Johnson Health Tech: VO_2 Mask for Biomechanics Research

(BME 200/300)

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Client: Johnson Health Tech: Grace Johnson and Staci Quam

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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 leakage, and allow for 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 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 mask 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 a treadmill or bike. 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 design, the team will perform VO_2 max testing following the provided protocol that is used with the existing VO_2 masks at Johnson Health Tech. A study will be done comparing the VO_2 readings using the new and existing masks. 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 [1]. The VO_2 readings using the new masks must be within 5% of the VO_2 readings using the existing masks.

d. Life in Service: The mask will be used for no longer than 20 minutes at a time for testing. 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 [1].

e. Shelf Life: The masks are aimed to be used for a long period of time since they will be reusable and easy to sanitize. They should be kept at room temperature where the material of the mask will not be damaged. The mask should go through sanitary gaps after every use. Soap and water will be sufficient to clean the mask.

f. Operating Environment: 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. 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: This design is based primarily on user comfort. The straps that run behind the head and around the ears should be able to be adjusted to where the net movement of the mask is zero. The silicon mask should not be able to 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. This design should be able to withstand any significant bending or movement at maximum human velocity, which is around 12 m/s or 28 mph [2]. Given this speed, the final design should be able to withstand 560 N or about 125 lbs of force [3].

h. Size: The client has directed the team to make two versions of the mask: a larger fitting one and a smaller fitting one. Each of the sizes must securely fit while preventing air leakage, and fit existing intake tubes. There are no direct size limitations on the mask, but the design should replicate the sizing of the current masks being used at Johnson Health Tech while incorporating the accommodation for glasses and comfort on the subject's face. The current measurements of the mask are 6" in height, 4.25" in width, and 3" in depth.

i. Weight: The client has made no indication about a weight restriction for the mask, however, there should not be much variance between the masks created and the existing masks. The optimal weight is similar to the existing weight, allowing for user comfort.

j. Materials: The mask will likely be made out of a rubber or silicone material, as the client's previous masks have been made out of rubber and/or silicone. There are no restrictions to material, but the chosen materials should cater to the user's comfort. The design prototype will be 3D printed with other materials to establish a design before the final material is implemented. 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: The shape of this mask will be very similar to a standard VO_2 mask and will be formed of a soft material, like silicone or rubber. The color of this mask will be blue and red, which also matches the sample VO_2 mask received. In general, this section is subject to change as the team works through the design process; however, professional and practical choices in terms of aesthetics, appearance, and finish for this product will be maintained.

2. Production Characteristics

a. Quantity: There will be a total of two masks created: one large mask and one small mask. The masks will likely be quite similar in design, the only significant difference being the size.

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 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 be in agreement with 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 [4]. There should be two mask sizes; the larger mask should be approximately 4.5 inches long, measuring from the centerline of the face while the smaller mask should be approximately 4 inches long, measuring from the centerline of the face. It should be a snug fit with minimal air leakage. Finally, it should not be stored in temperatures higher than 45 ℃ or lower than 0 ℃ [4].

b. Customer: The main concern of the customer is that the current mask model does not allow the wearer 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. The stresses and anxiety surrounding these activities can be greatly reduced if the wearer is able to successfully wear glasses and see correctly while performing these tasks. The device requires full sanitation between uses. This typically involves a soap and water mixture, as well as disinfectants. This allows the same mask to be used by many patients, after a sanitation gap, which increases the shelf life of the product. All data collected by the VO_2 testing should remain confidential.

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. A negative of this design is that it also does not allow glasses wearers to wear the mask and glasses at the same time [5]. 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 [6]. 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" [7]. 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] Korr Medical Technologies, "VO2 Instructional Document," Apr. 23, 2019.

[2] 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].

[3] 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.

[4] Muench, Jared. “Step+VO2 Validation.” 17 July 2018.

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[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].