Evaluation of Decontaminated N95 Respirators

NPPTL
National Personal Protective
Technology Laboratory

Date Tested: 11/17/2020 – 11/19/2020

Respirator Model(s): 3M 1860, 3M 1860S, 3M VFlex 1804

Tests: Filtration with NaCl (modified version of STP-0059), Manikin Fit Factor with Static Advanced Headform, and Strap Integrity with Tensile Testing

Decontamination Method: New FFRs were decontaminated with dense-phase carbon dioxide at 37°C above its supercritical pressure of 1100 psig with humidification for 90 minutes.

Decontamination Cycles: 1 cycle

While decontamination and reuse of FFRs are not consistent with standard and approved usage, these options may need to be considered when FFR shortages exist. This assessment was developed to quantify the filtration efficiency and manikin fit factor[1] of an N95 respirator that has been decontaminated. This assessment is not to determine the effectiveness of the decontamination procedure at killing pathogenic microorganisms. The results provided in this report are specific to the subset of samples that were provided to NPPTL for evaluation. These results may be used to update the CDC guidance for Crisis Capacity Strategies (during known shortages).

Thirty-one respirators that were unworn and not subjected to any pathogenic microorganisms were submitted for evaluation. This included 19 respirators that were subjected to 1 cycle of the supercritical carbon dioxide decontamination process and an additional 12 respirators that served as controls. Figure 1 photos document the procedures used. The samples were tested using a modified version of the NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059 to determine particulate filtration efficiency. The TSI, Inc. model 8130 using sodium chloride aerosol was used for the filtration evaluation. For the laboratory fit evaluation, a static manikin headform was used to quantify changes in manikin fit factor. The TSI, Inc. PortaCount® PRO+ 8038 in "N95 Enabled" mode was used for this evaluation. Additionally, tensile strength testing of the straps was performed to determine changes in strap integrity. The Instron® 5943 Tensile Tester was used for this evaluation. The full assessment plan can be found here.

Other notes: The 3M 1860, 3M 1860S and 3M VFlex 1804 treated respirators had observable fading of the printed information found on the outside and discoloration of the nosefoam and respirator material on the inside. Figure 1A-1E shows a comparison between a control sample and a treated sample of the noted respirator models. A strong odor and overall stiffness of the treated respirators was also observed.

3M 1860

Filtration Efficiency Results: The minimum and maximum filter efficiencies were 55.70% and 74.70%, respectively. All four treated respirators measured efficiencies less than the passing 95%. See Table 1.

Manikin Fit Factor Results: The manikin fit factor showed passing fit factors (≥100) for the two control respirators evaluated. The two treated samples received failing fit factors (< 100). See Table 2.

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[1]The American Industrial Hygiene Association defines the Manikin Fit Factor as "An expression related to the amount of leakage measured through the face or neck seal of a respirator mounted to a manikin under specified airflow and environmental conditions. If the challenge to the seal is an airborne substance, it is the ratio of its airborne concentration outside the respirator divided by the concentration that enters the respirator through the seal. If the challenge is airflow or air pressure, conditions and assumptions for quantifying leakage must be specified. Leakage from other sources (e.g., air purifying elements) must be essentially zero. The respirator may be mounted to the manikin without sealants; be partially sealed to the manikin; or be sealed to the manikin with artificially induced leaks."

Strap Integrity Results: The top straps showed a 9.38% increase in recorded force and the bottom straps showed a 8.73% increase in force. See Table 3.

<u>**3M 1860S**</u>

Filtration Efficiency Results: The minimum and maximum filter efficiencies were 57.70% and 84.90%, respectively. All five treated respirators measured efficiencies less than the passing 95%. See Table 4.

Manikin Fit Factor Results: The manikin fit factor showed passing fit factors (≥100) for the two control respirators evaluated. The two treated samples received failing fit factors (< 100). See Table 5.

Strap Integrity Results: The top straps showed a 5.62% increase in recorded force and the bottom straps showed a 10.16% increase in force. See Table 6.

<u>**3M VFlex 1804**</u>

Filtration Efficiency Results: The minimum and maximum filter efficiencies were 82.00% and 91.79%, respectively. All four treated respirators measured efficiencies less than the passing 95%. See Table 7.

Manikin Fit Factor Results: The manikin fit factor showed passing fit factors (≥100) for both the control and treated respirators. See Table 8.

Strap Integrity Results: The top straps showed a 1.55% increase in recorded force and the bottom straps showed a 10.26% increase in force. See Table 9.

Figure 1. Sample Observations

Fig. 1A. 3M 1860 Outside Control (Left), Treated (Right)

Fig. 1B. 3M 1860 Inside Control (Left), Treated (Right)

Fig. 1C. 3M 1860S Outside Control (Left), Treated (Right)

Fig. 1D. 3M 1860S Inside Control (Left), Treated (Right)

Fig. 1E. 3M VFlex 1804 Outside Control (Left), Treated (Right)

Figure 2. Laboratory Test Photos

Fig. 2A. Medium Static Advanced Headform (left to right: 3M 1860, 3M 1860S, VFlex 1804)

Fig. 2B. Instron 5943 Tensile Tester

Fig. 2C. TSI 8130 Filter Tester (left to right: 3M 1860, VFlex 1804)

Table 1. Filter Efficiency Evaluation – 3M 1860

Respirator Model, Decon Method, # of cycles	Treated Sample #	Flow Rate (Lpm)	Initial Filter Resistance (mmH$_2$O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
3M 1860, Controls	**Control 1**	85	9.0	0.424	0.783	99.22
	Control 2	85	8.9	0.350	0.577	99.42
3M 1860, Supercritical CO$_2$, 1 cycle Min Fil Eff: **55.70%** Max Fil Eff: **74.70%**	**1**	85	9.9	25.3	25.3	**74.70**
	2	85	9.6	43.4	44.3	**55.70**
	3	85	8.9	41.0	41.0	**59.00**
	4	85	9.1	39.7	39.7	**60.30**

Notes:
- The test method utilized in this assessment is not the NIOSH standard test procedure that is used for certification of respirators. Respirators assessed to this modified test plan do not necessarily meet the requirements of STP-0059, and therefore cannot be considered equivalent to N95 respirators that were tested to STP-0059.
- **BOLD** filter efficiencies < 95%.

Table 2. Manikin Fit Evaluation – 3M 1860

Manikin Fit Factor of Decontaminated N95s					
Respirator Model, Decon Method, # of cycles	**Treated Sample #**	**mFF Normal Breathing 1**	**mFF Deep Breathing**	**mFF Normal Breathing 2**	**Overall Manikin Fit Factor**
3M 1860, Controls Static Advanced Medium Headform (Hanson Robotics)	**Control 3**	200+	151	200+	181
	Control 4	200+	200+	200+	200+
3M 1860, Supercritical CO$_2$, 1 cycle Static Advanced Medium Headform (Hanson Robotics)	**5**	74	24	59	**42**
	6	88	13	23	**22**

Notes:
- Per OSHA 1910.134(f)(7), if the fit factor as determined through an OSHA-accepted quantitative fit testing protocol is equal to or greater than 100 for tight-fitting half facepieces, then the fit test has been passed for that respirator.
- This assessment does not include fit testing of people and only uses two exercises (normal and deep breathing) on a manikin headform.
- This assessment is a laboratory evaluation using a manikin headform and varies greatly from the OSHA individual fit test. This headform testing only includes normal breathing and deep breathing on a stationary (non-moving) headform; therefore, fit results from this assessment cannot be directly translated to using the standard OSHA-accepted test. Instead, this testing provides an indication of the change in fit performance (if any) associated with the decontamination of respirators.
- **BOLD** overall manikin fit factors < 100.

Table 3. Strap Integrity Evaluation – 3M 1860

Tensile Force in Respirator Straps of Decontaminated N95s (recorded force values are at 150% strain)			
Respirator Model, Decon Method, # of cycles	**Straps from Treated Sample #**	**Force in Top Strap (N)**	**Force in Bottom Strap (N)**
3M 1860, Controls	**Control 1**	2.757	3.110
	Control 2	2.797	3.242
	Control Strap Average	2.777	3.176
3M 1860, Supercritical CO$_2$, 1 cycle	**1**	3.009	3.367
	2	3.097	3.319
	3	3.043	3.485
	4	3.001	3.642
	Decontaminated Strap Average	3.038	3.453
	% Change ((Deconned – Controls)/ Controls)	9.38%	8.73%

Table 4. Filter Efficiency Evaluation – 3M 1860S

Respirator Model, Decon Method, # of cycles	Treated Sample #	Flow Rate (Lpm)	Initial Filter Resistance (mmH$_2$O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
3M 1860S, Controls	Control 1	85	12.5	0.395	0.783	99.22
	Control 2	85	13.8	0.361	0.577	99.42
3M 1860S, Supercritical CO$_2$, 1 cycle Min Fil Eff: **57.70%** Max Fil Eff: **84.90%**	1	85	12.6	41.30	42.00	**58.00**
	2	85	12.3	40.60	41.60	**58.40**
	3	85	12.2	42.30	42.30	**57.70**
	4	85	11.8	37.10	38.60	**61.40**
	5	85	14.1	14.70	15.10	**84.90**

Notes:

- The test method utilized in this assessment is not the NIOSH standard test procedure that is used for certification of respirators. Respirators assessed to this modified test plan do not necessarily meet the requirements of STP-0059, and therefore cannot be considered equivalent to N95 respirators that were tested to STP-0059.

- **BOLD** filter efficiencies < 95%.

Table 5. Manikin Fit Evaluation – 3M 1860S

Manikin Fit Factor of Decontaminated N95s					
Respirator Model, Decon Method, # of cycles	Treated Sample #	mFF Normal Breathing 1	mFF Deep Breathing	mFF Normal Breathing 2	Overall Manikin Fit Factor
3M 1860S, Controls	Control 3	200+	183	200+	194
Static Advanced Medium Headform (Hanson Robotics)	Control 4	200+	200+	200+	200+
3M 1860S, Supercritical CO_2, 1 cycle	6	11	6	10	**8**
Static Advanced Medium Headform (Hanson Robotics)	7	19	8	26	**13**

Notes:
- Per [OSHA 1910.134(f)(7)](#), if the fit factor as determined through an OSHA-accepted quantitative fit testing protocol is equal to or greater than 100 for tight-fitting half facepieces, then the fit test has been passed for that respirator.
- This assessment does not include fit testing of people and only uses two exercises (normal and deep breathing) on a manikin headform.
- This assessment is a laboratory evaluation using a manikin headform and varies greatly from the OSHA individual fit test. This headform testing only includes normal breathing and deep breathing on a stationary (non-moving) headform; therefore, fit results from this assessment cannot be directly translated to using the standard OSHA-accepted test. Instead, this testing provides an indication of the change in fit performance (if any) associated with the decontamination of respirators.
- **BOLD** overall manikin fit factors < 100.

Table 6. Strap Integrity Evaluation – 3M 1860S

Tensile Force in Respirator Straps of Decontaminated N95s (recorded force values are at 150% strain)			
Respirator Model, Decon Method, # of cycles	Straps from Treated Sample #	Force in Top Strap (N)	Force in Bottom Strap (N)
3M 1860S, Controls	Control 1	4.343	3.750
	Control 2	4.353	3.590
	Control Strap Average	4.348	3.670
3M 1860S, Supercritical CO_2, 1 cycle	1	4.614	4.033
	2	4.578	4.057
	3	4.626	4.051
	4	4.551	4.031
	Decontaminated Strap Average	4.592	4.043
	% Change ((Deconned – Controls)/ Controls)	5.62%	10.16%

Table 7. Filter Efficiency Evaluation – 3M VFlex 1804

Respirator Model, Decon Method, # of cycles	Treated Sample #	Flow Rate (Lpm)	Initial Filter Resistance (mmH$_2$O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
3M VFlex 1804, Controls	Control 1	85	4.5	0.132	0.223	99.78
	Control 2	85	4.9	0.308	0.448	99.55
3M VFlex 1804, Supercritical CO₂, 1 cycle Min Fil Eff: **82.00%** Max Fil Eff: **91.79%**	1	85	5.4	8.870	10.30	**89.70**
	2	85	4.7	16.80	18.00	**82.00**
	3	85	4.5	11.00	11.50	**88.50**
	4	85	4.7	7.630	8.210	**91.79**

Notes:
- The test method utilized in this assessment is not the NIOSH standard test procedure that is used for certification of respirators. Respirators assessed to this modified test plan do not necessarily meet the requirements of STP-0059, and therefore cannot be considered equivalent to N95 respirators that were tested to STP-0059.
- **BOLD** filter efficiencies < 95%.

Table 8. Manikin Fit Evaluation – 3M VFlex 1804

Manikin Fit Factor of Decontaminated N95s					
Respirator Model, Decon Method, # of cycles	**Treated Sample #**	**mFF Normal Breathing 1**	**mFF Deep Breathing**	**mFF Normal Breathing 2**	**Overall Manikin Fit Factor**
3M VFlex 1804, Controls	**Control 3**	200+	200+	200+	200+
Static Advanced Medium Headform (Hanson Robotics)	**Control 4**	200+	200+	200+	200+
3M VFlex 1804, Supercritical CO$_2$, 1 cycle	**5**	200+	67	200+	121
Static Advanced Medium Headform (Hanson Robotics)	**6**	200+	132	200+	171

Notes:
- Per OSHA 1910.134(f)(7), if the fit factor as determined through an OSHA-accepted quantitative fit testing protocol is equal to or greater than 100 for tight-fitting half facepieces, then the fit test has been passed for that respirator.
- This assessment does not include fit testing of people and only uses two exercises (normal and deep breathing) on a manikin headform.
- This assessment is a laboratory evaluation using a manikin headform and varies greatly from the OSHA individual fit test. This headform testing only includes normal breathing and deep breathing on a stationary (non-moving) headform; therefore, fit results from this assessment cannot be directly translated to using the standard OSHA-accepted test. Instead, this testing provides an indication of the change in fit performance (if any) associated with the decontamination of respirators.

Table 9. Strap Integrity Evaluation – 3M VFlex 1804

Tensile Force in Respirator Straps of Decontaminated N95s (recorded force values are at 150% strain)			
Respirator Model, Decon Method, # of cycles	**Straps from Treated Sample #**	**Force in Top Strap (N)**	**Force in Bottom Strap (N)**
3M VFlex 1804, Controls	**Control 1**	3.007	2.678
	Control 2	3.058	2.699
	Control Strap Average	3.033	2.689
3M VFlex 1804, Supercritical CO$_2$, 1 cycle	**1**	2.838	2.935
	2	3.192	2.869
	3	3.112	2.989
	4	3.178	3.067
	Decontaminated Strap Average	3.080	2.965
	% Change ((Deconned – Controls)/ Controls)	1.55%	10.26%