

Disclosures for bunnyPAPR™



Version history:

V0.01a: May 19, 2020 first version

V0.02b: May 20, 2020, added video links, updates from YouTube TrueEMR/Kuo

Links

Important Disclosures: tinyurl.com/bunnyPAPRdisclosuresV1 (this document)

Quickstart guide: <https://tinyurl.com/bunnyPAPRQuickStart> (recommended first)

Important Assembly Details: tinyurl.com/bunnyPAPR (recommended second)

Assembly Video: tinyurl.com/bunnyPaprV1Install

If you have any comments, questions, concerns, or feedback please refer to:

General Site: www.bunnypapr.org

More Info on [Why A PAPR?](#)

Email: info@bunnyPAPR.org

KEY ACTION ITEMS FOR USERS	2
General	2
Infectious Disease Control	3
Filter	3
Fan	4
Battery and cables	5
Bag	5
3D printed Parts	5
Disinfection and decontamination	5
CONCLUSIONS AND LEGAL	6
Additional Videos	8

KEY ACTION ITEMS FOR USERS

Inspect gear before using. Do not use gear that has material defects.

Always wear a surgical mask or n95 mask inside of the bunnyPAPR. The reason is that that gear is certified for use in hospital settings. Furthermore, if the wearer of a bunnyPAPR is infectious, the surgical/n95 mask will limit and/or prevent distribution of the infectious air.

Perform a fit test (like a QLFT) if you are looking to make sure “dirty” infectious air doesn’t bypass the filter.

Be aware of big and small breaths. Big inhales run the risk of backward-pressurizing the bag and dirty air may come in temporarily through the outflow/exhaust port. (Some bag deflation is normal.)

General

Use at your own risk.

Not FDA Approved.

The disclosures from maskson.org/info apply to our product as well. We use a similar filter mechanism.

WARNINGS

 CAUTION PROTECT YOURSELF: 1. USE WITH 15MM BACTERIAL / VIRAL FILTER 2. PERFORM SEAL TEST BEFORE EACH USE 3. COVER STRAPS DURING WEAR 4. SANITIZE WITH BLEACH PER INSTRUCTIONS Important Info: MasksOn.org	 WARNING FACE SHIELD FOR MEDICAL PURPOSES NOT FDA CLEARED OR APPROVED Important Info: MasksOn.org	NOT FDA APPROVED THIS FACE MASK MAY BE USED WHEN OTHER FDA CLEARED MASKS ARE UNAVAILABLE. NOT RECOMMENDED FOR USE IN A SURGICAL SETTING OR WHERE SIGNIFICANT EXPOSURE TO BODILY FLUIDS OR OTHER FLUIDS MAY BE EXPECTED. BODY CONTACTING MATERIALS: SILICONE RUBBER, FABRIC STRAPS Important Info: MasksOn.org
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This device has been authorized by FDA under an Emergency Use Authorization (EUA) for use by a healthcare provider (HCP) as personal protective equipment, and may be effective at preventing HCP exposure to certain particulates during face shield shortages by providing minimal or low barrier HCP protection to the wearer during COVID-19. This device is only authorized for the duration of the declaration that

circumstances justifying the authorization of emergency use under Section 564(b)(1) of the Act, 21 USC 360bbb-3(b)(1) unless the authorization is terminated or revoked sooner.

This device is not manufactured in compliance with 21 CFR Part 820, ISO 13485, or similar Quality Management System regulations.

- bunnyPAPR may ONLY be used when FDA cleared masks are unavailable
- bunnyPAPR is NOT recommended for use in a surgical setting or where significant exposure to liquid bodily or other hazardous fluids may be expected
- bunnyPAPR makes NO claims of antimicrobial or antiviral protection
- bunnyPAPR makes NO claims of infection prevention or reduction
- bunnyPAPR makes NO claims regarding flammability
- bunnyPAPR is intended for multiple uses by the same user.

Use at your own risk.

Kit provided for evaluation purposes. Read all instructions. Consult your infectious disease department and EHS department.

Infectious Disease Control

Consult your infectious disease control department for appropriateness of this emergency equipment, acceptable protocols for limiting the spread of infection, and decontamination procedures.

Filter

According to the FDA guidelines, we cannot make medical claims of viral protection. User and users' hospitals are encouraged to make their own decision regarding emergency and research-based use of a viral filter.

Viral filter information is based on the viral filter manufacturer specs and have not been independently tested.

See this video: [Viral filter selection: https://www.youtube.com/...](https://www.youtube.com/...)

Filter decontamination is a controversial and continuously shifting topic. See CDC recommendations.

Unless you really know what you are doing, it is recommended that a filter not be used beyond the duration it routinely is used in a surgical setting. These filters are often used for 12hour in surgical settings. Consult your infectious disease or EHS department.

Note for large users over 90kg:

Lower flow resistance IS desirable for more airflow. Most users are fine filters with 2 cm H₂O resistance at 60 LPM (that's the spec, not our run CFM). However, if user is in the 90Kg+, their baseline minute ventilation will near limits of what a higher resistance filter will handle. A lower 1.5 cmH₂O resistance at 60 LPM filter easily handles larger users. If local supply only has high resistance filters, large users would benefit from two parallel filters. I'll add an optional STL for dual filter soon. Average size users are fine, but there are some big people out there.

The flow rate is not guaranteed for this filter and fan combo. And adequate flow rate for your lungs and type of work may vary. Quote: this study and other studies indicate a minute volume of 33LPM when doing moderate work. If this is not meant for that level of activity, maybe you could just mention it in your guidelines. Links:

<https://multimedia.3m.com/mws/media/378601O/interpretation-of-inhalation-airflow-measurements.pdf>

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6720108/>

Do not sleep with this on or if you have a situation where you may pass out. There is risk of death from asphyxiation.

Fan

Make sure that the fan is operating correctly.

One tip is to tape the cables to the headband or arch-piece to provide some strain relief. Some people can pull too hard and separate the power cables from the fan.

Battery and cables

“when we’re talking about hospitals, patients, oxygen tanks and hoses etc....
I think we should at least make the recommendation of safer batteries” - user comment

USB Battery packs may have fire risk that is unsuitable for hospital setting.

To decrease the risk of fire, use a “UL listed” or otherwise certified battery pack.
Be wary of “dollar store” battery packs.

If in doubt, consider using a AA to 5V USB adapter (example: [this product](#) link)

Always have a spare battery handy in case your current battery runs out of charge.

Bag

Bags have suffocation risk if air flow decreases or the wearer loses consciousness.

bunnyPAPR should not be used in “solo” situations.

Use the “buddy system”.

3D printed Parts

3D printed parts may be reused, but they do have a risk of contamination.

Follow CDC recommendations consistent with the decontamination of hospital equipment.
Guidelines for plastic equipment is best.

When in doubt, throw it out. If you can find a local 3D printer, replacement parts cost about \$1-\$2 of materials.

Disinfection and decontamination

Follow CDC recommendations consistent with the decontamination of hospital equipment.

Guidelines for plastic equipment is best.

OSCMS provides a document on sanitization procedures depending on the material chosen:

https://docs.google.com/document/d/18wglUR_EHlZrVIUhgp2xzGuBhXCbtFdl3ESC8EefPgl/edit

Note that some materials do not react well to alcohol, bleach, heat, autoclave, or other cleaning techniques. THEY MAY MELT PLASTIC OR DISSOLVE PLASTIC.

We have not reviewed that document or confirmed those results. Please see OSCMS's disclaimers.

CONCLUSIONS AND LEGAL

Please stay safe in this complex and difficult time of Covid-19.

This equipment is NOT certified for use in medical settings in the US. Consult your legal department about whether this gear is okay to use.

The reasonableness to use this gear depends on a judgment call BY YOUR MEDICAL FACILITY.

Read all instructions for use and assembly on tinyurl.com/bunnyPAPR.

By using this experimental and not FDA-certified equipment, you understand the risks inherent in "improvised" gear that *may* provide protection but is untested. Protection has NOT been proven to be adequate.

You agree to

To the fullest extent permitted by law the recipient of information or gear shall indemnify, defend and hold harmless the owner, inventor, volunteers, and agents and employees of any of them from and against any claims, damages, losses and expenses, including but not limited to attorneys' fees, arising out of or resulting from use of this product, whether caused in whole or in part by the contractor, a subcontractor, anyone directly or indirectly employed by them or anyone for whose acts they may be liable.

Except as represented in this agreement, all work product by Developer is provided "AS IS". Other than as provided in this agreement, Developer makes no other warranties, express or

implied, and hereby disclaims all implied warranties, including any warranty of merchantability and warranty of fitness for a particular purpose.

For the above paragraph and other references in this document, “Developer” and “developer” refers to the inventor, any volunteers or staff at bunnyPAPR.org, and any associates or partners, where the discretion to name as an associate or partner is held jointly by the inventor and bunnyPAPR staff/volunteers.

FROM the OSCMS

(https://docs.google.com/document/d/1-71FJTml1Q1kjSDLP0EegMERjg_0kk_7UfaRE4r66Mg/e/dit#)

Good Samaritan Laws in the United States

In the United States, Good Samaritan laws offer legal protection from civil lawsuits to people who voluntarily provide reasonable aid to those who are injured, ill, in danger, or otherwise incapacitated. A claim of negligent care can also be raised if the injuries or illness were made worse by the volunteer's negligence. Laws generally do not exempt a Good Samaritan who acts in a willful, wanton or reckless manner in providing care, advice, or assistance.

We are providing you with the specifications you will need to manufacture items which are much-needed during this pandemic; however, you are responsible for your creations, so please practice due diligence (the care that a reasonable person exercises to avoid harm to other persons or their property). We want your contributions to help, not harm!

If you are familiar with similar laws in other countries, please reach out to us with relevant references.

References: [Good Samaritans](#) (US Legal)

For bunnyPAPR:

To the maximum extent permitted by law, the Developers claim legal protection via Good Samaritan Laws where healthcare professionals or at-risk people or everyday people are in danger of infection and the serious harm that comes from infection.

Please do not sue anyone.

Please. Please. Please.

Additional Videos

- Fan electrical assembly:
<https://drive.google.com/file/d/1phVLmRycZwPdfcOOofMrYJTG9CxSqRXIm/view?usp=sharing>
- video: how to fenestrate / pierce the bag: <https://youtu.be/MZ2L8orriFo?t=214>
- Inventor's YouTube channel:
<https://www.youtube.com/channel/UCDyGsgboscQITrPb5g7S6Kw>
- Viral filter selection: <https://www.youtube.com/watch?v=IlgNzBse14w>
- Assembly brief: https://www.youtube.com/watch?v=NXW0xUPI0_c
- Hackathon video: <https://youtu.be/sSDP1QZUJfo> or
<https://tinyurl.com/bunnyPAPR3minVideo>
- (add more here)