Evaluation of Decontaminated N95 Respirators

NPPTL
National Personal Protective Technology Laboratory

Date(s) Tested: 4/15/2020-4/20/2020

Respirator Model(s): 3M 1860, 3M1860S, Moldex 1512 Medium, Moldex 2200 M/L, 3M 8210, 3M V-flex 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: VPHP

Decontamination Cycles: 5 cycles

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).

Sixty respirators, of varying manufacturers/models, that were unworn and not subjected to any pathogenic microorganisms were submitted for evaluation. This included 50 respirators that were subjected to 5 cycles of the VPHP decontamination process and an additional 10 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: The maximum and minimum filter efficiency were as follows; Moldex 2200 M/L (99.25% and 97.54%); Moldex 1512 Medium (99.12% and 96.25%); 3M 8210 (99.72% and 99.48%); 3M 1860 (99.54% and 99.26%); 3M 1860S (99.73% and 99.01%); 3M V-flex 1804 (99.71% and 99.50%). All samples of all six respirator models had filtration efficiencies measured more than 95%. See Table 1 for Moldex respirators and Table 4 for 3M respirators.

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; 3M 8210; 3M 1860; 3M 1860S; 3M V-flex 1804. See Table 2 for Moldex respirators and Table 5 for 3M respirators.

The manikin fit factor did not show consistent passing fit factors for the following model; Moldex 2200 M/L (range = 34-200+). See Table 2.

[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."

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 Moldex 2200 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 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 following models for both top and bottom straps, respectively; Moldex 1512 Medium (11.32% and 9.49%); 3M 8210 (1.22% and 12.68%)

Increases in recorded force of the treated samples were found in the following models for both top and bottom straps, respectively; 3M 1860S (17.62% and 16.49%); 3M V-flex 1804 (7.41% and 8.76%).

Inconsistent changes were shown between top and bottom straps for the Moldex 2200 M/L, with the top straps showing a 4.92% increase in recorded force and the bottom a 5.00% decrease. This respirator also showed a significant detriment in fit. Changes in strap integrity could not be measured for the 3M 1860, as no controls were provided.

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 and Table 6 for 3M respirators.

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

Table 1. Filter Efficiency Evaluation – Moldex Respirators

Respirator Model, Decon Method, # of cycles	Treated Sample #	Flow Rate (Lpm)	Initial Filter Resistance (mmH_2O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
Moldex 2200 M/L, VPHP, 5 cycles Minimum Filter Efficiency: 97.54% Maximum Filter Efficiency: 99.25%	**1**	85	11.5	1.56	1.56	98.44%
	2	85	10.6	1.64	1.64	98.36%
	3	85	12.1	0.746	0.746	99.25%
	4	85	9.9	2.14	2.46	97.54%
	5	85	10.6	1.31	1.31	98.69%
	6	85	11.2	1.83	1.83	98.17%
	7	85	10.2	1.53	1.53	98.47%
	8	85	11.7	0.792	0.792	99.21%
	Control 1	85	11.0	1.66	n/a *	98.34%
Moldex 1512 Medium, VPHP, 5 cycles Minimum Filter Efficiency: 96.25% Maximum Filter Efficiency: 99.12%	**1**	85	9.5	2.94	3.11	96.89%
	2	85	8.9	1.22	2.59	97.41%
	3	85	9.1	1.31	3.75	96.25%
	4	85	9.2	1.24	1.24	98.76%
	5	85	9.1	0.915	0.915	99.09%
	6	85	9.1	1.01	1.01	98.99%
	7	85	9.2	0.884	0.884	99.12%
	8	85	8.7	1.12	1.12	98.88%
	Control 1	85	9.3	1.43	1.43	98.57%

***Instantaneous test only

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 – Moldex Respirators

Static Advanced Medium Headform (Hanson Robotics)

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, 5 cycles	**9**	200+	200+	200+	200+
	10	84	58	99	**77**
	11	34	38	30	**34**
	12	200+	191	200+	197
	Control 2	200+	146	142	159
Moldex 1512 Medium, VPHP, 5 cycles	**9**	146	95	107	112
	10	200+	200+	200+	200+
	11	200+	200+	200+	200+
	12	200+	200+	200+	200+
	Control 2	165	116	120	131

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 3. Strap Integrity Evaluation of Moldex Respirators

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, 5 cycles	**1**	n/a *	4.442
	2	5.397	n/a *
	3	5.318	5.059
	Decontaminated Strap Average	5.358	4.751
	Control 1	5.107	5.001
	% Change ((Deconned - Control) / Control)	4.92%	-5.00%
Moldex 1512 Medium, VPHP, 5 cycles	**Straps from Treated Sample #**	**Force in Top Strap (N)**	**Force in Bottom Strap (N)**
	1	3.162	2.850
	2	3.139	3.131
	3	2.986	3.028
	Decontaminated Strap Average	3.096	3.003
	Control 1	3.491	3.318
	% Change ((Deconned - Control) / Control)	-11.32%	-9.49%

*Technical difficulties during testing. Results not reportable.

Table 4. Filter Efficiency Evaluation – 3M Respirators

Respirator Model, Decon Method, # of cycles	Treated Sample #	Flow Rate (Lpm)	Initial Filter Resistance (mmH_2O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
3M 8210, VPHP, 5 cycles Min Fil Eff: 99.48% Max Fil Eff: 99.72%	**1**	85	7.7	0.128	0.300	99.70%
	2	85	7.1	0.227	0.498	99.50%
	3	85	7.4	0.155	0.445	99.56%
	4	85	7.4	0.185	0.517	99.48%
	5	85	7.1	0.100	0.280	99.72%
	Control 1	85	7.7	0.157	n/a *	99.84%
3M 1860, VPHP, 5 cycles Min Fil Eff: 99.26% Max Fil Eff: 99.54%	**1**	85	8.7	0.544	0.744	99.26%
	2	85	9.5	0.317	0.457	99.54%
	3	85	9.9	0.359	0.479	99.52%
	4	85	9.8	0.433	0.601	99.40%
	5	85	9.7	0.338	0.492	99.51%
3M 1860S, VPHP, 5 cycles Min Fil Eff: 99.01% Max Fil Eff: 99.73%	**1**	85	11.0	0.672	0.987	99.01%
	2	85	11.0	0.497	0.769	99.23%
	3	85	11.6	0.669	2.27	97.73%
	Control 1	85	13.9	0.699	0.699	99.30%
3M VFlex 1804, VPHP, 5 cycles Min Fil Eff: 99.50% Max Fil Eff: 99.71%	**1**	85	4.7	0.465	0.502	99.50%
	2	85	4.5	0.330	0.402	99.60%
	3	85	4.9	0.263	0.350	99.65%
	4	85	4.8	0.209	0.295	99.71%
	5	85	4.8	0.231	0.291	99.71%
	Control 1	85	4.6	0.214	0.282	99.72%

*instantaneous test only

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 Respirators

Static Advanced Medium Headform (Hanson Robotics)

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 8210, VPHP, 5 cycles	**6**	200+	200+	200+	200+
	7	200+	200+	200+	200+
	Control 2	200+	200+	200+	200+
3M 1860, VPHP, 5 cycles	**6**	200+	168	200+	188
	7	200+	200+	200+	200+
	Control	No control provided.			
3M 1860S, VPHP, 5 cycles	**4**	200+	200+	200+	200+
	5	200+	105	200+	154
	6	200+	168	200+	188
	Control 2	200+	200+	200+	200+
3M VFlex 1804, VPHP, 5 cycles	**6**	200+	200+	200+	200+
	7	148	111	116	123
	Control 2	200+	164	199	186

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 6. Strap Integrity Evaluation - 3M Respirators

Tensile Force in Respirator Straps of Decontaminated N95s (recorded force values are at 150% strain)			
3M 8210, VPHP, 5 cycles	**Straps from Treated Sample #**	**Force in Top Strap (N)**	**Force in Bottom Strap (N)**
	1	4.412	4.151
	2	4.434	4.009
	3	4.267	3.985
	Decontaminated Strap Average	4.371	4.048
	Control 1	4.425	4.652
	% Change ((Deconned - Control) / Control)	**-1.22%**	**-12.68%**
3M 1860, VPHP, 5 cycles	**Straps from Treated Sample #**	**Force in Top Strap (N)**	**Force in Bottom Strap (N)**
	1	3.079	3.332
	2	2.923	3.486
	3	3.026	3.341
	Decontaminated Strap Average	3.009	3.386
	Control 1	No control provided.	
	% Change ((Deconned - Control) / Control)		
3M 1860S, VPHP, 5 cycles	**Straps from Treated Sample #**	**Force in Top Strap (N)**	**Force in Bottom Strap (N)**
	1	3.670	3.381
	2	3.523	3.400
	3	3.615	3.263
	Decontaminated Strap Average	3.603	3.348
	Control 1	2.968	2.874
	% Change ((Deconned - Control) / Control)	**17.62%**	**16.49%**
3M VFlex 1804, VPHP, 5 cycles	**Straps from Treated Sample #**	**Force in Top Strap (N)**	**Force in Bottom Strap (N)**
	1	2.589	2.721
	2	2.490	2.647
	3	2.309	2.601
	Decontaminated Strap Average	2.463	2.656
	Control 1	2.293	2.442
	% Change ((Deconned - Control) / Control)	**7.41%**	**8.76%**