FACT SHEET FOR HEALTHCARE PERSONNEL

Bioquell Technology System for Decontaminating Compatible N95 respirators **December 4, 2020**

Coronavirus Disease 2019 (COVID-19)

You have been given a **decontaminated 3M N95 respirator with a model number of 1860, 8210, 1804, or 1870+** ("compatible N95 respirator") that has been decontaminated using a decontamination system that is authorized to decontaminate compatible N95 respirators **for single-user reuse by healthcare personnel (HCP) in a healthcare setting** (i.e., the same respirator is returned for reuse to the same HCP following its decontamination) to help prevent HCP exposure to pathogenic biological airborne particulates during the COVID-19 pandemic.

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of decontaminated, compatible N95 respirators. These compatible N95 respirators have been decontaminated using the Bioquell Technology System (hereafter referred to as "**decontaminated N95 respirators"** and **"Bioquell Technology System"** throughout this Fact Sheet).

Whether or not you use a surgical mask, respirator, or face shield, always follow infection control measures: wash hands, cover coughs and sneezes, stay home if you may be sick.

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC webpage for the most up to date information.

What do I need to know about the emergency use of the Bioquell Technology System and decontaminated N95 respirators?

- The Bioquell Technology System has been authorized for emergency use to decontaminate compatible N95 respirators for single-user reuse by HCP during the COVID-19 pandemic to prevent wearer exposure to pathogenic biological airborne particulates, including SARS-CoV-2.
- **Compatible N95 respirators are limited to 3M's N95 respirator models 1860, 8210, 1804, and 1870+**. The Bioquell Technology System is **not authorized** for use with any respirators other than 3M models 1860, 8210, 1804, and 1870+.
- Successful testing on decontaminated N95 respirators demonstrated acceptable performance through four (4) decontamination cycles for sporicidal activity, viricidal activity, filtration efficiency, breathability, form fit testing, and strap integrity testing, per compatible N95 respirator. This testing has proven a 6-log reduction in biological contaminant with biological and chemical indicators placed throughout the room focusing on areas of the room that would be most difficult for hydrogen peroxide vapor to reach.

- **Use of decontaminated N95 respirators**
  - ✓ Decontaminated N95 respirators are not sterile.
  - ✓ HCP must perform a user seal check of the decontaminated N95 respirator according to OSHA standard prior to beginning a shift. If the user seal check does not pass, the respirator must be discarded.
  - ✓ Inspect respirators after each use prior to submission for decontamination.
  - ✓ Discard respirators with visible soiling (e.g., blood) or damage – do not use and do not send for decontamination.
  - ✓ The number of times a respirator has been decontaminated is written on the respirator (maximum 4 times).
  - ✓ Report problems with decontaminated N95 respirators to your healthcare facility.

- **Monitor yourself for signs and symptoms** of potential infection with SARS-CoV-2 or other respiratory infection for up to and including 14 days after last contact with the SARS-CoV-2virus and related material, and promptly report such information your healthcare facility.

- **Report damage or discoloration** observed upon receipt of the decontaminated, N95 respirators, and potential exposure of HCP from breaks in or other damage to or degradation of the decontaminated N95 respirators to your healthcare facility.

- 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.

Use appropriate personal protective equipment (PPE) when caring for individuals suspected of having COVID-19 as outlined in the CDC webpages, including *Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the COVID-19 Pandemic Infection Control, and FAQ on PPE.*

Current information on COVID-19 for healthcare personnel is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

What are the known and potential benefits and risks of using decontaminated N95 respirators that were decontaminated using the Bioquell Technology System?

Potential benefits include:

- May help prevent exposure to airborne pathogens, and therefore reduce the risk of infection or illness
- Extends the usability of compatible N95 respirators by allowing for decontamination and single-user reuse

Potential risks include:

- Failure of filtration efficiency
- Reduced breathability
- Strap failure and ineffective face-fit
- Reused respirators may not have been effectively decontaminated of SARS-CoV-2 or other pathogens

Overview of the Bioquell Technology System

The Bioquell Technology System is a fixed and controlled decontamination process that uses vaporized hydrogen peroxide (VHP) for decontamination of compatible N95 respirators that are contaminated or potentially contaminated with SARS-CoV-2. For this emergency use authorization, N95 respirators are limited to four - respirators models from 3M: 1860, 8210, 1804, or 1870+.

Each decontamination cycle in the Bioquell Technology System consists of injecting VHP into the designated decontamination room until achieving a saturated atmosphere indicated by micro condensation; maintaining the VHP exposure for a 10-minute dwell time; and allowing the VHP to off gas to a level of 1 ppm prior to post decontamination processing. This decontamination system enables the single-user reuse of compatible N95 respirators that would otherwise be disposed of after a single use. However, respirators that are visibly soiled must be discarded and not reused or decontaminated.

FACT SHEET FOR HEALTHCARE PERSONNEL

Bioquell Technology System for Decontaminating Compatible N95 respirators **December 4, 2020**

Coronavirus Disease 2019 (COVID-19)

What is an EUA?

The United States Food and Drug Administration (FDA) has made the emergency use of the Bioquell Technology System to decontaminate compatible N95 respirators available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of medical devices due to insufficient supply during the COVID-19 pandemic.

The Bioquell Technology System has been made available under an EUA and has not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that the Bioquell Technology System may be effective at preventing HCP exposure to pathogenic biological airborne particulates during periods of insufficient respirator supply during the COVID-19 pandemic by decontaminating, for a maximum of 4 decontamination cycles per respirator, compatible N95 respirators that are contaminated or potentially contaminated with SARS- CoV-2 or other pathogenic microorganisms.

The EUA for the Bioquell Technology System is in effect for the duration of the COVID-19 declaration justifying emergency use of medical devices, unless terminated or revoked (after which the products may no longer be used).

Where can I go for updates and more information?

CDC webpages:
General: https://www.cdc.gov/COVID19
Healthcare Professionals:
https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the COVID-19 Pandemic:
https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
Infection Control:
https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html
FAQ on PPE:
https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html

FDA webpages:
General: www.fda.gov/novelcoronavirus
EUAs: https://www.fda.gov/medical-devices/emergency- situations-medical-devices/emergency-use-authorizations

Bioquell webpages:
General: www.bioquell.com, www.ecolab.com