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TITLE

Hygieia PAPR: a novel 3D printable powered air purifying respirator

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ABSTRACT

Objectives: To design a low-cost 3D printable Powered Air-Purifying Respirator (PAPR) that meets National Institute for Occupational Safety and Health (NIOSH) and Occupational Safety and Health Administration (OSHA) standards for loose-fitting PAPR and that can be made with a 3D printer and items purchased from a general merchandise store.

Design: Detailed description of components, assembly instructions, and testing of a novel PAPR design. The assembled PAPR must meet NIOSH standards of flow rate, 170 L/min, and OSHA fit factor for particle filtration, ≥250.

Main Outcome Measures: The PAPR design was run through a series of tests: air flow (L/min), particle filtration (quantitative and qualitative), and positive pressure measured inside the helmet (mm Hg).

Results: Flow rate was 443.32 L/min (NIOSH standard: minimum 170 L/min) and overall fit factor for particle filtration was 1362 (OSHA pass level: ≥250). The device passed qualitative particle filtration and measured peak pressure of 6mm Hg in the helmet.

Conclusions: The Hygieia PAPR is a low-cost, easily accessible, just–in–time 3D printable PAPR design that performed above NIOSH and OSHA standards for flow-rate and particle filtration for loose-fitting PAPR devices to be made and used when industry-made designs are unavailable.

Strengths and limitations of this study

- This study details a low-cost novel 3D printable PAPR that exceeds NIOSH and OSHA standards for flow-rate and particle filtration for loose-fitting PAPR devices that can be made by anyone with access to the internet, a 3D printer, and a general merchandise store.
- This design can be used to protect health care workers around the world while they perform essential procedures when the supply of industry-made designs is low.
- Current published alternate novel PAPR designs are very valuable but either contain expensive proprietary components or impede important sensory faculties (visual field, hearing ability).
- Downside of long print times is outweighed by the simplicity and cost benefits of this design
- Persons must have access to a 3D printer and a general merchandise store which is not always available in extremely rural, recourse-limited settings

INTRODUCTION

As of December, 2020, the COVID-19 pandemic has caused almost 1.5 million reported deaths worldwide. Despite concerted efforts across the globe, both diagnosed cases and death rates continue to rise.[1] Current evidence suggests the COVID-19 virus transmits via respiratory droplets between people in close proximity indoors, thus putting heath care workers at high risk.[2,3] Personal protective equipment (PPE) is one of the most important means by which healthcare workers are protected. However, hospitals across the globe have been experiencing

shortages of key equipment needed to safely care for these patients since early in the pandemic.[4,5] Despite months of efforts to rectify this shortage, hospitals and ambulatory facilities across the globe continue to struggle with inadequate supply. [5–7]

In addition to PPE supply not meeting the high demand, the cost of PPE has increased as hospitals are required to have more of it on hand.[8] In March 2020, the WHO called on industry and governments around the world to increase manufacturing by 40% as the supply of PPE was dangerously low.[9] Though industry manufacturing efforts escalated, the global 3D printing community stepped in to produce PPE and other devices in an effort to help those combating COVID-19 before industry-made designs could become available.[10,11] One type of PPE that has become increasingly important is the Powered Air-Purifying Respirator (PAPR). A PAPR pulls or pushes air through a HEPA filter (N95 grade or higher) and directs the air into an enclosed space to create a positive pressure environment for persons wearing the device. The device provides both a filtered air environment as well as a physical barrier against droplets and particulates.[12]

Healthcare facilities around the globe are struggling to provide workers with adequate PPE. However, hospitals in low-resource countries share the same supply chain as wealthier countries with less bargaining power.[5] PPE is a key component of controlling infection spread in both healthcare settings and the community, but a survey of hospitals in low-resource countries for the past 5 years confirms low quantities of available PPE; this supply shortage was made critical by the pandemic. [13, 5] In March, hospitals in Kathmandu, Nepal, commissioned the National Innovation Center to innovate and create PPE, allowing them to circumvent the global PPE supply chain.[14] It is these types of organizations around the world with whom we wish to connect, correspond, and collaborate to create the most effective tools for the greatest number of people. Given the shortage, barriers to access, and expense of PPE, the authors were inspired to design a 3D-printable PAPR that can be made with items purchased from a general merchandise store and a 3D printer for one tenth of the cost of an industry-made design meeting National Institute for Occupational Safety and Health (NIOSH) and Occupational Safety and Health Administration (OSHA) standards for loose-fitting PAPR devices.

METHODS

Components

The 3D printed parts were created on an Ender 5 Plus using a 0.4 mm nozzle and using the default "standard quality" slicer settings from Cura with the following parameters: Layer height: 0.2mm, Line width: 0.4 mm, Wall thickness: 0.8 mm, Wall line count: 2, Top/Bottom layers: 4, Infill: 20%, Infill pattern: Zig Zag. Filament was polylactic acid (PLA), no rafts or supports were used. Four pieces were printed (print times hr:min, weight and length of plastic required, cost): Head Piece (7:29, 108g, 37.98m, $2.10), Jaw Piece (3:44, 49g, 17.17m, $0.95), Filter Side of Power Box (7:10, 126g, 44.39m, $2.46) and Battery Side of Power Box (13:18, 220g, 77.38m, $4.29). Files can be found at: https://www.thingiverse.com/thing:4292619

The filter used is a 3M high efficiency particulate air (HEPA) filter intended for air filtration and rated to filter 99.97% of all airborne particles, including dust, allergens, bacteria, viruses, and more. The life is approximately 6 months based on 12 hours of use per day.[15] The 3D-printed case presses the adhesive seal around the lip of the filter side, preventing air leakage.

The batteries were chosen given that power tools are a common household item but can also easily be purchased if not on hand. The hose chosen is one of the more easily accessible hoses available in a hospital and can be found in a manual resuscitator kit. One-inch corrugated tubing can also be found at general merchandise stores. The fan is a centrifugal DC blower, 12V, 1A, with a maximum airflow of 16 cubic feet per minute. A blower was chosen primarily for the energy efficiency, increased air speed, and increased rate of airflow as compared to a regular fan.

Additional components needed are 4, 22–16–gauge male spade connectors, and a DC motor PWM speed controller (3V 6V 12V 24V 35V DC 5A 90W). Other hardware needed: Two plastic shower caps, one 7mil PVC clear binding cover plastic sheet, utility belt, thermal glue gun, and cyanoacrylate (CA) glue.

Patient and public involvement
No patients involved

Instructions Table 1 and Table 2 (See Fig 1 and Fig 2 for schematic and overview)

Table 1: **Helmet**
1) Trim the 7mil clear binding cover sheet to fit Jaw Piece.
2) Fit Jaw and Head Piece together and use CA glue to secure.
3) Cut shower cap down the center about halfway; hot glue the two sides where the upper jaw piece meets the head piece. Carefully continue to separate cap down center so that the sides can be hot glued down the jaw piece (Fig 3).
4) Tie desired elastic to boat cleats of Head Piece and cover top with second shower cap.

Table 2: **Power Box**	
Battery side – 1) Align 12V blower fan with indices, use hot glue gun to apply ring of glue around air–inlet to seal.	Filter Side – 6) Align HEPA filter and press in.
2) Connect 4 spade connectors to 4 wires, 2 longer to travel the length of the box (see Fig 4 for wiring diagram).	7) Align clam shell pieces and press together.
3) Thread wires though slots in battery holder pieces and use hot glue to seal wires and connectors at the bottom.	8) Fit utility belt through slots.
4) Complete battery, fan, and controller circuit as depicted in the wiring diagram (Fig 5); place speed controller in slot above fan.	9) Connect hose to head piece and power box.
5) Plug 12V batteries into holders.	

TESTING/RESULTS

Air flow rate was calculated by measuring air speed and multiplying it by the cross-sectional area at the measurement site. Air speed was determined using a HoldPeak HP-866B-APP anemometer (Zhuhai JiDa Huapu Instrument Co, Ltd., Zhuhai, China) with an accuracy of ±5%. 3D-printed adapters were used to place the anemometer in series between the hose and helmet. The cross–sectional area of the anemometer was measured at 0.0026 m^2 and air speed measured at 2.2 m/s, equaling a flow rate of 0.0074 m^3/s, or 443.32 L/min, well above the NIOSH minimum requirement of 170 L/min for loose–fitting PAPRs.[16]

Particle testing followed the OSHA 29CFR1910.134 protocol.[17] A port was placed at the base of the jaw piece by drilling a 4mm hole and placing a Portacount test probe 8025-N95R (TSI, Inc., Shoreview, MN, USA). CA glue was used to seal the probe against the plastic. The "mask" intake was connected to the port, while the "ambient" intake was 4 cm below. The particle counter used was the Portacount Pro+ Model 8038 (TSI, Inc., Shoreview, MN, USA). Particle count was measured with the PAPR powered on while performing different exercises each for one minute. Fit Factor (particle concentration outside the respirator divided by the particle concentration inside the respirator) was calculated for each of the following exercises (passing level is ≥250): normal and deep breathing (1433 and 1035, respectively), head side to side and up and down (1119 and 1384, respectively), talking (2515), and bending over (1663). Grimacing was omitted due to facial expression being irrelevant in a loose-fitting PAPR.

Qualitative particle filtration was assessed using the 3M Ft-30 N95 Respirator protocol and 3M bitter formula testing kits (3M, St. Paul, MN, USA).[18] The bitter formula was nebulized in the hood with the PAPR powered on for the full series of movements (see above for movements done during particle testing). The test was then repeated with the bitter formula nebulized immediately adjacent to the blower intake with the full series of movements. The subjects were all determined to be sensitive to the bitter formula, but the bitter formula was not tasted at any point during either test by any participants.

Positive pressure was measured by drilling a 6/32-inch port in the jaw piece of the helmet where an arterial line pressure sensor (TruWave Disposable Sensor, Edwards Lifesciences Corp., Irvine, CA, USA) was placed and thermal glued for a secure seal. The pressure transducer measured a peak pressure of 6mm Hg ±1mm Hg indicating positive pressure in the helmet with both regular and deep breathing. Other exercises were not performed as change in elevation of the helmet would affect the pressure reading by changing the water column of the arterial line.

PAPR devices are often tested for their ability to filter silica dust, usually for mining or other dusty work environments. Our PAPR device is intended for the health care setting and this test was deemed unnecessary.

DISCUSSION

Principal findings

The Hygieia PAPR is a novel 3D-printable PAPR design that performs above NIOSH and OSHA standards for flow-rate and particle filtration for loose-fitting PAPR devices. Additionally, the PAPR demonstrated positive pressure inside the helmet during normal and deep breathing.

Strengths and weakness

Compared to N95 respirators, PAPRs have a higher protective factor, provide more comfort to the wearer for prolonged periods of time, remove concerns of poor N95 fit and seal, and may decrease the effort needed to maintain the work of breathing.[19–21] PAPRs may be especially useful protection in aerosolizing procedures like dynamic resuscitation and nearly eliminate fogging of eye wear, shields, and hoods.[3,19,20,22] Additionally, N95 respirators have been shown to alter cerebral blood flow and cause headaches which can be alleviated by the addition of a PAPR.[23]

Though the individual cost of an N95 mask is small ($1.50), the true cost lies in fit testing.[22] If an N95 respirator does not fit, or an improper size is used, a seal cannot be achieved and the mask will not provide full protection.[24] A loose-fitting PAPR does not require fit testing and is able to be worn with facial hair.[20–22] However, an industry-designed PAPR can cost from $900 to over $1,200 US dollars with the addition of the battery and charger.[22] In comparison, the PAPR design detailed in this paper is one tenth of the cost, approximately $120.

The nature of 3D printing allows for rapid, easily executable changes. A perfect example would be the ability to change the battery cartridges to fit a different brand of drill battery. If working on a printer with a bed smaller than that of the Ender 5 Plus, the helmet can be split up into parts and glued together. Though print times may be a concern, if orchestrated properly, a PAPR can be made in less than 33 hours of total printing time and can be cleaned, reused, and shared (so long as proper cleaning is performed between each use). Furthermore, the authors feel that the drawback of a prolonged total print time is outweighed by the simplicity and cost benefits of this design.

To make the PAPR more environmentally-friendly, the authors designed an optional shell that can be printed and glued to the top of the helmet (Fig. 5). The shell is split into front and rear pieces (hr:min, weight and length of plastic required, cost): Front (4:11, 69g, 24.6m, $1.34), Rear (2:41, 42g, 14.88m, $0.82). This option allows the top to be wiped down as opposed to disposing of the top shower cap. (Testing data was collected on the original model with a second shower cap top instead of this shell. However, the optional shell does not induce any changes to the functional aspect of the jaw and headpiece and thus would cause no changes in the functional aspect of the overall respirator.)

Cleaning the PAPR can be easily achieved by using a bleach wipe. A recent study by Welch et al demonstrated that SARS-CoV-2 and two other surrogate coronaviruses (MHV and 229E) on 3D printed material were completely inactivated by a single application of 10% bleach, ammonium quaternary, 3% H2O2, or exposure to 70°C dry heat.[25] Other sources have shown sterilization by low-temperature hydrogen peroxide gas plasma, though this may not be a viable option for many settings.[26]

In relation to other studies

Some PAPR designs have already been published using 3D-printable adapters and parts.[12, 27] Such innovations are valuable additions to the literature in our time of worldwide PPE shortages. However, some designs incorporate more expensive or difficult to obtain components or may not fully account for the visibility and aural requirements of certain health care settings.

A benefit of this design in contrast to typical PAPR designs with hoods is that it does not cover the ears. This design avoids the ears while maintaining coverage of the rest of the face and critical orifices. Though preferable for protection, a hood can make communication challenging particularly in critical moments of care.

Unanswered questions and future research

One aspect that warrants further investigation is the placement of the blower fan. The fan may be more effective if placed after the filter and able to blow air directly into the hose; however, the downside to this configuration is the concern that fan particulates could be blown through the hose and, thus, into the respiratory tract of the wearer. Another question that should be addressed in future research is how to ensure consistent quality prints with different users around the world.

Meaning of the design and possible implementation

The COVID-19 pandemic has taxed the health care system and PPE to dangerous levels. If industry is unable to produce the necessary equipment for this, or any other respiratory virus in the future, in a timely fashion, and world PPE supplies are directed towards the highest bidder, we need a better solution that will protect health care workers around the world while they perform essential procedures. The Hygieia PAPR should be added to the proposed solutions as an easily reproducible, cost-effective, and reusable piece of PPE that can be used on its own or to increase the life span and comfort of other essential equipment (i.e. N95 masks).

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Author's Contributions: Jorge Nagel and Catherine Gilbert had the idea for the article and completed the PAPR design and testing, data collection, analysis, literature search, and interpretation and writing. Both Mr. Nagel and Ms. Gilbert contributed equally to this project and manuscript and are both guarantors of the overall content. Dr. Juan Duchesne contributed to the organization of the paper, guided testing procedures and protocols, was instrumental in data analysis and interpretation, and writing of the paper.

Competing interest: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

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data (including statistical reports and tables) in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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Data sharing: We will provide any data collected upon request.

Transparency declaration: The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Patients or the public WERE NOT involved in the design, or conduct, or reporting, or dissemination plans of our research

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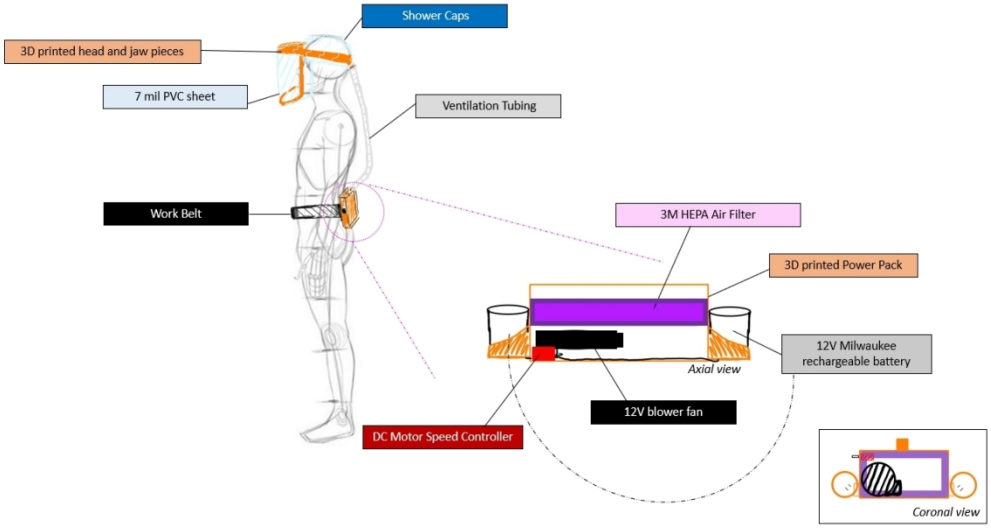

Figure 1 Schematic diagram of labeled components

109x59mm (300 x 300 DPI)

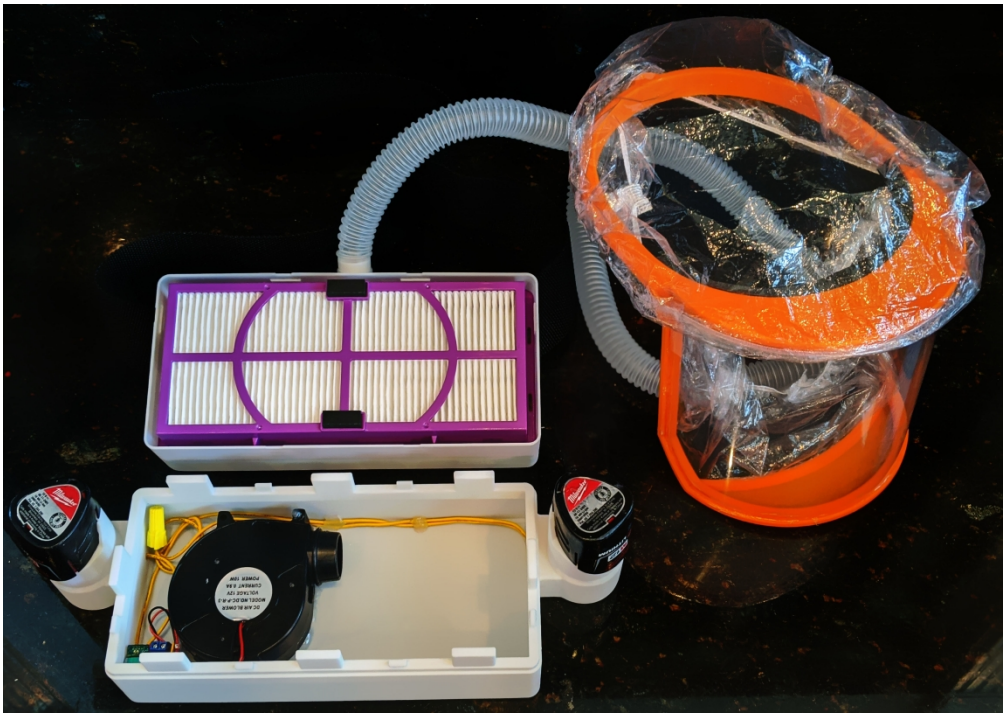

Figure 2 Assembled PAPR with open power box.

335x237mm (300 x 300 DPI)

Figure 3 Assembly of jaw piece and application of shower cap.

120x60mm (300 x 300 DPI)

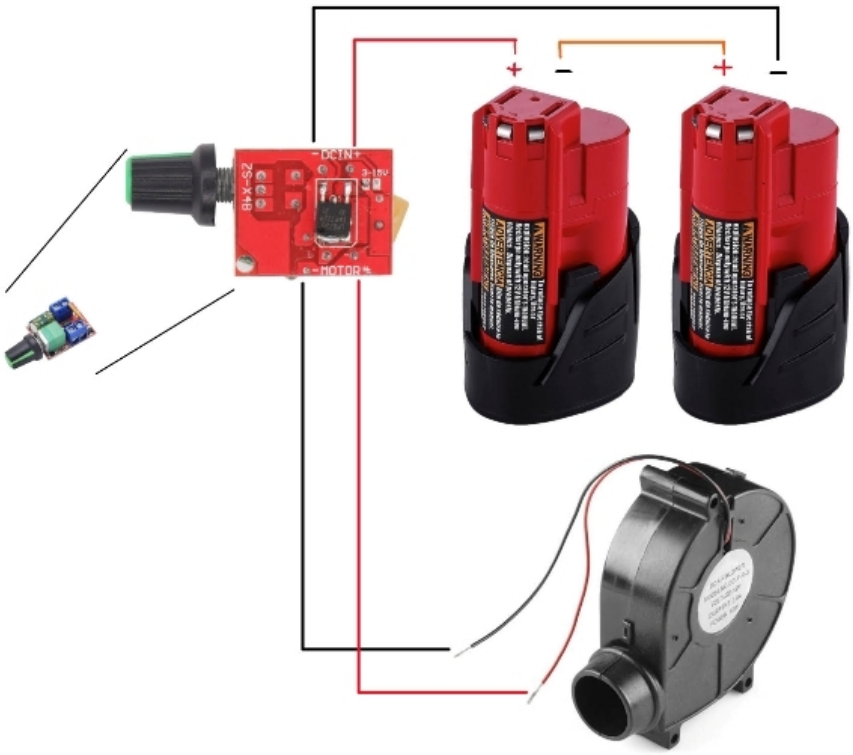

Figure 4 Wiring diagram for DC controller, batteries, and blower.

56x51mm (300 x 300 DPI)

Figure 5 a) Side- by-side comparison of assembled 3D printed helmet with optional top shell (left) or shower cap (right). b) 4 views of assembled helmet with shell. c) 4 views of assembled helmet with shower cap

609x250mm (300 x 300 DPI)

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TITLE

Hygieia PAPR: a novel 3D printable powered air purifying respirator

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ABSTRACT

Objectives: To design a low-cost 3D printable Powered Air-Purifying Respirator (PAPR) that meets National Institute for Occupational Safety and Health (NIOSH) standard for flow rate and Occupational Safety and Health Administration (OSHA) standard for particle filtration for loose-fitting PAPRs and that can be made with a 3D printer and widely available materials.

Design: Detailed description of components, assembly instructions, and testing of a novel PAPR design in an academic laboratory following respective protocols. The assembled PAPR must meet NIOSH standards of flow rate, 170 L/min, OSHA fit factor for particle filtration, ≥250, and maintain positive pressure during regular and deep breathing.

Main Outcome Measures: The PAPR design was run through a series of tests: air flow (L/min), particle filtration (quantitative and qualitative), and positive pressure measured inside the helmet (mm Hg).

Results: Flow rate was 443.32 L/min (NIOSH standard: minimum 170 L/min) and overall fit factor for particle filtration was 1362 (OSHA pass level: ≥500), n=1. The device passed qualitative particle filtration, n=2, and measured peak pressure of 6mm Hg (>0 mm Hg indicates positive pressure) in the helmet, n=1.

Conclusions: The Hygieia PAPR is a low-cost, easily accessible, just–in–time 3D printable PAPR design that meet minimum NIOSH and OSHA standards for flow-rate and particle filtration for loose-fitting PAPR devices to be made and used when industry-made designs are unavailable.

Strengths and limitations of this study

- This study details a low-cost novel 3D printable PAPR that meets NIOSH and OSHA minimum standards for flow-rate and particle filtration respectively for loose-fitting PAPR devices that can be made by anyone with access to the internet, a 3D printer, and a general merchandise store.
- This design can be used to protect health care workers around the world while they perform essential procedures when the supply of industry-made designs is low. Though this design was tested in an uncertified academic laboratory, not all NIOSH and OSHA standards were tested necessary for official certification, and it was not tested on end-users for clinical feedback.
- Current published alternate novel PAPR designs are very valuable but either contain expensive proprietary components or impede important sensory faculties (visual field, hearing ability) [31, 32].
- Downside of over 30 hours of print time is outweighed by the simplicity and cost benefits of this design
- Persons must have access to a 3D printer and a general merchandise store or online ordering and delivery which is not always available in rural, resource-limited settings

INTRODUCTION

As of June, 2021, the COVID-19 pandemic has caused approximately 3.84 million reported deaths worldwide.[1] Fortunately, the vaccination effort that began in December, 2020, has resulted in the decline of incidence and deaths from COVID-19 since early 2021.[2] Current evidence suggests the COVID-19 virus transmits via respiratory droplets between people in close proximity indoors, thus putting heath care workers at high risk.[3,4] Personal protective equipment (PPE) is one of the most important means by which healthcare workers are protected. However, at the start of the pandemic, hospitals across the globe experienced shortages of key equipment needed to safely care for these patients.[5,6] For months, hospitals and ambulatory facilities across the globe struggled with inadequate supply. [6-8]

In addition to PPE supply not meeting the high demand, the cost of PPE increased as hospitals were required to have more of it on hand.[9] In March 2020, the WHO called on industry and governments around the world to increase manufacturing as the supply of PPE was dangerously low.[10] Though industry manufacturing efforts escalated, the global 3D printing community stepped in to produce PPE to help those combating COVID-19 before industry-made designs could become available.[11,12] One type of PPE that has become increasingly important is the Powered Air-Purifying Respirator (PAPR). A PAPR pulls or pushes air through a HEPA filter (99.97% efficacy at 0.3µ particle size) and directs the air into an enclosed space to create a positive pressure environment for persons wearing the device. The device provides both a filtered air environment as well as a physical barrier against droplets and particulates.[13]

In the early months of the pandemic, healthcare facilities around the globe struggled to provide workers with adequate PPE. However, hospitals in low-resource countries were at an even greater disadvantage as they share the same supply chain as wealthier countries with less bargaining power.[6] Given the shortage, barriers to access, and expense of PPE, the authors were inspired to design an emergency use 3D-printable PAPR that can be made with widely available materials and a 3D printer for one tenth of the cost of an industry-made design meeting the National Institute for Occupational Safety and Health (NIOSH) standard for flow rate and Occupational Safety and Health Administration (OSHA) standard for particle filtration for loose-fitting PAPR devices.

METHODS

Components

The 3D printed parts were created on an Ender 5 Plus using a 0.4 mm nozzle and using the default "standard quality" slicer settings from Cura with the following parameters: Layer height: 0.2mm, Line width: 0.4 mm, Wall thickness: 0.8 mm, Wall line count: 2, Top/Bottom layers: 4, Infill: 20%, Infill pattern: Zig Zag. Filament was polylactic acid (PLA), no rafts or supports were used. Four pieces were printed (print times hr:min, weight and length of plastic required, cost): Head Piece (7:29, 108g, 37.98m, $2.10), Jaw Piece (3:44, 49g, 17.17m, $0.95), Filter Side of Power Box (7:10, 126g, 44.39m, $2.46) and Battery Side of Power Box (13:18, 220g, 77.38m, $4.29). Files can be found at: https://www.thingiverse.com/thing:4292619

The filter used is a 3M high efficiency particulate air (HEPA) filter (3M, Saint Paul, Minnesota, USA) intended for air filtration and rated and certified to filter 99.97% of all airborne particles,

including dust, allergens, bacteria, viruses, and more. The life is approximately 6 months based on 12 hours of use per day.[14]

The authors choose to use two 12V Milwaukee batteries (Milwaukee Tool, Brookfield, Wisconsin, USA), used for power tools, because these tools are often a common household item or can easily be purchased if not on hand. Battery charge time is 30-45 min at 1.5 Amp/h. The hose chosen is one of the more easily accessible hoses available in a hospital and can be found in a manual resuscitator kit (Ambu Inc., Columbia Maryland, USA). One-inch corrugated tubing is also widely available. The fan is a centrifugal DC blower, 12V, 1A, with a maximum airflow of 16 cubic feet per minute (COM-11270, SparkFun Electronics, Niwot, Colorado, USA). A centrifugal blower was chosen primarily for the energy efficiency, increased air speed, and increased rate of airflow as compared to an axial fan.

Additional components needed are 4, 22–16–gauge male spade connectors, and a DC motor PWM speed controller (3V 6V 12V 24V 35V DC 5A 90W). Other hardware needed: Two plastic shower caps, one 7mil PVC clear binding cover plastic sheet (CSF Binding Supplies, Norton Shores, Michigan, USA), utility belt (Husky, Bolton, Caledon, Canada) , thermal glue gun (Elmer's Products Inc, Atlanta, Georgia, USA), cyanoacrylate (CA) glue (Loctite, Düsseldorf, Germany), 3/32 inch abrasion-resistant elastics cord (McMaster-Carr, Elmhurst, Illinois, USA), and ¾ inch x 7/16 inch rubber foam weatherstrip tape (Thermwell Products Co. Inc., South Mahwah, New Jersey, USA).

All components, including the HEPA filter, are widely available online, at home improvements stores, or general merchandise store. A supply shortage of any one component is possible; however, it is unlikely.

Patient and public involvement
No patients involved

Instructions Table 1 and Table 2 (See Fig 1 and Fig 2 for schematic and overview)

Table 1: **Helmet**
1) Trim the 7mil clear binding cover sheet to fit Jaw Piece. Place the cover sheet into the slit in the Headpiece.
2) Align and fit Head Piece + cover sheet together with the Jaw Piece. Cover sheet will fit into slit in Jaw Piece. Use CA glue to secure. (see Fig 3a & 3b)
3) Cut shower cap down the center about halfway; hot glue the two sides where the upper jaw piece meets the head piece. Carefully continue to separate cap down center so that the sides can be hot glued down the jaw piece (Fig 3 c-f).
4) Measure and cut 8 inches of foam weatherstrip tape and place adhesive side against the inner portion of Helmet where the forehead will be. Cut 8 inches of elastic and tie to boat cleats of Head Piece. Cover top with second shower cap.

Table 2: **Power Box**	
Battery side – 1) Align 12V blower fan with indices, use hot glue gun to apply ring of glue around air–inlet to seal.	Filter Side – 6) Align HEPA filter and press in.
2) Connect 4 spade connectors to 4 wires, 2 longer to travel the length of the box (see Fig 4 for wiring diagram).	7) Align clam shell pieces and press together.
3) Thread wires though slots in battery holder pieces and use hot glue to seal wires and connectors at the bottom.	8) Fit utility belt through slots.
4) Complete battery, fan, and controller circuit as depicted in the wiring diagram (Fig 4); place speed controller in slot above fan.	9) Connect hose to head piece and power box.
5) Plug 12V batteries into holders.	

Configuration and Mechanism

The blower fan is used to create a positive pressure in the chamber prior to the filter. Air is thus forced through the filter onto the downstream conduit, which is at all times at a greater pressure than ambient. This positive pressure gradient ensures that no unfiltered air enters the system despite imperfect seals to the outside. Fig. 5 demonstrates the flow of air from the blower, through the filter, and out the outlet of the Power Box through the hose. The seal between the HEPA filter and the Filter Side of the Power Box is the most important seal of the design and ensures that no unfiltered air goes through the helmet to the wearer. To ensure a tight seal, the built-in adhesive rubber-seal around the HEPA filter is pressed into the lip of the Filter Side (Fig 5.2.A) by the prongs on the Battery Side (Fig 5.1.a), maintaining constant pressure, thus ensuring a secure seal around the filter.

The connections between the hose and the Power Box and the Helmet are all interference fit. The outside diameter of the 3D printed parts was intentionally enlarged such that it creates an interference with the inner diameter of the hose. Additionally, a ridge was added to the 3D printed connection on the Helmet and Filter Side to match the corrugations of the hose, thus increasing seal integrity and preventing accidental disconnection (Fig 5.2.B). We acknowledge that there are imperfect seals throughout the device. However, so long as positive pressure is maintained in the helmet, the air leaking through the seals may decrease efficiency but does not compromise the filtered air.

TESTING/RESULTS

Air flow rate was calculated by measuring air speed and multiplying it by the cross-sectional area at the measurement site. Air speed was determined using a HoldPeak HP-866B-APP anemometer (Zhuhai JiDa Huapu Instrument Co, Ltd., Zhuhai, China) with an accuracy of ±5%. 3D-printed adapters were used to place the anemometer in series between the hose and helmet. The helmet was donned and the power was turned on full. The cross–sectional area of the

anemometer was measured at 0.0026 m^2 and air speed measured at 2.2 m/s, equaling a flow rate of 0.0074 m^3/s, or 443.32 L/min, well above the NIOSH minimum requirement of 170 L/min for loose–fitting PAPRs.[15] Airflow measurements were taken while the device was being worn and the units were in operation. The current prototype has demonstrated an approximate run time of 45min.

Particle testing followed the OSHA 29CFR1910.134, Appendix A. C. 3. Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol.[16] A port was placed at the base of the jaw piece by drilling a 4mm hole and placing a Portacount test probe 8025-N95R (TSI, Inc., Shoreview, MN, USA). CA glue was used to seal the probe against the plastic. The "mask" intake was connected to the port, while the "ambient" intake was 4 cm below. The particle counter used was the Portacount Pro+ Model 8038 (TSI, Inc., Shoreview, MN, USA).

The subject (n=1) donned the helmet with the installed particle counter and particle count was measured with the PAPR powered on while the subject performing different exercises each for one minute. Fit Factor (particle concentration outside the respirator divided by the particle concentration inside the respirator) was calculated for each of the following exercises (passing level is ≥500)[16]: normal and deep breathing (1433 and 1035, respectively), head side to side and up and down (1119 and 1384, respectively), talking (2515), and bending over (1663). Grimacing was omitted due to facial expression being irrelevant in a loose-fitting PAPR.

Qualitative fit test was assessed using the 3M Ft-30 N95 Respirator protocol and 3M bitter formula testing kits (3M, St. Paul, MN, USA).[17] The bitter formula was nebulized in the hood with the PAPR powered on for the full series of movements (see above for movements done during particle testing). The test was then repeated with the bitter formula nebulized immediately adjacent to the blower intake with the full series of movements. The subjects (n=2) were determined to be sensitive to the bitter formula, but the bitter formula was not tasted at any point during either test by either participant. Qualitative testing was done to mimic the testing done during N95 fit testing. This testing is quick and easy to perform and is widely available in healthcare facilities or can be purchased online for minimal cost. A particle counter is expensive and less available in non-university health care settings.

Positive pressure was measured by drilling a 6/32-inch port in the jaw piece of the helmet where an arterial line pressure sensor (TruWave Disposable Sensor, Edwards Lifesciences Corp., Irvine, CA, USA) was placed and thermal glued for a secure seal. The pressure transducer measured a peak pressure of 6mm Hg ±1mm Hg indicating positive pressure in the helmet with both regular and deep breathing. Other exercises were not performed as change in elevation of the helmet would affect the pressure reading by changing the water column of the arterial line. This test demonstrates that positive pressure is maintained throughout the system, indicating that contaminated ambient air cannot leak into the system despite potential imperfect seals. Note, all qualitative and quantitative tests were done on the same prototype with the pressure test being performed last as the sensors altered the integrity of the jaw piece.

PAPR devices are often tested for their ability to filter silica dust, usually for mining or other dusty work environments. Our PAPR device is intended for the health care setting and this test was deemed unnecessary.

To make the PAPR more environmentally-friendly, the authors designed an optional shell that can be printed and glued to the top of the helmet (Fig. 6). The shell is split into front and rear pieces (hr:min, weight and length of plastic required, cost): Front (4:11, 69g, 24.6m, $1.34), Rear (2:41, 42g, 14.88m, $0.82). This option allows the top to be wiped down as opposed to disposing of the top shower cap. (Testing data was collected on the original model with a second shower cap top instead of this shell. However, the optional shell does not induce any changes to the functional aspect of the jaw and headpiece and thus would cause no changes in the functional aspect of the overall respirator.)

DISCUSSION

Principal findings

The Hygieia PAPR is a novel 3D-printable PAPR design that meets minimum standards for NIOSH and OSHA flow-rate and particle filtration, respectively, for loose-fitting PAPR devices. Additionally, the PAPR demonstrated positive pressure inside the helmet during normal and deep breathing.

Strengths and weakness

Compared to N95 respirators, PAPRs have a higher protective factor, provide more comfort to the wearer for prolonged periods of time, remove concerns of poor N95 fit and seal, and may decrease the effort needed to maintain the work of breathing.[18-20] PAPRs may be especially useful protection in aerosolizing procedures like dynamic resuscitation and nearly eliminate fogging of eye wear, shields, and hoods.[4,18,19,21] Additionally, N95 respirators have been shown to alter cerebral blood flow and cause headaches which can be alleviated by the addition of a PAPR.[22]

Though the individual cost of an N95 mask is small ($1.50), the true cost lies in fit testing.[21] If an N95 respirator does not fit, or an improper size is used, a seal cannot be achieved and the mask will not provide full protection.[23] Additionally, depending on the respirator model and accuracy of fit testing, 1-20% of wearers will have an inappropriate respirator assigned to them, putting them at risk to potential exposures. [24] A loose-fitting PAPR does not require fit testing and is able to be worn with facial hair.[19-21] However, an industry-designed PAPR can cost from $900 to over $1,200 US dollars with the addition of the battery and charger.[21] In comparison, the PAPR design detailed in this paper is one tenth of the cost, approximately $120 for the materials.

Once of the most signficant advantages of this PAPR design is the ability to use components from different manufacturers than those detailed in the Methods so long as it has the same specifications. As an example, the fan must be a centrifugal DC blower, 12V, 1A, with a maximum airflow of 16 cubic feet per minute, but the company and manufacturer do not affect the function of the design. This also applies to the batteries, switch, hose, and belt.

The nature of 3D printing allows for rapid, easily executable changes. An example would be the ability to change the battery cartridges to fit a different brand of drill battery. If working on a printer with a bed smaller than that of the Ender 5 Plus, the helmet can be split up into parts and glued together. Though print times may be a concern, if orchestrated properly, a PAPR can be

made in less than 33 hours of total printing time and can be cleaned, reused, and shared (so long as proper cleaning is performed between each use). Furthermore, the authors feel that the drawback of a prolonged total print time is outweighed by the simplicity and cost benefits of this design.

The helmet length and width were designed to be large enough to accommodate the majority of head dimensions. However, if the current design does not fit several adjustments can be made. The foam in the front of the helmet is primary for comfort, any other padding material can be used to increase or decrease the helmet diameter, so long as it does not cover the vents in the helmet. Similarly, the elastic used can be exchanged for another type of elastic, string, or tie, that will help secure the helmet to the wearers head. Lastly, if the current dimensions of the helmet or Jaw Piece still do not fit the wearer comfortably, they can be altered in the .stl file before being printed. The shower cap attached to the Jaw Piece can be adjusted for comfort by gluing additional shower cap elastic to the Jaw Piece on each side where it meets the Head Piece. These adjustments are for comfort and will not alter the flow-rate, particle filtration, or positive-pressure of this loose-fitting PAPR design.

The fan has been intentionally placed before the filter in order to ensure that any potential particulates generated by the fan itself are forced to go through the filter, thus preventing them from reaching the user. We acknowledge this choice leads to a drop in overall system efficiency. It is for this reason that commercial units place the fan after the filter. However, these novel methods of user-dependent manufacturing lack the stringent sourcing controls otherwise used in traditional medical equipment manufacturing and thus we believe it is better to sacrifice efficiency in order to ensure the user's safety.

The 12V batteries are wired in series resulting in a higher voltage with a lower current system to drive adequate airflow. It also allows for a more robust system given the flexible nature of the hose connecting the Power Box to the Head Piece and the critically important maintenance of high flow rate. The authors acknowledged a higher voltage system would reduce the life of the current fan but put higher value on the maintenance of air flow rate. 24V blower fans are slightly less common but can be found at similar cost and can likely be used with similar results.

Cleaning the PAPR can be easily achieved by using a bleach wipe. A recent study by Welch et al demonstrated that SARS-CoV-2 and two other surrogate coronaviruses (MHV and 229E) on 3D printed material were completely inactivated by a single application of 10% bleach, ammonium quaternary, 3% H2O2, or exposure to 70°C dry heat.[25] Other sources have shown sterilization by low-temperature hydrogen peroxide gas plasma, though this may not be a viable option for many settings.[26] Some elements of the PAPR may not be sufficiently cleaned with a wipe, like the utility belt made with poly web material. For thorough cleaning, the belt should be removed from the Power Box and submerged in a basin filled with either ethanol or isopropyl alcohol.[27] Additionally, alternate belt materials that are easier to clean can be used to strap the Power Box to the wearer.

The authors were inspired to design the Hygieia PAPR as an option for emergency-use PPE when industry-made designs are unavailable. PPE is a key component of controlling infection spread in both healthcare settings and the community, but a survey of hospitals in low-resource

countries for the past 5 years confirms low quantities of available PPE; this supply shortage was made critical by the pandemic.[6,28] In March, hospitals in Kathmandu, Nepal, commissioned the National Innovation Center to innovate and create PPE, allowing them to circumvent the global PPE supply chain.[29] It is these types of organizations around the world with whom we wish to connect, correspond, and collaborate to create the most effective tools for the greatest number of people.

Limitations

Our testing was done in the academic laboratory at Tulane University which, though accurate, is not a formal, nationally certified testing center. Though we meet the minimum standards for flow rate (NIOSH) and particle filtration (OSHA), we did not perform all the tests that would qualify us for formal NIOSH and OSHA PAPR certification. Several tests performed during this certification process are to test the integrity of the filter (NIOSH-42 CFR, Part 84)[15]. We used a 3M HEPA filter previously certified to meet these standards and emphasized a tight seal between the filter and Power Box to ensure adequate filtration.[30]

Certified PAPRs undergo many more tests than were performed on the design detailed in this paper (housing sealing testing, oil aerosol testing, communicating performance testing, and control systems alarms for flow rate testing). However, due to lack of access to appropriate equipment, we did not perform these tests on the PAPR design. We narrowed our focus to flow rate and particle filtration, as they are the most relevant variables in an emergency situation. This PAPR should only be used in emergency situations, and users should proceed with caution when considering use in healthcare settings. The Hygieia PAPR was not tested on end-users for clinical feedback and was not, to the authors knowledge, used in clinical or high-level PEE situations.

In relation to other studies

Some PAPR designs have already been published using 3D-printable adapters and parts.[13,31,32] Erickson et al. observed that Stryker Flyte helmets and used in orthopeadic surgery is, in-essence, a PAPR without the filtration. The authors 3D printed an adapter to connect HEPA filters to the air-intake system; thus, creating a PAPR with minimal addition to a preexisting system.[13] This is an innovative way of using available resources. However, not all hospitals are equipped to perform orthopeadic surgery and do not have the Stryker Flyte helmets on hand. Additionally, the hood for the helmet covers the ears which can decrease the hearing ability of the wearer, potentially detrimental to communication between healthcare workers in emergent situations.

Hubbard et al., modified a Scott Safety self-contained breathing apparatus (SCBA) into a PAPR, primarily for fire fights and other first responders to use during the PPE shortage. A SCBA uses compressed air fed to an air-tight mask via a pressure regulator, providing clean air to the wearing, but impractical and cost prohibitive for long term use. The authors modified the SCBA mask with a HEPA filter at the air intake attached to a powered fan in a 3D printed casing, creating a PAPR.[32] Similar to the design by Erickson et al., this PAPR is a cost-effective solution if the SCBA mask is readily available. Additionally, the design of the SCBA mask might impede full visual field necessary for medical procedures.

Nazarious et al., designed a mini wearable cleanroom and biosafety system or, a Pressure Optimized PowEred Respirator (PROPER). The blower fan and power system is similar to that of the Hygieia Power Box with the addition of a safety-fuse and a Lithium ion rechargeable powerbank as the power source. The main difference lies in the hood comprised of a face shield frame, the hood adapter and flange, the helmet fitting (adjustable head straps), and SMS head fabric. The SMS material used for the hood and clean room garment set is single use.[31] This is an inexpensive helmet-based respirator system that can be made with widely available components. However, it costs approximately $250 USD per device, compared to $120 for the Hygieia PAPR, and has more, small components that add to the complexity of the device.

These innovations are valuable additions to the literature in a time of worldwide PPE shortages and are tailored to specific settings and environments. However, the incorporation of more expensive or difficult to obtain components, using designs with many components, or working within the limitations of the visibility and aural requirements of certain health care settings, may make these designs less optimal for the more resource limited health care settings.

The Hygieia PAPR is inexpensive, requires no proprietary parts, and has a minimal number of components. The design of the helmet allows for nearly full visual field and provides full coverage of the rest of the face and critical orifices. Some PAPR designs use a hood to increase coverage (ears, hair, and shoulders), but can make communication challenging particularly in critical moments of care.[21] This PAPR is a valuable addition to the literature and pool of options for emergency PPE.

Unanswered questions and future research

Aspects that warrant further investigation are elements of efficiency and optimization. The placement of the blower fan and imperfect seals do not optimize the power and positive pressure generated. The current batteries are widely available but are heavy, bulky, and do not have an extensive run time and alternatives should be considered. Future research should also test a larger diameter hose to see if greater flow rate can be achieved with less power. Future research will include more testing on certified equipment for more accurate and formal measurements. Another question that should be addressed in future research is how to ensure consistent quality prints with different users around the world.

Meaning of the design and possible implementation

The COVID-19 pandemic has taxed the health care system and PPE to dangerous levels. If industry is unable to produce the necessary equipment for this, or any other respiratory virus in the future, in a timely fashion, and world PPE supplies are directed towards the highest bidder, we need a better solution that will protect health care workers around the world while they perform essential procedures. The Hygieia PAPR should be added to the proposed solutions as an easily reproducible, cost-effective, and reusable piece of PPE that can be used on its own or to increase the life span and comfort of other essential equipment (i.e. N95 masks).

STAEMENTS

Disclaimer: The designs and other information ("the Design") made available in this article is at

an early stage of development. Accordingly, specific results are not guaranteed, and the Design provided here is provided ‘‘AS IS” and without any express or implied warranties, representations or undertakings. As examples, but without limiting the foregoing, Tulane University and their employees and students do not give any warranty or guarantee that the Design is of merchantable or satisfactory quality, is fit for any particular purpose, complies with any sample or description including the requirements for medical device registration, or are viable, uncontaminated, safe or non-toxic, accurate, up to date or complete. Tulane University and the authors have not performed any searches or investigations into the existence of any third-party rights that may affect the Design. Anyone may use the Design entirely at their own risk, and Tulane University and/or the authors are not liable for such use of the Design, including without limitation any direct or indirect losses. Any users of the design should appropriately attribute the author.

Human and Animal Rights: This work involved testing of the equipment on a human subject to validate the qualitative and quantitative testing. The tests were voluntarily performed on the authors and an informed consent was obtained for experimentation. We ensure that the work described has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans; Uniform Requirements for manuscripts submitted to Biomedical journals.

Ethics Approval Statement

This study did not require ethical approval as the only human subjects involved in the study were the authors, minimal to no risk was present, and informed consent was acquired from the authors at the time of original data collection.

Author’s Contributions: Jorge Nagel and Catherine Gilbert had the idea for the article and completed the PAPR design and testing, data collection, analysis, literature search, and interpretation and writing. Both Mr. Nagel and Ms. Gilbert contributed equally to this project and manuscript and are both guarantors of the overall content. Dr. Juan Duchesne contributed to the organization of the paper, guided testing procedures and protocols, was instrumental in data analysis and interpretation, and writing of the paper.

Competing interest: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

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Data sharing: We will provide any data collected upon request.

Transparency declaration: The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Patients or the public WERE NOT involved in the design, or conduct, or reporting, or dissemination plans of our research

Figure Captions

Figure 1 Schematic diagram of labeled components. **A)** 3D printed Head and Jaw Pieces **B)** 7 mil PVC sheet **C)** Shower cap **D)** Ventilation Tubing/corrugated hose **E)** Work belt **F)** 3D printed Power Box **G)** 3M HEPA air filter **H)** 12V blower fan **I)** 12V Milwaukee rechargeable battery **J)** DC motor speed controller.

Figure 2 Assembled PAPR with open power box. **A)** 3D printed Head and Jaw Pieces **B)** 7 mil PVC sheet **C)** Shower cap **D)** Ventilation Tubing/corrugated hose **E)** Work belt **F)** 3D printed Power Box **G)** 3M HEPA air filter **H)** 12V blower fan **I)** 12V Milwaukee rechargeable battery **J)** DC motor speed controller.

Figure 3 Assembly of jaw piece and application of shower cap. a) Apply CA glue to Jaw Piece joint b) align Jaw Piece and Head Piece with 7 mil cover sheet and join. c) Once shower cap is cut down the center about halfway; hot glue the two sides where the upper jaw piece meets the head piece. d-f) Carefully continue to separate cap down center so that the sides can be hot glued down the side and to the center of the Jaw Piece.

Figure 4 Wiring diagram for DC controller, batteries, and blower.

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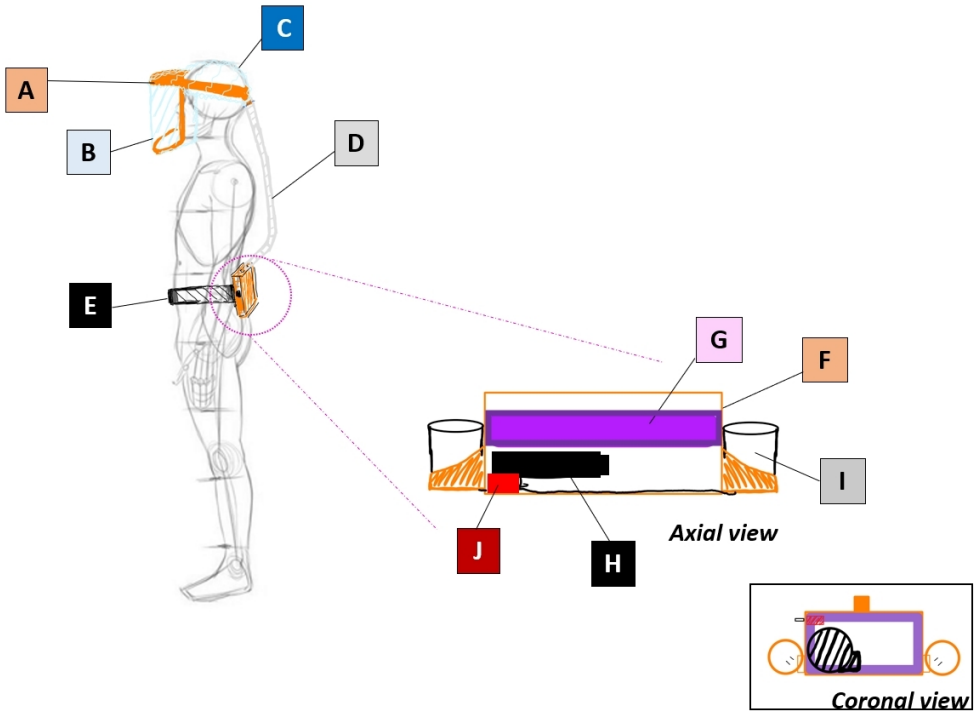

Figure 1 Schematic diagram of labeled components. A) 3D printed Head and Jaw Pieces B) 7 mil PVC sheet C) Shower cap D) Ventilation Tubing/corrugated hose E) Work belt F) 3D printed Power Box G) 3M HEPA air filter H) 12V blower fan I) 12V Milwaukee rechargeable battery J) DC motor speed controller.

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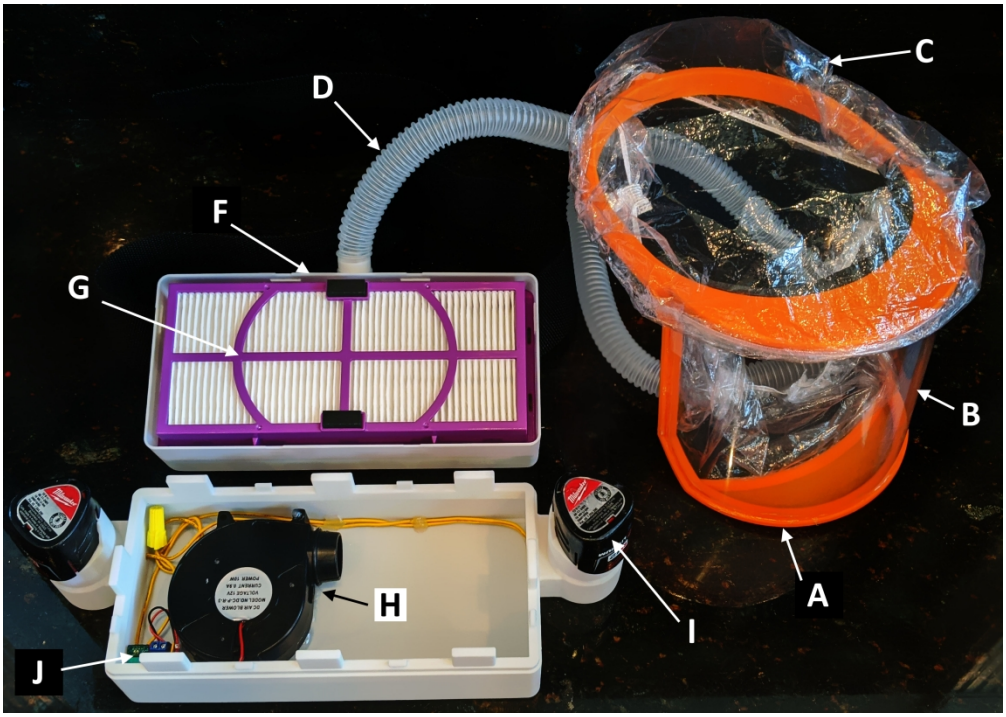

Figure 2 Assembled PAPR with open power box. A) 3D printed Head and Jaw Pieces B) 7 mil PVC sheet C) Shower cap D) Ventilation Tubing/corrugated hose E) Work belt F) 3D printed Power Box G) 3M HEPA air filter H) 12V blower fan I) 12V Milwaukee rechargeable battery J) DC motor speed controller.

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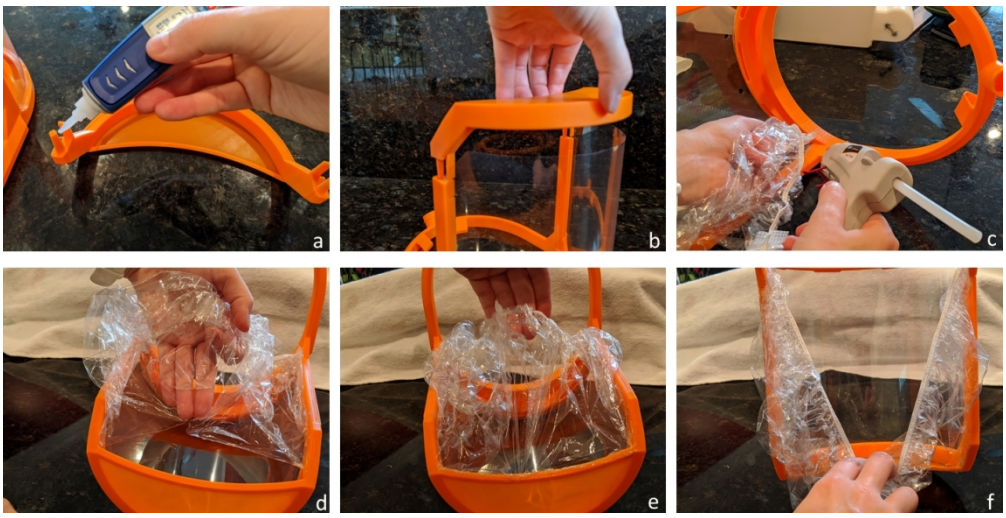

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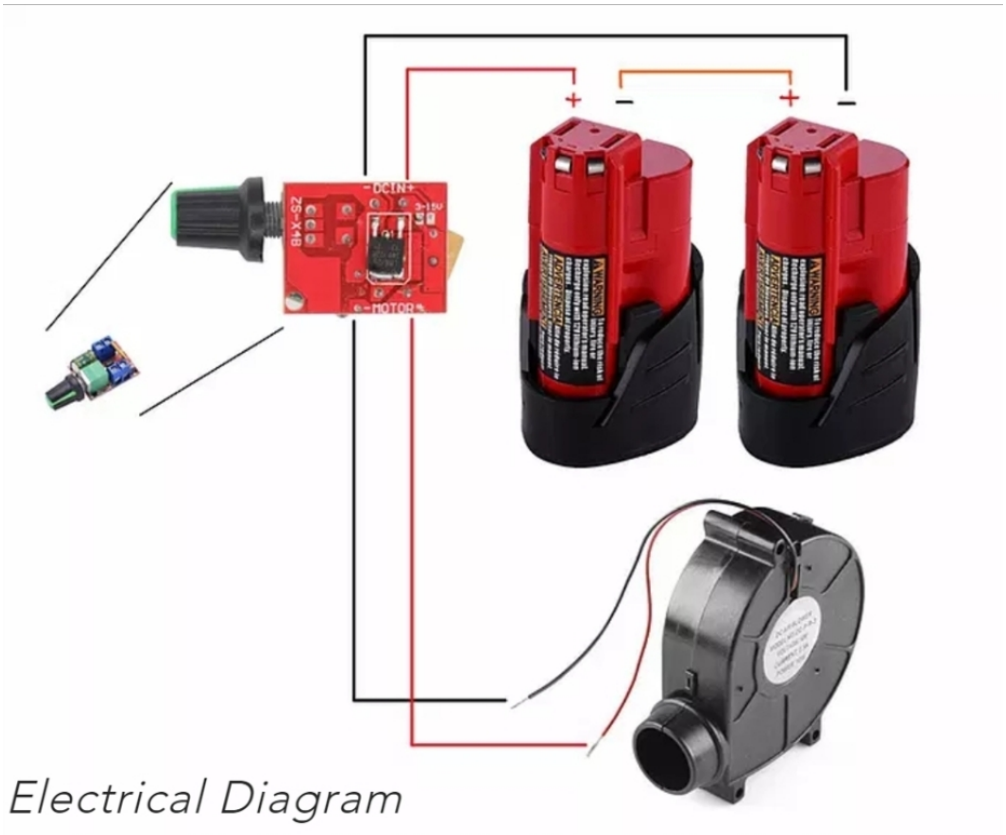
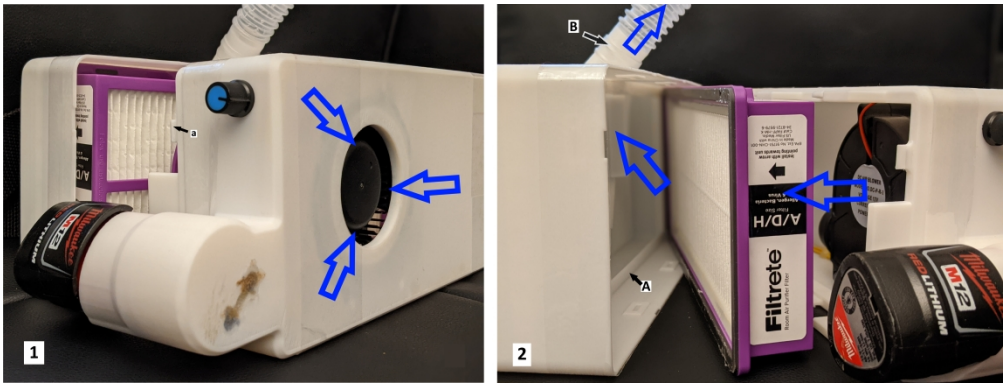


Figure 4 Wiring diagram for DC controller, batteries, and blower.

78x65mm (300 x 300 DPI)



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674x256mm (300 x 300 DPI)

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609x250mm (300 x 300 DPI)

By Standard Number / 1910.134 App A - Fit Testing Procedures (Mandatory).

- **Part Number:** 1910
- **Part Number Title:** Occupational Safety and Health Standards
- **Subpart:** 1910 Subpart I
- **Subpart Title:** Personal Protective Equipment
- **Standard Number:** 1910.134 App A
- **Title:** Fit Testing Procedures (Mandatory).
- **GPO Source:** e-CFR

Appendix A to §1910.134—Fit Testing Procedures (Mandatory)

Part I. OSHA-Accepted Fit Test Protocols

A. Fit Testing Procedures—General Requirements

The employer shall conduct fit testing using the following procedures. The requirements in this appendix apply to all OSHA-accepted fit test methods, both QLFT and QNFT.

1. The test subject shall be allowed to pick the most acceptable respirator from a sufficient number of respirator models and sizes so that the respirator is acceptable to, and correctly fits, the user.

2. Prior to the selection process, the test subject shall be shown how to put on a respirator, how it should be positioned on the face, how to set strap tension and how to determine an acceptable fit. A mirror shall be available to assist the subject in evaluating the fit and positioning of the respirator. This instruction may not constitute the subject's formal training on respirator use, because it is only a review.

3. The test subject shall be informed that he/she is being asked to select the respirator that provides the most acceptable fit. Each respirator represents a different size and shape, and if fitted and used properly, will provide adequate protection.

4. The test subject shall be instructed to hold each chosen facepiece up to the face and eliminate those that obviously do not give an acceptable fit.

5. The more acceptable facepieces are noted in case the one selected proves unacceptable; the most comfortable mask is donned and worn at least five minutes to assess comfort. Assistance in assessing comfort can be given by discussing the points in the following item A.6. If the test subject is not familiar with using a particular respirator, the test subject shall be directed to don the mask several times and to adjust the straps each time to become adept at setting proper tension on the straps.

6. Assessment of comfort shall include a review of the following points with the test subject and allowing the test subject adequate time to determine the comfort of the respirator:

(a) Position of the mask on the nose

(b) Room for eye protection

(c) Room to talk

(d) Position of mask on face and cheeks

7. The following criteria shall be used to help determine the adequacy of the respirator fit:

(a) Chin properly placed;

(b) Adequate strap tension, not overly tightened;

(c) Fit across nose bridge;

(d) Respirator of proper size to span distance from nose to chin;

(e) Tendency of respirator to slip;

(f) Self-observation in mirror to evaluate fit and respirator position.

8. The test subject shall conduct a user seal check, either the negative and positive pressure seal checks described in appendix B-1 of this section or those recommended by the respirator manufacturer which provide equivalent protection to the procedures in appendix B-1. Before conducting the negative and positive pressure checks, the subject shall be told to seat the mask on the face by moving the head from side-to-side and up and down slowly while taking in a few slow deep breaths. Another facepiece shall be selected and retested if the test subject fails the user seal check tests.

9. The test shall not be conducted if there is any hair growth between the skin and the facepiece sealing surface, such as stubble beard growth, beard, mustache or sideburns which cross the respirator sealing surface. Any type of apparel which interferes with a satisfactory fit shall be altered or removed.

10. If a test subject exhibits difficulty in breathing during the tests, she or he shall be referred to a physician or other licensed health care professional, as appropriate, to determine whether the test subject can wear a respirator while performing her or his duties.

11. If the employee finds the fit of the respirator unacceptable, the test subject shall be given the opportunity to select a different respirator and to be retested.

12. Exercise regimen. Prior to the commencement of the fit test, the test subject shall be given a description of the fit test and the test subject's responsibilities during the test procedure. The description of the process shall include a description of the test exercises that the subject will be performing. The respirator to be tested shall be worn for at least 5 minutes before the start of the fit test.

13. The fit test shall be performed while the test subject is wearing any applicable safety equipment that may be worn during actual respirator use which could interfere with respirator fit.

14. Test Exercises.

(a) Employers must perform the following test exercises for all fit testing methods prescribed in this appendix, except for the two modified ambient aerosol CNC quantitative fit testing protocols, the CNP quantitative fit testing protocol, and the CNP REDON quantitative fit testing protocol. For the modified ambient aerosol CNC quantitative fit testing protocols, employers shall ensure that the test subjects (*i.e.*, employees) perform the exercise procedure specified in Part I.C.4(b) of this appendix for full-facepiece and half-mask elastomeric respirators, or the exercise procedure specified in Part I.C.5(b) for filtering facepiece respirators. Employers shall ensure that the test subjects (i.e., employees) perform the exercise procedure specified in Part I.C.6(b) of this appendix for the CNP quantitative fit testing protocol, or the exercise procedure described in Part I.C.7(b) of this appendix for the CNP REDON quantitative fit testing protocol. For the remaining fit testing methods, employers shall ensure that the test exercises are performed in the appropriate test environment in the following manner:

(1) Normal breathing. In a normal standing position, without talking, the subject shall breathe normally.

(2) Deep breathing. In a normal standing position, the subject shall breathe slowly and deeply, taking caution so as not to hyperventilate.

(3) Turning head side to side. Standing in place, the subject shall slowly turn his/her head from side to side between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side.

(4) Moving head up and down. Standing in place, the subject shall slowly move his/her head up and down. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

(5) Talking. The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song.

Rainbow Passage

When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond reach, his friends say he is looking for the pot of gold at the end of the rainbow.

(6) Grimace. The test subject shall grimace by smiling or frowning. (This applies only to QNFT testing; it is not performed for QLFT)

(7) Bending over. The test subject shall bend at the waist as if he/she were to touch his/her toes. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT or QLFT units that do not permit bending over at the waist.

(8) Normal breathing. Same as exercise (1).

(b) Each test exercise shall be performed for one minute except for the grimace exercise which shall be performed for 15 seconds. The test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become unacceptable, another model of respirator shall be tried. The respirator shall not be adjusted once the fit test exercises begin. Any adjustment voids the test, and the fit test must be repeated.

B. Qualitative Fit Test (QLFT) Protocols

1. General

(a) The employer shall ensure that persons administering QLFT are able to prepare test solutions, calibrate equipment and perform tests properly, recognize invalid tests, and ensure that test equipment is in proper working order.

(b) The employer shall ensure that QLFT equipment is kept clean and well maintained so as to operate within the parameters for which it was designed.

2. Isoamyl Acetate Protocol

Note: This protocol is not appropriate to use for the fit testing of particulate respirators. If used to fit test particulate respirators, the respirator must be equipped with an organic vapor filter.

(a) Odor Threshold Screening

Odor threshold screening, performed without wearing a respirator, is intended to determine if the individual tested can detect the odor of isoamyl acetate at low levels.

(1) Three 1 liter glass jars with metal lids are required.

(2) Odor-free water (e.g., distilled or spring water) at approximately 25 °C (77 °F) shall be used for the solutions.

(3) The isoamyl acetate (IAA) (also known at isopentyl acetate) stock solution is prepared by adding 1 ml of pure IAA to 800 ml of odor-free water in a 1 liter jar, closing the lid and shaking for 30 seconds. A new solution shall be prepared at least weekly.

(4) The screening test shall be conducted in a room separate from the room used for actual fit testing. The two rooms shall be well-ventilated to prevent the odor of IAA from becoming evident in the general room air where testing takes place.

(5) The odor test solution is prepared in a second jar by placing 0.4 ml of the stock solution into 500 ml of odor-free water using a clean dropper or pipette. The solution shall be shaken for 30 seconds and allowed to stand for two to three minutes so that the IAA concentration above the liquid may reach equilibrium. This solution shall be used for only one day.

(6) A test blank shall be prepared in a third jar by adding 500 cc of odor-free water.

(7) The odor test and test blank jar lids shall be labeled (e.g., 1 and 2) for jar identification. Labels shall be placed on the lids so that they can be peeled off periodically and switched to maintain the integrity of the test.

(8) The following instruction shall be typed on a card and placed on the table in front of the two test jars (i.e., 1 and 2): “The purpose of this test is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contains a small amount of banana oil. Be sure the covers are on tight, then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the test conductor which bottle contains banana oil.”

(9) The mixtures used in the IAA odor detection test shall be prepared in an area separate from where the test is performed, in order to prevent olfactory fatigue in the subject.

(10) If the test subject is unable to correctly identify the jar containing the odor test solution, the IAA qualitative fit test shall not be performed.

(11) If the test subject correctly identifies the jar containing the odor test solution, the test subject may proceed to respirator selection and fit testing.

(b) Isoamyl Acetate Fit Test

(1) The fit test chamber shall be a clear 55-gallon drum liner suspended inverted over a 2-foot diameter frame so that the top of the chamber is about 6 inches above the test subject's head. If no drum liner is available, a similar chamber shall be constructed using plastic sheeting. The inside top center of the chamber shall have a small hook attached.

(2) Each respirator used for the fitting and fit testing shall be equipped with organic vapor cartridges or offer protection against organic vapors.

(3) After selecting, donning, and properly adjusting a respirator, the test subject shall wear it to the fit testing room. This room shall be separate from the room used for odor threshold screening and respirator selection, and shall be well-ventilated, as by an exhaust fan or lab hood, to prevent general room contamination.

(4) A copy of the test exercises and any prepared text from which the subject is to read shall be taped to the inside of the test chamber.

(5) Upon entering the test chamber, the test subject shall be given a 6-inch by 5-inch piece of paper towel, or other porous, absorbent, single-ply material, folded in half and wetted with 0.75 ml of pure IAA. The test subject shall hang the wet towel on the hook at the top of the chamber. An IAA test swab or ampule may be substituted for the

IAA wetted paper towel provided it has been demonstrated that the alternative IAA source will generate an IAA test atmosphere with a concentration equivalent to that generated by the paper towel method.

(6) Allow two minutes for the IAA test concentration to stabilize before starting the fit test exercises. This would be an appropriate time to talk with the test subject; to explain the fit test, the importance of his/her cooperation, and the purpose for the test exercises; or to demonstrate some of the exercises.

(7) If at any time during the test, the subject detects the banana-like odor of IAA, the test is failed. The subject shall quickly exit from the test chamber and leave the test area to avoid olfactory fatigue.

(8) If the test is failed, the subject shall return to the selection room and remove the respirator. The test subject shall repeat the odor sensitivity test, select and put on another respirator, return to the test area and again begin the fit test procedure described in (b) (1) through (7) above. The process continues until a respirator that fits well has been found. Should the odor sensitivity test be failed, the subject shall wait at least 5 minutes before retesting. Odor sensitivity will usually have returned by this time.

(9) If the subject passes the test, the efficiency of the test procedure shall be demonstrated by having the subject break the respirator face seal and take a breath before exiting the chamber.

(10) When the test subject leaves the chamber, the subject shall remove the saturated towel and return it to the person conducting the test, so that there is no significant IAA concentration buildup in the chamber during subsequent tests. The used towels shall be kept in a self-sealing plastic bag to keep the test area from being contaminated.

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 ¾ -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.

4. Bitrex™ (Denatonium Benzoate) Solution Aerosol Qualitative Fit Test Protocol

The Bitrex™ (Denatonium benzoate) solution aerosol QLFT protocol uses the published saccharin test protocol because that protocol is widely accepted. Bitrex is routinely used as a taste aversion agent in household liquids which children should not be drinking and is endorsed by the American Medical Association, the National Safety Council, and the American Association of Poison Control Centers. 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 Bitrex taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of Bitrex.

(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 (30.5 cm) in diameter by 14 inches (35.6 cm) tall. The front portion of the enclosure shall be clear from the respirator and allow free movement 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 ¾ 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 or her slightly open mouth with tongue extended. The subject is instructed to report when he/she detects a bitter taste.

(4) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, the test conductor shall spray the Threshold Check Solution into the enclosure. This Nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The Threshold Check Solution is prepared by adding 13.5 milligrams of Bitrex to 100 ml of 5% salt (NaCl) solution in distilled water.

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

(7) An initial ten squeezes are repeated rapidly and then the test subject is asked whether the Bitrex can be tasted. If the test subject reports tasting the bitter 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 Bitrex is tasted. If the test subject reports tasting the bitter 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 Bitrex is tasted. If the test subject reports tasting the bitter 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 Bitrex is not tasted after 30 squeezes (step 10), the test subject is unable to taste Bitrex and may not perform the Bitrex fit test.

(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 to dry, and refilled at least each morning and afternoon or at least every four hours.

(b) Bitrex 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 as that described in 4. (a) above.

(3) The test subject shall don the enclosure while wearing the respirator selected according to section I. A. of this appendix. The respirator shall be properly adjusted and equipped with any type 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 337.5 mg of Bitrex to 200 ml of a 5% salt (NaCl) solution in warm water.

(6) As before, the test subject shall breathe through his or her slightly open mouth with tongue extended, and be instructed to report if he/she tastes the bitter taste of Bitrex.

(7) The nebulizer is inserted into the hole in the front of the enclosure and an initial concentration of the 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.

(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 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 Bitrex is detected. If the test subject does not report tasting the Bitrex, the test is passed.

(11) If the taste of Bitrex 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).

5. Irritant Smoke (Stannic Chloride) Protocol

This qualitative fit test uses a person's response to the irritating chemicals released in the “smoke” produced by a stannic chloride ventilation smoke tube to detect leakage into the respirator.

(a) General Requirements and Precautions

(1) The respirator to be tested shall be equipped with high efficiency particulate air (HEPA) or P100 series filter(s).

(2) Only stannic chloride smoke tubes shall be used for this protocol.

(3) No form of test enclosure or hood for the test subject shall be used.

(4) The smoke can be irritating to the eyes, lungs, and nasal passages. The test conductor shall take precautions to minimize the test subject's exposure to irritant smoke. Sensitivity varies, and certain individuals may respond to a greater degree to irritant smoke. Care shall be taken when performing the sensitivity screening checks that determine whether the test subject can detect irritant smoke to use only the minimum amount of smoke necessary to elicit a response from the test subject.

(5) The fit test shall be performed in an area with adequate ventilation to prevent exposure of the person conducting the fit test or the build-up of irritant smoke in the general atmosphere.

(b) Sensitivity Screening Check

The person to be tested must demonstrate his or her ability to detect a weak concentration of the irritant smoke.

(1) The test operator shall break both ends of a ventilation smoke tube containing stannic chloride, and attach one end of the smoke tube to a low flow air pump set to deliver 200 milliliters per minute, or an aspirator squeeze bulb. The test operator shall cover the other end of the smoke tube with a short piece of tubing to prevent potential injury from the jagged end of the smoke tube.

(2) The test operator shall advise the test subject that the smoke can be irritating to the eyes, lungs, and nasal passages and instruct the subject to keep his/her eyes closed while the test is performed.

(3) The test subject shall be allowed to smell a weak concentration of the irritant smoke before the respirator is donned to become familiar with its irritating properties and to determine if he/she can detect the irritating properties of the smoke. The test operator shall carefully direct a small amount of the irritant smoke in the test subject's direction to determine that he/she can detect it.

(c) Irritant Smoke Fit Test Procedure

(1) The person being fit tested shall don the respirator without assistance, and perform the required user seal check(s).

(2) The test subject shall be instructed to keep his/her eyes closed.

(3) The test operator shall direct the stream of irritant smoke from the smoke tube toward the faceseal area of the test subject, using the low flow pump or the squeeze bulb. The test operator shall begin at least 12 inches from the facepiece and move the smoke stream around the whole perimeter of the mask. The operator shall gradually make two more passes around the perimeter of the mask, moving to within six inches of the respirator.

(4) If the person being tested has not had an involuntary response and/or detected the irritant smoke, proceed with the test exercises.

(5) The exercises identified in section I.A. 14. of this appendix shall be performed by the test subject while the respirator seal is being continually challenged by the smoke, directed around the perimeter of the respirator at a distance of six inches.

(6) If the person being fit tested reports detecting the irritant smoke at any time, the test is failed. The person being retested must repeat the entire sensitivity check and fit test procedure.

(7) Each test subject passing the irritant smoke test without evidence of a response (involuntary cough, irritation) shall be given a second sensitivity screening check, with the smoke from the same smoke tube used during the fit test, once the respirator has been removed, to determine whether he/she still reacts to the smoke. Failure to evoke a response shall void the fit test.

(8) If a response is produced during this second sensitivity check, then the fit test is passed.

C. Quantitative Fit Test (QNFT) Protocols

The following quantitative fit testing procedures have been demonstrated to be acceptable: Quantitative fit testing using a non-hazardous test aerosol (such as corn oil, polyethylene glycol 400 [PEG 400], di-2-ethyl hexyl sebacate [DEHS], or sodium chloride) generated in a test chamber, and employing instrumentation to quantify the fit of the respirator; Quantitative fit testing using ambient aerosol as the test agent and appropriate instrumentation (condensation nuclei counter) to quantify the respirator fit; Quantitative fit testing using controlled negative pressure and appropriate instrumentation to measure the volumetric leak rate of a facepiece to quantify the respirator fit.

1. General

(a) The employer shall ensure that persons administering QNFT are able to calibrate equipment and perform tests properly, recognize invalid tests, calculate fit factors properly and ensure that test equipment is in proper working order.

(b) The employer shall ensure that QNFT equipment is kept clean, and is maintained and calibrated according to the manufacturer's instructions so as to operate at the parameters for which it was designed.

2. Generated Aerosol Quantitative Fit Testing Protocol

(a) Apparatus.

(1) Instrumentation. Aerosol generation, dilution, and measurement systems using particulates (corn oil, polyethylene glycol 400 [PEG 400], di-2-ethyl hexyl sebacate [DEHS] or sodium chloride) as test aerosols shall be used for quantitative fit testing.

(2) Test chamber. The test chamber shall be large enough to permit all test subjects to perform freely all required exercises without disturbing the test agent concentration or the measurement apparatus. The test chamber shall be equipped and constructed so that the test agent is effectively isolated from the ambient air, yet uniform in concentration throughout the chamber.

(3) When testing air-purifying respirators, the normal filter or cartridge element shall be replaced with a high efficiency particulate air (HEPA) or P100 series filter supplied by the same manufacturer.

(4) The sampling instrument shall be selected so that a computer record or strip chart record may be made of the test showing the rise and fall of the test agent concentration with each inspiration and expiration at fit factors of at least 2,000. Integrators or computers that integrate the amount of test agent penetration leakage into the respirator for each exercise may be used provided a record of the readings is made.

(5) The combination of substitute air-purifying elements, test agent and test agent concentration shall be such that the test subject is not exposed in excess of an established exposure limit for the test agent at any time during the testing process, based upon the length of the exposure and the exposure limit duration.

(6) The sampling port on the test specimen respirator shall be placed and constructed so that no leakage occurs around the port (e.g., where the respirator is probed), a free air flow is allowed into the sampling line at all times, and there is no interference with the fit or performance of the respirator. The in-mask sampling device (probe) shall be designed and used so that the air sample is drawn from the breathing zone of the test subject, midway between the nose and mouth and with the probe extending into the facepiece cavity at least ¼ inch.

(7) The test setup shall permit the person administering the test to observe the test subject inside the chamber during the test.

(8) The equipment generating the test atmosphere shall maintain the concentration of test agent constant to within a 10 percent variation for the duration of the test.

(9) The time lag (interval between an event and the recording of the event on the strip chart or computer or integrator) shall be kept to a minimum. There shall be a clear association between the occurrence of an event and its being recorded.

(10) The sampling line tubing for the test chamber atmosphere and for the respirator sampling port shall be of equal diameter and of the same material. The length of the two lines shall be equal.

(11) The exhaust flow from the test chamber shall pass through an appropriate filter (i.e., high efficiency particulate filter) before release.

(12) When sodium chloride aerosol is used, the relative humidity inside the test chamber shall not exceed 50 percent.

(13) The limitations of instrument detection shall be taken into account when determining the fit factor.

(14) Test respirators shall be maintained in proper working order and be inspected regularly for deficiencies such as cracks or missing valves and gaskets.

(b) Procedural Requirements.

(1) When performing the initial user seal check using a positive or negative pressure check, the sampling line shall be crimped closed in order to avoid air pressure leakage during either of these pressure checks.

(2) The use of an abbreviated screening QLFT test is optional. Such a test may be utilized in order to quickly identify poor fitting respirators that passed the positive and/or negative pressure test and reduce the amount of QNFT time. The use of the CNC QNFT instrument in the count mode is another optional method to obtain a quick estimate of fit and eliminate poor fitting respirators before going on to perform a full QNFT.

(3) A reasonably stable test agent concentration shall be measured in the test chamber prior to testing. For canopy or shower curtain types of test units, the determination of the test agent's stability may be established after the test subject has entered the test environment.

(4) Immediately after the subject enters the test chamber, the test agent concentration inside the respirator shall be measured to ensure that the peak penetration does not exceed 5 percent for a half mask or 1 percent for a full facepiece respirator.

(5) A stable test agent concentration shall be obtained prior to the actual start of testing.

(6) Respirator restraining straps shall not be over-tightened for testing. The straps shall be adjusted by the wearer without assistance from other persons to give a reasonably comfortable fit typical of normal use. The respirator shall not be adjusted once the fit test exercises begin.

(7) The test shall be terminated whenever any single peak penetration exceeds 5 percent for half masks and 1 percent for full facepiece respirators. The test subject shall be refitted and retested.

(8) Calculation of fit factors.

(i) The fit factor shall be determined for the quantitative fit test by taking the ratio of the average chamber concentration to the concentration measured inside the respirator for each test exercise except the grimace exercise.

(ii) The average test chamber concentration shall be calculated as the arithmetic average of the concentration measured before and after each test (i.e., 7 exercises) or the arithmetic average of the concentration measured before and after each exercise or the true average measured continuously during the respirator sample.

(iii) The concentration of the challenge agent inside the respirator shall be determined by one of the following methods:

(A) Average peak penetration method means the method of determining test agent penetration into the respirator utilizing a strip chart recorder, integrator, or computer. The agent penetration is determined by an average of the peak heights on the graph or by computer integration, for each exercise except the grimace exercise. Integrators or computers that calculate the actual test agent penetration into the respirator for each exercise will also be considered to meet the requirements of the average peak penetration method.

(B) Maximum peak penetration method means the method of determining test agent penetration in the respirator as determined by strip chart recordings of the test. The highest peak penetration for a given exercise is taken to be representative of average penetration into the respirator for that exercise.

(C) Integration by calculation of the area under the individual peak for each exercise except the grimace exercise. This includes computerized integration.

(D) The calculation of the overall fit factor using individual exercise fit factors involves first converting the exercise fit factors to penetration values, determining the average, and then converting that result back to a fit factor. This procedure is described in the following equation:

$$\text{Overall Fit Factor} = \frac{\text{Number of exercises}}{1/ff_1 + 1/ff_2 + 1/ff_3 + 1/ff_4 + 1/ff_5 + 1/ff_6 + 1/ff_7 + 1/ff_8}$$

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Where ff1, ff2, ff3, etc. are the fit factors for exercises 1, 2, 3, etc.

(9) The test subject shall not be permitted to wear a half mask or quarter facepiece respirator unless a minimum fit factor of 100 is obtained, or a full facepiece respirator unless a minimum fit factor of 500 is obtained.

(10) Filters used for quantitative fit testing shall be replaced whenever increased breathing resistance is encountered, or when the test agent has altered the integrity of the filter media.

3. Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol.

The ambient aerosol condensation nuclei counter (CNC) quantitative fit testing (PortaCount®) protocol quantitatively fit tests respirators with the use of a probe. The probed respirator is only used for quantitative fit tests. A probed respirator has a special sampling device, installed on the respirator, that allows the probe to sample the air from inside the mask. A probed respirator is required for each make, style, model, and size that the employer uses and can be obtained from the respirator manufacturer or distributor. The primary CNC instrument manufacturer, TSI Incorporated, also provides probe attachments (TSI mask sampling adapters) that permit fit testing in an employee's own respirator. A minimum fit factor pass level of at least 100 is necessary for a half-mask respirator (elastomeric or filtering facepiece), and a minimum fit factor pass level of at least 500 is required for a full-facepiece elastomeric respirator. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) PortaCount® Fit Test Requirements. (1) Check the respirator to make sure the sampling probe and line are properly attached to the facepiece and that the respirator is fitted with a particulate filter capable of preventing significant penetration by the ambient particles used for the fit test (e.g., NIOSH 42 CFR 84 series 100, series 99, or series 95 particulate filter) per manufacturer's instruction.

(2) Instruct the person to be tested to don the respirator for five minutes before the fit test starts. This purges the ambient particles trapped inside the respirator and permits the wearer to make certain the respirator is comfortable. This individual shall already have been trained on how to wear the respirator properly.

(3) Check the following conditions for the adequacy of the respirator fit: Chin properly placed; Adequate strap tension, not overly tightened; Fit across nose bridge; Respirator of proper size to span distance from nose to chin; Tendency of the respirator to slip; Self-observation in a mirror to evaluate fit and respirator position.

(4) Have the person wearing the respirator do a user seal check. If leakage is detected, determine the cause. If leakage is from a poorly fitting facepiece, try another size of the same model respirator, or another model of respirator.

(5) Follow the manufacturer's instructions for operating the PortaCount® and proceed with the test.

(6) The test subject shall be instructed to perform the exercises in section I. A. 14. of this appendix.

(7) After the test exercises, the test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become unacceptable, another model of respirator shall be tried.

(b) PortaCount® Test Instrument.

(1) The PortaCount® will automatically stop and calculate the overall fit factor for the entire set of exercises. The overall fit factor is what counts. The Pass or Fail message will indicate whether or not the test was successful. If the test was a Pass, the fit test is over.

(2) Since the pass or fail criterion of the PortaCount® is user programmable, the test operator shall ensure that the pass or fail criterion meet the requirements for minimum respirator performance in this Appendix.

(3) A record of the test needs to be kept on file, assuming the fit test was successful. The record must contain the test subject's name; overall fit factor; make, model, style, and size of respirator used; and date tested.

4. Modified ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol for full-facepiece and half-mask elastomeric respirators.

(a) When administering this protocol to test subjects, employers shall comply with the requirements specified in Part I.C.3 of this appendix (ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol), except they shall use the test exercises described below in paragraph (b) of this protocol instead of the test exercises specified in section I.C.3(a)(6) of this appendix.

(b) Employers shall ensure that each test subject being fit tested using this protocol follows the exercise and duration procedures, including the order of administration, described in Table A-1 of this appendix.

Table A-1-- Modified Ambient Aerosal CNC Quantitative Fit Testing Protocol for Full Facepiece and Half-Mask Elastomeric Respirators

Exercises[1]	Exercise procedure	Measurement procedure
Bending Over	The test subject shall bend at the waist, as if going to touch his/her toes for 50 seconds and inhale 2 times at the bottom[2].	A 20 second ambient sample, followed by a 30 second mask sample.
Jogging-in-Place	The test subject shall jog in place comfortably for 30 seconds	A 30 second mask sample.
Head Side-to-Side	The test subject shall stand in place, slowly turning his/her head from side to side for 30 seconds and inhale 2 times at each extreme[2].	A 30 second mask sample.

Head Up-and-Down	The test subject shall stand in place, slowly moving his/her head up and down for 39 seconds and inhale 2 times at each extreme[2].	A 30 second mask sample followed by a 9 second ambient sample.

[1]Exercises are listed in the order in which they are to be administered.
[2]It is optional for test subjects to take additional breaths at other times during this exercise.

5. Modified ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol for filtering facepiece respirators.

(a) When administering this protocol to test subjects, employers shall comply with the requirements specified in Part I.C.3 of this appendix (ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol), except they shall use the test exercises described below in paragraph (b) of this protocol instead of the test exercises specified in section I.C.3(a)(6) of this appendix.

(b) Employers shall ensure that each test subject being fit tested using this protocol follows the exercise and duration procedures, including the order of administration, described in Table A–2 of this appendix

TABLE A–2— MODIFIED AMBIENT AEROSAL CNC QUANTITATIVE FIT TESTING PROTOCOL FOR FILTERING FACEPIECE RESPIRATORS

Exercises[1]	Exercise procedure	Measurement procedure
Bending Over	The test subject shall bend at the waist, as if going to touch his/her toes for 50 seconds and inhale 2 times at the bottom[2].	A 20 second ambient sample, followed by a 30 second mask sample.
Talking	The test subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor for 30 seconds. He/she will either read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song.	A 30 second mask sample.
Head Side-to-Side	The test subject shall stand in place, slowly turning his/her head from side to side for 30 seconds and inhale 2 times at each extreme[2].	A 30 second mask sample.
Head Up-and-Down	The test subject shall stand in place, slowly moving his/her head up and down for 39 seconds and inhale 2 times at each extreme[2].	A 30 second mask sample followed by a 9 second ambient sample.

[1]Exercises are listed in the order in which they are to be administered.
[2]It is optional for test subjects to take additional breaths at other times during this exercise.

6. Controlled negative pressure (CNP) quantitative fit testing protocol.

The CNP protocol provides an alternative to aerosol fit test methods. The CNP fit test method technology is based on exhausting air from a temporarily sealed respirator facepiece to generate and then maintain a constant negative pressure inside the facepiece. The rate of air exhaust is controlled so that a constant negative pressure is maintained in the respirator during the fit test. The level of pressure is selected to replicate the mean inspiratory pressure that causes leakage into the respirator under normal use conditions. With pressure held constant, air flow out of the respirator is equal to air flow into the respirator. Therefore, measurement of the exhaust stream that is required to hold the pressure in the temporarily sealed respirator constant yields a direct measure of leakage air flow into the respirator. The CNP fit test method measures leak rates through the facepiece as a method for determining the facepiece fit for negative pressure respirators. The CNP instrument manufacturer Occupational Health Dynamics of Birmingham, Alabama also provides attachments (sampling manifolds) that replace the filter cartridges to permit fit testing in an employee's own respirator. To perform the test, the test subject closes his or her mouth and holds his/her breath, after which an air pump removes air from the respirator facepiece at a pre-selected constant pressure. The facepiece fit is expressed as the leak rate through the facepiece, expressed as milliliters per minute. The quality and validity of the CNP fit tests are determined by the degree to which the in-mask pressure tracks the test pressure during the system measurement time of approximately five seconds. Instantaneous feedback in the form of a real-time pressure trace of the in-mask pressure is provided and used to determine test validity and quality. A minimum fit factor pass level of 100 is necessary for a half-mask respirator and a minimum fit factor of at least 500 is required for a full facepiece respirator. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) CNP Fit Test Requirements.

(1) The instrument shall have a non-adjustable test pressure of 15.0 mm water pressure.

(2) The CNP system defaults selected for test pressure shall be set at −15 mm of water (-0.58 inches of water) and the modeled inspiratory flow rate shall be 53.8 liters per minute for performing fit tests.

Note: CNP systems have built-in capability to conduct fit testing that is specific to unique work rate, mask, and gender situations that might apply in a specific workplace. Use of system default values, which were selected to represent respirator wear with medium cartridge resistance at a low-moderate work rate, will allow inter-test comparison of the respirator fit.)

(3) The individual who conducts the CNP fit testing shall be thoroughly trained to perform the test.

(4) The respirator filter or cartridge needs to be replaced with the CNP test manifold. The inhalation valve downstream from the manifold either needs to be temporarily removed or propped open.

(5) The employer must train the test subject to hold his or her breath for at least 10 seconds.

(6) The test subject must don the test respirator without any assistance from the test administrator who is conducting the CNP fit test. The respirator must not be adjusted once the fit-test exercises begin. Any adjustment voids the test, and the test subject must repeat the fit test.

(7) The QNFT protocol shall be followed according to section I. C. 1. of this appendix with an exception for the CNP test exercises.

(b) CNP Test Exercises.

(1) Normal breathing. In a normal standing position, without talking, the subject shall breathe normally for 1 minute. After the normal breathing exercise, the subject needs to hold head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(2) Deep breathing. In a normal standing position, the subject shall breathe slowly and deeply for 1 minute, being careful not to hyperventilate. After the deep breathing exercise, the subject shall hold his or her head straight ahead and hold his or her breath for 10 seconds during test measurement.

(3) Turning head side to side. Standing in place, the subject shall slowly turn his or her head from side to side between the extreme positions on each side for 1 minute. The head shall be held at each extreme momentarily so the subject can inhale at each side. After the turning head side to side exercise, the subject needs to hold head full left and hold his or her breath for 10 seconds during test measurement. Next, the subject needs to hold head full right and hold his or her breath for 10 seconds during test measurement.

(4) Moving head up and down. Standing in place, the subject shall slowly move his or her head up and down for 1 minute. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling). After the moving head up and down exercise, the subject shall hold his or her head full up and hold his or her breath for 10 seconds during test measurement. Next, the subject shall hold his or her head full down and hold his or her breath for 10 seconds during test measurement.

(5) Talking. The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song for 1 minute. After the talking exercise, the subject shall hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(6) Grimace. The test subject shall grimace by smiling or frowning for 15 seconds.

(7) Bending Over. The test subject shall bend at the waist as if he or she were to touch his or her toes for 1 minute. Jogging in place shall be substituted for this exercise in those test environments such as shroud-type QNFT units that prohibit bending at the waist. After the bending over exercise, the subject shall hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(8) Normal Breathing. The test subject shall remove and re-don the respirator within a one-minute period. Then, in a normal standing position, without talking, the subject shall breathe normally for 1 minute. After the normal breathing exercise, the subject shall hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement. After the test exercises, the test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become unacceptable, another model of a respirator shall be tried.

(c) CNP Test Instrument.

(1) The test instrument must have an effective audio-warning device, or a visual-warning device in the form of a screen tracing, that indicates when the test subject fails to hold his or her breath during the test. The test must be terminated and restarted from the beginning when the test subject fails to hold his or her breath during the test. The test subject then may be refitted and retested.

(2) A record of the test shall be kept on file, assuming the fit test was successful. The record must contain the test subject's name; overall fit factor; make, model, style and size of respirator used; and date tested.

7. Controlled negative pressure (CNP) REDON quantitative fit testing protocol.

(a) When administering this protocol to test subjects, employers must comply with the requirements specified in paragraphs (a) and (c) of part I.C.6 of this appendix (``Controlled negative pressure (CNP) quantitative fit testing protocol,'') as well as use the test exercises described below in paragraph (b) of this protocol instead of the test exercises specified in paragraph (b) of part I.C.6 of this appendix.

(b) Employers must ensure that each test subject being fit tested using this protocol follows the exercise and measurement procedures, including the order of administration described in Table A-3 of this appendix.

Table A-3—CNP REDON Quantitative Fit Testing Protocol

Exercises[1]	Exercise procedure	Measurement procedure

Facing Forward	Stand and breathe normally, without talking, for 30 seconds	Face forward, while holding breath for 10 seconds.
Bending Over	Bend at the waist, as if going to touch his or her toes, for 30 seconds	Face parallel to the floor, while holding breath for 10 seconds
Head Shaking	For about three seconds, shake head back and forth vigorously several times while shouting	Face forward, while holding breath for 10 seconds
REDON 1	Remove the respirator mask, loosen all facepiece straps, and then redon the respirator mask	Face forward, while holding breath for 10 seconds.
REDON 2	Remove the respirator mask, loosen all facepiece straps, and then redon the respirator mask again	Face forward, while holding breath for 10 seconds.

[1]Exercises are listed in the order in which they are to be administered.

(c) After completing the test exercises, the test administrator must question each test subject regarding the comfort of the respirator. When a test subject states that the respirator is unacceptable, the employer must ensure that the test administrator repeats the protocol using another respirator model.

(d) Employers must determine the overall fit factor for each test subject by calculating the harmonic mean of the fit testing exercises as follows:

$$\text{Overall Fit Factor} = \frac{N}{\left[1/FF_1 + 1/FF_2 + \ldots\ 1/FF_N\right]}$$

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Where:

N = The number of exercises;

FF1 = The fit factor for the first exercise;

FF2 = The fit factor for the second exercise; and

FFN = The fit factor for the nth exercise.

Part II. New Fit Test Protocols

A. Any person may submit to OSHA an application for approval of a new fit test protocol. If the application meets the following criteria, OSHA will initiate a rulemaking proceeding under section 6(b)(7) of the OSH Act to determine whether to list the new protocol as an approved protocol in this appendix A.

B. The application must include a detailed description of the proposed new fit test protocol. This application must be supported by either:

1. A test report prepared by an independent government research laboratory (e.g., Lawrence Livermore National Laboratory, Los Alamos National Laboratory, the National Institute for Standards and Technology) stating that the laboratory has tested the protocol and had found it to be accurate and reliable; or

2. An article that has been published in a peer-reviewed industrial hygiene journal describing the protocol and explaining how test data support the protocol's accuracy and reliability.

C. If OSHA determines that additional information is required before the Agency commences a rulemaking proceeding under this section, OSHA will so notify the applicant and afford the applicant the opportunity to submit the supplemental information. Initiation of a rulemaking proceeding will be deferred until OSHA has received and evaluated the supplemental information.

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DEPARTMENT OF LABOR

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TITLE

Hygieia PAPR: a novel 3D printable powered air purifying respirator

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ABSTRACT

Objectives: To design a low-cost 3D printable Powered Air-Purifying Respirator (PAPR) that meets National Institute for Occupational Safety and Health (NIOSH) standard for flow rate and Occupational Safety and Health Administration (OSHA) standard for particle filtration for loose-fitting PAPRs and that can be made with a 3D printer and widely available materials.

Design: Detailed description of components, assembly instructions, and testing of a novel PAPR design in an academic laboratory following respective protocols. The assembled PAPR must meet NIOSH standards of flow rate, 170 L/min, OSHA fit factor for particle filtration, ≥250, and maintain positive pressure during regular and deep breathing.

Main Outcome Measures: The PAPR design was run through a series of tests: air flow (L/min), particle filtration (quantitative and qualitative), and positive pressure measured inside the helmet (mm Hg).

Results: Flow rate was 443.32 L/min (NIOSH standard: minimum 170 L/min) and overall fit factor for particle filtration was 1362 (OSHA pass level: ≥500), n=1. The device passed qualitative particle filtration, n=2, and measured peak pressure of 6mm Hg (>0 mm Hg indicates positive pressure) in the helmet, n=1.

Conclusions: The Hygieia PAPR is a low-cost, easily accessible, just–in–time 3D printable PAPR design that meet minimum NIOSH and OSHA standards for flow-rate and particle filtration for loose-fitting PAPR devices to be made and used when industry-made designs are unavailable.

Strengths and limitations of this study

- This study details a low-cost novel 3D printable PAPR that meets NIOSH and OSHA minimum standards for flow-rate and particle filtration respectively for loose-fitting PAPR devices that can be made by anyone with access to the internet, a 3D printer, and a general merchandise store.
- This design can be used to protect health care workers around the world while they perform essential procedures when the supply of industry-made designs is low. Though this design was tested in an uncertified academic laboratory, not all NIOSH and OSHA standards were tested necessary for official certification, and it was not tested on end-users for clinical feedback.
- Current published alternate novel PAPR designs are very valuable but either contain expensive proprietary components or impede important sensory faculties (visual field, hearing ability) [31, 32].
- Downside of over 30 hours of print time is should be weighed against by the simplicity and cost benefits of this design
- Persons must have access to a 3D printer and a general merchandise store or online ordering and delivery which is not always available in rural, resource-limited settings

INTRODUCTION

As of June, 2021, the COVID-19 pandemic has caused approximately 3.84 million reported deaths worldwide.[1] Fortunately, the vaccination effort that began in December, 2020, has resulted in the decline of incidence and deaths from COVID-19 since early 2021.[2] Current evidence suggests the COVID-19 virus transmits via respiratory droplets between people in close proximity indoors, thus putting heath care workers at high risk.[3,4] Personal protective equipment (PPE) is one of the most important means by which healthcare workers are protected. However, at the start of the pandemic, hospitals across the globe experienced shortages of key equipment needed to safely care for these patients.[5,6] For months, hospitals and ambulatory facilities across the globe struggled with inadequate supply. [6-8]

In addition to PPE supply not meeting the high demand, the cost of PPE increased as hospitals were required to have more of it on hand.[9] In March 2020, the WHO called on industry and governments around the world to increase manufacturing as the supply of PPE was dangerously low.[10] Though industry manufacturing efforts escalated, the global 3D printing community began to produce PPE to help those combating COVID-19 before industry-made designs could become available.[11,12] One type of PPE that has become increasingly important is the Powered Air-Purifying Respirator (PAPR). A PAPR pulls or pushes air through a high-efficiency particulate arrestance (HEPA) filter (99.97% efficacy at 0.3μ particle size) and directs the air into an enclosed space to create a positive pressure environment for persons wearing the device. The device provides both a filtered air environment as well as a physical barrier against droplets and particulates.[13]

In the early months of the pandemic, healthcare facilities around the globe struggled to provide workers with adequate PPE. However, hospitals in low-resource countries were at an even greater disadvantage as they share the same supply chain as wealthier countries with less bargaining power.[6] Given the shortage, barriers to access, and expense of PPE, the authors were inspired to design an emergency use 3D printable PAPR that can be made with widely available materials and a 3D printer for one tenth of the cost of an industry-made design meeting the National Institute for Occupational Safety and Health (NIOSH) standard for flow rate and Occupational Safety and Health Administration (OSHA) standard for particle filtration for loose-fitting PAPR devices.

METHODS

Components

The 3D printed parts were created on an Ender 5 Plus using a 0.4 mm nozzle and using the default "standard quality" slicer settings from Cura with the following parameters: Layer height: 0.2mm, Line width: 0.4 mm, Wall thickness: 0.8 mm, Wall line count: 2, Top/Bottom layers: 4, Infill: 20%, Infill pattern: Zig Zag. Filament was polylactic acid (PLA), no rafts or supports were used. Four pieces were printed (print times hr:min, weight and length of plastic required, cost): Head Piece (7:29, 108g, 37.98m, $2.10), Jaw Piece (3:44, 49g, 17.17m, $0.95), Filter Side of Power Box (7:10, 126g, 44.39m, $2.46) and Battery Side of Power Box (13:18, 220g, 77.38m, $4.29). Files can be found at: https://www.thingiverse.com/thing:4292619

The filter used is a 3M high efficiency particulate air (HEPA) filter (3M, Saint Paul, Minnesota, USA) intended for air filtration and rated and certified to filter 99.97% of all airborne particles,

including dust, allergens, bacteria, viruses, and more. The filter life is approximately 6 months based on 12 hours of use per day.[14]

The authors choose to use two 12V Milwaukee batteries (Milwaukee Tool, Brookfield, Wisconsin, USA), used for power tools, because these tools are often a common household item or can easily be purchased if not on hand. Battery charge time is 40 min at 3 A. The hose chosen is one of the more easily accessible hoses available in a hospital and can be found in a manual resuscitator kit (Ambu Inc., Columbia Maryland, USA). One-inch corrugated tubing is also widely available online or at general merchandise stores. The fan is a centrifugal DC blower, 12V, 1A, with a maximum airflow of 16 cubic feet per minute (COM-11270, SparkFun Electronics, Niwot, Colorado, USA). A centrifugal blower was chosen primarily for the energy efficiency, increased air speed, and increased rate of airflow as compared to an axial fan.

Additional components needed are 4, 22–16–gauge male spade connectors, and a DC motor PWM speed controller (3V 6V 12V 24V 35V DC 5A 90W). Other hardware needed: Two plastic shower caps, one 7mil PVC clear binding cover plastic sheet (CSF Binding Supplies, Norton Shores, Michigan, USA), utility belt (Husky, Bolton, Caledon, Canada) , thermal glue gun (Elmer's Products Inc, Atlanta, Georgia, USA), cyanoacrylate (CA) glue (Loctite, Düsseldorf, Germany), 3/32 inch abrasion-resistant elastics cord (McMaster-Carr, Elmhurst, Illinois, USA), and ¾ inch x 7/16 inch rubber foam weatherstrip tape (Thermwell Products Co. Inc., South Mahwah, New Jersey, USA).

All components, including the HEPA filter, are widely available online, at home improvements stores, or general merchandise store. A supply shortage of any one component is possible; however, it is unlikely.

Patient and public involvement
No patients involved

Instructions Table 1 and Table 2 (See Fig 1 and Fig 2 for schematic and overview)

Table 1: **Helmet**
1) Trim the 7mil clear binding cover sheet to fit Jaw Piece. Place the cover sheet into the slit in the Headpiece.
2) Align and fit Head Piece + cover sheet together with the Jaw Piece. Cover sheet will fit into slit in Jaw Piece. Use CA glue to secure. (Fig 3a & 3b)
3) Cut shower cap down the center about halfway; hot glue the two sides where the upper jaw piece meets the head piece. Carefully continue to separate cap down center so that the sides can be hot glued down the jaw piece (Fig 3 c-f).
4) Measure and cut 8 inches of foam weatherstrip tape and place adhesive side against the inner portion of Helmet where the forehead will be. Cut 8 inches of elastic and tie to boat-cleat protrusions of Head Piece (Fig 4b arrow). Cover top with second shower cap.

Table 2: **Power Box**	
Battery side – 1) Align 12V blower fan with indices, use hot glue gun to apply ring of glue around air–inlet to seal.	Filter Side – 6) Align HEPA filter and press in.
2) Connect 4 spade connectors to 4 wires, 2 longer to travel the length of the box (see Fig 5 for wiring diagram).	7) Align clam shell pieces and press together.
3) Thread wires though slots in battery holder pieces and use hot glue to seal wires and connectors at the bottom.	8) Fit utility belt through slots.
4) Complete battery, fan, and controller circuit as depicted in the wiring diagram (Fig 5); place speed controller in slot above fan.	9) Connect hose to head piece and power box.
5) Plug 12V batteries into holders.	

Configuration and Mechanism

The blower fan is used to create a positive pressure in the chamber prior to the filter. Air is thus forced through the filter onto the downstream conduit, which is at all times at a greater pressure than ambient. This positive pressure gradient ensures that no unfiltered air enters the system despite imperfect seals to the outside. Fig 6 demonstrates the flow of air from the blower, through the filter, and out the outlet of the Power Box through the hose. The seal between the HEPA filter and the Filter Side of the Power Box is the most important seal of the design and ensures that no unfiltered air goes through the helmet to the wearer. To ensure a tight seal, the built-in adhesive rubber-seal around the HEPA filter is pressed into the lip of the Filter Side (Fig 6.2.A) by the prongs on the Battery Side (Fig 6.1.a), maintaining constant pressure, thus ensuring a secure seal around the filter.

The connections between the hose and the Power Box and the Helmet are all interference fit. The outside diameter of the 3D printed parts was intentionally enlarged such that it creates an interference with the inner diameter of the hose. Additionally, a ridge was added to the 3D printed connection on the Helmet and Filter Side to match the corrugations of the hose, thus increasing seal integrity and preventing accidental disconnection (Fig 6.2.B). We acknowledge that there are imperfect seals throughout the device. However, so long as positive pressure is maintained in the helmet, the air leaking through the seals may decrease efficiency but does not compromise the filtered air.

TESTING/RESULTS

Air flow rate was calculated by measuring air speed and multiplying it by the cross-sectional area at the measurement site. Air speed was determined using a HoldPeak HP-866B-APP anemometer (Zhuhai JiDa Huapu Instrument Co, Ltd., Zhuhai, China) with an accuracy of ±5%. 3D printed adapters were used to place the anemometer in series between the hose and helmet. The helmet was donned and the power was turned on full. The cross–sectional area of the

anemometer was measured at 0.0026 m^2 and air speed measured at 2.2 m/s, equaling a flow rate of 0.0074 m^3/s, or 443.32 L/min, well above the NIOSH minimum requirement of 170 L/min for loose–fitting PAPRs.[15] Airflow measurements were taken while the device was being worn and the units were in operation. The current prototype has demonstrated an approximate run time of 45min.

Particle testing followed the OSHA 29CFR1910.134, Appendix A. C. 3. Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol.[16] A port was placed at the base of the jaw piece by drilling a 4mm hole and placing a Portacount test probe 8025-N95R (TSI, Inc., Shoreview, MN, USA). CA glue was used to seal the probe against the plastic. The "mask" intake was connected to the port, while the "ambient" intake was 4 cm below. The particle counter used was the Portacount Pro+ Model 8038 (TSI, Inc., Shoreview, MN, USA). The non-hazardous test aerosol was created using an ultrasonic humidifier with tap water to generate particles.

The subject (n=1) donned the helmet with the installed particle counter and particle count was measured with the PAPR powered on while the subject performed different exercises each for one minute. Fit Factor (particle concentration outside the respirator divided by the particle concentration inside the respirator) was calculated for each of the following exercises (passing level is ≥500)[16]: normal and deep breathing (1433 and 1035, respectively), head side to side and up and down (1119 and 1384, respectively), talking (2515), and bending over (1663). Grimacing was omitted due to facial expression being irrelevant in a loose-fitting PAPR.

Qualitative fit test was assessed using the 3M Ft-30 N95 Respirator protocol and 3M bitter formula testing kits (3M, St. Paul, MN, USA).[17] The bitter formula was nebulized in the hood with the PAPR powered on for the full series of movements (see above for movements done during particle testing). The test was then repeated with the bitter formula nebulized immediately adjacent to the blower intake with the full series of movements. The subjects (n=2) were determined to be sensitive to the bitter formula, but the bitter formula was not tasted at any point during either test by either participant. Qualitative testing was done to mimic the testing done during N95 fit testing. This testing is quick and easy to perform and is widely available in healthcare facilities or can be purchased online for minimal cost. A particle counter is expensive and less available in non-university health care settings.

Positive pressure was measured by drilling a 6/32-inch port in the jaw piece of the helmet where an arterial line pressure sensor (TruWave Disposable Sensor, Edwards Lifesciences Corp., Irvine, CA, USA) was placed and thermal glued for a secure seal. The pressure transducer measured a peak pressure of 6mm Hg ±1mm Hg indicating positive pressure in the helmet with both regular and deep breathing. Other exercises were not performed as change in elevation of the helmet would affect the pressure reading by changing the water column of the arterial line. This test demonstrates that positive pressure is maintained throughout the system, indicating that contaminated ambient air cannot leak into the system despite potential imperfect seals. Note, all qualitative and quantitative tests were done on the same prototype with the pressure test being performed last as the sensors altered the integrity of the jaw piece.

PAPR devices are often tested for their ability to filter silica dust, usually for mining or other dusty work environments. Our PAPR device is intended for the health care setting and this test was deemed unnecessary.

To make the PAPR more environmentally-friendly, the authors designed an optional shell that can be printed and glued to the top of the helmet (Fig 4). The shell is split into front and rear pieces (hr:min, weight and length of plastic required, cost): Front (4:11, 69g, 24.6m, $1.34), Rear (2:41, 42g, 14.88m, $0.82). This option allows the top to be wiped down as opposed to disposing of the top shower cap. (Testing data was collected on the original model with a second shower cap top instead of this shell. However, the optional shell does not induce any changes to the functional aspect of the jaw and headpiece and thus would cause no changes in the functional aspect of the overall respirator.)

DISCUSSION

Principal findings

The Hygieia PAPR is a novel 3D printable PAPR design that meets minimum standards for NIOSH and OSHA flow-rate and particle filtration, respectively, for loose-fitting PAPR devices. Additionally, the PAPR demonstrated positive pressure inside the helmet during normal and deep breathing.

Strengths and weakness

Compared to N95 respirators, PAPRs have a higher protective factor, provide more comfort to the wearer for prolonged periods of time, remove concerns of poor N95 fit and seal, and may decrease the effort needed to maintain the work of breathing.[18-20] PAPRs may be especially useful protection in aerosolizing procedures like dynamic resuscitation and nearly eliminate fogging of eye wear, shields, and hoods.[4,18,19,21] Additionally, N95 respirators have been shown to alter cerebral blood flow and cause headaches which can be alleviated by the addition of a PAPR.[22]

Though the individual cost of an N95 mask is small ($1.50), the true cost lies in fit testing.[21] If an N95 respirator does not fit, or an improper size is used, a seal cannot be achieved and the mask will not provide full protection.[23] Additionally, depending on the respirator model and accuracy of fit testing, 1-20% of wearers will have an inappropriate respirator assigned to them, putting them at risk to potential exposures. [24] A loose-fitting PAPR does not require fit testing and is able to be worn with facial hair.[19-21] However, an industry-designed PAPR can cost from $900 to over $1,200 US dollars with the addition of the battery and charger.[21] In comparison, the PAPR design detailed in this paper is one tenth of the cost, approximately $120 for the materials.

One of the most signficant advantages of this PAPR design is the ability to use components from different manufacturers than those detailed in the Methods so long as it has the same specifications. As an example, the batteries must be 12V drill batteries, but the company and manufacturer do not affect the function of the design.

The nature of 3D printing allows for rapid, easily executable changes. An example would be the ability to change the battery cartridges to fit a different brand of drill battery. If working on a printer with a bed smaller than that of the Ender 5 Plus, the helmet can be split up into parts and

glued together. Though print times may be a concern, if orchestrated properly, a PAPR can be made in less than 33 hours of total printing time and can be cleaned, reused, and shared (so long as proper cleaning is performed between each use). The drawback of a prolonged total print time is potentially outweighed by the simplicity and cost benefits of this design.

The helmet length and width were designed to be large enough to accommodate the majority of head dimensions. However, if the current design does not fit a given user several adjustments can be made. The foam in the front of the helmet is primary for comfort, any other padding material can be used to increase or decrease the helmet diameter, so long as the padding material does not cover the vents in the helmet. Similarly, the elastic used can be exchanged for another type of elastic, string, or tie, that will help secure the helmet to the wearers head. Lastly, if the current dimensions of the helmet or Jaw Piece still do not fit the wearer comfortably, they can be altered in the .stl file before being printed. The shower cap attached to the Jaw Piece can be adjusted for comfort by gluing additional shower cap elastic to the Jaw Piece on each side where it meets the Head Piece. These adjustments are for comfort and will not alter the flow-rate, particle filtration, or positive-pressure of this loose-fitting PAPR design.

The fan has been intentionally placed before the filter to ensure positive pressure throughout the system. A fan placed before the filter would create a negative pressure and the potential for unfiltered air seeping into the system. Additionally, potential particulates generated by the fan itself are forced to go through the filter, thus preventing them from reaching the user. Commercial units often place the fan after the filter. However, these novel methods of user-dependent manufacturing lack the stringent sourcing controls otherwise used in traditional medical equipment manufacturing and thus we believe it is better to ensure the user's safety. Concerns about difficulty cleaning the fan input impeller are mitigated by the air being filtered after the fan.

The 12V batteries are wired in series resulting in a higher voltage with a lower current system to drive adequate airflow. It also allows for a more robust system given the flexible nature of the hose connecting the Power Box to the Head Piece and the critically important maintenance of high flow rate. The authors acknowledged using a 12V fan is non ideal and would recommend using a 24V fan instead. 24V blower fans are can be found at similar cost and can likely be used with similar results.

Cleaning the PAPR can be easily achieved by using a bleach wipe. A recent study by Welch et al demonstrated that SARS-CoV-2 and two other surrogate coronaviruses (MHV and 229E) on 3D printed material were completely inactivated by a single application of 10% bleach, ammonium quaternary, 3% H2O2, or exposure to 70°C dry heat.[25] Other sources have shown sterilization by low-temperature hydrogen peroxide gas plasma, though this may not be a viable option for many settings.[26] Some elements of the PAPR may not be sufficiently cleaned with a wipe, like the utility belt made with poly web material. For thorough cleaning, the belt should be removed from the Power Box and submerged in a basin filled with either ethanol or isopropyl alcohol.[27] Additionally, alternate belt materials that are easier to clean can be used to strap the Power Box to the wearer.

The authors were inspired to design the Hygieia PAPR as an option for emergency-use PPE when industry-made designs are unavailable. PPE is a key component of controlling infection spread in both healthcare settings and the community, but a survey of hospitals in low-resource countries for the past 5 years confirms low quantities of available PPE; this supply shortage was made critical by the pandemic.[6,28] In March, hospitals in Kathmandu, Nepal, commissioned the National Innovation Center to innovate and create PPE, allowing them to circumvent the global PPE supply chain.[29] It is these types of organizations around the world with whom we wish to connect, correspond, and collaborate to create the most effective tools for the greatest number of people.

Limitations

Our testing was done in the academic laboratory at Tulane University which, though accurate, is not a formal, nationally certified testing center. Though we meet the minimum standards for flow rate (NIOSH) and particle filtration (OSHA), we did not perform all the tests that would qualify us for formal NIOSH and OSHA PAPR certification. Several tests performed during this certification process are to test the integrity of the filter (NIOSH-42 CFR, Part 84)[15]. We used a 3M HEPA filter previously certified to meet these standards and emphasized a tight seal between the filter and Power Box to ensure adequate filtration.[30]

Certified PAPRs undergo many more tests than were performed on the design detailed in this paper (housing sealing testing, oil aerosol testing, communicating performance testing, and control systems alarms for flow rate testing). However, due to lack of access to appropriate equipment, we did not perform these tests on the PAPR design. We narrowed our focus to flow rate and particle filtration, as they are the most relevant variables in an emergency situation. We used the OSHA 29CFR1910.134, Appendix A. C. 3 protocol for particle filtration. The non-hazardous test aerosol used was created with an ultrasonic humidifier and tap water. According to the protocol, the preferred aerosols used are corn oil, polyethylene glycol 400 [PEG 400], di-2-ethyl hexyl sebacate [DEHS], or sodium chloride.[16] In order to obtain NIOSH certification, the manufacturer needs to be certified for minimum quality control standards. This PAPR does not have official NIOSH or OSHA certification and should only be used in emergency situations, and users should proceed with caution when considering use in healthcare settings. The Hygieia PAPR was not tested on end-users for clinical feedback and was not, to the authors knowledge, used in clinical or high-level PEE situations.

In relation to other studies

Some PAPR designs have already been published using 3D printable adapters and parts.[13,31,32] Erickson et al. observed that Stryker Flyte helmet worn during orthopeadic surgery is, in-essence, a PAPR without the filtration. The authors 3D printed an adapter to connect HEPA filters to the air-intake system; thus, creating a PAPR with minimal addition to a preexisting system.[13] This is an innovative way of using available resources. However, not all hospitals are equipped to perform orthopeadic surgery and do not have the Stryker Flyte helmets on hand. Additionally, the hood for the helmet covers the ears which can decrease the hearing ability of the wearer, potentially detrimental to communication between healthcare workers in emergent situations.

Hubbard et al., modified a Scott Safety self-contained breathing apparatus (SCBA) into a PAPR, primarily for fire fights and other first responders to use during the PPE shortage. A SCBA uses compressed air fed to an air-tight mask via a pressure regulator, providing clean air to the wearing, but impractical and cost prohibitive for long term use. The authors modified the SCBA mask with a HEPA filter at the air intake attached to a powered fan in a 3D printed casing, creating a PAPR.[32] Similar to the design by Erickson et al., this PAPR is a cost-effective solution if the SCBA mask is readily available. Additionally, the design of the SCBA mask might impede full visual field necessary for medical procedures.

Nazarious et al., designed a mini wearable cleanroom and biosafety system or, a Pressure Optimized PowEred Respirator (PROPER). The blower fan and power system is similar to that of the Hygieia Power Box with the addition of a safety-fuse and a Lithium ion rechargeable powerbank as the power source. The main difference lies in the hood comprised of a face shield frame, the hood adapter and flange, the helmet fitting (adjustable head straps), and SMS head fabric. The SMS material used for the hood and clean room garment set is single use.[31] This is an inexpensive helmet-based respirator system that can be made with widely available components. However, it costs approximately $250 USD per device, compared to $120 for the Hygieia PAPR, and has more, small components that add to the complexity of the device.

These innovations are valuable additions to the literature in a time of worldwide PPE shortages and are tailored to specific settings and environments. However, the incorporation of more expensive or difficult to obtain components, using designs with many components, or working within the limitations of the visibility and aural requirements of certain health care settings, may make these designs less optimal for the more resource limited health care settings.

The Hygieia PAPR is inexpensive, requires no proprietary parts, and has a minimal number of components. The design of the helmet allows for nearly full visual field and provides full coverage of the rest of the face and critical orifices. Some PAPR designs use a hood to increase coverage (ears, hair, and shoulders), but can make communication challenging particularly in critical moments of care.[21] This PAPR is a valuable addition to the literature and pool of options for emergency PPE.

Unanswered questions and future research

Aspects that warrant further investigation are elements of efficiency and optimization. The imperfect seals do not optimize the power and positive pressure generated. Qualitative and quantitative testing will need to be redone with a 24V fan. The current batteries are widely available but are heavy, bulky, and do not have an extensive run time and alternatives should be considered. Future research should also test a larger diameter hose to see if greater flow rate can be achieved with less power. Future research will include more testing on certified equipment for more accurate and formal measurements. Another question that should be addressed in future research is how to ensure consistent quality prints with different users around the world.

Meaning of the design and possible implementation

The COVID-19 pandemic has taxed the health care system and PPE to dangerous levels. If industry is unable to produce the necessary equipment for this, or any other respiratory virus in the future, in a timely fashion, and world PPE supplies are directed towards the highest bidder,

we need a better solution that will protect health care workers around the world while they perform essential procedures. The Hygieia PAPR should be added to the proposed solutions as an easily reproducible, cost-effective, and reusable piece of PPE that can be used on its own or to increase the life span and comfort of other essential equipment (i.e. N95 masks).

STAEMENTS

Disclaimer: The designs and other information ("the Design") made available in this article is at an early stage of development. Accordingly, specific results are not guaranteed, and the Design provided here is provided ''AS IS" and without any express or implied warranties, representations or undertakings. As examples, but without limiting the foregoing, Tulane University and their employees and students do not give any warranty or guarantee that the Design is of merchantable or satisfactory quality, is fit for any particular purpose, complies with any sample or description including the requirements for medical device registration, or are viable, uncontaminated, safe or non-toxic, accurate, up to date or complete. Tulane University and the authors have not performed any searches or investigations into the existence of any third-party rights that may affect the Design. Anyone may use the Design entirely at their own risk, and Tulane University and/or the authors are not liable for such use of the Design, including without limitation any direct or indirect losses. Any users of the design should appropriately attribute the author.

Human and Animal Rights: This work involved testing of the equipment on a human subject to validate the qualitative and quantitative testing. The tests were voluntarily performed on the authors and an informed consent was obtained for experimentation. We ensure that the work described has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans; Uniform Requirements for manuscripts submitted to Biomedical journals.

Ethics Approval Statement

This study did not require ethical approval as the only human subjects involved in the study were the authors, minimal to no risk was present, and informed consent was acquired from the authors at the time of original data collection.

Author's Contributions: Jorge Nagel and Catherine Gilbert had the idea for the article and completed the PAPR design and testing, data collection, analysis, literature search, and interpretation and writing. Both Mr. Nagel and Ms. Gilbert contributed equally to this project and manuscript and are both guarantors of the overall content. Dr. Juan Duchesne contributed to the organization of the paper, guided testing procedures and protocols, was instrumental in data analysis and interpretation, and writing of the paper.

Competing interest: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

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Transparency declaration: The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Patients or the public WERE NOT involved in the design, or conduct, or reporting, or dissemination plans of our research

Figure Captions

Figure 1 Schematic diagram of labeled components. **A)** 3D printed Head and Jaw Pieces **B)** 7 mil PVC sheet **C)** Shower cap **D)** Ventilation Tubing/corrugated hose **E)** Work belt **F)** 3D printed Power Box **G)** 3M HEPA air filter **H)** 12V blower fan **I)** 12V Milwaukee rechargeable battery **J)** DC motor speed controller.

Figure 2 Assembled PAPR with open power box. **A)** 3D printed Head and Jaw Pieces **B)** 7 mil PVC sheet **C)** Shower cap **D)** Ventilation Tubing/corrugated hose **F)** 3D printed Power Box **G)** 3M HEPA air filter **H)** 12V blower fan **I)** 12V Milwaukee rechargeable battery **J)** DC motor speed controller. (Work belt, **E** in Fig 1, is not pictured)

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Figure 5 Wiring diagram for DC controller, batteries, and blower.

Figure 6 Shows the Hygiea Power Box dissembled to visualize specific components and direction of air-flow (as indicated by the blue arrows). The prongs on the Battery Side (1.a) press the HEPA filter into the lip of the Filter Side (2.A). A ridge on the hose connection increases seal integrity and prevents accidental disconnection (2.B).

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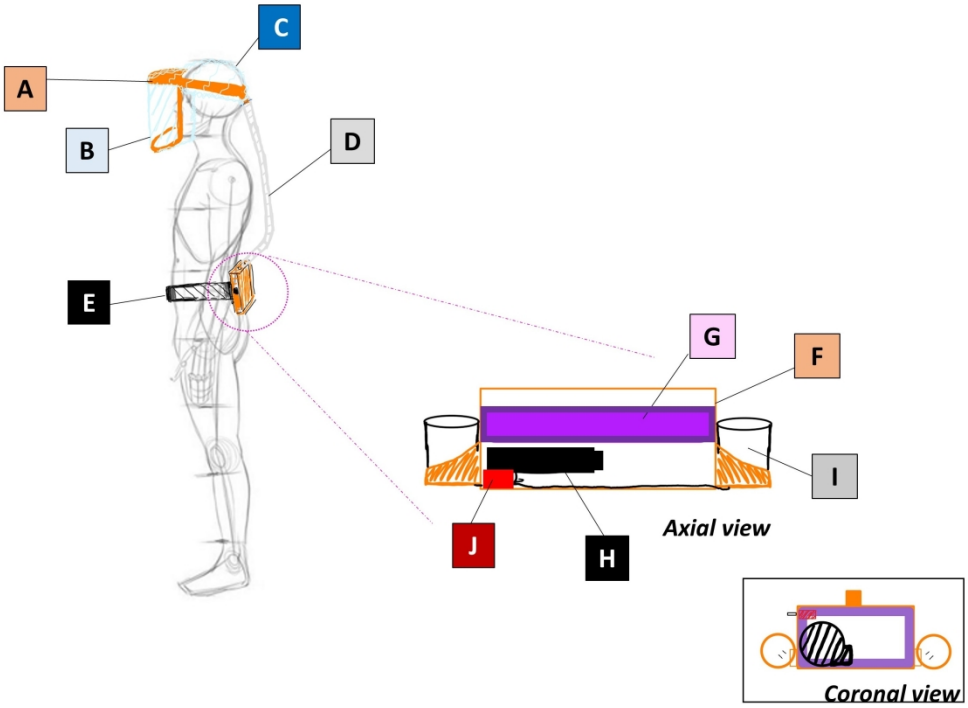

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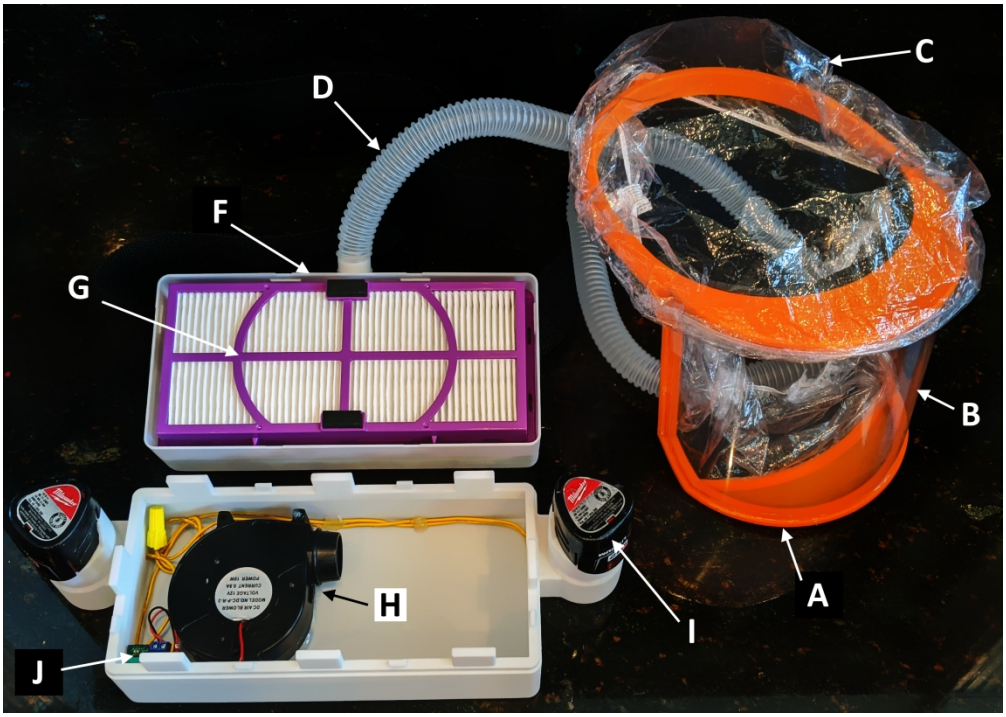
251x189mm (300 x 300 DPI)



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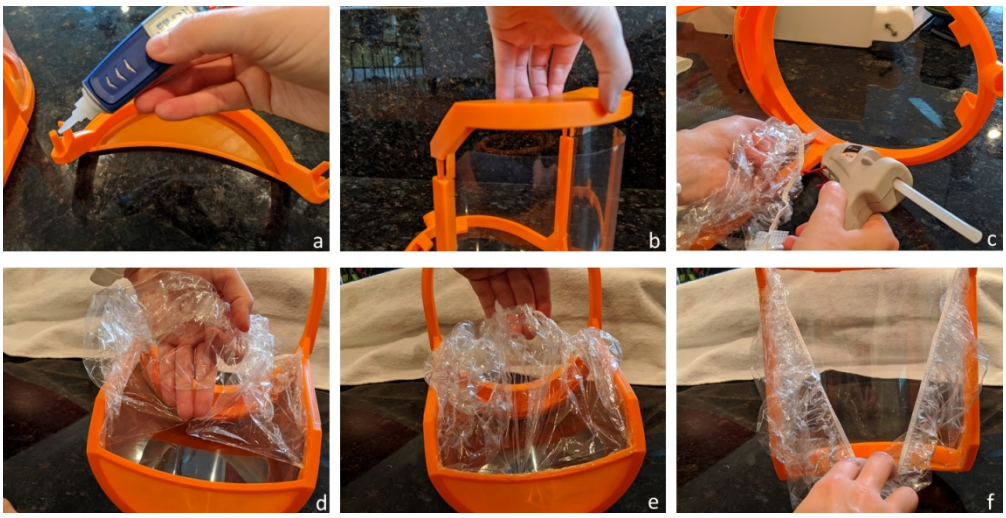
335x237mm (300 x 300 DPI)



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120x60mm (300 x 300 DPI)

Figure 4 a) Side- by-side comparison of assembled 3D printed helmet with optional top shell (left) or shower cap (right). b) 4 views of assembled helmet with shell. Arrow pointing to boat-cleat attachment-point for elastic. c) 4 views of assembled helmet with shower cap

609x250mm (300 x 300 DPI)

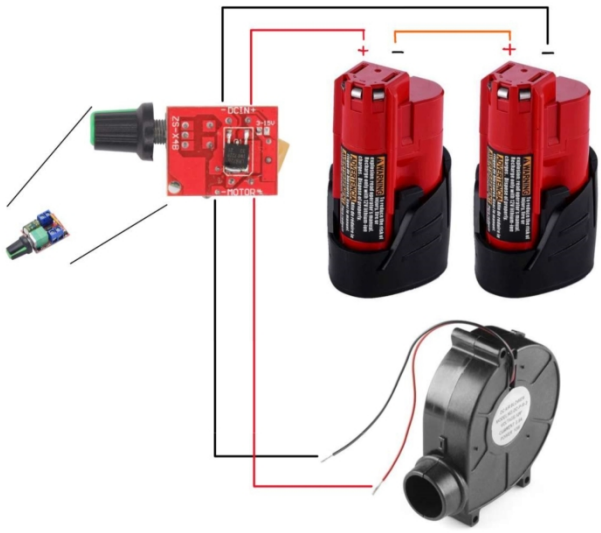
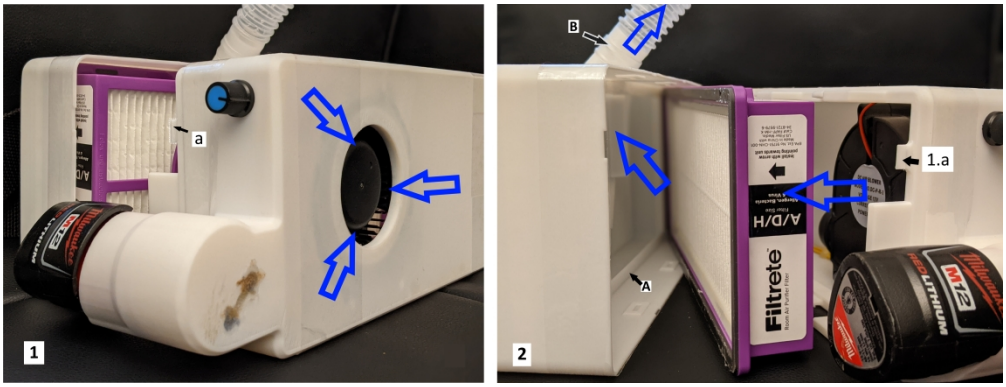


Figure 5 Wiring diagram for DC controller, batteries, and blower.

338x190mm (300 x 300 DPI)



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674x256mm (300 x 300 DPI)

By Standard Number / 1910.134 App A - Fit Testing Procedures (Mandatory).

- **Part Number:** 1910
- **Part Number Title:** Occupational Safety and Health Standards
- **Subpart:** 1910 Subpart I
- **Subpart Title:** Personal Protective Equipment
- **Standard Number:** 1910.134 App A
- **Title:** Fit Testing Procedures (Mandatory).
- **GPO Source:** e-CFR

Appendix A to §1910.134—Fit Testing Procedures (Mandatory)

Part I. OSHA-Accepted Fit Test Protocols

A. Fit Testing Procedures—General Requirements

The employer shall conduct fit testing using the following procedures. The requirements in this appendix apply to all OSHA-accepted fit test methods, both QLFT and QNFT.

1. The test subject shall be allowed to pick the most acceptable respirator from a sufficient number of respirator models and sizes so that the respirator is acceptable to, and correctly fits, the user.

2. Prior to the selection process, the test subject shall be shown how to put on a respirator, how it should be positioned on the face, how to set strap tension and how to determine an acceptable fit. A mirror shall be available to assist the subject in evaluating the fit and positioning of the respirator. This instruction may not constitute the subject's formal training on respirator use, because it is only a review.

3. The test subject shall be informed that he/she is being asked to select the respirator that provides the most acceptable fit. Each respirator represents a different size and shape, and if fitted and used properly, will provide adequate protection.

4. The test subject shall be instructed to hold each chosen facepiece up to the face and eliminate those that obviously do not give an acceptable fit.

5. The more acceptable facepieces are noted in case the one selected proves unacceptable; the most comfortable mask is donned and worn at least five minutes to assess comfort. Assistance in assessing comfort can be given by discussing the points in the following item A.6. If the test subject is not familiar with using a particular respirator, the test subject shall be directed to don the mask several times and to adjust the straps each time to become adept at setting proper tension on the straps.

6. Assessment of comfort shall include a review of the following points with the test subject and allowing the test subject adequate time to determine the comfort of the respirator:

(a) Position of the mask on the nose

(b) Room for eye protection

(c) Room to talk

(d) Position of mask on face and cheeks

7. The following criteria shall be used to help determine the adequacy of the respirator fit:

(a) Chin properly placed;

(b) Adequate strap tension, not overly tightened;

(c) Fit across nose bridge;

(d) Respirator of proper size to span distance from nose to chin;

(e) Tendency of respirator to slip;

(f) Self-observation in mirror to evaluate fit and respirator position.

8. The test subject shall conduct a user seal check, either the negative and positive pressure seal checks described in appendix B-1 of this section or those recommended by the respirator manufacturer which provide equivalent protection to the procedures in appendix B-1. Before conducting the negative and positive pressure checks, the subject shall be told to seat the mask on the face by moving the head from side-to-side and up and down slowly while taking in a few slow deep breaths. Another facepiece shall be selected and retested if the test subject fails the user seal check tests.

9. The test shall not be conducted if there is any hair growth between the skin and the facepiece sealing surface, such as stubble beard growth, beard, mustache or sideburns which cross the respirator sealing surface. Any type of apparel which interferes with a satisfactory fit shall be altered or removed.

10. If a test subject exhibits difficulty in breathing during the tests, she or he shall be referred to a physician or other licensed health care professional, as appropriate, to determine whether the test subject can wear a respirator while performing her or his duties.

11. If the employee finds the fit of the respirator unacceptable, the test subject shall be given the opportunity to select a different respirator and to be retested.

12. Exercise regimen. Prior to the commencement of the fit test, the test subject shall be given a description of the fit test and the test subject's responsibilities during the test procedure. The description of the process shall include a description of the test exercises that the subject will be performing. The respirator to be tested shall be worn for at least 5 minutes before the start of the fit test.

13. The fit test shall be performed while the test subject is wearing any applicable safety equipment that may be worn during actual respirator use which could interfere with respirator fit.

14. Test Exercises.

(a) Employers must perform the following test exercises for all fit testing methods prescribed in this appendix, except for the two modified ambient aerosol CNC quantitative fit testing protocols, the CNP quantitative fit testing protocol, and the CNP REDON quantitative fit testing protocol. For the modified ambient aerosol CNC quantitative fit testing protocols, employers shall ensure that the test subjects (*i.e.*, employees) perform the exercise procedure specified in Part I.C.4(b) of this appendix for full-facepiece and half-mask elastomeric respirators, or the exercise procedure specified in Part I.C.5(b) for filtering facepiece respirators. Employers shall ensure that the test subjects (i.e., employees) perform the exercise procedure specified in Part I.C.6(b) of this appendix for the CNP quantitative fit testing protocol, or the exercise procedure described in Part I.C.7(b) of this appendix for the CNP REDON quantitative fit testing protocol. For the remaining fit testing methods, employers shall ensure that the test exercises are performed in the appropriate test environment in the following manner:

(1) Normal breathing. In a normal standing position, without talking, the subject shall breathe normally.

(2) Deep breathing. In a normal standing position, the subject shall breathe slowly and deeply, taking caution so as not to hyperventilate.

(3) Turning head side to side. Standing in place, the subject shall slowly turn his/her head from side to side between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side.

(4) Moving head up and down. Standing in place, the subject shall slowly move his/her head up and down. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

(5) Talking. The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song.

Rainbow Passage

When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond reach, his friends say he is looking for the pot of gold at the end of the rainbow.

(6) Grimace. The test subject shall grimace by smiling or frowning. (This applies only to QNFT testing; it is not performed for QLFT)

(7) Bending over. The test subject shall bend at the waist as if he/she were to touch his/her toes. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT or QLFT units that do not permit bending over at the waist.

(8) Normal breathing. Same as exercise (1).

(b) Each test exercise shall be performed for one minute except for the grimace exercise which shall be performed for 15 seconds. The test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become unacceptable, another model of respirator shall be tried. The respirator shall not be adjusted once the fit test exercises begin. Any adjustment voids the test, and the fit test must be repeated.

B. Qualitative Fit Test (QLFT) Protocols

1. General

(a) The employer shall ensure that persons administering QLFT are able to prepare test solutions, calibrate equipment and perform tests properly, recognize invalid tests, and ensure that test equipment is in proper working order.

(b) The employer shall ensure that QLFT equipment is kept clean and well maintained so as to operate within the parameters for which it was designed.

2. Isoamyl Acetate Protocol

Note: This protocol is not appropriate to use for the fit testing of particulate respirators. If used to fit test particulate respirators, the respirator must be equipped with an organic vapor filter.

(a) Odor Threshold Screening

Odor threshold screening, performed without wearing a respirator, is intended to determine if the individual tested can detect the odor of isoamyl acetate at low levels.

(1) Three 1 liter glass jars with metal lids are required.

(2) Odor-free water (e.g., distilled or spring water) at approximately 25 °C (77 °F) shall be used for the solutions.

(3) The isoamyl acetate (IAA) (also known at isopentyl acetate) stock solution is prepared by adding 1 ml of pure IAA to 800 ml of odor-free water in a 1 liter jar, closing the lid and shaking for 30 seconds. A new solution shall be prepared at least weekly.

(4) The screening test shall be conducted in a room separate from the room used for actual fit testing. The two rooms shall be well-ventilated to prevent the odor of IAA from becoming evident in the general room air where testing takes place.

(5) The odor test solution is prepared in a second jar by placing 0.4 ml of the stock solution into 500 ml of odor-free water using a clean dropper or pipette. The solution shall be shaken for 30 seconds and allowed to stand for two to three minutes so that the IAA concentration above the liquid may reach equilibrium. This solution shall be used for only one day.

(6) A test blank shall be prepared in a third jar by adding 500 cc of odor-free water.

(7) The odor test and test blank jar lids shall be labeled (e.g., 1 and 2) for jar identification. Labels shall be placed on the lids so that they can be peeled off periodically and switched to maintain the integrity of the test.

(8) The following instruction shall be typed on a card and placed on the table in front of the two test jars (i.e., 1 and 2): “The purpose of this test is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contains a small amount of banana oil. Be sure the covers are on tight, then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the test conductor which bottle contains banana oil.”

(9) The mixtures used in the IAA odor detection test shall be prepared in an area separate from where the test is performed, in order to prevent olfactory fatigue in the subject.

(10) If the test subject is unable to correctly identify the jar containing the odor test solution, the IAA qualitative fit test shall not be performed.

(11) If the test subject correctly identifies the jar containing the odor test solution, the test subject may proceed to respirator selection and fit testing.

(b) Isoamyl Acetate Fit Test

(1) The fit test chamber shall be a clear 55-gallon drum liner suspended inverted over a 2-foot diameter frame so that the top of the chamber is about 6 inches above the test subject's head. If no drum liner is available, a similar chamber shall be constructed using plastic sheeting. The inside top center of the chamber shall have a small hook attached.

(2) Each respirator used for the fitting and fit testing shall be equipped with organic vapor cartridges or offer protection against organic vapors.

(3) After selecting, donning, and properly adjusting a respirator, the test subject shall wear it to the fit testing room. This room shall be separate from the room used for odor threshold screening and respirator selection, and shall be well-ventilated, as by an exhaust fan or lab hood, to prevent general room contamination.

(4) A copy of the test exercises and any prepared text from which the subject is to read shall be taped to the inside of the test chamber.

(5) Upon entering the test chamber, the test subject shall be given a 6-inch by 5-inch piece of paper towel, or other porous, absorbent, single-ply material, folded in half and wetted with 0.75 ml of pure IAA. The test subject shall hang the wet towel on the hook at the top of the chamber. An IAA test swab or ampule may be substituted for the

IAA wetted paper towel provided it has been demonstrated that the alternative IAA source will generate an IAA test atmosphere with a concentration equivalent to that generated by the paper towel method.

(6) Allow two minutes for the IAA test concentration to stabilize before starting the fit test exercises. This would be an appropriate time to talk with the test subject; to explain the fit test, the importance of his/her cooperation, and the purpose for the test exercises; or to demonstrate some of the exercises.

(7) If at any time during the test, the subject detects the banana-like odor of IAA, the test is failed. The subject shall quickly exit from the test chamber and leave the test area to avoid olfactory fatigue.

(8) If the test is failed, the subject shall return to the selection room and remove the respirator. The test subject shall repeat the odor sensitivity test, select and put on another respirator, return to the test area and again begin the fit test procedure described in (b) (1) through (7) above. The process continues until a respirator that fits well has been found. Should the odor sensitivity test be failed, the subject shall wait at least 5 minutes before retesting. Odor sensitivity will usually have returned by this time.

(9) If the subject passes the test, the efficiency of the test procedure shall be demonstrated by having the subject break the respirator face seal and take a breath before exiting the chamber.

(10) When the test subject leaves the chamber, the subject shall remove the saturated towel and return it to the person conducting the test, so that there is no significant IAA concentration buildup in the chamber during subsequent tests. The used towels shall be kept in a self-sealing plastic bag to keep the test area from being contaminated.

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 ¾ -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.

4. Bitrex™ (Denatonium Benzoate) Solution Aerosol Qualitative Fit Test Protocol

The Bitrex™ (Denatonium benzoate) solution aerosol QLFT protocol uses the published saccharin test protocol because that protocol is widely accepted. Bitrex is routinely used as a taste aversion agent in household liquids which children should not be drinking and is endorsed by the American Medical Association, the National Safety Council, and the American Association of Poison Control Centers. 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 Bitrex taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of Bitrex.

(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 (30.5 cm) in diameter by 14 inches (35.6 cm) tall. The front portion of the enclosure shall be clear from the respirator and allow free movement 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 ¾ 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 or her slightly open mouth with tongue extended. The subject is instructed to report when he/she detects a bitter taste.

(4) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, the test conductor shall spray the Threshold Check Solution into the enclosure. This Nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The Threshold Check Solution is prepared by adding 13.5 milligrams of Bitrex to 100 ml of 5% salt (NaCl) solution in distilled water.

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

(7) An initial ten squeezes are repeated rapidly and then the test subject is asked whether the Bitrex can be tasted. If the test subject reports tasting the bitter 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 Bitrex is tasted. If the test subject reports tasting the bitter 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 Bitrex is tasted. If the test subject reports tasting the bitter 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 Bitrex is not tasted after 30 squeezes (step 10), the test subject is unable to taste Bitrex and may not perform the Bitrex fit test.

(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 to dry, and refilled at least each morning and afternoon or at least every four hours.

(b) Bitrex 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 as that described in 4. (a) above.

(3) The test subject shall don the enclosure while wearing the respirator selected according to section I. A. of this appendix. The respirator shall be properly adjusted and equipped with any type 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 337.5 mg of Bitrex to 200 ml of a 5% salt (NaCl) solution in warm water.

(6) As before, the test subject shall breathe through his or her slightly open mouth with tongue extended, and be instructed to report if he/she tastes the bitter taste of Bitrex.

(7) The nebulizer is inserted into the hole in the front of the enclosure and an initial concentration of the 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.

(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 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 Bitrex is detected. If the test subject does not report tasting the Bitrex, the test is passed.

(11) If the taste of Bitrex 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).

5. Irritant Smoke (Stannic Chloride) Protocol

This qualitative fit test uses a person's response to the irritating chemicals released in the “smoke” produced by a stannic chloride ventilation smoke tube to detect leakage into the respirator.

(a) General Requirements and Precautions

(1) The respirator to be tested shall be equipped with high efficiency particulate air (HEPA) or P100 series filter(s).

(2) Only stannic chloride smoke tubes shall be used for this protocol.

(3) No form of test enclosure or hood for the test subject shall be used.

(4) The smoke can be irritating to the eyes, lungs, and nasal passages. The test conductor shall take precautions to minimize the test subject's exposure to irritant smoke. Sensitivity varies, and certain individuals may respond to a greater degree to irritant smoke. Care shall be taken when performing the sensitivity screening checks that determine whether the test subject can detect irritant smoke to use only the minimum amount of smoke necessary to elicit a response from the test subject.

(5) The fit test shall be performed in an area with adequate ventilation to prevent exposure of the person conducting the fit test or the build-up of irritant smoke in the general atmosphere.

(b) Sensitivity Screening Check

The person to be tested must demonstrate his or her ability to detect a weak concentration of the irritant smoke.

(1) The test operator shall break both ends of a ventilation smoke tube containing stannic chloride, and attach one end of the smoke tube to a low flow air pump set to deliver 200 milliliters per minute, or an aspirator squeeze bulb. The test operator shall cover the other end of the smoke tube with a short piece of tubing to prevent potential injury from the jagged end of the smoke tube.

(2) The test operator shall advise the test subject that the smoke can be irritating to the eyes, lungs, and nasal passages and instruct the subject to keep his/her eyes closed while the test is performed.

(3) The test subject shall be allowed to smell a weak concentration of the irritant smoke before the respirator is donned to become familiar with its irritating properties and to determine if he/she can detect the irritating properties of the smoke. The test operator shall carefully direct a small amount of the irritant smoke in the test subject's direction to determine that he/she can detect it.

(c) Irritant Smoke Fit Test Procedure

(1) The person being fit tested shall don the respirator without assistance, and perform the required user seal check(s).

(2) The test subject shall be instructed to keep his/her eyes closed.

(3) The test operator shall direct the stream of irritant smoke from the smoke tube toward the faceseal area of the test subject, using the low flow pump or the squeeze bulb. The test operator shall begin at least 12 inches from the facepiece and move the smoke stream around the whole perimeter of the mask. The operator shall gradually make two more passes around the perimeter of the mask, moving to within six inches of the respirator.

(4) If the person being tested has not had an involuntary response and/or detected the irritant smoke, proceed with the test exercises.

(5) The exercises identified in section I.A. 14. of this appendix shall be performed by the test subject while the respirator seal is being continually challenged by the smoke, directed around the perimeter of the respirator at a distance of six inches.

(6) If the person being fit tested reports detecting the irritant smoke at any time, the test is failed. The person being retested must repeat the entire sensitivity check and fit test procedure.

(7) Each test subject passing the irritant smoke test without evidence of a response (involuntary cough, irritation) shall be given a second sensitivity screening check, with the smoke from the same smoke tube used during the fit test, once the respirator has been removed, to determine whether he/she still reacts to the smoke. Failure to evoke a response shall void the fit test.

(8) If a response is produced during this second sensitivity check, then the fit test is passed.

C. Quantitative Fit Test (QNFT) Protocols

The following quantitative fit testing procedures have been demonstrated to be acceptable: Quantitative fit testing using a non-hazardous test aerosol (such as corn oil, polyethylene glycol 400 [PEG 400], di-2-ethyl hexyl sebacate [DEHS], or sodium chloride) generated in a test chamber, and employing instrumentation to quantify the fit of the respirator; Quantitative fit testing using ambient aerosol as the test agent and appropriate instrumentation (condensation nuclei counter) to quantify the respirator fit; Quantitative fit testing using controlled negative pressure and appropriate instrumentation to measure the volumetric leak rate of a facepiece to quantify the respirator fit.

1. General

(a) The employer shall ensure that persons administering QNFT are able to calibrate equipment and perform tests properly, recognize invalid tests, calculate fit factors properly and ensure that test equipment is in proper working order.

(b) The employer shall ensure that QNFT equipment is kept clean, and is maintained and calibrated according to the manufacturer's instructions so as to operate at the parameters for which it was designed.

2. Generated Aerosol Quantitative Fit Testing Protocol

(a) Apparatus.

(1) Instrumentation. Aerosol generation, dilution, and measurement systems using particulates (corn oil, polyethylene glycol 400 [PEG 400], di-2-ethyl hexyl sebacate [DEHS] or sodium chloride) as test aerosols shall be used for quantitative fit testing.

(2) Test chamber. The test chamber shall be large enough to permit all test subjects to perform freely all required exercises without disturbing the test agent concentration or the measurement apparatus. The test chamber shall be equipped and constructed so that the test agent is effectively isolated from the ambient air, yet uniform in concentration throughout the chamber.

(3) When testing air-purifying respirators, the normal filter or cartridge element shall be replaced with a high efficiency particulate air (HEPA) or P100 series filter supplied by the same manufacturer.

(4) The sampling instrument shall be selected so that a computer record or strip chart record may be made of the test showing the rise and fall of the test agent concentration with each inspiration and expiration at fit factors of at least 2,000. Integrators or computers that integrate the amount of test agent penetration leakage into the respirator for each exercise may be used provided a record of the readings is made.

(5) The combination of substitute air-purifying elements, test agent and test agent concentration shall be such that the test subject is not exposed in excess of an established exposure limit for the test agent at any time during the testing process, based upon the length of the exposure and the exposure limit duration.

(6) The sampling port on the test specimen respirator shall be placed and constructed so that no leakage occurs around the port (e.g., where the respirator is probed), a free air flow is allowed into the sampling line at all times, and there is no interference with the fit or performance of the respirator. The in-mask sampling device (probe) shall be designed and used so that the air sample is drawn from the breathing zone of the test subject, midway between the nose and mouth and with the probe extending into the facepiece cavity at least ¼ inch.

(7) The test setup shall permit the person administering the test to observe the test subject inside the chamber during the test.

(8) The equipment generating the test atmosphere shall maintain the concentration of test agent constant to within a 10 percent variation for the duration of the test.

(9) The time lag (interval between an event and the recording of the event on the strip chart or computer or integrator) shall be kept to a minimum. There shall be a clear association between the occurrence of an event and its being recorded.

(10) The sampling line tubing for the test chamber atmosphere and for the respirator sampling port shall be of equal diameter and of the same material. The length of the two lines shall be equal.

(11) The exhaust flow from the test chamber shall pass through an appropriate filter (i.e., high efficiency particulate filter) before release.

(12) When sodium chloride aerosol is used, the relative humidity inside the test chamber shall not exceed 50 percent.

(13) The limitations of instrument detection shall be taken into account when determining the fit factor.

(14) Test respirators shall be maintained in proper working order and be inspected regularly for deficiencies such as cracks or missing valves and gaskets.

(b) Procedural Requirements.

(1) When performing the initial user seal check using a positive or negative pressure check, the sampling line shall be crimped closed in order to avoid air pressure leakage during either of these pressure checks.

(2) The use of an abbreviated screening QLFT test is optional. Such a test may be utilized in order to quickly identify poor fitting respirators that passed the positive and/or negative pressure test and reduce the amount of QNFT time. The use of the CNC QNFT instrument in the count mode is another optional method to obtain a quick estimate of fit and eliminate poor fitting respirators before going on to perform a full QNFT.

(3) A reasonably stable test agent concentration shall be measured in the test chamber prior to testing. For canopy or shower curtain types of test units, the determination of the test agent's stability may be established after the test subject has entered the test environment.

(4) Immediately after the subject enters the test chamber, the test agent concentration inside the respirator shall be measured to ensure that the peak penetration does not exceed 5 percent for a half mask or 1 percent for a full facepiece respirator.

(5) A stable test agent concentration shall be obtained prior to the actual start of testing.

(6) Respirator restraining straps shall not be over-tightened for testing. The straps shall be adjusted by the wearer without assistance from other persons to give a reasonably comfortable fit typical of normal use. The respirator shall not be adjusted once the fit test exercises begin.

(7) The test shall be terminated whenever any single peak penetration exceeds 5 percent for half masks and 1 percent for full facepiece respirators. The test subject shall be refitted and retested.

(8) Calculation of fit factors.

(i) The fit factor shall be determined for the quantitative fit test by taking the ratio of the average chamber concentration to the concentration measured inside the respirator for each test exercise except the grimace exercise.

(ii) The average test chamber concentration shall be calculated as the arithmetic average of the concentration measured before and after each test (i.e., 7 exercises) or the arithmetic average of the concentration measured before and after each exercise or the true average measured continuously during the respirator sample.

(iii) The concentration of the challenge agent inside the respirator shall be determined by one of the following methods:

(A) Average peak penetration method means the method of determining test agent penetration into the respirator utilizing a strip chart recorder, integrator, or computer. The agent penetration is determined by an average of the peak heights on the graph or by computer integration, for each exercise except the grimace exercise. Integrators or computers that calculate the actual test agent penetration into the respirator for each exercise will also be considered to meet the requirements of the average peak penetration method.

(B) Maximum peak penetration method means the method of determining test agent penetration in the respirator as determined by strip chart recordings of the test. The highest peak penetration for a given exercise is taken to be representative of average penetration into the respirator for that exercise.

(C) Integration by calculation of the area under the individual peak for each exercise except the grimace exercise. This includes computerized integration.

(D) The calculation of the overall fit factor using individual exercise fit factors involves first converting the exercise fit factors to penetration values, determining the average, and then converting that result back to a fit factor. This procedure is described in the following equation:

$$\text{Overall Fit Factor} = \frac{\text{Number of exercises}}{1/ff_1 + 1/ff_2 + 1/ff_3 + 1/ff_4 + 1/ff_5 + 1/ff_6 + 1/ff_7 + 1/ff_8}$$

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Where ff1, ff2, ff3, etc. are the fit factors for exercises 1, 2, 3, etc.

(9) The test subject shall not be permitted to wear a half mask or quarter facepiece respirator unless a minimum fit factor of 100 is obtained, or a full facepiece respirator unless a minimum fit factor of 500 is obtained.

(10) Filters used for quantitative fit testing shall be replaced whenever increased breathing resistance is encountered, or when the test agent has altered the integrity of the filter media.

3. Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol.

The ambient aerosol condensation nuclei counter (CNC) quantitative fit testing (PortaCount®) protocol quantitatively fit tests respirators with the use of a probe. The probed respirator is only used for quantitative fit tests. A probed respirator has a special sampling device, installed on the respirator, that allows the probe to sample the air from inside the mask. A probed respirator is required for each make, style, model, and size that the employer uses and can be obtained from the respirator manufacturer or distributor. The primary CNC instrument manufacturer, TSI Incorporated, also provides probe attachments (TSI mask sampling adapters) that permit fit testing in an employee's own respirator. A minimum fit factor pass level of at least 100 is necessary for a half-mask respirator (elastomeric or filtering facepiece), and a minimum fit factor pass level of at least 500 is required for a full-facepiece elastomeric respirator. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) PortaCount® Fit Test Requirements. (1) Check the respirator to make sure the sampling probe and line are properly attached to the facepiece and that the respirator is fitted with a particulate filter capable of preventing significant penetration by the ambient particles used for the fit test (e.g., NIOSH 42 CFR 84 series 100, series 99, or series 95 particulate filter) per manufacturer's instruction.

(2) Instruct the person to be tested to don the respirator for five minutes before the fit test starts. This purges the ambient particles trapped inside the respirator and permits the wearer to make certain the respirator is comfortable. This individual shall already have been trained on how to wear the respirator properly.

(3) Check the following conditions for the adequacy of the respirator fit: Chin properly placed; Adequate strap tension, not overly tightened; Fit across nose bridge; Respirator of proper size to span distance from nose to chin; Tendency of the respirator to slip; Self-observation in a mirror to evaluate fit and respirator position.

(4) Have the person wearing the respirator do a user seal check. If leakage is detected, determine the cause. If leakage is from a poorly fitting facepiece, try another size of the same model respirator, or another model of respirator.

(5) Follow the manufacturer's instructions for operating the PortaCount® and proceed with the test.

(6) The test subject shall be instructed to perform the exercises in section I. A. 14. of this appendix.

(7) After the test exercises, the test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become unacceptable, another model of respirator shall be tried.

(b) PortaCount® Test Instrument.

(1) The PortaCount® will automatically stop and calculate the overall fit factor for the entire set of exercises. The overall fit factor is what counts. The Pass or Fail message will indicate whether or not the test was successful. If the test was a Pass, the fit test is over.

(2) Since the pass or fail criterion of the PortaCount® is user programmable, the test operator shall ensure that the pass or fail criterion meet the requirements for minimum respirator performance in this Appendix.

(3) A record of the test needs to be kept on file, assuming the fit test was successful. The record must contain the test subject's name; overall fit factor; make, model, style, and size of respirator used; and date tested.

4. Modified ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol for full-facepiece and half-mask elastomeric respirators.

(a) When administering this protocol to test subjects, employers shall comply with the requirements specified in Part I.C.3 of this appendix (ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol), except they shall use the test exercises described below in paragraph (b) of this protocol instead of the test exercises specified in section I.C.3(a)(6) of this appendix.

(b) Employers shall ensure that each test subject being fit tested using this protocol follows the exercise and duration procedures, including the order of administration, described in Table A-1 of this appendix.

Table A-1-- Modified Ambient Aerosal CNC Quantitative Fit Testing Protocol for Full Facepiece and Half-Mask Elastomeric Respirators

Exercises[1]	Exercise procedure	Measurement procedure
Bending Over	The test subject shall bend at the waist, as if going to touch his/her toes for 50 seconds and inhale 2 times at the bottom[2].	A 20 second ambient sample, followed by a 30 second mask sample.
Jogging-in-Place	The test subject shall jog in place comfortably for 30 seconds	A 30 second mask sample.
Head Side-to-Side	The test subject shall stand in place, slowly turning his/her head from side to side for 30 seconds and inhale 2 times at each extreme[2].	A 30 second mask sample.

Head Up-and-Down	The test subject shall stand in place, slowly moving his/her head up and down for 39 seconds and inhale 2 times at each extreme[2].	A 30 second mask sample followed by a 9 second ambient sample.

[1]Exercises are listed in the order in which they are to be administered.
[2]It is optional for test subjects to take additional breaths at other times during this exercise.

5. Modified ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol for filtering facepiece respirators.

(a) When administering this protocol to test subjects, employers shall comply with the requirements specified in Part I.C.3 of this appendix (ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol), except they shall use the test exercises described below in paragraph (b) of this protocol instead of the test exercises specified in section I.C.3(a)(6) of this appendix.

(b) Employers shall ensure that each test subject being fit tested using this protocol follows the exercise and duration procedures, including the order of administration, described in Table A–2 of this appendix

TABLE A–2— MODIFIED AMBIENT AEROSAL CNC QUANTITATIVE FIT TESTING PROTOCOL FOR FILTERING FACEPIECE RESPIRATORS

Exercises[1]	Exercise procedure	Measurement procedure
Bending Over	The test subject shall bend at the waist, as if going to touch his/her toes for 50 seconds and inhale 2 times at the bottom[2].	A 20 second ambient sample, followed by a 30 second mask sample.
Talking	The test subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor for 30 seconds. He/she will either read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song.	A 30 second mask sample.
Head Side-to-Side	The test subject shall stand in place, slowly turning his/her head from side to side for 30 seconds and inhale 2 times at each extreme[2].	A 30 second mask sample.
Head Up-and-Down	The test subject shall stand in place, slowly moving his/her head up and down for 39 seconds and inhale 2 times at each extreme[2].	A 30 second mask sample followed by a 9 second ambient sample.

[1]Exercises are listed in the order in which they are to be administered.
[2]It is optional for test subjects to take additional breaths at other times during this exercise.

6. Controlled negative pressure (CNP) quantitative fit testing protocol.

The CNP protocol provides an alternative to aerosol fit test methods. The CNP fit test method technology is based on exhausting air from a temporarily sealed respirator facepiece to generate and then maintain a constant negative pressure inside the facepiece. The rate of air exhaust is controlled so that a constant negative pressure is maintained in the respirator during the fit test. The level of pressure is selected to replicate the mean inspiratory pressure that causes leakage into the respirator under normal use conditions. With pressure held constant, air flow out of the respirator is equal to air flow into the respirator. Therefore, measurement of the exhaust stream that is required to hold the pressure in the temporarily sealed respirator constant yields a direct measure of leakage air flow into the respirator. The CNP fit test method measures leak rates through the facepiece as a method for determining the facepiece fit for negative pressure respirators. The CNP instrument manufacturer Occupational Health Dynamics of Birmingham, Alabama also provides attachments (sampling manifolds) that replace the filter cartridges to permit fit testing in an employee's own respirator. To perform the test, the test subject closes his or her mouth and holds his/her breath, after which an air pump removes air from the respirator facepiece at a pre-selected constant pressure. The facepiece fit is expressed as the leak rate through the facepiece, expressed as milliliters per minute. The quality and validity of the CNP fit tests are determined by the degree to which the in-mask pressure tracks the test pressure during the system measurement time of approximately five seconds. Instantaneous feedback in the form of a real-time pressure trace of the in-mask pressure is provided and used to determine test validity and quality. A minimum fit factor pass level of 100 is necessary for a half-mask respirator and a minimum fit factor of at least 500 is required for a full facepiece respirator. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) CNP Fit Test Requirements.

(1) The instrument shall have a non-adjustable test pressure of 15.0 mm water pressure.

(2) The CNP system defaults selected for test pressure shall be set at −15 mm of water (-0.58 inches of water) and the modeled inspiratory flow rate shall be 53.8 liters per minute for performing fit tests.

Note: CNP systems have built-in capability to conduct fit testing that is specific to unique work rate, mask, and gender situations that might apply in a specific workplace. Use of system default values, which were selected to represent respirator wear with medium cartridge resistance at a low-moderate work rate, will allow inter-test comparison of the respirator fit.)

(3) The individual who conducts the CNP fit testing shall be thoroughly trained to perform the test.

(4) The respirator filter or cartridge needs to be replaced with the CNP test manifold. The inhalation valve downstream from the manifold either needs to be temporarily removed or propped open.

(5) The employer must train the test subject to hold his or her breath for at least 10 seconds.

(6) The test subject must don the test respirator without any assistance from the test administrator who is conducting the CNP fit test. The respirator must not be adjusted once the fit-test exercises begin. Any adjustment voids the test, and the test subject must repeat the fit test.

(7) The QNFT protocol shall be followed according to section I. C. 1. of this appendix with an exception for the CNP test exercises.

(b) CNP Test Exercises.

(1) Normal breathing. In a normal standing position, without talking, the subject shall breathe normally for 1 minute. After the normal breathing exercise, the subject needs to hold head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(2) Deep breathing. In a normal standing position, the subject shall breathe slowly and deeply for 1 minute, being careful not to hyperventilate. After the deep breathing exercise, the subject shall hold his or her head straight ahead and hold his or her breath for 10 seconds during test measurement.

(3) Turning head side to side. Standing in place, the subject shall slowly turn his or her head from side to side between the extreme positions on each side for 1 minute. The head shall be held at each extreme momentarily so the subject can inhale at each side. After the turning head side to side exercise, the subject needs to hold head full left and hold his or her breath for 10 seconds during test measurement. Next, the subject needs to hold head full right and hold his or her breath for 10 seconds during test measurement.

(4) Moving head up and down. Standing in place, the subject shall slowly move his or her head up and down for 1 minute. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling). After the moving head up and down exercise, the subject shall hold his or her head full up and hold his or her breath for 10 seconds during test measurement. Next, the subject shall hold his or her head full down and hold his or her breath for 10 seconds during test measurement.

(5) Talking. The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song for 1 minute. After the talking exercise, the subject shall hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(6) Grimace. The test subject shall grimace by smiling or frowning for 15 seconds.

(7) Bending Over. The test subject shall bend at the waist as if he or she were to touch his or her toes for 1 minute. Jogging in place shall be substituted for this exercise in those test environments such as shroud-type QNFT units that prohibit bending at the waist. After the bending over exercise, the subject shall hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(8) Normal Breathing. The test subject shall remove and re-don the respirator within a one-minute period. Then, in a normal standing position, without talking, the subject shall breathe normally for 1 minute. After the normal breathing exercise, the subject shall hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement. After the test exercises, the test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become unacceptable, another model of a respirator shall be tried.

(c) CNP Test Instrument.

(1) The test instrument must have an effective audio-warning device, or a visual-warning device in the form of a screen tracing, that indicates when the test subject fails to hold his or her breath during the test. The test must be terminated and restarted from the beginning when the test subject fails to hold his or her breath during the test. The test subject then may be refitted and retested.

(2) A record of the test shall be kept on file, assuming the fit test was successful. The record must contain the test subject's name; overall fit factor; make, model, style and size of respirator used; and date tested.

7. Controlled negative pressure (CNP) REDON quantitative fit testing protocol.

(a) When administering this protocol to test subjects, employers must comply with the requirements specified in paragraphs (a) and (c) of part I.C.6 of this appendix (``Controlled negative pressure (CNP) quantitative fit testing protocol,'') as well as use the test exercises described below in paragraph (b) of this protocol instead of the test exercises specified in paragraph (b) of part I.C.6 of this appendix.

(b) Employers must ensure that each test subject being fit tested using this protocol follows the exercise and measurement procedures, including the order of administration described in Table A-3 of this appendix.

Table A-3—CNP REDON Quantitative Fit Testing Protocol

Exercises[1]	Exercise procedure	Measurement procedure

Facing Forward	Stand and breathe normally, without talking, for 30 seconds	Face forward, while holding breath for 10 seconds.
Bending Over	Bend at the waist, as if going to touch his or her toes, for 30 seconds	Face parallel to the floor, while holding breath for 10 seconds
Head Shaking	For about three seconds, shake head back and forth vigorously several times while shouting	Face forward, while holding breath for 10 seconds
REDON 1	Remove the respirator mask, loosen all facepiece straps, and then redon the respirator mask	Face forward, while holding breath for 10 seconds.
REDON 2	Remove the respirator mask, loosen all facepiece straps, and then redon the respirator mask again	Face forward, while holding breath for 10 seconds.

[1]Exercises are listed in the order in which they are to be administered.

(c) After completing the test exercises, the test administrator must question each test subject regarding the comfort of the respirator. When a test subject states that the respirator is unacceptable, the employer must ensure that the test administrator repeats the protocol using another respirator model.

(d) Employers must determine the overall fit factor for each test subject by calculating the harmonic mean of the fit testing exercises as follows:

$$\text{Overall Fit Factor} = \frac{N}{\left[1/FF_1 + 1/FF_2 + \ldots\ 1/FF_N\right]}$$

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Where:

N = The number of exercises;

FF1 = The fit factor for the first exercise;

FF2 = The fit factor for the second exercise; and

FFN = The fit factor for the nth exercise.

Part II. New Fit Test Protocols

A. Any person may submit to OSHA an application for approval of a new fit test protocol. If the application meets the following criteria, OSHA will initiate a rulemaking proceeding under section 6(b)(7) of the OSH Act to determine whether to list the new protocol as an approved protocol in this appendix A.

B. The application must include a detailed description of the proposed new fit test protocol. This application must be supported by either:

1. A test report prepared by an independent government research laboratory (e.g., Lawrence Livermore National Laboratory, Los Alamos National Laboratory, the National Institute for Standards and Technology) stating that the laboratory has tested the protocol and had found it to be accurate and reliable; or

2. An article that has been published in a peer-reviewed industrial hygiene journal describing the protocol and explaining how test data support the protocol's accuracy and reliability.

C. If OSHA determines that additional information is required before the Agency commences a rulemaking proceeding under this section, OSHA will so notify the applicant and afford the applicant the opportunity to submit the supplemental information. Initiation of a rulemaking proceeding will be deferred until OSHA has received and evaluated the supplemental information.

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TITLE

A novel 3D printable powered air purifying respirator for emergency use during PPE shortage of the COVID-19 pandemic: a study protocol and device safety analysis.

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ABSTRACT

Objectives: To design a low-cost 3D printable Powered Air-Purifying Respirator (PAPR) that meets National Institute for Occupational Safety and Health (NIOSH) standard for flow rate and Occupational Safety and Health Administration (OSHA) standard for particle filtration for loose-fitting PAPRs and that can be made with a 3D printer and widely available materials.

Design: Detailed description of components, assembly instructions, and testing of a novel PAPR design in an academic laboratory following respective protocols. The assembled PAPR must meet NIOSH standards of flow rate, 170 L/min, OSHA fit factor for particle filtration, ≥250, and maintain positive pressure during regular and deep breathing.

Main Outcome Measures: The PAPR design was run through a series of tests: air flow (L/min), particle filtration (quantitative and qualitative), and positive pressure measured inside the helmet (mm Hg).

Results: Flow rate was 443.32 L/min (NIOSH standard: minimum 170 L/min) and overall fit factor for particle filtration was 1362 (OSHA pass level: ≥500), n=1. The device passed qualitative particle filtration, n=2, and measured peak pressure of 6mm Hg (>0 mm Hg indicates positive pressure) in the helmet, n=1.

Conclusions: The Hygieia PAPR is a low-cost, easily accessible, just–in–time 3D printable PAPR design that meet minimum NIOSH and OSHA standards for flow-rate and particle filtration for loose-fitting PAPR devices to be made and used when industry-made designs are unavailable.

Strengths and limitations of this study

- This study details a low-cost novel 3D printable PAPR that meets NIOSH and OSHA minimum standards for flow-rate and particle filtration respectively for loose-fitting PAPR devices that can be made by anyone with access to the internet, a 3D printer, and a general merchandise store.
- This design can be used to protect health care workers around the world while they perform essential procedures when the supply of industry-made designs is low. Though this design was tested in an uncertified academic laboratory, not all NIOSH and OSHA standards were tested necessary for official certification, and it was not tested on end-users for clinical feedback.
- Current published alternate novel PAPR designs are very valuable but either contain expensive proprietary components or impede important sensory faculties (visual field, hearing ability) [31, 32].
- Downside of over 30 hours of print time is should be weighed against by the simplicity and cost benefits of this design
- Persons must have access to a 3D printer and a general merchandise store or online ordering and delivery which is not always available in rural, resource-limited settings

INTRODUCTION

As of June, 2021, the COVID-19 pandemic has caused approximately 3.84 million reported deaths worldwide.[1] Fortunately, the vaccination effort that began in December, 2020, has resulted in the decline of incidence and deaths from COVID-19 since early 2021.[2] Current evidence suggests the COVID-19 virus transmits via respiratory droplets between people in close proximity indoors, thus putting heath care workers at high risk.[3,4] Personal protective equipment (PPE) is one of the most important means by which healthcare workers are protected. However, at the start of the pandemic, hospitals across the globe experienced shortages of key equipment needed to safely care for these patients.[5,6] For months, hospitals and ambulatory facilities across the globe struggled with inadequate supply. [6-8]

In addition to PPE supply not meeting the high demand, the cost of PPE increased as hospitals were required to have more of it on hand.[9] In March 2020, the WHO called on industry and governments around the world to increase manufacturing as the supply of PPE was dangerously low.[10] Though industry manufacturing efforts escalated, the global 3D printing community began to produce PPE to help those combating COVID-19 before industry-made designs could become available.[11,12] One type of PPE that has become increasingly important is the Powered Air-Purifying Respirator (PAPR). A PAPR pulls or pushes air through a high-efficiency particulate arrestance (HEPA) filter (99.97% efficacy at 0.3μ particle size) and directs the air into an enclosed space to create a positive pressure environment for persons wearing the device. The device provides both a filtered air environment as well as a physical barrier against droplets and particulates.[13]

In the early months of the pandemic, healthcare facilities around the globe struggled to provide workers with adequate PPE. However, hospitals in low-resource countries were at an even greater disadvantage as they share the same supply chain as wealthier countries with less bargaining power.[6] Given the shortage, barriers to access, and expense of PPE, the authors were inspired to design an emergency use 3D printable PAPR that can be made with widely available materials and a 3D printer for one tenth of the cost of an industry-made design meeting the National Institute for Occupational Safety and Health (NIOSH) standard for flow rate and Occupational Safety and Health Administration (OSHA) standard for particle filtration for loose-fitting PAPR devices.

METHODS

Components

The 3D printed parts were created on an Ender 5 Plus using a 0.4 mm nozzle and using the default "standard quality" slicer settings from Cura with the following parameters: Layer height: 0.2mm, Line width: 0.4 mm, Wall thickness: 0.8 mm, Wall line count: 2, Top/Bottom layers: 4, Infill: 20%, Infill pattern: Zig Zag. Filament was polylactic acid (PLA), no rafts or supports were used. Four pieces were printed (print times hr:min, weight and length of plastic required, cost): Head Piece (7:29, 108g, 37.98m, $2.10), Jaw Piece (3:44, 49g, 17.17m, $0.95), Filter Side of Power Box (7:10, 126g, 44.39m, $2.46) and Battery Side of Power Box (13:18, 220g, 77.38m, $4.29). Files can be found at: https://www.thingiverse.com/thing:4292619

The filter used is a 3M high efficiency particulate air (HEPA) filter (3M, Saint Paul, Minnesota, USA) intended for air filtration and rated and certified to filter 99.97% of all airborne particles,

including dust, allergens, bacteria, viruses, and more. The filter life is approximately 6 months based on 12 hours of use per day.[14]

The authors choose to use two 12V Milwaukee batteries (Milwaukee Tool, Brookfield, Wisconsin, USA), used for power tools, because these tools are often a common household item or can easily be purchased if not on hand. Battery charge time is 40 min at 3 A. The hose chosen is one of the more easily accessible hoses available in a hospital and can be found in a manual resuscitator kit (Ambu Inc., Columbia Maryland, USA). One-inch corrugated tubing is also widely available online or at general merchandise stores. The fan is a centrifugal DC blower, 12V, 1A, with a maximum airflow of 16 cubic feet per minute (COM-11270, SparkFun Electronics, Niwot, Colorado, USA). A centrifugal blower was chosen primarily for the energy efficiency, increased air speed, and increased rate of airflow as compared to an axial fan.

Additional components needed are 4, 22–16–gauge male spade connectors, and a DC motor PWM speed controller (3V 6V 12V 24V 35V DC 5A 90W). Other hardware needed: Two plastic shower caps, one 7mil PVC clear binding cover plastic sheet (CSF Binding Supplies, Norton Shores, Michigan, USA), utility belt (Husky, Bolton, Caledon, Canada) , thermal glue gun (Elmer's Products Inc, Atlanta, Georgia, USA), cyanoacrylate (CA) glue (Loctite, Düsseldorf, Germany), 3/32 inch abrasion-resistant elastics cord (McMaster-Carr, Elmhurst, Illinois, USA), and ¾ inch x 7/16 inch rubber foam weatherstrip tape (Thermwell Products Co. Inc., South Mahwah, New Jersey, USA).

All components, including the HEPA filter, are widely available online, at home improvements stores, or general merchandise store. A supply shortage of any one component is possible; however, it is unlikely.

Patient and public involvement
No patients involved

Instructions Table 1 and Table 2 (See Fig 1 and Fig 2 for schematic and overview)

Table 1: **Helmet**
1) Trim the 7mil clear binding cover sheet to fit Jaw Piece. Place the cover sheet into the slit in the Headpiece.
2) Align and fit Head Piece + cover sheet together with the Jaw Piece. Cover sheet will fit into slit in Jaw Piece. Use CA glue to secure. (Fig 3a & 3b)
3) Cut shower cap down the center about halfway; hot glue the two sides where the upper jaw piece meets the head piece. Carefully continue to separate cap down center so that the sides can be hot glued down the jaw piece (Fig 3 c-f).
4) Measure and cut 8 inches of foam weatherstrip tape and place adhesive side against the inner portion of Helmet where the forehead will be. Cover top with second shower cap (Fig 4a, helmet on right). Cut 8 inches of elastic and tie to boat-cleat protrusions of Head Piece (Fig 4b arrow). See Fig 4c for 4 views of completed helmet design.

Table 2: **Power Box**	
Battery side – 1) Align 12V blower fan with indices, use hot glue gun to apply ring of glue around air–inlet to seal.	Filter Side – 6) Align HEPA filter and press in.
2) Connect 4 spade connectors to 4 wires, 2 longer to travel the length of the box (see Fig 5 for wiring diagram).	7) Align clam shell pieces and press together.
3) Thread wires though slots in battery holder pieces and use hot glue to seal wires and connectors at the bottom.	8) Fit utility belt through slots.
4) Complete battery, fan, and controller circuit as depicted in the wiring diagram (Fig 5); place speed controller in slot above fan.	9) Connect hose to head piece and power box.
5) Plug 12V batteries into holders.	

Configuration and Mechanism

The blower fan is used to create a positive pressure in the chamber prior to the filter. Air is thus forced through the filter onto the downstream conduit, which is at all times at a greater pressure than ambient. This positive pressure gradient ensures that no unfiltered air enters the system despite imperfect seals to the outside. Fig 6 demonstrates the flow of air from the blower, through the filter, and out the outlet of the Power Box through the hose. The seal between the HEPA filter and the Filter Side of the Power Box is the most important seal of the design and ensures that no unfiltered air goes through the helmet to the wearer. To ensure a tight seal, the built-in adhesive rubber-seal around the HEPA filter is pressed into the lip of the Filter Side (Fig 6.2.A) by the prongs on the Battery Side (Fig 6.1.a), maintaining constant pressure, thus ensuring a secure seal around the filter.

The connections between the hose and the Power Box and the Helmet are all interference fit. The outside diameter of the 3D printed parts was intentionally enlarged such that it creates an interference with the inner diameter of the hose. Additionally, a ridge was added to the 3D printed connection on the Helmet and Filter Side to match the corrugations of the hose, thus increasing seal integrity and preventing accidental disconnection (Fig 6.2.B). We acknowledge that there are imperfect seals throughout the device. However, so long as positive pressure is maintained in the helmet, the air leaking through the seals may decrease efficiency but does not compromise the filtered air.

TESTING/RESULTS

Air flow rate was calculated by measuring air speed and multiplying it by the cross-sectional area at the measurement site. Air speed was determined using a HoldPeak HP-866B-APP anemometer (Zhuhai JiDa Huapu Instrument Co, Ltd., Zhuhai, China) with an accuracy of ±5%. 3D printed adapters were used to place the anemometer in series between the hose and helmet. The helmet was donned and the power was turned on full. The cross–sectional area of the

anemometer was measured at 0.0026 m^2 and air speed measured at 2.2 m/s, equaling a flow rate of 0.0074 m^3/s, or 443.32 L/min, well above the NIOSH minimum requirement of 170 L/min for loose–fitting PAPRs.[15] Airflow measurements were taken while the device was being worn and the units were in operation. The current prototype has demonstrated an approximate run time of 45min.

Particle testing followed the OSHA 29CFR1910.134, Appendix A. C. 3. Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol.[16] A port was placed at the base of the jaw piece by drilling a 4mm hole and placing a Portacount test probe 8025-N95R (TSI, Inc., Shoreview, MN, USA). CA glue was used to seal the probe against the plastic. The "mask" intake was connected to the port, while the "ambient" intake was 4 cm below. The particle counter used was the Portacount Pro+ Model 8038 (TSI, Inc., Shoreview, MN, USA). The non-hazardous test aerosol was created using an ultrasonic humidifier with tap water to generate particles.

The subject (n=1) donned the helmet with the installed particle counter and particle count was measured with the PAPR powered on while the subject performed different exercises each for one minute. Fit Factor (particle concentration outside the respirator divided by the particle concentration inside the respirator) was calculated for each of the following exercises (passing level is ≥500)[16]: normal and deep breathing (1433 and 1035, respectively), head side to side and up and down (1119 and 1384, respectively), talking (2515), and bending over (1663). Grimacing was omitted due to facial expression being irrelevant in a loose-fitting PAPR.

Qualitative fit test was assessed using the 3M Ft-30 N95 Respirator protocol and 3M bitter formula testing kits (3M, St. Paul, MN, USA).[17] The bitter formula was nebulized in the hood with the PAPR powered on for the full series of movements (see above for movements done during particle testing). The test was then repeated with the bitter formula nebulized immediately adjacent to the blower intake with the full series of movements. The subjects (n=2) were determined to be sensitive to the bitter formula, but the bitter formula was not tasted at any point during either test by either participant. Qualitative testing was done to mimic the testing done during N95 fit testing. This testing is quick and easy to perform and is widely available in healthcare facilities or can be purchased online for minimal cost. A particle counter is expensive and less available in non-university health care settings.

Positive pressure was measured by drilling a 6/32-inch port in the jaw piece of the helmet where an arterial line pressure sensor (TruWave Disposable Sensor, Edwards Lifesciences Corp., Irvine, CA, USA) was placed and thermal glued for a secure seal. The pressure transducer measured a peak pressure of 6mm Hg ±1mm Hg indicating positive pressure in the helmet with both regular and deep breathing. Other exercises were not performed as change in elevation of the helmet would affect the pressure reading by changing the water column of the arterial line. This test demonstrates that positive pressure is maintained throughout the system, indicating that contaminated ambient air cannot leak into the system despite potential imperfect seals. Note, all qualitative and quantitative tests were done on the same prototype with the pressure test being performed last as the sensors altered the integrity of the jaw piece.

PAPR devices are often tested for their ability to filter silica dust, usually for mining or other dusty work environments. Our PAPR device is intended for the health care setting and this test was deemed unnecessary.

To make the PAPR more environmentally-friendly, the authors designed an optional shell that can be printed and glued to the top of the helmet (Fig 4a helmet on left, Fig 4b 4 views of completed helmet with optional shell). The shell is split into front and rear pieces (hr:min, weight and length of plastic required, cost): Front (4:11, 69g, 24.6m, $1.34), Rear (2:41, 42g, 14.88m, $0.82). This option allows the top to be wiped down as opposed to disposing of the top shower cap. (Testing data was collected on the original model with a second shower cap top instead of this shell. However, the optional shell does not induce any changes to the functional aspect of the jaw and headpiece and thus would cause no changes in the functional aspect of the overall respirator.)

DISCUSSION

Principal findings

The Hygieia PAPR is a novel 3D printable PAPR design that meets minimum standards for NIOSH and OSHA flow-rate and particle filtration, respectively, for loose-fitting PAPR devices. Additionally, the PAPR demonstrated positive pressure inside the helmet during normal and deep breathing.

Strengths and weakness

Compared to N95 respirators, PAPRs have a higher protective factor, provide more comfort to the wearer for prolonged periods of time, remove concerns of poor N95 fit and seal, and may decrease the effort needed to maintain the work of breathing.[18-20] PAPRs may be especially useful protection in aerosolizing procedures like dynamic resuscitation and nearly eliminate fogging of eye wear, shields, and hoods.[4,18,19,21] Additionally, N95 respirators have been shown to alter cerebral blood flow and cause headaches which can be alleviated by the addition of a PAPR.[22]

Though the individual cost of an N95 mask is small ($1.50), the true cost lies in fit testing.[21] If an N95 respirator does not fit, or an improper size is used, a seal cannot be achieved and the mask will not provide full protection.[23] Additionally, depending on the respirator model and accuracy of fit testing, 1-20% of wearers will have an inappropriate respirator assigned to them, putting them at risk to potential exposures. [24] A loose-fitting PAPR does not require fit testing and is able to be worn with facial hair.[19-21] However, an industry-designed PAPR can cost from $900 to over $1,200 US dollars with the addition of the battery and charger.[21] In comparison, the PAPR design detailed in this paper is one tenth of the cost, approximately $120 for the materials.

One of the most signficant advantages of this PAPR design is the ability to use components from different manufacturers than those detailed in the Methods so long as it has the same specifications. As an example, the batteries must be 12V drill batteries, but the company and manufacturer do not affect the function of the design (the battery, or series of batteries, used should be rated so that they provide enough discharge current to drive the blower).

The nature of 3D printing allows for rapid, easily executable changes. An example would be the ability to change the battery cartridges to fit a different brand of drill battery. If working on a printer with a bed smaller than that of the Ender 5 Plus, the helmet can be split up into parts and glued together. Though print times may be a concern, if orchestrated properly, a PAPR can be made in less than 33 hours of total printing time and can be cleaned, reused, and shared (so long as proper cleaning is performed between each use). The drawback of a prolonged total print time is potentially outweighed by the simplicity and cost benefits of this design.

The helmet length and width were designed to be large enough to accommodate the majority of head dimensions. However, if the current design does not fit a given user several adjustments can be made. The foam in the front of the helmet is primary for comfort, any other padding material can be used to increase or decrease the helmet diameter, so long as the padding material does not cover the vents in the helmet. Similarly, the elastic used can be exchanged for another type of elastic, string, or tie, that will help secure the helmet to the wearers head. Lastly, if the current dimensions of the helmet or Jaw Piece still do not fit the wearer comfortably, they can be altered in the .stl file before being printed. The shower cap attached to the Jaw Piece can be adjusted for comfort by gluing additional shower cap elastic to the Jaw Piece on each side where it meets the Head Piece. These adjustments are for comfort and will not alter the flow-rate, particle filtration, or positive-pressure of this loose-fitting PAPR design.

The fan has been intentionally placed before the filter to ensure positive pressure throughout the system. A fan placed after the filter would create a negative pressure and the potential for unfiltered air seeping into the system. Additionally, potential particulates generated by the fan itself are forced to go through the filter, thus preventing them from reaching the user. Commercial units often place the fan after the filter. However, these novel methods of user-dependent manufacturing lack the stringent sourcing controls otherwise used in traditional medical equipment manufacturing and thus we believe it is better to ensure the user's safety. Concerns about difficulty cleaning the fan input impeller are mitigated by the air being filtered after the fan.

The 12V batteries are wired in series resulting in a higher voltage with a lower current system to drive adequate airflow. It also allows for a more robust system given the flexible nature of the hose connecting the Power Box to the Head Piece and the critically important maintenance of high flow rate. The authors acknowledged using a 12V fan is non ideal and would recommend using a 24V fan instead. 24V blower fans are can be found at similar cost and can likely be used with similar results.

Cleaning the PAPR can be easily achieved by using a bleach wipe. A recent study by Welch et al demonstrated that SARS-CoV-2 and two other surrogate coronaviruses (MHV and 229E) on 3D printed material were completely inactivated by a single application of 10% bleach, ammonium quaternary, 3% H2O2, or exposure to 70°C dry heat.[25] Other sources have shown sterilization by low-temperature hydrogen peroxide gas plasma, though this may not be a viable option for many settings.[26] Some elements of the PAPR may not be sufficiently cleaned with a wipe, like the utility belt made with poly web material. For thorough cleaning, the belt should be removed from the Power Box and submerged in a basin filled with either ethanol or isopropyl alcohol.[27]

Additionally, alternate belt materials that are easier to clean can be used to strap the Power Box to the wearer.

The authors were inspired to design the Hygieia PAPR as an option for emergency-use PPE when industry-made designs are unavailable. PPE is a key component of controlling infection spread in both healthcare settings and the community, but a survey of hospitals in low-resource countries for the past 5 years confirms low quantities of available PPE; this supply shortage was made critical by the pandemic.[6,28] In March, hospitals in Kathmandu, Nepal, commissioned the National Innovation Center to innovate and create PPE, allowing them to circumvent the global PPE supply chain.[29] It is these types of organizations around the world with whom we wish to connect, correspond, and collaborate to create the most effective tools for the greatest number of people.

Limitations

Our testing was done in the academic laboratory at Tulane University which, though accurate, is not a formal, nationally certified testing center. Though we meet the minimum standards for flow rate (NIOSH) and particle filtration (OSHA), we did not perform all the tests that would qualify us for formal NIOSH and OSHA PAPR certification. Several tests performed during this certification process are to test the integrity of the filter (NIOSH-42 CFR, Part 84)[15]. We used a 3M HEPA filter previously certified to meet these standards and emphasized a tight seal between the filter and Power Box to ensure adequate filtration.[30]

Certified PAPRs undergo many more tests than were performed on the design detailed in this paper (housing sealing testing, oil aerosol testing, communicating performance testing, and control systems alarms for flow rate testing). However, due to lack of access to appropriate equipment, we did not perform these tests on the PAPR design. We narrowed our focus to flow rate and particle filtration, as they are the most relevant variables in an emergency situation. We used the OSHA 29CFR1910.134, Appendix A. C. 3 protocol for particle filtration. The non-hazardous test aerosol used was created with an ultrasonic humidifier and tap water. According to the protocol, the preferred aerosols used are corn oil, polyethylene glycol 400 [PEG 400], di-2-ethyl hexyl sebacate [DEHS], or sodium chloride.[16] In order to obtain NIOSH certification, the manufacturer needs to be certified for minimum quality control standards. This PAPR does not have official NIOSH or OSHA certification and should only be used in emergency situations, and users should proceed with caution when considering use in healthcare settings. The Hygieia PAPR was not tested on end-users for clinical feedback and was not, to the authors knowledge, used in clinical or high-level PEE situations.

In relation to other studies

Some PAPR designs have already been published using 3D printable adapters and parts.[13,31,32] Erickson et al. observed that Stryker Flyte helmet worn during orthopeadic surgery is, in-essence, a PAPR without the filtration. The authors 3D printed an adapter to connect HEPA filters to the air-intake system; thus, creating a PAPR with minimal addition to a preexisting system.[13] This is an innovative way of using available resources. However, not all hospitals are equipped to perform orthopeadic surgery and do not have the Stryker Flyte helmets on hand. Additionally, the hood for the helmet covers the ears which can decrease the hearing ability of

the wearer, potentially detrimental to communication between healthcare workers in emergent situations.

Hubbard et al., modified a Scott Safety self-contained breathing apparatus (SCBA) into a PAPR, primarily for fire fights and other first responders to use during the PPE shortage. A SCBA uses compressed air fed to an air-tight mask via a pressure regulator, providing clean air to the wearing, but impractical and cost prohibitive for long term use. The authors modified the SCBA mask with a HEPA filter at the air intake attached to a powered fan in a 3D printed casing, creating a PAPR.[32] Similar to the design by Erickson et al., this PAPR is a cost-effective solution if the SCBA mask is readily available. Additionally, the design of the SCBA mask might impede full visual field necessary for medical procedures.

Nazarious et al., designed a mini wearable cleanroom and biosafety system or, a Pressure Optimized PowEred Respirator (PROPER). The blower fan and power system is similar to that of the Hygieia Power Box with the addition of a safety-fuse and a Lithium ion rechargeable powerbank as the power source. The main difference lies in the hood comprised of a face shield frame, the hood adapter and flange, the helmet fitting (adjustable head straps), and SMS head fabric. The SMS material used for the hood and clean room garment set is single use.[31] This is an inexpensive helmet-based respirator system that can be made with widely available components. However, it costs approximately $250 USD per device, compared to $120 for the Hygieia PAPR, and has more, small components that add to the complexity of the device.

These innovations are valuable additions to the literature in a time of worldwide PPE shortages and are tailored to specific settings and environments. However, the incorporation of more expensive or difficult to obtain components, using designs with many components, or working within the limitations of the visibility and aural requirements of certain health care settings, may make these designs less optimal for the more resource limited health care settings.

The Hygieia PAPR is inexpensive, requires no proprietary parts, and has a minimal number of components. The design of the helmet allows for nearly full visual field and provides full coverage of the rest of the face and critical orifices. Some PAPR designs use a hood to increase coverage (ears, hair, and shoulders), but can make communication challenging particularly in critical moments of care.[21] This PAPR is a valuable addition to the literature and pool of options for emergency PPE.

Unanswered questions and future research

Aspects that warrant further investigation are elements of efficiency and optimization. The imperfect seals do not optimize the power and positive pressure generated. Qualitative and quantitative testing will need to be redone with a 24V fan. The current batteries are widely available but are heavy, bulky, and do not have an extensive run time and alternatives should be considered. Future research should also test a larger diameter hose to see if greater flow rate can be achieved with less power. Future research will include more testing on certified equipment for more accurate and formal measurements. Another question that should be addressed in future research is how to ensure consistent quality prints with different users around the world.

Meaning of the design and possible implementation

The COVID-19 pandemic has taxed the health care system and PPE to dangerous levels. If industry is unable to produce the necessary equipment for this, or any other respiratory virus in the future, in a timely fashion, and world PPE supplies are directed towards the highest bidder, we need a better solution that will protect health care workers around the world while they perform essential procedures. The Hygieia PAPR should be added to the proposed solutions as an easily reproducible, cost-effective, and reusable piece of PPE that can be used on its own or to increase the life span and comfort of other essential equipment (i.e. N95 masks).

STAEMENTS

Disclaimer: The designs and other information ("the Design") made available in this article is at an early stage of development. Accordingly, specific results are not guaranteed, and the Design provided here is provided ''AS IS" and without any express or implied warranties, representations or undertakings. As examples, but without limiting the foregoing, Tulane University and their employees and students do not give any warranty or guarantee that the Design is of merchantable or satisfactory quality, is fit for any particular purpose, complies with any sample or description including the requirements for medical device registration, or are viable, uncontaminated, safe or non-toxic, accurate, up to date or complete. Tulane University and the authors have not performed any searches or investigations into the existence of any third-party rights that may affect the Design. Anyone may use the Design entirely at their own risk, and Tulane University and/or the authors are not liable for such use of the Design, including without limitation any direct or indirect losses. Any users of the design should appropriately attribute the author.

Human and Animal Rights: This work involved testing of the equipment on a human subject to validate the qualitative and quantitative testing. The tests were voluntarily performed on the authors and an informed consent was obtained for experimentation. We ensure that the work described has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans; Uniform Requirements for manuscripts submitted to Biomedical journals.

Ethics Approval Statement

This study did not require ethical approval as the only human subjects involved in the study were the authors, minimal to no risk was present, and informed consent was acquired from the authors at the time of original data collection.

Author's Contributions: Jorge Nagel and Catherine Gilbert had the idea for the article and completed the PAPR design and testing, data collection, analysis, literature search, and interpretation and writing. Both Mr. Nagel and Ms. Gilbert contributed equally to this project and manuscript and are both guarantors of the overall content. Dr. Juan Duchesne contributed to the organization of the paper, guided testing procedures and protocols, was instrumental in data analysis and interpretation, and writing of the paper.

Competing interest: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no support from any organisation for the

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Data sharing: We will provide any data collected upon request.

Transparency declaration: The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Patients or the public WERE NOT involved in the design, or conduct, or reporting, or dissemination plans of our research

Figure Captions

Figure 1 Schematic diagram of labeled components. **A)** 3D printed Head and Jaw Pieces **B)** 7 mil PVC sheet **C)** Shower cap **D)** Ventilation Tubing/corrugated hose **E)** Work belt **F)** 3D printed Power Box **G)** 3M HEPA air filter **H)** 12V blower fan **I)** 12V Milwaukee rechargeable battery **J)** DC motor speed controller.

Figure 2 Assembled PAPR with open power box. **A)** 3D printed Head and Jaw Pieces **B)** 7 mil PVC sheet **C)** Shower cap **D)** Ventilation Tubing/corrugated hose **F)** 3D printed Power Box **G)** 3M HEPA air filter **H)** 12V blower fan **I)** 12V Milwaukee rechargeable battery **J)** DC motor speed controller. (Work belt, **E** in Fig 1, is not pictured)

Figure 3 Assembly of jaw piece and application of shower cap. a) Apply CA glue to Jaw Piece joint b) align Jaw Piece and Head Piece with 7 mil cover sheet and join. c) Once shower cap is cut down the center about halfway; hot glue the two sides where the upper jaw piece meets the head piece. d-f) Carefully continue to separate cap down center so that the sides can be hot glued down the side and to the center of the Jaw Piece.

Figure 4 a) Side- by-side comparison of assembled 3D printed helmet with optional top shell (left) or shower cap (right). b) 4 views of assembled helmet with shell. Arrow pointing to boat-cleat attachment-point for elastic. c) 4 views of assembled helmet with shower cap

Figure 5 Wiring diagram for DC controller, batteries, and blower.

Figure 6 Shows the Hygiea Power Box dissembled to visualize specific components and direction of air-flow (as indicated by the blue arrows). The prongs on the Battery Side (1.a) press the HEPA filter into the lip of the Filter Side (2.A). A ridge on the hose connection increases seal integrity and prevents accidental disconnection (2.B).

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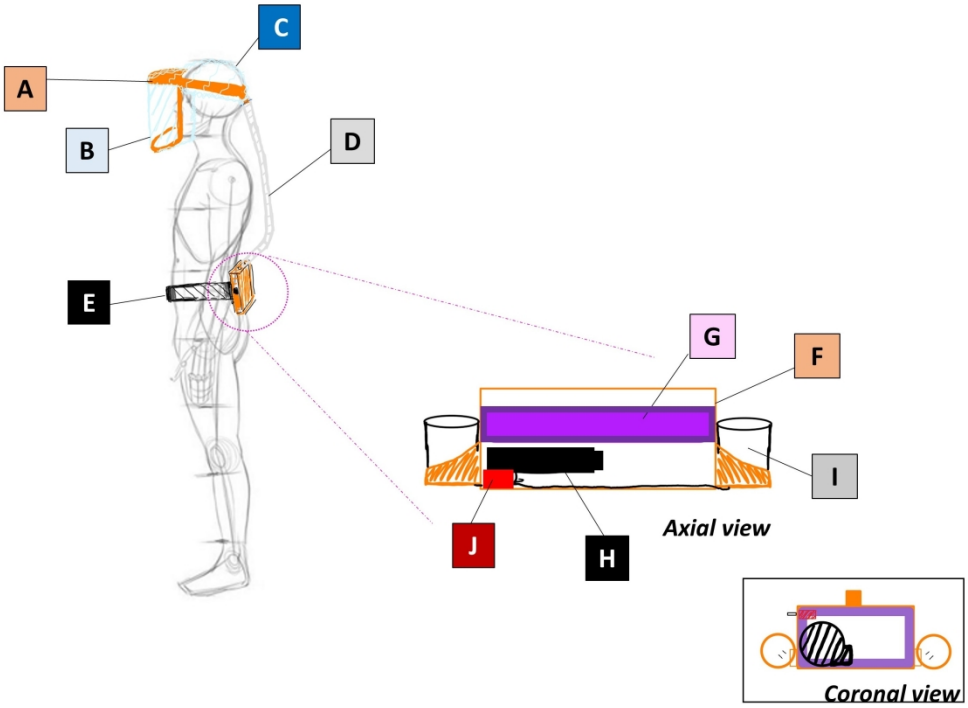

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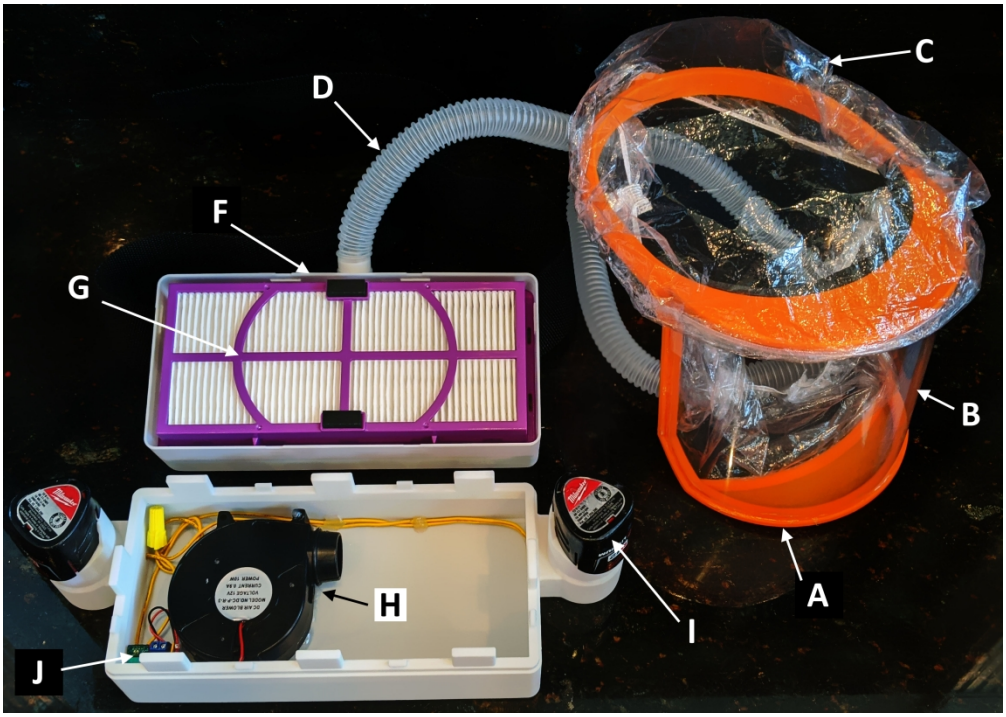
251x189mm (300 x 300 DPI)



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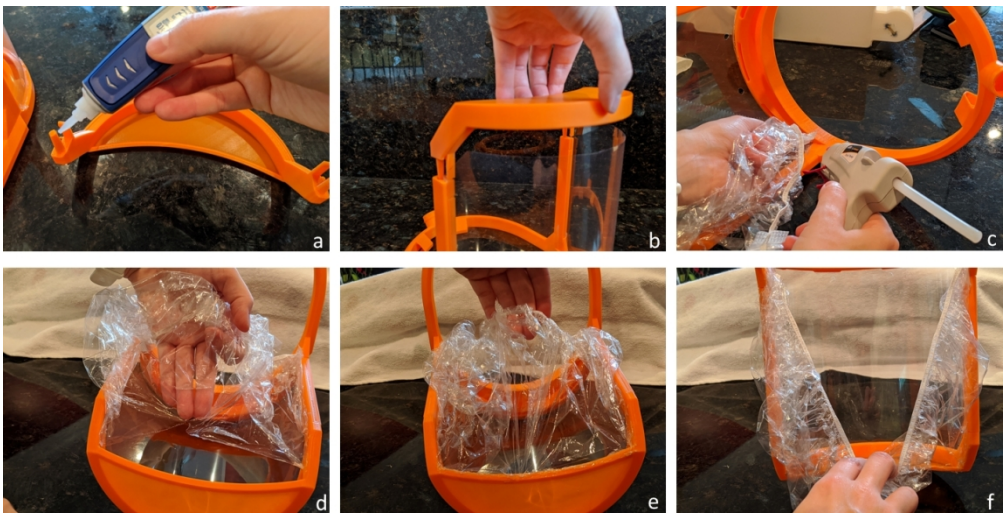

Figure 3 Assembly of jaw piece and application of shower cap. a) Apply CA glue to Jaw Piece joint b) align Jaw Piece and Head Piece with 7 mil cover sheet and join. c) Once shower cap is cut down the center about halfway; hot glue the two sides where the upper jaw piece meets the head piece. d-f) Carefully continue to separate cap down center so that the sides can be hot glued down the side and to the center of the Jaw Piece.

120x60mm (300 x 300 DPI)

Figure 4 a) Side- by-side comparison of assembled 3D printed helmet with optional top shell (left) or shower cap (right). b) 4 views of assembled helmet with shell. Arrow pointing to boat-cleat attachment-point for elastic. c) 4 views of assembled helmet with shower cap

609x250mm (300 x 300 DPI)

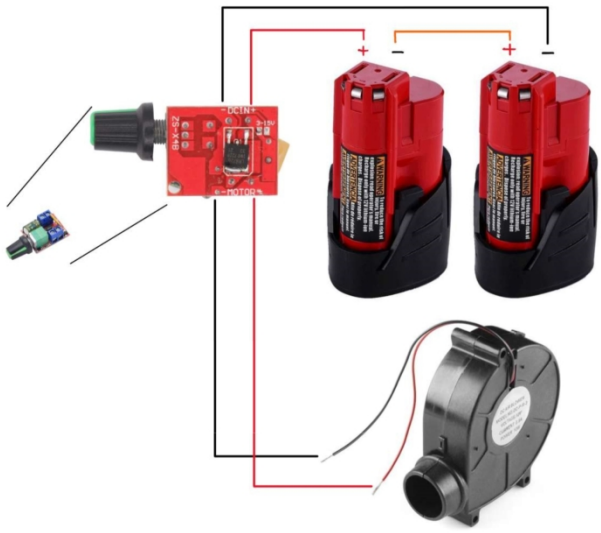

Figure 5 Wiring diagram for DC controller, batteries, and blower.

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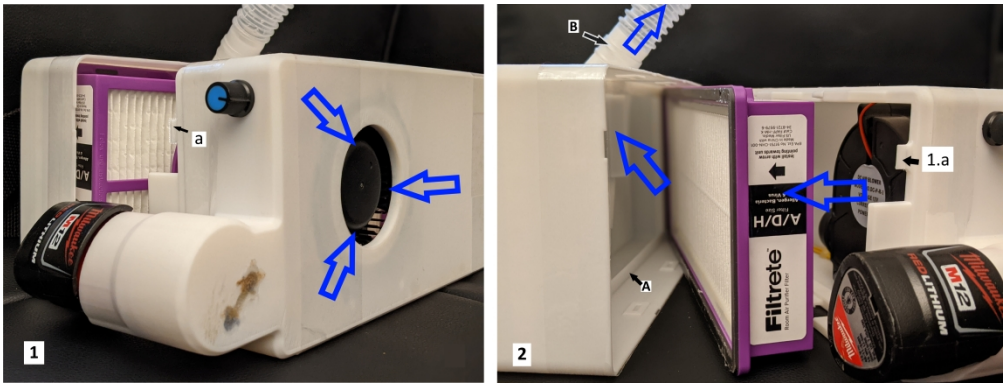

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674x256mm (300 x 300 DPI)