

FACT SHEET FOR HEALTHCARE PERSONNEL

Lumin LM3000 for Bioburden Reduction of Compatible N95 Respirators

December 3, 2020

Coronavirus
Disease 2019
(COVID-19)

You have been given a **bioburden reduced N95 respirator** that has been bioburden reduced using a system that is authorized for bioburden reduction of 3M Model 1860 N95 respirators (“compatible N95 respirators”) **for single-user reuse by healthcare personnel (HCP) in a healthcare setting** (i.e., the same respirator is returned for reuse to the same HCP following its bioburden reduction) to supplement the Centers for Disease Control and Prevention (CDC) reuse recommendations to help prevent HCP 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 bioburden reduced, compatible N95 respirators. These compatible N95 respirators have been bioburden reduced using the Lumin LM3000 Bioburden Reduction UV System (hereafter referred to as “**bioburden reduced N95 respirators**” and “**Lumin LM3000**” 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 Lumin LM3000 and bioburden reduced N95 respirators?

- The Lumin LM3000 has been authorized for emergency use for bioburden reduction of compatible N95 respirators for single-user reuse by HCP during the COVID-19 pandemic to prevent wearer exposure to pathogenic biological airborne particulates, including SARS-CoV-2.
 - **Compatible N95 respirators are limited to the 3M Model 1860 N95 respirators only.** The Lumin LM3000 is **not authorized** for use with any other respirator model or any other type of personal protective equipment.
- 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, Recommended Guidance for Extended Use and Limited Reuse of N95 Filtering Facepiece Respirators in Healthcare Settings, and Summary for Healthcare Facilities: Strategies for Optimizing the Supply of N95 Respirators during Shortages*.
- Consistent with CDC reuse recommendations, it is critical that the **compatible N95 respirator must be allowed to rest for 5 days** to reduce the risk of inhaling pathogens that may remain in the filter material.
- Bioburden reduction requires all surfaces and components of the respirator, including the straps, be exposed to adequate doses of UV light. Any shadowing or obstruction resulting from device features, load organization, or chamber design could prevent successful bioburden reduction. Therefore, place a single, compatible N95 respirator in the Lumin LM3000 for bioburden reduction.
- Compatible N95 respirators used in the Lumin LM3000 must be free of visible damage and

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soil/contamination (e.g., blood, respiratory or nasal secretions, or other bodily fluids; makeup, sunscreen, or other soil). Discard any soiled respirator.

- Sunscreens block UV light. The Lumin LM3000 may not be effective on N95 respirators tainted by facially applied sunscreen.
- Successful testing on bioburden reduced N95 respirators demonstrated acceptable performance through 4 bioburden reduction cycles for viricidal activity and qualitative fit testing. Testing demonstrated a 3-log mean reduction in non-enveloped virus applied to the surface of compatible N95 respirators.

- **Use of bioburden reduced N95 respirators:**

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.

- ✓ Inspect compatible N95 respirators after each use prior to submission for bioburden reduction.
- ✓ 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 close contact with any patient co-infected with an infectious disease requiring 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 taking 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.
- ✓ Report problems with bioburden reduced N95 respirators to your healthcare facility.

- **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 bioburden reduced N95 respirators, and potential exposure of HCP from breaks in or other damage to or degradation of the bioburden reduced N95 respirators to your healthcare facility.
- Respirators that are NIOSH-approved before bioburden reduction (<https://www.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 check the respirator labeling. If a respirator is no longer NIOSH-approved after use of the particular bioburden

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reduction 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 bioburden reduced N95 respirators that were bioburden reduced using the Lumin LM3000?

Potential benefits include:

- May help prevent exposure to airborne pathogens, and therefore reduce the risk of infection or illness
- Extends the usability and reuse of compatible N95 respirators by additionally performing a 3-log mean bioburden reduction beyond the natural decay of SARS-CoV-2 when CDC recommendations are followed alone
- Lumin LM3000 is small, lightweight, portable, and economical, allowing for bioburden reduction of compatible N95 respirators at mobile or smaller healthcare facilities

Potential risks include:

- Inadequate bioburden reduction of SARS-CoV-2 or other pathogens due to insufficient UV delivery to respirators
- Failure of filtration efficiency
- Reduced breathability
- Strap failure and ineffective face-fit
- UV exposure
- Electrical and Electromagnetic Compatibility (EMC) hazards

Overview of the Lumin LM3000

The Lumin LM3000 utilizes ultraviolet germicidal irradiation (UVGI) 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 exposing the inside of the surface of the respirator for 5 minutes. The Lumin LM3000 emits UV-C light at 254 nm under a nominal dose of 1 J/cm². **Two 5 minute cycles of 1 J/cm², one 5 minute cycle on each side of the compatible N95 respirator, is considered one bioburden reduction cycle.** A UV dosimetry strip with a sensitivity of 1 J/cm² is placed in every cycle to confirm the proper dose has been provided. The Lumin LM3000 supports single-user reuse of compatible N95 respirators in addition to, and not in lieu of, the CDC reuse recommendations (e.g., store respirator in a breathable paper bag for a minimum of five days between each use).

The Lumin LM3000 is only authorized to reduce the bioburden of 3M Model 1860 N95 respirators. The Lumin LM3000 is not authorized for use with any other respirator model or other types of personal protective equipment.

Respirators that are visibly soiled or that have been exposed to bodily fluids or used in aerosol-generating procedures must be discarded and not reused or bioburden reduced.

What is an EUA?

The United States Food and Drug Administration (FDA) has made the emergency use of the Lumin LM3000 to reduce the bioburden on 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 due to insufficient supply during the COVID-19 pandemic.

The Lumin LM3000 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

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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 that the Lumin LM3000 may be effective at preventing HCP exposure to pathogenic biological airborne particulates during periods of insufficient respirator supply during the COVID-19 pandemic by reducing the bioburden, for a maximum of 4 bioburden reduction cycles, or 5 donnings, whichever comes first, per respirator, on compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms.

The EUA for the Lumin LM3000 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 PPE:

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

Decontamination and Reuse of Filtering Facepiece Respirators:

<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:

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

Summary for Healthcare Facilities: Strategies for Optimizing the Supply of N95 Respirators during Shortages:

<https://www.cdc.gov/coronavirus/2019-ncov/hcp/checklist-n95-strategy.html>

FDA webpages:

General: www.fda.gov/novelcoronavirus

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

REVIEW

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