Course Webpage

Medical Devices Lab

Course: ESE3400

Units: 1.0 CU
Term: Fall 2022
When: Lecture: MW 5:15-6:15pm, Lab: T 5:15-8:15pm (all times are EST)
Where: Lecture: Moore 212, Lab: Detkin Lab
Instructor: Tania Khanna (Levine 262, seas: taniak)
Instructor Office Hours: W 1-2:30pm (in person), or by appointment
TA: Sydney Sofronici (seas: ssofroni) (office hours: F 10-11am (TBD))

Prerequisites: None, but ESE 2150 and/or ESE 2240 are recommended
Quick Links: [Course Objectives] [Grading] [Policies] [Fall 2022 Calendar] [Reading] [Ed Discussion]

Catalog Level Description: With the demand for personalized medicine and health care, the need for consumer medical devices has risen. Traditionally devices have been designed from the ground up, but with more standardized components and software tools devices can be built to fulfill this need. This course will introduce design of medical devices. Students will learn the basics of sensors, signal conditioning, data acquisition and analysis, biopotential, biopotential electrodes, biomedical instrumentation, examples of biological signal measurement and electronics safety. This will be a lab based inquiry into medical device design.

Role and Objectives

Students will:

- Utilize sensors to monitor biometric signals
- Design differential analog circuitry to acquire and condition biometric signal
- Employ circuitry to digitize and transmit data wirelessly via Bluetooth
- Build and populate a PCB given circuit schematic
- Extract biometrics (eg. Heart rate, respiration, etc.) from discrete-time signal
- Relate time-domain behaviour to frequency domain content of discrete time signals
- Implement simple digital filters

Rough Syllabus (by weeks)

https://www.seas.upenn.edu/~ese3400/

ESE3400: Medical Devices Lab

Lec 1: August 31, 2022

Introduction and Overview

Where I come from

- Analog VLSI Circuit Design (analog design)
- Convex Optimization (system design)
  - System Hierarchical Optimization
- Biomedical Electronics
- Biometric Data Acquisition (signal processing)
  - Compressive Sampling
- ADC Design (mixed signal)
- Low Energy Circuits (digital design)
  - Adiabatic Charging

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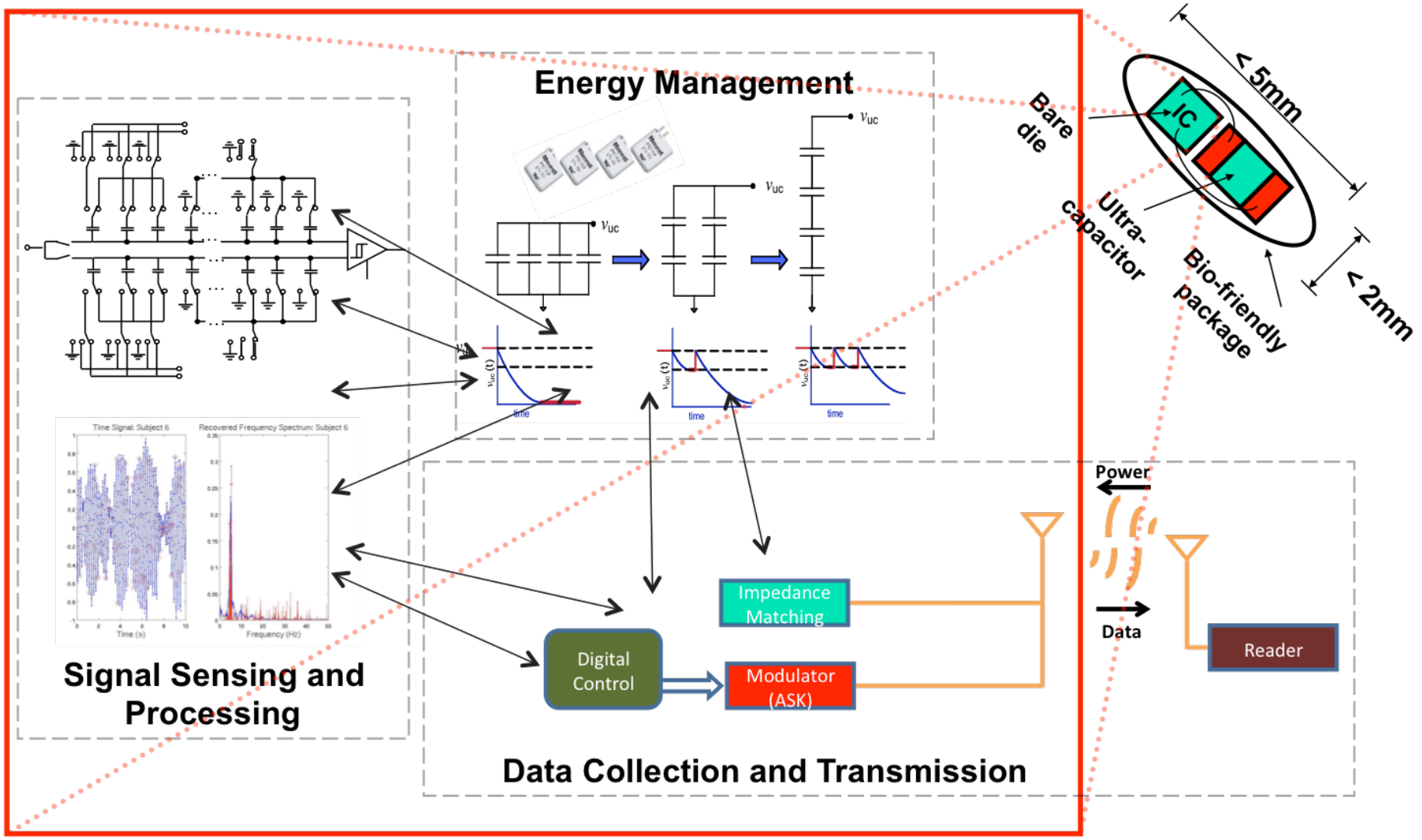
CIRCUITS, CIRCUITS, CIRCUITS

MicroImplant: An Electronic Platform for Minimally Invasive Sensory Monitors



Course Structure: Staff

- Course Staff (complete info on course website)
- Instructor: Tania Khanna (she/her)
  - In person OH: W 1-2:30 pm
  - Or OH by appointment
  - Email: taniak@seas.upenn.edu
    - Best way to reach me

TA: Sydney Sofronici

- PhD Student in Troy Olsson research group
- Undergraduate degree in Biomedical Engineering
- In person OH:
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Lecture Outline

- Course Overview
  - Motivating questions and examples
  - What this course is about
  - Learning objectives
  - What you need to know
- Course Details
  - Course structure
  - Course policies
  - Course content

Medical Devices

- An apparatus used in the diagnosis, mitigation, therapy, or prevention of a disease not through a chemical action (i.e is not a drug)
- Eg.
  - Blood pressure monitor *diagnoses* hypertension
  - Ablation catheter destroys Barret's esophagus precancerous cells *mitigates* the spread of cancer
  - Cochlear implant is *therapy* for hearing ability
  - A condom *prevents* STI infection

Motivating Questions

- What is the clinical need?
- What biometric signals are needed if any?
  - What sensors can acquire this?
  - Is diagnosis needed?
- What medical intervention/stimulation is needed?
  - Electrical stimulation for mitigation or therapy?

Motivating Questions (con't)

- What is the use model of the device?
  - Long term/short term use?
  - Does it need to be mobile?
  - Power source/management?
  - Is it wearable or implantable?
  - Data management/transmission?
- Patient and operator safety concerns?

Sample Medical Device

- Surgical/N95 masks

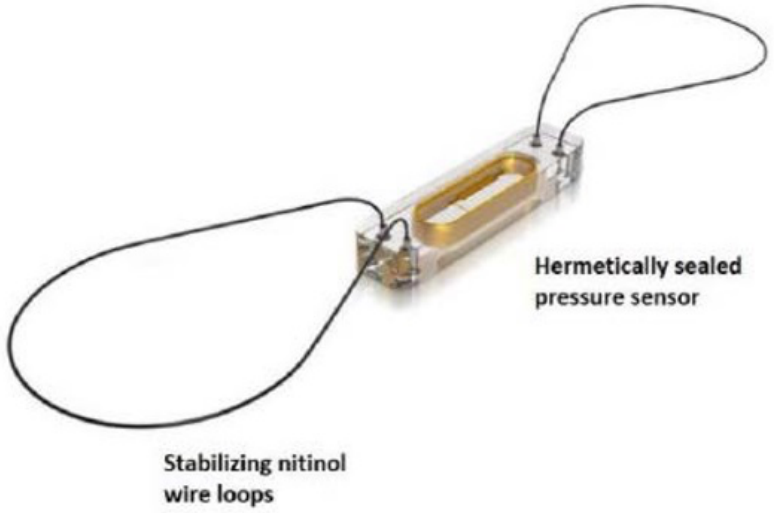
Sample Medical Device

- IV administration set

- Cosmetic filler injection

Electrical Medical Devices

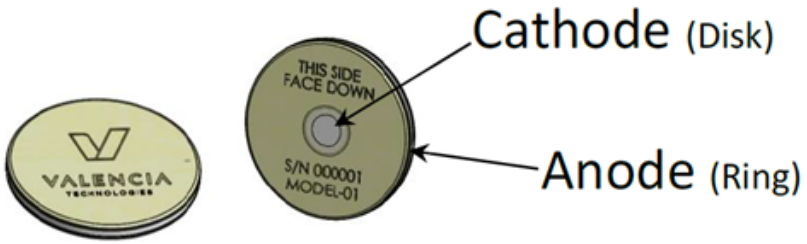
- CardioMEMS HF System



- The CardioMEMS HF System wirelessly measures and monitors pulmonary artery (PA) pressure and heart rate for patients with heart failure. The system consists of an implantable pulmonary artery (PA) sensor, delivery system, and patient electronics system.

Electrical Medical Devices

- eCoin Peripheral Neurostimulator



- The eCoin Peripheral Neurostimulator System generates electrical pulses to help stimulate nerves related to bladder control in people with urgency urinary incontinence, or a sudden urge to urinate that causes some urine to leak out. The device is implanted under the skin near the ankle and is controlled by a healthcare provider using a remote control.

Electrical Medical Device

- Nucleus 24 Cochlear Implant System

- The Nucleus 24 Cochlear Implant System is an implant that gives a person access to sound by directly stimulating the hearing nerve (auditory nerve). The cochlear implant system consists of an internal and an external component.

Electrical Medical Devices

- Eversense E3 Continuous Glucose Monitoring System

- The Eversense E3 Continuous Glucose Monitoring (CGM) System gives real-time blood sugar (glucose) readings every five minutes for people with diabetes. The system consists of an implantable fluorescence-based sensor, a transmitter, and a mobile app for displaying glucose values, trends and alerts on the patient's compatible mobile device (smart phone, tablet, etc.).

FDA Medical Device Approval

- FDA regulating medical devices since 1938
  - For safety since 1960s…

- List of recently approved medical devices:
  - https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/recently-approved-devices

Course Objective

- Acquire a thorough understanding of the basic principles and challenges of medical device design
  - Focus on concepts that are unlikely to expire
  - Preparation for further study of state-of-the-art "fine-tuned" realizations (I.e. Picking the right part for the right problem)
- Strategy
  - Acquire breadth via a complete system walkthrough and a survey of existing medical device systems
  - Acquire depth through hands-on lab based project
    - EKG with wireless communication via Bluetooth

Learning Objectives

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Learning Objectives

- In other words…

  - Hands on lab experience

What you need to know

- ESE 2150 and ESE 2240 are recommended, but not necessary
- We will cover what we think you need to know broadly

Course Structure: Websites

- Website (http://www.seas.upenn.edu/~ese3400/)
  - Course calendar is used for all handouts (lecture slides, lab handouts, and readings)
  - Canvas used for assignment submission and grades
  - Ed Discussion used for announcements and discussions

ESE3400 Fall 2022 Working Schedule

Wk	Lect.	Date		Lecture	Slides	Due	Reading
1		8/30	T	No Lab			review course webpage completely
	1	8/31	W	Intro/Overview			
2		9/5	M	Labor Day			
		9/6	T	Lab 1: Sensors			
	2	9/7	W	Biomedical Platforms/Systems			2.2.3
3	3	9/12	M	Sensing Principle			2.1.2
		9/13	T	Lab 2: Filters			
	4	9/14	W	Bionetric Signals			2.2.1.1
4	5	9/19	M	Physical and Chemical Sensors			2.2.1.1, 2.2.2, 3.1
		9/20	T	Lab 3: LT SPICE Tutorial			
	6	9/21	W	Signal Condiitoning			3.2, 3.3
5	7	9/26	M	Interface Circuits, Pt 1			3.4
		9/27	T	Lab 4: Signal Conditioning (Breadboard Level)			
	8	9/28	W	Interface Circuits, Pt 2			3.4
	9	10/3	M	Thread Based Devices			2.3

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Course Structure: Lectures

- Mask required
- MW 5:15pm Lecture in Moore 212
- Statistically and empirically speaking, you will do better if you come to lecture
- Better if interactive, **everyone** engaged
  - Asking and answering questions
  - Actively thinking about material every day

Course Structure: Labs

- Required Attendance
  - Contact me ahead of time for extenuating circumstances
- Individual Labs with deliverables
  - Data with findings and conclusions
  - Demo or video demo

Course Structure: Textbook

- Textbook
  - S. Sonkusale, M. S. Baghini, S. Aeron, *Flexible Bioelectronics with Power Autonomous Sensing and Data Analytics*, Springer, 2022
  - G. Baura, *Medical Device Technologies,* 2nd Edition, Academic Press, 2020
  - A. V. Oppenheim and R. W. Schafer (with J. R. Buck), *Discrete-Time Signal Processing.* 3rd. Edition, Prentice-Hall, 2010
- Not required, but readings on website corresponds to these texts if you want more information/further reading

Course Structure: Labs/Quizzes

- Labs – 10 total [30%]
  - Deliverables due by next lab period
  - Submit/demo in lab or submit in Canvas if more time is needed
- Final demo/presentation – Built-up through labs [40%]
  - Final demos and presentations in last week of class
- Quizes – 2 total [30%]
  - In class

Course Structure: Admin

- Use course calendar
  - Lectures online before class
    - Reserve the right to change them (usually minor)
  - Labs linked
  - Reading for whole term specified
    - Optional, mostly for more information/further reading

Course Policies

- Individual work (HW & Project*)
  - CAD drawings, simulations, analysis, writeups, presentations
  - May discuss strategies, but acknowledge help

Course Content

- Signal Sensing/Conditioning [6 weeks]
- Data conversion/Sampling [3 weeks]
- DSP/Digital Communication [3 weeks]

Course Content (con't)

- Signal Sensing/Conditioning
  - Biometric Signals
  - Sensing Principle
  - Signal Conditioning
    - Signal amplification
    - Continuous time filtering
- Labs: sensors, filters, signal conditioning (simulation and bread boarding), PCB design

Course Content (con't)

- Data conversion/Sampling
  - DSM and SAR ADCs
  - Sampling and reconstructions
  - Compressive Sampling
- Labs: Data convertor characterization

Course Content (con't)

- DSP/Digital Communication
  - Discrete time signals and systems
  - Oversampling and Noise Shaping
  - Digital Filters
  - Wireless communication (Bluetooth)
- Labs: Python DSP labs, Bluetooth communication

Big Ideas

- Medical devices are used in diagnosis, mitigation, therapy and prevention
  - Broad definition and we will focus on the electrical component

Admin

- Find web, get text, assigned reading…
  - http://www.seas.upenn.edu/~ese3400
  - https://edstem.org/us/courses/27462/discussion/
  - https://canvas.upenn.edu/courses/
- To do:
  - Come to lab on Tuesday!