

Instructions for Duke Decontamination Facility: Decontamination of Compatible N95 Respirators with Hydrogen Peroxide Vapor

INTRODUCTION

Due to personal protective equipment (PPE) shortages during the COVID-19 pandemic, it has become necessary to decontaminate and reuse compatible N95 respirators. Using Hydrogen Peroxide Vapor and a Hydrogen Peroxide Vapor generator offers many advantages to the decontamination process. Biological indicators (1×10^6 of *Geobacillus stearothermophilus* spores) and chemical indicators were used to ensure that the bioburden was appropriately reduced.

EMERGENCY USE AUTHORIZATION INFORMATION

The Duke Decontamination System with Hydrogen Peroxide Vapor has been authorized by FDA under an Emergency Use Authorization (EUA) for use in decontaminating compatible N95 respirators for multiple-user reuse by healthcare personnel to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates during the COVID-19 outbreak.

Compatible N95 respirators are either authorized NIOSH-approved filtering facepiece respirators (FFRs) or respirators that are authorized and listed in Exhibit 1 to FDA's emergency use authorization (EUA) for non-NIOSH-approved imported FFRs that are not manufactured in China, and that do not have exhalation valves or a duck-billed design, and do not contain cellulose-based materials or antimicrobial agents.

The Duke Decontamination System with Hydrogen Peroxide Vapor has neither been cleared nor approved for this use. The Duke Decontamination System with Hydrogen Peroxide Vapor 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 declaration is terminated or the authorization is revoked sooner.

Respirators that are NIOSH-approved before decontamination (<https://wwwn.cdc.gov/niosh-cel/>) only retain their NIOSH approval status post-decontamination if the respirator manufacturer permits the use of the decontamination method with the specific system and cycle parameters. To determine the NIOSH approval status of a specific decontaminated NIOSH-approved respirator, please check with the respirator manufacturer and/or check the respirator labeling. If a respirator is no longer NIOSH-approved after use of the particular decontamination method, its performance (i.e., fit, filtration, and breathability) might not consistently meet NIOSH-approved N95 standards.

PURPOSE

The purpose of this document is to assure that effective decontamination of compatible N95 respirators is achieved when Hydrogen Peroxide Vapor is utilized and that there is appropriate Quality Control of the decontaminated, compatible N95 respirators prior to the staff using them.

PROCEDURES

Compatible N95 respirators will be brought to the Duke location in boxes/bags. The outside of the boxes/bags will be decontaminated by disinfectant wipes to make it safe for handling during transport. The compatible N95 respirators will be arranged on shelves of stainless steel racks with the interior of the compatible N95 respirator facing upward. The racks will be in a decontamination room.

Follow the Decon Room Steps below.

The room will be properly sealed prior to start of the decontamination run to prevent leakage of Hydrogen Peroxide Vapor into the adjacent spaces. Supply and exhaust dampers will be closed and the edges of the doorways taped to ensure that vapor does not escape the room during the decontamination process. Similarly, any other openings or fixtures within the room were sealed to prevent leakage. Warning signs will be attached to the outside of the door to prevent people from accidentally entering the room. The hydrogen peroxide sensor will be used to detect any leakage from the room. It is equipped with a hydrogen peroxide sensor, which is capable of detecting 0.1 parts per million (ppm) in air.

CYCLE RUN STAGES

Each Hydrogen Peroxide Vapor run consists of the following stages:

- Conditioning
- Pre-gassing
- Gassing
- Gassing Dwell
- Aeration

During the aeration stage, it is common to introduce fresh air into the room to increase the rate of catalytic conversion of hydrogen peroxide vapor into oxygen and water.

When levels of Hydrogen Peroxide Vapor have come down to 1ppm, the tape sealing the door can be removed. Staff should monitor hydrogen peroxide levels prior to entering the room, and enter only when it is safe to do so. The door can be left open to allow for further aeration.

A receipt of the cycle will be produced throughout the process. If the run finishes without error, sign the signature line on the receipt. The receipt should be kept in all instances and logged in the binder.

N95 Respirator Aeration

- Check hydrogen peroxide levels in the decon room.
- If the levels of hydrogen peroxide in the decon room are less than 1.0 ppm, it is safe to enter.
- Record the time out.
- Roll the racks out of the decon room and into the aeration room.
- Wait a minimum of 4 hours for N95 respirators to aerate completely.

Follow Bulk Packaging Steps or Local Quality Assurance (OA) & Packaging Steps below to package the decontaminated, compatible N95 respirators.

Biological Indicators

- At least 1 biological indicator (BIs) should be run per load.
- Place BIs in designated spots.
- After racks are removed from the room, remove BIs.
- Place BIs in media, then placed upright into a 55°C incubator.
- After 12-24 hours, check for turbidity in media. If there is growth in the media, it should

look turbid. No growth should look clear, similar to a new tube of media.

- Document BI results for up to 7 days in the Biological Indicators Daily Check Log.

Chemical Indicators

- At least 1 chemical indicator (CIs) should be run per load.
- Place CIs in designated spots.
- After racks are removed from the room, remove CIs.
- Document CI results to confirm >6-log inactivation.

CHEMICAL HAZARDS

- The Hydrogen Peroxide Generator uses a 30% hydrogen peroxide solution, which is an irritant. Care must be taken to prevent accidental direct contact with the chemical. The following precautions are required while refilling the hydrogen peroxide solution container:
 - Disposable gloves, lab coat/gown, and face shield are required
 - Care must be taken to avoid splash and splatter

DECON ROOM STEPS

1. Wear appropriate PPE:
Gloves, Gown, N95 respirator, Faceshield, Hair/Beard Bonnet
2. Put BI/CI on top shelf in assigned location (preferably away from the source of Hydrogen Peroxide Vapor generation).
3. Place a clean/dirty sign on each rack with 'dirty' side facing you.
4. Bring a bin into room. Open bins only in the decon room!
5. Lay the N95 respirators inside facing up on the shelf without touching each other in a 7x3 grid.
6. Stack empty bins in the room. All surfaces must be exposed.
7. Bring the Hydrogen Peroxide Vapor generator into the room and plug it into the outlet, if it is not already set up.
8. Bring the aeration unit into the room and plug into the outlet, if it is not already set up.
9. Ensure that the control lectern is outside the room, plugged in.
10. Step outside the room. **Change gloves.**
11. While wearing PPE, tape around the doorway.
12. Start the Bioquell™ Hydrogen Peroxide Vapor generator to decontaminate using the Hydrogen Peroxide Vapor Setup and Operations Steps contained in these instructions.
13. Remove PPE when you exit decontamination room and discard in the waste bin. (All PPE must be worn before stepping back in).
14. Wait 1 hour after the aeration step begins to enter room. Use the PortaSens II™ to check H₂O₂ levels before entering. The levels must be below 1ppm.
15. Bring racks out to AERATION AREA and wait for a minimum of 4 hours for full aeration.

If error occurs, call Dr. Matthew Stiegel (919-681-4219). If a cycle aborts, assume that the N95 respirators are not decontaminated. Follow SOP for emergencies.

Hydrogen Peroxide Vapor Setup and Operations Steps

1. Remove the lectern by holding the handles of the lectern and leaning the top back towards you.
2. Place the lectern outside the room, near an electrical socket.
3. Place the base unit and the aeration units in their validated positions in the decon room. The arrow on the top of the aeration unit must be pointed toward the side wall.
4. The electrical cables for the base unit and the aeration units are in the bottom of the unit, under where the aeration units are stored.
5. **DO NOT USE ANY DAMAGED CABLES**, replace with adequately rated alternatives.
6. Plug the longer power cable into the base unit, and the other end into the **A** side of the socket labeled **DP-SB-13** and turn the power on. Turn on the white switch on the base unit above the power connection. The light ring will illuminate. *Ensure the white switch is not obstructed, as it is the main disconnect device.*
7. Plug the shorter cable into the side of the aeration unit, and plug the other end into the **C** side of the socket labeled **DP- SB-13**.
8. Turn on the power at the back of the aeration unit using the white switch and after a short time the fan will start, and the wireless indicator will illuminate. *Ensure the white switch is not obstructed, as it is the main disconnect device.*
9. Remove the wound power cable from the lectern, and plug the cable into the socket at the lower rear of the lectern.
10. Plug into the hallway socket and turn the power on. The screen will illuminate.

Loading Hydrogen Peroxide Bottles

WARNING: Always wear a pair of gloves and goggles before handling the bottle of hydrogen peroxide.

1. To access the bottles, push the silver button at the center of the black plunger. The plunger will be released and will move up.
2. Obtain a new bottle and check the outer bag for any signs of liquid. If liquid is present, do not use the bottle. Treat the liquid as hydrogen peroxide and take the necessary precautions. If no liquid is present, remove the bottle from the bag, and remove the lid carefully by turning counter clockwise. Retain the lid.
3. Carefully remove the internal rubber yellow cap by pulling it off. Retain the cap.
4. Pull the bottle tray open with one hand while placing the bottle in the insert in the bottle carrier with the other.





5. Ensure that the stud at the bottom of the holder lines-up with the indent on the bottom of the bottle. It may be necessary to rotate the bottle until it drops down into its correct position.
6. Push the black plunger down until it clicks and stays down.

Note – avoid pressing the silver button during this step, as the silver button releases the mechanism.

Bottles may be left in the vaporizer between decontamination cycles.

To remove bottles: Release the plunger as noted in 1, above, and remove the bottle. Ensure that both the yellow cap and the bottle's screw cap are put back on, even if the bottle is empty.

Operating the Hydrogen Peroxide Generator

- Check that the low level hydrogen peroxide sensor is working.
 - To start, remove the cap over the sensor if present and then hold down the green button.
 - The display will count down from 3 and then start.
- Place the sensor in the recess on the lectern. If the sensor is not working, do not run a cycle.
- Ensure the door is completely sealed with tape.
- **WARNING** – Ensure all possible openings and conduits into the enclosure are properly sealed. If large leaks occur and high concentration Hydrogen Peroxide escapes into areas where people are present, it can cause serious harm. Use tape to seal door.
- Next, log on to the system. Press the icon in the top right of the screen then select **Operator** and enter **oper** as the password. Click OK. When logged ON the User Name will be displayed in the top right of the screen. The Log on period will expire after 5 minutes of inactivity if not in cycle, after which it will be necessary to log on again.
- To start decontamination cycle press this icon  .
- Choose “Decon Cycle” in the menu and then press  .
- Press this icon  again. Note that this icon is not visible and the lights are white if the unit is prevented from starting (the light ring on the base unit and the lectern will be green if the cycle can be started).
- Confirm that the cycle is to be started by pressing  .
- The cycle will then begin and process through the five stages until the decontamination is complete.

BULK PACKAGING STEPS

Note: “Bulk Packaging” will be done to take decontaminated, compatible N95 respirators to Central Packaging where QA will be performed on each N95 respirator and packaged according to model & size.


IMPORTANT: PLACE N95 RESPIRATORS FROM ONLY ONE RUN INTO A BIN. DO NOT MIX RUNS TOGETHER.

1. Wipe inside and lid of a white bin with bleach wipes.
2. Wait for bleach to dry before putting N95 respirators inside.
3. Fill out a notecard with run #, date, time and initials of the individual performing the packaging.
4. Put notecard into plastic pocket on side of bin.
5. Count and stack N95 respirators together and lay the stacks into the bin.
6. Upon completion, fill out log to reflect total number of decontaminated, compatible N95 respirators sent to Central Packaging for QA.

Local QA & Packaging Steps

Note: Following decontamination and transport, if Central Packaging is not performing QA, use these instructions to perform QA for decontaminated, compatible N95 respirators and prepare for their next use.

IMPORTANT! If N95 respirators do NOT pass steps 1 through 4, discard!

1. Check N95 respirator for any overall wear & tear, if damaged, discard.
2. Check for makeup and other materials, if soiled, discard.
3. Check the metal nose piece, if damaged, discard.
4. Check elastic straps, pull 2x, look for breakage, discard if bad.
5. Mark strap with 1 decon line; **discard if the N95 respirator already has 4 tick marks** (as shown below).

6. Check size/model # and pack in the appropriate prepared box.
7. Put QA sticker on box, label: 'Q/A', Initials, Size, Run #, Run Date, & Run Time.
8. Wipe a clean bin with disinfectant wipes, inside and out.
9. Place packaged boxes of decontaminated, compatible N95 respirators into a clean bin. Close lid.
10. Place a card labeled with Initials, Run #, Run Date, & Run Start Time on the clean bin.
11. Place the bin in the 'Clean Bin Pick Up' area.

EMERGENCIES

Fire or other security alarm

- In the event of a fire or security alarm, there will be an audible alarm.
- Proceed through the emergency exit at the end of the hallway in an orderly fashion.
- If the emergency exit is blocked, exit through the entry door.

Equipment Error

If the Hydrogen Peroxide Vapor unit display monitor shows an ERROR at any point during the process:

- Do not panic. Call Dr. Matthew Stiegel at 919-681-4219.
- If the cycle is aborted, assume that the N95 respirators are not decontaminated. Do not enter the decon room without full PPE.

For All Other Emergencies

Refer to the Emergency Response calendar found in the facility or call 911.