Academic Year	2023/2024	**Semester**	1, 2
Course Coordinator	Assoc Prof. Song Juha		
Course Code	BG4122		
Course Title	Medical Device Design (Core)		
Pre-requisites	BG3105 Biomedical Instrumentation		
No of AUs	6		
Contact Hours	36 hours lecture, 126 hours of lab work		
Proposal Date	07/02/2023		

Course Aims

This course aims to provide final-year students with the opportunity to work in teams to design and produce a medical device through integration and implement of knowledge in bioengineering. The student teams will learn a project's key features and will plan out major deliverables, to facilitate conceptualization and selection of designs to achieve the desired project goals. Then, they will demonstrate their proposed medical devices through prototypes produced in the lab.

Intended Learning Outcomes (ILO)

By the end of this course, you (as a group of students) would be able to:

1. Perform need specification and identify the need statement for a biomedical project
2. Apply ideation strategies towards conceptualisation of solutions to identified clinical problems
3. Assess strengths and weaknesses of generated concepts
4. Design and produce a prototype medical device
5. Write technical report on a product prototype
6. Manage a project within given time and financial constraints
7. Showcase your prototype through demonstrations and presentations
8. Work as an effective member of a team

Course Content

There will be no specific reading materials provided in the class. Suggested materials will be dependent on the project. The module is based on hands-on design work in the lab.

Assessment (includes both continuous and summative assessment)

Component	Course LO Tested	Related Programme LO or Graduate Attributes	Weighting	Team /Individual	Assessment rubrics
(a) Proposal presentation on need specification and concept selection	1-3	EAB SLOs f,I,j,k	10%	Team	Refer to appendix 1
(b) Interim demo (x2)	4,6,7,8	EAB SLOs a, c, d, e, i, j	20%	Individual & Team	Refer to appendix 2

(c) Interim project progress report	1-3,5,6, 8	EAB SLOs a, b, c, d, e, f, i, j, k	15%	Team	Refer to appendix 3
(d) Final product demo	4,6-8	EAB SLOs a, c, d, e, i, j	40%	Individual & Team	Refer to appendix 2
(e) Final project report	5,6,8	EAB SLOs a, b, c, d, e, f, i, j, k	15%	Team	Refer to appendix 3
(f) peer-evaluation	8	EAB SLOs i,	Moderation factor	Individual	Refer to appendix 4
Total	100%				

Note: The course duration is 2 semesters. Students will have to register the course for both semesters. All assessments will be conducted in the 2nd Semester.

Formative feedback

Every week in the lab sessions the students will get feedback on the progress in the project. Mid-term demo: after mid-term demo the students will get feedback

Learning and Teaching approach

Approach	**How does this approach support students in achieving the learning outcomes?**
Lecture	Lectures during the first semester will provide background on how to manage a biomedical project, with real life examples not detailed in textbooks / reference material. In the meantime, students will discuss the rationale and the details of the project during those lectures. Various approaches to complete the design will be discussed. Since this will be done in groups, students can form groups, discuss with their friends etc. All the other resources that will be available to the student to complete the project will also be elaborated.
Lab sessions	The project will be carried out in the lab, where you will have access to various instruments (oscilloscope, power supply, function generator, 3D printer, multi-meter, electronic components etc.). During these session we will have hands-on work on design and implementation of electrical circuits and signal processing. Every week during the lab session, students can discuss, debug their problems, brainstorm their idea on the implementation of special features in their product to the instruction of the module.

Reading and References

1. P.G. Yock, S. Zenios, J. Makower, T.J. Brinton, U.N. Kumar, & F.T. Jay Watkins,

"Biodesign: the process of innovating medical technologies" 2nd Ed., Publisher Cambridge University Press.
2. Gail D. Baura. Medical Device Technologies: A Systems-based Overview using Engineering Standards. Amsterdam; Boston: Elsevier/Academic Press, 2012.
3. James E. Moore, Jr., Duncan J. Maitland. Biomedical Technology and Devices. Boca Raton: CRC Press, 2013.
4. Giuseppe Andreoni, Massimo Barbieri, Barbara Colombo. Developing Biomedical Devices: Design, Innovation and Protection. Cham: Springer, 2014.

Course Policies and Student Responsibilities

General: This module requires you to engage in self-directed learning. You are expected to complete all online activities. You are expected to learn basic electronic circuit design, matlab/labview programming. You are expected to work in a group of 8-10 students. You need to plan and distribute the workload among all the members of the group. You are expected to take responsibility to follow up with other group members to complete task. You are expected to take necessary note and course related announcements. You are expected to participate in all discussions and activities.

Lab demo (mid-term and final): You are required to attend all the lab demos and submit reports.
Absenteeism: Lab demons consists of 55% of students' course grade. Absence from lab demos without officially approved leave will result in no marks and affect students' overall course grade.

Academic Integrity

Good academic work depends on honesty and ethical behaviour. The quality of your work as a student relies on adhering to the principles of academic integrity and to the NTU Honour Code, a set of values shared by the whole university community. Truth, Trust and Justice are at the core of NTU's shared values.

As a student, it is important that you recognize your responsibilities in understanding and applying the principles of academic integrity in all the work you do at NTU. Not knowing what is involved in maintaining academic integrity does not excuse academic dishonesty. You need to actively equip yourself with strategies to avoid all forms of academic dishonesty, including plagiarism, academic fraud, collusion and cheating. If you are uncertain of the definitions of any of these terms, you should go to the academic integrity website for more information. Consult your instructor(s) if you need any clarification about the requirements of academic integrity in the course.

Course Instructors

Instructor	Office Location	Phone	Email
Song Juha	N1.3-B2-06	6513 8298	songjuha@ntu.edu.sg

Planned Weekly Schedule

Week	Topic	Course LO	Readings/ Activities
Sem 1			
1	Introduction to Course; overview of Biodesign methodology	1	None
2-3	Need specification	To identify the need statement for a biomedical project	Chapter 2.1-2.4 of textbook; Worksheet
4-5	Concept generation	To explore concepts for the need statement	Chapter 3.1 of textbook
6-7	Concept evaluation	To assess strengths and weaknesses of generated concepts	Chapter 4.1 and 4.2 of textbook
8	Proposal presentation on need specification and concept selection	To present the proposed prototype with rationales for the project	Provide rationales and plan of the proposed biomedical project, indicating what are the deliverables, key requirements; share the first design of proposed prototype
9-12	Lab sessions	Debug any difficulties, discuss progress, consultation	Hands-on lab sessions, electrical circuit design, use of instruments, programming, 3D printing
13-14	First interim demo	To demonstrate the project progress	Prepare domo setup, props, tools etc. Demo your progress. Q&A sessions, evaluation of project report
Sem 2			
1	Debrief and planning	To review the progress of the first semester and share the plans for the second semester	Team discussion, planning and revising
2-6	Lab sessions	Debug any difficulties, discuss progress, consultation	Hands-on lab sessions, electrical circuit design, use of instruments, programming, 3D printing

7	Second interim demo	To demonstrate the project progress	Prepare domo setup, props, tools etc. Demo your progress. Q&A sessions, evaluation of project report
8-12	Lab sessions	Debug any difficulties, discuss progress, consultation	Hands-on lab sessions, electrical circuit design, use of instruments, programming, 3D printing
13-14	Final Demo	To demonstrate the final product resulted from the project	Prepare domo setup, props, tools etc. Demo your product. Q&A sessions, evaluation of project report

Appendix 1: Assessment Criteria for Project Proposal

Grouping: Each project group consists of ~8-10 students.

Division of Work: Discuss with members on how the work should be divided. Declare each group members name and what part of the work they have done in the project reports. Your mark will be largely based on the quality of your own work and your group's performance.

Criteria	Unsatisfactory: <40%	Borderline: 40% to 49%	Satisfactory: 50% to 69%	Very good: 70% to 89%	Exemplary: >90%
Collate and present findings from Need Research (20%)	Material presented irrelevant and off topic	Material covered inadequate in two or three out of four topics listed above	Material covered adequate for proposal	Material covered adequately in all topics, with outstanding research in 1 or 2 topics	Outstanding research in all 4 topics
Synthesise information to obtain meaningful conclusions (20%)	No effort to analyse research	Analysis poorly substantiated	Major points captured in summary statements	Outstanding, unique insights obtained from research in 1 or 2 topics	Outstanding, unique insights in all 4 topics.
Describe concept and how it fits the criteria (20%)	Concept poorly described and unable to meet defined criteria	Concept poorly described or insufficient consideration for criteria	Concept adequately described and meets criteria	Concept elaborated with some unique features	Concept elaborated with unique features derived from insights
Provide analysis of IP position (20%)	IP search inadequately performed	IP search results missing critical patents	Logical search process yielding major relevant patents	Comprehensive search extending beyond patents	Comprehensive search extending beyond desktop research and presentation of logicl risk mitigating steps

Provide analysis of regulatory position (20%)	Regulatory analysis contextually irrelevant (e.g. wrong geography)	Regulatory analysis performed with inappropriate justification	Logical presentation of device classification and identified pathway	Clear presentation of follow on steps from preliminary research	Comprehensively evaluated regulatory risks with sound regulatory plan

Appendix 2: Assessment Criteria for Group Project

You will use your creativity and your knowledge about hardware and software design for prototyping shape and function of a medical device.

The module is based on hands-on design work in the lab.

Division of Work: Discuss with members on how the work should be divided. Declare each group members name and what part of the work they have done in the project reports. Your mark will be largely based on the quality of your own work and your group's performance in the interim and final demo. The formula for the overall grade is provided in appendix 4.

Criteria	Unsatisfactory: <40%	Borderline: 40% to 49%	Satisfactory: 50% to 74%	Very good: 75% to 85%	Exemplary: >85%
Knowledge & Comprehension Understanding of principles of biomedical signal processing to design biomedical device (25%)	Lacks understanding of the principles of biomedical signal processing and how to design medical device for heart rate monitoring.	Partial understanding of the principles of biomedical signal processing and how to design medical device for heart rate monitoring.	Good understanding of the principles of biomedical signal processing and how to design medical device for heart rate monitoring.	Good and comprehensive understanding of the principles of biomedical signal processing and how to design medical device for heart rate monitoring.	Very good and comprehensive understanding of the principles of biomedical signal processing and how to design medical device for heart rate monitoring.
Application Applying signal processing principles to solve problems (25%)	Not able to design filters to remove noises from the signal and amplify them.	Partially able to design filters to remove noises from the signal and amplify them.	Able to design filters to remove noises from the signal and amplify them.	Good design of the filters to remove noises from the signal and amplify them.	Excellent design of the filters to remove noises from the signal and amplify them.
Evaluation	Not able to choose of software and hardware to design	Partially able to choose software and hardware to design	Able to choose software and hardware to design	Good choice of software and hardware to design	Excellent choice of software and hardware to design

Able to evaluate which software and hardware options will be most appropriate for designing the medical device (25%)	compact heart rate monitoring system.	compact heart rate monitoring system.	compact heart rate monitoring system.	compact heart rate monitoring system.	compact heart rate monitoring system.
Analysis Able to analyze problems, make reasonable assumptions, and choose appropriate methods (25%)	Unable to make reasonable assumptions and judgment according to the nature of the problems, uncertain about drawing any conclusions.	Can make reasonable assumptions and judgment, but the choice of methods are not appropriate, uncertain about the accuracy of the outcome.	Can make reasonable assumptions and judgment, can choose appropriate methods and predict the outcome mostly, but not necessarily the best choice.	Can make reasonable assumptions and judgment, can choose appropriate methods and predict the outcome, can draw reasonable conclusions.	Can make correct assumptions, can choose appropriate methods to solve the problem and draw conclusions. Can identify potential problems and tailor the process accordingly.

Appendix 3: Assessment Criteria for Group Project Report

Criteria (Team)		Unsatisfactory (1)	Satisfactory (4)	Good (7)	Exemplary (10)	Score (1-10)
Quality of written communication	Language and format (10%)	No scientific language, with grammatical and spelling errors, poorly constructed sentences; incorrect use of referencing; report is not properly formatted	Some use of scientific language, with grammatical and spelling errors; correct use of referencing in most of the report; report is properly formatted	Use of scientific language, with few grammatical and no spelling errors; correct use of referencing throughout; properly constructed sentences, well-organized chapters and properly formatted report	Use of stylish scientific language, with no grammatical or spelling errors; properly formatted report; correct use of referencing throughout; report is very well written and draws you to read more	
	Figures and tables (10%)	Errors in figure legends; no formatting is done; cannot tell the different contents apart	No errors; standard figure format; no efforts to improve the appearance of the figures	Free of any errors; clear efforts to make the figures more readable and attractive	Free of any errors; various designs (shapes and colors) are incorporated in the figures and tables	
Design and implementation (30%)		The medical device design is not described; Choices of parameters and implementation details are missing	The medical device design is described but without much details; Choices of parameters and implementation details are provided minimally	The medical device design is described in details; Choices of parameters and implementation details are provided	The medical device design is described in extreme details; Choices of parameters and implementation details are provided meticulously	

Project Management (10%)		No project objectives presented; no schedule on milestones for tasks provided	No project objectives presented; no schedule on milestones for tasks provided	No project objectives presented; no schedule on milestones for tasks provided	Project objectives clearly stated and explained; concise and feasible schedule on milestones for tasks provided; project completed ahead of schedule	
Experimental results and Analysis	Quality and relevance of results (30%)	No results presented;	Results are poor;	Results are good;	Results are excellent;	
	Analysis of the results (10%)	no analysis	analysis is poorly done	proper analysis was done	in depth analysis was done	

Appendix 4: Assessment Criteria for Peer Evaluation

Each student in the group is required to rate the contribution of other group members. All evaluations are held in confidence so no student will know how other group members rate his/her contribution. You are to evaluate other group members fairly and objectively, bearing in mind the implications for the other members' grades (explained below). It is absolutely essential for you to submit your peer evaluation form to get marks. To factor peer evaluations into the marks for your homework assignment, the following computation will be used:

- If, on average, a student receives a rating of 9 or more, that student receives 100% of the group's grade.
- If, on average, a student receives a rating of less than 9, that student receives a specific percentage of the group's grade to be determined by the formulae below:

An average rating of 8 to < 9 = 90% + (average rating obtained - 8)*10
An average rating of 7 to < 8 = 80% + (average rating obtained - 7)*10
An average rating of 6 to < 7 = 70% + (average rating obtained - 6)*10
An average rating of 5 to < 6 = 60% + (average rating obtained - 5)*10
An average rating of 4 to < 5 = 50% + (average rating obtained - 4)*10
An average rating of 3 to < 4 = 40% + (average rating obtained - 3)*10
An average rating of < 3 will be investigated by your instructor and the student may receive 0-40% of group grades.

Example 1:
Assume the overall group assignment is 30 marks, and out of 30 your group got 30 marks. A student with an average rating of 9.10 gets 100% of 30 marks, i.e., 30 marks. An average rating of 6.29 means that a student gets 72.9% (or 70%+(6.29-6)*10) of 30 marks, i.e., 21.87 marks.

Example 2:
Assume the overall group assignment is 30 marks, and out of 30 your group got 20 marks. A student with an average rating of 9.10 gets 100% of 20 marks, i.e., 20 marks. An average rating of 6.29 means that a student gets 72.9% (or 70%+(6.29-6)*10) of 20 marks, i.e., 14.58 marks.

Your instructor reserves the right to review the student ratings for questionable circumstances, which include, but are not limited to, acts of discrimination or malice.

Criteria	Yourself	Member 1	Member 2	Member 3	Member 4	Member 5
Contributed the fair share of work (Score: 0 to 10)						
TOTAL						
Comments, if any						

Appendix 5: The EAB (Engineering Accreditation Board) Accreditation SLOs (Student Learning Outcomes)

a) **Engineering knowledge:** Apply the knowledge of mathematics, natural science, engineering fundamentals, and an engineering specialisation to the solution of complex engineering problems
b) **Problem Analysis:** Identify, formulate, research literature, and analyse complex engineering problems reaching substantiated conclusions using first principles of mathematics, natural sciences, and engineering sciences.
c) **Design/development of Solutions:** Design solutions for complex engineering problems and design system components or processes that meet the specified needs with appropriate consideration for public health and safety, cultural, societal, and environmental considerations.
d) **Investigation:** Conduct investigations of complex problems using research-based knowledge and research methods including design of experiments, analysis and interpretation of data, and synthesis of the information to provide valid conclusions.
e) **Modern Tool Usage:** Create, select, and apply appropriate techniques, resources, and modern engineering and IT tools including prediction and modelling to complex engineering activities with an understanding of the limitations
f) **The engineer and Society:** Apply reasoning informed by the contextual knowledge to assess societal, health, safety, legal, and cultural issues and the consequent responsibilities relevant to the professional engineering practice.
g) **Environment and Sustainability:** Understand the impact of the professional engineering solutions in societal and environmental contexts, and demonstrate the knowledge of, and need for the sustainable development.
h) **Ethics:** Apply ethical principles and commit to professional ethics and responsibilities and norms of the engineering practice.
i) **Individual and Team Work:** Function effectively as an individual, and as a member or leader in diverse teams and in multidisciplinary settings.
j) **Communication:** Communicate effectively on complex engineering activities with the engineering community and with society at large, such as, being able to comprehend and write effective reports and design documentation, make effective presentations, and give and receive clear instructions.
k) **Project Management and Finance:** Demonstrate knowledge and understanding of the engineering and management principles and economic decision-making, and apply these to one's own work, as a member and leader in a team, to manage projects and in multidisciplinary environments.
l) **Life-long Learning:** Recognise the need for, and have the preparation and ability to engage in independent and life-long learning in the broadest context of technological change