Evaluation of Decontaminated N95 Respirators

Date(s) Tested: 4/27/2020-4/30/2020

Respirator Model(s): Moldex 1512 Medium, Moldex 2200 M/L, 3M 8210, 3M V-flex 1804, 3M 1860, Sperian One-Fit, Sperian N1105 M/L, Sperian N1125 M/L

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: 5 (Sperian One-Fit, Sperian N1105 M/L, and Sperian N1125 M/L)

10 (Moldex 1512 Medium, Moldex 2200 M/L, 3M 8210, 3M V-flex 1804, 3M 1860)

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).

134 respirators, of varying manufacturers/models, that were unworn and not subjected to any pathogenic microorganisms were submitted for evaluation. This included 45 respirators subjected to 5 cycles of the VPHP decontamination process, 75 respirators subjected to 10 cycles, and an additional 14 respirators that served as controls. Samples were donned/doffed in between each decontamination cycle. 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: The minimum and maximum filter efficiencies were as follows; Moldex 2200 M/L (94.27% and 98.79%); Moldex 1512 Medium (95.19% and 99.40%); 3M 8210 (99.37% and 99.60%); 3M 1860 (99.02% and 99.47%); 3M V-flex 1804 (99.28% and 99.59%); Sperian N1105 M/L (99.54% and 99.85%); Sperian N1125 M/L (99.13% and 99.88%); Sperian One-Fit (98.90% and 99.75%). All samples of all respirator models, except for the Moldex 2200 M/L, had filtration efficiencies measured more than 95%. The Moldex 2200 M/L had one sample with a filter efficiency less than 95%. See Table 1 for Moldex respirators, Table 4 for 3M respirators, and Table 7 for Sperian respirators.

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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."

Manikin Fit Factor Results: The manikin fit factor showed passing fit factors (greater than 100) for all samples of the following models; Moldex 1512 Medium; Moldex 2200 M/L; 3M 8210; 3M 1860; Sperian N1105 M/L. See Table 2 for Moldex respirators, Table 5 for 3M respirators, and Table 8 for Sperian respirators.

The manikin fit factor did not show consistent passing fit factors for the following models; 3M V-flex 1804 (range = 27-200+) or the Sperian N1125 M/L (range = 99-200+). See Tables 5 and 8.

The manikin fit test procedure used in this assessment did not show any detriments in fit associated with the decontamination method used for all models, except for the 3M V-flex 1804 and Sperian N1125 M/L. 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 these models, 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 following models for both top and bottom straps, respectively; Moldex 1512 Medium (10.01% and 11.78%); Sperian One-Fit (0.5% and 1.52%).

Increases in recorded force of the treated samples were found in the following models for both top and bottom straps, respectively; 3M V-flex 1804 (25.76% and 22.73%); Sperian N1105 M/L (7.31% and 24.03%); Sperian N1125 M/L (9.32% and 18.69%); and 3M 1860 (17.23% and 37.57%).

Inconsistent changes were shown between top and bottom straps for the following; Moldex 2200 M/L, with the top straps showing a 10.43% increase in recorded force and the bottom an 11.23% decrease; 3M 8210, with the top straps showing a 0.54% increase and the bottom a 10.08% decrease.

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 Moldex respirators, Table 6 for 3M respirators, and Table 9 for Sperian respirators.

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

Table 1. Filter Efficiency Evaluation – Moldex

Respirator Model, Decon Method, # of cycles	Treated Sample #	Flow Rate (Lpm)	Initial Filter Resistance (mmH₂O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
Moldex 2200 M/L, VPHP, 10 cycles Minimum Filter Efficiency: **94.27%** Maximum Filter Efficiency: 98.79%	**1**	85	10.9	1.21	1.21	98.79
	2	85	10.2	2.49	2.49	97.51
	3	85	9.5	2.59	2.59	97.41
	4	85	10.3	2.16	2.16	97.84
	5	85	9.9	4.48	4.48	95.52
	6	85	10.3	3.00	5.73	**94.27**
	7	85	10.0	2.49	2.49	97.51
	8	85	10.3	1.54	1.54	98.46
	9	85	11.1	1.94	1.94	98.06
	10	85	11.0	1.63	1.63	98.37
	Control 1	85	10.5	1.91	1.91	98.09
Moldex 1512 Medium, VPHP, 10 cycles Minimum Filter Efficiency: 95.19% Maximum Filter Efficiency: 99.40%	**1**	85	10.4	0.601	0.601	99.40
	2	85	9.0	2.15	2.15	97.85
	3	85	8.6	3.24	4.18	95.82
	4	85	9.3	1.83	1.83	98.17
	5	85	9.8	1.13	1.13	98.87
	6	85	9.6	1.36	1.36	98.64
	7	85	8.6	1.52	1.52	98.48
	8	85	9.6	1.44	4.81	95.19
	9	85	10.8	1.50	1.50	98.50
	10	85	8.9	1.71	3.98	96.02
	Control 1	85	8.7	2.80	2.80	97.20

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 Evaluations – Moldex

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
Moldex 2200 M/L, VPHP, 10 cycles Static Advanced Medium Headform (Hanson Robotics)	**11**	200+	200+	200+	200+
	12	200+	194	200+	198
	13	200+	98	200+	149
	14	200+	169	200+	189
	15	200+	200+	200+	200+
	Control 2	200+	200+	200+	200+
Moldex 1512 Medium, VPHP, 10 cycles Static Advanced Medium Headform (Hanson Robotics)	**11**	200+	200+	200+	200+
	12	200+	121	173	158
	13	200+	200+	200+	200+
	14	200+	200+	200+	200+
	15	200+	200+	200+	200+
	Control 2	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.
- 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 - Moldex

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)**
Moldex 2200 M/L, VPHP, 10 cycles	1	5.117	4.498
	2	4.800	4.165
	3	5.061	4.322
	Decontaminated Strap Average	4.993	4.328
	Control 1	4.521	4.876
	% Change ((Deconned - Control) / Control)	10.43%	-11.23%
Moldex 1512 Medium, VPHP, 10 cycles	**Straps from Treated Sample #**	**Force in Top Strap (N)**	**Force in Bottom Strap (N)**
	1	3.042	2.848
	2	2.869	2.708
	3	3.022	2.684
	Decontaminated Strap Average	2.978	2.747
	Control 1	3.309	3.114
	% Change ((Deconned - Control) / Control)	-10.01%	-11.78%

Table 4. Filter Efficiency Evaluation – 3M

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 8210, VPHP, 10 cycles Min Fil Eff: 99.37% Max Fil Eff: 99.60%	**1**	85	7.7	0.239	0.555	99.45
	2	85	8.2	0.190	0.400	99.60
	3	85	8.0	0.196	0.570	99.43
	4	85	7.6	0.212	0.532	99.47
	5	85	8.0	0.145	0.401	99.60
	6	85	8.1	0.223	0.612	99.39
	7	85	7.6	0.389	0.664	99.37
	8	85	7.9	0.180	0.452	99.55
	9	85	7.8	0.144	0.409	99.59
	10	85	8.2	0.203	0.534	99.47
	Control 1	85	7.8	0.151	0.404	99.60
3M 1860, VPHP, 10 cycles Min Fil Eff: 99.02% Max Fil Eff: 99.47%	**1**	85	9.1	0.533	0.976	99.02
	2	85	9.7	0.566	0.740	99.26
	3	85	9.2	0.429	0.566	99.43
	4	85	10.6	0.602	0.707	99.29
	5	85	9.5	0.447	0.645	99.36
	6	85	9.4	0.509	0.739	99.26
	7	85	9.4	0.509	0.739	99.26
	8	85	9.5	0.307	0.533	99.47
	9	85	10.6	0.711	0.711	99.29
	10	85	9.8	0.425	0.613	99.39
	Control 1	n/a*				
3M VFlex 1804, VPHP, 10 cycles Min Fil Eff: 99.28% Max Fil Eff: 99.59%	**1**	85	4.6	0.368	0.465	99.54
	2	85	5.0	0.471	0.525	99.48
	3	85	4.7	0.361	0.455	99.55
	4	85	4.7	0.353	0.469	99.53
	5	85	4.8	0.395	0.499	99.50
	6	85	4.8	0.317	0.420	99.58
	7	85	4.8	0.287	0.408	99.59
	8	85	4.6	0.367	0.450	99.55
	9	85	4.6	0.212	0.720	99.28
	10	85	4.5	0.330	0.409	99.59
	Control 1	85	4.8	0.237	0.343	99.66

*no control provided

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

Respirator Model, Decon Method, # of cycles	Treated Sample #	mFF Normal Breathing 1	mFF Deep Breathing	mFF Normal Breathing 2	Overall Manikin Fit Factor
Manikin Fit Factor (mFF) of Decontaminated N95s					
3M 8210, VPHP, 10 cycles Static Advanced Medium Headform (Hanson Robotics)	11	200+	200+	200+	200+
	12	200+	200+	200+	200+
	13	132	117	103	116
	14	200+	200+	200+	200+
	15	200+	200+	200+	200+
	Control 2	200+	166	200+	187
3M 1860, VPHP, 10 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 2	n/a*			
3M VFlex 1804, VPHP, 10 cycles Static Advanced Medium Headform (Hanson Robotics)	11	200+	200+	200+	200+
	12	29	24	30	**27**
	13	165	86	156	125
	14	200+	200+	200+	200+
	15	141	98	132	121
	Control 2	200+	200+	200+	200+

*no control provided

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 - 3M

	Tensile Force in Respirator Straps of Decontaminated N95s (recorded force values are at 150% strain)		
	Straps from Treated Sample #	**Force in Top Strap (N)**	**Force in Bottom Strap (N)**
3M 8210, VPHP, 10 cycles	1	4.286	3.886
	2	4.415	4.015
	3	4.411	3.855
	Decontaminated Strap Average	4.371	3.919
	Control 1	4.347	4.358
	% Change ((Deconned - Control) / Control)	0.54%	-10.08%
	Straps from Treated Sample #	**Force in Top Strap (N)**	**Force in Bottom Strap (N)**
3M 1860, VPHP, 10 cycles	1	3.105	3.686
	2	3.147	3.589
	3	3.136	3.525
	Decontaminated Strap Average	3.129	3.600
	Control 1	2.701	2.534
	Control 2	2.637	2.695
	Control Strap Average	2.669	2.615
	% Change ((Deconned - Control) / Control)	17.23%	37.57%
	Straps from Treated Sample #	**Force in Top Strap (N)**	**Force in Bottom Strap (N)**
3M VFlex 1804, VPHP, 10 cycles	1	2.711	2.788
	2	2.548	2.645
	3	2.494	2.656
	Decontaminated Strap Average	2.584	2.696
	Control 1	2.055	2.197
	% Change ((Deconned - Control) / Control)	25.76%	22.73%

Table 7. Filter Efficiency Evaluation – Sperian

Respirator Model, Decon Method, # of cycles	Treated Sample #	Flow Rate (Lpm)	Initial Filter Resistance (mmH₂O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
Sperian N1105 M/L, VPHP, 5 cycles Min Fil Eff: 99.54% Max Fil Eff: 99.85%	1	85	11.3	0.235	0.243	99.76
	2	85	11.2	0.168	0.172	99.83
	3	85	11.4	0.299	0.305	99.70
	4	85	11.4	0.229	0.236	99.76
	5	85	11.8	0.149	0.153	99.85
	6	85	11.6	0.181	0.188	99.81
	7	85	10.8	0.262	0.262	99.74
	8	85	11.4	0.201	0.209	99.79
	9	85	11.3	0.206	0.458	99.54
	10	85	11.4	0.190	0.190	99.81
	Control 1	85	11.5	0.129	0.135	99.87
Sperian N1125 M/L, VPHP, 5 cycles Min Fil Eff: 99.13% Max Fil Eff: 99.88%	1	85	14.3	0.565	0.565	99.44
	2	85	11.7	0.435	0.450	99.55
	3	85	12.5	0.872	0.872	99.13
	4	85	13.8	0.147	0.171	99.83
	5	85	13.1	0.294	0.309	99.69
	6	85	13.0	0.260	0.265	99.74
	7	85	14.3	0.122	0.122	99.88
	8	85	13.1	0.281	0.289	99.71
	9	85	12.7	0.851	0.867	99.13
	10	85	14.0	0.715	0.716	99.28
	Control 1	85	14.9	0.944	0.957	99.04
Sperian One-Fit, VPHP, 5 cycles Min Fil Eff: 98.90% Max Fil Eff: 99.75%	1	85	11.1	0.277	0.293	99.71
	2	85	9.8	0.243	0.263	99.74
	3	85	9.7	0.410	0.430	99.57
	4	85	10.9	0.329	0.336	99.66
	5	85	10.0	0.331	0.331	99.67
	6	85	10.3	0.737	0.739	99.26
	7	85	10.5	0.656	0.661	99.34
	8	85	11.4	0.470	0.470	99.53
	9	85	10.1	0.811	1.10	98.90
	10	85	9.9	0.345	0.345	99.66
	11	85	10.0	0.479	0.493	99.51
	12	85	11.2	0.923	0.934	99.07
	13	85	10.0	0.734	0.759	99.24
	14	85	10.9	0.249	0.252	99.75
	15	85	9.7	0.858	0.858	99.14
	Control 1	85	9.2	0.773	0.785	99.22

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 8. Manikin Fit Evaluation – Sperian

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
Sperian OneFit, VPHP, 5 cycles	11	n/a*			
	12				
	13				
	14				
	15				
	Control 2				
Sperian N1105 M/L, VPHP, 5 cycles Static Advanced Large Headform (Lunar Studios)	11	200+	200+	200+	200+
	12	200+	144	200+	177
	13	200+	200+	200+	200+
	14	200+	200+	200+	200+
	15	200+	123	200+	166
	Control 2	200+	147	200+	179
Sperian N1125 M/L, VPHP, 5 cycles Static Advanced Large Headform (Lunar Studios)	11	87	90	165	105
	12	200+	167	200+	188
	13	79	102	126	**99**
	14	200+	125	200+	167
	15	200+	90	192	141
	Control 2	200+	200+	200+	200+

*unable to achieve adequate fit (overall mFF >= 100) on control respirator, so reliable fit test results cannot be reported-sample #'s 11-15 were tested for filtration

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 9. Strap Integrity Evaluation - Sperian

	Tensile Force in Respirator Straps of Decontaminated N95s (recorded force values are at 150% strain)		
	Straps from Treated Sample #	**Force in Top Strap (N)**	**Force in Bottom Strap (N)**
Sperian OneFit, VPHP, 5 cycles	1	6.405	11.648
	2	8.956	10.498
	3	9.674	12.277
	Decontaminated Strap Average	8.345	11.474
	Control 1	8.387	11.651
	% Change ((Deconned - Control) / Control)	-0.5%	-1.52%
Sperian N1105 M/L, VPHP, 5 cycles	**Straps from Treated Sample #**	**Force in Top Strap (N)**	**Force in Bottom Strap (N)**
	1	1.772	1.914
	2	1.871	1.977
	3	1.801	1.884
	Decontaminated Strap Average	1.815	1.925
	Control 1	1.691	1.552
	% Change ((Deconned - Control) / Control)	7.31%	24.03%
Sperian N1125 M/L, VPHP, 5 cycles	**Straps from Treated Sample #**	**Force in Top Strap (N)**	**Force in Bottom Strap (N)**
	1	1.836	2.067
	2	1.770	1.948
	3	1.861	1.707
	Decontaminated Strap Average	1.822	1.907
	Control 1	1.667	1.607
	% Change ((Deconned - Control) / Control)	9.32%	18.69%