LightStrike™ Pulsed Xenon UV: Disinfection of N95 Respirators

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 disposed of. 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]

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 other viable disinfection 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.

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].

3M has issued guidance that UVGI should not be used for N95 respirator disinfection because of physical damage which compromised the filter material and the elastic bands. This test used a mercury based UV system, not a pulsed xenon based UV system. Xenex exposed the 3M 8511 mask to 12 disinfection cycles (60 minutes) and it passed a fit test conducted by a certified occupational health nurse using a TSI PortaCount 838 Plus. Testing was conducted in compliance with OSHA 29 CFR 1910-134. Additionally, the elasticity of the head bands was not impacted by this exposure. 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.[4]

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. Disinfection with UV light is an additional step that facilities may elect to perform. Is it not required as a part of the respirator reuse recommendations.[5]

Disinfection Protocol Options

There are several disinfection processes available depending on the style of respirators the facility uses and 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
3. Disinfection of Cup or Duck Bill style respirators using a table

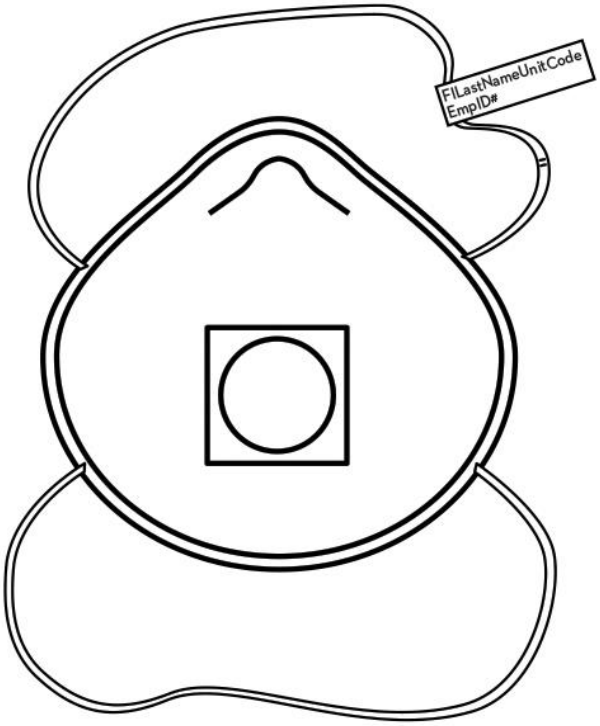
Figure 1. Duck Bill Style Respirator

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.[6]
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 respirator. 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 the unit. The bag the respirator was sent in will be disposed of.

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



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.
7. Respirators will have a small degree of degradation from exposure to the UV light, and 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.[6] 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 pathogens claim.

Transportation of Respirators From Disinfection Area Back to Unit

1. After completing the disinfection process (LDP, clothesline, table) 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.[7].
2. Once the respirators have been arranged on the shelf, zip the door flap closes 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 disinfected and ready to be returned to the units.

Figure 4. LDP with door open and respirators on rack

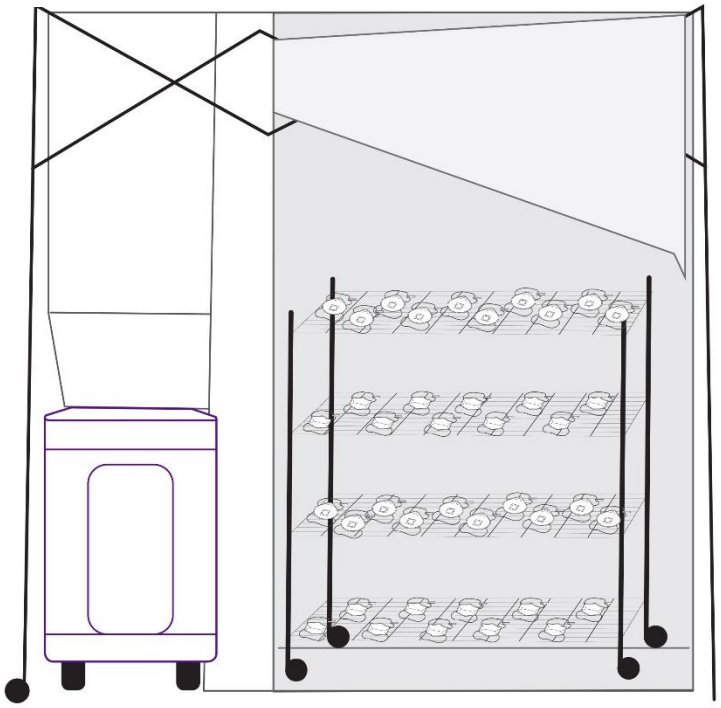


Figure 5. LDP with door flap closed while disinfection cycle is running

Disinfection of Cup or Duck Bill Style Respirators Using a Clothesline

1. Using a cable/wire and IV poles, set up a full 360 degrees around the robot, at a distance of 1-2 meter. Two rows of cable/wire will be need 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) Note that a small opening is left in the perimeter to allow access to the robot to start the disinfection cycle.
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

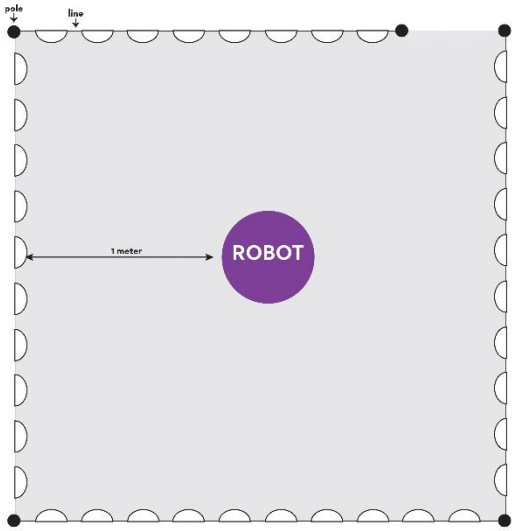
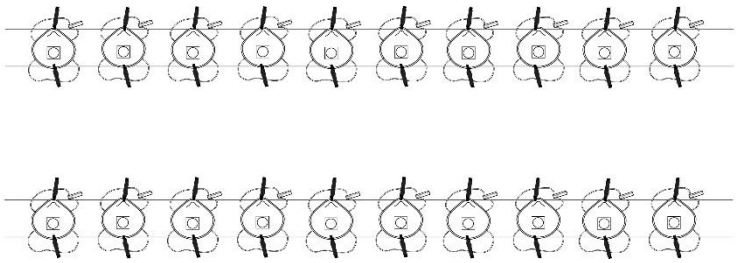
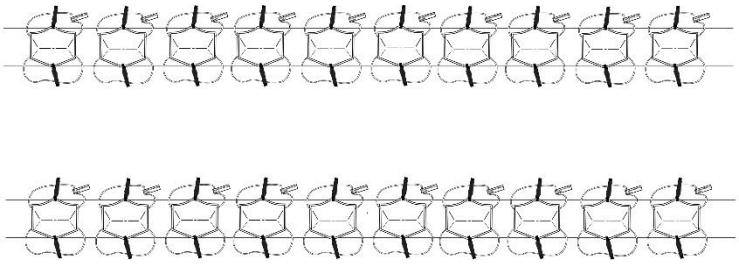


Figure 7. Close up of molded cup style respirators on clothes line



    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. The respirators are now disinfected and ready to be returned to the units.

Disinfection of Cup or Duck Bill Style Respirators Using a Table

5. Set up tables in a full 360˚circle around the robot, at a distance of 1-2 meters. Place the robot in the center of the tables. One table can be temporarily moved to allow access to the robot to start the disinfection cycle. Return the table to the position shown in the figures prior to leaving the room for disinfection.
6. For molded cup style respirators:
    a. Place all the respirators on the table with the chin portion facing inward toward the robot. (Figure 9)
    b. Perform a 5-minute disinfection cycle with the LightStrike Robot. Staff will need to exit the room for the duration of the disinfection cycle.
    c. Don clean gloves. By grasping the lower elastic strap (which received UV disinfection), rotate all the respirators so that the nose bridge portion faces toward the robot. (Figure 10)
    d. Perform another 5-minute disinfection cycle with the LightStrike Robot. Staff will need to exit the room for the duration of the disinfection cycle. The respirators are now disinfected and ready to be returned to the units.

Figure 10. Aerial view of molded cup style respirators for first disinfection cycle. Chin portion of respirator is facing the robot

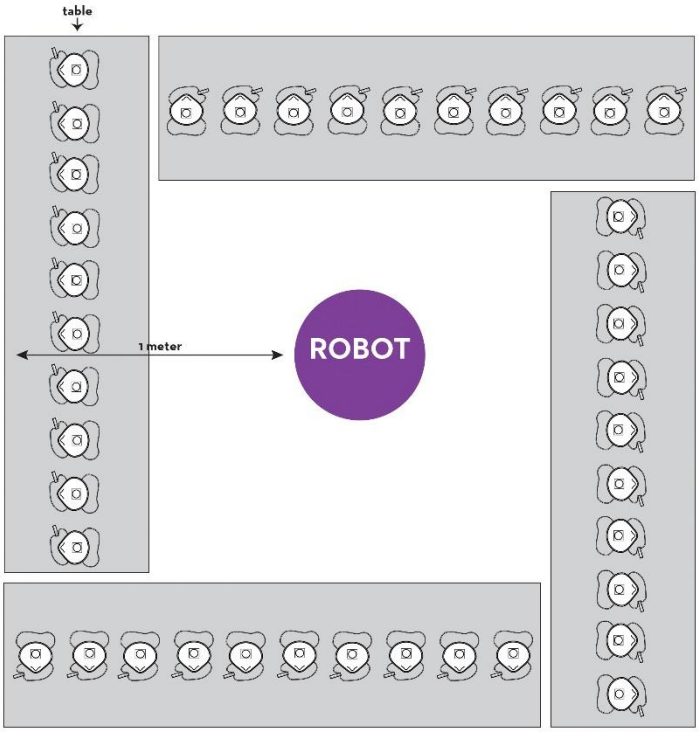
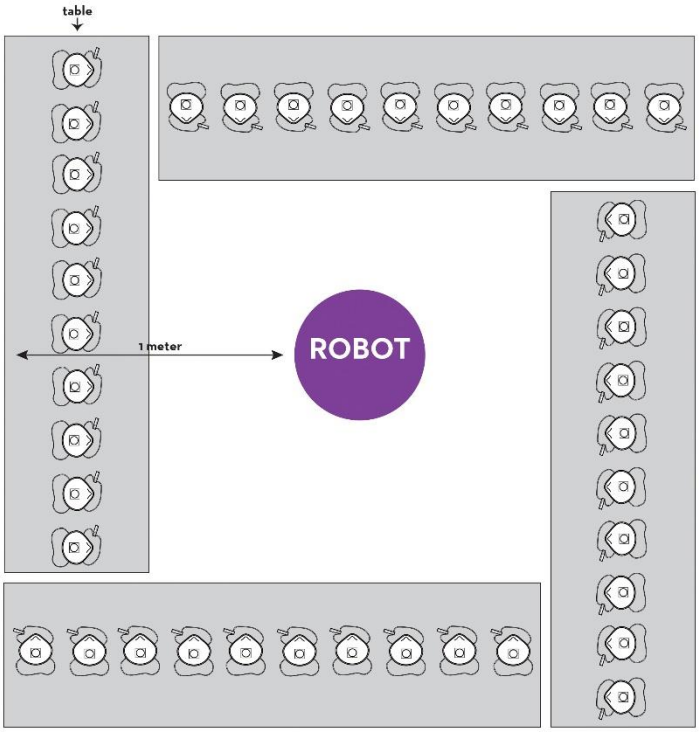


Figure 9. Aerial view of molded cup style respirators for second disinfection cycle. Nose bridge portion of respirator is facing the robot



7. For duck bill style respirators:
    a. DO NOT “bloom” the respirators as described in the clothes line protocol. Leave them flat.
    b. Place all the respirators on the table with the top portion facing upward. (Figure 11)
    c. Perform a 5-minute disinfection cycle with the LightStrike Robot. Staff will need to exit the room for the duration of the disinfection cycle.
    d. Don clean gloves. By grasping the elastic straps (which received UV disinfection), flip all the respirators so that the bottom portion of the respirator faces upward. (Figure 12)
    e. Perform another 5-minute disinfection cycle with the LightStrike Robot. Staff will need to exit the room for the duration of the disinfection cycle. The respirators are now

disinfected and ready to be returned to the units.

Figure 11. Aerial view of duck bill style respirators for first disinfection cycle. Top portion of respirator is facing up

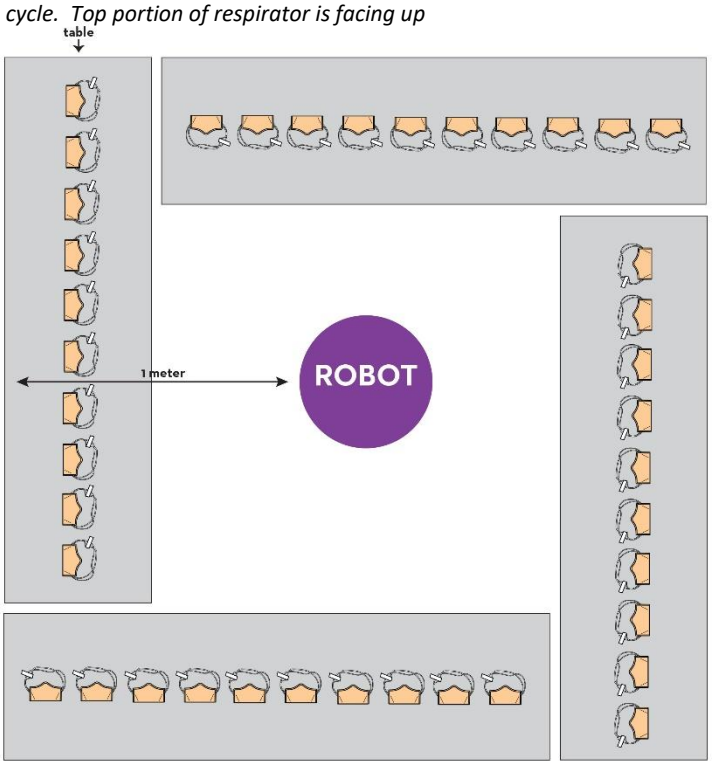
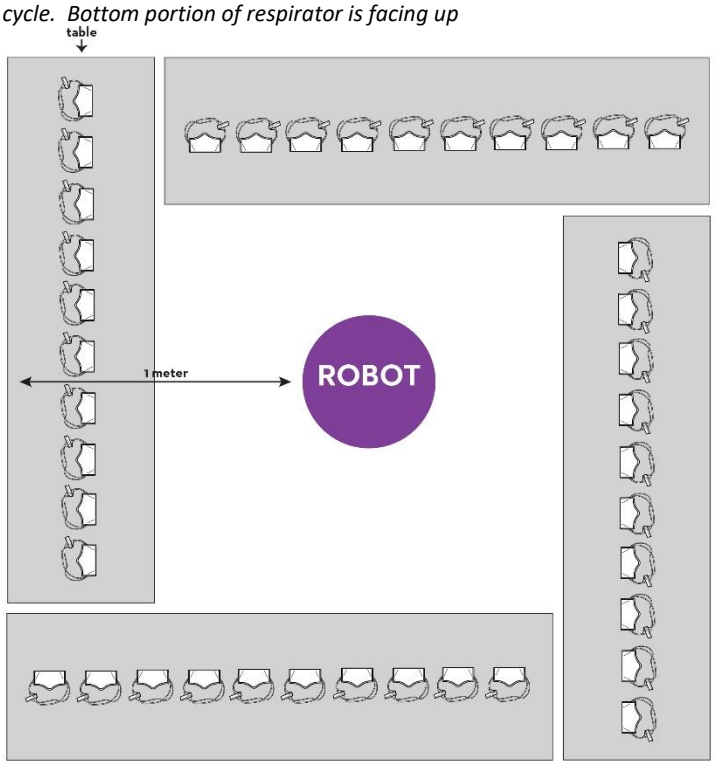


Figure 12. Aerial view of duck bill style respirators for second disinfection cycle. Bottom portion of respirator is facing up



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