

Appendix (Figures/Data/Tables):

Appendix 1. Prototype Model

Appendix 2. Note on Assembly

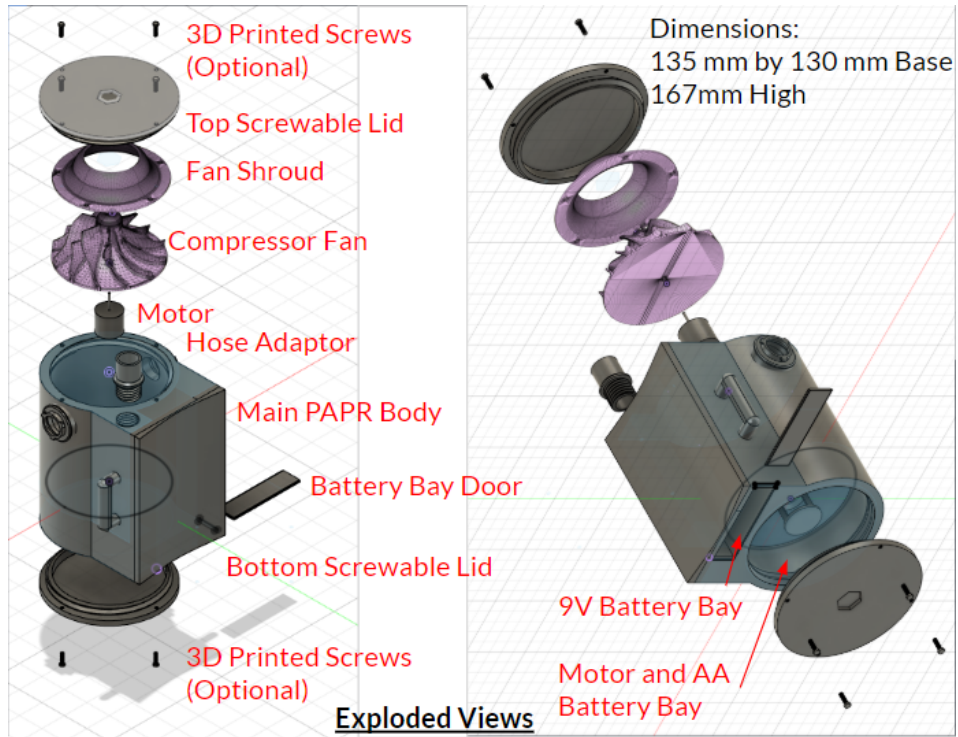
Appendix 3. Charts and Data Tables

Appendix 4. Filter Construction Protocol

Appendix 5. Citations

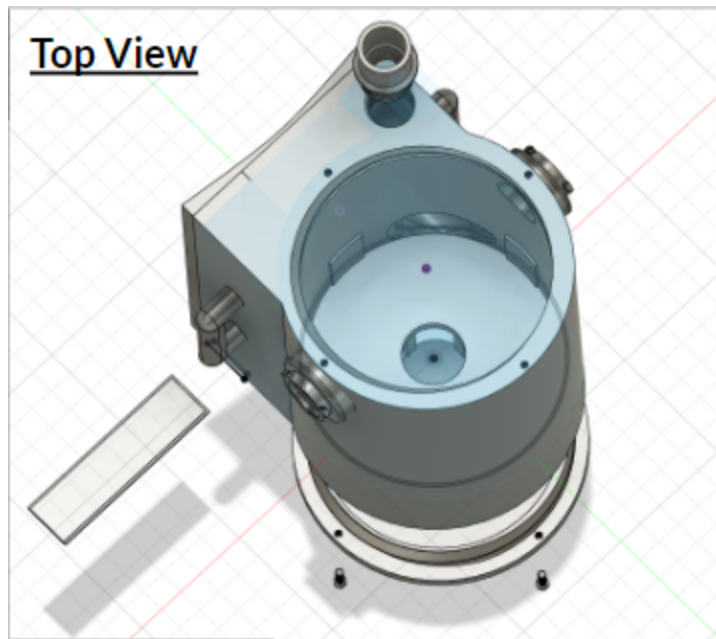
Appendix 1. Prototype Model

Model A. Exploded Views of PAPR Device



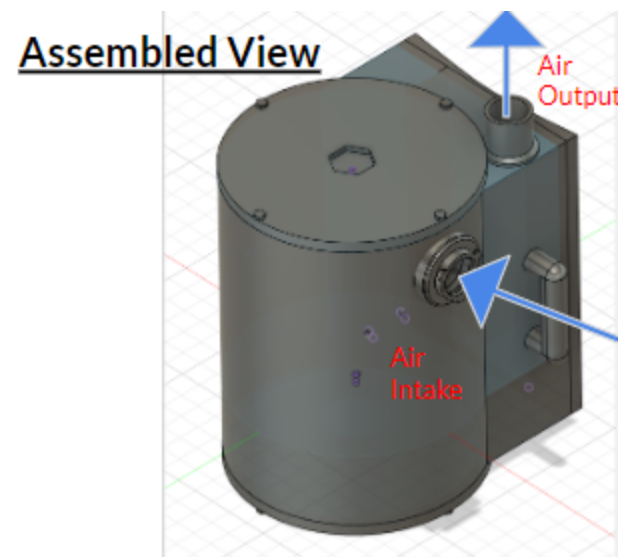
See above image for exploded views of PAPR Device

Model B. Exploded Top View of PAPR Device



See above image for exploded Top View of PAPR Device

Model C. Assembled View of PAPR Device



See above image for assembled view of PAPR Device

Model D. 3D Printed of PAPR Device, CPAP Hose, and Adapted Snorkel Mask



See above: Image of paPURE prototype connected to CPAP hose and snorkel mask. Powered by 4 9V and 4 AA batteries.

Appendix 2. Assembly Notes/Procedure

1. Design Printing

- CAD and STL files will be distributed to approved parties (regulatory pending)
- Printing Instruction will include guidelines for 3D printing, such as a ranking of preferred filaments if available (ABS followed by PLA, will probably be most prevalent and accessible, thus guidelines will focus on adapting these material suitably)

2. Post-Processing

- Minute plastic particles can reside on the surface of 3D prints that are produced by the 3D printer itself, thus simple cleaning with water and soap will quell concerns of plastic inhalation.^[11]
- Additional post-processing, such as deburring of support structure attachment points may be needed depending on the utilized 3D printer and filament used.
- Post-processing may include the addition of solutions that help to seal the device, such as a paraffin wax coating (e.g. diluted vaseline), however concerns of porosity may be soothed by simply modifying the thickness of centrais design walls and modified the way in which the printer deposits the material (referenced below). Smoothing of ABS and suitable material with acetone/other accessible solvents may also be experimented with as a means to procure a hermetically sealed device. Industry PAPRs with porous surfaces used today, requiring testing we would like to implement (“The TIL tests will involve three different challenges: corn oil, which is also used for CBRN respirators; sodium chloride aerosol; and a sulfur hexafluoride challenge for respirators that may be tight-fitting but have some kind of a porous barrier that needs to be evaluated.”)^{[2][10]}

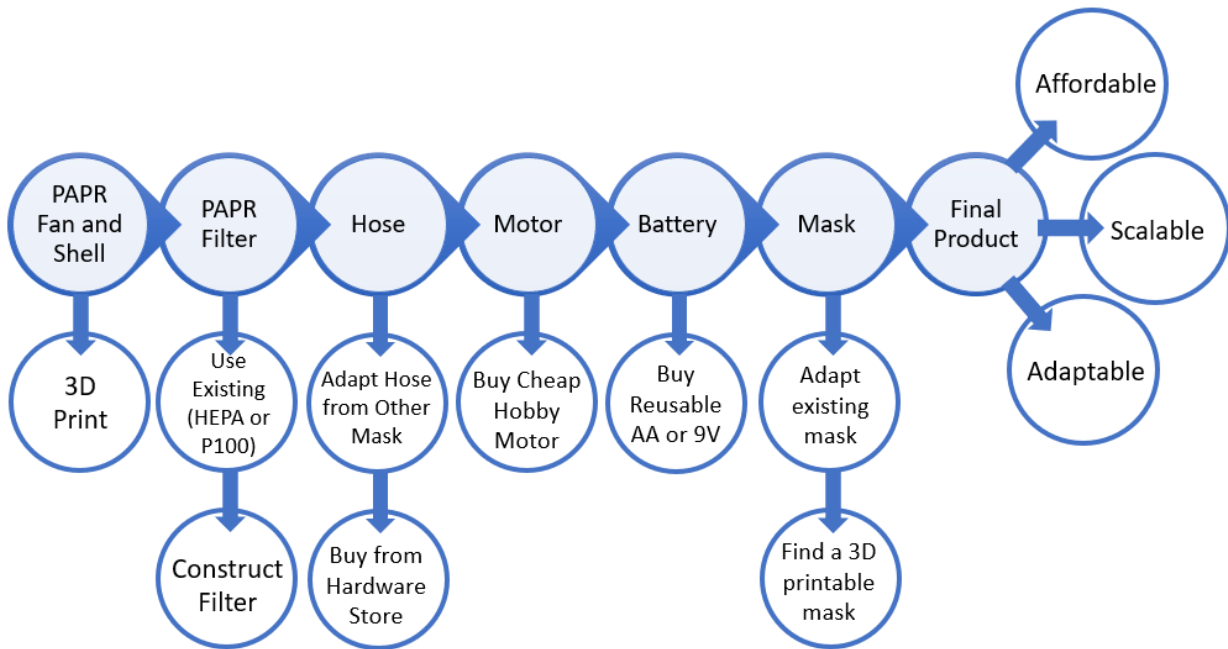
3. Assembly

- After any post-processing, the design will be moved into a laminar flow hood if available to assemble in complete sterility:
 - If wax is needed and utilized for sealing, a vaseline-ethanol solution may be used to:
 - Ethanol sterilize components
 - (If a concern) seal any minute pores with vaseline when the ethanol evaporates
 - In this case, this post-processing would be done in laminar flow hood
- The design would be sterilized with available methods:
 - Ethanol bath (or previous vaseline-ethanol bath)
 - Hydrogen peroxide Vapor Sterilization
 - “Morphological deformations induced by the hydrogen peroxide sterilization are sub-millimeter and acceptable for surgical use ... The hydrogen peroxide sterilization is, therefore, an alternative to ... steam sterilization (autoclave)”^[17]
 - Autoclave (depending on filament type (e.g. nylon, polypropylene , acetal); unlikely due to filament low accessibility)
- Instructions will indicate how to wire up the batteries in series. 9V batteries will be snapped and then taped together, while AA batteries will utilize adhesive tape and aluminum foil strips to join the batteries.
- Aluminum foil strips and adhesive tape will also be used to connect the equivalent battery terminals to the motor in a later step
- Both the motor and batteries are fitted into the device.

- The air compressor fan is lowered onto the motor axel (with both adaptors and customizable/pre-designed compressor fan files provided to mechanically link the axel and fan).
 - The fan shroud into the central cylinder, resting above the fan on 4 supports around the edge
 - The battery bay door will be used to seal the 9V section. The screwable top will then be threaded onto the PAPR body. All doors and threadings will be lubricated with paraffin wax (e.g. vaseline) in order to reduce threading friction, as well as ensure a more airtight device
 - (Optional) 3D Printed or Metal Screws can be used to tighten the lids
 - The hose adaptor (customizable to hose type) will then be threaded onto air output port (lubricated with vaseline)
 - Packing tape will be applied to:
 - The battery bay cover
 - The the side lip of the top lid
 - The hose adaptor-hose interface
 - The the side lip of the bottom lid will be sealed in a future step
 - Power on the device by connecting the leads of the power supply to the motor
 - Lubricate and thread on the bottom lid. Seal with packing tape.
4. Initial Testing (Optional But Recommended)
- Air-gap testing should be done after assembly looking for leaks
 - Sucrose/alternative testing methods should be carried out prior to device usage in a clinical setting

Appendix 3. Charts and Data Tables

Figure 1. Envisioned Product Pipeline



See above image for summary of product pipelines (including options to obtain device components).

Figure 2. Potential Partners (Current Industry Leaders in Respirator Manufacturing)
ESTIMATED U.S. MARKET SHARES OF ATMOSPHERE SUPPLYING RESPIRATOR MANUFACTURERS, 2013 (%)

Manufacturer	Market Share (%)
Honeywell	25
Scott Safety/Tyco	20
Mine Safety Appliances (MSA)	20
Others	35
Total	100

Source: BCC Research

See above image for summary of market leaders in PPE industry. We are considering partnerships with some of these well established industry leaders.

Figure 3. Cost Comparison of Current PAPR/N95 Technology and paPURE Technology

Equipment Type	Cost
Regular PAPR ^[2]	<u>\$1800</u>
N95 ^[18]	<u>\$320</u> (current max cost due to shortage)
Total Cost of Prototype, Assuming CPAP mask, CPAP hose, hobby motor and P100 filter used (most expensive path) ^{[19][20][21][22]}	\$42 (auxiliary materials) + \$113.50 (3D prototype—assuming model is ordered online, most expensive option) = ~ <u>\$150</u>

See above chart for cost comparison of current PAPR and N95 technology and our technology. Our solution is over 10 times more affordable (with the most expensive components in use).

Figure 4. Projected Timeline Summary

Completion Date	Deliverable
April 4th, 2020	Occurring Simultaneously: - Filter Testing - Flow Rate Testing - Longevity Testing (continued use-life)
April 4th, 2020	Submission for FDA Approval
April 13th, 2020	FDA Approval
April 13th, 2020	Roll-out to hospitals, clinics, etc.

Figure 5. Adaptable Resources

01	PAPR system (fan, shell, filter)	• 3D printable, no middle man manufacturer • Existing filters can be bought • Filter can be made (affordable and reusable)
02	Mask	• Design is adaptable to existing masks: ◦ CPAP masks ◦ Snorkeling/Scuba gear ◦ Current PAPR ◦ Potentially N95 ◦ Face shields
03	Hose	• Easily available for all hospitals • Existing hoses can be adapted from: ◦ CPAP/ventilator hosing ◦ Snorkeling/Scuba gear
04	Motor & Batteries	• General hobby grade motors work ◦ Identified at less than \$5 • Rechargeable double A or 9V batteries increase longevity of the device

Appendix 4. Filter Construction Protocol

Alternative Surgical Mask Filter Procedure:

[Only to be used as a last resort if such filters are unavailable]

1. Obtain an high-efficiency HVAC filter that falls under the HEPA category or under MERV 14. Many hospitals have A/C systems with this filter as it is the best quality. [NOTE: HEPA is the only form of filter that can reliably filter coronavirus. MERV14 IS NOT guaranteed to do so, but it is the second best option. MERV14 has between 50% and 75% efficiency for filtering particles between 0.30 and 1 micron in size (such as bacteria, most smoke, sneeze nuclei)]. At least MERV14 will be present in hospitals as it has been mandated that this is the minimum filter needed by authorities.
2. Cut 4-5 circles out of the filter with about a 50 mm diameter. Then, cut 2 circles out of a surgical mask, about a 65 mm diameter. Stack the smaller circles together and lay them in-between the 2 surgical mask circles.
3. There are multiple methods of adhesive: sewing is the likely best option, followed by staples, close in proximity. To ensure strong fit, a heat-resistant adhesive can also be administered [super glue is one option]. This will be the filter.
4. Dissolve 4 teaspoons of salt (can be higher) into 1 cup of boiling water. Let cool slightly (not too much in order to maintain sterility), then immerse the filter in the solution for about a minute. Hospital grade saline solution is suitable if the solution is at LEAST 1.5M.
5. Lay the filter on a sterile rack with a collection pan underneath. The filter could also be laid directly on the pan to minimize salt loss. Wait overnight, and the water will evaporate and a hard salt film will appear around the filter, providing an extra layer of protection. OR if you are running low on time, use a laboratory oven set to 200 degrees Fahrenheit, place the filter on a rack with the collection pan underneath, and heat for about 20 minutes. Watch closely- do not leave unattended for safety precautions. The filter will also yield a hardened salt coating around the surgical mask exterior.
6. To preserve the salt coating, it is recommended the filter be wrapped in any type of sterile fabric to keep salt from chipping off. This fabric wrap doesn't necessarily have to be completely sealed, as for re-use the fabric would need to be removed. It can be sealed via hot glue or some other sterile adhesive.
7. When the filter needs to be reused, simply sterilize the fabric wrap via steam/bleach and repeat the salt coating procedure on the filter itself, providing the filter has stayed in-tact throughout its use. An additional UV light irradiation step or bleach soak (followed by overnight dry) could also further ensure that the filter has been sterilized.

*Note: Conduct procedure in a flow hood or sterile environment. Ensure the materials used to build the materials are also sterile- including any scissors, adhesives, sewing materials or staples. (This can be sterilized via steam, bleach or autoclave if available)

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