Modular Sterile Manufacturing Cleanroom

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Project Description

Original Project Description: Create a 12' x 8' modular ISO 7 Cleanroom with FFU's. Convert the current cleanroom into a gowning room.

New Project Description: Create a 12' X 16' modular ISO 7 cleanroom Using FFU's while also converting the current cleanroom to a gowning room

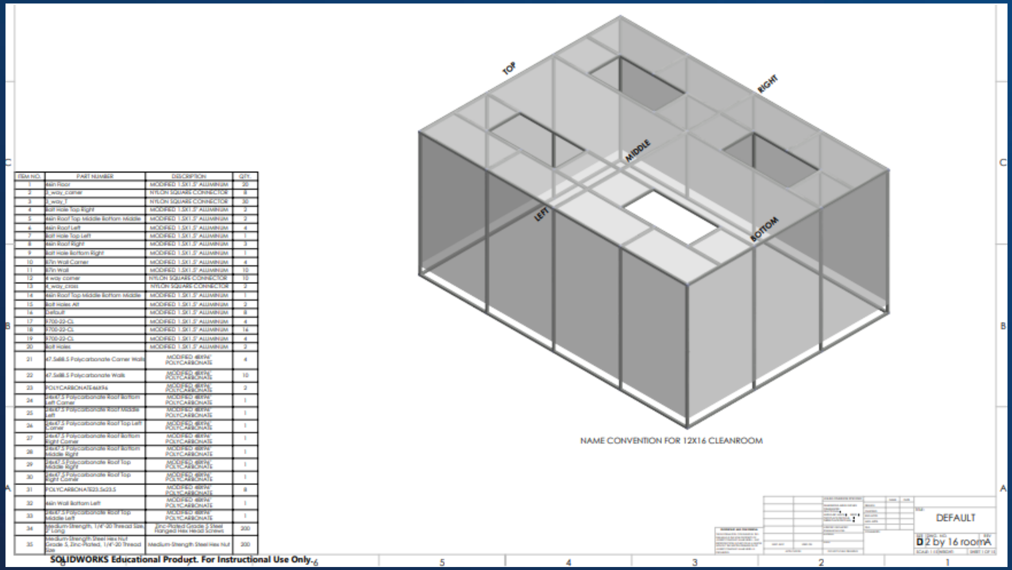

Figure 1: 12' x 16' Cleanroom design

Design Description

- The design remains generally the same, but now twice as large
- Sub-assemblies are still the same, besides fan number and location
  - Wall Material – Polycarbonate
  - Frame Material – Aluminum square tubing
  - Frame connections – Nylon/Fiberglass tube connectors
  - Material connection – Nuts and Bolts
  - Fan Location/number - 4 fans, spaced equally from each other and the walls

Page 2 of the drawing demonstrates how the frame will be built, including the tube connectors and Square tubing

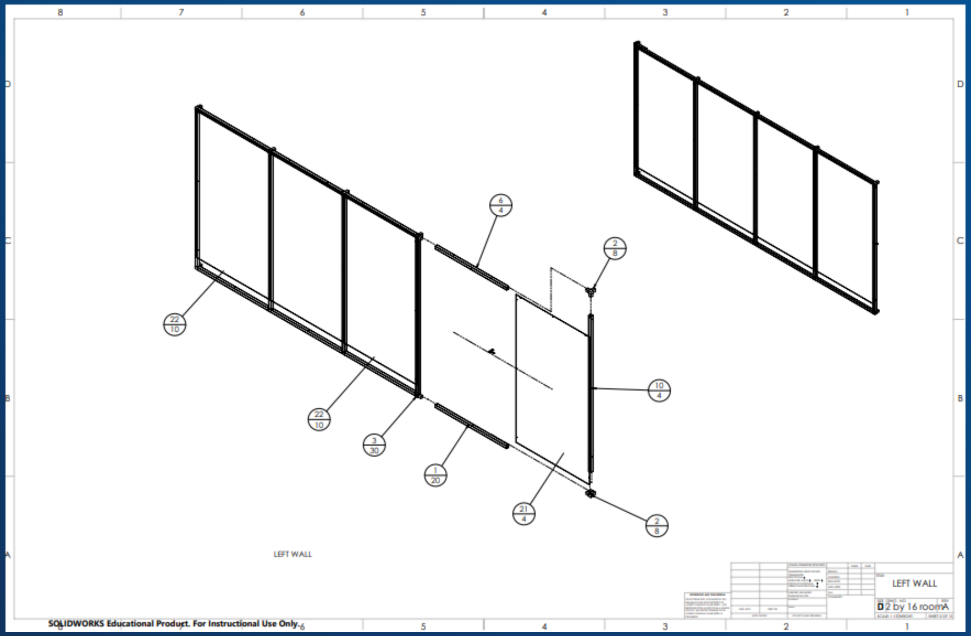

Figure 2: Page 2 of CAD drawing packet

Design Description

Page 5 in the CAD drawing packet demonstrates the method used to attach the walls to the frame, and the locations the nuts and bolts will be used

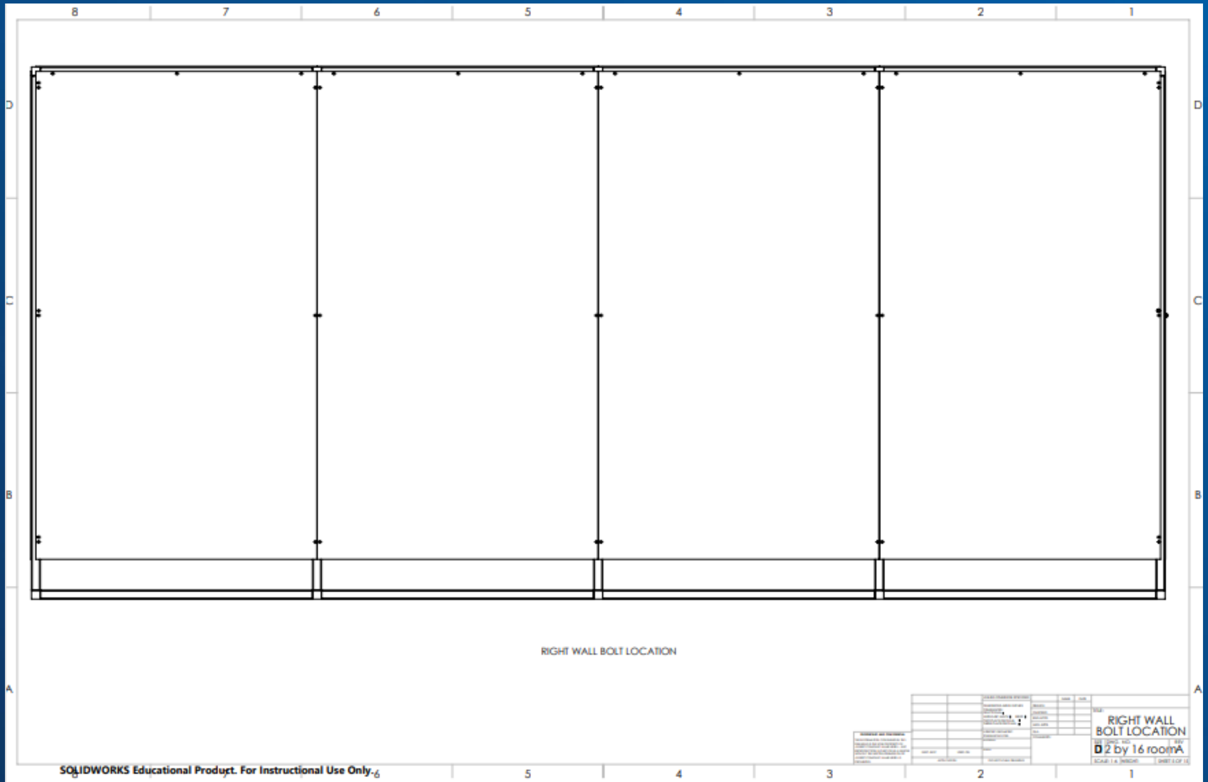

Figure 3: 16-foot wall of the Cleanroom

Design Requirements

- Customer Requirements:
1. Modular
2. Transportable
3. Spacious
4. ISO Class 7 Compliant
5. Generator Backup Power

- Engineering Requirements:
1. Room Area: $> 48ft^2$
2. Positive Pressure: $\geq 0.02\ Pa$
3. Particle Count: $< 352{,}000\ particles/m^3$
4. Particle Size: $< 0.5\ \mu m$
5. Airflow: $> 0.051\ m/s$
6. Ceiling Coverage: $> 15\%$
7. Reynold's Number: ≤ 2300
8. Power: $\sim 7200\ W$

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

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

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

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

Figure 4: Updated QFD

Engineering Calculations

Structure:

- Structural analysis to be done using Ansys or Solidworks simulation, this will be virtual prototype 2

- The goal of this prototype is to determine if support columns will be needed for our new 12'x16' design

- Ansys will be used to find maximum deflection and maximum stress for 2 designs; one with support columns, and one without

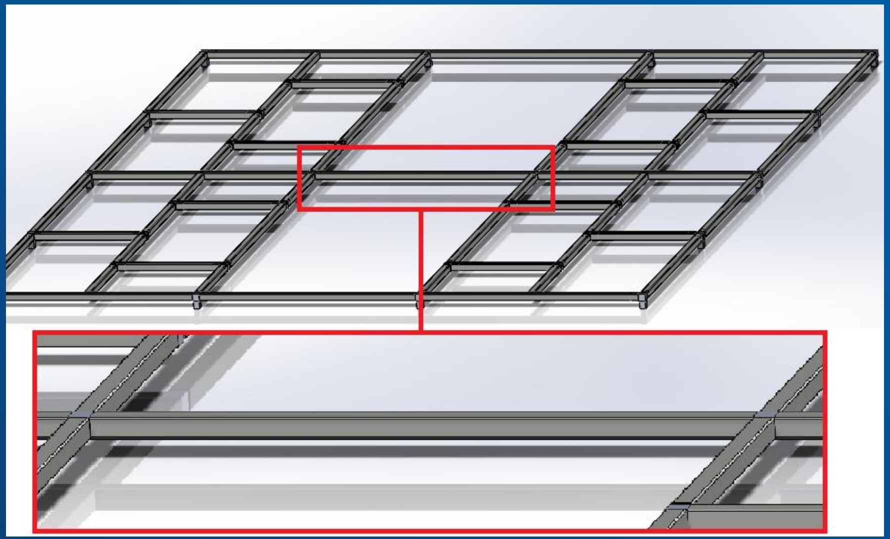

Figure 5: The CAD ceiling for without support

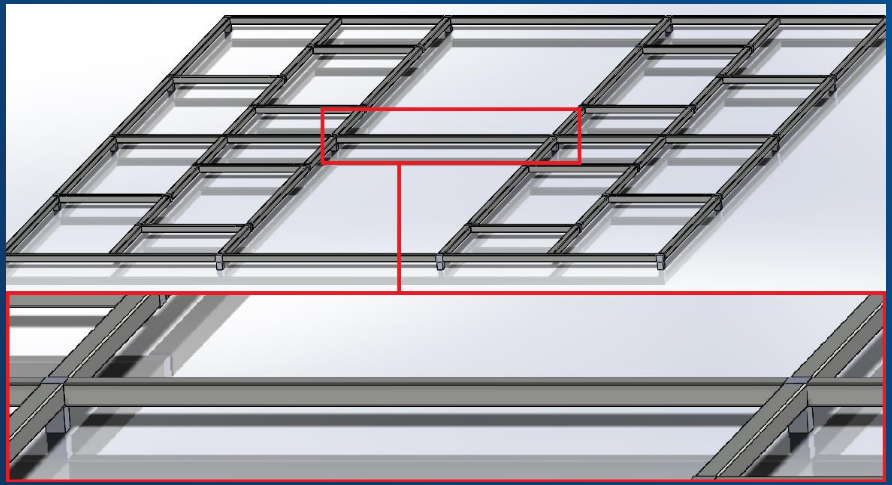

Figure 6: The CAD ceiling with support columns

Engineering Calculations

Polycarbonate Wall:

- Polycarbonate Wall: Using SolidWorks Simulation to find out how much pressure it can handle while using minimum amount of bolts to hold up the walls

- Goal: Finding out the least number of bolts and nuts that can be used before yielding from gravity and air pressure.

- Process: Experimenting with the number of Bolts and pressure that the polycarbonate can handle without yielding

- Max Stress Before Yielding: 60 MPa
- Minimum amount of pressure for an efficient cleanroom: 0.2 Pa

Engineering Calculations

Gravity and Air Pressure SolidWorks Simulation

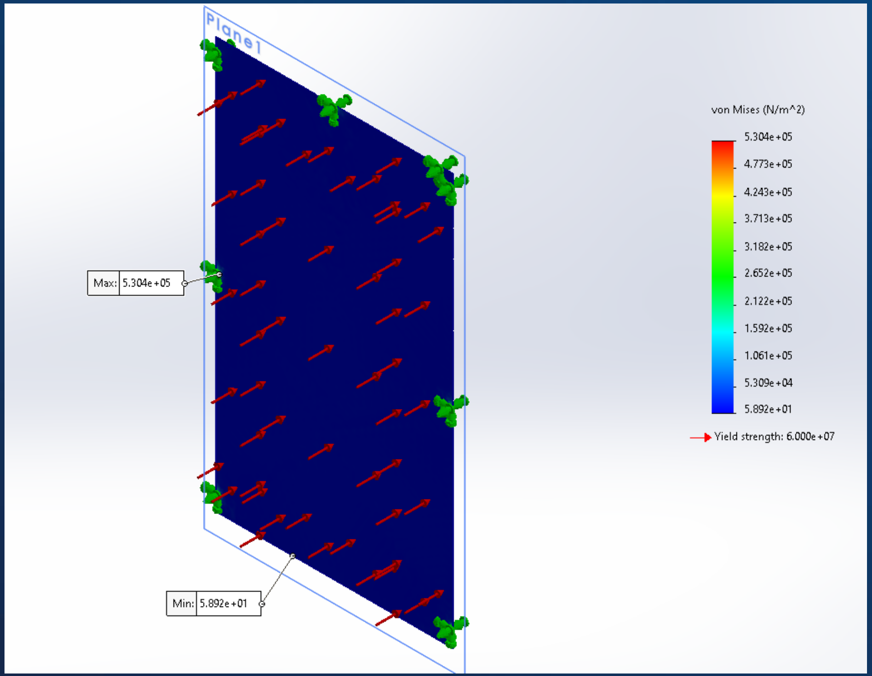

Figure 7: Polycarbonate Testing for Maximum Air Pressure in SolidWorks Simulation

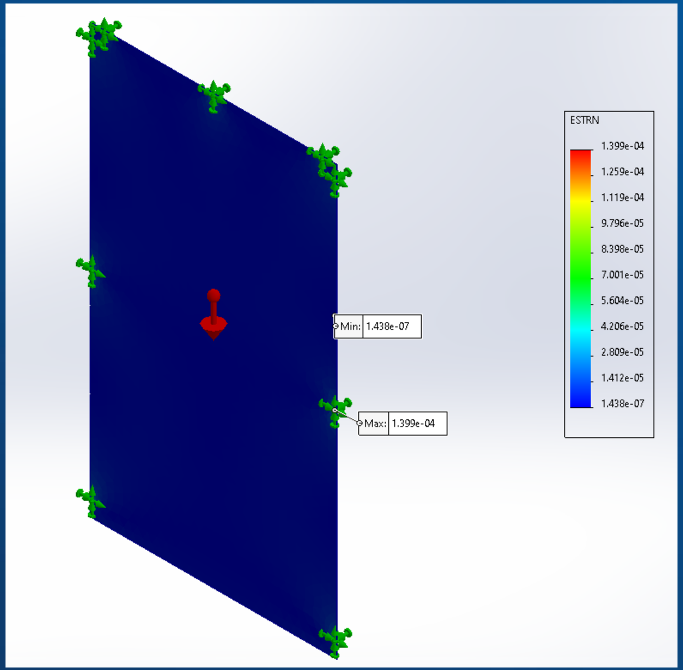

Figure 8: Polycarbonate Testing for Bolt amount and location in SolidWorks Simulation

These Simulation can find the Stress, Strain, and Displacement Values

Engineering Calculations

Computational Fluid Dynamics:

- Updated FFU Number:

Recommended Air Changes and Ceiling Coverage

ISO Class	Air Changes Per Hour	Ceiling Coverage
ISO 1	500-750	80-100%
ISO 2	500-750	80-100%
ISO 3	500-750	60-100%
ISO 4	400-750	50-90%
ISO 5	240-600	35-70%
ISO 6	150-240	25-40%
ISO 7	60-150	15-25%
ISO 8	5-60	5-15%

Figure 4: Ceiling Coverage Requirements

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

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

Upcoming Ansys CFD Simulations for Technical Analysis:

- Goals:

1. How far should the cleanroom walls be off the ground?
2. What speed should the FFUs be to maintain pressure, airflow, and particle count?

Engineering Calculations

Updated Cost Analysis:

New Framing Cost: $ 2,608.74

New Connector Cost: $ 564.91

Wall Material Cost: $ 2,198.02

FFU Cost: $ 4,608 ~ round to $5,000 to try and account for shipping and tax

Total Cost: $ 10,371.67

Framing cost : 80/20
Connector cost : Esto Connectors
Wall material cost : Eplastics

Design Validation

Table 1: Failure Modes and Effects Analysis (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	

Upcoming Testing of Engineering Requirements (to be completed on the assembled cleanroom in the designated lab space):

- Wall height: test various heights of walls before cutting materials down to size
- Fan speed setting: anemometer and particle counter at different speeds
- Room pressure: barometer
- Particle count: utilizing particle counter
- Battery load: utilizing all FFUs attached to backup battery for several hours

Schedule

Build Timeline for 2024:

- End of year 2023: All materials ordered and set for delivery by February 1st
- February 13th: Cleanroom 67% built – entire frame built with screw holes pre-drilled, all walls installed/screwed into place, all FFUs installed, experimental testing for wall height
- March 1st: Complete SOPs for assembly and gowning
- March 6th: Cleanroom 100% built – backup power installed and tested, complete all ISO Class 7 related testing
- April 3rd: Cleanroom certified for ISO Class 7 use, final poster complete
- April 10th: Prep for final product demo, final testing results, and presentation

Budget

Current Budget : 10K, Hoping to get 12-13K
Anticipated expenses: ~ $10,371.67
Actual Expenses to Date: None

Fundraising Update: Currently constructing a Budget proposal to Dr. Razavians Biomedical Club for extra funds.

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THANK YOU!

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