Validation and Performance Evaluation of a Face Mask Air Filtration System

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Abstract

This work seeks to validate a filtration facemask concept proposed by the start-up company, O2O2 ltd, to enable a functional proof of concept prototype to be physically tested and compared with conventional facemask solutions. Conventional filtration facemasks use an unreliable physical face-seal to prevent infiltration of polluted air into the mask space while the proposed facemask does not require physical sealing, instead using fans to draw air through a filter and pressurize the mask space in front of a user's mouth and nose before venting around the mask perimeter. This method provides the user with an 'air-citadel' of filtered air to prevent infiltration of polluted air and is compatible with more face shapes and facial features such as facial hair.

The first stage of this report details computational simulations of the proposed mask system on realistic facial geometry. This is aimed to validate the feasibility of the facemask system and detail the required fan functional requirements during steady-state breathing up to an assumed 70% exertion effort to simulate 'moderate exercise'.

The second stage details the creation, build and use of a synthetic head testing system used to physically test of a proof of concept facemask prototype. This testing system validated previous computational simulations and identified the minimum vent flows required up to an oral inhalation demand of 103 L/min. Results were used to support an ethics application for a clinical study so that a functional proof of concept prototype mask could be tested.

The final stage details a clinical study involving five participants undergoing moderate exercise on an exercycle. Participants wore a functional proof of concept prototype facemask and three popular commercially available systems while a sampling method measured air-qualities within the mask space. Results of this clinical study enabled further validation of the air-citadel concept and allowed for comparisons to be made against current commercially available facemask solutions.

Results of all three stages unanimously indicated that the proposed facemask system could successfully be used to protect a user from inhaling polluted air in a contaminated environment undergoing moderate exercise. The clinical study also identified competitive advantages of the prototype mask which would justify a strong business case for commercialization of the technology.

Contents

Table of Figures

List of Tables

Appendix Table of Figures

Appendix List of Tables

Attestation of Authorship

I hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person (except where explicitly defined in the acknowledgements), nor material which to a substantial extent has been submitted for the award of any other degree or diploma of a university or other institution of higher learning.

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Confidential Information

This thesis contains confidential information sensitive to the sponsor company, O2O2 and includes a 36-month embargo

Chapter 1: Air Pollution and Facemasks

1.0 Introduction

This report documents the support provided to the sponsor start-up company, O2O2 ltd, to assist in understanding the feasibility, functional requirements and quantifying any advantages of their proposed new filtration facemask design over the current filtration solutions, aimed at protecting users from air-pollution. This information will be used by O2O2 to support a business case to commercialize the technology. In this chapter, air pollution and existing filtration facemask solutions will be discussed, along with O2O2's proposed solution and the methodology and tools used to support the company.

1.1 Background

Up to 92% of the world's population live in areas with levels of air pollution exceeding recommended limits[1]. Current popular solutions to directly protect human airways from air pollution are particle-filtration masks that cover a user's face and mouth, filtering air before it is inhaled. These solutions rely on achieving a good pneumatic seal around a user's face which is problematic due to the variance in face shapes, the presence of facial hair, and commonly leak around the cheek-bone area [2].

The start-up company, O2O2 ltd, aims to improve on these problems by using a portable, pressurized air filtration mask which does not rely on a physical face seal to prevent infiltration of polluted ambient air from being inhaled. This method is expected to improve user compatibility by offering protection to a larger range of face shapes and to users with facial hair. This is achieved using fans to blow air into a transparent mask suspended in front of a user's face creating a protective 'clean air citadel' around their mouth and nose. Excess air is supplied into the mask with the constant outflow creating an above ambient-pressure 'air-seal' between the face and mask. This eliminates the need for a sealing between the face and mask as used by conventional styles.

The investigation provides an understanding of the feasibility, functional requirements and quantifies the advantages of this new mask design. Feasibility and functional requirements were found using computational fluid dynamics (CFD) simulations using conceptual mask geometry and realistic facial geometry. Two stages of practical tests follow CFD simulations, the first involving a functional mask prototype being tested on a synthetic

head, simulated inhaling in a controlled contaminated air environment to validate the CFD models and provide evidence for a subsequent ethics application for a clinical study. The second stage involved a clinical study consisting of 5 participants undergoing mild exercise wearing 4 filtration facemask systems including an O2O2 functional prototype. Sensors measured air qualities inside the masks and coupled with user perception regarding air quality feedback, allowed for comparisons between the functional mask prototype to existing facemask air filtration solutions. This final stage allowed for further validation of CFD simulations and informed the sponsor company, O2O2, of advantages and disadvantages of their new mask system to assist the company with product development and support a business case to commercialize the technology.

1.2 Air pollution

Air-pollution refers to gasses or particles introduced into the atmosphere that have the ability to do harm to human airways and health. The air-pollution category of interest for this report is fine-particle pollution typically found in large cities. Sources of fine particulate may be natural, such as dust from deserts which are the main pollution source of middle-eastern countries [3], ash from volcanoes or salt-spray from oceans, however, a large amount of harm-causing pollutants are man-made. These man-made sources can be from burning fossil fuels in vehicles, power stations and other industrial activities. They may also be from more benign activities such as household cooking.

The Environmental Protection Agency (EPA) of the United States of America first implemented standards for fine particular-pollution, creating the PM2.5 and PM10 standards in 1971 which measure the concentration of particles with aerodynamic diameters below 2.5um and 10um respectively [4]. These measurement standards have become the worldwide standard for measuring particle levels. The latest update stated recommended limits on 24 hour and annual average PM2.5 concentrations exposure of 13ug/m^3 and 35 ug/m^3 respectively. PM10 24 hour and annual concentration exposures are also set at 150 ug/m^3 and 50ug/m^3 respectively [5].

Fine-particle pollution is widespread around the world with one model showing 92% of the world's population are living in regions exceeding the World Health Organizations recommended PM2.5 limits [1]. The negative health impacts on this group of people having to live in an environment with high levels of pollution are huge. Here, fine particles

can travel far down into the lungs and affect the respiratory system, causing diseases such as asthma [6]. Direct links have also been found correlating an increase in air pollution to an increased risk of lung cancer with each 10 ug/m^3 increase in fine particulate increasing lung cancer mortality by 8% [7]. These negative health impacts lead to over 4.3 million people dying per year from household pollution sources such as cooking using fuel-based heating elements, and over 4 million people dying from ambient sources [1, 6, 8].

While it will take a long period of time to reduce the man-made sources of air-pollution, it is possible to protect users from its main effects by preventing people from inhaling these fine particles through the use of facemasks.

1.3 Existing Solutions

The main method of personally protecting users from air pollution is using face air-filtration systems such as respirators consisting of a rubber mask with replaceable filter elements, or paper filtration masks where the filter element forms the mask itself. Air Filtration masks are used commonly around the world to protect users from air-pollution by filtering contaminants out of the air stream before they are inhaled. These masks cover the mouth and nose of users to ensure only filtered air is inhaled.

Respirators and paper filtration masks are secured on the face using rubber straps around the head which are tightened so that the mask pushes against the users face to create a pressure seal. The effectiveness of the mask system in protecting a user from air pollution depends on the filtration efficiency of the mask as well as the effectiveness of the pressure seal around the face. Figure 1.1 shows 3 popular pressure sealing masks and how they are fitted to a face.

Figure 1.1: 3 Popular pressure sealing masks

Popular choices of face mask systems such as N95 paper-filtration masks, as shown in figure 1.1(c), have been tested to achieve good filtration with 99.5% of particles above 0.75um being filtered when the mask is fully sealed to a face [9]. However, this filtration efficiency is rarely obtained due to poor face sealing around the outside of the mask. Sealing between the mask and face must be perfect to ensure ambient polluted air first flows through the filter. In practice, this can be difficult to realize over a large population range given the variation in shapes and sizes of faces and the presence of facial hair. These types of facemasks also commonly experience leaks around the nose and cheek-bone areas where facial features vary among users [2]. Sealing between the mask and face is also affected by the presence of facial hair, with increases of leakage between 20-1000 times greater compared to clean-shaven users [10, 11]. Feedback from healthcare workers who frequently use N95 masks show this area as a popular development request with one study showing over 40% of male participants preferred a mask that they could wear with facial hair [12].

Respirators and paper filtration masks can lead to work output performance degradations with users unable to achieve the same work output of those not wearing a mask due to psychological or physiological impacts such as anxiety or from a reduced air-quality [13, 14]. The largest negative performance impact, however, is on anxious users who feel more discomfort wearing filtration masks and realize a lower work output [14].

Air-temperature and humidity inside conventional face sealed respirators and paper-filtration masks is increased which reduces the human body's ability to remove heat generated by muscles. For users relying on inhaled air for cooling, such as those wearing protective clothing, the chance of hyperthermia can be increased [15]. The increase in temperature also promotes increased sweating for heat removal which can be uncomfortable for a user, speed up dehydration and potentially promote the occurrence of mask leakage at the pressure seal.

Respirators and paper-filter masks trap exhaled air which, coupled with increased breathing resistance, can increase mask CO_2 levels. Rebreathing of high levels of CO_2 can increase arterial-CO_2 concentrations with numerous negative impacts such as fatigue, weakness and dizziness [16].

1.4 New ‘Air citadel’ Facemask – O2O2 ltd Innovation

The startup company sponsoring this project, O2O2 ltd, has proposed a new design of a portable face-mask filtration system. Fan units would be mounted on the side of the head, pulling air through filters and pushing it into the mask-domain at an excess volumetric flow rate than what is needed during inhalation. With air being filtered before the fan units, the roles of the mask shell would be to direct clean filtered air to the mouth and nose while minimizing contact with the face. This creates a clean, filtered air citadel around the nose and mouth that does not require a face seal as excess air is vented between the face and mask.

At the time of commencing this project, the sponsor company, O2O2 ltd, aimed to focus on technology development towards protecting users in contact with ambient pollution during moderate exercise such as while commuting on a bicycle.

With the filtration efficiency of existing commercially-available masks already high, the companies main focus-area is to improve a masks ability with withstand infiltrating polluted air around the perimeter of the mask. Instead of relying on a physical seal between the mask and face, the new system features a steady excess supply of filtered air that raises the air pressure inside the mask above ambient. With the mask above ambient pressure, no ambient air should be sucked through the gap between the mask and the users face during inhalation. Excess mask air is vented between the mask and face through a clearance referred to as the ‘air-gap’. This conceptual method of leak protection is purely theoretical to the sponsor company and the main goals of this project are to validate this concept and determine fan and air-gap requirements to enable the mask to effectively protect users. It also seeks to compare air quality and comfort between different mask types during moderate exertion.

Advantages of this system are that the mask does not need to touch the users face to protect them from contaminated air infiltration within a polluted environment. This is beneficial as mask leakage may be less affected by face shapes and facial features such as facial hair which the current mask solutions cannot cope with.

The sponsor company anticipates that the air quality inside the new facemask will be improved for the user with expected reductions in temperature, humidity and CO_2 levels

compared commercially available mask systems due to an increased purging of the mask volume domain.

Work required to flow air through filters is done by the fan motors and air is supplied at a slight positive pressure which should mean identical or reduced inhalation work compared to a user not wearing any mask. This contrasts with a respirator and other commercially available mask systems which require a large negative pressure to create airflow through the resistive filters. This leads to largely increased inhalation work by the user, the popular N95 mask can increase inhalation resistance as much as 126% [17]

Exhalation work is expected to slightly increase compared to a user not wearing a mask, with the user exhaling against a slightly above-ambient mask pressure and through the air-gap around the perimeter of the mask. Exhalation work is expected to be significantly lower than Respirator or N95 masks which commonly vent through small valves that still pose a significant exhalation resistance. Cheaper un-valved N95 masks can increase exhalation resistance as much as 122% [17] The expected increase in exhalation resistance for the O2O2 mask is favoured over an inhalation resistance increase with less associated negative impacts [18]. With the decrease in both inhalation and exhalation work compared to existing respirator or N95 mask solutions it is expected that breathing effort will be significantly reduced. Figures 1.2 and 1.3 show the proposed facemask system and how the air is expected to flow into the mask and out the air-gaps.

Figure 1.2:Rendering of proposed facemask system showing filters and fan units mounted on the sides

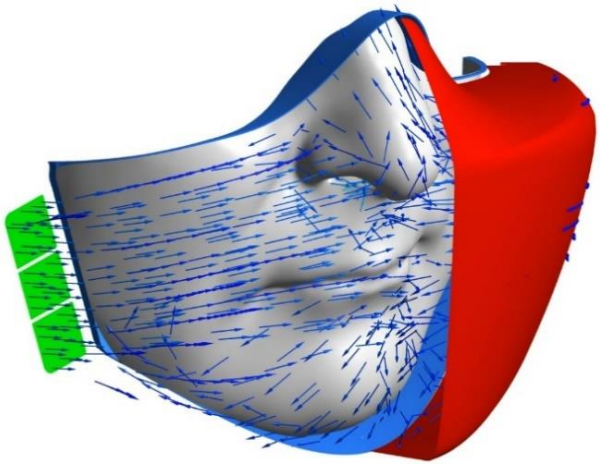


Figure 1.3:Expected airflow through facemask system and out of the air-gaps

1.5 Design and Technology Assistance to Sponsor Company

The project sponsor start-up company, O2O2 ltd, required assistance in developing and validating their proposed design due to gaps in knowledge. This project seeks to determine:

- **Whether the air-seal concept could work to protect a user from air contamination**
- **An understanding of the fan performance requirements to achieve the air-seal in a proof of concept prototype**
- **An understanding of how the new proof of concept mask compares to existing solutions during real breathing conditions**

CFD simulations will first assess the feasibility of the mask concept in creating a leak-free air citadel and give an understanding of fan performance requirements needed by the new mask when worn by a user undergoing mild exercise. CFD Simulations will start off using simplified mask and facial geometry until computer-aided-design (CAD) model geometry of a proof of concept prototype is available from the company. From there, realistic facial geometry will also be applied.

Physical testing of a proof of concept air-citadel mask using a realistic, breathing synthetic head model will follow up CFD simulations to validate the computational results regarding contaminated air leakage. This will also test the proof of concept prototype masks ability to maintain a leak-free air citadel in an extremely polluted environment. This testing will be vital to support an ethics approval for subsequent comparative human testing using a range of commercially available facemasks.

The final validation entails the comparison of a functional O2O2 facemask prototype to existing commercial air filtration systems by users exercising within a contaminated air environment. This will allow for validation of the CFD and synthetic head models while allowing for validation of the O2O2 ltd facemask system performance claims, through comparisons against commercially-available filtration systems. This will be done through performance-related measurements of oxygen, carbon dioxide, temperature levels, humidity levels and mask infiltration of polluted air as well as user-centric feedback. These were requested by the sponsor company to help with product development and support in building a business case to commercialize the technology.

1.6 Computational Simulations

CFD simulations are computer models simulating fluid dynamics problems that are used to predict fluid flows. Most models involve the simulation of turbulence which can be done using modified Navier Stokes (NS) equations. Navier Stokes equations are the most widely used governing equations for fluid momentum but are impossible to directly solve for due to the infinite degrees of freedom for a turbulent flow field [19].

Large Eddy Simulation (LES) models use the governing NS equations but apply filters to separate and only resolve large eddies, leaving the smaller ones, typically smaller than the model mesh size, to be found through more compact models [20]. This form of modelling excels at predicting time-dependent eddies in transient simulations and has recently found popularity due to the increase in processing power available from modern computers. It is however still computationally too expensive for most simulations not run on a server and struggles to resolve turbulence for extremely complicated models.

Reynolds-averages Navier-Stokes (RANS) equations are more widely-used than LES models with most problems able to be solved with sufficient accuracy. They are created by time-averaging NS equations [21] to reduce complexity but in doing so introduce unknown Reynolds stresses within the averaging procedure, leaving the RANS equations open. Turbulence models have been developed to solve for the unknown Reynolds stresses using transport equations with numerical methods that iterate over time to find the approximate solution.

O2O2 Mask fluid flow simulations using RANS turbulence models will be undertaken in this project, using Ansys Fluent which is a popular program used to simulate LES and RANS models to predict fluid flow.

1.6.1 Turbulence Models

Each turbulence model has strengths and disadvantages depending on what it has been developed to solve. The main RANS turbulence models widely used are now summarized:

Spalart-Allmaras

The most basic Spalart-Allmaras model uses 1 transport equation to solve for kinetic eddy turbulent viscosity. It was originally designed for aerospace and is good at predicting flows with low levels of flow separation [22] while also being very computationally cheap. This

model requires an extremely fine mesh resolution near the wall to resolve the boundary layer with a Y+ of 1 and at least 15-20 cells in height.

K-Epsilon

The K-Epsilon (k-ε) model advances from the Spalart-Allmaras model, including 2 transport equations to model turbulent kinetic energy, k, and turbulence dissipation rate, ε. This model is widely used, fast to solve for and provides reasonable accuracy. The downside to this model is its inability to accurately predict near the wall for large adverse pressure gradients [23], due to the model relying on resolving of the viscous layer near the wall through the use of wall-functions which are discussed in section 1.6.3

K-Omega

The K-Omega (K-ω) model advances from the K-Epsilon model, retaining the transport equation to model turbulent kinetic energy, k, but solving for specific turbulence dissipation rate. This model provides a substantial increase in accuracy near the wall layer compared to the K-Epsilon model due to directly resolving the boundary layer and switching to use wall-functions away from walls. Downsides to this model are that it is sensitive in regions outside the boundary layer [23].

K-ω-SST

The K-Omega Shear Stress Transport (K-ω-SST) model is a hybrid of K-Epsilon and K-omega models. It uses the K-Omega near the wall for improved wall turbulence prediction and the K-Epsilon model once away from the wall. A blending function blends the 2 models. This model combines the advantages of both which also strongly improve flow separation prediction, which the 2 models alone underpredict [23]. Disadvantages of this model are that is it can over-predict laminar-turbulent flow separation.

Transition SST (gamma-Retheta-SST)

This model is based on the K-ω-SST model and incorporates 2 more transport models to include intermittency and transition onset criteria [24]. Improvements were also made towards blending between the K-ω and k-ε models. These changes have been shown to offer an improved determination of laminar-turbulent transition locations compared to the above models mentioned [25].

1.6.2 Meshing and Discretization Methods

Discretizing the desired problem geometry into a mesh consisting of a network of connected points allows for the use of 3 schemes compatible with being solved numerically. These are finite difference, finite volume or finite element methods. Finite volume is the most commonly used CFD technique which this project will use. This involves splitting up the geometry into finite volume cells with the variable of interest commonly being in the centre of the cell [26]. Discretization schemes are then used as interpolation profiles to interpolate partial differential equations from nodes, where each RANS equation has an individual scheme. Generally, a more complex discretization scheme offers improved accuracy with the reduction of robustness. Common schemes include first-order upwind, second-order upwind and QUICK.

Algorithms for solving each individual discretizing scheme are commonly known as pressure-velocity coupling schemes. Common algorithms include SIMPLE, SIMPLEC, Coupled and PISO, where SIMPLE and SIMPLEC are the most common for steady-state simulations with SIMPLE being the default in Ansys Fluent [27]. Each algorithm has problem-dependent strengths and weaknesses that can affect a simulation such as speed of convergence or robustness [28].

Under-relaxation factors can be used to stabilize the convergence of nonlinear numerical schemes and are commonly used with discretization schemes. All equations solved the pressure-based solver have associated under-relaxation factors [29]. Default under-relaxation factors are usually used but can be reduced to steady convergence with the disadvantage of taking longer to reach a desired convergence.

Finite volume meshes are categorized as structured or unstructured. A structured mesh uses efficient cell storage and indexing but cannot be used for extremely complex geometry. An unstructured mesh is used to resolve more complex shapes but has inefficient storage and access by the CFD solver. A hybrid mesh consisting of structured and unstructured cells can offer a balance between fast cell accessibility by the solver, which can speed up the simulation while allowing for meshing of complex geometries. Figure 1.4 below shows an example of structured and unstructured meshes where the structured mesh nodes positions can easily be found using a matrix, however, the unstructured mesh is more difficult.

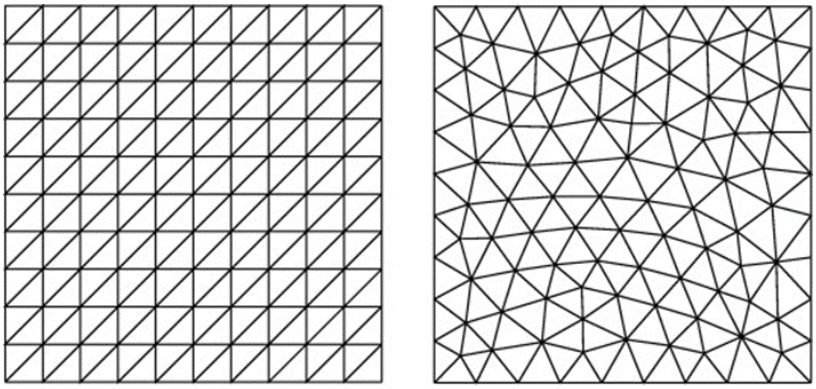


Figure 1.4: Comparison of structured and unstructured meshes [30]

The most common 3D cell shapes used in meshes are hexahedron, tetrahedron, pyramid and triangular prism. Tetrahedrons are the most used cell type, commonly used in unstructured meshes due to their quick generation and fast solving due to the low node count per cell. Hexahedron cells are commonly used in structured meshes and offer high accuracy due to the high node count per cell. Pyramid cells are commonly used as transition cells to join hexahedron cells to tetrahedron cells. Finally, triangular prism cells are commonly used to resolve the boundary layer near the wall of the mesh. A hybrid mesh consisting of all cell shapes can offer a balance between keeping a low node count, resolving areas of high curvature and be used to join unstructured meshes to structured meshes.

1.6.3 Wall Boundary Effect

The presence of a solid wall boundary effects the structure and behaviour of turbulent flow and the velocity-flow profile of turbulent flow is complex. Law of the Wall splits up this velocity-flow profile into regions dependent on a non-dimensional distance Y+ from the wall [31] to be modelled separately. Models have been developed to split the velocity-flow profile into many segments, but it is common to split it into 3 regions, the viscous sub-layer, buffer layer, and outer layer. Y+ is approximated dependent on friction velocity, distance between the closest wall and the kinematic viscosity of the fluid.

In the outer layer far away from the wall Reynolds numbers are very large and turbulence is fully developed, indicating inertia forces on the fluid overwhelm viscous forces [31] so the velocity-curve shape is largely dictated from these inertia forces.

In a region closer to the wall, Reynolds numbers and turbulence reduce and therefore inertia forces on the fluid are reduced and viscous forces are increased. The velocity-curve in this region is dictated by both inertia forces and viscous forces. This region is known as the buffer layer.

In a region very close to the wall, turbulence is very small and viscous forces overwhelm inertia forces to dictate the velocity-flow curve which can then be approximated using a simple equation only knowing the fluid density, wall stress, fluid dynamic viscosity and distance from the wall [20]. This is known as the viscous sub-layer and this region contains information regarding very small turbulent eddy motion close to the wall.

Wall functions inside some turbulent models calculate Y+ and use it to model velocity-curve profiles dependent on distance from the wall which allows for a low mesh-resolution near the wall, but not all turbulence models include wall functions and it is easier to refine the resolution of the mesh near the wall using inflation layers. This allows each segment of the velocity-flow profile to have a high resolution to predict the velocity-curve profile. The first cell height off of the wall can be approximated and set based off a desired Y+ value. First layer Y+ value is largely model-dependent with some preferring very low Y+ values below 1 and some suiting higher values. Turbulent models relying on wall functions can even be negatively affected if the first layer cell height Y+ value is too small.

1.6.4 Mesh Generation

The meshing process can be done using external dedicated software, but this project will use the automated meshing software build into Ansys. The process of Ansys meshing is simple, firstly a CAD model is imported, mesh settings are specified and finally, the meshing program will automatically run to generate the mesh. Common settings to use are shape functions that determine cell size based on curvature and distance between walls as well as inflation layers to improve the resolution near the wall to increase boundary-layer resolution.

It is very important to ensure a good mesh as some RANS models can have convergence issues with a poor mesh or their results strongly affected. Mesh metrics can be used after generation to ensure high cell quality and evaluate different cell properties. Some of the common mesh metrics used include orthogonal quality, skewness and aspect ratio.

1.6.5 Model Setup

Boundary conditions are used to define the fluid flow problem in Fluent, these are regions of the mesh that need to be defined so the solver knows their purpose and define what is being solved. The internal structure of the mesh is automatically defined but features such as fluid inlets, outlets, walls need to be specified. Inlets can be specified to be mass flow inlets (for a known mass flow), velocity inlets (for a known velocity) or pressure inlets (for a known average pressure on the inlet). Within each inlet and outlet boundary condition set are turbulence parameters, temperature and other details that need to be defined. With boundary conditions containing a substantial portion of a model's information, it is important that these are correctly set. Ansys recommend using default turbulence parameters of 5% turbulence intensity and a viscosity ratio of 10 when the inlet has no turbulence information available [32].

1.6.6 Model Running

After a problem is set up it is initialized as each cell contains no numerical value. Initializing involves an initial guess to set a numerical value to each cell. It is important to generate an accurate initial guess as some RANS models can diverge easily with a poor guess. Initialization can be made based off a boundary condition such as an inlet or using an iterative initialization algorithm.

After initialization, simulation can begin and start to converge on an approximate solution. The more the simulation can converge the better it can be trusted to show an accurate solution. Convergence graphs showing variable fluctuations can be used to show solving progress and many properties are visible or can be set up, criteria can be set for each property to ensure all have sufficiently converged. The base convergence criteria for Ansys Fluent and their values are:

- **Continuity – 1e-4**
- **X-Velocity – 1e-3**
- **Y-Velocity – 1e-3**
- **Z-Velocity – 1e-3**
- **Energy – 1e-3 (with energy equation turned on)**
- **K – 1e-3 (with applicable turbulence model)**

- **ε – 1e-3 (with applicable turbulence model)**
- **ω – 1e-3 (with applicable turbulence model)**
- **Intermittency – 1e-3 (with Transition SST model)**
- **Retheta – 1e-3 (with Transition SST model)**

Convergence for default values shown above are the minimum for an acceptable simulation but common practice is to tighten up values 1 or 2 magnitudes higher [33]. A good base point for simulations is to increase the magnitude of all values by 1, using 1e-5 for continuity and 1e-4 for all other applicable values. Each magnitude added to the convergence criteria increases the simulation difficulty, requiring a high-quality mesh and longer simulation times.

1.7 Conclusions

In this chapter, the justification for and details of a new proposed facemask design has been described along with the aims of the project regarding determining the viability of maintaining a filtered air-citadel in front of the face. This will require fan and air-gap specifications to be determined that can sustain this air-citadel over a range of inhalation airflow rates as well as planning of subsequent physical testing to validate these specifications generated.

The use of CFD simulations in the next chapter will determine the concept viability and specifically the fan and air-gap specifications for a functional proof of concept prototype facemask system.

Chapter 2: Computational Simulation

2.0 Introduction

In this chapter, the viability of a new concept pressurized face mask system is assessed over a range of steady-state maximal breathing rates. This was achieved using computational fluid dynamics (CFD) simulations of 4 different mask geometries using Ansys Fluent. This commenced with a simplified model before developing to a simulation representative of a proof of concept prototype mask and realistic facial geometry.

Each simulation was assessed on its ability to create and sustain a citadel of filtered clean air over the mouth and nose of a face without contaminated ambient air infiltrating through the air-gaps between the edge of the mask and face. Minimal fan performance and mask venting requirements during simulated breathing during moderate exercise are determined for 4 different test conditions. Results of these simulations will be used to specify fan performance requirements for a functional proof of concept prototype.

2.1 Simulation Criteria:

Given the operating parameters of the new pressurized face mask have not been determined, the simulation criteria of fan inflow, breath rates and vent flow first need to be specified. It is important that all four simulation models use the same criteria to keep results consistent.

2.1.1 Inhalation Criteria

For safety, it is assumed that during inhalation, mass flow out of the mask vents must remain above 0.6 g/s, this is also called the 'bias flow'. This nominal value was selected to minimize CO_2 build-up within the mask space and to also ensure that all air available for breathing has passed through a filtration system. This prevents polluted ambient air infiltrating the facemask air-gap by ensuring the mask air-citadel remains above atmospheric pressure, so no air is drawn in through the air-gaps. Results of simulations were visually checked for localized low-pressure zones around the air-gap to ensure no backflow occurred and that this 0.6g/s vent flow rate could work for all inhalation demands. This value of vent outflow is based on accepted mask bias flow rates typical of continuous positive air pressure (CPAP) machines [34, 35] which prevent CO_2 rebreathing.

Figure 2.1 shows a schematic representation of airflows during simulated inhalation. While simulating for a fixed bias flow will not identify the minimum bias flow rates to sustain a leak-free air-citadel, it is too computationally expensive to do repeat simulations to identify the minimum bias flow rates over the inhalation airflow range.

Figure 2.1: Schematic representation of model air flows during simulated inhalation

2.1.2 Exhalation Criteria

The exhalation design criteria were based on mass flow through the filter not dropping below a nominal figure of 0.6g/s. This ensures airflow through the filtration unit remains as a positive inflow into the mask and exhaled air does not backflow and contaminate the filter. Figure 2.2 shows a schematic representation of airflows during simulated exhalation.

Figure 2.2: Schematic representation of model air flows during simulated exhalation

2.1.3 Oral Inhalation Breath Rates

Oral mass inhalation rates used in simulations using an oral breathing route ranged from 1.5 to 4.5 g/s. These were based on extrapolating peak inhalation and exhalation tidal volumetric airflow rates for adult individuals engaging in various effort levels from 40 to

80% [36] which equated to 104.8 to 243.3 L/min. These peak 40% and 80% volume flow rates were converted to a mass flow rate value as boundary conditions of computer simulations required a mass flow rate and temperature value. Assuming an air density of 1.225Kg/m^3 at sea level and 15 °C gave converted peak oral inhalation mass flow rates ranging from 2.2 to 5.1 g/s. 1.5 and 4.5 g/s values selected as the lower and upper simulation limits were from extrapolating suitable airflow rates for effort levels ranging from 30 to 70% as it was assumed the effort level of users wearing the new O2O2 ltd facemask during mild exercise would be lower.

2.1.4 Nasal Inhalation Breath Rates

Nasal mass inhalation rates used in the simulations of models using a nasal breathing route ranged from 0.6 to 2.0 g/s. The upper airflow limit of 2.0 g/s was based on peak nasal inhalation tidal airflow rates for adult individuals at the switchover point from nasal to oral breathing which equated to a mean maximum volumetric inhalation rate of 97.2 L/min [37]. This peak volume flow rate was converted to a mass flow rate value as boundary conditions of computer simulations required a mass flow rate and temperature value. Assuming an air density of 1.225 kg/m^3 at sea level, 15 °c, gave the peak nasal inhalation mass flow rate of approximately 2.0 g/s.

2.1.5 Mask Leakage Criteria

Leakage was assessed by looking at contours of pressure along the air gap with contours showing sub-ambient pressure indicating a leak. Nominal minimum leakage pressure criteria were chosen to be 0.1 Pa below ambient pressure. This was chosen as pressures between 0 and -0.1 could be solution inaccuracies and might not indicate the possibility of ambient air infiltrating the mask space.

2.2 Model 1: Characterizing fan requirements during simulated oral breathing using simplified mask and facial geometry

This first model involved computer simulations of a simplified model consisting of approximate representations of mask and facial geometry. Both oral inhalation and exhalation were simulated, with exhalation rates assumed to be identical to inhalation rates.

2.2.1 Model Geometry

A virtual representation of a proof of principal mask prototype was provided by the sponsor company, O2O2, and drawn up as a simplified 3D CAD model. Air Inlet tubes were specified by O2O2 as 10mmx40mm rectangular sections. Other dimensions were taken from the proof of principle prototype or assumed. In this case, given this model did not employ a geometric face, the air gap sizing between the face and mask surfaces was assumed to be 8mm deep.

This first model assumes that the user would be exclusively mouth breathing and facial geometry was simplified to an extruded arc to represent the face surface. Simplified lip geometry to funnel air into a representative elliptical-shaped mouth opening was also employed. The final simplified model geometry, shown in figure 2.3, has coloured regions to highlight the air inlets, air-gap and mouth faces.

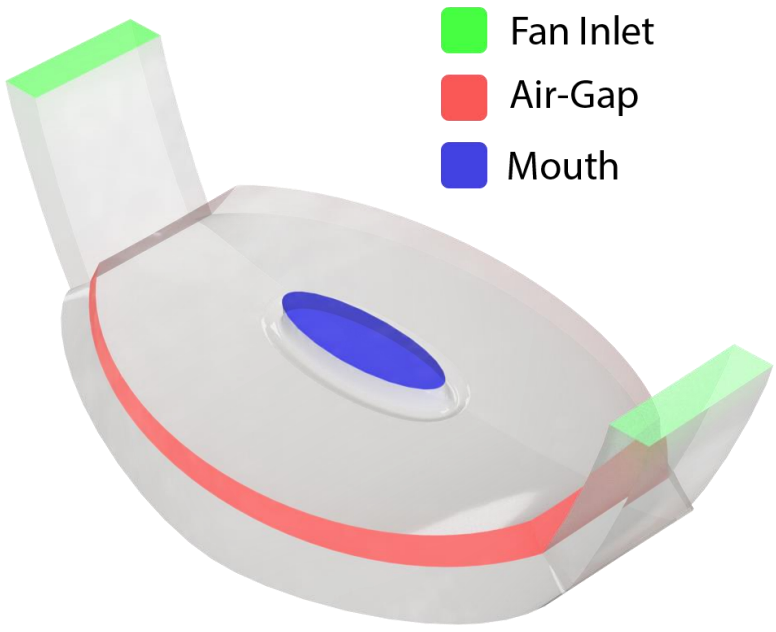


Figure 2.3: Simplified representation of mask system detailing regions of inflow, outflow and oral breathing route

2.2.2 Model Meshing

Meshing is the discretization of the previously described 3D CAD model to a represent the model using a network of linked points (nodes) through which the CFD software can solve for pressures and flow rates. Mesh quality and mesh resolution directly impact simulation results so both need to be carefully considered. The final mesh applied in this phase of the study was a balance between obtaining sufficient resolution and mesh quality. Having a good mesh quality achieves improved result reliability, simulation stability and fast convergence while having a high mesh resolution can capture more flow detail of the geometry and is necessary for keeping mesh quality high in high curvature areas. The disadvantage to increased mesh resolution is an increase computational time, therefore resolution refinements were reserved for specific regions of high interest, which in this case was the mouth and mask vent air-gap.

Figure 2.4: Final mesh showing refined areas around the mouth

2.2.3 Ansys Fluent Setup

CFD analysis was undertaken using Ansys Fluent with solutions being solved under steady state airflow conditions which allowed the inlet, mouth and air-gap mass flows to be specified using conservation of mass. Completion of the simulation resulted in the solution for minimum inlet fan pressures to meet the desired inlet mass flow rates.

Turbulence model: k-ε (K-Epsilon), used for ease of convergence, computationally cheap and to include turbulent flow. Default wall functions used.

Solution method (Scheme): Simplec, the Simplec scheme was found to converge well this model and no change to the default under-relaxation factors was required to assist with convergence.

Boundary Conditions:

Inlet: Inlet Mass Flow 2.1-5.1 g/s, direction normal to inlet surface, default turbulence parameters used due to unknown fan turbulence information – Pressure to be solved
Nasal orifice: Outlet with a goal mass flow rate – Pressure to be solved
Air gap: Outlet with a goal mass flow rate – Pressure to be solved

2.2.4 Results

Four sets of results were obtained for both inhalation and exhalation breathing phases. These produced area-average total pressures (combined static pressures + dynamic pressures) and mass flows at the mouth, air-gap and inlet. Identifying the inlet pressures and assessing for leaks were the main objectives to understand if the facemask concept was viable and the identify the minimum-fan performance requirements. The results for inhalation and exhalation are shown in tables 2.1 and 2.2 respectively. Figures indicating flow details can be seen in Appendix A.

Table 2.1: Inhalation results for Model 1

Inlet Pressure (Pa)	Inlet Mass flow (g/s)	Mouth Mass flow (g/s)	Mouth Pressure (Pa)	Average Airgap Pressure (Pa)	Airgap Mass flow (g/s)
5.676316	2.1	1.5	-0.8057765	0.4079425	0.6
11.644106	3.1	2.5	-2.6613259	1.09088	0.6
19.452945	4.1	3.5	-4.3213712	1.8439143	0.6
29.615621	5.1	4.5	-9.0063414	3.5543489	0.6

Table 2.2: Exhalation results for Model 1

Inlet Pressure (Pa)	Inlet Mass flow (g/s)	Mouth Mass flow (g/s)	Mouth Pressure (Pa)	Average Airgap Pressure (Pa)	Airgap Mass flow (g/s)
1.0809528	0.6	1.5	2.6152507	0.64473184	-2.0999358
1.9015627	0.6	2.5	6.4596251	1.6804933	-3.1000155
3.0485306	0.6	3.5	11.817687	3.249195	-4.0997219
4.317284	0.6	4.5	18.608446	5.2645112	-5.1000573

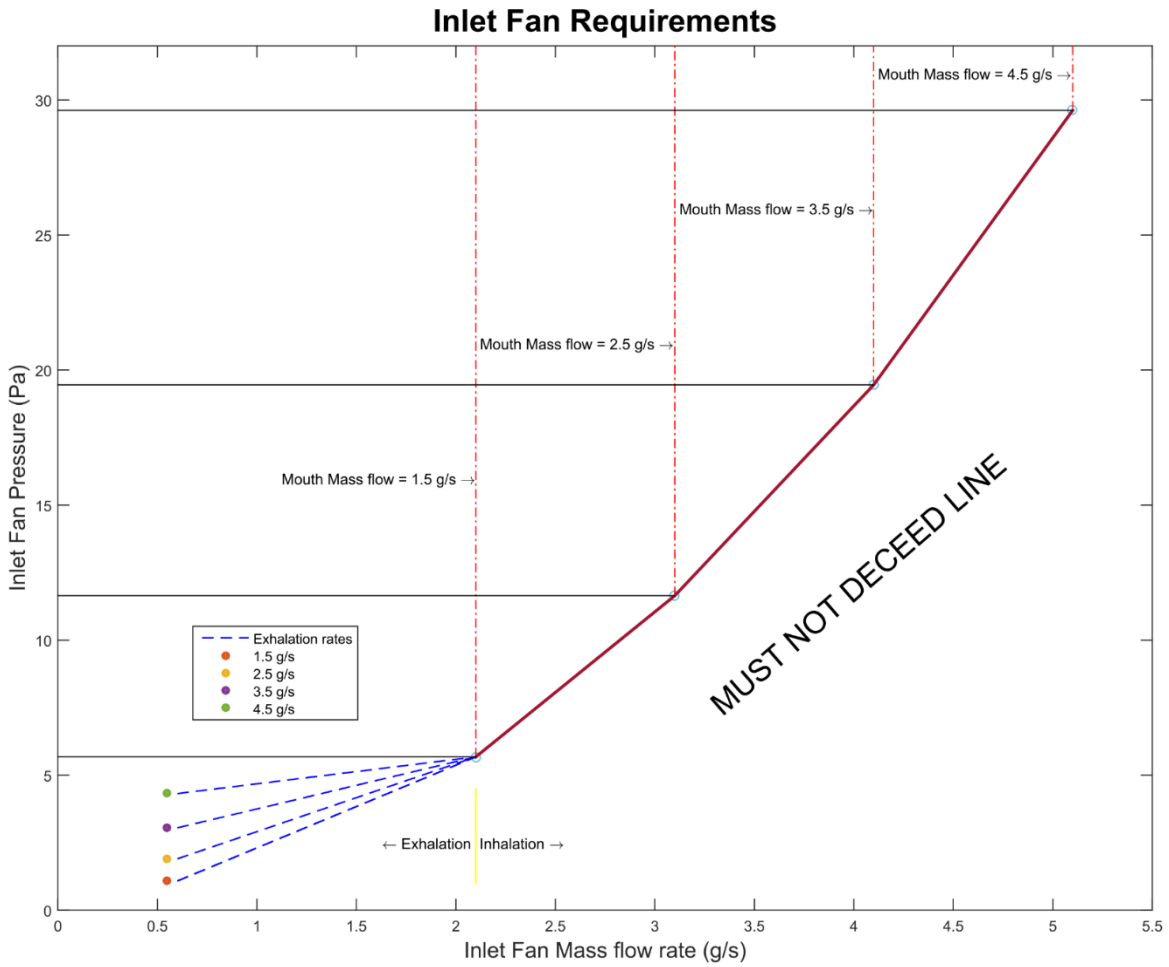


Figure 2.5:Fan minimum performance specifications over a range of inhalation and exhalation breath rates

The inlet fan requirements, shown in Figure 2.5 demonstrate the minimum inlet fan performance characteristics required to meet the mouth mass flow and minimum mask vent requirements. The red trend line is solved using inhalation criteria specified in section 2-1.1 while the blue exhalation rate lines are solved for using exhalation criteria specified in section 2-1.2. To ensure both design criteria are met, the inlet pressure must not fall below the red trend line or below the applicable individual dots for any given combined inlet mass flow rate. The trend shows that an exponential increase in pressure is required to deliver high mouth mass flow rates. This is typical of pressurized breathing systems and is caused by the throttling effect experienced at both the fan inlets and mouth.

2.2.4.2 Facemask air-gap vent requirements

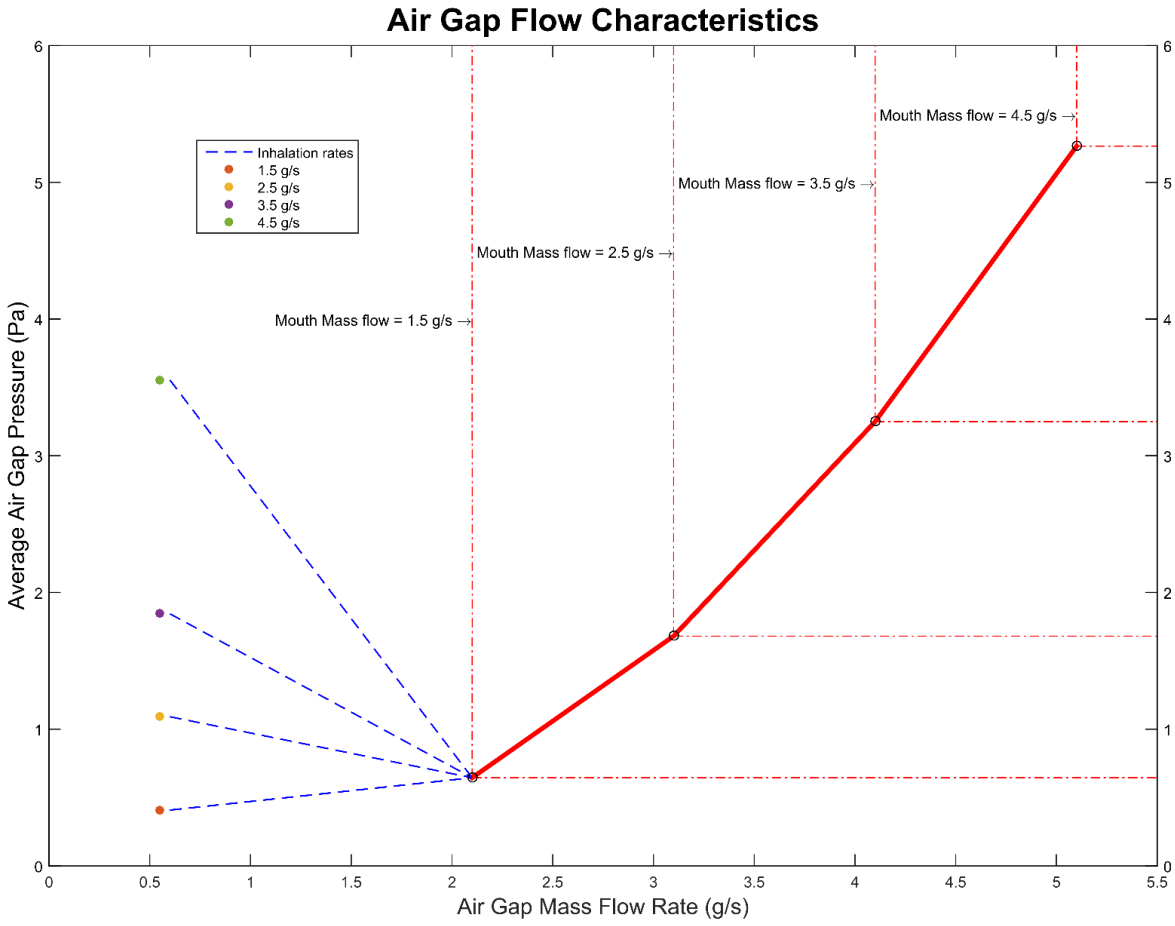


Figure 2.6: Mask vent pressures over a range of inhalation and exhalation peak breath rates

Figure 2.6 shows the average mask air-gap pressure over the inhalation and exhalation rates. Despite the mask vent pressure never reaching 0 Pa, at low breathing flow rates the vent pressure drops below 1 pascal and could be susceptible to external interaction, such as background airflow around the mask, causing infiltration of contaminated ambient air. Due to this, air-gap sizing should be kept low to minimize the effect of external factors and increase the pressure gradient across the air-gap.

The red trend line was solved using inhalation criteria specified in section 2.1.1 while the blue exhalation rate lines were solved for using exhalation criteria specified in section 2.1.2. For this simplified model, the air gap through which air vents from the mask were specified at 8 mm around the entire perimeter. In practice, this was not feasible to employ in a functional design embodiment given the drying effect a continuous airflow will have as it passes across eyes. Further detail design varying the facemask air-gap can overcome this issue while providing sufficient mask air venting. This will be undertaken later by the sponsor company O2O2 ltd.

2.2.5 Model 1 Conclusion

Initial simulations of the proposed concept mask system were a success and showed the inlet fans must maintain a minimum pressure of 29.6 Pa at a combined mass flow rate of 5.1 g/s (250 L/min) to meet the highest inhalation rate at a medium intensity exercise level. The next simulation of model 2 will help to consider the effect facial morphology has on mask performance.

Conceptual fan selection feedback was sent to O2O2 which allowed motor sizing to be undertaken using the minimum fan performance curve provided by Figure 2.5. This figure shows the mask vent flow characteristics for the specified constant air-gap of 8 mm for exhalation and inhalation.

Exhalation results showed little effect on fan motor requirements so are not required to be simulated for proceeding models.

2.3 Model 2: Characterizing initial fan requirements during simulated nasal breathing using realistic facial morphology and a simplified mask

This model differentiates from the earlier one by simulating air flow through the simplified mask attached to anatomically correct facial geometry and exclusively nasal inhalation. Using anatomically correct facial geometry acquired by 3D-scanning of a face, it provides a more accurate prediction of mask, fan and vent performance characteristics for the simplified mask model.

2.3.1 Model Geometry

The virtual representation of the physical prototype was further developed from model 1 to include full facial morphology. Model 1 indicated the importance of best-representing airway openings to achieve reliable results. Understanding this, the geometry used in model 2 included a section of real nasal geometry created from MRI scans. This geometry was modified to smoothly meet up with the nasal openings of the external facial geometry acquired from 3D-scanning. The mask shape was modified slightly to closely fit this 3D-scanned face to keep air-gap areas low and is shown in Figure 2.7. To minimize the dry-eye effect caused by airflow over the eyes, the air-gap for this model was not uniform and reduced drastically in size under the eyes.

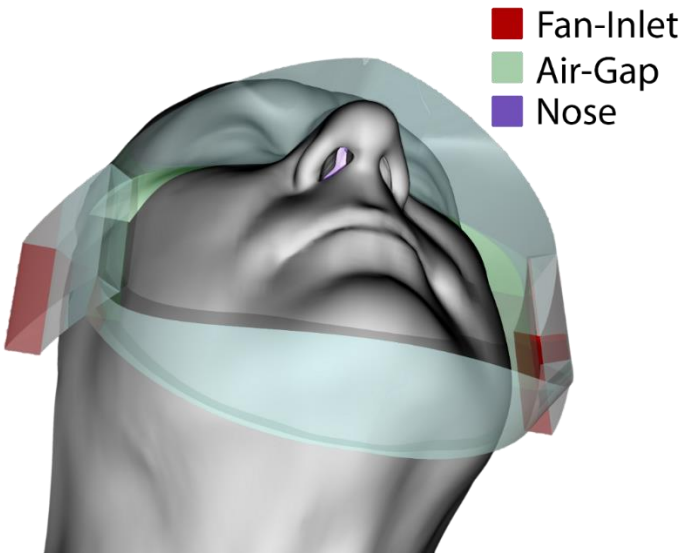


Figure 2.7:Representation of updated mask system detailing regions of inflow, outflow and nasal breathing route

2.3.2 Model Meshing

As applied in model 1, having a good balance of mesh quality and resolution is critical as the mesh directly relates to the stability and results of the simulation. Meshing with this more detailed mask was a big challenge and took a lot of refinement to get to an acceptable quality. One main area of change was the addition of wall inflation layers to assist in predicting velocity-profiles near the walls which was required by the k-ω turbulence model due to the lack of wall-functions that the k-ε turbulence model used in model 1. Inflation was specified with 5 steps and a growth rate of 1.2. These inflation layers were added to the inlet ducts, nasal airways and face surface, as shown in figures 2.8 and 2.9. Inlet refinements improved flow prediction at the inlet leading to improved prediction of inlet pressures. Face inflation led to improved prediction of air-gap flow and nasal airway inflation lead to better prediction of airflow up the narrow airway openings. The final mesh had 7.56 million cells and 2.53 million nodes which increased significantly compared to model 1 due to the more complex facial geometry.

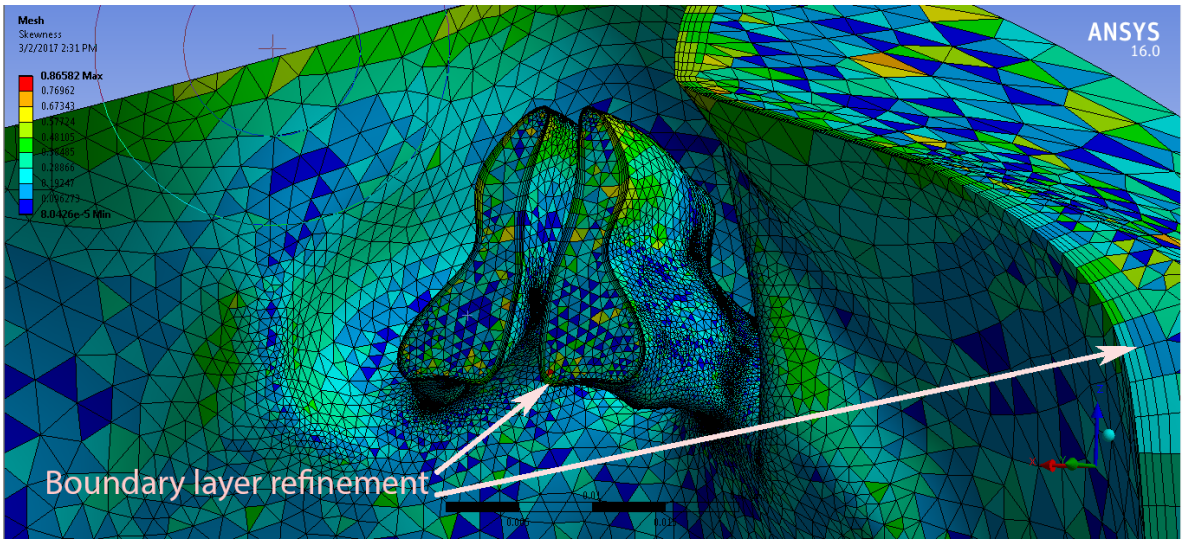


Figure 2.8: Mesh of model 2 showing areas of boundary layer refinement on nasal airway and facial surfaces

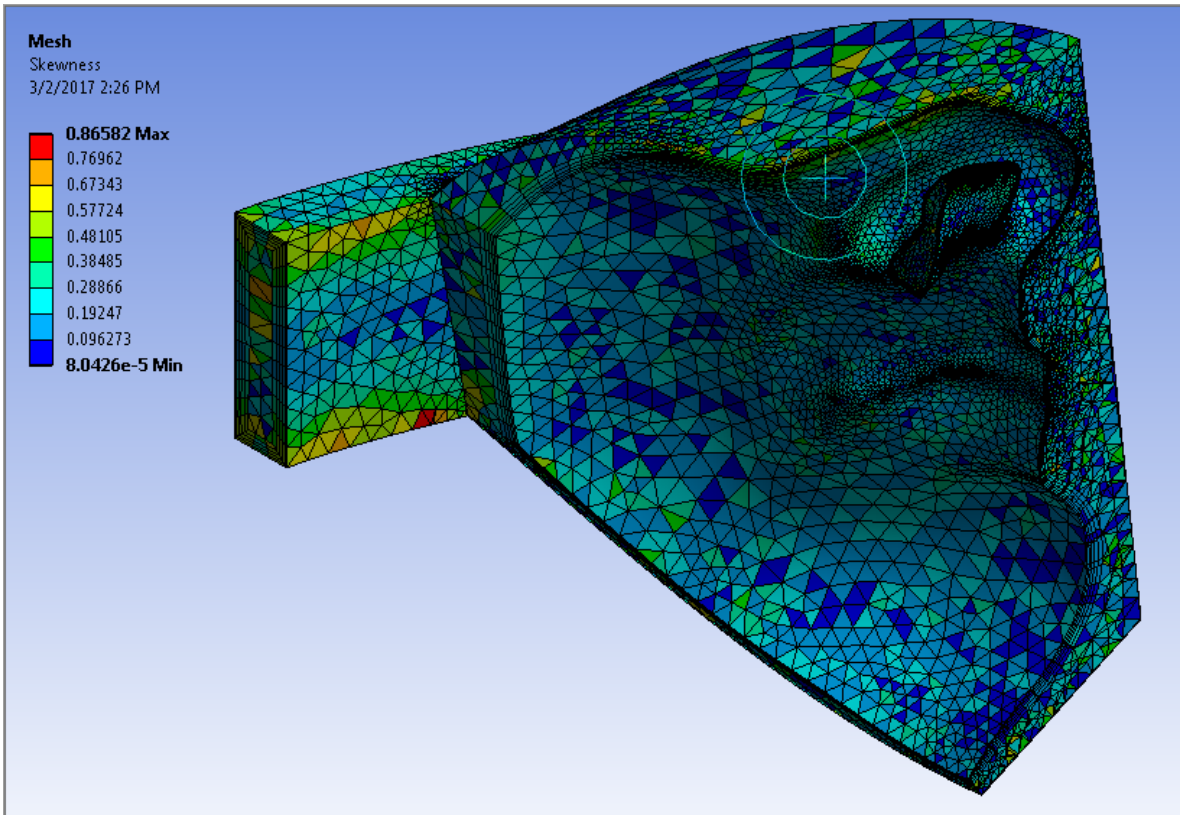


Figure 2.9: Mesh cross section of model 2 showing boundary layer refinement on air-inlet ducts and near face surface

2.3.3 Ansys Fluent Setup

Turbulence model: k-ω (K-Omega) was used as the turbulence model to better-predict flows near the wall compared to the k-ε turbulence model as used in the first mask model.

Pressure-velocity coupling scheme: Simplec

Boundary Conditions:

Inlet: Inlet Mass Flow 1.2-2.5 g/s, direction normal to inlet surface, default turbulence parameters used due to unknown fan turbulence information – Pressure to be solved

Nasal orifice: Outlet with a goal mass flow rate – Pressure to be solved

Air gap: Outlet with a goal 0.6g/s mass flow rate – Pressure to be solved

2.3.4 Results

Six sets of results shown in Table 2.3 were obtained for the nasal inhalation phase for nasal airflow rates between 0.6 to 2 g/s. These produced area-average total pressures (combined static pressures + dynamic pressures) and mass flows at the nose, air-gap and inlet locations. Figures indicating flow details can be seen in Appendix A.

Table 2.3: Nasal inhalation results for Model 2

Inlet Pressure (Pa)	Inlet Mass flow (g/s)	Nasal Mass flow (g/s)	Nasal Pressure (Pa)	Average Air-gap Pressure (Pa)	Air-gap Mass flow (g/s)
1.4567087	1.2	0.6	-10.36861	0.060471569	0.6
2.1956808	1.5	0.9	-22.80304	0.08675896	0.6
3.0798038	1.8	1.2	-39.20509	0.12043224	0.6
4.1057164	2.1	1.5	-60.17742	0.15848652	0.6
5.2704387	2.4	1.8	-85.58998	0.2009145	0.6
6.1236688	2.6	2.0	-106.2805	0.23305802	0.6

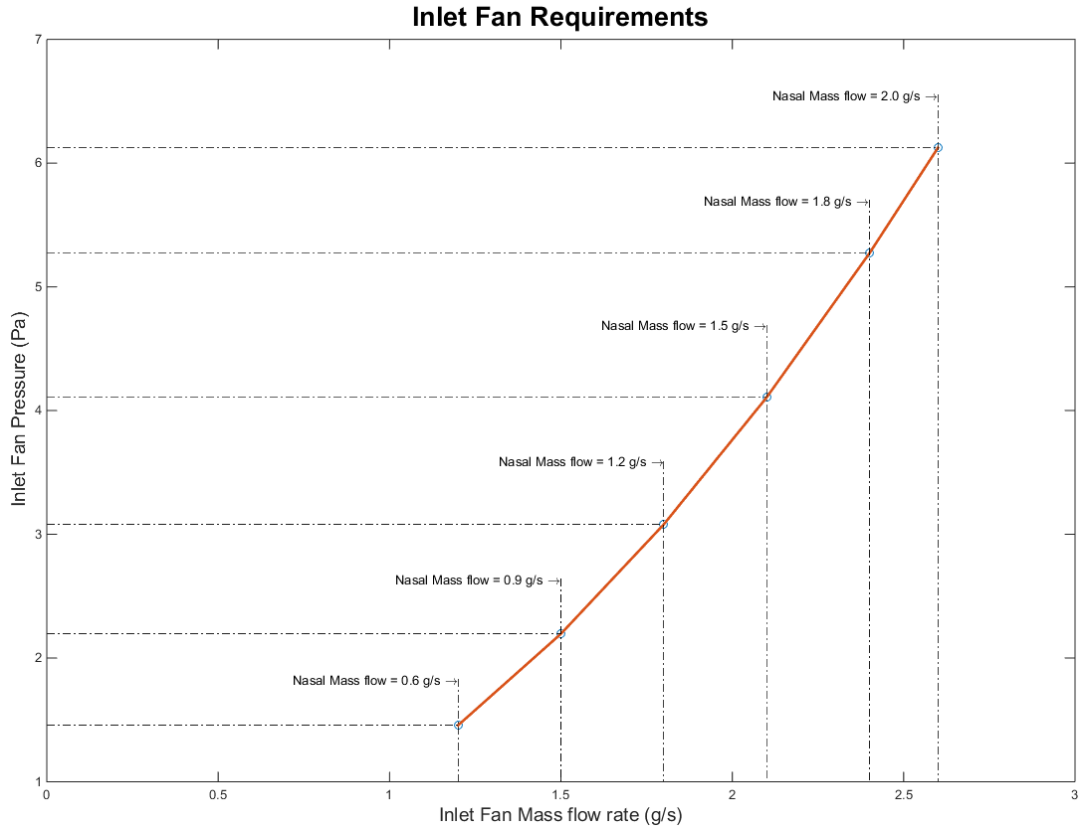


Figure 2.10:Minimum fan requirements over a range of peak nasal flow rates for model 2

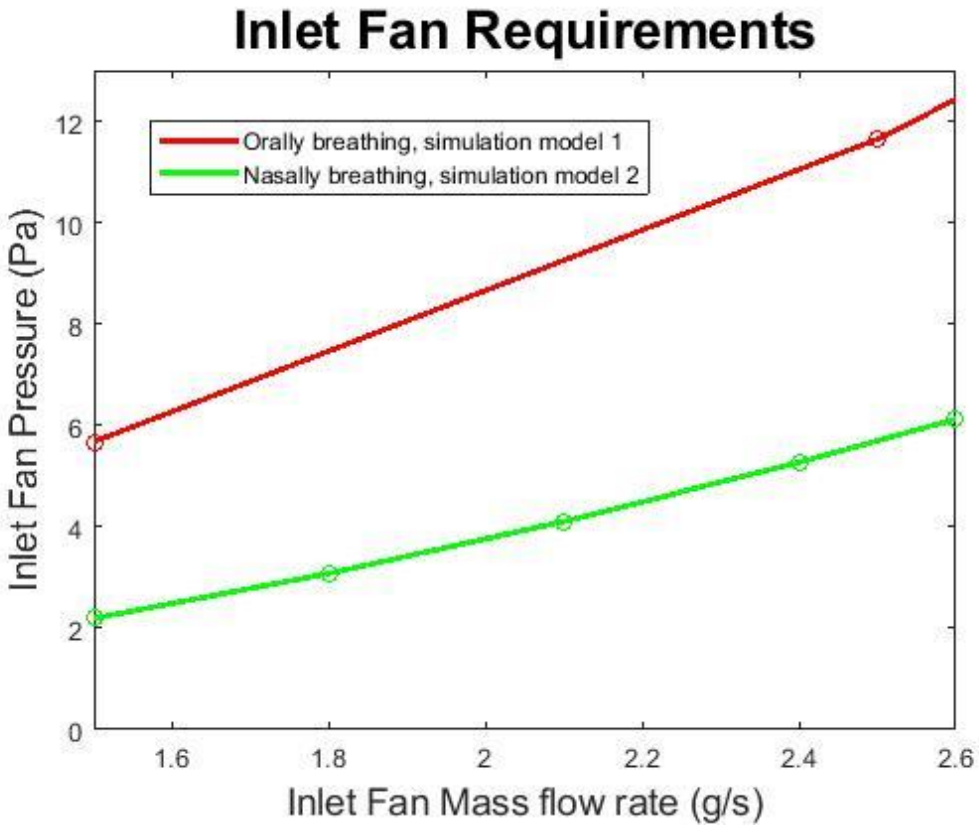


Figure 2.11:Inlet fan requirements comparing model 1 to model 2

Figure 2.10 demonstrates the minimum inlet fan performance characteristics required to meet the mass flow requirements at the nose during simulated nasal inhalation using inhalation criteria set in section 2-1.1 and inhalation rates from section 2-1.4. Solving for an oral breathing route will identify the fan requirements for higher inlet air flows and the 2 sets of data could then form 1 fan performance graph to meet all breathing needs.

The results of simulation models, orally breathing with simplified mask and facial geometry, 3, and nasally breathing with simplified mask geometry and realistic facial geometry, 4, were plotted together for comparison as shown in figure 2.11. This was done as these models share a small 1.5 to 2.6 g/s overlap in inhalation simulation ranges. There is a trend correlation between the two models as can be expected however model 2 is seen to require approximately half the inlet pressure. This is most likely due to air-gap vent geometry variations between the 2 models.

2.3.5 Model 2 Conclusion

Simulations of model 2 produced fan inlet requirements approximately half of those derived in the first model. Differences in results are thought to be due to minor mask geometry changes, the use of real facial geometry affecting the new air gap vent shape and area as well as changing to the more advanced k-ε turbulence model.

2.4 Model 3: Characterizing fan requirements during simulated nasal breathing using both realistic facial geometry and a prototype mask

Model 3 differs from model 2 by changing the mask geometry to that from a proof of concept prototype mask which was supplied by the sponsor company, O2O2. Results of this simulation were important as the proof of concept prototype was intended to be the first pressure-controlled mask, therefore this model will be used to update required inlet pressures to size the fans and validate minimum facemask vent air pressures. Facial geometry from model 2 was used with the same nasal inhalation route to keep correlation between the models. This meant that result differences were more reflective of mask geometry changes. The sponsor company, O2O2 ltd, were interested in pressure values near the centre of the mask for selection of a pressure sensor to implement a pressure-controlled fan control loop. For this reason, pressure data was recorded at a location near the center of the mask called Point 1, as indicated by figure 2.12. "

2.4.1 Model Geometry

For simulation, only a watertight thin-walled model is needed for mesh generation, so the inner surfaces of a supplied prototype mask model were used. Figure 2.12 shows this watertight and simplified model on the left and on the 3D-scanned face before model trimming on the right. This new mask varies the inlet sizing from an assumed rectangular shape to a larger, rectangular shape including airflow straighteners that split the inlet duct into 3 smaller rectangles. The simulation assumes that the airflow straighteners effectively straighten the flow so that the simulated flow into the mask is normal to the inlet surfaces.

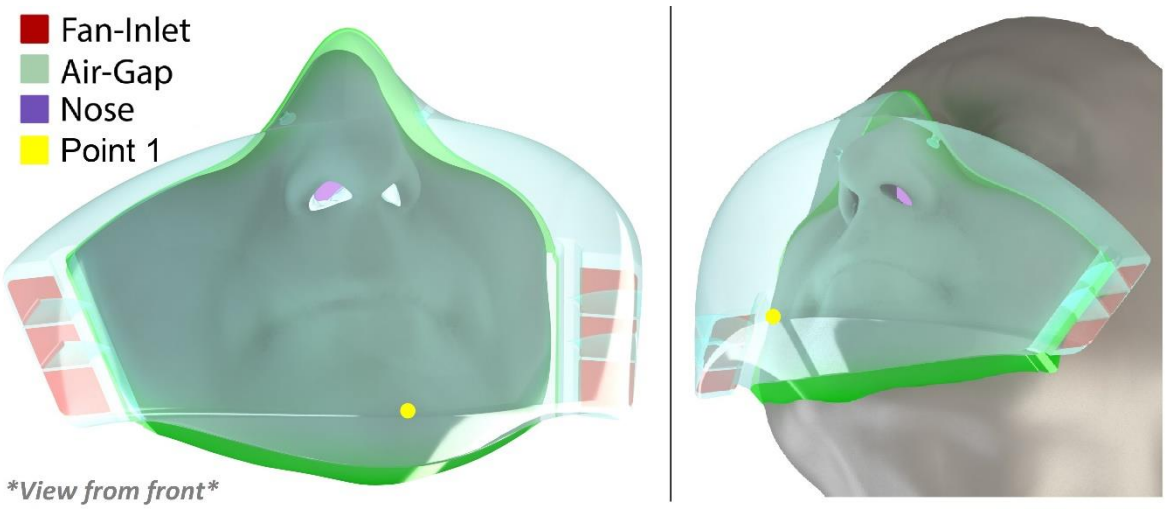


Figure 2.12:Mask shown on 3D-scanned face model showing air-gap, inlet and outlet geometry

2.4.2 Model Meshing

This model was more difficult to mesh than the previous model due to the increased complexity of the mask geometry. The model needed to first be simplified in Ansys Design Modeler by merging as many surfaces as possible to reduce the complexity which otherwise caused errors in the surface mesh. Areas such as the air inlets needed more detail and the sharp edges of the air gap were difficult to mesh to acceptable levels of skewness, orthogonal quality and aspect ratio which were the 3 main mesh metrics used to validate this mesh. Shown in figure 2.13 is a coloured surface mesh showing skewness, where low skewness is a positive metric. Most skewness was low and shown to be under 0.5 with large skewness areas being near sharp edges, such as those surrounding the air-gap where locally increasing the mesh resolution was able to resolve most of these areas. The final mesh had 2.26 million cells and 500 thousand nodes. This node and cell count is much lower than what was used in model 2 while achieving improved mesh metrics. This reduction in mesh size was needed to counter the otherwise large computational time increase that would have occurred with model 3's more advanced turbulence model.

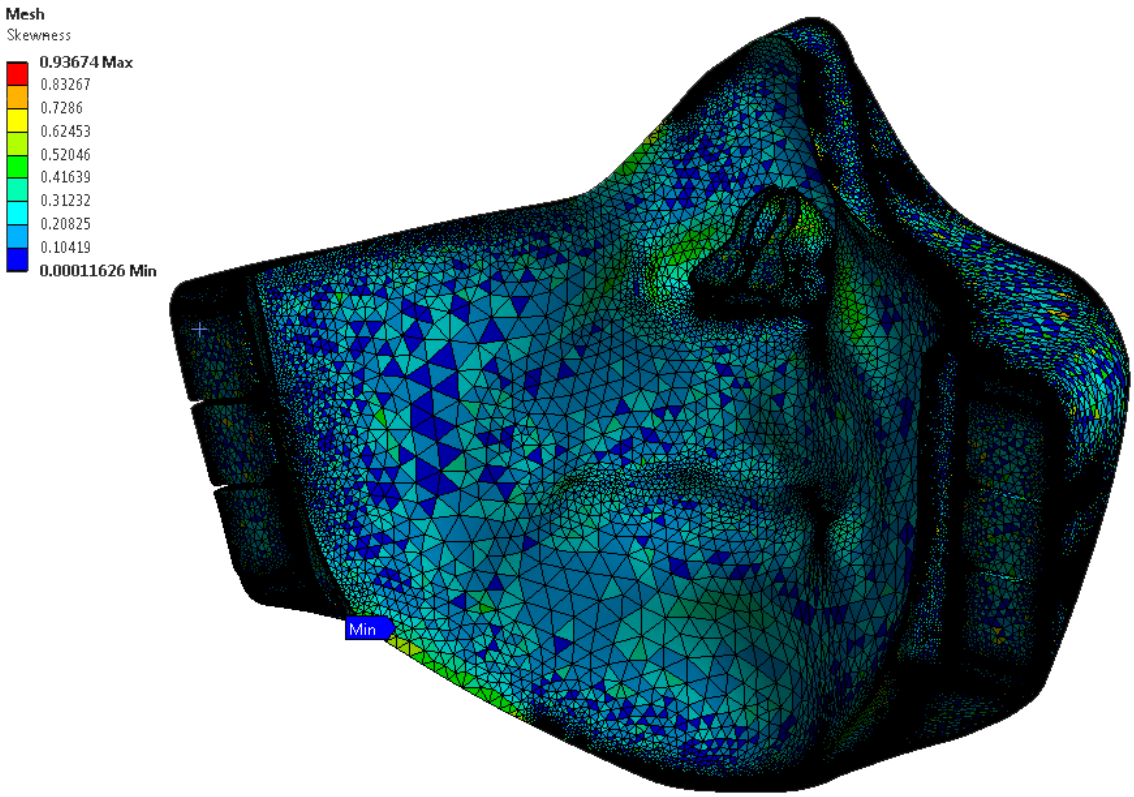


Figure 2.13:Surface mesh viewed from behind the model showing low levels of skewness

2.4.3 Ansys Fluent Setup

Turbulence Model: k-ω-SST (K-Omega SST) was used as the turbulence model due to it combining the benefits of both k-ε and k-ω turbulence models used in models 1 and 2 respectively. This improved model was much harder to solve for than the k-ε model, requiring the mesh metrics used to be exceptional and initialization to be close. The mask model was found to diverge and be unsolvable when initialized using hybrid initialization, so this was initialized based on the air-inlets.

Pressure-velocity coupling scheme: Simplec

Boundary Conditions:

Inlet: Inlet Mass Flow 1.2-2.6 g/s, direction normal to inlet surface, default turbulence parameters used due to unknown fan turbulence information – Pressure to be solved

Nasal orifice: Outlet with a goal mass flow rate – Pressure to be solved

Air gap: Outlet with a goal 0.6 g/s mass flow rate – Pressure to be solved

2.4.4 Results

Table 2.4: Nasal inhalation results for Model 3

Inlet Pressure (Pa)	Inlet Mass flow (g/s)	Nasal Mass flow (g/s)	Average Air-gap Pressure (Pa)	Total Pressure Point 1 (Pa)	Static pressure Point 1 (Pa)	Air-gap Mass flow (g/s)
2.059512	2.6	2.0	0.184317	0.54325	0.37235	0.6
1.91959	2.5	1.9	0.171861	0.51733	0.3664	0.6
1.6579	2.3	1.7	0.14806	0.47115	0.37112	0.6
1.401141	2.1	1.5	0.12312	0.39878	0.3205	0.6
1.175863	1.9	1.3	0.10735	0.35525	0.2948	0.6
0.964	1.7	1.1	0.0898	0.299	0.256	0.6
0.77231	1.5	0.9	0.07415	0.24525	0.2174	0.6
0.59936	1.3	0.7	0.06000	0.1906	0.17402	0.6
0.520079	1.2	0.6	0.054879	0.17127	0.1584	0.6

Nine simulation data-sets were obtained for flow rates between 0.6 and 2.0 g/s compared to mask model 2 which only had 6 sets of data. Figure 2.14 shows these data sets graphed resulting in the fan performance requirements for mask model 3 for a head exclusively nasal breathing. Due to a large number of data points this curve achieved a strong trend line which shows a slight exponential increase in fan pressure is required as the inhalation demand increases like that of model 2. Pressure results at Point 1 indicate that a pressure sensor to be used for feedback in a fan control loop must be able to read a static pressure between approximately 0.15 and 0.4 pascals while nasally breathing. A figure indicating flow details can be seen in Appendix A.

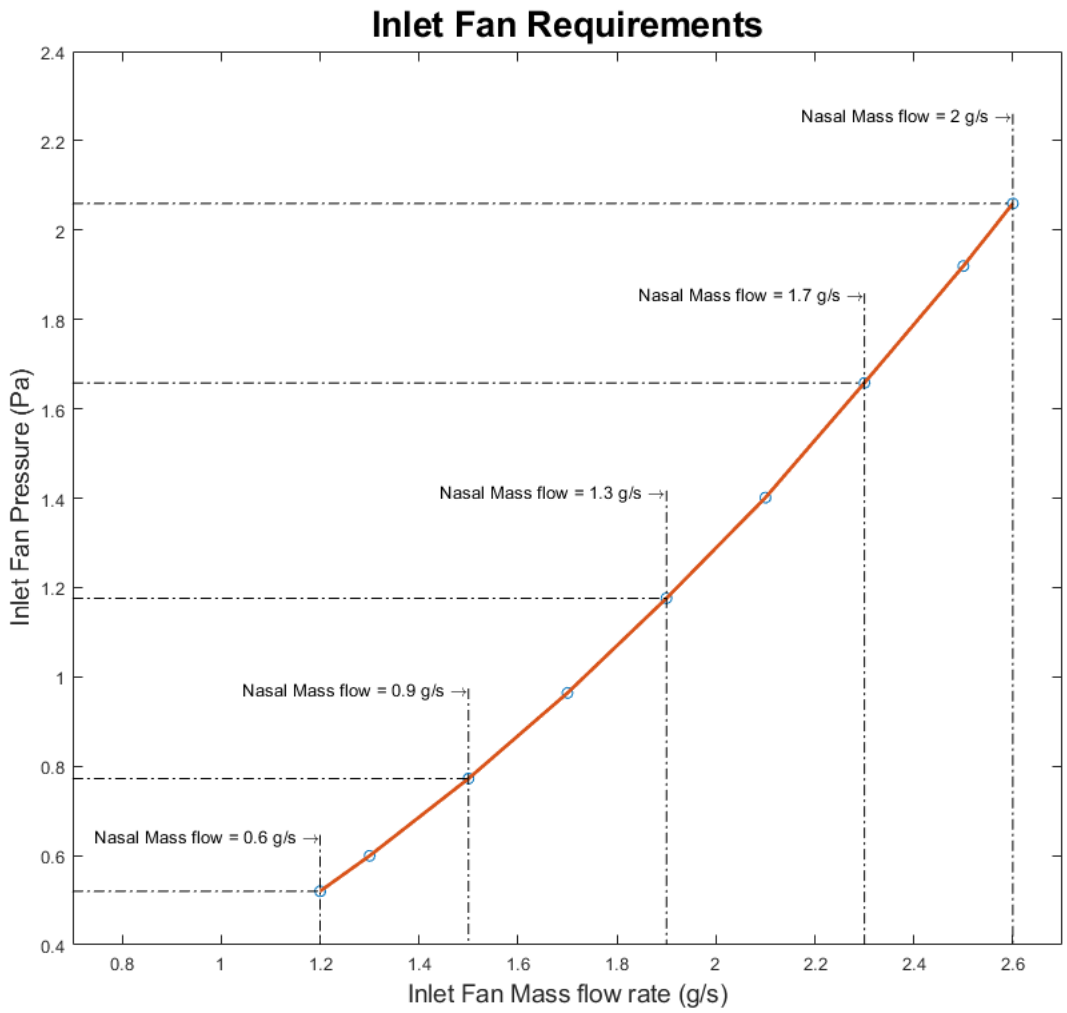


Figure 2.14:Minimum fan requirements over a range of peak nasal flow rates for model 3

2.4.5 Model 3 Conclusion

Simulations of model 3 show inlet pressure results approximately one-third of those shown to be required in model 2. The most likely cause of this is the significantly differing inlet and air gap geometry. The inlet on the proposed proof of concept prototype mask is 60% larger in area than the initial proof of principal mask concept used in models 1 and 2 and does not duct air into the mask domain. This change in the proof of concept prototype mask would reduce pressure losses in pushing air down the inlet ducts. Air-gap pressures are between approximately 0.055 to 0.184 Pa which correlates well to model 2's approximately 0.06 to 0.233 Pa. This slight reduction could be due to a marginally larger air-gap size or due to the change from the k-ω to k-ω-SST turbulence model.

2.5 Model 4: Characterizing fan requirements during simulated oral breathing using both realistic facial geometry and a prototype mask

2.5.0 Introduction

This final model differs from the third model by simulating an oral breathing route rather than nasal and utilized differing facial geometry with an open mouth. Since the oral airway has a much higher peak airflow rate than the nasal airways, this model will provide fan performance requirements for the highest inhalation demands. Low airflow rates were also simulated down to an oral inhalation demand of 1 g/s compared to the oral inhalation rates simulated in the previous oral simulation in model 1 which only simulated down to 1.5 g/s, this is to improve the overlap in inhalation airflow rates between models 3 and 4.

2.5.1 Model Geometry

This model used different facial geometry from the third model, scanning a different face with the mouth open rather than closed. Figure 2.15 shows the completed model to be used for CFD simulations. With the mouth open, the jaw is lowered and the air-gap around the side of the face is noticeably larger than the previous model.

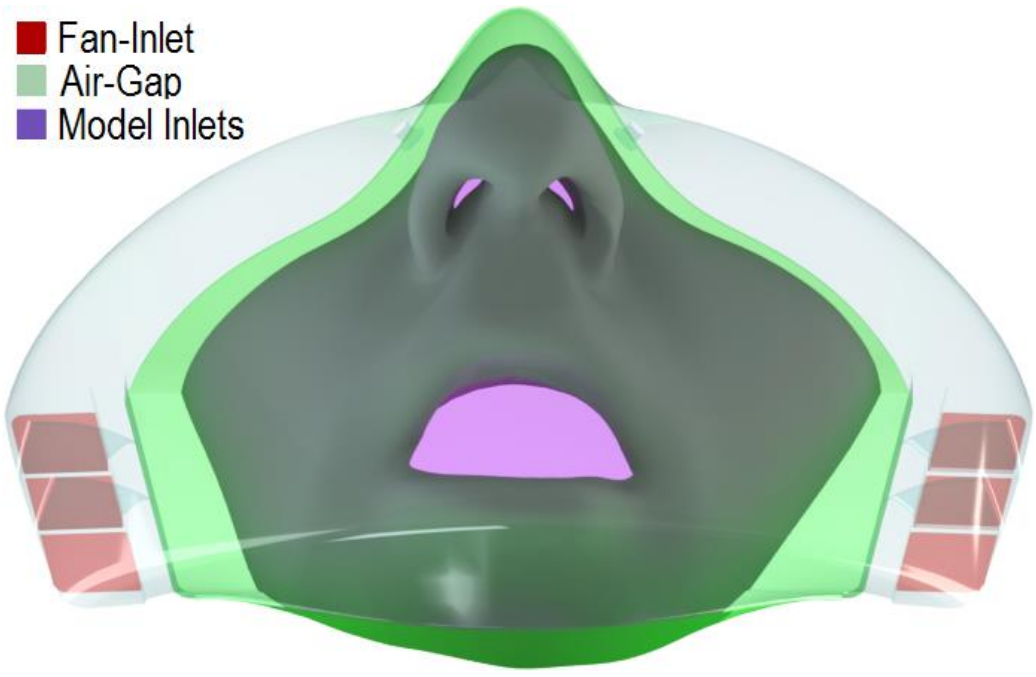


Figure 2.15:Sealed Mask-face model used for meshing of model 4

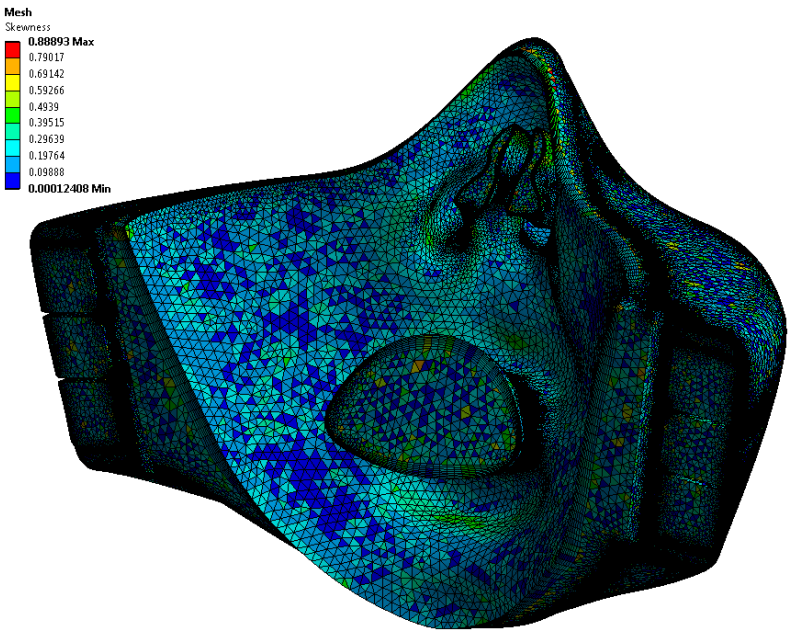


Figure 2.16:Mesh of model 4, colours indicating levels of skewness

2.5.2 Model Meshing

Model 4 was meshed similar to model 3 and had a slight improvement on the orthogonal quality, skewness and aspect ratio mesh metrics used to evaluate quality, with a reduction in maximum skewness from 0.93 to 0.88 as shown in figure 2.16. This model required slightly more cells and nodes to achieve the higher quality with 2.92 million cells and 667 thousand nodes used.

2.5.3 Ansys Fluent Setup

Turbulence model: Transition Shear Stress Transport (Transition SST) was used as it provided improved model convergence while also being more advanced, which should lead to improved prediction of turbulent flow compared to the k-ω-SST model used in model 3.

Pressure-velocity coupling scheme: Simplec

Boundary Conditions:

Inlet: Inlet Mass Flow 1.6-5.1 g/s, direction normal to inlet surface, default turbulence parameters used due to unknown fan turbulence information – Pressure to be solved

Nasal orifice: Outlet with a goal mass flow rate – Pressure to be solved

Air gap: Outlet with a goal mass flow rate – Pressure to be solved

2.5.4 Results

Table 2.5: Oral inhalation results for Model 4

Inlet Pressure (Pa)	Inlet Mass flow (g/s)	Oral Mass flow (g/s)	Average Air-gap Pressure (Pa)	Total Pressure Point 1 (Pa)	Static pressure Point 1 (Pa)	Air-gap Mass flow (g/s)
0.90233857	1.6	1	0.1254863	0.50852621	0.49894094	0.6
1.5542122	2.1	1.5	0.25157961	0.76821113	0.72765666	0.6
2.5517028	2.6	2	0.57870294	0.40606588	0.15475918	0.6
3.5409997	3.1	2.5	0.79666901	0.65172106	0.19864257	0.6
4.7101081	3.6	3.0	1.0605965	0.8933441	0.23163919	0.6
6.0417213	4.1	3.5	1.4172666	1.6402841	1.1149353	0.6
7.2714842	4.6	4.0	1.538236	1.8681217	1.1378872	0.6
9.0946781	5.1	4.5	2.1467217	2.64481	1.4255291	0.6

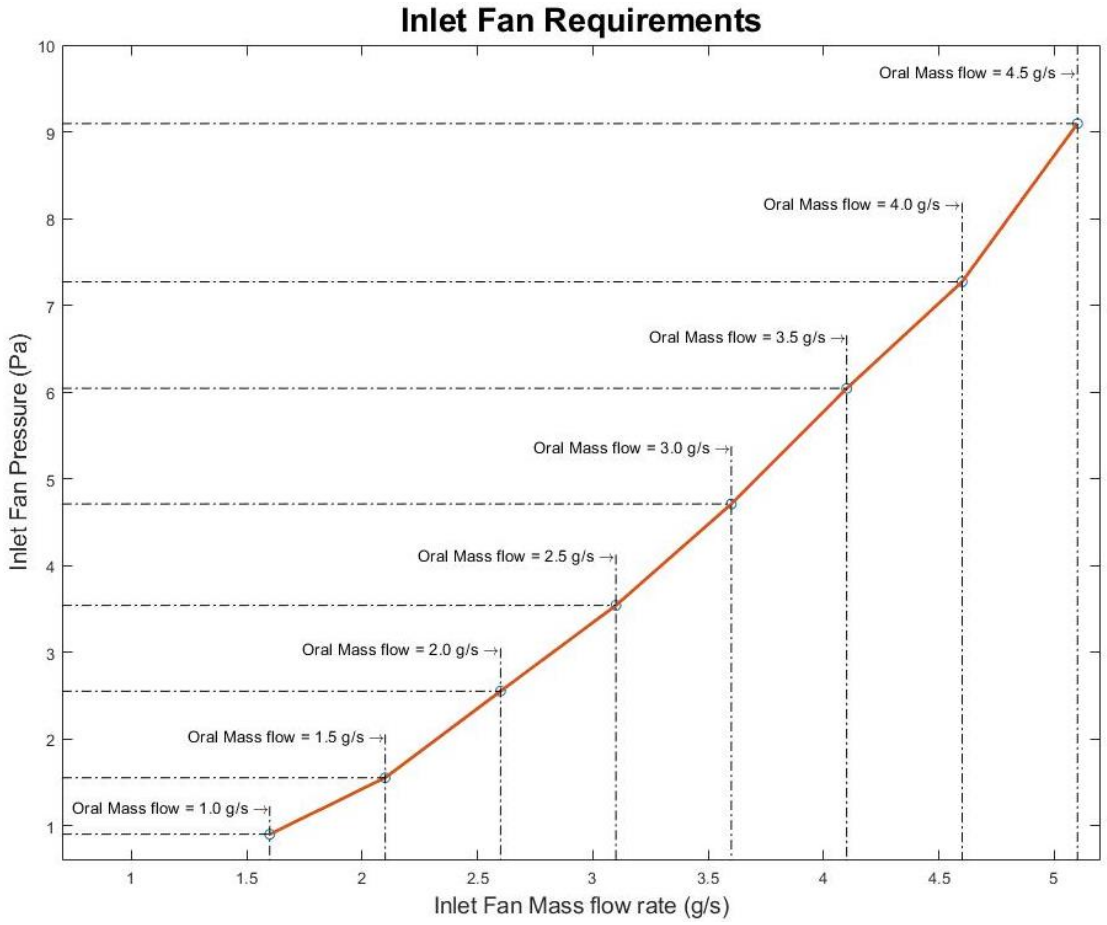


Figure 2.17:Minimum fan requirements over a range of peak oral flow rates for model 4

The results of simulation models, nasally breathing, 3 and orally breathing, 4, were compared to check for simulation correlation as these share a small 1.6 to 2.6 g/s over-lap in inhalation simulation ranges. Figure 2.18 shows the minimum fan requirements curves of both models in the applicable overlap range up to a 2.6 grams per second inlet flow rate. There is a strong correlation between these two models as can be expected and the oral breathing route of model 2 was seen to require slightly higher fan inlet pressures to maintain mask vent levels above the minimum value of 0.1g/s. This is most likely due to different air-gaps between the 2 face shapes in each simulation. In the oral model, the jaw is lowered to open the mouth which created a larger gap around the sides of the face and jaw, increasing air-gap area. This larger air-gap could explain the increase in pressure required. The solver was also changed to a more advanced Transition SST model which may also be a contributing factor to the slightly different pressures. Pressure results at Point 1 indicate that a pressure sensor to be used for feedback in a fan control loop must be able to read a static pressure between approximately 0.15 and 1.4 pascals while orally breathing.

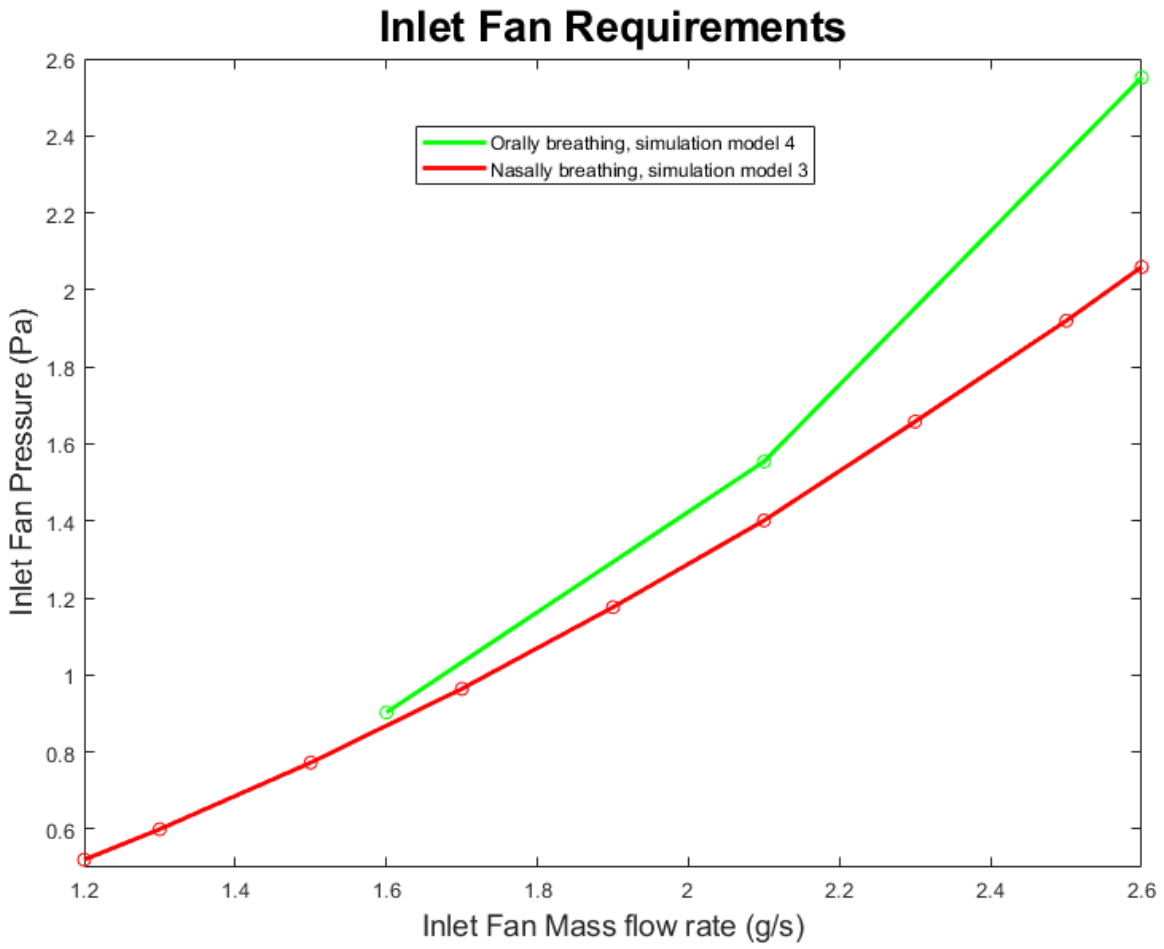


Figure 2.18:Inlet fan requirements comparing oral breathing model 4 to nasal breathing of head model 3

Conclusions

This chapter has shown that a pressurized air filtration mask could have the ability to create and maintain a pressured air-citadel around the face with no infiltration of ambient air through the air-gap vents. Simulation results indicate that a 0.6 g/s mask vent flow is large enough to protect the mask from ambient air infiltration at all desired inhalation air flow rates. Minimum fan requirements were derived for a model using realistic facial geometry and a proof of concept prototype that will be used in selecting fans for succeeding mask prototypes. Although air-gap geometry was not directly investigated it was seen to have an impact on the minimum fan requirements to maintain the leak-free air-citadel.

In chapter 4, a synthetic head model capable of steady state nasal and oral inhalation will be used to validate the CFD results obtained in this chapter by testing a functional proof of concept and identifying the minimum air-gap vent flows over a range of steady-state inhalation demands. The 3D-scanned facial geometry used in model 4 will be used to create the physical, synthetic head model to assist the correlation between the CFD results of model 4 and physical testing.

Chapter 3: Design, Build and Testing of Functional Proof of Concept Facemask Prototype

3.0 Introduction

In this chapter, the detailed design and testing of a functional proof of concept facemask prototype is undertaken to validate the derived operating fan air delivery characteristics identified in chapter 2. Previous simulations have shown that a 30 L/min (0.6g/s) vent flow would suffice and prevent leakage for all desired inhalation flow rates. A synthetic head model will be developed to test a functional proof of concept prototype facemask system and find vent leakage thresholds at different mask inlet and inhalation volume flow rates which can then be compared to this CFD-validated 30 L/min bias flow. It is important to validate RANS computer simulations with experimental data as these are reliant on many assumptions such as the chosen turbulence model, settings of the turbulence model and mesh quality.

3.1 Design of a Synthetic Head Testing System

A physical synthetic head was developed to assess mask leakage in a polluted environment during simulated inhalation. This apparatus allowed for mask leakage-thresholds to be identified and demonstrated that the principal of a positive-pressure seal-less mask was viable in maintaining a pressurized air-citadel. Results for the synthetic head testing were also needed to support an ethics application to allow for human testing of the functional proof of concept prototype facemask system.

The complete synthetic head model testing system consisted of 3 subsystems that needed to be developed. These were the breathing head that pulled in air through oral and nasal airways of a head model, the air intake system to the mask and the portable sensor-array that sampled air inside the mask for leakage.

3.1.1 Synthetic Head Concept Design

A realistic, physical head model needed to be designed with the ability to select between nasal or oral breathing routes for steady-state inhalation rates that could be controlled by the user. This was achieved by using ducts that joined the oral and 2 nasal openings of a head to a constant air vacuum source.

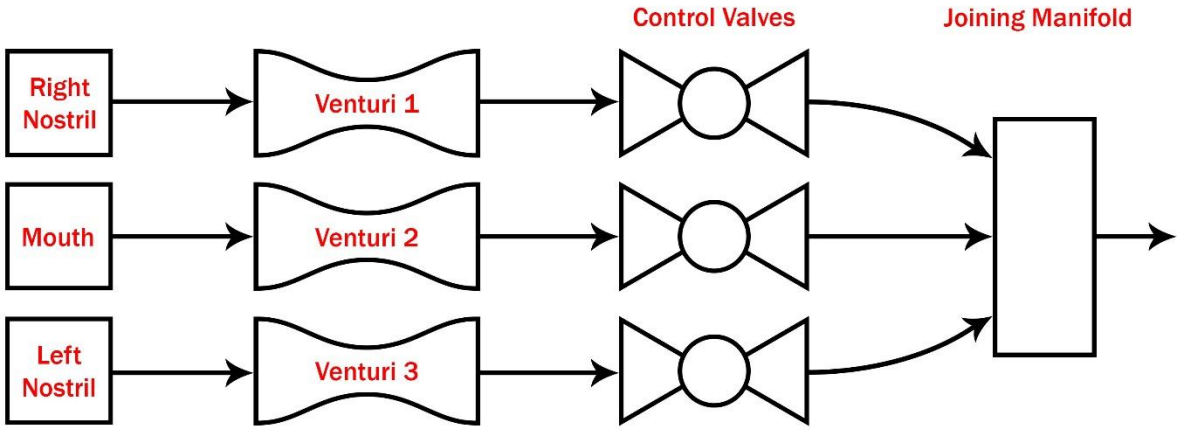


Figure 3.1: Schematic Diagram showing airflow partitioning method

Each duct had a method of controlling and sensing airflow to allow for variation of exclusively nasal or oral breathing routes that enabled testing with the same breathing conditions as the CFD models in chapter 2. A schematic diagram of this system is shown in figure 3.1.

Due to the need to measure low flow rates and tight cost constraints on the project, Venturi flow meters (venturis) were selected as the chosen option to measure airflow and PVC ball valves were used as the method of throttling the air flow. These venturis will be incorporated into the design, being 3D-printed along with the head and other ducting components.

3.1.2 Head Geometry

The head geometry used to create the exterior of the model off was first acquired by 3D-scanning an individual's head and shoulders. The head scanned was the same one used earlier in the final CFD simulation in section 2.5, to keep consistency between the physical testing and computer simulations. The participant wore a swimming cap due to the difficulties in scanning hair which enabled the full head to be scanned.

The raw 3D scan resulted in a triangular mesh geometry comprised of thousands of small triangle surfaces which had many holes and defects. These defects were fixed and patched before sending the mesh model to the CAD package in which more editable and smooth NURBS surfaces were created by approximate surface fitting. Larger defects such as those

shown in figure 3.2, where the scanning program filled the mouth and nose airway openings, did not resolve the ears well or wrinkles from the swimming cap were fixed during or after surface fitting.

Surface fitting involved splitting up the triangular mesh geometry into sections and fitting approximate NURBS surfaces to them. Each section had optimal smoothing settings used to either keep fine details or smooth out problematic areas. Examples of this are the top of the head that required a high level of smoothing due to wrinkles caused by the swimming cap contrasting the front of the face that required a low level of smoothing to ensure minimal loss of detail of facial features. These separately fitted surfaces did not align due to the different smoothing factors used so gaps were left between them and the parts were blended together. An example of a closed mouth model with ears, face and head surfaces blended together is shown in figure B-1 of appendix B.

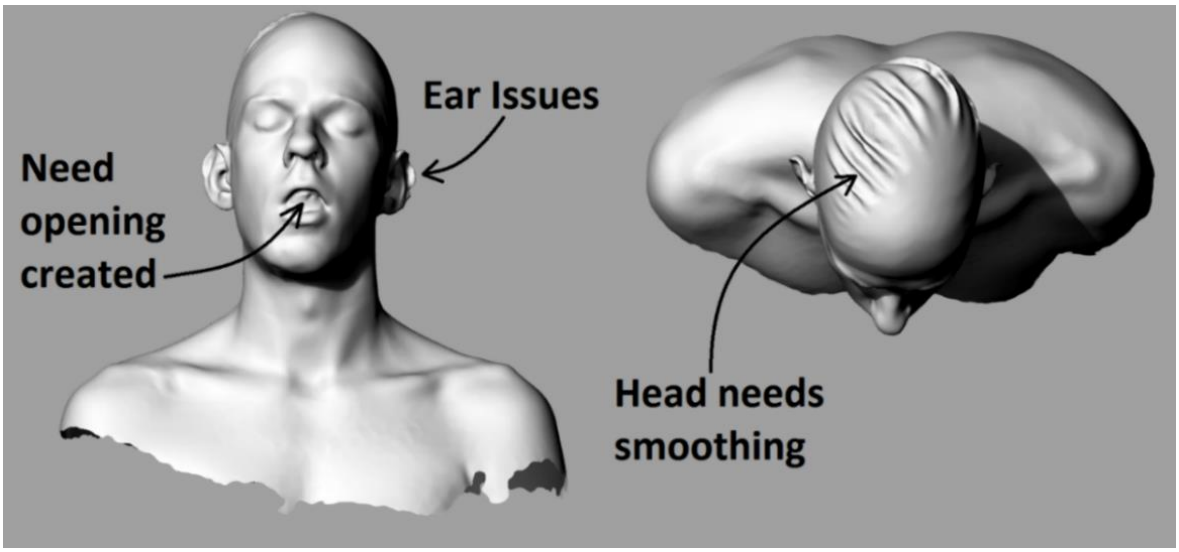


Figure 3.2: Examples of 3D-scanning issues

3.1.3 Air Ducting and Flow Measurement

Having the head model completed with airway openings the ducts were sized. Air ducts were to remain internal of the synthetic head and exit near the bottom of the model through the back of the neck region. This ensured that the head remained unobstructed for the fitting of masks, a diagram of this configuration is shown in figure 3.3. The ducts were circular in cross-sectional shape and included calibrated venturis to enable volumetric flow measurement through differential pressure measurement.

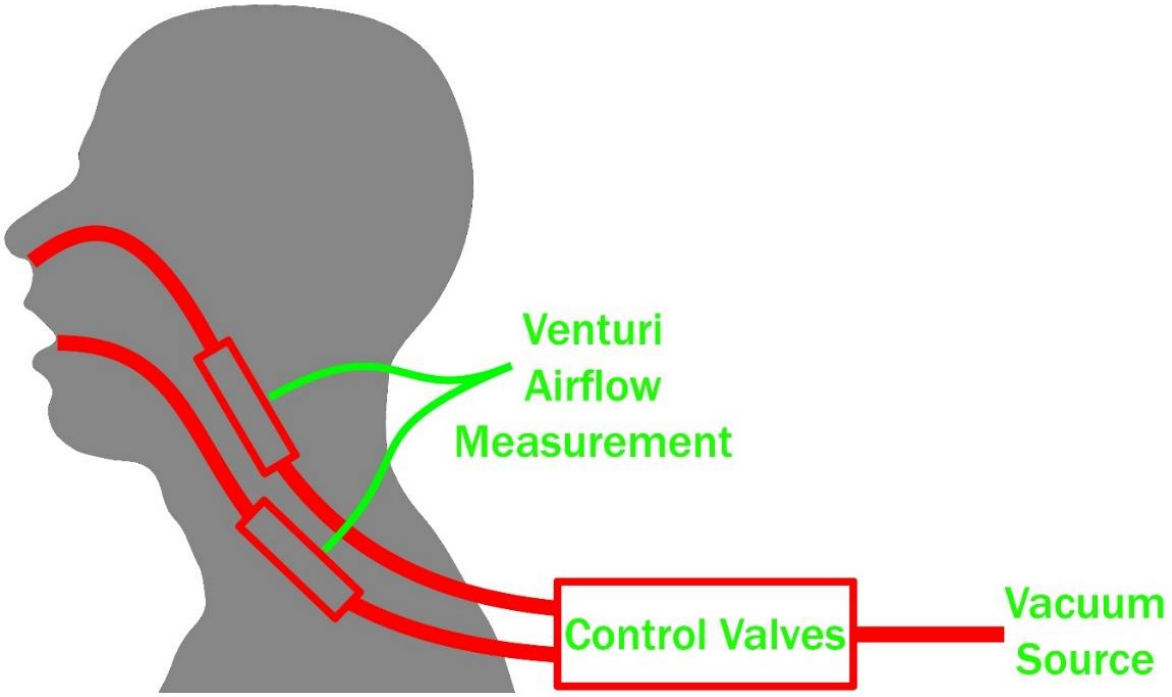


Figure 3.3: Schematic of ducting between the head model orifice and vacuum source

Ansys Fluent was used to confirm the venturi sizing and diameter of piping to ensure that sufficient sensitivity of pressure changes could be measured over the desired flow ranges of 0 to 220 L/min for the nasal airway and 0 to 100 L/min for the nasal airways. The larger diameter of the ducts was based off the maximum dimensions that could be fitted into the head model while the minimum diameters were determined by CFD simulations relative to the desired pressure difference of 125 Pa for the oral airway and 25 Pa for the nasal airways at maximum airflow rates. These pressure differences were to suit the Sensirion SDP610 125 and 25-Pa sensors available to the project. Pressure sensors were read using an Arduino Due microcontroller which was calibrated once the head was assembled using a calibration curve. This enabled real-time readout of the mass flow rates through the serial monitor of a laptop. Details of this Arduino setup can be found in Appendix B.

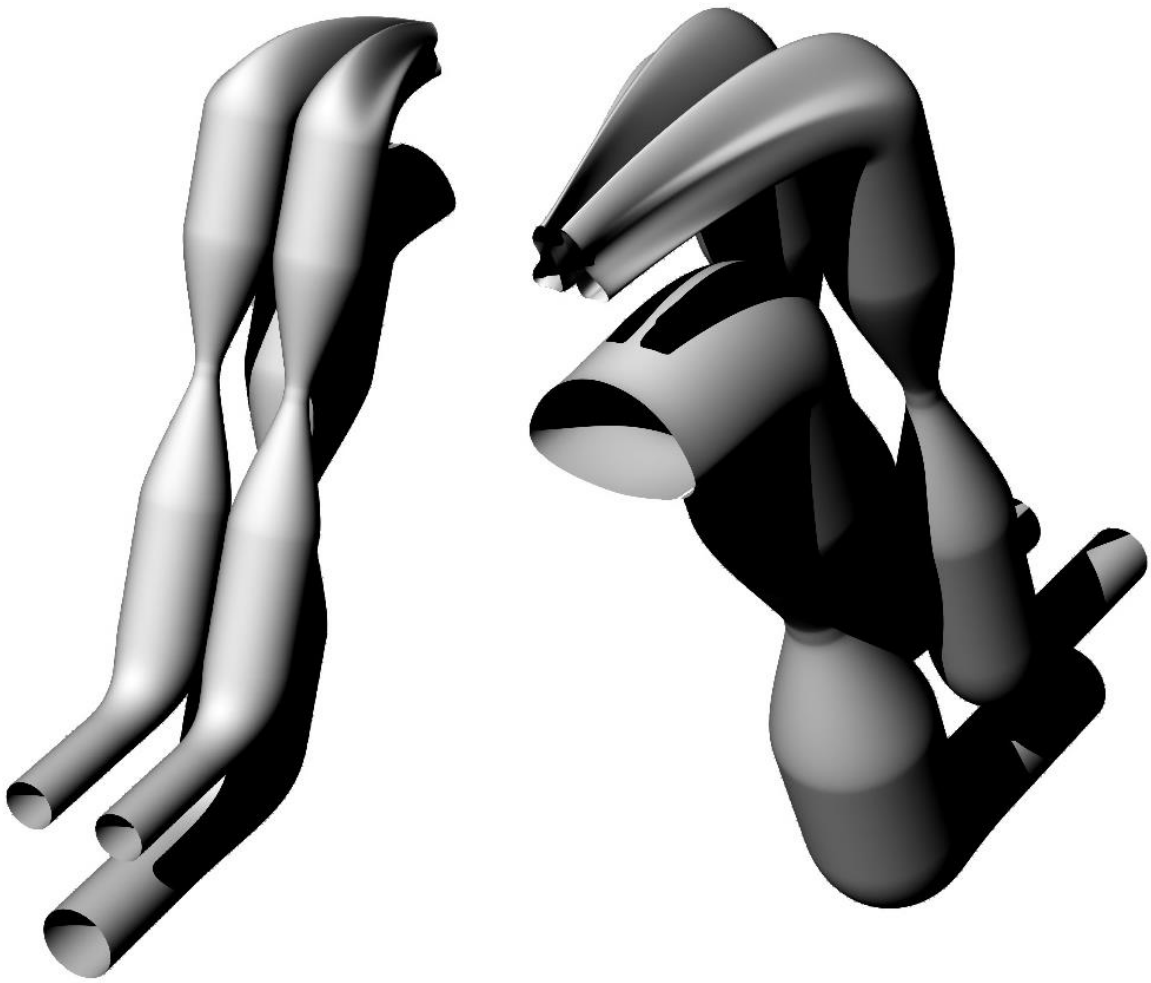


Figure 3.4: Final internal airway ducting surfaces

3.1.4 3D-Printing Synthetic Head Model

Figure 3.5 shows the completed head and shoulder surfaces and positioning of the venturis in the model synthetic head general arrangement prior to 3D printing. At this stage, the model is comprised of surfaces which have no thickness. For 3D printing, each surface needed to be offset to account for printing material thickness and the whole model was split up into pieces to meet printing volume and overhang constraints of the Makerbot Z18 and Anet A8 printers which were used to print the model parts. The model thickness was selected to be 2mm to ensure the model will be durable and not break during testing and regular handling. The material thickness for the head surfaces and final exterior head model smoothing was completed in Autodesk Meshmixer software which was more specialized towards 3D-printing inorganic models.

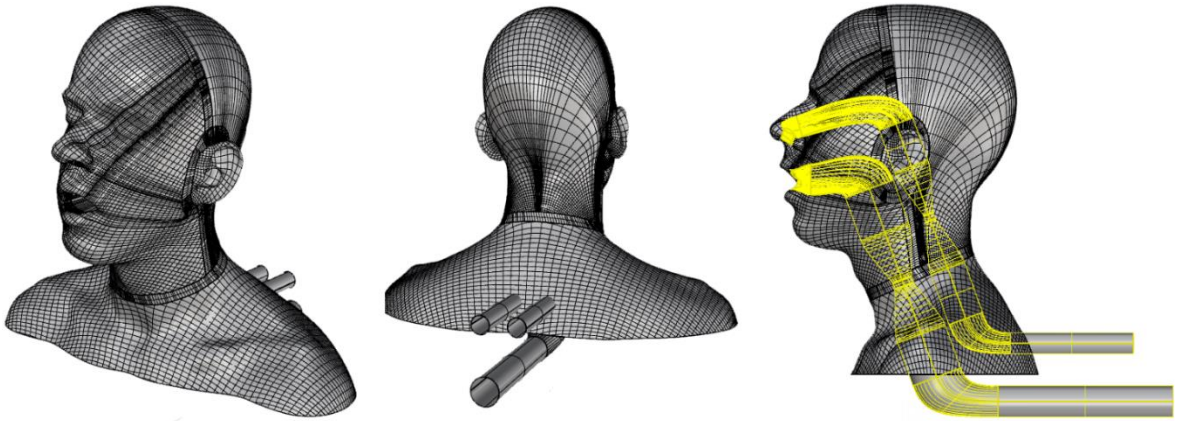


Figure 3.5: Model including shoulders and airflow ducting

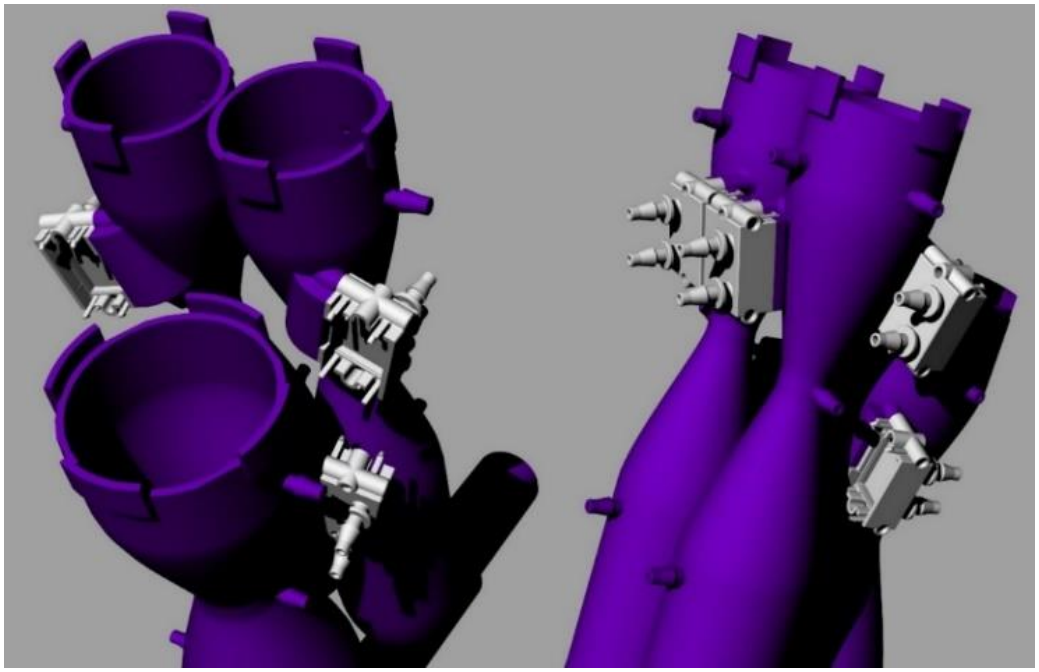


Figure 3.6: Pressure sensor placement on the ducting

Having offset for a wall thickness, attachments and mounting areas were created for the pressure sensors to be bolted onto, shown in figure 3.6. These were located to allow for easy access and fit inside the synthetic head model. To enable 3D-printing, these tube attachments and sensor mounts needed to be removed from the model and be printed as separate parts, this was due to these parts over-hanging the main model which would make it difficult to print and degrade print quality. Figure 3.7 shows the exploded model and all the separate parts ready for printing.

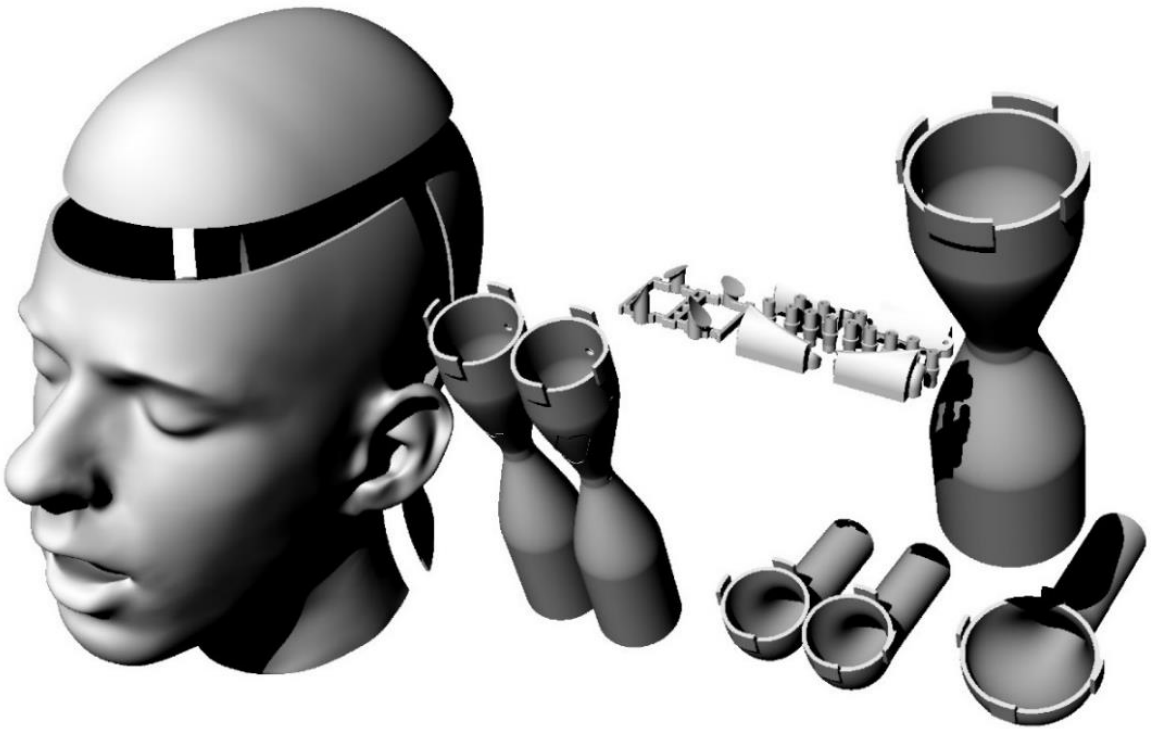


Figure 3.7:Model Split up into parts ready for 3D-printing

Once printed, the various components making up the synthetic head model were glued together using cyanoacrylate glue which bonded and sealed the joins. Due to locating tabs or recesses in surfaces, components were easily aligned and put together. The back and top cap of the head were left removable so that sensors could be accessed if necessary. Tubes joining the pressure sensors to the press fit attachments on the model were cut to length, but these had a thin wall thickness so had to be longer than expected to prevent tube kinking which could affect the pressure sensors, leading to incorrect airflow rates being read.

Figure 3.8: Assembled 3D printed head showing ducting and sensor placement

3.2 Face Mask Air Inflow Ducting

With no fan motors implemented, airflow into the new facemask system required an external pressurized airflow source to maintain a clean air citadel around the face that was both measurable and controllable. For initial validation testing, air was drawn from a clean air source using 2 continuous positive airway pressure (CPAP) machines which could each supply air at 2 kPa and flow 140 L/min. 2 valves are used after the airflow source to control the airflow into the mask, the first a relief valve to vent excess air from the system and the second for fine control. A TSI 4040G volume flow meter was placed after the control valves to sense airflow. This volume flow meter was selected as it provided an acceptable

2% accuracy, had an ideal measuring range between 0 and 300 L/min [38] and one was available for use. Figure 3.9 shows the basic layout of this system.

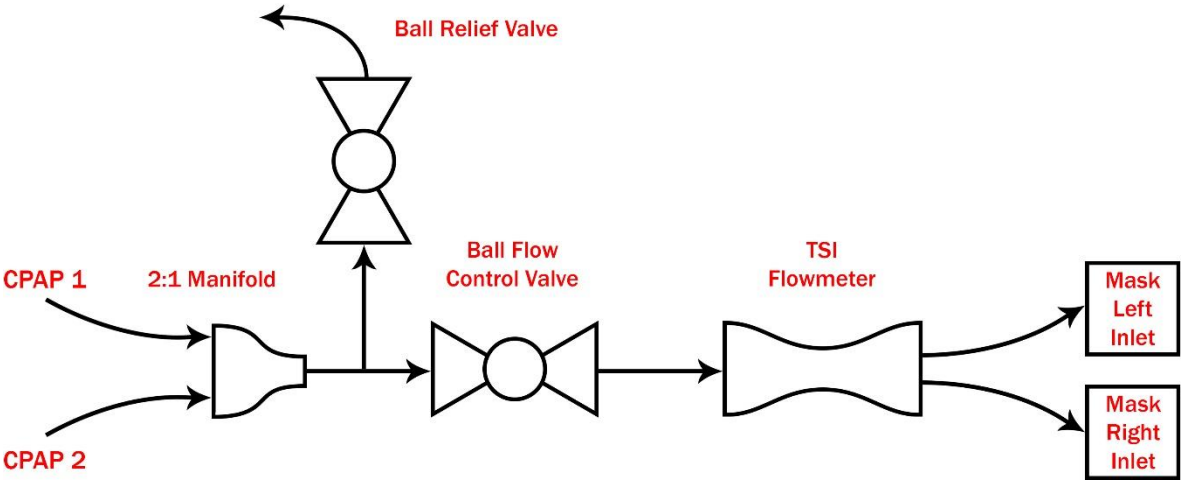


Figure 3.9: Simplified Ducting diagram

Figure 3.10: Completed mask airflow inlet ducting system

Figure 3.10 shows the assembled mask airflow inlet ducting system. Ducting was 3D-printed with tape used to seal the system.

Figure 3.11 to shows how the mask is fitted in reference to the head model. The ducts bend outwards around the face to provide clearance between the ears and face.

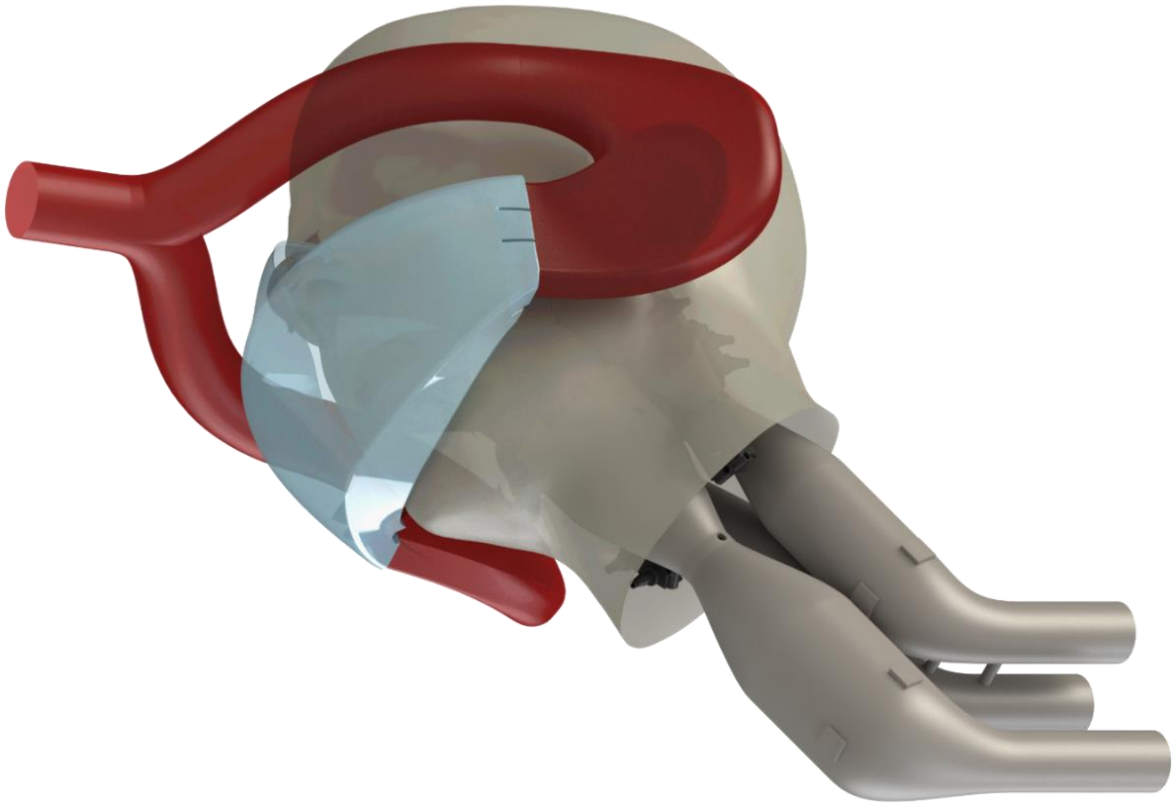


Figure 3.11:Rendering showing placement of the mask ducting system on the head model

3.3 Air Quality Testing

A sensor platform was developed with the goal of determining the air-citadel performance of the new facemask system. This system was used to measure air conditions both within the face mask and ambient conditions around the facemask. The effectiveness of the air-citadel could then be determined by comparing these two results.

The system was intended to be used for the synthetic head model to validate the facemask concept, before leading onto use in human testing if initial tests proved successful. The functional purpose of the sensor platform during synthetic head testing is to detect infiltration of contaminated ambient air within the mask air-citadel. Additional air-quality sensors were included in the platform to measure other environmental conditions during human testing. These included air oxygen levels, carbon dioxide (CO_2) levels, temperature and relative humidity, as requested by the project sponsor company, O2O2 ltd.

Each required sensor for the platform needed to be selected and its geometry understood before the arrangement of the testing system could be planned.

3.3.1 Particle Detection

A pollutant needed to be selected that could be distinguished inside the mask using electronic sensors and not have any potential negative health effects to a human participant breathing within the contaminated environment. The ideal pollutant needed to be filtered out by particle masks to rule out filtration efficiency as an influencing factor. If the pollutant was measured, it would only be introduced into the mask space by a mask leak. The pollutant also needed to be measurable by electronic means. The 2 main categories of pollutants considered were gaseous or particulate, the chosen option was particulate pollution sourced from burning candles. The pollutant levels were ascertained from particle concentrations using a Plantower PMS5003 optical particle sensor. Full pollutant discussion and selection of this sensor given in appendix B.

3.3.2 Temperature and Humidity Sensors

The ideal humidity and temperature sensors needed to have fast response times of less than half a second to achieve breath-by-breath measurements, if this response time was slow then only average mask measurements would be recorded. The sensors also needed to be very small to enable placement inside the mask space which would allow for direct measurement and fast response.

For humidity measurements, a Sensirion SHT75 humidity sensor was used as it fulfilled the special requirement, being extremely small and was available for use. This sensor had a slow response time of 8 seconds which only allowed for average mask humidity levels to be recorded, however, no other humidity sensors were found with significantly lower response times that would justify a change from this sensor.

For temperature measurements, a fast-response T-type Omega 5TC-TT-T-40-72, thin wire thermocouple was selected as it was one of the fastest responding thermocouples with a response time down to 0.4 seconds, dependent on airflow rates over the sensing-junction. It also has one of the shortest measurement ranges to keep accuracy high. Full selection discussion for both humidity and temperature sensors is given appendix B.

3.3.3 Carbon Dioxide Sensor:

CO_2 levels within the masks will be important to measure and compare during human testing as they can be used as an indicator of how well each mask cycles fresh air. If a mask

traps exhaled air then rebreathing this air raises CO_2 levels which can lead to negative performance impacts such as fatigue and dizziness, as discussed in section 1.3. Capnography is the waveform measurement of inhaled and exhaled CO_2 levels and is used in many forms of healthcare, looking at Capnography literature was a good indicator to the expected CO_2 levels in the mask that will be measured. Literature showed that CO_2 partial pressure peaks in exhaled air around 4-5.6% (30-43mmhg) with normal breathing [39], this is slightly higher if hypoventilation is occurring. The ideal sensor measuring range is for a 0-10% CO_2 volume and the sensor should have a fast response time to try measure the CO_2 waveform during inhalation and exhalation rather than a mask average. The CO_2 sensor selected was a Gas Sensing Solutions (GSS) SprintIR6s as it offered a 0-10% CO_2 volume measurement range option and had the lowest response time of less than 1 second, dependent on the air flow rate through the sensor. Appendix B discusses the other sensor options considered.

3.3.4 Blood Oxygen Saturation

It is important that athletes get a sufficient supply of oxygen as it is used to oxidize stored glucose to adenosine triphosphate (ATP), used as a fuel by the muscles to do work [40]. If oxygen saturation levels in the blood are low, then an increased blood flow rate and respiration rate would result as a compensatory mechanism to fulfil a certain oxygen requirement.

The project sponsor company, O2O2 ltd, were interested in these oxygen saturation values as differences in participant blood oxygen saturation levels could relate to the differences affecting gas exchange between different types of filtration masks.

Pulse oximetry was the selected option for continuously measuring blood-oxygen saturation levels as it was the only non-invasive method found and therefore the only method that could be used for later clinical. Secondly, it was the fastest method of measuring oxygen saturation levels compared to the other methods which would typically take many minutes to acquire and analyse blood samples. This would have the disadvantage of leaving few samples to compare over the duration of a test. Appendix B discusses the other options considered, including Arterial Blood Gas (ABG) analysis and Co-oximeters. The selected pulse oximeter sensor was a Protocentral AFE4490 Oximeter as this was capable of integrating with the sensor package rather than a standalone unit.

3.3.5 Oxygen Gas Sensors

The sponsor company were also interested in measuring mask air oxygen levels to see if different mask types had any effect. Sensors were sought to have very fast response times of less than 1 second, if possible, to measure breath by breath measurement rather than an average of mask oxygen levels. The sensors were required to measure the mask air oxygen levels without creating a potential mask leak from the contaminated ambient environment. The two main categories that fulfilled these requirements were medical grade air sampling machines and canister style galvanic diving rebreathing sensors. A CiTiceL AO2, galvanic style oxygen sensor was selected as it offered a good balance between cost, size and response time, although most galvanic style oxygen sensors had similar specifications regarding response time. Further Information on the oxygen sensor selection process can be found in Appendix B.

3.3.6 Final Sensor Selection

SpO2 / Pulse	Protocentral AFE4490
Carbon dioxide	GSS SprintIR6s
Humidity	Sensirion SHT75
Temperature	Omega T-type 5TC-TT-T-40-72
Particle Sensor	Plantower PMS5003
Oxygen	CiTiceL AO2 galvanic sensor

3.4 Sensor Housing Design

This section derives a supporting mounting structure for the selected sensors and control airflows.

The CO_2, Oxygen and particle sensors were placed outside the mask due to spatial constraints which limit the placement for such large sensors in the mask. The humidity sensor and fast response temperature sensor were able to be kept within the mask space due to their small size. This meant that air needed to be sampled from the mask domain through a small tube and first flow past the CO2 sensor, then the oxygen sensor and finally through the particle sensor before exhausting to the environment. A schematic diagram of this arrangement can be seen in figure 3.12.

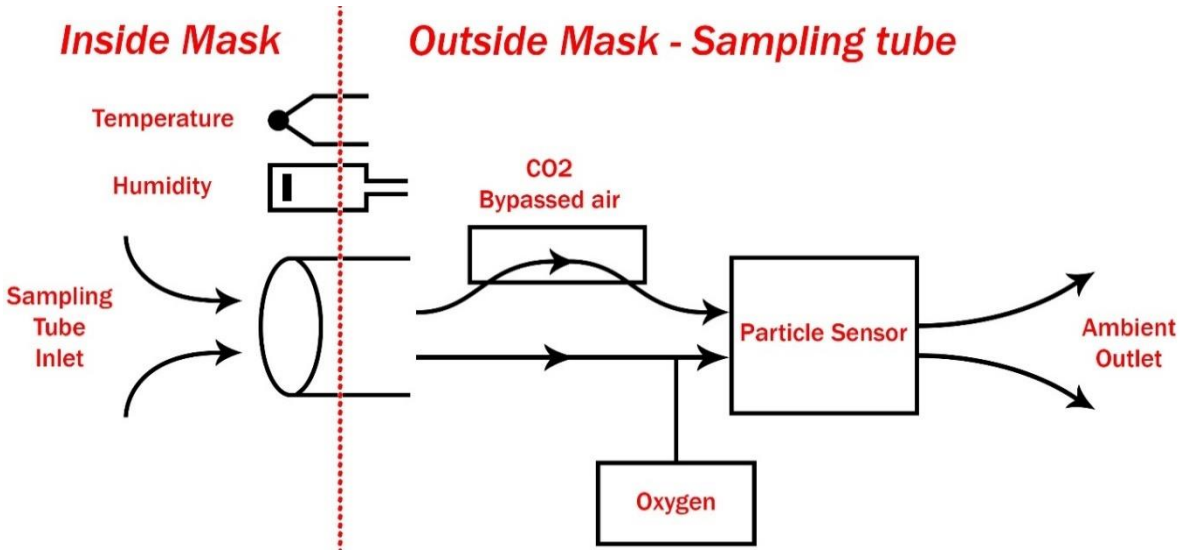


Figure 3.12: Diagram of sensors and arrangement used

A sealed manifold was designed to hold the CO_2, oxygen and particle sensors and duct air to meet each sensors airflow requirements. The CO_2 sensor required a small amount of air to be flown through it which was done by introducing a restriction in the system to promote flow through this sensor while the oxygen sensor simply had air blown over it. The particle sensor needed the total volume flow to keep a fast response time and to maintain flow within the manufactured calibrated range. As not all sensors were designed to be run in a closed environment, it was important that the manifold ducting system sealed well to ensure that no contaminated ambient air also being was measured. Two booster fans were added to pull air through the sampling tube and overcome pressure losses while ensuring sufficient airflow passed through the particle sensor. The housing included mounting points for an Arduino Mega microcontroller to be bolted to which included a breakout board and all wiring. The Arduino microcontroller handled sensor processing and output lines of data via the serial monitor which was logged to a laptop and could be opened in Matlab for post-processing and noise filtering. Further details of this system including CFD simulations to validate the CO_2 bypass restrictor, simulations of the manifold system to size booster fans and Arduino code can be found in Appendix B.

Renderings of the completed manifold, shown in figures 3.13 and 3.14, show the smooth circular ducting inside and the supporting structure outside with features such as the mounting point, alignment tabs for the particle sensor and screw holes for bolting to the

back plate behind the particle sensor. The manifold is split up into top and lower sections with the fans being placed inside when the two halves are glued together.

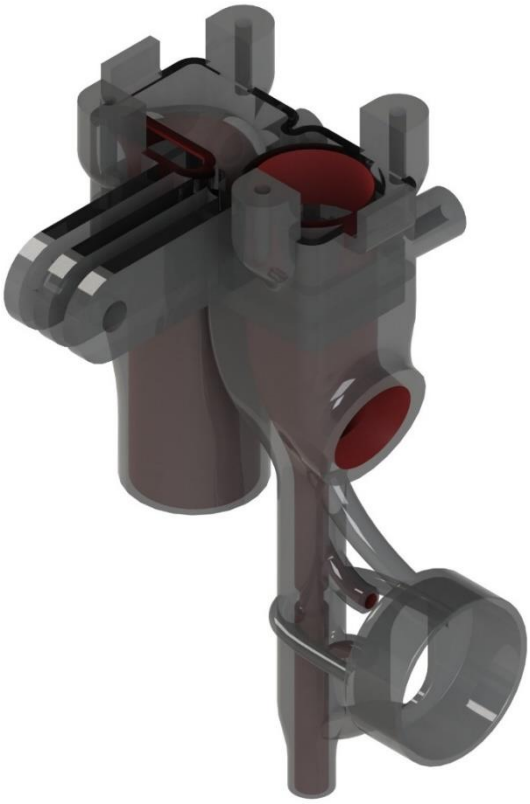


Figure 3.13:Completed manifold including fans, ready for sensors

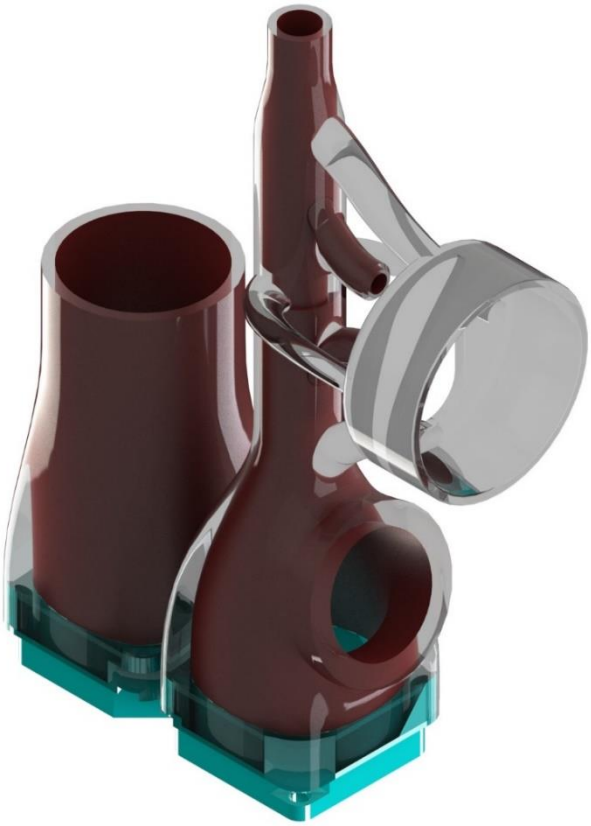


Figure 3.14:Top half of the manifold showing how the fans are positioned (blue)

Figure 3.15 shows the sensor package completed. Given the SprintIR6s CO2 sensor was a newly released product, and had delays in ordering, a temporary CO2 sampling tube was put in its place to allow CO2 measurements from a LR2000 nitric oxide/CO2 Gas Analyser that was available for use. A Sensirion SDP610-25 pressure sensor was also included to sense changes in mask pressure.

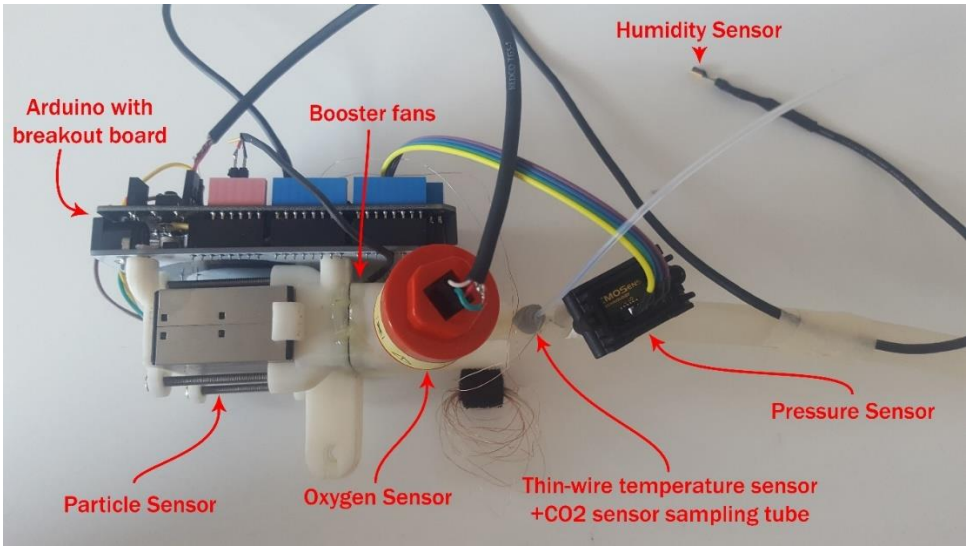


Figure 3.15:Assembled sensor sampling package

3.5 Completed Test Setup

Figure 3.16 shows the test platform setup for use which includes the breathing synthetic head, mask sensor platform and mask air inflow ducting system. The 2 CPAP machines of the inflow ducting system were sealed off in the cabinet to the right so that the contaminated air could not be pumped into the face mask. A household vacuum cleaner provided a vacuum source to simulate steady-state inhalation, pulling air through a set of control valves.

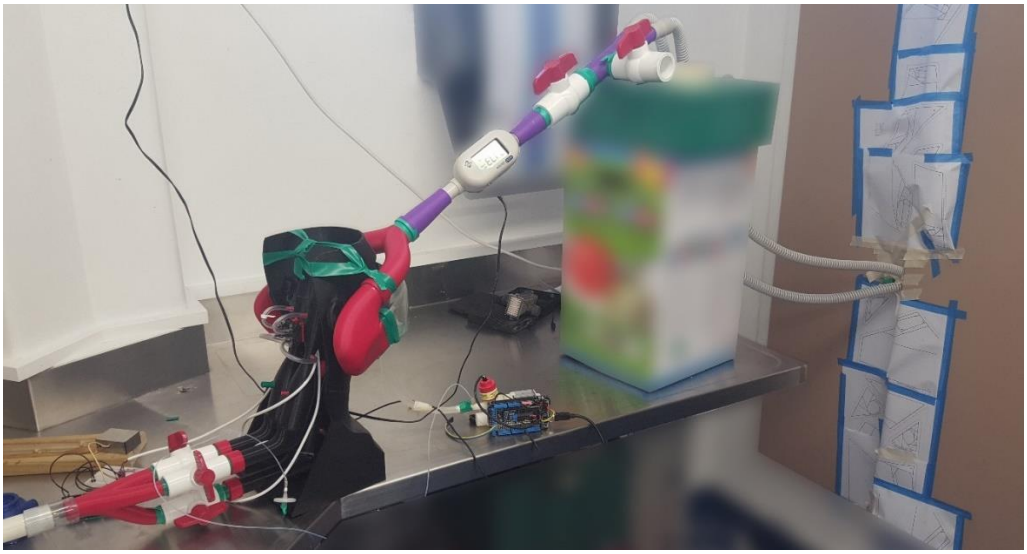


Figure 3.16:Assembled test setup

3.6 Testing Results

The particle sensing system that sampled air quality in the mask was measured to draw approximately 4 L/min of air. Bias flow results were adjusted for by removing this value with table 3.1 showing the final adjusted results. A Full results table showing pollution readings until leakage stops is available in Appendix C.

Table 3.1: Minimum bias flow results

Mask Flow (L/min)	Mouth Flow (L/min)	Min Bias (L/min) adjusted
157	103	50
140	85	47
120	75	41
103	65	34
80	55	26
60	35	21

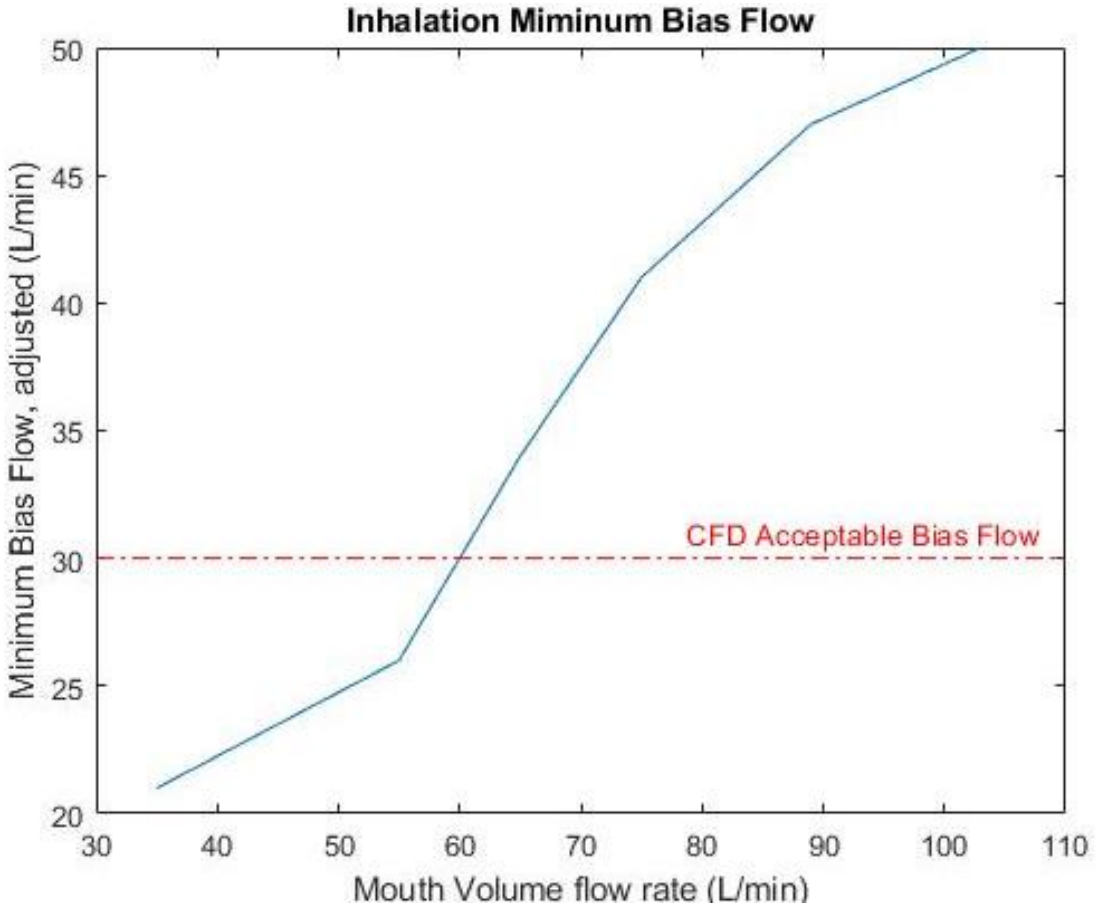


Figure 3.17:Minimum bias flow vs inhalation demand graph

Plotting the mouth flow vs minimum bias results in a curve indicating the minimum bias flow that must be used to keep the citadel from leaking, as shown in figure 3.17. This curve shows an increase in bias flow is needed as the mouth demand increases. The minimum bias flow rate did not stay below the fixed CFD-predicted acceptable 30L/min bias flow rate which is indicated by the horizontal red line on figure 3.17 and was previously shown to stop ambient air infiltration for all desired inhalation ranges. The trend would be hard to extrapolate to find out expected minimum bias flows for the higher inhalation results that could not be simulated due to airflow source constraints.

3.7 Discussion

Issues arose in the first test where the sealed off closet that housed the 2 CPAP machines was still pulling in contaminated air from the testing room through the unsealed ceiling airspace. Air from the CPAP machines had PM1, PM2.5 and PM10 concentrations of approximately 20 $\mu g/m^3$ with levels in the testing room ranging from 80 to 210. A filter was put before the air flow meter of the mask to reduce these concentrations to near-zero, but this then reduced the maximum flow rate of air that could be provided from 220 L/min to 157 L/min.

The mask inlet air volume flow rate was then reduced in 20 L/min flow deductions and the mouth flow rates varied accordingly until particle counts reached 3 or below. This defined the minimal air inflow rates required to maintain mask air-citadel integrity.

Given the purpose of this experiment was to validate the air-citadel concept and identify minimum airflow rates required to maintain the mask air-citadel during maximal inhalation, nasal airflows were not tested. It could be beneficial, however, to do further testing using the nasal airflow partitioning control built into the synthetic head to understand any effects on the air-citadel caused by uneven nostril inhalation demand.

During testing, it was found that the air gap size strongly affected results. This was not unexpected as previous CFD models suggested this may be a factor, but the impact of this change was far greater than anticipated. Here the minimum mask bias flows needed to be over twice the expected flow rates. This difference was due to the supplied prototype mask supplied by the sponsor company having modifications to the shape around the nose meaning the mask placement on the face differed compared to the computer simulations, and air-gap geometry was larger. Because of this finding, mask air-gap geometry was

modified to more closely represent that used in the CFD model and minimum bias flow results more than halved.

As shown in table 3.1, the inlet flow was varied from 157 L/min to 60 L/min in 20 L/min deductions, giving 6 data points. It would be beneficial to repeat testing with an airflow source capable of flowing much higher to identify the minimum bias flows at the desired maximum steady-state inhalation rate of 250 litres per minute. However, 157 L/min will be ample for use in individuals undergoing ‘moderate exercise’.

Results are for a mask with matched airflows between the left and right air inlets. Implementing flow partitioning control between the left and right inlets would be excellent future work to simulate and understand the effects of imbalanced motors on the mask air-citadel.

Conclusions

This chapter has validated that the functional proof of concept facemask can be used to create an air-citadel in front of a face without infiltration of polluted ambient air.

While the bias flow results did not exactly match those of the CFD simulations, which indicated that a steady 30 L/min bias flow would suffice for all desired flow conditions, the air-gap sizing of the physical model differed considerably compared to the CFD model. Air-gap geometry was shown to have a large impact on the minimum bias flows needed to keep the citadel leak-free with the minimum bias flows decreasing as the air-gap sizing is decreased. It is therefore expected that if the air-gap was smaller and more like the CFD model then results would more closely correlate.

In the next chapter, a functional prototype face mask system will be tested on participants undergoing moderate exercise with a contaminated air environment. This will help to confirm a leakage-free citadel is possible on participants when more factors such as variable air-gap sizing due to facial changes and head motion are introduced and compare leakage to existing mask solution

Chapter 4: Facemask Clinical Validation

4.0 Introduction

In the previous chapter, it was shown that the functional proof of concept prototype facemask could provide and sustain a filtered air-citadel around the nose and mouth over a range of simulated inhalation rates. In this chapter, a new functional proof of concept O2O2 prototype mask is compared to three existing commercially available face mask filtration solutions by qualitatively assessing mask air quality and subjectively assessing user comfort during moderate exercise. Testing was done within the same contaminated environment as used for synthetic head testing, using 5 participants with varying face shapes, ages and fitness levels.

This chapter aims to validate the computational simulations and physical testing previously undertaken and reported in chapters 2 and 3 respectively. Both of these previous tests have shown that showed an air-citadel mask could be worn to protect a user from inhaling contaminated air. This chapter also seeks to validate fan performance specifications identified earlier in chapter 2, as the fans used in the functional prototype mask were selected by the sponsor company to meet the predicted fan-performance criteria.

4.1 Test Setup

The setup differs from the desired setup with the GSS SprintIR6s carbon dioxide and Omega 5TC-TT-T-40-72 temperature sensors being replaced due to availability issues while the Protocentral pulse oximeter was replaced due to inconsistent heart rate readings. The final setup for testing is as shown below.

Sensor Array

Mask Temperature: RS-PRO 397-1589 – Fast-response (<1s) 0.075mm diameter K type thermocouple

Oxygen levels: CiTiceL AO2 (galvanic type) – 5 second response time

Mask Humidity: Sensirion SHT75 – 8 second humidity response time

Pollutant sensor: Plantower PMS5003

Other Measurement Devices

S_PO_2 / Pulse: ETCO2/SpO2 Monitor (Novametric Medical Systems, USA). SN 80-160600N17

CO2: LR2000 nitric oxide/CO2 Gas Analyser (Logan Research Led, UK) – real-time gas analyser. 200 ms response time, 20HZ sampling frequency

Loading System

Exercycle: York Barbell C510 Exercycle (York Barbell Corp, USA). SN L5549/318206

Cognitive Test

Laptop performed Stroop test

Particle Source

Candles: 3 table candles (National Candles ltd NZ) were used as the source of particulate during the testing

4.2 Test Configuration

Figure 4.1 shows the 4 masks that were used in the testing

Figure 4.1:Masks used for participant testing. A-Respro Techno Sportsa- Techno gold filter; B-3M 6000- ABEK1 filter; C-3M N95; D-Functional O2O2 prototype

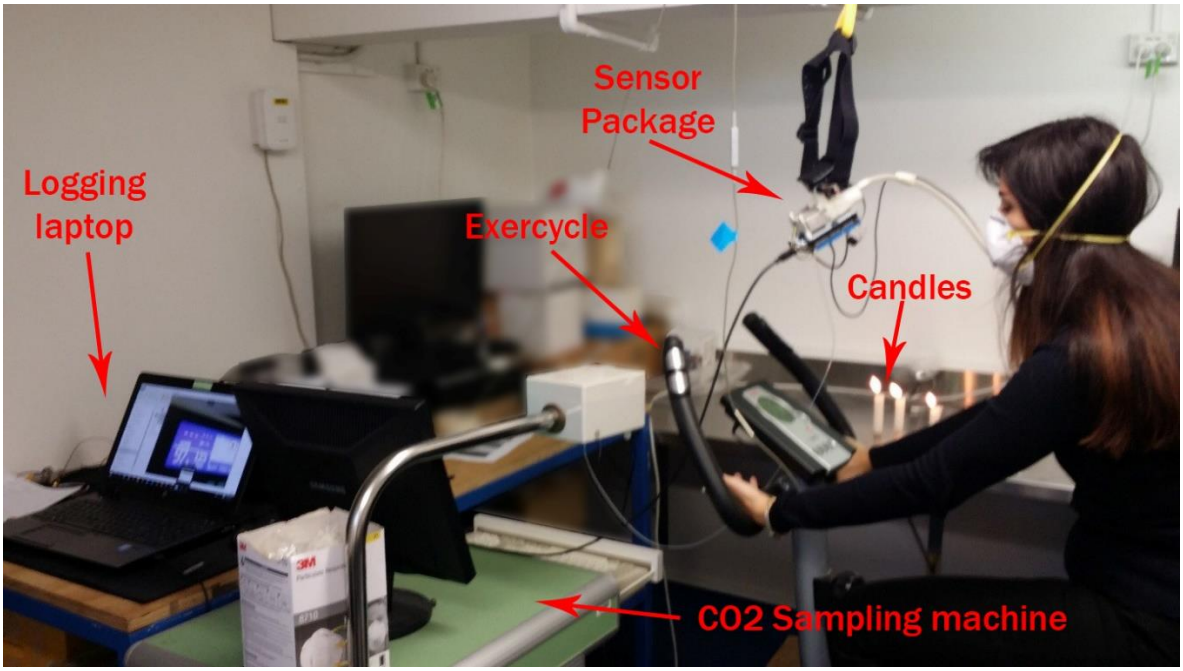


Figure 4.2: Testing configuration showing testing components

Figure 4.2 shows the test configuration during normal use. An exercycle was used at the participant loading system so participants heads would remain relatively still and reduce interference from the apparent airflow, which could occur from other exercising methods such as running on a treadmill.

4.3 Methodology

4.3.1 Participant Recruitment

Volunteer participants were sought for the test and gave informed consent. Participants ranged in age, fitness levels, face shapes and facial hair representative of the population distribution. This enabled testing of the air citadel efficiency in achieving an effective pneumatic face seal over a range of users. Testing using the synthetic head provided supportive evidence for an ethics approval of this pilot study by Auckland University of Technology Ethics Committee (AUTEC), ethics application #17/277. The ethics application form and approval letter can be found in Appendix F.

4.3.2 Load Standardization Benchmark

Prior to mask testing and to ensure each participant would undertake 'moderate' exercise, as defined by a perceived participant exertion level of 10-12 using the borg test (defined in Appendix D), each individual undertook progressively increased cycling loads and cadence rates until their heart rate reached a prescribed level that would then be applied during mask testing.

Procedure

- **Participants began exercising and once warmed-up (assumed 5 minutes), perceived exertion levels (RPE) measured using the Borg test [41]**
- **Cadence rate set at a comfortable rate between 75-90 rpm and exercycle resistance varied until participant perceived exertion was within the range of 'moderate exercise' on the Borg scale. Test duration totals 20 minutes**
- **Participant's heart rate, breathing frequency and blood oxygen saturation levels (SpO2) recorded**

4.3.3 Mask Testing

Participants tested each mask once and tests were done in a random order.

Procedure

- **Participants began exercising with a light level of exertion approximately half of the tested exertion levels for a warm-up period of 5 minutes**
- **Mask and sensing system was fitted to the participant**
- **Sensing system was turned on**
- **Candles (pollution source) were lit**
- **Participants resumed exercise and intensity is increased to standardized levels over a 2-minute period**
- **Exercise continued at the standardized levels for a period of 20 minutes and sensing system logged data over this time period.**
- **Mask was removed from the participant and used to measure ambient conditions.**
- **Photographs of the participant's face were taken identifying any mask indentation or marks left on the participant.**

4.3.4 Performance Measures

Mask Testing

In-mask air-quality measurements

- **Particulate count and concentration: Pm1.0 Pm2.5 Pm10**
- **Gasses: Oxygen and Carbon dioxide**
- **Relative humidity levels**
- **Air-temperature**

Ambient-air measurements (Post-exercise)

- **Particulate count and concentration: Pm1.0 Pm2.5 Pm10**
- **Gasses: Oxygen and Carbon dioxide**
- **Relative humidity levels**
- **Air-temperature**

4.3.5 Facial impressions from mask fitment

Images of each participant after each completed test to visually identify any areas of impressions caused by the mask

4.3.6 Subjective Feedback

Participant feedback was sought after each test with pre-specified ranges, specifically assessing:

- **Mask comfort - comfortable to very uncomfortable**
- **Mask fit – good to extremely poor**
- **Temperature and humidity – fresh and cool to very hot and humid**
- **Mask odour – ambient like to smelly**
- **Breathing difficulty – very easy to difficult**

4.4 Results

Given the small sample size, the results for each participant are presented and discussed for each qualitative and quality measure and subjective user assessment.

4.4.1 Particle Concentration

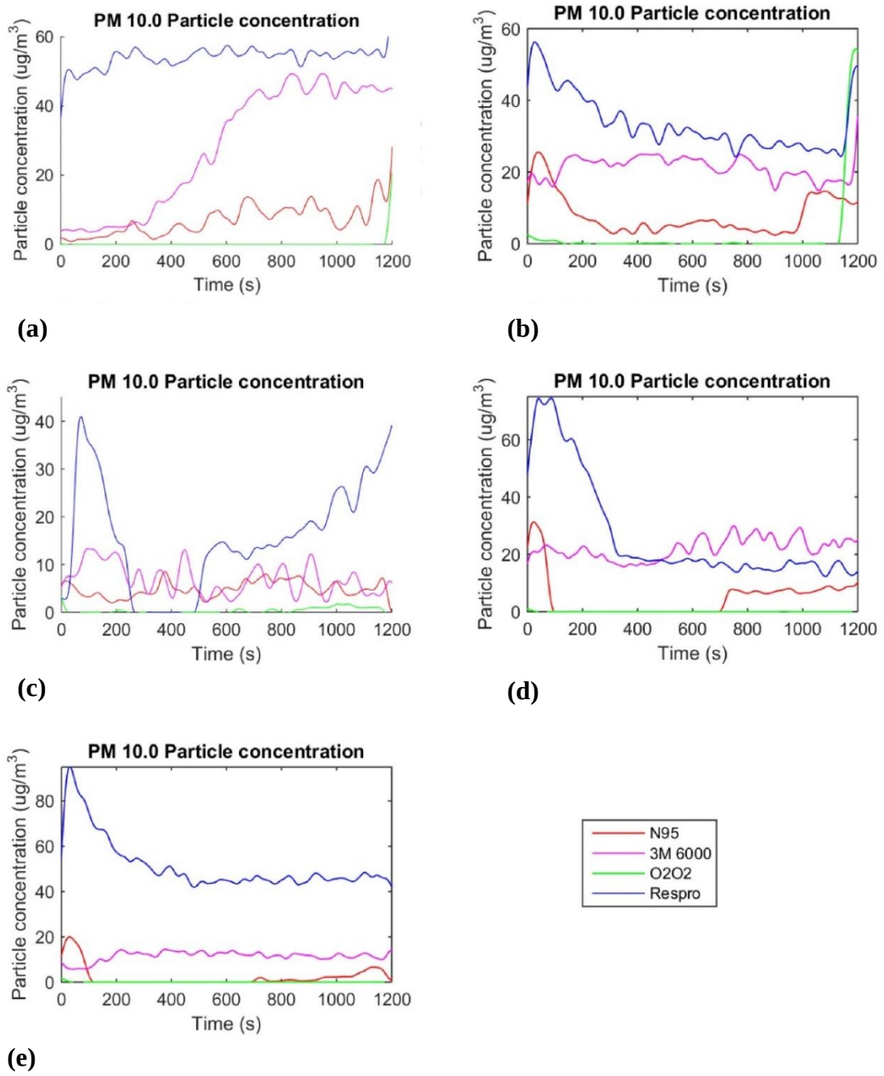


Figure 4.3:Participant Mask PM2.5 concentration levels. (a)-Participant 1; (b)-Participant 3; (c)-Participant 4; (d)-Participant 5; (e)-Participant 6

4.4.1.1 Particle Leakage Discussion

Particle concentrations of PM1, PM2.5 and PM10 were recorded. These indicate the concentration of particles inside the masks air domain in ug/m^3 of particle diameters below 1um, 2.5um and 10um respectively. Only PM10 results are discussed while the remaining results are available in appendix D. PM10 was selected to report on due to masks filtering larger particles well, meaning results better-compared leakage rather than filter efficiency, however, PM10 results are representative of PM1 and PM2.5 results.

4.4.1.2 Comparing O2O2 Mask Performance to Existing Solutions

Respro

Air within the Respro mask was seen to have high particle concentrations between approximately 20 to 60 ug/m^3, indicating large mask leakage. Participant 4 had PM10 concentrations dip to zero between 300-500 seconds of testing before steadily increasing, this is thought to be caused by a sensor malfunction.

3M N95

Concentration readings were low and varied between approximately 10-20 ug/m^3, significantly lower than the 3M 6000 mask but significantly higher than the O2O2 mask. Participant 5 experienced a sensor malfunction for the first 700 seconds of testing where concentration levels were reading 0 but were seen to then sit at a concentration of 10 ug/m^3.

3M 6000

This mask had a surprisingly high leakage with concentration readings between approximately 10-40 ug/m^3. For a duration of participant 5's test shown by figure 4.3(D) it was the poorest performing mask and in participant 1's test shown by figure 4.3(A) the concentration levels steadily increased, indicating a leak.

O2O2 PM2.5

concentrations inside the O2O2 functional prototype stayed near 0 ug/m^3 for most of the tests apart from participant 4, which recorded a period up to approximately 4 ug/m^3. Participant 3 removed the mask early at 1150 seconds, as can be seen in figure 4.3(b) where PM2.5 levels increased to near-ambient levels.

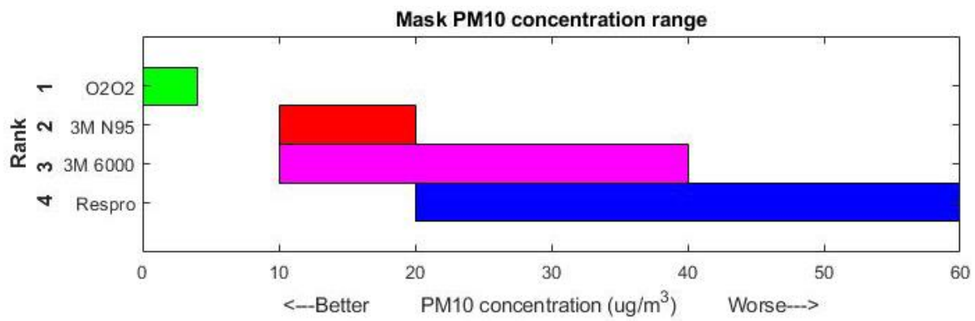


Figure 4.4:Range of PM10 concentration and overall ranking lowest to highest

4.4.2 Mask Air Temperature Above Ambient Levels

Figure 4.5:Participant Mask temperature levels. (a)-Participant 1; (b)-Participant 3; (c)-Participant 4; (d)-Participant 5; (e)-Participant 6

4.4.2.1 Mask-temperature Discussion

Results shown are the difference between mask temperature levels while testing and average ambient levels recorded at the end of testing. The sharp changes in the graph are caused by the sensors extremely fast, sub 1 second response time recording breath by breath changes.

4.4.2.2 Comparing O2O2 Mask Performance to Existing Solutions

Respro

Results demonstrated an approximate 6-7 °C increase in mask temperature above ambient levels.

3M N95

This mask showed the largest increase in temperature that ranged from approximately 6-10 °C above ambient

3M 6000

This mask was one of the cooler masks over the range of tests with an increase in temperature that ranged from approximately 5-8 °C above ambient levels.

O2O2

This mask was by far the coolest for all participants except participant 3 where it was similar to the 3M 6000 mask for that user. The temperature increase over ambient was approximately 2-5 °C with most users experiencing a 2-4 °C increase.

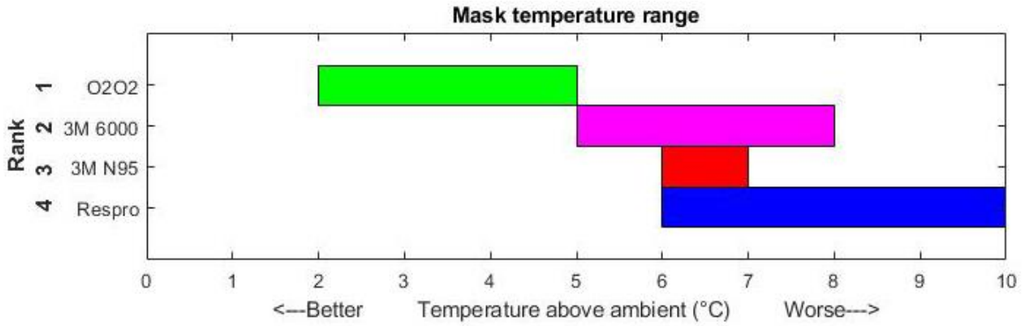


Figure 4.6:Range of mask temperature levels and overall ranking lowest to highest

4.4.3 Mask Air Relative Humidity

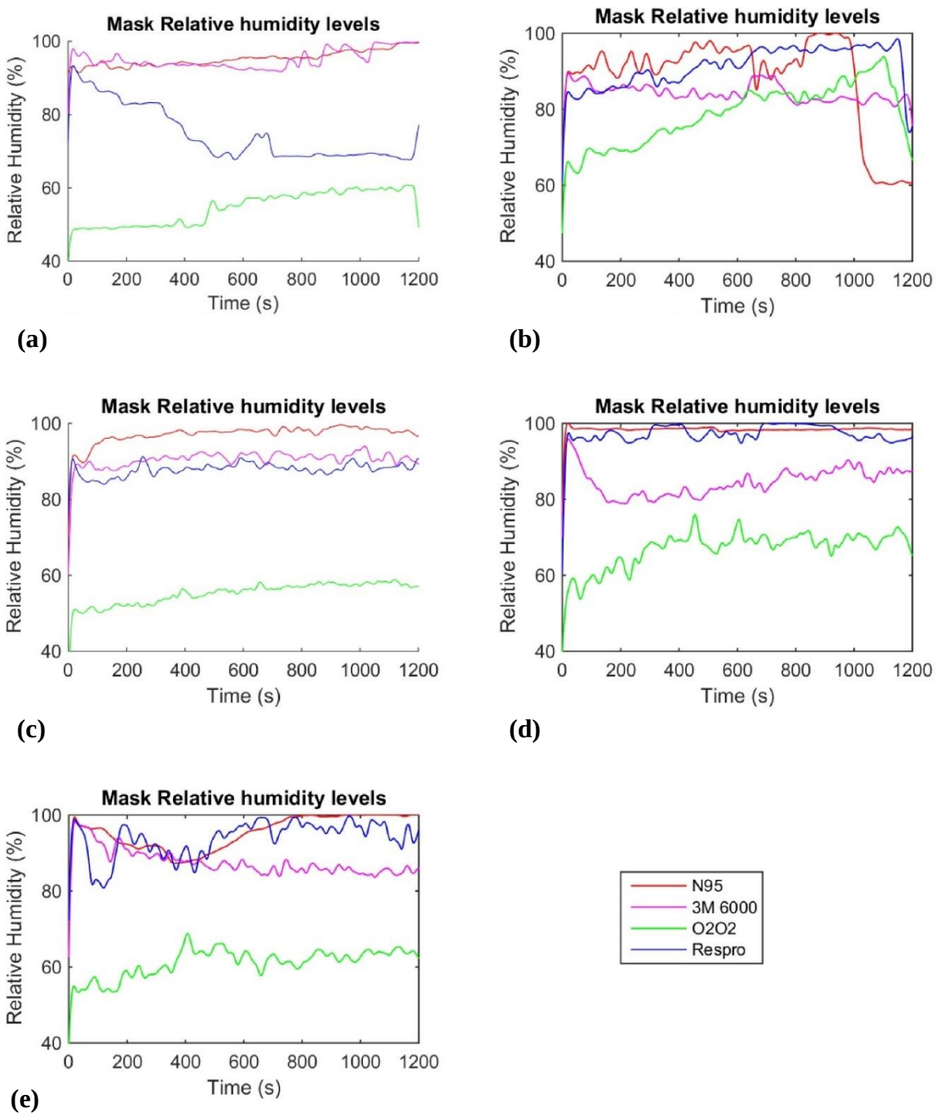


Figure 4.7:Participant Mask humidity levels. (a)-Participant 1; (b)-Participant 3; (c)-Participant 4; (d)-Participant 5; (e)-Participant 6

4.4.3.1 Mask Humidity Discussion

Measuring mask humidity allows for comparison of O2O2 ltd, functional prototype mask performance to existing solutions.

4.4.3.2 Comparing O2O2 Mask Performance to Existing Solutions

Respro

The Respro mask varied in relative humidity between 70-100%, with all participants except participant 1 experiencing humidity levels between 80-100%.

3M N95

The 3M N95 mask was the most humid mask tested. This correlates to the previous temperature results listing it as the hottest mask. Humidity ranged from 90-100% with all participants experiencing a humidity period near 100% during their tests.

3M 6000

This mask, over all participant tests, had the second lowest humidity levels with humidity ranging from 80-100% but most of the time sitting in the 80-90% region.

O2O2

This had the lowest humidity of the masks tested with humidity of all participants expect participant 3 having humidity levels between 50-70%. Participant 3 had a high humidity level that increased over the duration of the test from 60-90%. This outlier result correlates with the temperature increase of participant 3 also being significantly higher than the other participants wearing the O2O2 mask and is most likely due to a small air-gap size.

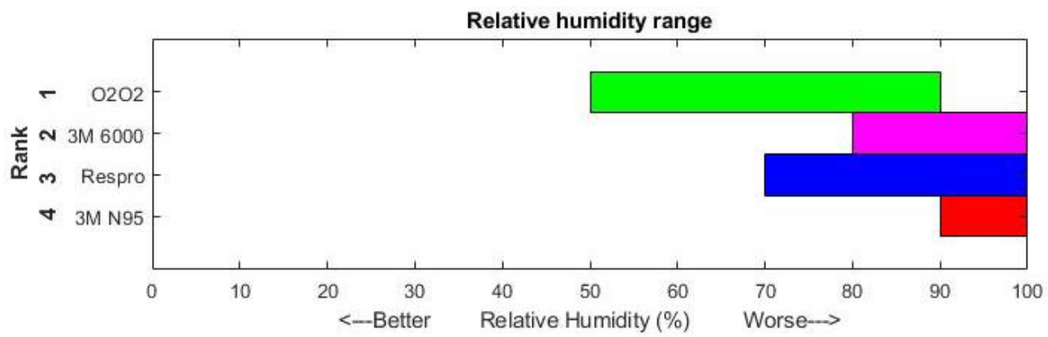
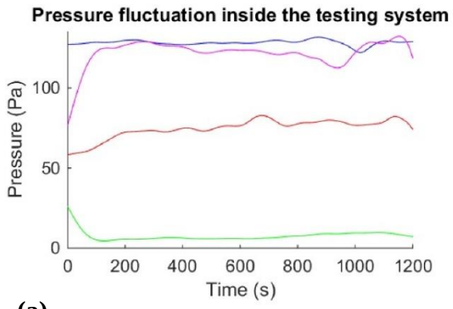


Figure 4.8:Range of humidity levels and overall mask ranking (lowest to highest

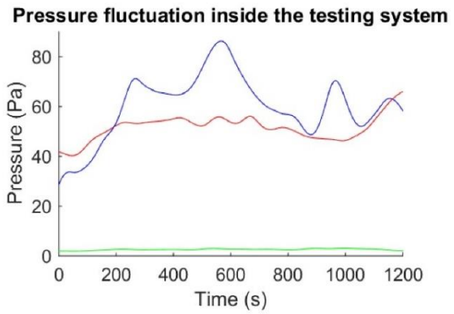
4.4.4 Mask Pressure Fluctuation



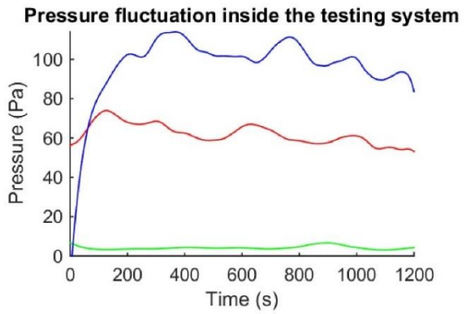
(a)

No data available

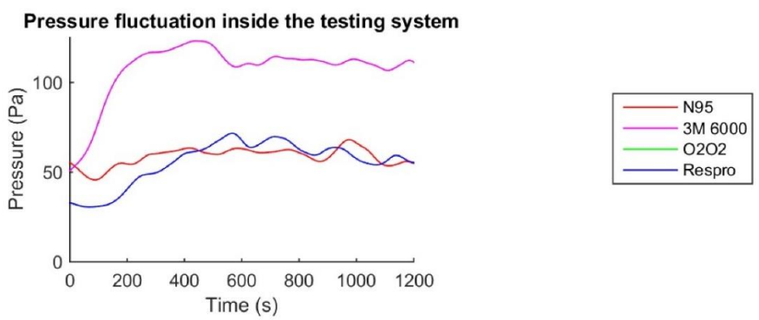
(b)



(c)



(d)



(e)

Figure 4.9:Participant Mask pressure fluctuation levels. (a)-Participant 1; (b)-Participant 3; (c)-Participant 4; (d)-Participant 5; (e)-Participant 6

4.4.4.1 Mask Pressure Fluctuation Discussion

Mask pressure fluctuations are an indicator of the breathing work required to flow air in and out of the mask domain. A high-pressure fluctuation indicates a large amount of additional work that is needed for a participant to breathe, an ideal mask will have a pressure fluctuation of 0 pascals indicating no additional breathing work will be needed.

The pressure sensor of the test-platform stopped working during testing and due to the random testing order, some participants have missing mask pressure fluctuation data. Because of this, no pressure fluctuation data was available for participant 3. Due to the low number of successful participant results, results should be taken as a possible indication. A higher sample size of successful results is needed to further confirm result trends.

4.4.4.2 Comparing O2O2 Mask Performance to Existing Solutions

Respro

This mask had 4 data sets available, 2 of which showed a pressure fluctuation of above 100 pascals and 2 showing pressure fluctuations between 50 to 80 pascals. It is believed to have higher pressure fluctuations than the 3M N95 mask but less than the 3M 6000 mask. A larger sample size is needed to confirm this.

3M N95

This mask had 4 data sets available, results showed good correlation with all participants pressure fluctuations near 60 pascals. This mask had the second lowest pressure fluctuation.

3M 6000

This mask only had 2 pressure curves meaning it was difficult to see a correlation, however, both curves were similar and showed pressure fluctuations above 100 pascals. It is presumed that this mask has the highest-pressure fluctuation, but a larger sample size is required.

O2O2

This mask only had 3 pressure curves to base a correlation off, however, all masks showed a very low-pressure fluctuation below 10 pascals meaning it was the mask with the lowest pressure fluctuation

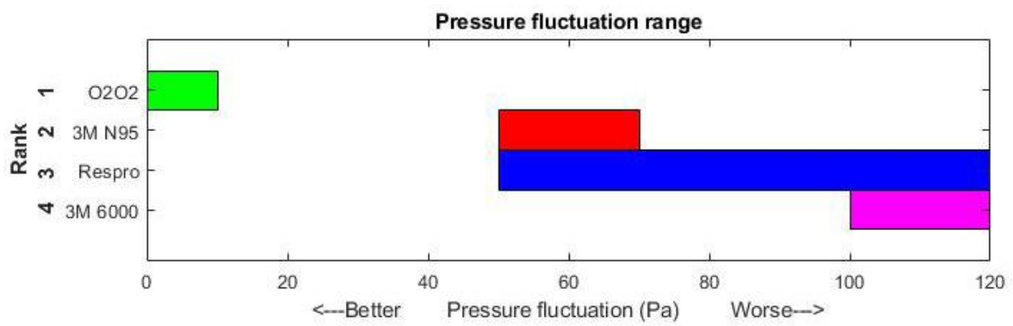


Figure 4.10: Range of pressure fluctuations and overall mask ranking lowest to highest

4.4.5.0 Peak CO_2 levels

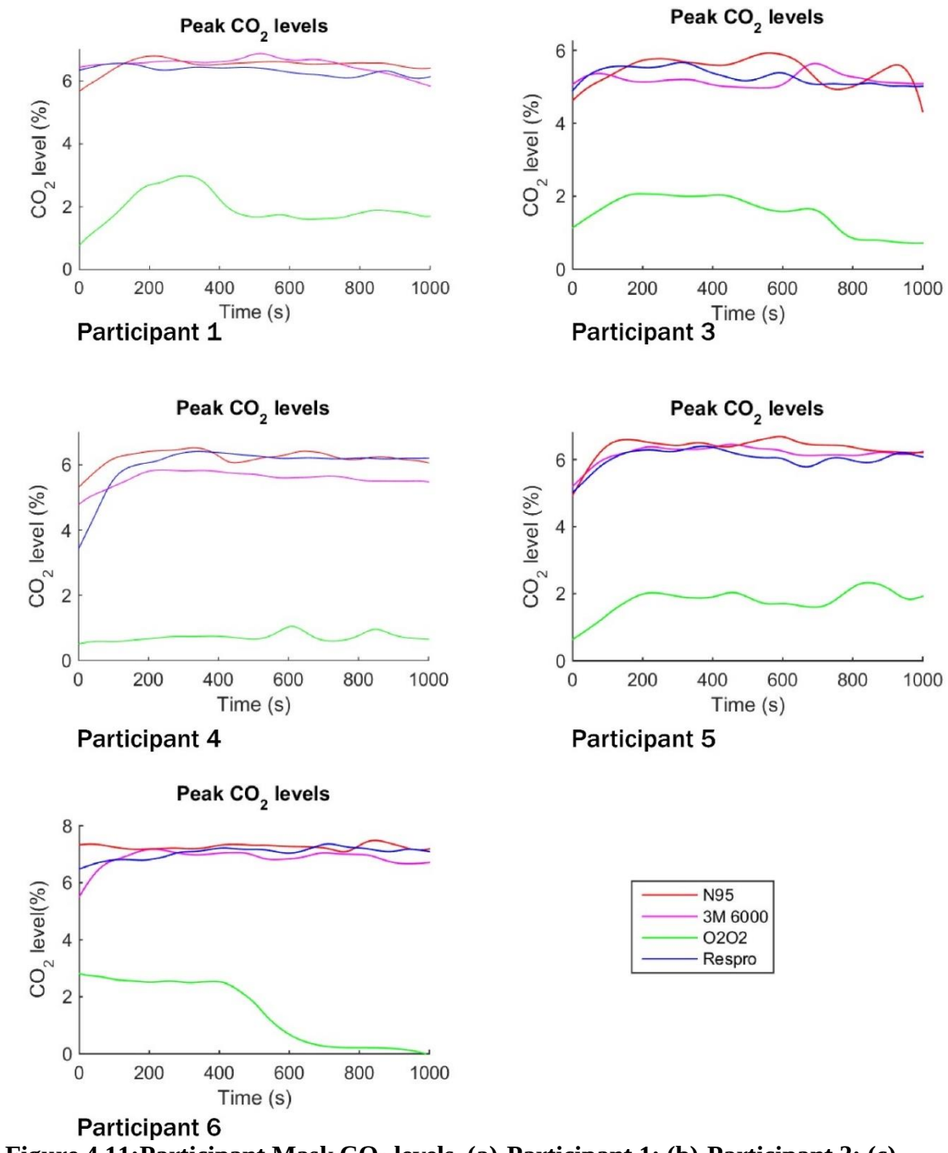


Figure 4.11:Participant Mask CO_2 levels. (a)-Participant 1; (b)-Participant 3; (c)-Participant 4; (d)-Participant 5; (e)-Participant 6

4.4.5.1 Mask Peak CO_2 Discussion

Peak CO_2 levels indicate how well the masks can purge exhaled air from the masks. A high CO_2 level indicates low purging and that exhaled air stays inside the mask for longer.

4.4.4.2 Comparing O2O2 Mask Performance to Existing Solutions

Respro

This mask had remarkably similar peak CO_2 levels to the 3M N95 and 3M 6000 masks with peak CO_2 levels between 6 and 8%. Over all participant tests, it is marginally lower than the 3M N95 and has the third highest peak CO_2 levels.

3M N95

This mask has marginally higher peak CO_2levels than the Respro mask and has marginally higher peak CO_2 levels over all participant tests.

3M 6000

This mask is slightly lower than the Respro mask in peak CO_2 levels over the participant tests and has the second lowest peak CO_2 levels.

O2O2

This mask constantly had peak CO_2 levels under 2% for all participants apart from participant 6, which initially had a 3% peak CO_2 level for the first 400 seconds before dropping below 1%.

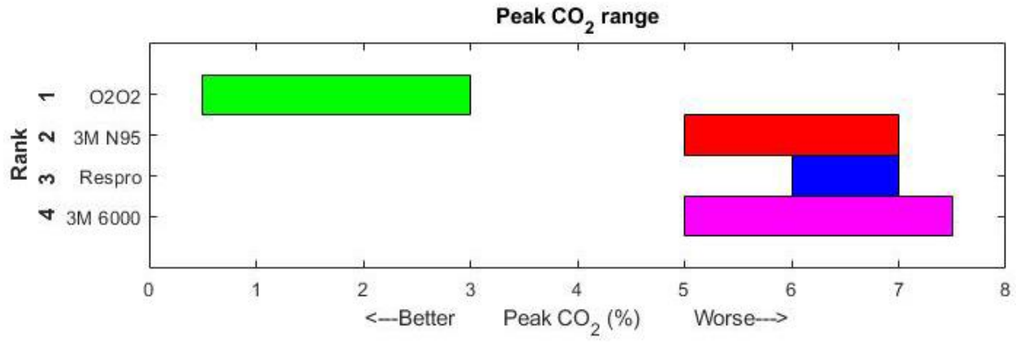


Figure 4.12:Range of peak CO_2 levels and overall mask ranking lowest to highest

Rankings are in the order of maximum peak CO_2 level, penalizing high peak levels rather than rewarding a lower average. With the small sample size, it is hard to rank the 3M N95, 3M 6000 and Respro masks against each other due to all being very similar in peak CO_2. A larger sample size is needed to confirm this ranking.

4.5 Mask Physical Impressions on Participants

Photos were taken immediately after each test had concluded to identify physical impressions left on participants faces. This helped in understanding fitment issues in the mask filtration solutions tested and how the O2O2 functional prototype could be modified for a better fit.

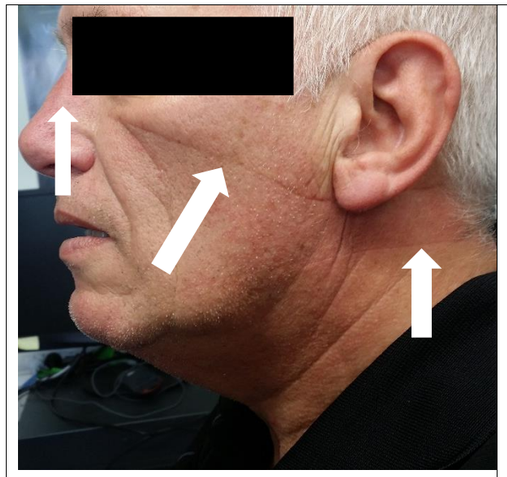


Figure 4.13 (a): Immediately after test wearing Respro face mask.

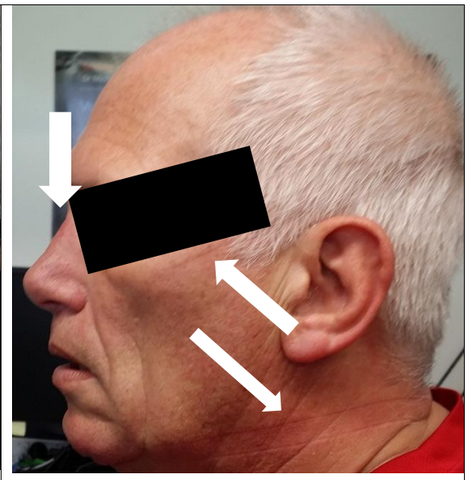
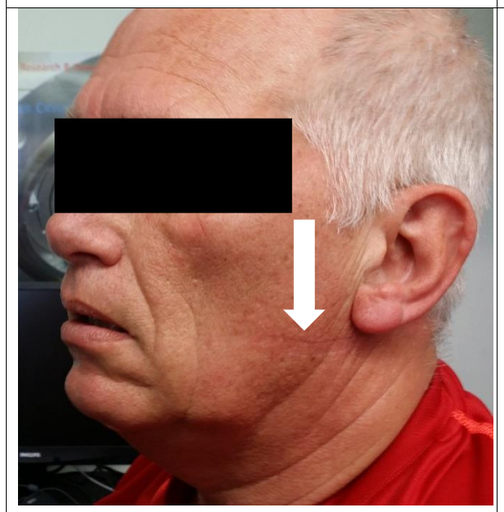


Figure 4.13 (b): Immediately after test wearing 3M 6000 face mask.



4.13 (c): Immediately after test wearing N95 face mask.

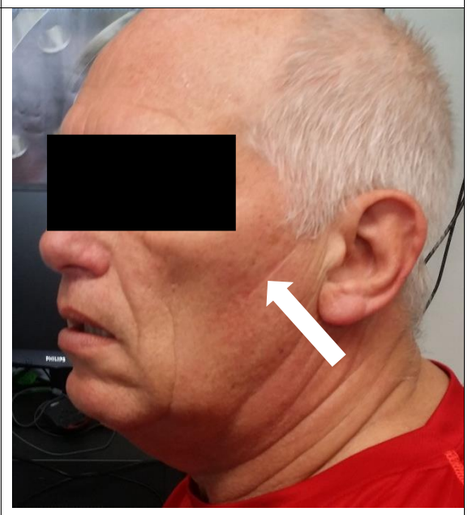


Figure 4.13 (d): Immediately after test wearing o2o2 face mask.

Figure 4.13:Images of Participant 3 face marking immediately after testing

4.5.1 Discussion

The 3-existing 3M N95, 3M 6000 and Respro mask solutions all relied on a ‘press-fit’ sealing method, which required the masks to be pressing firmly on the participant’s faces to create a seal. This pressing of the masks left temporary facial markings on the participants, which participant subjective feedback in section 4.5.1 indicates to be uncomfortable. Figure 4.13 shows facial markings on participant 3, where markings from the 3M N95, 3M 6000 and Respro masks are representative of those experienced by all participants.

Facial-marking, acne, bruising and even open-sores are some of the common side-effects of press-fit CPAP facial masks over long periods of use [42], it is expected that some of these very negative side-effects could occur to users wearing press-fit particle filtration masks such as the 3M N95, 3M 6000 and Respro masks tested over long periods of time.

Unlike the 3M N95, 3M 6000 and Respro masks, the O2O2 mask does not require physical sealing on the face, which should reduce the physical side-effects associated with press-fit masks. Participant 3 is shown as they were the only user to experience facial markings from the O2O2 mask, as shown in figure 4.13(d) with a mark on the side of the face. As the O2O2 mask does not reply on a press-fit seal, as well as the location of the marking being in a region designed to have an air gap, it is expected that the marking was due to the mask being too small for the participants wide face-shape.

While only participant 3 is shown, images of the other participants are available in Appendix E.

4.6 Participant Subjective Feedback

User-centric feedback was sought from the participants regarding mask fit and comfort, air quality, breathing effort and odour as requested by the sponsor company. This was sought to assist in meeting goal 2, to assist the sponsor company in comparing their mask to existing solutions and provide feedback that could assist in product development of the next prototype evolution.

Graphs below rank the masks from best (top) to worse (bottom) with percentages of user feedback shown. Green colours represent positive feedback transitioning to red colours indicating strong negative feedback. Detailed colour keys are included with each graph.

4.6.1 Mask Fit and Comfort

Figures 4.14 and 4.15 show perceived mask fit and mask comfort which are grouped together due to participant comments including mask fit and comfort together.

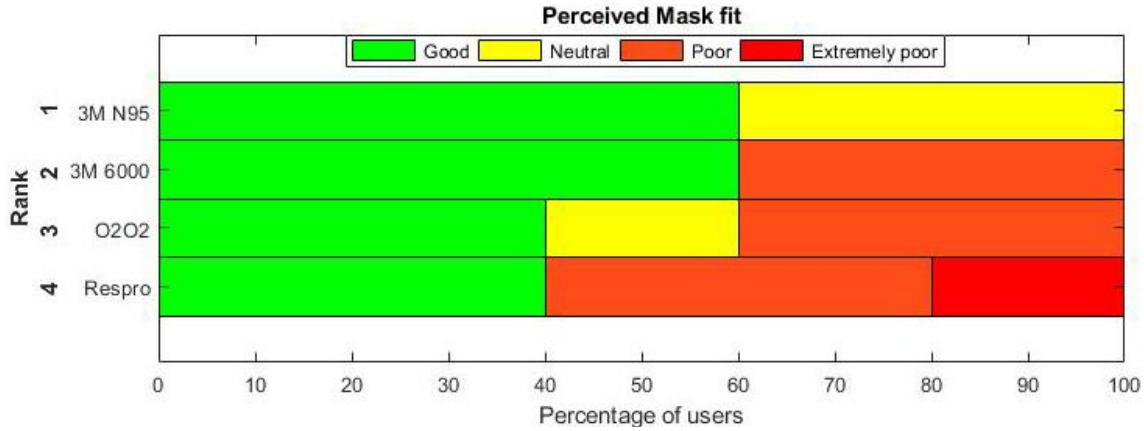


Figure 4.14:Breakdown of mask fit feedback and rankings

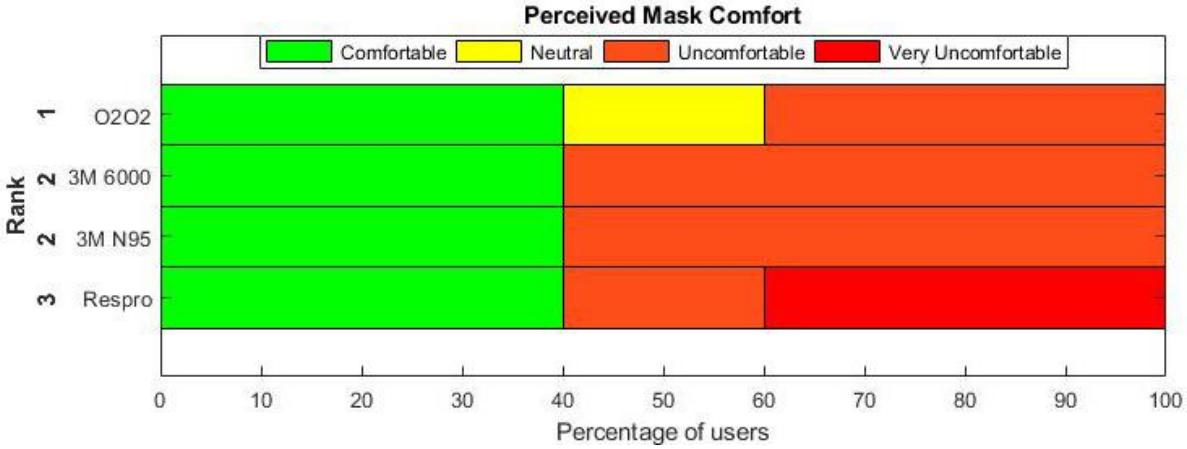


Figure 4.15:Breakdown of perceived mask comfort and rankings

4.6.1.1 Discussion

Mask fit feedback was important as it was an indicator of how well the masks could fit a population. Comfort feedback was also important as the functional purpose of the O2O2 mask was to protect users from air pollution and the mask needed to remain comfortable over long periods of time to span a commuting journey.

4.6.1.2 Summary of participant comments associated with mask fit and comfort

Respro

- ***Loose fit, mask falls down my face and pinches my nose, restricting airflow.***
- ***Bit of a pinch on top of my nose and made my face quite sweaty.***
- ***It was awful, tight and pushed against my nose. I couldn't breathe.***
- ***Initially seemed OK but during exercise it choked me as it felt a tight fit. My face felt hot and scratchy.***

N95

- ***Mask felt scratchy on my face.***
- ***Felt soft on my face, maybe a little claustrophobic in mouth area as not a big mask.***
- ***It was tight and pushed on my nose.***

3M 6000

- ***Mask pressed heavily onto my nose and I could feel my pulse around the mask perimeter.***
- ***Good fit at first however when you start breathing/wearing it for a while it feels tighter.***
- ***Nothing too annoying when still but could feel a little bit sore/tight around the nose area when moving head around. Gets sweaty.***

O2O2

- ***It felt like it was going to fall off.***
- ***Felt Straps mainly of plastic are a bit annoying as when I move my head it falls off. Mask also pinches nose if not sitting right.***
- ***It pushed my nose.***
- ***Clunky and not a proper fit.***

4.6.2 Mask Air Quality – Temperature/Humidity and Odour

Figure 4.16 shows participant feedback regarding temperature and humidity which were graphed together. This was done as it was easier for participants to identify mask 'stuffiness' rather than temperature and humidity separately due, to humidity affecting perceived temperature feeling. Figure 4.17, odour, is shown below as some comments from participants include temperature/humidity and odour which cannot be separated.

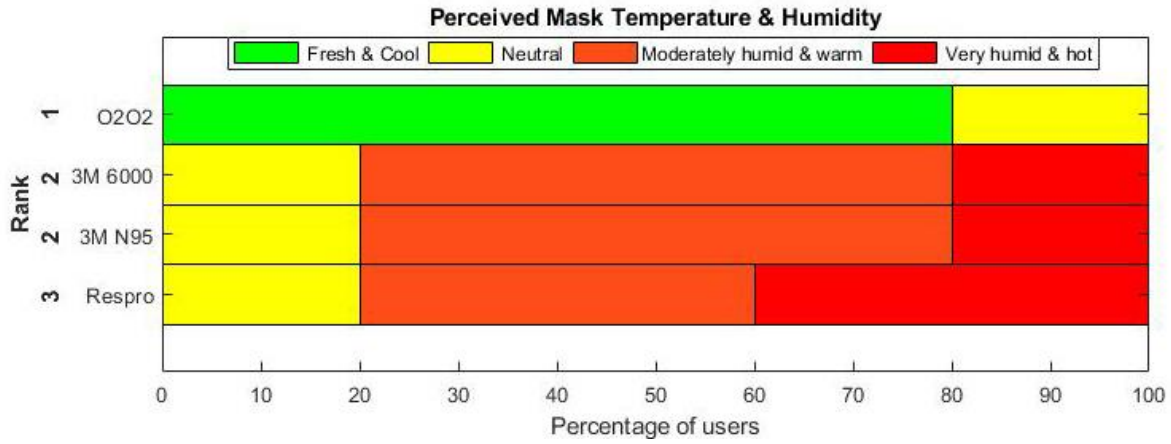


Figure 4.16:Breakdown of perceived mask temperature/humidity and mask rankings

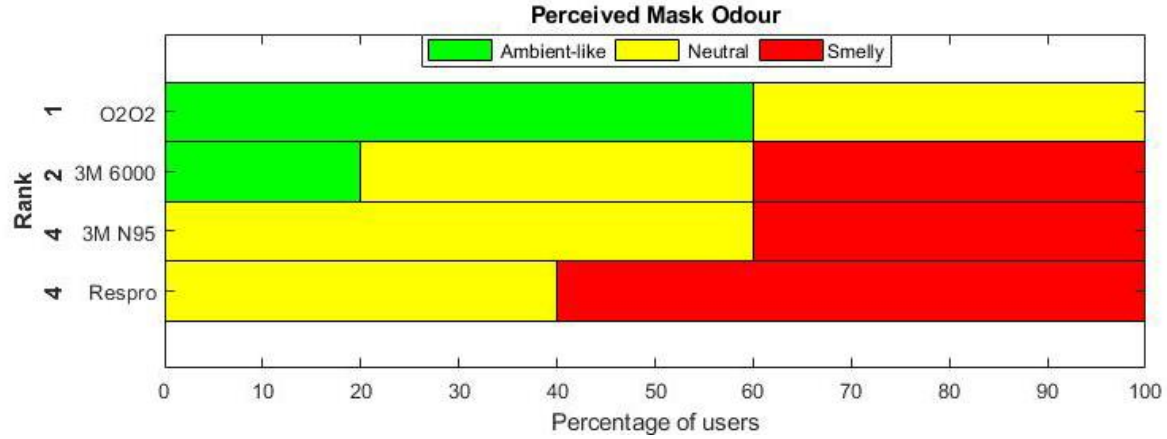


Figure 4.17:Breakdown of perceived mask odour and mask rankings

4.6.2.1 Discussion

Like comfort, air-quality needs to be good for participants to wear the mask over long periods of time. Air-quality assessments were regarding odour as well as temperature and humidity which could impact participants perceived endurance levels. Rankings of perceived mask temperature and humidity match measured temperature and humidity rankings in section 4.3.2.3 and 4.3.3.3 respectively.

4.6.2.2 Summary of participant comments associated with temperature, humidity and odour:

Respro

- ***Very uncomfortable.***
- ***Smelly but mix of nice and odd smells.***
- ***Very humid, I can taste sweat running between my nose and mouth.***

N95

- ***Smelling old breath.***
- ***It was smelly because I breathe with my mouth.***
- ***My face got hot & wet.***

3M 6000

- ***Hardly any odour however it gets very humid and hot.***
- ***Air smelt strange. Mask had lots of heat and water.***
- ***Nothing noticeable once using it.***

O2O2

- ***It felt like I was breathing dry fresh air.***
- ***My nose & rest of my face was relatively cool.***

4.6.3 Mask Breathing Difficulty (effort)

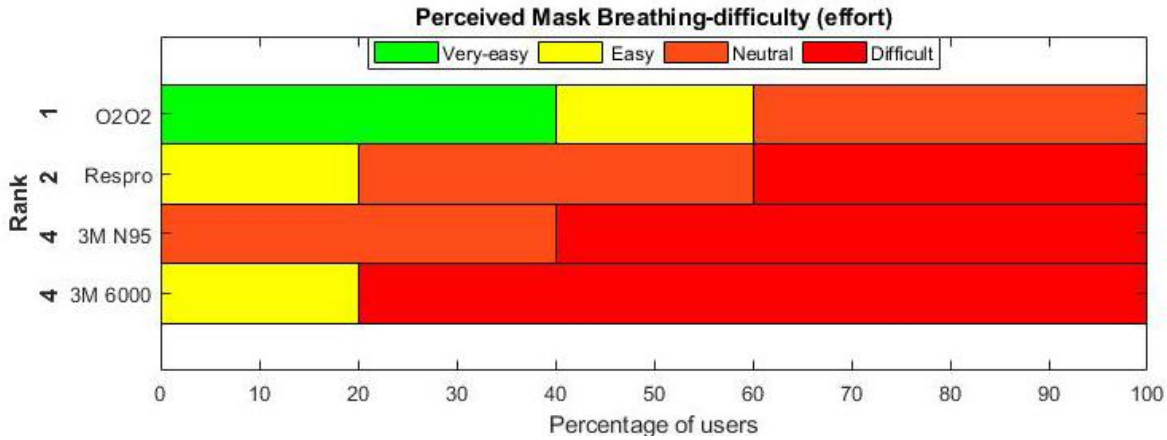


Figure 4.18:Breakdown of perceived mask breathing difficulty and rankings

4.6.3.1 Discussion

Feedback was sought on mask breathing difficulty which regarded additional breathing effort needed to overcome the mask's filtration. Minimizing additional breathing work was important in reducing any negative impacts on the performance of mask users while exercising. Ranking of perceived breathing difficulty matches to measured pressure fluctuation rankings in 4.3.4.2.

4.6.3.2 Summary of participant comments associated with breathing difficulty:

Respro

- ***Awful.***
- ***Needed to suck harder to inhale.***
- ***Didn't find the need to breathe through my mouth.***
- ***Not difficult but felt some restriction.***

N95

- ***Felt harder to get fresh air.***
- ***More effort per breath.***
- ***Nose felt semi-blocked or pinched.***
- ***Slight breathing effort but managed test with nasal breathing only.***

3M 6000

- ***Couldn't easily breathe through my nose so had to mouth breath.***
- ***I had to breathe in through my nose and out through my mouth to be able to breathe properly.***
- ***Felt a little bit claustrophobic.***

O2O2

- ***Noticeably easier to breathe once turned on, as time went on my mouth felt drier.***
- ***When turned on there was a lot of air flow past my eyes which caused eye irritation.***
- ***There is a bit of noise that makes it hard to hear talking.***
- ***It was very easy to breathe in.***
- ***Just like normal.***

4.7 Conclusions

The O2O2 functional prototype mask particle concentration results showed negligible leakage into the mask air-citadel. This further validated the computational and physical models created in chapters 2 and 3 respectively and showed that a functional prototype can be used to protect a user from inhaling polluted ambient air. This also validated that the minimum fan performance requirements derived in chapter 2 were correct. When compared to the Respro, 3M N95 and 3M 6000 masks also tested the O2O2 functional prototype facemask was shown to offer superior user protection from particulate inhalation during moderate exercise. This is attributed to poor face-sealing for some participants using the other facemask systems.

The O2O2 functional prototype sustained substantially lower mask air temperature and humidity levels than the Respro, 3M N95 and 3M 6000 facemask solutions. This is attributed to the other facemask systems trapping exhaled hot and humid air.

The O2O2 functional prototype sustained substantially lower peak CO_2 levels than the Respro, 3M N95 and 3M 6000 facemask solutions. This is attributed to the other facemask systems trapping exhaled air containing high levels of CO_2.

The Respro, 3M N95 and 3M 6000 facemasks all showed larger pressure fluctuations within the masks than the O2O2 functional prototype. This indicates that the O2O2

facemask requires the least amount of additional breathing work. This is attributed to the other facemask systems requiring the facemask user to provide the filtration work whereas with the O2O2 facemask, the filtration work is done by the fan units.

Subjective feedback results rank the O2O2 mask as the preferable mask for having the least amount of breathing effort, the lowest odour and temperature levels and as the most comfortable mask. Users were, however, dissatisfied with the fit of the O2O2 mask and preferred the 3M N95 or 3M 6000 facemasks in this metric.

The next chapter will summarize findings from this report.

Discussion/Conclusions and Future Work

5.0 Introduction

This project was undertaken to assist the sponsor company, O2O2 ltd, in understanding the feasibility, functional requirements and quantifying any advantages of their new proposed facemask system. Their new facemask aimed to improve on current technologies at protecting users from air pollution which is a worldwide problem leading to millions of deaths per year. Research goals of this project were to understand if the fundamental air-citadel concept was a viable method at preventing infiltration of polluted air into the filtered air mask space. It also sought to determine the minimum fan performance requirements to create and maintain this air-citadel and to understand how a functional proof of concept facemask built compares to existing facemask solutions. This project was able to successfully address these research questions and validated that an air-citadel facemask was not only possible but also provided competitive advantages over some of the popular current solutions which justifies a strong commercial business case for the sponsor company.

5.1 Discussion

Chapter 2 first used CFD simulations to virtually model an O2O2 ltd concept facemask using realistic facial geometry during inhalation, with inhalation rates up to an approximate 70% effort level. This chapter showed that the air-citadel concept was viable in preventing infiltration of polluted air into the filtered air mask space but needed further physical testing to confirm. Results also derived minimum fan performance requirements to create and maintain this air-citadel for a fixed vent flow of 0.6 g/s which was shown to be an acceptable vent flow rate to prevent ambient air infiltration, these indicated that the fans must provide a pressure up to approximately 9.1 Pa at the maximum flow rate of 5.1 g/s.

Design and building of a synthetic head and testing apparatus was undertaken in chapter 3 to enable a functional proof of concept prototype mask to be physically tested. It also provided further validation of the air-citadel concept previously analysed in chapter 2. This new type of mask had a measurable and controllable external airflow source ducted to the mask's inlets and the synthetic head model had a steady-state inhalation flow rate that could also be measured and controlled. The synthetic head's inhalation flow rate demand

and the mask's airflow supply were varied, and an air-quality testing apparatus developed for the project. This was used to identify the minimum vent flows required to create and maintain an air-citadel that did not allow for infiltration of polluted ambient air. Results of testing showed that an air-citadel could be created to protect a head from infiltration of polluted ambient air at all simulated inhalation ranges, however, the minimum vent flows required to do so were not below the 0.6g/s (30L/min) air flow rate shown to be acceptable by CFD simulations. The minimum vent flows required were below this 30 L/min value for oral inhalation rates up to 60 L/min but then increased to 50 L/min at an oral inhalation flow rate of 103 L/min. This was the highest value that could be tested due to limitations on the air-delivery system into the facemask. Results of this chapter were also needed to support an ethics application to commence a clinical study to test a functional proof of concept prototype including filtration and fan units on human participants.

A clinical study was undertaken in chapter 4 involving 5 participants who each undertook mild exercise for a period of 20 minutes and while wearing 4 filtration facemask solutions, including a functional O2O2 ltd proof of concept prototype. During this period a sampling system measured air-qualities inside the mask space volumes. This testing further validated that an air-citadel mask could be used to protect a user from inhaling polluted air in a contaminated environment as predicted by previous computer simulations and synthetic head testing. Testing also validated that the minimum fan-requirements derived in CFD simulations were correct as fans used in the functional proof of concept mask were selected by the sponsor company, O2O2, based on these predicted requirements.

The clinical study also allowed for comparison between an air-citadel mask and three existing popular filtration solutions. Measured data from the air-quality testing system showed that the O2O2 functional proof of concept prototype using the air-citadel principle offered superior user protection from particulate inhalation, substantially lower mask air temperature and humidity levels, vastly reduced peak CO_2 levels and lower pressure fluctuations within the mask spaces indicating the lowest additional breathing work required by participants.

Participant subjective feedback of the clinical study indicated that the O2O2 proof of concept prototype was the preferred facemask filtration system in regards to comfort,

temperature and humidity, odour and had the lowest breathing effort out of the masks tested. Users were, however, dissatisfied with the fit of the O2O2 mask.

5.2 Conclusions

This project assessed the facemask citadel concept using CFD and found it technically viable. Further simulation and physical testing of a functional proof-of-concept prototype enabled the specification of the fan motor air delivery requirements. This led to the clinical testing of a prototype O2O2 facemask that demonstrated better air quality and air comfort when compared to current commercial facemask solutions. This finding provided support and evidence to justify a strong commercial business case for the sponsor company, O2O2 ltd.

5.3 Future work

CFD simulations assumed that airflow from the fan motors into the mask was normal to the inlet surfaces of the mask geometry and that default air turbulence values in Ansys Fluent were representative of airflows of the fans that would be selected by O2O2. It would be beneficial to re-simulate the CFD models once better understanding the turbulence levels and airflow direction of fans selected by O2O2. This could improve understanding of the effects air inlet direction and turbulence could have on maintaining the air-citadel in front of the face.

Due to computational and time requirements, CFD simulations relied on simulating using a fixed bias flow and checking for leakage. An improved method to better correlate physical testing of the synthetic head to computer simulations would involve repeat simulations to identify the minimum bias flow rates like the method used in testing of the physical head.

It would be beneficial to find an airflow source for the physical synthetic head testing capable of supplying the higher airflows up to 250 L/min that the testing system was unable to provide. This would allow validation of the maximum steady-state inhalation airflows up to the desired

Human testing in chapter 5 used five participants and trends were difficult to identify. While it would be beneficial to have a greater sample size to improve confidence in the trends identified, further funding beyond the scope of this project is required.

6.0 References

1. World Health Organisation, *WHO releases country estimates on air pollution exposure and health impact*. 2016.
2. Roberge, R.J., et al., *Infrared imaging for leak detection of N95 filtering facepiece respirators: A pilot study.* American Journal of Industrial Medicine, 2011. **54**(8): p. 628-636.
3. Furman, H.K.H., *Dust Storms in the Middle East: Sources of Origin and Their Temporal Characteristics.* Indoor and Built Environment, 2003. **12**(6): p. 419-426.
4. Unites States Environmental Protection Agency, *What are the Air Quality Standards for PM?* 2017
5. United States Environmental Protection Agency, *Draft Integrated Review Plan for the National Ambient Air Quality Standards for Particulate Matter*. 2016
6. Ghorani-Azam, A., B. Riahi-Zanjani, and M. Balali-Mood, *Effects of air pollution on human health and practical measures for prevention in Iran.* Journal of research in medical sciences: the official journal of Isfahan University of Medical Sciences, 2016. **21**.
7. Pope, I.C., et al., *Lung cancer, cardiopulmonary mortality, and long-term exposure to fine particulate air pollution.* JAMA, 2002. **287**(9): p. 1132-1141.
8. Lelieveld, J., et al., *The contribution of outdoor air pollution sources to premature mortality on a global scale.* Nature, 2015. **525**: p. 367.
9. Qian, Y., et al., *Performance of N95 Respirators: Filtration Efficiency for Airborne Microbial and Inert Particles.* American Industrial Hygiene Association Journal, 1998. **59**(2): p. 128-132.
10. Skretvedt, O.T. and J.G. Loschiavo, *Effect of facial hair on the face seal of negative-pressure respirators.* Am Ind Hyg Assoc J, 1984. **45**(1): p. 63-6.
11. Stobbe, T.J., R.A. daRoza, and M.A. Watkins, *Facial hair and respirator fit: a review of the literature.* Am Ind Hyg Assoc J, 1988. **49**(4): p. 199-204.
12. Baig, A.S., et al., *Health care workers' views about respirator use and features that should be included in the next generation of respirators.* American Journal of Infection Control, 2010. **38**(1): p. 18-25.
13. Johnson, A.T., *Respirator masks protect health but impact performance: a review.* Journal of Biological Engineering, 2016. **10**(1): p. 4.
14. Johnson, A.T., et al., *Influence of Anxiety Level on Work Performance With and Without a Respirator Mask.* American Industrial Hygiene Association Journal, 1995. **56**(9): p. 858-865.
15. Laferty, E.A. and R.T. McKay, *Physiologic effects and measurement of carbon dioxide and oxygen levels during qualitative respirator fit testing.* Journal of Chemical Health and Safety, 2006. **13**(5): p. 22-28.
16. Smith, C.L., J.L. Whitelaw, and B. Davies, *Carbon dioxide rebreathing in respiratory protective devices: influence of speech and work rate in full-face masks.* Ergonomics, 2013. **56**(5): p. 781-790.
17. Lee, H.P. and D.Y. Wang, *Objective Assessment of Increase in Breathing Resistance of N95 Respirators on Human Subjects.* The Annals of Occupational Hygiene, 2011. **55**(8): p. 917-921.
18. Kabir, M.M., et al. *Effect of resistive inspiratory and expiratory loading on cardio-respiratory interaction in healthy subjects*. in *2014 36th Annual International Conference of the IEEE Engineering in Medicine and Biology Society*. 2014.

19. Saad, T., *Turbulence modeling for beginners*. University of Tennessee space institute, 2011.
20. Versteeg, H.K. and W. Malalasekera, *An introduction to computational fluid dynamics: the finite volume method*. 2007: Pearson Education.
21. Blazek, J., *Computational fluid dynamics : principles and applications*. 2015: Boston, Massachusetts : Elsevier, [2015] Third edition.
22. Gatis, J. *Investigating the Spalart Allmaras Turbulence Model*. N.D
23. Menter, F.R., M. Kuntz, and R. Langtry, *Ten years of industrial experience with the SST turbulence model.* Turbulence, heat and mass transfer, 2003. **4**(1): p. 625-632.
24. Coder, J.G., C. *The Langtry-Menter 4-equation Transitional SST Model*. 2017; Available from: https://turbmodels.larc.nasa.gov/langtrymenter_4eqn.html.
25. Gamboa, F.J.L., *NUMERICAL ANALYSIS OF AN WING SAIL AERODYNAMIC CHARACTERISTICS USING COMPUTATIONAL FLUID DYNAMICS - PART I*. 2010, University of Lisbon.
26. *Finite Volume*. 2012; Available from: https://www.cfd-online.com/Wiki/Finite_volume.
27. Fluent Inc. *25.9.1 Choosing the Pressure-Velocity Coupling Method*. 2006; Available from: https://www.sharcnet.ca/Software/Fluent6/html/ug/node1021.htm.
28. Andersson, B., et al., *Computational fluid dynamics for engineers*. 2011: Cambridge University Press.
29. Ansys, I. *25.9.2 Setting Under-Relaxation Factors*. Ansys Fluent 6.3 Users Guide 2006; Available from: https://www.sharcnet.ca/Software/Fluent6/html/ug/node1022.htm.
30. Hiester, H.R., et al., *Assessment of spurious mixing in adaptive mesh simulations of the two-dimensional lock-exchange*. Vol. 73. 2014. 30–44.
31. Brennen, C., *Internet Book on Fluid Dynamics*. 2004: Dankat Publishing.
32. Ansys, I. *Lecture 7: Turbulence Modeling*. Introduction to Ansys Fluent 2014.
33. Franke, J., et al. *Recommendations on the use of CFD in wind engineering*. in *Cost action C*. 2004.
34. Gönençer, H., et al., *High-frequency oscillatory ventilation: a better tool for lung protection?* Critical Care, 2004. **8**(1): p. P21.
35. White, G., *Equipment theory for respiratory care*. 2014: Cengage Learning.
36. Janssen, L., et al., *Interpretation of inhalation airflow measurements for respirator design and testing.* JOURNAL-INTERNATIONAL SOCIETY FOR RESPIRATORY PROTECTION, 2005. **22**(3/4): p. 122.
37. Niinimaa, V., et al., *The switching point from nasal to oronasal breathing.* Respiration Physiology, 1980. **42**(1): p. 61-71.
38. TSI Incorporated, *Model 4040/4043/4045 General PurposeThermal Mass Flowmeter*. 2002, Transcat.
39. CareFusion, *Capnography handbook - Respiratory critical care*. 2010
40. Chemistry, R.S.o. *Respiration*. Available from: http://www.rsc.org/Education/Teachers/Resources/cfb/respiration.htm.
41. Centers for Disease Control and Prevention. *Perceived Exertion (Borg Rating of Perceived Exertion Scale)*. 2015; Available from: https://www.cdc.gov/physicalactivity/basics/measuring/exertion.htm.
42. US Expediters Inc (dba CPAP.com). *CPAP Common Side Effects*. Available from: https://www.cpap.com/cpap-faq/Common-Side-Effects.html.
43. Barrentine, *Safety Data Sheet - Citronella Lantern & Torch Oil*. 2013.

44. TSI Incorporated, *PID Response Factors for VOCs*. 2011.
45. Oars Weel, *Workplace Environmental Exposure Level - Menthol*. 2014.
46. Becquemin, M., et al., *Particle size in the smoke produced by six different types of cigarette.* Revue des maladies respiratoires, 2007. **24**(7): p. 845-852.
47. Ingebrethsen, B.J., S.K. Cole, and S.L. Alderman, *Electronic cigarette aerosol particle size distribution measurements.* Inhalation toxicology, 2012. **24**(14): p. 976-984.
48. Czogala, J., et al., *Secondhand exposure to vapors from electronic cigarettes.* nicotine & tobacco research, 2013. **16**(6): p. 655-662.
49. Coloradoci, *Particle Size Chart*.
50. Chuang, H.-C., T. Jones, and K. BéruBé, *Combustion particles emitted during church services: Implications for human respiratory health.* Environment International, 2012. **40**: p. 137-142.
51. Yong, Z., *Digital universal particle concentration sensor - PMS5003 series data manual*. 2016.
52. AQICN.org. *The Plantower PMS5003 and PMS7003 Air Quality Sensor experiment*. Available from: http://aqicn.org/sensor/pms5003-7003/.
53. Nafis, C. *Air Quality Monitoring*. 2012; Available from: http://www.howmuchsnow.com/arduino/airquality/.
54. Weekly, K., et al. *Low-cost coarse airborne particulate matter sensing for indoor occupancy detection*. in *Automation Science and Engineering (CASE), 2013 IEEE International Conference on*. 2013. IEEE.
55. AQICN.org. *The Shinyei experiment - Real-time Air Quality readings from Beijing*. Available from: http://aqicn.org/sensor/shinyei/.
56. Sensirion, *Datasheet SHT7x*. 2011.
57. Elektronik, *HC103M2*.
58. Measurement Specialties, I., *HTU21D(F) Sensor - Digital Relative Humidity sensor with Temperature output*. 2013.
59. Omega. *Fine Gage Bare Wire Thermocouple Elements, J, K, T, E, N, R & S*. Available from: https://www.omega.com/pptst/IRCO_CHAL_P13R_P10R.html.
60. MD, B.S.K. *Response Time of Analyzer*. 2012; Available from: http://www.capnography.com/physics/chemical-method-of-co2-measurement?id=64.
61. CO2Meter, I., *CO2 Engine K30 FR*.
62. Gas Sensing Solutions, *SprintIR™ High Speed Carbon Dioxide Sensor*. 2016.
63. Gas Sensing Solutions, *SprintIR6S Ultra-fast response Carbon Dioxide Sensor*. 2017.
64. Gas Sensing Solutions, *MinIR™ Low Power Carbon Dioxide Sensor*

2017.
65. SGX Sensortech, *IR1 Single Gas Series Datasheet*. 2016.
66. Haymond, S., *Oxygen Saturationm - A Guide to Laboratory Assessment*, in *Clinical Laboratory News*. 2006.
67. Chan, E.D., M.M. Chan, and M.M. Chan, *Pulse oximetry: Understanding its basic principles facilitates appreciation of its limitations.* Respiratory Medicine, 2013. **107**(6): p. 789-799.
68. Servomex Group Ltd, *PM1116 Fast Oxygen Transducer Instruction manual* 2014.
69. OxyCheq. *R33S1 Oxygen Sensor*. Available from: https://www.oxycheq.com/r33s1-oxygen-sensor.html.

70. Supply, P.M. *OXYGEN SENSOR OEM PSR-11-917-MH1*. Available from: http://pacificmedicalsupply.com/oxygen-sensor-oem-psr-11-917-mh1/.
71. Alphasense, *O2-G2 Oxygen Sensor*. 2015.
72. CiTiceL, *Product Datasheet - AO2 Oxygen Sensor*. 2017.

7.0 Appendices

Appendix A : CFD Simulation Results

Model 1 – Simplified mask and facial geometry

Mouth Mass flow rate: 3.5 grams per second

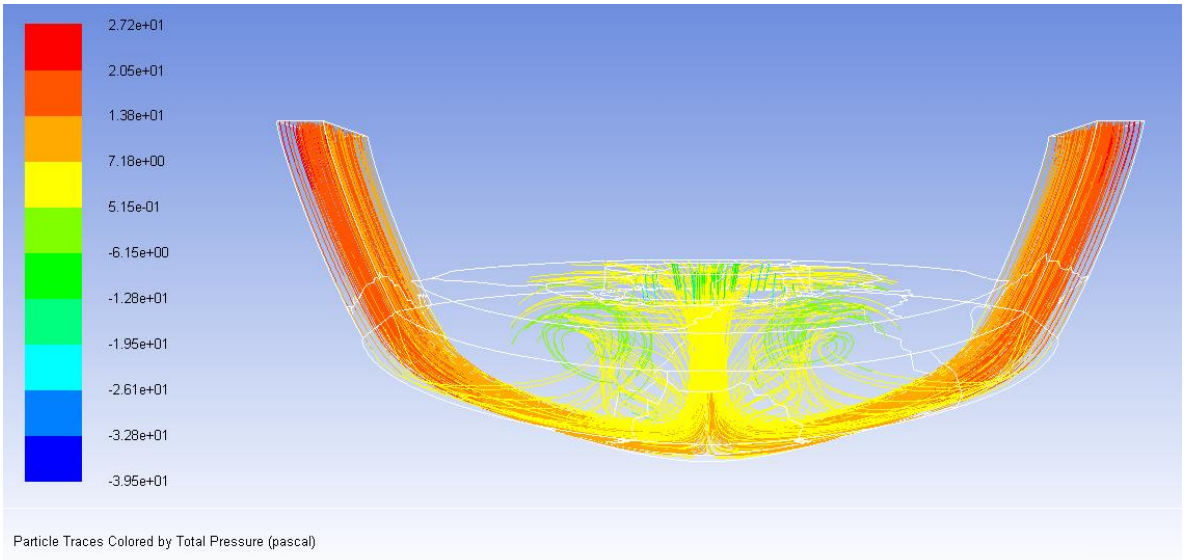


Figure A-1: Top view of particle tracks showing how flow moves through the mask and into the mouth

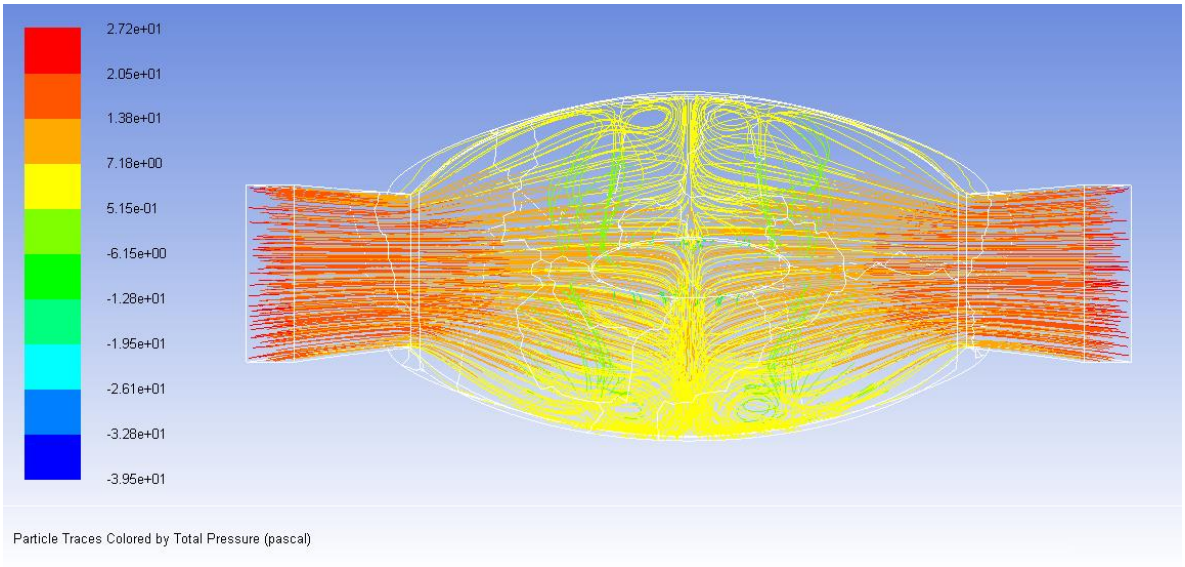


Figure A-2: Front view of Particle tracks showing the two air streams colliding and turbulence through the center of the mask

Mouth Mass flow rate: 2.5 grams per second

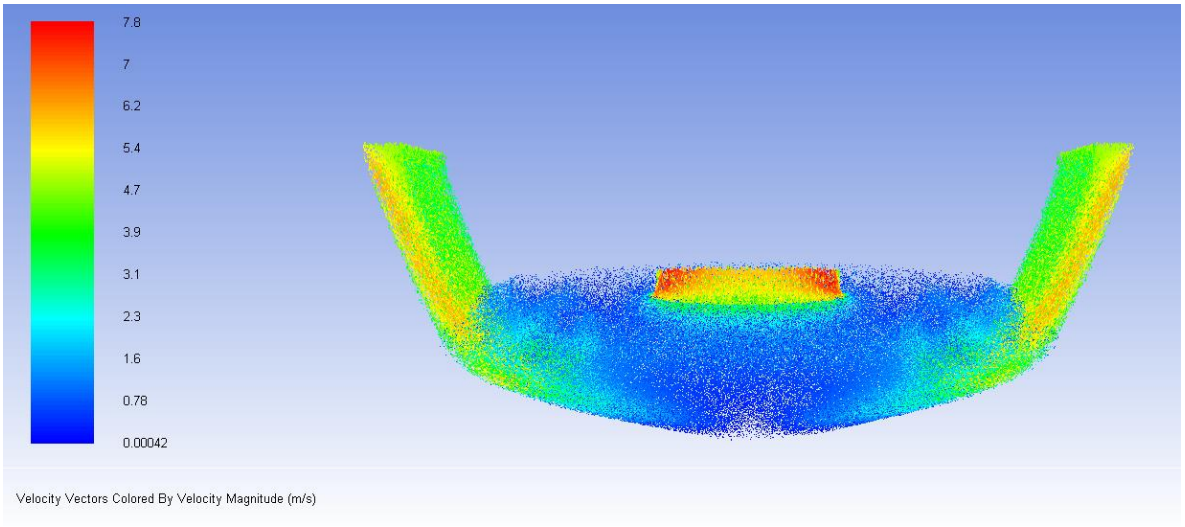


Figure A-3: Top view showing velocity vectors to identify regions of fast-moving air, especially air being funnelled into the mouth

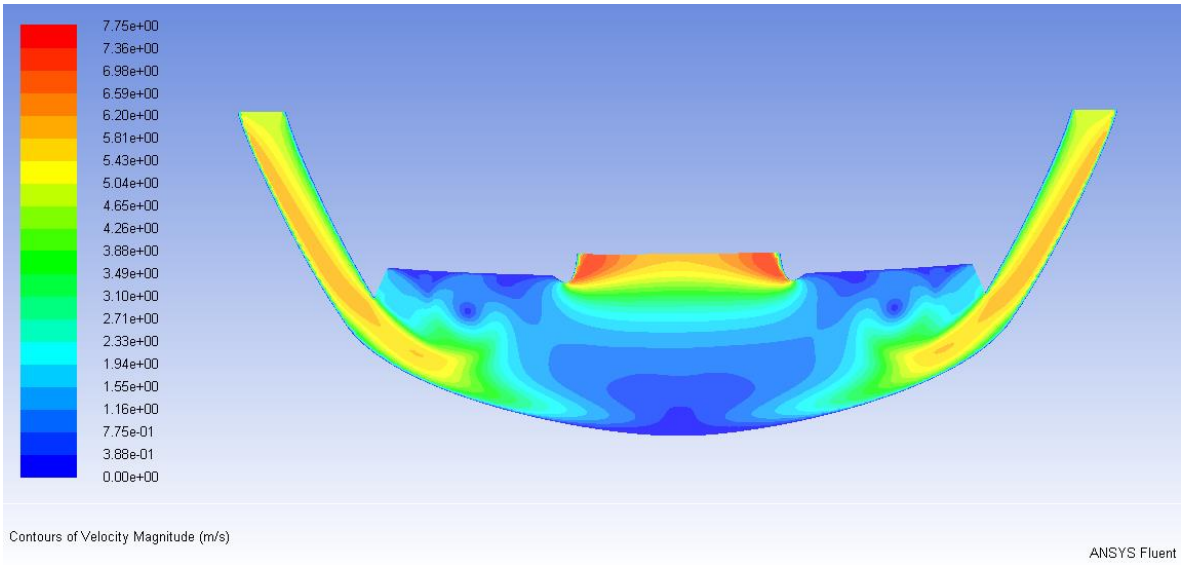


Figure A-4: Top view section through the center of the mask showing velocity contours and regions of fast moving and turbulent air

Mouth Mass flow rate: 2.5 grams per second

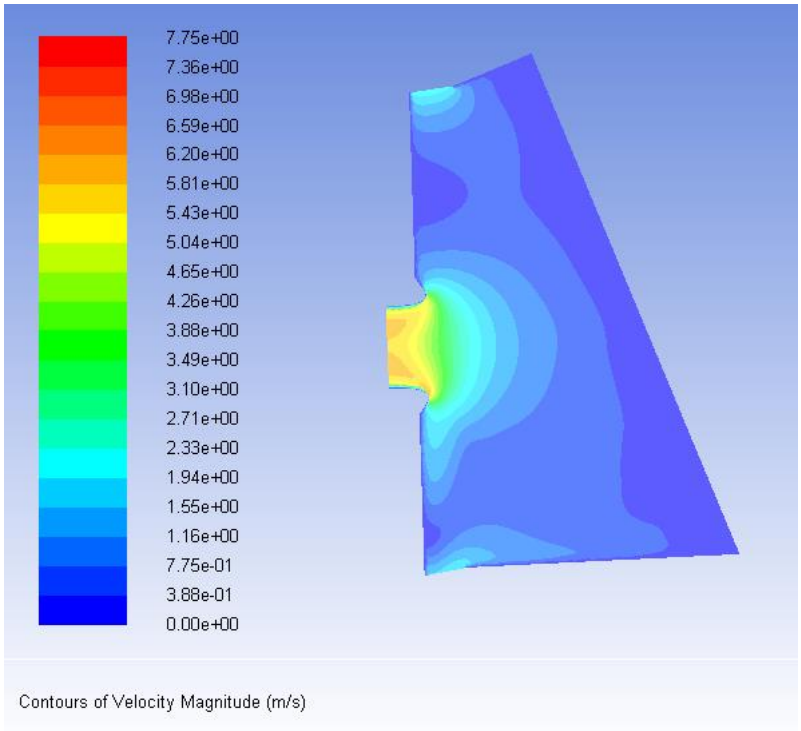


Figure A-5: Side view section through the mask showing air moving out of the masks air gaps and air flow into the mouth

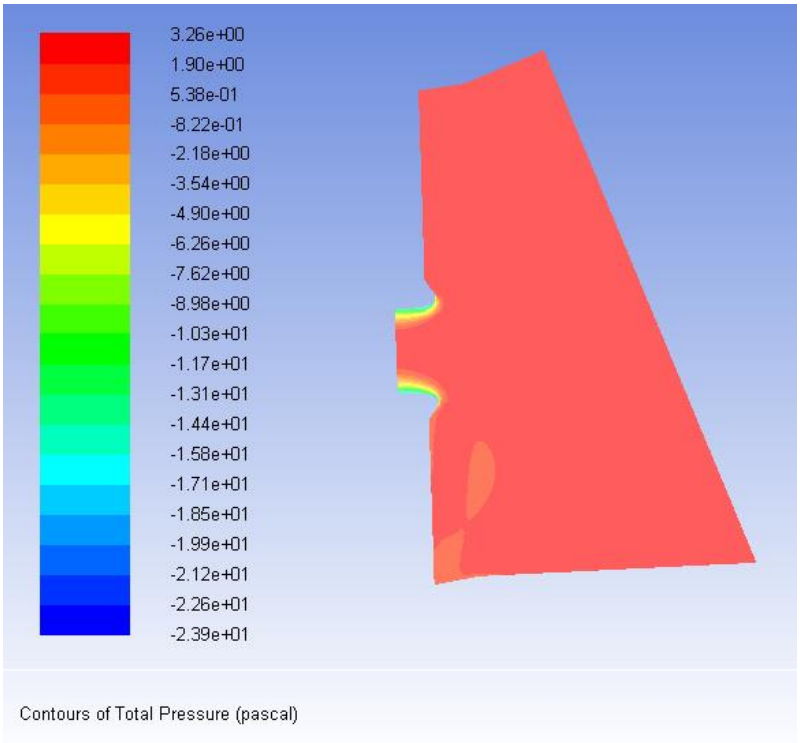


Figure A-6: Side view section showing low pressures with air being funneled into the mouth

Mouth Mass flow rate: 2.5 grams per second

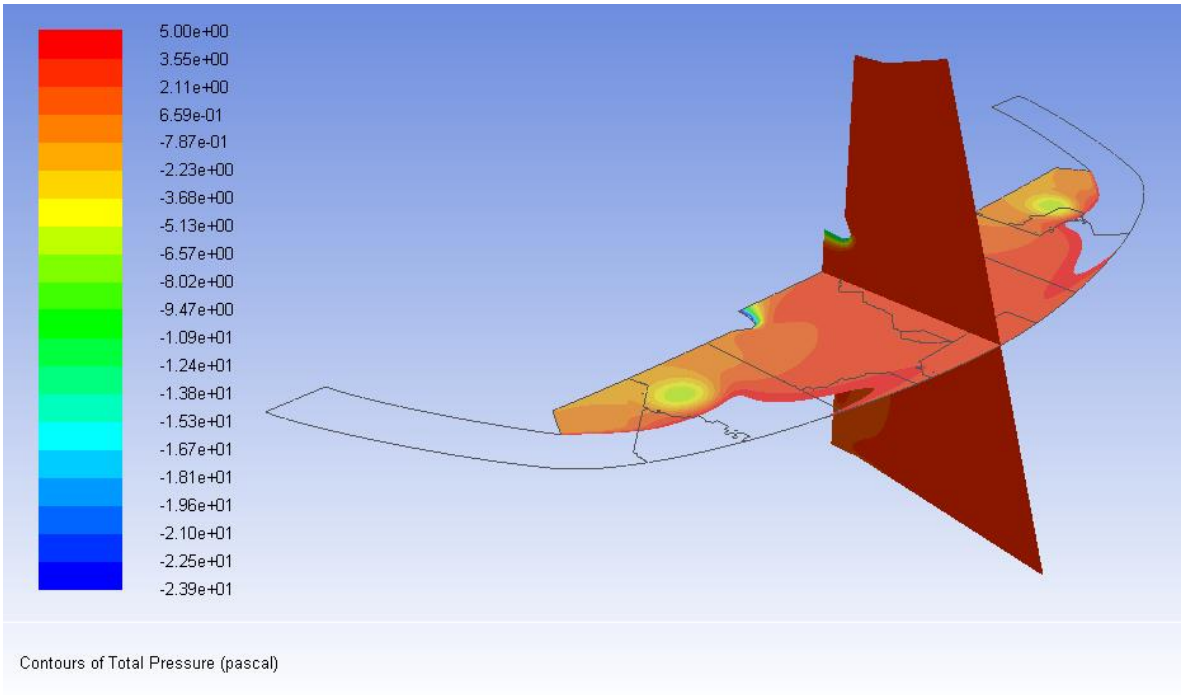


Figure A-7: Combined vertical + horizontal sections showing turbulent flow in the mask

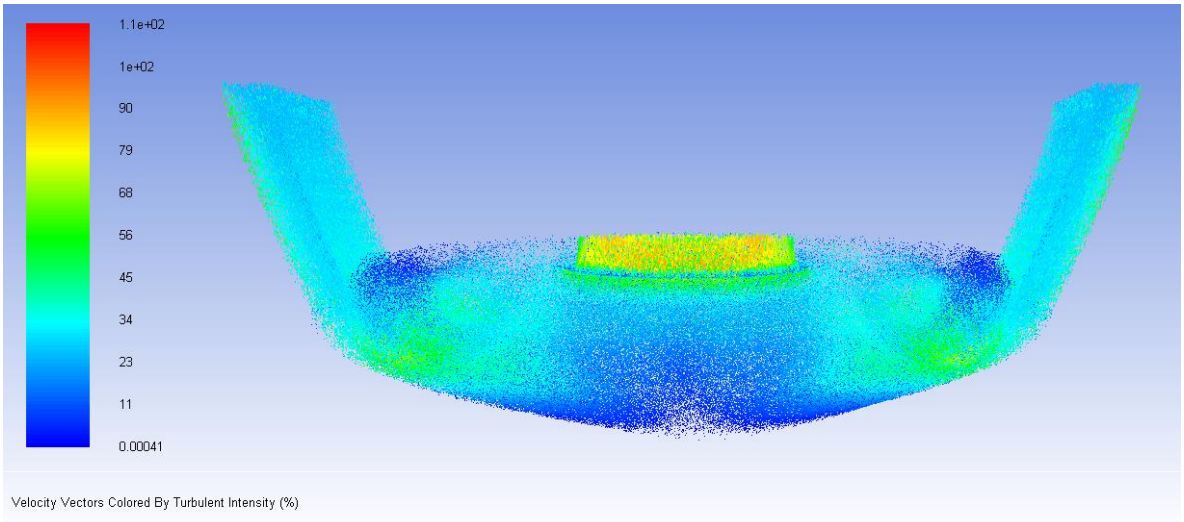


Figure A-7: Top view showing vectors of turbulence to identify turbulent areas on the mask walls and inside the mouth

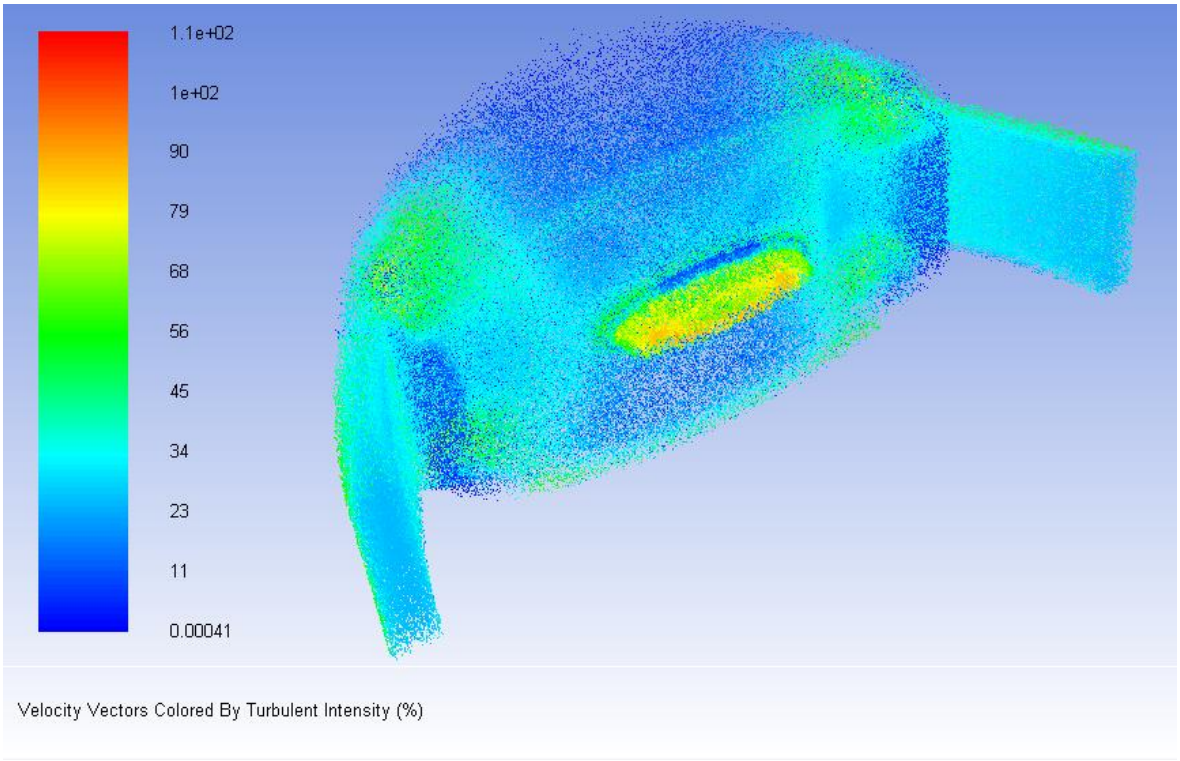


Figure A-8: Isometric view showing vectors of turbulence showing little turbulence at the top and bottom of the mask near the center

Model 2 – Simplified mask with realistic facial geometry

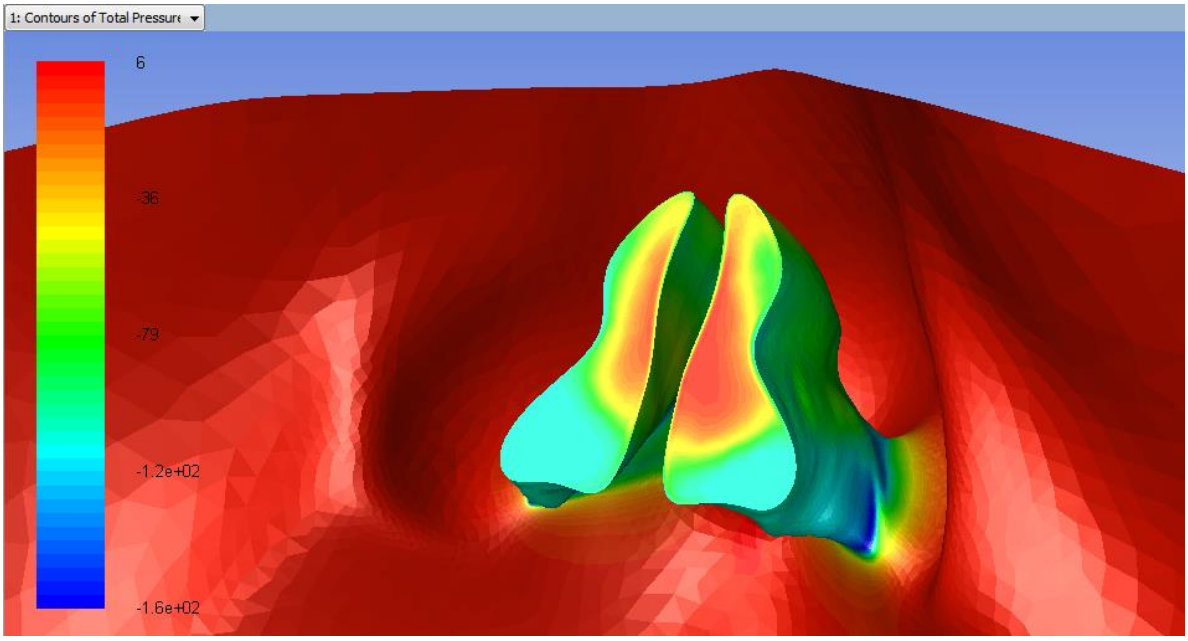


Figure A-9: Isometric view from behind the face surface showing areas of high pressure in the centre of the cross sections indicating a central area of flow

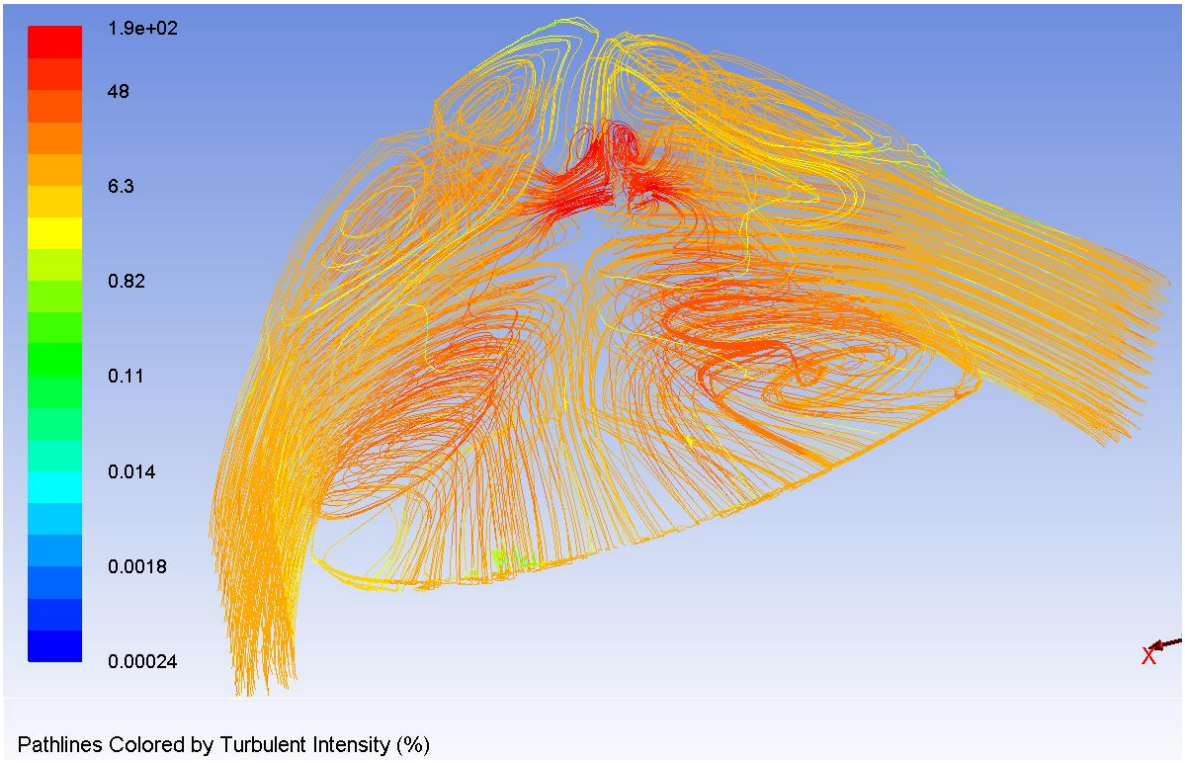


Figure A-10: Isometric view of particle tracks showing how air flows through the mask and areas of turbulence. Red indicates high turbulence intensity

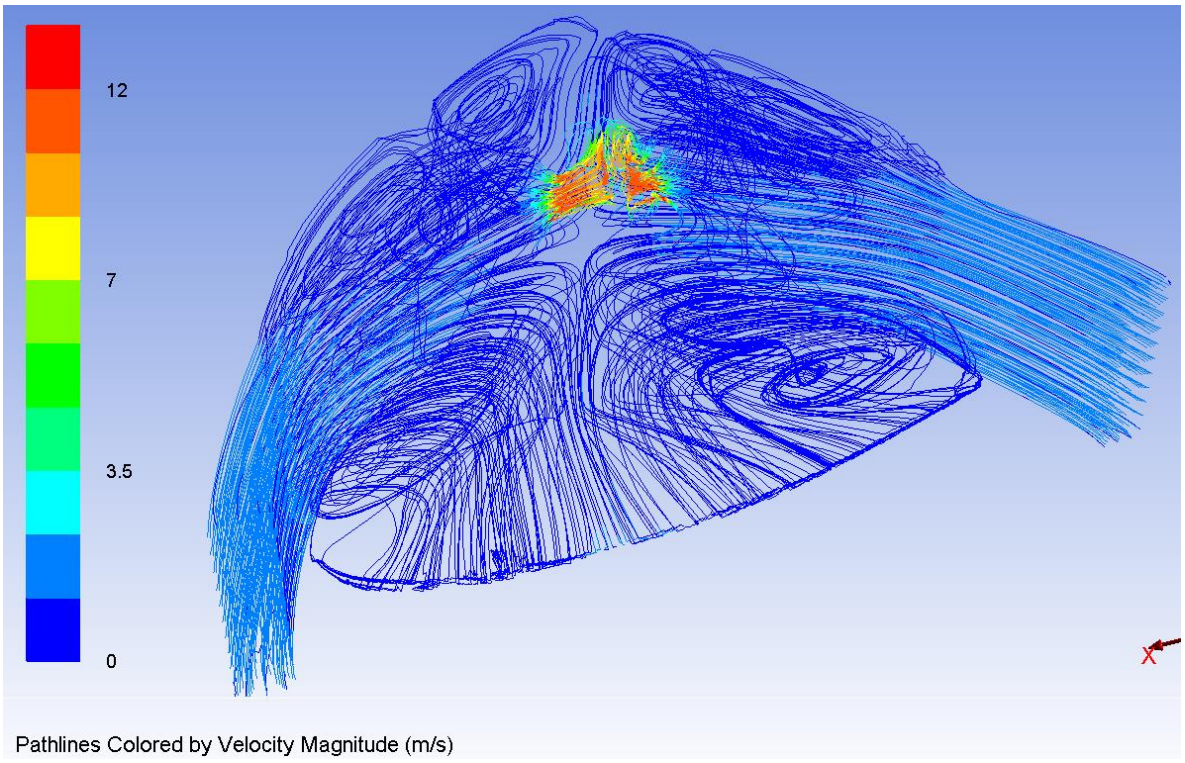


Figure A-11: Particle tracks showing how airflow in the mask is relatively slow compared to the inlets and how airflow is accelerated into the nose

Model 3 – Proof of Concept prototype mask with realistic facial geometry

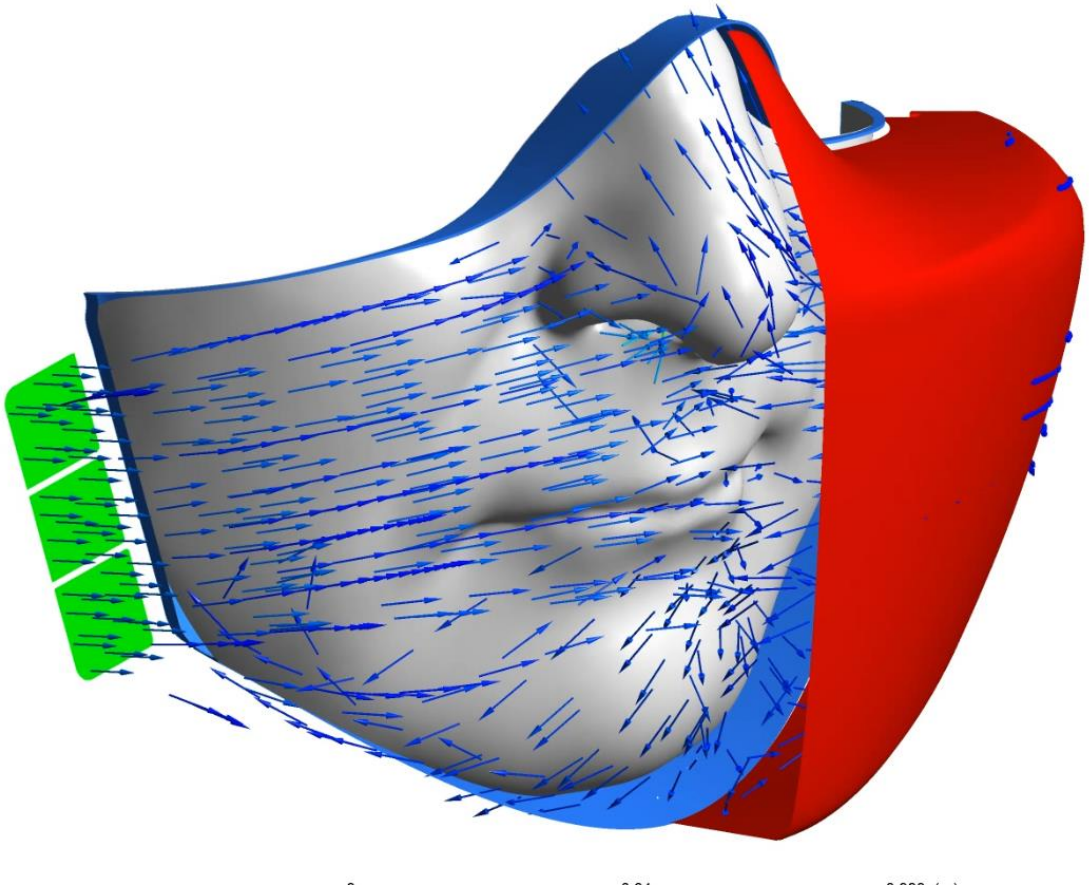


Figure A-12: Arrows indicating airflow direction into the mask and nasal airways

Appendix B – Design of synthetic head testing system

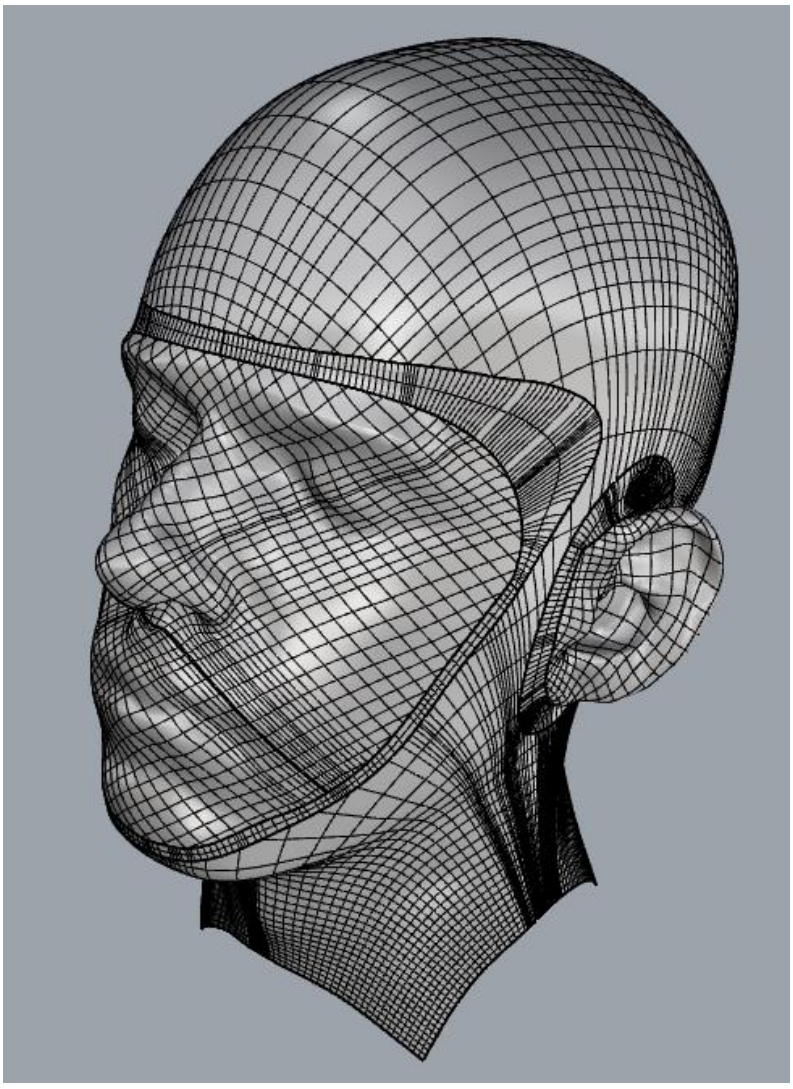


Figure B-1: Surfaces build around the 3D-scan showing 3 main surfaces, the front of the face, head and ears and the blending between these

Head Venturi Ducting Validation

Figures B-1 and B-2 show contours of static pressures at airflow rates of 4.5 and 1.0 grams per second for the oral venturi. The pressure sensor will read the pressure difference between the middle of the constriction and the top just before the tube starts to decrease in diameter, as circled in figute B-2. For the 4.5 grams per second simulation these pressures are approximately -5 pascals and -122 pascals, giving a pressure difference of approximately 117 pascals. At 1 gram per second, which is just below the lowest oral mass flow simulated of 1.5 grams per second, this difference is shown to be approximately 5 pascals which is still in an acceptable

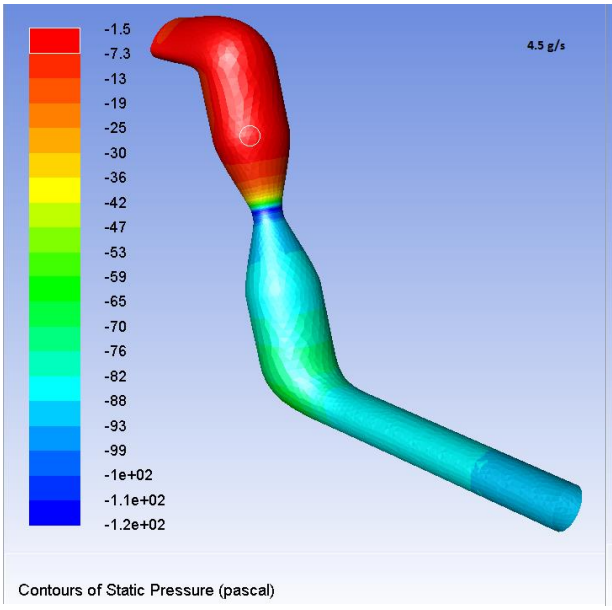


Figure B-2: Simulation of the mouth-ducting showing static pressure at 4.5 grams per second air flow rate

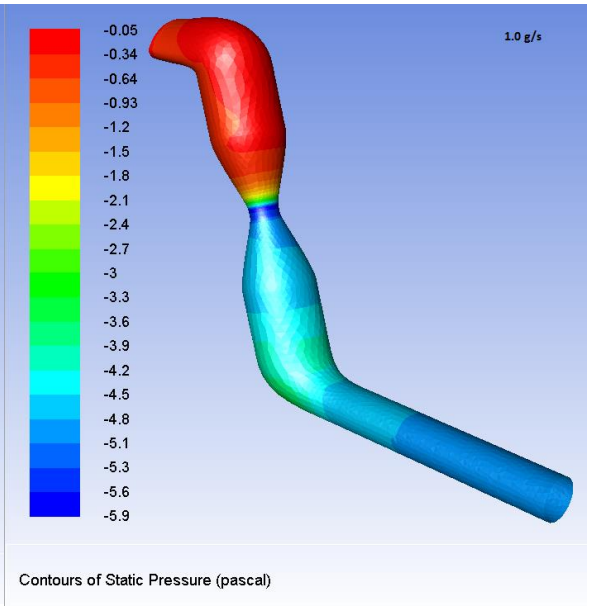


Figure B-3: Simulation of the mouth-ducting showing static pressure at 1.0 grams per second air flow rate

reading range for the SDP610-125 sensor.

Mask airflow source attempts

The first attempt used a high static pressure Nidec Servo D1225C12B5AP 12V fan as well as a Power Logic PLA12025S12M 12V 120mm fan from a computer as the airflow source. These were designed to be stacked in series using custom adapters to increase the output pressure and pushed air through a custom manifold which reduced the duct diameter to a flow meter. 2 differing designs of adapters were designed to allow this stacking of fans. The first design simply rotated the fan 45 degrees to allow for screwing together, in the second design the fans were aligned and featured details to allow for screws and nuts to slot into the corner to bolt fans together individually. These methods were chosen to keep the required screw lengths short.

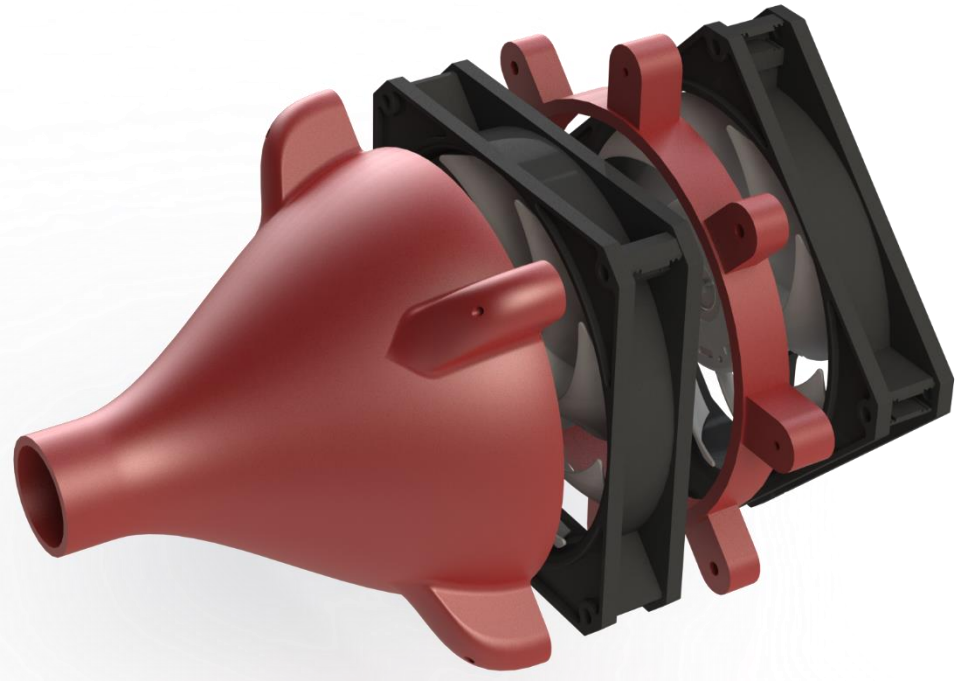


Figure B-4: Initial fan spacer concept showing staggered fans

Figure B-5: Final, more advanced fan stacking arrangement using slide in bolts and nuts for the spacer

Unfortunately once assembled these could not overcome the manifold and testing the flow through the manifold with the Nidec fan at full speed in push configuration flowing around 6 litres per minute and the Power Logic fan flowing around 3.5 litres per minute, much lower than the 250 litres per minute ideal flow rate for testing extreme peak inhilation. These fans worked much better in a pull configuration with the Power Logic fan flowing up to 16.5 litres per minute when over-volted to 15.0 volts, this pull configuration was to assess if the fans could be used to pull the air through the head but airflow results were still far below needed. figure B-6 shows this setup for testing the fan and manifold a pull configuration for the Power Logic fan with figure B-7 showing maximum volume air flow rates in push and pull configurations. This low flow rate was seen with 2 different fan designs and was assumed to be caused by the large clearance gap between the blades and fan housing which allowed most of the air moved by the fan to esape through this gap. Since testing of 1 fan in push showed such low flow rates, no further testing was done with

2 fans in series as it was not expected to achieve anywhere near 250 litres per minute of flow in push or pull configurations.

Figure B-6: Fan testing arrangement for a push configuration

Figure B-7: Peak fan flows in pull (top) and push (bottom) configurations showing the fan is more effective at pulling air

the second airflow source that was able to provide enough air flow was from another vacuum cleaner, setup to use the vacuum cleaners exhaust. This was beneficial as it solved the problem of ducting clean air from outside, the vacuum cleaners hose could simply be placed outside the room, pulling fresh air inside. Figure B-8 shows the layout of this system, the vacuum cleaner exhaust manifold will be sealed onto the vacuum cleaner and blow air into a 2 way junction, a relief valve will be used to minimize pressure build up when throttling low mass flow rates to the mask, as the vacuum cleaner needs high air flow to keep the motor from overheating. This relief valve also allows for more controllability when adjusting the flow into the mask. The flow will then be measured before it is split into two and ducted to each mask inlet. As there are no control valves on the ducts to the mask inlets this split must be symetrical to try keep equal flow between each side.

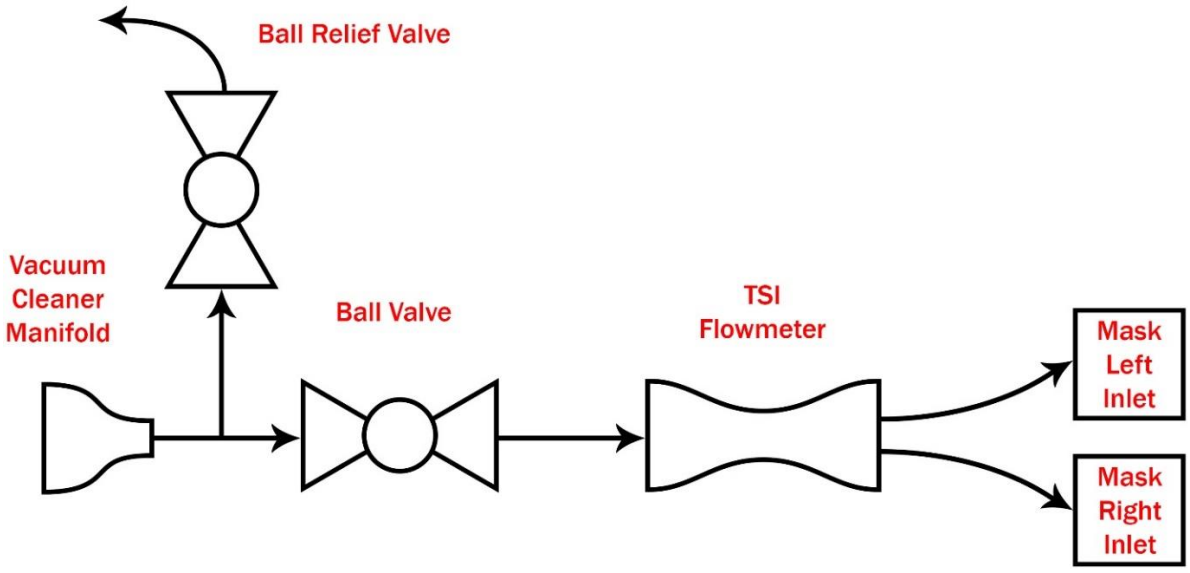


Figure B-8: Diagram of vacuum cleaner exhaust manifold as the air source

The orange vacuum cleaner included in figure B-12 below was initially attempted to be used as the vacuum source for the head model however it was old and the seals were leaking so it was unable to flow the requested 220 litres per minute. A replacement vacuum cleaner was purchased to provide this airflow source but the unforseen demand of 2 vacuum cleaners meant that the more powerful, newer vacuum cleaner was used as the higher airflow source for the mask intake and the orange one had to be rebuilt and modified to provide enough flow.

Figure B-9 shows the exhaust filter and cover from the newer vacuum cleaner that was 3D-scanned and used as a basis of an exhaust manifold design that could be inserted into the vacuum cleaner. It was painted with a white chalk pen to create more of a matte surface and had locating stickers placed on and around it to assist with 3D-scanning, the exhaust filter for this cover is visible in the background. The new manifold, as shown in figure B-10 included a removable grating with the same design as the existing cover to allow the exhaust filter to remain in. This exhaust filter, along with the filter before the airflow sensor, made sure that the air into the mask would be as clean as possible to minimize false readings from outside pollution.

Figure B-9: Exhaust cover off the vacuum cleaner being 3D-scanned

Figure B-10: Rendering of the first exhaust manifold concept showing the removable filter support

Figure B-11: Exhaust manifold prototypes with the final high-quality print at the bottom

figure B-12 below shows the completed test rig using the final vacuum cleaner exhaust-manifold airflow source, this had 2 revisions to the vacuum cleaner exhaust manifold as shown in figure B-11. The first one relied on an external T junction for the valves and the later version included the relief valve into the manifold to try reduce pressure losses to increase the flow and keep exhaust temperatures down. Unfortunately the air temperature under testing was almost 50 degrees celcius as shown by the TSI 4040G air flow meter, which was an issue as the mass flow rate of air was low for a measurable volume flow rate and the head-venturis were calibrated at ambient temperature. This affected testing results and the decision was made to find another air flow source.

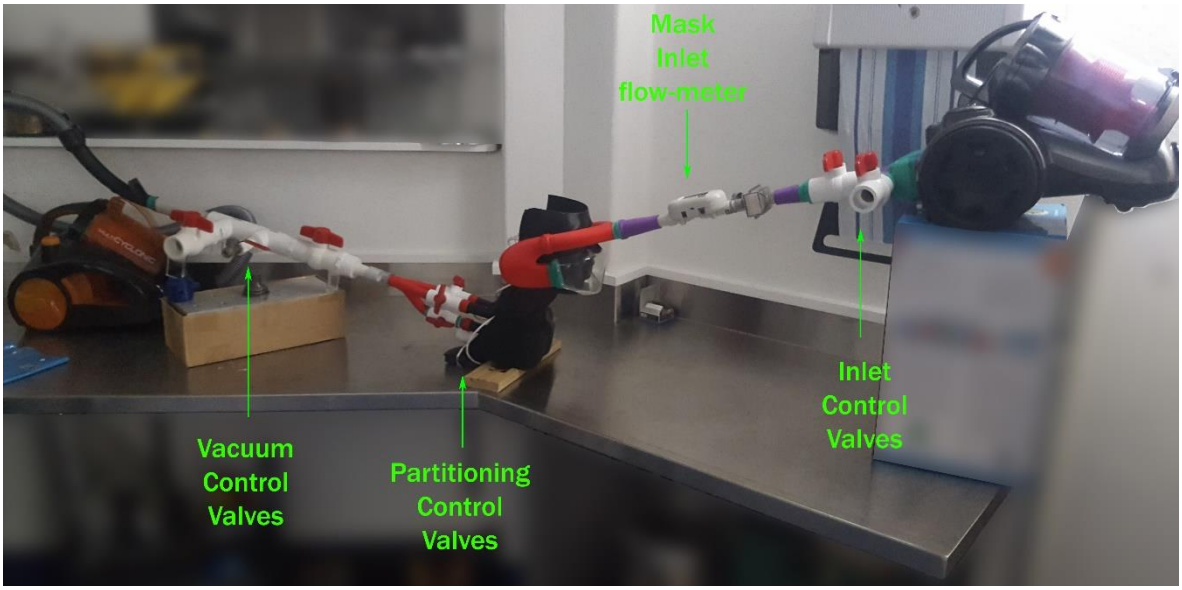


Figure B-12: Full test setup with the vacuum cleaner as the air flow source

Arduino Due Microcontroller – Head model Venturi flow meter control

An Arduino due microcontroller was used to connect and read out the Sensirion pressure sensors for the head model.

This head model had flow rates between 0 and 250 litres per minute pulled through it through the oral route which was measured using the TSI 4040G flow meter and the pressure differences noted. Due to the inconsistencies in the vacuum source and the fluctuations in the volume flow rate readout, the minimum and maximum pressures and indicated flow rates were recorded during an approximately 1-minute period which allowed the vertical and horizontal error bars to be plotted. A 6^{th} order polynomial curve was fitted using the centre-point median values as shown below in figure X, this curve went through all the data point error boxes apart from 1 data point at 100 litres per minute which was an outliner. The Nasal venturi flow meters were calibrated in a similar method, however the

pressure difference was much higher than simulated which limited their ability to measure only up to 27 litres per minute each.

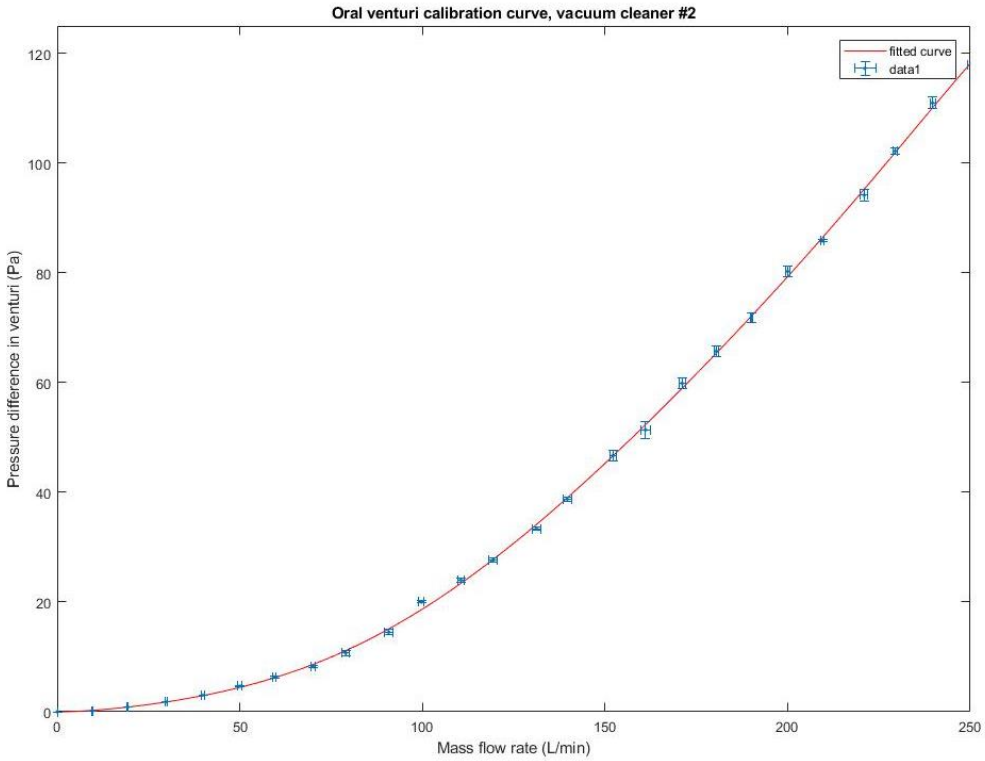


Figure B-13: Calibration curve for the mouth Venturi flow meter

Pollutant selection for testing apparatus

Volatile Organic Compounds (VOC's)

The first pollutant that was considered was a volatile organic compound. These are a family of carbon-based chemicals with low boiling temperatures. While most naturally occurring VOC's are created by plants, many non-natural VOC's exist. VOC's were of interest due to their potency meaning they can be sensed electronically in low concentrations. Disadvantages to VOC's are that most are not safe for inhalation. The best expected VOC option which is widely used around the world in candles, citronella, is listed as being extremely unsafe if inhaled and is recommended to only be used in an outdoor setting [43]. Acceptable exposure limits of typical VOC's are shown in figure B-14.

Level	Hygienic Rating	Recommendation	Exposure Limit	TVOC [ppb]
5 Unhealty	Situation not acceptable	Use only if unavoidable / Intense ventilation necessary	hours	2200 – 5500
4 Poor	Major objections	Intensified ventilation / airing necessary Search for sources	< 1 month	660 – 2200
3 Moderate	Some objections	Intensified ventilation / airing recommended Search for sources	< 12 months	220 – 660
2 Good	No relevant objections	Ventilation / airing recommended	no limit	65 – 220
1 Excellent	No objections	Target value	no limit	0 – 65

Table 2 TVOC guidelines issued by the German Federal Environmental Agency[7]

Figure B-14: VOC exposure guidelines

Menthol, while being an organic compound, has little information regarding sensing using VOC sensors, the best chance of being sensed is by using a photoionization detector (PID), a device which is used to measure most VOC's very precisely. Article [44] from Trust Science Innovation (TSI) shows response factors and minimum detectible thresholds for various compounds including Citronellal which is shown to be detectible down to 5 parts per million using TSI's precise parts per billion range of PID sensors and readable down to 100 parts per million using their parts per million range of PID sensors, both of which would require unhealthy concentrations of Citronellal when using the TVOC guidelines above. Menthol has the same chemical formula as Citronellal while having a high vapor pressure meaning it may be possible to sense using a high sensitivity PID sensor with a

sensitivity in the parts per billion range, however, these sensors from TSI are very expensive and without any other known examples of measuring Menthol with a PID VOC sensor it is unknown if this is truly possible. Due to the time and budget constraints this was too risky of an option to choose.

Menthol odour test

Menthol odour is easily distinguished, with an average threshold of identification through nasal inhalation for young persons of 0.26 ppm and for elderly persons 0.7 ppm [45]. Indicating a very low level of menthol is required for a basic binary test which could prove whether contaminants are entering mask domains or not and could be more accurate than most VOC sensors can measure, even for un-trained or elderly persons.

This odour test has the bonus of directly distinguishing the testing agent whereas VOC sensors are unable to identify individual VOC's but measure the concentration of a large range of VOC's. A highly sensitive VOC sensor may have interference in results if any other background VOC sources are present. Unfortunately, this test while being potentially very accurate for human testing, would not work with the artificial breathing head model which required electrical sensors to provide the feedback. Secondly, this test can only be a binary test as asking participants concentration levels is subjective. Finally, participants could have impairments which could limit their ability to smell menthol, these impairments could be screened for, but it is good to rely on electrical sensors which would be consistent in measuring.

Diffusion tubes

Diffusion tubes are glass tubes that change colour when a specified gas is introduced such as NO2, they can be very small, cheap to buy and are good at distinguishing certain gasses but have the disadvantage of taking hours to get any visible response, this does not suit the desired testing method which needs to be done in minutes for human testing, this would be an acceptable method for the head model which can be left running for long periods of time but results would take multiple days to compile.

Optical Particle Sensing

Optical particle sensors can measure the number of particulates in the air. They work by having a small stream of air flowing through the beam of a laser, which shines into a light trap. A photo detector can measure the light scattered off the particles and with electrical filtering is able to calculate the approximate number and size of particles in the airflow.

PM2.5 sensors are the most common standard that readout the concentration of particles with a diameter of 2.5 micro meters or below in the air. Some sensors can output the number of particles below a certain diameter, which is useful for determining the number of particles between 2 different particle sizes. If an introduced pollutant has a known particle size range, then this could be bracketed to directly count the number of pollutant particles.

The disadvantage to pollutant sensing using particle sensors is that they require airflow (typically 5 L/min) to make these readings which will require sampling a small amount of airflow from the mask domain and reduce in accuracy with the extremely small particles.

Particle sizes of possible pollutants

Consumer handheld PM2.5 sensors can be sensitive enough to read particle sizes from 0.3 microns although counting reliability decreases, so this was taken into consideration. Below is a basic comparison of the top 4 options. Candles were selected as the pollutant based off their lower health risk compared to most other options and the large variance in particle sizes meaning candles could be changed until one was found to output a desired particle size under normal combustion.

Table B-1: Overview and comparison of possible pollutants

Pollutant	Particle Size (um)	Sensibility	Health Risk
Cigarette	Average 0.2-0.25	High	High
Electronic-Cigarette	Average 0.25-0.45	Medium	Medium
Candle	Varying	High	Medium
Sea-Fog	1-50	Unknown	Unknown

Pollutants for particle sensing

Smoking: average particle size between 0.2-0.25 micro meters. One study showed second hand smoke is as small as 0.09 micro meters on average [46], too small to be accurately sensed with most particle sensors

Electronic cigarettes: average particle size 0.25-0.45 micro-meters [47]. A study was done to assess the sensibility of E-Cigarette vapor in a room [48]. Results showed that Nicotine and PM2.5 dust particles from Electronic cigarette vapours are easily distinguishable from background but VOC sensing did not work as the VOC's from Electronic cigarette smoke are small. This is backed up by a study suggesting.

Sea Fog: This has a large particle diameter of 1-50 micro-meters [49] which could be sensed well and the mainly salt-composition could be a very safe option for inhalation compared to others.

Candles: Candles output particles with extremely varying particle diameters. A study was done investigating combustion particles released during church services [50] which measured PM2.5 and PM10 concentrations, results indicated that candles are easily sensible in the desired PM2.5 and PM10 regions.

PM2.5 Particle sensor units

Particle sensors were selected with sensitivity, source-ability, cost and user feedback being key factors. The chosen particle sensor was the Plantower PMS5003 due to its low cost, good user support and reasonable sensitivity. The second option would have been the Dylos DC1100 Pro but results showed the Plantower unit having similar sensitivity at a much lower price.

Table B-2: Overview and comparison of particle sensor units

Sensor	Sensitivity	Cost	Source-ability	User Feedback
Plantower PMS3003	Medium	Low	Medium	Average
Plantower PMS5003	Medium/high	Low	High	Good
Plantower PMS7003	Medium	Low	High	Varying
Dylos DC1100 Pro	High	High	High	Excellent
Sharp GP2Y1010AU0F	Low	Low	High	Poor
Shinyei PPD42NS	Low	Low	High	Poor

Particle Sensor units

Plantower PMS3003 – This is one of the earliest models that Plantower produced with a sensible range down to particles sized 0.3 microns

Plantower PMS5003 – This is the most common Plantower sensor with sensitivity down to a particle size of 0.3 micron. This unit can be as a standalone sensor (approx. $20 USD) or with a digital screen attached showing readouts of PM1, PM2.5 and PM10 levels for $70 NZD [51] from third-party shops.

Plantower PMS7003 – The latest Plantower particle sensor, along with the earlier models this also has a sensible range to 0.3 microns. User feedback indicates that the PMS7003, while being the latest generation of PMS PM2.5 sensors, has a high deviation between individual units and the 5003 may be the more stable unit. The PMS3003 lacks in design compared to the 2 newer PMS5003 and PMS7003 sensors and constantly over-read levels.

These results were the outcome of tests of multiple units against an industry-level Beta Attenuating Monitoring (BAM) machine [52].

Dylos DC1100 Pro – This handheld particle sensor is the gold-standard for handheld particle sensors but is now no longer recommended as its accuracy can be matched by the PMS range of sensors at a fraction of the cost. Unit price $300 USD

Sharp GP2Y1010AU0F – This widely used sensor is a cheap unit but was tested to not be so precise at measuring when particle concentrations are low compared to the Dylos DC1100 Pro [53]. For this reason, it will not be chosen.

Shinyei PPD42NS - This extremely low-cost unit relies on convection from a resistive element inside the unit to heat up the air to promote airflow through the sensor around instead of using a fan. This airflow rate is relatively slow, causing a slow response time, however it could be modified to use a fan and disable the heating element. Unfortunately while one study showed it to be accurate [54], further work showed it to be inaccurate with fine particles [55]. This sensor looks to have great potential for the extremely low cost but could be a hit or miss dependent on the actual sensor and the calibration used.

Temperature / Humidity Sensors

Sensirion Humidity Sensors:

Most viable is the SHT7X series consisting of the SHT71 and SHT75 sensors [56], where the SHT75 is more precise. Both sensors feature 4 pin designs on a very small PCB which makes plugging in and mounting easy.

Other sensors exist with similar or improved accuracy (SHT35, SHT25) but are bare-chips only and require hand soldering to a PCB, mainly being designed as chips to be sold to manufacturers to be mounted in production-grade boards. Due to the low need of temperature sensors of only 2 units to measure the conditions inside and outside the mask, the chosen sensor will be the SHT75. Both SHT71 and SHT75 sensors are held by the lab so the decision comes down to accuracy and cost. The SHT75 has an accuracy of 1.8% relative humidity and +- 0.3 degrees Celsius while the SHT71 model has an increased accuracy of +- 3% relative humidity and the same +- 0.3 degrees Celsius for temperature accuracy. All the Sensirion models have the same 8 second response time (63%) for humidity while some models have a lower response time for temperature, the SHT3X series

has a temperature response time (63%) of 2 seconds while he SHT7X series has a temperature response time (63%) of 5 seconds. Considering the availability, ease of install and not critical spatial constraint, the SHT7X series will still be the better option.

Fast Response Humidity sensors

Standalone fast response humidity sensors are available whereas the capacitance varies with humidity. An external control circuit is required to convert this to the desired humidity value.

EPulse HC103M2 [57]– Very small 6mm x 2.5mm sensor, 2 wire (needs to be soldered on pad) stated to have a sub-3 second response time at 23 degrees Celsius, this response time can be reduced with forced airflow.

Adafruit HTU21D(F) [58]- Low cost ($16 USD), relatively fast response time 5s min- 10s max, not very compact. Common board for hobbyists.

Thin-wire thermocouples:

Thermocouples can be used to measure temperature, they consist of 2 different metals joined together to form a junction which generates a small electromotive force (EMF) which can be measured using a sensitive voltmeter. This EMF value varies dependent on the temperature of the junction and can be calibrated for to measure a range of temperatures. Different metal selections, or junction types, change the temperature range of the thermocouple. The required measuring range is between approximately 10 to 40 degrees Celsius which is very low compared to most types of thermocouple which measure in the hundreds of degrees.

Temperature can be measured with a fast response time if thin-wire thermocouples are use. The thinner the thermocouple junction is, the lower the thermal mass of the junction is and the faster it can reach equilibrium. Therefore, the fastest response thermocouple will likely be the one with the smallest junction. Manufacturer, Omega, make a wide range of thermocouples and sell basic thin-wire thermocouples [59] of differing materials and junction types.

Un-sheathed thin-wire thermocouples

R and S Type thermocouples can be bought in 0.001 inch / 0.025mm junctions which have response times of 0.05 seconds in still air and 0.004 seconds in fast moving (65+km/h) air. R/S thermocouples are limited to 150mm lengths, price $42 USD per thermocouple

Other J/T/K/E thermocouples can be bought in 0.002 / 0.05mm junctions, interpolating this gives a response time of 0.16 seconds in still air. Lengths are 300mm and pricing for a 5 pack is $47 USD

Insulated thin-wire thermocouples

Insulated wire thermocouples with exposed junctions are available for purchase although these have thicker wire and the smallest wire size is 0.08mm. Calculating the response time based off area and the graph this gives a response time of 0.4 seconds in still air.

While this response time is not as low as the unsheathed thin wire thermocouple, it may be the better option due to being pre-sheathed to avoid damage and coming in long 1m or 2m lengths instead of 150mm lengths. An Omega 5TC-TT-T-40-72 thermocouple is a T type thermocouple with a 0.08mm junction.

CO2 Sensors

It was found that most consumer grade CO2 sensors available for purchase were relatively slow in response time compared to clinical Capnograph machines which can have response times of 50-600ms [60], the ideal CO2 sensor was to have a very fast response time that was able to measure the waveform of CO2 in inhaled and exhaled breathing which would help better understand the differences of CO2 levels in each of the masks.

Fast response time CO2 sensors required air to be pumped over them and were typically a bit larger in size. An advantage of this pumping of airflow is that the sensors could be mounted outside the mask which reduced the amount of volume the sensors needed inside the masks. The top 5 CO2 sensors are listed below for comparison. CO2 sensors were investigated looking for small form factor, fast response time and low cost as the main factors.

K-30 [61] – This is an OEM sensor with a measuring range of 0-10,000 parts per million, about 1% exhaled CO2. It is relatively fast with samples read twice per second (2Hz) and it

has a 2 second 90% response time. It is required for air to be pumped through it at 0.5 litres per minute. Pricing is $275 for an evaluation kit.

Gas Sensing Solutions (GSS) SprintIR [62]– 20Hz sensor with 0-20% and 0-100% CO2 sensing. Pricing is approximately $155. Dimensions are large being 45mm long, 25mm wide and 21mm high.

SprintIR6s [63]– This is an evolution of the SprintIR sensor which has a lower sampling volume to increase response time. Response time at lower flow rates (0.1L/min) is 2 seconds while this decreases to less than 0.5 seconds at a 0.5L/min flow rate. This sensor was just becoming available on the market at the time of selection and required some waiting for stock to become available. Pricing was the highest of the 5 options presented with the bare sensor being £220.00 and an evaluation kit including a USB cable and software to allow logging of results to a computer. It is also one of the smallest CO2 sensor packages with a cylindrical shape 23.8mm in diameter and 24mm high.

MiniIR sensor [64] – This sensor was considered for its very small cylindrical form but a very slow 10s response time made it not practical for use.

SGX Sensortech IR11BR [65] – Small form factor, 19mm high, 20mm diameter and cylindrical, 0-100% CO2 measurement, $250 NZD, slow response time of 20s (T90, maximum)

Blood-Oxygen Concentration measurement

Measurable methods

Arterial Blood Gas (ABG) analysis – This method is often used in hospitals and involves sampling a small volume of blood from a patient's artery using a syringe or an arterial catheter. The blood is then analysed with a blood gas analyser which measures the partial pressure of oxygen (pO2) and can calculate oxygen saturation (SaO2) [66]

CO-Oximeter – This is the most accurate method of sensing saturated oxygen levels [66] and is done in hospitals as like the arterial blood gas analysis, it is invasive. It uses multiple waveforms of light to analyse a blood sample to measure various forms of haemoglobin. It can then use these results to estimate arterial oxygen saturation levels [66].

Pulse Oximeter – This is a non-invasive method measures Peripheral Capillary Oxygen Saturation (SpO2) levels by emitting 2 waveforms of light and measuring the absorption to estimate the number of oxygen-saturated and unsaturated haemoglobin in the blood, as the 2 waveforms are absorbed differently by oxygen saturated and unsaturated blood. The peripheral capillary oxygen saturation is then calculated for as the percentage of saturated haemoglobin in the blood. In individuals with no underlying health conditions, this can be a relatively good indicator at estimating the arterial oxygen saturation levels (SaO2) [67].

Pulse oximeters Selection

Pulse oximeters are widely available in many forms in which a few options were considered as suitable methods for the test apparatus.

Portable Sensors

Portable sensors included standalone finger mounted units which can log data to an SD card or streamed data to a mobile phone via Bluetooth and wrist mounted units with a graphical display that can display and log levels (with a small finger mounted sensor)

Wired sensors

Wired sensors included large desk-mounted setups such as the ETCO2/SpO2 Monitor unit in the Bio Design Lab which had the advantages of having the finger mounted sensor on a long cable back to the processing unit which could log, display and output data via an RS232 connection but were very big and heavy for transporting and reading this signal via RS232 could be problematic.

Wired sensors that were Arduino-compatible were favourable for the streamline package that they could offer, integrating into the sensor data collection package, logging both oxygen saturation levels and pulse and displaying this data along with the other sensors on a display. The best option was a Protocentral AFE4490 Oximeter which included all basic code to run and a GUI application for graphing the data real-time. Other features of this oximeter are that the package is very small and could be portable if need be.

Raw sensors (standalone chips)

Raw sensors were cheap as they are OEM chips that are meant for producers looking to integrate pulse oximetry into their products, but these required too much work to get

running and calibrated. For the ease of use and the small quantity of sensor packages required, it was chosen to save time and go for a ready-made package.

Oxygen Sensors

Medical Grade

PM1116 [68] – This was a second hand ex-hospital oxygen measuring unit found for sale. It was a hospital-grade standalone oxygen measuring unit with a very fast response time of 0.35 to 0.77 seconds dependent on the airflow rate into the unit which was variable due to a variable speed pump. Varying the pump changed the airflow from between 100 to 200 millilitres of air per minute. The second-hand price of this unit was $276 but it had an unknown brand-new price due the limited market meaning pricing was not readily available. The downsides to this unit are that being a standalone unit, it won't integrate into the Arduino system desired along with the other sensors, that it requires very conditioned air that has a low humidity, that the air must be filtered for particles to keep particle sizes under 3 micron and it must be placed in a location with low vibration and movement.

Diving Rebreathing oxygen Sensors

Canister style electro-galvanic oxygen sensors are widely used in diving rebreathing setups where accurate oxygen level monitoring is required. These are cylindrical shaped sensors that are screwed into airflow tubes or ducts, a small amount of air passes through the sensor which has a galvanic fuel cell inside, commonly consisting of lead. This fuel cell reacts with oxygen in the air and outputs a current at a set voltage, dependent on the materials of the fuel cell. Oxygen levels can then be calibrated dependent on the current output of the sensor. Due to the chemical nature, these sensors degrade over time dependent on the levels oxygen they are exposed to until the fuel cell is completely oxidized but they are recommended to be replaced after one year of use due to the current output changing over the lifetime.

R33S1 [69] - This is a popular sensor for rebreathing setups. It has a slow, 6 second response time. One end of the cylinder is threaded for installing into an airflow source and the other has an electrical connector on it. Accuracy is specified to be 2% of full scale.

PSR-11-917-MH1 [70] - This was the fastest galvanic-type rebreathing sensor that could be sourced with a short response time of 4 seconds while retaining a full-scale accuracy of 2%. The cheapest pricing was approximately $120

O2-G2 [71]– This was the smallest galvanic oxygen sensor that could be sourced with a 20mm diameter and only 10mm in height. While the size was extremely small for a galvanic sensor, the response time was very slow, 15 seconds to measure a 90% change. This slow response time was expected to be due to the small size making the fuel cell smaller, reducing the surface area in contact with oxygen. It was very cheap with pricing starting from $50.

AO2 [72] – This sensor was a balance between a small size, fast response time and low cost with a 29.3mm diameter and being 31.75mm high. Response time (t90) was specified to be 5 seconds, just 1 second slower than the fastest galvanic sensor. Pricing was very cheap with the cheapest listing price of $57

Poseidon 6011-063 Solid State Oxygen sensor - This smaller canister sensor is designed to be a drop-in replacement for conventional galvanic oxygen sensors used in diving rebreathers. It operates using a different technique to measure oxygen, illuminating dyes inside the sensor with red light and measuring the oxygen dependent near-infrared light response given off by these dyes. It boasts a faster response time compared to conventional rebreather sensors, lower power usage and smaller form factor. Unfortunately, this sensor has only just been released and full specifications regarding response time and accuracy are not available. Due to the extremely high pricing of this sensor and the un-released full specifications it was not selected as a viable option but could be an excellent choice for future work once specifications are released.

CO2 sensor housing design

The CO2 sensor required 0.5 to 1 litre per minute of airflow through it to have a fast response time. A restriction was put in the pipe with 2 openings either side of this to partition flow and allow a route through the CO2 sensor. This restriction was simulated using Ansys fluent to check how much flow was being partitioned through the CO2 sensor for a 5 litre per minute volume flow rate. While no data was available from the manufacturer regarding the pressure loss through the sensor, it was simplified to a small constriction in the bypass tube that went around the pipe restriction. CFD Results showed that for a 5 Litre per minute airflow rate the CO2 sensor would have a flow rate of approximately 0.7 litres per minute for the given constriction which is perfectly in the acceptable range.

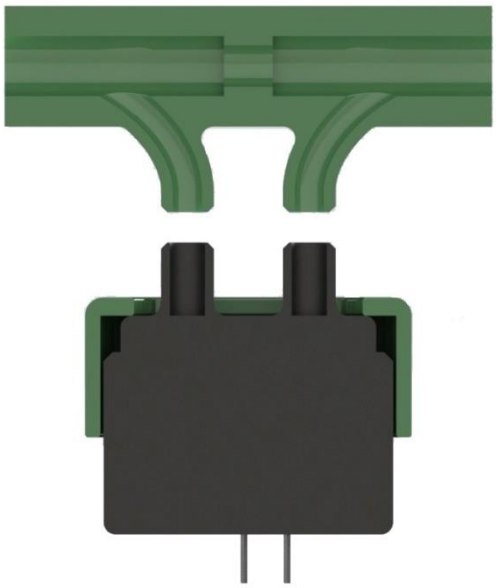


Figure B-15: Section showing CO2 sensor and pipe restrictor

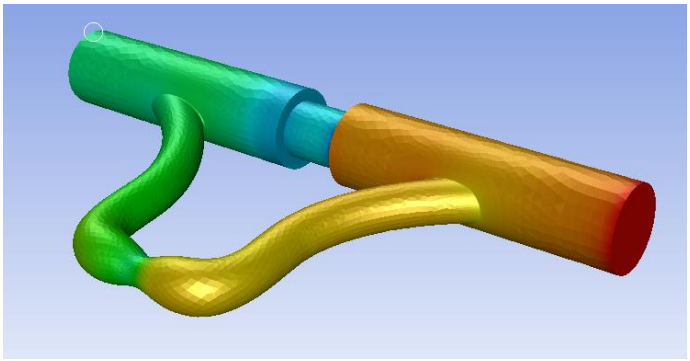


Figure B-16: Bypass restrictor simulated in Ansys Fluent (contours of static pressure shown)

Particle Sensor Manifold CFD Simulation

The particle sensor was sensitive to changes in the airflow rate which meant that the pressure at the intake of the particle sensor needed to be at atmospheric pressure to keep the flow rate close to the calibrated flow rate, the manufacturer was unable to provide flow rate data for the sensor but similar sensors had a flow rate of 5 litres per minute so this was assumed to be similar. A simulation of the tube with the Oxygen sensor, CO2 sensor and 400mm long sampling tube was done in Ansys Fluent to unserstand the static pressure loss between the mask and the sensor intake. Simulations showed that the pressure drop between the particle sensor intake and the end of the tube in the mask was approximately 100 Pascals for a 5 litre per minute flow rate. This pressure drop was offset by using 2 Sunon GM0501PFV1-8 fans, used in a series configuration where the static pressure increases would add. These fans could supply a 67 pascal static pressure each at the desired flow rate of 5 litres per minute and had a small size of 20mm wide and high and 10mm thick which perfectly fits in line with the 20mm thick particle sensor.

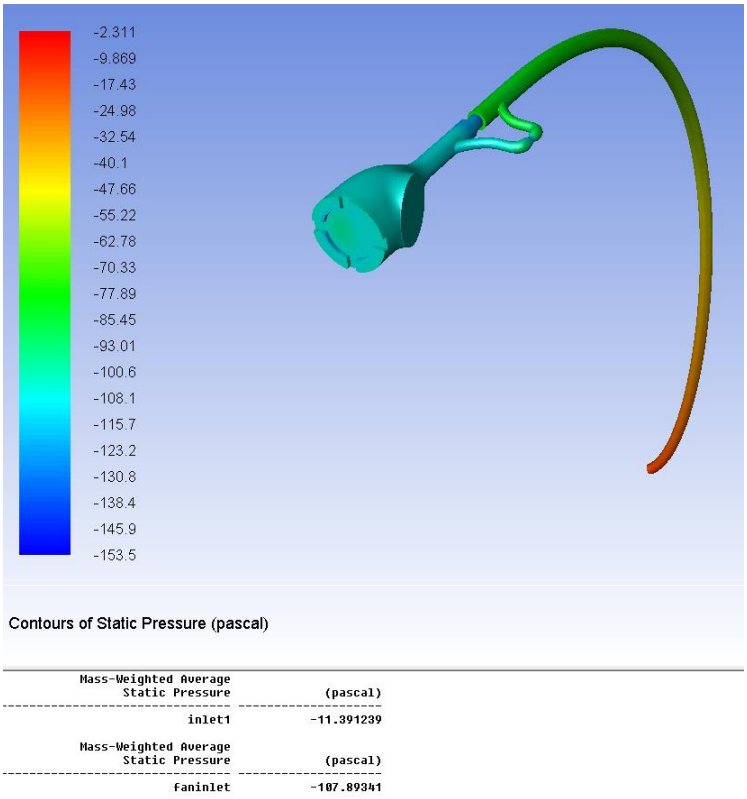


Figure B-17: Pressure contours showing pressure drop through the manifold and tube of approximately 100 pascals

Arduino Mega Microcontroller – Sensor package detail.

An Arduino Mega was used to interface the sensors and output a line of data containing measurements from all the sensors. Each sensor output a data value separated by a comma which could then be read using the development program, Processing, and finally logged to a file. This data could be seen real time using the Arduino IDE serial monitor while simultaneously being read and logged to a file using the development program, Processing. All Arduino code and Processing code is included at the end of the appendix section due to the large amount of code.

A breakout board was needed as most sensors could not be directly plugged in, such as the SDP610 pressure sensor which required a MOSFET voltage level shifter to 3.3V from the Arduino Mega's 5V or the Oxygen sensor which needed an amplifier to amplify the small voltage output to be read by one of the Arduino Mega's analog inputs.

Pictures of parts after 3D-printing

Figure B-18: 3D-Printed ducting showing sensor placement

Figure B-19: 3D-printed head parts

Appendix C – Synthetic head results

Table C-1: Physical testing - Leakage / bias flow results

Inlet Flow	Mouth flow	Ambient PM1.0	Ambient PM2.5	Ambient PM10	Mask PM1.0	Mask PM2.5	Mask PM10
157	128	82	122	142	12	14	14
	122	91	140	159	12	15	15
	116	83	123	140	5	5	5
	103	**92**	**137**	**158**	**2**	**3**	**3**
140	101	142	265	317	15	21	22
	95	145	231	268	6	7	7
	90	141	237	293	5	6	6
	89	**154**	**215**	**248**	**3**	**3**	**3**
120	90	153	216	239	11	12	12
	85	151	204	219	5	6	6
	8	151	198	215	4	5	5
	75	**159**	**203**	**218**	**3**	**3**	**3**
103	80	140	175	180	11	12	12
	75	146	181	189	5	6	6
	70	131	159	169	3	4	4
	65	**130**	**156**	**164**	**2**	**2**	**2**
80	65	129	155	161	11	12	12
	61	136	162	165	8	8	8
	55	**141**	**167**	**175**	**3**	**3**	**3**
60	46	150	182	190	17	18	18
	40	157	193	199	7	7	7
	38	164	193	199	4	4	5
	35	**159**	**194**	**195**	**2**	**2**	**2**

Appendix D – Human testing results

Borg Rating of Perceived Exertion

The Borg Rating of Perceived Exertion (RPE) is a method that can be used to measure exercise intensity.

It involves self-identifying perceived physical exertion on an offset scale between 6 to 20 where 6 correlates to no exertion and 20 correlates to the maximum exertion possible. A rating of 10-12 on the Borg scale is regarded as a good indicator of moderate exercise. A correlation exists between the borg scale and heart rate where heart rate can be approximated based on multiplying a perceived exertion level by 10. Table E-1 shows the Borg scale

Table E-1: Borg rating of perceived exertion (RPE)

Borg Rating	Perceived Level of exertion
6	No exertion at all
7	
7.5	Extremely light
8	
9	Very light
10	
11	Light
12	
13	Somewhat hard
14	
15	Hard (heavy)
16	
17	Very hard
18	
19	Extremely hard
20	Maximal exertion

Equipment setup

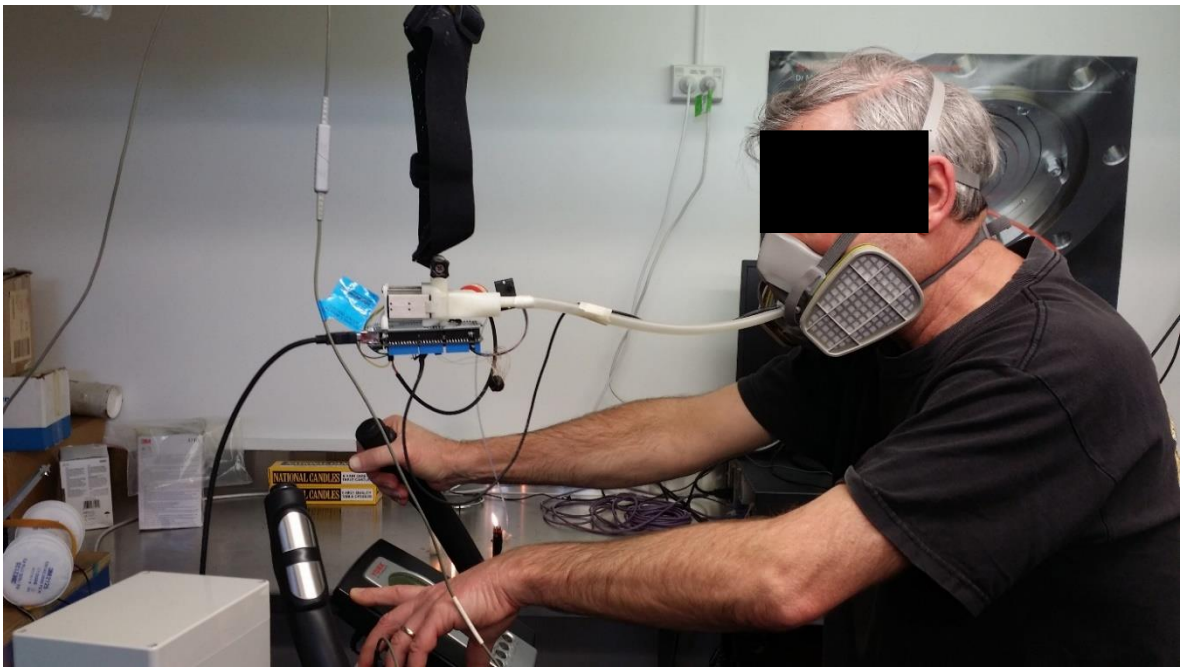


Figure C-1: Participant undertaking test showing face mask sensor array and sampling tube.

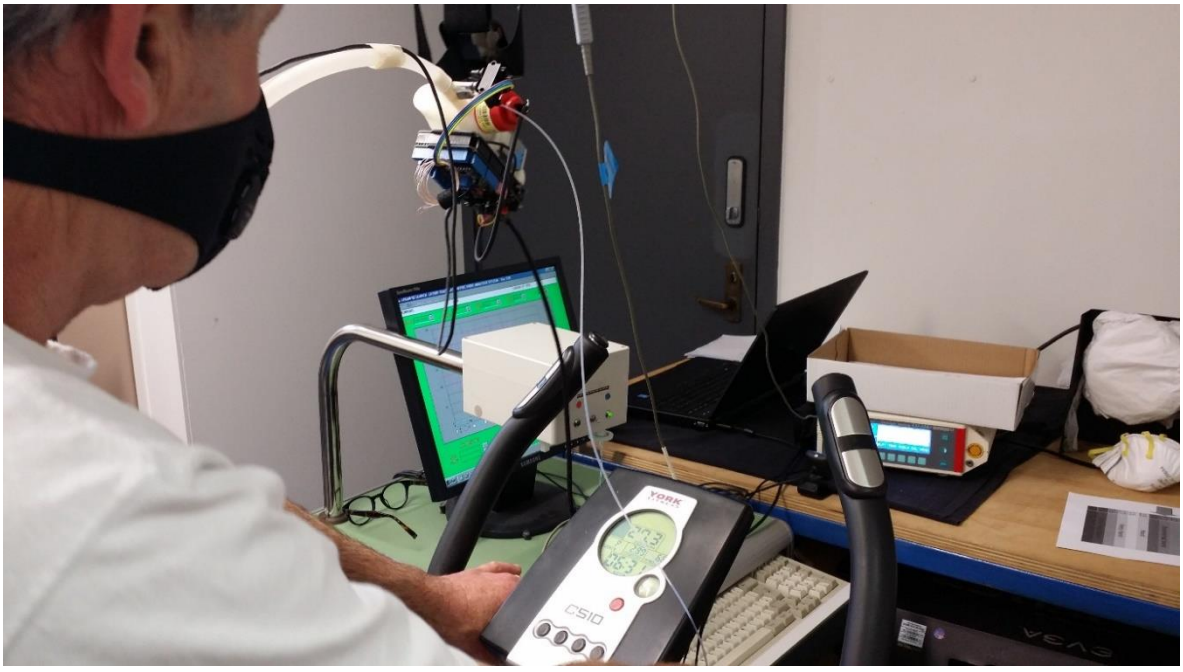


Figure C-2: Equipment set up showing testing within controlled environment.

Particle Results unshown in main body

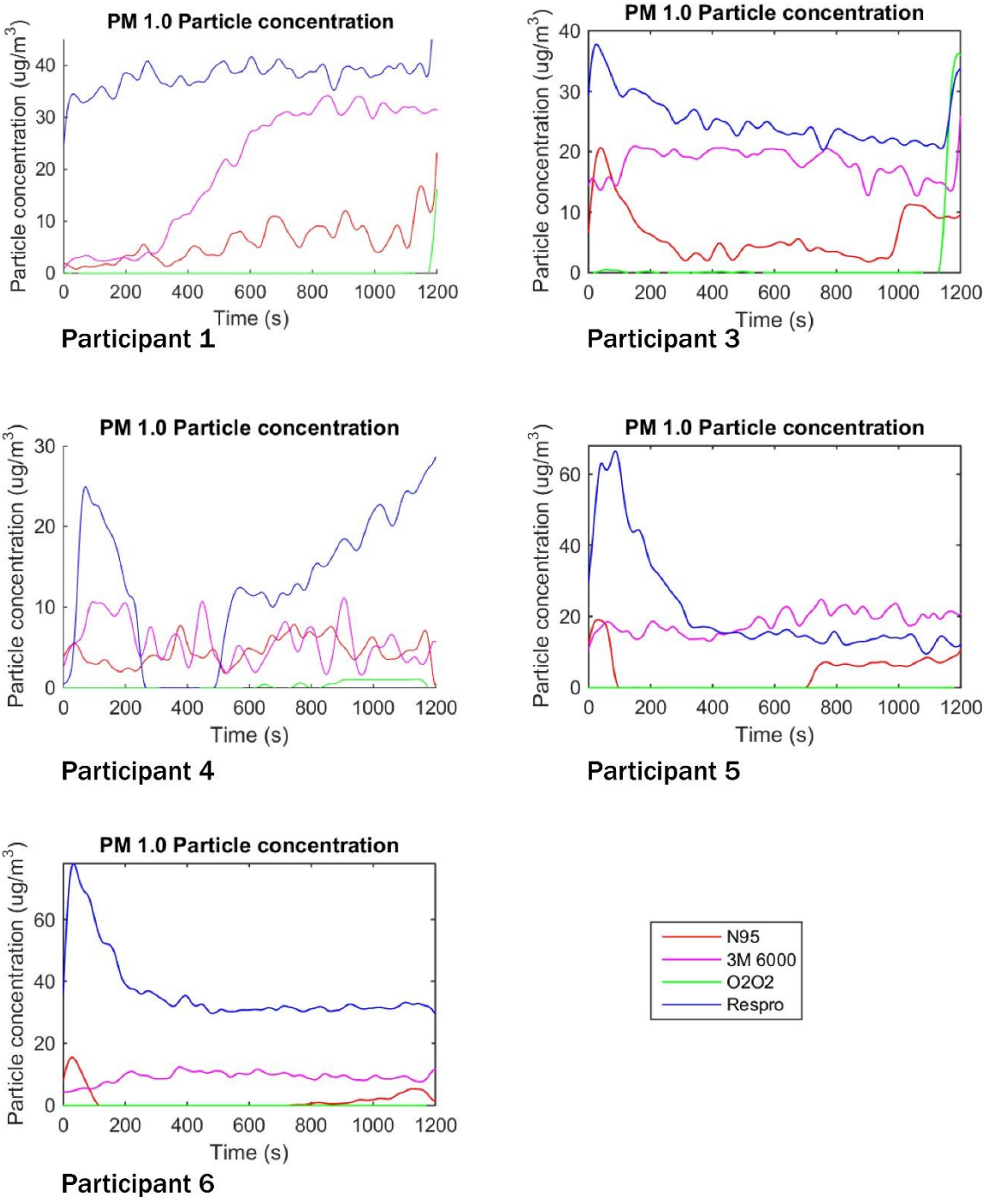


Figure C-3: PM1 concentrations inside masks during testing

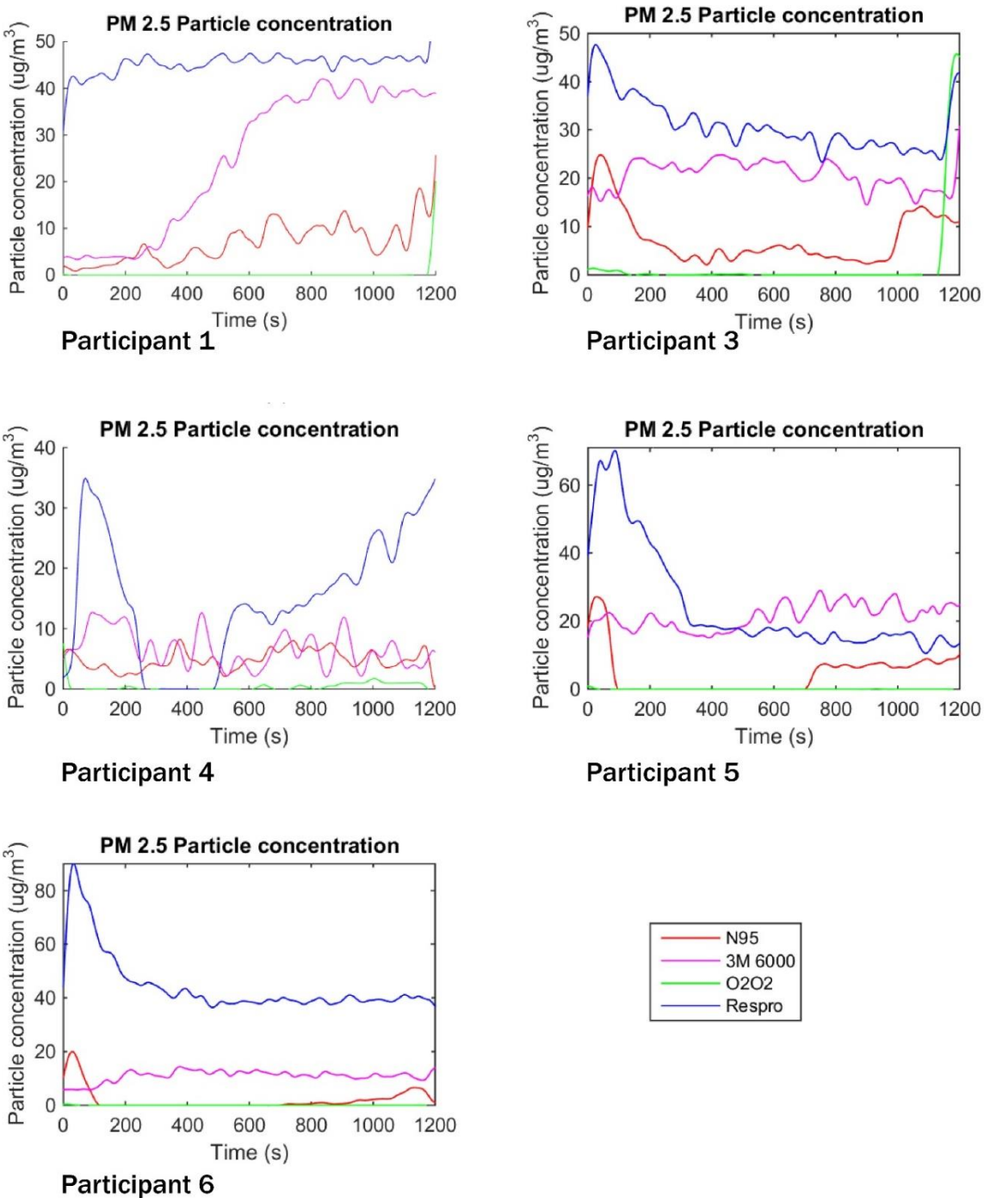


Figure C-4: PM10 concentrations inside masks during testing

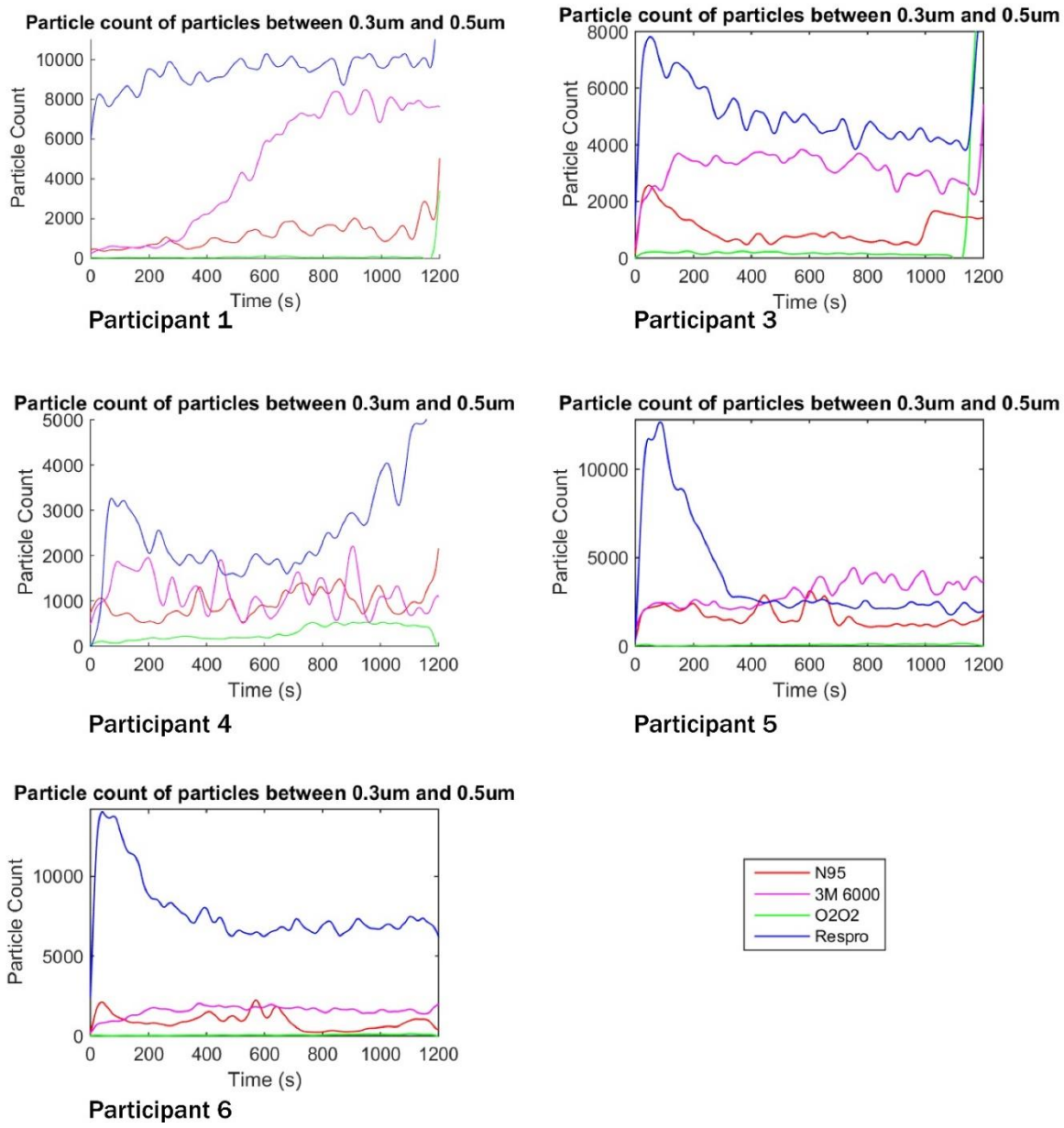


Figure C-5: Number of particles counted between 0.3um and 0.5um inside masks during testing

Images of markings on participants Post-testing

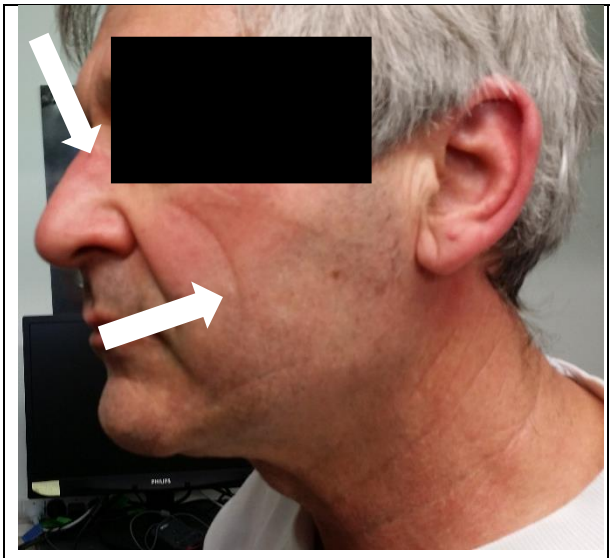


Figure C-6-A: Marking from Respro face mask

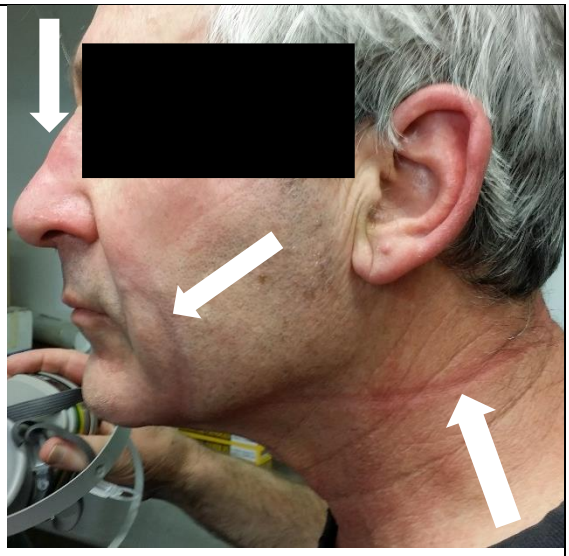


Figure C-6-B: Marking from 3M 600 face mask

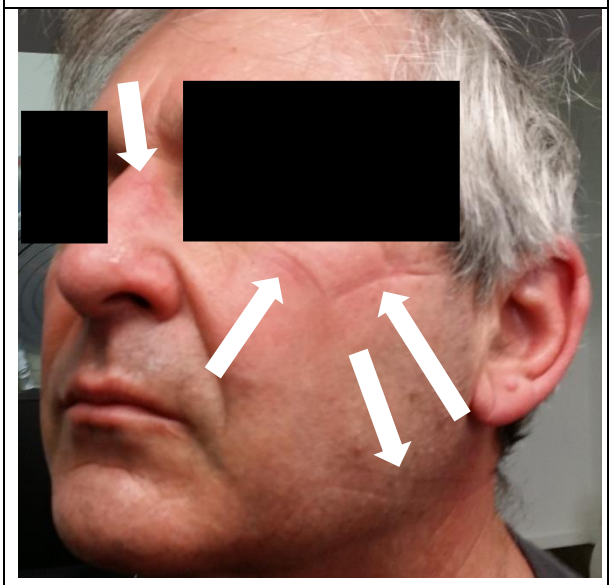


Figure C-6-C: Marking from 3M N95 face mask

Image not available

Figure C-6-D: Marking from O2O2 facemask

Figure C-6: Images of Participant 1 face marking immediately after testing

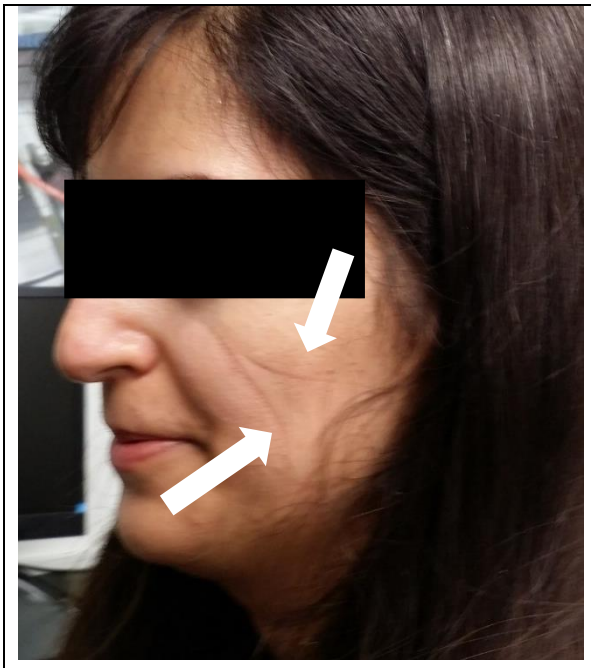


Figure C-7-A: Immediately after test wearing Respro face mask.

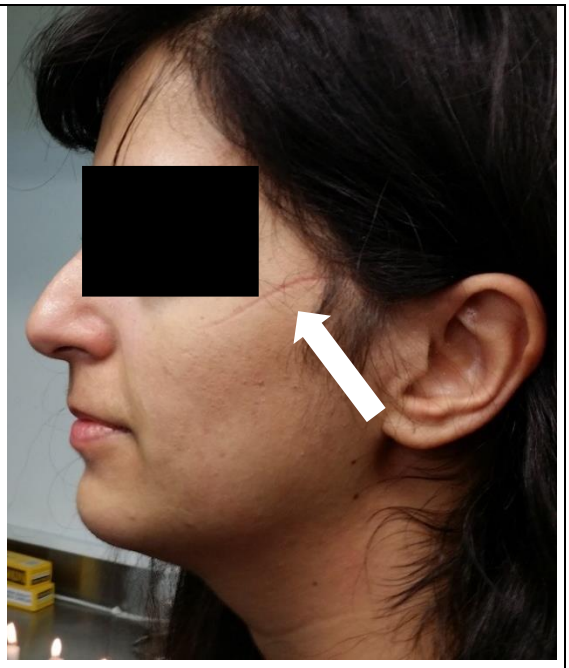


Figure C-7-B Immediately after test wearing 3M 6000 face mask.

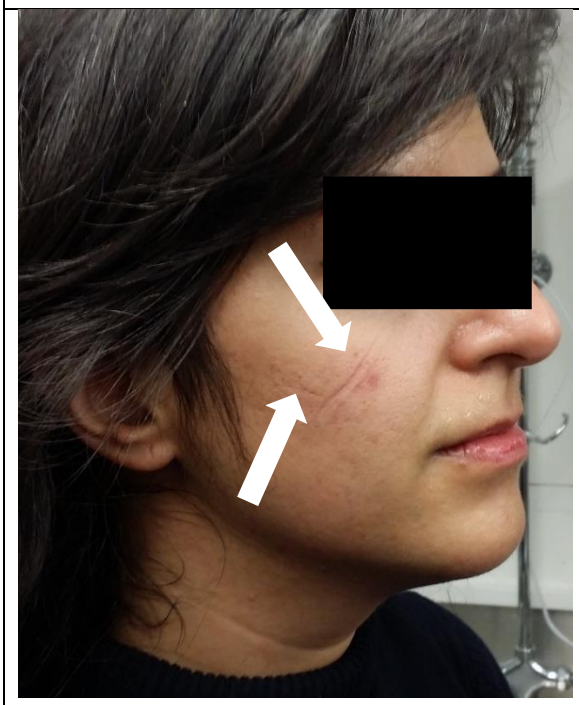


Figure C-7-C: Immediately after test wearing N95 face mask.

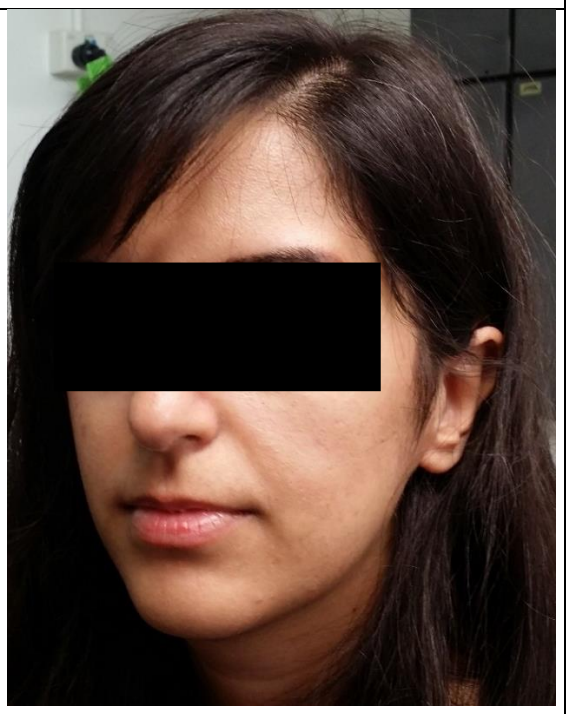


Figure C-7-D: Immediately after test wearing o2o2 face mask.

Figure C-7: Images of Participant 4 face marking immediately after testing

Figure C-8-A: Immediately after test wearing Respro face mask.

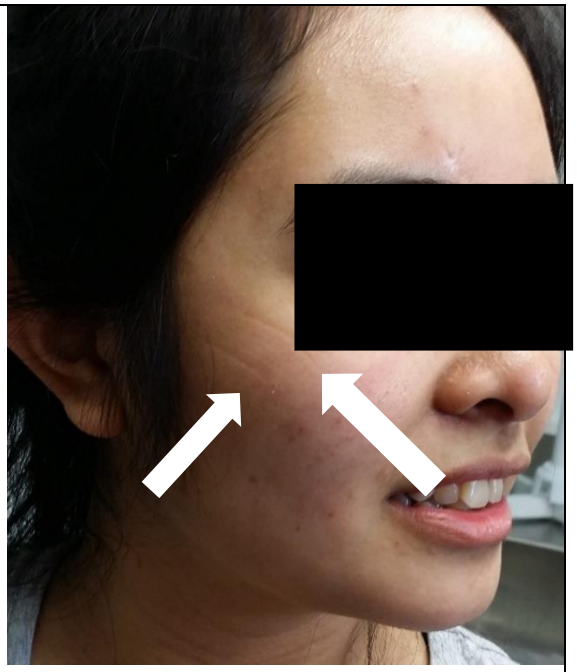


Figure C-8-B: Immediately after test wearing 3M 6000 face mask.

Figure C-8-C: Immediately after test wearing N95 face mask.

Figure C-8-D: Immediately after test wearing O2O2 face mask.

Figure C-8: Images of Participant 5 face marking immediately after testing

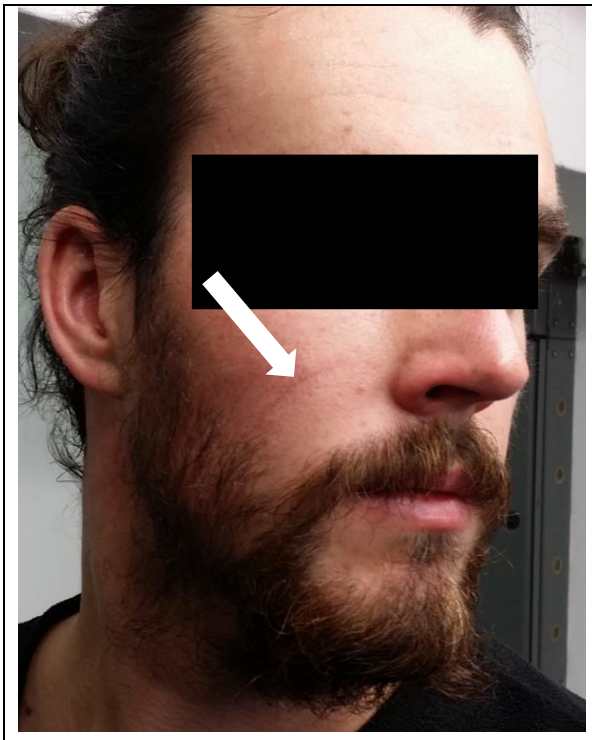


Figure C-9-A: Immediately after test wearing Respro face mask.

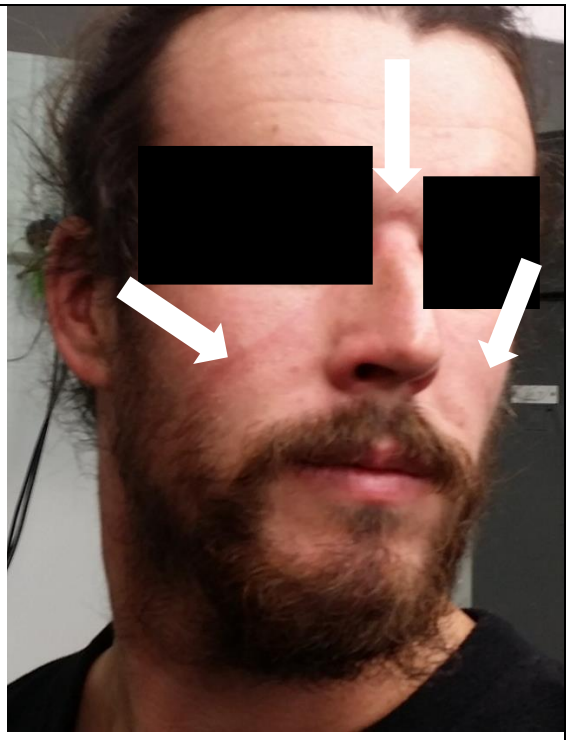


Figure C-9-B: Immediately after test wearing 3M 6000 face mask.

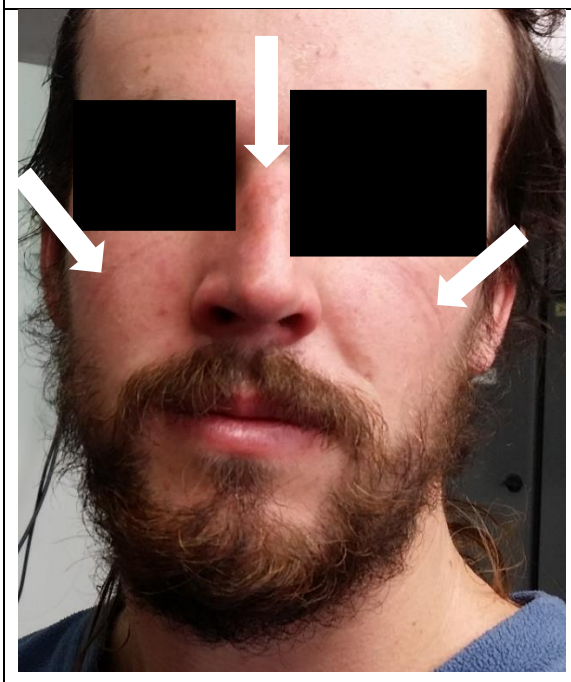


Figure C-9-C: Immediately after test wearing N95 face mask.

Image not available

Figure C-9-D: Immediately after test wearing O2O2 face mask.

Figure C-9: Images of Participant 6 face immediately after testing

Appendix E – Arduino Code

The following code is used to run the Arduino Mega sensor package:

```
//Particle Sensor
long pmcf10=0;
long pmcf25=0;
long pmcf100=0;
long pmat10=0;
long pmat25=0;
long pmat100=0;
long pmat03=0;
long pmat05=0;
long pmatdp=0;
char buf[50];

//Sensirion Temp/Humidy Sensor
#include <Sensirion.h>
const uint8_t dataPin  =  3;
const uint8_t clockPin =  2;
float temperature;
float humidity;
float dewpoint;
Sensirion tempSensor = Sensirion(dataPin, clockPin);

void setup() {

  //Particle Sensor
  Serial1.begin(9600);
  Serial.begin(9600);
  Serial.println( "PM1.0, PM2.5, PM10.0, PC0.3+ , PC0.5+, PC0.3-0.5, SR Temp,
Humidity, DP temp    ");

}


void loop()
{
  //Particle Sensor
  int count = 0;
  unsigned char c;
  unsigned char high;
  int fail1 = 0;
  int fail2 = 0;

  while (Serial1.available()) {
    c = Serial1.read();
```

```
    if((count==0 && c!=0x42) || (count==1 && c!=0x4d)){
      fail1 = 1;
      break;
    }
    if(count > 19){
      break;

    }
    else if(count == 4 || count == 6 || count == 8 || count == 10 || count == 12 || count ==
14 || count == 16 || count == 18)
    {
      high = c;
    }
    else if(count == 5){
      pmcf10 = 256*high + c;
      //delay(2);
    }
    else if(count == 7){
      pmcf25 = 256*high + c;
      //delay(2);
    }
    else if(count == 9){
      pmcf100 = 256*high + c;
      //delay(2);
    }
    else if(count == 11){
      pmat10 = 256*high + c;
      //delay(2);
    }
    else if(count == 13){
      pmat25 = 256*high + c;
      //delay(2);
    }
    else if(count == 15){
      pmat100 = 256*high + c;
      //delay(2);
    }
    else if(count == 17){
      pmat03 = 256*high + c;
      //delay(2);
    }
    else if(count == 19){
      pmat05 = 256*high + c;
      //delay(2);
       pmatdp = pmat03 - pmat05;
      //delay(2);
      break;
    }
```

```
   count++;
  }
  while(Serial1.available()) Serial1.read();

  int count2 = 0;
  unsigned char c2;
  unsigned char high2;



 //Sensirion temp/humidity sensor
 tempSensor.measure(&temperature, &humidity, &dewpoint);

   if (fail1 == 0)   //Display if all sensors are error free
  {
      Serial.print(pmat10);
      Serial.print(", ");
      Serial.print(pmat25);
      Serial.print(", ");
      Serial.print(pmat100);
      Serial.print(", ");
      Serial.print(pmat03);
      Serial.print(", ");
      Serial.print(pmat05);
      Serial.print(", ");
      Serial.print(pmatdp);
      Serial.print(", ");
      Serial.print( (((4.96000*analogReading/adc.getMaxPossibleReading())-2.0511) /
0.9116 )*100);
      Serial.print(", ");
      Serial.print(max.readThermocoupleTemperature());
      Serial.print(", ");
      Serial.print(temperature);
      Serial.print(", ");
      Serial.print(humidity);
      Serial.print(", ");
      Serial.print(dewpoint);
      Serial.println();
      Serial.print(difPressure);
     Serial.println();

  }

  delay(200);
}
```

The following code is used in the head model to read pressure from the Sensirion pressure sensors and output the mass flow. A 6th order polynomial curve is inverse solved to find the oral mass flow using the bisection root finding method. The code below solves for the oral route with the nasal measurements turned off.

```
/**********************************************************************
 * ReadSDP6x
 * Reads SDP6x sensor using SDP6x class
 * Class.Function(Scale factor, I2C address)
 * SDP6x.GetPressureDiff(Scale factor, I2C address)
 *
 *  Scale factor 240 for 125Pa sensor
 *  Scale factor 60 for 500Pa sensor
 **********************************************************************/

#include <Wire.h>
#include "SDP6x.h"

float difPressure1;
float difPressure2;
float difPressure3;

float Pc;
float Pc1;
float Pc2;
float p1 =-0.02218;
float p2 = 0.3062;
float p3 = 0.1582;
float p4 =-1.277;
float p5 = 11.31;
float p6 = 36.65;
float p7 = 27.02;

float p12 =2.185e-09;
float p22 = -2.205e-07;
float p32 =8.749e-06;
float p42 =-0.0002206;
float p52 = 0.003095;
float p62 = 0.02865;
float p72 =-0.1337;
float p82 = 0.02782;


const int numReadings = 100;

int readings1[numReadings];      // the readings from the analog input
```

```
int readings2[numReadings];
int readings3[numReadings];
int readIndex = 0;              // the index of the current reading
float total1 = 0;               // the running total
float total2 = 0;
float total3 = 0;
float average1 = 0.00000;               // the average
float average2 = 0.00000;
float average3 = 0.00000;

//Particle Sensor
long pmcf10=0;
long pmcf25=0;
long pmcf100=0;
long pmat10=0;
long pmat25=0;
long pmat100=0;
long pmat03=0;
long pmat05=0;
long pmatdp=0;
char buf[50];

void setup()
{
  Wire.begin();
  Serial.begin(9600);
  Serial1.begin(9600);
  difPressure1 = 0.0;
  difPressure2= 0.0;
  difPressure3= 0.0;

  // initialize all the readings to 0:
  for (int thisReading = 0; thisReading < numReadings; thisReading++) {
      readings1[thisReading] = 0;
      readings2[thisReading] = 0;
      readings3[thisReading] = 0;
  }

}

void loop()
{
 //Particle Sensor
  int count = 0;
  unsigned char c;
  unsigned char high;
  int fail1 = 0;
  int fail2 = 0;
```

```
  while (Serial1.available()) {
    c = Serial1.read();
    if((count==0 && c!=0x42) || (count==1 && c!=0x4d)){
      fail1 = 1;
      break;
    }
    if(count > 19){
      break;

    }
    else if(count == 4 || count == 6 || count == 8 || count == 10 || count == 12 || count ==
14 || count == 16 || count == 18)
    {
      high = c;
    }
    else if(count == 5){
      pmcf10 = 256*high + c;
      //delay(2);
    }
    else if(count == 7){
      pmcf25 = 256*high + c;
      //delay(2);
    }
    else if(count == 9){
      pmcf100 = 256*high + c;
      //delay(2);
    }
    else if(count == 11){
      pmat10 = 256*high + c;
      //delay(2);
    }
    else if(count == 13){
      pmat25 = 256*high + c;
      //delay(2);
    }
    else if(count == 15){
      pmat100 = 256*high + c;
      //delay(2);
    }
    else if(count == 17){
      pmat03 = 256*high + c;
      //delay(2);
    }
    else if(count == 19){
      pmat05 = 256*high + c;
      //delay(2);
       pmatdp = pmat03 - pmat05;
```

```
    //delay(2);
    break;
   }
  count++;
 }
 while(Serial1.available()) Serial1.read();

 int count2 = 0;
 unsigned char c2;
 unsigned char high2;

//Pressure Sensors
//Read Pressure,       scaling factors:1200-25Pa, 240-125Pa,60-500Pa
 difPressure1 = SDP6x.GetPressureDiff(240.0,0x21);
 //difPressure1 = 1;
 //difPressure2 = SDP6x.GetPressureDiff(1200.0,0x22);
 difPressure2 = 0;
 //difPressure3 = SDP6x.GetPressureDiff(1200.0,0x23);
 difPressure3 = 0;
 //Make sure pressure is positive
 difPressure1 = abs(difPressure1);
 difPressure2 = abs(difPressure2);
 difPressure3 = abs(difPressure3);

 // subtract the last reading:
 total1 = total1 - readings1[readIndex];
 total2 = total2 - readings2[readIndex];
 total3 = total3 - readings3[readIndex];

 // read from the sensor:
 readings1[readIndex] = difPressure1;
 readings2[readIndex] = difPressure2;
 readings3[readIndex] = difPressure3;


 // add the reading to the total:
 total1 = total1 + readings1[readIndex];
 total2 = total2 + readings2[readIndex];
 total3 = total3 + readings3[readIndex];

 // advance to the next position in the array:
 readIndex = readIndex + 1;

 // if we're at the end of the array...
 if (readIndex >= numReadings) {
  // ...wrap around to the beginning:
  readIndex = 0;
 }
```

```
  // calculate the average:
  average1 = total1 / numReadings;
  average2 = total2 / numReadings;
  average3 = total3 / numReadings;




 if((readIndex == 25) || (readIndex == 50) || (readIndex == 75) || (readIndex == 100) ){

 // Serial.print("Pressure Differential Sensor 2 (Pa): ");
 // Serial.print(difPressure2);
//  Serial.print("\n");
 // Serial.println();
 //Serial.print(difPressure);
 //Serial.print(" ");


  //Bisection root find for Mass flow 1 (Mouth)
  float PR = average1;
  float Pu = 250;
  float Pl = 0;
  float Difference = 300;
  //float DP = p1*pow(x,8) + p2*pow(x,7) + p3*pow(x,6) + p4*pow(x,5) + p5*pow(x,4) +
p6*pow(x,3) + p7*pow(x,2) + p8*x + p9;
  //float DP = p1*pow(Pc,7) + p2*pow(Pc,6) + p3*pow(Pc,5) + p4*pow(Pc,4) +
p5*pow(Pc,3) + p6*pow(Pc,2) + p7*Pc + p8;

  if (PR <= 0.1){
    Pc1 =0;
  }
  else {

 while ((Difference > 0.01) && (Pc > 0) ) {

  Pc = (Pu+Pl)/2;
  //Serial.print("Pc: ");
  //Serial.println(Pc);
  float DP = p1*pow(Pc,6) + p2*pow(Pc,5) + p3*pow(Pc,4) + p4*pow(Pc,3) +
p5*pow(Pc,2) + p6*Pc + p7;
  //Serial.print("DP: ");
  //Serial.println(DP);
```

```
  if (DP > PR){
      Pu = Pc;
      Pl = Pl;
     Difference = Pu-Pl;
  }
  else if (DP < PR){
     Pu = Pu;
     Pl = Pc;
     Difference = Pu-Pl;
  }
  //Serial.print("Root: ");
  //Serial.println(Pc);
  //Serial.print("Difference: ");
  //Serial.println(Difference);
  //Serial.print("Pu: ");
  //Serial.println(Pu);
  //Serial.print("Pl: ");
  //Serial.println(Pl);

  }
 Pc1 = Pc;
  }


  //Bisection root find for Mass flow 2 (Nasal 1)


  PR = average2;
  Pu = 35;
  Pl = 0;
  Difference = 300;
  //float DP = p1*pow(x,8) + p2*pow(x,7) + p3*pow(x,6) + p4*pow(x,5) + p5*pow(x,4) +
p6*pow(x,3) + p7*pow(x,2) + p8*x + p9;

  if (PR <= 0.1){
    Pc2 =0;
  }
  else {

 while (Difference > 0.01){

  Pc = (Pu+Pl)/2;
  //Serial.print("Pc: ");
  //Serial.println(Pc);
  double DP = p12*pow(Pc,7) + p22*pow(Pc,6) + p32*pow(Pc,5) + p42*pow(Pc,4) +
p52*pow(Pc,3) + p62*pow(Pc,2) + p72*Pc + p8;
  //Serial.print("DP: ");
  //Serial.println(DP);
```

```
 if (DP > PR){
     Pu = Pc;
     Pl = Pl;
    Difference = Pu-Pl;
 }
 else if (DP < PR){
    Pu = Pu;
    Pl = Pc;
    Difference = Pu-Pl;
 }
 //Serial.print("Root: ");
 //Serial.println(Pc);
 //Serial.print("Difference: ");
 //Serial.println(Difference);
 //Serial.print("Pu: ");
 //Serial.println(Pu);
 //Serial.print("Pl: ");
 //Serial.println(Pl);

 }
Pc2 = Pc;

 }
Serial.println(" ");
Serial.print("DP1: ");
Serial.println(average1);
Serial.print("Final Root (Flow): ");
Serial.println(Pc1);
Serial.println(" ");
Serial.print("DP2: ");
Serial.println(average2);
Serial.print("Final Root (Flow) Nasal 1: ");
Serial.println(Pc2);
Serial.println(" ");
Serial.print("DP3: ");
Serial.println(average3);
Serial.println(" ");

Serial.print("Particle sensor: ");
Serial.print(pmat10);
Serial.print(", ");
Serial.print(pmat25);
Serial.print(", ");
Serial.print(pmat100);
Serial.print(", ");
Serial.print(pmat03);
Serial.print(", ");
Serial.print(pmat05);
```

```
 Serial.println(" ");
  }
}
```

The following Matlab code is used to smooth and fit curves of the data once the data file has been opened and data cleaned for any errors such as infinite numbers. It uses Matlabs curve fit toolbox to fit smoothing splines. This code is run once per test to curve fit each mask of a participant to form a data set.

```
n = 1;
for Humidityn = 1:length(Pressure)
    ElapsedSeconds(n,1) = (hour1(n)*60*60+minute1(n)*60+second1(n))-
(hour1(1)*60*60+minute1(1)*60+second1(1));

    %if Pressure(n,1) > 150
     %   Pressure(n,1) = 0;
    %end

    %if Pressure(n,1) < -150
    %    Pressure(n,1) = 0;
    %end

    if PC03(n) < 0
        PC03(n) = 0;
    end
    if PC05(n) < 0
        PC05(n) = 0;
    end
    if PC_03to05(n) < 0
        PC_03to05(n) = 0;
    end
    if PM10(n) < 0
        PM10(n) = 0;
    end
    if PM25(n) < 0
        PM25(n) = 0;
    end
    if PM100(n) < 0
        PM100(n) = 0;
    end
    n = n+1;
end

n = 1;

%get rid of double readings per second
n = 1;
for n = 2:(length(Pressure)-1)
    if ElapsedSeconds(n) == ElapsedSeconds((n-1))
        ElapsedSeconds(n)=ElapsedSeconds(n)+0.1;
    end
    n = n+1;
```

```
end

%Find peaks, troghs and average baseline pressure
[pks,locs]=findpeaks(Pressure,ElapsedSeconds,'MinPeakDistance',1,'MinPeak
Height',-33.5);
[pks2,locs2]=findpeaks(abs(Pressure),ElapsedSeconds,'MinPeakDistance',1,'
MinPeakHeight',34);
pks2 = pks2 * -1;
PA = mean(Pressure(1300:1479)); %CheckThisRange!

%Offset baseline off pressure Peaks
n = 1;
for n = 1:length(pks)
   pks(n) = pks(n) + abs(PA);
    n = n + 1;
end
%Offset baseline off pressure troughs
n = 1;
for n = 1:length(pks2)
  pks2(n) = pks2(n) + abs(PA);
  n = n + 1;
end

%Find Length for Pressure curve
if (locs(length(locs)) < locs2(length(locs2)) )
   XLIM = locs(length(locs));
else
    XLIM = locs2(length(locs2));
end

%Fit Pressure curves
PressureUpperf = fit(locs,pks,'smoothingspline','SmoothingParam',1e-05 );
PressureLowerf = fit(locs2,pks2,'smoothingspline','SmoothingParam',1e-
05);
%Fit temperature curves
AtmTempf =
fit(ElapsedSeconds,FR_temp,'smoothingspline','SmoothingParam',0.0001);
MaskTempf =
fit(ElapsedSeconds,SL_temp,'smoothingspline','SmoothingParam',0.001);
%Fit Particle curves
PM1f =
fit(ElapsedSeconds,PM10,'smoothingspline','SmoothingParam',0.0001);
PM2p5f =
fit(ElapsedSeconds,PM25,'smoothingspline','SmoothingParam',0.0001);
PM10f =
fit(ElapsedSeconds,PM100,'smoothingspline','SmoothingParam',0.0001);
PC03f = fit(ElapsedSeconds,PC03,'smoothingspline','SmoothingParam',1e-
05);
PC05f =
fit(ElapsedSeconds,PC05,'smoothingspline','SmoothingParam',0.0001);
PC0305f =
fit(ElapsedSeconds,PC_03to05,'smoothingspline','SmoothingParam',0.0001);
%Fit Humidity curve
Humidityf =
fit(ElapsedSeconds,Humidity,'smoothingspline','SmoothingParam',0.001);

n1=1;
%DelP = [];
```

```
Time2 = [];
for n1 = 1:length(Pressure)
    DelP(n1,1) = PressureUpperf(n1)-PressureLowerf(n1);
    Time2(n1,1) = n1;
    DelT(n1,1) = MaskTempf(n1)-AtmTempf(n1);
    n1 = n1+1;
end

DelPf = fit(Time2,DelP,'smoothingspline');
DelTempf = fit(Time2,DelT,'smoothingspline');

%Plot Graphs%
%           %
%           %
figure(1)
plot(PressureUpperf,'r');
hold on
plot(PressureLowerf,'g');
legend('Upper Pressure','Lower pressure','Pressure difference')
hold on
plot(DelPf,'b');
hold off
xlim([0 XLIM]);
xlabel('Time (s)')
ylabel('Pressure (Pa)')
title('Pressure fluctuation inside the testing system')

figure(2)
plot(AtmTempf,'r')
hold on
plot(MaskTempf,'g')
hold on
plot(DelTempf,'b')
hold off
xlim([0 length(Pressure)]);
legend('Atmospheric','Mask','Delta')
xlabel('Time (s)')
ylabel('Temperature (c)')
title('Temperature Readings')

figure(3)
plot(PM1f,'r')
hold on
plot(PM2p5f,'g')
hold on
plot(PM10f,'b')
xlim([0 length(PC03)]);
legend('PM1.0','PM2.5','PM10.0')
xlabel('Time (s)')
ylabel('Particle Concentration (ug/m^3)')
title('Particle concentration over time')

figure(4)
plot(PC03f,'r')
hold on
plot(PC05f,'g')
hold on
plot(PC0305f,'b')
```

```
legend('No. of particles above 0.3um','No. of particles above 0.5um','No.
of particles between 0.3um and 0.5um')
xlim([0 length(PC03)]);
title('Number of particles between 0.3um and 0.5um')
xlabel('Time (s)')
ylabel('Number of particles')
%set(gca, 'YScale', 'log')
```

Having fit curves to the data for each of the mask types, the curves can be plotted to compare values between the masks using the following code:

```
subplot(4,2,1);
fig = gcf;
fig.PaperUnits = 'inches';
fig.PaperPosition = [0 -0.5 8.3 11.7];
hold all
plot(DelTempf_P1_N95,'r')
plot(DelTempf_P1_M6000,'m')
plot(DelTempf_P1_O2O2,'g')
plot(DelTempf_P1_Resp,'b')
hold on
xlim([0 1200]);
ylim([0 9]);
legend('3M 6000','N95','O2O2','Respro')
xlabel('Time (s)')
ylabel('Temperature above ambient (c)')
title('Mask temperature above ambient')
hold on

subplot(4,2,2);
hold all
plot(Humidityf_P1_N95,'r')
hold all
plot(Humidityf_P1_M6000,'m')
hold on
plot(Humidityf_P1_O2O2,'g')
hold on
plot(Humidityf_P1_Resp,'b')
hold on
xlim([0 1200]);
ylim([40 100]);
legend('N95','3M 6000','O2O2','Respro')
xlabel('Time (s)')
ylabel('Relative Humidity (%)')
title('Mask Relative humidity levels')
%set(gca, 'YScale', 'log')
hold on

subplot(4,2,3);
hold all
plot(PM1f_P1_N95,'r')
hold all
plot(PM1f_P1_M6000,'m')
hold on
plot(PM1f_P1_O2O2,'g')
hold on
```

```
plot(PM1f_P1_Resp,'b')
xlim([0 1200]);
ylim([0 45]);
legend('N95','3M 6000','O2O2','Respro')
xlabel('Time (s)')
ylabel('Particle concentration (ug/m^3)')
title('PM 1.0 Particle concentration')
%set(gca, 'YScale', 'log')
hold on

subplot(4,2,4);
hold all
plot(PM2p5f_P1_N95,'r')
hold all
plot(PM2p5f_P1_M6000,'m')
hold on
plot(PM2p5f_P1_O2O2,'g')
hold on
plot(PM2p5f_P1_Resp,'b')
xlim([0 1200]);
ylim([0 50]);
legend('N95','3M 6000','O2O2','Respro')
xlabel('Time (s)')
ylabel('Particle concentration (ug/m^3)')
title('PM 2.5 Particle concentration')
hold on

subplot(4,2,5);
hold all
%set(gca, 'YScale', 'log')
plot(PM10f_P1_N95,'r')
hold all
plot(PM10f_P1_M6000,'m')
hold on
plot(PM10f_P1_O2O2,'g')
hold on
plot(PM10f_P1_Resp,'b')
xlim([0 1200]);
hold on
ylim([0 60]);
hold on
legend('N95','3M 6000','O2O2','Respro')
xlabel('Time (s)')
ylabel('Particle concentration (ug/m^3)')
title('PM 10.0 Particle concentration')
hold on

subplot(4,2,6);
hold all
plot(PC0305f_P1_N95,'r')
hold all
plot(PC0305f_P1_M6000,'m')
hold on
plot(PC0305f_P1_O2O2,'g')
hold on
plot(PC0305f_P1_Resp,'b')
xlim([0 1200]);
ylim([0 11000]);
```

```
hold on
legend('N95','3M 6000','O2O2','Respro')
xlabel('Time (s)')
ylabel('Particle Count')
title('Particle count of particles between 0.3um and 0.5um')
%set(gca, 'YScale', 'log')
hold on

subplot(4,2,7);
hold all
plot(DelPf_P1_N95,'r');
hold on
plot(DelPf_P1_O2O2,'g');
hold on
plot(DelPf_P1_Resp,'b');
hold on
plot(DelPf_P1_M6000,'m');
hold on
legend('N95','O2O2','Respro','3M 6000')
hold on
xlim([0 1200]);
ylim([0 135]);
hold on
xlabel('Time (s)')
hold on
ylabel('Pressure (Pa)')
hold on
title('Pressure fluctuation inside the testing system')
hold off
set(gcf,'Renderer','zbuffer')
%for n = 1:1100
 %   testTemp((2*n-1),1)=AtmTemp_P1_M6000(n);
 %   testTemp((2*n),1)=AtmTemp_P4_M6000(n);
%end

P = subplot(4,2,8)
hold all
plot(M6000uf,'m');
hold on
plot(O2O2uf,'g');
plot(N95uf,'r');
plot(Respuf,'b');
xlim([0 1000]);
ylim([0 7]);
xlabel('Time (s)')
ylabel('CO_2 level (%)')
legend('3M 6000','O2O2','N95','Respro')
title('Peak CO_2 levels')


fig = gcf;
fig.PaperUnits = 'inches';
fig.PaperPosition = [0 -.5 8.3 11.3];
```

AUTEC Secretariat

Auckland University of Technology
D-88, WU406 Level 4 WU Building City Campus
T: +64 9 921 9999 ext. 8316
E: ethics@aut.ac.nz
www.aut.ac.nz/researchethics

11 September 2017

David White
Faculty of Design and Creative Technologies

Dear David

Re Ethics Application: **17/277 Investigation into face mask performance**

Thank you for providing evidence as requested, which satisfies the points raised by the Auckland University of Technology Ethics Committee (AUTEC).

Your ethics application has been approved for three years until 11 September 2020.

Standard Conditions of Approval

1. A progress report is due annually on the anniversary of the approval date, using form EA2, which is available online through http://www.aut.ac.nz/researchethics.
2. A final report is due at the expiration of the approval period, or, upon completion of project, using form EA3, which is available online through http://www.aut.ac.nz/researchethics.
3. Any amendments to the project must be approved by AUTEC prior to being implemented. Amendments can be requested using the EA2 form: http://www.aut.ac.nz/researchethics.
4. Any serious or unexpected adverse events must be reported to AUTEC Secretariat as a matter of priority.
5. Any unforeseen events that might affect continued ethical acceptability of the project should also be reported to the AUTEC Secretariat as a matter of priority.

Please quote the application number and title on all future correspondence related to this project.

AUTEC grants ethical approval only. If you require management approval for access for your research from another institution or organisation then you are responsible for obtaining it. You are reminded that it is your responsibility to ensure that the spelling and grammar of documents being provided to participants or external organisations is of a high standard.

For any enquiries, please contact ethics@aut.ac.nz

Yours sincerely,

Kate O'Connor
Executive Manager
Auckland University of Technology Ethics Committee

Cc: jrw0306@aut.ac.nz; Chris Whittington; Manpreet Singh

Please do not staple your application

Auckland University of Technology Ethics Committee (AUTEC)

TE WĀNANGA ARONUI O TĀMAKI MAKAU RAU

EA1

For AUTEC Secretariat Use only

_____/_____

APPLICATION FOR ETHICS APPROVAL BY AUTEC

Please print this application single sided in greyscale and do not staple. Once this application has been completed and signed, please read the notes at the end of the form for information about submission of the application for review.

NOTES ABOUT COMPLETION

- Ethics review is a community review of the ethical aspects of a research proposal. Responses should use clear everyday language with appropriate definitions being provided should the use of technical or academic jargon be necessary.
- The AUTEC Secretariat and your AUTEC Faculty Representative are able to provide you with assistance and guidance with the completion of this application which may help expedite the granting of ethics approval.
- The information in this application needs to be clearly stated and to contain sufficient details to enable AUTEC to make an informed decision about the ethical quality of the research. Responses that do not provide sufficient information may delay approval because further information will be sought. Overly long responses may also delay approval when unnecessary information hinders clarity. In general, each response should not exceed 100 words.
- AUTEC reserves the right not to consider applications that are incomplete or inadequate. Please do not alter the formatting or numbering of the form in any way or remove any of the help text.
- Comprehensive information about ethics approval and what may be required is available online at http://aut.ac.nz/researchethics
- The information provided in this application will be used for the purposes of granting ethics approval. It may also be provided to the University Postgraduate Centre, the University Research Office, or the University's insurers for purposes relating to AUT's interests.
- The Form is focussed around AUTEC's ethical principles, which are in accordance with the *Guidelines for the approval of ethics committees* in New Zealand.

To respond to a question, please place your cursor in the space following the question and its notes and begin typing.

A. *Project Information*

A.1. What is the title of the research?

If you will be using a different title in documents to that being used as your working title, please provide both, clearly indicating which title will be used for what purpose.

Investigation into face mask performance

A.2. Is this application for research that is being undertaken in stages? ☐ Yes ☒ No

If the answer is 'Yes' please answer A.2.1 and the following sections, otherwise please answer A.3 and continue from there.

A.2.1. Does this application cover all the stages of the research? ☐ Yes ☐ No

If the answer is 'No' please provide details here of which stages are being covered by this application, otherwise please answer A.3 and continue from there.

A.3. Who is the applicant?

When the research is part of the requirements for a qualification at AUT, then the applicant is always the primary supervisor. Otherwise, the applicant is the researcher primarily responsible for the research, to whom all enquiries and correspondence relating to this application will be addressed.

Dr David White

A.4. Further information about the applicant.

A.4.1. In which faculty, directorate, or research centre is the applicant located?

BioDesign Lab, School of Engineering, Computer & Mathematical Sciences, Faculty of Design and Creative Technologies

A.4.2. What are the applicant's qualifications?

PhD, 2013

Master of Engineering (Mechanical), 2003

Bachelor of Engineering (Mechanical), 1996

New Zealand Certificate in Engineering, NZCE, (Mechanical), 1986

A.4.3. What is the applicant's email address?

An email address at which the applicant can be contacted is essential.

david.white@aut.ac.nz

A.4.4. At which telephone numbers can the applicant be contacted during the day?

921-9999 ext.8352

A.5. Research Instruments

A.5.1. Which of the following does the research use:

☐ ***a written or electronic questionnaire or survey*** ☐ ***focus groups*** ☐ ***interviews***
☐ ***observation*** ☐ ***participant observation*** ☐ ***ethnography*** ☐ ***photographs***
☐ ***videos*** ☐ ***other visual recordings*** ☐ ***a creative, artistic, or design process***
☒ ***performance tests***
☒ ***some other research instrument (please specify)***

Each participant, acting as their own control, will perform a alertness test (Stroop test) for mental focus pre-testing, will perform moderate exercise on a stationary bike in a controlled environment without any mask, followed by repeated exercise whilst wearing four varieties of facemasks in randomized order. Sampling of the air inside facemasks will be performed and analysed by sensors that will measure levels of exhaled gasses, vapour particle deposition, temperature and humidity inside the facemask. A blood O_2 saturating meter attached to participant's finger will measure their blood oxygen saturation levels and heart rate. Harmless and very low levels of flavoured vapour will be introduced in the surroundings to measure facemask performance in blocking odours. Participants will be given an alertness test again to complete at the end, to quantify any change in metal focus and fatigue.

Please attach to this application form all the relevant research protocols. These may include: Indicative questions (for interviews or focus groups); a copy of the finalised questionnaire or survey in the format that it will be presented to participants (for a written or electronic questionnaire or survey); a protocol indicating how the data will be recorded (e.g. audiotape, videotape, note-taking) for focus groups or interviews (Note: when focus groups are being recorded, you will need to make sure there is provision for explicit consent on the Consent Form and attach to this Application Form examples of indicative questions or the full focus group schedule. Please note that there are specific confidentiality issues associated with focus groups that need to be addressed); a copy of the observation protocol that will be used (for observations); full information about the use of visual recordings of any sort, including appropriate protocols and consent processes; protocols for any creative, artistic, or design process; a copy of the protocols for the instruments and the instruments that will be used to record results if you will use some other research instrument.

A.5.2. Who will be transcribing or recording the data?

If someone other than the applicant or primary researcher will be transcribing the interview or focus group records or taking the notes, you will need to provide a confidentiality agreement with this Application Form.

Measurement and recording of data will be performed by Research Manager, Bradley Nixon and Research Assistant, Manpreet Singh.

A.6. Please provide a brief plain English summary of the research (300 words maximum).

We want to measure exhaled gasses, temperature & humidity and odours inside the facemasks whilst performing moderate exercise. Conventional, commercially available facemasks are associated with discomfort as they trap exhaled air inside and are face-sealed. Due to trapping of the exhaled air, the facemask becomes hot & humid and air quality is not always ideal as oxygen levels fall. The face-seals are also not always effective due to facial hair and tight seals leave marks on the user's face. We will use variety of conventional facemasks and compare their performance to a newly developed transparent face-mask. Sampling of the air quality inside all of the masks will be done using a sampling tube connected to gas sensors. An odorant (very low levels of flavoured vapour) will be introduced in the surrounding environment to challenge the effectiveness of face-seal in blocking odour

particles. This sampled mask air will be analysed by sensors and recorded on computer for later analysis. This analysis involves comparison of mask air quality to that detected in the surroundings. The participants will also be given an alertness test (Stroop test) before and after the testing.

A.7. Additional Research Information

A.7.1. Is this research an intervention study? ☒ Yes ☐ No

For research in general, what is the difference between intervention, interaction, and observation? Intervention includes both physical procedures by which data are gathered and manipulations of the participant or participant's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between the investigator and participant that are performed for research purposes. Observation is neither an intervention nor an interaction. (cf https://www.gvsu.edu/hrrc/faq-definitions-35.htm).

Within health and disability research, 'intervention study' has the meaning given to it by the National Ethics Advisory Council's Ethical Guidelines for Intervention Studies; namely, a study in which the investigator controls and studies the intervention(s) provided to participants for the purpose of adding to knowledge of the health effects of the intervention(s). The term 'intervention study' is often used interchangeably with the terms 'experimental study' and 'clinical trial' (s.24 Standard Operating Procedures for Health and Disability Ethics Committees).

A.7.2. Is this Health and Disability Research? ☐ Yes ☒ No

Health and disability research is research that aims to generate knowledge for the purpose of improving health and independence outcomes (s.21 Standard Operating Procedures for Health and Disability Ethics Committees).

A.7.3. Does this research involve people in their capacity as consumers of health or disability support services, or in their capacity as relatives or caregivers of consumers of health or disability support services, or as volunteers in clinical trials (including, for the avoidance of doubt, bioequivalence and bioavailability studies)? ☐ Yes ☒ No

---

B. *The Ethical Principle of Research Adequacy*

AUTEC recognises that different research paradigms may inform the conception and design of projects. It adopts the following minimal criteria of adequacy: the project must have clear research goals; its design must make it possible to meet those goals; and the project should not be trivial but should potentially contribute to the advancement of knowledge to an extent that warrants any cost or risk to participants.

B.1. Is the applicant the person doing most of the research (the primary researcher)? ☐ Yes ☒ No

If the answer is 'No' please answer B.1.1 and the following sections, otherwise please answer B.2 and continue from there.

B.1.1. What is the name of the primary researcher if it is someone other than the applicant?

Bradley Nixon

B.1.2. What are the primary researcher's completed qualifications?

Bachelor of Engineering (Hons) (Mechanical) 2016

B.1.3. What is the primary researcher's email address?

An email address at which the primary researcher can be contacted is essential.

jrw0306@aut.ac.nz

B.1.4. At which telephone numbers can the primary researcher be contacted during the day?

(027) 951-1390

B.2. Is the primary researcher

☐ an AUT staff member ☒ an AUT student

If the primary researcher is an AUT staff member, please answer B.2.1 and the following sections, otherwise please answer B.3 and continue from there.

B.2.1. In which faculty, directorate, or research centre is the primary researcher employed?

If the response to this section is the same as that already given to section A.4.1 above, please skip this section and go to section B.2.2.

B.2.2. In which school or department is the primary researcher employed?

B.3. When the primary researcher is a student:

B.3.1. What is their Student ID Number?

1383535

B.3.2. In which faculty are they enrolled?

Design and Creative Technologies

B.3.3. In which school, department, or Research Centre are they enrolled?

BioDesign Lab, School of Engineering, Computer & Mathematical Sciences

B.4. What is the primary researcher's experience or expertise in this area of research?

Where the primary researcher is a student at AUT, please identify the applicant's experience or expertise in this area of research as well.

Bradley undertook a summer internship in 2016/2017 at BioDesign Lab undertaking computational modelling of the facemask airflows. Earlier Bradley had completed his BE (Hons) qualification at AUT, graduating late 2016.

B.5. Who is in charge of data collection?

Bradley Nixon and Manpreet Singh

B.6. Who will interact with the participants?

Bradley Nixon and Manpreet Singh

B.7. Is this research being undertaken as part of a qualification? ☒ Yes ☐ No

If the answer is 'Yes' please answer B.7.1 and the following sections, otherwise please answer B.8 and continue from there.

B.7.1. What is the name of the qualification?

Master of Engineering being studied by Bradley Nixon

B.7.2. In which institution will the qualification be undertaken?

BioDesign Lab, Auckland University of Technology

B.8. Details of Other Researchers or Investigators

B.8.1. Will any other people be involved as researchers, co- investigators, or supervisors? ☒ Yes ☐ No

If the answer is 'Yes' please answer B.8.1.1 and the following sections, otherwise please answer B.8.2 and continue from there.

B.8.1.1 What are the names of any other people involved as researchers, investigators, or supervisors?

Supervisor - Chris Whittington, Research Assistant - Manpreet Singh

B.8.1.2 Where do they work?

Chris Whittington – BioDesign Lab, School of Engineering, Computing and Mathematical Sciences, AUT.

Manpreet Singh –BioDesign Lab Research Assistant & O2O2 Student Intern.

B.8.1.3 What will their roles be in the research?

Chris will Co- supervise the research performed by Bradley Nixon

Manpreet Singh will assist Bradley Nixon in data collection

B.8.1.4 What are their completed qualifications?

Chris Whittington:

- Master of Engineering (Dist.)
- BSc (Hons) Mechanical Engineering
- Post Graduate Diploma Management
- Post Graduate Diploma in Marketing
- Post Graduate Diploma in Tertiary Teaching
- Trade Certificate (Toolmaking) UK

Manpreet Singh:

- Bachelor of Engineering (Hons) Mechanical Engineering

B.8.2. Will any research organisation or other organisation be involved in the research? ☐ Yes ☒ No

If the answer is 'Yes' please answer B.8.2.1 and the following sections, otherwise please answer B.9 and continue from there.

B.8.2.1 What are the names of the organisations?

B.8.2.2 Where are they located?

B.8.2.3 What will their roles be in the research?

B.9. Why are you doing this research and what is its aim and background?

Please provide the key outcomes or research questions and an academic rationale with sufficient information, including relevant references, to place the project in perspective and to allow the project's significance to be assessed.

This research is part of Bradley Nixon's academic qualification (Master of Engineering) and aims to compare the air filtration performance and comfort of conventional sealed facemask to a new type of unsealed facemask system. Bradley has previously modelled mask airflows but this computational work needs to be validated. The air quality within conventional facemasks is not ideal due to exhaled air being trapped inside. Conventional facemasks are also uncomfortable to wear, as the mask air gets hot, humid. The face-seal in conventional masks is not always effective due to facial hair enabling odours to penetrate the face seal. The new mask also being tested does not require a face-seal which also improves comfort level. This seal-free mask is also transparent and does not obscure wearer's face which aids communication between the wearer and any observer.

B.10. What are the potential benefits of this research to the participants, the researcher, and the wider community?

Facemasks are worn by community for wide range of reasons. The air quality inside the conventional facemasks is not always ideal due to trapping of exhaled air. In addition to reduced air quality, they are uncomfortable to wear, as they get hot, humid and have tight face-seals. The effectiveness of the pressure seals reduces with people who have facial hair. Conventional mask reduce communications as they obscure the face. This research will benefit in designing of facemasks that have increased comfort, can be worn by people with facial hair and aids communication by showing wearer's face. This research will also help Bradley Nixon in obtaining his qualification (Master of Engineering) at AUT University.

B.11. What are the theoretical frameworks or methodological approaches being used?

B.12. How will data be gathered and processed?

Data will be collected automatically by our data acquisition system and stored by computer without presentation. Each participant, acting as their own control will undertake five separate test sessions. The first load standardisation session requires each participant to perform moderate exercise, defined by the Borg Test, on an Exercycle in a controlled environment without any mask. This will be followed by four separate sessions where the standardised load is applied during moderate exercise while the participants wear different facemasks assigned in random order. Each facemask will have a tube attached for gas sampling the exhaled air and sampled air will be analysed by sensors to measure gases, particulates, temperature and humidity inside the facemask. A blood oxygen saturation sensor will also be attached to the participant's ring finger to measure their blood oxygen saturation levels and heart rate. During the facemask testing, harmless and very low levels of flavoured vapour will be introduced in the surroundings to measure facemask odour blocking performance. Before and after the test, the participants will be given a quick alertness test (Stroop test) to solve on phone/tablet to assess their alertness level.

B.13. How will the data be analysed?

Please provide the statistical (for quantitative research) or methodological (for qualitative or other research) justification for analysing the data in this way.

Statistical analysis of the data will be undertaken by comparing ambient air conditions to that found inside the facemasks during testing. Specific measured parameters include oxygen and carbon dioxide concentration, air temperature and humidity and odour particle count. Comparison will be made between ambient and mask conditions for each of the four masks tested. Stroop test data will be analysed for change in alertness level pre and post-test.

B.14. Has any peer review taken place? ☐ Yes ☒ No

If your answer is 'Yes', please specify and provide evidence e.g. a letter of confirmation.

☐ ***AUT Competitive Grant*** ☐ ***External Competitive Research Grant***

☐ ***PGR1*** ☐ ***PGR2*** ☐ ***PGR9*** ☐ ***Independent Peer Review****

Optional exemplars for evidencing peer review are available from the Ministry of Health (HDEC) website (http://ethics.health.govt.nz/) or from the Forms section of the Research Ethics website (http://aut.ac.nz/researchethics)

C. *General Project Details*

C.1. Likely Research Output

C.1.1. What are the likely outputs of this research?

☒ ***a thesis*** ☐ ***a dissertation*** ☒ ***a research paper*** ☒ ***a journal article***

☐ ***a book*** ☒ ***conference paper*** ☐ ***a documentary*** ☐ ***an exhibition***

☐ ***a film*** ☐ ***some other artwork*** ☐ ***other academic publications or presentations***

☐ ***Some other output, please specify***

C.2. Research Location and Duration

C.2.1. In which countries and cities/localities will the data collection occur?

Auckland University of Technology, Auckland, New Zealand

C.2.1.1 Exactly where will any face to face data collection occur?

If face to face data collection will occur in participants' homes or similarly private spaces, then a Researcher Safety Protocol needs to be provided with this application.

AUT BioDesign Lab, Auckland University of Technology, Auckland, New Zealand

C.2.2. In which countries and cities/localities will the data analysis occur?

AUT BioDesign Lab, Auckland University of Technology, Auckland, New Zealand

C.2.3. When is the data collection scheduled to commence?

September 2017 to March 2018

C.3. Research Participants

C.3.1. Who are the participants?

Normal healthy adults aged 18 to 60 years

C.3.2. How many participants are being recruited for this research?

If you are unsure, please provide an indicative range.

5 – 20 participants

C.3.3. What criteria will be used to choose who to invite as participants?

It is desired that participants cover a range of age, gender and ethnicity representative of the population so they will be selected in order to fulfil this goal. Participants must have overall good health, no respiratory irregularities, no medication and preferably be a non-smoker or having quit smoking at least two years ago. It is also desired that some participants have facial hair to test face-seal leakage. A subset of participants must have facial hair as pressure seals on conventional masks are not effective with facial hair and this study aims to test performance of masks with facial hair. It is also desired that participants are have BMI < 30 as they need to be able to wear the facemasks while undertaking moderate exercise.

C.3.3.1 How will you select participants from those recruited if more people than you need for the study agree to participate?

The selection of participants from those recruited will be based on their availability to attend five scheduled study times. Participants must be physically fit, able to perform moderate exercise for 20 minutes during each of the five sessions and tolerate wearing facemasks for the duration of testing. It is desired that some participants must have facial hair as this study aims to test performance of masks with facial hair as well.

C.3.4. Will any people be excluded from participating in the study? ☒ Yes ☐ No

Exclusion criteria apply only to potential participants who meet the inclusion criteria. An exclusion criterion is any characteristic that ought to disqualify any potential participant from recruitment into the study. Consider exclusion criteria when there are heightened risks due to power differences in the relationship, recent injury, or other characteristics that might place potential participants at unreasonable risk of harms.

If the answer to this question is 'Yes' please answer C.3.4.1 and the following sections, otherwise please answer C.3.5 and continue from there.

C.3.4.1 What criteria will be used to exclude people from the study?

People who do not fit the masks. People with BMI >30 and people who are unfit considering their health concerns. Potential participants who declare any of the following will excluded from the study:

- A medical condition that could have impact the results, such as a neurological condition, orthopaedic pathology of the lower limbs, or uncontrolled medical problem which would prevent moderate intensity physical activity
- Unstable heart condition
- Co-morbidities that would detrimentally affect the person's ability to participate in a cycle exercise task

C.3.4.2 Why is this exclusion necessary for this study?

- Mask fit becomes unreliable when BMI > 30
- Overweight people can be potentially unfit and this gives rise to risk during moderate exercise.
- Unstable heart condition, orthopaedic pathology of the lower limbs gives rise to risk during moderate exercise

C.3.5. Recruitment of participants.

Please describe in detail the recruitment processes that will be used. If you will be recruiting by advertisement or email, please attach a copy to this Application Form

C.3.5.1 How will the initial contact with potential participants occur?

Posters will be used to invite volunteers to participate in this study.

C.3.5.2 How will the contact details of potential participants be collected and by whom?

Participant contact details will be obtained from their initial contact with the Project Manager and Research Assistant.

C.3.5.3 How will potential participants be invited to participate?

People enquiring in response to the posters will be sent a Participant Information Sheet which provides further detailed information and invites them to participate in the study.

C.3.5.4 How much time will potential participants have to consider the invitation?

10 days

C.3.5.5 How will potential participants respond to the invitation?

By contacting the Project Manager or Research Assistant via email or phone.

C.3.5.6 How will potential participants give consent?

Participants give their consent based on the information provided by the Participant Consent Form and additional information provided by the Project Manager.

C.3.5.7 How and when will the inclusion criteria and exclusion criteria given in sections C.3.2 and C.3.3 be applied?

After the initial contact, the inclusion and exclusion criteria will be provided to potential participants in the Participant Information Sheet.

C.3.5.8 Will there be any follow up invitations for potential participants?

No

D. *Partnership, Participation and Protection*

D.1. How does the design and practice of this research implement the principle of Partnership in the interaction between the researcher and other participants?

How will your research design and practice encourage a mutual respect and benefit and participant autonomy and ownership? How will you ensure that participants and researchers will act honourably and with good faith towards each other? Are the outcomes designed to benefit the participants and/or their social or cultural group? How will the information and knowledge provided by the participants be acknowledged?

Dialogue between the researchers and participants will occur covering the justification for this research, the purpose and rationale behind the procedures to be undertaken as well as answering questions relating to this work. After consent has been offered by the participant to proceed; throughout this study confirmation will be sought from the participant that the procedure is being conducted in a courteous and considerate manner.

By ensuring a continual dialogue occurs between participants and researchers throughout the duration of this study, which explains the justification and rationale for actions undertaken, will ensure both parties act honourably and in good faith to each other. This will also involve seeking permission from the other party prior to undertaking any procedure.

D.2. How does the design and practice of this research implement the principle of Participation in the interaction between the researcher and other participants?

What is the actual role of participants in your research project? Will participants be asked to inform or influence the nature of the research, its aims, or its methodology? Will participants be involved in conducting the research or is their principal involvement one of sharing information or data? Do participants have a formal role as stakeholders e.g. as the funders and/or beneficiaries of the research? What role will participants have in the research outputs (e.g. will they be asked to approve transcripts or drafts)?

The role of the participants is to perform moderate exercise without wearing any mask and perform the same exercise whilst wearing four varieties of facemasks. The participants will have to attend 5 separate sessions for each testing. The participants will have their exhaled air sampled by sensors. The participants will have their blood oxygen saturation levels and heartrate measured by a sensor attached to their finger. Participants will also complete a short alertness test (Stroop test) pre and post the testing to have their mental focus recorded on every visit.

None of the participants will have a formal role as stakeholders.

D.3. How does the design and practice of this research implement the principle of Protection in the interaction between the researcher and other participants?

How will you actively protect participants from deceit, harm and coercion through the design and practice of your research? How will the privacy of participants and researchers be protected? How will any power imbalances inherent in the relationships between the participants and researchers be managed? How will any cultural or other diversity be respected?

Protection of the participant from deceit, harm and coercion has been designed into this study in three ways. Firstly, the information supplied by the Participant Information Sheet will ensure they are aware of the rationale, purpose and methodology. Secondly, the Participant understands that their involvement is entirely voluntary and they can choose to withdraw at any time and for any reason prior to completion of the pilot study. Thirdly, throughout this study there will be a dialogue between the Researchers and Participant to communicate not only procedures and seek permission for these to proceed but also to enable the participant to express concerns and remain informed. Included in this dialogue will be the communication of any discomfort experienced by the participant and any mitigating action undertaken by the researchers.

Privacy of the participants and researchers will be protected through a process of ensuring that the participants remain anonymous to each other and the only contact they have will be directly with the Project Manager and Researchers. Data collected by the researchers, specific to each participant, will be stored using a reference number that can only be referred back to the participant through the demographic data form that is held securely in a separate location to the data.

Management of the power imbalance inherent in the relationship between participants and researchers will be managed through a process of continual dialogue where procedures are explained and justified by the researchers and the seeking of consent from the participant prior to proceeding.

Respect for participant cultural or other diversity of the participant will be ensured through a process of continual dialogue where procedures are explained and justified by the researchers and the seeking of consent from the participant prior to proceeding.

Participants will be screened prior to inclusion in the study for relevant contraindications and cautions to moderate intensity exercise (i.e. cardiac conditions, metabolic conditions, hypertension, arthritis and/or musculoskeletal pain). Very low and safe levels of flavoured vapour will be used to compare the odour blocking performance of the facemasks. A New Zealand Ministry of Health Regulatory Impact Statement proposes secondary exposure to e-cigarette flavoured vapour does not cause any harm [2]. In addition, participants and data collectors will be wearing facemasks, so this further minimizes any risk. The facemasks used are safe and approved to be worn for wide range of applications.

Research outputs will not contain any reference to individual participants or enable them to be identified in any way, as only summary findings will be published. Because of this, participants will have no role in the research outputs, but they will be invited to view the research results/ informed if they choose during signing consent form.

E. *Social and Cultural Sensitivity (including the obligations of the Treaty of Waitangi)*

E.1. What familiarity does the researcher have with the social and cultural context of the participants?

Healthy adults used within this study span over a broad variety of different races.

E.2. What consultation has occurred?

Research procedures should be appropriate to the participants. Researchers have a responsibility to inform themselves of, and take the steps necessary to respect the values, practices, and beliefs of the cultures and social groups of all participants. This usually requires consultation or discussion with appropriate people or groups to ensure that the language and research approaches being used are relevant and effective. Consultation should begin as early as possible when designing the project and should continue throughout its duration.

All researchers are encouraged to make themselves familiar with Te Ara Tika: Guidelines for Maori Research Ethics: A framework for researchers and ethics committee members which is able to be accessed through the Research Ethics website. Researchers may also find Te Kaahui Maangai a directory of Iwi and Maaori organisations to be helpful. This may be accessed via the Te Puni Kookiri website (http://www.tkm.govt.nz/). As well as these documents, the Health Research Council has published Pacific Health Research Guidelines, and Guidelines on research involving children. (see http://www.hrc.govt.nz). There are also guidelines by various organisations about researching with other populations that researchers will find helpful.

E.2.1. With whom has the consultation occurred?

Please provide written evidence that the consultation has occurred.

E.2.2. How has this consultation affected the design and practice of this research?

Not applicable

E.3. Does this research target Māori participants? ☐ Yes ☒ No

All researchers are encouraged to make themselves familiar with Te Ara Tika: Guidelines for Maori Research Ethics: A framework for researchers and ethics committee members

If your answer is 'No', please go to section E.4 and continue from there. If you answered 'Yes', please answer the next question.

E.3.1. Which iwi or hapu are involved?

E.4. Does this research target participants of particular cultures or social groups? ☐ Yes ☒ No

AUTEC defines the phrase 'specific cultures or social groups' broadly. In section 2.5 of Applying for Ethics Approval: Guidelines and Procedures it uses the examples of Chinese mothers and paraplegics. This is to identify their distinctiveness, the first as a cultural group, the second as a social group. Other examples of cultural groups may be Korean students, Samoan husbands, Cook Islanders etc., while other examples of social groups may be nurse aides, accountants, rugby players, rough sleepers (homeless people who sleep in public places) etc. Please refer to Section 2.5 of AUTEC's Applying for Ethics Approval: Guidelines and Procedures (accessible in the Ethics Knowledge Base online via http://www.aut.ac.nz/about/ethics) and to the relevant Frequently Asked Questions section in the Ethics Knowledge Base.

If your answer is 'No', please go to section E.5 and continue from there. If you answered 'Yes', please answer the next question.

E.4.1. Which cultures or social groups are involved?

E.5. Does this research focus on an area of research that involves Treaty obligations? ☐ Yes ☒ No

All researchers are encouraged to make themselves familiar with Te Ara Tika: Guidelines for Maori Research Ethics: A framework for researchers and ethics committee members.

If your answer is 'No', please go to section E.6 and continue from there. If you answered 'Yes', please answer the next question.

E.5.1. Which treaty obligations are involved?

E.6. Will the findings of this study be of particular interest to specific cultures or social groups? ☐ Yes ☒ No

If the answer is 'Yes' please answer E.6.1 and the following sections, otherwise please answer F.1 and continue from there.

E.6.1. To which iwi, hapū, culture or social groups will the findings be of interest?

E.6.2. How will the findings be made available to these groups?

F. *Respect for the Vulnerability of Some Participants*

"Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. Individuals whose willingness to volunteer in a research study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate may also be considered vulnerable." (Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, World Health Organisation).

F.1. Will your research involve any of the following groups of participants? ☐ Yes ☒ No

If your research involves any of these groups of participants, please clearly indicate which ones and then answer F.2 and the following section, otherwise please answer G.1 and continue from there.

☐ people unable to give informed consent? ☐ your (or your supervisor's) own students?
☐ preschool children? ☐ children aged between five and sixteen years?
☐ legal minors aged between sixteen and twenty years?
☐ People lacking the mental capacity for consent?
☐ people in a dependent situation (e.g. people with a disability, or residents of a hospital, nursing home or prison or patients highly dependent on medical care)?
☐ people who are vulnerable for some other reason (e.g. the elderly, persons who have suffered abuse, persons who are not competent in English, new immigrants)? – please specify

F.2. How is respect for the vulnerability of these participants reflected in the design and practice of your research?

F.3. What consultation has occurred to ensure that this will be effective?

Please provide evidence of the consultation that has occurred.

G. *Informed and Voluntary Consent*

G.1. How will information about the project be given to potential participants?

A copy of all information that will be given to prospective participants is to be attached to this Application Form. If written information is to be provided to participants, you are advised to use the Information Sheet exemplar. The language in which the information is provided is to be appropriate to the potential participants and translations need to be provided when necessary.

General information will initially be given from the poster; however, more detailed and specific information will be given to prospective participants by the Participant Information Sheet that will be sent out in answer to initial enquiries. Those who respond and wish to participate in the study will be interviewed by the Project Manager, which provides an arena for detailed informed dialogue to occur and further information to be given.

G.2. How will the consent of participants be obtained and evidenced?

AUTEC requires consent to be obtained and usually evidenced in writing. A copy of the Consent Form which will be used is to be attached to this application. If this will not be the case, please provide a justification for the alternative approach and details of the alternative consent process. Please note that consent must be obtained from any participant aged 16 years or older. Participants under 16 years of age are unable to give consent, which needs to be given by their parent or legal guardian. AUTEC requires that participants under the age of 16 assent to their participation. When the nature of the research requires it, AUTEC may also require that consent be sought from parents or legal guardians for participants aged between 16 and twenty years. For further information please refer to AUTEC's Applying for Ethics Approval: Guidelines and Procedures.

Participants will discuss the objectives and data acquisition process with the Project Manager prior to reading and completing the Consent Form. Time to ensure the consent is both informed and voluntary will vary depending upon the discussion and questions raised and should take around 10 to 20 minutes.

G.3. Will any of the participants have difficulty giving informed consent on their own behalf?

☐ Yes ☒ No

Please consider physical or mental condition, age, language, legal status, or other barriers.

If the answer is 'Yes' please answer G.3.1 and the following sections, otherwise please answer G.4 and continue from there.

G.3.1. If participants are not competent to give fully informed consent, who will consent on their behalf?

Researchers are advised that the circumstances in which consent is legally able to be given by a person on behalf of another are very constrained. Generally speaking, only parents or legal guardians may give consent on behalf of a legal minor and only a person with an enduring power of attorney may give consent on behalf of an adult who lacks capacity.

G.3.2. How will these participants be asked to provide assent to participation?

Whenever consent by another person is possible and legally acceptable, it is still necessary to take the wishes of the participant into account, taking into consideration any limitations they may have in understanding or communicating them.

G.4. Is there a need for translation or interpreting? ☐ Yes ☒ No

If your answer is 'Yes', please provide copies of any translations with this application and any Confidentiality Agreement required for translators or interpreters.

H. *Respect for Rights of Privacy and Confidentiality*

H.1. How will the privacy and confidentiality of participants be protected?

Please note that anonymity and confidentiality are different. For AUTEC's purposes, 'Anonymity' means that the researcher is unable to identify who the participant is in any given case. If the participants will be anonymous, please state how, otherwise, if the researcher will know who the participants are, please describe how the participants' privacy issues and the confidentiality of their information will be managed.

The research is not anonymous, but all participant information will be kept confidential. Only normalized and aggregated data findings will be reported. All information is kept confidential within the research team.

H.2. How will individuals or groups be identified in the final report?

If participants or groups will be identified, please state how this will happen, why, and how the participants will give consent.

Only aggregate data will be reported, in such a form that no individuals or groups can be identified from it.

H.3. What information on the participants will be obtained from third parties?

This includes use of third parties, such as employers or professional organisations, in recruitment.

None

H.4. How will potential participants' contact details be obtained for the purposes of recruitment?

Participant contact details will be obtained from their initial contact with the Project Manager and Research Assistant.

H.5. What identifiable information on the participants will be given to third parties?

None

H.6. Who will have access to the data during the data collection and analysis stages?

Researchers identified with this project.

H.7. Who will have access to the data after the findings have been produced?

Researchers identified with this project

H.8. Are there any plans for the future use of the data beyond those already described? ☐ Yes ☒ No

The applicant's attention is drawn to the requirements of the Privacy Act 1993 (see Appendix I of AUTEC's Applying for Ethics Approval: Guidelines and Procedures). Information may only be used for the purpose for which it was collected so if there are plans for the future use of the data, then this needs to be explained in the Information Sheets for participants. If you have answered 'Yes' to this question, please answer section H.8.1.1 and continue from there. If you answered 'No' to this question, please go to section H.9 and proceed from there.

H.8.1.1 If data will be stored in a database, who will have access to that information, how will it be used, for what will it be used, and how have participants consented to this?

H.8.1.2 Will any contact details be stored for future use and if so, who will have access to them, how will they be used, for what will they be used, and how have participants consented to this?

H.9. Where will the data be stored once the analysis is complete?

Please provide the exact storage location. AUTEC normally requires that the data be stored securely on AUT premises in a location separate from the consent forms. Electronic data should be downloaded to an external storage device (e.g. an external hard drive, a memory stick etc.) and securely stored. If you are proposing an alternative arrangement, please explain why.

Electronic data will be stored in the Applicant's AUT Wellesley Campus office, located in WD402, in a locked filing cabinet.

H.9.1. For how long will the data be stored after completion of analysis?

AUTEC normally requires that the data be stored securely for a minimum of six years, or ten years for health data. If you are proposing an alternative arrangement, please explain why.

10 years

H.9.2. How will the data be destroyed?

If the data will not be destroyed, please explain why, identify how it will be safely maintained, and provide appropriate informed consent protocols.

The original data will be stored for a period of 10 years from the completion of the project. After this period, the original data will be securely deleted from the secure hard drive.

H.10. Who will have access to the Consent Forms?

Only the Project Manager will have access to the consent forms.

H.11. Where will the completed Consent Forms be stored?

Please provide the exact storage location. AUTEC normally requires that the Consent Forms be stored securely on AUT premises in a location separate from the data. If you are proposing an alternative arrangement, please explain why.

Consent forms will be stored in a locked cabinet in the Design & Creative Technologies Faculty Research office, level 6 WA Building.

H.11.1. For how long will the completed Consent Forms be stored?

AUTEC normally requires that the Consent Forms be stored securely for a minimum of six years, or ten years in the case of research involving health data. If you are proposing an alternative arrangement, please explain why.

10 years.

H.11.2. How will the Consent Forms be destroyed?

If the Consent Forms will not be destroyed, please explain why.

Consent forms will be destroyed by secure document destruction

H.12. Does your project involve the use of previously collected information or biological samples for which there was no explicit consent for this research? ☐ Yes ☒ No

If the answer is 'Yes' please answer H.12.1 and the following sections, otherwise please answer H.13 and continue from there.

H.12.1. What previously collected data will be involved?

H.12.2. Who collected the data originally?

H.12.2.1 Why was the information originally collected?

H.12.2.2 For what purposes was consent originally given when the information was collected?

H.12.3. How will the data be accessed?

H.13. Does your project involve any research about organisational practices where information of a personal or sensitive nature may be collected and / or where participants may be identified? ☐ **Yes** ☒ **No**

If the answer is 'Yes' please answer H.13.1 and the following sections, otherwise please answer I.1 and continue from there.

H.13.1. How will organisational permission be obtained and recorded?

H.13.2. Will the organisation know who the participants are?

H.13.3. How will the identity of the participants be kept confidential?

I. *Minimisation of risk*

I.1. Risks to Participants

Please consider the possibility of moral, physical, psychological or emotional risks to participants, including issues of confidentiality and privacy, from the perspective of the participants, and not only from the perspective of someone familiar with the subject matter and research practices involved. Please clearly state what is likely to be an issue, how probable it is, and how this will be minimised or mitigated (e.g. participants do not need to answer a question that they find embarrassing, or they may terminate an interview, or there may be a qualified counsellor present in the interview, or the findings will be reported in a way that ensures that participants cannot be individually identified, etc.) Possible risks and their mitigation should be fully described in the Information Sheets for participants.

I.1.1. How much time will participants be required to give to the project?

It will take between ten to fifteen minutes to recruit participants and gain informed consent. The preparation for the measurement setup is approximately 10 minutes. Participants will be required to attend 5 sessions of 45 minutes each. This study asks participants for a significant commitment of time and energy, this commitment is discussed in the Participant Information Sheet and will be reiterated to participants when discussing the study with the research team. Participants are able to terminate an experimental session at any stage and the researchers will monitor all sessions closely.

I.1.2. What level of discomfort or embarrassment may participants be likely to experience?

Participants may find the exercise moderately physically demanding and may experience the fatigue and physical discomfort that is sometimes associated with starting a new exercise regime. To minimize this risk, exercise intensity is determined based on the individuals' abilities and fitness and is closely monitored [1].The participants will be given appropriate rest between each of the sessions.

I.1.3. In what ways might participants be at risk in this research?

There are no procedures applied to the participants that could have any short or long-term side effects. Very low and safe levels of flavoured vapour will be used as an odorant for particle tracking. The participants may smell very low amounts of the flavoured vapour which does not pose any risks to participants as identified in regulatory impact statement by NZ Health Ministry [2]. In addition, participants and data collectors will be wearing facemasks, so this further minimizes any risk. The participant will be wearing sealed and non-sealed facemasks. The face-sealed facemasks are safe and approved to be worn for range of activities but might get humid and hot due to exhaled air. This however does not pose any risk to the participants.

Participants will be screened prior to inclusion in the study for relevant contraindications and cautions to moderate intensity exercise (i.e. cardiac conditions, metabolic conditions, hypertension, arthritis and/or musculoskeletal pain).

I.1.4. In what ways are the participants likely to experience risk or discomfort as a result of cultural, employment, financial or similar pressures?

The cultural concern of having a stranger contact your head is addressed by raising this concern in the Participant Information Sheet and advising that permission and confirmation will be sought both at the beginning and throughout the trial. Time availability will be discussed during the interview with the Project Manager and is identified in the Participant Information sheet.

I.1.5. Will your project involve processes that are potentially disadvantageous to a person or group, such as the collection of information, images etc. which may expose that person/group to discrimination, criticism, or loss of privacy? ☐ Yes ☒ No

If your answer is 'Yes', please detail how these risks will be managed and how participants will be informed about them.

I.1.6. Will your research involve collection of information about illegal behaviour(s) which could place the participants at current or future risk of criminal or civil liability or be damaging to their financial standing, employability, professional or personal relationships? ☐ Yes ☒ No

If your answer is 'Yes', please detail how these risks will be managed and how participants will be informed about them.

I.1.7. If the participants are likely to experience any significant discomfort, embarrassment, incapacity, or psychological disturbance, please state what consideration you have given to the provision of counselling or post-interview support, at no cost to the participants, should it be required.

Adult research participants in Auckland are able to utilise counselling support from the AUT Counselling Team, otherwise you may have to consider local providers for participants who are located nationwide, or in some particular geographical area or who are children. You may discuss the potential for participant psychological impact or harm with the Head of AUT Counselling, if you require. Please check the relevant Frequently Asked Question on the research ethics website as well and ensure the appropriate wording in included in the Information Sheet when counselling opportunities need to be offered.

I.1.8. Will any use of human remains, tissue or body fluids which does not require submission to a Health and Disability Ethics Committee occur in the research? ☐ Yes ☒ No

e.g. finger pricks, urine samples, etc. (please refer to section 13 of AUTEC's Applying for Ethics Approval: Guidelines and Procedures). If your answer is yes, please provide full details of all arrangements, including details of agreements for treatment, how participants will be able to request return of their samples in accordance with right 7 (9) of the Code of Health and Disability Services Consumers' Rights, etc.

I.1.9. Will this research involve potentially hazardous substances? ☐ Yes ☒ No

e.g. radioactive material, biological substances (please refer to section 15 of AUTEC's Applying for Ethics Approval: Guidelines and Procedures and the Hazardous Substances and New Organisms Act 1996).

If the answer is 'Yes', please provide full details, including hazardous substance management plan.

I.2. Risks to Researchers

If this project will involve interviewing participants in private homes, undertaking research overseas, in unfamiliar cultural contexts, or going into similarly vulnerable situations, then a Researcher Safety protocol should be designed and appended to this application. This should identify simple and effective processes for keeping someone informed of the researcher's whereabouts and provide for appropriate levels of assistance.

I.2.1. Are the researchers likely to be at risk? ☐ Yes ☒ No

If the answer is 'Yes' please answer I.2.1.1 and then continue, otherwise please answer I.3 and continue from there.

I.2.1.1 In what ways might the researchers be at risk and how will this be managed?

I.3. Risks to AUT

I.3.1. Is AUT or its reputation likely to be at risk because of this research? ☐ Yes ☒ No

If the answer is 'Yes' please answer I.3.1.1 and then continue, otherwise please answer I.3.2 and continue from there.

I.3.1.1 In what ways might AUT be at risk in this research?

Please identify how and detail the processes that will be put in place to minimise any harm.

I.3.2. Are AUT staff and/or students likely to encounter physical hazards during this project? ☐ Yes ☒ No

If yes, please provide a hazard management protocol identifying how harm from these hazards will be eliminated or minimised.

J. *Truthfulness and limitation of deception*

J.1. How will feedback on or a summary of the research findings be disseminated to participants (individuals or groups)?

Please ensure that this information is included in the Information Sheet.

J.2. Does your research include any deception of the participants, such as non-disclosure of aims or use of control groups, concealment, or covert observations? ☐ Yes ☒ No

Deception of participants in research may involve deception, concealment or covert observation. Deception of participants conflicts with the principle of informed consent, but in some areas of research it may sometimes be justified to withhold information about the purposes and procedures of the research. Researchers must make clear the precise nature and extent of any deception and why it is thought necessary. Emphasis on the need for consent does not mean that covert research can never be approved. Any departure from the standard of properly informed consent must be acceptable when measured against possible benefit to the participants and the importance of the knowledge to be gained as a result of the project or teaching session. This must be addressed in all applications. Please refer to Section 2.4 of AUTEC's Applying for Ethics Approval: Guidelines and Procedures when considering this question.

If the answer is 'Yes' please answer J.2.1 and the following sections, otherwise please answer J.3 and continue from there.

J.2.1. Is deception involved?

J.2.2. Why is this deception necessary?

J.2.3. How will disclosure and informed consent be managed?

J.3. Will this research involve use of a control group? ☐ Yes ☒ No o

If the answer is 'Yes' please answer J.3.1 and the following sections, otherwise please answer K.1 and continue from there.

Each participant will act as their own control.

J.3.1. How will the Control Group be managed?

J.3.2. What percentage of participants will be involved in the control group?

J.3.3. What information about the use of a control group will be given to the participants and when?

K. *Avoidance of Conflict of Interest*

Researchers have a responsibility to ensure that any conflict between their responsibilities as a researcher and other duties or responsibilities they have towards participants or others is adequately managed. For example, academic staff members who propose to involve their students as participants in research need to ensure that no conflict arises between their roles as teacher and researcher, particularly in view of the dependent relationship between student and teacher, and of the need to preserve integrity in assessment processes. Likewise researchers have a responsibility to ensure that any conflict of interest between participants is adequately managed for example, managers participating in the same research as their staff.

K.1. What conflicts of interest are likely to arise as a consequence of the researchers' professional, social, financial, or cultural relationships?

None

K.2. What possibly coercive influences or power imbalances are there in the professional, social, financial, or cultural relationships between the researchers and the participants or between participants (e.g. dependent relationships such as teacher/student; parent/child; employer/employee; pastor/congregation etc.)?

We will not be recruiting students or patients associated with any of the Researchers.

K.3. How will these conflicts of interest, coercive influences or power imbalances be managed through the research's design and practice and how will any adverse effects that may arise from them be mitigated?

K.4. Does your project involve payments or other financial inducements (including koha, reasonable contribution towards travel expenses or time, or entry into a modest prize draw) to participants? ☒ Yes ☐ No

If the answer is 'Yes' please answer K.4.1 and the following sections, otherwise please answer K.5 and continue from there.

K.4.1. What form will the payment, inducement, or koha take?

Supermarket Gift Card

K.4.2. Of what value will any payment, gift or koha be?

$50

K.4.3. Will potential participants be informed about any payment, gift or koha as part of the recruitment process, and if so, why and how?

Potential participants will not be advised of this gift during recruitment. Participants who agree to undertake the trial by signing the Participant Consent Form will then be advised of this gift.

K.5. Have any applications for financial support for this project been (or will be) made to a source external to ☒ Yes ☐ No

If the answer is 'Yes' please answer K.5.1 and the following sections, otherwise please answer K.6 and continue from there.

K.5.1. What financial support for this project is being provided (or will be provided) by a source external to AUT?

Student Stipend is being paid to Research Manager, Bradley Nixon and Research Assistant, Manpreet Singh is undertaking paid student internship.

K.5.2. Who is the external funder?

O2O2 FACEWEAR (Previously – Air Guard)

K.5.3. What is the amount of financial support involved?

K.5.4. How is/are the funder/s involved in the design and management of the research?

Funder is not involved in design or management of the research and will only receive aggregated and normalised findings of mask performance.

K.6. Have any applications been (or will be) submitted to an AUT Faculty Research Grants Committee or other AUT funding entity? ☐ Yes ☒ No

If the answer is 'Yes' please answer K.6.1 and the following sections, otherwise please answer K.7 and continue from there.

K.6.1. What financial support for this project is being provided (or will be provided) by an AUT Faculty Research Grants Committee or other AUT funding entity?

K.6.2. What is the amount of financial support involved?

K.6.3. How is/are the funder/s involved in the design and management of the research?

K.7. Is funding already available, or is it awaiting decision?

K.8. Do the applicant or the researchers, investigators or research organisations mentioned in Part B of this application have any financial interests in the outcome of this project?
☒ Yes ☐ No

If the response is 'Yes', please provide full details about the financial interests and how any conflicts of interest are being managed, otherwise, please respond to section K.9 and continue from there.

The company (O2O2) providing student stipend and student internship are not involved in the design or management of this study and will only receive aggregated and normalised findings of mask performance.

K.9. Are the participants expected to pay in any way for any services associated with this research? ☐ Yes ☒ No

If the response is 'Yes', please provide full details about the charges and describe how any benefits will balance the burdens involved as well as how any conflicts of interest are being managed. Otherwise please respond to section L.1 and continue from there.

L. *Respect for Property*

Researchers must ensure that processes do not violate or infringe legal or culturally determined property rights. These may include factors such as land and goods, works of art and craft, spiritual treasures and information.

L.1. Will this research impact upon property owned by someone other than the researcher?
☐ Yes ☒ Noo

If the answer is 'Yes' please answer L.1.1 and the following sections, otherwise please answer L.2 and continue from there.

L.1.1. How will this be managed?

L.2. How do contexts to which copyright or Intellectual Property apply (e.g. research instruments, social media, virtual worlds etc.) affect this research and how will this be managed?

Particular attention should be paid to the legal and ethical dimensions of intellectual property. Care must be taken to acknowledge and reference the ideas of all contributors and others and to obtain any necessary permissions to use the

intellectual property of others. Teachers and researchers are referred to AUT's Intellectual Property Policy for further guidance.

This research has no impact on intellectual property as the O2O2 facemask technology is already protected by international patent.

M. *References*

Please include any references relating to your responses in this application in the standard format used in your discipline.

1. ACSM | News Releases. Acsmorg. 2017. Available at: http://www.acsm.org/about-acsm/media-room/news-releases/2011/08/01/no-hoop-dream----hooping-can-help-control-body-weight. Accessed August 9, 2017.
2. Regulation of e-cigarettes and emerging tobacco and nicotine-delivery products. Ministry of Health NZ. 2017. Available at: http://www.health.govt.nz/about-ministry/legislation-and-regulation/regulatory-impact-statements/regulation-e-cigarettes-and-emerging-tobacco-and-nicotine-delivery-products. Accessed August 10, 2017.

N. *Checklist*

Please ensure all applicable sections of this form have been completed and all appropriate documentation is attached as incomplete applications will not be considered by AUTEC.

Have you discussed this application with your AUTEC Faculty Representative, the Executive Secretary, or the Ethics Coordinator? ☒ *Yes* ☐ *No*

Is this application related to an earlier ethics application? If yes, please provide the application number of the earlier application. ☐ *Yes* ☒ *No*

Are you seeking ethics approval from another ethics committee for this research? If yes, please identify the other committee. ☐ *Yes* ☒ *No*

Section A	***Project information provided***	☒
Section B	***Research Adequacy information provided***	☒
Section C	***Project details provided***	☒
Section D	***Three Principles information provided***	☒
Section E	***Social and Cultural Sensitivity information provided***	☒
Section F	***Vulnerability information provided***	☒
Section G	***Consent information provided***	☒
Section H	***Privacy information provided***	☒
Section I	***Risk information provided***	☒
Section J	***Truthfulness information provided***	☒
Section K	***Conflict of Interest information provided***	☒
Section L	***Respect for Property information provided***	☒
Section M	***References provided***	☒
Section N	***Checklists completed***	☒
Section O.1 and 2	***Applicant and student declarations signed and dated***	☒
Section O.3	***Authorising signature provided***	☒

Spelling and Grammar Check (please note that a high standard of spelling and grammar is required in documents that are issued with AUTEC approval)

Attached Documents (where applicable)

Participant Information Sheet(s)	☒
Consent Form(s)	☒
Questionnaire(s)	☐
Indicative Questions for Interviews or Focus Groups	☐
Observation Protocols	☐
Recording Protocols for Tests	☒
Advertisement(s)	☒
Researcher Safety Protocol	☐
Hazardous Substance Management Plan	☐
Any Confidentiality Agreement(s)	☒
Any translations that are needed	☐
Other Documentation	☐

Declarations

O.1. Declaration by Applicant

Please tick the boxes below.

☒ ***The information in this application is complete and accurate to the best of my knowledge and belief. I take full responsibility for it.***

☒ ***In conducting this study, I agree to abide by all applicable laws and regulations, and established ethical standards contained in AUTEC's Applying for Ethics Approval: Guidelines and Procedures and internationally recognised codes of ethics.***

☒ ***I will continue to comply with AUTEC's Applying for Ethics Approval: Guidelines and Procedures, including its requirements for the submission of annual progress reports, amendments to the research protocols before they are used, and completion reports.***

☒ ***I understand that brief details of this application may be made publicly available and may also be provided to the University Postgraduate Centre, the University Research Office, or the University's insurers for purposes relating to AUT's interests.***

12/08/17

Signature ***Date***

O.2. Declaration by Student Researcher

Please tick the boxes below.

☐ ***The information in this application is complete and accurate to the best of my knowledge and belief.***

☐ ***In conducting this study, I agree to abide by all applicable laws and regulations, and established ethical standards contained in AUTEC's Applying for Ethics Approval: Guidelines and Procedures and internationally recognised codes of ethics.***

☐ ***I will continue to comply with AUTEC's Applying for Ethics Approval: Guidelines and Procedures, including its requirements for the submission of annual progress reports, amendments to the research protocols before they are used, and completion reports.***

☐ ***I understand that brief details of this application may be made publicly available and may also be provided to the University Postgraduate Centre, the University Research Office, or the University's insurers for purposes relating to AUT's interests.***

14/08/17

Signature ***Date***

O.3. Authorisation by Head of Faculty/School/Programme/Centre

Please tick the boxes below.

☐ ***The information in this application is complete and accurate to the best of my knowledge and belief.***

☐ ***In authorising this study, I declare that the applicant is adequately qualified to undertake or supervise this research and that to the best of my knowledge and belief adequate resources are available for this research and all appropriate local research governance issues have been addressed.***

☐ ***I understand that brief details of this application may be made publicly available and may also be provided to the University Postgraduate Centre, the University Research Office, or the University's insurers for purposes relating to AUT's interests.***

Signature ***Date***

Notes for submitting the completed application for review by AUTEC

- Please ensure that you are using the current version of this form before submitting your application.
- Please ensure that all questions on the form have been answered and that no part of the form has been deleted.
- Please provide ***one*** printed, single sided, A4, and signed copy of the application and all related documents.
- Please deliver or post to the AUTEC Secretariat, room WU406, fourth floor, WU Building, City Campus. The internal mail code is D-88. The courier address is 46 Wakefield Street, Auckland 1010. Alternatively, please hand the application to the Research Ethics Advisor in person at one of the Drop In sessions at any of the four campuses (http://www.aut.ac.nz/researchethics/resources/workshops-and-drop-inns).
- Applications should be submitted once they have been finalised. For a particular meeting it needs to have been received in the AUTEC Secretariat by midday on the relevant agenda closing day [AUTEC's meeting dates are listed in the website at http://www.aut.ac.nz/researchethics]
- If sending applications by internal mail, please post them at least two days earlier to allow for any delay that may occur.
- Late applications will be placed on the agenda for the following meeting.

MINIMAL RISK CHECKLIST

Your application may be appropriate for an expedited review if it poses no more than minimal risk of harm to participants. To assist AUTEC's Secretariat to screen the application for assignment to the correct review pathway, please complete the following checklist:

Does the research involve any of the following?

ANONYMOUS SURVEY ASSESSMENT

		Yes	No
1	The collection of anonymous and non-sensitive survey/questionnaire data only. *(If YES is checked, the application may receive an expedited review if the data is from adults and poses no foreseeable risks to participants OR where any foreseeable risk is no more than inconvenience – no further questions on this checklist need be answered.)*	☐	☒

MINIMAL RISK ASSESSMENT[1]

		Yes	No
2	Participants who are unable to give informed consent (including children under 16 years old), or who are particularly vulnerable or in a dependent situation, (e.g. people with learning difficulties, over-researched groups, people in care facilities, or patients highly dependent on medical care)?	☐	☒
3	A reasonable expectation of causing participants physical pain beyond mild discomfort, or that experienced by the participants on an every-day basis, or any emotional discomfort, embarrassment, or psychological or spiritual harm, (e.g. asking participants to recall upsetting events)?	☐	☒
4	Research processes which may elicit information about any participant's involvement in illegal activities, or activities that represent a risk to themselves or others, (e.g. drug use or professional misconduct)?	☐	☒
5	Collection of any human tissue, blood or other samples, or invasive or intrusive physical examination or testing?	☐	☒
6	The administration of any drugs, medicines, supplements, placebo or non-food substances?	☐	☒
7	An intervention of any form of exercise, or other physical regime that is different to the participants' normal activities (e.g. dietary, sleep)?	☒	☐
8	Participants who are being asked to give information of a personal nature about their colleagues, employers, teachers, or coaches (or any other person who is in a power relationship with them), and where the identity of participants or their organisation may be inferred?	☐	☒
9	Any situation which may put the researcher at risk of harm? (E.g. gathering data in private homes)?	☐	☒
10	The use of previously collected biological samples or identifiable personal information for which there was no explicit consent for this research?	☐	☒
11	Any matters of commercially sensitive information?	☐	☒
12	Any financial interest in the outcome of the research by any member(s) of the research team?	☐	☒
13	People who are not giving consent to be part of the study, or the use of any deception, concealment or covert observations in non-public places, including social media?	☐	☒
14	Participants who are in a dependent or unequal relationship with any member(s) of the research team (e.g. where the researcher is a lecturer/ teacher/ health care provider/ coach/ employer/ manager/ or relative etc.) of any of the participants?	☐	☒

[1] If "No" is checked to all items 2-14, the application's status as Minimal Risk will be checked by the Secretariat, and may be forwarded to expedited review. Applications with more than Minimal Risk (any one "yes" to questions 2-14 above), and applications where the checklist is not completed will appear on AUTEC's next agenda.