



Fact Sheet for Healthcare Personnel

Decontamination of N95 Respirators

You have been given a **decontaminated N95 respirator that has been decontaminated using a decontamination system for reuse by healthcare personnel in a healthcare setting to help prevent healthcare personnel exposure to pathogenic biologic 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 **N95 respirator**.

Decontaminated **N95 respirators** that have been processed using **Bioquell hydrogen peroxide vapor technology** are authorized for use by healthcare personnel in a healthcare setting during the COVID-19 pandemic.

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. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

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

What do I need to know about the emergency use of a decontaminated N95 respirator?

- ▶ **The Bioquell hydrogen peroxide vapor technology** has been authorized for emergency use to decontaminate **N95 respirators** by healthcare personnel during the COVID-19 pandemic to prevent wearer exposure to pathogenic airborne particulates.
- ▶ Successful testing on **decontaminated N95 respirators** demonstrated acceptable performance through 20 decontamination cycles
- ▶ **Use of decontaminated N95 respirators:** Inspect the N95 respirators for damage, visible soiling and lack of information in tracking the number of decontamination cycles. Do not use damaged, soil or untracked respirators.
- ▶ Monitor healthcare personnel 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-2 virus and related material, and promptly report such information to **appropriate personnel in your healthcare facility**.
- ▶ **Report damage or discoloration** observed upon receipt of the decontaminated N95 respirator.





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 Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings, Infection Control, and FAQ about 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?

Potential benefits include: Reuse of compatible N95 respirators to prevent exposure to pathogenic biological airborne particulates where there are insufficient supplies.

Potential risks include: If the N95 respirators are not effectively decontaminated, then healthcare personnel could potentially be exposed to pathogenic biological airborne particles.

Overview of the Bioquell hydrogen peroxide vapor technology

Bioquell technology uses 35% Hydrogen Peroxide Vapor to deliver a consistent and reliable >6-log decontamination of surfaces. Bioquell Biological Indicators (BI) or calibrated Chemical Indicators (CI) are used in the decontamination process to ensure a successful decontamination of the N95 respirators.

What is an Interim Order?

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 the **Bioquell** Decontamination System to decontaminate **N95 respirators**. The Interim Order, as signed by the Minister of Health, allows certain medical devices that may not fully meet regulatory requirements to be imported and sold in Canada. This measure by the Canadian government is designed to help address shortages during the COVID-19 pandemic.

The **Bioquell** Decontamination System has been made available under an Interim Order and has not undergone the same type of review as a Health Canada-approved or cleared device. Health Canada may approve a "Covid-19 Medical Device" when certain criteria are met, including when there are no adequate, approved, available alternatives. Based on the totality of scientific evidence available, it is reasonable to believe that the **Bioquell** Decontamination System may be effective at preventing healthcare personnel exposure to pathogenic airborne particulates during periods of insufficient respirator supply during the COVID-19 pandemic by decontaminating, for a maximum of 20 decontamination cycles per **N95 respirator** that are contaminated or potentially contaminated with SARS-CoV-2 or other pathogenic microorganisms.

The Interim Order for the **Bioquell** Decontamination 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).

Reporting

- Report all incidents concerning contaminated N95 Masks to the healthcare facility.
- Report all adverse events to the Canada Vigilance Program at 1-866-235-3345 or hc.vigilance.sc@canada.ca

Where can I go for updates and more information?

HEALTH CANADA WEBPAGES:

General: www.canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19.html

Healthcare Professionals: www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/health-professionals.html?topic=tilelink

Personal Protection Equipment: www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/covid-19-personal-protective-equipment.html

Interim Order Explanatory Note: www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/covid19-interim-order-drugs-medical-devices-special-foods/note.html

CDC WEBPAGES:

General: www.cdc.gov/COVID19

Healthcare Professionals: www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html

Infection Prevention and Control Recommendations in Healthcare Settings: www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html

Infection Control: www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html

FAQ on Personal Protective Equipment: www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html

FDA WEBPAGES:

General: www.fda.gov/novelcoronavirus

EUAs: www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations