Instructions for Healthcare Personnel:

Emergency Decontamination of Compatible N95 Respirators Using the Bioquell Technology System

*These respirators have been decontaminated to deactivate the SARS-CoV-2 virus, but they are not sterile.

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 by the Bioquell Technology System.

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+.**
- **Healthcare personnel must perform a user seal check of the decontaminated, compatible N95 respirator according to OSHA standard prior to beginning a shift. If the user seal check does not pass, discard the respirator.**
- **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 4 decontamination cycles.**
- **Discard any compatible N95 respirator whose traceability was lost or number of decontamination cycles not able to be identified.**
- **Decontaminated, compatible N95 respirators are not sterile.**
- **Do not use decontaminated, compatible N95 respirators during surgical procedures.**
- **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 authorization is revoked sooner.**

Compatible N95 Respirator Marking and Collection:

The following are important steps to help avoid potential respirator mix-up or additional exposure risk.

1. Locate the designated compatible N95 respirator collection station at your healthcare facility (i.e., hospital floor/unit).
2. Each station must have a bag or plastic sealed container provided by the healthcare facility to collect compatible N95 respirators.
   NOTE: Bags or plastic sealed containers are for compatible N95 respirators only. Do not throw other personal protective equipment (PPE), paper towels, or waste in the collection bag or container.
3. Confirm that 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.
4. With a permanent marker, label your own individual compatible N95 respirator (NOTE: permanent marker can fade with repeated decontaminations – periodic reapplication may be necessary. Alternatively, your healthcare facility may implement a system that uses a permanently-affixed, laminated tag applied to the rear strap of the respirator).
   a. Externally label the following:
      i. A unique identifier or code for each individual compatible N95 respirator as provided by your healthcare facility;
      ii. Additional identifiers designated by your healthcare facility serving as a location identifier to correspond to a specific location/floor/unit within your healthcare facility.
   b. Internally label the following:
      i. Your name;
      ii. Decontamination cycle number (discard when soiled, damaged, or decontaminated 4 times).
   c. Each compatible N95 respirator must be placed in an individual paper bag and must be labeled with the individual's name prior to placing in collection bag or container.
5. Place your compatible N95 respirator in the collection bag or container at the designated collection station for your unit.
6. In addition to these instructions, you must follow all instructions provided by your healthcare facility about PPE when collecting contaminated, compatible N95 respirators.
7. As compatible N95 respirators are presented for decontamination and after a decontamination cycle, a record for each compatible N95 respirator must be created or updated. The unique identifier provided in step 4 above must be connected to each cycle in order to effectively trace the number of decontamination cycles for each compatible N95 respirator.

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