National Technical University of Ukraine
«IGOR SIKORSKY
KYIV POLYTECHNIC INSTITUTE

Department of Biomedical Engineering

FUNDAMENTALS OF CLINICAL ENGINEERING AND RADIOLOGY II. EXPERTISE AND ENGINEERING SUPPORT OF MEDICAL EQUIPMENT

Syllabus

Requisites of the discipline	
Level of high education	***First (bachelor's)***
Branch of knowledge	*16 Chemical and bioengineering*
Specialty	*163 Biomedical Engineering*
Educational program	*Medical engineering*
Status of the discipline	*Normative*
Learning form	*full-time / day / mixed / remote*
Semester	*4th year, autumn semester*
Course scope	*3.5 credits / 105 hours*
Semester control / control measures	*Exam, modular control work*
Schedule	*According to the schedule on the website http://rozklad.kpi.ua/*
Language	*English*
Information about course supervisor and lecturers	***Lecturer, seminars:*** ***Lecturer:*** *Associate Professor of Biomedical Engineering, PhD of Technical Sciences, Dubko Andrii Grigorovich,* *intellect.kpi.ua/profile/dag5;* *http://www.nas.gov.ua/UA/PersonalSite/Pages/default.aspx?PersonID=0000016737* *http://orcid.org/0000-0001-6070-3945* *https://www.scopus.com/authid/detail.uri?authorId=55226164600.* ***Practical:*** *Associate Professor of Biomedical Engineering, PhD of Technical Sciences, Dubko Andrii Grigorovich,* *intellect.kpi.ua/profile/dag5;* *http://www.nas.gov.ua/UA/PersonalSite/Pages/default.aspx?PersonID=0000016737* *http://orcid.org/0000-0001-6070-3945* *https://www.scopus.com/authid/detail.uri?authorId=55226164600.*
Course placement	*Sikorsky Platform - course " Fundamentals of Clinical Engineering and Radiology II. Expertise and Engineering Support of Medical Equipment"*

Curriculum of the discipline

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

The subject of the discipline " Fundamentals of Clinical Engineering and Radiology II. Expertise and Engineering Support of Medical Equipment" is to form students' understanding of the principles, skills and practical skills in the examination and engineering support of medical equipment. The purpose of teaching the discipline is to provide students with theoretical knowledge and the formation of practical skills in the ability to solve complex specialized problems and practical problems of creation, operation and testing of medical devices, devices and complexes for surgery, therapy and diagnostics, circuit design, calculation and modeling of the main units of medical equipment, development and modeling of modern medical technologies.

The objectives of the discipline are:

- *mastering the general principles of use of regulations governing the circulation of medical devices;*
- *mastering the procedure and procedure for conducting the main stages of registration of medical equipment or medical devices;*
- *mastering the procedure and procedure for examinations and tests of medical devices;*
- *mastering knowledge about the reliability of medical equipment;*
- *acquisition of knowledge on maintenance and repair of medical equipment.*

The purpose of the discipline the formation higher competencies:

- *Ability to apply knowledge in practical situations.*
- *Knowledge and understanding of the subject area and understanding of professional activity.*
- *Ability to communicate in the state language both orally and in writing.*
- *Skills in the use of information and communication technologies.*
- *Ability to conduct research at the appropriate level.*
- *Ability to search, process and analyze information from various sources.*
- *Ability to generate new ideas (creativity).*
- *Ability to make informed decisions.*
- *Ability to communicate with representatives of other professional groups of different levels (with experts from other fields of knowledge / types of economic activity).*

The program learning outcomes after studying the discipline "Fundamentals of Clinical Engineering and Radiology II. Expertise and Engineering Support of Medical Equipment" are:

- *Possession of engineering methods of calculation of elements of devices and systems of medical appointment and a choice of classical and newest constructional materials.*
- *Knowledge of design tools for devices, devices and systems for medical and biological purposes.*
- *Knowledge of methods of designing digital and microprocessor systems for medical purposes.*
- *Apply knowledge of the basics of mathematics, physics and biophysics, bioengineering, chemistry, engineering graphics, mechanics, resistance and strength of materials, properties of gases and liquids, electronics, computer science, obtaining and analyzing signals and images, automatic control, systems analysis and decision making methods at the level required to solve the problems of biomedical engineering.*
- *Understanding of theoretical and practical approaches to the creation and management of medical equipment and medical equipment.*

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

The discipline " Fundamentals of Clinical Engineering and Radiology II. Expertise and Engineering Support of Medical Equipment" belongs to the cycle of professional training and has an interdisciplinary nature. It integrates according to its subject knowledge from other disciplines: Electrical Engineering and Electronics; Analog and digital circuitry; Biomedical devices, apparatus and complexes. According to the structural and logical scheme of the training program, the discipline " Fundamentals of Clinical Engineering and Radiology II. Expertise and Engineering Support of Medical Equipment" is closely related to other disciplines in modern research in the specialty, including disciplines: Devices for monitoring human physiological parameters; Pre-diploma practice.

3.The content of the discipline

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

Section 1. State regulation of the circulation of medical devices
Topic 1.1. Basic legal acts.
Topic 1.2 Accreditation of conformity assessment bodies.
Topic 1.3. State supervision (control) in the field of economic activity.
Topic 1.4. Permitting system in the field of economic activity

Section 2. Basic requirements for metrology, standardization and certification of medical devices.
Topic 2.1. Metrological service and metrological system in Ukraine.
Topic 2.2. Theoretical and legal bases of standardization.
Topic 2.3 Technical conditions of Ukraine. Development guidelines.
Topic 2.4 The essence and objectives of certification.

Section 3. Technical regulations for medical devices.
Topic 3.1. System of assessment of conformity of medical equipment to the requirements of Technical regulations.
Topic 3.2. Classification of medical devices.
Topic 3.3. Self-declaration to the Technical Regulations. Conformity assessment in the designated body
Topic 3.4. Obtaining a certificate for the party. Recognition of EU certificates in Ukraine.
Topic 3.5. Measuring equipment (Regulations №94). Restrictions on the use of hazardous substances in electrical and electronic equipment (Regulation №139).
Topic 3.6. Formation of a technical file.
Topic 3.7. Development and implementation of ISO 13485 quality management system.
Topic 3.8. Labeling of packaging of medical devices.
Topic 3.9. Examination of medical equipment. Expert institutions for examinations and tests of medical equipment.
Topic 3.10. Clinical trials of medical equipment. Bioethical examination.

Section 4. Intellectual property protection

Topic.4.1. Copyright objects. Inventions. Useful models. Industrial designs. Trademark of a medicinal product or medical device;
Topic.4.2. Trademark registration: preliminary search and preparation for registration.

Section 5. Disinfection, pre-sterilization cleaning and sterilization of medical devices.
Topic 5.1. Terms. Requirements for sterilization.
Topic 5.2. Sterilization, methods of implementation, control of efficiency.
Topic 5.3. Technological process of sterilization.

Section 6. Maintenance and repair of medical equipment.
Topic 6.1. Basic concepts of reliability. Object life cycle. Failures of medical equipment.
Topic 6.2. Monitoring the safety of medical devices.
Topic 6.3. Stages and content of complex maintenance of medical equipment.
Topic 6.4. Repair of medical equipment.
Topic 6.5. Electrical safety of electronic medical devices.

4. Learning materials and resources

Basic literature, which should be used to master the discipline, is developed independently to prepare forpractical classes and in the context of distance learning. It is suggested to use additional literature and Internet resources to perform modular tests, prepare reports, presentations, write essays based on the results of independent work.

1. *Medical Devices and Human Engineering. Edited by: Joseph D. Bronzino, Donald R. Peterson. © Taylor & Francis Group - 2015. 858 p.*
2. *Medical Device Design. Innovation from Concept to Market . First edition. Peter J. Ogrodnik.. Academic Press is an imprint of Elsevier - 2013. Kidlington, Oxford. 275 p.*
3. *Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices. In All Health Care Settings, 3rd edition. Provincial Infectious Diseases Advisory Committee (PIDAC) . May 2013. – 117 p.*
4. *Medical Equipment Maintenance Manual. A first line maintenance guide for end users. Ministry of Health and Family Welfare, New Delhi. October 2010. – 79 p.*
5. *Core Medical Equipment. © World Health Organization 2011. – 56p.*
6. *Maintainability, Maintenance, and Reliability for Engineers. B.S. Dhillon. Taylor & Francis Group, LLC. – 2006.*
7. *Safety Evaluation of Pharmaceuticals and Medical Devices. International Regulatory Guidelines. Shayne C. Gad. © Springer Science+Business Media, LLC 2011. – 126 p.*
8. *Medical equipment maintenance programme overview. WHO Medical device technical series. © World Health Organization - 2011. 87 p.*
9. *Reliable Design of Medical Devices. Second Edition. Richard Fries. Taylor & Francis Group. - 2006.475 p.*
10. *MEDICAL DEVICE REGULATIONS. Global overview and guiding principles. © World Health Organization - 2003. 54 p.*
11. *A Software Risk Management Capability Model for Medical Device Software. John Burton. Ph.D. 2008. Submitted to the University of Limerick, May, - 2008. 198 p.*
12. *INTERNATIONAL STANDARD IEC 60601-1. Medical electrical equipment. Part 1: General requirements for basic safety and essential performance. Third edition - 2005. – 777 p.*
13. *Safety Evaluation of Medical Devices. Shayne Cox Gad. Marcel Dekker, Inc.- 2002. – 558 p.*
14. *The Biomedical Engineering Handbook. Third Edition. Edited by Joseph D. Bronzino. Taylor & Francis Group, - 2006. – 1404 p.*

Educational content

5. Methods of mastering the discipline (educational component)

№ s/n	Subject	Program learning outcomes	The main tasks	
			Control measure	Deadline
1.	Basic legal acts.	PLO 2 PLO 31	Practical work 1	1-2nd week
2.	Metrological service and metrological system in Ukraine.	PLO 24 PLO 31	Practical work 2	3-4th week
3.	Technical conditions of Ukraine. Development guidelines.	PLO 3 PLO 31	Practical work 3	5-6th week
4.	Classification of medical devices.	PLO 3 PLO 31	Practical work 4	7-8th week
5.	Formation of a technical file.	PLO 3 PLO 4 PLO 24	Practical work 5	9-10th week
6.	Labeling of packaging of medical devices.	PLO 31	Practical work 6	11th week
7.	Trademark registration: preliminary search and preparation for registration.	PLO 3 PLO 31	Practical work 7	12-13th week
8.	Modular control work	PLO 24	Writing a modular test	14th week
9.	Abstract	PLO 24	Registration and submission of work	15-16th week

6. Independent student work

One of the main types of semester control *during the mastering of the discipline " Fundamentals of Clinical Engineering and Radiology II. Expertise and Engineering Support of Medical Equipment" is the implementation of the abstract. The abstract is performed in accordance with the requirements, within the period specified by the teacher.*

The main purpose *of the abstract is to solve a theoretical problem using the theoretical material learned in lectures and independently. The student can write an essay only on a topic agreed with the teacher.*

Approximate topics of abstracts:

№1 Organization of quality control and safety of medical devices.
№2 Import and territory of Ukraine of medical devices.
№3 Biomedical clinical study of a medical device.
№4 Bioethical examination of medical devices.
№5 Intersectoral systems of standards.
№6 Medical and technical requirements for medical devices.

The title page of the abstract 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; topic of the abstract; last name and first name of the student, course, number of the academic group, year.

The title page is followed by a detailed plan (content) of the abstract, 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 volume of the abstract, depending on the chosen topic, can vary from 15 to 25 pages of the main text (in agreement with the teacher). The volume of the abstract is determined by the student's ability to briefly and comprehensively explain the results.

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, to indicate the author, the title of the article, and then provide the address of the site on the Internet.

The abstract is evaluated by the following criteria: logic of the plan; completeness and depth of disclosure of the topic; 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 abstracts for review: 16th week of study.

The abstract 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 scheduled for the current lesson or consultations.

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

The abstract submitted for review 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*		

** 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 "Fundamentals of Clinical Engineering and Radiology II. Expertise and Engineering Support of Medical Equipment" 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 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	21	1,5	14	21
2.	Execution and protection of practical works	21	3	7	21
3.	Modular control work	8	8	1	8
4.	Abstract	10	10	1	10
5.	Exam	40	40	1	40
				Total	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	≥ 40points
	Execution practical work	PW №№1-4	+	+
		PW №№5-7	-	+
	Express control works / test tasks	At least 4 of any lectures	+	-
		At least 10 of any lectures	-	+
	Modular control work	Estimated MCW	-	+
	Abstract	Evaluation of the abstract	-	-

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 exam	***Критерій***
1	*Current rating*	*RD ≥ 30*
2	*Obtaining a positive assessment for the performed calculation and graphic work*	*More than 6 points*
3	*All practical works are tested*	*More than 6 points*
4	*Writing at least 6 express tests / tests*	*More than 6 points*

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

Mandatory conditions for admission to the exam:
1. Activity in practical classes.
2. Positive result of the first attestation and the second attestation.
3. Attending lectures.

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

Number points	*Assessment on the university scale*
100-95	*Perfectly / Відмінно*
94-85	*Very good / Дуже добре*
84-75	*Good / Добре*
74-65	*Satisfactorily / Задовільно*
64-60	*Enough / Достатньо*
Less 60	*Unsatisfactorily / Незадовільно*
Admission conditions are not met	*Not allowed / Не допущено*

The exam is held orally.

9. Additional information on the discipline (educational component)

The list of questions for preparation for modular control work, and also for preparation for examination 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 control / test tasks, practical work).

Work program of the discipline (syllabus):

Compiled by *Associate Professor of Biomedical Engineering, PhD of Technical Sciences, Dubko Andrii Grigorovich.*

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

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

Appendix 1 to the syllabus of the discipline

" Fundamentals of Clinical Engineering and Radiology II. Expertise and Engineering Support of Medical Equipment"

The list of questions for preparation for modular control work, as well as to prepare for the exam

1. *Define the term biomedical equipment (BMA).*
2. *Give the requirements for biomedical equipment in the form of a block diagram.*
3. *Give a list of general requirements for biomedical equipment.*
4. *Give a list of special requirements for biomedical equipment.*
5. *Give the main trends in the design of medical equipment.*
6. *What are the main regulations governing the circulation of medical devices?*
7. *How does the metrological service and metrological system in Ukraine work?*
8. *Explain the theoretical and legal basis of standardization.*
9. *Explain the nature and objectives of certification?*
10. *What is the need for a system for assessing the compliance of medical equipment with the requirements of the Technical Regulations?*
11. *How are medical devices classified?*
12. *Basic requirements for biomedical equipment software.*
13. *Assignment of graphic symbols for marking medical devices.*
14. *Give the symbol "Reuse FORBIDDEN".*
15. *Give the symbols: "USE TO", "BATCH CODE" "REGISTRATION NUMBER".*
16. *Give the symbols: "DATE OF MANUFACTURE", "STERILITY", "NUMBER BY CATALOG".*
17. *Give the symbols: "CAUTION! GET ACQUAINTED WITH ACCOMPANYING DOCUMENTS "," MANUFACTURER "," AUTHORIZED REPRESENTATIVE OF THE EUROPEAN UNION ".*
18. *Give the symbols: "UPPER TEMPERATURE LIMIT", "LOWER TEMPERATURE LIMIT", "TEMPERATURE LIMIT".*
19. *Give the symbols: "INTRODUCTION TO THE INSTRUCTIONS FOR USE", "BIOLOGICAL RISKS".*
20. *Define the concept - measuring instruments for medical purposes).?*
21. *Define the concept - medical devices .*
22. *Define the concept - medical devices of single production.*
23. *Define the concept - acceptance test.*
24. *Define the concept - the state entrance test.*
25. *Define the concept - a qualifying test.*
26. *Define the concept - a clinical trial.*
27. *Define the concept - the developer of medical devices.*
28. *Define the concept - a manufacturer of medical devices.*
29. *Define the concept - Certificate of state registration of medical devices.*
30. *Define the concept - instructions for use (use) of a medical device.*
31. *Give the main stages of development and attitude to the production of medical devices.*
32. *Describe the medical and technical requirements. Give the contents of the MTV.*
33. *Describe the technical conditions (TU). Give the content of the TU.*
34. *List the main organizations for the certification of medical devices.*
35. *Describe DUO "Polytechmed".*
36. *The main functions of DUO "Polytechmed".*
37. *Describe DUO "Ukrmetrteststandard".*
38. *Sphere of activity "Ukrmetrteststandard".*
39. *The main functions of "Ukrmetrteststandard".*

40. List the objects of copyright.
41. How is a trademark registered?
42. What are the requirements for sterilization?
43. How the safety of medical devices is monitored.
44. Give the stages and content of comprehensive maintenance of medical equipment.