June 17, 2016
Poster Number FRIDAY-344

Assessment of Half-Mask Elastomeric Respirator and Powered Air-Purifying Respirator Reprocessing for an Influenza Pandemic

C. Lawrence, D. Mills, M. Sandoval, D. Harnish, B. Heimbuch

Applied Research Associates, Inc.
(850) 914-3188
dharnish@ara.com

ABSTRACT

Many health care agencies are considering the use of reusable respiratory protection devices (RPDs) to mitigate an RPD shortage due to an influenza pandemic. US regulators are also considering stockpiling reusable RPDs for a pandemic event, but limited data exists on cleaning and disinfection of these devices. This study focuses on 1) determining if standard protocols provided by the Occupational Safety and Health Administration (OSHA) and manufacturers are capable of disinfecting influenza-contaminated reusable RPDs and 2) assess the durability and performance of these devices after being treated up to 150 times using inert aerosol filtration testing and manikin-based face piece fit procedures.

Five half-mask elastomeric respirator (HMER) and three powered air-purifying respirator (PAPR) models were contaminated with influenza and artificial skin oil (sebum) on five unique surfaces. Triplicate RPDs per model were cleaned, or cleaned and decontaminated using standard protocols. Presence of viable influenza was determined via swab sampling and a median tissue culture infectious dose ($TCID_{50}$) assay with Madin-Darby Canine Kidney cells. Filtration efficiency testing and manikin-based fit assessments were performed on HMERs and PAPRs after 75 and 150 cleaning and decontamination cycles.

No detectable influenza was found on all models of HMERs and PAPRs regardless of inoculation location or treatment. The mean log reduction was ~5-log $TCID_{50}$ for the HMER/PAPR bodies and on the PAPR hoods, but was lower on some straps (~3-log $TCID_{50}$). Treated HMERs and PAPRs showed no significant degradation in filtration efficiency or fit performance.

These data provide the first evidence that HMERs and PAPRs contaminated with influenza (and sebum) are capable of being disinfected using OSHA or manufacturer-defined cleaning protocols. Cleaning alone was shown to be sufficient for removing/killing influenza. Fit and filtration performance test data indicate the devices would be acceptable for use after 150 cleaning and disinfection treatments. These combined data should provide confidence to hospitals that HMERs and PAPRs can be effectively reprocessed. Time and logistics required for RPD reprocessing may be significant; future work will focus on evaluating automated methods.

METHODS

Using a cleaning and decontamination (C/D) protocol based on OSHA and manufacturer guidance, five HMER models and three PAPR models were evaluated for 1) H1N1 influenza decontamination efficacy and 2) durability after 75 and 150 C/D cycles.

HMER MODELS


3M 6200


3M 7502


Scott XCEL


Sperian Blue-1


North 7700

PAPR MODELS

3M Breathe Easy

3M Air-Mate


3M PAPR Hood


Syntech MAXAIR

CLEANING STUDIES

- Nine respirators were tested for each respirator model – three control, three cleaned only, and three cleaned and disinfected.


HMER Cleaning

Inoculum Location Examples

- Each respirator was inoculated with ten 1-µL droplets of 9-$log_{10}TCID_{50}$ H1N1 influenza in multiple locations, allowed to dry for 25 minutes, then overlaid with ~5 mg of sebum (artificial skin oil).
- HMERs were cleaned and disinfected by wiping with a 0.5% Neutrawash solution, rinsing with water, soaking in 0.1% household bleach for 2 minutes, and then rinsing.
- Based on manufacturer guidance, unprotected filter cartridges were not cleaned.
- PAPRs were cleaned and disinfected by wiping with a 0.5% Neutrawash solution, wiping with a wet sponge to remove detergent, and then wiping with a PDI SaniCloth (quat ammonia and alcohol) disinfectant.
- After treatment, inoculated areas were sampled using moist swabs that were subsequently extracted. Inoculated straps were cut and directly extracted. Extracts were titered in MDCK cells using $TCID_{50}$ assays according to WHO protocol.

DURABILITY STUDIES

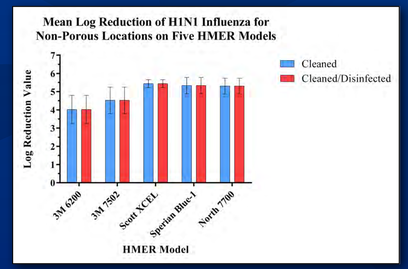

HMER Fit Test

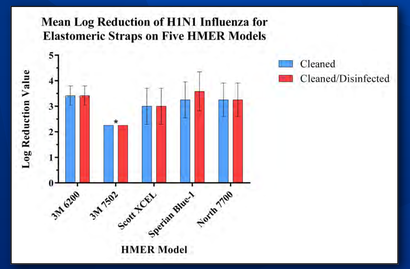

PAPR TIL Test

TSI Automated Filter Tester 8130

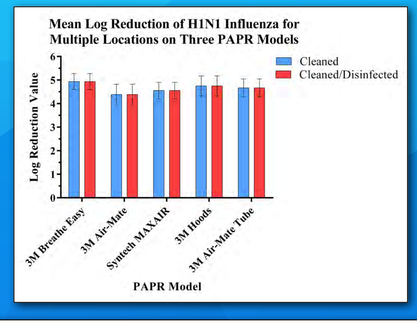
- Three replicates of each respirator model were cleaned and disinfected 75 and 150 times, then evaluated for functionality and performance after multiple C/D cycles at the National Institute for Occupational Safety & Health (NIOSH); three untreated replicates were evaluated as well.
- Filtration efficiency of filter cartridges was determined using both NaCl and dioctyl phthalate (DOP) aerosols generated by a TSI Automated Filter Tester 8130 according to standard NIOSH protocol.
- HMER fit factors and PAPR total inward leakage (TIL) were determined by donning respirators onto a medium- or large-sized static advanced headform connected to an artificial breathing system, then sampling the aerosol using a TSI 8038 PortaCount.

RESULTS





*There is no error bar due to no extraction of influenza from the control straps in 2 of the tests



Performance Evaluation of Five HMER Models After Cleaning/Decontamination Cycles

Durability test	Cycles	3M 6200	3M 7502	Scott XCEL	Sperian Blue 1	North 7700
NaCl penetration test	0	0.004 ± 0.002%	0.004 ± 0.002%	-	-	-
(Passing ≤ 0.03%)	75	0.005 ± 0.002%	0.004 ± 0.001%	-	-	-
	150	0.004 ± 0.003%	0.003 ± 0.002%	-	-	-
DOP penetration test	0	0.002 ± 0.001%	0.002 ± 0.001%	-	-	-
(Passing ≤ 0.03%)	75	-	-	-	-	-
	150	0.002 ± 0.001%	0.002 ± 0.001%	-	-	-
Fit testing[a]	0	35,500 ˣ/ 5	13,800 ˣ/ 8	8,390 ˣ/ 4	32,900 ˣ/ 5	17,000 ˣ/ 5
(Passing ≥ 1000)	75	43,400 ˣ/ 7	21,300 ˣ/ 4	63,900 ˣ/ 3	72,900 ˣ/ 3	14,300 ˣ/ 5
	150	25,000 ˣ/ 4	6,540 ˣ/ 2	71,099 ˣ/ 4	24,700 ˣ/ 3	86,900 ˣ/ 2

[a] *Fit factor data is reported in geometric mean and standard deviation*

Performace Evaluation of Three PAPR Models After Cleaning/Decontamination Cycles

Durability test	Type	3M Breathe Easy	3M Air-Mate	Syntech MAXAIR
DOP penetration test	0	0.000 ± 0.000%	0.006 ± 0.006%	0.005 ± 0.003%
(Passing ≤ 0.03%)	75	-	-	-
	150	0.000 ± 0.000%	0.003 ± 0.001%	0.002 ± 0.002%
Total inward leakage[a,b]	0	53,700 ˣ/ 3	54,100 ˣ/ 2	4,010 ˣ/ 1
	75	-	43,400 ˣ/ 2	3,770 ˣ/ 2
	150	64,000 ˣ/ 2	43,200 ˣ/ 3	2,410 ˣ/ 2

[a] *Fit factor data is reported in geometric mean and standard deviation*
[b] *Total inward leakage was not able to be performed using the Breathe Easy at 75 cycles*

CONCLUSIONS

- The data from this study indicates that the manual C/D protocols based on OSHA and manufacturer guidance for HMERs and PAPRs were effective at removing/killing influenza while in the presence of a soiling agent.
- The effectiveness of cleaning alone was equivalent to both cleaning and disinfection at removing/killing influenza.
- Durability data indicates that HMERs and PAPRs can be cleaned up to 150 times without significant degradation to respirator functionality and performance.
- Future work will focus on additional performance testing and evaluating the effectiveness of automated C/D procedures using a medical washer/disinfector.

ACKNOWLEDGEMENTS

We graciously thank the United States Food and Drug Administration Medical Countermeasures Initiative (MCMi) Regulatory Science Extramural Research program for funding this work under contract number HHSF223201400158C. We also thank the National Institute for Occupational Safety and Health (NIOSH) National Personal Protective Technology Laboratory (NPPTL) for collaborating on this research.

The published material represents the position of the authors and not necessarily that of the FDA.