліджень [Електронний ресурс] : навчальний посібник навчальний посібник для здобувачів ступеня бакалавра за освітньою програмою «Медична інженерія» спеціальності 163 «Біомедична інженерія» / КПІ ім. Ігоря Сікорського ; уклад. М. Ф. Богомолов, В. В. Шликов, В. Б. Максименко. – Електронні текстові данні (1 файл 3,67 Мбайт). – Київ : КПІ ім. Ігоря Сікорського», 2021. – 150 с.*
6. *Методи та засоби діагностики. Сучасні оптоелектронні діагностичні прилади [Електронний ресурс] : навчальний посібник для здобувачів ступеня бакалавра за освітньою програмою «Медична інженерія» спеціальності 163 «Біомедична інженерія» / КПІ ім. Ігоря Сікорського ; уклад. М. Ф. Богомолов, В. Б. Максименко, В. В. Шликов ; КПІ ім. Ігоря Сікорського. – Електронні текстові данні (1 файл 4,3 Мбайт). – Київ : КПІ ім. Ігоря Сікорського», 2021. – 125 с.*
7. *Лабораторна та аналітична техніка. Практикум [Електронний ресурс] : навч. посіб. для здобувачів ступеня бакалавра за освіт. програмою «Медична інженерія» спец. 163 Біомедична інженерія / КПІ ім. Ігоря Сікорського ; уклад.: М. Ф. Богомолов, С. І. Вовянко, В. В. Шликов. – Електрон. текст. дані (1 файл: 3,86 Мбайт). – Київ : КПІ ім. Ігоря Сікорського, 2025. – 142 с.*
8. *Богомолов, М. Ф. Біомедичні сенсорні системи. Конспект лекцій [Електронний ресурс] : навч. посіб. для здобувачів ступеня бакалавра за освіт. програмою «Медична інженерія» спец. 163 «Біомедична інженерія» / М. Ф. Богомолов, С. І. Вовянко ; КПІ ім. Ігоря Сікорського. – Електрон. текст. дані (1 файл: 4,44 Мбайт). – Київ: КПІ ім. Ігоря Сікорського, 2025. – 122 с.*
9. *Розробка та експлуатація фізіотерапевтичних медичних приладів. Конспект лекцій [Електронний ресурс] : навчальний посібник для здобувачів ступеня бакалавра за спеціальністю 163 Біомедична інженерія / КПІ ім. Ігоря Сікорського ; уклад.: М. Ф. Богомолов, В. В. Шликов. – Електронні текстові дані (1 файл: 1,83 Мбайт). – Київ : КПІ ім. Ігоря Сікорського, 2024. – 78 с.*

Additional literature:

1. *Уварова І.В. / Біосумісні матеріали для медичних виробів / Уварова І.В.,Максименко В.Б. / Навчальний посібник ФБМІ НТУУ «КПІ» – Київ: КІМ, 2013 – 232 с.*
2. *Абакумов В.Г. Реєстрація, обробка та контроль біомедичних сигналів / В.Г. Абакумов, З.Ю. Готра, С.М. Злепко та ін. – Вінниця: ВНТУ, 2011. – 352 с. 5.*
3. *Кулик А.Я., Нікольський О.І., Ревенок В.І. Кулик Я.А. Схемотехніка медичної електронної апаратури / Монографія. – Вінниця: ВНМУ, 2020. – 167 с.*
4. *Кулик А.Я. Комп'ютерні системи та інформаційні технології / Монографія. / А.Я.Кулик, В.В. Мотигін, Я.А. Кулик, Б.П. Книш – Вінниця: ВНМУ, 2020. – 299 с.*
5. *Чалий О.В. Медична та біологічна фізика / О.В. Чалий, Я.В. Цехмістер, Б.Т. Агапов та ін.; за ред. проф. О.В. Чалого. – Вінниця: Нова книга, 2013. – 528 с.*
6. *Яворовський О.П., Охорона праці в медичній галузі: підручник / О.П. Яворовський, І.В. Сергета, Ю.О. Паустовський, В.І. Зенкіна та ін. – Всеукраїнське спеціалізоване видавництво «Медицина», 2021. – 488 с.*
7. *Сливко Е.І./ Медична і біологічна фізика: Навчальний посібник для студентів спеціальності 222 «Медицина»/ Е.І. Сливко, О.З. Мельнікова, О.З.Іванченко, Н.С. Біляк. - Запоріжжя, 2018.- 291 с.*
8. *Чумаченко Т. О. / Стерилізація інструментарію медичного призначення : метод. вказ. для самост. роботи лікарів-інтернів з дисципліни «Епідеміологія» / упоряд. Т. О. Чумаченко, М. В. Райлян, Ю. І. Поливянна та ін. – Харків : ХНМУ, 2020. – 32 с.*
9. *Булах І.Є. / Комп'ютерне моделювання у фармації: навчальний посібник (ВНЗ IV р. а.) / І.Є. Булах, Л.П. Войтенко, І.П. Кривенко. / – Всеукраїнське спеціалізоване видавництво «Медицина», 2017, 2-е вид., випр. – 208 с.*
10. *Мороз А.С. / Медична хімія / А.С. Мороз . – Нова Книга, 2013. – 776 с.*

Educational Content

5. Methods of mastering the discipline (educational component)

№ s/n	*Subject*	*Program learning outcomes*	*The main tasks*	
			Control measure	*Deadline*
	Section 1. Classification of Medical Devices			
1	*Subject 1.1. Classification of medical devices. Basics of metrology for medical instruments. Key standards for evaluation, operation, and implementation of biotechnical, medical-technical, and bioengineering tools and methods. Regulatory documents governing certification procedures.*	*PRN 2 PRN 4*	*Practical work 1*	*1th week*
	Section 2. Non-Invasive Medical Devices			
2	*Subject 2.1. Devices in contact with damaged skin or mucous membranes. Dressings. Recommendations for selecting equipment to ensure therapeutic effects.*	*PRN 12*	*Practical work 2*	*2nd week*
3	*Subject 2.2. Devices that either do not contact the patient directly or only contact intact skin. Devices primarily intended for external support. Practical approaches to the development and management of rehabilitation devices.*	*PRN 8*	*Practical work 3*	*3rd week*
	Section 3. Invasive Medical Devices			
4	*Subject 3.1. Surgical invasive devices intended for*	*PRN 2*	*Practical work*	*4th week*

	temporary use. Recommendations for evaluating biocompatibility and operational techniques.		*4*	
5	*Subject 3.2. Surgical invasive medical devices for short-term use (<60 min) and surgical instruments/fixators (>60 min <30 days). Recommendations for equipment selection.*	*PRN 12*		
6	*Subject 3.3. Endoprostheses and implants (>30 days). Artificial organs and materials for their construction. Implementation of biotechnical, medical-technical, and bioengineering tools and methods.*	*PRN 2*	*Practical work 5*	*5th week*
7	*Subject 3.4. Devices inserted through body openings for diagnostic, therapeutic, or surgical purposes. Endoscopes for dental, ophthalmological, urological, gastroenterological, and ENT applications. Recommendations for equipment selection for diagnostics and treatment.*	*PRN 12*	*Practical work 6*	*6th week*
8	*Subject 3.5. Cardiovascular catheters. Analysis of signals transmitted from organs to devices and processing of diagnostic information (signals and images).*	*PRN 13*		
	Section 4. Active Medical Devices			
9	*Subject 4.1. Active therapeutic devices for energy management or exchange, including equipment for physiotherapy. Signals transmitted from organs to devices.*	*PRN 13*	*Practical work 7*	*7-9th week*
10	*Subject 4.2. Active devices for diagnostics and monitoring, including diagnostic or therapeutic radiology. Analysis and processing of diagnostic information (signals and images). Equipment selection for ensuring diagnostic procedures.* *Subject 4.2.1. Diagnostic ultrasound.* *Subject 4.2.2. Electrocardiographs and electroencephalographs.* *Subject 4.2.3. Optical devices and sensors for monitoring human physiological parameters (pulse oximetry, non-invasive and invasive measurement of pressure, temperature, blood coagulation, glucose monitoring).*	*PRN 12* *PRN 13*	*Practical work 8* *Practical work 9* *Practical work 10*	
11	*Subject 4.3. Devices that alter the biological or chemical composition of human tissues, cells, blood, or other body fluids, intended for implantation or administration. Theoretical and practical approaches to the development and management of medical equipment.* *Subject 4.3.1. Artificial circulation and oxygenators.* *Subject 4.3.2. Hemodialysis. Devices for temporary storage or transport of organs for transplantation.*	*PRN 8*	*Practical work 11* *Practical work 12*	*10th week*

12	*Subject 4.4. Active devices intended for administration or removal of drugs, body fluids, or other substances. Development and implementation of modern diagnostic and therapeutic methods. Improvement of technical components of medical devices.* *Subject 4.4.1. Pumps and artificial hearts.* *Subject 4.4.2. Artificial lung ventilation.*	*PRN 23*	*Practical work 13* *Practical work 14*	*11th week*
13	*Subject 4.5. Other active devices, including equipment for disinfection, cleaning, irrigation, humidification, or sterilization. Regulatory and technical documentation governing procedures.*	*PRN 4*		*12th week*
14	*Subject 4.6. Devices made using human or animal tissues, cells, or derivatives. Biotechnology in biomedical engineering.*	*PRN 23*	*Practical work 15*	*13th week*
15	*Subject 4.7. Devices containing or made from nanomaterials. Nanotechnology in biomedical engineering.*	*PRN 23*	*Practical work 16*	*14th week*
	Section 5. Information Technologies in Medicine and Bioengineering			
16	*Subject 5.1. Software designed to provide information for decision-making in diagnostics or therapy, or software intended for monitoring physiological processes. Development and implementation of modern diagnostic and therapeutic methods.*	*PRN 23*	*Practical work 17*	*15th week*
17	*Модульна контрольна робота*		*Practical work 18*	
18	*Розрахунково-графічна робота*	*PRN 2* *PRN 4* *PRN 8* *PRN 12* *PRN 13* *PRN 23*	*Registration and submission of work*	

Practical works

*The main objectives of the practical training sessions are to **reinforce the core principles** of the discipline "Biomedical Devices, Apparatus and Complexes" through the completion of specially formulated tasks and the study of real components of biomedical equipment, which are also used in students' master's projects.*

Each practical session includes: assessment of students' knowledge, skills, and competencies; examination and discussion of biomedical devices, equipment, and systems; solving control tasks, checking solutions, and evaluating results.

Grades obtained by students for individual practical sessions are recorded in the class journal and are taken into account when determining the final grade (or rating) for the course.

№ s/n	*Practical work topic*	*Duration in hours*
1	***Classification of Medical Devices and Metrology Content*** *Classification of medical devices according to international and national standards (MDR, ISO, DSTU).*	*2*

	Analysis of examples of medical devices by risk classes. ***Metrological characteristics of medical instruments.*** *Study of measurement errors, as well as calibration and verification of medical devices.*	
2	***Medical Dressings and Devices for Contact with Damaged Skin and Mucous Membranes*** *Medical dressings and devices designed for contact with damaged skin and mucous membranes.* *Assessment of materials, sterility, and biocompatibility of such devices.*	*2*
3	***Non-Invasive Devices for External Patient Support*** *Non-invasive devices intended for external support of the patient.* *Orthoses, bandages, immobilization systems, and assistive rehabilitation devices.*	*2*
4	***Surgical Invasive Devices for Temporary Use*** *Surgical invasive devices for temporary use: instruments, needles, scalpels; safety and sterilization requirements.* *Short-term invasive devices (<60 minutes): design features and safe usage guidelines.* *Long-term invasive devices (>60 minutes – <30 days): fixators, drainage systems, and postoperative devices.*	*2*
5	***Long-Term Implants and Endoprostheses (>30 Days)*** *Implants and endoprostheses intended for long-term use (>30 days).* *Materials, mechanical properties, and biocompatibility of implants.*	*2*
6	***Endoscopic Devices for Diagnosis and Treatment*** *Endoscopic devices used for diagnostic and therapeutic purposes.* *Types of endoscopes: gastroscopes, bronchoscopes, cystoscopes, and dental endoscopes.*	*2*
7	***Cardiovascular Catheters and Guidewires*** *Types and materials of cardiovascular catheters and guidewires.* *Associated risks and quality control procedures.*	*2*
8	***Active Therapeutic Devices and Physiotherapy Equipment*** *Principles of operation, modes of use, and safety parameters of active therapeutic devices and physiotherapy equipment.*	*2*
9	***Active Diagnostic Devices for Ultrasound Imaging*** *Ultrasound diagnostic devices: transducers, scanning modes, and safety standards.*	*2*
10	***Electrocardiographs and Electroencephalographs*** *Recording, filtering, and analysis of biosignals using ECG and EEG devices.*	*2*
11	***Optical and Sensor Systems for Monitoring Physiological Parameters*** *Monitoring devices for physiological parameters: pulse oximetry, blood pressure, body temperature, and glucose measurement.*	*2*
12	***Active Devices for Altering the Biological Composition of Blood and Body Fluids*** *Devices: artificial circulation systems, oxygenators, and hemodialysis equipment.*	*2*
13	***Devices for Temporary Storage and Transport of Organs*** *Equipment: cryogenic systems, transport containers, and environmental requirements for organ preservation.*	*2*
14	***Devices for Administration and Removal of Drugs and Fluids*** *Equipment: infusion pumps, injectors, and aspiration systems.*	*2*
15	***Mechanical Ventilation Devices and Respiratory Support Systems*** *Ventilation modes, sensors, and monitoring of respiratory parameters.*	*2*

16	***Specialized Active Medical Devices*** *Functions: sterilization, disinfection, and cleaning.* *Advanced materials: devices made from human or animal tissues and cells, as well as nanomaterials.*	*2*
17	***Medical Software and Information Technologies in Bioengineering*** *Evaluation of software for diagnostics, monitoring, and support of clinical decision-making.*	*2*
18	*Module test work*	*2*
Total hours		*36*

6. Independent student work

One of the main forms of semester assessment in the course " Biomedical Devices, Apparatus and Complexes " is the preparation for lectures, practical sessions, express control tasks/tests, and individual assignments.

***Види самостійної роботи**:*

№ s/n	Types of work submitted for independent work	Duration in hours IW
1	*Review of lecture material and study of questions assigned for independent work*	10
2	*Preparation for practical works*	24
3	*Preparation for modular control work*	4
4	*Performance of computational and graphic work*	10
5	*Preparation for the Final test*	30
	Total hours	78

Distribution of hours of independent work of students by educational content topics:

№ s/n	Titles of topics and questions to be studied independently and references to educational literature	Duration in hours IW
1	***Selection of the Topic for the Individual Assignment*** *Students choose a specific biomedical device and analyze it according to the following components:*	
1.1	***General Description of the Method (Device) in Medicine*** *Overview of the **application of the method or device** in medical practice.* ***Purpose** and **objectives** of its use.*	5
1.2	***Theoretical Part*** *Detailed description of the **biophysics and fundamental principles** underlying the operation of the method or device.*	12
1.3	***Technical Part*** *Description of the **equipment used**, including **schematics and operating principles**.* ***Technical specifications** and its **application in treatment**.*	12
1.4	***Practical Part*** ***Implementation of the method** worldwide and in Ukraine.* ***Applications in research** and clinical practice.* ***Future perspectives and potential developments**.*	5
2	***Modular test work***	4
3	***Computational and graphic work***	10
4	***Final test***	30
	Total hours	78

One of the main forms of semester assessment *in the course "Biomedical Devices, Apparatus and Complexes" is the* ***completion of a calculation and graphical assignment****.*

- *The* ***calculation and graphical work*** *is carried out according to the requirements and within the deadlines set by the instructor.*
- *The* ***main goal*** *of the assignment is to* ***solve a practical problem*** *using the theoretical material learned in lectures, as well as the practical skills acquired during lab and practical sessions.*
- *Students may only complete a calculation and graphical assignment on a* ***topic approved by the instructor****.*

Approximate subject of calculation and graphic work:

№ з/п	Назви тем
1	*Metrological Support and Measurement Accuracy in Biomedical Devices*
2	*Classification of Biomedical Devices by Safety Level and Clinical Risk*
3	*Biocompatibility of Materials in the Design of Non-Invasive Biomedical Devices*
4	*External Support Biomedical Devices: Design Features and Principles of Operation*
5	*Surgical Instruments in Biomedical Engineering: Materials, Sterilization, and Standards*
6	*Temporarily Used Invasive Biomedical Devices: Indications and Limitations*
7	*Implantable Biomedical Devices and Endoprostheses: Engineering Approaches and Biocompatibility Challenges*
8	*Endoscopic Biomedical Systems: Design Principles and Application Areas*
9	*Cardiovascular Catheters: Construction, Materials, and Usage Risks*
10	*Active Therapeutic Biomedical Devices: Types of Energy and Mechanisms of Tissue Interaction*
11	*Recording and Analysis of Bioelectrical Signals in Medical Diagnostics*
12	*Optical and Sensor Biomedical Devices for Monitoring Physiological Parameters*
13	*Artificial Circulation and Oxygenation Systems: Engineering Solutions and Clinical Significance*
14	*Devices for Administration and Removal of Fluids in the Body: Infusion Systems and Mechanical Ventilation Devices*
15	*Reliability, Functional Safety, and Standardization of Biomedical Devices and Systems*

The title page of the calculation and graphic work should have the following content: the name of the university; name of the faculty; name of department; name of specialty, name of educational-professional program, name of academic discipline; theme of calculation and graphic work; surname and name of the student, course, number of the academic group, year.

The title page is followed by a detailed plan (content) of the calculation and graphic work, which should highlight the introduction, sections of the main content (main topics studied), their subdivisions (if necessary), conclusion, list of sources used. The table of contents on the right indicates the page numbers at the beginning of each question. Each section begins on a new page.

The total amount of calculation and graphic work, depending on the chosen topic can vary from 25 to 40 pages of the main text (in consultation with the teacher). The amount of computational and graphic work is determined by the student's ability to briefly and at the same time comprehensively explain and analyze the program code in the Code Composer Studio environment.

Mandatory requirement: clear reference to sources of information. All figures, facts, opinions of scientists, quotations, formulas should have a reference in the form [2, p. 54] (the first digit means the number of the source in the list of references given at the end of the creative work, and the second digit - the page number in this source). It is desirable to use tables, diagrams, graphs, charts, etc. The list of used sources (not less than 10 sources) is made out according to operating rules. If the information is taken from the Internet, you need, as for ordinary literature, specify the author, the title of the article, and then provide

the address of the site on the Internet.

Calculation and graphic work is evaluated by the following criteria: logic of the plan; completeness and depth of topic disclosure; reliability of the received data; reflection of practical materials and results of calculations; correctness of formulation of conclusions of the received results and conclusions; design; substantiation of the student's own opinion on this issue in the form of a conclusion.

Deadline for submission of calculation and graphic work for verification: 15-16th week of study.

Calculation and graphic work is not tested for plagiarism, but must meet the requirements of academic integrity. In case of academic dishonesty, the work is canceled and not checked.

Policy and Control

7. 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*
Improving practical work	*1 points (for each practical work)*	*Untimely implementation and test of practical work*	*From -0.5 points to -5 points (depending on the delivery date)*
Passing distance courses on topics that are agreed with teachers	*5 points*	*Untimely execution and test of calculation and graphic work*	*From -2 points to -20 points (depending on the construction period)*
Registration of scientific work for participation in the competition of student scientific works	*10 points*		
Writing abstracts, articles, participation in international, national and / or other events or competitions on the subject of the discipline	*5 points*		

** якщо контрольний захід був пропущений з поважної причини (хвороба, яка підтверджена довідкою встановленого зразку) – штрафні бали не нараховуються.*

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 " Biomedical Devices, Apparatus and Complexes " 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.

8. Monitor and evaluate the system of evaluation of learning outcomes (Rating System of Evaluation)

Evaluation system (current control):

№ s/n	Control measure	Weight points	Number	Total
1	Express control works / test tasks	10	2	20

2	Execution and test of practical works	5	4	20
3	Modular control work (MCW)	15	1	15
4	Calculation and graphic work (CGW)	15	1	15
5	Test work[1]	30	1	30
	Всього			100

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			The first CC	The second CC
Deadline of calendar controls			8th week	14th week
Conditions for obtaining a positive result from the calendar control	Current rating		≥ 24 points	≥ 42 балів
	Execution practical work	Part № 1-2	+	+
		Part № 3-4	-	+
	Express control works / test tasks	At least 4 of any lectures	+	-
		At least 8 of any lectures	-	+
	Modular control work	Estimated MCW	-	+
	Calculation and graphic work	Estimated CGW	-	-

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

Semester certification of students

Mandatory condition for admission to the test		Criterion
1	Current rating	RD ≥ 42
2	Obtaining a positive assessment for the performed calculation and graphic work	More than 8 points
3	All practical works are tested	More than 14 points
4	All laboratory works are tested	More than 14 points

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:

Number points	Assessment on the university scale
100-95	Perfectly

[1] *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.*

94-85	*Very good*
84-75	*Good*
74-65	*Satisfactorily*
64-60	*Enough*
Less 60	*Unsatisfactorily*
Admission conditions are not met	*Not allowed*

9. 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 "Biomedical Devices, Apparatus and Complexes".

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 discipline (syllabus):

Compiled by *Professor of the Department of Biomedical Engineering, D.Med.Sc., Prof. Vitaliy B. Maksymenko, Associate Professor of the Department of Biomedical Engineering, Ph.D. in Technical Sciences, Assoc. Prof. Maryna M. Sychyk.*

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

Approved by *the Methodical Commission of the Faculty of Biomedical Engineering (protocol № 9 of June 26, 2024)*

Appendix 1.

For syllabus of the discipline "Biomedical Devices, Apparatus and Complexes"

Program learning outcomes (extended form)

As a result of studying the academic discipline "Biomedical Devices, Apparatus and Complexes ", students will be able to:

Learning outcomes (PRN)		Compliance of Learning Outcomes with Competencies according to the Higher Education Standard [6]	
		General Competencies (**soft skills**)	Special Competencies (**professional**)
PRN 2	*Formulate logical conclusions and reasoned recommendations regarding the assessment, operation, and implementation of biotechnical, medical-technical, and bioengineering tools and methods.*	*ZK 1 - Ability to apply knowledge in practical situations.*	FK 3 - *Ability to study and apply new methods and tools for analysis, modeling, design, and optimization of medical devices and systems*
PRN 4	*Apply the provisions of regulatory and technical documents governing the procedure for product certification, production certification*	*ZK 1 - Ability to apply knowledge in practical situations.* *ZK 2 - Knowledge and understanding of the subject area and understanding of professional activities*	FK 12 - *Ability to ensure and monitor compliance with safety and biomedical ethics when working with medical equipment*
PRN 8	Understand theoretical and practical approaches to the creation and management of medical equipment and medical technology	*ZK 1 - Ability to apply knowledge in practical situations.*	FK 3 - *Ability to study and apply new methods and tools for analysis, modeling, design, and optimization of medical devices and systems*
PRN 12	*Provide recommendations for selecting equipment to facilitate diagnosis and treatment*	*ZK 1 - Ability to apply knowledge in practical situations.* *ZK 2 - Knowledge and understanding of the subject area and understanding of professional activities*	FK 8 - *Ability to conduct research and observation on the interaction of biological, natural, and artificial systems (prostheses, artificial organs, etc.*
PRN 13	Be able to analyze signals transmitted from organs to devices and process diagnostic information (signals and images).	*ZK 1 - Ability to apply knowledge in practical situations.* *ZK 2 - Knowledge and understanding of the subject area and understanding of professional activities.*	FK 8 - *Ability to conduct research and observation on the interaction of biological, natural, and artificial systems (prostheses, artificial organs, etc.*

Learning outcomes (PRN)		Compliance of Learning Outcomes with Competencies according to the Higher Education Standard [6]	
		General Competencies (**soft skills**)	Special Competencies (**professional**)
PRN 23	Development and implementation of modern diagnostic and therapeutic methods associated with the use of biotechnology, computer, and nanotechnology through the improvement of technical elements of medical devices and systems, as well as medical products, in the process of professional activity	*ZK 1 - Ability to apply knowledge in practical situations.* *ZK 2 - Knowledge and understanding of the subject area and understanding of professional activities.* *ZK 6 - Ability to search, process, and analyze information from various sources*	FK 3 - *Ability to study and apply new methods and tools for analysis, modeling, design, and optimization of medical devices and systems*

[6] 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".

Appendix 2.

For syllabus of the discipline "Biomedical Devices, Apparatus and Complexes"

The list of questions for preparation for module control work,

And also for preparation for test

General Provisions, Classification, and Standards

1. *Concept of a biomedical device, apparatus, and biomedical complex*
2. *Classification of medical devices by purpose*
3. *Classification of biomedical devices by risk class*
4. *Main stages of the medical device lifecycle*
5. *Regulatory framework for medical devices in Ukraine*
6. *International standards for medical devices (ISO, IEC, MDR)*
7. *Requirements for labeling and technical documentation of medical devices*
8. *Role of a biomedical engineer in the design and operation of medical devices*

Metrology and Measurements

9. Main metrological characteristics of biomedical devices
10. Types of measurement errors and their causes
11. Methods for reducing errors in biomedical measurement systems
12. Calibration and verification of biomedical devices
13. Features of measuring human physiological parameters
14. Requirements for accuracy and reliability of medical measurements.

Non-invasive Biomedical Devices

15. Non-invasive medical devices: definition and classification
16. Devices for contact with damaged skin and mucous membranes
17. Dressings and wound coverings: types and functional properties
18. Biocompatibility of materials used in non-invasive medical devices
19. Devices for contact with intact skin
20. External support and rehabilitation devices (orthoses, bandages)

Endoscopic and Catheter Systems

29. Devices introduced through natural body orifices
30. Classification of endoscopic biomedical systems
31. Principle of operation and construction of an endoscope
32. Applications of endoscopic systems in medicine
33. Cardiovascular catheters: purpose and classification
34. Materials and design features of catheters
35. Risks and complications associated with catheter use

Active Therapeutic Biomedical Devices

36. Active medical devices: definition and characteristics
37. Active therapeutic biomedical devices and their classification
38. Physiotherapy devices: principles of operation
39. Types of energy used in therapeutic devices
40. Safety parameters of active therapeutic devices

Active Diagnostic and Monitoring Systems

41. Active diagnostic biomedical devices

42. Principles of ultrasound diagnostics
43. Main components and operating modes of ultrasound devices
44. Principle of operation of the electrocardiograph
45. Principle of operation of the electroencephalograph
46. Bioelectric signals: sources and registration methods
47. Optical methods for monitoring physiological parameters
48. Principle of pulse oximeter operation
49. Methods for measuring blood pressure
50. Continuous patient monitoring systems

Devices for Blood and Biological Fluid Processing
51. Devices that alter the biological composition of blood and fluids
52. Artificial circulation systems: purpose and structure
53. Oxygenators: principle of operation and main characteristics
54. Hemodialysis: physical principles and equipment
55. Devices for temporary storage and transport of organs

Life Support and Infusion Systems
56. Devices for administration and removal of drugs and fluids
57. Infusion and syringe pumps
58. Mechanical ventilators: purpose and modes
59. Key parameters and control systems in ventilators
60. Artificial heart and mechanical circulatory support systems

---

Інші біомедичні прилади та сучасні напрями
61. Активні пристрої для стерилізації та дезінфекції.
62. Пристрої для очищення, промивання та зволоження.
63. Біомедичні вироби з використанням тканин і клітин.
64. Біомедичні прилади з наноматеріалами.
65. Переваги та ризики застосування нанотехнологій у медицині.

Safety, Reliability, and Information Technologies
66. Reliability of biomedical devices and reliability indicators
67. Functional and electrical safety of medical equipment
68. Risk management in the design of biomedical systems
69. Integrated biomedical devices and complexes
70. Medical software as a component of biomedical devices