INSPQ INSTITUT NATIONAL DE SANTÉ PUBLIQUE DU QUÉBEC

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

CENTRE D'EXPERTISE EN RETRAITEMENT DES DISPOSITIFS MÉDICAUX – INTERIM RECOMMENDATIONS

September 30, 2021 - version 5.0. Changes are indicated in yellow.

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 surrounding the SARS-CoV-2 virus (COVID-19) as well as the authorizations issued by Health Canada for new disinfection technologies for N95 filtering facepiece respirators (FFRs) are evolving, the elements covered and the conclusions and recommendations in this document are subject to change. Health care facilities must therefore verify that the technologies, at the time of their use, are still authorized by Health Canada under the Interim Order for COVID-19 (Health Canada, 2021a). In case of conflicting information between the manufacturer's instructions and the studies cited in this document or any other study, the manufacturer's instructions shall take precedence.

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

At the start of the COVID-19 pandemic, the CERDM evaluated the available options for disinfection of FFRs in the context of a potential shortage of FFRs in health care facilities (INSPQ, 2021a). This represents a solution of last resort to be applied when there is an anticipated shortage[1] in order to be able to distribute them to workers only during a real shortage[2] and when all other strategies for addressing the shortage of N95 FFRs are insufficient (INSPQ, 2021c). 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.

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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).

As of the date of this document, all of Health Canada's approvals for N95 FFR disinfection remain in effect (Health Canada 2021a), although the Food and Drug Administration (FDA) has revoked its approvals. Indeed, the FDA considers that American health care facilities should no longer face shortages of FFRs, owing to increased domestic production. Therefore, the disinfection of N95 FFRs is no longer authorized in the United States (FDA, 2021a,b,c). In Canada, local production and supply of FFRs has improved, but uncertainties regarding the evolving health situation remain. Health care facilities must follow the guidelines of the Ministère de la Santé et des Services sociaux (MSSS) to assess the status of an N95 FFR shortage. In addition, N95 FFRs may only be disinfected using a technology authorized by Health Canada (2021a) under the Interim Order for COVID-19 and in accordance with the manufacturers' instructions. The CERDM also recommends following the guidelines for the process of collecting, disinfecting and storing N95 FFRs (INSPQ, 2021d).

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.

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 used by Health Canada (2020a, 2021a) to authorize a technology under the Interim Order for COVID-19:

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, 2021a). This section presents the technologies and equipment approved by Health Canada and their specifications. Table A1 in the Annex summarizes this information.

In the United States, from January 2021 and until the FDA revoked their approval (2021c), under the Emergency Use Authorization (EUA), manufacturers specified in their instructions additional restrictions for the disinfection of N95 FFRs using low-temperature sterilizers, steam sterilizers and the Bioquell room vaporizer.

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 for COVID-19 (Health Canada, 2021a) and have issued disinfection instructions:

- Stryker (2020): Sterizone VP4;
- ASP (2021): STERRAD 100S, STERRAD NX and STERRAD 100NX;
- Steris (2020a): V-PRO 1Plus, V-PRO maX, V-PRO maX2, V-PRO S2.

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).

It should be noted that the manufacturer ASP (2021) has added to its instructions additional restrictions on the types of N95 FFRs that can be disinfected (see Table A1).

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 (2021a) under the Interim Order applicable to the COVID-19 pandemic.

- Ecolab Bioquell (2020): BQ50, L4, PROTEQ, Q10.

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, 2021a) 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)

Two manufacturers have received approval for their technology from Health Canada under the Interim Order applicable to the COVID-19 pandemic (Health Canada, 2021a) and have issued disinfection instructions for the following models:

- Steris (2020b): Amsco 400, Century medium;
- SciCan Ltd. (2021): BRAVO 17V, BRAVO 21V.

This low-cost technology could be easily implemented in MDRDs. However, it is impossible to move the Steris 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.

With respect to the Steris sterilizer, this technology has the advantage of being compatible with some models of N95 FFRs containing cellulose. However, 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 using UVC irradiation combined with other technologies

Some manufacturers have developed technologies for disinfecting N95 FFRs that combine several technologies, including UVC. Two of them have had their N95 FFR disinfection technology approved by Health Canada under the Interim Order for COVID-19 (Health Canada, 2021a) and have issued disinfection instructions for the following models:

- Clean Works Medical (2020a,b): Clean Flow Health Care Mini combining UVC irradiation with hydrogen peroxide and ozone;
- Medera Technologies Inc./PureTech™ (2021): PureTech™ disinfection device.

Despite Health Canada's authorization of PureTech™ (2021a) under the UVC irradiation device category for disinfection, the manufacturer's instructions indicate that several technologies (microwaves, hydrogen peroxide and ozone) are combined with UVC irradiation. Note that a 24-hour aeration period is required after disinfection of the N95 FFRs (PureTech™, 2021).

To our knowledge, these devices are 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 sometimes 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 addition, Health Canada has provided clarification regarding the disinfection of N95 FFRs and aerosol-generating medical procedures (AGMPs). Indeed, it has been noted (Health Canada, 2021b) that disinfected N95 FFRs "can be used for AGMP when: correctly fitted and used with other appropriate personal protective equipment (PPE)."

However, Health Canada also specifies that N95 FFRs used during an AGMP cannot then be disinfected for subsequent use; they must be discarded. To the best of the CERDM's knowledge, this added precaution of Health Canada's had not been required by the FDA.

Technologies not yet approved by Health Canada

No disinfection devices using UVC irradiation alone have been approved by Health Canada.

Dry heat disinfection of N95 FFRs is not authorized by Health Canada. This disinfection process requires high temperatures and long cycle times to allow for viral inactivation, which could affect the integrity of N95 FFRs (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. This technology is also not authorized by Health Canada.

Recommendations

Health care institutions must comply with the MSSS guidelines for assessing the status of an N95 FFR shortage. In addition, they must verify that the technologies, at the time of their use, are still authorized by Health Canada under the Interim Order for COVID-19 (Health Canada, 2021a).

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);
- 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, 2021a);
- Health Canada's recommendations regarding disinfection of N95 FFRs and concerning AGMPs (Health Canada, 2021b);
- 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 instructions of the manufacturer of the PureTech™ device also specify a 24-hour aeration period following disinfection;
- The CERDM's guidelines (INSPQ, 2021d), to develop for the facility an internal disinfection procedure, covering from the collection of single-use N95 FFRs up to their storage.

Disinfection of single-use 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.

Annex

Table A1 Health Canada authorizations for the disinfection of N95 FFRs

Disinfection device	Manufacturer (models)	Date of authorization (Health Canada, 2021a)	Characteristics
Low-temperature sterilizer (hydrogen peroxide and ozone)	Stryker (Sterizone VP4)	April 5, 2020	▶ Single wearer ▶ 2 disinfections allowed ▶ Not compatible with N95 FFRs containing cellulose, paper, natural rubber or latex (Stryker, 2020 a,b)

Low-temperature sterilizer (hydrogen peroxide plasma)	ASP
	(STERRAD 100S, STERRAD NX, STERRAD 100NX)
		April 9, 2020	▶ Single wearer
			▶ 2 disinfections allowed
			▶ Not compatible with N95 FFRs
			  ▶ containing cellulose or paper
			  ▶ with exhalation valves
			  ▶ duckbill shaped
			  ▶ authorized under the emergency use authorization for disposable filtering respirators not certified by NIOSH or manufactured in China (ASP, 2021)
			▶ Up to 480 FFRs per day depending on the model
			(FDA, 2020b)

Low-temperature sterilizer (vaporized hydrogen peroxide)	Steris (V-PRO 1 Plus, V-PRO MAX, PRO MAX2, V-PRO S2)	April 15, 2020 (V-PRO 1 Plus, V-PRO MAX, PRO MAX2) September 16, 2020 (V-PRO S2)	▶ Single wearer ▶ 10 disinfections allowed ▶ Not compatible with N95 FFRs containing cellulose or paper (Steris, 2020a)
Hydrogen peroxide vaporizer (room disinfection device)	Bioquell (BQ50, L4, PROTEQ, Q10)	April 20, 2020	▶ Single wearer ▶ 20 disinfections allowed ▶ Not compatible with N95 FFRs containing cellulose or paper ▶ Authorized for 400 N95 FFRs (approximately 1,000 N95 FFRs per cycle, tested and validated, with the possibility of validating higher quantities) (Bioquell, 2020a,b)

Table A1 Health Canada authorizations for the disinfection of N95 FFRs (continued)

Disinfection device	Manufacturer (models)	Date of authorization (Health Canada, 2021a)	Characteristics
High-temperature sterilizer (moist heat: steam sterilizer)	Steris (AMSCO 400, AMSCO Century Medium)	July 23, 2020	▶ Single wearer ▶ 10 disinfections allowed ▶ Compatible with some cellulose N95 FFRs ▶ Compatible with the 3M N95 FFRs: 1860, 1860S, 1804, 1804S, 8110S, 1805, 1805S, 1870+ and 9210+ ▶ Up to 180 FFRs/cycle depending on the model ▶ Non standard cycle (65 °C, 30 minutes) specific to N95 FFRs must be programed (Steris, 2020b,c)
High-temperature sterilizer (moist heat: steam sterilizer)	SciCan Ltd. (BRAVO 17V, BRAVO 21V)	January 21, 2021	▶ Single wearer ▶ 10 disinfections allowed ▶ Compatible with the 3M N95 FFR models 1870+ and 9210+ ▶ Up to 5 FFRs/cycle (SciCan, 2021)
Disinfection device combining several technologies (UVC, vaporized hydrogen peroxide and ozone)	Clean Works Medical (Clean Flow Health Care Mini)	April 13, 2020	▶ Single wearer recommended ▶ 10 disinfections allowed ▶ Not compatible with N95 FFRs containing cellulose, natural rubber or latex ▶ Up to 800 FFRs/hour (Clean Works, 2020a,b)
Disinfection device combining several technologies (UVC, microwaves, hydrogen peroxide and ozone)	Medera Technologies Inc. (Puretech™ disinfection device)	May 5, 2021	▶ Single wearer ▶ 10 disinfections allowed ▶ 1 FFR/cycle ▶ Compatible with N95 FFR models Moldex series 1500 N95 ▶ Requires a direct exhaust ventilation hood and the Hamilton Beach EM031MFW microwave oven (Puretech™, 2021)

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Record of modifications

Version	Date	Pages	Modifications
5.0	2021-09-30	1 2 3 4 5 6-7	▶ Clarifications made to the note of warning ▶ Clarifications made to the Context section: revocation of FDA authorizations ▶ Revision of the instructions for Canada for low-temperature sterilization of N95 FFRs by the manufacturer ASP ▶ Updating of technologies and equipment approved by Health Canada (SciCan Ltd and Medera Technologies Inc.) ▶ Health Canada recommendations concerning the disinfection of N95 FFRs and for AGMPs ▶ Addition of Table A1 on the technologies (taken from INSPQ, 2021a)
4.0	2020-12-07	1 2 2-3-5 3 4 1 to 8	▶ 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) ▶ Precautions to be considered concerning the number of disinfection cycles ▶ Additional information concerning dry heat ▶ Harmonization of nomenclature (filtering facepiece respirators vs masks) throughout the document
3.0	2020-05-21		▶ 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
2.0 (In French only)	2020-04-16		▶ Objective of document added ▶ Technology and equipment authorized by Health Canada specified under the Interim Order with regard to COVID-19 (Health Canada, 2020b)
1.0 (In French only)	2020-04-02		▶ Creation of interim recommendations

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TRANSLATION

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The French version of this document, 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

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