

## Evaluation of Decontaminated N95 Respirators

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**Date Tested:** 6/3/2020 – 6/8/2020

**Respirator Model(s):** 3M 8511 and Sperian N1105

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

**Decontamination Method:** VPHP

**Decontamination Cycles:** 10 cycles (Sperian N1105) and 20 cycles (3M 8511)

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).

38 respirators that were unworn and not subjected to any pathogenic microorganisms were submitted for evaluation. This included 15 respirators that were subjected to 10 cycles of the VPHP decontamination process, 15 respirators subjected to 20 cycles, and an additional 8 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](#).

**Filtration Efficiency Results:** All respirators measured more than 95%. Two of the ten respirators measured efficiencies less than 95%. See Tables 1 and 4.

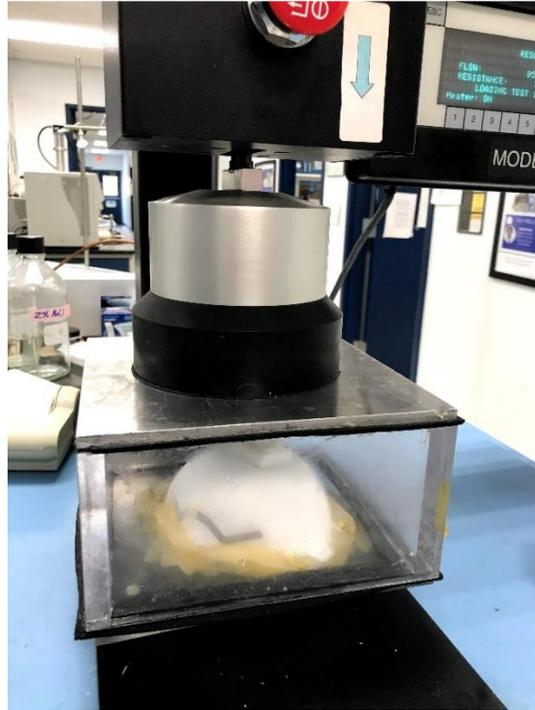
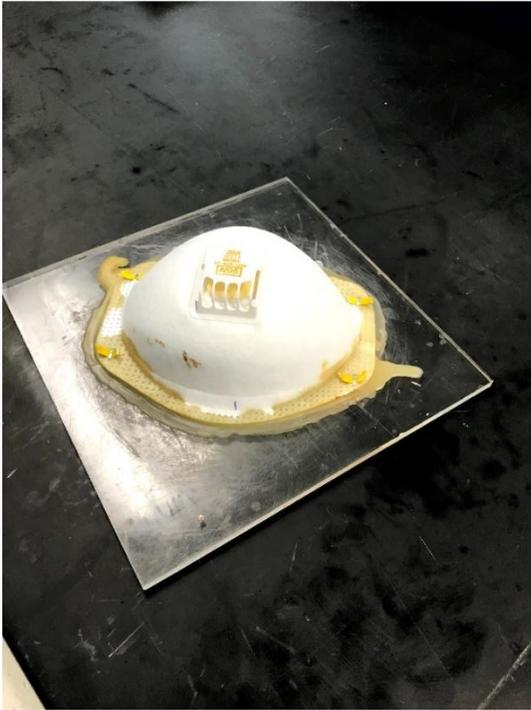
**Manikin Fit Factor Results:** The manikin fit factor showed passing fit factors (greater than 100) for all respirators evaluated. See Tables 2 and 5.

**Strap Integrity Results:** No visual degradation of the straps was observed. The Sperian N1105 (10 cycles) showed increases in force for both the top and bottom straps, while the 3M 8511 (20 cycles) showed an increase in the top strap but virtually no change in the bottom strap. See Tables 3 and 6.

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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.”

Figure 1. Laboratory Test Photos



**Table 1. Filter Efficiency Evaluation - Sperian N1105**

<b>Respirator Model, Decon Method, # of cycles</b>	<b>Treated Sample #</b>	<b>Flow Rate (Lpm)</b>	<b>Initial Filter Resistance (mmH<sub>2</sub>O)</b>	<b>Initial Percent Leakage (%)</b>	<b>Maximum Percent Leakage (%)</b>	<b>Filter Efficiency (%)</b>
<b>Sperian N1105, VPHP, 10 Cycles</b>  Min Fil Eff: 99.74%  Max Fil Eff: 99.88%	<b>1</b>	85	13.1	0.146	0.171	99.83
	<b>2</b>	85	13.3	0.149	0.170	99.83
	<b>3</b>	85	11.4	0.178	0.204	99.80
	<b>4</b>	85	12.6	0.115	0.132	99.87
	<b>5</b>	85	12.0	0.209	0.252	99.75
	<b>6</b>	85	12.9	0.103	0.133	99.87
	<b>7</b>	85	11.5	0.142	0.162	99.84
	<b>8</b>	85	11.3	0.255	0.261	99.74
	<b>9</b>	85	12.9	0.141	0.146	99.85
	<b>10</b>	85	11.8	0.155	0.174	99.83
	<b>Control 1</b>	85	11.8	0.145	0.166	99.83
	<b>Control 2</b>	85	12.7	0.103	0.118	99.88

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 Evaluation - Sperian N1105**

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
Sperian N1105, VPHP, 10 Cycles  Static Advanced Large Headform (Lunar Studios)	11	155	102	118	121
	12	134	103	108	113
	13	200+	164	200+	187
	14	172	67	128	105
	15	184	97	163	137
	Control 3	131	86	120	109
	Control 4	128	91	116	109

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 - Sperian N1105**

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)
Sperian N1105, VPHP, 10 Cycles	1	1.744	1.780
	2	1.730	1.616
	3	1.888	1.904
	Decontaminated Strap Average	1.787	1.767
	Control 1	1.602	1.582
	Control 2	1.631	1.798
	Control Strap Average	1.617	1.690
	% Change ((Deconned - Controls) / Controls)		10.5%

**Table 4. Filter Efficiency Evaluation - 3M 8511**

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 8511, VPHP, 20 Cycles</b>  Min Fil Eff: 99.26%  Max Fil Eff: 99.73%	<b>1</b>	85	7.1	0.238	0.450	99.55
	<b>2</b>	85	7.4	0.152	0.381	99.62
	<b>3</b>	85	7.3	0.260	0.559	99.44
	<b>4</b>	85	7.2	0.067	0.275	99.73
	<b>5</b>	85	6.7	0.228	0.411	99.59
	<b>6</b>	85	7.1	0.150	0.313	99.69
	<b>7</b>	85	6.9	0.250	0.513	99.49
	<b>8</b>	85	6.6	0.318	0.621	99.38
	<b>9</b>	85	7.0	0.306	0.479	99.52
	<b>10</b>	85	6.2	0.344	0.745	99.26
	<b>Control 1</b>	85	6.4	0.165	0.541	99.46
	<b>Control 2</b>	85	6.5	0.202	0.371	99.63

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 5. Manikin Fit Evaluation - 3M 8511**

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 8511, VPHP, 20 Cycles  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	200+	200+	200+	200+
	Control 3	200+	200+	200+	200+
	Control 4	200+	200+	200+	200+

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.
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**Table 6. Strap Integrity Evaluation - 3M 8511**

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 8511, VPHP, 20 Cycles	1	3.079	2.894
	2	3.608	3.091
	3	3.705	3.132
	Decontaminated Strap Average	3.464	3.039
	Control 1	2.974	3.126
	Control 2	2.894	2.945
	Control Strap Average	2.934	3.036
	% Change ((Deconned - Controls) / Controls)		18.1%