Evaluation of Decontaminated N95 Respirators



Date Tested: 6/19/2020 – 6/23/2020

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. Each FFR is placed in a Ziploc bag, which are put in a box in a tumble dryer. Each cycle is performed at a setting to achieve temperatures > 80°C for > 70 minutes.

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 factor¹ 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: All respirators measured more than 95%. See Tables 1, 4, and 7.

Manikin Fit Factor Results: The manikin fit factor showed passing fit factors (greater than 100) for all respirators evaluated. See Tables 2, 5, and 8.

Strap Integrity Results: No visual degradation of the straps was observed. Inconsistent changes were shown between the 3M 8511 top and bottom straps, with the top strap showing a decrease in recorded force and the bottom strap showing an increase in force. Both the 3M 1860 and Halyard 62126 top and bottom straps showed decreases in recorded force. See Tables 3, 6, and 9.

Other notes: Respirator information on the outer surface of the 3M 1860 was blurred/illegible. Respirator name on front of Halyard 62126 was blurred/illegible.

¹The 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 – 3M 1860

Respirator Model, Decon Method, # of cycles	Treated Sample #	Flow Rate (Lpm)	Initial Filter Resistance (mmH₂O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
	1	85	8.7	0.425	0.938	99.06
	2	85	7.7	0.619	1.25	98.75
	3	85	7.6	2.73	2.88	97.12
	4	85	8.9	0.649	2.00	98.00
3M 1860, Dry	5	85	8.0	2.70	2.70	97.30
Heat, 3 cycles	6	85	7.9	0.537	1.11	98.89
Min Fil Eff: 95.08%	7	85	8.1	0.579	1.13	98.87
Max Fil Eff: 98.89%	8	85	8.9	4.91	4.92	95.08
	9	85	8.3	0.692	1.43	98.57
	10	85	8.3	0.578	1.11	98.89
	Control 1	85	8.6	0.531	1.04	98.96
	Control 2	85	8.5	0.466	1.08	98.92
	Control 3	85	8.8	0.424	0.874	99.13

• 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 1860

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		
	11	200+	200+	200+	200+		
3M 1860, Dry	12	200+	200+	200+	200+		
Heat, 3 cycles	13	200+	200+	200+	200+		
Static Advanced	14	200+	200+	200+	200+		
Medium Headform (Hanson Robotics)	15	200+	200+	200+	200+		
	Control 4	200+	192	200+	198		
	Control 5	200+	200+	200+	200+		

- 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 1860

Tensile Force in Respirator Straps of Decontaminated N95s							
(recorded force values are at 150% strain)							
Respirator Model, Decon	Straps from Treated Sample #	Force in Top	Force in Bottom				
Method, # of cycles	Straps from Treated Sample #	Strap (N)	Strap (N)				
	1	2.711	2.458				
	2	2.802	2.528				
	3	2.667	2.517				
	Decontaminated Strap Average	2.727	2.501				
3M 1860, Dry Heat, 3 cycles	Control 1	2.928	2.591				
	Control 2	2.907	2.540				
	Control Strap Average	2.918	2.566				
	% Change ((Deconned - Controls) / Controls)	-6.55%	-2.53%				

Table 4. Filter Efficiency Evaluation - Halyard 62126

Respirator Model, Decon Method, # of cycles	Treated Sample #	Flow Rate (Lpm)	Initial Filter Resistance (mmH₂O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
	1	85	10.8	1.88	1.92	98.08
	2	85	10.7	1.66	1.73	98.27
	3	85	10.1	1.66	1.67	98.33
	4	85	10.5	1.17	1.32	98.68
Halyard 62126, Dry	5	85	10.8	2.51	2.69	97.31
Heat, 3 cycles	6	85	10.7	1.34	1.37	98.63
Min Fil Eff: 97.31%	7	85	10.5	2.09	2.14	97.86
Max Fil Eff: 99.32%	8	85	10.9	1.681	0.681	99.32
	9	85	10.5	1.66	1.66	98.34
	10	85	10.5	0.768	0.768	99.23
	Control 1	85	11.7	1.04	1.06	98.94
	Control 2	85	11.5	0.348	0.352	99.65
	Control 3	85	11.4	0.968	0.971	99.03

• 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 62126

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,	11	189	150	200+	177		
	12	200+	200+	200+	200+		
Dry Heat, 3 cycles	13	160	105	142	131		
Static Advanced	14	200+	148	197	178		
Large Headform (Lunar Studios)	15	128	80	180	116		
	Control 4	200+	181	200+	194		
	Control 5	120	159	85	114		

- 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 62126

Tensile Force in Respirator Straps of Decontaminated N95s							
(recorded force values are at 150% strain) Respirator Model, Decon Strang from Treated Sample # Force in Top Force in Bottom							
Method, # of cycles	Straps from Treated Sample #	Strap (N)	Strap (N)				
	1	2.144	2.187				
	2	2.132	2.209				
	3	2.181	2.268				
Halvard 62126 Dry Hoat 2	Decontaminated Strap Average	2.152	2.221				
Halyard 62126, Dry Heat, 3 cycles	Control 1	2.283	2.343				
,,,,,,	Control 2	2.228	2.345				
	Control Strap Average	2.256	2.344				
	% Change ((Deconned - Controls) / Controls)	-4.61%	-5.25%				

Table 7. Filter Efficiency Evaluation – 3M 8511

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 (%)
	1	85	7.6	0.355	1.07	98.93
	2	85	6.9	0.496	1.35	98.65
	3	85	6.9	0.577	1.16	98.84
	4	85	6.1	0.348	1.06	98.94
3M 8511, Dry	5	85	7.6	0.385	1.04	98.96
Heat, 3 cycles	6	85	7.4	1.37	1.86	98.14
Min Fil Eff: 98.14%	7	85	7.4	0.328	0.959	99.04
Max Fil Eff: 99.12%	8	85	8.7	0.616	1.61	98.39
	9	85	8.3	0.483	1.16	98.84
	10	85	6.6	0.277	0.876	99.12
	Control 1	85	7.4	1.03	1.27	98.73
	Control 2	85	7.6	0.251	0.544	99.46
	Control 3	85	7.3	0.356	0.954	99.05

• 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 – 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		
	11	200+	199	200+	200		
3M 8511, Dry	12	200+	200+	200+	200+		
Heat, 3 cycles	13	200+	200+	200+	200+		
Static Advanced	14	200+	200+	200+	200+		
Medium Headform (Hanson Robotics)	15	200+	88	195	140		
	Control 4	200+	200+	200+	200+		
	Control 5	200+	200+	200+	200+		

- 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 9. Strap Integrity Evaluation - 3M 8511

	Table 5. Strap Integrity Evaluation Sivi 6511						
Tensile Force in Respirator Straps of Decontaminated N95s							
(recorded force values are at 150% strain)							
Respirator Model, Decon	Force in Top Force in Botton						
Method, # of cycles	Straps from Treated Sample #	Strap (N)	Strap (N)				
	1	2.782	2.837				
	2	2.767	2.864				
	3	2.677	2.855				
	Decontaminated Strap	2.742	2.852				
	Average						
3M 8511, Dry Heat, 3 cycles	Control 1	3.072	2.576				
	Control 2	3.166	2.622				
	Control Strap Average	3.119	2.599				
	% Change						
	((Deconned - Controls) /	-12.09%	9.73%				
	Controls)						