D.I.Y. Clean Hood

Sponsor: Dr. Ben Hawkins, Department of Biomedical Engineering

A Senior Project
Presented to
the Faculty of the Biomedical Engineering Department
California Polytechnic State University, San Luis Obispo

In Partial Fulfillment
of the Requirements for the Degree
Bachelor of Science, Biomedical Engineering

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Executive Summary

The DIY Clean Hood is a low-cost, sterile, and accessible scientific workspace intended for installation in the BioElectroFluidics Lab of California Polytechnic State University's (San Luis Obispo) Biomedical Engineering Department (BMED), under the sponsorship of Dr. Benjamin Hawkins, PhD. As normal Clean Hood, Biosafety Cabinets, and the like are generally too expensive for a university, a competitive solution to an expensive problem can assist research students and professors alike continue their own work with an inexpensive yet effective environment.

Specific design elements that the customer requirements entailed for the project include a low-particle-count air filtration system, positive pressure air flow inside the vessel, and compatibility with common cleaning agents. These critical details for the DIY Clean Hood are to ensure that the cell cultures being cultivated and studied are free from any foreign contaminants or agents that could compromise the product. Unlike the original, mislabeled identification of the project as a "DIY Biosafety Cabinet", it is not the responsibility of the Clean Hood to protect either the environment or the user of the DIY Clean Hood. Despite the non-hazardous conditions of the cells being manipulated, proper design components and features ensure sterility and effectiveness. Other notable design elements of the DIY Clean Hood include a 15 degree angled, swinging sash opening, an air filtration system utilizing a HEPA (High-Efficiency Particulate Air) filter, an installed UV light for an additional sterilization option, and a wide opening for comfortable mobility while using the Clean Hood. The project was a recipient of the Biomedical Engineering Department's Hannah-Forbes Grant, which allows the DIY Clean Hood project an additional $500 towards any necessary purchases and bringing the total budget to $700.

Due to the onset of the COVID-19 pandemic, the project required its focus to shift from a manufacturing and qualification testing standpoint to a more design and technically-centered frame, as several factors prevented the project from proceeding originally as planned. These included, but were not limited to, the closure of manufacturing and assembly facilities on the Cal Poly campus, anticipated delays in material acquisition due to non-essential items, social distancing of team members, and limited alternative build options. This decision was agreed upon in correspondence with project sponsor Dr. Hawkins, Engineering Design overseer Dr. Michael Whitt, and the members of the DIY Clean Hood Team.

As a result, the DIY Clean Hood prepared a final, detailed design for the product to ensure all customer requirements were met in approaches the team thought would provide the best performance and usability; the BioElectroFluidics lab will find a team of their own in late 2020 to build the device using the enclosed detailed designs, and qualify the product with the DIY Clean Hood's testing protocols.

Statement of Work

This Statement of Work (SOW) is between the DIY Clean Hood Team (formerly known as the Biosafety Cabinet Team), Dr. Benjamin Hawkins and the BioElectroFluidics research team. It outlines the DIY Clean Hood Team's long term goals and how they will be fulfilled in a timely manner.

Effective as of **02/03/2020**. Modified **03/08/2020**.

Introduction

The BioElectroFluidics research team at Cal Poly San Luis Obispo is currently developing cell cultures in dishes filled with an agar medium. The cells are incubated in an adjacent facility with a sterile environment; however, there is currently no sterile workspace available for the team to seed the cells and work with them past the incubation period. The DIY Clean Hood Team will address the current lack of a necessary workspace in the BMED department.

Background

Customer Meeting

To establish a working background knowledge of the aims and vision from our sponsor, Dr. Ben Hawkins from the Department of Biomedical Engineering, an initial meeting was scheduled. Our sponsor's initial vision for the project can be seen below in **Figure 1**. The project sponsor has clearly requested that the DIY Clean Hood creates a workspace with a low air particulate count via a positive pressure space inside the cabinet, inhibiting airflow into the device from under the sash. The sponsor has also stated that a HEPA (High Efficiency Particulate Air) filter would be favorable, but not necessary with respect to budget constraints. The sponsor has stated that an internal UV lamp would be nice for post-operation sterilization, but at the minimum the device should be compatible with cleaning materials that use bleach and ethanol. Additionally, the DIY Clean Hood Team was asked to explore the possibility of an angled sash for easier operation.

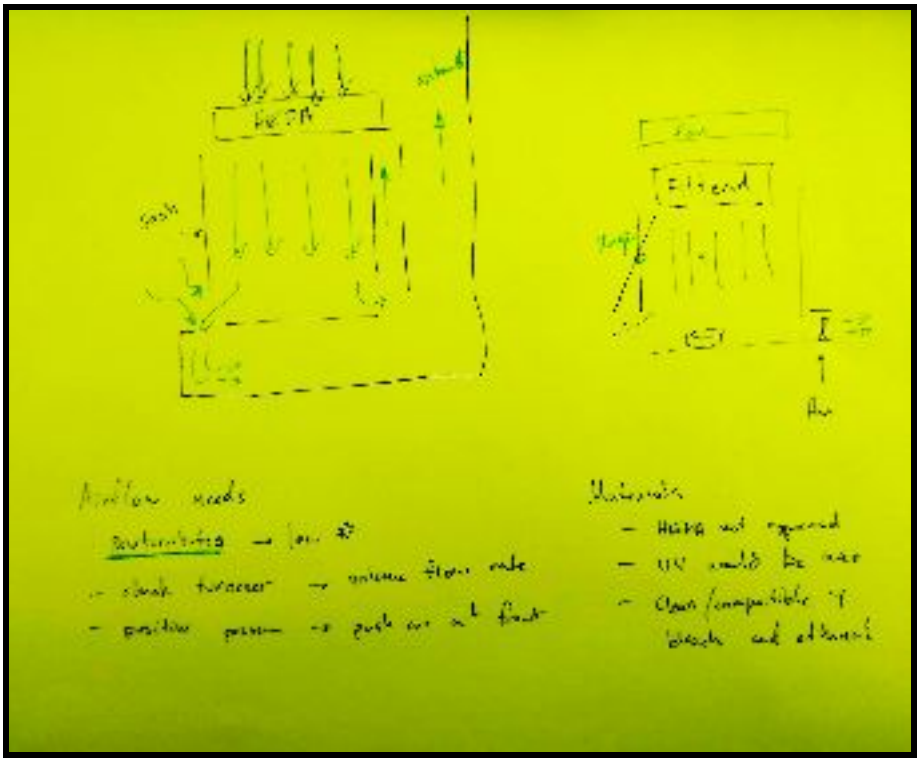


Figure 1. Client Vision for the DIY Clean Hood Project. The project sponsor's functional/material requirements and desired capabilities.

To obtain background information on existing products, an extensive search of existing cabinets, clean hoods, and their features was performed and can be seen below in **Table I**. A patent search was also performed for much of the same purpose, and can be seen below in **Table II**.

Table I. Current Competitors Along with Defining Characteristics.

Manufacturer Name	Description
Nuaire's LabGard ES NU-540 Class II , Type A2 Biosafety Cabinet	● Utilizes Unidirectional Laminar Airflow. ● Uses 105 fpm inflow under the sash to protect the user ● Lowered work space for spill protection and ease of use ● Features: Digital Pressure Monitor, Energy Saving Mode, High Efficiency ECM Motor
Labogene's Class II "Mars" BioSafety Cabinet (A-1)	● Class 2 designated workspace possessing a HEPA dual air filtration system ● Positive pressure within the system, the cabinet (as outlined in A-1) draws air through the front aperture of the system, thereby sending it through the HEPA filters, where 30% of the filtered air will be exhausted and 70% will be blown into the workspace ● Possesses a noise-reduction system as to minimize the fan volume and technical noise from the cabinet system ● Glass panel and air system, are designed to protect the operator and the environment; angled front glass panel.
Thermo Scientific™ 1300 Series Class II, Type A2 Biological Safety Cabinet	● Reduces operating costs up to 75% over traditional biological safety cabinets with AC motors ● Real-time airflow adjustments ensure inflow and downflow velocities remain steady. ● Includes UV light for sterilization
Germfree's Class II Type A Biosafety Cabinets	● Removes organisms and particulates 0.3 micron in size with an efficiency of 99.99% ● Recirculates 70% of the air through a HEPA filter ● 100% stainless steel frame for durability and corrosion resistance

Thomas Scientific Labconco Purifier Logic Class II A2 Biosafety Cabinet (A-2)	● 10* angled sash ● Utilizes HEPA filtration system to protect users, environment, and products. Displays HEPA remaining filter life, Quality of Life information panels, and more. ● Possesses an internal UV lamp for sterilization (subject to user preference) ● Many models with different accessory arrangements, designed to match a specific lab arrangement or customer preference.

Table II. Related Patents Followed by Brief Description.

Patent No.	Description
62009036	A cabinet with capabilities of monitoring internal UV intensity/atmospheric conditions.
14249693	A cabinet with versatile ventilation cabilities (variable fan speed)
20100267321	Utilizes a sensor of do detect openings in the cabinet and automatically turn on/off the motor
9144910	Allows for greater user mobility by incorporating smaller windows on the sash that gloves can fit through
9095802	Allows for access to filter through workspace

Existing Literature

A literature search was performed, and bullet point summaries of the main features and conclusions obtained from these papers can be seen below. Full references of each of the papers described can be seen at the end of the Statement of Work.

"Evaluating Containment Effectiveness of A2 and B2 biological safety cabinets" (Taylor, et al.)

- Researchers were trying to determine if an A2 biological safety cabinet could minimize contaminants and filter workspace air as effectively as a B2 biological safety cabinet. B2 cabinets are used for the handling of stable, volatile compounds and materials; the A2 cabinet was explored to see if it too would be able to handle the same category of operable material.

- Design of Experiments called for 5 trials (3 testing the prequalification capabilities, and 2 testing the containment capabilities), with the containment capabilities being trialed with tracer gas testing and "cyclophosphamide sampling during sterile compounding of the drug material".
- Results were that the A2 cabinet demonstrated satisfactory ability in containing the tracer gas and cyclophosphamide, and concluded that the A2 could be a suitable alternative to B2 biosafety cabinets.

"The Effects of Ultraviolet Light on Bacteria Suspended in Air" (Sharp)

- Researchers were trying to determine the effects of UV lighting on bacteria suspended in the air. This comes after previous research on the use of short wave UV lighting during surgical operations.
- It was found that bacterial growth could be modeled as a function of UV light intensity. The specific intensity needed to completely inhibit growth depended on the type of bacteria (staph required less energy than E-coli).
- The light exposure time remained constant at 1.06 seconds for all of the tests.

Use of Ultraviolet Lights in Biological Safety Cabinets: A Contrarian View(Meechan, et al)

- Researchers explored the negative/positive claims about the effects of Ultraviolet lights in biological safety cabinets with respect to the user and the biological specimen.
- They determined that bacterial mutation to a completely uv resistant phenotype is impossible
- UV lamps were found to be advantageous in that they left no physical residue unlike some chemical disinfectants
- UV lamps are not an effective measure for disinfecting the exterior of the cabinet.
- Chemical disinfectants take significantly longer than their UV counterparts (10 minutes vs <2 sec).
- UV lamps risk damaging specimens and the user if misused; however, many cabinets have failsafe mechanisms to prevent this from happening.

Comparison of Decontamination Efficacy of Cleaning Solutions on a Biological Safety Cabinet Workbench Contaminated by Cyclophosphamide (Ade, et al)

- Previous studies had shown that while the surface of biosafety cabinets had been satisfactory in reducing contaminant levels, no studies were able to completely remove any residual traces of contaminant cyclophosphamide.
- 2 cabinets (class II, type B2) were contaminated in three spots with cyclophosphamide, and subsequently three cleaning solutions were applied: quaternary ammonium, sodium hypochlorite 0.02%, and sodium hypochlorite 2%. The experimental sampling was performed five times.
- While all three offered a more than 97% decontamination rate, the sodium hypochlorite 2% required the fewest amount of wipes before total decontamination was completed.

Processing sputum specimen without biosafety cabinet; how safe are we? (Poudyal, et al)

- Researchers assessed the contamination risk in the acid fast staining process with is usually conducted under a biosafety hood

- It was found that polymicrobial growth rate was between 3-40% depending on laboratory technique. Safe technique can mitigate a significant amount of risk.
- The researchers did conclude that clinical specimens should still be processed under a biosafety hood to minimize the risk of transmission of infectious specimens to the handler.

Current Industry Standards & Classifications

In order to obtain a background on the classification and rating of how effective our device needed to be, background research was performed on various standards that are used worldwide. Both the Biosafety Cabinet Protection Standards and Air Particulate Filtration Standards can be seen in summary below.

Biosafety Cabinet Protection Standards (NSF International Standard 49)

- Class 1: designed for personnel and environmental protection
- Class 2: designed for personnel, product and environmental protection for microbiological work
- A1: minimum inflow velocity of 75 fpm through sash opening. Used for work with biological
- agents without toxic chemicals
- A2: minimum inflow velocity of 100 fpm through sash opening. Used for work with biological agents with minute quantities of hazardous chemicals.
- B1: minimum inflow velocity of 75 fpm through sash opening (utilizes HEPA filter). Used for work with minute quantities of toxic chemicals
- B2: minimum inflow velocity of 100 fpm through sash opening (utilizes HEPA filter). Used with hazardous chemicals (no air recirculation)
- C1: minimum inflow velocity of 105 fpm through sash opening. Can alternate between type A and B.
- Class 3: totally enclosed. Ventilated with attached gloves for performing operations within the cabinet. Highest level of air purity.

Air Particulate Filtration Standards (ISO14644-1:2015)

While the former Federal Standard 209E for Air Particulate Count was cancelled in 2001, biosafety cabinets and cleanrooms are often still classified by manufacturers with those classifications. For the DIY Clean Hood, the ISO14644 represents the approximate air particulate thresholds for cleanrooms and ares. ISO14644 supersedes the late FED STD 209E, and provides more specific particulate thresholds for the sponsor's design specifications, as seen below in **Table III**:

Table III. ISO Classification Standards.

Class	Maximum particles/m						FED STD 209E equivalent
	≥0.1 µm	≥0.2 µm	≥0.3 µm	≥0.5 µm	≥1 µm	≥5 µm	
ISO 1	10[b]	d	d	d	d	e	
ISO 2	100	24[b]	10[b]	d	d	e	
ISO 3	1,000	237	102	35[b]	d	e	Class 1
ISO 4	10,000	2,370	1,020	352	83[b]	e	Class 10
ISO 5	100,000	23,700	10,200	3,520	832	d,e,f	Class 100
ISO 6	1,000,000	237,000	102,000	35,200	8,320	293	Class 1,000
ISO 7	c	c	c	352,000	83,200	2,930	Class 10,000
ISO 8	c	c	c	3,520,000	832,000	29,300	Class 100,000
ISO 9	c	c	c	35,200,000	8,320,000	293,000	Room air

Objectives

The objective of this project is to create a DIY biosafety cabinet to provide a clean workspace for the BioElectroFluidics research team at Cal Poly San Luis Obispo. This project will meet the following basic needs: low air particulate count, low cost, and self contained. The device must fit within an envelope of 4'x2.5'x3.5', and must be powered from a 120 Volt AC wall outlet. A summary of various specifications outlined by our sponsor have been listed below.

- "Relatively" clean, filtered air (low particulate number)
- Sash is non-essential (can either be fabric, glass or plastic), but desired
- HEPA filter is not required
- UV light is non-essential but desired
- Must be clean/compatible with bleach and ethanol
- Cabinet atmosphere is positively pressured (air flows down and out of the cabinet)

A rudimentary plan for testing these specifications can be seen in the following paragraph, with a more detailed plan to be determined at a later date. Upon assembly of the unit with the filtration system, the BioSafety Cabinet will need to be tested for three critical design components: the air filtration system, the positive air pressure value inside the workspace, and cleaning compatibility.

Low particulate count in air can be measured with a "particulate count meter", which would be provided by the project sponsor, Dr. Ben Hawkins. The particulate counter would take in samples of the moving air within the Clean Hood workspace, then estimate the number of particles in a cubic meter with the taken air sample.

Material compatibility for cleaning agents for the workspace (ethanol, bleach) will be determined prior to DIY Clean Hood material selection and design. The material of the cabinet should also not degrade due to the chemicals being used to clean. The efficacy of the filtration and cleanliness of the Clean Hood will be measured with a workspace contamination test consisting of petri dishes (some closed, some exposed). The air filtration system does not require it to use a HEPA filter to accomplish the cabinet's goal of a low particulate count. However, the filter of choice should still be enough such that open cultures of cells will not be contaminated. This will be tested by allowing the unit to run continuously while 2 petri dishes of agar - one open and one closed - will sit inside the workspace for an extended period of time, and checking to see that the open agar dish does not possess contamination.

Exhaust system and positive pressure will be tested by measuring the flow rate of the workspace air and verifying that positive pressure exists within the workspace environment, with laminar air flow such that the BioElectroFluidics device remains undisturbed by the inbound air. This will be accomplished using an air flow meter (checking for air movement through the workspace and out the back of the device) and an ambient pressure sensor (verifying the pressure inside the workspace is greater than standard atmosphere). Inside the chamber of the BioSafety Cabinet, the air should flow in from the top of the unit, and out the front and rear of the workspace. In addition, the turnover rate (volumetric flow rate) will also need to be measured. The goal is that air should always be pushed out of the workspace, recaptured by the unit, and exhausted out of a designated port. This can be tested by releasing a colored smoke inside, and watching where the smoke flows, and assuring that none leaks out the front.

It should be noted that the DIY Clean Hood possesses no specifications that are deemed "high-risk" in the sense of hazards or dangers to the operator of the cabinet or the environment of the Clean Hood's location. There are no requirements (per sponsor's specifications) detailing specifications necessary for safety to the operator, high-risk operations, or vulnerable components.

Project Management

We expect to follow a linear method of product development for our DIY Clean Hood, using a "waterfall method" of project advancement (that is, the next step isn't able to be initiated until the previous task is completed). Figuring that with the DIY Clean Hood relying each preceding step, the phases of the project (listed in the timeline below) are the critical path essentially.

For our design, we aim to tackle the Clean Hood in three steps: The Frame and associated moving parts (I.e. viewing glass), The Air Filtration System, and the Cleaning Mechanism. These areas of focus

are all outlined below in **Table IV** within both the design phases, the assembly phase, and qualifications phase.

Table IV. Timeline of Deliverables

Timeline of Deliverables (circa 1-28-2020)			
Project Phase/Deliverable	**Duration**	**Start Date**	**End Date**
Project Kick-Off / Meeting with Sponsor	0 Days	1/21	1/21
External Research and Market Analysis	5 Days	1/21	1/27
Initial Design Phase	20 Days	1/27	2/24
Concept Design Review + Prep	4 Days	2/25	2/28
Critical Design Review + Prep	6 Days	2/28	3/9
Material Acquisition*	15 Days	3/10	3/30
Assembly*	31 Days	3/31	5/12
Qualifications Testing*	7 Days	5/13	5/21
*Exposition Presentation + Prep	7 Days	5/22	6/1

Certain deliverables have to be removed or pushed back due to current events

References

Adé, A., Chauchat, L., Frève, J. O., Gagné, S., Caron, N., & Bussières, J. F. (2017). Comparison of Decontamination Efficacy of Cleaning Solutions on a Biological Safety Cabinet Workbench Contaminated by Cyclophosphamide. The Canadian journal of hospital pharmacy, 70(6), 407–414. https://doi.org/10.4212/cjhp.v70i6.1708

Alex V Taylor, B.S. Chemical Engineering, Nicholas Baker, Pharm.D., M.P.H, Morgan Hulsey, B.S. Bioengineering, Corbin C Bennett, Pharm.D., M.P.H, Matthew Meiners, B.A. Chemistry, Ben A Gonzales, B.S., P.E, Evaluating containment effectiveness of A2 and B2 biological safety

cabinets, American Journal of Health-System Pharmacy, Volume 76, Issue 9, 1 May 2019, Pages 599–607, https://doi.org/10.1093/ajhp/zxz030

Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration. (2015, December 09). Retrieved June 01, 2020, from https://www.iso.org/standard/53394.html

Poudyal, A., Tuladhar, S., Gurung, R., Bhattarai, N. R., & Khanal, B. (2018). Processing sputum specimen without biosafety cabinet; how safe are we?. International Journal of Biomedical Research, 9(7), 268-271. https://doi.org/10.7439/ijbr.v9i7.4808

Sharp D. G. (1940). The Effects of Ultraviolet Light on Bacteria Suspended in Air. Journal of bacteriology, 39(5), 535–547.

Network Diagram

Figure 2: Timeline of Project as of Project Completion, 06/1/2020

GANTT CHART

		Task Mode	Task Name	Duration	Start	Finish	Predecessors
1	✓		Initial Meeting with Sponsor	0 days	Tue 1/21/20	Tue 1/21/20	
2	✓		External Research and Market Analysis	5 days	Tue 1/21/20	Mon 1/27/2(	1
7	✓		Initial Design	13 days	Mon 1/27/2(	Thu 2/13/20	2
22	✓		Concept Design Review	7 days	Fri 2/14/20	Mon 2/24/2(	7
26	✓		Critical Design Review	10 days	Tue 2/25/20	Mon 3/9/20	22,25
30	✓		Project Evaluation and Refocusing Due to COVID-19	24 days	Tue 3/10/20	Fri 4/10/20	26
31	✓		Virtual Assembly Completion	17 days	Sat 4/11/20	Mon 5/4/20	30
45	✓		Qualifying - Finalization of Test Protocols	10 days	Tue 5/5/20	Mon 5/18/2(	31,44
50	✓		Exposition	10 days	Tue 5/19/20	Mon 6/1/20	45,49

Figure 3: GANTT Chart of Completed Project 06/01/2020

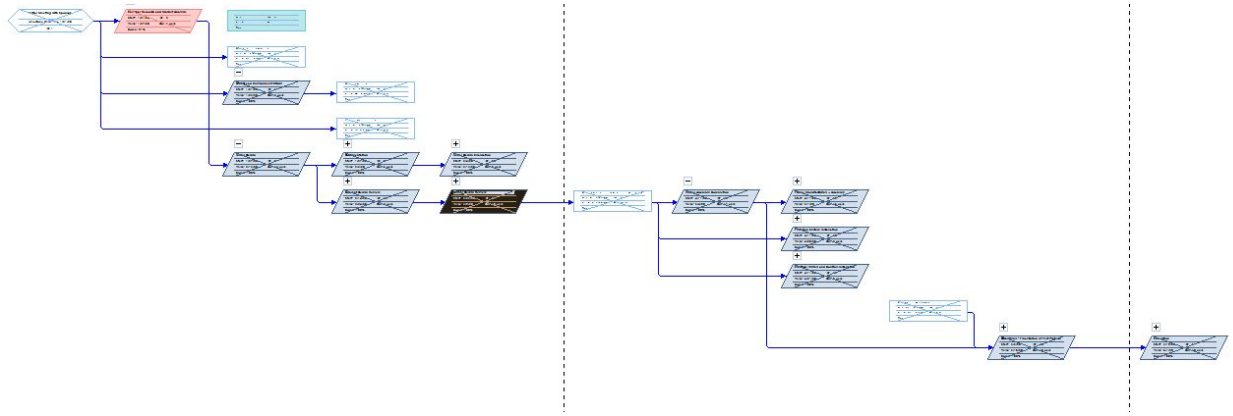


Figure 4: Zoomed-out Flow of Network Diagram 06/01/2020

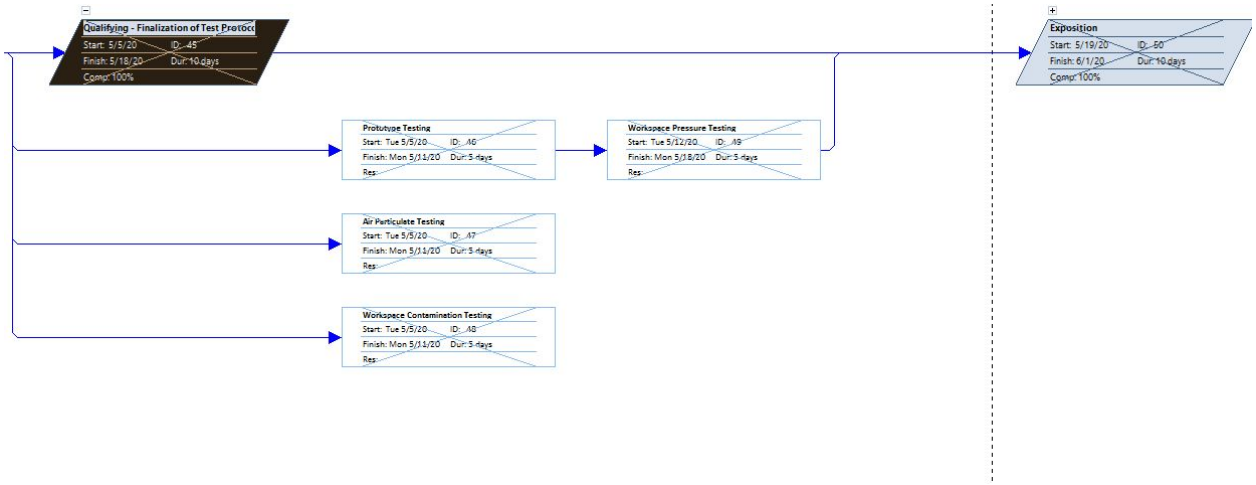


Figure 5: Portion of Network Diagram as of Project Completion 06/01/2020, with completed tasks for Qualification Testing and Exposition Presentation Preparation

The Network Diagram is an invaluable tool utilized by various engineering entities to track deliverables in a project for any products or devices in development, and can be utilized for logistical, planning, and decision-making purposes. When gauging how long each component of work will take, or steps in each phase, the timeline comes together with the project's overall duration; this sequence shows the critical path - the necessary steps that will take the longest for project completion - and the breath of leeway if delays should incur. Over the course of a project's development, the network diagram can undergo revisions and updates that reflect these delays should they be necessary.

In the initial network diagram, the timeline for the project contained several encompassing project phases, with individual tasks under each phase umbrella. These phases (in order of advancement) were "Meeting with Sponsor, External Research, Initial Design, Concept Design Review, Critical Design Review, Materials Acquisition, Manufacturing and Assembly, Qualification Testing, and Exposition Preparation" with a target completion date for June 1st. The largest items that would require the greatest amount of time for completion were material acquisitions (due to the three weeks between the end of Winter Quarter 2020 and the start of Spring Quarter 2020), the assembly of the DIY Clean Hood (as

evident by the amounts of machine shop work to be done), and the qualifications testing (to ensure the prototype device met all of the customer requirements).

Unfortunately, with the rapid onset of the COVID-19 pandemic and subsequent deterrent mechanism initiated at the academic, local, and state levels, it became increasingly evident that the assembly of the unit would no longer be possible: all access to Cal Poly on-campus services, including the Machine Shops, would be closed for an extended, indefinite amount of time. Thus, along with many aspects of the project, the Network Diagram had to be updated to reflect the new direction that the project would be taking. With the new scope directed towards a completed project design kit, the Network Diagram and associated figures (Figures 2, 3, and 4) reflect the virtual new scope of the DIY Clean Hood Project while maintaining the original target completion date of 06/01/2020. Despite this significant delay to the overall project, each deliverable for the DIY Clean Hood was always met on time.

Indications for Use

The DIY Clean Hood is a cabinet indicated for use by students and faculty in the Department of Biomedical Engineering at California Polytechnic State University - San Luis Obispo, participating in research pertaining to the BioElectroFluidics Group Lab. The cabinet is self-containing, cost effective, occupies a minimal footprint of laboratory workspace, and possesses an ISO 5 equivalent air filtration system that maintains a low particulate count (ISO 14644-1).

The DIY Clean Hood is intended for the sterile handling of cells, with airflow suitable for the handling of non-biohazardous biological specimens. It is not intended for protecting the user nor the lab environment from hazardous biological agents.

Budget

As seen below in **Figure 6**, our current budget is ~$800 based on our latest detailed design, which is over our current funds of $700.00 from a combination of the Department of Biomedical Engineering at Cal Poly and the Hannah Forbes Foundation. This does not include any possible manufacturing costs, as it was assumed that all manufacturing would occur on-site. This unexpected overage could be due to price surges during the current global pandemic, as the materials in our previous versions have not been over our original budget. It should be noted that these prices and availability of materials are subject to change at any time. It should also be noted that all the electrical components required to power the electrical features of the Clean Hood (including the intake and exhaust fans, among others) have not been included in this budget and would be provided by the lab.

Item Description	Product No.	Associated Purpose	Quantity	Cost/Unit	Total Cost	Vendor	Link (if applicable)
HEPA Box Air Filter, 24"x12"	2153K33	Filter air	1	122.73	122.73	McMasterCarr	https://www.mcmaster.com/2153K33
Noctua NF-A20 FLX, Premium Quiet Fan, 3-Pin (200x30mm, Brown)	B071PFLMFT	Move air in and out of clean hood	3	29.95	89.85	Amazon	N/A
Clean Room Hinge	1795A1	Attach sash door to frame	4	19.79	79.16	McMasterCarr	https://www.mcmaster.com/1795A1
Polycarbonate Sheets 12"X24" .019in 3pk	21-11	Sash door	1	21.23	21.23	Amazon	N/A
2020 Aluminum Extrusion, 4m long	16U247	Frame of the clean hood	4	33.75	135.00	Grainger	https://www.grainger.com/product/80-20-Framing-Extrusion-16U247?
Boeray 10pc 90degree 2020 Connectors	N/A	Connecting frame	2	23.00	46.00	Amazon	N/A
Kootans 4pc 90degree 3-way 2020 Connectors	XC5003	Connecting frame	1	10.59	10.59	Amazon	N/A
Apevia ATX-RA500W Raptor 500W Power Supply	ATX-RA500W	Power all the electronics in the clean hood	1	14.49	14.49	Amazon	N/A
Arduino Nano Microcontroller	B07VX7MX27	Control the pressure sensor and corresponding indicator	1	12.50	12.50	Amazon	N/A
Unthreaded-Hole Oval Pull Handle	14895A42	Sash door handles	4	2.05	8.20	McMasterCarr	https://www.mcmaster.com/14895A42
Pressure Sensor	3965	Sense pressure within the clean hood's workspace	1	14.95	14.95	Adafruit	N/A
HVAC Grill 12"x12"	18425K59	Disperse air to workspace	1	19.75	19.75	McMasterCarr	https://www.mcmaster.com/18425K59
HDPE Sheet 8'x4', 0.188" thick	1ZAT4	Encloses workspace, filter, and electronics	2	105.00	210.00	Grainger	https://www.grainger.com/product/POLYMERSHAPES-Sheet-Stock-1ZAT4
Aluminum Sheet 24'X36" .019 in	57794	Interior Housing	2	16.23	32.46	Amazon	N/A
				Total Cost	816.91		

Figure 6. Budget Spreadsheet (Excel)

Last updated: 6/1/2020

Customer Requirements

Upon meeting with our sponsor, Dr. Ben Hawkins, the following customer requirements (and desires) were outlined:

- Occupy small space to fit in the BioElectroFluidics Lab
- “Relatively” clean, filtered air (low particulate number)
- Sash is non-essential (can either be fabric, glass or plastic) but desired
- Air needs to be filtered, but HEPA filter is not required
- UV light is non-essential but desired
- All cabinet materials must be clean/compatible with bleach and ethanol
- Cabinet atmosphere is positively pressured (air flows down and out, measured)

Specification Development

Based on the customer requirements outlined above, the following engineering specifications were developed:

- Dimensions of Occupied Space: 4'x2.5'x3.5'
- Sash: Tempered Glass/Acrylic
- HEPA filter (HEPA H10): pass more than 15% of 0.1 micron particles per liter of air.
- <10,200 particles that are ≥.3 μm per cubic meter (ISO 5, ISO14644-1)
- $\text{Pressure}_{\text{Cabinet}} > \text{Pressure}_{\text{Atmosphere}}$
- UV Lamp: 254 nm wavelength (if incorporated)

TAM and Competitive Advantage

The diagram showing the Total Available Market (TAM) for biosafety cabinets/clean hoods is featured in **Figure 7** below. All references for the numbers quoted are included with the diagram.

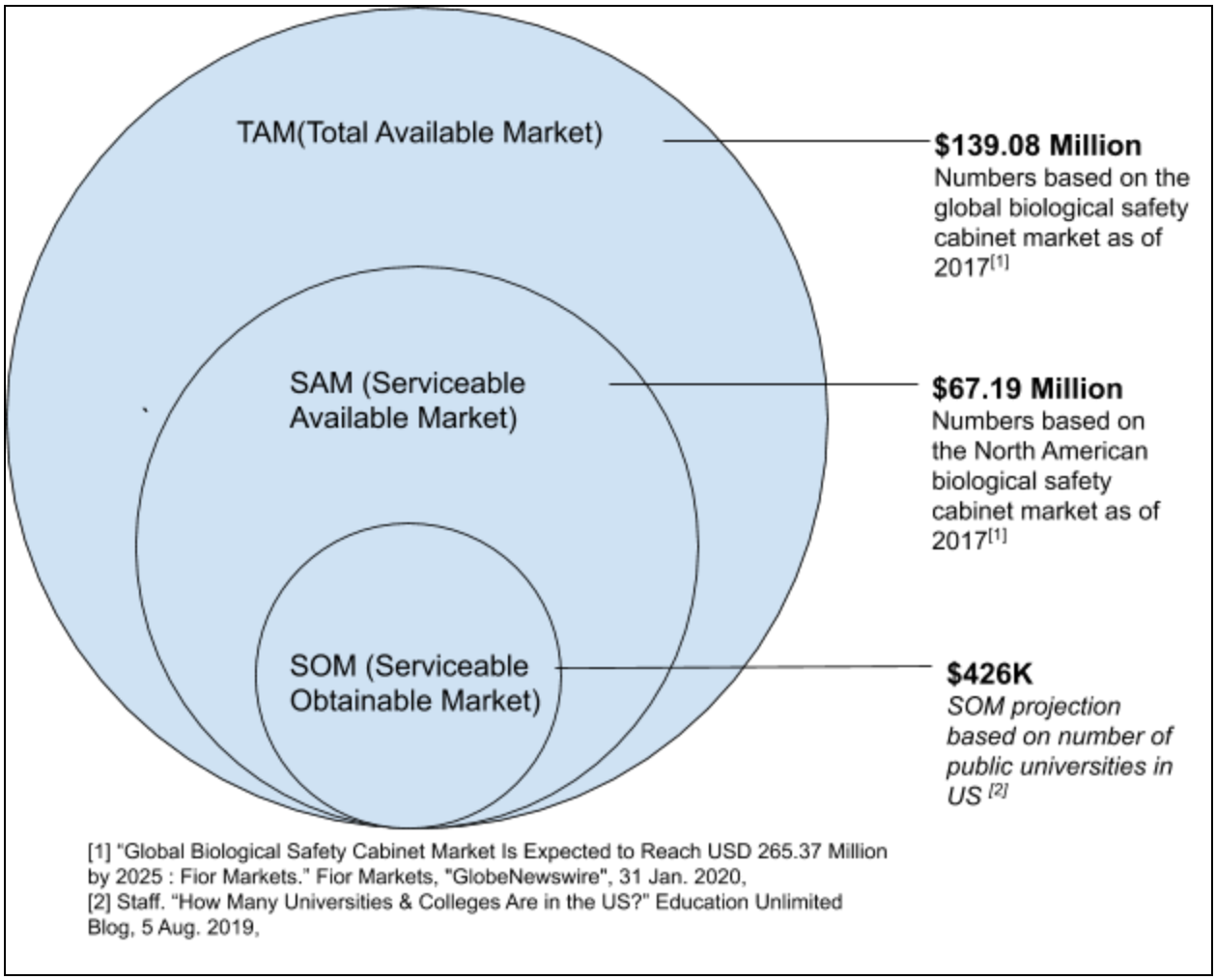


Figure 7. Total Available Market (TAM) diagram for biosafety cabinets.

The Competitive Advantage Matrix is included below in **Table V**. The two competitors examined include an option from Sentry and Labconco, two leaders in the biosafety cabinet market. As seen, the device only provides a competitive advantage in terms of total cost - there are many other options on the market that would work just as well, if not better, when compared to the device proposed in this project. This aligns with the initial goal of this project, which was to develop an alternative version that would reduce costs while maintaining the same amount of functionality as devices already available on the market.

Table V. Competitive Advantage Matrix for Clean Hoods & Biosafety Cabinets

Factor	Sentry 18" Wide Portable Clean Room	Labconco 304480020 Purifier 4' Axiom Class II Type C1 Biosafety Cabinet
Sterile working area within the device	5	4
Total cost of the unit	3	1
Easy to see into sterile workspace while working	3	4
Ability to maintain low particulate count	4	5
Ability to clean all surfaces with bleach/ethanol	4	4

Intellectual Property Assessment

To further understand the current technology available for biosafety cabinets and clean hoods, and prevent patent infringement during our design phase, an intellectual property assessment was performed. In **Tables VI** and **VII** below, patents that were currently pending approval as well as accepted patents relating to biosafety cabinets were assessed, respectively.

Table VI. Patent Applications Currently Pending and Potential Infringements

Application No.	Patent Title	Potential Patent Infringements	How to Address
62009036	BioSafety Cabinet Monitor	1) Wherein the sash is configured to move up and down. 2) wherein at least one sensor comprises a sensor configured to determine if the location of the sash is below a predetermined level.	1) The first claim is obvious to those skilled in the art 2) We can avoid this by using a mechanical element to stop ventilation function/alert the user when the sash is opened
14249693	Biosafety Cabinet with versatile exhaust system	1) wherein said exhaust blower is powered by a programmable variable speed motor and wherein the speed of said motor increases as resistance to airflow increases whereby a constant volume of air is exhausted. 2) wherein said exhaust zone is positioned within at least a front portion of the work area adjacent the access opening.	1) We do not plan on using a variable motor speed. We figure that one speed should suffice 2) This is not a novel idea. Many biosafety cabinets utilize an exhaust in front of the workspace to draw in air at the interface of the external and internal environment.
20100267321	Air curtain-isolated biosafety cabinet	1) wherein said door is a telescopic sliding door. 2) wherein said door has a handle to move said door to further control the opening of said door.	1) This is not a novel idea, and we could also design our door in a different manner. 2) This also could be solved by designing our door in a different manner (such as a sliding glass door), and is also not a novel idea that has been utilized by many other biosafety cabinets.

Table VII. Issued Patents and Potential Infringements

Patent No	Patent Title	Potential Patent Infringements	How to Address
2007/0184769 A1	Biological Safety Cabinet	1) The bio-safety cabinet as claimed in claim 1, further comprising: a UV lamp intensity measurement meter. 2) The bio-safety cabinet as claimed in claim 1, further comprising a removable front portion of a glass sash track, the removability of which provides allows for said glass sash to be lifted up for cleaning of the back (interior) side of said glass sash.	1) We don't need to address the UV intensity within our device. 2) We do not intend to make a glass sash. We do intend to make the sash removable for cleaning purposes; however, that falls under the category of obvious.
9,144,910	Biosafety cabinetry	1) wherein only one of the plurality of transparent small windows is attached with the pair of gloves. 2) further comprising a glove panel removably installed in the front opening to be below the front shutter, the glove panel being attached with a glove.	1) In this biosafety cabinet, it has not only a sash but also smaller windows for more restricted access into the cabinet. We can avoid infringing on this idea by not incorporating this feature into our design, and having just a sash. 2) We can avoid copyright infringement in our design by not including a glove panel in our design, which will not be included since protecting the user is outside of our indications for use.
9,095,802	Biosafety Cabinets With Air Filters Accessible Through The Work Chamber	1) The biological safety cabinet of claim 5, wherein the air filter housing is stainless steel. 2) The biological safety cabinet of claim 1, wherein the at least one air filter has dimensions no greater than 33 inches enabling the at least one air filter to fit within a standard 55 gallon hazardous material disposal container.	1) The claim does not hold water because it is obvious. WE can also avoid infringement by just using a different material 2) The safety cabinet we intend on building is not meant to be utilized for hazardous waste disposal due to space constraints. We intend to build a substantially smaller more compact unit

Conjoint Analysis

A conjoint analysis was used to determine the product characteristics that are most important from a customer's perspective, which will ultimately aid in the final product's success. A table was generated to show the factors and corresponding levels, as seen below in **Table VIII**.

Table VIII. Factors and Levels Used in Conjoint Analysis

Factor	Level 1 (0)	Level 2 (1)
Cost	$150	$50
Noise-Level	Noticeable	Low-hum
Cleaning Method	Manual	Self-cleaning (UV)

The table above follows the 3 factor/2 level full factorial design method, which leads to the use of an L_4 Orthogonal Array. To collect customer data, 4 cards were generated and then distributed to collect an eventual sample size of 9. The description of each card can be seen below in **Table IX**:

Table IX. Listing of Conjoint Cards

Card #	*Cost*	*Noise-Level*	*Cleaning Method*
1	$50	Low-hum	Manual
2	$50	Noticeable	Self-cleaning (UV)
3	$150	Low-hum	Manual
4	$150	Noticeable	Self-cleaning (UV)

A multivariate regression statistical analysis was then simulated in Excel. The results can be seen below in **Figure 8**. In order to determine if a factor has "significance," the p-value should be less than 0.05. Our p-values for our "Cost" and "Noise-Level" factors were 0.081 and .766, respectively. Based on the information collected from our classmates, none of the factors we decided to focus on for this survey (Cost, Noise-Level, Cleaning Method) had any significance after running our conjoint analysis in Excel. It is important to add that for "Cleaning Method," we were unable to generate a p-value. This is most likely the case because we did not generate a large enough sample size from our classmates to calculate this value. It should also be noted that this method should be done with physicians or subject matter experts (SMEs) to run a more accurate conjoint analysis.

SUMMARY OUTPUT								
Regression Statistics								
Multiple R	0.3022549							
R Square	0.091358025							
Adjusted R Square	0.005985784							
Standard Error	1.11312948							
Observations	36							
ANOVA								
	df	*SS*	*MS*	*F*	*Significance F*			
Regression	3	4.111111111	1.37037	1.658967	0.195433015			
Residual	33	40.88888889	1.239057					
Total	36	45						
	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	2.888888889	0.321332802	8.990333	2.17E-10	2.235132387	3.542645	2.235132387	3.542645391
Cost	-0.666666667	0.37104316	-1.79674	0.081536	-1.421559652	0.088226	-1.421559652	0.088226318
Noise-Level	-0.111111111	0.37104316	-0.29946	0.76647	-0.866004096	0.643782	-0.866004096	0.643781874
Cleaning Method	0	0	65535	#NUM!	0	0	0	0

Figure 8. Excel output of the multivariate regression statistical simulation used for the conjoint analysis.

Morphology

Table X. Device Morphology

Morphology						
Product: DIY Biosafety Cabinet	Organization Name : Cal Poly San Luis Obispo BMED, on behalf of BMED BioElectroFluidics Laboratory					
Function	Concept 1	Concept 2	Concept 3	Concept 4	Concept 5	Concept 6
Air Diffusion (Path of Airflow)	Planar Mesh Vent	Conical Air Distributor	Side Vents	Parallel, Thin Vents	*	*
Material Choice	Aluminum frame, HDPE walls	Aluminum frame, PET walls	Aluminum frame, tempered glass walls	*	*	*
Promote Visibility	15° Angled Sash	Angled Mirror	Camera with External Display	Interior Fluorescent Lighting	*	*
Sash Designs to Access Workspace	Vertical Sliding	Removable (Magnetic)	Hinged Upward	Horizontally Sliding	*	*
Team member: Sam Porter	Team member: Ryan Staples	Prepared by: Sam Porter, Ryan Shimogaki, Ryan Staples				
Team member: Ryan Shimogaki	Team member: N/A	Checked by:	Approved by:			
The Mechanical Design Process Professor David G. Ullman Copyright 2008, McGraw Hill	Designed by Form # 15.0					

Concept Evaluation

Concept Design I

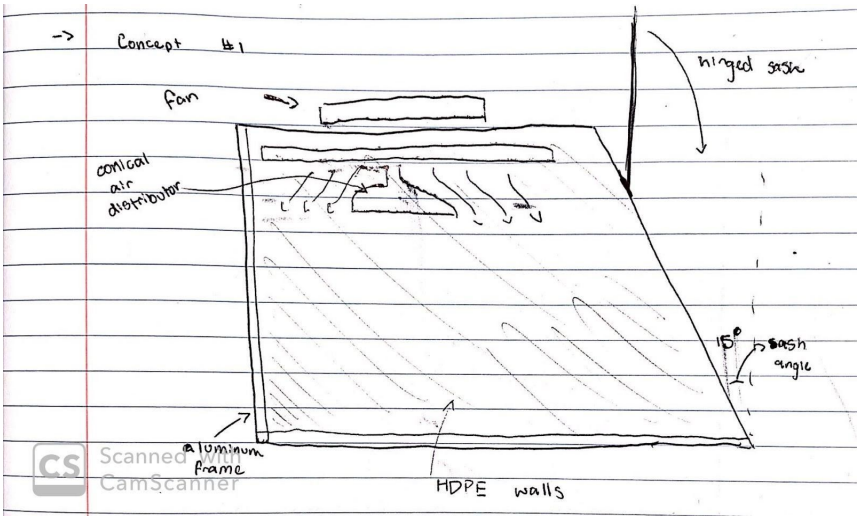


Figure 9. Sketch of Concept Design I.

Concept Design I was developed picking one concept from each of the 4 functions listed above. It has HDPE walls with an aluminum frame, which should be sturdy enough to support any biological materials without breaking/bending. The conical air distributor should distribute air evenly over the workspace to prevent the creation of jet streams. A sash angle of 15deg will allow the user to view the workspace from the top-down. A hinged sash that swings up will be out of the way of the user and allow for the most mobility in the workspace.

Concept Design II

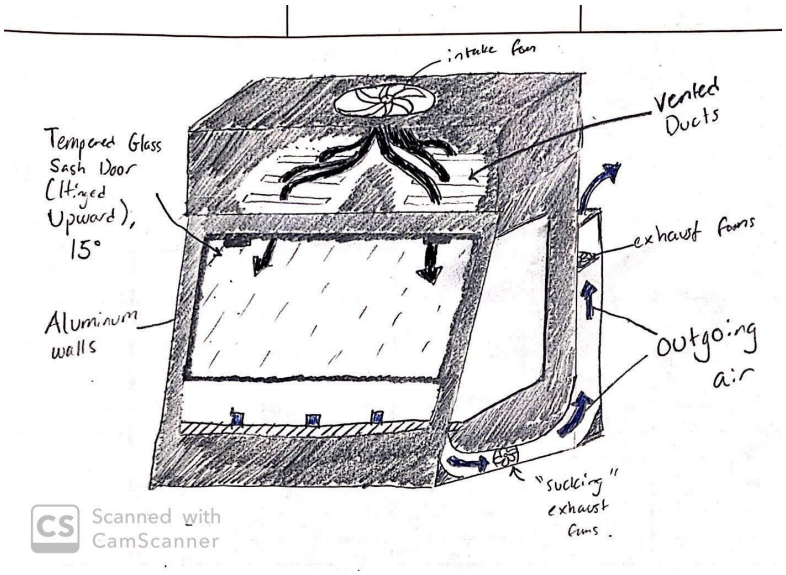
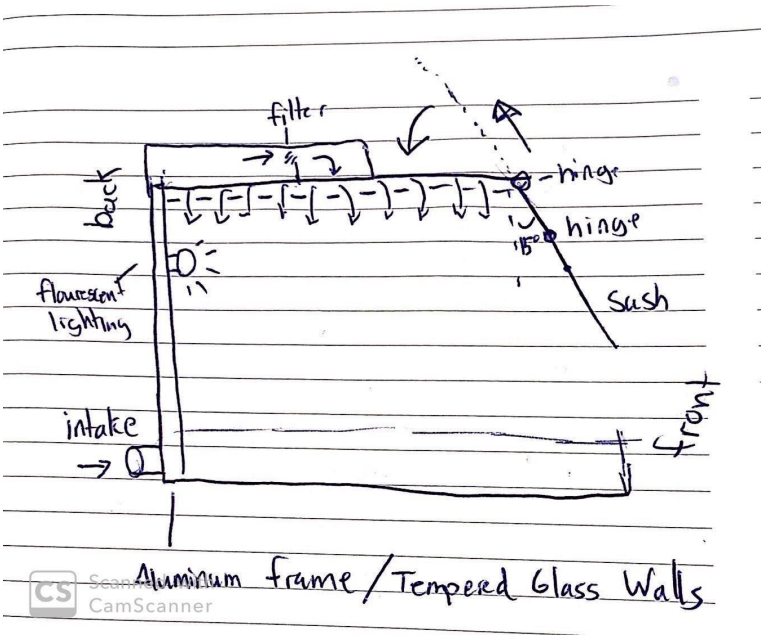


Figure 10. Sketch of Concept Design II.

Concept Design II was envisioned by utilizing known features of competitive products while incorporating some exploratory features that fulfill the design requirements of the machine. It features an all aluminum body with a HDPE workspace surface, such that it is structurally sound while providing top-quality air flow and installation for features. With the vented openings at the top of the cabinet, the air will be able to evenly flow downward, such that a positive pressure environment is maintained. In addition, for visibility and usability purposes, the viewing door has been set to a 15* angle with a tempered glass composition, while having the ability to be hinged and moved upward for greater accessibility. Lastly, vents on the bottom of the workspace surface draw air into it, where it is then exhausted to the environment out the back.

Concept Design III



spe

Figure 11. Sketch of Concept Design III.

Concept Design III utilizes an aluminum frame for the housing with tempered glass walls for increased visibility into the workspace from multiple directions. It has a meshed opening at the top to evenly distribute air throughout the workspace. The mesh openings will be smaller towards the center of the opening and larger at the edges to accommodate for the pressure gradient across the horizontal plane. The sash itself will be capable of sliding upwards at a 15deg angle and then will fold backwards on a hinge. Ideally it would have a flourescent lighting strip inside to light the workspace while avoiding harming the specimens.

Pugh Matrix

We determined that the cost, feasibility, and air dispersion capabilities were of the highest importance; therefore, they each received a 20% weight factor. This was followed by ergonomics and visibility, each with 15% weighting, which didn't end up varying too much between designs. We determined the weighting scale based on our project sponsor's initial directives. A Pugh Matrix was developed below in **Table XI** to determine which concept would be chosen for the conceptual model.

Table XI. Pugh Matrix of Conceptual Designs

Pugh Matrix - A Decision Matrix				
	Problem/Situation:	DIY Biosafety Cabinet		
		1	2	3
		Alternatives		
Criteria	**Weight**	Choice 1 (Datum)	Choice 2	Choice 3
Cost	20	**0**	**-1**	**-1**
Ability to Sterilize	10	**0**	**0**	**0**
Ergonomics(ease of use)	15	**0**	**0**	**0**
Feasibility	20	**0**	**-1**	**-1**
Visibility	15	**0**	**0**	**1**
Air Dispersion	20	**0**	**1**	**1**
	100			
	Totals	0	-20	-5
	Rank	1	3	2

Based on the Pugh Matrix, it was determined that Concept Design I was the best of the options. To further generate a concept model, it was determined that a CAD drawing would be best for a proof of concept model. This model would have the intentions of being purely a dimensional analysis to ensure there are no conflicting parts. This will also give us a better sense of the quantity of materials needed to be purchased.

Conceptual Model

Based on the Pugh Matrix, it was determined that Concept Design I was the best of the options. 20mmx20mm Aluminum Extrusions make the frame of the cabinet, with HDPE walls being slid into the slots of the extrusions to create a general box shape. There is a 12” enclosure at the top of the cabinet, which houses the intake fan and HEPA filters. The sash incorporates a hinged mechanism that swings out, with an easy to use handle for grasping. In addition, there is a 186mm fan in the rear of the cabinet, in order to provide outgoing airflow.

This model development phase has demonstrated how fluid the concepts are at this stage in development. As the design was implemented into a CAD drawing, numerous improvements were made to the original concept presented above. It should also be noted that some of the smallest components of the device can be the most difficult to accurately model. The drawings below represent the conceptual model based on Concept Design I.

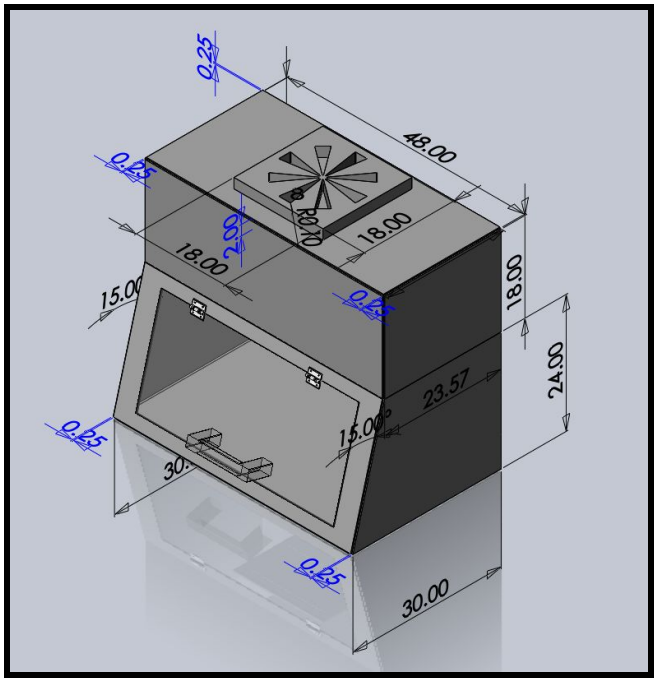


Figure 12. Isometric View.

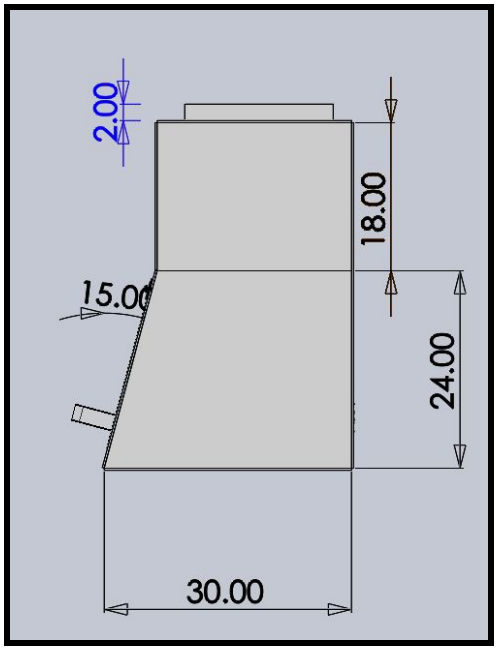


Figure 13. Front View.

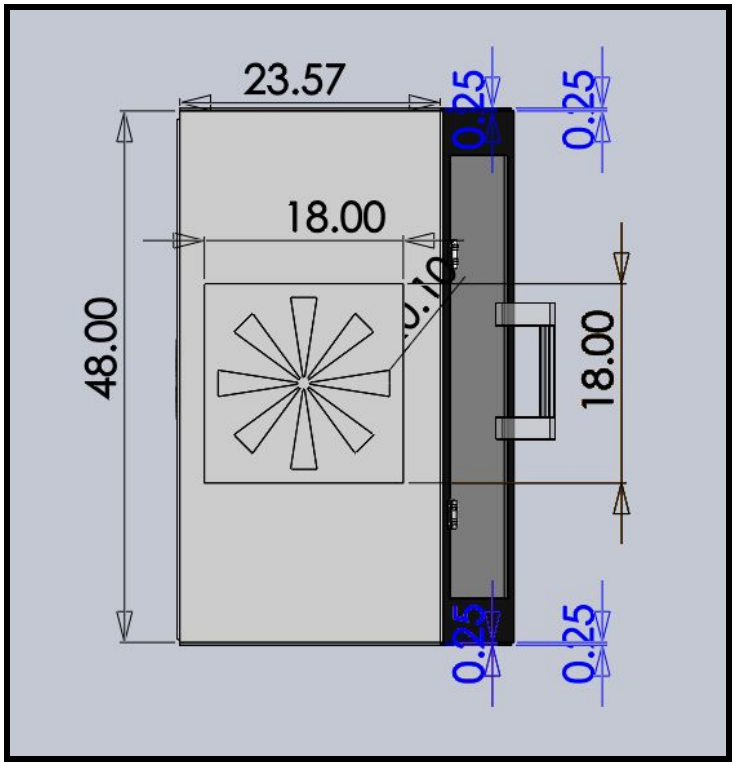


Figure 14. Top View.

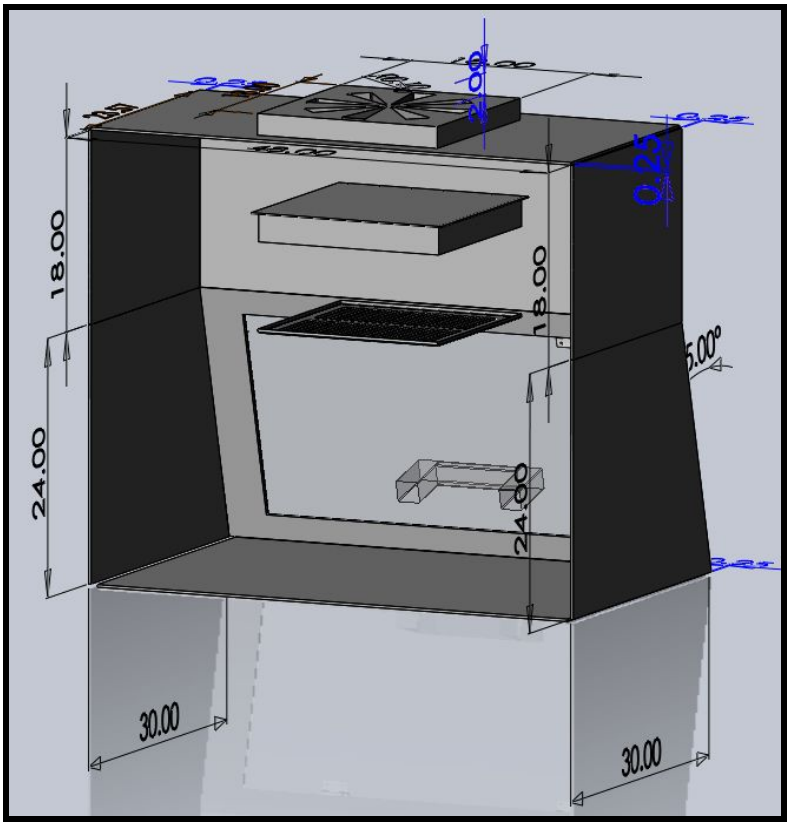


Figure 15. Isometric View 2.

Detailed Design

The following figures display various viewpoints of the final detailed design of the DIY Clean Hood in Solidworks 2019. The numbers have been omitted from these images for the sake of simplicity - it should be noted that the entirety of the clean hood fits within a 4'x2.5'x3' envelope. The collection of detailed drawings has been delivered to our sponsor, Dr. Ben Hawkins.

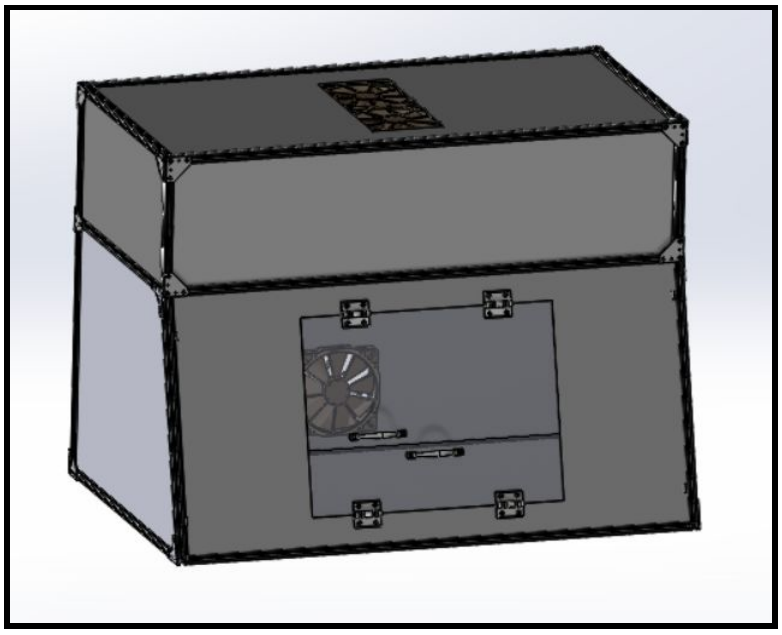


Figure 16. Isometric View 1.

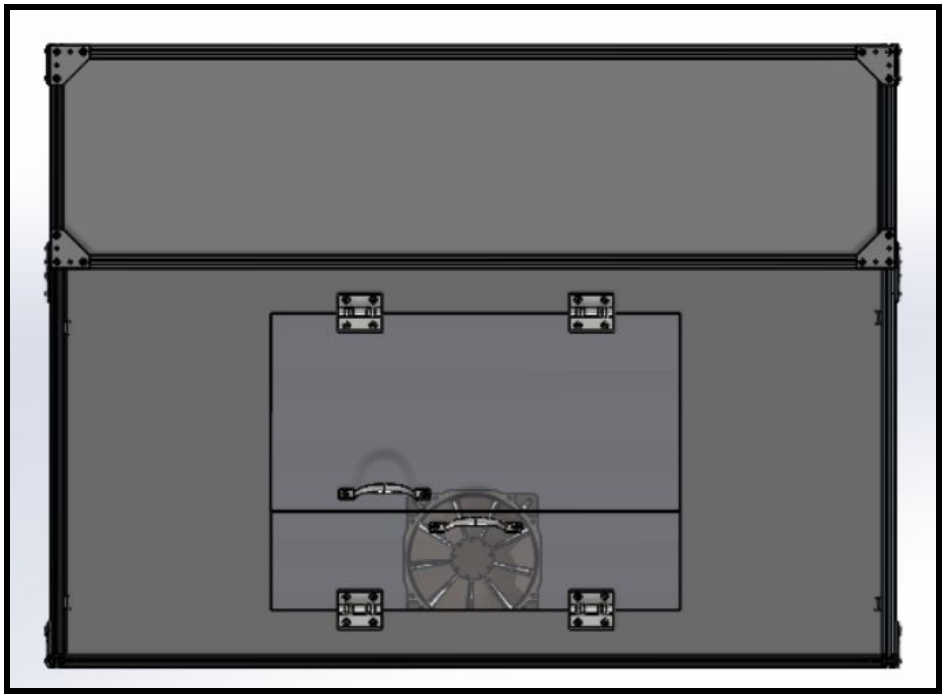


Figure 17. Frontal View.

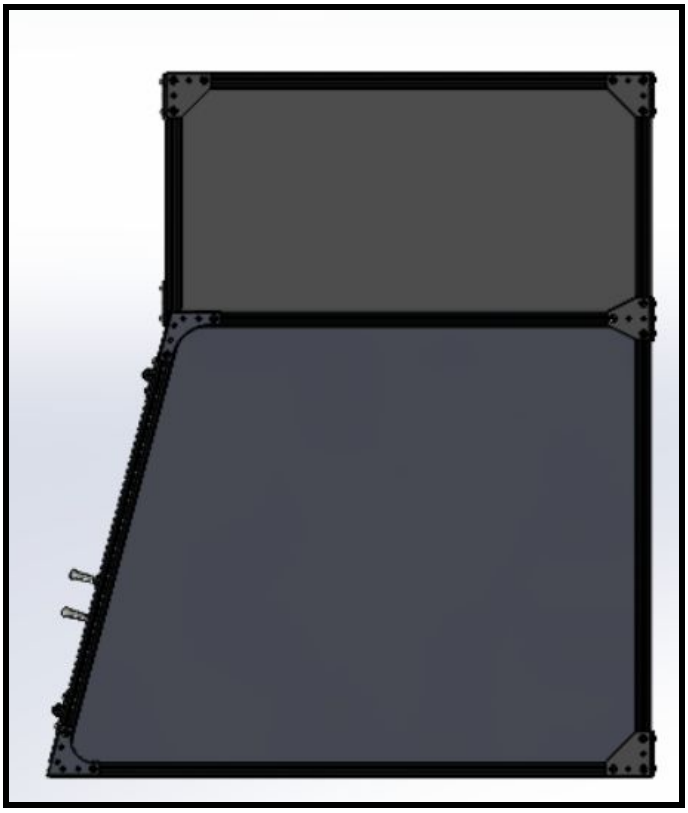


Figure 18. Side View.

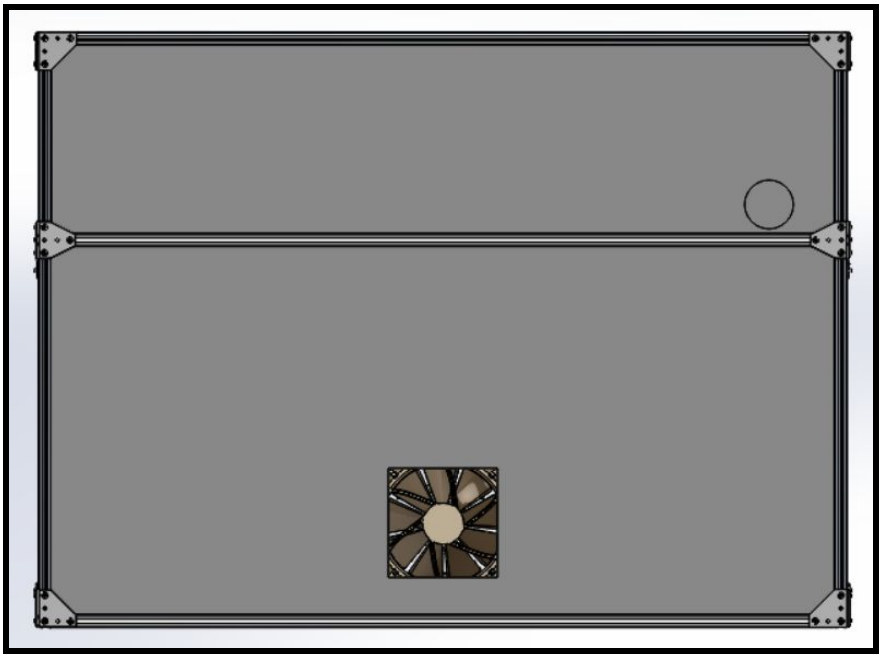


Figure 19. Back View.

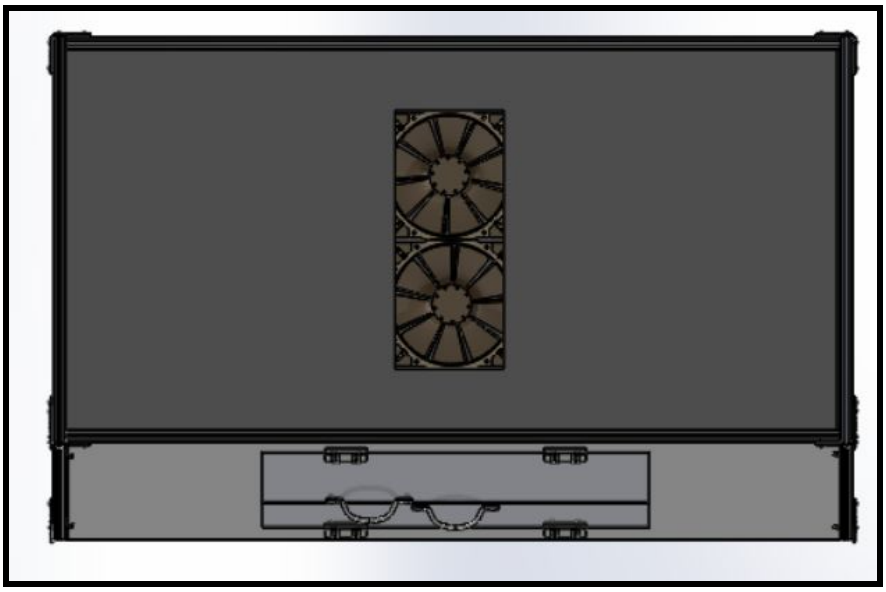


Figure 20. Top View.

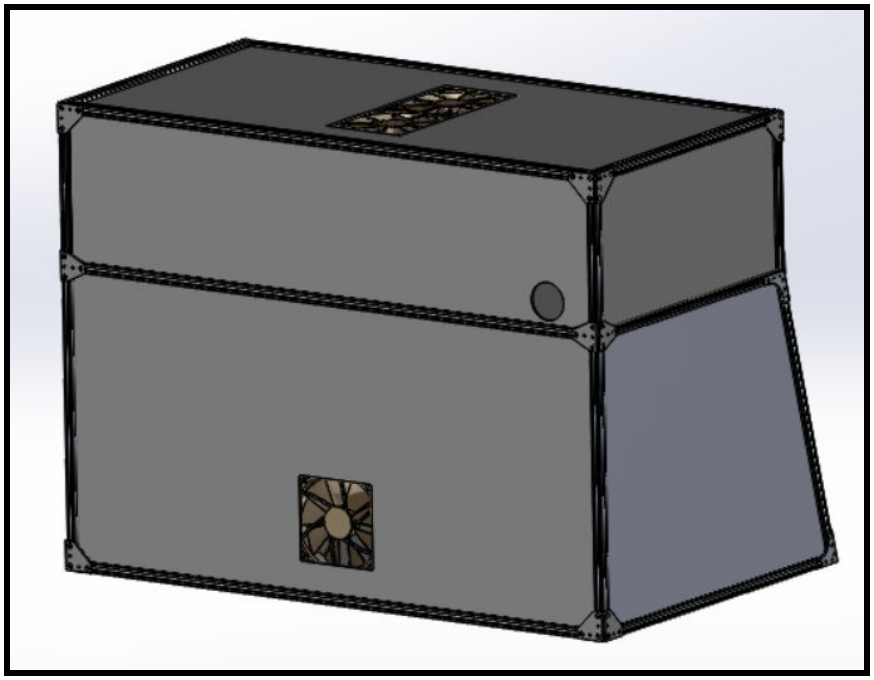


Figure 21. Isometric View 2.

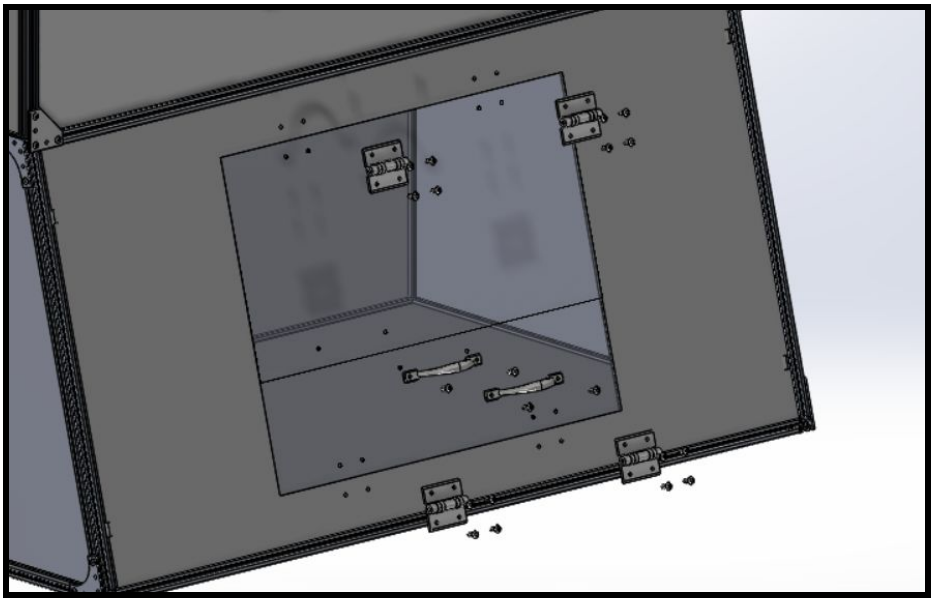


Figure 22. Sash Door Exploded View.

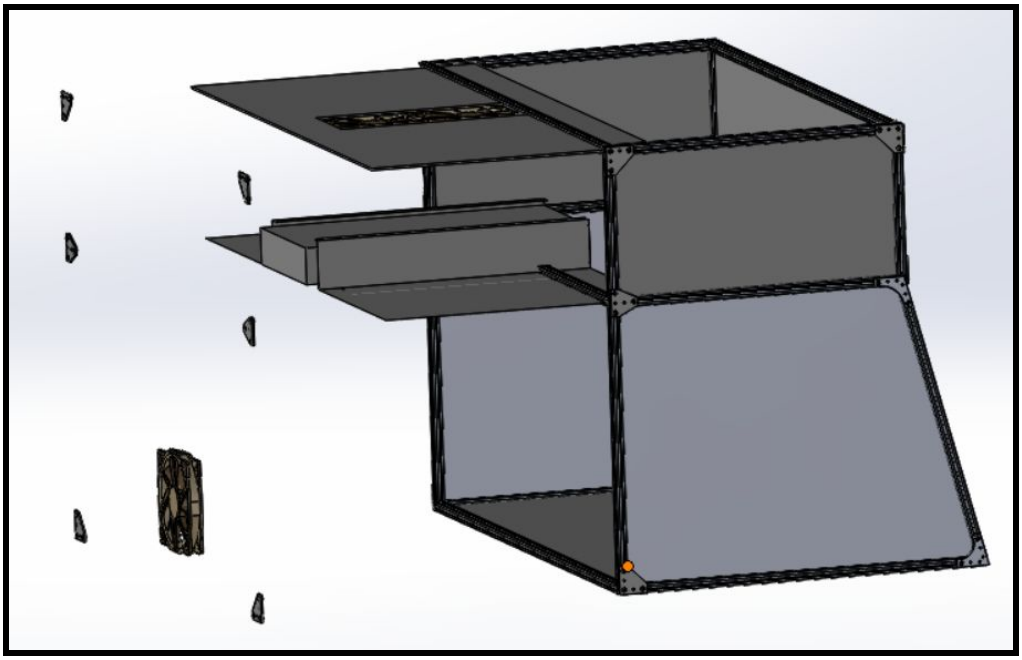


Figure 23. Internal Housing Exploded View (Back Walls Removed)

Prototype Manufacturing Plan

As seen in **Figure 24** below, the prototype manufacturing plan provides an outline for machining and assembly of the detailed design that was presented above. The raw materials are to be ordered according to the bill of materials provided above. The orange boxes represent general manufacturing project plan phases, the white boxes represent specific manufacturing deliverables within the phase, and the blue boxes contain all the necessary tools and machinery to complete all the manufacturing deliverables in the phase. A basic outline of obtaining materials, machining the frame of the device, assembling the frame, wiring the electronic sub-assembly, and assembling all the features is to be followed. A more detailed manufacturing plan will be delivered to our sponsor, Dr. Ben Hawkins, and can also be found in the Appendix.

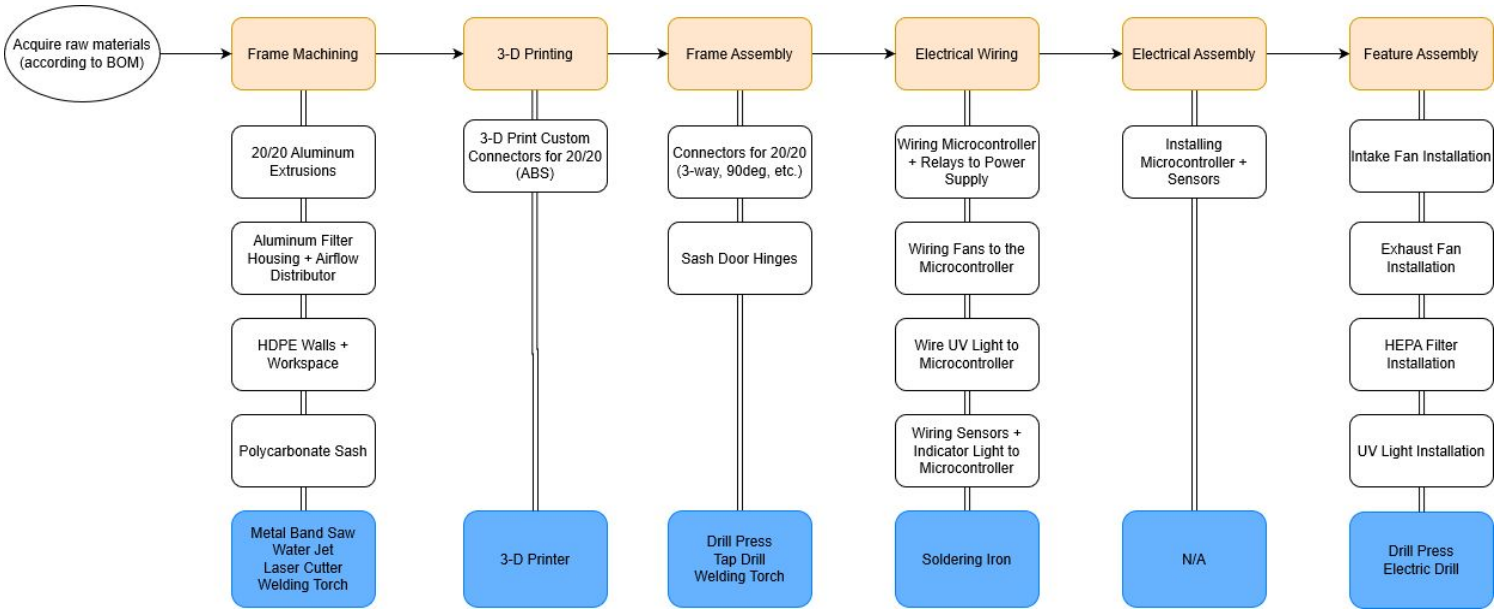


Figure 24. Flow Diagram of Manufacturing Process. It should be noted that the orange boxes represent general manufacturing project phases, the white boxes represent specific manufacturing deliverables to be completed, and blue boxes encompass the tools and machinery necessary to complete the project phase.

Test Protocols

The following three (3) tests will be used to help qualify and assess the effectiveness of the DIY Clean Hood. These tests are intended to meet the engineering metrics defined by the sponsor earlier in the report. These are subject to change as the project progresses and the sponsor's needs change.

Particulate Count Test

A particulate count test will be performed to test the engineering metric of obtaining an ISO Class 5 designation inside the DIY Clean Hood's workspace. This test will be performed in the BioElectroFluidics Lab space. It will require the use of a particulate count meter, which is to be provided by our sponsor, Dr. Hawkins (as well as any training necessary to use the device). The particle count meter will be used at 3 different regions of the workspace and 1 control outside and repeated by 3 different operators (the 3 members of the project team). This will lead to a total sample size of 12. In order to meet the engineering metric required by our sponsor, we expect this test to adhere to the ISO Class 5 designation listed below in order for the test to be successful.

Class	Maximum particles/m						FED STD 209E equivalent
	≥0.1 µm	≥0.2 µm	≥0.3 µm	≥0.5 µm	≥1 µm	≥5 µm	
ISO 1	10[b]	[d]	[d]	[d]	[d]	[e]	
ISO 2	100	24[b]	10[b]	[d]	[d]	[e]	
ISO 3	1,000	237	102	35[b]	[d]	[e]	Class 1
ISO 4	10,000	2,370	1,020	352	83[b]	[e]	Class 10
ISO 5	100,000	23,700	10,200	3,520	832	[d,e,f]	Class 100
ISO 6	1,000,000	237,000	102,000	35,200	8,320	293	Class 1,000
ISO 7	[c]	[c]	[c]	352,000	83,200	2,930	Class 10,000
ISO 8	[c]	[c]	[c]	3,520,000	832,000	29,300	Class 100,000
ISO 9	[c]	[c]	[c]	35,200,000	8,320,000	293,000	Room air

Materials:

- Particulate Count Meter

Facilities:

- The test will be conducted in the BioElectroFluidics Lab

Null Hypothesis:

- Particulate count readings **exceeding** 3520ppm for particles >.5microns

Alternate Hypothesis:

- Particulate count readings **below** 3520ppm for particles >.5microns

Procedure:

1. Run the clean hood for approx. 5 mins to purge out contaminated air.

2. Using the particulate count meter, take readings at the following locations: at the front of the workspace, the middle of the workspace, the back of the workspace, and outside of the clean hood.
3. Record the resultant particulate count in ppm
4. Repeat for all 3 group members.

Expected Results:

Ideally, we would like to see that the clean hood meets the ISO class 5 standard of less than 3520 ppm for particles larger than .5 microns. However, a statistically significant difference between particle count inside and outside the clean hood will also be acceptable.

Workspace Contamination Test

To test for contamination and sterilization of the Clean Hood, the following test materials will be acquired: 5 petri dishes with Tryptic Soy Agar (TSA), cotton swabs, distilled water, and a sharpie. For testing the air for contaminants, two TSA plates (petri dishes) are placed in the center of the workspace, with the device's air flow system operating, with an additional one outside of the Clean Hood. The TSA plate outside of the Clean Hood is uncovered, and allowed to be exposed to the normal air. One plate inside the workspace is covered, to serve as the control for having no contaminant development, while the remaining TSA plate is left uncovered.

With the Clean Hood operating normally overnight (8-12 hours), the petri dishes are exposed to the air, becoming inoculated. Next, the dishes are incubated at 25*C for 24-48 hours. Once finished, the growth on the plates is measured; for the filtration to be considered sterile, there needs to be less than 10 CFU (colony-forming units) per 100mL. Only if the TSA plate exposed to the workspace air has less than this CFU threshold can the DIY Clean Hood meet the sponsor's filtration specification.

Though not necessary, testing the effectiveness of the UV light for sterilization can be performed by turning on the light for an unspecified amount of time. With a cotton swab dipped in distilled water, the workspace of the Clean Hood is swabbed, where one of the remaining TSA plates is inoculated with the cotton swab. Repeat the incubation procedure, with the same CFU guideline: if the growth dish has less than 10 CFU per 100 mL, then the UV light is certified as a non-chemical sterilization method for the workspace.

The Workspace Contamination Test is a critical measurement of the DIY Clean Hood, as it will assure that the product is qualified to be handling important cell cultures in a sterile, safe environment for the product. To reiterate, the DIY Clean Hood implements important decontamination features, like a UV interior light in addition to workspace compatibility for common laboratory cleaning agents for the protection of the product. It is not the focus of the DIY Clean Hood to protect the Hood operator or the environment for which the Hood resides. With the Workspace Contamination Test, it is expected that there is little to no biological growth within the chamber.

Materials:

- 5 Petri Dishes with TSA (Trypticase Soy Agar)
- Tape
- Sharpie Marker
- Sterile Cotton Swabs for Inoculation
- Distilled Water

Facilities:

- BioElectroFluidics Lab
- Incubator set to 20*C (68*F)

Null Hypothesis:

- Growth >= 10 CFU/100mL.

Alternative Hypothesis:

- Growth < 10 CFU/100mL.

Procedure:

1. Gather necessary testing components.
2. Douse one cotton swab with sterile water, and swab the surface of the Clean Hood workspace with the cotton swab. Then, using inoculation techniques, streak the TSA plate with the cotton swab, and then promptly close the dish with the petri dish lid.
3. Secure the petri dish with some tape so the lid and dish do not separate. Label appropriately with the sharpie as "WORKSPACE - NO Filtration", and deposit in an incubator set to 20*C.
4. Take an additional swab and TSA dish, and swab a spot in the environment around the clean hood (this can be the exterior of the Clean Hood, the laboratory bench surface, a chair, etc.). Inoculate the dish similar to steps 2 and 3, labelling it as the CONTROL.
5. Next, turn on the UV light inside the Clean Hood and allow the hood to be sterilized for an hour. Then, use a new cotton swab to inoculate a TSA plate by swabbing the workspace surface and inoculating a TSA plate labelled "Workspace - UV". Seal with tape and place in the incubator with the other dishes.
6. Allow the colonies to incubate for 48 hours after inoculation, then remove the TSA plates. Visually inspecting each plate, count the number of colonies in each dish. A colony is parameterized as a singular dot or bunch of microbial growth.
7. Once the TSA plates have been identified, repeat the inoculation experiment, but replace the method of sterilization with using common cleaning agents for laboratory surfaces, such as ethanol.

Expected Result:

For the control and pre-sterilization TSA plates, we should observe typical microbial and contaminant growth on the agar surface - simulating normal environmental conditions in which an unsterile environment could influence the testing product. If the experimental TSA plates have less that 10 individual colonies by visual inspection, then we can reject the null hypothesis and accept the alternative hypothesis. With rejecting the null hypothesis, we would certify the Clean Hood to be sufficiently sterile enough to conform to the sponsor's parameters for the product.

Workspace Pressure Testing

A workspace pressure test will be performed to confirm that our workspace has attained a positive pressure value, therefore indicating a net airflow out of the workspace. This test will be performed in the BioElectroFluidics Lab space. The materials required, which will be provided to us by our sponsor, Dr. Hawkins, are an air flow meter, ambient pressure sensor, and a microcontroller. The air flow meter will be used at the sash opening after running the system for 5 minutes, 1 hour, and 8 hours (overnight). The pressure sensor and microcontroller will be used to record pressure values also at 5

minutes, 1 hour, and 8 hours (overnight) inside the workspace. Both of these tests combined will result in a total sample size of 6. In order for the test to be successful, the air flow meter should measure a positive flow leaving the sash opening and leaving the exhaust fan in the back of our workspace. The pressure sensor should consistently detect a pressure greater than atmospheric pressure (1 atm) to ensure that our workspace is achieving a positive pressure.

Materials:

- Pressure Sensor & Microcontroller (of DIY Clean Hood)
- Air Flow Meter

Facilities:

- BMED BioElectroFluidics Lab

Null Hypothesis:

- Workspace Pressure = 1 atm

Alternative Hypothesis:

- Workspace Pressure > 1 atm

Procedure:

1. The DIY Clean Hood will be turned on and allowed to run continuously for 5 minutes prior to testing, in order to establish an equilibrium.
2. At 5 minutes of continuous running, the air flow meter is used to measure the air flow inside the workspace, and the pressure sensor records the pressure.
3. This is repeated after 1 hour has passed, and again after 8 hours have passed.
4. These figures are recorded in a table of figures.

Expected Result:

If there is a consistent reading of pressure greater than 1 atm inside the workspace, along with sufficient air flow through the system, then we can reject the null hypothesis and accept the alternative hypothesis. With assurance of consistent positive pressure inside the DIY Clean Hood, only air that has passed through the HEPA filter will occupy the interior of the Clean Hood.

Testing Data and Analyses

In light of current events, data collection from the prototype is not feasible. Using theoretical parameters, we calculated the number of times the volume of air in the device is recycled. We recognize that the actual air cycle rate will likely be lower than calculated due to air filter resistance. It has been shown that air filters reduce the effective CFU of a fan. Similarly, the interior geometry will affect air flow calculations. In order to attain accurate numbers for air cycle rate, we recommend that an air flow meter is used.

Parameters:

- Workspace Interior Volume = **17 ft^3**
- Input Fan Max Rate = **80 cfm**
- Exhaust Fan Max Rate = **80 cfm**

Assumptions:

- Fan specifications provided by manufacturer are accurate
- No impediment to air intake or exhaust
- Empty workspace (occupied workspace will have a higher cycle time)
- Filter resistance not factored in

$$Cycle\ Time\ =\ \frac{17\ ft^3}{(80\frac{ft^3}{min}+(2\times 80\frac{ft^3}{min})}\times\frac{60\ sec}{1\ min}$$

$$Cycle\ Time\ =\ 4.25\ sec$$

At most, **14 cycles per min** are achievable

Conclusions

With this device, we hope to address the lack of a sterile workspace for the BioElectroFluidics laboratory. Unfortunately, at the current stage of development, the design team can only ascertain that the geometric specifications and cleaning specifications of the device have been met. As a result of current events, we have been unable to validate that all all product specifications have been met. The ability of the device to maintain positive pressure, as well as the functionality of the workspace decontamination procedure have not been validated. Additionally, we cannot conclude at this time whether the device meets ISO class 5 requirements. We have outlined a set of test protocols above to verify that all of the prescribed specifications and customer requirements have been met. Final verifications of the device's efficacy will be left to Dr. Ben Hawkins and members of the BioElectroFluidics research team.

Discussion

From the initial meeting with our sponsor, Dr. Ben Hawkins of the California Polytechnic State University's Biomedical Engineering Department, the DIY Clean Hood had a rough scope of what was to be accomplished: to provide a clean and sterile workspace for the handling of non-hazardous cell cultures in an environment of positive pressure and constant, filtered air flow. For the filter, it was intended for the filter to be HEPA-certified, an ISO standardized particulate level that ensures environmental controls on foreign particles and potential airborne contaminants.

In the Initial Design phase of the project, several different ideas were proposed for different facets of the DIY Clean Hood, then called the "DIY Biosafety Cabinet": different materials and mechanisms for the sliding sash, the assembled frame and exterior, the fan filtration system, and the included UV light sterilization option. For example, the sliding sash had concepts of a 0* degree angle and a 15 degree angle, which choices of acrylic, tempered glass, or other plastic for the material.

After our research on biosafety cabinets, clean hoods, clean benches, and similar technologies, we came to the conclusion that it would be no longer accurate to deem our project as a biosafety cabinet, since our project's scope was to ensure the safety of the cell cultures being manipulated; it was not the intention of our device to provide protection for the user nor the environment of the device. As a result, we opted in mid-February to design our device along the parameters of a Clean Hood, which provides a sterile space for biological products. The geometry of the device was largely based on the constraints of the operation space. However, we also took into consideration the dimensions of commercially available parts in order to make the manufacturing process easier. While designing the device we had to balance between what we desired in our product and what was achievable in a 2 quarter time frame. Some of the features of the cabinet that were brought up in discussion had to be put on hold due to time and monetary constraints.

With the Critical Design of the DIY Clean Hood completed in mid-March, the design of the device was finalized for anticipation of future material acquisition and device manufacturing. Unfortunately, it was just after the presentation of our Critical Design that the COVID-19 pandemic forced closures of all on-campus facilities: the Cal Poly Machine Shops, the BioElectroFluidics Lab, and in-person access to advisers. In addition, material acquisition of prototype parts would have had notable delays due to prioritized shipping management of necessary COVID-related items, as well as prevention of team collaborations on any assembly or testing purposes.

As a result of the events, it was decided between the team members along with the consultation of the BMED 456 instructor Dr. Whitt, that the project proceeds in a primarily design-focused scope. This decision came as last-resort options, such as sending manufacturing and assembling to third-party affiliates, were found to be inadequate or unfeasible. With the changed project timeline in April and early May, the DIY Clean Hood Team found some additional alterations that could benefit the prototype's

eventual build performance. One example is that the intake fans, which would pass air through the HEPA filter and into the DIY Clean Hood workspace, would provide an air flow rate significantly higher than what would be desired; the fans were reduced in size to provide a more modest flow to the filter and workspace while maintaining positive pressure flow through the device.

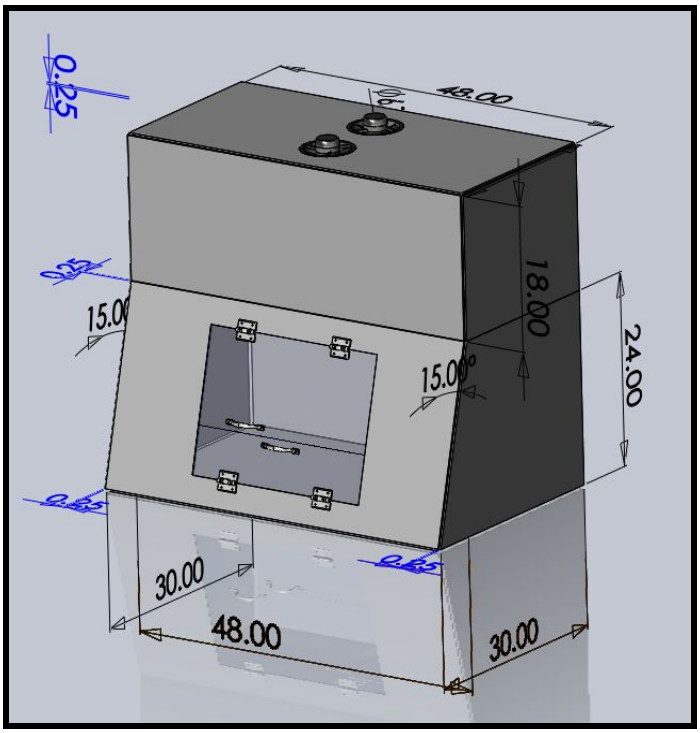
After 20 weeks of diligent work on the DIY Clean Hood for the BioElectroFluidics Lab, we are very satisfied in the realization of our prototype's design and have the fullest confidence in its future qualifications testing and the DIY Clean Hood's anticipated meeting of all customer requirements. Though we were saddened to be unable to build and test our prototype, we look forward to the eventual construction and installation of our DIY Clean Hood in the BMED BioElectricFluidics Lab

Appendix

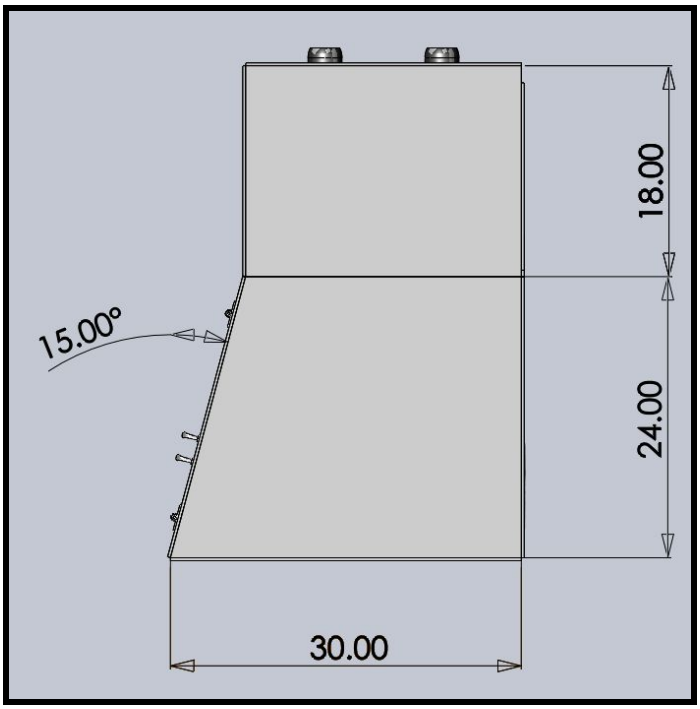
Appendix A: House of Quality

		Who?	How?						Now?				
		CP BMED Research Students & Faculty	Filter grade	Size of Cabinet	Angle of Sash	Fan Intake Rate	UV Lamp addition	Device Material		Labonco (x)	Competitors	Sentry Air Systems (o)	
									1 (poor)	2 (passable)	3 (decent)	4 (very good)	5 (excellent)
What?		**Who vs. What**	**What vs. How**						**Now vs. What**				
Device Charecteristics	Ability to clean all surfaceswith bleach and/or ethanol	10		3	1		9	9				x o	
	Easy to lift/transport to another location	3		3				9		x			
	Easy to replace air filter	2	3								o		
	Ability to be powered with standard 120V AC outlet	7				3	3						x o
	Device Lifespan	10	3	1	1		1	9				o	x
	Total Cost of Unit	10	9	3	1	1	9	9	x	o			
	Total size of device fits in 4'x2.5'x3.5' large space	5		9			3	3	x	o			
Device Ergonomics	comfortable handle cell cultures in the sterile area	8		9		3					o	x	
	Easy to see into sterile workspace while working	8		3	9			3			o	x	
Device Functionality	Sterile working area within the device	17	9			3	9					o	x
	Positive pressure within the cabinet	8		3		9						x o	
	Ability to maintain low particulate count (standard turnover rate within the cabinet)	10	9	1		3						o	x
	Ability to light working area while not effecting biological material	2		1							o		x
		100	22.36363636	15.51515152	6.181818182	12.60606061	22.96969697	20.36363636					
			How Much?										
	Customer Importance		22.36363636	15.51515152	6.181818182	12.60606061	22.96969697	20.36363636					
	Customer Delighted		TBD	TBD	TBD	TBD	TBD	TBD					
	Customer Disgusted		TBD	TBD	TBD	TBD	TBD	TBD					

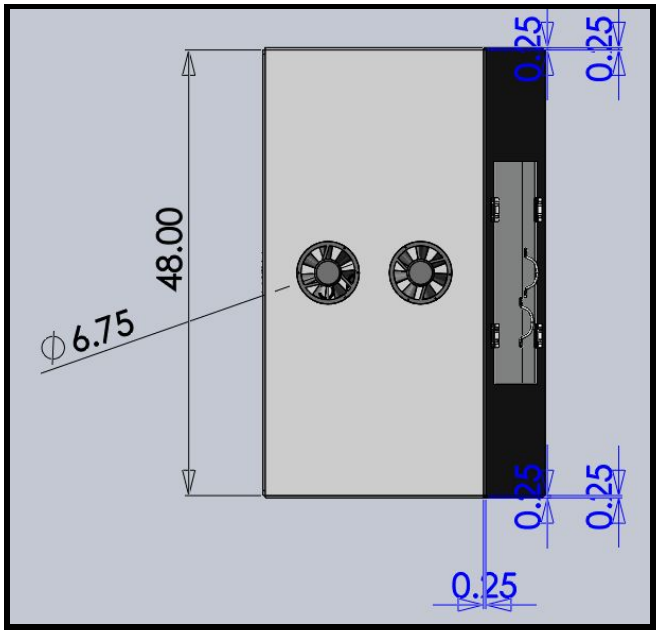
Appendix B: Detailed Design - First Draft



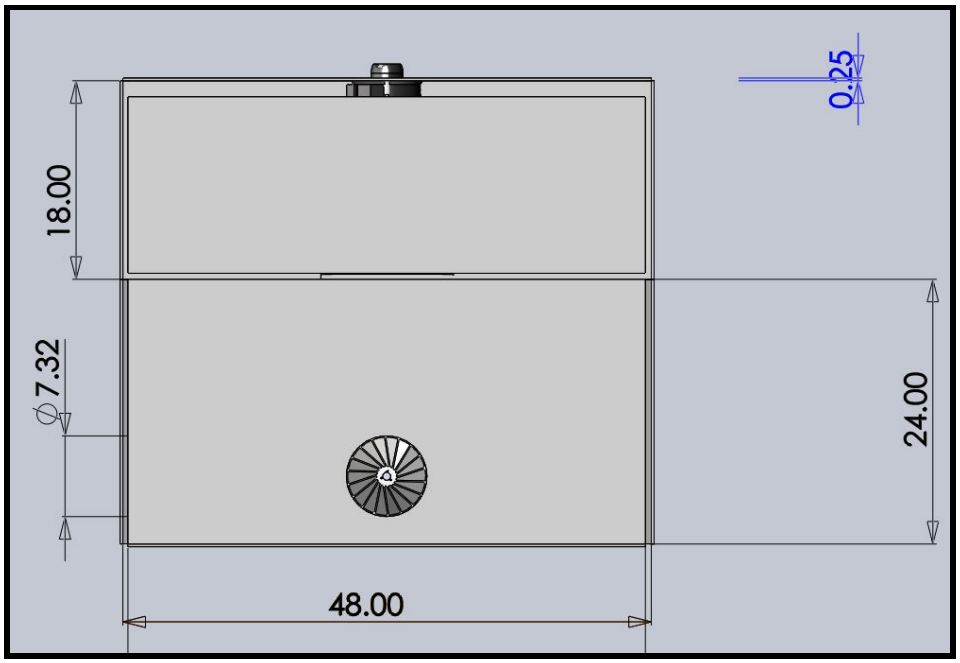
Isometric View



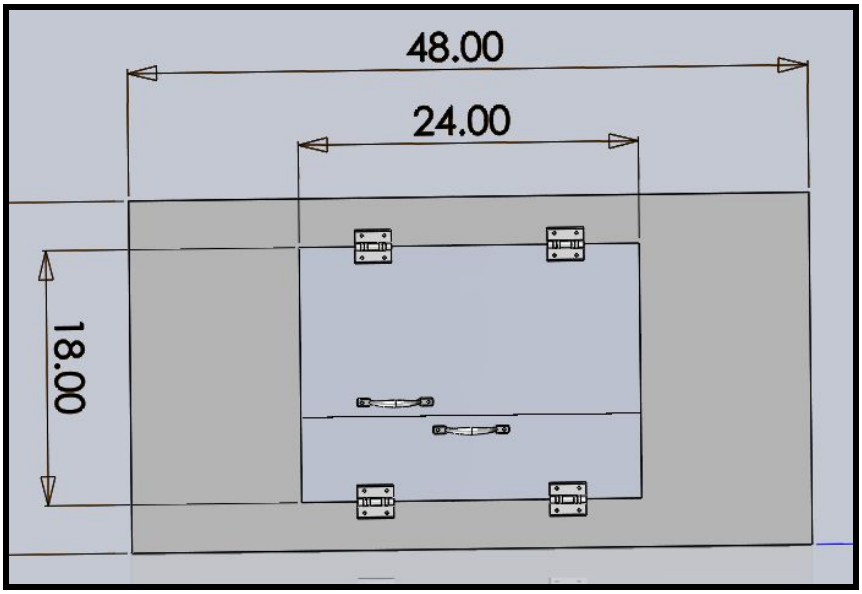
Side View



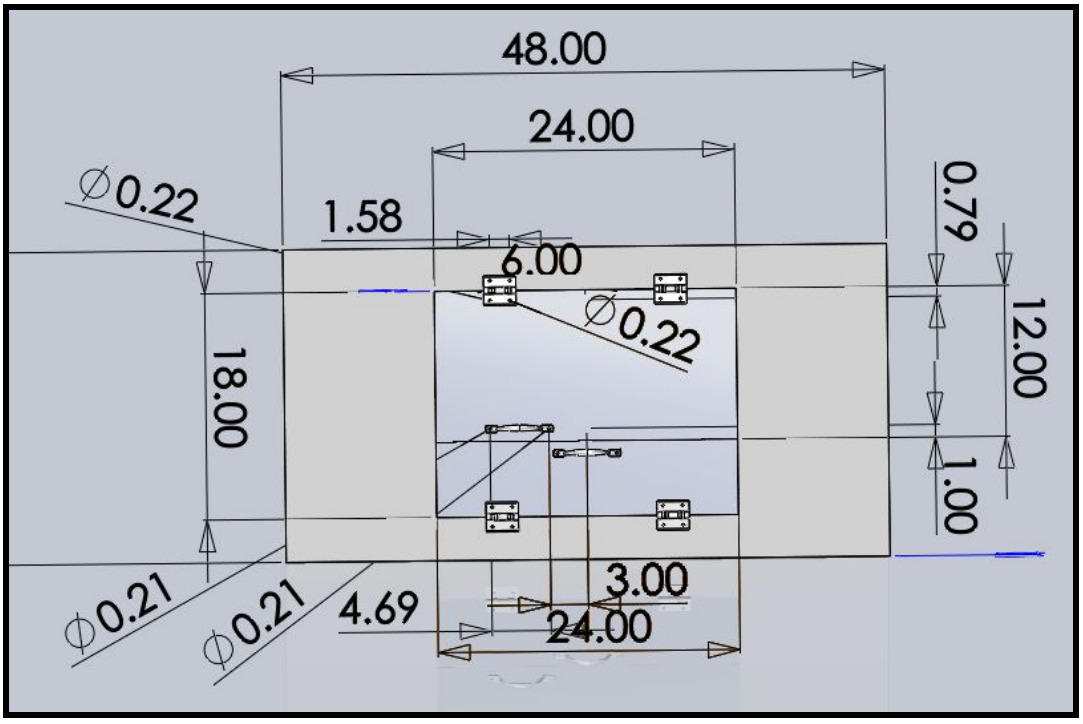
Top View



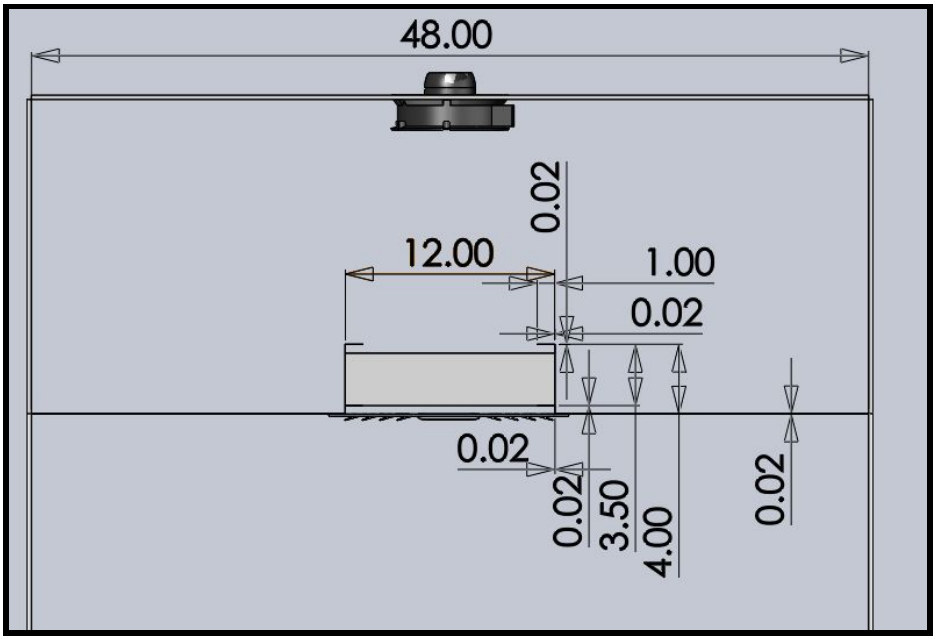
Back View



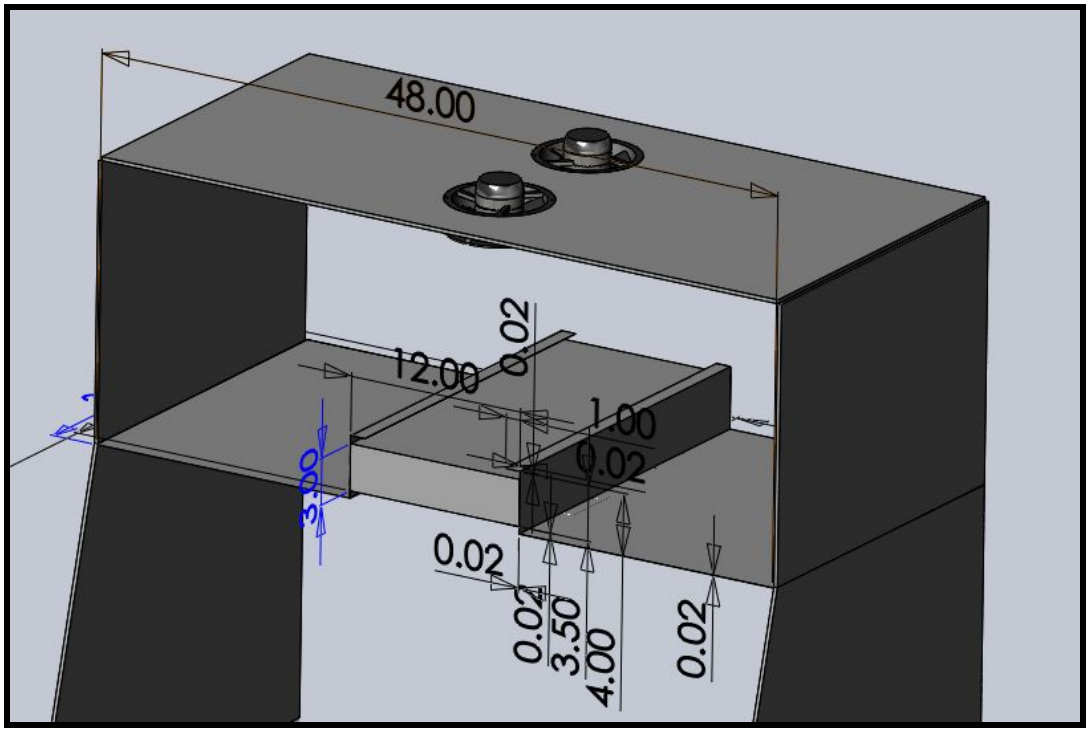
Sash Dimensions



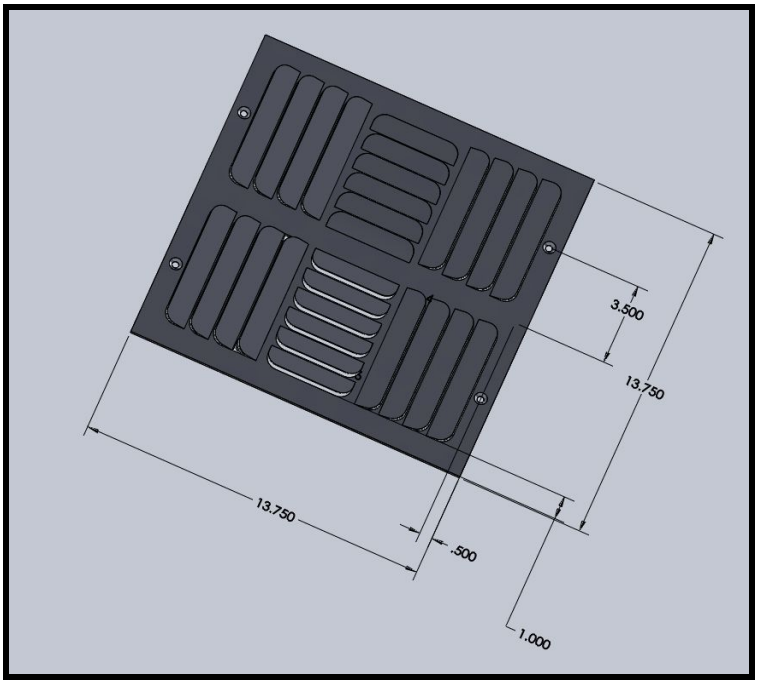
Sash Full Dimensions



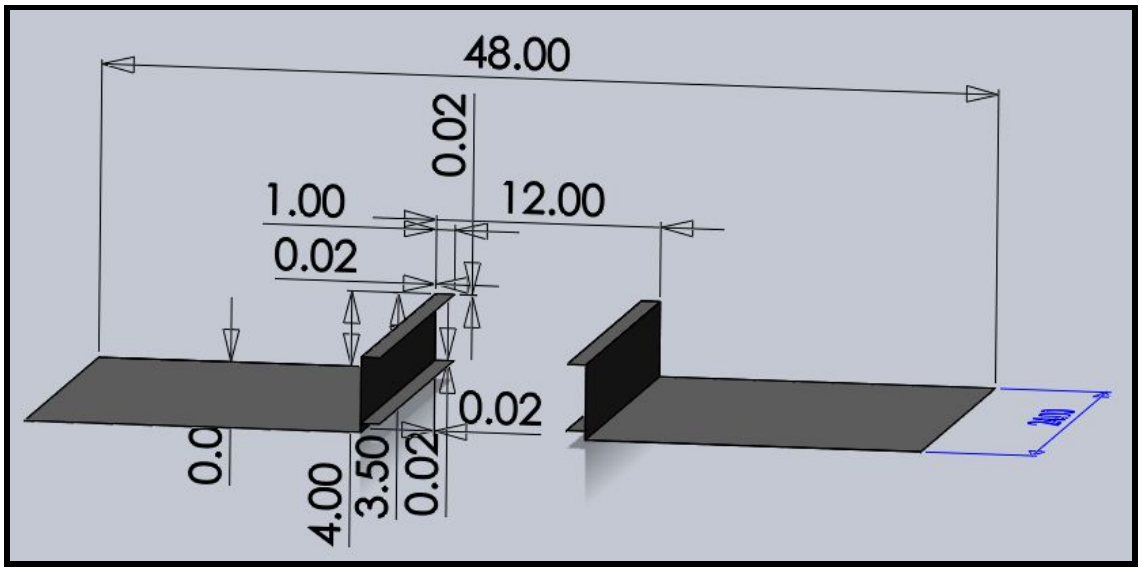
Internal Housing Dimensions



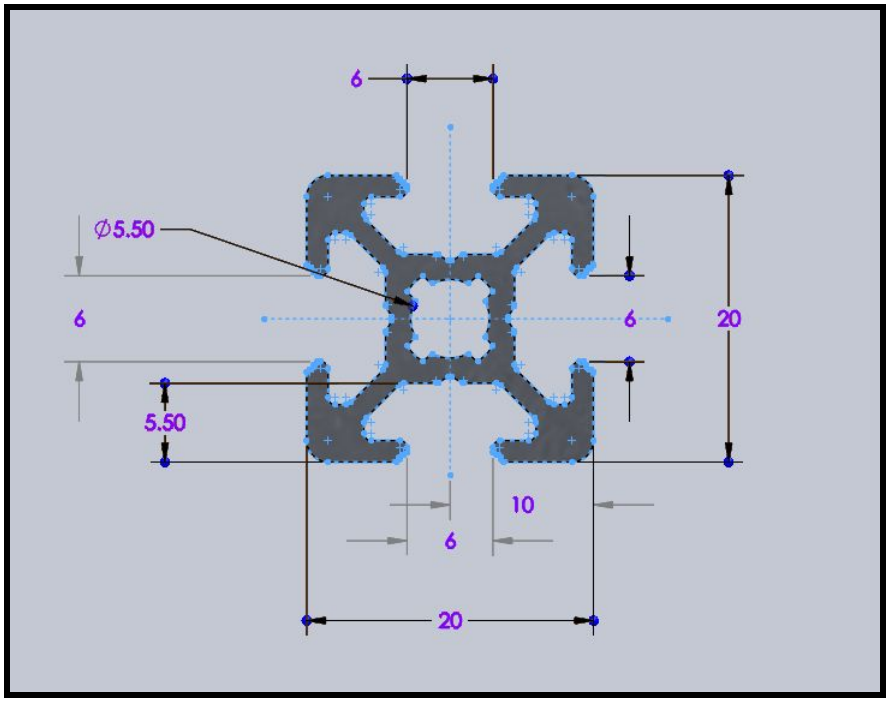
Internal Housing Dimensions



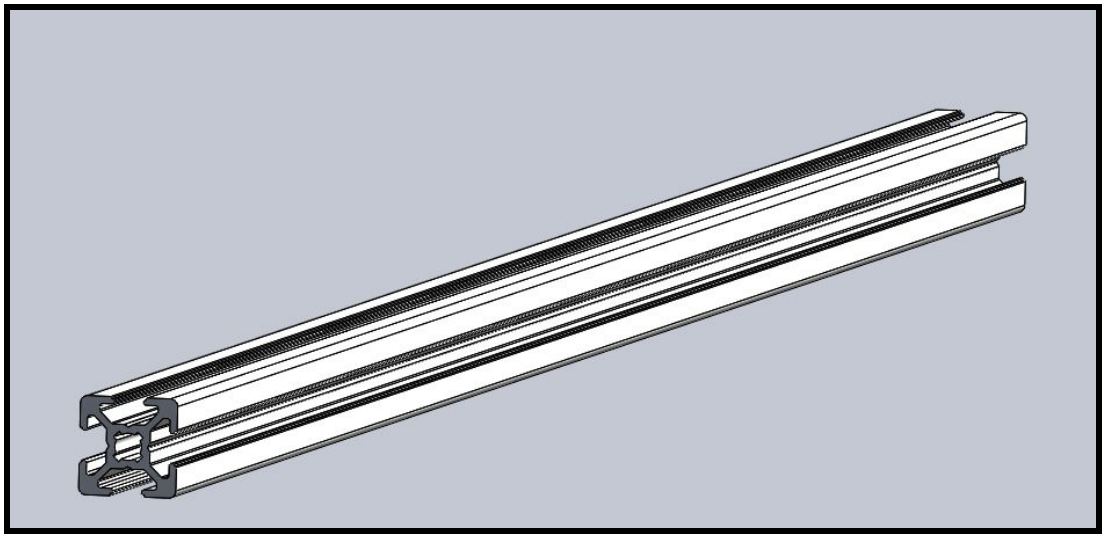
Vent Dimensions



Filter Housing



20/20 Extrusion Dimensions



20/20 Extrusion Isometric

Appendix C: Operation Manual

DIY Clean Hood Operation Manual

Proper Installation

1) Position the clean hood on a stable, level surface.
2) Ensure that airflow at the intake vent is not blocked by giving at least 5 cm of clearance behind the cabinet
3) All surfaces in front of the intake should be decontaminated with 70% IPA and dusted regularly

Using the Clean Hood

***Note**: The clean hood should only be used by a trained operator*

***Note**: This Clean Hood is only designed to mitigate specimen and material contamination. It provides no protection to the user.*

1) Before turning on the CH, check that the intake vent is clear of obstructions
2) Place all items into the hood before use
3) Decontaminate all items and workspace before use
4) After turning on the hood, wait 5 mins to allow for the hood to allow for the cabinet to fully filter any contaminated air
5) When not in use, the upper sash door should be lowered
6) After using the hood: decontaminate the workspace, close both sash doors, then activate UV Lamp

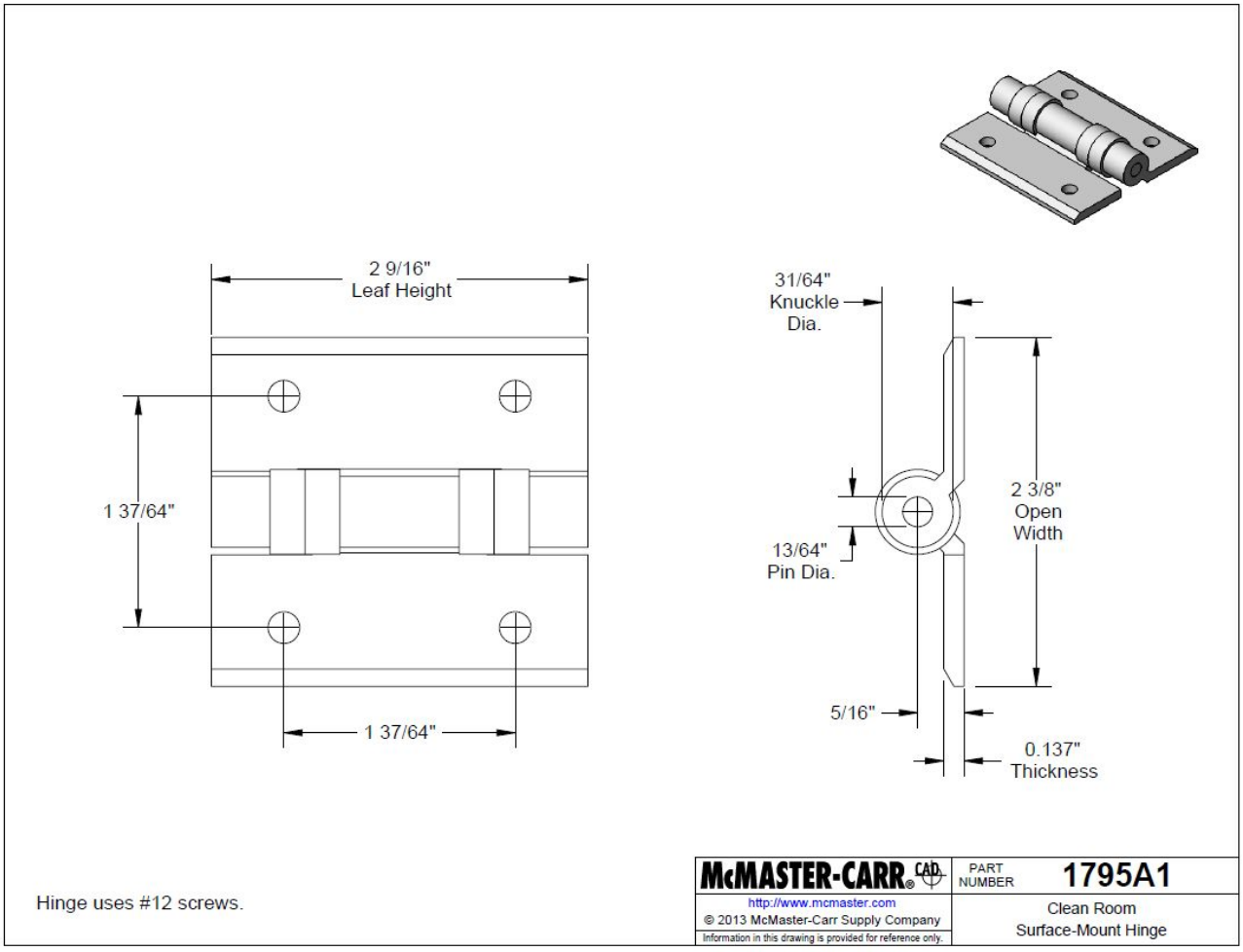
Device Maintenance

1) CH should only be cleaned with bleach or ethanol
2) Before replacing the filter, check that device is OFF and unplugged
3) Use gloves when replacing hood filter

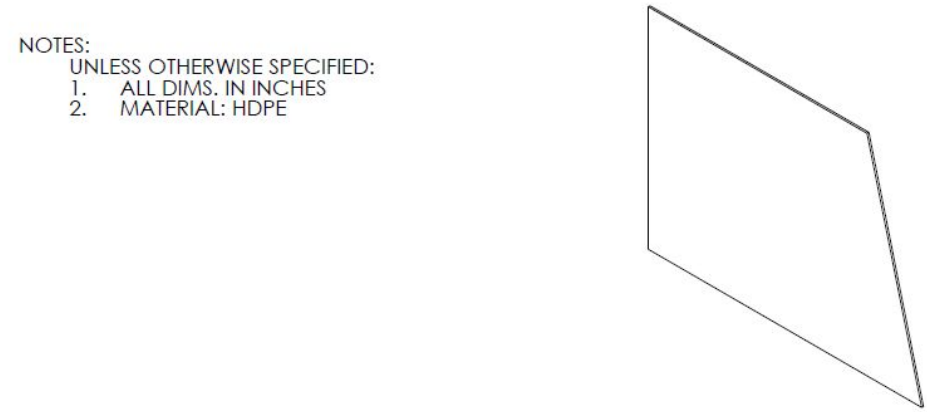
Safe Use of Clean Hood

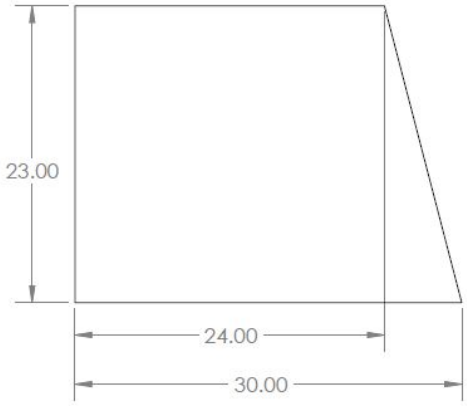
1) CH should NOT be used near open flames including: bunsen burners or candles
2) Clean all spills immediately
3) Overcrowding workspace can lead to insufficient airflow
4) DO NOT place any hazardous materials in the device
5) DO NOT look directly at UV Lamp when in use

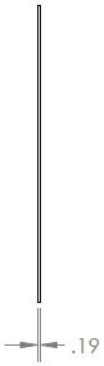
Appendix D: Sample of Engineering Drawings Provided to the Sponsor



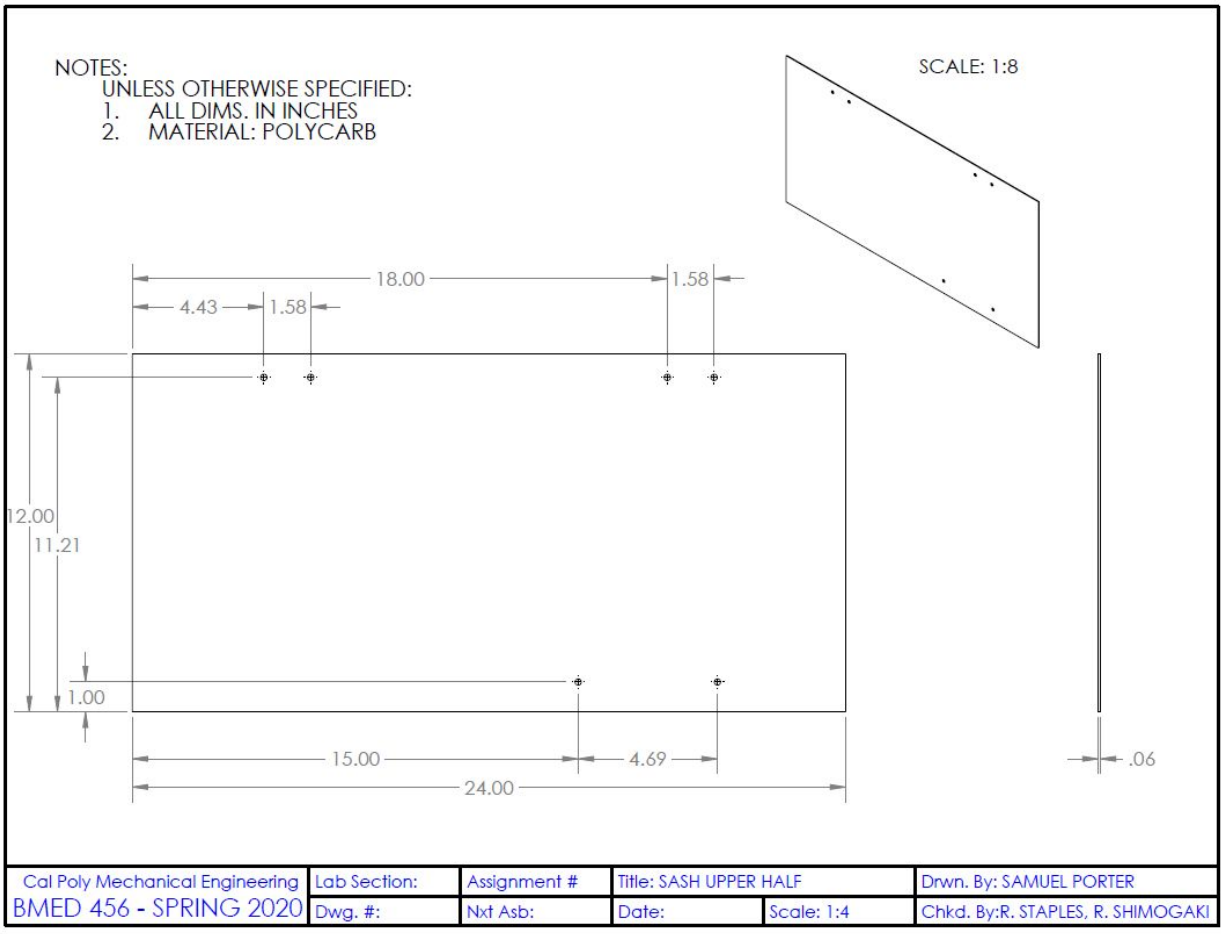
NOTES:
UNLESS OTHERWISE SPECIFIED:
1. ALL DIMS. IN INCHES
2. MATERIAL: HDPE







Cal Poly Mechanical Engineering	Lab Section:	Assignment #	Title:LOWER SIDE WALL		Drwn. By: SAMUEL PORTER
BMED 456 - SPRING 2020	Dwg. #:	Nxt Asb:	Date:	Scale:1:10	Chkd. By: R. STAPLES, R. SHIMOGAKI


NOTES:
UNLESS OTHERWISE SPECIFIED:
1. ALL DIMS. IN INCHES
2. MATERIAL: POLYCARB
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12.00
11.21
1.00
15.00
4.69
24.00
.06
Cal Poly Mechanical Engineering
BMED 456 - SPRING 2020
Lab Section:
Dwg. #:
Assignment #
Nxt Asb:
Title: SASH UPPER HALF
Date:
Scale: 1:4
Drwn. By: SAMUEL PORTER
Chkd. By:R. STAPLES, R. SHIMOGAKI