Evaluation of Decontaminated N95 Respirators

NPPTL
National Personal Protective
Technology Laboratory

Date Tested: 12/1/2020 – 12/4/2020

Respirator Model(s): 3M 1860 and 3M 8210

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

Decontamination Method: MSU Extension Dry Heat Decontamination System for N95 Respirators. This system uses dry heat at 85 °C (185 °F) for 50 minutes. This allows for come-up temperature of masks and any variation in oven temperature throughout the cycle to achieve the Critical Control Point of 75°C (167°F) for 30 minutes.

Decontamination Cycles: 4 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).

Fifty-three respirators that were unworn and not subjected to any pathogenic microorganisms were submitted for evaluation. This included 43 respirators that were subjected to 4 cycles of the Dry Heat 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.

Other notes: The 3M 1860 and 3M 8210 treated samples had observable blurring of the printed information found on the front of the respirators. Discoloration of the 3M 1860 treated straps were also noted. Figures 1A-1C show a comparison between a control sample and a treated sample of these observations.

3M 1860

Filtration Efficiency Results: The minimum and maximum filter efficiencies were 98.14% and 99.02%, respectively. All respirators measured more than 95%. See Table 1.

Manikin Fit Factor Results: The manikin fit factor showed passing fit factors (≥ 100) for the controls and five out of the six treated respirators evaluated. One of the treated respirators had a failing fit factor (< 100). See table 2.

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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."

Strap Integrity Results: The top straps showed a 16.98% increase in recorded force and the bottom straps showed a 2.08% increase in force. See Table 3.

3M 8210

Filtration Efficiency Results: The minimum and maximum filter efficiencies were 97.33% and 99.96%, respectively. All respirators measured more than 95%. See Table 4.

Manikin Fit Factor Results: The manikin fit factor showed passing fit factors (≥ 100) for all respirators evaluated. See Table 5.

Strap Integrity Results: The top straps showed a 19.71% increase in recorded force and the bottom straps showed a 42.90% increase in force. See Table 6.

Figure 1. Sample Observations

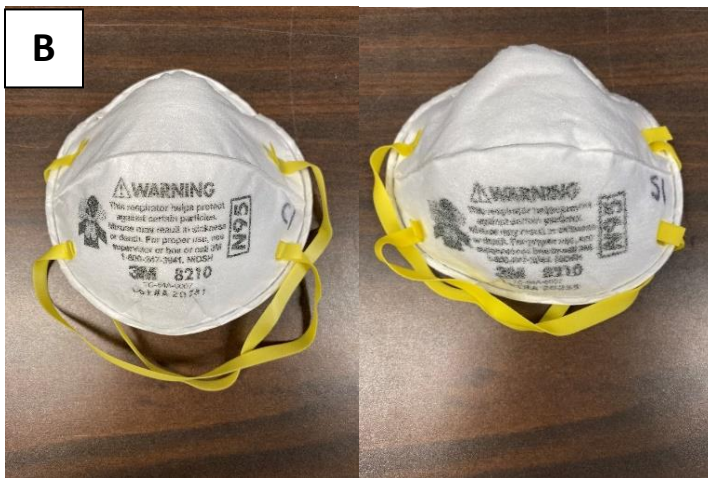Fig. 1A. 3M 1860 Printed Information. Control (Left), Treated (Right)

Fig. 1B. 3M 8210 Printed Information. Control (Left), Treated (Right)

Fig. 1C. 3M 1860 Strap Discoloration. Control (Left), Treated (Right)

Figure 2. Laboratory Test Photos

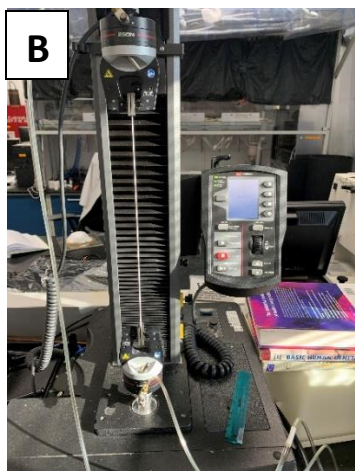**Fig. 2A. Medium Static Advanced Headform. 3M 1860 (Left), 3M 8210 (Right)**

Fig. 2B. Instron 5943 Tensile Tester

Fig. 2C. TSI 8130 Filter Tester 3M 1860 (Left), 3M 8210 (Right)

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 (%)
3M 1860, Controls	Control 1	85	11.4	0.712	0.717	99.28
	Control 2	85	9.0	0.413	0.672	99.33
	Control 3	85	11.3	0.936	0.986	99.01
3M 1860, Dry Heat, 4 cycles Min Fil Eff: 98.14% Max Fil Eff: 99.02%	1	85	8.1	0.534	0.990	99.01
	2	85	7.9	0.722	1.150	98.85
	3	85	8.5	0.561	0.980	99.02
	4	85	8.4	0.807	1.370	98.63
	5	85	8.9	0.649	1.090	98.91
	6	85	8.8	0.541	1.020	98.98
	7	85	9.3	0.729	1.180	98.82
	8	85	8.9	0.521	1.130	98.87
	9	85	8.5	0.961	1.860	98.14
	10	85	8.5	0.654	1.100	98.90
	11	85	11.2	1.04	1.300	98.70
	12	85	9.0	0.884	1.540	98.46
	13	85	10.0	0.799	1.230	98.77
	14	85	9.8	0.826	1.550	98.45
	15	85	8.5	0.969	1.710	98.29

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 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
3M 1860, Controls	Control 4	200+	200+	200+	200+
	Control 5	200+	200+	200+	200+
3M 1860, Dry Heat, 4 Cycles Static Advanced Medium Headform (Hanson Robotics)	16	200+	125	164	157
	17	200+	180	200+	193
	18	200+	172	200+	190
	19	200+	200+	200+	200+
	20	84	58	55	**64**
	21	166	77	197	125

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 < 100.

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 Method, # of cycles	Straps from Treated Sample #	Force in Top Strap (N)	Force in Bottom Strap (N)
3M 1860, Controls	Control 1	2.657	2.426
	Control 2	2.755	2.460
	Control 3	2.767	2.485
	Control Strap Average	2.726	2.457
3M 1860, Dry Heat, 4 cycles	1	3.341	2.626
	2	2.969	2.533
	3	3.113	2.383
	4	3.333	2.490
	Decontaminated Strap Average	3.189	2.508
	% Change ((Deconned - Controls)/ Controls)	16.98%	2.08%

Table 4. Filter Efficiency Evaluation – 3M 8210

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, Controls	**Control 1**	85	11.1	0.869	0.869	99.13
	Control 2	85	9.8	0.700	0.280	99.72
	Control 3	85	9.0	0.094	2.090	97.91
3M 8210, Dry Heat, 4 cycles Min Fil Eff: 97.33% Max Fil Eff: 99.96%	**1**	85	7.7	0.234	0.554	99.45
	2	85	9.9	0.098	0.286	99.71
	3	85	8.6	0.265	0.558	99.44
	4	85	9.1	0.136	0.352	99.65
	5	85	8.8	1.840	2.380	97.62
	6	85	9.4	0.076	0.265	99.74
	7	85	9.6	0.860	0.907	99.09
	8	85	11.3	1.950	2.010	97.99
	9	85	8.8	1.110	1.290	98.71
	10	85	10.9	0.428	0.428	99.57
	11	85	12.8	0.696	0.768	99.23
	12	85	9.0	0.297	0.677	99.32
	13	85	9.3	0.660	0.982	99.02
	14	85	9.4	2.560	2.670	97.33
	15	85	10.0	0.086	0.040	99.96

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 8210

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 8210, Controls	**Control 4**	200+	174	200+	191
	Control 5	200+	183	200+	194
3M 8210, Dry Heat, 4 Cycles Static Advanced Medium Headform (Hanson Robotics)	**16**	200+	200+	200+	200+
	17	200+	200+	200+	200+
	18	200+	200+	200+	200+
	19	200+	200+	200+	200+
	20	200+	174	200+	191
	21	200+	200+	200+	200+
	22	200+	200+	171	189

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 8210

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 8210, Controls	**Control 1**	4.372	4.396
	Control 2	4.594	4.542
	Control 3	4.379	4.399
	Control Strap Average	4.448	4.446
3M 8210, Dry Heat, 4 cycles	**1**	5.258	6.502
	2	5.065	6.247
	3	5.663	6.417
	4	5.312	6.248
	Decontaminated Strap Average	5.325	6.354
	% Change ((Deconned - Controls)/ Controls)	19.71%	42.90%