Evaluation of Decontaminated N95 Respirators

NPPTL
National Personal Protective Technology Laboratory

Date Tested: 1/5/2021 – 1/8/2021

Respirator Model(s): Halyard Fluidshield 46727, 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: Bioquell Proteq Unit Hydrogen Peroxide Vapor (HPV) decontamination with >480 ppm HPV, a 900 second dwell period, and 1,800 seconds aeration time.

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).

Forty respirators that were unworn and not subjected to any pathogenic microorganisms were submitted for evaluation. This included 30 respirators that were subjected to 5 cycles of the HPV decontamination process and an additional 10 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.

Halyard 46727

Filtration Efficiency Results: The minimum and maximum filter efficiencies were 98.44% and 99.74%, respectively. All respirators measured filter 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 4.56% increase in recorded force and the bottom straps showed a 4.73% increase 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."

3M 1860

Filtration Efficiency Results: The minimum and maximum filter efficiencies were 98.67% and 99.37%, respectively. All respirators measured filter efficiencies greater than 95%. See Table 4.

Manikin Fit Factor Results: The manikin fit factor showed passing fit factors (≥ 100) for all respirators evaluated. See Table 5.

Strap Integrity Results: The top straps showed a 16.18% increase in recorded force and the bottom straps showed a 19.22% increase in force. See Table 6.

Figure 1. Laboratory Test Photos

Fig. 1A. Large Static Advanced Headform (Halyard 46727)

Fig. 1B. Medium Static Advanced Headform (3M 1860)

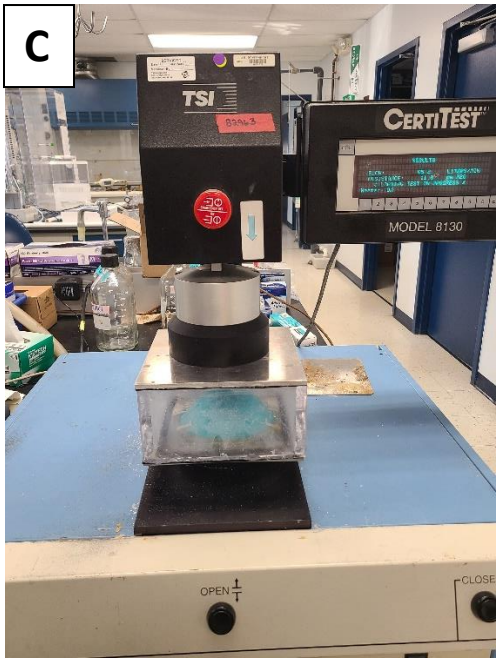

Fig. 1C. TSI 8130 Filter Tester

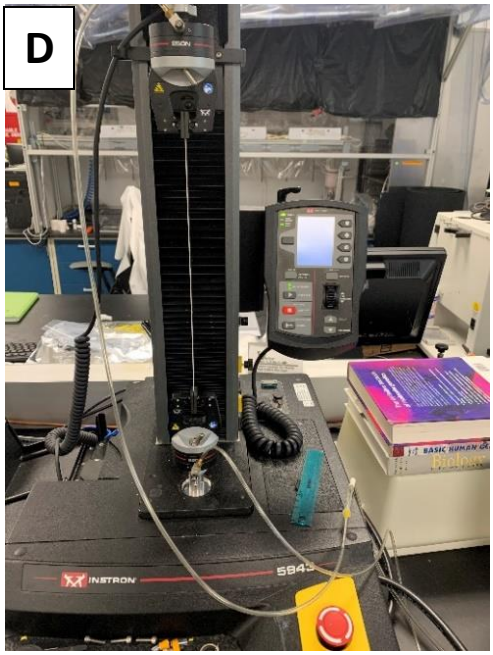

Fig. 1D. Instron 5943 Tensile Tester

Table 1. Filter Efficiency Evaluation – Halyard 46727

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 46727, Controls	**Control 1**	85	9.6	1.100	1.100	98.90
	Control 2	85	10.3	0.870	0.874	99.13
	Control 3	85	10.8	0.856	0.856	99.14
Halyard 46727, HPV, 5 cycles Min Fil Eff: 98.44% Max Fil Eff: 99.74%	**1**	85	11.0	0.883	0.883	99.12
	2	85	10.4	0.690	0.690	99.31
	3	85	12.8	0.348	0.362	99.64
	4	85	10.8	1.430	1.430	98.57
	5	85	19.4	0.262	0.262	99.74
	6	85	11.6	0.783	0.783	99.22
	7	85	11.7	0.957	0.957	99.04
	8	85	10.8	0.720	0.721	99.28
	9	85	11.5	1.560	1.560	98.44
	10	85	11.1	0.267	0.306	99.69

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 – Halyard 46727

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 46727, Controls Static Advanced Large Headform (Lunar Studios)	**Control 4**	200+	121	200+	164
	Control 5	171	86	200+	134
Halyard 46727, HPV, 5 cycles Static Advanced Large Headform (Lunar Studios)	**11**	200+	200+	174	191
	12	200+	178	200+	192
	13	200+	200+	200+	200+
	14	200+	60	200+	113
	15	200+	125	189	164

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 – Halyard 46727

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 46727, Controls	**Control 1**	2.267	2.295
	Control 2	2.329	2.364
	Control 3	2.372	2.312
	Control Strap Average	2.323	2.324
Halyard 46727, HPV, 5 cycles	**1**	2.501	2.420
	2	2.442	2.404
	3	2.368	2.436
	4	2.406	2.477
	Decontaminated Strap Average	2.429	2.434
	% Change ((Deconned - Controls)/ Controls)	4.56%	4.73%

Table 4. Filter Efficiency Evaluation – 3M 1860

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	8.4	0.490	0.807	99.19
	Control 2	85	9.1	0.396	0.690	99.31
	Control 3	85	10.0	0.581	0.802	99.20
3M 1860, HPV, 5 cycles Min Fil Eff: 98.67% Max Fil Eff: 99.37%	**1**	85	8.7	0.538	0.829	99.17
	2	85	8.3	0.510	0.938	99.06
	3	85	9.2	0.501	0.819	99.18
	4	85	8.8	0.358	0.629	99.37
	5	85	9.7	0.466	0.869	99.13
	6	85	9.1	0.608	0.950	99.05
	7	85	8.6	0.651	1.040	98.96
	8	85	8.6	0.498	0.880	99.12
	9	85	8.3	0.557	0.925	99.08
	10	85	10.1	1.090	1.330	98.67

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 5. Manikin Fit Evaluation – 3M 1860

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, Controls Static Advanced Medium Headform (Hanson Robotics)	**Control 4**	200+	173	200+	190
	Control 5	200+	200+	200+	200+
3M 1860, HPV, 5 cycles Static Advanced Medium Headform (Hanson Robotics)	**11**	200+	196	200+	199
	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 6. Strap Integrity Evaluation – 3M 1860

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	**1**	2.789	2.920
	2	2.784	2.857
	3	2.864	3.027
	Control Strap Average	2.812	2.935
3M 1860, HPV, 5 cycles	**1**	3.253	3.543
	2	3.215	3.497
	3	3.284	3.473
	4	3.314	3.481
	Decontaminated Strap Average	3.267	3.499
	% Change ((Deconned - Controls)/ Controls	16.18%	19.22%