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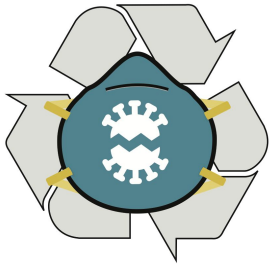
Ask N95DECON & MGB Webinar International Outreach Expanding PPE for the Frontline



Dr. Hana El-Samad, PhD

Dr. Allison Squires, PhD

Tyler Chen, PhD Student

Dr. Orhun K. Muratoglu, PhD

Dr. Felicity Billings, M.D.

Dr. Jill R. Crittenden, PhD

N95 Respirator Decontamination & Reuse

Dr. Samantha M. Grist, PhD

Dr. John Doyle, PhD

Dr. Andrew Barnard, PhD

Dr. Thomas Baer, PhD

Dr. Martin Purschke, PhD

Cole Meisenhelder, PhD Student

N95DECON

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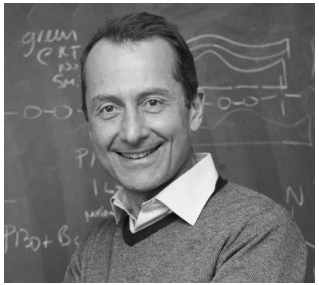
Organizers:
N95DECON
MGB Re-Use COVID Innovation Group

Dr. Hana El-Samad, PhD
University of California, San Francisco

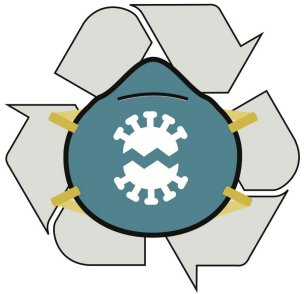


Dr. Orhun K. Muratoglu, PhD
Massachusetts General Hospital

Best practice is to use new N95 FFRs. Decontamination does not solve the PPE shortage crisis, and is an emergency practice during the COVID-19 pandemic.

N95DECON Consortium

- 105 scientists from 10 different institutions;
  - Unbiased, interdisciplinary, & no financial conflicts
  - PhDs, MDs, RNs, IHs, students
  - ~ 5 weeks ago
- Evaluate existing literature on N95 decontamination methods
- Publish Technical Reports and Fact Sheets
- Coordinate and execute research



Method agnostic - We understand there is no single best solution

Independent - Entirely volunteer-based, not backed by any financial interest

Science-based - All information in our publications is subjected to rigorous review and debate

Learn more: https://N95DECON.org **@N95DECON**

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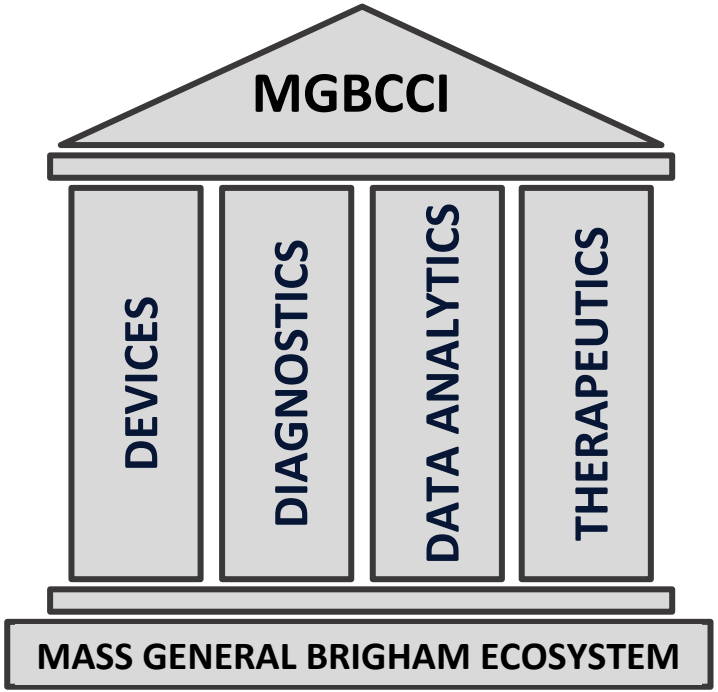
MGB COVID Innovation Center

The mission of the MGB Center for COVID Innovation is to organize and consolidate the **rapid investigation and clinical deployment of devices**, **diagnostics**, **data analytics**, and **therapeutics** developed by researchers and clinicians in the Mass General Brigham (MGB) ecosystem, aimed at combating the COVID-19 crisis.



Gary Tearney (MGH) & David Walt (BWH)

Learn more: https://covidinnovation.partners.org

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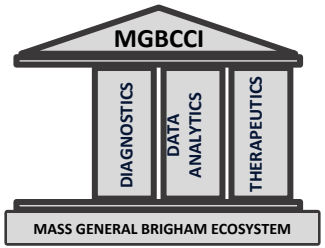
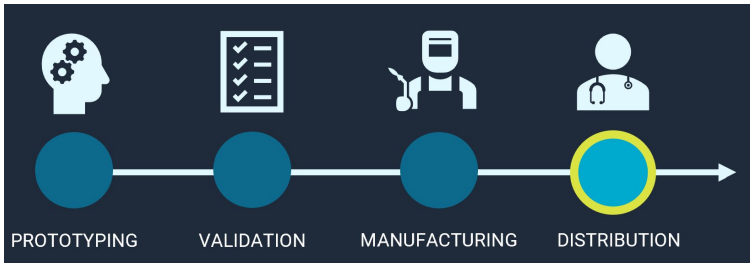
MGB COVID Innovation Center - Reuse

DEVICES

- N95
- Swabs
- Face Shields
  - **Reuse**
- Ventilators
- Full Body Protection
- Surgical Masks
- Validation

- Response to N95 Shortage
- 160+ Participants
- Researchers, engineers, clinicians and innovators
- 6 weeks of innovation and counting





Learn more: https://covidinnovation.partners.org/devices-reuse/

What you will learn today -

Evidence and Implementation

BACKGROUND

- What is an N95?
- Do's and Don'ts
- Principles for N95 Decontamination

METHODS

- UV-C
- Heat
- Hydrogen Peroxide Vapor

CONSIDERATIONS

- Filtration Efficiency
- Fit Test
- Bioburden Reduction

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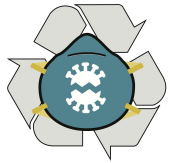
Disclaimers: Data and experience pertains to NIOSH-certified N95 respirators only *(NIOSH: The U.S. National Institute for Occupational Safety and Health).* There may be variation between different mask manufacturers and models



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What is an N95 Respirator?

Dr. Allison Squires, Ph.D.
Neubauer Family Assistant Professor of Molecular Engineering
The University of Chicago

Types of Masks and Respirators (U.S.)

Medical Masks

(Cloth masks, molded medical masks)

Filtering Facepiece Respirator (FFR)

(**N95 and others:** N99, N100, R95, P95, P100,)

Elastomeric Respirator

Powered Air Purifying Respirator (PAPR)

(SCBA, Supplied-air respirators)

International standards similar to N95

USA: N95
Europe: FFP2
China: KN95
Australia: P2
Korea: Korea 1st Class
Japan: DS

Certification/ Class (Standard)	N95 (NIOSH-42C FR84)	FFP2 (EN 149-2001)	KN95 (GB2626-2006)	P2 (AS/NZ 1716:2012)	Korea 1st Class (KMOEL - 2017-64)	DS (Japan JMHLW-Notification 214, 2018)
Filter performance – (must be ≥ X% efficient)	≥ 95%	≥ 94%	≥ 95%	≥ 94%	≥ 94%	≥ 95%
Test agent	NaCl	NaCl and paraffin oil	NaCl	NaCl	NaCl and paraffin oil	NaCl
Flow rate	85 L/min	95 L/min	85 L/min	95 L/min	95 L/min	85 L/min
Total inward leakage (TIL)* – tested on human subjects each performing exercises	N/A	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (individual and arithmetic mean)	≤ 8% leakage (arithmetic mean)	Inward Leakage measured and included in User Instructions
Inhalation resistance – max pressure drop	≤ 343 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min) ≤ 500 Pa (clogging)	≤ 350 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	Varied – see above	85 L/min	Varied – see above	Varied – see above	40 L/min
Exhalation resistance - max pressure drop	≤ 245 Pa	≤ 300 Pa	≤ 250 Pa	≤ 120 Pa	≤ 300 Pa	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)

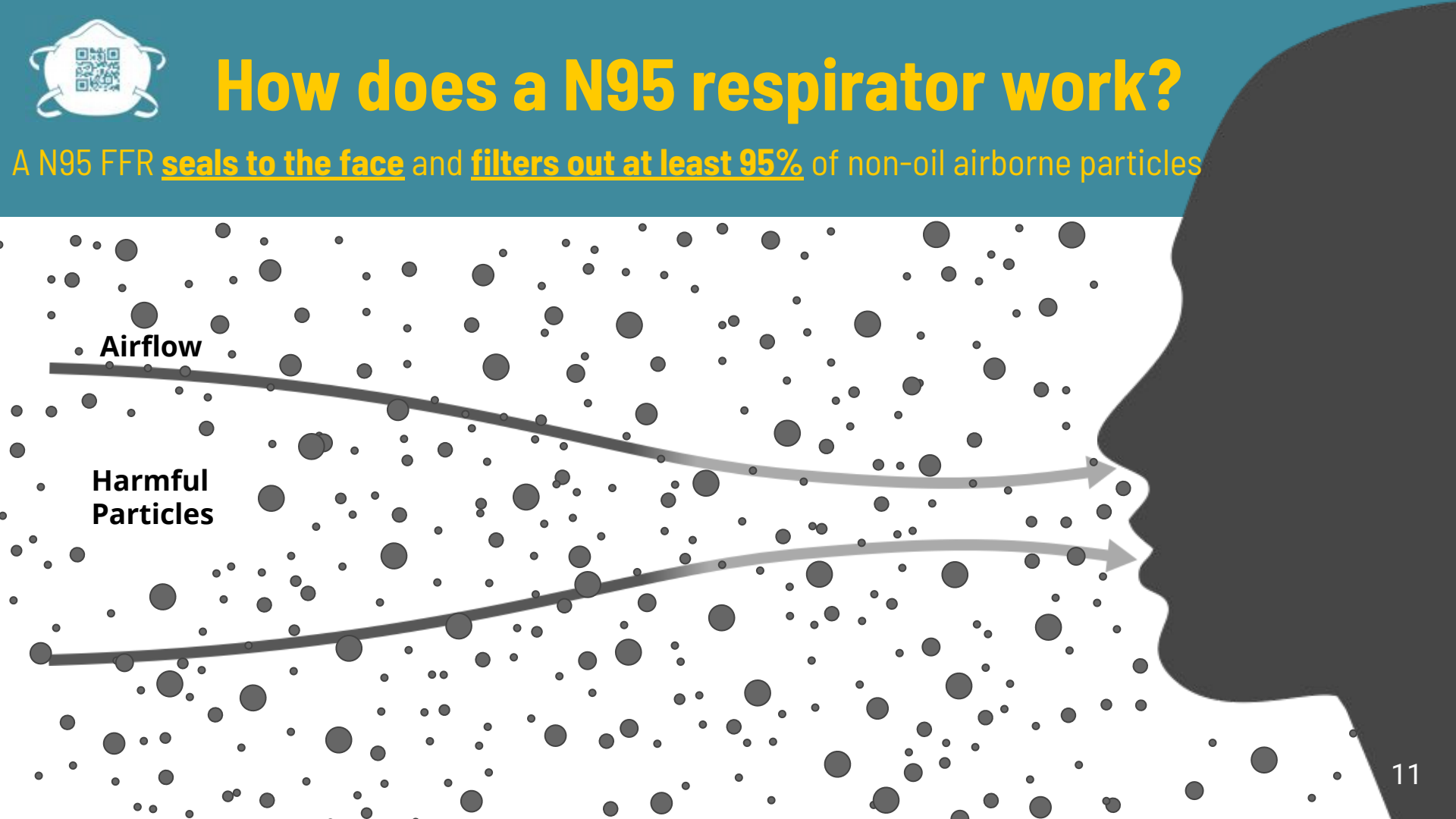
https://multimedia.3m.com/mws/media/1791500O/comparison-ffp2-kn95-n95-filtering-facepiece-respirator-classes-tb.pdf

‘N95 Respirator’: What’s in a name?

- First letter:
  - **‘N’ = Non-oil resistant** (‘R’ = Oil-Resistant, ‘P’ = Oil-Proof)
- Percent efficiency:
  - **‘95’ means 95% of particles filtered** (tested at 0.3 µm diameter)
  - ‘100’ means > 99.7% filtered; ‘99’ is 99% filtered
- Type:
  - **Respirator implies all inhaled air is filtered**
  - ‘Mask’: implies a barrier which may not be sealed
  - ‘Surgical’: Provides a hydrophobic splash barrier
  - ‘PAPR’: Personal air purifying respirator

How does a N95 respirator work?

A N95 FFR **seals to the face** and **filters out at least 95%** of non-oil airborne particles



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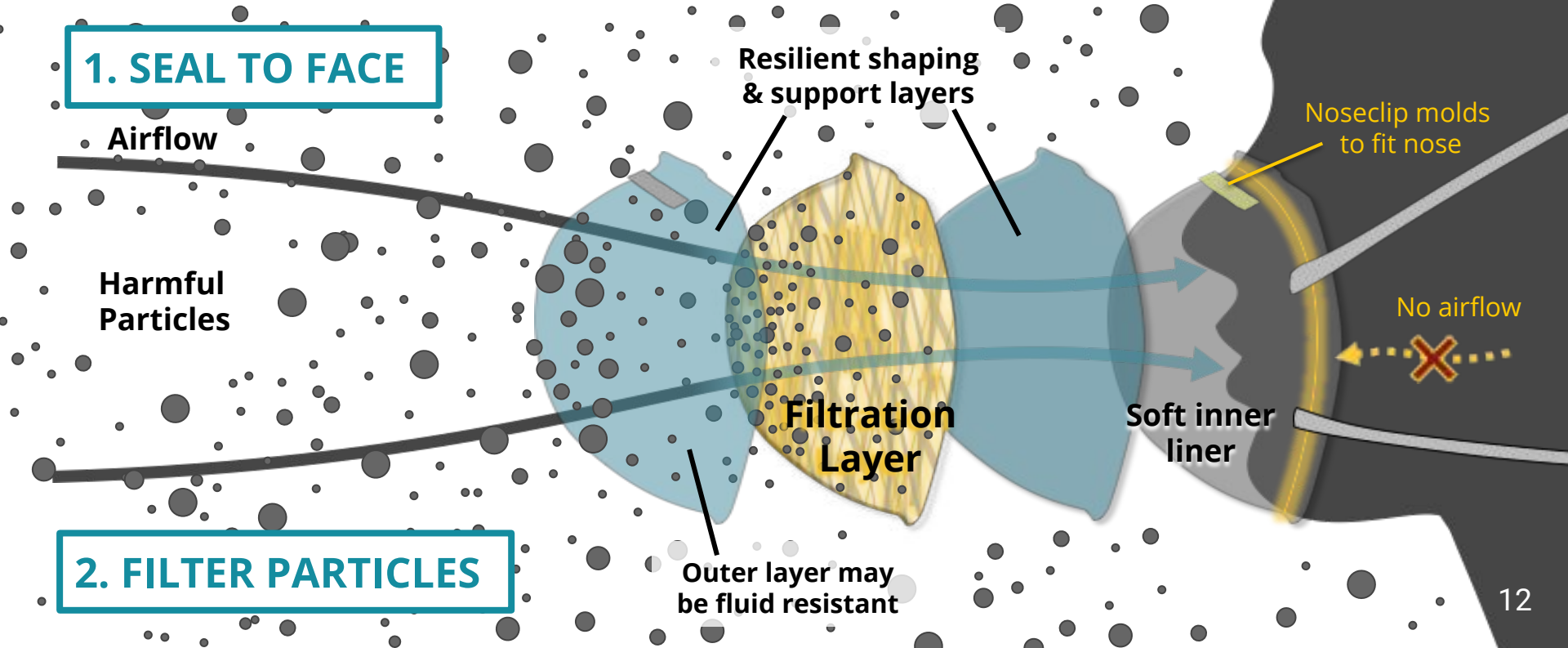


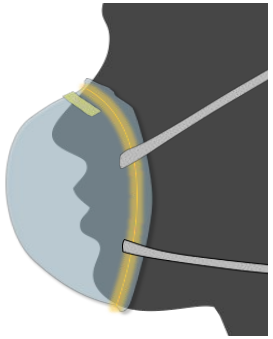
More about… Filtration Fit

KEY FUNCTIONAL FEATURES

Typically non-woven, meltblown polypropylene
Electrets trap droplets by **electrostatic charge**
Pores larger than virus (breathable) still effective

A tight seal to the face **forces air through the filtration layer.**

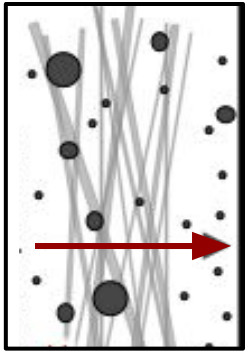
Users **must check seal** qualitatively for each use (seal check) and thoroughly once per year (fit test)



CAUTION! Processes that damage filtration or fit are unsafe.

Filtration efficiency can be reduced by physical damage to the filter or a change in filter charge

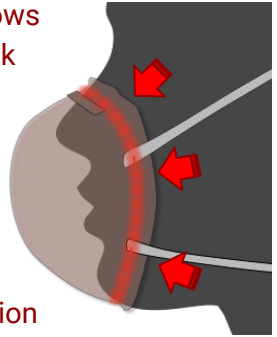
If fibers lose charge, **particles can pass through** to the user.



An inadequate seal allows harmful particles to leak around the edge.

A poor seal could be caused by:

- Poor Fit
- Facial Hair
- Structural degradation



Healthcare vs. Non-Healthcare Features

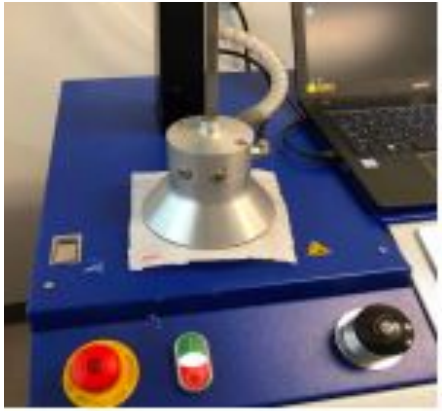
Vented masks provide protection for the wearer,
but **no protection for others**

N95 respirator
for healthcare use

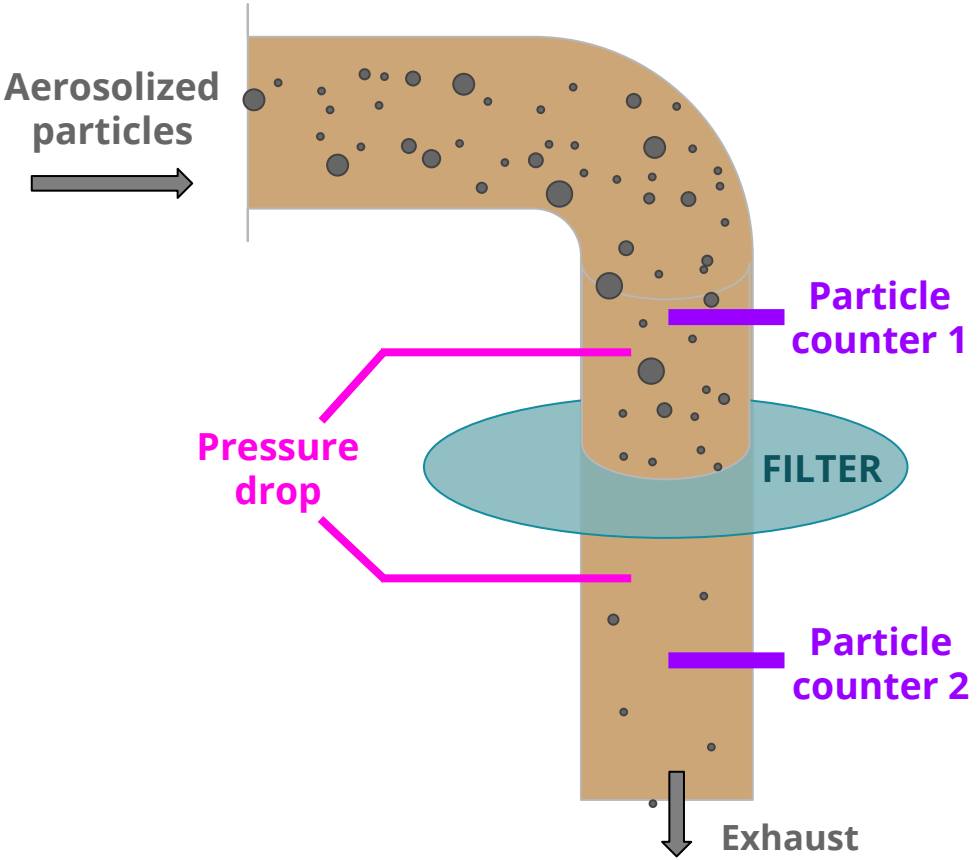
N95 respirator with vent for industrial use
(**not for healthcare use**)

How to validate N95s in the lab

Counterfeit N95s can be identified by **quantitative testing** of filtration



Standard **NIOSH TSI 8130A** measures **filtration efficiency** (%)[1] and **pressure drop** (mm H2O)[2]



1. https://www.tandfonline.com/doi/full/10.1080/15459624.2016.1225157?src=recsys&
2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4499853/

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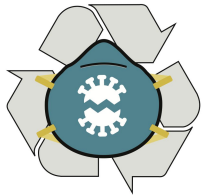
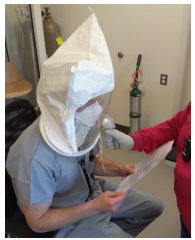
Do’s and Don’ts of N95 Wear

Dr. Felicity Billings, M.D.
Anesthesiologist, Brigham and Women’s Hospital
Instructor in Anesthesia, Harvard Medical School



Fit Testing: Finding Appropriate N95 for Each User

- Determines which N95 model fits a user's face
- After fit test, wearer is approved for specific model of N95
- Occupational regulations (US OSHA) normally require this annually
- Emergency guidance March 2020
  - Only initial fit testing required
  - Annual fit testing suspended



Fit testing procedure:

- Hood placed over head, then aerosolized substance sprayed into hood
  - User tastes sweet (saccharin) or bitter (bitrex)
- Education in proper N95 donning (how to put on and adjust N95)
- User puts N95 on, then aerosolized spray applied again inside hood. Fit test passed if user does NOT taste the aerosolized spray.
- Normal as well as deep breathing (by reading text out loud)
- Position changes: turning head, bending

https://www.osha.gov/video/respiratory_protection/fittesting.html

Proper Donning & Doffing of N95

Donning (putting PPE on):

- Label mask: permanent marker (e.g. Sharpie)
- Cup N95 in hand and place onto chin and nose
- Place upper strap
- Place lower strap
- Adjust straps and nosepiece
- Perform user seal check with clean gloves

- Don other PPE, following hospital guidelines

Doffing (taking PPE off):

- Risk of self-contamination
- Follow hospital guidelines specific to PPE worn
- PPE varies by role, hospital, country

- N95 is removed last, outside of patient room
- Use clean gloves
- Do not touch front of N95
- Front of all PPE considered contaminated
- Only touch the straps behind your head
- Perform hand hygiene after doffing

https://www.n95decon.org/example-processes#instructional-handouts

N95 Extended Use and Reuse Due to PPE Shortage

- CDC recommends extended use/reuse due to COVID-related PPE shortage
  - PPE conservation strategy also includes limiting N95 use to necessary personnel, and using alternative respirators when possible (e.g. PAPR)

- Extended use: wearing same N95 respirator for extended period of time
  - Same staff member wearing N95 without doffing
  - Patients with same pathogen or in same ward/hospital area

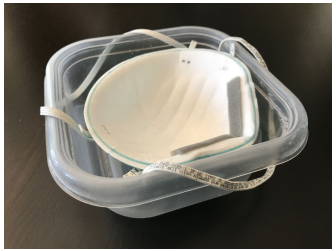
- Reuse: using same N95 respirator for multiple patient encounters, donning and doffing N95 between encounters
  - Requires storage of N95 between patient encounters
  - Proper storage and donning/doffing technique important due to risk of self-contamination

https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html

N95 Storage for Reuse: Do's and Don'ts

Do:

- Encourage staff to save and reuse N95s instead of throwing them in the trash
- Provide containers that staff can label and keep with them
    - Take-out containers
    - Plastic food storage container with holes
    - Aerated
    - These become contaminated



Don't:

- Save and store heavily contaminated N95 (e.g. aerosol-generating procedures)
    - These should be immediately decontaminated
- Share N95 between users without decontamination
- Allow straps to touch front of used N95
- Use sealed plastic containers without air flow

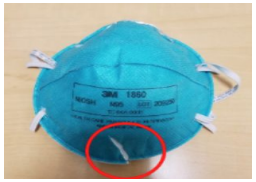
Which N95s Can be Decontaminated?

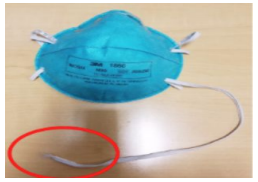
Do Decontaminate:

- After aerosol-generating procedures in COVID+ patients
- Based on their PPE shortage, each hospital must give guidance to staff on how long to reuse before decontamination
  - Stock levels
  - Decontamination turnaround time
  - Number of decontamination cycles planned

Don't Decontaminate:

- Visibly soiled
  - Makeup
  - Oils such as vaseline
  - Blood or bodily fluids
- Straps torn or inelastic
- Visible structural issues (e.g. tears)



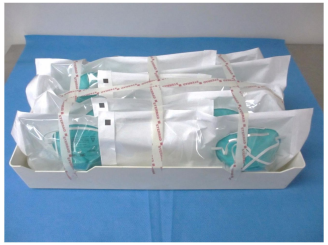


https://www.n95decon.org/example-processes#instructional-handouts

Setting Up an Infrastructure for Decontamination

Communication

- Early communication
- Frequent communication as process changes
- Use pictures



- Staff empowerment - ask for their help!

Organization

- Start collecting early
- Set up a collection and delivery process
  - Use existing infrastructure
  - Re-task personnel from idle departments
  - Ensure proper PPE
- Use a simple mask labelling system
  - If returning to user: name & unit location
  - Mark decontamination cycle number on N95
- Do not combine methods
  - e.g. UVC and H_2O_2
  - No scientific evidence of effects of combining methods on N95 integrity

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N95 Decontamination Principles:

Filtration, Fit, Bioburden, Residue

Tyler Chen, PhD Student
Bioengineering Knight-Hennessy Scholar
Stanford University

Filtration, Fit, Bioburden, Residue

An effective decontamination method must...

- ❏ Preserve N95 filtration (>95% of particles)
- ❏ Preserve N95 fit (tight seal to face)
- ❏ Reduce bioburden (kill viruses and other pathogens)
- ❏ Not introduce additional hazards (e.g. hazardous residue)

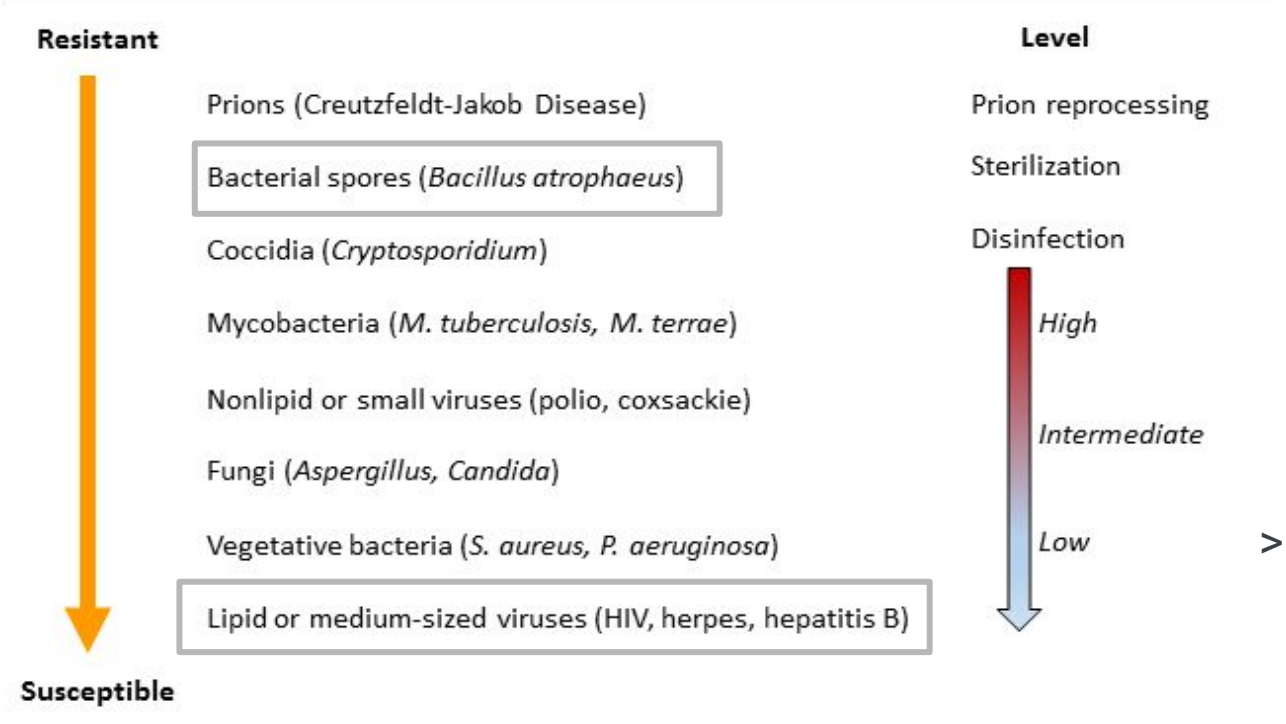
N95 Performance: Filtration and Fit

The number of decontamination cycles before an N95 is damaged depends on the N95 model and the decontamination method. See www.n95decon.org/publications.

Even without decontamination, some N95 models lose proper fit (seal to face) after putting on mask 5 times, others lose fit after >15 times.[1] User seal check is crucial before each reuse!

[1](Bergman et al. 2012) http://dx.doi.org/10.1016/j.ajic.2011.05.003

Bioburden Reduction - Hierarchy



Sterilization:
> 6-log kill of spores (99.9999%)

Minimum Viral Inactivation:
> 3-log kill of SARS-CoV-2 (99.9%)

FDA: “Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)”

Bioburden Inactivation - Evaluation of Decontamination Methods

Ideally: Validate sterilization with appropriate bacterial spore indicators

- SARS-CoV-2 virus (BSL3 facility - high biosafety level)
- Surrogate virus (e.g. Phi6, MS2 phage) (BSL1-2 facility - lower biosafety level)
- Consider other pathogens found in hospital environment (e.g. MRSA, *C botulinum and C difficile spores)* and test decontamination efficacy against these

n95decon.org/caution

Methods NOT to Use

Damages N95 filtration

Soap

Alcohol

Bleach Immersion

Gamma Radiation

Does not inactivate virus

Overnight Storage	Insufficient Time
UV-A/B (e.g. Nail Salon)	Insufficient UV-C
Sunlight	Insufficient UV-C

Dangerous to health

Bringing potentially biohazardous masks home is highly dangerous and has significant contamination risk. Decontamination should occur only in secured environments. Bleach residue may also be hazardous.

N95 Decontamination Principles

- N95 filtration efficiency
- N95 fit
  - Highly method-dependent
- Bioburden inactivation/reduction
  - At least 3-log reduction of SARS-CoV-2
  - Preferably use sterilization methods with 6-log reduction of bacterial spores
- Minimize hazardous residues
  - Inhalation/contact hazard

Decontamination methods to be discussed today:

- Vaporized hydrogen peroxide
- UV-C germicidal irradiation
- Humid heat

https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html

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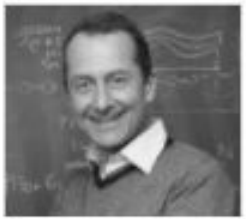
Q&A on N95 Decontamination Basics

Our Panelists

Dr. Hana El-Samad, PhD

Dr. Allison Squires, Ph.D

Dr. Felicity Billings,M.D.



Dr. Orhun K. Muratoglu, PhD

Tyler Chen, PhD Student

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Hydrogen Peroxide Vapor: Evidence

Dr. Jill R. Crittenden, PhD
Research Scientist,
Massachusetts Institute of Technology

H_2O_2 Decontamination Methods

Method	Name	Description	Example Providers
H_2O_2 Vapor/Vapor Phase H_2O_2	HPV/VPHP	Wet H_2O_2 vapor, >500 ppm	Bioquell (Claris)** Battelle CCDS™** Sterilucent*
Vaporized H_2O_2	VHP™	Dry H_2O_2 vapor application to N95, >750 ppm	Steris (V-PRO* and ARD)
Aerosolized H_2O_2	aHP	H_2O_2 (+ additive) microdroplets application to N95, 80-150 ppm	Curis®
Vaporized H_2O_2 followed by ozone	VHP	H_2O_2 vapor application to N95, subsequently reacted with ozone	Stryker (STERIZONE®; VP4*)
Ionized H_2O_2	iHP®	H_2O_2 (+ additive) ionized by plasma prior to application to N95	Tomi™ (SteraMist®)
H_2O_2 Gas Plasma	HPGP	H_2O_2 vapor application to N95, subsequently converted to plasma by electric field	ASP (STERRAD™; for 100NX only use Express Cycle!!)*
Liquid H_2O_2		N95 are submerged in 6% H_2O_2 liquid for 30 min, time required for sufficient aeration is not known	

Approved by FDA Emergency Use Authorization for *single-user reuse or **general reuse

Advantages of H_2O_2 Methods

- H_2O_2 is a strong sterilant, reacting with many biological substances to produce reactive oxygen species that destroy membrane lipids, proteins, and DNA/RNA
- Reactive with biological substances in the absence of heat (good for decontaminating plastics and other heat-sensitive materials)
- Can penetrate dark spaces (unlike light)
- Final breakdown products are non-harmful (H_2O and O_2)

Disadvantages of H_2O_2 Methods

- H_2O_2 is a respiratory hazard requiring controlled air-flow for application and sufficient aeration of mask
- Requires equipment that is usually expensive, and trained personnel
- Equipment-specific protocols must be applied

Effective Pathogen and Viral Inactivation

See n95decon.org for references

N95 model	Dose	Time (min)	Biological specimen	Effectiveness (log reduction)
3M 1860	HPV (Bioquell) 2 g/min then 0.5 g/min	vapor 20; dwell 150	*G stearothermophilus spores*	≥6
3M 1860, 1870, 1804 and AO 1054	VHP™ (Steris) 5 g/min then 2.2 g/min	vapor 3; dwell 30	SARS-CoV-2	≥6
3M 1860, 1870+, 8511, 9211, HW N11125	Curis	aerosol 12; dwell 50	Herpes Simplex Virus 1 Coxsackievirus B3 Phage phi6	≥6
Biological indicators placed under 3M 1860 and Halyard 46767	SteraMist (TOMI)	ionized vapor 15; dwell 20	*G stearothermophilus spores*	≥6

Pass Fit and Filtration (with appropriate protocol)

See n95decon.org for references

N95 model	Dose	Time (min)	Cycles	Filtration	Fit
6 models	HPGP (STERRAD 100S, 100NX)	55	1	>99.2%	Pass
6 models	HPGP (STERRAD 100S, 100NX) Standard cycle	55	3-5	<95%	Fail
6 models	HPV (Bioquell)	gas 15; dwell 120	3	>97%	
3M 1860	HPV (Bioquell)	gas 20; dwell 150	10 - 50	>99%	
3M 1860	HPV (Bioquell)	gas 25; dwell 20	1 (10)	Not tested	Pass
3M 1860S	VHP™ (Steris) 410 ppm	3 h	1	>98.8%	
3M 1860, Halyard Fluidshield	Halosil	gas 15; dwell 120	1 - 5	>99.3 (3M), >95.5 (HF)	
Gerson 2130, 3M 8210	SteraMist (TOMI™)	ionized vapor 15; dwell 20	2	>97%	Pass
3M 1860, Halyard 46767	SteraMist (TOMI™)	ionized vapor 15; dwell 20	5	>97%	

Method Summary: H_2O_2

Implementation Criteria

Safety-trained personnel

Machine-specific protocols (check FDA site)

For whole room set-up, check hospital protocols (see N95Decon.org) and checklist: https://www.nist.gov/services-resources/software/tool-evaluation-vaporized-hydrogen-peroxide-disinfection-n95-masks-small)

Bioburden Reduction

Biological or chemical indicator should be included for each cycle

N95 Performance

Model of N95 - H_2O_2 is not compatible with cellulose

Check cycle # allowed for specific method

Other Concerns

Use machine-specific methods approved for N95 decontamination

Check time required for aeration

Check whether method is compatible with Tyvek pouch

See n95decon.org/hpv for more information

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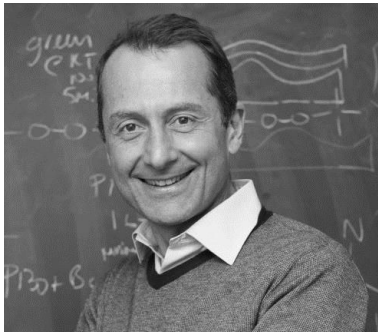
Hydrogen Peroxide Vapor: Implementation



Dr. Orhun Muratoglu, PhD

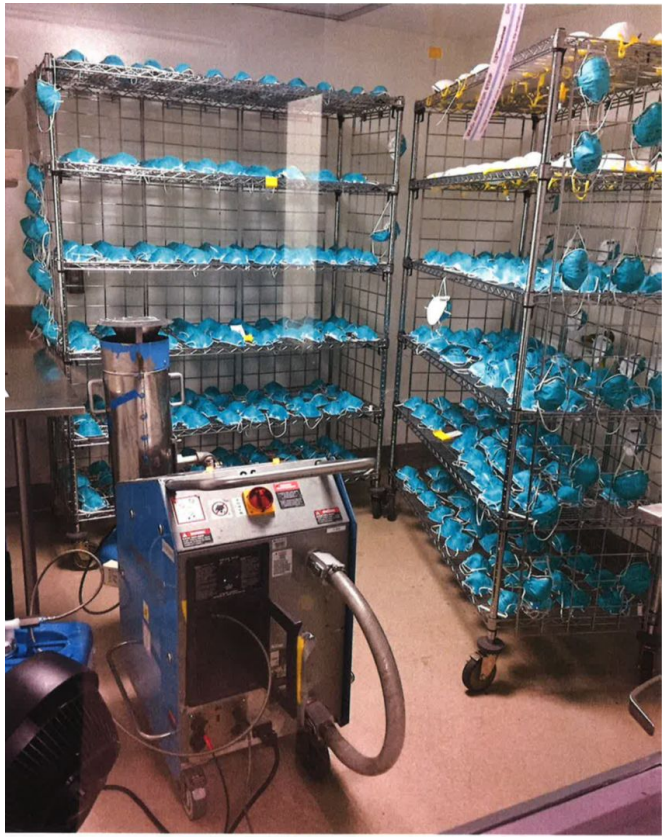
Professor, Harvard Medical School

Alan Gary Scholar, Director Harris Ortho Lab,

Massachusetts General Hospital, MGB Covid Innovation Center

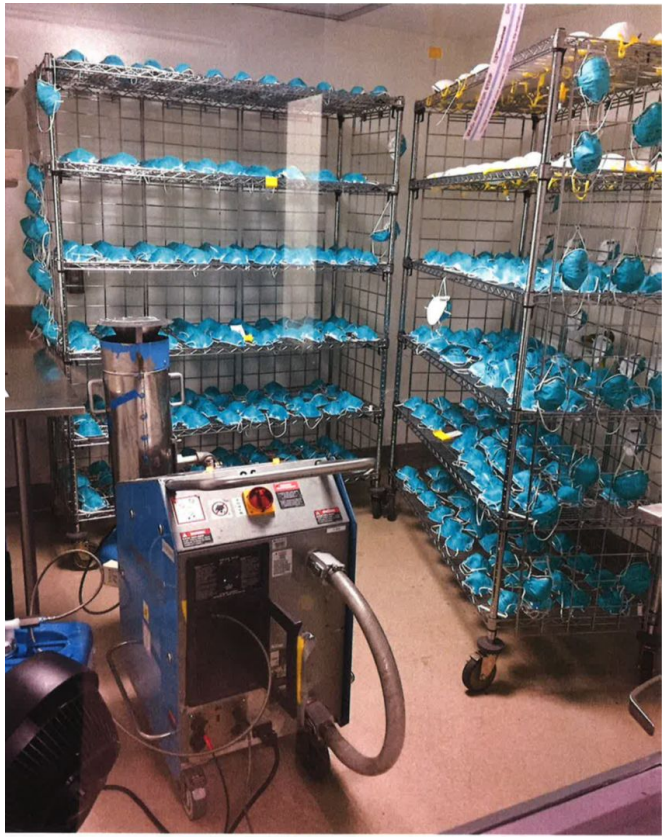
Hydrogen Peroxide Vapor (VHP) Implementation

- Duke
  - Bioquell Clarus
- U Iowa
  - SteraMist
- Brigham
  - SteraMist
- MGH
  - Steris ARD1000



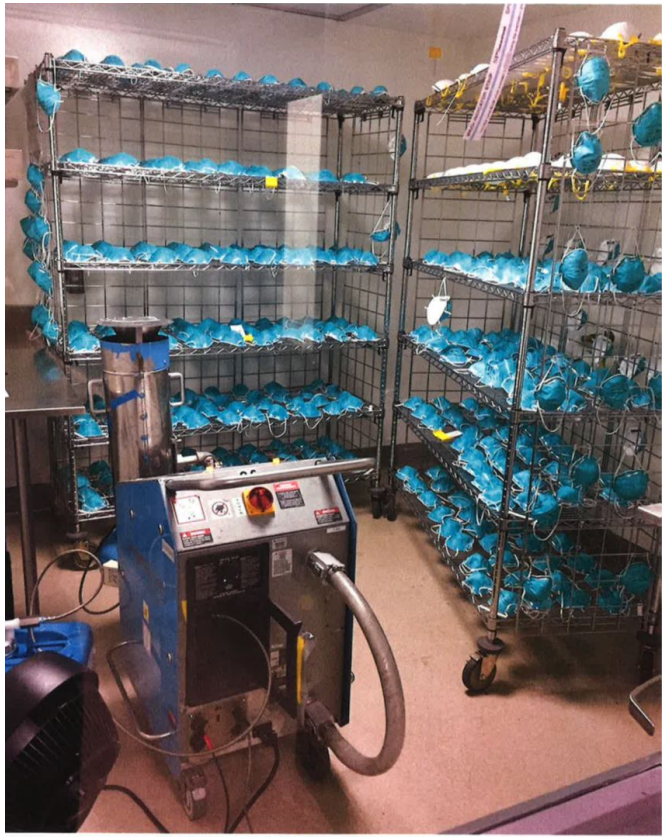
VHP - Steris ARD1000 Generator

- Ramp up to 400-500 ppm in 15 min
- Hold at 400-500 ppm for 3 hours
- Degas until <1 ppm



VHP - Steris ARD1000 Generator

- Chemical indicators
  - All passed
- Biological indicators
  - All passed after 7 day incubation



VHP - Filtration Efficiency

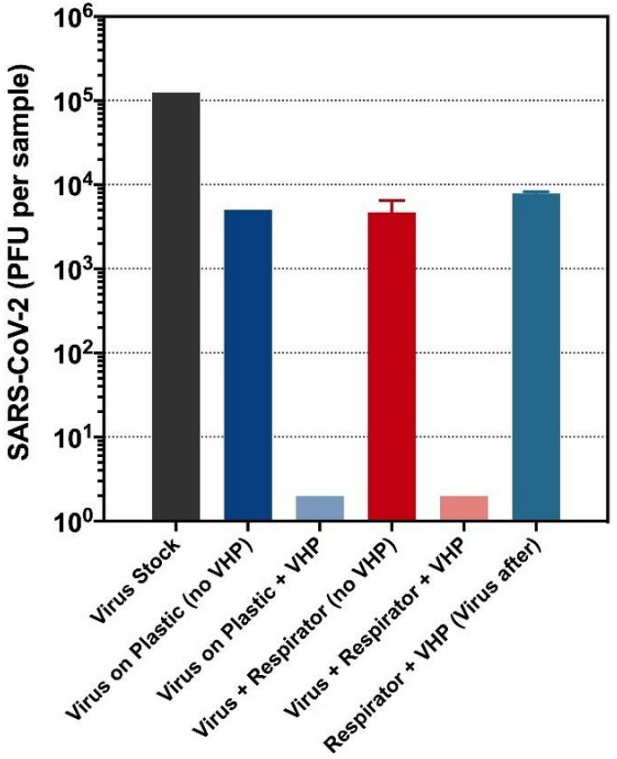
	Number of Cycles Tested	**FE Efficiency**
3M Tested Steris VPro	10	Pass
Battelle	20	Pass
MGB Steris AR1000	1	Pass

VHP - Fit Test and Residuals

- All Steris decontaminated masks have passed the fit test
- No significant residual H_2O_2 was found on masks post decontamination

SARS CoV-2 Bioburden Reduction

- Spiked masks with virus
- Decontaminated with Steris VHP AR1000 at 410± 83 ppm for 3hrs and off-gas for 4.5hrs.
- Virus plaque assay
- 4 log viral reduction (no residual virus detected)



MedRXIV (2020) DOI: 10.1101/2020.04.11.20062026

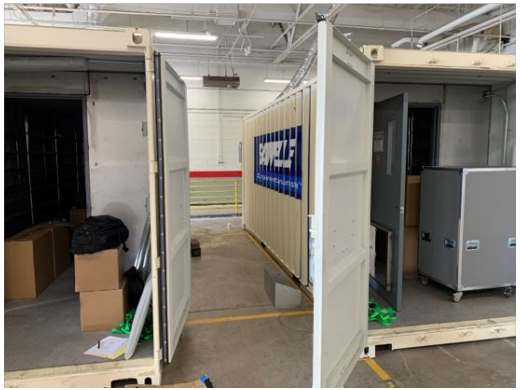
VHP Implementation: Conclusions

- 400-500 ppm VHP for 3 hours
- Mask performance not compromised
  - Filtration efficiency unchanged
  - Fit-test - no change
- Bacterial spore reduction
  - 6-log
- SARS-CoV-2 reduction
  - 4-log

Battelle H_2O_2 Vapor

- 80K masks a day
- Cleared by FDA under an EUA

Label with fine-point Sharpie



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UV-C: Evidence

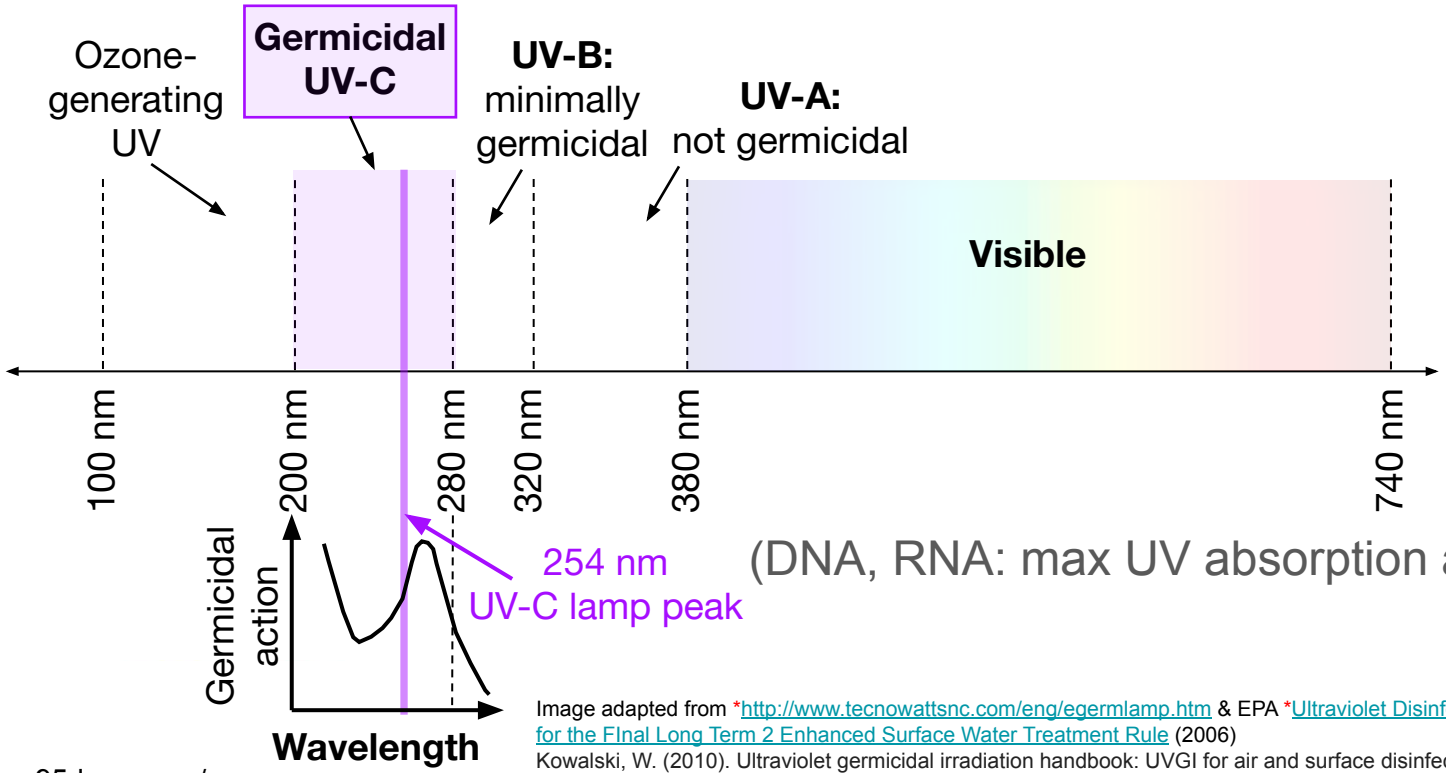
Dr. Samantha M. Grist, PhD
Postdoctoral Fellow, Bioengineering, University of California, Berkeley

Representing the N95DECON UV-C Team:
Alisha Geldert, Anjali Gopal, Alison Su, Dr. Halleh Balch, Ph.D., Prof. Amy E. Herr, Ph.D.

For more information, please see: www.n95decon.org/uvc

UV-C Decon Depends on Wavelength

UV-C irradiation inactivates pathogens by damaging their genomic material.



(DNA, RNA: max UV absorption at 260 nm)

Image adapted from *http://www.tecnowattsnc.com/eng/egermlamp.htm & EPA *Ultraviolet Disinfection Guidance Manual for the FInal Long Term 2 Enhanced Surface Water Treatment Rule (2006)

Kowalski, W. (2010). Ultraviolet germicidal irradiation handbook: UVGI for air and surface disinfection. *Springer science & business media.*

https://www.n95decon.org/uvc

UV-C: Impact on Viral Inactivation

UV-C irradiation dose of ≥1.0 J/cm^2 at 254 nm peak wavelength inactivates viruses similar to SARS-CoV-2 (≥3-log) on the majority of tested N95 facepieces.

- N95 FFR straps require a secondary decontamination method (Mills et al., 2018).
- UV-C transmission through N95 material is dependent on N95 model (Fisher and Shaffer, 2011).
  - ~3-400x lower UV-C at inner filter than at surface → 1.0 J/cm^2 UV-C may not be sufficient for all models.
- **Not all pathogens may be inactivated** with 1.0 J/cm^2 UV-C.

Study	Organism	Material	UV-C dose	Efficacy
Lore et al., 2012	H5N1	N95 FFR (3M 1860, 3M 1870)	1.8 J/cm^2	> 4-log reduction
Heimbuch & Harnish, 2019	Influenza (H1N1, H5N1, H7N9) & coronavirus (MERS-CoV, SARS-CoV)	N95 FFR (3M 1870)	1.0 J/cm^2	No detectable virus (≥ 3.95-log reduction) for all organisms
Mills et al., 2018	H1N1	N95 FFR (15 models)	1.0 J/cm^2	≥ 3-log reduction for 12/15 facepieces and 7/15 straps
*Heimbuch & Harnish, 2019	H1N1	N95 FFR (15 models)	1.0 J/cm^2	≥ 3-log reduction for 11/15 FFR and 4/15 straps

Woo, M. H., et al. (2012). *Appl. Environ. Microbiol.*, *78*(16), 5781-5787.
Lore, M. B., et al. (2012). *Annals of occupational hygiene*, *56*(1), 92-101.
*Heimbuch, B. K., & Harnish, D. (2019). Research to Mitigate a Shortage of Respiratory Protection Devices During Public Health Emergencies.
Fisher, E. M., & Shaffer, R. E. (2011). *Journal of applied microbiology*, *110*(1), 287-295.
Mills, D., et al. (2018). *American journal of infection control*, *46*(7), e49-e55.

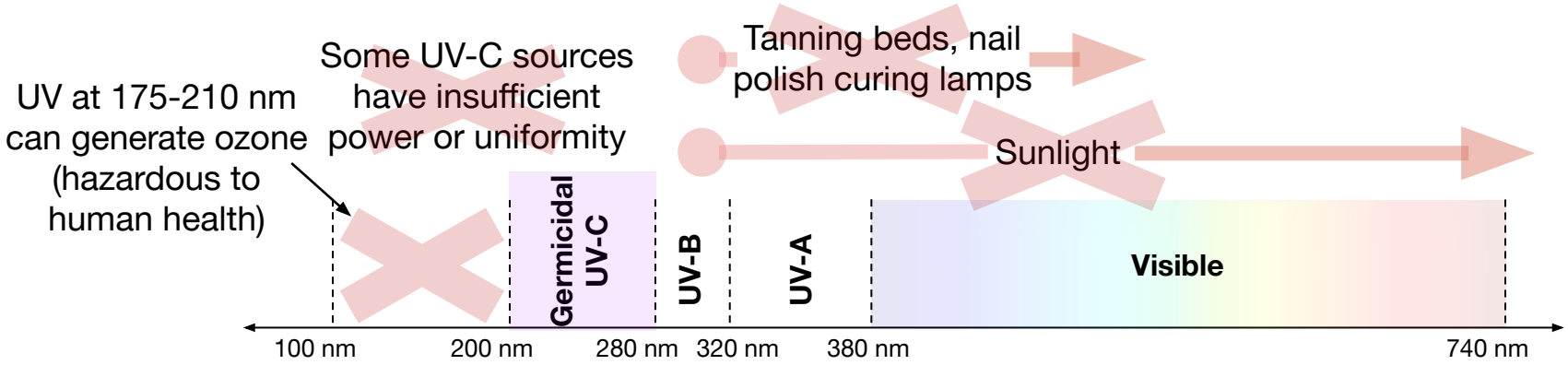
UV-C: Impact on Filtration & Fit

- N95 keeps fit and filter performance after 10-20 cycles of 1.0-1.2 J/cm^2 UV-C (*Heimbuch & Harnish, 2019), and is damaged at much higher UV-C doses (≥ 120 J/cm^2) (Lindsley, 2015).
- Fit degradation due to repeated donning/doffing alone likely the limiting factor for reuse; fit factor below OSHA standard of 100 after 5-15 don/doff cycles (Bergman, 2012).

Author	N95 model	UVGI dose (J/cm^2)	Particle Penetration	Breathing Resistance (mmH$_2$O; max = 25)	Respirator Material Damage (out of 13 layers)	Strap Damage
*Heimbuch & Harnish, 2019	N95 FFRs (15 models)	1.0-1.2	0.18-3.29% (10 cycles) 0.12- 2.74% (20 cycles)	4.53-14.93	No obvious effect from UV-C. Fit degradation from donning/doffing.	No significant difference from UV-C alone. Fit degradation from donning/doffing.
Lindsley et al., 2015	3M 1860	120-950	1-2.5%	10-13	General decrease of strength 120 J/cm^2 dose = 2 layers significantly impacted 950 J/cm^2 = 10 layers significantly impacted	Statistically significant decrease in breaking strength for dosage ≥590 J/cm^2 (≥10% decrease of mean strength)
	3M 9210	120-950	1-2.5%	10-13		
	GE1730	120-950	3-5%	10		
	KC46727	120-950	3-5%	15-20		

*Heimbuch, B. K., & Harnish, D. (2019). Research to Mitigate a Shortage of Respiratory Protection Devices During Public Health Emergencies.
Lindsley, W. G., et al. (2015). *Journal of occupational and environmental hygiene*, *12*(8), 509-517.
Bergman, M. S., et al. (2012). *American journal of infection control*, *40*(4), 375-380.

UV-C: Inappropriate Sources & Precautions



- **<u>Crucial step</u>: For any UV source, validate <u>≥1.0 J/cm^2 UV-C dose</u> reaches <u>all surfaces of all N95s</u> using a calibrated, UV-C-specific sensor.**
- Not all pathogens inactivated at this dose (WILL NOT protect against all bacterial and fungal co-infection risks).
- There is evidence that higher humidity (>60% RH) yields less effective UV-C decontamination (Woo et al., 2012).
- Implementation requires robust industrial hygiene workflow returning each N95 to its original user.

https://www.cdc.gov/nceh/features/uv-radiation-safety/index.html
Lytle, C. D., & Sagripanti, J. L. (2005). *Journal of virology,* 79(22), 14244-14252.
Sagripanti, J. L., & Lytle, C. D. (2007). *Photochemistry and photobiology,* 83(5), 1278-1282.
Woo, et al. (2012). *Applied and Environmental Microbiology,* 78(16), 5781-5787.
Carratalà, A., et al. (2013). *International journal of food microbiology*, *164*(2-3), 128-134.
O'Sullivan, N. A., & Tait, C. P. (2014). *Australasian Journal of Dermatology*, *55*(2), 99-106.
Kowalski, W. (2010). Ultraviolet germicidal irradiation handbook: UVGI for air and surface disinfection. *Springer science & business media.*

Method Summary: UV-C

Implementation Criteria:

≥1 J/cm^2 UV-C on all N95 surfaces
Dose validation with **UV-C specific sensor**

Bioburden Reduction

If all surfaces exposed to ≥1J/cm^2, likely to sufficiently inactivate SARS-CoV-2

Bioburden reduction depends on N95 model

Straps require secondary decontamination

May NOT inactivate all other pathogens → return each N95 to original user

N95 Performance

Filtration and fit preserved for 10-20 cycles at 1J/cm^2 on several N95 models

UV-C causes material degradation at higher doses of ~100 J/cm^2

Other Concerns

UV-C can cause eye and skin damage

Home UV is NOT effective

Sunlight is NOT effective

UV-C lamps can produce ozone

See **n95decon.org/uvc** for a more complete report of the evidence for and cautions of this method

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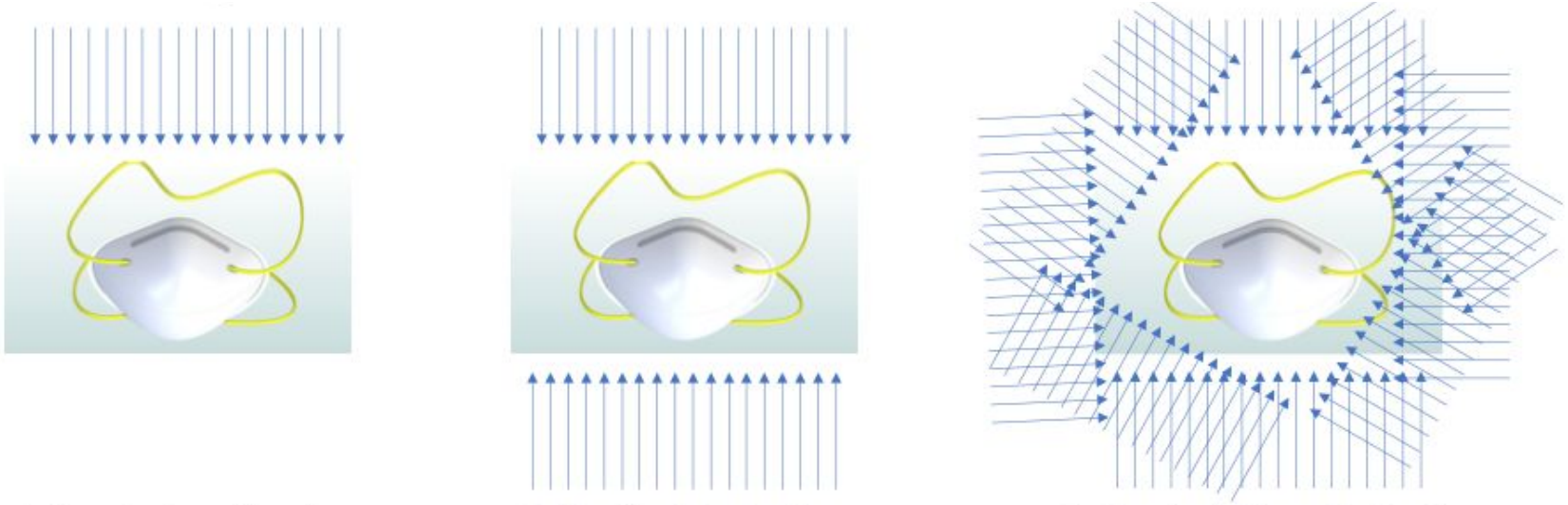
UV-C: Implementation

Dr. Thomas Baer, PhD
Stanford University

Design criteria for UV-C decontamination chambers



1. Illuminate uniformly

2. Illuminate both sides

3. Illuminate from all directions

UV-C Precautions

1. Use only non-ozone producing lamps.
2. Do not expose bare skin or unprotected eyes directly to UV-C light.
3. Minimize breathing chamber air if ozone smell detected when loading/unloading.

UV-C light sources: UVGI vs. LED

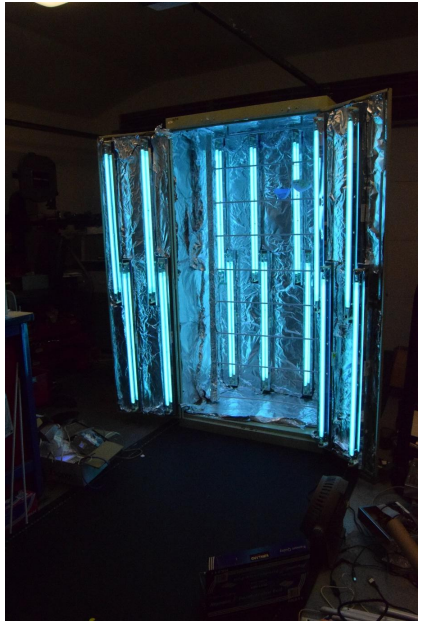
Light Source	Pros	Cons
UVGI (Germicidal Lamps)	• Industry standard formats • High power at 255 nm • Long life • High efficiency	• Power cycling accelerates degradation • Wide area emitter • Limited emitter geometries • Multiple visible and UV outputs • Certain lamps create ozone
LED (Light Emitting Diodes)	• Flexible optical formats • Emission wavelength 270 nm • High brightness • Power cycling	• No industry standard formats • Lower average power than lamps • Variable lifetimes • Power cycling impact not well known

High-throughput UV-C Chamber Design

CAD model and completed UV-C chamber construction

- 16 UV-C , 8 W, 90 cm long germicidal lamps
- Mounted to the back and doors of foil lined metal storage cabinet (72”H x 36” W x 24” D)
- Lamps are spaced 23 cm apart in two banks
- Uniform and isotropic emission was measured consistent with optical models
- 1 J/cm^2 fluence levels reached in under 180 seconds
- Capacity 30 to 50 masks per batch, 5 minutes/batch, 5,000 to 10,000 N95 masks per day

UV-C Decon Cabinet Construction



4/13/2020 4:10 PM

4/14/2020 9:38 AM

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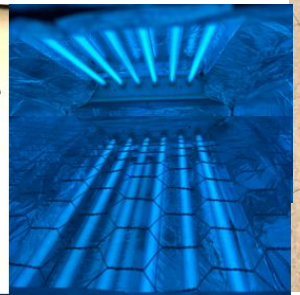
UV-C: Implementation

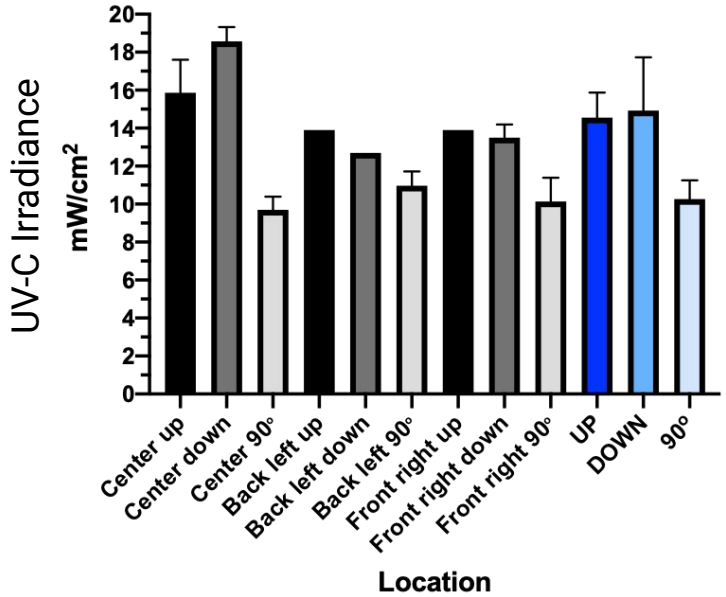
Dr. Martin Purschke, PhD
Wellman Center for Photomedicine
Massachusetts General Hospital

MGH UV-C N95 Decontamination Unit Design

- Enclosed box: 36” (L) x 24” (W) x 20” (H)
- Inside covered with bonded Al foil to reflect UV-C
- 12 standard low-pressure Hg germicidal lamps (254 nm, 30 W). 6 in top and 6 in bottom bank
- Near-uniform spatial irradiance distribution inside the enclosure
- User safety: no UV-C leakage, door interlock, automated timer shut off
- Fast (2 min) and user friendly



Performance of MGH UV-C N95 Decontamination Unit



Lowest irradiance: 8.9 mW/cm^2

8.9 mW/cm^2 x 120 sec = 1.068 J/cm^2

Cycle time: 2 minutes

Mask fit test ✓

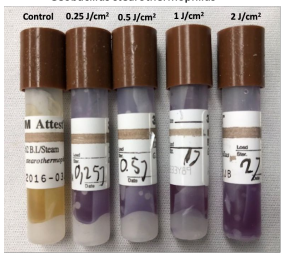
Mask performance test ✓

Bacterial spores test ✓

Geobacillus stearothermophilus

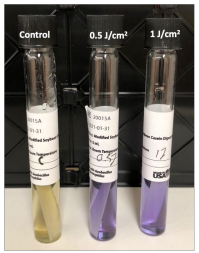
Bacillus pumilus

Geobacillus stearothermophilus



5 log reduction after 48 h

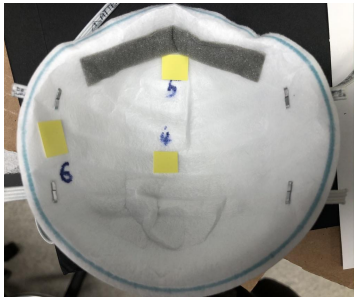
bacillus pumilus

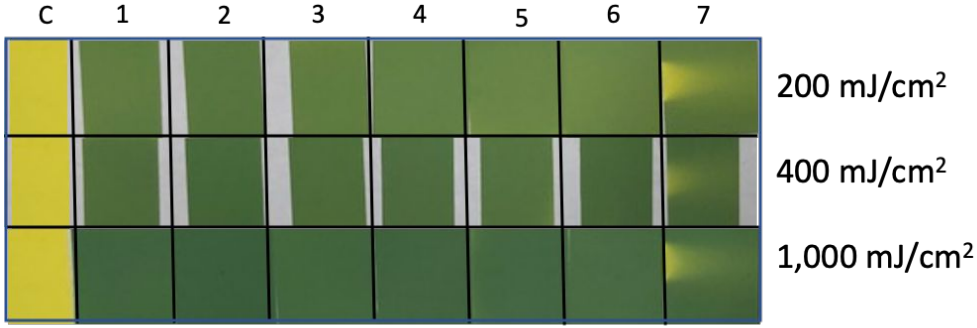


6 log reduction after 7 days

Shadowing of UV-C on the Masks

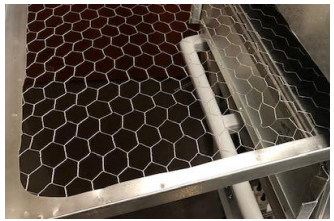
Shadowing on the mask





UV INTENSITY LABELS reach saturation at about 0.5 J/cm^2

Shadowing from the grid



0.1 J/cm^2 0.5 J/cm^2 1 J/cm^2

- Sufficient exposure with 1 J/cm^2 UV-C for the entire mask surface
- Some shadowing under straps (location 7)
- Tray generates some shadowing at low UV-C dose 0.1 J/cm^2

UV-C Implementation in a Hospital Setting

Preparing compatible N95 respirators for decontamination:

1. Write name and/or other identifier using permanent marker (e.g., Sharpie) on the outer surface of the mask
2. Inspect respirators after each use prior to submission for decontamination

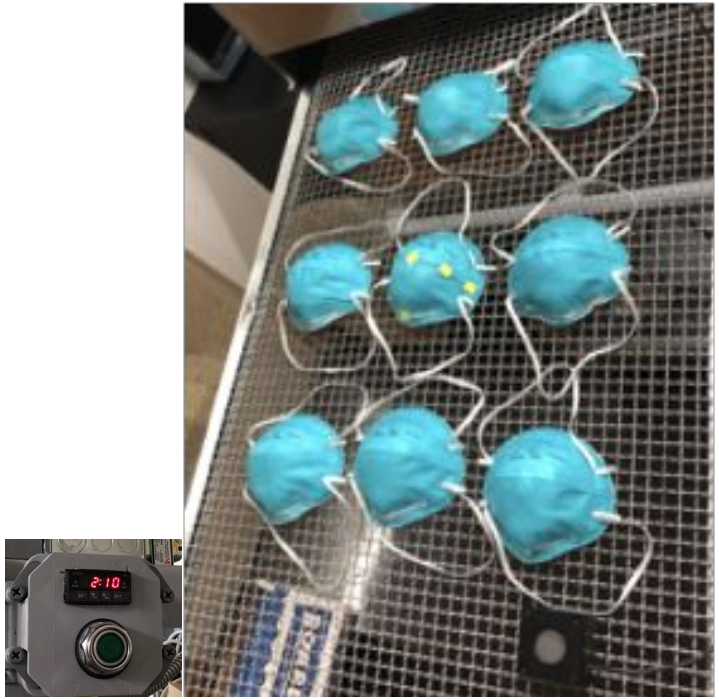
   (Discard the N95 respirator mask, if soiled, damaged or 5 x decontaminated)
3. Place ONE used N95 respirators in a paper bag or other container

https://www.nebraskamed.com/sites/default/files/documents/covid-19/n-95-decon-process.pdf

UV-C Implementation in a Hospital Setting

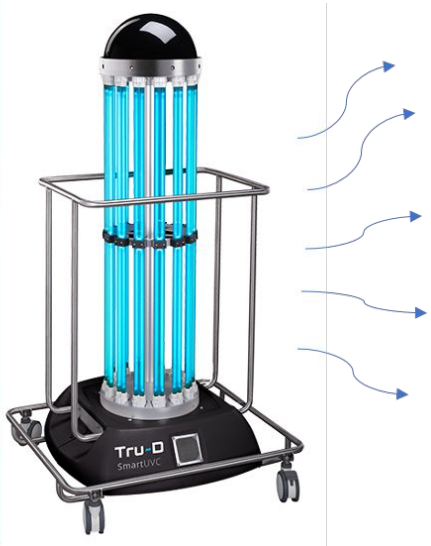
Use of UVC Decontamination Unit:

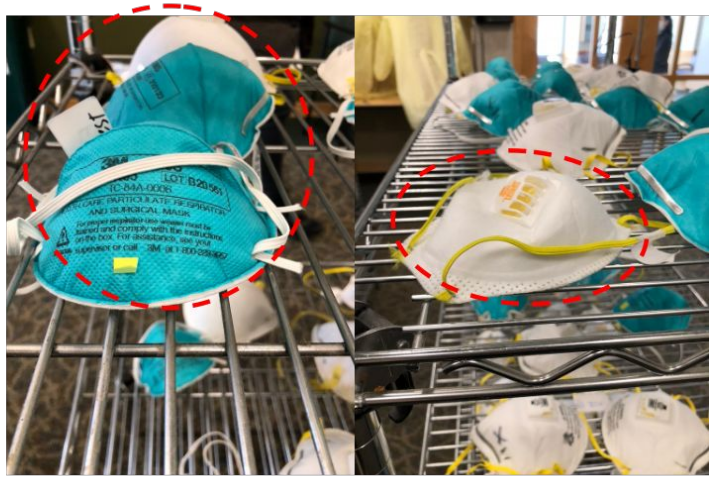
1. Wear **eye** and **skin** protection (goggles, gloves)
2. Open unit and place masks on tray. **Avoid** shadowing (straps, labels on mask)
3. Remove gloves, close unit and start decontamination cycle for 2 min
4. After unit turns off automatically, re-glove and and pull out tray
5. Remove mask, mark it as decontaminated and place it in new “user labeled” paper bag or other container for pick up



https://www.nebraskamed.com/sites/default/files/documents/covid-19/n-95-decon-process.pdf

Importance of Proper Use of UV-C Implementation





These UVC lamps are designed for room disinfection

There are re-purposed for single sided irradiation of N95 masks

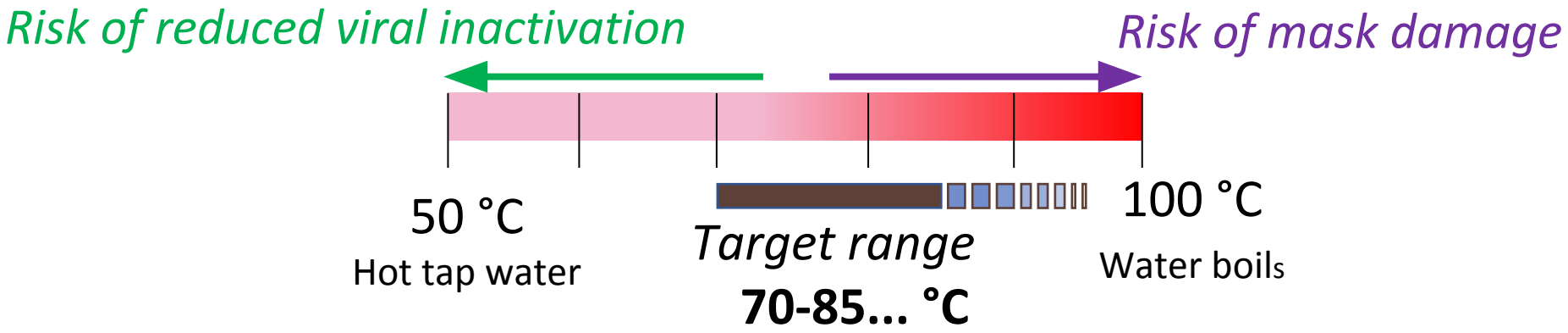
Improper use causes shadowing and can lead to insufficient decontamination

Heat: Evidence

Dr. John Doyle, PhD
Henry B. Silsbee Professor of Physics
Harvard University

Heat - Introduction to method

Heat + Time + Humidity = Viral Inactivation



Possible Target Relative Humidity 50-85%

Humidity effects: Casanova et. al. doi:10.1128/AEM.02291-09, McDevitt e. Al. doi:10.1128/AEM.02674-09

https://www.n95decon.org/heat

Heat - Impact on viral inactivation

- Evidence for heat inactivation of SARS-CoV-2 on N95 FFRs
  - *70°C, dry, 60 min >3.3 log reduction *in lab conditions*[1]
  - *121°C, autoclave, 15 min sterilization[2]

- Inactivation may depend on viral environment (e.g. mucus, saliva)
  - DO NOT USE 60°C for 30 min as target for N95 FFR decontamination
  - 70°C, dry, 60 min may not be sufficient in clinical setting

- Humidity may improve SARS-CoV-2 inactivation, based on other viruses[4,5,6] *

*70-85 °C will not inactivate all possible bacteria and spores

(1) Fischer, R. J. et al. doi: 10.1101/2020.04.11.20062018 (pp)*
(2) Kumar, A. et al. doi: 10.1101/2020.04.05.20049346*
(3) Heimbuch, B. K. et al. doi:10.1016/j.ajic.2010.07.004.
(4) McDevitt, J. et al. doi: 10.1128/AEM.02674-09
(5) Lore, M. B. et al., doi: 10.1093/annhyg/mer054
(6) Wiggington, K. R. et al. doi: https://doi.org/10.1101/2020.04.28.20084038*

Heat - Impact on filtration & fit

- 85 °C & 80% RH - 1860, 8210+,1870 all pass quantitative fit&filtration, 5 cycles
- 121 °C autoclave - 1870 passes quantitative fit tests, 5 cycles. 1860 fails (molded)

	Fit	Filtration
60 °C & 80% RH (three 30-minute cycles)		
○ 3M [1860, 1870, 8000, 8210], Moldex 2200, KC PFR95-270 passed fit and filtrations tests (1)	✓	✓
100 °C dry heat (one 60-minute cycle)		
○ 3M [1860, 1870, 8000, 8210], Moldex 2200 passed filtration tests (2)		✓
○ KC PFR95-270 failed filtration tests at 100 °C but passed 90 °C (2)		✗
85 °C & 80% RH (FIVE 30-minute cycles)		
■ 3M 1860, 3M 1870, 3M 8210+ passed fit and filtration tests (3)	✓	✓
75 °C & 100% RH or 100 °C & <30% RH (20 30-minute cycles)		
○ No impact to filtration efficiency of meltblown fabric used as filtration material in N95s (4)		✓
Autoclave treatment (121 °C, steam, 15 minutes)		
○ 3M 1870, 3M1804S, Aearo 1054s (layered models) passed quantitative fit tests, ten cycles (5)	✓	
○ 3M 1860 (molded) failed fit tests after its second 15-minute cycle (5)	✗	

(1) Bergman et al., doi: 10.1177/155892501000500405
(2) Viscusi et al., doi: 10.1093/annhyg/mep070
(3) Anderegg et al., doi: 10.1101/2020.04.09.20059758*
(4) Liao et al., doi: 10.1101/2020.04.01.20050443*
(5) Kumar et al., doi: 10.1101/2020.04.05.20049346*

Durability under heat-humidity treatment **may depend on N95 model**. Now only a **few studies on autoclave treatment and oven-based heat treatment with both high temperature and high RH**, which are the most likely parameters for sufficient SARS-CoV-2 inactivation.

Method Summary: Heat

Implementation Criteria

Temperature Range **70-85°C**
Possible Humidity Range **50-80% RH**
Target Duration Range **>1hr**
Other temperatures/humidities being studied

Bioburden Reduction

Promising conditions for SARS-CoV-2 inactivation on N95 FFR are likely to be 70-85°C, humidity >50%, for >60 minutes, *but data is limited*

May NOT inactivate all other pathogens

N95 Performance

Many common masks retain fit and filtration after 5 cycles at 85°C and 80% humidity, 30 minutes

Other

Approach: N95 put inside container; container into oven; can add water for moisture; target 5 cycles max

Calibrate and monitor heat and humidity, no direct exposure to heating element

Not yet validated in an FDA-approved process

n95decon.org/heat *updated regularly,* active research, new results coming

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Heat: Cautions for Implementation

Cole Meisenhelder, PhD Student
Harvard University

Heat - Autoclave Cautions

- Effectiveness is extremely model dependent:
  - Pleated N95 models (3M 1870) pass quantitative fit test for 5 treatments
  - Molded N95 models (3M 1860) fail fit tests
- Few studies include filtration efficiency, ongoing research

3M 1870 Pleated N95

3M 1860 Molded N95

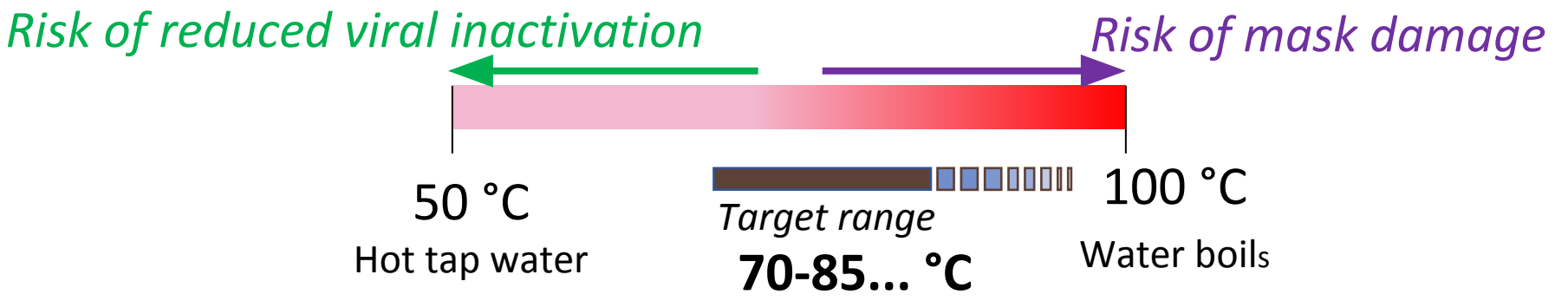
Heat - Microwave Generated Steam (MGS) Cautions

- No data for MGS inactivation of coronaviruses
- 2 minutes shown to inactivate other viruses (1,2)
- Limited testing for multiple cycles
    - Tested models withstand at least **1 cycle**
    - Some models passed fit and filtration for **3 cycles**
    - Filtration may degrade after **5 cycles** (3)
- Metal components may present **sparking hazard**

(1) Heimbuch et al. doi: 10.1016/j.ajic.2010.07.004
(2) Zulauf et al.*, doi: 10.1101/2020.04.22.20076117
(3) Liao et al.*, doi: 10.1101/2020.04.01.20050443

Heat - Humid/Dry Heat Cautions

- Careful temperature and humidity control is critical
- **Not Sterilization** - Prevent cross contamination and use indexed return to user methods
- N95 metal nose pieces may require secondary decontamination at lower temperatures



Possible Target Relative humidity 50-85%

(1) Fischer et al.*, doi: 10.1101/2020.04.11.20062018

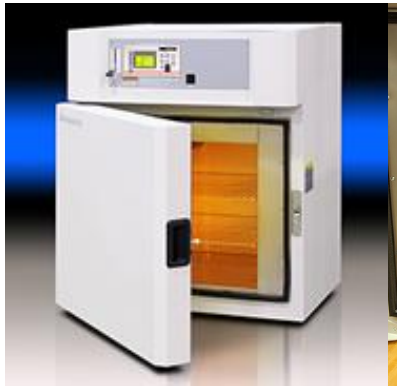
Heat - schematic of implementation

User

+

N95 in Container

Wet paper Towel for Humidity



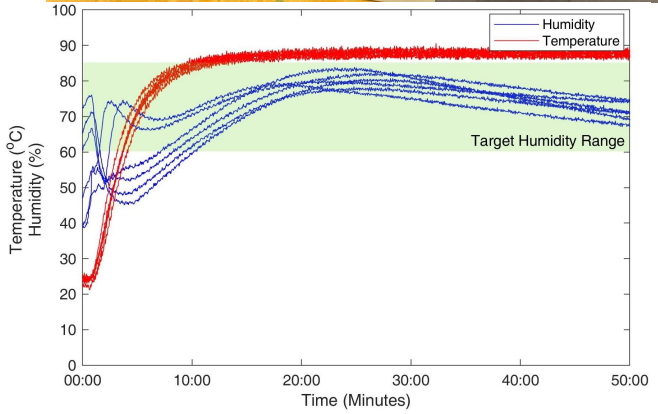
Oven

Humidity effects: Casanova et. al. doi:10.1128/AEM.02291-09, McDevitt e. Al. doi:10.1128/AEM.02674-09

https://www.n95decon.org/heat

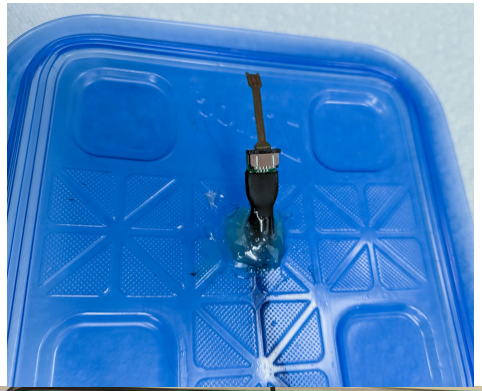
Heat - Prototype Implementation

- Targeting 85°C & 60-80% RH
- Forced air convection oven, no direct line of sight to heating elements
- Ziploc containers prevent cross contamination, allow humidity control
- Paper towel calibrated volume of water produces good humidity control
- 5 minutes of drying sufficient
- 3.7 cubic foot oven could process >1000 N95s per day



Heat - Verification and Validation of Setup

- Must verify critical parameters:
  - Target temperature
  - Target humidity
  - Time at target temperature and humidity
- Use electronic sensors capable of operating in 70-85°C up to 100% RH
- Do not rely on oven thermostat
- Validate for multiple locations
- Determine warm up time



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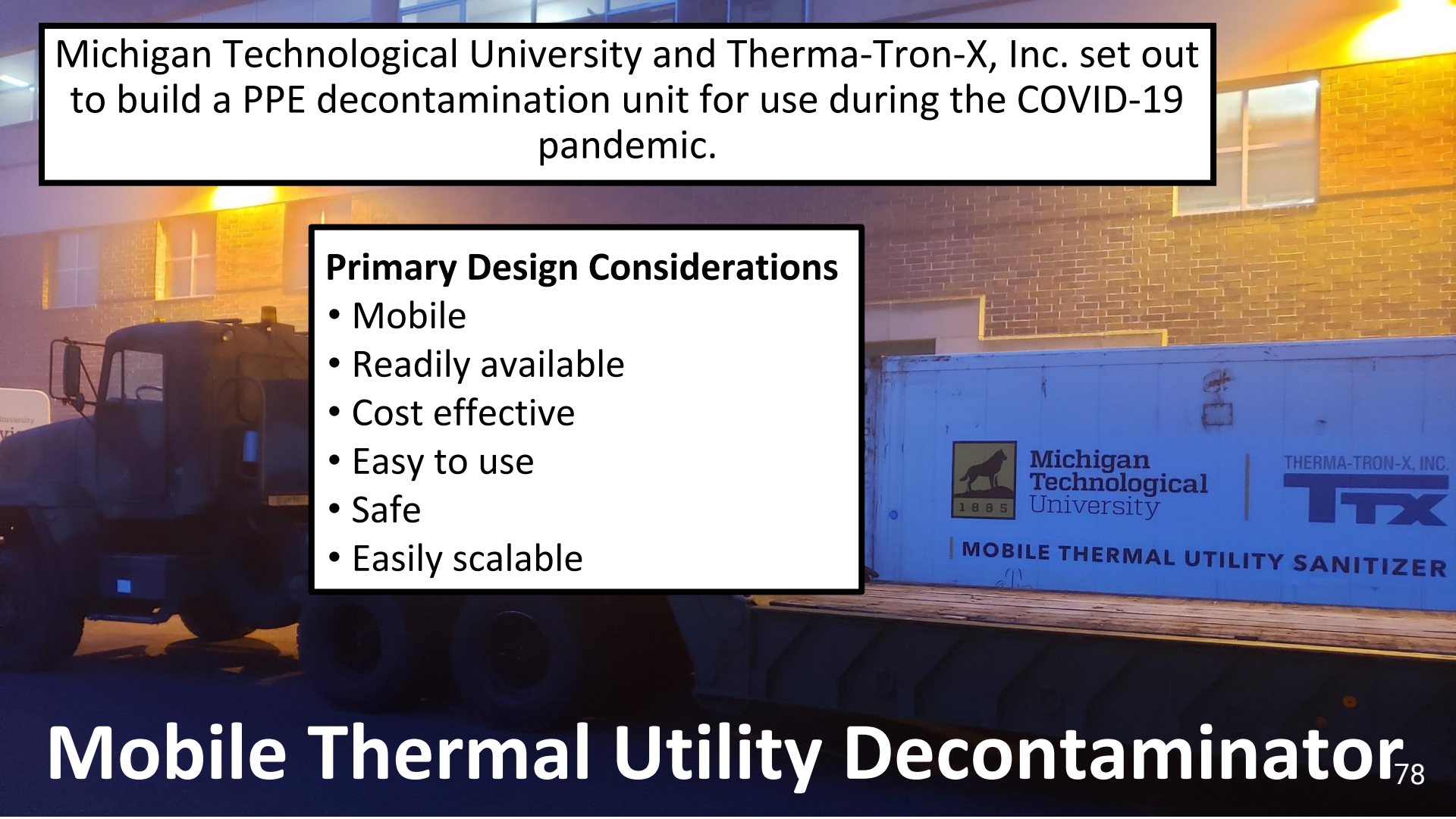
Heat: Implementation

Andrew Barnard, Associate Professor, Mechanical Engineering
Director of the Great Lakes Research Center
Michigan Technological University

Michigan Technological University and Therma-Tron-X, Inc. set out to build a PPE decontamination unit for use during the COVID-19 pandemic.

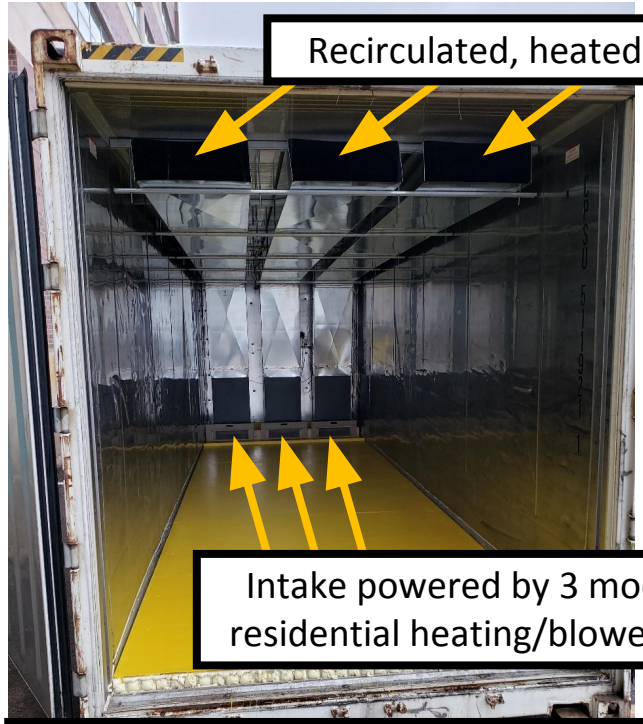
Primary Design Considerations

- Mobile
- Readily available
- Cost effective
- Easy to use
- Safe
- Easily scalable



Mobile Thermal Utility Decontaminator

First generation prototype



Recirculated, heated exhaust

Intake powered by 3 modified residential heating/blower units

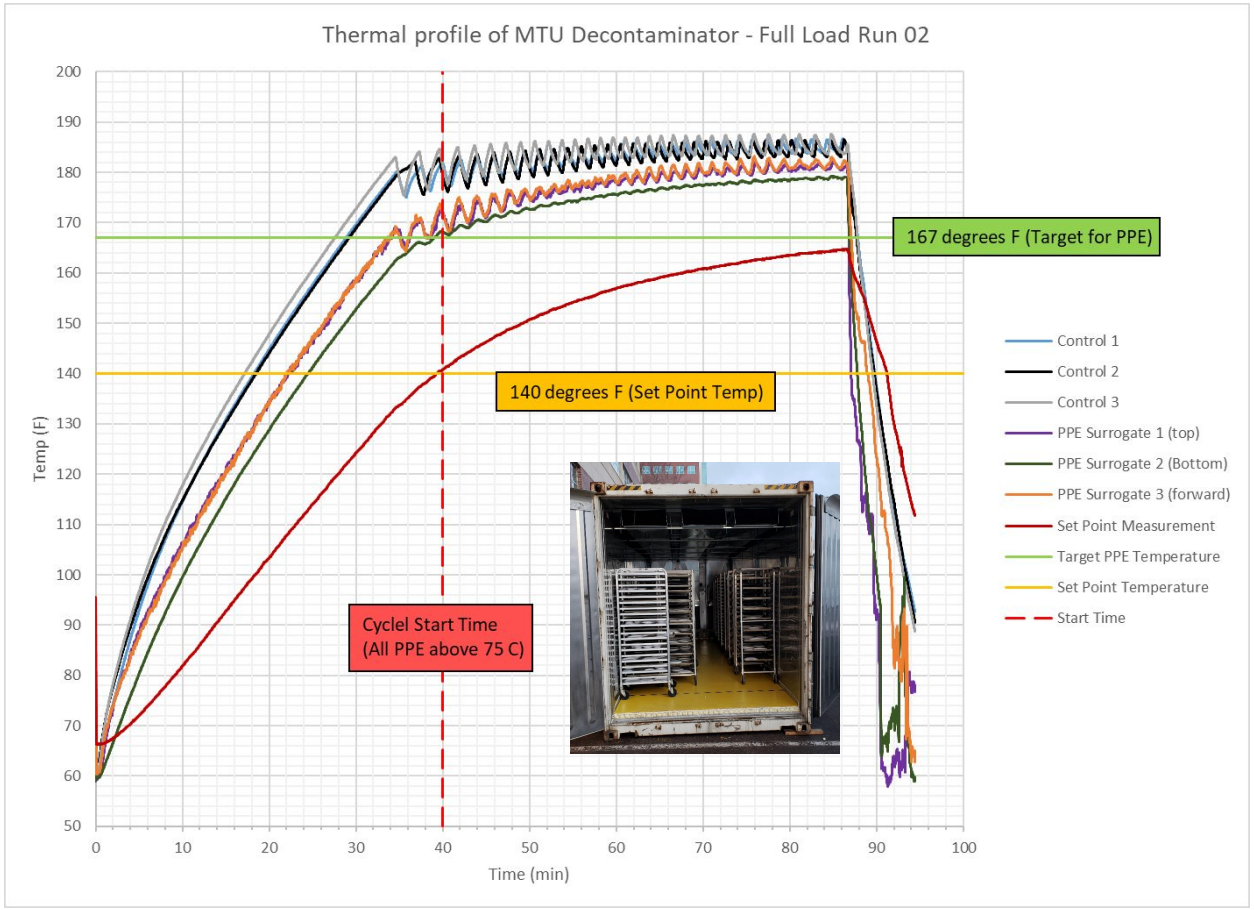
Temperature controllable
(temperature and time can be decreased/increased; adaptable for use with humidification)

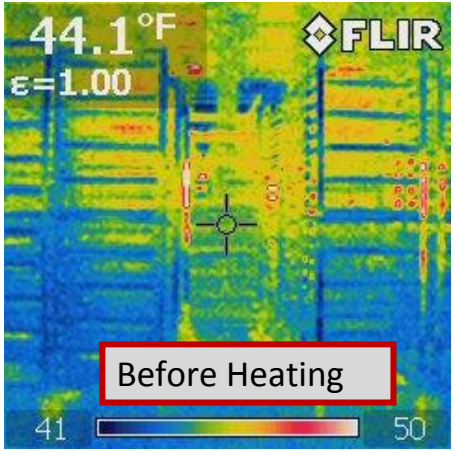
Controlled with residential thermostats

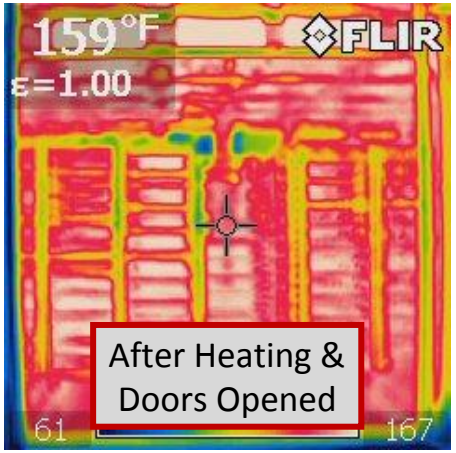
PPE rolled in on portable rack

Portable 40 foot insulated container can hold 5000 N95s per run

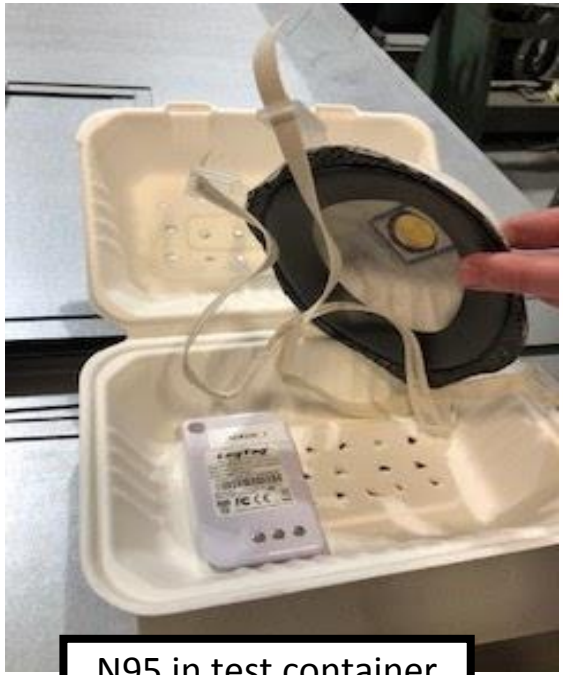
First version: programmable heat



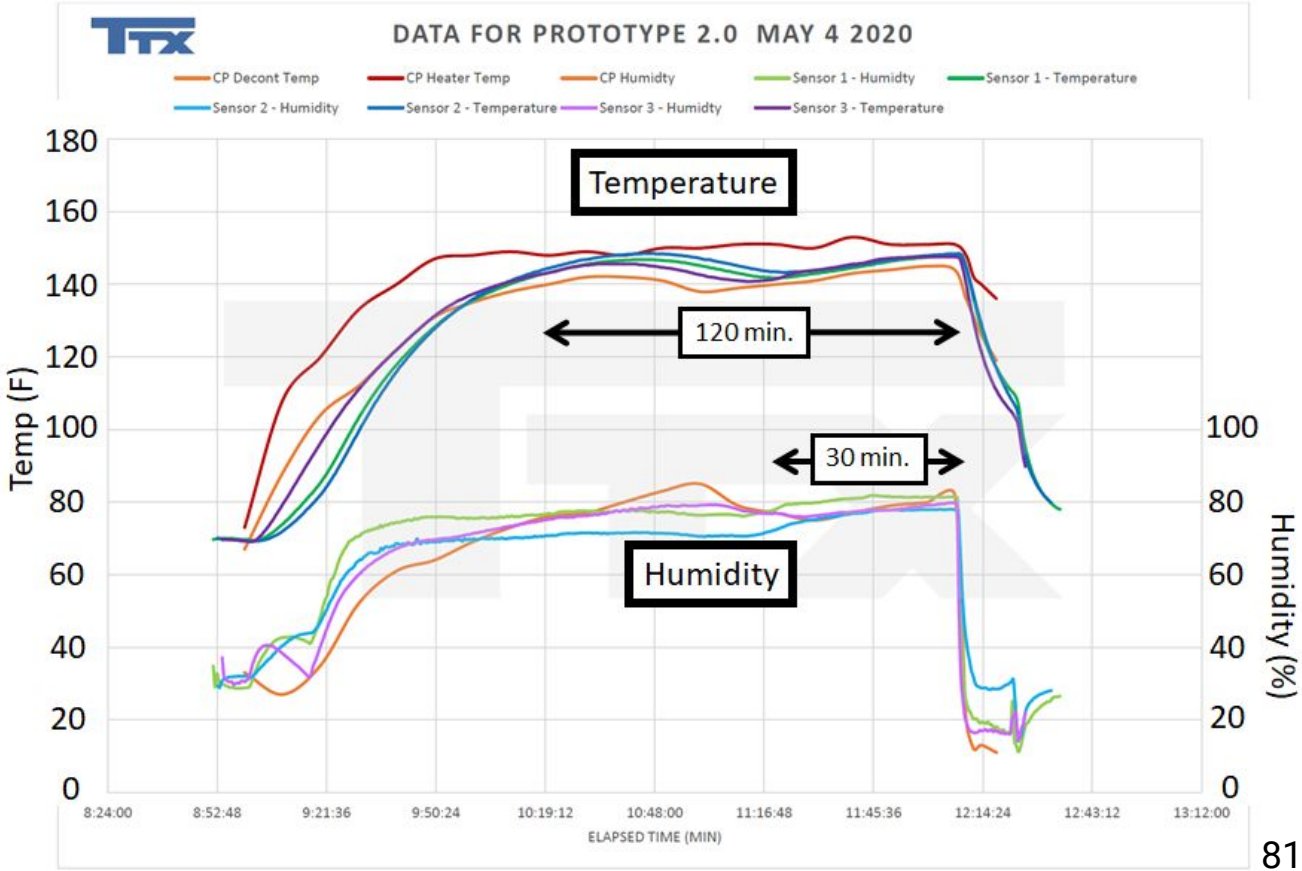




Second version: programmable heat + humidity



N95 in test container with data logger



Protocol is vital to avoid cross contamination

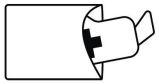
PROTOCOL FOR COLLECTION OF USED PPE

STEP 1: INSPECT PPE

Inpect PPE for holes, tears, obvious damage, or visible soil (including makeup, blood) and discard PPE so affected to remove from circulation. See **Decon or Dispose Instruction Card** for more detailed intructions.

STEP 2: LABEL PPE

Employees will need to self-label PPE with employee name, hospital area and number of decontamination cycles using a permanent marker.



STEP 3: PLACE PPE IN BAG

Place PPE in an FDA-approved sterilization pouch (see FDA 510K database product code FRG for compatible options) that can withstand up to 80 °C temperatures. In the event of a shortage of FDA approved sterilization pouches or rolls, and during emergency use only, paper bags could be substituted as a contingency plan.

STEP 4: LABEL BAG

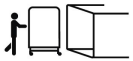
Label bags on the outside employee's name and hospital areae. Placing PPE in a bag prevents cross contamination on the racks.

STEP 5: PLACE BAG ON RACK

Place bag on a baking tray on the rack, which has lips around the edges to prevent PPE from falling off in transit.

STEP 6: COVER WHEELED RACKS

Wheeled rack should have a biohazard label and be covered with either a reusable or disposable clear, form-fit plastic cover to prevent cross-contamination as racks move throughout the hospital. Each wheeled rack can hold up to 170 units of PPE.



STEP 7: TRANSPORT WHEELED RACKS

Hospital collection staff delivers biohazard wheeled racks to the Mobile Thermal Utility Decontaminator (MTUD) unit at the hospital's loading dock or in the parking lot.

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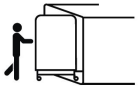
PROTOCOL FOR HEAT TREATING PPE IN THE MOBILE THERMAL UTILITY DECONTAMINATOR (PAGE 1)



STEP 1: PUSH RACKS INTO MTUD

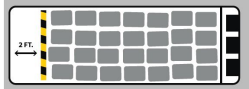
Hospital staff will serve as an operator and fill MTUD with wheeled racks. A maximum of 28 racks can fit in the MTUD holding a total of about 5000 units of PPE.

STEP 2: REMOVE RACK COVERS

Plastic covers on wheeled racks are removed after the racks are placed into the MTUD. This allows heated air to flow freely over the bagged PPE.

STEP 3: SORT RACK COVERS

Reusable rack covers will be cleaned between uses with an FDA-approved disinfectant method prior to reuse. Disposable rack covers will be treated as biohazard and disposed of properly by hospital staff.



STEP 4: ENSURE RACKS ARE WITHIN ALLOWED AREA

Racks should be placed within the marked floor area of the MTUD. Areas where racks should not be located are beyond the bump barrier on the furnace end of the chamber, and within 2' of the doors (as marked by yellow and black stripes on the floor). This ensures that PPE are not placed in abnormally cool or high flow velocity sections of the chamber.

STEP 5: CHECK AND PREVENT METAL CONTACT WITH PPE

During MTUD loading, ensure that all PPE is not touching metal racks, and is separated by the sterilization pouches. This ensures that electro-statically charged PPE (ESD) are not touching hot metal.

Michigan Technological University

PROTOCOL FOR HEAT TREATING PPE IN THE MOBILE THERMAL UTILITY DECONTAMINATOR (PAGE 2)

STEP 6: SEAL CHAMBER

Doors are closed and sealed with locking latches so the heat chamber is sealed.

STEP 7: TURN ON HEATING UNITS

Turn on 3 heat switches to start the tempurature cycle.

STEP 8: DISINFECT DOORS AND HANDLES

As the chamber is heating, wipe the outer doors and door handles of the MTUD with disinfectant to kill any virus on the doors and avoid recontamination of PPE upon opening the doors.

STEP 9: START CYCLE TIMER

When set point temperature is reached, the set point indicator light illuminates. Begin a timed heat soak cycle for 30 minutes. Temperature is maintained through automatic thermostats. The current MTUD prototype does not have a control for automatic timers. Use an external device like a watch or mobile device to track the cycle time.

STEP 10: TURN OFF HEATING UNITS

When the heat soak cycle is complete according to your time tracking, manually disable the heating units, using the three heat switches, and open the doors. The fans will remain on and rapidly expel the heated air from the chamber.

STEP 11: OPEN CHAMBER AND WHEEL RACKS OUT

After 30 seconds, the operator can safely enter the chamber with gloves to retrieve the wheeled racks. Wheeled racks will be hot, but will cool quickly (less than 5 minutes).

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PROTOCOL FOR HEAT TREATING PPE IN THE MOBILE THERMAL UTILITY DECONTAMINATOR (PAGE 3)

STEP 12: REPLACE BIOHAZARD LABELS ON CARTS

Replace the biohazard labels on the racks with a label that reads: **Decontaminated by heat treatment for SARS-CoV-2 - FOR USE ONLY BY ORIGINAL USER**

STEP 13: COVER RACKS

Place disinfected resuable, or new disposable, rack covers on the racks to avoid cross-contamination as racks are wheeled through the hospital.

STEP 14: WHEEL RACKS TO ORIGIN AREA

Staff wheel the covered racks to the appropriate area from where they came, based on the origin label.

STEP 15: DISTRIBUTE DECONTAMINATED PPE

In the origin area, place racks of decontaminated PPE away from the drop-off area, and hospital staff can collect their own marked PPE. In the event of a choke point in retrieving PPE, individual trays on the racks could be delivered to specific points in the hospital, such as a single nurses' station.

STEP 16: DISINFECT RACKS AND TRAYS

After all decontaminated PPE are dispersed to staff, disinfect racks and trays with FDA-approved disinfection methods prior to next use.

Michigan Technological University

In process with FDA Emergency Use Authorization

Heat - Implementation Conclusions

Humid/Dry Heat

Need careful control of **heat** and **humidity**

Achievable with ovens

Easily scalable

Not Sterilization

Autoclave

Molded N95s failed

Research ongoing for pleated models

Microwave Steam

No inactivation data with coronaviruses yet

Filtration after 3 cycles needs further study

Concluding Remarks

BACKGROUND

- What is an N95?
- Do's and Don'ts
- Principles for N95 Decontamination

METHODS

- UV-C
- Humid/Dry Heat
- Hydrogen Peroxide Vapor

CONSIDERATIONS

- Filtration Efficiency
- Fit Test
- Bioburden Reduction

Disclaimers: Data and experience pertains to NIOSH-certified N95 respirators only
(NIOSH: The U.S. National Institute for Occupational Safety and Health).
There may be variation between different mask manufacturers and models

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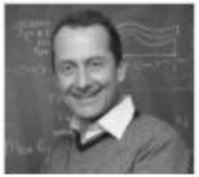
Q&A

Please fill out post-webinar survey! We want your feedback!
https://tinyurl.com/y83grrxc

Our Panelists

Hydrogen Peroxide

Dr. Jill R. Crittenden, PhD



Dr. Orhun K. Muratoglu, PhD

UV-C

Dr. Samantha Grist, PhD

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Heat

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Dr. John Doyle, PhD

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N95DECON

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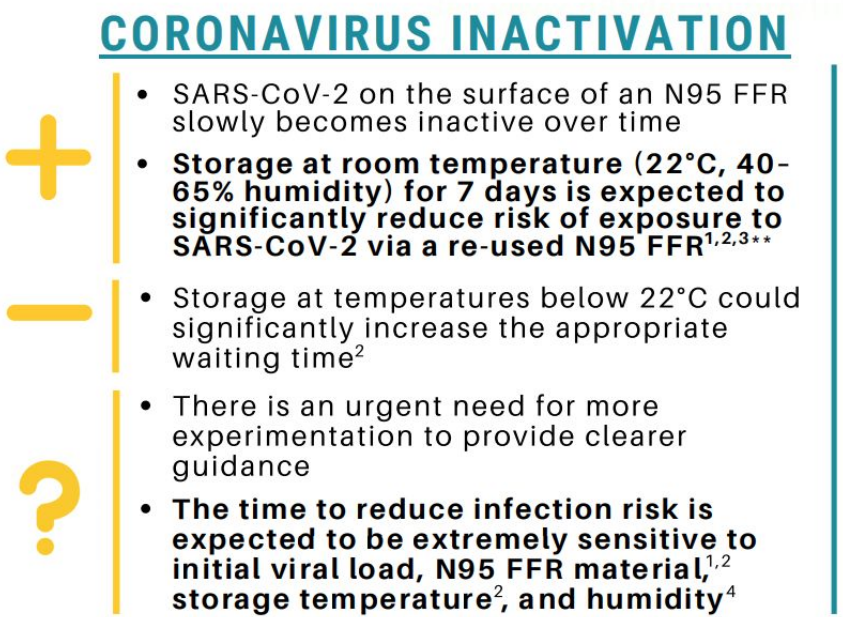
Email: n95decon@gmail.com
@N95Decon

Other Resources & Initiatives

- CDC Guidance on extended use and limited reuse of N95 FFR
  https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html
- CDC Guidance on N95 FFR Decontamination
  https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.htm
- Greater Boston Pandemic Fabrication Team: https://www.panfab.org/
- Recorded ACOEM Webinars on COVID-19 https://acoem.org/Learning/Webinars

SARS-CoV-2 Inactivation on N95 at Room Temperature



Takeaways:

- Insufficient data, **only use if there is no other choice** for decontamination
- Room temperature storage in a clean, breathable container for 7 days may adequately inactivate SARS-CoV-2 on an N95
- Overnight storage is NOT sufficient
- Does NOT protect against bacteria or mold
- Return N95 to original user

[1] Van Doremalen, et al 2020; [2] Chin, et al 2020; [3*] Fischer, et al 2020; [4] Lin & Marr 2020

https://www.n95decon.org/time