Evaluation of Decontaminated N95 Respirators

NPPTL
National Personal Protective Technology Laboratory

Date Tested: 10/19/2020 – 10/21/2020

Respirator Model(s): Halyard Fluidshield 46767 Regular

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

Decontamination Method: The Clean Sleep Hyperion is a closed, free-standing mobile chamber specifically designed for sanitizing soft surfaces. The Hyperion's proprietary technology utilizes UVC light and infrared heat. In independent laboratory tests, using an FDA approved protocol, the Hyperion eliminated 99.9% of viruses and bacteria on N95 respirators. Each cycle has a time duration of 90 minutes at a temperature of 175°F.

Decontamination Cycles: 3 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 3 cycles of the UVC light/infrared 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 97.89% and 99.62%, respectively. All ten respirators measured efficiencies 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. 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.

Strap Integrity Results: Inconsistent changes were shown between the top and bottom straps, with the top straps showing a 3.16% increase in recorded force and the bottom straps showing a 0.90% decrease in force. 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. Large Static Advanced Headform

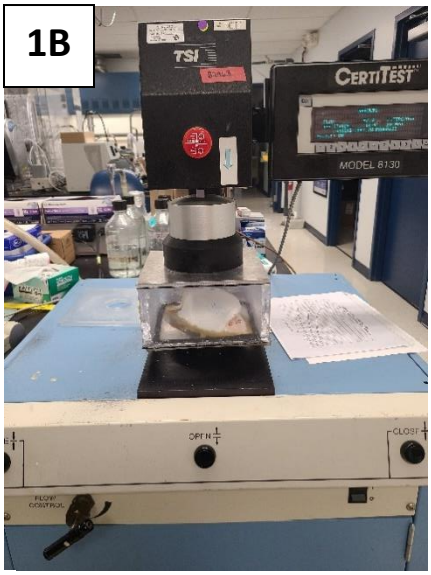

Fig 1B. TSI 8130 Filter Tester

Fig 1C. Instron 5934 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 (%)
Halyard Fluidshield 46767 Regular, controls	**Control 1**	85	12.3	0.483	0.493	99.51
	Control 2	85	12.0	0.496	0.497	99.50
	Control 3	85	12.8	0.541	0.541	99.46
Halyard Fluidshield 46767 Regular, UVC light/infrared heat, 3 cycles Min Fil Eff: 97.89% Max Fil Eff: 99.62%	**1**	85	12.3	0.465	0.465	99.54
	2	85	12.6	0.601	0.601	99.40
	3	85	15.1	0.518	0.518	99.48
	4	85	16.2	0.437	0.437	99.56
	5	85	12.9	0.724	0.724	99.28
	6	85	12.6	1.130	1.13	98.87
	7	85	13.8	2.010	2.11	97.89
	8	85	13.7	0.444	0.444	99.56
	9	85	13.1	0.370	0.384	99.62
	10	85	12.9	0.845	0.845	99.16

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**
Halyard Fluidshield 46767 Regular, controls Large Static Advanced Headform (Lunar Studio)	**Control 4**	200+	200+	200+	200+
	Control 5	200+	191	200+	197
Halyard Fluidshield 46767 Regular, UVC light/infrared heat, 3 cycles Large Static Advanced Headform (Lunar Studio)	**11**	200+	200+	200+	200+
	12	200+	200+	200+	200+
	13	200+	200+	200+	200+
	14	200+	167	200+	188
	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)**
Halyard Fluidshield 46767 Regular, controls	**Control 1**	2.275	2.317
	Control 2	2.169	2.314
	Control 3	2.267	2.333
	Control Strap Average	2.237	2.321
Halyard Fluidshield 46767 Regular, UVC light/infrared heat, 3 cycles	**1**	2.288	2.346
	2	2.360	2.256
	3	2.275	2.299
	Decontaminated Strap Average	2.308	2.300
	% Change ((Deconned - Controls)/ Controls)	3.16%	-0.90%