Introduction to Medical Device Prototyping

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Purpose of the Course
- Learning about conceiving, designing and building a medical device prototype.
- Learning technical skills and working in teams.
- Appreciation of the numerous resources available to you.
- Preparation for Senior Design projects.
- Improving opportunities for internships and employment.

Course Content
- Engineering drawing with SolidWorks.
- Rapid prototyping with 3D FDM printing.
- Fabrication with machine tools (saws, drill, lathe and mill), and laser and water jet cutters.
- Biomaterials and biocompatibility.
- Analog and digital electronics simulation, breadboarding and making circuit boards.
- Microcontroller programming, and interfacing with various sensors and actuators.
**Example: An Epinephrine Injector**

![Image of an Epinephrine Injector]

**Design Objectives & Mechanism...**

![Diagram of Design Objectives & Mechanism]

**Engineering Drawings..**

![Engineering Drawings of the Epinephrine Injector]
Definition of a Medical Device (ISO)

- Any instrument, apparatus, appliance, material or other article, including software, whether used alone or in combination, intended by the manufacturer to be used for human beings solely or principally for the following purposes:
  - Diagnosis, prevention, monitoring, treatment or alleviation of disease;
  - Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
  - Investigation, replacement or modification of the anatomy or of a physiological process;
  - Control of conception.

Example: Ultrasonic Mobility Aid
Example: A Bladder Clot Irrigation Kit

A Cervical Extrication Collar

Example: A Stair Guidance System
**Example**: Data Processing for Lung Bx

**SolidWorks & Computer Aided Design**

**Workstations**

Earl E. Bakken Medical Devices Center
Anderson Student Innovation Labs in Mechanical engineering
3D FDM Printing...

Anderson Labs in Mechanical Engineering...

Machining & Assembly...

Hardinge Lathe

Bridgeport Mill

Student Machine Shop

MECHE 176
Biomaterials & Biocompatibility...

- Abdominal aortic aneurysm graft.

Polymer Properties & Uses...

The WATCHMAN LAAC Device is a catheter-delivered heart implant designed to close the left atrial appendage (LAA). PET knit fabric mesh.

Access sheath is made from Polytetrafluoroethylene (PTFE) (Teflon).

Fabricating Electronic Circuits...
Transistor Amplifier #1

Amplifiers are an analog circuit and we operate the transistor in its linear region.

Specifications:
1. AC voltage gain of 4 (V_{in} to V_{out}).
2. Peak to peak signal swing of 4 V.
3. Transistor beta is 100.
4. I_{c} is 10 mA
5. V_{CBO} or V_{c} is set at 8 V (swings 6-10 V).
6. V_{CE} and V_{c} are set at 4 V. This keeps the transistor linear.
7. V_{BE} is 0.6 V.


Common Emitter Amplifier

f(t) = \frac{1}{t^2 + t + 0.01}

f(t) = \frac{1}{2t}

V_{in} = \frac{-200 k\Omega \times 0.01 \mu F \times 1}{2 \mu F} \times 0.005 s

V_{out} = 0.8 V

V_{in} = \frac{2 \times 0.8 V \times 2 \mu F}{200 k\Omega}

V_{out} = 0.8 V

Triangle wave input and square wave output.

Symmetric 100 Hz triangle wave with peak voltage of 1 volt range as a 2 volt peak to peak.


Designing Digital Circuits...

4-Bit Binary Counter
Breadboarding Your Designs...

Designing Circuit Boards...

Using Microcontrollers

Debouncing a Pushbutton
**Incorporating Sensors and Actuators…**

![Diagram of sensors and actuators]

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**Industry Tour**

Tour of Smiths Medical 3D polyjet printing facility and intensive care unit simulation.

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**Website – Lectures**

- [Lecture Notes](#)
- [CAGI Website](#)
- [CAD/CAE Website](#)

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Purpose & Content of the course.
Definition of a medical device.
Evolution of a medical device.
Senior design project examples.
Earl E. Bakken Medical Devices Center and the Anderson Student Innovation Labs.
Industry tour.
Website