



Solutions in Respiratory and Sleep Therapy

Instructions for Healthcare Personnel: Preparation and Collection of Compatible N95 Respirators for Bioburden Reduction Using the Lumin LM3000 Bioburden Reduction UV System

The U.S. Food and Drug Administration has issued an Emergency Use Authorization (EUA) for the emergency use of the Lumin LM3000 Bioburden Reduction UV System (hereafter referred to as the “Lumin LM3000”) for use in bioburden reduction of 3M model 1860 N95 respirators (also referred to as “compatible N95 respirators”) for single-user reuse by healthcare personnel (HCP) to supplement the Centers for Disease Control and Prevention (CDC) reuse recommendations. Healthcare personnel should follow these instructions, as well as procedures at their healthcare facility, to prepare compatible N95 respirators for bioburden reduction using the Lumin LM3000.

The Lumin LM3000 has been authorized by FDA under an EUA for bioburden reduction of **3M model 1860 N95 respirators only** for single-user reuse by HCP to supplement CDC reuse recommendations to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates. The Lumin LM3000 has not been FDA cleared or approved for this use. The Lumin LM3000 is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices, during the COVID-19 outbreak, under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Respirators that are NIOSH-approved before bioburden reduction (<https://wwwn.cdc.gov/niosh-cel/>) only retain their NIOSH approval status post-bioburden reduction if the respirator manufacturer permits the use of the bioburden reduction method with the specific system and cycle parameters. To determine the NIOSH approval status of a specific bioburden-reduced NIOSH-approved respirator, please check with the respirator manufacturer and/or the respirator labeling. If a respirator is no longer NIOSH-approved after use of the particular bioburden reduction method, its performance (i.e., fit, filtration, and breathability) might not consistently meet NIOSH-approved N95 standards.

WARNING: The Lumin LM3000 does not sterilize or decontaminate. Prior to use of the Lumin LM3000 to reduce bioburden on the compatible N95 respirator, the respirator must be placed in a breathable paper bag and held for a minimum of 5 days, in accordance with the CDC recommendations for reuse of N95 respirators.

The Lumin LM3000 utilizes a 10 minute ultraviolet germicidal irradiation (UVGI) cycle to reduce the bioburden on one compatible N95 respirator at a time by exposing the outer surface of the respirator for 5 minutes followed by the exposing the inside surface of the respirator for 5 minutes. Use of the Lumin LM3000 for bioburden reduction on compatible N95 respirators permits single-user reuse of respirators up to 4 times, or a total of 5 respirator uses. If used as directed, the Lumin LM3000 offers a reliable method for achieving a 3-log mean reduction in non-enveloped virus, which provides additional safety when used to supplement the CDC reuse recommendations of a 5-day wait time.

Intended Environments for Use: The Lumin LM3000 is intended for single-user reuse by healthcare personnel serving in healthcare settings, including nursing homes, assisted living facilities, primary care offices, and clinics.



Caution: Bioburden reduction is not decontamination or sterilization. Specifically, bioburden reduction is a term used to indicate that a product or process provides a lower level of pathogen reduction than a product or process that provides decontamination, disinfection, or sterilization. However, information on bioburden reduction shows this method may be effective against SARS-CoV-2 when used as a supplement to CDC reuse recommendations. Please refer to the CDC recommendations for Decontamination and Reuse of Filtering Facepiece Respirators, available at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html>, Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings, available at <https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html>, and Summary for Healthcare Facilities: Strategies for Optimizing the Supply of N95 Respirators during Shortages, available at <https://www.cdc.gov/coronavirus/2019-ncov/hcp/checklist-n95-strategy.html>. Consistent with CDC reuse recommendations, it is critical that the respirator must be allowed to rest for 5 days to reduce the risk of inhaling pathogens that may remain in the filter material.

Caution: The Lumin LM3000 Bioburden Reduction UV System is only authorized for use with the 3M model 1860 N95 respirator. The Lumin LM3000 is not authorized for use with any other respirator model or any other types of personal protective equipment.

Caution: Sunscreens block UV light. The Lumin LM3000 may not be effective on N95 respirators tainted with facially applied sunscreen.

Caution: Compatible N95 respirators used in the Lumin LM3000 Bioburden Reduction UV System must be free of visible damage and soil/contamination (e.g., blood, respiratory or nasal secretions, or other bodily fluids; makeup, sunscreen, or other soil). Discard any soiled respirator.

The instructions below provide critical information regarding use/reuse of N95 respirators. For complete and up-to-date recommendations, please see CDC's reuse recommendations, available at the website links provided above.

- Discard compatible N95 respirators after 4 bioburden reduction cycles or 5 donnings, whichever comes first.
- Discard any compatible N95 respirator whose traceability was lost (name or number of cycles are not clear).
- Discard compatible N95 respirators that were used during aerosol generating procedures.
- Discard compatible N95 respirators following contact with any patient co-infected with an infectious disease requiring respiratory or contact precautions.
- Discard compatible N95 respirators that are damaged, discolored, or visibly soiled.
- Discard any compatible N95 respirator that becomes hard to breathe through.

- Consider use of a cleanable face shield (preferred) over a compatible N95 respirator and/or other steps (e.g., masking patients, use of engineering controls), when feasible to reduce surface contamination of the respirator.
- Use a pair of clean gloves when donning a compatible N95 respirator and performing a user seal check.
- Discard gloves after the compatible N95 respirator is donned and any adjustments are made to ensure the respirator is sitting comfortably on your face with a good seal.
- Avoid touching the inside of the respirator. If inadvertent contact is made with the inside of the respirator, discard the respirator and gloves.
- Healthcare personnel must perform a user seal check of the compatible N95 respirator according to OSHA standard prior to beginning a shift. If the user seal check does not pass, discard the respirator.

Compatible N95 Respirator Marking and Collection

The healthcare facility will institute a standard process for chain of custody to ensure that contaminated, compatible N95 respirators are separated from bioburden reduced, compatible N95 respirators at all times and that your compatible N95 respirator is returned to you (i.e., single-user reuse).

The healthcare facility will create a collection station at the point of respirator use, with a container to collect the paper bags with contaminated, compatible N95 respirators.

Prior to bioburden reduction:

1. Prior to first use of a compatible N95 respirator, use a permanent marker to label the individual compatible N95 respirator with your name and any other needed identifying information.
2. After each use of the compatible N95 respirator, place the respirator into an unused paper bag and then remove your gloves, disposing of them in a biohazard waste bin.
3. With clean hands, label the paper bag with your name and any other needed identifying information, the date, and the word "CONTAMINATED".
4. Compatible N95 respirators with visible soil, wear, or damage, or 4 tick marks must not be placed in the paper bag. Dispose of the respirator in a biohazard waste bin.
5. Transfer paper bag to "contaminated" holding area and log in the compatible N95 respirator in the Chain of Custody Log Form.
6. Place the bag in the designated contaminated respirator collection area, where it will be held for a minimum of 5 days.

Following bioburden reduction:

1. After a minimum of 5 days and after a bioburden reduction cycle, your bioburden reduced, compatible N95 respirator will be placed in an unused paper bag labeled with your name and the phrase "READY FOR USE," and placed in the location designated for respirators that can be re-used.

2. Remove the bioburden reduced, compatible N95 respirator from the paper bag with clean (nonsterile) gloves. After bioburden reduction and prior to donning your bioburden reduced, compatible N95 respirator, check the respirator for the following:

- Confirm that the name and/or identifying information on the respirator is yours.
- Assess the respirator visually for damage to straps or mask filter; discard if damaged.
- Assess the respirator visually for soil; discard if soiled.
- Assess the tick marks on the respirator; if 5 or more tick marks are present, discard the respirator.
- Put on the respirator with gloved hands and assess for fit and seal; discard if fit is poor.

Caution: Discard any compatible N95 respirator whose traceability was lost (name or number of cycles are not clear).

Reporting: Report any problems with the bioburden reduced, compatible N95 respirators to your healthcare facility.

REVOKED