Evaluation of Decontaminated N95 Respirators

NPPTL
National Personal Protective Technology Laboratory

Date Tested: 10/5/2020

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. Each cycle has a time duration of 90 minutes at a temperature of 175°F.

Decontamination Cycles: 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 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 5 cycles of the UVC light/infrared heat decontamination process and an additional 5 respirators that served as controls. Figure 1 photos show how the samples looked upon arrival. Figure 2 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 61.90% and 93.77%, respectively. All ten decontaminated respirators measured less than 95%. See Table 1.

Manikin Fit Factor Results: The manikin fit factor showed failing fit factors (less than 100) for all decontaminated respirators evaluated. Testing stopped after observing manikin fit factor results of <100 for 3 treated samples. See Table 2.

Strap Integrity Results: Visual discoloration of the decontaminated straps was observed (shown in Fig. 1C). Inconsistent changes were shown between the top and bottom straps with the top strap showing a 1.14% increase in recorded force and the bottom strap showing a 0.73% decrease in recorded force. See Table 3.

Note: The decontaminated respirator samples submitted for testing were observed to have significant damage when compared to the control submissions. The decontaminated samples were folded/bent, the filter media was flaking off, the nosepieces were lifting up from the mask adhesive, and the straps had notable discoloration. Pictures showing the comparison between the submitted controls and decontaminated samples are provided in Figures 1 and 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."

Figure 1. Samples (as received)

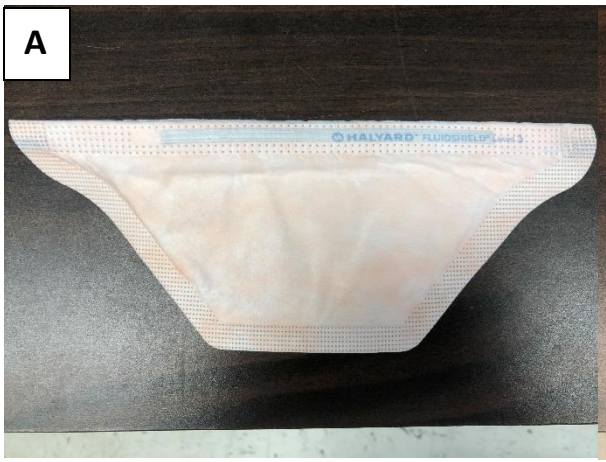

Fig 1A. Control-Front

Fig 1A. Control-Back

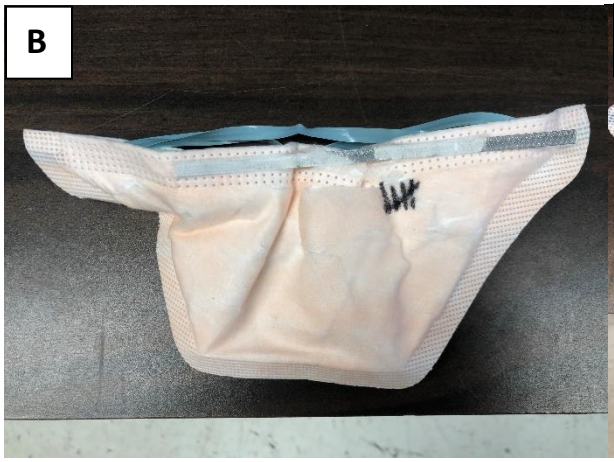

Fig 1B. Sample-Front

Fig 1B. Sample-Back

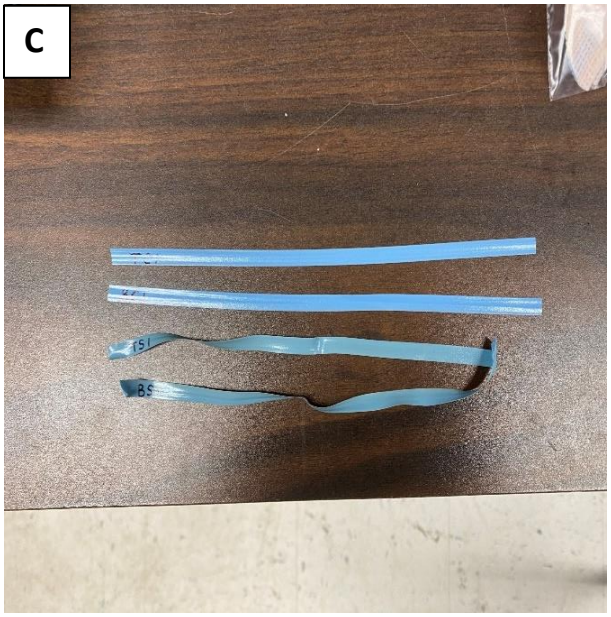

Fig 1C. Control Straps (Top), Sample Straps (Bottom)

Figure 2. Laboratory Test Photos

Fig 2A. Large Static Advanced Headform-Control

Fig 2A. Large Static Advanced Headform-Sample

Fig 2B. Instron 5943 Tensile Tester

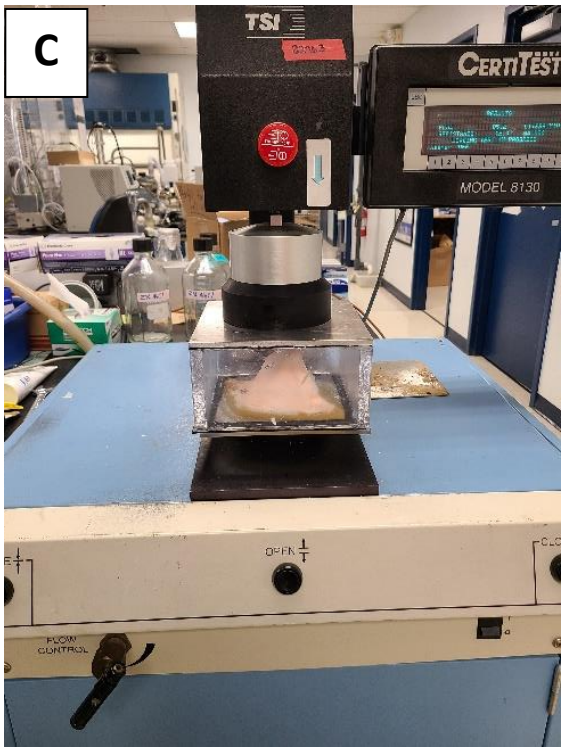

Fig 2C. TSI 8130 Filter Tester

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 (%)
Halyard Fluidshield 46767 Regular, controls	**Control 1**	85	12.6	0.654	0.654	99.35
	Control 2	85	14.3	0.212	0.214	99.79
	Control 3	85	15.0	0.584	0.627	99.37
Halyard Fluidshield 46767 Regular, UVC light/infrared heat, 5 cycles Min Fil Eff: **61.90%** Max Fil Eff: **93.77%**	**1**	85	9.1	10.1	10.1	**89.90**
	2	85	9.6	6.23	6.23	**93.77**
	3	85	6.9	28.6	28.6	**71.40**
	4	85	6.6	25.6	27.0	**73.00**
	5	85	7.4	20.6	20.6	**79.40**
	6	85	7.1	16.6	16.6	**83.40**
	7	85	5.9	38.1	38.1	**61.90**
	8	85	7.9	16.4	17.6	**82.40**
	9	85	9.5	7.91	7.91	**92.09**
	10	85	10.1	6.85	6.85	**93.15**

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.
- **BOLD** filter efficiencies < 95%.

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	129	142	151
	Control 5	136	104	136	123
Halyard Fluidshield 46767 Regular, UVC light/infrared heat, 5 cycles Large Static Advanced Headform (Lunar Studio)	**11**	3	2	3	**2**
	12	5	6	7	**5**
	13	3	2	3	**2**
	14	*	*	*	*
	15	*	*	*	*

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.
- * Samples not tested because treated samples 11-13 achieved 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)**
Halyard Fluidshield 46767 Regular, controls	**Control 1**	2.372	2.326
	Control 2	2.395	2.359
	Control 3	2.334	2.337
	Control Strap Average	2.367	2.341
Halyard Fluidshield 46767 Regular, UVC light/infrared heat, 5 cycles	**1**	2.386	2.301
	2	2.354	2.373
	3	2.426	2.307
	4	2.410	2.313
	Decontaminated Strap Average	2.394	2.324
	% Change ((Deconned - Controls)/ Controls)	1.14%	-0.73%