Course Admin Slides

IE590: Human Factors and Medical Devices

Lecture: Grissom 126, MWF 11:30 - 12:20

Instructor:
Dr. Denny Yu
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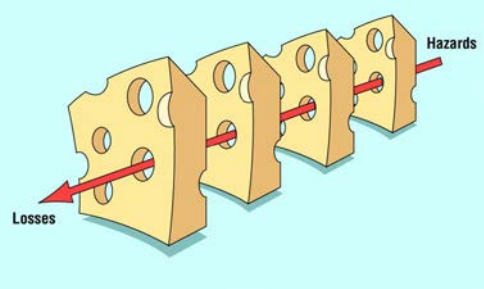
Office hours (GRIS 268):
After MW 1230-1p and by appointment

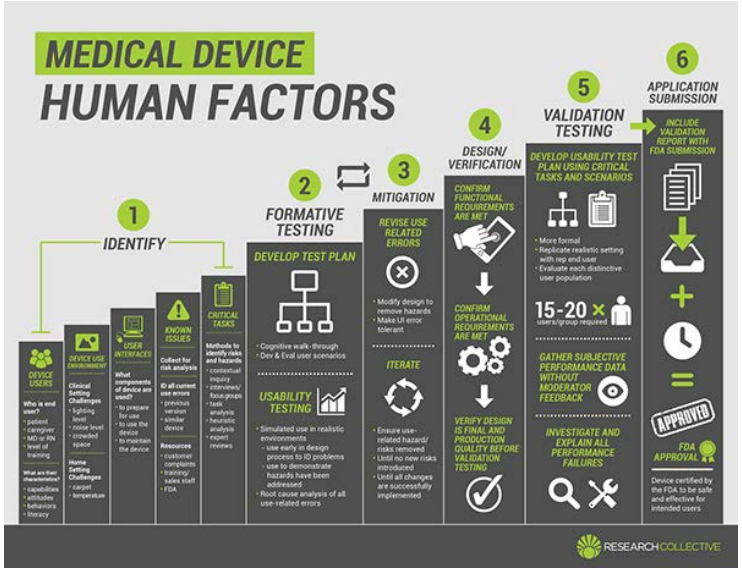
COURSE OVERVIEW

This course is to:

1. introduce the human factors applications in medical devices,
2. review the state-of-the-art Human Factors Engineering techniques,
3. understand and identify factors that impact patient and provider safety, and
4. apply course knowledge to fulfill federal and international human factors requirements
    a. e.g., HE75

Students are expected to take active roles in class to lead the review and discussion of text readings/research papers/case studies; **students must be well-prepared and engage guest speakers**. During the semester, students may be required to attend seminars/workshops in related topics or visit healthcare facilities outside of the regular scheduled lecture time. Equivalent hours of lecture will be omitted as appropriate.





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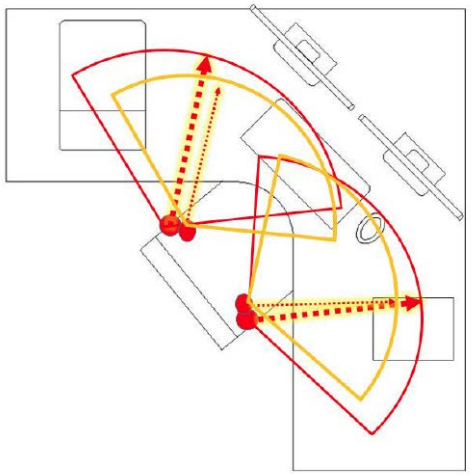
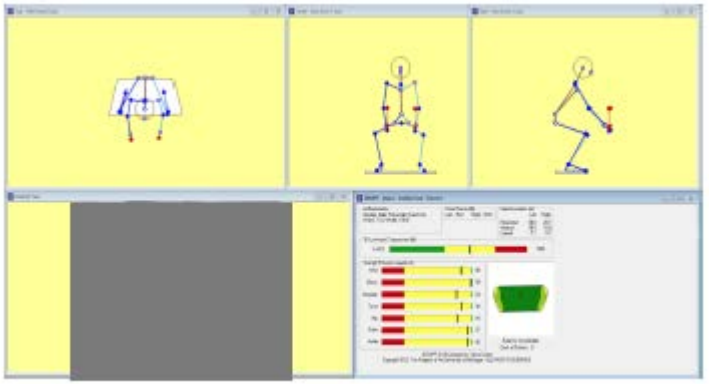
WHAT THIS COURSE WILL COVER (SELECT TOPICS*)

Skills and knowledge medical device companies expect Human Factors Engineers to know!





(Figure 8. 3DSSPP simulation with 50lb. bag)

*Additional topics will also be covered

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COURSE OUTCOMES

- The student will be able to **identify human performance and environment** factors that impact safety
- The student will be able to **perform formative and summative evaluations** and usability testing.
- The student will be able to **apply sensor-based, video-based, and observation-based techniques** to determine its usability, ergonomics and desirability.
- The student will be able to **conduct a** user-centered design approach
- The student will be able to **design and analyze** human-subject research for medical device, using either standard task analysis methods, work sampling, or synthetic data systems (e.g., digital human models) in patient, work, or simulation settings.
- The student will be able to **effectively write technical reports** regarding device analysis studies and recommendations.
- The student will be able to **effectively present** methods, analysis and recommendations.

WHAT THIS COURSE WILL NOT COVER

- Purely cognitive phenomena, Neural network or cognitive modeling
- Team behavior
- FDA and IEC standards outside the scope of human factors
- Facilities layout and manufacturing process
- Prototyping
- Market research

LAYOUT OF THE COURSE

- The focus of the course is on teaching you human factors concepts, regulatory requirements, and tools/approach to use for medical devices, but we must cover some background information first. So we will cover some material on anthropometry and physiology first, then move into application of these principles for analysis, assessment, and design. For most of the course, this will be a “do things” class and not a “know things” class.

- The lectures will supplement the posted notes and reading with explanations, examples, and exercises.

- Occasionally (~20-25 lectures), class will start with a very short attendance check. Attendance taken at all guest and student presentations

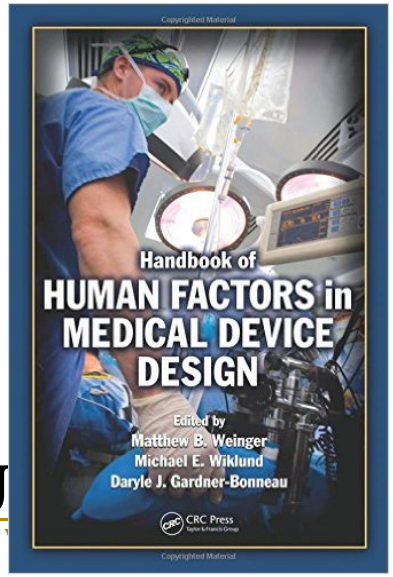
- Guest lectures from academia and industry will be invited to present their real-world experiences with human factors/medical devices (~target 8 guest lectures)

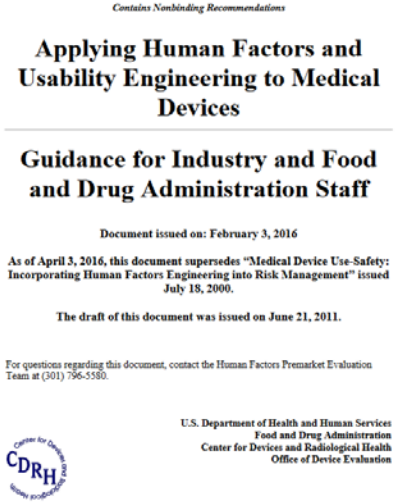
- There will be one in-class tests.

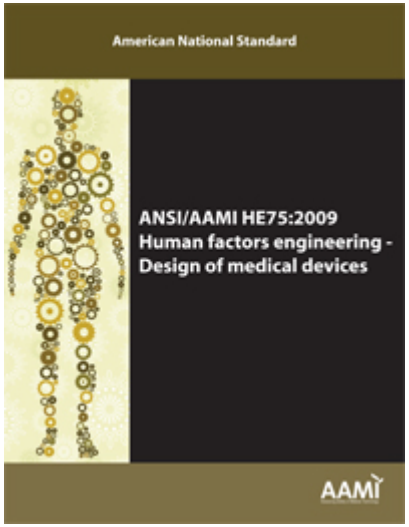
- There will be a final project and a final exam.

COURSE TEXTS (FOR REFERENCE)

- We will be skipping around rather than covering the materials sequentially.
  - **Handbook of Human Factors in Medical Device Design-**-Edited by Matthew B . Weinger , Michael E . Wiklund and Daryle J . Gardner-Bonneau
  - **FDA 2016 Applying Human Factors and Usability Engineering to Medical Devices-**-Guidance for Industry and Food and Drug Administration Staff
  - **ANSI/AAMI/IEC 62366:2007**/(R)2013 Medical devices - Application of usability engineering to medical devices.
  - **ANSI/AAMI HE75, 2009(R)2013** Human Factor Engineering---Design of Medical Devices







CLASS PREPARATION

- Brief readings, if required, will be posted 48 hours prior to lecture start
    - Typical assignment would be to prepare 3-4 discussion questions based on uploaded materials
- Class presentations will be assigned 2-3 weeks prior

GRADING

- Tests **(10% of total grade)**
  - One in-class closed-book test ***(10%)***
- Participation **(30%)**
  - Attendance in class is critical to facilitating discussion on course topics
  - Attendance is required for guest speakers and student presentations
  - Will randomly take attendance, turning in class discussion questions or short assignments (next bullet point) ~20-25 times throughout semester
- Presentations/short reports **(35%)**
  - Student(s) will select ~1-2 course topics to *upload* materials and present to class, e.g., case study, demo, recent research publications ***(20%)***
  - ~5+ Short assignments (e.g., IRB), speaker evals, etc. ***(10%)***
  - Additional presentations will be extra credit if time allows
- Project **(25%)**
  - Team assigned ~halfway through semester with supply budget ~$35 per group
  - In-class presentation and written report on your work
  - May require travel
  - Can utilize your previous medical device works

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GRADING

- No makeup “participation” allowed; 5 non-attendance will be dropped, but attendance at guest/student speakers required unless notify instructor with documentation prior to class (e.g., medical note, interview offer, conference acceptance)

- No makeups for tests are allowed unless notify instructor with documentation prior to class (e.g., medical note, interview offer, conference acceptance)

- You must bring your student ID with you to exam

- All test regrade requests must be submitted in writing (no later than two weeks after grades are posted) to the instructor during office hours or after class. The regrade request must include the entire test and the reason that additional points are being requested. The entire work will be regraded, and your grade may go up or down

GRADING (GENERAL)

- The grading boundaries will be no harsher than:

  93 A, 90 A-, 87 B+, 83 B, 80 B-, 77 C+, 73 C, 70 C-, 65 D

- The instructor reserves the right to adjust the grading boundaries to the advantage of students. However only the scale above is *guaranteed*. Student circumstances external to IE590 will not be taken into consideration when determining grade boundaries.

- Due to FERPA regulations and time constraints, it will not be possible to return graded materials in class. You may pick up any graded materials during office hours.

- All students seeking accommodations should coordinate their accommodations in this class through the DRC. Any students requiring accommodations should notify me as soon as possible.

IMPORTANT DATES

- Midterm – Friday 3/8/2019 ?
- No class
    - MLK Day; Monday 1/21/19
    - 1/18/19
    - HFES Healthcare Conference; Monday/Wednesday 3/24-3/27/19
    - Spring Break; M-F 3/11-3/15/19
- Project Presentations – 4/22-4/26