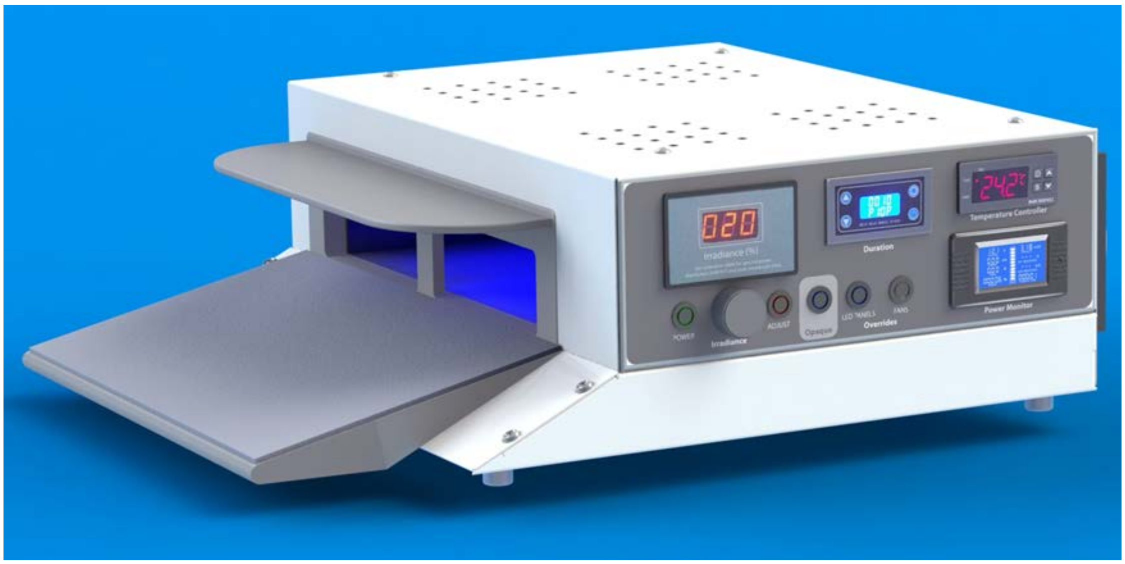
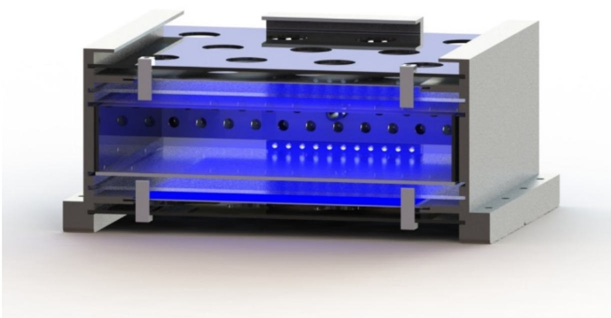
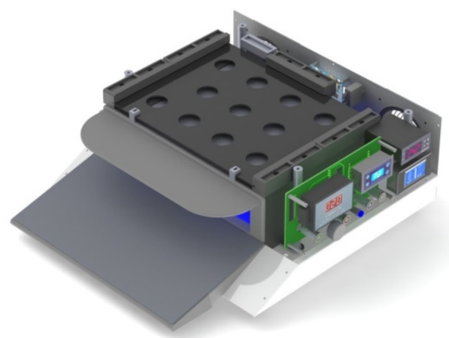
Raynaud’s Project Manual

Phototherapy Device for Studying the Effects of Blue Light on Patients with Raynaud’s Phenomenon







University of Minnesota
Department of Biomedical Engineering

Brett Levac, James Kerber, Kushal Sehgal, Emily Wagner, Jennifer Chmura, Jerry Molitor and Steven Saliterman

Distributable Abridged Version April 20, 2024

Contents

Part 1 – Introduction and Raynaud's Project Team

1.1 Discovery, Ideation, Invention & Prototype

A collaboration of undergraduate students, clinicians, and biomedical engineers undertook developing a therapy for vasospasm symptoms in patients with Raynaud's phenomenon in 2017. Our journey began with a written request by a physician on behalf of his wife, seeking a non-pharmacologic therapeutic option for her Raynaud's symptoms. We explored the pathophysiology of the disorder, and current therapy. We decided to pursue cellular signaling mechanisms of microvascular structures. Our collective experience in photonics, medical devices, and management of patients with this disorder proved beneficial.

Among the challenges was creating a precision low-level light source at a specified light wavelength to modulate s signaling pathway of the microvascular structures. The PTD has evolved from a foam-board mockup, through three prototypes, to the present research tool. Hopefully, what we learned can be translated into low-energy consuming hand and feet garments, with embedded light sources for patient use.

On January 9, 2024, the authors and the University of Minnesota received a utility patent (U.S. 11,865,357) for the light-based treatment devices and methods.

On March 26, 2024 the project was published in the Annals of Biomedical Engineering, titled: *An Experimental Phototherapy Device for Studying the Effects of Blue Light on Patients with Raynaud's Phenomenon*. (https://doi.org/10.1007/s10439-024-03487-z)

A clinical study was approved by the University of Minnesota Institutional Review Board. Once funded and underway, this will begin the *development phase* for a potential treatment option. To avoid a conflict of interest and potential concerns with study blinding, our new role will be to provide only technical assistance to the clinical study investigators.

1.2 Phototherapy Device

The ***Phototherapy Device (PTD-1)*** is a research tool for studying the effects of blue light on the symptoms of patients with Raynaud's disease and phenomenon. The goal is to develop new forms of treatment for use in marketable devices, such as a stationary unit or wearable glove. Initial studies will look at the effects of blue light.

The material described in this ***Manual*** is a consolidation of many years of undergraduate student teamwork. All original designs have been thoroughly reviewed and reworked where necessary. The present embodiment is the result of three previous iterations of student prototypes - beginning with simple foam-board mockups to full scale subassemblies. Much of the electronic circuitry was designed and hand-wired in the previous iteration. Some of the preliminary work was done in the Earl Bakken Medical Devices Center, Student Machine Shop (Polaris Labs), and Anderson Student Laboratories.

Foam-board Mockup

For continuity and integration, all of the original sketches, drawings and schematics have been redrawn, and the present device constructed in Prof. Saliterman's lab. Advanced design tools, including simulation of light rays have been applied, printed circuit boards substituted for hand wiring, and rapid prototyping supplemented with standard manufacturing techniques where feasible.

Prototype 3

1.3 Raynaud's Project Team

Participants

The project began in 2017 and remains active, involving an interdisciplinary team - biomedical and electrical engineering, intellectual property law, public health, rheumatology and internal medicine. Jennifer Chmura and Brett Levac had previously addressed use of blue light in the treatment of neonatal jaundice, developing a treatment device that could be used in the economic and resource deprived areas of Nigeria. This Bakken Medical Devices Center intern team was led by Prof. Saliterman.

Upon completion of the neonatal jaundice project, Saliterman asked members of the team if they wanted to participate in a new project, addressing the need for treating the symptoms of Raynaud's phenomenon; and exploring the possibility that blue light may be useful in treating symptoms of vasospasm associated with this disease. Undergraduates James

Kerber and Kushal Sehgal joined the team. Dr. Jerry Molitor, a Rheumatologist, also joined the effort. After further investigation we realized that to study the use of blue light, a precision low-power phototherapy device was needed. The basic implementation, including a clinical study and proposed translational devices, were brainstormed. A provisional patent was filed and renewed a year later. Chmura left the team for other pursuits upon conversion of the provisional application to a utility patent application.

Emily Wagner joined the team from the Physiology department as a Directed Undergraduate Research project.

Design and Fabrication of the Phototherapy Device

Realization of the phototherapy device took place in the *BMEN 3151 Medical Device Practicum cours*e (Levac, Kerber, & Sehgal).

The team submitted a study protocol that was approved by the University of Minnesota Intuitional Review Board. By this point Levac, Kerber and Sehgal entered graduate programs. During the COVID lockdown (with special permission), Kerber, Wagner, Sehgal and Prof. Saliterman completed over 20 trial runs of various facets of the proposed clinical study, serving as both healthy volunteers and research assistants. This served to refine both the study protocol and instrumentation.

Levac, with assistance from Kerber, Wagner, Molitor, and Saliterman, then wrote a paper describing the instrumentation and proposed study.

The *investigative phase* of the project is chronicled in **Part 2 - Photo History**.

Acknowledgements

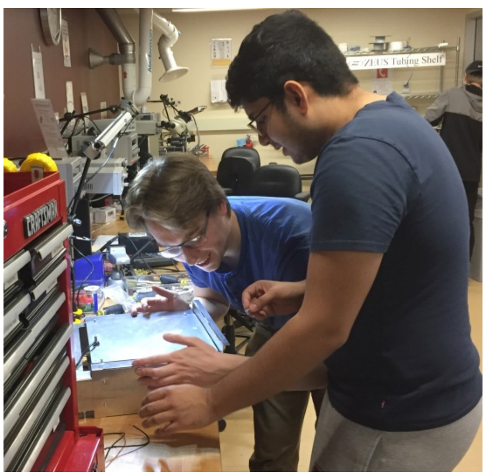
The team is grateful for assistance from the University of Minnesota Polaris Labs; EBMDC; Vaughn Schmid and the University of Minnesta Technology Commercialization; Qi Shao and the John Bischof Lab; the Institute for Engineering in Medicine; Ronald Bystrom in the CSE Shop; Paul Bearmon; Geoffrey Harms in the Research Machine Shop, St. Paul Campus; University of Minnesota Institutional Review Board, its facilitators and staff; and Greg Rabenort & Mark Wichser at J & E Shakopee for powder-coating our fabricated sheet metal enclosure. And to the many others whose contributions may have been small, but were essential.

Thank you!

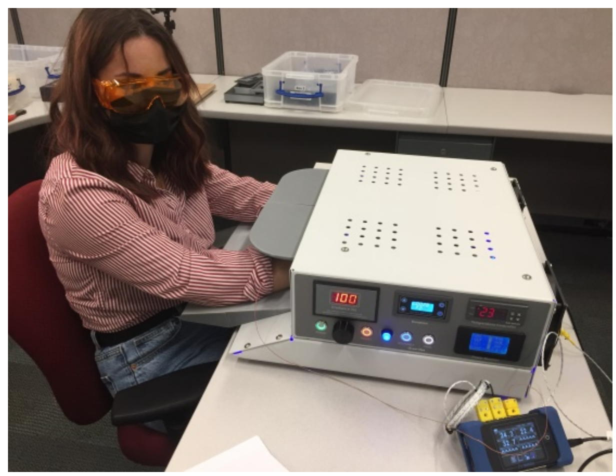
Team Members

Brett Levac

Jennifer Chmura



James Kerber and Kushal Sehgal



Emily Wagner

Jerry Molitor

Steven Saliterman

Publication Author Biographies (April 5, 2024)

Brett Levac is currently a PhD student in the Chandra Family Department of Electrical and Computer Engineering at the University of Texas at Austin where he is a recipient of an Engineering Doctoral Fellowship and the Tolbert Endowed Fellowship in Electrical Engineering. He received a BE in Electrical Engineering from the University of Minnesota in 2020. His primary interests lie at the intersection of electrical engineering and medicine.

James Kerber is currently a law student at the University of Minnesota Law School and a patent agent at Shumaker & Sieffert in Woodbury, MN. He received his Master of Biomedical Engineering in 2021 and his Bachelor of Biomedical Engineering in 2020, both from the University of Minnesota. His interests lie in the intersection of engineering and law.

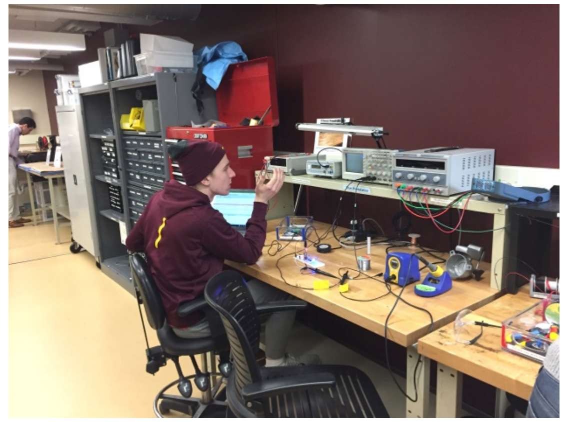
Emily Wagner is currently a Master of Public Health Student at the University of New England. She received a BA in Human Physiology from the University of Minnesota in 2022.

Jerry A. Molitor is professor of medicine in the Department of Medicine at the University of Minnesota, division of Rheumatic and Autoimmune Diseases, and Chief of Rheumatology at the Minneapolis VA Medical Center. He directs the University of Minnesota multidisciplinary Scleroderma clinic.

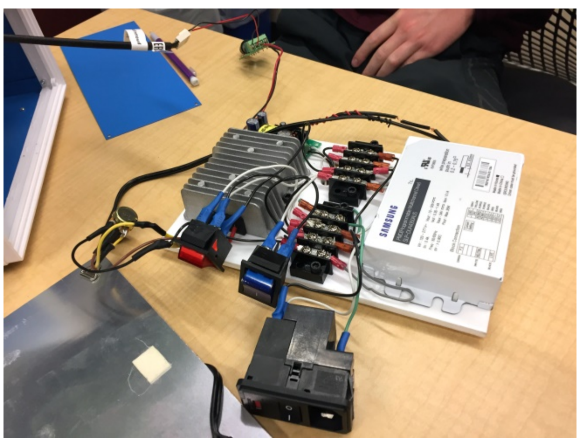
Steven S. Saliterman is a professor at the University of Minnesota and teaches in the Department of Biomedical Engineering. He received his medical degree from the Mayo Medical School in 1977, and specialty degree in Internal Medicine from the Mayo Clinic in 1980. He worked at the NASA Johnson Space Center as an intern in the Life Sciences Division (1973, 1974), and as a Research Fellow at the NASA Ames Research Center Cardiovascular Lab (1976). He is a past Chair, Department of Medicine at Methodist Hospital, and is a VentureWell Faculty Grant recipient. His research is in vascular disease, medical devices and education, and he is author of the SPIE textbook: *Fundamentals of BioMEMS and Medical Microdevices*. He is a member of SPIE, the international society for optics and photonics, and Fellow of the American College of Physicians (ACP). He is co-chair and moderator of the 2024 Design of Medical Devices (DMD) *Medical Education Training Contributing Papers Topics*.

Part 2 – Photo History

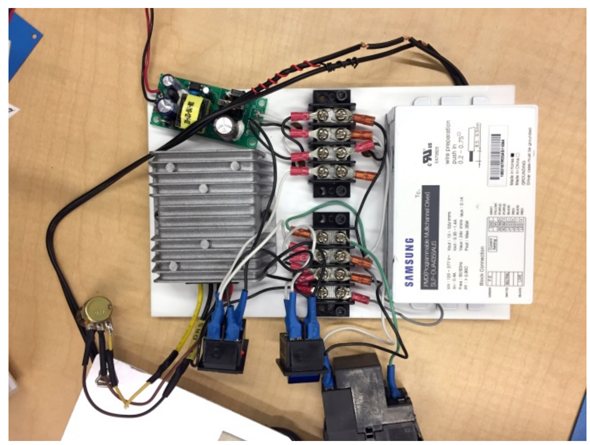
Brett Levac at Axman



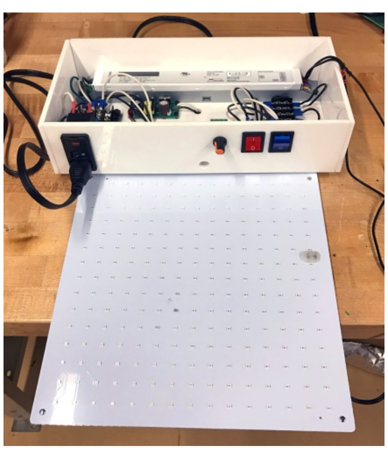
Brett Levac in MDC



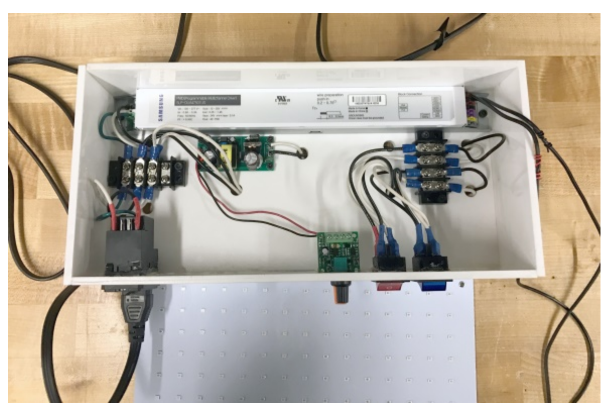
Prototype #1



Prototype #1



Prototype #2



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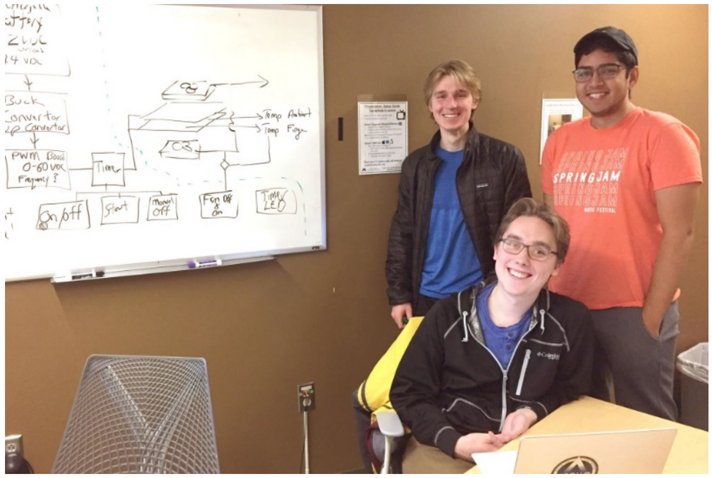
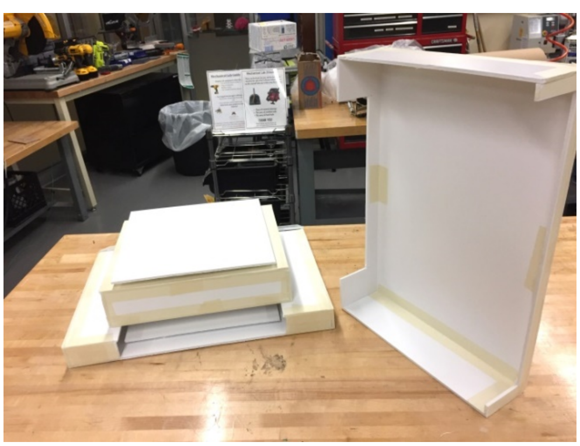
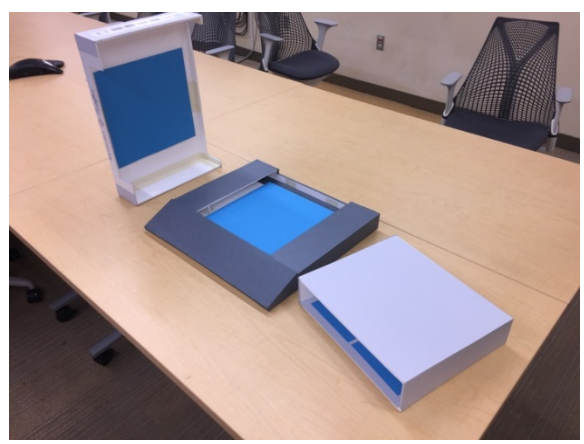


Brett Levac, Kushal Sehgal and James Kerber in MDC


Brett Levac in Prof. Saliterman’s office


Jennifer Chmura in MDC

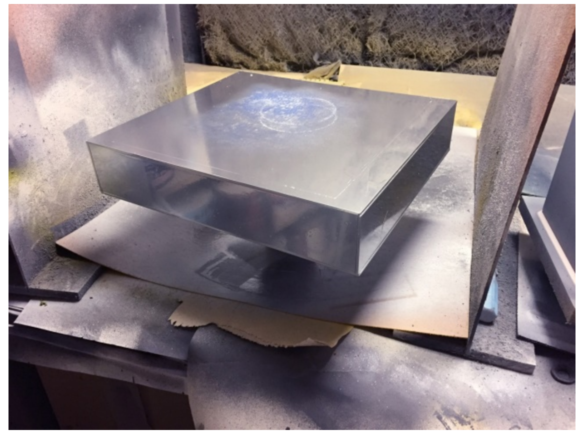

Foamboard Mockup


Foamboard Mockup with Attached Artwork

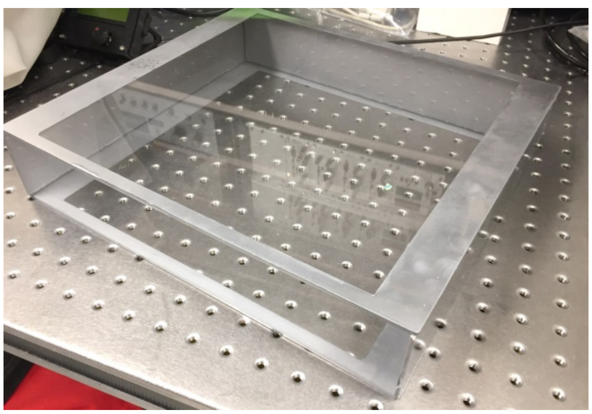
Foamboard Mockup with Attached Artwork

Kushal Sehgal and James Kerber in MDC

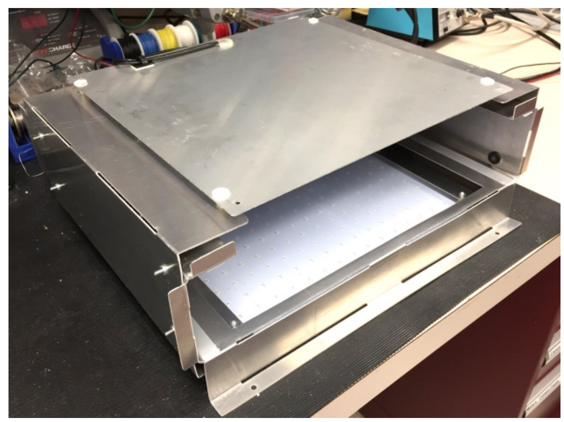
Hand Enclosure Prototype



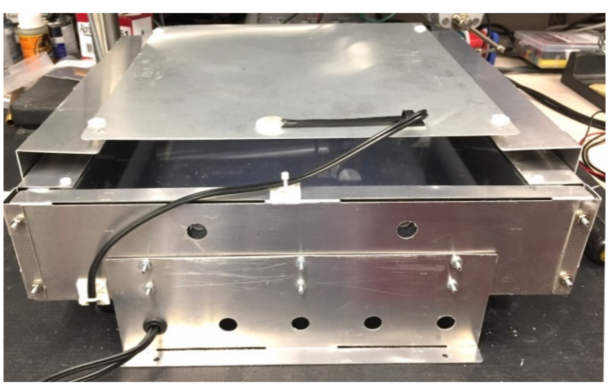
Hand Enclosure Prototype Masked & Painted



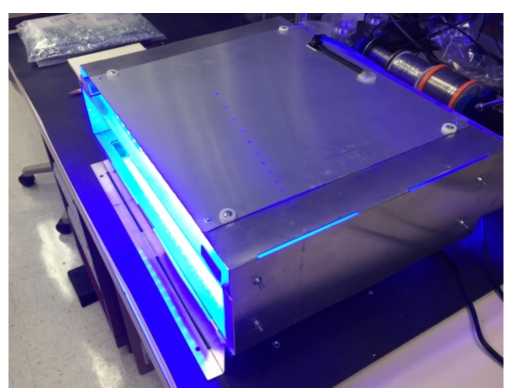
Hand Enclosure Prototype Masking Removed



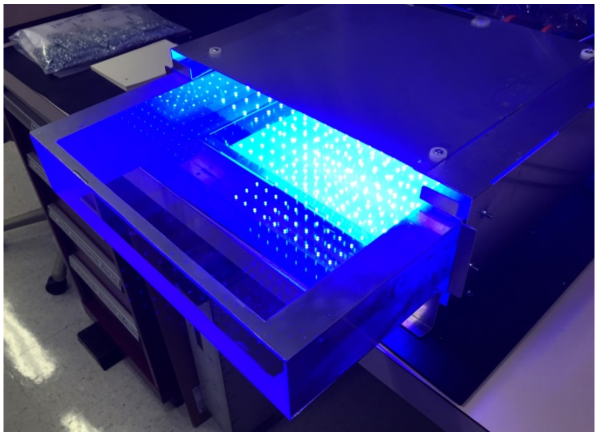
Prototype Optical Stack Front View



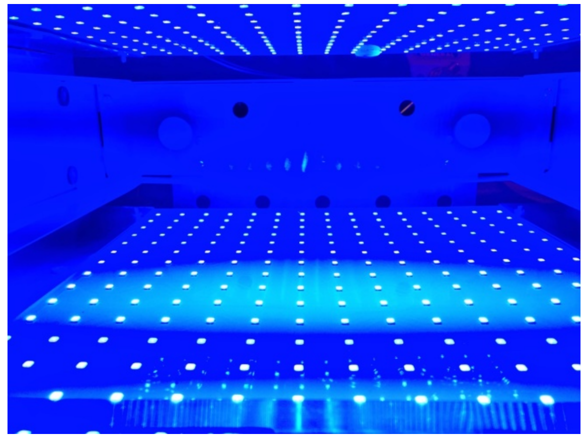
Prototype Optical Stack Side View



Prototype Optical Stack with Powered LED Panels

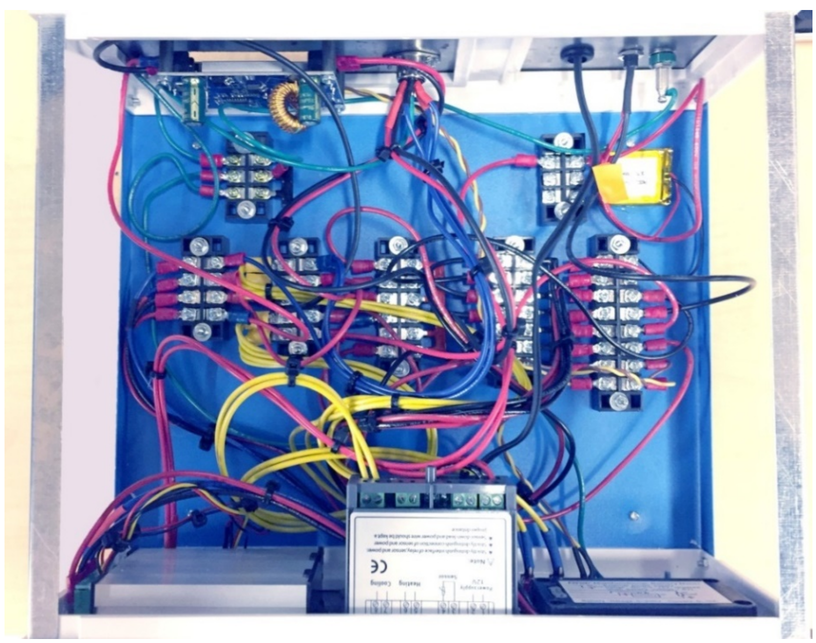


Prototype Optical Stack & Hand Compartment



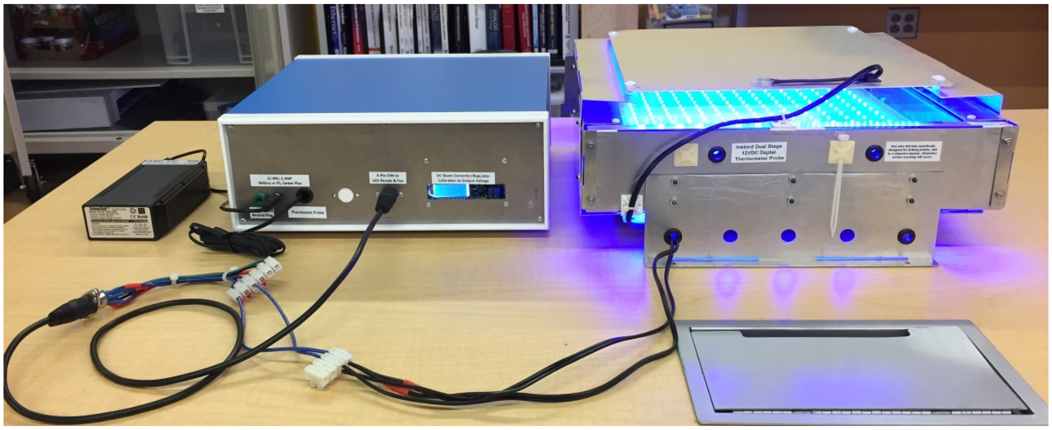
Inside the Hand Compartment

Prototype #3 Front View

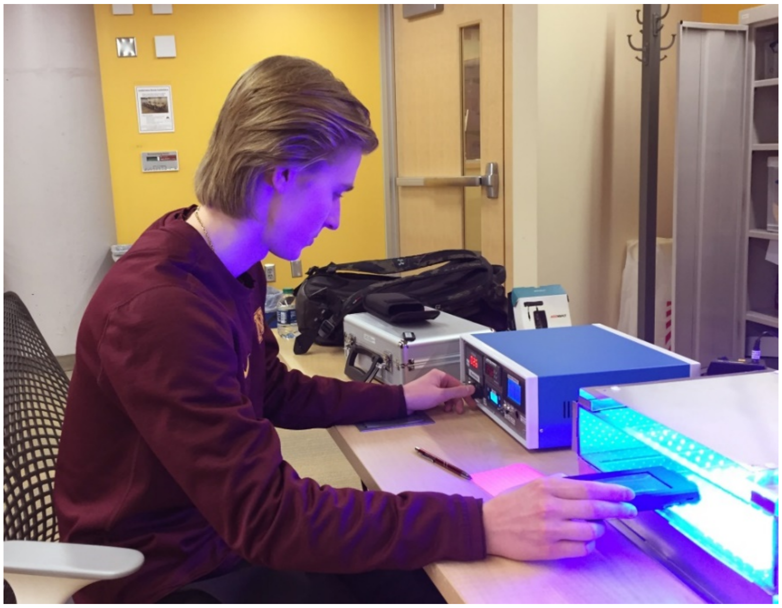


Prototype #3 Wiring

Prototype #3 with Prototype Optical Stack, Front View

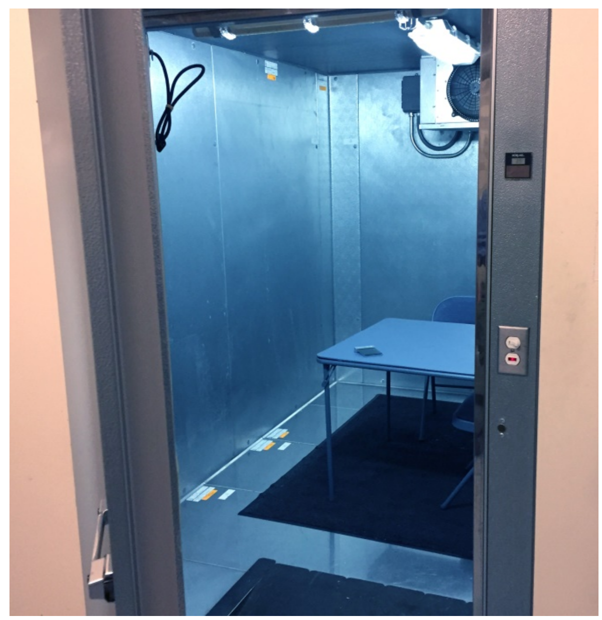


Prototype #3 with Prototype Optical Stack, Back View



Brett Levac Checking Prototype with Spectrophotometer

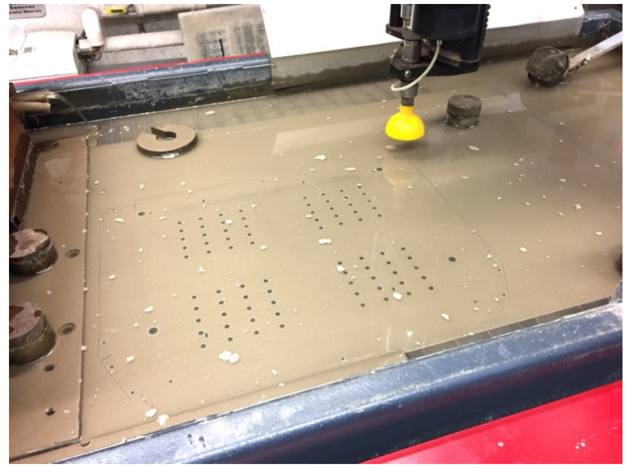
Clinical & Translational Science Institute



Cold Room Adjacent to Study Area Room

Jerry Molitor in Study Area Room

Student Machine Shop Waterjet Cutter



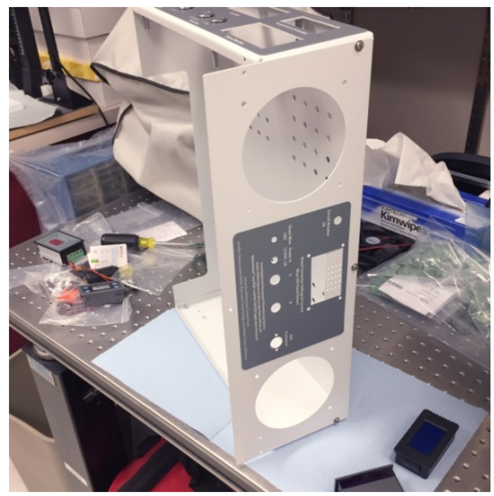
Student Machine Shop Waterjet Cutter

Parts from the Waterjet Cutter Ready for Bending in Polaris Labs

Post-Bending

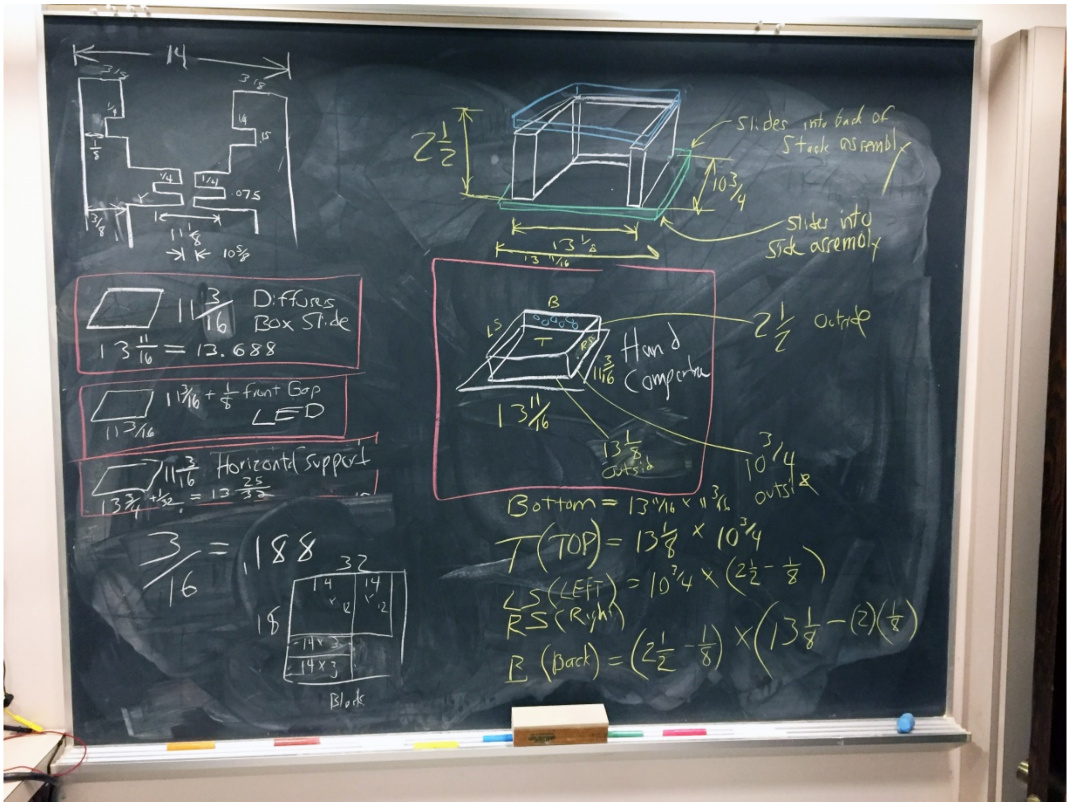
Post-Powder Coating

Assembly

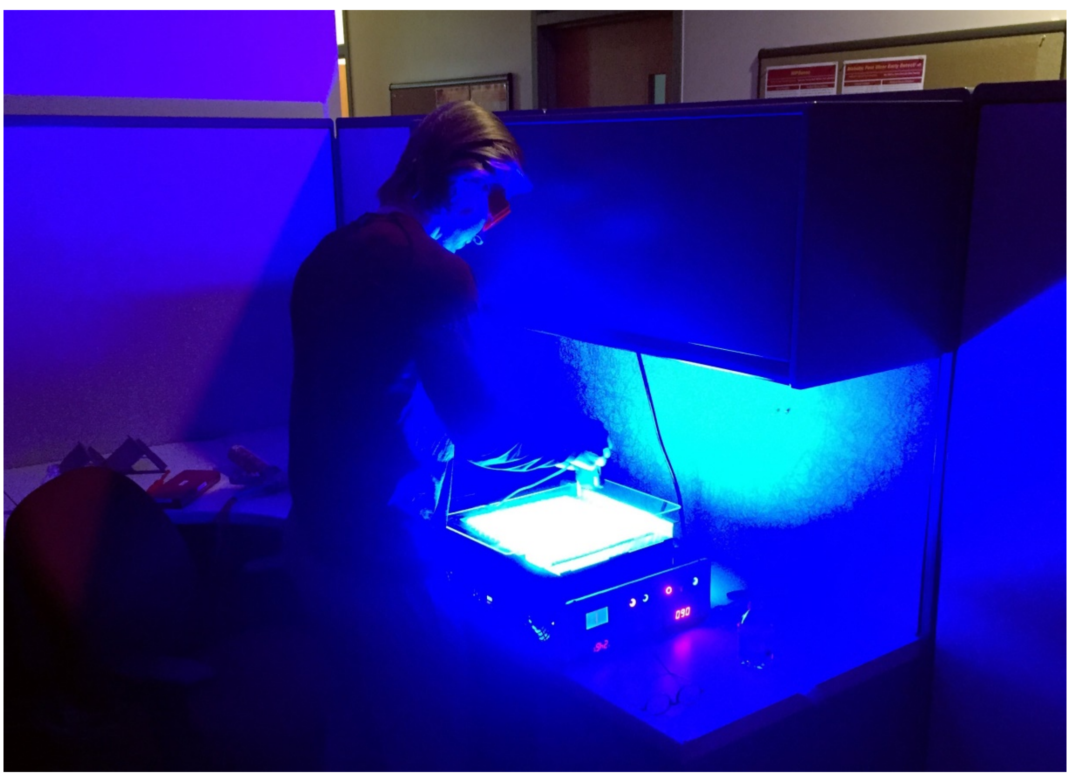


Assembly

Final Assembly & Testing in Prof. Saliterman's lab



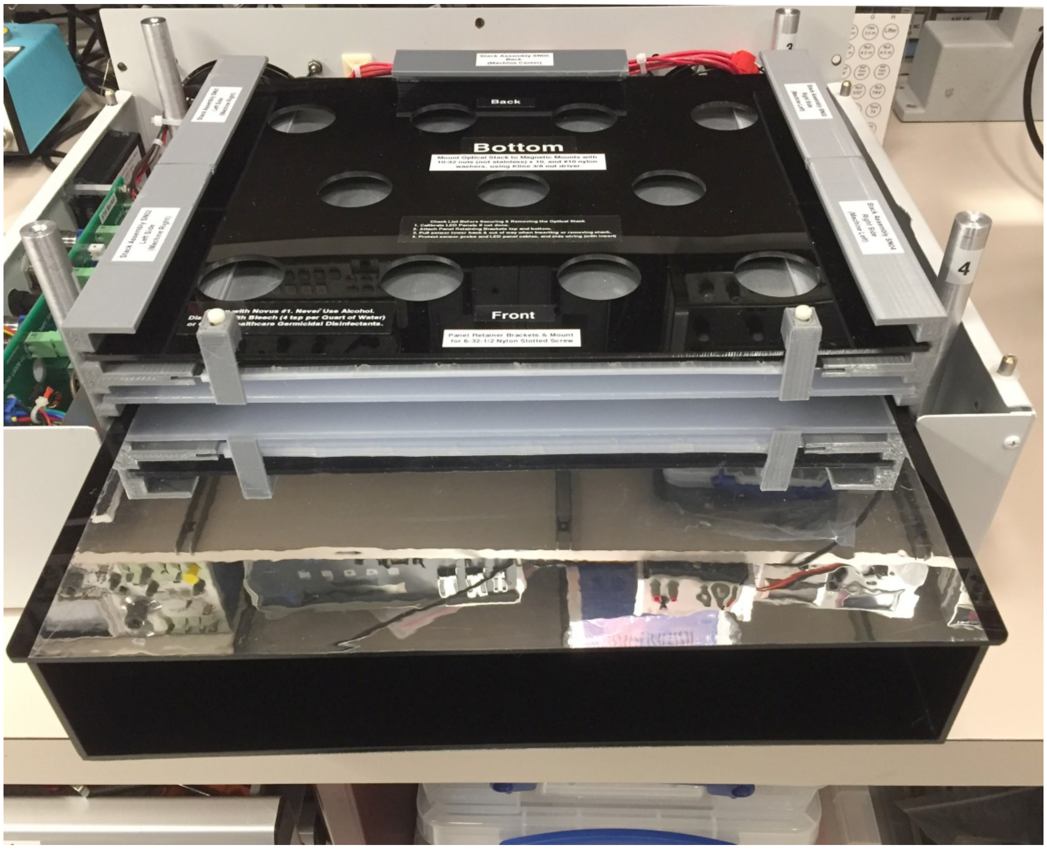
Daily Work-in-Progress Prof. Saliterman's lab



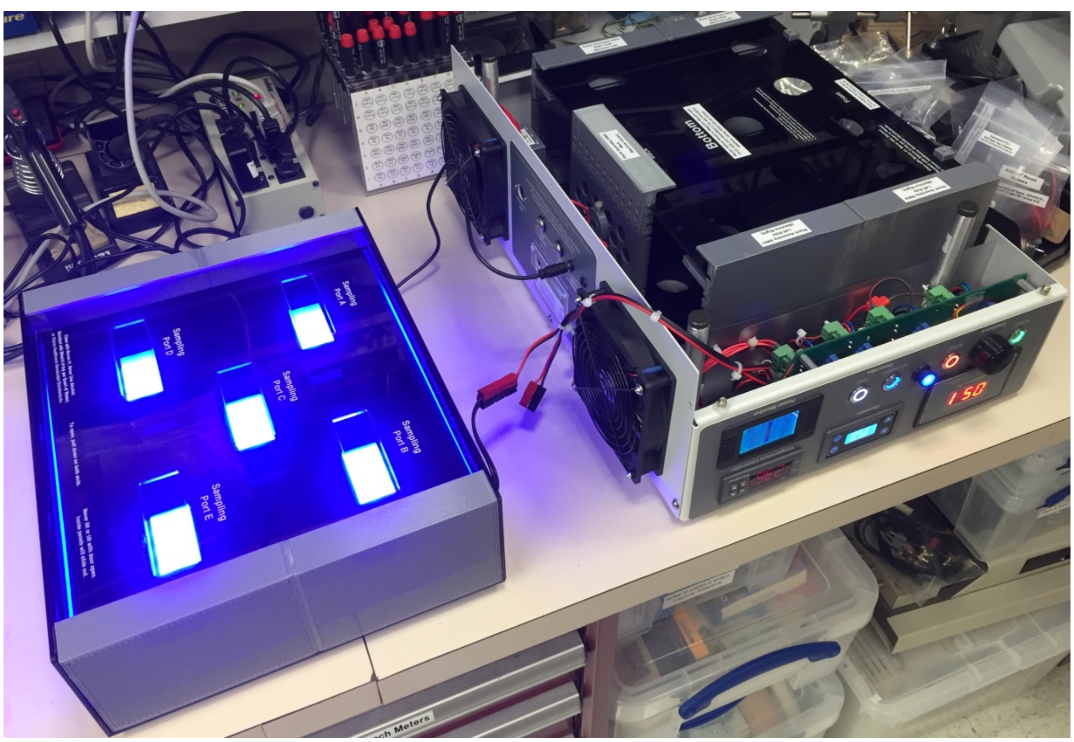
Brett Levac Developing Calibration Technique for LED Panels outside Prof. Saliterman's office

Solvent Bonding (Dichloromethane CH_2Cl) Optical Stack Parts in Prof. Saliterman's lab.

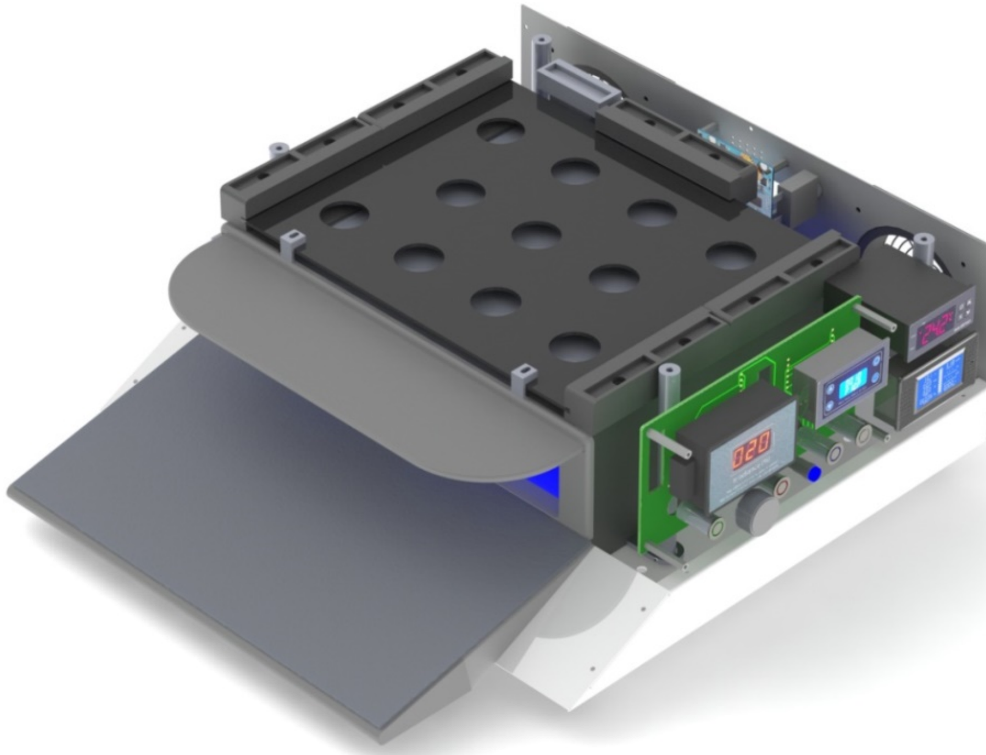
Solvent Bonding Optical Stack in Prof. Saliterman's lab



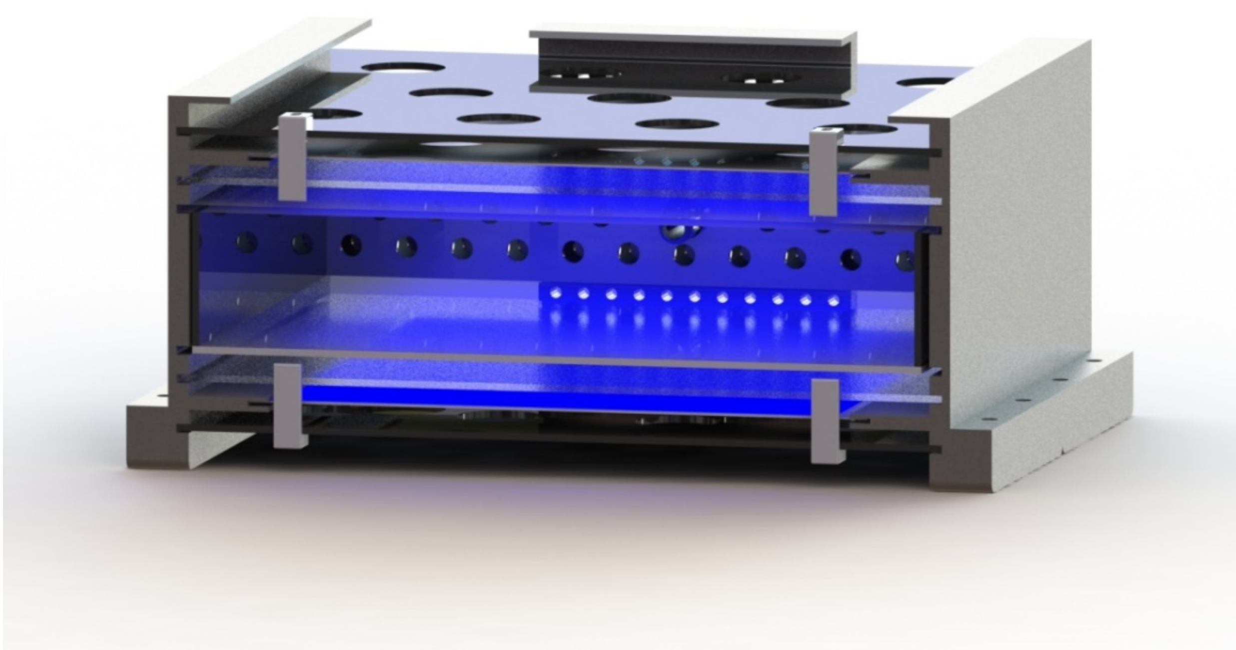
Testing Insertion of Opaque Hand Enclosure into Optical Stack



Calibration of an LED Panel in Prof. Saliterman's lab



Computer Rendering of Subassemblies



Computer Rendering of Optical Stack

Custom IR Imaging Camera Stand Undergoing Testing

Test Placement & Fastening Technique for Skin/Finger Thermocouple outside Prof. Saliterman’s office. Medical grade paper tape works well.

James Kerber & Emily Wagner Rehearsing Study Protocol outside Prof. Saliterman's office Summer 2021

Kushal Sehgal, James Kerber & Emily Wagner Rehearsing the Study Protocol

Part 3 – Operating Manual

3.1 Introduction

The **Phototherapy Device** is an instrument for studying the effects of low energy blue light irradiance of the hands for symptoms of patients with Raynaud's disease or phenomenon. The mechanism of action is at the cellular signalling level and the potential usefulness for vasodilation has been previously studied in animal models.

The **Phototherapy Device** is designed for both experimental and control (sham) groups. All procedures and operation of the equipment are the same for both groups except that the sham treatment group is not exposed to the blue light generated. Either a clear or opaque plastic hand compartment is inserted into the main unit by the investigator, depending on the forthcoming session being actual treatment or sham treatment respectively. The two compartments are otherwise identical in construction.

The **Phototherapy Device** can be utilized for either a single or double blinded study, although initially being configured for a single-blinded study. All procedures, settings and operation of the blue light source and fans are identical for both experimental and sham groups. The participant wears eyewear that blocks blue light, and the hand compartment is shielded from view. There is no direct or reflected blue light visible to either group. There is no perceptible difference to the participant between actual treatment and sham treatment other than as related to the blue light therapy. The instrument control panel and settings are not visible to the participant.

The unit delivers visible blue light irradiance to the upper and lower surfaces of the hands for a specified duration of time. The spectral power density of the blue light does not exceed 375 $\mu W/cm^2$ at a wavelength of 451 nm. (There is no ultraviolet or laser light.)

As a study instrument the ability to adjust settings and to monitor the operation for conformity to study parameters and safety is of paramount importance. It also has an ability to emulate achievable conditions in other treatment embodiments, such as a glove. This includes an ability to operate from battery sources and to monitor performance. The hand compartment temperature is thermostatically controlled.

Ancillary equipment includes an **Omega Temperature Data Logger** for recording finger, hand compartment and room ambient temperature; **stand** mounted **Hti Thermal Imaging Camera** for taking infrared images of the hands before and after blue light exposure; and **Honeywell Ultraspec® 2000 Safety Eyewear** designed to block blue light. Optionally a clear plastic partition may be placed between the participant and research assistant to reduce the risk of COVID-19 transmission. The interchangeable hand compartments and eyewear are disinfected with Clorox wipes or similar agent after every use. Special considerations for performing a study during the COVID-19 pandemic have been submitted as part of the research protocol to the Institutional Review Board (IRB).

3.2 Features

The **Phototherapy Device** consists of a clear plastic hand compartment inside of a larger metal enclosure, and placed between two LED (light emitting diode) panels (above and below). Controls allow for setting the irradiance and time of exposure based on the study parameters. Additional controls include a power on/off switch, and overrides switches for testing the internal fans and LED panels. It is a low voltage device operated from a UL approved, 12-volt DC power adaptor that plugs into a 110-volt AC wall receptacle.

Internally a hand compartment sits within an optical stack made of the following: upper vented stabilizer, upper blue LED panel, microsphere embedded acrylic diffuser, hand compartment with top and bottom acrylic surfaces, lower diffuser, lower blue LED panel and lower stabilizer.

Shown is the internal optical stack. A sham treatment opaque acrylic hand compartment is partially slid into the device for demonstration purposes.

The optical stack is a distinct unit that may be removed by a technician for servicing if necessary. A similar optical stack exists within the **LED Light Panel Calibrator**, a device used to calibrate the blue-light LED panels.

The **Phototherapy Device** has a handle and is portable. It has an instrument panel cover that also serves as a support base with bumper feet for standing the unit on end. There is a front light shield & bezel though which a participant’s hands are inserted. This two-part bezel is magnetically attached, and may be removed to exchange hand compartments (clear vs opaque).

There is a pre-configured thermostat that operates two rear fans to assist in maintaining the internal hand compartment temperature within a few degrees Celsius of ambient room temperature. There are power monitors to record voltage and current of the system and the blue LED panels separately, used for monitoring the health of the system.

A rear control panel contains a DC power adaptor jack and port for passing through the hand compartment thermocouple. There is also a small LED display for reading the voltage and current to the blue LED panels, and technician-only accessible calibration controls. Muffin fans provide for gentle air flow through the system (including hand compartments) from front, top and bottom to the back.

The hand compartments (both clear and opaque) contain two plates of staggered holes at their rear that allow air to pass from the front to the rear of the unit with no perceptible air flow to the participant. There is an internal thermocouple that is self-positioning whenever a hand compartment is inserted.

A vinyl arm pad is placed on the front sloping section of the unit and table so that the hands may rest comfortable in the unit's hand compartment. The hands are isolated from the internal workings and electronics of the unit. The pad may be removed easily for cleaning and disinfecting between participants.

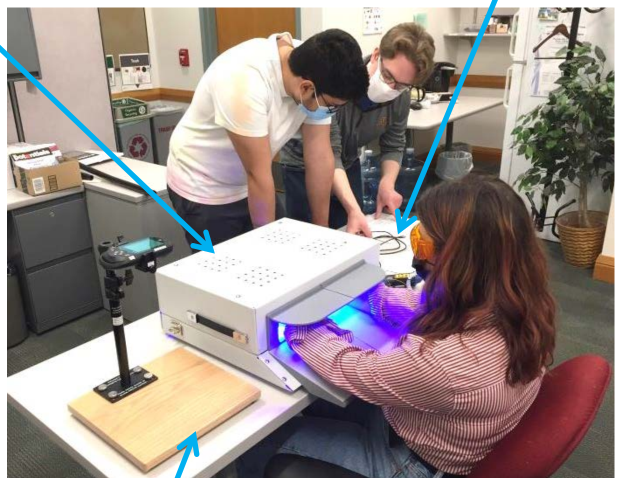
Additional safety features include a thermally protected low voltage DC power adaptor (low voltage) & fuse, sham hand compartment detection, total power cutoff when a hand compartment is removed (or not present), compartmentalization and isolation of electronics (except for finger sensors), and security cable attachment.

3.3 Installation, Startup and Overview of Controls & Displays

Installation & Startup

The **Phototherapy Device**, stand with **Thermal Imaging Camera** and **Omega Temperature Data Logger** should be placed on a table similar to the photo below (the camera may need to be on the right side for research assistant convenience). An optional computer and display may be placed facing away from the participant to better observe the temperature recording. The participant is seated in front of the unit while the research assistant faces the control panel on the right side. The research assistant must also be able to read a meter in back of the machine at the start of the day prior to studies, to record voltage and current be delivered to the blue LED panels during a short test illumination.

Once a hand compartment has been secured within the metal enclosure, the **POWER** button above may be pressed **on**, turning the system on. Resetting the timer is accomplished by using the same **POWER** button. A research assistant's presence is required whenever a participant is present.



Right Side Control Panel

Temperature Controller (PTD)

The **Temperature Controller** should come on when the **Phototherapy Device** is turned on. (If necessary, press the power key 1s to turn on and 3s to turn off.) The screen normally displays the current temperature inside the phototherapy device (sampling air exiting via the rear muffin fans).

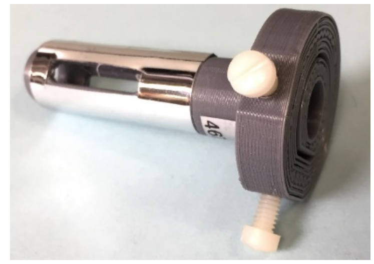
The fans are set to come on automatically. If they are not running (they blow outward in back), then they should be tested by briefly turning **on** the **FAN Override** button (it latches on & off).

The thermostat is by default set well below ambient room temperature so that the fans come on whenever the blue LED panels are illuminated. This will assure that the air temperature inside the hand compartment will stay within a few degrees of ambient room temperature. (Raising the thermostat above room temperature should only be done when the study protocol requires a hand compartment temperature greater than ambient room temperature, and should be done by a technician.) The Inkbird display has its own NTC (thermistor) sensor.

Hand Compartment Temperature Sensor Holder

The hand compartments may be inserted and removed without disturbing a fixed rear thermocouple holder that protrudes slightly into the hand enclosure to record air temperature. The sensor is connected to the **Omega Temperature Data Logger with an extender cable**.

The thermocouple are aligned by a technician and ordinarily does not need further adjustment unless the instrument is serviced. Each hand enclosure has a hole in back that allows the sensor holder to be automatically positioned, even when compartments are being swapped one for another by the research assistant.



Airflow through the hand compartment also includes airflow through the sensor holder. The thermocouple lead exits the back of the unit for connection to the **Omega Temperature Data Logger**.

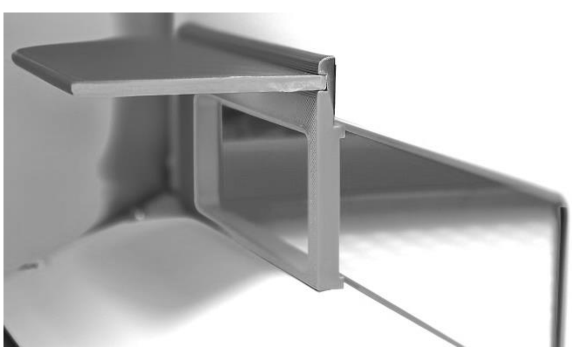
Hand Compartments & Hooded Bezels

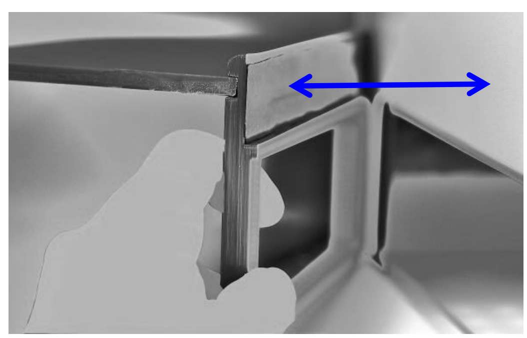
There are two types of hand compartments – experimental (clear plastic) and sham (opaque black plastic with external reflective Mylar to prevent heating from light energy conversion). The **Phototherapy Device** has sensors to determine if no hand enclosure is installed (or improperly installed), and which type. A blue indicator light signals that a sham unit is present. Operation of the system is otherwise identical for both participant groups. Each hand compartment is labeled with a serial number.

The clear plastic experimental group unit is shown above, and the opaque black Mylar-covered control (sham) group unit below. Each unit is numbered. Notice the notch on the back of the base of the sham compartment that allows automatic sensing of which type of hand compartment has been inserted.

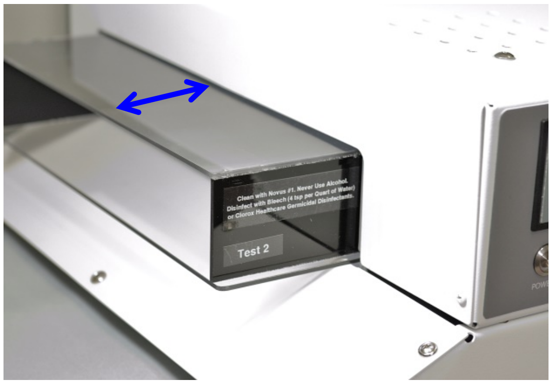
An “Opaque” indicator on the control panel lights whenever the control group black Mylar-covered hand compartment (sham) is installed instead of the experimental group clear plastic hand compartment. The display is not visible to the participant (or anyone else wearing blue light blocking eyewear).

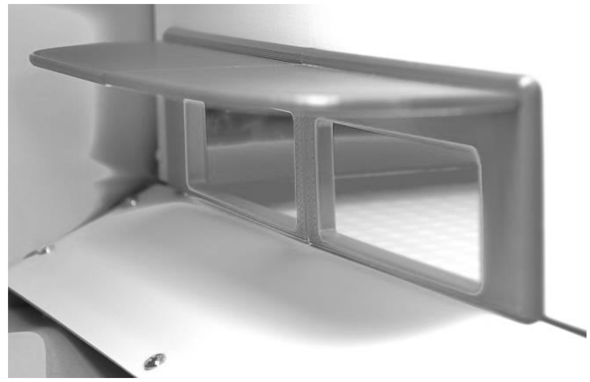
The hand compartments are installed by pulling off each magnetic hooded front bezel from the center outward, sliding the previous hand compartment out (lightly pull out with your fingers on the inside of both ends), and inserting the new unit in. It should seat fully with a slight push at the end. The magnetic hooded bezels may be replaced one at a time, outside edge first. Adjust the bezels slightly by hand to bring them together in the middle and level on top. The blue LED panel lights should be off during this process.





Pull the hooded bezel at the centermost column to remove. Do not pull the bezel out by pulling on the extended hood. Notice that the bezel gently locks the hand cabinet in place. Never lift the **Phototherapy Device** cabinet while a hand compartment is inside, or it may slide out.



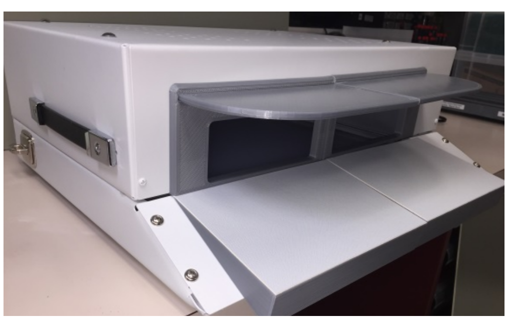


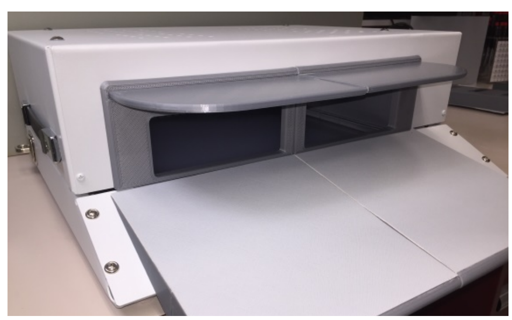
Wearing nitrile gloves gently slide the compartments in or out along the internal guides at the base. Be careful not to drop or damage the hand compartment. It is easily broken.

Once removed disinfect the inside of the hand compartment with a Clorox® Healthcare Germicidal Wipe rather than alcohol. Store the unused compartment away from sight in its designated container. If a participant is done, also clean the vinyl cushion and their eyewear.

Arm Rests

No arm rests are necessary if the participant is standing. When sitting, there are options for a short and long arm rest. The long has been found preferable. The arm rests are covered with vinyl on top,
and may be disinfected in the usual manner. Other gray plastic areas such as bezel, hood and small section under the wrists are made of PLA, and should be quickly and gently disinfected, as PLA will in time absorb water.





Short and long arm rests. These are fastened by magnets, and should be *gently* laid into place. Rather than sliding, align the top edge first and gently lower the front. To reposition, lift the front up, move left or right, then lower it back into place.

Setting Irradiance

It is then necessary to press the **ADJUST** button, and use the **black knob** to adjust the **Irradiance %** (spectral power distribution). Once the **Duration Timer** is started the blue LED panels will come on.

The calibration tables are used to relate the displayed **Irradiance (%)** to the actual **spectral power distribution** in milliwatts per meter squared (mW/M^2) to which the dorsal and palmar surfaces of the hands are exposed.

Duration Timer

The **Duration Timer** is set for the planned exposure time, and when activated will turn the LED panels on for the predetermined amount of time. The time is preconfigured to run in minutes. The preset amount of time the LED panels are on is determined by the study protocol (preset to 20 mins).

"OUT" is displayed here when the blue LED panels are on, and will flash when paused.

Timer Status

Setting Control

(Exposure duration is

Start & Pause

Up and down keys are for setup and technician use.

If the display disappears press any key momentarily to turn the back light back on. "P2:0P" refers to modes of operation preset by a technician.

Press the **Start** button to start the blue LED panels. The **Out** display indicates that the panels are being powered, and the **timer status** counts down the remaining time. When the timer ends and the panels turn off, the **Out** display will disappear. Pressing **Pause** while the LEDs are on will turn them off and the **Out** display will now flash. Pressing **Pause** again will resume timing. To reset the timer, it is necessary to turn off power to the **Phototherapy Device** and restart. If the indicator display turns off anytime during a timed-exposure, pressing any button momentarily turns the display back on

System Power Monitor

The **System Power Monitor** provides an instantaneous reading of the DC adaptor or battery power supply voltage, current draw and power consumption of the entire phototherapy unit. This power is run through a 400-mA circuit breaker in back of the unit. When used with a battery instead of the DC adaptor power source, it is measure mAH (milliamp hour) capacity of the battery and run time. While there are no settings, and the research assistant should log the voltage and current with each study after activating the LED lamps as verification that the unit is operating normally.

3.4 Omega Temperature Data Logger

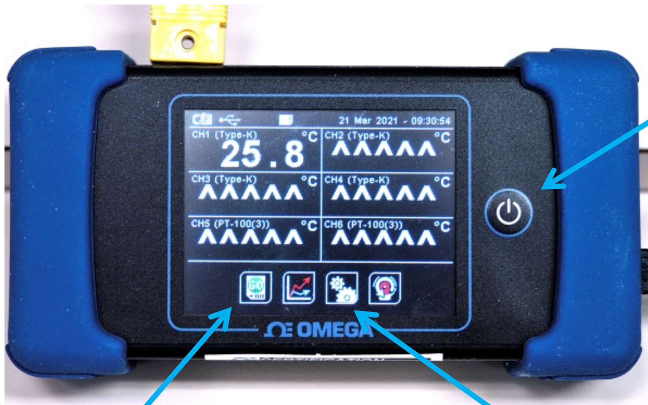
Overview

Three calibrated **Type K thermocouples** are connected to the top of an **Omega RDXL6SD-USB Temperature Logger**. **Channel 1** is the hand compartment's temperature; **Channel 2** is the ambient room temperature and **Channel 3** is the participant's finger temperature. When the logger is started continuous recording of the three channels begins and ends then the recoding is stopped. Data is stored in an Excel spreadsheet format on the **SD Memory Card** located on the left-hand side of the unit, and interrogated after the study. All three channels may be monitored on the unit's display and/or on a PC application by way of a USB cable located on the left-hand side. Sampling is based on the study parameters, and is preset to every 30 seconds.

Type K Thermocouple Connectors

SD Card Slot

Power Switch

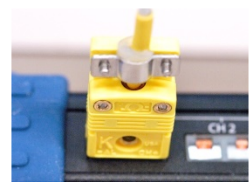


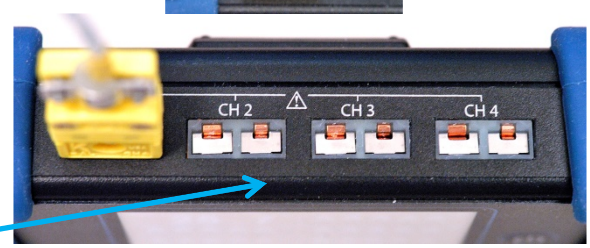
USB Port for Charg-
ing & PC Interface

Record "Go" & "Stop" Control

Settings

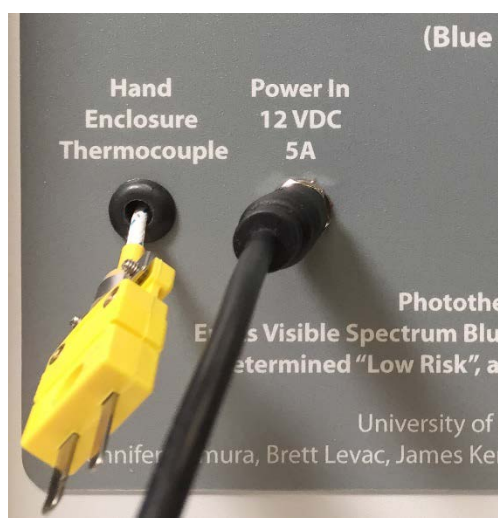
Back Rest





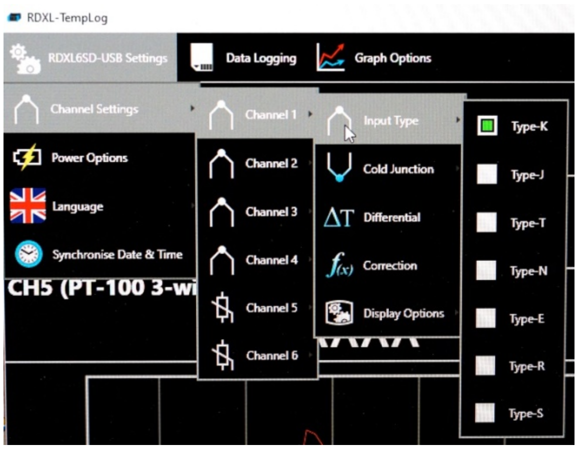
Type K Thermocouple Ports & 2-pin Plugs

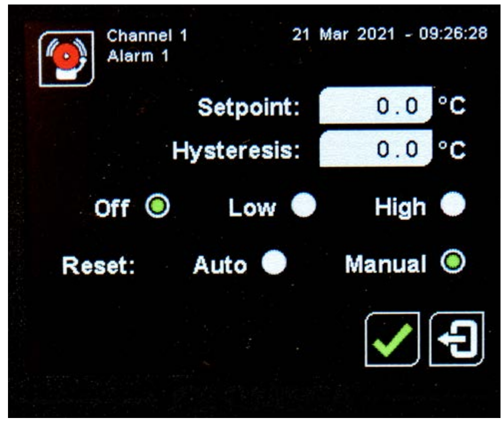
Rear male connector for Type K female to male extender cable.



Settings Using Omega RDXL-TempLog Software

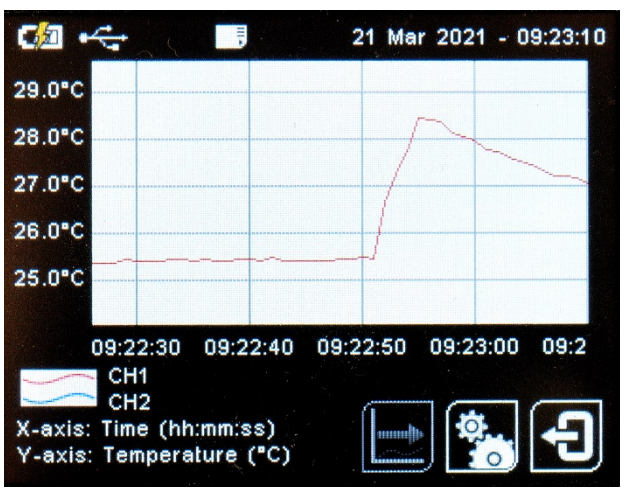
Channels 1 to 3 inputs should be "Type K." The alarm setpoint should be 35 degrees Celsius by default, or specified by the study protocol,

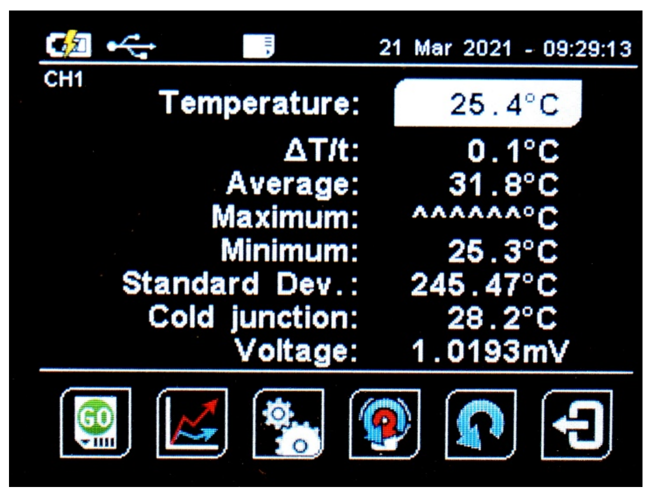




Data

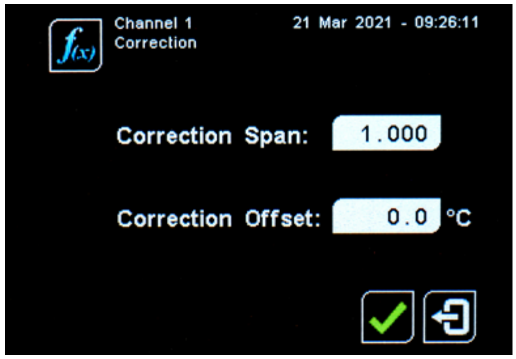
Windows® program above showing setting menu for each channel and thermocouple. Settings can be performed on either the Windows® application or directly on the units' touch screen display. The hand compartment is monitored for overheating.





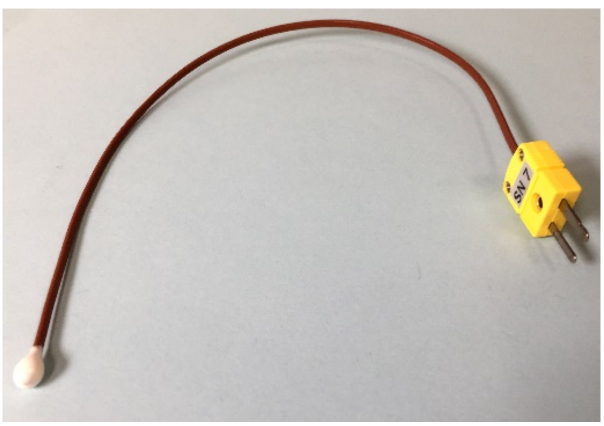
Temperature for multiple channels is graphed on the unit and/or Windows application. Specific channel data may be recalled as shown above. Data is recorded on an Excel spreadsheet format on the SD card, and may be downloaded later with time stamp.

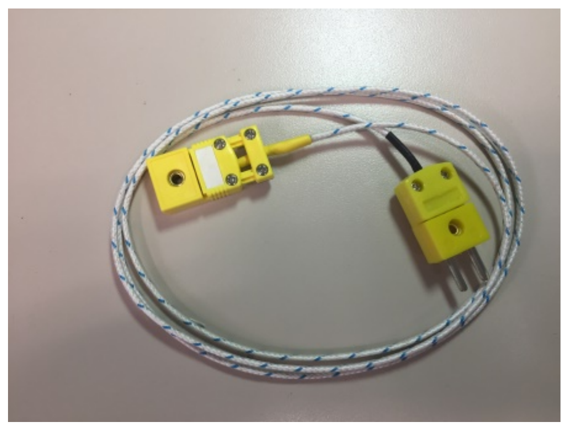
Thermocouple Offset



Each **thermocouple** has its own calibration offset that must be entered into the **Omega Temperature Data Logger**.

Hand Compartment & Ambient Temperature Thermocouples & Extender Cable



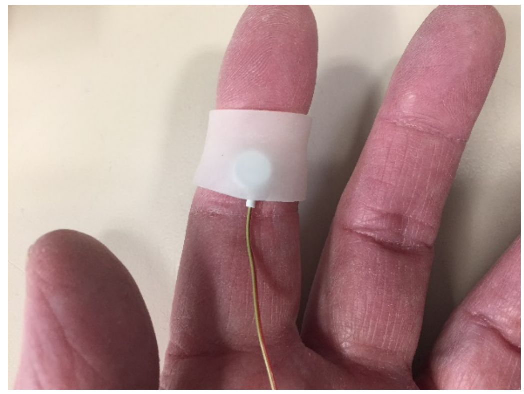


Channel 1 is for the hand chamber thermocouple (left above) utilizing the **Yellow Type K, M-F Extender Cable** (right above). **Channel 2** is for ambient room air measurement, and a short Type K thermocouple is used, with the probe end dangling in air. (The internal thermocouple is identical to the ambient temperature unit.)

3.5 Skin Temperature and Laser Doppler Flow Measurement

Finger Temperature Recording (Option 1)

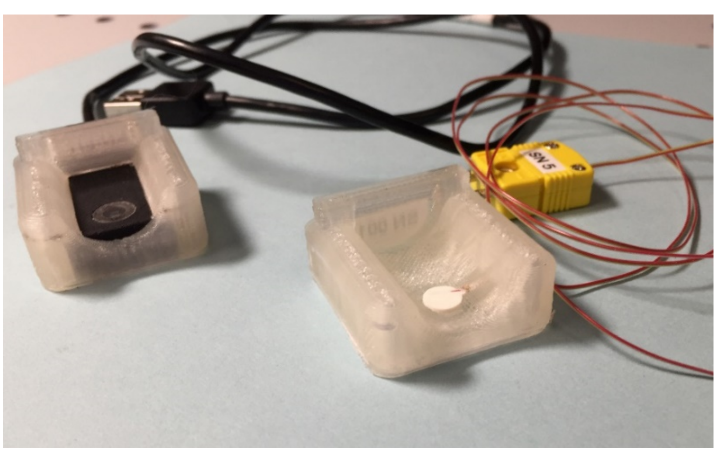
3M Nexcare is a medical grade, breathable, transparent tape used to affix a thermocouple to the palmer surface of the pointer finger, center of the middle phalanx. The shiny side (reflective Mylar) should be facing away from the skin. Another piece of tape is used to affix the wire at the wrist.

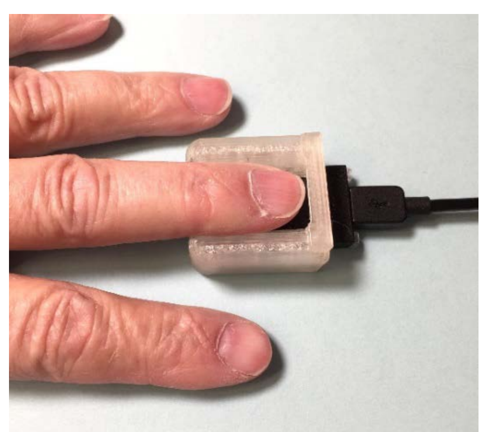


The thermocouple is then connected to **Channel 3** on the **Omega Temperature Data Logger.** Data is stored on an SD card or optionally a computer running the program **RDXL-TempLog** from Omega can be used to change settings, observe live streaming of data and record all channels simultaneously. Channels 1-3 of the unit have been preset to Type K thermocouple.

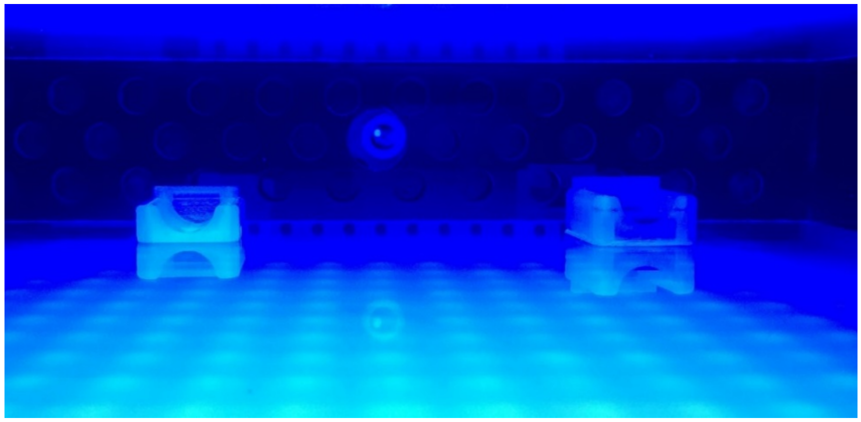
Finger Temperature (Option 2) with Laser Doppler Flow Recording

An alternative way of assessing for vasodilation is to measure flow through a single finger using a laser doppler flow probe (courtesy of Kyocera Int.). A finger – sensor holder has been made from clear PLA allowing insertion of a demonstration flow sensor “kit” by sliding it into the back of the holder. A similar holder has been made for the epoxy casted thermocouple.

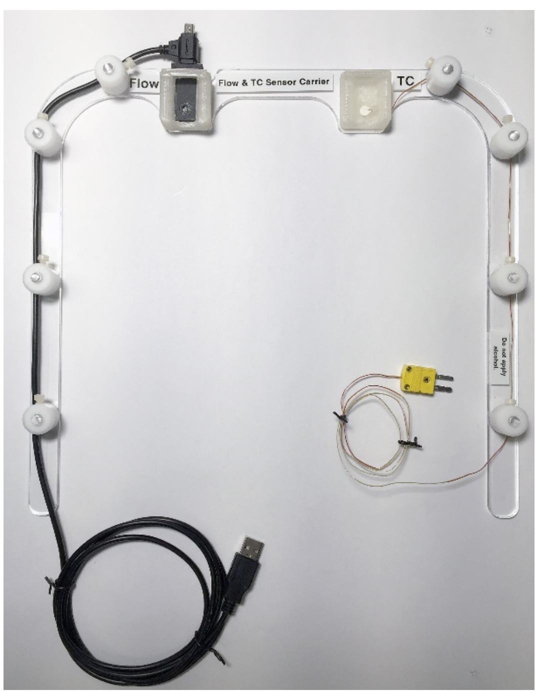




By affixing the holders in the compartment (and bringing the wires to the side and out the front), there is greater reproducibly of the data, more stable signal, better controlled contact pressure, and alleviation of the need to tape anything to the subject. This saves considerable time during a study.



On the left is the doppler flow sensor, and on the right the thermocouple holder. (The hand compartment thermocouple holder is seen in the middle.) The laser doppler flow sensor connects to a computer via USB, and software allows for visualizing and recording heart in beats per minute and flow in ml/minute. An Excel file is produced, and a graph can be made of the data within Excel.



The laser doppler flow sensor and thermocouple sensor are mounted onto an acrylic carrier that fits into the hand compartment after it is installed. USB and thermocouple wires exit the front of the hand compartment on either side, and are connected to the computer (Kyocera Int. flow recording software), and the Omega temperature logger.

Temperature Data Retrieval

There is an **SD Memory Card** on the left side of the **Omega Temperature Data Logger.** Once all data is collected, turn the unit off and remove the card by first gently pushing in. Use a USB transfer device (similar to that shown on the left below) to mount the **SD Memory Card** onto your computer's USB port. The folders present on the card are shown with dates. Copy and paste the folder to your computer. It will be in .csv format.

Below is an Excel spreadsheet taken off the **SD Memory Card** and converted from .csv to .xlsx file type, and annotated (in purple) with events from the **Study Data Sheet**, channel location, and comments:

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S
2	Date: -/-/2021																		
3	Note: Clock 1 hr Slow/SSS																		
4	Comment: Temperature recording ended prior to delayed photos./SSS																		
5																			
6	Event/SSS	Time	Sample No.	Channel 1	Channel 2	Channel 3	Channel 4	Channel 5	Channel 6	Cold Junction 1	Cold Junction 2	Cold Junction 3	Cold Junction 4	Voltage 1	Voltage 2	Voltage 3	Voltage 4	Resistance 5	Resistance 6
7				°C	°C	°C	°C	°C	°C	°C	°C	°C	°C	mV	mV	mV	mV	Ω	Ω
8				Chamber	Ambient	Ring Finger													
9	Pre-Photos/Start of Test/ Minimum Temp	5/14/2021 9:50	0	23.6	22.7	30.3	High	High	High	24.3	24.7	25.2	25.8	-0.03	-0.0848	0.2073	High	High	High
10		5/14/2021 9:50	1	23.7	22.5	30.4	High	High	High	24.3	24.7	25.3	25.8	-0.0248	-0.0886	0.2095	High	High	High
11		5/14/2021 9:51	2	23.8	22.5	30.4	High	High	High	24.3	24.7	25.2	25.7	-0.0204	-0.0893	0.2114	High	High	High
12		5/14/2021 9:51	3	24.5	22.5	30.7	High	High	High	24.4	24.8	25.2	25.8	0.0038	-0.0923	0.2225	High	High	High
13		5/14/2021 9:52	4	24.5	22.5	30.7	High	High	High	24.4	24.8	25.2	25.8	0.0041	-0.0929	0.2224	High	High	High
14		5/14/2021 9:52	5	24.7	22.5	30.8	High	High	High	24.4	24.7	25.3	25.8	0.0132	-0.0902	0.2276	High	High	High
15		5/14/2021 9:53	6	24.9	22.4	30.9	High	High	High	24.4	24.8	25.2	25.8	0.0199	-0.0944	0.232	High	High	High
16		5/14/2021 9:54	7	25.3	22.5	31.2	High	High	High	24.5	24.8	25.2	25.8	0.0334	-0.0894	0.2413	High	High	High
17		5/14/2021 9:54	8	25.3	22.5	31.3	High	High	High	24.4	24.8	25.2	25.8	0.0367	-0.0962	0.2461	High	High	High
18		5/14/2021 9:55	9	25.4	22.5	31.4	High	High	High	24.5	24.8	25.2	25.7	0.0399	-0.0939	0.2522	High	High	High
19		5/14/2021 9:55	10	25.5	22.5	31.6	High	High	High	24.5	24.8	25.2	25.8	0.043	-0.0939	0.2578	High	High	High
20		5/14/2021 9:56	11	25.6	22.5	31.6	High	High	High	24.5	24.8	25.2	25.8	0.0457	-0.094	0.2637	High	High	High
21		5/14/2021 9:56	12	25.7	22.4	31.8	High	High	High	24.5	24.8	25.1	25.8	0.0487	-0.0947	0.2702	High	High	High
22		5/14/2021 9:57	13	25.7	22.6	31.9	High	High	High	24.5	24.8	25.2	25.7	0.0523	-0.091	0.276	High	High	High
23		5/14/2021 9:57	14	25.8	22.5	32	High	High	High	24.5	24.8	25.2	25.7	0.0557	-0.0929	0.2821	High	High	High
24		5/14/2021 9:58	15	25.8	22.7	32.1	High	High	High	24.4	24.8	25.1	25.7	0.0553	-0.0823	0.2862	High	High	High

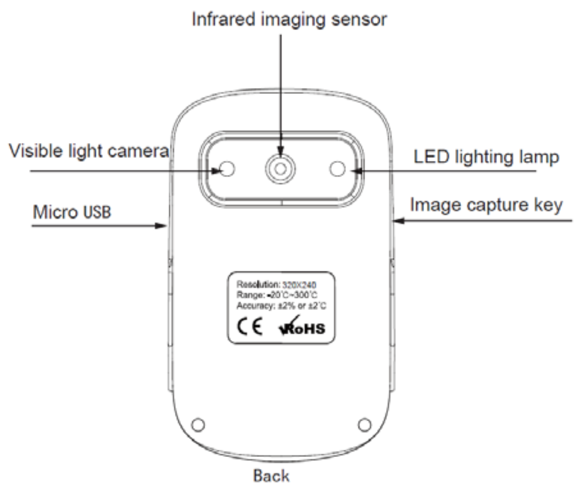
Relevant data is in the first 6 columns – event, date & time, sample number, channels 1-3.

3.6 Thermal Imaging Camera

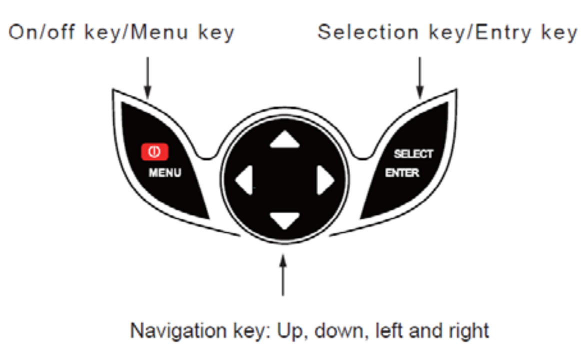
Overview

The **Hti HT-A2 Thermal imaging Camera** is for taking infrared images of the hands before and after blue light exposure. It is meant to supplement temperature data from the thermocouple located on a finger, and recorded on the **Omega Temperature Data Logger**. Do not leave plugged into the USB charger longer than 24 hours.

The camera integrates real-time thermal images with visible light camera images. It is an economical solution to comparing heat distribution across the dorsal and palmer surfaces of the hands before and after light exposure for comparison purposes. While not specifically designed for skin temperature measurement, it does provide qualitative data that may correlate with changes in circulation from application of blue light. (More advanced technology and other means of accessing circulation are presently being explored, but presently none of these technologies are available.)



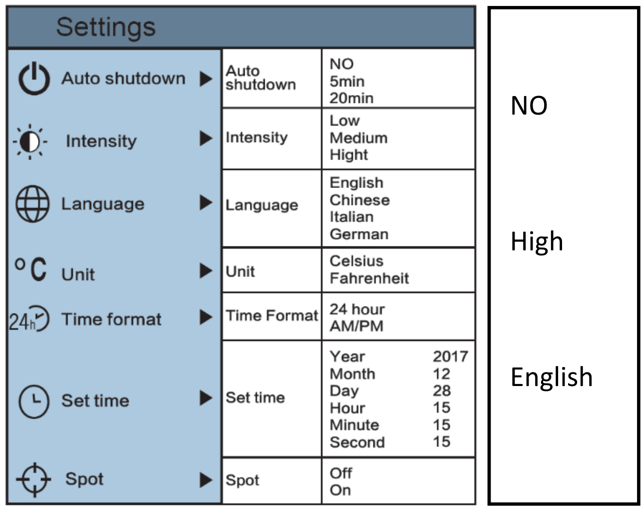
The camera and stand are set to provide an image of both hands when positioned similar to their position in the hand compartment. Images are obtained of (1) dorsal and (2) palmar surfaces of the hands, the (3) palmer surface middle finder with crosshairs over the middle pharynx. These are taken immediately before and after either actual or sham treatment. Images may be retrieved by downloading to a computer with a USB cable directly from the camera.



Pressing the POWER key will turn the camera on. Holding the POWER key for 3 seconds will turn it off.

Preliminary Settings

The camera should be configured as shown below. Press the **Power/Menu** key, select Setting (gear icon) in the main menu, and press the forward key to enter the “setting” submenu.

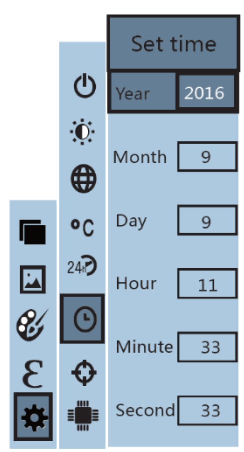


Display Description

Color or gray scale may be used to depict relative temperature from low to high in the field of vision. There are two digital readouts of temperature. One is at the center cursor and the other is at the highest temperature.

Time of Day

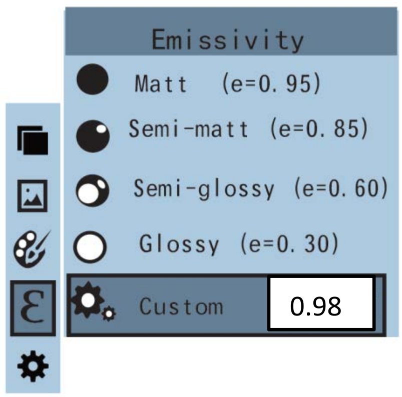
Press the **Power/Menu** key, select the clock in the main menu, and press the forward key to enter the “Set Time” submenu enter the date and time.



Emissivity

The emissivity of the surface of a material is its effectiveness in emitting energy as thermal radiation. Thermal radiation is electromagnetic radiation that may include both visible radiation and infrared radiation, which is not visible to human eyes. Different materials have different thermal radiation emissivity. The Hti HT-A2 can be adjusted from 0.01 - 1.00 emissivity. The emissivity of human skin is 0.98, and this should be entered into the custom menu.

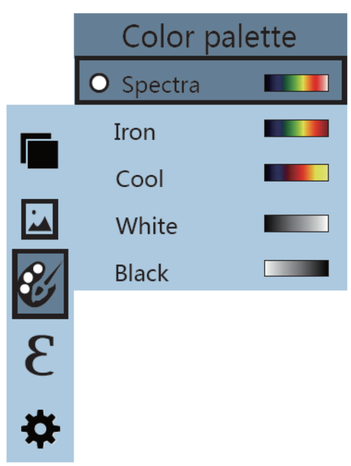
Press the **Power/Menu** key, select Emissivity (**ε**) in the main menu, and press the forward key to enter the "setting" submenu. Scroll down to "Custom," and enter "0.98".



Color Palette

A pseudo-color display of the infrared image is defined by color palette. "Black & white" and "white & black" palettes provide for the most linear representation of temperature gradient. The "Rainbow palate provides for better thermal contrast, and is reasonable to use for our purposes.

Press the **Power/Menu** key, select "Color Palette" in the main menu, and press the forward key to enter the submenu. Select "Spectra".



Taking & Retrieving Images

Item select arrows. Pressing the center changes the ratio of thermal imaging to visible light imaging.

ON/OFF, Menu and “Yes” button

Select, Enter and “No” button.

Micro-USB port for retrieving pictures (on side)

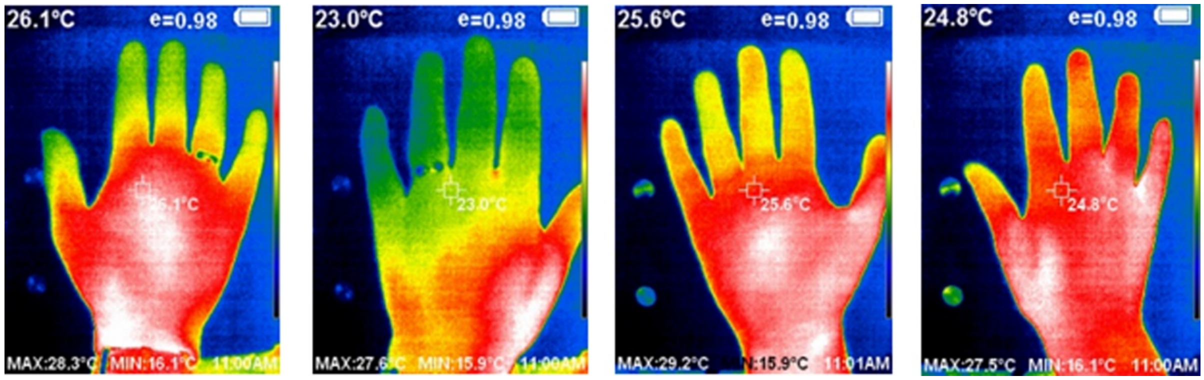
Camera mount clamp knob.

Visually inspect the picture before pressing shutter release.

Shutter release button to take a picture.

Dorsal view – the hands are placed just above the surface and not touching it.

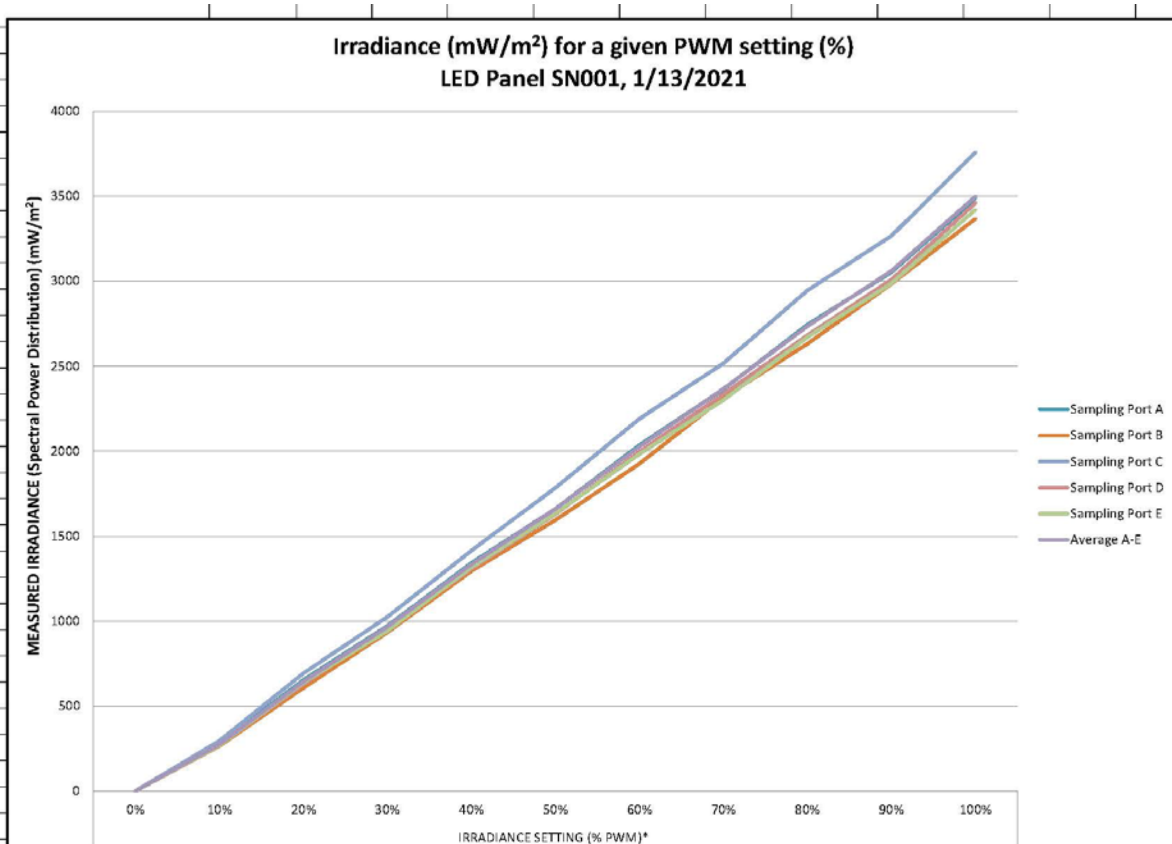
Palmer view.



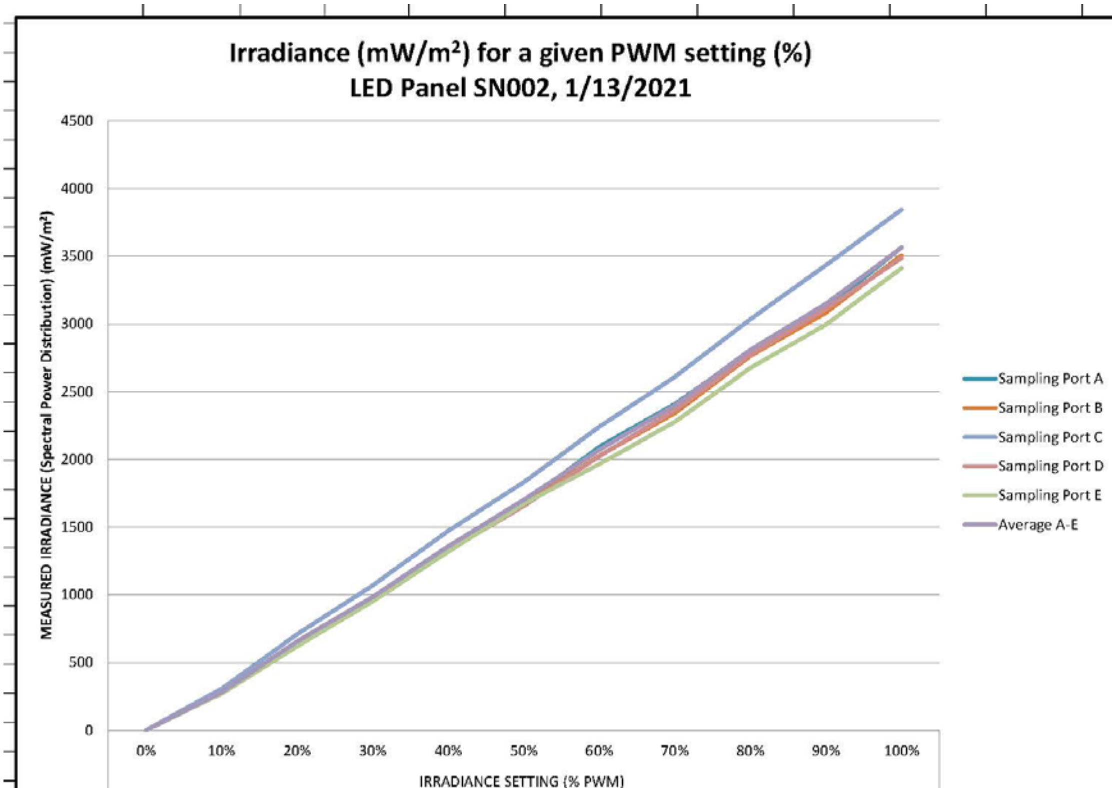
Representative baseline images - palmar and dorsal surfaces, left and right hands. The thermal images show temperature as a false-color gradient (a spectrum bar is visible on the right-hand side of the images), based on the minimum and maximum temperatures recorded and displayed at the bottom of the images. More useful for study purposes is the ability to sample any point in the image using an adjustable cursor, allowing measurement to 0.1 degree Celsius over specific anatomical landmarks as specified by the clinical study protocol. This measurement is shown in the upper left-hand corner of the image. Study participant data based on use of the PTD is deferred to a future clinical study and will be the subject of another paper.

3.7 Blue LED Panel Calibration Charts

Date: 1/13/2021											
LED Panel: SN001											
Technician: Steven S. Saliterman											
Location: Saliterman Lab											
Spectrophotometer: UPRtek MK350N Premium, SN: HS12BJBA0035 (Certification of Calibration on File, Calibration Date 3/15/2019)											
Calibration Apparatus: LED Panel Light Calibrator (Saliterman & Levac)											
	IRRADIANCE SETTING (% PWM)*										
	0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
Step-Up Voltage (V)	42.05	42.05	42.05	42.00	42.00	42.00	42.05	42.05	42.00	42.00	42.00
Current (A)	0.000	0.025	0.055	0.080	0.115	0.145	0.180	0.210	0.250	0.275	0.315
Peak Wavelenght (nm)		451	451	451	450	450	451	450	450	450	450
Irradiance or Spectral Power Distribution (mW/m2)**											
Sampling Port A	0.00	278.29	654.27	972.36	1342.52	1660.74	2035.32	2364.03	2744.75	3054.17	3488.23
Sampling Port B	0.00	265.69	608.92	935.15	1295.39	1594.52	1927.34	2314.52	2632.35	2984.98	3368.03
Sampling Port C	0.00	295.49	694.18	1025.88	1415.37	1785.48	2191.32	2517.62	2945.93	3266.67	3756.35
Sampling Port D	0.00	269.22	631.02	958.62	1307.21	1629.04	1997.09	2335.91	2682.12	3010.31	3459.30
Sampling Port E	0.00	269.38	640.67	943.48	1317.59	1634.21	1982.84	2301.34	2670.66	2987.32	3421.78
Average A-E	0.00	275.61	645.81	967.10	1335.62	1660.80	2026.78	2366.68	2735.16	3060.69	3498.74
	(* Based on Pulse Width Modulation Setting of 0 to 100% at a fixed Step-Up Voltage of 42.05 VDC to the LED Panel)										
	(** 1 mW/m2 = .0001 mW/cm2)										

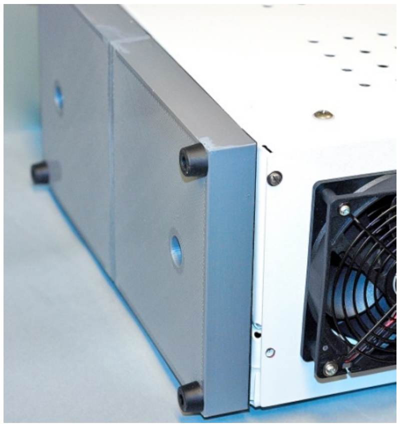
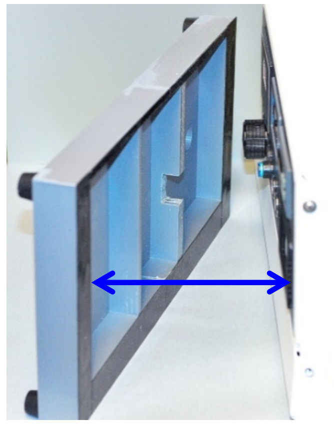


Date: 1/13/2021											
LED Panel: SN002											
Technician: Steven S. Saliterman											
Location: Saliterman Lab											
Spectrophotometer: UPRtek MK350N Premium, SN: HS12BJBA0035 (Certification of Calibration on File, Calibration Date 3/15/2019)											
Calibration Apparatus: LED Panel Light Calibrator (Saliterman & Levac)											
	IRRADIANCE SETTING (% PWM)										
	0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
Step-Up Voltage (V)	42.05	42.05	42.00	42.00	42.00	42.00	42.00	42.00	42.00	42.00	42.00
Current (A)	0.000	0.025	0.065	0.095	0.135	0.170	0.210	0.234	0.275	0.315	0.355
Peak Wavelenght (nm)	453	453	453	453	453	453	453	453	453	453	453
Irradiance or Spectral Power Distribution (mW/m2)**											
Sampling Port A	0.00	275.96	655.5	977.57	1348.76	1678.08	2091.65	2409.05	2801.28	3116.55	3564.54
Sampling Port B	0.00	277.40	648.31	953.00	1324.57	1667.17	2027.05	2341.95	2763.56	3084.44	3507.64
Sampling Port C	0.00	305.29	709.72	1069.12	1472.26	1831.17	2239.49	2608.03	3036.22	3435.06	3843.83
Sampling Port D	0.00	277.05	652.86	965.77	1326.49	1656.38	2023.43	2363.94	2772.56	3110.80	3488.06
Sampling Port E	0.00	269.52	620.07	951.79	1318.70	1671.86	1966.06	2275.80	2675.88	2996.10	3412.06
Average A-E	0.00	281.04	657.29	983.45	1358.16	1700.93	2069.54	2399.75	2809.90	3148.59	3563.23
	(* Based on Pulse Width Modulation Setting of 0 to 100% at a fixed Step-Up Voltage of 42.05 VDC to the LED Panel)										
	(** 1 mW/m2 = .0001 mW/cm2)										
Supplemental Data											
Sampling Port C											
No Clear Panel						1866.55					3905.17
No Diffuser Panel						1990.61					4132.33
No Clear or Diffuser						2047.45					Over Exposure
%Transmittance Clear						98.10%					98.43%
%Transmittance Diffuser						91.99%					93.02%
%Combined						89.44%					Not Determined



3.8 Transporting the Phototherapy Device

Carry Base/Control Panel Cover

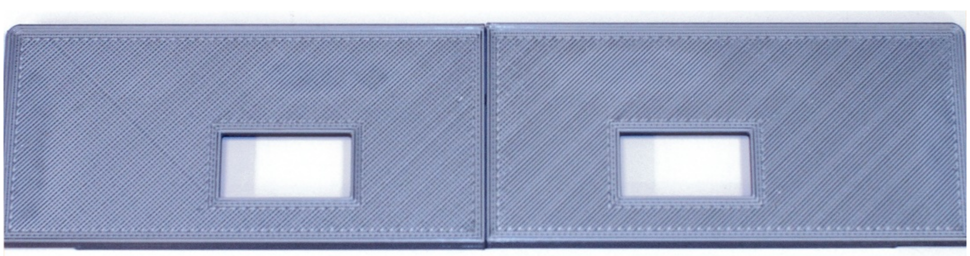
The **Phototherapy Device** weighs 31 pounds (14 kg), and the magnetic control panel cover must be attached when the unit is lifted by its handle. The cover also serves as a base with rubber bumper feet to allow the machine to rest on end with the handle up.

Handle & Security Cable Mount

Care should be taken when shifting from a horizontal to upright position so as not to displace the control panel cover. A lockable cable may be placed through the security mount and around a table leg to discourage theft.

Transport Case


The **Pelican Products 1690 Case** is for transporting the **Phototherapy Device**. Ancillary equipment and the hand compartments are packaged separately. The case is heavily padded, and has integrated wheels and handles on either end. The **Phototherapy Device** is placed flat in the case, and it is advisable to have two people lift and place the unit securely. The hooded bezels in front should be removed and the magnetic flat cover bezels installed in their place (below).



Part 4 – Servicing

4.1 Service Tools

Tool Pouch

Required Service Tools Together in Pouch

1 Cable ties
2 Hex driver Wiha 263/ 1.3-0.05” x 40
3 Hex driver Wiha 2631/ 5/64” x 50
4 Knife, utility
5 Magnetic Pickup
6 Magnifier
7 Multimeter
8 Nut Driver Klein ¼ Magnetic (Muffin fans nuts)

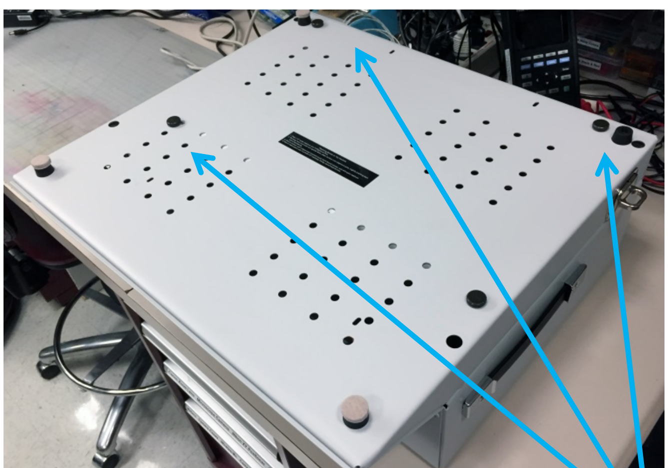
9 Nut Driver Klein 3/8 Magnetic (Stack #10 nuts)
10 Nut Driver Klein 5/16 Magnetic
11 Pliers, long nose
12 Pliers, standard
13 Pouch, Funowlet
14 Ruler, 6” English/Metric
15 Screwdriver – Klein 601/3 Slot
16 Screwdriver – Klein 603.4 Phillips
17 Screwdriver – Klein 603/3 Phillips
18 Screwdriver Wiha Phillips driver 261/PH1 x 60
19 Screwdriver Wiha slot 260/ 2.5 x 50
20 Scribe (collapsable)
21 Solder
22 Soldering iron
23 Solder vacuum removal tool
24 Solder wick
25 Tweezers, long
26 Wire cutter
27 Wire stripper

4.2 How to Disassembly and Reassembly the Cabinet

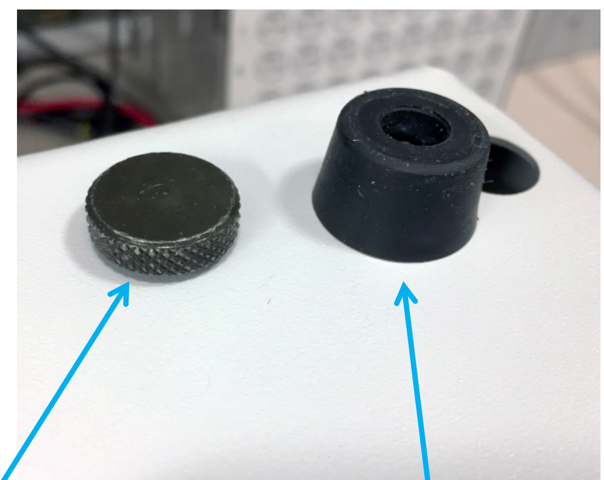
Bottom Section Removal

Basically, everything is mounted to the top section (except the arm rest), and the bottom section is simply fastened to the top section in an inverted position. The back panel should remain affixed to the top section unless being repaired itself.

1. Disconnect power and any other cables.
2. The armrest, front bezel/hood and hand compartment should be removed. (These are magnetically mounted.)
3. Place the device inverted on a large pad to protect the device and table surface.
4. Remove four thumb screws.
5. Remove 3 Phillips screws - the bottom section only - center and left & right screws, from the back panel with a screw driver.
6. Lift the bottom section upward and off the 4 top section alignment pins; set aside.



Inverted Unit Bottom Surface



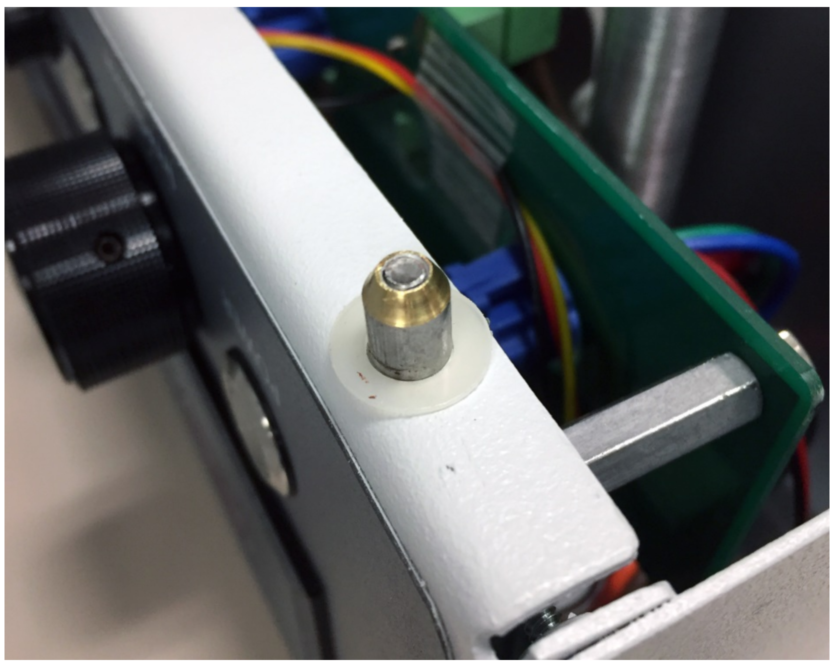
Thumbscrews x 4
These hold the bottom section to the top section.

Bottom Bumper Foot x 4

Bottom Section Attachment

Reverse the steps above to reattach the bottom section. Be certain that there are no loose wires, and that the optical stack is secure (screwed to magnetic mounts). Double check that the sensor posts for the hand compartment has been slid back into position. If not done previously, check that the microswitches are making contact by temporarily inserting a hand compartment.

When first placing the bottom on the 4 alignment pins, push the back panel slightly backwards to improve mating the bottom to top sections. Note the nylon washer over the alignment pin below.

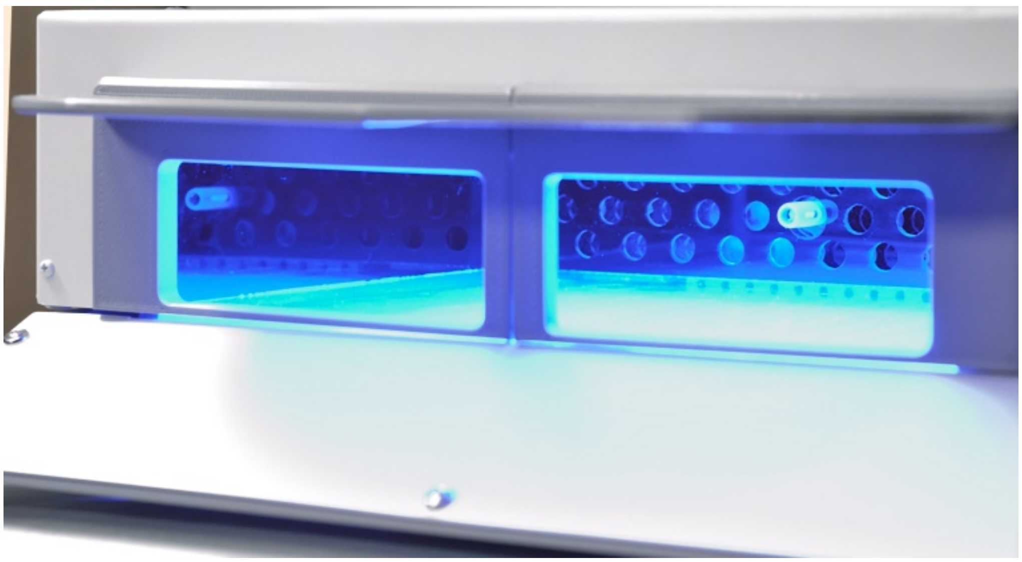


One of Four Alignment Pins

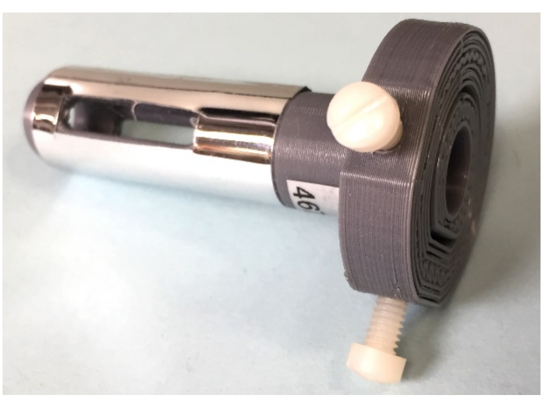
(Note that the front armrest metal panel and back metal panel generally should not be removed from the upper section assembly ordinarily.)

4.3 How to Install the Hand Compartment Thermocouple & Thermistor

The hand compartments may be inserted and removed without disturbing a fixed thermocouple holder that protrudes slightly into the hand enclosure to record air temperature. The thermocouple wire exits the rear of the unit and connects to the Omega temperature logger with an extension cable. A second sensor, a thermistor, is positioned to measure the temperature of air leaving the unit at one of the rear muffin fans. This is connected to the Inkbird control panel thermoregulator. Both are aligned by a technician and ordinarily do not need further adjustment unless the instrument is serviced. Each hand enclosure has a hole in back that allows the thermocouple holder to protrude through it, even when compartments are being swapped by the research assistance.

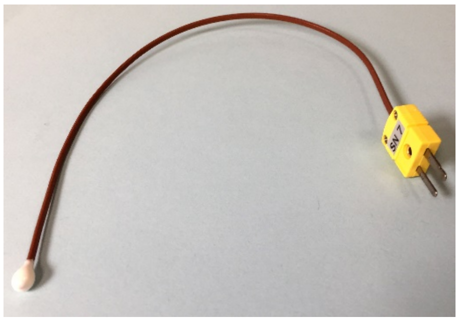


Front view with the Clear Experimental Hand Enclosure & Thermocouple Holder

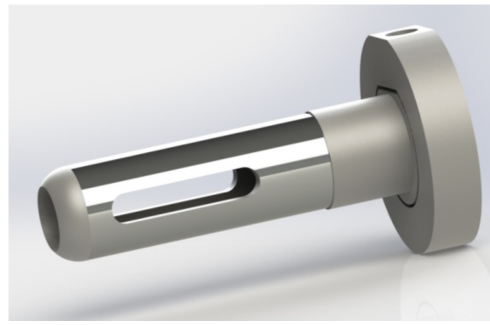


Thermocouple Holder & Mounting Collar

The holder allows for air to move over the sensor. The thermocouple wire exits the back of the unit for connection to the Omega temperature logger (ambient room temperature and a finger thermocouple are also connected to the Omega unit). When installing, the wire tip is inserted through the back panel port and then into the hole in back of the holder.



Hand Enclosure and Ambient Air Thermocouple Design

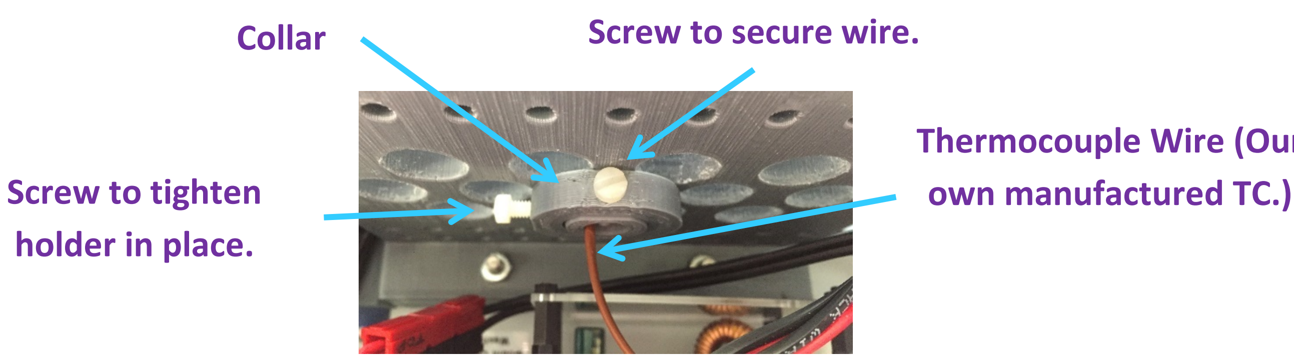


Probe Holder

The holder does the following:

1. Protects, locates and secures the sensor wires reproducibly.
2. Shrouds the wires from direct light irradiance, and reflects light away.
3. Allows air to flow from the front and sides to the back.
4. Allows for minimal use of a white heat-transmitting epoxy coating around the senor wire junction, improving response time. (This coating also protects the junction and wires.)

The collar of the thermocouple holder is permanently attached to the back wall of the optical stack. There are two nylon screws – one tightens the holder in place (the screw is on the side), and the other holds the wires in place (located on top).



Back Wall of Optical Stack, Bottom Up

It works best to place the wire into the holder after both the optical stack and holder are secured in place. You need to look inside the unit from the front to position properly. (The top screw needs to be backed out most of the way to permit the wire to pass through.) Gently tighten the top screw to secure the wire once positioned.

4.4 How to Insert and Remove the Optical Stack

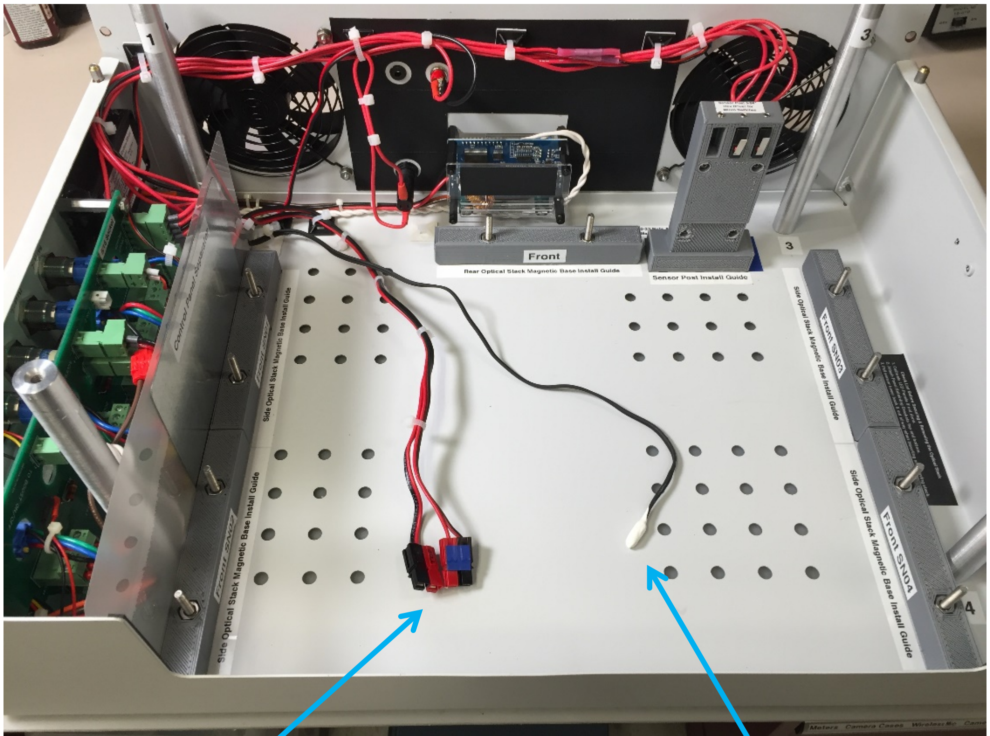
The optical stack is handled bottom-side up, and easily grasped by the overhanging bottom edges of the side walls. The two sets of diffusers and blue-light LED panels are slid into the unit while outside the cabinet, and secured with 4 front panel retaining brackets screwed to the top and bottom surfaces. These extend down the front sufficiently to keep the panels from sliding out. This must be done before attempting to place the unit into the cabinet. **Never move the optical stack around without the 4 retaining brackets, or the panels will slide out and fall.**

Optical Stack Bottom Up

Before installation, look inside the cabinet and move the microswitch sensor block back-wards, about an inch behind the guide line. Failure to do so will result in damage to the switches. The post is held down magnetically and has a neoprene seal. The best way to move it is to rock it slightly front-to-back- to-front (this is also true for the other magnetic mounts).

Sensor Post with microswitches
- note positioning arrow.

Also look for the two red & black connectors that connect to the upper and lower LED panels. Gently swing them over the back panel, outside the cabinet. Do the same for the black thermistor wire.



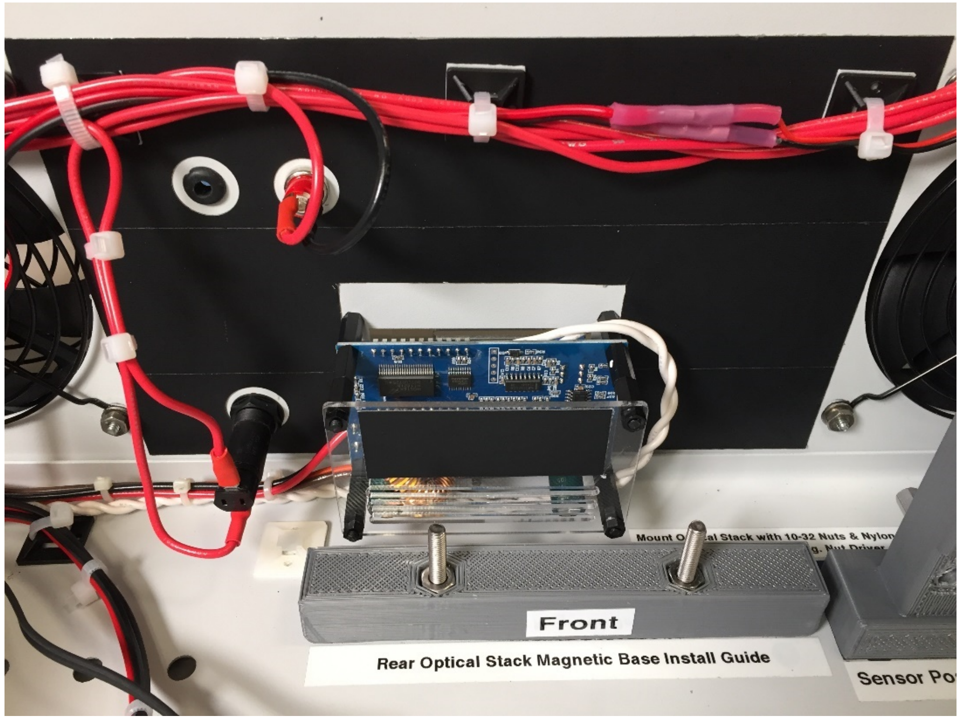
Inside the Inverted Top Section

LED Panel Power Connectors x 2 (Observe Polarity and Color-Coded Panel Designation)

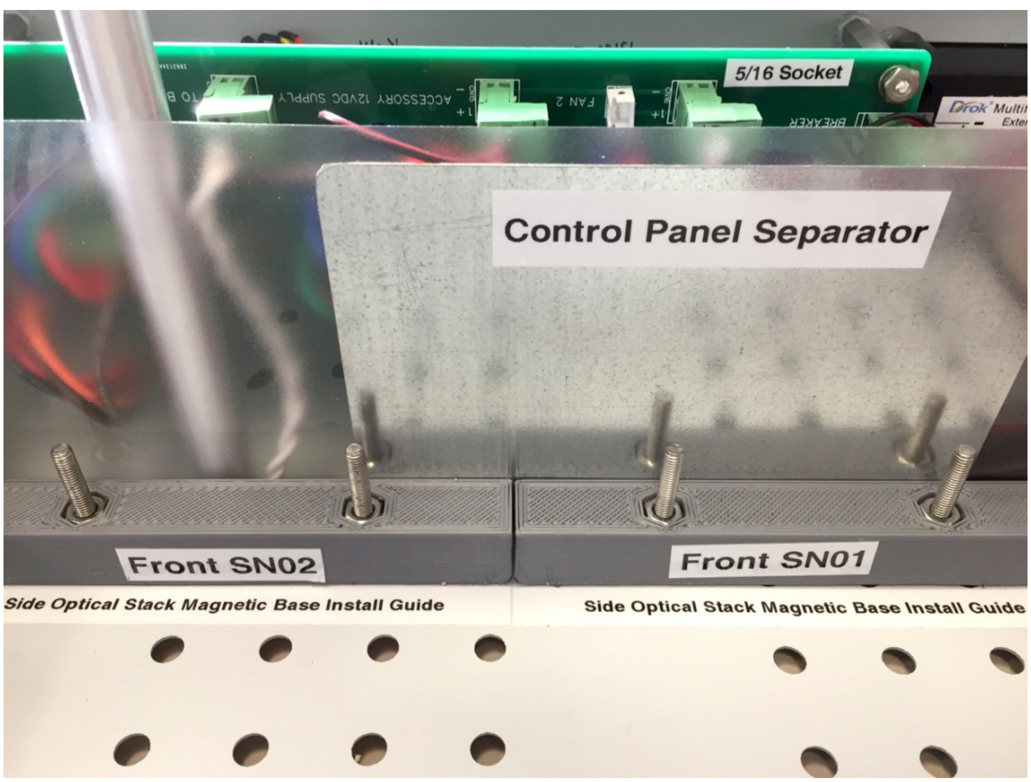
Ink Bird Thermoregulator Thermistor Wire

If not already present, place the five magnetic blocks with extended threaded screws around the perimeter based on the labeled guides. You may need to adjust these the first time so that the optical stack aligns over the bolts. Be careful of the LED driver board on the back panel when inserting the optical stack. It is protected by a fire-retardant polycarbonate sheet.

Secure the optical stack with ten #10 nuts using the long magnetic nut driver. Be sure the flame-retardant polycarbonate separator panel is between the circuit board and the magnetic mounts.



Inside inverted top section, looking towards back. The Sensor Post should be moved back when inserting or removing the Optical Stack.

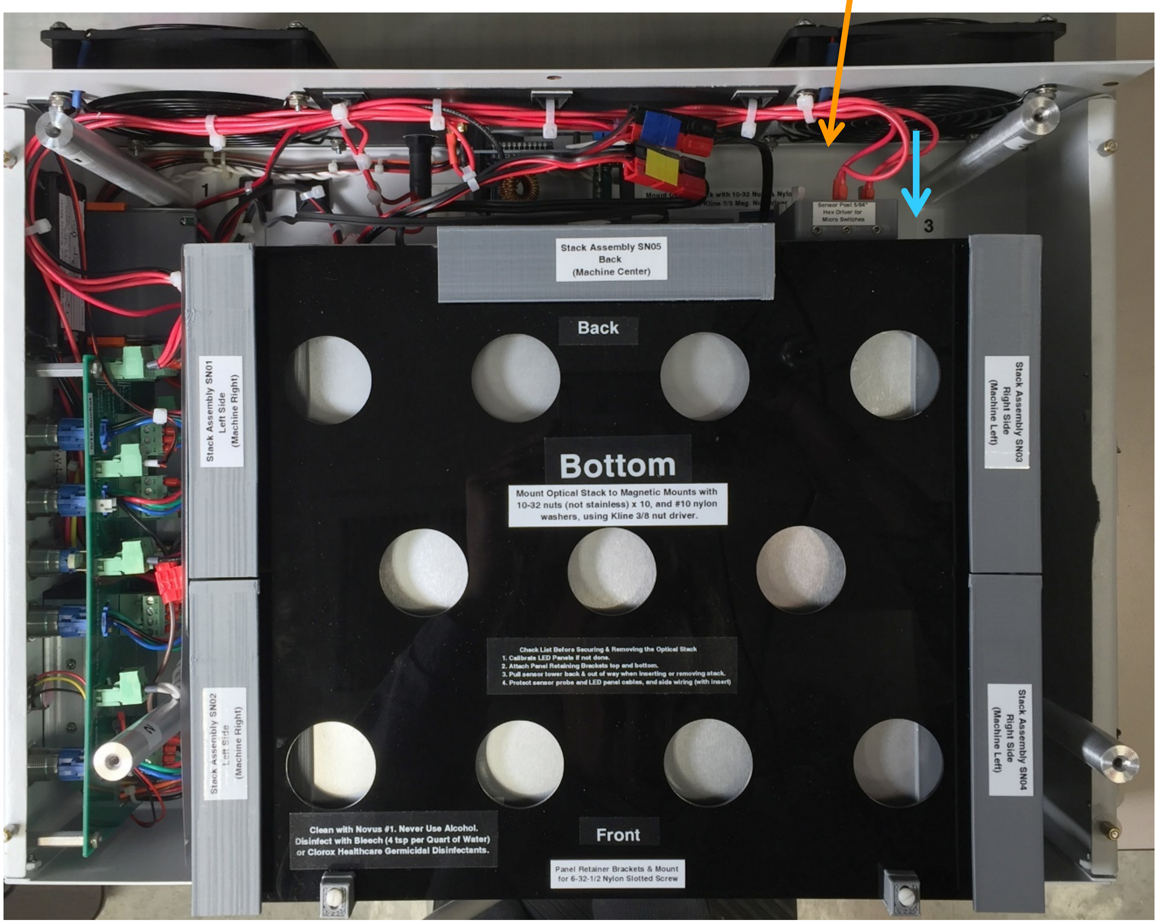


Inside inverted top section, looking towards circuit board.

When properly placed the optical stack should look like the picture below, and near flush and centered with the front opening. Note the sensor post is still slid back. Once the stack is secured, move the sensor post into position. You can slide both the experiment and opaque sham hand compartments *upside-down** into the stack to be sure the microswitches are properly engaging. Listen for the soft “click” pf the switches making and breaking contact as their small levers move. **The hand compartment must be removed after the alignment, prior to attaching the bottom section and turning the unit upright. Failure to do so will result in its sliding out and falling. The hand compartment is only secure when the front hooded bezel is in place.**

(*The bottom of the hand compartment is the surface with the slides on the side. This surface slides into the stack just above the hand rest.)

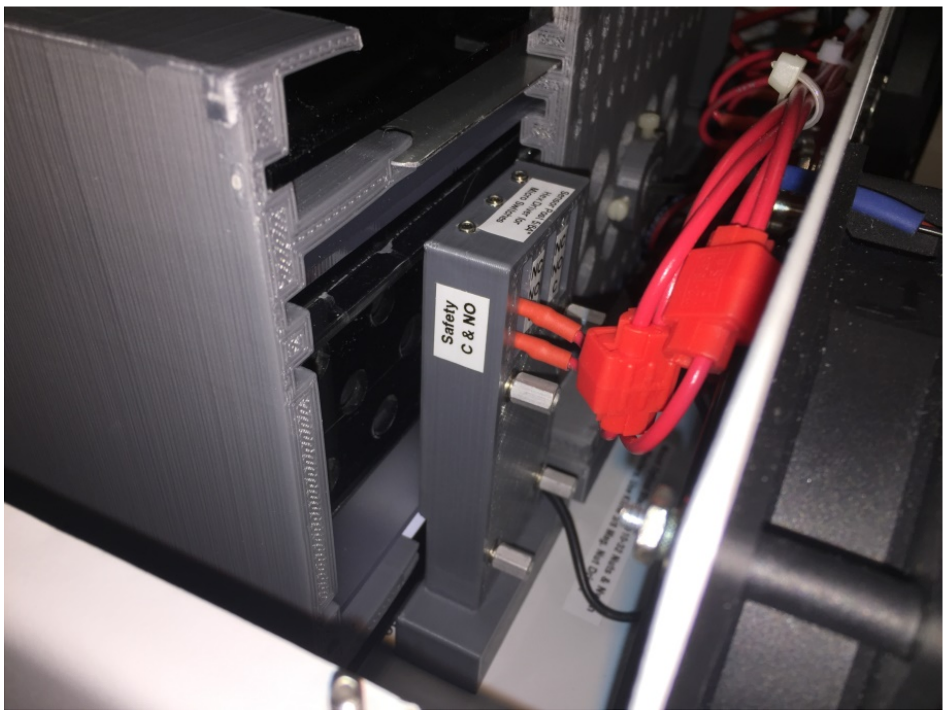
Move (wiggle) the sensor post forward.



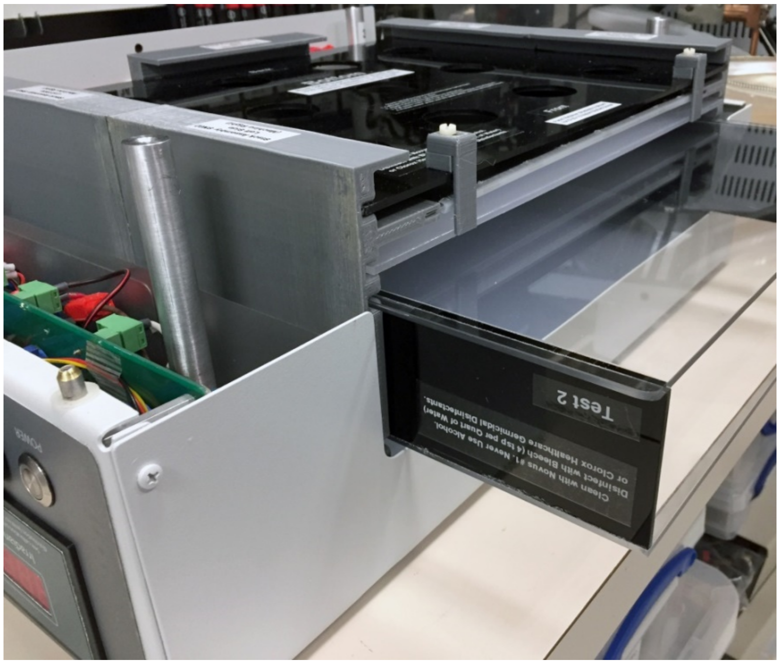
Inside Inverted Top Section with Optical Stack Installed

The optical sensor is shown below in proper position. When the opaque sham hand compartment is firmly in place, one microswitch will be closed and the other open (aligned with the open notch in the back of the hand compartment). When the clear experimental hand compartment is firmly in place, both switches will be closed (levers pushed in). When properly adjusted, the sensor post magnetic base should not rotate backwards when a hand compartment is inserted.

Realignment ordinarily is not necessary unless the optical stack is removed for serving, or the machine is jarred. In the latter instance, simply remove the cabinet bottom and realign.



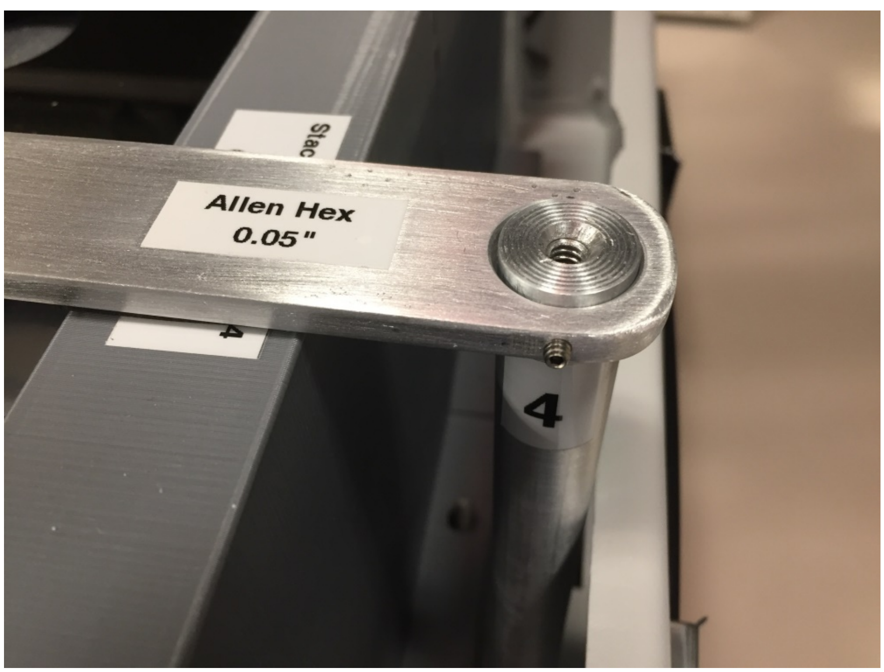
Correct Position of the Sensor Post



Installed Optical Stack with Hand Compartment

Finish installation by placing the retaining bar horizontally from one front post to the other, and securing with a hex driver. Push the bar down gently then tighten (below). Connect the red and black connectors to the LED panels. Reverse the steps above to remove the optical stack. (A hand compartment is also seen above partially inserted.)

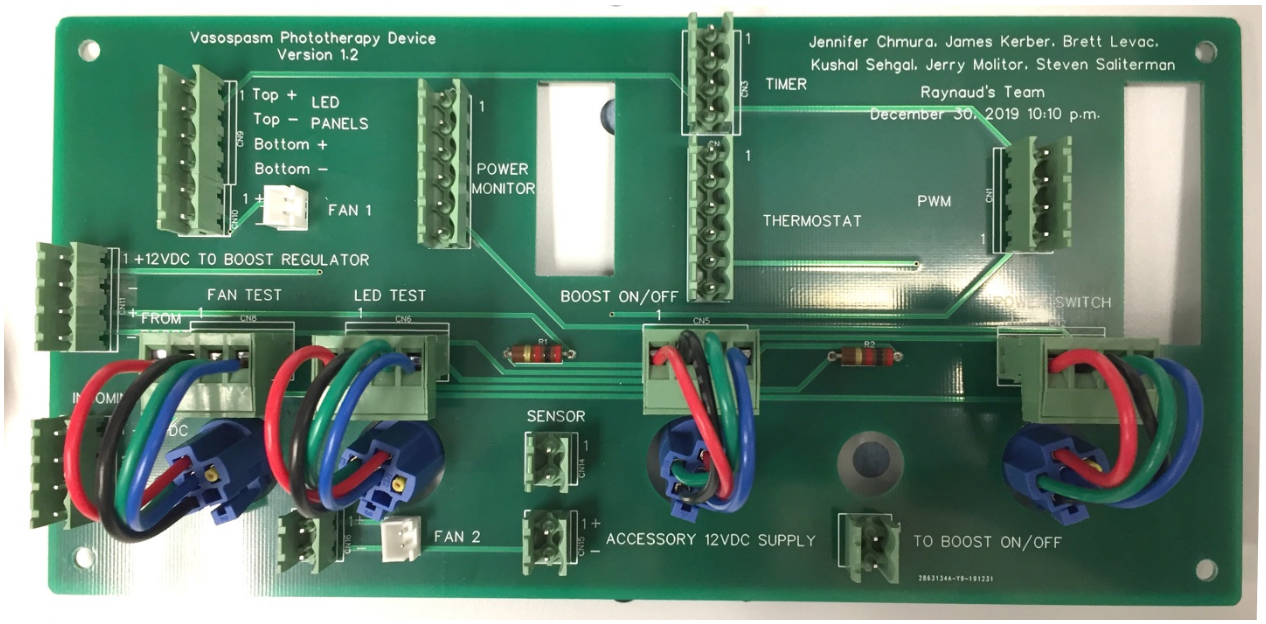
Proceed with installing the hand compartment thermocouple wire (Appendix C).



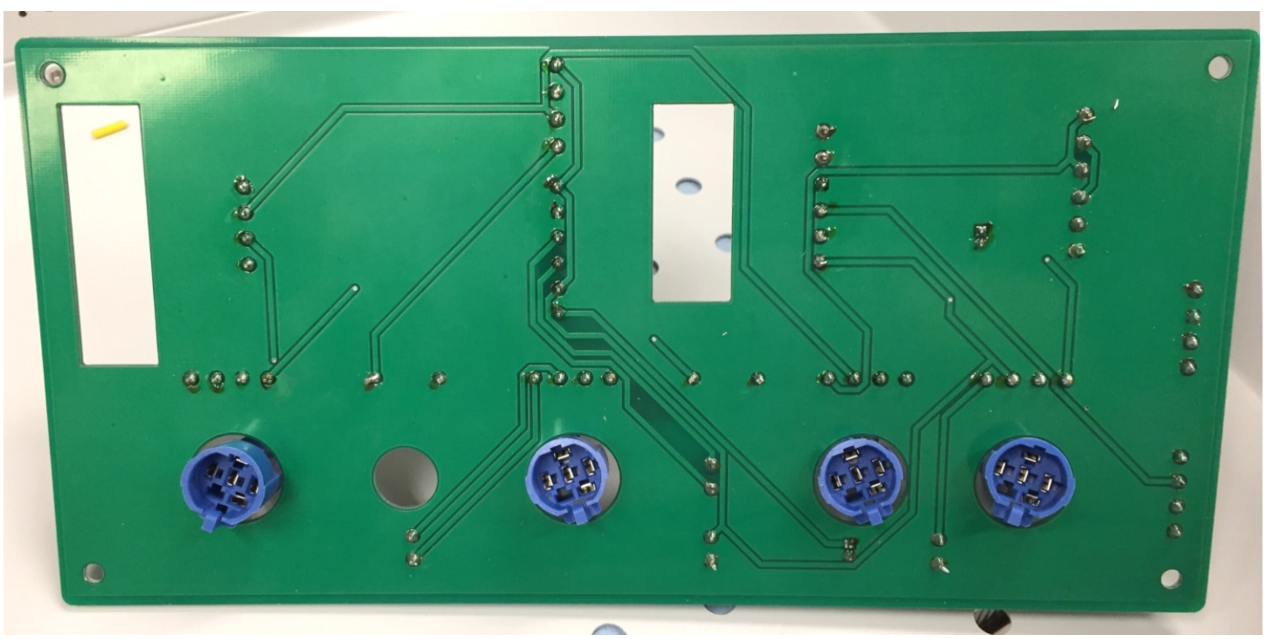
Optical Stack Retaining Bar

4.5 Access to the Printed Circuit Board (PCB), Side & Back Panel Components, Sensor Post & Muffin Fans

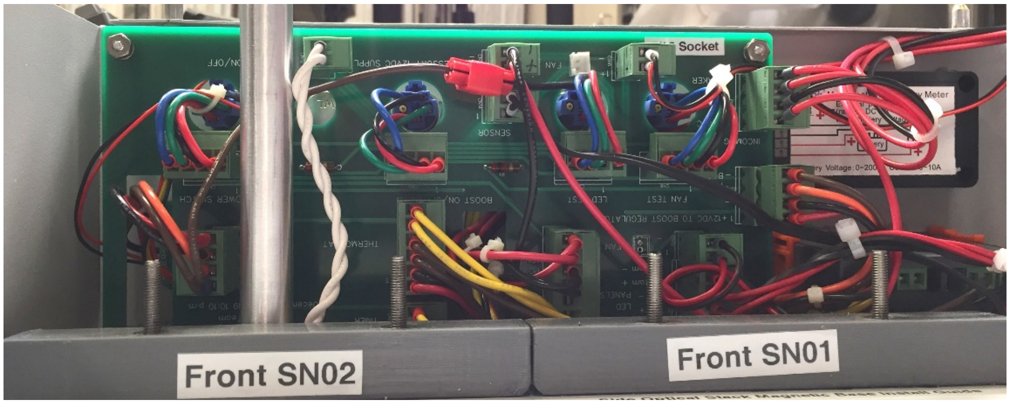
To access these components, remove the bottom section, optical stack and polycarbonate divider sheet between the optical stack and circuit board.



PCB Top or *Populated Side*

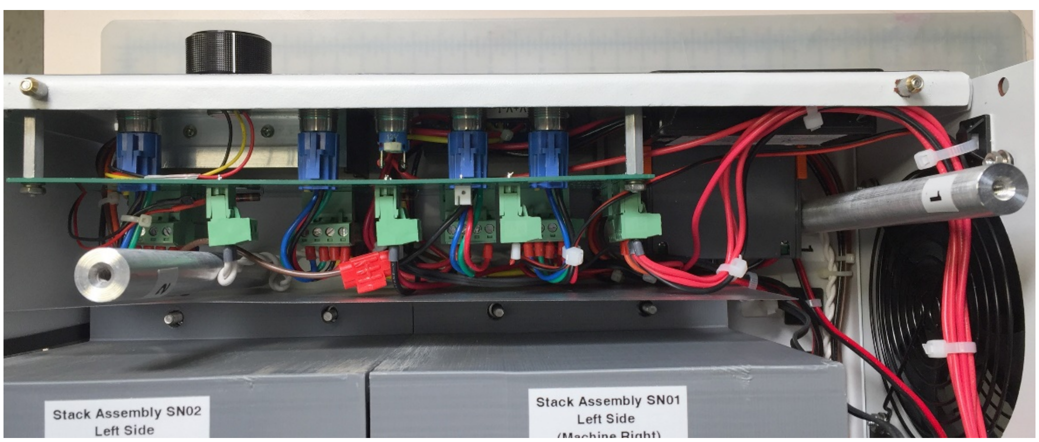


PCB Bottom Side



Installed Printed Circuit Board

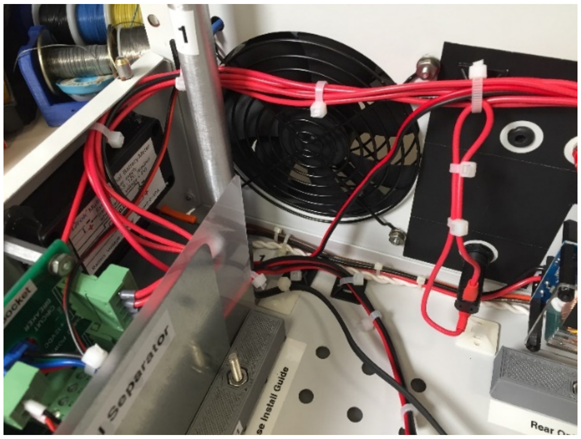
Inverted Top Section Showing PCB Relative to the Control Panel



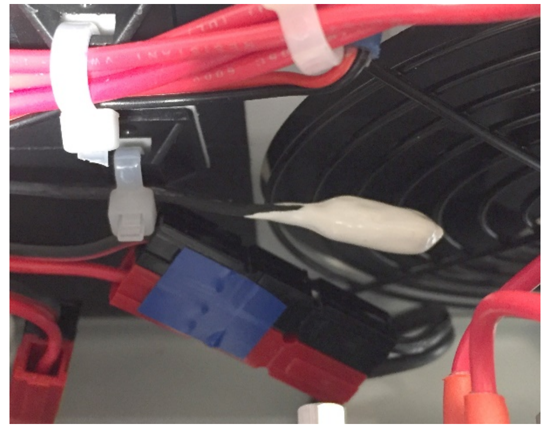
Inverted Top Section, Overhead View of PCB

Inverted Top Section, Control Panel Cluster inside View During Assembly

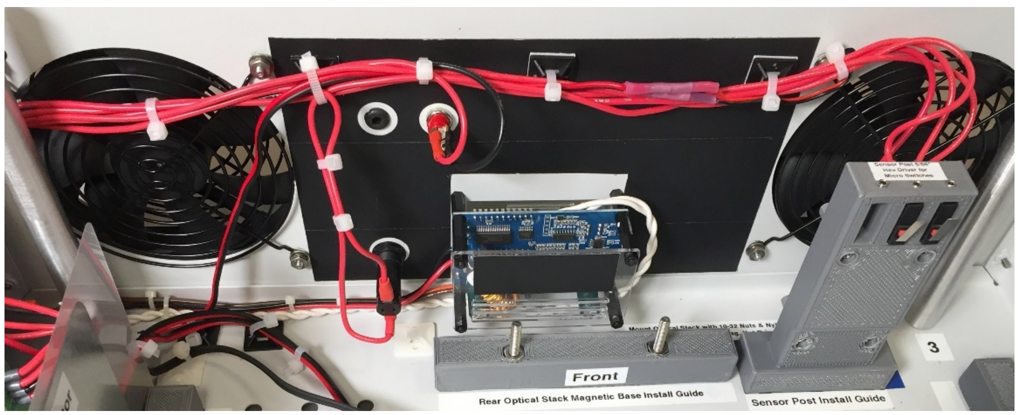
Inverted Top Section, PCB Placement behind Control Panel Cluster



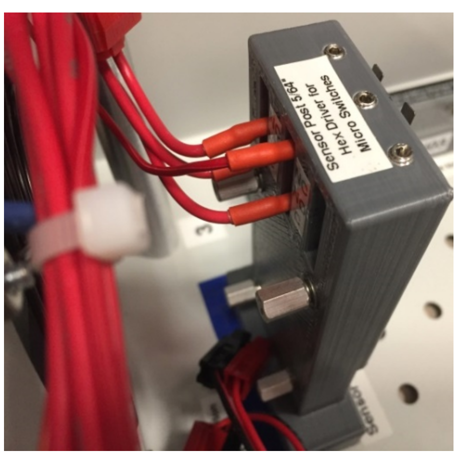
Inverted Top Section, Muffin Fan



Inkbird thermistor sampling outgoing air from the PTD at the muffin fan.



Inverted Top Section, Rear Panel, Boost Convertor (LED Driver) is in the Center & Sensor Post is on the Right



Inverted Top Section, Back of Sensor Post & Alignment Guides

4.6 How to Calibrate the LED panels

Calibrating the LED panels requires inverting the phototherapy device and removing the bottom section. The optical stack must be removed if the present panels are to be calibrated. The 4 panel retaining brackets are removed, and the LED panels are disconnected from power and slipped out of the stack.

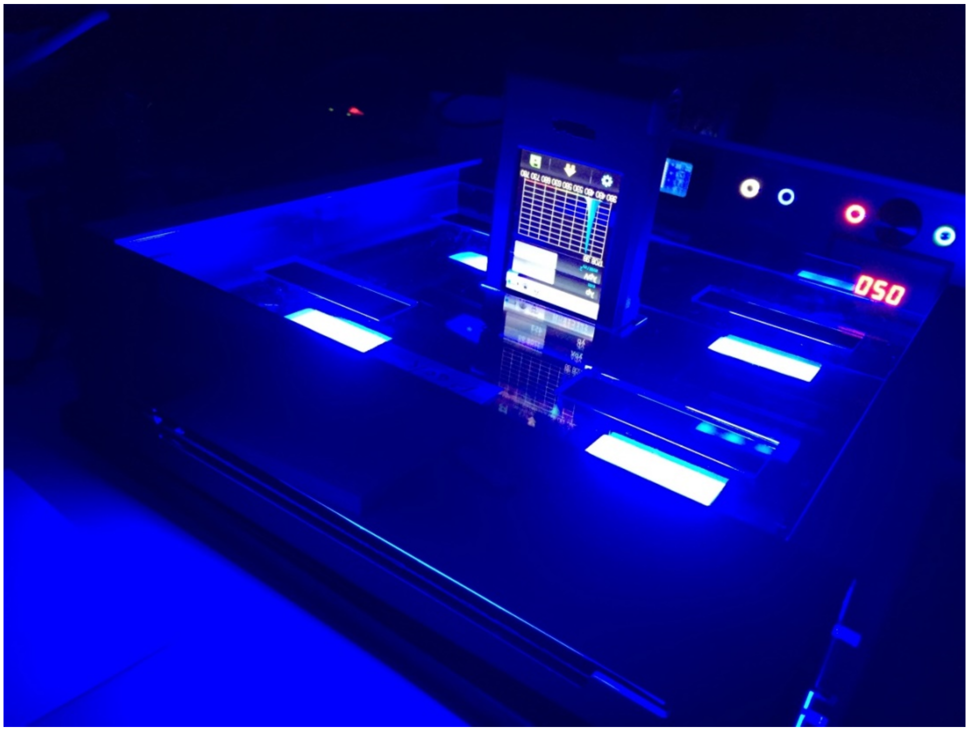
The LED panels are calibrated outside of the optical stack, one at a time in the L*ED Light Panel Calibrator*. During the calibration the panel is powered by the *Phototherapy Device*. In this manner the current draw of each panel can be determined. (The power supply must be of sufficient wattage to operate two panels).

The LED panel being tested is slid into the calibrator through the back, allowing the connector and cable to remain in back of the unit. The panel is then connected to the appropriate connector in the phototherapy device (an extension/jumper cable can be used). When done, the LED panel is pulled from the front. (The front door is only opened to remove the diffuser or clear acrylic sheet, or to assist in removing an LED panel.)

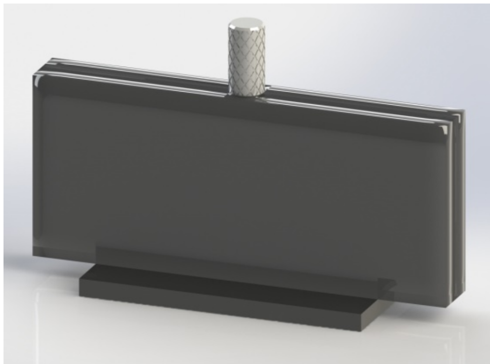
Five sampling points have been arbitrarily chosen to cover five regions of the LED panel. Negligible drop-off of the irradiance has been found when sampling from the center of the panel towards the edges (see calibration report). Each LED panel (with its unique serial number) has its own calibration curve. Little variation from panel to panel has been found, and the diffuser arrangement in the internal optical stack provides for uniform spectral power distribution across the surface (upper or lower) of the internal hand compartment.

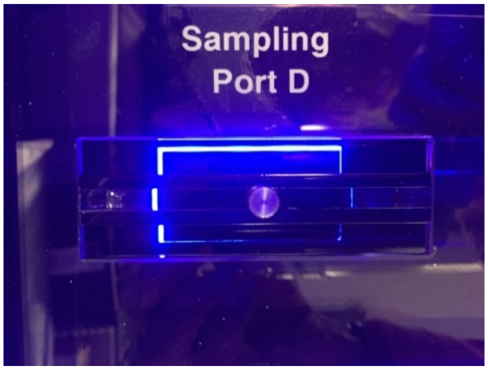
Calibrator, Hinged Front Door and LED Panel Insertion Slot

There are five openings on top into which the spectrophotometer is lowered one at a time to obtain readings at a specific setting of irradiance (percent PWM). The unused ports may be covered by inserting four plugs, thus blocking the blue light. Increment the irradiance from 0 to 100% in 10% increments. Record the irradiance and wavelength for each of the five ports before increasing the irradiance. A total of 55 samples are obtained for each panel.



The port plugs are not shown in the photograph above, but ordinarily would be in each of the open ports. The phototherapy device inverted top section is seen in the background, and is set at 50% irradiance.

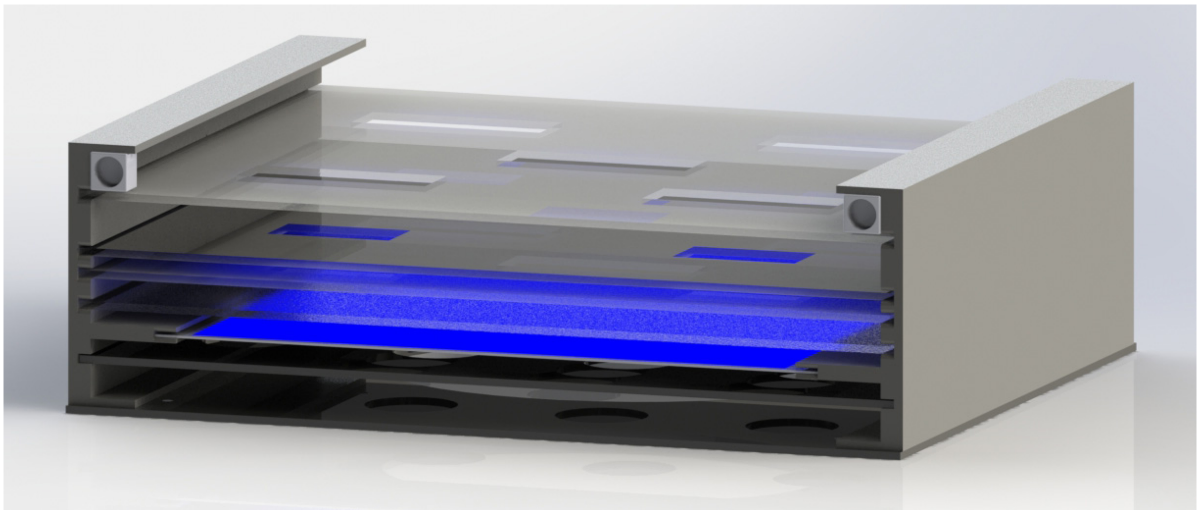




The port plug sits atop and into the black second panel, blocking stray blue light for the benefit of the technician.

The calibrator stack replicates the conditions in the optical stack within the phototherapy device for a single panel. Instead of the entire hand compartment a single acrlylic sheet of similar size and material is used.

Stack Arrangement – Clear acrylic spectrophotometer positioner, black acrylic spectrophotometer sensor rest, micro-bead diffuser (same as optical stack), clear acrylic (replicates top of hand com-partment), blue LED panel, horizontal support (same as optical stack) and bottom.



Calibrator Stack Assembly

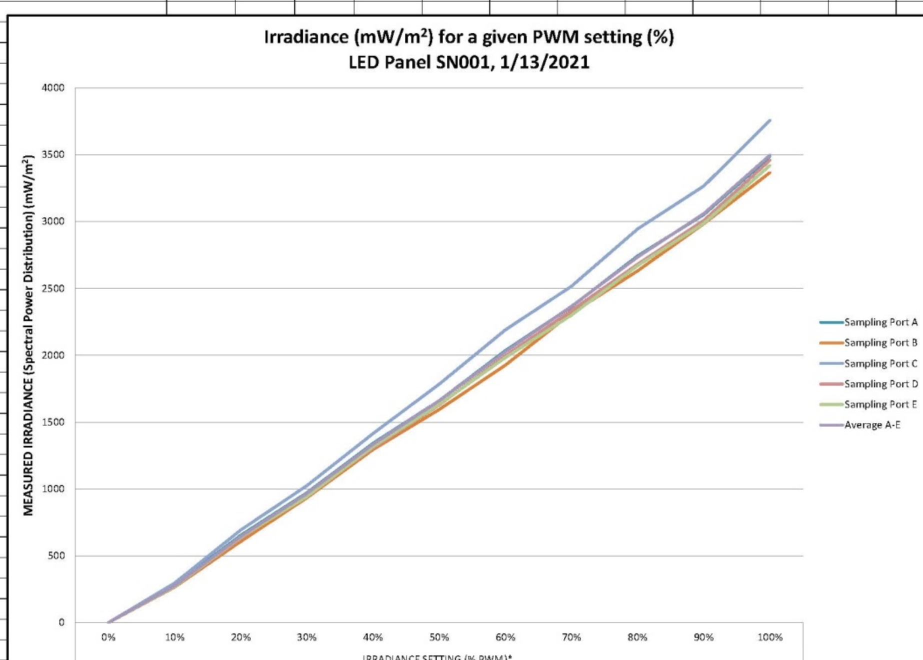
The UPRtek handheld spectrophotometer placed into one of the ports for measurement.

Date: 1/13/2021
LED Panel: SN001
Technician: Steven S. Saliterman
Location: Saliterman Lab
Spectrophotometer: UPRtek MK350N Premium, SN: HS12BJBA0035 (Certification of Calibration on File, Calibration Date 3/15/2019)
Calibration Apparatus: LED Panel Light Calibrator (Saliterman & Levac)

IRRADIANCE SETTING (% PWM)*

	0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
Step-Up Voltage (V)	42.05	42.05	42.05	42.00	42.00	42.00	42.05	42.05	42.00	42.00	42.00
Current (A)	0.000	0.025	0.055	0.080	0.115	0.145	0.180	0.210	0.250	0.275	0.315
Peak Wavelenght (nm)		451	451	451	450	450	451	450	450	450	450
Irradiance or Spectral Power Distribution (mW/m2)**											
Sampling Port A	0.00	278.29	654.27	972.36	1342.52	1660.74	2035.32	2364.03	2744.75	3054.17	3488.23
Sampling Port B	0.00	265.69	608.92	935.15	1295.39	1594.52	1927.34	2314.52	2632.35	2984.98	3368.03
Sampling Port C	0.00	295.49	694.18	1025.88	1415.37	1785.48	2191.32	2517.62	2945.93	3266.67	3756.35
Sampling Port D	0.00	269.22	631.02	958.62	1307.21	1629.04	1997.09	2335.91	2682.12	3010.31	3459.30
Sampling Port E	0.00	269.38	640.67	943.48	1317.59	1634.21	1982.84	2301.34	2670.66	2987.32	3421.78
Average A-E	0.00	275.61	645.81	967.10	1335.62	1660.80	2026.78	2366.68	2735.16	3060.69	3498.74

(* Based on Pulse Width Modulation Setting of 0 to 100% at a fixed Step-Up Voltage of 42.05 VDC to the LED Panel)
(** 1 mW/m2 = .0001 mW/cm2)



Date: 1/13/2021

LED Panel: SN002

Technician: Steven S. Saliterman

Location: Saliterman Lab

Spectrophotometer: UPRtek MK350N Premium, SN: HS12BJBA0035 (Certification of Calibration on File, Calibration Date 3/15/2019)

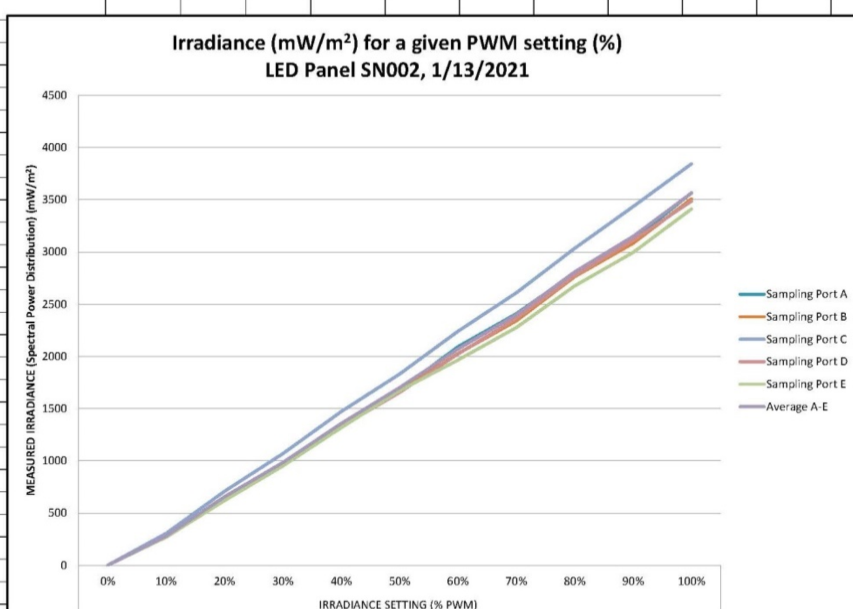
Calibration Apparatus: LED Panel Light Calibrator (Saliterman & Levac)

	IRRADIANCE SETTING (% PWM)										
	0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
Step-Up Voltage (V)	42.05	42.05	42.00	42.00	42.00	42.00	42.00	42.00	42.00	42.00	42.00
Current (A)	0.000	0.025	0.065	0.095	0.135	0.170	0.210	0.234	0.275	0.315	0.355
Peak Wavelenght (nm)	453	453	453	453	453	453	453	453	453	453	453
Irradiance or Spectral Power Distribution (mW/m2)**											
Sampling Port A	0.00	275.96	655.5	977.57	1348.76	1678.08	2091.65	2409.05	2801.28	3116.55	3564.54
Sampling Port B	0.00	277.40	648.31	953.00	1324.57	1667.17	2027.05	2341.95	2763.56	3084.44	3507.64
Sampling Port C	0.00	305.29	709.72	1069.12	1472.26	1831.17	2239.49	2608.03	3036.22	3435.06	3843.83
Sampling Port D	0.00	277.05	652.86	965.77	1326.49	1656.38	2023.43	2363.94	2772.56	3110.80	3488.06
Sampling Port E	0.00	269.52	620.07	951.79	1318.70	1671.86	1966.06	2275.80	2675.88	2996.10	3412.06
Average A-E	0.00	281.04	657.29	983.45	1358.16	1700.93	2069.54	2399.75	2809.90	3148.59	3563.23

(* Based on Pulse Width Modulation Setting of 0 to 100% at a fixed Step-Up Voltage of 42.05 VDC to the LED Panel)

(** 1 mW/m2 = .0001 mW/cm2)

Supplemental Data	50%	100%
Sampling Port C		
No Clear Panel	1866.55	3905.17
No Diffuser Panel	1990.61	4132.33
No Clear or Diffuser	2047.45	Over Exposure
%Transmittance Clear	98.10%	98.43%
%Transmittance Diffuser	91.99%	93.02%
%Combined	89.44%	Not Determined



4.7 Maintenance

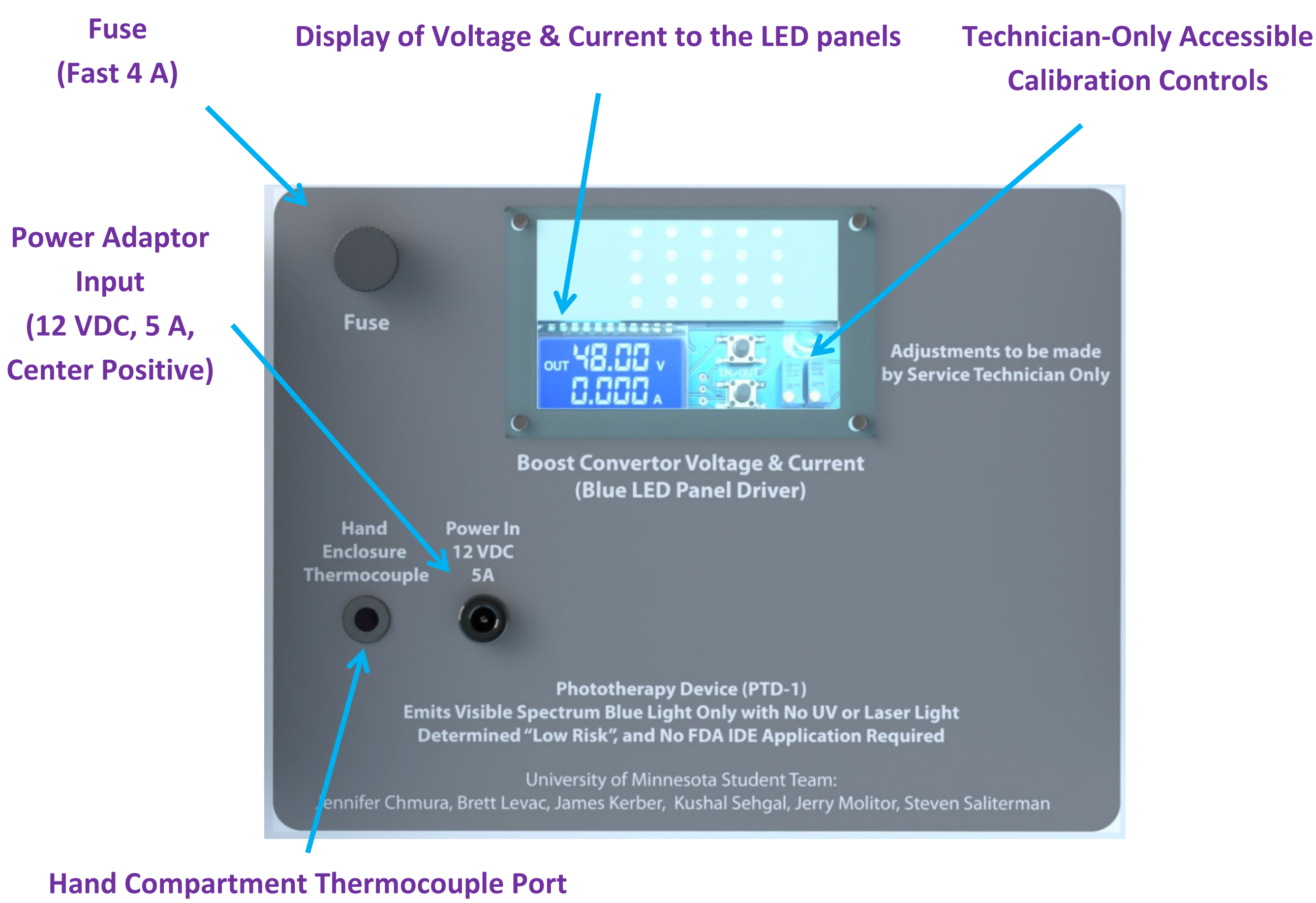
General Care & Sanitizing

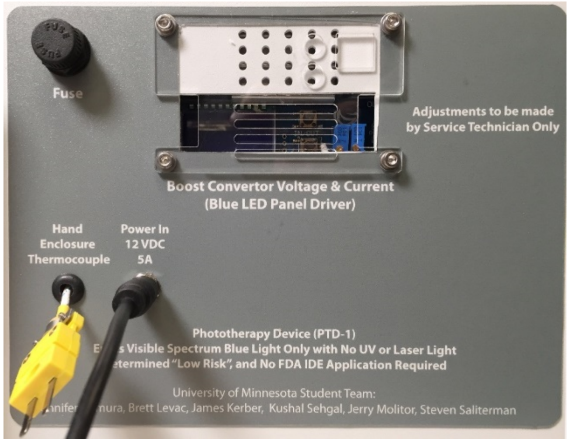
The system and LED driver power should be recorded at the time of installation and periodically as designated by the study protocol (to assure proper functioning of the unit).

The LED panels should be calibrated annually, when serviced or if power readings are not within range. (See service manual.)

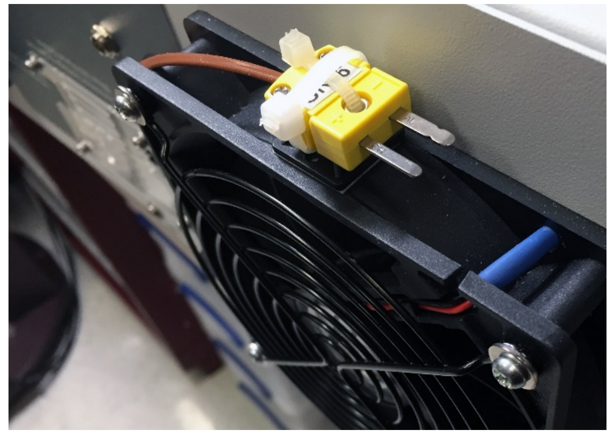
The plastic hand compartment and vinyl pad should be cleaned and disinfected between participants by wearing nitrile gloves and using Clorox® Healthcare Germicidal Wipe. <u>Do not use alcohol to clean plastic surfaces.</u>

Rear Panel





Thermocouple Connector & DC Adaptor



Connector fastened to bottom of muffin fan for connection to the extender cable.

For setup and maintenance purposes there is an "LED PANEL" override button on the control panel which when pressed (latches) turns the LED panels on and off. (They do not turn the LED panels off if they are activated by the timer). The circular indicator lights will also come on when either the LED panels (blue) or fans (white) are on. This occurs if either turned on automatically or by pressing one of the buttons. These buttons latch (not momentary), and must be pressed again to unlatch, similar to the power on/off button.

Control Panel Overrides

4.8 Specifications

General

Power Source: 12 VDC, 5A, 60-watt UL approved adaptor with thermal cutoff
Unit Power: 37 watts maximum.
Blue Light Spectral Power Density (above and below hands): 350 $\mu W/cm^2$ maximum*.
Blue light wavelength: visible spectrum, 451 nm.
LED driver voltage: 42 VDC +/-1 volt
LED driver current (both displays combined): 0 – 700 ma.
Dimensions (W x L X H): 20 x 18 x 7.5 inches (51 x 46 x 19 cm).
Weight: 31 pounds (14 kg).
Hand Compartment: Plexiglass – disinfect with Clorox® Healthcare Germicidal Wipe or equivalent, not alcohol.
Additional Safety Features:

- Automatic detection of opaque sham vs clear experimental hand compartments.
- Blue LED panels are automatically timed.
- Separate hand compartment and internal PTD temperature monitoring.
- Automatic power cutoff when a hand compartment is removed.
- Fuse
- No high voltage, UV light, ultrasonic, magnetic or high frequency emission.

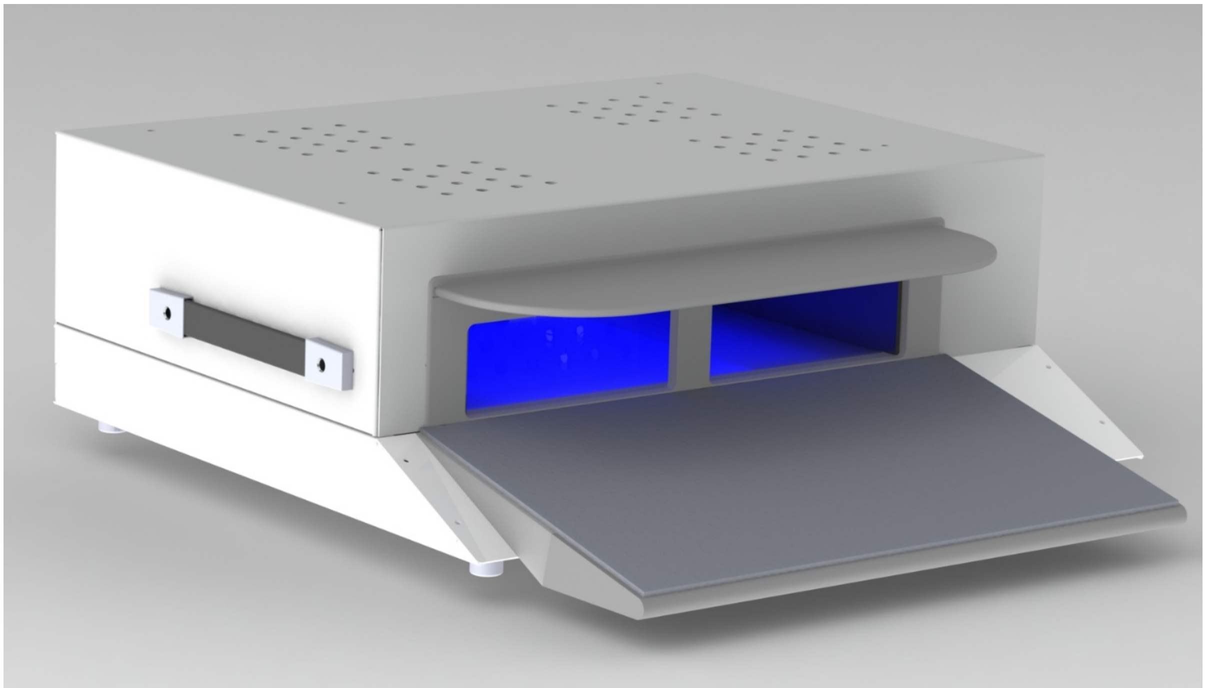
* 350 $\mu W/cm^2$ = 3500 mW/m^2 (from calibration table) = 3.75 W/m^2

DC Power Adaptor

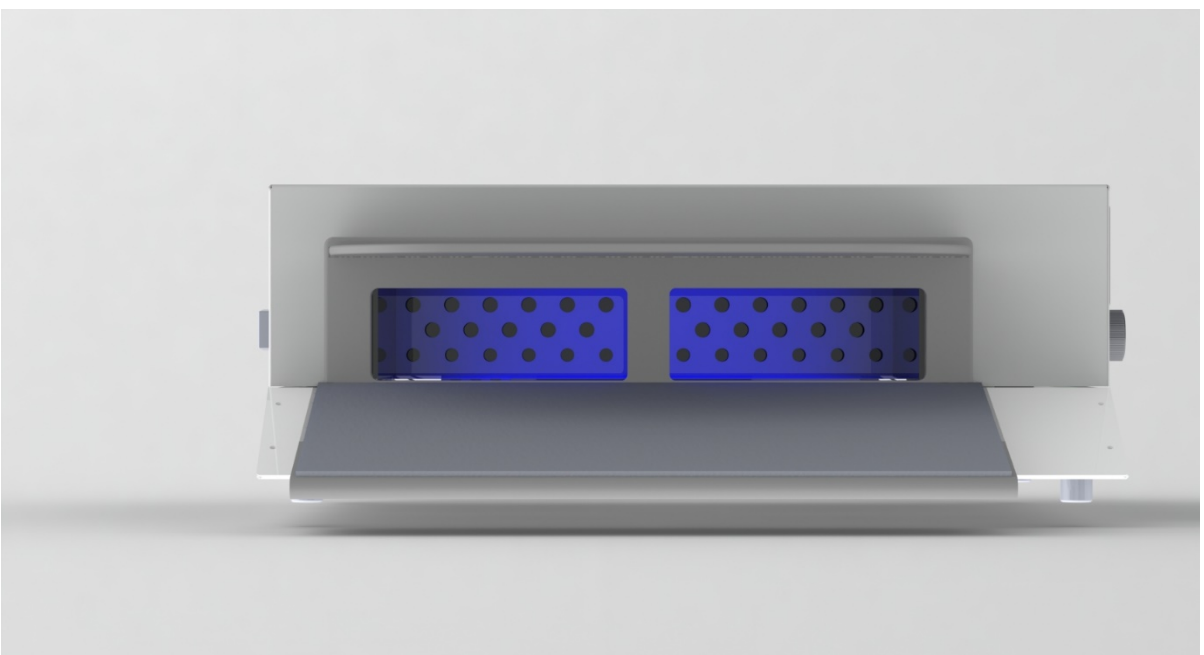
Part 5 – Design

5.1 Primary Cabinet Assemblies

Left Oblique – Top & Bottom Sections

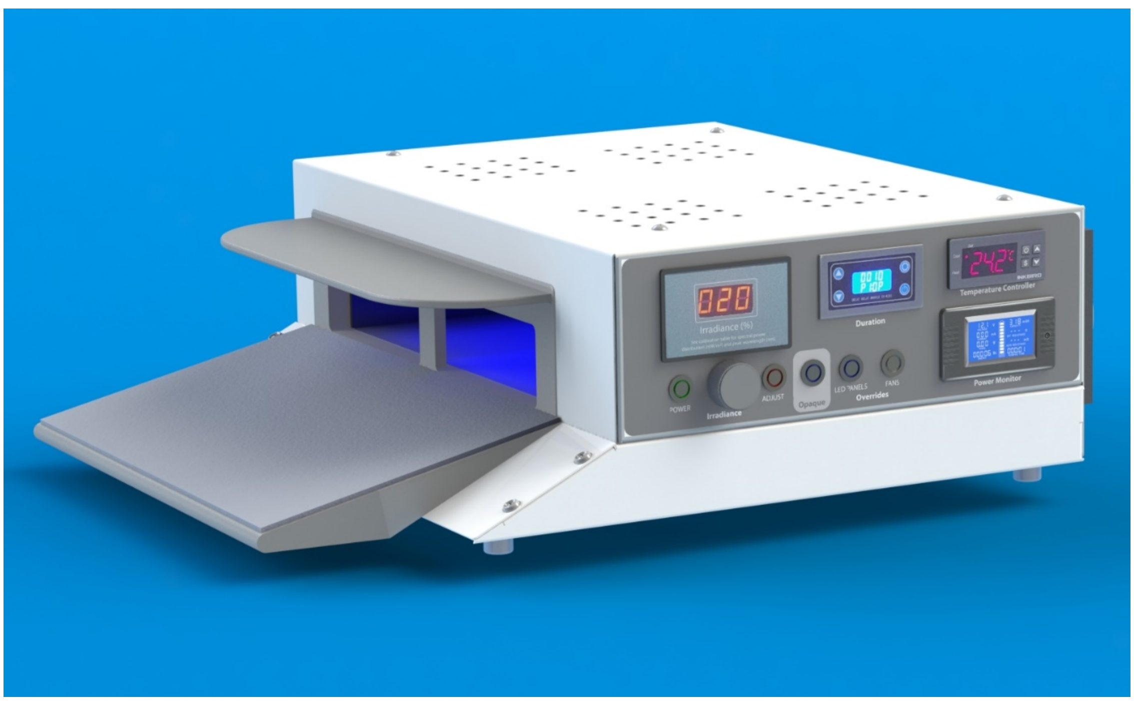


Front – Armrest, Hood, Front Bezel and Hand Compartment



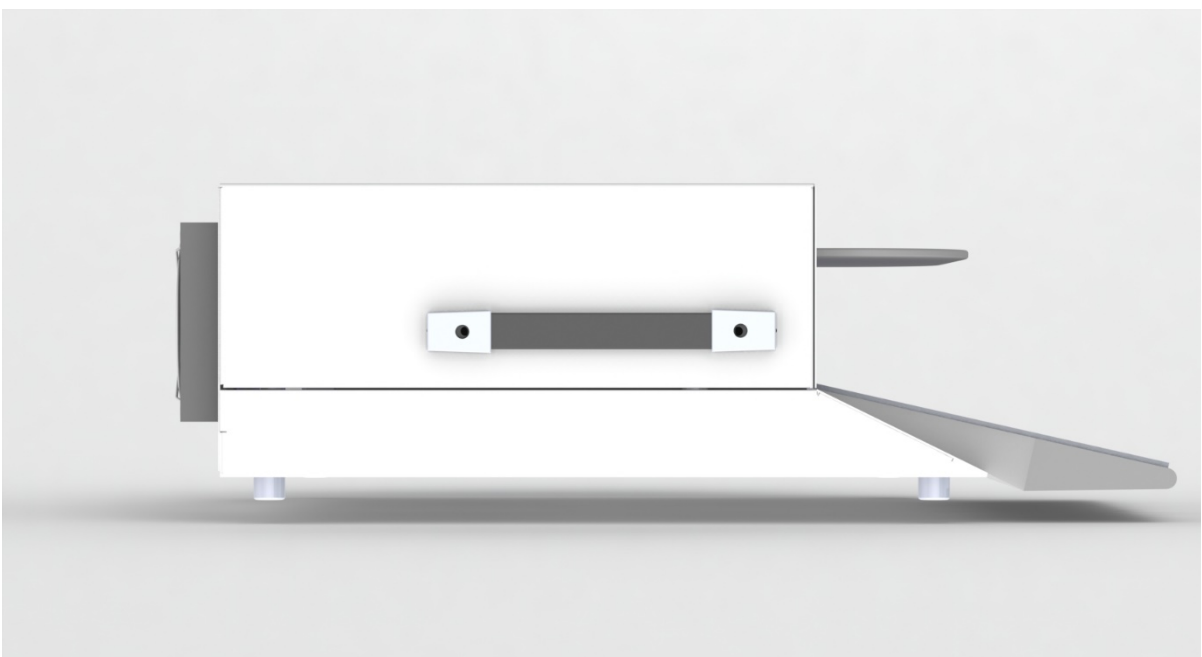
Right Side

Right Anterior Oblique

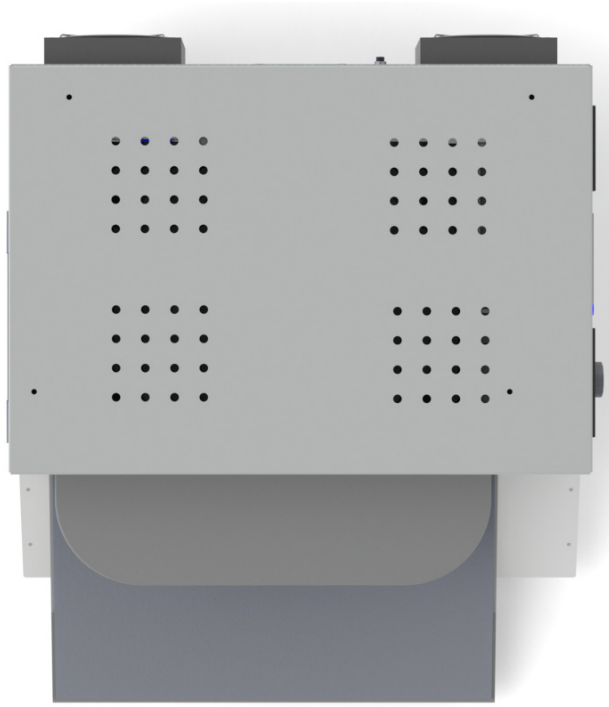


Rear - Fans, LED Power Monitor, Fuse, Power Jack, Thermocouple Exit Port

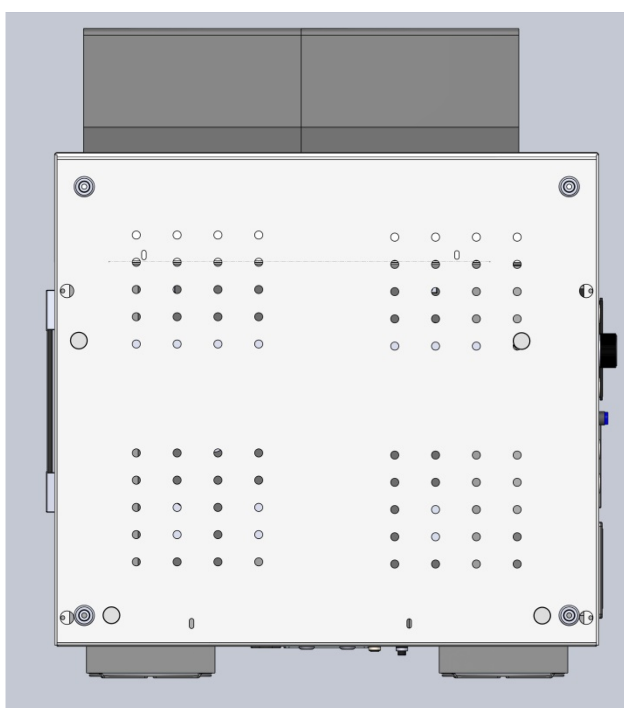
Left Side - Handle



Top – Fans, Hood and Armrest



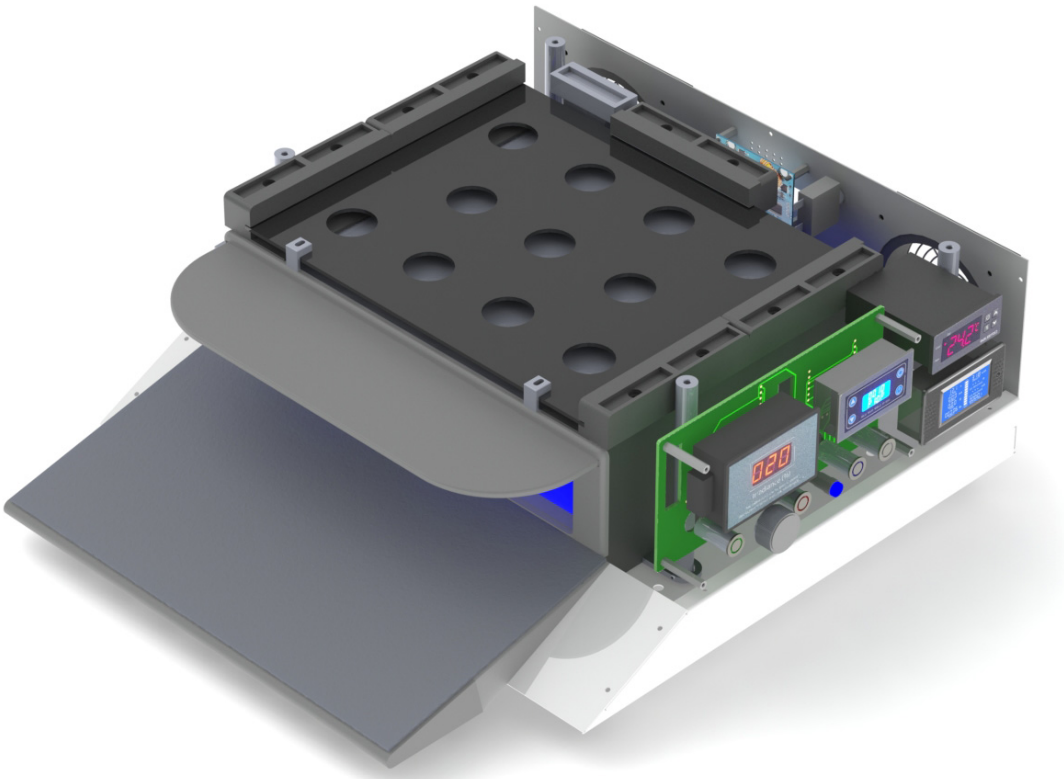
Bottom – Feet & Thumbscrews

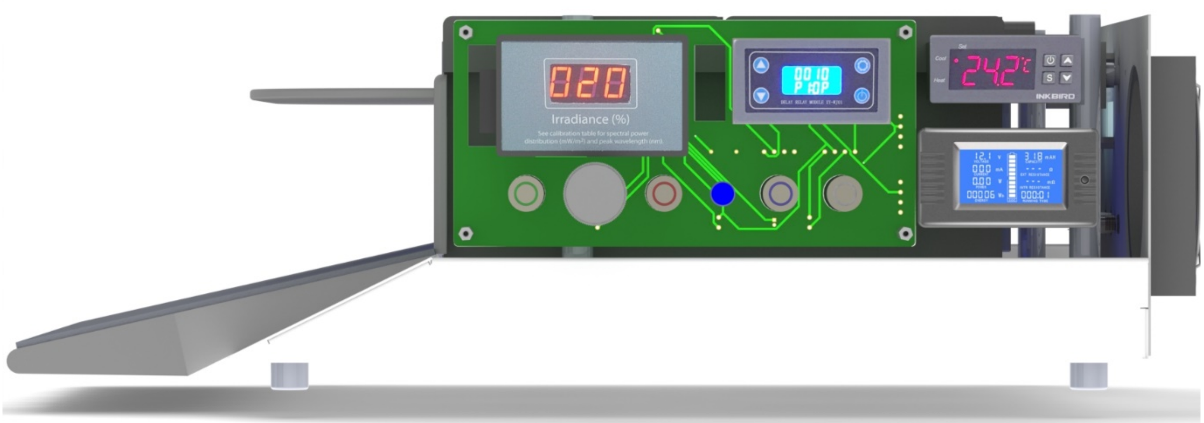


5.2 Right Side Control & Back Panels

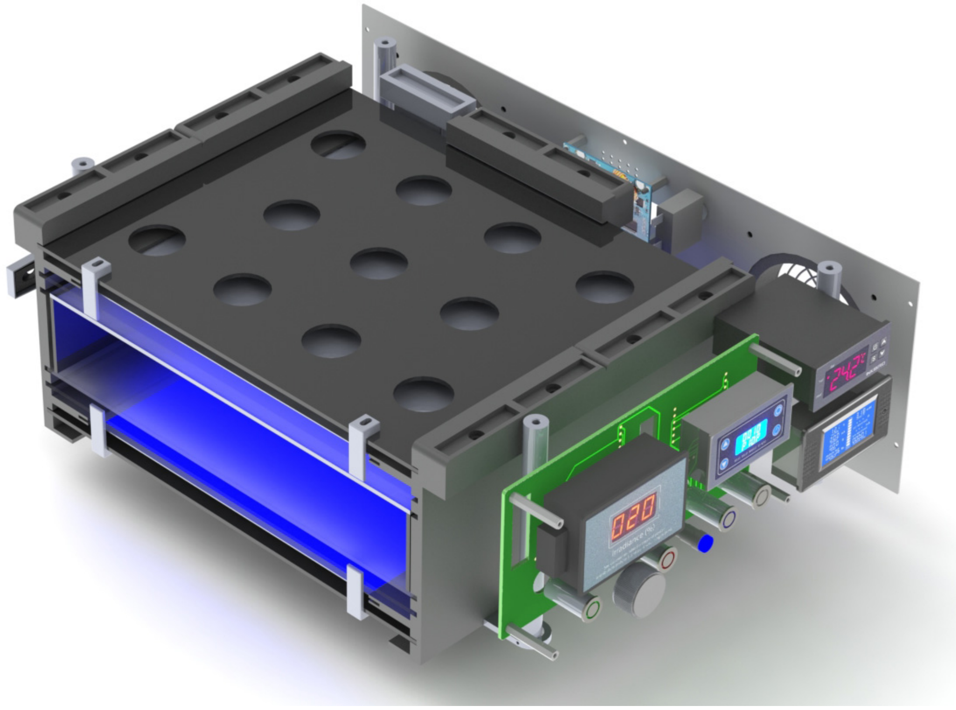
5.3 Subassemblies

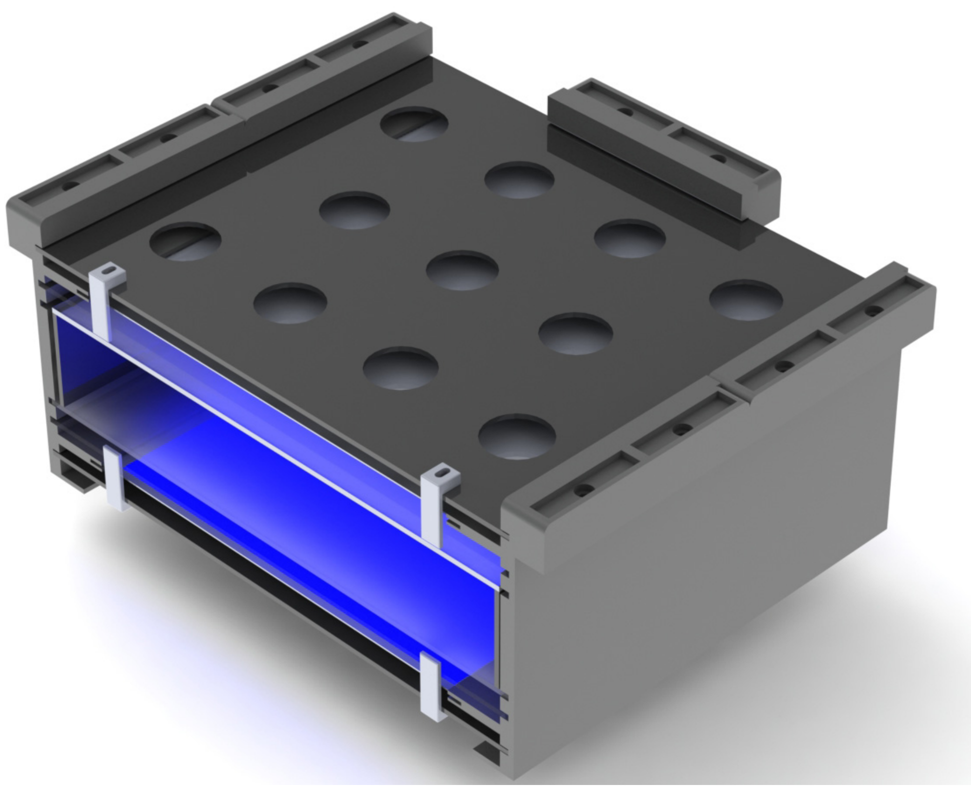
Bottom Part – Armrest, Hood & Bezel, Optical Stack with Magnet Pockets, Circuit Board, Electronic Components, Rear Panel





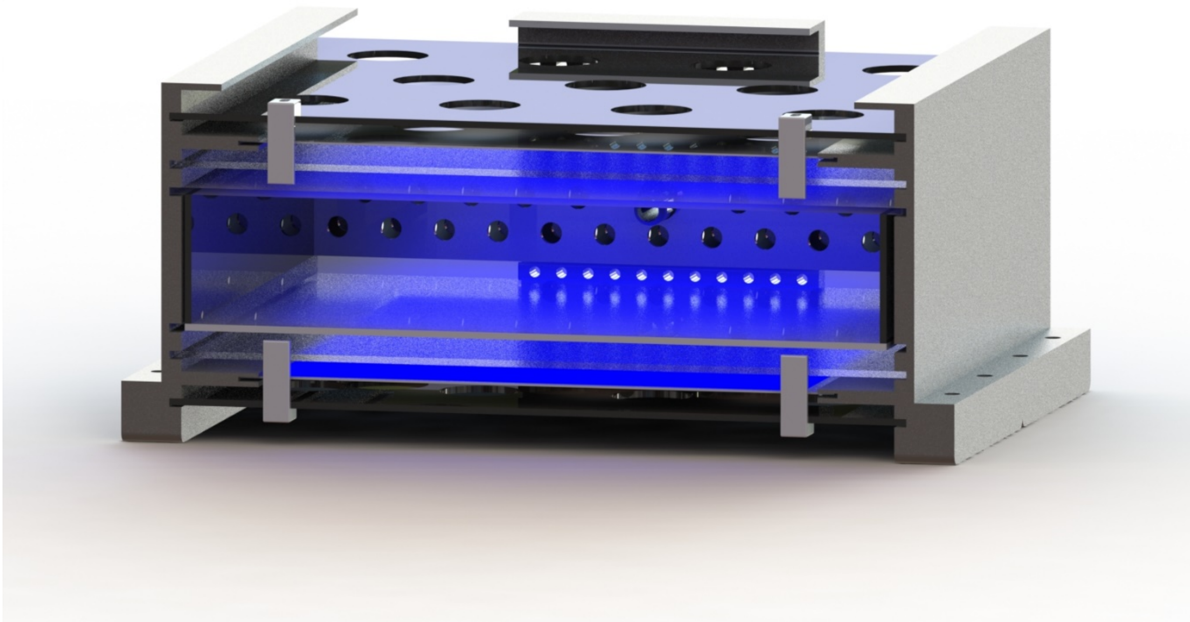
Optical Stack, Electronic Components and Back Panel



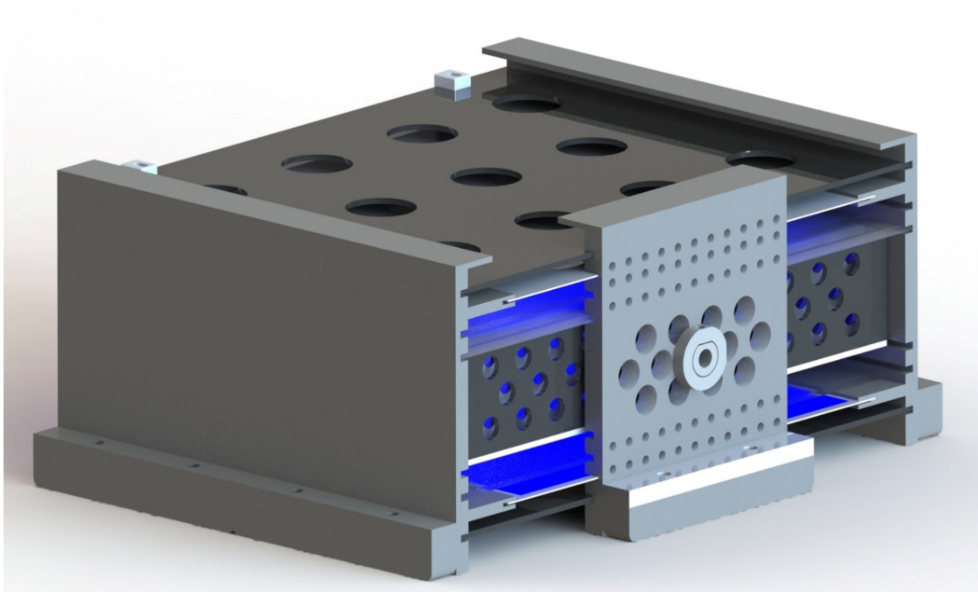


Optical Stack Arrangement

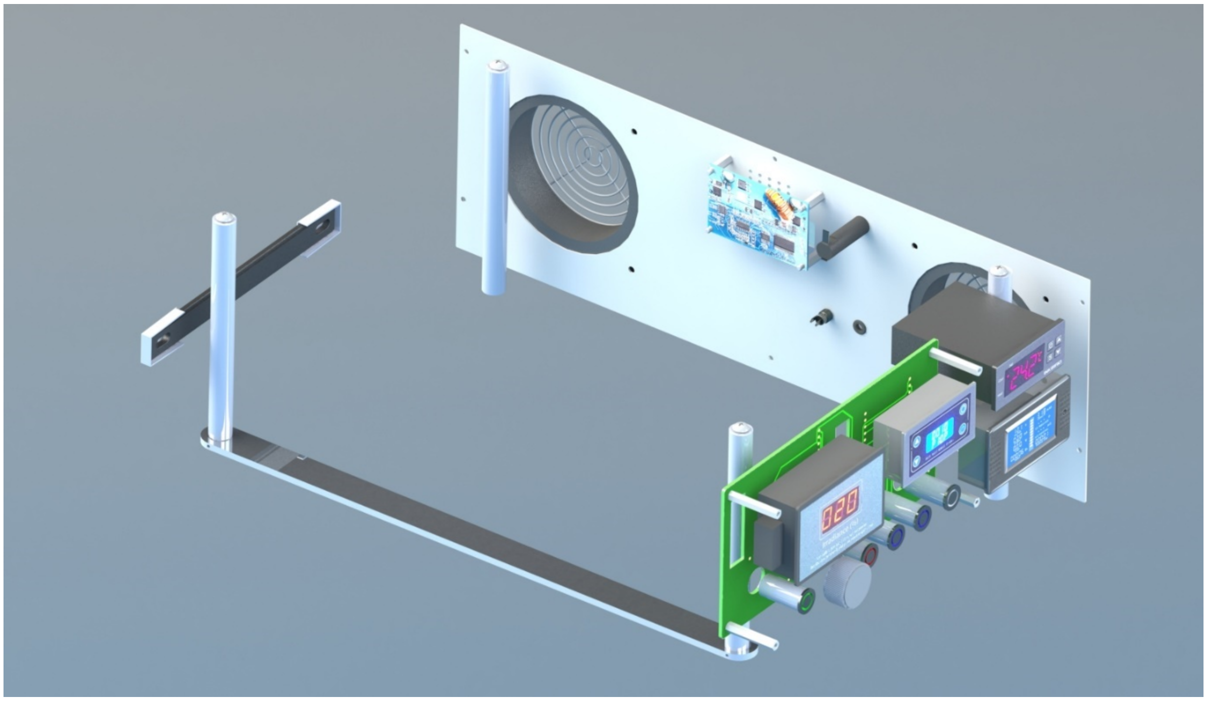
Top to bottom: Stabilizer, LED Panel, Micro-Bead Diffuser Panel, Slide-in Hand Compartment, Diffuser, LED Panel, Stabilizer; Left, Right and Back Walls, Panel Retaining Clips; Light-Ray Simulation Analysis



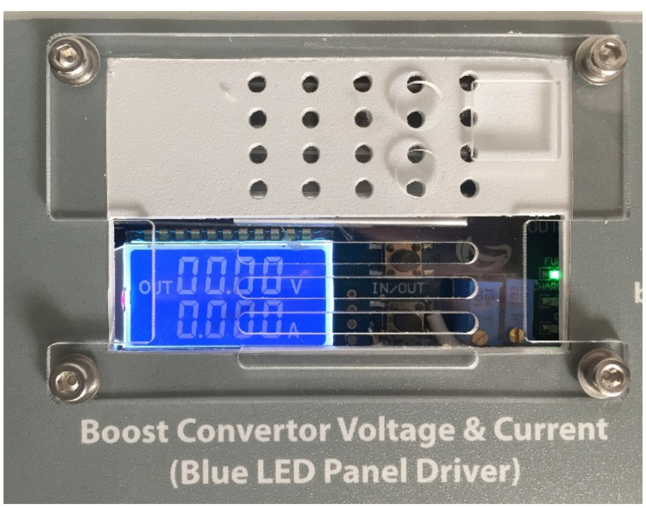
Rear of Optical Stack Showing Thermocouple Holder and Collar

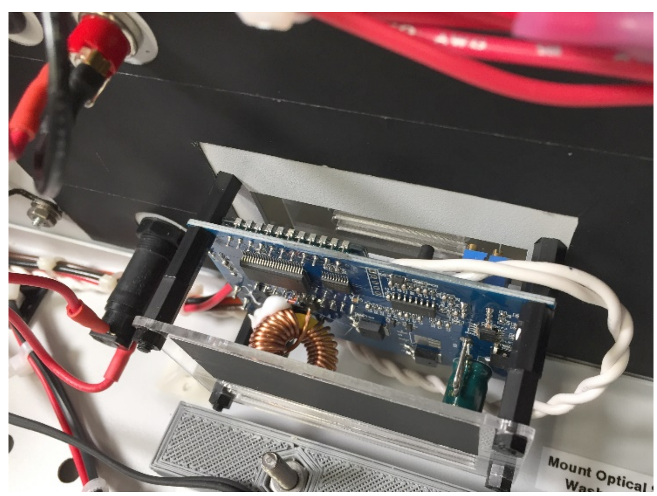


Handle, Optical Stack Retaining Bar, Top to Bottom Posts, Circuit Boards, Electronic Components, Handle, Muffin Fans & Back Panel



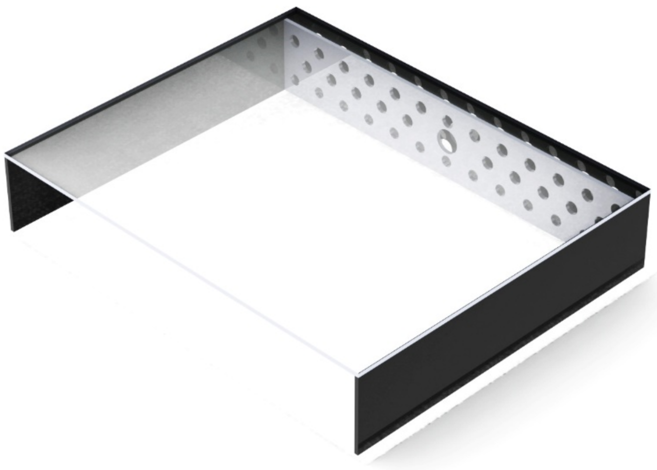
Boost Converter LED Driver, Power Adaptor Jack and Fuse (Inside View), & Light Absorbing Foil

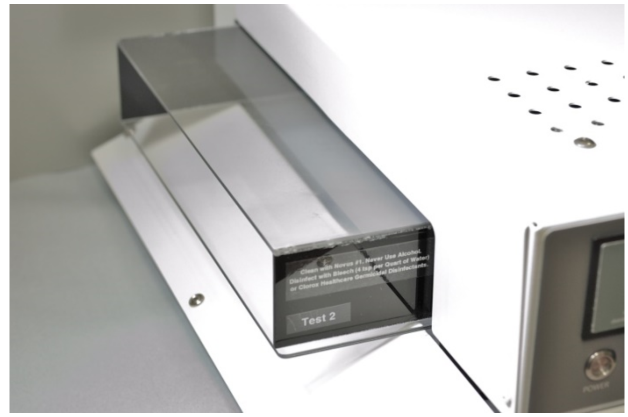


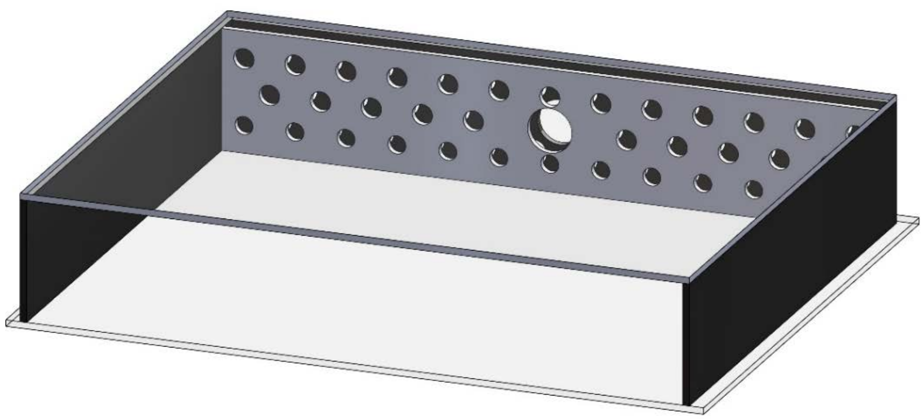


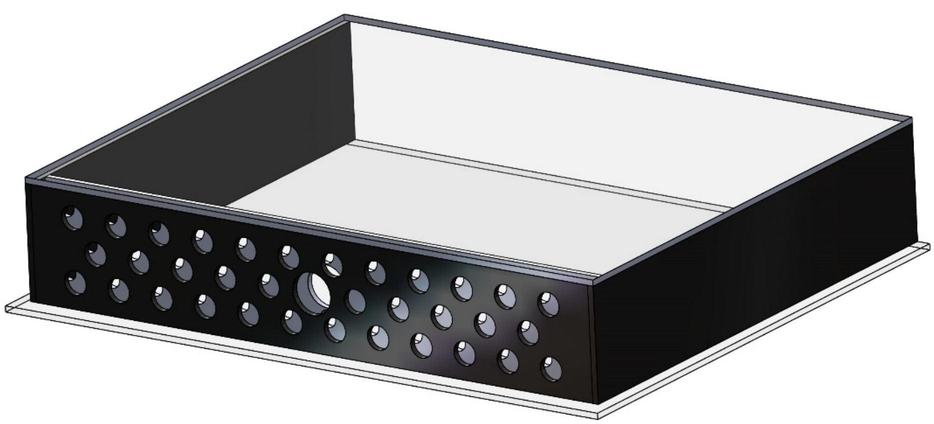
5.4 Hand Compartments

Clear Experimental – Clear Acrylic



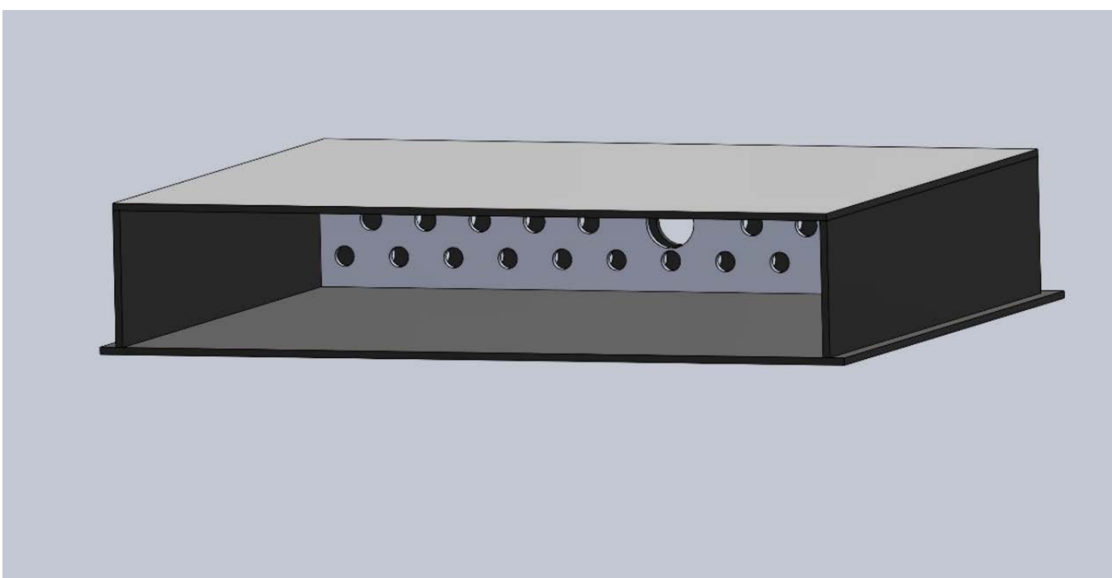


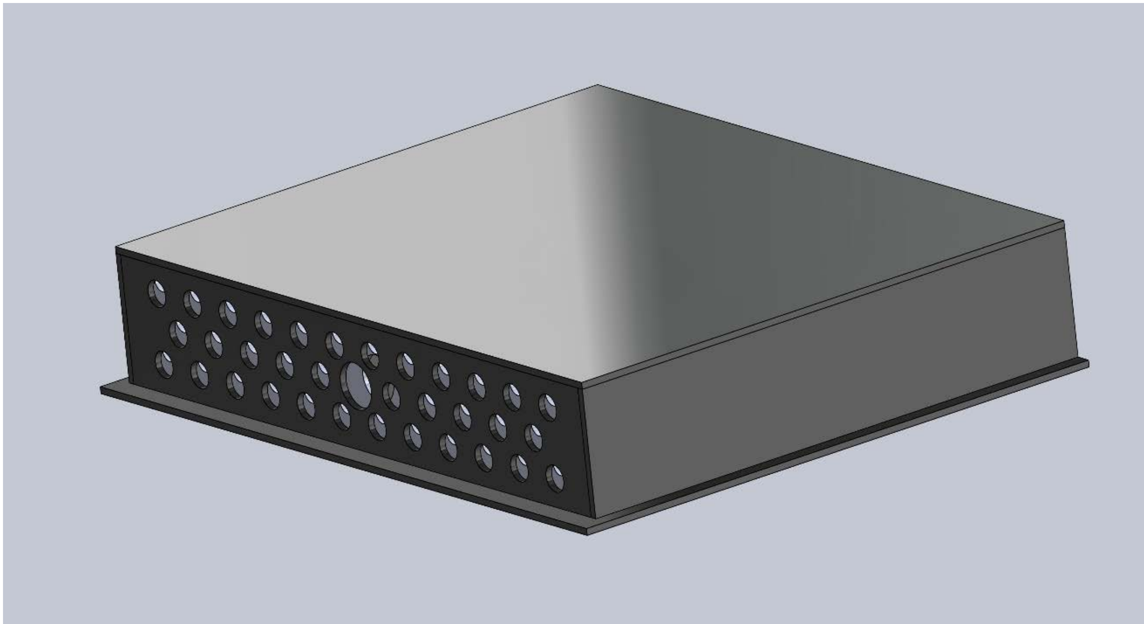




Opaque Sham – Black Acrylic with Reflective Mylar

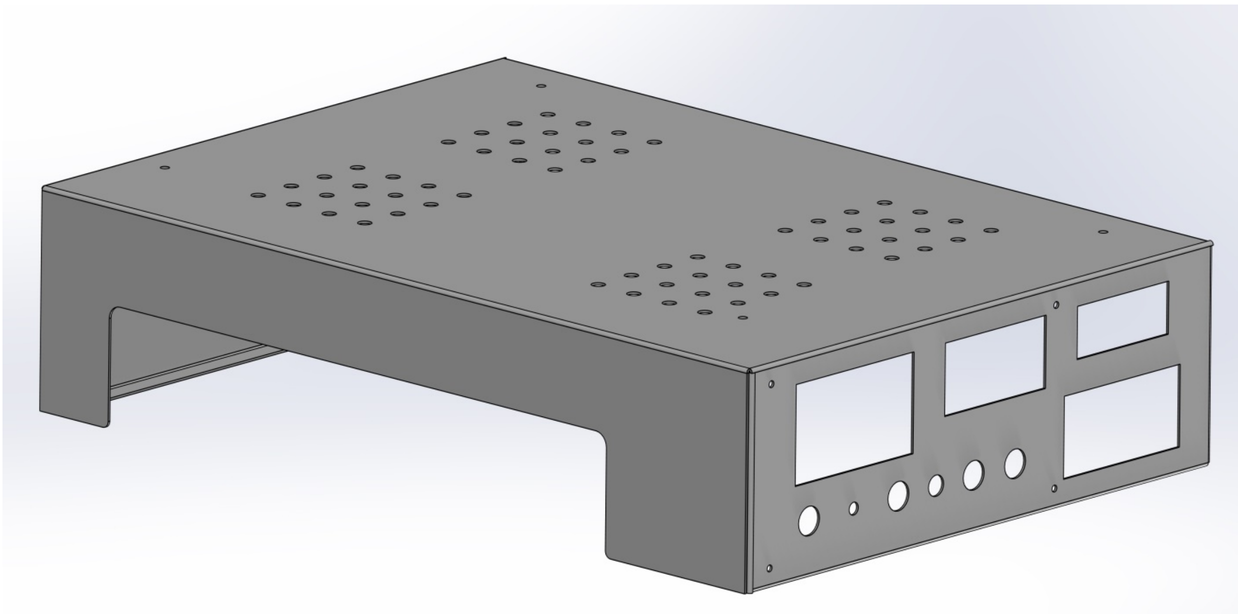
Front & back views, showing the back notch for microswitch sensor.

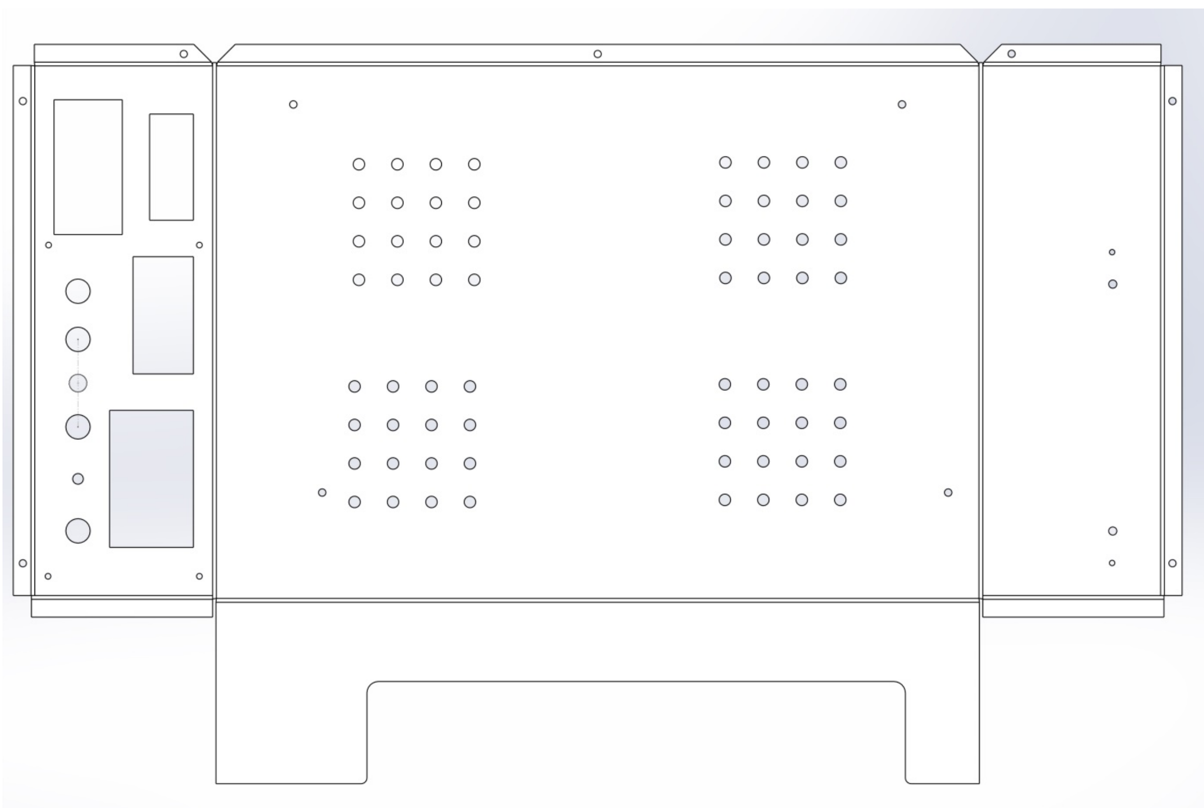




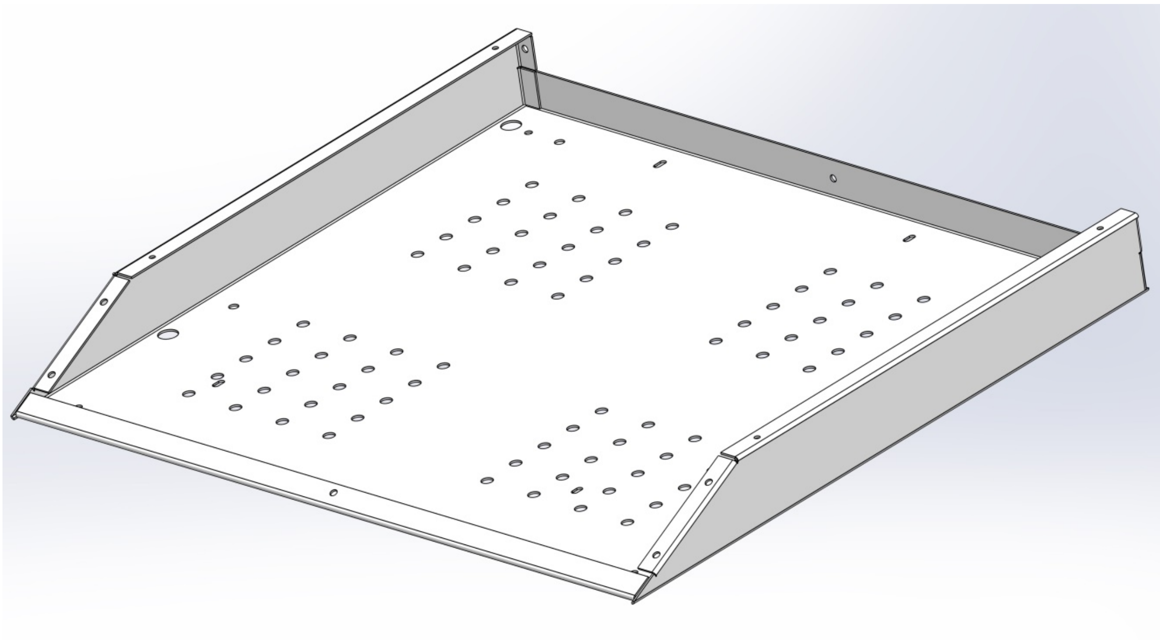
5.5 Cabinet Parts

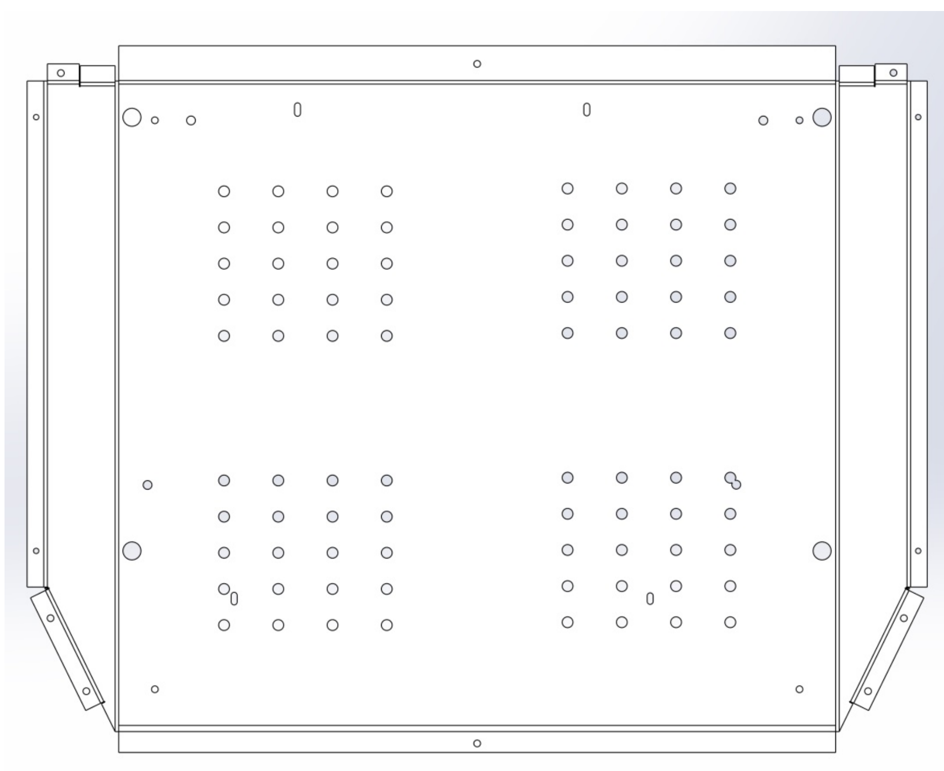
Top Section of Cabinet Folded & Unfolded (Sheet Metal)



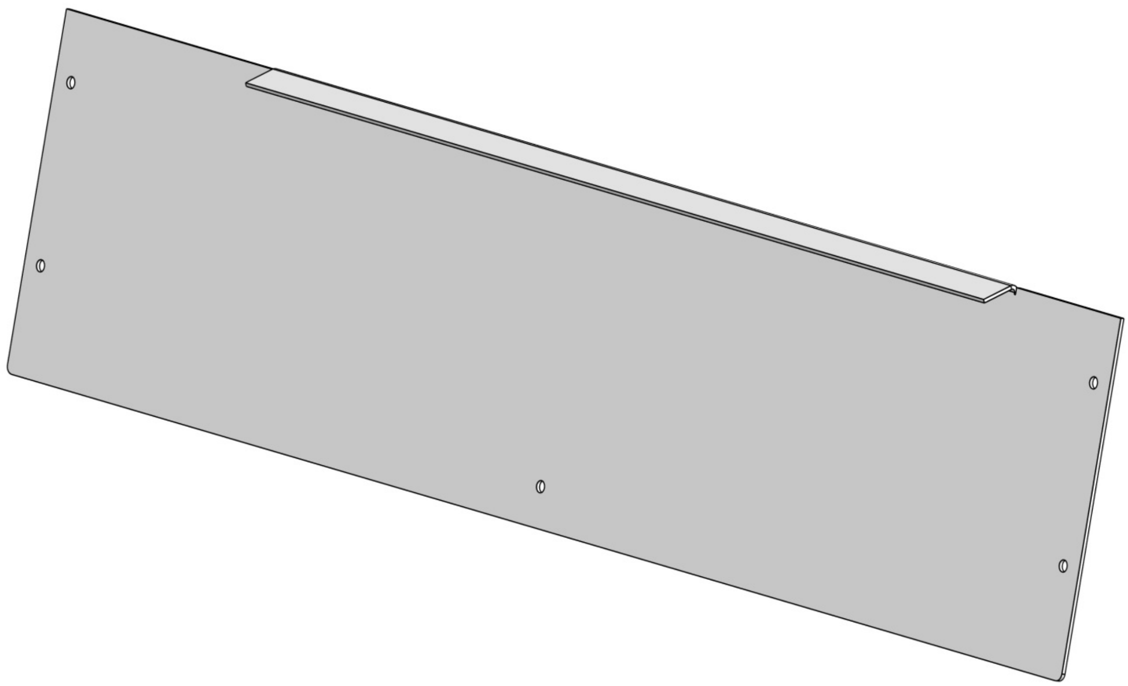


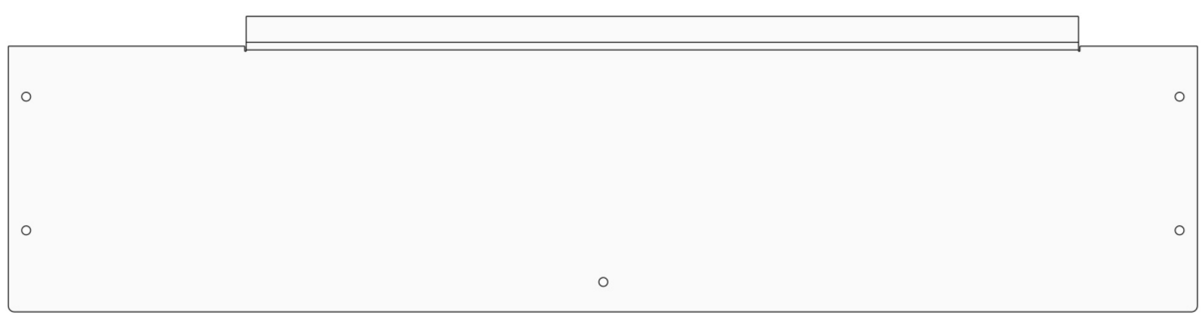
Bottom Section of Cabinet Folded & Unfolded (Sheet Metal)



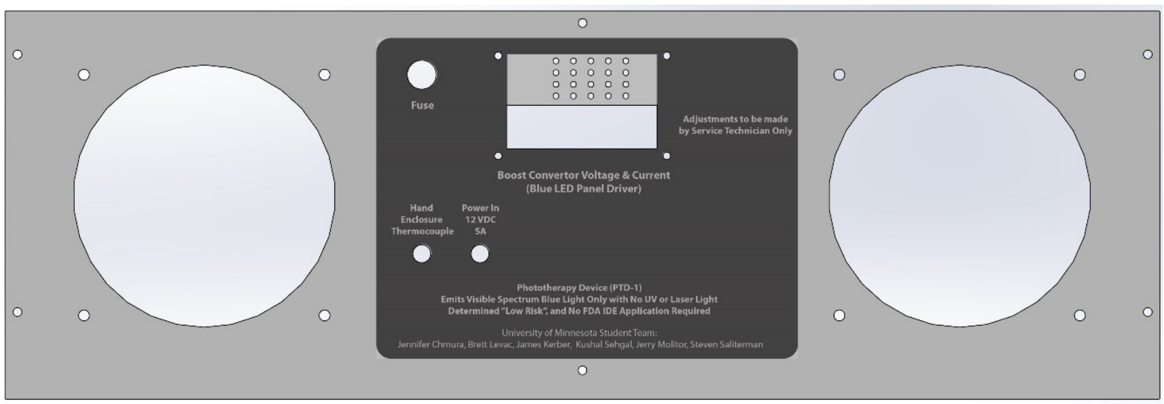


“Hand Rest” of Cabinet Folded & Unfolded (Sheet Metal)



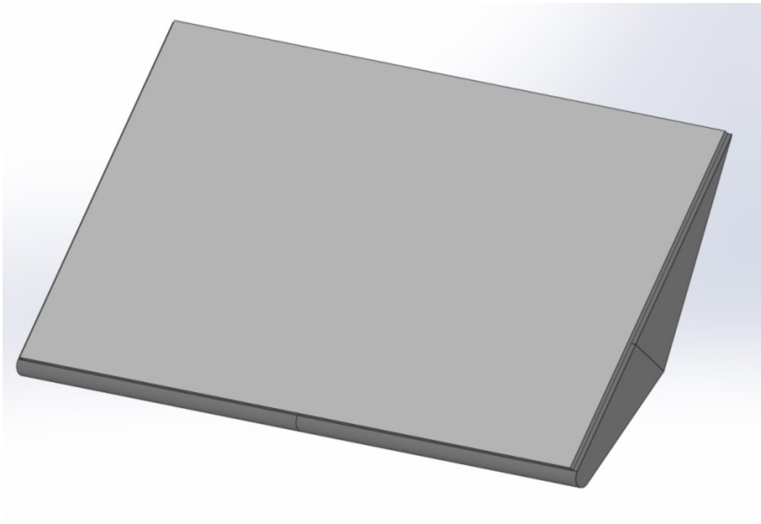


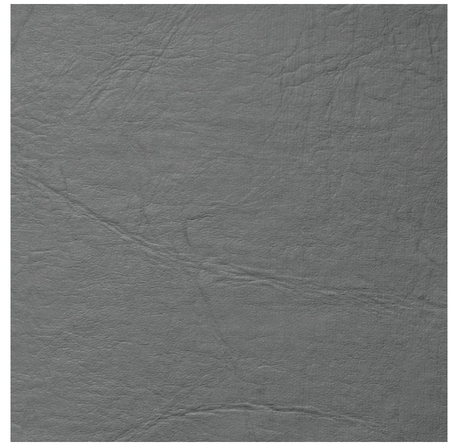
Back Panel (Sheet Metal)



Security Cable Attachment

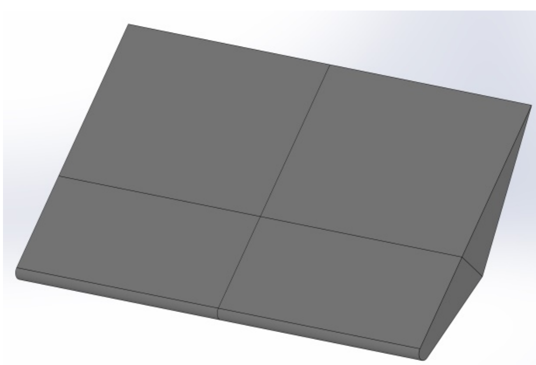
Forearm Assembly with Vinyl Cushion Cover – Sits atop the Cabinet Armrest

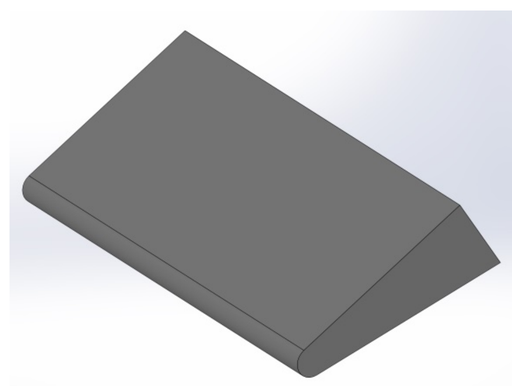


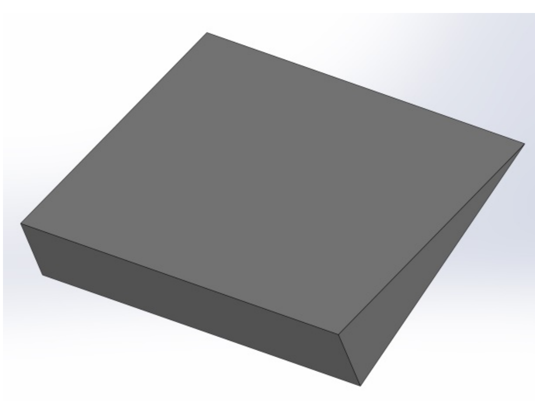


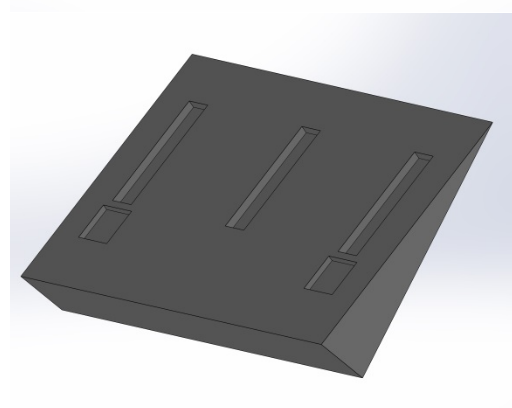
Grey Weatherproof Faux Leather Finish Marine Vinyl

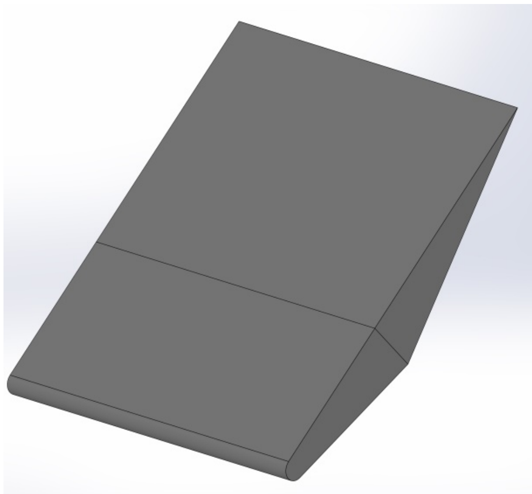
Parts of the Forearm Cushion Assembly Showing Magnet Pockets

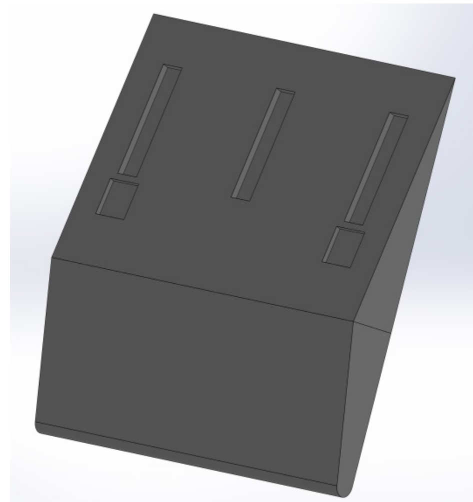






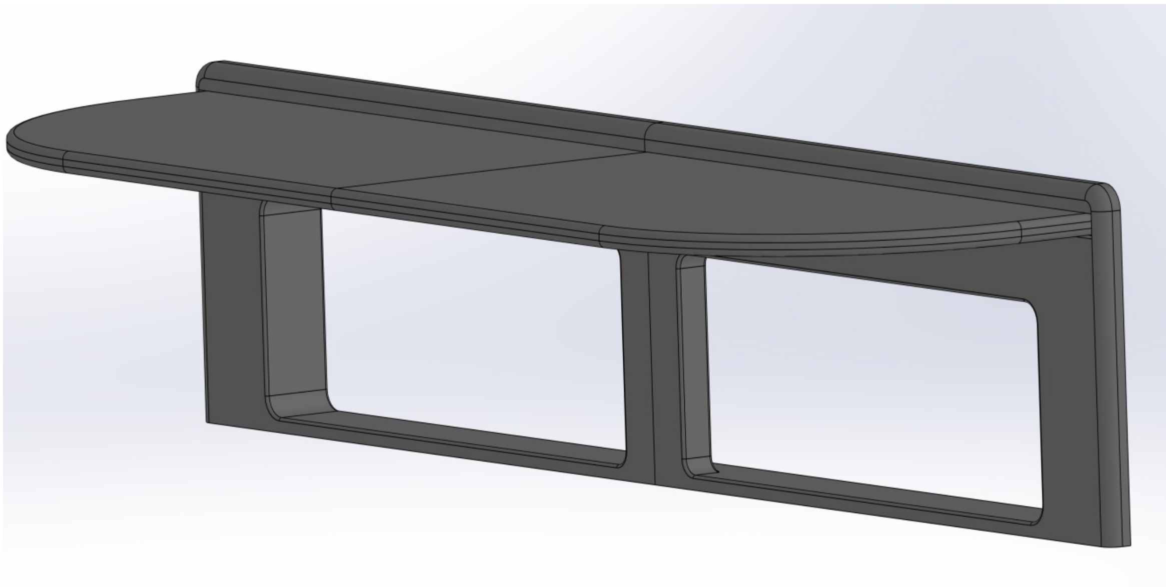


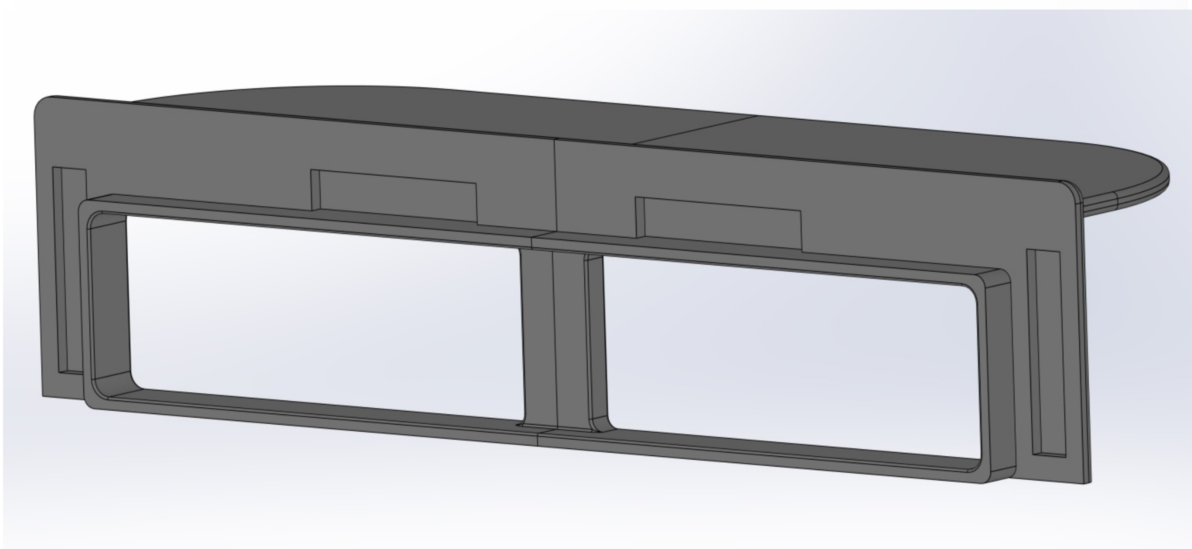




Hooded Bezel Front & Back Assembly with Magnet Pockets

This 3D FDM printed assembly sits in front of the hand enclosure is magnetically attached to the outside of the top section.

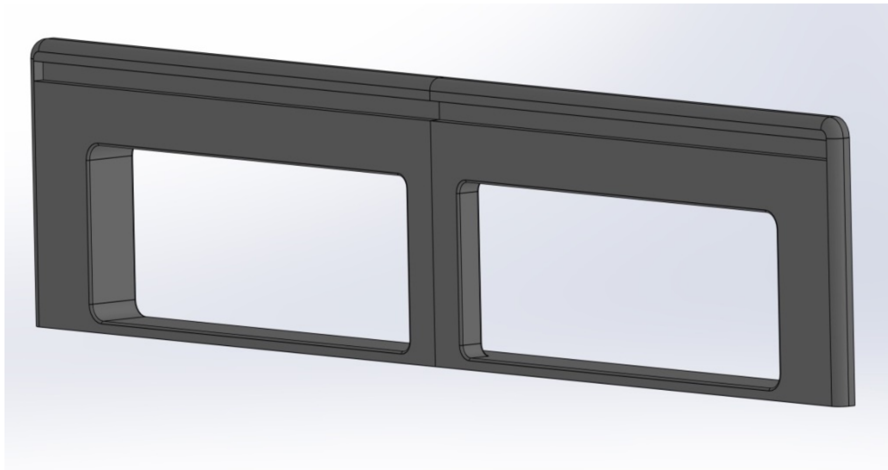




Rare Earth neodymium N48 bar-block magnets (60 x 10 x 4 mm) are secured with generous amount of Loctite Liquid Professional Super Glue to the PLA FDM printed parts. A thin neoprene sheet is then superglued over this.

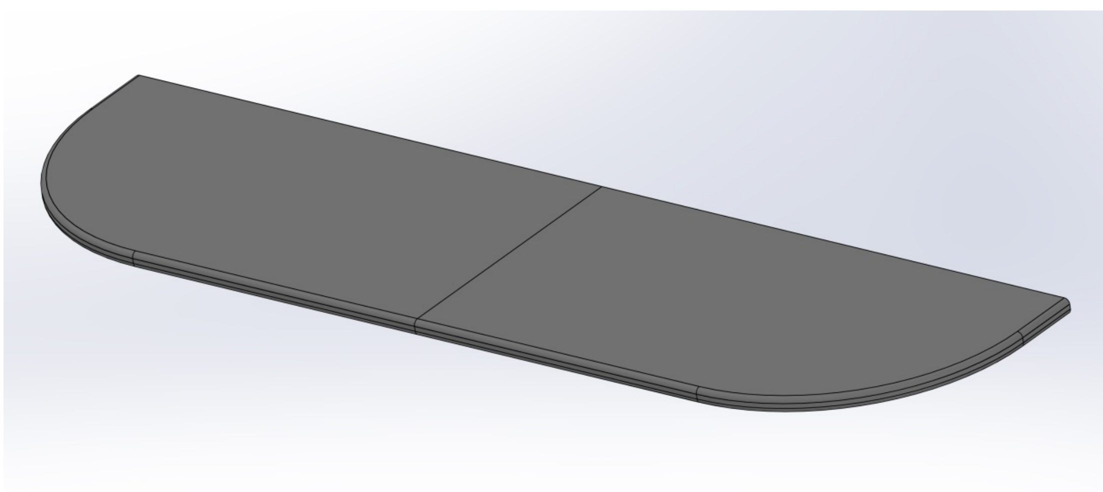
(A better magnet is one with counter bores filled with glue - purchased as “5 mm” but actually 4 mm when removed from the unnecessary metal holder. A thinner (3 mm thick) magnet can be used for easier removal from the cabinet.)

Front Bezel (Made as a 2-part Split)



Dip each end (1 mm) in methylene chloride solvent in a glass tray for 60 seconds prior to bonding the sections together. Place and lift sections on supports so that only the parts being bonded contact each other, and not the table. Hold together for 5 minutes.

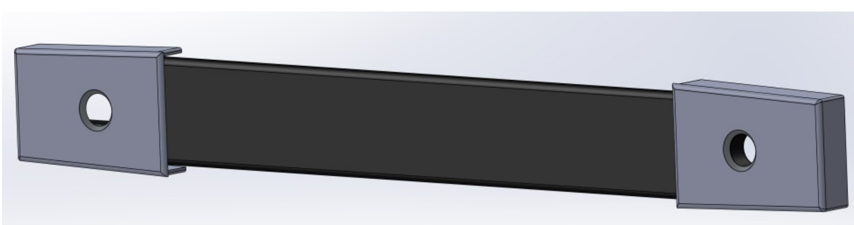
Hood (Made as a 2-Part Split)

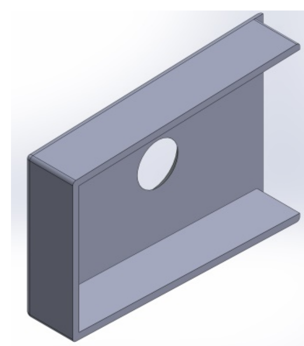


Use a syringe & needle with methylene chloride to bond the hood to the bezel. Make 3-4 runs of solvent along the bond, allowing it to wick in.

Bottom to Top Section Aluminum Fastening Posts (4 Required)

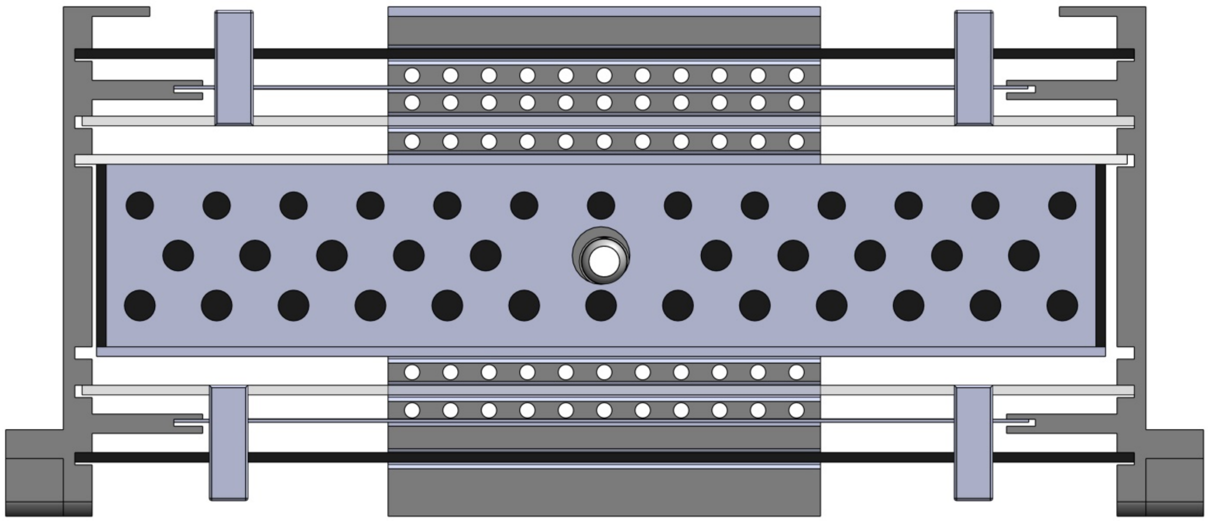
Handle with Chrome Fasteners



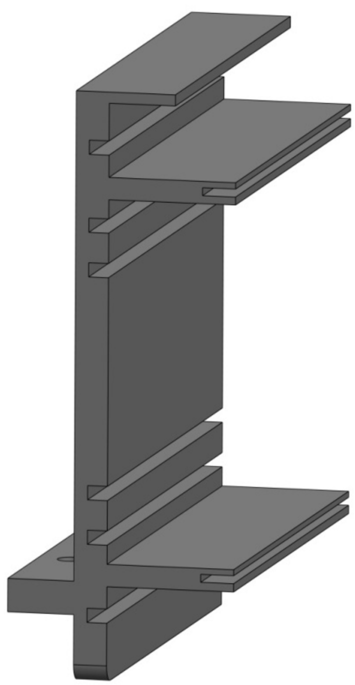


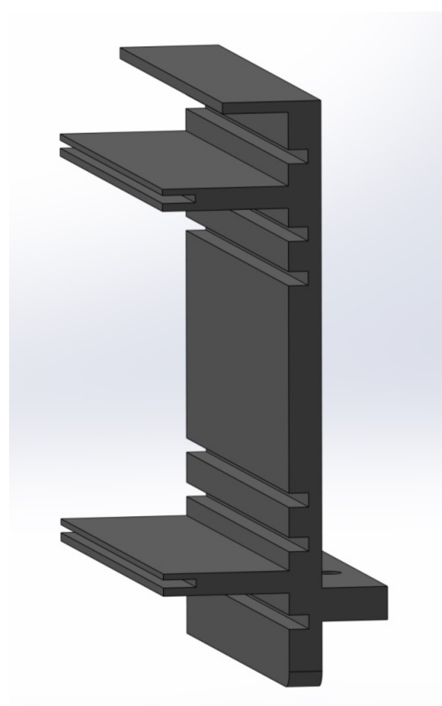
5.6 Optical Stack

Front

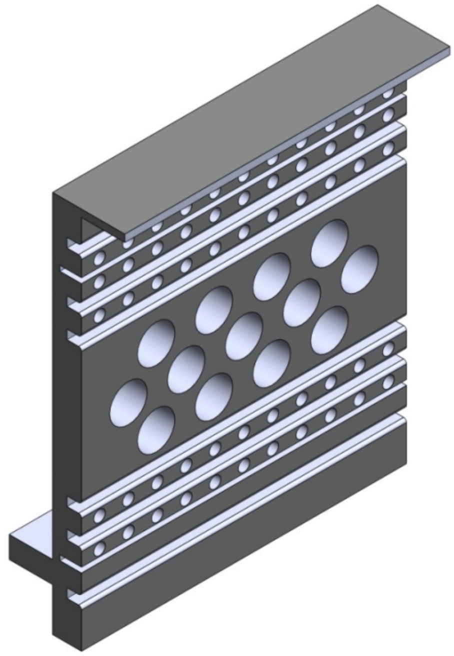


Left and Right-Side Walls (2 of each Required)

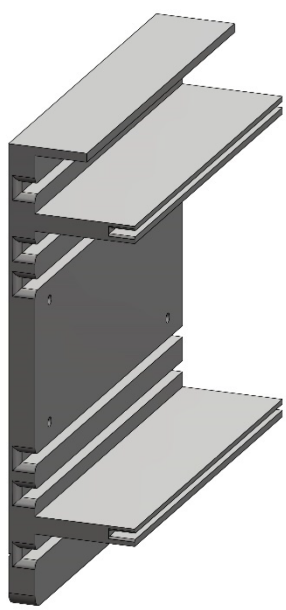


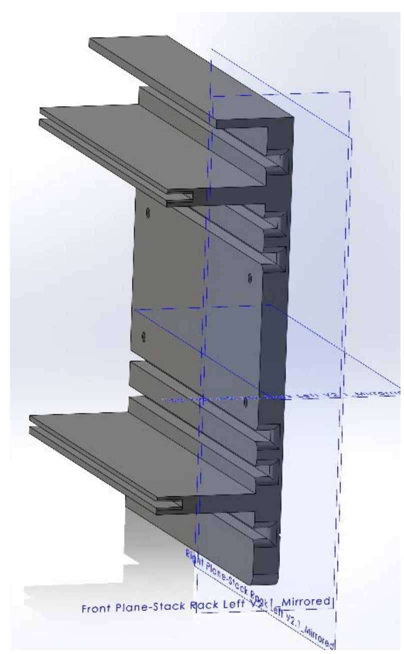


Back Wall

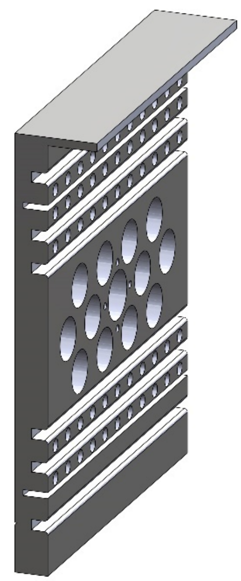


Left and Right-Side Walls (2 of each Required) Potential Revision

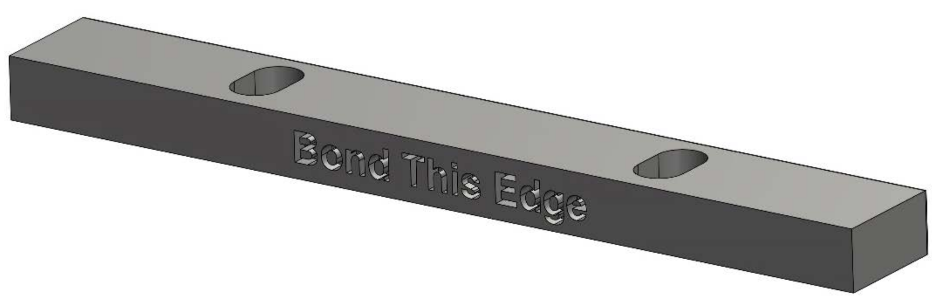




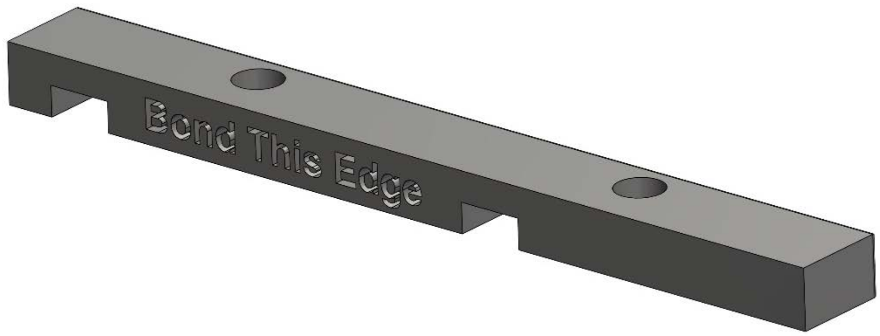
Back Wall Potential Revision



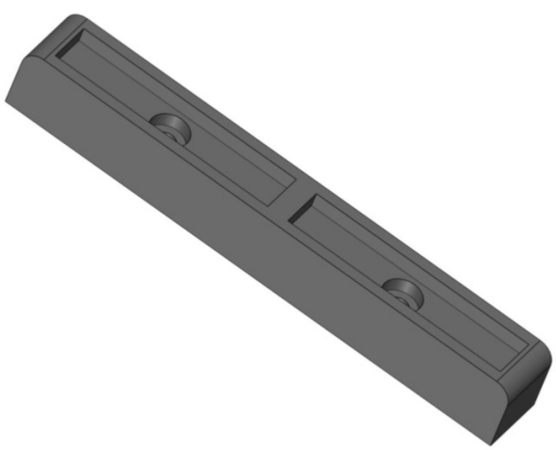
Side Wall Mounting Bracket Potential Revision (4 Required)

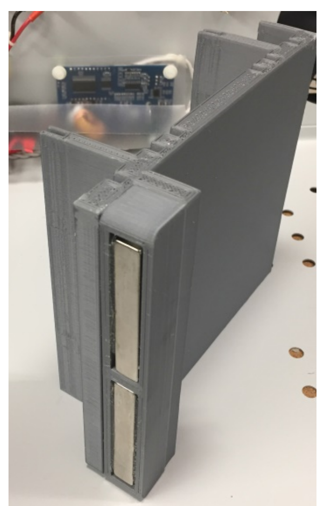


Back Wall Mounting Bracket Potential Revision

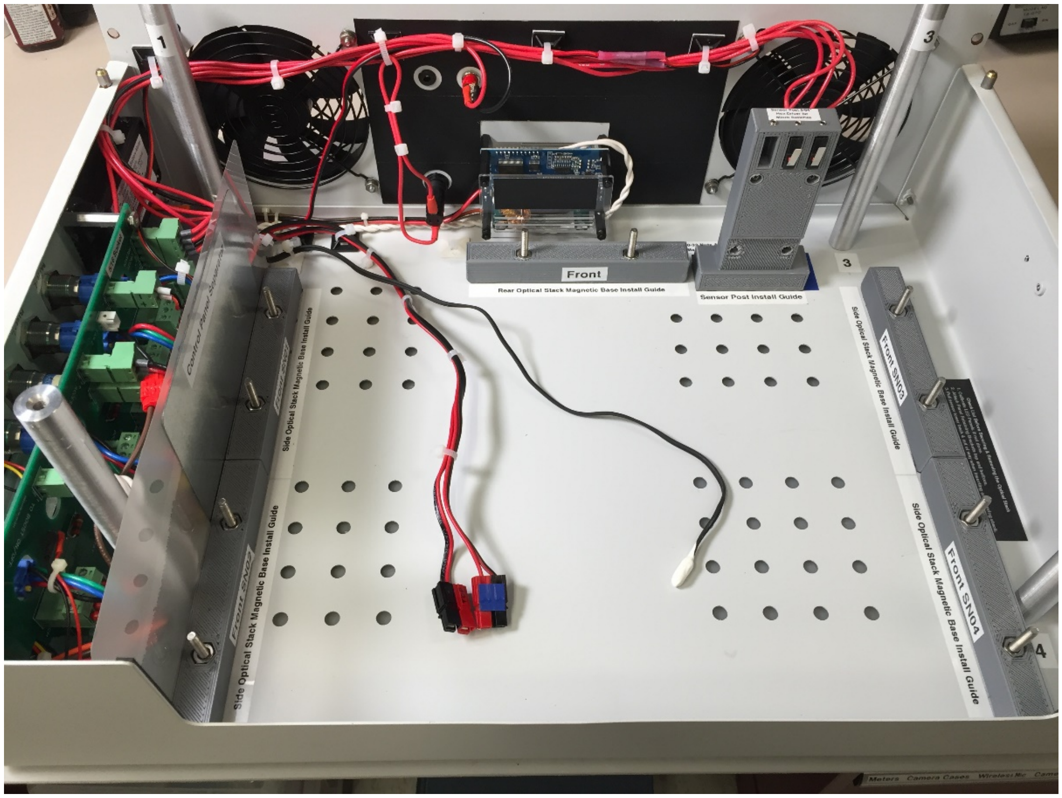


Magnetic Mounts with Pockets (5 Required)

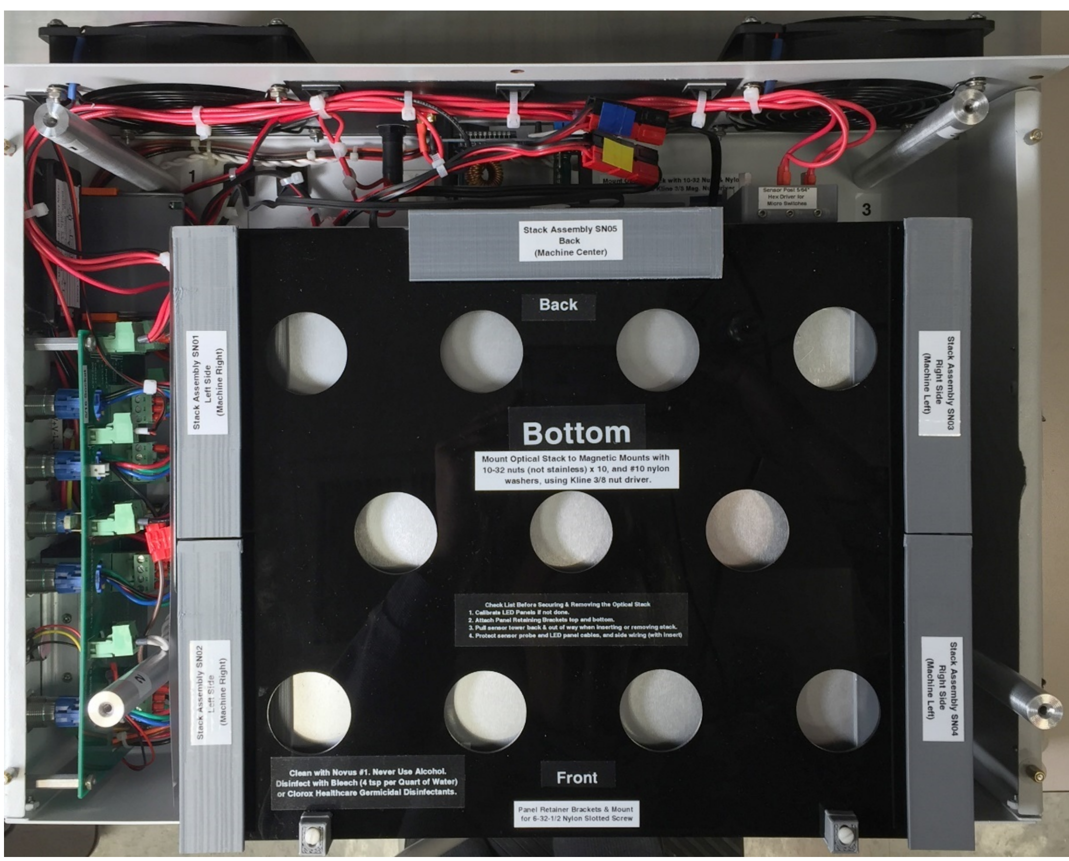




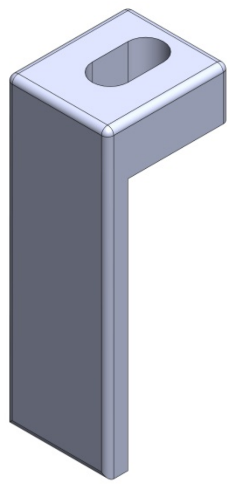
Rare Earth neodymium N48 bar-block magnets (60 x 10 x 4 mm) are secured with Loctite Liquid Professional Super Glue to the PLA FDM printed parts. A thin neoprene sheet is then super-glued over this.

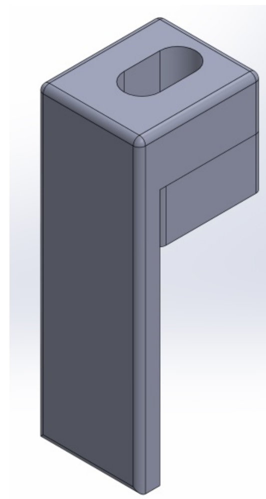


Five Magnetic Mounts (above) allow the Optical Stack to be secured (below).
(This is done with a long magnetic nut driver.)

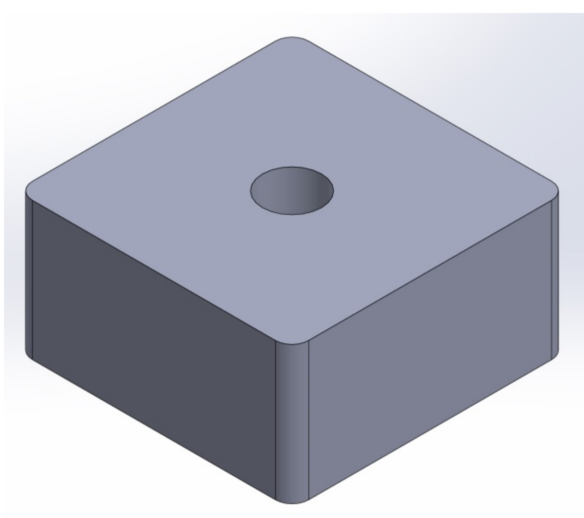


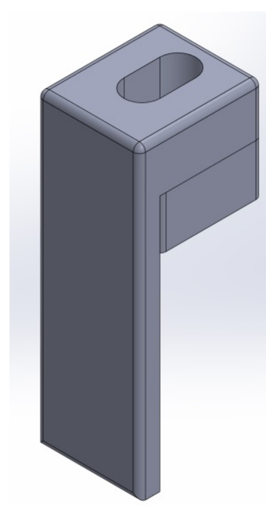
Panel Retaining Bracket & Assembly (4 Required)



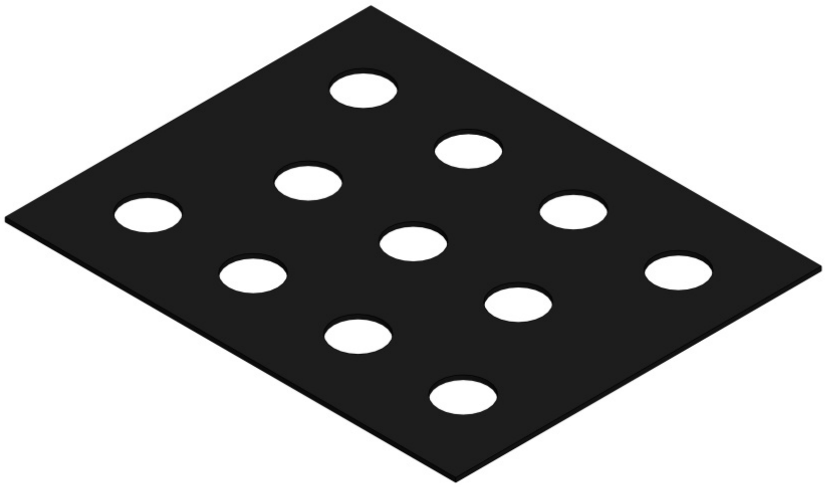


Panel Retaining Bracket Mount (4 Required)

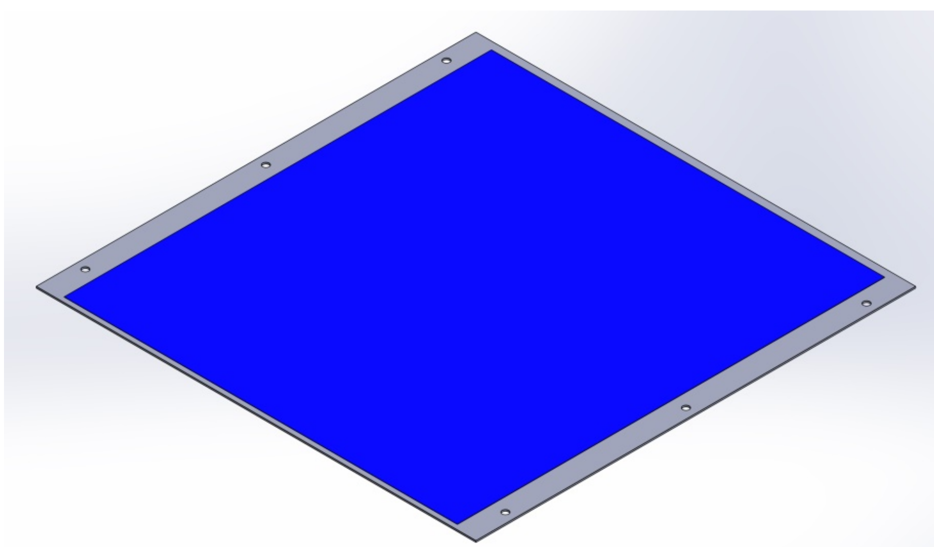




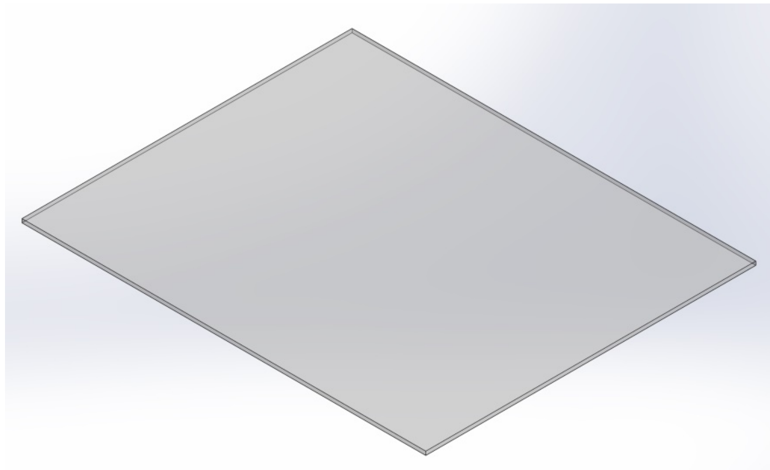
Horizontal Support (2 Required) Forms Rigid Assembly with Walls



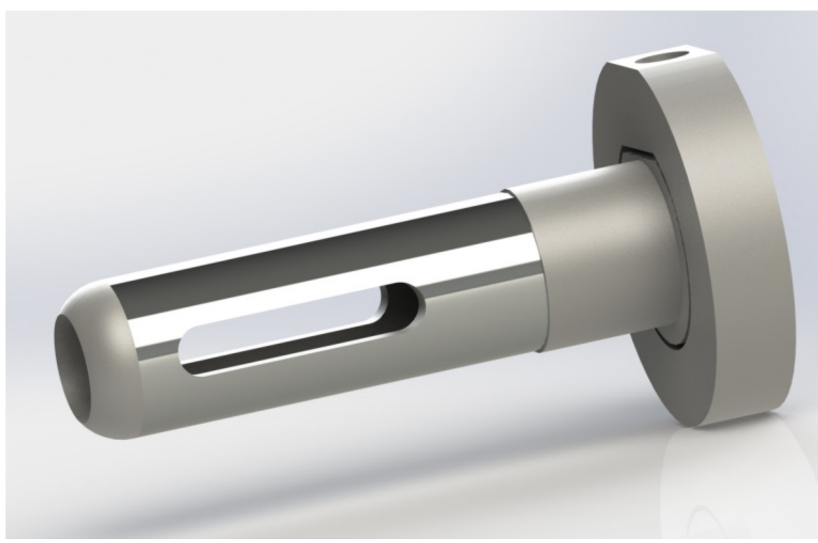
LED Panel (2 Required) Slide-In

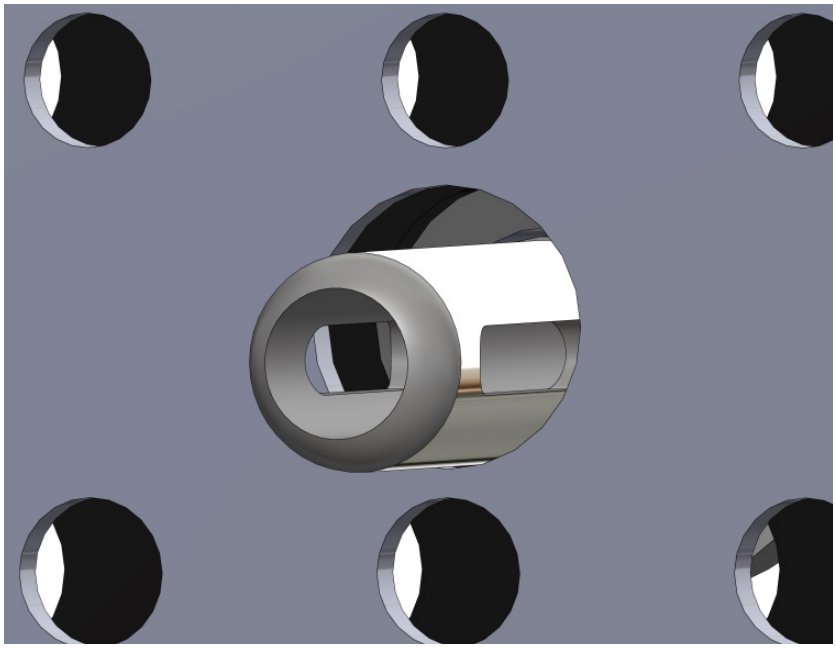


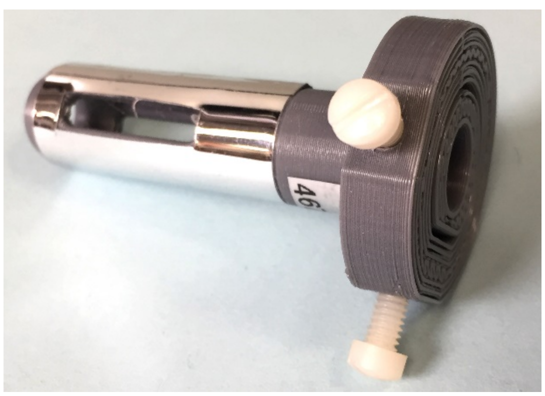
Diffuser (2 Required) Slide-In (Microbead Acrylic)



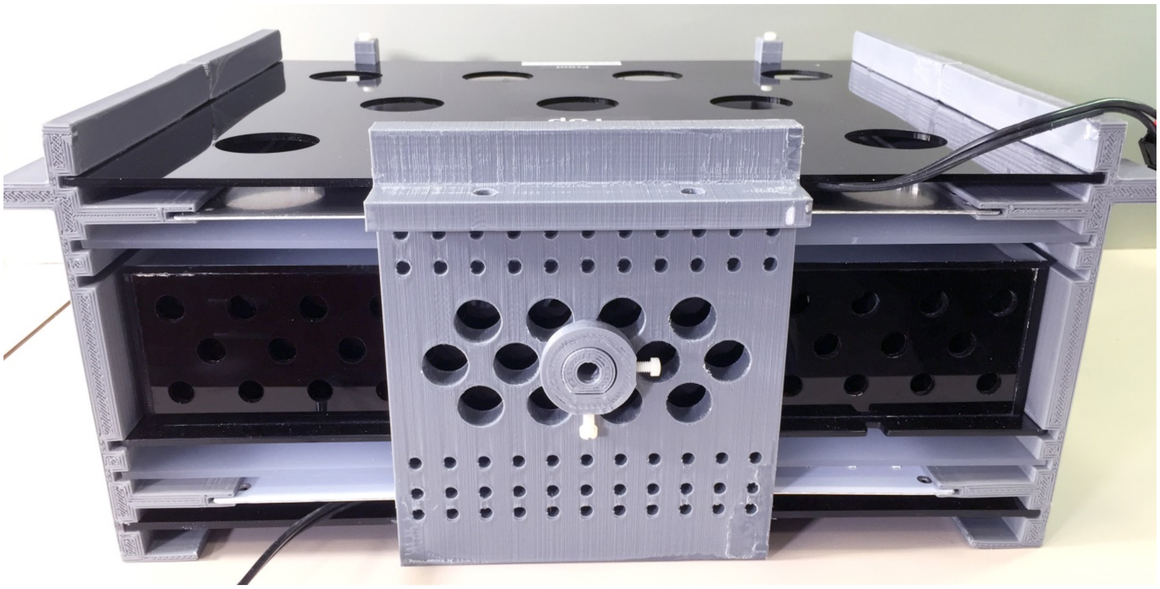
Thermocouple Holder & Collar with Reflective Mylar Sleeve







Use Loctite Super Glue to adhere the collar directly to the back of the back section of the optical stack. Be sure the holes are dilled and tapped first for the fillister nylon screws. Loctite Super Glue is also used to bond the reflective Mylar to the holder tube.

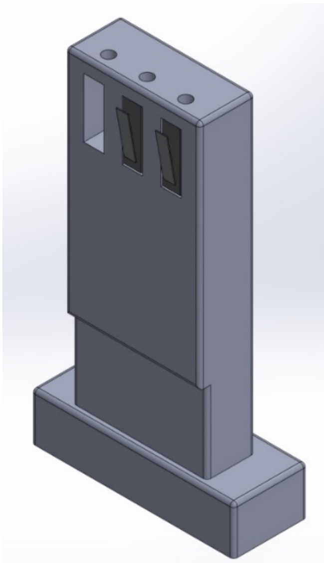


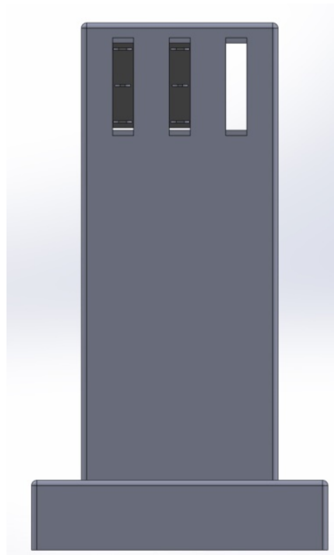
The probe collar is glued directly to the back of the optical stack. Note the orientation of the screws. When viewed in the inverted top section for servicing, the screw is fac-ing up towards the technician.

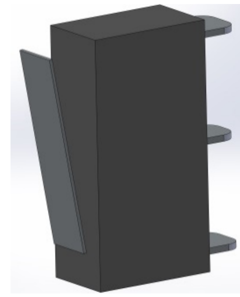
Retaining Bar

5.7 Sensor Post for Hand Compartment

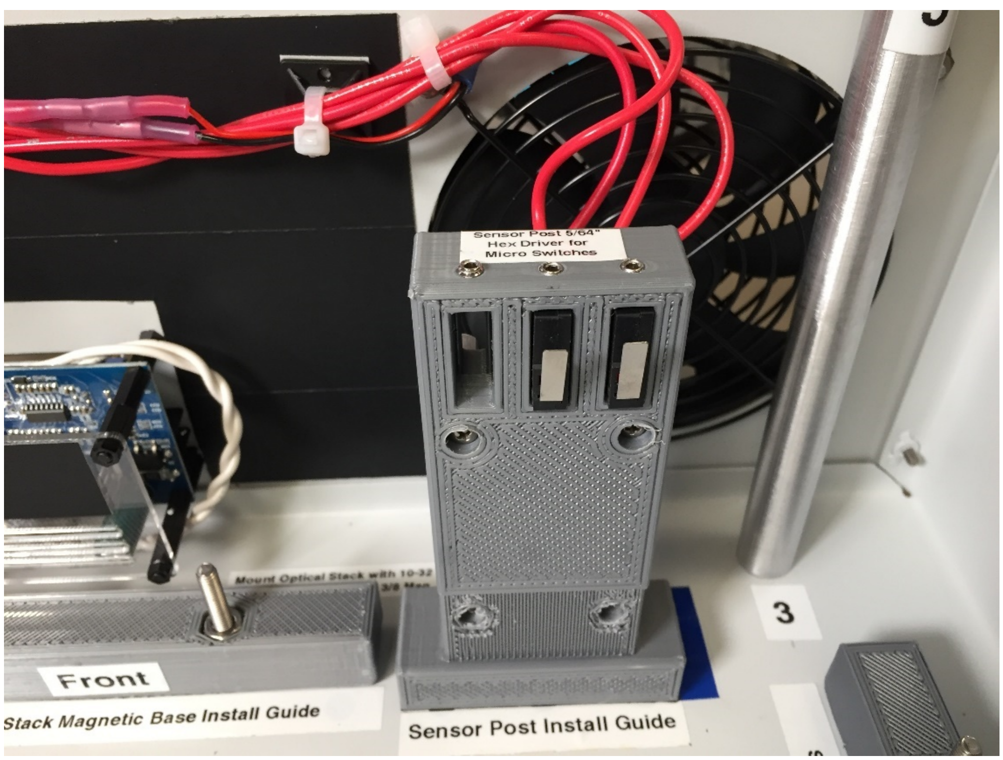
Front oblique and back views & microswitch (two switches Required - Safety Cutoff and Compartment Identifier).



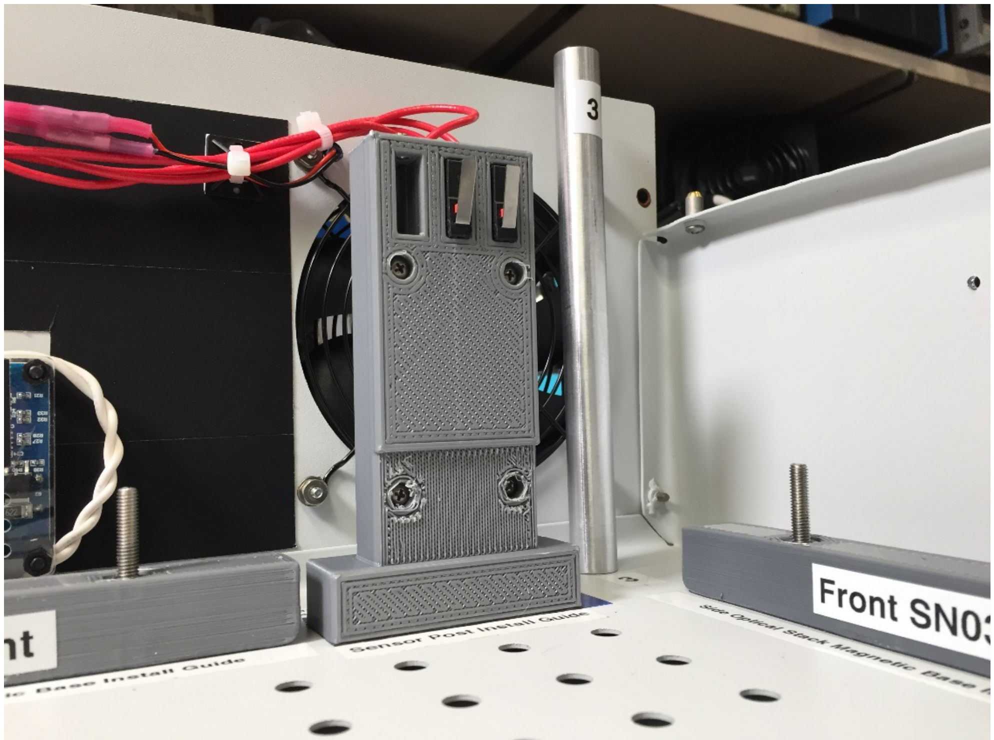




A rare earth neodymium N48 bar-block magnet (60 x 10 x 4 mm) is secured with Loctite Liquid Professional Super Glue to the PLA FDM printed part.

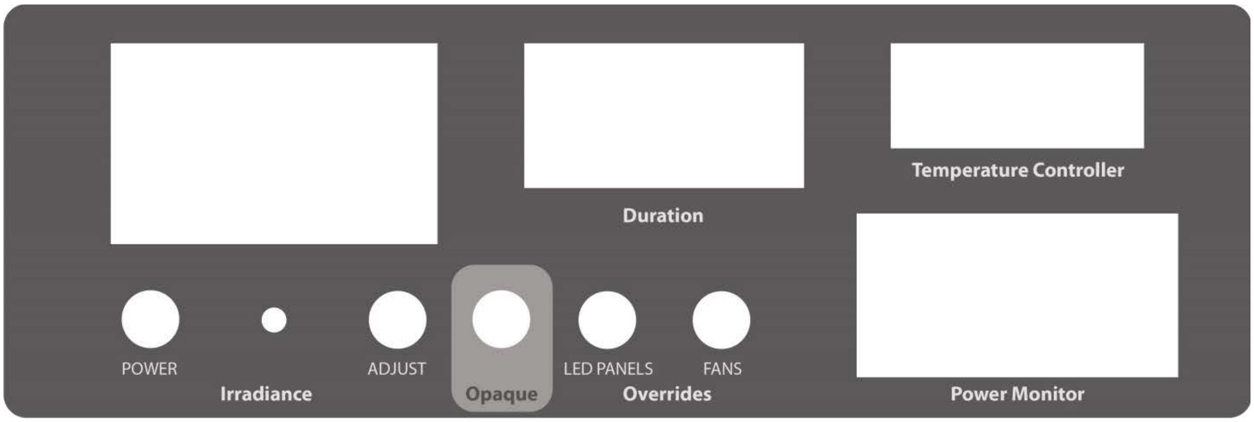


A properly placed sensor post is shown for illustration purposes only. It must be pulled back and out of the way for insertion of the optical stack.

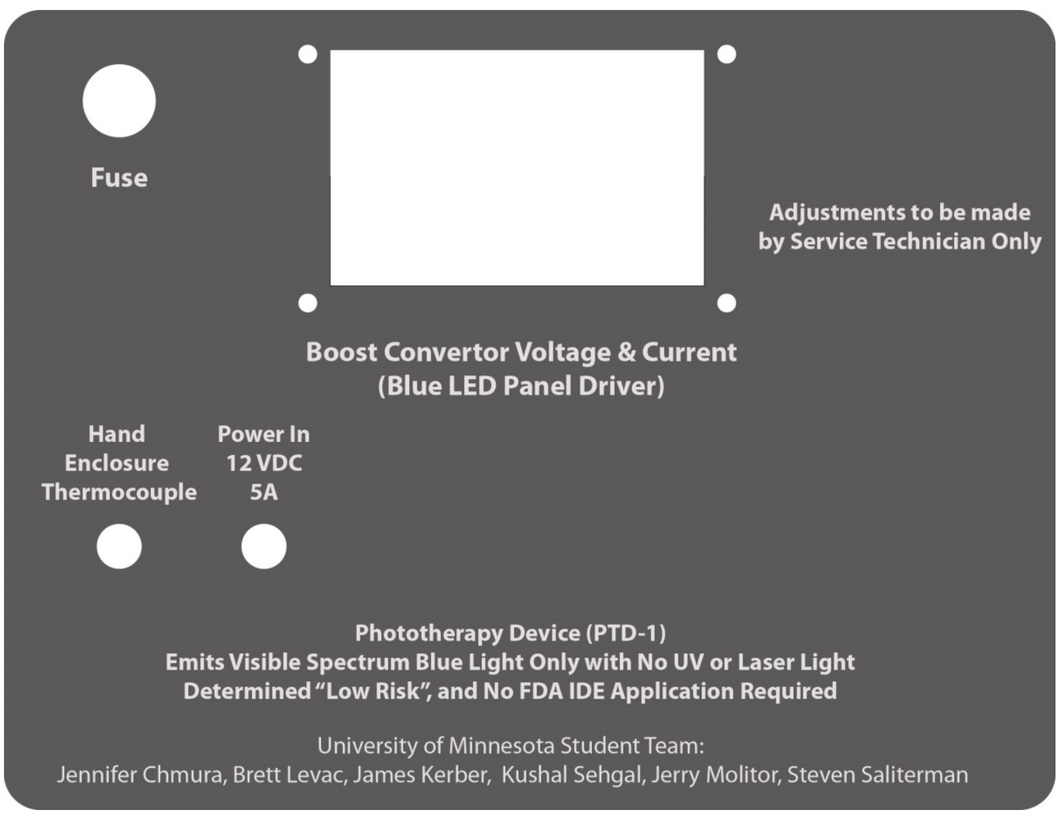

3
Sensor Post Install Guide

5.8 Polycarbonate (Lexan) Panels & Artwork

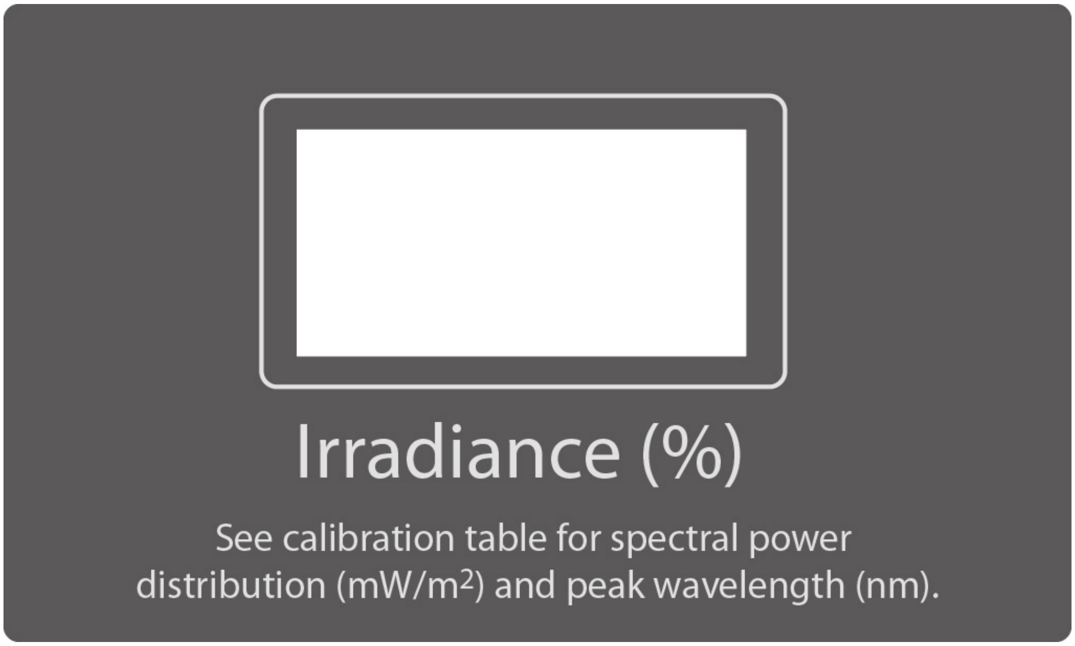
Right Side Control Panel



Back Panel

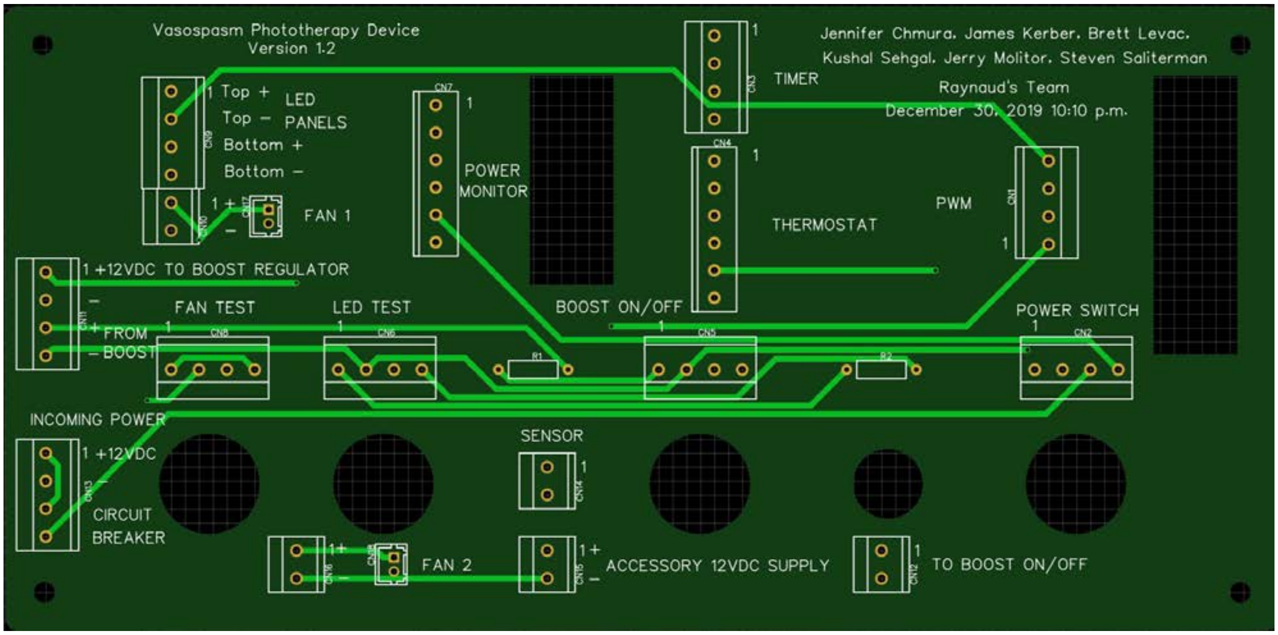


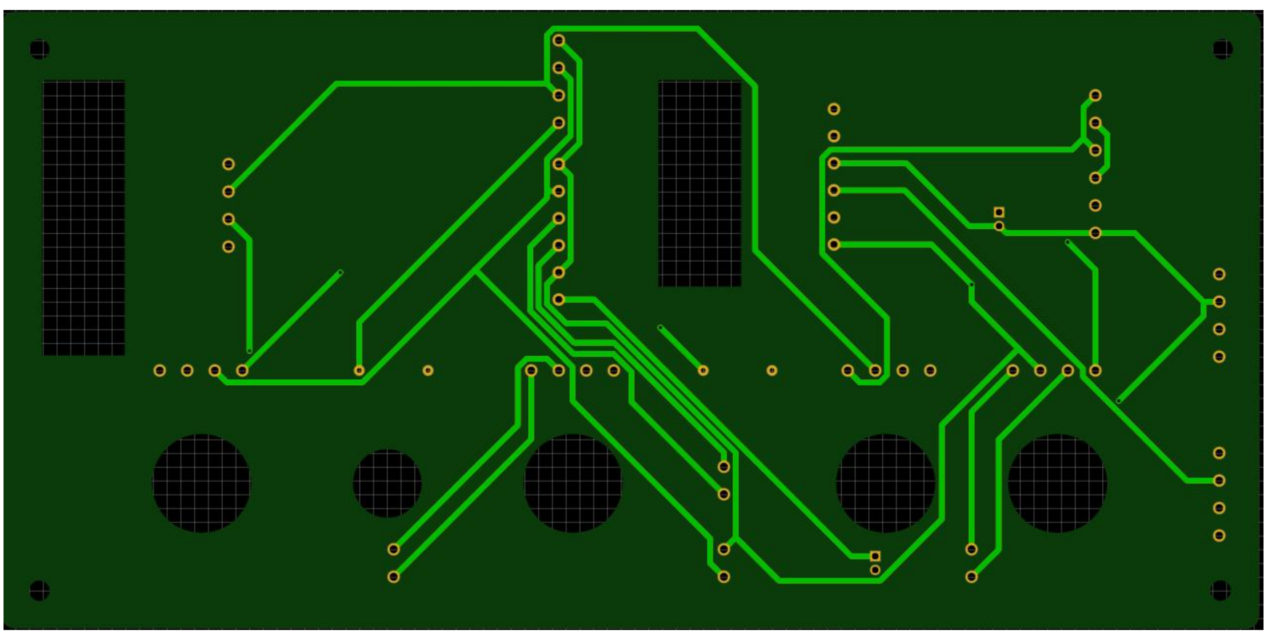
Relabeling of Pulse Width Modulator Meter



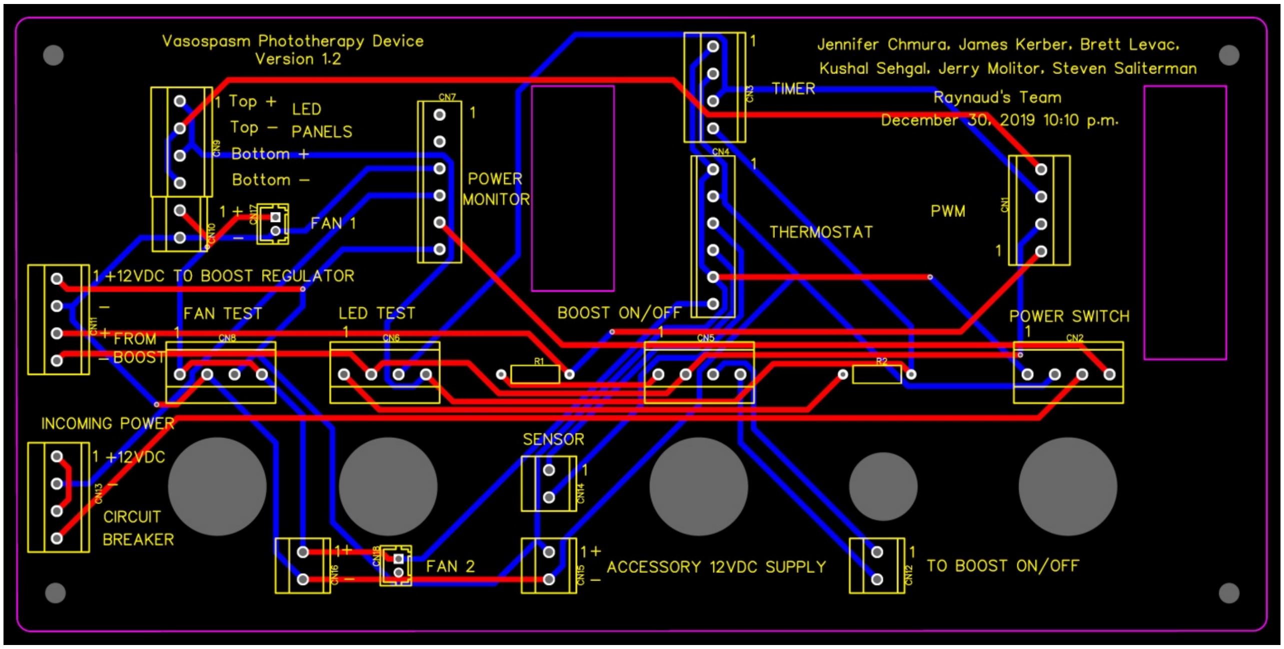
5.9 Printed Circuit Board

Photo-realistic Images – Top & Back

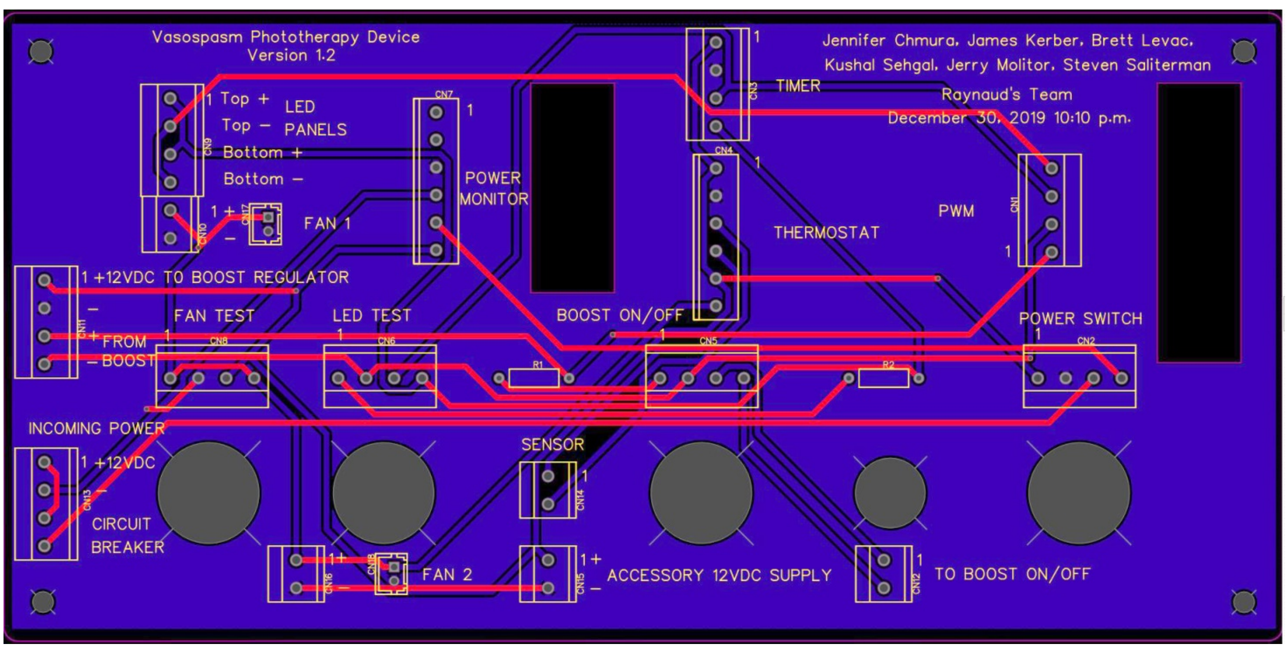




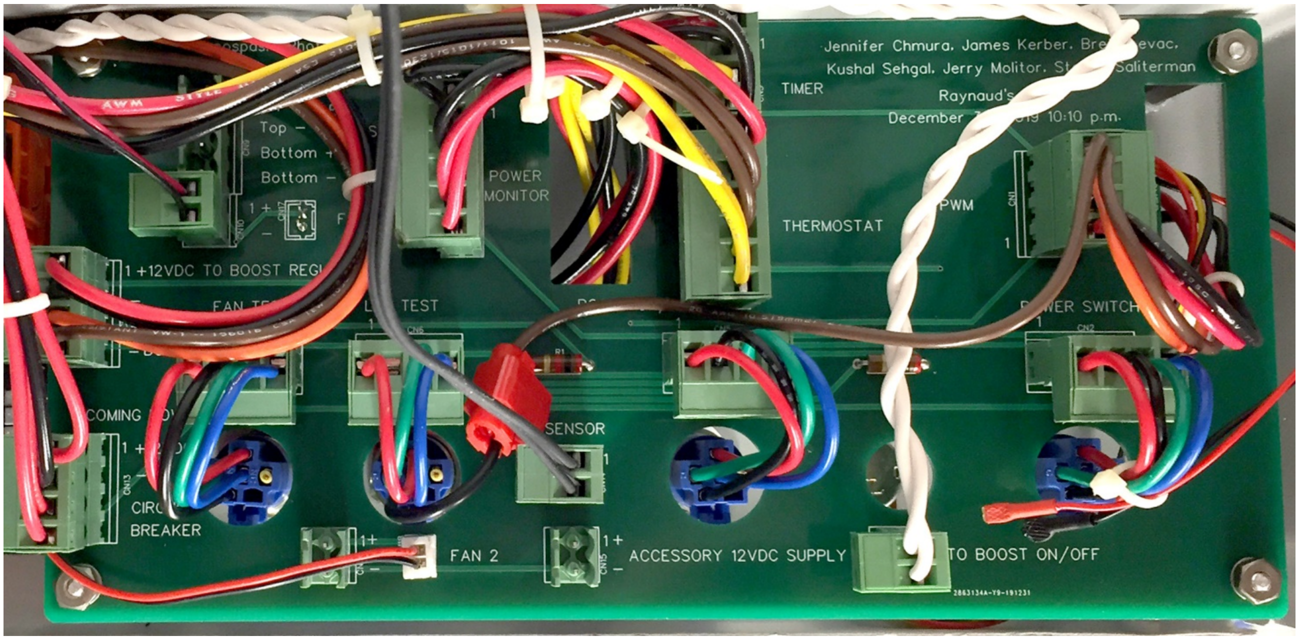
Autorouter Process

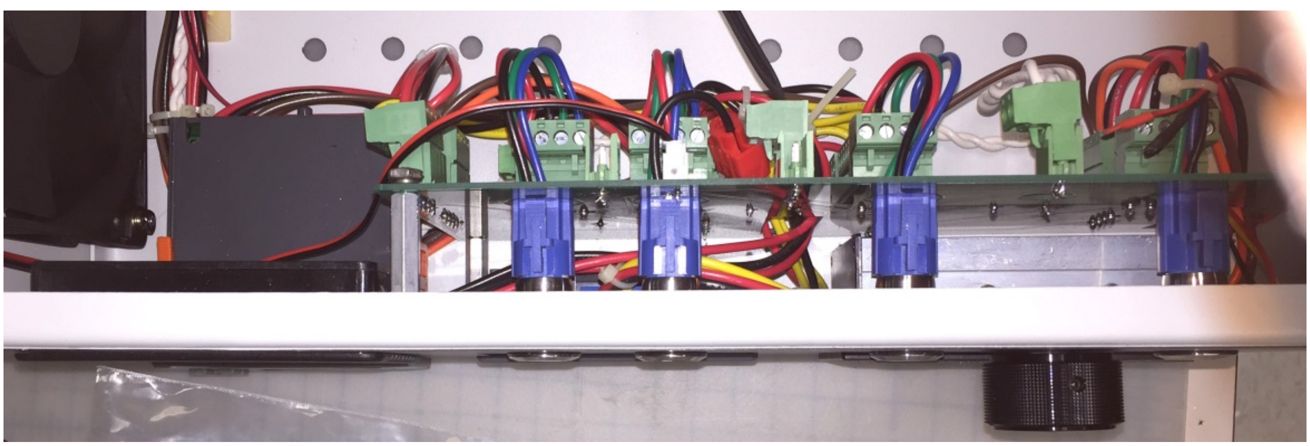


Multilayer Image



Populated PCB as Installed (Top and Edge Views)

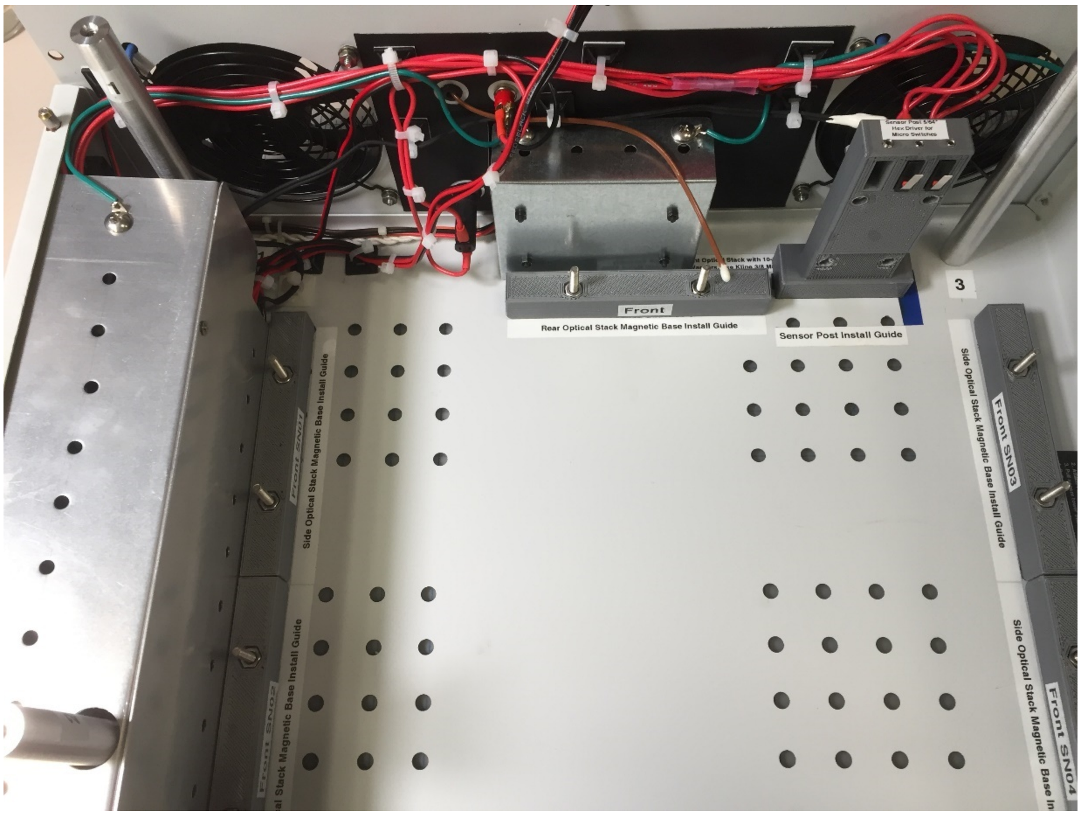




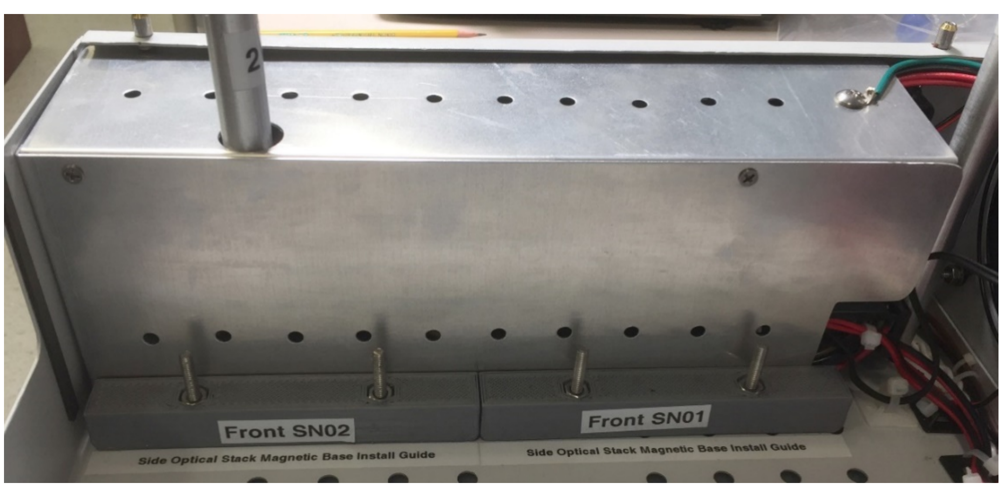
5.10 Electromagnetic Interference & Requirements

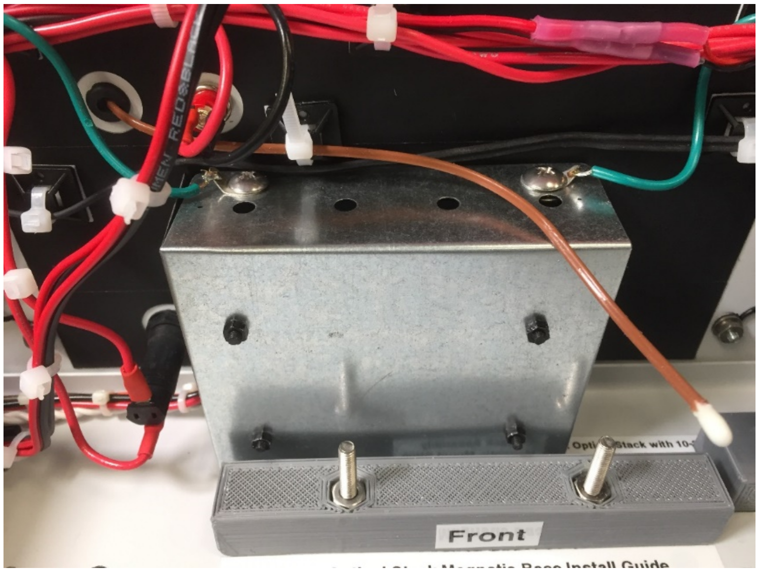
EMI

The laser doppler flow sensor is susceptible to electromagnetic interference (EMI) generating by the phototherapy device, especially the boost convertor open-coil inductor. To lessen the effects, both aluminum and ferromagnetic shielding were employed to address the sources of EMI.



Aluminum shielding on the left covers the control panel instruments, printed circuit board and most wiring (above and below).





On the left is a galvanized steel (high magnetic permeability) cover for the boost converter. On the right is an external grounding terminal. The phototherapy device must be attached to a quality earth ground for best operation of the laser doppler flow sensor. The internal EMI shielding and cabinet (upper and lower sections) are grounded (green wire). Mu-Metal is an alternative choice.

FDA, Medical Device & FCC Requirements

While the phototherapy device described here is a research instrument and not a medical device, it is beneficial to consider its potential as a medical device ("How to Determine if Your Product is a Medical Device" https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device), and the ramifications for design, safety and labeling.

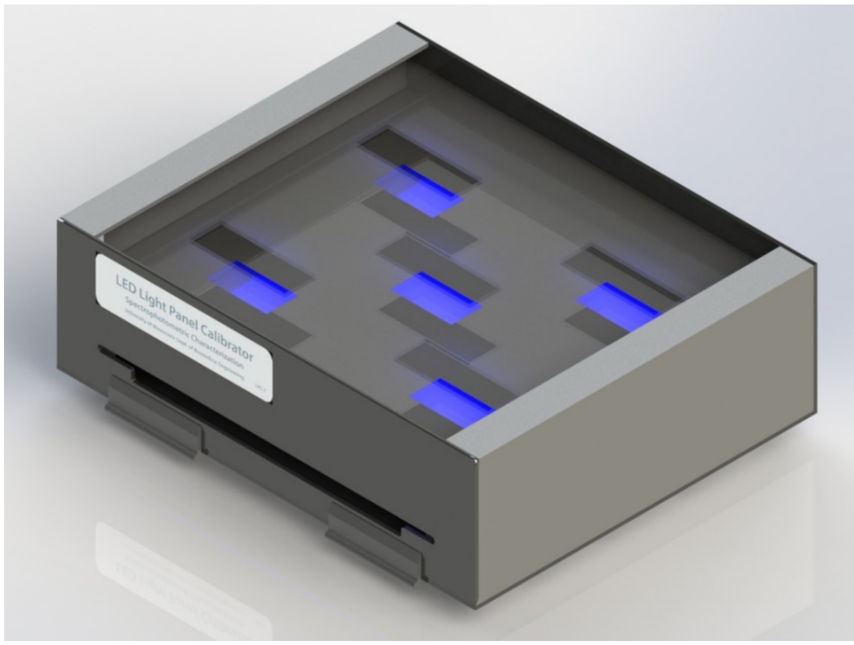
The FDA document "Does this product Emit Radiation" (https://www.fda.gov/medical-devices/classify-your-medical-device/does-product-emit-radiation) assists in determining if a particular product needs further consideration. Labeling of radiation emitting products applies to all products that emit sonic, infrasonic, or ultrasonic radiation as the result of operation of an electronic circuit (https://www.fda.gov/medical-devices/device-labeling/labeling-requirements-radiation-emitting-devices-and-products#light).

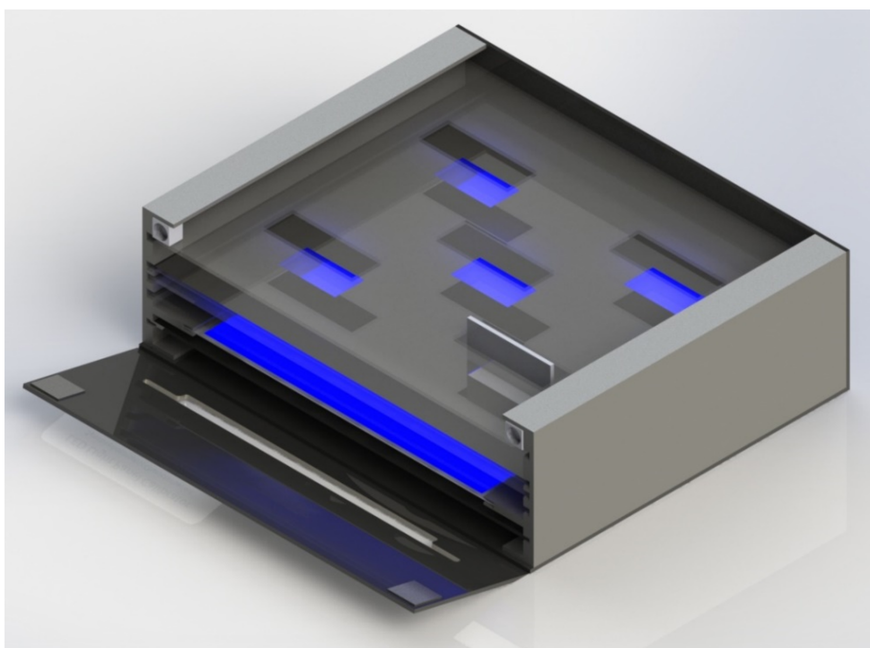
The FCC Equipment Authorization Approval Guide is found here: https://www.fcc.gov/engineering-technology/laboratory-division/general/equipment-authorization, and applies to RF

5.11 Calibrator for the LED Panels

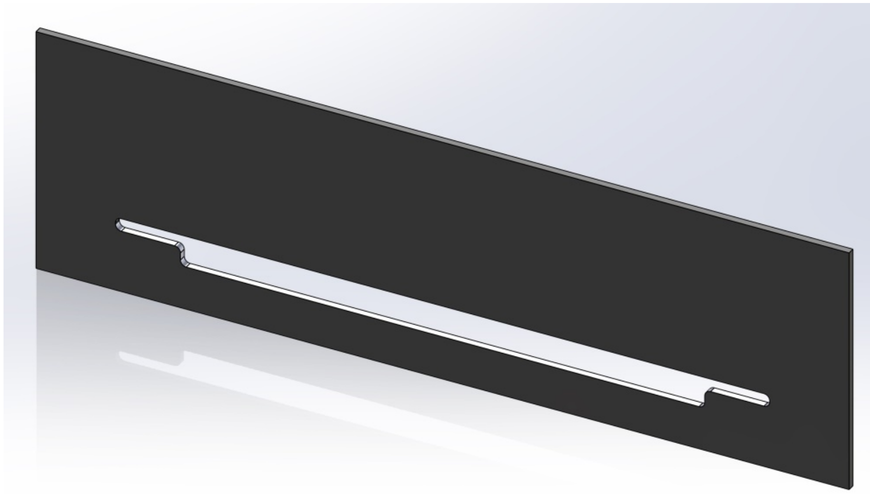
Right Front Oblique

The front door moves up & down on hinges. One of four port plugs is seen on the lower right.



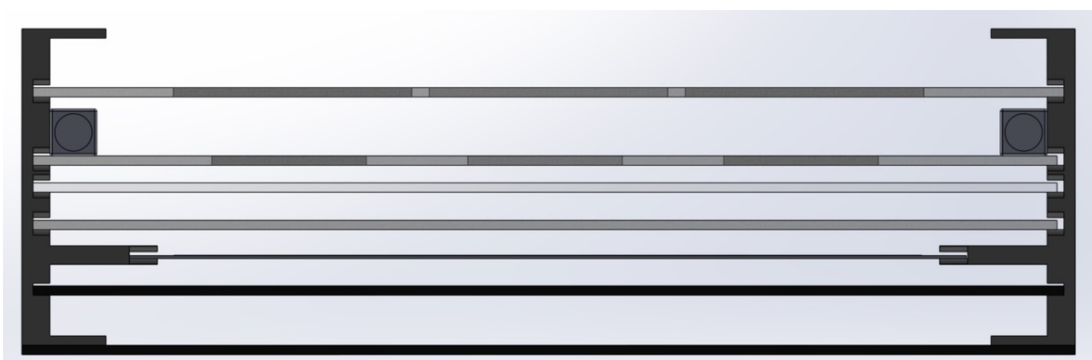


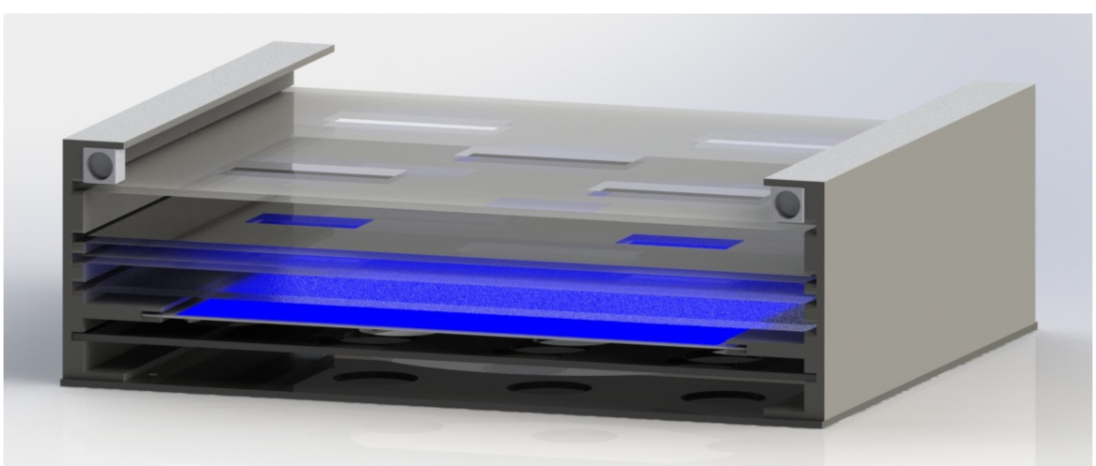
Back



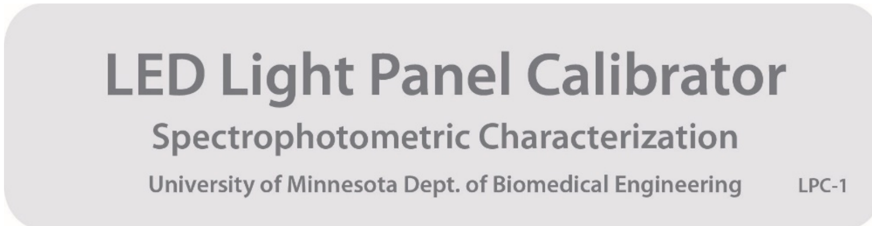
Stack Arrangement

From top to bottom: clear acrylic spectrophotometer positioner, black acrylic spectrophotometer sensor rest, micro-bead diffuser (same as in the *Optical Stack*), clear acrylic (replicates top of hand compartment), blue LED panel, horizontal support (same as in the *Optical Stack*) and bottom.

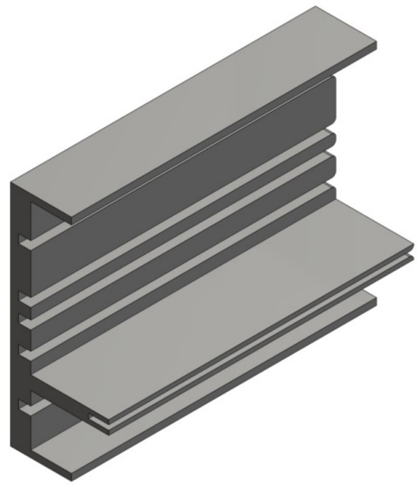




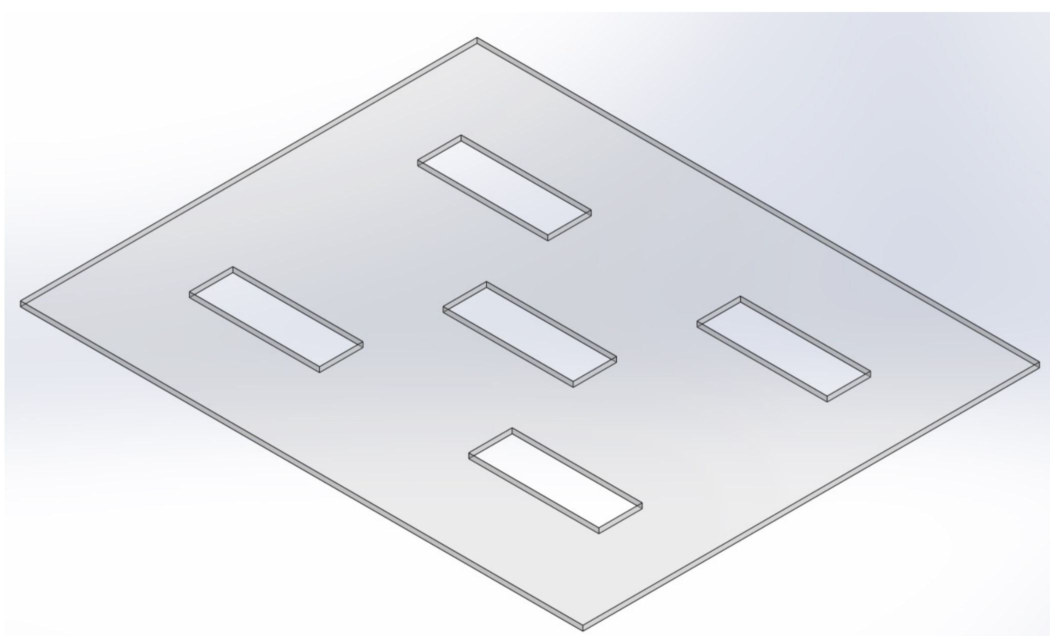
Decal



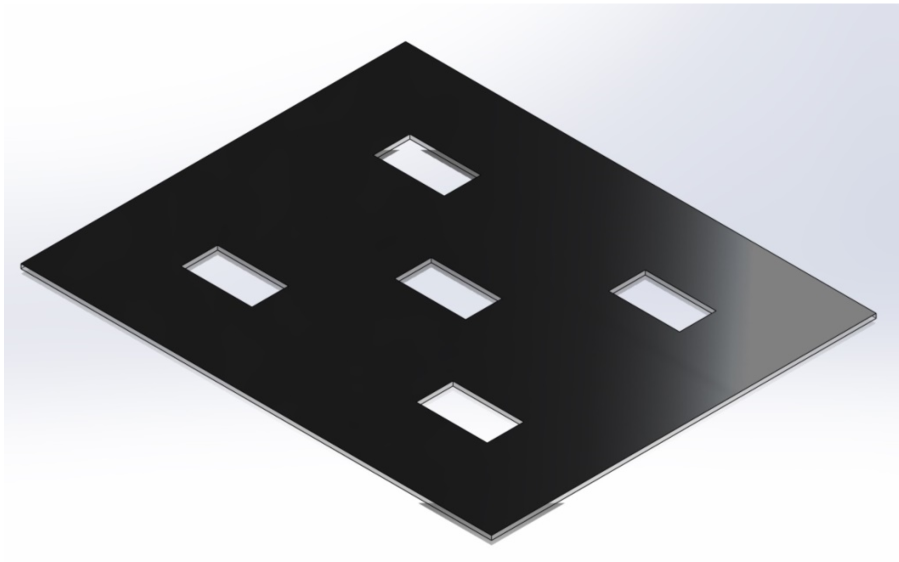
Left and Right Wall (4 Required)



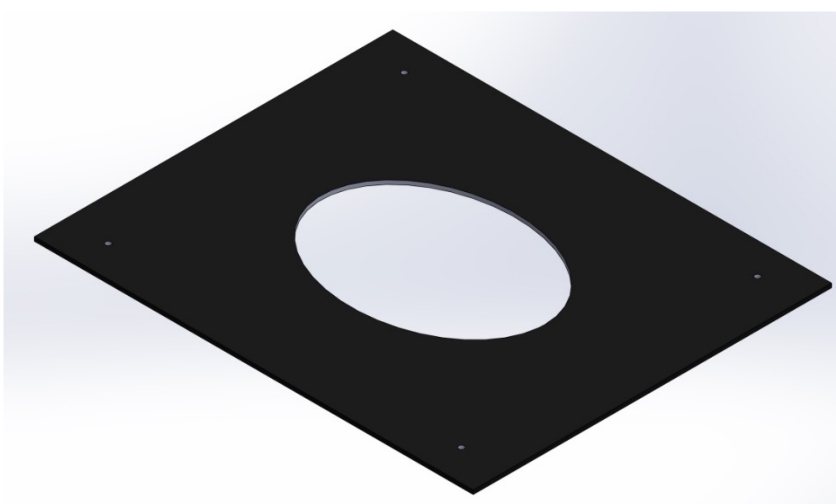
Spectrophotometer Positioner



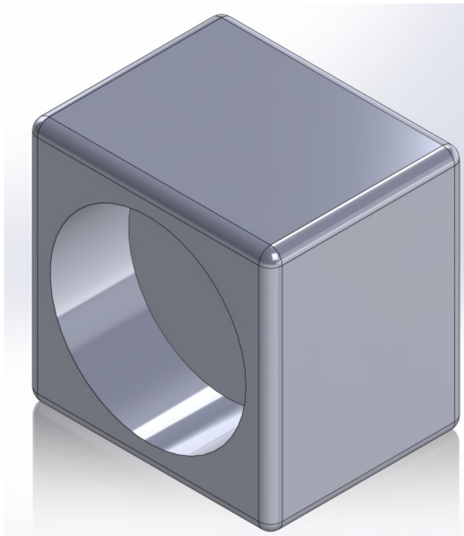
Spectrophotometer Sensor-End Frame Rest



Bottom

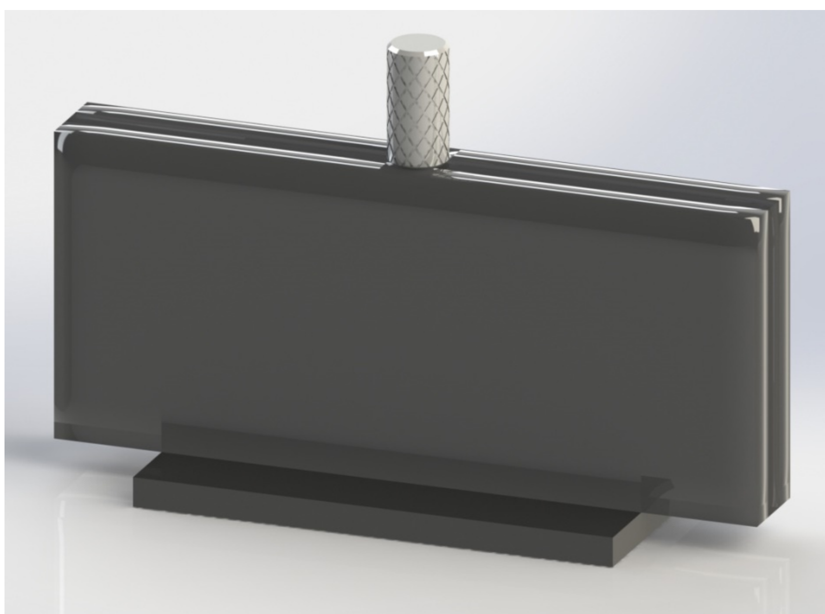


Front Door Magnetic Latch with Pocket

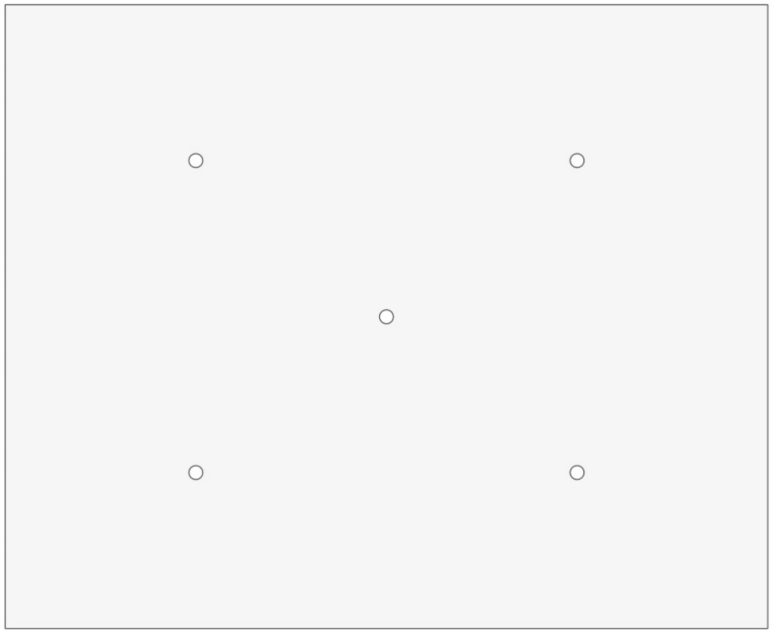


Disc Magnets 12 mm x 6 mm
(1/2" dia. x 1/4" thick)

Rectangular Plug & Handle Assembly (4 Required)



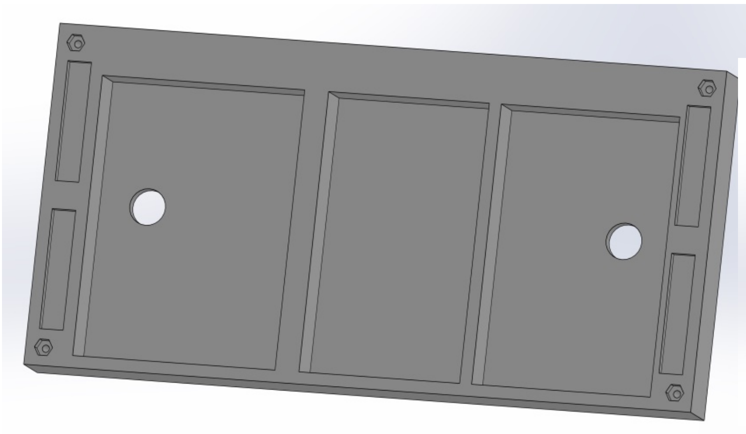
Calibrator Sampling Points

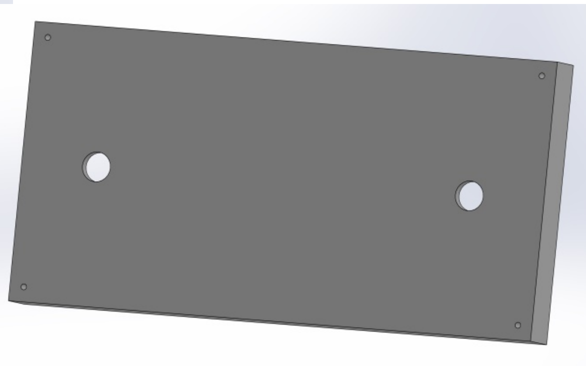


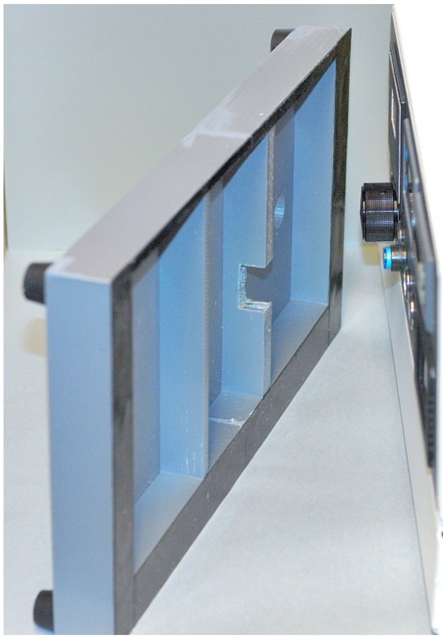

Sampling Port A
Sampling Port B
Sampling Port C
Sampling Port D
Sampling Port E
Clean with Novus #1. Never Use Alcohol.
Disinfect with Bleach (4 tsp per Quart of Water)
or Clorox Healthcare Germicidal Disinfectants.
To open, pull down on both ends.
Never lift or tilt with door open.
Inside panels will slide out.

5.12 Transport Covers

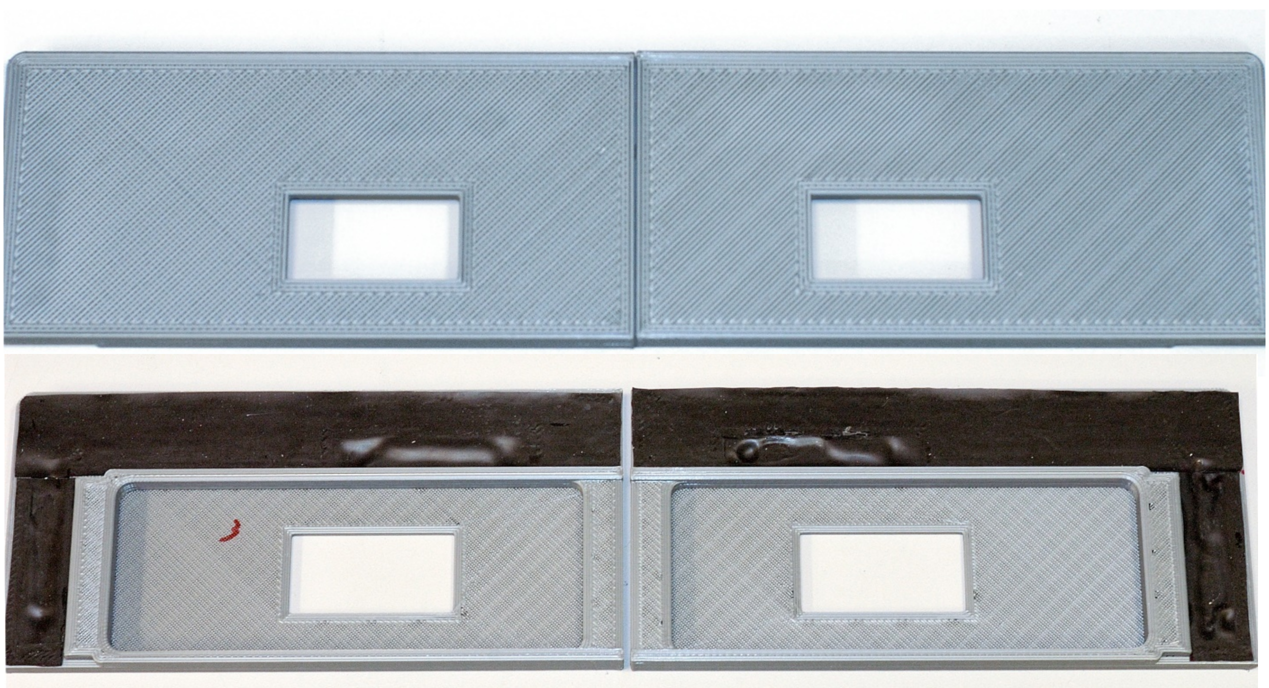
Right Side Control Panel







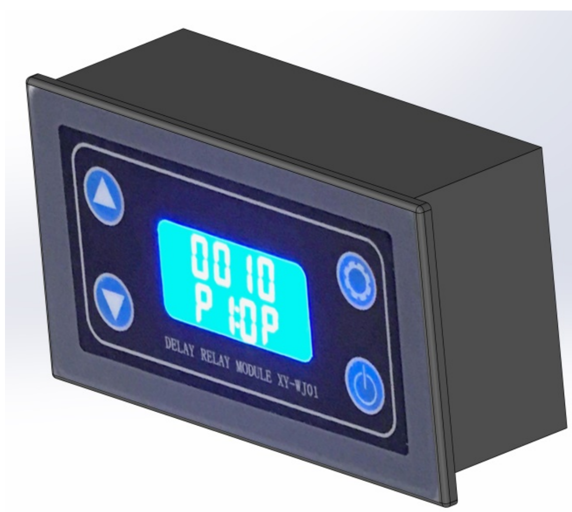
Magnetic Transport Front Bezel (Replaces Hooded Bezel)



5.13 Instrument Custom CAD Models

Irradiance Meter (A Relabeled PWM Meter)

Duration Timer



Temperature Controller

DC Power Monitor

5.14 Instrument Component Specifications

PWM and Drok Boost Converter

Vikye Motor Speed Control Digital Regulator (PWM Device)

The LED panels are powered and dimmed by use of a pulse width modulator (PWM) and a step-up converter. A motor speed controller generates a PWM waveform which is then fed to a step-up converter suitable for driving the LED panels directly. The PWM potentiometer changes the ratio of ON to OFF time of a given cycle, and has the effect of brightening or diming the LED panels. The step-up (or boost) converter (next section) allows for setting a specific voltage to drive the LED panels, with display of the set voltage and delivered current.

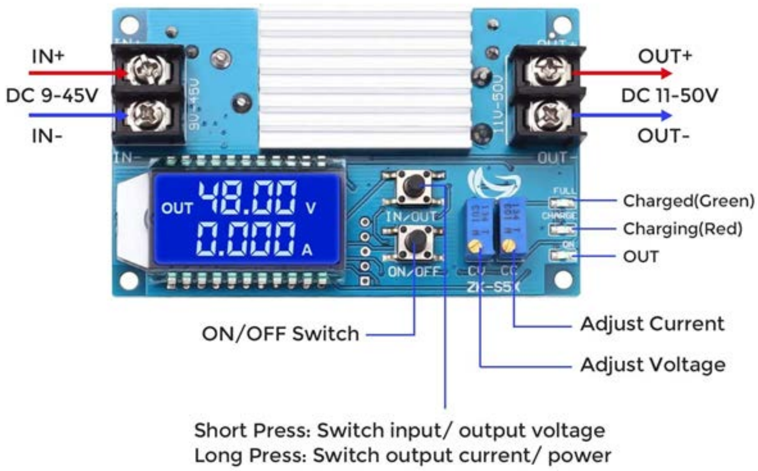
By presetting the voltage, the LED panels can be calibrated for irradiance vs PWM ratio (cycle of ON time to total cycle width). The PWM ratio is display as 0 to 100%. Adjusting the PWM has the effect of bringing the LED panels from off to their brightest setting (predetermined by the voltage setting of the step-up converter). There is a linear relationship between the PWM and irradiance (as confirmed when calibrating).

Irradiance is adjusted by first pushing the “Adjust” button (control panel on the right side), which turns on the PWM device. The last setting is displayed. Selecting a particular irradiance requires using the calibration table to select the corresponding percent setting.

Drok Boost Converter (9~45 VDC to 11-50 VDC)

Controls are accessible only when servicing. The output voltage (V) and current (A) should be confirmed periodically as within specifications. Turn the phototherapy device on, adjust the irradiance and manually turn the blue light LED panels on with the LED override switch (blue-ringed LED) on the main control panel. Turn the override switch off when done. The LED panel voltage and current are read from the back of the unit. (Actual readings are shown on the top display only.)

The voltage has been preset to 42 volts, and the current shown below, 0.6 amps is the current being drawn by two LED panels at 100%.



Application 1 - As Step-up Power Module w/Overcurrent Protection

(1) Adjust CV constant voltage potentiometer to set target output voltage.

(2)Rotate CC potentiometer counterclockwise 20 full turns more at first to set target overcurrent protection value. Then test and using. (Note: Screen will display "Err" if load current is higher than overcurrent protection value. Then you need rotate CC potentiometer clockwise to increase output current.)

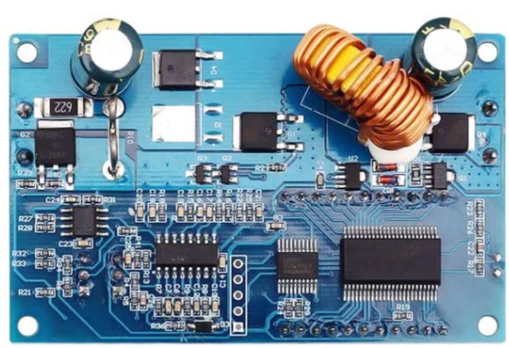
Please Follow Specific Instruction in User Manual at "Technical Specification" Section.

Input Voltage/ Output Current

Output Voltage/ Output Current

Input Voltage/ Output Power

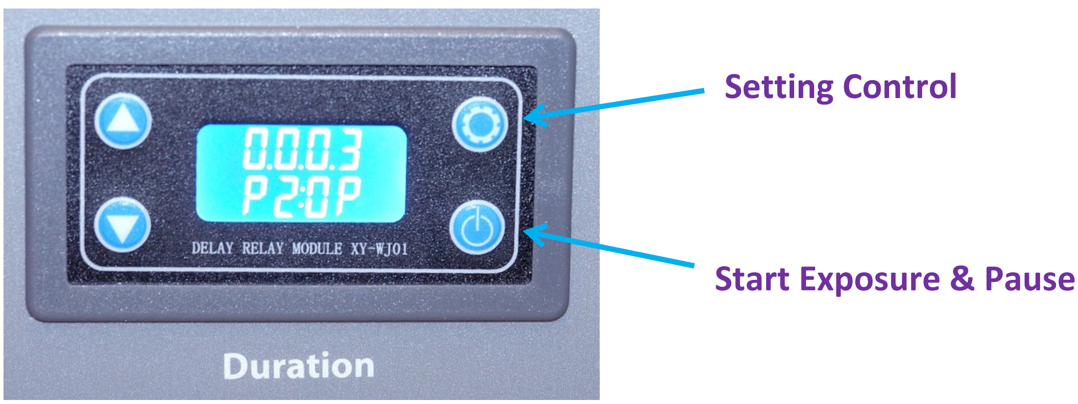
Output Voltage/ Output Power



Duration Timer (DROK delay relay module XY-WJ01)

The Duration Timer is set for the planned exposure time, and when activated by the Duration Timer, will turn the LED panels on for the predetermined amount of time. The time of blue light exposure is set and controlled by the duration time. The time is preconfigured to run in minutes. The amount of time the LED panels are on is determined by the study protocol and preset. (See the **Programming** directions below).

Press the "Trigger" button to start the blue LED panels. The "Out" display indicates the panels are being powered, and the "time status/time" counts down the remaining time. When the timer ends and the panels turn off the "Out" display will disappear. Pressing "Pause" while the LEDs are on will turn them off and "Out" will flash. Press "Pause" again and the timing will resume until done. To reset the timer it is necessary to turn off power to the phototherapy device and restart. If the indicator display turns off anytime during a timed-exposure, pressing any button momentarily turns the display back on.



Thermoregulator (Inkbird ITC-1000F)

The fans are set to come on automatically. If they are not running (they blow outward in back), then they should be tested by pressing the “FAN” override button (it latches off & on).

The thermostat is by default set well below ambient room temperature so that the fans come on whenever the blue LED panels are illuminated. This will assure that the air temperature inside the hand compartment will stay within a few degrees of ambient room temperature. (Raising the thermostat above room temperature should only be done when the study protocol requires a hand compartment temperature greater than ambient room temperature, and would require the addition of an active heating element to the system)

Temperature Controller for Fans

The Temperature Controller (TC) should come on when the phototherapy device is turned on. If necessary, press the TC power key 1s to turn on and 3s to turn off. The screen normally displays the current temperature inside the hand compartment. The operator should record the temperature at the start and end of a session.

Changing Thermostat Temperature

While the operator should not need to change the settings of the temperature controller, the following information is provided in the event the study parameters call for a hand compartment temperature greater than room ambient temperature.

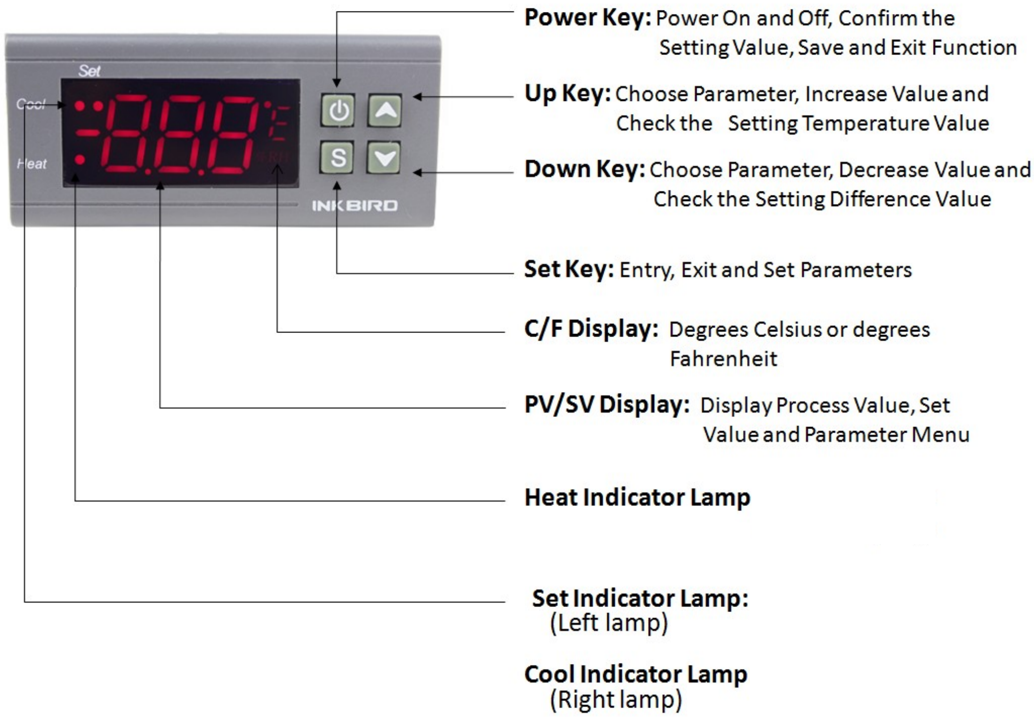
The display initially shows the temperature inside the hand compartment. Pressing the up-arrow key once displays the temperature setting.

To enter the set mode, hold the “S” key for 3s. The “set” indicator lamp will go on, and the screen displays the first menu code, “TS” (see chart below).

Pressing the up and down arrows will now display the various menu items and codes. Pressing “S” again will allow entry of the parameters for that menu item. When the parameter value starts to flash, use the up and down arrow keys to change its value.

After setting the parameters for that menu item, press “S” to exit and the parameter value will stop flashing. Pressing the TC power key momentarily will save the parameter and return to normal operation.]

Code	Function	Set range	Default	Display
TS	Temperature Set Value	-50~99.9 °C	10.0 °C	tS
DS	Difference Set Value	0.3~15 °C	1.0 °C	dS
PT	Compressor Delay	0~10 minutes	0	Pt
CA	Temperature Calibration Value	-15 °C~15 °C	0 °C	CA
CF	Fahrenheit or Celsius Setting		C	CF

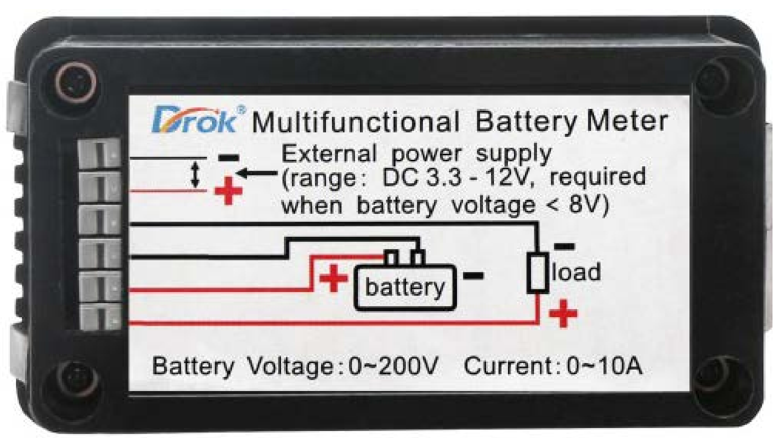


Multimeter (Drok 9-in-1 DC Multimeter)

The Power Monitor provides an instantaneous reading of the DC adaptor or battery power supply voltage, current draw and power consumption of the entire phototherapy unit. This power is runs through a fuse in back of the unit. When used with a battery instead of the DC adaptor power source, it is measure mAH (milliamp hour) capacity of the battery and run time.

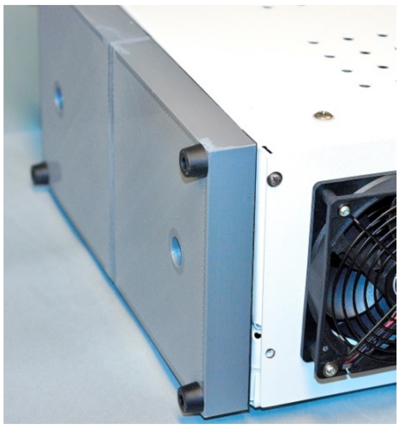
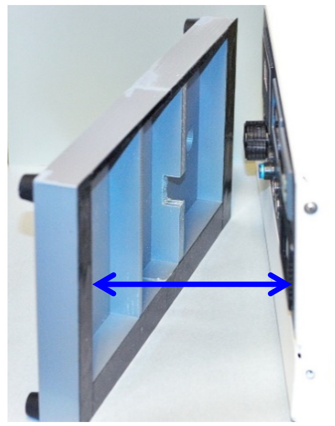
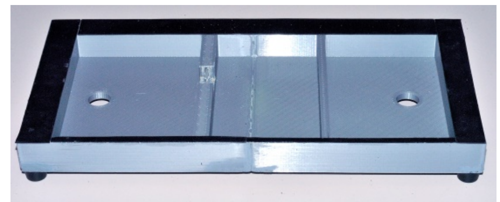
While there are no settings, and the operator should log the voltage and current with each study after activating the LED lamps as verification that unit is operating normally.

This is the back side of the meter (not visible to the operator). It is included here as a reference when using a battery source. There are wires for optionally connecting a 3.3 VDC lithium-ion battery inside the unit by a technician.



Part 6 – Transporting the Phototherapy Device

6.1 Carry Base/Control Panel Cover


The **Phototherapy Device** weighs 31 pounds (14 kg), and the magnetic control panel cover must be attached when the unit is lifted by its handle. The cover also serves as a base with rubber bumper feet to allow the machine to rest on end with the handle up.

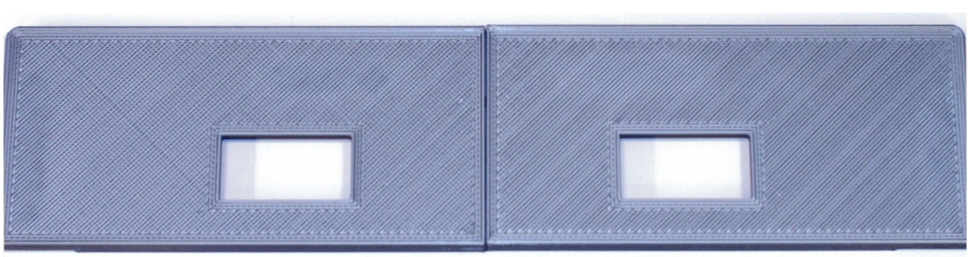
6.2 Handle & Security Cable Mount

Care should be taken when shifting from a horizontal to upright position so as not to displace the control panel cover. A lockable cable may be placed through the security mount and around a table leg to discourage theft.

6.3 Transport Case

The **Pelican Products 1690 Case** is for transporting the **Phototherapy Device**. Ancillary equipment and the hand compartments are packaged separately. The case is heavily padded, and has integrated wheels and handles on either end. The **Phototherapy Device** is placed flat in the case, and it is advisable to have two people lift and place the unit securely. The hooded bezels in front should be removed and the magnetic flat cover bezels installed in their place (below).

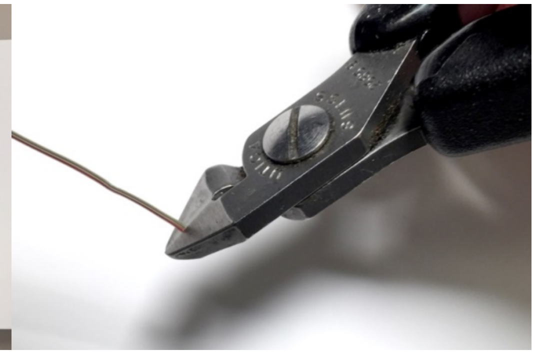
6.4 Front Cover Bezel for Transport



Part 7 – Thermocouples

7.1 Thermocouple Wire

Type K, PFA Insulated 30-gauge, Solid Wire (TT-K-30)



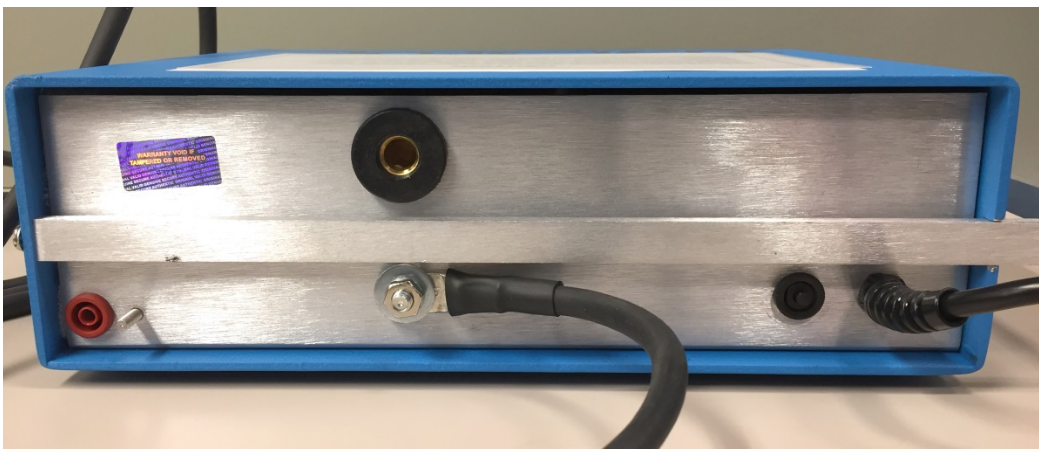
Wire Cutter

Type K, PFA Insulated, 24-gauge, Stranded Wire (TT-K-24S-SLE)

Type K, PFA Insulated, 24-gauge, Solid Wire (TT-K-24-SLE)

7.2 Thermocouple Welder

Front of the DCC Corporation *Hot Spot Plus* capacitive discharge welder. For more information see the appendix.



Back Side of the Welder

Connecting terminal to the Graphite Electrode Block

Tools and cables for Spot Welding

Welder Controls & Accessories

Turn the DCC Hot Spot Plus on and set the power level (detailed below). The charging light goes off once charged to that level. It immediately starts recharging after a discharge. (It does not have a built-in discharge - you must set any lower value first, and then discharge using the two washers (below). It will then charge to the new lower level.)

Controls on the Welder

Power Switch & Level Setting **Charging Light** **Hold Button to Ready a Weld** **Hi/Low Power Setting**

(Top Row) Magnifier, Welding Tool Holder & Mini-Pliers, Graphite Electrode Block & Cable, Thermocouple Safety Eyewear, Wire, Welder, (Bottom Row) Discharge Washers, X-Acto Knife & Cover, Long-Nose and Flat Pliers, Wire Cutter and Ruler.

Safety Glasses for Capacitive Discharge Welding

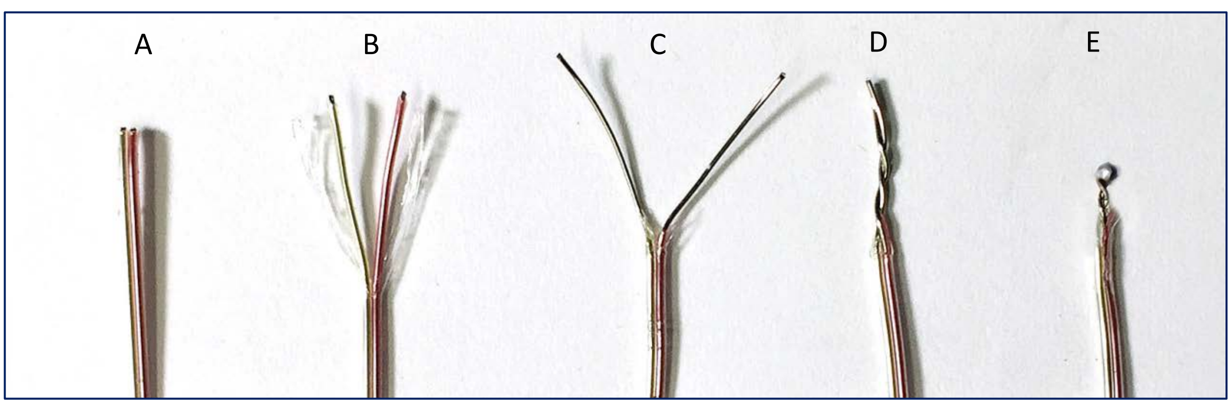
Flat-Surface Mini-Pliers with Male Connector & Welding Handle

Preparing the Wire for Welding

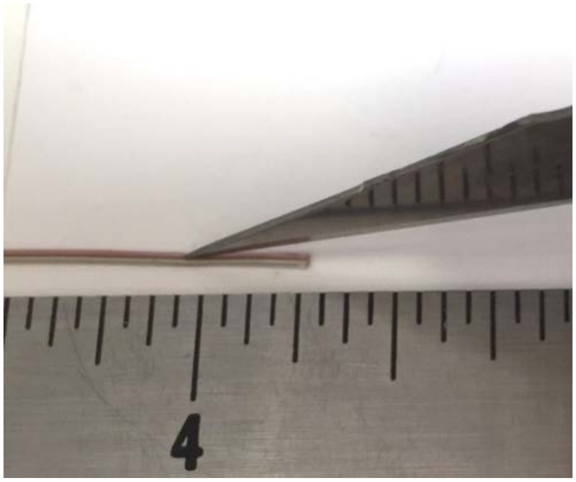
For the Type K thermocouple, the positive wire is **yellow** (Chromega, nickel-chromium, NiCr) and the negative wire is **red** (Alomega, nickel aluminum, Ni-Al). The connectors are yellow. The thinner terminal is positive, and the wider terminal is negative.

Temperature ranges vary with different wire gauges and insulation.

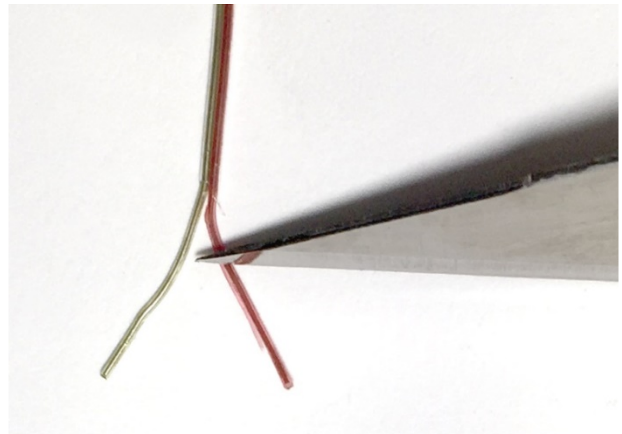
Observe polarity: **yellow/positive/Chromega/thin terminal** & **red/negative/Alomega/magnetic/wide terminal** with all connections and extensions. Note the Alomega bare wire is *magnetic*, and this property can be used to identify it.



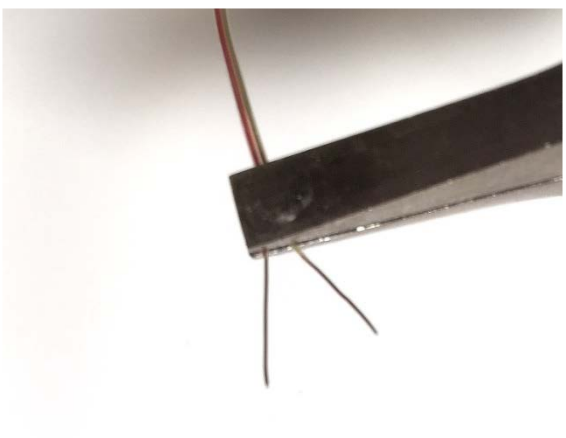
Steps for preparing the weld junction. For 30-gauge wire: (A) Cut wire square and to length, (B) Separate wires 1/2” and trim outer insulation, (C) Slightly score then pull off individual wire insulation, (D) Twist bare wires & (E) Weld the bead. (Steps are detailed below.)



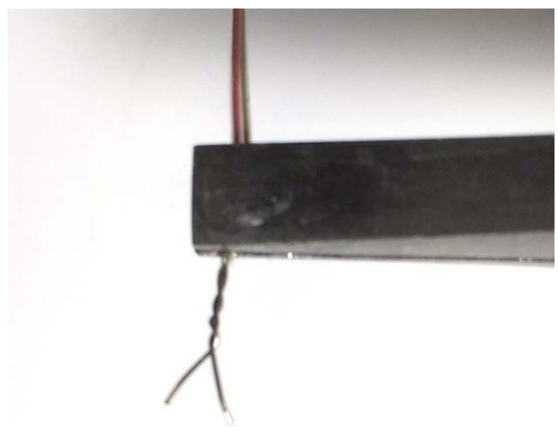
Measure and separate the two wires ~1/2" using an X-Acto Knife.



Slightly score the individual wire insulation, grasp with your finger nail and another finger, and firmly pull-off the insulation.



Hold the wire & bare wires as shown with the flat pliers.



Twist the wires all the way to the end.

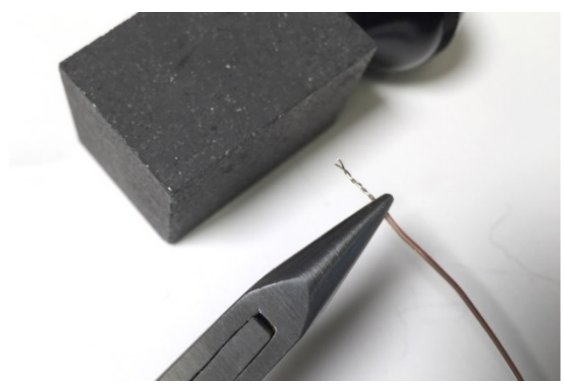
Making the Weld Bead

60-110
Watts

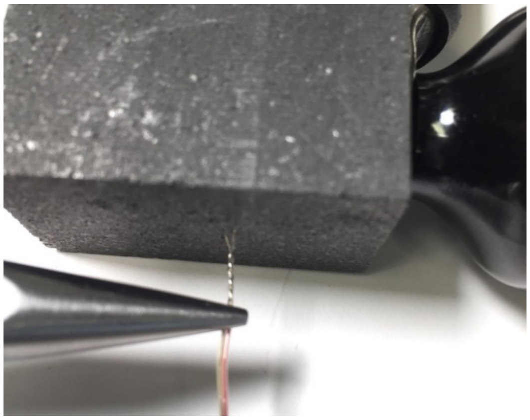
15 Watts x Once

For 30-gauge wire, set to ~15 watts and discharge once. For 24 stranded gauge set at ~60-110 watts, and discharge once. You will need to experiment & practice. The capacitors are charged and ready when the green light is on. Going from a higher setting to a lower setting requires first discharging the capacitor (use a metal washer.)

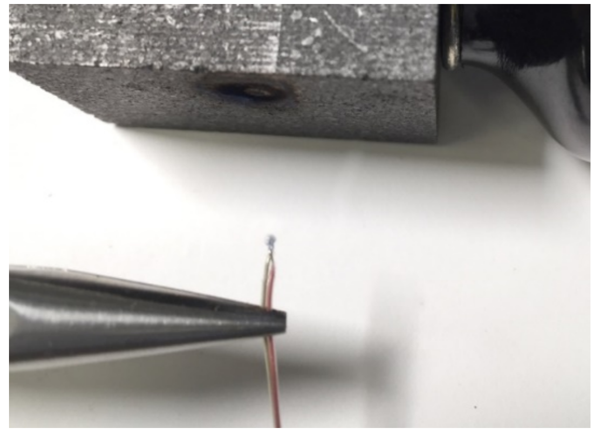
Graphite Welding Electrode Block & Cable



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



Press and hold the Weld button on the welder, then touch-off the tip of the twisted wire to the graphite block. It will spark/discharge weld immediately.



Post-Contact Capacitive Discharge Weld

Examples of Weld Beads

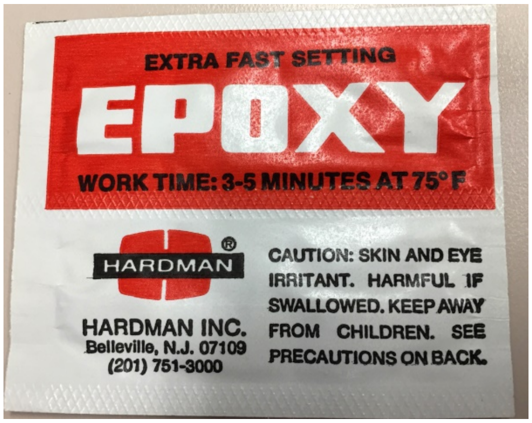
30-gauge Solid with Twist

24-gauge Solid with Twist

24-gauge Stranded – No twist

7.3 Heat Conductive Epoxy for Coating and Casting

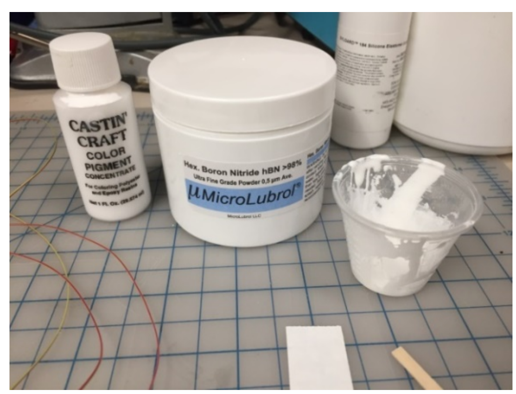
The following is the Raynaud's team proprietary methodology.



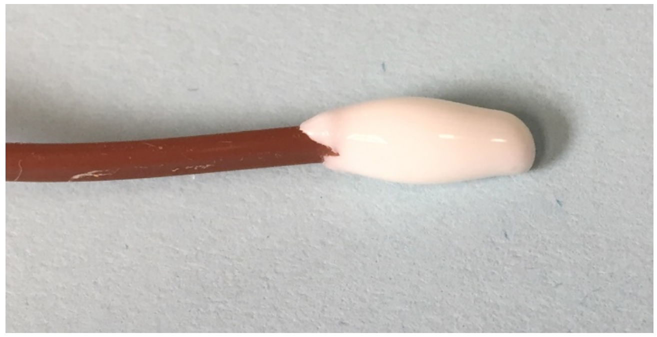
Add the Micro Lubrol (0.2g Hex Boron Nitride) Powder

Add One Packet Fast Setting Epoxy

Add One Drop White Color

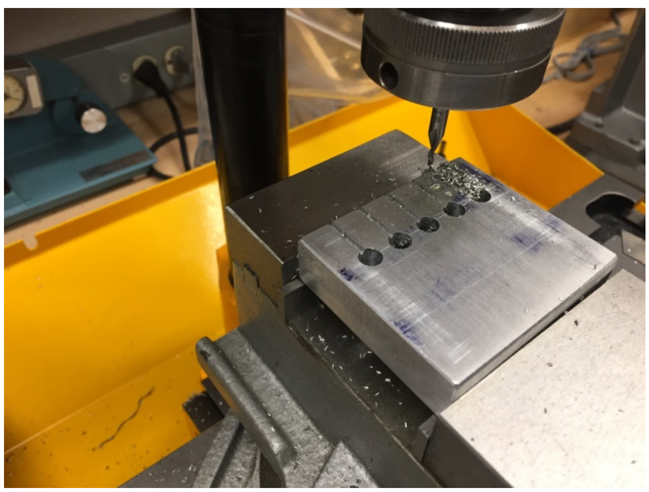


Mix contents using 2oz cup.



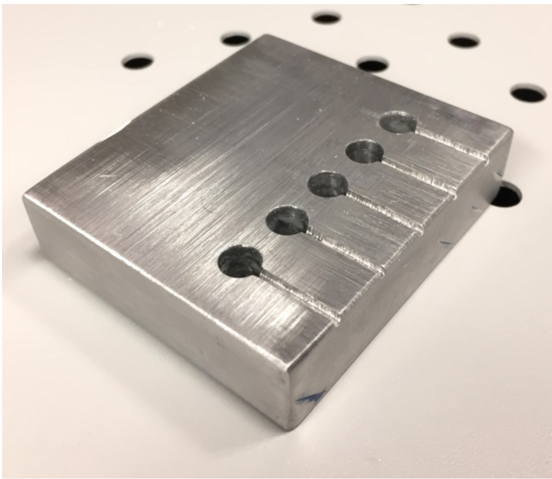
After mixing, dip the probe into the epoxy and stir slightly to create a coating of epoxy around the weld bead. Afterwards, repeatedly alternate holding the tip straight up, then inverted, until a uniform cover is created. This takes five minutes to set. (Sagging of the epoxy will occur if you do not do this.)

7.4 Construction of the Sensing Junction Mold



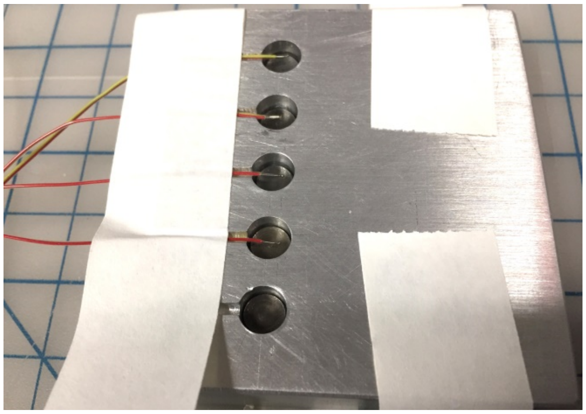
Drill press, mill and reamer are used to make precision holes through a block of aluminum. The holes are the diameter of the desired epoxy electrode. Slip-in steel doll pins (next section) determine the thickness of the electrode.

7.5 Encapsulating the Sensing Junction with Heat Conductive Epoxy

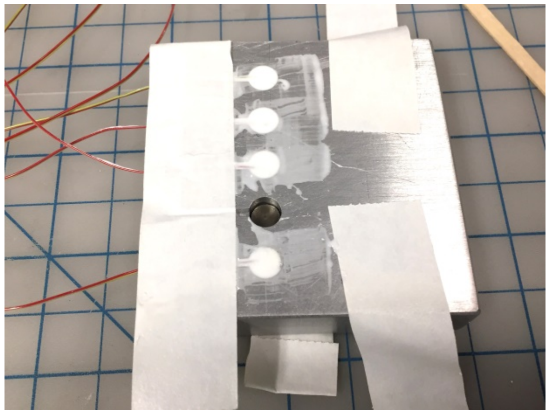


Aluminum Mold for Casting Probes

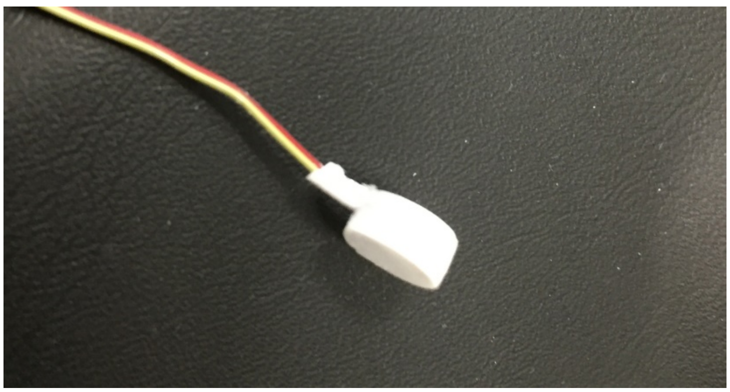
The Longer the Doll Pin the Thinner the Probe



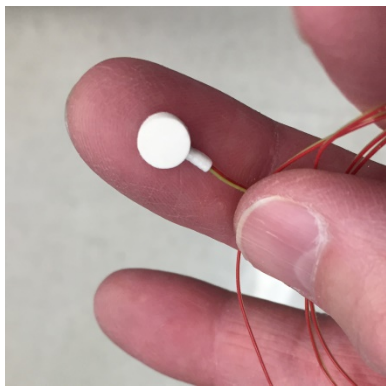
Positioning of Multiple Sensor Junctions



Filling with Heat Conductive Epoxy

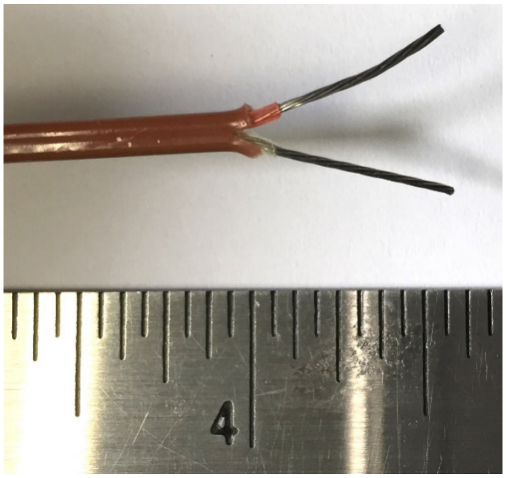


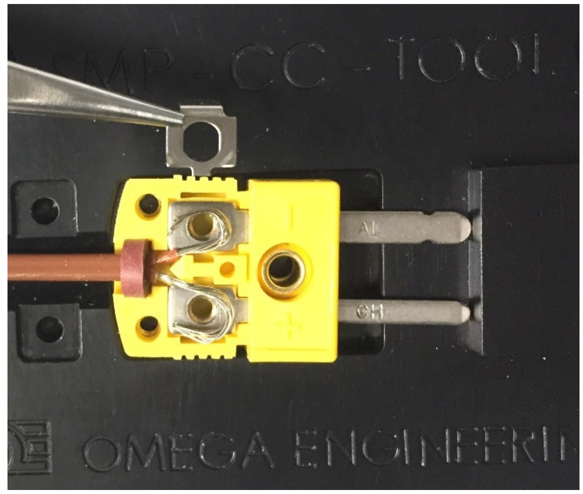
Demolded Thermocouple Probe



Placement on Finger

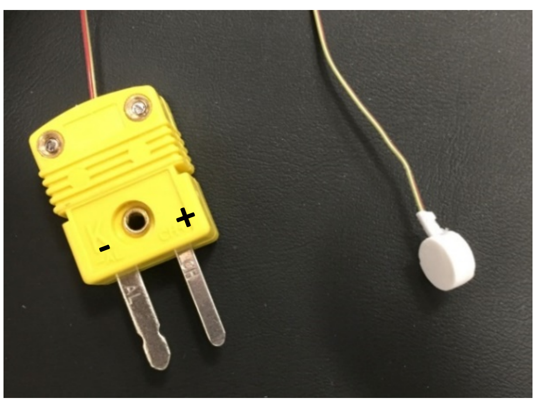
7.6 Type K Thermocouple Connectors, 2 Pole





Type K Thermocouple Wire (TT-K-24S-SLE), Male Mini-Connector (SMPW-CC-K-M-ROHS) and Omega Assembly Tool (SMP-CC-TOOL).

Reminder - be sure to observe polarity: **yellow/positive/Chromega/thin terminal** & **red/negative/Alomega/ magnetic/wide terminal** through all connectors and extensions.



Finished Connector with 30-gauge wire and epoxy casting.

Type K Female Mini-Connector for Extender Cable

7.7 Simplified Calibration

Accuracy

Accuracy is the amount of error when taking a temperature measurement, and is referred to as tolerance or error.

Thermocouple accuracy depends on the Thermocouple type, its range of interest, the purity of the material, electrical noise (EMI and RFI), corrosion, junction degradation, and the manufacturing process. Thermocouples are available with standard grade tolerances or special grade tolerances called Class 2 and Class 1 respectively. The most common control-ling international standard is IEC-60584-2 while the most common U.S. standard is ASTM E230. Each standard publishes limits of tolerance for compliance (How to Determine Thermocouple Accuracy with Initial Calibration Tolerances, Learning Instrumentation and Control Engineering, instrumentationtoolbox.com).

Calibration in a Certified Laboratory

Thermocouples are typically tolerance tested for compliance with the American Society for Testing and materials. This involves measuring the voltage at various temperatures and calculating the error from standard tables (Fluke Calibration, How to Calibrate a Thermo-couple). There are different procedures depending on whether an internal vs external reference junction is being used. A thermocouple should be calibrated over the entire temperature range it is to be used. There are various commercial furnaces, ice-point references and other cooling means to derive stable temperatures for calibration purposes.

One-Point Calibration

For our purposes, given a need for reasonable accuracy over a limited temperature range (ambient air to body temperature) a simple one-point or two-point calibration may be performed to correct for sensor offset errors. The assumption for one-point calibration is that the sensor is linear and has the correct slope over the desired measurement range. This technique can also check for changes from age or environment induced deterioration.

To do this, take a measurement with the thermocouple and compare with a reference standard. The “offset” is the difference in the two temperature readings. If you were writing code for a microcontroller, you would incorporate this offset into your measurement.

Two-Point Calibration

Two-point calibration rescales the output and is capable of correcting for both slope and offset errors. This is preferrable to single-point calibration for the thermocouples, but not always necessary. We should see consistency in our measurements from one unit to the next, and when not, we may be suspicious of a poor weld bead or improper connection. (Nevertheless, this is not the same as calibration to NIST standards that would be performed in a certified calibration laboratory.)

For our purposes ice water and boiling water provide two easily obtained reference points. As with single-point calibration, take measurements with our thermocouple and the calibrated reference thermocouple. These are physical standards, and at sea level atmospheric pressure, water boils at 100 °C and the triple point is 0.01 °C. (Correction for differences in atmospheric pressures may be incorporated.) Triple point of water is the temperature and pressure at the three phases (gas, solid, liquid) coexist in thermodynamic equilibrium (Wikipedia). (There are commercial devices for achieving accurate triple point references.)

A satisfactory ice point reference can be made from ice cubes made from distilled or deionized water, and prepared with an ice shaver (or finely crushed). Fill a Dewar with 1/3 distilled water (not tap water), then add the shaved ice until full, pouring off water until moist ice is on top. Occasionally pouring off water and adding shaved ice will keep the system going. Allow 15 minutes to stabilize before each reading.

Thermocouple under test, reference TC, Dewar with distilled water ice bath, and the Omega CL23A Calibrator – Thermometer.

These are the steps to get a corrected reading:

1. Record low and high measurements for the thermocouple under test (TL and TH).
2. Record low and high measurements for the reference thermocouple (RL and RH).
3. Corrected Value = (((TH-TL) *Reference Range))/Test Range) + Reference Low
   Where Reference Range is RH-RL, and Test Range is TH-TL.

For example:
Measured: RL= 0.01°C, RH=100°C
Therefore, Reference Range = 100 - .01 = 99.99°C
Measured: TL=--.05°C, TH = 96°C
Therefore, Test Range = (96-(-.05)) = 96.5°C

For a measurement with our thermocouple, we read 37°C.
The Corrected Value = (((37 + 0.5) * 99.99) / 96.5) + 0.01 = 38.9°C

(For more on calibration see A. Schossler https://e2bcal.com/author/aschossler/, and B. Earl https://learn.adafruit.com/calibrating-sensors/single-point-calibration.)

7.8 Testing

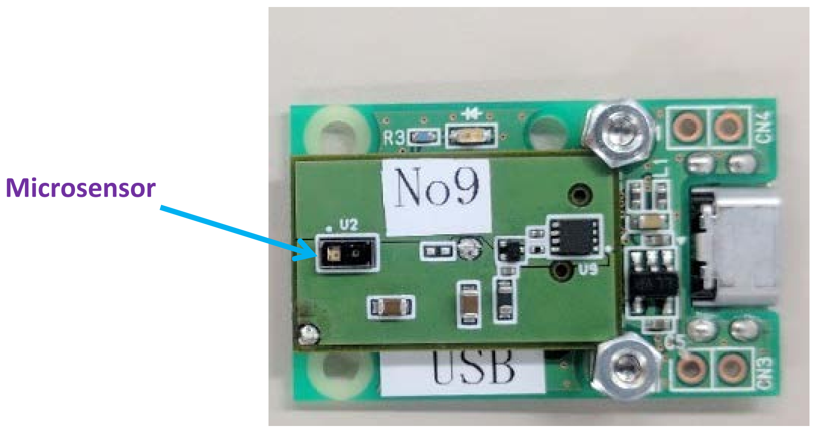
The Type K thermocouple is connected to the top of an Omega RDXL6SD-USB Temperature Logger.

Part 8 – Laser Doppler Blood Flow Measurement

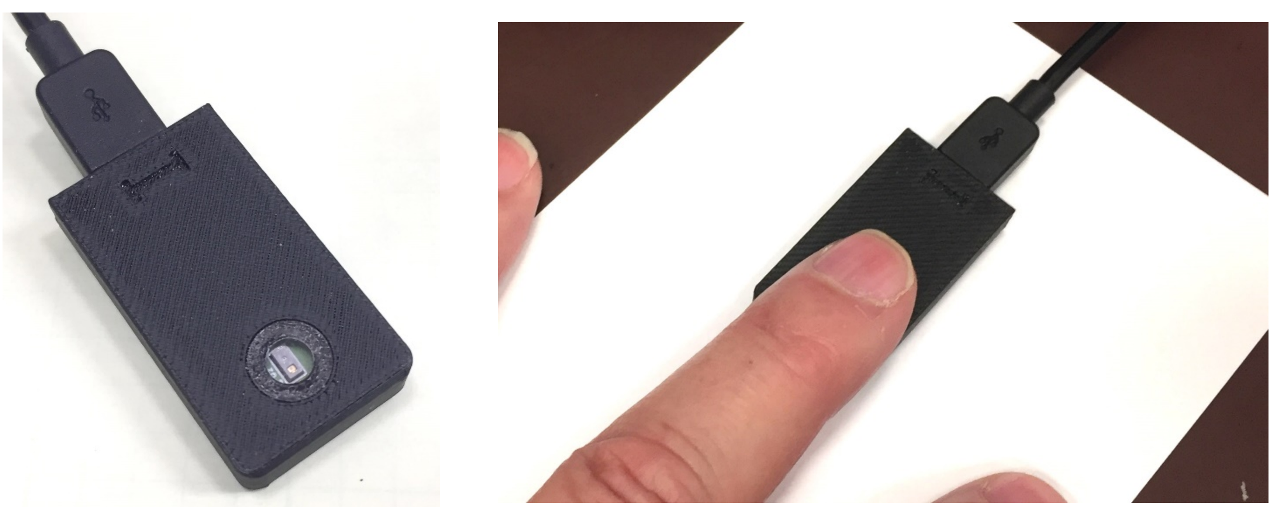
8.1 Laser Doppler Flow Sensor Version 1

Laser doppler blood flow sensors work on the principle of laser doppler shift, whereby incident and reflected laser light on the skin surface can be analyzed and used to determine fluid velocity and flow. Measuring cutaneous flow in one finger could possibly be used as an indicator of vasodilation based on the melanopsin mechanism. It is unknown if much effect would be seen in a healthy subject vs someone who has symptoms of Raynaud's disease or phenomenon.

A circuit board housed in a small enclosure with a window, has been placed in a custom adaptor to form fit to the distal finger with minimum contact pressure over the sensor window.

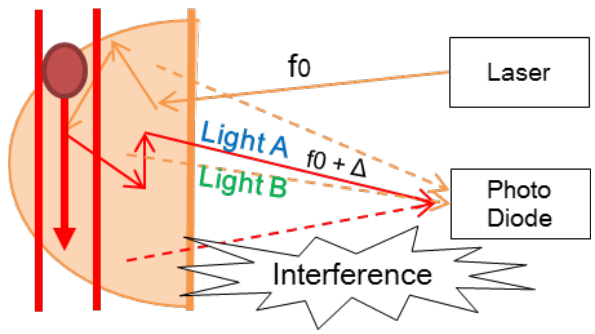


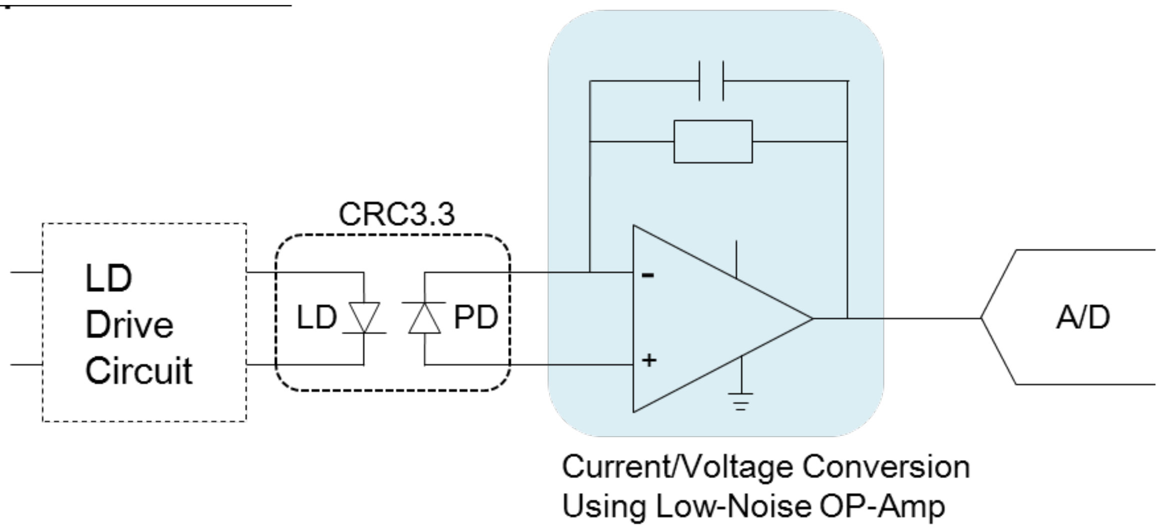
Circuit Board

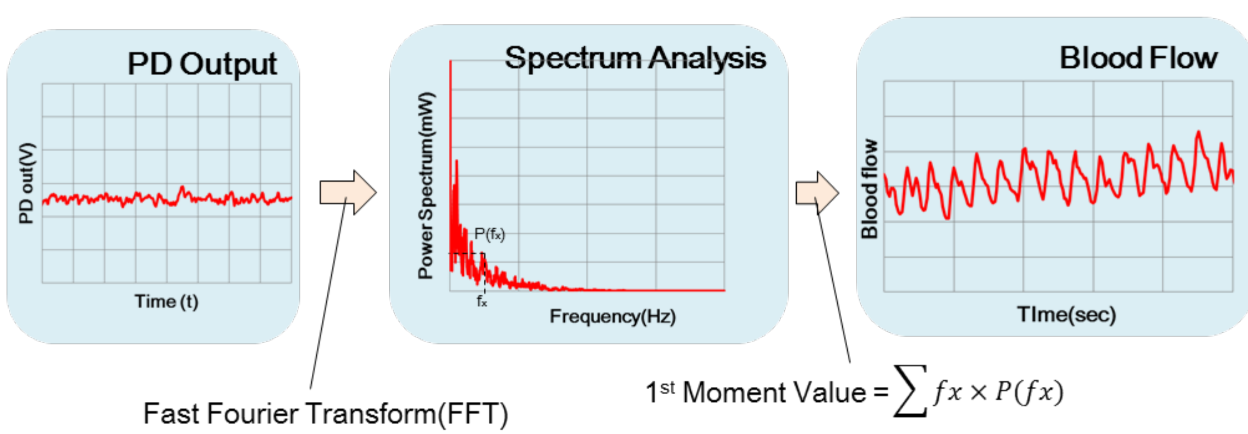


Sensor Evaluation Kit & Demonstration without the Finger Holder

Principle of Operation

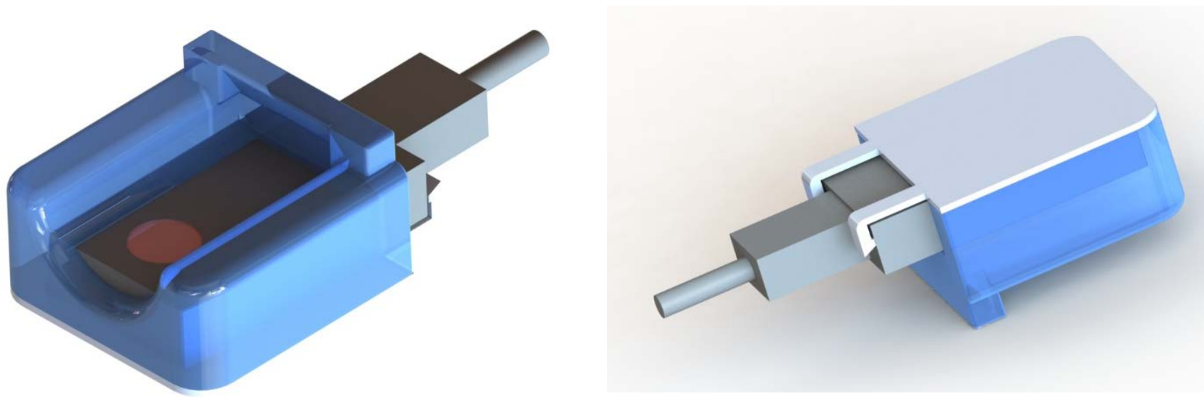






Images Courtesy of Kyocera International

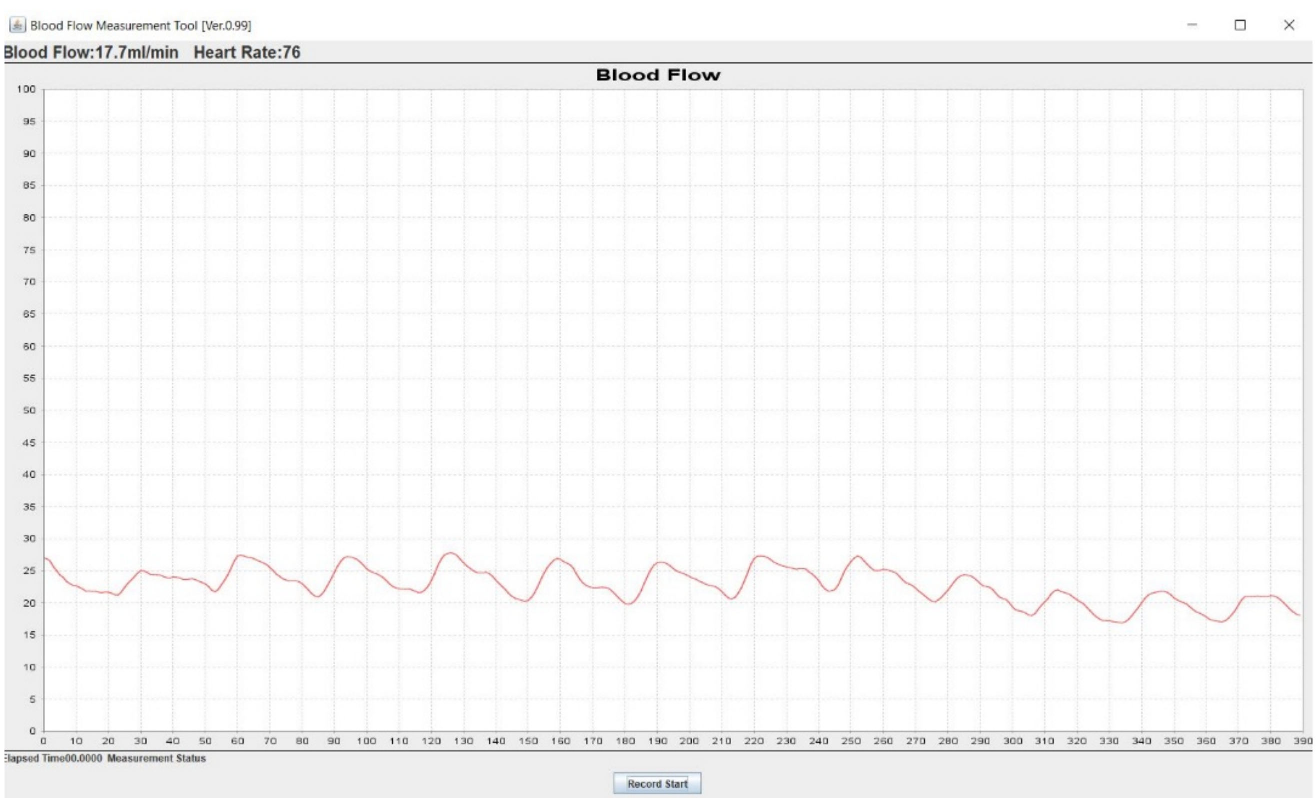
Initial Custom Finger Holder & Sensor



Sensor, Finger Holder and Mini-USB Connector Rendering. ideally this should be molded in PDMS or another soft polymer. Presently a clear PLA polymer is being used.

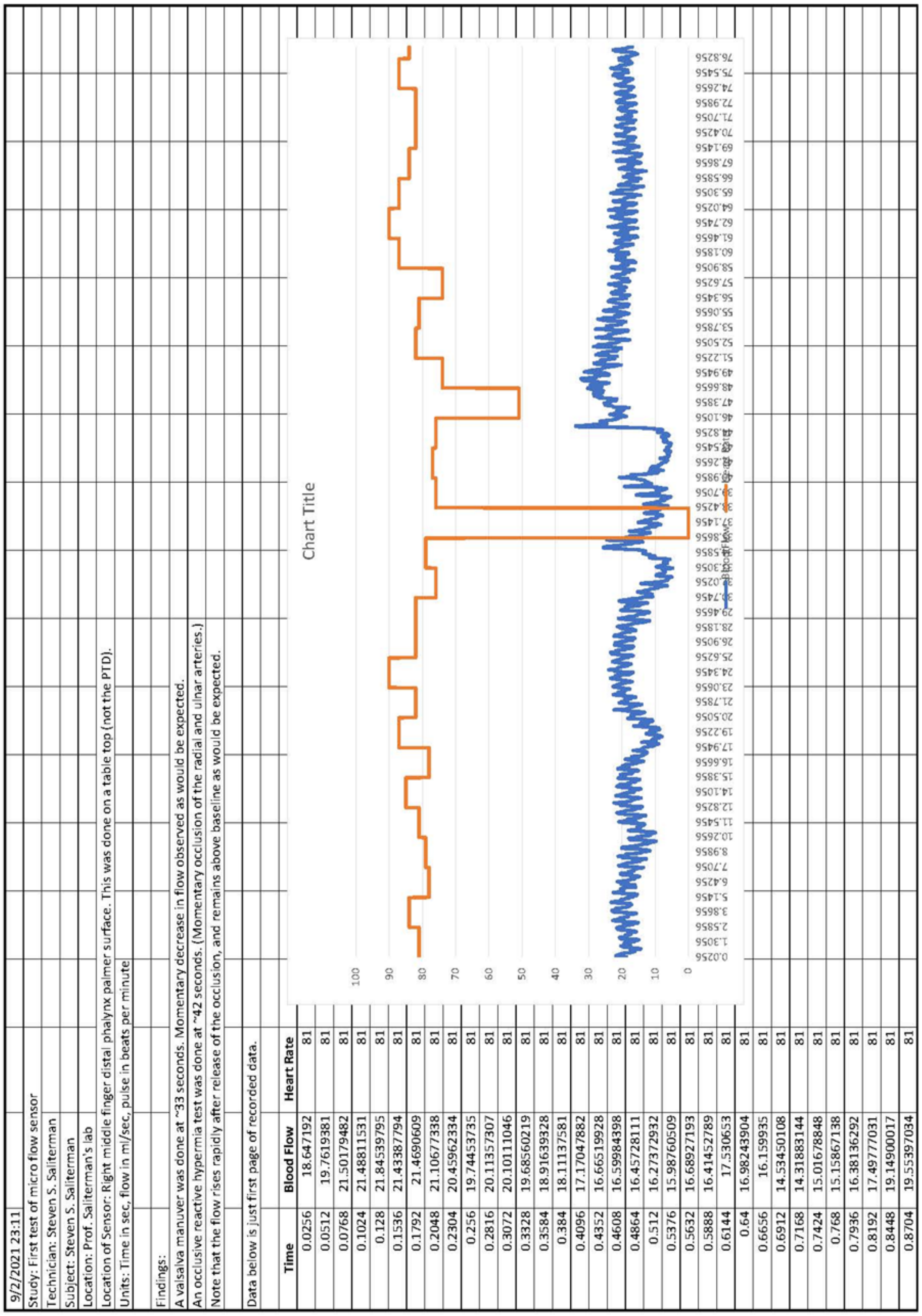
Sample Output Data

The data obtained from this sensor could be correlated with planned thermal imaging and temperature recording (perhaps before and after rather than continuous).



Screen capture of sensor output. This may be recorded.

Demonstration of Reactive Hyperemia



9/2/2021 23:11
Study: First test of micro flow sensor
Technician: Steven S. Saliterman
Subject: Steven S. Saliterman
Location: Prof. Saliterman's lab
Location of Sensor: Right middle finger distal phalynx palmer surface. This was done on a table top (not the PTD).
Units: Time in sec, flow in ml/sec, pulse in beats per minute

Findings:
A valsalva manuver was done at ~33 seconds. Momentary decrease in flow observed as would be expected.
An occlusive reactive hypermia test was done at ~42 seconds. (Momentary occlusion of the radial and ulnar arteries.)
Note that the flow rises rapidly after release of the occlusion, and remains above baseline as would be expected.

Data below is just first page of recorded data.

Time	Blood Flow	Heart Rate
0.0256	18.647192	81
0.0512	19.7619381	81
0.0768	21.50179482	81
0.1024	21.48811531	81
0.128	21.84539795	81
0.1536	21.43387794	81
0.1792	21.4690609	81
0.2048	21.10677338	81
0.2304	20.45962334	81
0.256	19.74453735	81
0.2816	20.11357307	81
0.3072	20.10111046	81
0.3328	19.68560219	81
0.3584	18.91639328	81
0.384	18.11137581	81
0.4096	17.17047882	81
0.4352	16.66519928	81
0.4608	16.59984398	81
0.4864	16.45728111	81
0.512	16.27372932	81
0.5376	15.98760509	81
0.5632	16.68927193	81
0.5888	16.41452789	81
0.6144	17.530653	81
0.64	16.98243904	81
0.6656	16.159935	81
0.6912	14.53450108	81
0.7168	14.31883144	81
0.7424	15.01678848	81
0.768	15.15867138	81
0.7936	16.38136292	81
0.8192	17.49777031	81
0.8448	19.14900017	81
0.8704	19.55397034	81

First test of the doppler flow sensor on 9/2/2021. (Bench test without the phototherapy device or custom finger holder.)

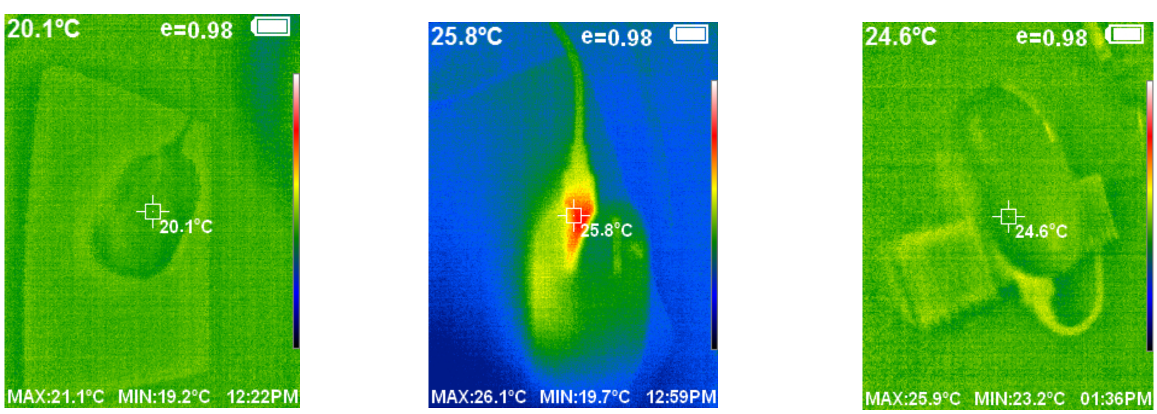
8.2 Laser Doppler Flow Sensor Version 2

In late October 2021 Kyocera Int. provided us with a finger-clip mounted laser doppler flow sensor for use in the phototherapy device. Extensive testing of this device was done to understand its advantages and limitations. It did provide repeatability of contact pressure, something that could not be done by simply resting a finger on the previous finger holder, even with the addition of an elastic strap over the finger. Moreover, the net pressure was much less than we could achieve, revealing higher flows and systolic-diastolic amplitude differences.

We discovered that laser doppler flow probes are problematic by design. They heat up when used continuously. This is demonstrated in the thermal imaging below of the finger-clip sensor initially, and after being powered by its USB connection for 35 minutes on a low heat conductive desktop surface. Temperature of the housing and sensor window were observed to heat from their own electronic components. This heating was demonstrated as being sufficient to change blood flow.

To overcome this limitation, the sensor was mounted on an aluminum plate with 3M thermally conductive adhesive. Two small fluted heat sinks were placed alongside the sensor on the plate. Repeat thermal imaging after being powered for 35 minutes inside the hand compartment, with fans operating, showed satisfactory dissipation of the heat. Inside images of the sensor itself, with its laser operating showed it to be warm. We speculated that this heat would be insufficient to interfere with differentiation of flow from exposure to blue light, but would require a period of equilibration.

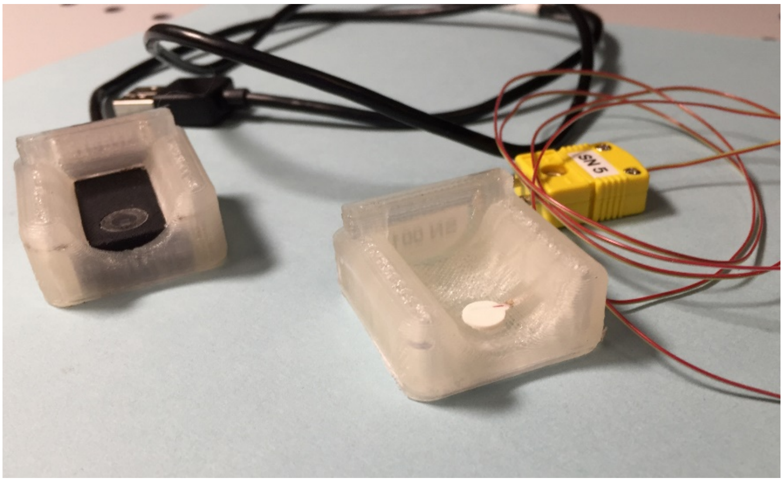
Testing performed October 26, 2021 confirmed this. We observed a short time was necessary for equilibration of the sensor with the finger, and attributed this to the heat generated by the sensor itself. We also discovered that there was significantly increased blood flow with exposure to blue light then comparing the opaque (sham) with the clear (experimental) hand compartments – all other factors being equal (same sensors, shielding, settings and activation of the blue LED panels). The increased flow (after equilibration) and hand warming (measured with a thermocouple on the contralateral hand) could only be attributed to blue light exposure.

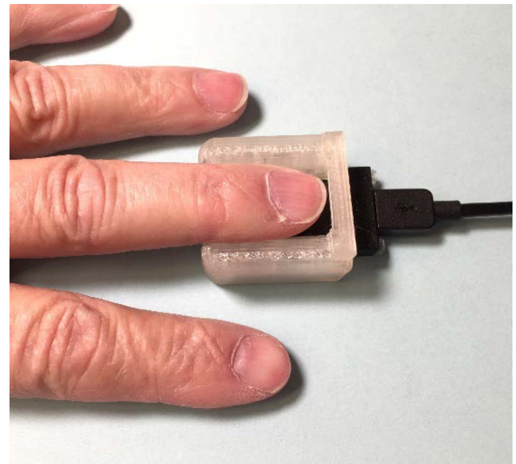


Thermal imaging of the finger-clip laser doppler flow sensor on October 25, 2021. On the left is its initial (unpowered) state on a desktop insulator. The middle image is after 35-minute application of power. The right image is after 35 minutes on a custom heat sink.

Part 9 - Flow and Temperature Sensor Holders

Original Flow and Temperature Sensors

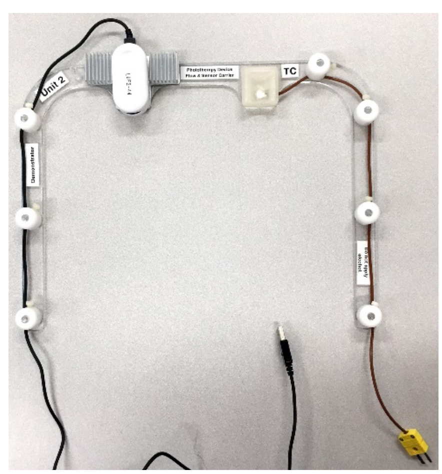




A 3D FDM printing of the flow sensor finger holder and similar thermocouple holder are shown above. The ¼” custom molded Type K thermocouple neatly inserts into the bottom of the holder, protruding slightly to make firm contact with the finger. The bottom of the thermocouple has a Mylar reflective surface. Both finger holders are made by 3D printing clear PLA, giving a translucent appearance.

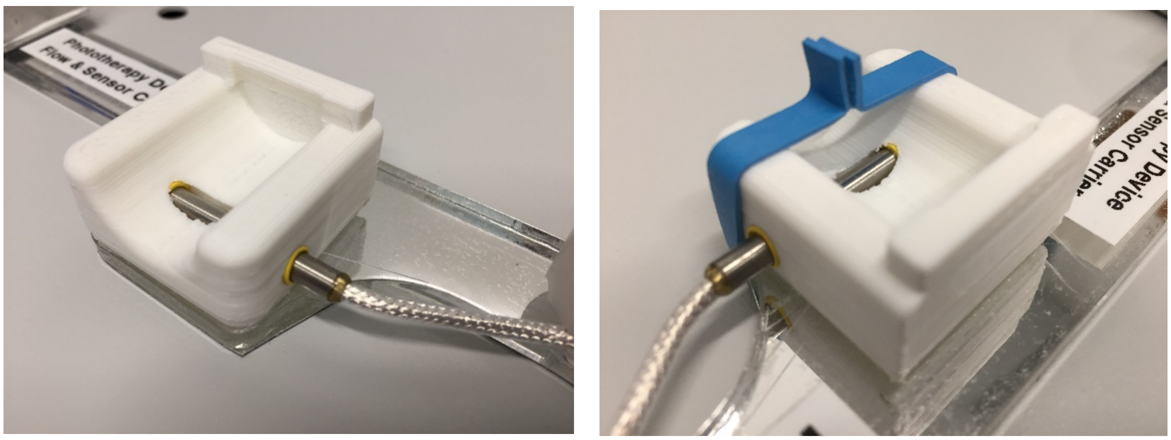
Updated Finger-Clip Style Flow Sensor (Same Internally)

With the addition of the finger-clip flow sensor, a revised sensor carrier was created (photo below). By affixing the holders in the compartment (and bringing the wires to the side and out the front), there was greater reproducibly of the data, more stable signal, better controlled contact pressure, and alleviation of the need to tape anything to the subject. (This saves considerable time during a study and inconvenience to a participant during a study.)

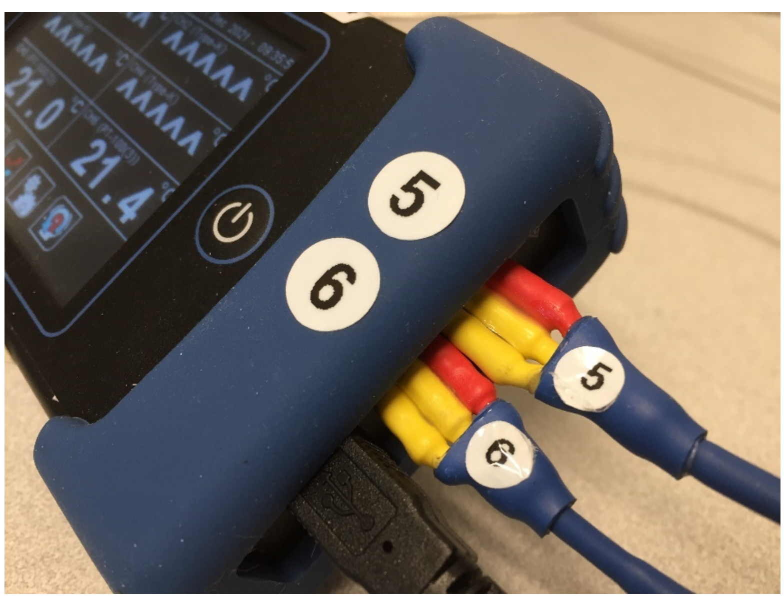


New RTD Temperature Sensors & Revised Finger Holder

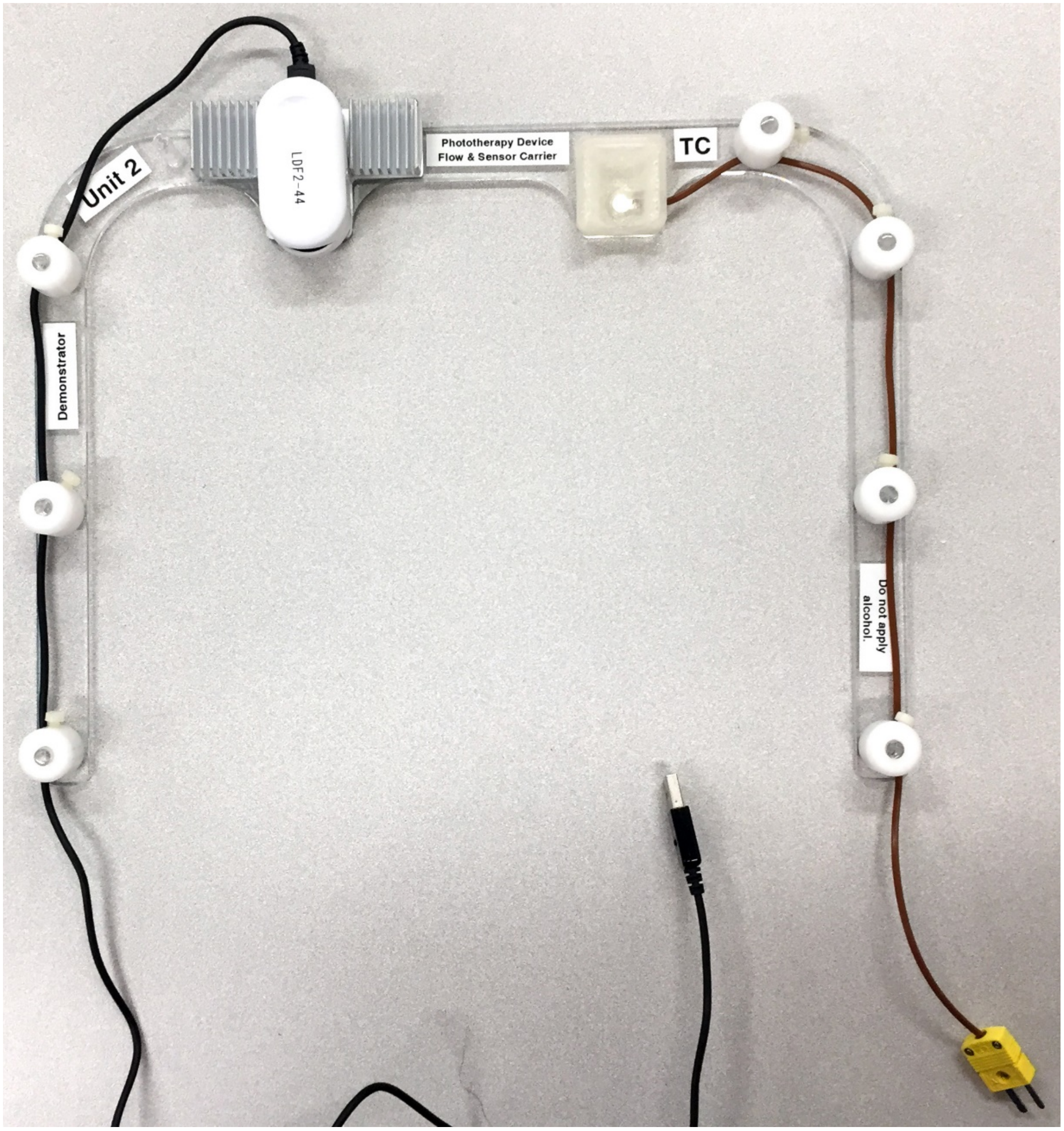
Tests of the finger thermocouple sensor in December 2021 showed the EMI was affecting the temperature reading – elevation of temperature were observed whenever the blue lights were on, even when no hand was present in the compartment. These readings were not as high as when a finger was present, but did necessitate changing to an RTD-Pt100 sensor for greater immunity to noise. This did prove beneficial, although peak rises with a hand present were less than before. The thermocouple used for air sampling the hand compartment temperature was also changed to an RTD-Pt100 sensor.



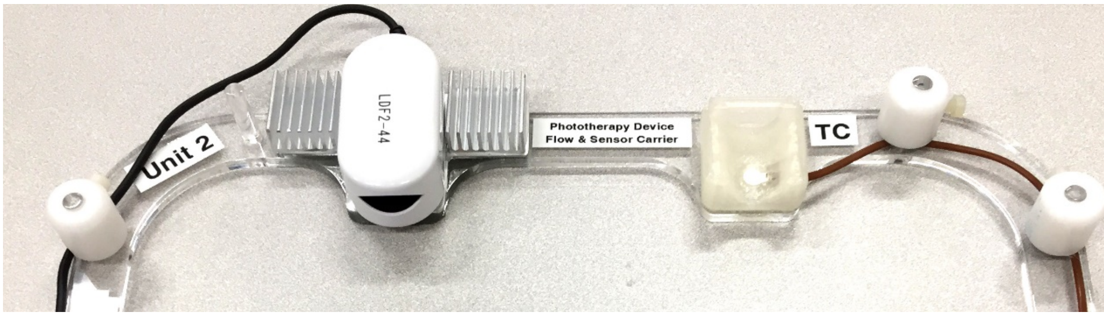
RTD-Pt100 sensor in a modified finger holder. The yellow rings are vinyl heat shrink tubing that suspend the sensor in the holder. The sheath is fiberglass. A blue elastic band (on the right) holds the finger down. This is connected to RTD Pt-100 input (port 5) on the Omega temperature logger (below) with a specially constructed 3-prong connector. The compartment air-sampling RTD sensor is also shown (port 6).



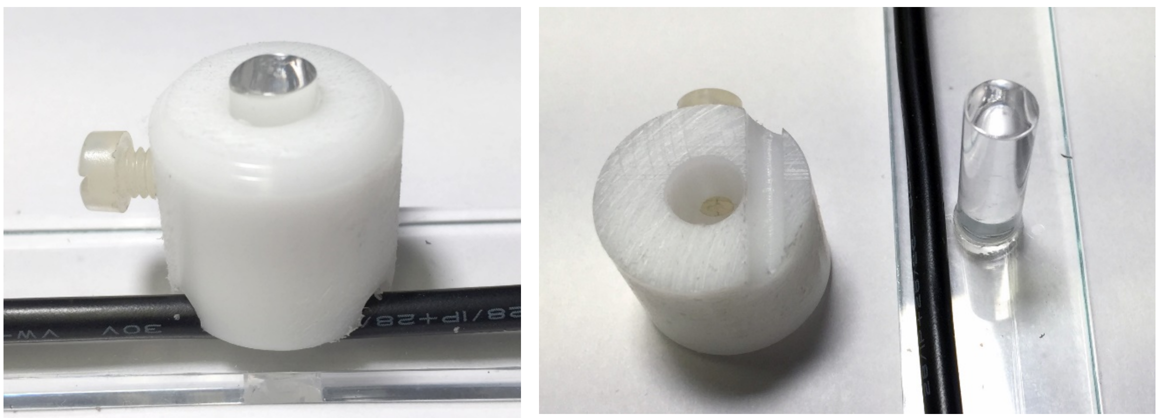
Part 10 – Laser Doppler Flow and Finger Thermocouple Sensor Carrier



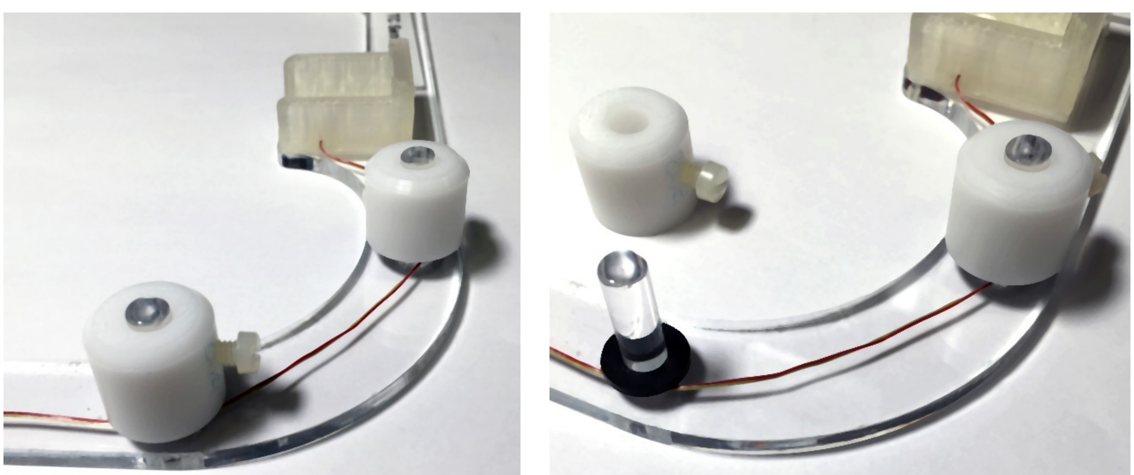
Acrylic sensor carrier for the finger-clip laser doppler flow and thermocouple sensors. Note the white Delrin wire binding clamps on each side, allowing the wires & connectors to exit the hand compartment out front on either side of the arm rest. (See Part 7 for an updated view of the new RTD-Pt100 sensor and finger holder.)



Laser doppler flow and thermocouple sensors positioned for the middle finger of each hand. These are bonded to the carrier with 3M 467MP high performance adhesive (re-



The flow sensor PVC-insulated micro-USB cable runs through the contoured channel on bottom of the white Delrin clamp. The clamp is secured with a nylon screw to the acrylic post.



The PFT-insulated thermocouple wire is secured by a neoprene washer and flat bottom Delrin clamp.

Part 11 – Labeled Polycarbonate Panel

The following illustrates the Raynaud’s team proprietary methodology for rapid prototyping a control panel. This has been performed a few times with various control panel updates.

11.1 Material Needed

1. Polycarbonate film 0.10” (10 mil) thick, one side velvet, one side gloss (VG). Sheets: 24 x 48”. (Lexan 8A35 or equivalent)
2. Drytac PSF25015 Optically clear, ultra-smooth mounting adhesive film – two sided, suitable for use between a glossy print and a plastic surface. Comes as 25” x 15’
3. 3M Scotch 467MP Hi Performance Adhesive (panel double side mounting adhesive)
4. Artwork on Epson Ultra-Premium Photo Paper Luster printed on e.g., an Epson R2000.

11.2 Tools Needed

1. Alcohol
2. Burnishing tool
3. Corner radius shear (optional)
4. Cutting board
5. Drafting tape (to hold polycarbonate and rulers down)
6. Heavy duty scissors or fabric scissors (to cut polycarbonate and adhesive film)
7. Industrial & custom punches (holes and shapes) and wrench (optional)
8. Large-hole paper punch (optional)
9. Long reach paper punch
10. Metal or rubber roller
11. Metal T square (for trimming) or ruler
12. Precision Brand Punch & Die set (optional)
13. Roper Whitney #5 hand held punch & die set (optional)
14. Scribe (making locating holes)
15. Utility knife with new blade (to cut polycarbonate)
16. X-Acto knife (to trim 3M mounting adhesive)

DRYTAC®

PSF25015

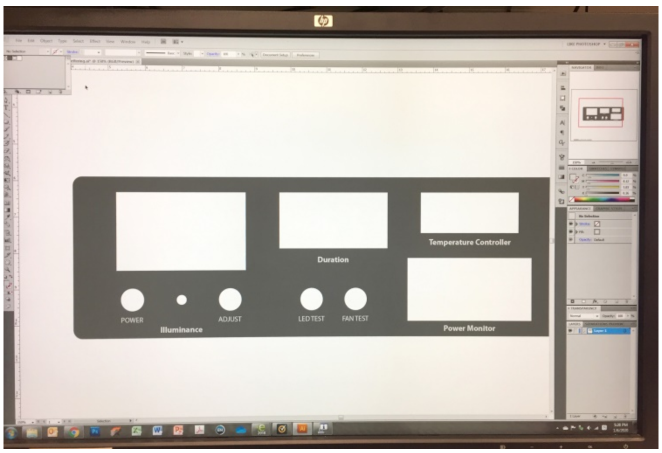
Facemount®

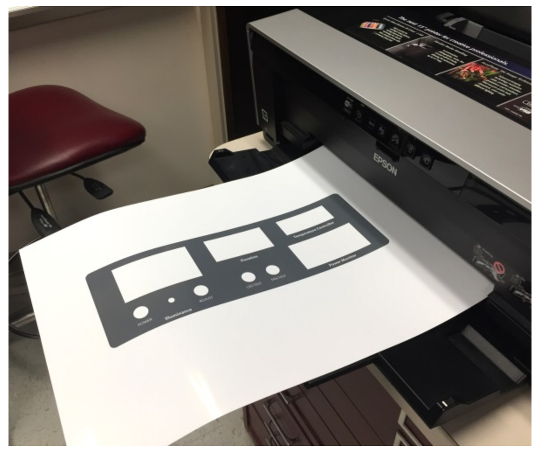
Optically clear, ultra-smooth mounting adhesive

25" x 15' (635mm x 4,5m)

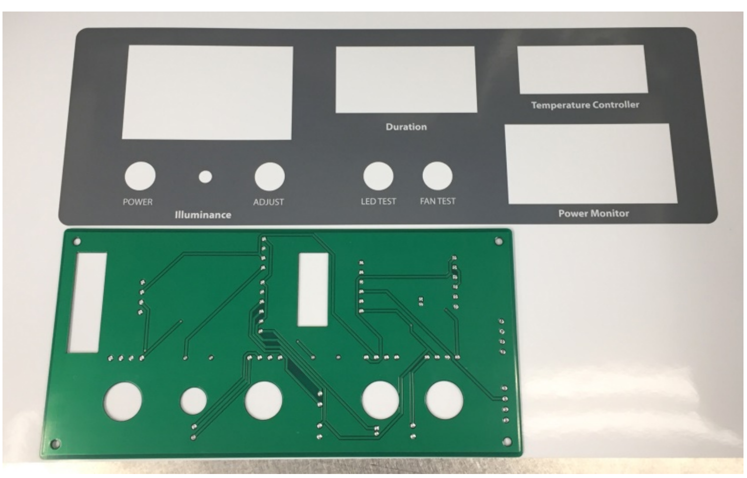
11.3 Construction

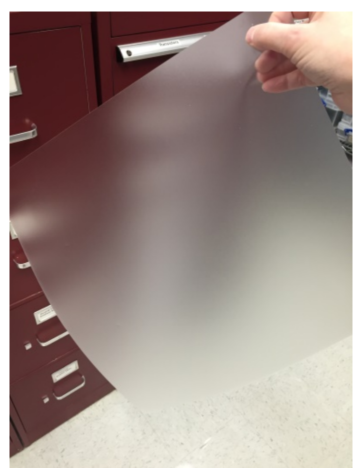
Create your artwork using Adobe Illustrator or similar software. If you have a CAD file with the board outline in a .DXF with proper scale, this can be used to assist in illustrating and later cutting with a laser cutter. Using a laser cutter however is not necessary. An Epson R2000 printer is being used below with Epson Ultra-Premium Photo Paper Luster.

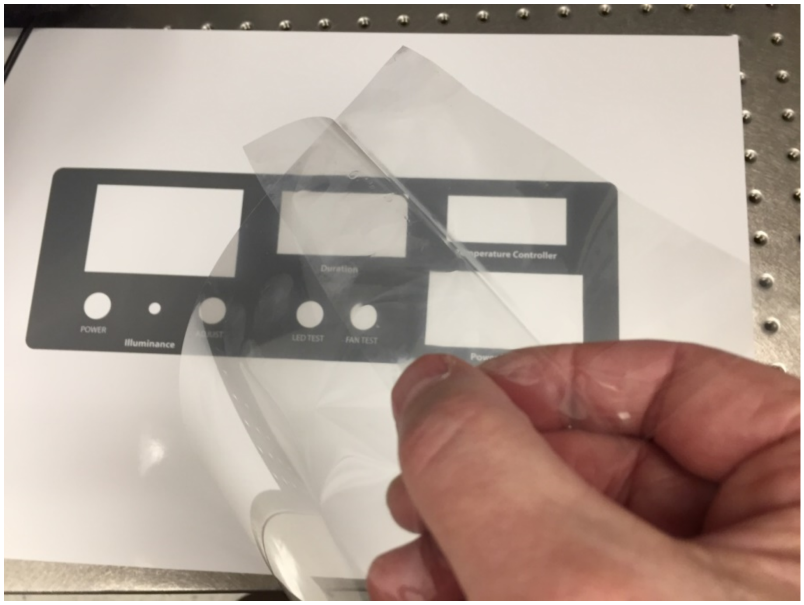




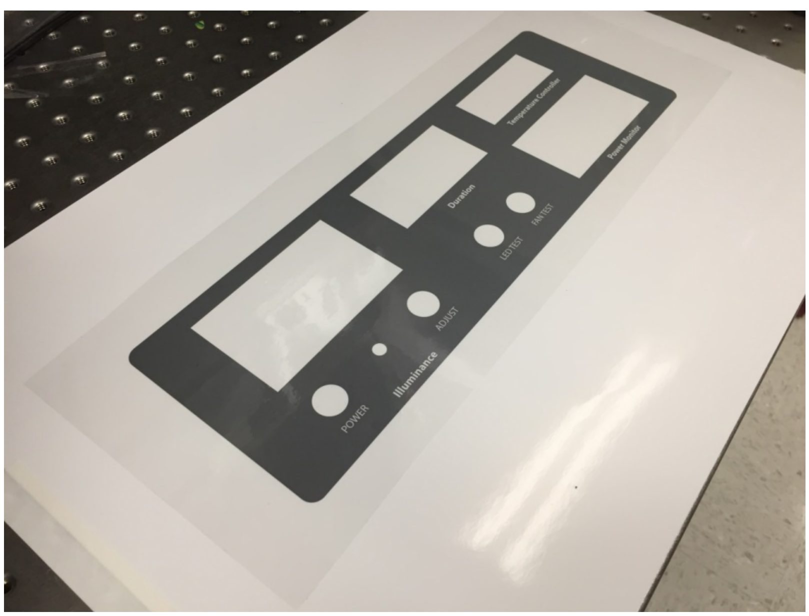
The finished print should be allowed to dry a few hours. Compare the print with reference materials to confirm your dimensions and scale, e.g. the printed circuit board below. On the right below is a piece from the 24” x 48” polycarbonate film. It is firm but flexible. The velvet side is facing us. In the steps below the front of the color print will be adhered to the back glossy side of the polycarbonate sheet. When bound together the polycarbonate appears transparent with a very slightly texture and durable surface.





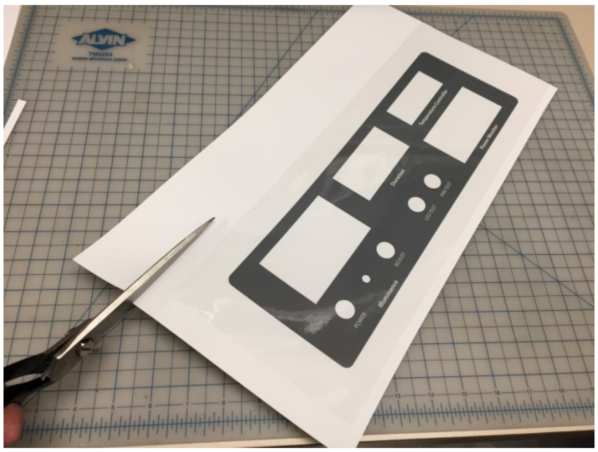


Cut sufficient Drytac to more that cover the artwork, but still remain on the photo paper. Super B (19 x 13”) paper is being used in the example. Peel back one side of the adhesive film, and fold creating an underneath pull edge as you place the film sticky-side down a few inches ahead of the artwork on one end. Gradually pull of the under layer as you press the glossy film evenly across the width of the artwork, until all of the artwork is covered, plus an extra few inches. Pull slowly and smooth behind with your fist



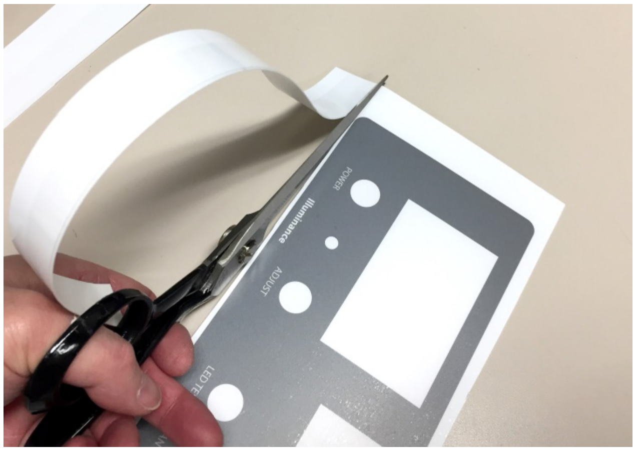
Next trim the photo paper to within 1-2 inches of the edge of the artwork. Set this aside – you will later be doing a similar step as before, except this time pressing the artwork against the glossy side of the polycarbonate panel.

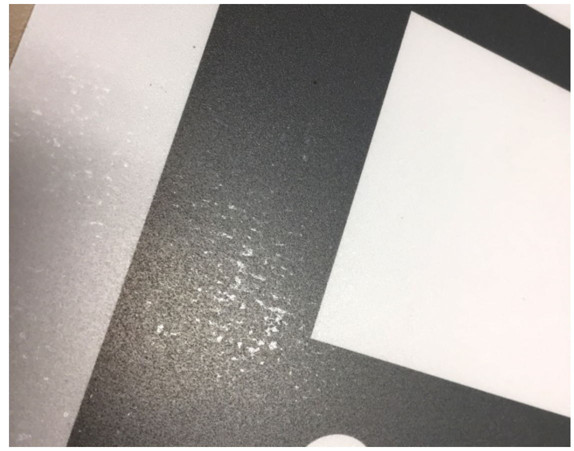
Cut a piece of polycarbonate larger that trimmed artwork, and tape it down glossy side up on the cutting board. Clean its surface with a lint free cloth and alcohol.



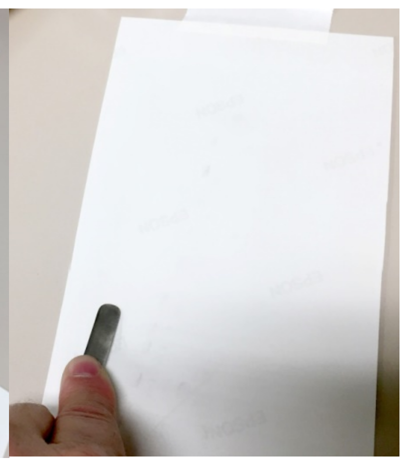
Just as before, peel one end of the adhesive film cover and fold back as shown below. The sticky-side will now be the front of the artwork. Invert and affix to one end of the polycarbonate panel. Gradually pull the protective sheet underneath away, exposing the sticky surface. As you do this, press & smooth the back of the artwork with your fingers along its width so that it is adhering to the polycarbonate without bubbles.

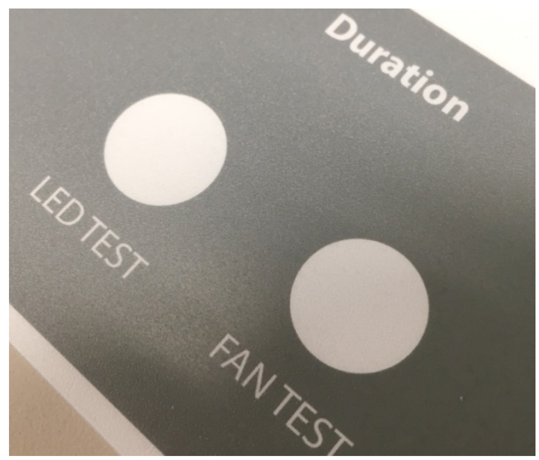
Roll the back side of the artwork to remove fine bubbles and improve adherence. Next trim the polycarbonate covered artwork within a ½" of the artwork edge. If you look closely in the light, you will notice that there are some areas with <u>very fine</u> air bubbles. Large air pockets are troublesome – try to move the bubble to the end or an inner area that is going to be trimmed. As a last measure before repeating everything, try making a tiny X-Acto cut behind the artwork, and see if the air bubble can be removed.



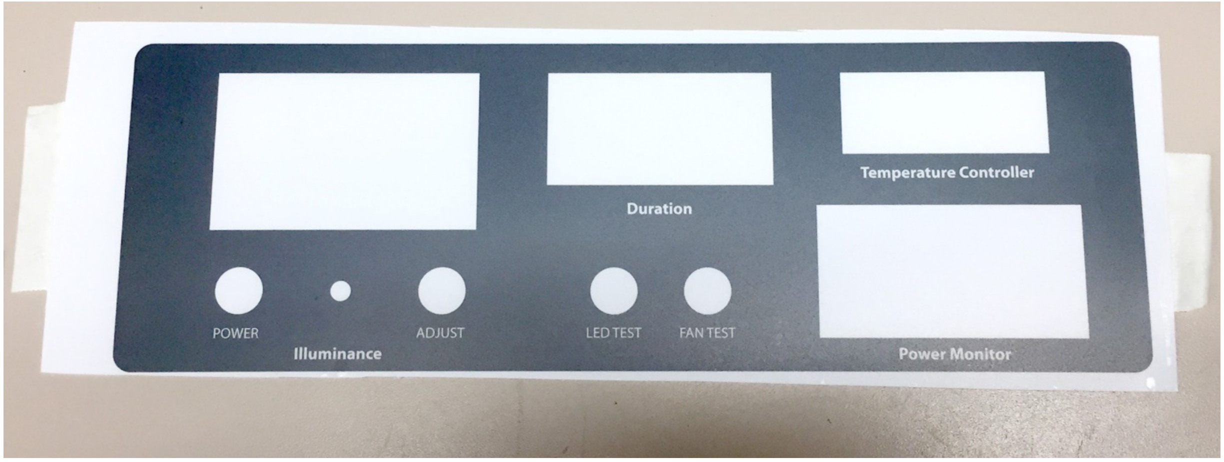


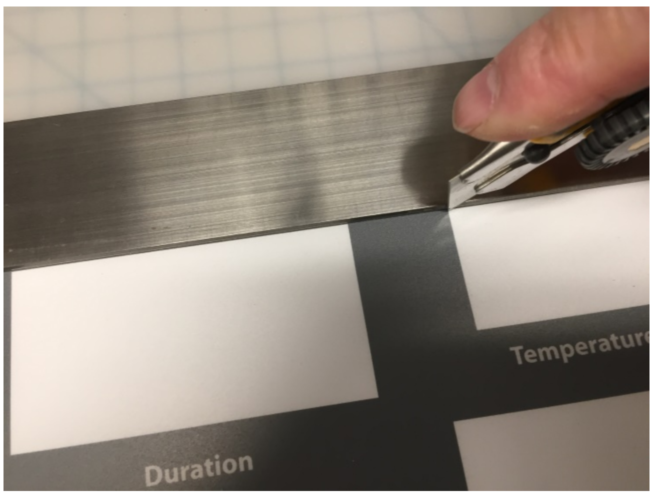
The fine air bubbles can be removed by burnishing the entire sheet from the front or back side with a tool as illustrated. The front surface should now look smooth and free of air.



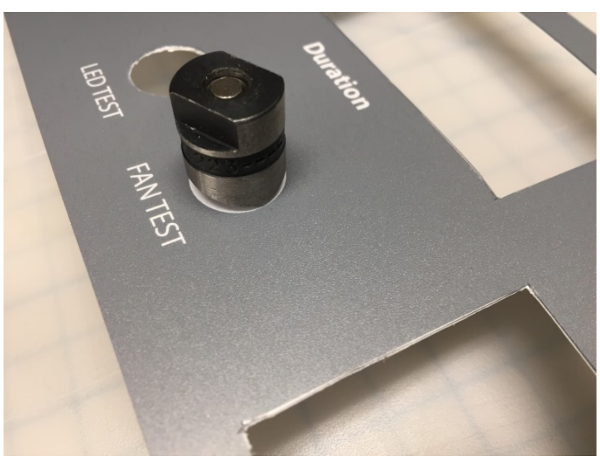


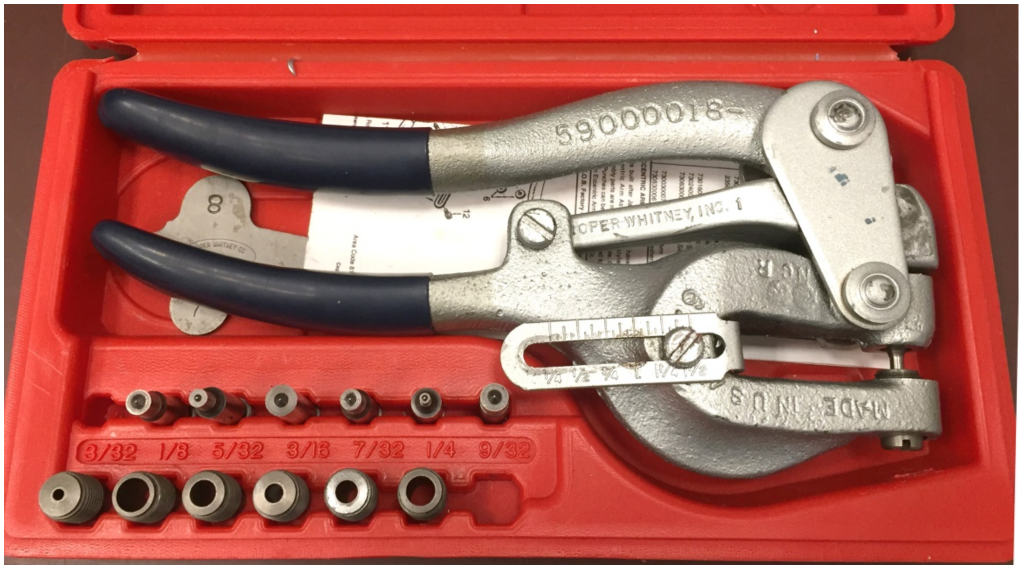
You now need to trim away the unwanted areas and border. You can use several tools to accomplish this. Simple trimming around the perimeter and inner rectangles can be done with a metal ruler and/or T-square. Tape down both the artwork and the metal ruler before cutting, and avoid over cuts. These can be avoided by first penetrating the polycarbonate at each end of the line ~mm (a simple plunge), with the blade direction being towards the center. Now make your cut in whichever direction you prefer, and stop your blade when you reach the previous plunge cut at the other end. Remember, the front side is polycarbonate, and the back is the back side you the photo paper.





Small circles can often be punched with a long reach hand paper punch, custom hand punches, and the Roper #5 hand punch tool. The latter has miniature punch and die sets. Greenlee (Emerson Electric) and others makes *chassis* punches (punch and die sets) in all sorts of shapes and sizes. Notice the side in which the punch is pulled *into* the die below by turning the wrench. The artwork side end can also be held with a wrench or a vise.

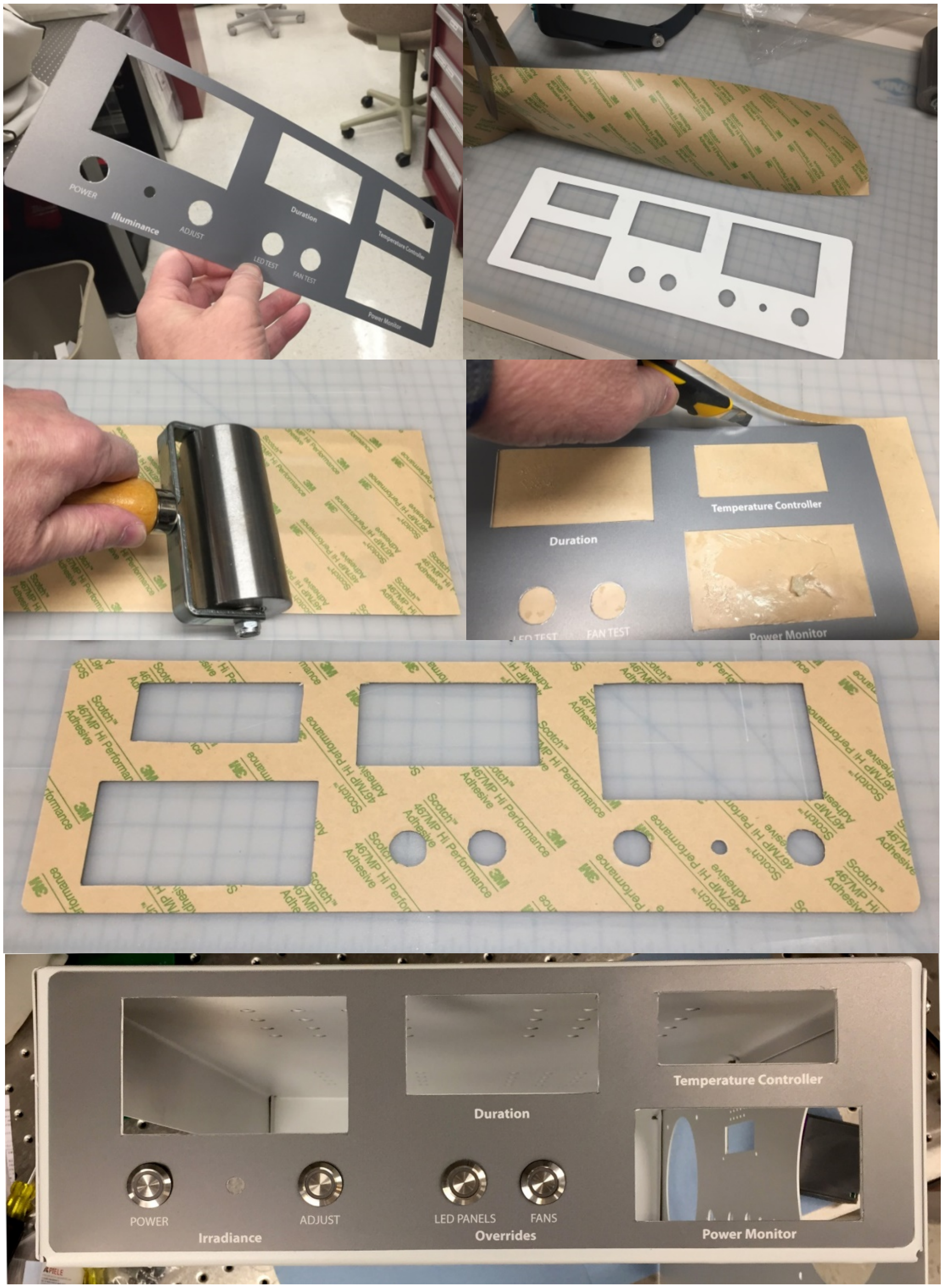




Roper Whitney #5 Punch & Die Set. Individual punches and dies are placed into the tool. The polycarbonate panel is then held between the punch and die, and the handles carefully squeezed together, creating the punched hole.

Precision Brand Punch & Die set. The punch is aligned in the top hole of the jig, over the area to be punched. The punch is firmly struck by the hammer driving it into a pre-aligned die hole below the polycarbonate, creating a clean hole.

Once all of the unwanted polycarbonate has been removed, apply the 3M mounting tape to the back surface, and roll smooth. Flip the artwork over and trim away excess adhesive areas with an X-Acto knife. The panel is then permanently applied to a cured painted surface.



Appendix A: Poster Presentation December 9, 2019

Vasospasm Treatment

BMEN 3151 *Medical Device Practicum*

Advisors: Steven Saliterman and Jerry Molitor
Team Members: Jen Churma, James Kerber, Brett Levac, and Kushal Sehgal

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.

A photo realistic rendering of the first iteration of the device which shall be used in the preliminary studies is as follows. This is a rendering of what we hope to produce for the preliminary studies. Special thanks to Professor Saliterman for this rendering.

Team Photo

Appendix B: Light Energy & Limits of Exposure

The limit for skin exposure at a wavelength of 453 nm, which considers the duration of the exposure, is the following energy density:*

$$500\ \frac{Joules\ (J)}{cm^2} = \frac{energy}{unit\ area}$$

Each PTD LED panel generates the maximum following energy flux:

$$3500\ \frac{milliwatt}{m^2} = 3.5\ \frac{Watt\ (W)}{m^2} = \frac{rate\ of\ energy\ transfer}{unit\ area}$$

and given,

$$1\ W = 1\ \frac{J}{s} \quad or \quad 1\ J = 1\ Ws, \quad and \quad 1\,\frac{W}{m^2} = 10^{-4}\,\frac{W}{cm^2}$$

then for a duration of e.g., 30 minutes, or 1800 seconds, the following is the energy density:

$$3.5\ \times 10^{-4}\,\frac{W}{cm^2} \times 1800\ s\ \times \frac{1\,J}{1\ Ws} = .630\,\frac{J}{cm^2}$$

which is well below the limit.

The exposure duration is set by an electronic timer on the console and is programmed in advance. Recalibration requires placing the machine in calibration mode, and uses of a physical key to access.

*Liebmann J, Born M, Kolb-Bachofen V. Blue-Light Irradiation Regulates Proliferation and Differentiation in Human Skin Cells. *J Invest Dermatol*. Jan 2010;130(1):259-269. doi:10.1038/jid.2009.19.

Appendix C: Gamma Scientific Spectroradiometer

MK350N Premium Handheld Spectroradiometer

The MK350N Premium is a lightweight, portable and easy-to-use spectral illuminance (lux) meter or spectral light meter. It is designed for fast and accurate illuminance measurements for general lighting and LED applications. Designed to be intuitive and user-friendly, it is ideal for measuring light parameters such as lux, CCT, CRI, CIE Chromaticity Coordinates, Ra, R1 to R15, wavelength and others. The device also includes an integrated flicker meter.

Precision, Power and Portability

In a Compact & Lightweight Package

With an intuitive, user-friendly interface, the MK350N Premium offers a dynamic range from 5 to 100,000 lux. The advanced CCD high-speed spectral sensor enables stable and accurate data capture in as little as 3 seconds.

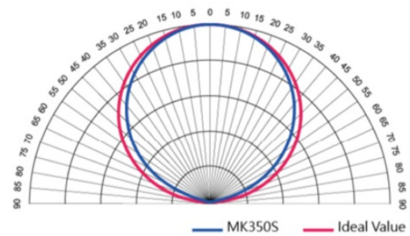
- Completely Stand-Alone Operation - no other equipment necessary (e.g., PC, Smartphone, etc.)
- More than 40 units of measurement
- Built-in file browser allows for quick access to previously saved data
- 3.5" color touch screen with intuitive menu selection
- Conforms to ISO 14001, JIS, DIN and IECQ standards
- Wi-Fi remote control option with IOS or Android applications
- Automatic continuous measurements with data-save to an SD card
- NIST Traceable calibration

contact@gamma-sci.com | +1.858.279.8034 | www.gamma-sci.com

Key Measurement Modes & Display Results

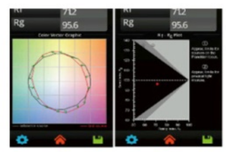
Integrated Cosine Receptor

The integrated cosine receptor is optimized to conform to both JIS AA and DIN B standards.



TM 30-15

This standard, developed by the Illuminating Engineering Society (IES) in 2015 provides for an accurate and consistent method of measuring lighting parameters such as CRI, GAI and CQS.



Rf (Color Fidelity)	0-100	80↑
Rg (Color Saturation)	0-140	80-120

Flicker

With a sampling rate of 100kHz, parameters such as Flicker percentage, Flicker Index and Stroboscopic Effect Visibility and Flicker Risk Mode can be accurately determined.

System Specifications		
Capture Function	One-time or continuous	
Operation Mode	Stand-alone, WiFi or USB (to PC, mobile device or tablet)	
Integration Mode	Auto or Manual	
Automatic Dark Calibration	Auto mode	
Measuring Modes	Basic CIE 1976 Chromaticity Browser Spectrum TM30-15 Option CRI Flicker CIE 1931 Chromaticity Frequency	
Measuring Capabilities	Light & Color Parameter	Illuminance (lux) or Foot-candle (FC) Correlated Color Temperature (K) CIE Chromaticity Coordinates CIE 1931 x,y CIE 1976 u', v' CIE 1931 XYZ ΔX, ΔY, ΔU', ΔV' Delta UV; DUV Dominant wavelength; Hue, λd (nm) Chroma Purity (%) Scotopic and Photopic ratio: S/P
	Light & Color Evaluation	Color Rendering Index (CRI, Ra) R1 to R15 Color Quality Scale (CQS) Gamut Area Index (GAI) TM-30-15 (Rf, Rg, Color Vector Graphic) Television Lighting Consistency Index (TLCI)
	Flicker	Flicker Frequency (Hz) Flicker Percentage (%) Flicker Index Stroboscopic Effect Visibility Measure (SVM)
	Spectral Radiation	Spectral Power Distribution (SPD) mW/m^2 Peak Wavelength (λp) nm Peak Wavelength Value (λpV) mW/m^2 Integration time (I-time) Scotopic and Photopic ratio (s/P)

MK350N Premium Handheld Spectroradiometer

GAMMA SCIENTIFIC

System Specifications		
Sensor	CMOS linear image sensor	
Wavelength Range	380 to 780 nm	
Wavelength Data Increment	1 nm	
Spectral Bandwidth	12 nm (half power bandwidth)	
Wavelength Reproducibility	± 1 nm (assumes stable input light source)	
Measurement Range	5 to 100,000 lux	
Illuminance[1] [From 0.05 to 5000 cd/m²]	Accuracy	± 5%
	Repeatability (2σ)	± 0.2% from 100 to 100,000 lux ± 0.5% from 5 to 100 lux
Color[1, 2]	Accuracy	x y: ± 0.002 from 100 to 100,000 lux x y: ± 0.0025 from 5 to 100 lux
	Repeatability	± 0.0005 in CIE 1931 x,y
	Repeatability (2σ)	x y: ± 0.0002 from 500 to 100,000 lux x y: ± 0.0004 from 30 to 500 lux x y: ± 0.001 from 5 to 30 lux
CCT Accuracy	± 2%	
CRI Accuracy at Ra	± 1.5%	
Stray Light	-25 dB maximum (550 ± 40nm monochromatic source)	
Integration Time Range	100 µsec to 1 sec	
Digital Resolution	16 bitv	

Flicker	
Measurement Range	5 to 100,000 lux
Sampling Rate	100 kHz
Frequency Range	5 to 50 kHz
Frequency Resolution	2, 4, 8, 16, 32 Hz
Flicker Accuracy	± 5%

System Configuration	
Display	320 x 240 (3.5 in) resistive touch LCD
Maximum Files	68,000 with 8 GB SD card, compatible with Excel® and JPG
Battery Operation	Up to 5 hours, onboard 3.7 V Li-ion
External Power	Adapter (included), 2500mAh via USB connector
Data Interface	SD card (SD2.0.SDHC up to 32 GB) or mini USB port (USB 2.0) or WiFi SD card (IOS or Android)
Dimensions	148 mm (5.9 in) H x 78 mm (3.1 in) W x 24 mm (.95 in) D 225 g (0.5 lbs) including battery
Language Options	English, Traditional Chinese, Simplified Chinese, Japanese, Spanish, German, French, Italian, Russian
Camera Resolution	2M pixels

[1] At 23 ± 2° C and relative humidity ≤ 50%
[2] Illuminant A at 2,856 K at 20,000 lux
[3] 0 Hz AC/DC 10% sine wave unless otherwise specified

Specifications are subject to change without notice.

Rev 08.08.19

CE

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Appendix D: Omega Thermocouple Wire Chart

Thermocouple Wire

Duplex Insulated

OMEGA™

K — Duplex Insulated CHROMEGA™-ALOMEGA™ Duplex ANSI Type K

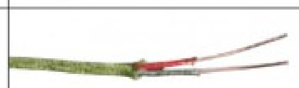
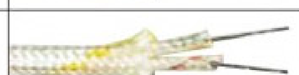
ANSI Color Code: Positive Wire, Yellow; Negative Wire, Red; Overall, Brown

ANSI color code shown | To order IEC color code visit us online

Insulation	AWG No.	Model Number	Type Wire	Insulation		Max. Temp		Nominal Size mm (inch)	Wt.† kg/300 m (lb/1000')
				Conductor	Overall	°C	°F		
Ceramic*	14	**XC-K-14**	Solid	None	None	1090	2000	3.6 x 5.0 (0.140 x 0.200)	18 (38)
	20	**XC-K-20**	Solid			980	1800	3.4 x 4.8 (0.135 x 0.190)	8 (16)
	20	**XT-K-20**	Solid			980	1800	2.7 x 3.9 (0.105 x 0.155)	7 (15)
	24	**XC-K-24**	Solid			870	1600	2.9 x 4.4 (0.115 x 0.175)	6 (12)
	24	**XT-K-24**	Solid			870	1600	2.2 x 3.4 (0.088 x 0.132)	5 (11)
Vitreous Silica*	20	**XR-K-20**	Solid	Refrasil	Refrasil	870	1600	2.9 x 4.6 (0.115 x 0.180)	6 (14)
Silica*	14	**XS-K-14**	Solid	Silica	Silica	1090	2000	3.6 x 5.0 (0.140 x 0.200)	16 (35)
	20	**XS-K-20**	Solid			980	1800	2.7 x 3.9 (0.105 x 0.155)	6 (12)
	24	**XS-K-24**	Solid			870	1600	2.2 x 3.4 (0.088 x 0.132)	5 (10)
High Temp. Glass**	20	**HH-K-20**	Solid	High Temp Glass	High Temp Glass	704	1300	1.5 x 2.7 (0.060 x 0.105)	4 (9)
	24	**HH-K-24**	Solid			704	1300	1.4 x 2.3 (0.055 x 0.090)	3 (5)
Glass	20	**GG-K-20**	Solid	Glass Braid	Glass Braid	482	900	1.5 x 2.1 (0.060 x 0.095)	4 (9)
	20S	**GG-K-20S**	7 x 28	Glass Braid		482	900	1.5 x 2.5 (0.060 x 0.100)	4 (9)
	24	**GG-K-24**	Solid	Glass Braid		482	900	1.3 x 2.0 (0.050 x 0.080)	3 (5)
	24S	**GG-K-24S**	7 x 32	Glass Braid		482	900	1.3 x 2.2 (0.050 x 0.085)	3 (5)
	26	**GG-K-26**	Solid	Glass Wrap		482	900	1.1 x 1.9 (0.045 x 0.075)	2 (4)
	28	**GG-K-28**	Solid	Glass Wrap		482	900	1.0 x 1.4 (0.040 x 0.055)	2 (3)
	30	**GG-K-30**	Solid	Glass Wrap		482	900	0.9 x 1.3 (0.037 x 0.050)	2 (3)
	36	**GG-K-36**	Solid	Glass Wrap		482	900	0.8 x 1.1 (0.033 x 0.045)	1 (2)
Glass with Stainless Steel Overbraid	20	**GG-K-20-SB**	Solid	Glass	Stainless Steel Braid over Glass	482	900	2.3 x 3.0 (0.090 x 0.120)	6 (14)
	20S	**GG-K-20S-SB**	7 x 28			482	900	2.3 x 3.2 (0.090 x 0.127)	7 (15)
	24	**GG-K-24-SB**	Solid			482	900	2.2 x 3.0 (0.085 x 0.117)	5 (11)
	24S	**GG-K-24S-SB**	7 x 32			482	900	2.0 x 2.8 (0.080 x 0.110)	5 (11)
Kapton Fused Polymide Tape	20	**KK-K-20**	Solid	Fused Polymide Tape	Fused Polymide Tape	260	500	1.5 x 2.5 (0.060 x 0.100)	5 (11)
	20S	**KK-K-20S**	7 x 28			260	500	1.5 x 2.7 (0.060 x 0.105)	5 (11)
	24	**KK-K-24**	Solid			260	500	1.3 x 1.9 (0.050 x 0.075)	3 (6)
	24S	**KK-K-24S**	7 x 32			260	500	1.3 x 2.2 (0.050 x 0.085)	3 (6)
	30	**KK-K-30**	Solid			260	500	0.6 x 1.1 (0.026 x 0.044)	3 (5)
PFA Glass	30	**TG-K-30**	Solid	PFA	Glass Braid	260	500	0.9 x 1.2 (0.034 x 0.047)	1 (2)
	36	**TG-K-36**	Solid			260	500	0.7 x 1.0 (0.028 x 0.038)	1 (2)
	40	**TG-K-40**	Solid			260	500	0.7 x 0.9 (0.026 x 0.035)	1 (2)
Neoflon PFA (High Perfomance)	20	**TT-K-20**	Solid	PFA	PFA	260	500	1.7 x 3.0 (0.068 x 0.116)	5 (11)
	20	**TT-K-20S**	7 x 28			260	500	1.9 x 3.2 (0.073 x 0.126)	5 (11)
	22	**TT-K-22S**	7 x 30			260	500	1.7 x 3.4 (0.065 x 0.133)	4 (9)
	24	**TT-K-24**	Solid			260	500	1.4 x 2.4 (0.056 x 0.093)	3 (6)
	24	**TT-K-24S**	7 x 32			260	500	1.6 x 2.6 (0.063 x 0.102)	3 (6)
	30	**TT-K-30††**	Solid			260	500	0.6 x 1.0 (0.024 x 0.040)	1 (2)
	36	**TT-K-36††**	Solid			260	500	0.5 x 0.8 (0.019 x 0.030)	1 (2)
	40	**TT-K-40††**	Solid			260	500	0.4 x 0.7 (0.017 x 0.026)	1 (2)
PFA Polymer w/Twisted and Shielded Conductors	20	**TT-K-20-TWSH**	Solid	PFA Polymer	PFA Polymer and Shielding	260	500	3.7 (0.15)	9 (20)
	20S	**TT-K-20S-TWSH**	7 x 28			260	500	3.8 (0.15)	9 (20)
	24	**TT-K-24-TWSH**	Solid			260	500	2.7 (0.11)	4 (9)
	24S	**TT-K-24S-TWSH**	7 x 32			260	500	2.9 (0.12)	4 (9)
Neoflon FEP	20	**FF-K-20**	Solid	FEP	FEP	200	392	1.7 x 3.0 (0.068 x 0.116)	5 (11)
	24	**FF-K-24**	Solid			200	392	1.7 x 3.0 (0.056 x 0.092)	3 (6)
FEP Polymer w/Twisted and Shielded Conductors	20	**FF-K-20-TWSH**	Solid	FEP Polymer	FEP Polymer and Shielding	200	392	3.7 (0.15)	9 (20)
	20S	**FF-K-20S-TWSH**	7 x 28			200	392	3.8 (0.15)	9 (20)
	24	**FF-K-24-TWSH**	Solid			200	392	2.7 (0.11)	4 (9)
	24S	**FF-K-24S-TWSH**	7 x 32			200	392	2.9 (0.12)	4 (9)
TFE Tape Polymer	20	**TFE-K-20**	Solid	TFE Tape Polymer	Fused TFE Tape Polymer	260	500	1.5 x 2.5 (0.060 x 0.100)	5 (11)
	20S	**TFE-K-20S**	7 x 28			260	500	1.5 x 2.7 (0.060 x 0.105)	5 (11)
	24	**TFE-K-24**	Solid			260	500	1.3 x 1.9 (0.050 x 0.075)	3 (6)
	24S	**TFE-K-24S**	7 x 32			260	500	1.3 x 2.2 (0.050 x 0.085)	3 (6)
Polyvinyl	24	**PR-K-24**	Solid	Polyvinyl	(Rip Cord)*** (Polyvinyl)	105	221	1.4 x 2.3 (0.050 x 0.086)	3 (5)
	24	**PP-K-24S**	7 x 32			105	221	2.0 x 3.4 (0.082 x 0.134)	3 (5)

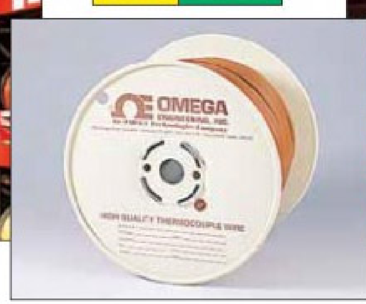
† Weight of spool and wire rounded to the next highest kg (lb) (does not include packing material). *†† Overall color clear.*
*††† To order special limits of error wire, add **"-SLE"** to model number before spool length.* ** Has color tracers on jacket and conductors.*
*** HH Wire has trace thread in positive leg, negative leg is red, overall has trace thread.* **** Two insulated leads bonded together, but with no overwrap.*
Additional Type K insulated wires are available. See Fused Tape Insulated TFE-K and KK-K Series.
***Ordering Example: XC-K-20-SLE-1000,** 1000' (300 m) of Type K duplex insulated special limits of error thermocouple wire.*

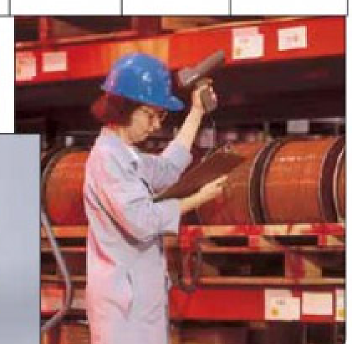
Wire Insulation Identification

Insulation Code	Insulation		Appearance of Thermocouple Grade Wire	Temperature Range, Insulation	Abrasion Resistance	Flexibility	Water Submersion
	Overall	Conductors					
PP (Extension Grade-EXPP)	Polyvinyl Chloride (PVC)	Polyvinyl Chloride (PVC)		-40 to 105°C -40 to 221°F	Good	Excellent	Good
FF (Extension Grade-EXFF)	FEP or Neoflon	FEP or Neoflon		-200 to 200°C -338 to 392°F	Excellent	Good	Excellent
TT (Extension Grade-EXTT)	PFA or Neoflon	PFA or Neoflon		-267 to 260°C -450 to 500°F	Excellent	Good	Excellent
KK	Kapton	Kapton		-267 to 260°C -450 to 500°F	Excellent	Good	Good
TG	Glass Braid	PFA or Neoflon		-73 to 260°C -100 to 500°F	Good	Good	Excellent
GG (Extension Grade-EXGG)	Glass Braid	Glass Braid		-73 to 482°C -100 to 900°F	Poor	Good	Poor
HH	High Temp Glass Braid	High Temp Glass Braid		-73 to 871°C -100 to 1300°F	Poor	Good	Poor
XR	Refrasil Braid	Refrasil Braid		-73 to 871°C -100 to 1600°F	Poor	Good to 315°C (600°F)	Poor to 315°C (600°F)
XC Standard Braid XL-Loose Braid XT-Tight Braid	Nextel Braid	Nextel Braid		-73 to 1204°C -100 to 2200°F	Poor	Good	Poor
XS	Silica	Silica		-73 to 1038°C -100 to 1990°F	Poor	Good	Poor
TFE	TFE	TFE		-267 to 260°C -450 to 500°F	Excellent	Good	Excellent

ANSI color code shown

To order IEC color code visit us online





H-5

Appendix E: DCC Thermocouple Welder Brochure

Search Catalog: By Keyword Go

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DCC Corporation

VIEW PRODUCTS

- HotSpot I Thermocouple Welder
- HotSpot II Thermocouple Welder
- HotSpot PLUS Capacitive Discharge Stud & Thermocouple Welder
- Welder Expansion Kits
- Welder Accessories
- Thermocouple Wire
- HotSpot Users

HotSpot *PLUS* Capacitive Discharge Stud & Thermocouple Welder

See Video

Buy Now

The HotSpot *PLUS* is the newest member of DCC's HotSpot Capacitive Discharge line. It offers the latest electronic design in DCC's welder family. Several convenience, reliability, and safety improvements were incorporated in the newest welder. The power ratings of critical components have been significantly increased, welding initiation control was added to the handheld tool holder, multiple operations are faster, and no stored energy is released until the welding elements are in contact.

The HotSpot *PLUS* doubles the power range of the HotSpot series and offers several fixturing and welding attachments to facilitate simple spot welding, stud welding, and pin welding modes. In addition, the HotSpot *PLUS* provides standard and heavy wire thermocouple welding functions.

The HotSpot *PLUS* is designed to handle the attachment of heavy wires, light gauge studs and weldable pins to metal surfaces. It can also close larger tubes than the HotSpot II unit and aid in wire harness strap spot welding and insulation blanket installation. Its controllable weld energy capability matches the needs of strain gauge attachment applications.

QUICK ACTION The HotSpot *PLUS* is light and portable so you can move it right to where you need to make welds, fixture hardware, and attach thermocouples. The actual welding time is a fraction of a second and the short recycle interval, even at full power, will allow you to make 6 or more welds a minute, even quicker for ordinary gauge thermocouples.

EASY-TO-USE Anyone can quickly become proficient in the use of the HotSpot *PLUS*. While sophisticated internally, the HotSpot *PLUS* provides the operator with a firing button and simple on/off and energy level adjustment. The dual capability of pin and thermocouple welding makes the HotSpot *PLUS* particularly attractive for applications currently employing stud welders and thermocouple attachment units.

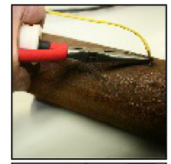
FLEXIBLE The HotSpot *PLUS* welder is a dual range high-energy unit that has the versatility to provide fine control as well as the high power capability needed for heavier welds. Front panel indicators and controls allow the operator to easily monitor the status, set the energy level, and initiate a weld cycle. A remote firing switch is also provided on the attachment handle.

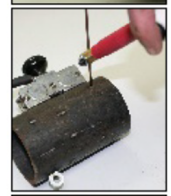
The HotSpot *PLUS* operates only from AC power. A battery-powered version of the unit is not offered but it can be driven by a low power battery to AC converter. It weighs only 18 lbs. and it's compact design makes it a very portable package.

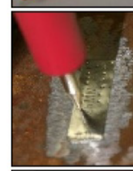
HotSpot *PLUS* Specification & Price List

SIZE - 3.5" High, 8.5" Deep, 11.5" Wide (less handle)

WEIGHT-18 Pounds







STORED WELD ENERGY - 5 to 525 Watt seconds
WELD CAPABILITY - Welds up to #10 studs, #10 pins, and #12 gauge wire pairs
CYCLE TIME - Charging time at maximum energy setting is less than 10 seconds
CONTROLS - Provides energy adjustment control, 2 position energy range switch, on/off ac power switch, and LED displays to indicate charging and energy storage status.
POWER - Uses 120 VAC 60 Hz line power (220 VAC 50 Hz optional) Circuit protected by 1.5 Amp line breaker

CONTROLS, INDICATORS, TOOLS and OVERLOAD PROTECTION

The **HotSpot *PLUS*** is powered from the AC line through an isolation transformer and stored energy level circuitry. Front panel indicators and controls allow the operator to easily monitor the status of the unit, determine the level of energy to be transferred to the storage capacitors, and initiate a weld cycle. The maximum power output of the **HotSpot*PLUS*** is approximately 500 Joules. The power level is set by the position of the front panel control knob. The power ranges, high or low, are selected by a two position toggle switch. Initiation of the welding discharge is controlled by a front panel snap action push button switch, a similar companion switch on the hand tool accessory holder, or an optional foot switch.

The power range switch and energy level control set the voltage to which the energy storage capacitors are charged. Peak voltage on the low range is approximately 35 VDC and on the high range 75 VDC. The stored energy is proportional to the square of the capacitor voltage. Increasing the setting of the control knob will cause the capacitor to be charged to a higher level. However, decreasing the setting will not immediately reduce the value already stored, so a welding cycle will always release an energy pulse equal to the highest power setting since the last recent discharge. A resettable circuit breaker in the primary AC line is accessible on the unit's back panel and protects against damage from internal circuit shorts and similar fault conditions.

A handheld tool control assembly and included cable are available for attaching the standard welding pliers and other optional specialized tools.

Click Here **for larger images of the available attachments (pin welder, spot welder, stud welder and foot switch attachments).**

* * * * * * * *

HotSpot *PLUS* Power and Energy Level Control Unit **(525 Watt Sec.)**.....$ 1,399.95 each
Price Includes: Eye Shielding Protective Goggles, Carbon Block, Grounding Magnet, Instruction Booklet, Attachment Cable with Handheld Control Assembly & Pliers.

Spot Welding Attachment Tool..$ 79.00 each

Stud Welding Attachment Tool (collet not included)..............................$ 79.00 each

Insul Pin #10 Attachment Tool..$ 100.00 each

Insul Pin #12 Attachment Tool..$ 100.00 each

Spot Welding Tips pk of 6 ....$ 29.95 each

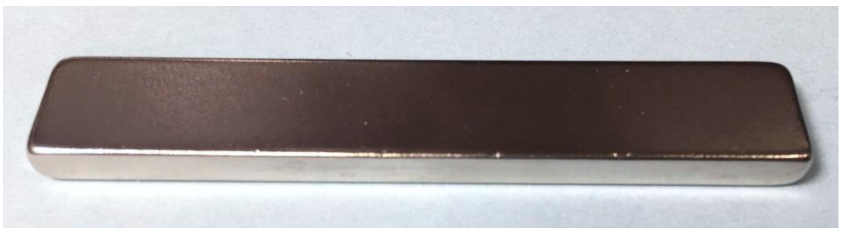
HotSpot PLUS Welding Pliers..$ 54.95 each

Foot Switch and 12' connecting cable ....$ 67.95 each

DCC Corporation | 7250-B Westfield Ave. Lower Level | Pennsauken, NJ 08110 | 856-662-7272

Appendix F: Magnets & Adhesive

Rare Earth Neodymium N48 Bar-Block Magnet (60 x 10 x 4 mm) with Countersinks



Rare Earth Neodymium N48 Bar-Block Magnet (60 x 10 x 4 mm)

Rare Earth Neodymium N48 Bar-Block Magnet (60 x 10 x 3 mm)

Loctite Liquid Professional Super Glue is used for magnets, vinyl and neoprene sheet materials (to PLA parts).

Disc magnets 12 mm x 6 mm (1/2" dia. x 1/4" thick) are used to latch the *Calibrator* front door.

Neoprene Sheet 1/32” or 1/64” is used to cover magnet areas.

Appendix G: Omega RDXL6SD-USB Certificate of Calibration

OMEGA™

Certificate of Calibration

for

UNIVERSITY OF MINNESOTA

Customer PO: **0001896883** **Model #:** **RDXL6SD-USB**

Report #: **HC00801397** **Cal-3** **Serial #:** **0102-001803**

Omega Engineering, Inc. hereby certifies that the above instrumentation has been calibrated and tested to meet or exceed the published specifications. This calibration and testing was performed using instrumentation and standards that are traceable to the National Institute of Standards and Technology. Omega Engineering, Inc. is in compliance with ISO 9001, ISO 10012-1, and ANSI/NCSL Z540-1-1994. This certificate shall not be reproduced, except in full, without the written consent of Omega Engineering, Inc.

* Indicates Out Of Tolerance Condition

Accuracy of UUT: SEE MANUAL

Range	Standard	As Found	As Left
TC-K °C Ch1	-95	-94.9	-94.9
	0	-0.1	-0.1
	1360	1361	1361
TC-K °C Ch2	-95	-94.9	-94.9
	0	0.0	0.0
	1360	1361	1361
TC-K °C Ch3	-95	-94.9	-94.9
	0	0.0	0.0
	1360	1361	1361
TC-K °C Ch4	-95	-94.7	-94.7
	0	0.2	0.2
	1360	1361	1361
Pt100 Ch5	-100	-99.8	-99.8
	800	800.7	800.7
Pt100 Ch5	-100	-99.8	-99.8
	800	800.8	800.8

Max calibration System Uncertainty : 8 ppm (DC), ± 0.01%(ohms), ± 0.1°C

Calibration Standards	**NIST Test #**	**Control #**	**Cal Due:**
Omega CL525	10NNCL10209	CL-102-09	10/29/2020
IET Labs HARS-X-6-0.01 Decade Box	10NNRE09814	RE-098-14	2/22/2021

Test Conditions : Temp 22°C, ± 5°C RH Below 80% **Procedure: QAP-2100**

Accepted By: [signature] **Lab Representative** **Certified by:** [signature] **Technician** **Date:** 2/17/2020

Due Date: 2/17/2021

Page 1 of 1

OMEGA Engineering, Inc. | Pureland Industrial Park | One Omega Circle | Swedesboro, NJ 08085

omega.com

WCS-0638A_rev0218

Appendix H: Boost Converter Specifications

The WHDTS (or DROK) 5A DC 11 V-50 V LCD adjustable constant voltage, constant current, step-up power supply module can display input/output voltage, current, power and display status with high definition. It can adjust stable output voltage and current.

This converter module can be used as A Boost Power Supply Module w/Overcurrent Protection and also A Simple Charger, efficient and practical.

Applications:
1) Boost power supply module
2) Battery charger
3) Instrument voltage display
4) Test meter
5) Circuit test
6) Power conversion

Parameters:
Size w/Shell: 3.14 x 2 x 1.5 in
Working Voltage & Current: DC 9V-45 V; 30 mA
Output Voltage: DC 11-50 V
Output Current: 5A (Disabled output if more than 5A)
Output Power: 90W (Disabled output if more than 90W)
Voltage Display Range: 0~50 V
Voltage Display Precision: ±0.3 V
Voltage Display Resolution: 0.05 V
Current Display Range: 0 - 5A Current Display
Resolution: ±0.1 A
Current Display Precision: 0.005 A
Conversion Efficiency: About 96%
Short Protection: Yes
Anti-reverse Protection: Yes
Anti-back-flow Protection: Yes
Working Temperature Range: 20°C ~ 85°C
Working Humidity Range: 0% ~ 95% RH

Package Includes:
1x 5A Step Up Power Supply Module 1x Heat Sink
2 x Acrylic covers
2 x Black button cap
4 x M3 x 25 mm copper standoff
4 x M3 x 8+6 mm copper standoff
8 x M3 x 5 mm screw

Alarm Interface Error Reports:

1 >. "Err": Output voltage is lower than input voltage.
2>. "OP": Overload output power alarm(>90W)
3>. "OU": Overload output voltage alarm(>SOV)
4>. "OC": Overload output current alarm(>SA)

To set default output to "ON", hold "SET" for three seconds. Then press "SET" to cycle through the options until you get to the screen where the "OFF" on the left is flashing. Press the "UP" or "DOWN" button to change it too "ON". Hold down "SET" for an additional 3 seconds to save settings.

Appendix I: Blue LED Panel Specifications

Power Supply Requirement: AC 85-265 V, 50/60 Hz

Input Current: 0.4 A max

Output Voltage: DC 18-55 V

Output Current: 500 mA ± 5%

Adaptor Power Conversion Rate: PF>0.95

Power: 22 W

LED Quantity: 225 pcs

Lumen: 29271 m

Wavelength: 450 nm (Blue)

LEDs Type: SMD2835

Power Cord Length: 59" (1.5 m)

Light Panel Size (L x W x H): 11 5/16" x 11 5/16" x 3/16" (28.8 x 28.8 x 0.418 cm)

Lifespan: more than 50,000 hours

Working Temperature: -10 to 50° Celsius (14-to-122-degree Fahrenheit)

Working Humidity: less than 95%

(Also see separate the **Calibrator for the LED Panels** section and **DROK Boost Converter Specifications.)**