<u>Instructions for Healthcare Facilities:</u> Emergency Decontamination of Compatible N95 or N95-equivalent Respirators Using the 3B Medical Inc., 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, manufactured by 3B Medical Inc, in decontaminating compatible N95 or N95-equivalent respirators ("compatible N95 respirators") in healthcare facility for single-user reuse by healthcare personnel. The Lumin LM3000 Decontamination UV System utilizes a 5 minute ultra violet germicidal irradiation (UVGI) cycle twice to decontaminate one compatible N95 respirator at a time and permits single-user re-use up to 10 times. Healthcare personnel should follow these instructions, as well as procedures at their healthcare facility, to prepare compatible N95 respirators for decontamination in a Lumin LM300 Decontamination UV System; please refer to the Lumin User Manual for complete instructions for use.

- **Due to incompatibility, the Lumin LM3000 Decontamination UV System is not authorized for use with respirators that are soft-bodied respirators, foldable respirators, filters made of hydrophilic materials, and respirators with expiratory valves**
- **Do not use decontaminated compatible N95 Respirators during surgical procedures.**
- **Only use for outpatient and patient examination procedures.**
- **All compatible N95 respirators used in the Lumin LM3000 Decontamination UV System must be free of visible damage and soil/contamination (e.g. blood, dried sputum, makeup, soil, bodily fluids).**
- **Compatible N95 respirators should be discarded after 10 decontamination cycles.**
- **Any compatible N95 respirator whose traceability was lost or number of decontamination cycles not able to be identified should be discarded**

- Decontaminated compatible N95 Respirators are not Sterile.
- The Lumin LM3000 Decontamination UV System inactivates the SARS-CoV-2 virus on compatible N95 respirators
- Testing has not been conducted to show its effectiveness to reduce levels of other pathogens on compatible N95 respirators.

Materials Needed:

1. Gloves
2. Disinfecting wipes
3. Permanent marking tool

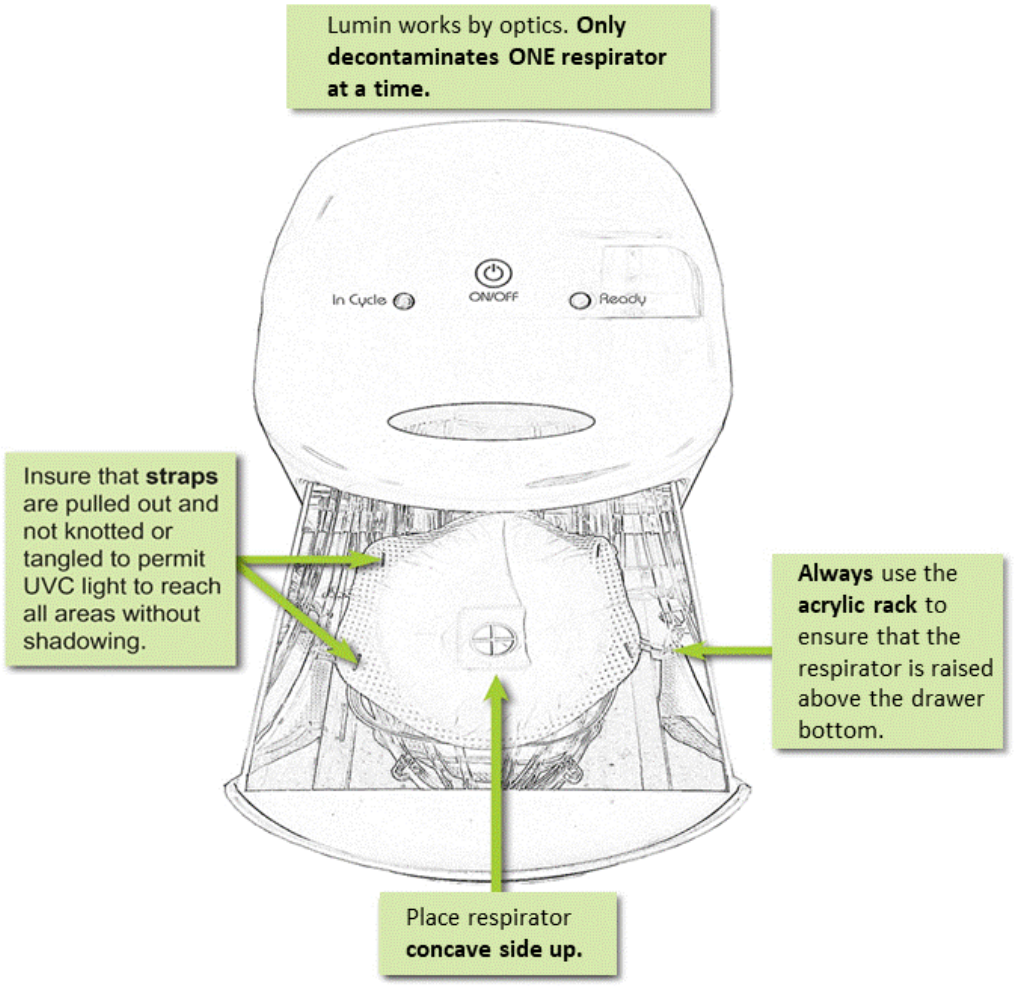
Compatible N95 Respirator Marking:

1. Ensure uniform system to mark each use of respirator. For example, with a permanent marker, the healthcare personnel should label their own individual compatible N95 respirators with their name, identifiers, and number of reprocessing cycles (such as a tick mark). Note: the compatible N95 respirators may be decontaminated a maximum of 10 times.

N95 Respirator Collection and Instructions for Use By a Single Healthcare Person

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 disinfecting wipe to open the drawer to avoid contaminating the outside of the Lumin LM3000 Decontamination UV System device.

3. Place the respirator concave side up on the acrylic rack. **Please see graphic below**.
4. 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.
5. Press the start button. The Lumin LM3000 Decontamination UV System 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.)
6. Wash hands thoroughly for 20 seconds or use hand sanitizer prior to removing your respirator from the Lumin LM3000 Decontamination UV System to avoid cross contamination.
7. Each successive decontamination of the respirator should be marked as a check on the respirator
8. Discard respirator after 10 uses



N95 Respirator Collection, Transportation, and Instructions for Institutional Use

If the Lumin LM3000 Decontamination UV System 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 masks for decontamination should individually mark their mask with name or employee number and place individually in a poly bag before depositing.

Chain of Custody:
3B Medical Inc., recommends that healthcare workers pouch their respirators at the end of use with their

name or other identifier written on the mask and pouch with a permanent marker. Permanent markers are used with the VHP process to mark decontamination pouches and wrap (used once). To maintain the decontamination cycle count, the healthcare worker should place a tick mark on the respirator each time the healthcare worker prepares the respirator for decontamination. The healthcare worker should confirm that their name is legible prior to placing the respirator in the bag and that there is no visible soil or damage to the respirator. If any visible soil or any damage is present, the respirator should be discarded.

3B Medical Inc., recommends that each department utilize clean trays or containers that are normally utilized to deliver surgical instruments to the Operating Room to collect the masks. When the pouched respirators are ready to be transported to the Sterile Processing Decontamination area, they should be transported in a closed case cart to minimize risk of environmental contamination. The case cart should have a hospital-controlled tag or identifier that indicates the location in the hospital where the respirators were utilized. The case cart should be transported to Sterile Processing to the decontamination area by transport personnel assigned by the healthcare facility with training for transport of the material. Unload the respirators in the decontamination area. 3B Medical Inc., recommends that the sterile processing staff following existing processes to decontaminate the case carts and sterilize the transport trays or container for re-use and delivery back to patient areas. Transfer the pouched respirators through the pass-through window along with the location identifier. Retrieve the pouched N95 respirators and place in the Lumin LM 3000 Decontamination UV System for processing. The sterile processing staff should adhere to department policy for documenting load contents for the sterilizer. Upon completion of the decontamination cycle, the respirators should be loaded back in sterilized trays or containers and placed in a closed case cart following department policy for identifying/labeling processed loads. The documentation needs to include a clean copy of the location identifier to ensure return of the respirators to the original location in the facility for distribution of each respirator to the original healthcare worker. Upon return of the respirators to the appropriate individuals, they should be checked to ensure that the name or other identifier is still legible. If not legible, or if the respirator is damaged, the respirator should be discarded.

1. Assigned employee should use gloves and exercise caution and aseptic technique in transferring respirators from the poly bag
2. Healthcare personnel should place one single respirator at a time concave side up in the Lumin LM3000 Decontamination UV System.
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 mask.)
5. Each successive decontamination of the respirator should be marked as a check on the respirator
6. Upon completion of the cycle, the decontaminated, compatible N95 respirators are ready for use. **Compatible N95 respirators may be processed a maximum of 10 times.**

After the Lumin LM 3000 Decontamination UV System process is complete:

Reuse Information:

The Lumin LM3000 Decontamination UV System may be used throughout the day per the needs of the healthcare facility, as each decontamination cycle is 10 minutes the Lumin LM3000 Decontamination UV System may be used continuously after each cycle has completed.

Additional Information:

1. Prior to use, healthcare personnel should inspect decontaminated, compatible N95 respirators for visible damage and soil/contamination (i.e., blood, dried sputum, makeup, soil). Respirators that are

damaged or contain visible soil should be discarded.

2. It is strongly recommended to maintain chain of custody on the compatible N95 respirator to minimize the risk of cross-contamination between individuals.

General Instructions for Care and Maintenance of the Device:

1. Avoid cross-contamination by using disinfecting wipes to wipe the exterior of the Lumin LM3000 Decontamination UV System . Particular care should be used in frequent disinfecting of the drawer handle.
2. Replace the UVC lamp annually to ensure that the device consistently delivers high performance germicidal levels of UVC.
3. 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.

Reporting to 3B Medical Inc:
Healthcare facilities should report any discoloration or other signs of degradation with a decontaminated respirator to 3B Medical Inc., and the healthcare facility should discard the respirator. Healthcare facilities using the decontaminated, compatible N95 respirators should monitor healthcare personnel who use such respirators for the signs and symptoms of potential infection with SARS-CoV-2 or other respiratory infection and promptly report such information to 3B Medical Inc., so that 3B Medical Inc., can provide a weekly report to FDA.

Reports of adverse events should be reported up to and including 14 days after the last contact with suspected SARS-CoV-2 virus. Report Adverse events, including problems with test performance or results, 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