

# Options for the decontamination and reuse of respirators in the context of the COVID-19 pandemic

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## Summary

In the context of the COVID-19 pandemic, there is a worldwide shortage of respirators or filtering face pieces (FFP). Due to the shortage of these devices, they should be prioritised for use in healthcare settings when aerosol-generating procedures (AGPs) are performed. Several different procedures have been tested for decontamination of respirators in the event of shortage. The most useful methods are highlighted in the overview table in the conclusions.

Guiding principles for reuse are:

- Respirators which have been visibly contaminated (e.g. during procedure at intubated patients, such as suction cleaning of airways, taking probes, extubation attempts, etc.) or are damaged or not fitting, should be discarded and cannot be taken for re-use or decontamination procedures.
- Respirators may be protected by a medical face mask in order to prevent soiling.
- Use of new 'expired respirators' (manufacturers expiry date) is possible if they were properly stored until use.

A quite feasible approach for reuse of respirators seems to be providing each healthcare worker with a set of minimum five respirators (potential SARS-CoV-2 contamination of the four respirators not in use will be inactivated after five days). Irrespective of which method of decontamination is applied, a fit-check prior to re-use is necessary. If the fit check is not passed, the respirator should be discarded.

## Scope of this document

This document provides an overview of the evidence on the available methods for decontaminating respirators or filtering face pieces (FFP), in the event of shortages, used in healthcare settings providing care to possible, probable or confirmed COVID-19 patients.

## Target audience

Public health authorities and hospital administrators in EU/EEA countries and the United Kingdom.

## Background

The number of reported COVID-19 cases has increased rapidly in several EU/EEA countries and the UK. As a consequence, there have been shortages of personal protective equipment (PPE), in particular respirators or filtering face pieces (FFP) categories 2 and 3 (FFP2/FFP3).

A FFP, is designed to protect the wearer from exposure to airborne contaminants (e.g. from inhaling infectious agents associated with inhaling small and large particle droplets) and is classified as personal protective equipment (PPE) [1]. FFPs are mainly used by healthcare workers to protect themselves, especially during aerosol-generating procedures. Valved FFPs are not appropriate for use as a means of source control since they do not prevent the release of exhaled respiratory particles from the wearer into the environment [2].

Filtering face pieces comply with requirements defined in European Standard EN 149:2001+A1:2009. FFP2 correspond to N95, as defined by U.S. standard NIOSH 42 CFR Part 84.

The FFPs are licensed for single use and must be discarded when they get wet or soiled with patient's bodily fluids, when they no longer fit properly, or if breathing through the FFPs becomes difficult (due, for example, to the increased humidity concentration inside the FFP). A FFP also needs to be discarded after being used during an aerosol-generating procedure (AGP), as it is considered heavily contaminated.

Although FFPs are licensed for single use, a number of approaches have been proposed to optimise their use, including methods to ration and/or decontaminate and reuse them in the context of preparedness planning for influenza pandemics, and because of the recent severe shortages in the framework of the COVID-19 pandemic [3,4].

During periods of increased need for care, approaches for optimising the use of FFPs include:

- Reserve FFPs for use in airborne-generating procedures (AGPs);
- Use of medical face masks (surgical masks)<sup>1</sup> if the supply of FFPs is limited for most patient contacts which don't involve procedures that can lead to the production of aerosols;
- Designate staff assigned to particular activities, who will use the same FFP during the shift performing the same activity [5]. In this case, the FFP should not be removed for the entire time of use.

So far, manufacturers have had no reason or incentive to develop methods for decontamination of FFPs, however, currently there is an urgent need to develop reusable FFPs that can be decontaminated [4].

## Cleaning and decontamination for single-use filtering face pieces

SARS-CoV-2, the virus causing COVID-19, survives in the environment, including on surfaces of various materials such as iron, cardboard and tissue. The environmental stability of SARS-CoV-2 is up to three hours in the air post-aerosolisation, up to four hours on copper, up to 24 hours on cardboard and up to two to three days on plastic and stainless steel, albeit with significantly decreased titres [6]. Although these findings resulted from experiments in a controlled environment and should be interpreted with caution, they also provide some indirect evidence of the risk posed by the contamination of the outer surface of respirators and surgical masks used in patient care.

Before the current COVID-19 pandemic, decontamination of FFPs was discouraged and the approach was mostly aimed towards extending their use, either by reuse for a limited number of times by the same health professional or by maximising their use (e.g. by extending the duration of one-time wearing) by designated staff for a particular activity. The reuse of a FFP has been considered acceptable for a limited time and by the same healthcare worker e.g. when entering the patient's room in the care of patients with tuberculosis. This approach could be extended in the context of the COVID-19 pandemic if there is shortage of FFPs.

The potential contamination of the outer surface of FFPs entails a risk for the infection of the health professional when reusing it; it is plausible that the risk of contamination can be reduced by placing a medical face mask over the FFP, or wearing a face shield that can be cleaned.

In order to be applicable in healthcare settings the decontamination method should effectively remove the viral particles, should be harmless to the user, and should not damage the functionality of the various elements of the FFP [4].

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<sup>1</sup> Surgical masks are classified as medical devices according to the European Standard EN 14683:2014. They are single use and their decontamination and reuse in healthcare settings is discouraged.

## Options for filtering face pieces decontamination and reuse

When considering an effective method for FFP decontamination and reuse, the following points should be taken into consideration:

- The method should inactivate the contaminating organisms;
- The function of the FFP should not be compromised in terms of:
  - Filtration efficiency
  - Fitting performance.
- The method should not leave any chemical residues that can be harmful to the wearer.

General measures should be applied by the wearer when using a decontaminated FFP:

- The FFP should be visually inspected before putting it on and discarded if any component looks degraded or structurally modified;
- Practice strict hand hygiene before and after putting on or touching the FFP (e.g. after adjusting it);
- Use of gloves is recommended for donning and adjusting the FFP, and to perform the fit check. Only the external part of the FFP should be touched;
- The FFP should be discarded, if the fit check fails.

The following methods have been investigated for the decontamination of FFP.

### Steam sterilisation

Steam sterilisation is a procedure routinely used in hospitals. Respirator deformation or failing fit-test after steam sterilisation at 134°C was reported in a study performed in the Netherlands, depending on the type of respirator used [7]. Research published in 2012 by Lore et al. [8] demonstrated the effectiveness of microwave generated steam (MGS) in inactivating viral particles of influenza virus on two models of N95 respirators. Heimbuch et al., in 2010 [9] had also shown the effectiveness of MGS in reducing viable influenza virus of > 4 logs on N95 respirators, with only one of the six models tested showing a slight separation of the foam at the nose cushion. Bergman et al. [10] also reported physical deformation for certain N95 models, specifically separation of the inner foam nose cushion, yet maintained adequate aerosol penetration and filter airflow resistance after three cycles. When using steam bags for the disinfection of N95 respirators contaminated with bacteriophages, Fischer et al reported [11] 99.99% efficacy in inactivating the contaminant and that water absorption was dependent on the respirator model. The steam had little effect on the filtration efficiency, which remained above 95%. In a recent pre-print by Liao et al. [12], it was shown that steam treatment on N95 compatible melt-blown fabric did not considerably impact the efficiency and pressure drop in the first three steam treatment cycles. In a study published by Bergman et al. in 2011 [13], the authors reported how three applications of MGS did not cause significant changes (pass rate ≥ 90%) in respirator fit in the three types of N95 respirators tested.

### Hydrogen peroxide vapour

One study commissioned by the US Food and Drug Administration (FDA) showed that hydrogen peroxide vapour (HPV) was effective in decontaminating N95 respirators (the U.S. equivalent of FFP2 respirators) from a single organism for multiple cycles of decontamination. The respirator maintained its function even after 10–20 cycles of HPV, but showed signs of degradation thereafter [14]. On 29 March 2020, the FDA approved a HPV-based commercial decontamination method for N95 respirators not containing cellulose for emergency use [15]. Other studies did not detect any macroscopic damage and deformity on N95 respirators when performing three [10] to five [16] decontamination cycles. The respirators maintained adequate aerosol filtration efficacy and filter airflow resistance after performing one [17] to three HPV cycles [10]. A pilot study in the Netherlands indicated that HPV is effective for two decontamination cycles without deformation while retaining filtration capacity as assessed by a rapid fit-test<sup>2</sup>, suggesting that the tested FFP2 respirators (models without cellulose) can be re-used up to two times. A possible disadvantage of this method is that harmful concentrations of hydrogen peroxide may remain on the respirator for days after decontamination. Another concern is that deformation may occur after repeated decontamination cycles [7].

Decontamination studies performed using HPV for SARS-CoV-2 demonstrated that after treatment (10 minutes dehumidification, three minutes conditioning (5 gram/minute), 30 minutes decontamination (2.2 gram/minute) and 20 minutes aeration), no SARS-CoV-2 virus was recovered on the N95 respirator and that structural and functional integrity was maintained for up to 10 sterilisation cycles [18]. Similarly, Fisher et al. [19], found that SARS-CoV-2 is rapidly inactivated by HPV on N95 respirators, while maintaining acceptable integrity and performance after three cycles of decontamination.

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<sup>2</sup> Fit-test: Ratio of particles outside to particles inside mask using TSI PortACount Pro+ 8038. Unused mask (control): ratio=162; RIVM considers fit-test sufficient if the ratio is >100 after the decontamination process.

### Other application of hydrogen peroxide

Cramer et al. [20] tested ionized hydrogen peroxide (IHP) for decontamination of N95 respirators; they found that IHP allowed for at least a 9-log kill of bacterial spores after a single cycle of decontamination, and that N95 masks could retain filtration efficiency and adequate fit for up to 5 decontamination cycles.

Liquid hydrogen peroxide (LHP) decontamination has been tested by Bergman and colleagues, using 30 minutes submersion in 6% solution of hydrogen peroxide. The filtration performance of six N95 respirators was maintained after three cycles of decontamination. Decontamination and fitting performance were not tested [10].

Bergman et al. tested also the hydrogen peroxide gas plasma (HPGP) method on six types of N95 respirators. They found that after 3 decontamination cycles, the filtration performance of four of the six types deteriorated [10].

### Gamma irradiation

This method is commonly used for the large-scale sterilisation of medical devices and food items. The necessary equipment is not commonly available in hospitals. A study indicated that a dose of 20 kGy (2MRad) is sufficient for the inactivation of coronaviruses [21]. Ongoing studies of gamma irradiation with a 24 kGy dose to sterilise respirators identified possible deformation of the respirator, with compromised inner filtering layer and poor fit on the face. A study in the Netherlands showed no deformation of one FFP2 mask after gamma irradiation with 25kGy, but the fit-test after the decontamination process failed [7]. A study by Lin et al. [22] examining filtering characteristics after irradiation, found that treatment with 10-30kGy affected N95 models filter capacity by increasing aerosol penetration, despite maintaining acceptable inspiratory breathing resistance.

### Ultraviolet germicidal irradiation

Ultraviolet germicidal irradiation (UVGI) is a promising method, which uses the germicidal activity of UV-C radiation. The two main methodological caveats are the dose of radiation required and the shadow effects produced by the structure of the respirator, which could prevent the UV rays from reaching the microorganisms and therefore limit decontamination efficiency.

Different independent researchers have shown no significant effects on filter airflow penetration and filter airflow resistance up to several cycles of UV-C application [10,17]; Liao et al. [12] reported N95 respirators treated with UV-C (254 nm, 17mW/cm<sup>2</sup>) were able to withstand 10 cycles of treatment and showed small degradation at 20 cycles. In a study published by Bergman et al. in 2011 [13], the authors reported how three applications of UVGI did not cause significant changes (passing rate  $\geq 90\%$ ) in respirator fit in the three N95 respirators tested.

Fisher and Shaffer [23] have shown that the application of UV-C (on circular coupons excised from N95 respirators) resulted in at least a 3 log reduction in viable MS2 bacteriophages. According to their findings, the UV-C transmits into and through the respirators materials. The porosity of the inner and outer layers allows UV-C to reach the internal filtering medium (IFM), however the exposure time required to achieve that varies widely among different N95 respirator models (range 2 to 266 minutes).

Significant reductions ( $>4$  log) of viable H1N1 influenza virus after treatment with UVGI (254 nm, 1.6-2.0 mW/cm<sup>2</sup>, 15 min) was reported by Heimbuch et al. [9] on six models of N95 respirators, without obvious signs of deterioration or deformation after the treatment. Reduction ( $\geq 3$  log) in influenza virus viability was also observed in the study published by Mills et al. [24], in which they have analysed 15 different N95 respirators models. They concluded that respirator decontamination and reuse using UVGI can be effective, however implementation of a UVGI method will require careful consideration of respirator model, material type, and design. Lore et al. [8] reported viricidal activity of high-intensity UVGI after a 15-min exposure to two models of N95 respirators on which influenza (A/H5N1) virus was applied as aerosolized droplets.

### Microwave irradiation

Few studies have investigated the possible use of dry microwave for respirator decontamination. Viscusi et al. [17] used microwave oven irradiation on nine models of respirators (N95 and P100). Microwave oven irradiation melted samples from two respirators models. Filter aerosol filtration and filter airflow resistance were not affected in seven of the nine tested models. Germicidal effect and fit performance were not assessed. In general, the use of microwave oven radiation for decontamination of respirators lacks evidence of effectiveness. An important point to consider is that the metal noseband may produce sparks during the process potentially damaging the oven.

### Ethylene oxide

Ethylene oxide sterilisation is a low temperature method preferred for sterilising sensitive equipment such as endoscopes, which cannot be sufficiently decontaminated by hand or autoclaved. This method has the inherent risk of persistence of the ethylene oxide in the respirator, which is harmful to the user. Viscusi et al. and Bergman et al. [10,17] reported that this method does not affect the filter aerosol penetration, filter airflow resistance, or physical appearance of the respirators. Kumar et al. [18] reported structural and functional integrity maintained after three cycles and no microbiological contamination with vesicular stomatitis virus (VSV) detected on respirators after one hour exposure and 12 hours aeration time.

## Moist heat incubation

The use of moist heat incubation (MHI) is a promising approach for the decontamination and reuse of respirators. Heimbuch et al. [9] found that the use of warm/moist heat for 30 minutes (WMH 65°C ± 5°C/85% ± 5% RH) provided an average > 4 log reduction of viable H1N1 influenza virus dispersed on different particulate N95 models. After a 30-minute cycle, no obvious signs of deterioration or deformation were registered. Similar results have been presented by Lore et al. [8], who report that MHI is fully effective in inactivating influenza A/H5N1 virus particles on N95 respirators after a 20 minute treatment. The maintenance of respirator characteristics has been tested by Bergman et al. [10], who found that filter airflow penetration and filter airflow resistance of N95 respirators were preserved after three cycles of decontamination. Partial separation of the inner foam nose cushion from the respirators was registered in one respirator model. Bergman et al. [13] reported how three applications of moist heat did not cause significant changes (passing rate ≥ 90%) in respirator fit in the three N95 respirators tested.

## Dry heat treatment

Liao et al. [12] report no considerable degradation of filtration properties on melt-blown fabrics (the material out of which respirators are constructed), with initial efficiency ≥95%, up to 20 cycles when using a static-air oven at 75°C for 30 min per cycle. At up to 100°C there was little to no change in filtration efficiency and pressure drop. In this publication the authors highlight that steam may decrease efficiency and that humidity should be kept low when approaching 100°C. Similar results were obtained by Fisher et al. [19] using dry heat at 70°C for up to 60 minutes on fabric from N95 respirators. They found that filtration performance was not reduced after a single decontamination cycle, however there was a drop in filtration performance after subsequent rounds of decontamination. Dry heat decontamination also inactivated SARS-CoV-2 more rapidly on N95 fabric than steel. The authors highlighted that dry heat should be applied for sufficient time to ensure the reduction in virus concentration. Viscusi et al. [17] reported that the degree to which temperature affects filter aerosol penetration and component melting is model specific. They reported melting in some models when temperature above 100°C was applied.

## Autoclave treatment

Autoclaving is a common procedure in the healthcare setting. After decontamination using an autoclave at 121 °C for 15 min, no SARS-CoV-2 virus were recovered from different models of N95 respirators [18]. Structural and functional integrity was maintained after one cycle for six models of N95 respirator, but after the first cycle only four of the six models tested maintained their performance (up to 10 cycles) [18]. Lin et al. [22] reported that one of the five N95 models tested suffered increased aerosol penetration exceeding the 5% certification penetration limit, but all models satisfied the breathing resistance requirement.

## Alcohol solution

Ethanol is known to be very effective in inactivating SARS-CoV-2 and it has also been used by Fischer et al. [19] on N95 respirators. However, although filtration performance was not reduced after a single decontamination using ethanol, subsequent rounds of decontamination caused a sharp drop in filtration performance [19]. This is also confirmed by Liao et al. [12], who reported a drastic degradation of the filtration efficiency while the pressure drop remained comparable after application of ethanol by immersion of melt-blown fabrics and air drying.

## Chlorine based solutions

Chlorine based solutions (bleach) are known to be effective in the inactivation of SARS-CoV-2 [25], however their use in decontaminating respirators is strongly discouraged due to their effect on several components (e.g. metallic nosebands, staples, nose pads, etc.) [10,17]. Liao et al. [12] reported a drastic degradation of the filtration efficiency whereas other authors [10,17] reported that filter aerosol penetration and filter airflow resistance were not affected after treatment with bleach up to three cycles. Viscusi et al. report that after 16 hours of air-drying, the respirators were dry to the touch and all still smelled of bleach [17].

# Other approaches for reuse of filtering face pieces

The US Centers for Disease Control and Prevention (CDC) propose a simple approach for the reuse of FFPs without the need to apply a particular decontamination method. It consists of providing each healthcare worker with a set of minimum five FFPs. Each FFP is to be used for one work shift and then stored in a breathable paper bag for at least five days before being reused. This approach aims to reduce or eliminate SARS-CoV-2 potentially contaminating the FFP, based on the evidence about the survival of the virus in the environment [26]. US CDC highlight that the FFPs should be considered still contaminated and therefore precautions should be followed when reused and that decontamination procedures should be applied only if five FFPs per healthcare worker are not

available [26]. When applying this approach, the lifespan of a FFP and methods to assess for potential compromise of the characteristics of the FFP (e.g. the maintenance of filtration and fitting performance) should be considered.

## Precautionary measures when re-using a decontaminated filtering face pieces

As a precautionary measure, a decontaminated FFP should be treated as still potentially contaminated and the following measures are suggested:

- The FFP should be checked for its integrity and discarded if any macroscopic degradation is identified;
- Gloves should be worn when touching the decontaminated FFP;
- Strict hand hygiene by using an alcohol based hand rub solution should be practiced when touching the FFP (for wearing, removing, adjusting, etc.);
- The internal part of the FFP shouldn't be touched;
- The external part of the FFP should be touched as little as possible (e.g. only for adjustment);
- A fit check should be performed each time the FFP is reused. If the fit check is not passed, the FFP should be discarded.

## Use of expired single-use filtering face pieces

Stockpiles in some countries include FFP2 or FFP3 that have exceeded their manufacturer-designated shelf life. Manufacturers provide an expiry date to guarantee the quality of the product. Early results from an ongoing study of the U.S. CDC National Institute for Occupation Safety and Health (NIOSH) show that several N95 models manufactured between 2003 and 2013, many of which were expired, continued to perform in accordance with NIOSH standards [27].

Considering these findings and in the context of the current increased needs for PPE for healthcare workers, stocks of expired single-use FFP2 and FFP3, if available, can be used to protect healthcare personnel provided that:

- The FFPs were safely stored in a place without exposure to the sun, excess humidity or pests (e.g. insects, rodents);
- Samples from the equipment boxes show that they are in good working condition, well-fitting (after a fit check) and without any deterioration for example on the elastic bands and the nose bridge.

**Table 1. Summary of the approaches for FFP decontamination and reuse: expected effect and limitations.**

		Decontamination/ Sterilisation†	Filtration capacity	Fitting/ Shape	Main considerations on the method	Practicability in healthcare settings††	References
Radiation	Gamma irradiation	+	+/-	-	Respirators physical deformation or failing of the fit-test, and increased aerosol penetration are considered the main disadvantages	✘	[7,21,22]
	Ultraviolet germicidal irradiation (UVGI)	+	+	+	No physical deformation or failing of the fit-test after several cycles of application, efficacy in decontamination shown in recent experiments. The two main caveats are the dose of radiation required and the shadow effects produced by the structure of the respirator which could interfere with the decontamination	✓/✘	[8-10,12,13,17,23,24]
Gas	Ethylene oxide	+	+	+	Consistent risk of persistence of the ethylene oxide in the respirator, which is harmful to the user	✓/✘	[10,17,18]
Steam	Steam sterilisation	+	+	+/-	Respirators physical deformation or failing of the fit-test	✘	[7-13]
	Autoclave	+	+/-	+	After one cycle of decontamination, some respirators didn't maintain their performance. In one study, the method resulted in increased aerosol penetration in a respirator model	✘	[18,22]
Heat	Moist heat incubation (MHI)	+	+	+/-	Physical deformation (partial separation of the inner foam nose cushion from the respirators) can result from this method	✓/✘	[8-10,13]
	Dry heat treatment (DHT)	+	+	+/-	Physical deformation can result from this method at high temperatures, filtration performance was reduced after multiple decontamination cycles	✓/✘	[12,17,19]

	Decontamination/ Sterilisation†	Filtration capacity	Fitting/ Shape	Main considerations on the method	Practicability in healthcare settings††	References	
Chemical	Microwave	N/A	+/-	N/A	Respirators can melt	✘	[17]
	Hydrogen peroxide vapour (HPV)	+	+	+	Harmful concentrations of hydrogen peroxide which may persist on the respirator and possible deformation which may occur after repeated cycles are considered the main possible disadvantages	✓/✘	[7,10,14-19]
	Alcohol solution	+	+/-	N/A	Drop in filtration performance observed after immersion of melt-blown fabrics and air drying or after subsequent cycles of decontamination	✘	[12,19]
	Chlorine solution	+	+/-	-	Effect on several components (e.g. metallic nosebands, staples, nose pads, etc.) and persistence of smell of bleach. Controversial results on the impact on filtration	✘	[10,12,17,25]
Five respirators per healthcare worker for consecutive re-using	N/A	N/A	N/A	Proposed by US CDC, it is based on the time-dependent inactivation of the SARS-CoV-2 potentially contaminating the FFP.	✓	[26]	

For decontamination/sterilisation: +, effective; N/A, not assessed. For filtration capacity and fitting/shape: +, maintained; -, not maintained; +/-, limited maintenance or not consistent data from different studies in the literature; N/A, not assessed. For practicability in healthcare settings: ✓, practicable; ✘, not practicable; ✓/✘, practicable with limitations.

† The decontamination/sterilisation efficacy has been studied using various microorganisms; please refer to the individual sections above and to the references for more complete information.

†† The practicability in healthcare settings takes into account the availability of the method in healthcare settings and the overall effects of the method on decontamination/sterilisation, filtration and fitting/shape.

## Conclusions

The methods presented above for FFP decontamination and reuse are only considered as extraordinary last-resort methods due to shortage of FFP supplies. They should be applied after a careful evaluation of the situation and after exploring the possibility of resource-conscious, rational use of FFPs, for example by extending the FFP lifespan, and having in mind the product use instructions provided by FFP manufacturers. National public health authorities, and groups studying such methods are encouraged to share their results as soon as they become available.

Among the various methods for decontamination of FFPs, several options show a favourable profile when considering effectiveness while not causing significant deterioration in filtration and breathability at least for some decontamination cycles. Such options include ultraviolet germicidal irradiation (UVGI), ethylene oxide, hydrogen peroxide vapour and to some extent dry and moist heat. When it comes to favourable options in terms of effectiveness not causing significant deterioration, and practicality in healthcare settings, the provision of a set of five FFPs to individual healthcare workers for consecutive re-use may be the more practical choice. Decontamination with hydrogen peroxide vapour or ethylene oxide can be considered only if a safe evaporation time and protocol could be determined.

Each of the methods described in this report have caveats that need to be taken into account before deciding which one is the most suitable in each particular setting. The effects of each of these methods depend also on the specific conditions applied and on the model of FFP.

Cleaning of reusable equipment before sterilisation is recommended, but there are no available data on the effective and non-damaging cleaning methods for single-use equipment such as FFPs. Quality checks of the applied sterilisation methods (including the establishment of quality indicators) are necessary to ensure the safety of the equipment to be reused.

## Contributing ECDC experts

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