Evaluation of Decontaminated N95 Respirators

Date Tested: 5/8/2020 – 5/12/2020
Respirator Model(s): 3M 8511, 3M 1860, Halyard 62126

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

Decontamination Method: Heat-based decontamination method using commercial laundry dryers. FFRs are placed in sealed Ziploc bags inside boxes installed in dryer tumbler. 3 cycles at 70°C for 60 min.

Decontamination Cycles: 3 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).

60 respirators that were unworn and not subjected to any pathogenic microorganisms were submitted for evaluation. This included 45 respirators that were subjected to 3 cycles of the dry heat decontamination process and an additional 15 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 minimum and maximum filter efficiencies were the following; 3M 1860 (98.53% and 99.33%); 3M 8511 (99.09% and 99.82%); Halyard 62126 (99.18% and 99.78%). All respirators measured more 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. The manikin fit test procedure used in this assessment did not show any detriments in fit associated with the decontamination method used. See Tables 2 and 5.

Strap Integrity Results: No visual degradation of the straps was observed. All models showed decreases in recorded force for the top and bottom straps, respectively; 3M 1860 (1.76% and 3.24%); 3M 8511 (4.77% and 3.69%); Halyard 62126 (4.38% and 3.29%). 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.

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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."

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.

Other notes: The respirator information text on the front of the 3M 1860 was blurred and illegible. The respirator name on the front of the Halyard 62126 was also blurred and illegible.

Figure 1. Laboratory Test Photos

Table 1. 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 1860, dry heat, 3 cycles Min Fil Eff: 98.53% Max Fil Eff: 99.33%	1	85	9.1	0.525	0.763	99.24
	2	85	8.9	1.06	1.47	98.53
	3	85	9.6	0.534	0.853	99.15
	4	85	9.0	0.468	0.671	99.33
	5	85	8.6	0.455	0.725	99.28
	6	85	8.9	0.446	0.793	99.21
	7	85	9.3	0.588	0.914	99.09
	8	85	8.8	0.504	0.826	99.17
	9	85	8.5	0.523	0.878	99.12
	10	85	8.2	0.630	1.05	98.95
	Control 1	85	9.5	0.418	0.687	99.31
	Control 2	85	9.5	0.371	0.642	99.36
	Control 3	85	9.2	0.289	0.470	99.53
3M 8511, dry heat, 3 cycles Min Fil Eff: 99.09% Max Fil Eff: 99.82%	1	85	7.6	0.169	0.295	99.71
	2	85	7.4	0.194	0.455	99.55
	3	85	7.6	0.171	0.252	99.75
	4	85	6.9	0.234	0.482	99.52
	5	85	7.6	0.171	0.356	99.64
	6	85	7.5	0.104	0.206	99.79
	7	85	7.6	0.111	0.189	99.81
	8	85	7.7	0.115	0.310	99.69
	9	85	8.1	0.081	0.185	99.82
	10	85	7.6	0.795	0.913	99.09
	Control 1	85	8.4	0.209	0.335	99.67
	Control 2	85	8.3	0.053	0.166	99.83
	Control 3	85	9.1	0.411	0.492	99.51

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 – 3M

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, dry heat, 3 cycles Static Advanced Medium Headform (Hanson Robotics)	**11**	107	184	145	138
	12	200+	200+	200+	200+
	13	200+	127	200+	168
	14	190	161	134	159
	15	200+	168	182	182
	Control 4	200+	200+	200+	200+
	Control 5	200+	200+	200+	200+
3M 8511, dry heat, 3 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 4	200+	200+	200+	200+
	Control 5	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 – 3M

Respirator Model, Decon Method, # of cycles	Straps from Treated Sample #	Force in Top Strap (N)	Force in Bottom Strap (N)
Tensile Force in Respirator Straps of Decontaminated N95s (recorded force values are at 150% strain)			
3M 1860, dry heat, 3 cycles	1	2.797	2.543
	2	2.704	2.666
	3	2.729	2.589
	Decontaminated Strap Average	2.743	2.599
	Control 1	2.791	2.660
	Control 2	2.793	2.712
	Control Strap Average	2.792	2.686
	% Change ((Deconned - Controls) / Controls)	-1.76%	-3.24%
3M 8511, dry heat, 3 cycles	1	2.581	2.645
	2	2.674	2.793
	3	2.891	2.634
	Decontaminated Strap Average	2.715	2.691
	Control 1	2.813	2.856
	Control 2	2.889	2.731
	Control Strap Average	2.851	2.794
	% Change ((Deconned - Controls) / Controls)	-4.77%	-3.69%

Table 4. Filter Efficiency Evaluation – Halyard

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 (%)
Halyard 62126, dry heat, 3 cycles Min Fil Eff: 99.18% Max Fil Eff: 99.78%	1	85	10.6	0.233	0.216	99.78
	2	85	10.9	0.282	0.282	99.72
	3	85	10.7	0.301	0.301	99.70
	4	85	11.9	0.434	0.434	99.57
	5	85	11.0	0.301	0.301	99.70
	6	85	10.6	0.538	0.540	99.46
	7	85	10.9	0.681	0.689	99.31
	8	85	10.6	0.369	0.369	99.63
	9	85	10.3	0.820	0.820	99.18
	10	85	10.9	0.277	0.286	99.71
	Control 1	85	12.0	0.296	0.296	99.70
	Control 2	85	11.0	0.409	0.409	99.59
	Control 3	85	12.1	0.718	0.718	99.28

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 – Halyard

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**
Halyard 62126, dry heat, 3 cycles Static Advanced Large Headform (Lunar Studios)	**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 4	200+	200+	200+	200+
	Control 5	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 6. Strap Integrity Evaluation – Halyard

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)**
Halyard 62126, dry heat, 3 cycles	**1**	2.294	2.341
	2	2.249	2.316
	3	2.195	2.301
	Decontaminated Strap Average	2.246	2.319
	Control 1	2.339	2.405
	Control 2	2.359	2.390
	Control Strap Average	2.349	2.398
	% Change ((Deconned - Controls) / Controls)	-4.38%	-3.29%