Evaluation of Decontaminated N95 Respirators

NPPTL
National Personal Protective Technology Laboratory

Date Tested: 9/17/2020

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: UV-C irradiation produced by low pressure mercury germicidal 254nm lamps that are contained within an enclosure designed to protect users from harmful exposure to the UV-C irradiation. The enclosure was a UV-Concepts Inc. model UVE (UV-C Enclosure). There are 19 lamps that are strategically positioned within this enclosure: 6 lamps on each side wall, 4 on the rear wall, and 3 on the ceiling. The interior side of the door has a highly reflective surface, and each lamp is surrounded by a curved highly reflective material. This enclosure design minimizes shadowing, which allows for 360-degree irradiation exposure to the target subject. The N95 masks are clipped to a rack with the exterior surfaces of the masks facing towards the lamps. The masks are also staggered on the rack to provide exposure both on the outside and inside of the masks. The cycle is 180 seconds and produces ~1000 mJ/cm² of UV-C "dose." This process was then repeated 10 times.

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).

Ten respirators that were unworn and not subjected to any pathogenic microorganisms were submitted for evaluation. This included 7 respirators that were subjected to 10 cycles of the UV-C (1000 mJ/cm²) irradiation decontamination process and an additional 3 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 greater 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. A decrease in recorded force for both the top and bottom straps were measured. 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."

Figure 1. Laboratory Test Photos

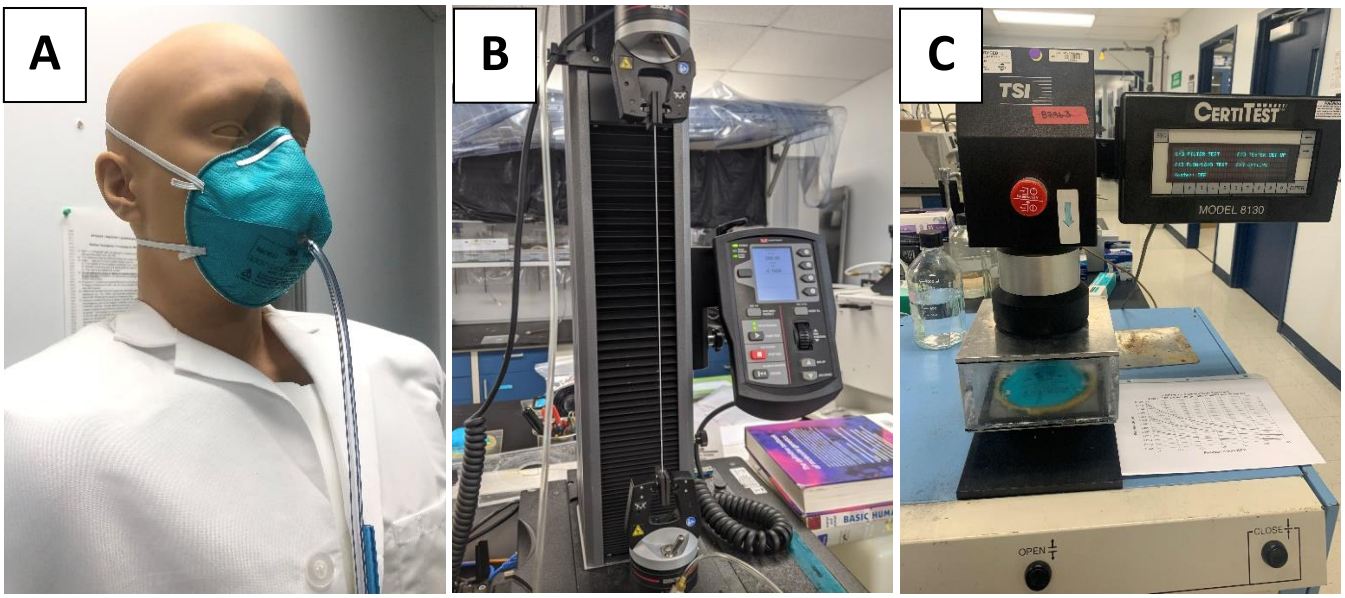

Fig 1A. Static Advanced Headform **Fig 1B. Instron 5943 Tensile Tester** **Fig 1C. TSI 8130 Filter Tester**

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, controls	**Control 1**	85	9.1	0.390	0.654	99.35
	Control 2	85	9.0	1.42	2.20	97.80
3M 1860, UV-C (1000 mJ/cm^2), 10 cycles	**1**	85	9.4	0.762	1.03	98.97
	2	85	10.0	0.311	0.465	99.54
Min Fil Eff: 98.97%	**3**	85	9.4	0.326	0.529	99.47
	4	85	9.7	0.168	0.388	99.61
Max Fil Eff: 99.61%	**5**	85	10.0	0.944	0.944	99.06

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 3**	127	99	123	115
3M 1860, UV-C (1000 mJ/cm²), 10 cycles Static Advanced Medium Headform (Hanson Robotics)	**6**	200+	200+	200+	200+
	7	200+	101	158	141

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, controls	**Control 1**	3.074	2.749
	Control 2	2.408	2.927
	Control Strap Average	2.741	2.838
3M 1860, UV-C (1000 mJ/cm²), 10 cycles	**1**	2.775	2.726
	2	2.711	2.608
	3	2.647	2.842
	Decontaminated Strap Average	2.711	2.725
	% Change ((Deconned – Controls)/ Controls)	-1.09%	-3.98%