Evaluation of Decontaminated N95 Respirators

NPPTL
National Personal Protective Technology Laboratory

Date Tested: 8/24/2020 – 8/31/2020

Respirator Model(s): 3M 1860

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

Decontamination Method: Each N95 respirator was exposed to ultrasonically created sub-micron droplets of a 1.06% peracetic acid (PAA) solution containing 0.88% hydrogen peroxide, 0.18% acetic acid, and 98.04% reverse osmosis water, all at room temperature. The N95 respirators were hung to provide adequate spacing to allow for full surface contact without shadowing. The treatment process requires approximately 1 hour and 16 minutes. The N95 respirators were allowed to air out until there was no vinegar odor.

Decontamination Cycles: 1 cycle; 3 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).

30 respirators that were unworn and not subjected to any pathogenic microorganisms were submitted for evaluation. This included 8 respirators that were subjected to 1 cycle of the PAA decontamination process, 8 respirators subjected to 3 cycles, 8 respirators subjected to 5 cycles, and an additional 6 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 Table 1.

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

Strap Integrity Results: No visual degradation of the straps was observed. Treated straps showed increases in recorded force at 1, 3, and 5 cycles. See Table 3.

[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."

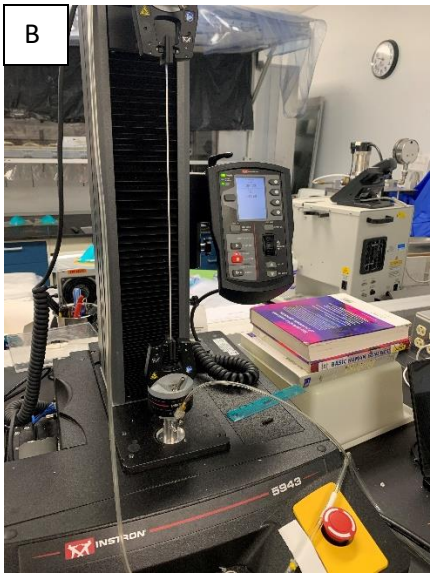

Fig 1A. Static Advanced Headform **Fig 1B. Instron 5943 Tensile Tester** **Fig 1C. TSI 8130 Filter Tester**

Table 1. Filter Efficiency Evaluation

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	**Control 1**	85	9.3	0.261	0.534	99.47
	Control 2	85	9.9	1.14	1.14	98.86
	Control 3	85	9.2	0.332	0.590	99.41
	Control 4	85	9.1	0.290	0.568	99.43
3M 1860, PAA, 1 cycle Min Fil Eff: 98.58% Max Fil Eff: 99.02%	**1**	85	9.3	0.577	0.978	99.02
	2	85	9.3	0.520	1.11	98.89
	3	85	8.8	0.331	1.2	98.80
	4	85	9.4	1.2	1.42	98.58
	5	85	9.5	0.258	1.0	99.00
3M 1860, PAA, 3 cycles Min Fil Eff: 99.08% Max Fil Eff: 99.49%	**1**	85	9.1	0.370	0.689	99.31
	2	85	9.1	0.362	0.674	99.33
	3	85	9.1	0.531	0.925	99.08
	4	85	9.6	0.424	0.791	99.21
	5	85	9.6	0.265	0.514	99.49
3M 1860, PAA, 5 cycles Min Fil Eff: 98.64% Max Fil Eff: 99.29%	**1**	85	8.9	0.380	0.898	99.10
	2	85	8.7	0.445	1.02	98.98
	3	85	8.5	0.81	1.36	98.64
	4	85	9.7	0.33	0.731	99.27
	5	85	9.9	0.335	0.707	99.29

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

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)	**Control 5**	200+	200+	200+	200+
	Control 6	200+	122	200+	165
3M 1860, PAA, 1 cycle Static Advanced Medium Headform (Hanson Robotics)	**6**	200+	137	200+	174
	7	123	77	131	104
	8	200+	61	143	106
3M 1860, PAA, 3 cycles Static Advanced Medium Headform (Hanson Robotics)	**6**	176	88	200+	136
	7	200+	177	200+	192
	8	138	83	127	110
3M 1860, PAA, 5 cycles Static Advanced Medium Headform (Hanson Robotics)	**6**	133	82	129	109
	7	126	92	140	115
	8	200+	109	200+	157

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

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	**Control 1**	2.607	2.923
	Control 2	2.645	2.865
	Control 3	2.647	2.964
	Control 4	2.701	2.780
	Control Strap Average	2.65	2.883
3M 1860, PAA, 1 cycle	**1**	2.654	2.954
	2	2.673	2.897
	3	2.836	2.956
	Decontaminated Strap Average	2.721	2.936
	% Change ((Deconned - Controls) / Controls)	2.68%	1.84%
3M 1860, PAA, 3 cycles	**1**	2.622	2.915
	2	2.730	3.012
	3	2.631	2.947
	Decontaminated Strap Average	2.661	2.958
	% Change ((Deconned - Controls) / Controls)	0.42%	2.60%
3M 1860, PAA, 5 cycles	**1**	2.825	2.791
	2	2.697	2.902
	3	2.688	3.043
	Decontaminated Strap Average	2.737	2.912
	% Change ((Deconned - Controls) / Controls)	3.28%	1.01%