Modular Sterile Manufacturing Cleanroom

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Background

- Description of project: Create a modular ISO Class 7 cleanroom with fan filter unit (FFU). Convert current cleanroom into a gowning room.

- Clients/sponsors:

Timothy Becker

Aneuvas Technologies Inc

- Purpose of Cleanroom:
  - Manufacturing of medical devices in a sterile environment

Black Box and Functional Model

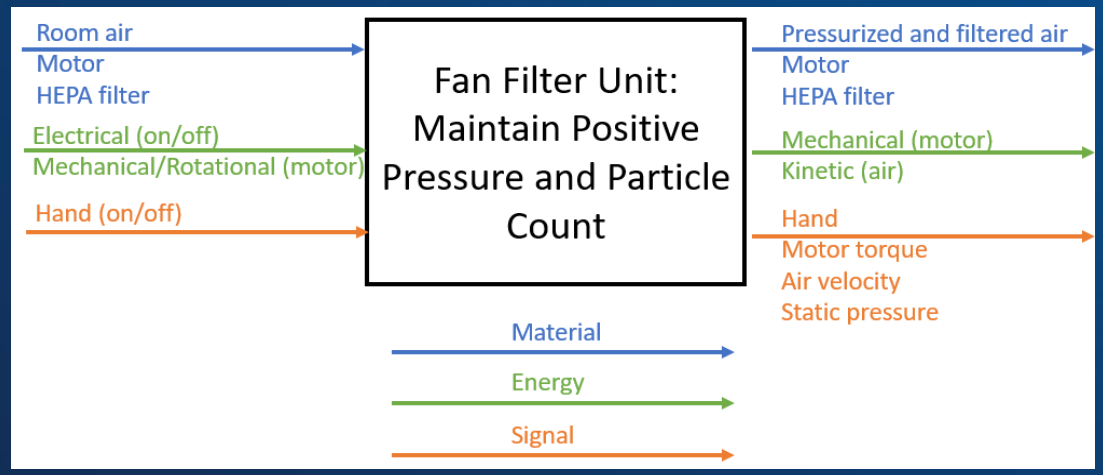


Figure 1: FFU Black Box Model

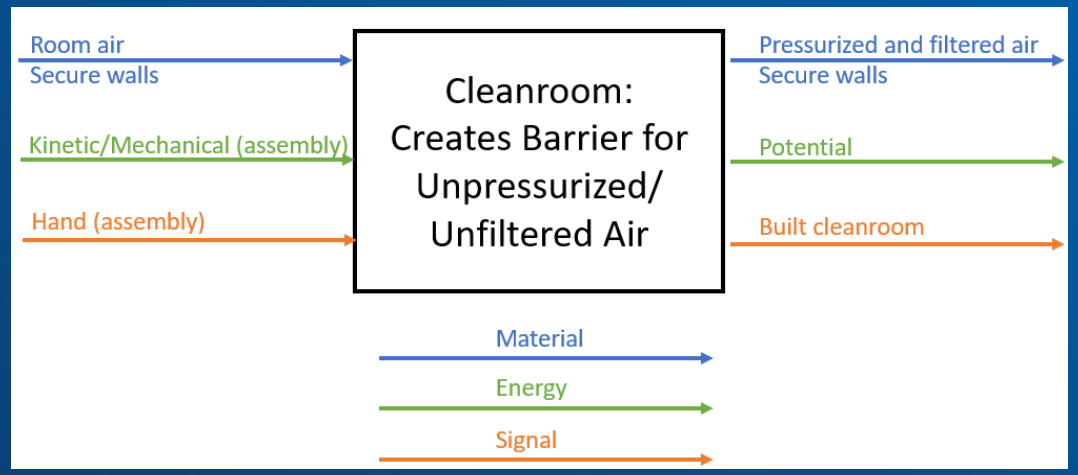


Figure 2: Cleanroom Black Box Model

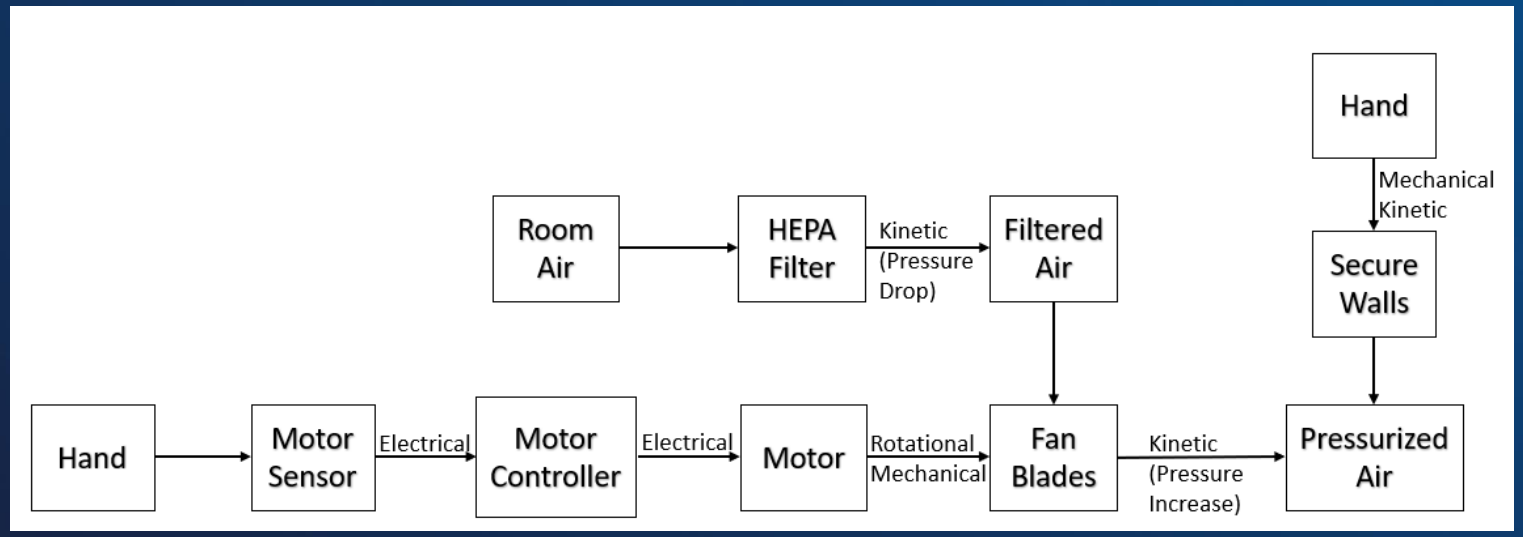


Figure 3: Functional Model

Concept Generation: Morphological Matrix

Table 1: 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 		

Subfunctions:

1. Frame Connections
2. Material Connections
3. Wall/Ceiling Material
4. Fan Number/Location
5. Frame Size

[1] - [10]

Frame Connections:

-Connections between frames

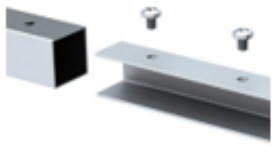
-Must be able to handle Shear and Flexural forces

-Must be easy to assemble and disassemble

	Material	Yield Strength	Tensile Strength	Modulus of Elasticity	Default Price	Machining/Extra price
Wield	6005A – T61*	21000	19500	10 x 10^6	-	18 per lb
Telescoping	Nylon	5800	11500	450000	4	0
Joint Screw	Stainless steel	30000	75000	28 x 10^6	12	3.5
80/20 T Slots	6005A – T61	43000	39000	10 x 10^6	5 to 30	3 to 20
Units	-	*(Psi)*	*(Psi)*	*(Psi)*	*(Usd)*	*(Usd)*

Figure 4: Spec Sheet for Frame Connections

Table 2: Frame Connections Advantages/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

Frame Connections:

Shear Flow Calculation

$$\tau max = \frac{V * Q}{I * t}$$

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

$$100lbs = 3.02lbf$$

$$Vmax = 3.02lbf$$

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

$$t = \frac{1.5in}{2} = 0.75in$$

$$\tau \mathbf{max} = \mathbf{1.96psi}$$

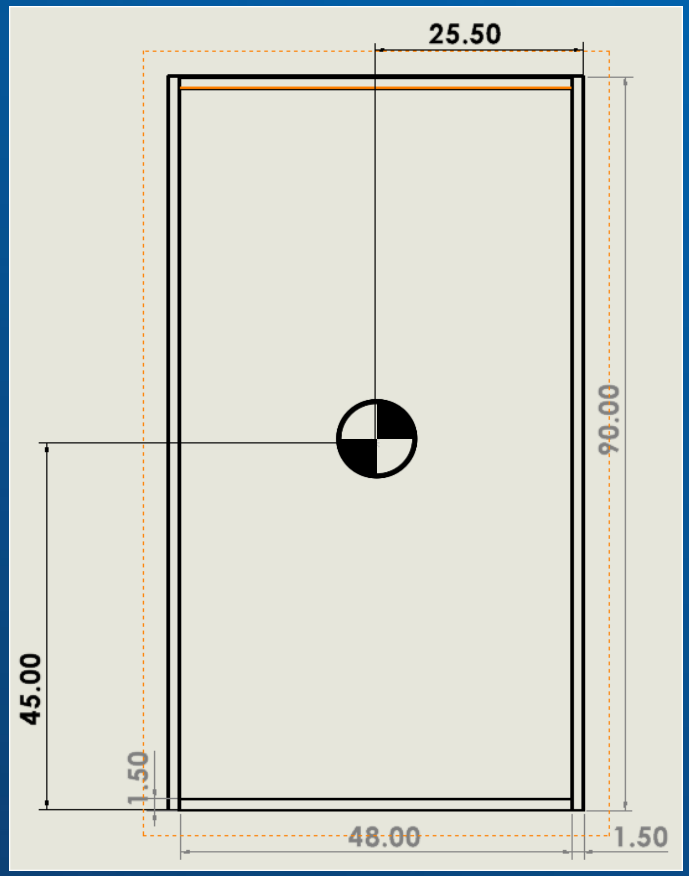


Figure 5: Surface area of frame with Centre of Gravity

Tmax = Max Torsion

Vmax = Max Shear

I = Moment of Inertia

Q = 1st Moment Area

t = Width Across Section

Frame Connections:

Selection Criteria:

1. **Modularity**: How easy it is to Assemble, Disassemble
2. **Price**: Price of connection
3. **Yield Strength:** Highest amount of stress without permanent deformation
4. **Interference:** If connections size will interfere with others
5. **Small Quantity:** Number of extra parts required for connection
6. **Ease of use:** How easy it is to Assemble/Disassemble
7. **Stability:** How stable the frame can be.

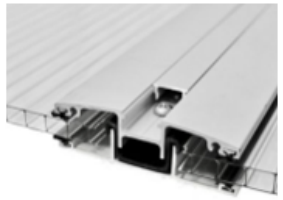
Table 3: Frame Connections Decision Matrix

		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**

Material Connections:

- Material connections are how the walls will be attached to the frame
- Hard wall weight: 9.5lbs
- Soft wall weight: 9.75lbs

Table 6: Material Connections 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

Material Connections:

- Criteria

1. **Durability**: life expectancy in years
2. **Modularity**: ease of changing configuration/assembly
3. **Strength**: Strength of connection in lbs
4. **Seal Tightness**: gas loss in in^3/s
5. **Aesthetic**: subjective and unmeasurable

Table 5: Measurable Criteria per Variant. (Seal tightness not yet tested)

Criteria	Magnets	Adhesive	Screws	Slots
Durability hard-walled (years)	Indefinite	Indefinite	Indefinite	Indefinite
Durability soft-walled (years)	3-5	Indefinite	Indefinite	Indefinite
Strength (lbs)	10.84	45900	21875	17500
Seal Tightness (in^3/s)	-	-	-	-

Strength of magnets[3]
Strength and durability of Adhesives[5]
Strength of Aluminum/screws[4]

Table 7: 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**

Slotted connections would best fit the criteria, however, require the use of 80/20 T-slots in the "Frame connection" subfunction

Wall Material:

Soft Wall Vs Hard Wall Materials

- Off-gassing: release of a dissolved, trapped, or absorbed gas in a material
- VOCs: Volatile Organic Compounds

Cost Analysis:

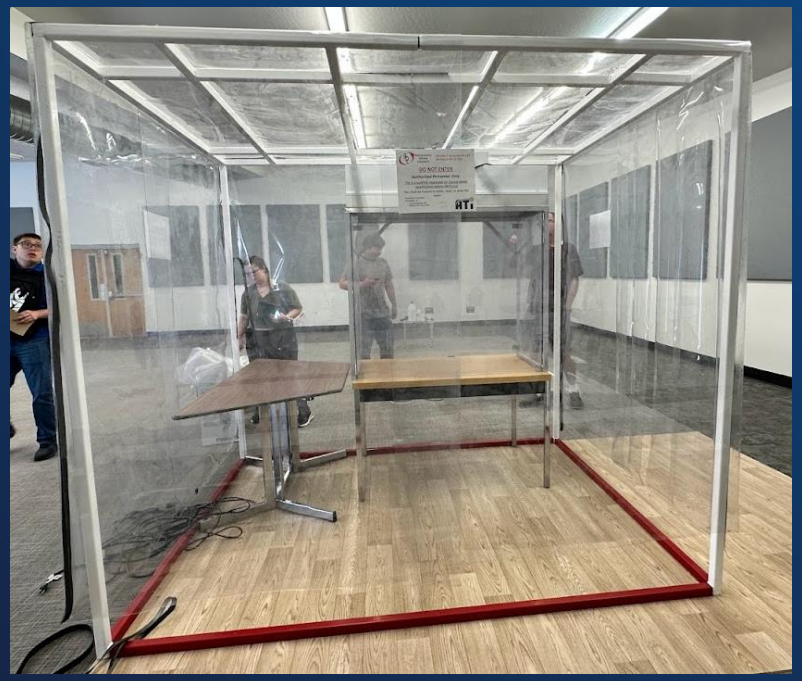
- Vinyl: ~$200
- Polycarbonate for 10x10 and 12x8: $1774.49

Table 8: Wall Material Advantages/Disadvantages

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

Wall Material:

Vinyl Longevity:



Figures 6-8: Current Vinyl Cleanroom

Wall Material:

Criteria:

1. Cost: price of all wall material for 10x10 or 12x8 configuration
2. Customer Preference
3. VOCS
4. Longevity

Table 9: Frame Size 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**

Frame size:

Cost Analysis:

Table 10: Frame Cost Analysis

Cost Breakdown		
	12x8	10x10
Framing	$1,661.14	$1,649.39
Connectors	$305.53	$431.82
Wall Material	$1,561.75	$1,561.75
Total	$3,528.42	$3,642.96

- Framing: 80/20 Aluminum Square tubing
- Connectors: Estos Nylon injection molding connectors
- Wall Material: Eplastics 1/16th inch 48"x 96" poly carbonate sheets

❑ Prices include Tax and Shipping estimations

Table 11: Frame Size Advantages/Disadvantages

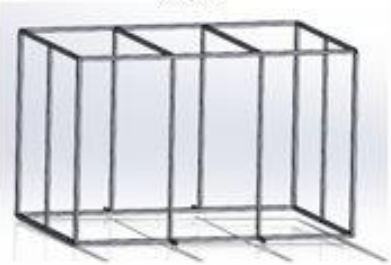
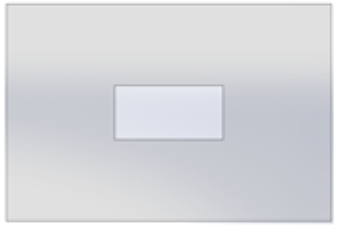
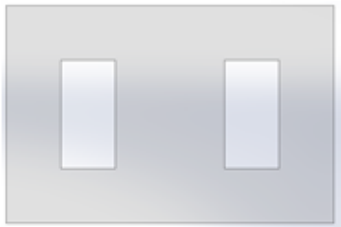
Frame Size	Advantages	Disadvantages
10x10 	- Direct customer request - Total area of 100 square feet of floor space	-Unevenly spaced support beams will require additional material cutting
12x8 	- Evenly spaced bars will require no material cutting - Uses same material requirements as 10x10 - Symmetrical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

Table 12: 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**

Fan Number:

Table 13: Fan Number/Location Concept Variants

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

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 9: ISO Ceiling Coverage Requirements

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

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

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

Fan Locations:

- Ansys Fluent CFD Analysis:
  - Reynold's Number Outputs:
    - Centered Fans: 3441.3 (Transitional flow)
    - Cornered Fans: 3703.6 (Turbulent flow)

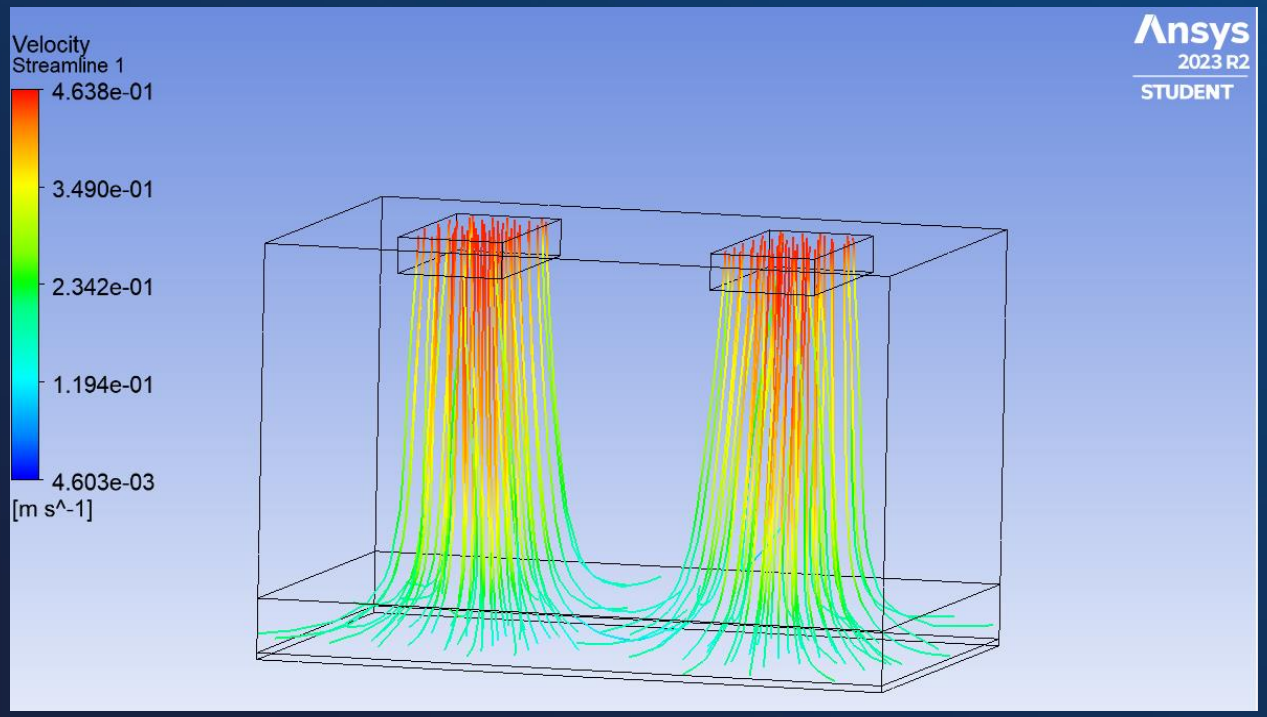


Figure 10: 2 Centered Fans Streamline Simulation

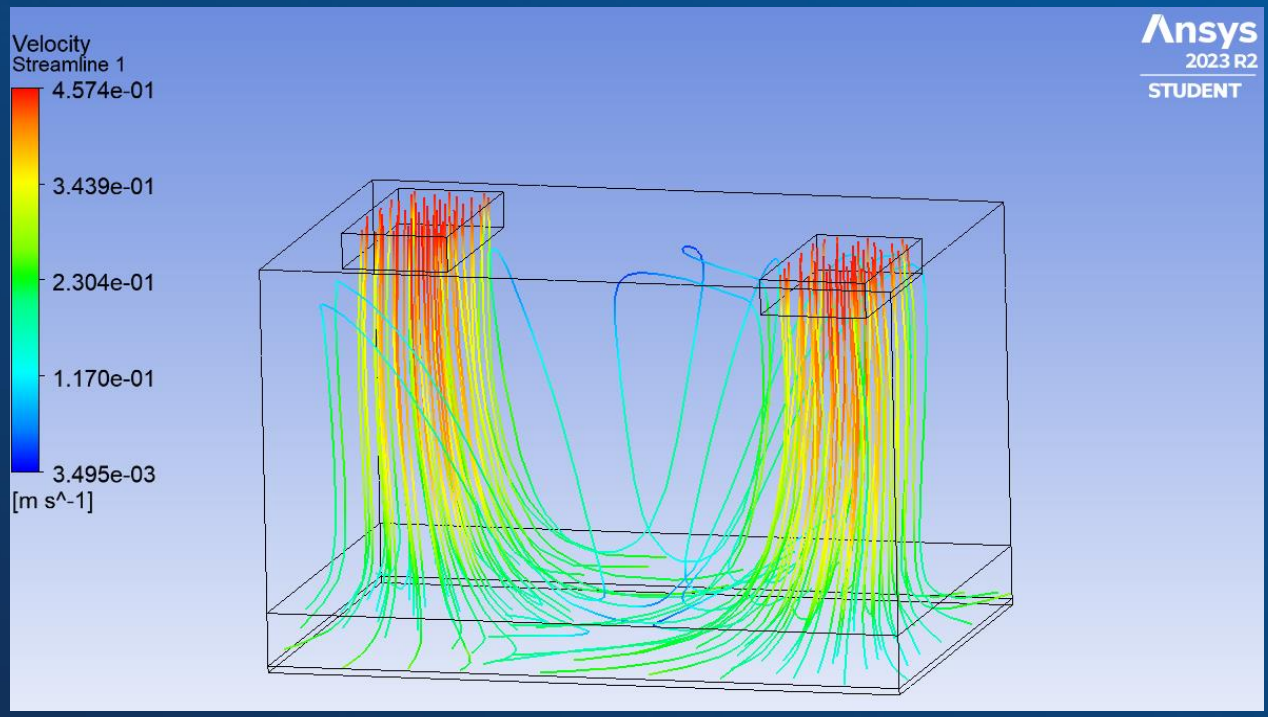


Figure 11: 2 Cornered Fans Streamline Simulation

Fan Number and Location:

Structural Load Analysis:

2 Centered Fans			
Material geometry	Moment of inertia (in^4)	Max bending stress (psi)	Factor of Safety
Tube	.2127	3966.9	8.823
T-slot S	.2631	3207.0	10.91
T-slot L	.1921	4392.2	7.969
T-slot UL	.1765	4780.5	7.321

Figure 12: Centered Fan Load Analysis

2 Cornered Fans			
Material geometry	Moment of inertia(in^4)	Max bending stress (psi)	Factor of Safety
Tube	.2127	2820.9	12.41
T-slot S	.2631	2280.5	15.35
T-slot L	.1921	3123.4	11.21
T-slot UL	.1765	3399.4	10.30

Figure 13: Cornered Fan Load Analysis

$$I = .2127in^4$$

$$L = 22.5in$$

$$F = 50lbs$$

$$c = 1.5in$$

$$M_{Max} = F * L$$

$$\sigma_{max} = \frac{Mc}{I}$$

$$\sigma_{max} = 3966.9psi$$

$$V_{max} = 50lb$$

Particle Count Analysis:

Whisper Flow Filter Specifications:

- MERV 7 Pre-Filter: 50% efficiency at $3\mu m$
- HEPA Filter: 99.99% efficiency at $0.3\mu m$

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 14: Cleanroom Particle Count Requirements

Fan Number and Location:

Criteria:

1. Cost: price of FFU in dollars
2. Flow Distribution: type of flow (Reynolds Number)
3. Structural Load: Max bending stress and Factor of Safety
4. Particle count: μm

Table 14: 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**

Final Concept:

- Final Design:
  - Square tubing Nylon connections
  - 1.5"x1.5" aluminum tube frame
  - Walls secured with screws
  - Hard polycarbonate walls
  - 2 centered fan locations
- The frame and material connections provide the strongest and most modular design
- Hard polycarbonate walls for durability and professional look
- 2 fans are required to meet ISO class 7 standards, centered to keep transitional flow

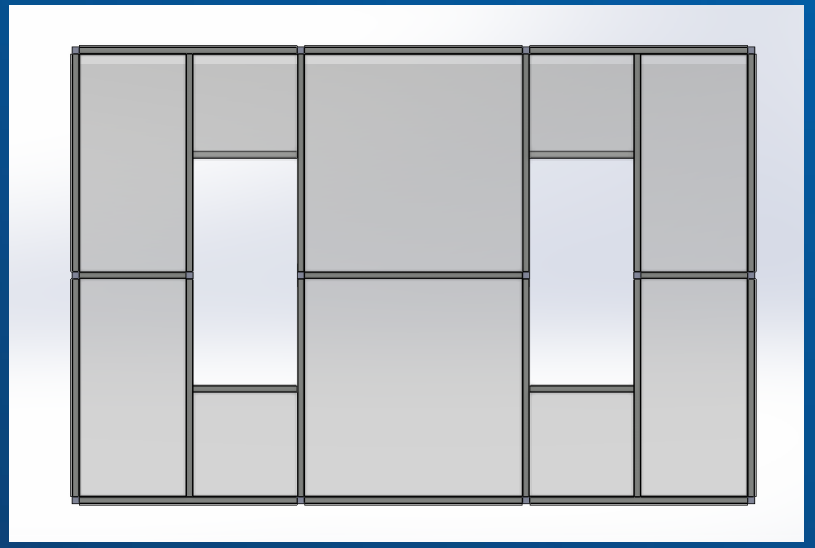


Figure 15: CAD Top View

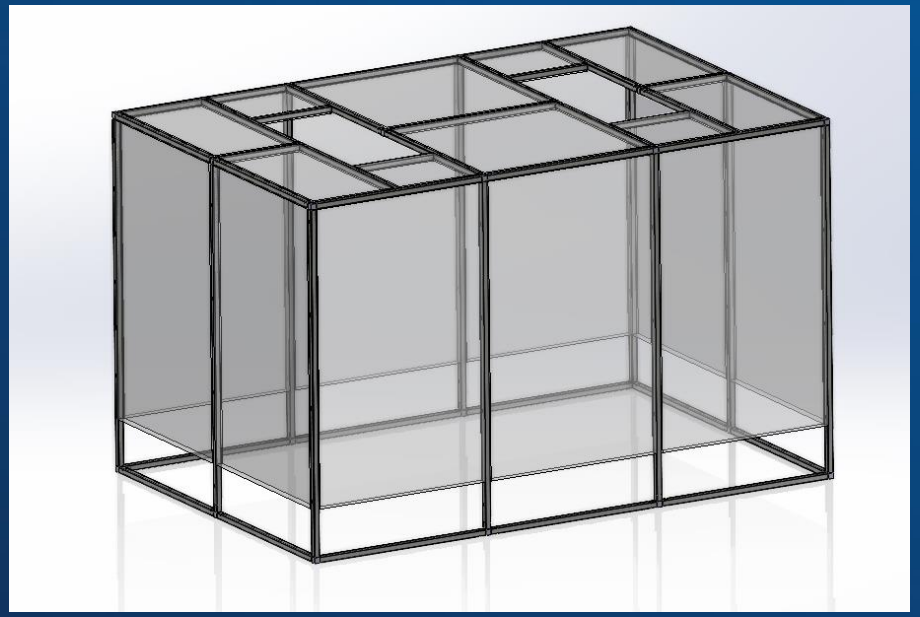


Figure 16: Isometric View

Schedule:

TASK	ASSIGNED TO	PROGRESS	START	END
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		0%	10/10/23	10/27/23
Background		90%	10/10/23	10/27/23
Requirements		90%	10/10/23	10/27/23
Research Within Design Space		80%	10/10/23	10/27/23
Design Concepts		100%	10/10/23	10/27/23
Conclusion		0%	10/10/23	10/27/23
Prototype 1				
CAD		95%	10/10/23	11/6/23
3D Printed Components		0%	10/10/23	11/6/23
Non-3D Printed Components		0%	10/10/23	11/6/23

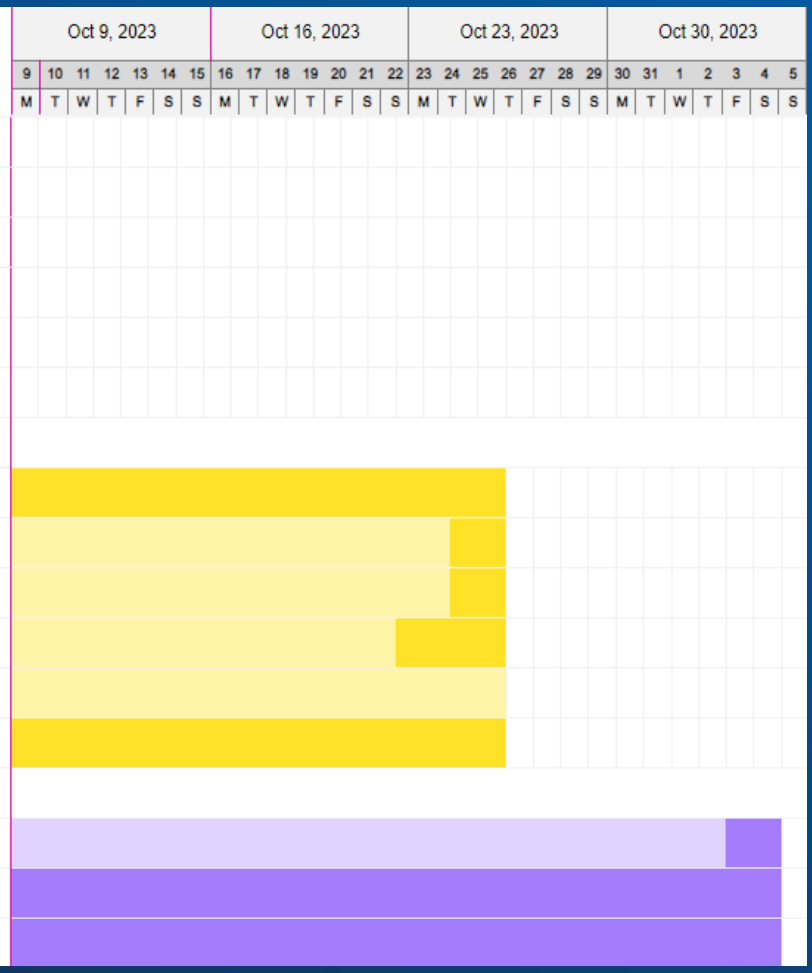


Figure 17: Gantt Chart

Budget

Current Budget : $5K - $10K

Projected Expenses: $7K

60%- Materials (Aluminum tubing)
20%- FFU
15%- Backup Battery
5%- Prototyping

10% Fundraising: Reach out to other departments and teams who will use the cleanroom (No Update yet)

BOM:

Table 15: Bill of Materials

BOM										
	Part #	Part Name	Qty	Description	Functions	Material	Dimensions	Cost per unit	Total Cost	Link to cost estimate
	1	Aluminum square tubing	29	Frame material		Aluminum	1.5"x 1.5" -46"			
	2	Aluminum square tubing	10	Frame material		Aluminum	1.5"x 1.5" -87"			
	3	Aluminum square tubing	4	Frame material		Aluminum	1.5"x1.5"-22"			
	4	Aluminum square tubing	2	Frame material		Aluminum	1.5"x 1.5"-22.5"	$0.49 per inch	$1,661.14	https://8020.net/9700.html
	5	1.5" Straight Base connector	10	Frame connector	Connects frame	Nylon/Black	1.5"	$6.65		https://estoconnectors.com/product/5323150/
	6	1.5" 3-way Tee Connector	10	Frame connector	Connects frame	Nylon/Black	1.5"	$8.93		https://estoconnectors.com/product/532150/
	7	1.5" 3-way Corner Connector	8	Frame connector	Connects frame	Nylon/Black	1.5"	$8.93		https://estoconnectors.com/product/533150/
	8	1.5" 4-way Corner Connector	6	Frame Connector	Connects frame	Nylon/Black	1.5"	$9.98	$305.53	https://estoconnectors.com/product/545150/
	9	Polycarbonate sheets	19	Wall material	Covers 12x8 frame and 6x8 frame	Polycarbonate	1/16"x48"x96"	$67.41	$1,774.49	https://www.eplastics.com/LEXAN-CLR-0-060AM48X96?quantity=19
	10	FFU	2	Filter fan unit	Filters air within the room	Poweder coated steel	2'x4'	$1,152	$2,304.00	https://www.terrauniversal.com/whisperflow-fan-filter-units.html
Total									$6,045.16	

References

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THANK YOU!

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