Evaluation of Decontaminated N95 Respirators

NPPTL
National Personal Protective Technology Laboratory

Date Tested: 5/8/2020 – 5/11/2020

Respirator Model: 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: DiKlor®-G Sterilization: FFRs subjected to the DiKlor®-G Sterilization Process are loaded into an air-tight sterilization chamber with temperature and humidity control and monitoring devices and air sampling devices. Before DiKlor®-G is introduced, the temperature and relative humidity inside the chamber must be held continuously at/ above 70°F and 75% RH for at least one hour to precondition contaminated FFRs. These temperature and humidity conditions must be maintained and continuously monitored throughout the sterilization process to ensure successful sterilization. DiKlor®-G is then introduced in the chamber until a concentration of 100 ppm_v has been achieved. Quantitative analysis of the DiKlor®-G concentration is regularly performed over the course of the sterilization process. This DiKlor®-G concentration is maintained for at least 8 continuous hours, or until 800 CT (ppm_v·hrs) has been achieved. After reaching the CT target, residual DiKlor®-G is scrubbed from the sterilization chamber before re-entry or retrieval of the sterile FFRs.

Decontamination Cycles: 6 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).

20 respirators that were unworn and not subjected to any pathogenic microorganisms were submitted for evaluation. This included 15 respirators that were subjected to 6 cycles of the DiKlor-G® Sterilization 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 99.13% and 99.62%, respectively. 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. The manikin fit test procedure used in this assessment did not show any detriments in fit associated with the decontamination method used. See Table 2.

[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."

Strap Integrity Results: No visual degradation of the straps was observed. Both the top (11.7%) and bottom (12%) straps showed increases in recorded force. While the exact correlation between the force exerted by straps and fit is not well understood, higher force values may be associated with a tighter fit of the respirator to the face. Significant reductions in this force would be associated with a loss of elasticity of the straps, thereby reducing their ability to create a tight fit. See Table 3.

Other notes: The nosepiece foam on the 3M 1860 (6 cycles) was discolored (brown color, whereas control was gray.

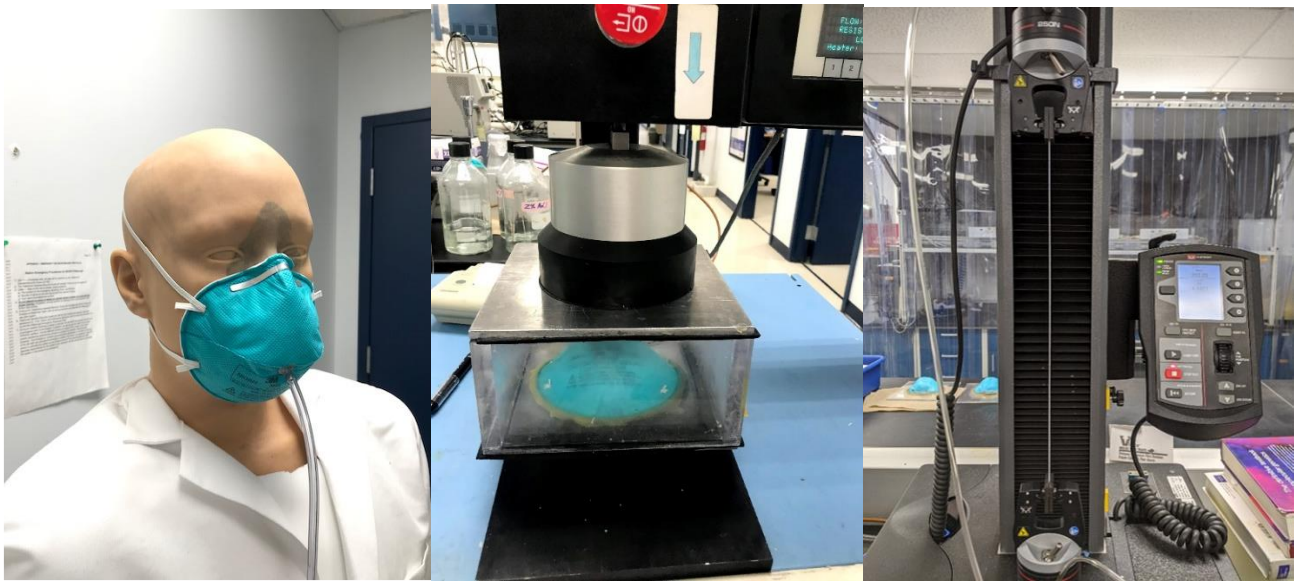

Figure 1. Laboratory Test Photos

Table 1. Filter Efficiency Evaluation

Respirator Model, Decon Method, # of cycles	Treated Sample #	Flow Rate (Lpm)	Initial Filter Resistance (mmH_2O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
3M 1860, DiKlor-G, 6 cycles Min Fil Eff: 99.13% Max Fil Eff: 99.62%	**1**	85	8.2	0.402	0.604	99.40
	2	85	9.8	0.796	0.621	99.38
	3	85	9.0	0.397	0.575	99.43
	4	85	8.3	0.575	0.874	99.13
	5	85	9.3	0.259	0.386	99.61
	6	85	9.4	0.343	0.532	99.47
	7	85	8.8	0.494	0.619	99.38
	8	85	8.8	0.260	0.381	99.62
	9	85	8.9	0.359	0.551	99.45
	10	85	8.6	0.402	0.605	99.40
	Control 1	85	8.5	0.333	0.468	99.53
	Control 2	85	8.9	0.444	0.568	99.43
	Control 3	85	8.6	0.292	0.409	99.59

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, DiKlor-G, 6 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+	188	200+	196
	Control 5	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 1860, DiKlor-G, 6 cycles	**1**	3.207	3.124
	2	3.165	2.893
	3	3.178	2.931
	Decontaminated Strap Average	3.183	2.983
	Control 1	2.904	2.614
	Control 2	2.796	2.712
	Control Strap Average	2.85	2.663
	% Change ((Deconned - Controls) / Controls)	11.7%	12%