Introduction to Medical Device Prototyping

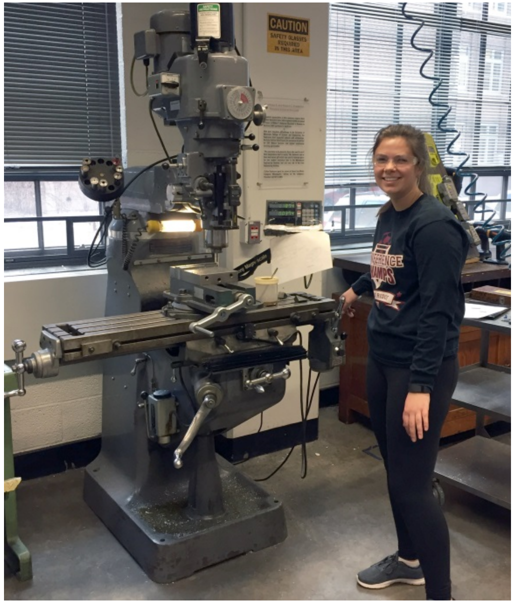
Prof. Steven S. Saliterman
Introductory Medical Device Prototyping
Department of Biomedical Engineering, University of Minnesota
http://saliterman.umn.edu/

Purpose of the Course

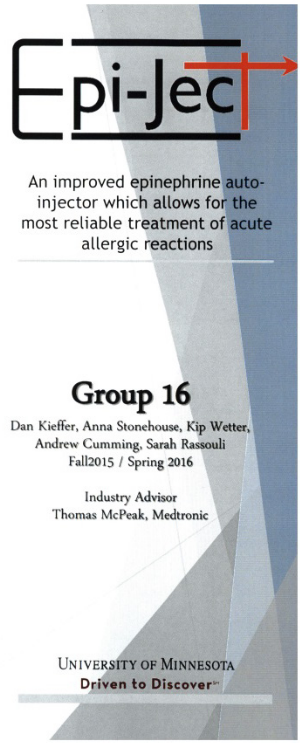
- Learning about conceiving, designing and building a medical device prototype.
- Learning *technical skills* and *working in teams*.
- Appreciation of the numerous *resources* available to you.
- Preparation for *Senior Design* projects.
- Improving opportunities for *internships* and *employment*.

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 programing, and interfacing with various sensors and actuators.



Example: An Epinephrine Injector



Epi-Ject

An improved epinephrine auto-injector which allows for the most reliable treatment of acute allergic reactions

Group 16

Dan Kieffer, Anna Stonehouse, Kip Wetter, Andrew Cumming, Sarah Rassouli
Fall2015 / Spring 2016

Industry Advisor
Thomas McPeak, Medtronic

University of Minnesota
Driven to Discover

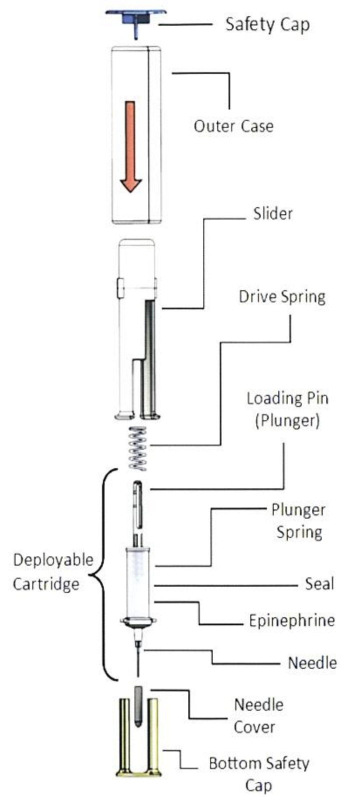
Design Objectives & Mechanism…

Epi-Ject's Design Objectives

The main objective of the Epi-Ject device design was to target the current market for epinephrine auto-injectors, and improve upon the limitations faced by current devices in this field. This device further aims to maintain the safety, portability, and ease of use that is achieved by current auto-injectors such as the EpiPen and Auvi-Q. The Epi-Ject accounts for the leading cause of device misuse, which is a reactionary and immediate removal of the needle from the patient's leg. The Epi-Ject's self-contained epinephrine cartridge is fully ejected from the device upon activation into the patient's leg. The outer shell of the device is able to be pulled back leaving the epinephrine cartridge to deliver the full amount of medication. The time of delivery for the full dosage of epinephrine is half that of devices that are currently on the market, increasing the likelihood of a full epinephrine dosage delivery.

COLLEGE OF Science & Engineering

UNIVERSITY OF MINNESOTA

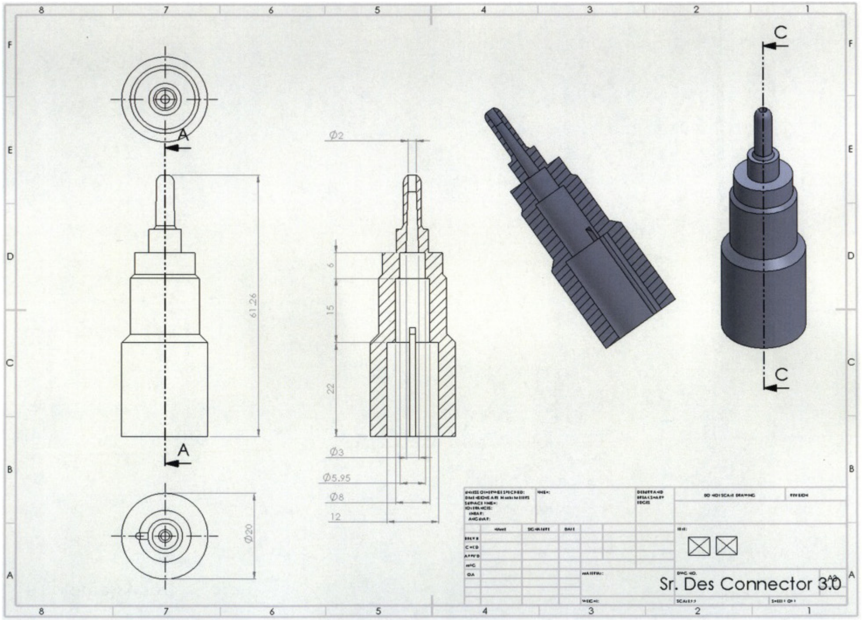


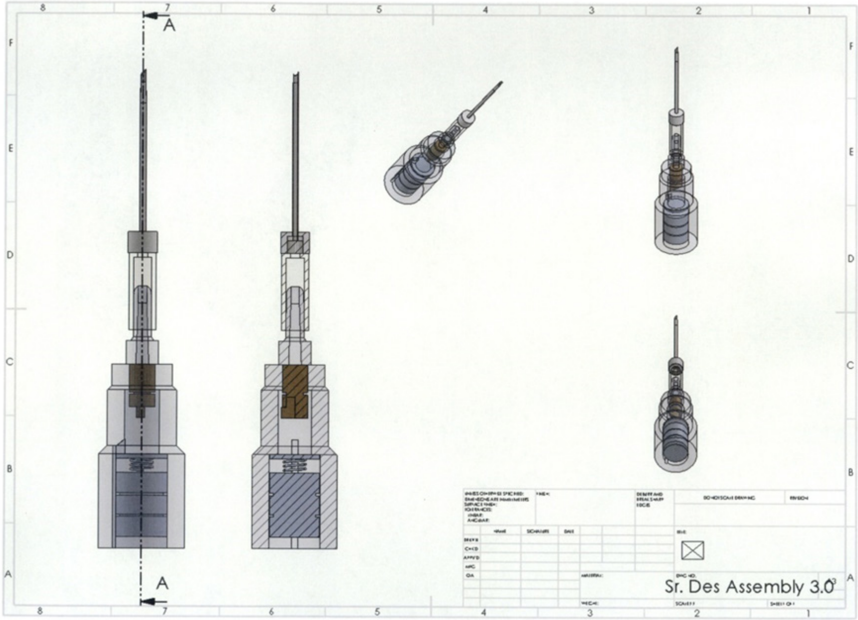
Mechanism of Action

The needle is injected into the thigh in the same manner as current auto-injectors

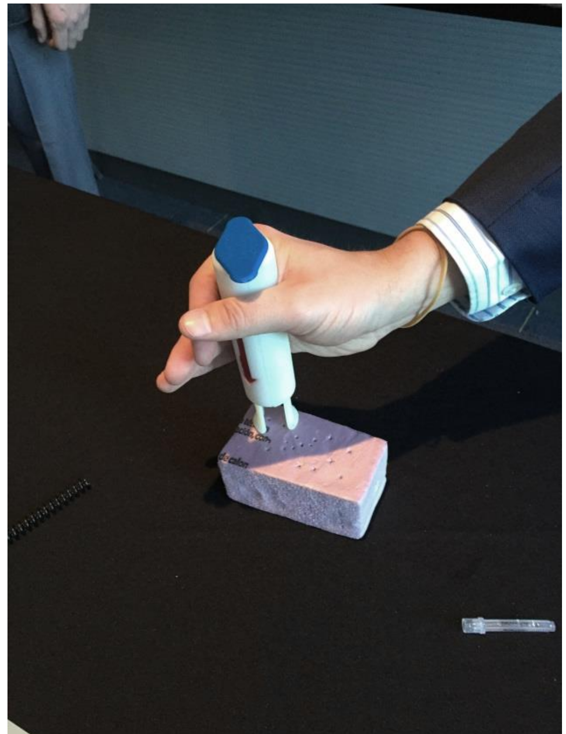
After the needle Is inserted into the thigh, the epinephrine injecting cartridge is ejected from the outer casing when there is an immediate reaction to pull back.

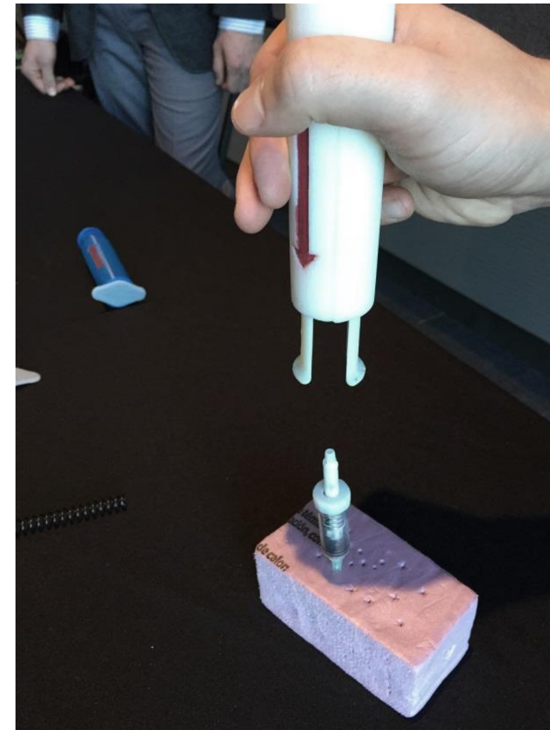
Engineering Drawings..





Demonstration…

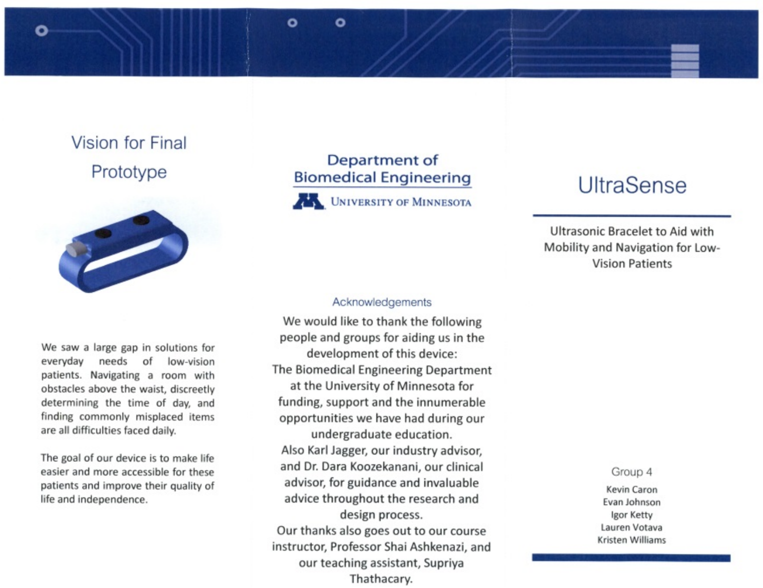




Definition of a Medical Device (ISO)

- 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


Vision for Final Prototype

We saw a large gap in solutions for everyday needs of low-vision patients. Navigating a room with obstacles above the waist, discreetly determining the time of day, and finding commonly misplaced items are all difficulties faced daily.

The goal of our device is to make life easier and more accessible for these patients and improve their quality of life and independence.

Department of Biomedical Engineering

University of Minnesota

Acknowledgements

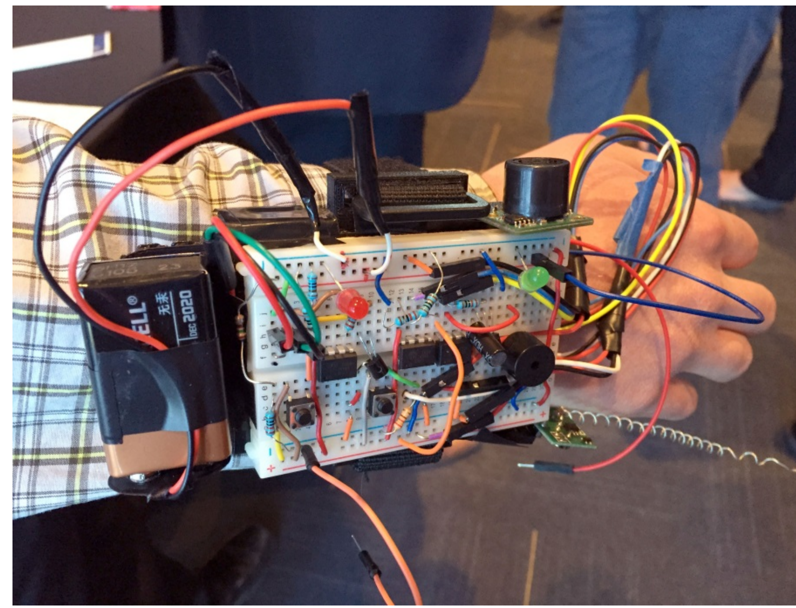
We would like to thank the following people and groups for aiding us in the development of this device:
The Biomedical Engineering Department at the University of Minnesota for funding, support and the innumerable opportunities we have had during our undergraduate education.
Also Karl Jagger, our industry advisor, and Dr. Dara Koozekanani, our clinical advisor, for guidance and invaluable advice throughout the research and design process.
Our thanks also goes out to our course instructor, Professor Shai Ashkenazi, and our teaching assistant, Supriya Thathacary.

UltraSense

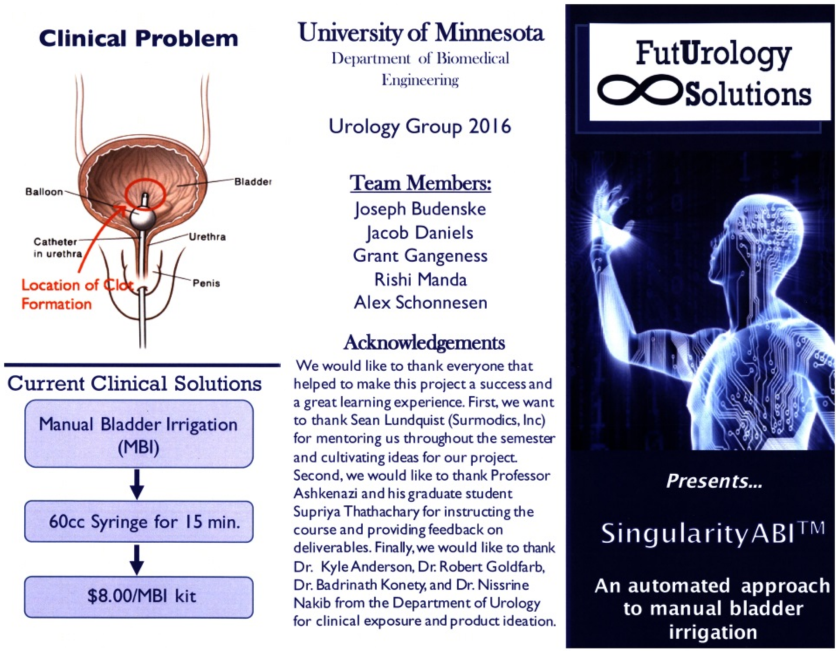
Ultrasonic Bracelet to Aid with Mobility and Navigation for Low-Vision Patients

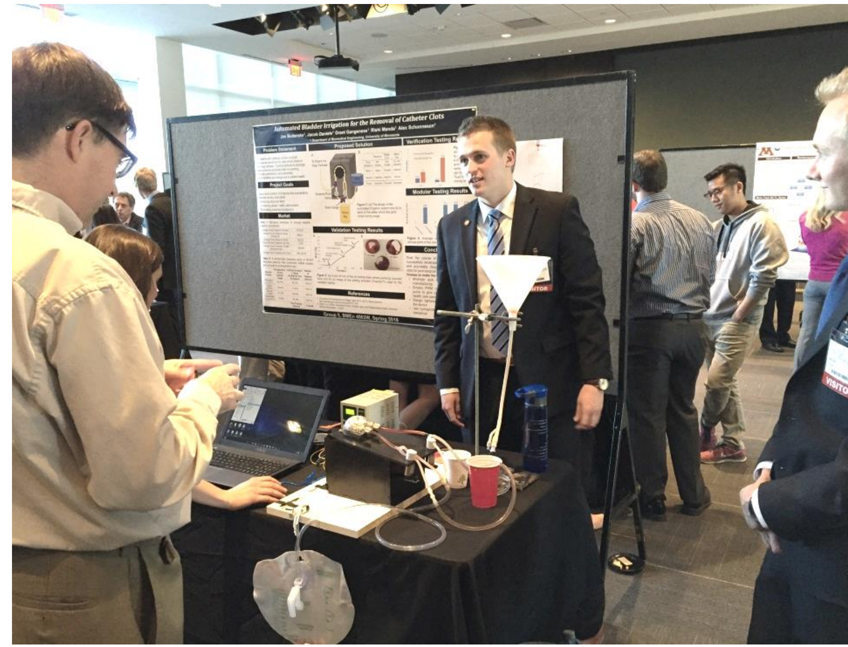
Group 4

Kevin Caron
Evan Johnson
Igor Ketty
Lauren Votava
Kristen Williams

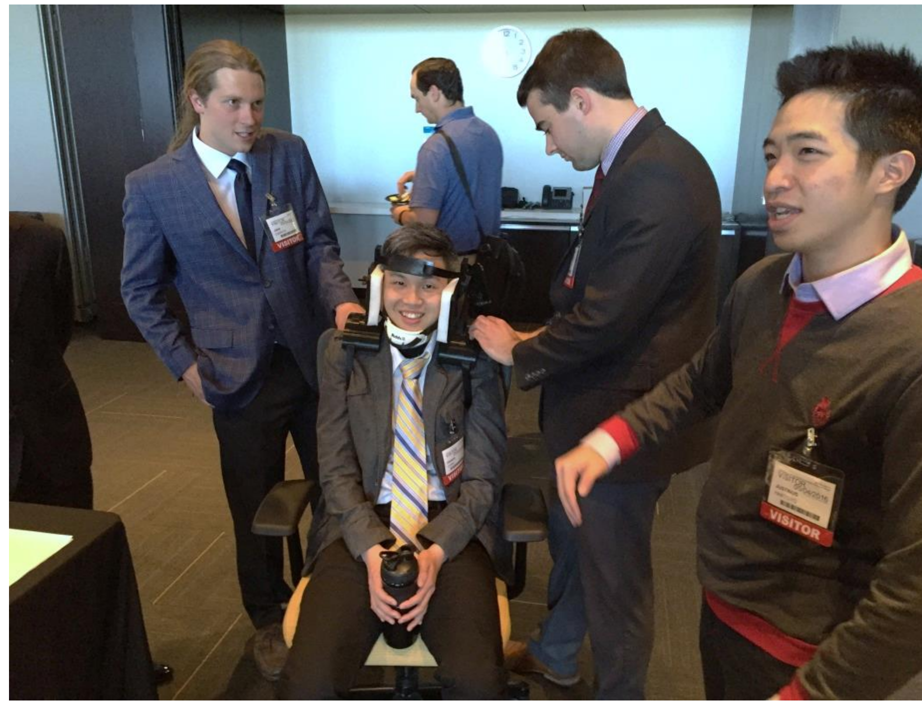


Example: A Bladder Clot Irrigation Kit





A Cervical Extrication Collar



Example: A Stair Guidance System

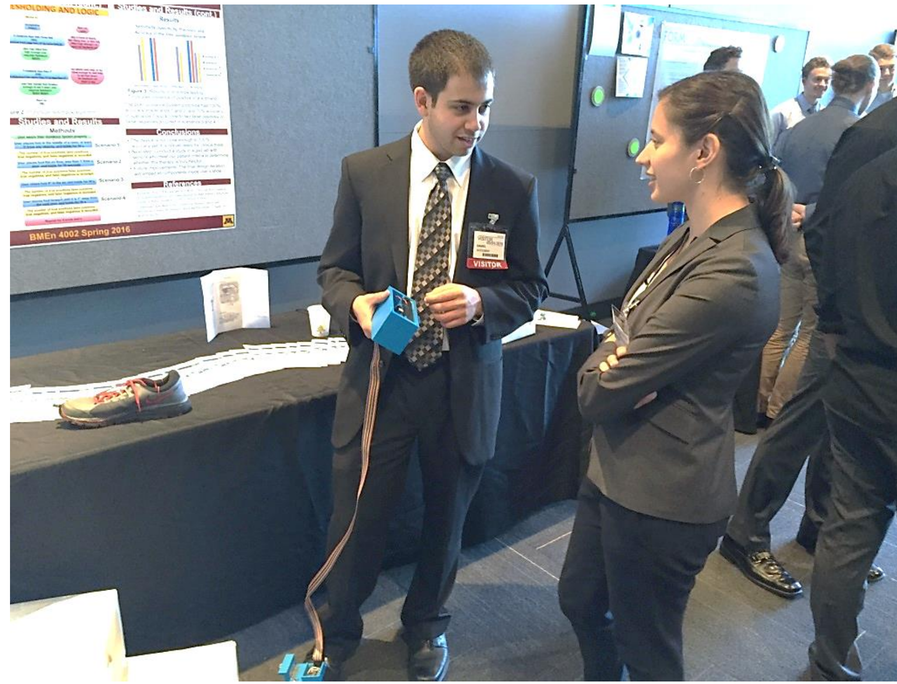
Stair Guidance System

Bringing Independence to Seniors

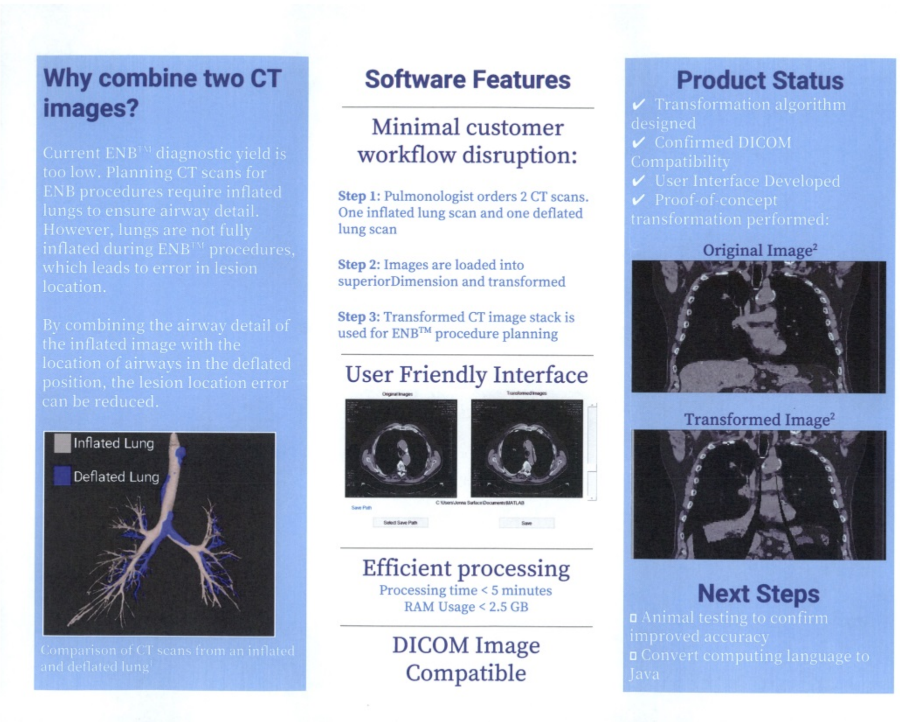
Spring 2016

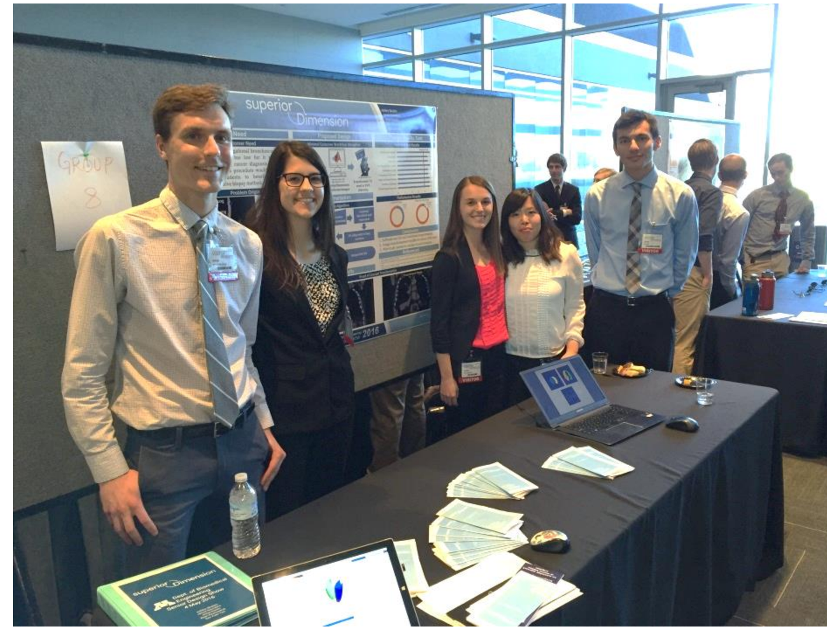
Mohab Eid | Daniel Goodman | Emily Gray Joseph Lombardi | Ahmed Youssef

Advised by Dr. Steven Saliterman

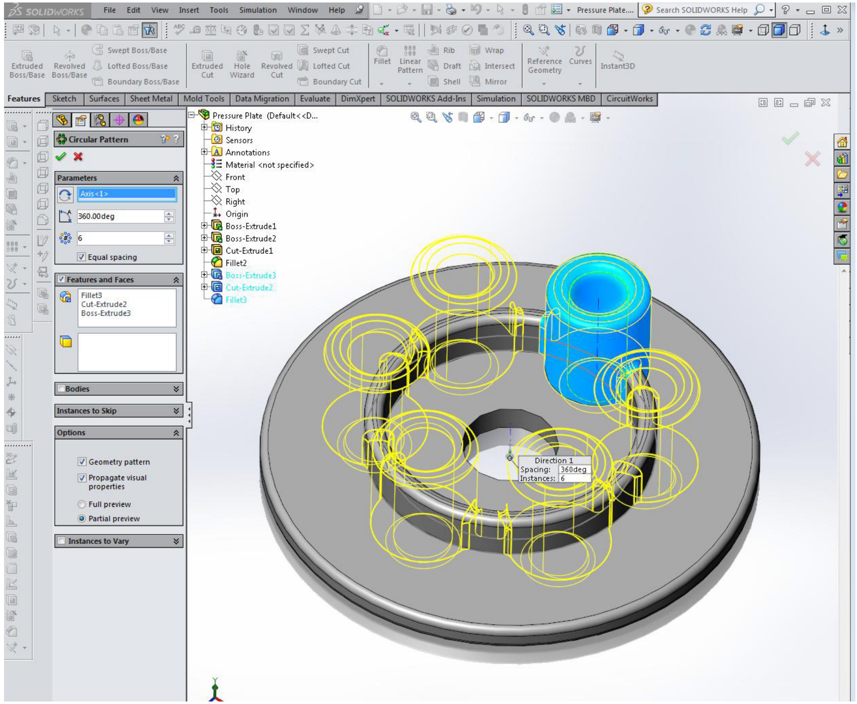


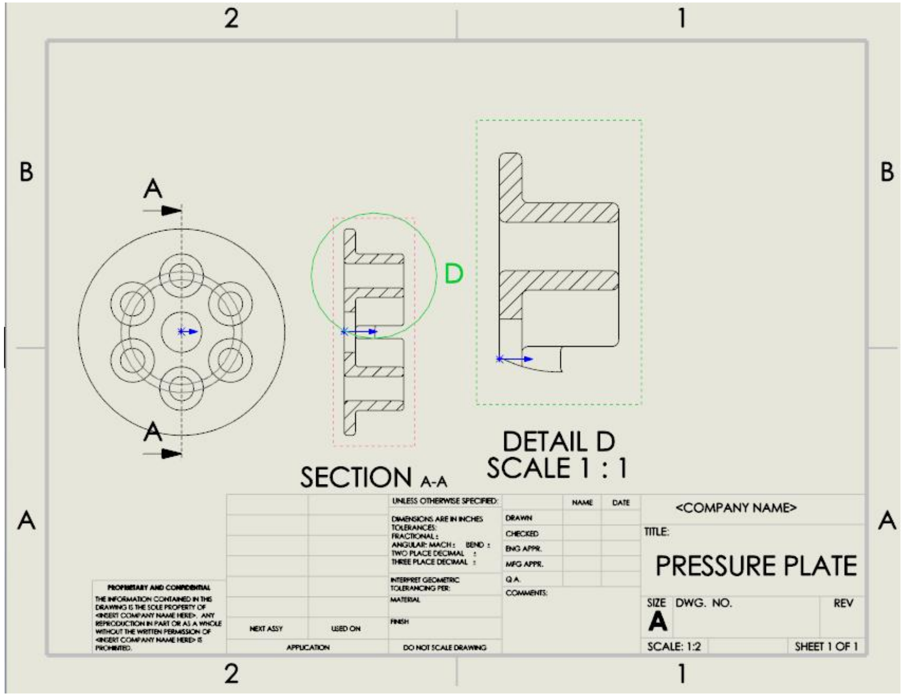
Example: Data Processing for Lung Bx





SolidWorks & Computer Aided Design…



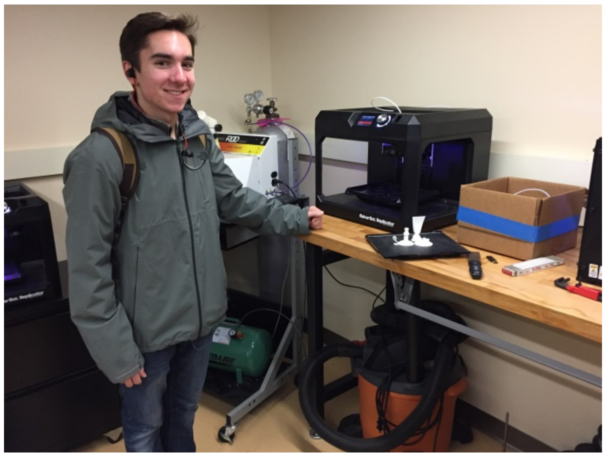


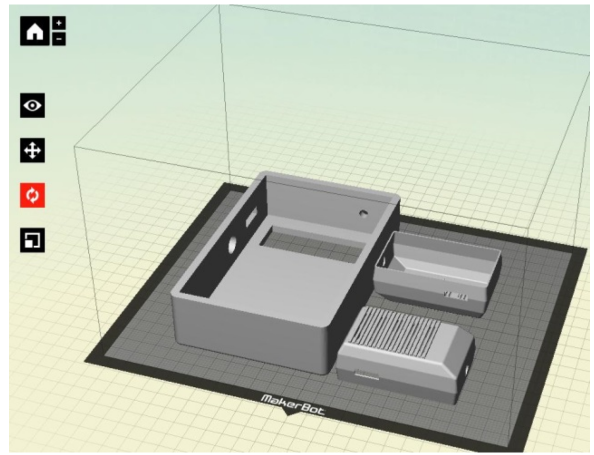
Workstations…

Earl E. Bakken Medical Devices Center

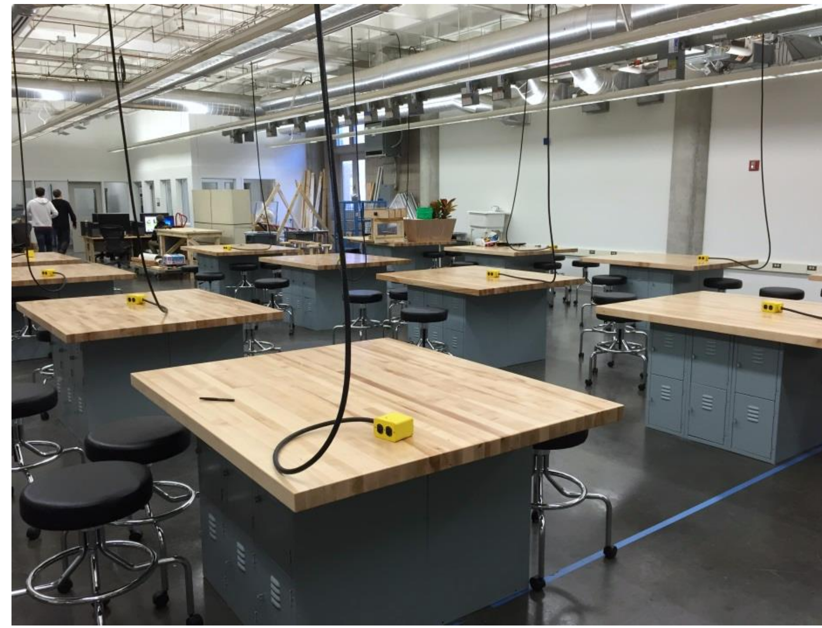
Anderson Student Innovation Labs in Mechanical engineering

3D FDM Printing…





Anderson Labs in Mechanical Engineering…



Machining & Assembly…

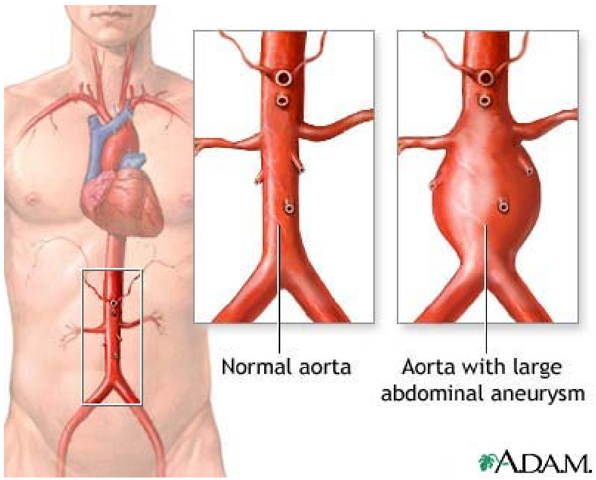
Hardinge Lathe

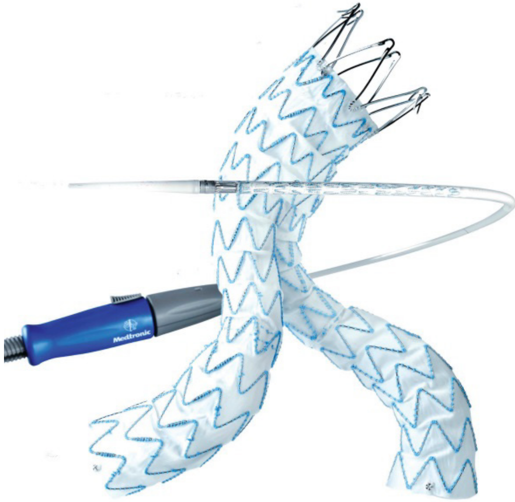
Bridgeport Mill

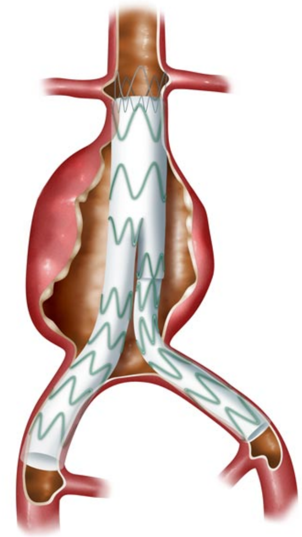
Student Machine Shop
MECHE 176

Biomaterials & Biocompatibility…

- Abdominal aortic aneurysm graft.

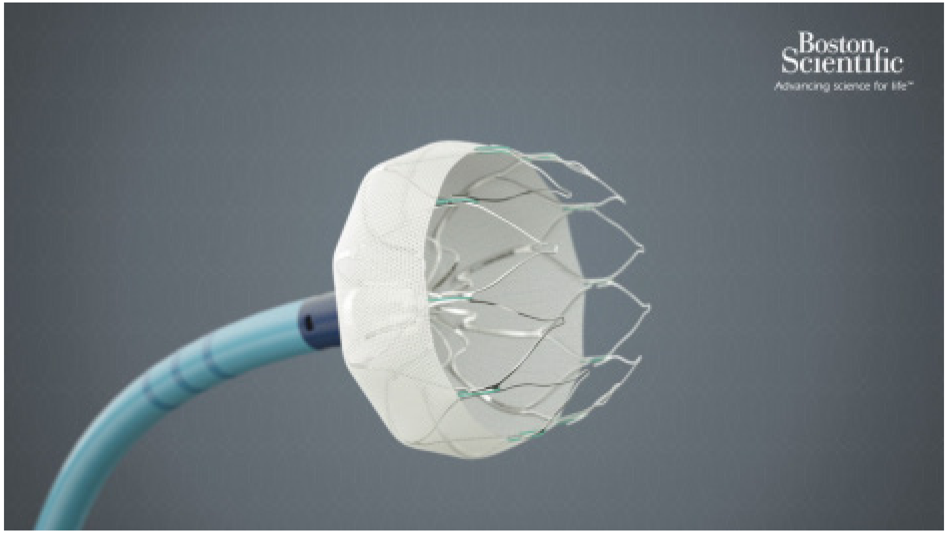




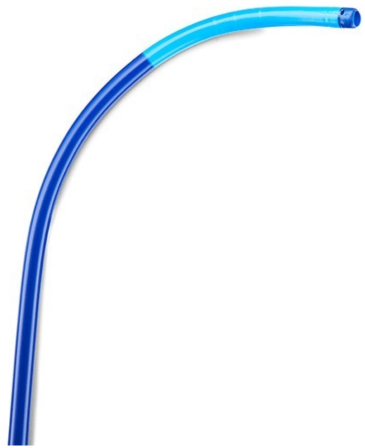


(Left) Image Courtesy of NIH Medline Plus
(Center & Right) Images courtesy of Medtronic

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.

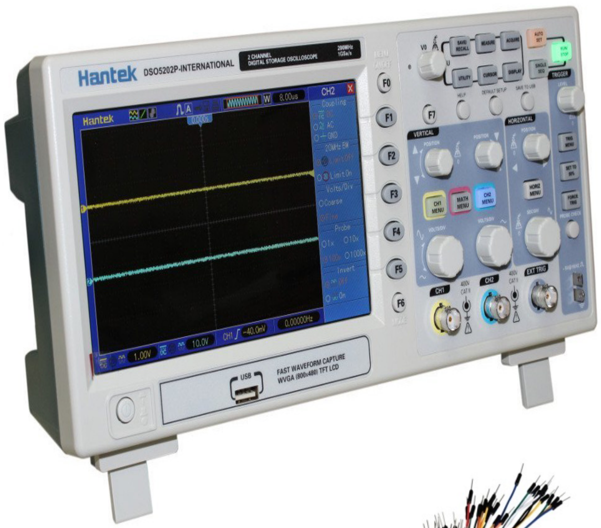


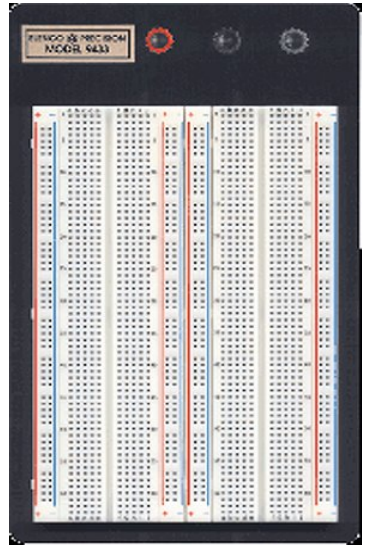
Access sheath is made from Polytetrafluoroethylene (PTFE) (Teflon)

Images courtesy Boston Scientific.

Electronics

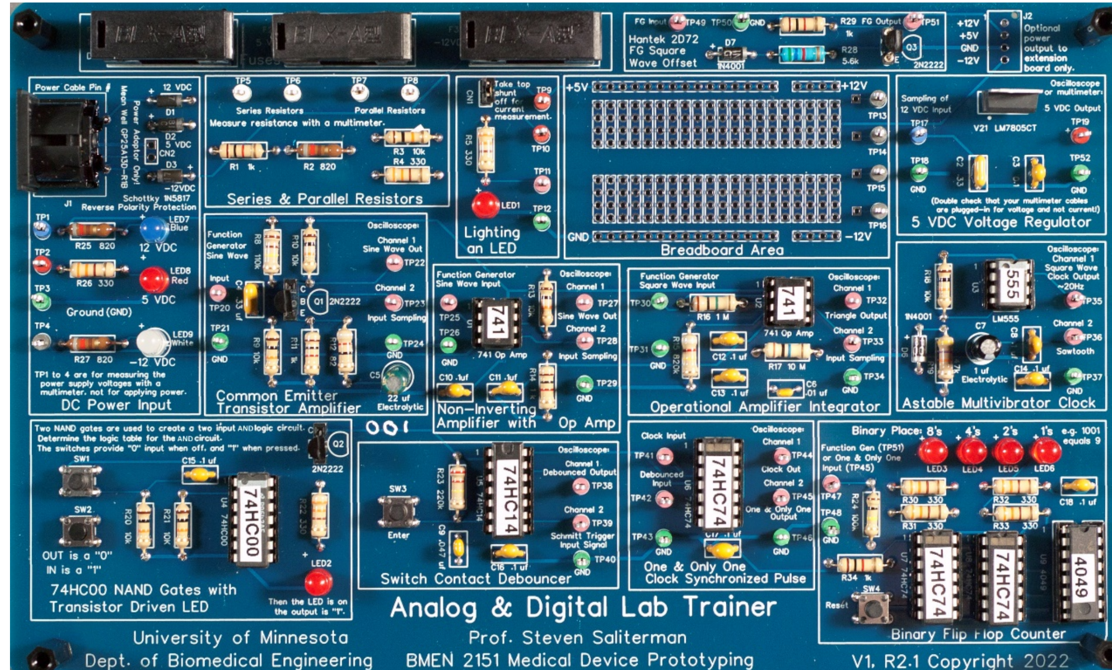
Traditional Bench Setup





New Home Lab Box Setup...

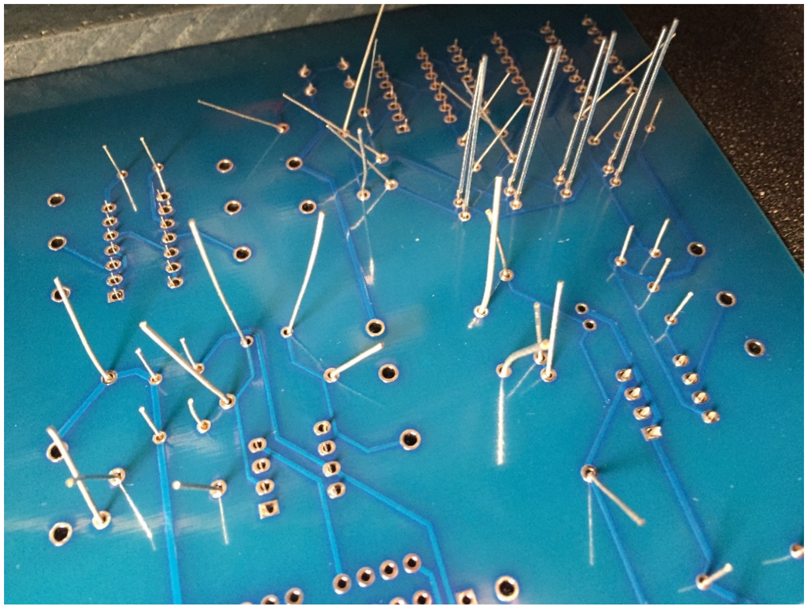
New Analog &Digital Lab Trainer…



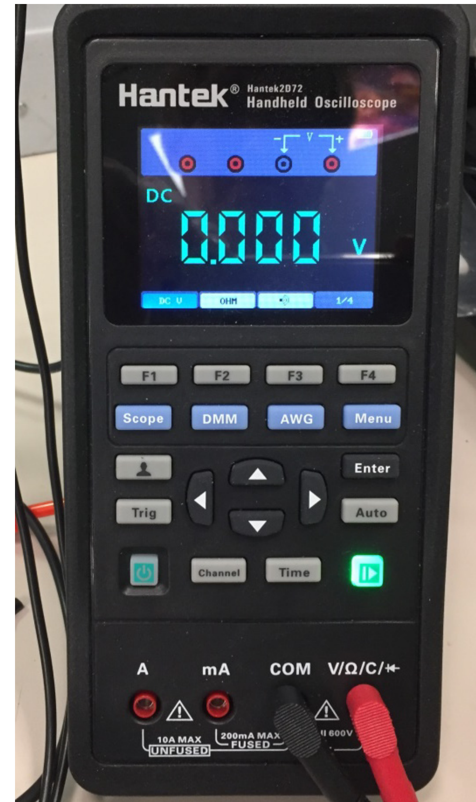
Populating a Board with Components

Prof. Steven S. Saliterman

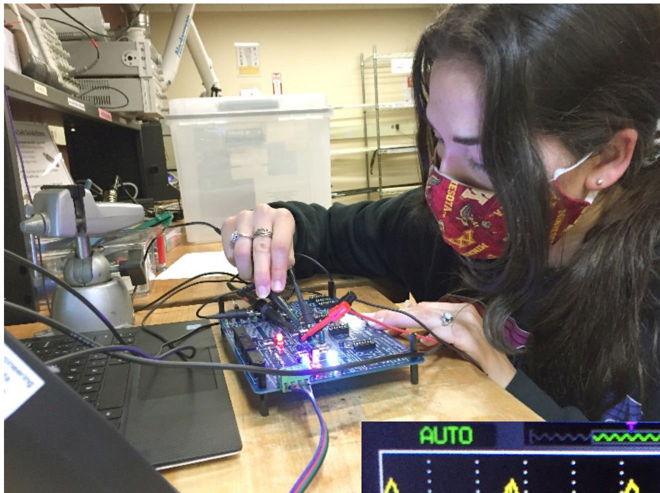
Assembly & Soldering…

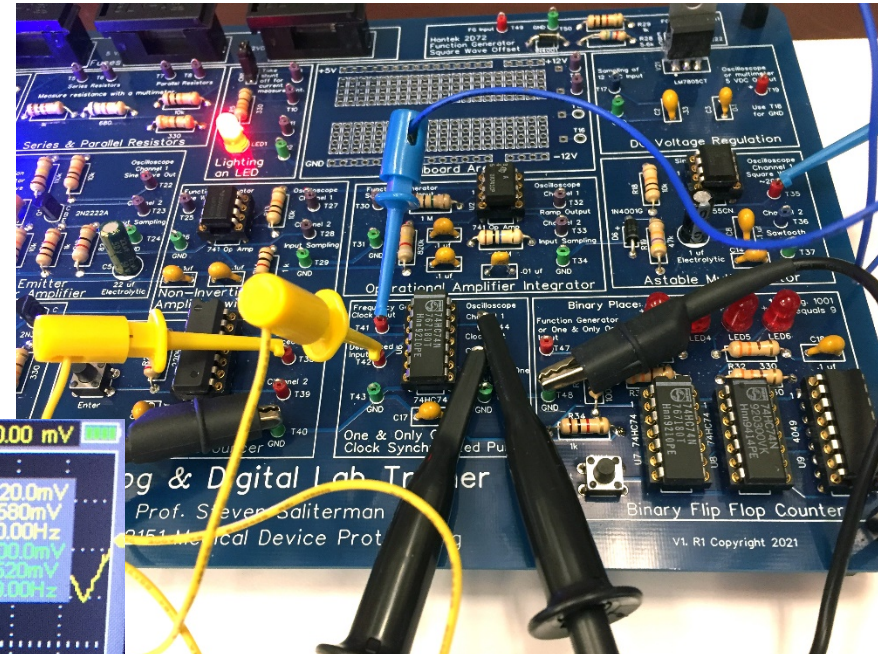


Three Instruments-in-One…

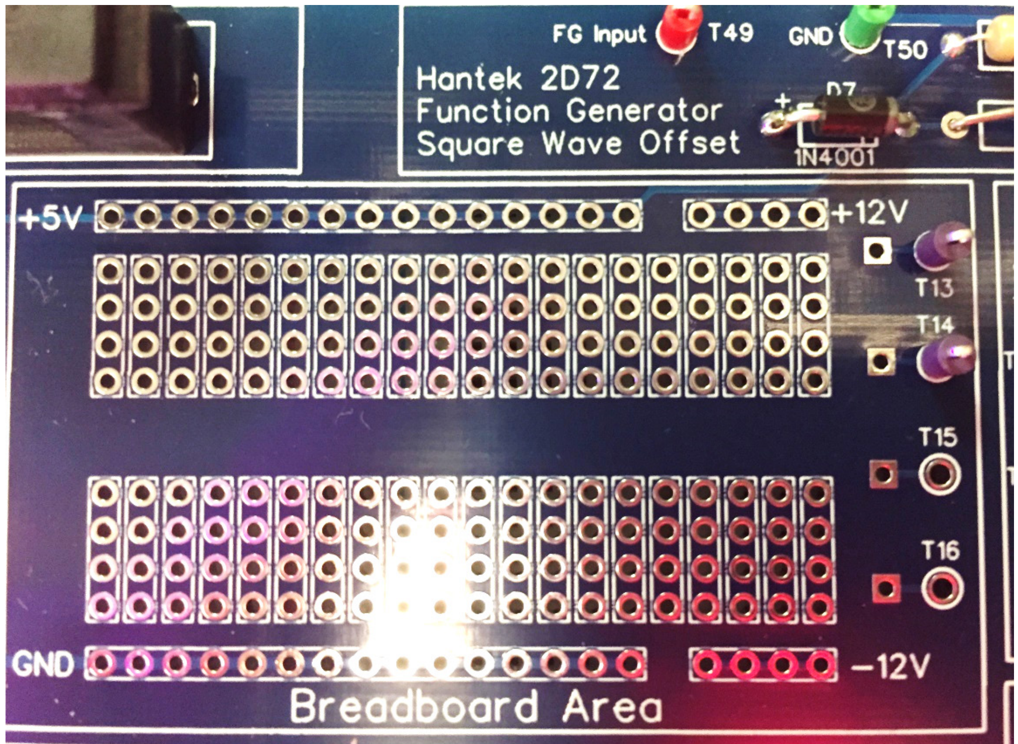


Signal Analysis…



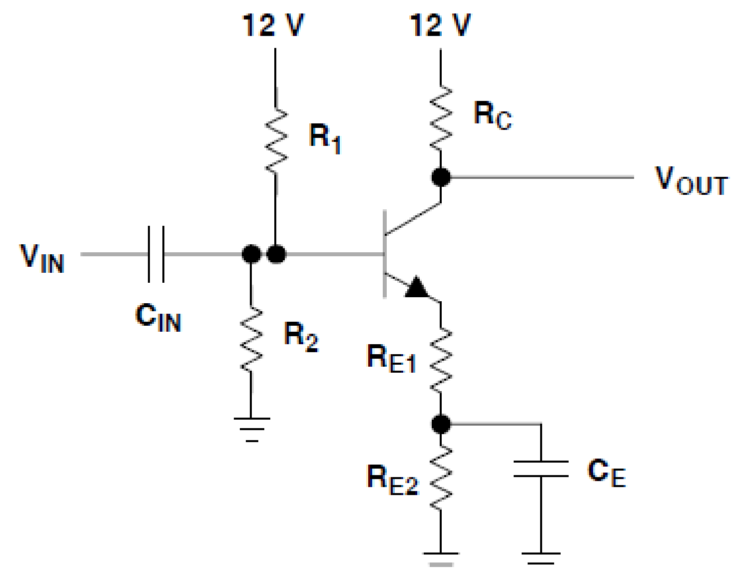


Breadboard Area for Sensors & Actuators…



Designing Analog Circuits…

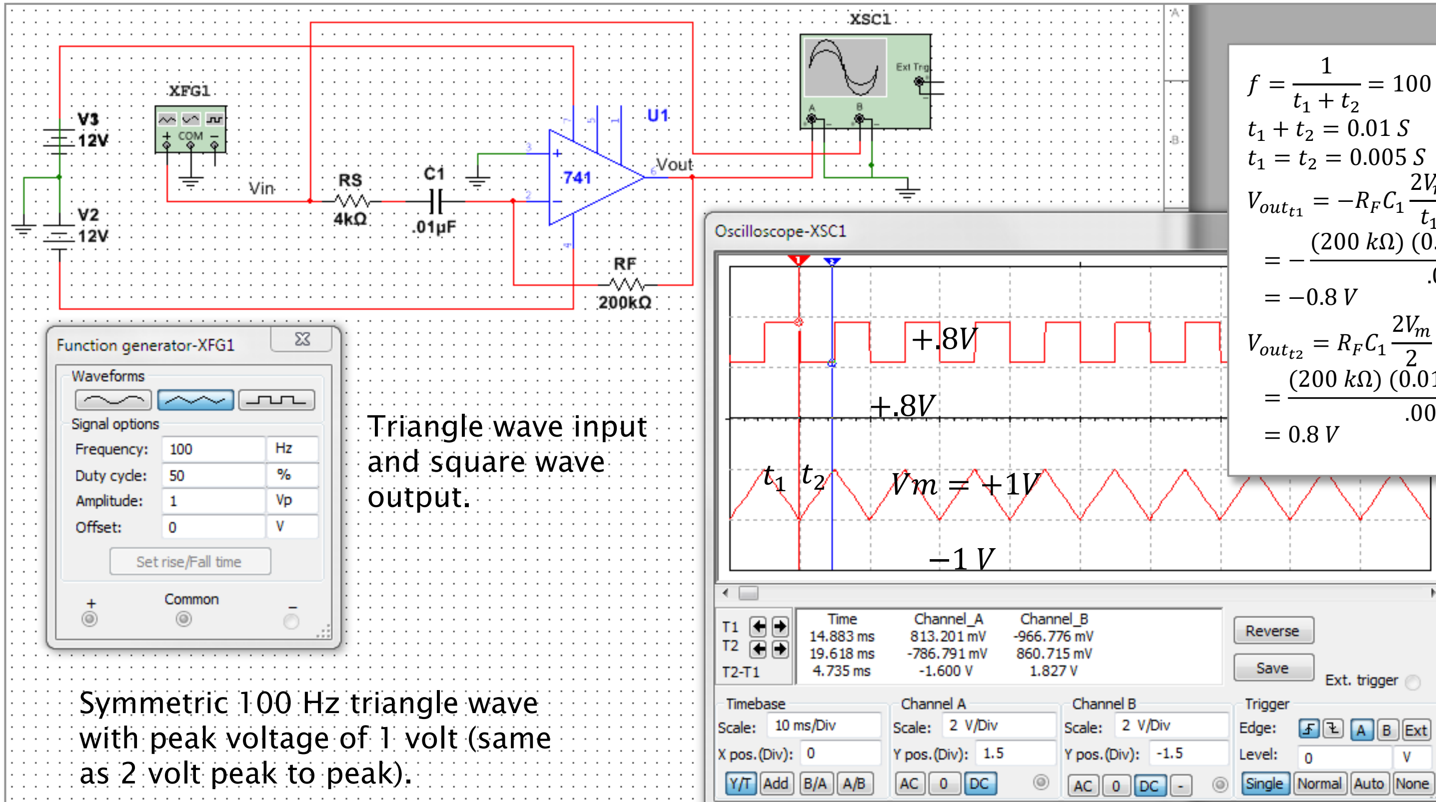
- Transistor Amplifier #1
- Amplifiers are an *analog circuit* and we operate the transistor in its *linear* region.
- Specifications:
  1. AC voltage gain of 4 (V_{in} to V_{out}).
  2. Peak to peak signal swing of 4 V.
  3. Transistor beta is 100.
  4. I_C is 10 mA
  5. V_{OUT} or V_C is set at 8 V (swings 6–10 V).
  6. V_{CE} and V_E are set at 4 V. This keeps the transistor linear.
  7. V_{BE} is 0.6 V.



Common Emitter Amplifier

Mancini, R . *Op Amps for Everyone*, Texas Instruments, Dallas, TX (2002)

Multisim (Simulation Program with IC Emphasis)…



Triangle wave input and square wave output.

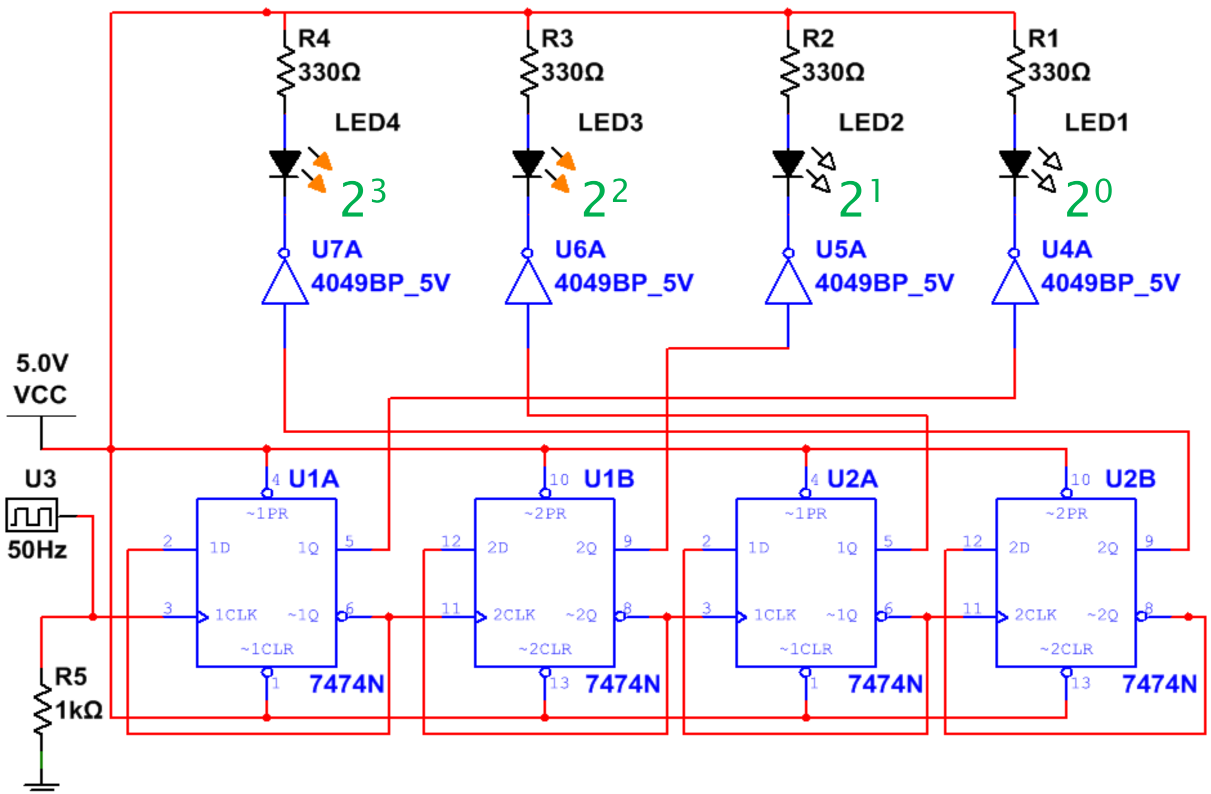
Symmetric 100 Hz triangle wave with peak voltage of 1 volt (same as 2 volt peak to peak).

$$f = \frac{1}{t_1 + t_2} = 100\ Hz$$
$$t_1 + t_2 = 0.01\ S$$
$$t_1 = t_2 = 0.005\ S$$
$$V_{out_{t1}} = -R_F C_1 \frac{2V_m}{t_1}$$
$$= -\frac{(200\ k\Omega)\ (0.01\ \mu F)\ (2)\ (1\ V)}{.005\ S}$$
$$= -0.8\ V$$
$$V_{out_{t2}} = R_F C_1 \frac{2V_m}{2}$$
$$= \frac{(200\ k\Omega)\ (0.01\ \mu F)\ (2)\ (1\ V)}{.005\ S}$$
$$= 0.8\ V$$

Differentiator

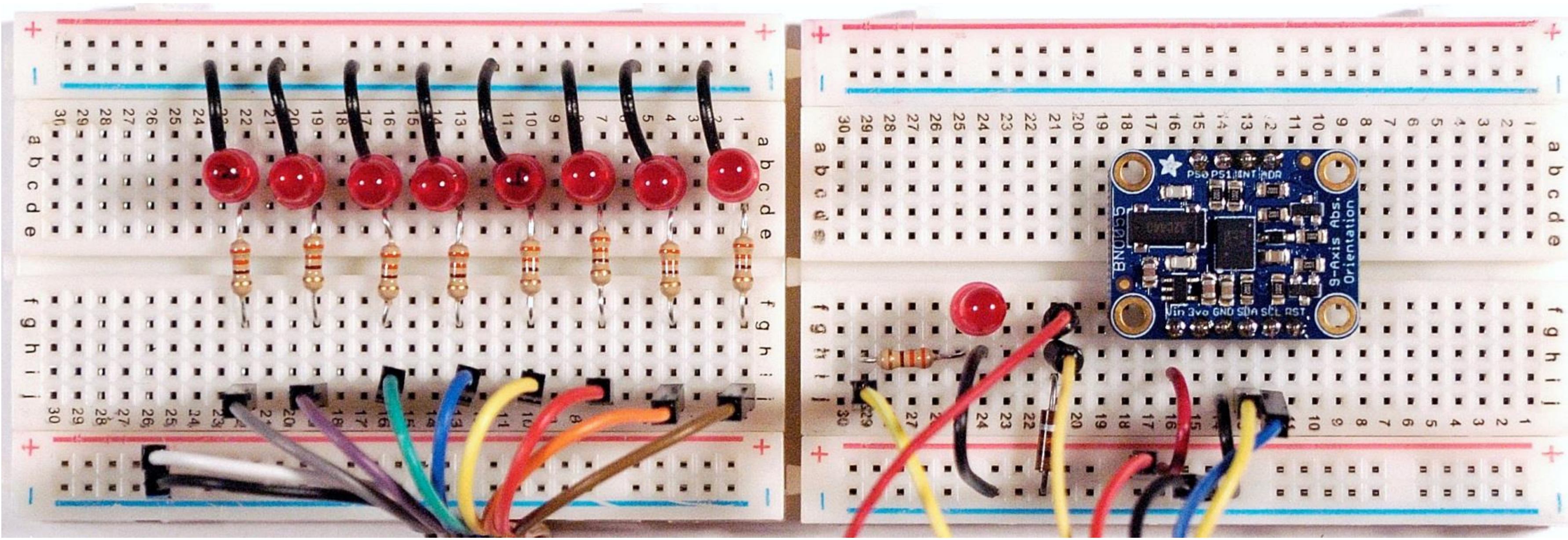
See *Differentiator* in Berlin, H.M., *Design of Op-Amp Circuits*, H.W. Sams, Carmel, IN (1977)

Designing Digital Circuits…

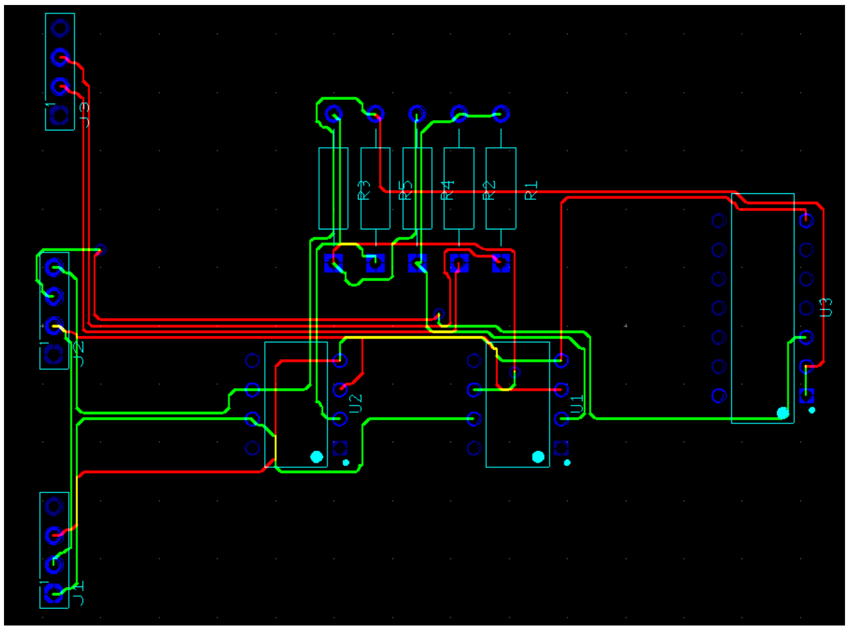


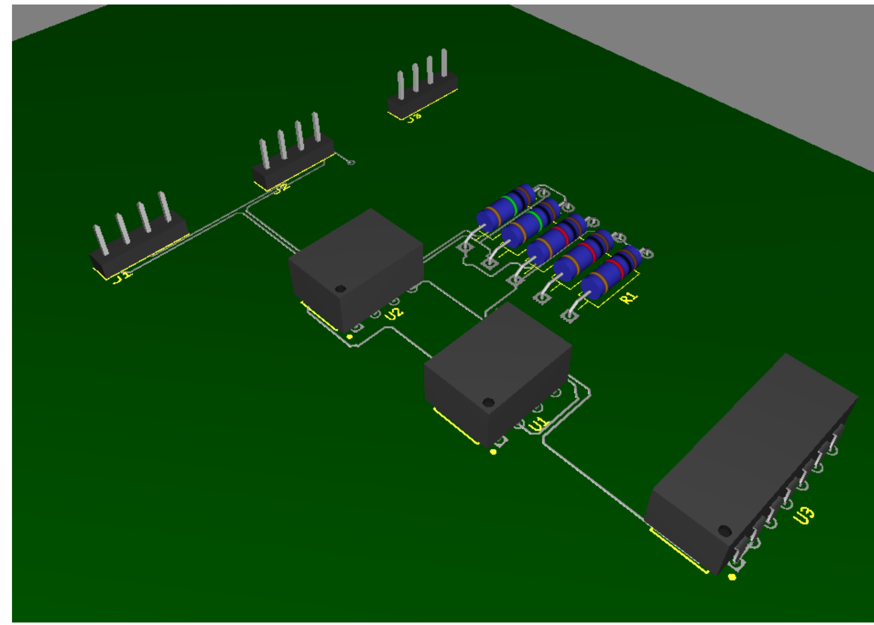
4-Bit Binary Counter

Breadboarding Your Designs…

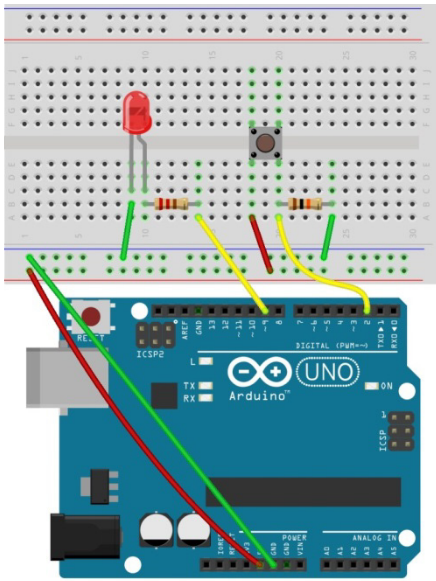


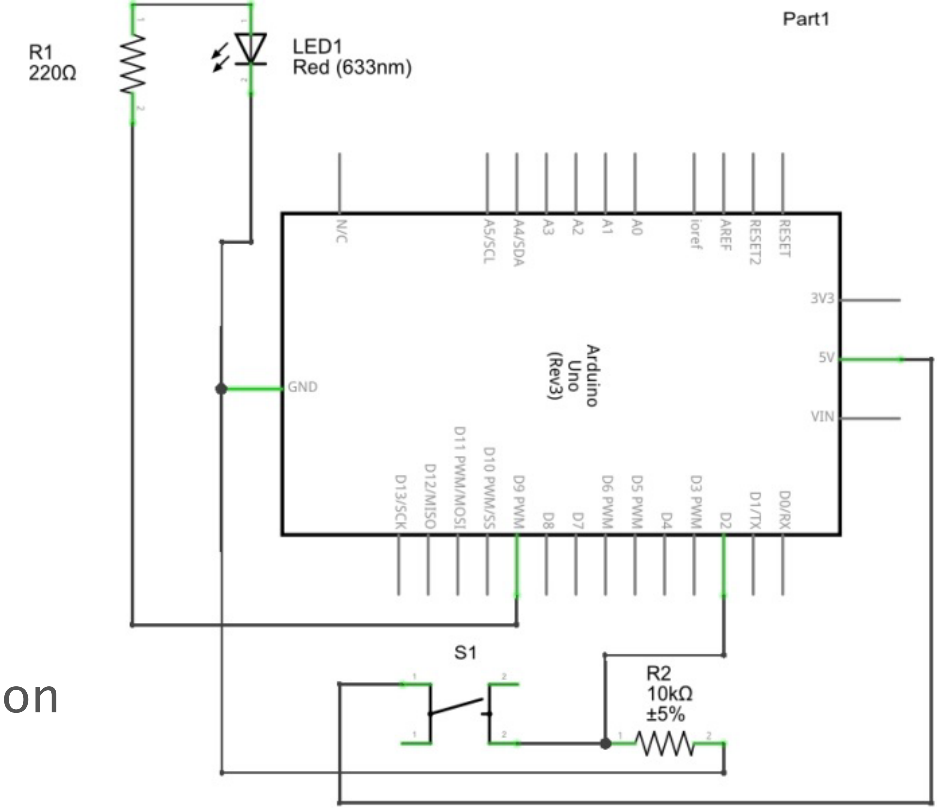
Designing Circuit Boards…





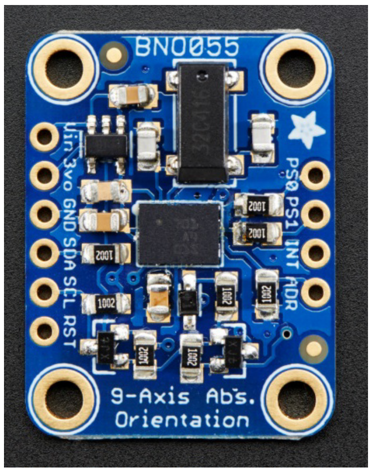
Using Microcontrollers

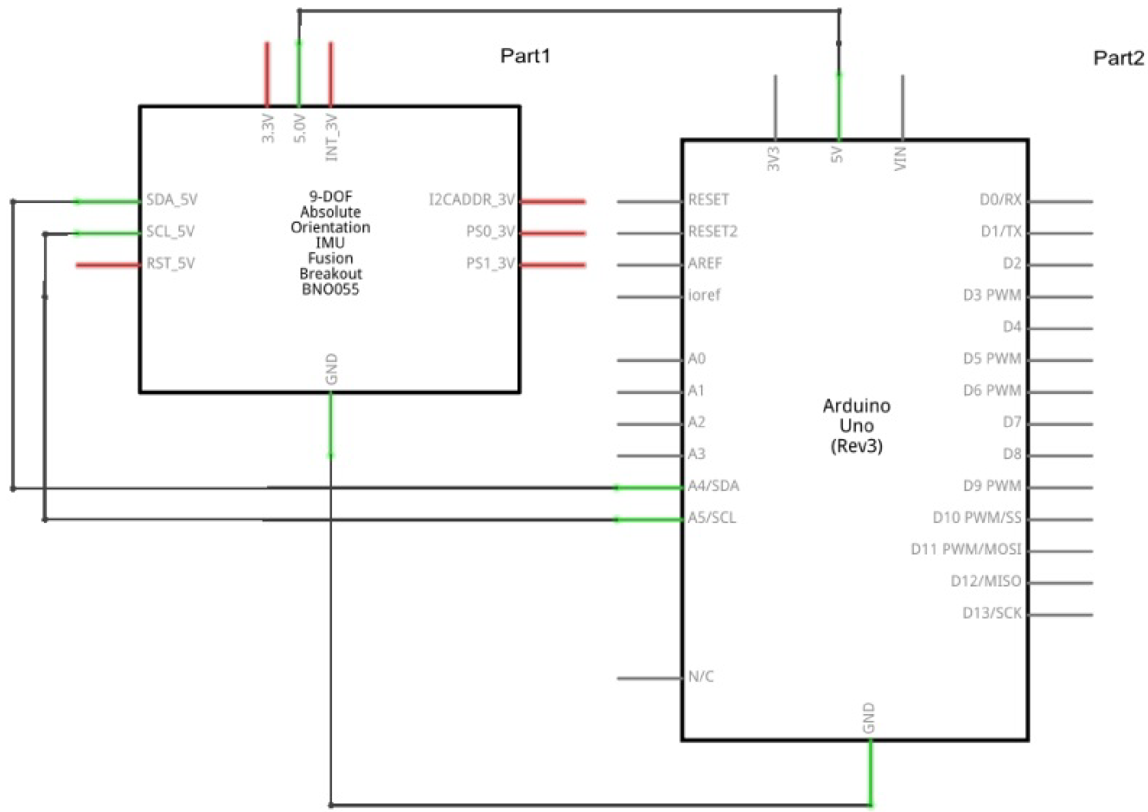




Debouncing a Pushbutton

Incorporating Sensors and Actuators…





Website – Lectures

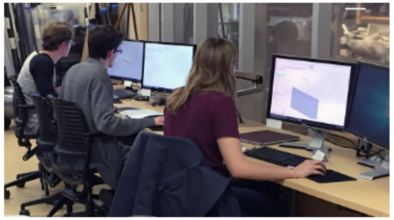
Using Chrome?

You need to periodically clear "cached images and files" (under Settings/Clear Browsing Data) in order to download the latest version of any of the files below.

Syllabus Items

- Syllabus
- Class 1 Schedule (Mornings 001/002)
- Class 2 Schedule (Afternoons 003/004)
- Course Flyer
- Graded Classwork

CAD Workstation...



Lectures for BMEN 2151

- Intro to Medical Device Prototyping
- Fundamentals of Engineering Drawing
- 3D Printing
- Laser Cutting
- Machine Shop Overview
- Anatomical Models from Imaging Data
- Biomaterials 1: Overview
- Biomaterials 2: Polymers
- Biocompatibility
- Analog 1: Circuit Theory
- Analog 2: Semiconductors
- Analog 3: Operational Amplifiers
- Digital 1: Logic Gates
- Digital 2: Applications
- Arduino 1: Structures & Variables
- Arduino 2: Digital & Analog Functions
- Arduino 3: More Functions
- Sensor Principles
- Actuators & Motors
- Medical Device Innovation

Handouts for BMEN 2151

- Introduction to Prototyping Handout
- Engineering Drawing Handout
- 3D Printing Handout
- Laser Cutting Handout
- Machine Shop Overview Handout
- Anatomical Models Handout
- Biomaterials 1: Overview Handout
- Biomaterials 2: Polymers Handout
- Biocompatibility Handout
- Analog 1 : Circuit Theory Handout
- Analog 2: Semiconductors Handout
- Analog 3: Op Amps Handout
- Digital 1: Logic Gates Handout
- Digital 2: Applications Handout
- Arduino 1 Handout
- Arduino 2 Handout
- Arduino 3 Handout
- Sensor Principles Handout
- Actuators & Motors Handout
- Medical Device Innovation Handout

Website – Solidworks, Shop & Labs

BMEN 2151 Demonstrations, Shop & Lab Workbooks

Using Chrome?

You need to periodically clear "cached images and files" (under Settings/Clear Browsing Data) in order to download the latest version of any of the files below.

SolidWorks Demonstrations

- SolidWorks Demo 1: Pressure Plate
- SolidWorks Demo 2: Candle Holder
- SolidWorks Demo 3: Hammer Head
- SolidWorks Demo 4: Sheet Metal Box
- SolidWorks Demo 5: Arm & Pistons
- SolidWorks Demo 6: DimXpert

Using the Mill...

Self-Review Items

- Machine Shop 1: Facilities
- Machine Shop 2: Hand Tools
- Machine Shop 3: Machine Tools
- Machine Shop 4: Mill
- Machine Shop 5: Lathe
- Test & Measurement
- Sensor & Actuator Modules
- Fabricating Electronic Circuits
- Programming in C

Electronics Lab...

Lab Workbooks for BMEN 2151

- Workbook Assignments Lab 1-3
- Workbook Assignments Labs 4-8
- Lab 1: Engineering Drawing, 3D Printing & Laser Cutting
- Lab 2: Machining
- Lab 3: Analog Electronics
- Lab 4: Digital Electronics
- Lab 5: Soldering
- Lab 6: Arduino
- Lab 7: Microcontroller Motor Interfacing
- Lab 8: Sensors

Additional Lab Items

- Part Drawings for Lab 2
- Overview of Cables & Test Leads
- Program Code for Labs 5 & 6
- Instructions for Clock Kit
- Available Project Supplies
- Available Project Parts: MDC Electronics Lab

Website – More Resources

BMEN 2151 Additional Material

Advanced Topics

- Geometric Dim. & Tolerancing (password required)
- CAM - HSMXpress
- CNC Lathe Overview
- CNC Mill Programming
- CNC Lathe Programming
- Fundamentals of CNC Machining (password required)
- Medical Device Polymers
- Advanced C Programming
- Solid State Power Switching

Part & Material Vendors

- Adafruit
- Axe-Man Surplus (University Ave.)
- University College of Design
- Digi-Key
- Discount Steel
- ECE Depot in Keller Hall
- Jameco
- Other Materials Sources
- SparkFun

Prototyping Resources

- Useful Prototyping Links
- Prototyping References
- Prototyping Books
- Adafruit Motor Shield
- Sunfounder Sensor Kit for Arduino

Equipment Instruction Manuals

- FeelTech Funtion Generator Manual
- Hantek Oscilloscope Manual
- JDS Function Generator
- MK-328 TR-LCR-ESR Tester
- Multimeter Manual
- TekPower Supply Manual

Campus Resources

- Campus Map
- Medical Devices Center
- Anderson Student Labs

List of Multisim Files

- List of Multisim Files

Anderson Student Labs Dedication 2017...

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.
- Home Lab Box
- Website