



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 groups to complete a design project that aims to improve a medical device. Each student will start by selecting an everyday medical device to determine use-related hazards that stem from user errors and then propose an improved design. To verify that improvements have the potential to reduce user error, good design practices and detailed reference to standards must be used to support your claims.

2. Learning Outcomes and Graduate Attributes

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

1. Understand how the ANSI/AAMI HE75 standard applies 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. Evaluate the usability of a medical device
6. Propose improvements to an existing medical device

3. Timetable

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

4. Course Instructors

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. Textbook

Required

Both of the following texts 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	1 st Edition (2016)
Publisher	CRC Press, Taylor & Francis Group
Library Link	http://go.utlib.ca/cat/11201654

Suggested

You will be able to find a wealth of information in the University of Toronto Library system regarding many of the topics introduced in this course (e.g., Human Factors Methods, Human Factors in Medical Device Design, Designing Usability into Medical Products, etc.). While there are many specialized topics in human factors, you may find the following general interest books a good start to get you thinking about broader issues related to the influence that human factors have on design:

Title	Usability testing of medical devices
Author(s)	Michael Wiklund, Jonathan Kendler, Allison Strochlic
Edition, Year	2 nd Edition (2016)
Publisher	CRC Press, Taylor & Francis Group
Library Link	http://go.utlib.ca/cat/11203481

Title	The Human Factor: Revolutionizing the Way People Live with Technology
Author(s)	Kim Vicente
Edition, Year	1 st Edition (2003)
Publisher	Vintage Canada
Library Link	http://go.utlib.ca/cat/10761199



6. Final Grade Determination

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

Component	Learning Outcome(s) Evaluated	Weight	
Active Participation	1 – 6	10	%
Naloxone Injection Activity	3 – 6	10	%
Problem Evaluation	1 – 4	35	%
HE75 Collaboration	1 & 2	20	%
HE75 Oral Exam	1, 2, & 6	25	%
Total:		100	%

Active Participation

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

Naloxone Injection Activity

Each person will receive a package that will allow them to complete an activity at home. The stages of the activity will map to the topics covered in this course and provide a common experience for the entire group to discuss aspects of human factors engineering applied to a design problem.

Problem Evaluation

Each person will select an everyday medical device to analyze. If you already own a device, you are free to use it or you may purchase a device and receive up to \$20 reimbursement. This assignment has major components related to drafting a task analysis, providing a peer review, revising the task analysis, and submitting a problem evaluation report that expands upon the task analysis to investigate user errors and the risks associated with them.

HE75 Collaboration and Oral Exam

The ANSI/AAMI HE75 standard will be used to interact with your peers and inform how you would redesign the everyday medical device you have chosen from a human factors engineering perspective. The collaboration will be based on reading, creating annotations, and replying to comments left by your peers. The Oral exam will consist of testing your knowledge of the HE75 standard based on sections assigned to you and sections of your own choosing which apply to your medical device.



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 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 engine.

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 if supported by written documentation. Exceptions will only be considered within seven days of the deliverable in question and include valid supporting documentation. The most common piece of supporting documentation is the U of T Verification of Student Illness or Injury Form. A doctor's note, which simply states that the "student cannot write" is insufficient. If possible, please have your doctor complete the form at the time of your visit. A verification that indicates the doctor was told of your illness after the fact is typically insufficient. Please note the successful submission of a completed U of T Verification of Student Illness or Injury Form does not necessarily mean your exception will be accommodated. The severity, duration and date of the illness may be taken into consideration when making a decision regarding an exception. Regarding other exceptions: official supporting documentation must outline your situation and the dates you were affected. For example, if you were in a traffic accident, you could submit the police accident report; if someone in your family passed away, you could submit a copy of the death certificate or funeral notice. The supporting documentation you need to attach to your petition or appeal must be relevant to your situation.

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 “Course Q & A” forum located 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 respond 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).