Engineering Calculations Summary

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Top Level Design Summary

For this year’s capstone, the engineering team must create a 12’x16’ ISO Class 7 Cleanroom with four Filter Fan Units (FFU) and convert the current 6’x8’ cleanroom into a gowning room. The solution to this problem is to build a cleanroom with 1.5’x1.5’ Aluminum square tubing, Telescoping Nylon Connectors, and 1/16’ polycarbonate walls, while using the extra materials to convert the current cleanroom into a gowning room. The engineering team was successful in creating the final design shown in **Figure 1** while adhering to the client's request.

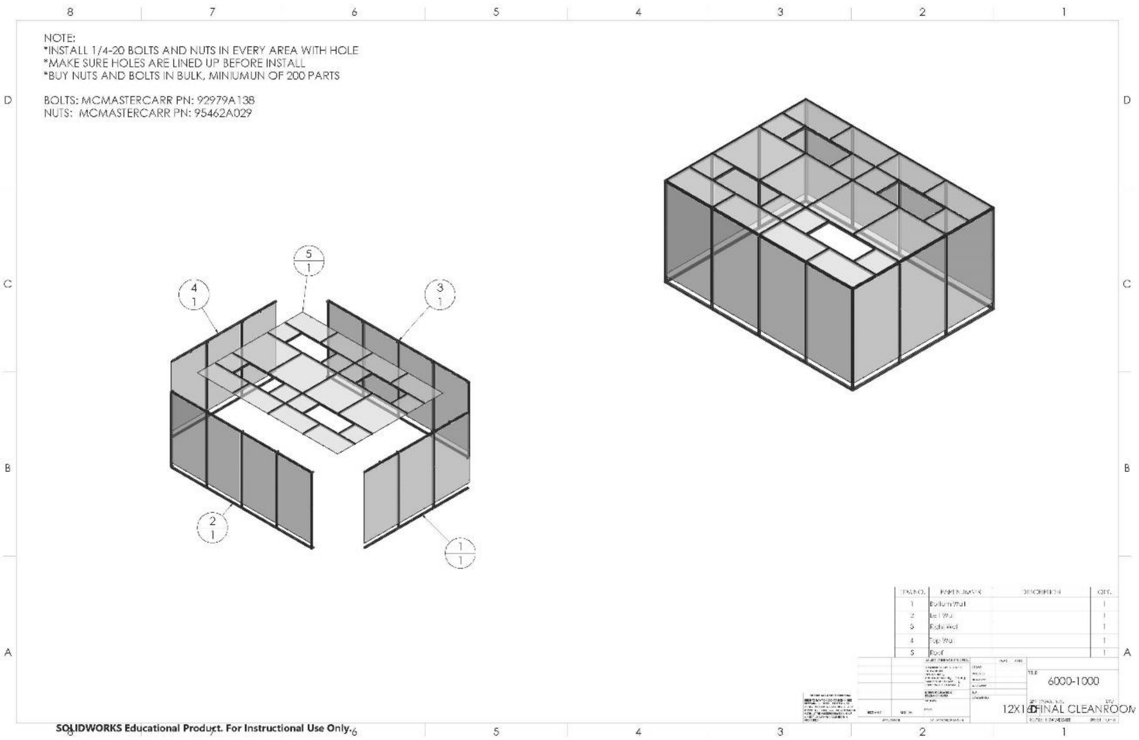

Figure 1: Final Design of Cleanroom with Labeled Sub-Systems

The cleanroom will be made up of 5 sub-systems, each made up of multiple components, including the 1.5x1.5’ Aluminum square tubing, Telescoping Nylon Connectors, 1/16’ thick polycarbonate walls, ¼-20 nuts and bolts with a built-in washer. The names of the 5 sub-systems are: Top Wall, Bottom Wall, Left Wall, Right Wall, and Roof. It is important to have these sub-systems in place so the engineering team can identify which part goes to which sub-systems, while having a visual representation on how the cleanroom will be assembled. The following will have information about each sub-system, including the uses and **Table 1** with materials.

Table 1: Sub-System Materials and Item Count

Top Wall	Bottom Wall	Left Wall	Right Wall	Roof
3x 46in Square Tube 2x 87in Square Tube 2x 22.5in Square Tube 2x 22in Square Tube 3x 47.5x82.5x0.0625 in Poly Walls 6x nylon connector 24x 1/4x20 2in Bolts 24x 1/4x20 Nuts	3x 46in Square Tube 2x 87in Square Tube 2x 22.5in Square Tube 2x 22in Square Tube 3x 47.5x82.5x0.0625 in Poly Walls 6x nylon connector 24x 1/4x20 2in Bolts 24x 1/4x20 Nuts	8x 46in Square Tube 5x 87in Square Tube 10x nylon connectors 4x 47.5x82.5x0.0625 in Poly Walls	8x 46in Square Tube 5x 87in Square Tube 10x nylon connectors 4x 47.5x82.5x0.0625 in Poly Walls	3x 46in Square Tube 22x 22.5in Square Tube 24x 22in Square Tube 4x 24x47.5x0.0625in Poly Walls 4x 47.5x47.5x0.0625 in Poly Walls 8x 24x47.5x0.0625in Poly Walls 4x 23.5x23.5x0.0625 in Poly Walls

Top Wall: Will hold the North Side of the Cleanroom, can be removed to extend the cleanroom

Bottom Wall: Will hold the South Side of the Cleanroom, can be removed to extend the cleanroom

Left Wall: Will hold the West Side of the Cleanroom, can be removed to extend the cleanroom. Recommended wall side to create an entrance.

Right Wall: Will hold the East Side of the Cleanroom, can be removed to extend the cleanroom. Recommended wall side to create an entrance.

Roof: Located on top of the cleanroom, the Roof Subsystem will enclose the frame while holding up the Filter Fan Unit.

Customer Requirements (CRs)

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

Engineering Requirements (ERs)

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

- Positive pressure: The positive pressure difference between the inside and outside of the cleanroom must be a minimum of 0.2 Pa [1]. This value represents a lower limit as pressure in the cleanroom can be greater than 0.2Pa and still maintain particle count. The main constraint to the overall pressure difference is that it must be maintained with people moving in and out of the cleanroom.

- Particle count and size: Particle count and particle size must meet the ISO Class 7 requirements of a maximum of 352,000 particles of size greater than 0.5, 83,200 particles of size greater than 1, and 2,930 particles of size greater than 5 [2]. 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 [3]. Airflow like positive pressure, particle count, and size will be measured as a minimum limit with the strictest requirement of 10 ft/s and 60 air changes per hour. The airflow rate is constrained by the speed of the FFUs.

- Ceiling coverage: Ceiling coverage must be 15-20% covered with FFUs [2]. This design will aim to meet the minimum limit of 15% ceiling coverage. The biggest constraint on ceiling coverage is the structural supports of the ceiling frame. The frame 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 [4].

- Power: An initial power requirement estimate for all FFUs is 7200W. A full electrical load analysis will be performed on the cleanroom model in upcoming engineering analyses. Power will be assessed as a limit as well. The constraints to the cleanroom's power requirements include the capability and cost of the backup battery units.

House of Quality (QFD)

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

Summary of Standards, Codes, and Regulations

The aluminum beams used in the cleanroom are 6005A-T61. They follow the standards ASTM B221, ASTM B241, and ASTM B429 [10]. ASTM B221 is the "Standard Specification for Aluminum and Aluminum-Alloy Extruded Bars, Rods, Wire, Profiles, and Tubes" that describes tensile properties, elongation, yield strengths, etc. requirements for aluminum [14]. ASTM B241 is the "Standard Specification for Aluminum and Aluminum-Alloy Seamless Pipe and Seamless Extruded Tube" that describes the required extrusion process for the aluminum [15]. ASTM B429 is the "Standard Specification for Aluminum-Alloy Extruded Structural Pipe and Tube" that describes the approved methods for extruding, square-cutting, and milling aluminum alloy pipes [16].

The bolts used in the cleanroom design are zinc-plated grade 5 flanged hex head medium-strength 1/4"-20 thread. They follow two standards: IFI 111 and. IFI 111 is the "Industrial Fasteners Institute Dimensions of Hex Flange Screws" that gives specifications on basic major diameter of the threads along with thickness, height, radius, and thickness specifications [11]. SAE J429 is the "Mechanical and Quality Requirements for Externally Threaded Fasteners" [13].

The nuts used in the cleanroom design are medium strength steel hex nuts grade 5 zinc plated 1/4"-20 thread. They follow ASME B18.2.2 "Nuts for General Applications: Machine Screw Nuts, Hex, Square, Hex Flange, and Coupling Nuts (Inch Series)". This standard has specifications for location at true position with respect to the axis of the nut body with distance tolerances [9].

The cleanroom FFUs performance were tested with the ANSI/AMCA 210-07 and ANSI/ASHAE 51-07 test standards for Certified Aerodynamic Performance Rating [7]. ANSI/AMCA 210-07 and ANSI/ASHAE 51-07 is the "Laboratory Methods of Testing Fans for Certified Aerodynamics" which describes how to test a fan for airflow rate, pressure developed, power consumption, air density, speed of rotation, and efficiency [8].

The standards for the overall cleanroom design are the ISO requirements for a Class 7 cleanroom. The ISO Class 7 requirements are summarized above in the engineering requirements section of the report. All ISO Class 7 requirements were considered in the engineering requirements. The International Standard ISO also provides instructions for collecting and testing air samples in ISO 14644. The team will use these standards to design the testing plan for the built cleanroom.

The completed cleanroom will be designed to manufacture sterile biological products that will be sold in the United States and will thus be required to follow the current good manufacturing practices (cGMP) outlined by the Food and Drug Administration (FDA). The cGMP regulations that will apply to the cleanroom are provided in the Code of Federal Regulation (CFR), specifically 21 CFR 210-211 and 21 CFR 600-680 [5]. The team will use these regulations to design the monitoring systems, air filtration system, and sanitizing practices [6]. The FFUs will function as both the monitoring system for air pressure and the air filtration system for dust/microorganisms. The other FDA requirements are humidity and temperature monitoring which will be done by the in-room air conditioning system. Lastly, the sanitizing practices will be included in the team's operational manual for the cleanroom.

Summary of Equations and Solutions

Load Cases

The main point of failure of the frame is the ceiling beams which need to hold the weight of four 50lb FFUs, as the columns are stressed in the direction, they are strongest in based on geometry. For this reason, extra attention is paid to the bending stresses in the ceiling beams. The main method of correcting for any weak points found through the calculations is to change the material or geometry of the frame sections.

The main point of failure of this system will be the walls of the cleaning room. The reasoning behind this is that the walls are only supported by the Nuts and bolts of the frame and nothing else. This can either cause the wall or the hardware to yield. The Maximum weight that the polycarbonate wall can endure is 10lbs. To ensure that the walls are not heavy for the frames and hardware, The software SolidWorks Simulation Toolbox was used to simulate this scenario. This was done by first adding the mechanical properties of the polycarbonate walls, then adding the bolts as constraints while applying a gravitational force. This setup will simulate hanging the polycarbonate walls onto the frame. By doing this analysis, it will help us identify the number of bolts which goes with the customer requirement of being easily assembled. It will also give Stress, Strain, and deflection values which will help the engineering team determine if it will yield.

The worst-case scenario load case for particle count would be that the particle count exceeds 352,000 particles of size greater than $0.5\mu m$, 83,200 particles of size greater than 1 μm, and 2,930 particles of size greater than 5 μm [2]. The particle count would be exceeded during normal operation if there were not enough FFUs, the FFU filters were not replaced, and/or one or more FFUs lost power. The number of FFUs was calculated using simple ceiling area ratios. The FFU ceiling coverage to cleanroom area needs to be between 15% and 20% [2]. Filter maintenance will be included in the cleanroom operation's manual. Power will be evaluated in a separate engineering calculation.

The load cases for airflow would be that the air velocity and air changes per hour are too low to maintain positive pressure and air filtration. The air velocity must be at least 0.051-0.076 m/s or 10-15 ft/s for the entire room and there must be at least 60 – 90 air changes per hour [3] throughout the cleanroom. The air velocity and air changes per hour are dependent of three design factors: the number of fans, location of the fans in the ceiling structure, and gap between the bottom of the polycarbonate walls and the floor.

The load case for the back-up batteries is that either the voltage rating of the batteries is insufficient for the FFUs, or that the Amp-hour rating of the batteries does not provide back-up power for a long enough time to protect the cleanroom from regular power outages. The total load on the back up battery is 2280 W, when the FFUs are on the medium setting, this load is used to calculate the minimum rating required by the back-up batteries. Either of these failures could result in the cleanroom losing its ISO 7 certification and would require recertification.

The load case for the team's budget would be that all purchasing, manufacturing, and prototypes would exceed the original $10,000 budget with the $2,000 fundraising from our sponsors Gore Medical and The NAU Bioengineering Club. The budget would only be exceeded if there were unexpected errors in any of the structural analyses the team has done, or the client changes/adds any unexpected deliverables.

Frame Equations and Solutions

The initial analysis of the beams and columns making up the frame were done to determine if the designed ceiling configuration could support the weight of the four FFUs. Equations **(1) – (3)** show the maximum stress, strain, and factor of safety for the load applied to the beams.

$$\sigma = \frac{Mc}{I} \tag{1}$$

$$\sigma = \frac{F}{A} \tag{2}$$

$$f_s = \frac{\sigma}{S_y} \tag{3}$$

From these calculations the factor of safety in the normal load case of four 50lb FFUs loaded centrally in each quadrant of the cleanroom's roof is found to be 2.5. These rudimentary calculations informed the decision to use 1.5 in square aluminum tubing for the frame.

Once the frame material was chosen a more comprehensive analysis of the ceiling was done using an Ansys simulation to find the maximum stress and strain in the design with the same load case, these were 3.57kpsi in an aluminum beam, and .00657in/in in a nylon composite connector as shown in **Figures 2 and 3**. A "real geometry" analysis was done on a small section of the ceiling to confirm the simplified geometry was accurate and showed that the real geometry experienced even less stress and strain. This informed the decision not to use support columns in the center of the room, as the simulation showed they were not necessary, and the client requested we only use central support columns if it was unavoidable.

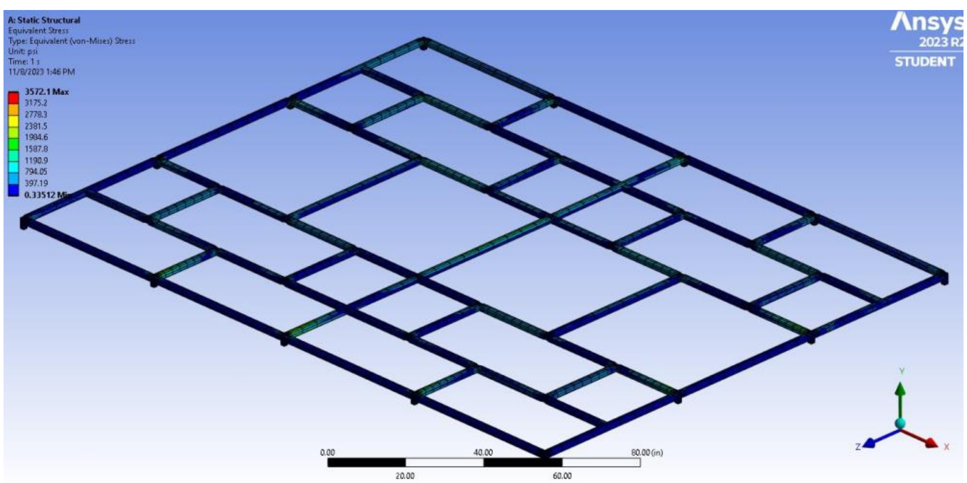

Figure 2: Ansys simulation of the cleanroom ceiling with stress in psi

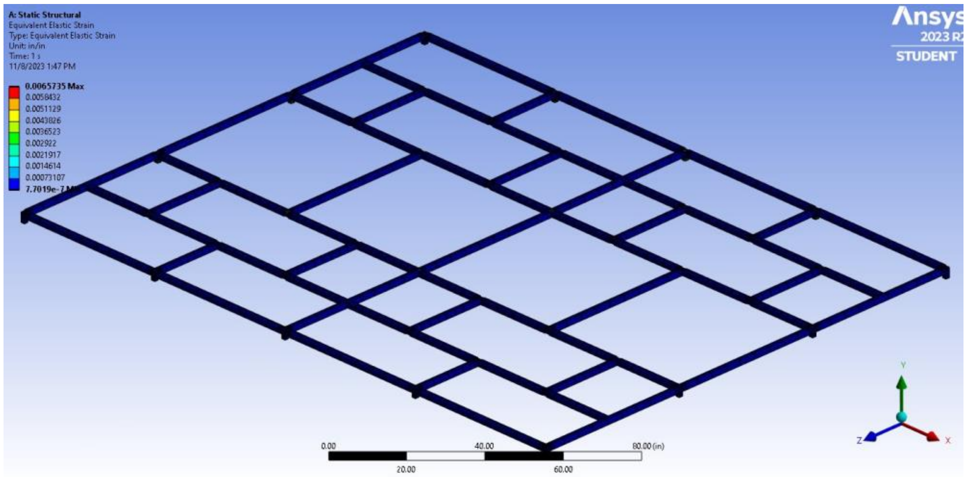

Figure 3: Ansys simulation of the cleanroom ceiling with strain in in/in

Polycarbonate Walls Equations and Solutions

Next, the polycarbonate walls were examined to determine if the aluminum frames could support the polycarbonate and how many bolts/nuts would be required to hold up the walls. In the SolidWorks Simulation Tool, the polycarbonate wall dimensions that the cleanroom will be using are 47.5’x88.5’x.0625’ with a Modular of Elasticity of 60MPa. The clearance hole for the polycarbonate wall will have fixed constraints to simulate the bolts holding the material. To simulate gravity, a force value of 9.81 m/s^2 will be applied to the polycarbonate walls to simulate the material hanging from the wall. The labeled constraints and force location are shown in **Figure 4**. With all the variables labeled, SolidWorks can now calculate the stress, strain, and deflection that the polycarbonate wall will endure. Photos of the results can be seen in **Appendix B**.

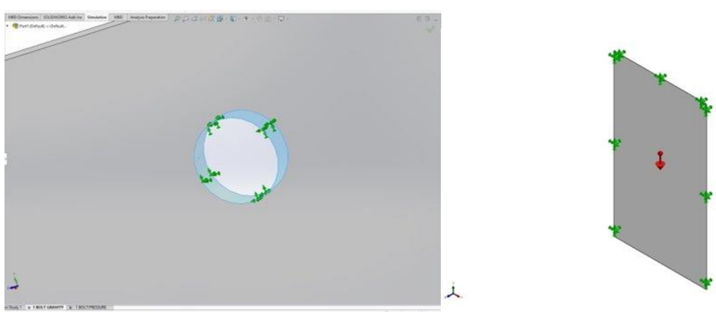

Figure 4: Constraints and Force Location in SolidWorks Simulation

By running the SolidWorks Simulation Tool, The Stress, Strain, and deflection is now determined. The polycarbonate walls are experiencing 0.485MPa of Stress, 1.399*10^-4 Strain, and 5.468 µm. Compared to the Modular of Elasticity, the Polycarbonate Wall will not shear, therefore the walls will not be too heavy for the screws and the frame.

Fan Filter Unit Equations and Solutions

The particle count is maintained by the FFU standards that were described above. Based on those standards, the FFUs are certified to cover a certain room area based on the fan to room area ratio. Therefore, the only calculation needed to determine the minimum number of fans was the percentage of ceiling coverage shown in **(4).** 4 FFUs is the minimum number of fans that meets the percentage requirements of 15-20% coverage. Any number of FFUs over 4 would meet beyond the ISO Class 7 requirements and potentially qualify a lower-class cleanroom. Therefore, keeping budget in mind, the team chose to use 4 FFUs. The placement of the fans on the ceiling was determined in a separate analysis.

$$Ceiling\ Coverage = \frac{Area\ FFUs}{Area\ Cleanroom\ Ceiling} \quad \textbf{(4)}$$

$$3\ FFUs: \frac{3(2X4)}{12x16} = 12.5\%$$

$$4\ FFUs: \frac{4(2X4)}{12x16} = 16.67\%$$

The airflow velocity, room air changes per hour, and general turbulence were determined for multiple configurations of FFU locations, FFU speeds, and wall gap heights. First the FFU locations were determined on a quarter scale version of the 12’x16’ cleanroom. The fans were placed at two different locations and compared in a Computational Fluid Dynamics (CFD) analysis using the input velocities for the FFUs based on the FFU specifications shown in **Figure 5**.

WHISPERFLOW® FFU PERFORMANCE DATA					
Nominal Unit Size (ft.)	Filter	Sound (dB) @90FPM	AIR FLOW (CFM)		
			HIGH	MED	LOW
2' x 4'	HEPA	49	800	720	590

Figure 5: FFU Performance Specifications [8]

Two FFU locations were tested, one with the FFUs centered and one with the FFUs in opposite corners. This simulation was mainly done to examine turbulence differences with the different configurations. The two configurations are shown in **Figures 6 and 7**. The cornered configuration showed an increase in turbulence/air mixing compared to the centered configuration.

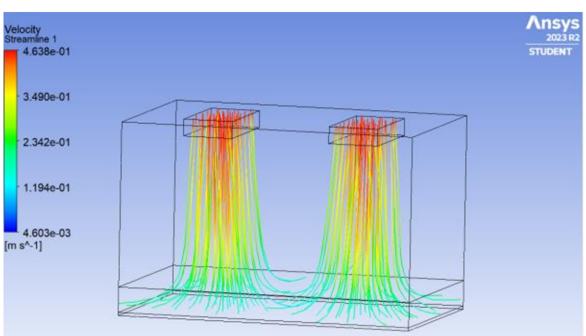

Figure 6: Centered FFU Configuration

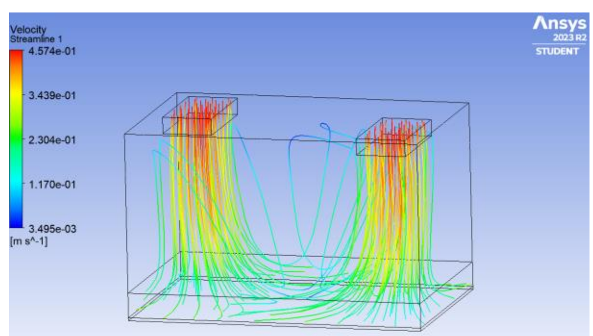

Figure 7: Cornered FFU Configuration

Lastly, the wall gap height and FFU speed were optimized using an updated Ansys simulation with the 12'x16' cleanroom with 4 centered FFUs. The output velocities of the different FFU speeds were calculated using the given air flows from **Figure 5** and the cleanroom area. The input velocity for each FFU speed was set to the lower specification limit of 10 ft/min (0.051 m/s). The calculations for the output velocities are shown in **(5)**.

$$\text{High: } V = \frac{Q}{A} = \frac{4(800)}{12(16)} = 16.67\ ft/min\ (0.0847\ m/s) \quad \textbf{(5)}$$
$$\text{Medium: } V = \frac{Q}{A} = \frac{4(720)}{12(16)} = 15\ ft/min\ (0.0762\ m/s)$$
$$\text{Low: } V = \frac{Q}{A} = \frac{4(590)}{12(16)} = 12.29\ ft/min\ (0.0624\ m/s)$$

Four different wall gap heights (4", 6'', 8'', or 12'') were tested for each of the three FFU speeds. Each simulation exit velocity was recorded and averaged to determine if the airflow velocity specifications were met for that FFU speed/wall gap height combination. The average velocity and air changes per hour calculations are shown in **Table 2** with a conclusion on if the wall height and FFU speed setting combination meets specifications. Based on the simulation results, all wall gap heights pass specification on high and medium FFU speeds. Screenshots of each simulation result are shown in **Appendix C**.

Table 2: Summary of CFD Results

Wall Height	FFU Speed	Exit Velocity Range (m/s)	Average Velocity (m/s)	Above Velocity Specifications (0.051 m/s)
4"	High	0.04390 – 0.08644	0.0652	Yes
4"	Medium	0.03929 – 0.07775	0.0585	Yes
4"	Low	0.03198 – 0.06365	0.0478	No
6''	High	0.04396 – 0.08671	0.0653	Yes
6''	Medium	0.03947 – 0.07799	0.0587	Yes
6''	Low	0.03227 – 0.06386	0.0481	No
8''	High	0.04370 – 0.08631	0.0650	Yes
8''	Medium	0.03929 – 0.07762	0.0585	Yes
8"	Low	0.03209 – 0.06354	0.0478	No
12"	High	0.04364 – 0.08639	0.0650	Yes
12"	Medium	0.03941 – 0.07770	0.0586	Yes
12"	Low	0.03210 – 0.06359	0.0478	No

Back-Up Battery Equations and Solutions

The calculations for back-up time **(6)** and **(7)** were used to inform the required battery rating. The total load is only concerning the FFUs which consume 380 W each or 2280 W total when set to medium speed. Using **(6)** the minimum Amp-hour rating for an hour of back up time is 200Ah.

$$Back-up\ Time\ (h) = \frac{Rating(Ah) \cdot Rating(V) \cdot \#\ of\ batteries \cdot efficiency}{Load(W)} \quad \textbf{(6)}\ [12]$$

$$Load_{total} = \Sigma Load_{individual} \quad \textbf{(7)}\ [12]$$

Cost Analysis Equations and Solutions

The cost analysis for all materials to construct the cleanroom was calculated for the 12’ x 16’ size design. The analysis is broken down into framing, connectors, wall material, FFUs, and a back-up battery.

Framing
To be able to construct an accurate cost analysis of the framing, inventory of all the lengths of 80/20 1.5” square aluminum tubing that will be used to construct this design is necessary. Those are as follows:

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

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

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

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

The total cost of the connectors comes to $564.91.

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

FFUs
The cleanroom will require four 4 new FFUs which comes out to $5,400.

Back-Up Battery
The back-up battery with an Amp-hour rating of 200Ah will cost approximately $600.

The total cost for the entire build comes out to $11,371.67.

Factors of Safety

The factors of safety were calculated for the bolts, ceiling bending, and polycarbonate walls for the design to ensure the safety of the design prior to manufacturing. The Factors of Safety were calculated using **(8)**.

$$Factor\ of\ Safety = \frac{Yield\ Strength}{Maximum\ Stress} \tag{8}$$

The yield strength, maximum stress, and calculated factors of safety are shown in **Table 3**.

Table 3: Factors of Safety for Various Sub-Systems

Sub-system	Yield Strength (MPa)	Max Stress (MPa)	Factor of Safety
Bolts	758	0.034	22294.7
Ceiling bending	61.53	24.61	2.5
Polycarbonate Wall	60	0.485	123.7

The maximum stress for each sub-system was determined using Solidworks and Ansys simulations. **Figure 8** shows the ceiling beam that experiences the maximum stress in the design.

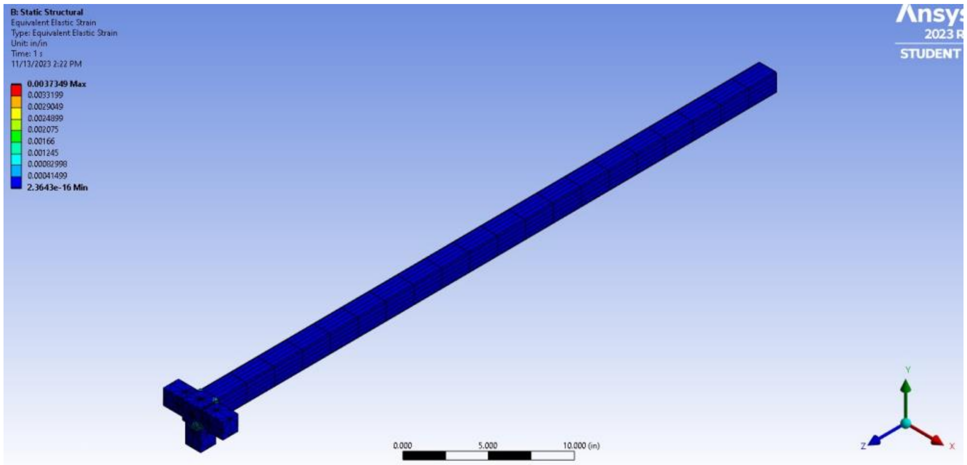

Figure 8: Section of ceiling which experiences max stress with real geometry.

Applied Solutions

The largest influence on all the applied solutions was budget. The material for the cleanroom frame was selected as aluminum initially to preserve budget. The alternative steel beams would have been initially more expensive for the materials and would have required welding and powder coating. Once the material was selected the maximum stress, strain, and factor of safety calculations were done to confirm aluminum beams could support the weight of the FFUs with the designed ceiling structure.

The polycarbonate wall calculations confirmed the selected polycarbonate sheets could be successfully supported by the aluminum frame. The calculations also determined the number of bolts that would be required to hold the walls. The number of bolts then determined how to space out the holes to be manufactured on the frame.

The number of FFU, location of FFU, FFU speed, and wall gap height calculations all dictated aspects of the final cleanroom design. The minimum number of FFUs required to maintain air pressure and filtration was calculated as four. Since the project is on a budget and the FFUs are very expensive, the team selected four FFUs only. More FFUs could allow the cleanroom to be qualified as a lower ISO class, but budget does not allow for that option. The location of the FFUs was chosen as centered since it created less turbulent flow. Less turbulent flow will help the cleanroom stay sterile. The FFU speeds of medium and high for all wall gap heights passed specifications. Since the team is also setting up a back-up battery system, medium was selected for the fan speed since it will use less power. The back-up battery requirements also partially drove the decision to have only four FFUs. More FFUs would pull more power and would require a more expensive battery.

Flow Charts and other Diagrams

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 9**. 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 10** was used to understand what roles the cleanroom structure itself plays in maintaining positive pressure and particle count. This design project will not be designing a FFU therefore it will be essential for the design team to understand all interactions between the FFU and cleanroom.

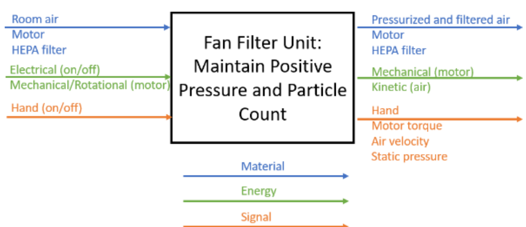

Figure 9: FFU Black Box Model

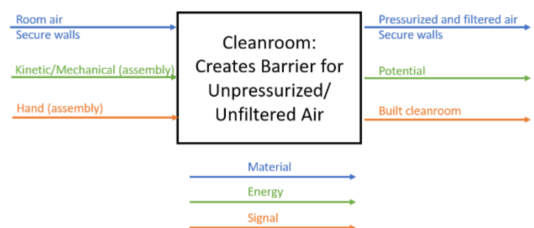

Figure 10: Cleanroom Black Box Model

The material, energy, and signal inputs and outputs from the black box models were used to construct one functional model. The functional model (**Figure 11**) was used to understand which aspects of the FFU create positive pressure and filtered air and how those functions interact with the cleanroom.

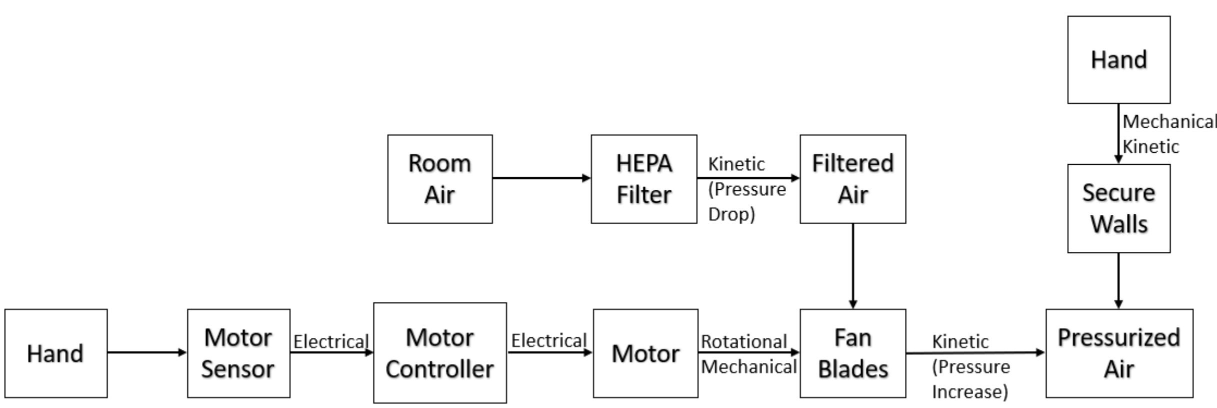

Figure 11: FFU and Cleanroom Functional Model

Moving Forward

Moving forward with the project, the team has mostly budget considerations left. The client doubled the requested size of the cleanroom which significantly increased the cost of the project, resulting in the need for additional fundraising.

The design aspects that still need to be determined are the thickness of the polycarbonate walls and the wall gap height which have not been determined yet because they require testing on the physical polycarbonate sheets. To determine sheet thickness, bending and strength testing will be done on two different thicknesses: 1/16" and 1/8". Manufacturing testing with also be done to determine if the sheets can be machined without being damaged. Based on the thickness testing, a thickness will be chosen. If the 1/8" walls are unnecessarily robust and the 1/16" are inadequate, 3/32" walls will be ordered instead. The polycarbonate walls are a large portion of the budget; therefore, the team wants to choose the minimum adequate thickness needed. For the wall gap height, velocity testing will be done with the walls in place prior to being cut to determine if one of the wall heights performs better.

In addition to selecting thickness for the polycarbonate walls, the team needs to perform additional yield calculations on the walls in horizonal positions to mimic how the walls will likely be assembled with the beams. If the walls are assembled with the beams lying flat, the walls will experience increased extra acceleration when they are stood up. The team needs to ensure the walls can handle the additional stress without bending or breaking otherwise a new manufacturing approach will need to be considered.

The back-up battery calculations were done initially for the cleanroom based on the FFU specifications tables but have not been tested on the actual FFUs or with the electrical outlets in the lab area. Additionally, the current budget does not include the back-up battery. Since the budget has been exceeded, the team is unsure if the back-up battery will remain a part of the design.

The team has also not settled on an assembly plan for when the beams and walls are delivered. The yield calculations should help decide if the walls should be attached horizontally or vertically. Additionally, the ceiling assembly will need to be completed differently from the walls.

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Appendix A: House of Quality

System QFD

Project:	**Modular Sterile Manufacturing Clean Room**
Date:	9-18-23

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

		1	2	3	4	5	6	7
1	Room Area							
2	Positive Pressure	6						
3	Particle Count	6	6					
4	Particle Size	6	6	9				
5	Airflow	6	6	3	3			
6	Ceiling Coverage	9	6	9	9	6		
7	Reynold's Number	6	3	1	1	9	6	
8	Power Requirement	1	3	3	3	3	1	3

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

Appendix B: Visual Results of the SolidWorks Simulation Tool for Stress, Strain, and Deflection

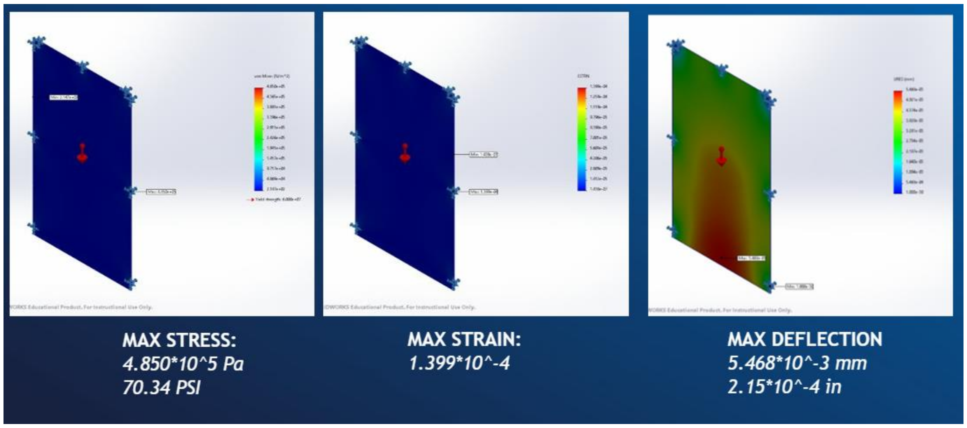

Figure D1: Max Stress, Max Strain, and Max Deflection Results from SolidWorks Simulation.

Appendix C: Computational Fluid Dynamics Simulations

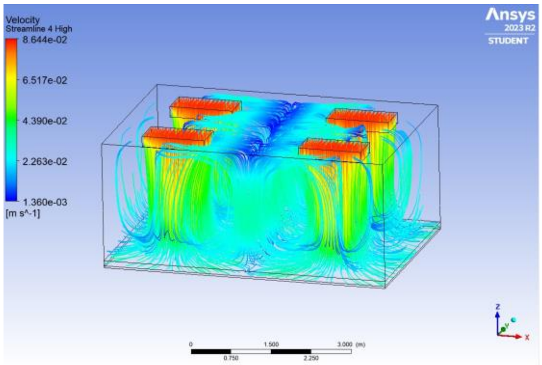

Figure C1: Streamline 4” Gap High Speed

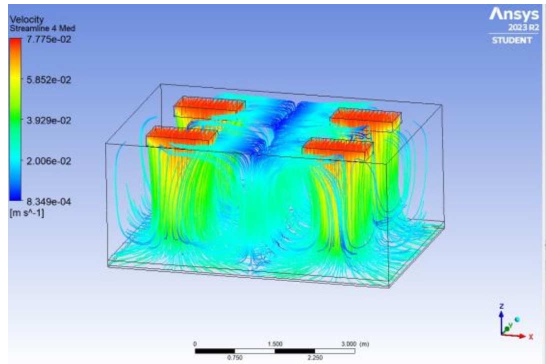

Figure C2: Streamline Gap 4” Medium Speed

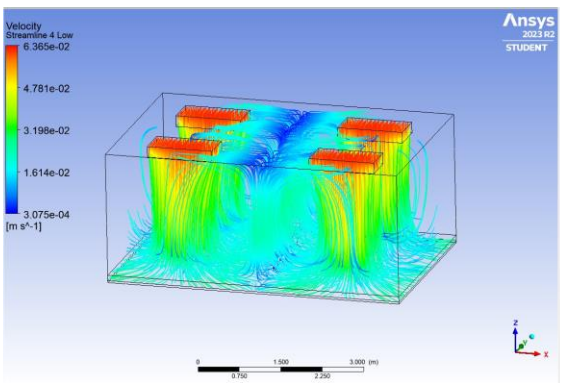

Figure C3: Streamline 4” Gap Low Speed

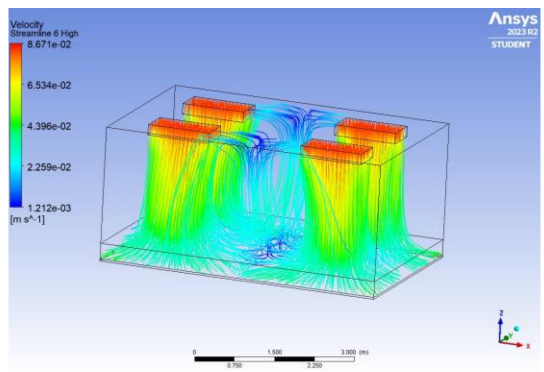

Figure C4: Streamline 6” Gap High Speed

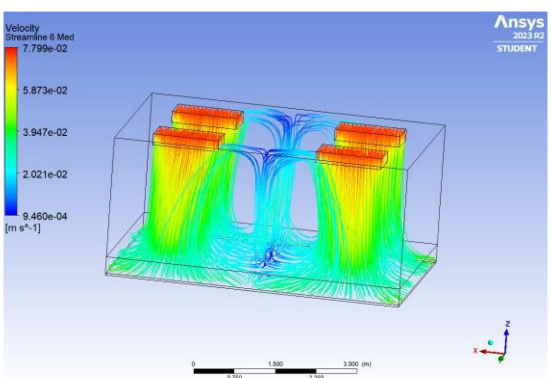

Figure C5: Streamline Gap 6” Medium

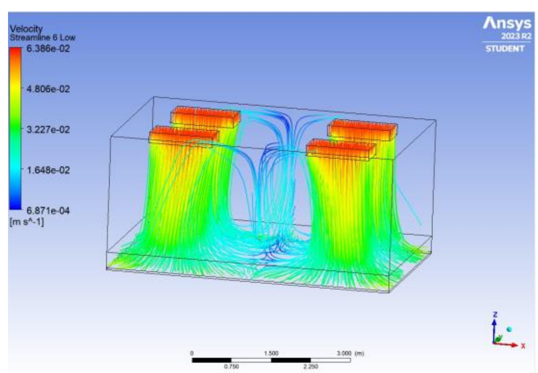

Figure C6: Streamline 6” Gap Low Speed

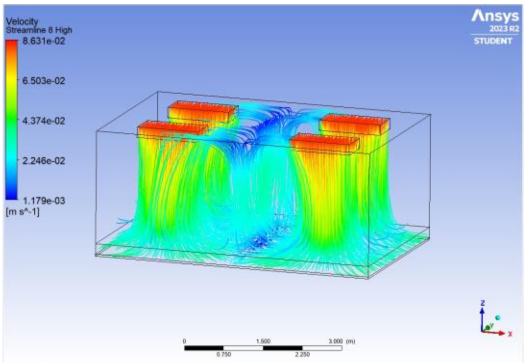

Figure C7: Streamline 8” Gap High Speed

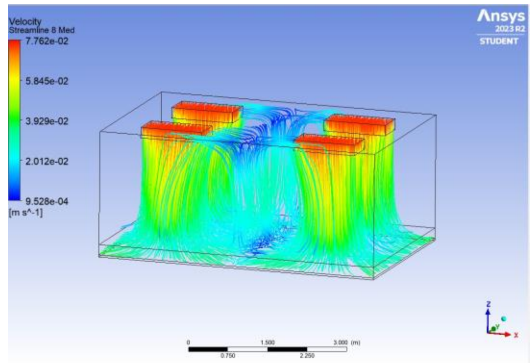

Figure C8: Streamline Gap 8” Medium Speed

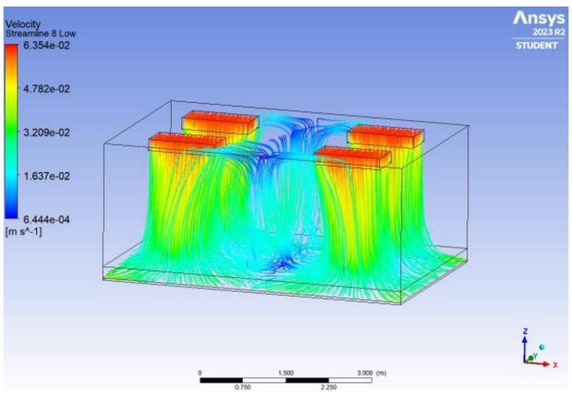

Figure C9: Streamline 8” Gap Low Speed

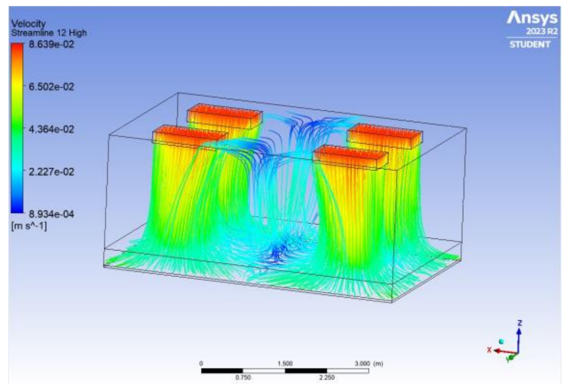

Figure C10: Streamline 12” Gap High Speed

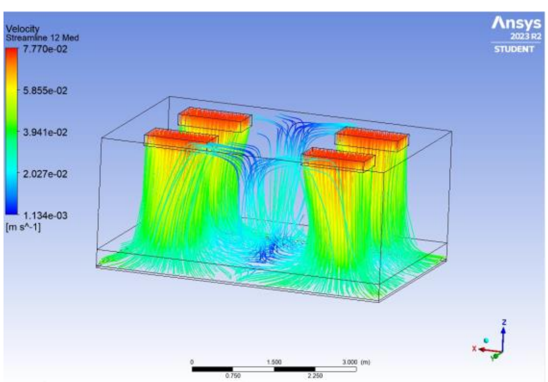

Figure C11: Streamline Gap 12” Medium Speed

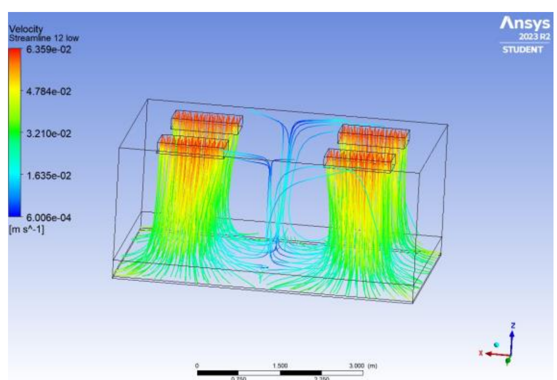

Figure C12: Streamline 12” Gap Low Speed