

## BME500: Medical Device and System Design for Clinical Engineers

### Course Dates

CRN(s):	Section A01 CRN: 13935
Term:	2022
Course Start:	2022-09-07
Course End:	2022-12-21
Withdrawal with 100% reduction of tuition fees:	2022-09-20
Withdrawal with 50% reduction of tuition fees:	2022-10-11
Last day for withdrawal (no fees returned):	2022-10-31

### Scheduled Meeting Times (M=Mon, T=Tue, W=Wed, R=Thu, F=Fri)

Section:	Location:	Classes Start:	Classes End:	Days of week:	Hours of day:	Instructor:
A01	CLE A118	2022-09-07	2022-12-05	TWF	10:30-11:20	Karolina Papera Valente

### Instructor(s)

Name: **Karolina Papera Valente**  
 Office: EOW 331  
 Phone: (250) 721-8696  
 Email: kvalente at uvic dot ca

Office Hours:                      Comments  
 Mon 12:00pm-01:00pm

### Online Learning, Teaching, and Tools

**Lectures:** Lectures will be F2F.

**Office Hours** Office hours will be on Mondays, from noon to 1 pm at EOW 331.

### Prerequisites & Co-requisites

#### TA Information

TA Name	E-mail	Office
TBD	TBD	TBD

### Textbooks

### Course Objectives

Clinical engineering concepts for integrating technology into health care. Focuses on patient/physician interactions with technologies. Design methodology; recognizing and defining open-ended biomedical engineering problems, problem definition, concept generation, project planning, modelling, analysis, decision making, design synthesis, prototyping and testing. Examination of trends in medical devices from local and global standpoints.

### Learning Outcomes

1) Classify and organize medical devices by category and types 2) Compile Medical Devices' regulations, according to FDA and Canada Health 3) Demonstrate knowledge on the creation of a production submission 4) Implement Design Planning on the creation of system designs 5) Evaluate the system designs and risk management

### Assessment

Weight & Date(s) of Assessment	Weight	Date
Quizzes	30%	4 quizzes in total, Sep 30, Oct 14, Nov 4, Nov 25
Assignments	30%	5 assignments in total, Sep 23, Oct 7, Oct 21, Nov 18, Nov 30
Project	40%	Outline Sep 30, Presentation Nov 30 and Dec 2, Final Report Dec 5

### Assignments

Assignments	30%	5 assignments in total, Sep 23, Oct 7, Oct 21, Nov 18, Nov 30
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Assignments will be posted on brightspace.

### Quizzes

Quizzes will happen during lecture time.

### Project

Project details will be posted on brightspace. Projects will be performed in groups and an outline is to be submitted by September 30, 2022. Project presentations will happen during lecture time on November 30 and December 2. The final project report is to be submitted by December 5, 2022.

### Notes

**NOTES ON WORK COMPELETION** Failure to complete and submit all Laboratories will result in a grade of N.

**NOTES** The final grade obtained from the above marking scheme for the purpose of GPA calculation will be based on the percentage-to-grade point conversion table as listed in the current Undergraduate Calendar.

**COURSE LECTURE NOTES** Unless otherwise noted, all course materials supplied to students in this course are intended for use in this course only. These materials are NOT to be re-circulated digitally, whether by email or by uploading or copying to websites, or to others not enrolled in this course. Violation of this policy may in some cases constitute a breach of academic integrity as defined in the UVic Calendar.

**SUPPLEMENTAL EXAM** There will be no supplemental examination for this course.

### Course Schedule

Perhaps an overall term schedule of assignments, quizzes, and exams is more appropriate for your course?

Module	Topics
1.	Introduction to Medical Devices
2.	Requirements for Medical Devices
3.	Standards and guidance documents
4.	Product Definition and Approval
5.	Introduction to System Design for Clinical Engineers
6.	Understanding Health Information Systems & Case Studies
7.	Risk Assessment

### Grading System

The University of Victoria follows a percentage grading system in which the instructor will submit grades in percentages. The University will use the following Senate approved standardized grading scale to assign letter grades. Both the

percentage mark and the letter grade will be recorded on the academic record and transcripts.

Passing Grades	GPA	Percentage	Description
A+	9	90 - 100	<b>Exceptional work.</b> Technically flawless and original work demonstrating insight, understanding and independent application or extension of course expectations; often publishable.
A	8	85 - 89	<b>Outstanding work.</b> Demonstrates a very high level of integration of material demonstrating insight, understanding and independent application or extension of course expectations.
A-	7	80 - 84	<b>Excellent work.</b> Represents a high level of integration, comprehensiveness and complexity, as well as a mastery level of relevant techniques/concepts.
B+	6	77 - 79	<b>Very good work.</b> Represents a satisfactory level of integration, comprehensiveness and complexity; demonstrates a sound level of analysis with no major weakness.
B	5	73 - 76	<b>Acceptable work that fulfills the expectations of the course.</b> Represents a satisfactory level of integration of key concepts/procedures. However, comprehensiveness or technical skills may be lacking.
B-	4	70 - 72	<b>Unacceptable work revealing some deficiencies in knowledge, understanding or techniques.</b> Represents an unacceptable level of integration, comprehensiveness and complexity. Mastery of some relevant techniques or concepts lacking.
C+	3	65 - 69	<b>Unacceptable work revealing some deficiencies in knowledge, understanding or techniques.</b> Represents an unacceptable level of integration, comprehensiveness and complexity. Mastery of some relevant techniques or concepts lacking.
C	2	60 - 64	<b>Unacceptable work revealing some deficiencies in knowledge, understanding or techniques.</b> Represents an unacceptable level of integration, comprehensiveness and complexity. Mastery of some relevant techniques or concepts lacking.
D	1	50 - 59	<b>Unacceptable work revealing some deficiencies in knowledge, understanding or techniques.</b> Represents an unacceptable level of integration, comprehensiveness and complexity. Mastery of some relevant techniques or concepts lacking.
F	0	0 - 49	<b>Failing grade.</b> Unsatisfactory performance. Wrote final examination and completed course requirements.

**Note:** Every grade of 4.0 (B-) or lower in a course taken for credit in the Faculty of Graduate Studies must be reviewed by the supervisory committee of the student and a recommendation made to the Dean of Graduate Studies. Such students will not be allowed to register in the next session until approved to do so by the Dean.

### Course Experience Survey (CES)

I value your feedback on this course. Towards the end of term you will have the opportunity to complete a confidential course experience survey (CES) regarding your learning experience. The survey is vital to providing feedback to me regarding the course and my teaching, as well as to help the department improve the overall program for students in the future. When it is time for you to complete the survey, you will receive an email inviting you to do so. If you do not receive an email invitation, you can go directly to the [CES site](#)

You will need to use your UVic NetLink ID to access the survey, which can be done on your laptop, tablet or mobile device. I will remind you closer to the time, but please be thinking about this important activity, especially the following three questions, during the course.

- What strengths did your instructor demonstrate that helped you learn in this course?
- Please provide specific suggestions as to how the instructor could have helped you learn more effectively.
- Please provide specific suggestions as to how this course could be improved.

### General Information

**Note to Students:** Students who have issues with the conduct of the course should discuss them with the instructor first. If these discussions do not resolve the issue, then students should feel free to contact the Chair of the Department by email or the Assistant to the Chair to set up an appointment.

Centre for Accessible Learning (CAL) <https://www.uvic.ca/services/cal/>

## [Discrimination and Harassment Policy \(GV0205\)](#)

**Sexualized Violence Prevention and Response at UVic:** UVic takes sexualized violence seriously, and has raised the bar for what is considered acceptable behaviour. We encourage students to learn more about how the university defines sexualized violence and its overall approach by visiting <https://www.uvic.ca/sexualizedviolence/>. If you or someone you know has been impacted by sexualized violence and needs information, advice, and/or support please contact the sexualized violence resource office in Equity and Human Rights (EQHR). Whether or not you have been directly impacted, if you want to take part in the important prevention work taking place on campus, you can also reach out: **Where:** Sexualized violence resource office in EQHR; Sedgewick C119 **Phone:** 250.721.8021 **Email:** svpcoordinator@uvic.ca **Web:** <https://www.uvic.ca/sexualizedviolence/>

**Office of the Ombudsperson:** The Office of the Ombudsperson is an independent and impartial resource to assist with the fair resolution of student issues. A confidential consultation can help you understand your rights and responsibilities. The Ombudsperson can also clarify information, help navigate procedures, assist with problem-solving, facilitate communication, provide feedback on an appeal, investigate and make recommendations. **Phone:** 250-721-8357 **Email:** ombuddy@uvic.ca **Web:** <https://uvicombudsperson.ca/>

**Electronic devices in labs and lectures:** No unauthorized audio or video recording of lectures is permitted.

**Electronic devices in midterms and exams:** Calculators are only permitted for examinations and tests if explicitly authorized and the type of calculator permitted may be restricted. No other electronic devices (e.g. cell phones, pagers, PDA, etc.) may be used during examinations or tests unless explicitly authorized.

### Faculty of Engineering, University of Victoria Standards for Professional Behavior

It is the responsibility of all members of the Faculty of Engineering, students, staff, and faculty, to adhere to and promote standards of professional behavior that support an effective learning environment that prepares graduates for careers as professionals... You are advised to read the Faculty of Engineering document [Standards for Professional Behavior](#) which contains important information regarding conduct in courses, labs, and in the general use of facilities.

**Graduate Students' Society** The Graduate Students' Society (GSS) serves all students registered in an Graduate degree program. For information on GSS activities, events and services navigate to <https://gss.uvic.ca/> .

## Attendance

Students are expected to attend all classes in which they are enrolled. An academic unit may require a student to withdraw from a course if the student is registered in another course that conflicts with it in time. An instructor may refuse a student admission to a lecture or laboratory because of lateness, misconduct, inattention or failure to meet the responsibilities of the course. Students who neglect their academic work, including assignments, may be refused permission to write the final examination in a course. Instructors must inform students at the beginning of term in writing of the minimum attendance required at lectures and in laboratories in order to qualify to write examinations. Students who are absent because of illness, an accident or family affliction should report to their instructors upon their return to classes.

[https://www.uvic.ca/calendar/future/grad/index.php#/policy/SJJ2lif\\_V?bc=true&bcCurrent=09%20-%20Attendance&bcGroup=Faculty%20Academic%20Regulations&bcltemType=policies](https://www.uvic.ca/calendar/future/grad/index.php#/policy/SJJ2lif_V?bc=true&bcCurrent=09%20-%20Attendance&bcGroup=Faculty%20Academic%20Regulations&bcltemType=policies)

## Academic Integrity

Academic integrity is intellectual honesty and responsibility for academic work that you submit individual or group work. It involves commitment to the values of honesty, trust, and responsibility. It is expected that students will respect these ethical values in all activities related to learning, teaching, research, and service. Therefore, plagiarism and other acts against academic integrity are serious academic offences.

**The responsibility of the institution** Instructors and academic units have the responsibility to ensure that standards of academic honesty are met. By doing so, the institution recognizes students for their hard work and assures them that other students do not have an unfair advantage through cheating on essays, exams, and projects.

**The responsibility of the student** Plagiarism sometimes occurs due to a misunderstanding regarding the rules of academic integrity, but it is the responsibility of the student to know them. If you are unsure about the standards for citations or for referencing your sources, ask your instructor. Depending on the severity of the case, penalties include a warning, a failing grade, a record on the student's transcript, or a suspension.

It is your responsibility to understand the University's policy on [Academic Integrity](#).

## Equality

This course aims to provide equal opportunities and access for all students to enjoy the benefits and privileges of the class and its curriculum and to meet the syllabus requirements. Reasonable and appropriate accommodation will be made available to students with documented disabilities (physical, mental, learning) in order to give them the opportunity to successfully meet the essential requirements of the course. The accommodation will not alter academic standards or learning outcomes, although the student may be allowed to demonstrate knowledge and skills in a different way. It is not necessary for you to reveal your disability and/or confidential medical information to the course instructor. If you believe that you may require accommodation, the course instructor can provide you with information about confidential resources on campus that can assist you in arranging for appropriate accommodation. Alternatively, you may want to contact the Centre for Accessible Learning (formerly the Resource Centre for Students with a Disability) located in the Campus Services Building.

The University of Victoria is committed to promoting, providing, and protecting a positive, and supportive and safe learning and working environment for all its members.

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