ES 227: Medical Device Design (G) – Spring 2012 Syllabus

Tues/Thurs 3.30-5pm (Pierce 209)
Prerequisite: Permission of instructor required. Preference for ES51, ES96 or machine design experience. Graduate course but open to qualified junior and senior undergraduate students.

Course Overview

Project-based course on the design of medical devices to address needs identified by hospital-based clinicians. Students work in teams with physicians to develop a novel device. The design process includes: needs finding; problem identification; prior art searches; strategy and concept generation; estimation; sketching; sketch modeling; machine elements, ergonomics and prototyping. Emphasis will be on the development of creative designs that are motivated by analytical models. There will also be a number of lectures on specific aspects pertinent to medical devices including intellectual property, market analysis and an overview of some existing devices. This course will have a significant communication component as students will present ideas in class and at an industry forum. Students will also write a publication quality final paper, which they will be encouraged to submit to a conference or journal.

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Medical Device Teaching Fellow: Ellen Roche, 60 Oxford St, eroche@seas.harvard.edu
Design Education Teaching Fellow: Donal Holland, 60 Oxford St, donal@seas.harvard.edu

Learning Objectives

Students completing this course should be able to:

- Perform needs finding and generate design requirements
- Follow a deterministic engineering design process to create new products
- Utilize fundamental design principles, machine elements, manufacturing and assembly techniques
- Apply engineering theory to practice
- Manage projects and communicate their results in a professional manner
- Work effectively in teams
- Understand the necessary steps to take an idea to a prototype
- Perform risk assessment and countermeasure development

Course Website

- Course iSite: *http://isites.harvard.edu/icb/icb.do?keyword=k83947*

Text Books

- Biodesign: The Process of Innovating Medical Technologies, Zenios, Makower, Yock, CU Press
- http://web.mit.edu/2.75/resources/FUNdaMENTALS.html
- For others see course "Reading List"

Grading

There are no problem sets and no tests. Grading will be as follows

Final prototype	40%
Project management (following schedule, presentations, paper, design notebook)	35%
Peer Reviews	15%
Professionalism, class attendance and participation	10%

Time Commitment

There will be two 1.5 hour lectures, 3hr lab plus one one-hour team meeting with the course staff each week. In addition, students should plan on spending an additional 6-8 hours a week on the project for team

scheduled meetings and prototyping sessions, as well as visits to hospitals to see facilities, observe medical procedures and meet with their clinician "customers".

Laboratory Facilities and Prototyping

Teams will have a budget of ~$3K for prototyping and testing their solution. In general this will be used for purchasing components and final manufacturing of parts. Purchases need to be approved by course staff during weekly meetings before orders can be placed. The class facilities are on the Pierce Hall ground floor, rooms G7a, G12a and G12b. The computers in G12a have SolidWorks and other relevant software. Students will have to be trained on the machines before being allowed to operate them. Many teams will also want to fabricate their own parts – in particular for the lab and early stage of the term project. Available resources include

- G12 Machine shop (bandsaw, drill press, tools, fastners etc)
- 3D printer in G6a; CNC Milling machines in G6a; Laser cutter in G11

Laboratory Assignment

In addition to the project, there will be a single laboratory session each week. The purpose and format of each of these will vary each week. These will be a chance for you to get support from the course staff on applying what you learnt in lecture each week to weekly milestones, help familiarize you with shop tools and equipment so that you can succeed with the project prototype. On occasion we will ask team to present their work from lab or weekly milestones in lecture to the rest of the class.

Weekly Team Meetings

Weekly one-hour team meetings for each team will be arranged with the course staff to review progress and brainstorm/solve project design problems as well as locate appropriate resources. Please prepare for these meetings by organizing the results and conclusions your team accumulated since the previous meeting and any questions you would like to ask the course staff.

Documentation

Students are expected to maintain lab notebooks with sketches, calculations, pasted in pictures, etc, which are informally reviewed during meetings and factor into grading, however their primary function is to document the design process, especially with regards to building a design history file and determining inventorship. The instructors also keep notebooks which they updated during meetings and presentations and use them to manage the teams and document their own contributions.

Other documentation, in addition to the design notebook, should be posted to the class (secure) Wiki which will document the development and progress of your project. This Wiki will be viewable by other teams and the staff and will be consulted during class. It is critical to document (write) as-you-go else, because come the end of the semester, it will not be possible to completely write up a great project.

Final Deliverables

Students are expecting to deliver a professional looking functioning proof-of-concept prototype that solves the unmet clinical need identified by the physician that they are working with. At the end of the semester teams will give 20 minute presentations to the class as well as an audience of representatives from the Boston Area medical community (MDs, VCs, and top researchers) and other interested parties.

The team is responsible for submitting a final report in the form of a journal article suitable for the ASME Journal of Medical Devices (http://asmedl.aip.org/MedicalDevices). This document should be approximately 20 pages double spaced plus figures; details go in Appendices. An "A" grade project is one that is presented in form and content that is actually ready to be submitted to a peer-reviewed journal. Students will submit a draft of their final paper to course staff a week before the final deliverable and course staff will provide detail suggestions for improvement.

Spring 2011 Schedule

Please note that schedule may be modified as circumstances demand during the course of the term.

	Week Start Date	Tuesday Lecture	Thursday Lecture	Lab	Reading (for Lectures and Tasks of following week) Refer to reading list on iSites for more detail on books and updates)	Tasks & Project Milestones (due Tues of next week)
1	1/23	Welcome Course Overview and Logistics IP Overview Sam Liss from OTD.	**Clinician Presentations**	• Sign up for Lab Access • Solid Works: Part and assembly tutorials	Text Book and Chapter • Biodesign. Section 2.1, 2.2 and pages 235/236 • Fundmentals topic 1 Cranial Drill case study • Clinical Problem • Background research	Tasks • Sign up for machine shop and safety training: Feb 3rd at 9am and 1pm in Physics Machine Shop • Background research on presented clinical problems Milestones • SW parts and assembly files submitted
2	1/30	**Clinician Presentations** Students meet after class to form teams.	Teams Announced FRDPARRC and strategies, concepts, modules Patent and Literature Review: Techniques and Resources *Mallory Stark, Barker Library, HBS* *Anne Craig, Director of Intellectual Property, Harvard University*	• Teams meet together with course staff • Reviewing the Literature and Patents: Where to search and how to organize the data. • Overview of prototyping tools (Mill, 3D printer, Laser Cutter). One team member assigned to each.	Text Book and Chapter • Designing Usability Into Medical Products by Wiklund and Wilcox, Chapters 5, 6 and 9 • Biodesign. Section 1.2, 3.1, 3.2 and pages 235/236 Cranial Drill case study • Needs finding and observation	Tasks • ***Research*** strategy options, and current standard of care and create preliminary list of questions • Schedule meeting for needs finding research Milestones • Top 3 project choices submitted • Safety training completed • Document understanding of presented clinical problem (template) • Mission statement (see examples) • Team Wiki's should be functional • Patent and Literature Review Complete with References (patent PDFs uploaded to Wiki)
3	2/6	Ethnography, Needs Finding and Problem Identification: *Miriam Zisook* *Industrial Designer*	Fundamental Design Principles and Evaluation of Ideas	• User-Centric Design Process: Preparing for interviews and observations	Text Book and Chapter • PDF of blog on iSite • Sketching text book chapters 1 and 2 Case study • Sketching and sketch modeling	Tasks • Choose and plan research methods for interaction with clinician • ***Ask*** your questions to one or more clinicians and implement user research plan Milestones • Documented research methods plan • Documented results of research methods plan • Top 3 strategies selected, and described with their FRDPARRC tables completed

4	2/13	Sketching and sketch modeling. *Miriam Zisook* *Industrial Designer*	Using modeling and experimentation to evaluate design concepts	• Sketching & Modeling: creating good sketches and physical models to illustrate concepts	Text Book and Chapter • Manufacturing Engineering and Technology Section 1.4 • Mott Chapter 13 Cranial Drill case study • Strategies and strategy selection • Strategy Presentation	Tasks • Build SW model and physical model for each of the strategies • ***Show*** strategies to clinician to get feedback Milestones • Document sketching, physical and SW modeling of strategies • Document in detail the feedback you got from clinician • FRDPARRC for each strategy
5	2/20	Manufacturing and design for manufacture Overview of material selection and machine elements	**Teams' Strategy Presentations**	• Lab on developing concepts and determining whether modeling or experimentation is appropriate for evaluation	Text Book and Chapter • Mott Chapter 21 • PDFs on iSite • Fundamentals topic 8 Cranial Drill case study • Development of three concepts to implement chosen strategy	Tasks • Develop at least three concepts for how to implement the chose strategy • Create plan for evaluation of concepts Milestones • Best Strategy Selected with its FRDPARRC table complete • Summary documents for analysis / bench level experiments for concept selection
6	2/27	Actuators	Sensors, Transducers % Instrumentation *Diana Young, PhD* *Electrical Engineer and Wyss Technology Development Fellow*	• Assist with model making both looks like and functional models • Support of use of manufacturing tools in teaching labs	Text Book and Chapter • Fundamentals topics 5 and 6 Transmissions • PDFs on iSite Cranial Drill case study • Bench level experiment to select preferred concept • Concept Presentation	Tasks • Build SW model and physical model for each of the concepts • Perform first order analysis or bench level experiments for concepts • ***Show and Play*** with your models with your clinician Milestones • Document sketching, physical and SW modeling of concepts • Document in detail the feedback you got from clinician • Top 3 concepts selected, described with their FRDPARRC tables and solid models

7	3/5	Transmissions	**Teams' Concept Presentations**	• Lab on finalizing selected concept and identifying different modules of device	Text Book and Chapter • Fundamentals topic 9 • Mott chapters 11,18,20 • Shigley (9E) chapters 8 and 9 Cranial Drill case study • Detailed analytical model to select components	Tasks • Identify the different modules, including Most Critical Module (MCM), for the best concept and assign responsibility Milestones • One page documents summarizing analysis / bench level experiments for concept selection • Best Concept Selected with its FRDPARRC table complete • Detailed schedule to completion uploaded
8	3/12	Spring Recess	Spring Recess	Spring Recess	Spring Recess	Milestones • Take a break, climb a mountain or jump in a lake! But if you are behind, get you and schedule aligned.
9	3/19	Linkages	Medical Devices 101: Design of a Motion Compensating Catheter for Cardiac Applications. *Dr. Sam Kesner, Lecturer, Harvard School of Engineering and Applied Sciences*	• Lab to support MCM engineering analysis and creation of full SW model (tolerancing etc for MCM)	Text Book and Chapter • Fundamentals topic 10 • Mott Chapters 14, 16 • Shigley (9E) chapters 11 and 12	Tasks • Create detailed solid model of most critical module (includes models of all custom machined and off-the-shelf component parts) • Create rough SW models of other modules Milestones • MCM engineering analysis and bench level experiments complete and documented • SW model of full assembly complete with all detail for MCM
10	3/26	Interfaces: Flexures, bearings	Medical Devices 101: Screening Biomedical Device Design Concepts. *Josh Tolkoff, Managing Director Ironwood Capital and Richard Anders, Founder and Executive Director, Mass Medical Angels*	• Lab to support MCM engineering analysis and creation of full SW model (tolerancing etc for MCM)	Text Book and Chapter • Fundamentals on Interfaces • Snap Fit Guide Case study • Sample final papers on cranial drill and ultrasound needle guide	Tasks • Refine MCM SolidWorks model based on analysis and feedback from weekly meeting and lab feedback • ***Play*** with your prototype parts with your clinician and document the interaction/results • Begin detailed engineering of other modules Milestones • Document results of interaction with clinician • Detailed plan, and task list for remaining time and updated schedule to completion updated

11	4/2	Solidworks and Prototyping *Peter Kjeer, Senior Mechanical and Systems Lab Manager, SEAS Undergraduate Teaching Labs*	Medical Devices 101: IDEO Medical Device Design Process and Case Studies *José Colucci Jr., Director, Health & Wellness IDEO*	• Lab to support preparation of final paper (come with draft and look for feedback)	Text Book and Chapter • TBD Case study • Design Review Presentation	Task • Begin working on final paper abstract, first paragraph & structure outline • Finalize detailed engineering of other modules • Complete detail SW models of all modules Milestones • Full SW model complete with all off the shelf parts and custom components with manufacturing plan for design review presentation
12	4/9	No class, work on projects.	**Teams' Design Review Presentations**	• Lab to support preparation of final part drawing, interacting with vendors and placing all orders	Text Book and Chapter • Biodesign: TBD Case study • Detailed engineering drawings off to machine shop and component parts ordered for cranial drill	Task • ***Show*** final detailed design and sketch model to clinician and document feedback • Refine full SW model based on feedback from design review in class and clinician feedback • Begin final manufacturing Milestones • Document feedback from clinician • Update plan, and task list for remaining time and updated schedule to completion • Parts out to external shops for manufacture and components ordered from vendors
13	4/16	Intellectual Property Next Steps now you have a Prototype: *Sam Liss and Anne Craig from the Harvard Office of Technology Development and outside patent attorney*	Medical Devices 101: Case Studies on Medical Device Design from Industry *Mike Ferragamo, Engineering Fellow, ASDD, Smith and Nephew*	• Help with development of testing plan	Text Book and Chapter • Biodesign: TBD Case Study • Final presentation example and template • Final papers	Tasks • Finalize manufacturing and assembly • Prepare testing plan Milestones • MCM complete and demonstrated • Testing plan documented • Machining complete • Full assembly competed

14	4/23	Medical Devices 101: Commercializing New Medical Devices *Aaron Sandoski, Managing Director, Norwich Ventures*	Class working session, aka last chance saloon!	• Presentation dry run. Make sure you practice, its kind of a big deal!: • Help with final paper preparation	Text Book and Chapter • TBD	Tasks • Prepare final presentation • Prepare final paper • ***Test*** your completed prototype in a realistic clinical setting with your physician Milestones • Final presentation and final papers due to course staff for feedback • Final paper draft due • Testing complete and documented
15	4/30	Reading Period	Reading Period	Practice, practice, practice!		
16	5/7	**Final Evening Presentations**				Final Presentation: Data and time TBA Teams will present for 20 mins with 10 mins for Q&A.