

# LightStrike™ Pulsed Xenon UV: Disinfection of N95 Respirators

Revision 2: Effective April 17, 2020

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With the anticipated surge in COVID-19 patients in US hospitals, the available supply of N95 respirators is likely insufficient. Under normal conditions, respirators should be worn once and then discarded. However, with the high demand during a patient surge, this process would rapidly deplete the available supply. CDC is recommending that facilities consider reuse of respirators in order to conserve the supply for as long as possible.

A concern with reuse is the contamination of the exterior surface of the respirator with potentially infectious viral particles. While there has been little research on the risk of a respirator serving as a fomite, resulting in self-inoculation of a healthcare provider, this possibility cannot be ruled out. From the National Personal Protective Technology Laboratory “Similar to other potential fomites (e.g., surfaces, medical devices, and stethoscopes), assessing the level of risk of self-inoculation associated with touching a used FFR is complex.”[1]

Data resulting from prior testing indicates that the LightStrike Robot was able to deactivate MERS-CoV on glass carriers,[2] and Canine Parvovirus on PPE (surgical gowns and face shields).[3]

A possible process for disinfection of N95 respirators is provided below. This process is not approved by the FDA, CDC or any other governmental authority. The use of the LightStrike Robots for this purpose is not within the manufacturer’s recommended uses, and we are providing this information only in light of customer requests and CDC’s reuse recommendations due to the unprecedented demand for respirators caused by the COVID-19 public health emergency. Given the lack of testing and governmental recommendation and/or approval, any use of the LightStrike Robot for disinfection of N95 Respirators should only be undertaken if reuse of the respirator is not otherwise avoidable, and there are no respirator sterilization options available. Xenex makes no representation that the disinfection of the N95 respirators will prevent any individual from contracting COVID-19 or any other disease. Further, repeated disinfection of the N95 Respirator should be minimized if possible.

The disinfection process presented here is used to reduce the viral load that may be present on respirators, but does not meet the FDA reprocessing standard of sterilizing the respirators (6 log reduction). Because this is not a sterilization process, respirators should be handled as though they are potentially contaminated even after the disinfection process has occurred. Xenex is not seeking FDA approval for use of the LightStrike Robot for respirator reprocessing (sterilization), and does not intend or offer the LightStrike Robot for this use. We understand that some hospitals are using their existing LightStrike Robots for respirator disinfection under these emergency circumstances (in addition to environmental disinfection of surfaces), but are doing so based upon their own determination.

3M has issued updated guidance on the impact of disinfection with LightStrike robots on the filtration efficiency and fit of the respirators.[4] Testing was performed on three different respirator models (1860, 8210, and 1804) for a total of 10 disinfection cycles. 3M concluded that the LightStrike decontaminated respirators did not show degradation in filtration or fit. Per 3M, this testing is also applicable to respirator models 1860S and 1804S. NIOSH recommends limiting reuse of a respirator to no more than 5 reuses to ensure adequate safety. The number of UV disinfection cycles tested exceeds the NIOSH recommendations, so the limit on the number of times a respirator can be disinfected is set at 5 times to comply with the NIOSH recommendation.[5]

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**NOTE:** These protocols developed by Xenex only apply to the LightStrike Robot. The Xenex team cannot recommend the use of this protocol for other UV systems. Cycle times are based on the X4 Robot model. For the V3 model, a 5-minute cycle can be used. For the X5 model, a 4-minute cycle can be used. Disinfection with UV light is an additional step that facilities may elect to perform. It is not required as a part of the respirator reuse recommendations.[6]

## Disinfection Protocol Options

There are two disinfection processes available depending on the method of achieving UV exposure. Please see the options listed below to identify the appropriate protocol for your facility. Each disinfection process is outlined in detail later in the document.

1. Disinfection of Cup or Duck Bill style respirators in a Light Strike Disinfection Pod
2. Disinfection of Cup or Duck Bill style respirators using a clothesline/rack system

Figure 1. Duck Bill Style Respirator



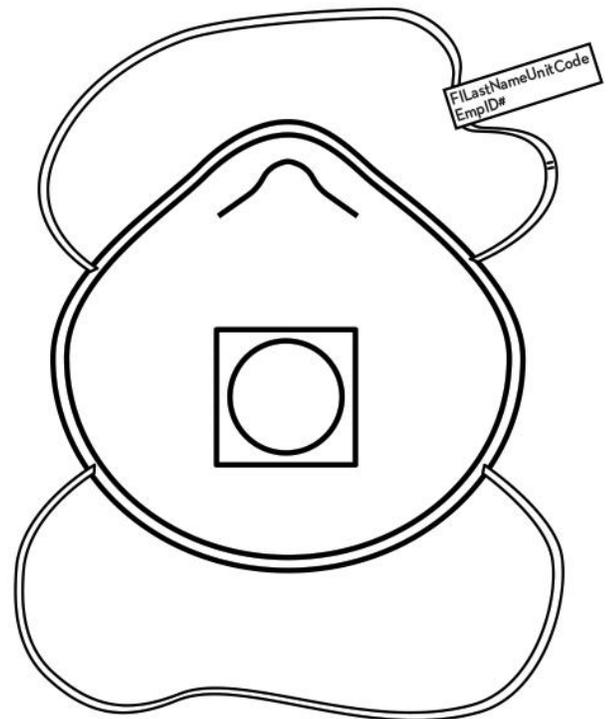
Figure 2. Molded "Cup" Style Respirator



## Transporting Respirators from Units to Disinfection Area

1. A small adhesive label should be placed on the elastic band of the respirator with the healthcare workers name, ID number, and unit. (Figure 3) Labeling should NOT be done on the filter material itself, as this may damage the respirator.[7]
2. When the respirator is ready for disinfection, place it in a paper bag, and label the bag with the healthcare workers name and unit where the respirator needs to be returned after disinfection.
3. Place the bag with the respirator inside in the designated "dirty" drop-off location for the unit.
4. Respirators will be collected from the units on a cart and brought to a central disinfection location within the hospital. Staff who collect respirators will need to perform hand hygiene and wear gloves when performing collection. After all respirators on a unit have been collected, the staff member will remove their gloves and perform hand hygiene. The cart with the respirators will then be brought to the central disinfection location.
5. In the disinfection location, a staff member will perform hand hygiene and then don gloves, gown, and a procedure mask. They will then remove all respirators from the paper bags. During removal, the staff member will read the name and location written on the bag to another staff member, who will write the information on a clean bag to be used when the respirator is returned to

Figure 3. Respirator with employee label attached and disinfection tracking marks on elastic band



the unit. The bag the respirator was sent in will be disposed of.

6. Prior to disinfection, all respirators should be inspected for signs of visible soil, or for physical damage (punctures/tears/creases). Respirators with signs of damage or visible soil should be discarded. The presence of light makeup on the interior of the respirator should not significantly inhibit the UV disinfection process.
7. NIOSH recommends that respirators not be reused more than 5 times, so the number of times a respirator has been disinfected should be tracked. A small mark can be made on the elastic band with a permanent marker before each disinfection is completed. (Figure 3) Tracking marks should NOT be made on the filter material itself, as this may damage the respirator.[7] Disinfection should not be completed more than five times on an individual respirator.
8. Respirators should be placed according to the disinfection process the facility will be using (LDP, clothesline, table). Each disinfection process is outlined on the following pages.
9. The cart used to transport the respirators should be disinfected with an EPA registered disinfectant with an emerging viral pathogen claim.

## Transportation of Respirators From Disinfection Area Back to Unit

1. After completing the disinfection process (LDP or clothesline) the staff manning the disinfection location should perform hand hygiene and don clean gloves.
2. Disinfected respirators should be matched with the labeled clean bag that matches the name and unit on the tag of the respirator.
3. Disinfected respirators in the clean bags should be returned to the units for re-use by staff.

## Disinfection of Cup or Duck Bill Style Respirators in a LightStrike Disinfection Pod (LDP)

1. Respirators should be oriented in a manner that maximizes UV exposure to the exterior surface. In the LDP, this is accomplished by placing the respirators on a wire rack inside the LDP. (Figure 4) Respirators should not overlap on the wire rack. The LDP has a highly reflective lining that allows for 360° disinfection of items with a single 5-minute cycle of the Robot.[8].
2. Once the respirators have been arranged on the shelf, zip the door flap closed and dock the Robot into the ring housing on the side of the LDP. Assure that the ring housing sits over the dome of the Robot and down against the black top housing. (Figure 5)
3. Perform a 5-minute disinfection cycle with the LightStrike Robot. The respirators are now ready to be returned to the units.

Figure 4. LDP with door open and respirators on rack

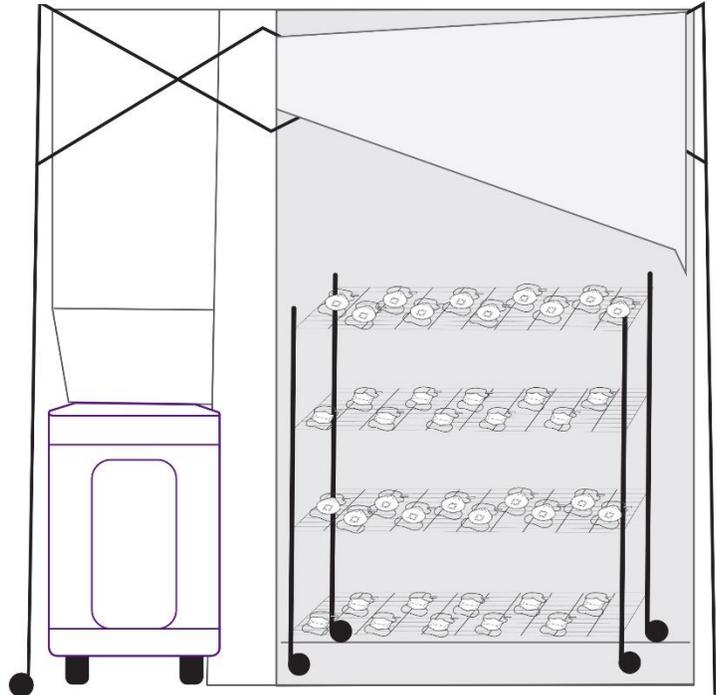
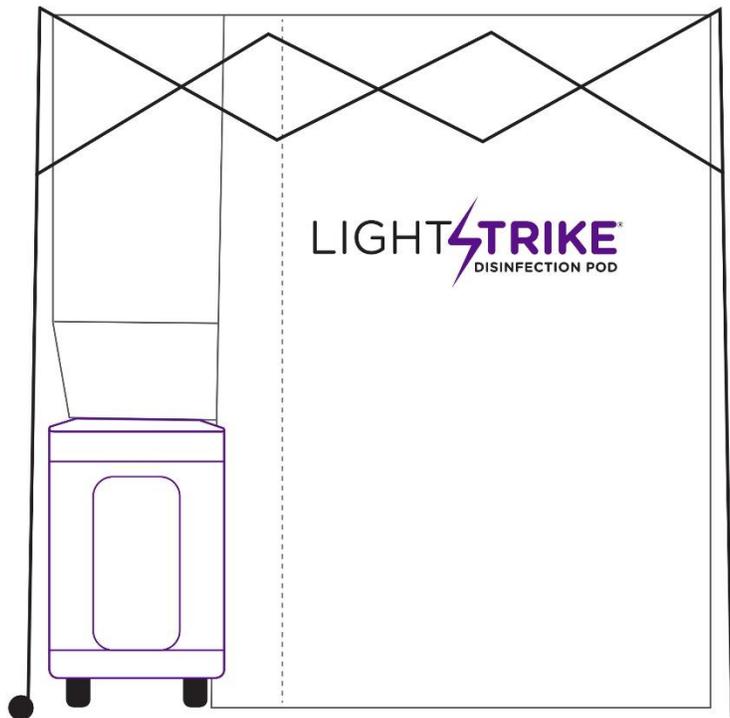


Figure 5. LDP with door flap closed while disinfection cycle is running



## Disinfection of Cup or Duck Bill Style Respirators Using a Clothesline

1. Using a cable/wire and metal racks, set up a full 360 degrees around the Robot, at a distance of 1-2 meters. Two rows of cable/wire will be needed for each row of respirators that will be disinfected; one cable/wire to secure the top and one to secure the bottom. Rows of respirators should be at least 1 meter, and not greater than 2 meters from the floor. Respirator outside this range may not receive a sufficient dose of UV light. (Figure 6).
2. Place the Robot in the center of the disinfection area.
3. Respirators should be oriented in a manner that maximizes UV exposure to the exterior surface. Using clothes pins or binder clips, secure the respirators to the line so that the exterior surface of the respirators faces forward.
  - a. For molded cup style respirators: Clip the top and bottom of the respirator to the cable/wire to prevent it from pivoting down due to the center of gravity of the respirator. (Figure 7)

Figure 6. Aerial view of clothesline disinfection area

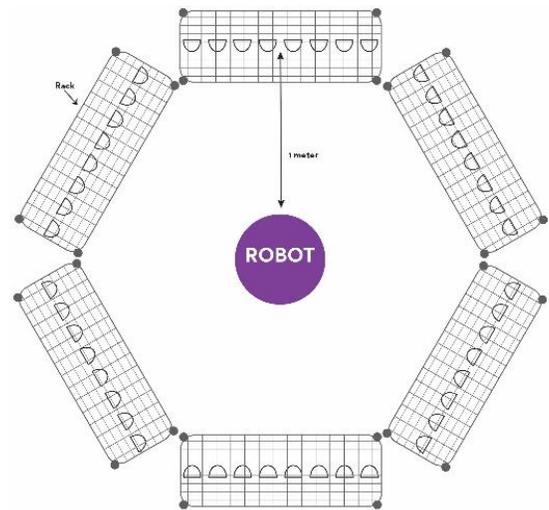
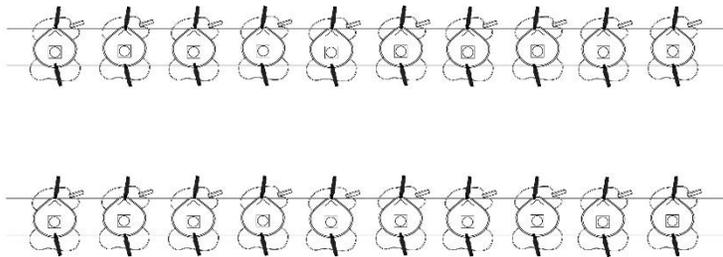
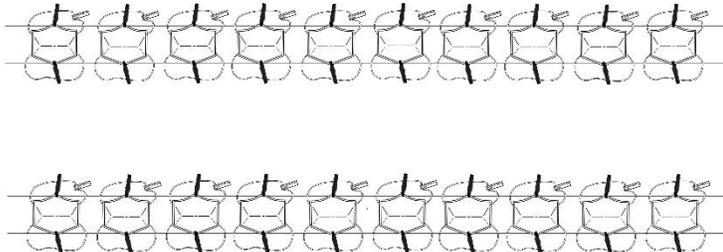


Figure 7. Close up of molded cup style respirators on clothes line



- b. For duck bill style respirators, slightly push the corners of the respirator together to “bloom” it open. Be careful to avoid touching the interior of the respirator in this process. Clip the top and bottom of the respirator to the cable/wire to prevent it from pivoting down due to the center of gravity of the respirator. (Figure 8)

Figure 8. Close up of duck bill style respirators on clothes line

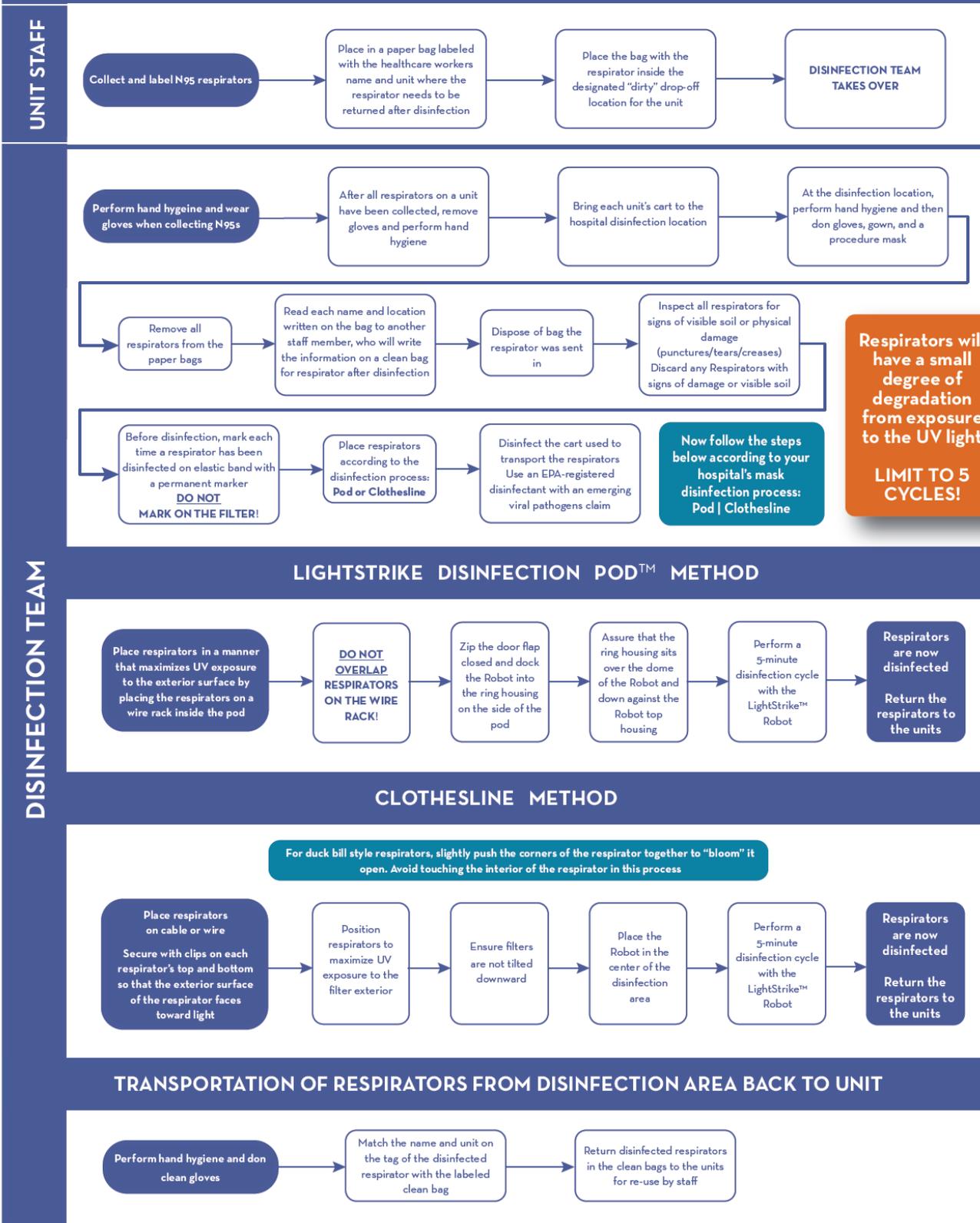


4. Perform a 5-minute disinfection cycle with the LightStrike Robot. Staff will need to exit the room for the duration of the disinfection cycle.
5. If desired, the respirators can be rotated 180° so that the interior faces the robot and another 5-minute cycle can be performed. Staff will need to exit the room for the duration of the disinfection cycle. Disinfection of the interior of the respirator is optional.
6. The respirators are now ready to be returned to the units.

PROCESS FLOW

N95 Respirator Disinfection Process with LightStrike™ Pulsed Xenon UV

LABEL EACH RESPIRATOR BAND WITH HEALTHCARE WORKER'S NAME, ID NUMBER, AND UNIT



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## References:

1. Fisher, E.M. and R.E. Shaffer, *Considerations for recommending extended use and limited reuse of filtering facepiece respirators in health care settings*. J Occup Environ Hyg, 2014. **11**(8): p. D115-28.
2. Stibich, M. and J. Stachowiak, *The microbiological impact of pulsed xenon ultraviolet disinfection on resistant bacteria, bacterial spore and fungi and viruses*. Southern African Journal of Infectious Diseases, 2016. **31**(1): p. 12-15.
3. Jinadatha, C., et al., *Disinfecting personal protective equipment with pulsed xenon ultraviolet as a risk mitigation strategy for health care workers*. Am J Infect Control, 2015. **43**(4): p. 412-4.
4. 3M. *Decontamination Methods for 3M N95 Respirators*. 2020 [cited 2020 April 16]; Available from: <https://multimedia.3m.com/mws/media/18248690/decontamination-methods-for-3m-n95-respirators-technical-bulletin.pdf>.
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6. Prevention, C.f.D.C.a. *Strategies for Optimizing the Supply of N95 Respirators: Contingency Capacity Strategies*. 2020 [cited 2020 March 23]; Available from: <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/contingency-capacity-strategies.html>.
7. Rebmann, T., *APIC Position Paper: Extending the Use and/or Reusing Respiratory Protection in Healthcare Settings During Disasters 2009*.
8. Reid, D., et al., *Germicidal irradiation of portable medical equipment: Mitigating microbes and improving the margin of safety using a novel, point of care, germicidal disinfection pod*. Am J Infect Control, 2020. **48**(1): p. 103-105.