Modular Sterile Cleanroom

Conceptual Design Report Template

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DISCLAIMER

EXECUTIVE SUMMARY

The "Modular Sterile Cleanroom" project aims to design an ISO Class 7 modular sterile cleanroom with a fan filter unit (FFU) to be used in the manufacturing of medical devices. The project will also convert a current cleanroom into a gowning room that connects to the designed cleanroom. The cleanroom will meet customer and engineering requirements related to modularity, capacity, and ISO Class 7 standards.

This report will outline the detailed project objectives as identified by the project client and sponsors. All course and client deliverables will be described in detail. The team also set success matrices to measure the progress and outcome of the project. Customer and engineering requirements were created and detailed. A House of Quality compared all customer and engineering requirements by weighing their importance within the overall design. The most important engineering requirements were those related to the customer requirement of meeting ISO Class 7 standards such as maintaining positive pressure, particle count, particle size, airflow, ceiling coverage, and Reynold's number.

Benchmarking of other modular cleanroom designs was researched to determine the advantages and disadvantages of different cleanroom subfunctions. The current cleanroom design is the most beneficial benchmark as the design team can test and manipulate it in person. Literature reviews were completed by each team member focusing on different design aspects. The literature reviews consist of peer reviewed journal articles, textbooks, manuals, and websites focusing on the subtopics of structural integrity/material connections, particle and flow requirements, cleanroom materials, and pressure/ temperature requirements. All literature review sources served to help the team complete engineering analysis, mathematical modeling, concept generation, and prototyping.

The engineering analysis and mathematical modeling was divided among structural, thermodynamic, and computational fluid dynamic (CFD) analyses. Structural analysis calculated frame connection shear forces to be used during the concept selection process. Thermodynamic analysis determined pressure requirements for the cleanroom design. CFD analysis determined the placement of FFUs on the cleanroom ceiling to also be used in the concept selection process.

Black box and functional models of the FFU and cleanroom were used to identify subfunctions for the concept generation. The generated subfunctions frame connections, material connections, wall/ceiling material, fan number/location, and frame size are further developed into concept variants. Each concept variant advantage and disadvantage were used to create select criteria for each variant. The selection criteria and weighted and ranked to determine the best concept variant of each subfunction. The final concept variants of each subfunction chosen were square tubing nylon frame connections, screws to connect the materials, all hard wall polycarbonate wall and ceiling materials, two centered FFUs, and a 12' x 8' frame size.

A budget, schedule, and Bill of Materials (BOM) was compiled for the final design. The BOM outlines all components, materials, subassemblies, and quantities of parts required for manufacturing. A Failure Modes and Effects Analysis (FMEA) was then compiled on the final design to identify all critical potential failures and design mitigations to address or prevent the failures from occurring.

Initial virtual prototyping was completed using Ansys and Solidworks simulation programs to determine if structural supports are required to safely hold the fans weight, if the polycarbonate walls can maintain the positive pressure of the cleanroom, and how many bolts will be required to attach the bolts to the polycarbonate walls. Lastly, future testing was outlined that will be completed for future prototypes.

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1 BACKGROUND

The background of the project will be separated into the project description, deliverables, and success matrices. This section will act as a reference point for the project entirety to ensure the design team is meeting project objectives and deliverables.

1.1 Project Description

1.1.1 Project Title: Modular Sterile Manufacturing Cleanroom

1.1.2 Project Overview/Summary

The "Modular Sterile Cleanroom" project aims to facilitate the production of medical devices used in stroke treatment by establishing a specialized cleanroom environment. The project involves the design, construction, and testing of a filter-fan unit (FFU) and an extended modular curtained cleanroom area. The cleanroom must adhere to strict standards, ensuring a particle-free and sterile environment for the assembly of critical medical devices. The modular design allows for easy disassembly and reassembly, promoting flexibility and scalability in the manufacturing process.

1.1.3 Sponsors/Client

The client/sponsor for the project is Timothy A. Becker and his company Aneuvas Technologies Inc. Aneuvas Technologies Inc (ATI) is a medical device company organized around bringing a new neurovascular device (PPODA-QT) to clinical trials and potentially to the marketplace for treatment of aneurysms.

1.1.4 Project Objectives

The project objectives include to develop and justify the following attributes, including but not limited to:

- FFU compatibility with both the cleanroom and gowning room, ensuring adequate airflow to maintain positive pressure within the cleanroom.
- Design the cleanroom to accommodate up to 6 workers per module, considering necessary equipment.
- Allocate approximately 12' x 16' floor space.
- Integrate the existing 3-person cleanroom with the newly designed cleanroom.
- Repurpose the current 3-person cleanroom as a gowning room to ensure compliance with sterile manufacturing protocols.
- Create a new floor plan incorporating assembly station and testing tables.
- Implement cleanroom compliant storage for gowning, emphasizing adherence to proper gowning procedures.
- Conduct airborne particle counts and adhere to specific cleanroom standards for thorough cleanroom validation.
- Document repeatable manufacturing and laboratory processes to ensure consistency and quality control in the production of medical devices.
- Secure additional funds to extend the cleanroom from the initial 12’ x 8’ design into the updated 12’ by 16’ design.

1.2 Deliverables

1.2.1 Course Deliverables

Course deliverables are divided into presentations, reports, and prototypes.

1.2.1.1 Presentations

Presentation 1 introduced the project, included benchmarks and research used to begin designing to the customer's requirement. Presentation 2 included concept generation, along with calculations and analysis to identify the concepts that best fit the customer requirements, and an up-to-date budget and schedule. Presentation 3 introduced the 1st prototype, the questions the prototype answers, and described in detail the final design that was selected.

1.2.1.2 Reports

Report 1 elaborated on the information shared in Presentations 1 & 2. Report 2 contains Report 1, as well as elaborating on information shared in Presentation 3 and Prototype 1.

1.2.1.3 Prototypes

The first prototypes were virtual prototypes to determine the required thickness of the polycarbonate walls, placement of number of necessary hardware, and weight distribution of the FFUs. Pressure and structural load simulations using Solidworks and Ansys were used. The second prototypes will help determine the height of the cleanroom walls off the ground and the type of gasketing material to be used to seal the cleanroom.

1.2.2 Client Deliverables

Client deliverables are reflective of the project's objectives. The initial goal of the cleanroom design was to create a modular, spacious, and affordable cleanroom for use by Dr. Becker and other stakeholders. Based on additional funding availability, the team has expanded the cleanroom design size to a 12' x 16' cleanroom.

1.3 Success Metrics

To consider this project a success it must meet the project objectives, course deliverables, client deliverables, customer requirements, engineering requirements, and manufacturability. To confirm this has been achieved the team will complete manufacturing as early as possible in 2024. This will allow time to test the design's engineering requirements as well as have the cleanrooms certified by a registered organization before the conclusion of the school year. Another benefit of beginning manufacturing early is that it provides time to correct any mistakes made during the design process.

2 REQUIREMENTS

Requirements of the design project were divided into customer and engineering requirements. Customer requirements were those general design requirements requested by the project's client. Engineering requirements were expanded customer requirements into quantifiable measurements and/or calculations that can be done to satisfy the customer requirements. A House of Quality was generated to compare the customer and engineering requirements with each other as well as with other benchmarked designs.

2.1 Customer Requirements (CRs)

Based on the client's initial project requirements the team set the customer requirements as modular, transportable, spacious, ISO Class 7 compliant, and generator backup power. Modular refers to the finished cleanroom's ability to be disassembled and reassembled with ease. With a modular cleanroom comes a transportable one. The client requested a cleanroom that can be disassembled and transported if needed to other locations. The client also requested a spacious cleanroom with the ability to house at least six people. Since the cleanroom will be used for medical device manufacturing, it needs to be ISO Class 7 compliant to be certified at the end of the project. Lastly, the client would like a backup generator system to be incorporated in the design to maintain ISO Class 7 certificates when a power outage occurs.

2.2 Engineering Requirements (ERs)

The engineering requirements selected by the design team were generated directly from the customer requirements. The first two customer requirements of modular and transportable are ease of construction-based requirements and will not be evaluated as engineering requirements. Instead, they will be considered during the design for manufacturing process. The customer requirement of spacious directly relates to the engineering requirement of room area. The customer requirement of ISO Class 7 compliant encompasses six engineering requirements: positive pressure, particle count, particle size, airflow, ceiling coverage, and Reynold's number. Lastly, the customer requirement of generator back up power relates to the engineering requirement of power. The thresholds, limits, and constraints of each engineering requirement is detailed below.

- Spacious: The minimum requirement for room area will be greater than the current cleanroom size of $48ft^2$. However, the design team aims to have an area closer to $100ft^2$ to account for the customer requirement of housing six people. Constraints to the spaciousness of the room include support beams. The client does not want support beams in the room if possible.
- Positive pressure: The positive pressure difference between the inside and outside of the cleanroom must be a minimum of 0.2 Pa [1]. This value represents a lower limit as pressure in the cleanroom can be greater than 0.2Pa and still maintain particle count. The main constraint to the overall pressure difference is that is must be maintained with people moving in and out of the cleanroom.
- Particle count and size: Particle count and particle size must meet the ISO Class 7 requirements of a maximum of 352,000 particles of size greater than $0.5\mu m$, 83,200 particles of size greater than $1\mu m$, and 2,930 particles of size greater than $5\mu m$ [2]. The particle count and size are measured as a minimum limit. The particle count and size is constrained by the FFU HEPA filter and speed. The strictest requirement for the particle count and size is the maximum of 352,000 particles of size greater than $0.5\mu m$. Therefore, that constraint will be used as the main engineering requirement for particle size and count.
- Airflow: Airflow must meet the requirement of 0.051-0.076 m/s or 10-15 ft/s for the entire room and 60 – 90 air changes per hour [3]. Airflow like positive pressure, particle count and size will be measured as a minimum limit with the strictest requirement of 10 ft/s and 60 air changes per

hour. The airflow rate is constrained by the speed of the FFUs.

- Ceiling coverage: Ceiling coverage must be 15-20% covered with FFUs [2]. This design will aim to meet the minimum limit of 15% ceiling coverage. The biggest constraint on ceiling coverage is the structural supports of the ceiling frame. The frame will need to be specifically designed to support the weight of the minimum fan requirements.
- Reynold's number: Reynold's number must be less than 3500 to be considered transitional flow and less than 2300 to be considered laminar flow [4].
- Power: An initial power requirement estimate for all FFUs is 7200W. A full electrical load analysis will be performed on the cleanroom model in upcoming engineering analyses. Power will be assessed as a limit as well. The constraints to the power requirements of the cleanroom include the capability and cost of the backup battery units.

2.3 House of Quality (HoQ)

The team developed a House of Quality, shown in **Appendix A**, to compare the customer requirements with the engineering requirements. First, the customer requirements were given weights on a scale of 1 to 5. 1 represents less important and 5 represents more important. Then, the customer requirements were directly compared against the engineering requirements on a 1, 3, 6, or 9 ranking system. 1 showed a low correlation between the requirements, 3 and 6 a medium correlation, and 9 a high correction. Positive numbers showed a positive correlation and negative numbers show a negative correlation. Cells left blank were identified as having no correlation. Based on the rankings of the customer and engineering requirements, the absolute and relative technical importance was calculated. Absolute technical importance was calculated by weighing the customer weight against the rankings. The relative technical importance was then determined based on the absolute technical importance ratings. Room Area ended up ranking the highest of the engineering requirements. This was because it was the only technical requirement with correlations to the modular and transportable customer requirements. The ISO Class 7 compliant requirements all ranked second and third. However, the design team will treat these requirements as more important than the room area going forward. The cleanroom cannot be certified regardless of room area unless it meets the ISO Class 7 requirements. The last ranking engineering requirement was the power requirement. Adding generator backup power is a low priority customer requirement and therefore will also be treated as the lowest priority engineering requirement.

3 Research Within Your Design Space

3.1 Benchmarking

3.1.1 Current Cleanroom Design (ISO 7):

The first cleanroom design featured in benchmarking is the current cleanroom design the team is to reimagine for this project located in **Figure 1.**

Figure 1: Current Cleanroom Design

This cleanroom is 6' x 8' in size and the frame consists of steel that is powder coated and welded together and is disassembles into two pieces. The wall material used here is a vinyl curtain covering the whole enclosure and is using magnetic adhesive strips as connectors. The design consists of one FFU, distributed by Terra Universal, Part no. 6601-24-H. The FFU is 2' x 4' in size, uses a HEPA filter, has top side filter replacement, and can be used up to ISO 5 applications. This cleanroom cost $2000 to build.

3.1.2 Softwall Cleanroom (Clean Air Products) ISO 8-4:

The second cleanroom design in benchmarking is the Vertical Flow Soft Wall Portable cleanroom distributed by clean air products as shown in **Figure 2** below.

Figure 2: Vertical Flow Softwall 4'x4' Cleanroom

The Vertical Flow Softwall Portable Cleanroom by clean air products features a modular cleanroom design that can be manufactured up to 12ft without adding any addition supports or hanging points. The design consists of a modular bolt-together design that simplifies initial assembly and future additions. All frame components are painted in a durable and cleanroom approved white powder coated finish. This design utilizes aluminum T-bars with polyurethane foam gaskets that form the ceiling grid. Included with transparent clear 40 mil flame retardant curtains attached to the frame with dual lock [5].

3.1.3 Hard Wall Cleanroom (Clean Air Products) ISO 8-4:

The final cleanroom design for benchmarking is the Vertical Flow Hard Wall Modular Cleanroom distributed by clean air solutions shown below in **Figure 3**.

Figure 3: Vertical Flow Hard Wall Modular Cleanroom

The Vertical Flow Hard Wall Cleanroom can distribute up to 34 ft and the interior height of 8ft up to 14 ft high. This design consists of a gasketed T-bar ceiling grid and offers an attractive design. The cleanroom is stated to be easily assembled and easily expandable/upgradable. The cleanroom is also offered as single pass or recirculating and allows for adjustable internal pressures up to 0.1 in W.C. The room can be distributed from class 100,000 to class 10 [5].

3.2 Literature Review

3.2.1 Structural Integrity/Material Connections – Logan Bennett

"Geometric and Structural Design of Foldable Structures" [6]

This paper details the strength and use of folding structures, which has value to this project as the goal is modularity and ease of assembly. This paper helped to remove foldable structures as an option as it showed the complexity and lack of strength of the scissor mechanism was not outweighed by any benefits.

"Connections in Steel Structures IV: Behavior, Strength and Design" [7]

This is a report publishing the proceedings of the "*Fourth International Workshop on Connections in Steel Structures*". Specifically, the "Costs related to the connections" section helped to rule out certain connections that would be too expensive to justify, based on the minimum requirements for the connections. It also helped to rule out steel entirely due to the costs associated with powder coating.

"Analysis and experimental verification of the strength of telescopic booms for construction machinery" [8]

This journal was made specifically for telescopic booms of heavy machinery, however the conclusions reached were applicable to smaller fewer mechanical uses. This was used to narrow the options for our frame as well as the forced required to hold the frame steady using telescoping beams and columns was more than could be achieved easily and cheaply.

"Steel Connections – Types and Uses," [9]

This is a web page that gives brief descriptions of different commonly used steel connections. Though the final design uses aluminum, the information here is applicable to aluminum as well as steel. The webpage was used to make sure all options for connections were considered before moving forward with the final design.

“Beam Designer” [10]

This webpage calculates maximum stress, moments, and shear for customizable beam conditions, including mounting style, moments of inertia, load distribution, and material. This was primarily used to confirm calculations made by hand regarding the load placed on the ceiling beams used to hold up the FFUs.

“Machinery’s Handbook, 25th ed.” [11]

This book contains material strengths, as well as equations used to design the structural elements of the frame. It also provides advice on factors of safety and where certain materials are best utilized. It helped to settle on the aluminum frame.

“Magnet pull force: Measure strength of magnet: Magnets holding power” [17]

A quick guide describing the mechanics of magnetic fasteners. This information will be used in the concept generation to determine the validity of magnets as a connection material.

“ANSYS Workbench Tutorial - Introduction to Static Structural” [35]

This is a YouTube tutorial video for Ansys static structural, it was the primary source used in order to create the virtual prototype justifying the design of the ceiling of the Cleanroom.

“Ansys Workbench Guide - University of Sydney” [40]

A document which was used when the YouTube video above was not detailed enough. Details the process of creating an Ansys static structural simulation.

“Electric Circuits” [41]

A textbook used in EE classes that is to be used for the analysis of the cleanrooms power requirements, includes AC and DC examples as well as all theory necessary for this project’s purposes.

3.2.2 Particle Count and Flow Requirements – Michelle Borzick

“Air Flow Rates” – Clean Rooms West [3]

The Clean Rooms West website provides measurable values for the average airflow across the entire cleanroom, air changes per hour, and ceiling coverage requirements for an ISO Class 7 cleanroom. The standard for airflow across the entire room in 0.051-0.076 m/sec or 10-15 ft/min. The average air changes per hour is 60-90. The average airflow requirements will be used to compare measured airflow in the cleanroom during the construction phase to ensure the cleanroom standards are being maintained.

“Cleanroom ISO 7 Specifications” – Clean Air Products [2]

The Clean Air Products website breaks down quality and standard requirements for all ISO classes of cleanrooms. The most valuable information for the design team from this website is the particle count requirements for the ISO Class 7 cleanroom shown in **Figure 4** below. The particle count requirements as well as the air flow requirements from the previous sources will be used in the Fluid Analysis to help determine cleanroom size and FFU placement. The air flow velocities and changes per hour requirements will be used to simulate air flow with different FFU placements. The particle count requirements will be tested once the initial cleanroom has been built.

Maximum Number of Particles in Air
(Particles per cubic meter)

ISO Class	Fed-Std 209E Class	Particle Size					
		≥ 0.1µm	≥ 0.2µm	≥ 0.3µm	≥ 0.5µm	≥1µm	≥ 5µm
ISO 1		10	2				
ISO 2		100	24	10	4		
ISO 3	(Class 1)	1,000	237	102	35	8	
ISO 4	(Class 10)	10,000	2,370	1,020	352	83	
ISO 5	(Class 100)	100,000	23,700	10,200	3,520	832	29
ISO 6	(Class 1,000)	1,000,000	237,000	102,000	35,200	8,320	293
ISO 7	(Class 10,000)				352,000	83,200	2,930
ISO 8	(Class 100,000)				3,520,000	832,000	29,300

Figure 4: Cleanroom Particle Count Requirements

“Designing Air Flow Systems” [12]

This manual describes the types of air flows, types of air systems, pressure losses in an air system, fan performance specifications, and pressure calculations. First, the laminar and turbulent flow areas of an air system are described. Laminar flow is seen parallel in the centers of air systems and turbulent flow is seen perpendicular to the center and parallel to the outer edges of the system. Because of the mixed laminar and turbulent flows, most systems fall into a transitional flow category. This information will be used to determine what locations to calculate flow type in. Next the manual describes how pressure loss occurs in air systems. The pressure can be broken down into component pressure losses, dynamic pressure losses, and frictional pressure losses. The component pressure losses in the team’s cleanroom would be the known pressures of the FFUs. Dynamic pressure losses will be negligible because the cleanroom structure will not change shape or direction as pipes do. Frictional pressure losses will be present on the cleanroom walls but will also be considered negligible. These pressure losses will be accounted for when simulating the air flow of the cleanroom.

“Analysis and experiments on the characteristics of airflow and the air cleanliness protection region under fan filter units in cleanrooms” [13]

This peer reviewed article from the journal *Sustainability* explores how to reduce the amount of air supply required for cleanrooms using FFUs. To determine how to reduce air supply, the research team experimented using three different FFU sizes and four air supply velocities. The resulting airstream velocities and particulate concentrations were measured. The experimental methods will be studied by the team to help design experimental studies on the build cleanroom for FFU placement.

“Impact of the speed of airflow in a cleanroom on the degree of Air Pollution” [14]

This peer reviewed article from the Journal of Applied Sciences studied how different fan velocities impacted the particulate concentrations of a cleanroom. The same FFU was tested on different speeds and particle counts were taken at various locations in the cleanroom. Like the previous study, the experimental methods of the experiment will be studied to help determine the best experimental methods for upcoming particle count experiments.

"Experimental investigation of particle dispersion in cleanrooms of electronic industry under different area ratios and speeds of fan filter units" [15]

This peer reviewed article from the Journal of Building Engineering studied the impact of reducing air supply volume of FFUs to save energy. They performed experiments on three different FFU speed ratios, four particle source locations with 16 subzones, and two FFU area ratios. The study found that air supply volume could be reduced by almost half while maintaining particle removal requirements. They also found that reducing the FFU area ratio negatively impacted the particle removal and that regardless of air speed the particle removal away was decreased for areas away from directly under the FFU. Like the previous studies, this experiment will be considered to design a velocity and particle count experiment on the design team's cleanroom.

Introduction to Fluid Mechanics [4]

The Introduction of Fluid Mechanics textbook will be used to find equations for laminar/turbulent flow and air flow principles. Equations for Reynolds number and Bernoulli's Principle will be used in calculations to determine if the cleanroom airflow is laminar or turbulent and if pressure gradients are maintained appropriately.

"Cleanroom Fan Filter Units" [30]

This website has all the specifications of the WhisperFlow FFUs that will be used in the cleanroom design. The specifications will be used to determine filter life expectancies, velocity output, pressure drop, and power usage of the fan. The filter expectancies will be used to determine a maintenance schedule to mitigate potential risks to the cleanroom's cleanliness. The velocity out and pressure drop will be used in Computational Fluid Dynamic analyses and as experimental comparisons. The power usage will be used to determine the necessary backup battery power to run the FFUs.

"Ansys Fluids" [38]

The Ansys website will be used to explore the different Computational Fluid Dynamics simulations and tutorials available in Ansys to be performed on the cleanroom to answer various fluid dynamic design questions. Some of the ISO Class 7 requirements like airflow, air exchange rate, and positive pressure can be simulated using Ansys Fluid.

Understanding Air Pressure in Cleanrooms [39]

This website describes how air pressure in cleanrooms works and why cleanrooms require pressure differentials. This information will be used when designing the experiment that will be used in the second prototypes. The prototype will explore the airflow and pressure of current cleanroom that will be converted into a gowning room. Using this website, the team can make inferences with the pressure data collected during the experiment.

3.2.3 Cleanroom Materials – Gia Neve

"Modular Softwall Cleanrooms: Cleanroom design," [19]

This website provided a large amount of information on the design of soft wall cleanrooms and the advantages associated with them. This website contributed and was used to aid the concept selection process when deciding between soft wall deigns opposed to a hard wall design.

“Materials Science and Engineering” [20]

This textbook was used to supply the team with helpful equations for understanding how a material acts under stress and strain. While the team did not end up needing to do much else with this source, it could still become relevant in the future when constructing our virtual prototype one.

“Clean Room Design: Minimizing Contamination Through Proper Design” [21]

This book provided detailed guidance on all aspects of cleanroom airflow, the mechanics of airflow, and how contamination is carried through the room. This book mapped the effect of human interference on unidirectional airflow and the potential of contamination. The main area of this book that was used was the laminar flow section used when deciding what flow patterns are needed for our design.

"Softwall Cleanrooms," [5]

This is a website for clean air products which had numerous explanations and definitions used within our report. This website goes into detail on the differences between soft wall and hard wall cleanrooms and their specific applications. This was used greatly when finding benchmarks and the concept selection for hard walls vs soft walls. Because Clean Air Products are a distributer of cleanrooms, this provides the team with valuable insight to how much premade cleanrooms can cost, which impacted our deign heavily.

"FS209E and ISO Cleanroom Standards," [22]

This source is a document containing valuable information on iso cleanroom standards and how to obtain them. This document is very useful as Terra Universal (the distributor of this document) is the company that distributes the FFUs the team plans to use for our cleanroom design.

“Comparison of Conventional Cleanrooms” [23]

This source is a report that goes into heavy detain about the fundamentals of a cleanroom, cleanroom standards, cleaning procedures, modular cleanrooms, filtration, etc. The only use of this book thus far has been to understand the cleanroom classes and designs that best fit the teams need, however, this report will remain as a very useful tool as the testing and monitoring stages of the design begin.

"Cost-effective Clean Room Designs," [24]

This paper looks at the underlying principles of cleanroom technology and explains how the associated stringent requirements can be met in the most cost-effective way possible. This paper provided good insight on what parts of our design can be made more cost effective and what is worth spending more money on for better quality assurance.

ePlastics [25]

This website was used to appropriately calculate costs and evaluate what type of plastic or rigid material would be best suited to enclose our cleanroom.

Esto Connectors [26]

This website was used to appropriately calculate costs and evaluate what connector type would be best suited to bind our cleanroom together while still upholding modularity.

80/20 [27]

This website was used to appropriately calculate costs and evaluate what type of framing material would be best suited to be the skeleton of our cleanroom.

3.2.4 Pressure and Temperature Requirements – Aaron Reynoza

“FUNDAMENTALS OF ENGINEERING THERMODYNAMICS” [28]

In this textbook, it provides a table that states the characteristics of air based on a few properties. The difference between the cleanroom and the environment. It is important to use this resource because it will allow the team to get air properties in a timely manner. This textbook also gives information of water, which will be helpful when the cleanroom environment gets humid.

“Characterization of minienvironments in a cleanroom: Design characteristics and environmental performance,” [29]

From the article, it describes the ways to maintain pressurization for a positive pressure and negative pressure in a minienvironment. A minienvironment has a strict regulation to be labeled as a clean environment. While different from a cleanroom, the article does give information on what the minimum pressure difference. Based on our customer requirements, the pressure in the cleanroom will be a positive pressure. To maintain an effective cleanroom, the minimum pressure that is required is 0.2Pa.

“Maintaining Area or Room Pressurization in Manufacturing and Healthcare” [30]

On the website, the article talks about the importance of pressurization in the cleanroom. The website also gives a value on the amount of air changes required to be a clean environment. The amount of air changes is 20 ACH (Air Changes per Hour). Based on the description of the cleanroom, it is important to keep a positive pressure cleanroom is because it does not allow outside particles to go inside the cleanroom.

“The development of fan filter unit with flow rate feedback control in a cleanroom,” [31]

The article is about the importance of an adjustable flow rate for the filter fan unit. It states that it is important to control the flow rate because it will make the cleanroom air supply stable. It is also important to control the air velocity of the filter fan unit because it can also affect the amount of air changes.

“Humidity and the Ideal Gas Law,” [32]

The website article describes the relationship between Humidity and the Ideal Gas Law. The articles stats that when the air gets humid, it will have an increase element of H2O which will change the properties. Based on the provided chart, if the humidity percentages increases, the moister content of air also increases. This is important for the team because it gets humid in Flagstaff which will affect the cleanroom.

"Analysis Thermodynamic Analysis of Air Conditioning System of Clean Rooms," [33]

The article describes the effects of an Air Conditioning System inside the cleanroom. The researchers analyzed an air conditioning system by its exergy generation, and the thermodynamic efficiency. The article describes that during hot and humid days, the coefficient of exergy increases while during cold days, the coefficient of exergy decreases. The information provided will inform the team on the effects of an air conditioning unit of a cleanroom.

3.2.5 Prototyping for Material Connections – Aaron Reynoza

"Polycarbonate | Designerdata," [45]

On the Designer data website, it displays the generic mechanical properties of Polycarbonate. Information including Yield Strength, Tensile Strength, and Shear Modulus are given in the website. The reason why this information is important is because it allows the team to accurately input the characteristics of a Polycarbonate Sheet when doing a virtual Prototype. This will give the team accurate results based on the mechanical properties of Polycarbonate.

"McMaster-Carr Zinc-Plated Grade 5 Steel Flanged Hex Head Screws," [46]

McMaster-Carr is a vendor website that allows users to buy products including screws. On this page, McMaster-Carr shows the dimensions of a ¼"-20 Flange Bolt and CAD Drawings. The importance of this website is that it allows the team to accurately represent the Bolt during a Virtual Prototype.

"Simulation Studies - 2023 - SOLIDWORKS Help," [47]
The Simulation Studies for SolidWorks is a page with official references to help the team with the SolidWorks Simulation Tool. The page includes tutorials, Tips, and information about creating an accurate simulation which will help get valuable information. It is important to have this source is because it allows the team to quickly look up information and solve issues on the Official SolidWorks page.

3.3 Mathematical Modeling

3.3.1 Structural Analysis – Logan Bennett

3.3.1.1 Frame Connections Shear Force Analysis

To identify the amount of shear force and torsion force being applied to the connections, a shear flow analysis must be made. The Shear flow analysis can determine the maximum shear and torsion force that can be applied to a frame. For this calculation, A 4x8 ft frame will be used to do the calculation, since this design will be common for our cleanroom. The force being applied to the frame will be the weights of the two filter fan units which will be applied to the single frame. This will calculate the worst-case scenario for the frame since all the weight will only act on the frame instead of multiple ones. Throughout this section will show the process of doing the shear flow analysis. The maximum shear force will be calculated using **(1)** where τ_{max} is the shear force in psi, V is the force of the FFUs in lbf, Q is the moment area of the frame in inches, I is the Moment of Inertia in in^4, and t is the beam thickness in inches.

$$\tau_{max=}\frac{VQ}{It} \tag{1}$$

The first step of calculating the shear flow is to find the Moment of Inertia location of the 4x8 feet frame using the 1.5x1.5-inch extruded aluminum. Since the frame is a rectangle, the location of the Moment of Inertia will be in the center of shape. With the given dimensions, the team were able to find the Moment of Inertia location of the frames shown in **Figure 5**.

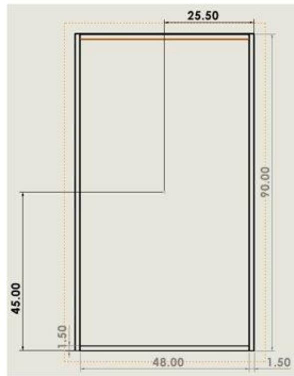


Figure 5: Location of Moment of Inertia in Frame

The next step was to find the first moment area of the frame was calculated in **(2)** by choosing a section of the beam and using its properties to generate a solution. The beam properties that is useful is it the length (l), height (h), and the distance (d) from the frame moment of inertia to the local Moment of Inertia.

$$Q = l * h * d \tag{2}$$

$$Q = (48in) * (1.5in) * (44.25in) = 3186\ in$$

For the maximum shear stress, the only force that will act on the frame will be the weight of the FFUs. The total weight of the FFUs is 200 lbm, which is 6440 lbf when converting the mass into a force in **(3)**.

$$V_{max} = 200\ lbm * 32.2\ slug = 6440\ lbf \tag{3}$$

To calculate the Moment of Inertia, the team would have to use the specific rectangle MOI equation. Since the frame is not a complete rectangle, the moment of inertia will use the outside dimensions, and subtract it from the inside dimensions in **(4)**.

$$I = \frac{51(90)^3}{12} in^4 - \frac{48(87)^3}{12} in^4 = 6523.75in^4 \tag{4}$$

The last variable that needs to be solve is the width across the section, which is solved by dividing the beam width by 2 in **(5)**.

$$t = \frac{w}{2} = \frac{1.5\ in}{2} = 0.75in \tag{5}$$

With all the variables, the Max torsion that the frame will experience will be 4193.4 psi as shown in **(6)**.

$$\tau_{max} = \frac{VQ}{It} = \frac{6440lbf(3186in)}{6523.75in^4(0.75in)} = 4193.4\ psi \tag{6}$$

3.3.2 Thermodynamics Analysis – Aaron Reynoza

3.3.2.1 Pressure and Temperature Requirements

It is important to maintain an air positive pressure difference in the cleanroom so it can have a sterile environment. To prove that the cleanroom will work, the Ideal Gas Law **(7)** will be used to calculate the pressure difference based on the properties inside and outside the cleanroom. The variables in the Ideal Gas Law are shown in **Table 1.**

$$pv = \frac{mRT}{M} \quad \textbf{(7)}$$

Table 1: Table of Variables

Variable	Description
p	Pressure (psi)
v	Volume (ft^3)
m	Mass(lb)
R	Universal Gas Constant ($\frac{ft \cdot ibf}{Rmol \cdot R}$)
T	Temperature (R)
M	Molar mass ($\frac{lb}{lbmol}$)

Before doing calculations of the pressure difference, information about the variables and assumption were gathered from the location of the cleanroom and the Thermodynamics textbook [25] in equations **(8)** through **(12)**.

$$p1 = 30.5(inHG) = 14.98(psi) \quad \textbf{(8)}$$

$$v1 = 444564.1(ft^3) \quad \textbf{(9)}$$

$$T1 = 70(F) = 529.67(R) \quad \textbf{(10)}$$

$$R = 1545(\frac{ft * lbf}{lbmol}) \quad \textbf{(11)}$$

$$M = 28.97(\frac{lb}{lbmol}) \quad \textbf{(12)}$$

The outside properties of the air will help determine the mass of the air since the team did not acquire the tool to measure. After rearranging the Ideal Gas Law to solve for mass **(13)**, the air mass was 3394.74 lb.

$$m = \frac{pvM}{RT} \rightarrow m = 3394.7(lb) \quad \textbf{(13)}$$

To be able to solve the pressure of the cleanroom, a few assumptions will be made including the air mass of the environment is the same as the cleanroom, and the inside temperature will be 50°F. This will help simplify the Ideal Gas Law by adding value to the air properties of the cleanroom. The inside cleanroom calculations are shown in **(14)** to **(18)**.

$$v2 = 720ft^3 \quad \textbf{(14)}$$

$$T = 50(F) = 509.67(R) \quad \textbf{(15)}$$

$$R = 1545(\frac{ft * lbf}{lbmol}) \quad \textbf{(16)}$$

$$M = 28.97(\frac{lb}{lbmol}) \quad \textbf{(17)}$$

$$m = 3394.74(lb) \quad \textbf{(18)}$$

Rearranging the Ideal Gas Law to solve for pressure **(19)**, the calculated pressure was 889.97 psi.

$$p = \frac{mRT}{vM} \rightarrow p = 899.97(psi) \tag{19}$$

With both pressures labeled, the pressure difference that the cleanroom **(20)** is 874.99 psi, which converted to pascals, will be 6.03 MPa.

$$p2 - p1 = (899.97 - 14.98)(psi) = 874.99(psi) = 6.03(MPa) \tag{20}$$

3.3.3 Fluid Dynamics Analysis – Michelle Borzick

3.3.3.1 Fan Number Requirements

The fan number requirement was determined by the ISO Class 7 minimum standard requirement of 15% for ceiling coverage ratios. The ceiling coverage was calculated using a simple area ratio shown in Equation 21.

$$Ceiling\ Coverage = \frac{Area\ FFUs}{Area\ Cleanroom\ Ceiling} \tag{21}$$

The ceiling coverage with only one FFU is 8.33% **(22)** which does not meet the standard requirement. The ceiling coverage with two FFUs is 16.67% **(23)** which does meet the standard. Therefore, the team moved forward with a two FFU configuration. Since the new cleanroom model has been doubled to a 12x16 configuration, the ceiling coverage can also be doubled to four fans and maintain the same ceiling coverage **(24)**.

$$Ceiling\ Coverage\ 1\ Fan = \frac{2x4}{12x8} = 8.33\% \tag{22}$$

$$Ceiling\ Coverage\ 2\ Fans = \frac{2(2x4)}{12x8} = 16.67\% \tag{23}$$

$$Ceiling\ Coverage\ 4\ Fans = \frac{4(2x4)}{12x16} = 16.67\% \tag{24}$$

3.3.3.2 Computational Fluid Dynamics Analysis

A Computer Fluid Dynamic (CFD) analysis was completed to determine the best ceiling configuration of the two FFUs. An Ansys Fluent CFD analysis was completed using a simplified model of the 12x8 cleanroom. Like the fan number calculations, the fan location determination can be doubled to be applied to the updated 12x16 dimension cleanroom. Assumptions made in this simulation are constant and equally distributed airflow leaving the FFUs, no impact on the HEPA filter condition, and a set wall gap of 8in. Simulations for two different fan configurations were completed, one with the two fans mirrored and centered on the ceiling and one with the two fans in the corners of the ceiling. The simulation was run using the velocity output of the fans set to 0.4572 m/s or 90 ft/min as specified by the WhisperFlow FFU specifications [30]. The simulation output was set to 0.2 Pa as specified by the cleanroom pressure standard [1]. The simulations output Reynold's numbers for the streamlines created for the different configurations. The streamline results for the centered fans are shown in **Figure 6** and for the cornered fans in **Figure 7**. The centered fans had a Reynold's number of 3441.3 representing transitional flow and the cornered fans had a Reynold's number of 3703.6 representing turbulent flow. Additional CFD simulations and experiment verifications will be done to determine the impact of different fan speeds and different wall height gaps on the airflow.

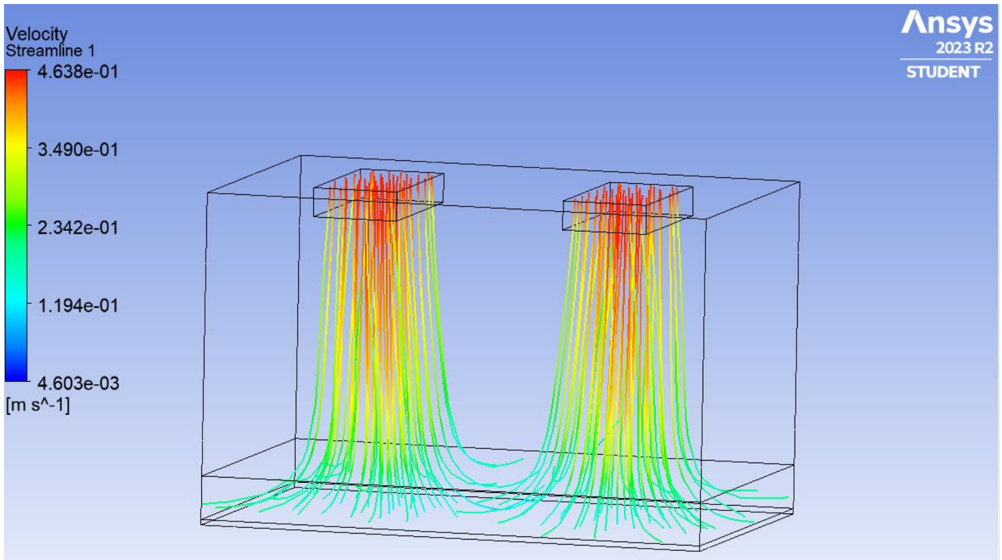


Figure 6: Centered Fans Streamline Simulation

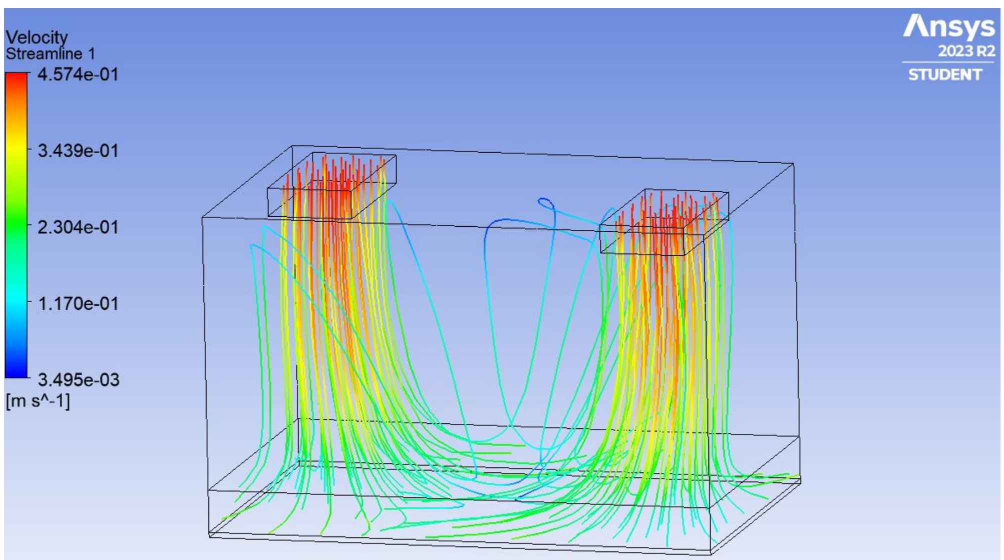


Figure 7: Cornered Fans Streamline Simulation

4 Design Concepts

4.1 Functional Decomposition

A functional model and black box model were created to begin the concept generation portion of design. A black box model for the FFU and cleanroom were made to understand how the FFU and cleanroom uses material, energy, and signals to maintain function. The black box model for the FFU is shown in **Figure 8**. The FFU black box model was used to understand how a FFU maintains positive pressure and acceptable particle count. The FFU for the cleanroom shown in **Figure 9** was used to understand what roles the cleanroom structure itself plays in maintaining positive pressure and particle count. This design project will not be designing a FFU therefore it will be essential for the design team to understand all interactions between the FFU and cleanroom.

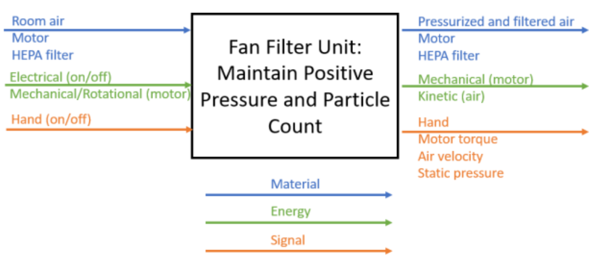


Figure 8: FFU Black Box Model

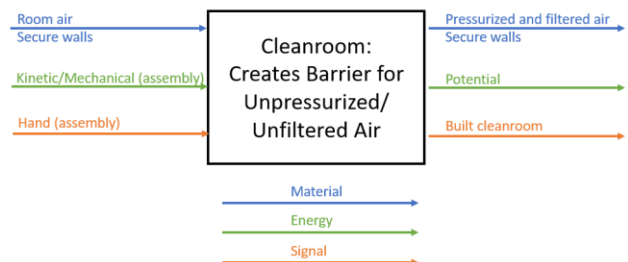


Figure 9: Cleanroom Black Box Model

The material, energy, and signal inputs and outputs from the black box models were used to construct one functional model. The functional model (**Figure 10**) was used to understand which aspects of the FFU create positive pressure and filtered air and how those functions interact with the cleanroom.

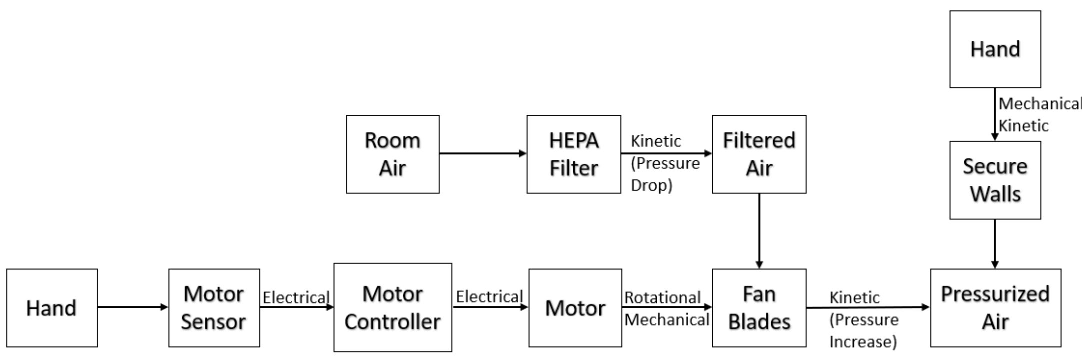
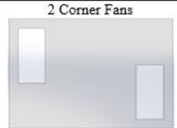
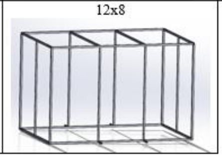


Figure 10: FFU and Cleanroom Functional Model

4.2 Concept Generation

To determine the important subfunctions and concept variations of the design, the team created a morphological matrix of all important subfunctions to the design with all concept variations possible. The morphological matrix is shown in **Table 2**. The subfunctions chosen were frame connections, material connections, wall/ceiling material, fan number/location, and frame size. Concept variants were brainstormed and all recorded.

Table 2: Morphological Matrix

Subfunctions	Concept Variants			
Frame Connections	Square Tubing Nylon Connectors 	T-Slots (80/20) 	Welded 	Screwed Joints 
Material Connections	Magnets 	Adhesive 	Slide in Frames 	Screws 
Wall/Ceiling Material	All Vinyl Soft Wall 	All Polycarbonate Hard Wall 	Polycarbonate Walls with Vinyl Ceiling 	Vinyl Walls with Polycarbonate Ceiling 
Fan Number/Locations	1 Centered Fan 	2 Off-Center Fans 	2 Corner Fans 	
Frame Size	10x10 	12x8 		

A detailed summary table of all advantages and disadvantages for each subfunction are shown in each subfunction section below. All concept variants of each subjunction will be discussed in detail in the following sections. Each concept variant will then be compared in a decision matrix to determine the final design concept that will be used as that subfunction in the final design.

4.2.1 Frame Connections

Frame connections are the components which the beam will be connected to create a frame. The 4 frame connections that will be used are the Nylon Square tubing connectors, 80/20 Specific T-Slotted connections, screwed joints, and welding. Based on the mathematical modeling of the frame connections, it must handle the maximum shear stress of 3.02 lbf and a torsion stress of 1.96 psi. For the customer requirement the frame connections must be affordable, can be assembled, disassembled, and have modularity.

4.2.1.1 Nylon

With the square nylon tubing connectors, the advantage of this frame connection allows modularity. To assemble the frame with nylon connectors, the user must insert these components between the beam and then secure it by hitting it with a rubber mallet. This will allow the user to create many designs of the frame while not interfering with other parts. Since the nylon connectors are inserted by a mallet, The modularity also comes with good stability because the rough textures on the nylon connector allow friction between the beams which makes them stationary. One last advantage of square tubing connectors is the material. With the material nylon, buying or manufacturing these connectors will be cheap which goes with the customer requirement of being affordable [35]. Along with some advantages comes at a cost of disadvantages. The material Nylon has Modulus of Elasticity is 4.50*10^5 psi [34], which means that this material is the weakest to handle shear and torsional stress compared to other frame connections.

Another disadvantage is that for the number of beams required to connect, a unique tube connector design must be used which will increase the number of unique parts required which will increase the price. One last disadvantage that comes with the nylon connector is optional, but if the customer wants to hide the connections, the beams must be altered by machining which will cost money.

4.2.1.2 T-Slots

With T-slot connections, they offer a variety of connection types which only applies to the T-slotted extruded aluminum. Since this connection has many ways to connect the beams, one of the advantages of T-Slot connections is that they become modular. The connection types vary from screw-ins, gausset brackets, triangle plates, and anchoring which all works with the T-Slotted Aluminum [29]. Another advantage with this connection type is that they have a strong connection between the beams which will increase the stability of the frame. A disadvantage that comes with T-Slots connections is that it is expensive to use. Based on the specific connection, the price range for the T-Slots connections can be between 3 dollars to 20 dollars. Another disadvantage is that it requires an extra number of components just to use the T-Slots, which will decrease the ease of building the frames and increase the price. One last disadvantage is that it's not effective against external forces, because to use these connectors, an adapter has to be used which slides in the T-Slot gaps and has a possibility of sliding.

4.2.1.3 Welding

One of the most common frame connections that can be used is welding. One of the advantages of welding is that this connection does not need extra components when creating the frame, which reduces the number of parts required to assemble. Another advantage of welding is that it creates permanent fixtures and because of this, it allows the aluminum frame to be stable [33]. One last advantage that comes with welding is that it creates strong connections between frames, which adds to the stability to the frame. With these advantages, come with many disadvantages which go against the customer and engineering requirements. One issue that can happen is that the quality of the world will affect the stability of the frames. When reviewing the previous cleanroom for this project, the group noticed that the welding quality was not good which created an unstable frame. Another disadvantage to welding is that it does not allow the cleanroom to be modular, which goes against the customer's requirements. One last disadvantage of welding is that it is expensive, the reason is that the price for welding aluminum is more than the price of steel [32].

4.2.1.4 Screwed Joints

One last frame connector is screwed joints for square tubing, while is similar to the 90/20 T-Slot bars, these connections do require machining for these connections to work. One advantage of these connectors is that they are inexpensive since a lot of these parts are available to purchase. Another advantage of these connections is that they are easy to assemble and disassemble because the only tool required to install these screwed joints is a screwdriver One last advantage is that these screw joint parts can be replaced in a cheap and timely manner, which keeps maintenance cost to the minimum. Some of the disadvantages of the screwed joints is that they require machining of the beams to use these connections, which will increase the cost. One other disadvantage is they take up space so that it interferes with other parts which decreases the options of modularity. One last disadvantage of screwed joints is that they require a lot of extra parts to be used properly, which does make it harder to assemble and disassemble.

4.2.2 Material Connections

Material connections are the method used to attach the walls to the frames. The 4 styles analyzed were magnetic, adhesive, slide-in, and bolts/washers. The main requirements are that the style of connection must be capable of holding the full weight of the walls, and that the seals can be made to be airtight.

4.2.2.1 Magnetic

Magnetic connections are what are used in the current cleanroom (which will be converted into a gowning room). After 3 years of use, the plastic deformations in the soft walls have caused the magnetic strips from the current cleanroom to no longer hold the walls to the frame. However, this would not be a problem with a hard walled design. Due to this the biggest requirement of this option is that it can hold up the weight of hard polycarbonate walls. The strongest magnetic strips were found to have a magnetic pull force of only 30.3lbf [17], and since the walls will be attached vertically, that translates to 10.84lbf of friction holding the walls up [16]. This technically meets the requirement of for 9.5lb walls, but just barely. This method of material connection would need to be used in conjunction with another.

4.2.2.2 Adhesive

Adhesives come in many forms, but for this analysis high strength structural glue was used. A major drawback of adhesives with regards to this design is that it is a permanent connection. Since modularity is a major goal of this project this almost immediately takes this option off the board. To make sure all options were considered fully, a strength calculation was still done, and the strongest adhesive found [17] far exceeds the required strength of the material connections. So be exact, the surface area allotted to the adhesives would theoretically be able to hold 45kips.

4.2.2.3 Slide-in-Frame

This would work due to the geometry of t-slotted frames. The t-slots have a slot that is generally used for connection hardware; however, it also runs the length of the beam and would create a perfect slot for the walls to sit. This would make the design highly modular, as no machining is required on the frame or the walls. The major drawback of this option is that t-slotted frames are required. The walls would be held up by an insert 2 friction-based inserts per wall tile and would be able to hold 17.5 kips, far exceeding the required strength.

4.2.2.4 Bolts/Nuts

The final option is bolts and washers, this is the simplest and most commonly used of the 4 options. Holes are drilled into the frame and wall material, and the walls are attached with nuts and bolts. Using standard bolts that can be bought extremely cheaply from any hardware store, it was found with only 5 bolts per wall tile this method could hold 21.9 kips, again, far exceeding the required strength. A layer of foam or rubber between the wall and the frame would also make this airtight. The only major drawback of this design is the required machining; however, members of this team have access to mills and very little machining is required.

4.2.3 Wall Material

The cleanroom's wall material encompasses the external enclosure or structural components that define the spatial boundaries. While the client has not stipulated explicit customer requirements, a comprehensive comparison between soft wall and hard wall applications is imperative to discern the optimal modular design solution. The objective of the design deliberation is to achieve a cost-effective and durable wall configuration that simultaneously aligns with the client's aesthetic preferences and functional requirements.

4.2.3.1 Soft Wall Materials

Soft wall enclosures typically focus primarily on how easily portable they are. The portable design allows for easy assembly, disassembly, storing, cost effective, and temporary applications. The soft wall design would consist of a vinyl curtain material to be draped over the frame of the room and attached using an adhesive or magnets. This was how the current cleanroom was designed as seen in **Figure 11.** However, while being cheap to manufacture, the quality is also of cheap caliber. The vinyl used in these applications tend to off gas a large number of VOCs into air for an extended amount of time. Off-gassing is the release of a dissolved, trapped, or absorbed gas in a material, while VOCs are volatile organic compounds.

Figure 11: Current Cleanroom Design

4.2.3.2 Hard Wall Materials

While Hard Wall Materials tend to be more expensive, and less modular than soft wall designs, they provide a more structurally sound enclosure. Hard wall construction also allows for increased volumes of internal air pressure, which can help minimize dirty air from entering the room. This type of design using a polycarbonate material provides a better and more consistent performance. Also, compared to a soft wall construction, the life span of a rigid wall material is much more extensive. For example, the current design the team is reimagining (located in **Figures 12** and **13**), is constructed of soft vinyl curtains attached to the frame with adhesive magnetic strips. This design is already deconstructing after only 4 years since its completion, as shown in Figure #, the curtains are no longer straight and have warped a bit. The adhesive from the magnetic strips have also spread causing the strips to peel off. A rigid application would eliminate the warping of the walls and the use of magnetic strips all together.


Figures 12 and **13:** A closer look at the effects of time on the current soft wall cleanroom

4.2.4 Frame Size

The frame size of the cleanroom is the actual dimensions of the cleanroom. The client requested a 10' x 10' or 100 sq/ft sized enclosure that can house up to 6 people at once as the current cleanroom is only 6' x

8’ in size. When researching potential materials for the cleanroom walls, polycarbonate sheets became the standard to use if following through with a hard wall design. These sheets come in 4 feet long by 8 feet tall sheets which impacted the design of the frame size. This led to the consideration of a 12’ x 8’ concept.

4.1.4.1 10’ x 10’

The 10’ x 10’ designs main advantage is that it is a direct request from the client. However, when taking into consideration the rigid sheets dimensions, the 10’ x 10’ design would produce material waste as the lengths are not evenly divisible by 4.

4.1.4.2 12’ x 8’

The 12’ x 8’ design was constructed with the idea of eliminating material waste and providing a more aesthetically pleasing design while still being cost effective. The 12’ x 8’ design meets these criteria, but the only drawback is that the 12’ x 8’ is slightly smaller than the 10’ x 10’ at 96 sq/ft.

4.2.5 Fan Number/Location

The last subfunction is the FFU number and location. The airflow, pressure, and particle count of the cleanroom are dependent on selecting the appropriate FFU number and placing them in the best locations to maintain the cleanroom’s airflow, pressure, and particle count requirements per the ISO Class 7 standards. Fan number options for the cleanroom included one fan or two. Fan location is mainly dependent on ceiling frame structure and airflow. If one FFU is used, it will need to be centered in the ceiling. However, if two FFUs are used there are different options to balance the fans in the frame structure while also considering the distribution of airflow in the room for different fan configurations.

4.3 Selection Criteria

4.3.1 Frame Connections

The selection criteria for the wall material were as follows listed from highest to lowest importance: cost, modularity, yield strength, stability, interference, small quantity, and ease of use. Cost is weighted at 50% and references the total cost of all frame connection components required for the 12’ x 8’ design. Modularity is weighted at 15% and refers to the design’s customizability measured in number of possible designs. Yield strength is weighted at 10% and refers to highest amount of stress the material can handle without permanent deformation measured in MPa. Stability is weighted at 10% and is how stable the frame can be without movement measured by displacement of the frame. Interference is weighted at 5% and describes if the connection pieces will interfere with each other or other structural members. Small quantity is weighted at 5% and refers to the number of parts required for all frame connections. Lastly, ease of use is weighted at 5% and refers to the how easily the design can be assembled and disassembled.

4.3.2 Material Connections

The selection criteria for the wall material are as follows listed from highest to lowest importance: durability, modularity, strength, seal tightness, and aesthetics. Durability is weighted at 25% and is the expected lifespan of the connection material measured in years. Modularity is weighted at 25% and is the ease of assembly, disassembly, transport, and reorientation of the design. Strength is next weighted at 20% and refers to the wall weights the connection can hold measured in lbs. Seal tightness is next and refers to the gas loss measured in in^3/s. Lastly, aesthetics is weighted at 10% and is the subjective opinion of the client and design team.

4.3.3 Wall Material

The selection criteria for the wall material are as follows listed from highest to lowest importance: cost, customer preference, VOCs, and longevity. Cost is weighted at 30% and refers to how cost effective the design is including all wall and ceiling materials for one 12' x 8' cleanroom. Customer preference is weighted at 30% and is the subjective preference of the client. VOCs is weighted at 20% and refers to how much off-gassing the material produces and for how long. Lastly, longevity is weighted at 20% and refers to the life span of the design considering disassembly, transport, and reassembly.

4.3.4 Frame Size

The selection criteria for the wall material are as follows listed from highest to lowest importance: manufacturing ability, cost, customer preference, and aesthetics. Manufacturing ability is weighted at 40% and refers to how easy the design is to manufacture while accounting for waste. Cost is weighted next at 35% and considers how cost effective the design is. Customer preference is weighted at 20% and is the subjective preference of the client. Aesthetics is weighted at 5% and refers to how pleasing the design is to look at and will be another subjective measurement determined by the client and design team.

4.3.5 Fan Number and Location

The selection criteria for the fan number and location are as follows listed from highest to lowest importance: particle count, flow distribution, structural load, and cost. Particle count is weighted at 40% and refers to the number of particles in the room measured in particles per cubic meter. Flow distribution is weighted at 35% and encompasses the output velocity and Reynold's number of the air in the cleanroom. Structural load is weighted at 20% and refers to the stability of FFU weights on the ceiling structure. Cost is weighted last at 5% and refers to the total cost of the FFUs and material configurations of the ceiling structure.

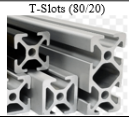
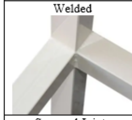
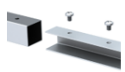
4.4 Concept Selection

Concept Selection was completed for the selected 12' x 8' cleanroom design. All cost analysis shown in this section is for the 12' x 8' design only and will be updated in the "Other Engineering Calculations" section of this report to reflect the updated 12' x 16' design.

4.4.1 Frame Connections

The advantages and disadvantages of the different frame connection concept variants were compared in **Table 3**. The square modular tubing is very modular, inexpensive, and high in stability. However, it has decreased yield and shear strengths and requires specific designs that cannot be modified after purchase. T-slots are also very modular and allow for a plethora of different connection designs but are more expensive than other options. Welded parts do not require extra connection pieces but have poor modularity. Screwed joints are inexpensive, easily replaced when damaged, and very modular. However, screws require extra milling of the wall material and may require additional connection materials. The advantages and disadvantages were weighed in a decision matrix to choose a concept variant.

Table 3: Frame Connections Advantages and Disadvantages

Frame Connections	Advantages	Disadvantages
Square Tubing Nylon Connectors 	-Very modular -Inexpensive -Allows strong structure stability	-Requires altering frame -require specific design for different types of connections -weak connection material for yield and shear strength
T-Slots (80/20) 	-Very modular -Allows many connection types - Strong connections between frames	-Expensive - Requires many components for connections -Not effective against external forces
Welded 	-Creates permanent fixtures -No extra components required - Allows for strong connections	-Does not allow modularity -Expensive -Quality of wield can affect stability
Screwed Joints 	-Inexpensive -Parts are replaceable - Can be assembled/disassembled easily.	-Requires milling for frame and joint -Takes up space which effects other parts -Require many components for connections

In the decision matrix below (**Table 4**), the team left out the frame connections of wielding because it does not follow the costumer's criteria of being modular. After scoring each criterion, the team has concluded that the square nylon tubing connector will be the best option for frame connections.

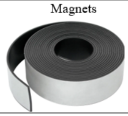
Table 4: Decision Matrix for Frame Connections

		CV 80/20 T-Slot		**CV** Square tubing Connector		**CV** Screw Joints	
Selection Criteria	**Weight (%)**	Score	Weighted Score	Score	Weighted Score	Score	Weighted Score
Modularity	15	3	.45	3	.45	2	.30
Price	50	1	.50	3	1.50	2	1.00
Yield Strength	10	2	.20	1	.10	3	.30
Stability	10	1	.10	3	.30	3	.30
Interference	5	3	.15	3	.15	1	.05
Small quantity	5	1	.05	3	.15	1	.05
Ease of Use	5	2	.10	3	.15	2	.10
Total	100	13	**1.55**	18	**2.80**	14	**2.1**

4.4.2 Material Connections

The advantages and disadvantages of the material connections are listed in **Table 5**. Magnets are inexpensive but can degrade over time, leave residue on the frame, and disconnect with slight wall shifting. Adhesive is also inexpensive but causes/collects particulation, off-gassing, can degrade over time, leave residue on the frame, and disconnect with slight wall shifting [18]. Slide in frames are higher modular and create strong connections but are only applicable with t-slot frames. Lastly, screws are inexpensive, create strong connections and are highly modular but could cause cracking or tearing of the wall material if not installed well.

Table 5: Material Connection Advantages/Disadvantages

Material Connections	Advantages	Disadvantages
Magnets 	- Inexpensive	- Adhesive connection degrades over time - Adhesive residue on frame - Shifting of vinyl/ polycarbonate panels could cause disconnection
Adhesive 	- Inexpensive	- Particulation - Off-gases - Strength degrades over time - Shifting of vinyl/polycarbonate panels could cause disconnection - Collects particulates
Slide in Frames 	- High modularity – easy to assemble and disassemble - Strong connection	- Only works with t-slots. Would have to modify other frame material to accommodate
Screws 	- Inexpensive - Strong connection - High modularity – easy to assemble and disassemble	-Could cause tearing of vinyl/cracking of polycarbonate panels

While slide-in-frame is the decision made here, the cost of using t-slots over square tubing tipped the scales in favor of screwed in hardware. The difference was only found in the aesthetic criteria as well, which was the criteria with the lowest weight demonstrated below in **Table 6**.

Table 6: Decision matrix for material connections

		Magnets		**Adhesive**		**Screws**		**Slots**	
Selection Criteria	**Weight (%)**	Score	Weighted Score	Score	Weighted Score	Score	Weighted Score	Score	Weighted Score
Durability	25	1	0.25	2	0.5	3	0.75	3	0.75
Modularity	25	2	0.5	1	0.25	3	0.75	3	0.75
Strength	20	1	0.2	2	0.2	3	0.6	3	0.6
Seal Tightness	20	2	0.4	2	0.2	3	0.6	3	0.6
Aesthetics	10	1	0.1	2	0.2	2	0.2	3	0.3
Total	**100**		**1.45**		**1.35**		**2.9**		**3.0**

4.4.3 Wall Material

The selection process for the wall material started with a comparison of the advantages and disadvantages between the two designs as described in **Figure 14**. As shown, the advantages of the soft wall design are only that it is inexpensive while the hard wall design provides less air leakage, longer life span, and has a more professional appearance. It is also stated that the hard wall design is client preferred, this was not specifically stated at the beginning of the project but was later mentioned by the client as not necessary but preferred. The disadvantages state the soft wall expels VOCs, increases potential air leakage, has a decreased life span, and could potentially become less modular over time. Moreover, the disadvantages of the hard wall application are only that it is a more expensive design choice.

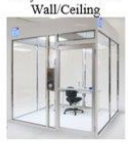
Wall/Ceiling Material	Advantages	Disadvantages
Vinyl Soft Wall/Ceiling 	- Inexpensive	- Contains VOCS - Increased air leakage - Deteriorates over time - Less modular than polycarbonate
Polycarbonate Hard Wall/Ceiling 	-Client preferred - Less air leakage - Longer life span - More professional appearance	- More expensive

Figure 14: Advantages vs Disadvantages between soft wall and hard wall designs

To be able to accurately weigh the selection criteria, a cost analysis of both designs was completed. To purchase enough vinyl to cover one unit of our cleanroom, it would cost around $200. For the Hard wall application, the largest sheets of polycarbonate found were to be 4ft long by 8 ft tall at 1/16 of an inch thick, distributed by ePlastics. With this size in mind, to cover all walls and ceiling and not considering doors or holes within the enclosure, it was calculated that the team would need to purchase 13 panels for one unit. As stated on the ePlastics website, as you purchase more individual units of a product, the overall price drops. This breakdown is shown in **Table 7**. At 13 units, the team can expect each sheet to cost $67.41, adding to a total of $876.33. accounting for shipping and taxes, the total price comes out to $1,296.96, and for budgeting purposes the team can round this to a closing price of $1,300.

Table 7: Price of Polycarbonate sheets per unit quantity supplied by ePlastics.

Quantity	1 – 2	3 – 9	10 – 19	20 – 29	30 – 49	50 +
Price	$82.08	$76.13	$67.41	$63.84	$60.27	$54.32

Now that there is a cost understanding between the designs, a decision matrix can be constructed as shown below in **Table 8.**

Table 8: Wall Material Decision Matrix

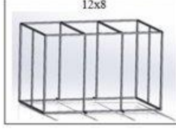
		Hard Wall (Polycarbonate)		Soft Wall (Vinyl)	
Selection Criteria	**Weight (%)**	Score	Weighted Score	Score	Weighted Score
Cost	30	2	0.15	3	0.9
Customer preference	30	3	0.9	1	0.3
VOCS	20	2	0.4	1	0.2
Longevity	20	3	0.6	2	0.4
Total	**100**		**2.05**		**1.8**

Each selection criteria are weighted with an associated score. While the soft wall design dominates in cost effectiveness, it falls short in customer preference, VOCs, and longevity, leading to the hardwall design becoming the best choice for the design.

4.4.4 Frame Size

The Selection process for the frame sizing also incorporates the use of an advantages vs disadvantages table shown in **Table 9**. It states that the 10’ x 10’ designs only advantage is that it was a direct customer request, while the 12’ x 8’ design is evenly spaced resulting in less material waste, uses the same material requirements as the 10’ x 10’ design, and has a symmetrical design that is more aesthetically pleasing. The disadvantages associated with the 10’ x 10’ are that because of the uneven spacing of the supports caused by the polycarbonate sheet sizing, the design requires material cutting and material waste. The only disadvantage of the 12’ x 8’ design is that it is slightly smaller, coming in at 96 sq/ft instead of the 100sq/ft given by the 10’ x 10’ design.

Table 9: Frame size Advantages Vs Disadvantages

Frame Size	Advantages	Disadvantages
10x10 	- Direct customer request - Total area of 100 square feet of floor space	-Unevenly spaced support beams will require additional material cutting
12x8 	- Evenly spaced bars will require no material cutting - Uses same material requirements as 10x10 - Symmetrical design requires less assembly time	- Less total area - 96 square feet of floor space

To being weighing each selection criteria, another cost analysis was conducted that compares the cost of framing, connectors, and wall material for each design.

4.4.4.1 10’ x 10’ Frame Size

Framing

To be able to construct an accurate cost analysis of the framing, inventory of all the lengths of 80/20 square aluminum tubing will be used to construct this design is necessary. Those are as follows:

- 18: 47” Beams
- 12: 87” Beams
- 8: 20” Beams
- 8: 18.5” Beams
- 4: 8.5” Beams
- 1: 53” Beam

Using the square Aluminum tubing with part no. 9700 costing $0.49 per inch, the sum is $1,262.00. After tax and shipping the final cost is $1,649.39.

Connectors

The connectors to be used within the design are distributed from Esto connectors. The parts list consists of the following:

- 14: 1.5” Straight Base Connectors
- 4: 1.5” 4-Way Cross Connectors
- 20: 1.5” 3-Way Tee Connectors
- 8: 1.5” 3-Way Corner Connectors

The total cost of the connectors comes out to $431.82.

Wall Material

The wall material cost for both frame sizes is the same, coming out to about $1,300.

4.4.4.2 12' x 8' Frame Size

Framing

To be able to construct an accurate cost analysis of the framing, inventory of all the lengths of 80/20 square aluminum tubing that will be used to construct this design is necessary. Those are as follows:

- 29: 46" Beams
- 10: 87" Beams
- 4: 22" Beams
- 2: 22.5" Beams

Using the square Aluminum tubing with part no. 9700 costing $0.49 per inch, the sum is $1,262.69. After tax and shipping the final cost is $1,661.14.

Connectors

The connectors to be used within the design are distributed from Esto connectors. The parts list consists of the following:

- 10: 1.5" Straight Base Connectors
- 6: 1.5" 4-Way Cross Connectors
- 10: 1.5" 3-Way Tee Connectors
- 8: 1.5" 3-Way Corner Connectors

The total cost of the connectors comes out to $305.53.

Wall Material

The wall material cost for both frame sizes is the same, coming out to about $1,300.

All cost calculations are summarized in **Table 10.**

Table 10: Cost Analysis of Frame designs

	12' x 8'	10' x 10'
Framing	$1661.14	$1649.39
Connectors	$305.53	$431.82
Wall Material	$1300	$1300
Total Cost:	$3266.67	$3381.21

When deciphering the data, it is apparent that the framing cost of the 12' x 8' design is slightly larger than the 10' x 10', however, the 10' x 10' design requires more connectors because of its uneven design, resulting in a higher total cost. The decision matrix was used to produce the most optimal design. This is shown in **Table 11** below. It is apparent from the table that the 12' x 8' design is the winner and will be what the team moves forward with for the final design phase.

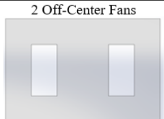
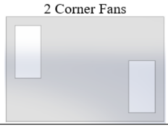
Table 11: Frame Size Decision Matrix

		12x8		10x10	
Selection Criteria	**Weight (%)**	Score	Weighted Score	Score	Weighted Score
Cost	35	3	1.05	2	.7
Manufacturing ability	40	3	1.2	2	.8
Customer preference	20	3	.6	3	.6
Aesthetics	5	3	.15	2	.1
Total	**100**		**3**		**2.2**

4.4.5 Frame Number and Location

For the concept selection of the FFU number and location, first the advantages and disadvantages of all concept variants were listed in **Table 12**. The advantages of the single centered fan include that it is less expensive and creates less turbulent air flow than two fans. However, as was determined in the engineering analysis, a single FFU does not allow the cleanroom design to meet ISO Class 7 standards and was thus ruled out of the design options. The remaining concept variants for two fans both meet ISO Class 7 standards and are more expensive than one fan.

Table 12: Fan Number/Locations Advantages and Disadvantages

Fan Number/Location	Advantages	Disadvantages
1 Centered Fan 	- Less expensive	- Does not meet ISO7 filter fan unit ceiling coverage requirement
2 Off-Center Fans 	- Meets ISO7 filter fan unit ceiling coverage requirement	- More expensive than 1 fan
2 Corner Fans 	- Meets ISO7 filter fan unit ceiling coverage requirement	- More expensive than 1 fan

Since the one FFU design does not meet standards, it was not considered in the decision matrix shown in **Table 13**.

Table 13: Fan Number/Location Decision Matrix

		2 Fans Off-Center		2 Fans Cornered	
Selection Criteria	**Weight (%)**	Score	Weighted Score	Score	Weighted Score
Cost	5	2	0.1	2	0.1
Flow Distribution	35	3	1.05	2	0.7
Structural Load	20	2	0.4	3	0.6
Particle Count	40	3	1.2	3	1.2
Total	**100**		**2.75**		**2.6**

The cost of both designs is the same for the two fans and ceiling materials. The flow distribution was better in the centered fans designed as shown in the CFD simulations. The structural load of the concept variant with the fans on the corners was stronger than with the fans in the middle as shown in the structural analysis calculations above. Both designs were equally efficient in meeting particle count requirements since they both utilize two identical fans of equal filtering capacity. With the weighted criteria considered, the highest scoring concept variant is the two centered fans. This design will be doubled for the new cleanroom design with 4 fans total, 2 centered fans along each half of the room.

5 Schedule and Budget

5.1 Schedule

A Gantt chart was created to track the progress of all project deliverables throughout the semester. The completed first semester Gantt chart and predicted second semester Gantt chart is shown in **Appendix B**. General themes for the next semester include beginning and completing the cleanroom manufacturing ahead of the suggested schedule to allow for cleanroom certification time. The Spring 2024 semester Gantt chart was organized by deadline but does not reflect the assignments being assigned to individual team members yet.

5.2 Budget

The project's budget has undergone an expansion, necessitating efforts to secure additional funding. the project's scope has since doubled in size and know exceeds the originally allocated budget of $10,000, prompting the team to explore alternative funding. To secure additional funding, the team reached out to the Bioengineering Club with a well-documented proposal seeking a grant of $2,500. This outreach is an essential step in adapting to the evolving needs of the project, and the team is currently eagerly awaiting the Bioengineering Club's response to the proposal. The team will continue to secure additional funds as necessary for the expanding project.

5.3 Bill of Materials (BoM)

A bill of materials (BOM) located below in **Table 14** serves as a comprehensive and structured list outlining the components, materials, sub-assemblies, and quantities required to manufacture a particular product. The BOM not only specifies the physical parts but also includes critical information such as part numbers, descriptions, and unit of measure, facilitating effective communication and coordination among various stakeholders in the production process. This document acts as a foundational reference for production planning, cost estimation, and inventory management, ensuring that all necessary elements are accounted for in the creation of a final product.

Table 14: Bill of Materials

BOM													
Part #	Part Name	Qty	Description	Material	Purchased Vs Manufactured	Vender	Vender PO #	Manufacturer #	Lead Time	Cost per Unit ($)	Unit Discount ($)	Estimated Tax/Shipping	Cost ($)
1	Ready Tube	47	46"	Aluminum	Purchased	80/20	9700	N/A	Unknown	$25.33	none		$1,190.51
2	Ready Tube	14	87"	Aluminum	Purchased	80/20	9700	N/A	Unknown	$45.42	none		$635.88
3	Ready Tube	6	22.5"	Aluminum	Purchased	80/20	9700	N/A	Unknown	$13.82	none		$82.92
4	Ready Tube	10	22"	Aluminum	Purchased	80/20	9700	N/A	Unknown	$13.57	none	$563.73	$135.70
5	4-way Corner Connector	6	1.5" Connectors for frames	Nylon	Purchased	Esto Connectors	545150	N/A	Unknown	$9.98	none	Unknown	$59.88
6	3-way Corner Connector	8	1.5" Connectors for frames	Nylon	Purchased	Esto Connectors	533150	N/A	Unknown	$8.93	none	Unknown	$71.44
7	3-way Tee Connector	18	1.5" Connectors for frames	Nylon	Purchased	Esto Connectors	532150	N/A	Unknown	$8.93	none	Unknown	$160.74
8	4-way Cross Connector	4	1.5" Connectors for frames	Nylon	Purchased	Esto Connectors	544150	N/A	Unknown	$16.73	none	Unknown	$66.92
9	Straight Base Connector	20	1.5" Connectors for frames	Nylon	Purchased	Esto Connectors	5323150	N/A	Unknown	$6.65	none	Unknown	$133.00
10	Clear Polycarbonate Sheet	31	1/16" X 48" X 96" Wall Matertial	Polycarbonate	Purchased	Eplastics	PCCLR0.060AM48X96	N/A	Unknown	$60.27	none	$475.22	$1,868.37
11	Fan Filter Unit ; WhisperFlow	4	2'x4', HEPA, 120 V	Powder-Coated Steel	Purchased	Terra Universal	6601-24-H	N/A	1-3 business days	$1,152.00	($115.00)		$4,148.00
12	Power Cord for Filter Unit	4	300V, 10A,MIN4 PL to 16AWG	Unknown	Purchased	Terra Universal	6601-13	N/A	1-3 business days	$64.00	none	$956.37	$256.00
13	Manufacturing holes	200				Our Team			2-3 weeks				$0.00
14	3D printed Prototype	20	Beams and 3 way connectors to test gasketing types						5 days				Donated
Total												$1,995.32	$8,809.36
Final Cost													$10,804.68

6 Design Validation and Initial Prototypes

6.1 Failure Modes and Effects Analysis (FMEA)

A FMEA was created to identify the critical potential failures and identify the design mitigations to address and prevent the failures. The potential failure modes were organized by the main parts of the cleanroom: the fan filter unit, cleanroom frame, cleanroom walls, and back-up battery. The potential failure modes for each main part were identified along with the potential effects of the failure, severity of the failure, potential causes/mechanisms of the failure, the rate of occurrence, the current design controls test to identify the failure, the overall risk priority number, and the recommended actions if the failure were to occur.

The fan filter unit had two potential failure modes: the HEPA filter is dirty, and the fan turns off. To mitigate issues with the HEPA filters and fans, the team will have a strict maintenance schedule to be followed by the owners of the cleanroom. The HEPA filters will be recommended to be changed every 3 years and the MERV pre-filter to be changed every 6 months [30]. To prevent issues with the fan turning off, the team will also have regularly scheduled maintenance/testing to ensure the fan airflow output is being maintained and will ensure adequate backup battery is available for the fans to maintain speed.

The cleanroom frame had four potential failure modes: aluminum beam cracks or breaks in the walls, the aluminum beam cracks or breaks in the ceiling, a screw comes loose, or a screw falls out. The cleanroom walls had four potential failure modes: a polycarbonate sheet cracks, a polycarbonate sheet breaks or falls, unauthorized entry into the cleanroom, and external/internal pressure on the walls. Damage to the cleanroom frame and walls is most likely during assembly, disassembly, or transport. To mitigate these issues, the team will provide assembly and disassembly Standard Operating Procedures (SOPs). The SOPs will include assembly/disassembly instructions as well as full inspections of all frame and wall materials prior to assembly or disassembly. The team will also provide purchasing sources to replace any damaged frame or wall components. An additional mitigation for potential ceiling beam cracks due to increased weight will be to ensure the design can withstand the necessary fan weight with a large factor of safety. The same approach will be used for the potential external or internal wall pressures. The bolt and wall placement will be designed to withstand significantly more pressure than required by the positive pressure air. To mitigate issues with unauthorized cleanroom entries, the team will provide training materials for the cleanroom owners to use as well as signage to place around the cleanroom indicating unauthorized personnel are prohibited.

Lastly, the back-up battery had two potential failure modes: the battery does not engage in a power outage, and the battery does not provide enough power. To prevent issues with the backup battery supply not engaging or being insufficient to power the cleanroom, the team will do thorough testing with the selected battery supply to ensure it can independently sustain the cleanroom for several hours. Regular maintenance checks will be completed on the battery as well to ensure the battery is worked as intended when needed.

For the full FMEA with all potential causes, current design control tests, and recommended actions reference **Appendix C**.

6.2 Initial Prototyping

6.2.1 Virtual Prototype 1: Structural Supports

The first prototype involved creating an Ansys simulation of the ceiling of the cleanroom. The purpose of the simulation was to find whether structural support columns are necessary to satisfy the updated size requirement (12' x 16'). The client informed the team he would prefer the cleanroom to not have any support columns unless necessary to achieve the larger size.

A simplified CAD design was made which only included the ceiling to reduce mesh complexity. In Ansys, materials were chosen based on their material properties such as density, Young's modulus, yield strength, and Poisson's ratio. Fixed supports were placed on every nylon composite join which represented where the ceiling will be supported by a wall column. Gravity was added as an acceleration and the weight from the four 50 lbs fans were simulated on the slots they will fit into on the final design.

To test the necessity of support columns two tests were done, one with columns and one without. First, the simulation without the columns was run. The results of the total deformation, strain, and stress on the ceiling frame without the support columns are shown in **Figures 15** to **17**.

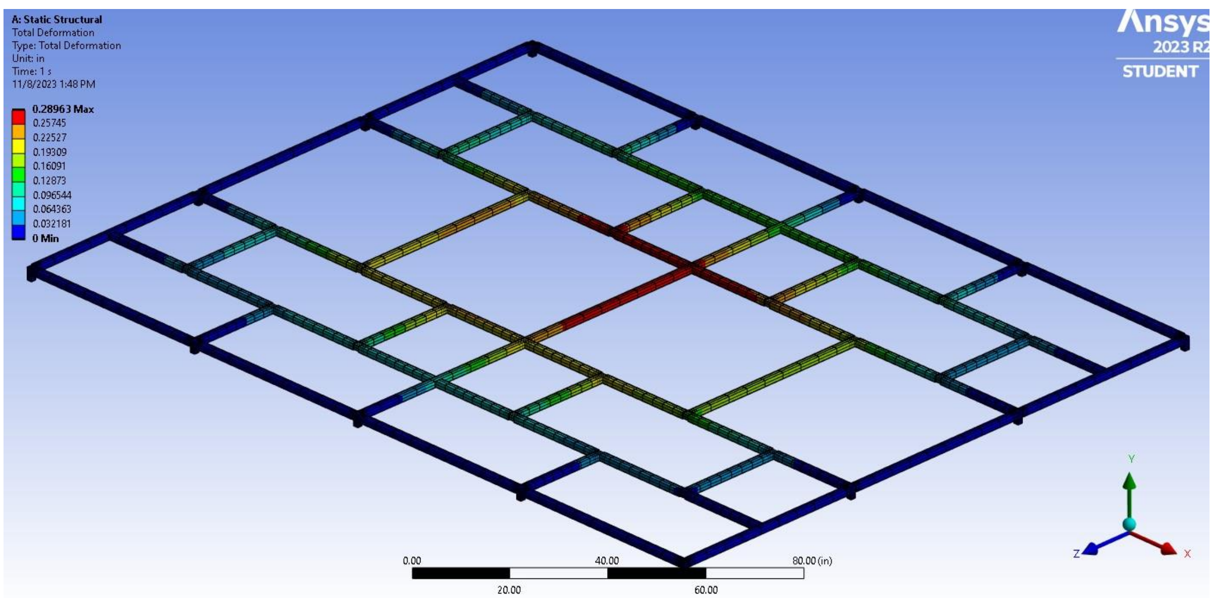


Figure 15: Total deformation without support columns.

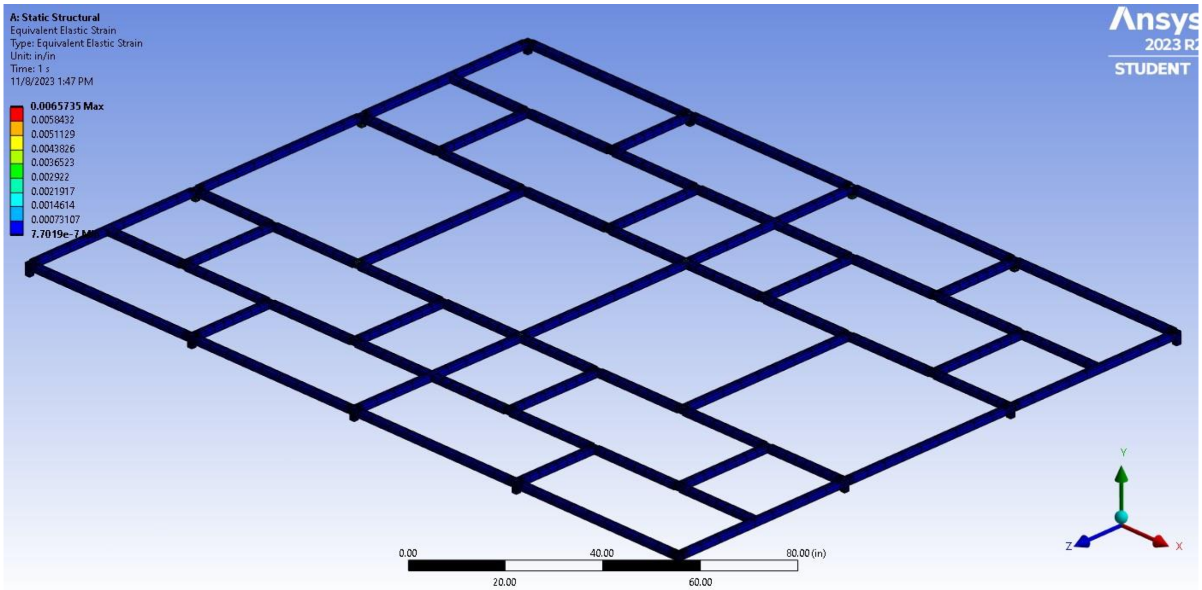


Figure 16: Strain without support columns

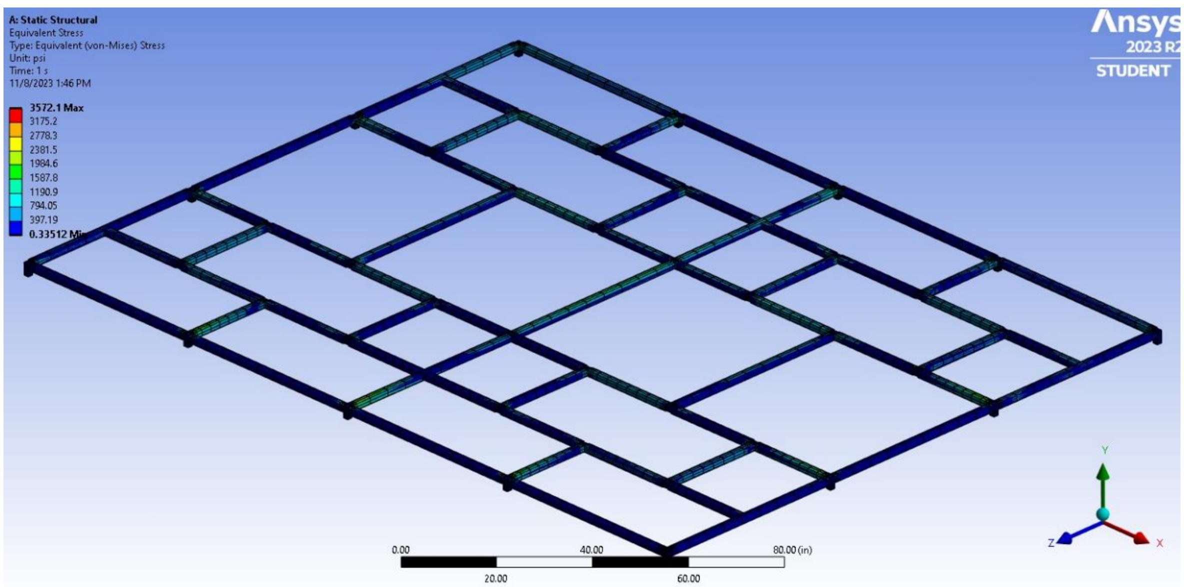


Figure 17: Stress without support columns

Then the same process was done with added fixed points where the additional support columns would be located, and the system was solved again. The results of the total deformation, strain, and stress on the ceiling frame with the support columns are shown in **Figures 18** to **20**.

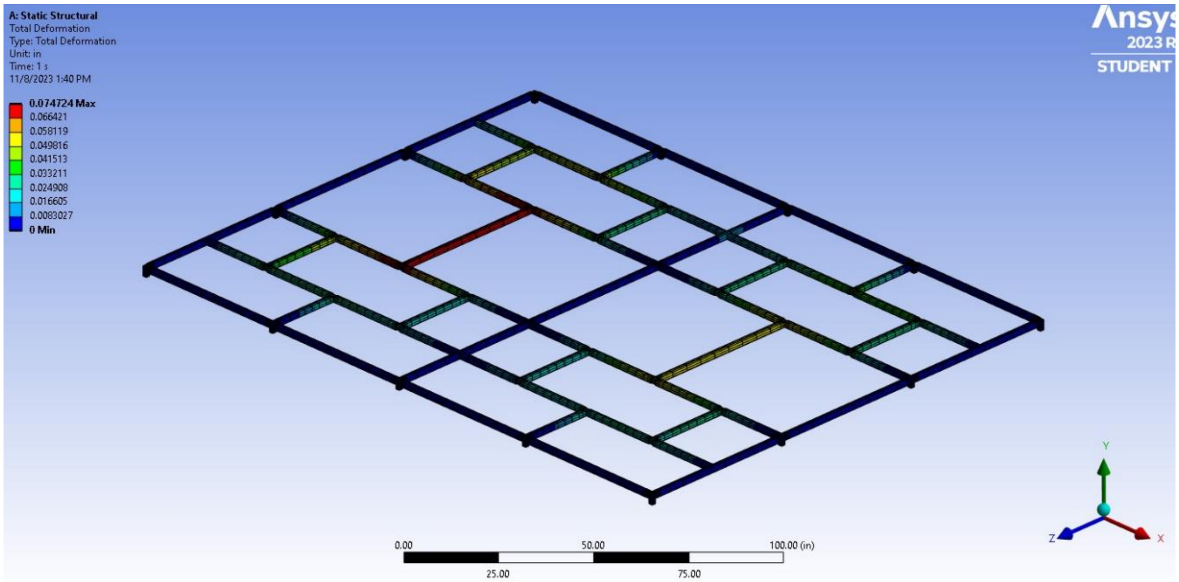


Figure 18: Total deformation with support columns

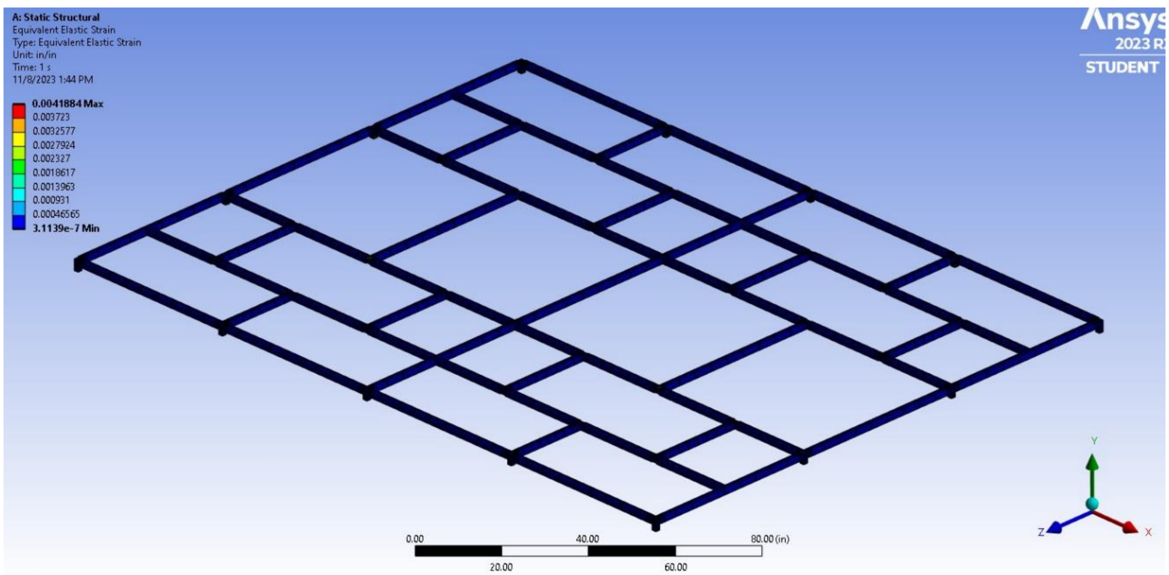


Figure 19: Strain with support columns

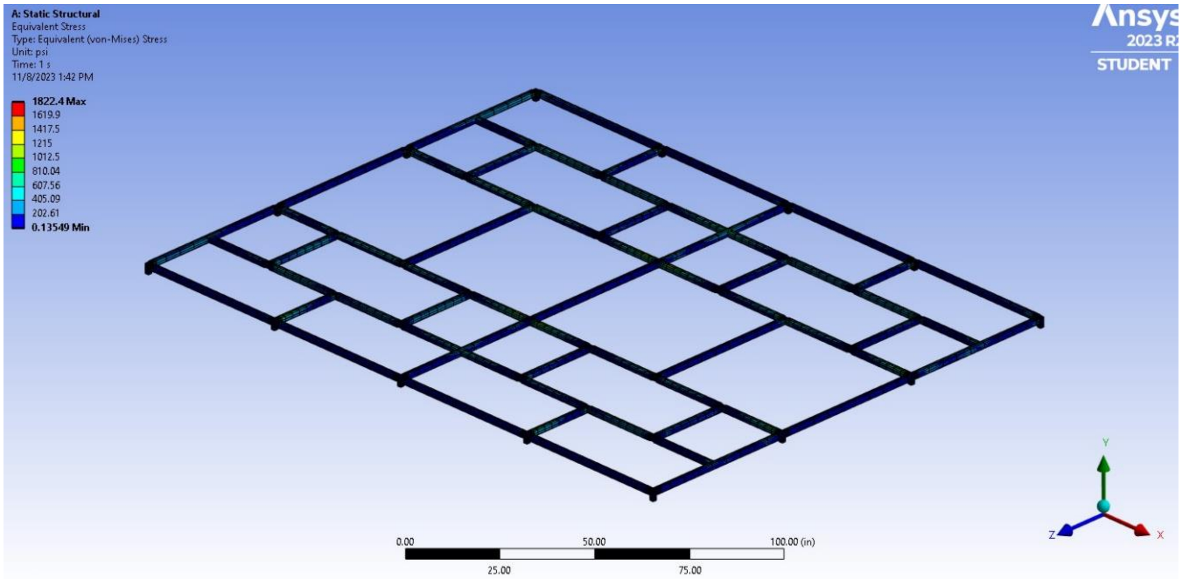


Figure 20: Stress with support columns.

A summary of the results for both the support columns and no columns is shown in **Table 14**.

Table 14: Maximum stress, strain, and total deformation in both tests.

	With Supports	Without Supports
Max Stress (psi)	1822	3572
Max Strain (in/in)	0.00419	0.00657
Max Total Deformation (in)	0.0747	0.2896

The second test found that while the supports did decrease max stress, strain, and total deformation, the decrease was not practically significant enough to justify going against the clients wishes by adding structural support columns. The unsupported columns can safely sustain the weight of the four fans. To confirm the simplified geometry was not skewing the results, a third simulation was created on a pair of the most centralized weight-bearing members that experience the maximum stress in the full sized and simplified simulations as shown in **Figure 21**.

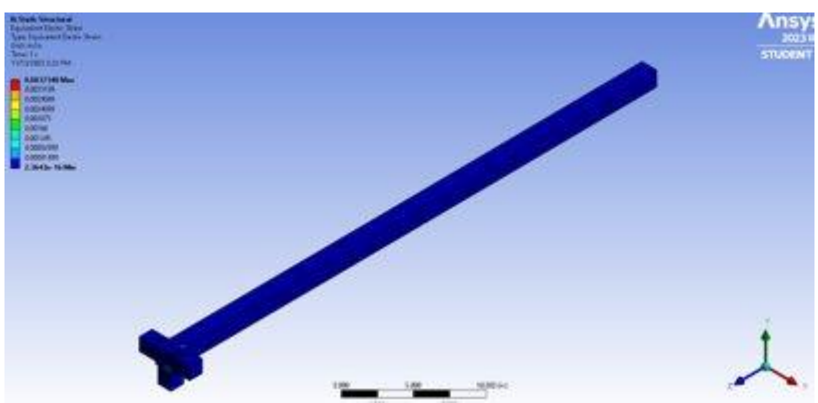


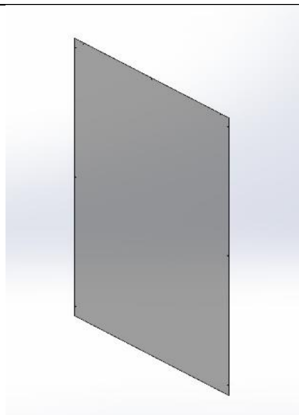
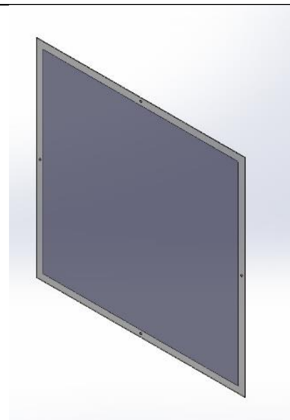
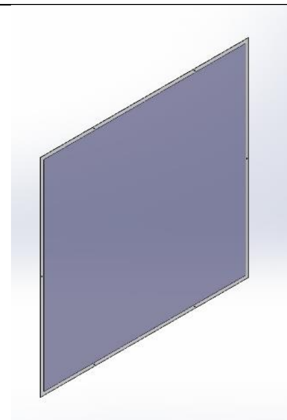
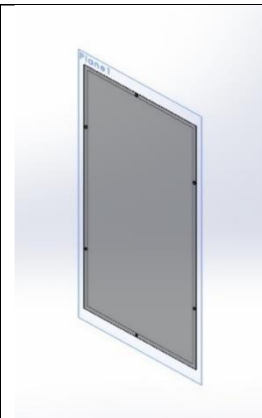
Figure 21: Actual geometry simulation of the highest stress structural members

This additional simulation showed the resultant strain was lower than the simplified geometry, which is expected as the design of the real parts are manufactured to be more resistant to bending stress. The results of this simulation lead the team to remove consideration of support columns from the design process. The manufacturing timeline of the project will allow the team to test the ceiling more rigorously before the project's conclusion.

6.2.2 Virtual Prototype 2: Polycarbonate Sheets

For the second prototype, the team tested out the characteristics of the polycarbonate sheets to see if it is appropriate material in the cleanroom design. The question that the prototype investigated was what the minimum number of bolts that can be used to support the polycarbonate sheets and what is the maximum amount of pressure the sheets can handle before yielding. To figure out the values for these questions, Simulation Toolbox was used to obtain values for the stress, strain, and deflection of each sheet. The team tested four unique polycarbonate sheets, one wall type, and three roof types. **Table 15** displays the four unique polycarbonate sheets that will be use in the cleanroom.

Table 15: Dimensions and type of Polycarbonate Sheets in the Cleanroom

			
47.5"x88.5"x1/16" Wall	23.5"x23.5"x1/16" Roof	46.75"x46.75" x1/16" Roof	24"x47.5" x1/16" Roof

To get the required values for the sheets, two testing procedures were used: a gravity test and a max pressure test. The gravity test determined the minimum amounts of bolts that can be used for holding up the sheets. The max pressure test determined the maximum pressure that the polycarbonate sheets can handle before yielding. Each of the tests gave the stress, strain, and deflection of each individual polycarbonate sheet. The constants used in the gravity and max pressure tests for the polycarbonate sheets, cleanroom, and bolts are shown in **Table 16**.

Table 16: Values of Polycarbonate Sheets, Cleanroom, and Bolt Characteristics.

Modulus of Elasticity (MPA)	Minimum Pressure Difference (Pa)	Polycarbonate Sheet Density (lb/in^3)	Maximum Weight (lb)	Bolt Size (Standard)
60	0.2	0.03472	10	¼"-20

Gravity Test

The gravity test helped determine the minimum number of bolts required to hold up the polycarbonate sheets. The setup for this test was set with constraints of ¼”-20 Clearance Hole located along the members with gravity force as shown in **Figure 22**. This setup simulated the bolts holding up the sheets and whether the weight of the polycarbonate sheets will cause the members to yield. The results from this test gave the team values of stress, strain, and deflection of the polycarbonate sheets which is in **Table 17**.

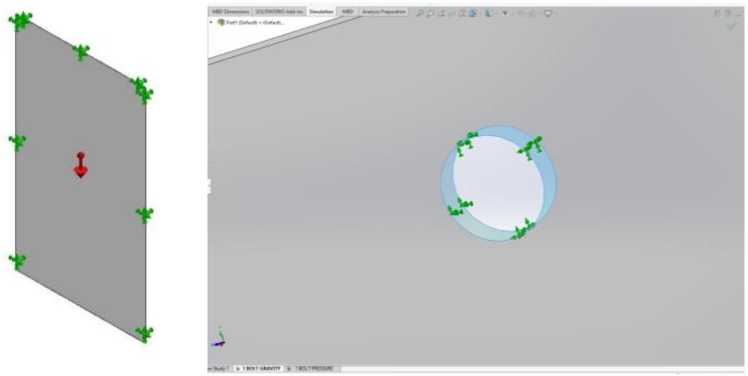
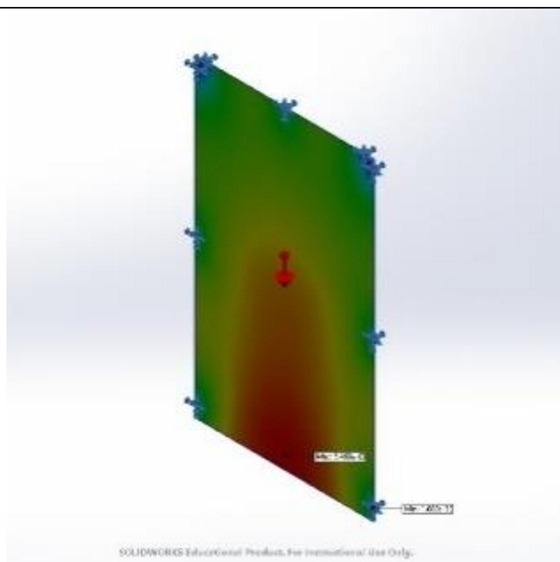
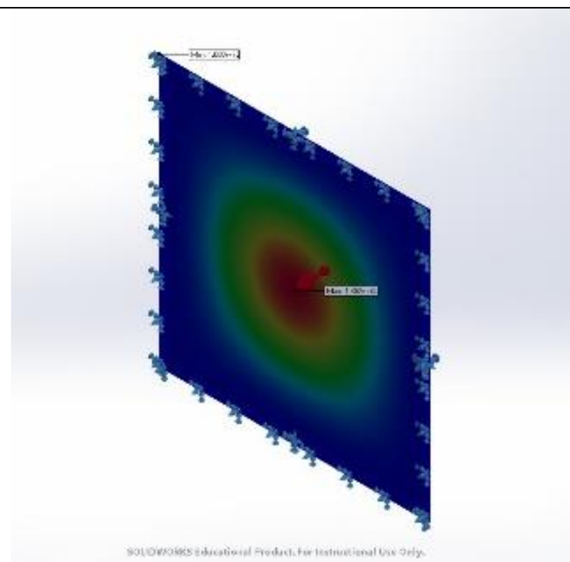
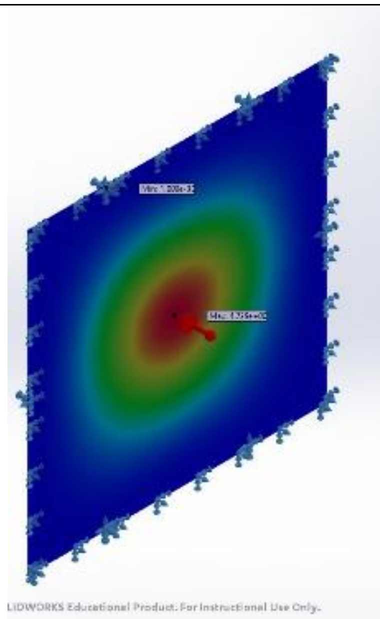
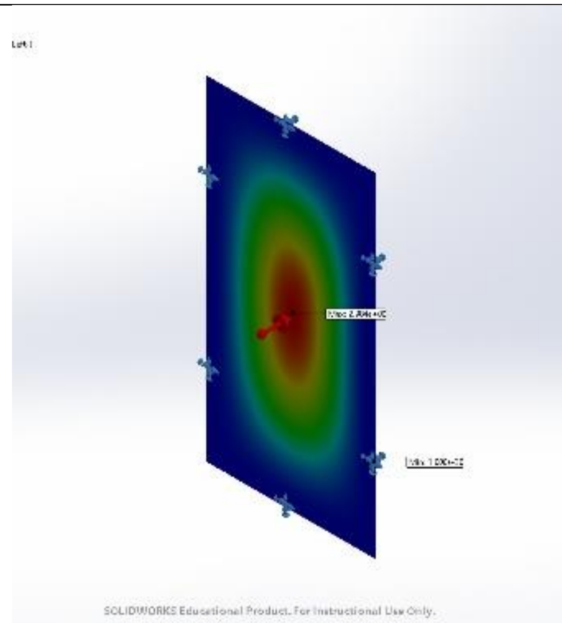


Figure 22: Visualizations of Bolt Constraints and Gravity Force

Table 17: Stress, Strain, and Deflection Results from Gravity Test

 47.5x88.5			 23.5x23.5		
MAX STRESS	MAX STRAIN	MAX DEFLECTION	MAX STRESS	MAX STRAIN	MAX DEFLECTION
$4.850 * 10^5\ Pa$ $70.34\ Psi$	$1.399 * 10^{-4}$	$5.468 * 10^{-3}\ mm$ $2.15 * 10^{-4}\ in$	$2.90 * 10^5\ Pa$ $36.12\ Psi$	$1.580 * 10^{-5}$	$1.382\ mm$ $5.44 * 10^{-2}\ in$

 46.75x46.75			 24x47.5		
MAX STRESS	MAX STRAIN	MAX DEFLECTION	MAX STRESS	MAX STRAIN	MAX DEFLECTION
$64.35\ Pa$ $9.33 * 10^{-3}\ Psi$	$9.858 * 10^{-5}$	$5.468 * 10^{-3}\ mm$ $2.15 * 10^{-4}\ in$	$70.43\ Pa$ $1.02 * 10^{-4}\ Psi$	$1.093 * 10^{-4}$	$2.984\ mm$ $0.117\ in$

Max Pressure Test

With the ax pressure test, it will help calculate the maximum pressure that each Polycarbonate Sheet that it can handle. For the setup, the area of the bolt's washer and nuts will be the constraint and for the pressure force, it will affect a certain area since the whole sheet is not experiencing the pressure. To find the value, the team would have to manually input the pressure force onto the sheets and figure out the maximum pressure it can handle before yielding. All results can be found in **Table 18**.

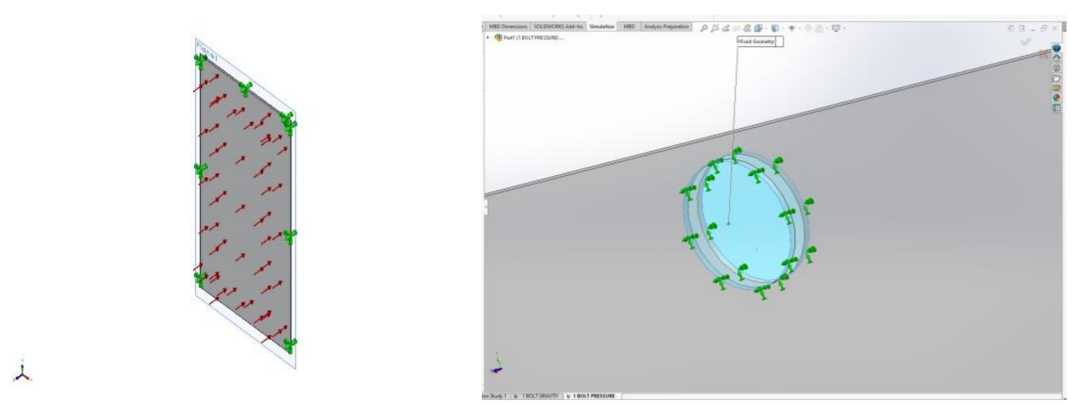
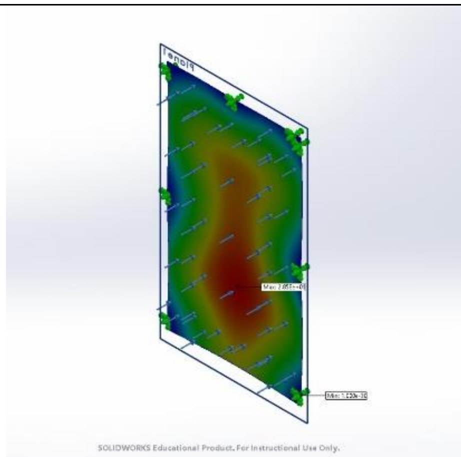
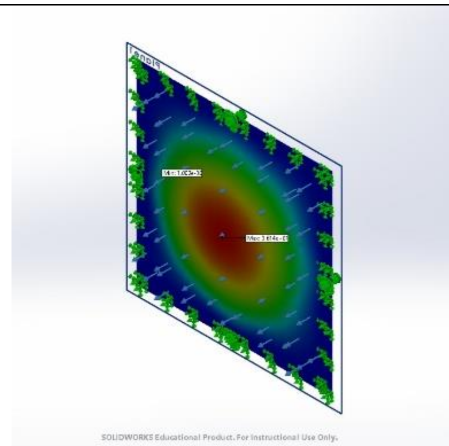
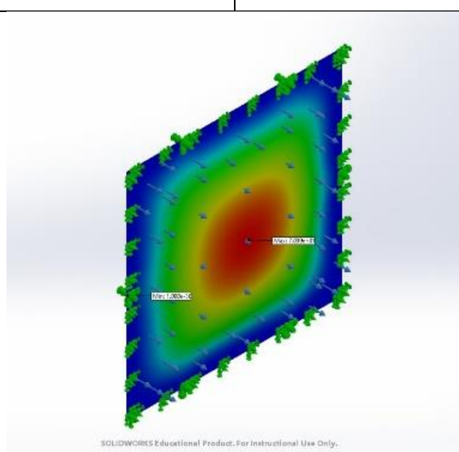


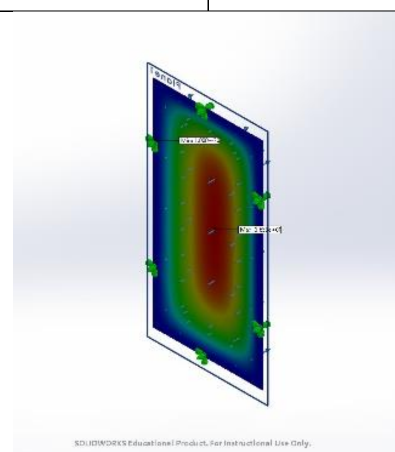
Figure 23: Visualizations of the Washer Constraints and Pressure Area

Table 18: Maximum Pressure and Deflection Results from the Max Pressure Test

<table>
<tr><td colspan="2">

47.5x88.5</td><td colspan="2">

23.5x23.5</td></tr>
<tr><td>Max Pressure</td><td>Max Deflection</td><td>Max Pressure</td><td>Max Deflection</td></tr>
<tr><td>200 Pa
0.029 Psi</td><td>28.58 mm
1.125 in</td><td>84000 Pa
12.18 Psi</td><td>36.14 mm
1.422 in</td></tr>
<tr><td colspan="2">

46.75x46.75</td><td colspan="2">

24x47.5</td></tr>
<tr><td>Max Pressure</td><td>Max Deflection</td><td>Max Pressure</td><td>Max Deflection</td></tr>
<tr><td>34000 Pa
4.931 Psi</td><td>70.39 mm
2.771 in</td><td>41000 Pa
5.947 Psi</td><td>36.59 mm
1.440 in</td></tr>
</table>

Conclusion

After completing both testing for the polycarbonate sheets, the team confirmed that the current design will be sufficient to handle the weight and pressure difference of the cleanroom with 200 nuts and bolts. These calculations where the second iteration of the polycarbonate testing, with the first iteration being completed with 352 nuts and bolts. Using both iterations the bolt location and amount was optimized and the maximum pressure the sheets can handle was determined without doing physical testing. All stress, strain, and deflection testing figures for the other sheet sizes are shown in **Appendix D**.

6.3 Other Engineering Calculations

6.3.1 Updated Cost Analysis

The cost analysis for all materials to construct the cleanroom was redone to account for the updated 12' x 16' size design.

6.3.2 12' x 16' Frame Size

Framing

To be able to construct an accurate cost analysis of the framing, inventory of all the lengths of 80/20 square aluminum tubing that will be used to construct this design is necessary. Those are as follows:

- 46: 47" Beams
- 14: 87" Beams
- 10: 22" Beams
- 6: 22.5" Beams

Using the square Aluminum tubing with part no. 9700 costing $0.49 per inch, the sum is $2,045.01. After tax and shipping the final cost is $2608.74.

Connectors

The connectors to be used within the design are distributed from Esto connectors. The parts list consists of the following:

- 20: 1.5" Straight Base Connectors
- 4: 1.5" 4-Way Cross Connectors
- 18: 1.5" 3-Way Tee Connectors
- 8: 1.5" 3-Way Corner Connectors
- 8: 1.5" 4-Way Corner Connectors

The total cost of the connectors comes out to $564.91.

Wall Material

The wall material cost for 31 sheets to cover the 12' x 16' cleanroom and the gowning room comes out to $2,198.02.

6.4 Future Testing Potential

Future virtual prototypes and experimental testing will be completed to answer the following additional questions: what the necessary gap of the walls is, what speed the fan should be set to, what back-up battery is required to run the cleanroom, and what gasketing material should be used to seal the walls and frame. Ansys CFD simulations will be completed using different wall gap heights and different fan input speeds. The same testing will be done experimentally on the current 6x8 cleanroom with one FFU to mimic a quarter scale of the final cleanroom design. A full electrical load analysis will be completed on the cleanroom structure, mainly the FFUs, to determine what back-up battery power is required to run the cleanroom in the event of a power outage. Lastly, a physical prototype will be completed using sections of the frames and walls to test different gasketing materials. Once the final cleanroom design is built, the final testing done will be pressure readings, flow readings, and particle counting to ensure the design will pass ISO Class 7 certification.

7 CONCLUSIONS

The objective of the design project is to create a sterile environment to produce medical devices by designing and constructing a cleanroom. This will be achieved by a filtered fan unit that provides a positive pressure difference inside the cleanroom. The design goals for the cleanroom are to make it an ISO Class 7 cleanroom while being modular, affordable, easy to assemble, and disassemble. This is achieved by using multiple engineering techniques to narrow down our design requirements. The design requirements for the project include having laminar flow, strong frame connections, good frame support, positive pressure difference, optimized fan placement, strong material connections, affordability, and modularity.

The group has concluded that the design will include beams of 1.5x1.5-inch aluminum tubing, two filter fan units located off-center of the cleanroom, an 8x12x7.5 feet cleanroom, and attaching polycarbonate walls with screws. Initial prototypes were completed to help the team determine if the final selected design will be feasible for the manufacturing of the cleanroom. The cleanroom dimensions were doubled between the first and second reports. The structural load of the FFUs was tested to determine if structural support beams will be required to support the increased cleanroom dimensions. Gravity and maximum pressure simulations were completed to determine if the polycarbonate sheets connected to the frame by screws can handle the weight of gravity and the positive pressure in the cleanroom. The simulations also determined the minimum number of nuts and bolts that will be required for connecting the sheets. Updated cost analysis with a complete Bill of Materials helped the team plan funding for the next semester. The project is currently on track to begin purchasing components and beginning early manufacturing.

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9 APPENDICES

9.1 Appendix A: House of Quality

System QFD

Project:	**Modular Sterile Manufacturing Clean Room**
Date:	10-28-23

Legend	
A	Dr. Becker Current Design
B	Clean Air Cleanroom
C	Global Industrial Cleanroom

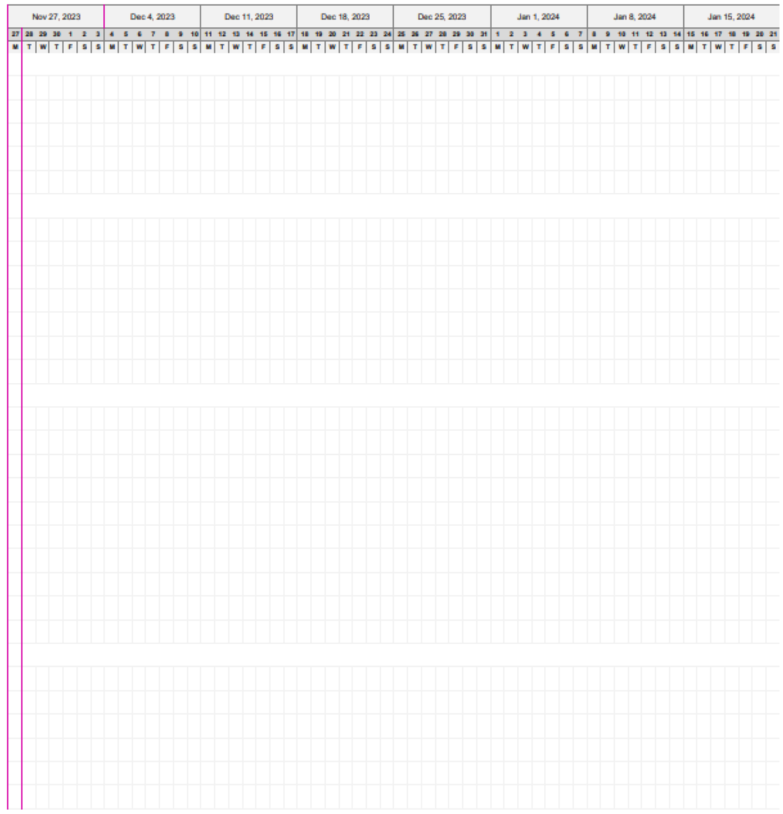
	Room Area	Positive Pressure	Particle Count	Particle Size	Airflow	Ceiling Coverage	Reynold's Number
Room Area							
Positive Pressure	6						
Particle Count	6	6					
Particle Size	6	6	9				
Airflow	6	6	3	3			
Ceiling Coverage	9	6	9	9	6		
Reynold's Number	6	3	1	1	9	6	
Power Requirement	1	3	3	3	3	1	3

		Engineering Requirements								**Customer Opinion Survey**				
Customer Requirements	**Weight**	Room Area	Positive Pressure	Particle Count	Particle Size	Airflow	Ceiling Coverage	Reynold's Number	Power Requirement	1 *Poor*	2	3 *Acceptable*	4	5 *Excellent*
Modular	5	3									C		AB	
Transportable	3	3									C	AB		
Spacious	4	9	-1	-1	-1	-1					A		C	B
ISO Class 7 Compliant	5	3	9	9	9	9	9	6	1				A	BC
Generator Backup Power	2	1	1	1	1	1		1	9	ABC				
Engineering Requirement Units		ft^2	Pa	particles/m^3	µm	m/s	N/A	N/A	W					
Engineering Requirement Targets		48	0.02	352,000	0.5	0.051	15%	2300	7200					
Absolute Technical Importance		77	43	43	43	43	45	32	23					
Relative Technical Importance		1	3	3	3	3	2	4	5					

Figure 24: Modular Sterile Cleanroom House of Quality

Appendix B: Gantt Charts

TASK	ASSIGNED TO	PROGRESS	START	END
Team Charter				
Team Purpose	Aaron	100%	9/6/23	9/8/23
Team Goals	Logan	100%	9/6/23	9/8/23
Team Personalities/Roles	All	100%	9/6/23	9/8/23
Ground Rules	Gia	100%	9/6/23	9/8/23
Potential Barriers/Coping	Michelle	100%	9/6/23	9/8/23
Presentation 1				
Project Description	Aaron	100%	9/11/23	9/18/23
Background/Benchmarking	Gia	100%	9/11/23	9/18/23
Customer/Technical Requirements/QFD	Logan/Michelle	100%	9/11/23	9/18/23
Lit Review	All	100%	9/11/23	9/18/23
Math Modeling	All	100%	9/11/23	9/18/23
Schedule	Michelle	100%	9/11/23	9/18/23
Budget	Gia	100%	9/11/23	9/18/23
Presentation 2				
Project Description		100%	9/19/23	9/24/23
Concept Generation - Top Level		100%	9/19/23	9/24/23
Concept Generation - Sub-Assembly Level		100%	9/19/23	9/24/23
Engineering Calculations	All	100%	9/19/23	10/1/23
Concept Evaluation - Charts		100%	9/19/23	10/8/23
Concept Evaluation - Design Summary		100%	9/19/23	10/8/23
Concept Evaluation - CAD		100%	9/19/23	10/8/23
Schedule - Gantt Chart		100%	9/19/23	10/8/23
Budget		100%	9/19/23	10/1/23
Bill of Materials		100%	9/19/23	10/8/23
Report 1				
Executive Summary		100%	10/10/23	10/27/23
Background		100%	10/10/23	10/27/23
Requirements		100%	10/10/23	10/27/23
Research Within Design Space		100%	10/10/23	10/27/23
Design Concepts		100%	10/10/23	10/27/23
Conclusion		100%	10/10/23	10/27/23



TASK	ASSIGNED TO	PROGRESS	START	END
Presentation 3				
Project Description	Gia	100%	10/27/23	11/6/23
Design Description	Aaron	100%	10/27/23	11/6/23
Design Requirements	Michelle	100%	10/27/23	11/6/23
Engineering Calculations	All	100%	10/27/23	11/6/23
Design Validation	Michelle	100%	10/27/23	11/6/23
Schedule	Michelle	100%	10/27/23	11/6/23
Budget	Gia	100%	10/27/23	11/6/23
Prototype 1				
Virtual 1 - Structural Analysis	Logan	100%	10/27/23	11/13/23
Virtual 2 - Polycarbonate Sheets Analysis	Aaron	100%	10/27/23	11/13/23
Report 2				
Executive Summary	All	0%	11/13/23	11/27/23
Report 1 Material Transfer	All	100%	11/13/23	11/27/23
Schedule	Michelle	90%	11/13/23	11/27/23
Budget	Gia	0%	11/13/23	11/27/23
BOM	Gia	0%	11/13/23	11/27/23
FMEA	Michelle	0%	11/13/23	11/27/23
Initial Prototyping	Aaron & Logan	0%	11/13/23	11/27/23
Other Engineering Calcs - Cost Analysis	Gia	0%		
Future Testing Potential	Michelle	100%	11/13/23	11/27/23
Prototype 2				
Physical 1 - Gasketing Determination	All	0%	10/27/23	11/13/23
Physical 2 - Flow Experiments	Gia & Michelle	50%	10/27/23	11/13/23

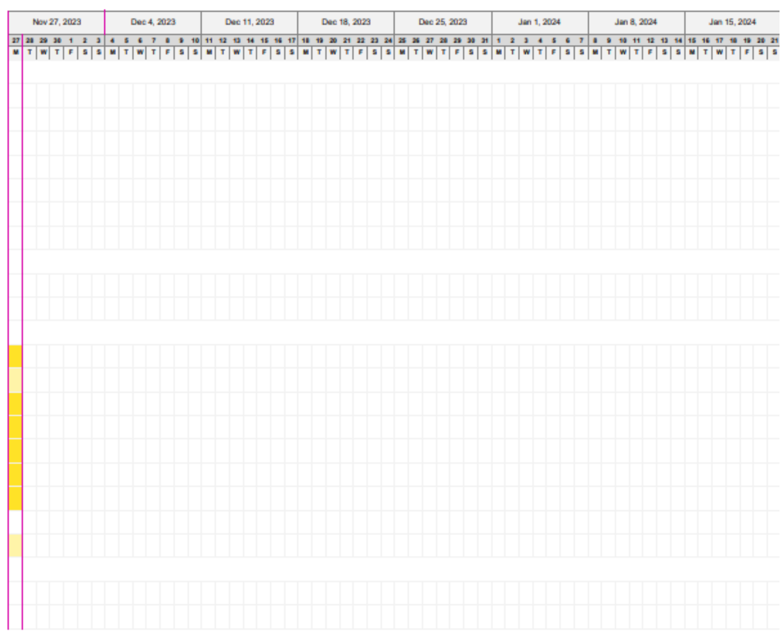


Figure 25: Fall 2023 Gantt Chart

Appendix B: Gantt Charts

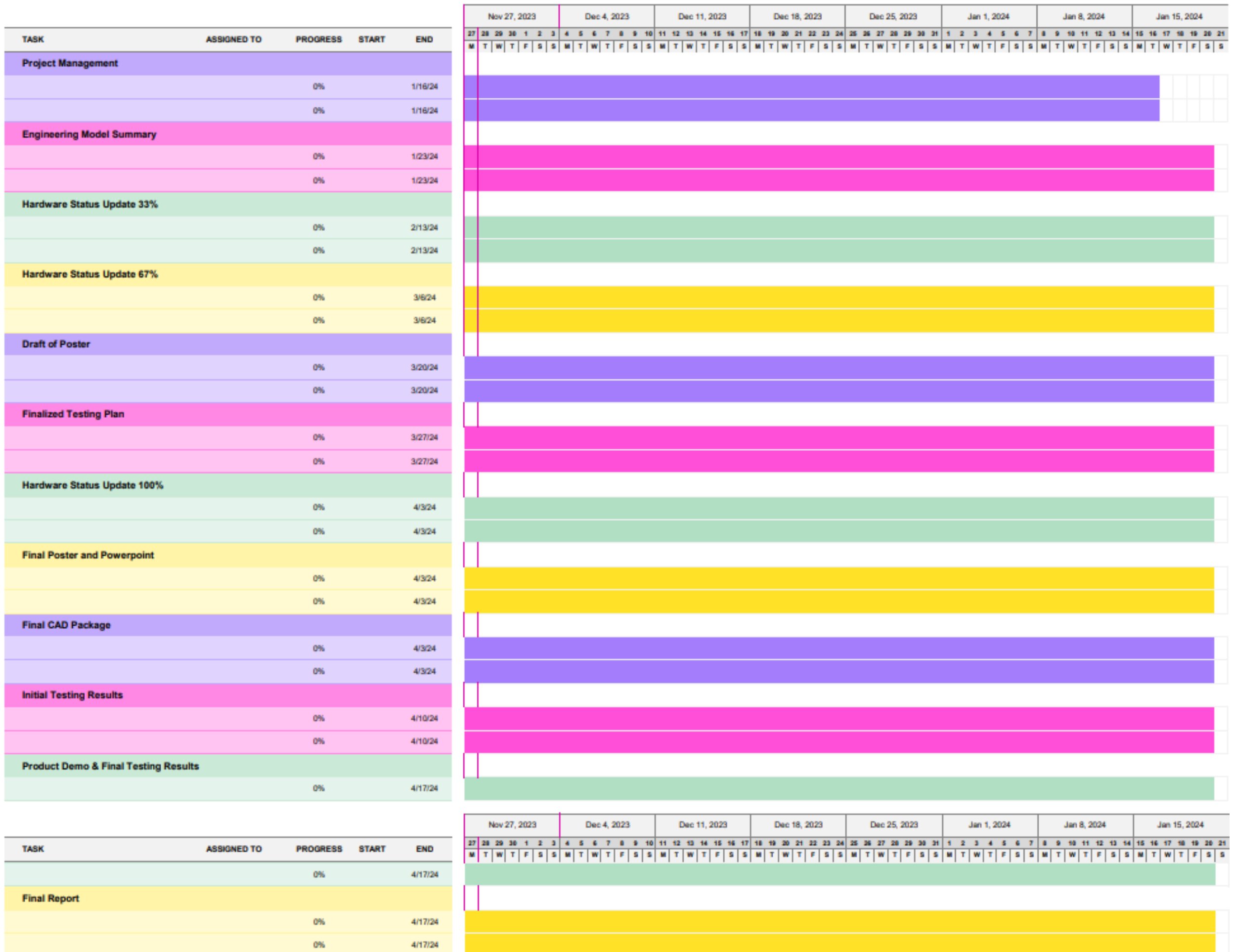


Figure 26: Spring 2024 Gantt Chart

Appendix C: Failure Modes and Effects Analysis (FMEA)

Table 19a: FMEA

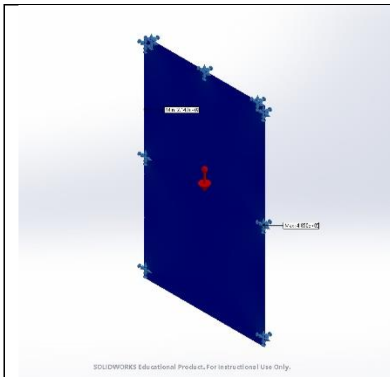
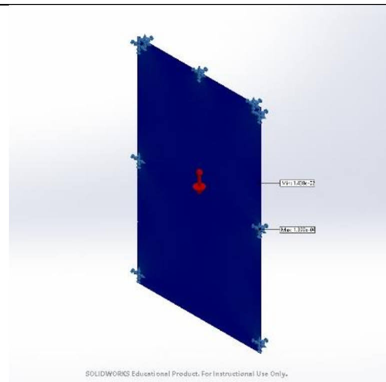
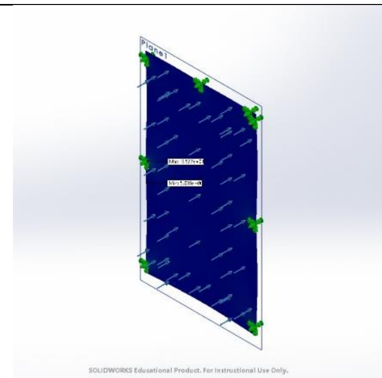
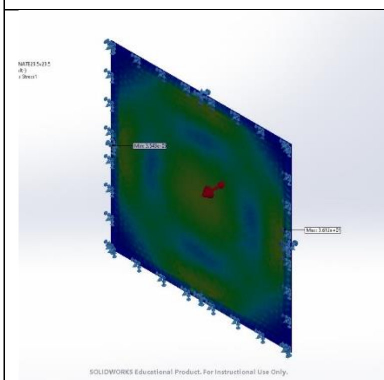
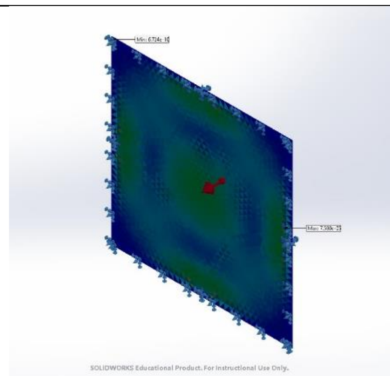
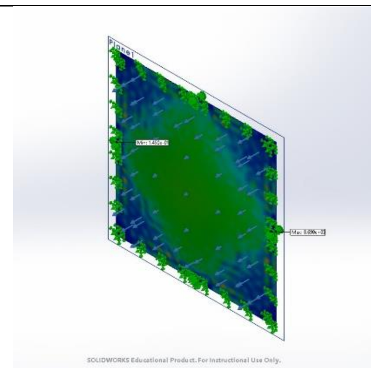
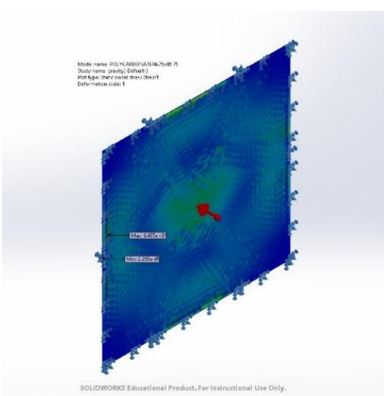
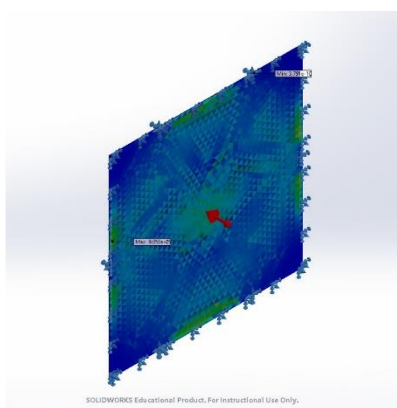
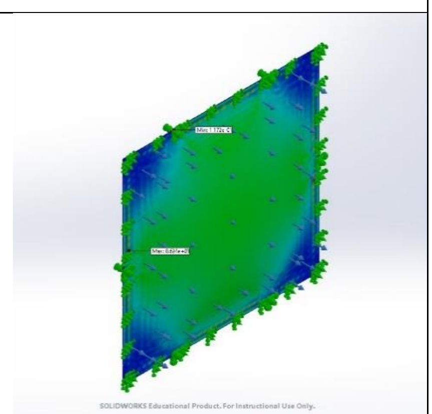
Product Name: Modular Sterile Cleanroom		Development Team: Logan Bennet, Michelle Borzick, Gia Neve, Aaron Reynoza				Page No 1 of 1 Date: November 2023			
Part and Functions	**Potential Failure Mode**	**Potential Effect(s) of Failure**	**Severity (S)**	**Potential Causes and Mechanisms of Failure**	**Occurance (O)**	**Current Design Controls Test**	**Detection (D)**	**RPN**	**Recommended Action**
Fan Filter Unit: maintains airflow, pressure, and particle count requirements	HEPA filter needs replaced	Increased particle count	5	Inadequate maintanence	1	Regularly scheduled maintanence	3	15	Replace HEPA filter
		Increased particle count	5	Power outage	3	Backup battery		15	Maintenance or replace battery
		Loss of positive pressure	8	Inadequate power supply	1	Backup battery		8	Maintenance or replace battery
		Decreased airflow	8					8	
	Fan turns off	Loss of ISO Class 7 Certification	8	Fan motor burnout	1	Regularly scheduled maintanence	1	8	Replace fan filter unit
		Pressure leak	5	Inadequate maintanence	1	Regularly scheduled maintanence		10	Repair (if possible) or replace aluminum beams
		Increased particle count	5	Increased load	2	Weight specification documentation	2	20	Remove additional load, repair/replace aluminum beams
						Inspection prior to assembly			
						Regularly scheduled maintanence			
						SOPs for assembly and disassmbly			
	Aluminum beam cracks or breaks in walls	Decreased wall structural integrity	6	Damage during assembly, disassembly, or transport	3	Training to SOPs	1	18	Repair (if possible) or replace aluminum beams
		Fan falls	8	Inadequate maintanence	1	Regularly scheduled maintanence		8	Repair (if possible) or replace aluminum beams
		Increased particle count	5	Increased load	2	Weight specification documentation		10	Remove additional load, repair/replace aluminum beams
		Loss of positive pressure	8			Inspection prior to assembly		24	
		Decreased airflow	8			Regularly scheduled maintanence		24	
						SOPs for assembly and disassmbly		24	
	Aluminum beam cracks or breaks in ceiling	Loss of ISO Class 7 Certification	8	Damage during assembly, disassembly, or transport	3	Training to SOPs	1	24	Repair (if possible) or replace aluminum beams
						SOPs for assembly and disassmbly		20	
				Incorrect assembly	1	Training to SOPs		20	
				Natural loosening over time	1	Regularly scheduled maintanence		20	
	Loose screw	Pressure leak	5	Inadequate maintanence	1	Regularly scheduled maintanence	4	20	Tighten screw
						SOPs for assembly and disassmbly		15	
		Pressure leak	5	Incorrect assembly	1	Training to SOPs		15	
				Natural loosening over time	1	Regularly scheduled maintanence		18	
Cleanroom Frame: provides structural support for walls and fan filter units	Screw falls out	Decreased wall structural integrity	6	Inadequate maintanence	1	Regularly scheduled maintanence	3	18	Tighten or replace screw

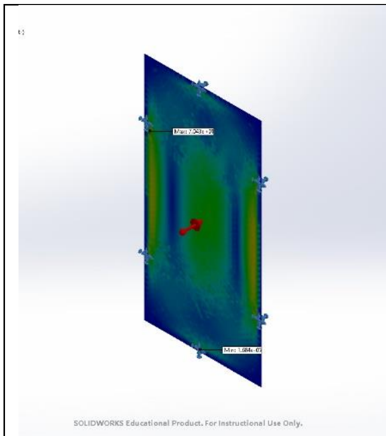
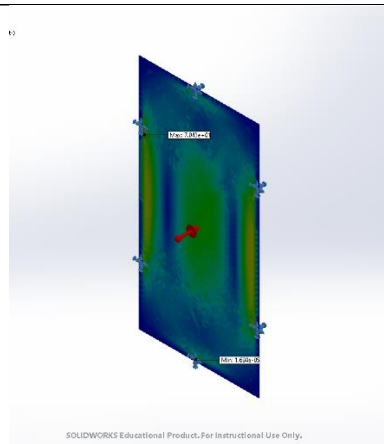
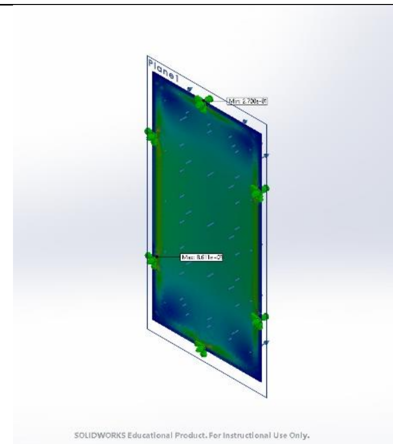
Table 19b: FMEA

Cleanroom Walls: provide barrier between clean and external environments	Polycarbonate sheet cracks	Increased particle count	5	Damage during assembly, disassembly, or transport	3	Inspection prior to assembly	2	30	Repair (if possible) or replace polycarbonate sheets
						Regularly scheduled maintanence		30	
		Pressure leak	5			SOPs for assembly and disassmbly		30	
						Training to SOPs		30	
	Polycarbonate sheet breaks or falls	Increased particle count	5	Damage during assembly, disassembly, or transport	3	Inspection prior to assembly	1	15	Repair (if possible) or replace polycarbonate sheets
		Loss of positive pressure	8			Regularly scheduled maintanence		24	
						SOPs for assembly and disassmbly		24	
		Loss of ISO Class 7 Certification	8			Training to SOPs		24	
	Unauthorized entry	Increased particle count	5	Inadequate training or signage	1	Training to SOPs	1	5	Train personnel
						Signage on cleanroom entries		5	Add or increase signage
	External or internal pressure on the walls	Decreased wall structural integrity	6	Inadequate training	1	Training to SOPs	4	24	Train personnel
				Accidental human or machine movement	1	Training to SOPs		24	Train personnel
Back-Up Battery: provides power for filter fan units in the event of a power outage	Battery does not engage in power outage	Increased particle count	5	Incorrect assembly	1	SOPs for assembly and disassmbly	1	5	Reexamine SOP validity
		Loss of positive pressure	8			Training to SOPs		8	Train personnel
		Decreased airflow	8	Battery needs replaced	1	Regularly scheduled maintanence		8	Replace battery
		Loss of ISO Class 7 Certification	8					8	
	Battery does not provide enough power	Increased particle count	5	Inadequate battery	1	Power specification documentation	2	10	Replace battery
		Loss of positive pressure	8					16	
		Decreased airflow	8	Battery needs replaced	1	Regularly scheduled maintanence		16	Replace battery
		Loss of ISO Class 7 Certification	8					16	

Appendix D: Virtual Prototype 1 Polycarbonate Sheets

Table 20: Results from Gravity Test and Max Pressure Test

		
47.5x88.5 Max Stress	47.5x88.5 Max Strain	47.5x88.5 Max Pressure
		
23.5x23.5 Max Stress	23.5x23.5 Max Strain	23.5x23.5 Max Pressure
		
46.75x46.75 Max Stress	46.75x46.75 Max Strain	46.75x46.75 Max Pressure

		
24x47.5 Max Stress	24x47.5 Max Strain	24x47.5 Max Pressure