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N95 respirator decontamination: a study in reusability

C.-G. Wang a, Z. Li a, S. Liu a, C.T. Ng b, M. Marzuki c, d, P.S. Jeslyn Wong b, B. Tan c, d, A. Lee c, d, C.F. Hui Lim c, d, P. Bifani c, d, Z. Fang b, J.C. Ching Wong b, Y.X. Setoh b, Y.Y. Yang e, C.H. Mun f, S.Z. Fiona Phua f, W.Q. Lim f, L. Lin g, A.R. Cook h, H. Tanoto a, L.-C. Ng b, i, j, j, A. Singhal c, d, **, j, Y.W. Leong a, **, j, X.J. Loh a, *, j

a Institute of Materials Research and Engineering (IMRE), Agency for Science, Technology and Research (A*STAR), 2 Fusionopolis Way, Innovis, No. 08-03, 138634, Singapore
b Environmental Health Institute, National Environment Agency (NEA), 11 Biopolis Way No.06-05/08 Helios Block, 138667, Singapore
c A*STAR Infectious Diseases Labs, Agency for Science, Technology and Research (A*STAR), 8A Biomedical Grove, 138648, Singapore
d Singapore Immunology Network (SIgN), Agency for Science, Technology and Research (A*STAR), 8A Biomedical Grove, 138648, Singapore
e Institute of Bioengineering and Bioimaging, Agency for Science, Technology and Research (A*STAR), 31 Biopolis Way, Nanos, 138669, Singapore
f DSO National Laboratories, 12 Science Park Drive, 118225, Singapore
g ST Engineering Aerospace Engines Pte Ltd, 501 Airport Rd, 539931, Singapore
h Saw Swee Hock School of Public Health, National University of Singapore and National University Health System, 12 Science Drive 2, 117549, Singapore
i School of Biological Sciences, Nanyang Technological University, 60 Nanyang Drive, 637551, Singapore

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A B S T R A C T

The coronavirus disease 2019 (COVID-19) pandemic had caused a severe depletion of the worldwide supply of N95 respirators. The development of methods to effectively decontaminate N95 respirators while maintaining their integrity is crucial for respirator regeneration and reuse. In this study, we systematically evaluated five respirator decontamination methods using vaporized hydrogen peroxide (VHP) or ultraviolet (254 nm wavelength, UVC) radiation. Through testing the bioburden, filtration, fluid resistance, and fit (shape) of the decontaminated respirators, we found that the decontamination methods using BioQuell VHP, custom VHP container, Steris VHP, and Sterrad VHP effectively inactivated Cardiovirus (3-log10 reduction) and bacteria (6-log10 reduction) without compromising the respirator integrity after 2–15 cycles. Hope UVC system was capable of inactivating Cardiovirus (3-log10 reduction) but exhibited relatively poorer bactericidal activity. These methods are capable of decontaminating 10–1000 respirators per batch with varied decontamination times (10–200 min). Our findings show that N95 respirators treated by the previously mentioned decontamination methods are safe and effective for reuse by industry, laboratories, and hospitals.

1. Introduction

The coronavirus disease 2019 (COVID-19) pandemic has spread worldwide. Various solutions have been proposed to combat the spread of the virus, including sanitization [1]. Other novel and interesting solutions to handle the pandemic have also come up, such as the use of ionizer plants to enhance ventilation or a smart mask to monitor the vital signs of COVID-19 patients [2,3]. However, there has been no other more urgent need than the increasing need for personal protective equipment (PPE). PPE is the primary line of defense for health care workers in their daily routines. The novel severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) remains viable for hours in aerosols and droplets generated by coughing or sneezing and could be transmitted person-to-person via direct (inhalation or contact with mucosal surfaces) or indirect routes (contact with virus-contaminated surfaces followed by transmitting to a person) [4–6].

Human exhalation droplets are generally less than 5 μm in diameter (dry state) or larger (wet state) [7,8]. Filtering facepiece...

References

[1] [2] [3] [4] [5] [6] [7] [8]
particles with 95% efficiency and provide high protection to filter out human exhalation droplets [9–11]. As with other PPEs, N95 FFRs were in serious shortage because of the COVID-19 pandemic. To address this issue, the development of regeneration approaches to decontaminate and reuse N95 FFRs was an essential and pragmatic interim solution to prolong the supply of critical PPE [12–14]. N95 FFRs are negative-pressure air-purifying particulate respirators and need to be approved by National Institute for Occupational Safety and Health (NIOSH). Although these respirators are designed and recommended for single use, the evaluation of their safety and reusability post-decontamination is of strategic interest internationally. Several dry and wet decontamination methods have been reported to disinfect masks using heat, ozone, ultraviolet (UV) radiation, steam, alcohol, ethylene oxide vapor, and vaporized hydrogen peroxide (VHP) [15–19].

Based on the guidance document from the Food and Drug Administration (FDA) ‘Enforcement Policy for Face Masks and Respirators During the COVID-19 Public Health Emergency (PHE)’ (FDA Guidance, May 2020), an effective decontamination method must (1) inactivate the target organism, such as the virus that causes COVID-19; (2) not damage the respirator’s filtration efficiency; (3) not affect the respirator’s fit; (4) not affect the liquid barrier performance if it is a fluid resistance respirator; and (v) be safe for the person wearing the respirator [20–22]. The main N95 FFR manufacturer 3M reported a few recommended methods, including the use of VHP, steam, heat, and UV radiation, for decontamination without deterioration of the protection properties. Research has been conducted using industrial systems or home appliances for N95 FFR decontamination. Nguyen et al. reported the use of dry heat (100°C, 5% relative humidity, 50 min) generated by an electric cooker to decontaminate N95 FFRs. The filtration performance and shape of the FFR did not degrade after 20 cycles of the dry heat treatment [17]. Kumar et al. investigated different decontamination methods for N95 FFRs. The results demonstrated that peracetic acid dry fogging, VHP, autoclaving, and moist heat treatment are effective against SARS-CoV-2 and maintain the FFR integrity up to five decontamination cycles [18]. Song et al. reported that the use of dry heat at 60°C or 70°C for 1 h could effectively kill or inactivate respiratory bacteria, one fungi species, and the H1N1 indicator virus to decontaminate surgical face masks and N95 FFRs [19]. The decontaminated N95 FFRs exhibited filtering efficiency of aerosol as 98%, which is similar to the value (99%) of new FFRs. Warriner et al. recently reported a continuous process using hydroxyl-radicals for FFR decontamination. The process was effective in inactivating bacterial and human coronavirus without negative effects on the FFR functionality [23]. Although these studies demonstrated effective methods for N95 FFR decontamination and reuse, a majority of the studies used home electronics or small-scale laboratory equipment, which are not suitable for large-scale application. In addition, the decontaminated FFRs were generally evaluated by a single property, such as microbial inactivation or filtration efficacy. A comprehensive evaluation of different decontamination methods is desired but less studied.

In this report, we investigated the validity and efficacy of five decontamination methods using VHP and UV radiation for N95 FFR reuse. The VHP decontamination methods were either authorized by FDA for emergency use or were adapted from authorized methods and able to decontaminate 10 to 1,000 FFRs per operation cycle. The UV radiation method requires only 10 min per decontamination cycle without using chemicals (e.g. hydrogen peroxide). Therefore, these methods were considered promising for urgent deployment and with good accessibility by laboratory, hospital, and industry. Through testing the bioburden, filtration, fluid resistance, and fit of the decontaminated FFRs, the usefulness and limitations of the five decontamination methods are evaluated.

2. Materials and methods

2.1. Materials

Surgical fluid-resistant N95 FFRs (Model 1860 [resistance: 120 mm Hg] and 1860S [resistance: 80 mmHg]; 3M Co. Ltd., USA) were used for all tests describe in the following sections. These non-cellulose N95 FFRs are commonly used in hospitals in Singapore. Respirator samples were prepared and analyzed in biosafety level 2 (BSL-2) laboratories after decontamination tests.

2.2. Decontamination methods

Decontamination methods were evaluated and performed by using a chemical VHP method and a photoradiation short-wavelength UV (UVC; wavelength 254 nm) method. Three commercially available VHP systems (BioQuell, Steris, and Sterrad), one customized VHP container (VHPC), and a Hope UVC system are established for the tests. The customized VHPC uses a Steris VHP generator, which is an adaptation of the Battelle solution (USA). Table 1 summarizes the decontamination methods used in this study.

| Table 1 | Summary of the decontamination methods. |
|---|---|
| Decontamination method | Description | Decontamination cyclesa | Capacity per cycleb | Decontamination time (min)c |
| **BioQuell VHP** | VHP-based system for large throughput room/container decontamination | 1, 5, 10, 15, or 20 | 400 | 107 |
| **Custom VHP container** (VHPC) | Large throughput VHP-based system in a special-purpose built 20 ft container | 1, 5, 10, 15, or 20 | ca. 1,000 | 200 |
| **Steris VHP** | Steris VPro Max unit for small throughput decontamination | 1 or 10 | 10 | 28 |
| **Sterrad VHP** | Sterrad 100NX AllClear unit for small throughput decontamination | 1 or 2 | 10 | 24 |
| **Hope UVC** | Small throughput chamber with UVC 254 nm lamps | 1 or 5 | 10 | 10 |

a The number of decontamination cycles applied on FFRs before test.
b Maximum number of FFRs per decontamination cycle.
c Processing time per decontamination cycle.
d With Health Canada approval.
e With FDA-EUA approval.
2.3. Bioburden test

Bioburden tests were performed to determine the viricidal as well as sporicidal or mycobacterial activities before and after decontamination of the FFRs. Mengovirus (vMC0, belonging to genus cardiovirus) as well as spores of Gram-positive bacteria Geobacillus stearothermophilus and bacteria of Mycobacterium genus viz. Mycobacterium smegmatis were used for these tests. The agents were selected for the decontamination tests because of their biological safety, experimental relevance, and accessibility [24]. Mengovirus, which is a non-enveloped BSL-2 Cardiovirus, was selected as non-enveloped viruses typically have greater resistance to inactivation than enveloped viruses. G. stearothermophilus was chosen because of its ability to form spores, whereas Mycobacterium spp. was selected because it is known to be more chemically resistant than other bacterial species. The bioburden tests were evaluated with two Emergency Use Authorization recommended criteria as (1) 3-log_{10} (99.9%) reduction in virucidal activity and (2) 6-log_{10} (99.9999%) reduction in mycobacterial or sporicidal activity to define the completion of decontamination.

2.4. Filtration efficiency test

Filtration efficiency of the FFRs was determined via bacterial filtration efficiency (BFE) and particle filtration efficiency (PFE) tests in line with the guidelines of the FDA and Ministry of Health of Singapore [25–27]. BFE test determines the filtration efficiency by comparing the bacterial control counts to test article effluent counts. The BFE tests were evaluated with ASTM F2101-01 standard as over 98% filtration efficiency for particles with or below 3 μm diameter [28]. PFE test evaluates the non-viable particle retention or filtration efficiency of the respirators at submicron levels. The PFE tests were evaluated with NIOSH method as over 95% filtration efficiency for airborne particles with 0.3 μm diameter. The experimental details of BFE and PFE tests are described in Supporting Information.

2.5. Fluid resistance test

The fluid resistance test for the N95 FFRs was conducted using synthetic blood to simulate the splatter of bodily fluids onto the samples. The sample was visually inspected to determine the penetration of the fluid into the inner surface. The experimental details are described in Supporting Information.

2.6. Quantitative respirator fit examination

A clinical trial involving 10 healthy volunteers were recruited for the quantitative mask fit test. The clinical trial testing protocol and ethics review and safeguard were approved under the DSO National Laboratories and Singapore Armed Forces (DSO-SAF) Institutional Review Board (IRB No: 0022/2020, Singapore). The respirator fit examination was conducted using the procedure from Occupational Safety and Health Administration (OSHA) protocol no. 29 CFR 1910.134. Briefly, each volunteer donned a decontaminated N95 FFR

### Table 2

| Test                  | Requirement                                      | Description                                                                 |
|-----------------------|--------------------------------------------------|------------------------------------------------------------------------------|
| Decontamination       | Virucidal activity: ≥3-log_{10} reduction         | Evidence to demonstrate a robust ability to reduce bioburden on the FFRs    |
|                       | Mycobacterial or sporicidal activity: ≥6-log_{10} reduction |                                                                             |
| Filtration            | Particle filtration efficiency (PFE): ≥95%       | Evidence to demonstrate that repeated exposure to reprocessing cycles does not interfere with the particle and bacteria filtration ability or breathability of the FFRs |
|                       | for airborne particles with 0.3 μm diameter      |                                                                             |
|                       | Bacterial filtration efficiency (BFE): ≥98%      |                                                                             |
|                       | for particles with or below 3 μm diameter        |                                                                             |
| Fluid resistance      | Resistance of 120 mm Hg synthetic blood penetration | Evidence to demonstrate liquid barrier performance                           |
| Fit                   | Fit factor > 100                                 | 1) Evidence to demonstrate that repeated exposure to the reprocessing cycle steps does not decrease the ability of the FFR to form a tight fit to the user’s face  |
|                       |                                                  | 2) Evidence to demonstrate that the reprocessing cycle steps do not compromise the integrity of the elastic bands to maintain an appropriate fit to the wearer |

**Fig. 1.** Image of the inner side of an N95 FFR whereby L1 and L2 are inoculation locations.
that was connected to the PortaCount (TSI PortaCount Pro + Respirator FitFester, Model 8048-1) and performed a series of physical activities to obtain an overall fit factor score. The physical activities include breathing normally and deeply, moving head up-and-down and side-to-side, bending over and talking. Fit score for each physical activity was then averaged. An overall fit score greater than 100 is required for N95 respirators as stated in the previously mentioned OSHA protocol.

2.7. Statistical analysis

The difference between the test and control masks was calculated from the difference in mean log_{10} TCID_{50} per carrier value for Mengovirus or mean log_{10} pfu/carrier for G. stearothermophilus and M. smegmatis. The value for the limit of detection of the respective titration assays was used for masks that had no detectable growth.
For each experiment, a one-sided hypothesis test that the difference in mean \( \log_{10} \text{TCID}_{50} \) per carrier or \( \log_{10} \text{pfu} \) per carrier scores was at least 3-log_{10} (Mengovirus) or 6-log_{10} (G. stearothermophilus and M. smegmatis) was conducted. These differences correspond to at least a thousand-fold and million-fold difference on the linear scale. The analysis was performed using R (Bell Labs).

3. Results and discussion

3.1. Study design

According to the FDA guidance described previously, the viral and bacterial decontamination, filtration, fluid resistance, and fit tests were performed to evaluate the usefulness of the decontaminated N95 FFRs. Currently, most of the studies are applicable for laboratory scale and did not evaluate the five requirements comprehensively. The requirement and description of the tests are shown in Table 2. For decontamination, filtration, and fluid resistance tests, the decontaminated FFRs and the decontamination processes were examined and evaluated based on the FDA guidance. For the fit examination, the evaluation was based on the feedback and observation of volunteers.

3.2. Decontamination of FFR — Phase 1

Five decontamination methods, namely, BioQuell VHP, VHPC, Steris VHP, Sterrad VHP, and Hope UVC, were used for the decontamination of FFRs. Mengovirus and two types of bacteria, G. stearothermophilus and M. smegmatis, were spiked respectively onto experimental FFRs and six control FFRs with or without simulated body fluids (0.2% mucin and 0.2% sodium chloride; Fig. 1, L1 and L2 positions, respectively). Decontamination of the experimental FFRs was conducted once via the different decontamination methods, and the FFRs were then subjected to bioburden tests to determine the load of inactivated viruses or bacteria that remained on the surface after decontamination, and thus, the efficacy of the decontamination method was assessed.

Mengovirus, which is a non-enveloped BSL-2 Cardiovirus, was used to evaluate the virus decontamination efficacy of the five decontamination methods. In this test, 30 experimental FFRs and six control FFRs were spiked with Mengovirus (location L1, Fig. 1) and Mengovirus with 0.2% saline (sodium chloride solution) as synthetic sweat and 0.2% mucin as synthetic saliva (at location L2, Fig. 1). The experimental FFRs were decontaminated once and subjected to bioburden tests.

From an original spike concentration of 5.56- to 8.89-log_{10} TCID_{50}/carrier, Mengovirus titers of 2.15- to 6.90-log_{10} TCID_{50}/carrier were recovered from the inoculation sites of the control FFRs. As shown in Fig. 2 and Tables S2 and S3, BioQuell VHP and Steris VHP successfully achieved \( >3\)-log_{10} reduction of Mengovirus at location L1 (without saline and mucin), whereas only VHPC displayed \( >3\)-log_{10} reduction of Mengovirus at location L2 (with saline and mucin). It was noted that the decontamination efficacy of several VHP systems could not be fairly evaluated and may be underestimated in our Phase I study because of lower-than-expected recovery of virus from the control FFRs.

Hope UVC carries a small chamber for decontaminating 10 respirators in 10 min without using chemicals (e.g. hydrogen peroxide), offering a facile and cost-effective decontamination process. Hope UVC was effective at inactivating Mengovirus and achieved \( 3\)-log_{10} virucidal reduction on the FFRs in the presence (3.82-log_{10} reduction) or absence (4.41-log_{10} reduction) of saline and mucin (Fig. 3). The TCID_{50} data and microscopic images of Mengovirus recovery are shown in Tables S6–S11 and Figs. S1–S4.

We also used G. stearothermophilus and M. smegmatis for the decontamination and bioburden tests. G. stearothermophilus or M. smegmatis were spiked onto the experimental and control FFRs. The experimental FFRs were similarly decontaminated using the five methods described previously. Although there was a nearly 6-log_{10} reduction when compared with the spiked load, the decontamination did not meet the FDA requirement when compared with the bacterial recovery from the control FFRs. The results indicated that all four VHP methods were efficient to achieve certain reduction (ranging from 3.23- to 5.17-log_{10} Reduction) for G. stearothermophilus (48 h incubation; Fig. 4A; Table S4) and M. smegmatis (72 h incubation; Fig. 4B; Table S5). However, the decontamination effectiveness of the VHP systems could not be demonstrated to meet the recommendations from the FDA guidance. The low recovery (\( \leq 5.73\)-log_{10} CFU/carryer) of bacteria from the control FFRs inevitably limited the achievement of decontamination tests. The reduction thus cannot be attributed to the decontamination process.

Apart from VHP methods, Hope UVC was also applied for FFR decontamination of G. stearothermophilus and M. smegmatis. After treatment using Hope UVC, the viable load of G. stearothermophilus (Fig. 5A) that remained on the experimental FFRs was similar to that of control FFRs (4.64-log_{10} CFU/carryer [treated] and 5.31-log_{10} CFU/carryer [control]). This result indicated that the Hope UVC system was not effective at decontaminating G. stearothermophilus on the FFRs. Hope UVC was also found to be less effective in inactivating M. smegmatis (Fig. 5B) than the other VHP methods, achieving only 4.44-log_{10} reduction after UVC treatment. The recovery colonies were dispersive from 0.69- to 3.31-log_{10} CFU/carryer, indicating that the decontamination is less effective for all tested FFRs. Although Hope UVC was effective at inactivating Mengovirus, it is less effective

![Fig. 3](image-url) Phase 1 Hope UVC treatment and bioburden test results and recovery of (A) Mengovirus (with saline and mucin) and (B) Mengovirus (without saline and mucin). Points on scatterplot indicate individual titers obtained from treated test masks (red points) or untreated control masks (blue points). The mean values are also indicated for the test masks (red point, bottom of each figure) and control masks (blue diamond, bottom of each figure; spread of diamond encompasses the 95% confidence interval).
against the bacteria strains that we tested. The poor bacterial decontamination efficacy of Hope UVC did not support further investigation in our Phase II examination.

3.3. Decontamination of FFR — Phase II

In our Phase I FFR decontamination test, we noted poor recovery of the challenge organisms from the control (untreated) FFRs, which limited the achievement of the >3-log_{10} reduction requirement for Mengovirus and >6-log_{10} reduction requirement for bacteria. We were also motivated by the observation that no hydrogen peroxide or other toxic residues remained on the VHP-treated FFRs, suggesting that the N95 FFRs are safe for reuse if efficacy was supported. Therefore, a Phase II study was conducted using a higher initial concentration of challenge organism to re-evaluate the efficacy of the VHP systems.

BioQuell VHP, custom VHPC, Steris VHP, and Sterrad VHP were again tested against Mengovirus using a higher virus concentration of 7.15- to 8.15-log_{10} TCID_{50}/carrier and was conducted as two independent runs (Run I and Run II, six control and six test masks [12 masks in total] per run for BioQuell and VHPC; three control and three test masks [six masks in total] per run for Steris and Sterrad).
In Phase II, the recovery of virus from control FFRs was much higher, with a mean recovery of 7.05- to 7.36-log10 TCID50 per carrier of Mengovirus across all four VHP methods (Fig. 6 and Table S12). In the treated FFRs, between 1.4- to 1.9-log10 TCID50 per carrier Mengovirus were recovered, resulting in a 5.13- to 5.54-log10 reduction in Mengovirus across all four VHP methods and fulfilling the >3-log10 reduction recommendation from the FDA guidance.

Similarly, the M. smegmatis challenge was repeated using a higher initial concentration of 7.72-log10 CFU/carrier. The M. smegmatis experiment was similarly conducted as two independent runs (see Table S13 for details). In Phase II, the recovery of M. smegmatis from the control FFRs was in the range of 7.21- to 7.67-log10 cfu/carrier. In the treated FFRs, only 0.20- to 0.22-log10 cfu/carrier could be recovered, resulting in a 6.99- to 7.45-log10 reduction of M. smegmatis across all four VHP methods (Fig. 7 and Table S13), and similarly fulfilling the >6-log10 reduction recommendation set by the FDA guidance.

3.4. Filtration efficacy test

PFE and BFE tests were conducted on the FFRs after the respirators were subjected to the various decontamination methods. The maximum cycles of the decontamination systems were used to FFRs, and the filtration efficacy of the decontaminated respirators were evaluated. The testing results are summarized in Table 4. All respirators treated with BioQuell VHP (20 cycles), VHPC (20 cycles), Steris VHP (10 cycles), or Hope UVC (10 cycles) passed the PFE tests (>95%) with average PFE values over 99%. For FFRs treated with Sterrad VHP (two cycles), 28 FFRs out of 30 passed the PFE tests. The appearance of crumpling FFRs at the inner surfaces of the FFRs that
The crumpling may occur during transportation or as a result of the vacuum treatment during the decontamination process. The FFRs with crumpling exhibited inferior PFE values (<95%). Therefore, Sterrad decontamination method may affect the respirator PFE although no visible tear or puncture to the outer and inner parts of the FFRs. It is also worthy to note that no crumpled FFR was generated when the Sterrad VHP decontamination cycle was repeated with the ALLClear function turned off. (The ALLClear is an optional function using a small amount of plasma to increase the decontamination productivity in Sterrad VHP system. Plasma may deteriorate the filter materials and function.) All the decontaminated FFRs (30 over 30) using Sterrad VHP but without ALLClear function passed the PFE test (≥95%). Further bioburden tests are necessary to confirm the decontamination efficacy of Sterrad VHP without ALLClear function.

In summary, BioQuell VHP, VHPC, Steris VHP, Sterrad VHP (without ALLClear function), and Hope UVC methods exhibited no negative effect on PFE and BFE of FFRs. Sterrad VHP with ALLClear function would occasionally render crumpling on the FFRs, causing the decrease of PFE.

3.5. Fluid resistance test

ASTM F1862/F1862 M standard was used to evaluate the fluid resistance of FFRs, as shown in Fig. 9. At least 29 of 32 FFRs should exhibit no penetration of synthetic blood to pass the fluid resistance test. More than 6.9-log_{10} reduction of M. smegmatis titer was observed. The crumpling may occur during transportation or as a result of the vacuum treatment during the decontamination process. The FFRs with crumpling exhibited inferior PFE values (<95%). Therefore, Sterrad decontamination method may affect the respirator PFE although no visible tear or puncture to the outer and inner parts of the FFRs. It is also worthy to note that no crumpled FFR was generated when the Sterrad VHP decontamination cycle was repeated with the ALLClear function turned off. (The ALLClear is an optional function using a small amount of plasma to increase the decontamination productivity in Sterrad VHP system. Plasma may deteriorate the filter materials and function.) All the decontaminated FFRs (30 over 30) using Sterrad VHP but without ALLClear function passed the PFE test (≥95%). Further bioburden tests are necessary to confirm the decontamination efficacy of Sterrad VHP without ALLClear function.

Similarly, for BFE evaluation, FFRs were decontaminated under the maximum cycles within each decontamination method. The BFE test setup is shown in Fig. 8, and the results are summarized in Table 3. All FFRs passed the BFE test (>98%), with an average BFE value over 95%, except for two FFRs after decontamination with BioQuell VHP for 20 cycles. However, the failure of the BFE tests could be attributed to experimental error. As shown in Fig. 8, droplets spiked with bacteria from the glass column may have entered and contaminated the stage 1 impactor plate during the removal of the FFR sample, leading to false positives. Typically, the aerosol particles measuring 2–3 μm would have been captured in stages 3–5 of the impactor, resulting in significant growth of bacteria colonies as was evident in the measurement of the control. Nevertheless, bacteria colonies were not detected at stages 3–5 in the failed samples, indicating that these were false positives caused by experimental error. Therefore, BioQuell VHP is also an effective decontamination method without deteriorating the BFE of FFRs.

In summary, BioQuell VHP, VHPC, Steris VHP, Sterrad VHP (without ALLClear function), and Hope UVC methods exhibited no negative effect on PFE and BFE of FFRs. Sterrad VHP with ALLClear function would occasionally render crumpling on the FFRs, causing the decrease of PFE.
resistance test. The fluid resistance test results of FFRs after maximum cycles of decontamination are summarized in Table 4. It is found that for each decontamination method, more than 30 decontaminated FFRs maintain their fluid resistance over 120 mm Hg for preventing synthetic blood penetration. The result emphasized no deterioration in the fluid resistance of the FFRs regardless of the decontamination method.

3.6. Fit examination

A quantitative fit examination was conducted with 10 participants, of which five were males and five were females. Before examination, N95 FFRs were decontaminated with BioQuell VHP (5, 10, 15, and 20 cycles), VHPC (5, 10, 15, and 20 cycles), Steris VHP (10 cycles), Sterrad VHP (two cycles), or Hope UVC (five cycles). Face seal and odor checking was evaluated to determine the reusability of decontaminated FFRs in real case application. Decontaminated FFRs are deemed to provide good face seal when they passed the fit test. The fit examination results are summarized in Table 5. BioQuell VHP and VHPC decontaminated FFRs maintained their original forms when the decontamination cycles were below 15. A few FFRs were observed with a deformed shape when the decontamination cycles reached 20 (Fig. S6a). FFRs could maintain the shapes after applying Steris VHP and Sterrad VHP decontamination. However, the inner side of a few FFRs was observed to be crumpled after treating with Steris VHP (Fig. S6b). N95 FFRs decontaminated by Hope UVC were deformed because of the physical stretching when mounting onto the frame of Hope UVC (Fig. S6c).

### Table 3

| Decontamination method | Decontamination cycles | Number (ratio) of FFR with PFE ≥ 95% | Average PFE% | Number (ratio) of FFR with BFE > 98% | Average BFE% |
|------------------------|------------------------|-------------------------------------|--------------|------------------------------------|--------------|
| BioQuell VHP           | 20                     | 30 (100%)                           | 99.6         | 28 (93%)                           | 99.2         |
| VHPC                   | 20                     | 30 (100%)                           | 99.4         | 30 (100%)                           | 100c         |
| Steris VHP             | 10                     | 30 (100%)                           | 99.5         | 30 (100%)                           | 99.9         |
| Sterrad VHP           | 2                      | 28 (93%)                            | 98.0         | 30 (100%)                           | 99.9         |
| Hope UVC               | 5                      | 30 (100%)                           | 99.7         | 30 (100%)                           | 99.9         |

a The number of decontamination cycles applied on FFRs before test.

b Average values of the tested FFR.

c Calculated value as 99.95%.

d With ALLClear function.

Fig. 9. Images of (a) fluid resistance tester, (b) synthetic blood spraying process (the blue arrow indicates a tested FFR), (c) an FFR sample before fluid projection, and (d) an FFR sample after fluid resistance test.
4. Conclusions

N95 FFRs are highly important and effective PPE to prevent the spread of SARS-CoV-2 and other airborne infectious diseases. In this research, we studied five decontamination methods using VHP or UV radiation for N95 FFR decontamination and reuse. Decontamination efficacy, filtration efficacy, fluid resistance, and shape (fit) tests of the decontaminated FFRs were examined to evaluate the decontamination methods. BioQuell VHP and VHPC are effective in inactivating *M. smegmatis* and *Mengovirus* without compromising the filtration efficacy, fluid resistance, and fit of the FFRs up to 15 decontamination cycles. Furthermore, BioQuell VHP and VHPC are capable of decontaminating more than 400 FFRs per batch, which are beneficial for industry use. Steris VHP and Sterrad VHP exhibited superior decontamination abilities for *M. smegmatis* and *Mengovirus*. Steris VHP also exhibited the highest performance to maintain FFR integrity (filtration, fluid resistance, and shape) among the five decontamination methods. Sterrad VHP could also highly maintain the FFR performance but slightly deteriorate PFE. Hope UVC was effective in inactivating *Mengovirus* (>3-log10 reduction); however, it was not amenable for inactivating *G. stearothermophilus* and *M. smegmatis*. FFRs with Hope UVC decontamination showed high filtration efficacy and fluid resistance, but a few FFRs could not maintain their shapes and thus failed the FFR fit test. Steris VHP and Sterrad VHP are compact equipment with small throughput (10 respirators per batch) for rapid (<28 min) and effective FFR decontamination and reduction of virucidal activity, which is practical for laboratory or hospital use.

**Authors’ contributions**

C.G.W. and Z.L. searched the references and wrote the article. S.L. coordinated mask decontaminations, PFE, and fluid resistance test. C.T.N., P.S.J.W., Z.F., J.C.C.W., Y.X.S., M.M., B.T., A.L., C.F.H.L., and P.B. contributed to bioburden test. Y.Y.Y. contributed to BFE analysis. C.H.M., S.Z.F.P., and W.Q.L. contributed to fit test analysis. L.Y. contributed to PFE analysis. A.R.C. performed the statistical analysis for bioburden test. H.T. coordinated and revised the article. A.S., L.C.N., and Y.W.L. coordinated the project. X.J.L. conceived the idea and initiated the project. All the authors have critically revised the scientific content of this article and approved the final version.

**Declaration of competing interest**

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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**Appendix A. Supplementary data**

Supplementary data to this article can be found online at https://doi.org/10.1016/j.mtadv.2021.100148.

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