

Instructions for Healthcare Personnel:

Emergency Decontamination of Compatible N95 or N95-Equivalent Respirators in Lumin LM 3000 Decontamination UV System

The U.S. Food and Drug Administration has authorized an Emergency Use Authorization (EUA) for the emergency use of the Lumin LM 3000 Decontamination UV System for use (hereafter referred to as the "Lumin System"") in decontaminating compatible N95 or N95-equivalent respirators ("compatible N95 respirators") in healthcare facilities. The Lumin System cycle to be used in decontamination of compatible N95 respirators is a 10 minute UVC. Healthcare personnel should follow these instructions, as well as procedures at their healthcare facility, to prepare compatible N95 respirators for decontamination in a Lumin System; please refer to the Lumin System User's Guide for complete instructions for use.

- Do not use decontaminated compatible N95 Respirators during surgical procedures.
- Only use for outpatient and patient examination procedures.
- Decontaminated N95 Respirators are not sterile.



CAUTION: Due to incompatibility, the Lumin LM3000 Decontamination UV System is not authorized for use with soft-bodied respirators, foldable respirators, filters made of hydrophilic materials, and respirators with expiratory valves.

Materials Needed:

Compatible N95 Respirator Marking: Ensure uniform system to mark each use of respirator.

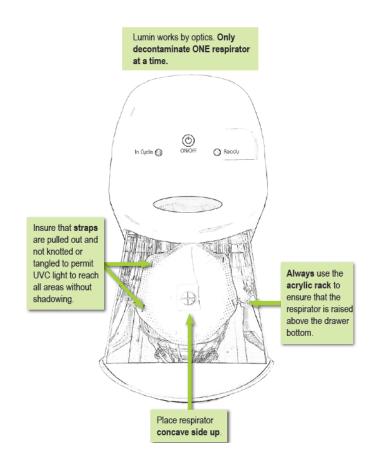
- 1. Gloves
- 2. Decontaminating wipes
- 3. Permanent marking tool

To Decontaminate Compatible N95 Respirators in a Lumin System: N95 Respirator Marking, Collection, and Instructions for Individual Use

- 1. Visually inspect the respirator for obvious signs of wear and tear, and discard any respirator with any fluid or stain.
- 2. Use gloves or a decontaminating wipe to open the Lumin drawer to avoid contaminating the outside of the Lumin device.
- 3. Place the N95 respirator concave side up on the acrylic rack. Please see graphic on right.
- 4. Press the start button. Lumin is pre-programmed for a 5 minute cycle. After completed, flip mask to convex side and ensure straps are untangled to permit UVC light to reach all areas without shadowing. Press start button again. (Another 5 minute cycle, for a total of 10 minutes per respirator).
- 5. Wash hands thoroughly for 20 seconds or use hand sanitizer prior to removing your respirator from Lumin to avoid cross contamination.
- 6. Each successive use of the respirator should be marked as a check on the respirator.
- 7. Discard respirator after 10 uses.

N95 Respirator Marking, Collection, and Instructions for Institutional Use

- If Lumin is used in a higher volume institutional setting, it may become more practical to assign an employee to handle all respirator decontamination. In that setting, personnel depositing respirators for decontamination should individually mark their respirator with name or employee number and individually bag before depositing.
- 2. Assigned employee should use gloves and exercise caution and aseptic technique in transferring respirators from the poly bag and placing the respirator concave side up in the Lumin.
- 3. To ensure decontamination 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.
- 4. Press the start button. Lumin is pre-programmed for a 5 minute cycle. After completed, flip mask to convex side and ensure straps are untangled to permit UVC light to reach all areas without shadowing. Press start button again. (Another 5 minute cycle, for a total of 10 minutes per respirator).
- 5. Each successive use of the respirator should be marked as a check on the respirator
- 6. Discard respirator after 10 uses.



Reuse Information:

The Lumin may be used throughout the day per the needs of the healthcare facility, as each decontamination cycle per respirator is 10 minutes the Lumin may be used continuously after each decontamination cycle has completed.

Additional Information: General Instructions for Care and Maintenance of the Device

Avoid cross-contamination by using decontaminating wipes to wipe the exterior of Lumin. Particular care should be used in frequent decontaminating of the drawer handle.

Replace the Lumin UVC lamp annually to ensure that the device consistently delivers high performance germicidal levels of UVC.

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.

