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Journal of Occupational and Environmental Hygiene

doi: 10.1080/15459624.2020.1829633

Date of Publication from Ext Publisher: November 2020



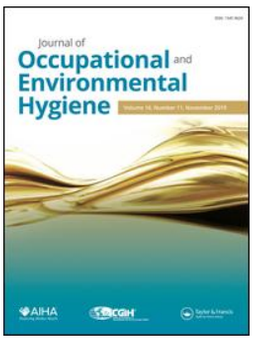
**Defence Research and Development Canada**
**External Literature (P)**
DRDC-RDDC-2020-P221
December 2020



Canada

**IMPORTANT INFORMATIVE STATEMENTS**

This document was reviewed for Controlled Goods by Defence Research and Development Canada using the Schedule to the *Defence Production Act*.



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Journal of Occupational and Environmental Hygiene

ISSN: (Print) (Online) Journal homepage: https://oeh.tandfonline.com/loi/uoeh20

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**To cite this article:** Scott Duncan , Paul Bodurtha , Cara Bourgeois , Eva Dickson , Cheryl Jensen & Syed Naqvi (2020): The impact of extreme reuse and extended wear conditions on protection provided by a surgical-style N95 filtering facepiece respirator, Journal of Occupational and Environmental Hygiene, DOI: 10.1080/15459624.2020.1829633

**To link to this article:** https://doi.org/10.1080/15459624.2020.1829633

JOURNAL OF OCCUPATIONAL AND ENVIRONMENTAL HYGIENE
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# The impact of extreme reuse and extended wear conditions on protection provided by a surgical-style N95 filtering facepiece respirator

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**ABSTRACT**

Most respirators employed in health care settings, and often in first responder and industrial settings, are intended for single-use: the user dons the respirator, performs a work activity, and then doffs and discards the respirator. However, in the current COVID-19 pandemic, in the presence of persistent shortages of personal protective equipment, extended use and reuse of filtering facepiece respirators are routinely contemplated by many health care organizations. Further, there is considerable current effort to understand the effect of sterilization on the possibility of reuse, and some investigations of performance have been conducted. While the ability of such a respirator to continue to provide effective protection after repeated sanitization cycles is a critical component of implementing its reuse, of equal importance is an understanding of the impact that reusing the respirator multiple times in a day while performing work tasks, and even extending its wear over multiple days, has on the workplace protective performance. In this study, we subjected a stockpiled quantitatively fitted surgical style N95 filtering facepiece respirator device to extreme reuse and extended wear conditions (up to 19 uses over a duration of 5 days) and measured its protective performance at regular intervals, including simulated workplace protection factor measurements using total inward leakage. With this respirator, it was shown to be possible to maintain protection corresponding to an assigned protection factor greater than 10 under extreme usage conditions provided an individual is properly trained in the use of, and expertly fitted in, the respirator. Other factors such as hygiene and strap breakage are likely to place limits on reuse.

**KEYWORDS**

Condensation particle counter; pandemic; quantitative respirator fit testing; simulated workplace protection factor

## Introduction

The pandemic event now underway (World Health Organization [WHO] 2020) involving the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the disease-causing organism for COVID-19, has caused a significant shortage of personal protective equipment (PPE), specifically filtering facepiece respirator (FFR) devices such as N95 respirators, across the globe. As a result, all levels of the government down to individual health care organizations have been forced to manage their stocks to compensate for supply chain uncertainty and high usage needs in critical care units in order to maintain the health and safety of frontline workers at risk of being exposed to SARS-CoV-2.

Most respirators employed in health care settings, and often in first responder and industrial settings, are intended for single use in which the user dons the respirator, performs a work activity (such as seeing a single patient), and then doffs and discards the respirator. The concept of reusing single-use FFRs during shortages in the context of a health care setting has been thoroughly discussed previously (US National Research Council [US NRC] 2006; Fisher and Shaffer 2014; US Centers for Disease Control and Prevention [US CDC] 2020; Yorio et al. 2020). The term reuse consists of donning of an FFR by a health care worker (HCW), wearing it for one patient and then doffing it, repeated multiple times, while the term extended use consists of an HCW donning an FFR and wearing it for multiple tasks/patients without doffing and redonning in between. The consensus is that both reuse and extended use may be considered under certain circumstances to manage FFR supplies if there is

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Supplemental data for this article is available online at https://doi.org/10.1080/15459624.2020.1829633. AIHA and ACGIH members may also access supplementary material at http://oeh.tandfonline.com.

an immediate or anticipated respirator shortage due to an unfolding pathogenic event. Extended use has been proposed as preferable to limited reuse because the latter increases the risk of self-inoculation through contact transmission from the respirator to the HCW (Fisher and Shaffer 2014). It has further been proposed by these authors that a safety margin be applied when implementing an FFR reuse policy, limiting the number of times FFRs are donned and doffed to no more than five times.

If these approaches are to be effective, protection performance of FFRs commonly used by HCWs must be maintained for longer than originally intended by the manufacturer. This performance is determined both by the efficacy of the seal between the FFR and the skin of the face and by the efficiency of the filter material. Inward leakage of aerosol at the face seal is significantly more difficult to control and requires that the individual wearing the FFR undergo a qualitative or quantitative fit test to determine that the respirator is appropriately sized and has been properly donned to ensure the required level of protection. Canadian standard CAN/CSA Z94.4-18 (Canadian Standards Association [CSA] 2018) and the US Occupational Safety and Health Administration (2009) (US Code of Federal Regulations [US CFR] 2004) require that users achieve a minimum fit factor (FF) equivalent to 100 prior to a respirator being issued (for FFRs, the FF does not reflect penetration through the filter, but only leakage around the face seal).

A quantitative fit test (QNFT) is used to select an appropriate size or model for an individual, and it is not necessarily expected to predict performance in use. When the FFR is subsequently employed in the work place and the user is performing typical workplace tasks, the assigned protection factor (APF) of such a device is 10 (CSA 2018; US Occupational Safety and Health Administration [US OSHA] 2009), meaning that its protection in the workplace should not on average be less than this value for the large majority of wearers. This value was determined by evaluating FFRs using a series of workplace or simulated workplace protection factor (SWPF) assessments, performed under controlled conditions, with the protection factor (PF) over an entire series of representative activities being assessed. A number of related studies are discussed below.

Numerous studies on N95 FFRs and other half-mask styles have helped to establish the relation between fit testing outcomes, observed workplace performance, and APFs. Lee et al. (2008) compared the protection performance of N95 respirators and surgical masks. Duling et al. (2007) looked at SWPF values for half-mask respiratory protective devices, validating the notion that in order for an APF of 10 to be achieved, previous quantitative or qualitative fit testing is required. A number of studies subsequently investigated the relation between fit testing outcomes and workplace protection (Hauge et al. 2012, Sietsema et al. 2015, Sietsema and Brosseau 2018). Initial FF was shown to be indicative of the protection performance achieved during three simulated health care tasks subsequently completed by HCWs (Hauge et al. 2012). Later studies (Sietsema et al. 2015, Sietsema and Brosseau (2018) showed a good correlation between FFs and the SWPF result (measuring face seal leakage only) when the respirator was not doffed in between. He et al. (2015) measured the SWPF performance of N95 and P100 filtering facepiece and elastomeric half-mask respirators when challenged with an aerosol in two particle size ranges, with no difference found. Or et al. (2016) and Wu (2018) measured real-time face seal leakage for different models of N95 respirators using optical particle counting-based instruments, with Or et al. finding an instantaneous PF of less than 10 more frequently in nurses performing moving exercises with heavy activity, in clinical settings.

A great deal of the current effort on reuse of FFRs has focused on the ability to sterilize the respirators between uses and the concomitant effect that the decontamination process has on material integrity, fit, and filtration performance (Battelle 2016; Bergman et al. 2010; Fisher and Shaffer 2011; Goyal et al. 2014; Lin et al. 2017; Lin et al. 2018; Lowe et al. 2020; Mills et al. 2018; Schwartz et al. 2020; Viscusi et al. 2009; Webb 2011). The issue of the performance of the respirator itself after multiple reuses, in the absence of sterilization, has been less well studied. A study that looked at N95 filter media exposed to simulated use once a week for several months noted a reduction in filtration efficiency of several models (Moyer and Bergman 2000). The reuse of different N95 FFR devices donned and doffed up to 20 times with only 2 min between reuses showed that the protection performance tended to decrease overall but five total wears could be achieved with the FF not dropping below 100 (Bergman et al. 2012). In a follow-on study (Vuma et al. 2019) evaluating the effect of multiple donnings on respirator fit in health laboratory service employees examining six wears, training of the wearer to maintain repeated correct donning was more important than any loss of ability of the FFR to fit. A report by the Emergency Care Research Institute [ECRI] 2020) on the safety of extended use and reuse

of N95 respirators provides practical guidance on the potential risks and benefits that clinical centers should consider during decision making about N95 respirator reuse or extended use.

In summary, it is important to understand the impact that reusing the FFR multiple times in a day performing work tasks, and even extending the wear of the FFR over multiple days, has on the workplace protective performance. In this study, we subjected a quantitatively fitted N95 FFR device to extreme reuse and extended wear conditions over a duration of up to 5 days. Over the course of the trial, a single FFR saw up to 19 wears, five end-of-day protection factor measurements, and three SWPF evaluations. Accordingly, our results provide an assessment of the overall protection performance of an N95 FFR device in terms of number of wears and wear time. It should be noted that unlike previous SWPF studies by Sietsema et al. (2015), Sietsema and Brosseau (2018), and Hauge et al. (2012), for this study the total inward aerosol leakage (i.e., leakage of particulates through both the respirator face seal and filter) has been measured at the most penetrating particle size for N95 filters. This is relevant, as any change in performance of the filter will also be captured in this study. Other qualitative observations were obtained from the wearers regarding the state of the respirator over the course of the evaluations. To the best of our knowledge, there has been no other study that has completed such a comprehensive assessment of the protection provided by a surgical style N95 filtering facepiece respirator under extreme reuse and extended wear conditions.

## Materials and methods

Additional details on all of the methodologies are provided in online Supplementary Materials for this paper.

### *Test subjects and quantitative fit testing (QNFT)*

The study used one model of a NIOSH (US National Institute for Occupational Safety and Health [US NIOSH] 2019) certified N95 filtering facepiece respirator (3M 1870, one standard size, St. Paul, MN), which is FDA approved as a surgical mask and currently being used out of stockpile. Subjects for the study were recruited from Defence Research and Development Canada (DRDC) Suffield Research Center (Ralston, Alberta, Canada) and were chosen based on obtaining a subject pool of both males and females, with a wide distribution of age, height, and weight. Eight subjects were trained and successfully quantitatively fit tested using the TSI PortaCount model 8038 (Shoreview, MN), in the chosen respirator according to Z94.4-18 (CSA 2018), in order to achieve required protection levels (fit factor of at least 100). A sampling probe (TSI Model 8025-N95 Adaptor Kit, Shoreview, MN) was affixed at the center of the respirator, between the mouth and nose of the subject, and a sampling tube from the measuring instrument was attached to the probe. As per CSA (2018), subjects wore their safety glasses during the test to assess possible equipment integration issues that might affect protection.

Of the eight subjects, Subjects 1–7 executed the reuse study and Subject 8 was the control. Comparing with the bivariate panel described by Zhuang et al. (2007) for facial size distribution, five subjects were of smaller facial sizes, and three were of larger facial sizes.

### *Respirator reuses and extended wear*

With the exception of the control subject, or in the case of a major defect in which case the item was replaced, each subject wore a single FFR for the protection measurements for up to 5 days with up to four reuses each day, and wore a variety of additional relevant PPE. Over the course of these reuses a substantial workday activity regime was undertaken that consisted of 60–80 min of walking and moving between floors in a building by stairs, 60–80 min of paper and computer work related activities, and 60–80 min of task-based activities involving bending, kneeling, reaching, lifting, and so on. The respirator was stored between uses in a typical approach to that performed by HCW. Various protection performance evaluations and inspections of the FFR were performed at intervals.

In more detail, each day, the subject inspected the respirator for obvious defects before donning and continued to wear the respirator for the remainder of the day, removing for 15–30 min at approximately 1.5-hr intervals to simulate reuse. These times were based on discussions with health care workers on the use of N95 respirators in health care settings, giving 3–4 reuses per day, for a total over 5 days of up to 18 reuses (19 wears). The respirator was handled as though contaminated, and hung to dry between donnings, according to instructions currently given to health care workers.

During each wear, the subjects performed a set of tasks, which consisted of three series of activities: walking hallways and stairs (20 min), "passive" workplace activities (30 min), and "active" workplace activities (30 min). At the end of a session of tasks, the subjects doffed their respirator, took a break for 15 min (or 30 min for lunch), and then redonned it to continue with another session of tasks, i.e., the next wear. This was repeated three or four times in a day for total number of wears of 3–4 per day, and total daily wear time up to 6.25 hr.

For the daily tasks, the "passive" workplace activities were those such as paper and computer work, sitting and operating an analytical instrument, and other low work rate activities. "Active" workplace activities were those such as cleaning, re-arranging, sorting and moving lab equipment and accessories, as well as work activities above head level, at waist level and in squat/kneeling position.

During the daily tasks all subjects wore safety glasses (with an anti-fog coating, 3M Secure Fit Eyewear, St. Paul, MN) all day, a lab coat and nitrile gloves when in the labs, and medical scrubs on the days they were to perform an SWPF. The subjects inspected and then donned the FFR according to manufacturer's instructions with the aid of a mirror, and performed a seal check afterwards. After doffing, the FFR was stored unfolded (with the pleats spread to aid in drying) in an open brown paper bag, which hung on the wall in an open office area.

### Control subject

The control subject in the study was used to assess the general magnitude of the variation in the protection received from the chosen model of N95 FFR when worn for a single use. The control was issued a N95 FFR each day, fresh from box, and wore it for 1.5 hr, including protection measurements performed every day as described below.

### Simulated workplace protection factor (SWPF) testing

On Days 1, 3, and 5, at different times of the day, reuse subjects performed a SWPF test following the test requirements from Annex C of CSA Z1610-11(R16) (Canadian Standards Association [CSA] 2016). (One test subject performed an additional SWPF on Day 4 with a replacement respirator, which had been issued when a head strap broke on the original one.) Within the SWPF test chamber, sodium chloride aerosol generators (TSI Model 8026, TSI. Inc., Shoreview, MN) were used to maintain a steady uniform concentration throughout the space. The concentration inside and outside the respirator were measured simultaneously, by use of a dual channel, water-based, condensation particle counter (wearable respirator protection assessment system, TSI Inc.). The test was performed without doffing the respirator, and the test subject wore an ensemble similar to that of health care workers that currently wear FFRs, which was a disposable face shield, the same safety glasses as used during the daily tasks, full protective gown, and nitrile gloves. This test was performed every day for the control subject.

The total duration of the activity routine was 31 min, consisting of a sequence of 10 one-min activities, repeated 3 times, and a 1-min rest period at the end of the routine. The activities used here included those that first responders, the military and/or health care providers could perform in a workplace setting which could potentially have a negative impact on the protection performance of the respirator, and might also result in dislodgement due to integration problems from wearing safety glasses and a face shield. Head and body motions to increase the subject's work rate, and cause potential strain on the respirator, were also included in the activity routine. As the subjects themselves were not first responders, military or health care workers, general, relevant typical activities were chosen that the subjects could perform without the need for special job-related training. Such activities included lunging, bending over, small jump in place, crowd control gestures, squat and examine and check for vitals on a manikin, facial movements, jog on the spot, turn head side to side, and nod head up and down.

### General respirator protection factor (GRPF) testing

At the beginning of the trial, and at the end of each day, a general respirator protection factor (GRPF) test was performed on all subjects to assess whether the respirator was still providing adequate protection and to evaluate any degradation in protection performance over the day of wear. The same seven activities that were used for the QNFT were used for this test, composed of seven activities of different head and face motions, with each activity 20 sec in duration. Similar to the SWPF test, the total inward aerosol leakage was measured (i.e., leakage of particulates through the respirator face seal and filter), using the same salt aerosol concentration and size distribution. The subjects wore their safety glasses during the test. The GRPF test

**Table 1.** Wear matrix for the study. Subjects 3 and 6 were issued a second, replacement FFR on Day 4 and Day 3, respectively, due to strap failure.

| | Subject 1 | | Subject 2 | | Subject 3 (FFR1) | | Subject 4 | | Subject 5 | | Subject 6 (FFR1) | | Subject 7 | | Subject 3 (FFR2) | | Subject 6 (FFR2) | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Total wear time (hr) | No. of wears per day | Total wear time (hr) | No. of wears per day | Total wear time (rh) | No. of wears per day | Total wear time (hr) | No. of wears per day | Total wear time (hr) | No. of wears per day | Total wear time (hr) | No. of wears per day | Total wear time (hr) | No. of wears per day | Total wear time (hr) | No. of wears per day | Total wear time (hr) | No. of wears per day |
| QNFT and initial GRPF | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | | | | |
| Day 1 | 5.75 | 3 | 5.75 | 3 | 5.25 | 3 | 5.75 | 3 | 5.75 | 3 | 5.25 | 3 | 5.75 | 3 | | | | |
| Day 2 | 6.25 | 4 | 6.25 | 4 | 4.75 | 3 | 4.75 | 3 | 6.25 | 4 | 4.75 | 3 | 6.25 | 4 | | | | |
| Day 3 | 6.25 | 4 | 6.25 | 4 | 6.25 | 4 | 6.25 | 4 | 6.25 | 4 | 3 | 2 | 6.25 | 4 | | | 3.25 | 2 |
| Day 4 | 6.25 | 4 | 6.25 | 4 | | | 6.25 | 4 | 6.25 | 4 | | | 6.25 | 4 | 6.25 | 4 | 6.25 | 4 |
| Day 5 | 4.75 | 3 | 4.75 | 3 | | | 6.25 | 4 | 4.75 | 3 | | | 4.75 | 3 | 6.25 | 4 | 6.25 | 4 |
| Total | 30.25 | 19 | 30.25 | 19 | 17.25 | 11 | 30.25 | 19 | 30.25 | 19 | 14 | 9 | 30.25 | 19 | 12.5 | 8 | 15.75 | 10 |

**Table 2.** Summary of protection results. Subjects 3 and 6 were issued a second, replacement FFR on Day 4 and Day 3, respectively, due to strap failure.

| Subject 1 | | | Subject 2 | | | Subject 3 | | | Subject 4 | | | Subject 5 | | | Subject 6 | | | Subject 7 | | | Control | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Day # | GRPF (# wears) | SWPF (# wears) | Day # | GRPF (# wears) | SWPF (# wears) | Day # | GRPF (# wears) | SWPF (# wears) | Day # | GRPF (# wears) | SWPF (# wears) | Day # | GRPF (# wears) | SWPF (# wears) | Day # | GRPF (# wears) | SWPF (# wears) | Day # | GRPF (# wears) | SWPF (# wears) | Day # | GRPF (# wears) | SWPF (# wears) |
| Initial GRPF | 115 (1) | | Initial GRPF | 241 (1) | – | Initial GRPF | 108 (1) | – | Initial GRPF | 195 (1) | – | Initial GRPF | 100 (1) | – | Initial GRPF | 427 (1) | – | Initial GRPF | 176 (1) | – | Initial GRPF | 173 (1) | – |
| Day 1 | 166 (4) | 83 (2) | Day 1 | 152 (4) | 38 (2) | Day 1 | 77 (4) | 63 (2) | Day 1 | 83 (4) | 32 (2) | Day 1 | 52 (4) | 21 (2) | Day 1 | 101 (4) | 83 (3) | Day 1 | 48 (3) | 20 (1) | Day 1 | 70 (1) | 57 (1) |
| Day 2 | 65 (8) | – | Day 2 | 40 (8) | – | Day 2 | 41 (7) | – | Day 2 | 99 (8) | – | Day 2 | 89 (8) | – | Day 2 | 161 (7) | – | Day 2 | 87 (8) | – | Day 2 | 13 (1) | 16 (1) |
| Day 3 | 67 (12) | 61 (9) | Day 3 | 127 (12) | 62 (9) | Day 3 | 75 (11) | 45 (9) | Day 3 | 101 (11) | 46 (9) | Day 3 | 100 (12) | 35 (9) | Day 3 | 169 (2) | 48 (9) | Day 3 | 135 (12) | 52 (9) | Day 3 | 45 (1) | 37 (1) |
| Day 4 | 90 (16) | – | Day 4 | 72 (16) | – | Day 4 | 60 (4) | – | Day 4 | 59 (15) | – | Day 4 | 77 (16) | – | Day 4 | 140 (6) | 84 (6) | Day 4 | 58 (16) | – | Day 4 | 101 (1) | 56 (1) |
| Day 5 | 80 (19) | 54 (16) | Day 5 | 143 (19) | 51 (16) | Day 5 | 42 (8) | 51 (6) | Day 5 | 53 (19) | 26 (17) | Day 5 | 33 (19) | 10 (17) | Day 5 | 158 (10) | 61 (10) | Day 5 | 89 (19) | 47 (17) | Day 5 | 70 (1) | 61 (1) |

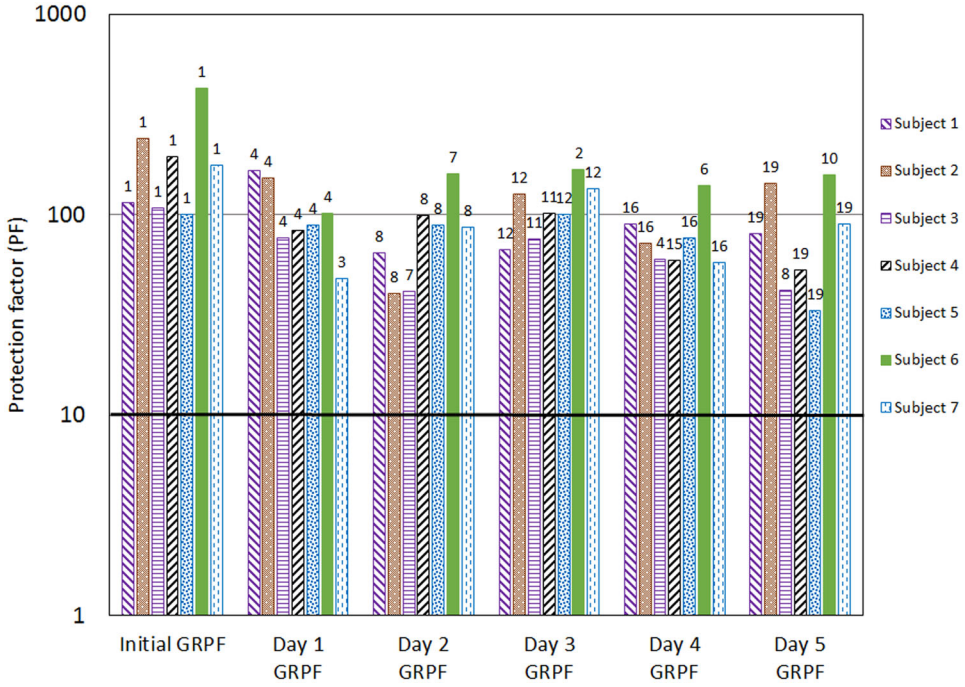


**Figure 1.** Results of daily measurements of GRPF for each reuse subject. The values above the bars are the total number of FFR wears at the time of the measurement. Subjects 3 and 6 were issued a second, replacement FFR on Day 4 and Day 3, respectively, due to strap failure.

performed at the beginning of the trial series is referred to as the initial GRPF test.

### *Data analysis*

Linear curve fitting was used to assess the strength of correlation between GRPF and SWPF for the test subjects and the control. Statistical paired t-tests for means (alpha = 0.05) were performed to assess: (a) whether the instantaneous PFs observed over the entire SWPF activity routine were significantly different at different wears or on different test days, for selected test subjects; and (b) whether the initial GRPF results were statistically different to the GRPF results after 18–19 wears on Day 5. An analysis of variance (ANOVA) was performed on the SWPF results organized into four groups of wear (1, 4–6, 9–10, 17), from all eight subjects, to assess whether the protection provided by the respirator degraded over the 5 days of use.

## Results

### *Wear and reuse matrix*

Table 1 shows the wear and reuse matrix achieved with the seven reuse subjects, where each wear consists of a single donning/doffing sequence with various activities performed while wearing, generally lasting on the order of 1–2 hr. For five of seven of the reuse subjects, a single FFR was worn through the entire study. For Subjects 3 and 6, a strap on the FFR broke partway through the test series, and each continued with a second, replacement FFR.

### *GRPF and SWPF*

Table 2 summarizes all of the protection results obtained from GRPF and SWPF testing for all eight subjects.

Figures 1 and 2 illustrate the protection results for the reuse subjects obtained from the GRPF testing (completed at the start of the reuse trial and at the end of each day). Recall that the GRPF results measure total inward leakage whereas the QNFT FF test, which was completed in the process of issuing a respirator to the test subjects, measures only leakage at the face seal. The initial GRPF and the end-of-day GRPF results ranged, respectively, from 100–426 and 13–169.

There were no instances amongst the subjects where the GRPF was observed to decrease sequentially in value as a function of the number of reuses completed over the entire 5-day trial. Otherwise, on a day-to-day basis, as the number of reuses increased, the GRPF appeared variable by either increasing or decreasing relative to the day prior. It was apparent however, that after 18–19 wears on Day 5, the GRPF for all test subjects was less than the initial GRPF measured at the time that the FFRs were

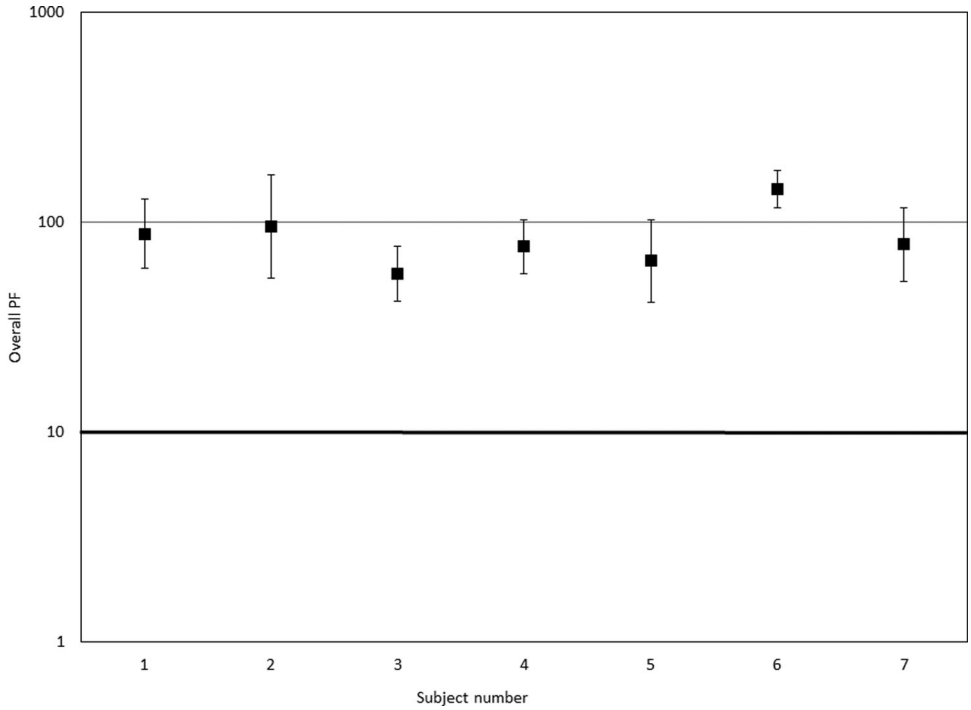


**Figure 2.** Results of daily measurements of GRPF expressed as geometric mean and standard deviation for each reuse subject.

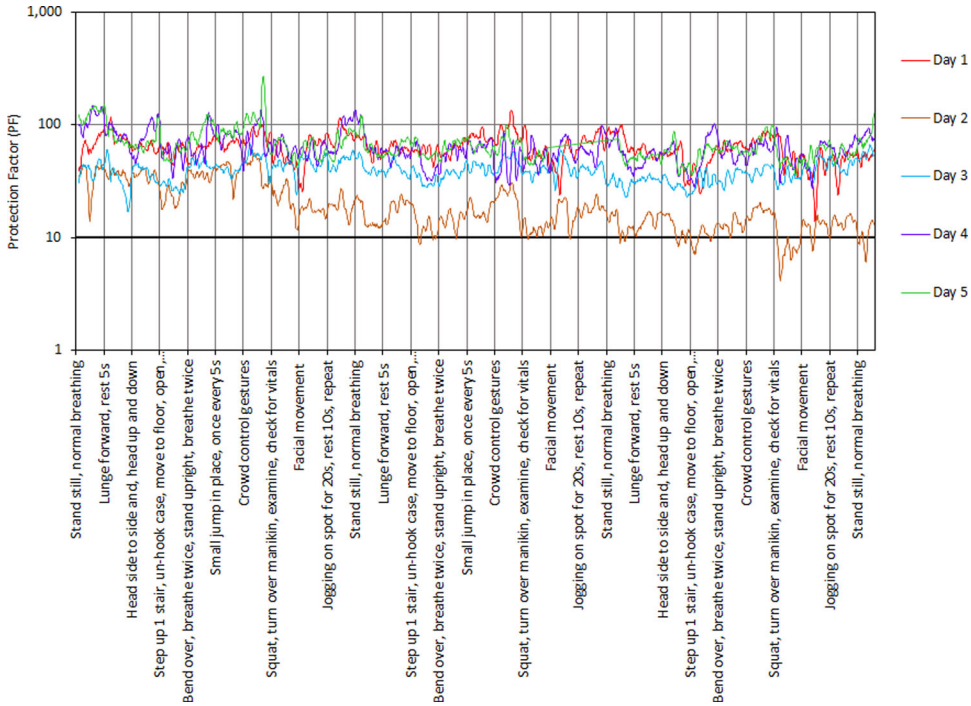


**Figure 3.** SWPF results for control subject. Single wear for each test.

quantitatively fitted to the subjects as confirmed by a Student's t-test single tail (alpha = 0.05).

The SWPF values for all the test subjects ranged from 10–84. For the SWPF of the control subject (Figure 3), who wore 5 FFRs for a single use each, 4 of the 5 instantaneous SWPF curves showed a PF of 30 or above most of the time, with overall SWPF values of 57, 37, 56, and 61. One of the five yielded notably worse protection (Day 2, SWPF 16) that had dropped down to a PF of 10 by the end of the routine. A statistical paired t-test for means (alpha = 0.05) was performed by comparing the instantaneous PFs for Day 2, at the same time interval and over the entire duration of the activity routine, to each of the other days. The test confirmed that the instantaneous SWPF curve for Day 2 was significantly different when compared to each of the other

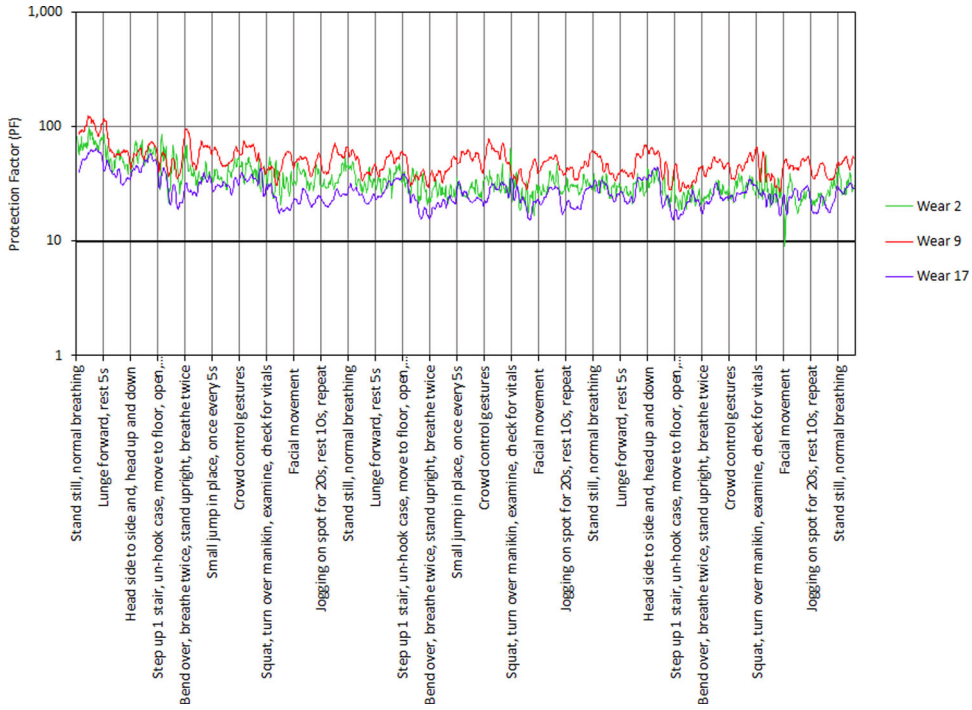


**Figure 4.** SWPF results for Subject 4.

days. Overall, SWPF values achieved by the control were above the APF of 10.

Most subjects performed three SWPF tests, and one whose FFR strap broke performed four. Some subjects obtained quite reproducible results for multiple wears as evident in the instantaneous SWPF results for Subjects 4 and 6 (Figures 4 and 5, respectively), and some less so as observed from Subject 5 (Figure 6). For some subjects, small seal breaks resulted in short drops in protection of a few seconds below PF 10, as evident in in the instantaneous SWPF results for Subject 2 (Figure 7), but no subject exhibited sustained protection below that value. Subject 2 (Figure 7) had particular difficulties turning the mannequin onto its side (Activity 8) during the first SWPF test, thus causing extra strain on the respirator, and as a consequence short drops in protection below a PF of 10 were observed. For the next SWPF trial, the subject manipulated the mannequin in a manner causing less physical exertion, and as a result, the drops in protection were less extreme during this activity. Subject 5 obtained an overall SWPF value of 10 after 17 wears (Table 2), and the instantaneous PFs measured clearly reflect this as evidenced by the green curve in Figure 6, but the remaining SWPF values for all subjects were comfortably higher than the APF of 10.

### *Other observations related to wear and reuse*

Clearly, the strap failure for two of the subjects was worthy of note. However, this occurred during donning and/or doffing; no straps failed during wear. Most subjects said they felt the elasticity of the straps had degraded over the course of the week.

Other observations made by Subjects 1–7 are summarized as follows, where they compared their experience at the beginning and end of the week. Not unexpectedly, extended and repeated use tended to cause discomfort and pain from chafing or restriction of motion. Presence, absence, and location of hair were noted as factors in maintaining or losing strap placement or causing discomfort. Four of seven found that the odor from the respirator grew significantly worse, including those two who changed respirators due to strap breakage. One subject observed slight delamination of the inner layer of the respirator on the last day.

## Discussion

This study investigated the impact that extreme use conditions had on a surgical style N95 FFR. Devices of this type are one of the main sources of respiratory protection in health care settings involving the care of infected persons and medically generated aerosol procedures and surgery. Their use also extends to first responders including paramedics, firefighters, and police.

A single FFR was worn for up to 5 days with up to four reuses each day, with a variety of additional relevant PPE. Over the course of these reuses a substantial full workday activity regime was undertaken that

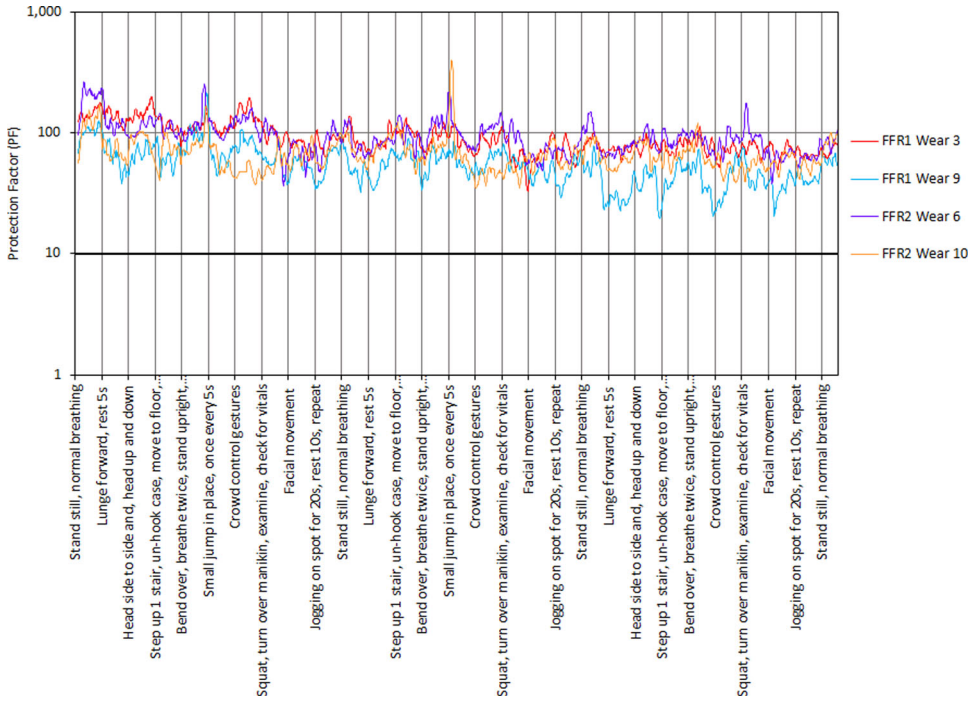


**Figure 5.** SWPF results for Subject 6. Two FFRs were tested: FFR1 and a second, replacement respirator FFR2, due to strap failure.

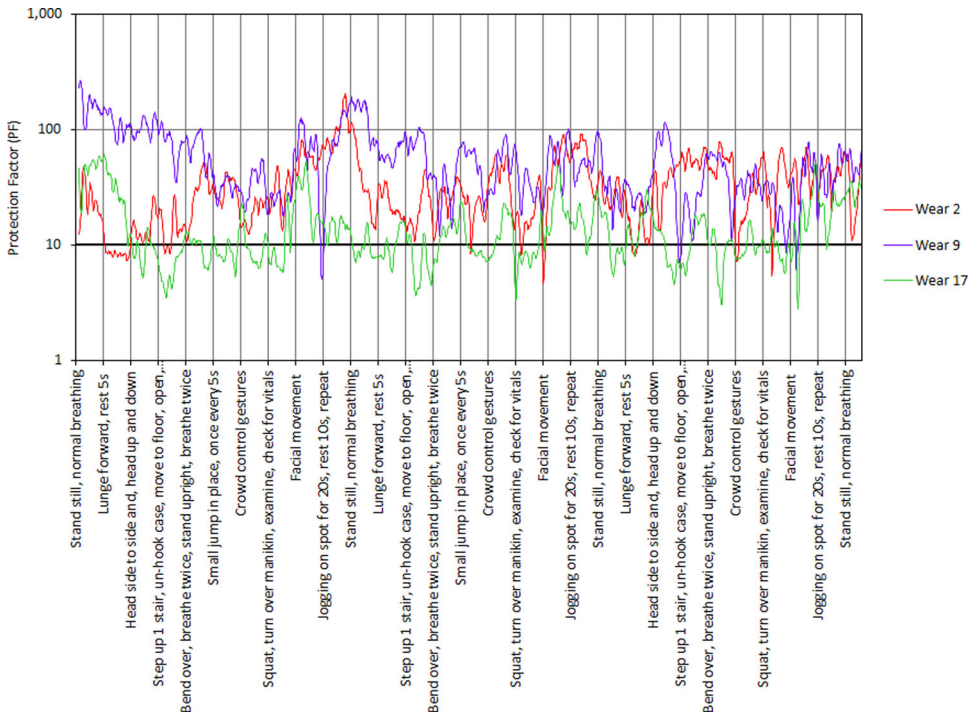


**Figure 6.** SWPF results for Subject 5.

had the effect of straining the FFR with changes in breathing rate, perspiration levels, and facial and body movement, as well as potential interferences between the additional eyewear/headgear and the FFR. Subjecting a FFR device designed for single use to such extreme usage is outside the norm and the intent here is not to encourage that it become so. However, in exceptional circumstances when coping with a pandemic where shortages of PPE have been identified, it becomes extremely important to understand both the limitations of PPE as well as its capabilities when employed in a manner not envisaged in its original design.

The approved FFR under evaluation is currently in use by law enforcement in Canada for the pandemic response. It had been stockpiled for a number of years

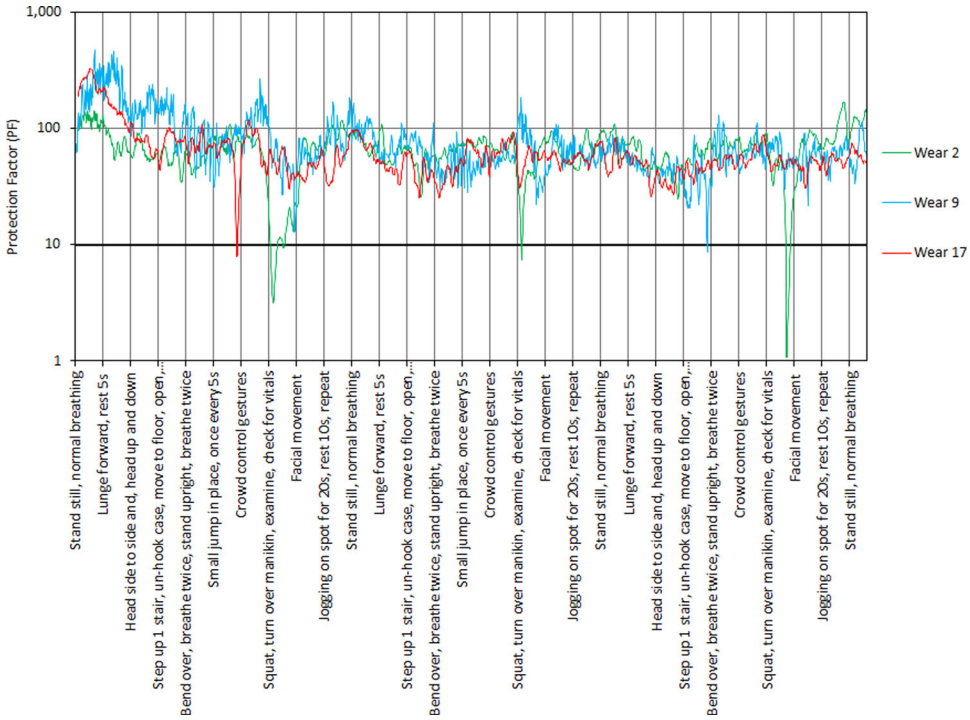


**Figure 7.** SWPF results for Subject 2.

under controlled conditions, had no expiry date provided by the manufacturer at time of sale (although subsequently the manufacturer released a letter indicating a 5-year expiry date [3M, 2020]), and this model has been discontinued (replaced by a slightly improved version called the 3M Aura 1870+). Given this, the results obtained are potentially on the conservative side compared with newer items.

### *Study limitations*

The limitations of the study are given as follows. It evaluated the protection performance of a single type of N95 filtering facepiece respirator, a surgical style offered in a single size. Thus, the study is not generalizable to all styles of filtering facepiece respirators. That being said, this design is expected to be a common type of N95 FFR used by HCW and other first responders and the results are therefore an indication of the relationship between reuses, extended wear and protection performance. The study evaluated seven test subjects as part of the wear/reuse cycle (and one control subject who wore a new respirator each day). More subjects might have shown that some individuals strained the respirator fit in different ways, particularly given that there were more smaller face sizes tested than larger. Although this study focused on N95 FFR use by HCW, general activities performed by other frontline user groups (e.g., military, police, and paramedics) responding to the SARS-CoV-2 pandemic were included, and therefore the generalized activity regimen may not fully represent performance in use for any specific user community.

### *GRPF and its correlation with SWPF*

It was noted that (including the data for the two replacements FFRs) after 18–19 wearer use sessions on Day 5, the GRPF for all subjects was less than the initial GRPF measured at the time that the FFRs were quantitatively fitted to the subjects (Student's t-test single tail alpha 0.05). However, it remains unclear how much of this degradation is due to reduction in quality of fit, and how much is due to a reduction in the care that was taken to fit the respirator as time progressed (as was concluded by Vuma et al. (2019)); this latter factor is difficult to control for in a human study. It is likely that some degradation of quality of fit, as a result of reduced care in donning taken by the wearer, would occur in reality, and that without some form of quantitative check of donning quality on a regular basis, this effect could reduce the protection provided to a wearer over a long period of time by any FFR style, whether new or used.

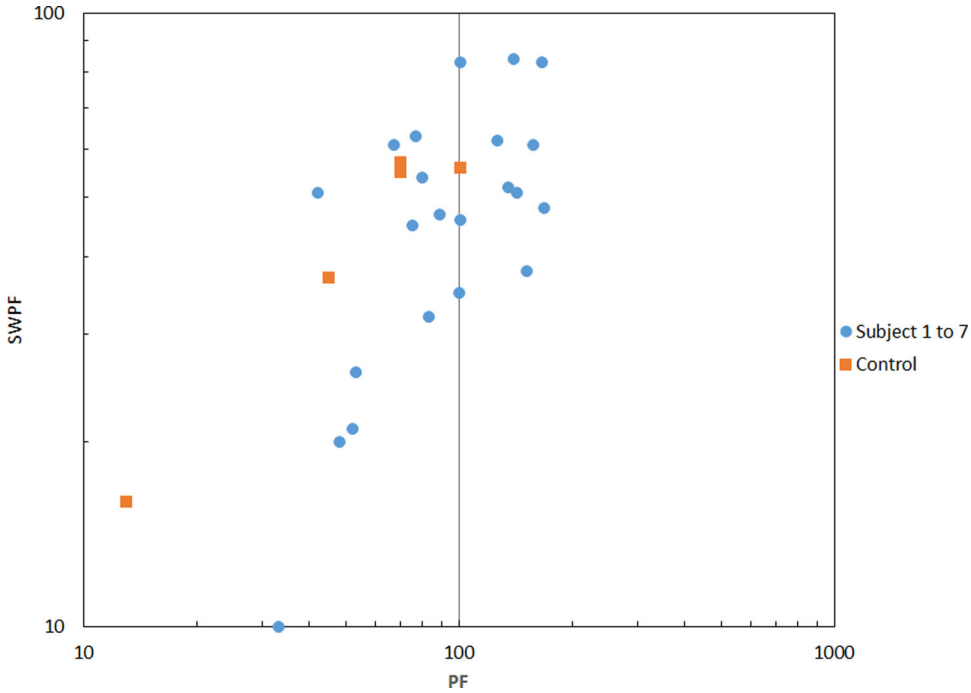


**Figure 8.** Correlation between SWPF and GRPF where both were obtained on the same respirator on the same day. For the control, the values were obtained during the same wear. Linear regression "least squares" analysis calculated R2 values for the control subject and the group of test subjects of 0.80 and 0.34, respectively.

The correlation obtained between GRPF and SWPF is illustrated in Figure 8. Not surprisingly, the values for the SWPF are lower than those measured for the GRPF, given the difference in duration of the test and degree of movement. It can be stated that no subject in this study obtained a SWPF or GRPF value less than 10 (the APF) for up to 19 uses over 5 days, which involved a total of up to 30.25 hr of workplace activity wearing the same FFR.

It is also worth noting that the GRPF results are a reasonable predictor of the SWPF results even under these extreme use conditions (Figure 8). Since the GRPF and the SWPF were always obtained for different wears for the reuse test subjects, it is to be expected that the correlation between the two values should be present but not strong, given the expected variability in donning and effects of wear on dislodging of respirator. Conversely, as has been previously observed (Sietsema and Brosseau 2018), the correlation can be expected to be stronger for the control subject, for whom the data were obtained for the same wear. Linear regression analysis using the "least squares" method suggested a stronger correlation between GRPF and SWPF for the control subject compared with the group of test subjects, with $R^2$ values of 0.80 and 0.34, respectively. As one example, the drop on Day 2 in the GRPF for the control subject, who wore a new FFR for a single use each day (Table 2), can be directly correlated to an event that occurred when the control was completing an activity 8 min into the SWPF test (Figure 3). The reduction in protection was probably due to a shift in the FFR on the control's face resulting in a breach of the face seal. After this occurred, the protection performance did not recover for the remainder of the FFR use.

Figure 9 provides the geometric mean and standard deviation of the SWPF results over the 5 days (organized into four groups by number of wears: 1, 4–6, 9–10, 17), as well as the combined values (n = 27) from the eight subjects, and these results are given in Table 3. The upper and lower bounds at two geometric standard deviations from the geometric mean as given in Table 3 encompass 95% of a log-normal distribution, demonstrating that for the most part, wearers would comfortably achieve an APF of 10 until perhaps the uses corresponding to the final day of testing. ANOVA, performed on the log of the SWPF results between the four groups of wear, showed that the protection results provided by the respirator for different wear numbers were not significantly different, i.e., there was no significant degradation in respirator SWPF over the 5 days of use.

### *Extended wear and reuse*

The SWPF results for the control subject indicate that while donning and performance are likely to be relatively reproducible, there will be occasional donnings

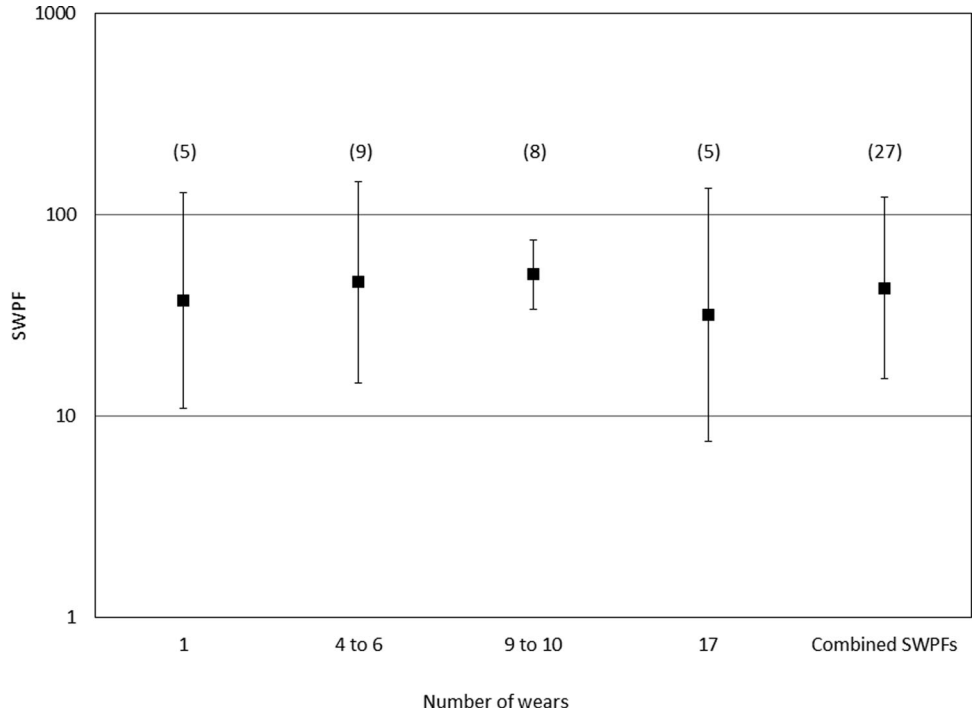


**Figure 9.** The geometric mean SWPF value vs. number of wears, as well as the combined SWPF values from the eight subjects. The value in parentheses indicates the number of tests for each value, and the error bars represent 2 times the geometric standard deviation (as 95% of a log-normal distribution lies between the two error bars).

**Table 3.** Distribution of SWPF results vs. number of wears.

| # wears | # SWPF tests | Geometric mean SWPF value | Two times the geometric standard deviation | Upper boundary SWPF value | Lower boundary SWPF value |
|---|---|---|---|---|---|
| 1 | 5 | 37 | 3.2 | 119 | 11 |
| 4 to 6 | 9 | 46 | 3.2 | 146 | 15 |
| 9 to 10 | 8 | 50 | 1.5 | 75 | 34 |
| 17 | 5 | 32 | 4.2 | 134 | 8 |
| Combined | 27 | 43 | 2.8 | 121 | 15 |

whose resulting protection performance is outside the norm. The results obtained for the subjects who performed wear/reuse tests did not give rise to any significant behavior that was unlike that of the control subject that performed multiple single wears, yielding many elements of reproducible or "typical" protection behavior for the given wearer, and occasional outliers.

The study suggests that for this particular N95 FFR model, it continues to deliver appropriate protection performance above or equal to the APF of 10 for up to 19 wears for the majority of wearers. There is some difference in the protection obtained each time the item is worn, but there is no clear evidence to suggest that this is due to anything other than variations in the quality of the donning or incidental or variable changes in the strain on the respirator due to activities. While it is clear that the strap durability is insufficient to guarantee continued performance indefinitely, replacement of the item at the time of donning or doffing when the strap seems most likely to break is easy to perform and would have no impact on workplace protection. Given the observations by the subjects that the straps did not provide as much tension by the end of the 5 days of wear, strap degradation will eventually affect workplace protection outcomes, although with the exception of breakage, it did not appear to do so in a systematic way over the extended wear and reuse period of these tests (up to 5 days of wear and 19 uses), for this model of respirator.

Given that many HCWs work 12-hr shifts rather than 8-hr shifts, resulting in cumulative wear longer than the 6.25 hr maximum per day in this study, an area for future study would involve test subjects simulating the wear of the respirator for 12-hr shifts with 3–4 shifts in a week.

### *Moisture saturation*

It is noteworthy to mention that the total amount of moisture that the inside of the FFRs were exposed to in this study is far more than for a single use. Clearly,

despite the moisture exposure, the FFRs continued to perform as expected regarding filtration and fit. We observed no major degradation in the physical integrity of the FFR due the extreme moisture exposure, although one subject observed slight delamination on the last day, which did not affect protective performance. However, the increase in odor over the course of the study may have been due to growth of microorganisms with a concomitant reduction of sterility of the item. Storing the items in paper bags between uses, intended in a health care setting to reduce exposure to outside contamination, may well have resulted in an insufficient rate of drying overnight, given how moisture-saturated the items were by end-of-day. For organizations that allow a long time between uses, for example one week before the next day of use (which permits complete drying of the respirator and will kill many organisms), this consideration would likely be less important. In the context of sterilization prior to reuse, this issue would be addressed as part of the sterilization process.

## Conclusions

Under an extreme usage scenario, a single surgical style N95 filtering facepiece respirator continued to deliver appropriate protection performance above or equal to the APF of 10 for up to 19 wears/uses, over a five-day period. There is no evidence to suggest that the observed variation in workplace protection performance is due to anything other than random effects of donning and wear. The results from this study provide evidence that with a certain N95 FFR it is possible to maintain an APF greater than 10 under extreme usage conditions provided an individual is properly trained in the use of, and expertly fitted in, the respirator. While it is clear that the strap durability is insufficient to guarantee continued performance for this many uses, replacement of the item at the time of donning or doffing when the strap seems most likely to break is easy to perform and would have no impact on workplace protection. Other factors such as hygiene are likely to place limits on reuse. The limitations of the study suggest that this approach should be used as guidance to verify the protection performance of other styles and models of N95 FFRs under anticipated usage conditions. It should not be taken for granted that all N95 FFRs will perform as was observed in this study.

## Acknowledgments

We would like to thank the Royal Canadian Mounted Police for their kind support in donating N95 respirators and lending some of their equipment for the study, the test subjects from DRDC Suffield Research Centre for their time and support of the study, and Canadian Forces Base Suffield G4 Stores, for the tent structure used for the SWPF test chamber. This study was funded by Defence Research and Development Canada.

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1. ORIGINATOR (Name and address of the organization preparing the document. A DRDC Centre sponsoring a contractor's report, or tasking agency, is entered in Section 8.)

Journal of Occupational and Environmental Hygiene
Taylor & Francis Group
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The impact of extreme reuse and extended wear conditions on protection provided by a surgical-style N95 filtering facepiece respirator

4. AUTHORS (Last name, followed by initials – ranks, titles, etc., not to be used)

Bodurtha, P.; Dickson, E. F.; Duncan, S.; Bourgeois, C.; Jensen, C.; Naqvi. S.

| 5. DATE OF PUBLICATION (Month and year of publication of document.) | 6a. NO. OF PAGES (Total pages, including Annexes, excluding DCD, covering and verso pages.) | 6b. NO. OF REFS (Total references cited.) |
|---|---|---|
| November 2020 | 15 | 35 |

7. DOCUMENT CATEGORY (e.g., Scientific Report, Contract Report, Scientific Letter.)

External Literature (P)

8. SPONSORING CENTRE (The name and address of the department project office or laboratory sponsoring the research and development.)

DRDC – Suffield Research Centre
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| 9a. PROJECT OR GRANT NO. (If appropriate, the applicable research and development project or grant number under which the document was written. Please specify whether project or grant.) | 9b. CONTRACT NO. (If appropriate, the applicable number under which the document was written.) |
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12. KEYWORDS, DESCRIPTORS or IDENTIFIERS (Use semi-colon as a delimiter.)

condensation particle counter; quantitative respirator fit testing; simulated workplace protection factor; pandemic

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Most respirators employed in health care settings, and often in first responder and industrial settings, are intended for single-use; the user dons the respirator, performs a work activity, and then doffs and discards the respirator. However in the current COVID-19 pandemic, in the presence of persistent shortages of personal protective equipment, extended use and reuse are routinely contemplated by many health care organizations. Further, there is considerable current effort to understand the effect of sterilization on the possibility of reuse, and some investigations of performance have been conducted. While the ability of a filtering facepiece respirator to continue to provide effective protection after repeated sanitization cycles is a critical component of implementing respirator reuse, of equal importance is an understanding of the impact that reusing the filtering facepiece respirator multiple times in a day while performing work tasks, and even extending the wear of the respirator over multiple days, has on the workplace protective performance. In this study, we subjected a stockpiled quantitatively fitted surgical style N95 filtering facepiece respirator device to extreme reuse and extended wear conditions (up to 19 uses over a duration of five days), and measured its protective performance at regular intervals, including simulated workplace protection factor measurements using total inward leakage. With this respirator, it was shown to be possible to maintain protection corresponding to an assigned protection factor greater than 10 under extreme usage conditions provided an individual is properly trained in the use of, and expertly fitted in, the respirator. Other factors such as hygiene and strap breakage are likely to place limits on reuse.