Modular Sterile Cleanroom Final Testing Results and Product Demonstration

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Design Requirement Summary

Customer Requirements:

- **CR1: Modular** – can be assembled and disassembled in a business day with a small crew of people
- **CR2: Transportable** – can be transported in sections
- **CR3: Spacious** – can hold at least 6 people
- **CR4: Safe** – can support the weight of the FFUs
- **CR5: ISO Class 7 Compliant** – meets particle count, airflow, and ceiling coverage requirements.

Engineering Requirements:

ER1: Spacious – room area around 192 ft^2 (12’ x 16’)

ER2: Particle Count and Size - $< 0\mu g$ particles, < 0.5 µm particle size

ER3: Airflow - ≥ 90 ft/min, ≥ 60 air changes/hour

ER4: Ceiling Coverage - ≥ 15%

ER5: Reynold’s Number - $< 1 * 10^7$

ER6: Deflection – 0in

Top Level Testing Summary

Table 1: Test Summary

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 suit, 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

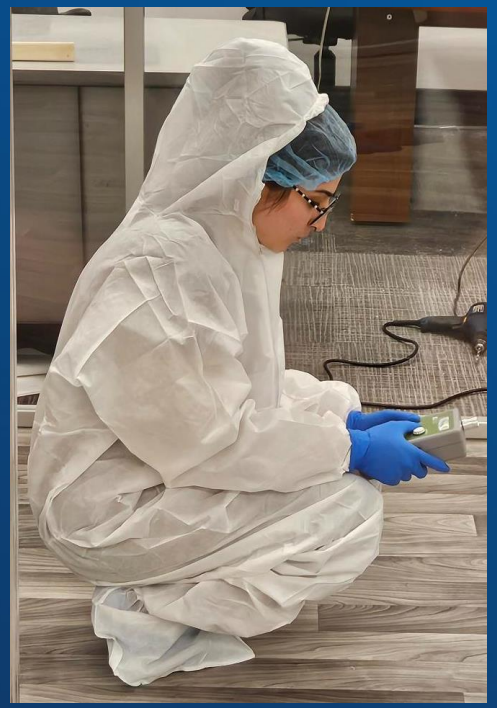
Particle Count Testing Plan

Goal:

- All particle count measurements within the acceptable range.

Procedure:

1. Obtain calibrated aerosol mass monitor.
2. Put on hair net, cleanroom suit, and sterile gloves. Enter sterilized cleanroom.
3. Test particle count in each designated quadrant and corner. For all measurements, measure at 0, 2, 4, and 6ft above the ground.
4. Record all particle counts on specification sheet.



Figures 1-2: Aerosol Mass Monitoring

Particle Count Results

Table 2: Particle Count Testing Results

Location	Height (ft)	Aerosol Mass (μg)	Average Aerosol Mass (μg)
Corner 1	0	0.0	0.0
	2	0.0	
	4	0.0	
	6	0.0	
Corner 2	0	0.0	0.025
	2	0.0	
	4	0.0	
	6	0.1	
Corner 3	0	0.0	0.0
	2	0.0	
	4	0.0	
	6	0.0	
Corner 4	0	0.1	0.025
	2	0.0	
	4	0.0	
	6	0.0	
Center Quadrant 1	0	0.0	0.0
	2	0.0	
	4	0.0	
	6	0.0	
Center Quadrant 2	0	0.0	0.025
	2	0.0	
	4	0.1	
	6	0.0	
Center Quadrant 3	0	0.0	0.025
	2	0.1	
	4	0.0	
	6	0.0	
Center Quadrant 4	0	0.1	0.025
	2	0.0	
	4	0.0	
	6	0.0	
Center Quadrant 5	0	0.0	0.025
	2	0.0	
	4	0.1	
	6	0.0	
Center Quadrant 6	0	0.0	0.025
	2	0.1	
	4	0.0	
	6	0.0	
Center Quadrant 7	0	0.0	0.0
	2	0.0	
	4	0.0	
	6	0.0	
Center Quadrant 8	0	0.0	0.025
	2	0.1	
	4	0.0	
	6	0.0	
Cleanroom Total Average Aerosol Mass (μg)			0.01

Modularity Testing Plan

Goal:

- Estimate assembly and disassembly time to determine if cleanroom is modular.
- Identify smaller transportable sections of design.
- Able to assemble or disassemble cleanroom in one business day.

Procedure:

1. Obtain assembly manual and all required materials.
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.
4. Assemble the ceiling in the 5 quadrants as shown. Assemble in quadrant order.
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.

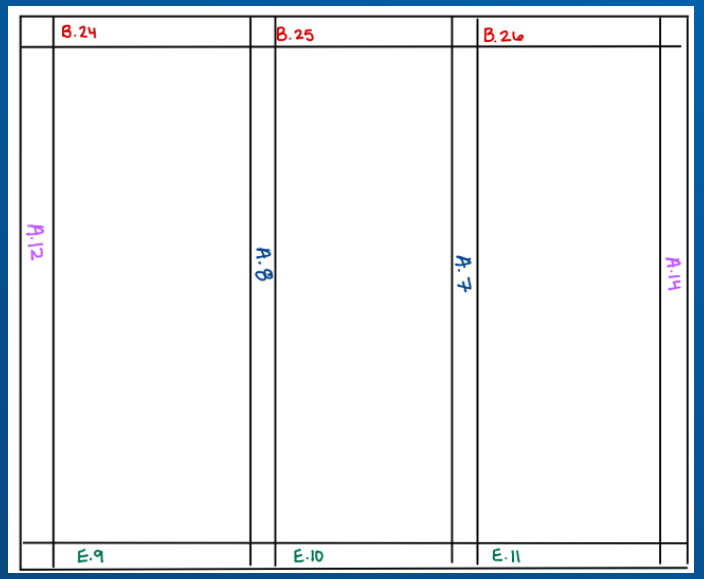


Figure 3: 12ft Wall

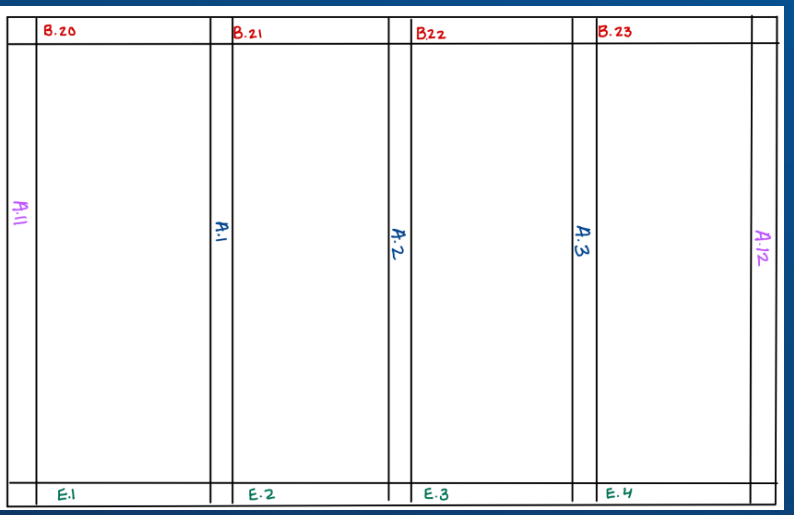


Figure 4: 16ft Wall

Modularity Results

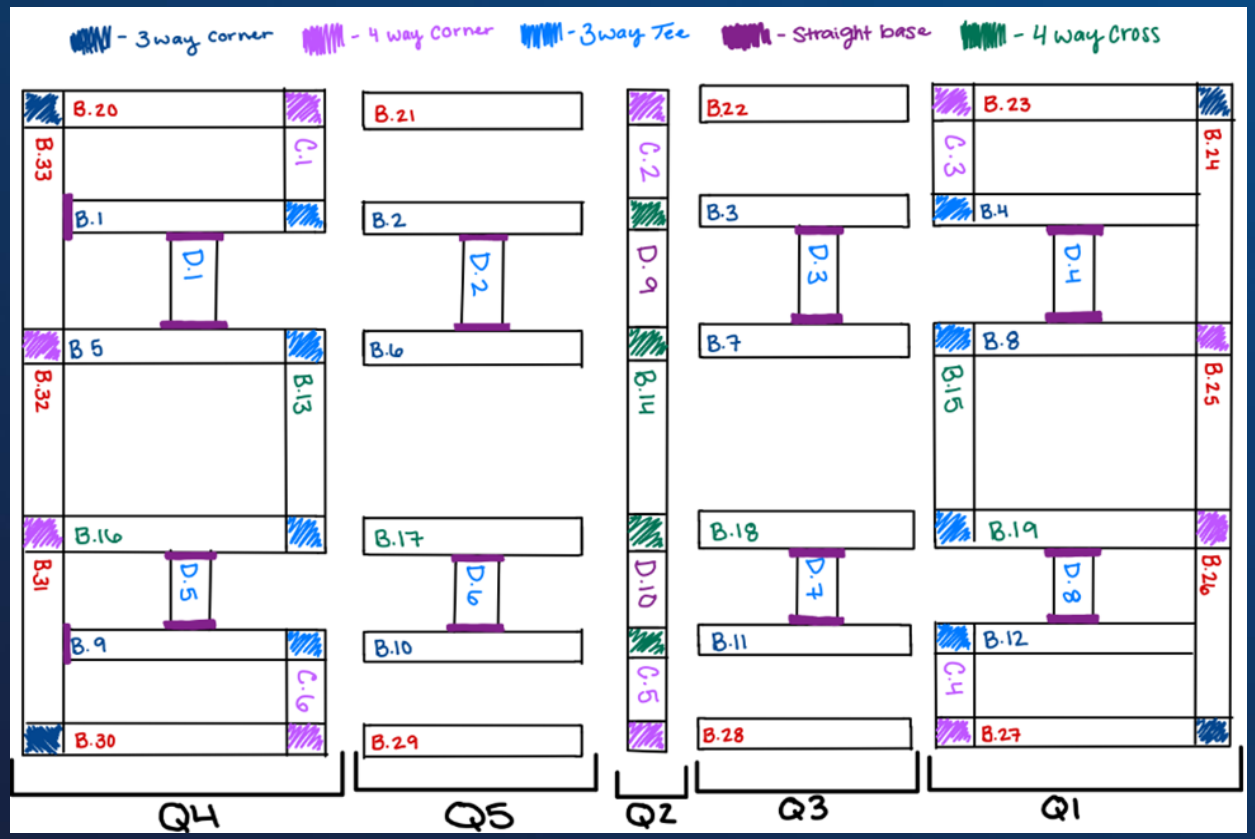


Figure 5: Ceiling Quadrants

Table 3: 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**

Deflection Testing Plan

Goal:

- Determine best support beam configuration - smallest deflection, ceiling height 90in

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

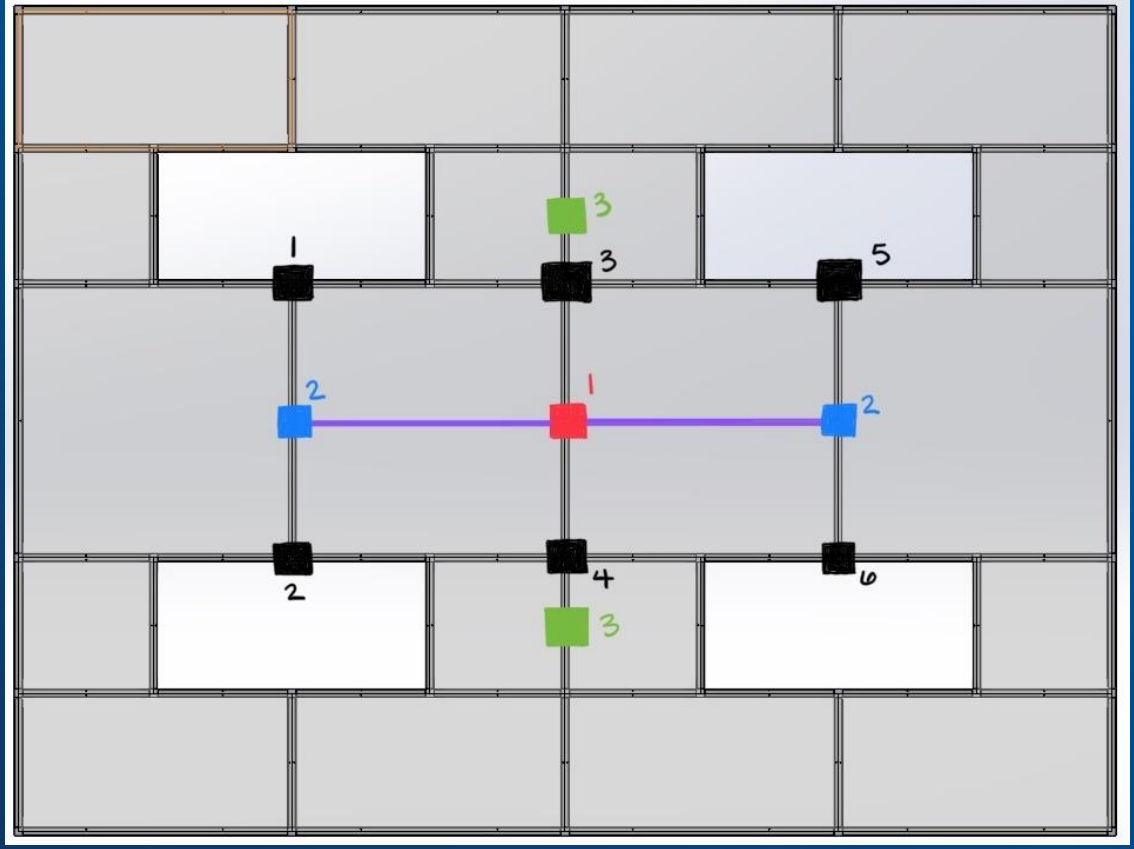


Figure 6: Deflection Points and Support Beam Configurations

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

Deflection Results

Results:

- Support Beam Config 4: 2 off center supports with a centralized ceiling beam.

Figure 7: Deflection Measurement

Table 4: Deflection Testing Results

Deflection Point	No Support Beams	Support Beam Config 1	Support Beam Config 2	Support Beam Config 3	Support Beam Config 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”

Airflow Testing Plan:

Goal:

- Average velocities >90 ft/min.
- Air changes per hour > 60.
- Reynold's Number < $1 * 10^7$

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

Figure 8: Anemometer

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

$$Air\ changes = \frac{Average\ Velocity * Outlet\ Area * 60}{Cleanroom\ Volume}$$

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

Airflow Results:

Table 5: 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	$6.58 * 10^4$
FFU 2	53	56	54.5	44	$5.43 * 10^4$
FFU 3	68	74	71	58	$7.07 * 10^4$
FFU 4	71	77	74	61	$7.37 * 10^4$
Outlet 1	105	114	109.5	89	$1.09 * 10^5$
Outlet 2	93	111	102	83	$1.02 * 10^5$
Outlet 3	92	104	98	80	$9.76 * 10^4$
Outlet 4	113	118	115.5	94	$1.15 * 10^5$
Outlet 5	126	136	131	107	$1.31 * 10^5$
Outlet 6	105	118	111.5	91	$1.11 * 10^5$
Outlet 7	119	127	123	100	$1.23 * 10^5$
Outlet 8	119	124	121.5	99	$1.21 * 10^5$
Outlet 9	108	114	111	90	$1.11 * 10^5$
Outlet 10	113	118	115.5	94	$1.15 * 10^5$
Outlet 11	108	111	109.5	89	$1.09 * 10^5$
Outlet 12	94	98	96	78	$9.56 * 10^4$
Cleanroom Averages:			100.6	81.6	$1.00 * 10^5$

Anemometer Specifications:
Accuracy: ± 5 ft/min
Resolution: 1 ft/min

Results:
- Average Velocity > 90 ft/min
- Average air changes/hour > 60
- Average Reynold's Number is laminar

Area Testing Plan and Results:

Goal: Area of the cleanroom is around 12'x16' to accommodate at least 6 people. Ceiling coverage of cleanroom is > 15%.

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.

$$A = LxW$$

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

Table 6: 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%	

Results:

- Area of the cleanroom was sufficient to hold 6 people.
- Ceiling coverage is >15%.

Specification Sheet Preparation

Table 7: Customer Requirements Summary Table

Customer Requirement	CR Met? (✓ or X)	Client Acceptable? (✓ or X)
Modular	✓	✓
Transportable	✓	✓
Spacious	✓	✓
Safe	✓	✓
ISO Class 7 Compliant	✓	✓

Table 8: Engineering Requirements Summary Table

Engineering Requirement	Target	Tolerance	Measured/ Calculated Value	ER Met? (✓ or X)	Client Acceptable? (✓ or X)
Spacious	$192\ ft^2$	$\pm 10 ft^2$	$185.4\ ft^2$	✓	✓
Particle Count	$0\ \mu g\ of\ particles\ size > 0.5\ \mu m$	N/A	$0.01\ \mu g$	✓	✓
Airflow	$> 90 ft/min,$ $> 60\ air\ changes$	N/A	$100.6\ ft/min,$ $911\ air\ changes$	✓	✓
Ceiling Coverage	$> 15\%$	N/A	15.7%	✓	✓
Reynold's Number	$< 1 * 10^7$	N/A	$1 * 10^5$	✓	✓

QFD

Updates:

- Removed ER for positive pressure

System QFD

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

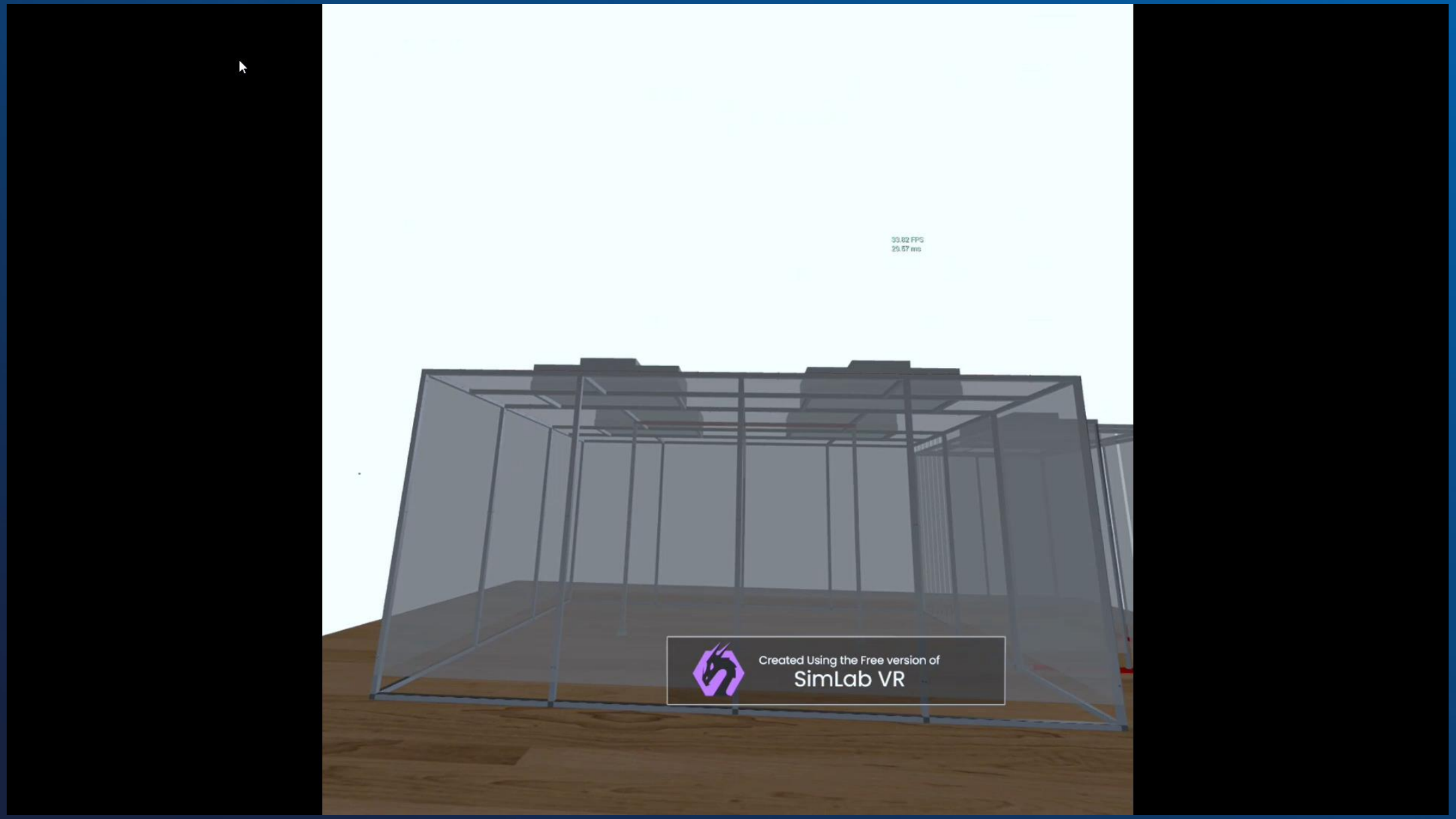
1	Room Area								
3	Particle Count	6							
4	Particle Size	6	9						
5	Airflow	6	3	3					
6	Ceiling Coverage	9	9	9	6				
	Reynold's Number	6	1	1	9	6			
7	Deflection	9				6			

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

			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 9: QFD

Product Demonstration



THANK YOU!

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