Evaluation of Decontaminated N95 Respirators

NPPTL
National Personal Protective
Technology Laboratory

Date Tested: 7/10/2020 – 7/16/2020

Respirator Model(s): 3M 9205+

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

Decontamination Method: VPHP

Decontamination Cycles: 5, 10 & 20 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).

53 respirators that were unworn and not subjected to any pathogenic microorganisms were submitted for evaluation. This included 15 respirators that were subjected to 5 cycles of the VPHP decontamination process, 15 respirators subjected to 10 cycles, 15 respirators subjected to 20 cycles, and an additional 8 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. Decreases in recorded force were shown for both the top and bottom straps at 5, 10, and 20 cycles. See Table 3.

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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."
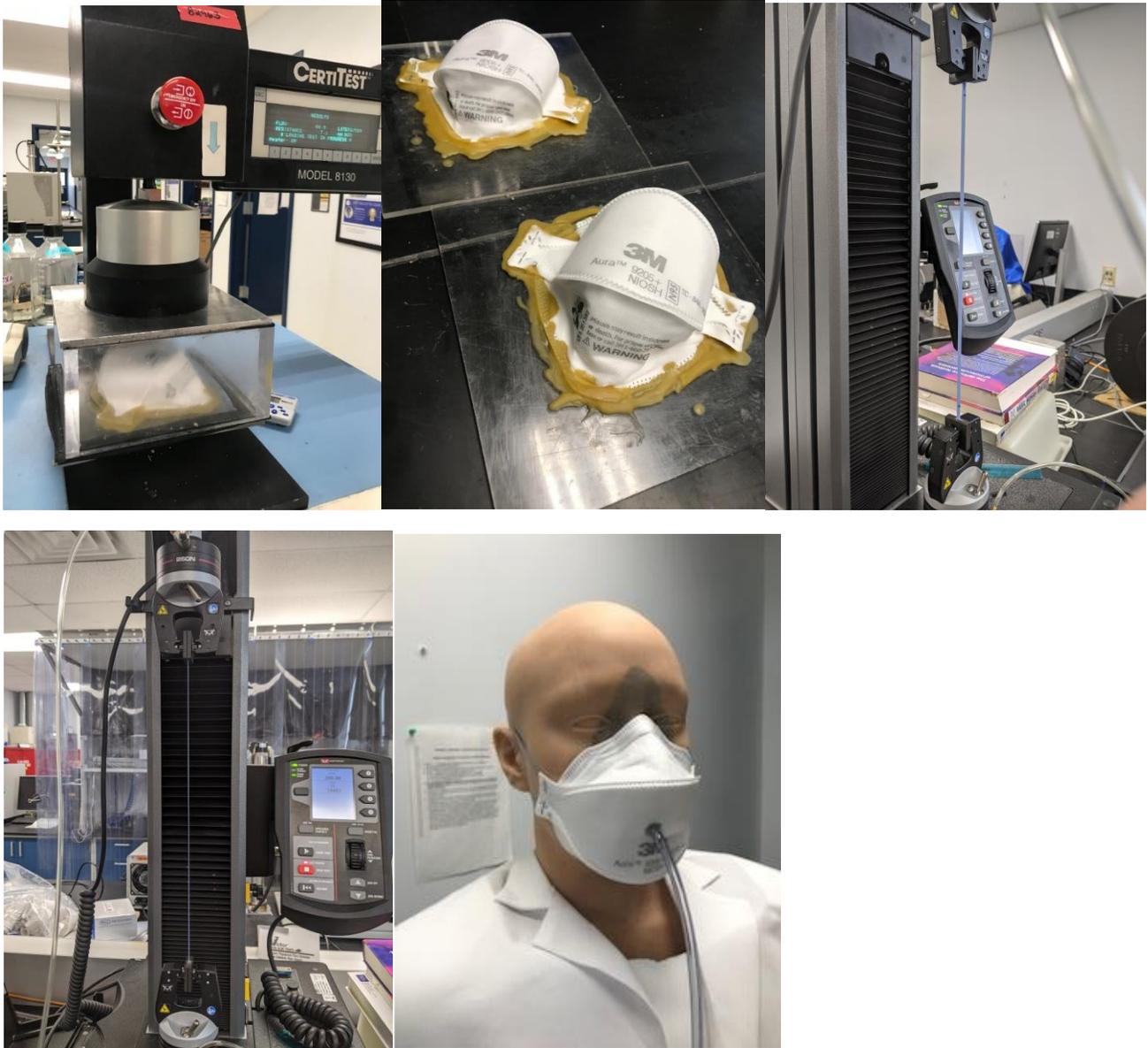
Figure 1. Laboratory Test Photos

Table 1. Filter Efficiency Evaluation

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 9205+, VPHP, 5 cycles Min Fil Eff: 98.11% Max Fil Eff: 99.86%	**1**	85	7.0	0.920	1.02	98.98
	2	85	6.8	1.83	1.89	98.11
	3	85	6.7	0.124	0.209	99.79
	4	85	6.7	0.066	0.144	99.86
	5	85	6.6	0.214	0.265	99.74
	6	85	7.1	0.546	0.615	99.39
	7	85	6.6	0.211	0.274	99.73
	8	85	6.9	0.436	0.494	99.51
	9	85	6.9	1.72	1.89	98.11
	10	85	6.8	0.435	0.552	99.45
	Control 1	85	6.9	0.063	0.201	99.80
3M 9205+, VPHP, 10 cycles Min Fil Eff: 97.77% Max Fil Eff: 99.78%	**1**	85	6.8	0.105	0.236	99.76
	2	85	7.1	0.723	0.726	99.27
	3	85	6.7	0.990	1.07	98.93
	4	85	6.4	2.09	2.23	97.77
	5	85	6.5	0.969	1.02	98.98
	6	85	6.9	0.573	0.704	99.30
	7	85	6.7	0.444	0.599	99.40
	8	85	6.9	0.428	0.520	99.48
	9	85	7.0	0.170	0.224	99.78
	10	85	6.5	1.37	1.42	98.58
	Control 2	85	7.3	1.26	1.37	98.63
3M 9205+, VPHP, 20 cycles Min Fil Eff: 96.13% Max Fil Eff: 99.69%	**1**	85	6.3	2.76	3.08	96.92
	2	85	5.8	2.50	2.59	97.41
	3	85	6.5	1.50	1.57	98.43
	4	85	6.3	1.52	1.63	98.37
	5	85	6.1	1.31	1.38	98.62
	6	85	6.8	0.277	0.315	99.69
	7	85	6.3	1.61	1.71	98.29
	8	85	5.9	1.71	1.71	98.29
	9	85	6.6	1.69	1.83	98.17
	10	85	5.8	3.49	3.87	96.13
	Control 1	85	6.5	0.795	0.905	99.10
	Control 2	85	6.7	0.065	0.179	99.82

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

Respirator Model, Decon Method, # of cycles	Treated Sample #	mFF Normal Breathing 1	mFF Deep Breathing	mFF Normal Breathing 2	Overall Manikin Fit Factor
Manikin Fit Factor of Decontaminated N95s					
3M 9205+, VPHP, 5 cycles Static Advanced Medium Headform (Hanson Robotics)	**11**	200+	200+	200+	200+
	12	200+	169	200+	189
	13	200+	200+	200+	200+
	14	200+	200+	200+	200+
	15	200+	200+	200+	200+
	Control 3	200+	200+	200+	200+
3M 9205+, VPHP, 10 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+
3M 9205+, VPHP, 20 cycles Static Advanced Medium Headform (Hanson Robotics)	**11**	175	166	165	169
	12	200+	200+	200+	200+
	13	200+	200+	200+	200+
	14	200+	200+	200+	200+
	15	200+	200+	200+	200+
	Control 3	200+	200+	200+	200+
	Control 4	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

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 9205+, VPHP, 5 cycles	1	1.534	1.511
	2	1.541	1.613
	3	1.582	1.579
	Decontaminated Strap Average	1.552	1.568
	Control 1	1.668	1.995
	Control Strap Average	1.731	1.948
	% Change ((Deconned - Controls) / Controls)	-10.34%	-19.51%
3M 9205+, VPHP, 10 cycles	1	1.492	1.678
	2	1.534	1.620
	3	1.438	1.479
	Decontaminated Strap Average	1.488	1.592
	Control 2	1.793	1.900
	Control Strap Average	1.731	1.948
	% Change ((Deconned - Controls) / Controls)	-14.04%	-18.28%
3M 9205+, VPHP, 20 cycles	1	1.377	1.611
	2	1.520	1.496
	3	1.433	1.590
	Decontaminated Strap Average	1.443	1.566
	Control 1	1.744	1.919
	Control 2	1.807	1.961
	Control Strap Average	1.776	1.94
	% Change ((Deconned - Controls) / Controls)	-18.75%	-19.28%