Adaptive Sterile Modular ISO Class 7 Biomedical Manufacturing Cleanroom

Final Report

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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 was also to convert a current cleanroom into a gowning room that connects to the designed cleanroom. This report will outline the detailed project objectives as identified by the project client and sponsors.

Customer requirements were modular, spacious, and ISO Class 7 compliant to name a few. 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. A House of Quality compared all customer and engineering requirements by weighing their importance within the overall design.

For research in the design space, first benchmarking of other modular cleanroom designs was researched to determine the advantages and disadvantages of different cleanroom subfunctions. Next, literature reviews were completed by each team member focusing on different design aspects. Last, mathematical modeling was completed for 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.

For design concept generation, first functional decomposition was completion using a black box and functional models of the FFU and cleanroom to identify subfunctions for the concept generation. The generated subfunctions were further developed into concept variants. Each concept variant was used to create select criteria for each variant. The selection criteria were weighted and ranked for final concept selection.

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.

For design validation and prototyping, a Failure Modes and Effects Analysis (FMEA) was compiled on the final design to identify all critical potential failures and design mitigations to address or prevent the failures from occurring. Next, initial virtual prototyping was completed using Ansys and Solidworks simulation programs to test support structure and bolt requirements. Physical prototyping was completed to determine gasketing material and FFU speed requirements. Additional cost analysis was conducted on the updated cleanroom dimensions. Future testing potential was explored for the cleanroom as well.

The final hardware design outlined the design iterations of the CAD and the final CAD design components.

For the testing plans, a top level testing summary described the overall testing plans that were completed to meet the individual customer and engineering requirements. Individual testing summary, procedures, and results for deflection, particle count, airflow, area, and modularity testing.

Lastly, this report includes a future work and conclusions section with closing thoughts on the overall project with suggestions on improvements for the project in the future.

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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 Summary

The "Adaptive Sterile Modular ISO Class 7 Biomedical Manufacturing Cleanroom" goal was to design, construct, and test a modular cleanroom while converting an existing smaller cleanroom into a gowning room. The cleanroom must adhere to strict standards, ensuring a particle-free and sterile environment for the manufacturing of critical medical devices. The modular design allows for easy disassembly and reassembly, promoting flexibility and scalability in the manufacturing process.

1.1.2 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.

1.1.3 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 zero particle count 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 status updates, UGRADS symposium, and reports.

1.2.1.1 Status Updates

The status updates were given as presentations based on the physical manufacturing progress and then again for the post-manufacturing testing process. For the manufacturing process, the status updates of the cleanroom were benchmarked at 33%, 67%, and 100% manufactured. The testing progress updates were given as initial and final testing progress updates based on which tests were completed at the time of the update. The initial testing update had 50% of testing complete and final testing had 100% testing complete.

1.2.1.2 UGRADS Symposium

The deliverables related to the UGRADS symposium were the abstract, poster, and final presentation in preparation for the undergraduate symposium on April 26, 2024.

1.2.1.3 Reports

The reports were the finalized testing plan, final report and assembly plan. The finalized testing plan detailed the summaries, procedures, results, and conclusions of each test that was performed on the cleanroom to meet the customer and engineering requirements. The final report is outlined in this document. The assembly plan outlined the assembly and disassembly instructions for the cleanroom as well as maintenance instructions.

1.2.2 Client Deliverables

Client deliverables are reflective of the project's objectives. Dr. Becker's deliverables for the cleanroom are an ISO class 7 certified, 12x16, modular, spacious cleanroom within the allocated budget for the design.

1.3 Success Metrics

This project will be considered a success if the project objectives, course deliverables, client deliverables, customer requirements, and engineering requirements were met. At the end of the project, the design team, course instructor, and client will determine if this objective was met. Manufacturing was started as early as possible in 2024 to allow for as much success as possible during the spring semester.

2 REQUIREMENTS

This section provides an overview of Customer Requirements (CRs) and Engineering Requirements (ERs) for the project. The CRs outline the client's expectations, which include modularity, transportability, spaciousness, ISO Class 7 compliance, and safety. Engineering Requirements, derived from the CRs, cover spaciousness, deflection, particle count and size, airflow, ceiling coverage, and Reynold’s number, detailing specific constraints.

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 safe. 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 the design to be safe, meaning that the frame should be able to withstand the weight of the FFUs.

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 deflection. The customer requirement of ISO Class 7 compliant encompasses six engineering requirements: particle count, particle size, airflow, ceiling coverage, and Reynold’s number. The thresholds, limits, and constraints of each engineering requirement are detailed below.

- **Spacious:** The minimum requirement for room area will be greater than the current cleanroom size of 48 ft^2. However, the design team aims to have an area closer to 100 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.
- **Deflection:** To meet the customer requirement of the cleanroom being safe, the ceiling configuration deflection should be as close to 0in as possible with the use of supports.
- **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, 83,200 particles of size greater than 1, and 2,930 particles of size greater than 5. The particle count and size are measured as a minimum limit. The particle count and size are constrained by the FFU HEPA filter and speed. The strictest requirement for the particle count and size is a maximum of 352,000 particles of size greater than 0.5. 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. 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. 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 must be 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.

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. Deflection ranked second. The ISO Class 7 compliant requirements all ranked third. However, the design team will treat deflection and the ISO requirements as more important than the room area going forward. The cleanroom cannot be certified unless it meets the ISO Class 7 requirements. The last ranking engineering requirement was Reynold's number since laminar flow is not required for cleanroom certification.

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 and can be seen 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 mechanical uses. This was used to narrow the options for our frame as well as the force 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 and equations used to design the frame's structural elements. 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.

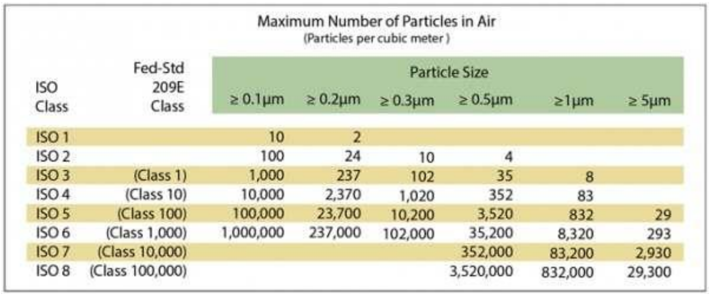
3.2.2 Particle Count and Flow Requirements – Michelle Borzick

“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 change 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 and air flow requirements from 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 strict regulations 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 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 states 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. This information is important 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 applied to the frame will be the weights of the two filter fan units 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 found the Moment of Inertia location of the frames shown in **Figure 4**.

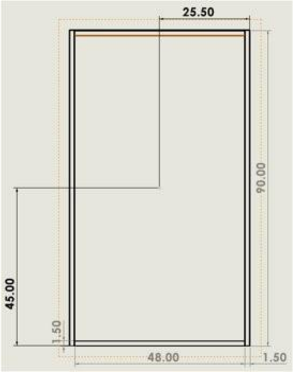


Figure 4: Location of Moment of Inertia in Frame

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.

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

$$Q = 48in * 1.5in * 44.25in = 3186in^3$$

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)**.

$$F = ma = \ 200lbm * \frac{32.2ft}{s} = 6440lbf \tag{3}$$

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)**.

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

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

$$t = \frac{w}{2} = \frac{1.5}{2} = .75in \tag{5}$$

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

$$\tau_{max} = VQ/It = 4194.4\,psi \tag{6}$$

3.3.1.2 Ceiling Frame Simulation

The area of most concern for structural stability is the ceiling. The FFUs are 50lbs each, and the ceiling is composed of several small sections connected using Estos nylon composite connectors, and the weight of the FFUs creates bending stress in the connections and the aluminum beams. To get ahead of this, an ANSYS simulation was done to determine whether structural support columns would be necessary in order to safely hold the FFUs in position above the cleanroom. **Figure 5** shows the results of that simulation with and without support columns. When testing the assembled clean room, it became clear that this testing was insufficient, and that despite the results, support columns were necessary. This is likely due to the tolerances in the true nylon composite connectors being larger than the tolerances used for the model.

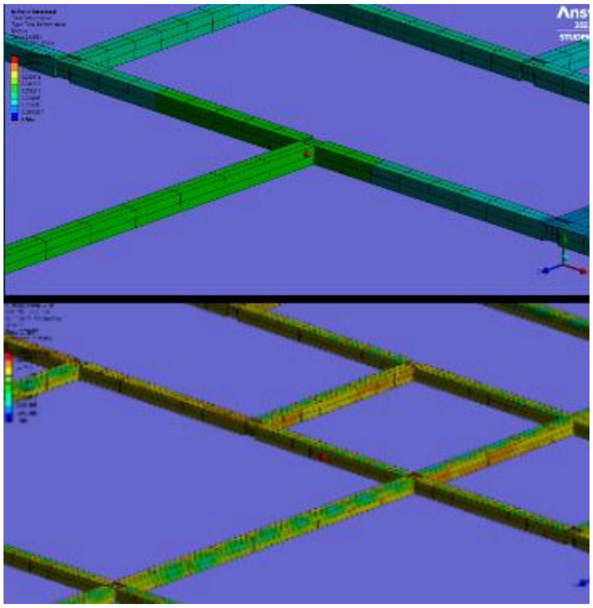


Figure 5: Maximum Deformation for The Loaded Ceiling with Supports (Top) vs Without Supports (Bottom)

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.**

$$pv = \frac{mRT}{M} \tag{7}$$

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)**.

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

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

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

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

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

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.

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

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)**.

$$v2 = 720ft^3 \tag{14}$$

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

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

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

$$m = 3394.74(lb) \tag{18}$$

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.

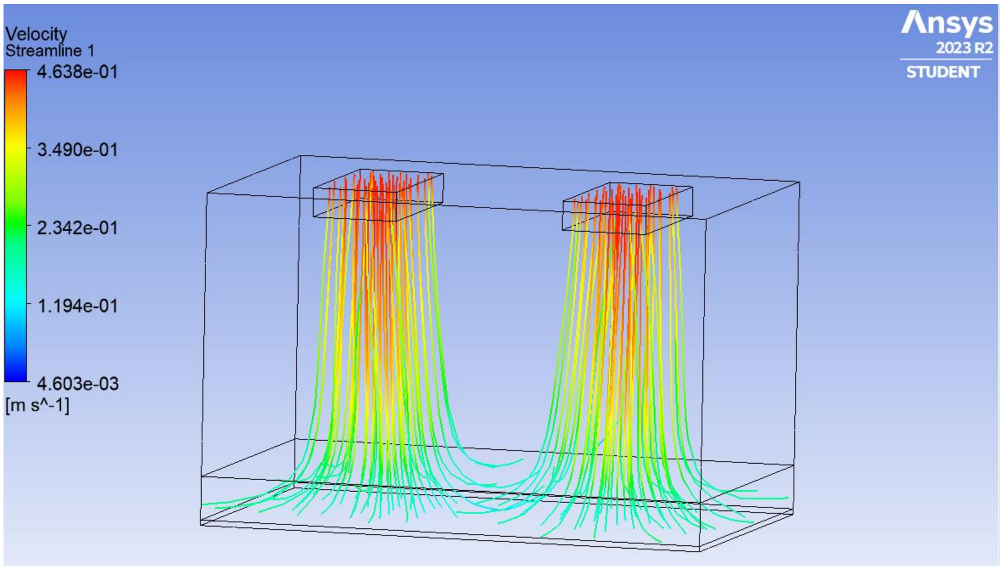


Figure 6: Centered Fans Streamline Simulation

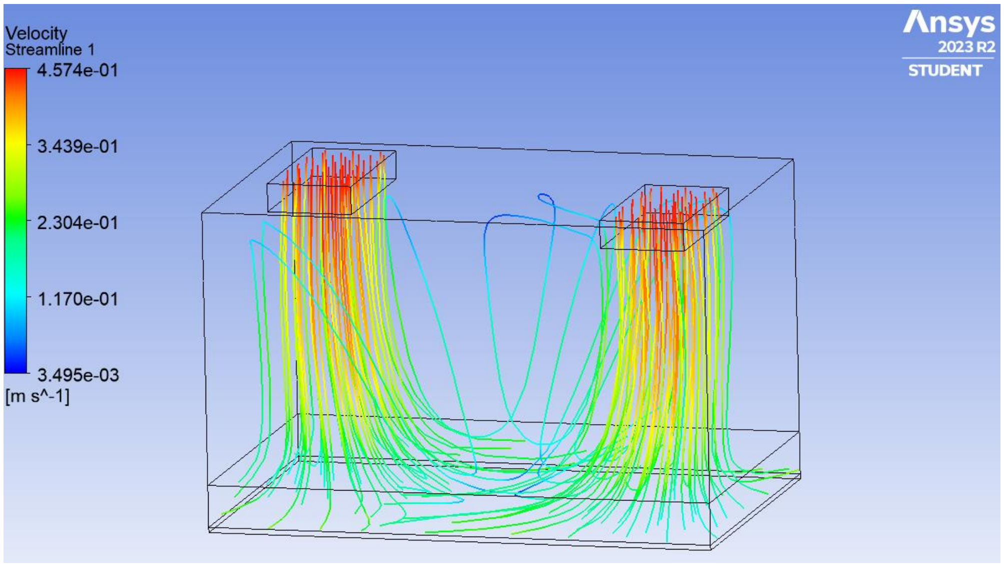


Figure 7: Cornered Fans Streamline Simulation

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 an FFU, therefore it will be essential for the design team to understand all interactions between the FFU and cleanroom.

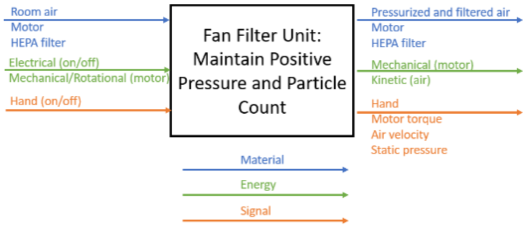


Figure 8: FFU Black Box Model

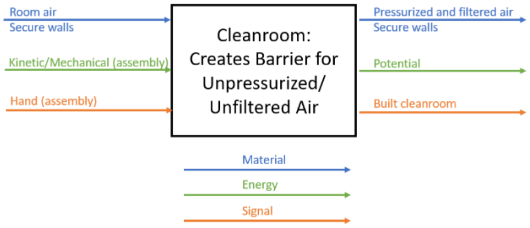


Figure 9: Cleanroom Black Box Model

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

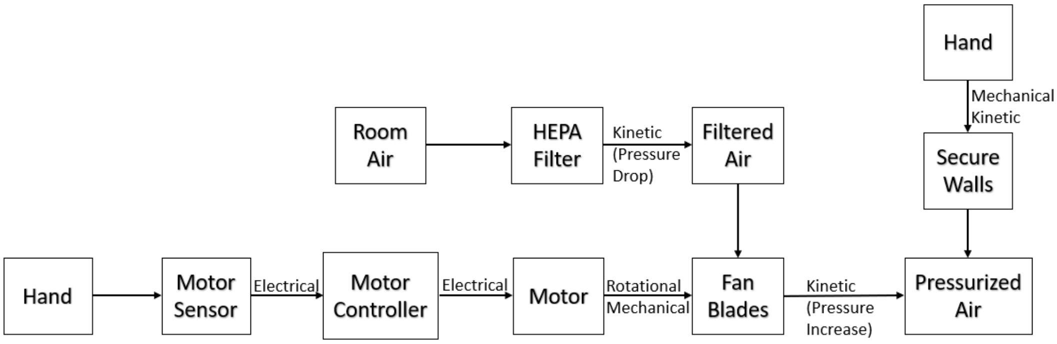
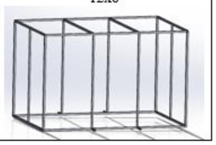


Figure 10: Cleanroom and FFU Functional Model

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 under the assumption of a 12' x 8' or a 10' x 10' cleanroom. Concepts still apply to the concept generation of a 12' x 16' cleanroom.

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 lb-f 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. 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 machine, 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, gusset 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 they are 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 must be used which is inserted in the T-Slot gaps and can slide around with external forces.

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. However, along with these advantages, there are also several disadvantages that may does not go with the customer and engineering requirements. One issue that can happen is that the quality of the wields 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 Joint

One last frame connector is screwed joints for square tubing, while similar to the 80/20 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 11**, 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 12-13: 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 a number of possible designs. Yield strength is weighted at 10% and refers to the 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 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 $\frac{in^3}{s}$. Lastly, aesthetics is weighed 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.

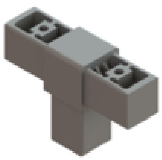
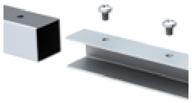
4.4 Concept Selection

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.

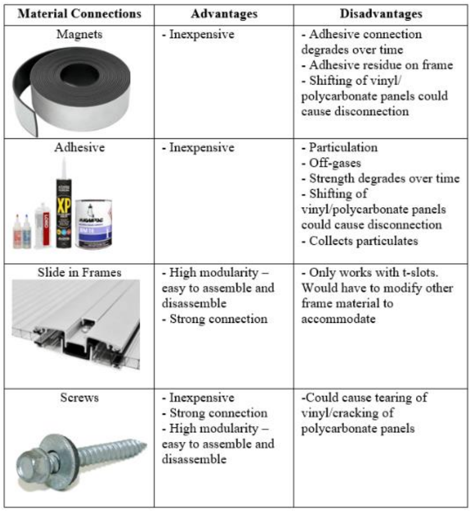
Table 4: Decision Matrix for Frame Connections

		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 particulate, 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

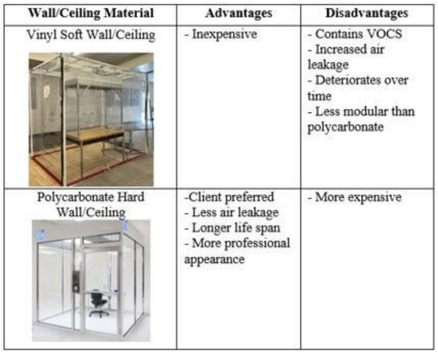
While slide-in-frame is the decision made here, the cost of using t-slots over square tubing tipped the scales in favor of screwed in hardware. The difference was only found in the aesthetic criteria, which were the lowest weight shown below in Table 6.

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.

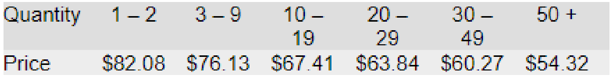


Wall/Ceiling Material	Advantages	Disadvantages
Vinyl Soft Wall/Ceiling	- Inexpensive	- Contains VOCS - Increased air leakage - Deteriorates over time - Less modular than polycarbonate
Polycarbonate Hard Wall/Ceiling	-Client preferred - Less air leakage - Longer life span - More professional appearance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

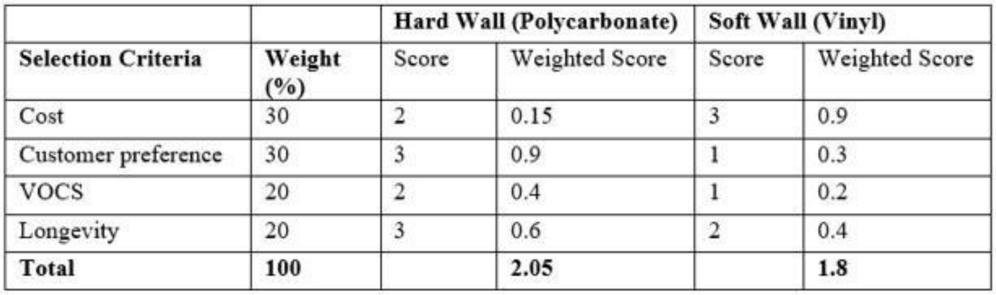
Table 7: Price of Polycarbonate sheets per unit quantity supplied by ePlastics.



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



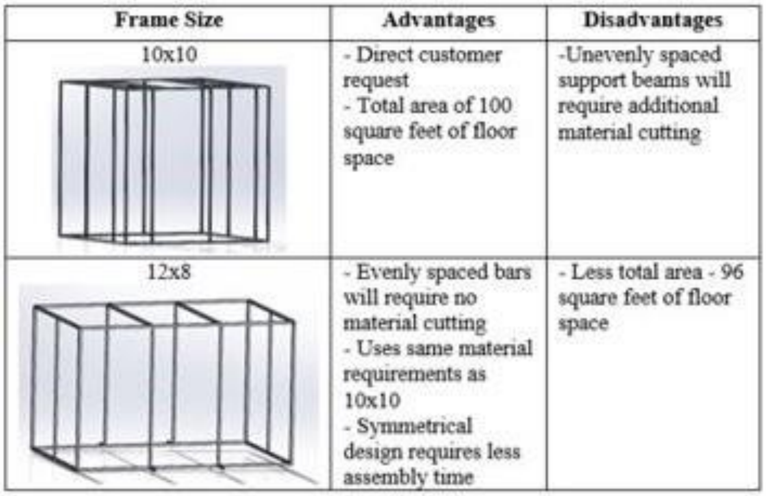
		Hard Wall (Polycarbonate)		**Soft Wall (Vinyl)**	
Selection Criteria	**Weight (%)**	Score	Weighted Score	Score	Weighted Score
Cost	30	2	0.15	3	0.9
Customer preference	30	3	0.9	1	0.3
VOCS	20	2	0.4	1	0.2
Longevity	20	3	0.6	2	0.4
Total	**100**		**2.05**		**1.8**

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 weigh 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.

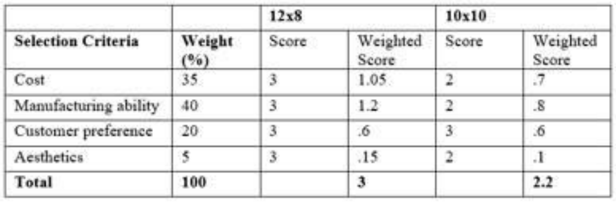
All cost calculations are summarized in **Table 10.**

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.

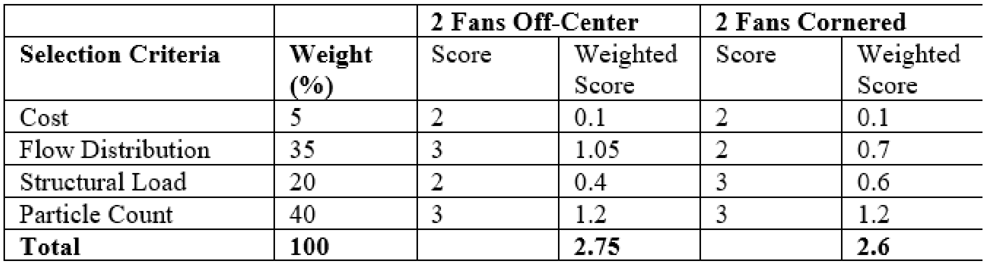
Table 12: Fan Number/Locations Advantages and Disadvantages

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 was 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 was the two centered fans. This design was 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 used to track the progress, components, and responsible team member for each project deliverable throughout the Fall and Spring semesters of the project. The full Gantt charts are shown in **Appendix B.**

5.2 *Budget*

The client initially allocated a budget of 10K for our original 12' x 8' cleanroom design. Additionally, the team secured 2K in funding from the NAU Bioengineering club and Gore Medical LLC. When it was determined that the project size would double, the budget was adjusted to 19K. A simplified cost analysis of all items purchased during the project is provided in Table 14, with a more detailed purchasing Bill of Materials (BOM) available in Appendix C.

Table 14: Simplified Purchasing BOM

Description	**Cost ($)**
Cleanroom	6,063.44
Gowning Room	732.70
Hardware	389.78
Prototypes	100.13
FFUs	5,360.37
Total Cost	12,646.42

5.3 *Bill of Materials (BoM)*

Located in **Appendix C** is a detailed Purchasing BOM **(Appendix C1)** and Manufacturing BOM **(Appendix C2)** which includes all items purchased and manufactured throughout the course of this project.

6 Design Validation and Initial Prototyping

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 FFU, cleanroom frame, and cleanroom walls. 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 FFU 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.

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

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 simulation found 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 it is necessary to support the ceiling given the larger length.

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 would 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**.

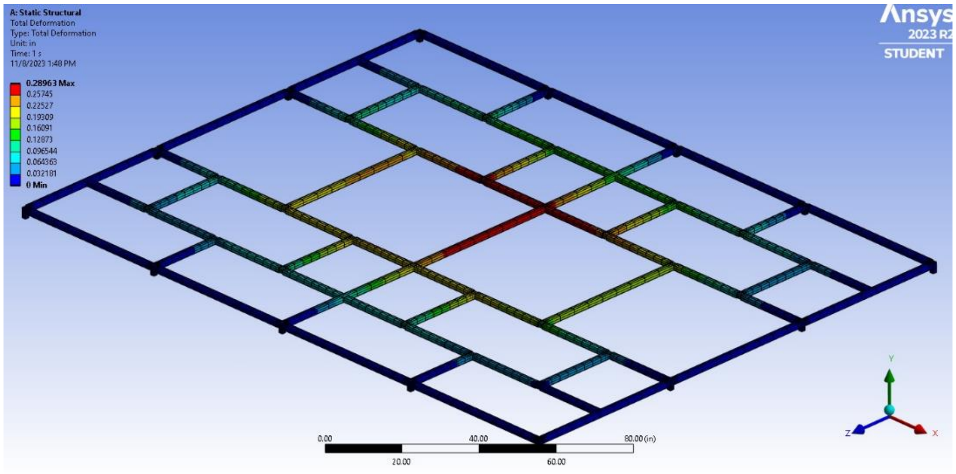


Figure 15: Total deformation without support columns.

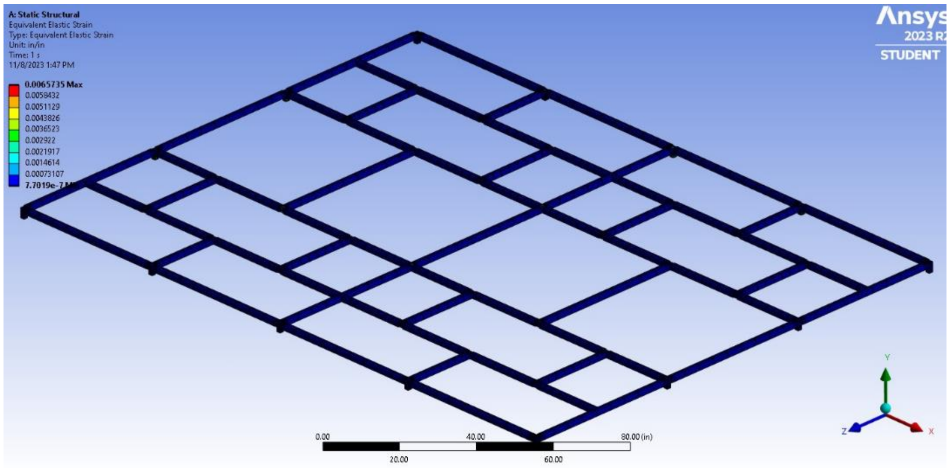


Figure 16: Strain without support columns

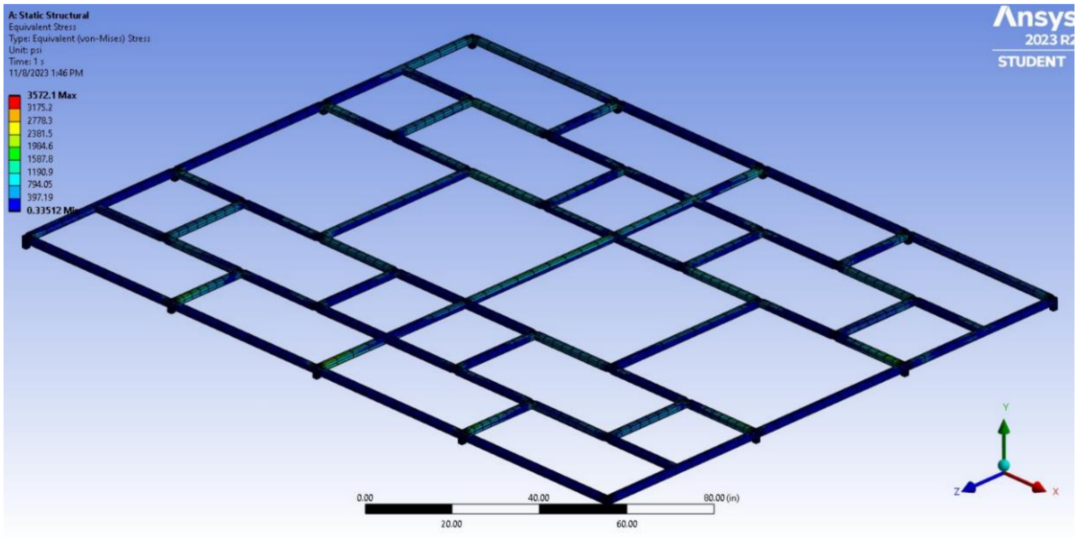


Figure 17: Stress without support columns

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**.

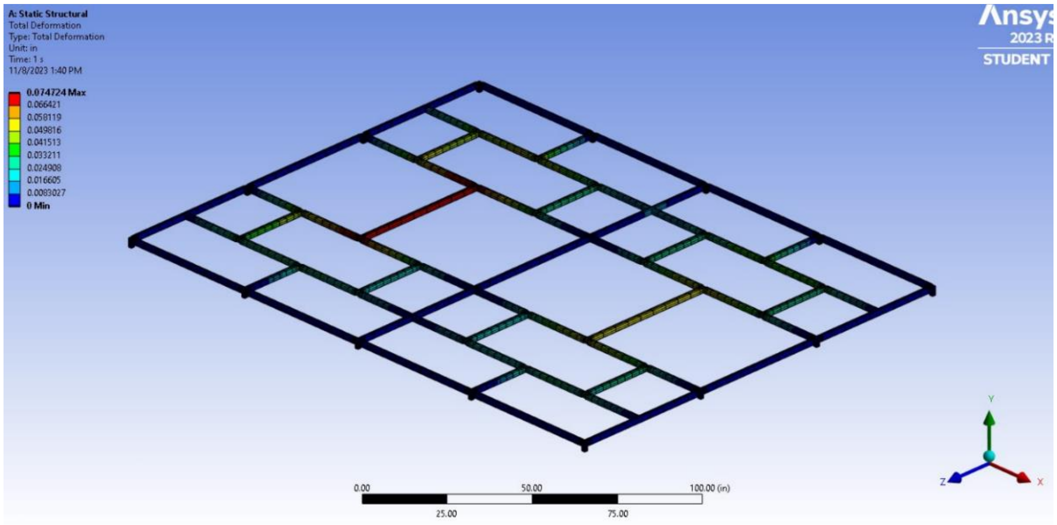


Figure 18: Total deformation with support columns

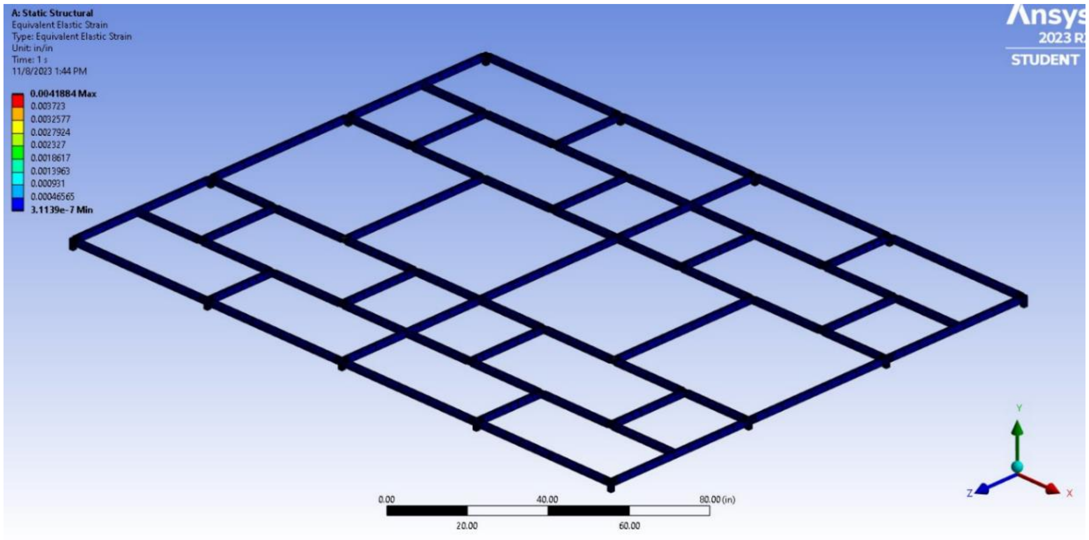


Figure 19: Strain with support columns

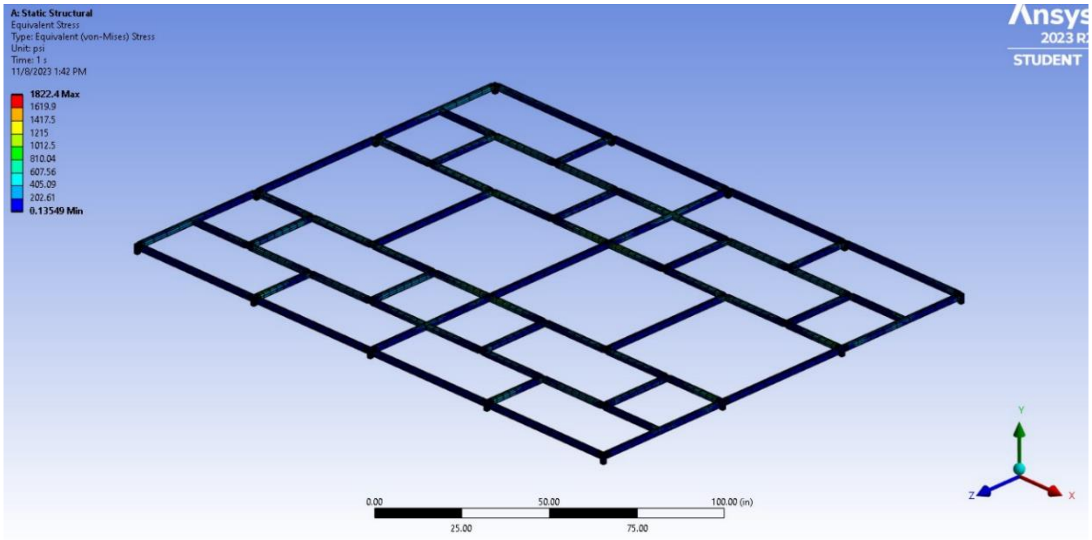


Figure 20: Stress with support columns.

A summary of the results for both the support columns and no columns is shown in **Table 15**.

Table 15: 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**.

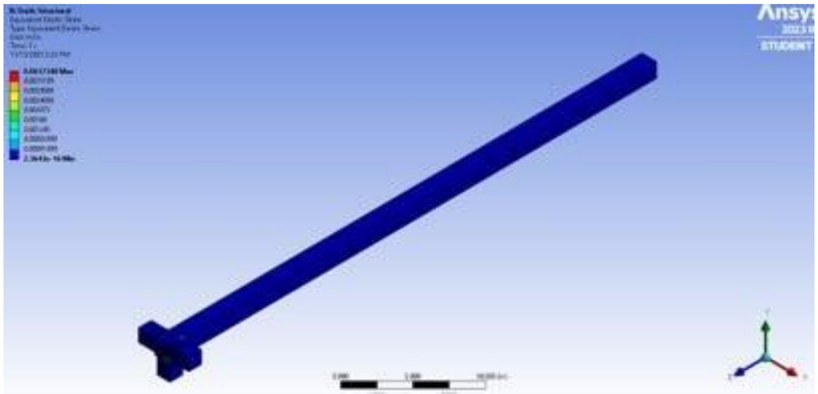


Figure 21: Actual geometry simulation of the highest stress structural members

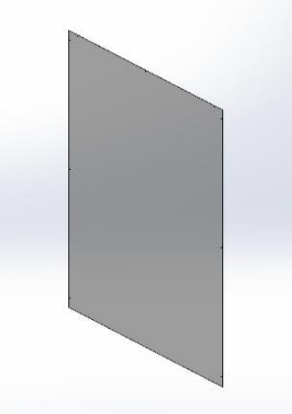
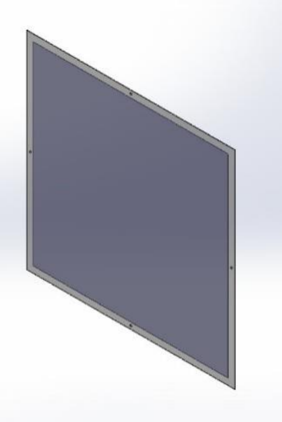
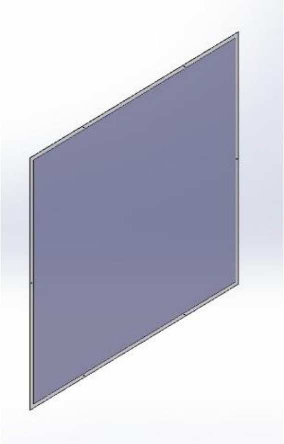
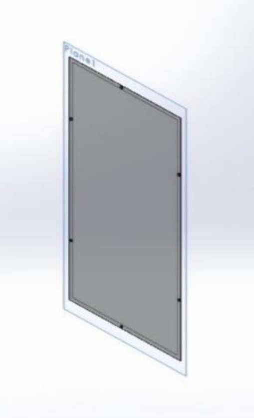
This additional simulation showed the resultant strain was lower than the simplified geometry, which is expected as the design of the real parts are manufactured to be more resistant to bending stress. The simulation's results led the team to remove support column consideration from the design process.

Upon real life assembly, it was found that the simulation did not account for the high tolerances of the actual connectors used, because of this discrepancy the real-world assembly experienced much higher deflection than anticipated, and support columns had to be added to make sure the occupants of the clean room were safe.

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 16** displays the four unique polycarbonate sheets that will be used in the cleanroom.

Table 16: 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 test gave the stress, strain, and deflection of each polycarbonate sheet. The constants used in the gravity and max pressure tests for the polycarbonate sheets, cleanroom, and bolts are shown in **Table 17**.

Table 17: 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 18**.

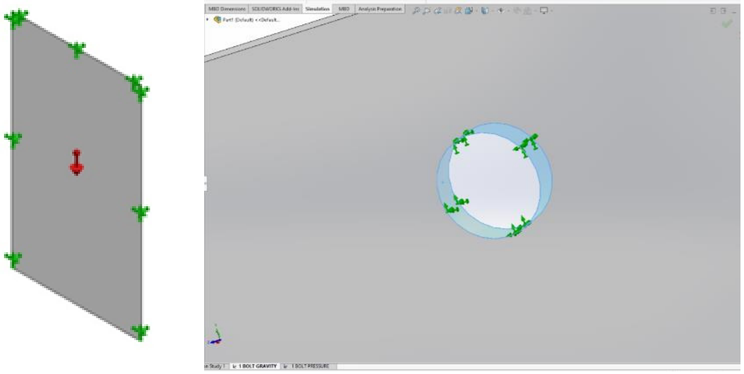


Figure 22: Visualizations of Bolt Constraints and Gravity Force

Table 18: Stress, Strain, and Deflection Results from Gravity Test

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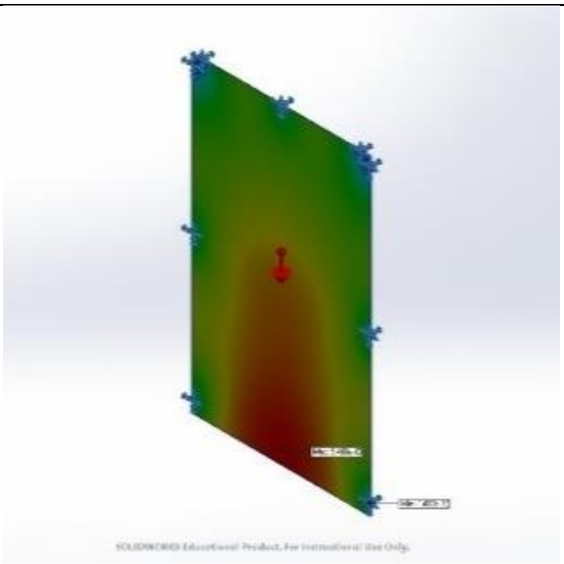
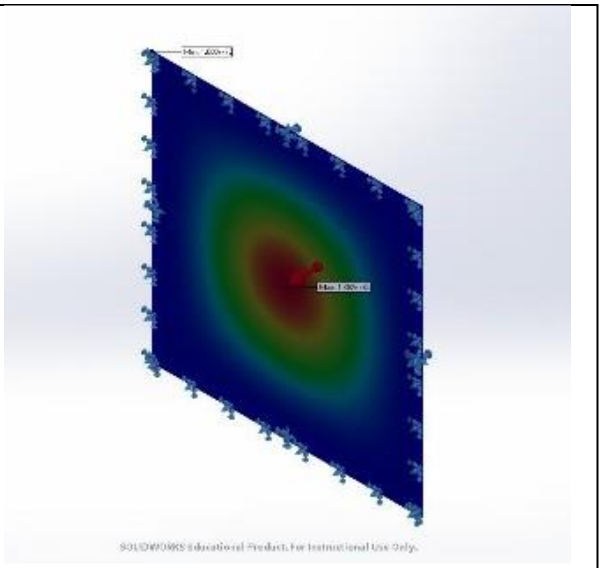
<tr><td colspan="3">
47.5x88.5</td><td colspan="3">
23.5x23.5</td></tr>
<tr><td>MAX STRESS</td><td>MAX STRAIN</td><td>MAX DEFLECTION</td><td>MAX STRESS</td><td>MAX STRAIN</td><td>MAX DEFLECTION</td></tr>
<tr><td>$4.850*10^5$ Pa
70.34 Psi</td><td>$1.399*10^{-4}$</td><td>$5.468*10^{-3}$ mm
$2.15*10^{-4}$ in</td><td>$2.90*10^5$ Pa
36.12 Psi</td><td>$1.580*10^{-5}$</td><td>1.382 mm
$5.44*10^{-2}$ in</td></tr>
</table>

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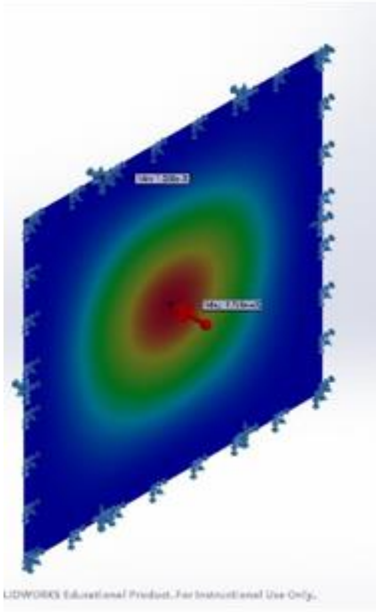
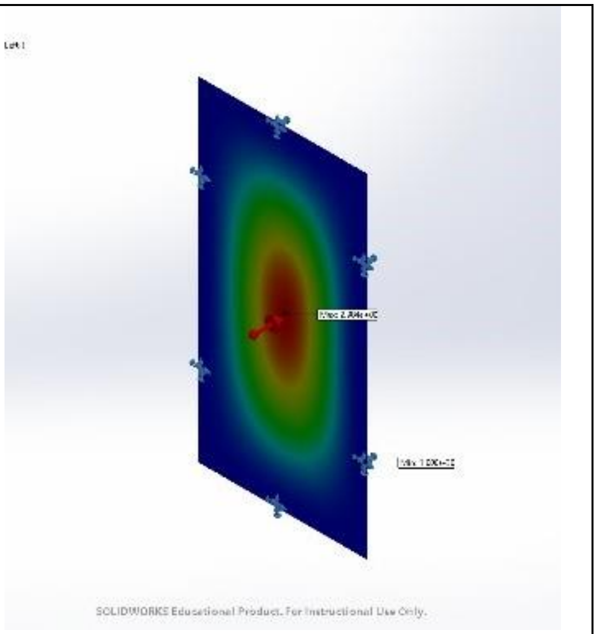
<td colspan="3">

46.75x46.75</td>
<td colspan="3">

24x47.5</td>
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<tr>
<td>MAX STRESS</td>
<td>MAX STRAIN</td>
<td>MAX DEFLECTIO</td>
<td>MAX STRESS</td>
<td>MAX STRAIN</td>
<td>MAX DEFLECTION</td>
</tr>
<tr>
<td>64.35 Pa
$9.33*10^{-3}$ Psi</td>
<td>$9.858*10^{-5}$</td>
<td>$5.468*10^{-3}$ mm
$2.15*10^{-4}$ in</td>
<td>70.43 Pa
$1.02*10^{-4}$ Psi</td>
<td>$1.093*10^{-4}$</td>
<td>2.984 mm
0.117 in</td>
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</table>

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 19**.

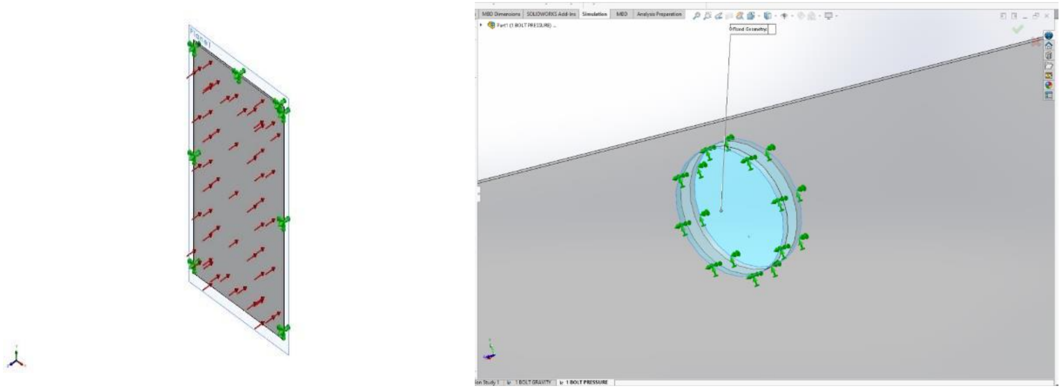
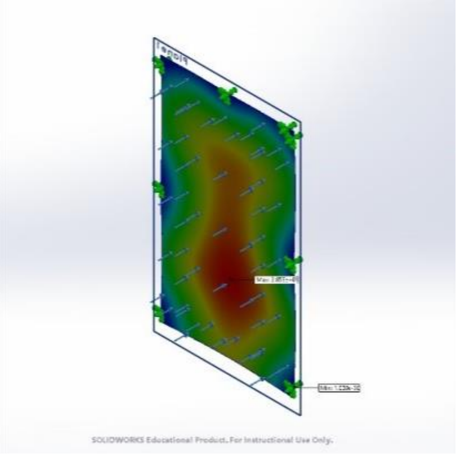
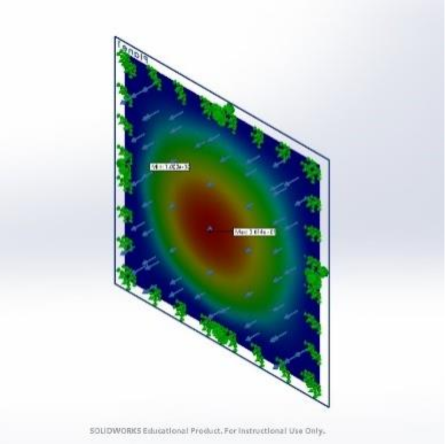
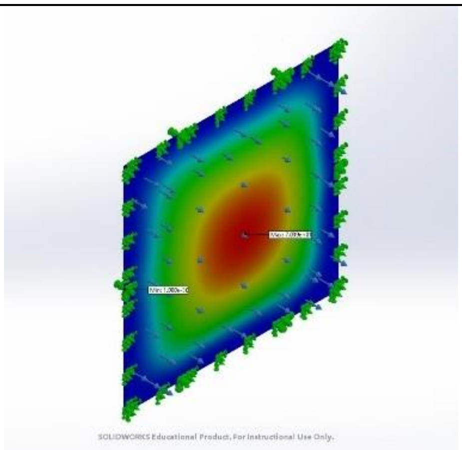
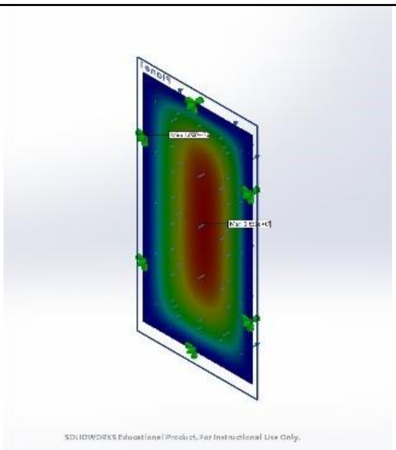


Figure 23: Visualizations of the Washer Constraints and Pressure Area

Table 19: Maximum Pressure and Deflection Results from the Max Pressure Test

 47.5x88.5		 23.5x23.5	
Max Pressure	Max Deflection	Max Pressure	Max Deflection
200 Pa 0.029 Psi	28.58 mm 1.125 in	84000 Pa 12.18 Psi	36.14 mm 1.422 in

<table>
<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 were 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 E**.

6.2.3 Physical Prototype 1: Gasketing Material

The first physical prototype tested 4 different gasketing materials on a small square wooden box made with acrylic sheets. Due to the cost of aluminum and polycarbonate, the prototype was made with cheaper materials of the same dimensions. The goal of testing gasketing materials was to determine if any gasketing would be needed in between the aluminum beams and polycarbonate sheets to prevent air leakage and maintain a strong enough seal for passing particle count results. The gasketing materials tested were a silicone sealant, rubber matting, removeable caulk, and sponge stripping. The prototype had a different gasket material placed on each side (with one side left with no material) and was filled with smoke to check for leaks. Each material was ranked for seal, modularity, cost, and aesthetics to determine the best gasketing material. The prototype testing determined the no gasketing material ranked the highest among the other gasketing materials.

6.2.4 Physical Prototype 2: FFU Speed and Wall Gap Height

The second physical prototype testing was completed on the original cleanroom. The cleanroom vinyl was modified to test different vinyl wall heights of 6in and 12in and different FFU speeds and low and high. Velocity measurements were taken at different locations along the floor of the cleanroom and compared to the ISO Class 7 requirements to help determine which wall height and FFU speeds should be considered for the larger cleanroom design. The results of the prototype were inconclusive but suggested the low speed FFU setting would not produce high enough airflow or air changes per hour.

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

6.3.2.1 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.

6.3.2.2 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.

6.3.2.3 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

6.4.1 ISO Compliance with Equipment

The ISO Class 7 compliance testing should be retested once the cleanroom is at its final state which would include having all equipment inside. This would include any tables, fume hoods, chairs, or shelfing units. Particle counting and airflow testing should be retested.

6.4.2 Creep Analysis of Nylon Composite Connectors

Analysis of creep in a member under constant stress is not something that can be tested reliably so soon after the assembly of the cleanroom, however some analysis should be done in the future to ensure that the long-term stability of the clean room ceiling can be safely assumed. Creep is a slow deformation due to a constant load, in the case of this project, the way to test it would be to measure the change of deflection over a long period of time and to graph it against time or logarithm of time allowing the team to predict the creep expected in the future.

Ideally, the deflection would not change, and creep is not a factor that will affect the longevity of the cleanroom. Unfortunately, as the team does not have access to the exact material properties of the nylon composite connectors, detailed theoretical analysis cannot be done either.

7 Final Hardware

7.1 Final Physical Design

The CAD model of the final physical design is shown in **Figure 24**. The final layout of the cleanroom was a12’x16’x7.5’ aluminum structure with polycarbonate walls mounted with screws. For the cleanroom ceiling, a 4-FFU design was located off-center with nylon composite connectors holding the 1.5” square aluminum beams together. The center of the cleanroom will have 2 vertical support beams supporting the highest deflection points and a horizontal support beam across the center of the ceiling. The team's final design is depicted as the 3rd iteration below in **Table 20**. As the semesters progressed and the customer needs were adapted, the design iterations were adjusted as well.

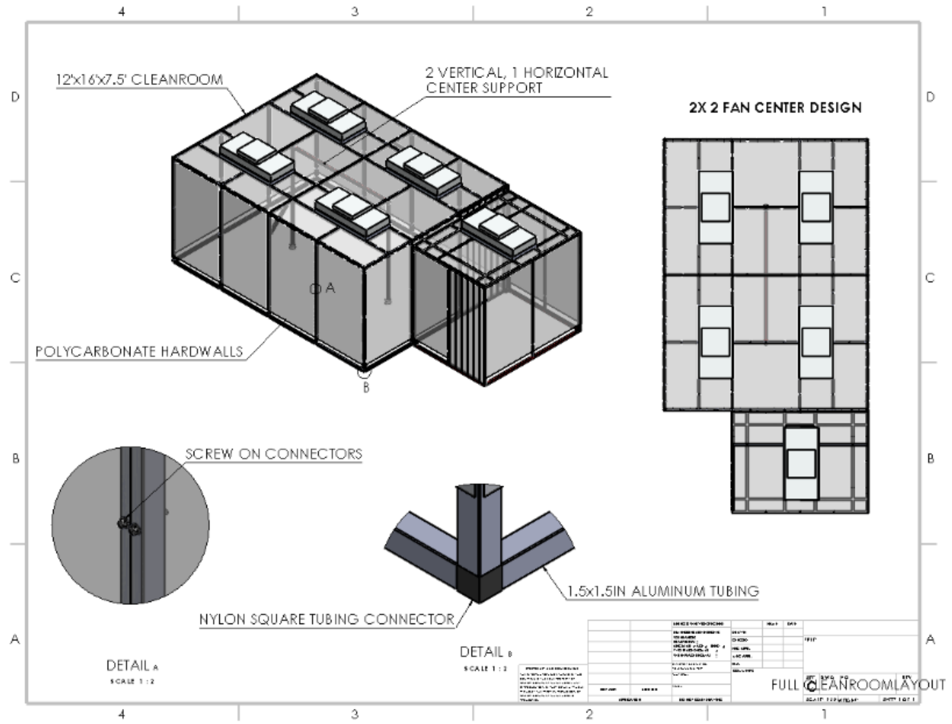
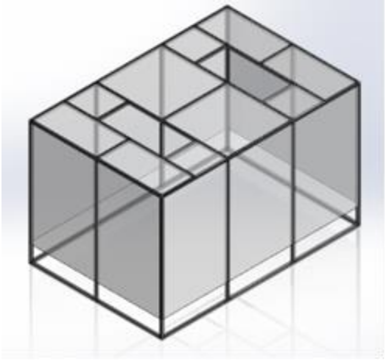
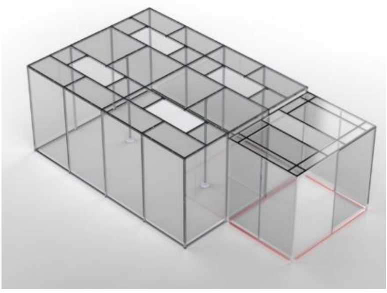


Figure 24: Final CAD Design with Labeled Concept Generation

Table 20: Costumer Requirement Summary for Each Design Iteration

Iteration	*Final CAD Design*	*Customer Requirement*
1		*ISO CLASS 7 Compliant Cleanroom *Back up Battery *Spacious with at least 10’x10’ or 12’x8’ of floor area *No internal supports *Modular *Affordable
2		* ISO CLASS 7 Compliant Cleanroom * Back up Battery *** Spacious with at least 12’x16’ floor area** * No internal supports * Modular *Affordable
3		* ISO CLASS 7 Compliant Cleanroom *** No Back up Battery** *** Spacious with at least 12’x16’ floor area** *** Internal supports** * Modular * Affordable

With all 3 configurations, most of the customer requirements were consistent with each other, this includes being an ISO Class 7 compliant cleanroom with affordable and modular materials. With iteration 1, the original intent was to create a 12'x8'x7.5' cleanroom with no internal supports and a backup battery system. The 2nd iteration was created at the request of the customer, which was to have a 12'x'16'x7.5' cleanroom while keeping to the previous customer requirements. With the last iteration, the customer wanted to have a 12'x'16'x7.5' with internal support and no back battery support system. The engineering team was able to upgrade each design iteration in a timely manner with little to no issues.

8 Final Testing

8.1 Top Level Testing Summary

Each customer and engineering requirement are addressed with a relevant test that are outlined in **Table 21**. The necessary equipment to perform each test are also listed.

Table 21: Test Summary Table

Experiment/Test	Relevant DRs	Testing Equipment Needed
Deflection	CR4 (Safe)	Tape measure
Particle Count	CR5 (ISO Class 7 Compliant) ER2 (Particle Count and Size)	Aerosol mass monitor, sterile gloves, hair net, cleanroom gown, ethanol solution
Airflow	CR5 (ISO Class 7 Compliant) ER3 (Airflow) ER5 (Reynold's Number)	Hot wire anemometer
Area	CR3 (Spacious) ER1 (Spacious) ER4 (Ceiling Coverage)	Tape measure
Modularity	CR1 (Modular) CR2 (Transportable)	Instruction manual, rubber mallet, ¼" torque wrench, ladder, timer

8.2 Detailed Testing Plan

8.2.1 Deflection Testing

8.2.1.1 Summary

The deflection test measured the distance between set points on the cleanroom roof to the floor to identify the lowest deflection points of the roof. These deflection points were used to determine where the vertical support beams should be located to limit deflection as much as possible. The testing was performed without support beams and with support beams in different locations. This test determined if CR4 was met. The equipment needed to perform the testing was only a measuring tape. The variables that were isolated for measurement were the different deflection locations. The variables that needed to be measured were the distance from the ceiling connector to the floor. The variables that needed to be calculated were the maximum shear and moment force using a 2D free body diagram to solve. This test was performed on the assembled cleanroom frame without FFUs on top.

8.2.1.2 Procedure

Procedure

1. Obtain a measuring tape and locate the 6 deflection points on the roof configuration.
2. For each of the support beam configurations, measure the distance from the top of the connector to the floor at each deflection point. Reference **Figure 25** for the deflection point locations and support beam configurations.

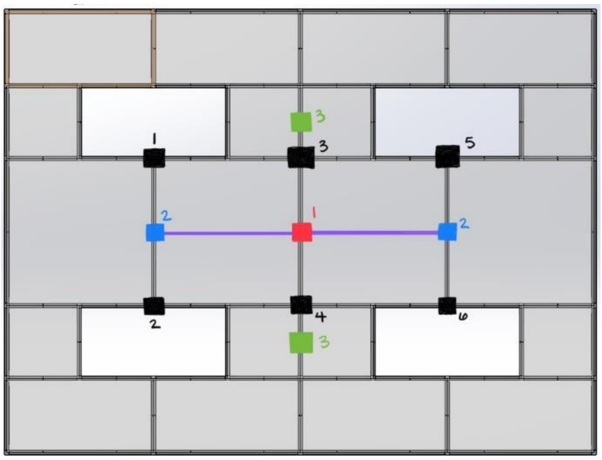


Figure 25: Support Beam Configurations

3. Record the distances on the specifications sheet.
4. Calculate the average deflection for each support configuration.

$$Average\ deflection = \frac{\Sigma\ deflection\ measurements}{Number\ deflection\ measurements}$$

8.2.1.3 *Results*

The deflection results for each of the support beam configurations are shown in Table 22. Support Beam Configuration 4 with 2 off-center supports and a central beam across the ceiling. The configuration showed a negative deflection without the weight of the FFUs present which would result in a net 0 deflection with the FFUs on the cleanroom ceiling.

Table 22: Deflection Testing Results

Deflection Point	**No Support Beams**	**Support Beam Configuration 1**	**Support Beam Configuration 2**	**Support Beam Configuration 3**	**Support Beam Configuration 4**
1	88.6"	89.4"	90.0"	88.8"	90.1"
2	88.6"	89.5"	90.0"	88.8"	90.1"
3	88.6"	90.0"	88.9"	90.0"	90.0"
4	88.6"	90.0"	88.9"	90.0"	90.0"
5	88.5"	89.5"	90.0"	88.8"	90.1"
6	88.9"	89.5"	90.0"	88.8"	90.1"
Average Beam Height	88.63"	89.65"	89.63"	89.2"	90.07"
Average Deflection	1.37”	0.35”	0.37”	0.8”	- 0.07”

8.2.2 Particle Count Testing

8.2.2.1 *Summary*

The particle count test measured the number of particles present in the air in various locations throughout the cleanroom. This test determined if CR5 and ER2 were met. The equipment needed to perform the testing was an aerosol mass monitor, sterile gloves, hair net, cleanroom suit, and ethanol solution. The variables that were isolated for measurement were the locations of the measurements. The variables that needed to be measured were the number of particles. This test was performed on the sterile fully constructed cleanroom.

8.2.2.2 Procedure

1. Obtain calibrated aerosol mass monitor.
2. Put on hair net, cleanroom suit, and sterile gloves. Enter the cleanroom.
3. Test particle count in each designated quadrant and corner. For all measurements, measure at 0, 2, 4, and 6ft above the ground. Reference **Figure 26** for quadrant locations.

1	3	5	7
2	4	6	8

Figure 26: Cleanroom Quadrant Layout

4. Record all particle counts on specification sheet.

8.2.2.3 Results

The particle counting results are shown in **Table 23**. The average particle count for the entire cleanroom was 0.019 μg.

Table 23: Particle Count Testing Results

Location	Height (ft)	Aerosol Mass (μg)	Average Aerosol Mass (μg)	Location	Height (ft)	Aerosol Mass (μg)	Average Aerosol Mass (μg)
Corner 1	0	0.0	0.0	Center Quadrant 3	0	0.0	0.0
	2	0.0			2	0.0	
	4	0.0			4	0.0	
	6	0.0			6	0.0	
Corner 2	0	0.0	0.0	Center Quadrant 4	0	0.0	0.0
	2	0.0			2	0.0	
	4	0.0			4	0.0	
	6	0.0			6	0.0	
Corner 3	0	0.0	0.0	Center Quadrant 5	0	0.0	0.0
	2	0.0			2	0.0	
	4	0.0			4	0.0	
	6	0.0			6	0.0	
Corner 4	0	0.0	0.0	Center Quadrant 6	0	0.0	0.0
	2	0.0			2	0.0	
	4	0.0			4	0.0	
	6	0.0			6	0.0	
Center Quadrant 1	0	0.0	0.0	Center Quadrant 7	0	0.0	0.0
	2	0.0			2	0.0	
	4	0.0			4	0.0	

	6	0.0			6	0.0	
Center Quadrant 2	0	0.0	0.0	Center Quadrant 8	0	0.0	0.0
	2	0.0			2	0.0	
	4	0.0			4	0.0	
	6	0.0			6	0.0	
Cleanroom Total Average Aerosol Mass (μg)							0.0

8.2.3 Airflow Testing

8.2.3.1 Summary

The airflow test measured the air velocity under each FFU in the cleanroom. This test determined if CR5, ER3, and ER5 were met. The equipment needed to perform the testing was a hot wire anemometer. The variables that were isolated for measurement were the height of velocity measurement. The variables that were calculated using the velocity measurements were the air changes per hour and Reynold's number of the location. This test was performed on the sterile fully constructed cleanroom.

8.2.3.2 Procedure

1. Obtain calibrated hot wire anemometer.
2. Enter the cleanroom.
3. Measure the minimum and maximum velocities under the center of each FFU and at the center of each outlet.
4. Record the velocities for each FFU and outlet location as labeled.

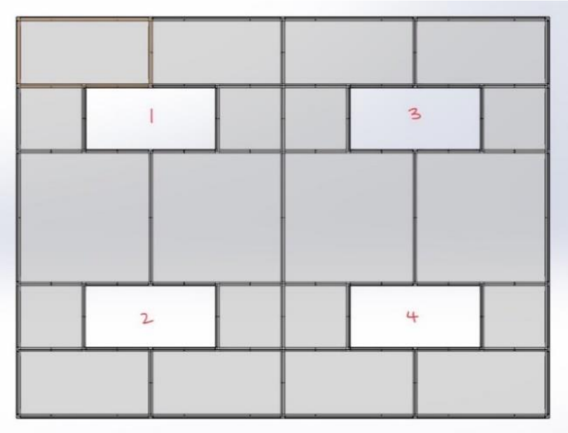


Figure 27: FFU Locations

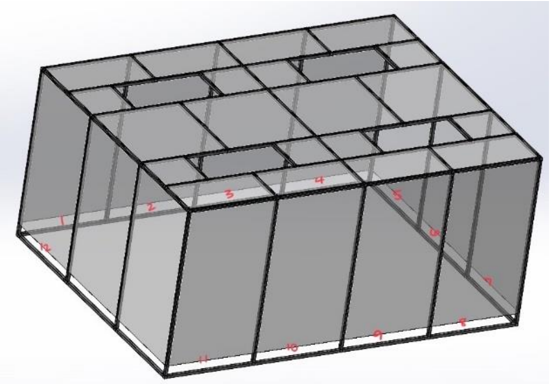


Figure 28: Outlet Locations

5. Calculate the average velocity, air changes per hour, and Reynold's number at each location.

$$Average\ velocity = \frac{\Sigma\ velocity\ measurements}{Number\ velocity\ measurements}$$

$$Air\ changes = \frac{Average\ Velocity * 60 * \#FFUs}{Outlet\ Volume}$$

$$Reynold's\ number = \frac{\rho V L}{\mu}$$

8.2.3.3 Results

The airflow counting results are shown in **Table 24**. The average airflow for the entire cleanroom was an average velocity of $100.6\ ft/min$, air changes per hour of 81.6, and a Reynold's Number of $1.09 * 10^5$. Reynold's number was calculated using a standard air density of 0.002948 $\frac{slugs}{ft^3}$ given an elevation of 7000ft, a dynamic viscosity of $3.637 * 10^{-7} lbs/ft^2$, an a characteristic length of 8ft for the internal height of the cleanroom.

Table 24: Airflow Testing Results

Measurement Location	**Minimum Velocity (ft/min)**	**Maximum Velocity (ft/min)**	**Average Velocity (ft/min)**	**Air Changes per Hour**	**Reynold's Number**
FFU 1	63	69	66	54	$7.13 * 10^4$
FFU 2	53	56	54.5	44	$5.89 * 10^4$
FFU 3	68	74	71	58	$7.67 * 10^4$
FFU 4	71	77	74	61	$8.00 * 10^4$
Outlet 1	105	114	109.5	89	$1.18 * 10^5$
Outlet 2	93	111	102	83	$1.10 * 10^5$
Outlet 3	92	104	98	80	$1.06 * 10^5$
Outlet 4	113	118	115.5	94	$1.25 * 10^5$
Outlet 5	126	136	131	107	$1.42 * 10^5$
Outlet 6	105	118	111.5	91	$1.21 * 10^5$
Outlet 7	119	127	123	100	$1.33 * 10^5$
Outlet 8	119	124	121.5	99	$1.31 * 10^5$
Outlet 9	108	114	111	90	$1.20 * 10^5$
Outlet 10	113	118	115.5	94	$1.25 * 10^5$
Outlet 11	108	111	109.5	89	$1.18 * 10^5$
Outlet 12	94	98	96	78	$1.04 * 10^5$
Cleanroom Averages:			100.6	81.6	$1.09 * 10^5$

8.2.4 Area

8.2.4.1 Summary

The area testing measured the square footage of the cleanroom. This test determined if CR3, ER1, and ER4 were met. The equipment needed to perform the test was a measuring tape and a calculator. The variables that were isolated for the measurement were the length and width of the cleanroom floor in feet. The variable that was calculated was the total area of the cleanroom.

8.2.4.2 Procedure

1. Obtain measuring tape and calculator.
2. Measure the length of the cleanroom floor from one corner to the next corner on the long side of the cleanroom.
3. Measure the width of the cleanroom floor from one corner to the next corner on the short side of the cleanroom.
4. Calculate area of cleanroom.
5. Measure the width and length of each FFU surface. Calculate the area of each FFU surface and then the average area of the FFU surfaces.
6. Calculate the ceiling coverage of the cleanroom.

8.2.4.3 Results

The airflow counting results are shown in **Table 25**. The area of cleanroom was $185.4\ ft^2$ and the ceiling coverage was 15.7%.

Table 25: Area Testing Results

	Cleanroom	***FFU***
Length (ft)	*15.75*	*3.88*
Width (ft)	*11.77*	*1.88*
Area (ft^2)	*185.4*	*7.29*
Ceiling Coverage (%)	*15.7%*	

8.2.5 Modularity

8.2.5.1 Summary

Modularity testing identified the most efficient way to assemble/disassemble the cleanroom and provided time estimates for those assemblies. This test determined if CR1 and CR2 were met. The equipment needed to perform the test included the assembly manual, all materials identified in the manual, a rubber mallet, a ¼" ratchet, at least one ladder, and a timer. The variable that was isolated was the cleanroom section to be assembled. The variable that was measured was the assembly time of each section to determine the overall assembly time.

8.2.5.2 Procedure

1. Obtain assembly manual and all required materials identified in the manual.

2. Assemble all E beams with connectors to form the perimeter of the cleanroom. Record time taken to assemble.
3. Assemble all A beams to perimeter as shown in **Figures 29-32**.

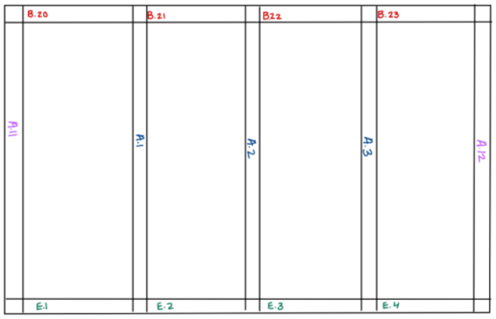


Figure 29: 18ft Wall 1

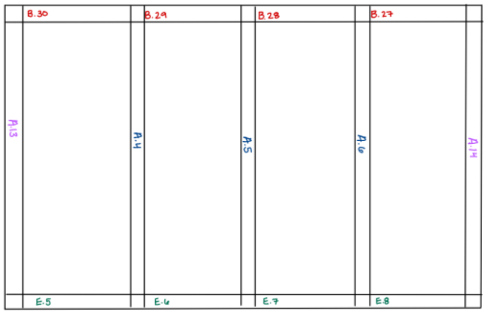


Figure 30: 18ft Wall 2

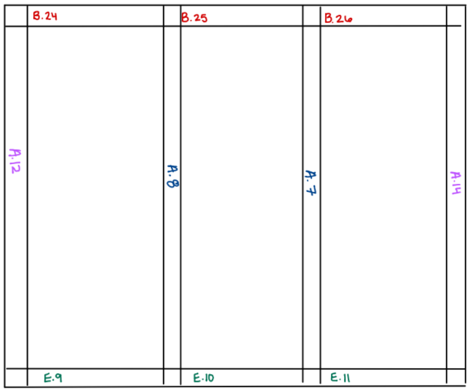


Figure 31: 12ft Wall 1

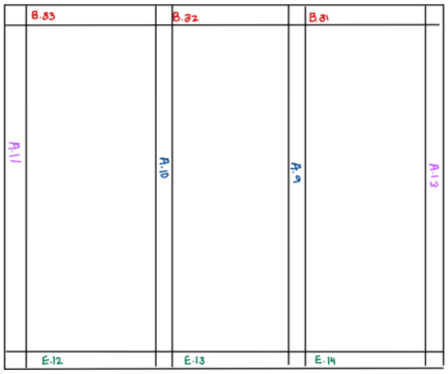


Figure 32: 12ft Wall 2

4. Assemble the ceiling in the 5 quadrants labeled in **Figure 33**. Assemble in quadrant order.

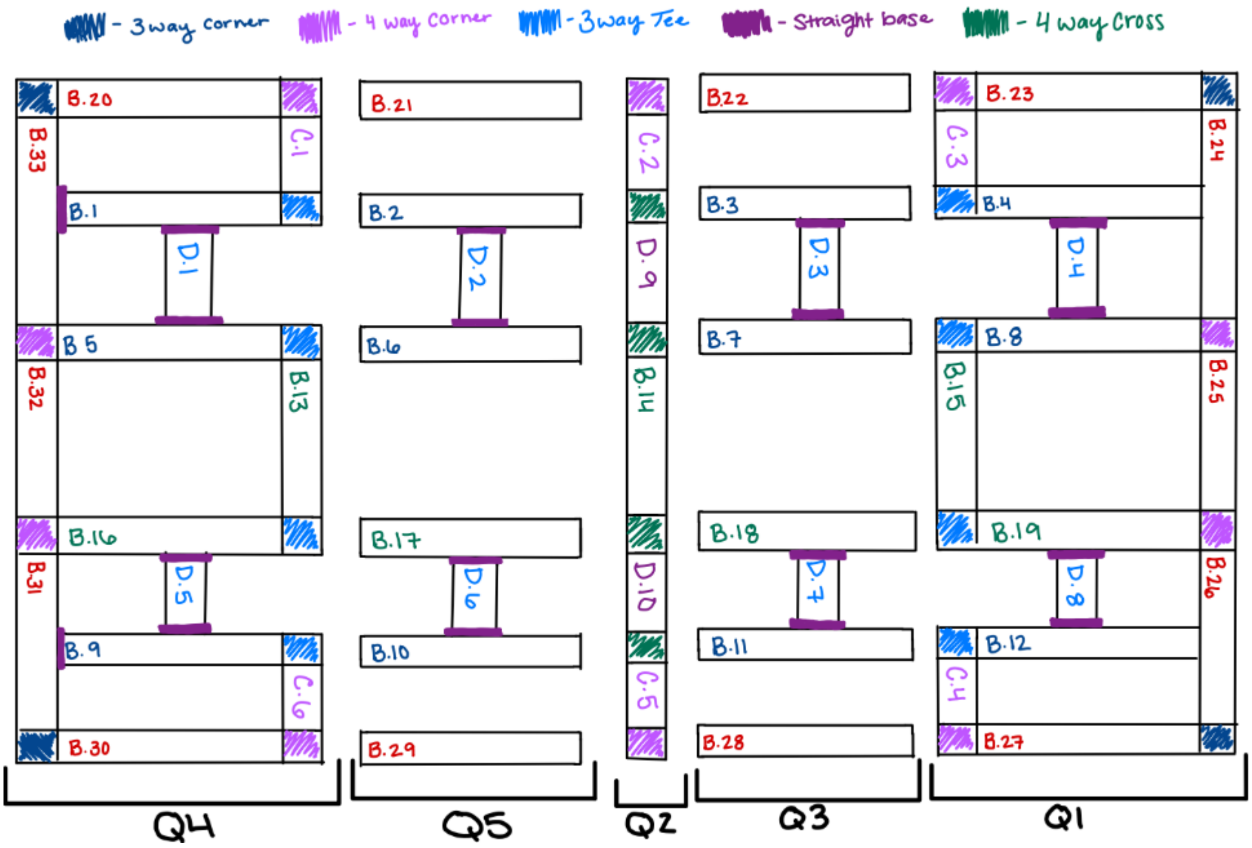


Figure 33: Ceiling Quadrants

5. Assemble all ceiling polycarbonate sheets using the required nuts and hex bolts outlined in the assembly.
6. Assemble all wall polycarbonate sheets using the required nuts and bolts outlined in the assembly.
7. Install vinyl sheets for doorway.
8. Install FFUs on ceiling. Plug in all electrical cords.

8.2.5.3 Results

The modularity results are shown in **Table 26**. The total assembly time was 7.25 hours and the disassembly time was 10.75 hours.

Table 26: Modularity Testing Results

Assembly Part	**# People Required**	**Assembly Time (Hrs)**	**Disassembly Time (Hrs)**
Perimeter	1	0.5	1.0
18ft Wall 1	2	0.5	1.0
18ft Wall 2	2	0.5	1.0

12ft Wall 1	2	0.25	0.5
12ft Wall 2	2	0.25	0.5
Ceiling Quadrants	3	1.5	3.0
Polycarbonate Ceiling	3	1.0	1.0
Polycarbonate Walls	2	1.5	1.5
Vinyl Door	1	0.25	0.25
FFUs	4	1.0	1.0
Total Assembly Time:		**7.25**	**10.75**

9 Future Work

For future potential works on the project, if given additional time or budget the cleanroom could prioritize several enhancements. First, non-vinyl doors with hinges or better mechanisms for improved functionality and durability could be installed. Additionally, the implementation of backup power systems to mitigate the impact of power outages could be incorporated. Lastly, conducting surface contamination tests post-certification process would enhance quality control measures. If the project could be completed from the beginning of the design process again, the design team would opt for aluminum t-slots instead of aluminum tubing to enhance modularity in the cleanroom design. Integrating support design earlier in the process would also have streamlined construction better and ensured structural integrity of the cleanroom of such substantial size. Lastly, dividing the cleanroom and gowning room manufacturing process into different steps would have optimized efficiency and quality compared to the initial approach.

10 CONCLUSIONS

The objective of the design project was to create a 12’ x 16’ ISO Class 7 cleanroom to be used for the manufacturing of medical devices. This was achieved by constructing a 1.5” square aluminum tubing frame structure with 1/16” polycarbonate walls and ceilings. 4 FFUs create filtered positive pressure airflow to maintain a zero-microgram particle count and a stable airflow for manufacturing. The cleanroom was specifically designed to be transportable and modular. It can be disassembled in 10.75 hours, separated into sections of any desirable size for easy relocation, and reassembled in 7.25 hours.

Several engineering techniques were utilized to narrow down the cleanroom design. Mathematical modeling and prototyping were completed to determining the appropriate structural supports, FFU placement, nut/bolt requirements, polycarbonate sheet thickness, frame/connector materials, and FFU speed. Thorough post-manufacturing testing was completed to confirm the structural integrity, modularity, and ISO Class 7 compliance of the cleanroom. All testing confirmed the cleanroom met the standards required for an ISO Class 7 cleanroom, while maintaining a safe working environment, integrating modularity, and introducing transportability. Looking forward to the future of modular controlled environments, the design team is proud to set a new standard in innovation.

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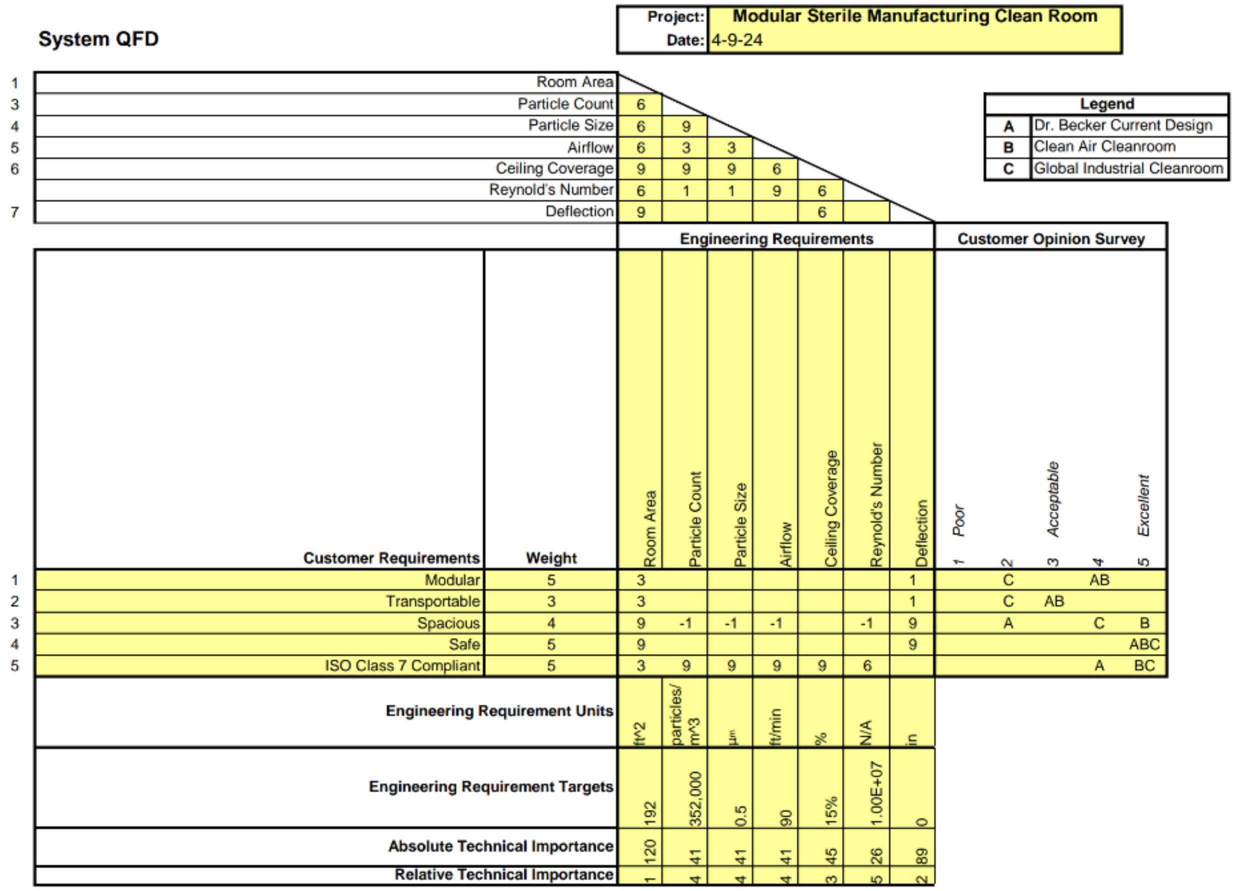
12 APPENDICES

12.1 Appendix A: QFD



System QFD

Project: **Modular Sterile Manufacturing Clean Room**
Date: 4-9-24

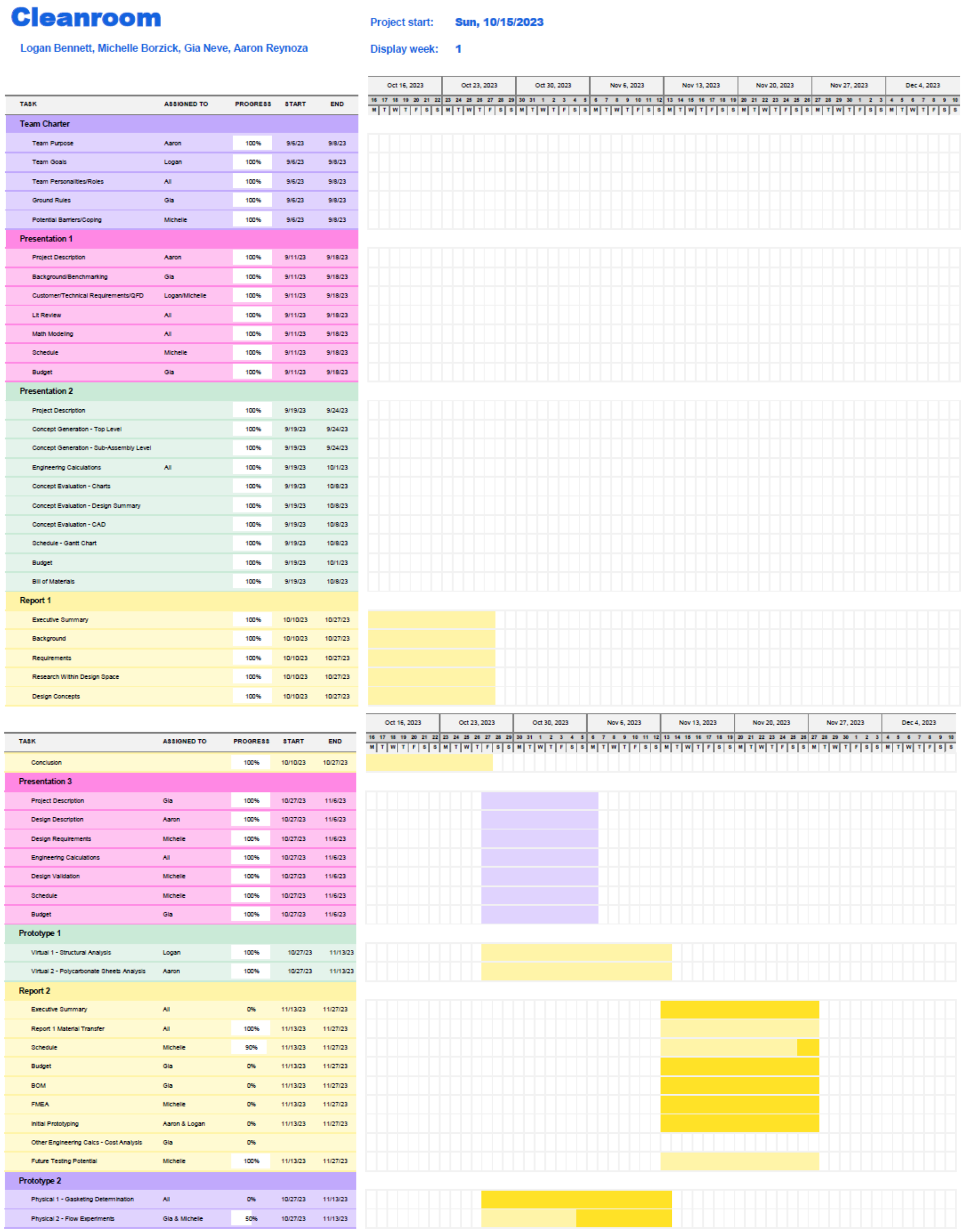
Legend	
A	Dr. Becker Current Design
B	Clean Air Cleanroom
C	Global Industrial Cleanroom

		Room Area	Particle Count	Particle Size	Airflow	Ceiling Coverage	Reynold's Number
1	Room Area						
3	Particle Count	6					
4	Particle Size	6	9				
5	Airflow	6	3	3			
6	Ceiling Coverage	9	9	9	6		
	Reynold's Number	6	1	1	9	6	
7	Deflection	9				6	

			Engineering Requirements							**Customer Opinion Survey**				
	Customer Requirements	**Weight**	Room Area	Particle Count	Particle Size	Airflow	Ceiling Coverage	Reynold's Number	Deflection	1 *Poor*	2	3 *Acceptable*	4	5 *Excellent*
1	Modular	5	3						1		C		AB	
2	Transportable	3	3						1		C	AB		
3	Spacious	4	9	-1	-1	-1		-1	9		A		C	B
4	Safe	5	9						9					ABC
5	ISO Class 7 Compliant	5	3	9	9	9	9	6					A	BC
	Engineering Requirement Units		ft^2	particles/ m^3	µm	ft/min	%	N/A	in					
	Engineering Requirement Targets		192	352,000	0.5	90	15%	1.00E+07	0					
	Absolute Technical Importance		120	41	41	41	45	26	89					
	Relative Technical Importance		1	4	4	4	3	5	2					

Figure A-1: QFD

12.2 *Appendix B1: Fall 2023 Gantt Chart*



Cleanroom

Logan Bennett, Michelle Borzick, Gia Neve, Aaron Reynoza

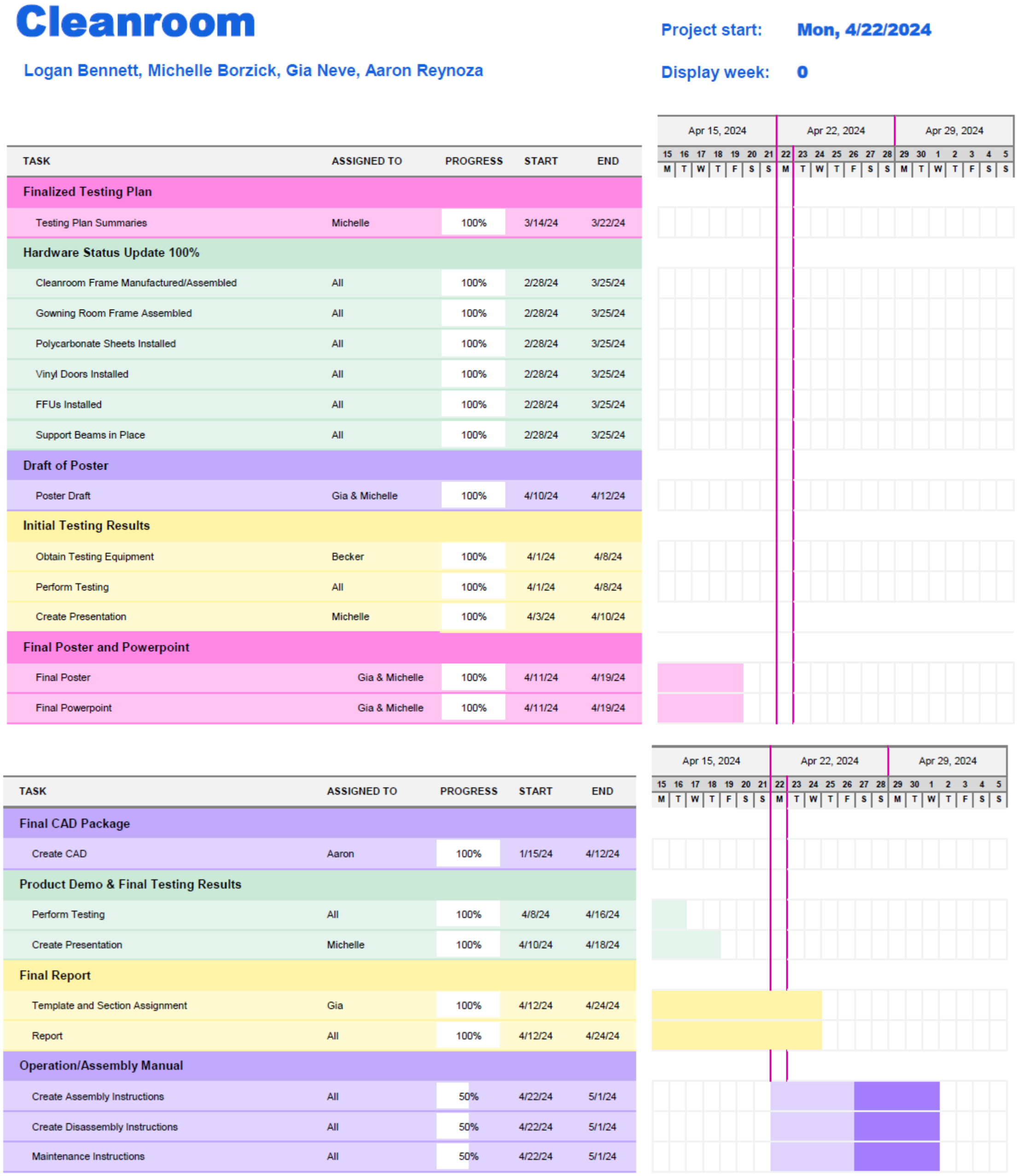
Project start: **Sun, 10/15/2023**

Display week: **1**

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
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 B1-1: Fall 2023 Gantt Chart

12.3 *Appendix B2: Spring 2024 Gantt Chart*



Cleanroom

Logan Bennett, Michelle Borzick, Gia Neve, Aaron Reynoza

Project start: Mon, 4/22/2024

Display week: 0

TASK	ASSIGNED TO	PROGRESS	START	END
Finalized Testing Plan				
Testing Plan Summaries	Michelle	100%	3/14/24	3/22/24
Hardware Status Update 100%				
Cleanroom Frame Manufactured/Assembled	All	100%	2/28/24	3/25/24
Gowning Room Frame Assembled	All	100%	2/28/24	3/25/24
Polycarbonate Sheets Installed	All	100%	2/28/24	3/25/24
Vinyl Doors Installed	All	100%	2/28/24	3/25/24
FFUs Installed	All	100%	2/28/24	3/25/24
Support Beams in Place	All	100%	2/28/24	3/25/24
Draft of Poster				
Poster Draft	Gia & Michelle	100%	4/10/24	4/12/24
Initial Testing Results				
Obtain Testing Equipment	Becker	100%	4/1/24	4/8/24
Perform Testing	All	100%	4/1/24	4/8/24
Create Presentation	Michelle	100%	4/3/24	4/10/24
Final Poster and Powerpoint				
Final Poster	Gia & Michelle	100%	4/11/24	4/19/24
Final Powerpoint	Gia & Michelle	100%	4/11/24	4/19/24

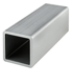
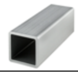
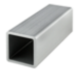
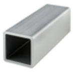
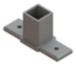
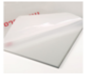
TASK	ASSIGNED TO	PROGRESS	START	END
Final CAD Package				
Create CAD	Aaron	100%	1/15/24	4/12/24
Product Demo & Final Testing Results				
Perform Testing	All	100%	4/8/24	4/16/24
Create Presentation	Michelle	100%	4/10/24	4/18/24
Final Report				
Template and Section Assignment	Gia	100%	4/12/24	4/24/24
Report	All	100%	4/12/24	4/24/24
Operation/Assembly Manual				
Create Assembly Instructions	All	50%	4/22/24	5/1/24
Create Disassembly Instructions	All	50%	4/22/24	5/1/24
Maintenance Instructions	All	50%	4/22/24	5/1/24

Figure B2-1: Spring 2024 Gantt Chart

12.4 Appendix C1: Purchasing BOM

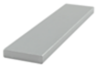
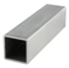
Table C1-1: Purchasing Bill of Materials, page 1

Purchasing BOM

Part #	Part Name	Qty	Description	Image	Material	Vender	Vender PO #	Lead Time	Cost per Unit ($)	Total Cost ($)	Total Cost with Tax & Shipping
1	Ready Tube	47	46"		Aluminum	80/20	9700	Unknown	$25.33	$1,190.51	$1,513.33
2	Ready Tube	14	87"		Aluminum	80/20	9700	Unknown	$45.42	$635.88	$853.85
3	Ready Tube	6	22.5"		Aluminum	80/20	9700	Unknown	$13.82	$82.92	$121.49
4	Ready Tube	10	22"		Aluminum	80/20	9700	Unknown	$13.57	$135.70	$188.20
5	4-way Corner Connector	12	1.5" Connectors for frames		Nylon	Esto Connectors	545150	Unknown	$9.98	$59.88	$161.83
6	3-way Corner Connector	8	1.5" Connectors for frames		Nylon	Esto Connectors	533150	Unknown	$8.93	$71.44	$85.11
7	3-way Tee Connector	18	1.5" Connectors for frames		Nylon	Esto Connectors	532150	Unknown	$8.93	$160.74	$189.76
8	4-way Cross Connector	4	1.5" Connectors for frames		Nylon	Esto Connectors	544150	Unknown	$16.73	$66.92	$80.59
9	Straight Base Connector	22	1.5" Connectors for frames		Nylon	Esto Connectors	5323150	Unknown	$6.65	$133.00	$175.38
10	Clear Polycarbonate Sheet	31	1/16" X 48" X 96" Wall Matertial		Polycarbonate	Eplastics	Unknown	Unknown		$2,500.00	$2,515.13
11	Clear Polycarbonate Sheet	1	1/8" X 48" X 96" Wall Matertial		Polycarbonate	Eplastics	PCCLR0.125AM48X96	Unknown	$389.53	$389.53	$389.53
12	Clear Polycarbonate Sheet	1	1/16" X 48" X 96" Wall Matertial		Polycarbonate	Eplastics	PCCLR0.060AM48X96	Unknown	$343.17	$343.17	$343.17

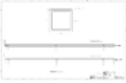
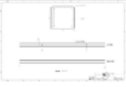
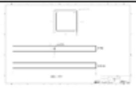
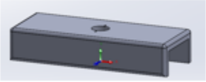
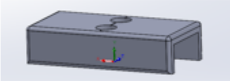
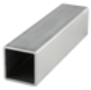
12.5 *Appendix C1: Purchasing BOM Cont.*

Table C1-2: Purchasing Bill of Materials, page 2.

13	Fan Filter Unit ; WhisperFlov	4	2'x4', HEPA, 120 V		Powder-Coated Steel	Terra Universal	6601-24-H	1-3 business days	$1,152.00	$4,148.00	$5,360.37
14	Power Cord for Filter Unit	4	300V, 10A,MIN4 PL to 16AWG		Unknown	Terra Universal	6601-13	1-3 business days	$64.00	$256.00	
15	Steel Flanged Hex Head Screws	300	Zinc-Plated Grade 5, Medium-Strength, 1/4"-20 Thread Size, 2" Long		Steel	McMaster Carr	92979A138	1-2 business days	$9.52	$114.24	$114.24
16	Medium-Strength Steel Hex Nut	300	Grade 5, Zinc-Plated, 1/4"-20 Thread Size		Steel	McMaster Carr	95462A029	1-2 business days	$8.95	$26.85	$26.85
17	Wood Beam	12	2x4x2"		Wood	Home Depot	N/A	N/A	N/A	Donated	$0.00
18	80/20 T-Slot Extrusions	4	2x 11.5ft & 2x 6ft		Aluminum	Ryans Garage	N/A	N/A	N/A	Donated	$0.00
19	80/20 aluminum Panels	4	1.5" x 84"		Aluminum	80/20	2635	1 week	N/A	$178.77	$178.77
20	Aluminum Square tubing	2	2x 8ft		ALuminum	Machine shop	N/A	N/A	N/A	$108.71	$108.71
21	Bolts	85	40 x 2.5", 20 x 1" , 25 2"		steel	Home Depot	812210 865658 2420	N/A	N/A	N/A	$34.07
22	Nuts	55	1/4" x 20		steel	Home Depot	801826	N/A	N/A	N/A	
23	WeatherWhite Premium Rubber Window Seal	2	5/16 in. x 19/32 in. x 10 ft.		Rubber	Home depot	43374636697	N/A	$10.93	$21.86	$24.07
24	Support Beam Base	2	2 tops, 2 bottoms		PVC pipe couplings	Home Co	4689864	N/A	$40.92	$81.84	$81.84
25	prototype 1	1	wooden beams,duct tape, 4 gasket materials		wood, rubber	home depot	N/A	N/A	N/A	N/A	$100.13
Total Cost											$12,646.42

12.6 *Appendix C2: Manufacturing BOM*

Table C2-1: Manufacturing Bill of Materials

Manufacturing BOM								
Part #	Part Name	Qty	Description	Image Location	Material	Manufacturer	Lead Time (hrs)	Manufacturing Location
A.1 - A.10	87" Variant 1	10	Top: 2 holes at 2", 40.4", 78.8"		Aluminum	Team	8	NAU Machine Shop
A.11 - A.14	87" Variant 2	4	Top: 1 hole at 2", 40.4", 78.8", Front: 1 hole at 2.5", 40.9", 78.3"		Aluminum	Team	3.2	NAU Machine Shop
B.1 - B.12	46" Variant 1	12	Top: 1 hole at 12", 36"		Aluminum	Team	2.4	NAU Machine Shop
B.13 - B.19	46" Variant 2	7	Top: 2 holes at 12", 36"		Aluminum	Team	2.8	NAU Machine Shop
B.20 - B.33	46" Variant 3	14	Top: 1 hole at 12", 36", Front: 1 hole at 5", 17", 29", 41"		Aluminum	Team	8.4	NAU Machine Shop
C.1 - C.6	22.5" Variant 1	6	Top: 2 holes at 11"		Aluminum	Team	1.2	NAU Machine Shop
D.1 - D.8	22" Variant 1	8	Bottom: 1 hole at 11"		Aluminum	Team	0.2	NAU Machine Shop
D.9 - D.10	22" Variant 2	2	Top: 2 holes at 11"		Aluminum	Team	0.4	NAU Machine Shop
F	16" X 48" X 96" Clear Polycarbonate Sheets	31	Hole placement, Bottom wall removal		Polycarbonate	Team	30	Dr. Becker's Lab
G	Steel Beams	33	Hole placement TBD		Powder Coated Steel	Team	9	Dr. Becker's Lab
H	Drill Template Beam	4	Beams to hold hole guides		Wood	Team	0.5	Dr. Becker's Lab
I	Hole Guides Single	2	3D printed holes guides for drill press		3D Printed Filament	Team	12	Michelle's House
J	Hole Guides Double	2	3D printed holes guides for drill press		3D Printed Filament	Team	12	Michelle's House
K	Cut 1"x1" AL beams to size	2	Cutiing to size		Aluminum	Gia&Logan	0.5	Machine Shop
L	Cut 80/20 Extrusions	2	Cutiing to 87"		Aluminum	Gia&Logan	0.5	Machine Shop

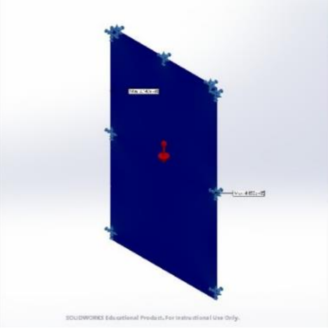
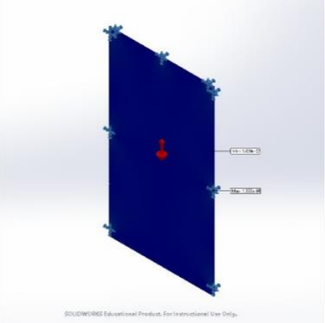
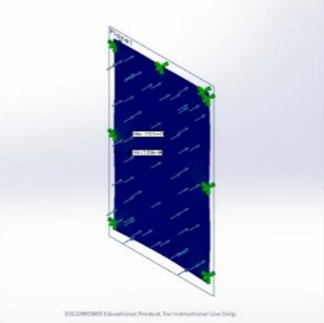
12.7 *Appendix D: FMEA*

Table D-1: 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
	Fan turns off	Increased particle count	5	Power outage	3	Backup battery	1	15	Maintenance or replace battery
		Loss of positive pressure	8	Inadequate power supply	1	Backup battery		8	Maintenance or replace battery
		Decreased airflow	8	Fan motor burnout	1	Regularly scheduled maintanence		8	Replace fan filter unit
		Loss of ISO Class 7 Certification	8					8	
Cleanroom Frame: provides structural support for walls and fan filter units	Aluminum beam cracks or breaks in walls	Pressure leak	5	Inadequate maintanence	1	Regularly scheduled maintanence	2	10	Repair (if possible) or replace aluminum beams
		Increased particle count	5	Increased load	2	Weight specification documentation		20	Remove additional load, repair/replace aluminum beams
		Decreased wall structural integrity	6	Damage during assembly, disassembly, or transport	3	Inspection prior to assembly	1	18	Repair (if possible) or replace aluminum beams
						Regularly scheduled maintanence			
						SOPs for assembly and disassmbly			
						Training to SOPs			
	Aluminum beam cracks or breaks in ceiling	Fan falls	8	Inadequate maintanence	1	Regularly scheduled maintanence	1	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	Damage during assembly, disassembly, or transport	3	Inspection prior to assembly		24	Repair (if possible) or replace aluminum beams
		Decreased airflow	8			Regularly scheduled maintanence		24	
		Loss of ISO Class 7 Certification	8			SOPs for assembly and disassmbly		24	
						Training to SOPs		24	
	Loose screw	Pressure leak	5	Incorrect assembly	1	SOPs for assembly and disassmbly	4	20	Tighten screw
						Training to SOPs		20	
				Natural loosening over time	1	Regularly scheduled maintanence		20	
				Inadequate maintanence	1	Regularly scheduled maintanence		20	
	Screw falls out	Pressure leak	5	Incorrect assembly	1	SOPs for assembly and disassmbly	3	15	Tighten or replace screw
						Training to SOPs		15	
		Decreased wall structural integrity	6	Natural loosening over time	1	Regularly scheduled maintanence		18	
				Inadequate maintanence	1	Regularly scheduled maintanence		18	
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

12.8 *Appendix E: Virtual Prototype 1 Polycarbonate Sheets*

Table E-1: Results from Gravity Test and Max Pressure Test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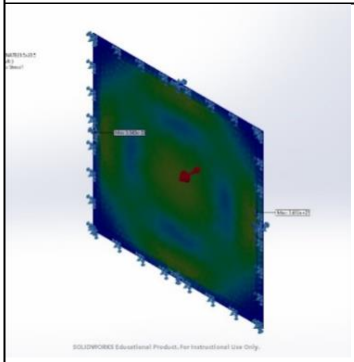
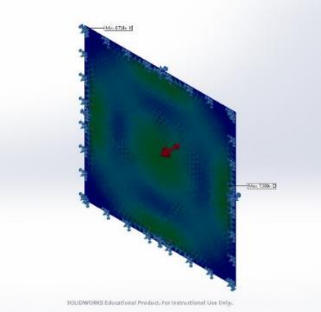
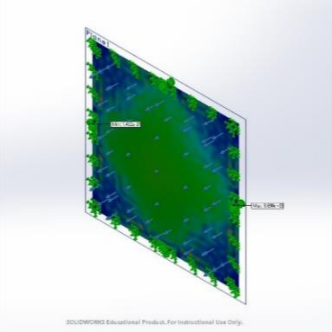
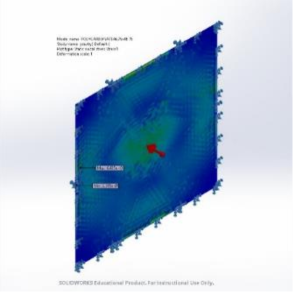
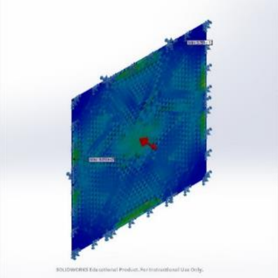
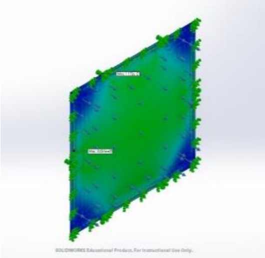
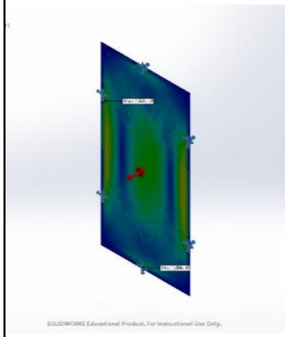
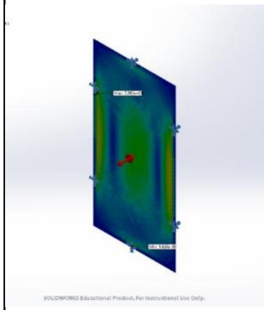
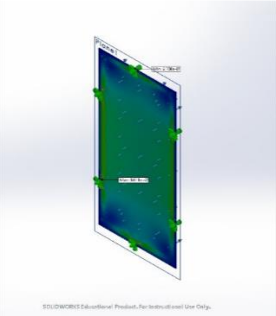
		
23.5x23.5 Max Stress	23.5x23.5 Max Strain	23.5x23.5 Max Pressure
		
46.75x46.75 Max Stress	46.75x46.75 Max Strain	46.75x46.75 Max Pressure
		
24x47.5 Max Stress	24x47.5 Max Strain	24x47.5 Max Pressure