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Dear CDRH-COVID19-Surgical Masks Team,

This Emergency Use Authorization application describes a customized conformal reusable N95 respirator (CCR) developed Fischell Institute for Biomedical Devices at the University of Maryland College Park (UMD). This reusable respirator is intended to be used with cleared commercially available N95 filters and has passed both qualitative fit testing with aerosolized saccharine at UMD and quantitative fit testing using the applied vacuum method at the Walter Reed National Military Medical Center. Additionally, the qualitative flow testing demonstrated that an adult can rapidly climb a flight of stairs without dyspnea when using the CCR respirator. These features render the CCR respirator compliant with true N95 respirator requirements, not just those for a civilian mask.

The COVID-19 pandemic has resulted in an ongoing and acute shortage of disposable and reusable N95 respirators. However, N95 filters for reusable N95 respirators are available. This proposal seeks to improve N95 access by providing a new source of the reusable component of commercially available N95 filters.

Detailed in this letter are a description of the customized conformal respirator, FDA approval status, need for the product, the production steps, materials used, safety and effectiveness (and the tests that have been executed to date on the respirator), discussion of risks and benefits, chemistry and manufacturing controls, finished product quantities; and sample instructions for use. Also attached for reference is the OSHA 1910.134 App A – Fit Testing Procedures, Section 3.

We would greatly appreciate any guidance on submitting a EUA for this proposed CCR respirator as a N95 respirator replacement.

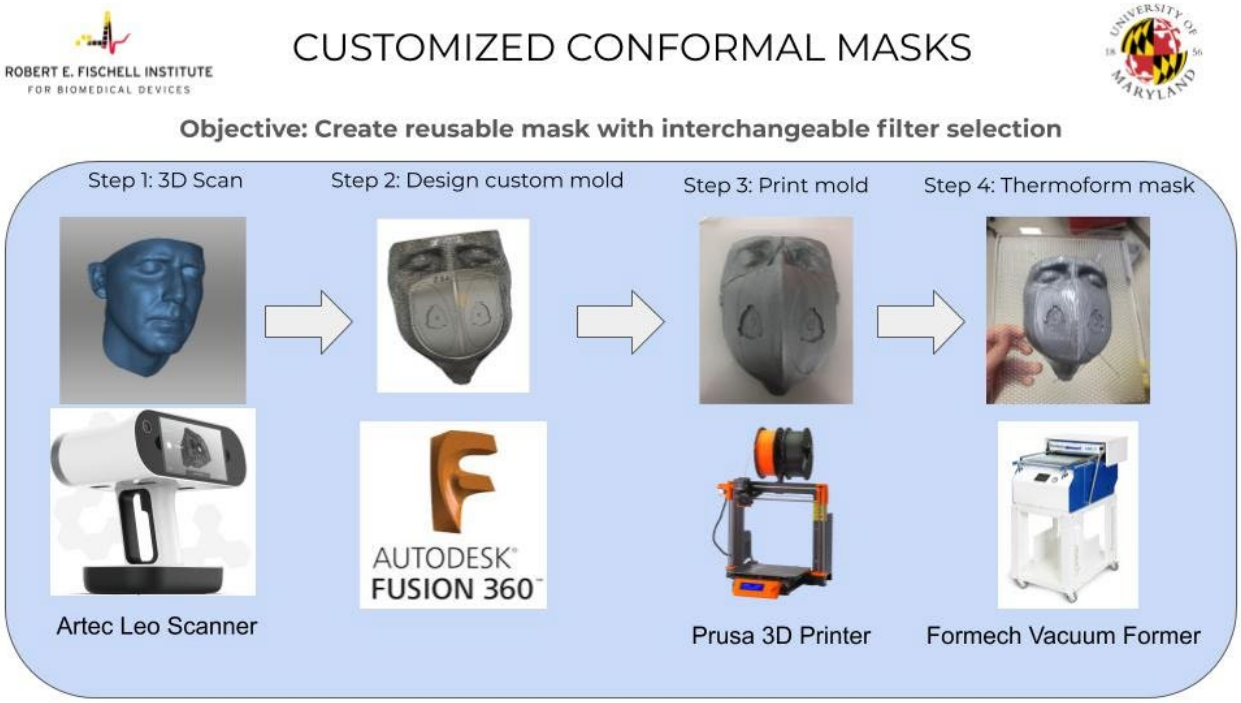
Sincerely,

Martha Wang

Description of Customized Conformal Respirator (CCR)

The Customized Conformal Respirator (CCR) described here seeks to address an immediate shortage of N95 respirators during the COVID 19 epidemic in the setting of available commercial, OSHA compliant and/or FDA cleared N95 filter material in canisters.

Investigator Kevin Aroom demonstrates wearing the CCR.



FDA Approval Status: The CCR is not approved for use and is a novel design.

Need for the Product: The CCR is proposed as a N95 respirator replacement. The N95 respirator is arguably one of the most important pieces of PPE used by clinicians. It is imperative that the respirator fit properly and provide adequate levels of filtration.

The COVID-19 pandemic has forced many to quickly engineer solutions to a rapid onset of resource austerity. One particularly acute shortage has been that of Personal Protective Equipment (PPE) that is donned by medical workers in the treatment of patients suspected of infection. Standard procedures put into place to limit spread of pathogens necessitate removal and disposal of PPE between cases. This leads to an enormous amount of waste and shortages of equipment; especially for crucial pieces like the N95 respirator.

CCR Production Process:

Step One: 3D Model Generation

The first step is to generate a 3D model of the user's face and neck. This can be performed by a number of different scanners that can use lasers, structured light, or photogrammetry to build a point cloud and subsequent mesh with approximately 0.5 -1 mm resolution of the facial features. The entire head is not needed for a scan, but the scan must provide a mesh between the eyebrows and upper neck. Then a software (associated with the scanner) is used to help refine the scan data and create a coherent model of the face.

Step 2: Creation of the model for the mold

The facial scan is imported as a point cloud into parametric-variable Computer Aided Design (CAD) software e.g. Solidworks, Autodesk 123D, etc. This type of program translates the mesh into a part that conforms to patient-specific anatomical contours of the face and adds an additional standardized geometrical volume for an opening around the nose and mouth. This standardized geometrical volume is also designed in CAD. It allows for filter attachment, mouth movement, and internal airflow to reduce internal condensation of expired moisture. The scanned geometry of the face and the additional CAD volume are independent parts subsequently assembled as a single continuous solid model. Head straps are locked into lateral fittings on the margins of the respirator flange to hold the respirator to the face. The method of manufacture enables the skin contacting flange to precisely fit patient specific facial anatomy without the necessity of facial measurements or scaling. Specific identification (UID) for each final finished product is embossed on the surface of the molded respirator.

Step 3: Rapid Fabrication

After the model is assembled in CAD, the digital file is then sent to a fused filament deposition (FFD) 3D printer (Prusa 3 FFD printer with Prusa poly-lactic acid (PLA)) for rapid fabrication. Multiple methods of 3D printing were evaluated and found to be sufficient. Early prototypes used models with 0.3mm layer height and were built in 8-10 hours. Alternative methods of 3D printing may also be applicable, but were not tested (e.g. mold release characteristics, etc.) A critical requirement is that the 3D printed assembly must be able to withstand the temperature levels of thermoforming without deformation or adherence to the thermoform material.

Step 4: Mask Thermoforming

After the model is 3D printed, a thin (~1mm) PETG or polycarbonate polymer sheet is heat softened and vacuum shaped by thermoforming (Formech mini). After cooling, the formed sheet is then cut away from the mold using a standard blade or ultrasonic cutter. Compressed air is used to help separate the formed sheet from the mold. The formed sheet is the reusable shell for the CCR. In function, it is intended to perform analogously to industrial respirators that utilize premade N95 filters in canisters. However, our proposed device utilizes thin thermoplastic that is considerably lighter, faster to manufacture and lower cost than commercial industrial respirators that use canister N95 filters. Complete respirators may be fabricated at the point of service with low cost thermoform equipment (e.g Vaquform™) and a consumer grade 3D printer.

1 Filter Port hardware

With the respirator shell removed from the mold, holes are punched in the thermoformed plastic to allow attachment of straps and filter ports. Separately manufactured port fittings are integrated into the respirator component to hold commercially available N95 filter material in commercially available filter canisters. 3D printed filter canisters may also be used if commercial filter canisters are unavailable. Our version of the respirator utilized industry standard filter port designs to allow for immediate use of a commercial filter retainer because these products were available. Alternative filter retainers and filter ports may be able to be used with little modification to the overall respirator design.

Materials Used and Sources:

- 3D printed respirators (pre-manufacture materials): PETG and PLA
- Thermoformed respirator: PETG (Polyethylene Terephthalate Glycol Modified) from McMaster-Carr, PN 85815K22 (https://www.mcmaster.com/85815k22)
- 3M P100 filter with bayonet port. Manufacturer Model #:07000
- 3M P95 filter with bayonet port. Manufacturer Model #:54356
- Commercially available N95 filters attached through bayonet ports 3M™ Cartridges 6000 Series, 3M™ Filter Adapter 603, 3M™ Filter Retainer 501, Reusable Respirators
- 3M Inhalation Port Gasket – 2 per port; one on respirator side, one between filter and the adapter
- Replacement screw threaded port adapters, filter cartridges and retainers were also 3D printed from PLA

Safety and Effectiveness: The CCR has been evaluated using the OSHA fit testing procedure currently recommended for evaluating the N95 respirator. This test is the saccharin solution aerosol leak test, described in OSHA 1910.134 App A – Fit Testing Procedures (attached). It was executed successfully. The CCR provides sufficient amount of contact with the face to make a proper seal. Additionally, quantitative fit testing using the applied vacuum method was successfully executed at the Walter Reed National Military medical Center. This qualitative flow testing demonstrated that an adult can rapidly climb a flight of stairs without dyspnea when using the CCR respirator. These features are expected to render the CCR respirator compliant with true N95 respirator requirements, not just those for a civilian respirator. However we recommend qualitative fit testing every end user with a sample of a finished user specific thermoformed respirator and a commercial, OSHA compliant and or FDA/cleared N95 filter to confirm safety and effectiveness before exposure to COVID-19.

Cleaning Methods

After leaving the infectious environment, the personal protective gown is removed, followed by the respirator from the face/head. The filter cartridges are removed and the CCR reusable shell is submerged into a bucket containing disinfectant soap and water and agitated by the user for washing. The user's gloves are then removed and the user performs additional personal hygiene as necessary. The CCR is removed from disinfectant after washing once the user is wearing waterproof gloves, and is thoroughly rinsed with water and air dried before reuse.

Biocompatibilty

Please note that biocompatibility studies have not been conducted for the post manufacture materials, but that our directions for use advise end-users to discontinue wearing the respirator in the event of skin rash or irritation. Furthermore the pre manufacture materials (PETG and PLA) are not known for biological contact hazards.

Discussion of Risks & Benefits:

The benefit to the proposed respirator is ready availability of a reusable respirator that can accept OSHA compliant and/or FDA-cleared N95 filter cartridges. The reusable components of this respirator are expected to be fabricated at low cost and at high volume at or near the clinical point of care. The design of the manufacturing process is intended to meet OSHA qualitative fit requirements and enable multiple reusable respirators to be rapidly fabricated from user-specific digital information. The reusable components of the respirator are expected to be safely cleaned using cold water and soap, by the end-user.

Furthermore, since the filters are commercially available and comply with OSHA requirements for airflow (e.g. 28 l/min) the entire respirator is expected to enable normal physical activity by the user. The use of these filters also enables reasonable assurance that the filtration effectiveness of the finished respirator will comply with the requirements for an N95 respirator.

Risks associated with the proposed device include absence of biocompatibility testing of the skin contacting thermoplastic, and head straps. A precaution statement advising users to be vigilant and discontinue use in the event of apparent signs of skin irritation or allergy is in the product instructions for use. Qualitative fit testing is recommended for a sample of the product and each user to assess that the manufacturing process faithfully captured the user's anatomy.

Chemistry and manufacturing controls: N/A in the context of the EUA. However, since this product is intended to be fabricated at or near the clinical point of care, each manufacturing site is advised to maintain records of each user – specific respirator, the number produced, date of fabrication and fit test results for each user-specific sample.

Finished product quantities: As this product is customized per wearer, there are limited number of finished products that have been developed for physicians. Production capacity is based on the speed of which the 3D printed face respirator and the thermoforming are executed. One production partner, Walter Reed National Military Medical Center, is able to print the respirator mold and in approximately 5 hours per respirator. Subsequent thermoforming of the respirator shell require approximately one minute per unit. Additional assembly of parts to finish and entire respirator takes another five minutes per respirator.

Sample Instructions for Use:

Intended Use: The CCR is intended to provide N95 airway protection for health care providers who may be exposed to a COVID-19 infectious environment when commercially available (OSHA compliant and/or FDA cleared) N95 respirators are not available.

Each CCR respirator shell is made specifically for an individual health care provider and is identified by the users name and the product UID embossed on the CCR reusable shell.

Pre-use Testing

New, unused filter cartridges, utilizing a commercial, OSHA compliant and/or FDA cleared N95 filter are inserted into each respirator ports. Attachment of cartridges must be and tight, so that the O-rings between sections of the port and the port to the shell are compressed, thereby assuring a hermetic seal between the filter and the respirator shell.

Each person utilizing their user-specific CCR for the first time should undergo and pass OSHA approved fit testing to verify that the respirator designed for them conforms to their facial anatomy. Respirator straps should be adjusted for a close fit to the face. After passing the OSHA fit test for one sample of the user-specific respirator, fit testing is not needed for additional samples of the respirator made specifically for the intended user from the same 3D scan and print unless the user has significantly changed body weight or other facial features.

Donning Instructions

Prior to exposure to an infectious environment, the user places the CCR onto their face as done in the OSHA fit test. The straps are placed over and around the head at the same level of tightness as in the prior successful fit test. The remainder of the personal protective equipment is also donned by the user.

Doffing Instructions

After leaving the infectious environment, the personal protective gown is removed, followed by the respirator from the face/head. The filter cartridges are removed and the CCR reusable shell is submerged into a bucket containing disinfectant soap and water and agitated by the user for washing. The user's gloves are then removed and the user performs additional personal hygiene as necessary. The CCR is removed from disinfectant after washing by wearing waterproof gloves, thoroughly rinsed with water and air dried before reuse.

PRECAUTIONS:

Do not use this mask if a close fit to the face is not achieved. Replace the mask to achieve a close fit. Proper fit requires that no airflow around the mask is present during inhalation or expiration.

Do not use this mask if there are openings, tears or split components of the CCR. Replace the damaged respirator immediately.

Discontinue use of this mask if any signs of skin irritation or rash appear. Pressure lines may appear in the skin as consequence of the elastic that holds the mask in place. If discomfort appears or skin pressure lines do not disappear rapidly, then discontinue use of the mask.

No natural latex rubber is used in the manufacture of this product.

3. Saccharin Solution Aerosol Protocol

The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Taste threshold screening. The saccharin taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of saccharin.

(1) During threshold screening as well as during fit testing, subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches in diameter by 14 inches tall with at least the front portion clear and that allows free movements of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # FT 14 and # FT 15 combined, is adequate.

(2) The test enclosure shall have a 3⁄4 -inch (1.9 cm) hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

(3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his/her slightly open mouth with tongue extended. The subject is instructed to report when he/she detects a sweet taste.

(4) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, the test conductor shall spray the threshold check solution into the enclosure. The nozzle is directed away from the nose and mouth of the person. This nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The threshold check solution is prepared by dissolving 0.83 gram of sodium saccharin USP in 100 ml of warm water. It can be prepared by putting 1 ml of the fit test solution (see (b)(5) below) in 100 ml of distilled water.

(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, then released and allowed to fully expand.

(7) Ten squeezes are repeated rapidly and then the test subject is asked whether the saccharin can be tasted. If the test subject reports tasting the sweet taste during the ten squeezes, the screening test is

completed. The taste threshold is noted as ten regardless of the number of squeezes actually completed.

(8) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted. If the test subject reports tasting the sweet taste during the second ten squeezes, the screening test is completed. The taste threshold is noted as twenty regardless of the number of squeezes actually completed.

(9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted. If the test subject reports tasting the sweet taste during the third set of ten squeezes, the screening test is completed. The taste threshold is noted as thirty regardless of the number of squeezes actually completed.

(10) The test conductor will take note of the number of squeezes required to solicit a taste response.

(11) If the saccharin is not tasted after 30 squeezes (step 10), the test subject is unable to taste saccharin and may not perform the saccharin fit test.

Note to paragraph 3(a): If the test subject eats or drinks something sweet before the screening test, he/she may be unable to taste the weak saccharin solution.

(12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

(13) Correct use of the nebulizer means that approximately 1 ml of liquid is used at a time in the nebulizer body.

(14) The nebulizer shall be thoroughly rinsed in water, shaken dry, and refilled at least each morning and afternoon or at least every four hours.

(b) Saccharin solution aerosol fit test procedure.

(1) The test subject may not eat, drink (except plain water), smoke, or chew gum for 15 minutes before the test.

(2) The fit test uses the same enclosure described in 3. (a) above.

(3) The test subject shall don the enclosure while wearing the respirator selected in section I. A. of this appendix. The respirator shall be properly adjusted and equipped with a particulate filter(s).

(4) A second DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

(5) The fit test solution is prepared by adding 83 grams of sodium saccharin to 100 ml of warm water.

(6) As before, the test subject shall breathe through the slightly open mouth with tongue extended, and report if he/she tastes the sweet taste of saccharin.

(7) The nebulizer is inserted into the hole in the front of the enclosure and an initial concentration of saccharin fit test solution is sprayed into the enclosure using the same number of squeezes (either 10, 20 or 30 squeezes) based on the number of squeezes required to elicit a taste response as noted during the screening test. A minimum of 10 squeezes is required.

(8) After generating the aerosol, the test subject shall be instructed to perform the exercises in section I. A. 14. of this appendix.

(9) Every 30 seconds the aerosol concentration shall be replenished using one half the original number of squeezes used initially (e.g., 5, 10 or 15).

(10) The test subject shall indicate to the test conductor if at any time during the fit test the taste of saccharin is detected. If the test subject does not report tasting the saccharin, the test is passed.

(11) If the taste of saccharin is detected, the fit is deemed unsatisfactory and the test is failed. A different respirator shall be tried and the entire test procedure is repeated (taste threshold screening and fit testing).

(12) Since the nebulizer has a tendency to clog during use, the test operator must make periodic checks of the nebulizer to ensure that it is not clogged. If clogging is found at the end of the test session, the test is invalid.