Johnson Health Tech: VO_2 Mask for Biomechanics Research

BME 200/300 Final Design Report | December 15, 2021

TEAM MEMBERS
Victoria Heiligenthal - *Team Leader*
Rachel Krueger - *Communicator*
Jakob Knauss - *BSAC*
Adrienne Rasmussen - *BWIG*
Tommy Kriewaldt - *BWIG*
Sinan Ozturk - *BPAG*

ADVISOR
Dr. Kip Ludwig, Dr. James Trevathan
Department of Biomedical Engineering
University of Wisconsin-Madison

CLIENT
Staci Quam, Grace Johnson
Johnson Health Tech

ABSTRACT

VO_2 max testing has become an integral tool used in multiple research areas. By completing a VO_2 max test, the cardiovascular fitness and health of a test subject can be determined. For testing, a subject goes through an intense aerobic activity for a specific amount of time while wearing a VO_2 mask that measures the total inhaled and exhaled air. Once the subject has reached exhaustion or VO_2 max values begin to plateau, the maximum VO_2 level can be observed. Although VO_2 max masks currently on the market are successful at providing accurate results, the comfort of the user is not always considered. Comfort is especially compromised for subjects with glasses since they do not fit over the VO_2 mask, preventing subjects from wearing them during testing. This causes disorientation in these users that could put them at risk for injury or anxiety. Therefore, the goal of this project is to create a VO_2 mask design that allows users to wear glasses during testing while maintaining the reliability of VO_2 max measurements. The design must be cost effective within a $400 budget and maintain its integrity during VO_2 max testing conditions. A VO_2 mask design that adds extension pieces to the sides of the mask to hold up the glasses during testing was developed. This design was tested using functional testing where users completed aerobic tests and ranked criteria to collect qualitative data to assess the mask's ability to meet the needs of the client.

TABLE OF CONTENTS

INTRODUCTION

Motivation

For all athletes, avid or elite, maximizing training and performance is key to reaching optimal athletic performance and maintaining healthy fitness. One way to evaluate the aerobic and endurance fitness of an athlete is by conducting VO_2 max tests. During these tests, the total volume of inhaled air, the percentage of oxygen and carbon dioxide in the exhaled air of the subject, and the subject's heart rate are collected through a VO_2 mask to calculate oxygen consumption. The intensity of the aerobic activity will increase periodically by increasing the speed, gradient (incline), power, or resistance of the exercise until the athlete can no longer continue. The greatest VO_2 value collected is the corresponding VO_2 max. Greater VO_2 max values correspond to higher levels of cardiovascular fitness, allowing the athlete to optimize their cardiovascular, lung, and muscle functions. The athlete will be able to work harder for longer and recover faster, given a higher VO_2 value [1].

It is extremely important for researchers to be able to collect accurate and reliable data during these aerobic fitness tests. Mask leakage must be minimized to ensure the oxygen consumption values of the athlete are accurate in order to provide the athlete with correct feedback on how to improve their performance. However, the subject should also be comfortable and relaxed during these already high-stress evaluations.

Impact of Design

During a standard VO_2 max test, stress and anxiety levels are typically high since the subject's body is being pushed to exhaustion. If there is something compromising the subject from completing the VO_2 max test properly or comfortably, the levels of stress and anxiety will continue to increase while also introducing other factors like an increased risk of injury or disorientation. These factors are relevant when subjects that rely on glasses to see comfortably are restricted from wearing those glasses during testing. By implementing this design to allow users to wear glasses during testing, the potential for an increase in stress, anxiety, injury, and disorientation is reduced and comfort during an already uncomfortable test is maximized.

Existing Devices

There are currently several different VO_2 mask products on the market. Although some devices claim they are compatible with the use of glasses, the team's client has struggled with allowing users to comfortably wear glasses during testing with their current mask. If the subject is unable to wear their glasses during testing, an increase in anxiety and disorientation can occur as well as an increase in the risk for injury of the subject if they cannot see properly. So, without being able to wear their glasses, the comfort and safety of the user is compromised.

One of the products currently on the market is the VO_2 Master Pro as shown in **Figure 1** below. This is a VO_2 mask design made and patented by VO_2 Master Health Sensors Inc. [2]. This battery-powered design holds the VM Pro attachment that contains the sensors, electronics, and tubes needed to power the VO_2 testing process. It attaches to a standard, silicone

Hans-Rudolph Face Mask, and is held in place by straps running to the rear end of the head [2]. The VO_2 Master Pro is also portable, meaning it can conduct VO_2 max tests virtually anywhere. In addition, it can upload the results of personal testing to a mobile app compatible with most devices.

Figure 1: VO_2 Master Pro Analyzer mask [3].

The K5 Metabolic System is another VO_2 mask design very similar to the VO_2 Master Pro in that it is both battery-powered and portable. Made by COSMED Co., this model also attaches directly to a standard silicone mask as seen below in **Figure 2**. Straps hold the mask, O_2 and CO_2 sensors, and other wires and tubes in place during VO_2 max testing. This design can switch between a variety of testing modes including resting energy expenditure testing, cardiopulmonary testing, and VO_2 max testing [4]. The K5 model also supports the transfer of VO_2 max testing data to a mobile device through bluetooth connection.

Figure 2: The K5 mask [5].

Lastly, the CardioCoach System, created by KORR Medical Technologies Inc., uses a machine to power the VO_2 max testing process. This design also uses the standard silicone *Hans-Rudolph Face Mask*, which connects to the machine through a plastic tube as shown below in **Figure 3**. The CardioCoach System controls the flow of air into and out of the mask, then analyzes the results by conducting a VO_2 max test through O_2 and CO_2 sensors [6]. The user must be in close proximity to the machine because the tube only stretches a few feet. This product also supports bluetooth sharing of VO_2 testing results to nearby mobile devices.

Figure 3: The CardioCoach mask [7].

These products share one common feature: the standard blue silicone mask. However, none of the masks provide a comfortable fit for subjects with glasses. During the design process, the team contacted the manufacturer of the mask currently used by Johnson Health Tech, Hans Rudolph, to see if 3D CAD models of the current mask could be obtained. In the conversation, the manufacturer claimed that the mask should be compatible with glasses. However, this is clearly not consistent with the client's experience using the mask. To address this, a design will be developed that is compatible with glasses while still allowing compatibility with the VO_2 max testing systems and accurate VO_2 max data collection.

Problem Statement

Metabolic tests, such as VO_2 max tests are important in determining the cardiovascular and aerobic fitness of athletes. During VO_2 max testing, athletes wear a VO_2 mask with an intake tube while performing an intense and high level form of exercise, like running or biking, until maximal effort and complete exhaustion. The concentration of oxygen inhaled and carbon dioxide exhaled are collected through the mask to determine how much oxygen the athlete uses during exercise as well as the maximum concentration of oxygen consumed. The more oxygen consumed, the more efficient the cardiovascular system is working. This means more oxygen can be delivered to the muscles, generating a greater energy output and enhancing physical performance [8]. There are VO_2 masks used during testing currently on the market, but improvements can still be made to make the testing more comfortable for participants.

Johnson Health Tech, an exercise manufacturing and research company, has faced problems with testing athletes that wear glasses while performing VO_2 max tests since they cannot wear their glasses with the masks. The design must be comfortable, prevent leakage, and allow for the athletes to wear glasses during testing.

BACKGROUND

Importance of VO_2 Max Testing

VO_2 max testing is generally considered to be one of the best indicators of cardiovascular fitness and aerobic endurance in athletes and test subjects. It is a measurement that reflects a person's capability to perform sustained, rigorous exercise by analyzing the maximum rate of oxygen consumption that could be reached during testing. The results of the test can also reflect a subject's health. The results of a VO_2 max test are dependent on three factors: the efficiency of the respiratory system to inhale and absorb oxygen; the ability of the cardiovascular system to efficiently pump, transport, and distribute oxygen around the body; and the ability of the muscles to consume and use large amounts of oxygen [1]. By analyzing and understanding the outcomes of VO_2 max testing, athletes can work on improving their VO_2 max with training, and other test subjects can focus on improving their fitness lifestyles for an overall healthier life.

Physiology of VO_2 Max Testing

During VO_2 max testing, the amount of oxygen uptake in the body is measured to determine the body's cardiopulmonary ability to transport and utilize oxygen in the mitochondria of skeletal muscles. This oxygen exchange from the atmospheric environment all the way to the mitochondrial cells in muscles is imperative for understanding the importance of VO_2 max testing. An example of a VO_2 max testing set-up is shown below in **Figure 4**.

Figure 4: VO_2 max testing set-up.

Oxygen is first brought into the body from the atmosphere as the inspiratory muscles of the body expand the lungs and create space for oxygen to enter. Carbon dioxide and oxygen is exchanged through the alveoli of the lungs, allowing oxygen to diffuse into the blood system. Once in the blood, hemoglobin in red blood cells binds to the oxygen molecules to carry it to areas of low oxygen in the body. During intense exercise, muscles lack oxygen, so it is taken to those skeletal muscles in need. The oxygen then diffuses into the capillary walls of the blood stream and binds to myoglobin. Myoglobin cells carry the oxygen molecules to the mitochondria cells within the muscles of the body. Once in the mitochondria, the oxygen becomes the last electron acceptor in the electron transport system and stimulates ATP production. This process is shown below in **Figure 5.** So, if more oxygen can be transferred quickly and efficiently to the mitochondria of muscle cells, more ATP and energy can be provided to skeletal muscles in the body during intense exercise and maximizing performance.

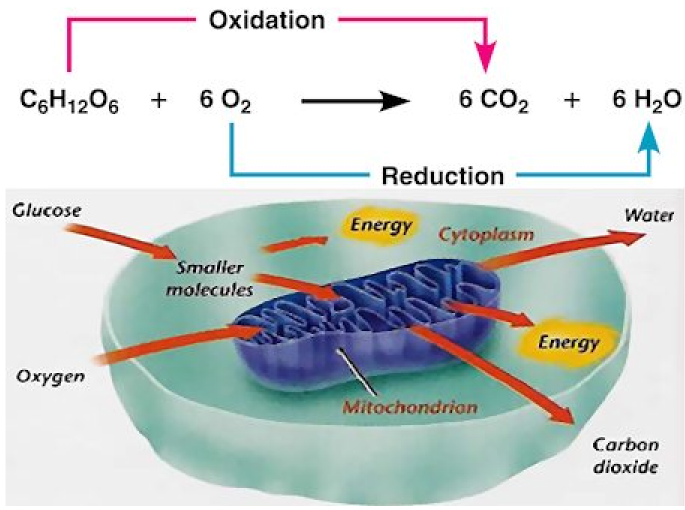


Figure 5: The use of oxygen in the mitochondria to generate ATP. This process occurs during VO_2 max testing.

Due to the physiology of oxygen exchange in the body to the mitochondrial cells of muscles, there are factors that can limit efficient VO_2 max testing. These factors include pulmonary diffusion size, cardiac output, carrying ability of oxygen in the blood, and the extraction of oxygen in skeletal muscles. Each of these factors limit oxygen from ultimately reaching the mitochondria in muscle cells to generate ATP, lowering the VO_2 max measurements [9].

VO_2 Max Testing and Normative Values

Although results from VO_2 max data can look different from person to person, the testing procedure is consistent for all subjects. VO_2 max values can be expressed as an absolute VO_2 max, the volume of oxygen consumed in liters per minute (L/min), or as a relative VO_2 max, the volume of oxygen consumed in milliliters per kilogram of bodyweight per minute (ml/kg/min). The typical recording of VO_2 max is in the range 25-45ml/kg/min [1]. However, this value can vary based on many different factors like sex, age, and physical actvity level. In order to measure VO_2 max accurately, the test must take place in a controlled laboratory environment. The tests require special gas analysis equipment including a face mask that is attached to a special gas analyzer. The analyzer measures the volume of inhaled air as well as the percentage of oxygen and carbon dioxide in the exhaled air. From these values, an accurate oxygen consumption measurement can be made.

In order to obtain VO_2 max values, tests require subjects to complete an incremental exercise test. In an incremental exercise test, intensity starts low and continually increases each time a work stage is completed. These increasing increments could be speed and gradient on a treadmill or power and resistance in cycling. The typical interval for increasing intensity is every 30-60 seconds. Incremental exercise tests will continue until the user cannot complete a work period or observed VO_2 levels begin to plateau. Ultimately, VO_2 max is measured from the highest average of VO_2 recorded over a 60 second period. Additional measurements can also be recorded, including heart rate [1].

Face Shape

Prior to modeling the design, variations in face shape were researched. It is important to account for this variability in order to construct an appropriate mask that fits all users.

The nasal root breadth measurement outlines the width of the nose bridge. A study which conducted analysis on average facial measurements found that the average measurement for nasal root breadth is 16.6 ± 2.3 mm for males and 16.3 ± 2.0 mm for females [10]. Another important dimension is the subnasale to sellion length, which is the measurement from the base of the nose to the bridge of the nose. The same study found that the average measurement for the subnasale to sellion length is 52.0 ± 4.1 mm for males and 48.2 ± 3.8 mm for female subjects [10]. Lastly, the average nose protrusion length is 21.1 ± 2.7 mm in males and 19.8 ± 2.7 mm in females [10]. The "±" measurements represent the survey's standard deviation range, in which 90% of all subjects' dimensions are located. The other 10% of recorded measurements are outside of this standard deviation range.

These measurements offer valuable insight into the face structure of a typical human. The variability of these dimensions are important to consider because the target audience of this project includes a wide range of people, who all rely on this mask to fit them comfortably and reliably. The design should be able to accommodate all users.

Client Information

Johnson Health Tech is a worldwide fitness and wellness equipment manufacturer and distributor based out of Cottage Grove, WI. The company develops exercise products such as treadmills, stationary bikes, ellipticals, and stair steppers across multiple brands. Outside of development, the company also utilizes a biomechanics lab where research is conducted to validate and support analysis claims as well as to conduct competitor comparison studies to evaluate their products against others on the market [11]. Johnson Health Tech also carries out VO_2 max studies as part of their ongoing data collection. Although the company already has a VO_2 mask for testing, the mask is not compatible or comfortable for users with glasses. The clients for this project under Johnson Health Tech have requested a mask design to be developed that is compatible with glasses.

Design Specifications

Aiming to allow users to wear masks during VO_2 max testing, Johnson Health Tech has requested a mask that is compatible with glasses that can be worn during the entirety of testing. The mask must be conducive to the intense exercise environment subjects are put in, and it should not alter the exercise gait of the participants during testing. The mask must withstand rigorous activities like biking or running for at least 20 minutes and should be reusable between tests after cleaning it with soap and water. Air leakage from the mask must also be minimized. Therefore, the mask should not move around on the face of the user, and it should be securely fit to their face. This will allow the VO_2 max values to be collected accurately across all subjects. The mask should be harmless and easy to use for the subject. For the design to be competitive in the market and meet the client's requirements, the budget of the design should not exceed $400. A complete list of specifications can be found in **Appendix A**.

PRELIMINARY DESIGNS

Design 1- Clips and Lower Bridge

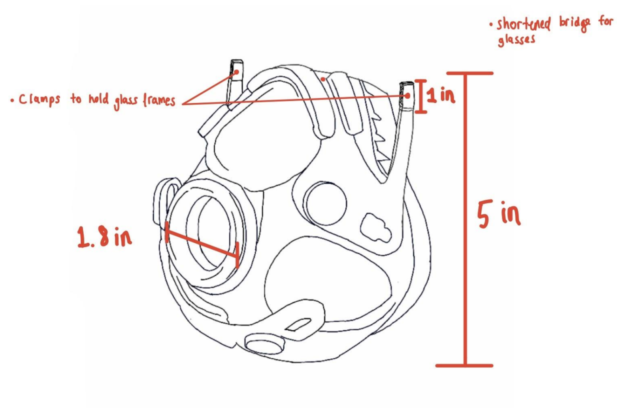


Figure 6: Sketch of the Clips and Lower Bridge design.

The first design is the Clips and Lower Bridge design, shown in **Figure 6**. This design lowers the area that covers the bridge of the nose by one inch to allow glasses to comfortably fit on the nose without interference from the mask. Two clips are attached to the sides of the mask, allowing the mask to secure the glasses in place. This prevents the mask from damaging the glasses during high intensity activities. The clips will latch onto the glasses legs, firmly holding them up. All other aspects of the mask will remain the same. The main concern with this design is that leakage of air from the mask could be possible by lowering the nose bridge. Depending on the face shape of the user, the mask might not fit as securely on their face if the nose bridge was lowered.

Design 2- Divot

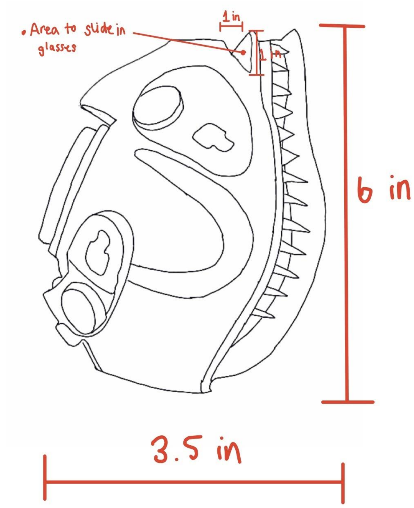


Figure 7: Sketch of the Divot design.

The second design is the Divot design, shown in **Figure 7**. This design allows the bridge of the glasses to fit into a 1 inch by 1 inch trench incorporated on the mask. All other aspects of the mask will remain the same as the current mask. This will ensure that the user is able to comfortably wear the mask while also wearing their glasses. The 1 inch by 1 inch trench was determined to be inclusive of all glasses possibilities [12]. However, by creating this divot at the nose bridge area, the mask could easily tear and be susceptible to air leakage. This would cause errors in the VO_2 readings during testing.

Design 3- Nose Clip and Mouthpiece

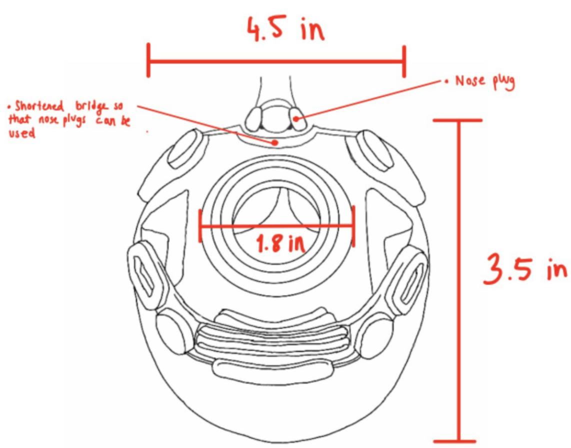


Figure 8: Sketch of the Nose Clip and Mouthpiece design.

The Nose Clip and Mouthpiece design, pictured in **Figure 8**, accounts for the most changes to the current design. First, the mask no longer covers any aspect of the nose. Instead, a nose plug clip is applied to the external part of the user's nose and does not allow air to flow in or out of the nose. All air flow will be filtered and collected through the mouth via a mouthpiece. The mask is shortened to 3.5 inches and the top of the mask rests in between the bottom of the nose and the upper lips of the user. All other aspects of the mask remain the same. Although this design would easily allow the user to wear glasses during testing, the comfortability of the design would be jeopardized.

PRELIMINARY DESIGN EVALUATION

Design Matrix

Criteria	Weight	Design 1 - Clips and Lower Bridge		Design 2 - Divot		Design 3 - Nose Clip	
Comfort	25	3/5	15	2/5	10	1/5	5
Accuracy	25	5/5	25	3/5	15	2/5	10
Durability	20	3/5	12	4/5	16	4/5	16
Ease of Use	15	4/5	12	5/5	15	3/5	9
Safety	10	5/5	10	4/5	8	4/5	8
Cost	5	5/5	5	5/5	5	5/5	5
Total	100		79		69		53

Figure 9: The team's design matrix.

<u>Comfort</u>

Comfort can be defined as the physical ease from pain that the mask user feels during testing. This category was tied for the highest weight because the client has stressed how the mask must not only allow users to wear glasses during testing, but it must also be comfortable for the user. Design 1 was awarded the highest score for this category because the user would likely experience the least discomfort from these modifications. The lower bridge of this mask would allow more facial freedom and the clips would comfortably hold glasses in place. The second design earned a slightly lower score because the indentation could potentially irritate the user's nose. Finally, the third design was named least comfortable because the nose clip needed to cut off air flow from the nose would be tight and likely harsh on the user's face.

<u>Accuracy</u>

The accuracy of the mask was tied with comfort for the highest weight category. Although the mask needs to allow users to wear glasses during testing, accuracy and reliability of the VO_2 max results cannot be compromised. The accuracy scores were determined based on how each design's results are expected to compare with the current Johnson Health Tech mask's results. Less expected variance between results would lead to a higher score on the design matrix. The first design is predicted to exhibit little to no deviation from the original design's results because the mask would be similarly secured to the face. Additionally, it was predicted that the second design could diverge from the previous results because the divot could put the mask at risk for air leakage from potential tears. The third design would be the least accurate because the nose airway is completely cut off from the rest of the mask.

Durability

Durability was weighted the next highest since the mask must withstand exercise tests without exhibiting damage. The first design received a three because the clips could potentially break off the mask after repeated use and testing. The second and third design scored fours because the designs would most likely not have many durability issues. These designs lack any additional attachments to the mask itself; thus, there is nothing to break off of them. The second design did not receive a perfect score due to the fact that the divot could potentially rip. The third design did not get a perfect score either, as the nose clip may be flimsy and perhaps not last long during testing.

Ease of Use

Ease of use was weighted based on how easy it would be for a user to use the mask. A higher score indicated that the design was easier to use. The first design scored a four because it is fairly easy to use. The user will only need to attach the clips to their glasses prior to testing. The second design got a perfect score because there are no additional steps that the user needs to take to put on or take off the mask. The third design earned the lowest score because the nose clip and mouthpiece could both present difficulty when putting it on since there are two separate components. This multistep process to put on and take off the mask earned it the lowest score.

Safety

Safety was weighted the next highest criteria. Safety relates to how much risk the user is at while wearing the mask. A higher score means that the user is at lower risk of harm. All three masks were relatively low risk. The first design is low risk since the mask does not have components that could jab, pierce, or hit the user. The clips could be seen as a safety risk, but their plastic coating will keep the user safe. The second design got a near perfect score because there is only a small potential that the divot could hurt the user’s nose. Lastly, the third design scored as it did because there is a chance that the nose clip could be a safety concern.

Cost

Cost was weighted last in the team’s design matrix since each design would be relatively inexpensive to fabricate and would stay within the client’s budget of $400. All three designs received a perfect score since creating them will remain under the client’s budget. None of the intended materials for developing the mask are very expensive, so production cost should be low for all of them.

Proposed Final Design

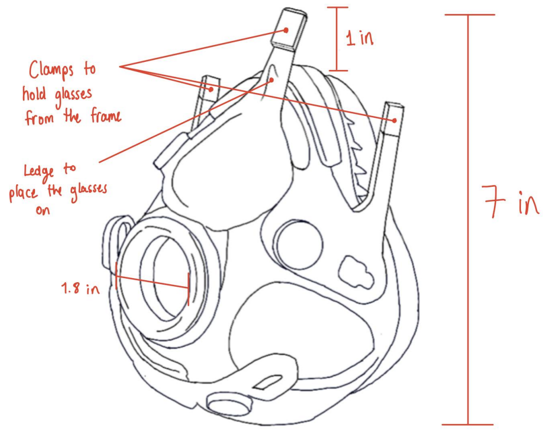
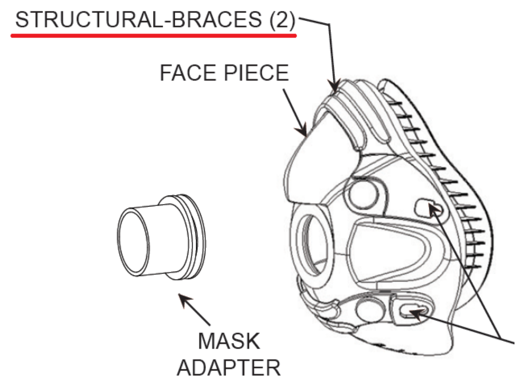


Figure 10: The team's proposed final design.

The proposed final design contains aspects of design 1, the clips and lower bridge design, and design 2, the divot design, and is illustrated in **Figure 10**. In terms of design 1, the final design will have two clips on the side that attach the glasses legs to the mask. In place of the divot, but in hopes to keep the general idea of design 2, the team is adding a third clip that will secure the bridge of the glasses to the mask as well. There will be a "ledge" on the center clip that will ensure the glasses do not slip out of place and will minimize vertical movement of the glasses. The mask will have the same dimensions as the original mask, but three clips will be added. This will ensure that the glasses are able to fit, that they stay in place, and that the mask is still able to function properly.

Although this was proposed for the final design, the final prototype is not an exact replica of the proposal. The final design only has two extension pieces, separate from the mask and attached independently to the top structural brace piece of the mask with velcro straps to secure the glasses. This will be further explained and discussed in the final prototype section below.

FABRICATION AND DEVELOPMENT PROCESS



Figures 11-12: Hans Rudolph VO_2 mask existing model. The left image shows the physical mask and the right image shows the drawing of the mask model [13].

Materials

The existing masks consist of a main silicone piece, a deformable inner layer that comes in contact with the user's face, and the structural brace pieces, made of polycarbonate thermoplastic, which attach to the straps that secure the mask to the user's face [14]. These polyurethane straps wrap around the head and are adjustable, ensuring a snug fit on every subject. The existing mask is pictured in **Figures 11-12** and the specifications are shown in **Figures 14-15**. The client has no issue with the materials present on the existing mask, so the team focused on material options for additional components of the design that would not compromise user comfortability since the goal was to assess user comfort and glasses fit while wearing the mask. Therefore, several physical prototypes were produced since qualitative variables were hard to assess using computer models and to ensure the mask would still be comfortable to wear during testing.

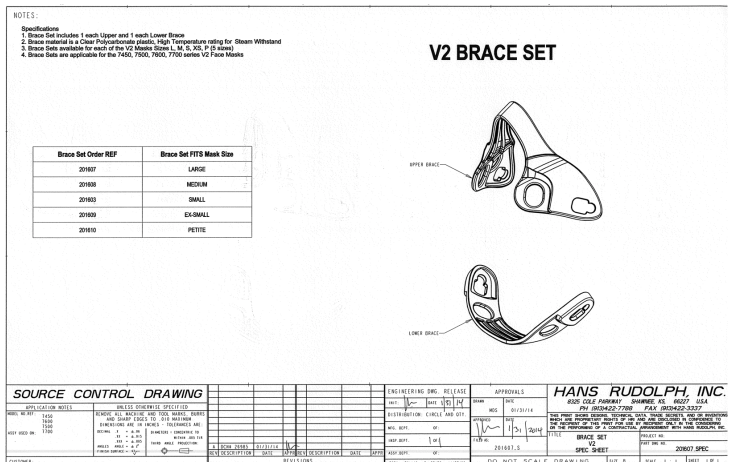
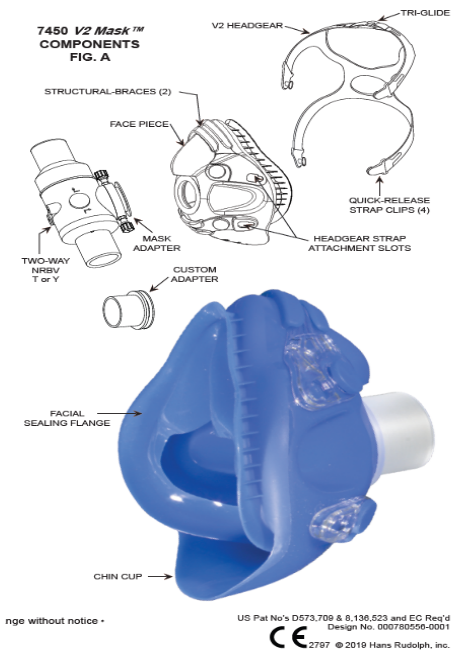
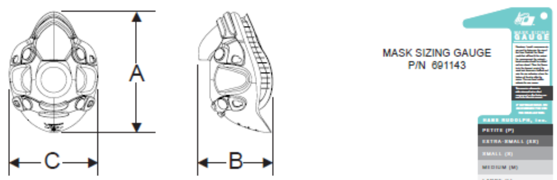


Figure 13: Specifications sheet of the structural brace pieces from Hans Rudolph, the mask manufacturer [13].

The extension component of the mask introduced three additional materials in the team's design. The original structural brace piece, made of tough plastic, is shown above in **Figure 13**, was altered in the final design to instead be made of a soft, resin plastic material. This material change was made to maintain a strong connection to the extension pieces, but also to ensure the extension pieces could still be attached and detached from the brace without much difficulty. It was also important that this elastic material would still provide connection for the headgear while avoiding alteration to the fit of the mask. The extension pieces are made of PLA, a tough and sturdy plastic used to hold the user's glasses in place and counteract any movement while in use. Due to the extension piece's rigid structure, the team felt that PLA plastic was the most effective choice. Lastly, velcro straps were chosen to attach to the subject's glasses from the extension pieces. The team wanted to be able to account for variations in face and glasses shapes, and velcro was the most versatile option to meet this requirement for all potential users. The length of the velcro straps can be cut to the user's need, making the extension piece design universal for all subjects. A full list of materials for each component of the design as well as the method to develop them can be found in **Appendix F.**



Characteristic	Mask face Piece Sizes				
	Large (L)	Medium (M)	Small (S)	Extra Small (ES)	Petite (P)
A (inches)	5.9	5.6	5.2	4.8	4.6
B (inches)	3.7	3.4	3.2	3.1	3.0
C (inches)	4.2	4.2	4.0	3.9	3.9
Deadspace (ml)	143	125	99	88	78
Weight (gm)	128	118	100	89	83



Figures 14-15: Model drawing of Hans Rudolph mask (left) and dimensions of different mask sizes the company produces (right) [14].

Methods

To generate the current design, the team first began by 3D scanning the top structural brace piece on the masks provided by the client [15]. The team wanted to be able to 3D print an identical copy of this piece, allowing the team to make the proposed alterations to the exact component. Initially, the team was going to model and print their own plastic bridge piece, but modeling the exact angles and lengths of the piece would have been difficult since the geometry and dimensions would be hard to replicate. The 3D scan of the top structural brace piece is shown below in **Figure 16.** From there, the team 3D printed the top structural brace piece from the 3D scan model using the 3D printers at the MakerSpace [16]. 3D printing was an effective option for prototyping this design because it was relatively inexpensive and quick. Using a drill press, a hole was drilled into the piece at the appropriate spot for the extension piece to fit in so it could go towards the face of the user.

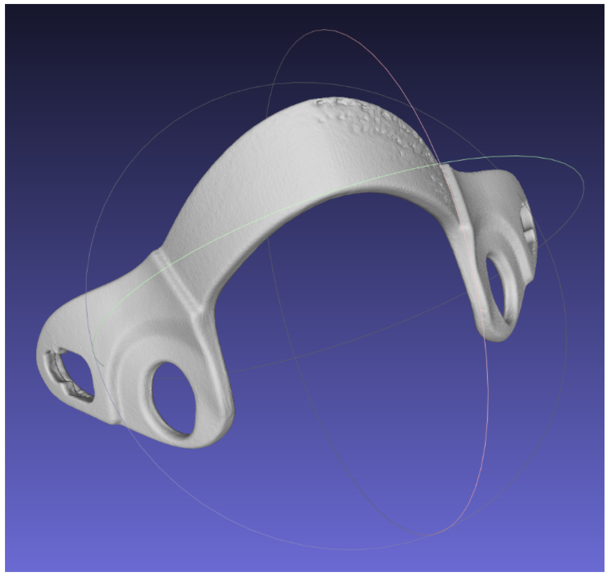


Figure 16: The 3D scan of the top structural brace piece from the original mask.

While this was being developed, the team also modeled the plastic extension piece that snaps into the structural brace piece of the mask. The team utilized SolidWorks to create this model. This model is shown below in **Figure 17**. A slit was included at the end of the piece to allow for the velcro straps to go through and wrap around the legs of the user's glasses to stabilize the glasses during testing. The extension piece was also 3D printed at the MakerSpace and was later sanded down by the team to remove impurities from printing. This process occurred twice, as the first extension pieces printed did not attach well to the legs of the user's glasses and slightly blocked the vision of the user. The final extension pieces were then inserted into the brace piece of the mask, specifically into the holes drilled, and the velcro straps were inserted into the slits at the end of the extension piece. These straps wrapped around the legs of the user's glasses while in use. A full list of the methods used to develop each component of the design as well as the materials they were made out of can be found in **Appendix F.**

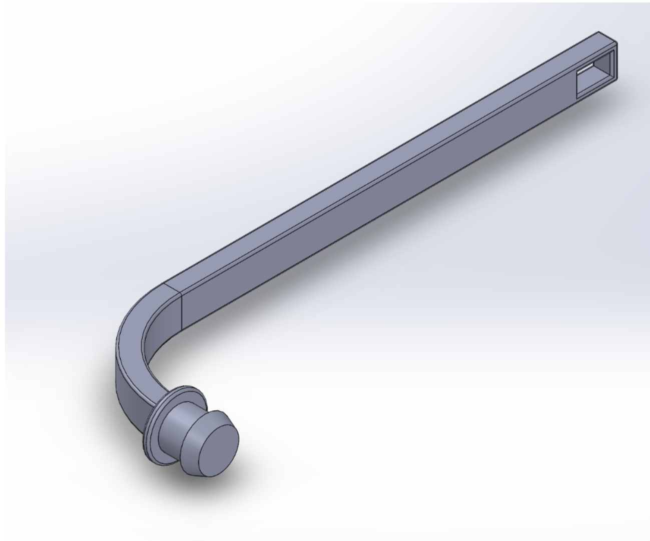


Figure 17: The SolidWorks model of the extension piece components of the design.

Final Prototype

Although the team did not follow through with the initial proposed design, modifications were made to the proposed final design to create the final design. The existing mask was kept entirely intact, and only the detachable top structural brace piece was modified. This piece attaches the straps to the mask and is positioned over the nose. In the team's design, it was also used to attach the extension pieces to the mask. Two holes, 6.5 mm in diameter, were drilled into the plastic piece near where the straps clipped on. An extension piece was inserted into each of these holes. The extension pieces were printed using PLA. The extension pieces are 65 mm in length with a 13.5 mm angle to curve toward the legs of the glasses. An 8.00 mm inner diameter of the insertion component and a 9 mm outer diameter allow the insertion component to fit snugly and firmly inside the plastic piece [17]. A total of four extension pieces were printed.

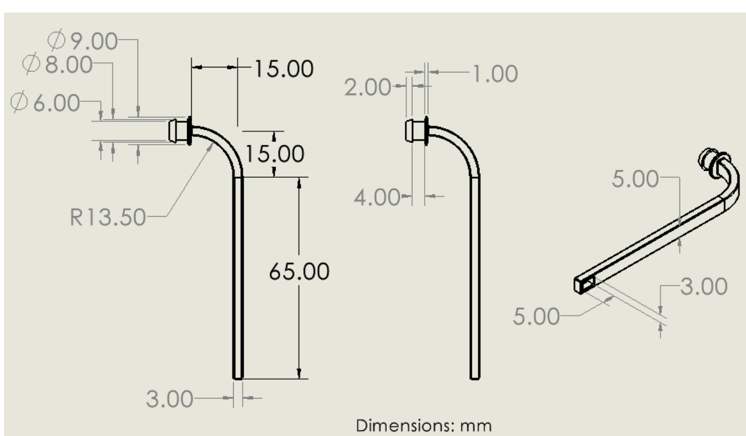


Figure 18: Dimensions of the final extension piece design.

The structural brace piece printed using the 3D scan of the original mask's structural brace piece has the same dimensions as the original. Although the sizes are not given in the manufacturers specifications sheet, the dimensions between the team's printed resin piece and the original structural piece are identical [13, 14]. Since the brace piece was printed using an elastic resin, the piece is able to be inserted into the hole by stretching the brace piece slightly, which allows the brace piece to firmly secure the extension pieces. At the distal end of the extension piece, there is a 3 mm wide by 5 mm tall slit to allow a velcro strap to be inserted. The dimensions described are shown above in **Figure 18**. The velcro strap secures to the extension piece by making one full loop around the slit. The glasses are secured to the mask by also making one full loop around the glasses legs. All other components of the original mask are the same. The final design is shown below in **Figures 19-20**. The final production cost for the final design under the $400 budget of $86.64. A full table of expenses can be found in **Appendix E.**

Figure 19-20: The proposed final design. The extension pieces connect to the newly printed structural brace piece and have slits that Velcro straps can insert into and wrap around the legs of the user's glasses to provide stability and comfort.

Testing

Initially, the team was planning to conduct an equivalence test between the design developed and the masks currently used by Johnson Health Tech to show the new design would still produce equivalent VO_2 max measurements while also allowing subjects to wear glasses during testing. These tests would have been carried out in the biomechanics lab at Johnson Health Tech under their protocols and procedures [18, 19]. Equivalence and noninferiority analysis tests and calculations would have been carried out to show the similarities in data between both masks. The equivalence test would have shown that if the VO_2 max values were within an equivalence margin, then the values would be considered “close enough” to be equivalent. The inferiority test also would utilize the equivalence margin to state that data from one mask was not inferior or superior to the other [20]. These tests would have helped to ensure the team’s mask design did not compromise comfort for accuracy of VO_2 max measurements. However, since the team is not changing the design on the mask itself but rather adding a component outside of the mask, the client preferred functional testing over equivalency testing.

In order to test the effectiveness of the mask design, the team completed functional testing of the design. Each test team member completed three, 5 minute aerobic exercise tests while wearing the VO_2 mask designed by the team. These aerobic exercises were biking, running on a treadmill, and using an elliptical. This testing was completed at the Nicholas Recreation Center at UW-Madison. The difficulty of the test was determined by the subject at a level they were comfortably challenged at to simulate the environment during a VO_2 max test. Post-test questions were asked to gain the subject’s opinions and experiences during testing. The subjects provided a ranked response from 1-5 based on the level that best matched their opinions and experiences, one indicating a poor performance of the mask and five representing a comfortable experience. By using a ranking system, uniformity across all test subjects was maintained to eliminate objectivity for adequate data analysis. Any comments from the subject were also collected for each exercise. Pre-testing procedures, like measuring the subject’s glasses, collecting demographic information, and ensuring the subject understood the tasks to perform, took place to ensure each subject completed the same testing process to provide the most reliable results. A source of error from testing was not conducting quantitative tests for the criteria. Alternative testing techniques could have been explored to collect quantitative data over the qualitative data that was collected to meet each criteria. For example, a video of the glasses on the user could have been taken during each test to measure the vertical excursion of them during testing, satisfying the movement of the glasses criteria category. However, it would have been difficult to quantitatively assess the other criteria using alternative testing methods.

A statistical analysis was conducted to provide quantitative outcomes for the collected qualitative data. This analysis, further discussed in the results section of the report, was chosen to help the team determine if the design met the needs of the client. With the new extension pieces added to the original design, it was expected that the rankings for each criteria would improve from the original design to the design with the extension pieces, showing the design was successful. The full testing outline the team followed can be found in **Appendix D**. Images during testing are also shown below in **Figures 21-23**.

By completing this testing, the design proved to meet most of the client requirements. The mask design was shown to allow users to comfortably wear glasses during testing, was practical and user friendly, was reusable with cleaning, and was under the production budget. Although the requirements of preventing air leakage, withstanding testing for 20 minutes, and operational during intense aerobic activities were not fully met during the functional testing conducted, it can be assumed that the mask would meet these criteria as well as it showed to meet them over a smaller period of time.

Figures 21-23: Images from testing using the extension pieces. Each team member completed short aerobic testing on the bike, treadmill and elliptical to rank specified criteria on a five point scale.

RESULTS

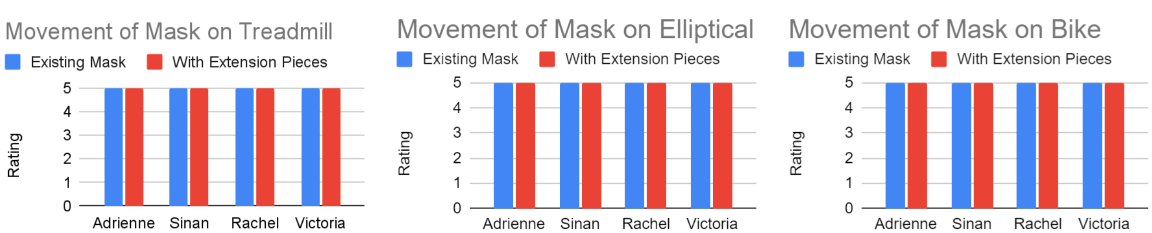


Figure 24: Survey results for each subject rating the movement of the mask for each activity.

Figure 24 displays the survey results for movement of the mask while performing each activity. None of the subjects observed any movement of the mask with either design. This was expected because the extension pieces should not directly affect how the mask fits on the user's face. The design was created to secure the glasses without affecting the fit of the mask on the user's face, which could impact VO_2 max testing results if there was any air leakage. These results do show that the headgear straps holding the mask to the user's face were able to properly clip into the 3D-printed brace piece as effectively as they connected to the original brace piece from the manufacturer. This variable would have been more important if the team was creating an entirely different mask from the mask currently used by our client.

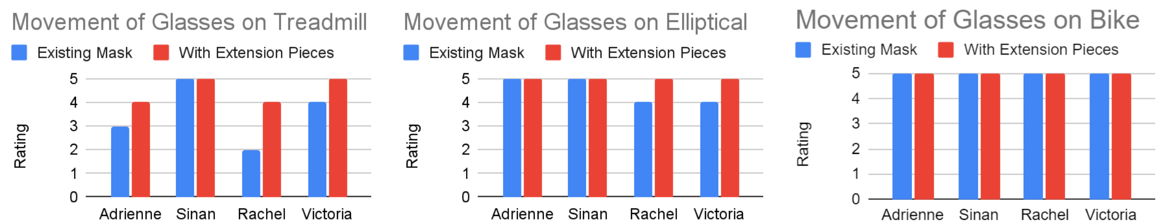


Figure 25: Survey results for each subject rating the movement of the glasses for each activity.

The survey responses for movement of the glasses while performing each exercise are displayed in **Figure 25**. This measurement most closely relates to the problem statement because the main goal of the design was to secure the glasses on the user's face to provide a safer testing environment for the user. No movement of the glasses was observed by any of the participants on the bike, and minimal changes were observed for the ratings while using the elliptical. Ratings were high for both designs on the bike and the elliptical because there was not much vertical movement involved while performing the activity that could greatly impact the movement of the glasses. However, three of the four participants observed less movement of the glasses with the extension pieces on the treadmill. Across the three activities, every subject observed consistent or decreased movement of the glasses with the extension pieces and velcro securing the glasses. While the team cannot provide statistically significant conclusions based on the limited sample size, these results are promising for the effectiveness of the design involving the extension pieces. In the future, the team could use a motion capture video system to measure and quantify the vertical movement of the glasses. The vertical movement measurements using the existing mask and using the mask with the extension pieces could be compared to quantitatively demonstrate the ability of the design in restricting that vertical motion.

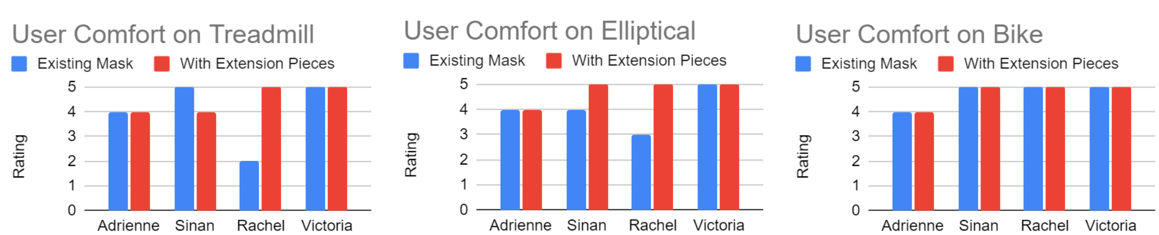


Figure 26: Survey results for each subject rating user comfort for each activity.

Figure 26 displays the results for the overall comfort of the combination of the mask and glasses during testing. No changes in ratings between the two designs were observed on the bike. Although comfort can be perceived differently for each user, it was still useful to see how people with different face shapes, glasses shapes, and personal preferences rate the two designs in comparison to one another.

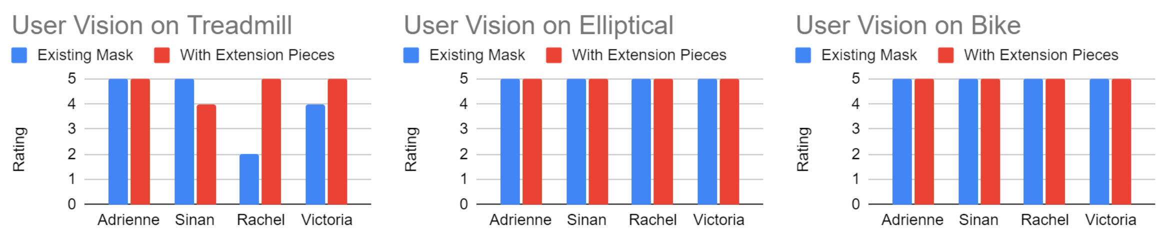


Figure 27: Survey results for each subject rating user vision for each activity.

User vision survey results are shown in **Figure 27**. No issues with vision were noted by the participants for the elliptical and bike activities. Differences in the ratings between the two designs were observed during the treadmill test. Two users observed an improvement in vision during the treadmill test, and one observed a decrease in vision. The impairment in vision was only noticed on the treadmill test because there was more vertical movement of the glasses while running. It is promising that the majority of users experienced an improvement of vision during testing to further meet the design goal of allowing users to see adequately during testing.

The Wilcoxon Signed Rank Test was chosen as the appropriate statistical test for analyzing the discrete, numerical data the team was collecting. This test is analogous to the paired t-test that is used to analyze continuous data. The discrete data cannot be assumed to follow a normal distribution, and the t-test is not robust against violations of this normality assumption for small sample sizes. Therefore, the t-test is not appropriate for this application, and the Wilcoxon Signed Rank Test offers a non-parametric alternative [21]. Another statistical test considered was the Sign Test. This test is very similar to the Wilcoxon Signed Rank Test because it is looking at the number of positive differences vs. negative differences between the two groups, but it does not take into account the rank (or magnitude) of the differences [22]. Although the team was unable to accurately run these tests due to the small sample size, some calculations and setup for the two tests can be found in **Appendix B**. It is important to note that the analysis has to be run individually for each criterion on each piece of equipment. Since the team evaluated four criteria (movement of mask, movement of glasses, user comfort, and user vision) on three pieces of equipment (treadmill, elliptical, and bike), a total of 12 tests need to be performed. Even though a statistical analysis cannot be performed and conclusions cannot be drawn from the data collected, some noticeable differences between the two mask design alternatives were observed based on survey responses and general observation from team members. Raw data can also be found in **Appendix C.**

A few points need to be taken into account when interpreting these results. First, the sample size was not large enough to run the Wilcoxon Signed Rank Test. A sample size greater than 5 is necessary to draw any statistically significant conclusions from the data [21]. Therefore, the trends observed in these trials cannot be used to draw conclusions about the design's ability to meet the design specifications. It is also important to note that a significant amount of bias could have been involved with the team rating their own design. Due to health concerns and availability of resources, this was the only option for performing functional testing. However, the team does hope to draw a larger and more randomized sample in the future to truly evaluate the effectiveness of the new design compared to the existing mask in improving the VO2 max testing experience for glasses users. A larger sample size would also allow the team to see if there is any correlation between the survey results and the glasses measurements to understand if there are any shapes or sizes of glasses that the design is unable to accommodate or is able to accommodate particularly well. Lastly, since all test subjects used their own glasses for testing, the experiences for each user could have differed. But, it is important to test using different glasses because when the design is used for true VO_2 max testing, all test subjects will have different glasses as well. Overall, the design showed that the criteria of the client were met by limiting the movement of the glasses, maintaining good vision throughout testing, and keeping subjects comfortable during testing.

DISCUSSION

Since the client requested functional testing of the design over equivalency testing, it is difficult to compare the results to other relevant research. If equivalency testing was carried out, the efficiency of collecting VO_2 max data between the developed mask design and the original mask would have been compared in hopes that the results were accurate. There has currently been no research done that evaluated the same criteria in a survey style test regarding a VO_2 mask. If the team was able to conduct equivalency testing, the VO_2 max data collected could have been compared to past studies that also collected the same data to compare results. The results could have also been compared to the collected data of the original mask to the data collected from the designed mask during a VO_2 max test.

Some sources of error throughout the design process included not collecting quantitative data during testing, not having a large enough sample size to complete a statistical analysis, introducing bias into testing by using team members as test subjects, and not being able to complete true VO_2 max testing. By collecting qualitative data over quantitative data, it makes testing more objective and variable while also making analyzing the outcomes more difficult. If quantitative data was instead collected, the results might be more reliable. The testing sample was also too small to run a statistical analysis test and it was also made up of team members. Not having enough test subjects resulted in making assumptions from the data, making it not as reliable. Although not intended, the team members of the design will naturally introduce bias into the survey-based testing. Lastly, without completing true VO_2 max testing, it is difficult to accurately and decisively say whether the design was successful since it was not tested in the actual environment it would be used in. However, assumptions were made with the situations at hand to best evaluate the design. Although there were sources of error throughout the design process, alternative ways to best interpret the successfulness of the design were followed.

When conducting research, it was important to maintain ethical considerations. It was important to ensure the subject was comfortable at all times during testing since wearing the mask could cause anxiety, fear, and claustrophobia to some individuals. It was also important to make sure the subject was safe at all times during testing. Since the subject was performing physical exercise at fairly intense levels, it is ethically important that the subject's health and safety was monitored in the case of an accident. These factors would also apply if true VO_2 max testing was conducted with the designed mask. If regular VO_2 max testing was conducted, the physical health of the subject would be even more important since the test subjects are pushing their bodies to its aerobic maximum. Regardless of whether the designed mask was tested functionally or with true VO_2 max testing, ethical standards had to be met.

Ultimately, the modeled mask with the included extension pieces and newly modeled structural brace piece will allow subjects undergoing VO_2 max testing to wear glasses comfortably during testing. The subjects will not have to be concerned with their glasses moving, falling off, or impeding testing, further aiding in reducing potential anxiety during testing and removing an increased risk of injury if their vision was compromised during testing. This design also has the potential to be implemented into other products that involve the impediment of glasses.

After evaluating the functionality of the design, not many changes have to be made since it was successful at securing glasses in place during aerobic testing. However, design changes cannot be solidified since the mask did not undergo true VO_2 max testing to compare its accuracy and performance to the original mask. But, this testing could occur in the future and if necessary, changes and investigations into alternate designs could be considered.

CONCLUSION

VO_2 max testing is a powerful tool in assessing cardiovascular and aerobic fitness levels. Unfortunately, of the VO_2 masks currently available, none provide a mask compatible with glasses. Subjects with glasses are required to perform the test without glasses, which could cause anxiety for the subject and result in an unsafe testing environment. Johnson Health Tech has asked the team to provide a solution that allows subjects to wear glasses during testing and accommodate users with diverse facial profiles and different glasses sizes.

As the team progressed through the design process, an alternate solution was found based on the initial preliminary developed designs. The final proposed design consisted of two additional extension pieces that would attach to the original mask provided at a newly designed top structural brace piece which can be seen in **Figures 19-20**. These additional parts acted to stabilize and secure the glasses while performing endurance testing. The extension pieces attach on either side of the top structural brace piece and extend upwards towards the legs of the user's glasses, attaching through a velcro strap that is inserted into slits at the end of the extension pieces. Because the original mask was not modified in any way, VO_2 max testing results would remain consistent, leading the team to perform functionality testing instead of equivalency VO_2

max testing between the original mask and the design developed by the team. From testing, the team concluded that the extension pieces were effective in lowering the movement of the glasses, maintaining comfortability and improving vision while performing physical exercise tests.

In the future, some changes could be made to the design and testing process. First, the sample size could be expanded to be able to run the Wilcoxon statistical analysis test and it should include test subjects outside of the design team. This will eliminate bias from testing as well as provide more reliable data through statistical analysis. In addition to these changes in testing, the design could also undergo true VO_2 max testing to observe if it is reliable in the environment it would be used. Lastly, alternative design options could be explored by changing the design of the face piece or investigating the preliminary designs developed by the team to see if any meet the criteria better than the current design. If these changes were made, Johnson Health Tech could better utilize the design.

REFERENCES

[1] "VO2 MAX 101 - HOW TO TEST, CALCULATE AND IMPROVE IT," *Training 4 Endurance*. https://training4endurance.co.uk/physiology-of-endurance/vo2max/ (accessed Oct. 18, 2021).

[2] *VM Pro Product Manual,* VO2 Master Health Sensors Inc., Vernon, BC, Canada, 2021, http://vo2master.com/wp-content/uploads/2020/02/Manual20200209.pdf (accessed Sept. 15, 2021).

[3] "VO2 Master Analyzer | VO2 Master." https://vo2master.com/analyzer/ (accessed Oct. 14, 2021)

[4] "COSMED - K5: Wearable Metabolic System for both laboratory and field testing." https://www.cosmed.com/en/products/cardio-pulmonary-exercise-test/k5 (accessed Oct. 18, 2021).

[5] "COSMED - K5: Wearable Metabolic System for both laboratory and field testing." https://www.cosmed.com/en/products/cardio-pulmonary-exercise-test/k5 (accessed Oct. 14, 2021).

[6] "CardioCoach VO2 Max Testing Equipment - KORR Medical Technologies." https://korr.com/products/vo2-max-testing-system/ (accessed Oct. 18, 2021).

[7] J. White, "CardioCoach VO2 Max Testing Equipment - KORR Medical Technologies," Aug. 23, 2013. https://korr.com/products/vo2-max-testing-system/ (accessed Oct. 14, 2021).

[8] "Vo2 Max Testing," *University of Virginia School of Medicine*. [Online]. Available: https://med.virginia.edu/exercise-physiology-core-laboratory/fitness-assessment-for-community-members/vo2-max-testing/. [Accessed: 13-Sep-2021].

[9] P. Batterson, "Physiology of Maximal Oxygen Consumption | VO2 Master." https://vo2master.com/physiology-of-maximal-oxygen-consumption/ (accessed Nov. 23, 2021).

[10] Ziqing Zhuang *et. al,* "A HEAD-AND-FACE ANTHROPOMETRIC SURVEY OF U.S. RESPIRATOR USERS," https://www.nap.edu/resource/11815/Anthrotech_report.pdf, NIOSH/NPPTL, Pittsburgh, PA, *and* Anthrotech, Yellow Springs, OH, May 28, 2004, (accessed Oct. 18, 2021).

[11] "Johnson Health Tech." https://www.johnsonhealthtech.com/us/eng/about-us (accessed Oct. 18, 2021).

[12] "HOW DO I FIND THE FRAME SIZE OF MY RAY-BAN SUNGLASSES AND EYEGLASSES?" Size Guide, Ray Ban Sunglasses, www.ray-ban.com/usa/size-guide. *Google Search: 'sizing guide glasses size chart.'*

[13] Hans Rudolph Inc., 2014. *V2 Brace Set*. [image].

[14] H. Rudolph, “Data Sheet... 7450 SeriesV2™ Mask ORO-NASAL,” p. 2.
[15] “3D Scanners,” *UW Makerspace*. https://making.engr.wisc.edu/3d-scanners-2/ (accessed Oct. 14, 2021).
[16] “3D Printers,” *UW Makerspace*. https://making.engr.wisc.edu/3d-printers-2/ (accessed Oct. 14, 2021).
[17] Rasmussen, A., 2021. *SolidWorks Mask Extension piece model*. [file]. [accessed Dec., 2021].
[18] J. Muench, "Step+ VO2 Validation," 2018.
[19] J. H. Tech, "VO2 Instructional JHT," 2019.
[20] E. Walker and A. S. Nowacki, “Understanding Equivalence and Noninferiority Testing,” *J Gen Intern Med*, vol. 26, no. 2, pp. 192–196, Feb. 2011, doi: 10.1007/s11606-010-1513-8.
[21] S. Glen, “Wilcoxon Signed Rank Test: Definition, How to Run, SPSS,” *Statistics How To*, Sep. 17, 2021. https://www.statisticshowto.com/wilcoxon-signed-rank-test/ (accessed Dec. 04, 2021).
[22] S. Glen, “Sign Test: Step by Step Calculation,” *Statistics How To*, Mar. 1, 2016. https://www.statisticshowto.com/sign-test/ (accessed Dec. 04, 2021).

APPENDIX

Appendix A: Product Design Specifications

Function:

Aerobic endurance tests, such as VO_2 max tests, are important in determining the aerobic fitness of athletes. During VO_2 max testing, athletes wear a VO_2 mask with an intake tube attached while performing an intense and high level form of exercise like running or biking. The concentration of oxygen inhaled and carbon dioxide exhaled are collected through the mask to determine how much oxygen the athlete uses during exercise as well as the maximum concentration of oxygen consumed. The more oxygen consumed, the more efficient the cardiovascular system is working, meaning more oxygen can be used to enhance physical performance. There are VO_2 masks used during testing currently on the market, but improvements can still be made to make the testing more comfortable for participants. Participants that wear glasses have posed a big concern, resulting in the need for the development of a VO_2 mask that can be worn comfortably with glasses. With current products on the market, users cannot wear glasses during testing. This can cause anxiety and worry in users since they can feel disoriented and uncomfortable, putting them at risk during testing. The design must be comfortable, prevent air leakage, and allow the athletes to wear glasses during testing while being able to function in the operating conditions and cost less than $400 to produce.

Client Requirements:

- The VO_2 mask must be designed to allow subjects with glasses to wear their glasses during VO_2 max testing
- Leakage of air must be limited
- Must be practical and user friendly
- Operational during intense exercise activity such as running, biking, or using an elliptical
- Production costs must not exceed $400
- Withstand testing for around 20 minutes
- Reusable with cleaning

Design requirements:

1. Physical and Operational Characteristics

a. Performance Requirements: The mask design must allow users with glasses to wear their glasses during the entirety of the VO_2 max data collection. The design must be conducive to the intense exercise environment subjects are put in and should not alter the exercise gait of the participants during testing. To prevent air leakage, it should not move around on the face of the user and should be securely fit to their face. This will allow the VO_2 max values to be collected accurately across all subjects.

b. Safety: The user must be allowed to wear glasses while the mask is on. Visual impairment causes a high safety risk as the user is performing testing at high speeds on aerobic machines. Performing the testing with their glasses on will also help the user feel more comfortable and less anxious. The mask should provide a snug fit, making sure all air is going through the mask in order to provide the most accurate VO_2 measurement. The mask also should not cause skin irritation or be uncomfortably tight on the user's face.

c. Accuracy and Reliability: To validate the functionality of the design, the team will perform functional testing of the mask design as per the client's requests. The team will collect qualitative data based on responses from test subjects during basic exercise testing. The qualitative responses will be ranked answers from different criteria on a 5 point scale based on the subject's experiences during timed intervals of treadmill running, biking, and using the elliptical. One indicates an uncomfortable experience and five represents a comfortable experience. The team will conduct a qualitative analysis of the responses to determine if the developed design will functionally meet the client's requirements. The statistical test that will be run on the collected survey-style data will be the Wilcoxon Signed Rank Test [1]. The testing will follow a protocol outline developed by the team. If the team were testing the accuracy of the mask, VO_2 max testing would have been conducted at the Johnson Health Tech biomechanics lab following the provided protocols that are used with the existing VO_2 masks at Johnson Health Tech. The VO_2 readings of the team's mask design and existing masks used by Johnson Health Tech would have been compared. The volume of O_2 consumed per minute (VO_2) and the volume of air expired per minute (V_e) are the only variables being measured that the mask could impact [2]. The VO_2 readings of the designed mask would have ideally been within 5% of the VO_2 readings using the existing mask.

d. Life in Service: The mask design will be used for no longer than 20 minutes at a time for testing. All pieces of the mask should also be reusable and easy to sanitize. It will be washed with soap and water and will be allowed to dry in between uses [2]. The mask is also steam autoclavable [3].

e. Shelf Life: The mask is aimed to be used across multiple tests since it will be reusable and easy to sanitize. The mask and headgear can stay in service for about 6 months or 25 disinfection cleanings [3]. They should be kept at room temperature where the material of the mask will not be damaged. The mask should be sanitized after every use. Soap and water will be sufficient for sanitizing the mask.

f. Operating Environment: The mask will be used in the biomechanics lab at Johnson Health Tech, but it could potentially be used in hospital or clinical settings as well. All components of the mask will be exposed to human contaminants such as saliva, mucus, sweat, and other pollutants in the body, albeit for only short periods of time. Temperature and humidity will also be contributing factors, even in an indoor environment, due to the participants expelling body heat and sweat. The mask should withstand temperatures ranging from 5-40 ℃ and humidity levels between 0-95% [3]. In storage, the mask is susceptible to common contaminants like dirt, dust, and other particles. These pollutants should have no impact during use, as the user of the VO_2 mask should be able to clean dirty areas before use.

g. Ergonomics: The design is based primarily on user comfort and functionality. The straps that run behind the head and around the ears should remain adjustable so the mask can fit comfortably on all users and minimize mask movement during testing. The silicon mask should not slide off the front of the face and should be comfortable for the user to wear. In addition, the user of the VO_2 mask should not experience any noticeable forces acting upon their glasses while in use that would cause pain or discomfort. This design should withstand any significant bending or movement during aerobic exercises at maximum human velocity, which is around 12 m/s or 28 mph [4]. Given this speed, the final design should be able to withstand 560 N or about 125 lbs of force [5].

h. Size: The client has directed the team to make one version of the mask based on the larger model given to us. This design must securely fit the user while preventing air leakage in connection with existing intake tubes. The current measurements of the mask used by Johnson Health Tech are 5.6" in height, 4.2" in width, and 3.4" in depth for the medium size [3]. The extension pieces designed were 65 mm in length, with a 13.5 mm angle to curve towards the legs of the glasses, a 7.50 (and 8.00 mm for another size created) mm for the inner diameter of the insertion component to the mask with a 9 mm outer diameter [6]. The structural brace piece printed by the team using the 3D scan of the original maks's structural brace piece had the same dimensions as the original piece. Although the sizes are not given in the manufacturers specifications sheet, the dimensions between the team's printed resin piece and the original structural piece are identical [3,7].

i. Weight: The client has made no indication about a weight restriction for the mask; however, there should not be much variance between the team's design and the existing mask since only the extension component is being added to the mask. The optimal weight is similar to the existing weight, allowing for user comfort. The current weight of the mask used by the client is 118g [3]. Since the extension pieces and the Velcro straps are the only additions to the current mask model, the weight should not vary much more than the current weight.

j. Materials: Since the mask is not being altered, the face piece will still be made of silicone rubber, the headgear will still be Polyurethane Foam Black and Nylon, the headgear hooks will be nylon, and the headgear strap clips will be Polypropylene. The extension piece will be made out of a 3D printed PLA plastic with a Velcro strap attached and the newly 3D printed structural brace pieces will be resin. There are no restrictions to material, but these materials are catered to the user's comfort. The tubes and valves that fit into the mask and are used in the client's BioMech Lab will also be provided.

k. Aesthetics, Appearance, and Finish: All characteristics of the current mask will remain the same, so the aesthetics, appearance, and finish of the mask itself will remain consistent with the current mask. The extension pieces are be black and L-shaped while the resin structural brace pieces are translucent. The Velcro strap is black and maintains a professional and sleek look alongside the rest of the design.

2. Production Characteristics

a. Quantity: A total of four extension pieces will be developed for the final prototype. Only two will be able to fit on the mask at one time. The other two pieces will be used if a piece breaks or becomes nonfunctional. Each extension piece will include a Velcro strap that can be cut to an appropriate length to hold each individual subject's glasses in place. This length will change from user-to-user. One top structural brace piece will also be produced.

b. Target Product Cost: The total budget for the mask is $400. The target is to keep the cost under the budget. The goal is to build a mask design that meets the client's needs and is cost efficient.

3. Miscellaneous

a. Standards and Specifications: For the mask to be in use, there are certain requirements. First of all, it should meet all FDA standards and specifications. It should be compatible with all sizes of glasses and should not interfere with any movement or exercise that could cause any danger. During testing, ventilation should be measured throughout the duration, while heart rate and VO_2 data should be monitored every 15 seconds. The mask should be durable enough to go through three different three minute tests with 20, 25, and 30 bpm trials [8]. The mask should be approximately 4.5" long, measuring from the centerline of the face. It should be a snug fit with minimal air leakage. Finally, it should only be stored in temperatures higher than 0℃ and lower than 45℃ [8].

b. Customer: The main concern of the customer is that the current mask model does not allow the subject to wear glasses while simultaneously wearing the mask. The client prefers the mask to be made out of rubber or silicone, but the team is able to prototype with whatever materials they see fit. The goal is that the mask is a snug fit and that there is minimal leakage to best measure VO_2 levels.

The customer would like the team to account for the biggest glasses size possible to ensure that the mask is designed for all glasses wearers. There should be no prejudice against people of any size, weight, age, gender, or background. The mask should be accessible to all people.

c. Patient-Related Concerns: The current mask covers the bridge of the nose, which does not allow the wearer to place glasses in the correct position. Not being able to wear glasses during these activities causes high levels of anxiousness in the wearer. This can also result in patient injury, as the wearer is unable to see correctly. Wearing contacts could be an alternative solution to this problem, but that might not be feasible for all users. Anxiety surrounding these activities can be greatly reduced if the wearer is able to successfully wear glasses and see properly while performing VO_2 testing. The device requires full sanitation, with a soap and water mixture and/or disinfectants, between uses. This allows the same mask to be used by many patients, which increases the overall shelf life of the product. All data collected by the VO_2 testing should remain confidential per U.S. law regarding doctor-patient confidentiality [9].

d. Competition: Many of the competing designs follow most of the same testing protocols and goals for use. One of the more recent designs has been used throughout the COVID-19 pandemic. This device includes a face piece, headgear, breathing valve adapter, breathing valve, and filter. A benefit of this device is that it is reusable and autoclavable. This allows for a longer shelf life, less product waste, and less cost associated long term. This mask is made of silicone and has a ripped support where it comes into contact with the face in order to prevent leakage out of the mask. Although the manufacturer claims the mask is compatible with glasses, the client has not found that to be the case [10]. Another similar device is the Master Analyzer. This is able to measure performance testing and resting metabolic testing simultaneously. Benefits associated with this design is that there are no backpacks, cables, or hoses, no calibration syringes or gas tanks, validated against the gold standard, filters ensure sanitation between users, and free mobile application for guided testing. Annual calibration and yearly maintenance allows for a long shelf life. This mask is also unable to provide for glasses wearers [11]. A final, more refined design was by simply using a mouthpiece and nose clip, rather than an entire headgear apparatus. Significantly less discomfort was experienced by users using the mouthpiece. The leakage from the mouthpiece compared to the headgear was found to be unproblematic. The methods associated with collecting data from mask users have proven to be difficult "due to the high incidence of losing the nose clip during exercise, the awkwardness and discomfort of the apparatus, and the loss of oral communication" [12]. Of the competing designs, the mouthpiece design is the only design on the market that allows the participants to wear glasses at the same time.

References

[1] Stephanie, “Wilcoxon Signed Rank Test: Definition, How to Run, SPSS,” *Statistics How To*, Sep. 17, 2021. https://www.statisticshowto.com/wilcoxon-signed-rank-test/ [accessed Dec. 06, 2021].

[2] Korr Medical Technologies, "VO2 Instructional Document," Apr. 23, 2019. (accessed Dec., 2021).

[3] H. Rudolph, “Data Sheet 7450 SeriesV2™ Mask ORO-NASAL,” p. 2. [accessed Dec., 2021].

[4] Fell, Andy. “Calculus Shows Just How FAST Usain Bolt Runs.” [Online]. *Futurity*, University of California-Davis, 25 Aug. 2016, www.futurity.org/usain-bolt-calculus-1233862-2/. [Accessed: 23-Sep-2021].

[5] Force Calculation: *Kriewaldt, Thomas*, Sep. 24, 2021, In the fastest ever 100m dash, run by Usain Bolt, the maximum acceleration was measured at just over 6 m/s^2. Given this sprinter weighed around 94 kg[1] at the time of the race, Newton’s Law: F=ma can be used to calculate the force against the user reaching peak human velocity [$F=(94kg)(6m/s^2)$]. This result gives us an estimate of around 560 N.

[6] Rasmussen, A., 2021. *SolidWorks Mask Extension piece model*. [file]. [accessed Dec., 2021].

[7] Hans Rudolph Inc., 2014. *V2 Brace Set*. [image]. [accessed Dec., 2021].

[8] Muench, Jared. “Step+VO2 Validation.” 17 July 2018. [accessed Dec., 2021].

[9] “Physician-Patient Privilege”, *Legal Information Institute.* [Online]. Available: https://www.law.cornell.edu/wex/physician-patient_privilege [Accessed: 6-Dec-2021]

[10] “Metabolic testing equipment, Cardiopulmonary testing systems,” *VacuMed*. [Online]. Available: https://www.vacumed.com/zcom/product/Product.do?compid=27&prodid= 8237. [Accessed: 22-Sep-2021].

[11] A. H. K. Montoye and R. Hinnen, “Vo2 master analyzer,” *VO2 Master*. [Online]. Available: https://vo2master.com/analyzer/. [Accessed: 22-Sep-2021].

[12] K. Brooks and D. JJ, “Measurement of aerobic capacity using mouthpiece vs. mask for data collection,” *OMICS International*, 18-Feb-2013. [Online]. Available: https://www.omicsonline.org/open-access/measurement-of-aerobic-capacity-using-mouthpiece-v-mask-for-data-collection-2165-7025.S2-002.php?aid=11715. [Accessed: 22-Sep-2021].

[1] Wood, Robert. “Anthropometric Measurements of the Men's 100m Olympic Champions.” [Online]. Topend Sports, Science, Training and Nutrition, Topend Sports Website, Dec. 2015, www.topendsports.com/events/summer/science/athletics-100m.htm. [Accessed: 23-Sep-2021].

Appendix B: Wilcoxon Signed Rank Test and Sign Test Sample Analysis

Wilcoxon Signed Rank Test Description: The null hypothesis says that the median of group one is equal to the median of group two. The alternative hypothesis says that the two medians are different. Absolute differences are ranked from least to greatest in ascending order. The rank awarded to tied differences is the average of the ranks associated with those numbers. For example, if there are three differences of 1 tied for rank 1, the rank awarded to each would be the average of 1, 2, and 3 → 2. T+ is the sum of the ranks for values with positive differences, and T- is the sum of the ranks for values with negative differences. The lesser of these two numbers is used as the test statistic. The critical value/statistic is given in a table based on the significance level and sample size. The test statistic is then compared to the critical value. If the test statistic is less than the critical value, then there is a significant difference between the two medians (reject the null hypothesis).
https://www.statisticshowto.com/wilcoxon-signed-rank-test/

Sign Test Description: This test is very similar to the Wilcoxon Signed Rank Test. The null hypothesis and alternative hypothesis are the same. No ranks are assigned, and results are based solely on whether each calculated difference is positive or negative. Find the p-value from a binomial distribution table and compare it to the significance level to determine whether to reject or fail to reject the null hypothesis.
https://www.statisticshowto.com/sign-test/

a. Wilcoxon Signed Rank Test: Movement of Mask

Movement of Mask (Treadmill)	*Original Mask*	*Our Mask*	*Difference*	*Absolute Difference*	*Rank*	*Results*
Adrienne	5	5	0	0	N/A	T+ = --, T- = --
Sinan	5	5	0	0	N/A	Wstat = --, Wcrit = --
Rachel	5	5	0	0	N/A	fail to reject Ho
Victoria	5	5	0	0	N/A	sample size too small
Movement of Mask (Elliptical)	*Original Mask*	*Our Mask*	*Difference*	*Absolute Difference*	*Rank*	*Results*
Adrienne	5	5	0	0	N/A	T+ = --, T- = --
Sinan	5	5	0	0	N/A	Wstat = --, Wcrit = --
Rachel	5	5	0	0	N/A	fail to reject Ho
Victoria	5	5	0	0	N/A	sample size too small
Movement of Mask (Bike)	*Original Mask*	*Our Mask*	*Difference*	*Absolute Difference*	*Rank*	*Results*
Adrienne	5	5	0	0	N/A	T+ = --, T- = --
Sinan	5	5	0	0	N/A	Wstat = --, Wcrit = --
Rachel	5	5	0	0	N/A	fail to reject Ho
Victoria	5	5	0	0	N/A	sample size too small

b. Wilcoxon Signed Rank Test: Movement of Glasses

Movement of Glasses (Treadmill)	*Original Mask*	*Our Mask*	*Difference*	*Absolute Difference*	*Rank*	*Results*
Adrienne	3	4	1	1	1.5	T+ = 6, T- = 0
Sinan	5	5	0	0	N/A	Wstat = 0, Wcrit = --
Rachel	2	4	2	2	3	fail to reject Ho
Victoria	4	5	1	1	1.5	sample size too small
Movement of Glasses (Elliptical)	*Original Mask*	*Our Mask*	*Difference*	*Absolute Difference*	*Rank*	*Results*
Adrienne	5	5	0	0	N/A	T+ = 3, T- = 0
Sinan	5	5	0	0	N/A	Wstat = 0, Wcrit = --
Rachel	4	5	1	1	1.5	fail to reject Ho
Victoria	4	5	1	1	1.5	sample size too small
Movement of Glasses (Bike)	*Original Mask*	*Our Mask*	*Difference*	*Absolute Difference*	*Rank*	*Results*
Adrienne	5	5	0	0	N/A	T+ = --, T- = --
Sinan	5	5	0	0	N/A	Wstat = --, Wcrit = --
Rachel	5	5	0	0	N/A	fail to reject Ho
Victoria	5	5	0	0	N/A	sample size too small

c. Wilcoxon Signed Rank Test: User Comfort

Comfort (Treadmill)	*Original Mask*	*Our Mask*	*Difference*	*Absolute Difference*	*Rank*	*Results*
Adrienne	4	4	0	0	N/A	T+ = 2, T- = 1
Sinan	5	4	-1	1	1	Wstat = 1, Wcrit = --
Rachel	2	5	3	3	2	fail to reject Ho
Victoria	5	5	0	0	N/A	sample size too small
Comfort (Elliptical)	*Original Mask*	*Our Mask*	*Difference*	*Absolute Difference*	*Rank*	*Results*
Adrienne	4	4	0	0	N/A	T+ = 3, T- = 0
Sinan	4	5	1	1	1	Wstat = 0, Wcrit = --
Rachel	3	5	2	2	2	fail to reject Ho
Victoria	5	5	0	0	N/A	sample size too small
Comfort (Bike)	*Original Mask*	*Our Mask*	*Difference*	*Absolute Difference*	*Rank*	*Results*
Adrienne	4	4	0	0	N/A	T+ = --, T- = --
Sinan	5	5	0	0	N/A	Wstat = --, Wcrit = --
Rachel	5	5	0	0	N/A	fail to reject Ho
Victoria	5	5	0	0	N/A	sample size too small

d. Wilcoxon Signed Rank Test: User Vision

Vision (Treadmill)	*Original Mask*	*Our Mask*	*Difference*	*Absolute Difference*	*Rank*	*Results*
Adrienne	5	5	0	0	N/A	T+ = 4.5, T- = 1.5
Sinan	5	4	-1	1	1.5	Wstat = 1.5, Wcrit = --
Rachel	2	5	3	3	3	fail to reject Ho
Victoria	4	5	1	1	1.5	sample size too small
Vision (Elliptical)	*Original Mask*	*Our Mask*	*Difference*	*Absolute Difference*	*Rank*	*Results*
Adrienne	5	5	0	0	N/A	T+ = --, T- = --
Sinan	5	5	0	0	N/A	Wstat = --, Wcrit = --
Rachel	5	5	0	0	N/A	fail to reject Ho
Victoria	5	5	0	0	N/A	sample size too small
Vision (Bike)	*Original Mask*	*Our Mask*	*Difference*	*Absolute Difference*	*Rank*	*Results*
Adrienne	5	5	0	0	N/A	T+ = --, T- = --
Sinan	5	5	0	0	N/A	Wstat = --, Wcrit = --
Rachel	5	5	0	0	N/A	fail to reject Ho
Victoria	5	5	0	0	N/A	sample size too small

e. Rank Test: Movement of Mask

Movement of Mask (Treadmill)	*Original Mask*	*Our Mask*	*Difference*	*Sign*
Adrienne	5	5	0	0
Sinan	5	5	0	0
Rachel	5	5	0	0
Victoria	5	5	0	0
Movement of Mask (Elliptical)	*Original Mask*	*Our Mask*	*Difference*	*Sign*
Adrienne	5	5	0	0
Sinan	5	5	0	0
Rachel	5	5	0	0
Victoria	5	5	0	0
Movement of Mask (Bike)	*Original Mask*	*Our Mask*	*Difference*	*Sign*
Adrienne	5	5	0	0
Sinan	5	5	0	0
Rachel	5	5	0	0
Victoria	5	5	0	0

f. Rank Test: Movement of Glasses

Movement of Glasses (Treadmill)	*Original Mask*	*Our Mask*	*Difference*	*Sign*	
Adrienne	3	4	1	1	positive
Sinan	5	5	0	0	
Rachel	2	4	2	1	positive
Victoria	4	5	1	1	positive
Movement of Glasses (Elliptical)	*Original Mask*	*Our Mask*	*Difference*	*Sign*	
Adrienne	5	5	0	0	
Sinan	5	5	0	0	
Rachel	4	5	1	1	positive
Victoria	4	5	1	1	positive
Movement of Glasses (Bike)	*Original Mask*	*Our Mask*	*Difference*	*Sign*	
Adrienne	5	5	0	0	
Sinan	5	5	0	0	
Rachel	5	5	0	0	
Victoria	5	5	0	0	

g. Rank Test: User Comfort

Comfort (Treadmill)	*Original Mask*	*Our Mask*	*Difference*	*Sign*	
Adrienne	4	4	0	0	
Sinan	5	4	-1	-1	negative
Rachel	2	5	3	1	positive
Victoria	5	5	0	0	
Comfort (Elliptical)	*Original Mask*	*Our Mask*	*Difference*	*Sign*	
Adrienne	4	4	0	0	
Sinan	4	5	1	1	positive
Rachel	3	5	2	1	positive
Victoria	5	5	0	0	
Comfort (Bike)	*Original Mask*	*Our Mask*	*Difference*	*Sign*	
Adrienne	4	4	0	0	
Sinan	5	5	0	0	
Rachel	5	5	0	0	
Victoria	5	5	0	0	

h. Rank Test: User Vision

Vision (Treadmill)	*Original Mask*	*Our Mask*	*Difference*	*Sign*	
Adrienne	5	5	0	0	
Sinan	5	4	-1	-1	negative
Rachel	2	5	3	1	positive
Victoria	4	5	1	1	positive
Vision (Elliptical)	*Original Mask*	*Our Mask*	*Difference*	*Sign*	
Adrienne	5	5	0	0	
Sinan	5	5	0	0	
Rachel	5	5	0	0	
Victoria	5	5	0	0	
Vision (Bike)	*Original Mask*	*Our Mask*	*Difference*	*Sign*	
Adrienne	5	5	0	0	
Sinan	5	5	0	0	
Rachel	5	5	0	0	
Victoria	5	5	0	0	

Appendix C: Raw Survey Results

a. *Movement of Mask*

Movement of Mask (Treadmill)		
	Existing Mask	*With Extension Pieces*
Adrienne	5	5
Sinan	5	5
Rachel	5	5
Victoria	5	5
Movement of Mask (Elliptical)		
	Existing Mask	*With Extension Pieces*
Adrienne	5	5
Sinan	5	5
Rachel	5	5
Victoria	5	5
Movement of Mask (Bike)		
	Existing Mask	*With Extension Pieces*
Adrienne	5	5
Sinan	5	5
Rachel	5	5
Victoria	5	5

b. Movement of Glasses

Movement of Glasses (Treadmill)		
	Existing Mask	*With Extension Pieces*
Adrienne	3	4
Sinan	5	5
Rachel	2	4
Victoria	4	5
Movement of Glasses (Elliptical)		
	Existing Mask	*With Extension Pieces*
Adrienne	5	5
Sinan	5	5
Rachel	4	5
Victoria	4	5
Movement of Glasses (Bike)		
	Existing Mask	*With Extension Pieces*
Adrienne	5	5
Sinan	5	5
Rachel	5	5
Victoria	5	5

c. User Comfort

Comfort (Treadmill)		
	Existing Mask	*With Extension Pieces*
Adrienne	4	4
Sinan	5	4
Rachel	2	5
Victoria	5	5
Comfort (Elliptical)		
	Existing Mask	*With Extension Pieces*
Adrienne	4	4
Sinan	4	5
Rachel	3	5
Victoria	5	5
Comfort (Bike)		
	Existing Mask	*With Extension Pieces*
Adrienne	4	4
Sinan	5	5
Rachel	5	5
Victoria	5	5

d. User Vision

Vision (Treadmill)		
	Existing Mask	*With Extension Pieces*
Adrienne	5	5
Sinan	5	4
Rachel	2	5
Victoria	4	5
Vision (Elliptical)		
	Existing Mask	*With Extension Pieces*
Adrienne	5	5
Sinan	5	5
Rachel	5	5
Victoria	5	5
Vision (Bike)		
	Existing Mask	*With Extension Pieces*
Adrienne	5	5
Sinan	5	5
Rachel	5	5
Victoria	5	5

e. User Demographics and Glasses Measurements

	Adrienne	Sinan	Rachel	Victoria
Length of legs	144.2	133.73	130	123.42
Lens Height	50.52	37.69	39.77	43.16
Bridge Width	12.62	14.09	11.71	16.29
Frame Width	60.77		60.11	54.23
Age	19	19	20	21
Sex	Female	Male	Female	Female

Appendix D: Testing Outline

VO_2 Mask Testing Outline for Johnson Health Tech | Fall, 2021

BME 200/300

TEAM MEMBERS

Victoria Heiligenthal - *Team Leader*
Rachel Krueger - *Communicator*
Jakob Knauss - *BSAC*
Adrienne Rasmussen - *BWIG*
Tommy Kriewaldt - *BWIG*
Sinan Ozturk - *BPAG*

ADVISOR

Dr. Kip Ludwig, Dr. James Trevathan
Department of Biomedical Engineering
University of Wisconsin-Madison

CLIENT

Staci Quam, Grace Johnson
Johnson Health Tech

GOAL

Based on the criteria and requests of Johnson Health Tech, the VO_2 mask design developed by the team will be tested via functional testing. Due to this, the team will not collect VO_2 max data from the mask during a VO_2 max aerobic test to quantitatively evaluate the mask and its quality after implementing the team's changes to allow users to wear glasses during testing. Instead, the team must collect qualitative data based on responses from the user during testing. The subject's tested will undergo the same process using both masks so data can be collected from both and compared between them. The team can then conduct a qualitative analysis of the responses to determine if the developed design will functionally meet the client's requirements.

OVERVIEW

Each test subject will undergo three, two minute aerobic exercise tests while wearing the VO_2 mask designed by the team. After the completion of all three tests, the mask will be cleaned and sanitized before the next subject is tested. Since the subject is not undergoing full VO_2 max with the appropriate setup, it could be difficult for the subject to breath while only wearing the mask. To account for this, the length of the aerobic exercise test is much shorter than a typical VO_2 max test of about 20 minutes, but it will be enough time to evaluate the design. The difficulty of the test will be determined by the subject at a level they are comfortably challenged at to emulate a true VO_2 max test. Post-test questions will be asked to gain the subject's opinions and experiences during each time of testing. The subjects will provide a ranked response from 1-5 based on the level that best matches their opinions and experiences, one indicating an uncomfortable experience and five representing a comfortable experience. By using a ranking system, this provides uniformity across all test subjects to eliminate objectivity and for easier data analysis. Any comments from the subject will also be collected at the end of testing. This same process and procedure will take place with the mask currently used by the client that does not accommodate for glasses. Pre-testing procedures will take place to ensure each subject undergoes the same testing process to provide the most accurate results and to gain demographic information from the subjects. A statistical analysis will then be conducted to provide quantitative outcomes for the collected qualitative data and to compare the comfortability of the team's design to the current mask used by the client. The results from the analysis will help the team determine if the design meets the needs of the client.

PRE-TESTING

To establish uniformity across all subjects, pre-testing procedures will take place to ensure the subject understands the purpose of the testing and the testing procedures. This will also help achieve accurate and consistent results.

1. Explain to the subject the purpose of testing and how their responses will impact the project

2. Inform the subject of the tests to follow, so they clearly understand the procedure
3. Measure the size of glasses the subject will use during testing including the length of the legs, lens height, the bridge width and the frame width.
4. Collect demographic information from subject
    a. Age and sex
5. Ensure the subject is equipped with adequate clothing for testing
    a. Wearing comfortable exercise clothing and athletic shoes
6. Ask the subject if they have any questions about the testing outline or have any further questions/comments regarding the project

BIKING

Each participant will begin with a 2 minute test on a stationary bike. The resistance level will be set by the subject. The resistance level will be one that the subjects believe they can hold for a 20 minute period. The level will be fairly comfortable, but should still challenge the subject to emulate similar experiences to an actual VO_2 max test. The subjects will then be asked the evaluation questions following the test before beginning the next test.

1. Assist the subject in putting on the mask and adjusting the straps for the glasses that provides the most comfortable fit for the subject
2. Allow the subject to find the resistance level they want to hold for the entirety of the test
3. Begin a 2 minute timer
4. Help the subject off the machine
5. Ask the subject post-test questions

ELLIPTICAL

Each participant will begin with a 2 minute test on an elliptical. The resistance level will be set by the subject. The resistance level will be one that the subjects believe they can hold for a 20 minute period. The level will be fairly comfortable, but should still challenge the subject to emulate similar experiences to an actual VO_2 max test. The subjects will then be asked the evaluation questions following the test before beginning the next test.

1. Assist the subject in putting on the mask and adjusting the straps for the glasses that provides the most comfortable fit for the subject
2. Allow the subject to find the resistance level they want to hold for the entirety of the test
3. Begin a 2 minute timer
4. Help the subject off the machine
5. Ask the subject post-test questions

RUNNING

Each participant will begin with a 2 minute test on a treadmill. The resistance level will be set by the subject. The resistance level will be one that the subjects believe they can hold for a 20 minute period. The level will be fairly comfortable, but should still challenge the subject to emulate similar experiences to an actual VO_2 max test. The subjects will then be asked the evaluation questions following the test.

1. Assist the subject in putting on the mask and adjusting the straps for the glasses that provides the most comfortable fit for the subject
2. Allow the subject to find the resistance level they want to hold for the entirety of the test
3. Begin a 2 minute timer
4. Help the subject off the machine
5. Assist the subject in taking off the mask
6. Ask the subject post-test questions
7. Sanitize the mask before the next subject is tested

RECORD RESPONSES

The questions will be asked to each subject post-workout. Each question will be the same for each type of exercise as well. The responses will be recorded from the subjects. than the comments questions, the subjects will be able to answer the questions by providing a number from 1-5 that best matches their responses; one indicating an uncomfortable experience and five representing a comfortable experience. By using this number scale, the opinions of the subjects can be put into a more quantitative form.

Rank the following questions from 1-5:
1. Comfortability of the mask
2. Movement/slippage of mask
3. Movement/slippage of glasses
4. Vision ability
5. Post-test comments:

*This process will be the same for subjects when testing with the current mask used by the client.

ANALYSIS OF RESPONSES

Following testing, the responses from each subject from each of the tests will be analyzed. The results will be compared from each exercise test for each individual subject, the combined overall results from each subject, the results from each individual test from all subjects and the results from each test combined from all the subjects. The statistical analysis chosen was the Wilcoxon Signed Rank Test since it can be run on data from survey studies [1]. This test will compare the responses from subjects using the current mask that does not accommodate for glasses with the team's design that does accommodate for glasses. Plots and tables will be generated to visually show the outcomes and statistical results. These results will be evaluated to determine if the requirements from the client are met.

References

[1] Stephanie, “Wilcoxon Signed Rank Test: Definition, How to Run, SPSS,” *Statistics How To*, Sep. 17, 2021. https://www.statisticshowto.com/wilcoxon-signed-rank-test/ (accessed Dec. 06, 2021).

Appendix E: Expense Report

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
Component 1								
Velcro Brand One-Wrap Tape	Color: Black Width: ⅜”	Velcro Brand	189754	10/31/2021	25	1.03	27.17	http://hookandloop.com/
Component 2								
Plastic Piece 3D Printing	Material: Resin Color: See through	Formlabs	N/A	11/11/2021	1	N/A	8.27	N/A
Component 3								
Makerspace Materials Fee	Access to 3D scanners and printers	N/A	N/A	11/05/2021	1	50.00	50.00	N/A
Component 4								
Extension Piece 3D Printing	Material: PLA Color: Red	Ultimaker	N/A	11/22/2021	4	N/A	0.64	N/A
Component 5								
Extension Piece 3D Printing 2.0	Material: PLA Color: Black	Ultimaker	N/A	12/1/2021	4	N/A	0.56	N/A
Component 6								
Printing Poster	Paper Type: satin Dimensions: 48”x36” Location: College Library	College Library Poster Print	N/A	12/9/2021	4	N/A	48.00	N/A
TOTAL:								**$134.64**

Appendix F: Table of Materials and Methods

Part	Material	Method
Top Structural Brace Piece	Resin	3D scanning of original piece from original mask, 3D printed
Extension Pieces	PLA	Modeled in SolidWorks, 3D printed
Velcro Straps	Velcro	Bought online, cut into appropriate length for user
Face Piece	Silicone	Did not alter from original
Bottom Structural Brace Piece	Polycarbonate Thermoplastic	Did not alter from original
Headgear Straps	Polyurethane	Did not alter from original