

COVID-19: Disinfection of N95 Single-Use Filtering Facepiece Respirators

CERDM – Interim Recommendations

December 7, 2020 - Version 4.0. Changes are indicated in yellow

Foreword

This publication uses the term “disinfection” of **N95 single-use filtering facepiece respirators (FFRs) (also called N95 masks)** to refer to the chemical or physical process that inactivates infectious agents. It should be noted that the various reference publications and documents on the subject consulted by the Centre d’expertise en retraitement des dispositifs médicaux (CERDM) use the terms “decontamination,” “disinfection,” or both. The CERDM has chosen the term “disinfection” to conform to the reprocessing nomenclature that is generally accepted in Canada (CSA Z314.18). According to this nomenclature, the term decontamination is more general and includes the process of cleaning followed by the inactivation of infectious agents. However, in the context of reprocessing of N95 FFRs, only one step, aimed at inhibiting various pathogenic microorganisms, is performed; therefore, it seems more accurate to use the term “disinfection”.

Context

The CERDM evaluated the available options for disinfection of FFRs in the context of a **potential shortage** of filtering facepiece respirators (FFRs) in health care facilities due to the COVID-19 pandemic (INSPQ, 2020a). This represents a solution of last resort to be applied when there **is an anticipated shortage¹ in order to be able to distribute them to workers only during a real shortage²** and when all other strategies for addressing the shortage of N95 FFRs are insufficient. In fact, this solution is not consistent with the guidelines of regulatory authorities regarding the reprocessing of single-use medical devices (SUMDs). This effort is being undertaken with the aim of identifying alternative strategies that can be added to the measures already available, to provide the best possible protection for workers in the event of a shortage.

Objective

This document is intended for decision makers, managers and clinical personnel involved in medical device reprocessing (MDR). It presents the technologies approved by Health Canada in the COVID-19 context as well as a promising - although as yet unauthorized - option for disinfecting N95 FFRs.

¹ Strategies to be applied in the event of an anticipated shortage, but while supplies are available (after verification with the procurement department and the ministère de la Santé et des Services sociaux (MSSS)).

² Strategies to be applied in the event of a known shortage (after verification with the procurement department and the MSSS).

Method

The CERDM carried out a non-exhaustive review of the literature on the options for disinfecting single-use N95 FFRs and contacted manufacturers of available equipment to identify the steps they have taken to validate such an approach. The CERDM also considered any steps that have been taken within the health network that were brought to its attention. Finally, it was possible to evaluate the options identified (INSPQ, 2020a) based on the following criteria, consistent with those of Health Canada (2020a):

- 1) the safety of health care workers, i.e., the effectiveness of the procedure in reducing pathogen burden, the integrity of the N95 FFR after disinfection (filtration efficiency and facepiece fit) and the absence of residual chemical hazard; and
- 2) feasibility, i.e., the availability of disinfection equipment, its performance and the requirements for the procedure.

It should be noted that for Health Canada to authorize an N95 FFR disinfection technology, the manufacturer must demonstrate a sterility assurance level (SAL) of 10^{-6} for the inactivation of spore-forming bacteria and a 4-log reduction for SARS-CoV-2 or recognized analogous viruses (Health Canada, 2020a).

Technologies and equipment approved by Health Canada

The CERDM summarized and analyzed the state of knowledge concerning the disinfection options for N95 FFRs and placed in perspective the advantages and limitations of each disinfection process identified (INSPQ, 2020a).

Low-temperature sterilizers (hydrogen peroxide plasma or vaporized hydrogen peroxide)

Disinfection of N95 FFRs in low-temperature sterilizers available in medical device reprocessing departments (MDRDs) is an easily accessible short-term solution that meets our evaluation criteria. The quantity of N95 FFRs that can be disinfected in low-temperature sterilizers, while not negligible, is significantly lower than that which could be achieved using other devices that can perform large-scale disinfection of N95 FFRs.

Currently, three manufacturers of low-temperature sterilizers have had their technology approved by Health Canada under the Interim Order applicable to the present pandemic (Health Canada, 2020b) and have issued disinfection instructions:

- ▶ Stryker: Sterizone VP4;
- ▶ ASP: STERRAD 100S, STERRAD NX and STERRAD 100NX;
- ▶ Steris: V-PRO 1Plus, V-PRO maX, V-PRO maX2.

Consideration should be given to the fact that these models are possibly already being used for the regular activities of MDRDs and carry a risk of cross contamination inside the sterile and clean zones of the MDRD.

Based on the results of the study conducted by the Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST, 2020), a drying period of at least one hour before disinfection is recommended depending on the time elapsed between the end of use and collection. In addition, an aeration period of 24 hours following the disinfection cycle is recommended for N95 FFRs, with the pouch closed. These CERDM recommendations apply to the instructions of the three low temperature sterilizer companies (ASP, Steris, Stryker).

Hydrogen peroxide vaporizer (room disinfection device)

Vaporized hydrogen peroxide is generated by vaporizing an aqueous solution of hydrogen peroxide, which is then diffused into a room by means of a room disinfection device.

- ▶ The technology of the manufacturer Bioquell was approved by Health Canada under the Interim Order applicable to the COVID-19 pandemic (Health Canada, 2020b).

This technology is an effective means of disinfecting a large number of FFRs at the same time. Depending on the characteristics of the device, the size of the room and the operating parameters, this technology could theoretically allow for a much higher yield (a possibility of approximately 1000 N95 FFRs per disinfection cycle after validation, INSPQ, 2020a) than low- or high-temperature sterilizers. Although this technology is rarely found at present within the health network, **some facilities now have access to it.**

High-temperature sterilizers (steam sterilizers)

Although the effectiveness of this technology has only been validated on a limited number of N95 FFR models produced by the company 3M, it has the advantage of being compatible with certain models that contain cellulose and thus offers a method that is complementary to other authorized disinfection methods that do not allow for the disinfection of N95 FFRs with cellulose.

- ▶ The manufacturer Steris has received approval for their technology from Health Canada under the Interim Order applicable to the COVID-19 pandemic (Health Canada, 2020b) and has issued disinfection instructions for the following models:
 - ▶ Steris: Amsco 400;
 - ▶ Steris: Century medium.

This low-cost technology could be easily implemented in MDRDs. However, it is impossible to move steam sterilizers from the setting in which they are used. This carries an increased risk of cross-contamination between the regular activities of the MDRD and the disinfection of N95 FFRs. Devices that cannot be moved to a room dedicated to disinfection carry a risk of cross-contamination, as is the case for low-temperature sterilizers. In addition, the steam sterilizer must be programmed to perform a cycle specific to the disinfection of N95 FFRs (decontamination cycle). This non-standard cycle (65 °C for 30 minutes) carries a significant risk of error on the part of personnel since the inadvertent use of this cycle could compromise the achievement of sterility of medical devices.

Disinfection device combining several technologies (UVC, vaporized hydrogen peroxide and ozone)

The following device was approved by Health Canada under the Interim Order (Health Canada, 2020b):

- ▶ Clean Works Medical: Clean Flow Health Care Mini.

This device, manufactured in Ontario, is used in the agri-food industry and could disinfect up to 800 N95 FFRs per hour. To our knowledge, this device is not currently being used in Québec health care facilities.

PRECAUTIONS TO BE CONSIDERED

It is important to respect the number of disinfection cycles authorized by the manufacturer: some authorize only two disinfection cycles, while others allow a greater number of cycles. In fact, the fit of some N95 FFR models is affected after five cycles of donning and removal of the FFR without a disinfection cycle (Bergman et al., 2012), and after just two cycles following low-temperature disinfection (Lieu et al., 2020).

Thus, it is advisable to verify whether the disinfected N95 FFR is able to ensure an adequate fit in compliance with infection prevention and control (ICP) measures (INSPQ, 2020e).

Technologies not yet approved by Health Canada

Promising option

Manufacturers of devices using UVC technology, recommended by ECRI, have applied to Health Canada to be authorized for disinfection of N95 FFRs.

Options not retained by the CERDM

Dry heat disinfection of N95 FFRs was not retained by the CERDM. This disinfection process requires high temperatures and long cycle times to allow for viral inactivation, which could affect the integrity of N95 FFRs. At present, there is insufficient data in the literature to support a conclusion regarding the effectiveness of dry heat (Diptanu et al., 2020).

However, tests conducted in Québec on the Nocospray device, using hydrogen peroxide nebulization, did not enable elimination of the pathogen burden and resulted in an accumulation of silver nitrate in the N95 FFR following disinfection cycles. Therefore, this technology was not retained as an option.

Recommendations

In the event of a shortage of N95 FFRs, the CERDM recommends following:

- ▶ The recommendations of the Comité sur les infections nosocomiales du Québec (CINQ), including that of optimizing the use of N95 FFRs and that concerning exceptional measures (INSPQ, 2020b,c,e);
- ▶ The manufacturers' instructions for the technologies approved by Health Canada for disinfection of single-use N95 FFRs under the Interim Order applicable to COVID-19 (Health Canada, 2020b);
- ▶ For low-temperature sterilizers, a minimum pre-treatment drying period of one hour, as well as a 24-hour aeration period following disinfection, to avoid the presence of hydrogen peroxide in the N95 FFR, based on the results of the study conducted by the IRSST (2020). This recommendation applies to the three manufacturers of low-temperature sterilizers (ASP, Steris, Stryker, etc.);
- ▶ The CERDM's guidelines (INSPQ, 2020d), to develop for the facility an internal disinfection procedure, covering from the collection of single-use N95 FFRs up to their storage.

Disinfection of N95 FFRs represents a solution of last resort to be applied when there is an anticipated shortage in order to be able to distribute them to workers only during a real shortage and when all other strategies for addressing the shortage of N95 FFRs are insufficient.

References

Bergman, M.S., Viscusi, D.J., Zhuang Z. et al. (2012). Impact of multiple consecutive donnings on filtering facepiece respirator fit. *American Journal of Infection Control*. 40(4):375-380. Retrieved from <https://pubmed.ncbi.nlm.nih.gov/21864945/>

CSA Group. Canadian Medical Device Reprocessing. Z314-18. August 2018.

Diptanu P., Ayush G. and Anand K.M. (2020). Exploring options for reprocessing of N95 Filtering Facepiece Respirators (N95-FFRs) amidst COVID-19 pandemic: a systematic review. *medRxiv*. September 3, 2020. Retrieved from <https://www.medrxiv.org/content/10.1101/2020.09.01.20179879v1.full.pdf>

Food and Drug Administration (FDA). (2020a). Enforcement Policy for Sterilizers, Disinfectant Devices and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, March, 2020.

Food and Drug Administration (FDA). (2020b). Hinton D.M., Battelle Memorial Institute, March 29, 2020. Retrieved from <https://www.fda.gov/media/136529/download>

Health Canada. (2020a). Notice – Important Regulatory Considerations for the Reprocessing of Single Use N95 Respirators during the COVID-19 Response. April 8, 2020. Retrieved from <https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/announcements/covid19-notice-reprocessing-n95-respirators.html>

Health Canada. (2020b). Medical devices for use against coronavirus (COVID-19): List of products authorized under Interim Order. April 15, 2020. Last updated September 14, 2020. Retrieved from <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/products-authorized-interim-order.html>

Institut national de santé publique du Québec (INSPQ). (2020a). COVID-19: Evaluation of Disinfection Options for N95 Filtering Facepiece Respirators in the Context of the Pandemic. April 2020. May 21, 2020 - Version 2.1. Retrieved from <https://www.inspq.qc.ca/en/publications/2971-disinfection-n95-covid19>

Institut national de santé publique du Québec (INSPQ). (2020b). Comité des infections nosocomiales du Québec (CINQ). SRAS-CoV-2 : Mesures de prévention et contrôle des infections pour les milieux de courte durée. Recommandations intérimaires. October 6, 2020 – Version 9. Retrieved from <https://www.inspq.qc.ca/publications/2906-pci-soins-aigus-covid19>

Institut national de santé publique du Québec (INSPQ). (2020c). Comité des infections nosocomiales du Québec (CINQ). Réutilisation des respirateurs N95 dans un contexte d'une pénurie réelle ou appréhendée lors de la pandémie de la COVID-19: Avis intérimaire. March 26, 2020. Updated September 11, 2020. – Version 3.1. Retrieved from <https://www.inspq.qc.ca/publications/2918-reutilisation-respirateurs-n95-covid19>

Institut national de santé publique du Québec (INSPQ). (2020d). COVID-19: Collection, Disinfection and Storage Processes for Single-Use N95 Filtering Facepiece Respirators: CERDM Interim Guidelines. June 30, 2020 - Version 2.3. Retrieved from <https://www.inspq.qc.ca/sites/default/files/covid/2965-disinfection-storage-single-use-N95-facepiece-respirators-covid19.pdf>

Institut national de santé publique du Québec (INSPQ). (2020e). COVID-19 : Mesures exceptionnelles pour les équipements de protection individuelle lors de pandémie : recommandations intérimaires. April 24, 2020 – Version 2.0. Retrieved from <https://www.inspq.qc.ca/publications/2957-mesures-exceptionnelles-protection-individuelle-covid19>

Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST). (2020). Recommandation sur le temps d'aération des appareils de protection respiratoire de type N95 après désinfection à la vapeur de peroxyde d'hydrogène dans un stérilisateur à basse température. September 2, 2020 version. Retrieved from <https://www.irsst.qc.ca/covid-19/avis-irsst/id/2733/recommandation-sur-le-temps-daeration-des-appareils-de-protection-respiratoire-de-type-n95-apres-desinfection-a-la-vapeur-de-peroxyde-dhydrogene-dans-un-sterilisateur-a-basse-temperature>

Lieu, A., Mah, J., Zanichelli, V., et al. (2020). Impact of extended use and decontamination with vaporized hydrogen peroxide on N95 respirator fit. *Am J Infect Control*. 2020 Dec;48(12):1457-1461. Retrieved from <https://pubmed.ncbi.nlm.nih.gov/32805321/>

Versions

Version	Date	Pages	Modifications
1.0 (In French only)	2020-04-02		<ul style="list-style-type: none"> ▶ Creation of interim recommendations
2.0 (In French only)	2020-04-16		<ul style="list-style-type: none"> ▶ Objective of document added ▶ Technology and equipment authorized by Health Canada specified under the Interim Order with regard to COVID-19 (Health Canada, 2020b)
3.0	2020-05-21		<ul style="list-style-type: none"> ▶ Definition of the term disinfection in the section entitled Foreword ▶ Updating of technologies and equipment approved by Health Canada (addition of hydrogen peroxide vaporizer and disinfection device combining several technologies) ▶ Clarification of recommendations
4.0	2020-12-07	<p>1</p> <p>2</p> <p>2-3-5</p> <p>3</p> <p>4</p> <p>1 to 8</p>	<ul style="list-style-type: none"> ▶ Clarifications made to the Context section ▶ Clarifications regarding the level of sterility assurance required by Health Canada in the Method section. ▶ Addition of recommendations (initial drying period and post-disinfection aeration time specified for low-temperature sterilizers) ▶ Updating of technologies and equipment approved by Health Canada (addition of high-temperature sterilization: steam sterilizer) ▶ Additional information concerning dry heat ▶ Harmonization of nomenclature (filtering facepiece respirators vs masks) throughout the document

Note: The elements of responses presented here are based on the information available at the time of writing this evaluation. Given that the situation and knowledge about the SARS-CoV-2 virus (COVID-19) as well as the authorizations issued by Health Canada for new disinfection technologies for N95 FFRs are evolving, the elements covered and the recommendations in this document are subject to change.

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The French version is entitled *COVID-19 : Désinfection des appareils de protection respiratoire N95 à usage unique* is also available on the website of the Institut national de santé publique du Québec at : <https://www.inspq.qc.ca/publications/2966-desinfection-protections-respiratoires-n95-covid19>

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