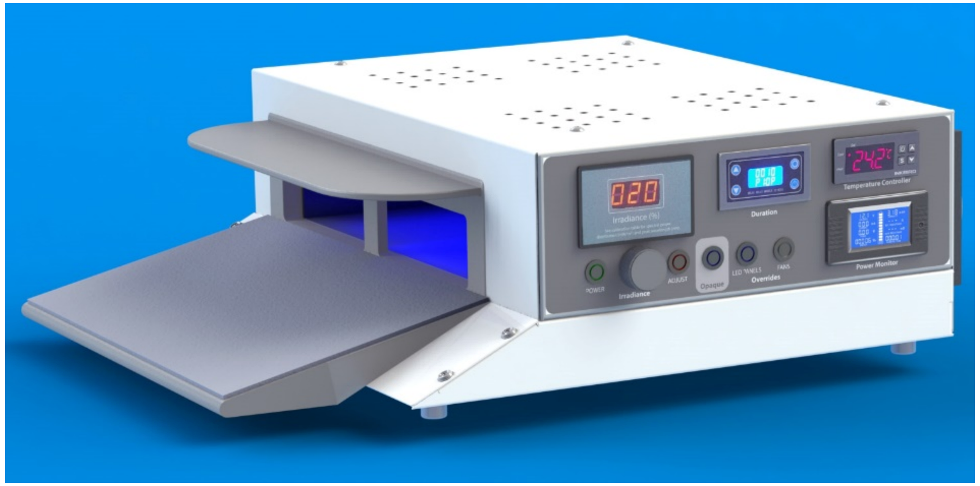
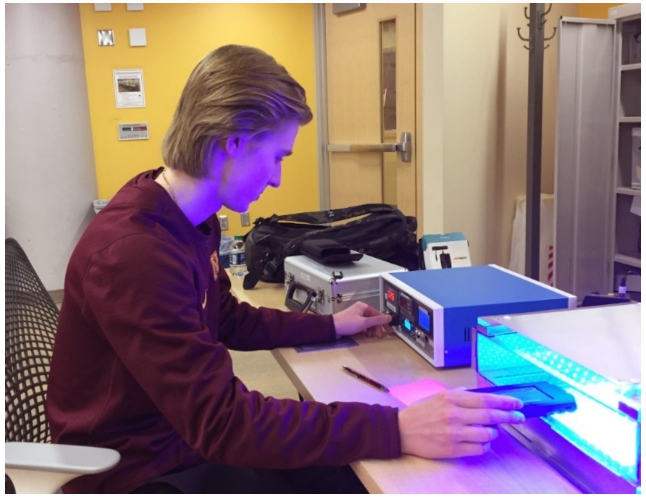
Medical Device Practicum

Advanced Prototyping

Prof. Steven S. Saliterman, http://saliterman.umn.edu/

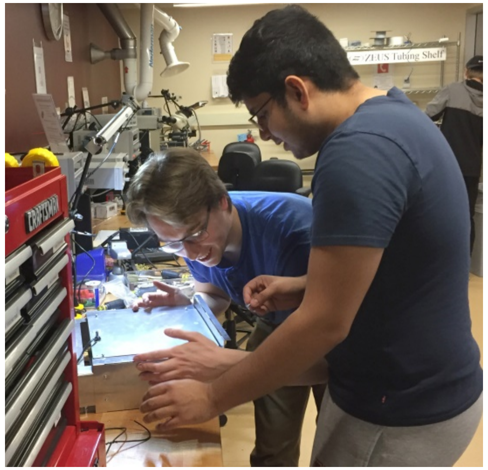




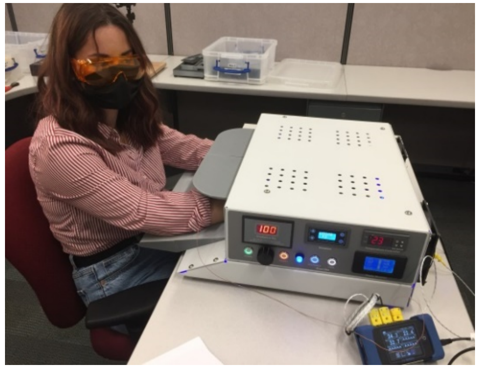
Raynaud's Team

Brett Levac

Jennifer Chmura



James Kerber and Kushal Sehgal



Emily Wagner

Dr. Jerry Molitor

Prof. Saliterman

BMEN 3151 Poster

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 manor with less potential side-effects."

Market Analysis

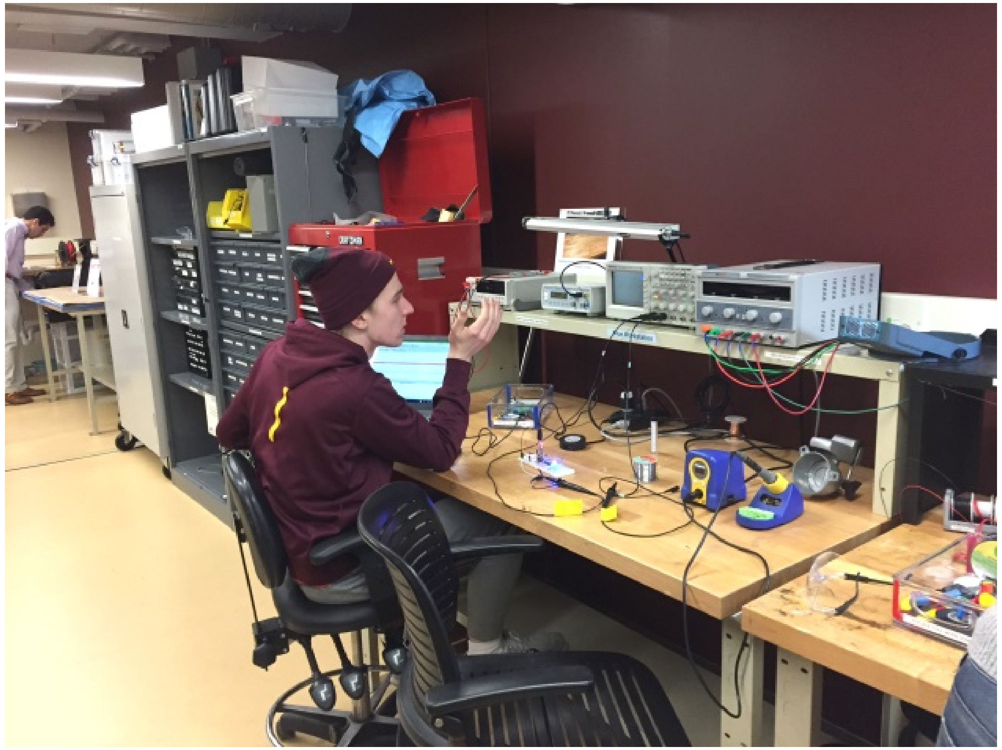
If we assume that one in five people with Raynaud's will develop gangrene each year, and use the cost code I73.01 (Raynaud's with gangrene) then the following calculations can be preformed.

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

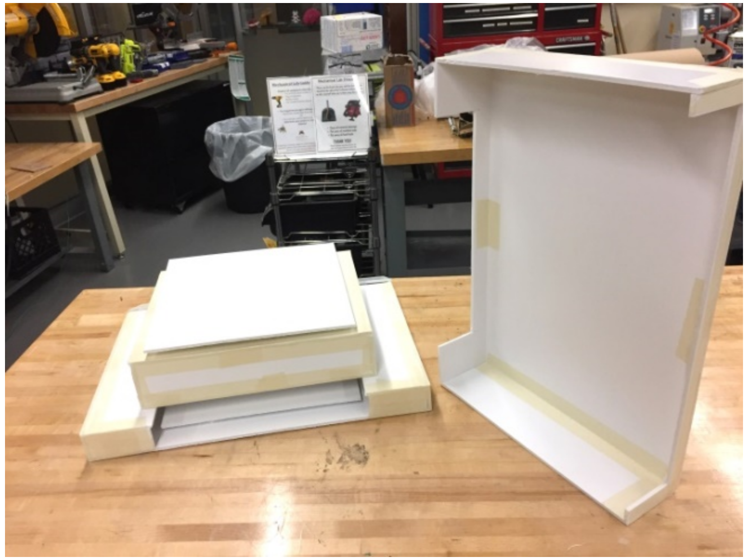
The first iteration of our design will include two LED panels which emit a 430nm wavelength of light, which triggers the vessels to widen thus reducing the symptoms of Raynaud's. This wavelength and its effects on vessels was shown by Sikka in "Melanopsin mediates light-dependent relaxation in blood 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.

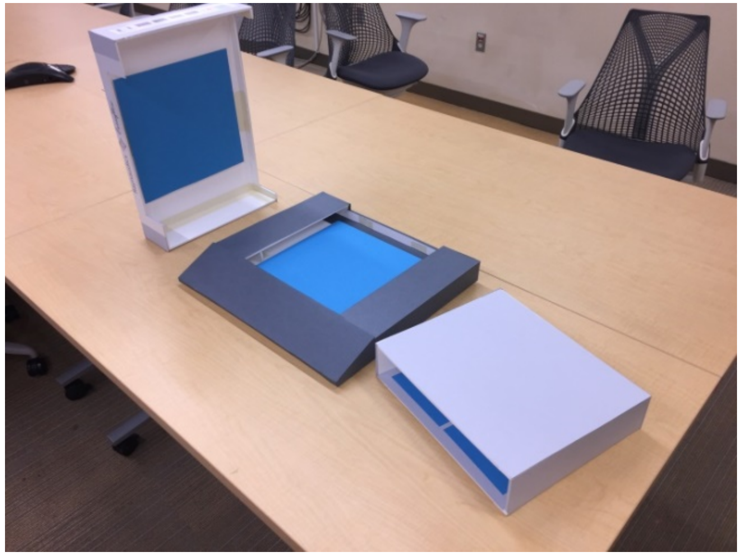
Photo History



Brett Levac at Axman Store & MDC

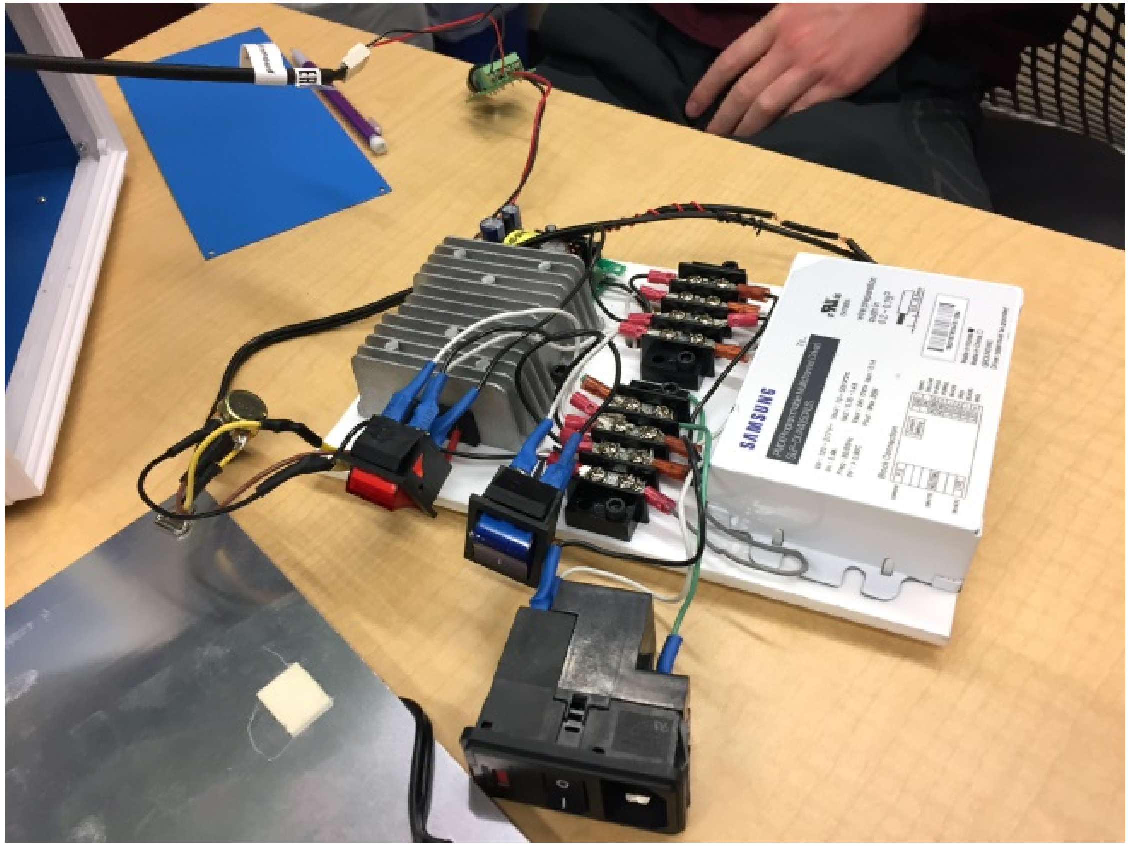
Foam Board Mockup

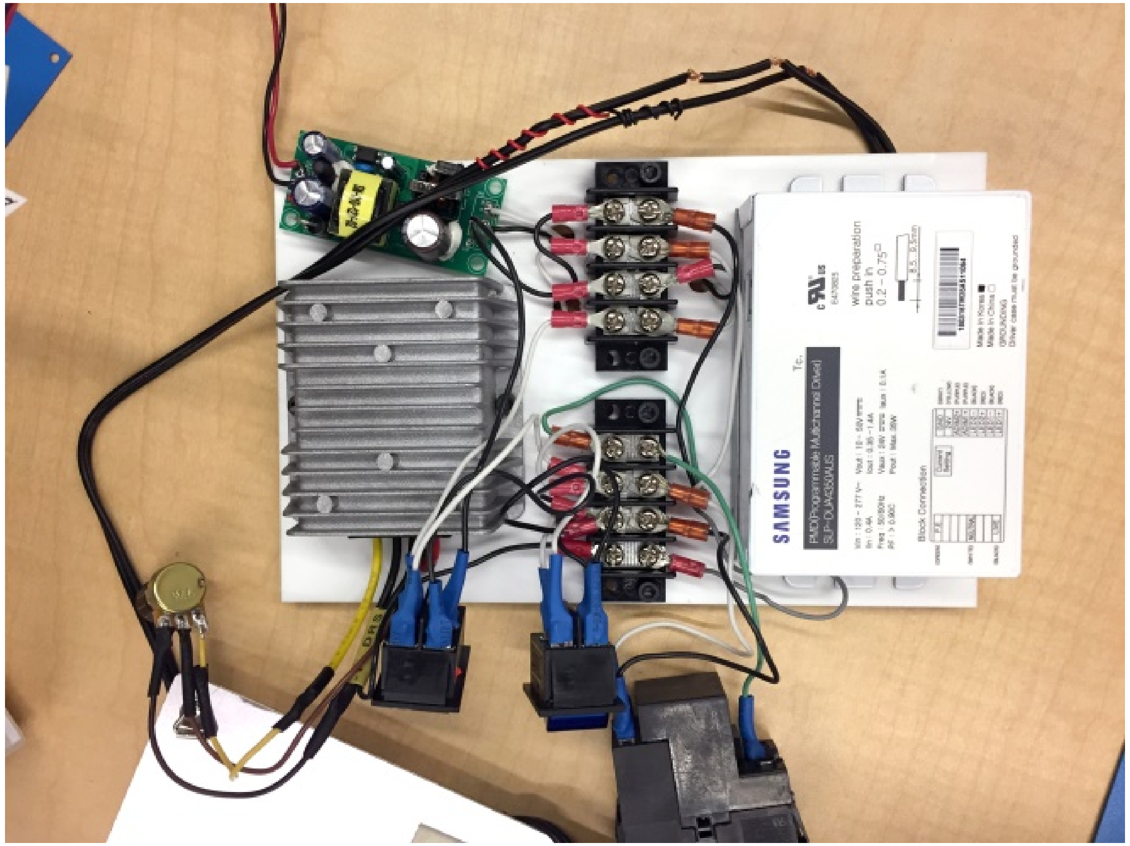




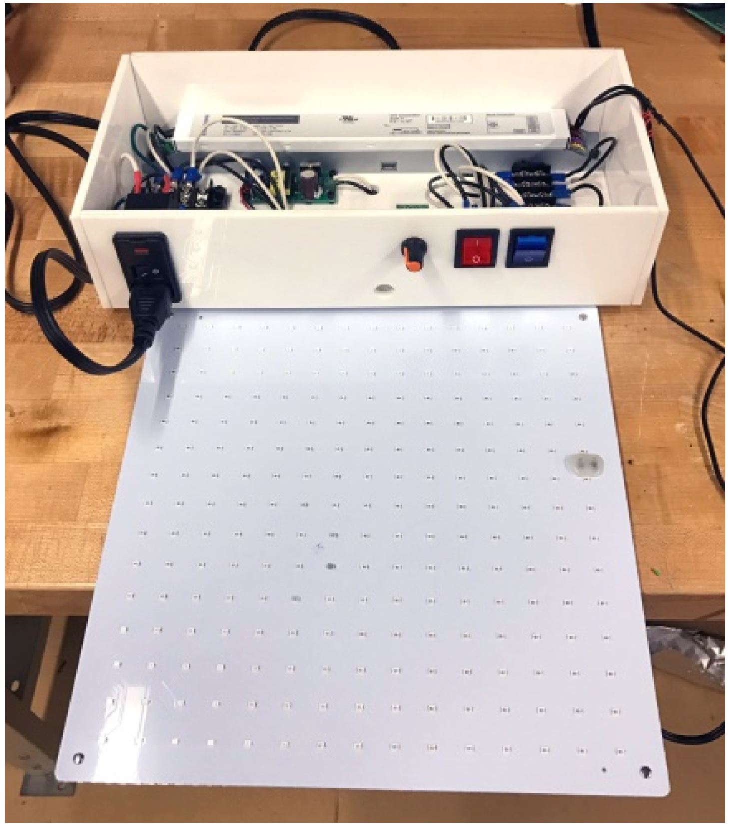
Formboard Mockup with Attached Artwork

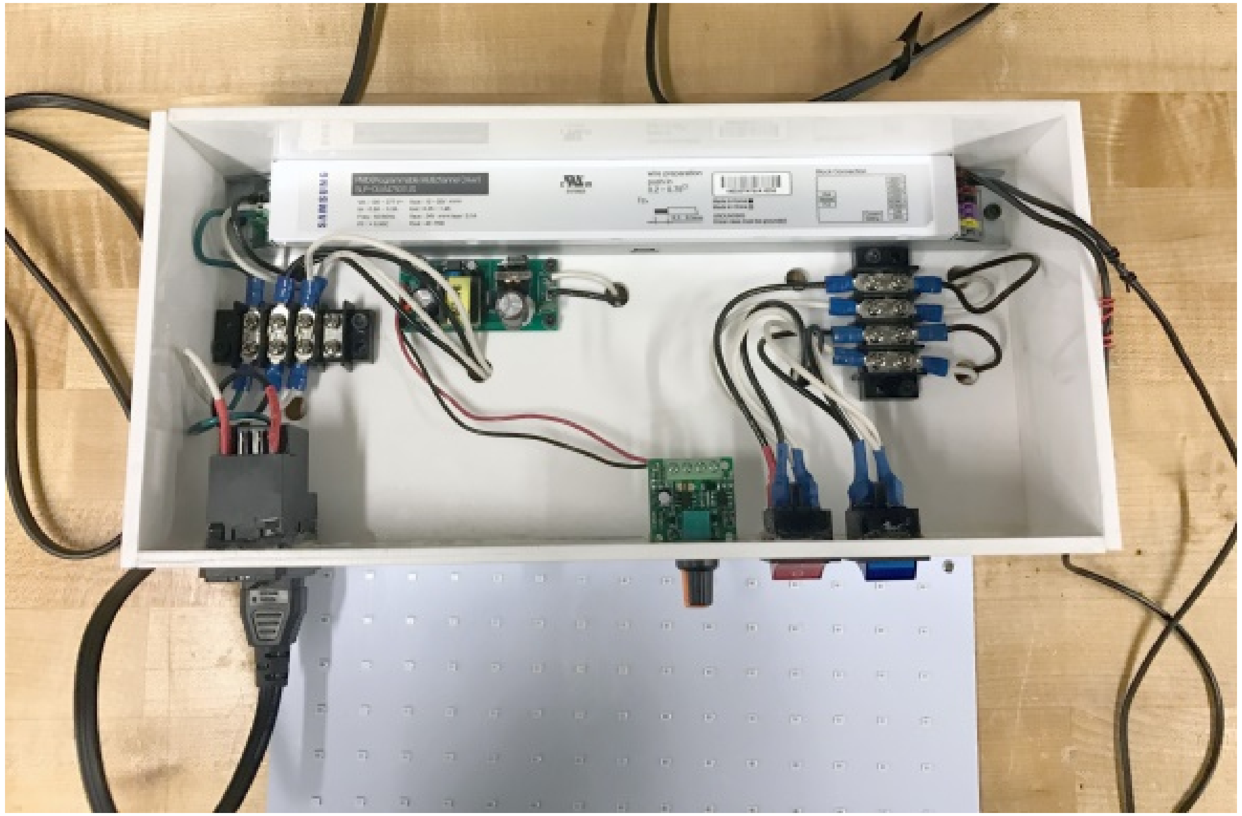
Prototype 1



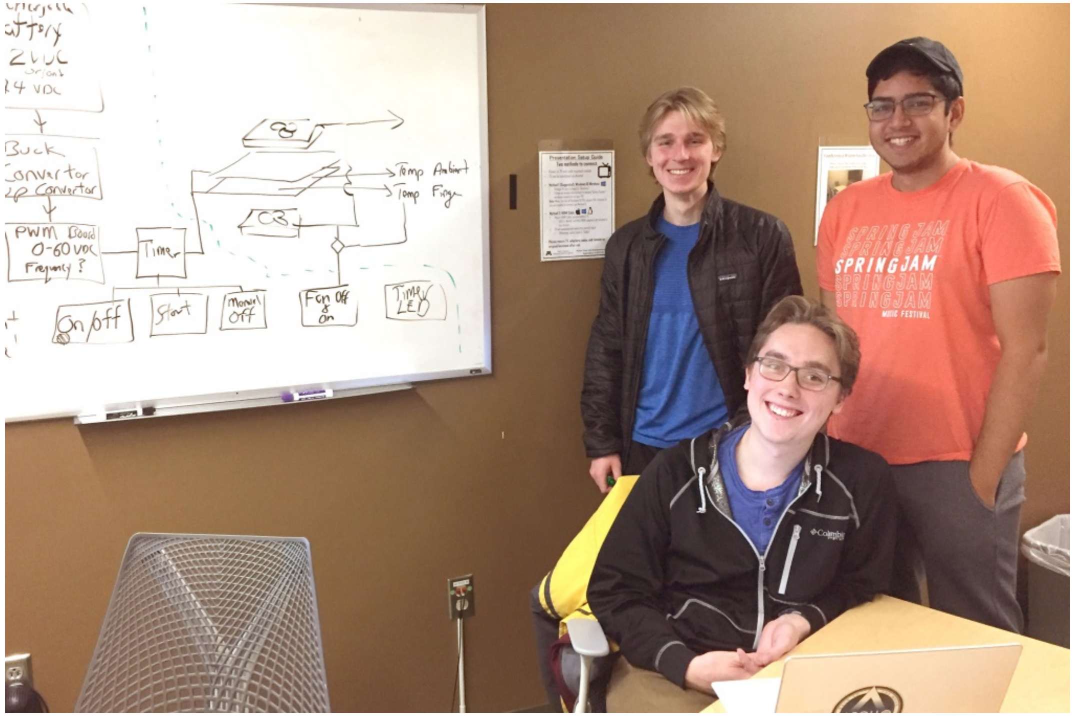


Prototype 2



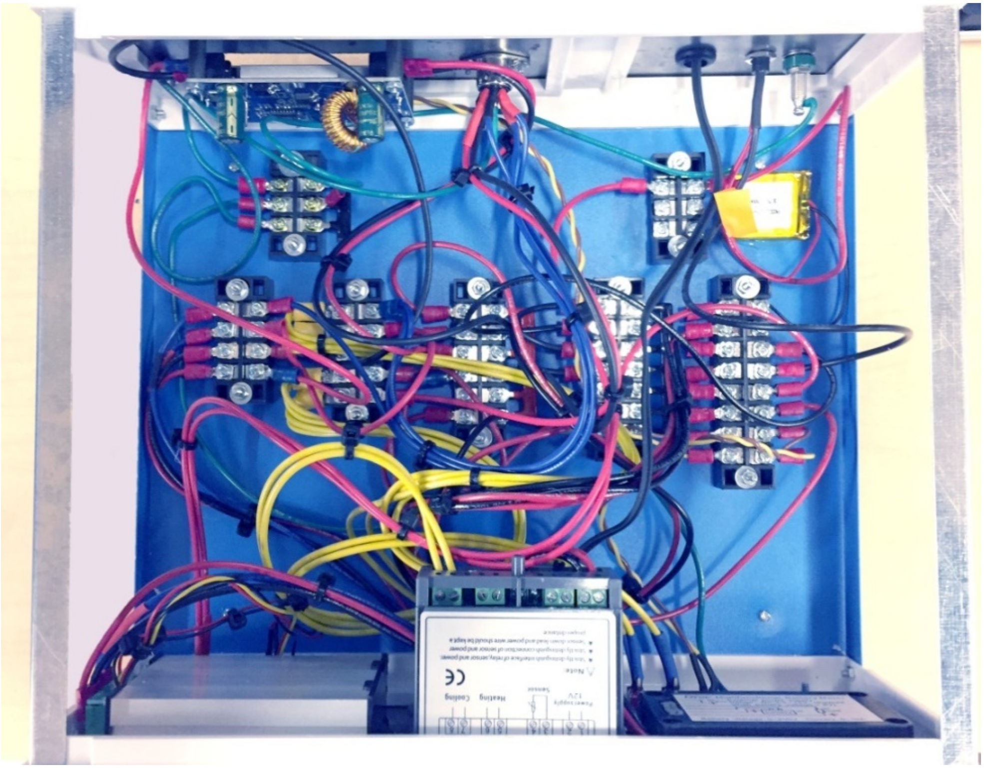


Ideation - Design Meetings



Brett Levac, Kushal Sehgal and James Kerber in MDC

Prototype 3



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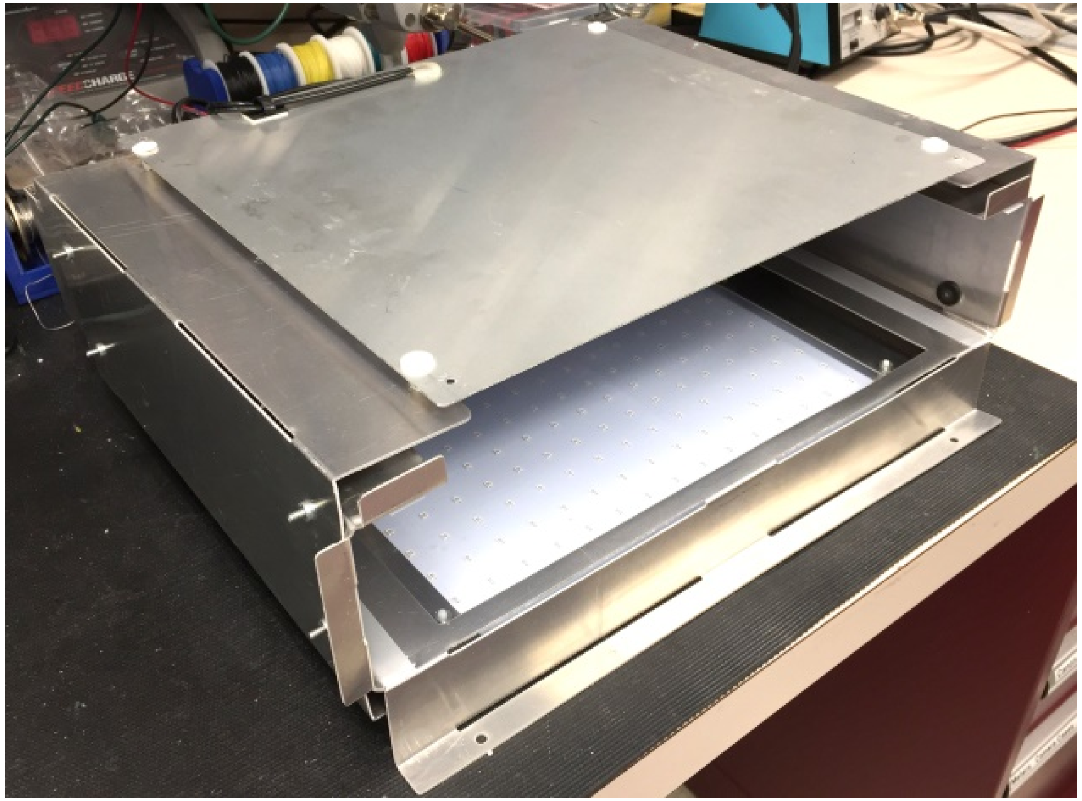
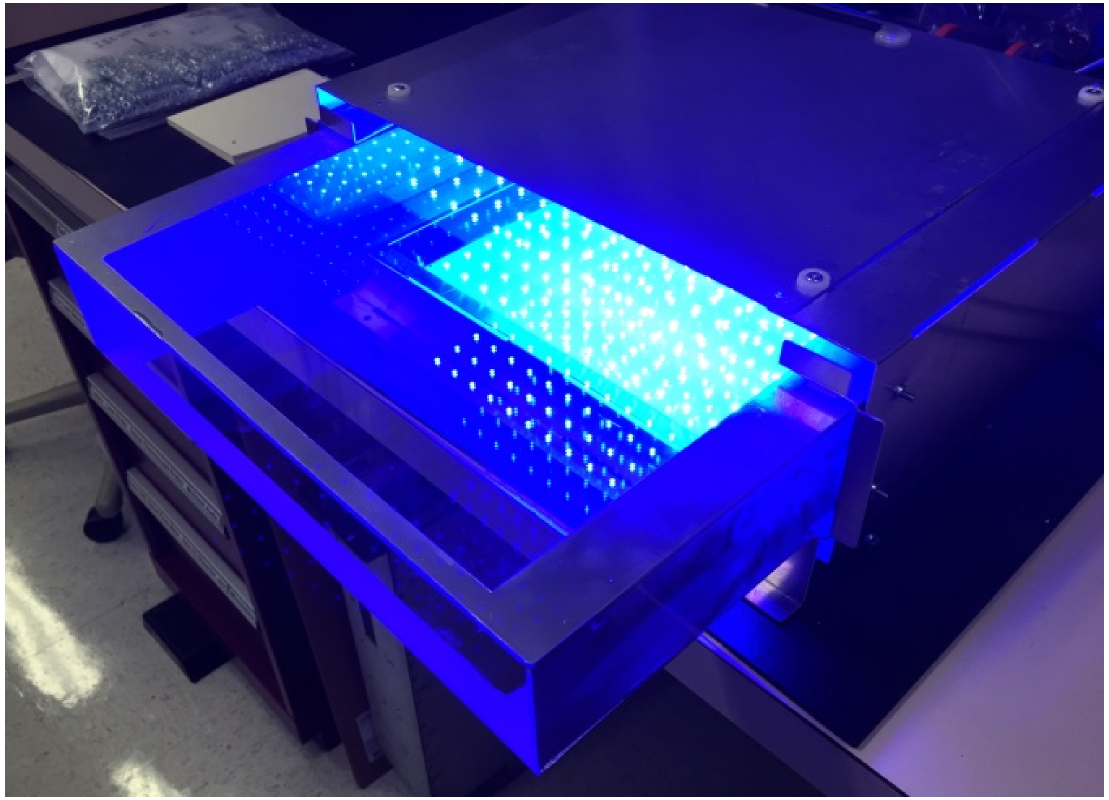
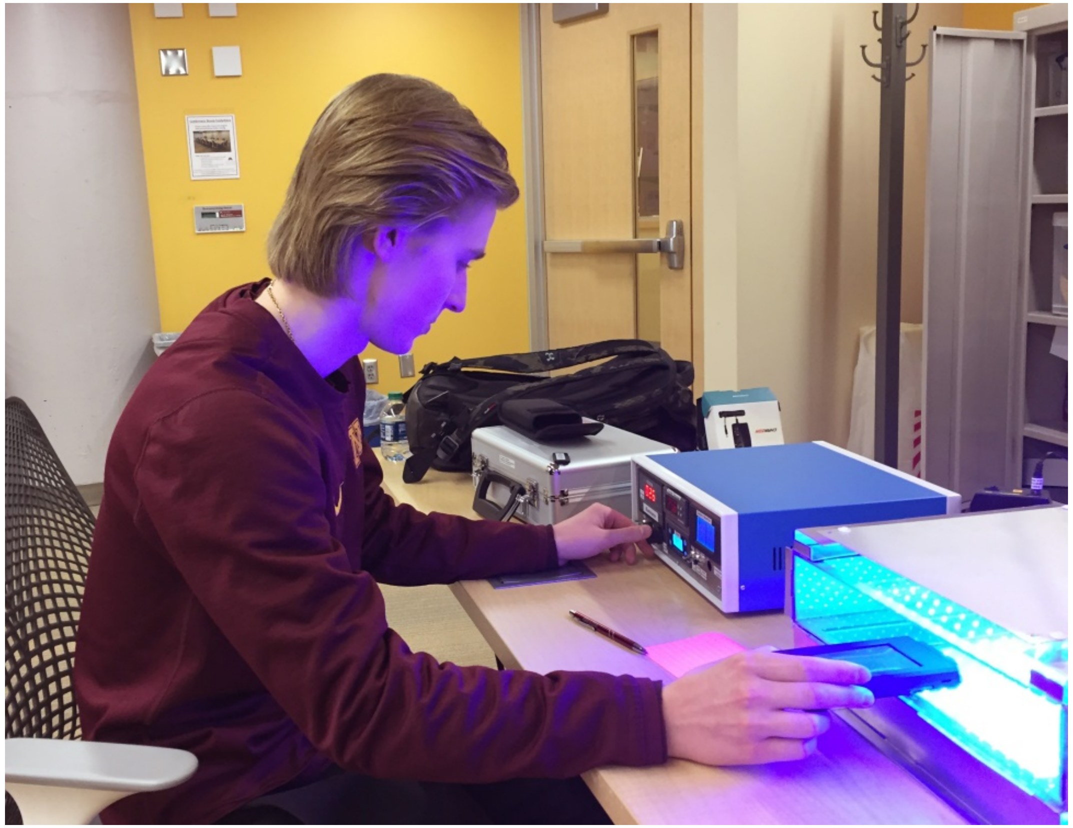
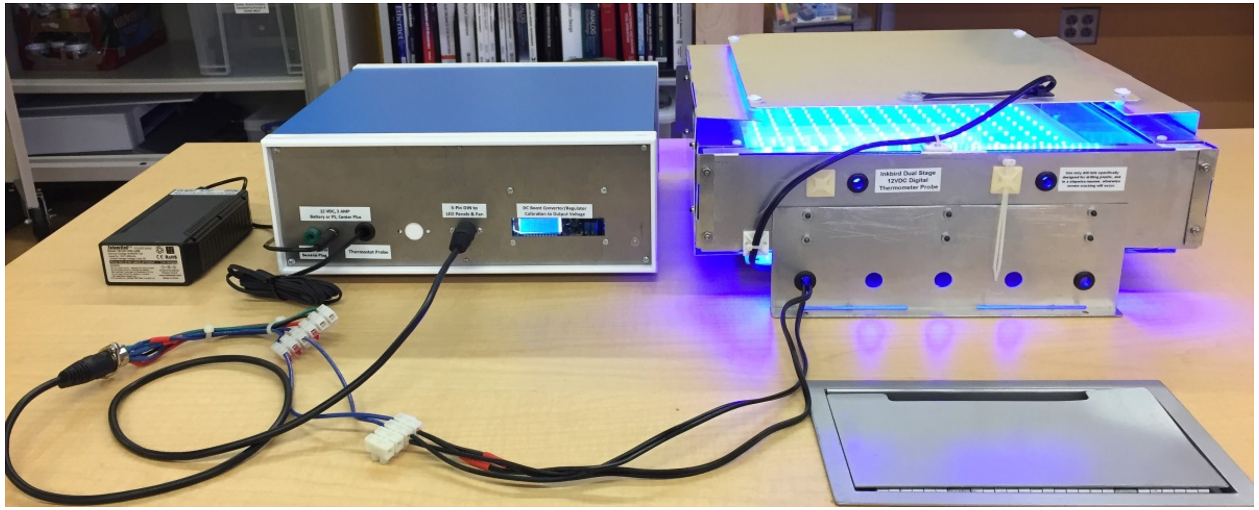


Prototype Optical Stack Front View



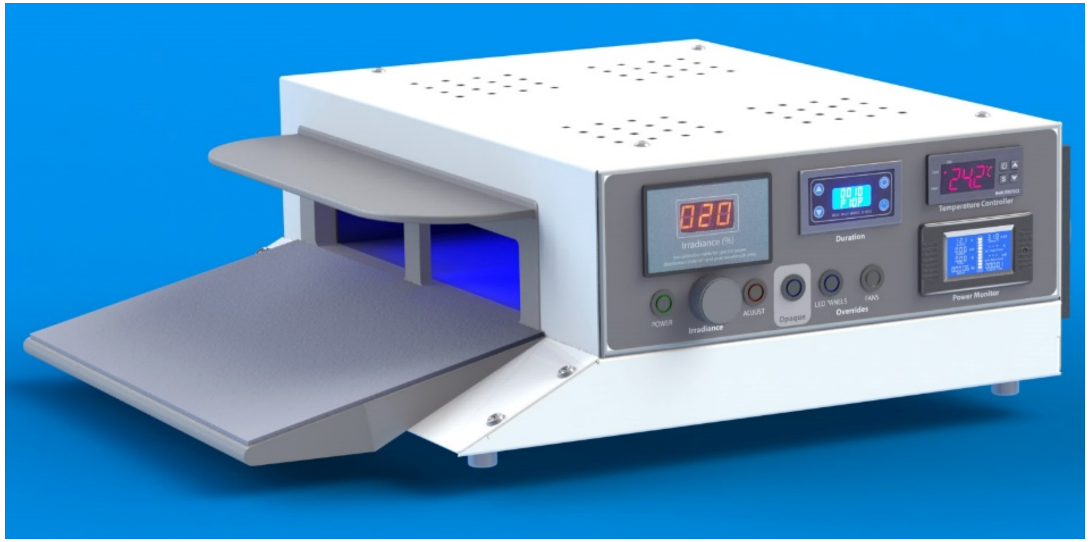
Prototype Optical Stack & Hand Compartment



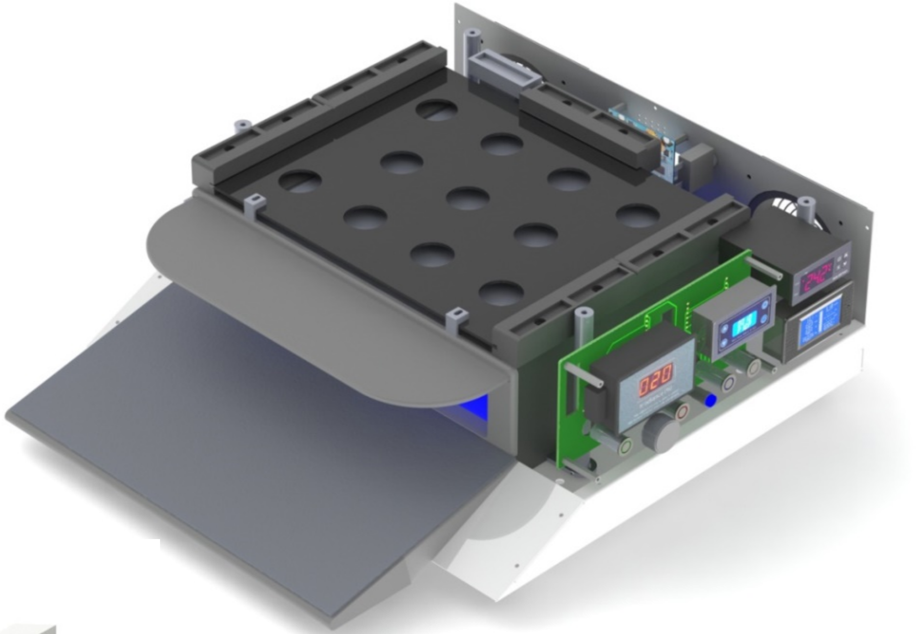


Brett Levac Checking Prototype with Spectrophotometer

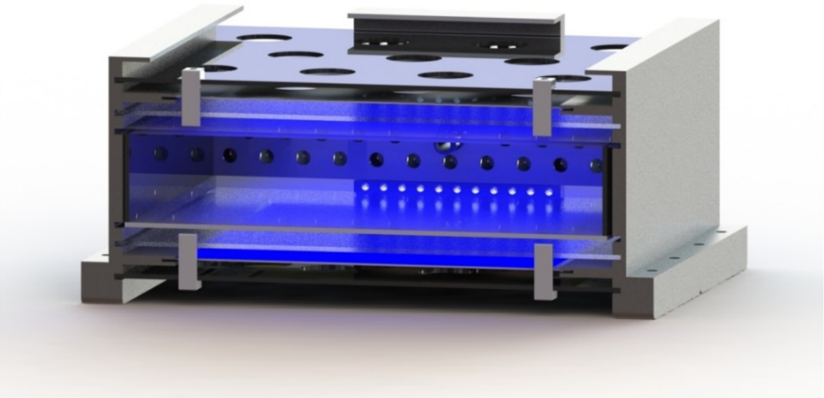
Prototype 4



Computer Rendering of Entire Assembly

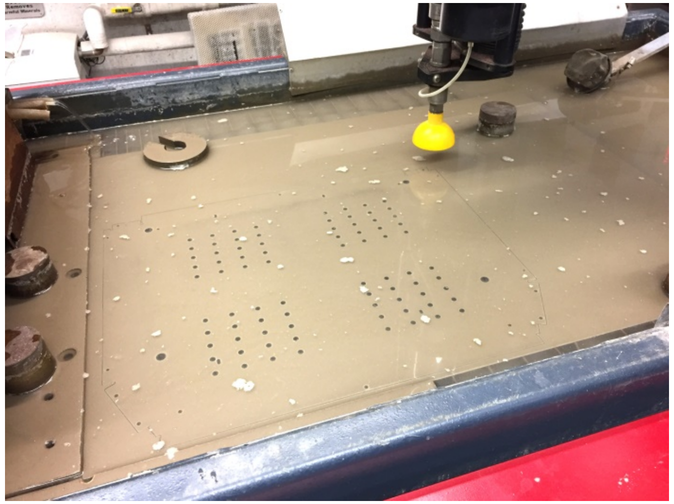


Cut-away View

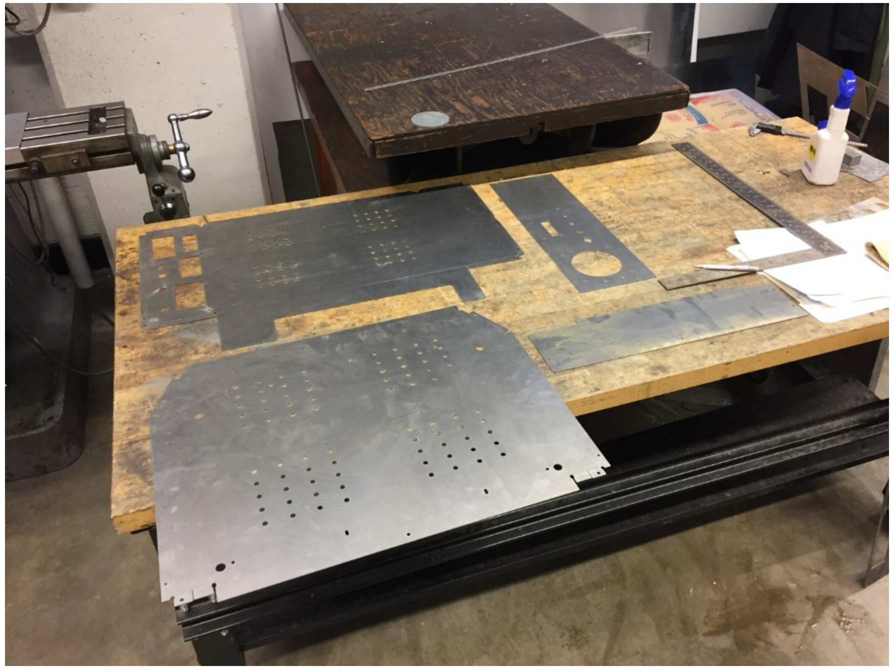


Computer Rendering of Optical Stack

Student Machine Shop



Waterjet Cutter



Parts Ready for Bending in a Brake

Steven S. Saliterman

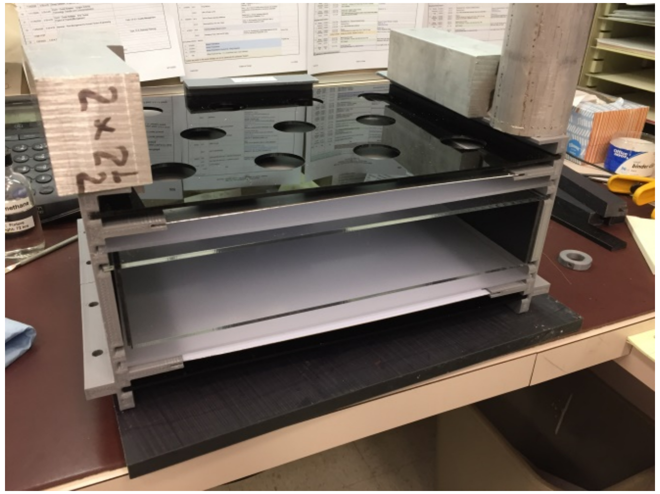
Finishing the Chassis

Post-Bending

Post-Powder Coating

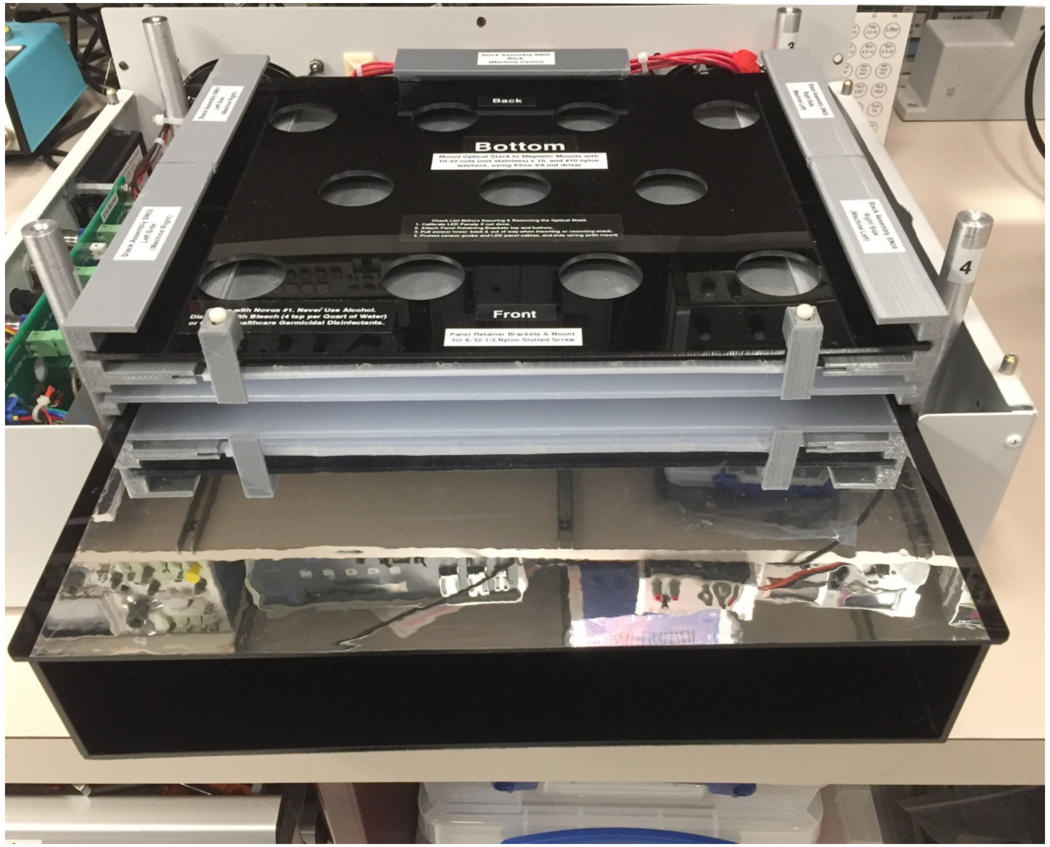
Assembly

Solvent Bonding Parts into Assemblies

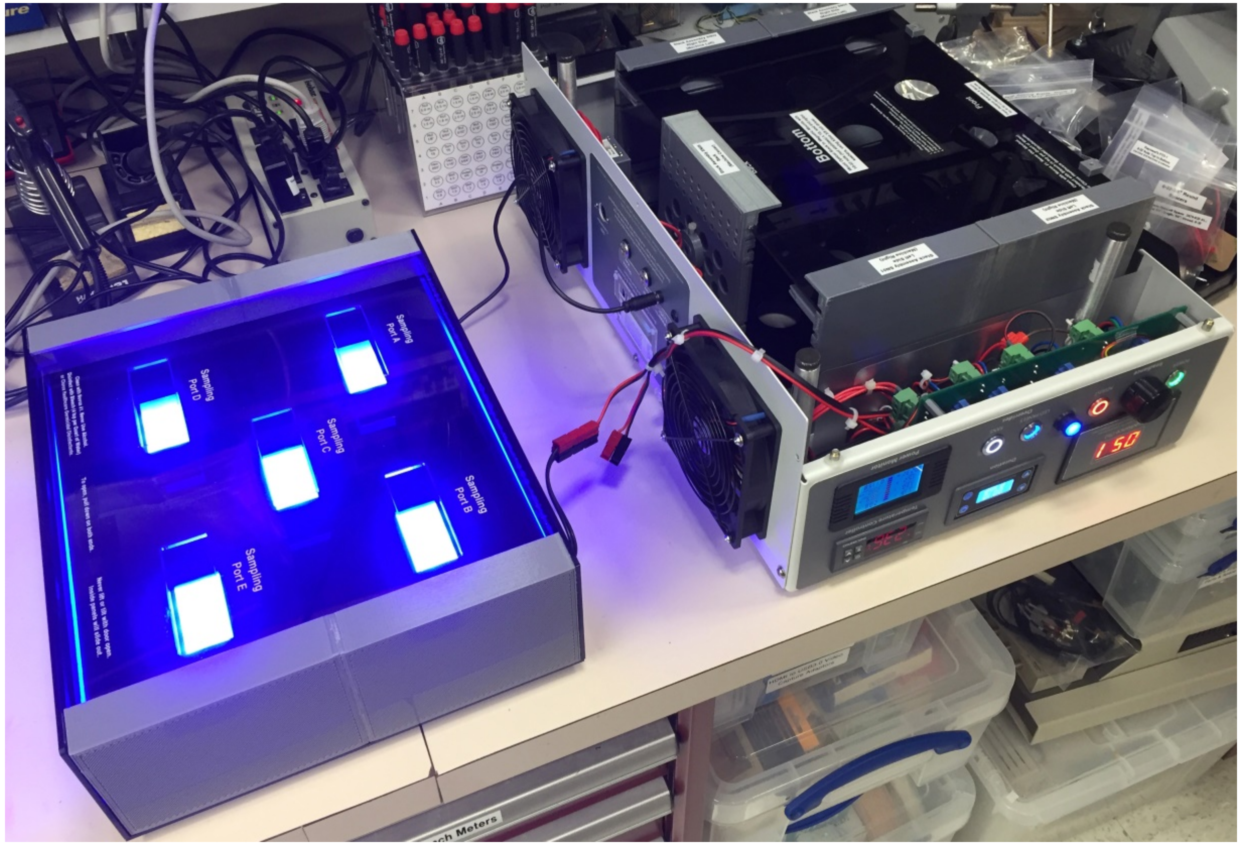


Optical Stack Assembly
Solvent for Plastics: Methylene Dichloride

Optical Stack, Hand Enclosure & Calibration

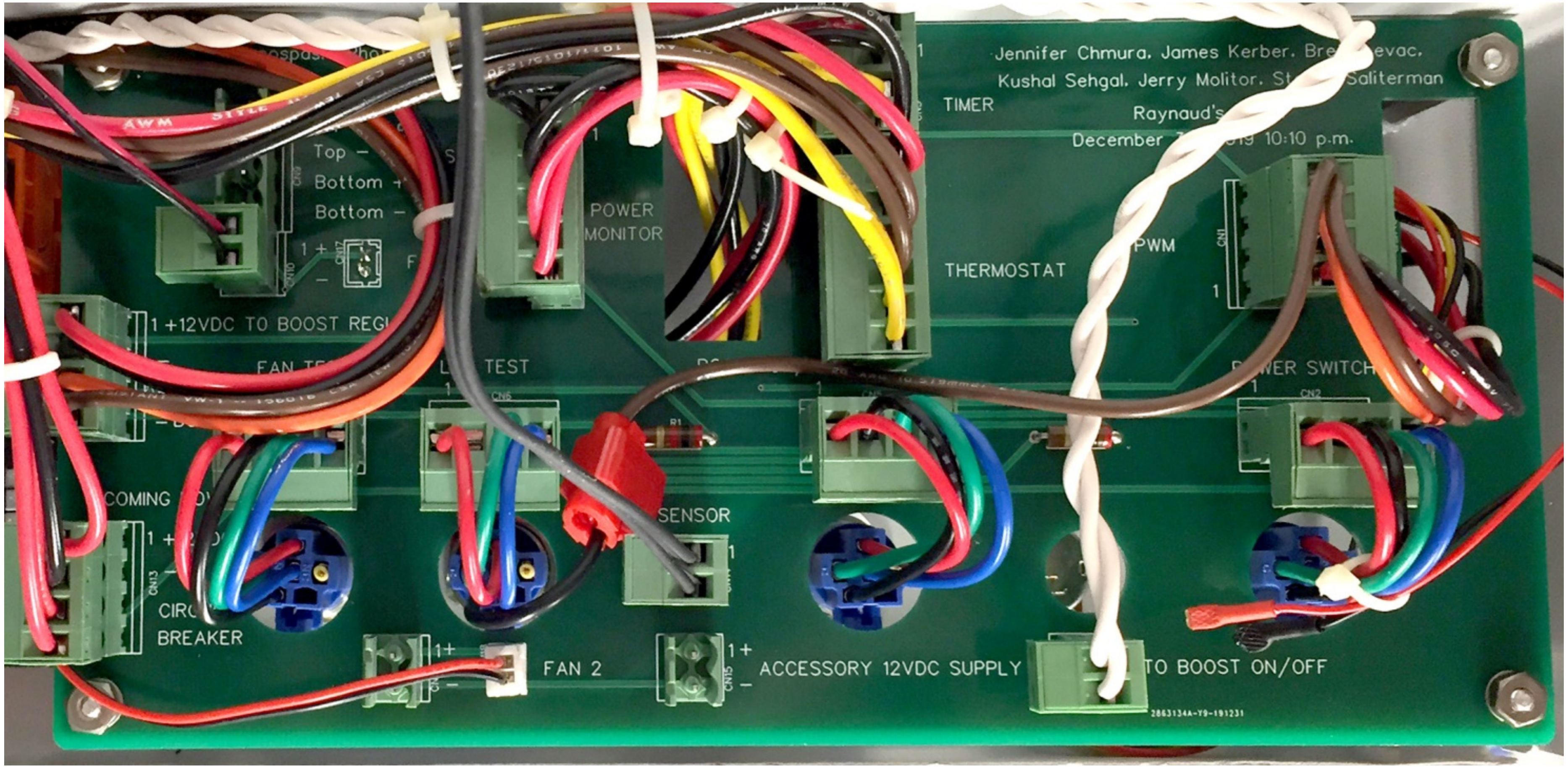


Insertion of Opaque Hand Enclosure into Optical Stack



Calibration of an LED Panel

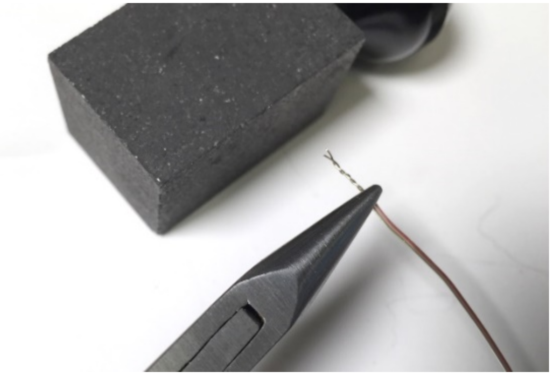
Printed Circuit Board



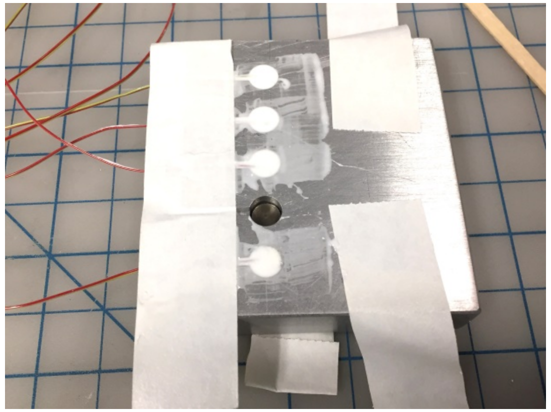
Making Thermocouples

Tools and Cables for Spot Welding

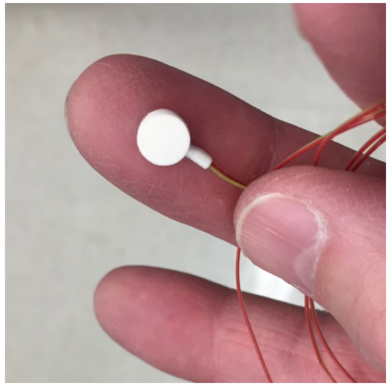
Graphite Welding Electrode Block & Cable



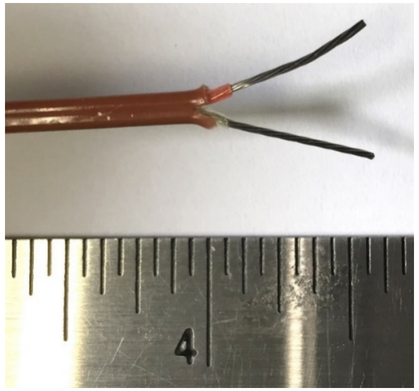
Wire held with welding pliers at the base of the twisted bare wire.

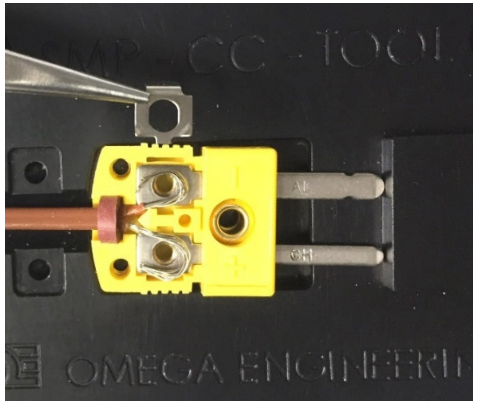


Aluminum Mold for Epoxy Encasement of Welded TC



Finished Sensor

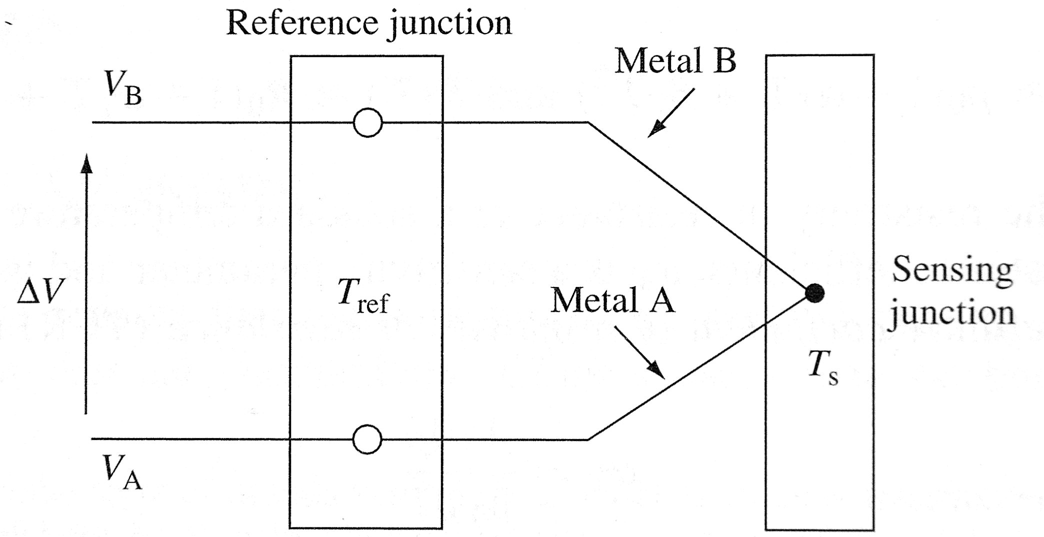




TC Connector Plug – Type K

Thermocouple Principle…

- Potentiometric devices fabricated by the joining of two different metals forming a sensing junction:
  - Based on the thermoelectric *Seebeck effect* in which a temperature difference in a conductor or semiconductor creates an electric voltage:



$$\Delta V = \alpha_s \Delta T$$

Where

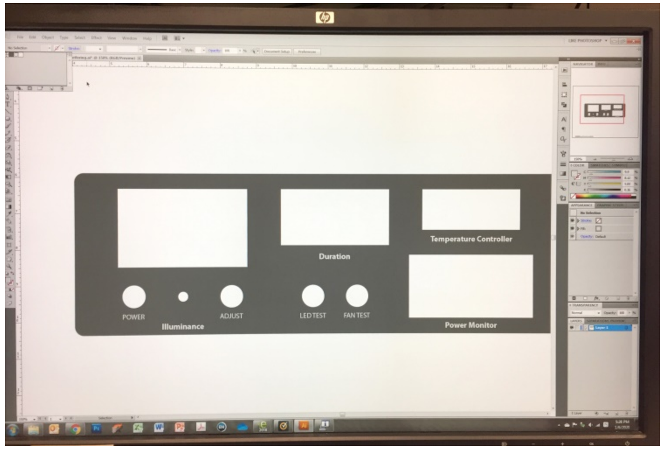
ΔV is the electrical voltage,

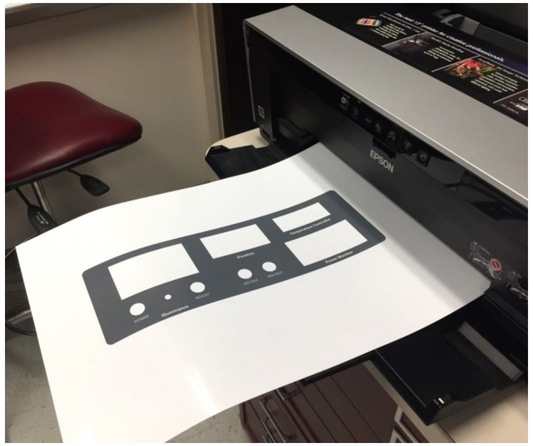
α_s is the Seebeck coefficient expressed in volts/K°, and

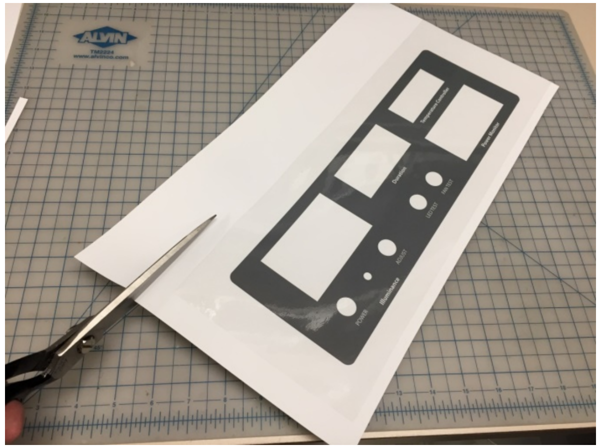
ΔT is the temperature difference (T_S - T_{ref}).

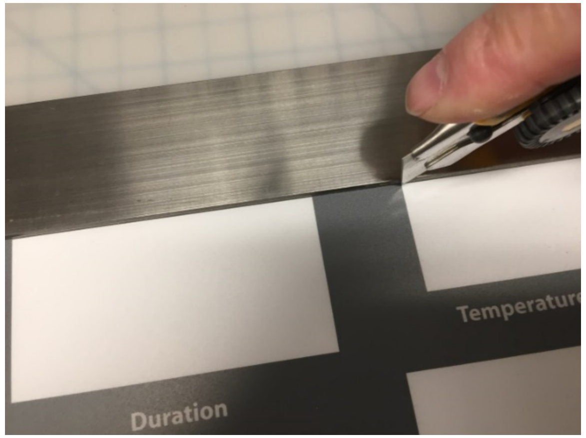
Gardner, JW, VK Varadan and OO Awadelkarim, *Microsensors, MEMS and Smart Devices*. John Wiley & Sons, Ltd. W. Sussex (2001).

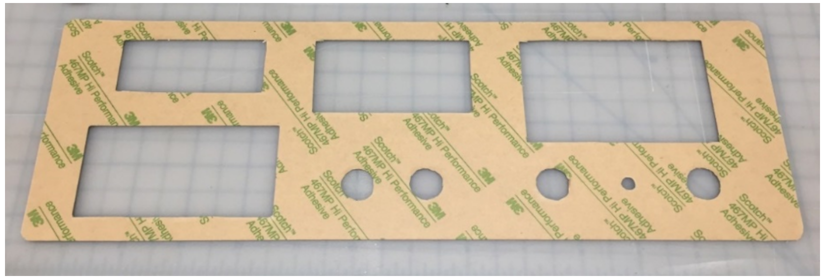
Polycarbonate Front Panel











Steven S. Saliterman

Final Device in Clinical Study Rehearsals

Kushal Sehgal, James Kerber & Emily Wagner