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Updated Information on Respirator Decontamination Systems

Office of Health Technology 4: Surgical and Infection Control Devices
Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health (CDRH)

Agenda

- Definition of Decontamination Systems
- Authorized Decontamination Systems
- Scope of Authorizations
- Resources
- Questions

Decontamination Systems for Filtering Facepiece Respirators (FFRs)

- Decontamination systems are devices intended to decontaminate certain medical devices, such as compatible N95 respirators, so they can be reused by healthcare personnel.
- The FDA issued Emergency Use Authorizations (EUAs) authorizing the emergency use of some decontamination systems to decontaminate certain respirators recognizing that availability of filtering facepiece respirators (FFRs) is an integral part of routine patient care during the COVID-19 pandemic.

Crisis Capacity Strategies and Decontaminated Filtering Facepiece Respirators (FFRs)

Q: When should decontamination systems for FFRs be used?

A: The CDC recommends as soon as new supplies can meet the projected demand, all reuse and decontamination of respirators should be discontinued. FFRs should only be reused when operating at crisis capacity due to the inability of FFR supplies to meet the demand.

CDC provides information on [Implementing Filtering Facepiece Respirator \(FFR\) Reuse, Including Reuse after Decontamination, When There Are Known Shortages of N95 Respirators.](#)



Types of Authorized Decontamination Systems

Decontamination systems that have been reissued EUAs are authorized to decontaminate compatible N95 respirators using the following technologies:

- Vaporized Hydrogen Peroxide (VHP)
- Steam
- VHP/ozone

Updates to Decontamination System EUAs

On January 21, 2021, the FDA reissued certain decontamination system EUAs by making the following changes, as applicable:

- Limit the maximum number of decontamination cycles to ≤ 4
 - Evidence demonstrates that significant respirator fit failure occurs after 5 donnings and doffings.

- Require post-authorization studies (PAS) to confirm the maximum number of decontamination cycles
 - Real world data on fit testing and filtration efficiency testing to demonstrate that respirator functional integrity is maintained.
 - Timely communication of PAS results in authorized labeling.

Updates to Decontamination System EUAs, continued

- Revised authorized labeling for decontamination systems intended for multiple-user reuse to ensure respirator fit
 - Evidence demonstrates that most contaminants that enter an N95 respirators are the result of face seal leakage; therefore, fit is important in respirator functional assessment.
 - End users must receive the same model of decontaminated, compatible N95 respirator for which they have been fit tested. And, if that model is unavailable, then healthcare facilities must provide fit testing prior to the use of an alternative model.
- Revised authorized labeling for all decontamination systems instructing users to perform OSHA self-seal check.
- Authorization excludes respirators with antimicrobials and duckbill respirators from decontamination.

Resources



- Previous Webinars from this Series, including recordings of a previous webinar on Decontaminating Respirators for Health Care Personnel Use, held on July 7, 2020:
<https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-series-respirators-and-other-personal-protective-equipment-ppe-health-care-personnel-use#previous>
- FDA Decontamination Systems for Personal Protective Equipment EUAs:
<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/decontamination-systems-personal-protective-equipment-euas>
- CDC Implementing FFR Reuse, Including Reuse after Decontamination, When There Are Known Shortages of N95 Respirators:
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html>
- CDC Strategies for Optimizing the Supply of N95 Respirators:
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html>
- CDC Personal Protective Equipment (PPE) Burn Rate Calculator:
<https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/burn-calculator.html>
- OSHA Protecting Workers: Guidance on Mitigating and Preventing the Spread of COVID-19 in the Workplace:
<https://www.osha.gov/coronavirus/safework>
- OSHA enforcement memoranda that include time-limited discretions:
https://www.osha.gov/coronavirus/standards#temp_enforcement_guidance

Questions?

Email: CDRH-COVID19-SurgicalMasks@fda.hhs.gov

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