

Evaluation of Decontaminated N95 Respirators

Date Tested: 10/7/2020-10/9/2020

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: Moist heat decontamination at 85°C and 65% RH for 15 minutes using the Cres Cor moist heat decontamination cabinet, which involved controlled convected heat and humidity introduced by a built-in water reservoir. With specially designed interiors to hold masks and respirators, these conditions demonstrated virus and mycobacterium kill at the preset time, temperature and humidity.

Decontamination Cycles: 1; 3; 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 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).

25 respirators that were unworn and not subjected to any pathogenic microorganisms were submitted for evaluation. This included 7 respirators that were subjected to 1 cycle of the moist heat decontamination process, 7 respirators subjected to 3 cycles, 7 respirators subjected to 5 cycles, and an additional 4 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: The minimum and maximum filter efficiencies were 98.04% and 99.34%, respectively. All respirators measured greater than 95%. See Table 1.

Manikin Fit Factor Results: The manikin fit factor showed passing fit factors (greater than 100) for 6 out of 11 respirators (including controls and decontaminated samples) evaluated. See Table 2.

Strap Integrity Results: No visual degradation of the straps was observed. Inconsistent changes were shown between the top and bottom straps. The top straps showed an increase in recorded force for all decontamination cycles. The bottom straps showed a decrease in recorded force for 1 and 3 cycles and an increase in recorded force for 5 cycles. See Table 3.

Other notes: Decontaminated samples had blurring of the printed information on the front of the respirators. Figure 1D shows a comparison of this observation between a control sample and a treated sample. The decontaminated samples also felt rougher to the touch on the inside when compared to the controls.

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

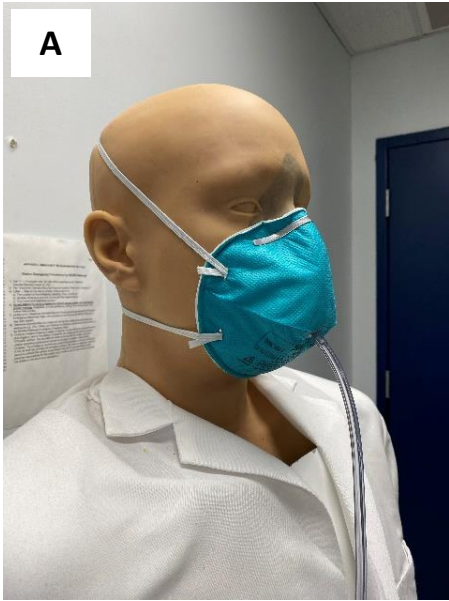


Fig 1A. Medium Static Advanced Headform



Fig 1B. Instron 5934 Tensile Tester

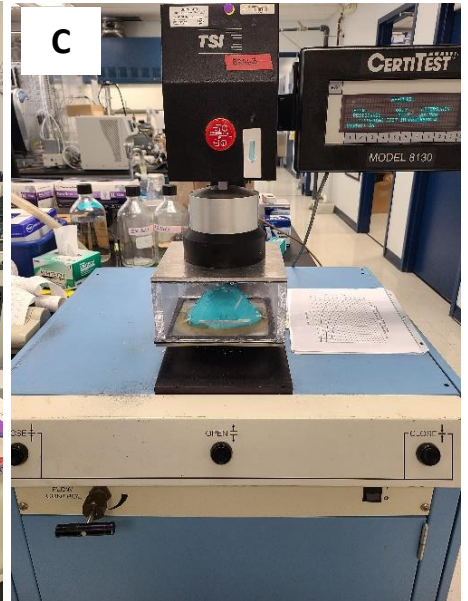


Fig 1C. TSI 8130 Filter Tester



Fig 1D. Printed Information-Control



Fig 1D. Printed Information-Sample

Table 1. Filter Efficiency Evaluation

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	9.0	0.414	0.774	99.23
	Control 2	85	8.5	0.446	0.734	99.27
3M 1860, moist heat, 1 cycle Min Fil Eff: 99.08% Max Fil Eff: 99.34%	1	85	8.5	0.529	0.921	99.08
	2	85	8.4	0.424	0.854	99.15
	3	85	8.1	0.297	0.658	99.34
	4	85	8.5	0.504	0.882	99.12
3M 1860, moist heat, 3 cycles Min Fil Eff: 99.05% Max Fil Eff: 99.25%	1	85	8.5	0.490	0.897	99.10
	2	85	9.0	0.337	0.753	99.25
	3	85	8.5	0.633	0.948	99.05
	4	85	8.3	0.429	0.773	99.23
3M 1860, moist heat, 5 cycles Min Fil Eff: 98.04% Max Fil Eff: 98.92%	1	85	9.6	1.29	1.29	98.71
	2	85	8.0	1.62	1.96	98.04
	3	85	8.6	0.806	1.41	98.59
	4	85	9.2	0.856	1.08	98.92

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, controls Static Advanced Medium Headform (Hanson Robotics)	Control 3	200+	160	200+	185
	Control 4	200+	200+	200+	200+
3M 1860, moist heat, 1 cycle Static Advanced Medium Headform (Hanson Robotics)	5	103	62	93	82
	6	130	69	94	91
	7	132	90	128	114
3M 1860, moist heat, 3 cycles Static Advanced Medium Headform (Hanson Robotics)	5	133	80	127	108
	6	48	36	38	86
	7	104	72	97	89
3M 1860, moist heat, 5 cycles Static Advanced Medium Headform (Hanson Robotics)	5	125	76	111	100
	6	114	94	155	116
	7	118	76	93	93

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, controls	Control 1	2.629	2.465
	Control 2	2.761	2.479
	Control Strap Average	2.695	2.472
3M 1860, moist heat, 1 cycle	1	2.713	2.336
	2	2.790	2.417
	3	2.743	2.468
	4	2.738	2.496
	Decontaminated Strap Average	2.746	2.429
	% Change ((Deconned - Controls)/ Controls)	1.89%	-1.73%
3M 1860, moist heat, 3 cycles	1	2.760	2.444
	2	2.858	2.389
	3	2.728	2.476
	4	2.680	2.564
	Decontaminated Strap Average	2.757	2.468
	% Change ((Deconned - Controls)/ Controls)	2.28%	-0.15%
3M 1860, moist heat, 5 cycles	1	2.777	2.482
	2	2.664	2.506
	3	2.812	2.455
	4	2.823	2.546
	Decontaminated Strap Average	2.769	2.497
	% Change ((Deconned - Controls)/ Controls)	2.75%	1.02%