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Decontamination of filtering facepiece respirators using a low-temperature-steam–2%-formaldehyde sterilization process during a pandemic: a safe alternative for re-use

M. Garcia-Haro [a,b], C. Bischofberger Valdés [a,b], J. Vicente-Guijarro [a,b,*], C. Díaz-Agero Pérez [b], M. Fabregate-Fuente [b,c], P. Moreno-Nunez [a,b], J.M. Aranaz-Andrés [a,b,d], on behalf of the COVID-19 Research Group of the Hospital Universitario Ramón y Cajal

[a] Servicio de Medicina Preventiva y Salud Pública, Hospital Universitario Ramón y Cajal, IRYCIS, Madrid, Spain
[b] Instituto Ramón y Cajal de Investigación Sanitaria, Madrid, Spain
[c] Servicio de Medicina Interna, Hospital Universitario Ramón y Cajal, IRYCIS, Madrid, Spain
[d] CIBER Epidemiología y Salud Pública, Spain

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SUMMARY

Background: The coronavirus disease 2019 pandemic has caused problems with respirator supplies. Re-use may minimize the impact of the shortage, but requires the availability of an efficient and safe decontamination method.
Aim: To determine whether low-temperature-steam–2%-formaldehyde (LTSF) sterilization is effective, preserves the properties of filtering facepiece (FFP) respirators and allows safe re-use.
Methods: Fourteen unused FFP2, FFP3 and N95 respirator models were subjected to two cycles of decontamination cycles. After the second cycle, each model was inspected visually and accumulated residual formaldehyde levels were analysed according to EN 14180. After one and two decontamination cycles, the fit factor (FF) of each model was tested, and penetration tests with sodium chloride aerosols were performed on five models.
Findings: Decontamination physically altered three of the 14 models. All of the residual formaldehyde values were below the permissible threshold. Irregular decreases and increases in FF were observed after each decontamination cycle. In the sodium chloride aerosol penetration test, three models obtained equivalent or superior results to those of the FFP classification with which they were marketed, both at baseline and after one and two cycles of decontamination, and two models had lower filtering capacity.

* Corresponding author. Address: Servicio de Medicina Preventiva y Salud Pública, Hospital Universitario Ramón y Cajal, IRYCIS, Ctra. de Colmenar Viejo, km. 9,100, 28034 Madrid, Spain. Tel.: +34 913 36 83 72.
E-mail address: jorge.vicente@salud.madrid.org (J. Vicente-Guijarro).

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Conclusion: One and two decontamination cycles using LTSF did not alter the structure of most (11/14) respirators tested, and did not degrade the fit or filtration capacity of any of the analysed respirators. The residual formaldehyde levels complied with EN 14180. This reprocessing method could be used in times of shortage of personal protective equipment.

Introduction

An outbreak of a novel coronavirus — severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), the causative agent of coronavirus disease 2019 (COVID-19) — was detected in December 2019 in Wuhan, China. This highly contagious virus spread rapidly to other countries, and a pandemic was declared by the World Health Organization in March 2020 [1].

SARS-CoV-2 is mainly transmitted among humans through secretions in the form of respiratory droplets >5 μm that can travel a distance of up to 1—2 m, and through contact with fomites or surfaces where these droplets have landed. As such, transmission control recommendations consist of droplet and contact precautions, including the use of surgical masks. Additionally, for procedures capable of generating aerosols, airborne precautions are recommended that include the use of filtering facepiece (FFP) respirators [2,3].

Surgical masks are single-use items. FFP respirators are generally discarded after use, but may be treated as limited-use devices (i.e. they can be re-used for a limited time, unless there is a risk of contamination by deposits of infectious particles on the surface). For example, when caring for patients with tuberculosis, it is acceptable for the same healthcare worker to re-use a respirator on a limited number of occasions. The respirator must be discarded if it gets wet, splashed with body fluids, does not fit properly, and after performing aerosol-generating procedures [4]. SARS-CoV-2 survives in the environment, including on surfaces composed of various materials (e.g. iron, cardboard, textiles), so the outer surfaces of surgical masks and respirators can become contaminated rapidly, resulting in risk of infection if they are re-used [5,6].

FFP respirators are classified, from lower to higher filtration capacity, as FFP1, FFP2 and FFP3 according to UNE 149:2001; and as N95, N99 and N100 according to the National Institute for Occupational Safety and Health, (NIOSH), an affiliate agency of the US Centers for Disease Control and Prevention [7,8].

There is an acute shortage of personal protective equipment (PPE) available to healthcare centres, particularly respirators. As such, decontamination and re-use is essential. Quick and easy methods to re-use equipment already available in healthcare centres have been adopted since the H1N1 pandemic in 2009 [9—15].

One method of decontamination is based on formaldehyde. In 1999, the Instituto Nacional de Seguridad y Salud en el Trabajo (Spanish National Institute of Safety and Health at Work; INSST), a body attached to the Spanish Ministry of Employment and Social Security, established 0.3 ppm as the workplace exposure limit of formaldehyde allowed in the environment for short-term exposures. This threshold remains in place today [16].

This study investigated low-temperature-steam—2%-formaldehyde (LTSF) sterilization as a method to decontaminate FFP respirators that would respect the properties of the respirator and would be safe for users (chemical residue below the established threshold limit), using equipment already available in the hospital.

Methods

This study was undertaken at Ramón y Cajal University Hospital from 25th March to 23rd April 2020. Ramón y Cajal University Hospital is a public hospital with 1118 beds in northern Madrid. This region was among those with the highest numbers of patients hospitalized with COVID-19 in Spain. Ramón y Cajal University Hospital provides specialized assistance to 558,373 citizens, representing 8.51% of the population of Madrid.

The performance of 14 unused N95, FFP2 and FFP3 cellulose-free respirator models was evaluated. The study sample was selected opportunistically, and was based on the types of respirators available to the hospital during the pandemic.

Three units of each respirator model were used: one unit for each phase of the research (baseline, after one decontamination cycle and after two decontamination cycles). The following variables were recorded in these phases: external appearance of the respirator, flexibility and integrity of the elastic bands and other components, and fit factor (FF). At the end of the second cycle, the accumulated residual formaldehyde on the respirators was measured. Additionally, the filtering capacity was assessed in each phase in five respirator models.

FFP respirators were subjected to decontamination cycles performed in an LTSF sterilizer (Matachana 130LF; Matachana Group, Barcelona, Spain) which has been in regular use in the hospital's central sterilization department since 2014. This sterilizer complies with EN 14180:2014, and uses a mixture of steam and 2% formaldehyde in thermodynamic equilibrium. This model has a capacity of 145 L and was last validated in May 2019 according to ISO 25424:2018. Sterilization was performed at 78°C, with a standard duration of 153 min at full load (cycle times are theoretical and can differ in length depending on the size and type of load to be sterilized).

Respirators were wrapped individually in simple 200 x 200 mm, 70—80 g/m^2 mixed paper wraps (STERIS, Mentor, OH, USA) — a combination of medical-grade paper and transparent polymer, compatible with steam, ethylene oxide and formaldehyde sterilization processes — in accordance with EN ISO 11607 Parts 1—2 and EN 868. The packages were heat-sealed in accordance with ISO 11607, and a type-4 multi-variate chemical control brand (Matachana Group) was inserted in each package according to EN-ISO 11140-1. A biological control was

Table I
Difference in physical appearance and residual formaldehyde after two decontamination cycles

Respirator	Difference in physical appearance		Residual formaldehyde level (μg/cm^2)	
	Changes to external appearance	Rubber flexibility changes	Valve area	Respirator area
Bimedica Naturcare® FFP2 Conical with valve (128944)	No	No	0.16	Not detectable
Dräger X-plore® 1730 V FFP3	Nasal adjustment loosened, valve detached	No	0.14	0.04
Dräger X-Plore® 1920V FFP2	No	No	Not detectable	0.14
Dräger X-plore® 1930V FFP3	No	No	0.26	0.40
Dromex® 3231 FFP3 NR D	No	No	2.41	0.07
Garry Galaxy N95 Respirator Mask	No	No	N/A	1.53
HY 9330 FFP3 NR	No	No	N/A	3.99
Oxyline X310SV FFP3 NR D	Loose nasal adjustment	No	0.16	0.21
Pioneer® Safety EP005 FFP2	No	No	N/A	Not detectable
PURVIGOR KN95 3D	No	No	N/A	0.45
VENUS V-420-V	Loose nasal adjustment	No	0.23	0.16
3M™ Aura™ 9320+ FFP2 NR D	No	No	N/A	0.21
3M™ VFlex™ 1802S	No	No	N/A	0.35
3M™ 8822 FFP2 NR D	No	No	2.05	0.14

N/A, not applicable, respirator without valve; not detectable, value equivalent to that obtained in the sample used as a comparison control.

introduced in each decontamination cycle as a process quality parameter and in accordance with EN-ISO 11138-5, UNE-EN ISO 11607 and UNE-EN ISO 11140-1. Self-contained colorimetric vials with 10^6 colony-forming units of *Geobacillus stearothermophilus* (Matachana BM100; Matachana Group) were used, in accordance with EN-ISO 11138. The vials were packed in the same mixed paper used for the respirators, and placed in the centre of the load. When the cycle had finished, the biological indicators were incubated for 48 h at 56°C in a Steri-Record Incubator I-57-AB-MBP (gke-GmbH, Waldems, Germany) to test the effectiveness of the cycle. The respirators subjected to two cycles were sterilized with an interval of no more than 48 h between the two cycles.

To evaluate the external aspect of the respirators, all changes observed during visual inspection were recorded using photographs and logged, and any degradation of the elastic bands and other components was noted. This inspection was performed jointly by two members of the research team.

Formaldehyde residue on the respirators was measured in an external laboratory (Eurofins Analisis Alimentario S.L. Coslada, Madrid, Spain) according to the standardized procedures in ISO-10993-12 [17]. The samples analysed from each respirator did not correspond to the measurements or to the indicator material defined by UNE-EN 14180+A2:2014, which proposes a methodology for extraction, colour determination and acceptable formaldehyde residue thresholds. Therefore, according to Point 7.8 of UNE-EN ISO 25424:2011, which states that 'medical device manufacturers must evaluate the formaldehyde retention characteristics of the product compared with those of the desorption efficiency indicator', the values found were compared with UNE-EN 14180 Annex D, which lists the approximate residual values of different materials compared with filter paper (5 μg/cm^2 permissible threshold for formaldehyde residue) [18,19]. Sample absorption was measured at a wavelength of 560 nm using a Thermo Spectronic Helios α spectrophotometer (Thermo Fisher Scientific Inc., Waltham, MA, USA).

A quantitative fit test was performed, which can be used to perform fit tests on any close-fitting respirator. An instrument was used to test for possible leaks around the facial seal, and the FF (the ratio between the concentration of microscopic particles detected outside the respirator and the concentration of particles detected inside the respirator) was calculated. A continuous flow condensation particle counter, the TSI 8038 PortaCount Pro+Respirator Fit Tester (TSI Inc., Shoreview, MN, USA), which uses an ambient aerosol and does not require the use of a test chamber, was used [20]. All tests were performed with the same human subject: a 42-year-old male, slim build, clean shaven, non-smoker, with no pre-existing conditions, and no signs or symptoms of COVID-19 or any other respiratory disease. The subject had not eaten any food or drink during the previous 30 min (as required for the test) and was at ease, standing and breathing normally. All measurements were taken in the same room (33.85 m^3) with a controlled environment at a stable temperature between 25 and 26°C, with no draughts and 10.7 air renewals per hour. The subject was instructed on the correct placement of the respirators; he donned the respirator 5 min before starting the measurement, without outside help, and was not allowed to adjust the fit during the test. Once in place, measuring tubes were attached to a strap to prevent them from exerting any traction on the respirator that would alter the FF. Seven consecutive FF measurements were taken for 1 min at regular 10-s intervals. Photographs were taken of each of the measurements of the respirators in position on the subject, and their condition before and after the decontamination cycles. The median value and quartiles of FF at baseline and after each decontamination cycle were calculated using Stata 15 (Stata Corp., College Station, TX, USA). Subsequently, differences in FF between baseline and after one and two decontamination cycles were analysed (unpaired samples Mann–Whitney *U*-test) to detect differences in filtering capacity due to the sterilization process.

Additionally, for five of the respirator models selected opportunistically according to their availability in the hospital (3M Aura 9320+ FFP2, HY9330 FFP3, PURVIGOR KN95 3D FFP2,Garry Galaxy N95 Respirator Mask and VENUS V-420V N95), INSST carried out additional visual evaluations at baseline and after one and two decontamination cycles. INSST also performed a penetration test with sodium chloride aerosols based on UNE-EN 149: 2001+A1:2010 [7]. This penetration test was performed using a flow of sodium chloride aerosol at 95 L/min for 3.5 min, with a particle size equivalent to an average mass diameter of 0.6 μm. The percentage penetration was calculated, together with the equivalence of compliance with the results obtained (FFP1 if penetration <20%, FFP2 if penetration 6% and FFP3 if penetration <1%).

Results

All decontamination cycles were performed without incident, obtaining favourable results in the physical, chemical and biological controls. Physical defects after reprocessing were found in three of the 14 models, all of which involved loosening or detachment of the nasal fitting component. No changes were observed in the filter material, elastic bands or other components (Table I).

Regarding the quantification of residual formaldehyde in the processed respirators, all values were <5 μg/cm^2, the permissible threshold in materials according to EN 14180:2014 (Table I).

Regarding FF, six models (Bimedica Naturcare, Dromex 3231, Garry Galaxy, Pioneer Safety EP005, PURVIGOR KN95 and VENUS V-420-V) obtained a value <100. Among the other eight models, the following changes in FF ($P<0.05$) were obtained with respect to baseline: after one decontamination cycle, one model showed a decrease in FF to <100 (Oxyline X310SV), two models showed a decrease in FF to ≥100 (3M Aura and 3M 8822) and one model showed an increase in FF (Dräger X-plore 1930V); and after two decontamination cycles, three respirator models showed a decrease in FF to <100 (Oxyline X310SV, 3M VFlex and 3M 8822), one model showed a decrease in FF to ≥100 (3M Aura) and two models showed an increase in FF (Dräger X-plore 1730 V and Dräger X-plore 1930V) (Table II).

All of the models tested by INSST had satisfactory results on visual inspection. In the NaCl aerosol penetration test, three models (3M Aura, Garry Galaxy and Venus V-420V) had results equivalent or superior to the FFP classification with which they had been marketed, both at baseline and after one and two decontamination cycles. The HY9330 model, marketed as FFP3, obtained values equivalent to FFP2 at baseline, FFP1 after one decontamination cycle and FFP2 after two decontamination cycles. The Purvigor KN95, marketed as N95, achieved values equivalent to FFP2 at baseline, and FFP1 after one and two decontamination cycles (Table III).

Discussion

It is considered that hospitals should have sufficient supply to provide each healthcare worker in critical, surgical and assisted ventilation units with one respirator per shift, and one for extended use, depending on the workload of healthcare workers who deal with patients on the ward or in the

Table II
Fit factor after one and two decontamination cycles

Respirator	Fit factor				
	Baseline	After one cycle		After two cycles	
	Median (Q1–Q3)	Median (Q1–Q3)	One cycle vs baseline *P*-value	Median (Q1–Q3)	Two cycles vs baseline *P*-value
Bimedica Naturcare® FFP2 Conical with valve (128944)	1.37 (1.33–1.38)	13.64 (12.34–13.64)	0.002[a]	2.41 (2.32–2.72)	0.002[a]
Dräger X-plore® 1730 V FFP3	161.79 (146.58–176.87)	107.52 (102.64–147.05)	0.063	553.68 (511.16–558.63)	0.002[a]
Dräger X-Plore® 1920V FFP2	200.00 (200.00–200.00)	200.00 (200.00–200.00)	0.317	200.00 (200.00–200.00)	0.317
Dräger X-plore® 1930V FFP3	102.94 (97.59–110.85)	141.67 (136.22–148.11)	0.003[a]	221.85 (221.85–251.26)	0.002[a]
Dromex® 3231 FFP3 NR D	34.97 (31.04–42.99)	33.89 (29.86–39.28)	0.406	71.39 (63.99–80.68)	0.003[a]
Garry Galaxy N95 Respirator Mask	4.70 (4.45–4.98)	4.46 (4.34–4.62)	0.253	6.36 (6.01–6.48)	0.007[a]
HY 9330 FFP3 NR	902.44 (846.04–1747.87)	892.92 (892.92–1190.56)	0.847	885.60 (844.12–942.55)	0.565
Oxyline X310SV FFP3 NR D	214.00 (202.11–269.77)	55.02 (54.37–64.51)	0.002[b]	88.06 (82.91–95.29)	0.002[b]
Pioneer® Safety EP005 FFP2	17.42 (16.67–20.12)	17.58 (15.83–20.14)	0.848	14.80 (13.88–18.63)	0.140
PURVIGOR KN95 3D	7.32 (7.15–7.80)	6.69 (6.42–7.45)	0.110	9.60 (9.20–10.42)	0.003[a]
VENUS V-420-V	23.19 (22.22–25.40)	21.32 (20.92–22.37)	0.110	10.08 (9.81–10.98)	0.002[b]
3M™ Aura™ 9320+ FFP2 NR D	474.00 (454.25–546.92)	333.80 (278.17–388.35)	0.003[b]	307.63 (277.29–358.13)	0.013[b]
3M™ VFlex™ 1802S	104.30 (99.04–116.13)	100.44 (76.53–113.44)	0.565	82.54 (61.65–94.89)	0.009[b]
3M™ 8822 FFP2 NR D	200.00 (200.00–200.00)	115.33 (102.12–133.87)	0.001[b]	85.00 (80.28–86.85)	0.001[b]

Q1, Quartile 1; Q3, Quartile 3.
[a]Increase in fit factor with a *P*-value <0.05.
[b]Decrease in fit factor with a *P*-value <0.05.
For calculating median, Q1, Q3 and *P*-values, seven consecutive fit factor measurements were taken for 1 min at regular 10-s intervals in each phase of the research (baseline, after one decontamination cycle and after two decontamination cycles).
Three units of each respirator model were used, one for each phase of the research.

Table III
Evaluation by the Spanish Institute of Safety and Health at Work (INSST): complementary visual inspection and penetration test with sodium chloride aerosols

Respirator		Difference in physical appearance: Visual inspection (INSST)	Penetration of the filter material with NaCl spray (INSST)	
			Result	Compliance
HY 9330 FFP3 NR	Baseline	Satisfactory	3.925	FFP2
	After one decontamination cycle	Satisfactory	6.355	FFP1
	After two decontamination cycles	Satisfactory	2.383	FFP2
PURVIGOR KN95 3D	Baseline	Satisfactory	4.921	FFP2
	After one decontamination cycle	Satisfactory	19.635	FFP1
	After two decontamination cycles	Satisfactory	11.243	FFP1
Garry Galaxy N95 Respirator Mask	Baseline	Satisfactory	1.933	FFP2
	After one decontamination cycle	Satisfactory	1.860	FFP2
	After two decontamination cycles	Satisfactory	2.136	FFP2
VENUS V-420-V	Baseline	Satisfactory	2.051	FFP2
	After one decontamination cycle	Satisfactory	3.014	FFP2
	After two decontamination cycles	Satisfactory	5.656	FFP2
3M™ Aura™ 9320+ FFP2 NR D	Baseline	Satisfactory	0.171	FFP3
	After one decontamination cycle	Satisfactory	0.256	FFP3
	After two decontamination cycles	Satisfactory	0.316	FFP3

FFP, filtering facepiece.
Three units of each respirator model were used, one for each phase of the research (baseline, after one decontamination cycle and after two decontamination cycles).

emergency room [21]. The requirement for respirators according to these calculations can only be satisfied in normal conditions. Since the 2009 H1N1 pandemic, concern about a potential shortage of respirators has led to numerous studies of reprocessing methods that allow safe re-use of equipment already available in hospitals [9—15].

At present, FFP respirator manufacturers do not authorize decontamination or re-use in their technical data sheets. Only manufacturers can provide reliable guidance on how to decontaminate their products, but several reports on different decontamination methods have been published in recent weeks. In March 2020, the Dutch Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu) carried out a pilot study on reprocessing FFP2 respirators, which concluded that the respirators maintain their shape and capacity to retain particles after one and two decontamination cycles with hydrogen peroxide [22]. Weeks later, the US Food and Drug Administration issued an emergency use authorization to allow the use of a sterilization chamber hydrogen peroxide system to decontaminate N95 respirators [23]. This authorization was based on an extensive study performed in 2016 on an N95 model (3M 1860) which showed that the structural and functional characteristics of the respirators were not damaged after 50 decontamination cycles. The study showed the effectiveness of the system for a 6-log reduction of *G. stearothermophilus* spores [15]. The US NIOSH National Personal Protective Technology Laboratory has investigated the impact of several decontamination methods on filtration efficiency, the fit of FFP respirators to the face, and the ability to reduce viable viruses and bacteria in these respirators, and recommends further research in the area of ultraviolet (UV) germicidal irradiation, vaporous hydrogen peroxide and moist heat decontamination [24].

The COVID-19 pandemic has led to a considerable shortage of PPE, making it necessary to consider re-use. This study was undertaken to investigate respirator decontamination using LTSF rather than hydrogen peroxide or UV radiation sterilization for several reasons. The antimicrobial activity (including vegetative bacteria, fungi, viruses and spores) of formaldehyde in steam form as a sterilizing agent, and its penetrability have been widely studied, documented and used for the sterilization of healthcare materials [25,26]. No special packaging or subsequent aeration is required, any sterilization packaging that complies with UNE-EN ISO 11607-1 can be used, and it is compatible with most materials, other than polycarbonate and latex. Although the study hospital also has hydrogen peroxide plasma gas sterilizers, the authors chose to study the LTSF system based on the lower cost per cycle, and because, unlike hydrogen peroxide sterilization, the LTSF process is regulated by a specific standard (EN 14180:2014), thus giving more guarantees for user safety [19]. The cycle time of 153 min at 78°C, despite being longer than that of the hydrogen peroxide sterilizer, still makes respirators available for re-use in a time frame that meets current requirements. In addition, the LTSF system enables parametric release of materials (EN 14180:2014), saving time in materials management in the central sterilization department, provided that the sterilizers are validated according to ISO 25424 [18]. The accumulated formaldehyde residue on the respirators after two decontamination cycles was always below 5 $\mu g/cm^2$, the threshold recommended by EN 14180:2014, and was undetectable (value equivalent to that obtained in the sample used as the control) in some respirators.

However, formaldehyde is a recognized carcinogen that has been associated with nasopharyngeal carcinoma and other diseases [27]. The correct placement of a respirator will always

involve close proximity to the upper respiratory tract, and hence it will be close to tissues that are susceptible to the damaging action of this compound. Therefore, although different formaldehyde concentration thresholds established as safe by different guides or institutions could be respected, it will always be preferable to obtain an undetectable formaldehyde residue.

Aerosol penetration tests performed in five respirator models by INSST found that four models maintained their filtering capacity after two decontamination cycles. However, PURVIGOR KN95 3D performed as an FFP1 instead of an FFP2 as marketed.

Only three of the 14 respirator models showed visible physical changes after decontamination. The nasal fit of the respirators after decontamination appears to be better in models with an adjustable nasal rod integrated into the fabric compared with those with the rod over the respirator structure, and it is possible that the surface exposure of the metal rod increases the thermolability of the product. The results of this study suggest that, as well as mandatory technical requirements, healthcare institutions should consider other variables such as respirator design and number of parts when purchasing these products.

As for FF, the Occupational Safety and Health Administration states that FF should never be below 100 to ensure a safe fit [28]. However, this study found lower values for several models, which could be explained by the methodology used. In this study, the user was provided with general training in the use of respirators, but this was not individualized for each model and the test was performed even when the initial FF was below 100. Moreover, the absolute FF values are only applicable, by definition, to the specific test subject, and not to the entire population. In addition, healthcare workers do not usually have the option to calculate FF for each respirator in real time, so the study replicated their actual working conditions.

The results obtained (i.e. several deteriorations and improvements in FF) after one and two decontamination cycles, confirm the preliminary character of this research and could be explained by the limitations of the study, such as the small sample size in the FF assessment, or the FF measurement with a single test subject. Also, the use of one different unit for each respirator model for each phase of the research could affect this result, and other results of this study, due to possible variability between different units of the same respirator model.

Healthcare workers may become infected in clinical environments through exposure to a minimal number of microorganisms, so the correct fit of a respirator is a key factor in ensuring that it provides effective protection [29,30]. Spain is one of the countries with the highest number of cases of COVID-19 among healthcare workers, accounting for 20% of the total number of cases as of 21 April 2020, according to data issued by the Spanish Ministry of Health to the European Centre for Disease Prevention and Control [31]. Therefore, consideration should be given to including individual FF measurements of the respirator models used in each hospital in respiratory protection programmes regulating worker safety, and if this is not feasible, at least for staff who are usually assigned to high-risk areas, such as intensive care units, infectious disease services and emergency departments.

If this research was applied to clinical practice, it would be desirable to repeat the filtration test, FF and formaldehyde residue analysis for each model intended to be re-used due to variations between different respirator models. Likewise, due to the importance of the proper fit to the user's face, if a particular respirator unit is sterilized for re-use, it should be uniquely identified to be returned to its original user.

Regarding study limitations, it should be noted that the sample analysed was selected opportunistically using the respirator models available to staff at the time, and few units of each model were analysed. Due to shortages, the supply of respirators changed frequently, which made it impossible to carry out the evaluations on all models, and it was only possible to perform the penetration test for five of the 14 models. In any case, the results of this study represent preliminary investigations and should be interpreted with caution. There is a need to analyse a greater number of respirators and models to achieve more robust results.

A strength of this study is that reprocessing was performed under similar conditions to actual practice. All the residual formaldehyde and the different phases of the decontamination system were performed according to valid international standards. In addition, the research was undertaken on a large sample of different brands of respirators, obtaining results consistent with the initial study hypothesis.

In conclusion, despite the limitations mentioned above, the results of this study show that subjecting certain models of FFP2, FFP3 or N95 respirators to one or two decontamination cycles with 2% LTSF does not compromise their structure, fit or filtering capacity. Furthermore, the formaldehyde residue results comply with EN 14180, and this technique may be used in cases of respirator shortages such as the current pandemic situation.

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