PPE CASE

Personal Protective Equipment Conformity Assessment Studies and Evaluations

Assessment of Filtration Efficiency, Manikin Fit Performance, and Strap Performance for Decontaminated N95 Filtering Facepiece Respirators

National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)

This report summarizes the NIOSH assessments of filtration efficiency, manikin fit performance, and strap performance of NIOSH-approved N95 filtering facepiece respirators (FFRs) that have undergone various decontamination techniques. Based on the knowledge gained from these assessments, this report discusses important considerations when selecting techniques of FFR decontamination for occupational use. Findings from the NIOSH assessments indicate that FFR decontamination may have model-specific effects — the FFR manufacturer should be consulted before decontaminating any FFR.

The purpose of this assessment was to determine the effects of the decontamination process on the particulate filtration performance, manikin fit, and strap integrity of the respirator. It did not assess the reduction of the pathogen burden by the decontamination procedure.

Evaluation of a convenience sample of 1,354 N95 FFR units across 29 models found that 42% of the decontamination techniques evaluated (8 of 19) negatively impacted fit and/or filtration efficiency.

Background

Supplies of N95 filtering facepiece respirators (FFRs) can become depleted during wide-spread outbreaks of infectious respiratory illnesses. In order to supplement the national inventory of N95 FFRs during these times, the Centers for Disease Control and Prevention (CDC) suggested several supply optimization strategies (CDC 2020). Within these strategies, FFR reuse, including reuse after decontamination, when there are known shortages of N95 respirators may be considered.

Decontamination is a process to reduce the number of pathogens on used FFRs before reuse. An effective FFR decontamination technique should significantly reduce the pathogen burden, but not reduce a respirator's filtration performance or its ability to fit properly. Another consideration is that no hazardous chemical residue should be left on the FFR as a result of a decontamination process.

During non-emergencies, FFRs are considered limited-use products and are not approved for decontamination and reuse as standard of care. However, when there are known FFR shortages FFR decontamination and reuse may need to be implemented as a crisis capacity strategy to ensure continued availability after conventional and contingency strategies have been implemented. On March 29, 2020, the U.S. Food and Drug Administration (FDA) issued the first Emergency Use Authorization (EUA) for a decontamination technique to be considered to offset N95 FFR supply shortages. Since then, additional subsequent EUAs and revisions have been issued. The FDA Emergency Use Authorizations website should be checked for the most up-to-date information. Furthermore, the respirator manufacturer should be consulted about any impact that the decontamination technique has on their respirators before considering the use of any technique

How NIOSH Assessed FFRs that have Undergone a Decontamination Technique

The goal of the assessments discussed in this report is to provide information that can be used to inform decisions regarding implementing N95 FFR decontamination and reuse during national emergencies when respirator supplies are diminished. This study is ongoing. The results presented within this PPE CASE are from the time period of April 14, 2020 through December 01, 2020.

These assessments used new FFRs that had not been worn or exposed to any pathogenic microorganisms. In practice, donning a respirator multiple times can reduce the ability of the respirator to fit properly. While these assessments evaluated the performance of respirators that were decontaminated up to 30 cycles, CDC recommends limiting the number of donnings to no more than five in the absence of guidance from manufacturers or targeted evaluations of fit with repeated decontamination cycles.

NIOSH developed performance test methods to evaluate N95 FFRs following decontamination techniques (see Appendix B).

- NIOSH received requests from multiple organizations including hospitals, universities, private companies performing sterilization services, and government and private research laboratories to assess unused N95 FFRs that had undergone decontamination. Assessment requests required the respirator manufacturer name, model number, a detailed description of the decontamination technique and number of decontamination cycles applied, and whether the technique used was one authorized for emergency use by the FDA. NIOSH determined particulate filtration efficiency by using a modified version of the NIOSH Standard Test Procedure (STP)-0059.

- Manikin fit was determined using manikin headforms developed to represent the anthropometric sizes of US workers[1].
- NIOSH assessed strap integrity (difference in tensile force compared with controls) of the top and bottom straps by using a tensile tester, a device which measures tensile force by elongating (stretching) a test sample at 1 cm/sec until reaching by 200% strain. See Appendix B for more detailed procedures.
- FFRs were also visually inspected for signs of component damage or discoloration compared to controls (i.e. unused respirators of the same manufacturer and model).
- The selection of respirators to provide to NIOSH for testing was at the discretion of the submitter; however, NIOSH requested 15 decontaminated respirators and five new respirators to use as controls for each assessment.
- In total, NIOSH tested 1,354 respirators during this evaluation to support 39 assessments that are described in this report. Manufacturer lot-to-lot product variability was not considered in these assessments. It is possible that some of the variability in the data was due to lot-to-lot product differences. Table 1 summarizes the number of respirators tested by the provided decontamination dose as well as the number of decontamination cycles performed. Figure 1 displays the number of respirators tested by manufacturer and model number.

[1] Bergman, Michael S et al. "Development of an advanced respirator fit-test headform." *Journal of occupational and environmental hygiene* vol. 11,2 (2014): 117-25. doi:10.1080/15459624.2013.816434

Table 1 – Sample size by decontamination technique, dose described, cycle number, and respirator model

Technique	N	Doses Tested	N	Cycles Tested	N	Models Tested
Aerosolized Peracetic Acid (PAA)	24	76 min x 1.06% PAA solution	24	1 cycle	8	3M 1860 (n=8)
				3 cycles	8	3M 1860 (n=8)
				5 cycles	8	3M 1860 (n=8)
Chlorine Dioxide Gas	88	1000–2000 ppm-hr*	25	5 cycles	5	3M 8000 (n=5)
				10 cycles	5	3M 8000 (n=5)
				20 cycles	15	3M 8000 (n=15)
		2,500 ppm-hr*	4	4 cycles	4	3M 8200 (n=4)
		850 ppm-hr*	15	5 cycles	15	3M 8200 (n=15)
		720 ppm-hr*	44	1 cycle	14	3M V-Flex 1805 (n=14)
				4 cycles	30	3M 1860 (n=15), VWR 89201-508 (n=15)
Commercial Steamer	15	30 seconds at 100°C	15	10 cycles	15	3M 8210 (n=15)
DiKlor-G® Sterilization, Chlorine Dioxide	30	800 ppm-hr*	15	6 cycles	15	3M 8210 (n=15)
		Not reported	15	6 cycles	15	3M 1860 (n=15)
Dry Heat (commercial laundry dryer)	90	90 min at 80-85°C	45	3 cycles	45	3M 1860 (n=15), 3M 8511 (n=15), Halyard 62126 (n=15)
		70 min at 80-85°C	45	3 cycles	45	3M 1860 (n=15), 3M 8511 (n=15), Halyard 62126 (n=15)
Dry Heat (environmental chamber)	125	60 min at 75°C	30	5 cycles	30	3M 1860 (n=10), 3M 1870+ (n=10), Halyard 46727 (n=10)
		45 min at 75°C	95	10 cycles	95	3M 1860 (n=15), 3M 1860S (n=15), 3M 1870+ (n=15), 3M 8210+ (n=20), 3M 9205+ (n=15), 3M V-Flex 1804 (n=15)
Electron Beam Irradiation	10	25 kGy/cycle	10	1 cycle	4	3M 8200 (n=4)
				2 cycles	3	3M 8200 (n=3)
				3 cycles	3	3M 8200 (n=3)
Gaseous Ozone	5	450 ppm**	5	5 cycles	5	3M 1870 (n=5)
Gravity Steam	21	30 min at 121°C	21	3 cycles	21	3M 1860 (n=7), 3M 1870 (n=7), 3M V-Flex 1905 (n=7)
Methylene Blue	44	10µM spray (~7mL/cycle) + 100k lux light for 60 mins	44	5 cycles	44	3M 1860 (n=10), 3M 1860S (n=15), 3M 1870+ (n=10), Halyard 46727 (n=9)
Microwave generated plasma	14	45 seconds	14	3 cycles	14	3M 1860 (n=7), 3M 8210 (n=7)

Table 1 Continued – Sample size by decontamination technique, dose described, cycle number, and respirator model

Technique	N	Doses Tested	N	Cycles Tested	N	Models Tested
Moist Heat	45	60 min at 100°C & 100%RH	24	1 cycle	8	3M 1860 (n=8)
				3 cycles	8	3M 1860 (n=8)
				5 cycles	8	3M 1860 (n=8)
		15 min at 85°C & 65%RH	21	1 cycle	7	3M 1860 (n=7)
				3 cycles	7	3M 1860 (n=7)
				5 cycles	7	3M 1860 (n=7)
Plasma Discharge Reactive Oxygen Species	12	500 ppm-min*	12	1 cycle	6	BYD DE2322 (n=3), Prestige Ameritech RP88020 (n=3)
				3 cycles	6	BYD DE2322 (n=3), Prestige Ameritech RP88020 (n=3)
Sterrad NX100 HPV/Low Temp Plasma	30	Not reported	30	2 cycles	30	3M 8511 (n=15), Halyard 46727 (n=15)
Stryker STERIZONE VP4 Sterilizer	30	Pre-set cycle (Cycle 1), 41°C	30	5 cycles	30	3M 1860 (n=10), 3M 1870+ (n=10), Halyard 46727 (n=10)
Supercritical Carbon Dioxide	34	60 min at 37°C & 1100 psig	15	10 cycles	15	3M 1860 (n=15)
		90 min at 37°C	19	1 cycle	19	3M 1860 (n=6), 3M 1860S (n=7), 3M V-Flex 1804 (n=6)
Ultraviolet Germicidal Irradiation (UVGI)	32	UV-C 254nm 1000 mJ/cm^2	12	10 cycles	12	3M 1860 (n=7), 3M 8210 (n=5)
		UV-C 254nm 500 mJ/cm^2	20	1 cycle	5	3M 1860S (n=5)
				3 cycles	5	3M 1860S (n=5)
				5 cycles	5	3M 1860S (n=5)
				10 cycles	5	3M 8210 (n=4), 3M 8210+ (n=1)
UVGI and Infrared Heat	28	90 min at 175°C	28	3 cycles	15	Halyard 46727 (n=15)
				5 cycles	13	Halyard 46727 (n=13)

Table 1 Continued – Sample size by decontamination method, dose described, cycle number, and respirator model

	N	Doses Tested	N	Cycles Tested	N	Models Tested
Vapor Phase Hydrogen Peroxide (VPHP)	677	25 min at 45°C with 35% HP	24	10 cycles	8	Makrite 9500-N95S (n=8)
				20 cycles	8	Makrite 9500-N95S (n=8)
				30 cycles	8	Makrite 9500-N95S (n=8)
		3 hours at 7%	125	1 cycle	25	3M 8000 (n=5), 3M 8210 (n=5), 3M 8210V (n=5), Crosstex GPRN95 (n=5), Moldex 1512 (n=5)
				2 cycles	25	3M 8000 (n=5), 3M 8210 (n=5), 3M 8210V (n=5), Crosstex GPRN95 (n=5), Moldex 1512 (n=5)
				3 cycles	25	3M 8000 (n=5), 3M 8210 (n=5), 3M 8210V (n=5), Crosstex GPRN95 (n=5), Moldex 1512 (n=5)
				4 cycles	25	3M 8000 (n=5), 3M 8210 (n=5), 3M 8210V (n=5), Crosstex GPRN95 (n=5), Moldex 1512 (n=5)
				5 cycles	25	3M 8000 (n=5), 3M 8210 (n=5), 3M 8210V (n=5), Crosstex GPRN95 (n=5), Moldex 1512 (n=5)
		Not reported	528	5 cycles	154	3M 1860 (n=7), 3M 1860S (n=6), 3M 8210 (n=7), 3M 8511 (n=15), 3M 9205+ (n=15), V-Flex 1804 (n=7), Gerson 1730 (n=14), Gerson 1740 (n=14), Moldex 1512 (n=12), Moldex 2200 (n=12), Sperian N1105 (n=15), Sperian N1125 (n=15), Sperian One-Fit (n=15)
				10 cycles	174	3M 1860 (n=15), 3M 8210 (n=15), 3M 8511 (n=15), 3M 9205+ (n=15), V-Flex 1804 (n=15), Gerson 1730 (n=15), Gerson 1740 (n=14), Moldex 1512 (n=15), Moldex 2200 (n=15), Sperian N1105 (n=15), Sperian N1125 (n=15), Sperian One-Fit (n=10)
				15 cycles	15	3M 1860 (n=15)
				20 cycles	185	3M 1860 (n=15), 3M 1870+ (n=10), 3M 8210 (n=15), 3M 8511 (n=15), 3M 9205+ (n=15), V-Flex 1804 (n=15), Gerson 1730 (n=15), Gerson 1740 (n=15), Moldex 1512 (n=15), Moldex 2200 (n=15), Sperian N1105 (n=15), Sperian N1125 (n=15), Sperian One-Fit (n=10)

*Concentration and time not reported; ** Time not reported

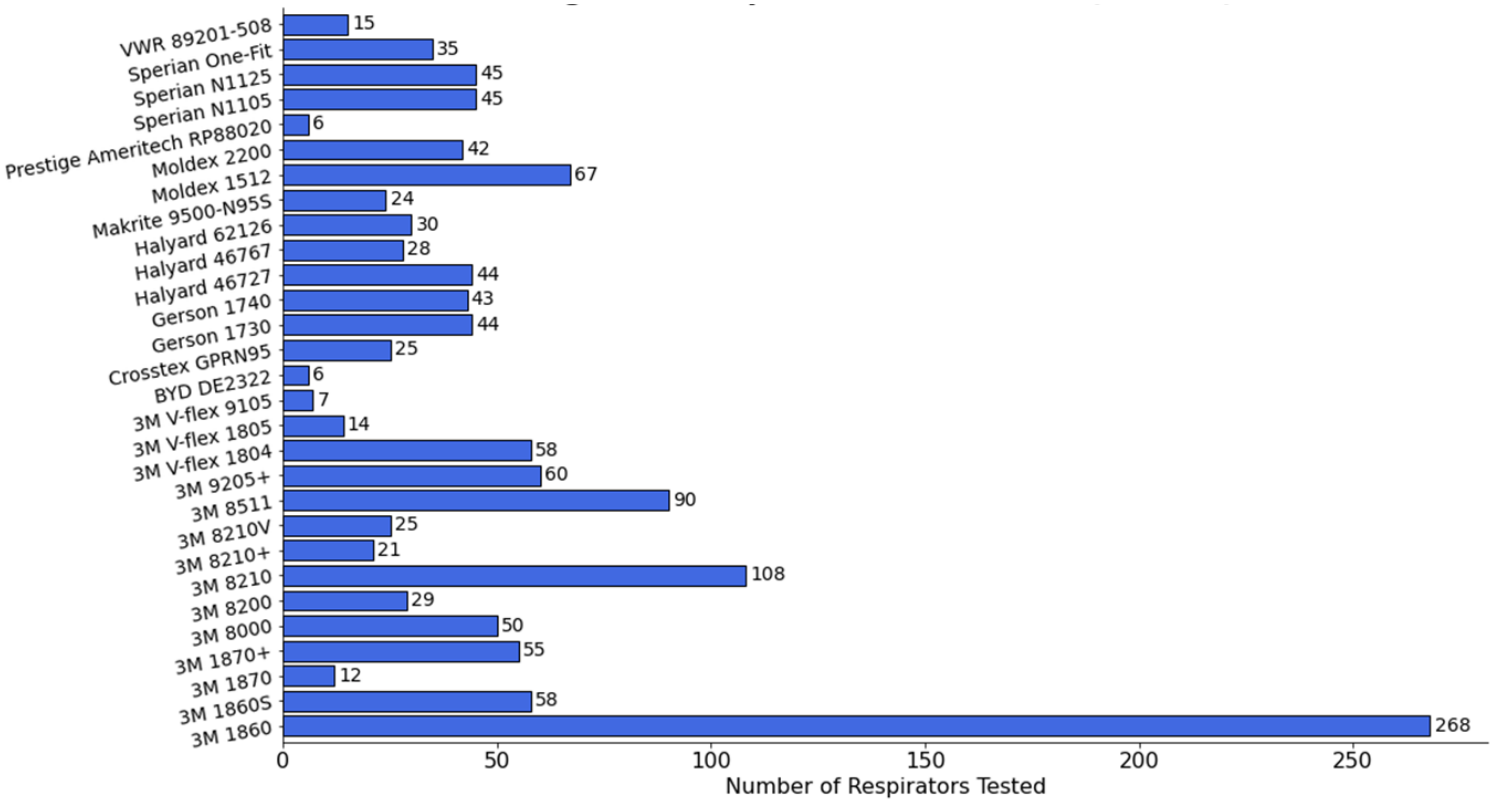

Figure 1 – Respirator Models Tested

CASE Results

Detailed results for each decontamination technique by dose, cycle number, and respirator model are presented as supplementary tables in the Appendix. Additionally, all detailed assessment reports are posted on the NIOSH website. Because not all respirators were tested with each decontamination method the results cannot be generalized. However, the results do suggest effects that can be further tested.

Table 2 displays the percent of decontaminated respirators that had ≥95% filtration efficiency by decontamination technique and the number of decontamination cycles. The majority of decontamination techniques and their stated treatment (dose and cycle) did not negatively impact filtration efficiency. However, filtration efficiency was impacted negatively for specific decontamination techniques and their stated treatment (dose and cycle). Specifically, respirators decontaminated using Electron Beam Irradiation, Microwave Generated Plasma, Supercritical Carbon Dioxide, and Ultraviolet Germicidal Irradiation (UVGI) used in combination with Infrared Heat showed filtration efficiency of <95% following decontamination compared to controls in some or all of the respirators tested. The remaining decontamination techniques did not have a substantial impact on filtration efficiency, with most or all of the decontaminated respirators having achieved ≥95% filtration efficiency across all numbers of cycles tested.

Table 2 – Percent of respirators with ≥95% filtration efficiency by decontamination technique and cycle number

	Number of decontamination cycles										
	All Cycles	**1**	**2**	**3**	**4**	**5**	**6**	**10**	**15**	**20**	**30**
PAA	100% n=15, m=1	100% n=5, m=1		100% n=5, m=1		100% n=5, m=1					
ClO^2 Gas	100% n=54, m=5	100% n=10, m=1			100% n=24, m=3	100% n=10, m=1				100% n=10, m=1	
Commercial Steamer	100% n=10, m=1							100% n=10, m=1			
DiKlor-G® Sterilization, ClO^2	100% n=20, m=2						100% n=20, m=2				
Dry Heat (laundry dryer)	100% n=60, m=3			100% n=60, m=3							
Dry Heat (environ. chamber)	100% n=81, m=7					100% n=21, m=3		100% n=60, m=6			
Electron Beam Irradiation	**0%** n=10, m=1	**0%** n=4, m=1	**0%** n=3, m=1	**0%** n=3, m=1							
Gaseous Ozone	100% n=5, m=1					100% n=5, m=1					
Gravity Steam	100% n=15, m=3			100% n=15, m=3							
Methylene Blue	96% n=32, m=4					96% n=32, m=4					
Microwave Generated Plasma	**90%** n=10, m=2			**90%** n=10, m=2							
Moist Heat	100% n=21, m=1	100% n=7, m=1		100% n=7, m=1		100% n=7, m=1					
Plasma Discharge ROS	100% n=12, m=2	100% n=6, m=2		100% n=6, m=2							
Sterrad NX100 HPV/LTP	100% n=20, m=2		100% n=20, m=2								
Stryker STERIZONE VP4 Sterilizer	100% n=21, m=3					100% n=21, m=3					
Supercritical CO^2	**0%** n=23, m=3	**0%** n=13, m=3						**0%** n=10, m=1			
UVGI	100% n=26, m=4	100% n=5, m=1		100% n=5, m=1		100% n=5, m=1		100% n=11, m=3			
UVGI and Infrared Heat	**50%** n=20, m=1			100% n=10, m=1		**0%** n=10, m=1					
VPHP	99% n=473, m=17	100% n=17, m=5	100% n=19, m=5	100% n=19, m=5	100% n=19, m=5	100% n=128, m=16		99% n=125, m=13	100% n=10, m=1	97% n=131, m=14	100% n=5, m=1

Percent for the "All Cycles" column was calculated as an average change weighted by the number of samples in each cycle number. Sample size (n) = number of decontaminated respirators tested for each cell. m = number of different models tested.

Acronyms: PAA=Aerosolized Peracetic Acid, ROS=Reactive Oxygen Species, LTP= Low Temp Plasma, UVGI=Ultraviolet Germicidal Irradiation, VPHP=Vapor Phase Hydrogen Peroxide

Table 3 displays the percent of respirators with manikin fit factors of ≥100 by decontamination technique and number of cycles. The percentage of control respirators (no decontamination) with a manikin fit factor of ≥100 by decontamination technique is also provided in Table 3 for comparison. Comparing the percentage of control respirators with the percentage of respirators across all decontamination cycles, clarifies that the manikin fit factor is reduced following some of the decontamination techniques. Specifically, Chlorine Dioxide Gas, Gravity Steam, Microwave Generated Plasma, Moist Heat, Sterrad NX100 Hydrogen Peroxide Vapor (HPV)/low temp plasma, Supercritical CO_2, UVGI in combination with infrared heat, and VPHP show a reduction in manikin fit in the decontaminated respirators compared to the controls, independent of the number of decontamination cycles. A reduction in manikin fit was not observed for the other 8 decontamination techniques, where the number of respirator models evaluated ranged from 5 to 44 for each decontamination technique. Table 3 does not break out the results by respirator model, thus the passing percentages shown in the table may have been impacted by the specific models tested. However, the number of different models tested within each cell is indicated within Table 3 to aid in this interpretation.

Figure 2 displays boxplots of the percentage change in strap tensile force between the control and decontaminated straps (decontaminated tensile force – control tensile force)/control tensile force) by decontamination technique and strap location (top or bottom strap). A value less than 0% indicates that there was less tensile force measured in the decontaminated strap than in the control straps. A value greater than 0% indicates there was more tensile force measured in the decontaminated strap than in the control. The strap integrity results were largely mixed with both positive and negative percent changes in tensile force within and between the decontamination techniques. Many of the techniques had an interquartile range that included 0%, which indicates no obvious reduction or increase in tensile force from decontaminated straps tested to control straps. However, the Commercial Steamer and DiKlor-G® Sterilization, Chlorine Dioxide techniques showed substantially increased tensile force in the decontaminated respirators versus the controls.

Table 3 – Percentage of respirators with a manikin fit factor of ≥100 by decontamination technique and cycle number

		Number of decontamination cycles										
	Control	**All Cycles**	**1**	**2**	**3**	**4**	**5**	**6**	**10**	**15**	**20**	**30**
PAA	100% n=2, m=1	100% n=9, m=1	100% n=3, m=1		100% n=3, m=1		100% n=3, m=1					
ClO^2 Gas	**93%** n=26, m=4	**83%** n=34, m=4	100% n=4, m=1			**50%** n=10, m=2	100% n=10, m=2		100% n=5, m=1		80% n=5, m=1	
Commercial Steamer	100% n=2, m=1	100% n=5, m=1							100% n=5, m=1			
DiKlor-G® Sterilization, ClO^2	100% n=4, m=2	100% n=10, m=2						100% n=10, m=2				
Dry Heat (laundry dryer)	100% n=12, m=3	100% n=30, m=3			100% n=30, m=3							
Dry Heat (environ. chamber)	**92%** n=12, m=7	**92%** n=44, m=7					100% n=9, m=3		**88%** n=35, m=6			
Gravity Steam	100% n=6, m=3	**67%** n=6, m=3			**67%** n=6, m=3							
Methylene Blue	100% n=2, m=1	100% n=12, m=4					100% n=12, m=4					
Microwave Generated Plasma	100% n=4, m=2	**75%** n=4, m=2			**75%** n=4, m=2							
Moist Heat	100% n=5, m=1	**22%** n=24, m=1	**17%** n=8, m=1		**17%** n=8, m=1		**33%** n=8, m=1					
Sterrad NX100 HPV/LTP	100% n=4, m=2	**60%** n=10, m=2		**60%** n=10, m=2								
Stryker STERIZONE VP4 Sterilizer	100% n=9, m=3	100% n=9, m=3					100% n=9, m=3					
Supercritical Carbon Dioxide	100% n=8, m=3	**45%** n=11, m=3	**33%** n=6, m=3						**80%** n=5, m=1			
UVGI	100% n=4, m=2	100% n=6, m=3							100% n=6, m=3			
UVGI and Infrared Heat	100% n=4, m=1	**50%** n=8, m=1			100% n=5, m=1		**0%** n=3, m=1					
VPHP	94% n=56, m=12	**88%** n=204, m=16	**60%** n=8, m=5	100% n=6, m=5	100% n=6, m=5	100% n=6, m=5	**94%** n=51, m=16		**90%** n=57, m=13	100% n=5, m=1	**86%** n=62, m=14	**0%** n=3, m=1

Percent for the "All Cycles" column was calculated as an average change weighted by the number of samples in each cycle number. Sample size (n) = number of decontaminated respirators tested for each cell. m = number of different models tested.

Acronyms: PAA=Aerosolized Peracetic Acid, ROS=Reactive Oxygen Species, LTP= Low Temp Plasma, UVGI=Ultraviolet Germicidal Irradiation, VPHP=Vapor Phase Hydrogen Peroxide

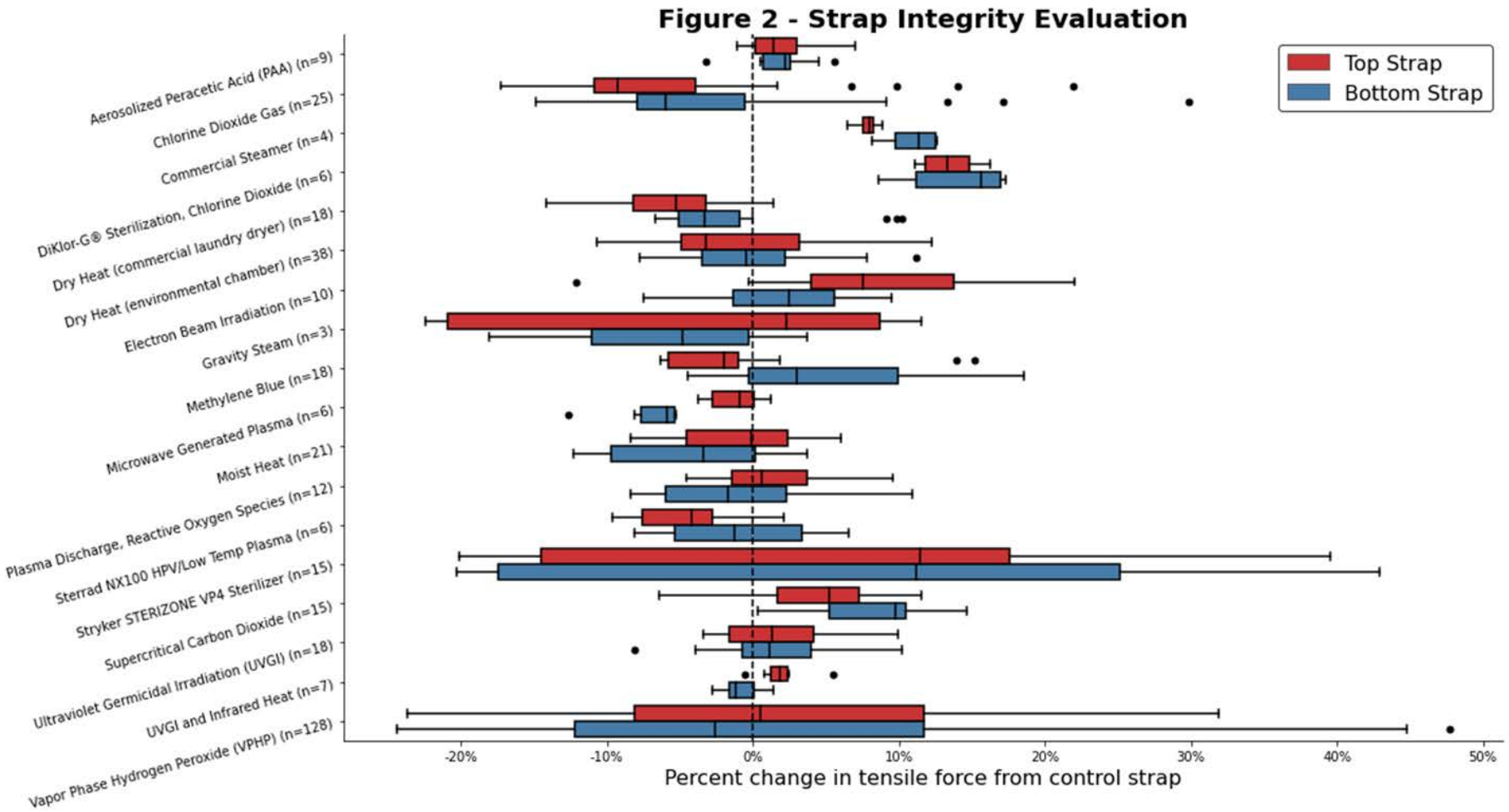
Figure 2 - Strap Integrity Evaluation
Top Strap
Bottom Strap
Aerosolized Peracetic Acid (PAA) (n=9)
Chlorine Dioxide Gas (n=25)
Commercial Steamer (n=4)
DiKlor-G® Sterilization, Chlorine Dioxide (n=6)
Dry Heat (commercial laundry dryer) (n=18)
Dry Heat (environmental chamber) (n=38)
Electron Beam Irradiation (n=10)
Gravity Steam (n=3)
Methylene Blue (n=18)
Microwave Generated Plasma (n=6)
Moist Heat (n=21)
Plasma Discharge, Reactive Oxygen Species (n=12)
Sterrad NX100 HPV/Low Temp Plasma (n=6)
Stryker STERIZONE VP4 Sterilizer (n=15)
Supercritical Carbon Dioxide (n=15)
Ultraviolet Germicidal Irradiation (UVGI) (n=18)
UVGI and Infrared Heat (n=7)
Vapor Phase Hydrogen Peroxide (VPHP) (n=128)
-20%
-10%
0%
10%
20%
30%
40%
50%
Percent change in tensile force from control strap

CASE Conclusions

The decontamination techniques and respirator models included in this assessment were not selected by NIOSH and were at the sole discretion of the decontamination providers. Therefore, this report includes an exploratory analysis of a convenience sample and may not be generalizable to all decontamination techniques or N95 FFRs.

The results of the evaluations suggest that some FFR decontamination techniques did not substantially impact filtration efficiency, manikin fit factor, or strap integrity while other techniques had a negative impact. Specifically, the following decontamination techniques were not shown to reduce filtration efficiency or manikin fit (**See Appendix B for specific information on FFR models tested, dose, and number of cycles**):

- PAA
- Chlorine dioxide gas
- Commercial steamer
- DiKlor-G® sterilization
- Dry heat in a commercial laundry dryer or environmental chamber
- Methylene blue plus light
- Stryker STERIZONE VP4 Sterilizer

The data suggest that these techniques practiced with their specified number of cycles and dose may not negatively impact FFR performance; however, studies should be developed that control for and explore various treatments across numerous models to provide greater confidence in these findings.

Some techniques reduced filtration efficiency to less than 95% in some or all of the tested FFRs:

- Supercritical CO_2 (evaluated for 3 models)
- Electron beam irradiation (evaluated for 1 model)
- UVGI in combination with infrared heat (evaluated for 1 model)

Some techniques negatively impacted manikin fit when compared to controls in some or all of the tested FFRs:

- FFRs decontaminated using gravity steam (evaluated for 2 models)
- Microwave generated plasma (evaluated for 2 models)
- Moist heat (evaluated for 1 model)
- Sterrad NX100 HPV/low temp plasma (evaluated for 2 models)
- Supercritical CO_2 (evaluated for 3 models)
- UVGI in combination with infrared heat (evaluated for 2 models)
- Vapor Phase Hydrogen Peroxide (VPHP) (evaluated for 16 models)

While the filtration efficiency and manikin fit results were stratified by the number of decontamination cycles in Tables 2 and 3 of this report, the number of cycles did not systematically influence the results. No obvious filtration or manikin fit degradation pattern was observed across the number of decontamination cycles in any of the techniques tested. For a more in-depth look at the data, see the supplementary tables in the appendix of this report. Each of the 19 supplementary tables presents filtration efficiency, manikin fit factor, and strap force change data for a separate decontamination

technique. Thus, evaluation of a convenience sample of 1,354 N95 FFR units across 29 models found that 42% of the decontamination techniques evaluated (8 of 19) negatively impacted fit and/or filtration efficiency.

The strap integrity evaluation results were largely mixed. The observed percent changes in tensile force between decontaminated and control straps, including both positive and negative changes within and between tested techniques. However, commercial steamer and DiKlor-G® sterilization did seem to result in increased strap tensile force compared with controls. Interpretation and potential translation of these results should consider that it is still unclear if observed changes in strap tensile force has a downstream influence on FFR fit. Therefore, further examination into this test technique and the impact on FFR fit is warranted.

Respirator manufacturers were made aware of the webpage of test results.

For some of the decontamination techniques that NIOSH tested, the FDA used these results in the evaluation of new decontamination technique EUA applications and to update or revoke existing EUAs.

NIOSH testing provided decontamination technique developers and service providers with laboratory-based data to ascertain the impact of their techniques on respirator performance.

Further Considerations for Decontamination and Reuse of Filtering Facepiece Respirators

- Healthcare organizations should review the FDA EUAs prior to incorporating decontamination techniques into a respiratory protection program. Only the FDA EUA approved techniques can be used in healthcare settings.
- The **respirator manufacturer should be consulted** about any impact that the decontamination technique has on their respirators before considering the use of any technique. Only respirator manufacturers can reliably provide guidance on how to decontaminate their specific models.
- **Decontamination and subsequent reuse of FFRs is a crisis strategy that should only be implemented during severe FFR shortages and no conventional or contingency strategies are viable. Decontamination is not consistent with NIOSH approved use of respirators.**
- **Decontamination does not extend the life of a respirator** and repeated donnings will reduce the fit factor of an FFR. FFRs may have fit failures after five donnings.[2]
- If you are contemplating incorporating decontamination techniques into your respiratory protection program as part of a crisis strategy, you should review the NIOSH Respirator Decontamination Assessment Results webpage, the Center for Disease Control and Prevention (CDC) webpage on Implementing Filtering Facepiece Respirator (FFR) Reuse, Including Reuse after Decontamination, When There Are Known Shortages of N95 Respirators, and OSHA's Coronavirus Disease (COVID-19) | Occupational Safety and Health Administration.

[2] Bergman, Michael S., et al. "Impact of multiple consecutive donnings on filtering facepiece respirator fit." American journal of infection control 40.4 (2012): 375-380.

- The fit factor of the FFR may be reduced with repeated donnings and even techniques that may not damage the FFR filter may require frequent fit evaluations. A protective approach recommended by the CDC is to limit the number of donnings to five and then dispose of the FFRs. Even with guidance on the maximum recommended number of donnings, it is important to thoroughly inspect a respirator each time it is used and discard it if it is soiled, damaged, difficult to breathe through, or you are unable to pass a seal check – even if it has not been used the maximum number of times specified by the CDC or the manufacturer.
- The effect of decontamination techniques on the security of the strap attachment to the mask was not completed in these assessments and should be considered in the future.
- The effect of decontamination technique was summarized across various FFR models consisting of differing product materials in this report. Consideration of the effect on individual FFR models and materials may be important to consider in the future.

Get More Information

Find NIOSH products and get answers to workplace safety and health questions: https://www.cdc.gov/niosh/npptl/

1-800-CDC-INFO (1-800-232-4636) | TTY: 1-888-232-6348
CDC/NIOSH INFO: cdc.gov/info | cdc.gov/niosh
Monthly NIOSH eNews: cdc.gov/niosh/eNews

Disclaimer

Mention of any company or product does not constitute endorsement by the National Institute for Occupational Safety and Health (NIOSH). In addition, citations to websites external to NIOSH do not constitute NIOSH endorsement of the sponsoring organizations or their programs or products. Furthermore, NIOSH is not responsible for the content of these websites. All web addresses referenced in this document were accessible as of the publication date.

Suggested Citation

NIOSH [2021] PPE CASE: Assessment of Filter Penetration Performance and Fit for Decontaminated N95 Respirators by Quinn, T., Bergman M., Strickland, K., Streeter, R., Vollmer, B., Meyers, J., Wilson, A., Pollard, J.P. Pittsburgh, PA U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, NPPTL Report Number P2021-0101.

Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

Appendix A. Supplementary Tables

Supplementary Table 1 – Aerosolized Peracetic Acid (PAA) results for filtration efficiency, manikin fit, and strap performance by model

Dose	Number of Cycles	Respirator Model	% with ≥95% filtration efficiency	% with manikin fit factor ≥100	% change in top strap tensile force from control	% change in bottom strap tensile force from control
76 min x 1.06% PAA solution	1 cycle	3M 1860	100% (n=5)	100% (n=3)	2.68 ± 3.78% (n=3)	1.83 ± 1.16% (n=3)
	3 cycles	3M 1860	100% (n=5)	100% (n=3)	0.42 ± 2.26% (n=3)	2.60 ± 1.72% (n=3)
	5 cycles	3M 1860	100% (n=5)	100% (n=3)	3.27 ± 2.89% (n=3)	1.01 ± 4.38% (n=3)

Supplementary Table 2 – Chlorine Dioxide Gas results for filtration efficiency, manikin fit, and strap performance by model

Dose	Number of Cycles	Respirator Model	% with ≥95% filtration efficiency	% with manikin fit factor ≥100	% change in top strap tensile force from control	% change in bottom strap tensile force from control
1000–2000 ppm-hr	5 cycles	3M 8000	---	100% (n=5)	-10.25 ± 1.41% (n=3)	-6.14 ± 0.75% (n=3)
	10 cycles	3M 8000	---	100% (n=5)	-15.04 ± 3.63% (n=3)	-6.15 ± 2.59% (n=3)
	20 cycles	3M 8000	100% (n=10)	80% (n=5)	-7.86 ± 2.10% (n=3)	-4.72 ± 2.54% (n=3)
2,500 ppm-hr	4 cycles	3M 8200	100% (n=4)	---	-11.56 ± 2.38% (n=4)	-7.11 ± 1.98% (n=4)
850 ppm-hr	5 cycles	3M 8200	100% (n=10)	100% (n=5)	-6.69 ± 2.78% (n=3)	-11.04 ± 3.88% (n=3)
720 ppm-hr	1 cycle	3M V-Flex 1805	100% (n=10)	100% (n=4)	0.54 ± 5.52% (n=3)	9.82 ± 3.21% (n=3)
	4 cycles	3M 1860	100% (n=10)	100% (n=5)	15.26 ± 6.17% (n=3)	18.38 ± 10.93% (n=3)
		VWR 89201-508	100% (n=10)	0% (n=5)	-6.15 ± 6.78% (n=3)	-5.57 ± 4.66% (n=3)

"---" indicates that no test was performed.

Supplementary Table 3 – Commercial Steamer results for filtration efficiency, manikin fit, and strap performance by model

Dose	Number of Cycles	Respirator Model	% with ≥95% filtration efficiency	% with manikin fit factor ≥100	% change in top strap tensile force from control	% change in bottom strap tensile force from control
30 seconds at 100°C	10 cycles	3M 8210	100% (n=10)	100% (n=5)	7.82 ± 1.02% (n=4)	10.86 ± 2.10% (n=4)

Supplementary Table 4 – DiKlor-G® Sterilization, Chlorine Dioxide results for filtration efficiency, manikin fit, and strap performance by model

Dose	Number of Cycles	Respirator Model	% with ≥95% filtration efficiency	% with manikin fit factor ≥100	% change in top strap tensile force from control	% change in bottom strap tensile force from control
800 ppm-hr	6 cycles	3M 8210	100% (n=10)	100% (n=5)	15.14 ± 1.07% (n=3)	16.05 ± 1.47% (n=3)
Not reported	6 cycles	3M 1860	100% (n=10)	100% (n=5)	11.70 ± 0.75% (n=3)	12.00 ± 4.65% (n=3)

Supplementary Table 5 – Dry Heat (commercial laundry dryer) results for filtration efficiency, manikin fit, and strap performance by model

Dose	Number of Cycles	Respirator Model	% with ≥95% filtration efficiency	% with manikin fit factor ≥100	% change in top strap tensile force from control	% change in bottom strap tensile force from control
90 min at 80-85°C	3 cycles	3M 1860	100% (n=10)	100% (n=5)	-1.74 ± 1.72% (n=3)	-3.23 ± 2.31% (n=3)
		3M 8511	100% (n=10)	100% (n=5)	-4.76 ± 5.58% (n=3)	-3.70 ± 3.18% (n=3)
		Halyard 62126	100% (n=10)	100% (n=5)	-4.38 ± 2.11% (n=3)	-3.28 ± 0.84% (n=3)
70 min at 80-85°C	3 cycles	3M 1860	100% (n=10)	100% (n=5)	-6.56 ± 2.36% (n=3)	-2.53 ± 1.47% (n=3)
		3M 8511	100% (n=10)	100% (n=5)	-12.09 ± 1.82% (n=3)	9.73 ± 0.53% (n=3)
		Halyard 62126	100% (n=10)	100% (n=5)	-4.60 ± 1.13% (n=3)	-5.23 ± 1.79% (n=3)

Supplementary Table 6 – Dry Heat (environmental chamber) results for filtration efficiency, manikin fit, and strap performance by model

Dose	Number of Cycles	Respirator Model	% with ≥95% filtration efficiency	% with manikin fit factor ≥100	% change in top strap tensile force from control	% change in bottom strap tensile force from control
60 min at 75°C	5 cycles	3M 1860	100% (n=7)	100% (n=3)	-4.31 ± 1.28% (n=5)	-1.23 ± 2.05% (n=5)
		3M 1870+	100% (n=7)	100% (n=3)	9.44 ± 1.93% (n=5)	1.43 ± 1.89% (n=5)
		Halyard 46717	100% (n=7)	100% (n=3)	-4.03 ± 0.62% (n=5)	-5.26 ± 1.39% (n=5)
45 min at 75°C	10 cycles	3M 1860	100% (n=10)	100% (n=5)	-5.62 ± 4.13% (n=4)	0.11 ± 3.81% (n=4)
		3M 1860S	100% (n=10)	100% (n=5)	-8.71 ± 2.08% (n=4)	-5.79 ± 2.06% (n=4)
		3M 1870+	100% (n=10)	100% (n=5)	3.25 ± 3.44% (n=4)	-1.28 ± 3.13% (n=4)
		3M 8210+	100% (n=10)	50% (n=10)	-0.40 ± 3.22% (n=3)	3.00 ± 3.05% (n=3)
		3M 9205+	100% (n=10)	100% (n=5)	5.90 ± 3.60% (n=4)	6.83 ± 3.59% (n=4)
		3M V-Flex 1804	100% (n=10)	80% (n=5)	-4.82 ± 1.79% (n=4)	0.59 ± 1.78% (n=4)

Supplementary Table 7 – Electron Beam Irradiation results for filtration efficiency, manikin fit, and strap performance by model

Dose	Number of Cycles	Respirator Model	% with ≥95% filtration efficiency	% with manikin fit factor ≥100	% change in top strap tensile force from control	% change in bottom strap tensile force from control
25 kGy/cycle	1 cycle	3M 8200	0% (n=4)	---	-0.40 ± 8.38% (n=4)	-1.29 ± 4.81% (n=4)
	2 cycles	3M 8200	0% (n=3)	---	11.78 ± 8.96% (n=3)	0.99 ± 5.05% (n=3)
	3 cycles	3M 8200	0% (n=3)	---	14.65 ± 3.25% (n=3)	7.20 ± 2.77% (n=3)

"---" indicates that no test was performed.

Supplementary Table 8 – Gaseous Ozone results for filtration efficiency, manikin fit, and strap performance by model

Dose	Number of Cycles	Respirator Model	% with ≥95% filtration efficiency	% with manikin fit factor ≥100	% change in top strap tensile force from control	% change in bottom strap tensile force from control
450 ppm	5 cycles	3M 1870	100% (n=5)	---	-0.23 ± 22.58% (n=3)	-5.32 ± 17.3% (n=3)

"---" indicates that no test was performed.

Supplementary Table 9 – Gravity Steam results for filtration efficiency, manikin fit, and strap performance by model

Dose	Number of Cycles	Respirator Model	% with ≥95% filtration efficiency	% with manikin fit factor ≥100	% change in top strap tensile force from control	% change in bottom strap tensile force from control
30 min at 121°C	3 cycles	3M 1860	100% (n=5)	0% (n-2)	9.85 ± 1.48% (n=3)	2.11 ± 2.1% (n=3)
		3M 1870	100% (n=5)	100% (n=2)	-21.57 ± 0.74% (n=3)	-5.71 ± 4.97% (n=3)
		3M V-Flex 1905	100% (n=5)	100% (n=2)	1.33 ± 5.49% (n=3)	-13.8 ± 3.99% (n=3)

Supplementary Table 10 – Methylene Blue results for filtration efficiency, manikin fit, and strap performance by model

Dose	Number of Cycles	Respirator Model	% with ≥95% filtration efficiency	% with manikin fit factor ≥100	% change in top strap tensile force from control	% change in bottom strap tensile force from control
10µM spray (~7mL/cycle) + 100k lux light for 60 mins	5 cycles	3M 1860	100% (n=7)	100% (n=3)	-3.67 ± 3.61% (n=5)	1.91 ± 3.83% (n=5)
		3M 1860S	82% (n=11)	100% (n=4)	-4.47 ± 2.34% (n=3)	4.88 ± 4.76% (n=3)
		3M 1870+	100% (n=7)	100% (n=3)	3.53 ± 10.21% (n=5)	14.37 ± 3.78% (n=5)
		Halyard 46727	100% (n=7)	100% (n=2)	-1.40 ± 0.76% (n=5)	-1.48 ± 1.55% (n=5)

Supplementary Table 11 – Microwave generated plasma results for filtration efficiency, manikin fit, and strap performance by model

Dose	Cycles Tested	Respirator Model	% with ≥95% filtration efficiency	% with manikin fit factor ≥100	% change in top strap tensile force from control	% change in bottom strap tensile force from control
45 seconds	3 cycles	3M 1860	100% (n=5)	100% (n=2)	-0.20 ± 1.37% (n=3)	-5.68 ± 0.55% (n=3)
		3M 8210	80% (n=5)	50% (n=2)	-2.25 ± 2.17% (n=3)	-8.69 ± 3.73% (n=3)

Supplementary Table 12 – Moist Heat results for filtration efficiency, manikin fit, and strap performance by model

Dose	Number of Cycles	Respirator Model	% with ≥95% filtration efficiency	% with manikin fit factor ≥100	% change in top strap tensile force from control	% change in bottom strap tensile force from control
60 min at 100°C & 100%RH	1 cycle	3M 1860	100% (n=3)	0% (n=5)	-5.29 ± 2.69% (n=3)	-8.58 ± 1.48% (n=3)
	3 cycles	3M 1860	100% (n=3)	0% (n=5)	-5.84 ± 1.47% (n=3)	-11.43 ± 0.85% (n=3)
	5 cycles	3M 1860	100% (n=3)	0% (n=5)	-5.10 ± 4.37% (n=3)	-10.40 ± 1.73% (n=3)
15 min at 85°C & 65%RH	1 cycle	3M 1860	100% (n=4)	33% (n=3)	1.89 ± 1.19% (n=4)	-1.73 ± 2.84% (n=4)
	3 cycles	3M 1860	100% (n=4)	33% (n=3)	2.28 ± 2.79% (n=4)	-0.15 ± 2.96% (n=4)
	5 cycles	3M 1860	100% (n=4)	33% (n=3)	2.75 ± 2.70% (n=4)	1.02 ± 1.56% (n=4)

Supplementary Table 13 – Plasma Discharge Reactive Oxygen Species results for filtration efficiency, manikin fit, and strap performance by model

Dose	Number of Cycles	Respirator Model	% with ≥95% filtration efficiency	% with manikin fit factor ≥100	% change in top strap tensile force from control	% change in bottom strap tensile force from control
500 ppm-min	1 cycle	BYD DE2322	100% (n=3)	---	-3.55 ± 1.19% (n=3)	-4.75 ± 4.38% (n=3)
		Prestige Ameritech RP88020	100% (n=3)	---	4.21 ± 5.4% (n=3)	3.79 ± 6.39% (n=3)
	3 cycles	BYD DE2322	100% (n=3)	---	1.93 ± 1.76% (n=3)	-4.87 ± 2.47% (n=3)
		Prestige Ameritech RP88020	100% (n=3)	---	1.73 ± 1.96% (n=3)	2.44 ± 4.05% (n=3)

"---" indicates that no test was performed.

Supplementary Table 14 – Sterrad NX100 HPV/Low Temp Plasma results for filtration efficiency, manikin fit, and strap performance by model

Dose	Cycles Tested	Respirator Model	% with ≥95% filtration efficiency	% with manikin fit factor ≥100	% change in top strap tensile force from control	% change in bottom strap tensile force from control
Not reported	2 cycles	3M 8511	100% (n=10)	40% (n=5)	-3.37 ± 5.88% (n=3)	3.62 ± 3.42% (n=3)
		Halyard 46727	100% (n=10)	80% (n=5)	-5.61 ± 2.57% (n=3)	-5.62 ± 3.00% (n=3)

Supplementary Table 15 – Stryker STERIZONE VP4 Sterilizer results for filtration efficiency, manikin fit, and strap performance by model

Dose	Number of Cycles	Respirator Model	% with ≥95% filtration efficiency	% with manikin fit factor ≥100	% change in top strap tensile force from control	% change in bottom strap tensile force from control
Pre-set cycle (Cycle 1), 41°C	5 cycles	3M 1860	100% (n=7)	100% (n=3)	27.52 ± 10.45% (n=5)	33.79 ± 8.57% (n=5)
		3M 1870+	100% (n=7)	100% (n=3)	11.95 ± 2.25% (n=5)	11.86 ± 4.56% (n=5)
		Halyard 46727	100% (n=7)	100% (n=3)	-17.20 ± 2.74% (n=5)	-18.75 ± 1.44% (n=5)

Supplementary Table 16 – Supercritical Carbon Dioxide results for filtration efficiency, manikin fit, and strap performance by model

Dose	Number of Cycles	Respirator Model	% with ≥95% filtration efficiency	% with manikin fit factor ≥100	% change in top strap tensile force from control	% change in bottom strap tensile force from control
60 min at 37°C & 1100 psig	10 cycles	3M 1860	0% (n=10)	80% (n=5)	-0.89 ± 1.42% (n=3)	2.17 ± 2.04% (n=3)
90 min at 37°C	1 cycle	3M 1860	0% (n=4)	0% (n=2)	9.38 ± 1.57% (n=4)	8.73 ± 4.53% (n=4)
		3M 1860S	0% (n=5)	0% (n=2)	5.62 ± 0.79% (n=4)	10.16 ± 0.35% (n=4)
		3M V-Flex 1804	0% (n=4)	100% (n=2)	1.55 ± 5.44% (n=4)	10.26 ± 3.12% (n=4)

Supplementary Table 17 – Ultraviolet Germicidal Irradiation (UVGI) results for filtration efficiency, manikin fit, and strap performance by model

Dose	Number of Cycles	Respirator Model	% with ≥95% filtration efficiency	% with manikin fit factor ≥100	% change in top strap tensile force from control	% change in bottom strap tensile force from control
UV-C 254nm 1000 mJ/cm^2	10 cycles	3M 1860	100% (n=5)	100% (n=2)	-1.09 ± 2.33% (n=3)	-3.97 ± 4.12% (n=3)
		3M 8210	100% (n=3)	100% (n=2)	1.85 ± 0.69% (n=3)	1.36 ± 1.66% (n=3)
UV-C 254nm 500 mJ/cm^2	1 cycle	3M 1860S	100% (n=5)	---	-0.84 ± 1.66% (n=3)	2.57 ± 1.50% (n=3)
	3 cycles	3M 1860S	100% (n=5)	---	0.17 ± 2.86% (n=3)	1.47 ± 4.54% (n=3)
	5 cycles	3M 1860S	100% (n=5)	---	5.12 ± 1.09% (n=3)	7.62 ± 2.32% (n=3)
	10 cycles	3M 1860	100% (n=5)	100% (n=1)	---	---
		3M 8210	100% (n=3)	100% (n=1)	5.65 ± 6.90% (n=3)	0.16 ± 2.48% (n=3)

"---" indicates that no test was performed.

Supplementary Table 18 – UVGI and Infrared Heat results for filtration efficiency, manikin fit, and strap performance by model

Dose	Number of Cycles	Respirator Model	% with ≥95% filtration efficiency	% with manikin fit factor ≥100	% change in top strap tensile force from control	% change in bottom strap tensile force from control
90 min at 175°C	3 cycles	Halyard 46767	100% (n=10)	100% (n=5)	3.16 ± 2.05% (n=3)	-0.89 ± 1.94% (n=3)
	5 cycles	Halyard 46767	0% (n=10)	0% (n=3)	1.14 ± 1.32% (n=4)	-0.75 ± 1.43% (n=4)

Supplementary Table 19 – Vapor Phase Hydrogen Peroxide (VPHP) results for filtration efficiency, manikin fit, and strap performance by model

Dose	Number of Cycles	Respirator Model	% with ≥95% filtration efficiency	% with manikin fit factor ≥100	% change in top strap tensile force from control	% change in bottom strap tensile force from control
25 min at 45°C with 35% HP	10 cycles	Makrite 9500-N95S	100% (n=5)	100% (n=3)	-6.59 ± 1.07% (n=5)	-2.60 ± 3.12% (n=5)
	20 cycles	Makrite 9500-N95S	60% (n=5)	33% (n=3)	-4.05 ± 2.85% (n=5)	0.13 ± 3.65% (n=5)
	30 cycles	Makrite 9500-N95S	100% (n=5)	0% (n=3)	-8.62 ± 4.41% (n=5)	-11.63 ± 1.29% (n=5)
3 hours at 7%	1 cycle	3M 8000	100% (n=4)	0% (n=1)	---	---
		3M 8210	100% (n=3)	100% (n=2)	---	---
		3M 8210V	100% (n=3)	100% (n=2)	---	---
		Crosstex GPRN95	100% (n=4)	0% (n=1)	---	---
		Moldex 1512	100% (n=3)	100% (n=2)	---	---
	2 cycles	3M 8000	100% (n=5)	---	---	---
		3M 8210	100% (n=3)	100% (n=2)	---	---
		3M 8210V	100% (n=3)	100% (n=2)	---	---
		Crosstex GPRN95	100% (n=5)	---	---	---
		Moldex 1512	100% (n=3)	100% (n=2)	---	---
	3 cycles	3M 8000	100% (n=5)	---	---	---
		3M 8210	100% (n=3)	100% (n=2)	---	---
		3M 8210V	100% (n=3)	100% (n=2)	---	---
		Crosstex GPRN95	100% (n=5)	---	---	---
		Moldex 1512	100% (n=3)	100% (n=2)	---	---
	4 cycles	3M 8000	100% (n=5)	---	---	---
		3M 8210	100% (n=3)	100% (n=2)	---	---
		3M 8210V	100% (n=3)	100% (n=2)	---	---
		Crosstex GPRN95	100% (n=5)	---	---	---
		Moldex 1512	100% (n=3)	100% (n=2)	---	---
	5 cycles	3M 8000	100% (n=5)	---	---	---
		3M 8210	100% (n=3)	100% (n=2)	---	---
		3M 8210V	100% (n=3)	100% (n=2)	---	---
		Crosstex GPRN95	100% (n=5)	---	---	---
		Moldex 1512	100% (n=3)	100% (n=2)	---	---

"---" indicates that no test was performed.

Supplementary Table 19 Continued – Vapor Phase Hydrogen Peroxide (VPHP) results for filtration efficiency, manikin fit, and strap performance by model

Dose	Number of Cycles	Respirator Model	% with ≥95% filtration efficiency	% with manikin fit factor ≥100	% change in top strap tensile force from control	% change in bottom strap tensile force from control
Not Reported	5 cycles	3M 1860	100% (n=5)	100% (n=2)	---	----
		3M 1860S	100% (n=3)	100% (n=3)	21.38 ± 2.50% (n=3)	16.49 ± 2.58% (n=3)
		3M 8210	100% (n=5)	100% (n=2)	-1.22 ± 2.05% (n=3)	-12.98 ± 1.93% (n=3)
		3M 8511	100% (n=10)	100% (n=5)	13.10 ± 1.16% (n=3)	24.85 ± 2.69% (n=3)
		3M 9205+	100% (n=10)	100% (n=5)	-10.32 ± 1.50% (n=3)	-19.52 ± 2.67% (n=3)
		3M V-Flex 1804	100% (n=5)	100% (n=2)	7.40 ± 6.19% (n=3)	8.78 ± 2.48% (n=3)
		Gerson 1730	100% (n=10)	100% (n=4)	-3.78 ± 4.83% (n=3)	-3.95 ± 2.28% (n=3)
		Gerson 1740	100% (n=10)	75% (n=4)	-14.24 ± 5.05% (n=3)	-4.50 ± 6.58% (n=3)
		Moldex 1512	100% (n=8)	100% (n=4)	-11.32 ± 2.74% (n=3)	-9.49 ± 4.28% (n=3)
		Moldex 2200	100% (n=8)	50% (n=4)	4.91 ± 1.09% (n=2)	-5.01 ± 8.72% (n=2)
		Sperian N1105	100% (n=10)	100% (n=5)	7.31 ± 3.01% (n=3)	24.03 ± 3.06% (n=3)
		Sperian N1125	100% (n=10)	80% (n=5)	9.32 ± 2.82% (n=3)	18.69 ± 11.41% (n=3)
		Sperian One-Fit	100% (n=15)	---	-0.50 ± 20.48% (n=3)	-1.52 ± 7.74% (n=3)
	10 cycles	3M 1860	100% (n=10)	100% (n=5)	17.25 ± 0.82% (n=3)	37.67 ± 3.10% (n=3)
		3M 8210	100% (n=10)	100% (n=5)	0.54 ± 1.69% (n=3)	-10.08 ± 1.95% (n=3)
		3M 8511	100% (n=10)	100% (n=5)	15.25 ± 12.15% (n=3)	23.43 ± 1.35% (n=3)
		3M 9205+	100% (n=10)	100% (n=5)	-14.04 ± 2.78% (n=3)	-18.26 ± 5.25% (n=3)
		3M V-Flex 1804	100% (n=10)	80% (n=5)	25.76 ± 5.50% (n=3)	22.73 ± 3.62% (n=3)
		Gerson 1730	100% (n=10)	100% (n=5)	-19.68 ± 3.49% (n=3)	-16.38 ± 7.29% (n=3)
		Gerson 1740	100% (n=10)	25% (n=4)	-4.38 ± 3.81% (n=3)	5.86 ± 6.81% (n=3)
		Moldex 1512	100% (n=10)	100% (n=5)	-10.01 ± 2.86% (n=3)	-11.80 ± 2.84% (n=3)
		Moldex 2200	90% (n=10)	100% (n=5)	10.43 ± 3.74% (n=3)	-11.23 ± 3.42% (n=3)
		Sperian N1105	100% (n=10)	100% (n=5)	10.53 ± 5.41% (n=3)	4.54 ± 8.55% (n=3)
		Sperian N1125	100% (n=10)	80% (n=5)	9.41 ± 4.80% (n=3)	-4.54 ± 7.70% (n=3)
		Sperian One-Fit	100% (n=10)	---	18.45 ± 14.87% (n=3)	-3.63 ± 19.95% (n=3)

"---" indicates that no test was performed.

Supplementary Table 19 Continued – Vapor Phase Hydrogen Peroxide (VPHP) results for filtration efficiency, manikin fit, and strap performance by model

Dose	Number of Cycles	Respirator Model	% with ≥95% filtration efficiency	% with manikin fit factor ≥100	% change in top strap tensile force from control	% change in bottom strap tensile force from control
Not Reported	15 cycles	3M 1860	100% (n=10)	100% (n=5)	22.42 ± 2.24% (n=3)	42.93 ± 5.96% (n=3)
	20 cycles	3M 1860	100% (n=10)	100% (n=5)	24.85 ± 1.62% (n=3)	39.06 ± 8.30% (n=3)
		3M 1870+	100% (n=6)	100% (n=4)	-15.29 ± 3.99% (n=3)	-17.81 ± 2.00% (n=3)
		3M 8210	100% (n=10)	100% (n=5)	-6.14 ± 0.90% (n=3)	-16.65 ± 3.57% (n=3)
		3M 8511	100% (n=10)	100% (n=5)	18.06 ± 11.48% (n=3)	0.10 ± 4.19% (n=3)
		3M 9205+	100% (n=10)	100% (n=5)	-18.73 ± 4.06% (n=3)	-19.30 ± 3.16% (n=3)
		3M V-Flex 1804	100% (n=10)	80% (n=5)	6.04 ± 7.71% (n=3)	5.94 ± 3.97% (n=3)
		Gerson 1730	100% (n=10)	100% (n=5)	0.13 ± 9.31% (n=3)	-5.33 ± 4.14% (n=3)
		Gerson 1740	100% (n=10)	100% (n=5)	1.27 ± 2.81% (n=3)	-8.83 ± 11.35% (n=3)
		Moldex 1512	100% (n=10)	100% (n=5)	-14.49 ± 2.20% (n=3)	-15.53 ± 2.60% (n=3)
		Moldex 2200	100% (n=10)	80% (n=5)	1.38 ± 6.31% (n=3)	3.84 ± 4.88% (n=3)
		Sperian N1105	100% (n=10)	80% (n=5)	5.56 ± 4.54% (n=3)	-10.25 ± 7.76% (n=3)
		Sperian N1125	100% (n=10)	40% (n=5)	0.24 ± 3.07% (n=3)	-6.42 ± 3.19% (n=3)
		Sperian One-Fit	100% (n=10)	---	3.62 ± 23.37% (n=3)	17.98 ± 5.19% (n=3)

"---" indicates that no test was performed.

APPENDIX B. N95 FFR PERFORMANCE EVALUATION METHODS

Particulate Filter Efficiency Testing

The maximum and minimum penetration value will be reported for the set of 10 respirators. If valves are present on the respirator, they will be sealed for testing. Each respirator will be tested on a TSI 8130 and/or 8130A Automated Filter Tester, set to the following parameters:

a. The flow rate will be set to 85.0 ± 4.0 Liters/Minute.
b. Aerosol concentration will not exceed 200 mg/m^3.
c. The particle size distribution will be 0.075 ± 0.020 micrometer with a geometric standard deviation not exceeding 1.86.
d. Each respirator will be tested for 10 minutes.
e. Maximum penetration will be recorded for each individual respirator

While some of the test parameters listed are consistent with NIOSH Standard Test Procedure TEB-APR-STP-0059 (STP-0059) [1], this modified test is different. Respirators assessed to this modified test plan do not meet the requirements of STP-0059, and therefore cannot be considered equivalent to N95 respirators that were tested to STP-0059. The values reported are only to provide an indication of filter efficiency following decontamination.

Static Advanced Headform Fit Evaluation

Static fit testing will be completed using a static advanced headform (StAH). A medium size StAH (Hanson Robotics Inc., Plano, TX) (corresponding to the medium size dimensions of the NIOSH Principal Component Analysis Panel), will be used to assess the static fit of respirators. Depending on the size of the respirator received and the perception of fit on the medium sized headform, a large sized StAH (Lunar Studios, Wylie, TX) may also be used. Overall manakin fit factor (mFFO) will be determined for 5 respirators that were subjected to decontamination procedures and an additional 2 control respirators that are new and were not decontaminated. This evaluation includes the assessment of mFFO using the below-described methodology.

The static advanced headform fit testing and tensile strength testing will be used to determine the anticipated changes in fit. The stress of the straps following the decontamination procedure will be compared to

[1] NIOSH Standard Test Procedure: https://www.cdc.gov/niosh/npptl/stps/pdfs/TEB-APR-STP-0059-508.pdf

that of the control respirators that did not undergo the decontamination technique. Therefore, the results of this testing will show any changes in tensile strength due to the decontamination technique. Likewise, the change in the overall manikin fit factor will be reported.

Headform Donning

Respirators will be donned to the headform following the respirator manufacturers' guidance for correct headstrap placement and adjustment of the bendable noseclip (for models so equipped). Manikin fit factor evaluations are performed utilizing a "screening" technique that was developed to quickly evaluate the seal of the respirator to the face of the StAH prior to beginning the actual fit factor evaluation. The screening technique first involves donning the respirator onto the StAH and making adjustments to the noseclip and head straps. Then, with the breathing machine operating at 11.2 lpm, the test operator observes a graphic display of real-time fit factors (FF) on the PortaCount® screen (real-time FF mode) where FFs are output approximately 1 per second. If the real-time output shows 10-consecutive FFs ≥ 100, then the test operator begins the actual fit factor evaluation. If not, the respirator is doffed, re-donned, adjusted, and reevaluated in real-time FF mode. Fit factor evaluations are started after the third attempt if fit criteria is not met after three attempts.

Headform Breathing

Respirator fit will be evaluated for the StAH under cyclic breathing conditions. The tube extending from the bottom of the StAH is connected to an inflatable (non-latex, powder-free) bladder inside an isolated, airtight, plastic cylinder. This configuration prevents any particles potentially generated by the simulator from entering the breathing zone of the StAH. A port on the cylinder is connected to a Series 1101 breathing simulator (Hans Rudolf, Inc., Shawnee, KS).

Two minute-volumes are used for manikin fit factor evaluation: normal breathing (14 breaths / min (bpm) x 800 ml tidal volume = 11.2 lpm) and deep breathing (12 bpm x 1700 ml tidal volume = 20.4 lpm). The use of only two exercises (normal and deep breathing) differs from the standard OSHA-accepted PortaCount® fit test which also includes dynamic movements and a speaking passage. Therefore, fit results from this assessment cannot be directly translated to using the standard OSHA-accepted test.

Manakin Fit Factor

Manikin fit factor (mFF) will be measured on the StAH using a PortaCount® Pro+ model 8038 Respirator Fit Tester (TSI, Inc., Shoreview, MN) operating in the N95-enabled mode. The PortaCount® utilizes condensation nuclei counting technology to enumerate individual particles and calculate a quantitative respirator mFF. The

test agent used will be ambient room aerosol supplemented with generated sodium chloride aerosol. A non-commercial software will automate the fit factor data collection.

An individual fit factor evaluation includes three successive 86-sec exercises: an initial normal breathing exercise (NB1), a deep breathing exercise (DB), and then a second normal breathing exercise (NB2). Each 86-sec exercise consists of four PortaCount® actions: ambient purge (6 sec), ambient sample (15 sec), mask purge (15 sec), and mask sample (50 sec). Four mFFs are obtained for each test—one for each of the three exercises and an overall exercise (mFFO), calculated as the harmonic mean of the mFFs from the three individual exercises.

Tensile Testing of Elastomeric Straps

Straps will be removed from 5 respirators as required for particulate filter efficiency testing. These straps include the top and bottom straps from 3 respirators that were subjected to the decontamination process and additional top and bottom straps from 2 control respirators that are new and have not undergone any decontamination process. The integrity of these elastomeric head straps will be assessed using an Instron 5943 tensile tester as follows.

1. Straps will be sectioned into 10-cm segments, with ~15 mm on each side to be clamped.
2. Straps will be inserted into the Instron and pulled at 1 cm/s until 200% strain (30 cm sample length) is reached.
3. This “pre-stretching” position will be held for 2 minutes.
4. Straps will be returned to their original position for 5 minutes and the new segment length will be measured after the 5 minutes.
5. Straps will be pulled at 1 cm/s until reaching 150% strain of the new length. This 150% strain position will be held for 30 seconds and the force at the end of the 30 seconds will be recorded.