



BIOMEDICAL DEVICES, APPARATUSES AND COMPLEXES

Working program of educational discipline (Syllabus)

Requisites of the Course

Cycle 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>Medical Engineering</i>
Course status	<i>Mandatory</i>
Mode of study	<i>full-time / day / mixed / remote</i>
Year of study/Semester	<i>3 year (spring / fall semester)</i>
ECTS workload	<i>4.5 ECTS credits / 135 hours</i>
Testing and Assessment	<i>Exam, Module Test</i>
Course schedule	<i>According to the schedule on the site http://rozklad.kpi.ua/</i>
Language of instruction	<i>English</i>
Information about course supervisor / teachers	<i>Lecturer: senior teacher off Department of BMI Zubkov Stanislav Vladimirovich, e-mail – szub284@gmail.com, Telegram - Stanislav Zubkov, +380962212622 Practice: senior teacher off Department of BMI Zubkov Stanislav Vladimirovich, e-mail – szub284@gmail.com, Telegram - Stanislav Zubkov, +380962212622</i>
Course placement	<i>own resource: https://drive.google.com/drive/folders/1awt89uSkuKr4HC4ioURpiA2OebDvsLo6?usp=sharing</i>

Distribution of hours

Semester	Lectures	Practical	Laboratory	Self-study
<i>Autumn/fall semester</i>	<i>18</i>	<i>36</i>	<i>-</i>	<i>45</i>

Outline of the Course

1. Course description, goals, objectives, and learning outcomes

Course "Biomedical Devices, Apparatuses and complexes" studies the application of methods and general principles of construction of medical devices related to the development and engineering of biological and medical devices and systems. The main purpose of the discipline "Biomedical Devices, Apparatuses and complexes" is the formation of students' ability to solve complex specialized problems,

knowledge of appropriate software, knowledge of standards and technical characteristics of device elements, the ability to use this knowledge in the design of medical devices.

Training in the discipline "Biomedical Devices, Apparatuses and complexes" is carried out on the basis of the student-centered approach and strategy of interaction of the teacher and the student for the purpose of mastering by students of a material and development at them of practical skills.

Course "Biomedical Devices, Apparatuses and complexes" on quantitative aspects. The first is about knowing the numerical value for the ranges of crucial aspects of physiology, such as the flows or forces within the body. The second is about discovering the relations between physiological parameters.

The Course integrates labs and problem sets to provide opportunities for practice and includes clinical applications relevant to the biomedical engineering student. Understanding the relations between physiological parameters, knowledge of ranges is a necessary basis for creating biotechnical means of maintaining or replacing vital functions of the body.

Required skill to study the Course:

skill: methods of programming, simulation and analysis of technical and biological systems; methods of automatic control theory; possession of MicroCap-12 software.

Competences: result of studying the discipline students will be able to:

- understand and use tools and methods of designing medical devices and apparatus;
- be able to search and summarize information on medical devices and apply it within its competence;
- to conduct research with the use of modern software tools for simulating life processes, including in technical and biological systems.

Practically to use the acquired knowledge of:

- methods of using models of industrial products to model the operation of medical systems;
- compilation of elementary models of organs and systems of the human body.
- general principles and trends in the development of modern medical systems;
- formulation and substantiation of technical requirements for medical systems;
- interpretation of biological objects as a complex of functional and dynamic links;
- use of modern theoretical methods and technical means to determine the parameters of technical and biological systems;
- processes that take place in medical devices, apparatus and biological objects and systems;
- to repair and maintenance of various electronic medical equipment

General competencies (OPP was put into effect by the Rector's Order NON/ 89/2021 of 19.04.2021):

GC 1 - Ability to apply knowledge in practical situations.

GC 2 - Knowledge and understanding of the subject area and understanding of professional activity.

GC 6 – Ability to searching, process and analyze information from various sources.

GC 7 – Ability to generate new ideas (creativity).

GC 8 – Ability to make well-grounded decisions.

Special (professional) competencies (OPP was put into effect by the Rector's Order NON/ 89/2021 of 19.04.2021):

PC 1 - Ability to use engineering software packages for research, analysis, processing and presentation of results, as well as for automated design of medical devices and systems.

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

PC 5 - Ability to apply physical, chemical, biological and mathematical methods in the analysis, modeling of the functioning of living organisms and biotechnical systems.

PC 6 - Ability to study the biological and technical aspects of the functioning and interaction of

artificial biological and biotechnical systems.

PC 9 - Ability to create tools and methodologies of scientific activity, evaluation and implementation of the results of modern developments, solutions and achievements of engineering and exact sciences in medicine and biology.

PC 14 - Ability to conduct experiments according to specified technical and medical methods, perform computer processing, analysis and synthesis of the results.

The program learning outcomes after studying the discipline "Biomedical Devices, Apparatuses and complexes" are (OPP was put into effect by the Rector's Order NON/89/2021 of 19.04.2021):

PLO 2 - Understanding the principles of operation of modern diagnostic equipment and systems for displaying biomedical information, the basics of relevant software.

PLO 7 - Possession of methods of research, design and construction of biomedical equipment, analysis and processing of experimental data.

PLO 8 - Knowledge of general requirements for the conditions of engineering, technological and scientific projects.

PLO 10 - Knowledge in the most advanced fields of education and professional activity and at the junction of different fields.

PLO 11 - Understanding the latest advances in biomedical engineering.

PLO 12 - Understanding ethical, environmental and commercial constraints in engineering practice

PLO 15 - Understanding of specialized conceptual principles acquired in the process of learning and / or professional activity at the level of the latest achievements, which are the basis for original thinking and innovation, in particular in the context of research.

PLO 16 - Knowledge of methods of design, construction, improvement and application of medical-technical and bioengineering products, devices, devices and systems with observance of technical requirements, and also to support their operation.

PLO 17 - Analysis and solution of complex medical-engineering and bioengineering problems with the use of mathematical methods and information technologies.

PLO 18 - Creation and improvement of means, methods and technologies of biomedical engineering for comprehensive research and development of bioengineering objects and systems of medical and technical purpose.

PLO 19 - Development, planning, use and substantiation of innovative projects of bioengineering facilities and systems of medical and technical purpose taking into account engineering, medical, legal, economic, ecological and social aspects, implementation of their information and methodological support.

PLO 20 - Assessment of biological and technical aspects and consequences of interaction of engineering and bioengineering objects with biological systems, anticipation of their mutual influence, legal, deontological and moral and ethical consequences of use.

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

Course "Biomedical Devices, Apparatuses and complexes" belongs to the cycle of professional training and has an interdisciplinary nature. It integrates according to its subject knowledge from other disciplines: Higher Mathematics, Fundamentals of Informatics, Theory of Automatic Control, Theory of Biomedical Signals, Mathematical Modeling of Biomedical Processes and Systems. According to the structural and logical scheme of the training program, the discipline "Biomedical devices, apparatus and

complexes-1. Diagnostic Technique "is closely related to other disciplines of training: Analysis and design of electronic medical equipment, Undergraduate practice and Diploma design.

3. Course Overview

The main parts and subjects that must be considered in the process of studying the course:

Section 1. Measuring devices for medical purposes

Topic 1.1. Fundamentals of metrology of medical devices. Basic standards.

Section 2. Electrocardiographic electrodes

Topic 2.1. Principles of operation of electrodes of electrocardiographs. Construction and technical characteristics.

Section 3. Electroencephalographic electrodes

Topic 3.1. Principles of electroencephalograph electrodes. Construction and technical characteristics.

Section 4. Pulseoximeter sensors

Topic 4.1. Principles of operation of optical sensors for pulseoximeters. Construction and technical characteristics.

Section 5. Pressure sensors

Topic 5.1. Principles of operation of tenzometric and piezoresistive deformation sensors. Construction and technical characteristics.

Section 6. Reographic electrodes

Topic 6.1. Principles of operation of reographic electrodes. Construction and technical characteristics.

Section 7. Sensors for phonocardiography

Topic 7.1. Principles of operation of phonocardiograph sensors. Construction and technical characteristics.

Section 8. Ultrasonic sensors

Topic 8.1. Principles of operation of ultrasonic sensors. Construction and technical characteristics.

4. Coursebooks and teaching resources

Basic:

- 1. Під.ред. Джон Г. Вебстер. Медичні прилади. Разработка и применение. «Медінформ», Київ 2004, 620 стор.*
- 2. Л.В.Ілясов. Биомедицинская измерительная техника. М., «Высшая школа», 2007, 175 стр.*
- 3. А.В. БЕРДНИКОВ, М.В. СЕМКО, Ю.А. ШИРОКОВА. МЕДИЦИНСКИЕ ПРИБОРЫ, АППАРАТЫ, СИСТЕМЫ И КОМПЛЕКСЫ. Часть I. "ТЕХНИЧЕСКИЕ МЕТОДЫ И АППАРАТЫ ДЛЯ ЭКСПРЕСС-ДИАГНОСТИКИ". Учебное пособие. Казань, КГТУ им. А.Н. Туполева, 2004.*
- 4. Кларк Д.В., Ньюман М. Р., Олсон В.Х. и др. Ред. Д.Г. Вебстер. Медицинские приборы. Разработка и применение. – К.: Медторг, 2004. - 620с.*
- 5. Яненко О. П., Перегудов С. Н., Куценко В. П. Медична техніка для терапії та діагностики: навчальний посібник / НТУУ «КПІ». Київ : НТУУ «КПІ», 2013.
<http://ela.kpi.ua/handle/123456789/2488>.*

Supplementary:

1. Рангайян Р.М. Анализ биомедицинских сигналов Практический подход. Под. ред. А.П. Немирко, М., «Физматлит», 2007,430 стр.
2. ПРАКТИКУМ до виконання лабораторних робіт з дисципліни «Прилади контролю фізіологічних параметрів людини (Прилади контролю фізіологічних параметрів людини-2)», ЛР1 та ЛР2. <https://cloud.mail.ru/public/DehU/duvXXZRwi>
3. К.Холльдак. Д.Вольф. Атлас и руководство по фонокардиографии и смежным механокардиографическим методам исследования. М., «Медицина», 1964г. <https://cloud.mail.ru/public/2qwd/7FQpVaVHZ>
4. Реографические измерения и оценка параметров сосудистой системы. Кисельгов Е.Н., Сергеев В.Г. ссылка: <https://cloud.mail.ru/public/Mpdo/8cyRwtAYr>

Educational content

5. Methods of mastering the discipline (educational component)

№ s/n	Subject	Program learning outcomes	The main tasks	
			Control measure	Deadline
1.	Topic 1.1. Fundamentals of metrology of medical devices. Basic standards.	PLO2; PLO7,8; PLO 10...12; PLO 15...20	Practice 1	1 week
2.	Topic 2.1. Principles of operation of electrodes of electrocardiographs. Construction and technical characteristics.	PLO 2; PLO7,8; PLO 10...12; PLO 15...20	Practice 2,3	2 week
3.	Topic 3.1. Principles of electroencephalograph electrodes. Construction and technical characteristics.	PLO 2; PLO7,8; PLO 10...12; PLO 15...20	Practice 3,4	3 week
4.	Topic 4.1. Principles of operation of optical sensors for pulse oximeters. Construction and technical characteristics.	PLO 2; PLO7,8; PLO 10...12; PLO 15...20	Practice 5,6	4 week
5.	Topic 5.1. Principles of operation of tenzometric and piezoresistive deformation sensors. Construction and technical characteristics.	PLO 2; PLO7,8; PLO 10...12; PLO 15...20	Practice 7,8	5 week
6.	Topic 6.1. Principles of operation of reographic electrodes. Construction and technical characteristics.	PLO 2; PLO7,8; PLO 10...12; PLO 15...20	Practice 9,10	6 week
7.	Topic 7.1. Principles of operation of phonocardiograph sensors. Construction and technical characteristics.	PLO 2; PLO7,8; PLO 10...12; PLO 15...20	Practice 11,12	7 week
8.	Topic 8.1. Principles of operation of ultrasonic sensors. Construction and technical characteristics.	PLO 2; PLO7,8; PLO 10...12; PLO 15...20	Practice 13,14	8 week
9	Module Test	PLO 2; PLO7,8; PLO 10...12; PLO 15...20	Practice 9	9 week

10	Exam	PLO 2; PLO7,8; PLO 10...12; PLO 15...20	-	On schedule session
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6. Self-study

One of the main types of semester control during the mastering of the discipline "Biomedical Devices, Apparatuses and complexes" is preparation for lectures, practical works, express control works / test tasks and Individual control tasks.

Policy and control

7. Attendance policy

Attending classes

Attendance at lectures (consultations) is highly recommended, as well as mandatory independent preparation for lectures. Attendance at practical classes is mandatory, as they are used to write express tests / tests / defense of practical work, grades for which are included in the current rating.

The assessment system is focused on obtaining points for student activity, as well as individual homework that can develop practical skills.

Control measures missed

Missed control measures for the protection of practical work must be worked out if there is a report at the next lesson, or at consultations.

Omissions of writing a module test and express test are not fulfilled. Skipped Module Test can be worked out in consultations.

Violation of deadlines, penalty points and rewarding points

Rewarding points		Penalty points*	
Criterion	Weight points	Criterion	Weight points
Practical or laboratory work improvement	1 point (for each work)	Untimely implementation of a practical work	From -0.5 points to -5 points (depending on the delivery date)
Online courses completed on the topics that are agreed with the teacher	5 points	Untimely implementation of a laboratory work	From -0.5 points to -5 points (depending on the delivery date)
Registration of scientific work for participation in the competition of student scientific works	10 points	Untimely implementation of a Module Test	From -0.5 points to -5 points (depending on the delivery date)
Writing of abstracts, articles, participation in international, national and / or other events or competitions on the subject of the Course	From 5 points to +10 points	Untimely implementation of a Home Control Work	From -2 points to -5 points (depending on the delivery date)

* 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 course "Biomedical Devices, Apparatuses and complexes" can be taught to the most of students with special educational needs.

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 and defense of a Home Control Work is carried out during self-study work of students in a remote mode (with a possibility of consultation with the teacher through e-mail, social networks).

Teaching in 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. Monitoring and grading policy

Grading system (current control):

No s/n	Control measure	%	Weight points	Number	Total
1.	Report on the implementation of practical work	0	0	20	Condition of admission
2.	Express control works / test tasks / defense of practical works	45	5	9	45
3.	Modular control work	15	15	1	15
4.	Exam	40	40	1	40
	Total				100

The applicant receives a positive credit score for the results of the semester, if he has a final rating for the semester of at least 60 points and has met the conditions of admission to the semester control, which are determined by the RSO.

With applicants who have met all the conditions of admission to the test and have a rating of less than 60 points, as well as with those applicants who want to increase their rating, the penultimate on the schedule of the discipline in the semester teacher conducts semester control in the form of modular control / test task.

If the grade for the modular test is less than the current rating, the "hard" RSO is used - the previous rating of the applicant according to item 2 (except for points for the semester individual task, items 3 and 4) is canceled and he receives a grade based on test results. work. This option forms a responsible attitude of the applicant to the decision to perform the test, forces him to critically assess the level of his training and carefully prepare for the test.

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
Current grade		≥ 21 points	≥ 37 points
Requirements to obtain a positive calendar control	Report on the implementation of practical work	Pr No.1-8	+
		Pr No.9	-
	Express control works / test tasks / defense of practical works	Minimum 50% of possible points on topics 1.1... 4.1	+
		Minimum 50% of possible points on topics 4.1... 8.1	-
	Personal control task №1	possible points on topics 1.1...4.1	+
	Personal control task №2	possible points on topics 5.1...8.1	-
	Modular control work		-

In the case of a plagiarism or an academic poor quality during training the control measure is not credited.

Semester certification of students

Mandatory requirements for the admission to the Final Test		Criterion
1	Current grade	RD ≥ 60
2	All laboratory works are completed	Report
3	Writing at least 5 express tests / tests	More than 25 points

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

Optional requirements for the admission to the Final Test:

1. Active work during practical classes.

2. *Positive result of the first and the second calendar control.*
3. *Attending of lectures.*

The final performance score or the results of the Final Test are adopted by university grading system as follows:

<i>Number points</i>	<i>Assessment on the university scale</i>
<i>100-95</i>	<i>Excellent / Відмінно</i>
<i>94-85</i>	<i>Very good / Дуже добре</i>
<i>84-75</i>	<i>Good / Добре</i>
<i>74-65</i>	<i>Satisfactory / Задовільно</i>
<i>64-60</i>	<i>Satisfactory / Достатньо</i>
<i>Less 60</i>	<i>Unsatisfactory / Незадовільно</i>
<i>The course requirements are not met</i>	<i>Not allowed / Не допущено</i>

9. Additional information on the course (educational component)

Module Test (MT), which is planned for the course and is designed for a total of two academic hours, is conducted in two practical classes.

The list of questions for preparation for Module Test, and also for preparation for credit is given in appendix 1.

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 tests, practical work).

Work program of the course (syllabus):

is developed by Senior Lecturer, Stanislav Zubkov.

Approved by the Department of Biomedical Engineering (protocol № ___ to _____)

Approved by the Methodical Commission of the Faculty of Biomedical Engineering (protocol № ___ to _____)

The list of questions for preparation for the Module Test, Exam

1. What is meant by the term "medical device", "medical device", "medical device"? Classification of medical devices according to the degree of potential risk.
2. Standardization of metrological characteristics of measuring instruments: absolute, relative, basic and additional errors.
3. The main characteristics of the dynamic error. Determination of the astatic system. Dependence of static error on the gain and the order of astaticism.
4. The main characteristics of the electrodes. Normalized characteristics of electrodes according to GOST 25995.
5. Equivalent scheme "skin - electrode". Influence on time and frequency characteristics.
6. Electrodes for registration of bioelectric potentials: the principle of measuring the drift voltage.
7. Electrodes for recording bioelectric potentials: the principle of measuring noise voltage.
8. Interference in ECG amplifiers. In-phase, differential interference. The scheme of their occurrence. Methods of suppression. The structure of the input stage.
9. Equivalent circuit of the input circuit of the biopotential amplifier. Influence of input impedance imbalance on in-phase interference suppression.
10. Equivalent circuit of the input circuit of the ECG channel with an instrumental amplifier. Coefficient of in-phase interference suppression of the input circuit.
11. Equivalent circuit of the input circuit of the ECG channel with an instrumental amplifier and disconnected neutral wire. Coefficient of in-phase interference suppression of the input circuit.
12. The ideal operational amplifier. Basic relations.
13. Inverting amplifier. Expression for gain.
14. Non-inverting amplifier. Expression for gain.
15. Inverting adder. Differential amplifier. Expression for gain.
16. Real operational amplifier. Basic relations.
17. The principle of suppression of in-phase interference in an instrumental amplifier.
18. Block diagram of the electrocardiograph. Assignment of the main functional units.
19. The influence of sampling frequency on the accuracy of ECG recording.
20. Classification of analog filters.
21. LACHH, transient function of low-order low-pass filter.
22. LACH, the transient function of the low-pass filter.
23. The main differences between digital and analog filters.
24. Block diagram of a phonocardiograph. Maas-Weber filters (m , t_1 , t_2 , h).
25. Bouguer-Lambert-Beer law for n -component solutions.
26. The principle of operation of pulse oximeters. PCO_2 calculation algorithm.
27. Block diagram of the pulseoximeter. Assignment of the main functional units.
28. Interpretation of photoplethysmograms. Artifacts. What measures a pulseoximeter and what does not.
29. Principles of construction of mathematical models of photoplethysmograms. Examples.
30. Hooke's law. Dependence of stress on deformation. Three main types of stress. Poisson's ratio.
31. The relationship between deformation and resistance of the strain gauge. Thesis sensitivity coefficient.
32. Design of pressure strain gauges. The conversion factor of the bridge circuit.
33. Design and principle of operation of capacitive pressure sensors. Basic relations.
34. The main metrological characteristics of devices for measuring blood pressure. Relationship between pulse wave parameters and mean pressure.

35. *Non-invasive pressure measurement. Principles of classification by accuracy of devices for measuring blood pressure by oscillometric method.*

36. *Typical design of a single-element acoustic transducer. Purpose of a damper, a matching layer and an acoustic lens*

37. *Direct and reverse piezoelectric effects in ultrasonic sensors. The relationship between deformation and electric field.*

38. *Formation of the radiation diagram in multi-element ultrasonic sensors. Types of scans.*

39. *Doppler effect. Frequency offset formula.*

40. *Block diagram of an ultrasonic Doppler device of pulsed radiation.*

41. *Block diagram of the ultrasonic Doppler device of continuous radiation.*

42. *Interpretation of the Doppler spectrum. Pulsation index (Purcelot).*

43. *Conductor impedance. LACH impedance of the conductor on the HF.*

44. *Total resistance of grounding wires.*

45. *Capacitor impedance. LACH impedance of the capacitor on the RF.*

46. *Impedance of inductance. LACH impedance inductance on HF .*

47. *Conductive interference in the network. Symmetrical and asymmetrical obstacles.*

48. *Winding-free and current-compensating chokes.*

49. *Principles of designing network filters.*

50. *Principles of measuring conductive and radio frequency interference. Norms of admissible obstacles.*

51. *Principles of electric field shielding.*