FACT SHEET FOR HEALTHCARE PERSONNEL

Lumin LM 3000 Bioburden Reduction UV System for Decontaminating Compatible N95

May 8, 2020

Coronavirus Disease 2019 (COVID-19)

You have been given a **N95 respirator or N95-equivalent respirator** ("N95 respirators with convex and concave surfaces") that has had the bioburden reduced using a bioburden reduction system **for single-user reuse by healthcare personnel in a healthcare setting** to help prevent healthcare personnel exposure to pathogenic biologic 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 3B Medical Inc.'s *Lumin LM 3000 Bioburden Reduction UV System,* (hereafter also referred to as "**bioburden reduced N95 respirators**" and or "**Lumin Bioburden Reduction Cycle**" throughout this Fact Sheet).

Bioburden Reduced N95 respirators that have been bioburden reduced using the Lumin LM 3000 Bioburden Reduction UV System are authorized for single-user reuse by healthcare personnel in a healthcare setting during the COVID-19 pandemic.

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. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

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 bioburden reduced N95 respirators?

- The Lumin LM 3000 Bioburden Reduced UV System has been authorized for emergency use to reduce the bioburden from N95 respirators that have convex and concave surfaces for single-user reuse by healthcare personnel during the COVID-19 pandemic to prevent wearer exposure to pathogenic airborne particulates.
  - ✓ N95 respirators are those that are **not** soft-bodied respirators, foldable respirators, duck billed respirators, filters made of hydrophilic materials, and respirators with expiratory valves

- [The Lumin LM3000 Bioburden Reduction UV System provided UV-C dose (minimum of 1J/cm^2) measurements and UVC irradiance testing for material compatibility on bioburden reduced N95 respirators. In addition, the Lumin LM3000 Bioburden Reduction demonstrated a 3 log reduction of Bacillus pumilus. The Lumin LM3000 Bioburden Reduction UV system demonstrated acceptable performance through 10 bioburden reduction cycles.

FACT SHEET FOR HEALTHCARE PERSONNEL

Lumin LM 3000 Bioburden Reduction UV System for Decontaminating Compatible N95

May 8, 2020

Coronavirus Disease 2019 (COVID-19)

- Bioburden Reduction of N95 Respirators that have concave and convex surfaces are not Sterile.
- The Lumin LM3000 Bioburden Reduction UV System inactivates the SARS-CoV-2 virus on N95 respirators that have concave and convex surfaces when exposed on both sides for 5 minute cycle on each side for a total of 10 minutes.
- Testing has not been conducted to show its effectiveness to reduce levels of other pathogens on N95 respirators.
- Bioburden Reduction requires all surfaces and features to be exposed to adequate doses of UV light. Any shadowing or obstruction resulting from device features, load organization or chamber design could prevent successful reduction in bioburden.

Preparing N95 respirators for Bioburden Reduction

- Place N95 respirators at the end of use into poly bags
- Write name and/or other identifier using a permanent marker so the respirator may be returned after successful decontamination
- Place a tick mark on respirator each time a respirator is prepared for bioburden reduction
- Seal the N95 respirator in the poly bag and place it into area for subsequent bioburden reduction per your healthcare facility's procedures
- **Discard if bioburden reduced 10 times** or if visibly soiled or damaged

Use of Lumin LM3000 Bioburden Reduction UV System

- Visually inspect the respirator for obvious signs of wear and tear. Discard any respirator with any fluid or stain.
- Use gloves or a disinfecting wipe to open the Lumin drawer to avoid contaminating the outside of the device.
- Place the N95 respirator concave side up on the acrylic rack.
- To ensure bioburden reduction of the straps, remove any tangles or knots from straps so that there is clear UVC light access to the full length of the straps.
- Press the start button. The Lumin LM3000 Bioburden Reduction UV System is pre-programmed for a 5 minute cycle.
- After the 5 minute cycle is completed, flip the respirator to the convex side and ensure straps are untangled to permit UVC light to reach all areas without shadowing.
- Press start button again an allow for the convex side to be exposed to the UVC dose for a 5 minutes, for a total of 10 minutes per respirator.
- Wash hands thoroughly for 20 seconds prior to removing respirator from the Lumin LM 3000 System to avoid cross contamination.
- Each successive decontamination of the respirator should be marked as a check on the respirator
- Discard N95 respirator after 10 uses

Preparing compatible N95 respirators for Use after Bioburden Reduction

- ✓ Complete a self-seal check prior doffing and submitting for decontamination. If respirator cannot be sealed appropriately, do not use and do not send for decontamination.
- ✓ Your name/ID should be placed using a permanent marker on the external outer edge of the mask prior to donning a new mask.

- ✓ Your mask will be returned to you after decontamination. You will not be given another users mask. You should confirm your name/ID on the mask prior to wearing.

Monitor healthcare personnel 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 3B Medical Inc.

Report damage or discoloration observed upon receipt of the bioburden reduced N95 respirator, and potential exposure of healthcare personnel from breaks or other damage or degradation of the bioburden reduced N95 respirators.

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 Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID- 19 in Healthcare Settings, Infection Control, and FAQ about 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?

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 or N95-equivalent respirators by allowing for bioburden reduction and single-user reuse.

Potential risks include:

- Inadequate disinfection due to improper placement of multiple items or masks during a single cycle. UVC systems work optically and are ineffective due to shadowing of other objects.
- Failure of filtration efficiency
- Reduced breathability
- Strap failure and ineffective face-fit
- Reused respirators may not have been effectively bioburden reduced of SARS- CoV-2 or other pathogens
- User should refrain from wearing sunscreen when using respirator as it will soil the respirator making it ineligible for use with the Lumin.

Overview of the Lumin LM 3000 Bioburden Reduction UV System

The Lumin LM 3000 Bioburden Reduction UV System is a self-contained bioburden reduction device that is normally used as an adjunct for cleaning CPAP Accessories (Masks, Hoses, and Water chamber). For this emergency use, the Lumin LM 3000 Reduction UV System is intended for bioburden reduction of compatible N95 or N95-equivalent respirators that are contaminated or potentially contaminated with SARS-CoV-2 and other pathogenic microorganisms. **N95 respirators that are soft-bodied respirators, foldable respirators, filters made of hydrophilic materials, and respirators with expiratory valves are not compatible with the Lumin LM 3000 UV Bioburden Reduction process**

The Lumin LM3000 **Bioburden Reduction** UV System works by delivering a relatively high dose of ultraviolet germicidal irradiation (UVGI). Each decontamination cycle results in an estimated irradiance of 1 J/cm^2 in a 5 minute cycle. The Lumin

LM3000 Bioburden Reduction UV System can bioburden reduce **one (1) N95 respirator** by performing a 5 minute cycle on the concave side and performing a 5 minute cycle on the convex side. The Lumin LM3000 Bioburden Reduction UV System enables single-user reuse of compatible N95 respirators that would otherwise be disposed of after a single use. However, respirators that are visibly soiled must be discarded and not reused or bioburden reduced.

What is an EUA?

The United States FDA has made the emergency use of the Lumin LM 3000 Bioburden Reduction UV System to bioburden reduce 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 Lumin LM 3000 Bioburden Reduction UV 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 that the Lumin LM 3000 Bioburden Reduction UV System may be effective at preventing healthcare personnel exposure to pathogenic airborne particulates during periods of insufficient respirator supply during the COVID-19 pandemic by decontaminating compatible N95 respirators, for a maximum of 10 bioburden reduction cycles per respirator, that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms.

The EUA for the Lumin LM 3000 Bioburden Reduction UV System by 3B Medical 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
Infection Prevention and Control Recommendations in Healthcare Settings: 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