LM3000

INSTRUCTIONS FOR HEALTHCARE FACILITIES: LUMIN LM3000 BIOBURDEN REDUCTION UV SYSTEM USER'S MANUAL

MODEL: LM3000

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.

EXPLANATION OF SYMBOLS USED


Equipment protected throughout by double insulation or reinforced insulation.


Refer to instruction manual.


Important information concerning your safety or the operation of your device.

COMPATIBLE N95 RESPIRATORS

The Lumin LM3000 is only authorized for use with the 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.

INTENDED ENVIRONMENTS FOR USE

The Lumin LM3000 Bioburden Reduction System is intended for bioburden reduction of compatible N95 respirators for single-user reuse by healthcare personnel serving in healthcare settings, including nursing homes, assisted living facilities, primary care offices, and clinics, to supplement CDC reuse recommendations.

SPECIFICATIONS

SKU:	LM3000
Weight:	5.5
Dimensions:	12.25 x 8.5 x 7.75”
Voltage:	AC 110 V 60Hz AC 220 V 50Hz
Power Rating:	13W

Environmental Conditions:

Storage Temperature: 0˚ to 120˚ F / 18˚ to 49˚ C
Operating Temperature: 20˚ to 100˚ F / 7˚ to 38˚
Humidity: Up to 93%, non condensing

Use of Lumin LM3000 Bioburden Reduction UV System

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 LM 3000 Reduction UV System is intended for use in bioburden reduction of compatible N95 respirators in healthcare facilities for single-user reuse by healthcare personnel to supplement CDC reuse recommendations.[1] The Lumin LM3000 Bioburden Reduction UV System supplements single-user reuse (i.e., the same respirator is returned for reuse to the same healthcare personnel following bioburden reduction) of compatible N95 respirators that are placed in a paper bag and held for a minimum of 5 days in accordance with CDC reuse recommendations. 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. A compatible N95 respirator can be worn up to 5 times, or after four bioburden reduction cycles using the Lumin LM3000, whichever comes first.

The Lumin LM3000 is authorized only for use as a supplement to CDC reuse recommendations for single-user reuse of N95 respirators. Place the compatible N95 respirator in a paper bag for a minimum of five days prior to placing the compatible N95 respirator in the Lumin LM3000.

The Lumin LM3000 Bioburden Reduction UV System works by delivering ultraviolet germicidal irradiation (UVGI). Each bioburden reduction cycle results in an estimated irradiance of 1 J/cm^2 per 5 minute cycle. The Lumin LM3000 Bioburden Reduction UV System can bioburden reduce one (1) compatible N95 respirator at a time by performing two 5-minute cycles, one with the outer surface of the respirator facing up and one with the inner surface of the respirator facing up. **Two 5 minute cycles of 1 J/cm^2 (i.e., one 5 minute cycle on each side of the compatible N95 respirator) is considered one bioburden reduction cycle.**

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 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

[1] The CDC has issued specific recommendations on the reuse of N95 respirators. 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.

- 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 the item placed in the device
- Failure of filtration efficiency
- Reduced breathability
- Strap failure and ineffective face-fit
- UV exposure
- Electrical and Electromagnetic Compatibility (EMC) hazards

What is bioburden reduction?

- **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 provide 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.
- 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 device.

How much virus will remain on my N95 respirator after use of the Lumin LM3000?

- The Lumin LM3000 will reduce the amount of virus on the N95 respirator by up to 99.9%. This means that if the N95 respirator had 1 million virus particles, 1000 may remain. Therefore, do not treat the N95 respirator as sterile. Touch it only with gloves, and do not share it.
- Testing has not been conducted to show that the Lumin LM3000 reduces all bacteria, molds, fungi, or viruses from the N95 respirator. Therefore, if the N95 respirator was used near a patient with another infectious disease, discard the respirator.

What N95 respirators can be put into the Lumin LM3000?

- **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.
- Do not put face masks, surgical masks, goggles, or other medical devices in the Lumin LM3000. The

LM3000 has not been authorized for use on any product other than 3M model 1860 N95 respirators.

Are there other measures to ensure the N95 respirator can be re-used?

- Re-use compatible N95 respirators only if they have been kept in a paper bag for a minimum of 5 days in addition to undergoing bioburden reduction using the Lumin LM3000. The compatible N95 respirator must be placed in the paper bag for a minimum of 5 days BEFORE use of the Lumin LM3000 in order to reduce contamination of the Lumin LM3000 when the respirator is placed in the drawer.
- Discard compatible N95 respirators after 4 bioburden reduction cycles or 5 donnings, whichever comes first.
- **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.
- **Caution:** Sunscreens block UV light. The Lumin LM3000 may not be effective on N95 respirators tainted with facially applied sunscreen.

The instructions below provide some 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.

Below are some examples of engineering controls and practices for healthcare facilities to implement in addition to the use of the bioburden reduction system. For complete and up-to-date recommendations, please see CDC's reuse recommendations, available at the website links provided above.

- Healthcare facilities shall perform a risk assessment to determine which additional CDC recommended

engineering controls and practices must be in place in order to use the Lumin LM3000.

- The healthcare worker will wear one respirator each day and store it in a breathable paper bag at the end of each shift. The respirator must not be used for at least 5 days.
- To minimize potential cross-contamination, store respirators so that they do not touch each other and the person using the respirator is clearly identified. Storage containers must be disposed of or cleaned regularly.
- Extend the use of N95 respirators by wearing the same N95 respirator for repeated close contact encounters with several different patients, without removing the respirator per CDC's recommendations on implementation of extended use.

DIRECTIONS FOR USE

Materials Needed:

1. Gloves
2. Facial/respiratory protection
3. Gown
4. Paper bags
5. Alcohol pads
6. Disinfecting wipes
7. Permanent marking tool
8. CONTROL-CURE® UV FASTCHECK™ STRIPS for 1,000 mJ/cm^2 exposures
9. UVC blocking goggles or glasses
10. Chain of Custody Log Form

Compatible N95 Respirator Collection and Transportation:

The healthcare facility will instate 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 the respirator is returned only to its previous respirator user (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. If compatible N95 respirators will be transported to the collection station from another room in the facility, the contaminated, compatible N95 respirators will be individually contained to prevent aerosolization of pathogens from the contaminated respirator or contact between two contaminated respirators.

The healthcare facility will designate and train all staff members who will perform bioburden reduction. Training will include collection, transportation, 5 day minimum wait time monitoring, inspection of the compatible N95 respirators for soil, inspection of the compatible N95 respirator for the number of donnings or cycles completed, correct operation of the Lumin LM3000, post-cycle inspection of compatible N95 respirators for integrity, and protocol to assure that the bioburden reduced, compatible N95 respirator is returned to the original user.

The healthcare facility will routinely screen individuals performing bioburden reduction for COVID-19 to ensure that personnel have not been exposed due to implementation of processes and that respirators are not contaminated by personnel.

Prior to first use of a compatible N95 respirator, the healthcare personnel will use a permanent marker to label the individual compatible N95 respirator with their name and any other needed identifying information. After each use of the compatible N95 respirator, the healthcare personnel will place the respirator into an unused paper bag and then remove their gloves. With clean hands, the personnel will label the paper bag with their name and any other needed identifying information, the date, and the word “CONTAMINATED”. The bag will be placed in or transported to the designated contaminated respirator collection area, where it will be held for a minimum of 5 days, and logged in the Chain of Custody Log Form.

Compatible N95 Respirator Collection and Instructions for Bioburden Reduction

Caution: UVC light presents a safety hazard to operators if exposed. Wear UVC-protective eye wear at all times.

<u>Preparation for bioburden reduction</u>

1. Don long sleeved coat, gloves, N95 respirator, goggles or face shield, and hair cover prior to

handling contaminated, compatible N95 respirators.

2. Check date on paper bag to ensure it has been held for at least 5 days prior to bioburden reduction.
3. Confirm the compatible N95 respirator is model 3M 1860 (aqua colored exterior).
4. Confirm the name on the compatible N95 respirator matches the name on the bag.
5. Discard bag in biohazard waste bin.
6. Visually inspect the compatible N95 respirator for:
   a) Wear (if damaged, discard and inform user)
   b) Soil (if soiled, discard and inform user)
   c) Number of tick marks (if 4 marks, discard and inform user).

Important: If the compatible N95 respirator has signs of wear, soil, or has lost traceability (name or number of cycles), discard the respirator and notify the user.

Bioburden reduction

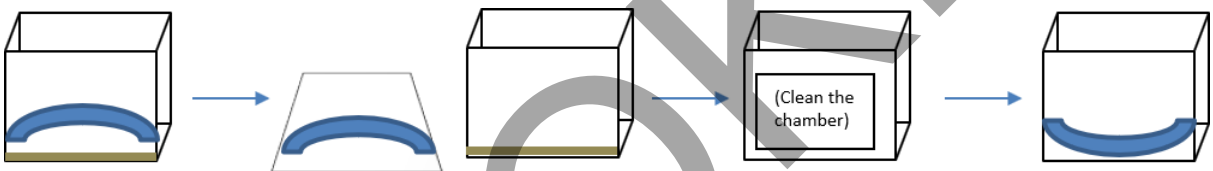
1. Open Lumin LM3000 drawer with clean gloved hands.
   Important: Lumin LM3000 works only when the compatible N95 respirator is directly exposed to the UV light. Place a single compatible N95 respirator in the device.
2. Place compatible N95 respirator in Lumin LM3000 drawer, with the outer surface of the compatible N95 respirator facing up. Please see graphic below.
3. Confirm that the elastic bands are not in the way of the UV light.
4. Change gloves.
5. Place an unused UV indicator strip, with sensitivity of 1 J/cm^2, in the drawer, facing up on the acrylic base of the drawer next to the compatible N95 respirator. This will change color if a complete dose has been delivered. 3B Medical recommends CONTROL-CURE® UV FASTCHECK™ STRIPS for 1,000 mJ/cm^2 exposures.
6. Close the drawer and press button to initiate 5 minute cycle. The Lumin LM3000 is pre-programmed for a 5 minute cycle.
   Caution: Do NOT open the drawer before the cycle is completed. If the drawer is opened before the cycle is complete, the compatible N95 respirator has not been fully irradiated. Repeat the complete 5 minute cycle.
7. Change gloves.
8. At conclusion of cycle, confirm the UV indicator strip has changed color to confirm a full dose of UV has been delivered.
   Caution: If the strip does not change color, the compatible N95 respirator has not been exposed to a sufficient dose of UV and must be put aside. Call 3B Medical for guidance and possible service. Do not use the device until 3B has provided instructions or serviced the device.

   Important: While the compatible N95 respirator is being exposed to UV, the surface of the UV drawer that is under the compatible N95 respirator is in contact with a contaminated respirator surface, and it is not being irradiated with UV because it is shielded from UV by the respirator. Therefore, the bottom of the drawer is contaminated and must be cleaned before the compatible N95 respirator is turned over, to prevent re-contamination of the outer surface of the respirator, which was already exposed to UV.

9. With clean gloves, remove the compatible N95 respirator and place on clean paper towel, with the outer surface of the compatible N95 respirator facing up.
10. Clean base of drawer with alcohol wipe or run a cycle of the Lumin LM3000 with no respirator to remove pathogens that remain in the drawer of the Lumin LM3000.
11. Change gloves.
12. Place the compatible N95 respirator in drawer, with the inner surface of the compatible N95 respirator facing up.
13. Confirm that the elastic bands are not in the way of the UV light.

14. Change gloves.
15. Place a UV indicator strip in the drawer, facing up.
16. Close drawer and press button to initiate 5 minute cycle.
17. Change gloves.
18. At conclusion of cycle, confirm the UV indicator strip has changed color to confirm a full dose of UV has been delivered.
    Caution: If the strip does not change color, the compatible N95 respirator has not been exposed to a sufficient dose of UV and must be put aside. Call 3B Medical for guidance and possible service. Do not use the device until 3B has provided instructions or serviced the device.

19. Remove the bioburden reduced, compatible N95 respirator from the Lumin LM3000.
20. Inspect the bioburden reduced, compatible N95 respirator for signs of damage to the respirator or elastic bands. If the respirator is damaged, the staff will discard the respirator and inform the user.
21. Add tick mark to the bioburden reduced, compatible N95 respirator.
22. Place the bioburden reduced, compatible N95 respirator in paper bag, label "READY FOR USE" and add user's name.
23. Move the bioburden reduced, compatible N95 respirators to the area designated for "READY FOR USE" respirators.



Schematic for one compatible N95 respirator:

- Run a cycle with the respirator's outer (blue) surface facing up.
- Remove the respirator, maintaining the orientation, and place on a clean paper towel.
- Clean the base of the drawer.
- Place respirator in drawer blue side down.
- Discard the paper towel.

Protection of Bioburden Reduction Staff

- Select a location for handling of contaminated, compatible N95 respirators and placement of the Lumin LM3000. It is recommended that the Lumin LM3000 be placed in a separate area, apart from any area used for clean/sterile supplies or food.
- Maintain the Chain of Custody Log Form at each bioburden reduction station.
- Handle all used, compatible N95 respirators as though they are contaminated.
- Don appropriate PPE (e.g., gloves, facial/respiratory protection, gown) when handling contaminated, compatible N95 respirators and while performing bioburden reduction to prevent transmission of pathogens between the respirators and bioburden reduction staff.
- Document the dates and names of all individuals whose compatible N95 respirators are placed in the Lumin LM3000 and the names of all persons performing the bioburden reduction. This will allow contact tracing in the event that an employee tests positive for COVID-19.
- Your facility will screen or test you regularly for COVID-19, as per facility practices.

Before first use of the Lumin LM3000, after replacing the bulb, and once per month:

Caution: UVC light presents a safety hazard to operators if exposed. Wear UVC-protective eye wear at all times.

1. Clean out the UV drawer with a wet cloth or paper towel to remove any residue or dust.
2. With the device unplugged and the drawer open, install the UV lamp (part number LM 1001) into the device and push firmly into place.
3. Don UVC blocking goggles or glasses.
4. Perform a test cycle without a respirator: place two commercially available UV chemical indicator strips, which change color when a dose of 1 J has been delivered, on the acrylic base on which the respirator will be located in future cycles. 3B Medical recommends CONTROL-CURE® UV FASTCHECK™ STRIPS for 1,000 mJ/cm^2 exposures. 1000 mJ = 1 J, the dose emitted in a 5 minute cycle in the Lumin LM3000.
5. Run a 5 minute cycle (1 J should be emitted).
6. Assess whether the indicator strips have changed color and whether the color change is even.
7. Remove the indicator strips and place two new strips at different locations on the acrylic base. Run a 5 minute cycle.
8. Assess whether the indicator strips have changed color and whether the color change is even.
9. **Caution**: <u>If the strips have not changed color, or if the color is not even across the strip, contact 3B Medical for assistance. Do not use the device until 3B Medical has provided a solution to ensure the dose is reliably and evenly delivered</u>.

General Instructions for Care and Maintenance of the Lumin LM3000:

Caution: The Lumin LM3000 Bioburden Reduction UV System's UVC output may start to deteriorate after 9,000 hours or 56,000 cycles. In heavy use environments (i.e., > 10 uses daily), it is recommended that the Lumin UVC bulb be replaced annually to ensure optimal efficacy.

Caution: As the Lumin LM3000 Bioburden Reduction UV System relies on light reflection, keep mirrored surfaces clean. Use only water and a mild dishwashing liquid to carefully wipe mirrored surface. Do not use any abrasive powders or liquids as these might scratch the polished mirrored surface and impair reflection and refraction.

1. Avoid cross-contamination by using disinfecting wipes (e.g., Lysol, Clorox, or any other EPA registered disinfecting wipes for COVID-19) to wipe the exterior of the Lumin LM3000 Bioburden Reduction UV System between uses. Particular care must be used in frequent disinfecting of the drawer handle.
2. Clean the inside of the Lumin LM3000 Bioburden Reduction UV System with an alcohol wipe after each use to prevent cross-contamination between respirators. As an alternative, you may run a 5 minute cycle without a respirator to clean the drawer.
3. As the Lumin LM3000 Bioburden Reduction UV System relies on light reflection, keep mirrored surfaces clean. Use only water and a mild dishwashing liquid to carefully wipe mirrored surface. Do not use any abrasive powders or liquids as these might scratch the polished mirrored surface and impair reflection and refraction.
4. The Lumin LM3000 Bioburden Reduction UV System's UVC output may start to deteriorate after 9,000 hours or 56,000 cycles. In heavy use environments (i.e., > 10 uses daily), it is recommended that the Lumin UVC bulb be replaced annually to insure optimal efficacy.
5. **CAUTION**: unplug the Lumin LM3000 before uncasing or replacing the UVC bulb.
6. Bulb disposal:
    - The UV bulb contains mercury. Dispose of the bulb as per local regulations for hazardous substance disposal.

- Handle the bulb as a contaminated surface. Don all appropriate PPE when handling a used bulb.

7. If you have any problems or questions concerning this device, please contact 3B Medical Technical Support at email: TechSupport@3Bproducts.com or by visiting the Support tab on our corporate website at www.3Bproducts.com and creating a support ticket. Alternatively, our technical support team is available during normal business hours (i.e. M-F 8:30 am to 5 pm) at (863) 226-6285.
8. **If the device malfunctions, continue with the 5-day minimum interval between reuses, as per the CDC reuse recommendations. Report any problems immediately to 3B Medical using the contact information provided above.**

REPORTING

Healthcare facilities must report any discoloration or other signs of degradation with a bioburden reduced, compatible N95 respirator to 3B Medical, and the healthcare facility must discard the respirator. Healthcare facilities must report adverse events of which they become aware related to the Lumin LM3000 and the bioburden reduced, compatible N95 respirators. This includes, but is not limited to, monitoring personnel using the Lumin LM3000 and healthcare personnel using the bioburden reduced, compatible N95 respirators for signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection and reporting such infections. **Report Adverse events** to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088.**

WARRANTY

The Lumin LM3000 is warrantied for a period of 2 years from time of purchase to be free from manufacturer defect or workmanship. Should you encounter a warranty issue please contact 3B Medical at www.3BLumin.com to submit a return authorization or email support@3bproducts.com.

It is at the discretion of 3B Medical to repair, replace, or exchange your Lumin LM3000 unit should it be necessary. 3B Medical is not liable for misuse, mishandling, or breach of this written guarantee. Attempts to alter the Lumin LM3000 in any way will void the warranty.

Please register your Lumin at www.3BLumin.com

LM3000 LUMIN BIOBURDEN REDUCTION UV SYSTEM

This device complies with Part 18 of the FCC Rules.

WARNING: This equipment has not been tested based on FDA-recognized standard IEC 60601-1-2:2014. It may produce electromagnetic disturbances that will affect the performance of other equipment. It may fail to perform as expected in the presence of electromagnetic disturbances from other equipment.

To reduce the risk associated with electromagnetic fields interfering with other devices in your healthcare facility:

- Plug the Lumin LM3000 system into a separate circuit.
- Place the device and its cables as far as possible from portable radiofrequency communications equipment and other electrical devices.
- Monitor the performance of this device and other adjacent electrical devices to verify that they are operating normally.

This equipment has been tested and found to comply with the limits for a Consumer ISM equipment, pursuant to Part 18 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

Please note that changes or modifications of this product is not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This product may cause interference to radio equipment and should not be installed near maritime safety communications equipment, ships at sea, or other critical navigation or communications equipment operating between 0.45-30 MHz.

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