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Filtering Facepiece Respirators and Viable Microbial Aerosols

NIOSH Personal Protective Technology Program Healthcare Stakeholder Meeting

Roundtable 3 – Emerging Topic - Considerations for Extending Respirator Supplies During an Outbreak or Pandemic

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FFR Decontamination Study

N95 Filtering Facepiece Respirators (FFRs) used for Study

3M 1860

3M 1870

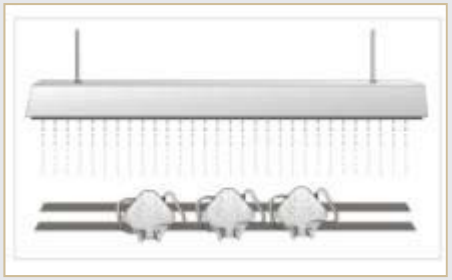
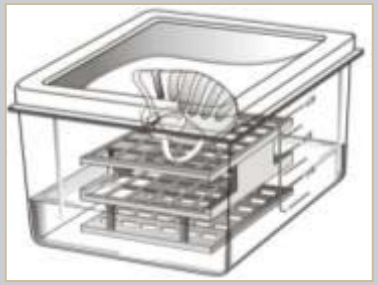
3M 8210

3M 8000

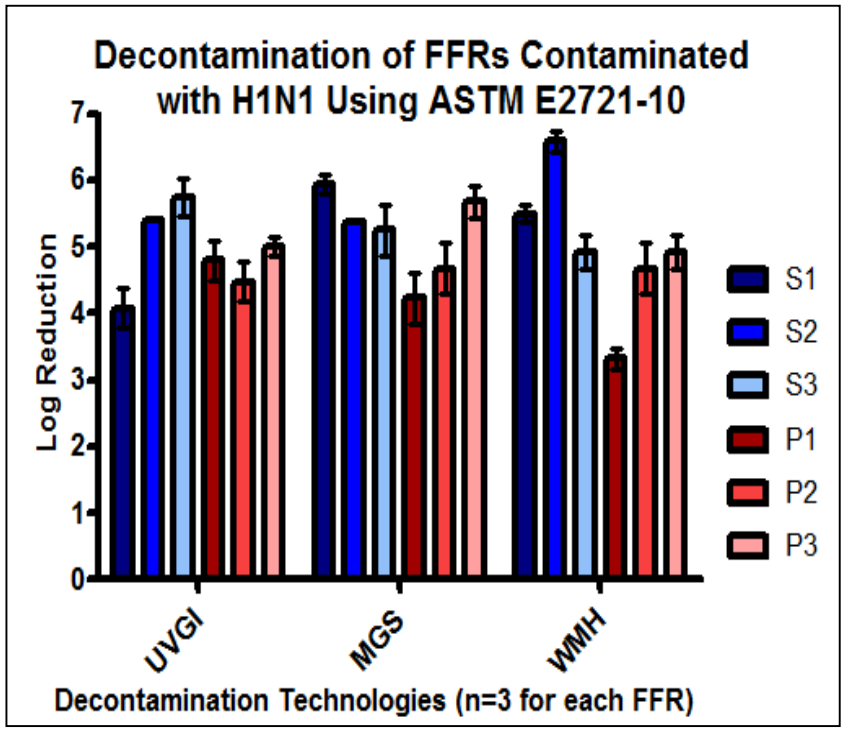
Kimberly-Clark

Moldex 2201

FFR Decontamination Study

Method	Conditions	Graphic
Microwave Generated Steam (MGS)	2-minute cycle on a water reservoir 1250 Watt microwave	
Ultraviolet Germicidal Irradiation (UVGI)	15-minute treatment @ 1.6 – 2.2 mW/cm^2 (1.8 $X10^4$ J/M^2)	
Low-Temperature Moist Heat (WMH)	30 minutes, 65 °C, 85% RH	

FFR Decontamination Study



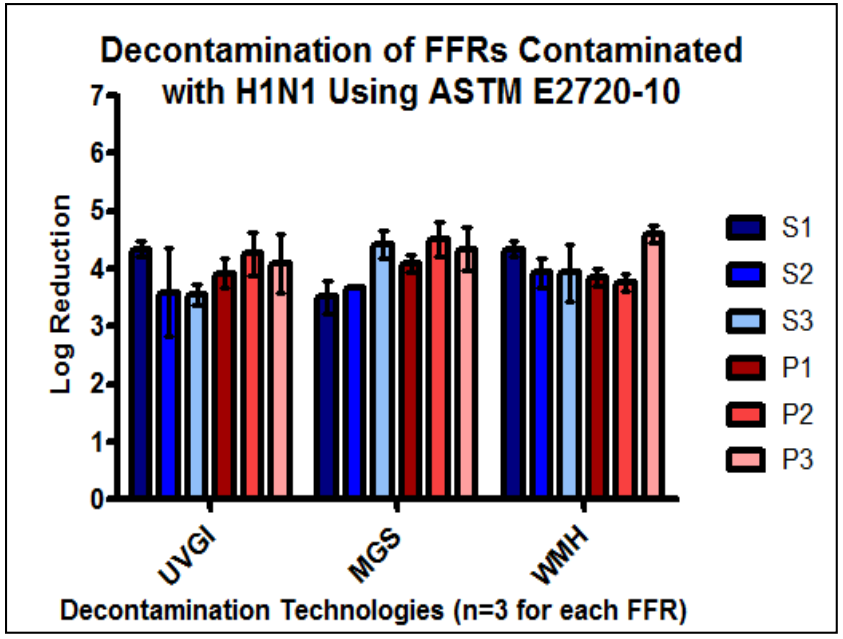
E35 Committee

- Similar results were obtained using low-path H5N1[1]

E2721: Standard test method for effectiveness of decontamination of air-permeable materials challenged with biological aerosols containing human pathogenic viruses

[1]Lore MB, **BK Heimbuch**, TL Brown, JD Wander, SH Hinrichs, Effectiveness of Three Decontamination Treatments against Influenza Virus Applied to Filtering Facepiece Respirators. Annals of Occupational Hygiene, 2012;56(1):92-101

FFR Decontamination Study



- Similar results were obtained using low-path H5N1[1]

ASTM 2720: Standard test method for evaluating the effectiveness of decontamination procedures on surfaces challenged with droplets containing human pathogenic viruses

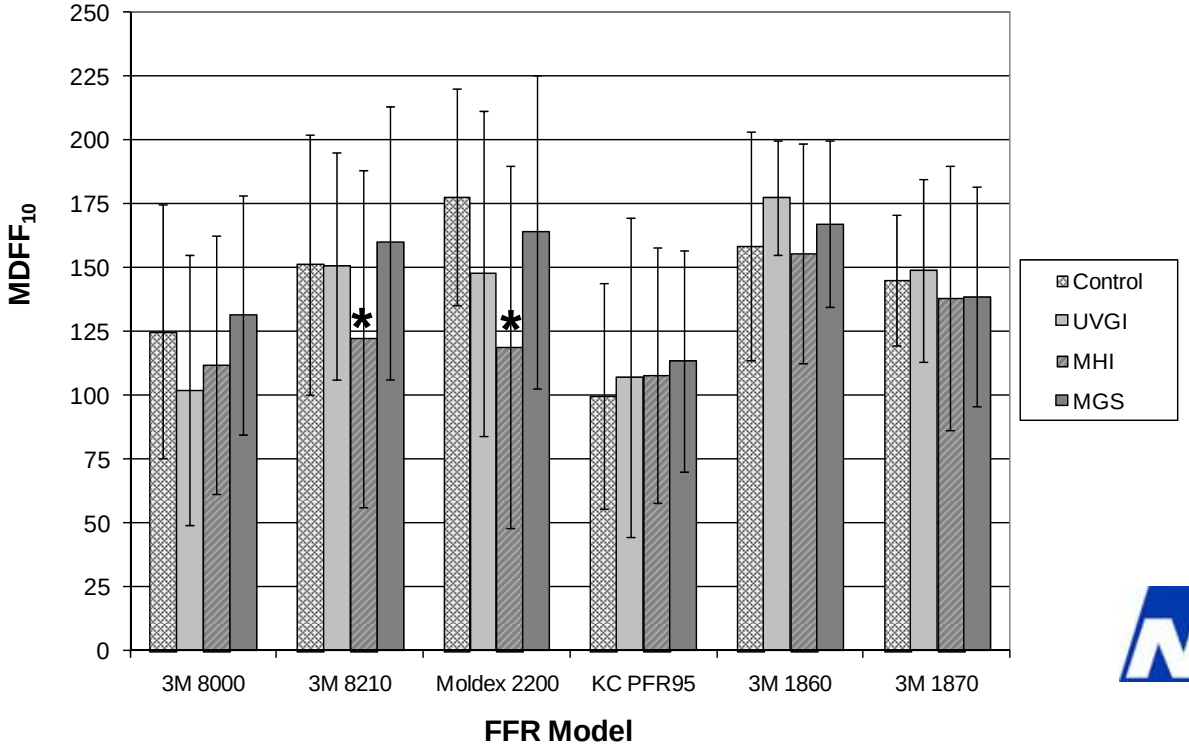
ASTM INTERNATIONAL

E35 Committee

[1]Lore MB, **BK Heimbuch**, TL Brown, JD Wander, SH Hinrichs, Effectiveness of Three Decontamination Treatments against Influenza Virus Applied to Filtering Facepiece Respirators. Annals of Occupational Hygiene, 2012;56(1):92-101

FFR Decontamination Study

Arithmetic Means and Standard Deviation MDFF10 Values across the Control and Three Decontamination Conditions for Six FFR Models



* Indicates a statistically significant reduction ($P < 0.05$) compared with the control

- Fit was not significantly degraded

FFR Decontamination Study

FFR	UVGI	MGS	WMH	Control
3M 8210	0.41 ± 0.24	0.08 ± 0.03	0.43 ± 0.37	0.62 ± 0.19
3M 8000	1.24 ± 0.22	1.33 ± 0.24	0.70 ± 0.07	0.88 ± 0.12
Moldex 2201	1.26 ± 0.25	1.25 ± 0.31	0.90 ± 0.29	2.05 ± 0.33
KC PFR	1.59 ± 0.27	2.14 ± 0.22	2.16 ± 0.10	2.12 ± 0.41
3M 1870	0.34 ± 0.40	0.52 ± 0.35	1.06 ± 0.56	0.63 ± 0.35
3M 1860S	0.66 ± 0.14	0.98 ± 0.39	0.58 ± 0.07	0.64 ± 0.07

- Filtration efficiency was not significantly degraded

NIOSH

FFR Cleaning Study

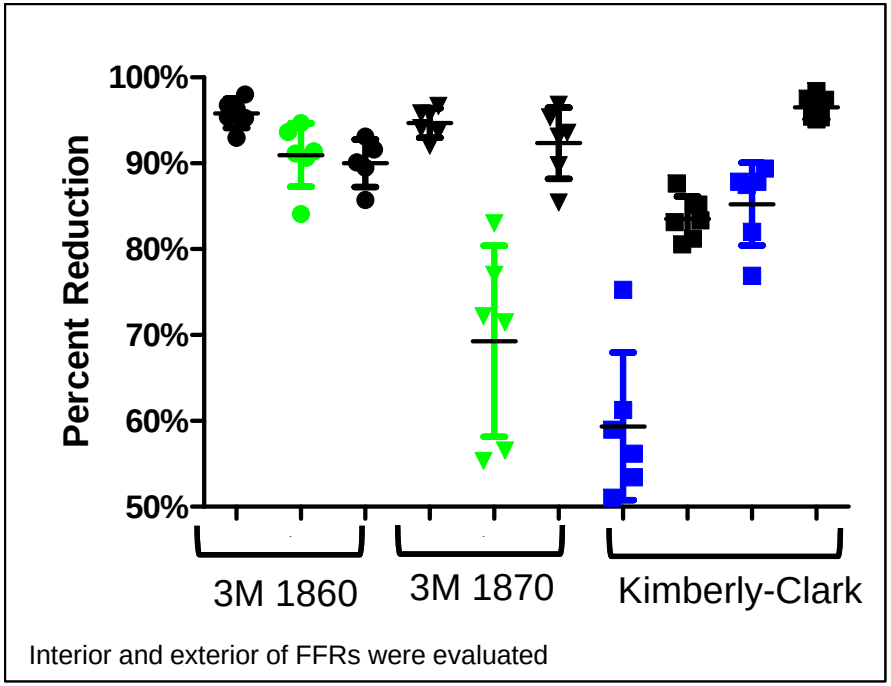
- The Food and Drug Administration (FDA) requires that reprocessed single-use medical devices be cleaned and sterilized, and that their functional performance be demonstrated[2]
- Cleaning studies were performed on 3M1860, 3M1870, and Kimberly-Clark N95 surgical FFRs contaminated with *S. aureus* and artificial saliva using ASTM E2721

Wipe Product	Active Ingredient
Pampers® Wipe	None
3M™ 504/07065 Respirator Cleaning Wipe	Benzalkonium Chloride (BAC)
Current Technology Inc. Hype-Wipe®	Hypochlorite (OCL)

[2]Medical Device User Fee and Modernization Act of 2002, Public Law 107–250.

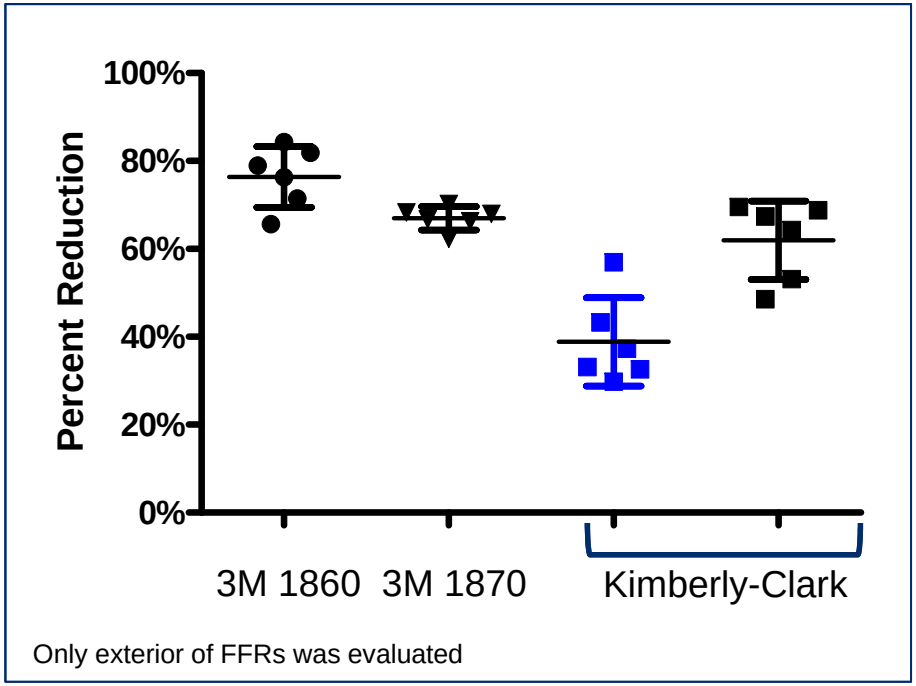
FFR Cleaning Study

S. aureus Removal using Pampers Wipe



Interior and exterior of FFRs were evaluated

Artificial Saliva Removal using Pampers Wipe



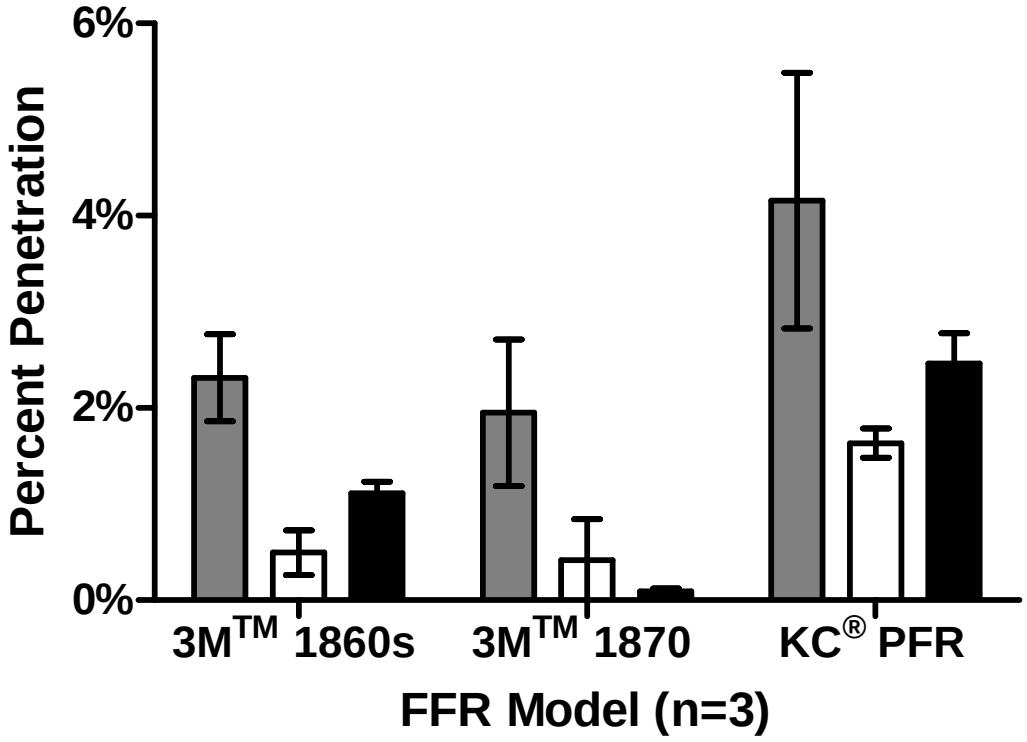
Only exterior of FFRs was evaluated

Nose pads | Edge Strips | FFR Fabric

- OCL wipe showed 4 – 5 log reduction of *S. aureus* on most surfaces
  - Nose pads for 3M1870 had1 – 2 log reduction
- BAC wipe showed 2 – 5 log reduction of *S. aureus* on all surfaces
  - Edge strips of Kimberly-Clark FFR showed 4 – 5 log reduction
- BAC wipe removal of artificial saliva was similar to Pampers wipe

FFR Cleaning Study

Effect of Cleaning on Particle Removal Efficiency



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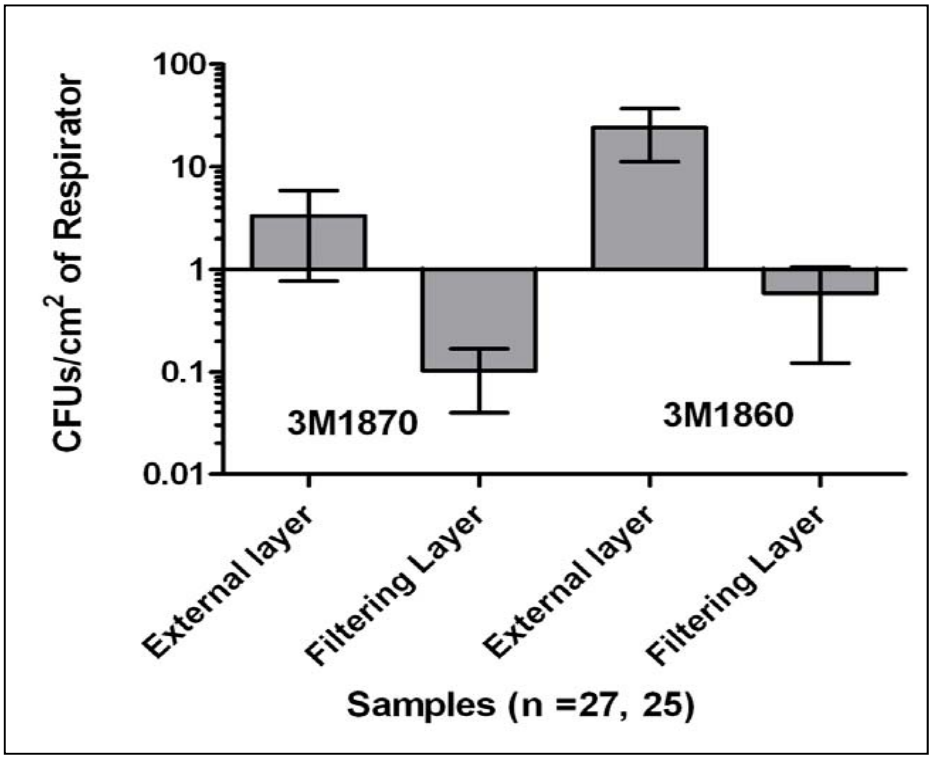
FFR Hospital Wear Study

- Environmental staff at Bay Medical Center (Panama City, FL) wore FFRs while cleaning discharged patient rooms

- FFR wear time was ~25 minutes
- Staff was trained to don and doff the FFRs to avoid contact contamination of the FFRs by touching
- Following doffing, the FFRs were deconstructed and bacterial isolates were collected using permissive media

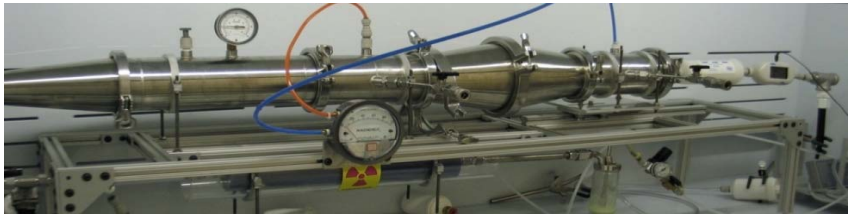
FFR Hospital Wear Study

Viable Bacterial Isolates Recovered From FFRs



- 73% of the Gram-positive and 67% of the Gram-negative isolates evaluated were resistant to oxacillin
- Vancomycin resistance was 9.2% and 36.7%, respectively

Viable H1N1 Evaluation of FFRs



Average Removal Efficiencies of 0.8-µm Particles at 85 LPM

FFR Model	Inert	H1N1 influenza	*p* -value
3M 1860S	99.85% ± 0.10%	99.27% ± 0.38%	0.08
3M 1870	99.90% ± 0.09%	99.13% ± 1.36%	0.45
Kimberly–Clark	99.72% ± 0.16%	98.93% ± 0.36%	0.02
SafeLife T5000	99.999% ± 0.001%	99.996% ± 0.002%[a]	0.09
GSK Actiprotect	99.94% ± 0.06%	99.23% ± 1.00%	0.19

Average Removal Efficiencies of 0.8-µm Particles at 170 LPM

FFR Model	Inert	H1N1 influenza	*p* -value
3M 1860S	99.37% ± 0.39%	98.56% ± 0.87%	0.13
3M 1870	99.96% ± 0.03%	99.59% ± 0.27%	0.14
Kimberly–Clark	98.37% ± 0.32%	96.29% ± 0.56%	0.02
SafeLife T5000	99.994% ± 0.009%	99.995% ± 0.002%[a]	0.9
GSK Actiprotect	99.23% ± 0.15%	96.29% ± 2.49%	0.09

Path Forward

Data from these studies can be used for both short-term and long-term solutions for mitigating an FFR shortage

Short-Term Solution

- FFRs are robust enough to be decontaminated
- FFRs cannot be cleaned according to FDA guidelines, but we do not think cleaning is necessary based on projected operational guidelines
- **Risk cannot be eliminated**, but could be reduced with a little more research aimed at specific risk factors
    1. Strain resistance risk
    2. Repeated exposure complications
    3. Universal application
    4. Increased decontamination cycles
    5. Transition preparations for UVGI technology

Path Forward

Data from these studies can be used for both short-term and long-term solutions for mitigating an FFR shortage

Long-Term Solution

- Data from these studies can be used to develop better FFRs
  - Reuse is approved within a shift
  - Reuse between patients will be allowed during a pandemic

- Development of a decontaminatable FFR is allowable and could meet current NIOSH and FDA approval guidelines[4]
  - Co-develop cleaning protocols/devices
  - Material and design features can be optimized based on our data

[4]Heimbuch BK, Harnish D. (2011) Discussions on Short-Term and Long-Term Solutions to Mitigate a Shortage of Filtering Facepiece Respirators Caused by Pandemic Influenza, Final Report from Interagency Meeting, Food and Drug Administration-Centers for Devices and Radiologic Health. Available from the Food and Drug Administration

Acknowledgements