HEALTHCARE

Emergency Decontamination of Compatible N95 or N95-Equivalent Respirators

Instructions for Healthcare Facilities

Health Canada has issued an authorization under the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19 for the emergency use of Ecolab's Bioquell Technology for use (hereafter referred to as the 'Bioquell System') in decontaminating compatible N95 or N95-equivalent respirators ('compatible N95 respirators') in healthcare facilities. Healthcare personnel should follow these instructions, as well as procedures at their healthcare facility, to prepare compatible N95 respirators for decontamination in a Bioquell System.

Please refer to the Bioquell System User's Guide for complete instructions for use.

- Due to incompatibility, the Bioquell system is not authorized for use with respirators that contain cellulose-based or paper materials.
- All compatible N95 respirators that will be decontaminated with the Bioquell System must be free of visible damage and visual soil/ contamination (e.g. blood, dried sputum, makeup, soil, bodily fluids).
- Compatible N95 Respirators that are visually soiled or damaged should not be collected for decontamination and must be discarded by healthcare providers.
- Compatible N95 respirators should be discarded after 20 decontamination cycles.
- Any compatible N95 respirator whose traceability was lost or number of decontamination cycles not able to be identified should be discarded.
- Decontaminated N95 Respirators are not sterile.

Materials Needed:

- Bioquell HPV Generator.
- Bioquell hydrogen peroxide sterilant (HPV-AQ).
- Bioquell Chemical Indicators (CI) or Biological Indicators (BI).
- Supplies needed for transportation, storage and handling of the N95 masks such as PPE, bags, bins, racks, writing and tracking tools (ex: logbook), and other miscellaneous items.

Compatible N95 Respirator Marking:

Review the N95 respirator product labeling to identify the material of construction. If the respirator contains cellulose-based materials, do NOT use the Bioquell decontamination system.

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Respirator Preparation and Room Selection

The steps provide guidance on the stages of the decontamination process, including collecting, and tracking of the N95 respirators, rooms selection & staging and processing using the Bioquell system.

Collecting and Tracking Compatible Respirators

Each hospital should determine, institute and oversee their best method for collecting masks. The following steps offer insights to help avoid potential product mix-up or additional exposure risk.

1. Create a collection station at the point of generation (i.e. hospital floor/unit).
2. Each station should have a bag or plastic sealed container provided by the healthcare facility 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 (such as gloves), paper towels, or waste in the collection bag.
3. With a permanent marker, healthcare personnel should label their own individual compatible N95 respirators (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. Externally label the following:
        i. A unique identifier or code for each individual mask as provided by the facility.
        ii. Additional identifiers designated by the organization serving as a location identifier to correspond to a specific location/floor/unit within the site.
    b. Internally label the following:
        i. Individual user's name.
4. Healthcare personnel should follow all instructions provided by their facility with regards to PPE when collecting respirators.
5. As respirators are presented for decontamination and after a cycle, a record for each respirator should be created or updated.
    a. The unique identifier provided in step 3 above should be connected to each cycle in order to effectively trace the number of cycles each respirator has received.

Room Selection for Decontamination and Reprocessing Decontaminated Respirators:

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

- proper setup of N95 respirators for decontamination;
- tested Bioquell biodecontamination cycles in a defined space with repeatable scenarios;
- collection of N95 respirators;
- safe and proper sorting of decontaminated masks to be returned to personnel promptly with limited exposure risk.

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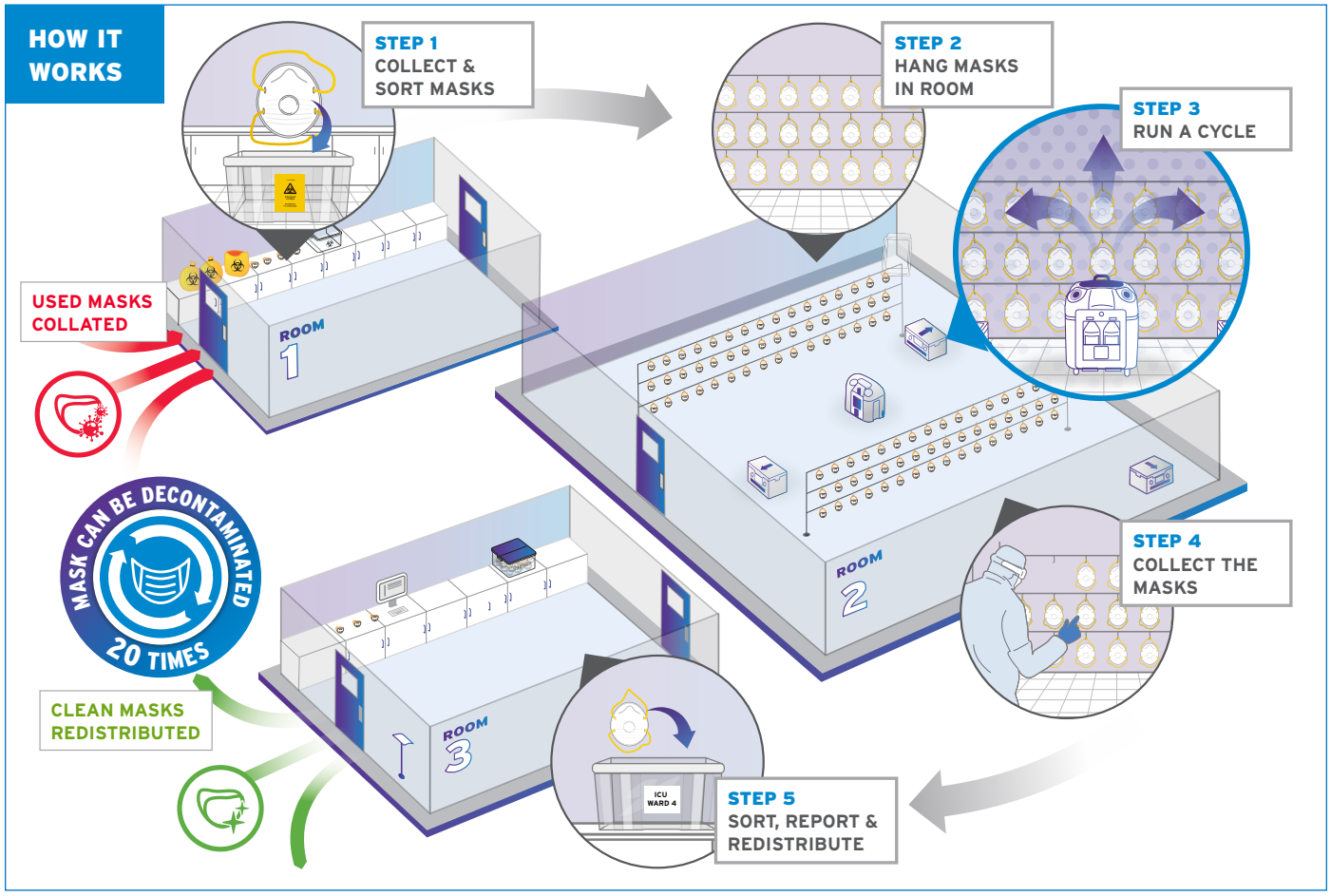
Room Allocation

Up to 3 rooms may be needed to properly perform decontamination and handle respirator storage and reprocessing.

These 3 rooms would ideally be adjacent to each other or linear. Access would 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, each healthcare system will be required to use their own standard operating procedures (SOP) to define PPE requirements and donning and doffing process.



- **Room 1** is the storage area for respirators collected to be decontaminated.
- **Room 2** will hold the racks or clotheslines used to process the respirators using the Bioquell decontamination system. The Bioquell process will always take place in this room. It should be ≥10m^3 up to 100m^3 (350 ft^3 to 3500 ft^3).
  - The room should 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 3** serves as the reprocessing room for sorting, recording and redistributing decontaminated masks.

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Room Preparation

Preparing Room 2 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 masks within the enclosure.
    a. Masks can be hung from the support means by a single strap and sufficiently spaced to prevent contact between masks. Bioquell decontamination is a surface contact process, and any contact point presents a possible occlusion site. Alternatively, masks may be presented on a wire shelving rack, well-spaced with minimum point contact, and should be positioned with the internal face pointing up.
    b. A hanging support should aim for minimal contact with the mask 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 should be strung between head and waist height to assist with the aeration process and located towards the edges of the room, as the 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 respirators. If using a bag, dispose of the bag once the respirators have been removed. If using a solid plastic container, follow the instruction in point 5.
4. Place up to a maximum of 400 masks within the enclosure.
    a. Check each mask during this time for contamination with blood, mucus, obvious damage or its reprocessing record indicates that it has already been reprocessed 20 times.
5. When a container is empty, wipe the interior with an efficacious product to remove any signs of visible contamination that may have transferred from the masks.
6. Place the container at an angle against the wall to provide point contact and allow the surfaces of the container and to be exposed to the decontamination cycle.
7. Place Bioquell Chemical Indicators (CIs) within the enclosure.
    a. CIs should be hung or taped to the hanging support. Follow the instructions for use for the CI. Place next to the mask furthest from the generator.
    b. Bioquell Biological Indicators (BIs) can be used instead of CIs. Note: CIs provide instantaneous verification of cycle performance. BIs require a minimum of 24 hours incubation to provide an initial result and should be incubated for 7 days.
    c. Follow all instruction in using and collecting CIs or BIs.

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Room Preparation Continued

8. Program the Bioquell vapor generator to deliver a 6-log sporicidal level of kill and aerate for 180 minutes. 6-log sporicidal level of kill is verified or determined using Biological Indicators (BI) or calibrated Chemical Indicators (CI).
    a. Refer to the Bioquell vapor generator use manual or contact your Bioquell representative should you require guidance on how to program the system in accordance with the above parameters.
9. Insert the Bioquell hydrogen peroxide sterilant into the vapor generator.
    a. Wear eye goggles and gloves when handling Bioquell hydrogen peroxide.
10. 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).
11. Confirm all vents are sealed with Bioquell or equivalent vent sealers.
12. Confirm aeration units are powered up.
13. Perform a final check on the positions and orientations of the respirators.
14. Exit the room and seal the door using Bioquell or equivalent tape.
15. Place "No Entry" notices on entry points to the room advising that a Bioquell cycle is in progress.
    a. Include a named contact and telephone number to call in case of emergency.
16. Turn on the low-level hydrogen peroxide monitor.
17. Initiate the cycle.
18. Use the low-level hydrogen peroxide monitor to check the enclosure for any possible leaks.
    a. Should a leak be detected, seal the source with Bioquell or equivalent tape.
19. 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 low-level monitor.
    a. If the monitor reads >1.0ppm, close the door and allow the room to continue aerating.
    b. Once the monitor reads ≤1.0ppm, turn off the Bioquell system.
20. Access the room, following proper PPE protocols and confirm that the chemical indicators show at least a 6 $\log^{10}$ reduction.
21. Collect the masks into the original (now decontaminated) plastic container, or if a bag was originally used, obtain a new one, and move them to Room 3 for recording and redistribution. Care shall be taken to prevent possible recontamination of the masks during the recording and redistribution process.
22. Save the cycle log if recorded electronically or retrieve the printout from the unit if present. (Not all Bioquell systems allow for this).
    a. Printouts / logs should be retained as evidence of cycle performance. CIs should not 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 cycle performance.

NOTE: In the event of an emergency, stop the cycle and activate the aeration units. When a cycle cannot be completed or if there are protocol deviations, we recommend scrapping the N95 respirators from the run.

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Additional Information

Reuse Information:

Each mask can be decontaminated only up to 20 times using the Bioquell system.

Additional Information:

Healthcare facilities that decontaminate the N95 masks using the Bioquell system are required to maintain responsibility for the following:

- Operational Execution: All aspects of the reprocessing steps including chain of custody, verification of effectiveness of the decontamination process and adverse event reporting according to their own internal policies. Bioquell will not manage these activities.
- Personnel: Recruitment, training and monitoring of personnel conducting the reprocessing of the N95 masks will be with the responsibility of the hospital management. Bioquell will not manage these activities.

General Instructions for Care and Maintenance of the Device:

Follow the manufacturer's instructions for care and maintenance of the N95 respirators.

ANY PROBLEMS SHOULD BE IMMEDIATELY REPORTED TO BIOQUELL
Contact: **+1-215-682-0225** or **solutions@bioquell.com**

WORLDWIDE HEADQUARTERS 1 Ecolab Place, St. Paul, MN 55102 USA
CANADA HEADQUARTERS 5105 Tomken Road, Mississauga, ON, Canada L4W 2X5
www.ecolab.com/lifesciences

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