University of Sana'a
Faculty of Engineering
Department: Biomedical Engineering
Title of the Program: Biomedical Engineering

Course Specification of Biomedical Systems Design

Course Code (BE367)

I. Course Identification and General Information:						
1	**Course Title:**	Biomedical Systems Design				
2	**Course Code & Number:**	BE367				
3	**Credit hours:**	C.H				TOTAL
		Th.	Seminar	Pr	Tr.	
		2	--	2	--	3
4	**Study level/ semester at which this course is offered:**	4^{th} Level / 2^{nd} Semester				
5	**Pre –requisite (if any):**	BE244, BE263, BE364				
6	**Co –requisite (if any):**	BE365				
7	**Program (s) in which the course is offered:**	Biomedical Engineering Program				
8	**Language of teaching the course:**	English				
9	**Location of Teaching the Course:**	Faculty of Engineering				
10	**Prepared by:**	Associate Prof. Dr. Khalil Al-Hatab				
11	**Reviewed by:**	Dr. ----				
12	**Date of Approval:**					

II. Course Description:

Biomedical Systems Design is a project-based course that expose students to the entire biomedical product design and development process from an idea to a product. The course material includes:

generic design and development process, design team management, product definition, concept generation and selection, product architecture, product documentation, product development, design for quality and robustness, human factors and industrial design, evaluation and miscellaneous issues. Through the class lectures, assignments, case studies, project and seminar, students will develop an intense, immersive, experiential opportunity to develop professional-level skills to adopt an interdisciplinary and integrated approach in the design and development of medical systems and assistive devices.

III. Course Intended learning outcomes (CILOs) of the course (maximum 8CILOs)		**Referenced PILOs** (Only write code number of referenced Program Intended learning outcomes)
Knowledge and Understanding: Upon successful completion of the undergraduate Biomedical Engineering Program, the graduates will be able to:		
a1	Explain the generic design and developments process and how it is relevant to the design and developments of a biomedical systems and associative devices.	A2 Clarify the design principles and techniques and the engineering materials characteristics and how these are relevant to the developments and technologies in a biomedical systems context.
a2	Understand the phases, procedures, concepts, principles, methodologies, tools and techniques applied to design and develop a biomedical product in a creative and innovative manner.	A4 Understand and give examples of design methods, knowledge tools, analytical skills, measurement techniques and methodologies for innovative and creative engineering solutions applied to healthcare problems and quality of life issues.
B. Cognitive/ Intellectual Skills: Upon successful completion of the undergraduate Biomedical Engineering Program, the graduates will be able to:		

b1	Review research literature, identify, formulate and analyze a real world problem statement, requirement to develop creative and innovative design solutions as a member of an engineering design team.	B2 Identify, formulate and solve the complex problems related to the Biomedical Engineering fields in a creative and innovative manner by using a systematic and analytical thinking methods.
b2	Conceptualize a certain biomedical system and product to be launched in the market within realistic constraints such as environmental, health and safety, ethical and professional behavior, societal political, manufacturability and sustainability.	B3 Design the biomedical systems or processes within realistic constraints such as economic, environmental, social, political, ethical, health and safety, manufacturability and sustainability.
C. Professional and Practical Skills: Upon successful completion of the undergraduate Biomedical Engineering Program, the graduates will be able to:		
c1	Recognize the ongoing need for additional knowledge, integrate and apply this knowledge to obtain the innovation solution of the product design and development project.	C1 Apply integrally knowledge of mathematics, life science, IT, design, business context and engineering practice to solve problems and to design systems/processes relevant to Biomedical Engineering.
c2	Use analytical tools, techniques, modern engineering tools, computational software packages for virtual design, including development, validation, and optimization of prototypes.	C2 Use a wide range of analytical tools, techniques, IT, modern engineering tools, software packages and develop required computer programs to solve, modeling and analyzing Biomedical Engineering problems.
c3	Apply industrials rules, standards and regulations and observe the appropriate steps to asses risks concerning biomedical systems practice.	C4 Use rules and regulations of industrial safety as well as safe and diagnose systems at work, evaluate performance and observe the appropriate steps to manage risks concerning biomedical

		systems.
c4	Recognize ethical and professional responsibilities in the development of biomedical products and must consider their impacts in global, economic, environmental, safety, confidentiality and quality of life issues.	C5 Demonstrate basic organizational and project management skills, apply quality assurance procedures, practice neatness and aesthetics and follow codes and standards to improve biomedical products design or services.
D. Transferable Skills: Upon successful completion of the undergraduate Biomedical Engineering Program, the graduates will be able to:		
d1	Function effectively as an individual, and as a member or leader in diverse teams, and in multidisciplinary settings.	D1 Lead and motivate individuals, show capability to work in stressful environments and within constraints, collaborate effectively within multidisciplinary team.
d2	Manage a design and development project tasks from start to finish that establish goals, plan tasks and meet deadlines.	D2 Acquire entrepreneurial skills and effectively manage tasks, time, processes and resources.
d3	Upgrade knowledge and understanding through Life-long Learning philosophy.	D3 Recognize the needs for, and engage in life-long self-learning.
d4	Utilize technical resources and perform effective background research, observations, and interviews.	D4 Refer to relevant literatures, search for information, use databases, as well as, evaluate information and evidence from various sources in biomedical engineering.
d5	Writing effective reports and design documentation and make effective presentations.	D5 Demonstrate efficient IT capabilities and communicate effectively both orally and in writing technical reports.

(A) Alignment Course Intended Learning Outcomes of Knowledge and Understanding to Teaching Strategies and Assessment Strategies:		
Course Intended Learning Outcomes	Teaching strategies	Assessment Strategies
a1. Explain the generic design and developments process and how it is relevant to the design and developments of a biomedical systems and associative devices.	• Interactive lectures & examples, • Interactive class discussions, • Case studies, • Exercises and home works, • Directed self- study, • Problem based learning, • Mini/major project.	• Written tests (mid and final terms and quizzes), • Project report • Coursework activities assessment, • Home works and assignments, • Presentations.
a2. Understand the phases, procedures, concepts, principles, methodologies, tools and techniques applied to design and develop a biomedical product in a creative and innovative manner.	• Interactive lectures & examples, • Interactive class discussions, • Case studies, • Exercises and home works, • Directed self- study, • Problem based learning, • Mini/major project.	• Written tests (mid and final terms and quizzes), • Project report • Coursework activities assessment, • Home works and assignments, • Presentations.

(B) Alignment Course Intended Learning Outcomes of Intellectual Skills to Teaching Strategies and Assessment Strategies:		
Course Intended Learning Outcomes	Teaching strategies	Assessment Strategies
b1. Review research literature, identify, formulate and analyze a real world problem statement,	• Interactive lectures & examples, • Presentation/seminar, • Interactive class	• Written tests (mid and final terms and quizzes), • Project report • Coursework activities

requirement to develop creative and innovative design solutions as a member of an engineering design team.	discussions, • Case studies, • Exercises and home works, • Directed self- study, • Problem based learning, • Field visits/training, • Mini/major project.	assessment, • Home works and assignments, • Presentations.
b2. Conceptualize a certain biomedical system and product to be launched in the market within realistic constraints such as environmental, health and safety, ethical and professional behavior, societal political, manufacturability and sustainability.	• Interactive lectures & examples, • Presentation/seminar, • Interactive class discussions, • Case studies, • Exercises and home works, • Directed self- study, • Problem based learning, • Field visits/training, • Mini/major project.	• Written tests (mid and final terms and quizzes), • Project report • Coursework activities assessment, • Home works and assignments, • Presentations.

(C) Alignment Course Intended Learning Outcomes of Professional and Practical Skills to Teaching Strategies and Assessment Strategies:

Course Intended Learning Outcomes	Teaching strategies	Assessment Strategies
c1. Recognize the ongoing need for additional knowledge, integrate and apply this knowledge to obtain the innovation solution of the product design and development project.	• Interactive lectures & examples, • Presentation/seminar, • Interactive class discussions, • Case studies, • Exercises and home works, • Directed self- study,	• Written tests (mid and final terms and quizzes), • Project report • Coursework activities assessment, • Home works and assignments,

	• Problem based learning, • Field visits/training, • Mini/major project.	• Presentations.
c2. Use analytical tools, techniques, modern engineering tools, computational software packages for virtual design, including development, validation, and optimization of prototypes.	• Interactive lectures & examples, • Presentation/seminar, • Interactive class discussions, • Case studies, • Exercises and home works, • Computer laboratory-based sessions • Directed self- study, • Problem based learning, • Field visits/training, • Mini/major project.	• Written tests (mid and final terms and quizzes), • Project report • Coursework activities assessment, • Home works and assignments, • Presentations.
c3. Apply industrials rules, standards and regulations and observe the appropriate steps to asses risks concerning biomedical systems practice.	• Interactive lectures & examples, • Presentation/seminar, • Interactive class discussions, • Case studies, • Exercises and home works, • Directed self- study, • Problem based learning, • Field visits/training, • Mini/major project.	• Written tests (mid and final terms and quizzes), • Project report • Coursework activities assessment, • Home works and assignments, • Presentations.
c4. Recognize ethical and professional responsibilities in the development of biomedical products and must consider their	• Mini/major project.	• Lab\Project report • Coursework activities assessment, • Home works and assignments,

impacts in global, economic, environmental, safety, confidentiality and quality of life issues.		• Presentations.

(D) Alignment Course Intended Learning Outcomes of Transferable Skills to Teaching Strategies and Assessment Strategies:

Course Intended Learning Outcomes	Teaching strategies	Assessment Strategies
d1. Function effectively as an individual, and as a member or leader in diverse teams, and in multidisciplinary settings.	• Case studies, • Workshops practices, • Problem based learning, • Team work (cooperative learning), • Field visits/training, • Mini/major project.	• Project report • Coursework activities assessment, • Presentations.
d2 Manage a design and development project tasks from start to finish that establish goals, plan tasks and meet deadlines.	• Case studies, • Workshops practices, • Problem based learning, • Team work (cooperative learning), • Field visits/training, • Mini/major project.	• Project report • Coursework activities assessment, • Presentations.
d3. Upgrade knowledge and understanding through Life-long Learning philosophy.	• Case studies, • Exercises and home works, • Directed self- study, • Problem based learning, • Field visits/training, • Mini/major project.	• Written tests (mid and final terms and quizzes), • Project report • Coursework activities assessment, • Home works and

		assignments, • Presentations.
d4. Utilize technical resources and perform effective background research, observations, and interviews.	• Interactive class discussions, • Case studies, • Exercises and home works, • Directed self- study, • Problem based learning, • Team work (cooperative learning), • Field visits/training, • Mini/major project.	• Written tests (mid and final terms and quizzes), • Project report • Coursework activities assessment, • Home works and assignments, • Presentations.
d5. Writing effective reports and design documentation and make effective presentations.	• Presentation/seminar, • Interactive class discussions, • Case studies, • Exercises and home works, • Directed self- study, • Problem based learning, • Team work (cooperative learning), • Field visits/training, • Mini/major project.	• Project report • Coursework activities assessment, • Home works and assignments, • Presentations.

IV. Course Content:

A – Theoretical Aspect:

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Order	Units/Topics List	Learning Outcomes	Sub Topics List	Number of Weeks	contact hours
1	**Introduction to Biomedical Engineering Design**	**a1, a2,c1**	– Course Overview – What Is Design? – The Essentials of Design—Overview – Biomedical Engineering Design – Medical Devices Definitions – Classifying Medical Devices – Classification and the Design Process – An Overview of the Industrial Design Process – The Design Life Cycle – Characteristics of Successful Product Development	**1**	**2**
2	**Development Process and Design Procedures**	**a1,a2,b1,b2, c1**	– Generic Product Development Process – Product Development Organizations – Opportunity Identification – Design Process versus Design Control – Design Models – Managing Design – Cross-Reference with Regulatory Requirements – Review of Guidelines – Overall Procedure – Audit /Review Procedure – Design Process and Procedures	**2 & 3**	**4**
3	**Design Team and Management**	**a1,a2,b1,b2, c1**	– Design Team Construction and Management – Student Design Team Construction and Management – Reporting Techniques – Design Project Data Management – Case Study-1	**4**	**2**
4	**Product**	**a1,a2,b1,b2, c1,c2**	– The Product Definition Process	**5 & 6**	**4**

	Definition		– Identifying Customer Needs – Developing the Statement of Need (or Brief) – Function Decomposition and Structure – Detailed Procedure to Establish Functional Structures – Benchmarking – Competitive Performance Benchmarking – Reverse Engineering and Product Dissection – Objective Trees – Determining Engineering Characteristics – Quality function deployment (QFD) – Product Specification – Detailed Procedure to Establish Product Specifications – Case Study-2		
5	**Concept Generation and Selection**	**a1,a2,b1,b2, c1,c2**	– Creative Space – Concept Generation Methods – Detailed Procedure to Establish Concept Generation – Overview of Methodology for Selecting Concepts and Ideas – Elementary Decision-Making Techniques – Concept Screening – Concept Scoring – Detailed Procedure to Establish Concept Testing – Prototyping – Case Study-3	**7**	**2**
6	**Mid-Term Theoretical Exam**	**a1,a2,b1,b2, c1,c2**	– All Preceding Lectures	**8**	**2**
7	**Product Architecture**	**a1,a2,b1,b2, c1,c2**	– The Process to Design Realization – Define Product Architecture	**9**	**2**

			– Implications of the Architecture – Steps in Developing Product Architecture – Configuration & Parametric Design – Dimensions and Tolerances – Biomaterials Performance characteristics, Selection Process and Testing – Modeling and Simulation Tools – Case Study-4		
8	**Product Development**	**a1,a2,b1,b2, c1,c2**	– Product Requirements – Design and Development Planning – System Requirements Specification – Design Input – Design Output – Formal Design Review – Design Verification – Design Validation – Design Transfer – Role of the Intern	**10**	**2**
10	**Design for Quality and Robustness**	**a1,a2,b1,b2, c1,c2**	– Design for Six Sigma (DFSS) – DFSS Methodology – DFSS Tools – Robust Design – Quality Function Deployment – Robust Design Failure Mode and Effects Analysis – Axiomatic Design – Design for Variation – Design of Experiments – Case Study-5	**11**	**2**
11	**Industrial Design (ID)**	**a1,a2,b1,b2, c1,c2,c3**	– Definition of Human Factors (HFs) – The Human, Hardware and Software Elements in HFs – HFs Process – Planning and Analysis of HFs – Conduct User Studies	**12**	**2**

			– Set Usability Goals – Design User Interface (UI) Concepts – Model the Test UI – Additional HFs Design Considerations – Fitts' Law – Set Usability Goals – Design UI Concepts – Model, Test Specify and the UI – Additional ID Considerations – Case Study-6		
12	**Evaluation (Validation and Verification)**	**a1,a2,b1,b2, c1,c2,c3**	– Safety and Risk – Factors Important for Medical Device Risk Assessment – Risk Management Process – Tools for Risk Estimation – Risk Analysis and Systems – Criteria-Based Evaluation – Testing Methodology – Types of Testing – Analysis of Test Data – Definitions of: **Reliability, Confidence Level, Confidence Limits, Mean Time Between Failures, Minimum Life.** – Types of Reliability – Failure Rate – Mean Time Between Failures – Graphical analysis	**13**	**2**
13	**Miscellaneous Issues**	**a1,a2,b1,b2, c1,c2,c3,c4**	– Design for "X" 1. Design for Manufacturability 2. Design for Assembly and Disassembly 3. Design for Reliability 4. Design for Maintainability 5. Design for Environment – Standards and Regulations 1. International Standards	**14 & 15**	**4**

			2. The 510(k) process 3. Pre-market Approval (PMA) 4. Medical Devices Directive (MDD) 5. Choosing the Appropriate Directive – Intellectual Property: Patents, Copyrights, Trade Secrets, and Licensing – Ethics Issues – Professional Issues		
14	**Final Theoretical Exam**	**a1,a2,b1,b2, c1,c2,c3**	– All Preceding Lectures	**16**	**2**
Number of Weeks /and Units Per Semester				**16**	**32**

B –Practical Aspect: (Project)

Order	Tasks/ Experiments	Number of Weeks	contact hours	Learning Outcomes
1	**Semester Project Information and Product Documentation:** – Semester Project Information – Documentation 1. Business proposal 2. Product specification 3. Design specification – Records: 1. The DHF 2. The DMR 3. The DHR 4. The TDF	**1**	**2**	**a1,a2, c1,c2, d5**

	– A Comparison of the Medical Device Records – Expectations for Student Project Documentation – Project Report Template Information – Presentation Information			
2	**Semester Project Selection:** – Students will also work with a partner to complete a semester project consisting of an in-depth case study of an existing or new medical device related to one of the following general categorized: 1. Orthopedic devices 2. Implantable electronic devices 3. Diagnostics 4. Therapeutic devices 5. Skin closure devices 6. Others – Project selection – Form a Team – They should examine the entire design and development process of a medical device and associative products..	**2**	**2**	**a1,a2,b1,b2, c1,c2,**
3	**SolidWorks module:** – A computer-aided design software package widely used in engineering in general, and biomedical industry in particular – Students will asked to revised their practice on using SolidWorks software.	**3**	**2**	**c1,c2**
4	**COMSOL module:** – A modeling package for the simulation of any physical process you can describe with partial differential equations (PDEs). It features state-of-the-art solvers that address complex problems	**4 & 5**	**4**	**c1,c2**

	quickly and accurately, while its intuitive structure is designed to provide ease of use and flexibility. – Students will asked to revised their practice on using COMSOL software.			
5	**Problem Definition:** – Students will be assigned a Case study and expected to identify opportunities and customer needs, generate design specifications, manage and plan out the project and maintain engineering notebooks throughout all phases of the project.	**6**	**2**	**a1,a2,b1,b2, c1,c2,c3,c4, d1,d2, d3,d4.d5**
6	**Concept Generation and Evaluation:** – Students will use brainstorming and decision evaluation tools to generate and evaluate solutions to reach a design consensus.	**7**	**2**	**a1,a2,b1,b2, c1,c2,c3,c4, d1,d2, d3,d4.d5**
7	**First project presentation:** – Students will be required to describe, explain, and support the progress and solutions of their project at above phases of the design process.	**8**	**2**	**a1,a2,b1,b2, c1,c2,c3,c4, d1,d2, d3,d4.d5**
8	**Detailed Design:** – Students will generate a paper design of their proposed prototype including device specifications, key materials and components, detailed drawings, and principle of operation with all choices justified and supported through proof-of-concept. **First Project Report:** – Initial information details about the project will be posted in the first report attached to the syllabus.	**9 &10**	**4**	**a1,a2,b1,b2, c1,c2,c3,c4, d1,d2, d3,d4.d5**

9	**Prototype Fabrication and Validation:** – Students will fabricate and conduct testing of their prototype, assess the degree to which the prototype meets the design specifications, and recommend design modifications to improve the prototype.	**11 - 13**	**6**	**a1,a2,b1,b2, c1,c2,c3,c4, d1,d2, d3,d4.d5**
10	**Second Project Presentation:** – Students will be required to describe, explain, and support the progress and solutions of their project at all phases of the design process.	**14**	**2**	**a1,a2,b1,b2, c1,c2,c3,c4, d1,d2, d3,d4.d5**
11	**Final Project Report:** – Final design details about the project will be posted in the final report.	**15**	**2**	**a1,a2,b1,b2, c1,c2,c3,c4, d1,d2, d3,d4.d5**
Number of Weeks /and Units Per Semester			**15**	**30**

C. Tutorial Aspect:

No.	Tutorial	Number of Weeks	Contact Hours	Learning Outcomes (CILOs)
1	None			
2				
Number of Weeks /and Units Per Semester		**0**	**0**	

V. Teaching Strategies of the Course:

V. Teaching Strategies of the Course:

- Interactive lectures & examples,
- Presentation/seminar,
- Interactive class discussions,
- Case studies,
- Exercises and home works,
- Computer laboratory-based sessions
- Directed self- study,
- Problem based learning,
- Team work (cooperative learning),
- Field visits/training,
- Mini/major project.

VI. Assessment Methods of the Course:

- Written tests (mid and final terms and quizzes),
- Project report
- Coursework activities assessment,
- Home works and assignments,
- Presentations.

VII. Assignments:

No	Assignments	Aligned CILOs(symbols)	Week Due	Mark

1	**Case study topics:** • Case studies are conducted in the class on a medical device that is related to one of the following general categorized: 1. Orthopedic devices 2. Implantable electronic devices 3. Diagnostics 4. Therapeutic devices 5. Skin closure devices 6. Others • Case studies should examine and will prepare and deliver a class presentation and submit a short written report covering one aspects of the design and development of a medical device and associative products.	**a1,a2,b1,b2,c1, c2,c3,c4,d1,d2, d3,d4**	Through course Semester	**10**
2	**Semester Project:** First project presentation	**a1,a2,b1,b2,c1, c2,c3,c4,d1,d2, d3,d4**	**8**	**2**
3	**Semester Project;** First project Report	**a1,a2,b1,b2,c1, c2,c3,c4,d1,d2, d3,d4**	**10**	**3**
4	**Semester Project:** Final project presentation	**a1,a2,b1,b2,c1, c2,c3,c4,d1,d2, d3,d4**	**14**	**5**
5	**Semester Project:** Final project Report	**a1,a2,b1,b2,c1, c2,c3,c4,d1,d2, d3,d4**	**15**	**10**
Total				**30**

VIII. Schedule of Assessment Tasks for Students During the Semester:

No.	Assessment Method	Week Due	Mark	Proportion of Final Assessment	Aligned Course Learning Outcomes
1	**Assignments**	Through course	30	20%	**a1,a2,b1,b2,c1,c2, c3,c4,d1,d2,d3,d4**

		Semester			
2	**Quizzes**	6 & 10	20	13.3%	**a1,a2,b1, b2, c1,c2**
3	**Midterm Theoretical Exam**	8	30	20%	**a1,a2,b1,b2, c1,c2,**
4	**Final Theoretical Exam**	16	70	46.7%	**a1,a2,b1,b2, c1,c2, c3,c4**
Total			150	100%	

IX. Learning Resources:

1- Required Textbook(s) (maximum two).

1. Paul H. King, Richard C. Fries, and Arthur T. Johnson, 2019, **Design of Biomedical Devices and Systems**, 4th Edition, CRC Press, USA.
2. Ulrich, K.T. and Eppringer, S.D., 2012, **Product Design and Development**, 5th Edition, USA, McGraw-Hill, Inc.

2- Essential References.

1. Claudio Becchetti Alessandro Neri, 2013, **Medical Instrument Design and Development: From Requirements to Market Placements**, 1st Edition, United Kingdom, John Wiley & Sons Ltd
2. Peter J. Ogrodnik, 2013, **Medical Device Design Innovation from Concept to Market**, 1st Edition, UK, Elsevier.
3. Myer Kutz, 2009, **Biomedical Engineering and Design Handbook Volume 1: Fundamentals**, 1st Edition, USA, McGraw-Hill.
4. Myer Kutz, 2009, **Biomedical Engineering and Design Handbook Volume 2: Applications**, USA, McGraw-Hill.

3- Electronic Materials and Web Sites *etc*.

Websites:

- www.ebiodesign.org
- www.fda.gov
- www.idsa.org/events/what-id.
- www.arts.gov/sites/default/files/Industrial-Design-Report-May2017-rev3.pdf.
- www.medicaldesignandoutsourcing.com/need-know-industrial-design-medtech/.
- www.mdtmag.com/article/2015/10/3-key-aspects-successful-medical-industrial-design.
- www.biomaterials.org

	• www.lib.umich.edu/database/link/10603. • www.matweb.com/main.htm • www.valvira.fi • www.afssaps.fr • www.sanita.it • www.imb.ie

X. Course Policies:

1	**Class Attendance:** A student should attend not less than 75 % of total hours of the subject; otherwise he/she will not be able to take the exam and will be considered as exam failure. If the student is absent due to illness, he/she should bring a proof statement from university Clinic. If the absent is more than 25% of a course total contact hours, student will be required to retake the entire course again.
2	**Tardy:** For late in attending the class, the student will be initially notified. If he repeated lateness in attending class, he/she will be considered as absent.
3	**Exam Attendance/Punctuality:** A student should attend the exam on time. He/she is permitted to attend an exam half one hour from exam beginning, after that he/she will not be permitted to take the exam and he/she will be considered as absent in exam
4	**Assignments & Projects**: In general one assignment is given to the students after each chapter; the student has to submit all the assignments for checking on time, mostly one week after given the assignment.
5	**Cheating**: For cheating in exam, a student will be considered as fail. In case the cheating is repeated three times during his/her study the student will be disengaged from the Faculty.
6	**Plagiarism**:

	Plagiarism is the attending of a student the exam of a course instead of another student. If the examination committee proofed a plagiarism of a student, he/she will be disengaged from the Faculty. The final disengagement of the student from the Faculty should be confirmed from the Student Council Affair of the university or according to the university roles.
7	**Other policies**: - Mobile phones are not allowed to use during a class lecture. It must be closed; **otherwise** the student will be asked to leave the lecture room. - Mobile phones are not allowed in class during the examination. - Lecture notes and assignments might be given directly to students using soft or hard copy.

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Faculty of Engineering
Department: Biomedical Engineering
Title of the Program: Biomedical Engineering

Template for Course Plan (Syllabus)

Biomedical Systems Design
BE367

I. Course Identification and General Information:					
1	**Course Title:**	Biomedical Systems Design			
2	**Course Code & Number:**	BE367			
3	**Credit Hours:**	**Credit Hours**	**Theory Hours**		**Pr.**
			Lecture	**Exercise**	
		3	2	--	2
4	**Study Level/ Semester at which this Course is offered:**	4^{th} Level / 2^{nd} Semester			
5	**Pre –Requisite (if any):**	BE244, BE263, BE364			
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7	**Program (s) in which the Course is Offered:**	Biomedical Engineering Program			
8	**Language of Teaching the Course:**	English			
9	**Location of Teaching the Course:**	Faculty of Engineering			
10	**Prepared by:**	Associate Prof. Dr. Khalil Al-Hatab			
11	**Reviewed by:**	Dr. ----			
12	**Date of Approval:**				

II. Course Description:

Biomedical Systems Design is a project-based course that expose students to the entire biomedical product design and development process from an idea to a product. The course material includes:

generic design and development process, design team management, product definition, concept generation and selection, product architecture, product documentation, product development, design for quality and robustness, human factors and industrial design, evaluation and miscellaneous issues. Through the class lectures, assignments, case studies, project and seminar, students will develop an intense, immersive, experiential opportunity to develop professional-level skills to adopt an interdisciplinary and integrated approach in the design and development of medical systems and assistive devices.

III. Course Intended Learning Outcomes (CILOs): (مخرجات تعلم المقرر)

A. Knowledge and Understanding: Upon successful completion of the course, students will be able to:	
a1	Explain the generic design and developments process and how it is relevant to the design and developments of a biomedical systems and associative devices.
a2	Understand the phases, procedures, concepts, principles, methodologies, tools and techniques applied to design and develop a biomedical product in a creative and innovative manner.
B. Intellectual Skills: Upon successful completion of the course, students will be able to:	
b1	Review research literature, identify, formulate and analyze a real world problem statement, requirement to develop creative and innovative design solutions as a member of an engineering design team.
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c1	Recognize the ongoing need for additional knowledge, integrate and apply this knowledge to obtain the innovation solution of the product design and development project.
c2	Use analytical tools, techniques, modern engineering tools, computational software packages for virtual design, including development, validation, and optimization of prototypes.

III. Course Intended Learning Outcomes (CILOs): (مخرجات تعلم المقرر)	
c3	Apply industrials rules, standards and regulations and observe the appropriate steps to asses risks concerning biomedical systems practice.
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d2	Manage a design and development project tasks from start to finish that establish goals, plan tasks and meet deadlines.
d3	Upgrade knowledge and understanding through Life-long Learning philosophy.
d4	Utilize technical resources and perform effective background research, observations, and interviews.
d5	Writing effective reports and design documentation and make effective presentations.

IV. Course Contents:

A. Theoretical Aspect:

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours
1	**Introduction to Biomedical Engineering Design**	– Course Overview – What Is Design? – The Essentials of Design—Overview – Biomedical Engineering Design – Medical Devices Definitions – Classifying Medical Devices – Classification and the Design Process – An Overview of the Industrial Design Process	**1**	**2**

IV. Course Contents:

A. Theoretical Aspect:

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours
		– The Design Life Cycle – Characteristics of Successful Product Development		
2	**Development Process and Design Procedures**	– Generic Product Development Process – Product Development Organizations – Opportunity Identification – Design Process versus Design Control – Design Models – Managing Design – Cross-Reference with Regulatory Requirements – Review of Guidelines – Overall Procedure – Audit /Review Procedure – Design Process and Procedures	**2 & 3**	**4**
3	**Design Team and Management**	– Design Team Construction and Management – Student Design Team Construction and Management – Reporting Techniques – Design Project Data Management – Case Study-1	**4**	**2**
4	**Product Definition**	– The Product Definition Process – Identifying Customer Needs – Developing the Statement of Need (or Brief) – Function Decomposition and Structure – Detailed Procedure to Establish Functional Structures – Benchmarking	**5 & 6**	**4**

IV. Course Contents:

A. Theoretical Aspect:

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours
		– Competitive Performance Benchmarking – Reverse Engineering and Product Dissection – Objective Trees – Determining Engineering Characteristics – Quality function deployment (QFD) – Product Specification – Detailed Procedure to Establish Product Specifications – Case Study-2		
5	**Concept Generation and Selection**	– Creative Space – Concept Generation Methods – Detailed Procedure to Establish Concept Generation – Overview of Methodology for Selecting Concepts and Ideas – Elementary Decision-Making Techniques – Concept Screening – Concept Scoring – Detailed Procedure to Establish Concept Testing – Prototyping – Case Study-3	**7**	**2**
6	**Mid-Term Theoretical Exam**	– All Preceding Lectures	**8**	**2**
7	**Product Architecture**	– The Process to Design Realization – Define Product Architecture – Implications of the Architecture – Steps in Developing Product Architecture – Configuration & Parametric Design	**9**	**2**

IV. Course Contents:

A. Theoretical Aspect:

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours
		– Dimensions and Tolerances – Biomaterials Performance characteristics, Selection Process and Testing – Modeling and Simulation Tools – Case Study-4		
9	**Product Development**	– Product Requirements – Design and Development Planning – System Requirements Specification – Design Input – Design Output – Formal Design Review – Design Verification – Design Validation – Design Transfer – Role of the Intern	**10**	**2**
10	**Design for Quality and Robustness**	– Design for Six Sigma (DFSS) – DFSS Methodology – DFSS Tools – Robust Design – Quality Function Deployment – Robust Design Failure Mode and Effects Analysis – Axiomatic Design – Design for Variation – Design of Experiments – Case Study-5	**11**	**2**
11	**Industrial Design**	– Definition of Human Factors (HFs) – The Human, Hardware and Software Elements in HFs – HFs Process	**12**	**2**

IV. Course Contents:

A. Theoretical Aspect:

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours
		– Planning and Analysis of HFs – Conduct User Studies – Set Usability Goals – Design User Interface (UI) Concepts – Model the Test UI – Additional HFs Design Considerations – Fitts' Law – Set Usability Goals – Design UI Concepts – Model, Test Specify and the UI – Additional ID Considerations – Case Study-6		
12	**Evaluation (Validation and Verification)**	– Safety and Risk – Factors Important for Medical Device Risk Assessment – Risk Management Process – Tools for Risk Estimation – Risk Analysis and Systems – Criteria-Based Evaluation – Testing Methodology – Types of Testing – Analysis of Test Data – Definitions of: **Reliability, Confidence Level, Confidence Limits, Mean Time Between Failures, Minimum Life.** – Types of Reliability – Failure Rate – Mean Time Between Failures – Graphical analysis	**13**	**2**
13	**Miscellaneous**	– Design for "X"	**14 & 15**	**4**

IV. Course Contents:

A. Theoretical Aspect:

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours
	Issues	6. Design for Manufacturability 7. Design for Assembly and Disassembly 8. Design for Reliability 9. Design for Maintainability 10. Design for Environment – Standards and Regulations 6. International Standards 7. The 510(k) process 8. Pre-market Approval (PMA) 9. Medical Devices Directive (MDD) 10. Choosing the Appropriate Directive – Intellectual Property: Patents, Copyrights, Trade Secrets, and Licensing – Ethics Issues – Professional Issues		
14	**Final Theoretical Exam**	– All Preceding Lectures	**16**	**2**
Number of Weeks /and Units Per Semester			**16**	**32**

B. Case Studies and Project Practical Aspect:

No.	Tasks/ Experiments	Number of Weeks	Contact Hours
1	**Semester Project Information and Product Documentation:** – Semester Project Information – Documentation	**1**	**2**

B. Case Studies and Project Practical Aspect:			
No.	**Tasks/ Experiments**	**Number of Weeks**	**Contact Hours**
	4. Business proposal 5. Product specification 6. Design specification – Records: 5. The DHF 6. The DMR 7. The DHR 8. The TDF – A Comparison of the Medical Device Records – Expectations for Student Project Documentation – Project Report Template Information – Presentation Information		
2	**Semester Project Selection:** – Students will also work with a partner to complete a semester project consisting of an in-depth case study of an existing or new medical device related to one of the following general categorized: 1. Orthopedic devices 2. Implantable electronic devices 3. Diagnostics 4. Therapeutic devices 5. Skin closure devices 6. Others – Project selection – Form a Team – They should examine the entire design and development process of a medical device and associative products..	**2**	**2**
3	**SolidWorks module:**	**3**	**2**

B. Case Studies and Project Practical Aspect:			
No.	**Tasks/ Experiments**	**Number of Weeks**	**Contact Hours**
	– A computer-aided design software package widely used in engineering in general, and biomedical industry in particular – Students will asked to revised their practice on using SolidWorks software.		
4	**COMSOL module:** – A modeling package for the simulation of any physical process you can describe with partial differential equations (PDEs). It features state-of-the-art solvers that address complex problems quickly and accurately, while its intuitive structure is designed to provide ease of use and flexibility. – Students will asked to revised their practice on using COMSOL software.	**4 & 5**	**4**
5	**Problem Definition:** – Students will be assigned a Case study and expected to identify opportunities and customer needs, generate design specifications, manage and plan out the project and maintain engineering notebooks throughout all phases of the project.	**6**	**2**
6	**Concept Generation and Evaluation:** – Students will use brainstorming and decision evaluation tools to generate and evaluate solutions to reach a design consensus.	**7**	**2**
7	**<u>First project presentation:</u>** – Students will be required to describe, explain, and	**8**	**2**

B. Case Studies and Project Practical Aspect:			
No.	**Tasks/ Experiments**	**Number of Weeks**	**Contact Hours**
	support the progress and solutions of their project at above phases of the design process.		
8	**Detailed Design:** – Students will generate a paper design of their proposed prototype including device specifications, key materials and components, detailed drawings, and principle of operation with all choices justified and supported through proof-of-concept. **First Project Report:** – Initial information details about the project will be posted in the first report attached to the syllabus.	**9 &10**	**4**
9	**Prototype Fabrication and Validation:** – Students will fabricate and conduct testing of their prototype, assess the degree to which the prototype meets the design specifications, and recommend design modifications to improve the prototype.	**11 - 13**	**6**
10	**Second Project Presentation:** – Students will be required to describe, explain, and support the progress and solutions of their project at all phases of the design process.	**14**	**2**
11	**Final Project Report:** – Final design details about the project will be posted in the final report.	**15**	**2**
Number of Weeks /and Units Per Semester		**15**	**30**

C. Tutorial Aspect:			
No.	**Tutorial**	**Number of Weeks**	**Contact Hours**
1	None		
Number of Weeks /and Units Per Semester			

V. Teaching Strategies of the Course:

- Interactive lectures & examples,
- Presentation/seminar,
- Interactive class discussions,
- Case studies,
- Exercises and home works,
- Computer laboratory-based sessions
- Directed self- study,
- Problem based learning,
- Team work (cooperative learning),
- Field visits/training,
- Mini/major project.

VI. Assessment Methods of the Course:

- Written tests (mid and final terms and quizzes),
- Project report
- Coursework activities assessment,
- Home works and assignments,
- Presentations.

VII. Assignments:

No.	Assignments	Week Due	Mark

VII. Assignments:

No.	Assignments	Week Due	Mark
1	**Case study topics:** • Case studies are conducted in the class on a medical device that is related to one of the following general categorized: 1. Orthopedic devices 2. Implantable electronic devices 3. Diagnostics 4. Therapeutic devices 5. Skin closure devices 6. Others • Case studies should examine and will prepare and deliver a class presentation and submit a short written report covering one aspects of the design and development of a medical device and associative products.	Through course Semester	**10**
2	**Semester Project:** First project presentation	**8**	**2**
3	**Semester Project;** First project Report	**10**	**3**
4	**Semester Project:** Final project presentation	**14**	**5**
5	**Semester Project:** Final project Report	**15**	**10**
Total			**30**

VIII. Schedule of Assessment Tasks for Students During the Semester:

No.	Assessment Method	Week Due	Mark	Proportion of Final Assessment
1	**Assignments**	Through course Semester	30	20%
2	**Quizzes**	6 & 10	20	13.3%
3	**Midterm Theoretical Exam**	8	30	20%

VIII. Schedule of Assessment Tasks for Students During the Semester:

No.	Assessment Method	Week Due	Mark	Proportion of Final Assessment
4	**Final Theoretical Exam**	16	70	46.7%
Total			**150**	**100%**

IX. Learning Resources:

- *Written in the following order:*

1- Required Textbook(s) (maximum two):

1. Paul H. King, Richard C. Fries, and Arthur T. Johnson, 2019, **Design of Biomedical Devices and Systems**, 4th Edition, CRC Press, USA.
2. Ulrich, K.T. and Eppringer, S.D., 2012, **Product Design and Development**, 5th Edition, USA, McGraw-Hill, Inc.

2- Essential References:

1. Claudio Becchetti Alessandro Neri, 2013, **Medical Instrument Design and Development: From Requirements to Market Placements**, 1st Edition, United Kingdom, John Wiley & Sons Ltd
2. Peter J. Ogrodnik, 2013, **Medical Device Design Innovation from Concept to Market**, 1st Edition, UK, Elsevier.
3. Myer Kutz, 2009, **Biomedical Engineering and Design Handbook Volume 1: Fundamentals**, 1st Edition, USA, McGraw-Hill.
4. Myer Kutz, 2009, **Biomedical Engineering and Design Handbook Volume 2: Applications**, USA, McGraw-Hill.

3- Electronic Materials and Web Sites etc.:

Websites:

- www.ebiodesign.org
- www.fda.gov
- www.idsa.org/events/what-id.
- www.arts.gov/sites/default/files/Industrial-Design-Report-May2017-rev3.pdf.
- www.medicaldesignandoutsourcing.com/need-know-industrial-design-medtech/.
- www.mdtmag.com/article/2015/10/3-key-aspects-successful-medical-industrial-design.
- www.biomaterials.org

IX. Learning Resources:

- www.lib.umich.edu/database/link/10603.
- www.matweb.com/main.htm
- www.valvira.fi
- www.afssaps.fr
- www.sanita.it
- www.imb.ie

X. Course Policies:

1	**Class Attendance:** A student should attend not less than 75 % of total hours of the subject; otherwise he/she will not be able to take the exam and will be considered as exam failure. If the student is absent due to illness, he/she should bring a proof statement from university Clinic. If the absent is more than 25% of a course total contact hours, student will be required to retake the entire course again.
2	**Tardy:** For late in attending the class, the student will be initially notified. If he repeated lateness in attending class, he/she will be considered as absent.
3	**Exam Attendance/Punctuality:** A student should attend the exam on time. He/she is permitted to attend an exam half one hour from exam beginning, after that he/she will not be permitted to take the exam and he/she will be considered as absent in exam
4	**Assignments & Projects:** In general one assignment is given to the students after each chapter; the student has to submit all the assignments for checking on time, mostly one week after given the assignment.
5	**Cheating:** For cheating in exam, a student will be considered as fail. In case the cheating is repeated three times during his/her study the student will be disengaged from the Faculty.

6	**Plagiarism:** Plagiarism is the attending of a student the exam of a course instead of another student. If the examination committee proofed a plagiarism of a student, he/she will be disengaged from the Faculty. The final disengagement of the student from the Faculty should be confirmed from the Student Council Affair of the university or according to the university roles.
7	**Other policies:** - Mobile phones are not allowed to use during a class lecture. It must be closed; **otherwise** the student will be asked to leave the lecture room. - Mobile phones are not allowed in class during the examination. - Lecture notes and assignments might be given directly to students using soft or hard copy.