Introduction to Medical Device Prototyping

Prof. Steven S. Saliterman
Introductory Medical Device Prototyping
Department of Biomedical Engineering, University of Minnesota
http://saliterman.umn.edu/

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 the Senior Design course.
- 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 programing, and interfacing with various sensors and actuators.
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.

An Ultrasonic Bracelet Mobility Aid
Triangle of Dependancy

Medical Device Companies and Entrepreneurs

Innovation

Universities and Government

Patients and Physicians

A Bladder Clot Irrigation Kit

A Cervical Extrication Collar
SolidWorks & Computer Aided Design...

Workstations...

3D FDM Printing...
Anderson Labs in Mechanical Engineering...

Machining & Assembly...

Biomaterials...

- Abdominal aortic aneurysm graft.

(Left) Image Courtesy of NIH Medline Plus
(Center & Right) Images courtesy of Medtronic
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).

Understanding Biocompatibility...

Slight irritation - mild infiltration of lymphocytes. Severe lymphohistiocytic response. Fibrous encapsulation around a previously implanted test material.

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. \(V_{out}\) or \(V_e\) is set at 8 V (swings 6–10 V).
6. \(V_{cc}\) and \(V_{be}\) are set at 4 V. This keeps the transistor linear.
7. \(V_{be}\) is 0.6 V.

Symmetric 100 Hz triangle wave with peak voltage of 1 volt (same as 2 volt peak to peak).

Differentiator


4-Bit Binary Counter
**Breadboarding Your Designs**

**Designing Circuit Boards**

**Using Microcontrollers**
Incorporating Sensors and Actuators...

Industry Tour

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

Summary

- 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.