Evaluation of Decontaminated N95 Respirators

NPPTL
National Personal Protective Technology Laboratory

Date Tested: 6/30/2020 – 7/6/2020

Respirator Model(s): 3M 1860, 3M 1870+, Halyard 46727

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

Decontamination Method:

1) Vaporized Hydrogen Peroxide (VHP) - Respirators were decontaminated using the pre-set cycle (Cycle 1) of Stryker's STERIZONE VP4 Sterilizer using hydrogen peroxide and ozone sterilants, at 41°C. After a full cycle the chamber was evacuated and ventilated. Decontamination procedure was repeated 5 times."

2) Methylene Blue + Light - Respirators were sprayed with a solution of 10µM concentration of methylene blue in deionized water. Respirators were sprayed, using a spray bottle, from 6 inches away, using 4 sprays on the top and 2 sprays underside which accounted for 7-8mL of solution. Respirator surfaces and straps were evenly coated with the solution. Coated respirators were immediately placed in the light source of 50,000 Lux intensity for 60 minutes. Respirators were dried, with a fan, for 30 minutes. Decontamination procedure was repeated 5 times.

3) Dry Heat - Performed in an SH-642 environmental chamber. The chamber can control a minimum relative humidity of 30% for temperatures <85 °C. The samples were heated in the chamber at 75 C for 60 min per cycle and 5 cycles heat treatment were performed. 3M 1870+ was decontaminated in original packaging. 3M 1860 and Halyard 46727 were decontaminated without packaging.

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).

109 respirators that were unworn and not subjected to any pathogenic microorganisms were submitted for evaluation. This included 30 respirators that were subjected to 5 cycles of the VHP decontamination process, 30 respirators subjects to 5 cycles of the methylene blue decontamination process, 30 respirators subjected to 5 cycles of the dry heat decontamination process, and an additional 19 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.

[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."

Filtration Efficiency Results: All treated 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: The straps of the 3M 1860 (VHP, 5 cycles) were frayed in several locations, and significant deterioration was observed (see Figure 1). The 3M 1860 (VHP, 5 cycles) showed increases in force in both the top and bottom straps.

No visual degradation of the straps of any other model/decontamination method was observed. Inconsistent changes were shown between the top and bottom straps with the top strap showing a decrease in recorded force and the bottom strap showing an increase in force for the 3M 1860 (Methylene Blue, 5 cycles). The 3M 1860 (dry heat, 5 cycles) and Halyard 46727 (all methods) showed decreases in recorded force for both the top and bottom straps. The 3M 1870+ (all methods) showed increases in recorded force for both the top and bottom straps. See Tables 3, 6, and 9.

Other notes: The nosepiece foam on the 3M 1860 (VHP, 5 cycles) was discolored (turned from gray to brown).

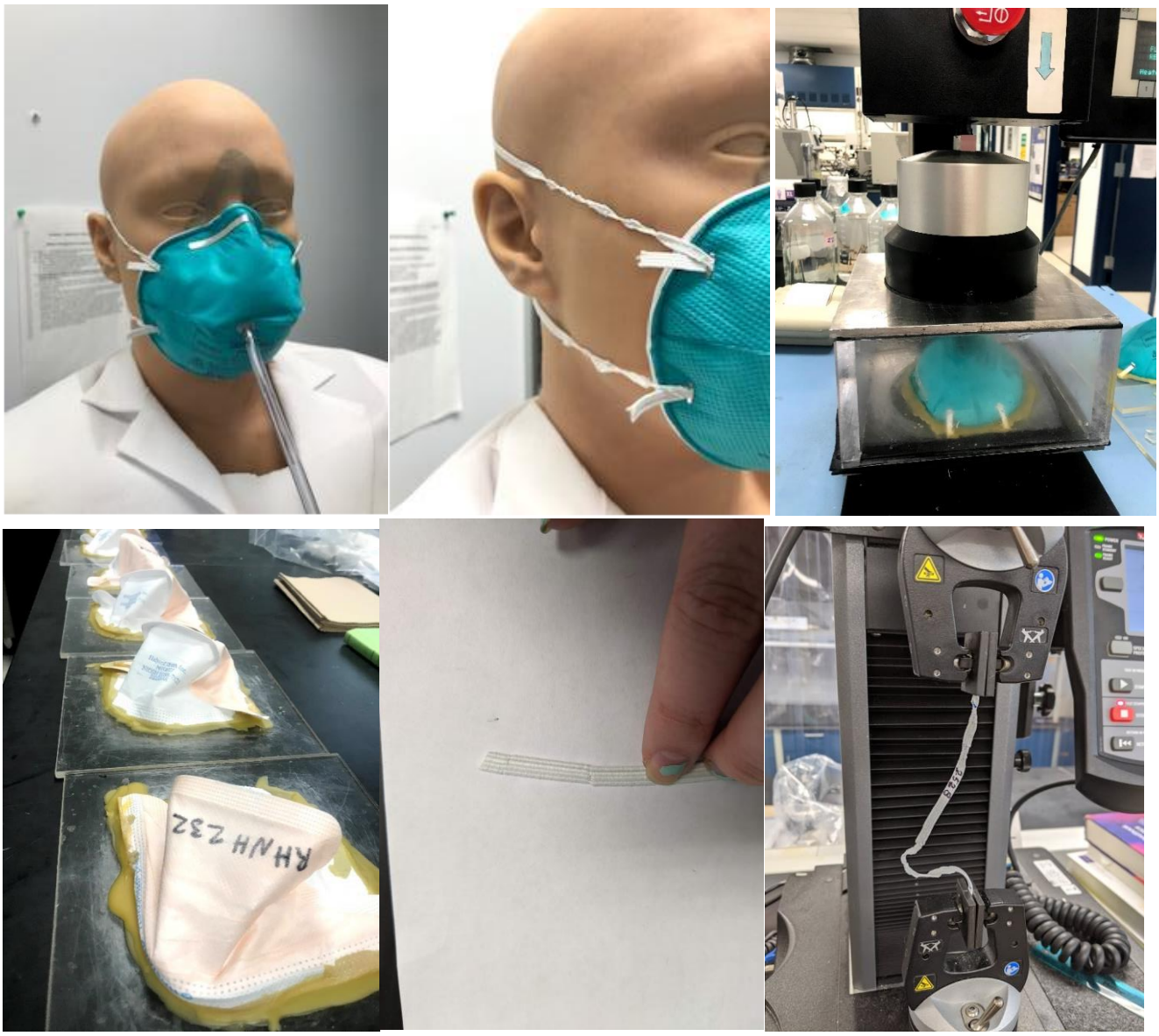

Figure 1. Laboratory Test Photos

Table 1. Filter Efficiency Evaluation – 3M 1860

Respirator Model, Decon Method, # of cycles	Treated Sample #	Flow Rate (Lpm)	Initial Filter Resistance (mmH_2O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
3M 1860, Control	**RMOH221**	85	8.4	0.517	1.02	98.98
	RMOH222	85	8.7	1.77	2.23	97.77
	RMOH297	85	9.1	0.468	1.10	98.90
	RMOH298	85	9.9	0.387	0.747	99.25
3M 1860, VHP, 5 Cycles Min Fil Eff: 97.67% Max Fil Eff: 98.97%	**RMTH252**	85	8.3	0.920	1.60	98.40
	RMTH253	85	8.1	0.649	1.42	98.58
	RMTH254	85	8.4	0.548	1.03	98.97
	RMTH255	85	7.8	0.839	1.54	98.46
	RMTH256	85	8.3	0.779	1.35	98.65
	RMTH257	85	8.2	0.660	1.41	98.59
	RMTH258	85	8.6	1.87	2.33	97.67
3M 1860, Methylene Blue, 5 Cycles Min Fil Eff: 98.34% Max Fil Eff: 99.00%	**RMNH226**	85	9.2	0.470	0.998	99.00
	RMNH227	85	8.4	0.583	1.04	98.96
	RMNH228	85	8.9	0.685	1.13	98.87
	RMNH229	85	8.0	0.876	1.66	98.34
	RMNH230	85	8.9	0.566	1.00	99.00
	RMNH231	85	8.9	0.738	1.09	98.91
	RMNH232	85	9.2	0.556	0.996	99.00
3M 1860, Dry Heat, 5 Cycles Min Fil Eff: 98.32% Max Fil Eff: 99.02%	**RMSH239**	85	8.7	0.524	0.990	99.01
	RMSH240	85	8.6	0.644	0.984	99.02
	RMSH241	85	9.1	0.618	1.09	98.91
	RMSH242	85	8.1	0.781	1.27	98.73
	RMSH243	85	8.5	0.833	1.30	98.70
	RMSH244	85	8.2	0.886	1.68	98.32
	RMSH245	85	8.4	0.755	1.17	98.83

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, Control Static Advanced Medium Headform (Hanson Robotics)	**RMOH223**	200+	200+	200+	200+
	RMOH224	200+	200+	200+	200+
	RMOH225	200+	200+	200+	200+
3M 1860, VHP, 5 Cycles Static Advanced Medium Headform (Hanson Robotics)	**RMTH259**	146	100	127	121
	RMTH260	183	132	150	152
	RMTH261	138	100	100	110
3M 1860, Methylene Blue, 5 Cycles Static Advanced Medium Headform (Hanson Robotics)	**RMNH233**	186	167	144	164
	RMNH234	200+	200+	200+	200+
	RMNH235	200+	200+	200+	200+
3M 1860, Dry Heat, 5 Cycles Static Advanced Medium Headform (Hanson Robotics)	**RMSH246**	200+	200+	200+	200+
	RMSH247	200+	200+	200+	200+
	RMSH248	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 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, Control	**RMOH221**	2.660	2.617
	RMOH222	2.635	2.511
	RMOH297	2.946	2.711
	RMOH298	3.081	2.989
	Control Strap Average	2.831	2.707
3M 1860, VHP, 5 Cycles	**RMTH252**	3.568	3.396
	RMTH253	3.379	3.829
	RMTH254	3.874	3.377
	RMTH255	3.950	3.637
	RMTH256	3.279	3.869
	Decontaminated Strap Average	3.61	3.622
	% Change ((Deconned - Controls) / Controls)	27.52%	33.80%
3M 1860, Methylene Blue, 5 Cycles	**RMNH226**	2.782	2.766
	RMNH227	2.657	2.769
	RMNH228	2.663	2.814
	RMNH229	2.882	2.586
	RMNH230	2.651	2.858
	Decontaminated Strap Average	2.727	2.759
	% Change ((Deconned - Controls) / Controls)	-3.67%	1.92%
3M 1860, Dry Heat, 5 Cycles	**RMSH239**	2.656	2.659
	RMSH240	2.690	2.605
	RMSH241	2.742	2.654
	RMSH242	2.739	2.696
	RMSH243	2.718	2.754
	Decontaminated Strap Average	2.709	2.674
	% Change ((Deconned - Controls) / Controls)	-4.31%	-1.22%

Table 4. Filter Efficiency Evaluation – Halyard 46727

Respirator Model, Decon Method, # of cycles	Treated Sample #	Flow Rate (Lpm)	Initial Filter Resistance (mmH_2O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
Halyard 46727, Control	**RHOH221**	85	10.9	0.509	0.524	99.48
	RHOH222	85	11.0	0.866	0.873	99.13
	RHOH297	85	10.9	0.828	0.834	99.17
	RHOH298	85	10.8	0.875	0.875	99.13
Halyard 46727, VHP, 5 Cycles Min Fil Eff: 97.89% Max Fil Eff: 99.33%	**RHTH252**	85	11.2	0.708	0.708	99.29
	RHTH253	85	11.4	1.63	1.67	98.33
	RHTH254	85	11.4	0.975	1.02	98.98
	RHTH255	85	10.8	0.721	0.725	99.28
	RHTH256	85	11.2	0.663	0.687	99.31
	RHTH257	85	11.7	0.666	0.668	99.33
	RHTH258	85	11.0	1.62	2.11	97.89
Halyard 46727, Methylene Blue, 5 Cycles Min Fil Eff: 97.24% Max Fil Eff: 99.44%	**RHNH226**	85	11.5	0.626	0.647	99.35
	RHNH227	85	11.0	2.66	2.76	97.24
	RHNH228	85	11.4	0.585	0.601	99.40
	RHNH229	85	11.1	0.562	0.562	99.44
	RHNH230	85	10.7	0.745	0.756	99.24
	RHNH231	85	11.3	1.00	1.02	98.98
	RHNH232	85	11.4	0.946	0.974	99.03
Halyard 46727, Dry Heat, 5 Cycles Min Fil Eff: 98.76% Max Fil Eff: 99.54%	**RHSH239**	85	11.3	0.770	0.789	99.21
	RHSH240	85	10.5	1.22	1.24	98.76
	RHSH241	85	10.9	0.572	0.588	99.41
	RHSH242	85	10.3	0.646	0.664	99.34
	RHSH243	85	10.9	1.04	1.07	98.93
	RHSH244	85	11.0	0.647	0.662	99.34
	RHSH245	85	11.5	0.454	0.465	99.54

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 46727

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 46727, Control Static Advanced Large Headform (Lunar Studios)	**RHOH223**	200+	200+	200+	200+
	RHOH224	200+	200+	200+	200+
	RHOH225	200+	150	151	164
Halyard 46727, VHP, 5 Cycles Static Advanced Large Headform (Lunar Studios)	**RHTH259**	200+	200+	200+	200+
	RHTH260	177	153	147	158
	RHTH261	200+	200+	200+	200+
Halyard 46727, Methylene Blue, 5 Cycles Static Advanced Large Headform (Lunar Studios)	**RHNH233**	N/A*			
	RHNH234	200+	200+	200+	200+
	RHNH235	200+	159	164	173
Halyard 46727, Dry Heat, 5 Cycles Static Advanced Large Headform (Lunar Studios)	**RHSH246**	165	149	142	152
	RHSH247	200+	200+	200+	200+
	RHSH248	158	130	126	137

*strap broke (at interface with respirator body) during donning- could not be fit tested

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 46727

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 46727, Control	**RHOH221**	2.382	2.416
	RHOH222	2.418	2.501
	RHOH297	2.380	2.448
	RHOH298	2.448	2.466
	Control Strap Average	2.407	2.458
Halyard 46727, VHP, 5 Cycles	**RHTH252**	2.092	2.046
	RHTH253	1.959	2.012
	RHTH254	2.023	2.002
	RHTH255	1.968	1.966
	RHTH256	1.923	1.960
	Decontaminated Strap Average	1.993	1.997
	% Change ((Deconned - Controls) / Controls)	-17.20%	-18.76%
Halyard 46727, Methylene Blue, 5 Cycles	**RHNH226**	2.341	2.419
	RHNH227	2.375	2.449
	RHNH228	2.383	2.359
	RHNH229	2.384	2.426
	RHNH230	2.383	2.455
	Decontaminated Strap Average	2.373	2.422
	% Change ((Deconned - Controls) / Controls)	-1.41%	-1.46%
Halyard 46727, Dry Heat, 5 Cycles	**RHSH239**	2.317	2.303
	RHSH240	2.329	2.321
	RHSH241	2.292	2.321
	RHSH242	2.298	2.388
	RHSH243	2.314	2.310
	Decontaminated Strap Average	2.31	2.329
	% Change ((Deconned - Controls) / Controls)	-4.03%	-5.25%

Table 7. Filter Efficiency Evaluation – 3M 1870+

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 1870+, Control	**R3OH221**	85	8.2	0.918	1.16	98.84
	R3OH222	85	8.1	0.515	0.583	99.42
3M 1870+, VHP, 5 Cycles Min Fil Eff: 99.52% Max Fil Eff: 99.89%	**R3TH252**	85	7.8	0.084	0.280	99.72
	R3TH253	85	8.9	0.030	0.114	99.89
	R3TH254	85	7.7	0.293	0.484	99.52
	R3TH255	85	7.6	0.115	0.348	99.65
	R3TH256	85	8.2	0.263	0.447	99.55
	R3TH257	85	8.0	0.038	0.137	99.86
	R3TH258	85	7.7	0.031	0.165	99.84
3M 1870+, Methylene Blue, 5 Cycles Min Fil Eff: 99.64% Max Fil Eff: 99.88%	**R3NH226**	85	7.5	0.047	0.124	99.88
	R3NH227	85	7.5	0.036	0.128	99.87
	R3NH228	85	7.3	0.110	0.212	99.79
	R3NH229	85	7.7	0.042	0.221	99.78
	R3NH230	85	7.4	0.068	0.318	99.68
	R3NH231	85	8.5	0.358	0.358	99.64
	R3NH232	85	7.6	0.026	0.156	99.84
3M 1870+, Dry Heat, 5 Cycles Min Fil Eff: 98.60% Max Fil Eff: 99.81%	**R3SH239**	85	7.3	1.12	1.40	98.60
	R3SH240	85	7.0	0.039	0.296	99.70
	R3SH241	85	8.3	1.21	1.21	98.79
	R3SH242	85	7.1	0.248	0.409	99.59
	R3SH243	85	7.1	0.117	0.287	99.71
	R3SH244	85	7.0	0.030	0.189	99.81
	R3SH245	85	7.0	0.287	0.473	99.53

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 – 3M 1870+

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 1870+, Control Static Advanced Medium Headform (Hanson Robotics)	**R3OH223**	200+	200+	200+	200+
	R3OH224	200+	200+	200+	200+
	R3OH225	200+	177	185	187
3M 1870+, VHP, 5 Cycles Static Advanced Medium Headform (Hanson Robotics)	**R3TH259**	200+	200+	200+	200+
	R3TH260	200+	179	184	187
	R3TH261	200+	200+	200+	200+
3M 1870, Methylene Blue, 5 Cycles Static Advanced Medium Headform (Hanson Robotics)	**R3NH233**	151	153	134	146
	R3NH234	166	148	166	160
	R3NH235	183	148	193	172
3M 1870+, Dry Heat, 5 Cycles Static Advanced Medium Headform (Hanson Robotics)	**R3SH246**	200+	189	200+	197
	R3SH247	118	120	106	114
	R3SH248	200+	181	179	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 9. Strap Integrity Evaluation – 3M 1870+

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 1870+, Control	**R3OH221**	1.703	1.813
	R3OH222	1.718	1.607
	Control Strap Average	1.711	1.71
3M 1870+, VHP, 5 Cycles	**R3TH252**	1.907	1.828
	R3TH253	1.955	1.849
	R3TH254	1.950	1.901
	R3TH255	1.861	1.990
	R3TH256	1.904	1.996
	Decontaminated Strap Average	1.915	1.913
	% Change ((Deconned - Controls) / Controls)	11.92%	11.87%
3M 1870+, Methylene Blue, 5 Cycles	**R3NH226**	1.658	1.975
	R3NH227	1.604	1.997
	R3NH228	1.674	2.028
	R3NH229	1.971	1.908
	R3NH230	1.950	1.871
	Decontaminated Strap Average	1.771	1.956
	% Change ((Deconned - Controls) / Controls)	3.51%	14.39%
3M 1870+, Dry Heat, 5 Cycles	**R3SH239**	1.831	1.768
	R3SH240	1.877	1.718
	R3SH241	1.877	1.729
	R3SH242	1.857	1.765
	R3SH243	1.921	1.692
	Decontaminated Strap Average	1.873	1.734
	% Change ((Deconned - Controls) / Controls)	9.47%	1.40%