Modular Sterile Manufacturing Clean Room

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Project Description

- Description of project: Create a 10x10 modular cleanroom and fan filter unit (FFU) design while converting the current cleanroom into a gowning room.

- Clients/sponsors:

Timothy Becker

David Willy

Aneuvas Technologies Inc

- Why is it important: Increases Dr. Becker manufacturing compacity which will save more lives and can be access by more students.

Background

- What is a cleanroom? What is a Filter Fan Unit (FFU)?
- Cleanroom Levels: ISO Class 7

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%

Fig. 1: Air Change and Ceiling Coverage Requirements

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

Fig. 2: Particle Count Requirements

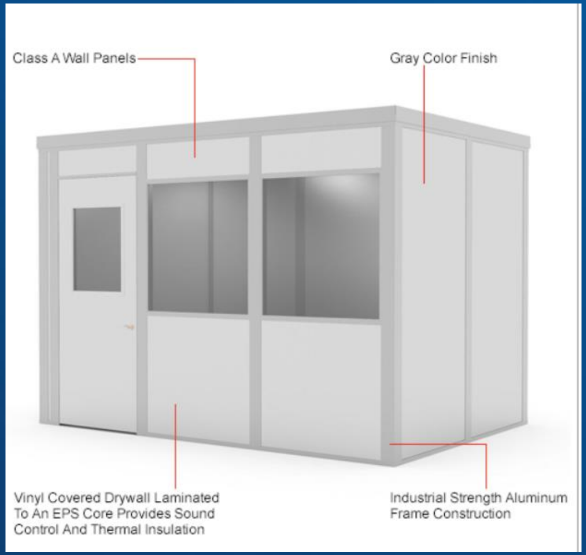
- Medical Device Manufacturing:
- Aneuvas: Aneurysm Stent Grafts

Benchmarking

3 Existing Designs:

Current Cleanroom (ROTC Building) ISO 7

Softwall Cleanroom (Clean Air Products) ISO 8-4



Modular Hardwall Clean room (Global Industrial) ISO 8

Customer and Engineering Requirements

Customer Requirements
- Modular
- Transportable
- Spacious
- Compliant with current clean room
- Compliant Gown Storage
- FFU with HEPA
- Backup power
- Alcohol safe materials

Engineering Requirements
- Positive pressure
- 10'x10'
- Class 7 clean room
- FFU power
- Cleanroom power draw/Battery voltage
- Filter unit strength
- Load Bearing frame
- Temperature and pressure regulated

Stretch Goals
- 10'x20' floor space
- Easily broken down and transported

QFD

System QFD

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

#	Technical Requirement	1	2	3	4	5	6	7
1	Creates and maintains positive pressure							
2	Dimensions	6						
3	Acceptable particle count	6	1					
4	FFU power	9	3	9				
5	Cleanroom power output	3	1		6			
6	Filter level			9	1			
7	Load bearing frame	1	6		3			
8	Temperature and pressure regulated	9	1	6	9	1		

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

#	Customer Needs	Weight	Creates and maintains positive pressure	Dimensions	Acceptable particle count	FFU power	Cleanroom power output	Filter level	Load bearing frame	Temperature and pressure regulated	1 Poor	2	3 Acceptable	4	5 Excellent
			Technical Requirements								Customer Opinion Survey				
1	Modular	5	-3	6	-3	0	0	0	6	-3		C		AB	
	Transportable	3	-3	6	-3	0	0	0	3	-3		C	AB		
2	Spacious	4	-1	9	-1	-3	-1	0	-3	-1		A		C	B
3	Room Connectability	5	-3	6	-1	0	0	0	3	-3	C	B	A		
4	Compliant Gown Storage	4	1	1	3	0	0	0	1	0		ABC			
5	FFU with HEPA	5	9	1	9	9	6	9	6	6		C		AB	
6	Generator Backup Power	2	6	0	6	9	9	0	1	3	ABC				
11	Alcohol Safe Materials	5	0	0	9	0	0	0	1	0					ABC
	Technical Requirement Units		atm	ft	particles/m^3	W	W	N/A	N	Pa					
	Technical Requirement Targets		20	10x10	352,000	430	>1000	MERV 17	2500	> 25					
	Absolute Technical Importance		18	123	81	51	44	45	83	-7					
	Relative Technical Importance		7	1	3	4	6	5	2	8					

Fig. 3: QFD

Literature Review

- General engineering resources, including stress equations, and material strengths
- Final Design has not been decided on
- Modularity and collapsibility are the focus
- These papers provide resources for one or multiple of the following options
  - Folding/scissor mechanism
  - Telescopic beams
  - Non-welded connections

Fig. 4: Steel framed building

References:

[1] M. Babaei and E. Sanaei, “Geometric and Structural Design of Foldable Structures,”

[2] R. T. Leon and W. S. Easterling, *Connections in Steel Structures IV: Behavior, Strength and Design: Proceedings of the Fourth International Workshop Held at Hotel Roanoke Convention and Conferenxce Center*

[3] Z. CUI, W. JIANG, and L. CHENG, “Analysis and experimental verification of the strength of telescopic booms for construction machinery,” *International Journal of Simulation: Systems, Science & Technology*, pp. 1–10, 2016. doi:10.5013/ijssst.a.17.27.33

[4] H. Jain, “Steel Connections – Types and Uses,” The Piping Mart,

[5] L. WebStructural, “Beam Designer,” WebStructural, https://webstructural.com/beam-designer.html (accessed Sep. 13, 2023).

[6] J. M. Amiss, F. D. Jones, H. H. Ryffel, R. E. Green, and C. J. McCauley, *Machinery’s Handbook*, 25th ed. New York, NY: Industrial Press, 1996.

Literature Review

- General equations for Thermodynamics, and includes property table for air
- Includes thermodynamics requirements for a Cleanroom
- Explains common issues and how to fix it
- Gives Thermodynamic properties for the Filter Fan Unit
- Simplify the Ideal Gas Law in humid conditions.

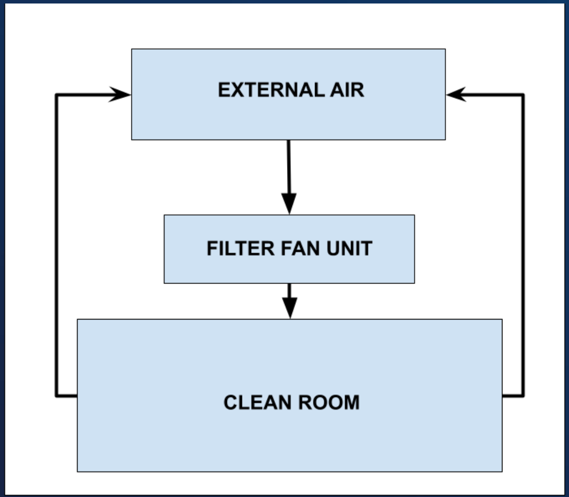


Fig. 5: Thermodynamic Flowchart for a Cleanroom

References:

[7] T. Oo, P. Thu, A. Zaharov, A. Ryabyshenkov, and N. Larionnov, "Analysis Thermodynamic Analysis of Air Conditioning System of Clean Rooms," *IEEE*, pp. 2227–2230, Mar. 2019, doi: 10.1109/EIConRus.2019.8657071.

[8] M. Moran and S. Howard, FUNDAMENTALS OF ENGINEERING THERMODYNAMICS, 8th ed. Wiley, 2014.

[9] T. Xu, "Characterization of minienvironments in a clean room: Design characteristics and environmental performance," Elsevier, vol. 42, no. 8, pp. 2993–3000, Aug. 2007, doi: https://doi.org/10.1016/j.buildenv.2006.10.020.

[10] Onicon Brand, "Maintaining Area or Room Pressurization in Manufacturing and Healthcare," Jul. 31, 2020. https://www.airmonitor.com/industrial/blog/maintaining-area-or-room-pressurization-in-manufacturing-and-healthcare/ (accessed Sep. 14, 2023).

[11] J.-J. Chen, C.-H. Lan, M.-S. Jeng, and T. Xu, "The development of fan filter unit with flow rate feedback control in a cleanroom," *Elsevier*, vol. 42, no. 10, pp. 3556–3561, Oct. 2007, doi: https://doi.org/10.1016/j.buildenv.2006.10.026.

[12]"Humidity and the Ideal Gas Law," *WES Energy and Environment, LLC*, May 04, 2020. https://wesenergyandenvironment.com/2020/05/04/humidity-and-the-ideal-gas-law-2/ (accessed Sep. 14, 2023).

Literature Review

- These papers provide resources for one or multiple of the following options
  - Manufacturing of cleanrooms
  - Clean room Designs
  - Clean room Comparisons
  - Material properties

Fig. 6: Terra Universal Cleanroom

References:

[13] W. Callister, Materials Science and Engineering, John Wiley & Sons, 2018.

[14] B. R. Bengt Ljungqvist, Clean Room Design: Minimizing Contamination Through Proper Design, CRC Press, 1996.

[15] "Softwall Cleanrooms," Clean Air Products, 2023. [Online]. Available: https://www.cleanairproducts.com/softwall-cleanrooms.

[16] Terra Universal : Critical Enviorment Solutions inc, "FS209E and ISO Cleanroom Standards," Terra Universal INC, Fullerton, 2012.

[17] M. Bedak, "Comparison of Conventional Cleanrooms, Restricted Access Barier Sysems, and Isolators," Vienna University of Applied Sciences , 2018.

[18] MDH Contamination Control, "Cost-effective Clean Room Designs," pp. 1-4, 1992.

Literature Review

Air Flow and Particulate Requirements:

- Average air flow and particulate requirements for maintaining a Level 7 clean room
- Fan Filter Unit:
  - Placement
  - Speed of fan to area of room ratio
  - Impact on particle count
  - HEPA filter compatibility

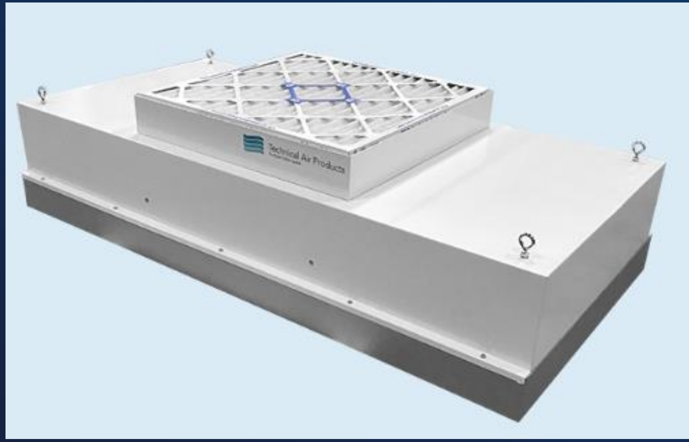


Fig. 7: Filter Fan Unit

References:

[19] "Air flow rates," Clean Rooms West, Inc., https://www.cleanroomswest.com/air-flow-rates/ (accessed Sep. 14, 2023).

[20] "ISO 7 cleanroom," ISO Class 7 Cleanrooms | Cleanroom ISO 7 Specifications, https://www.cleanairproducts.com/resources/industry-standards/iso7#:~:text=ISO%207%20Cleanroom%20Quality%20%26%20Standard%20Requirements&text=An%20ISO%207%20or%20Fed,%E2%89%A55%20%C2%B5m%20sized%20particles. (accessed Sep. 14, 2023).

[21] Captive Air Industries, "Designing Air Flow Systems," Air Flow, air systems, pressure, and Fan Performance, https://www.captiveaire.com/manuals/airsystemdesign/designairsystems.htm (accessed Sep. 14, 2023).

[22] H. Li, C. Huang, W. Yi, and C. Li, "Analysis and experiments on the characteristics of airflow and the air cleanliness protection region under fan filter units in cleanrooms," *Sustainability*, vol. 15, no. 17, p. 13268, 2023. doi:10.3390/su151713268.

[23] P. Mičko *et al.*, "Impact of the speed of airflow in a cleanroom on the degree of Air Pollution," *Applied Sciences*, vol. 12, no. 5, p. 2466, 2022. doi:10.3390/app12052466

[24] X. Shao *et al.*, "Experimental investigation of particle dispersion in cleanrooms of electronic industry under different area ratios and speeds of fan filter units," *Journal of Building Engineering*, vol. 43, p. 102590, 2021. doi:10.1016/j.jobe.2021.102590

Mathematical Modeling

Structural:

Truss analysis:

$$\sum F_y = 0, \sum F_x = 0$$

Bending:

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

$$I = \frac{bh^3}{12}$$

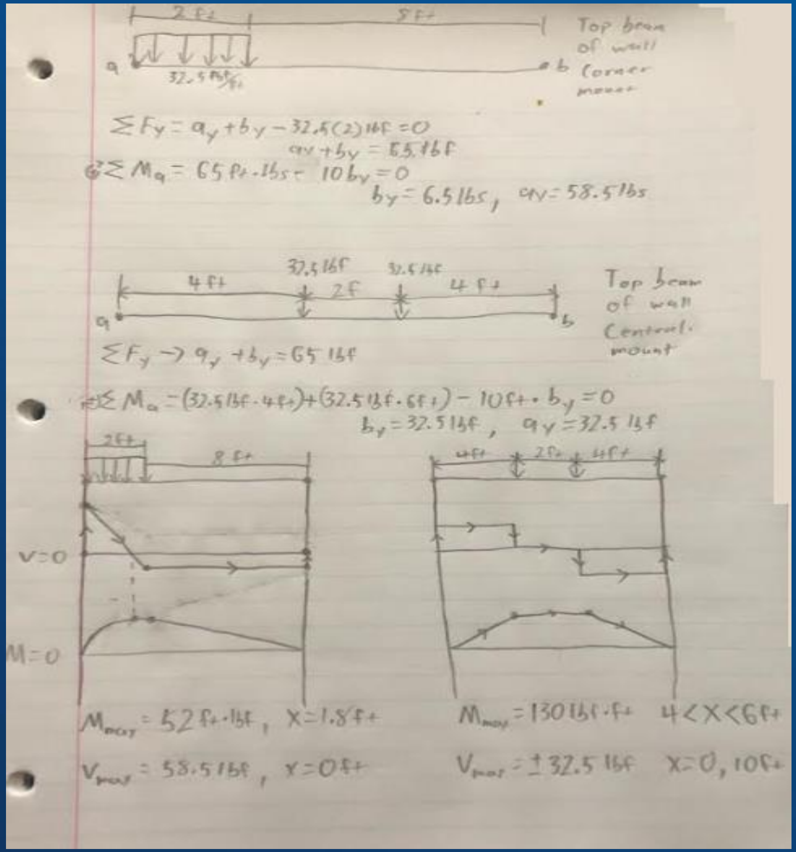


Fig. 8: Effect on moment and shear by placement of FFU

Mathematical Modeling

Material Analysis:

Stress (Normal):

$$\sigma = \frac{load}{Area} = \frac{L}{A}$$

Strain (Normal):

$$\varepsilon = \frac{Change\ in\ length}{Original\ Length} = \frac{\Delta L}{L}$$

Modulus of Elasticity:

$$E = \frac{Stress}{Strain} = \frac{\sigma}{\varepsilon}$$

Mathematical Modeling

Thermodynamics: 1st Law

$$\frac{dE_{CV}}{dt} = \dot{Q}_{CV} - \dot{W}_{CV} + \sum_i \dot{m}_i \left(h_i + \frac{{V_i}^2}{2} + gz_i \right) - \sum_e \dot{m}_e \left(h_e + \frac{{V_e}^2}{2} + gz_e \right)$$

$$\frac{dm_{CV}}{dt} = \sum_i \dot{m}_i - \sum_e \dot{m}_e$$

$$\boxed{\sum_i \dot{m}_i = \sum_e \dot{m}_e}$$

$$\dot{m} = \int \rho V_N \, dA = \rho(AV) = \frac{(AV)}{v} = \frac{\dot{\forall}}{v}$$

Thermodynamics: 2nd law

$$\underbrace{\sigma}_{\substack{entropy \\ production}} = \underbrace{\Delta S_{CM}}_{\substack{entropy \\ change \\ =0 \text{ if isentropic}}} - \underbrace{\int \frac{\delta Q_{CM}}{T}}_{\substack{entropy\ transfer \\ with\ heat\ transfer \\ =0 \text{ if adiabatic}}} \underbrace{\geq}_{\substack{=0 \text{ if reversible} \\ >0 \text{ if irreversible}}} 0$$

Mathematical Modeling

Air Flow Calculations:

- Mass Flow Rate:

$$\dot{m} = VA$$

- Reynold's Number for Laminar Flow:

$$Re = \frac{\rho V L}{\mu}$$

- Particle Count:

$$Particle\ Count = \frac{Particles}{V}$$

Schedule

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		0%	9/19/23	9/24/23
Concept Generation - Top Level		0%	9/19/23	9/24/23
Concept Generation - Sub-Assembly Level		0%	9/19/23	9/24/23
Engineering Calculations	All	0%	9/19/23	10/1/23
Concept Evaluation - Charts			9/19/23	10/8/23
Concept Evaluation - Design Summary			9/19/23	10/8/23
Concept Evaluation - CAD			9/19/23	10/8/23
Schedule - Gantt Chart			9/19/23	10/8/23
Budget			9/19/23	10/1/23
Bill of Materials		0%	9/19/23	10/8/23

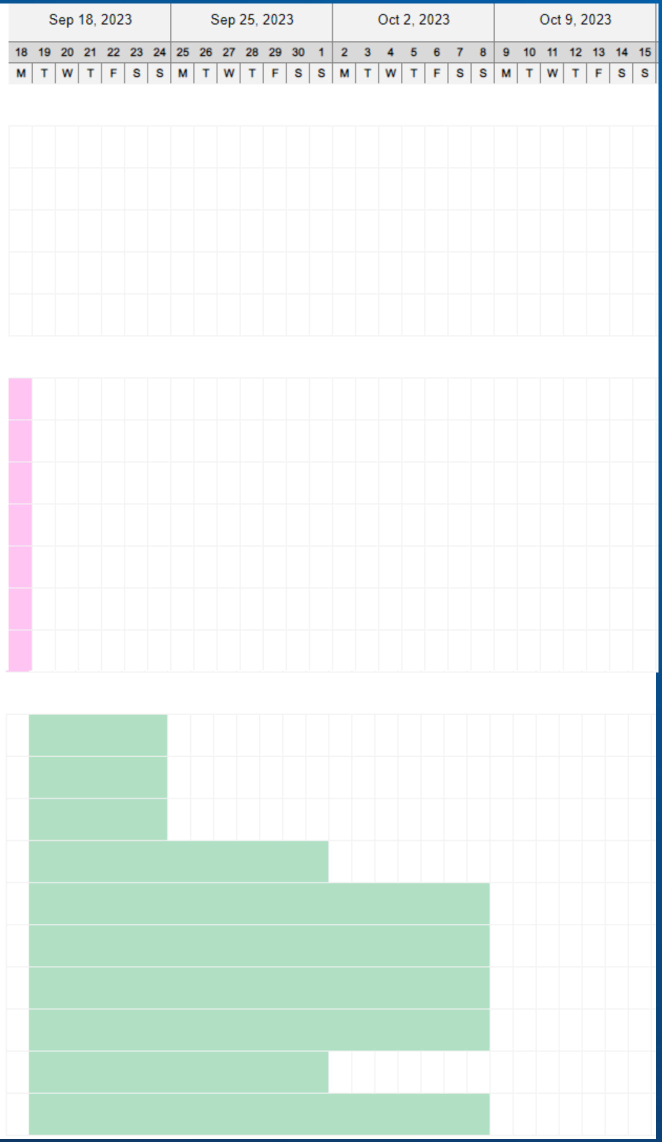


Fig. 9: Gantt Chart

Budget

Current Budget : $5K - $10K

Projected Expenses:

70%- Materials (Steel, Fans, Vinyl/Acrylic)
15%- Powder Coating
10%- Backup Battery
5%- Prototyping

10% Fundraising: Plan to reach out to other Research partners

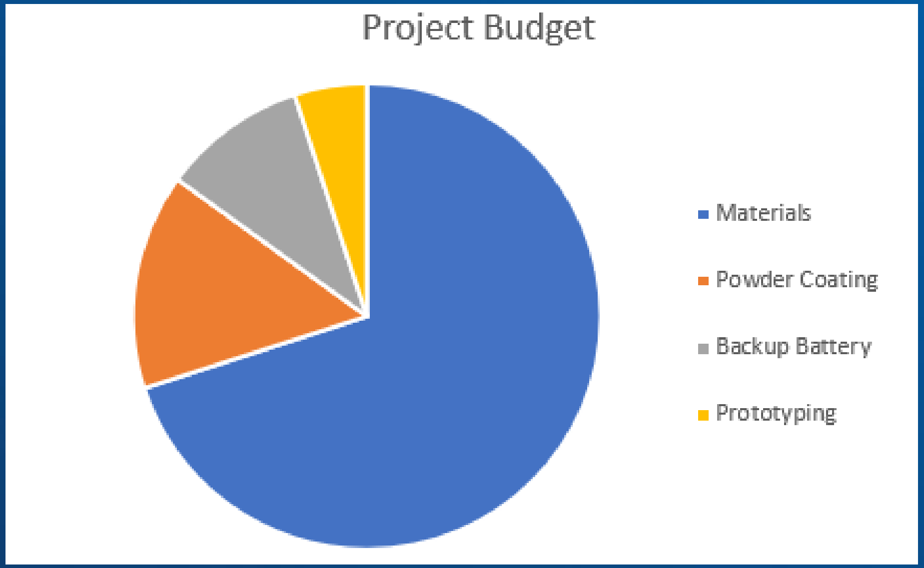


Fig. 10: Budget

THANK YOU!