SafER Medical Products

Transient Particle Tracking with Sealed Respiratory Shield
Technical Evaluation Report
CFD Results Summary , Rev. C

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Executive Summary

Respiratory Shield System CFD Study Summary

A computational fluid dynamics (CFD) study was performed to characterize the performance of a new respiratory shield used during emergency medical service procedures. The study was intended to assess the ability of the respiratory shield in removing micron-sized water droplets that can carry pathogens when a person breathes. Minimizing the spread and exposure to emergency medical workers of these airborne pathogens is the primary goal for this new system. The suction, located at the base of the respiratory shield, creates an inwards flow of air towards the patient which removes over 93% of 0.5 micron sized particles exhaled. The remaining particles are suspended within the shield or re-inhaled by the patient. The study also showed that the intended level of medication is still delivered to the patient from the nebulizer and ventilation system with this innovative air containment system.

Presentation Outline

- CFD Modeling Goals
- Computational Software & Hardware
- Flow Path Geometry
- Computational Mesh
- CFD Model Setup & Parameters
- CFD Model Results
  - Particle Removal – Exhalation Study
  - Ventilation/Nebulizer Particles – Inhalation Study
- Summary & Observations
- Appendices:
  A. Effect of Time Step
  B. Particle Mass Flow Rate Calculations

CFD Modeling Goals

- Create a computational fluid dynamics (CFD) model of a patient breathing with a ventilation nebulizer and the new respiratory shield suction system;
- Predict the trajectories of pathogen particles exhaled by a patient with and without the respiratory shield suction system;
- Determine the sensitivity of the particle removal and particle trapping to suction sweep gas flow rate;
- Provide animations to visualize the particle trajectories for the different simulations;
- Predict the improvement in pathogen particle removal when using the respiratory shield suction system.

ANSYS CFD & Camtasia Software

(ANSYS 2020R2, Camtasia Studio 8)

- ANSYS SpaceClaim
  - Shrink wrap and convert scanned surfaces into solid components
  - Create three-dimensional fluid volume for air flow path surrounding the patient's head
- ANSYS Fluent Meshing
  - Polyhedral-shaped mesh elements
- ANSYS Fluent
  - CFD solver
- ANSYS CFD-Post
  - Post processing and visualization of CFD solutions
- TechSmith Camtasia
  - Creating animations from Fluent PNG image files

SimuTech Computing Resources

STG-Central-4

- Dell Precision Tower T7810 Workstation
- Dual Intel Xeon (R) CPU E5-2680 v4 @2.40GHz 128 GB RAM
- 28 processors
- Windows 10 Pro

STG-Central-5

- Dell Precision T7920 Workstation
- Dual Intel Xeon Gold (R) 16 core CPUs 6130 @3.70GHz, 256 GB RAM
- 32 processors
- Windows 10 Pro

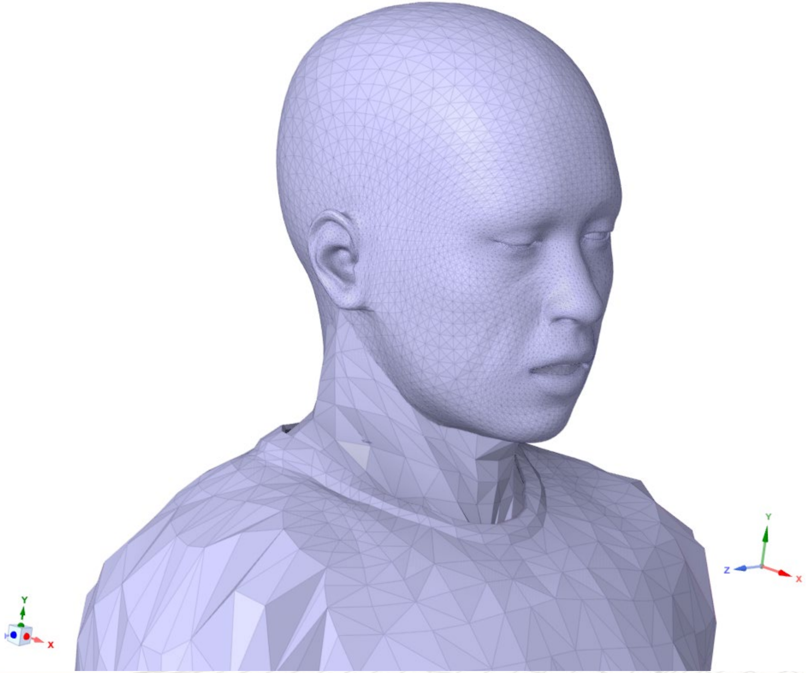
Flow Path Geometry
Air Volume Surrounding Patient's Head

Geometry Files
(images on following slides)

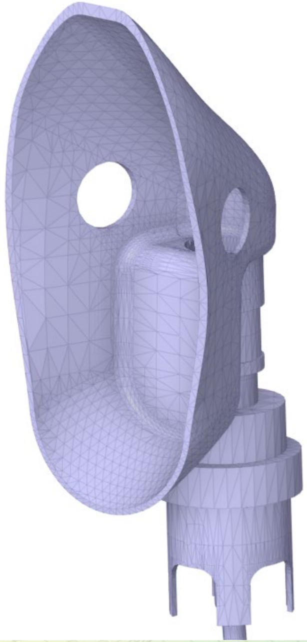
- Person: figure.obj (3/4/21)
- Nebulizer and mask: nebulizer.obj (3/4/21)
- Respiratory shield: 1119-0094.STEP (3/9/21)
- Nebulizer insert: Modified Nebulizer assembly.STEP (4/9/21)
- Upper mask seal: airflow blocker.stp (4/12/21)
- Lower mask seal: airflow blocker bottom.stp (5/5/21)

Geometry Images
(not to scale)

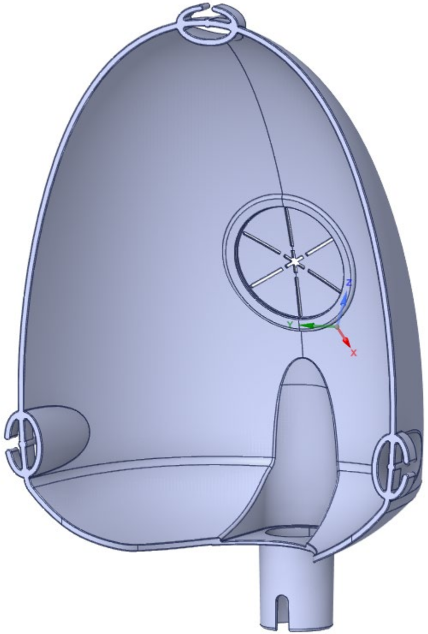
Person



Nebulizer & Mask



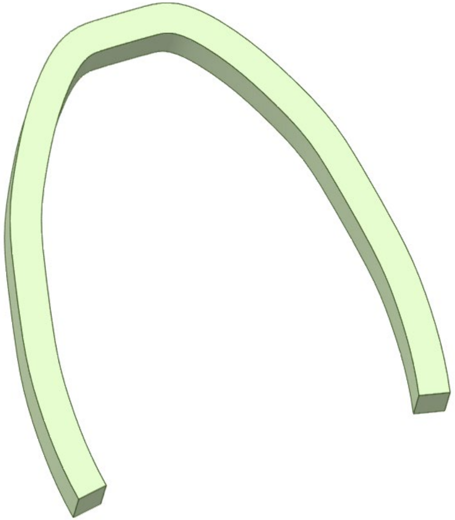
Respiratory Shield



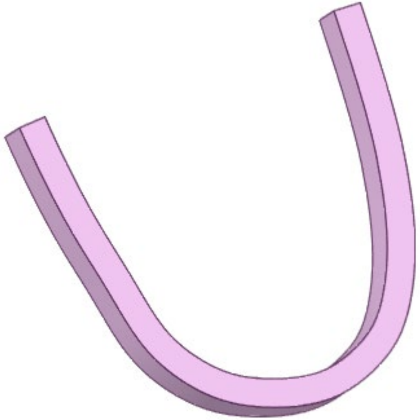
Geometry Images (cont')
(not to scale)

Modified Nebulizer Insert

Upper Mask Seal



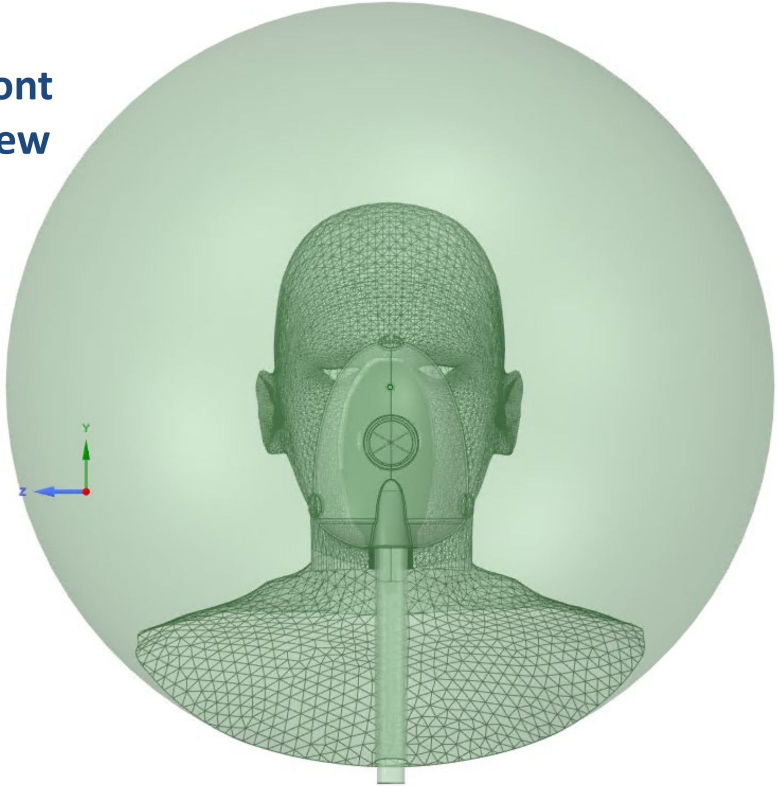
Lower Mask Seal



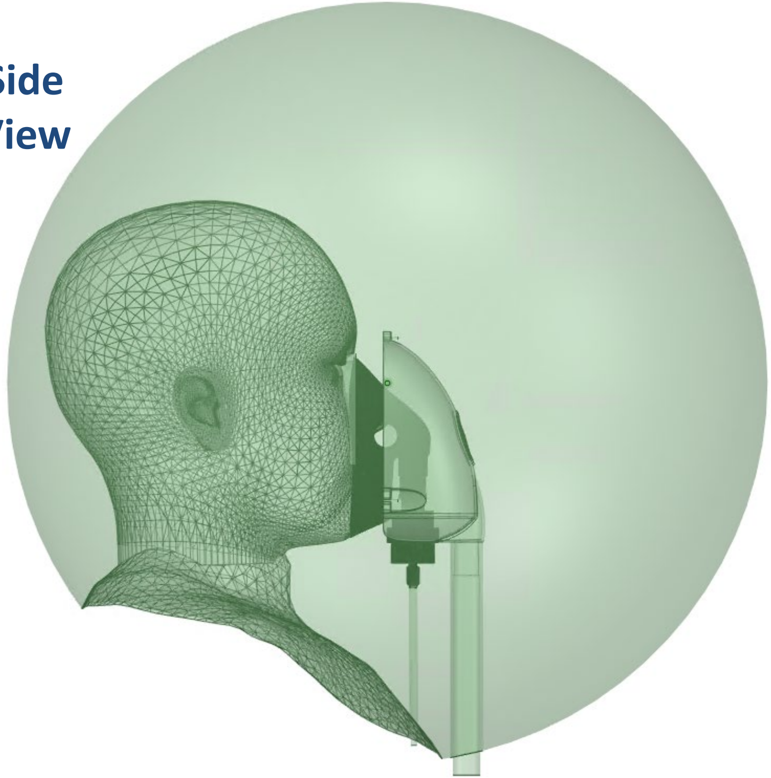
CFD Model

Air Surrounding Patient's Head

Front View

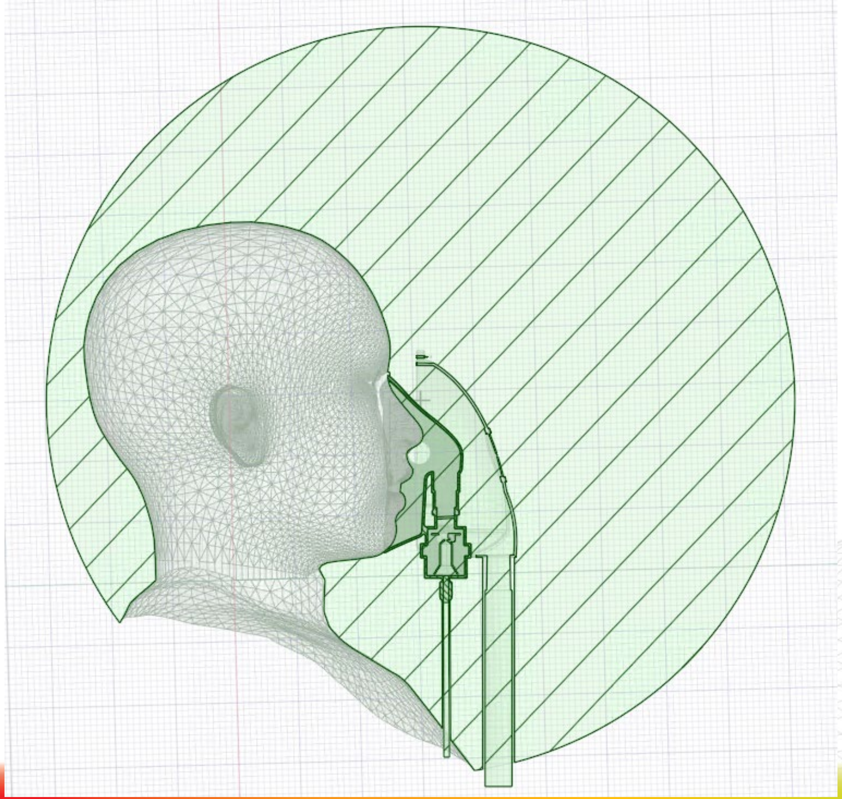


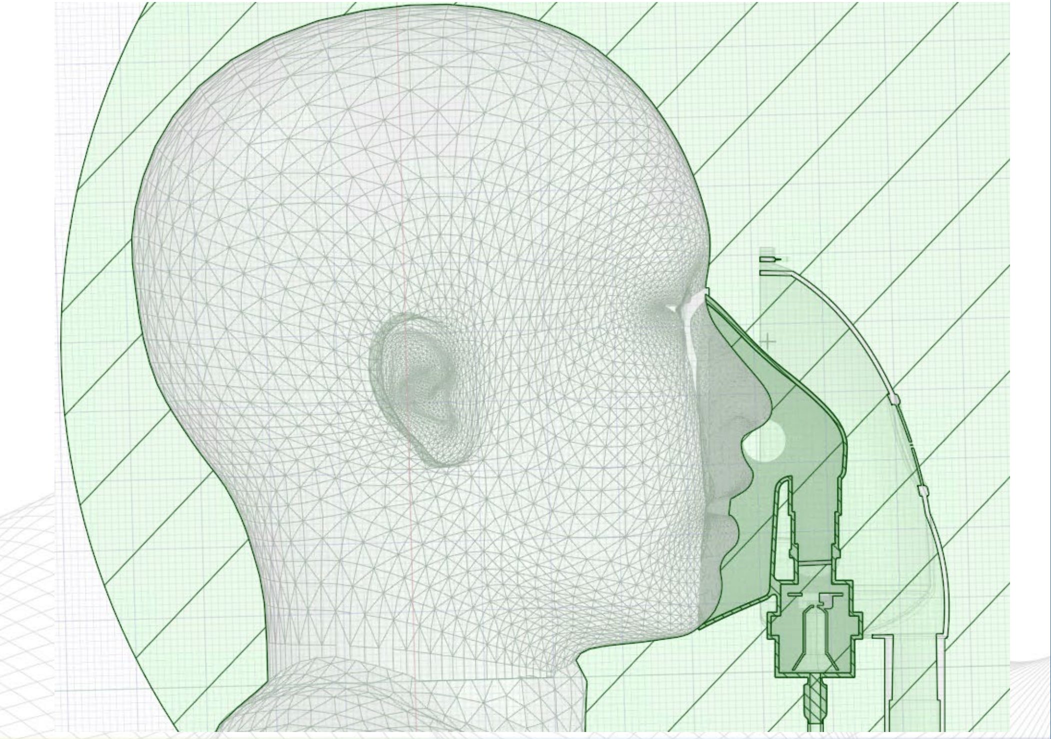
Side View



CFD Model

Cross-Sectional Views

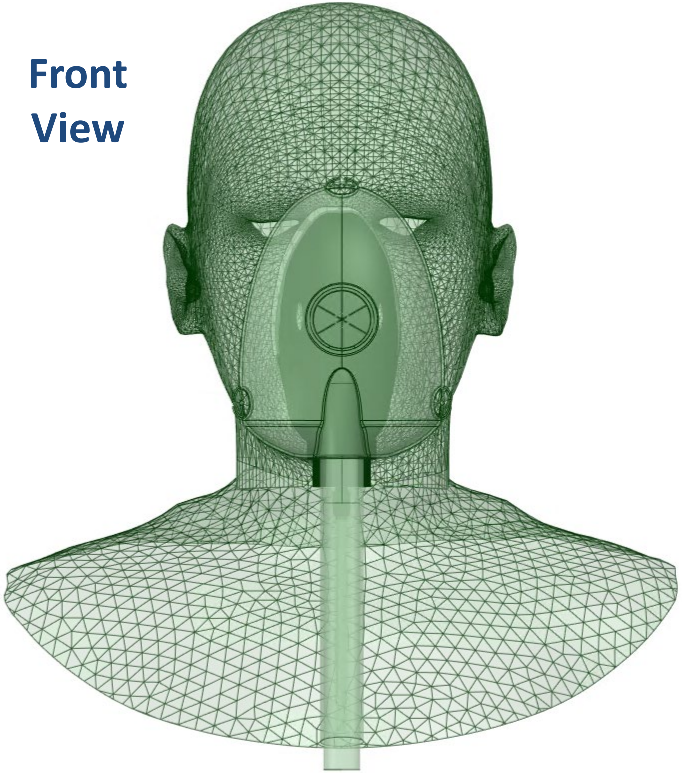




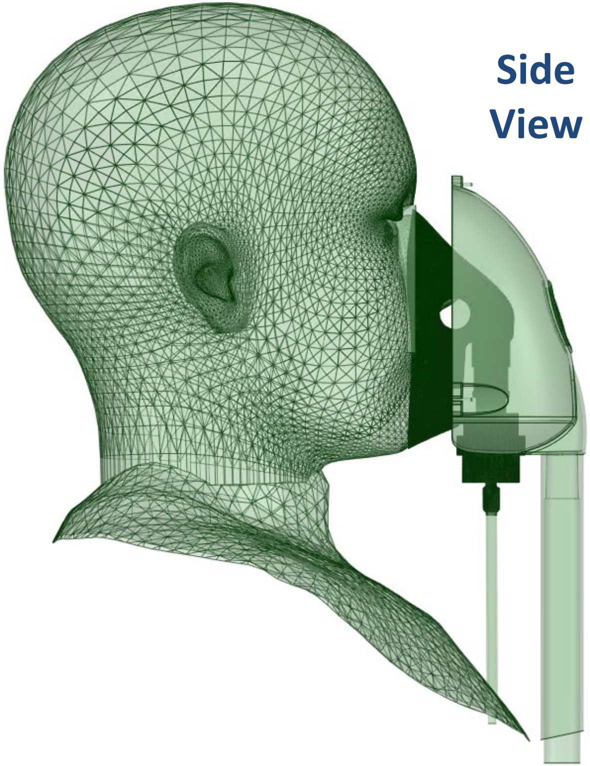
CFD Model

Mask & Respiratory Shield Placement

Front View

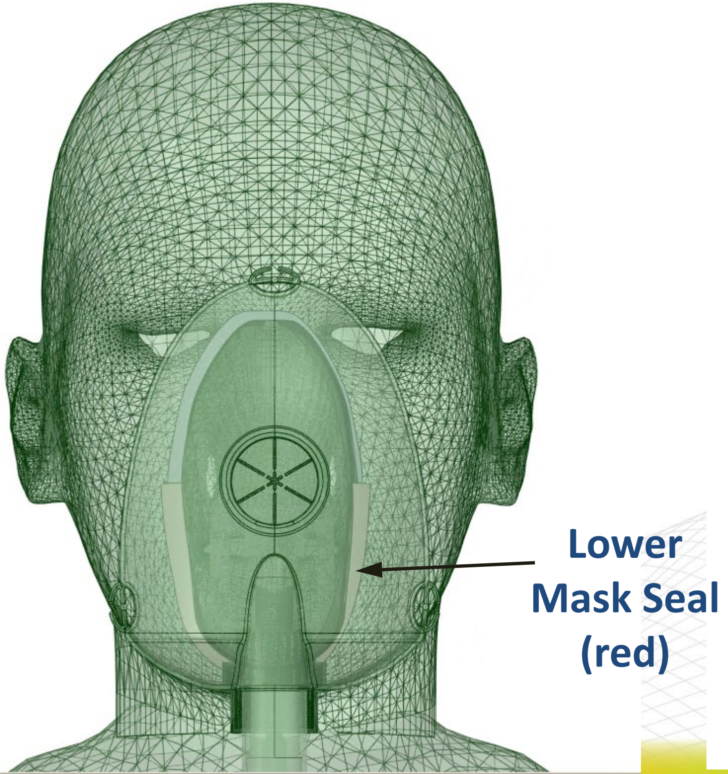


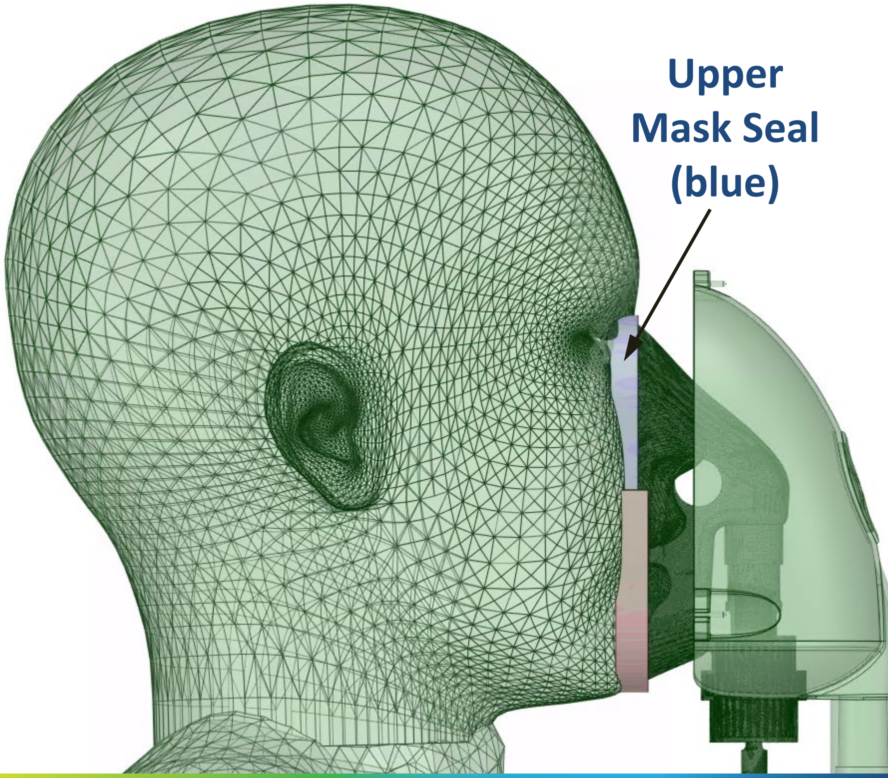
Side View



CFD Model

Upper and Lower Mask Seals

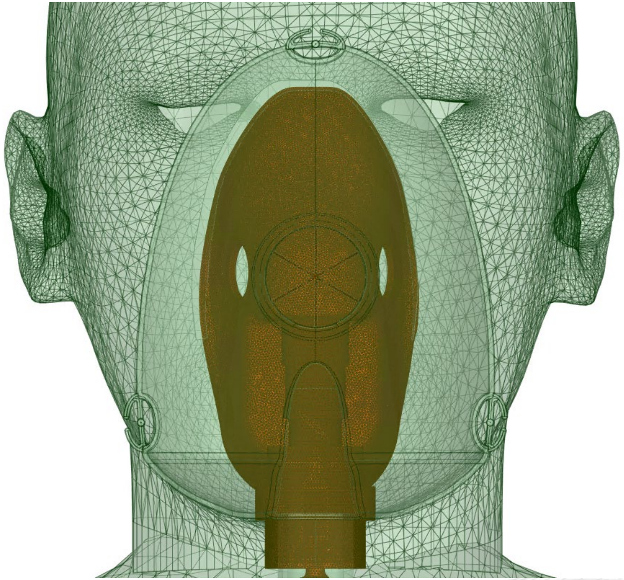




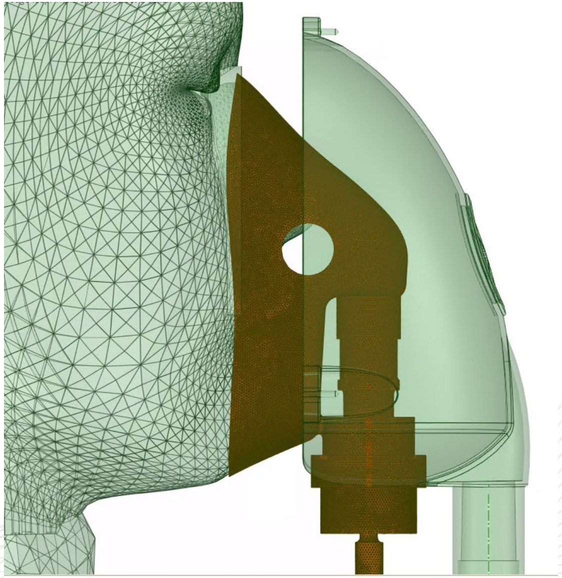
CFD Model – Three Views

Mask & Respiratory Shield Placement

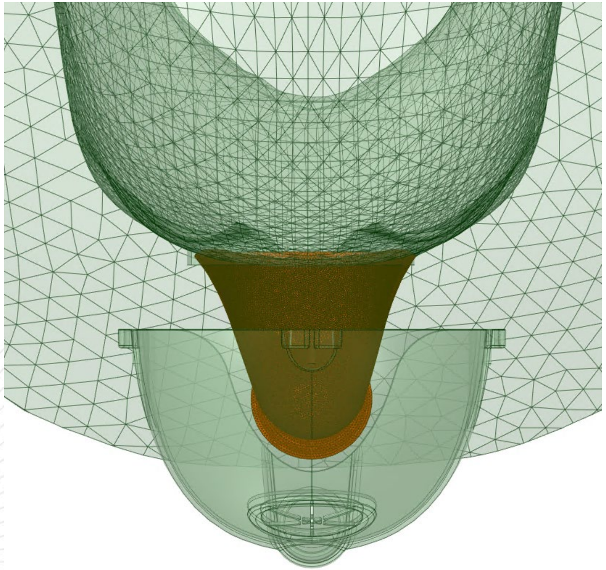
Front View



Side View



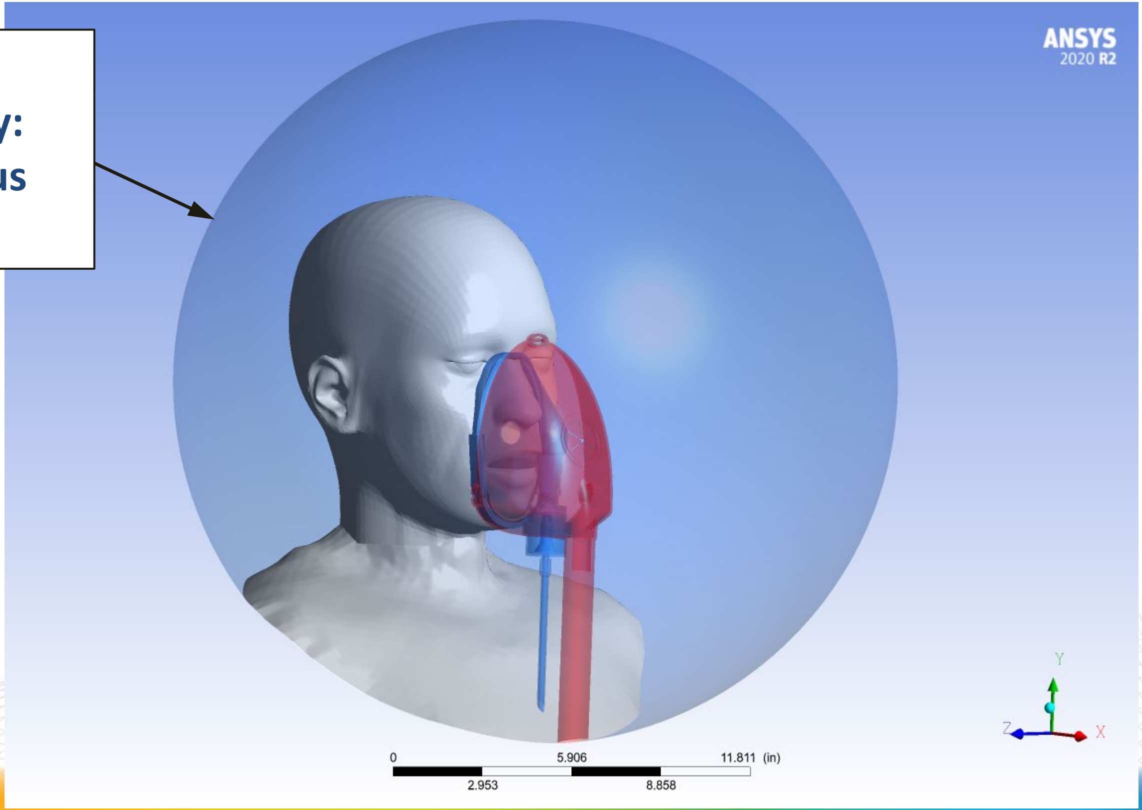
Top View



CFD Model

Air Surrounding Patient's Head

Outer Boundary: 12" Radius Sphere



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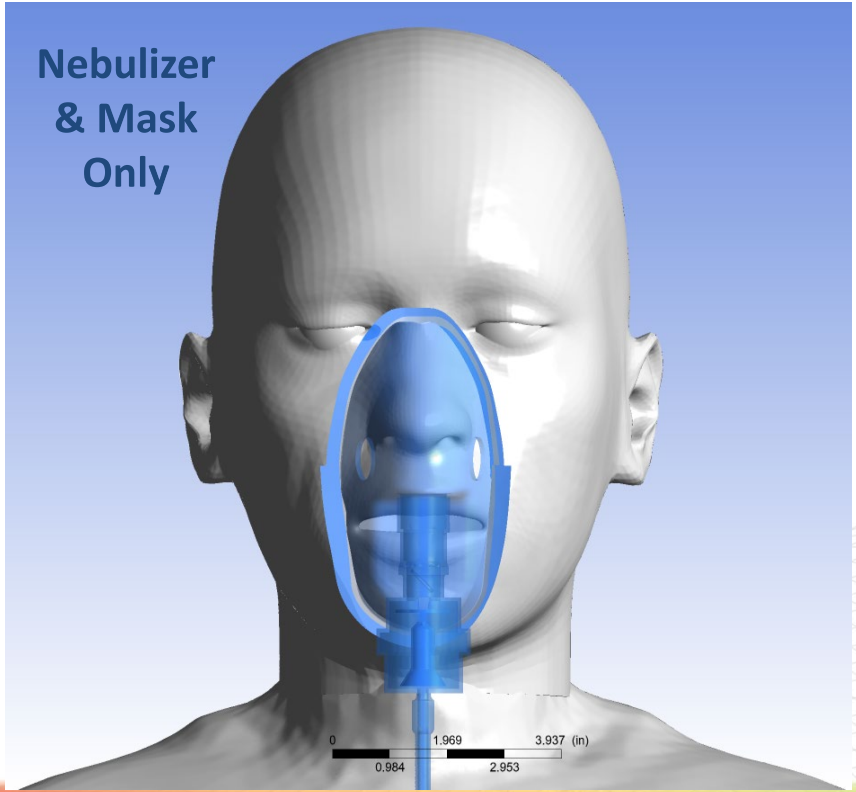
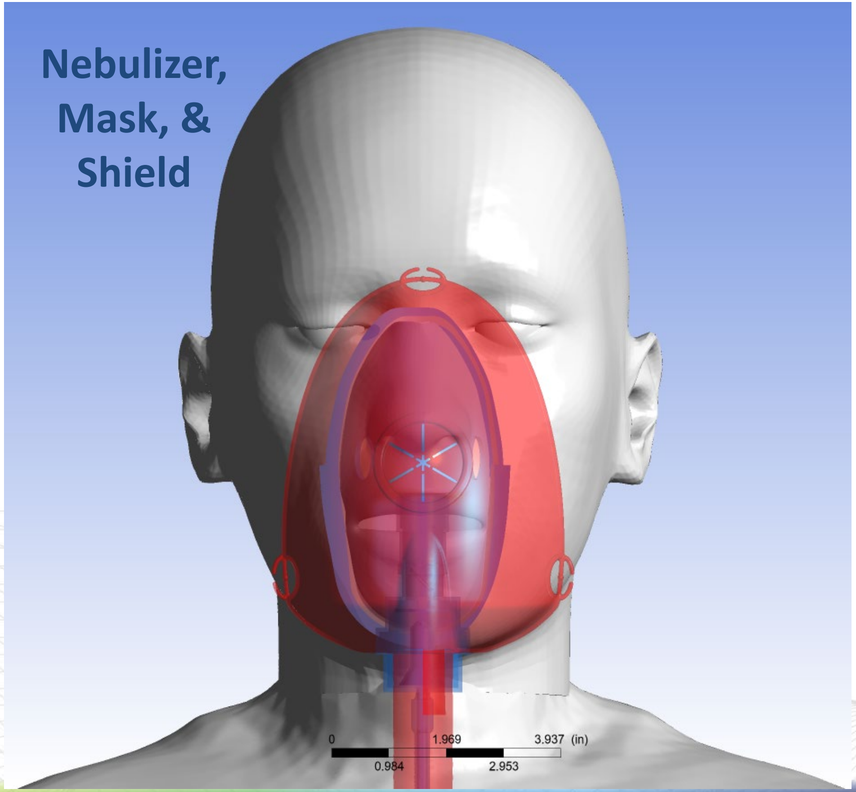
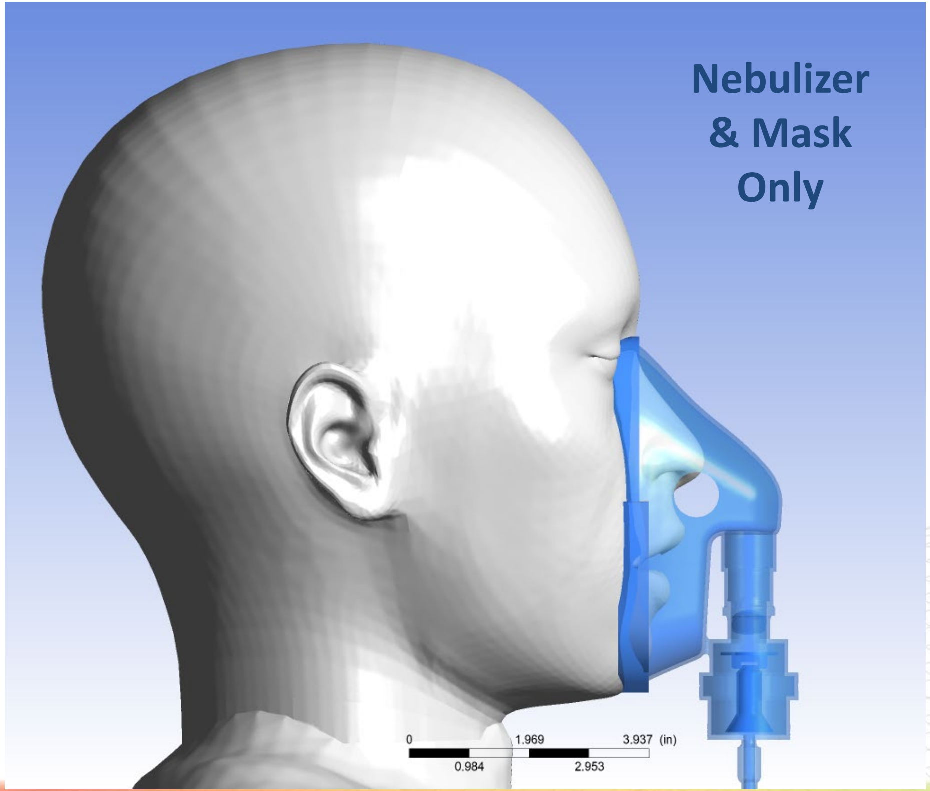
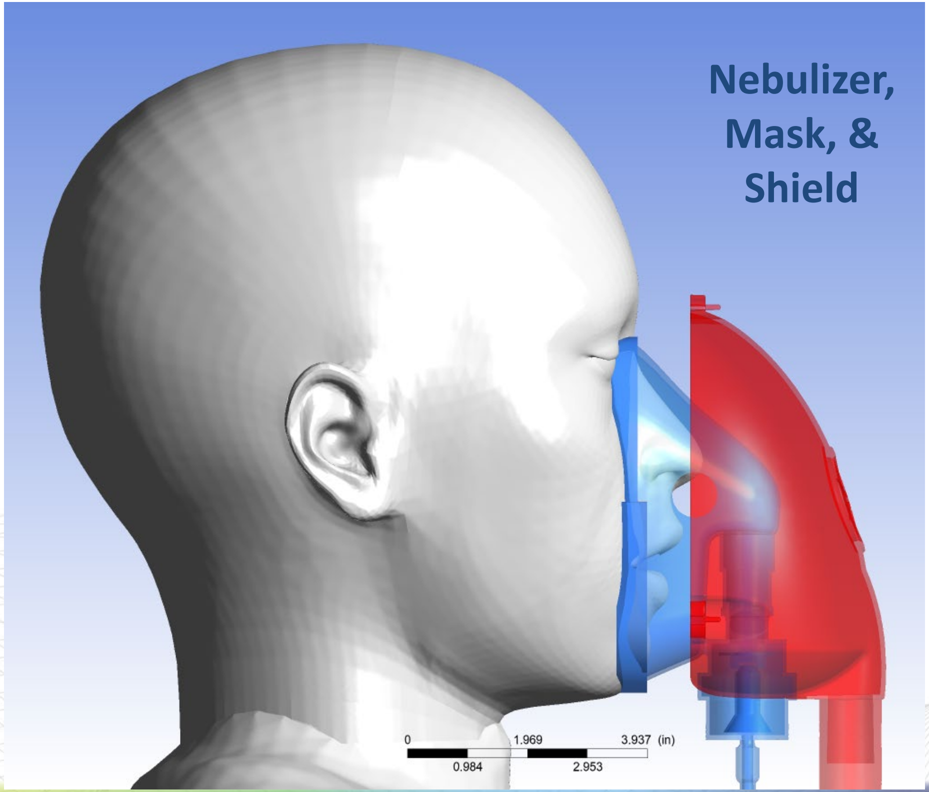
CFD Model – Front View



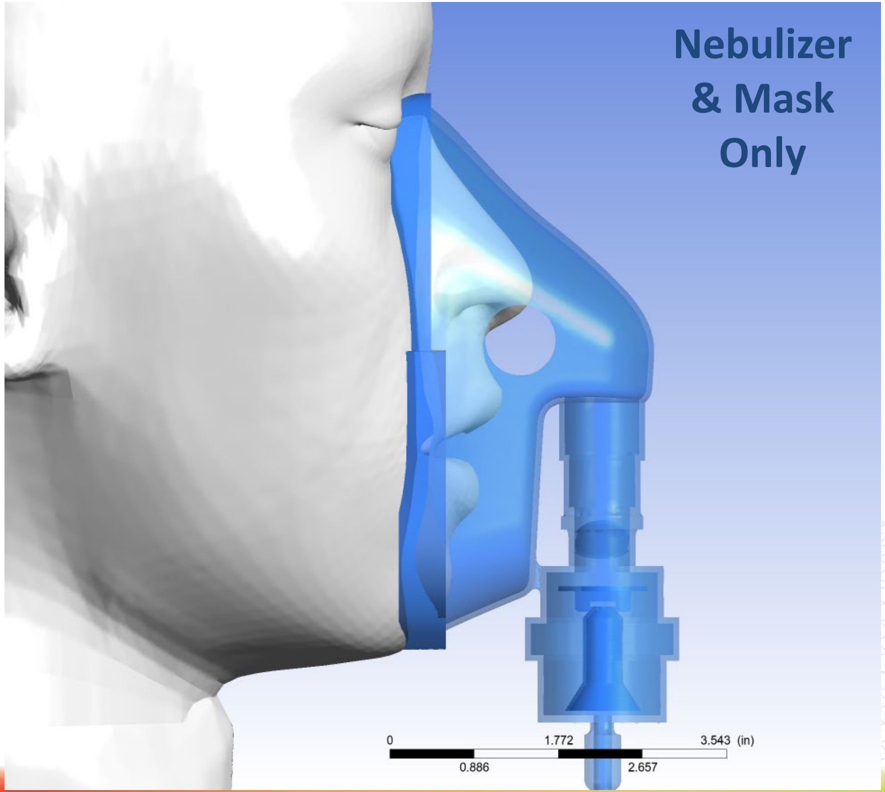


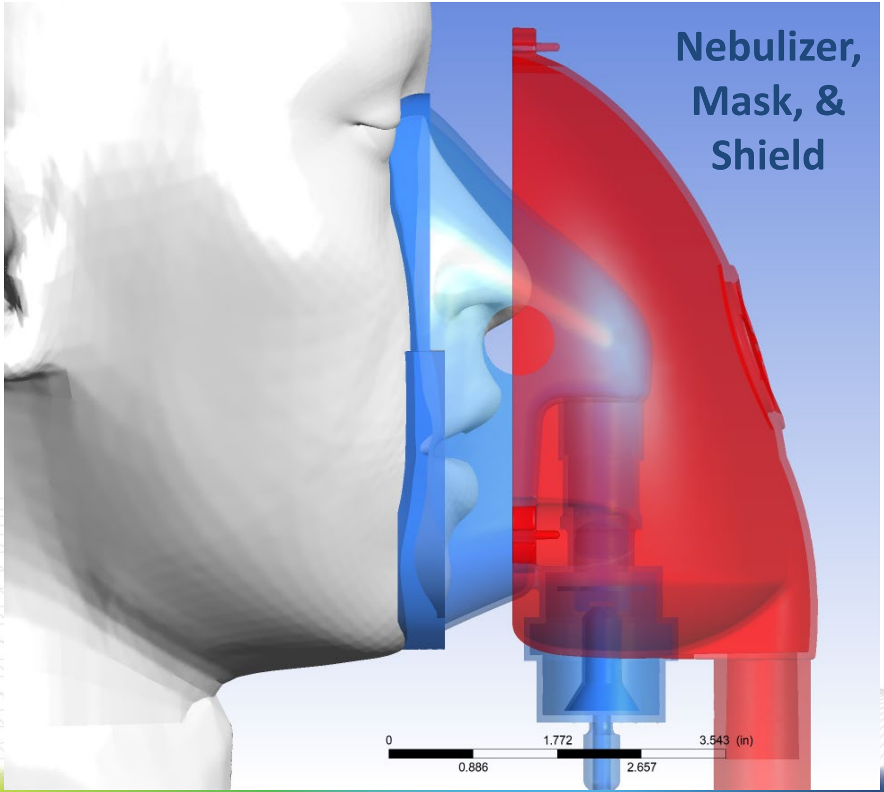
CFD Model – Side View



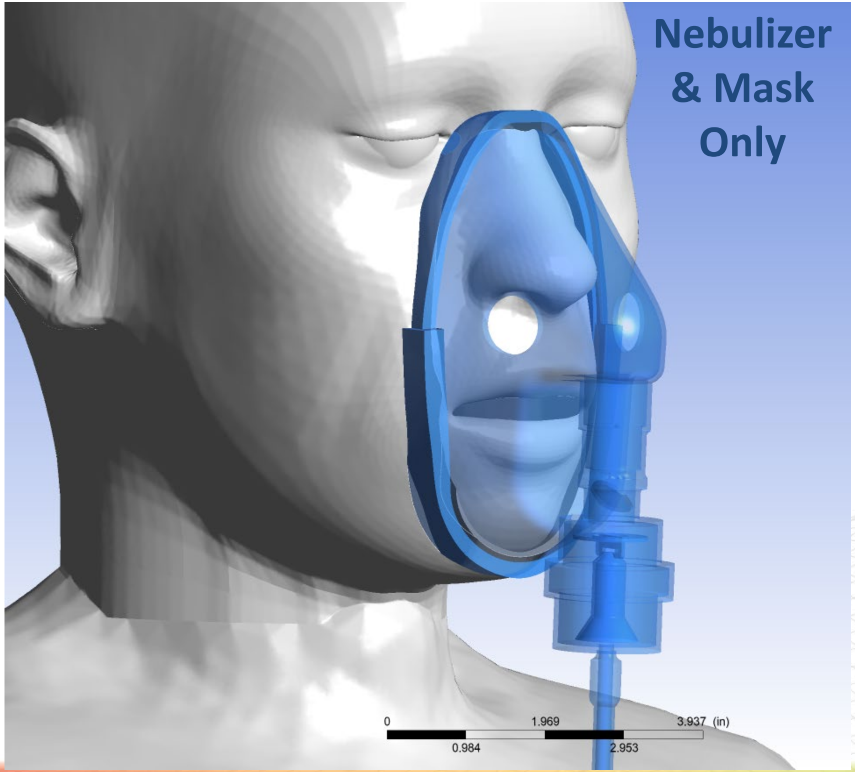


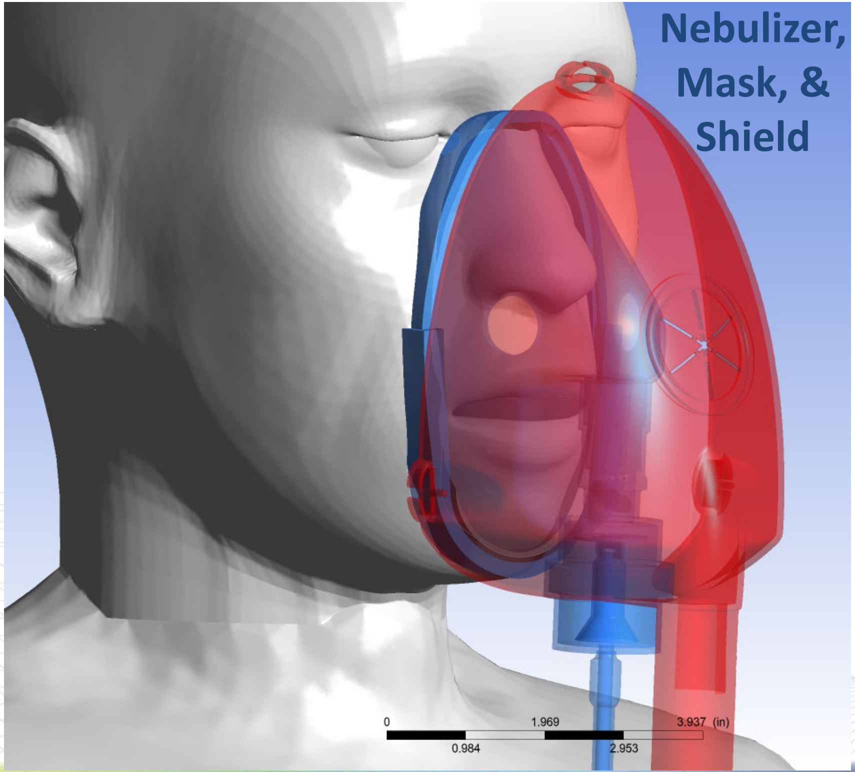
CFD Model – Side View Zoom





CFD Model – Iso-Metric View



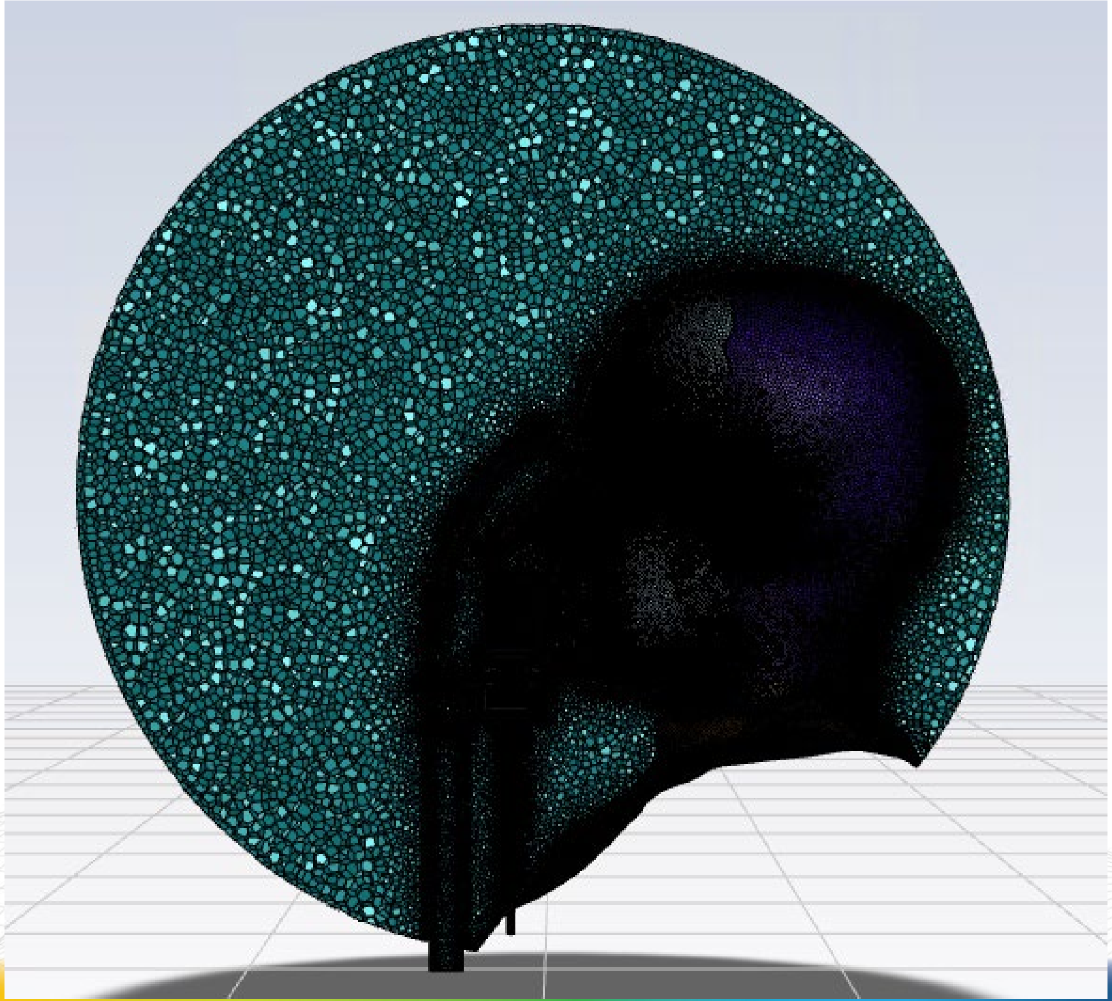


Computational Mesh

Fluent Meshing

- Watertight Geometry Meshing
- Surface element sizing:
  - Minimum size = 5.0e-04 m
  - Maximum size = 1.0e-02 m
- Curvature & Proximity
  - Curvature normal angle = 15°
  - Proximity, minimum number of elements in gaps = 3
- Boundary layers
  - Number of boundary (inflation) layers = 6
  - Smooth transition
- Volume element sizing:
  - Maximum cell length = 1.0e-02 m
- Total number of polyhedral volume elements = 5.84 M elements

Computational Mesh
(Cross-Sectional View)



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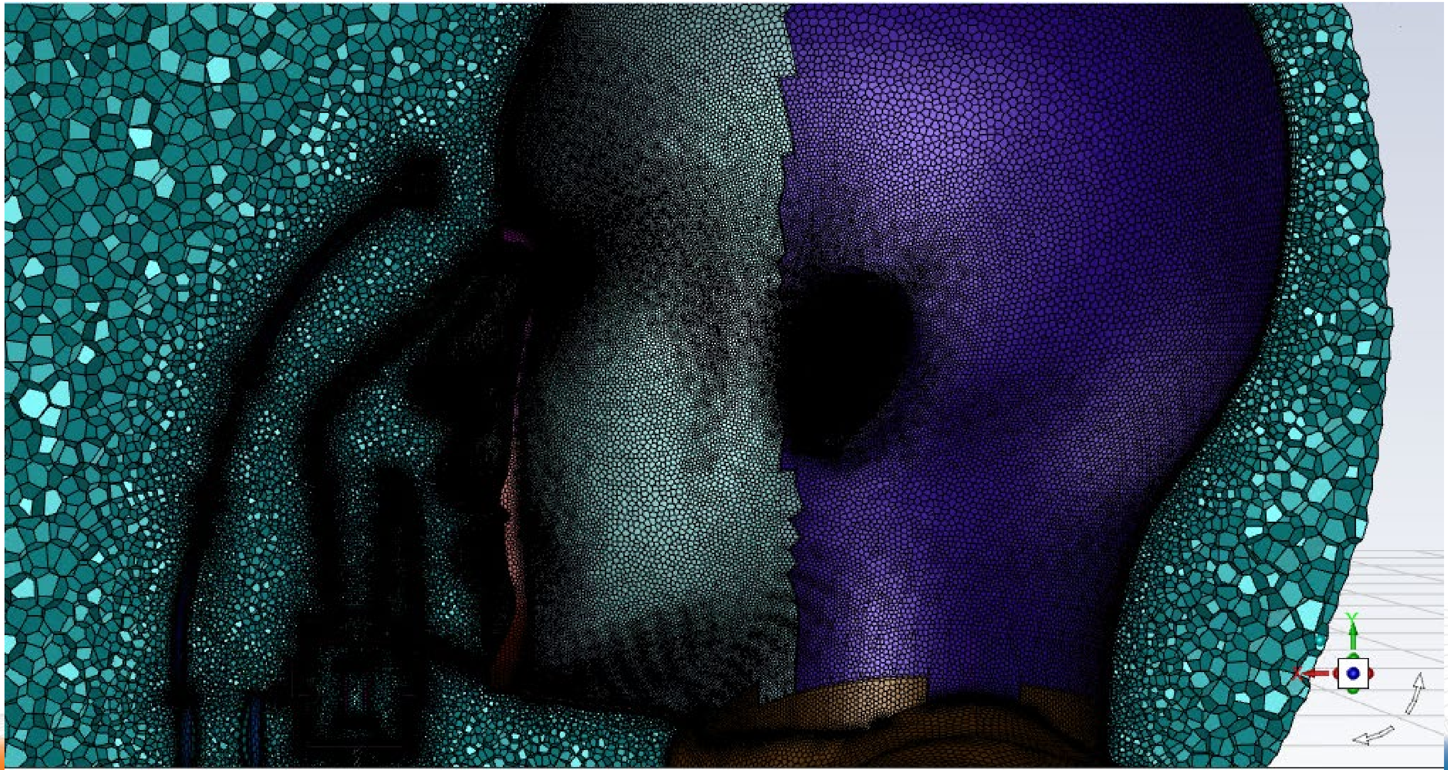
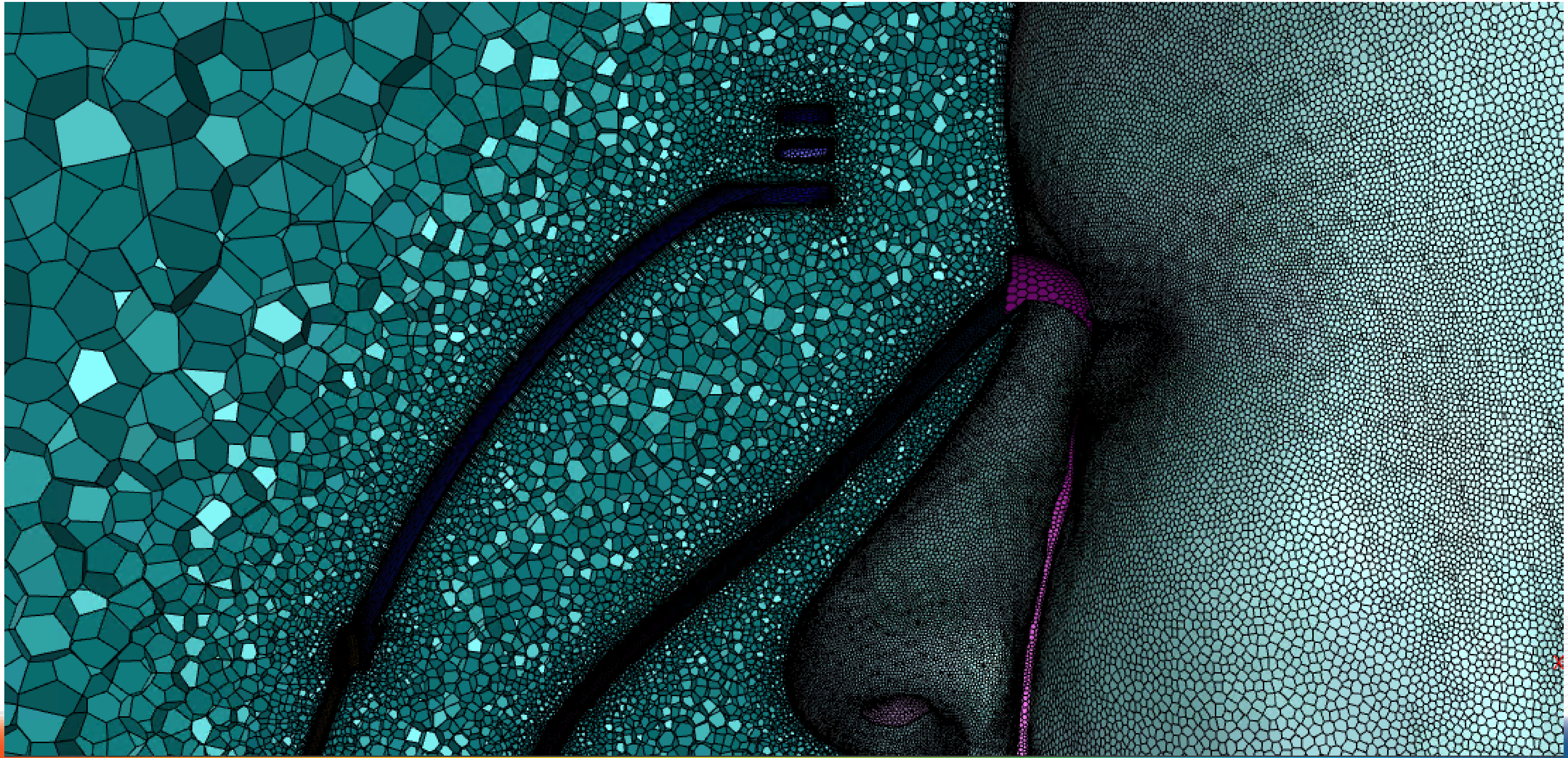
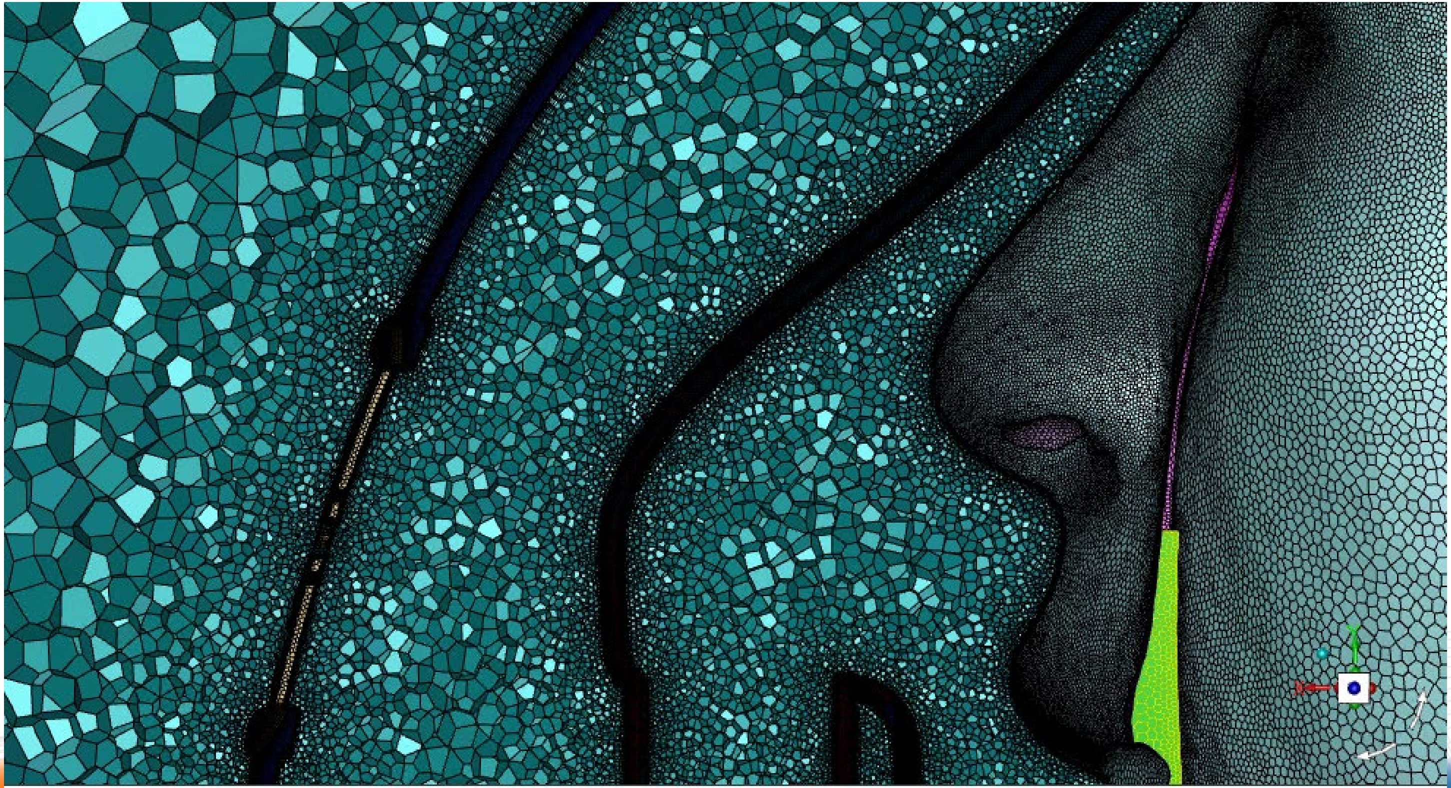
Computational Mesh - Zoom
(Cross-Sectional View)



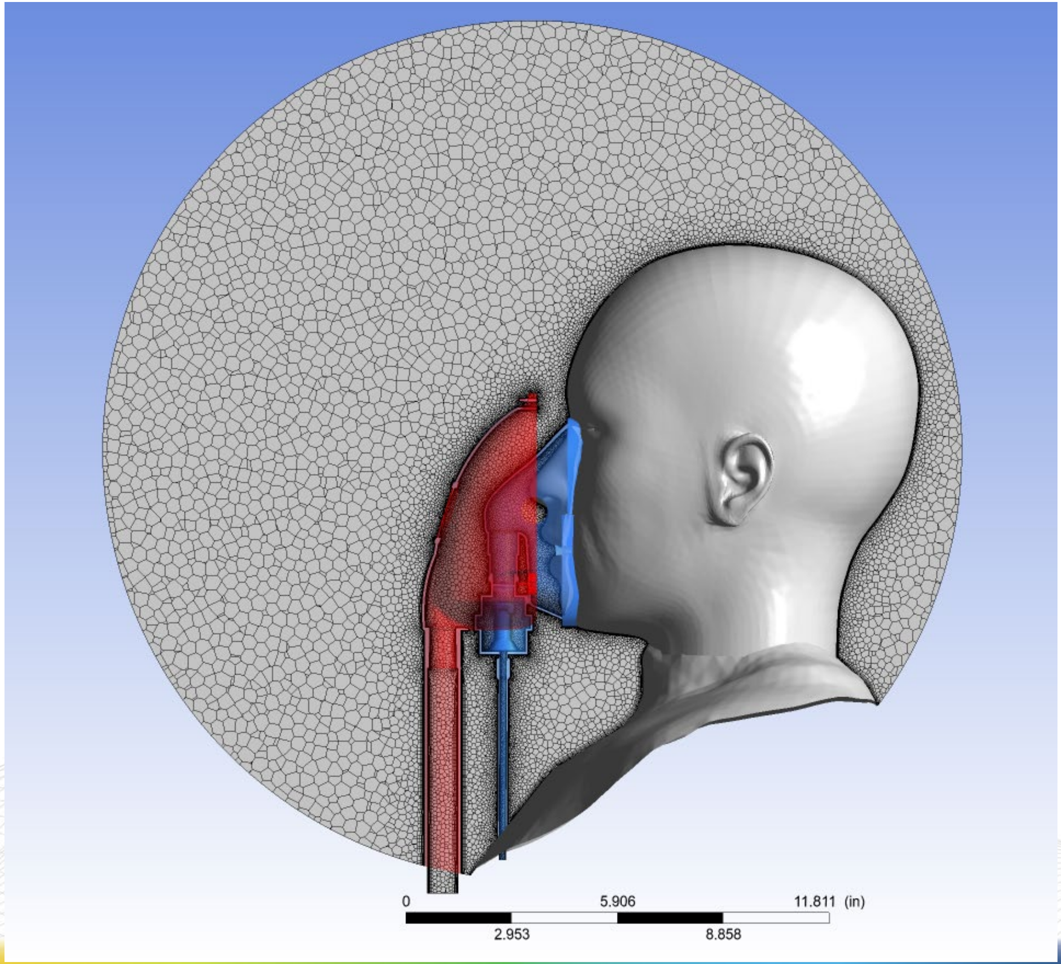
Computational Mesh – Eyes Region Zoom
(Cross-Sectional View)



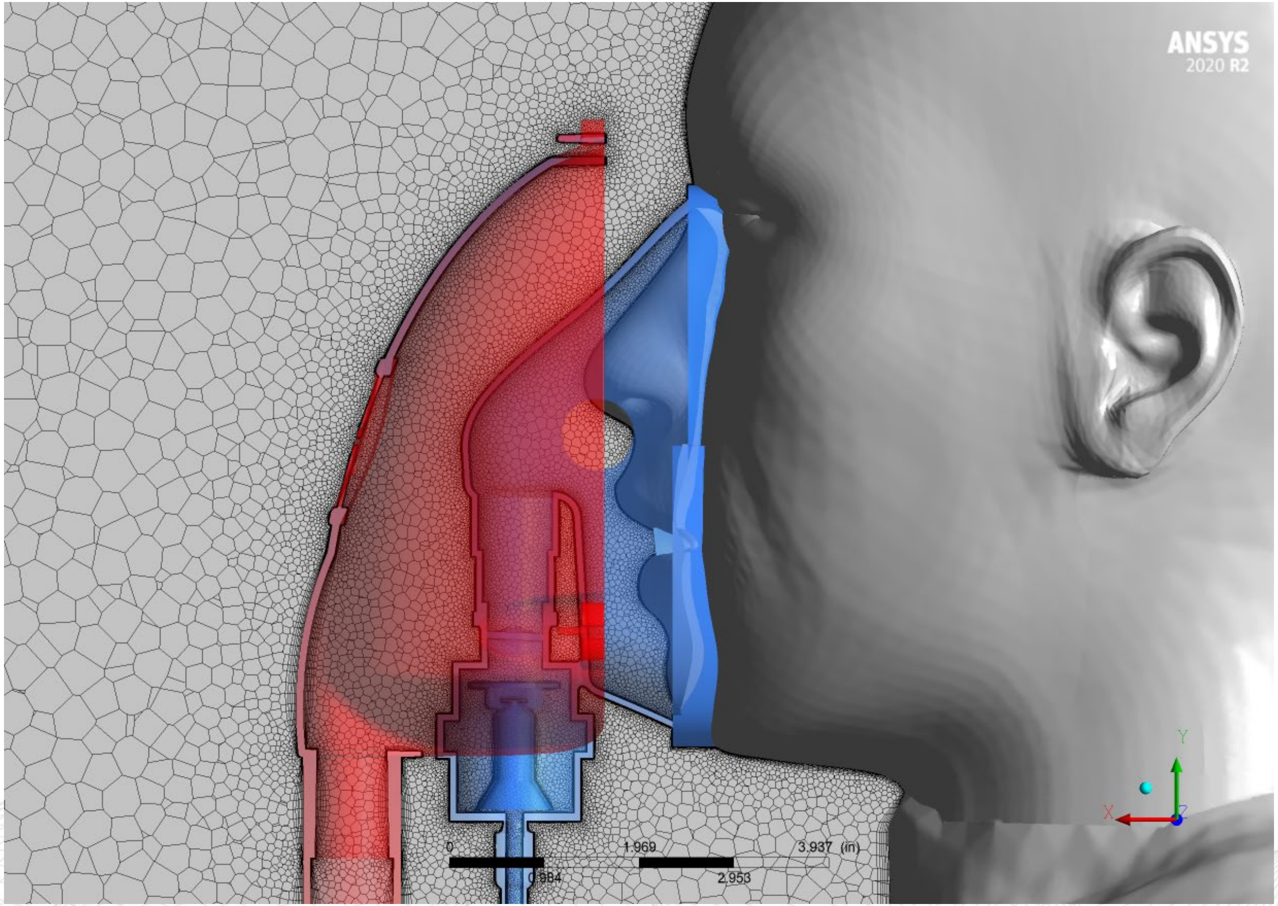
Computational Mesh – Nose Region Zoom
(Cross-Sectional View)



Computational Mesh
(Cross-Sectional View)



Computational Mesh – XY Plane (Cross-Sectional View)



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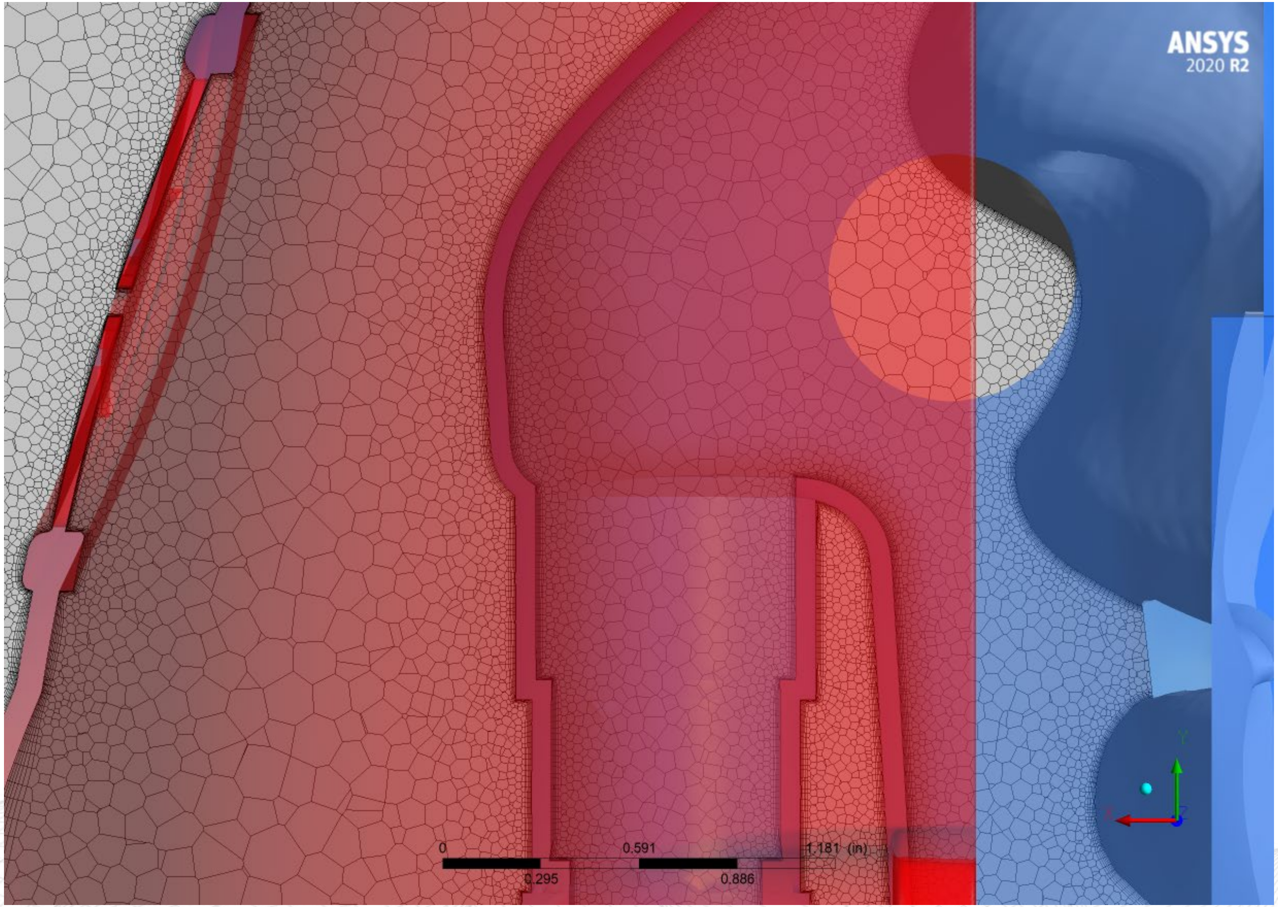
Computational Mesh – XY Plane Mouth Region
(Cross-Sectional View)



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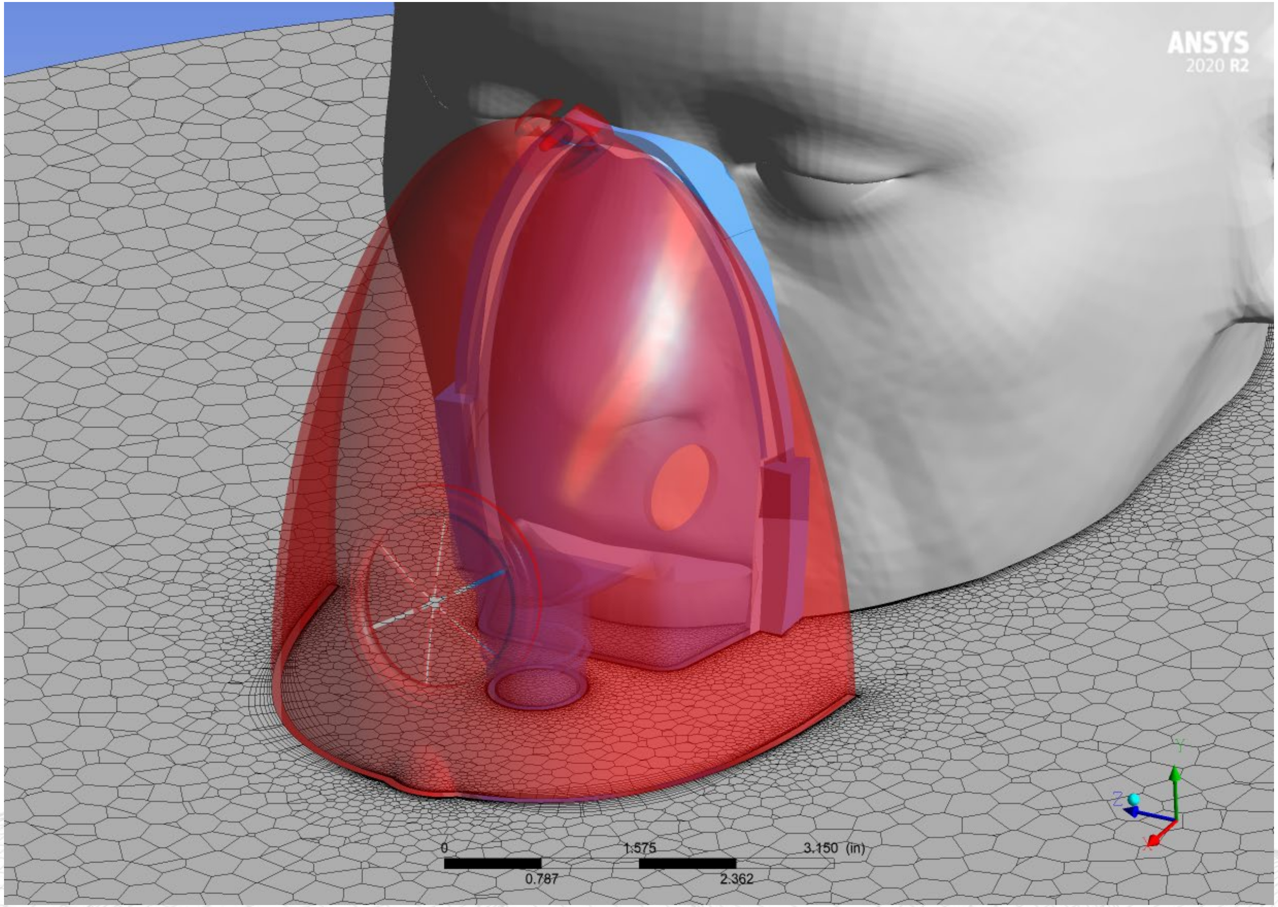
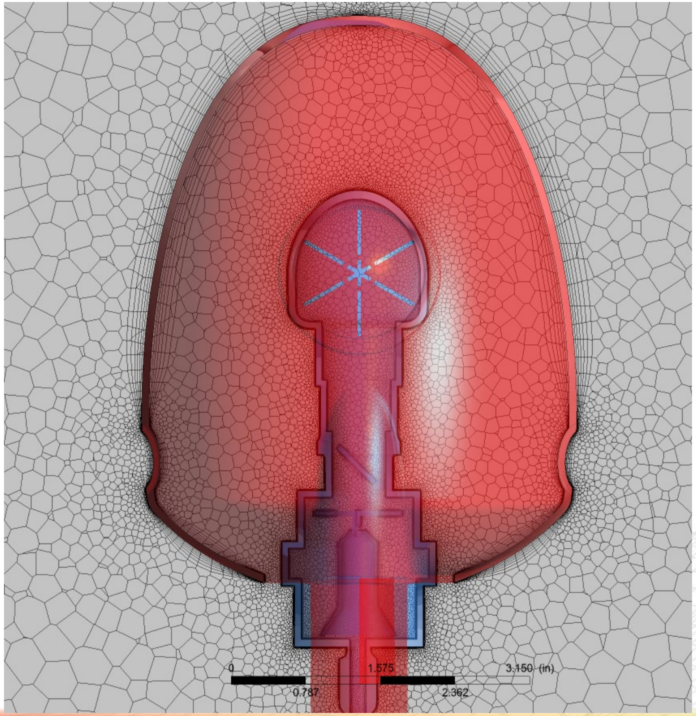
Computational Mesh - XZ Plane
(Cross-Sectional View)

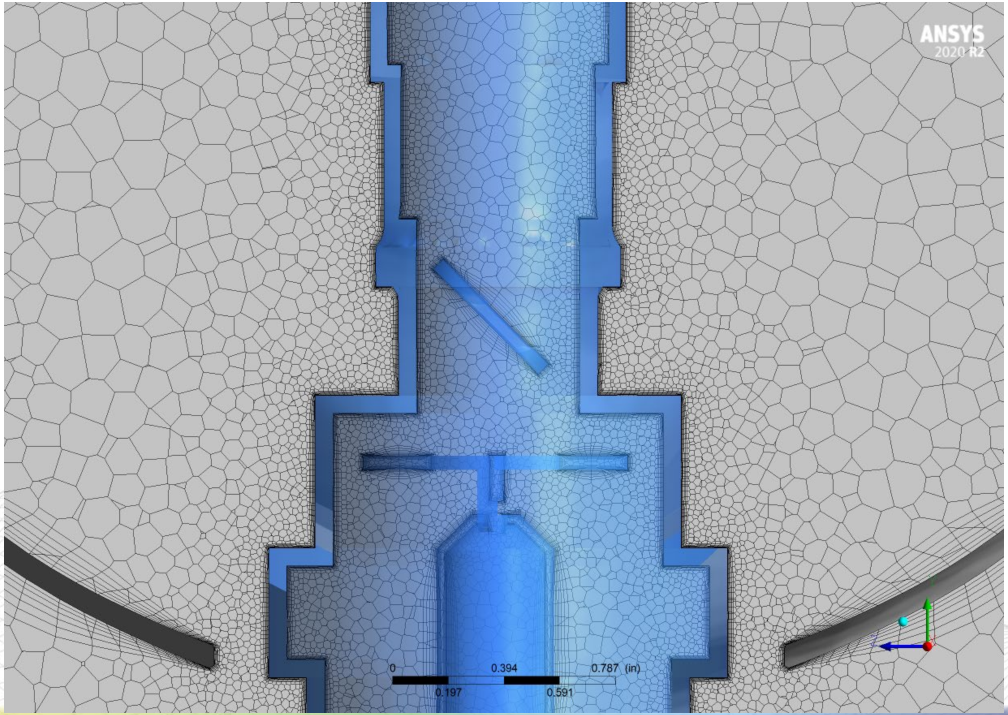


Computational Mesh – Front View

Shield & Nebulizer



Nebulizer w/o Shield (see Tilting Valve)



CFD Model
Setup & Parameters

CFD Model Setup - Overview

- 3D model of air surrounding a person's head
- Transient (time-dependent) simulations
  - Time step = 0.02 seconds
- Double precision solver
- Energy equation: on
- Gravity: on
  - -9.81 m/sec^2 in Y-direction
- Turbulent flow
  - k-omega shear stress transport (SST) turbulence model
- Discrete Phase Modeling
  - Unsteady particle tracking

Particle Injection Parameters

- Particle diameter = 0.5 μm
- Particle temperature = 34 °C
- Number of particles injected = 1000
- Particles exhaled at peak exhalation for 0.02 seconds (over one time step)
- Particle velocity magnitude = 2.002 m/sec
- Total particle flow rate = 3.26595e-12 kg/sec
- Particles released uniformly from person’s mouth (surface injection)

Particle Modeling Parameters

- Buoyancy: Boussinesq model
- Drag Law: Spherical (assumes spherical particles)
- Turbulent Dispersion: Discrete Random Walk Model
- Parcel Release Method: Standard (center of each cell on face)
- No interaction between particles and continuous phase
(i.e. one-way fluid/particle coupling)

Air & Particle Properties

- Air (ventilation gas and from surrounding atmosphere)
  - Temperature = 22 °C
  - Density = 1.196 kg/m^3
  - Viscosity = 1.823e-05 Pa*sec
  - Specific heat = 1006.43 J/(kg*K)
  - Thermal conductivity = 0.0242 W/(m*K)
- Air (person breathing)
  - Temperature = 34 °C
- Particles (water)
  - Density = 998.2 kg/m^3
  - Specific heat = 4182 J/(kg*K)

Inlet Boundary Conditions

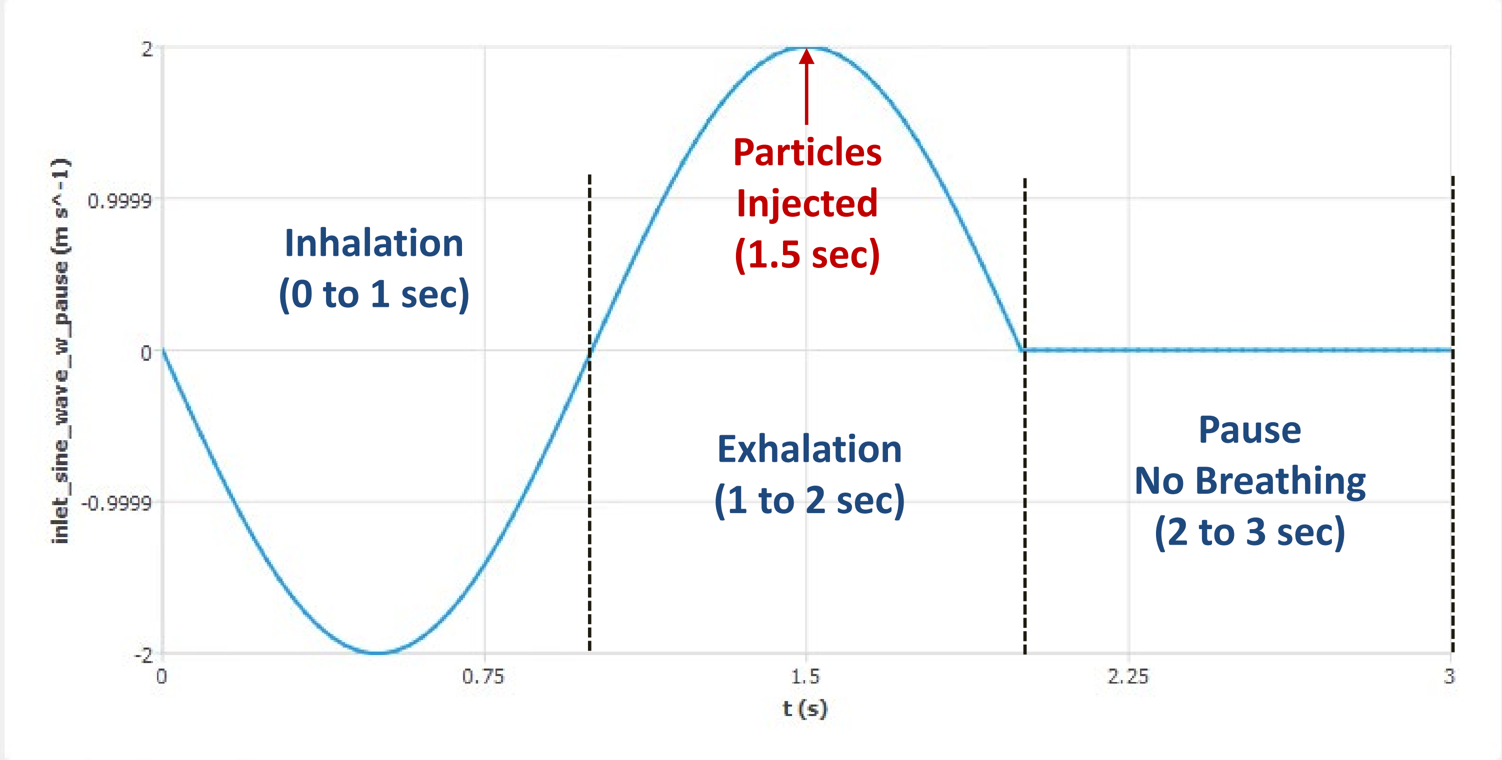
- Inlet, Mouth (velocity inlet)
  - Velocity: Sine wave with pause (see next two pages)
  - Area = 3.924 cm^2
  - Temperature = 34 °C
  - DPM: escape

- Inlet, Ventilation Gas (mass flow inlet)
  - 8 L/min (mass flow rate = 1.5947e-04 kg/sec)
  - Area = 0.1778 cm^2 (Dia. = 0.4757 cm = 0.1873 in)
  - Temperature = 22 °C
  - DPM: escape

- Inlet, Surrounding Atmosphere (pressure inlet)
  - Gauge total pressure = 0 Pa
  - Flow direction specification: Normal to boundary
  - Area = 1.0597 m^2 (Dia. = 30.48 cm = 12.0 in)
  - Temperature = 22 °C
  - DPM: escape

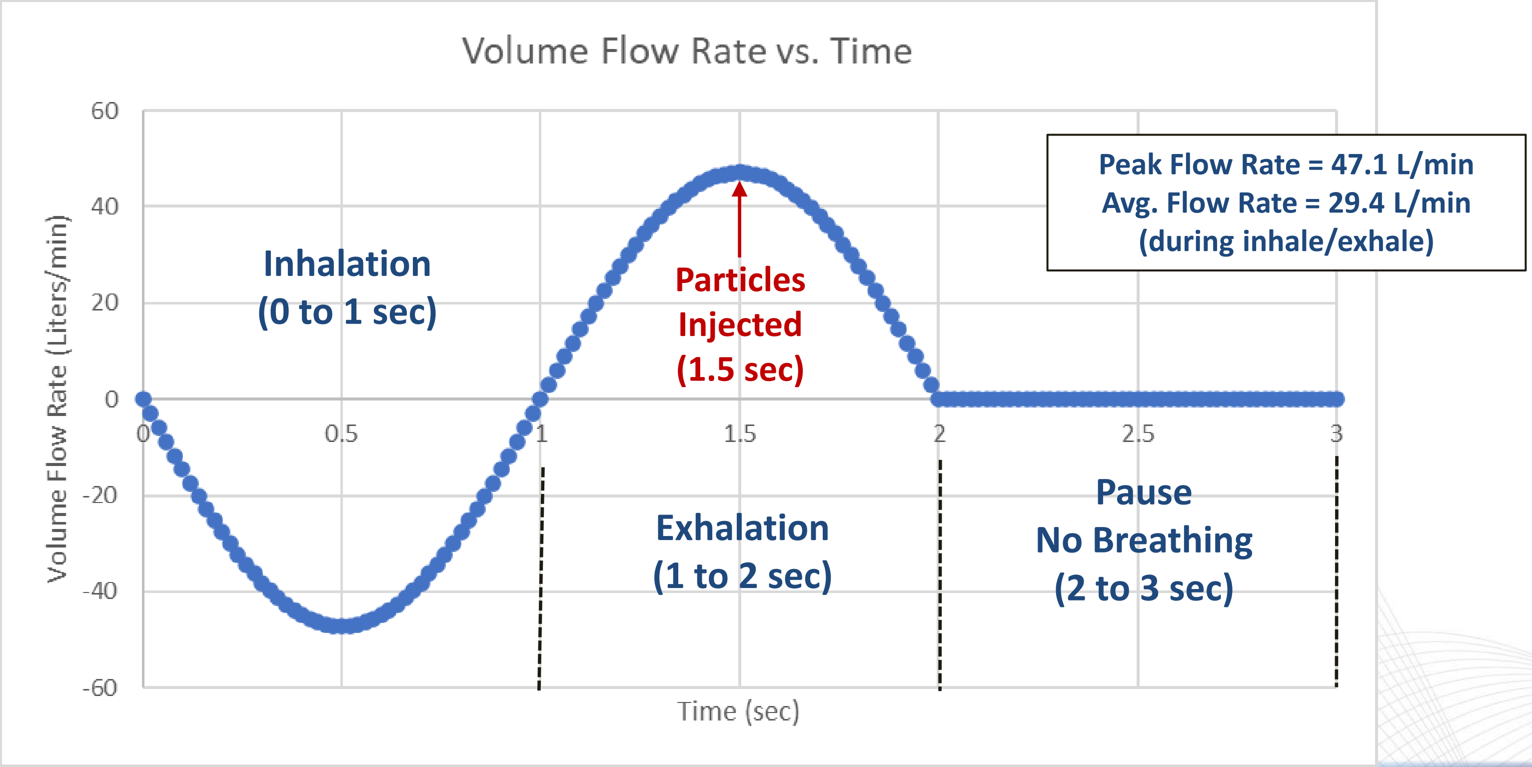
Repeating Breath Cycle – Velocity vs. Time*

(3 seconds - 1/3, 1/3, 1/3)



*File: Flow Rate Sine Wave 060221.xlsx

Repeating Breath Cycle – Flow Rate vs. Time
(3 seconds - 1/3, 1/3, 1/3)



*File: Flow Rate Sine Wave 060221.xlsx

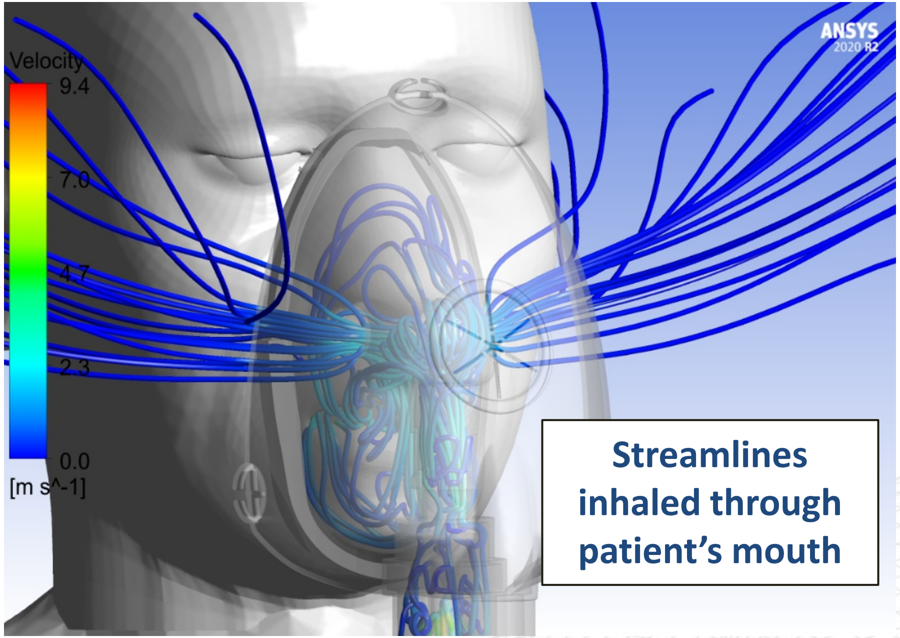
Outlet & Walls Boundary Conditions

- Outlet, Suction Tube (mass flow outlet)
  - Suction varied:
    - 0 L/min – Control with suction turned off
    - 180 L/min (mass flow rate = 3.588e-03 kg/sec)
    - 240 L/min (mass flow rate = 4.784e-03 kg/sec)
  - Area = 3.694 cm^2 (Dia. = 2.169 cm = 0.8538 in)
  - Temperature = 22 °C
  - DPM: escape

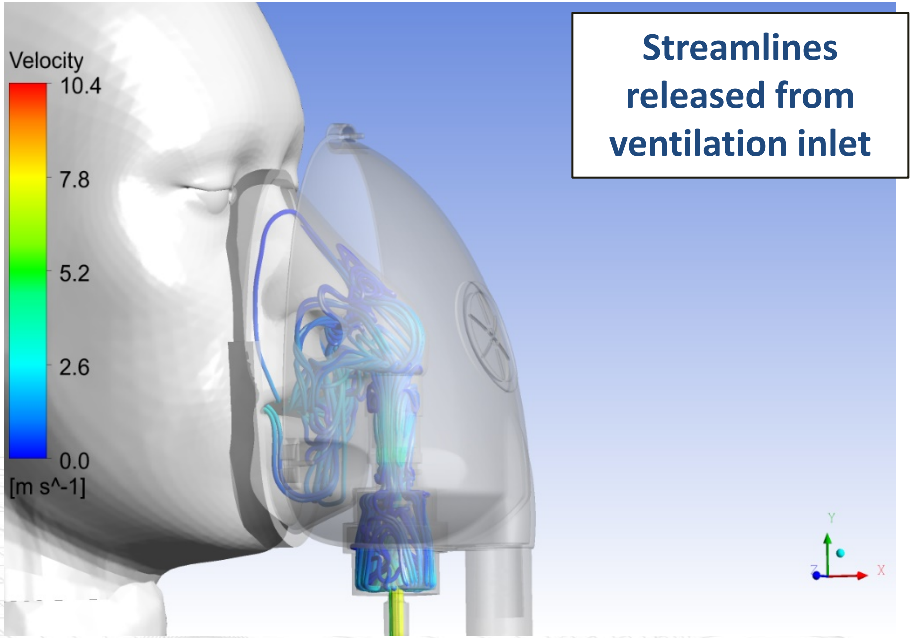
- All other surfaces (walls)
  - No slip (velocity = 0 m/sec)
  - Adiabatic (no heat flux)
  - DPM: escape (allows for counting of particles that would be trapped by walls)

CFD Results
Particle Removal – Exhalation Study

Peak Inhalation (6.5 sec) Streamlines colored by Flow Velocity



Streamlines inhaled through patient's mouth

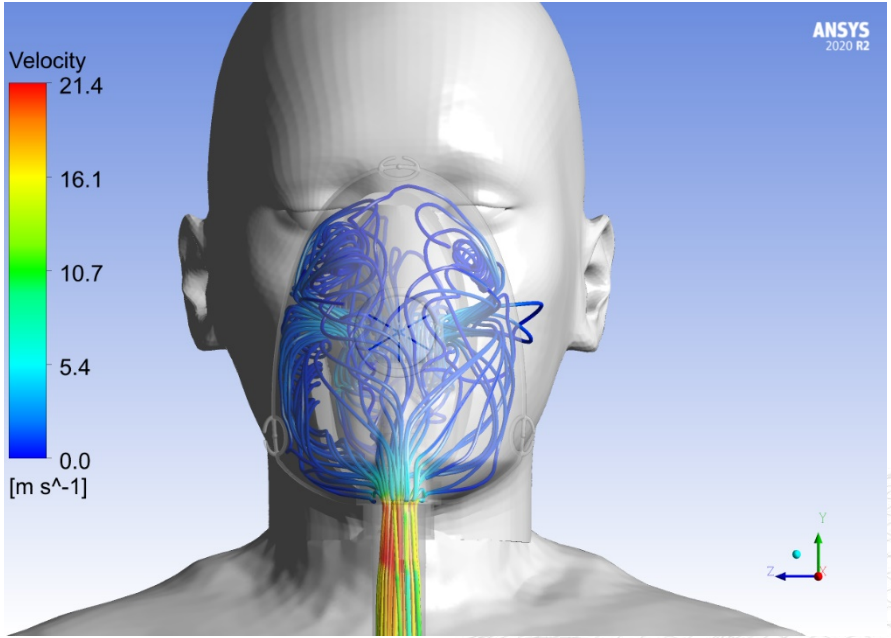


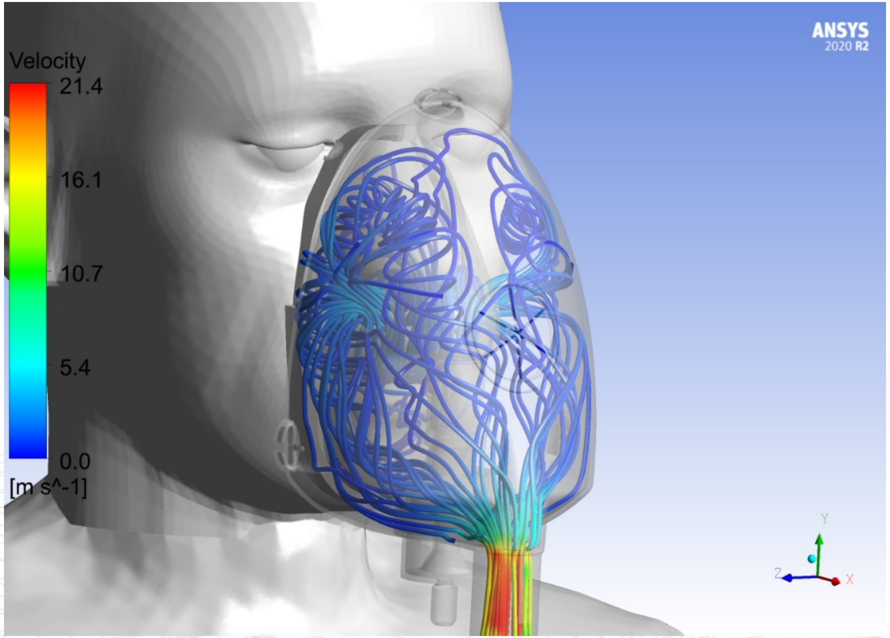
Streamlines released from ventilation inlet

Observations:

- Significant amount of air pulled in through mask side holes due to high flow rate (47.1 L/min) at peak inhalation. This helps to remove any particles between the shield and mask that were not previously removed
- **Streamlines released from nebulizer are pulled into the mouth and are not exiting through the suction system**

Peak Exhalation (4.5 sec) Streamlines colored by Flow Velocity

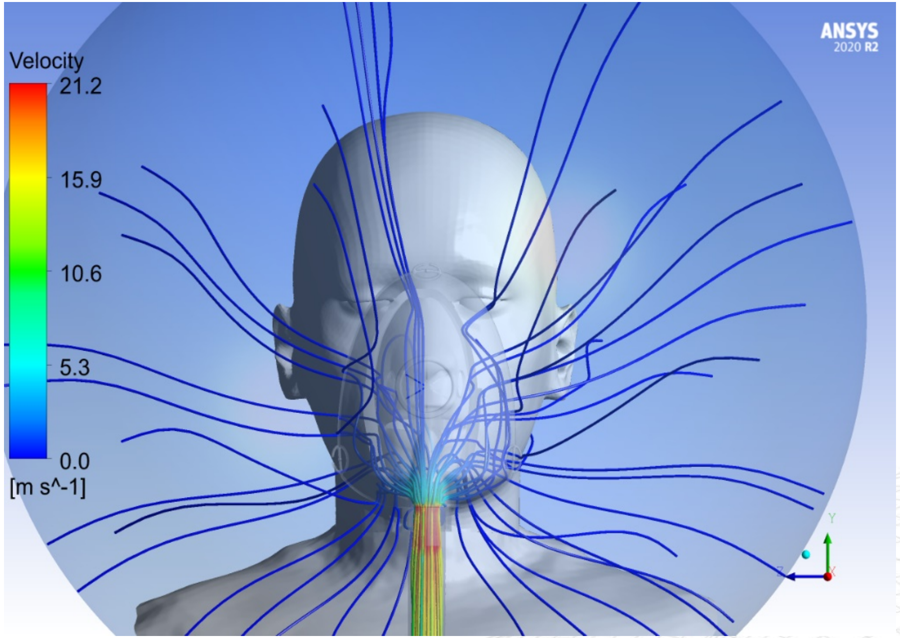


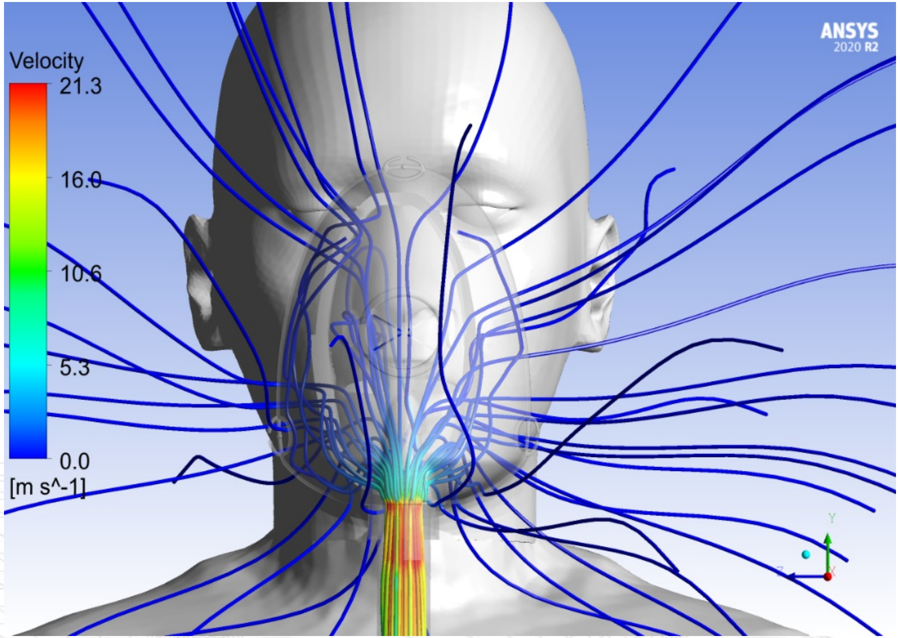


Observations:

- Flow velocity increases as air passes through the mask side holes and then exits through the suction system
- **Streamlines released from mouth are contained almost entirely within the shield and then exit through the suction system**

End of Pause (9.0 sec) Streamlines entering Suction System

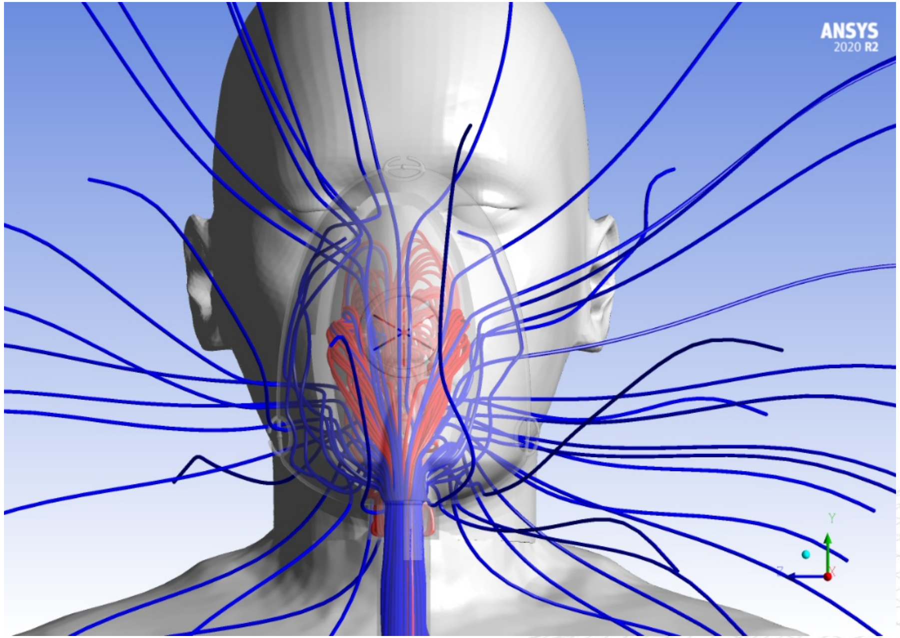


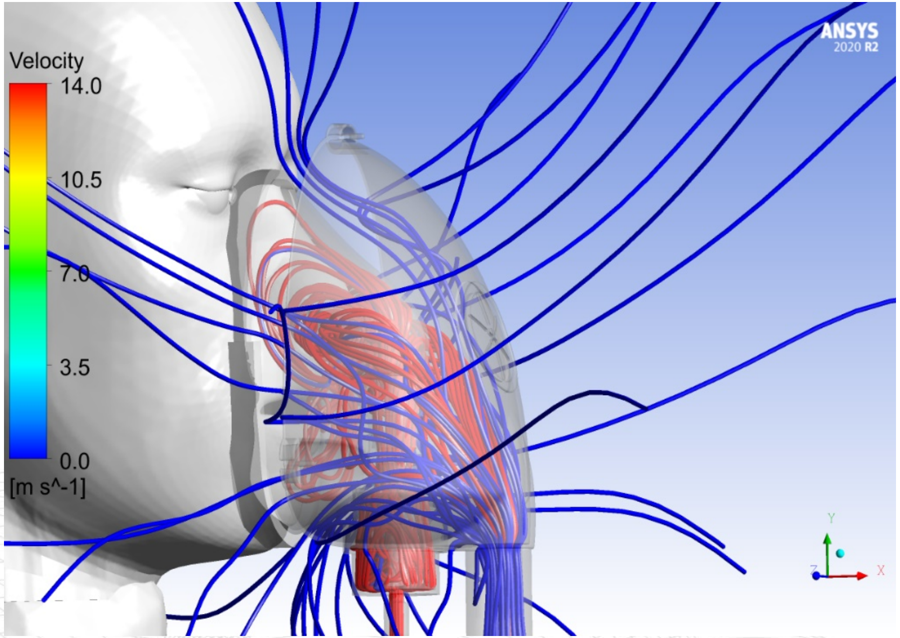


Observations:

- Suction system pulls in air from around the person's face and body
- **Air between mask and inner surfaces of shield is pulled inwards towards suction tube**
- Air flow velocity increases as approach entrance to the suction tube

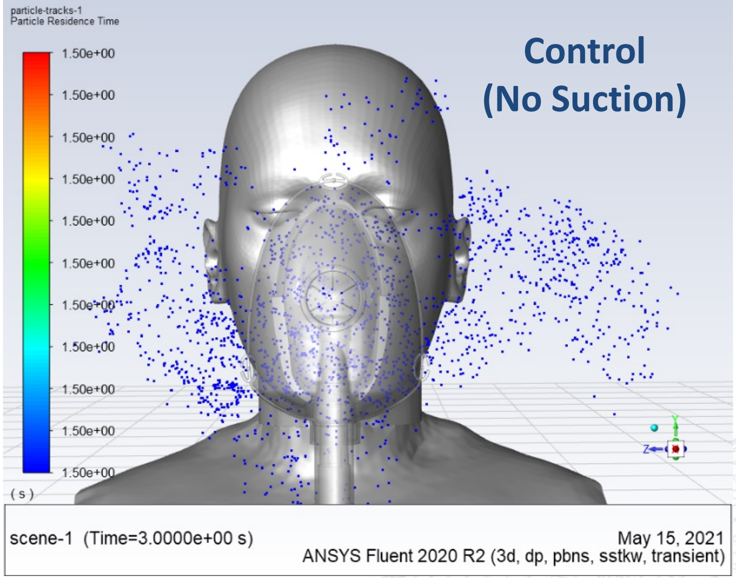
End of Pause (9.0 sec) Streamlines
(Red – Ventilator/Nebulizer, Blue – Suction)

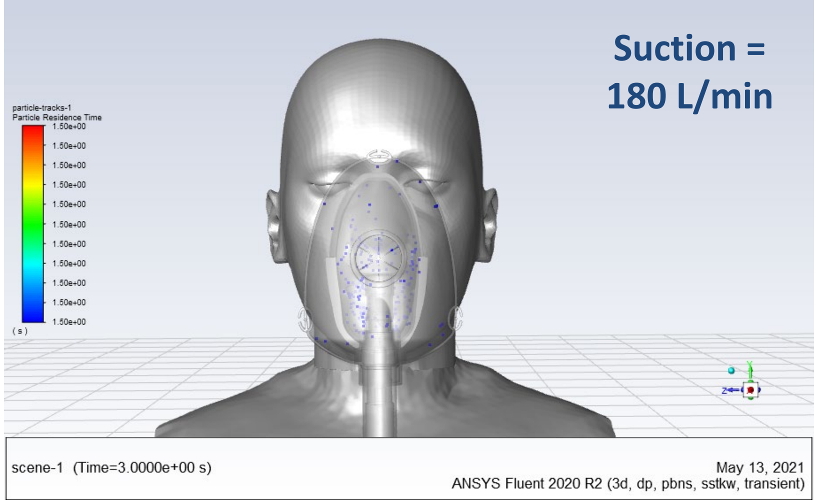


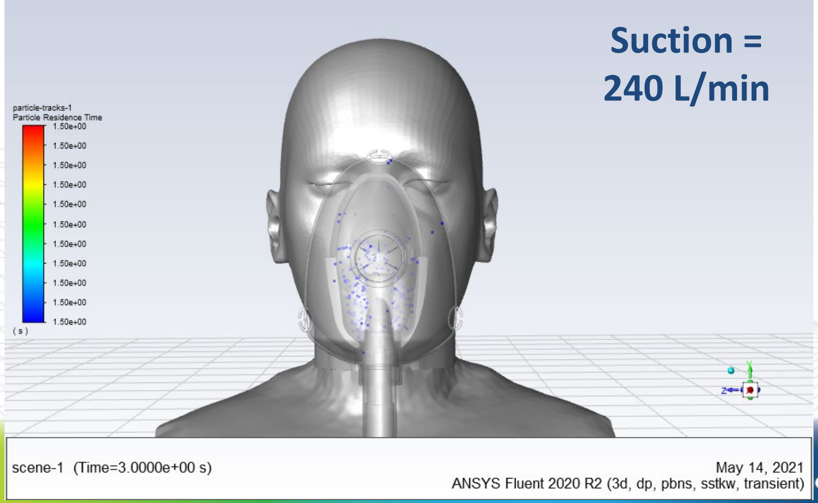


Observations:
- Suction system captures ventilation gas from nebulizer
- Suction system pulls in air from around the person’s face and body

Particles in Air (End of 1st Pause, 3.0 sec.)



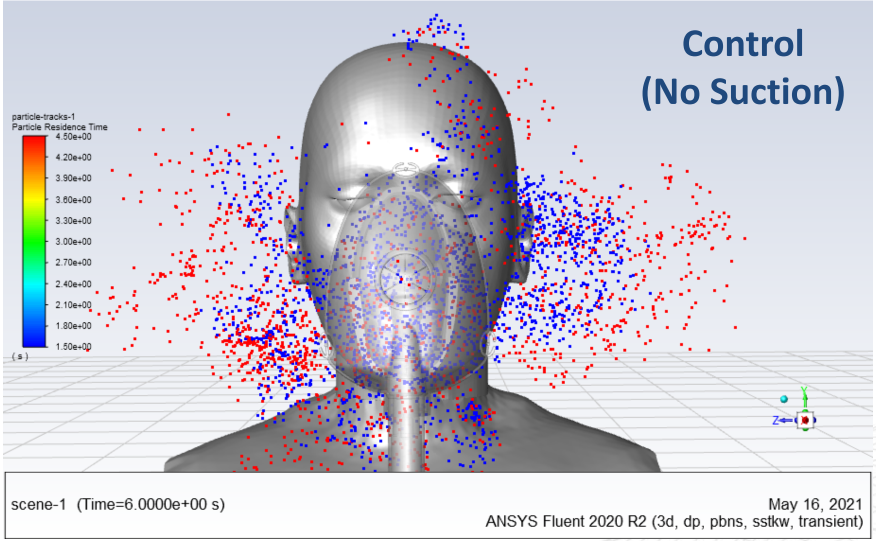


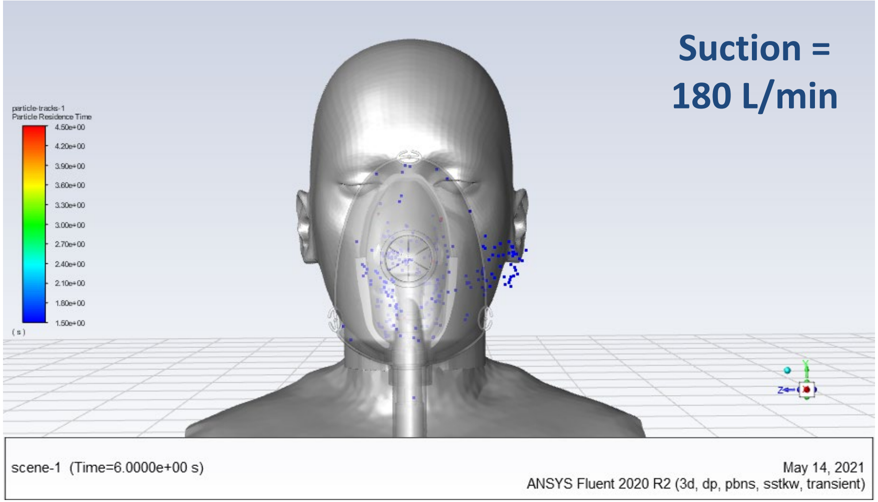


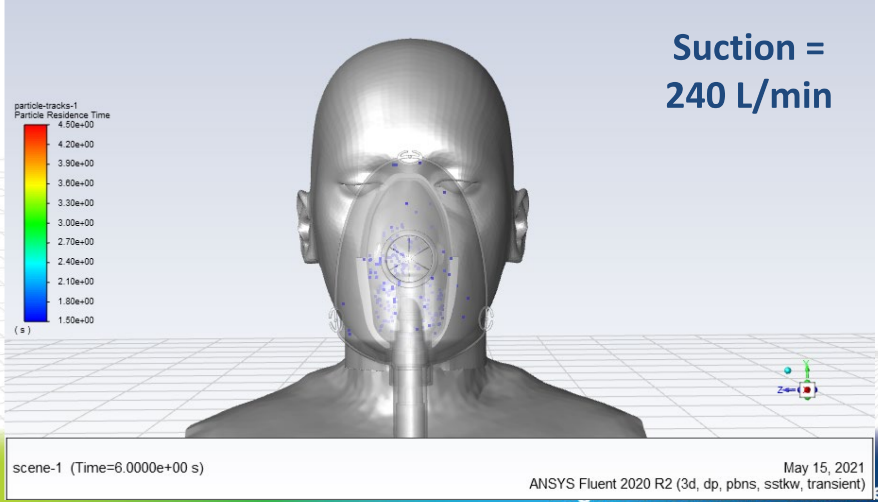
Observation:

- Significantly reduced number of particles remain in the air with both 180 and 240 L/min suction applied

Particles in Air (End of 2nd Pause, 6.0 sec.)



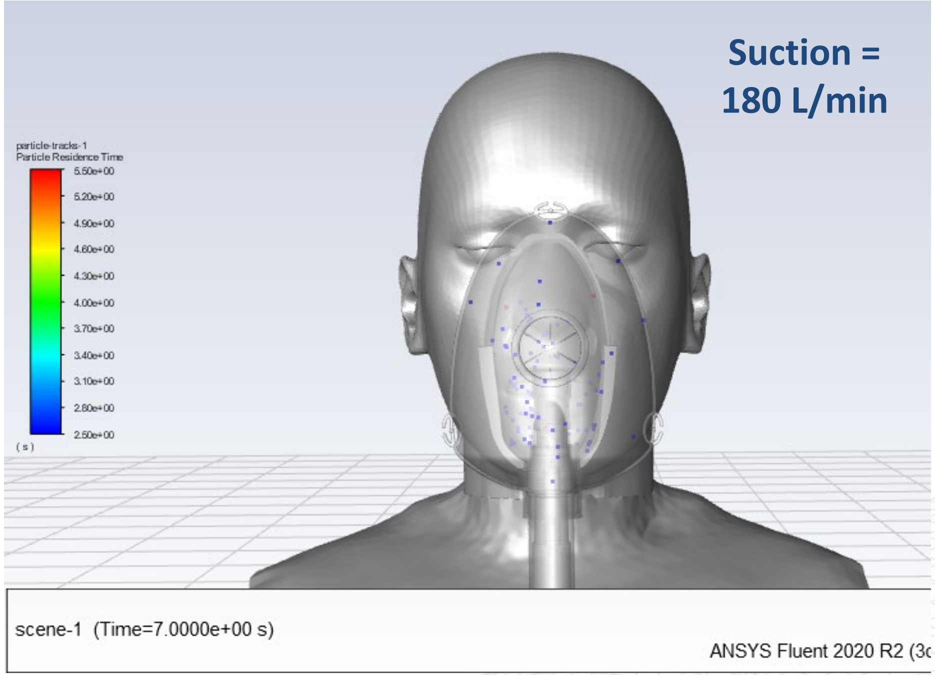


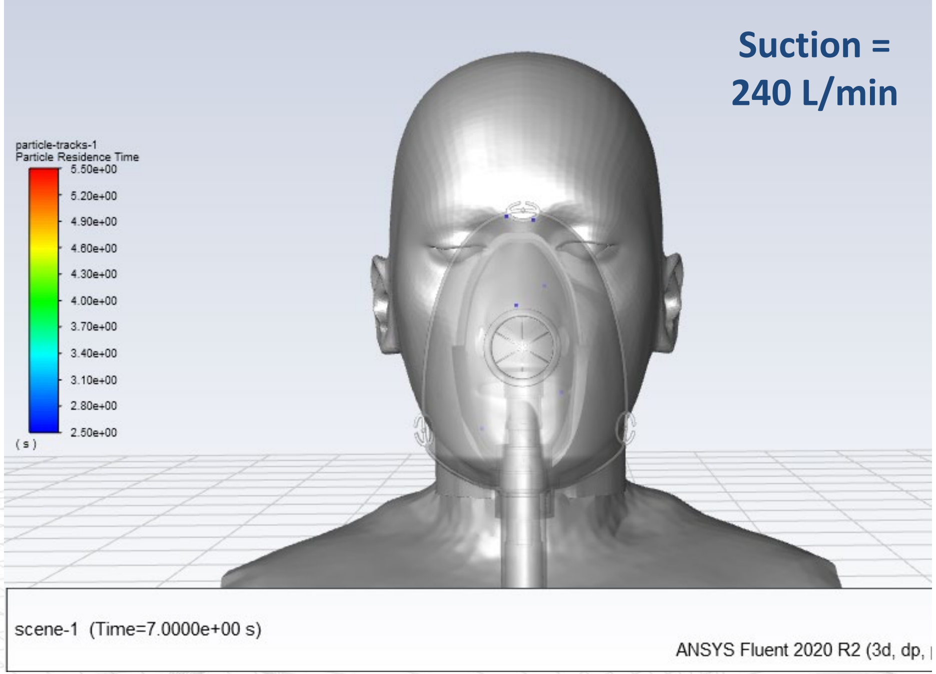


Observations:

- Significantly reduced number of particles remain in the air with both 180 and 240 L/min suction applied
- Improved particle removal with increased (240 L/min) suction

Particles in Air
(End of 3rd Inhalation, 7.0 sec.)





Observations:
- Improved particle removal with increased (240 L/min) suction
- Inhalation removes significant number of particle remaining following the pause period

Control – Particle Path Results
(Suction Flow Rate = 0 L/min)

	0.0 to 3.0 seconds		3.0 to 6.0 seconds	
	Number of Particles	% of Particles	Number of Particles	% of Particles
Particles Introduced thru Mouth	1000	--	1000	--
Particles Removed via Suction	0	0.0%	0	0.0%
Particles Trapped by Shield Walls	139	13.9%	135	13.5%
Particles Trapped by Other Walls	17	1.7%	13	1.3%
Particles Leaving Domain	0	0.0%	98	9.8%
Particles Still In Domain	844	84.4%	754	75.4%
Particles Still In Domain + Shield Trapped	983	98.3%	889	88.9%
Particles Still In Domain + Leaving + Shield Trapped	983	98.3%	987	98.7%

Observations:

- Very similar results for each breath cycle (repeatable)
- **On average, 98.5% of the particles remain in the air domain (1.5% are trapped by walls other than shield)**
- **The percentage of particles leaving the air flow domain increases with time (subsequent breath cycle)**

Particle Path Results
(Suction Flow Rate = 180 L/min)

	0.0 to 3.0 seconds		3.0 to 6.0 seconds	
	Number of Particles	% of Particles	Number of Particles	% of Particles
Particles Introduced thru Mouth	1000	--	1000	--
Particles Removed via Suction	614	61.4%	661	66.1%
Particles Trapped by Walls	294	29.4%	279	27.9%
Particles Leaving Domain	0	0.0%	0	0.0%
Particles Still In Domain	92	9.2%	60	6.0%
Particles Removed + Trapped	**908**	**90.8%**	**940**	**94.0%**

Observations:

- Very similar results for each breath cycle (repeatable)
- Reduction in number of particles still in domain for 2nd breath cycle (9.2% to 6.0%)
- **On average, 92.4% of the particles are removed from air domain (suction + trapped)**

Particle Path Results

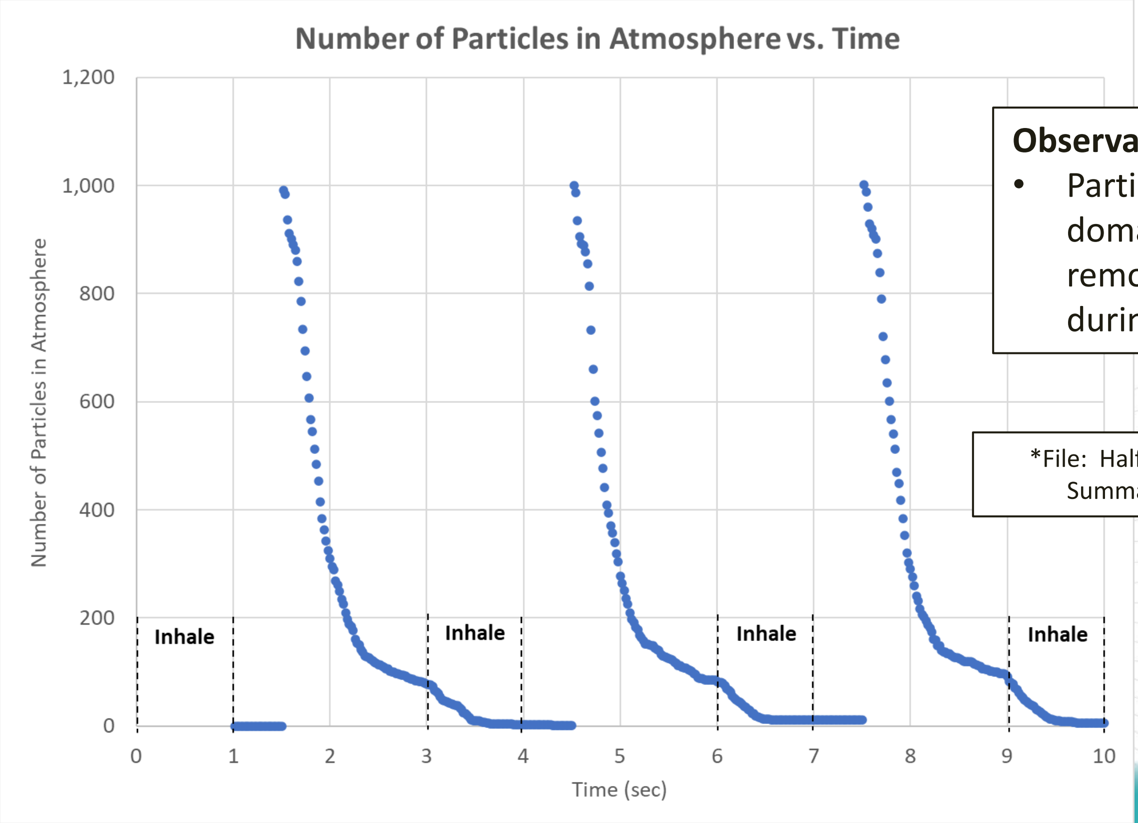
(Suction Flow Rate = 240 L/min)

	Transient Simulations - Time step = 0.02 seconds (Particles released at Peak Exhalation: 1.5, 4.5, and 7.5 seconds)					
	1.0 to 4.0 seconds (Breath Cycle #1)		4.0 to 7.0 seconds (Breath Cycle #2)		7.0 to 10.0 seconds (Breath Cycle #3)	
	Number of Particles	% of Particles	Number of Particles	% of Particles	Number of Particles	% of Particles
Particles Introduced thru Mouth	1000	--	1000	--	1000	--
Particles Removed via Suction	621	62.1%	629	62.9%	632	63.2%
Particles Trapped by Walls	301	30.1%	309	30.9%	299	29.9%
Particles Leaving Domain	0	0.0%	0	0.0%	0	0.0%
Particles Re-Inhaled	59	5.9%	60	6.0%	62	6.2%
Particles Still In Domain	19	1.9%	2	0.2%	7	0.7%
Particles Removed + Trapped	922	92.2%	938	93.8%	931	93.1%
Particles Removed + Trapped + Re-Inhaled	981	98.1%	998	99.8%	993	99.3%

Observations:

- Very similar results for each breath cycle (repeatable)
- **On average, 93.0% of the particles are removed from the air domain (suction + trapped)**
- **On average, 6.0% of the particles are re-inhaled by the patient**
- **On average, 1.0% of the particles remain in the air domain at end of inhalation**

Number of Particles Remaining in Air vs. Time*
(Suction Flow Rate = 240 L/min)



Observation:
- Particles remaining in the domain at end of pause are removed when patient inhales during next breath cycle

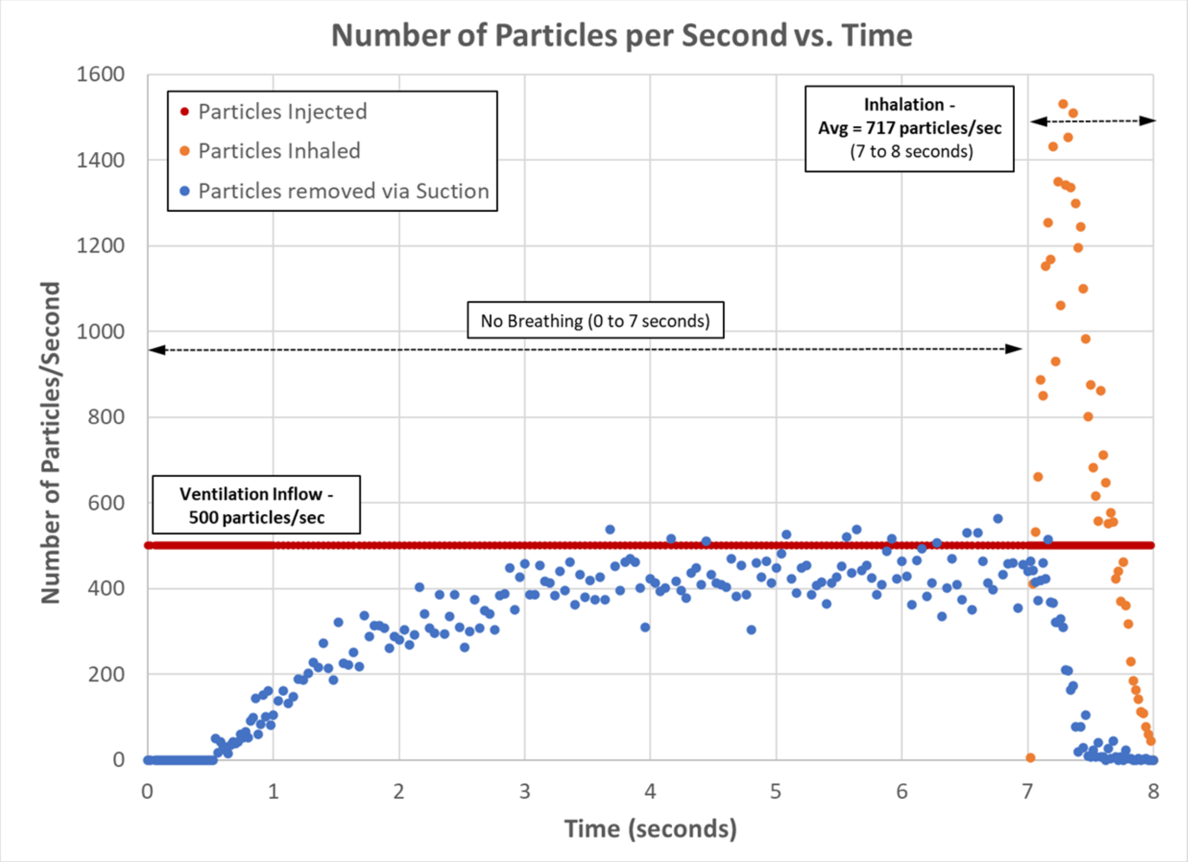
*File: Half Micron Particles Surface Escape 240 Lmin Summary 10 seconds Cumulative 052721.xlsx

CFD Results
Ventilation/Nebulizer Particles – Inhalation Study

Nebulizer Modeling Overview

- Particle diameter = 1 μm
- Injecting 500 particles/second from ventilation/nebulizer gas inlet
- Particles bounce off all walls (keep them in air flow stream)
- Flow rates:
  - Ventilation = 8 L/min
  - Suction = 240 L/min
- No Breath
  - 0 to 7 seconds
  - Goal is to establish near "steady-state" conditions for ventilation gas particles
- Inhalation (sine wave)
  - 7 to 8 seconds
  - Peak flow rate = 47.1 L/min
  - Average flow rate = 29.7 L/min

Particle Path Results – 1.0 μm Diameter Particles
(Suction Flow Rate = 240 L/min)



Observations:

- Reach quasi-steady inflow vs. suction outflow of particles (5 to 7 seconds)
- Average inhalation flow rate (29.7 L/min) is significantly higher than ventilation/ nebulizer flow rate (8 L/min)
- During inhalation (7 to 8 seconds), patient inhales more nebulizer particles (717) than enter through ventilator (500)
- Inhalation pulls in incoming particles from ventilator plus additional particles contained within the mask and shield
- During inhalation, the number of particles exiting through the suction system drops to near zero.
- **Suction system does not reduce the number of nebulizer particles delivered to the patient**

File: One Micron Particles Ventilation 240 Lmin Summary 8 sec Inhale 052621.xlsx

Summary
&
Observations

Summary & Observations
(Particle Removal - Exhalation Study)

- Control (suction turned off):
  - 1.5% of particles are trapped by mask and patient's face and body
  - **98.5% of the particles remain in the air domain (at end of pause period)**
  - The percentage of particles leaving the 12" flow domain increases with time (subsequent breath cycles)

- Suction flow rate = 180 Liters/min (average values over 2 breath cycles)
  - 92.4% of particles are removed from air domain due to suction or being trapped by surfaces
  - 6.0% of the particles remain in the air domain (at end of pause period)

- Suction flow rate = 240 Liters/min (average values over 3 breath cycles)
  - 93.0% of particles are removed from air domain due to suction or being trapped by surfaces
  - 6.0% of the particles are re-inhaled by the patient
  - **1% of the particles remain in the air domain (at end of inhalation period)**
  - **Slightly improved removal of particles remaining in air compared with 180 L/min**

Summary & Observations

(Ventilation/Nebulizer – Inhalation Study)

- Average inhalation flow rate (29.7 L/min) is significantly higher than ventilation/ nebulizer flow rate (8 L/min)
- During inhalation, an increased number of nebulizer particles are removed by the patient compared (717) with the number entering through ventilator (500)
- Inhalation pulls in and delivers additional particles additional nebulizer particles contained within the mask and shield
- During inhalation, the number of particles exiting through the suction system drops to near zero.
- **Suction system does not reduce the number of nebulizer particles delivered to the patient**

Summary & Observations (Overall Study)

- Benefits of the respiratory suction system
  - **Captures 93% of particles exhaled by patient (240 L/min)**
    - actively removes particles exhaled by patient (63%)
    - provides additional surface area for particles to be trapped (30%)
  - **Creates inward air flow patterns towards patient:**
    - contains exhaled particles within or near shield
    - enables re-inhalation of particles not yet removed from air (6%)
  - **1% of exhaled particles remain in flow domain (after re-inhalation), compared with 98.5% of exhaled particles without suction system**
  - **Suction system does not reduce the number of nebulizer particles delivered to the patient**

Appendix – A
Effect of Time Step

Particle Path Results

(Suction Flow Rate = 240 L/min)

	Time Step = 0.02 seconds		Time Step = 0.01 seconds		Percentage Difference	
	0.0 to 3.0 seconds		0.0 to 3.0 seconds		0.0 to 3.0 seconds	
	Number of Particles	% of Particles	Number of Particles	% of Particles	Number of Particles	% Change
Particles Introduced thru Mouth	1000	--	1000	--	--	--
Particles Removed via Suction	621	62.1%	610	61.0%	-11	-1.1%
Particles Trapped by Walls	301	30.1%	318	31.8%	17	1.7%
Particles Leaving Domain	0	0.0%	0	0.0%	0	0.0%
Particles Still In Domain	78	7.8%	72	7.2%	-6	-0.6%
Particles Removed + Trapped	**922**	**92.2%**	**928**	**92.8%**	**6**	**0.6%**
Particles Trapped by Shield Walls	*data not collected*	--	304	95.7% % Trapped		
Particles Trapped by Other Walls	*data not collected*	--	14	4.3% % Trapped		

Observation:

- Very small changes in percentages of particles removed and trapped when reducing transient time step in half (demonstrating 0.02 second time step is sufficient for capturing the particle paths predicted)

Appendix – B
Particle Mass Flow Rate Calculations

Particle Mass Flow Rate Calculations*

Particle Density	998	kg/m^3					
	Particle Dia.	***Particle Volume***	***Particle Mass***	***Injection Time***	***Number of Particles***	***Mass of Particles***	***Mass Flow Rate***
	(μ m)	***(m^3)***	***(kg)***	***(sec)***	***Injected***	***Injected***	***(kg/sec)***
Particles Introduced (0.5um)	0.5	6.54498E-20	6.53189E-17	0.02	1000	6.53189E-14	3.26595E-12
Particles Introduced (1 um)	1	5.23599E-19	5.22552E-16	0.02	1000	5.22552E-13	2.61276E-11
Particles Introduced (1 um)	1	5.23599E-19	5.22552E-16	1.00	500	2.61276E-13	2.61276E-13
Particles Introduced (1 um)	1	5.23599E-19	5.22552E-16	2.00	1000	5.22552E-13	2.61276E-13
Particles Introduced (10 um)	10	5.23599E-16	5.22552E-13	0.02	1000	5.22552E-10	2.61276E-08
Particles Introduced (20 um)	20	4.18879E-15	4.18041E-12	0.02	1000	4.18041E-09	2.09021E-07
Particles Introduced (40 um)	40	3.35103E-14	3.34433E-11	0.02	1000	3.34433E-08	1.67217E-06

*File: Particle Mass and Mass Flow Rate Calcs 052421.xlsx