



# Fact Sheet for Healthcare Personnel

Bioquell Hydrogen Peroxide Vapour Decontamination Systems for Decontaminating Compatible N95 and/or FFP2 Respirators. Coronavirus Disease 2019 (COVID-19)

Your healthcare facility is currently **decontaminating N95 and/or FFP2 respirators for reuse in a healthcare setting for emergency use**. These efforts are being undertaken to reduce healthcare personnel exposure to pathogenic biologic airborne particulates during the COVID-19 pandemic.

The **Fact Sheet** has been prepared to inform you of the significant known and potential risks and benefits of the emergency use of decontaminated N95 or FFP2 respirators. Please review the **Fact Sheet** in conjunction with the document provided to you, "Preparation and Collection of compatible N95 and/or FFP2 Respirators for Decontamination by the Bioquell Hydrogen Peroxide Vapour Technology".

Compatible N95 or FFP2 respirators have been decontaminated using Bioquell hydrogen peroxide vapour technology (hereafter referred to as "decontaminated N95 respirators" and "Bioquell" throughout this **Fact Sheet**). Decontaminated N95 respirators that have been decontaminated utilising the practice documented in the *Healthcare Facility Instructions* are authorised for use by healthcare personnel in a healthcare setting during the COVID-19 pandemic.

## What are the symptoms of COVID-19?

Symptoms from confirmed COVID-19 patients are like other upper-respiratory infections, including fever, cough and difficulty breathing. They range from mild to severe and appear 2-14 days after exposure, with a median incubation period of 5 days after exposure to the virus. However, limited information is currently available to characterise the full spectrum of clinical illness and timeframes associated with COVID-19.

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

## What do I need to know about the emergency use of decontaminated N95 respirators?

- ▶ **Bioquell** has been authorised for emergency use to decontaminate compatible **N95** or **FFP2** respirators for reuse by healthcare personnel during the COVID-19 pandemic to prevent wearer exposure to pathogenic airborne particulates.
  - Compatible **N95** or **FFP2** respirators under the Bioquell Emergency Use Authorisation are those that do not contain cellulose-based materials. Review the respirator product labelling to identify the material of construction.
- ▶ Successful testing on **decontaminated N95 respirators** demonstrated acceptable performance through 20 decontamination cycles for filtration efficiency, breathability, form fit testing, and strap integrity testing. Refer to "Final Report for the Bioquell Hydrogen Peroxide Vapour (HPV) Decontamination for Reuse of N95 Respirators", available at <https://www.fda.gov/media/136386/download>

## What are the known and potential benefits and risks of using decontaminated N95 respirators?

Potential **benefits** include:

- ▶ May help prevent exposure to airborne pathogens, and therefore risk of infection or illness
- ▶ Extends the usability of compatible N95 or FFP2 respirators by allowing for decontamination and 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 COVID-19 or other pathogens

#### Use of decontaminated N95 respirators:

- Prior to submission for decontamination, inspect respirators **after each use**.
- Discard respirators with **visible soiling** (e.g., blood) **or damage - do not use and do not send for decontamination**.
- **Cellulose-based materials should be considered incompatible** with the Bioquell decontamination process. Review the N95 respirator product labelling to identify the material of construction.
- The number of times a respirator has been decontaminated is logged by the hospital (maximum 20 times).
- **Report problems** with decontaminated N95 respirators to **your healthcare facility**.

- **Do not decontaminate valved respirators with the Bioquell System.**

- ▲ **Monitor healthcare personnel for signs and symptoms** of potential infection with COVID-19 or other respiratory infection for up to and including 14 days after last contact with the SARS-CoV-2 virus and related material.
- ▲ **Report damage or discoloration** observed upon receipt of the decontaminated N95 respirators, and potential exposure of healthcare personnel from breaks in or other damage to or degradation of the decontaminated N95 respirators.

Use appropriate personal protective equipment (PPE) when caring for individuals suspected of having COVID-19.

### Overview of the Bioquell Decontamination Process

The Bioquell hydrogen peroxide vapour is a proven bio decontamination technology for enclosed areas delivered using automated systems. This vapour phase hydrogen peroxide process uses a US EPA registered sterilant, providing a 6-log<sub>10</sub> sporicidal reduction on every exposed surface in the enclosed area. N95 or FFP2 respirators containing cellulose-based materials should not be used with the Bioquell decontamination process.

A single cycle is required to achieve successful decontamination of a compatible respirator. Every cycle operates under the same principles.

- ▲ First, the hydrogen peroxide vapour is dispersed through an enclosed area via a Bioquell generator. This continues until a saturated atmosphere is achieved resulting in the formation of micro-condensation.

- ▲ Dwell time follows in order to maintain the surface exposure to the hydrogen peroxide vapour.
- ▲ Afterward, the hydrogen peroxide vapour is removed from the enclosed area through aeration.
- ▲ The area is safe to enter after a level of  $\leq 1$  ppm is achieved from the vapour removal process.
- ▲ At this point, the respirators are ready for collection. No other steps are required with regards to the decontamination, such as additional wipe downs.
- ▲ To verify a successful process, Bioquell Biological Indicators (BI) or calibrated Chemical Indicators (CI) are dispersed throughout the enclosed space to indicate a successful decontamination cycle.

Bioquell decontamination enables the reuse of compatible N95 or FFP2 respirators that would otherwise be disposed of after a single use. However, respirators that are visibly soiled or damaged must be discarded and not reused or decontaminated.



#### About Bioquell's Efficacy

Bioquell has proven efficacy against a wide range of microorganisms. At any time, this information can be found on [www.bioquell.com](http://www.bioquell.com) or by contacting: [asiapac.service@bioquell.com](mailto:asiapac.service@bioquell.com). The Bioquell Hydrogen Peroxide Vapour Biological Efficacy document contains over 75 related studies connected to Bioquell's efficacy against a broad spectrum of pathogens ranging from enveloped viruses to bacterial spores.