

Instructions for Healthcare Facilities:

Preparation and Collection of Compatible N95 Respirators for Decontamination Using the Bioquell Technology System

The U.S. Food and Drug Administration has authorized an Emergency Use Authorization (EUA) for the emergency use of Ecolab's Bioquell Technology System (hereafter referred to as the "Bioquell Technology System") for use in decontaminating 3M N95 respirator models 1860, 8210, 1804, and 1870+ ("compatible N95 respirators") that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms, for a maximum of four (4) decontamination cycles per respirator, for single-user reuse (i.e., the same respirator is returned for reuse to the same healthcare personnel following its decontamination) by healthcare personnel to prevent exposure to pathogenic biological airborne particulates during the COVID-19 pandemic. Healthcare personnel must follow these instructions, as well as procedures at their healthcare facility, to prepare compatible N95 respirators for decontamination using the Bioquell Technology System; please refer to the Bioquell Technology System User's Manual for complete instructions for use.

All personnel involved in the collection and distribution of decontaminated, compatible N95 respirators and those using the decontaminated, compatible N95 respirators will be regularly screened for COVID-19 in accordance with the healthcare facility's procedures.

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.

- **The Bioquell Technology System is only authorized for use with 3M N95 respirator models 1860, 8210, 1804, and 1870+.**
- **All compatible N95 respirators that will be decontaminated with the Bioquell Technology System must be free of visible damage and visual soil or contamination (e.g., blood, dried sputum, makeup, bodily fluids).**
- **Discard and do not collect compatible N95 respirators that are visibly soiled or damaged.**
- **Discard compatible N95 respirators after exceeding four (4) decontamination cycles.**
- **Discard any compatible N95 respirators whose traceability was lost or number of decontamination cycles not able to be identified.**
- **Decontaminated, compatible N95 respirators are not sterile.**
- **The Bioquell Technology System has neither been cleared or approved by FDA, but**

has been authorized for emergency use by FDA under an EUA for the decontamination of compatible N95 respirators for single-user reuse by healthcare personnel to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates.

- **The emergency use of the Bioquell Technology System 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.**

Initiating the Decontamination Process:

The instructions outlined in this document ensure that your facility has been properly configured to deliver a controlled and monitored process for decontaminating compatible N95 respirators. After completion of the initial setup, verification is executed according to the following process, as outlined per the Conditions of Authorization:

- Bioquell Inc. will work with your healthcare facility to ensure that the room is properly configured for the Bioquell Technology System to deliver a controlled and monitored decontamination process. Bioquell Inc. will train designated personnel at your healthcare facility during the setup verification on execution of the decontamination process.
- Completion of such training and setup is documented with the form “Decontamination of Compatible N95 Respirators: Training and Setup Verification Form” (Setup Verification Form), which is completed, and then signed and submitted, along with photographic evidence, to solutions@bioquell.com.
- Bioquell Inc. will review the Setup Verification Form that is signed and completed by your healthcare facility. If it is found to be acceptable, Bioquell Inc. will sign the Setup Verification Form and share it with Ecolab Inc., Bioquell Inc.’s parent company, for final review and approval.
- Ecolab Inc. will review the Setup Verification Form that has been completed and signed by your healthcare facility and reviewed and signed by Bioquell Inc. If the Setup Verification Form is acceptable to Ecolab Inc., Ecolab Inc. will sign the Setup Verification Form and provide Bioquell Inc. and your healthcare facility with a final signed copy to indicate approval for your healthcare facility to begin routine decontamination operations.
- Please note that if requested by FDA, Ecolab Inc. must also submit the Setup Verification Form to FDA.

Healthcare Facility Responsibilities:

- Bioquell Inc. will train designated personnel at the healthcare facility during the setup verification on execution of the decontamination process according to the instructions outlined in this document. Bioquell Inc. will collect and maintain training records on the initial setup verification for designated healthcare facility personnel. Ecolab Inc. will have access to these records and make these records available to FDA on request. The healthcare facility will be responsible for any ongoing operational training.
- The healthcare facility maintains responsibility for ongoing operational execution of the decontamination process, including management of personnel using the Bioquell Technology System and training, as required as a condition of authorization under the EUA.

Decontamination Instructions

Materials Needed:

- Bioquell Vapor Generator (BQ50 or ProTeQ)
- Bioquell hydrogen peroxide sterilant (HPV-AQ)
- Bioquell Chemical Indicators (CI) and Biological Indicators (BI):
 - For initial setup and 2-week verification of the process control, BIs are required for release of decontaminated, compatible N95 respirators. Pending successful demonstration of the process control over the 2-week period, CIs can then be used to release the decontaminated, compatible N95 respirators. Healthcare facilities must always use 5 BIs and 5 CIs per decontamination load to confirm that decontamination cycles have been effectively conducted and to continue to monitor process control. Critical process parameters (room volume, injection rate, dwell time, and aeration) for the Bioquell Technology System must always be monitored even when using Bioquell biological indicators and Bioquell chemical indicators.
- Drager H₂O₂ monitor
- Supplies needed for transportation, storage, and handling of the N95 respirators such as personal protective equipment (PPE), bags, bins, racks, writing and tracking tools (e.g., logbook), and other miscellaneous items

Step 1: Collecting and Tracking Compatible N95 Respirators:

First, healthcare personnel must check to see if the N95 respirator is a 3M N95 respirator with one of the following model numbers: 1860, 8210, 1804, or 1870+. Only these 4 respirator models are authorized for use with the Bioquell Technology System.

Each healthcare facility must determine, institute, and implement their optimum method for collecting compatible N95 respirators. The following are important steps to help avoid potential respirator mix-up or additional exposure risk.

1. Create a collection station at the point of generation (i.e., hospital floor/unit).
2. Provide each station a bag or plastic sealed container to collect compatible N95 respirators.
 - a. **NOTE:** Bags or plastic sealed containers are for compatible N95 respirators only. Do not throw other personal protective equipment (PPE) (such as gloves), paper towels, or waste in the collection bag or container.
3. Enable healthcare personnel to label their own individual compatible N95 respirator (**NOTE:** permanent marker can fade with repeated decontaminations – periodic reapplication may be necessary. Alternatively, implement a permanently-affixed, laminated tag to the rear strap of the respirator).
 - a. Healthcare personnel must externally label the following:
 - i. A unique identifier or code for each individual compatible N95 respirator, as provided by the facility;
 - ii. Additional identifiers designated by the healthcare facility serving as a location identifier to correspond to a specific location/floor/unit within the facility.
 - b. Healthcare personnel must internally label the following:
 - i. Individual's name;
 - ii. Decontamination cycle number (discard respirator when soiled, damaged, or decontaminated 4 times).
 - c. Healthcare personnel must place each compatible N95 respirator in an individual paper bag and must be labeled with the individual's name prior to placing in collection bag or container.
4. Provide healthcare personnel instructions with regard to PPE when collecting compatible N95 respirators in accordance with the accompanying Instructions for Healthcare Personnel: Emergency Decontamination of Compatible N95 Respirators Using the Bioquell Technology System.
5. Create or update a record for each compatible N95 respirator as each one is presented for decontamination and after each decontamination cycle.
 - a. Connect the unique identifier (provided in step 3 above) to each decontamination cycle in order to effectively trace the number of decontamination cycles for each compatible N95 respirator.

Step 2: Room Selection for Decontamination:

Prior to taking any action, dedicated zones are required to ensure:

- Proper setup of compatible N95 respirators for decontamination;
- Tested Bioquell decontamination cycles in a defined space with repeatable processes;
- Collection of compatible N95 respirators;
- Safe and proper sorting of decontaminated, compatible N95 respirators to be returned to healthcare personnel promptly, with limited exposure risk.

A minimum of 2 rooms are required to properly perform decontamination and handle respirator storage and decontamination. One room shall be the dedicated respirator decontamination enclosure.

These rooms would ideally be adjacent to each other or linear. Access must also be restricted or protected to ensure minimal exposure risk to COVID-19 and during a Bioquell decontamination cycle.

For each stage of the process, from collection to redistribution, proper PPE (gloves, gown, N95 respirator, face-shield) must be donned. Each healthcare facility is recommended to implement their own standard operating procedures (SOP) for the donning and doffing process.

- **Room 1** will host the racks or clotheslines to hang the compatible N95 respirators, and the Bioquell Technology System. The decontamination process will always take place in this room. The room size must be 28 m³ for the ProTeQ or 30 m³ for the BQ50 (989 cubic feet or 1059 cubic feet, respectively).
 - The room must be constructed of standard, hard, non-absorbent materials, such as painted brick / block, painted drywall, painted plaster, painted / sealed timber, etc.
 - Suitable flooring materials include painted concrete, vinyl flooring, ceramic tile, etc.
 - Ceilings constructed of suspended ceiling tiles are acceptable, as long as all tiles are undamaged (no holes) and correctly fitted.
- **Room 2** serves as the room for sorting, recording, and redistributing decontaminated, compatible N95 respirators.

Step 3: Preparing Room 1 for the Decontamination:

- 1) Place the Bioquell vapor generator in the center of the room and evenly distribute the available aeration units around the enclosure.
- 2) Place or set up a means to support the compatible N95 respirators within the enclosure.
 - a. Compatible N95 respirators can be hung from the support means by a single strap and sufficiently spaced to prevent contact between respirators. **The Bioquell Technology System decontamination process is a surface contact process, and any contact point presents a possible occlusion site.** Alternatively, compatible N95 respirators may be presented on a wire shelving rack, well-spaced with minimum point contact, and must be positioned with the internal face pointing up.

- b. A hanging support that provides minimal contact with the compatible N95 respirator is necessary, and could include a series of “clotheslines”, wire, or other similar non-absorbent material (do not use cotton or string). Hanging hooks can be produced from standard paperclips.
 - c. Clotheslines strung between head and waist height will assist with the aeration process when located towards the edges of the room, as the Bioquell vapor generator shall be located in the center of the room.
 - d. Do not block nozzles or fans of the Bioquell vapor generator.
 - 3) Bring in the sealed containers of contaminated, compatible N95 respirators. Disinfect the outside of the bag/container with the appropriate disinfectant and wipe down. If using a bag, dispose of the bag once the contaminated, compatible N95 respirators have been removed. If using a solid plastic container, also follow the instructions in step 5 once the container is empty.
 - 4) Place up to a maximum of 160 compatible N95 respirators within the room.
 - a. Check each compatible N95 respirator during this time for contamination with blood, mucus, obvious damage, or if its decontamination record indicates that it has already been decontaminated 4 times. **A respirator must not be decontaminated if it is visibly soiled or if it has already been decontaminated 4 times.**
 - 5) If using containers, when the container is empty, wipe the interior with an efficacious product to remove any signs of visible contamination that may have transferred from the compatible N95 respirators. Place the container at an angle against the wall to provide point contact and allow the surfaces of the container to be exposed to the decontamination cycle.
 - 6) Place 5 Bioquell Biological Indicators (BIs) and 5 Bioquell Chemical Indicators (CIs) within the room.
 - a. BIs must be placed on each of the four walls and in the center of the room.
 - b. CIs must be hung or taped to the hanging support. Follow the instructions for use for the CIs: **Place CIs next to four (4) compatible N95 respirators in four (4) different locations furthest from the Bioquell vapor generator. Place the remaining CI at a central location.**
 - c. For initial setup and verification, release of decontaminated, compatible N95 respirators must be based on the use of Bioquell BIs. Please note that BIs require a minimum of 24 hours incubation to provide an initial result and must be incubated for 7 days. See Step 5: Cycle Verification for details.

7) **The critical process parameters for a decontamination cycle are room volume, injection rate, dwell time, and aeration and must always be monitored for each decontamination cycle.**

The following programming instructions ensure that the generator delivers a minimum of 10.3 g/m³ – 15 g/m³ of hydrogen peroxide to achieve a 6-log sporicidal level of kill, followed by 180 minutes of aeration or until the hydrogen peroxide concentration within the enclosure is ≤ 1.0ppm. **Note:** Initially, the decontaminated, compatible N95 respirators are released based on demonstrated process control using the results of the BIs over a two-week period. Following verification of the process, the decontaminated, compatible N95 respirators may be released using the results of CIs. Critical process parameters must always be monitored even when using Bioquell BIs and Bioquell CIs. See Step 5: Cycle Verification for details.

- Calculate the room volume by multiplying the average length, width, and height in meters of the room.
- Program your Bioquell vapor generator with the critical process parameters (Refer to Table 1).
- Refer to the ProTeQ User Manual or the BQ50 User Manual for the respective Bioquell vapor generator. Contact your Bioquell representative if you require further assistance.

Table 1: Programming of Critical Process Parameters

| Bioquell Vapor Generator | Injection Rate (max) | Injection Time Calculation | Dwell Time | Aeration Time |
|--------------------------|----------------------|--|--------------------------|--|
| ProTeQ | 16 g/min | $\frac{(Room\ Volume) * 10.3 * 60}{16}$ <i>Units: seconds</i> | 10 minutes (600 seconds) | 180 minutes or until concentration ≤ 1.0 ppm |
| BQ50 | 16 g/min | $(2 * Room\ Volume)$ <i>Units: seconds</i> | 10 minutes (600 seconds) | 180 minutes or until concentration ≤ 1.0 ppm |

For reference ONLY, the quantity of peroxide injected into a room is provided in Table 2. Increasing the quantity of hydrogen peroxide injected into the room results in an extension of the aeration time. Please keep the injection rate and dwell time to the minimum for the fastest possible cycle times.

Table 2: Quantity of Peroxide with Room Volume

| Room Volume | Quantity of peroxide @ 10.3 g/m ³ | Quantity of peroxide @ 15.0 g/m ³ |
|-------------------|---|---|
| 28 m ³ | 288 g | 420 g |
| 30 m ³ | 309 g | 450 g |

- Insert the Bioquell hydrogen peroxide sterilant into the Bioquell vapor generator. Wear eye goggles and gloves when handling Bioquell hydrogen peroxide.
- If the room has multiple entry points (i.e., doors), ensure that all but the primary entrance / exit are sealed using Bioquell tape or equivalent and locked (where appropriate).
- Confirm all vents are sealed with Bioquell or equivalent vent sealers.
- Confirm aeration units are powered up.
- Perform a final check on the positions and orientations of the respirators.
- Exit the room and seal the door using Bioquell or equivalent tape.
- Place “No Entry” notices on entry points to the room advising that a decontamination cycle is in progress, and include a named contact and telephone number to call in case of emergency.
- Turn on the Drager H₂O₂ low-level hydrogen peroxide monitor.
- Initiate the decontamination cycle.
- Use the low-level hydrogen peroxide monitor to check the enclosure for any possible leaks.
 - Should a leak be detected, seal the source with Bioquell or equivalent tape.

Note: In the event of an emergency, stop the decontamination cycle and activate the aeration units. When a decontamination cycle cannot be completed or if there are protocol deviations, discard the compatible N95 respirators from the run.

Step 4: Aerate the room:

- At the end of the aeration period, unseal and open the door wide enough to allow the environmental concentration of hydrogen peroxide to be measured

using the Drager H₂O₂ low-level monitor.

- If the Drager H₂O₂ monitor reads > 1.0 ppm, close the door and allow the room to continue aerating.
- Once the Drager H₂O₂ monitor reads ≤ 1.0ppm, turn off the Bioquell vapor generator.

Step 5: Cycle Verification:

- Access the room, following proper PPE protocols and confirm that the CIs show passing results of at least a 6-log reduction.
- If using BIs, retrieve and incubate them in accordance with the BI use instructions.

Note: For the first two weeks the sponsor must release the loads of decontaminated, compatible N95 respirators based on the BI results to demonstrate process control. After demonstration of the process control, then the sponsor may release the decontaminated, compatible N95 respirators based on the CI results. Healthcare facilities must always 5 BIs and 5 CIs per decontamination load to confirm that decontamination cycles have been effectively conducted and to continue to monitor process control. Critical process parameters (room volume, injection rate, dwell time, and aeration) must always be monitored.

- Save the decontamination cycle log if recorded electronically or retrieve the printout from the Bioquell Technology System, if present (note that not all Bioquell Technology Systems allow for printouts). Printouts / logs must be retained as evidence of decontamination cycle performance. CIs do not need to be retained, as their color may transition over time with exposure to the chemicals within normal air. A picture of the CIs immediately post cycle completion can provide evidence of decontamination cycle performance.

Step 6: Collection and Distribution of Decontaminated, Compatible N95 Respirators

- Collect the decontaminated, compatible N95 respirators into the original (now decontaminated) plastic container, or if a bag was originally used, obtain a new one, and move the respirators to Room 2 for recording and redistribution. Care shall be taken to prevent possible recontamination of the decontaminated, compatible N95 respirators during the recording and redistribution process.

Any problems should be immediately reported to Bioquell Inc.

Contact: +1-215-682-0225 or solutions@bioquell.com