

# Evaluation of Decontaminated N95 Respirators

**Date(s) Tested:** 4/17/2020-4/21/2020

**Respirator Model(s):** 3M 1860, 3M V-flex 1805, VWR 89201-508

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

**Decontamination Method:** ClorDiSys Solutions Minidox-M, Chlorine Dioxide Generator, Concentration: 1 mg/L, RH: 65%, Exposure: 720 ppm/hrs (120 min)

**Decontamination Cycles:** 4 cycles (3M 1860 and VWR), 1 cycle (3M V-flex 1805)

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<sup>1</sup> 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).

Fifty-nine respirators, of varying manufacturers/models, that were unworn and not subjected to any pathogenic microorganisms were submitted for evaluation. This included 30 respirators that were subjected to 4 cycles of the Chlorine Dioxide decontamination process, 14 respirators subjected to 1 cycle of the Chlorine Dioxide decontamination process, and an additional 15 respirators that served as controls. Figure 1 photos document the procedures used. Photos of the samples and information received are shown in Figures 2 and 3. 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](#).

**Filtration Efficiency Results:** The maximum and minimum filter efficiency were as follows; 3M 1860, 4 cycles (99.73% and 98.82%); 3M V-flex 1805, 1 cycle (99.80% and 99.50%); VWR 89201, 4 cycles (99.59% and 97.91%). All samples of all three respirator models had filtration efficiencies measured more than 95%. See Table 1 for 3M respirators and Table 4 for VWR.

**Manikin Fit Factor Results:** The manikin fit factor showed passing fit factors (greater than 100) for all samples of the 3M 1860 (4 cycles) and 3M V-flex 1804 (1 cycle). See Table 2 for 3M respirators.

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<sup>1</sup>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."

The manikin fit factor did not show consistent passing fit factors for the VWR 89201 (4 cycles) (range=37-96). See Table 5 for VWR respirators.

The manikin fit test procedure used in this assessment did not show any detriments in fit associated with the decontamination method used for the 3M 1860 (4 cycles) and 3M V-flex 1805 (1 cycle), though a significant reduction in manikin fit factor was seen in the VWR 89201 (4 cycles). We consider  $\geq 100$  as the passing criterion for Overall Manikin Fit Factor (mFF), as OSHA considers  $\geq 100$  as a passing Fit Factor (FF). Both control samples had an overall mFF  $\geq 100$ , while all five treated samples had an overall mFF  $\leq 100$ . These observations indicate a decreased fit of the treated samples as compared to the controls. Small changes in fit factors may be attributed to manufacturing variation, variation in donning on the manikin, the decontamination method, or a combination of these factors. Larger variations, as seen in this model, may require further research to understand the cause.

**Strap Integrity Results:** No visual degradation of the straps was observed. Decreases in recorded force of the treated samples were found in the VWR 89201 model for both top (6.15%) and bottom (5.57%) straps. This respirator also showed a significant detriment in fit.

Increases in recorded force of the treated samples were found in the following models for both top and bottom straps, respectively; 3M 1860 (15.24% and 18.37%); 3M V-flex 1805 (0.54% and 9.82%).

While the exact correlation between the force exerted by straps and fit is not well understood, higher force values may be associated with a tighter fit of the respirator to the face. Significant reductions in this force would be associated with a loss of elasticity of the straps, thereby reducing their ability to create a tight fit. See Table 3 for 3M respirators and Table 6 the VWR respirator.

**Other Notes:** The nosepiece foam on the 3M 1860 (4 cycles) was discolored (brown color, whereas the control was gray).



Figure 1. Laboratory test photos from a portion of respirators evaluated

**Table 1. Filter Efficiency Evaluation – 3M**

Respirator Model, Decon Method, # of cycles	Treated Sample #	Flow Rate (Lpm)	Initial Filter Resistance (mmH <sub>2</sub> O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
<b>3M 1860, Chlorine Dioxide, 4 cycles</b>  Min Fil Eff: 98.82%  Max Fil Eff: 99.73%	1	85	8.4	0.379	0.509	99.49
	2	85	8.3	0.247	0.412	99.59
	3	85	8.5	0.570	0.751	99.25
	4	85	9.3	0.226	1.18	98.82
	5	85	8.6	0.530	0.639	99.36
	6	85	8.6	0.402	0.525	99.48
	7	85	8.5	0.639	0.787	99.21
	8	85	9.1	0.294	0.555	99.45
	9	85	9.0	0.599	1.14	98.86
	10	85	9.1	0.243	0.319	99.68
	Control 1	85	9.1	0.379	0.509	99.63
	Control 2	85	9.4	0.247	0.412	99.73
	Control 3	85	8.7	0.570	0.751	99.69
<b>3M V-flex 1805, Chlorine Dioxide, 1 cycle</b>  Min Fil Eff: 99.80%  Max Fil Eff: 99.50%	1	85	3.7	0.145	0.200	99.80
	2	85	4.1	0.153	0.234	99.77
	3	85	3.7	0.170	0.269	99.73
	4	85	3.8	0.171	0.265	99.74
	5	85	3.7	0.174	0.271	99.73
	6	85	3.7	0.149	0.239	99.76
	7	85	3.7	0.167	0.276	99.72
	8	85	3.7	0.213	0.353	99.65
	9	85	3.8	0.232	0.293	99.71
	10	85	4.0	0.151	0.234	99.77
	Control 1	85	3.7	0.321	0.496	99.50
	Control 2	85	3.5	0.194	0.337	99.66
	Control 3	85	3.9	0.340	0.429	99.57

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.

**Table 2. Manikin Fit Evaluations – 3M**

Manikin Fit Factor (mFF) 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, Chlorine Dioxide, 4 cycles  Static Advanced Large Headform (Lunar Studios)	11	200+	200+	200+	200+
	12	200+	200+	200+	200+
	13	200+	200+	182	194
	14	200+	200+	200+	200+
	15	200+	200+	200+	200+
	Control 4	200+	200+	200+	200+
	Control 5	200+	200+	200+	200+
3M V-flex 1805, Chlorine Dioxide, 1 cycle  Static Advanced Medium Headform (Hanson Robotics)	11	200+	200+	200+	200+
	12	200+	200+	200+	200+
	13	200+	200+	200+	200+
	14	200+	200+	200+	200+
	15	n/a *			
	Control 4	200+	200+	200+	200+
	Control 5	200+	200+	200+	200+

\*only 14 samples were received of the 3M V-flex 1805

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 3. Strap Integrity Evaluation of 3M Respirators**

<b>Tensile Force in Respirator Straps of Decontaminated N95s (recorded force values are at 150% strain)</b>			
<b>Respirator Model, Decon Method, # of cycles</b>	<b>Straps from Treated Sample #</b>	<b>Force in Top Strap (N)</b>	<b>Force in Bottom Strap (N)</b>
<b>3M 1860, Chlorine Dioxide, 4 cycles</b>	<b>1</b>	3.529	3.598
	<b>2</b>	3.400	3.320
	<b>3</b>	3.776	3.988
	<b>Decontaminated Strap Average</b>	3.568	3.635
	<b>Control 1</b>	3.089	3.068
	<b>Control 2</b>	3.102	3.073
	<b>Control Average</b>	3.096	3.071
	<b>% Change ((Deconned - Control) / Control)</b>	15.24	18.37
<b>3M V-flex 1805, Chlorine Dioxide, 1 cycle</b>	<b>Straps from Treated Sample #</b>	<b>Force in Top Strap (N)</b>	<b>Force in Bottom Strap (N)</b>
	<b>1</b>	3.150	3.225
	<b>2</b>	2.836	3.160
	<b>3</b>	2.918	3.347
	<b>Decontaminated Strap Average</b>	2.968	3.244
	<b>Control 1</b>	2.981	2.843
	<b>Control 2</b>	2.922	3.064
	<b>Control Average</b>	2.952	2.954
<b>% Change ((Deconned - Control) / Control)</b>	0.54	9.82	

**Table 4. Filter Efficiency Evaluation – VWR**

Respirator Model, Decon Method, # of cycles	Treated Sample #	Flow Rate (Lpm)	Initial Filter Resistance (mmH <sub>2</sub> O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
<b>VWR 89201, Chlorine Dioxide, 4 cycles</b>  Min Fil Eff: 97.91%  Max Fil Eff: 99.59%	1	85	8.8	1.92	2.09	97.91
	2	85	9.4	1.36	1.51	98.49
	3	85	9.3	0.553	0.621	99.38
	4	85	8.9	1.11	1.79	98.21
	5	85	10.2	0.315	0.410	99.59
	6	85	9.5	1.01	1.24	98.76
	7	85	9.3	0.236	0.307	99.69
	8	85	9.0	0.815	0.921	99.08
	9	85	9.8	0.452	0.464	99.54
	10	85	8.9	0.807	0.944	99.06
	<b>Control 1</b>	85	9.0	5.26	5.63	<b>94.37</b>
	<b>Control 2</b>	85	8.5	0.743	0.743	99.26
	<b>Control 3</b>	85	9.5	4.14	4.16	95.84

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 Evaluations – VWR**

Manikin Fit Factor (mFF) 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
VWR 89201, Chlorine Dioxide, 4 cycles  Static Advanced Medium Headform (Hanson Robotics)	11	91	61	56	<b>67</b>
	12	200+	61	100	<b>96</b>
	13	126	50	70	<b>71</b>
	14	62	32	38	<b>41</b>
	15	33	34	47	<b>37</b>
	Control 4	200+	64	200+	117
	Control 5	200+	115	154	149

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 less than 100.

**Table 6. Strap Integrity Evaluation of VWR Respirator**

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)
VWR 89201, Chlorine Dioxide, 4 cycles	1	3.702	4.142
	2	3.727	3.758
	3	4.199	3.902
	Decontaminated Strap Average	3.876	3.934
	Control 1	4.095	4.074
	Control 2	4.164	4.257
	Control Average	4.130	4.166
	% Change ((Deconned - Control) / Control)	-6.15	-5.57