Evaluation of Decontaminated N95 Respirators

NPPTL
National Personal Protective Technology Laboratory

Date Tested: 2/11/2021 – 2/18/2021

Respirator Model(s): 3M VFlex 1804

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

Decontamination Method: Dry heat decontamination was performed in a 2 ft^3 environmental chamber. Each respirator was sealed in its own Tyvek sterilization pouch and loaded into the chamber. All respirators were exposed to cycles of 75-78°C recirculating hot air for 45 minutes, followed by cooling to ambient. 10 consecutive cycles of heat treatment were performed. Chemical indicators were affixed to the pouches to verify that the respirators reached the target decontamination temperature. Temperature profiles were also recorded to confirm that the air temperature in the chamber remained within specification for the entirety of the soak segment during each cycle.

Decontamination Cycles: 10 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).

Twenty respirators that were unworn and not subjected to any pathogenic microorganisms were submitted for evaluation. This included 15 respirators that were subjected to 10 cycles of the Dry Heat decontamination process and an additional 5 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 99.72% and 99.91%, respectively. All respirators measured efficiencies greater than 95%. See Table 1.

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

Strap Integrity Results: The top straps showed a 6.47% decrease in recorded force and the bottom straps showed a 9.17% decrease in force. See Table 3.

Other Notes: The 3M VFlex 1804 treated respirators had observable blurring of the printed information found on the respirators. Figure 1A-1B shows a comparison between a control sample and a treated sample.

[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. Sample Observations

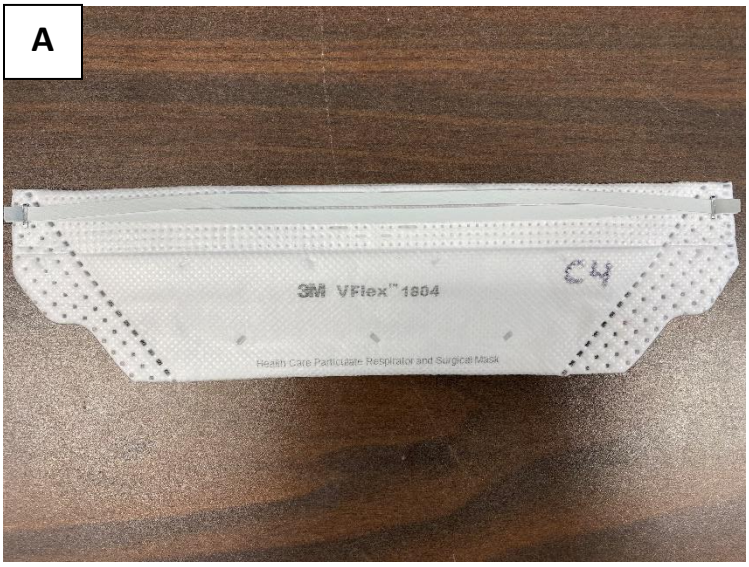

Fig. 1A. 3M VFlex 1804 - Control

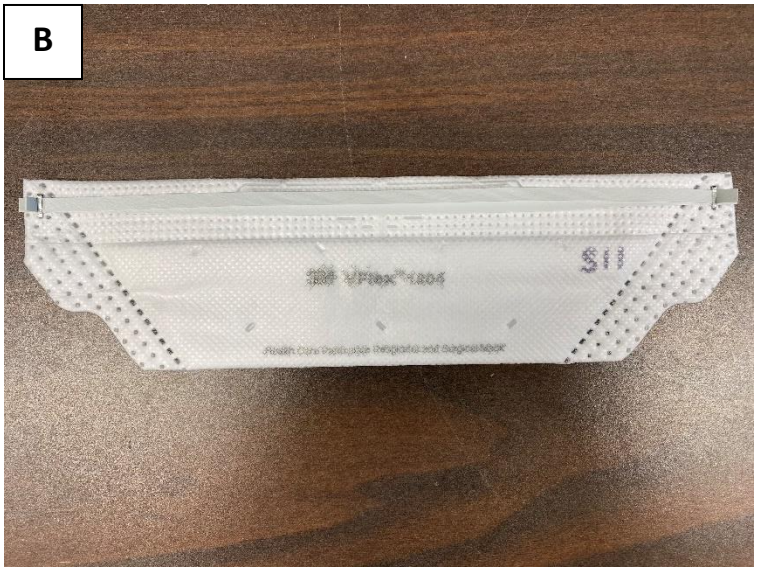

Fig. 1B. 3M VFlex 1804 - Sample

Figure 2. Laboratory Test Photos

Fig. 2A. TSI 8130 Filter Tester

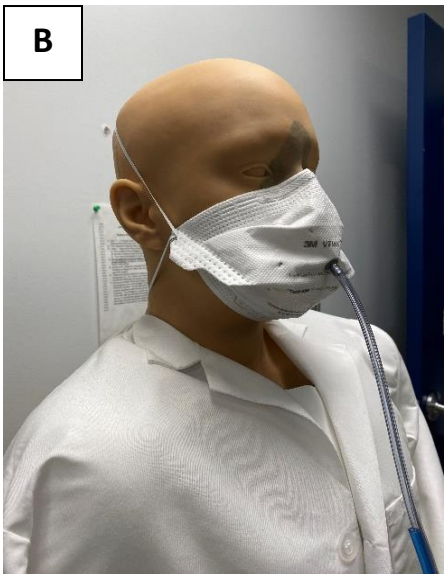

Fig. 2B. Medium Static Advanced Headform

Fig. 2C. Instron 5943 Tensile 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 VFlex 1804, Controls	**Control 1**	85	4.9	1.590	1.720	98.28
	Control 2	85	4.8	0.134	0.159	99.84
	Control 3	85	4.7	0.428	0.463	99.54
3M VFlex 1804, Dry Heat, 10 cycles Min Fil Eff: 99.72% Max Fil Eff: 99.91%	**1**	85	4.6	0.073	0.104	99.90
	2	85	4.7	0.055	0.114	99.89
	3	85	4.5	0.046	0.093	99.91
	4	85	4.2	0.064	0.097	99.90
	5	85	4.2	0.281	0.285	99.72
	6	85	5.1	0.105	0.119	99.88
	7	85	4.7	0.083	0.128	99.87
	8	85	4.6	0.136	0.168	99.83
	9	85	4.2	0.145	0.175	99.83
	10	85	4.6	0.097	0.135	99.87

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 VFlex 1804, Controls Static Advanced Medium Headform (Hanson Robotics)	**Control 4**	200+	200+	200+	200+
	Control 5	200+	200+	200+	200+
3M VFlex 1804, Dry Heat, 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+

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 VFlex 1804, Controls	**Control 1**	2.830	2.991
	Control 2	2.775	2.825
	Control 3	2.726	2.893
	Control Strap Average	2.777	2.903
3M VFlex 1804, Dry Heat, 10 cycles	**1**	2.597	2.741
	2	2.700	2.637
	3	2.338	2.484
	4	2.754	2.685
	Decontaminated Strap Average	2.597	2.637
	% Change ((Deconned – Controls)/ Controls)	-6.47%	-9.17%