N95 FFRs in Austere Situations (considerations for reuse and prolonged use)

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**Please note: this resource was compiled in a short period during a time of need, when "traditional regulations" are having to be re-evaluated for the safety of the public and healthcare workers. Suggestions here are based on research (all is cited), but is not condoned/evaluated by a governing body. This is just one person's attempt to be useful on a grander scale than just her normal clinical duties. As with everything in life, please critically analyze all you read, evaluate the citations yourself, and use (or don't use) as you see fit and proper.

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INTRODUCTION

Disposable N95 Filtering Facepiece Respirators (FFRs) [what in healthcare is colloquially known simply as an N95] can become depleted during any pandemic with respiratory transmission concern. While it is not recommended to reuse N95 FFRs, under exceptional circumstances this may become necessary.

Disclaimer this was created during the COVID-19 pandemic, so some information may be more directed toward COVID-19/viral contamination. Certain aspects may be different for various other contaminants. Also, references located in "info" sections.

Ideally this is anticipatory action, **before** a shortage of N95 FFRs becomes a reality.

In addition to prolonged use/reuse, consider:

- Minimizing number of individuals exposed/requiring N95 protection
- Prioritizing supply to those most at risk

- Utilization of other N95 FFR equivalents: elastomeric respirators & powered air purifying respirators (PAPR).

You MUST be fit tested to a specific N95 FFR and only use this model of mask. **EVERY time you don an N95 FFR you MUST conduct a "user seal check."** See Info tab for YouTube video - fast track to 3:10 min.

Manufacturer's recommendations around acceptable duration of use:
~8 hours (constantly or intermittently) or until filter becomes clogged and thus difficult to breathe through.

In reality, how long may these respirators work?
Hard to say. If you're using them in a clean (hospital) environment, logic suggests a lot longer than 8 hours. Especially if you're using "difficulty to breathe through" as your indicator for discarding.

- In support of this theory is an experiment done (with respect to air pollution) after reusing an FFP3 mask (higher rating than N95; ~N99) over 11 days (1.5 hrs/day = approx. 16.5 hrs). Fit testing compared the used respirator to a new one:
    - **New**: %particles blocked = 99.7
    - **11 day old**: %particles blocked = 98.3

INFO/REFERENCES
Much of these guidelines come from:
https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html

Article on transmission:
http://www.cidrap.umn.edu/news-perspective/2020/03/commentary-covid-19-transmission-messages-should-hinge-science

Considerations for prolonged/reuse in healthcare settings:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4610368/

CDC: resp protection options
https://blogs.cdc.gov/niosh-science-blog/2017/07/06/elastomerics/

CDC SARS recommendation doc:
https://www.cdc.gov/niosh/npptl/topics/respirators/factsheets/respsars.html

User Seal Check (skip to 3:10)
https://www.youtube.com/watch?v=pGXiUyAoEd8

11 day old FFP3 respirator:
https://smartairfilters.com/en/blog/how-long-masks-last/

http://med-fom-pediatrics.sites.olt.ubc.ca/files/2015/04/Respiratory-Protection-Program-FAQ142.pdf

N95 FFR BASICS

What does N95 actually mean? (Note: this is a North American classification system, the EU has a different system)

NIOSH Classification:
Letter - designates the filter's oil resistance

- N - not oil resistant
- R - oil resistant
- P - oil proof

Number - designates % particles at least 0.3 microns in size that are filtered out

- 95 - 95%
- 99 - 99%
- 100 - 99.97% (HEPA quality filter)

Viral particle size is generally <0.3 microns, but are within mucus/sputum, thus becoming larger.

Main mechanisms by which respirators filter air - **mechanical** (inertial impaction, interception, and diffusion).
Part of their functionality comes from the **electrostatic charge** applied to the filter fibres (not present in surgical masks). This allows the respirator to increase its efficacy without increasing respiratory resistance.

Filters are not sieves, there is a particle size that is the hardest for a filter to capture. This is called the "most penetrating particle size" (MPPS) and is size all filters are to test their efficacy against. Typically the MPPS is 0.3 microns.

Aerosolized "droplets":

- Larger 5-15 microns (typical droplet) - airborne x minutes
- Smaller <5 microns (droplet nuclei) - airborne x min-hrs

(all sizes decrease with time due to evaporation; thus droplets can become droplet nuclei)
Significant risk reduction with air currents/negative pressure spaces.

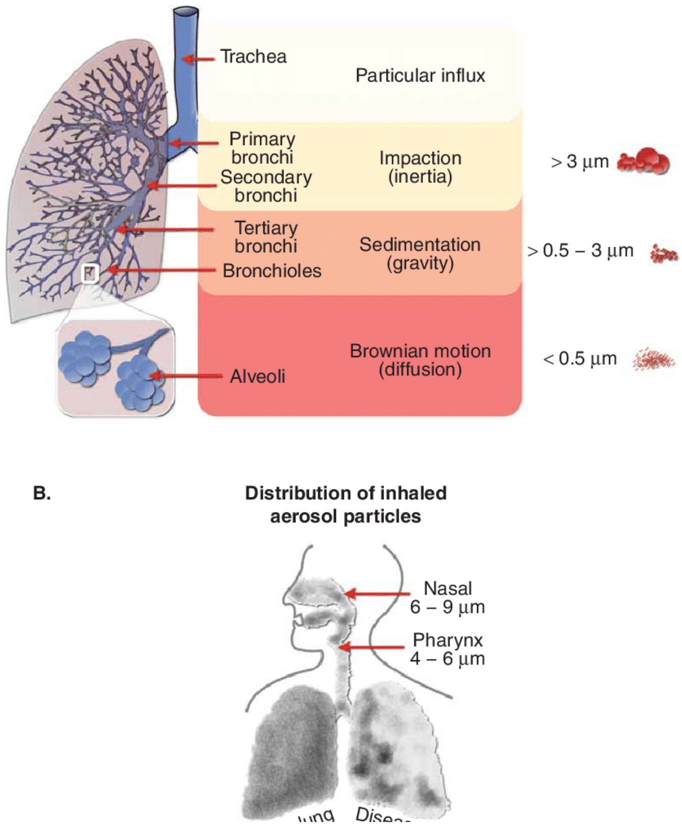
Human created droplets/droplet nuclei 0.5-12 microns

- Sneeze – 40,000 droplets
- Cough – 3000 droplet nuclei
- Talking 5 min – 3000 droplet nuclei

A study looking at N95 FFR protection against viral particles found 1 of 2 respirators tested did not provide the 95% protection level advertised (5.6%

penetration) with increased inhalational flows (heavy work of breathing). The other N95 FFR allowed max penetration ~4% a same increased flows.
NOTE the particle size associated with highest percent penetration was ~0.05 microns.

Particle	Size (in microns)
Beach sand	100 - 4,000
Human hair	50 - 140
Mold Spores	5.0 - 30
Cement dust	3 - 100
Pet dander	2.5 - 10
Anthrax	1.0 - 1.25
Vehicle emissions	1 - 150
Coal dust	1 - 100
Staph & Strep	0.8 - 1
Talcum powder	0.5 - 50
Asbestos	0.7 - 90
Insecticide dust	0.5 - 10
Pollens	0.35 - 250
Bacteria (range)	0.2 - 5
Ebola virus	0.2 - 0.3
Pneumonia	0.2 - 0.3
Whooping cough	0.2 - 0.3
Influenza (flu)	0.12 - 0.3
Chicken pox	0.12 - 0.2
Radioactive fallout	0.1 - 1
Viruses (range)	0.01 - 0.3
Oxygen	0.0005



https://ellessco.com/myair-mask/myair-technical-info
https://www.researchgate.net/figure/Pulmonary-deposition-of-inhaled-particles-and-their-way-of-separation-in-healthy_fig1_271764679

Table B. Size of Various Microorganisms

Microorganism (common name or disease)	Physical Size (µm)
Hepatitis virus (Hepatitis B)	0.042 - 0.047
Adenovirus (respiratory infections)	0.07 - 0.09
Filoviruses (Ebola)	0.08 diameter 0.79 - 0.97 length
Bunyaviridae (Hantavirus)	0.08 - 0.012
Orthomyxoviridae (Influenza A, B, & C)	0.08 - 0.012
Coronaviridae (SARS - CoV & MERS - CoV)	0.125
Variola Virus (Smallpox)	0.14 - 0.26 diameter 0.22 - 0.45 length
Mycobacterium tuberculosis (TB)	< 1 to > 5 diameter
Bacillus anthracis spore (Anthrax infection)	1.0 - 1.5 diameter

https://multimedia.3m.com/mws/media/409903O/respiratory-protection-against-biohazards.pdf

INFO/REFERENCES
https://www.ncbi.nlm.nih.gov/books/NBK143281/

Filter functions/MPPS:
https://blogs.cdc.gov/niosh-science-blog/2009/10/14/n95/

Influenza patient mask viral copies:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3591312/

https://multimedia.3m.com/mws/media/4099030/respiratory-protection-against-biohazards.pdf

Variance of N95 FFR protection for viral particles:
https://www.sciencedirect.com/science/article/pii/S0196655305009119?via%3Dihub

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<u>N95 FFR ALTERNATIVES</u>

For reference:
APF = Assigned Protection Factor
Essentially, higher the AFP the more protection it gives; N95 FFR has AFP of 10
There are AFP values on the picture examples of Elastomeric and PAPR example pics.

This may be the best solution in pandemic situations for multiple reasons; specifically elastomeric respirators

1. Sheer **number** of disposable N95 FFRs required. It has been previously estimated that if the USA were to experience a similar pandemic to the 1918 Spanish Flu, this country ALONE would require at least **1.95 billion** N95 FFRs. Conversely 3.4 million elastomeric respirators would be required.

2. **Cost** of protecting high-risk workers (stockpiling situation). Cost per person:
   - Disposable N95 FFRs = $240 USD/person
   - Elastomeric respirators = $40 USD/person

Barriers to implementation
Administration push back due to:
- "Patient perception" given "gas mask look".
- Not routinely used in healthcare, thus lack of guidance/best principles for safe implementation

This does have to be a civil discussion between frontline workers and administration to build a good working relationship

INFO/REFERENCES
Good slide deck on different types of respirators
https://slideplayer.com/slide/14084001/

Cost/number of N95 FFR vs Elastomeric:
https://www.nap.edu/read/25275/chapter/5

https://www.cdc.gov/niosh/npptl/pdfs/ElastomericPAPR-Healthcare-508.pdf

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ELASTOMERIC RESPIRATORS

This may be the best option for pandemic situations as filters can last for weeks-months in clean environments
Per OSHA - protective factor equal to N95 FFR
Each person is responsible for their own respirator, and fit test required

Half face and full face available

Synthetic/rubber face piece = easily disinfected (usually recommend bleach-water mixture, but each manufacturer has specific recommendations). May use alcohol on exterior surface between patients as needed.

Particulate filters would be needed, but the cartridge/filter combo can also be used (additional protection from fumes/gases) easily detachable/changeable.

- Filters - ? potential to be disinfected with UV-C or heat?
- Cartridges - pose more of a disinfection problem.

Study found **cleaning alone** (neutral detergent) was sufficient for killing/removing influenza virus.

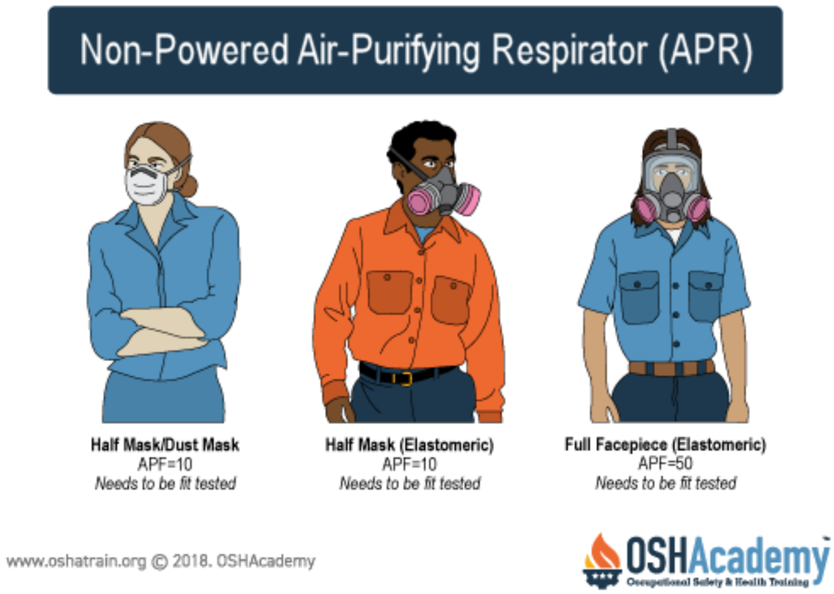
Disinfection:

- Facepiece (detached filters) - soak in solution of 30mL household bleach in 7.5 L of water. Scrub with soft bristle brush
- Rinse in fresh, warm water, leave to air dry

Video for demonstration of respirator disassembly/assembly for cleaning (not disinfection)
https://www.youtube.com/watch?v=Jp1XQ-7gtWc

INFO/REFERENCES
https://multimedia.3m.com/mws/media/4739370/3mtm-cleaning-reusable-respirators.pdf

Cleaning sufficient for killing/removing influenza virus:
https://www.ncbi.nlm.nih.gov/pubmed/28844381



<u>POWERED AIR PURIFYING RESPIRATOR (TIGHT FITTING)</u>

AKA PAPR
Superior respiratory protection compared to N95 FFR or elastomeric respirators due to the slight positive pressure the respirator generates to pull air through the filter. Thus less likely for seal to break from inspiration/negative pressure generation.

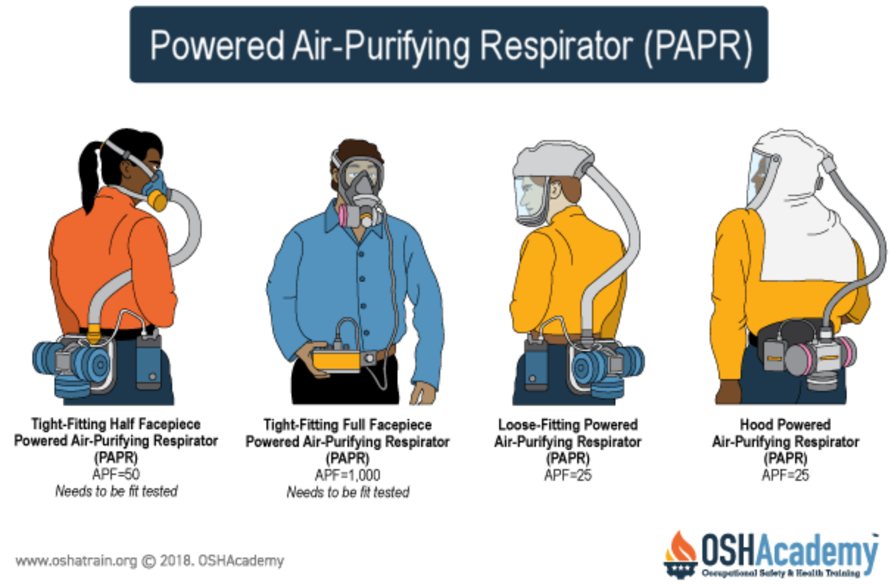
Half face or full face available

Disadvantages:
- Battery powered
- Ergonomics (bigger/bulkier)
- Peripheral vision restriction
- Higher initial cost

Expert opinion suggests that a PAPR is likely the safest way to deal with high-risk procedures (intubations - high concentration of viral exposure) in patients affected by coronaviruses.

INFO/REFERENCES
https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html

Expert opinion for PAPR and coronavirus:
http://www.cidrap.umn.edu/news-perspective/2014/05/commentary-protecting-health-workers-airborne-mers-cov-learning-sars



REUSE GUIDELINES

When this is generally appropriate:

- Contact transmission (fomites - object or material likely to carry infection) is not a concern (ex. TB prevention)

May need to employ this in low resource situations when breaking from work environment (meal, bathroom breaks)

How do determine if fit to reuse?

- No uniform good answer to this, big concern is going to be risk of contact transmission (Suggestion from the CDC that this is not the most important mode of transmission).
- General recommendation is to not use **>5 times** (some brands may have manufacturer's guidance here)

Tips on doing this as safely as possible:

- Use of shields to prevent N95 FFR contamination (cleanable face shield or surgical mask)
- Mask patients (surgical)
- Minimize touching N95 FFR/continuous hand hygiene

Storage options of used N95 FFRs:

1. Hang in a designated area
2. Place in clean/breathable container (ex. paper bag)

Storage tips:

- Ensure separation of N95 FFRs to avoid cross-contamination
- Clean or dispose of storage bags regularly

- Avoid contact with interior of FFR
- Label FFR to ensure **same user gets same FFR**

Study has shown little risk of contamination of inner surface of used respirator from migration of microorganisms during storage.

Concern/consideration with storage/hanging
Potential for viral (COVID-19 specific) particle release from contaminated clothing. High concentrations of viral RNA found in areas used for doffing in Wuhan makeshift hospital. (18-42 copies/m3).
Potential solution to this *- air current/negative pressure set up for doffing spaces. Air sampling in ICU and other patient care areas with negative pressure found to have no viral particles*

Donning used N95 FFR:
- Use clean gloves to don & dispose of them once happy with FFR fit/comfort

DO NOT reuse if FFR does not provide a proper seal (ex. loss of band elasticity) or meets other criteria to discard (see "When to discard" section)

INFO/RESOURCES
Viral particles in doffing space:
https://www.biorxiv.org/content/10.1101/2020.03.08.982637v1.full

Migration of microorganisms:
Johnson, B., Winters, D.R., Shreeve, T.R. and C.C. Coffey. Respirator filter reuse test using the laboratory simulant mycobacterium tuberculosis (H37RA strain). J. Am. Biol. Saf. Assoc. 3:105-116; 1998.

PROLONGED USE GUIDELINES

Key to success: N95 FFR must continue to fit and function properly during use period

When this is appropriate:
- Same pathogen affecting both/all patients
- Same location of patients (ward, tent, etc.)

Generally preferred method in low resource situations. Less N95 FFR touching = fewer opportunities for contact transmission

Tips to increase functional time:

- Use of shields to prevent N95 FFR contamination (cleanable face shield or surgical mask)
- Mask patients (surgical)
- Minimize touching FFR/continuous hand hygiene

INFO/RESOURCES
https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html

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WHEN TO DISCARD

Ideally discard N95 FFRs in these scenarios:

- Obviously damaged
- Difficult to breathe through
- After aerosol generating procedures.
- When notably/visibly contaminated (blood, secretions, bodily fluids)
- After close contact with a patient on contact precautions. (Technical recommendation but becomes a difficult disposal criteria in respiratory pandemics)

How to protect your N95 FFR from contamination:

- Use a cleanable face shield
- Give the patient a regular surgical mask
- Hand hygiene before and after touching N95 FFR (if needed for improved fit/comfort)

INFO/RESOURCES
https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html

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MICROORGANISMS ON N95 FFR

The extent to which microorganisms can persist/survive, their likelihood to act as fomites, and their ability to re-aerosolize is important for considering N95 FFR reuse.

Microorganism persistence/survival
On N95 FFR porous materials viral infectivity persists at least 8 hours, thus in situations where times between reuse <1h, majority of viral particles will remain viable.

- Studies on different strains of **H1N1** showed varying results. One found continued infective particles up to 6 days, another showed undetectable levels at 8 hrs on N95 FFRs.
- SARS-CoV-1 and SARS-CoV-2 remain viable on various surfaces >24hrs

- Specific to COVID-19: based on previous studies and CDC suggestion, transmission via fomites (objects that can carry infection) is less of a concern compared with droplet/close-range aerosol transmission. This does not mean it is not a concern.

Transfer efficiency (of particles from fomites)
No good research been done. Preliminary research suggests lower risk of transfer from porous materials and with low humidity.

Re-aerosolization from used N95 FFRs
In general, the larger the particle on the N95 FFR, the more likely it is to be re-aerosolized.

One study found particles 0.8-1.0 micron had percentage re-aerosolized of 0.02% when exposed to reentrainment velocities up to 400 cm/sec. Versus 6-7% re-aerosolization for 5 micron particles.

INFO/REFERENCES
Re-aerosolization of bacteria and particulate:
https://www.cdc.gov/niosh/nioshtic-2/00240845.html

SARS-CoV-1 and SARS-CoV-2
https://www.nejm.org/doi/full/10.1056/NEJMc2004973

H1N1 persistence on N95 FFR (paper 1):
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3623216/

H1N1 persistence on N95 FFR (paper 2):
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2955907/

SURGICAL MASKS, WHAT ARE THEY GOOD FOR?

This mask was designed to prevent an infectious person from spreading disease. Thus, NOT created for an ASYMPTOMATIC person to be wearing.

They are helpful for PPE from a perspective of gross contamination (being splashed or sprayed), but generally not recommended as a "filtering device" for respiratory protection.

Surgical masks do not have an APF rating by OSHA (see N95 alternatives section for APF details), thus their ability to reduce inhaled airborne particulate cannot be commented on, and should not be relied upon.

Study specifically on influenza particles from patients wearing surgical masks:

- Small droplets (<5 microns) contained 8.8x more viral copies compared to large droplets (>5 microns)
- Use of surgical masks decreased viral aerosol shedding.
    - In small droplets 2.8 fold reduction viral copies
    - In large droplets 25 fold reduction viral copies
    - Overall decreased viral shedding decreased 3.4 fold

Another study looking at **bacterial** respiratory infections in healthcare workers in Beijing when using N95 FFRs vs. surgical masks vs. no mask. Rates of bacterial colonization:
- N95 FFR = 2.8%
- Surgical mask = 5.3%
- No mask = 7.5%

A study (previously mentioned in N95 FFR Basics section) also evaluated % virion penetration through 2 types of surgical masks. Variation between the two was immense, one plateauing at ~20.5% penetration, the other allowing up to 84.5% penetration. Both at higher flow (heavy breathing) rates.

INFO/REFERENCES
https://multimedia.3m.com/mws/media/409903O/respiratory-protection-against-biohazards.pdf

Influenza patient mask viral copies:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3591312/

N95 vs. surgical vs. no mask
https://www.ncbi.nlm.nih.gov/pubmed/24472436

% virion penetration in surgical masks:
https://www.sciencedirect.com/science/article/pii/S0196655305009119?via%3Dihub

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<u>CLEANING/DISINFECTION N95 FFR</u>

Cleaning - removing visible noninfectious dirt or contaminants from an object
Disinfecting - killing/deactivating infectious microorganisms from an object

Potential issues with various proposed disinfection methods:
- <u>Heat/steam</u> - requires drying! may melt/degrade FFR
- <u>Chemical disinfectants</u> - odors/skin irritants
- <u>Alcohols</u> cannot be used - destroy electrostatic charge on FFR decreasing filtration ability.
- <u>UVGI (specific wavelength of UV-C)</u> - degrades polymers (what FFRs are made of) but reasonably promising at lower doses **likely best option**
- <u>Dry heat</u> - higher temps can melt polypropylene.

Moist heat and chemical disinfectants are not reviewed here in detail due to lack of feasibility/adherence in healthcare setting.

Disinfection does not address ability to **restore filter function** after prolonged use. The importance of this is likely minimal given evidence to suggest filters may not clog for many days-weeks in clean environment.

One study showed promising **ability to disinfect** N95 FFRs. Three methods tested were (all effective at eliminating influenza):
- Ultraviolet germicidal irradiation (UVGI; 254nm wavelength)
- Microwave-generated steam
- Moist heat

UVGI within this study - 15min at 1.8J/cm2 resulted in effective disinfection of FFRs contaminated with H5N1.

Potential for the following to also be applied to the elastomeric particulate filters? – Logically makes sense

Another UVGI study
Study exposed FFRs to doses of UV-C ranging from 120-950 J/cm2. Found:
- Small increase in particle penetrance (1.25%)
- Minimal effect on flow resistance
- Significant decrease in respirator material integrity (elastic straps not significantly affected), dose dependent and FFR model dependent
- Concluded that use of UVGI may work but likely for limited number of disinfections and would depend on FFR model.

Other considerations for usage of UV-C is the perceived concern it generates **ozone**. However, this should not be a concern given the only aspect of the UV spectrum that generates ozone is Vacuum UV (100-200nm wavelength). UV-C spectrum is between 200-280nm, but optimal germicidal capability is found ~254nm. **Additional safety layer** with germicidal UV-C bulbs is they are made with doped quartz glass, which actually blocks 185nm (the wavelength generally used to create ozone). Additionally, the 254nm wavelength can actually be used to destroy ozone.

Very few studies have been done using **dry heat** as a form of disinfection (advantage over wet heat – no drying!).
- One study found no visible changes to an N95 FFR at 80degC however was melted after 22 min at 160degC. (Melting point polypropylene 165degC)
- Another looking at SARS-CoV inactivation found complete inactivation of the virus at 75degC for 45 min (or 56-65degC for 90 min)

There is likely a role for heat in viral disinfection of N95 FFRs, however there is much less data on its effect on FFR particle penetrance or flow resistance when compared with UV-C.

INFO/REFERENCES

Example of UVGI protocol:
https://www.nebraskamed.com/sites/default/files/documents/covid-19/n-95-decon-process.pdf

UVGI specific:
https://www.ncbi.nlm.nih.gov/pubmed/25806411

3 methods evaluated:
https://www.ncbi.nlm.nih.gov/pubmed/21859950

UV-C and ozone:
http://www.uvresources.com/blog/the-ultraviolet-germicidal-irradiation-uv-c-wavelength/

https://www.oxidationtech.com/ozone/ozone-production/uv-lamp.html

Heat:
https://www.isrp.com/the-isrp-journal/journal-public-abstracts/1138-vol-24-no-3-and-no-4-2007-pp-93-107-viscusi-open-access/file

https://www.sciencedirect.com/science/article/pii/S016609340400179X