Medical Device Design – 2.75, 2.750, 6.4861, 6.4860, HST.552 (joint) – Spring 2024 Syllabus

Units	3 – 3 – 6
Prerequisites	One of the following 2.007, 2.008, 2.009, 6.101, 6.111, 6.115, 22.071 or instructor permission.
Updated	14 November 2023

Course Description

This course provides an intense project-based learning experience around the design of Medical Devices with foci ranging from mechanical to electro mechanical to electronics. Projects motivated by real-world clinical challenges provided by sponsors and clinicians who also help mentor teams. Covers the design process, project management, and fundamentals of mechanical and electrical circuit and sensor design. Students work in small teams to execute a substantial term project, with emphasis placed upon developing creative designs — via a deterministic design process — that are developed and optimized using analytical techniques. Includes mandatory lab. Instruction and practice in written and oral communication provided. Students taking graduate version complete additional assignments. Enrollment limited.

Up to date details and answers to questions that you might not thought of are available on the Information for Students page.

Website	meddevdesign.mit.edu
Lecture	Monday & Wednesday 13:00 – 14:30 EST, Room is also booked 12:30 – 13:00 & 14:30 – 15:00 for teams to meet
Location	Room 3-270

Schedule and details may change over the course of the semester – Canvas will always provide the most current information.

Listeners	Listeners cannot be assigned to project teams, but they are welcomed in lectures, with instructor permission.

Teaching Staff

MechE Instructor	**MechE Instructor**	**MechE Instructor**	**EE Instructor**	**MechE/IMES Advisor**
Prof. Alex Slocum Room: 3-445 slocum@mit.edu	Dr. Nevan Hanumara Room: 3-470 Phone: 617-258-8541 hanumara@mit.edu	Prof. Gio Traverso Room: 3-340 Phone: 617-253-5726 cgt20@mit.edu	Anthony Pennes Room: 38-575/38-501 Phone: 845-219-6691 ampennes@mit.edu	Prof. Ellen Roche Room: E25-344 Phone: 617-258-6024 etr@mit.edu
Comm. Instructor	**TA & Lab Safety**	**Course MD**	**Maker Guru**	**Course Administrator**
Dave Custer Room: 24-611B custer@mit.edu	Emma Rutherford Room: 3-443 emmakr@mit.edu	Dr. Jay Connor Mt. Auburn Hospital jcmdhandsurg@comcast.net	Coby Unger Hobby Shop cobyu@mit.edu	Kaila House Room: 3-461 kmhouse@mit.edu

Digital Assets

Canvas	web.mit.edu/canvas will be used for syllabus, lab materials, quizzes, surveys and class announcements
Class email	2.75-2024@mit.edu - Contacts the entire course students and staff (course announcements by Canvas)
Staff e-mail	2.75-staff@mit.edu - Contacts the course teaching staff
Slack	We will create a MIT Slack channel for each team and invite members to facilitate rapid communication
Team e-mails	Teams are additionally recommended to create their own Moira e-mail lists, with/without their mentors
Project Management	Trello (link to come) integrates with Slack
Wiki	The Wiki serves as long term course documentation

Lectures

The semester is split into two halves: In the first, we cover fundamental, applied topics in mechanical and electrical engineering and the engineering design process. And in the second, we transition to focus on healthcare industry-specific topics and feature invited guest speakers and case studies. Consult the Schedule for details.

Quizzes (but no P-Sets)

There will be frequent in-class quizzes / mini-assignments at the beginning / during lectures. (We may use Canvas, so please bring your laptops and/or iPads to class.) Some are based on the pre-readings or previous lectures and others will be conducted as real-time exercises. These compliment the lectures, as well as provide important feedback to students and instructors alike. There are no makeup quizzes, however we will drop the two lowest quizzes. See Absences & Support for more information.

There are no formal P-Sets, as the focus outside of class is on the labs and term projects.

Labs

During the first half of the semester there will be three lab assignments:

1. Design, build, and test a kinematic coupling (KC) which demonstrates the principles of exact constraint design, important for any mechanical device. This will be provided as a take-home kit.
2. Design, build, and test a simple, non-invasive electrocardiogram (ECG) which uses electrodes and circuitry, to view and report heart rate. This will be conducted in the EECS Lab with safety training required and scheduled help sessions.
3. Syringe pump lab, comprising an individual at-home preparation assignment, followed by in-class team build sessions.

The labs' objective is to familiarize students with concepts from both mechanical and electrical domains, foster the hands-on skills needed for R&D and work in a cross disciplinary team. All three labs can become part of your personal portfolio!

Team Term Project

Students will work in small 4 – 6 person teams to execute a substantial, health-focused project, which spans the entire term.

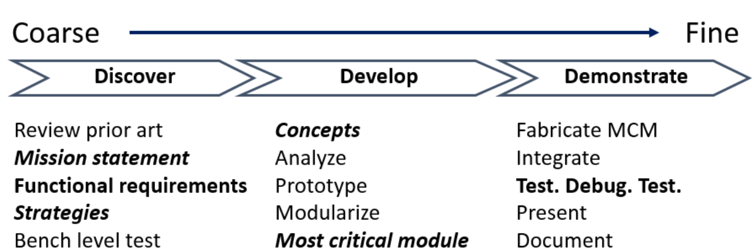
Project options will be presented by clinicians and companies at the beginning of term. You will be asked to *individually* rank your top project preferences, considering where your interests and skills can contribute the most. Teams will be formed by the staff based on preference and student background. Given the variety of projects and breath of students' interests and expertise, there have been few past difficulties in satisfying everyone.

Please understand that, given the project-clinician/proposer relationship, small teams and aggressive schedule, signing up for a project constitutes an implicit agreement to complete the class.

Likewise, project proposers commit to engaging with you on a regular basis and being a part of your team!

Together, we will follow a deterministic design process, which fosters creativity, is guided by analysis and experimentation, fosters peer-review and eschews hope-based design to rapidly and efficiently develop a proof-of-concept prototype solution. The process is roughly broken up into thirds:

1. Discover – Problem presentation by client, team formation, detailed problem understanding and appropriate analysis, investigation of prior art, definition of functional requirements and exploration of possible solution *strategies* and preliminary *concepts*
2. Develop – With a specific *strategy* selected, *concepts* are further explored until a *final concept* is identified to be developed, analyzed and tested. The design is divided into modules and initial attention focused on the *most critical module*.
3. Demonstrate – The entire system is fabricated, integrated and tested. Proper documentation is an important, oft shortchanged, step that begins the *design history file that documents the design's development*, essential for any quality product (ISO 9000) and especially for medical products (FDA and ISO 13485).



Three-phase, 14-week deterministic design process

At the end of the semester, success is defined as a working proof-of-concept prototype, documentation of the deterministic design process and an honest device performance evaluation, with respect to the original clinical need. In industry parlance, this is referred to as Verification & Validation (V&V), i.e., does your solution perform as intended and is it actually the correct solution?

Negative data, which occurs often in the world of R&D, is an acceptable outcome, provided the team has followed the deterministic design process, reflects on unexpected results and describes what could be improved / a recovery path, if the project continued.

Weekly Mentor Meetings

Each team will be assigned two course staff mentors who will meet with the team weekly. During mentor meetings we will review progress, brainstorm/solve project design problems, identify further needed resources, set tasks and milestones for the coming week and track individual and team progress. We aim to maintain a fair pace, commiserate with the course's 12 credits, and spread the workload evenly across the semester and team members.

In order to maximize productivity and minimize frustration, it is critical (and good professional practice) for each team to meet before the mentor meeting, conduct a *peer review* of their ideas and prepare an agenda that addresses three key questions:

1. What did you do last week?
2. What will you do this coming week?
3. What resources do you need?

Each team member is required to maintain individual notes and teams must also take weekly notes, see *Documentation*.

Bottom line, the better prepared a team is, the more the mentors can help you achieve a successful and satisfying conclusion!

Teamwork & Peer Evaluations

Teamwork is central to functioning of this class and any modern engineering endeavor and it is expected that students will work together in a *safe, professional, and collegial manner* as defined in MIT's policies and procedures, especially 9.0 Relations and Responsibilities Within the MIT Community.

During the first weeks of teamwork, please identify any perceived problems with your team's dynamics promptly, and bring them to the attention of your team members and/or the course staff, who will help resolve issues. This is important in the professional world where there are no "safe spaces" and issues must be addressed politely and proactively. We can help make 1/:(= :)

Just before mid-semester, an anonymous peer review will be conducted using the CATME tool, developed at Purdue. The results will be reviewed by the course staff, who will intervene as needed to help improve team performance. At the end of the course, team members will again review each other via CATME and the combined ratings can be used to adjust individual grades by up to a full letter. To be clear, the focus is on professional performance, not popularity.

Prototyping & Budget

Each team will have a budget of about $2,000 (exclusive of MIT overhead) to develop, prototype, and test their solution. Legitimate expenses include materials (components), services (such as machining), and local travel to collaborators, etc., but not food.

Purchases require pre-approval by your mentor or other course teaching staff, whose goal is to guide teams in an *efficient* use of their budgets. Always prototype with a plan and avoid shotgunning, i.e. buying stuff randomly. Consider the tradeoffs between the flexibility of fabricating in-house, your time, and using outside professional services. Compare pricing and look at lead times, even domestic suppliers can have surprising lead times, so planning is essential. The cheapest vendor is not always the best. We have many contacts who are accommodating to the needs of prototype projects and we are happy to have new suggestions. We maintain McMaster, Digi Key and Amazon accounts that must be used to place orders from these vendors.

The course Administrator will oversee team's accounts and purchasing. Each team must appoint a single person to coordinate with the Administrator and track your budget. No paperwork, no grade!

If you buy something locally you need to download two MIT tax free forms (ST-2, ST-5), since you can't be reimbursed for sales tax. All receipts must be turned in promptly to comply with MIT audit requirements.

Fabrication Facilities

Since each project is different, course staff will work individually with teams to identify and obtain the necessary resources.

PERG Lab (3-438)

Light fabrication and assembly space. Once the projects are underway, this will be accessible to teams 10 AM – 6 PM via card access. Additional hours can be arranged with the course staff. Teams will be provided with bench space and bins. As in industry, we expect team to mark and organize their workspace and return tools and equipment where they belong daily.

Safety training is required before you may use the space.
Lab Safety Officer – Steven Burcat – sburcat@mit.edu
Lab Manager – Nevan Hanumara – hanumara@mit.edu

EECS Lab (38-501)

For electronics-focused projects, bench space, instruments, tools, proto boards and lockers available.
Typical open hours M-F 9 AM -11:45 PM and Sunday 1 PM - 11:45 PM.

Safety training is required before you may use the space.
Lab Manger – Anthony Pennes ampennes@mit.edu

Other Spaces

Teams are welcome to use any other safe lab / fabrication facilities that they have access to and permission to use. Teams are responsible for keeping all workspaces clear and returning equipment to the proper storage to avoid access revocation.

Mobius - Locate and access some of the campus' 45 major maker spaces.

Hobby Shop – Newly reopened in the old Museum space, the Shop provides woodworking and metalworking tools and a wealth of expertise and advice. Shop contact Coby Unger, cobyu@mit.edu. (Membership required.)

Metropolis (6C-006B) – General fabrication, 3D printers, laser cutter, electronics bench, wood working, sewing machines, table saw.

The Deep (37-072) Metal milling/lathe, SLA 3D printers, water jet, mold making.

Edgerton Center Student Shop (6C-006) – Open to all MIT students, safety and machine operation training required.

MakerWorks - LMP (35-122) – Restricted to Mechanical Engineering students, safety training required.

QuickRoom - For spur of the moment meeting locations.

Huang-Hobbs BioMaker Space (26-035) – e-mail space for access information.

Projects requiring cell / tissue / BL2 work should coordinate with the instructors to access approved spaces.

Note: BeaverWorks should not be used for course 2.75 projects due to IP concerns.

If there are any questions / doubts regarding fabrication or safety - ask the course staff immediately.

Documentation

Documentation is required in the medical device industry, specifically a *design history file* and *design controls*, for regulatory approval. Read more about this courtesy of the FDA. It is also essential for establishing inventorship, building an IP portfolio and launching a successful company.

Notebooks - Each student is expected to maintain a paper or digital design notebook with sketches, calculations, and pictures that document their individual contributions, late night ideas and general project notes. These are often reviewed during mentor meetings and factor into grading, so always bring your notebook to your weekly mentor meeting!

Wiki - The Wiki serves as a long-term project archive, independent of Google, Dropbox, etc., and each team must create and maintain a page. Teams are expected to update it with their progress weekly, key notes from internal, project proposer and mentor meetings, key design decisions, important milestones, decision matrices, images and papers. Copies of all presentations must be posted to the Wiki. This Wiki is viewable by everyone in the class - look at past projects for inspiration!

Intellectual Property

While our focus is on learning, Intellectual Property (IP) is sometimes generated in this course and we follow the best practices and guidelines of the MIT Technology Licensing Office (TLO). It is essential that all team members keep bound, signed, dated and, ideally, witnessed if there is a likely inventive idea, design notebooks to record individual contributions. The definition of inventorship is strict, as we will discuss in lecture. Just being on the team or helping to build and test does not make a person an inventor.

IP created by students in an MIT course is generally considered property of the students, however, the inventors may opt to assign it to the MIT Technology Licensing Office for prosecution. Potential IP requires a disclosure to the TLO which will take appropriate course of action according to MIT policy.

Note that patents are expensive and not an end in themselves; it is rare that one is simply bought by a company and turned into a commercial success. We will talk about the hard path of building a company in the second half of the course. Contributing to a meaningful project, publishing a peer reviewed article and/or showcasing your project in your portfolio is likely the most valuable outcome of the course, in terms of career progression.

Communication

Communication is an integral part of any engineering endeavor and instruction will be provided in class and mentor meetings over the duration of the semester. This is a CI-M subject for MechE and EECS and can be used in place of 2.009. Graduate students, of course, also benefit from practice with communication skills.

Students are required to communicate as professionals throughout the course formally and informally, including:

- Weekly mentor meetings
- In-class strategy presentation
- In-class concept presentation

- In-class *Most Critical Module* review
- Final presentation
- Final journal quality and format article & one-page Executive Summary.

In-class Design Reviews & Presentations

Three in-class design reviews will be conducted in the manner of professional progress presentations. These are opportunities to harness the hive and receive fantastic feedback from the entire class, students and instructors alike, therefore, teams should briefly introduce or remind the audience about their project, dive right into an update with the most critical details and then identify the current challenges. The better these are elucidated, the more useful will be the feedback, so be sure to leave ample time for discussion. Everyone present is expected to participate, asking questions and provide constructive feedback.

The Final Presentations should cover the project's development and an honest evaluation of the results (V&V). We ask teams to also touch upon the clinical, technical and regulatory/IP/business aspects of the project. We invite industry visitors to the final presentations, and their questions and feedback have been invaluable in helping papers become publications and ongoing projects.

By the end of the course, every student will be comfortable talking about their work and ready to give a professional presentation.

Final Paper

Each team will write a final paper which must follow the guidelines and format of an established journal or conference, e.g., the ASME Journal of Medical Devices, ASME Journal of Mechanical Design or IEEE Transactions on Biomedical Engineering. This requirement has enabled many past teams to rapidly and successfully submit their work for peer reviewed publication! For examples see Past Projects and the MIT Emergency Ventilator Project, which began as a 2010 project and an ASME publication.

Write early and write often. It is critical to write as-you-go to prevent last minute, binge writing. By the end of Week 6, every team will start writing their journal article. Ideally, this drafting over time permits genuine reflection on your accomplishment that, in turn, allows you to more effectively communicate the value you have added.

Recommended Texts

1. FUNdaMENTALS of Design, A.H. Slocum, posted to the course website. This is a MUST download and read (as well as the design spreadsheets). Carefully reading and comprehending this design knowledge will lead the greatly enhanced design happiness in the class and in your professional design career.
2. Precision Machine Design, A.H. Slocum, for the serious deep thought machine designer. Copies are available from the course administrator at the author price.
3. *The Art of Electronics*, 3rd Edition, Horowitz and Hill, Cambridge University Press
4. *Practical Electronics for Inventors*, 4th Edition, Paul Scherz & Simon Monk, McGraw Hill Education

Grading

This is an advanced design course for students who are ready to step up to act as professional engineers! Therefore, as in industry, we do not provide detailed, weekly grades. We do, however, provide ongoing feedback each week during mentor meetings and will meet with any student individually to discuss progress and performance.

Work hard and efficiently and you will do great! Remember, a grade is not nearly as important as learning a structured design process, developing a prototype and documenting what you did with the team to bring it to life. The work from the course has helped many students find excellent industry jobs, successfully apply to graduate schools and even launch ventures!

Our goal is your success, in this course, professionally and in life!

Grading is based on MIT's definitions, where:

A	Exceptionally good performance, demonstrating a superior understanding of the subject matter, a foundation of extensive knowledge, and a skillful use of concepts and/or materials.
B	Good performance, demonstrating capacity to use the appropriate concepts, a good understanding of the subject matter, and an ability to handle the problems and materials encountered in the subject.
C	Adequate performance, demonstrating an adequate understanding of the subject matter, an ability to handle relatively simple problems, and adequate preparation for moving on to more advanced work in the field.

http://catalog.mit.edu/mit/procedures/academic-performance-grades/#gradestext

Term Project – Team Grade Execution of the design process Meeting scheduled milestones Efficient use of time and $ Quality of design & execution (details & execution)	35%
Individual Performance Contributions to project (monitored via mentor meetings) Use of lab notebook and peer review effectiveness Participation in class presentation Q&A	20%
Formal Communications Team Presentations Final Paper & Deliverables	20%
Quizzes	15%
Individual KC, EKG and Syringe Pump labs	10%
Total:	**100%**

Post-semester, should there be any grade concerns, students must provide their design notebook for review, be prepared to discuss any of the materials covered in the class and then accept that their grade may go up or down.

Absences & Support

We are committed to making this a positive learning experience for all of us, so please come and talk to us.

Absences

The professional world does not offer makeups and, although an occasional absence usually causes no issues, continued absences will incur your colleagues' wrath and boss' unwanted scrutiny. Therefore, we have a "no makeups" policy and ask each of you to be professionals: Communicate in advance if you know you must be absent and work proactively on your project deliverables. For both planed and emergency absences, we automatically drop two quizzes and have some flexibility to reschedule labs. With proper planning, most problems can be avoided and, together, we will keep everyone moving forward with minimal disruption.

If you do have significant travel or personal needs that might impact your ability to work effectively in a fast-paced team, you should probably NOT be taking the course. Please discuss any concerns with a member of the course staff at the beginning of the semester.

Support

We understand that life happens. If you are dealing with a personal or medical issue impacting your ability to attend class or complete work, we will work with you to develop a recovery plan. Please reach out to the course staff proactively.

In parallel, contact Student Support Services (S^3 for undergrads) or GradSupport. They will verify your situation, discuss with you how to address the missed work and help interface with other instructors and advisors.

Disability and Access Services

MIT values an inclusive environment. If you need an accommodation, please communicate with the course staff *at the beginning of the semester* to allow sufficient time for implementation of any services/accommodations that you may need. If you have not yet been approved for accommodations, please contact Disability and Access Services at das-student@mit.edu for assistance.

Schedule

This may be modified as circumstances demand during the course of the term – always see Canvas for the latest schedule.

Spring 2023 - Medical Device Design				
Wk	**Date**	**Lecture / Lab**	**Speaker(s)**	**Weekly Project Milestones**
1	5 February	Welcome to Medical Device Design Fundamentals 1/2/3	Nevan Hanumara Alex Slocum Dave Custer	Read this syllabus fully Come prepared with questions Have a design notebook
	7 February	Project Presentations	Project Proposers	
2	12 February	Project Presentations	Project Proposers	Project preferences due by Midday 13 February Schedule weekly team & mentor meetings Meet with project proposers (meet 1st as a team) Start prior art search
	14 February	Fundamentals 3/8/9 KC Lab released Communications & Teaming Teams Announced	Alex Slocum Alex Slocum Dave Custer Nevan Hanumara	
3	19 February	PRESIDENTS' DAY – HOLIDAY		Team Wiki page populated E-mail, Slack & Trello Documentation of prior art Mission statement drafted Functional requirements identified
	20 February (Monday sch.)	Prior art searching for Medical Devices Fundamentals 5/6 KC Lab Q&A	Nevan Hanumara Alex Slocum Alex Slocum	
	21 February	Practical Electronics – Op-Amps EKG Lab Released Mission Statement Exercise Journal articles & CATME overview	Anthony Pennes Anthony Pennes Nevan Hanumara Dave Custer	
4	26 February	Teams Strategy Design Review (presentation, all class feedback)	Teams	Before your presentation: FRDPARRC filled out Mission statement finalized Top Strategies & preliminary Concepts Key questions identified
	28 February	Teams Strategy Design Review (presentation, all class feedback) EKG Lab Part 1 Due	Teams	
5	4 March	Prototyping Resources Fundamentals – 7/10 KC Lab Due & Show & Tell	Nevan Hanumara Alex Slocum Alex Slocum	Top Strategy selected Peer evaluation #1 completed Investigate concepts for strategy Key analysis identified Draft paper Introduction
	6 March	Practical Electronics – Inputs/Outputs	Anthony Pennes	
6	11 March	*Class meets in 38-545* Syringe Pump Pre-lab – due	Anthony Everyone	Bench level experiments

		Syringe Pump Team Lab – build session		
	13 March	*Class meets in 38-545* Syringe Pump Team Lab – build session EKG Lab Part 2 Due	Everyone	
7	18 March	Team Concept Presentations (presentation, all class feedback)	Teams	Before your presentation: Top 3 Concepts identified Bench level experiment results
	20 March	Team Concept Presentations (presentation, all class feedback)	Teams	
8	25 March	SPRING BREAK		
	27 March	SPRING BREAK		
9	1 April	The Hidden Language of MedTech	Nikolai Begg, MIT Alum & Medtronic	Top Concept selected FRDPARRC completed for this Concept System architecture sketched Most critical module (MCM) identified Draft paper Background section
	3 April	Adventures in Gastroenterology	Gio Traverso	
10	8 April	Ethics in Animal & Human Subjects Testing	Gio Traverso, Cathy Ricciardi, Tatiana Urman	Schedule to completion reviewed with mentors Most critical module (MCM) designed Paper Design section begun Journal Identified – start formatting to fit
	10 April	MCM Design Review (presentation, all class feedback)	Teams	
11	15 April	PATRIOT'S DAY – HOLIDAY		MCM fabricated and tested Supporting modules designed Testing plan for review with mentors Draft paper Design section
	17 April	Prepare to be regulated & Digital Health	Rumi Young, BD	
12	22 April	Preparing the final communication deliverables Basics of Reimbursement	Dave Custer Charles Mathews, Clearview	Fabrication & Integration Last chance to order any final parts! Testing plan ready Draft paper Methods
	24 April	Scaling your device from 1 to 1 Billion	Martin Ebro, Novo Nordisk	
13	29 April	Portal Instruments Case study	Bobby Dyer (MIT Alum)	Commence Testing & Revise Draft paper Results section
	1 May	Basics of IP	Ben Rockney, MIT TLO	
14	6 May	Human Factors in MedTech Disclosures due to TLO	Nevan Hanumara	Experiments completed

	8 May	Final Discussion & Mentors Available		Draft Paper Discussion & Conclusions Compile full paper draft Presentation draft complete
15	Monday 13 May	FINAL PRESENTATIONS – 10-250 6 - 7 PM Preparation & Dinner 7 - 9 PM Presentations	Teams	Written deliverables due this week Journal Paper One-page Executive Summary Wiki updated with all materials Peer Evaluation #2 completed