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 validation testing to prove that design modifications yield a reduction in use-related errors.

Two main approaches will be presented in this course that should be applied as needed throughout the design project: 1) a top-down approach where "faults" (use-related errors) are deduced and the causes of a fault are identified and 2) a bottom-up approach where potential use errors and scenarios are identified that could lead to a "failure mode". 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, guest speakers, and interactions with healthcare and human factors professionals.

2. Learning Outcomes and Graduate Attributes

At the end of this course, you will be able to:
1. Justify the use of human factors standards
2. Analyze how users interact with medical devices
3. Investigate the cause of user errors
4. Propose improvements to an existing medical device
5. Create an improved medical device
6. Evaluate the usability of the medical device you created

3. Timetable

Section	Day of the Week	Start Time	End Time	Location
Lecture	Monday	09:00	11:00	RS412
Practicum	Bookable	N/A	N/A	MB64

Office Hours: Monday's 13:00 – 15:00 (with noted exceptions)

4.   Course Instructors

Course Coordinator

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

Design Studio Coordinator

Name	Phone	Office	Email
Max Giuliani	(416) 978-7188	MB78	design.ibbme@utoronto.ca

The design studio coordinator is available to help you use the resources in the Design Studio and Prototyping Suite, which may include light fabrication or rapid prototyping. Students are welcome to use the Design Studio during "Open Bookable Time"; see the online IBBME design studio link (http://www.ibbme.utoronto.ca/facilities/design-studio/calendar/) for availability.

IBBME safety policy requires that all students take part in safety training prior to using the Design Studio. A date for this has not been scheduled but would occur within the first 3 weeks of the term and will be coordinated amongst those interested and the coordinator if you plan on using the facilities. If students do NOT pass the safety test, they will be given one additional opportunity to rewrite and pass the test. The Design Studio introduction, safety presentation, and quiz should only take 30 minutes.

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

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	http://go.utlib.ca/cat/11203481

Title	Usability testing essentials: Read, Set… Test!
Author(s)	Carol Barnum
Edition, Year	1st Edition (2010)
Publisher	Morgan Kaufmann Publishers
Library Link	http://go.utlib.ca/cat/8093536

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

Title	The Design of Everyday Things
Author(s)	Don Norman
Edition, Year	1st Basic Paperback (2002)
Publisher	Basic Books

6. Final Grade Determination

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

Component	Learning Outcome(s) Evaluated	Due Date	Weight	
Individual				
Participation	1	Jan 18, 22, Feb 26, Mar 5, 19	5	%
Peer Review	4-6	Feb 26 (in Class)	5	%
Participation in Online Forum	2-4	Mar 19	5	%
Design Portfolio	1-6	Apr 9	10	%
Team				
Problem Proposal	1-3	Feb 16	20	%
Final Demonstration	1-6	Apr 9 (in Class)	15	%
Solution Report	4-6	Apr 16	40	%
Total:			100	%

Grading

Conversion from a score out of 100 to a letter grade will be done using a scale outlined in the University of Toronto Governing Council University Assessment and Grading Practices

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Policy:
(http://www.governingcouncil.utoronto.ca/Assets/Governing+Council+Digital+Assets/Policies/PDF/grading.pdf).

Individual

You will receive credit for individual contributions to the course and your team as follows:

Participation

Active participation is required for full participation marks, which means asking questions and engaging in discussions. Your physical presence in class, for the whole period, will be noted when guest speakers present talks during class, when your peers present their project progress, and when external evaluators provide a critique of your team's work. These days are noted on the course schedule but it is **your responsibility to stay informed of updates should a date change.**

A participation mark will be given for attending a Q & A session with a graduate nursing class (NUR1034) on Thursday January 18 in RS412 from 12:00 – 13:00. This session has been organized because the NUR1034 class is working on human factors projects to improve nursing care and you will have the chance to learn from practicing nurses what problems they have; for example: with medical devices they use regularly or "work-arounds" that they employ commonly. This session will be valuable because it may help your teams select a medical device to improve and/or make connections with healthcare users who may become potential test subjects for your project.

Peer Review

You should start thinking of possible viable solutions that may be used to solve your problems before the proposal is due. A peer review session after the reading break (week of February 19) will help you get an outside perspective. For more information, see the deliverable section below.

Participation in Online Forum

You are required to participate in the "Design Help" forum created in the discussion board. You will receive participation marks for asking questions (i.e., creating threads) and answering questions (i.e., replying to threads) posted by your peers in a respectful manner throughout the semester. The objective is to post: questions, requests for advice, or seek validation of ideas generated either individually or from your team and reply to the threads created by other individuals who are not on your team. Full marks will be given for creating at least 4 threads and replying to at least 10 threads that are not of your (or team's) own creation before the design critique held on March 19.

Team

You will work in teams (of ~ 4 people) to use human factors methods to identify design flaws of an existing medical device and then improve the device using human factors consideration in the redesign using prototypes to test whether the design has indeed been improved. Each team will have access to a total budget of $200 that can be used for material in

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the IBBME design studio or reimbursement of material purchased to create and test your designs.

7.   Deliverables

All **deadlines are 11:59 PM** on the date listed (unless otherwise noted)

Participation in Online Forum: Due Mar 19

The objective of the Design Help forum is to seek advice from outside your team or recruit volunteers for testing from the other students taking this course. Each individual must meet the 4 thread creation, 10 thread reply requirement by the deadline. You are free to continue asking questions past the deadline.

Design Portfolio: Review on Mar 19 (in Class); Final Due Apr 9

This artifact will document the work you have done individually or in collaboration with your teammates. Relevant material may include: brainstorming outcomes, doodles, sketches, drawings, interview transcripts, video observations, test results, etc. While it is expected that there will be overlap between teammates using similar content, each individual's portfolio must be a reflection of your individual experiences and narrative. The artifacts you include in your portfolio require context. At the highest level, this can include a statement of design approach, where you may outline your personal priorities relating to human factors and values around engineering design. You must consider how you balance elements of human factors investigation with design innovation. You also need to consider how the entire collection is framed:

- How should someone view the various elements of the portfolio?
- Is there a particular path an audience should take?
- Will you highlight different paths for different audiences?
- How will you link various artifacts from your particular project?

Design portfolios take many forms online: some are posted as PDFs, some created using web services such as Seelio, Wix and WordPress (N.B.: no particular site is being endorsed). The following examples are a place to start in terms of seeing the potential of a design portfolio; note, however, that they are not templates, nor are they necessarily the "best" way to present your work.

- http://blog.seelio.com/2013/02/20/engineering-portfolios/
- https://seelio.com/p/3u6/jacky-lau
- https://seelio.com/p/3pr/kirsten-lim
- https://seelio.com/p/370/shannon-x-yang
- https://seelio.com/p/3mg/franco-montalvo
- https://seelio.com/thomaswilson
- http://www.seanhammett.com
- http://www.williamjewett.com/about/

Holistic evaluation of your design portfolio will be made on the base expectation that you document a story (from problem identification to solution creation) of your medical device redesign. Below these base expectations would be large gaps or illogical flow that impede

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understanding of your design process and exceeding these base expectations would be an engaging story that you would have no problem showing to a future employer. A failing design portfolio would have zero to little effort given towards describing your individual design process or the clear plagiarism of another portfolio.

Peer Review: Need Statement Due Feb 19; Evaluation Due Feb 26 (in Class)

To help you get an outside perspective on solving your problem you must submit (in Blackboard) your need statement in a PDF document and at least 4 "How might we ___?" questions related to your problem by February 19. You must submit this in advance to allow the instructor to prepare for the February 26 class. **The lateness policy will be awarded to the whole team's peer review grades if the February 19 deadline is not met.**

In class on February 26, a problem-solving activity called "send-a-problem" will allow each team to solve problems and evaluate solutions. The final evaluation of solutions that each team provides will be written down and given to the team that drafted the original problem. Full peer review marks (and participation marks) will be given for the completion of this in-class activity.

Problem Proposal: Due Feb 16; Solution Report Due: Apr 16

The reports must be submitted as PDF documents. Additional details related to each deliverable are given in guideline documents posted on Blackboard, in the Guideline Documents folder located in the Course Materials Area.

The problem proposal will describe the user-related errors or design failures of an existing medical device and propose a problem to be solved.

The solution report will outline the redesign (e.g., with prototypes) of an existing medical device and show test results that indicate whether the changes lead to an actual improvement in performance or not. This report will also allow your team to iterate, improve, the analyses used in the problem proposal report (or perform new analyses) in response to peer feedback and critiques provided by external evaluators

Final Demonstration: Due Apr 9 (in Class)

Each team will demonstrate their improved medical device design and in this context all good demonstrations have something physical to demonstrate. The results of your usability testing will prove (or disprove) whether your use-related redesign efforts have been successful.

The oral presentation will be evaluated by the instructor and will be judged on an individual basis for the oral delivery of each presenter, and on a group basis for content and coherence of material. The other students presenting that evening will be part of the audience. Students in the audience are expected to take part by asking questions and becoming involved in the discussion of the other design projects. The point here is not to be critical of other projects so much as to learn about them. Audience participation is included as part of the oral presentation mark. All presenters are expected to stay for the entire duration of the final presentations.

Demonstrations should **last between 12 – 15 minutes**. You will be encouraged to wrap up if your presentation continues past maximum length of 15 minutes. Each team should submit a PDF of any presentation slides by the end of the day (i.e., April 9) for grading purposes.

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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 later than the due date posted will be awarded a **50% overall deduction every day that they are late.** Therefore, assignments handed in 1 day late will receive half the total marks and assignments handed in 2 days late will receive 0 marks. Exceptions may be accommodated for valid reasons, that are out of a student's control, (e.g., severe illness or injury, bereavement leave, severe accident, victim of crime, sudden loss of housing, or similar traumatic experience) and may be considered if supported by written documentation (e.g., University of Toronto Verification of Student Illness or Injury Form, or other applicable documents). Examples of invalid reasons would include situations where online submissions were not executed properly by a student, common computer problems – including computer crashes, or a student forgot the deadline.

Attendance Policy

No notification of your absence is necessary for regular classes. You will be expected to attend on January 18 (this date is outside of regularly scheduled class hours), January 22, February 26, March 5, and 19. If you have a conflict with the January 18 session you must notify the instructor to make accommodations. For other dates, if you have a time conflict (e.g., with a conference or religious obligation) you must notify the instructor at least 2 weeks prior to the deadline to make alternative arrangements and appropriate accommodations.

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 responded to emails within 3 business days.

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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 (www.governingcouncil.utoronto.ca/policies/behaveac.htm) 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).

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