BME 1802: Applying Human Factors to the Design of Medical Devices

1. Course Overview

This course will apply human factors engineering (also known as usability engineering) principles to the design of medical devices. The importance of testing medical devices in a health care setting, with realistic users, will be emphasized to understand why many medical devices fail to perform adequately. Students in this course will work in teams to complete a design project that aims to improve a medical device. Teams will start by evaluating an existing medical device (or working prototype) to determine use-related hazards that stem from user errors and then create an improved prototype. To verify that improvements are real, each team must complete testing to provide evidence that design modifications yield a reduction in use-related errors.

Throughout the course, topics will be covered to support the design project (e.g., task, error, and risk analyses and design methodologies) with hands-on lecture activities, case studies, and a tour of an industry facility.

2. Learning Outcomes and Graduate Attributes

At the end of this course, you will be able to:

1. Understand how human factor standards apply to medical device design.
2. Provide examples of how you used of human factors to make medical devices safer.
3. Investigate the cause of user errors.
4. Evaluate the risk of medical devices harming users.
5. Choose design methods that support human factors engineering.
6. Evaluate the usability of a medical device.

3. Timetable

Section	Day of the Week	Start Time	End Time	Location
Lecture	Friday	10:00	12:00	MY315

4. Course Instructor

Course Coordinator

Name	Phone	Office	Email
Prof. Bouwmeester	(416) 978-3702	MB 321A	chris.bouwmeester@utoronto.ca

Office Hours: https://calendly.com/chris-bouwmeester/office-hours

5. Textbooks

Required

NB. These are available as electronic resources through the University of Toronto libraries:

Title	Medical device use error: root cause analysis
Author(s)	Michael Wiklund, Andrea Dwyer, Erin Davis
Edition, Year	1st Edition (2016)
Publisher	CRC Press, Taylor & Francis Group
Library Link	Permalink

Title	Usability testing of medical devices
Author(s)	Michael Wiklund, Jonathan Kendler, Allison Strochlic
Edition, Year	2nd Edition (2016)
Publisher	CRC Press, Taylor & Francis Group
Library Link	Permalink

Title	Health design thinking: creating products and services for better health
Author(s)	Bon Ku, Ellen Lupton
Edition, Year	1st Edition (2020)
Publisher	Cambridge: MIT Press
Library Link	Permalink

Suggested

Title	The Human Factor: Revolutionizing the Way People Live with Technology
Author(s)	Kim Vicente
Edition, Year	1st Edition (2003)
Publisher	Vintage Canada
Library Link	Permalink

6. Final Grade Determination

The final grade in this course will be based on the following components:

Component	Learning Outcome(s) Evaluated	Weight
Individual		
Active Participation	1, 2, & 5	10 %
Problem Analysis: Draft	2 – 4	10 %
Problem Analysis: Peer Review	2 – 4	10 %
Team		
Problem Analysis: Interim Report and Optional Oral Review	1 – 4	20 %
Design Process: Final Report and Oral Exam	1 – 6	50 %
	Total:	100 %

Active Participation

Tasks include activities or quizzes used to prepare you for weekly discussion topics and interacting with you peers. See Quercus for details.

Problem Analysis: Draft and Peer Review

You will work in teams (of 5) to use human factors methods to identify design flaws of an existing medical device, but each individual will lead a human factors analysis. Students from other teams will provide a peer review of the draft analyses.

Problem Analysis: Interim Report and Oral Review

Each team will combine their individual analyses and write an interim report according to guidelines posted on Quercus. Each individual on each team will reflect on the work they contributed and participate in an oral review of their work completed to the mid-point of the course.

Design Process: Final Report and Oral Exam

Your team will propose a design solution that improves the device using human factors considerations. The most successful teams will prove that their solution improves the original design with usability testing. Each team will have access to a small budget of $100 for consumables or fabrication services. The final report collects all the work done during the semester and follows the format of the HFE/UE report as specified by the FDA Applying Human Factors and Usability Engineering to Medical Devices document. The oral exam allows each team to present or demonstration their work and defend their design process.

7. Deadlines

You must be aware of the deadlines associated with each deliverable listed on the Quercus course website. While the **report deadlines are 11:59 PM** on the dates listed on the Quercus course website, **other task deadlines are set at 10:00 AM** when deliverables need to be submitted before class starts.

8. Course Schedule

This is a tentative schedule of lecture topics and activities that may be subject to change based on how the semester develops. More detail is included in weekly "readings and content" pages posted in the Quercus modules and updates to the schedule will be reflected there.

Week	Date	Lecture Topic
1	Sept 6	Analyze a medical device activity introduction
2	Sept 13	Hierarchical Task Analysis: Naloxone kit activity
3	Sept 20	Error Analysis: Insulin/Epi pen activity
4	Sept 27	Healthcare Human Factors Lab Tour[1] 10:30 – 11:15 & 11:15 – 12:00
5	Oct 4	Risk analysis: Steerable sheath fault tree analysis activity
6	Oct 11	Heuristic analysis: Hand hygiene medical device design activity
7	Oct 18	Hierarchy of solution effectiveness
8	Oct 25	Optional oral reviews
9	Nov 1	Reading Break
10	Nov 8	Functional decomposition: Insulin/Epi pen activity User ecosystem: Design for centaurs
11	Nov 15	Usability study preparation
12	Nov 22	Peer usability testing Optional design critique
13	Nov 29	Peer usability testing Optional design critique
14	Dec 6 - 13	1-Hour oral exams

[1] Tour date changed/schedule updated on September 11

9. Course Policies

Academic Accommodations

Students with diverse learning styles and needs are welcome in this course. The University provides academic accommodations for students with disabilities in accordance with the terms of the Ontario Human Rights Code. This occurs through a collaborative process that acknowledges a collective obligation to develop an accessible learning environment that both meets the needs of students and preserves the essential academic requirements of the University's courses and programs. For more information on services and resources available to students, please contact Accessibility Services at (416) 978-8060 or http://www.studentlife.utoronto.ca/as. Should you have a Letter of Accommodation, you shall notify the instructor within the first 3 weeks of the term to allow appropriate accommodations to be integrated into the course.

Award for Lateness Policy

Deliverables received (considering the timestamp on Quercus only) after the posted deadline will be awarded a 1% per day deduction. Deliverables will only be accepted through the Quercus learning management system.

Exceptions may be accommodated for valid reasons, that are out of a student's control, (some examples may be: severe personal illness, illness or death of a close family member, personal or family crisis, or other extenuating circumstances) and may be considered.

You are encouraged to submit deliverables well before the deadline to ensure that you can verify your submission has been completed in Quercus. Examples of invalid reasons would include: situations related to computer or internet problems that result in late submissions (including computer crashes, local internet outages, or individual difficulties linking to Quercus), online submissions that were not executed properly by a student, a forgotten deadline, a lack of attention to a deadline date that was changed during the course, a student intended to submit at the deadline but was delayed, or a student submitted the deliverable in some other way that was not through Quercus.

Communication Policy

All course-related questions should be posted in the discussion board. If you have a question you should: 1) check the syllabus or guidelines for your answer, 2) check the Course Q & A forum to see if your question has already been answered, or 3) ask a peer directly. Every attempt will be made to respond within 3 business days to posts that need the attention of the instructor.

If necessary, please feel free to email the instructor regarding personal issues that may impact this course. BME1802 must be used at the beginning of the subject line to ensure prompt response to emails. Every attempt will be made to responded to emails within 3 business days.

Academic Integrity Message

Academic integrity is essential to the pursuit of learning and scholarship in a university, and to ensuring that a degree from the University of Toronto is a strong signal of each student's individual academic achievement. As a result, the University treats cases of cheating and

plagiarism very seriously. The University of Toronto's Code of Behaviour on Academic Matters outlines the behaviours that constitute academic dishonesty and the processes for addressing academic offences. Potential offences include, but are not limited to:

In papers and assignments:

- Using someone else's ideas or words without appropriate acknowledgement.
- Submitting your own work in more than one course without the permission of the instructor.
- Making up sources or facts.
- Obtaining or providing unauthorized assistance on any assignment.

In academic work:

- Falsifying institutional documents or grades.
- Falsifying or altering any documentation required by the University, including (but not limited to) doctor's notes.

All suspected cases of academic dishonesty will be investigated following procedures outlined in the Code of Behaviour on Academic Matters. If you have questions or concerns about what constitutes appropriate academic behaviour or appropriate research and citation methods, you are expected to seek out additional information on academic integrity from your instructor or from other institutional resources (see http://academicintegrity.utoronto.ca/).

Library Resources

University of Toronto Libraries provides access to a vast collection of online and print resources to faculty, staff, and students. In this course you will find the Techstreet database very useful for information regarding the applicable standards used in this course (https://subscriptions-techstreet-com.myaccess.library.utoronto.ca/subscriptions/index).

Research help is available by phone, e-mail, chat, and in-person. (See Library website for more details: https://onesearch.library.utoronto.ca/). Your IBBME reference and instruction librarian, located at the Engineering & Computer Science Library is Michelle Spence (michelle.spence@utoronto.ca).