

Evaluation of Decontaminated N95 Respirators

Date Tested: 10/9/2020 – 10/14/2020

Respirator Model(s): Makrite 9500-N95S

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

Decontamination Method: Conditioning of the chamber to 45°C over a 20-minute period. Then, a sterilization period of 25 minutes with vaporized H₂O₂ (35% concentration). The H₂O₂ is then inactivated using a catalyst for 60 minutes.

Decontamination Cycles: 10; 20; 30 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 factor¹ 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).

39 respirators that were unworn and not subjected to any pathogenic microorganisms were submitted for evaluation. This included 8 respirators that were subjected to 10 cycles of the VHP decontamination process, 8 subjected to 20 cycles, 8 subjected to 30 cycles, and an additional 15 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 85.60% and 99.55%, respectively. 13 of the 15 decontaminated respirators measured more than 95%. 2 of the 15 decontaminated respirators measured efficiencies less than 95%. See Table 1.

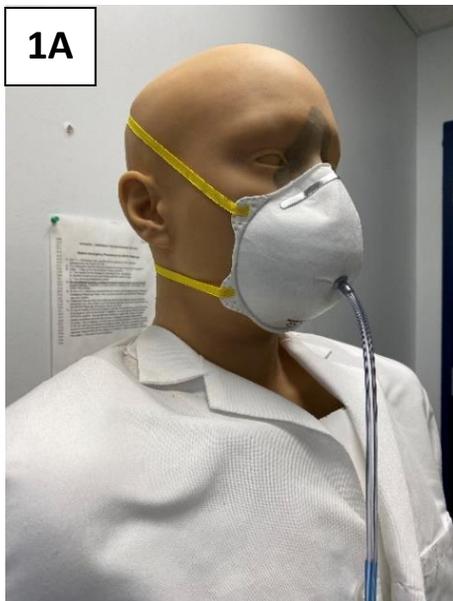
Manikin Fit Factor Results: The manikin fit factor showed passing fit factors (greater than 100) for 9 of the 15 respirators evaluated (this included controls and treated samples). 1 control and 5 treated samples showed failing fit factors that were less than 100. See Table 2.

Strap Integrity Results: All top straps showed a decrease in recorded force. The bottom straps from the 10 and 30 decontamination cycles showed a decrease in recorded force and the bottom straps from the 20 decontamination cycles showed an increase in recorded force. See Table 3.

Other notes: Discoloration of the nose foam was observed with the treated samples. Figures 1D and 1E show a comparison of this observation between a control sample (grey nose foam) and a treated sample (yellow/brown nose foam). The decontaminated samples were also observed to be stiffer and felt rougher to the touch on the inside when compared to the controls.

¹The 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



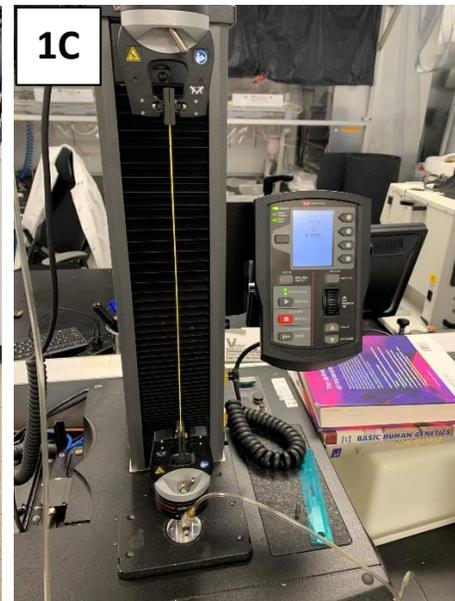
1A

Fig 1A. Medium Static advanced Headform



1B

Fig 1B. TSI 8130 Filter Tester



1C

Fig 1C. Instron 5934 Tensile Tester



1D

Fig 1D. Nose Foam-Control (grey)



1E

Fig 1E. Nose Foam-Sample (yellow/brown)

Table 1. Filter Efficiency Evaluation

Respirator Model, Decon Method, # of cycles	Treated Sample #	Flow Rate (Lpm)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
Makrite 9500-N95S, controls	Control 1	85	11.4	0.493	0.78	99.22
	Control 2	85	11.0	0.651	1.15	98.85
	Control 3	85	12.2	0.549	0.702	99.30
	Control 4	85	11.6	0.373	0.626	99.37
	Control 5	85	15.2	1.420	1.42	98.58
	Control 6	85	12.0	0.714	0.851	99.15
	Control 7	85	13.0	0.527	0.621	99.38
	Control 8	85	13.9	0.531	0.631	99.37
	Control 9	85	11.5	0.745	0.822	99.18
Makrite 9500-N95S, VHP, 10 cycles Min Fil Eff: 96.15% Max Fil Eff: 99.46%	1	85	10.4	0.922	1.34	98.66
	2	85	11.9	0.398	0.58	99.42
	3	85	11.8	3.710	3.85	96.15
	4	85	11.7	0.409	0.539	99.46
	5	85	10.5	0.307	0.604	99.40
Makrite 9500-N95S, VHP, 20 cycles Min Fil Eff: 85.60% Max Fil Eff: 99.55%	1	85	15.5	14.40	14.4	85.60
	2	85	12.1	2.040	2.24	97.76
	3	85	12.3	0.644	0.929	99.07
	4	85	12.7	0.381	0.454	99.55
	5	85	12.8	6.600	6.89	93.11
Makrite 9500-N95S, VHP, 30 cycles Min Fil Eff: 98.10% Max Fil Eff: 99.54%	1	85	10.2	0.965	1.9	98.10
	2	85	11.5	0.791	0.907	99.09
	3	85	12.2	0.386	0.463	99.54
	4	85	12.9	0.498	0.63	99.37
	5	85	11.9	0.485	0.527	99.47

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
Makrite 9500-N95S, controls Static Advanced Medium Headform (Hanson Robotics)	Control 10	200+	113	146	145
	Control 11	157	68	121	102
	Control 12	200+	117	200+	162
	Control 13	146	66	108	96
	Control 14	200+	112	92	121
	Control 15	179	73	102	103
Makrite 9500-N95S, VHP, 10 cycles Static Advanced Medium Headform (Hanson Robotics)	6	144	85	145	117
	7	151	88	116	113
	8	200+	175	200+	191
Makrite 9500-N95S, VHP, 20 cycles Static Advanced Medium Headform (Hanson Robotics)	6	150	47	69	71
	7	55	39	41	44
	8	200+	99	97	118
Makrite 9500-N95S, VHP, 30 cycles Static Advanced Medium Headform (Hanson Robotics)	6	33	25	28	28
	7	123	78	76	88
	8	45	25	56	37

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.

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)
Makrite 9500-N95S, controls	Control 1	3.450	4.068
	Control 2	3.891	3.920
	Control 3	3.910	4.110
	Control 4	3.567	3.679
	Control 5	3.933	3.814
	Control 6	3.963	3.559
	Control 7	3.968	3.789
	Control 8	3.889	3.883
	Control 9	4.027	3.884
	Control Strap Average	3.844	3.856
Makrite 9500-N95S, VHP, 10 cycles	1	3.521	3.716
	2	3.626	3.895
	3	3.588	3.694
	4	3.605	3.864
	5	3.613	3.609
	Decontaminated Strap Average	3.591	3.756
	% Change ((Deconned - Controls)/ Controls)	-6.59%	-2.60%
Makrite 9500-N95S, VHP, 20 cycles	1	3.572	3.835
	2	3.580	3.798
	3	3.707	3.925
	4	3.817	4.061
	5	3.765	3.686
	Decontaminated Strap Average	3.688	3.861
	% Change ((Deconned - Controls)/ Controls)	-4.05%	0.13%
Makrite 9500-N95S, VHP, 30 cycles	1	3.213	3.350
	2	3.560	3.384
	3	3.630	3.455
	4	3.581	3.464
	5	3.580	3.384
	Decontaminated Strap Average	3.513	3.407
	% Change ((Deconned - Controls)/ Controls)	-8.62%	-11.63%