Spring 2021

Pandemic Healthcare: Face Shield Modification

Nathan Giunto
njg55@zips.uakron.edu

Sefra Manos
sdm122@zips.uakron.edu

Brandon Ross
bmr106@zips.uakron.edu

Catherine Seno
ces147@zips.uakron.edu

Catherine Howell
ceh84@zips.uakron.edu

Pandemic Healthcare: Face Shield Modification

Nathan Giunto
Biomedical Engineering
The University of Akron
Akron, Ohio
njg55@uakron.edu

Catherine Howell
Biomedical Engineering
The University of Akron
Akron, Ohio
ceh84@uakron.edu

Sefra Manos
Biomedical Engineering
The University of Akron
Akron, Ohio
sdm122@uakron.edu

Brandon Ross
Biomedical Engineering
The University of Akron
Akron, Ohio
bmr106@uakron.edu

Catherine Seno
Biomedical Engineering
The University of Akron
Akron, Ohio
ces147@uakron.edu

***Abstract*—Current face shields used in home and institutional healthcare settings create hardships for their wearers, which makes normal work routines more difficult. Recent mandates require healthcare workers to wear both surgical masks as well as plastic face shields when tending to patients. Unfortunately, the majority of face shields have been designed for hospital settings, which does not address the specific requirements for in-home therapist use. Some of the issues include their restrictive size, tendency to fog, susceptibility to glare, and sterilization and re-use issues. The team proposed to design a face shield for homecare occupational therapists that addressed their unique set of requirements. A prototype face shield was developed and tested by several stakeholders to validate performance and refine the design. The design was then iterated as required to satisfy customer requirements and create a successful final design.**

Keywords—Face Shields, Healthcare, PPE, Pandemic, Safety, Biomedical Engineering

I. Introduction

Face shields play an important role in current personal protective equipment (PPE) as face shields aid in mitigating the spread of COVID-19. However, current face shield designs are inadequate and inconvenient for the user. Therefore, the team aimed to modify the overall face shield design for in-home healthcare workers to solve the problems associated with current, marketed designs.

A. Client Issues

To determine what issues arose from current face shield designs, the team conducted multiple interviews with healthcare workers. Based on the interviews, it was determined that the main issues associated with current designs were decreased visibility, work impedance, an inability to maintain user safety, fogging, bulkiness, and inadequate facial coverage. Though the team had no specific client to work with, the team felt that current face shields were simply inadequate for in-home healthcare workers and an important area to study and improve upon.

B. Current Products

Due to the need for face shields, multiple solutions and products have been released. The first approach was a hand-made face shield which used an A4-size overhead projector (OHP) sheet [1]. Another approach was a three dimensional (3D) printed model that was released to users for free. This was done by the National Institute of Health (NIH) which established a 3D print exchange for consumers [2]. Furthermore, a multitude of companies have released face shield designs over the course of this project. One marketed face shield design was released by AlphaProtech. This face shield claimed to offer the user great peripheral vision, anti-fog, came in full-face and half-face variants, and protected the user against non-hazardous liquid splash and light particles in a controlled environment [3].

Multiple patents have also been filed due to the increase in face shield designs being released. One patent (US9949517) was for a medical face shield. The patent showed a basic face shield design that consisted of a securing band for the user's forehead, a forehead cushion to increase user comfort, and a clear, flexible shield to offer the user adequate peripheral coverage [4].

C. COVID-19

COVID-19 is a virus that commonly causes symptoms such as fever, a dry cough, tachypnea (rapid breathing), and shortness of breath. However, these symptoms can worsen and hospitalize the infected individual. In extreme cases, the virus also leads to patient death. Additionally, COVID-19 is spread through both direct and indirect means. Therefore, the virus can spread through droplet transmission, human-to-human transmission, contaminated objects, and airborne contagion [5]. Based on data released by the Center for Disease Control and Prevention (CDC), there have been over 28,000,000 cases of COVID-19 in the United States and over 500,000 deaths since the pandemic started [6]. Since this pandemic is so severe with high infection and transmission rates, it was important to design a face shield that adequately protected the user from contracting the virus.

II. User Needs

The first stage of this project was to develop a set of user requirements by using information gathered through back-

ground research and user interviews. These user requirements were then utilized for the next stage gate, or the design inputs.

A. Clinical Problem

The clinical problem was the primary input for this stage gate. The team developed a problem statement based upon what issues needed to be resolved by the team's design. The statement was as follows: "Face shields generate numerous issues such as decreased visibility, work impedance, and an inability to maintain user safety due to fogging, bulkiness, and inadequate coverage, respectively."

B. Background Research

Face shields are classified as a Class I medical device [7]. Furthermore, face shields fall into adjunctive personal protective equipment (PPE) since they are meant to be used in conjunction with other personal protective equipment [8]. Current face shields are required for healthcare workers due to current PPE standards. However, face shields do not have fully standardized guidelines and vary between organizations. For example, the Occupational Safety and Health Administration (OSHA) utilizes significantly different guidelines and categorizations for face shields when compared to other organizations such as the American National Standards Institute (ANSI) [8]. OSHA defines face shields under their Bloodborne Pathogens standard [9]. Within this standard, face masks should be worn in conjunction with eye protection devices, such as face shields, whenever splashes, spray, spatter, droplets of blood, or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated [9]. However, ANSI defines face shields from a more industrial perspective. ANSI standards specify that face shields are designed to protect from impact, optical radiation, droplet and splash, and dust and fine particles [10]. Unlike OSHA, ANSI standards do not consider bloodborne pathogens or infectious particles within their standards [8]. The FDA has also recently released guidelines on face shields and face shield use. Overall, the main function of a face shield was defined as a barrier to mucous membranes to block aerosols of bodily fluids from encountering the user [8].

In terms of the researched structural components of a face shield, these included a visor, a frame, and a suspension system [8]. Common measurements were specified at 178 mm in length for ¾ coverage and a 230 mm length for full coverage [8]. These measurements also followed a one-size-fits all approach.

C. Interviews

During this first stage, multiple interviews with healthcare workers were conducted. Those interviewed included a pediatric home-care nurse, a CVICU nurse, a NICU nurse, and a medical school student. Based on these interviews, the main consensus was that current face shields cause issues such as fogging, glare, an uncomfortable fit, insufficient facial coverage, and job impediment.

D. Development of User Requirements

Based on the background research and user interviews conducted, the team developed a set of user requirements. The requirements were that the face shield should prevent fogging, reduce glare, allow for proper user movement, minimize job impedance, and sufficiently cover the user's face.

III. Design Inputs

This gate utilized the previously discussed user needs, or customer requirements, and translated them into design inputs (engineering requirements). Additionally, the user inputs were physical and performance characteristics that were used as a basis for the device, in this case the face shield, design.

A. QFD-Phase 1

As shown in Figures A1.1 and A1.2, a Quality Function Deployment (QFD) was performed for this stage. This allowed the team to form a list of engineering and technical requirements based on the customer requirements. The QFD was an important design aspect as it created a visual comparison between the customer requirements and the engineering and technical requirements. Additionally, the QFD compared the team's proposed product to currently marketed designs and contained functional requirements derived from the customer requirements. These requirements established qualities of the device that the engineering aspects focused on. Engineering requirement target values were then derived from the functional requirements. These allowed the team to determine testing methods to ensure product goals and customer requirements were met.

B. Extraction of Engineering Requirements

To determine the engineering requirements for the team's face shield design, the customer requirements were utilized to ensure that the user needs were met. Based on the information accumulated during the interviews of multiple healthcare workers and from the conducted research, the team determined multiple user needs. It was determined that there was a need for anti-fogging and anti-glare measures, increased coverage of the face to what is currently offered in order to establish sufficient coverage, minimization of job impedance, durability, overall comfort, and manufacturability which would include low-cost methods.

To determine the engineering and technical requirements, the proposed customer requirements, as mentioned in the previous paragraph, were investigated and expanded upon. A list of engineering requirements was then developed as shown in Table A1. The engineering requirements, which were updated as the design progressed, provided the team with specific, measurable targets to reach. The determined targets were then used to develop a device that improved upon current methods to meet specific customer goals and needs. Ultimately, it was decided that the face shield would need to undergo surface modification, be adjustable to a wide range of users, utilize simple and safe disinfection methods, and maintain a simple and durable design. It was also determined that surface modification should be utilized to eliminate fogging and glare. By preventing this form of visual obstruction, it ultimately im-

proved a healthcare professional's ability to see through the device and consequently improved patient care. Face shield adjustability allowed the device to fit a wide range of users comfortably. Additionally, component disinfection and device durability have become substantial issues during the COVID-19 pandemic. This is in consequence of the strained supply chain and limited access to necessary PPE. Therefore, the device was designed to withstand multiple uses. It was also determined that the disinfecting process should be quick, convenient, space efficient, and with minimal equipment. This allows a variety of healthcare professions to use the device in multiple scenarios and locations. Therefore, the simple design developed made it easier to stack and ship the face shields and minimize the required storage space. Due to the aforementioned factors, the cost of the device decreased accordingly. A sufficient design ensured that the wearer received adequate protection and minimal job and task impedance.

C. Preliminary Risk Assessment

To determine preliminary risks associated with the face shield, a Failure Mode and Effects Analysis (FMEA), as shown in Figures A2.1 to A2.6, was created. The FMEA focused on general risks associated with typical face shields and analyzed potential failure modes and the impact these failures had on a user. The FMEA also outlined risk mitigation techniques. Severity of harm, likelihood of occurrence, and the design process's ability to detect risk were all taken into consideration to determine if action was required. If it was determined action was required, mitigation techniques were determined for each risk. Within the FMEA, three components that could fail were outlined: the visor, the frame, and the suspension system. The visor was defined as the clear shield portion of the device. Therefore, the visor portion of the face shield was responsible for adequately covering the user's face and providing proper protection while still allowing the user visibility and full functionality of their head, neck, and arms. Therefore, failure in this component could potentially result in the user becoming exposed to infectious particles, becoming unable to perform their jobs properly, and experiencing discomfort. The frame was the portion of the device that interconnected the visor and the suspension system, protruding slightly from the face. Failure of the frame could also result in potential exposure to infectious particles, an inability to perform job tasks, and discomfort. The final component, or suspension system, was the head band that secured the face shield to the user. As before, failure of this component could result in infectious particle exposure, work difficulty, and discomfort. Failure of this component could also result in complete detachment of the face shield from the user's head.

IV. Design Process

The design process stage gate consisted of utilizing the previously determined engineering requirements as constraints to create component, or part, designs for the face shield.

A. Design Selection

To select a design for the face shield, the team brainstormed different concepts. The brainstormed concepts were then discussed by the team members and a design approach was chosen. Concepts were brainstormed for anti-fog, anti-glare, and shape and coverage solutions. In terms of the anti-fog, some ideas were to use a scuba diver coating, a pre-cured film, or a material that was not prone to fogging. Anti-glare approaches included a polarizable film, Glare Buster, which is an anti-glare product that is currently available on the market, or sending the face shield out to be pre-cured. There were also multiple ideas in terms of the face shield's shape and coverage. These included attaching the face shield to the neck of the user, goggles with a visor that attached to the bottom of them, an integrated shield that had goggles built into it, and an overall rounder design that curved to the user's face.

Based on the generated concepts, and evaluation using the QFD, the team decided that goggles with a face shield that extended down to protect the user's face were the best design option. This was because, based on the interviews conducted during the user needs phase, the users indicated that they preferred goggles to the typical face shield. Additionally, the team decided to use a material that was already resistant to glaring and fogging during use.

B. QFD-Phase 2

For this stage, a QFD was also developed as shown in Figures A3 and A4. Figure A3 displays the design concept QFD created, and Figure A4 is the parts design matrix that was developed for this stage. The purpose of the QFD during this stage was to outline conceptual design approaches that met the engineering requirements developed in the prior QFD. Additionally, the QFD provided a visual comparison of conceptual designs so that an appropriate design approach could be selected that met the engineering requirements.

C. Design FMEA

A Design Failure Mode and Effects Analysis (DFMEA) was created for this stage as shown in Figures A5.1 to A5.4. Like the FMEA developed during the design inputs stage, the DFMEA outlined potential failure modes and risks associated with the face shield. The DFMEA encompassed the same requirements as the FMEA and included a risk ranking based on failure severity. However, the DFMEA focused on the proposed conceptual design. Furthermore, it outlined three different components as the overall conceptual design changed. These components included the goggles with a visor extension, the supportive band, and the surface modified lenses/visor extension. The DFMEA encompassed the same requirements as the FMEA and included a risk ranking based on failure severity.

D. Preliminary Specifications

To develop preliminary specifications for the face shield design, the parts design matrix shown in Figure A4 was created. It used the engineering requirements as the inputs. This information was then used to select critical part requirements and to examine relationships between the engineering requirements and design components. Specifications were then determined for the critical part requirements. These specifications were de-

termined based on current, marketed products as the team's design needed to be equivalent to, or surpass, these designs.

V. Design Outputs

The design outputs stage gate ensured the team's design was adequate before proceeding to build the final device and prepared the team for the final stage of the design process.

A. Device Specifications

Device specifications that were important to device performance were developed in this gate. Since the device was developed for in-home healthcare workers, it was important that it provided adequate protection from respiratory droplets and met PPE guidelines. To prevent glare and fogging of the face shield, polycarbonate was chosen as it was pretreated to prevent these issues. To prevent work impedance, a curved design was developed that tapered closely to the user's face. To solve the issue of inadequate coverage, the curved design was developed, and goggles were chosen that fully protected the user's eyes. Lastly, to ensure the device was secure on the user, a neoprene band was attached to the safety goggles that was adjustable to the user. In terms of dimensional specifications, the polycarbonate goggles were 228.6 x 104.14 x 86.36 millimeters and 226.8 grams. The face shield attachment was 252.3 x 228.6 x 1.59 millimeters and designed to be below 150 grams.

B. Part Selection Process

To select parts for the final design of the face shield, decision matrices were created. As seen in Figure A6, a decision matrix for the safety goggles was created. It listed important criteria such as comfort, anti-fog, ventilation, cost, and strap material. Based on these properties, each pair of goggles was rated and the goggles with the highest score were chosen for the device. Figure A7 is the decision matrix that was created to choose the thermoplastic material being used for the face shield extension. It included criteria such as moldability, material clearness, durability, cost, and toxicity. Once again, criteria were ranked based on importance and a material was chosen based upon the highest score.

C. 3D Models and Drawings and Preliminary Prototype

Part and assembly drawings of the device were created for this stage of the design process. In Figure A8, it displays the dimensioned Solidworks part drawing of the created face shield attachment. Figure A9 shows the assembly drawing of the face shield attached to the goggles. These drawings were utilized to develop a model of the device before constructing it.

D. Bill of Materials (BOM)

Based on the selected parts and materials, a bill of materials (BOM) was created. It listed the parts and their respective costs. This was also utilized to determine the total cost of the project which was $43.57. The BOM can be seen in Figure A10.

E. Analytical Modeling and Calculations

To analyze whether the design could withstand being dropped, and whether it sufficiently protected the user, Solidworks and ANSYS simulations were utilized. Figure A11 displays the conducted Solidworks drop test. This test was conducted on both the face shield attachment and the assembly. By simulating a drop from a 2-meter height, it determined that a user could drop the device and it would be able to withstand the impact force. The ANSYS model in Figure A12 simulated whether the design would successfully act as a barrier to respiratory droplets, which was perhaps one of the most important goals of this device.

F. Design FMEA Risk Assessment

For this stage of the design process, the design FMEA was updated. It was changed to have the face shield component as its own part rather than considering it as a system with the goggles. The terminology was also updated so that the prevention of infectious particle exposure was not 100% guaranteed as no face shield can guarantee full protection of a user. The new section from the updated design FMEA is shown in Figures A13.1 and A13.2.

VI. Design Verification

Design verification was part of the design outputs design stage. Verification was used to ensure that the design outputs met the input requirements. To verify the design, calculations, Solidworks, and vendor specifications were utilized. In terms of verification calculations, the weight of the polycarbonate was found, and surface reflections were calculated. First, the weight of the polycarbonate used for the face shield attachment was calculated by multiplying the density of polycarbonate by the attachment's volume. Additionally, the face shield attachment was treated as an idealized rectangle.

$$\begin{aligned}\text{Volume} &= \text{length} * \text{width} * \text{thickness} \\ &= 16.5\ \text{cm} * 15.2\ \text{cm} * 0.158\ \text{cm} \\ &= 39.63\ \text{cm}^3\end{aligned}$$

The weight of the face shield in grams was then calculated by multiplying the density of polycarbonate by the previously determined volume.

$$\begin{aligned}\text{Weight} &= \text{density} * \text{volume} = \frac{1.22\ \text{g}}{\text{cm}^3} * 39.63\ \text{cm}^3 \\ &= 48.35\ \text{g}\end{aligned}$$

This value overestimated the weight of the face shield slightly since it assumed a rectangular shape. Therefore, it was safe to assume the face shield would be below the calculated weight. The surface reflection was then calculated using Snell's law and the Fresnel equations. By using Snell's law, as shown below, the angle of refraction of light through the polycarbonate could be calculated using the angle of incidence and the refractive index of the two materials.

$$n_1 \sin\theta_1 = n_2 \sin\theta_2$$

where n was the refractive index of the material and Θ was the incident angle. To calculate the refractive angles, incident angles of 0, 30, 45, and 60 degrees were used where n_1 was 1, or

the refractive index of air, n_2 was 1.59, or the refractive index of polycarbonate, Θ_1 was the incident angle, and Θ_2 was the desired refractive angle.

0˚:

$$1\sin(0) = 1.59\sin\theta_2$$
$$\theta_2 = 0°$$

30˚:

$$1\sin(30) = 1.59\sin\theta_2$$
$$\theta_2 = 18°$$

45˚:

$$1\sin(45) = 1.59\sin\theta_2$$
$$\theta_2 = 26°$$

60˚:

$$1\sin(60) = 1.59\sin\theta_2$$
$$\theta_2 = 33°$$

The calculated refractive angles were then inputted into Fresnel's equations, shown below, to calculate reflectance for natural, unpolarized light.

$$R_s = \frac{n_1\cos\theta_i - n_2\cos\theta_t}{n_1\cos\theta_i + n_2\cos\theta_t}$$
$$R_p = \frac{n_2\cos\theta_i - n_1\cos\theta_t}{n_2\cos\theta_i + n_1\cos\theta_t}$$
$$R_{eff} = \frac{1}{2}(R_s + R_p)$$

where R_s is the reflectivity of perpendicular polarized light, R_p is the reflectivity of parallel polarized light, Θ_i is the incident angle, Θ_t is the refractive angle, and R_{eff} is the effective reflectivity.

0˚:

$$R_s = \frac{1\cos(0) - 1.59\cos(0)}{1\cos(0) + 1.59\cos(0)} = 5.18\%$$
$$R_p = \frac{1.59\cos(0) - 1\cos(0)}{1.59\cos(0) + 1\cos(0)} = 5.18\%$$
$$R_{eff} = \frac{1}{2}(5.18 + 5.18) = 5.18\%$$

30˚:

$$R_s = \frac{1\cos(30) - 1.59\cos(18)}{1\cos(30) + 1.59\cos(18)} = 7.33\%$$
$$R_p = \frac{1.59\cos(30) - 1\cos(18)}{1.59\cos(30) + 1\cos(18)} = 3.38\%$$
$$R_{eff} = \frac{1}{2}(7.33 + 3.38) = 5.35\%$$

45˚:

$$R_s = \frac{1\cos(45) - 1.59\cos(26)}{1\cos(45) + 1.59\cos(26)} = 11.32\%$$
$$R_p = \frac{1.59\cos(45) - 1\cos(26)}{1.59\cos(45) + 1\cos(26)} = 1.28\%$$
$$R_{eff} = \frac{1}{2}(11.32 + 1.28) = 6.3\%$$

60˚:

$$R_s = \frac{1\cos(60) - 1.59\cos(33)}{1\cos(60) + 1.59\cos(33)} = 20.66\%$$
$$R_p = \frac{1.59\cos(60) - 1\cos(33)}{1.59\cos(60) + 1\cos(33)} = 0.07\%$$
$$R_{eff} = \frac{1}{2}(20.66 + 0.07) = 10.4\%$$

Since all calculated effective reflectivities were below 10%, they passed this portion of verification testing. Solidworks was utilized to dimension the model within the design specifications set by the team. Additionally, it was used to perform drop testing as shown in Figure A11. This was done to ensure the device could be dropped by the user and withstand the impact force. All other specifications were verified based on values given by the vendor. Based on the verification testing done by the team, the design met the engineering requirements. As shown in Table 1 below, the design passed when tested for the specifications listed. A more detailed verification table is shown in Figure A14.

Table 1. Summary of design verifications results

Design Specifications	Pass or Fail
Less than 150 grams	Pass
165 mm long by 152 mm wide	Pass
No more than 10% surface reflection (R_{eff}) at incident angles of 0, 30, 45, and 60 degrees	Pass
Light transmission greater than 85% at an incident angle of 0 degrees	Pass
Thickness of 2.54 mm or less	Pass
Strap tensile strength greater than or equal to 3.45 MPa	Pass
Inert material for face shield	Pass
Inert material for strap	Pass
Durable enough to withstand multiple uses, including potential drops from user height	Pass
Able to be sanitized	Pass

VII. Medical Device

This design stage was the final stage of the design process. In the medical device stage, the design outputs were utilized to fabricate a beta prototype. To create the prototype, a polycarbonate (PC) sheet was cut to a size of 16.5 cm by 15.2 cm with a bandsaw. The cut of piece of PC was then angled past the intended curvature. This was because thermoformed PC loses some of its curvature while it is cooling. By over-angling the plastic, it ensured that the result matched the intended angle. Next, the PC sheet was held in place with a large clamp. Heat was then applied with a heat gun to both sides of the sheet for five minutes to thermoform the material. Once the molded plastic cooled, a bead of epoxy was placed across the top of the face shield attachment and the bottom of the goggles. Then, it was held in place for 20 minutes to allow the epoxy to cure. Photos of the prototype are shown in Figure 1 below.

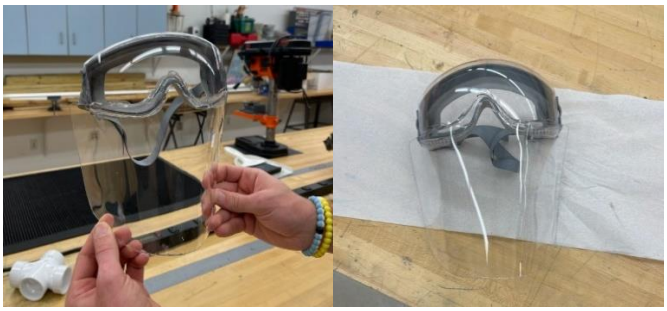


Figure 1. Face shield prototype created by the team

Once the prototype was completed, it underwent validation testing to ensure the design met the user requirements set at the beginning of the project. Additionally, a demonstration video of the completed prototype can be found at the following link: https://www.youtube.com/watch?v=VBTqoRx0Hvo.

VIII. Validation Testing

Before validation testing began, a validation plan was developed so that the team could test the device against the customer needs. The plan was developed so the team knew what process would be followed when testing the device. This plan is shown in Figure A15. After creating a plan, the device was tested for anti-fog, anti-glare, task impedance, comfort, and facial coverage or protection. To test anti-fog, an overall fog percentage area was evaluated. To do so, the face shield was placed in a refrigerator for one hour. Then, the device was moved to a room temperature environment. The fog level was then estimated, and the device passed if 0-25% of the face shield was covered by fog. The device passed this test as the goggles did not fog and the user's vision would not be obstructed. The next test was anti-glare. To test this validation portion, the user wore the face shield and reported whether glare was obstructing one's vision. The device passed this validation test as well. The third validation test was task impedance. To test this, the user was asked to wear the face shield and move one's head in all directions to determine range of motion and identify any mobility issues. The device failed this portion of validation testing. However, issues reported were due to how the prototype was built, and these issues would not occur if the device had been machine created. The fourth test was the comfort of the device. The user was asked to wear the face shield for a minimum of 15 minutes and provide feedback on comfort on a one to ten scale. The device passed this portion of testing. The final validation test was facial coverage and protection. To test this, the device was placed on a mannequin head wrapped in tissue paper. The setup was then sprayed with water through a fan. The device passed if below 30% of the tissue paper encountered the droplets. The device passed this test as well. Overall, the device performed as expected and device failure was only due to limitations with the design building process. The validation testing plan table, validation procedure, and validation results are shown in Figures A16-18.

IX. Risk Mitigation Process

A risk mitigation table was created to address how the overall benefits of the device would outweigh the residual risks. To identify risks posed by the device, the team brainstormed hazards and potential failure mechanisms that could occur. To do so, each component of the device was evaluated in terms of how it could break or fail so that the team could determine how to sufficiently protect the user when encountering infectious particles. The key risks identified included various components, such as the headband, goggles, face shield attachment, and the device, breaking. Other risks included improper fit, visual impairment, device degradation, bacterial growth, and allergic reactions to the materials in the device. To mitigate these risks, the team utilized flexible, oil and water resistant, durable, antimicrobial, and hypoallergenic materials. Additionally, a clasp mechanism was integrated into the goggles to ensure the headband and goggles were secure. If there was a failure that occurred in the headband of the device, a replacement band could be sold to the user. Since the created device was a prototype, there was still room for improvement in the creation of the device and face shield and goggle attachment methods. For the face shield, the overall benefits outweighed the risks because the device provided the user with increased comfort when compared to current products on the market while maintaining the same level of protection. The risk mitigation summary table is shown in Figure A19.

X. Marketing and Manufacturing Considerations

Since this face shield was designed for in-home healthcare workers, this is the population that the device will be marketed to. In 2019, there were 3,439,700 home health and personal care aide jobs available. This is an ever-expanding field with a projected job growth of 34%. By 2029, there is a projected employment of 4,599,200 positions [11]. Since face shields are a required form of PPE, it is expected that each worker will purchase at least one face shield. Due to the COVID-19 pandemic, the global revenue from face shield sales was over $1.7 billion in 2019 [12]. Additionally, in the United States, polycarbonate face shields can vary widely in price. For example, a reusable face shield from Honeywell costs $27.95 [13]. The team's face shield has an expected manufacturing cost of below $15.00, and a projected sale price of $30. Based on these projected costs, the price will be competitive with current products on the market.

XI. Summary Feasibility Discussion

Based on the results obtained during the medical device stage of design development, the face shield satisfied the need identified at the beginning of the effort. Though the prototype did not pass the task impedance portion of validation testing, this would be easily solvable by using machines to construct the device rather than having team members create it by hand in the workshop. Though the device manufacturing process could be improved, the team categorized the device as a prototype because it exhibited the intended form, fit, and function of the final goal product.

XII. Discussion, Lessons Learned, and Conclusions

The overall design of this device was simple. Therefore, the simplicity meant constant updating of the engineering requirements. Additionally, more specifications were required for the course, and these had to be added as the device design became more specific. Since the design process took place over one academic year, face shield designs were constantly changing and conforming to new standards, such as utilizing metric units for the finalized design. Because of this, the team's design had to constantly be updated and improved upon.

During the design process, the main issue arose during device prototyping. Due to the lack of commercial machinery available, it was difficult to execute a standardized design that fit the exact requirements specified at the beginning of the design process. Though the beta prototype was fully functional, there was room for improvement in the production process as noted by user feedback during the design validation process. It is also important to note that the team did not have a specific client for the device, and mitigated issues had to be determined by team members.

XIII. Future Work

Based on the final prototype, improvements could be made to the attachment method between the face shield and goggle components. As mentioned earlier, there are also improvements to be made with the final production process for the device. This is because issues arose when attaching the polycarbonate face shield to the goggles. If a commercialized manufacturing process was made available, it would solve this issue. This is because the device specifications would be more precise when utilizing commercial methods, such as injection molding, to create the product. Furthermore, a commercialized process would reduce the task impedance associated with the current prototype.

XIV. Individual Roles and Responsibilities

Throughout the project, all team members were expected to maintain their respective responsibilities. Accountability, documentation, and development of a project are skills that will be helpful, regardless of how each group member chooses to continue after graduation. Work was divided equally among individuals in order to maintain a constant and efficient workflow. During the project, all members recorded their contributions in the Team Worklog, continually updated the Table of Contents, aided in editing the Honors Report, and helped to create a device demonstration video.

a. Nathan Giunto

Nathan Giunto established an initial connection with the homecare customer to figure out customer requirements. He constructed the original alpha prototype which served as a good guideline for the direction that the beta prototype was designed in. He also helped construct the beta prototype and took it to the original customers for validation testing. Throughout each of the gates he contributed to the documentation for each gate throughout the duration of the project.

b. Catherine Howell

During the beginning stages of the project, Catherine's contributions consisted of research pertaining to the current standards, definitions, and regulations of face shields in healthcare. Face shields were found to be classified as a class I medical device, and standards regulating their use varied between organizations. A key characteristic of face shields that came out of this research was that they were meant to be used in conjunction with other PPE and not meant to be a standalone device for protection against infectious particles. In Gates 2 and 3, Catherine assisted with the development of multiple FMEAs, as well as organization of PowerPoint presentations. During Gate 4, Catherine's main contributions were in developing a bill of materials, decision matrices for parts, verifications for design inputs, and an initial validation plan to carry into Gate 5. Additionally, Catherine oversaw 3D printing the Solidworks models designed for the project. During Gate 5, this member contributed to the final beta prototype creation using the materials decided upon in Gate 4. Additionally, she was involved in validation testing of the product and documentation of the results.

c. Sefra Manos

During the initial stages of the project, this member aided in research pertaining to the project. Additionally, this member constructed the first FMEA, the second FMEA, or DFMEA, created the Gate 4 PowerPoint, organized the team and the Design History Files (DHF), helped construct the Honors Report, and finalized all team documents.

d. Brandon Ross

During the initial stages of the project, Brandon's contributions consisted of research into how the healthcare field was dealing with the COVID-19 pandemic. Face shields emerged as a big focus of this research. In Gate 2 and Gate 3, Brandon assisted with the development of multiple QFDs. The honors proposal was also worked on around this time. Brandon helped write the rough draft of the proposal. During Gate 4, Brandon's focus was analytical modeling. An ANSYS model of fluid flow around the face shield assembly was modeled. Brandon's Gate 5 contributions consisted of risk analysis.

e. Catherine Seno

When the project first began, Catherine's contributions included brainstorming ideas for the pandemic healthcare problem we were looking to solve. It also included research into what was currently on the market for face shields, and what was lacking. Catherine also conducted multiple interviews of medical professionals to get a better understanding of the issues they were facing regarding face shields, and what improvements they would like to see. Moving forward, Catherine helped to create multiple QFDs, as well as multiple gate review presentations. For Gate 4, she created the Solidworks models and drawings based on the decision matrices completed by the group regarding the goggles of choice.

XV. Professional and Ethical Responsibilities

The team's design considered how wasteful disposable face shields are. By throwing out a face shield after one use, this greatly increases the amount of plastic being put into the environment. Additionally, even if the polycarbonate being used is

biodegradable, it can still take hundreds of years to naturally decompose [14]. Therefore, to make a more environmentally friendly product, the team decided that the face shield should be reusable. Though the design still utilizes polycarbonate, much less of it will be disposed of since it can be used multiple times.

The team also considered economic and global impacts when designing this device. Due to the COVID-19 pandemic, PPE has become a requirement for healthcare workers. This makes face shields an added expense, and they should, therefore, be as inexpensive as possible. Protecting the user from COVID-19 was also an important consideration as this is a serious virus that ultimately should be prevented as much as possible. Furthermore, the sooner that this virus is overcome, the sooner society can begin to go back to a pre-virus lifestyle.

XVI. Acknowledgments

The team would like to thank Dr. Keszenheimer for working with the team throughout the design process and ensuring a successful project. Thanks are also extended to Mr. Paterson for working with the team during the prototyping process. Additionally, the team is grateful for the time put in by Dr. Alhalawani and Dr. Mahajan for taking the time to read this report throughout the project. Finally, the team would like to thank everyone who agreed to do interviews.

References

[1] Ino, Y., Yano, T., & Yamamoto, H. (2020). A new simple method of handmade face shield using A4-size OHP sheet, during the COVID-19 pandemic. *Digestive Endoscopy*, 32(5). doi:10.1111/den.13724

[2] DtM-v3.1 Face Shield PPE, 3D printable headband NO LOGO. (n.d.). Retrieved September 28, 2020, from https://3dprint.nih.gov/discover/3dpx-013359

[3] Critical Cover® Coverall® Face Shields. (n.d.). Retrieved September 28, 2020, from http://www.alphaprotech.com/product/166.aspx?catid=50

[4] PatSnap. (n.d.). Medical face shield. Retrieved September 28, 2020, from https://patents.patsnap.com/v/US9949517-medical-face-shield.html

[5] Lotfi, M., Hamblin, M. R., & Rezaei, N. (2020). COVID-19: Transmission, prevention, and potential therapeutic opportunities. *Clinica chimica acta; international journal of clinical chemistry*, *508*, 254–266. https://doi.org/10.1016/j.cca.2020.05.044

[6] CDC COVID Data Tracker. (n.d.). Retrieved March 03, 2021, from https://covid.cdc.gov/covid-data-tracker/#global-counts-rates

[7] US Food and Drug Administration. Issuance: Manufacturers of Face Shields;.2020.Available from: https://www.fda.gov/media/136842/download.

[8] Roberge, R. J. (2016). Face shields for infection control: A review. *Journal of Occupational and Environmental Hygiene, 13(4)*, 235-. doi:10.1080/15459624.2015.1095302

[9] Occupational Health and Safety Administration (OSHA) : "Blood Borne Pathogens Standard 1910.1030." Available at https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051 (accessed October 31, 2020).

[10] International Safety Equipment Association Eye and face protection selection tool. Available at https://www.safetyequipment.org/userfiles/File/Eye%20and%20Face%20Selection%20Guide%20tool(1).pdf (accessed October 31, 2020).

[11] Home health and personal Care aides : Occupational Outlook Handbook. (2021, March 08). Retrieved March 20, 2021, from https://www.bls.gov/ooh/healthcare/home-health-aides-and-personal-care-aides.htm

[12] Global face Shields market SIZE: Industry REPORT, 2020-2027. (n.d.). Retrieved March 20, 2021, from https://www.grandviewresearch.com/industry-analysis/face-shields-market

[13] Honeywell FACESHIELD Assembly, RATCHET Adjustment Suspension, black Frame, Clear lens - RWS-51032. (n.d.). Retrieved March 20, 2021, from https://www.honeywellstore.com/store/products/honeywell-adjustable-faceshield-rws-51032.htm?gclid=Cj0KCQjwutaCBhDfARIsAJHWnHvwcE6KPzinsLYkoweA1Tafoem3bhqt1WGxnM--jrxDvLGRtzA3OogaAgKBEALw_wcB

[14] Polycarbonate (PC). (n.d.). Retrieved March 22, 2021, from https://www.goecopure.com/biodegradable-polycarbonate-pc-plastic.aspx

APPENDIX A

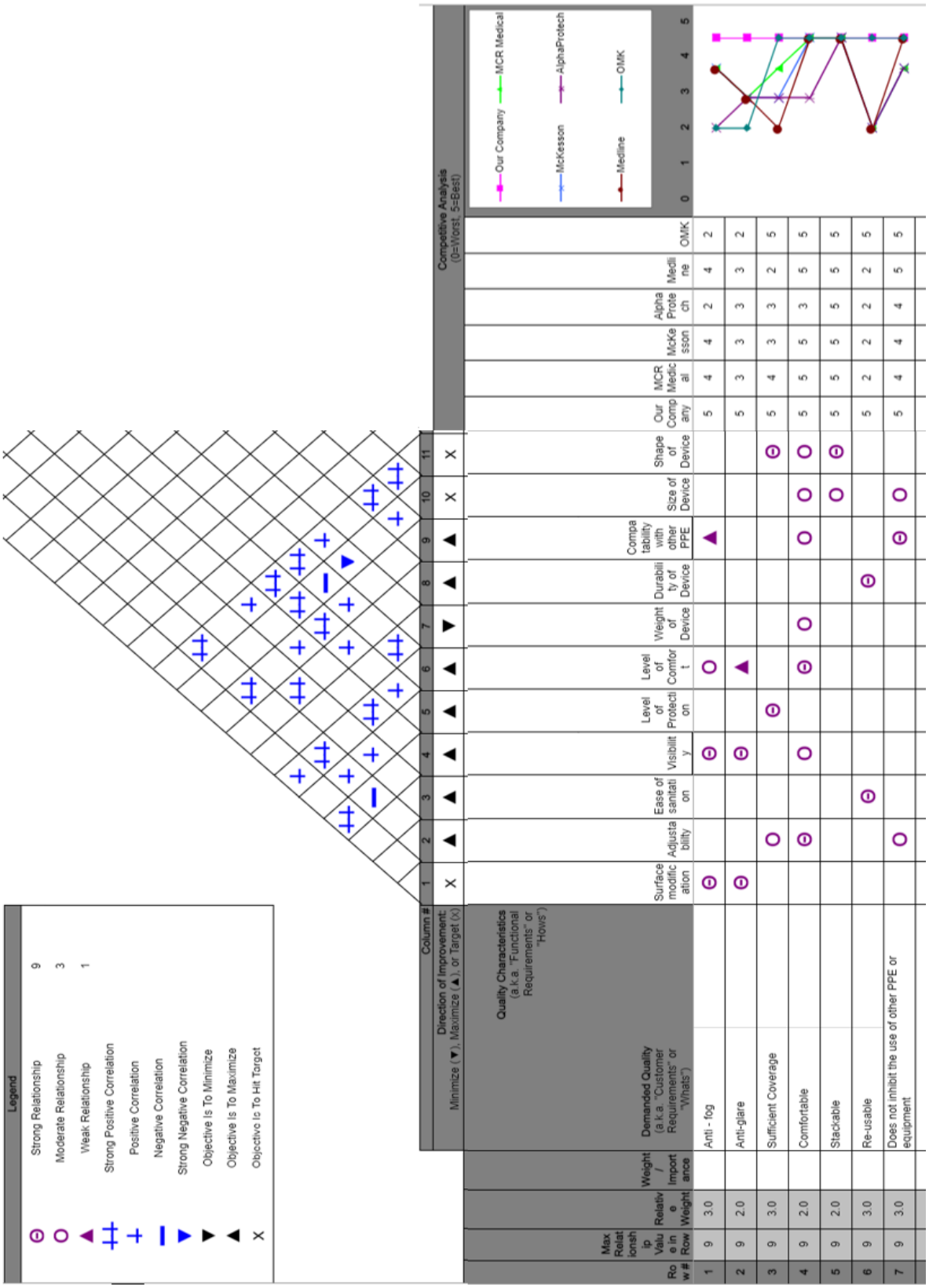


Figure A1.1 QFD for design inputs stage gate

Target or Limit Value	Anti-fog, anti-glare	At least three sizes	Sanitation must be possible in a small space (such as a car) in a complete manner in under 7 minutes	90% visibility, anti-fog, anti-glare	Complete coverage of the face, prevent droplets from entering any side of the shield	On a scale of 1-10 averages at least a 7 amongst interviewed users	Less than 150 grams	Withstand at least 10 uses	Does not inhibit the use of other PPE	Dimension: 178mm-230mm long, 230mm-305mm wide	Must not impede the completion of tasks
Difficulty (0=Easy to Accomplish, 10=Extremely Difficult)	8	4	3	8	9	9	8	7	8	6	8
Max Relationship Value in Column	9	9	9	9	9	9	3	9	9	3	9
Weight / Importance	45.0	36.0	27.0	51.0	27.0	29.0	6.0	27.0	36.0	21.0	51.0
Relative Weight	12.6	10.1	7.6	14.3	7.6	8.1	1.7	7.6	10.1	5.9	14.3

Figure A1.2 QFD (continued) for design inputs stage gate

Table A1. Engineering requirements determined from user needs

Engineering Requirements
Face shield weighs less than 150 grams
Face shield is 165 mm long by 152 mm wide
Below 10% surface reflection at incident angles of 0, 30, 45, and 60 degrees
Light transmission greater than 85% at a 0-degree incident angle
Face shield thickness at or below 2.54 mm
Strap tensile strength greater than or equal to 3.45 MPa
Face shield material is inert and biocompatible
Durability: the device can withstand multiple uses and potential drops
The device can be easily sanitized

No	Part Assembly Name	Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) Mechanism(s) of Failure	OCC	CLASS
1	Visor	Cover and protect user's face, including peripheral coverage	Visor breaks or bends	User no longer has adequate facial coverage	3	Overuse or improper use of face shield, improper fitting, or defective components.	3	KC
				Potential exposure to infectious particles				
			Visor degrades overtime	User no longer has adequate facial coverage	2	Overuse or long-term use	2	AO
				Potential exposure to infectious particles				
			Visor is not secure/ experiences movement	User no longer has adequate facial coverage	3	Wear in head strap mechanism	2	AO
				User experiences inconvenience/ nuisance in doing their job				
				User experiences discomfort				
				Potential exposure to infectious particles				
		Act as a window for user to be able to visualize the environment	Visor is impaired visually	User experiences inconvenience/ nuisance in doing their job	2	Patient bodily fluids dry onto outside of visor	3	AO
				User experiences discomfort.				
			Visor coating causes a biological hazard	User may experience a reaction due to biological hazard.	3	Allergies to surface modification material	2	AO

Figure A2.1 FMEA for design inputs stage

No	Part Assembly Name	CLASS	Suggested Mitigations	Verification	DET	RPN	Recommended Actions	Acting results				
								SEV	OCC	DET	CLASS	RPN
1	Visor	KC	Proper evalution of quality assurance process to decrease likihood of defective components and to ensure quality of sizes available to user	Repeat mechanical testing to simulate daily usage	10	90	Use a more flexible material or one that is less prone to breakage under limited applied force	2	2	10	AO	40
		AO	Use a durable material, rated for long-term use (up to 6 months) that is not likely to degrade	Utilize repetitive strength testing to determine life of shield and amount of degradation over time	8	32	Use a more wear-resistant material with increased flexibility	1	2	8	AO	16
		AO	Use a durable head strap material such as flexible plastic that can be adjusted using a clasp, rather than elastic that will wear over time	Test sizing between individuals and ensure a multi-fit design that fill snugly fit multiple individuals	9	54	Make sure visor has a better attachment that reduces movement	1	2	9	AO	18
		AO	Use an antimicrobial coating on the outside of the visor, give guidelines to user on how to properly sanitize and handle outside of visor after use	Test sanitization methods and various coatings that will clean the visor and keep it clean	8	48	Use a material that is oil/water-resistant to prevent sticking of fluids. Material could also be easily cleanable	1	2	8	AO	16
		AO	Use a hypoallergenic material for the surface coating	Research allergens and carcinogens, especially for users with high sensitivities	5	30	Use allergen-free/ hypoallergenic coating	1	1	5	AO	5

Figure A2.2 FMEA (continued) for design inputs stage

No	Part Assembly Name	Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) Mechanism(s) of Failure	OCC	CLASS
2	Frame	Responsible for holding and supporting the visor	Frame breaks	Visor is potentially no longer in place and sufficient coverage is lost	3	Overuse or improper use of face shield, improper fitting, or defective components.	2	AO
			Frame causes a biological hazard	User contracts infection	4	Improper sanitization methods	1	AO
			Frame is not secure, experiences movement	User may experience discomfort and skin damage	2	Improper fitting of frame, misuse, or defective components	2	AO

Figure A2.3 FMEA (continued) for design inputs stage

No	Part Assembly Name	Suggested Mitigations	Verification	DET	RPN	Recommended Actions	Acting results				
							SEV	OCC	DET	CLASS	RPN
2	Frame	Use a durable material rated for long-term use (6 months), properly evaluate quality assuracne program to decrease liklihood of defective components	Utilize mechanical testing in multiple trials to find breaking point	10	60	Use flexible material that is resistant to breaking	2	1	10	AO	20
		Give guidelines to user on how to properly sanitize and handle the frame after use, use an antimicrobial coating on the frame	Measure how long it takes toxic cleaners to dry in a variety of situations	5	20	Use non-toxic cleaning products or make component virus/bacteria resistant	2	1	5	AO	10
		Proper evalution of quality assurance process to decrease liklihood of defective components and to ensure quality of sizes available to user	Test sizing between individuals and ensure a multi-fit design that fill snugly fit multiple individuals	8	32	Use a more secure attachment component or method	1	1	8	AO	8

Figure A2.4 FMEA (continued) for design inputs stage

No	Part Assembly Name	Function	Potential Failure Mode	Potential Effect(s) of Failure	SEV	Potential Cause(s) Mechanism(s) of Failure	OCC	CLASS
3	Suspension System	Attaches to frame to suspend the visor/frame on the user	Breaks or bends	Does not adequately support frame and visor	3	Overuse or improper use of face shield, improper fitting, or defective components.	4	KC
			Fails to suspend visor/frame	Fails to provide adequate coverage	3	Unstable clasp/latch/fit mechanism	2	AO

Figure A2.5 FMEA (continued) for design inputs stage

No	Part Assembly Name	Suggested Mitigations	Verification	DET	RPN	Recommended Actions	Acting results				
							SEV	OCC	DET	CLASS	RPN
3	Suspension System	Use a durable material rated for long-term use (6 months) to create the suspension system, proper evaluation of quality assurance program to decrease liklihood of defective components	Complete multiple tensile tests to ensure system integrity and simulate daily use	10	120	Use a wear-resistant or stronger component	1	1	10	AO	10
		Use a durable material rated for long-term use (6 months) to create the latch for the suspension system, design a clasp/latch with minimal stress points to decrease liklihood of breakage over time	Complete multiple tensile tests to ensure system integrity and simulate daily use	8	48	Use a material that is less prone to breaking or one that is stiffer to properly support visor frame	1	1	8	AO	8

Figure A2.6 FMEA (continued) for design inputs stage

		Design Concepts														
Concept Requirements		Concept	A1	A2	B1	B2	B3	C1	C2				(A) Shape		(B) Anti-Fog		(C) Anti-Glare	
Surface Modifications			NA	NA	+	+	+	+	+	+	Better		A1	Goggle Shield	B1	Surface modification - Chemical Treatment	C1	Polarizable film
Adjustibility			+	-	NA	NA	NA	NA	NA	-	Worse		A2	Wider visor	B2	Surface modification - SCUBA diver coating	C2	Precured film
Ease of Sanitation			-	S	NA	NA	NA	NA	NA	S	Same				B3	Surface modification - Permanent film		
Visibility		Datum	S	S	+	+	+	+	+	NA	Not Applicable							
Level of Protection			+	+	S	S	S	S	S									
Level of Comfort			S	S	S	S	S	S	S									
Weight of Device			S	+	S	S	S	S	S									
Durability of Device			+	-	-	-	-	+	+									
Compatability with other PPE			+	-	NA	NA	NA	NA	NA									
Size of device			S	+	NA	NA	NA	NA	NA									
Shape of device			+	+	NA	NA	NA	NA	NA									
	+		5	4	2	2	2	3	3									
Totals	-		1	3	1	1	1	0	0									
	S		3	3	3	3	3	3	3									

Figure A3. QFD for design process with design concepts

			The Part Planning Matrix						
			Shape					Visibility	
		Input Requirements	Width	Comfort	Venntillation	Range of Motion	Material	Anti-Fog	Anti-Glare
Relationship	**Symbol**	Surface Modifications						●	●
Strong	●	Adjustibility	○	○	○	●			
Weak	○	Ease of Sanitation	○				●	○	○
		Visibility	●		●			●	●
		Level of Protection	●		●	○			
		Level of Comfort	○	●	○	●	●	○	○
		Weight of Device	●	○					
		Durability of Device					●	●	○
		Compatability with other PPE		●		●		○	○
		Size of device	●	●		●			
		Shape of device	●	●	●	●	○		
		Specifications	10 in.	Rating of 7+	2.6-3.9 L/s	Hor. Vert. 120º	Inert	Less than 15% coverage of face shield in standard temperature and humidity conditions	Less than 2% surface reflection

Figure A4. Design process QFD parts design matrix

No	Part Assembly Name	Function	Potential Failure Mode	Potential Effect(s) of Failure	Potential Cause(s) Mechanism(s) of Failure	SEV	OCC	CLASS
1	Goggles with Visor Extension	Cover and protect user's face, including peripheral coverage	System breaks or bends	User no longer has adequate facial coverage	Overuse or improper use of face shield, improper fitting, or defective components.	8	4	AO
				Potential exposure to infectious particles				
			Degradation of joint between the lenses and visor extension	User no longer has adequate facial coverage	Overuse or long-term use	7	4	AO
				Potential exposure to infectious particles				
			Accumulation of bacterial growth	User contracts infection	Degradation in antibacterial coating or not secure on user. Could also be due to a defective componenent	9	5	KC
			User experiences allergic reaction to material	Skin irritation	Allergenic material	4	2	AO
			System is not secure/ experiences movement	User no longer has adequate facial coverage	Wear in system or improper fitting	3	5	AO
				User experiences inconvenience/ nuisance in doing their job				
				User experiences discomfort				
				Potential exposure to infectious particles				
		Act as a window for user to be able to visualize the environment	User is impaired visually	User experiences inconvenience/ nuisance in doing their job	Patient bodily fluids dry onto outside of lense or condensation accumulates. Anti-fog coating degrades	4	4	AO
				User experiences discomfort.				
			Potential buildup of condensation	User experiences discomfort and a loss of adequate vision	Coating degrades	3	3	AO

Figure A5.1 DFMEA developed during the design process stage

No	Part Assembly Name	Suggested Mitigations	Verification	DET	RPN	Risk Ranking (Initial)	Recommended Actions	Acting results					Risk Ranking (After Mitigations)
								SEV	OCC	DET	CLASS	RPN	
1	Goggles with Visor Extension	Proper evalution of quality assurance process to decrease liklihood of defective components and to ensure quality of sizes available to user	Repeat mechanical testing to simulate daily usage	9	288	4	Use a more flexible material or one that is less prone to breakage under limited applied force	4	2	9	AO	72	4
		Use a durable material, rated for long-term use (up to 1 year) that is not likely to degrade	Utilize repetitive strength testing to determine life of joint and amount of degradation over time	5	140	3	Use a more wear-resistant material with increased flexibility	3	2	5	AO	30	3
		Suggest regular disinfecting of equipment, and consider system replacement	Test coating to determine overall effectiveness	2	90	5	Use a more durable and long-lasting coating. Advise consumers of proper sanitation methods	4	2	2	AO	16	2
		Use a hypoallergenic material	Undergo allergy testing with multiple individuals	5	40	1	Use hypoallergenic material	2	1	5	AO	10	2
		Use a durable head strap material such as flexible plastic that can be adjusted using a clasp, rather than elastic that will wear over time	Test sizing between individuals and ensure a multi-fit design that will snugly fit multiple individuals	6	90	2	Make sure system has a more secure attachment that reduces movement	2	2	6	AO	24	3
		Make sure coating is intact, otherwise system will need to be replaced	Test sanitization methods and various coatings that will clean the visor and keep it clean. Test in various lighting conditions.	9	144	3	Use a material that is oil/water-resistant to prevent sticking of fluids. Material could also be easily cleanable	2	2	9	AO	36	3
		Wipe down lense to remove condensation manually	Test component in a humid enviornment to monitor condesation buildup	9	81	2	Use a material that is oil/water-resistant to prevent sticking of fluids. Material could also be easily cleanable	1	1	9	AO	9	1

Figure A5.2 DFMEA (continued) developed during the design process stage

No	Part Assembly Name	Function	Potential Failure Mode	Potential Effect(s) of Failure	Potential Cause(s) Mechanism(s) of Failure	SEV	OCC	CLASS
2	Supportive Band	Responsible for holding and supporting the goggle and visor system on the user	Band snaps apart or detaches from goggles	System is potentially no longer in place and sufficient coverage is lost	Overuse or improper use of face shield, improper fitting, or defective components.	8	7	KC
			Band experiences a growth in bacteria	User contracts infection	Improper sanitization methods	9	3	AO
			Not secure and experiences movement	User may experience discomfort	Improper fitting of band, misuse, or defective components	3	6	AO
3	Surface Modified Lense/ Visor Extension	Acts as a protective barrier to minimize glare, fogging, and pathogen growth	Degrades over time	Does not adequately reduce glare, fogging, and antibacterial properties	Overuse or improper use of face shield, improper fitting, or defective components.	3	6	AO
			Bacterial growth on surface	User contracts infection	Surface coating degrades and loses antibacterial properties	9	4	AO

Figure A5.3 DFMEA (continued) developed during the design process stage

No	Part Assembly Name	Suggested Mitigations	Verification	DET	RPN	Risk Ranking (Initial)	Recommended Actions	Acting results					Risk Ranking (After Mitigations)
								SEV	OCC	DET	CLASS	RPN	
2	Supportive Band	Use a durable material rated for long-term use (1 year), properly evaluate quality assuracne program to decrease liklihood of defective components	Utilize mechanical testing in multiple trials to find breaking point	10	560	5	Use a more flexible material or one that is less prone to breakage under limited applied force. Also, sell replacement bands.	4	3	10	AO	120	5
		Give guidelines to user on how to properly sanitize and handle the system after use, use an antimicrobial coating on the band	Test antimicrobial properties and ensure proper sanitization methods	2	54	1	Use non-toxic cleaning products or make component virus/bacteria resistant	4	1	2	AO	8	1
		Proper evalution of quality assurance process to decrease liklihood of defective components and to ensure quality of sizes available to user	Test sizing between individuals and ensure a multi-fit design that fill snugly fit multiple individuals	5	90	2	Use a more secure attachment component or method	1	3	5	AO	15	2
3	Surface Modified Lense/ Visor Extension	Use a durable material rated for long-term use (1 year) to create the coating, proper evaluation of quality assurance program to decrease liklihood of defective components	Complete multiple tensile tests to ensure system integrity and simulate daily use	5	90	2	Use a wear-resistant or stronger coating that is long-lasting	1	3	5	AO	15	2
		Give guidelines to user on how to properly sanitize and handle the system after use	Test antimicrobial properties and ensure proper sanitization methods	2	72	2	Use non-toxic cleaning products or make component virus/bacteria resistant	4	2	2	AO	16	2

Figure A5.4 DFMEA (continued) developed during the design process stage

Laboratory Safety Goggles Decision Matrix	Comfortable/Ergonomic		Anti-Fog Coating		Ventilation		Less than $15		Strap Material			
	Importance?		Importance?		Importance?		Importance?		Importance?			
	3		3		2		2		2			
	Your rating:		Your rating:		Your rating:		Your rating:		Your rating:		Raw Score	Final Score
Uvex by Honeywell 9301 Futura Indirect Vent Goggle - S345C	4		5		3		5		5		22	53
UVEX Stealth Safety Goggles with Clear Uvextreme Anti-Fog Lens, Gray Body & Neoprene Headband (S3960C), Universal	4		5		4		5		5		23	55
Safety Glasses Over Prescription Goggles Lab Anti Fog Anti Scratch Eye Protection Glasses Chemistry Protective Eyewear For Science Onion Goggles For Women Woodworking welding	4		5		5		5		2		21	51
											0	0

Figure A6. Decision matrix for selection of goggles

Thermoplastics Decision Matrix		Moldable w/o manufacturing equipment		Clear		Durability		Less than $30		Non-toxic			
		Importance?		Importance?		Importance?		Importance?		Importance?			
		1		3		2		2		2			
		Your rating:		Your rating:		Your rating:		Your rating:		Your rating:		Raw Score	Final Score
Polycarbonate		3		5		5		5		4		22	46
Kydex		3		1		4		5		5		18	34
Acrylic		1		5		4		5		5		20	44
ABS		3		1		4		5		5		18	34

Figure A7. Decision matrix for selection of face shield thermoplastic material

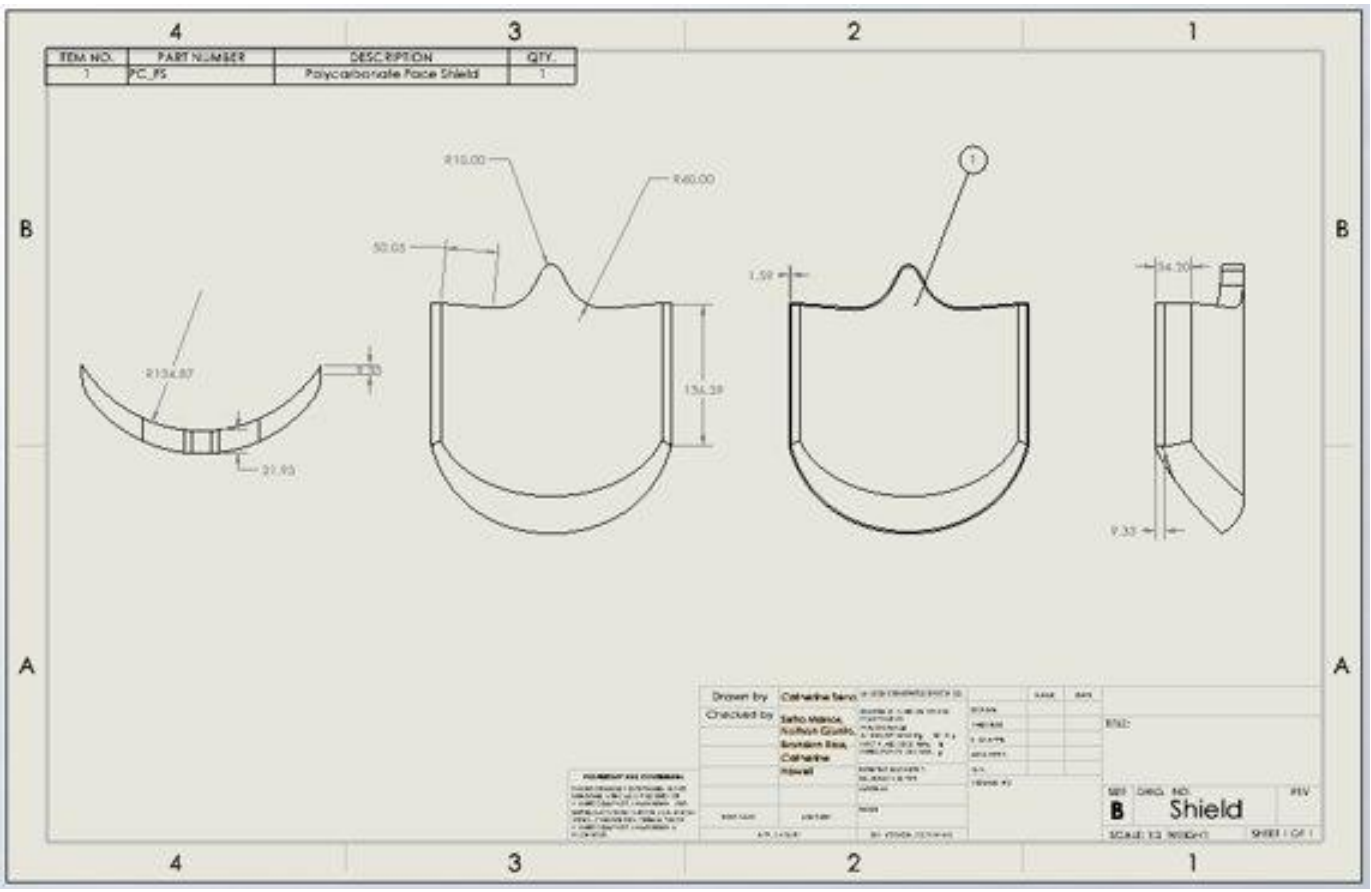


Figure A8. Part drawing of the face shield attachment

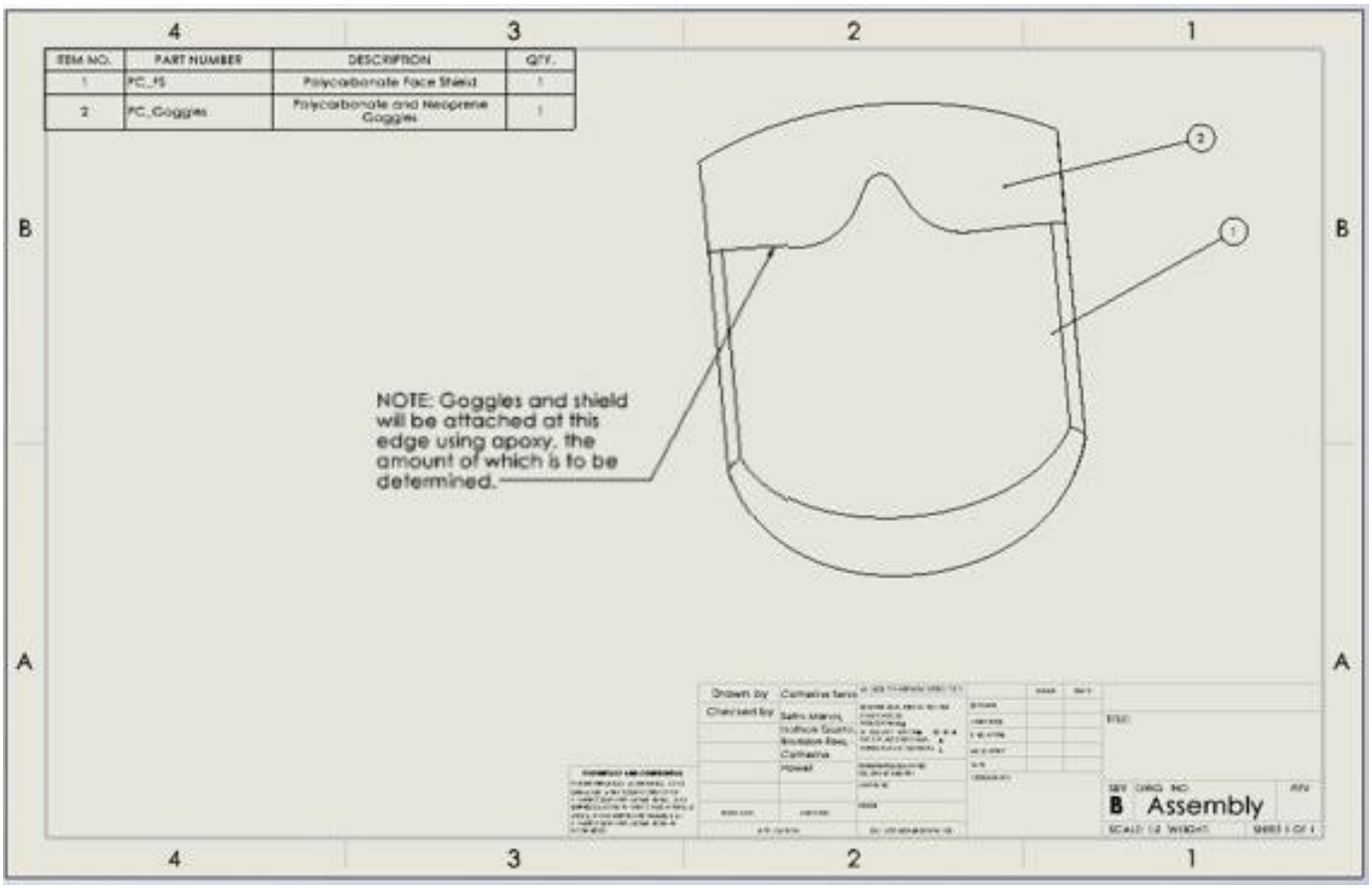


Figure A9. Assembly drawing of the face shield attached to the chosen goggles

Bill of Materials

Item number	Part Number	Quantity	Name	Material	Procurement Type	Vendor/Source	Price each	Typical Lead time
1	1-001	1	UVEX Stealth Safety Goggles with Clear Uvextreme Anti-Fog Lens, Gray Body & Neoprene Headband (S3960C), Universal	Polycarbonate and Neoprene	OTS	Honeywell	$14.99	1 week
2	1-002	1	Polycarbonate Sheet- 12" X 24" X 0.0625" (1/16")	Polycarbonate	OTS	Robosource	$24.99	1 week
3	1-003	1	Darice HC1060027 Syringe, Single	Adhesive Epoxy	OTS	Darice	$3.59	1 week

Figure A10. Bill of materials

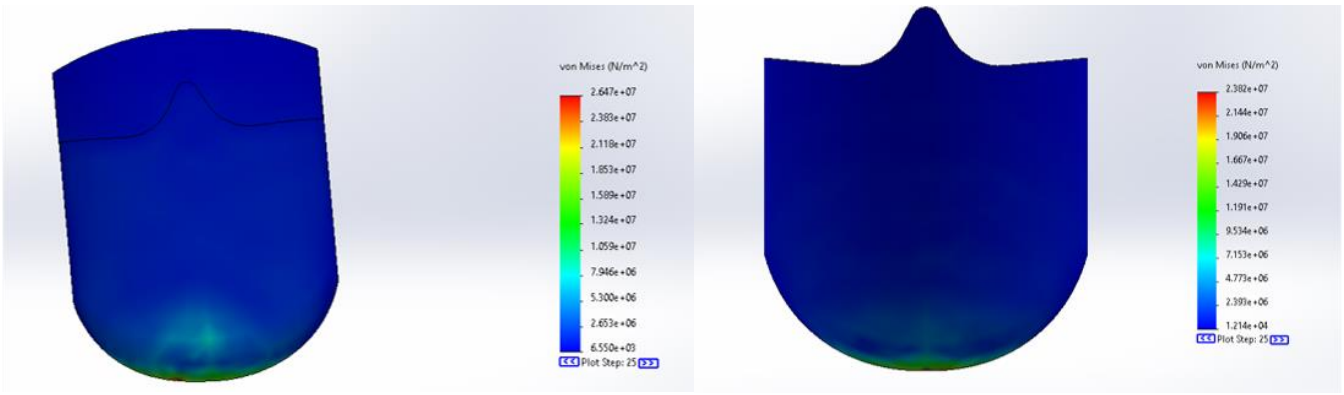


Figure A11. Solidworks drop test for both assembly and face shield

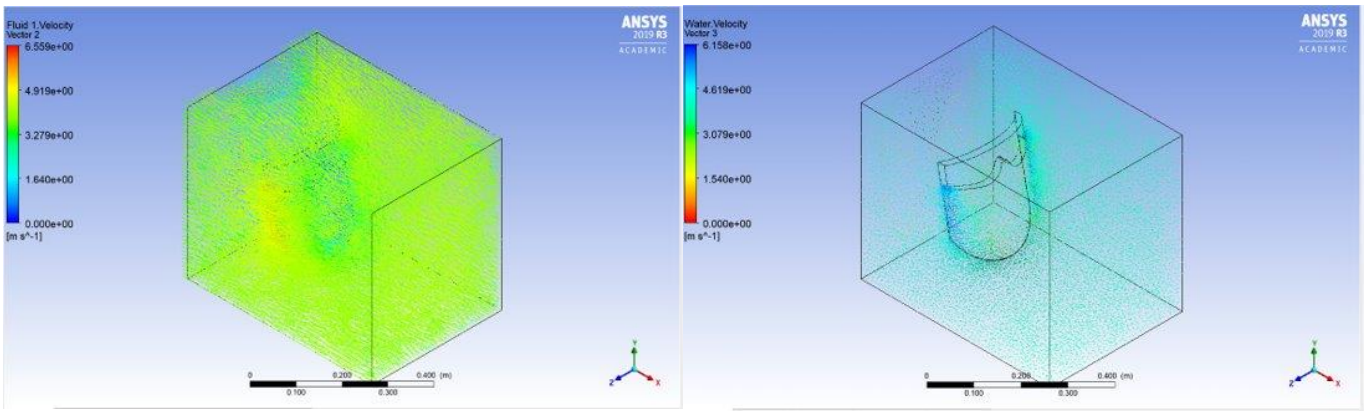


Figure A12. ANSYS fan and respiratory droplet dispersion test with air and water velocities

No	Part Assembly Name	Function	Potential Failure Mode	Potential Effect(s) of Failure	Potential Cause(s) Mechanism(s) of Failure	SEV	OCC
2	Face Shield Attachment	Cover and protect user's face, including peripheral coverage	System breaks or bends	User no longer has adequate facial coverage	Overuse or improper use of face shield, improper fitting, or defective components.	8	4
				Potential increased exposure to infectious particles			
			Degradation of adhesive between attachment and goggles	User no longer has adequate facial coverage	Overuse or long-term use	7	4
				Potential increased exposure to infectious particles			
			Accumulation of bacterial growth	User contracts infection	Degradation in antibacterial coating or not secure on user. Could also be due to a defective component	9	5
			System is not secure/ experiences movement	User no longer has adequate facial coverage	Wear in system or improper fitting	3	5
				User experiences inconvenience/ nuisance in doing their job			
				User experiences discomfort			
				Potential increased exposure to infectious particles			
			User is impaired visually	User experiences inconvenience/ nuisance in doing their job	Patient bodily fluids dry onto outside of lense or condensation accumulates. Anti-fog coating degrades. The system is simply too bulky and obstructs vision.	4	4
				User experiences discomfort.			
			Potential buildup of condensation	User experiences discomfort and a loss of adequate vision	Coating degrades	3	3

Figure A13.1 Updated design FMEA showing new component section

No	Part Assembly Name	CLASS	Suggested Mitigations	Verification	DET	RPN	Risk Ranking (Initial)	Recommended Actions	Acting results					Risk Ranking (After Mitigations)
									SEV	OCC	DET	CLASS	RPN	
2	Face Shield Attachment	AO	Proper evalution of quality assurance process to decrease liklihood of defective components and to ensure quality of sizes available to user	Repeat mechanical testing to simulate daily usage	9	288	4	Use a more flexible material or one that is less prone to breakage under limited applied force	4	2	9	AO	72	4
		AO	Use a durable or easily reappliable adhesive, rated for long-term use (up to 1 year) that is not likely to degrade	Utilize repetitive strength testing to determine life of joint and amount of degradation over time	5	140	3	Use a more wear-resistant material with increased flexibility	3	2	5	AO	30	3
		KC	Suggest regular disinfecting of equipment, and consider system replacement	Test coating to determine overall effectiveness	2	90	5	Use a more durable and long-lasting coating. Advise consumers of proper sanitation method	4	2	2	AO	16	2
		AO	Use a durable head strap material such as flexible plastic that can be adjusted using a clasp, rather than elastic that will wear over time	Test sizing between individuals and ensure a multi-fit design that will snugly fit multiple individuals	6	90	2	Make sure system has a more secure attachment that reduces movement	2	2	6	AO	24	3
		AO	Make sure coating is intact, otherwise system will need to be replaced. Could also make attachment as non-bulky as possible while still offering sufficient coverage.	Test sanitization methods and various coatings that will clean the visor and keep it clean. Test in various lighting conditions.	9	144	3	Use a material that is oil/water-resistant to prevent sticking of fluids. Material could also be easily cleanable	2	2	9	AO	36	3
		AO	Wipe down lense to remove condensation manually	Test component in a humid enviornment to monitor condesation buildup	9	81	2	Use a material that is oil/water-resistant to prevent sticking of fluids. Material could also be easily cleanable	1	1	9	AO	9	1

Figure A13.2 Updated design FMEA (continued) showing new component section

Engineering Specifications	Test Method	Date	Name of Tester	Acceptable Ranges	Pass	Fail
Less than 150 grams	Calculation of weight using density of polycarbonate and measurements of face shield from Solidworks	02/28/2021	Catherine Howell	150 grams +/- 5 grams	x	
165 mm long by 152 mm wide	Measurement of dimensions using Solidworks model	2/28/2021	Catherine Howell	Given values +/- 5 mm	x	
No more than 10% surface reflection at incident angles of 0, 30, 45, and 60 degrees	Calculation using Snell's Law, Fresnel's Equations, and index of refraction for air and polycarbonate	2/28/2021	Catherine Howell	Surface reflection no greater than 10%	x	
Light transmission greater than 85% at an incident angle of 0 degrees	Polycarbonate light transmission value given by vendor	2/28/2021	Outside vendor	Light transmission greater than 85%	x	
Thickness of 2.54 mm or less	Polycarbonate thickness given by vendor	2/28/2021	Outside vendor	Thickness within 2.54 mm +/- 1 mm	x	
Strap tensile strength > or equal to 3.45MPa	Neoprene tensile strength given by vendor	2/28/2021	Outside vendor	Tensile strength 3.54 MPa or greater	x	
Inert material for face shield	Biocompatibility testing as verified by outside vendor	2/28/2021	Outside vendor	Must meet ASTM F997 guidelines	x	
Inert material for strap	Biocompatibility testing as verified by outside vendor	2/28/2021	Outside vendor	Must meet ASTM D6977 guidelines	x	
Durable enough to withstand multiple uses, including potential drops from user height	Stimulate drop testing in solidworks, from a height of 6 ft	2/28/2021	Catherine Howell	Highest stress concentrations in drop testing must not exceed the ultimate tensile strength of polycarbonate	x	
Able to be sanitized	Sterilization testing of polycarbonate as verified by outside research	2/28/2021	Outside researcher	Polycarbonate is verified as sterilizable	x	

Figure A14. Design verifications table

What Is Being Tested	Protocol for Test	Who Will Perform Test	Where Test Should be Performed	Passing Conditions
Anti-fog	Measure percent area of face shield covered under standard temperature and humidity conditions as rated by OSHA	Student Engineer from the Pandemic Healthcare Team	Home healthcare environment	Less than 15% area covered by fog
	Measure percent area of face shield covered under worst case scenario conditions- going from a cold environment to warm environment rapidly	Student Engineer from the Pandemic Healthcare Team	From outside environment (<32 degrees Fahrenheit) to inside	Less than 50% area covered by fog
Anti-glare	Have target user wear face shield, giving indication of any visual impairment due to glare under work environment lighting conditions	Target User	Home healthcare environment	No user reported visual impairment due to glare
Impedance of tasks	Have user rotate face vertically and horizontally while wearing face shield, taking note if the face shield impedes motion in anyway	Student Engineer from the Pandemic Healthcare Team	Engineering lab, home healthcare environment, etc.	No impedance of user movement by the face shield
Comfort	Have target user wear face shield for at least 1 hour and rate comfort of the face shield on a scale from 1-10	Target User	Home healthcare environment	Average comfort rating of 7 or greater among at least 10 target users
Facial Coverage/Protection	Simulate droplet conditions using a fan and spray bottle. Equip mannequin with face shield, with layer of tissue paper underneath. Measure area of tissue paper that becomes contaminated with droplets while mannequin is wearing face shield.	Student Engineer from the Pandemic Healthcare Team	Engineering lab	Less than 5% contamination of tissue paper with droplets

Figure A15. Design validation plan

Customer Requirement Number	Customer Requirement	Validation Method	Validation Name	Validation Procedure Number
1	Anti-fog	Test	Fog percentage area evaluation	1
2	Anti-glare	Inspection/Demonstration	User evaluated visual impairment by glare	2
3	Impedance	Inspection/Demonstration	User evaluated task impairment	3
4	Comfort	Inspection/Demonstration	User evaluated comfort level	4
5	Facial Coverage/Protection	Test	Facial coverage evaluation	5

Figure A16. Validation testing plan table

Validation Procedure

-procedure number and summary name
-summary of validation
-setup
-detailed step by step
-acceptance criteria for pass or fail

Procedure Number 1: Fog percentage area evaluation

Summary

This validation allows for the evaluation of the percentage of fog that impairs the visual area of the face shield under worst-case scenario conditions. By moving the face shield from a cold environment to that of an environment at room temperature, worst-case scenario conditions are simulated. Worst-case scenario conditions increase the likelihood of precipitation, a.k.a. fog, onto the face shield. By simulating a worst-case scenario, the maximum possible amount of fog that would visually impair a user can be estimated.

Setup

For this validation, the only materials required are a refrigerator at a standard temperature ranging from 35 to 40 degrees Fahrenheit, and the beta prototype of the face shield. This test should be performed in an environment at room temperature, which ranges from 68 to 72 degrees Fahrenheit. This will simulate movement of the face shield from an outside environment into a working environment.

Steps of Procedure

- ☐ Place the beta prototype face shield into a refrigerator for 1 hour.
- ☐ After an hour has passed, remove face shield and place into room temperature environment. Give 30 seconds to 1 minute to allow fog to form over face shield.
- ☐ Estimate the amount of fog covering the visual area of the face shield, i.e., the amount of fog covering the goggles. Estimate either 0-25%, 25-50%, 50-75%, or greater than 75% coverage of the visual area.
- ☐ Record this measurement.
- ☐ Record whether beta prototype passes or fails in validation report based on acceptance criteria.

Acceptance Criteria for Pass or Fail

Passing criteria: 0-25% of the face shield becomes covered by fog

Failing criteria: Any rating over 0-25% coverage by fog is classified as failing

Procedure Number 2: User evaluated visual impairment by glare

Summary

This validation allows for visual impairment due to glare to be measured via user evaluation. By allowing the target user to wear the face shield under standard workplace lighting conditions, any issues with glare can be reported by the user.

Setup

For this validation, the beta prototype will be needed, as well as a target user willing to wear the shield and give feedback. This test should be performed in an environment with overhead lighting to simulate conditions of a workplace environment.

Steps of Procedure

- ☐ Have target user wear face shield, making sure overhead lights are on.
- ☐ Have user walk around environment, moving as if they would if they were at work. This should include rotation of the head to allow light to hit the face shield from various angles.
- ☐ While user is walking around environment, have them indicate to tester any incidences of glare that would impede them in a work environment.
- ☐ Record any incidences reported by the user, noting the conditions they occurred under, such as, the angle the head was rotated at, how they were facing light, etc.
- ☐ Record whether beta prototype passes or fails in validation report based on acceptance criteria.

Acceptance Criteria for Pass or Fail

Passing criteria: No user reported incidences of glare that the user feels would impair them in a working environment. There can be reported incidences of glare, as long as the user feels these would not significantly impair them under working conditions.

Failing criteria: Any user reported incident of glare that the user feels would significantly impair them in a working environment.

Procedure Number 3: User evaluated task impairment

Summary

This validation allows for task impairment due to the size and shape of the face shield to be evaluated via user feedback. This test can be performed in any type of environment, as long as user movement is not restricted.

Setup

For this validation, the beta prototype will be needed, as well as a target user willing to wear the shield and give feedback. As previously stated, this test can be performed in any type of environment, as long as user movement is not restricted.

Steps of Procedure

- ☐ Have target user wear face shield, making sure to adjust goggles strap to get a proper fit.
- ☐ Have user move head in all directions, testing a full range of motion while the user is wearing the face shield.
- ☐ Record any user impedance caused by the face shield. This includes any impedance of movement due to the face shield interacting with the user due to its size and shape.
- ☐ Record whether beta prototype passes or fails in validation report based on acceptance criteria.

Acceptance Criteria for Pass or Fail

Passing criteria: No user reported or observed instances of motion impedance by the face shield.

Failing criteria: Any user reported or observed instances of motion impedance by the face shield.

Procedure Number 4: User evaluated comfort level

Summary

This validation allows for the comfort level of the face shield to be evaluated via user feedback. This test can be performed in any environment. Ideally, this test should be done by having the target user take the face shield into a work environment and test wearing it throughout the normal workday. This will allow for evaluation of the face shield in the environment and conditions it was designed for.

Setup

For this validation, the beta prototype will be needed, as well as a target user willing to wear the shield and give feedback. As previously stated, this test can be performed in any type of environment.

Steps of Procedure

- ☐ Have target user wear face shield, making sure to adjust goggles strap to get a proper fit.
- ☐ Have user wear face shield for a minimum of 15 minutes, but preferably have them wear it throughout a day of work.
- ☐ After the user has worn the face shield for a prolonged period of time, have them rate the comfort level of the face shield on a scale of 1-10.
- ☐ Record the user feedback rating.
- ☐ Record whether beta prototype passes or fails in validation report based on acceptance criteria.

Acceptance Criteria for Pass or Fail

Passing criteria: User comfort rating of 7 or greater.

Failing criteria: User comfort rating of 6 or below.

Procedure Number 5: Facial coverage evaluation

Summary

This validation allows for the evaluation of the facial coverage and protection the face shield provides its user. This is done by seeing how many droplets can bypass the face shield, under simulated droplet conditions, making contact with a user's face. Droplet conditions will be simulated using a sprayable water-bottle and oscillating fan.

Setup

For this validation, the beta prototype will be needed. Additional supplies that will be needed include an oscillating fan, sprayable water bottle, white tissue paper, and a mannequin head or other type of bust that simulates a human head. This test can be performed in any environment, but the fan and mannequin head should be setup on a table to ensure they are at an approximately equal height level.

Steps of Procedure

- ☐ Take mannequin head and wrap in multiple layers of tissue paper from the eyeline down.
- ☐ Take spray bottle and fill with water, placing a few drops of food coloring in water.
- ☐ Place face shield on mannequin.
- ☐ Setup fan and mannequin on a table facing one another, 6 feet apart.
- ☐ Turn fan on medium setting, with oscillation.
- ☐ Spray water through fan while it is oscillating and facing the mannequin for 2 minutes.
- ☐ After two minutes, turn off fan and see how much of the tissue paper has come into contact with droplets by looking for food coloring on the tissue paper.
- ☐ Estimate the area of tissue paper that has come into contact with droplets. Estimate either 0-15%, 15-30%, 30-50%, or greater than 50% coverage of the tissue paper.
- ☐ Record results.
- ☐ Record whether beta prototype passes or fails in validation report based on acceptance criteria.

Acceptance Criteria for Pass or Fail

Passing criteria: 0-30% of tissue paper comes into contact with droplets.

Failing criteria: Over 30% of tissue paper comes into contact with droplets.

Figure A17. Validation testing procedure

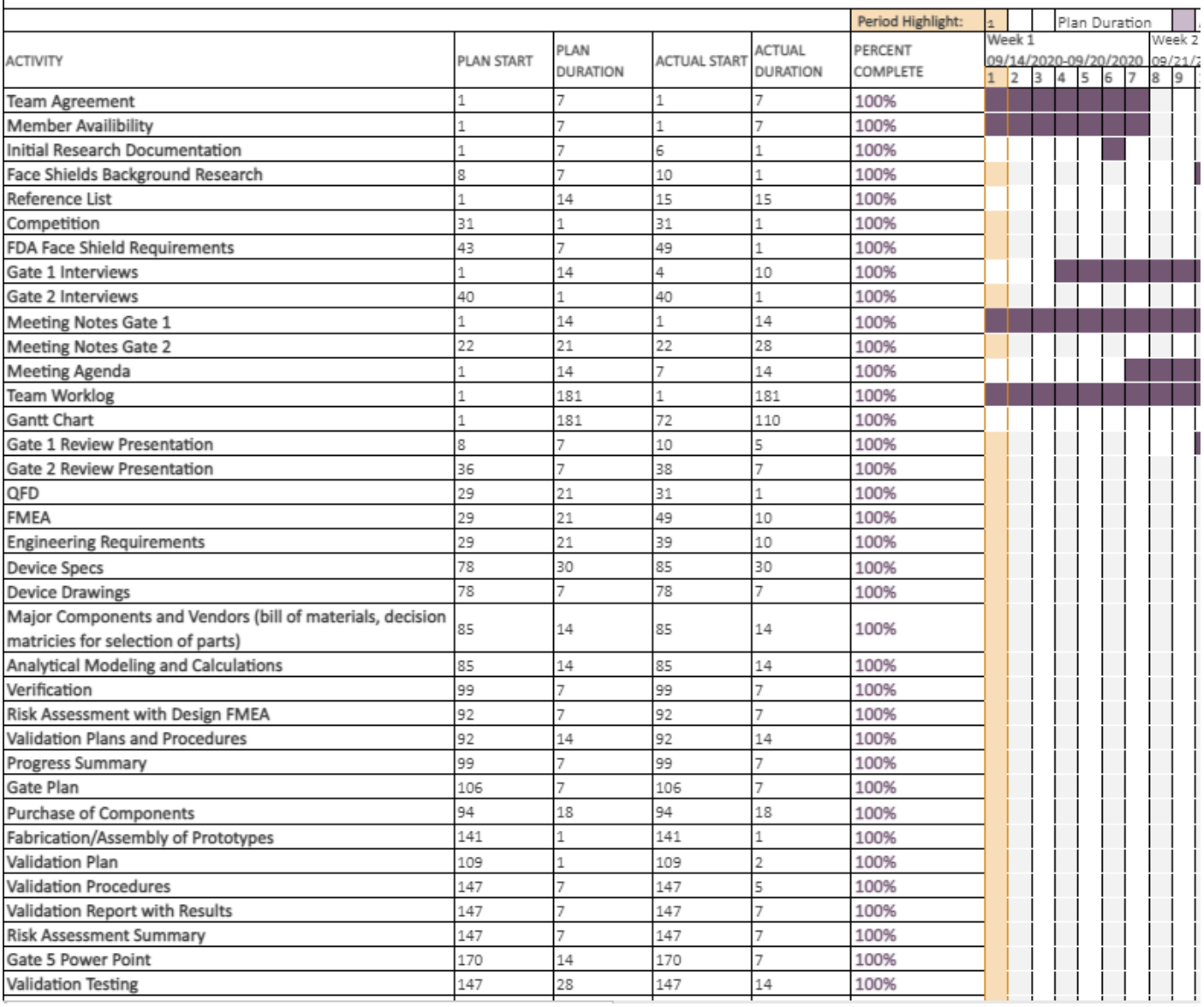
Validation Procedure Number	Validation Name	Passed	Failed	Comments
1	Fog percentage area evaluation	X		The goggles have no fog at all, while the polycarbonate does. This is not an issue as the user does not need anyone to see their face since they are also wearing a mask.
2	User evaluated visual impairment by glare	X		All users ranked 10 (highest)
3	User evaluated task impairment		X	The issues the user has are with the actual manufacturing, not the design. Would pass if manufactured by machine.
4	User evaluated comfort level	X		All users ranked 10 (comfort level)
5	Facial coverage evaluation	X		

Figure A18. Validation testing report

RPN	Risk	Summary of Risk	Risk Level	Summary of Mitigation
560	Headband failure	Overuse, improper use, or defective components results in improperly placed shield and potential exposure.	High	A more flexible material was chosen, making it less prone to breakages under load. Replacement bands can also be sold.
288	Goggles break	Overuse, improper use, or failure of components results in inadequate protection and potential exposure.	High	A more flexible material was chosen, making it less prone to breakages under load.
288	Face shield breaks	Overuse, improper use, or defective components results in inadequate facial coverage.	High	A more flexible material was chosen, making the shield less prone to breaking under load.
144	Visual Impairment	Condensation build up, bodily fluids drying on the outside of the lense, or degradation of the anti-fog coating inconviences the use, potentially causing discomfort	Moderate	Selected a material with a oil/water-resistant coating that is easily cleaned.
140	Broken Connection	The attachment between the lenses and the visor extension degrades potentially exposing user and leading to inadequate coverage	Moderate	Selected a material rated for long term use that is unlikely to degrade over time.
90	Bacterial Growth on Shield	Accumaltion of bacterial growth causes the user to contract an infection.	High	Regular disinfection of equipment has been recommended, along with replacement as needed.
90	Loose Face Shield	Wear in the system or an improper fit leads to the system no being secure. Can result in inadequate coverage, incovenience performing job tasks, discomfort, and potential exposure.	Low	Selected a flexible strap material that can be adjusted using a clasp mechanism, rather than an elastic band that wears overtime.
90	Insecure Band	Improper fitting band, misuse, or defective component results in user discomfort.	Low	Selected a clasp mechanism as a more secure attachment method.
90	Surface Modification Degradation	Overuse, improper use, or defective components cause the surface modification to degrade resulting in a loss of anti-fogging, anti-glare, and antibacterial properties.	Low	Selected a wear-resistant coating that will last for a longer period of time. Replace as needed.
81	Condensation Build-up	Condensation build up through a degraded coating can result in user discomfort and impaired vision.	Low	Suggested manual removal of condensation on lense and visor by the user. Chose a longer lasting coating.
72	Antibacterial Modification Failure	Antibacterial coating degrades, losing its anitbacterial properties, resulting in bacterial growth on surface and the user potentially contracts infection.	Low	Clean the surface regularly using non-toxic products. Selected bacteria resistant material.
54	Bacterial Growth on Band	Improper sanitation methods causes bacterial growth on the band, subjecting the user to potential infection.	Low	Provide guidelines for proper sanitation. Use antimicrobial coating on band.
40	Skin Irritation	Allergenic material causes skin irritation on the user.	Low	Selected a hypoallergenic material.
		Overall our device will provide the user with increased comfort while providing the same, if not improved, levels of protection as compared to competitiors. Although the risk of infection cannot be fully erased, our connected design will help lower the risks.		
		Future risk mitigation activities will focus on improvements to the joint between the goggles and the face shield.		

Figure A19. Risk summary table

Pandemic Healthcare: Face Shield Modification



ACTIVITY	PLAN START	PLAN DURATION	ACTUAL START	ACTUAL DURATION	PERCENT COMPLETE
Team Agreement	1	7	1	7	100%
Member Availibility	1	7	1	7	100%
Initial Research Documentation	1	7	6	1	100%
Face Shields Background Research	8	7	10	1	100%
Reference List	1	14	15	15	100%
Competition	31	1	31	1	100%
FDA Face Shield Requirements	43	7	49	1	100%
Gate 1 Interviews	1	14	4	10	100%
Gate 2 Interviews	40	1	40	1	100%
Meeting Notes Gate 1	1	14	1	14	100%
Meeting Notes Gate 2	22	21	22	28	100%
Meeting Agenda	1	14	7	14	100%
Team Worklog	1	181	1	181	100%
Gantt Chart	1	181	72	110	100%
Gate 1 Review Presentation	8	7	10	5	100%
Gate 2 Review Presentation	36	7	38	7	100%
QFD	29	21	31	1	100%
FMEA	29	21	49	10	100%
Engineering Requirements	29	21	39	10	100%
Device Specs	78	30	85	30	100%
Device Drawings	78	7	78	7	100%
Major Components and Vendors (bill of materials, decision matricies for selection of parts)	85	14	85	14	100%
Analytical Modeling and Calculations	85	14	85	14	100%
Verification	99	7	99	7	100%
Risk Assessment with Design FMEA	92	7	92	7	100%
Validation Plans and Procedures	92	14	92	14	100%
Progress Summary	99	7	99	7	100%
Gate Plan	106	7	106	7	100%
Purchase of Components	94	18	94	18	100%
Fabrication/Assembly of Prototypes	141	1	141	1	100%
Validation Plan	109	1	109	2	100%
Validation Procedures	147	7	147	5	100%
Validation Report with Results	147	7	147	7	100%
Risk Assessment Summary	147	7	147	7	100%
Gate 5 Power Point	170	14	170	7	100%
Validation Testing	147	28	147	14	100%

Figure A20. Gantt chart