

Disinfection and Reuse of Personal Protective Equipment

A global shortage of respirators (e.g., N95 and N100) and surgical masks has led the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) to recommend conservation and, when necessary, the reuse of respiratory personal protective equipment (PPE) in response to the COVID-19 (SARS-CoV-2) surge.^{24-25, 36-37} As a last resort, homemade masks should only be used when supplies of medical masks or respirators have been completely depleted.

This document is intended for use by a technical audience with an interest in the available information available regarding the disinfection and reuse of PPE. This document describes potential decontamination alternatives for single-use respiratory protection, which the CDC does not recommend except as part of a crisis capacity strategy. Respiratory protection includes air-purifying respirators (APRs) such as N95 and N100 filtering facepiece respirators (FFR), powered air purifying respirator (PAPRs), and half-mask elastomeric respirators (HMERs). There is limited to no science-based information available regarding effective disinfection methods for medical masks (also known as facemasks, surgical, isolation, dental, or medical procedure masks) and the recommendations in this document are based on subject matter expert evaluation of materials compatibility. Medical masks – whether they are commercial products or homemade alternatives – should be considered to provide protection ONLY against large-particle droplets or coarse splatter at best. Such masks are intended to prevent the individual wearing a surgical or cloth mask from infecting others and should not be considered to provide protection against aerosols or fine droplets that might be generated when COVID-19 infected individuals breath, talk, sneeze, or cough.

Table 1 lists disinfecting agents and processes that are likely to be efficacious against SARS-CoV-2. Studies have shown that vapor phase hydrogen peroxide (VPHP), thermal disinfection (heat), and ultraviolet germicidal irradiation (UVGI) exposure can be performed multiple times on the same FFRs, extending wear significantly beyond single use. However, only a subset of FFR models have been tested, and manufacturer differences in materials and construction may affect disinfection efficacy and/or filtering performance. Heavily soiled or damaged PPE is not appropriate for decontamination and reuse. The CDC recommends disposing single-use FFRs (e.g. N100 or N95) and surgical masks contaminated with blood or other bodily fluids.²⁹ Additionally, for some methods of disinfection, such as UVGI, efficacy is highly dependent on PPE composition and shape, positioning within the exposure area, as well as lamp power. The supporting scientific studies and manufacturer publications used to develop this table are referenced and further summarized on subsequent pages of this document.

Table 1. Disinfectants for FFRs and Surgical Masks¹

Disinfection Method	FFR	Surgical Mask
Soap and Water	INC	INC
Alcohol-based Sanitizers	INC	INC
Bleach	✘	INC
VPHP*	✓	✓
Heat	✓✓	✓
UVGI	✓✓	✓
References	1, 19, 22, 23, 25, 31	22, 31

✘ = do not use, may degrade equipment

INC = Incompatible/Ineffective

✓✓ = efficacy and compatibility verified in scientific or product literature

✓ = likely effective based on subject matter expert material compatibility assessment

*VPHP is not compatible with APRs and other PPE that may contain cellulose-based (aka paper or paper fiber-based) materials

Table 2 lists manufacturers and suppliers of disinfection/decontamination equipment with their website for reference. This list is not inclusive of all suppliers, nor does it imply endorsement by the Department of Homeland Security. Pricing is customized—meaning that a quotation for services is required.

Table 2. Selected Disinfection Equipment Manufacturers

Disinfection Method	Company	Production or On-site Service	Website
VPHP	Bioquell	BQ-50 and On-site	https://www.bioquell.com/
	Controlled Contamination Services	On-site	https://cleanroomcleaning.com/
	Pathogend	On-site	https://pathogend.com/
	Sterilucent	PSD-85	http://www.sterilucent.com/
	STERIS	VHP 1000ED and On-site	https://www.sterislifesciences.com/
UVGI	Lumalier	EDU	https://www.lumalier.com/
	MRSA-UV	Obelisk-UV	https://www.mrsa-uv.com/
	UltraViolet Devices, Inc.	UVDI-360	https://www.uvdi.com/

Efficacy of Respirators and Medical Masks

Commercial respiratory protective equipment such as powered air purifying respirator (PAPRs), half-mask elastomeric respirators (HMERS), and FFR (N100) demonstrate filtering efficiencies of 100% ($\geq 99.97\%$) and FFR (N95) of $\geq 95\%$. Surgical masks are intended to protect the patient from the individual wearing the mask and have a lower filtering efficiency, at 30-42%,^{5, 15, 26} but wearing them under a face shield to reduce splashes and large droplets will improve the protective factor. FFRs and surgical masks contain an electrostatic filter layer that attracts and traps particles and enhances their efficacy.

What if there are no APRs or medical masks available?

The CDC recommends using bandanas or handkerchiefs as a last resort makeshift mask when proper PPE is unavailable.²⁴ There is conflicting evidence whether cloth masks provide protection from respiratory infection. One study found a higher incidence of acquired flu like illness in healthcare personnel using cloth masks as compared to personnel who wore medical masks or used standard practices with optional mask use.²⁰ Cloth masks offer better protection when worn by an ill person to stop droplet spread from coughs and sneezes.¹⁰ If APRs and medical masks are not available and homemade or makeshift materials are the only alternative, choose fabrics that are densely woven (high thread count) and use multiple layers, preferably turning layers 45 degrees (on the bias) to improve barrier density. Fabrics may include thin towel (terrycloth), sheeting, t-shirt, and scarf materials (Table 3). Masks should be made to minimize gaps between the mask and skin and with pleats across the outside to maximize surface area, with a different lining or marking so that the mask is not accidentally worn with the contaminated side against the skin. The low filtration efficiencies of surgical masks and improvised medical masks summarized in Table 3 should help reinforce the previous caution that such masks offer limited protection against infectious aerosols or fine droplets.

Table 3. Aerosol Filtration Efficiency of Alternative Materials

Mask/Material	Filtration Efficiency*	Reference
Surgical mask	30-42%	5, 15, 26
Towel	34-40%	26
T-shirt	<14-51%	10, 26
Scarf	11-49%	10, 26
Bandana	2-13%	5, 15

* Note that these results are grouped in an apparent equal manner simply for convenience, and the sources should be reviewed if details are required. Each of the four cited examples used a different test and measurement technique; e.g., different aerosol sizes and particle types were used, some tested fit on Styrofoam head forms, others just used material samples, etc.

Supporting Documentation

The Department of Homeland Security Science and Technology Directorate Hazard Awareness and Characterization Technology Center developed this report to document and summarize the available literature on disinfection methods for filtering facepiece respirators (FFRs) and other personal protective equipment (PPE). This report is intended for use by healthcare personnel and first responders, and specifies the following information:

- Types of disinfectants available and their potential use for air-purifying respirators (APRs) and PPE decontamination (at this time, the Centers for Disease Control and Prevention (CDC) does not recommend decontamination of FFRs except as part of a crisis capacity strategy);
- Vendors that can provide commercial disinfection services;
- Literature supporting the efficacy of disinfectants for APRs and other PPE; and
- Alternative materials and their suitability for respiratory protection.

At this time, both the World Health Organization (WHO) and CDC have released statements regarding an imminent or already existing shortage of respiratory protection and other forms of PPE.^{24-25, 36-37} Those documents educate medical professionals, healthcare personnel (HCP), and first responders on best practices for extending the current PPE supply, such as what PPE should be worn during various procedures (medical, transport, etc.) and whether PPE can be worn while caring for several patients (e.g., extended wear and re-wear situations). Respiratory protection is of highest concern, because other hygiene practices such as engineering controls to isolate patients with diagnosed COVID-19 to minimize contact and appropriate handwashing can reduce exposure risk except during aerosol-producing procedures. The CDC has published guidance on potential decontamination of FFRs in a crisis standard of care and recommends ultraviolet germicidal irradiation (UVGI), vaporous phase hydrogen peroxide (VPHP, also known as VHP), and moist heat for use with specific FFR models.⁶ Manufacturer differences in composition and construction may reduce efficacy of disinfection or negatively impact material fit, form, or function post-treatment. Additional studies have shown that heat (>70°C (158°F) for 30 minutes) is efficacious against coronavirus and is included as a potential decontamination method.¹⁷

The primary goal of this document is to provide HCP and first responders with science-backed options for decontaminating respiratory protection and other PPE.¹ Additionally, this document

¹ It must be recognized that while many studies have evaluated various options for decontaminating respiratory protection and other PPE, no peer-reviewed studies have yet been released for the newly-identified COVID-19 (SARS-CoV-2). Knowledge gaps have

will report the variable results obtained with cloth masks, so that HCP can make informed decisions regarding the use of homemade or makeshift respiratory protection in the event of a complete outage of APRs and surgical masks in their area. The first two pages are intended to be a stand-alone flyer that can be distributed to healthcare safety professionals or respiratory program administrators for at-a-glance information about disinfection services and best practices if respiratory protection is unavailable in their area. The information in this Appendix summarizes the supporting scientific research and manufacturer claims; the disinfectant technologies (VPHP and UVGI) should only be implemented by trained professionals.

This document is meant to complement the CDC and WHO guidance. HCPs and first responders are advised to consult CDC or WHO, OSHA, and other official sources for the latest guidance, and their facility guidelines when making decisions to decontaminate and reuse single-use PPE and/or for use of alternative materials as respiratory protection.

Summary of Scientific Literature and Market Review

A scientific literature and market review were performed to collect information on options for disinfection of respiratory protective gear and other PPE and alternative materials for homemade or makeshift face masks. Protective gear should be used in accordance with the WHO and CDC guidelines, and decisions regarding the disinfection of PPE or use of alternative materials for PPE should be made in conjunction with the appropriate administrative authorities.

This section includes detailed scientific information about:

- Available types of disinfection and efficacy for various PPE; and
- Alternative materials and their suitability for respiratory protection.

VPHP, UVGI, and heat have been reported as suitable choices for disinfection of items contaminated with SARS-CoV-2.⁶ Because the virus originated late in 2019, no peer-reviewed studies have been published to date with SARS-CoV-2 directly. Instead, researchers used related viruses in the coronavirus family or surrogate organisms that are biologically similar to SARS-CoV-2 to assess disinfectant performance. A potentially significant limitation in the identified studies was that most used pristine challenge conditions, i.e. when the organism or inert particle was in a clean buffer such as saline or sterile distilled water, and when the APR had not been worn.^{2, 5} One study evaluated the effect of blood on VPHP efficacy.³⁵ Further research to confirm the efficacy of VPHP disinfection of APR for the virus in the presence of a broader range of physiological-relevant materials such as saliva, sputum, mucous, skin oil, etc. will improve the use of this technology during infectious disease outbreaks. Studies have been performed without bacterial or viral challenge to evaluate whether PPE materials degrade on exposure to various disinfectants. One such study by Viscusi, et al., (2009) evaluated the use of bleach, hydrogen peroxide vapor with low-temperature gas plasma (HPGP), UVGI, ethylene oxide, and microwave irradiation on several models of FFRs and found that UVGI, ethylene oxide, and HPGP were potentially suitable decontamination methods.³³ Neither UVGI or ethylene oxide caused observable damage, and the only noted change after treatment with HPGP was that metallic nosebands were slightly tarnished. Neither bleach nor microwave were deemed suitable for use. Bleach tarnished the metallic nosebands and left an odor even after 16 hours of drying and microwave irradiation melted multiple FFR models.³³ Note that only one cycle of decontamination was evaluated, and other research by Bergman *et al.* (2010) showed that within three HPGP

been and will continue to be identified and are the reason behind laboratory studies that DHS S&T HAC-TC will be conducting to evaluate various aspects of PPE decontamination.

decontamination cycles, four of six FFR models exhibited greater particle penetration as compared to the control.³ Other forms of VPHP are equally efficacious and more compatible with a range of FFRs as described below. Although the FDA reports that about 50% of sterile medical devices in the U.S. are sterilized by ethylene oxide (<https://www.fda.gov>), at the time of this report, no evidence was found in the literature to suggest that ethylene oxide is a suitable disinfectant for SARS-CoV-2 or other related coronaviruses.

Relevant information for PPE compatibility and efficacy is summarized below for each type of disinfectant.

VPHP

A limited variety of PPE has been subjected to VPHP decontamination, though completed studies indicate it is effective and does not adversely impact PPE performance. As previously mentioned, HPGP is not recommended for disinfection of FFRs due to observed effects on particle penetration post-treatment with some FFR models.³ The Association for the Advancement of Medical Instrumentation has developed a guideline for evaluating reesterilization of reusable medical devices, and a testing program that adheres to this guideline is in progress at Advanced Sterilization Products (ASP) for evaluating material compatibility of medical devices with the Sterrad® HPGP System. The functionality and compatibility testing program exposes devices to a preestablished number of VPHP reprocessing cycles—typically up to 100—and includes visual and microscopic evaluation of the effects of processing, functionality assessment by the device manufacturer, and a final report. Functionality testing may include evaluation of electrical function, optical function, mechanical function (*i.e.*, changes in strength, fit, or dimensions), and appearance.²² Materials passing the ASP test program and materials tested in other research projects, plus those listed by STERIS as compatible with VPHP are listed in Table 4.^{22, 27-28} It is reasonable to assume VPHP decontamination will be successful for PPE constructed from these materials and materials that have been tested in other research projects if treatment is performed in a manner consistent with published protocols. However, due to manufacturer differences between FFR models, some may be less compatible with VHP treatment.

Table 4. Materials Compatible with VPHP or HPGP¹ Treatment

Material	Reference
Acrylic	27-28
Acrylonitrile butadiene styrene	22
Aluminum	22
Buna-N vinyl rubber	28
Ceramic	22
Carbon fiber	27
Chlorinated polyvinyl chloride	22
Ethylene propylene diene monomer (EPDM)	22, 28
Fluoroelastomer	22
Glass	22, 27
Nylon	28
Polycarbonate	22, 27
Polyamide	27
Polyetherimide	22, 27
Polyetherketone Viton	22
Polyethersulfone	22
Polyethylene (LDPE, HDPE, UHMPE)	22, 27-28
Polymethylpentene	22
Polyphenylene oxide,	22

Polypropylene	22, 27-28
Polyvinyl chloride	22
Polyvinylidene fluoride	22
Polystyrene	22, 28
Polysulfone	22
Polyurethane	28
Silica	22
Most silicone rubber (and fluorinated silicone)	22, 27-28
Stainless steel	22, 28
Teflon (PTFE, PFA, FEP)	22
Tefzel	22
Titanium	22
Trifluorochloroethylene resins	22

¹It is assumed that materials compatible with HPGP will also tolerate VPHP decontamination.

There is no literature identified on VPHP of HMER, gowns, or eyewear/splash protection. The full composition of PPE materials should be used to determine if VPHP is appropriate; where the composition is unavailable, the following general notes may be useful: FFRs and surgical masks are typically made from polypropylene with an electret filter membrane and a nonwoven thermobond (FFRs) or paper layer (surgical masks).³¹ Tyvek suits are made from high-density polyethylene (HDPE). Disposable gowns are typically made of non-woven material. Raw materials include fibers of polypropylene, polyester, and polyethylene. Some gowns include plastic films to prevent liquid penetration.¹⁶ Eyewear can be made of polycarbonate (typically the lens and face shield portion), polyvinyl chloride, acetate, and polyethylene terephthalate.

Primary conclusions from the scientific literature regarding efficacy of VPHP decontamination for FFRs is summarized in the following section. Conclusions are in bold text with descriptions of supporting literature.

- **Decontamination of FFRs using VPHP may be efficacious against multiple viruses, including SARS-CoV-2 as indicated by testing with influenza, feline calicivirus, human adenovirus type 1, and transmissible gastroenteritis virus (TGEV), a SARS-CoV surrogate¹²**

This claim is based on a study by Goyal *et al.*, (2014), using a Bioquell Clarus L generator to treat stainless steel surfaces contaminated with TGEV, an alphacoronavirus related to severe acute respiratory syndrome (SARS), which resulted in >4-log reduction in TGEV and other viruses.¹²

Unpublished tests by Battelle have demonstrated VPHP decontamination efficacy against SARS-CoV-2 in lab conditions, and the U.S. Food & Drug Administration has issued an Emergency Use Authorization (EUA) for the “emergency use of the Battelle CCDS Critical Care Decontamination System™ ... for use in decontaminating compatible N95 or N95-equivalent respirators” for reuse by HCP. The CCDS is a VPHP-based system.³²

- **FFRs can be decontaminated using VPHP at a range of concentrations, but higher concentrations may be required if the viruses were deposited in complex bodily fluids (e.g., sputum or blood), which may act as a protectant³⁵**

Wood *et al.* (2020) investigated treatment of MS2 and Phi6 bacteriophages with low-concentration (25 ppm) VPHP, resulting in inactivation of both bacteriophages after a 2-hour exposure when diluted in phosphate buffered saline (PBS) and deposited on N95 FFRs, wood,

ceramic tile, glass, painted tape, and stainless steel.³⁵ Samples prepared identically and diluted in blood were still infectious after 3 days of 25 ppm VPHP exposure. A higher concentration of VPHP (>400 ppm) over 24 hours was effective against Phi6 diluted in blood on all surfaces and on MS2 diluted in blood on all surfaces except wood. These results indicate that low-concentration VPHP may effectively inactivate virus deposited as droplets or aerosols in fluids that are similar to PBS (e.g., tears, sweat, etc.), but that higher levels of VPHP may be required for virus deposited in complex fluids like sputum or blood.³⁵

- **FFRs (minimally 3M Model 1860 N95) can withstand up to 20 cycles of VPHP decontamination without compromising filter performance or degrading component parts²**

A pilot-scale study was performed using 3M Model 1860 N95 FFRs and VPHP generated with a Bioquell Clarus C decontamination system into a static glove box to evaluate the shortest cycle parameters that result in a 6-log reduction of *G. stearothersophilus* (Gs) spores on swatches and whole masks after droplet and aerosol exposure.² FFR performance was evaluated after exposure to 10, 20, 30, 40, or 50 decontamination cycles. A total of 85 FFRs were tested (15 for each set of decontamination cycles) for degradation, inert and biological aerosol collection efficiency, and fit/inhalation resistance. The cycle parameters used for N95 FFRs are listed in Table 5.

Table 5. VPHP Decontamination Parameters (Determined by Cycle Fractionation Testing)

Phase	Duration (minutes)	Rate of VPHP Injection (g/minutes)
Conditioning	10	NA
Gassing	20	2.0
Dwell	150	0.5
Aeration	300	NA

No change in aerosol collection efficiency was observed, even after 50 decontamination cycles; all FFRs collected >99% of inert and biological aerosols. However, after 30 cycles the elastic in the straps degraded when stretched and fit was compromised.

- **VPHP is not compatible with APRs and other PPE that may contain cellulose-based (aka paper or paper fiber-based) materials²¹**

Cellulose breaks down peroxide and reduces the effectiveness of the sterilization process. The FDA's EUA for the Battelle CCDS cautions that respirators containing cellulose-based materials are incompatible with the CCDS.³²

- **Large-scale VPHP generation is possible and efficacious against spore-forming bacteria in the presence of mixed non-porous and porous surfaces^{30, 34}**

Touati *et al.* (2017) evaluated low-concentration (<25 ppm) VPHP to treat large areas. Low-concentration VPHP was generated from an aqueous hydrogen peroxide solution in water and distributed by humidifier to evaluate spore-forming bacteria (*B. atrophaeus* var. *globigii*, Bg) inactivation on carpet and galvanized metal.³⁰ The large area, low-concentration VPHP treatment (generated from a 3% aqueous solution over a 7-day period) resulted in a >6-log reduction in Bg spores on all surfaces placed throughout the main floor of the test house. Test

samples placed in the attic demonstrated a <2.8-log reduction. Also tested were Gs bacterial indicator disks, which were evaluated as positive or negative for growth. The Gs indicators were found to be more resistant to VPHP than Bg. Increasing the concentration of VPHP to 3.8% resulted in full inactivation of Bg spores. The addition of furniture of mixed non-porous and porous surfaces had little effect on decontamination, if samples were placed in rooms with humidifiers generating VPHP.³⁰

A previous study (Wood *et al.*, 2016) showed that 5 ppm VPHP generated in this way over a 4-7 day treatment resulted in a 6-log reduction in *B. anthracis* spores on common manufacturing materials including wood, borosilicate glass, galvanized steel, carpet, laminate flooring, ceiling tile, concrete, and wall board.³⁴

UVGI

UVGI manufacturers are marketing their systems to the medical community for whole-room sanitization and research has been performed to determine if UVGI is suitable for disinfection and reuse of FFRs. Lindsley *et al.* (2015) tested coupons and straps from four models of N95 FFRs at multiple UVGI strengths (0, 120, 240, 470, and 950 J/cm²) to determine if filter penetration and resistance is affected by UVGI exposure. For 16 of 20 coupons the penetration level increased after UVGI exposure, although mean penetration levels before and after exposure were ≤5%, which is within acceptable limits. The flow resistance also increased after UVGI exposure (<6%) but remained within acceptable limits for use. The coupons and straps were significantly weaker after exposure to UVGI and became weaker with increasing UVGI strength. At low doses, UVGI disinfection may be repeated dozens of times before appreciably weakening the FFR.¹⁸

- **Decontamination of FFRs using UVGI may be efficacious against multiple viruses, including SARS-CoV-2 as indicated by testing with Influenza viruses, SARS, and MERS^{1, 23}**

UVGI decontamination of N95 FFRs and FFR coupons exposed to influenza virus H1N1 was evaluated in artificial saliva and artificial skin oil. A UV dose of 1 J/cm² over one minute was effective at inactivating influenza H1N1. Additional testing was performed with influenza H5N1, H7N9, SARS, and middle eastern respiratory syndrome (MERS) viruses using the same soiling conditions and UVGI disinfection resulted in a >3.95 log reduction across all samples.^{1, 17}

- **FFRs can withstand UVGI disinfection up to 20 cycles, but efficacy is dependent on FFR shape and material, and some models may off-gas volatile organic compounds¹**

UVGI treatment up to 20 cycles was not shown to damage FFRs or to negatively impact filtering performance. However, efficacy of UVGI decontamination was highly variable depending on the FFR shape and material. UVGI requires direct exposure for full effect, so UV light placement is critical for full inactivation and the presence of soiling agents (*e.g.*, saliva and sebum) may negatively impact treatment effectiveness. Additionally, some models had a singed odor after treatment. An off-gassing analysis detected eight volatile organic compounds well below permissible exposure limits.¹

- **FFRs can be decontaminated using UVGI at 1 J/cm², but higher doses may be required if the viruses were deposited/trapped in the inner layers of the respirator¹⁸**

Because UVGI can be attenuated by some materials and/or presence of surface soil, a higher dose of UVGI may be required to achieve complete disinfection of an FFR.¹⁸

- **Nebraska Medicine has adopted UV treatment and reuse for FFRs based on the research by Mills et al., 2018^{19, 23}**

Heat

Thermal inactivation has also been proposed as an appropriate treatment for disinfection and reuse of FFRs. A document authored by Tsai (University of Tennessee Research Foundation) suggests that FFRs can be decontaminated using heat (70°C (158°F) for 30 minutes), steam (125°C for 3 minutes), or boiling water. The author states these methods will preserve the electrostatic charge and preserve filtering efficiency. However, the treatment should be performed so that the masks do not contact a metal surface and without stirring (if boiled).³¹ This guidance appears to be suitable for personal use, but it is unclear whether it could be scaled to healthcare or commercial application where presumably hundreds or thousands of FFRs would need to be decontaminated. Additionally, the author does not describe whether testing was performed using the FFR or coupons and does not describe effects on ancillary materials like elastic straps or nose pieces.

- **Disinfection of SARS-CoV-2 using thermal treatment (>65°C / 149°F) is effective**

Leclercq *et al.* (2014) evaluated the effect of temperature on MERS-CoV in serum samples and found that at temperatures over 65°C (149°F), full inactivation could be achieved with 1 minute of treatment. Lower temperatures were also effective but required longer treatment times (e.g., at 56°C (132.8°F), a 4-log reduction was observed after 25 minutes of exposure.¹⁷

- At the time of this publication, there were no commercial entities found marketing a product to disinfect COVID-19 using heat. However, potential solutions for large-scale heat treatment would include commercial-scale electric heaters used for pesticide applications. These systems are used up to 60°C for various applications and may be suitable for treatment of FFRs, though presumably FFRs would need to be suspended, rather than laying on a metal rack, etc.
 - Green Tech Heat Solutions, models ePro 400, ePro 600, ePro 1400, <https://www.greentechheat.com/insects.php>
 - Tutco Heating Solutions Group, Farnam Custom Products, <https://farnam-custom.com/applications/killing-bedbugs-with-electric-heaters> provides custom applications with multiple types of heat sources (electric, steam, or propane)
- Autoclaves and ovens may be potentially efficacious but should not be used unless preliminary testing is done.

Disinfection of other PPE

- In general, PAPRs and HMERs are considered multiple-use devices and have accompanying manufacturer guidelines for disinfection and proper care.
- While no literature was found regarding disinfection of HMERs, VPHP was successfully used to disinfect positive pressure respiratory protection hoods, likely similar to a loose-fitting PAPR, with complete sterilization against *Geobacillus stearothermophilus*.¹⁴

Use of Alternative Materials for Respiratory Protection

Scientists have measured the protective filtration efficiencies of many household or personal materials (e.g., various clothing articles, toilet tissue, vacuum cleaner filters, etc.) from the late

1950s to the present. Several sources provide empirical data evaluating and comparing alternative materials to N95 respirators and surgical masks. Test methods employed the use of head forms or mannequins according to National Institute for Occupational Safety and Health (NIOSH) protocols or equivalent, except for historical studies that used human subjects. No studies were found evaluating filtering efficiency with virus or infectious virions, but one study evaluated a viral surrogate (bacteriophage MS2) and many of the studies targeted particle size ranges that would be applicable to virus aerosols (0.02 to 1 µm). Many of the tests investigated both dry and wet conditions for multiple materials. Where possible, data is presented in terms of filtering efficiency for comparison between studies.

The main conclusions and supporting research are summarized below:

- **N95 FFRs are the standard preferred respiratory protection and have been used as the positive control for all identified empirical tests of alternative materials.**
- **Commercial surgical masks are an accepted alternative to N95 respirators in certain medical situations. However, surgical masks consistently demonstrate between 30-42% filtering efficiency (for dust, saline, and mineral or paraffin oil) as compared to ≥95% for N95 respirators.**^{5, 15, 26}

Both WHO and CDC guidelines recommend respirator (or surgical mask if a respirator is unavailable) for use when in direct contact with patients and respirators for aerosol-generating procedures; the CDC further clarifies that surgical masks should be used for aerosol-generating procedures if respirators are no longer available.^{24, 36-37}

The single identified study performed with a viral surrogate demonstrated >89% filtration efficiency for commercial surgical masks against bacteriophage MS2 tested at 30 L/min flow rate (3X the flow rate tested in other studies). The tests were repeated for nine independent trials, but more research is warranted to know if the results are repeatable or applicable to another virus or surrogate.¹⁰ Note: because cloth masks may not create a seal against the face, gaps in fit will allow contaminated air to ingress around the filter and may lower the overall effectiveness. Filtering efficiencies reported between studies may not be directly applicable due to differences in the way testing was performed (*i.e.* whether in human subjects, human head forms, or other).

- **Cloth masks are less suitable for respiratory protection, even commercial cloth surgical masks. However, when worn by an ill person, cloth masks reduce the number of droplets and microorganisms produced by coughing.**

MacIntyre *et al.* (2015) performed a study with 1607 HCP in Hanoi, Vietnam, to determine if there was a difference in efficacy of medical masks (>95% efficiency, assumed to be FFRs) over cloth masks. Participants from 16 hospitals, each with ≥18 years on the job were assigned randomly to wear medical masks, cloth masks, or to follow normal hygiene procedures; each group was followed for five weeks -- four weeks of participation and a final week to observe for illness. The incidence of influenza-like illnesses was higher in the group wearing cloth masks than in either the medical mask or control groups. However, also notable is that handwashing was lowest in the cloth mask group (geometric mean of 11 washings daily as compared to 14 and 12 in the medical mask and control group, respectively).⁷ MacIntyre has since hypothesized that a lack of proper mask care (*i.e.*, frequently washing and drying the cloth masks) may have further contributed to the observed differences.⁴

Davies *et al.* (2013) evaluated surgical masks and homemade cloth masks for their ability to reduce the amount of microorganisms released during coughing. Droplets were collected from

healthy human volunteers while coughing not wearing a mask and wearing either a surgical mask or a homemade cloth mask. Both the cloth mask and the surgical mask reduced the number of microorganisms released during a cough.¹⁰

- **Homemade or makeshift cloth masks have been proposed for use when other APR, FFR, and surgical masks are unavailable.²⁴ Most household or personal materials have been demonstrated in laboratory tests to afford some protection, but the type of material and construction significantly impact efficacy. Homemade or makeshift respiratory protection made from alternative supplies may provide the best protection against droplets >5 µm and efficacy is expected to be lower for aerosols.**

Studies from the late 1950s and early 1960s claim that multiple materials demonstrated significant filtration efficiency, including toilet tissue, cotton handkerchiefs, and Turkish towel when applied in multiple layers (3, 8, or 2, respectively), but when this research was repeated in 1983, these results were not confirmed.^{8, 11, 13}

Decker *et al.* (1962) reported testing with cotton shirting and dress material, men's and women's handkerchiefs, rayon, muslin bed sheet, Turkish bath towel, toilet paper, and surgical mask and respirator controls against 1-5 µm bacterial particles.¹¹ This may be a partial review of Guyton *et al.*'s 1959 work.¹³ The results are summarized in two figures:

Respiratory Protection Provided by Common Household & Personal Items GEOMETRIC MEAN EFFICIENCY

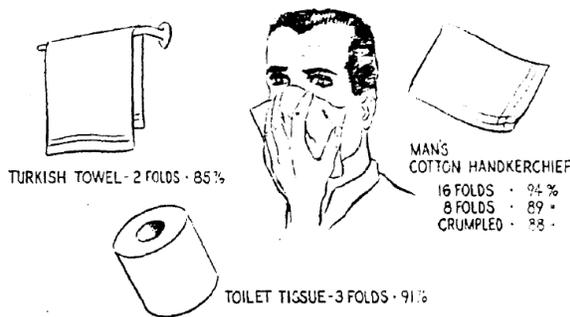


Figure 4. Respiratory Protection Provided by Common Household and Personal Items. (FD Neg C-6426)

Efficiency of Various Types of Surgical Masks and Respirators

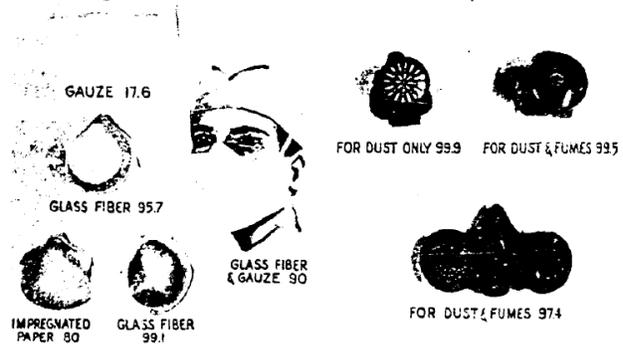


Figure 5. Air Filtration Efficiency of Various Types of Surgical Masks and Respirators. (FD Neg C-6425)

The most efficacious materials were 3 folds of toilet tissue (91%), 8 folds of cotton handkerchief (89%), and 2 folds of Turkish towel (85%); the cotton handkerchief when folded >8 times or crumpled was prohibitive to comfortable breathing.¹¹ Note that these values represent the filtration efficiency of these materials, and not the overall efficacy. Filtration efficiency is difficult to compare between studies because the test conditions are not equivalent.

Contemporary studies from 2006-2013 show a wide range of filtration efficiency for similar materials (e.g., T-shirts from <14 to 50.85%, scarves from 11 to 48.87%, which is likely due to differing materials composition and challenges); however, bandanas and handkerchief filtration

efficacy was fairly consistent, from 2-13% across tests (a 13% filtration efficiency means the wearer could still inhale 87 out of 100 virus aerosol particles).

Davies *et al.*, (2013) tested both the filtration efficiency of potential alternative mask materials and the efficacy of a homemade mask to reduce transmission of infectious droplets. To evaluate filtration efficiency, they challenged materials with *B. atrophaeus* (Bg) and bacteriophage MS2 aerosols to determine their filtration efficiencies; only MS2 results are discussed here.¹⁰ Tests were performed nine times for each material at 30 L/min (significantly higher than an adult human resting respiration rate, but less than 10% the flow of an average cough). A commercial surgical mask material was most efficient at 89.52%, with vacuum cleaner bag close behind at 85.85%. Tea towels, cotton mix, and antimicrobial pillowcase were around 70% efficient (72.46% to 68.90%). Although the vacuum cleaner bag was very efficient at removing particles, the pressure drop created was significant enough to make it unwearable. Likewise, the tea towel had a high pressure drop that may affect wearability. The remaining materials: linen, pillowcase, silk, 100% cotton T-shirt, and scarf, ranged from 61.67% to 48.87% efficient. Additionally, the researchers fit tested homemade masks created by 21 volunteers from 100% cotton T-shirt material using the TSI PortaCount Plus Respirator Fit Tester and N95-Companion Module model 8905. There was significant difference in fit between the surgical mask and homemade masks, though both reduced the number of microorganisms released during a cough. Additionally, as the materials were tested without washing or long wear, the researchers indicated that results may differ when exposed to moisture from exhalations or heat from extended wear that may affect the results.¹⁰ These researchers concluded that face masks may provide limited protection when used along with other engineering and hygiene practices, but are not reliable against aerosol transmission.

Several contemporary studies have been performed using saline aerosols. For instance, a study by Rengasamy *et al.* (2010) evaluated aerosol penetration of polydisperse and monodisperse NaCl particles through T-shirt and sweatshirt materials of various cotton/polyester blends, cotton towels, cotton scarves ranging from pocket square to fleece, and cloth masks of unknown composition compared to N95 respirator material.⁽¹¹⁾ The researchers used the NIOSH particulate respirator test protocol at two face velocities (5.5 and 16.6 cm/s). For the polydisperse NaCl (75 ± 20 nm median diameter / < 1.86 geometric standard deviation), all materials except one sweatshirt (Hanes, 70/30% cotton/polyester blend) had filtration efficiencies of < 40%. Results were reported as penetration level, and results were converted to filtration efficiency as specified in their study (*i.e.* filtration efficiency = 100% - penetration level). The Hanes sweatshirt performed best with a filtration efficiency of 60% at 5.5 cm/s face velocity and 43% at 16.5 cm/s face velocity. Other than the Hanes sweatshirt, towels performed best with a filtration efficiency of 34-40%, then other sweatshirts (18-30%), scarves (11-27%), and T-shirts (<14%). Overall, results were similar to the protection afforded by cloth masks (filtration efficiency between 10-30%), yet significantly lower than the N95's control filtration efficiency of 99.9% challenged with the polydisperse aerosols (75 ± 20 nm median diameter / < 1.86 geometric standard deviation) at 5.5 cm/s face velocity. The filtration efficiency for alternative materials challenged with monodisperse NaCl aerosols (0.02-1 µm) ranged from 3-60% at 5.5 cm/s. The researchers note that there are potential gaps in this research that could impact results; for instance, the study was performed with fine aerosols, not droplets; no testing was performed after wear or laundering; and form/fit testing was not evaluated.²⁶

A comprehensive study was performed by Jung *et al.* (2014) who tested 44 commercially-available masks (22 NIOSH or Korean Food and Drug Administration (KFDA)-approved masks; 19 non-approved medical, dental, or dust masks; and 3 handkerchiefs tested in 1-4 layers). The researchers used standard methods to measure NaCl and paraffin oil penetration.¹⁰ Some

mask categories in this study (e.g., *anti-yellow sand* – an environmental pollutant, *quarantine*, and *general*) are unclear or do not have an obvious U.S. corollary. Depending on which standard test was used, cotton handkerchiefs had approximate filtration efficiencies of 2% (1 layer) and 4-13% (4 layers) filtration efficiency. Surgical masks were about 41-42% efficient, dental masks 70-71%, and general nonwoven cotton masks were about 48-55% efficient.¹⁵

Bowen (2010) tested a bandana along with a surgical mask and dust mask against saline aerosols using a Styrofoam™ human head form with a volumetric flow rate of 8.75 L/min (slightly above the average resting rate). The mass median aerodynamic particle size was 1.6 μm, and protective efficiency calculated at 11.3% (bandana), 6.1% (dust mask), and 33.3% (surgical mask) as compared to an N95 respirator with 89.6% efficiency.⁵

Dato *et al.* (2006) report that an effective mask can be made from a 100% cotton Hanes T-shirt using 9 layers (one outer and 8 inner) stacked such that every two layers rotated (cross-grain) to the previous two layers.¹² It is unclear whether the cross-grain rotation is at a 90-degree or 45-degree (bias) angle, though 45-degrees would provide more coverage than 90-degrees for most fabric weaves. The mask was fit tested with a Portacount Plus Respirator Fit Tester with N95 Companion using ambient aerosols and achieved a fit factor of 67 (as compared to commercial N95 required 100). They report that it should not be used by someone with respiratory challenges, as presumably the multiple layers significantly restrict respiration.⁹

These ranges can be compared to surgical, dental, and similar masks that are generally in the 30 to 70% efficient range, and N95 respirators that are defined as being capable of removing ≥ 95% of 0.3 μm aerosols when properly fitted on the user. Additionally, the instructions in this publication may not be easily replicated and results may be affected by synthetic content of t-shirt materials.

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