

FACT SHEET FOR HEALTHCARE PERSONNEL

Technical Safety Services 20-CS Decontamination System for Decontaminating Compatible N95 Respirators
January 21, 2020

Coronavirus
Disease 2019
(COVID-19)

You have been given a **decontaminated N95 respirator** that has been decontaminated using a decontamination system that is authorized to decontaminate compatible N95 respirators **for multiple-user reuse by healthcare personnel (HCP) in a healthcare setting** (i.e., HCP may receive a different respirator following decontamination than the one they had previously used), to help prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic.

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of decontaminated, compatible N95 respirators. These compatible N95 respirators have been decontaminated using the Technical Safety Service's 20-CS Decontamination System (hereafter referred to as "**decontaminated N95 respirators**" and "**TSS Decontamination System**" throughout this Fact Sheet).

Whether or not you use a surgical mask, respirator, or face shield, always follow infection control measures: wash hands, cover coughs and sneezes, stay home if you may be sick.

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC webpage for the most up to date information.

What do I need to know about the emergency use of the TSS Decontamination System and decontaminated N95 respirators?

- The TSS Decontamination System has been authorized for emergency use to decontaminate compatible N95 respirators for multiple-user reuse by HCPs during the COVID-19 pandemic to prevent wearer exposure to pathogenic biological airborne particulates, including SARS-CoV-2.
- Compatible N95 respirators are those respirators that are NIOSH-approved, and do not contain cellulose-based materials, exhalation valves, antimicrobial agents, or duck-billed designs.
- The TSS 20-CS Decontamination System is **not authorized** for use with:
 - Respirators containing cellulose-based materials;
 - Respirators containing exhalation valves;
 - Respirators containing antimicrobial agents;
 - Respirators with duck-billed designs; and
 - Respirators that are authorized by the Non-NIOSH Approved Disposable Filtering Facepiece Respirators (FFRs) manufactured in China EUA and Imported, Non-NIOSH-Approved Disposable FFRs EUA.
- Successful testing on decontaminated N95 respirators demonstrated acceptable performance through four (4) decontamination cycles of compatible N95 respirators with the most difficult to kill bacterial spores; historical biological indicator inactivation data; filtration efficiency, fit testing and breathability testing following multiple decontamination cycles; and testing regarding hydrogen peroxide residuals after decontamination. FDA has concluded that such decontaminated, compatible N95 respirators are appropriate for multiple-user reuse for a maximum of 4 decontamination cycles per respirator during the COVID-19 pandemic.
- **Use of decontaminated N95 respirators:**
 - ✓ Decontaminated N95 respirators are not sterile
 - ✓ HCP must perform a user seal check of the decontaminated N95 respirator according to OSHA standards prior to beginning a shift. If the user seal

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- check does not pass, the respirator must be discarded
- ✓ HCP must receive the same model of decontaminated respirator for which they have been fit tested. If such model of respirator is unavailable, then healthcare facilities must provide HCP with fit testing prior to using an alternative model of decontaminated, compatible N95 respirator
- ✓ Inspect respirators after each use prior to submission for decontamination
- ✓ Discard respirators with visible soiling (e.g., blood) or damage - do not use and do not send for decontamination
- ✓ The number of times a respirator has been decontaminated is written on the respirator (maximum 4 times)
- ✓ Report problems with decontaminated N95 respirators to your healthcare facility
- Take a photo of any respirators found to not meet re-wear criteria as cited above. Submit this photo to covid19response@techsafety.com. To contact us, please email covid19response@techsafety.com and our support team will respond as soon as possible. You may also call 800.877.7742 for immediate assistance.
- **Monitor yourself for signs and symptoms** of potential infection with SARS-CoV-2 or other respiratory infection for up to and including 14 days after last contact with the SARS-CoV-2 virus and related material, and promptly report such information to your healthcare facility.
- **Report damage or discoloration** observed upon receipt of the decontaminated N95 respirators, and potential exposure of HCP from breaks in or other damage to or degradation of the decontaminated N95 respirators to your healthcare facility.
- Respirators that are NIOSH-approved before decontamination (<https://www.cdc.gov/niosh-cel/>) only retain their NIOSH approval status post-decontamination if the respirator manufacturer permits the use of the decontamination method with the specific system and cycle parameters. To determine the NIOSH approval status of a specific

decontaminated NIOSH-approved respirator, please check with the respirator manufacturer and/or check the respirator labeling. If a respirator is no longer NIOSH-approved after use of the particular decontamination method, its performance (i.e., fit, filtration, and breathability) might not consistently meet NIOSH-approved N95 standards.

Use appropriate personal protective equipment (PPE) when caring for individuals suspected of having COVID-19 as outlined in the CDC webpages, including *Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the COVID-19 Pandemic*, *Infection Control*, and *FAQ on PPE*.

Current information on COVID-19 for healthcare personnel is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

What are the known and potential benefits and risks of using decontaminated N95 respirators that were decontaminated using the TSS Decontamination System?

Potential benefits include:

- May help prevent exposure to airborne pathogens, and therefore reduce the risk of infection or illness
- Extends the usability of compatible N95 respirators by allowing for decontamination and reuse

Potential risks include:

- Failure of filtration efficiency
- Reduced breathability
- Strap failure and ineffective face-fit
- Reused respirators may not have been effectively decontaminated of SARS-CoV-2 or other pathogens
- Cross-contamination from ineffective decontamination

Overview of the TSS Decontamination System

The TSS Decontamination System is a mobile enclosure designed for decontamination of compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms with vaporized hydrogen peroxide

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(VHP). The system is designed to allow for flexibility in decontamination location, in that the TSS Decontamination System may be utilized at any location where space and safety requirements permit.

Respirators that are visibly soiled must be discarded and not reused or decontaminated.

What is an EUA?

The United States FDA has made the emergency use of the TSS Decontamination System to decontaminate compatible N95 respirators available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of medical devices, including alternative products used as medical devices, due to insufficient supply during the COVID-19 pandemic.

The TSS Decontamination System has been made available under an EUA and has not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe the TSS Decontamination System may be effective at preventing exposure to pathogenic biological airborne particulates when there are insufficient supplies of respirators during the COVID-19 pandemic by decontaminating, for a maximum of 4 decontamination cycles per respirator, compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms.

The EUA for the TSS Decontamination System is in effect for the duration of the COVID-19 declaration justifying emergency use of medical devices, unless terminated or revoked (after which the products may no longer be used).

Where can I go for updates and more information?

CDC webpages:

General: <https://www.cdc.gov/COVID19>

Healthcare Professionals:

<https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html>

Interim Infection Prevention and Control

Recommendations for Healthcare Personnel During the COVID-19 Pandemic:

<https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>

Infection Control: <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html>

FAQ on Personal Protective Equipment:

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html>

FDA webpages:

General: www.fda.gov/novelcoronavirus

EUAs: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

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