Republic of Yemen

Ministry of Higher Education & Scientific Research

Council of Academic Accreditation & Quality Assurance o

Higher Education (CAQA)

21 September University for medical and Applied Science

Faculty of Engineering and Computer

Department of Biomedical Engineering

Program of Biomedical Engineering

Course Specification of

Biomedical Systems Design

Course Code. (07.12.733)

2024

T4: This Template is Developed and Approved by CAQA-Yemen, 2023

Prepared by:	Reviewed by:	Head of the Department:	Quality Unit:	Dean:
Dr. Abdulsalam Al -Absi	Dr. -----	Dr. Awadh Al-Kubati	Dr. Mohammed Al-shamahi	Dr. Abdulrahman Obaid

I. General Information:

1.	Course Title:	Biomedical Systems Design				
2.	Course Code:	07.12.733				
3.	Credit Hours:	Credit Hours	Theory Contact Hours		Practical Contact Hours	
			Lecture	Tutorial /Seminar	Lab	Clinical
		3	2	--	2	--
4.	Level/ Semester at which this Course is offered:	4^{th} Level / 2^{nd} Semester				
5.	Pre –Requisite (if any):	Bioelectronics, Biomedical Devices 1&2, Biomedical Devices Maintenance 1				
6.	Co –Requisite (if any):	N/A				
7.	Program (s) in which the Course is Offered:	Bachelor of Biomedical Engineering				
8.	Language of Teaching the Course:	English/Arabic				
9.	Location of Teaching the Course:	Faculty of Medical Technology				
10.	Prepared by:	Dr. Abdulsalam Al-Absi				
11	Date and Number of Approval by Council:					

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. This course includes generic design and development process, design team management, product definition and architecture, concept generation and selection, product documentation and development, design for quality and robustness, human factors and industrial design, evaluation and miscellaneous issues. Through this course, the student will get an 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) : Upon successful completion of the course, students will be able to:		Referenced PILOs		
	A. Knowledge and Understanding:	**I, P or M/A**		
a1	Describe the general design and development process and its significance for the creation of biomedical systems and related devices.	P	A2	Clarify the biomedical devices maintenance principles and how these are important for solving biomedical devices and equipment's problems in health environment.
a2	Grasp the stages, procedures, concepts, principles, methodologies, tools, and techniques used to creatively and innovatively design and develop biomedical products.	P	A4	Understand an examples of a biomedical engineering technology concept and methods related to maintenance, measurement techniques, programming, creative engineering solutions, analytical skills, applied to healthcare quality and problems of medical devices issues.
	B. Intellectual Skills:			
b1	Review existing research literature to identify, formulate, and analyze a real-world problem statement and requirements for generating creative and innovative design solutions as part of an engineering design team.	P	B2	Analyze the impacts of problems related to the Biomedical equipments and its solution principles in a creative manner by using a systematic and analytical thinking methods.
b2	Envision a specific biomedical system and product to be introduced to the market while considering realistic constraints such as environmental, health and	P	B4	Apply the principles of biomedical devices maintenance and its various methods to work professionally in biomedical engineering field.

	safety, ethical and professional behavior, societal and political factors, manufacturability, and sustainability.			
	C. Professional and Practical Skills:			
c1	Employ analytical tools, techniques, modern engineering tools, and computational software for virtual design, including the development, validation, and optimization of prototypes.	P	C2	Evaluate an engineering technique, modern analytical tools and required computer programs to analyzing and solve the problems of medical devices.
c2	Adhere to industrial rules, standards, and regulations, taking the necessary steps to assess risks associated with biomedical systems practices.	M	C4	Comply the basic skills in use of techniques, apply quality assurance procedures, and follow safety standards in maintenance procedures.
	D. Transferable Skills:			
d1	Enhance knowledge and understanding through a commitment to lifelong learning.	M/A	D1	Pursue ongoing professional development and lifelong learning in the biomedical engineering filed.
I= Introduced, P=Practiced or M/A= Mastered/Advanced				

	(A) Alignment of Course Intended Learning Outcomes (Knowledge and Understanding) to Teaching Strategies and Assessment Methods:		
	Course Intended Learning Outcomes	**Teaching Strategies**	**Assessment Strategies**
a1	Describe the general design and development process and its significance for the creation of biomedical systems and related	- Interactive lectures & examples, - Interactive class discussions, - Case studies, - Directed self- study, - Problem based	- Written tests (mid and final terms and quizzes), - Project report - Coursework

	devices.	learning, - Mini/major project.	activities assessment, - Home works and assignments, - Presentations.
a2	Grasp the stages, procedures, concepts, principles, methodologies, tools, and techniques used to creatively and innovatively design and develop biomedical products.		
	(B) Alignment of Course Intended Learning Outcomes (Intellectual Skills) to Teaching Strategies and Assessment Methods:		
	Course Intended Learning Outcomes	**Teaching Strategies**	**Assessment Strategies**
b1	Review existing research literature to identify, formulate, and analyze a real-world problem statement and requirements for generating creative and innovative design solutions as part of an engineering design team.	- Interactive lectures - 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. se studies - Discussions - Self-learning	- Written tests (mid and final terms and quizzes), - Project report - Coursework activities assessment, - Home works and assignments, - Presentations.
b2	Envision a specific biomedical system and product to be introduced to the market while considering realistic constraints such as environmental, health and safety, ethical and professional behavior, societal and political factors, manufacturability, and sustainability.		
	(C) Alignment of Course Intended Learning Outcomes (Professional and Practical Skills) to Teaching Strategies and Assessment Methods:		

	Course Intended Learning Outcomes	Teaching Strategies	Assessment Strategies
c1	Employ analytical tools, techniques, modern engineering tools, and computational software for virtual design, including the development, validation, and optimization of prototypes.	- 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.
c2	Adhere to industrial rules, standards, and regulations, taking the necessary steps to assess risks associated with biomedical systems practices.		

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

	Course Intended Learning Outcomes	Teaching Strategies	Assessment Strategies
d1	Enhance knowledge and understanding through a commitment to lifelong learning.	- Case studies, - Problem based learning, - Team work (cooperative learning), - Field visits/training, - Mini/major project.	- Project report - Coursework activities assessment, - Presentations.

IV. Course Contents:

A. Theoretical Aspect:

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours	Learning Outcomes (CILOs)
1	**Introduction to Biomedical Engineering Design**	– Course Overview – What Is Design? – The Essentials of Design—Overview	1st	2	a1, a2

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours	Learning Outcomes (CILOs)
		– 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			
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	a1, a2, b1, b2
3	**Design Team and Management**	– Design Team Construction and Management – Student Design Team Construction and Management	4	2	a1, a2, b1, b2

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours	Learning Outcomes (CILOs)
		– Reporting Techniques – Design Project Data Management – Case Study-1			
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 – 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, 6	4	a1, a2, b1, b2, c1
5	**Concept Generation and Selection**	– Creative Space – Concept Generation Methods – Detailed Procedure to	7	2	a1, a2, b1, b2, c1

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours	Learning Outcomes (CILOs)
		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			
6	**Mid-Term Theoretical Exam**	– All previous topics	8	2	a1, a2, b1, b2, c1
7	**Product Architecture**	– The Process to Design Realization – Define Product Architecture – 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	9	2	a1, a2, b1, b2, c1
8	**Product**	– Product Requirements	10	2	a1, a2,

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours	Learning Outcomes (CILOs)
	Development	– Design and Development Planning – System Requirements Specification – Design Input – Design Output – Formal Design Review – Design Verification – Design Validation – Design Transfer – Role of the Intern			b1, b2, c1
9	**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	a1, a2, b1, b2, c1
10	**Industrial Design (ID)**	– Definition of Human Factors (HFs) – The Human, Hardware and Software Elements in HFs – HFs Process – Planning and Analysis of HFs – Conduct User Studies – Set Usability Goals	12	2	a1, a2, b1, b2, c1, c2

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours	Learning Outcomes (CILOs)
		– 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			
11	**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 o Level, Confidence Limits, Mean Time o Between Failures, Minimum Life. – Types of Reliability – Failure Rate – Mean Time Between Failures – Graphical analysis	13	2	a1, a2, b1, b2, c1, c2

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours	Learning Outcomes (CILOs)
12	**Miscellaneous Issues**	– 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 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, 15	4	a1, a2, b1, b2, c1, c2
13	**Final Theoretical Exam**	– All topics.	16	2	a1, b1, b2, c1, c2
Number of Weeks /and Units Per Semester			**16**	**32**	

B. Practical Aspect (Lab/Clinical) (if any):

No.	Tasks/ Experiments	Number of Weeks	Contact Hours	Learning Outcomes (CILOs)
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 – A Comparison of the Medical Device Records – Expectations for Student Project Documentation – Project Report Template Information – Presentation Information	1	2	a1, a2, c1, c2, d3
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	2	2	a1, a2, b1, c1, d1

No.	Tasks/ Experiments	Number of Weeks	Contact Hours	Learning Outcomes (CILOs)
	6. Others – Project selection – Form a Team – They should examine the entire design and development process of a medical device and associative products.			
3	**SolidWorks module:** – A computer-aided design software package widely used in engineering in general, and biomedical industry in particular – Students will ask to revised their practice on using SolidWorks software.	3	2	c1, c2, d1
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 ask to revised their practice on using COMSOL software.	4, 5	4	a2, b2, c2
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, c1, c2
6	**Concept Generation and Evaluation:**	7	2	b1, b2,

No.	Tasks/ Experiments	Number of Weeks	Contact Hours	Learning Outcomes (CILOs)
	• Students will use brainstorming and decision evaluation tools to generate and evaluate solutions to reach a design consensus.			c1, c2, d1
	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	b1, b2, c1, c2, d1
	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	b1, b2, c1, c2, d1
	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, 12	4	b1, b2, c1, c2, d1
	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.	13	2	b1, b2, c1, c2, d1

No.	Tasks/ Experiments	Number of Weeks	Contact Hours	Learning Outcomes (CILOs)
	Final Project Report: • Final design details about the project will be posted in the final report.	14	2	b1, b2, c1, c2, d1
Number of Weeks /and Units Per Semester		**14**	**28**	

C. Tutorial Aspect (if any):

No.	Tutorial	Number of Weeks	Contact Hours	Learning Outcomes (CILOs)
1	None			
2				
3				
4				
Number of Weeks /and Units Per Semester				

VI. 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.

VII. 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	Aligned CILOs (symbols)
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 aspect of the design and development of a medical device and associative products.	Through course Semester	10	a1, a2, b1, b2, c1, c2, d1
2	**Semester Project:** First project presentation	8	2	a1, a2, b1, b2, c1, c2, d1
3	**Semester Project:** First project report	10	3	a1, a2, b1, b2, c1, c2, d1
4	**Semester Project:** Final project	12	5	a1, a2, b1, b2,

No.	Assignments	Week Due	Mark	Aligned CILOs (symbols)
	presentation			c1, c2, d1
5	**Semester Project:** Final project report	14	10	a1, a2, b1, b2, c1, c2, d1
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 & Quizzes	Through course Semester	40	40%	a1- d1
2	Mid-Term Theoretical Exam	8	10	10%	a1, b1, b2
3	Final Theoretical Exam	16	50	50%	a1, a2, a3, b1, b2, b3
Total			100%	100%	-

IX. Learning Resources:

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

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

2- Essential References:

1. Claudio Becchetti Alessandro Neri, Medical Instrument Design and Development: From Requirements to Market Placements, 1st Ed., United Kingdom, John Wiley & Sons Ltd, 2013.
2. Peter J. Ogrodnik, Medical Device Design Innovation from Concept to Market, 1st

Ed., UK, Elsevier, 2013.

3. Myer Kutz, Biomedical Engineering and Design Handbook Volume 1: Fundamentals, 1st Ed., USA, McGraw-Hill, 2009.

4. Myer Kutz, Biomedical Engineering and Design Handbook Volume 2: Applications, USA, McGraw-Hill, 2009.

3- Electronic Materials and Web Sites etc.:

Websites:

1. www.arts.gov/sites/default/files/Industrial-Design-Report-May2017-rev3.pdf.
2. www.medicaldesignandoutsourcing.com/need-know-industrial-design-medtech/.
3. www.mdtmag.com/article/2015/10/3-key-aspects-successful-medical-industrial-design.

X. Course Policies: (Based on the Uniform Students' By law (2007)

1	**Class Attendance:** Class Attendance is mandatory. A student is considered absent and shall be banned from taking the final exam if his/her absence exceeds 25% of total classes.
2	**Tardiness:** A student will be considered late if he/she is not in class after 10 minutes of the start time of class.
3	**Exam Attendance/Punctuality:** No student shall be allowed to the exam hall after 30 minutes of the start time, and shall not leave the hall before half of the exam time has passed.
4	**Assignments & Projects:** Assignments and projects must be submitted on time. Students who delay their assignments or projects shall lose the mark allocated for the same.
5	**Cheating:** Cheating is an act of fraud that results in the cancelation of the student's exam or assignment. If it takes place in a final exam, the penalties stipulated for in the Uniform Students' Bylaw (2007) shall apply.
6	**Forgery and Impersonation:** Forgery/Impersonation is an act of fraud that results in the cancelation of the student's exam, assignment or project. If it takes place in a final exam, the penalties stipulated for in the Uniform Students' Bylaw (2007) shall apply.

7	**Other policies:** The University official regulations in force will be strictly observed and students shall comply with all rules and regulations of the examination set by the Department, Faculty and University Administration.

Faculty of Medical Technology

Department of Biomedical Engineering

Program of Biomedical Engineering

Course Plan (Syllabus) of

Biomedical Systems Design

Course Code. (07.12.733)

I. Information about Faculty Member Responsible for the Course:								
Name of Faculty Member:		Office Hours						
Location & Telephone No.:								
E-mail:		SAT	SUN	MON	TUE	WED	THU	

2024/2025

I. General Information:

11.	Course Title:	Biomedical Systems Design				
12.	Course Code:	07.12.733				
13.	Credit Hours:	Credit Hours	Theory Contact Hours		Practical Contact Hours	
			Lecture	Tutorial /Seminar	Lab	Clinical
		3	2	--	2	--
14.	Level/ Semester at which this Course is offered:	4^{th} Level / 2^{nd} Semester				
15.	Pre –Requisite (if any):	Bioelectronics, Biomedical Devices 1&2, Biomedical Devices Maintenance 1				
16.	Co –Requisite (if any):	N/A				
17.	Program (s) in which the Course is Offered:	Bachelor of Biomedical Engineering				
18.	Language of Teaching the Course:	English/Arabic				
19.	Location of Teaching the Course:	Faculty of Medical Technology				
20.	Prepared by:	Dr. Abdulsalam Al-Absi				
11	Date and Number of Approval by Council:					

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. This course includes generic design and development process, design team management, product definition and architecture, concept generation and selection, product documentation and development, design for quality and robustness, human factors and

industrial design, evaluation and miscellaneous issues. Through this course, the student will get an 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) :
Upon successful completion of the course, students will be able to:

	A. Knowledge and Understanding:
a1	Describe the general design and development process and its significance for the creation of biomedical systems and related devices.
a2	Grasp the stages, procedures, concepts, principles, methodologies, tools, and techniques used to creatively and innovatively design and develop biomedical products.
	B. Intellectual Skills:
b1	Review existing research literature to identify, formulate, and analyze a real-world problem statement and requirements for generating creative and innovative design solutions as part of an engineering design team.
b2	Envision a specific biomedical system and product to be introduced to the market while considering realistic constraints such as environmental, health and safety, ethical and professional behavior, societal and political factors, manufacturability, and sustainability.
	C. Professional and Practical Skills:
c1	Employ analytical tools, techniques, modern engineering tools, and computational software for virtual design, including the development, validation, and optimization of prototypes.
c2	Adhere to industrial rules, standards, and regulations, taking the necessary steps to assess risks associated with biomedical systems practices.
	D. Transferable Skills:
d1	Enhance knowledge and understanding through a commitment to lifelong learning.

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 – The Design Life Cycle – Characteristics of Successful Product Development	1st	2
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**	– Design Team Construction and	4	2

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours
	and Management	Management – Student Design Team Construction and Management – Reporting Techniques – Design Project Data Management – Case Study-1		
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 – 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, 6	4
5	Concept Generation and Selection	– Creative Space – Concept Generation Methods – Detailed Procedure to Establish Concept Generation	7	2

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours
		– 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		
6	**Mid-Term Theoretical Exam**	– All previous topics	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 – Dimensions and Tolerances – Biomaterials Performance characteristics, Selection Process and Testing – Modeling and Simulation Tools – Case Study-4	9	2
8	**Product Development**	– Product Requirements – Design and Development Planning – System Requirements Specification – Design Input – Design Output – Formal Design Review	10	2

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours
		– Design Verification – Design Validation – Design Transfer – Role of the Intern		
9	**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
10	**Industrial Design (ID)**	– Definition of Human Factors (HFs) – The Human, Hardware and Software Elements in HFs – HFs Process – 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	12	2

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours
		– Case Study-6		
11	**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 o Level, Confidence Limits, Mean Time o Between Failures, Minimum Life. – Types of Reliability – Failure Rate – Mean Time Between Failures – Graphical analysis	13	2
12	**Miscellaneous Issues**	– 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 2. The 510(k) process 3. Pre-market Approval (PMA)	14, 15	4

No.	Units/Topics List	Sub Topics List	Number of Weeks	Contact Hours
		4. Medical Devices Directive (MDD) 5. Choosing the Appropriate Directive – Intellectual Property: Patents, Copyrights, Trade Secrets, and Licensing – Ethics Issues – Professional Issues		
13	**Final Theoretical Exam**	– All topics.	16	2
Number of Weeks /and Units Per Semester			**16**	**32**

B. Practical Aspect (Lab/Clinical) (if any):

No.	Tasks/ Experiments	Number of Weeks	Contact Hours
1	**Semester Project Information and Product Documentation:** – Semester Project Information – Documentation 4. Business proposal 5. Product specification 6. Design specification – Records: 5. The DHF 6. The DMR 7. The DHR 8. The TDF	1	2

No.	Tasks/ Experiments	Number of Weeks	Contact Hours
	– 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: 7. Orthopedic devices 8. Implantable electronic devices 9. Diagnostics 10. Therapeutic devices 11. Skin closure devices 12. 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:** – A computer-aided design software package widely used in engineering in general, and biomedical industry in particular – Students will ask to revised their practice on using SolidWorks software.	3	2
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	4, 5	4

No.	Tasks/ Experiments	Number of Weeks	Contact Hours
	complex problems quickly and accurately, while its intuitive structure is designed to provide ease of use and flexibility. – Students will ask 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
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
	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
	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
	Prototype Fabrication and Validation: • Students will fabricate and conduct testing of their	11, 12	4

No.	Tasks/ Experiments	Number of Weeks	Contact Hours
	prototype, assess the degree to which the prototype meets the design specifications, and recommend design modifications to improve the prototype.		
	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.	13	2
	Final Project Report: • Final design details about the project will be posted in the final report.	14	2
Number of Weeks /and Units Per Semester		**14**	**28**

C. Tutorial Aspect (if any):

No.	Tutorial	Number of Weeks	Contact Hours
1	None		
2			
3			
4			
Number of Weeks /and Units Per Semester			

VI. 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.

VII. Assessment Methods:

- 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
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: 7. Orthopedic devices 8. Implantable electronic devices 9. Diagnostics 10. Therapeutic devices 11. Skin closure devices 12. Others • Case studies should examine and will prepare and deliver a class presentation and submit a short-written report covering one aspect 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

No.	Assignments	Week Due	Mark
4	**Semester Project:** Final project presentation	12	5
5	**Semester Project:** Final project report	14	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 & Quizzes**	Through course Semester	40	40%
2	**Mid-Term Theoretical Exam**	8	10	10%
3	**Final Theoretical Exam**	16	50	50%
Total			**100%**	**100%**

IX. Learning Resources:

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

3. Paul H. King, Richard C. Fries, and Arthur T. Johnson, Design of Biomedical Devices and Systems, 4th Ed., CRC Press, USA, 2019.

4. Ulrich, K.T. and Eppringer, S.D., Product Design and Development, 5th Edition, USA, McGraw-Hill, Inc., 2012.

2- Essential References:

5. Claudio Becchetti Alessandro Neri, Medical Instrument Design and Development: From Requirements to Market Placements, 1st Ed., United Kingdom, John Wiley & Sons Ltd, 2013.

6. Peter J. Ogrodnik, Medical Device Design Innovation from Concept to Market, 1st Ed., UK, Elsevier, 2013.

7. Myer Kutz, Biomedical Engineering and Design Handbook Volume 1:

Fundamentals, 1st Ed., USA, McGraw-Hill, 2009.

8. Myer Kutz, Biomedical Engineering and Design Handbook Volume 2: Applications, USA, McGraw-Hill, 2009.

3- Electronic Materials and Web Sites etc.:

Websites:

4. www.arts.gov/sites/default/files/Industrial-Design-Report-May2017-rev3.pdf.
5. www.medicaldesignandoutsourcing.com/need-know-industrial-design-medtech/.
6. www.mdtmag.com/article/2015/10/3-key-aspects-successful-medical-industrial-design.

X. Course Policies: (Based on the Uniform Students' By law (2007)

1	**Class Attendance:** Class Attendance is mandatory. A student is considered absent and shall be banned from taking the final exam if his/her absence exceeds 25% of total classes.
2	**Tardiness:** A student will be considered late if he/she is not in class after 10 minutes of the start time of class.
3	**Exam Attendance/Punctuality:** No student shall be allowed to the exam hall after 30 minutes of the start time, and shall not leave the hall before half of the exam time has passed.
4	**Assignments & Projects:** Assignments and projects must be submitted on time. Students who delay their assignments or projects shall lose the mark allocated for the same.
5	**Cheating:** Cheating is an act of fraud that results in the cancelation of the student's exam or assignment. If it takes place in a final exam, the penalties stipulated for in the Uniform Students' Bylaw (2007) shall apply.
6	**Forgery and Impersonation:** Forgery/Impersonation is an act of fraud that results in the cancelation of the student's exam, assignment or project. If it takes place in a final exam, the penalties stipulated for in the Uniform Students' Bylaw (2007) shall apply.
7	**Other policies:** The University official regulations in force will be strictly observed and students shall

	comply with all rules and regulations of the examination set by the Department, Faculty and University Administration.