PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	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.
AUTHORS	Nagel, Jorge; Gilbert, Catherine; Duchesne, Juan

VERSION 1 – REVIEW

REVIEWER	Plana, Deborah Harvard Medical School
REVIEW RETURNED	05-Mar-2021

GENERAL COMMENTS	The manuscript outlines the production of a low-cost PAPR using 3D-printing and commercially available resources. The design described by the authors can be quickly implemented in low-resource settings and could help increase local resilience to the current and future healthcare emergencies. However, a main concern in that the authors do not clearly state the limitations in their device testing procedures, and the associated safety concerns with using such a product in a healthcare setting. These and other major and minor points of improvement are described below. Major comments: -The introduction states that the design outlined in the paper meets “National Institute for Occupational Safety and Health (NIOSH) and Occupational Safety and Health Administration (OSHA) standards for loose-fitting PAPR devices." Four key caveats to these results should be described: 1) Filtration and flow rate are only two components of a long-list of technical device requirements required for formal device approval. The device described here was not tested for all the necessary NIOSH and OSHA specifications, including but not limited to housing sealing testing, oil aerosol testing, communicating performance testing, and control system alarms for low flow rates testing (https://www.cdc.gov/niosh/npptl/stps/aprespInterim.html; https://www.cdc.gov/niosh/npptl/stps/apresp.html). The authors should more explicitly state that they only tested a couple of dimensions for this low-cost design and that users should proceed with extreme caution when considering use in an emergency healthcare setting. They should also make clear that their design is not suitable for use in non-emergent conditions.

	2) The authors do not make clear that their testing was performed outside of nationally certified laboratories. While their testing in an academic setting can provide an approximation of product performance, it should not be equated with formal testing. 3) The authors should describe that their product does not meet the manufacturing and quality-control criteria needed for formal approval. 4) The authors should describe how the dimensions of the head piece and jaw piece were determined, if they are adjustable, and how they are expected to be compatible with different face/head shapes and sizes, ideally providing users with ways to identify incompatible fits that may compromise intended function. -In the Methods section, please provide more specific part and manufacturer information, including manufacturer city, for all products listed (i.e.: batteries, hose, blower, and utility belt). - On page 2, under Strengths and Limitations of this study, reference needed for the claim that alternate PAPR designs impede sight and hearing. - It is very unclear how the setup works. Is the inlet of the blower exposed to the ambient air? And does the blower pump the unfiltered air through the filter? Consider modifying Fig 1 and/or showing more pictures on Fig 2 to clarify this. - It's mentioned that two batteries, each 12V was used. According to Fig 4, these are connected in series, so the total voltage would be 24V. But the blower runs at 12V. The voltage of the battery and blower should be close to one another. - It is not clear how the hose connects to the helmet and power box and how secure these connections are. This is very critical to the design. - In Introduction, on page 3, it is noted that HEPA filter is N95 grade or higher. However, N95 has a filtration efficiency of 95%, whereas a HEPA filter has efficiency of 99.97% at 0.3 micron particle size. - Instructions given on Table 1 is not clear, particularly points 2 and 3. Consider elaborating on it and detailing it with pictures. What kind of an elastic is used on point 4? - What kind of a utility belt is used and is it amenable to sterilization by commonly used techniques? A fabric material is not conducive to sterilization using methods such as alcohol-based wipes. - It doesn't seem like any test is performed to check that the seal between the enclosure components and filter is good, i.e., that outside air cannot ingress into the part of the power box enclosure which contains filtered air. This is very critical to the design. Also, clarify that the sealing between the two clam shell components is not critical, but that between the filter and the filter side clam shell component is. - In the Methods section, please provide estimated availability of components, especially the HEPA filter. - In the results section, for flow rate testing, it is not clear if during the test, the opening in the helmet that seals around the head and neck, was closed, at least partially so as to simulate someone wearing it. When the PAPR is used, and the helmet is donned, this area will be closed, so that needs to be replicated in the test. Please mention if this test was done either by sealing off this opening, or with the helmet was donned on a person or

	mannequin. If the test was conducted with this open, it would lead to lowering of pressure drop and overestimation of flow rate, compared to that expected during operational use. - In the testing section, it is not clear what kind of particulate was used in testing the filtration capability of the PAPR. Was ambient particulate used? 42 CFR, Part 84, Subpart K, Section 84.180 specifies using salt based aerosol for testing filters. A filtration efficiency of at least 99.97% is needed. The protocol presented doesn't seem to align with NIOSH requirements, or be equivalent to them. - As per NIOSH TEB-APR-STP-0001, instantaneous filtration test using DOP aerosol is required for use of filters with PAPRs. - In the Results section, consider calling the qualitative particle filtration test a 'Qualitative fit test', as per NIOSH terminology. - An important piece of information to include would be duration of continuous use of the PAPR and charging time of batteries, along with charging current. -In the Results section, the design is described as not providing protection at the ears. Although this feature could perhaps improve audibility, it is also a substantial limitation of the product in terms of protection and could lead to reluctance amongst healthcare workers for use, even in emergent situations. Such a limitation should be more explicitly described in the text and if possible, provide references for clinician preferences and how they may vary depending on clinical context (e.g. acute care vs. ambulatory care; confirmed COVID-19 positive patients or persons under investigation vs. other patients) -In the Results section, the helmet production process is described. It appears that the design must be custom-made for each individual. If this is the case, please clearly describe that the design needs to be customized to different users. -In the Results section, clarify if fit-testing was performed on one subject and one prototype. -In the Results section, describe number of subjects undergoing qualitative fit-testing as well as demographic, height, and weight characteristics of the subjects. -In the Discussion, clarify that the PAPR likely meet minimum standards for flow-rate and particle filtration through an approximation of formal testing, but that these results should not be equated with formal measurements - Since the 3D printing method adopted would result in porous surface, appropriate sterilization of the surface is critical and should be discussed in greater detail. -The unanswered questions and future research section should more clearly describe the limitations outlined in the points above - Regarding the unanswered questions section: there is very little, perhaps non-existent, downside to having the blower after the filter, as most commercial PAPRs use this configuration, and fan particulates blowing through the hose to the facepiece is not a known problem. In fact, this is a better design, since if the fan is before the filters, it would have to be sterilized, and doing so on the inlet side of the blower with exposed fan blades is challenging. -All data associated with the design, including testing results, should be provided as part of the article in order to allow further use and modifications of this work Minor comments:

	Abstract: -In “Objective”, change to “loose-fitting PAPRs”. - In table 2, point 4, wiring diagram is said to be Fig 5, but it should be Fig 4. - In Methods, rephrase the first sentence about batteries to be more clear. - Mention the blower brand and model number. Does regular fan mean an axial fan? - In “Design”, consider mentioning the assessment of positive pressure for concordance with the “Main Outcome Measures” section, and also in what kind of facilities were used for testing (i.e.: academic laboratory following OSHA protocols). -In the “Results” section, provide brief explanation on the expected measured peak pressure. Strengths and limitations: -Change language from “exceeds” NIOSH/OSHA standards to “meets minimum standards.” -Quantify “long print times” -Describe limitations of design not being tested on end-users for clinical feedback, that the device does not meet all NIOSH/OSHA standards, and that testing was not performed through certified facilities. -Remove word “extremely” before rural and change “recourse-limited” to “resource-limited” Figures: -Please provide more legible labels or parts components in Figure 1 -Please label components on Figure 2 Discussion: - A cost of $120 is described for the design. Please expand on whether this cost is only for materials or also includes manufacturing expenses. -The paragraph that begins with “To make the PAPR more environmentally-friendly” would better fit in the Results section.

REVIEWER	Ballard, David Washington University in St Louis School of Medicine Mallinckrodt Institute of Radiology
REVIEW RETURNED	06-Apr-2021

GENERAL COMMENTS	The authors provide a novel method to 3D print a low cost PAPR which passed NIOSH and OSHA standards. The structure of the manuscript can be improved and some methodology items need to be clarified. A major point the authors need to clarify is how many people underwent quantitative and qualitative fit testing. I would suggest that the authors change the tone that this was in response to the early COVID pandemic and (presumably) did not have to be clinically implemented. The discussion should be lengthened, particularly with expanding on previously published studies. An IRB statement if approval was needed or not needed should be added. There have been at least 3 PAPR 3D printed papers in response to the COVID pandemic. The authors cite 2 of the 3 studies and

	mention them briefly and I ask them to summarize these studies more extensively. The writing style needs to be improved and some methodology items need to be clarified. The largest issue is, the readers do not know how many people underwent quantitative vs qualitative fit testing. I ask the authors to clarify this. The authors do not provide an IRB or IRB not required statement for the fit testing. Presumably, research participant underwent the fit testing and the study would likely qualify as non-human research, but this should be explicitly stated. Overall comments: 1. The writing style for the introduction and discussion should likely be updated to reflect PPE shortages in the early COVID-19 pandemic. The overall situation has substantially improved. The authors reference a timepoint of Dec 2020, so this was written before vaccination efforts became larger scale. Overall, I think the main pitch is the innovation of this 3D printed PAPR in pandemic situations to meet the need of potential PPE shortages. In reality, as far as I can tell, the novel 3D printed PAPR did not need to be and was not used in clinical or high-level PPE situation. I do not think this necessarily detracts from the merit of the study, but it needs to be transparently stated. 2. I am not sure why qualitative fit testing was performed if the quantitative fit testing (the better test) was also performed. Can you provide the readers some insights why it was? Otherwise, consider omitting it. I suppose an idea would be the qualitative fit testing may be more accessible to some people opposed to the quantitative fit testing. 3. How many people were tested for quantitative vs. qualitative. It does not say any metric of participant or subject in the quantitative paragraph. Was only one person tested? More than one person? It says subjects in the qualitative paragraph, so I assume >1 person for qualitative. Please specifically state the number of people tested for each method. State it in the abstract too. 4. With reporting the number of people tested, this should change the tone of the manuscript. Was IRB approval obtained, waived, or not required? Please state this. If not required / not human research, please state this. Were only research team members involved in the quantitative or qualitative testing (this last point does not necessarily need to be stated in the manuscript unless relevant to this IRB / ethical board statement). 5. The methods / results need to be better separated. The quantitative paragraph would likely be better split into talking about component of the quantitative fit testing then the >1000 passing fit factor numbers. 6. The authors state >250 for passing. I may be misinterpreting the document, but it is my understanding that the passing number

	for a full facepiece is greater than 500 (which the authors do achieve). Please verify this, “or a full facepiece respirator unless a minimum fit factor of 500 is obtained” https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppA 7. With the qualitative and quantitative testing, would cite the OSHA document: https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppA 8. I am not sure what this sentence means. Maybe the configuration for the batteries can be assembled with power tools? Please clarify, “The batteries were chosen given that power tools are a common household item but can also easily be purchased if not on hand.” 9. Would increase the length of the discussion and decrease the length of the discussion, perhaps shuffle some material. Please keep prior comments in mind about changing the tone from a current PPE shortage to the PPE shortages during the early COVID pandemic. 10. The authors need to summarize the referenced 3D printed PAPR studies, “Some PAPR designs have already been published using 3D-printable adapters and parts.12, 27.” Provide context and compares/contrasts to this design vs the authors. 11. I believe this may be an additional relevant reference for previous PAPR 3D printing studies , https://pubmed.ncbi.nlm.nih.gov/33043172/; “We provide a set of guidelines to build a low-cost 3D printed solution for an effective PAPR system and describe the procedures to validate it to comply with the biosafety level 3 requirements.” 12. A few wording choices that can be improved, e.g., general merchandise store --> widely available materials; A perfect example --> an example 13. N95 fit test failures are not common, but do happen. Would mention this to the readers, cite a source saying how often people fail N95s.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Dr. Deborah Plana, Harvard Medical School

Major comments:

-The introduction states that the design outlined in the paper meets “National Institute for Occupational Safety and Health (NIOSH) and Occupational Safety and Health Administration (OSHA) standards for loose-fitting PAPR devices." Four key caveats to these results should be described:

1) Filtration and flow rate are only two components of a long-list of technical device requirements required for formal device approval. The device described here was not tested for all the necessary NIOSH and OSHA specifications, including but not limited to housing sealing testing, oil aerosol testing, communicating performance testing, and control system alarms for low flow rates testing (https://www.cdc.gov/niosh/npptl/stps/aprespInterim.html; https://www.cdc.gov/niosh/npptl/stps/apresp.html).
The authors should more explicitly state that they only tested a couple of dimensions for this low-cost design and that users should proceed with extreme caution when considering use in an emergency healthcare setting. They should also make clear that their design is not suitable for use in non-emergent conditions.

You are right, there are many, very detailed qualifications for OSHA and NIOSH certifications. I have now specified in the introduction, and throughout the paper that we meet the minimum standards for the NIOSH guidelines flow rate and OSHA guidelines for particle filtration. We did not perform many of these tests as we did not have access or funds for much of the equipment. We understood flow rate and particle filtration to be the tests of utmost importance and indicate protection against droplet-borne viruses. We also tested pressure in the helmet during use to demonstrate no in-ward leakage of contaminated air (more detail later). A “Limitations” section has been added in the “Discussion” in which we state it should only be used in emergency situations.

2) The authors do not make clear that their testing was performed outside of nationally certified laboratories. While their testing in an academic setting can provide an approximation of product performance, it should not be equated with formal testing.

We now have stated in the Abstract, “Discussion” and “Strengths and limitations” sections that the PAPR was tested in an academic laboratorynot in a NIOSH/OSHA certified laboratory.

3) The authors should describe that their product does not meet the manufacturing and quality-control criteria needed for formal approval.

This has been stated in the new “Discussion – Limitations” section.

4) The authors should describe how the dimensions of the head piece and jaw piece were determined, if they are adjustable, and how they are expected to be compatible with different face/head shapes and sizes, ideally providing users with ways to identify incompatible fits that may compromise intended function.

Please see paragraph 5 of the “Strengths and weaknesses” in the “Discussion”

-In the Methods section, please provide more specific part and manufacturer information, including manufacturer city, for all products listed (i.e.: batteries, hose, blower, and utility belt).

Specification of these parts have been added.

- On page 2, under Strengths and Limitations of this study, reference needed for the claim that alternate PAPR designs impede sight and hearing.

Added

- It is very unclear how the setup works. Is the inlet of the blower exposed to the ambient air? And does the blower pump the unfiltered air through the filter? Consider modifying Fig 1 and/or showing more pictures on Fig 2 to clarify this.

We have added a “Configuration and Mechanism” section in the “Methods” and an additional figure (Now Fig 5) to better explain the set up.

- It’s mentioned that two batteries, each 12V was used. According to Fig 4, these are connected in series, so the total voltage would be 24V. But the blower runs at 12V. The voltage of the battery and blower should be close to one another.

We have added some clarification in the “Discussion”. Please see paragraph 7 of “Strengths and weaknesses”

- It is not clear how the hose connects to the helmet and power box and how secure these connections are. This is very critical to the design.

We have added a “Configuration and Mechanism” section in the “Methods” and an additional figure (Now Fig 5) to better explain the set up.

- In Introduction, on page 3, it is noted that HEPA filter is N95 grade or higher. However, N95 has a filtration efficiency of 95%, whereas a HEPA filter has efficiency of 99.97% at 0.3 micron particle size.

This was poor phrasing on our part. We have adjusted it for clarification.

- Instructions given on Table 1 is not clear, particularly points 2 and 3. Consider elaborating on it and detailing it with pictures. What kind of an elastic is used on point 4?

Points were elaborated and specified.

- What kind of a utility belt is used and is it amenable to sterilization by commonly used techniques? A fabric material is not conducive to sterilization using methods such as alcohol-based wipes.

This statement has been added to the Discussion “For thorough cleaning, the belt should be removed from the Power Box and submerged in a basin filled with either ethanol or isopropyl alcohol. (Meyers, 2021) Additionally, alternate belt materials that are easier to clean can be used to strap the Power Box to the wearer.”

- It doesn't seem like any test is performed to check that the seal between the enclosure components and filter is good, i.e., that outside air cannot ingress into the part of the power box enclosure which contains filtered air. This is very critical to the design. Also, clarify that the sealing between the two clam shell components is not critical, but that between the filter and the filter side clam shell component is.

Please see the added section on "Configuration and Mechanism" in the "Methods" section to address each of these points.

- In the Methods section, please provide estimated availability of components, especially the HEPA filter.

Added

- In the results section, for flow rate testing, it is not clear if during the test, the opening in the helmet that seals around the head and neck, was closed, at least partially so as to simulate someone wearing it. When the PAPR is used, and the helmet is donned, this area will be closed, so that needs to be replicated in the test. Please mention if this test was done either by sealing off this opening, or with the helmet was donned on a person or mannequin. If the test was conducted with this open, it would lead to lowering of pressure drop and overestimation of flow rate, compared to that expected during operational use.

The PAPR was donned by an author while flow rate testing was being done. We have added this detail to the "Methods" section.

- In the testing section, it is not clear what kind of particulate was used in testing the filtration capability of the PAPR. Was ambient particulate used? 42 CFR, Part 84, Subpart K, Section 84.180 specifies using salt based aerosol for testing filters. A filtration efficiency of at least 99.97% is needed. The protocol presented doesn't seem to align with NIOSH requirements, or be equivalent to them.
- As per NIOSH TEB-APR-STP-0001, instantaneous filtration test using DOP aerosol is required for use of filters with PAPRs.

Both this and the previous point are in reference to specific NIOSH standards and tests run to certify filters. The authors used a filter certified by 3M and to meet these standards but did not run these specific tests on the design. The was also added to the "Limitations" section.

- In the Results section, consider calling the qualitative particle filtration test a 'Qualitative fit test', as per NIOSH terminology.

Switched

- An important piece of information to include would be duration of continuous use of the PAPR and charging time of batteries, along with charging current.

This information was added to the "Results" and "Methods" sections.

-In the Results section, the design is described as not providing protection at the ears. Although this feature could perhaps improve audibility, it is also a substantial limitation of the product in terms of protection and could lead to reluctance amongst healthcare workers for use, even in emergent situations. Such a limitation should be more explicitly described in the text and if possible, provide references for clinician preferences and how they may vary depending on clinical context (e.g. acute care vs. ambulatory care; confirmed COVID-19 positive patients or persons under investigation vs. other patients)

Though respiratory diseases like COVID-19 can be infectious if it comes in contact with mucosal surfaces, like the eyes, it is unlikely to be infectious if it comes in contact with the ears. The outer ear is not mucosal tissue and wax acts as a barrier. Additionally, Several PAPR designs on the market do not cover the ears. The design not covering the ears does not put the wearer at a significantly greater risk of infection.

-In the Results section, the helmet production process is described. It appears that the design must be custom-made for each individual. If this is the case, please clearly describe that the design needs to be customized to different users.

Please see paragraph 5 of the “Strengths and weaknesses” in the “Discussion

-In the Results section, clarify if fit-testing was performed on one subject and one prototype.

This has been clarified.

-In the Results section, describe number of subjects undergoing qualitative fit-testing as well as demographic, height, and weight characteristics of the subjects.

The number of subjects has been described in the in the Results section. However, it is not necessary to describe the characteristics of each subject as the PAPR is loose-fitting and characteristics of the wearer do not alter it’s efficacy.

-In the Discussion, clarify that the PAPR likely meet minimum standards for flow-rate and particle filtration through an approximation of formal testing, but that these results should not be equated with formal measurements

This was addressed in the “Unanswered questions and future research” in the “Discussion”.

- Since the 3D printing method adopted would result in porous surface, appropriate sterilization of the surface is critical and should be discussed in greater detail.

Appropriate cleaning methods are addressed in the discussion in the “Strengths and weakness”. A study cited in the 8th paragraph of this section discusses appropriate cleaning methods of 3D printed material and lists several options that demonstrated the ability to inactivate surrogate coronaviruses including: a single application of 10% bleach, ammonium quaternary, 3% H_2O_2, or exposure to 70°C dry heat. Many of these options are widely available and are sufficient for inactivating concerning microbes.

-The unanswered questions and future research section should more clearly describe the limitations outlined in the points above

Added

- Regarding the unanswered questions section: there is very little, perhaps non-existent, downside to having the blower after the filter, as most commercial PAPRs use this configuration, and fan particulates blowing through the hose to the facepiece is not a known problem. In fact, this is a better design, since if the fan is before the filters, it would have to be sterilized, and doing so on the inlet side of the blower with exposed fan blades is challenging.

Please see the 6th paragraph of the “strengths and weakness” section of the “Discussion”

-All data associated with the design, including testing results, should be provided as part of the article in order to allow further use and modifications of this work

All data has been detailed in the manuscript. Original copies will be made available upon individual request to the author.

Minor comments: All minor comments were reviewed and addressed as suggested.
Abstract:
-In “Objective”, change to “loose-fitting PAPRs”. - done
- In table 2, point 4, wiring diagram is said to be Fig 5, but it should be Fig 4. - done
- In Methods, rephrase the first sentence about batteries to be more clear. - Rephrased
- Mention the blower brand and model number. Does regular fan mean an axial fan? – Yes, specified
- In “Design”, consider mentioning the assessment of positive pressure for concordance with the “Main Outcome Measures” section, and also in what kind of facilities were used for testing (i.e.: academic laboratory following OSHA protocols). – The assessment of positive pressure was added to the Design section and testing facilities were detailed.
-In the “Results” section, provide brief explanation on the expected measured peakressure. – There was no specific anticipated peak pressure. Pressure inside the helmet was measured to demonstrate positive pressure throughout the system. By demonstrating positive pressure throughout, we show that contaminated air is unable to leak into any potentially imperfect seals. Therefore, our expected pressure was >0 mmHg.
Strengths and limitations:
-Change language from “exceeds” NIOSH/OSHA standards to “meets minimum standards.” - done
-Quantify “long print times” – specified
-Describe limitations of design not being tested on end-users for clinical feedback, that the device does not meet all NIOSH/OSHA standards, and that testing was not performed through certified facilities. – limitations were detailed.
-Remove word “extremely” before rural and change “recourse-limited” to “resource-limited” - done
Figures:
-Please provide more legible labels or parts components in Figure 1 - relabeled
-Please label components on Figure 2 - labeled
Discussion:

- A cost of $120 is described for the design. Please expand on whether this cost is only for materials or also includes manufacturing expenses. – materials only, but manufacturing expenses are minimal (cost of electricity for 3D printing and labor costs)
-The paragraph that begins with “To make the PAPR more environmentally-friendly” would better fit in the Results section. - moved

Reviewer: 2
Dr. David Ballard, Washington University in St Louis School of Medicine Mallinckrodt Institute of Radiology

Overall comments:

1. The writing style for the introduction and discussion should likely be updated to reflect PPE shortages in the early COVID-19 pandemic. The overall situation has substantially improved. The authors reference a timepoint of Dec 2020, so this was written before vaccination efforts became larger scale. Overall, I think the main pitch is the innovation of this 3D printed PAPR in pandemic situations to meet the need of potential PPE shortages. In reality, as far as I can tell, the novel 3D printed PAPR did not need to be and was not used in clinical or high-level PPE situation. I do not think this necessarily detracts from the merit of the study, but it needs to be transparently stated.

You make a very good point. The tone of the introduction needed to be altered, particularly with the decline in incidence with the vaccine. Though our PAPR was never used on any large scale, after posting it on thingiverse.com we have had several people tell us they were going to make the design and look into wearing and adapting it for their work. One was a nurse, another a flight nurse. The design has been downloaded over 100 times and that is with minimal exposure. It is possible that it was not needed for used in the United States, but there is no indication that it might not be more needed in a nation with fewer resources. However, given that, to our knowledge it was never used in a clinical or high-level PPE situation, we will state as much.

2. I am not sure why qualitative fit testing was performed if the quantitative fit testing (the better test) was also performed. Can you provide the readers some insights why it was? Otherwise, consider omitting it. I suppose an idea would be the qualitative fit testing may be more accessible to some people opposed to the quantitative fit testing.

Qualitative testing was done to mimic the testing done during N95 fit testing. This testing is widely available at healthcare facilities or can easily be purchased online with limited resources. A particle counter is less available to the layperson and very expensive. I added this detail in the “Testing/Results” section.

3. How many people were tested for quantitative vs. qualitative. It does not say any metric of participant or subject in the quantitative paragraph. Was only one person tested? More than one person? It says subjects in the qualitative paragraph, so I assume >1 person for qualitative. Please specifically state the number of people tested for each method. State it in the abstract too.

The particle filtration, air flow, and pressure tests were performed on n=1. The qualitative fit test was performed on n=2. The subjects were the authors. This has been added to the “Testing/Results” section

and the abstract. More subjects were not tested because the device is not user specific and “fit” is not a factor.

4. With reporting the number of people tested, this should change the tone of the manuscript. Was IRB approval obtained, waived, or not required? Please state this. If not required / not human research, please state this. Were only research team members involved in the quantitative or qualitative testing (this last point does not necessarily need to be stated in the manuscript unless relevant to this IRB / ethical board statement).

IRB approval was not required given that the test subjects were the authors, though informed consent was obtained for the sake of thoroughness. These detailed were added to the “Statements” section

5. The methods / results need to be better separated. The quantitative paragraph would likely be better split into talking about component of the quantitative fit testing then the >1000 passing fit factor numbers.

The suggested separation has been added.

6. The authors state >250 for passing. I may be misinterpreting the document, but it is my understanding that the passing number for a full facepiece is greater than 500 (which the authors do achieve). Please verify this, “or a full facepiece respirator unless a minimum fit factor of 500 is obtained” https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppA

Thank you so much for catching this error. The particle filtration test notes that >250 is passing. However, as you importantly pointed out, OSHA’s standards are >500. These corrections have been made.

7. With the qualitative and quantitative testing, would cite the OSHA document: https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppA
I believe this source was already sited as Appendix A is included within the over arching protocol. However, I have specified in the “Testing/Results” section that Appendix A is the section of focus.

8. I am not sure what this sentence means. Maybe the configuration for the batteries can be assembled with power tools? Please clarify, “The batteries were chosen given that power tools are a common household item but can also easily be purchased if not on hand.”

This sentence was poorly phrased and I hope the rewrite provides clarification. “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.”

9. Would increase the length of the discussion and decrease the length of the discussion, perhaps shuffle some material. Please keep prior comments in mind about changing the tone from a current PPE shortage to the PPE shortages during the early COVID pandemic.
The introduction was shortened and moved to the discussion as well as the overall tone adjusted.

10. The authors need to summarize the referenced 3D printed PAPR studies, “Some PAPR designs have already been published using 3D-printable adapters and parts.12, 27.” Provide context and compares/contrasts to this design vs the authors.
The current designs have been detailed and compared/contrasted in the “Discussion” under the heading “In relation to other studies”.

11. I believe this may be an additional relevant reference for previous PAPR 3D printing studies , https://pubmed.ncbi.nlm.nih.gov/33043172/; “We provide a set of guidelines to build a low-cost 3D printed solution for an effective PAPR system and describe the procedures to validate it to comply with the biosafety level 3 requirements.”

This design/publication was added to the analysis mentioned in point 10.

12. A few wording choices that can be improved, e.g., general merchandise store --> widely available materials; A perfect example --> an example
These wording adjustments have been made.

13. N95 fit test failures are not common, but do happen. Would mention this to the readers, cite a source saying how often people fail N95s.
This was added to the second paragraph of the “Strengths and weaknesses” section of the “Discussion”. “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. (Campbell, 2020)”

VERSION 2 – REVIEW

REVIEWER	Plana, Deborah Harvard Medical School
REVIEW RETURNED	13-Jul-2021

GENERAL COMMENTS	Reviewer 1: Deborah Plana, Harvard Medical School, Boston, MA Akshay Kothakonda, Massachusetts Institute of Technology, Cambridge, MA Lyla Atta, Johns Hopkins University, Baltimore, MD Minor Comments 1. Please proofread grammar used throughout manuscript. Some suggested edits include: a. In the “strengths and limitations of this study” section, replace “outweighed” with “should be weighed against.” b. In Introduction, replace “stepped in” with “began.” c. In “Methods” page 3, replace “life” with “filter life.” d. On page 6, change “performing” to “performed.” e. Page 7, the paragraph “Once of the most significant…”, change “Once” to “One”. f. On page 7, change “so long as it” to ““so long as they.” g. The second sentence in “In relation to other studies” is difficult to follow; consider rewriting.

	h. On page 8, change “if the current design does not fit” to “if the current design does not fit a given user.” 2. For consistency throughout article, consider removing hyphen from “3D-printing” and “3D-printable.” 3. In Introduction, define “HEPA.” 4. Consider replacing Figures 1 and 4 with higher quality images. 5. On Figure 2, the work belt “E” is not shown. This should be noted on the figure caption or included as an additional figure. 6. On Figure 5, “1.a” is too small to be seen. 7. On page 4, charging time of 30-45 min at 1.5Amp/h does not make sense. The charging current should be specified in amperes instead of Amperes/Hour. 8. On page 4, it is mentioned that the hose used is taken from a manual resuscitator kit in a hospital. However, this contradicts the earlier statement that all parts can be either made with access to a 3D printer and a general merchandise store. 9. Point 4 on Table 1 is unclear; a figure or clarifying in text will help. For instance, “boat cleats” are not shown in any of the figures, nor mentioned prior. 10. On page 7, it is mentioned that any blower with a flow rate of 16 cfm can be used. However, static pressure of the blower is also important. The static pressure at a given flow rate must overcome pressure losses through the flow path. If someone was to use a blower different than that used in this paper, both maximum flow rate, as well as static pressure must exceed (or equal) the corresponding values of the current blower. 11. Would consider changing final sentence of first paragraph in page 8 to a more objective formulation: “The drawback of a prolonged total print time is potentially outweighed by the simplicity and cost benefits of this design.” 12. On page 8 and page 10, it is mentioned that having the fan before the filter leads to lower efficiency. However, this is not necessarily the case. The main issue with this configuration is the need to sterilize the blower inlet impeller, which is not easy. If there is a reference that states that this configuration leads to a lower efficiency, please provide that reference. 13. On page 8, it is unsafe to use a 24V battery with a 12V blower. The best practice is to use 12V battery for a 12V blower. There is a risk of the blower failing during use, which is not desirable. If the required flow rate can only be achieved using 24V battery, this limitation needs to be noted. 14. Please explicitly state in the results section that the test was done using ambient aerosol, and not salt aerosol, which is as per NIOSH requirements, although OSHA 29CFR1910.134 is said to have been followed. As per NIOSH/OSHA, salt aerosol is needed, which was not used. 15. To reiterate major comment 3 from the previous round of review: in the limitations section, it should be stated that in order to obtain NIOSH certification, the manufacturer needs to be certified for minimum quality control standards. This has not been done and any entity planning to obtain the certification to produce these devices needs to meet those requirements.

REVIEWER	Ballard, David Washington University in St Louis School of Medicine Mallinckrodt Institute of Radiology

REVIEW RETURNED	05-Jul-2021

GENERAL COMMENTS	The authors have done a great job in revising their manuscript and intently addressing my concerns along with the other reviewer's comments. I commend the authors on their study and the improvements in their revised manuscript.

VERSION 2 – AUTHOR RESPONSE

Reviewer 1:

Deborah Plana, Harvard Medical School, Boston, MA

Akshay Kothakonda, Massachusetts Institute of Technology, Cambridge, MA

Lyla Atta, Johns Hopkins University, Baltimore, MD

Minor Comments

1. Please proofread grammar used throughout manuscript. Some suggested edits include:

In the "strengths and limitations of this study" section, replace "outweighed" with "should be weighed against." Done

In Introduction, replace "stepped in" with "began." Done

In "Methods" page 3, replace "life" with "filter life." Done

On page 6, change "performing" to "performed." Done

Page 7, the paragraph "Once of the most significant…", change "Once" to "One". Done

On page 7, change "so long as it" to ""so long as they." Changed it to padding material for clarification.

The second sentence in "In relation to other studies" is difficult to follow; consider rewriting. Rewritten

On page 8, change "if the current design does not fit" to "if the current design does not fit a given user." Done

2. For consistency throughout article, consider removing hyphen from "3D-printing" and "3D-printable." Hyphens have been removed.

3. In Introduction, define "HEPA." It has been defined.

4. Consider replacing Figures 1 and 4 with higher quality images. Done

5. On Figure 2, the work belt “E” is not shown. This should be noted on the figure caption or included as an additional figure. We have clarified that it is not pictured.

6. On Figure 5, “1.a” is too small to be seen. Made larger and made additional label on the paired image.

7. On page 4, charging time of 30-45 min at 1.5Amp/h does not make sense. The charging current should be specified in amperes instead of Amperes/Hour. Please see correction.

8. On page 4, it is mentioned that the hose used is taken from a manual resuscitator kit in a hospital. However, this contradicts the earlier statement that all parts can be either made with access to a 3D printer and a general merchandise store.

We do state that as the reasoning for why we chose the hose. Given the intended use of this design, we anticipate that it will be a commonality for those making the design and wanted to bring this resource to the makers attention. However, we also mention that one-inch corrugated tubing (which is the same size and material used in the resuscitator kit) is widely available. We have now clarified that widely available means online or at general merchandise stores.

9. Point 4 on Table 1 is unclear; a figure or clarifying in text will help. For instance, “boat cleats” are not shown in any of the figures, nor mentioned prior. Added an arrow to Figure 6 to show boat-cleat protrusion attachment point.

10. On page 7, it is mentioned that any blower with a flow rate of 16 cfm can be used. However, static pressure of the blower is also important. The static pressure at a given flow rate must overcome pressure losses through the flow path. If someone was to use a blower different than that used in this paper, both maximum flow rate, as well as static pressure must exceed (or equal) the corresponding values of the current blower.

The purpose of that sentence was to provide an example of the manufacturer not being significant, so long as it has the same specifications. You are correct that the static pressure is a key specification for the fan. For simplicity, we have changed the example to the battery manufacturer.

11. Would consider changing final sentence of first paragraph in page 8 to a more objective formulation: “The drawback of a prolonged total print time is potentially outweighed by the simplicity and cost benefits of this design.” Adjusted

12. On page 8 and page 10, it is mentioned that having the fan before the filter leads to lower efficiency. However, this is not necessarily the case. The main issue with this configuration is the need to sterilize the blower inlet impeller, which is not easy. If there is a reference that states that this configuration leads to a lower efficiency, please provide that reference.

You make a good point. We are unsure if efficiency is compromised by the position of the fan. We have removed these statements. While the current position of the fan exposes it to potential contamination, this problem is mitigated by the fact that even with a contaminated fan, then air is still filtered afterwards. The concern of difficulty of cleaning the inlet impeller are primarily relieved by the air being filtered after the air goes through the fan.

13. On page 8, it is unsafe to use a 24V battery with a 12V blower. The best practice is to use 12V battery for a 12V blower. There is a risk of the blower failing during use, which is not desirable. If the required flow rate can only be achieved using 24V battery, this limitation needs to be noted.

We acknowledge that using a 12V fan is not ideal. The fan was used as it is what was most available at the time. We did all of our testing with that fan, met standards and did not have any problems with the fan. However, given safety concerns, we will encourage readers to use a 24 V. We will also note that test will need to be redone with the 24 V fan.

14. Please explicitly state in the results section that the test was done using ambient aerosol, and not salt aerosol, which is as per NIOSH requirements, although OSHA 29CFR1910.134 is said to have been followed. As per NIOSH/OSHA, salt aerosol is needed, which was not used. According to the protocol a non-hazardous aerosol is to be used, including corn oil, polyethylene glycol 400 [PEG 400], di-2-ethyl hexyl sebacate [DEHS], or sodium chloride. We used an ultrasonic humidifier and tap water. We have added this to the methods and limitations sections of the paper.

15. To reiterate major comment 3 from the previous round of review: in the limitations section, it should be stated that in order to obtain NIOSH certification, the manufacturer needs to be certified for minimum quality control standards. This has not been done and any entity planning to obtain the certification to produce these devices needs to meet those requirements.

This has been added to the second paragraph of the limitations.

Reviewer: 2

Dr. David Ballard, Washington University in St Louis School of Medicine Mallinckrodt Institute of Radiology

Thank you kindly for reading the manuscript and for your thoughtful consideration. We greatly appreciate your time.

VERSION 3 – REVIEW

REVIEWER	Plana, Deborah Harvard Medical School
REVIEW RETURNED	02-Aug-2021

GENERAL COMMENTS	The majority of reviewer comments have been addressed; two minor points remain: -With regards to comment 10, it should be mentioned that the battery or series of batteries used should be rated so that they provide enough discharge current to drive the blower. -With regards to comment 12, page 8, third paragraph, second sentence, we believe the sentence should read "A fan placed after the filter...". We appreciate the authors working with us throughout the review process and congratulate them on the revised manuscript. Deborah Plana, Harvard Medical School, Boston, MA Akshay Kothakonda, Massachusetts Institute of Technology, Cambridge, MA Lyla Atta, Johns Hopkins University, Baltimore, MD

VERSION 3 – AUTHOR RESPONSE

Reviewer:

Deborah Plana, Harvard Medical School, Boston, MA

Akshay Kothakonda, Massachusetts Institute of Technology, Cambridge, MA

Lyla Atta, Johns Hopkins University, Baltimore, MD

-With regards to comment 10, it should be mentioned that the battery or series of batteries used should be rated so that they provide enough discharge current to drive the blower. We have added this phrasing.

-With regards to comment 12, page 8, third paragraph, second sentence, we believe the sentence should read "A fan placed after the filter...". Thank you for noting this error. It is indeed supposed to be “a fan placed after the filter”.