"Expert Perspectives on UV as a Tool for N95 Decontamination"

Goal:

- *To promote open dialogue on the use of UV disinfection technologies in combating the COVID-19 Pandemic*

Objective:

Focusing on Decontaminating N95 Respirators with UV

- *Provide an overview of the FDA & CDC regulatory guidance, medical & scientific basis and issues*
- *To obtain input for a response to FDA and CDC expressing issues and constructive comments*

"Expert Perspectives on UV as a Tool for N95 Decontamination"

- **Introduction**
  Troy Cowan, IUVA HAI Group Leader
- **Thoughts on FDA & CDC N95 Disinfection Guidelines**
  Ernest R. Blatchley III, Ph.D, Purdue University
- **COVID-19/SARS-CoV-2 basics**
  John M. Boyce, MD, Yale University School of Medicine (ret.)
- **Basics of N95 Masks**
  Barry Hunt, Prescientx
- **Overview of ECRI efficacy testing guidelines**
  Mairead Smith, ECRI Institute
- **Panel Discussion**
  - *Sam Guzman, American Ultraviolet*
  - *Rich Simons, Ph.D, AquiSense Technology*
  - *Richard Martinello, MD, Yale Univ. School of Medicine*
  - *Matthew Hardwick, Ph.D, ResInnova Laboratories*
  - *James Malley, Ph.D, Univ. of New Hampshire*
- *Q&A's!*

INTERNATIONAL IUVA ULTRAVIOLET ASSOCIATION

"Expert Perspectives on UV as a Tool for N95 Decontamination"

Summary of Federal Guidelines

Ernest R. Blatchley III, Ph.D., P.E., BCEE, F. ASCE
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Definitions and Terminology

- From CDC: *Introduction, Methods, Definition of Terms: Guideline for Disinfection and Sterilization in Healthcare Facilities* (2008)
  - "***Disinfection*** describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects"
  - "***Decontamination*** removes pathogenic microorganisms from objects so they are safe to handle, use, or discard."
- Focus is on UVC (germicidal) radiation: $200\ nm \leq \lambda \leq 280\ nm$
- Dose Units: $1\ \frac{J}{cm^2} \equiv 1000\ \frac{mJ}{cm^2}$
- Irradiance/Fluence Rate Units: $1\ \frac{W}{cm^2} \equiv 1000\ \frac{mW}{cm^2}$

Definition Text From: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/introduction.html

FDA Guidance: *Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised): Guidance for Industry and Food and Drug Administration Staff*

- Guidance issued without public comment to facilitate immediate implementation (subject to public comment)
- Guidance provided to expand access to PPE (including N95)
- Alternative approaches allowed, if they satisfy requirements
- Disinfection/Decontamination used interchangeably

Document Download: https://www.fda.gov/media/136449/download

Process Description

- Critical process parameters
  - UVC dose
  - Relative humidity
- Chemical Indicators (CI) and Biological Indicators (BI) should be applied as a worst-case challenge

- Viricidal activity $\geq 3 \log_{10}$
  - SARS
  - MERS
  - TGEV
- Mycobacterial activity $\geq 6 \log_{10}$
- Sporicidal activity $\geq 6 \log_{10}$
- Material compatibility
- Filter performance

INTERNATIONAL IUVA ULTRAVIOLET ASSOCIATION

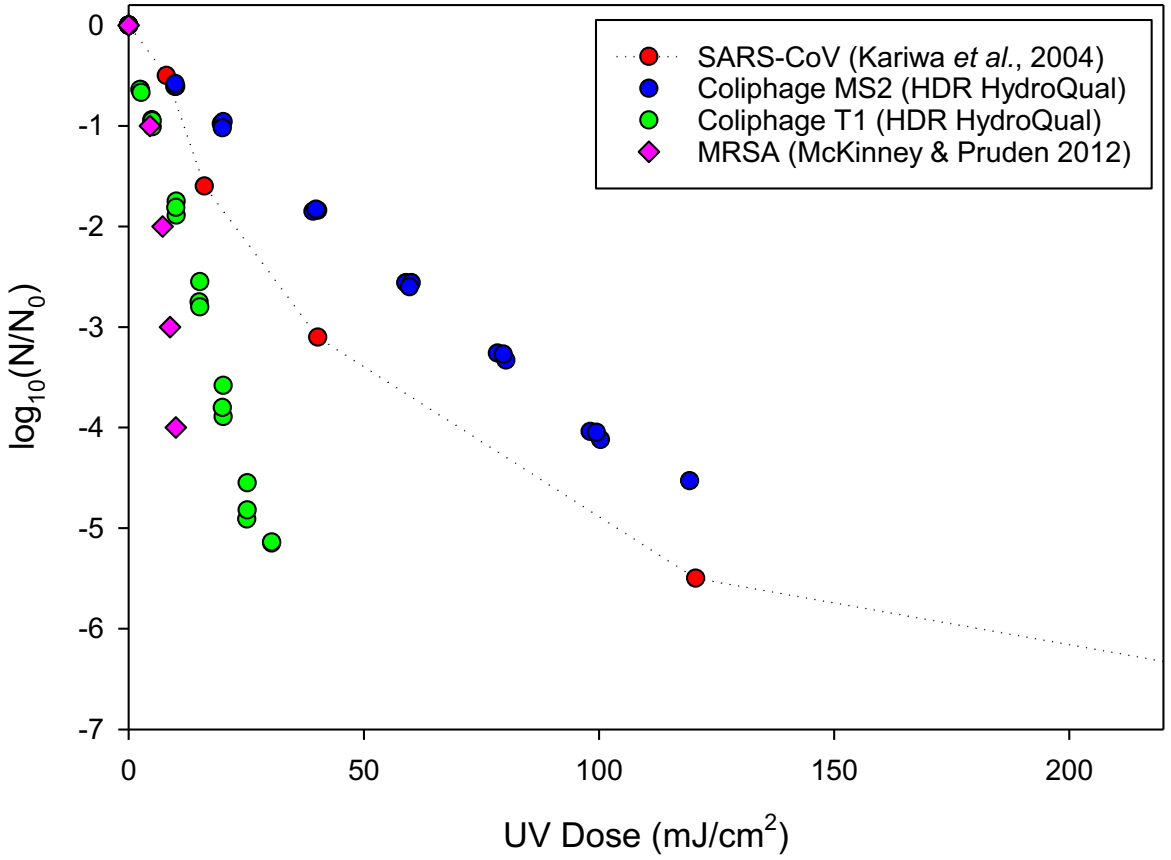
CDC Guidance: *Decontamination and Reuse of Filtering Facepiece Respirators*

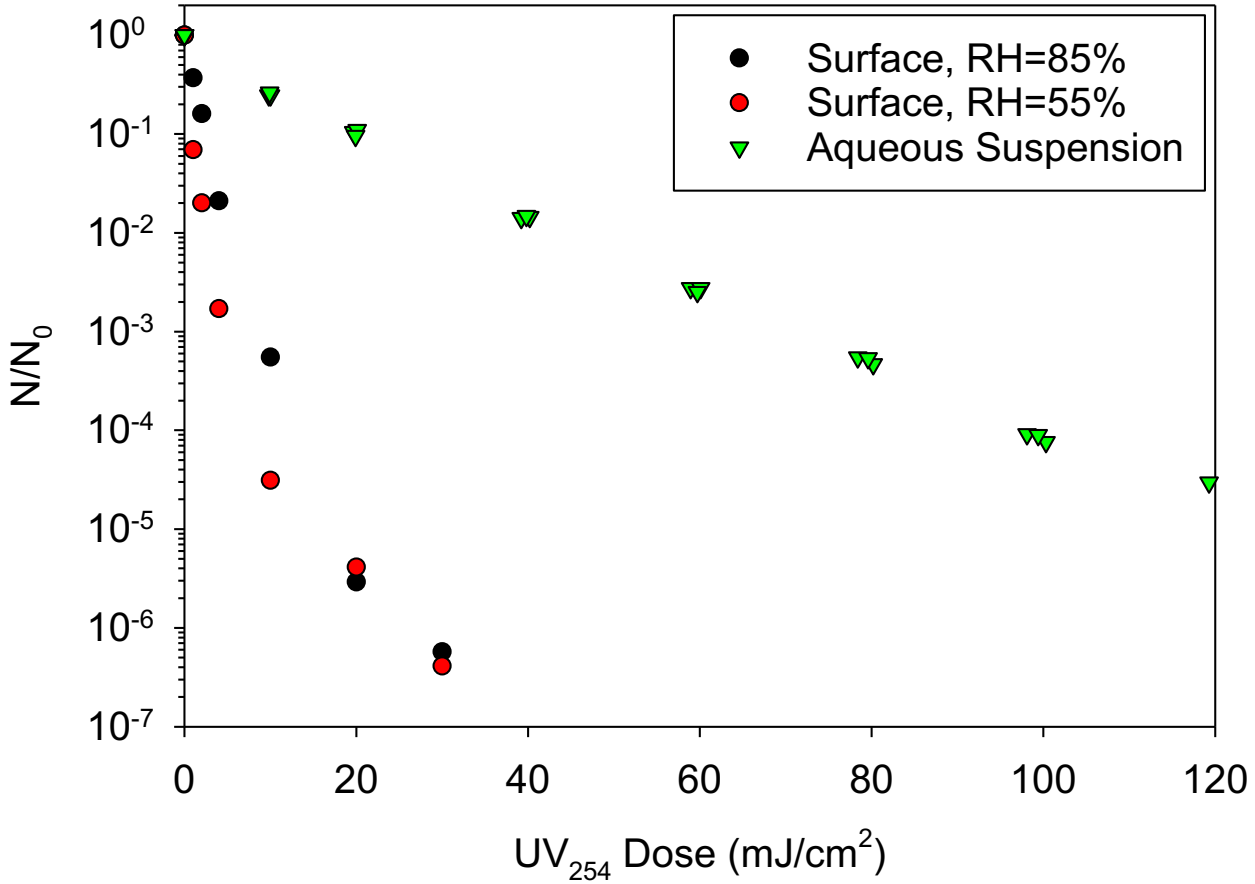
- "Decontamination" used to describe process
- Decontamination should:
  - Reduce pathogen burden
  - Maintain FFR function
  - No residual chemical hazard

- Literature findings
  - Filter performance retained after repeated exposures 500-950,000 mJ/cm^2
  - $\geq$ 3 log$_{10}$ inactivation achieved 500-1800 mJ/cm^2
    - Influenza A (H1N1)
    - Avian influenza A virus (H5N1),
    - Low pathogenic Influenza A (H7N9),
    - Avian influenza A (H7N9),
    - MERS-CoV
    - SARS-CoV
    - Influenza A/PR/8/34
    - MS2 bacteriophage
  - "Shadowing effects" are critical

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

UV_{254} Dose-Response Behavior SARS-CoV and Surrogates (MS2)





Data for MS2 inactivation on surfaces from:
Chun-Chieh Tseng & Chih-Shan Li (2007) "Inactivation of Viruses on Surfaces by Ultraviolet Germicidal Irradiation," *Journal of Occupational and Environmental Hygiene*, **4**:6, 400-405, DOI: 10.1080/15459620701329012.

MS2 Action Spectrum

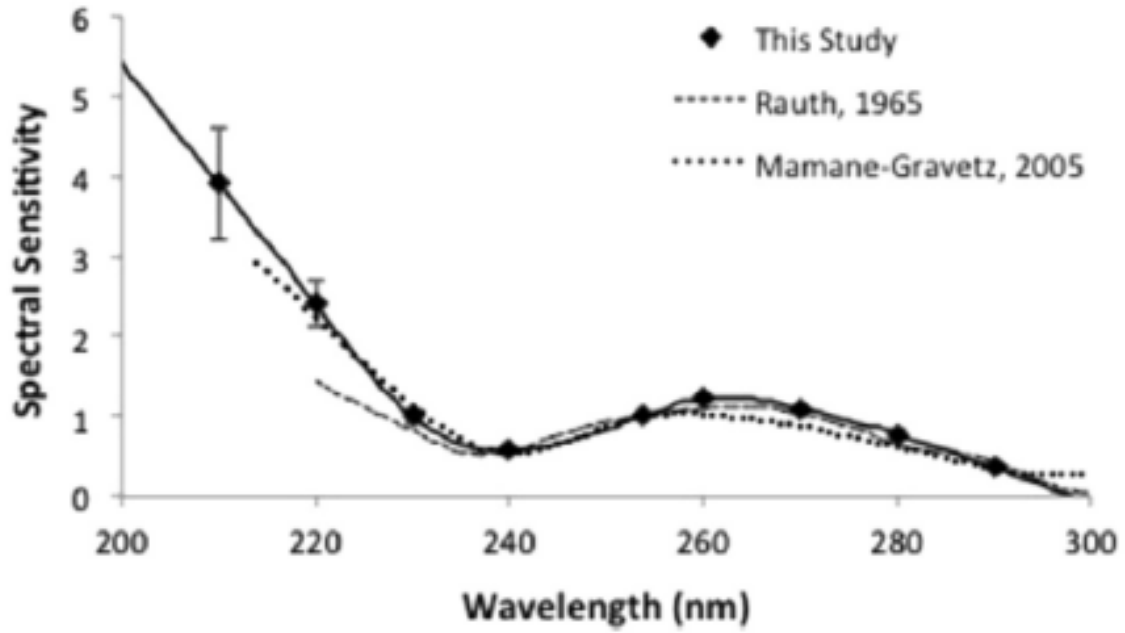


Fig. 4 – Relative spectral sensitivity of MS2 Coliphage to UV light as compared with previous studies (Rauth, 1965; Mamane-Gravetz, Linden et al. 2005). Error bars represent 1 standard deviation from the mean sensitivity value. $n = 4$ for 240 nm, 253.7 nm, 260 nm, and 270 nm and $n = 3$ for all other wavelengths tested.

WATER RESEARCH 70 (2015) 27–37

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/watres

Action spectra for validation of pathogen disinfection in medium-pressure ultraviolet (UV) systems

Sara E. Beck [a], *Harold B. Wright* [b], *Thomas M. Hargy* [c], *Thomas C. Larason* [d], *Karl G. Linden* [a,*]

[a] Department of Civil, Environmental, and Architectural Engineering, University of Colorado Boulder, UCB 428, Boulder, CO 80309, USA
[b] Carollo Engineers, 12592 West Explorer Drive, Suite 200, Boise, Idaho 83713, USA
[c] Corona Environmental Consulting, 318 Overlake Dr, Fairfax, VT 05454, USA
[d] National Institute of Standards and Technology, 100 Bureau Dr., Gaithersburg, MD 20899, USA

Action Spectra Examples

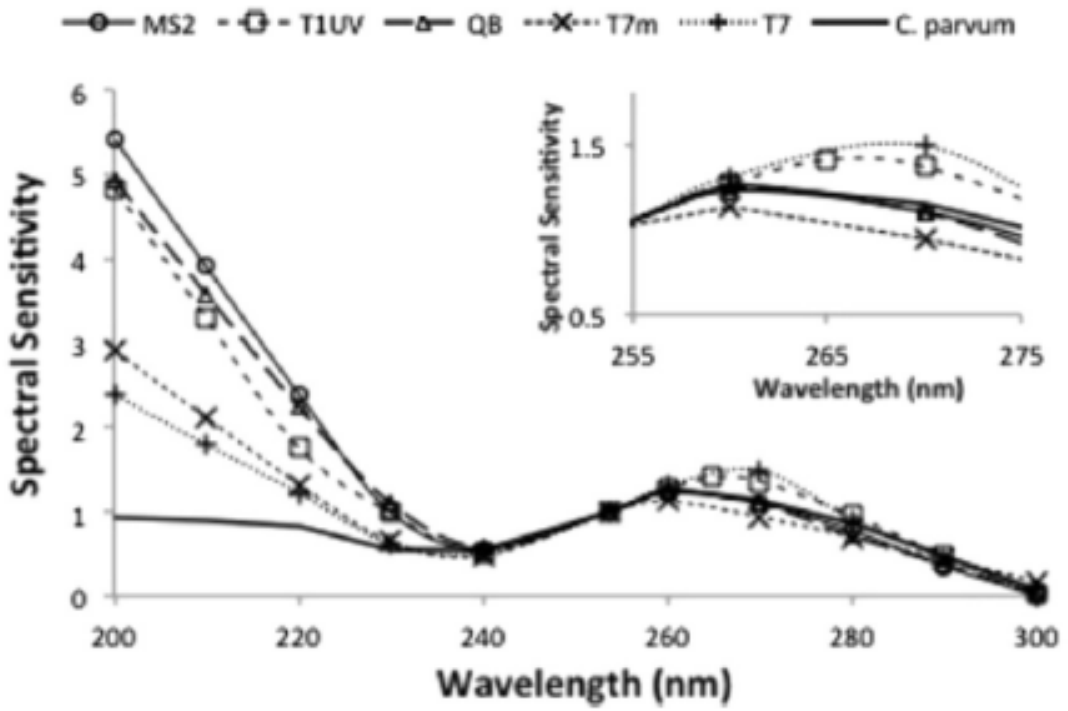


Fig. 5 – Relative spectral sensitivity of MS2, T1UV, Q Beta, T7m, and T7 Coliphages and *C. parvum* to UV light from the tunable laser. Note data points at 200 and 300 nm are extrapolated.

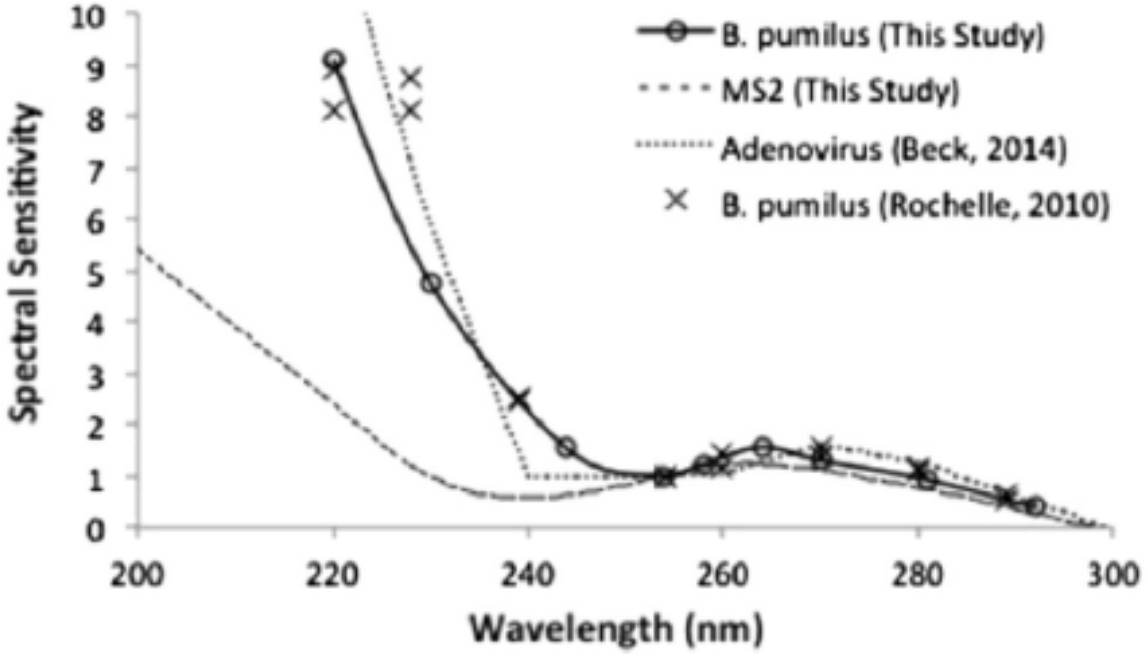


Fig. 6 – Relative spectral sensitivity of *Bacillus pumilus* to MP UV light with bandpass filters as compared with a *B. pumilus* spectrum from the literature (Rochelle et al., 2010) and the MS2 and adenovirus 2 (Beck et al., 2014) spectral sensitivity to UV light from the tunable laser.

Images from: Beck *et al.* (2015) "Action spectra for validation of pathogen disinfection in medium-pressure ultraviolet (UV) disinfection systems," *Water Research*, **70**, 27-37.

Introduction to SARS-CoV-2 and COVID-19

John M. Boyce, MD

J.M. Boyce Consulting, LLC

Middletown, CT

Disclosure: JMB is a consultant to, and has received travel support from and presented at conferences supported by Diversey and GOJO Industries

Origin of COVID-19

- **December 2019 - First cases of COVID-19 illness occurred among individuals who are believed to have been exposed at Huanan Seafood Market in Wuhan, China which also marketed other animals**
- **The disease called COVID-19 is caused by a new coronavirus, named SARS-CoV-2**
- **Animals possibly responsible for the transmission to humans at the market are unknown**
  - **Bats are likely to have been original source**
  - **Transmission from bats to pangolins may have resulted in development of SARS-CoV-2, with subsequent transmission to humans**

Most Likely Source of SARS-CoV-2

Li Q et al. N Engl J Med 2020 [Epub ahead of print]
Chen N et al. Lancet 2020 [Epub ahead of print]
Sun P et al. J Med Virol 2020 [Epub ahead of print]
Wang D et al. JAMA 2020 [Epub ahead of print]
Huang C et al. Lancet 2020 [Epub ahead of print]

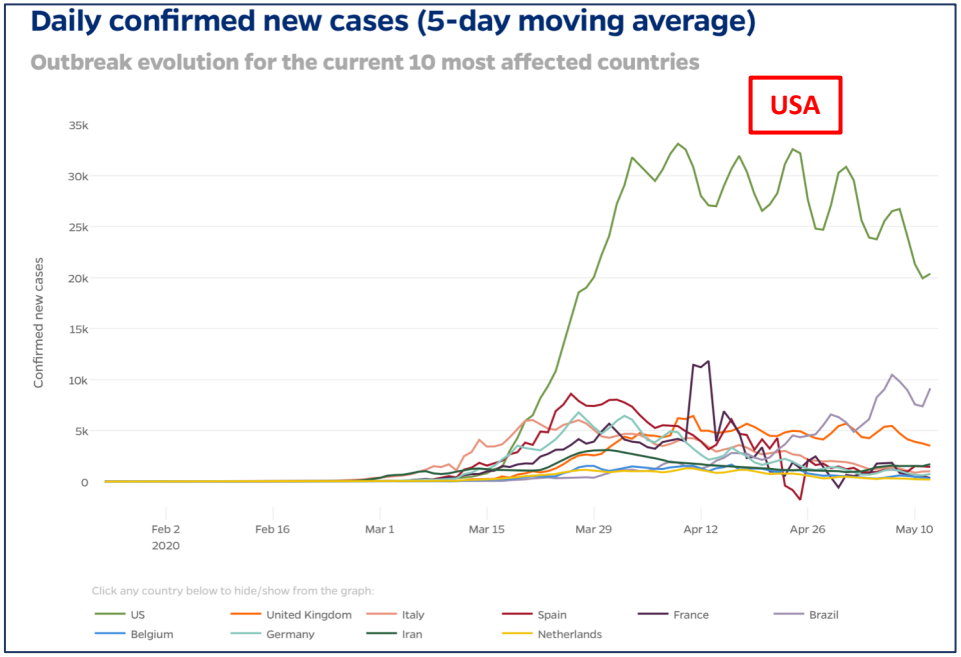
Current Status of COVID-19
May 14, 2020

- **Total Cases: 4,369,410**
- **Total Deaths: 297,569**

- **Number of countries & territories affected: 188**

- **New cases continue to occur in the U.S.**

- **Cases in US: 1,390,764**
- **Deaths in US: 84,136**



Source: Johns Hopkins Coronavirus Resource Center

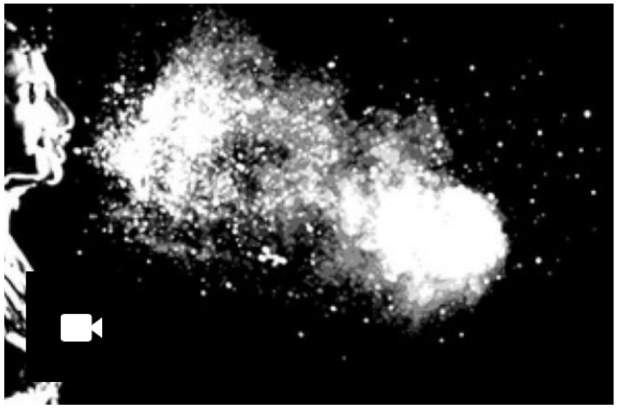
Modes of Transmission of Coronaviruses

- **Person-to-person transmission via large droplets**
  - **Coughing/sneezing/talking**
  - **Asymptomatic individuals can transmit SARS-CoV-2**

- **<u>Possible</u> transmission by touching contaminated surfaces**
  - **Surfaces contaminated by respiratory secretions**
  - **Surfaces potentially contaminated by patients who present with diarrhea containing SARS-CoV-2**

- **Increasing evidence suggests that airborne transmission via tiny droplet nuclei suspended in air may also occur**

Droplets Caused by Sneeze



Source: Lydia Bourouiba, MIT

Yu P et al. J Infect Dis 2020 [Epub ahead of print] Chan JF et al. Lancet 2020;395:514
Chen N et al. Lancet 2020 [Epub ahead of print] Zhang W et al. Emerg Microbes Infect 2020;9:386
https://www.cdc.gov/coronavirus/2019-ncov/about/transmission.html
Bourouiba L NEJM 2016;375:e15 Bourouiba L JAMA 2020 doi: 10.1001/jama.2020.4756

Clinical Features of COVID-19

- **Host risk factors**
  - Male gender
  - Advanced age
  - Underlying conditions
    - Diabetes
    - Heart disease
    - Obesity
- **Average incubation period:**
  - 5 days (range: 2 -14)
- **Case fatality rate: ~ 1%**

Clinical findings

Signs/Symptoms	Frequency
Fever	83% - 98%
Cough	59% - 81%
Shortness of breath	31%
Fatigue	70% - 75%
Muscle aches	11%
Loss of smell or taste	15%
Confusion	9%
Sore throat	5%
Diarrhea	2%
Bilateral pneumonia	75%
Diffuse lung infiltrates	14% - 90%
Kawasaki-like syndrome	Few children
COVID-19 toe lesions	

Chen N et al. Lancet 2020;395:507
Huang C et al. Lancet 2020;395:497
Wang D et al. JAMA 2020 [Epub ahead of print]
Zhang JJ et al. Allergy 2020 [Epub ahead of print]
Lee Y et al. J Korean Med Sci 2020;35:e174
Nirenberg MS et al. J Am Podiatr Med Assoc 2020 [Epub ahead of print]

Prevention Measures

General Measures

- When coughing or sneezing,
  - Cover your mouth and nose with a tissue
  - Or cover your mouth and nose with your sleeve
- Social distancing (≥ 6 feet apart)
- Avoid touching your eyes, nose, mouth
- Stay home when you are sick
- Clean and disinfect frequently touched objects using regular household cleaning spray or wipe (hospital-grade disinfectant in hospital)

Healthcare personnel

- N95 respirators (medical masks if not available), face shields and gowns for direct care of suspect or proven COVID-19 patients
- Social distancing to extent possible

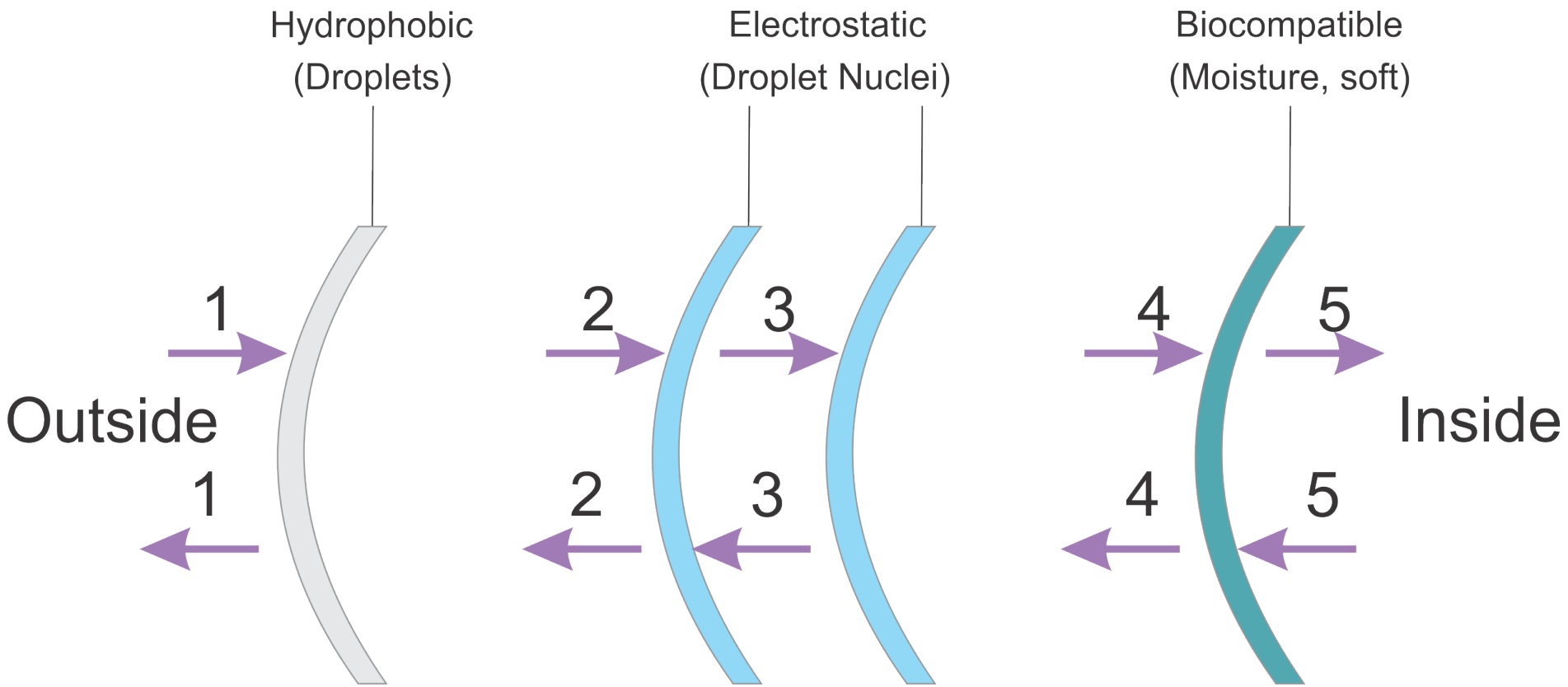
Hand Hygiene

- Wash your hands often with soap and water for at least 20 seconds, especially after going to the bathroom ; before eating; and after blowing your nose, coughing or sneezing
- If soap and water are not readily available, use an alcohol-based hand sanitizer with at least 60% alcohol
- Alcohol-based hand sanitizers are very effective against coronaviruses
- However, if hands are visibly dirty, wash hands with soap and water

https://www.cdc.gov/coronavirus/2019-ncov/about/prevention-treatment.html

Thank you for your attention

Anatomy of N95 Mask



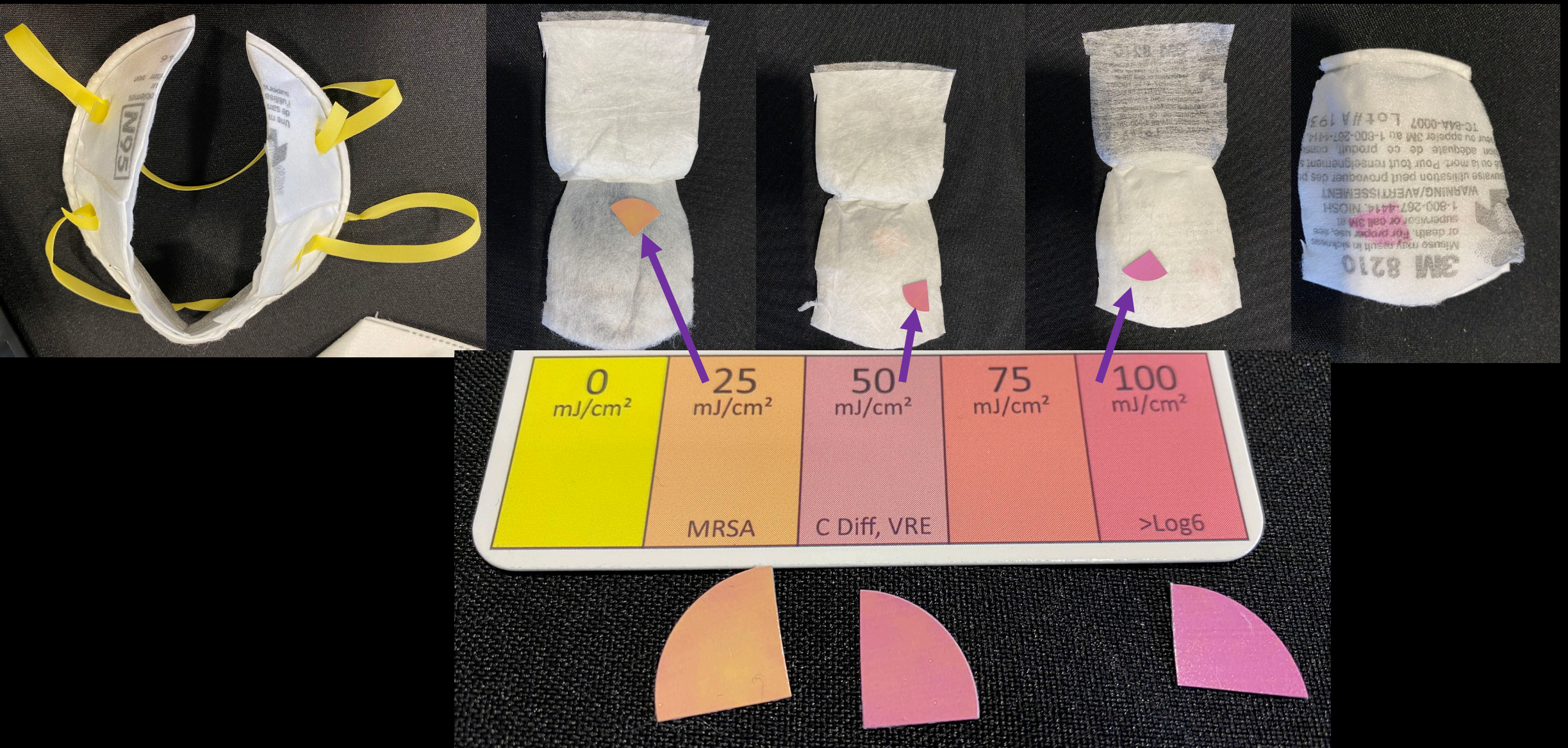
N95 Mask Layer UV_{254} Penetration

(UV_{254} source front side of mask)

Biocompatible

Electrostatic

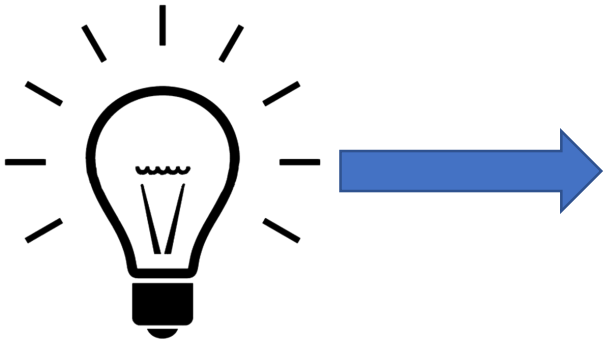
Hydrophobic

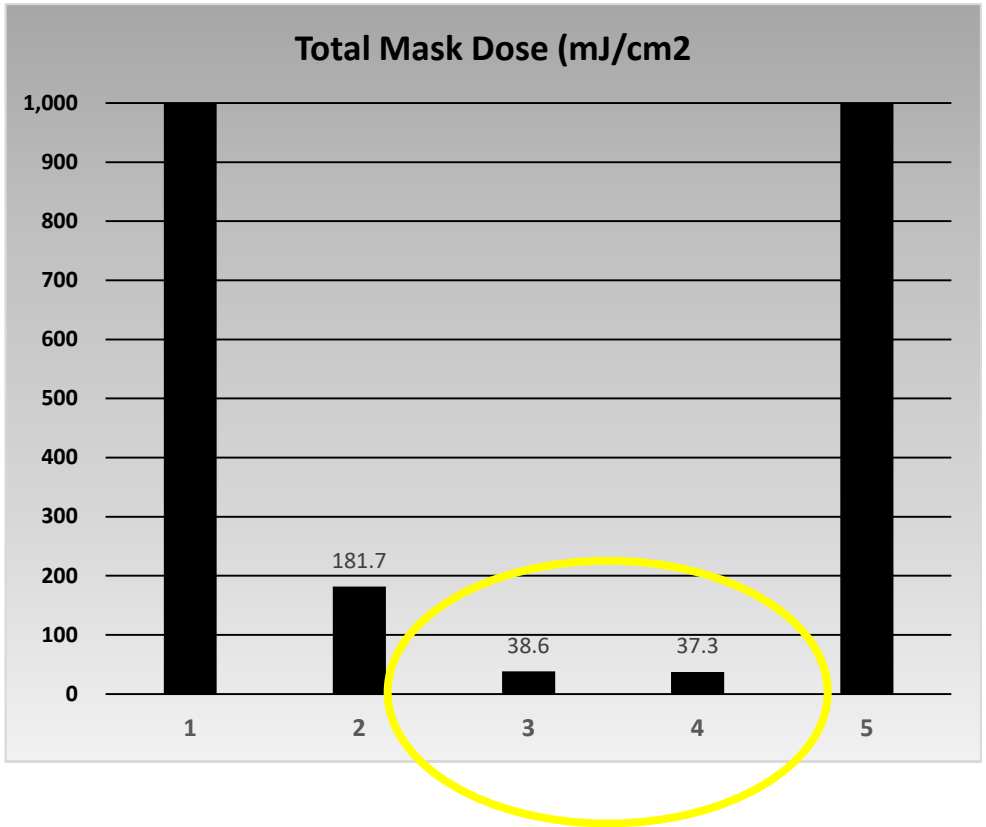


UV_{254} Dose Applied to N95 Mask Layers

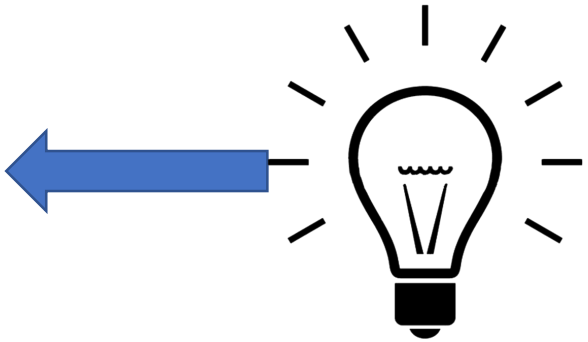
3M Model 8210

Outside of Mask





Inside of Mask



UV_{254} Disinfection Dose vs Mask Integrity

2,000 mJ/cm2

Typical 3Log disinfection dose

20,000 mJ/cm2

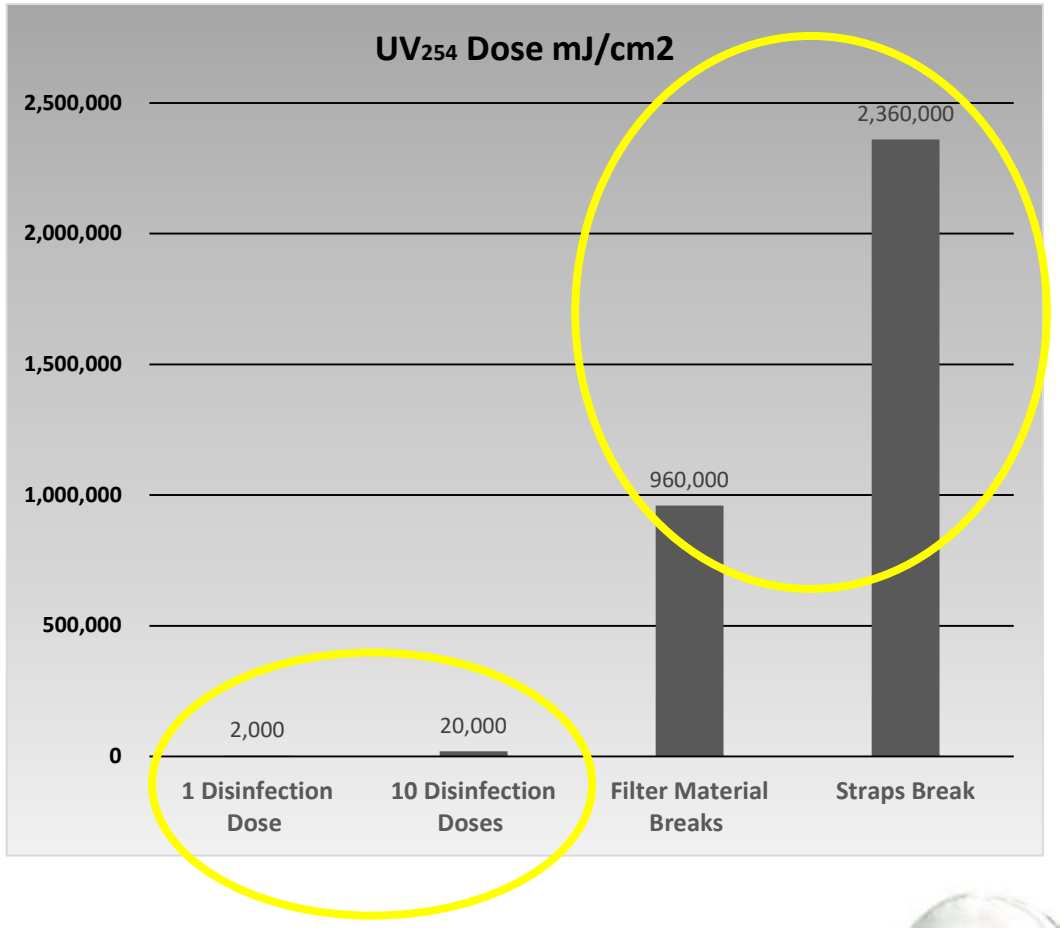
Total dose of 10 cycles

120,000 to 960,000 mJ/cm2*

< 1.25% particle penetration
little effect on the flow resistance
reduced strength of material

2,360,000 mJ/cm2 *

reduced the breaking strength of the straps by 20-51%.



Effects of Ultraviolet Germicidal Irradiation (UVGI) on N95 Respirator Filtration Performance and Structural Integrity
William G Lindsley[1], Stephen B Martin Jr, Robert E Thewlis, Khachatur Sarkisian, Julian O Nwoko, Kenneth R Mead, John D Noti
Journal of Environ Hyg 2015;12(8):509-17

N95 Masks Trap Virus Particles Primarily Through Electrostatic Charge

[UT Researcher's Nonwoven Fabrics Protect the Health of More Than a Billion People](#)

August 27, 2019

"Peter's novel method uses an electric field to ionize the neutral air to generate ions and electrons, which then charge the nonwoven fibers through field and induction. Using his innovative approach, the charged nonwoven fabric can filter particles in the air ten times more efficiently than uncharged fabrics without adversely increasing the air resistance."

Dr. Peter Tsai, PhD

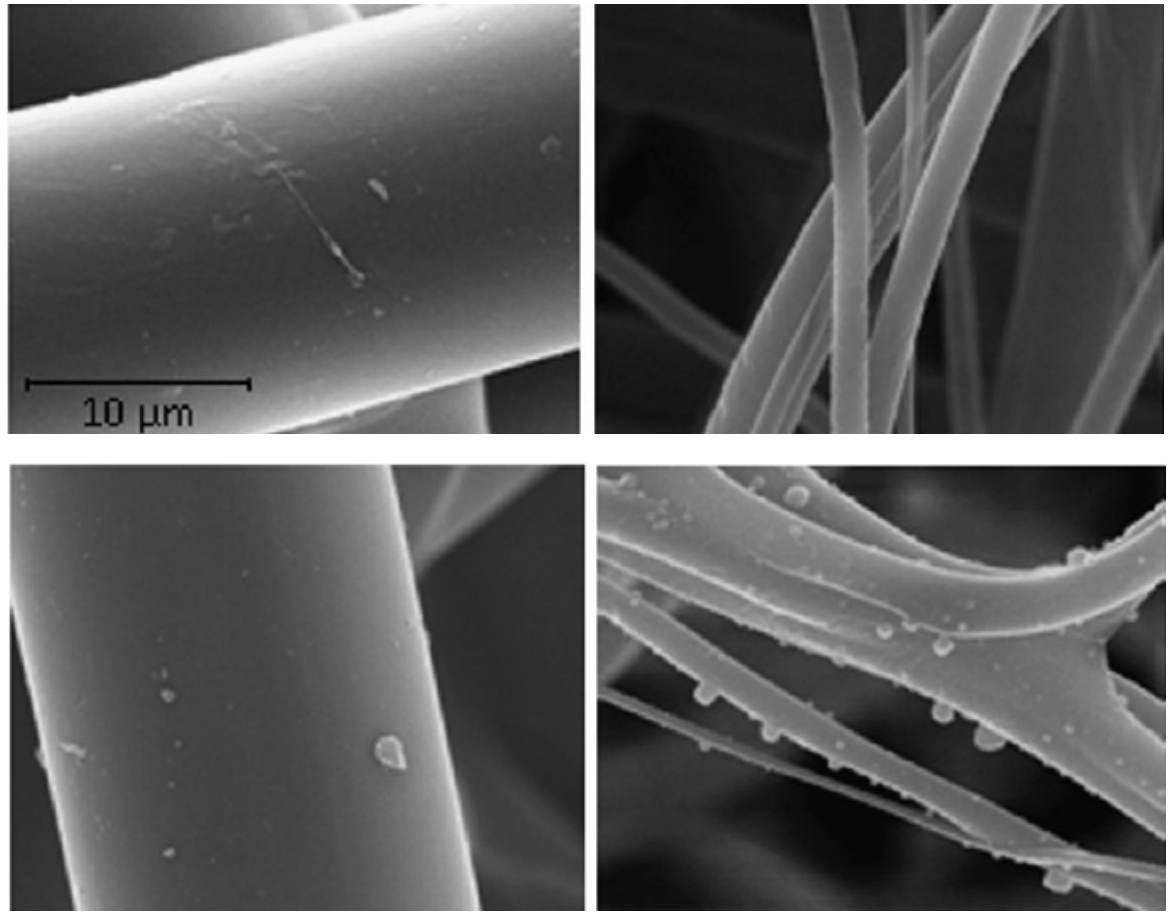
University of Tennessee Research Foundation

Father of Charged Filtration

Reaerosolization of MS2 Bacteriophage from an N95 Filtering Facepiece Respirator by Simulated Coughing

EDWARD M. FISHER1, AARON W. RICHARDSON2, SHANNON D. HARPEST2, KENT C. HOFACRE2 and RONALD E. SHAFFER1*
1National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, Pittsburgh, PA 15236, USA; 2Battelle Memorial Institute, Columbus, OH 43201, USA Ann. Occup. Hyg., Vol. 56, No. 3, pp. 315–325, 2012

Patient ← Outer Layer — Inner Layer → HCW



Droplets

<.0001%

~ Zero

Droplet Nuclei

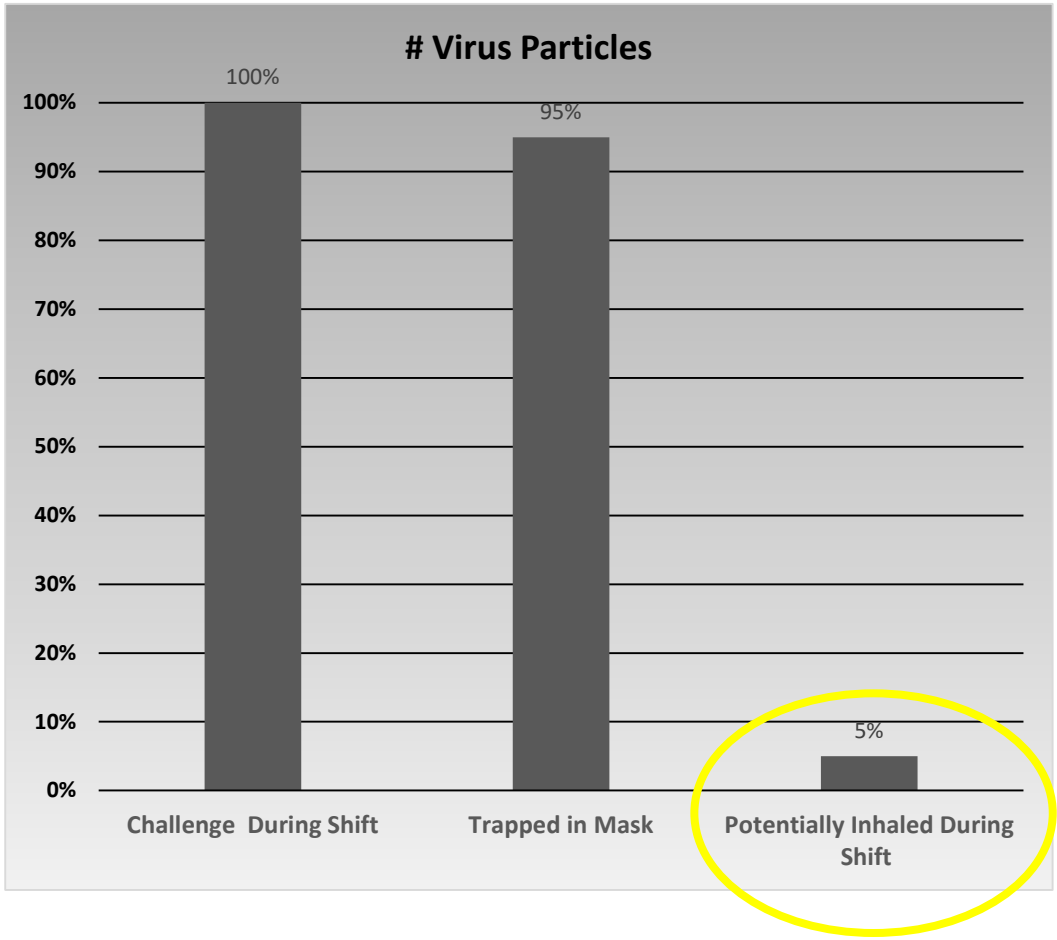
<0.21%

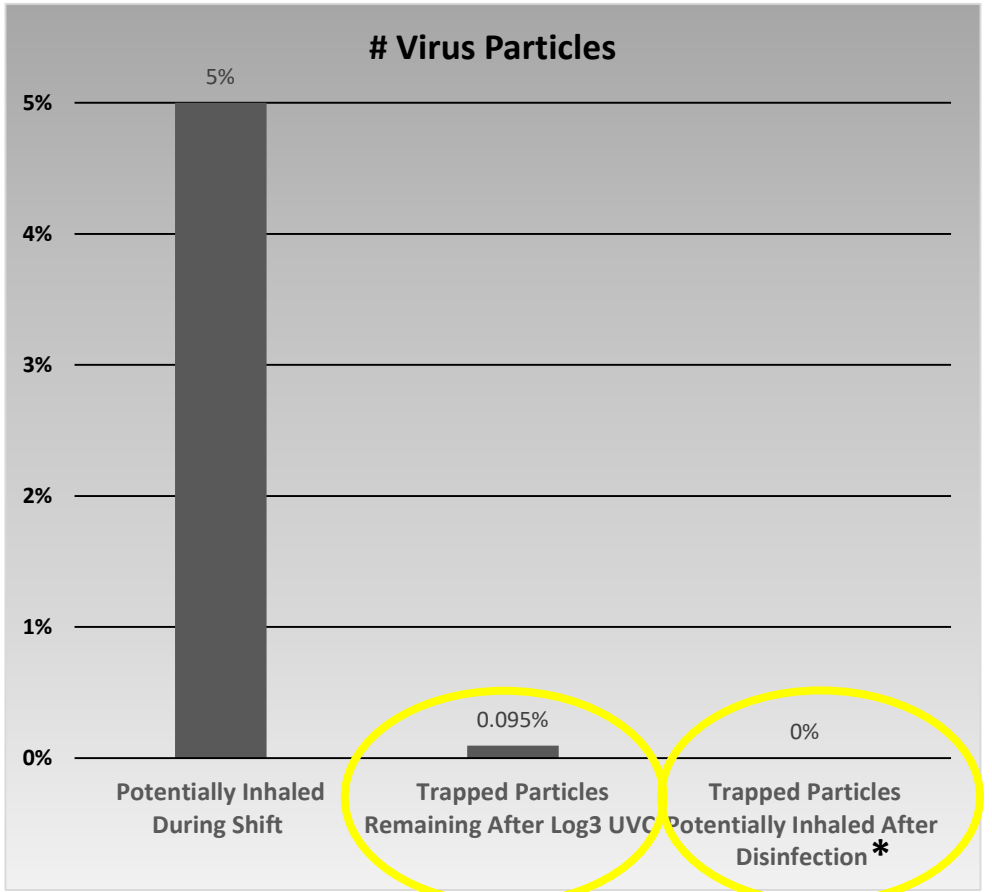
~ Zero

Qian et al 1997
"particle reaerosolization from FFRs were not registered for velocities under 200 cm/s because the air drag forces were not sufficient to overcome the adhesion forces between the particles and the filter fibers."

"…for most respiratory viruses the risks due to reaerosolization…can be considered negligible…"

Relative Risk





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Ann. Occup. Hyg., Vol. 56, No. 3, pp. 315–325, 2012

ECRI

The Most Trusted Voice in Healthcare

ECRI Recommendations for UV_{254} Decontamination of N95s

Mairead Smith

Senior Project Engineer

msmith@ecri.org

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The New York Times

ECRI's Guidance

Mid-March

ECRI received first questions about UV_{254} decontamination of N95 FFRs

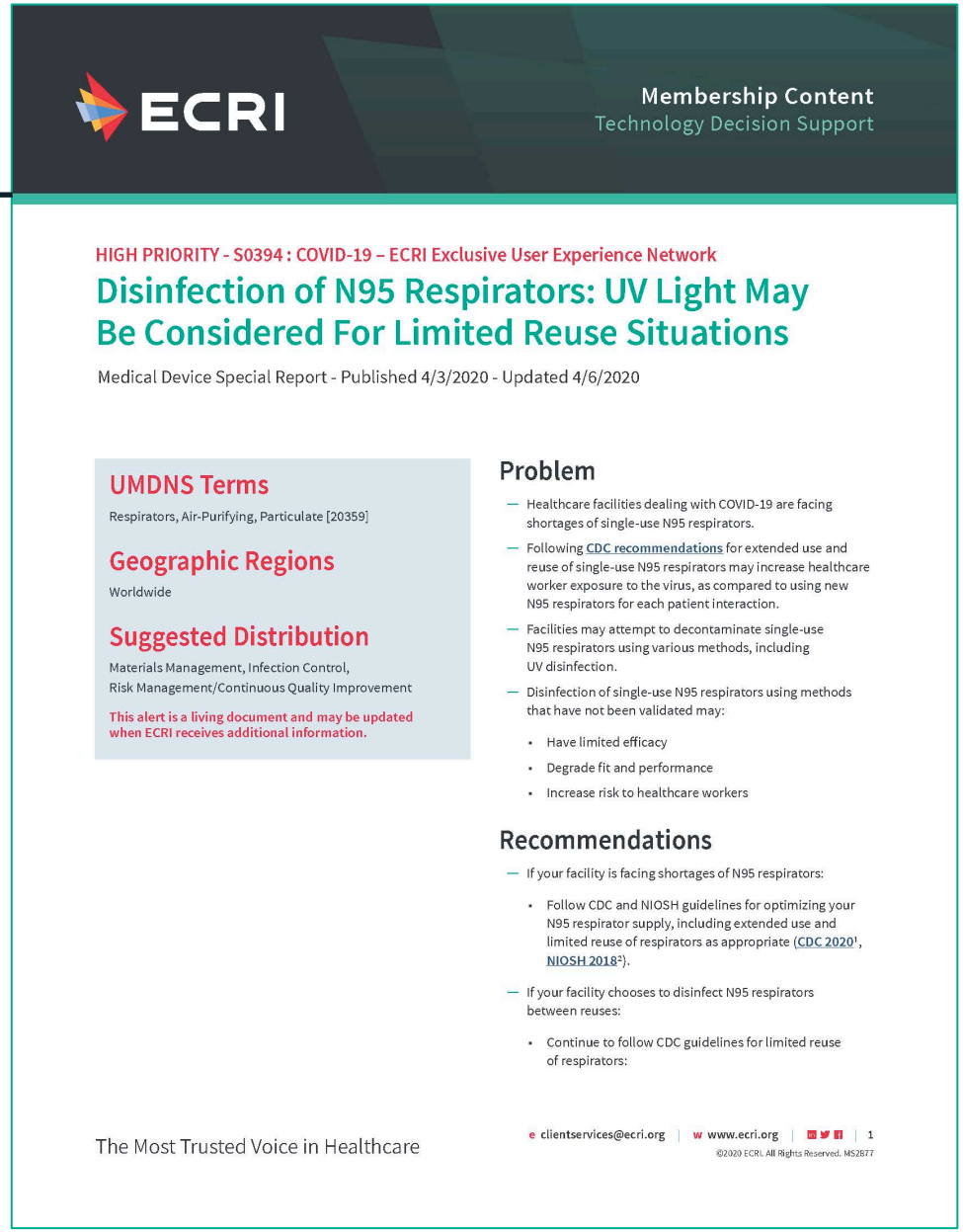
Late March

Review of literature
Analysis of dose data

April 3, 2020

ECRI published a statement

Disinfection of N95 Respirators: UV Light May Be Considered for Limited Reuse Situations
https://assets.ecri.org/PDF/COVID-19-Resource-Center/COVID-19-Clinical-Care/COVID-Alert-UV-Disinfection.pdf



ECRI

Membership Content
Technology Decision Support

HIGH PRIORITY - S0394 : COVID-19 – ECRI Exclusive User Experience Network

Disinfection of N95 Respirators: UV Light May Be Considered For Limited Reuse Situations

Medical Device Special Report - Published 4/3/2020 - Updated 4/6/2020

UMDNS Terms

Respirators, Air-Purifying, Particulate [20359]

Geographic Regions

Worldwide

Suggested Distribution

Materials Management, Infection Control, Risk Management/Continuous Quality Improvement

This alert is a living document and may be updated when ECRI receives additional information.

Problem

- Healthcare facilities dealing with COVID-19 are facing shortages of single-use N95 respirators.
- Following CDC recommendations for extended use and reuse of single-use N95 respirators may increase healthcare worker exposure to the virus, as compared to using new N95 respirators for each patient interaction.
- Facilities may attempt to decontaminate single-use N95 respirators using various methods, including UV disinfection.
- Disinfection of single-use N95 respirators using methods that have not been validated may:
  - Have limited efficacy
  - Degrade fit and performance
  - Increase risk to healthcare workers

Recommendations

- If your facility is facing shortages of N95 respirators:
  - Follow CDC and NIOSH guidelines for optimizing your N95 respirator supply, including extended use and limited reuse of respirators as appropriate (CDC 2020[1], NIOSH 2018[2]).
- If your facility chooses to disinfect N95 respirators between reuses:
  - Continue to follow CDC guidelines for limited reuse of respirators:

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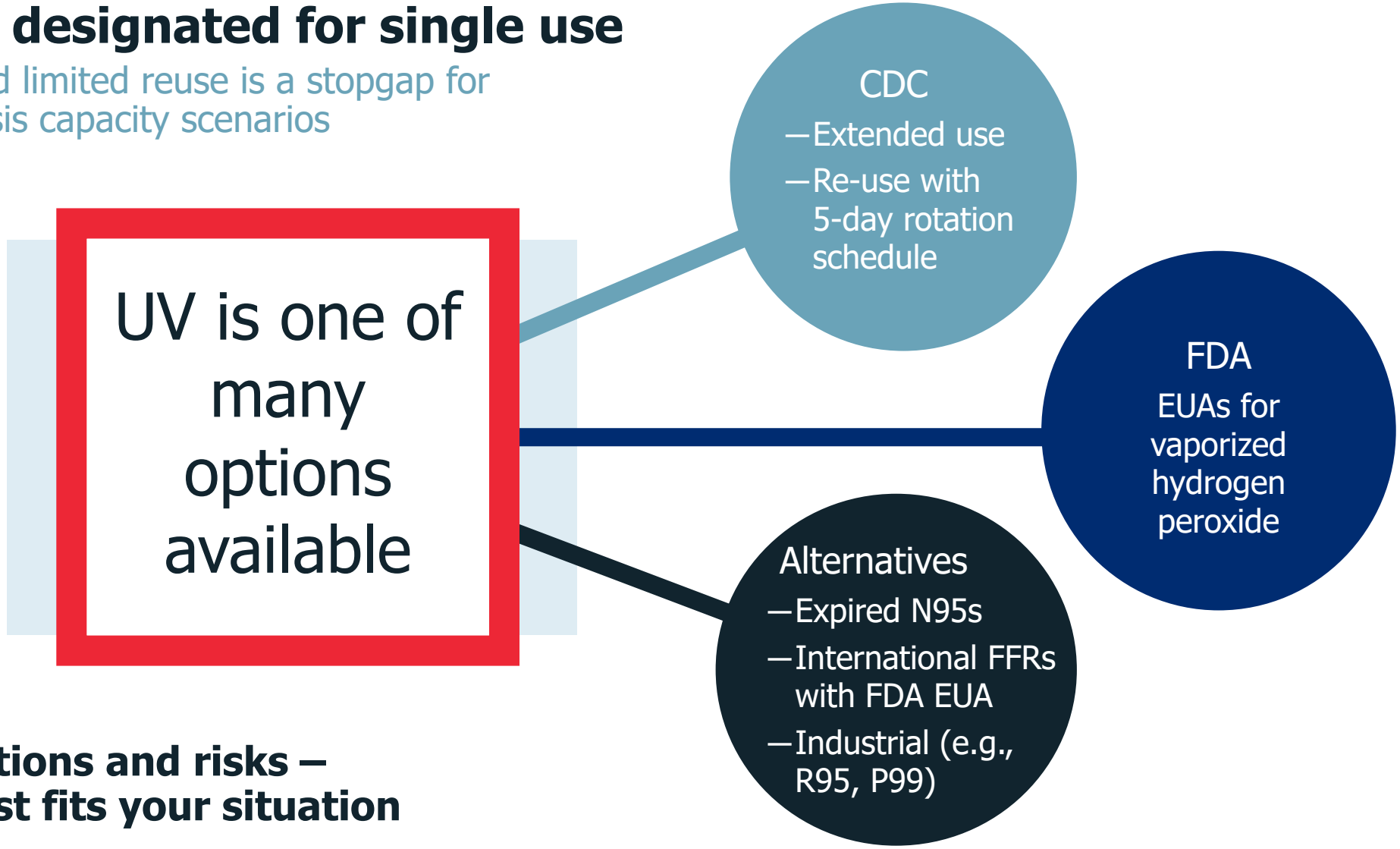
e clientservices@ecri.org | w www.ecri.org | 1

N95 FFRs are designated for single use

All extended use and limited reuse is a stopgap for contingency and crisis capacity scenarios



Consider the options and risks – choose what best fits your situation

ECRI's Recommendations for UV Decontamination

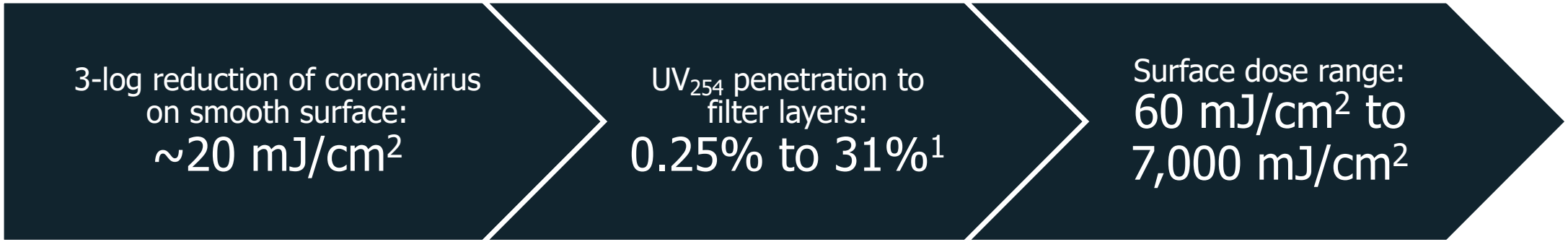
Follow CDC guidelines for limited reuse

- One wearer per N95
- Hand hygiene before/after touching N95
- New gloves to don, check seal
- Discard N95s that:
  - Are visibly soiled
  - Are difficult to breathe through
  - Were used in aerosol-generating procedures

UV Towers

- Hang N95s (propped open) in clean, empty room
- Minimize shadowing
- Place UV_{254} device 5 ft in front of N95s (≤7 ft)
- ≥5 min cycle/side for dose of 150-500 mJ/cm^2

Dose Rationale



Previous studies have focused on contact transmission, not reaerosolization

Risk Management

Low Doses
60-500 mJ/cm²

- Disinfect superficial layers
- Viruses in internal filter may persist[2]
- Risk of re-aerosolization may be low[3]
- Studies focus on self-inoculation by touching N95s[4,5]

Watch for signs of degradation:

- Tears
- Discoloration
- Poor fit
- Breathing resistance

Diminishing returns at high doses

- Organism response plateaus beyond a certain dose level

Shadowing matters

- Even with high doses, N95 shape and shadowing can limit effectiveness

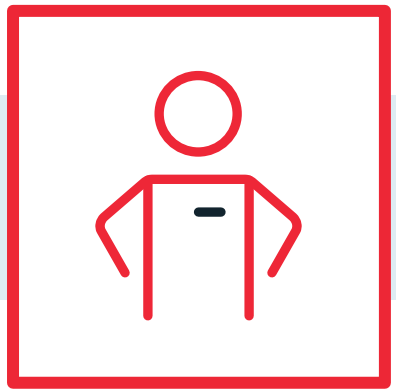
High Doses
500-1,000 mJ/cm²

- Conservative, increase UV_{254} penetration into filter
- May increase risk of N95 degradation, but little evidence[6,7]
- May not be realistic with small devices

New, Unproven Devices: What's Important?

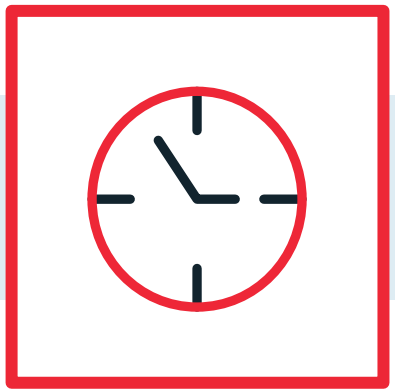
Performance:

- Wavelength
- Intensity
- Dose capabilities
- Coverage



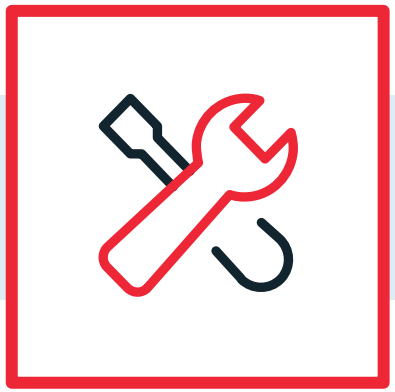
Safety Features

- UVC leakage
- Auto shutoff when door opened
- Cycle early termination option



Workflow

- Ease of use
- N95 FFR capacity
- Cycle time
- Guidance and support



Maintenance

- Ease of cleaning/disinfection
- Protection against lamp damage

Stay Tuned For Updates!

Limitations

Complete sterilization is not possible with UV

Questions Remain:

1. "Safe" log reduction of SARS-CoV-2 for N95s
2. Required UV dose

Ongoing Research

May be months before high quality, peer-reviewed studies are published

Citations

1. Fisher EM, Shaffer RE. A method to determine the available UV-C dose for the decontamination of filtering facepiece respirators. J Appl Microbiol 2011 Jan. Available from: https://sfamjournals.onlinelibrary.wiley.com/doi/full/10.1111/j.1365-2672.2010.04881.x.

2. Fisher EM, Shaffer RE. A method to determine the available UV-C dose for the decontamination of filtering facepiece respirators. J Appl Microbiol 2011 Jan. Available from: https://sfamjournals.onlinelibrary.wiley.com/doi/full/10.1111/j.1365-2672.2010.04881.x.

3. Fisher EM, Richardson AW, Harpest SD, et al. Reaerosolization of MS2 bacteriophage from an N95 filtering facepiece respirator by simulated coughing. Ann Occup Hyg 2012 Apr. Available from: https://academic.oup.com/annweh/article/56/3/315/168940.

4. Centers for Disease Control and Prevention (CDC). Strategies for optimizing the supply of N95 respirators [online]. 2020 Feb 19 [cited 2020 Apr 2]. Available from Internet: https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html.

5. Fisher EM, Shaffer RE. Considerations for recommending extended use and limited reuse of filtering facepiece respirators in health care settings. J Occup Environ Hyg 2014. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4610368/.

6. Lore MB, Heimbuch BK, Brown TL, et al. Effectiveness of three decontamination treatments against influenza virus applied to filtering facepiece respirators. Ann Occup Hyg 2012 Jan. Available from: https://academic.oup.com/annweh/article/56/1/92/166111.

7. Lindsley WG, Martin SB Jr, Thewlis RE, et al. Effects of Ultraviolet Germicidal Irradiation (UVGI) on N95 Respirator Filtration Performance and Structural Integrity. J Occup Environ Hyg 2015. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4699414/.

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"Expert Perspectives on UV as a Tool for N95 Decontamination"

- SARS CoV-2 Surrogates (biosafety level 2)
  - 229E – alpha coronavirus
  - OC43 – beta coronavirus
- Inoculation
  - Aerosol
  - Droplet
- Standard Test Methods
  - ISO 18184:
    - Test against different layers or a cross-section of the whole mask?

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