

Welcome to BMEN 3151

Medical Device Practicum 2022

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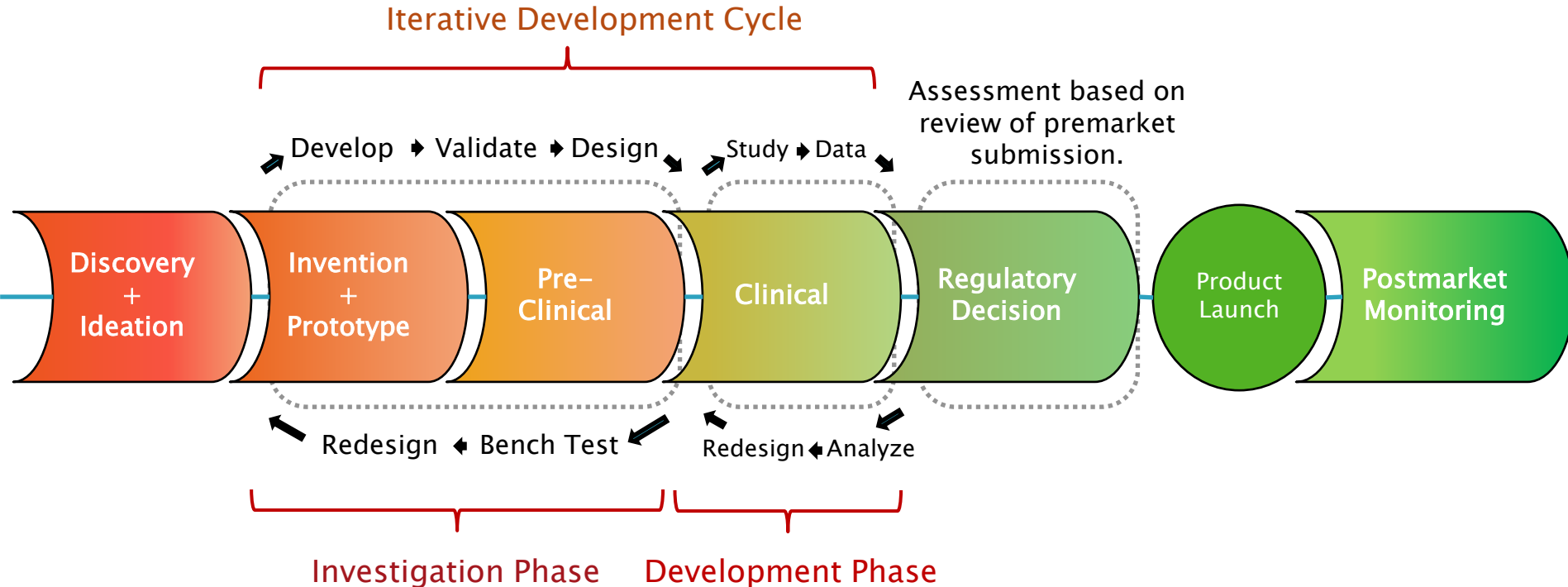
<http://saliterman.umn.edu/>



Topics Today

- ▶ *Team: Peacock Medical*
- ▶ Highlights of *Medical Device Innovation*
- ▶ *Team: Raynaud's Phototherapy Device*
- ▶ Selecting a Medical Device Project & Supplies

Medical Device Development Pathway



First Determine is There A Need?

- ▶ **Need** driven rather than **technology** driven.
 - Select a **clinical area**.
 - **Observe** procedures.
 - What is the underlying **problem**?
 - Create a **need statement**.
 - “A way to reduce back pain with bending”
 - **NOT** “A device to immobilize the back.”
 - **Brainstorm** solutions.
 - Perform a **business analysis**.

Adopted from Tolkoﬀ, J, *Ideation in Medical Device Development: Finding Clinic Needs*, CIMIT CRAASH Course. cimet.org.

Conduct Ideation Sessions

- ▶ Understand the problem.
- ▶ Define an acceptable degree of *transcendence* – deviation from existing ideas and solutions.
- ▶ Resources available – your *Team*.
- ▶ Structuring the meeting.
- ▶ Sources of inspiration.
- ▶ Good practices (Osborn, A.T. *Applied Imagination*)
 - Go for quantity.
 - Encourage unexpected ideas.
 - Defer judgment.
 - Combine and improve ideas.

- ▶ Provide breaks.
- ▶ Create and enforce rules.
 - e.g. stay focused, do not tell stories and do not criticize.
- ▶ Getting stuck.
- ▶ Positive motivation and incentive.
- ▶ Concluding thoughts.
 - Document the session – process, people involved, sources of inspiration.

Understand FDA Regulations

▶ Premarket Requirements

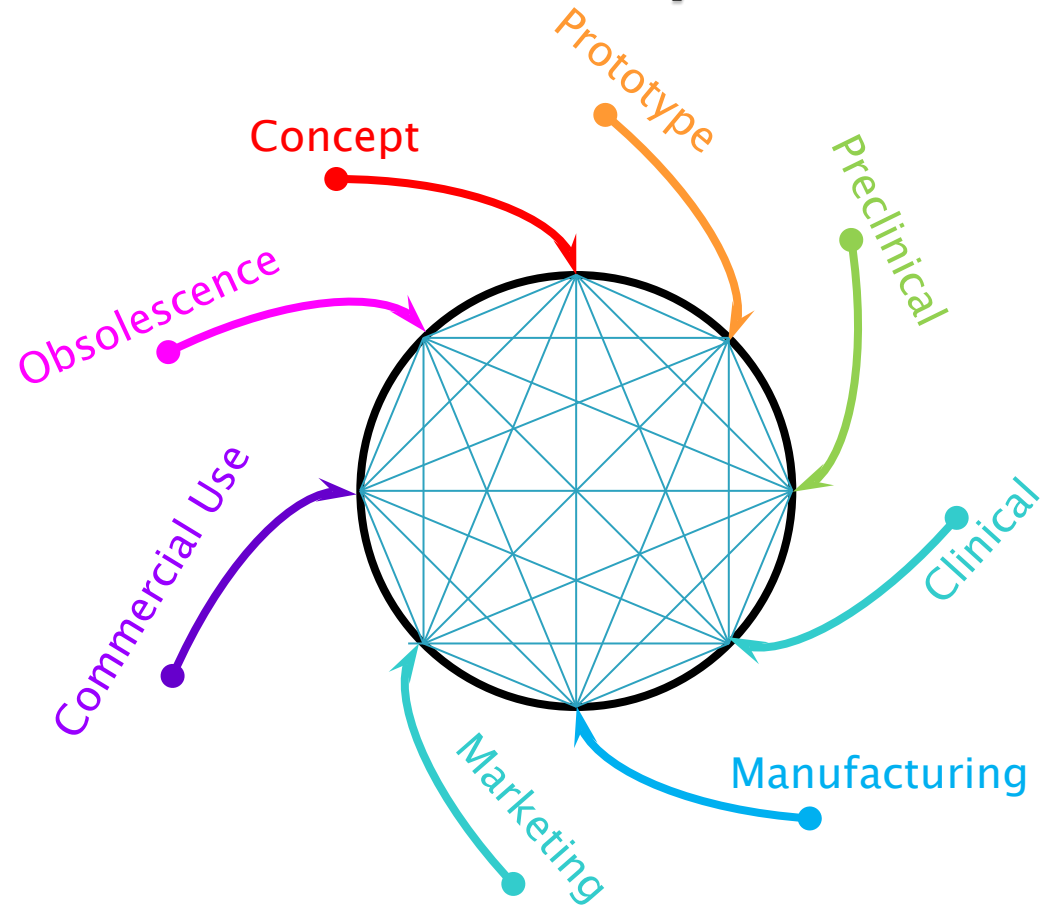
- Product Classification – Type I, II or III
- Premarket Approval (PMA)
 - PMA Supplements.
 - Evaluations of the PMA and PMA Supplement Process.
 - Humanitarian Device Exemption (HDE).
- 510(k) Notification – Substantially Equivalent Device
 - Assessments of the 510(k) Process

▶ Post-Market Requirements

- Postmarket Surveillance Studies.
 - Adverse Event Reporting, Medical Device Tracking, UDI (Unique Device ID)
- National Medical Device Evaluation System.
- Labeling and Manufacturing
- Compliance and Enforcement

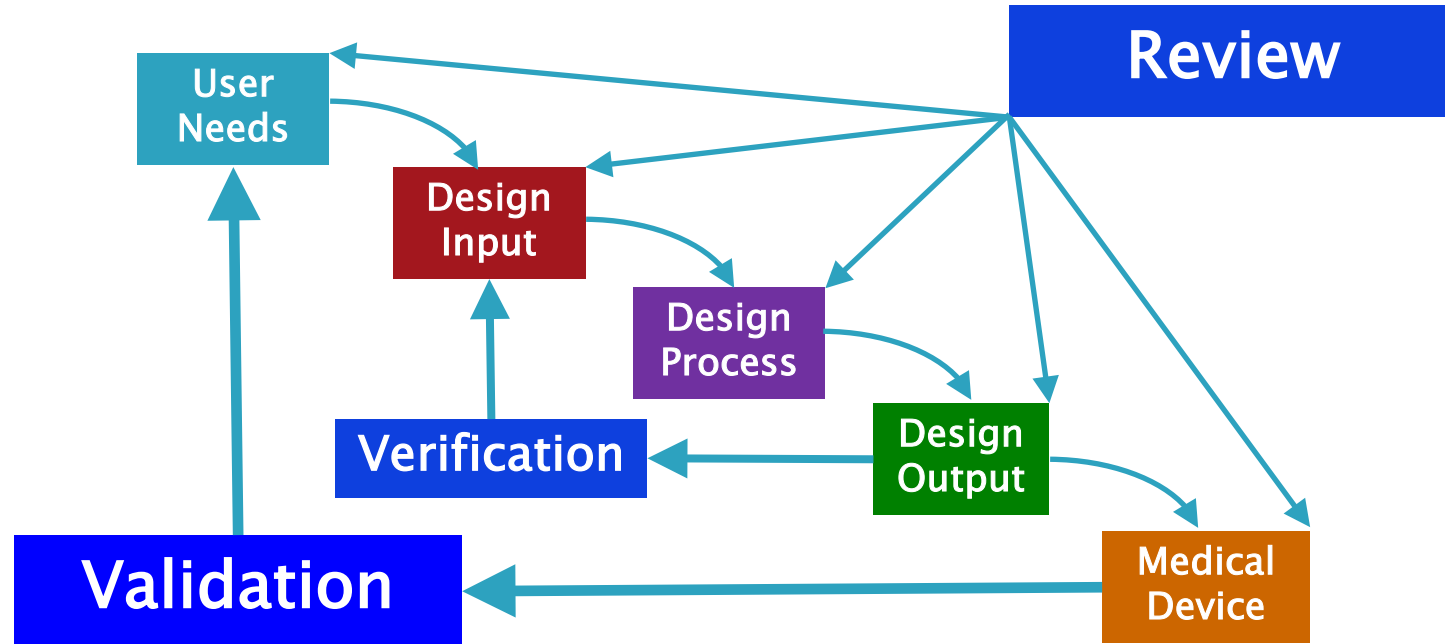
Consider the Total Product Life Cycle

“Medical device development is an iterative process that rapidly incorporates preclinical, clinical, and manufacturing experience into next-generation concept and design.”



Adopted from CDRH *Innovation Initiative*, February 2011.
(Center for Devices and Radiological Health)

Waterfall Design Process



Example – Infusion Pump...



User Need - Pump must function in an operating room environment.

Design Input – Pump must function uninterrupted when used with other products that generate an electromagnetic field.

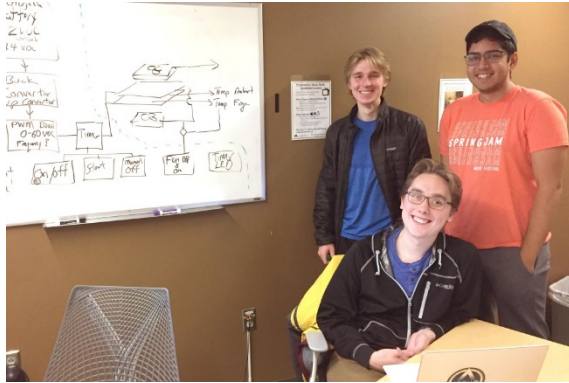
Design Output – (1) PCB with filtering, (2) Pump EMI shield, (3) software signal filtering code and error handling code.

Design Review

Design Verification – (1) Simulated EMI testing on hardware and software, (2) Dimensional verification shield, (3) Verification of system error handling due to EMI.

Design Validation – (1) EMC testing to industry standards, (2) simulated EMI testing in high EMI environment, (3) *Risk analysis* converting EMI, (4) *Software validation* for filtering code.

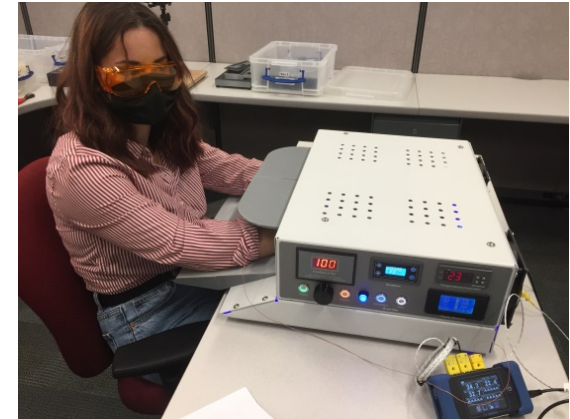
Raynaud's Phototherapy Device



Brett Levac, Kushal Sehgal and James Kerber



Jennifer Chmura



Emily Wagner

Clinical Problem

Raynaud's is a disease which presents itself as digital immobility, pain, and flushed colour whenever the patient is exposed to cold temperatures. This is thought to be caused by restricted blood flow, however the underlying mechanisms are not well understood. It is thought to be caused by an underlying autoimmune issue and is commonly genetic. If this disease is not treated by keeping the affected areas warm and cleaning these areas properly, sores can develop. If these sores are not treated correctly gangrene or open wounds may develop. This can be life threatening if not properly treated. This disease is quite common, occurring in 3-5% of the United States population. This disease typically does not result in death, however the sores that develop as a result of the reduced blood flow can be life threatening. The symptoms can sometimes be reduced with calcium channel blockers and vasodilators; however, the effectiveness of these drugs is commonly lower than hoped and may result in side effects for many patients.

Needs Statement

“Patients suffering from Raynaud's need an effective way to reduce Raynaud's symptoms without drugs, in a cost effective manner with less potential side-effects.”

Market Analysis

If we assume that one in five people with Raynaud's will develop gangrene each year, and use the cost code I73.01 (Raynaud's with gangrene) then the following calculations can be preformed.

330 million (The number of people in the US)

* 4% of population (The approximate percent of the population with Raynaud's)

* \$9,697 (Cost per treatment of Raynaud's with gangrene)

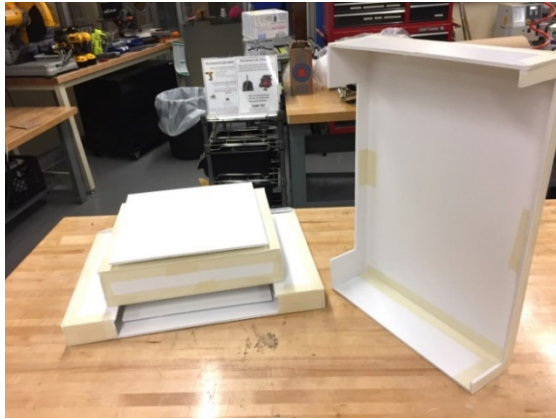
* 1/5 (Percent of Raynaud's suffers that get gangrene each year)

= \$25.6 billion/ year in the treatment of resulting gangrene disease alone. This does not account for the societal impact of the discomfort and pain nor does it account for other, non gangrene complications resulting from this disease.

Medical Device Solution

The first iteration of our design will include two LED panels which emit a 430nm wavelength of light, which triggers the vessels to widen thus reducing the symptoms of Raynaud's. This wavelength and its effects on vessels was shown by Sikka in "Melanopsin mediates light-dependent relaxation in blood vessels" which demonstrated efficacy of blue light to vasodilate in rat aortas, however this has not been shown in humans. This device is meant to be an initial exploratory device. After the IRB procedures, if we have proof that this treatment method provides promising results in human studies, we seek to adapt this prototype to a design that is in the form of gloves. These gloves will come with linings containing micro LEDs emitting light in the 430nm regime or have fiber optics to deliver the light. This design will allow users to stay on the move while still receiving treatment.

1st Prototype– Foamboard



Formboard Mockup

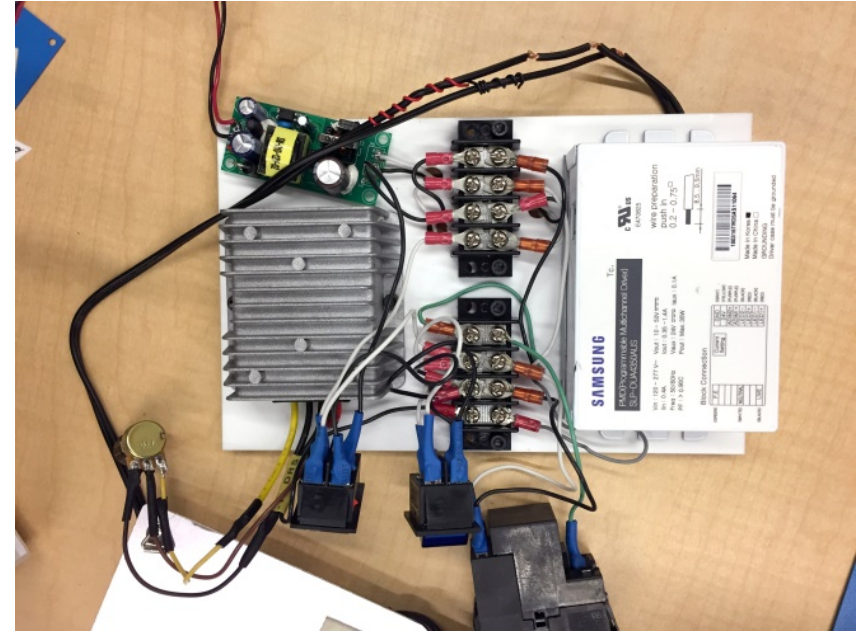
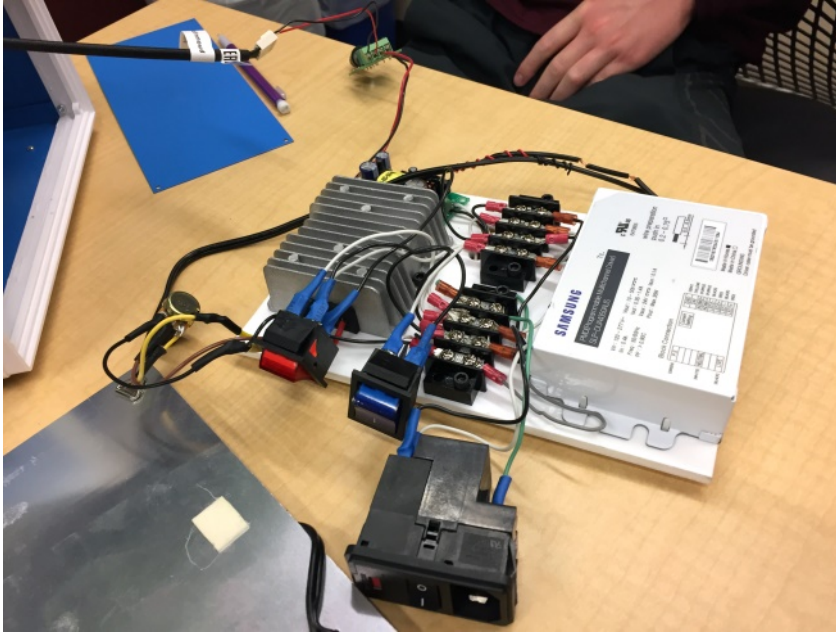


Attached Artwork

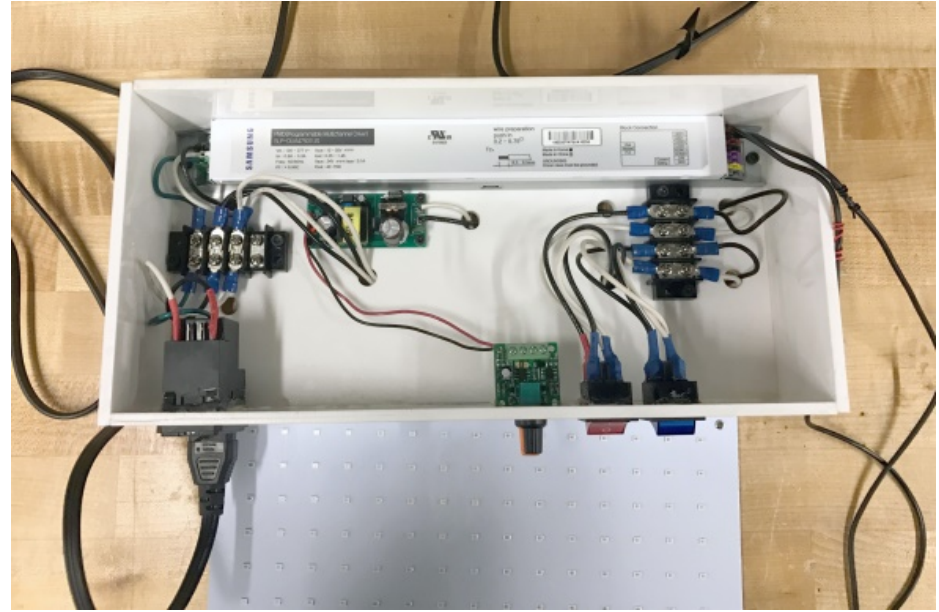
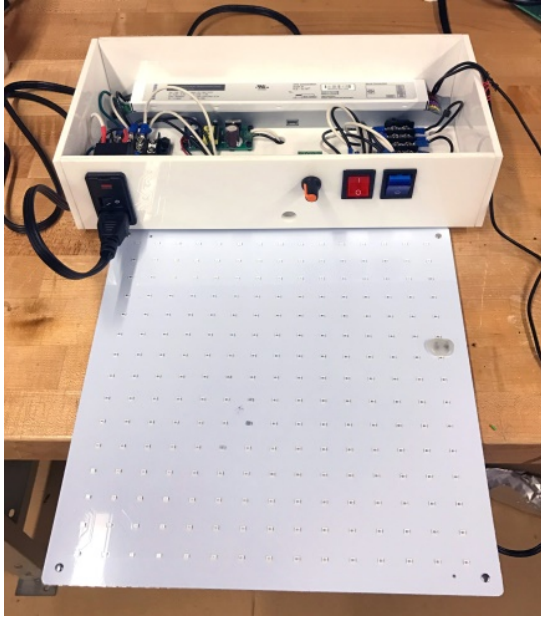


Assembly

2nd Prototype

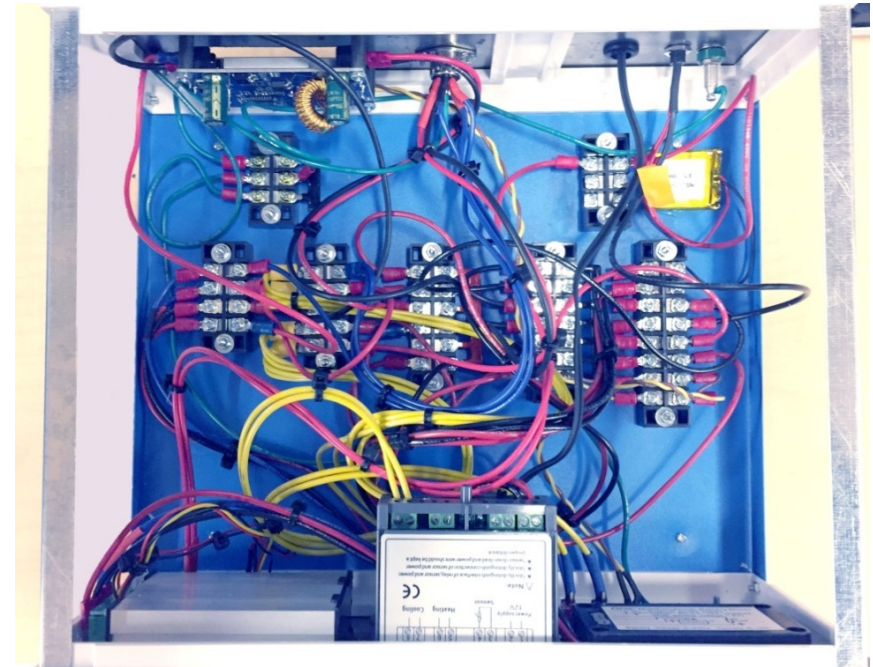


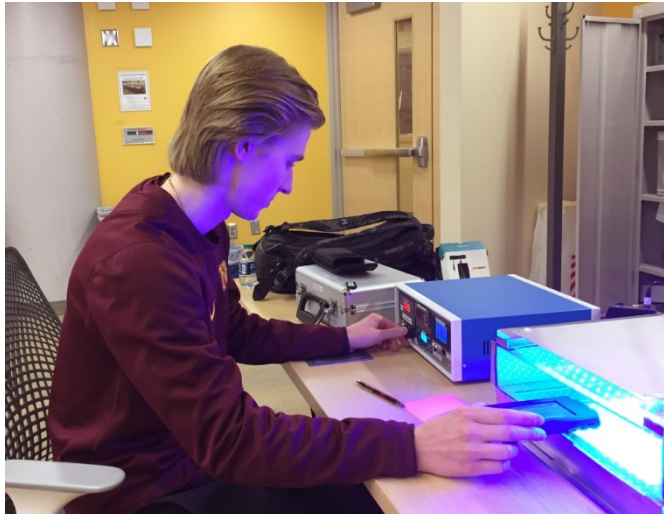
Driving & Dimming an LED Panel



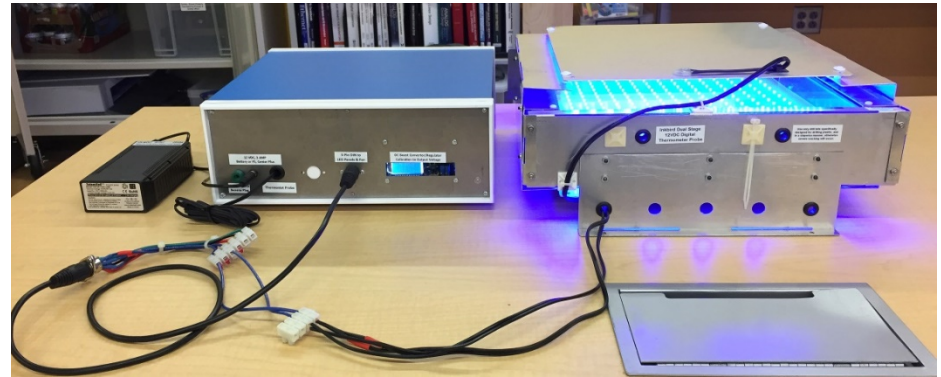
Revised Design & Enclosure

3rd Prototype



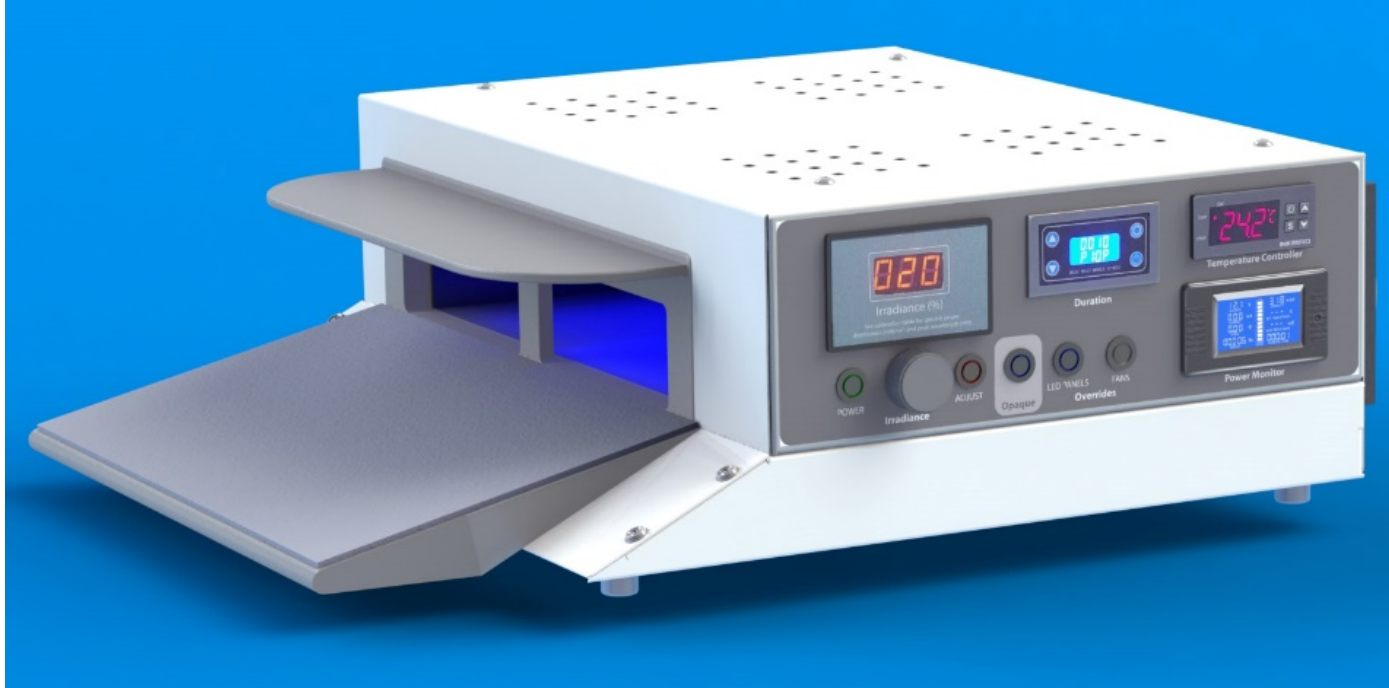


Brett Levac Checking Prototype Controller & Hand Compartment with Spectrophotometer

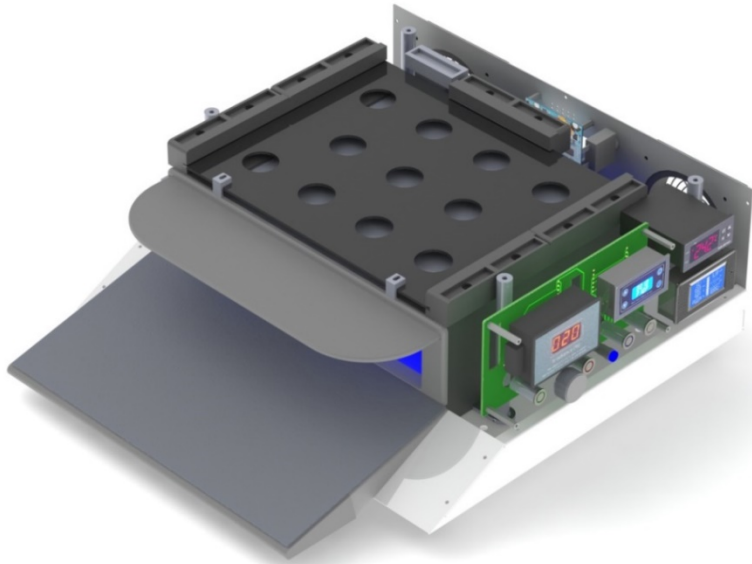


Back View

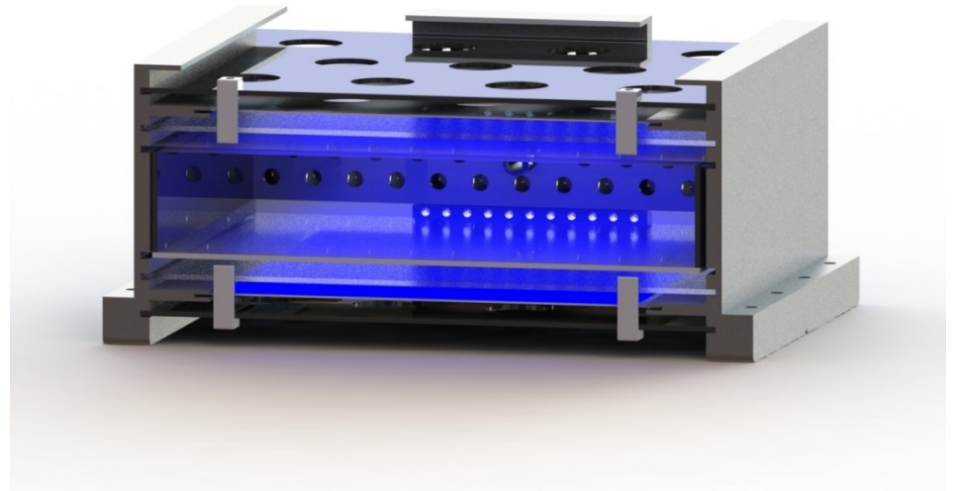
4th Prototype



SolidWorks Rendering

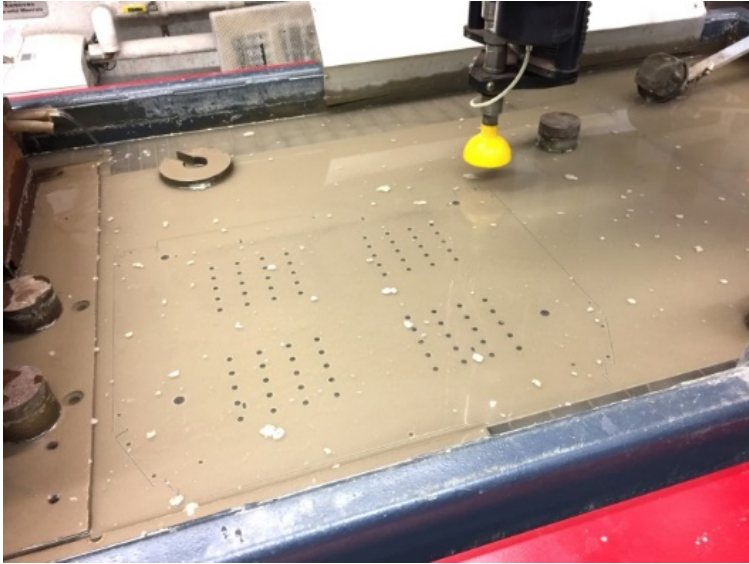


View of Subassemblies



Optical Stack

Techniques



Student Machine Shop Waterjet Cutter



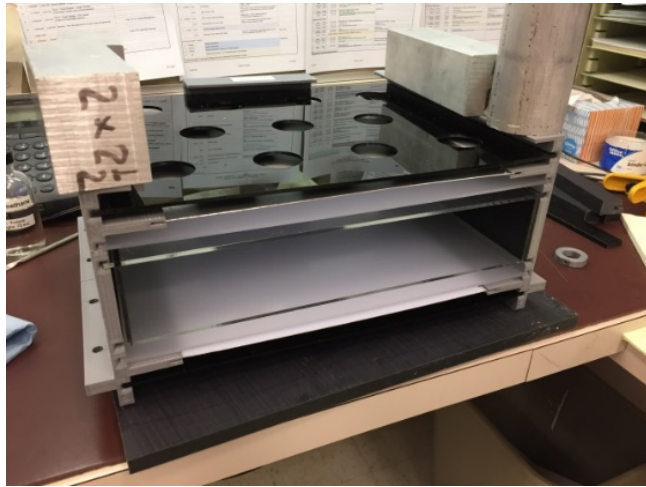
Parts Ready for Bending



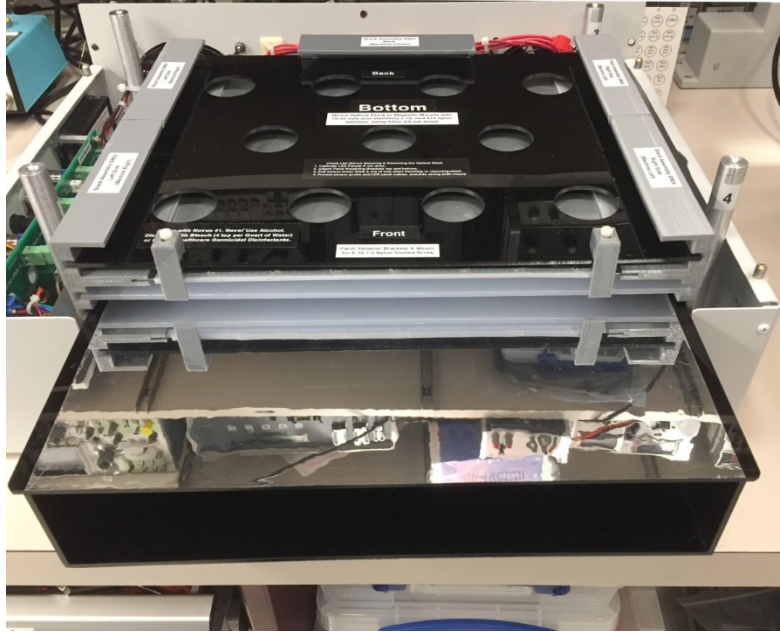
After Bending in Brake



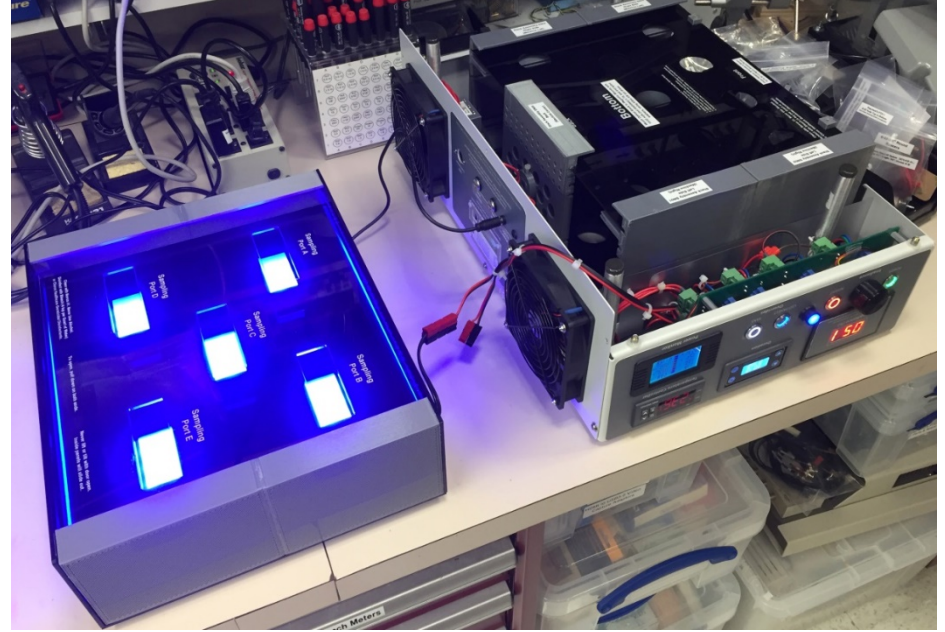
After Powder Coat Finish



Solvent Bonding the Optical the Optical Stack Components
(Into which the hand Compartment is Placed)



Testing Insertion of Opaque Hand Enclosure into Optical Stack

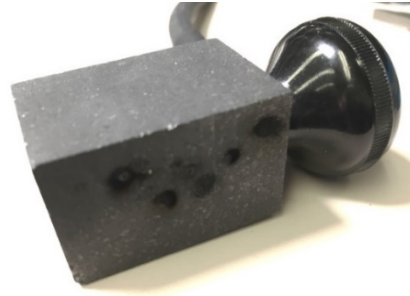


Calibration of an LED Panel

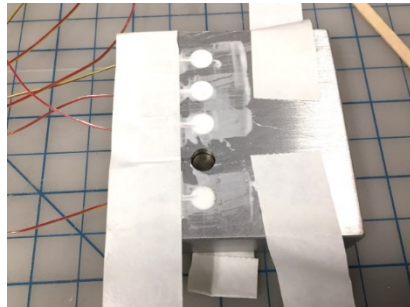
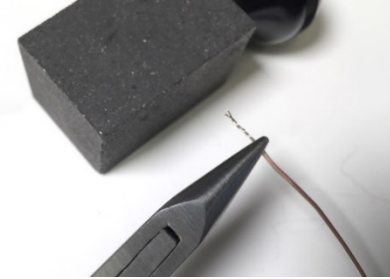
Making Thermocouples



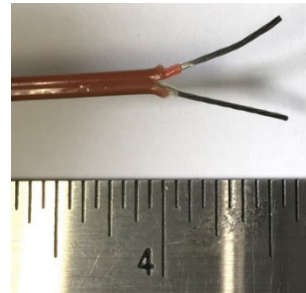
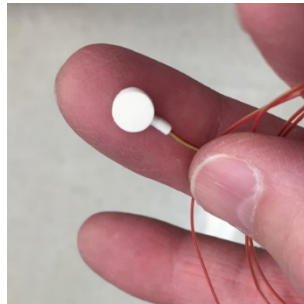
Tools and Cables for Spot Welding



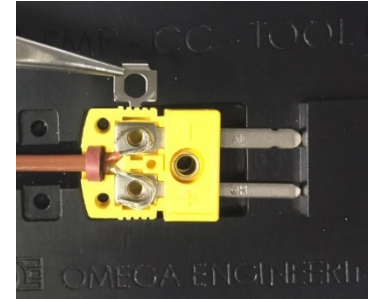
Graphite Welding Electrode Block & Wire Being Welded



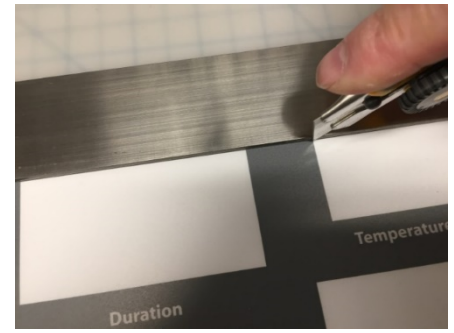
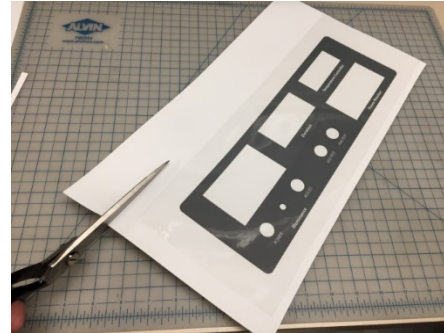
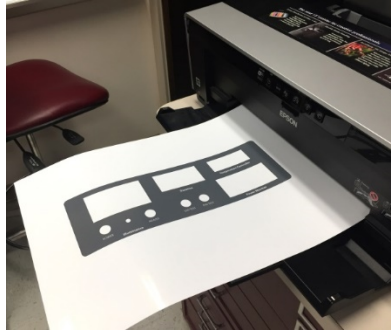
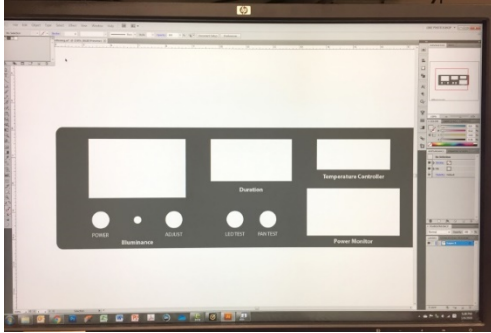
Encasing Welded Bead in Epoxy
with Custom Mold



Finished Type K Thermocouple Wire
and , Male Mini-Connector



Making the Polycarbonate Control Panel



Clinical Trail Rehearsing



Next Steps

- ▶ See *Selecting a Medical Device Project*.
- ▶ See slide set *Clinical Problem Selection*.
- ▶ See *Clinical Problem Selection Worksheet*.
- ▶ Next week each team will present its *Worksheet Discovery & Ideation* progress.
- ▶ The week after, you will present your *Worksheet Investigative Phase* items.
- ▶ Begin work on your project and poster (I will provide a poster template).