

Face Fit testing of FFP3 respirators: the impact of sampling port location

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The Approved Code of Practice to the Control of Substances Hazardous to Health (COSHH) Regulations 2002 (as amended) states that, if respiratory protective equipment (RPE) is required, any tight-fitting respirators used should be face-fit tested using a suitable method, by a competent person.

Suitable methods for fit testing of tight-fitting RPE check that a specific model and size of respirator seals adequately to the wearer's face with no gaps through which airborne hazardous substances can enter.

The study objectives were to determine if there was a difference in fit factors and in the within-wearer variability between the flush (flush with the inside surface of the respirator) and extended (extended into the wearer's breathing zone) ports used in fit testing, for filtering facepiece class 3 (FFP3) respirators.

Fit testing research was carried out with human volunteers on a variety of FFP3 respirators using both flush and extended ports.

The results provide an evidence base for why an extended port should be used in fit testing.

The study provides evidence that the repeatability of the fit test did not differ by port location and that effective fit testing can be carried out using an extended port.

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Face Fit testing of FFP3 respirators: the impact of sampling port location

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Research ethics statement

Ethical approval for this study was given by the University of Sheffield Medical School Research Ethics Committee [under HSL33, approved 20.10.2023].

Key Messages

Filtering facepiece (FFP) disposable respirators are widely used in a variety of industries within Great Britain to protect workers from inhalable, airborne particulate hazardous substances, after all other measures in the Control of Substances Hazardous to Health Regulations 2002 (COSHH) (as amended) hierarchy of control have been exhausted. FFP respirators rely on a tight seal to the wearer's face. Any leakage into the respirator from not having a tight seal to the face may have serious ill health effects; the specific health effect would depend on the hazardous substance the worker is being protected from. A face fit test (often shortened to just 'fit test') is a method of determining whether a specific make, model and size of respirator fits an individual, providing a tight fit (seal) to the face. Fit testing methods are described in Health and Safety Executive (HSE) document INDG 479 'Guidance on respiratory protective equipment (RPE) fit testing'.

There are multiple fit testing methods. One common method is an "ambient particle counting method". When using this method, an air sample is taken from inside the respirator using a "sampling port". This is a metal probe inserted into the respirator material. It is preferred by HSE to extend the sampling port inside the respirator (the "extended port"), rather than flush with the surface of the inside of the respirator (the "flush port"), to ensure that the sample being taken is representative of air being breathed in by the wearer i.e. it is taken from within the breathing zone inside the mask. HSE scientists undertook research using FFP3 classification respirators to determine whether an acceptable fit test can be carried out using a flush port as opposed to the extended port.

The study found statistically significant evidence that the fit test result depended on the location of the sample port (i.e., extended or flush); the flush port gave fit factor results that were, on average, 16 to 17% higher than the extended port. This difference is small enough that it is unlikely to affect the outcome of a fit test, unless the fit test result is expected to be close to the pass/fail value – for example, an individual who passes with a result of 115 using the flush port, may have failed with a result of 99 using the extended port. The research has identified that using the flush port in this situation would result in a false pass, and provides an evidence base for why an extended port should be used.

There was no statistical evidence that the repeatability (within-wearer variability) of the fit test result differed by port location.

The research provides evidence that effective fit testing can be carried out using an extended port.

FFP3 classification respirators were used to conduct this study and while no FFP1 or FFP2 respirators were tested, they are similar enough in design to FFP3 respirators that the same results might be expected to apply.

Executive Summary

Overview

Filtering facepiece (FFP) disposable respirators are a form of respiratory protective equipment (RPE) widely used in a variety of industries within Great Britain (GB) and throughout the world. FFPs are used as a means to protect the wearer from exposure to inhalable, airborne hazardous dusts after all other measures in the Control of Substances Hazardous to Health Regulations 2002 (COSHH) (as amended) hierarchy of control have been exhausted. There are three types of FFP respirator, which are classified as FFP1, FFP2 and FFP3. FFP1s have the least efficient filters, whilst FFP3s have the most efficient filters. FFPs rely on a tight seal to the wearer's face and, therefore, must have a good fit on the individual wearer. Individual faces are all different shapes and sizes, and no single size/model of respirator will fit every individual face. A face fit test (often shortened to just 'fit test') is a method of determining whether a specific make, model and size of respirator is capable of fitting an individual person and must be carried out during the RPE selection process to determine the suitability of the RPE for the wearer.

The fit testing methods used in GB are described in Health and Safety Executive (HSE) document INDG 479 'Guidance on respiratory protective equipment (RPE) fit testing'. One common method uses an ambient particle counting instrument, which measures the particles inside and outside of the respirator. The ratio of the particles outside, to inside of the respirator, is described as a 'fit factor', and is a measure of the quality of the fit of the respirator. The method is also quantitative with the advantage that results from different fit tests can be compared. A higher 'fit factor' indicates a better fit (provided that the fit test is carried out correctly). According to the INDG 479, for the fit of FFP3 respirators to be considered adequate, the fit factor must be higher than 100 while the wearer performs several exercises.

HSE guidance INDG 479 and HSG 53 'Respiratory protective equipment at work – a practical guide' gives guidance that a fit test should be repeated whenever there is a change to the RPE type, size, model or material, or whenever there is a change to the circumstances of the wearer that could alter the fit of the RPE. Examples include a change in weight, dental work, facial changes around the face seal area, facial piercings and any changes to other head-worn personal protective equipment.

In order to take an air sample from inside the respirator, a port must be fitted to the respirator. INDG 479 recommends that the in-respirator sample is taken at a point close to the wearer's face and approximately mid-way between the nose and mouth, described in INDG 479 as the "breathing zone". Sampling from the breathing zone can be achieved by extending the port inside the respirator. The breathing zone is the best location for taking the in-respirator air sample because any leakage coming around the face seal of the respirator must pass through the breathing zone before the wearer can breathe it in. An in-

respirator air sample taken from the breathing zone should therefore be representative of what the wearer is inhaling.

While it is preferred by HSE to extend the sampling port inside the respirator, to sample from the wearer's breathing zone (described in this report as the "extended port"), in reality, many fit testers do not extend this port. Instead, the sample is typically taken from a location flush with the inside surface of the respirator (the "flush port"). In relation to the location of the port, depending on the leak location and potential for incomplete mixing with the air drawn in through the filtering material, the flush and extended ports may give different measurements, and hence a different fit test result, even if the actual fit of the respirator is the same.

In the workplace, a wearer will have a designated make, model and size of respirator, as determined by a fit test. Every time a wearer puts this respirator on, they will do so in a slightly different way, for example, they may adjust the head straps differently. This means that the fit of the respirator is not always the same from each time of wearing to the next, resulting in a better or a worse fit. Carrying out an effective pre-use wearer seal check (also referred to as a "fit check") can help the wearer to identify serious problems with the fit but will not completely eliminate the variability. The variability in the fit of the respirator for individuals leads to variability in fit factors and fit test results. This is the 'within-wearer variability' in fit and represents the repeatability of the test method on the same individual. It is, therefore, important to determine if the repeatability of the fit test result is impacted by the port location.

This aim of research was to determine if a fit test conducted using the flush port, as opposed to the extended port, is acceptable.

Objectives

The study objectives were:

1. to determine if there is a difference in fit factors between the flush and extended ports for FFP3 respirators.
2. to determine if there is a difference in the within-wearer variability between the flush and extended ports for FFP3 respirators.

Methods

Twenty volunteers undertook three fit tests on each of four different models of FFP3 respirator, giving 12 fit tests per volunteer and 240 fit tests in total. The four FFP3 respirator models chosen for the study were anonymised and named Model A to D.

Each fit test was carried out with two of the same models of calibrated ambient particle counting devices (TSI PortaCount), one measuring from a flush port and one measuring from an extended port, such that they were sampling simultaneously. The test order for

each volunteer was randomised. The fit tests were carried out according to the protocol and fit testing exercises described in INDG 479.

Results

There was a statistically significant difference in the fit test result when the sample port was flush with the inside surface of the respirator (flush port), compared to when it was sampled directly in the breathing zone (extended port). On average, combining all four models of respirators tested, the flush port gave a minimum exercise fit factor (when looking at each of the individual exercises undertaken during the full fit test) that was 17% (95% confidence interval, 95%CI 11-24%) higher and an overall fit factor (taking into account all exercises combined) that was 16% (95%CI 9-22%) higher than the extended port. There was some weak statistical evidence that the difference in overall fit factor depended on respirator model, with estimates ranging from 7% to 26%.

The within-wearer variability was not statistically significantly different when comparing the results from the two sampling ports, except for one respirator model where the variability for the minimum fit factor was statistically significantly lower for the flush port. However, it was found that this result was due to two outlying datapoints. Overall, therefore, there was no evidence that the sampling port location impacted the within-wearer variability and, hence, the repeatability of the test.

Conclusion

This study found that there was a statistically significant difference in the fit test result depending on the location of the port used. On average, the flush port provided results that were, on average, 16 to 17% greater than when using the extended port. This difference is small enough that it is unlikely to affect the outcome of a fit test, unless the fit test result is expected to be close to the pass/fail value of 100 – for example, an individual who passes with a result of 115 using the flush port, may have failed with a result of 99 using the extended port. This research has identified that using the flush port in this situation would result in a false pass.

Statistical analysis of the within-wearer variability for the flush and extended port found no evidence that one method provided better or worse test repeatability than the other.

While FFP1 or FFP2 respirators were not tested in this study, they are similar enough in design to FFP3 respirators that the same results might be expected to apply. The findings in this report cannot be extended to include reusable half-mask and full-face respirators as these are different in design to FFP3s.

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1 Introduction

Respiratory Protective Equipment (RPE) is used as a means to protect the wearer from exposure to respiratory hazards such as hazardous dusts, gases and vapours, after all other measures in the hierarchy of control have been exhausted, directed in the Control of Substances Hazardous to Health Regulations 2002 (COSHH) (as amended) - Approved Code of Practice (HSE, 2013c). RPE is widely used in Great Britain (GB) to protect workers against respiratory hazards (Thompson and Wake, 2007). Many types of RPE are tight-fitting and require a good seal between the respirator and the wearer's face in order to provide adequate protection. Examples of tight fitting RPE include filtering facepiece (FFP), half mask and full facemask respirators. Human faces come in many shapes and sizes; therefore, it is unlikely that any single model of respirator will fit everyone.

As part of the selection process of RPE, face fit testing (often shortened to just 'fit testing') should be carried out to determine that the RPE fits the wearer. COSHH stipulates that tight fitting RPE should be fit tested as part of the selection process. This is similarly stipulated in the ACOPs supporting the Control of Lead at Work Regulations (HSE, 2002), the Control of Asbestos Regulations (HSE, 2013a), the Confined Spaces Regulations (HSE, 2014) and the Ionising Radiations Regulations (HSE, 2017). Fit testing is a means of ensuring that a specific make, model and size of respirator is capable of fitting a specific wearer and is included in HSE's guidance on the use of RPE (HSE, 2013b).

A common method of fit testing in GB is by ambient particle counting. The concentrations of harmless airborne particles inside and outside of a respirator are measured while the respirator is worn, and the ratio of the two concentrations is taken as the "fit factor". The method is also quantitative with the advantage that results from different fit tests can be compared. The fit factor is a measure of how well the respirator fits the wearer, presented as a number. A higher fit factor indicates a better fit. The ambient dust in the air can be used as the test agent, although this may be supplemented with a generated sodium chloride (salt) aerosol. In order to pass the fit test, the fit factor must be higher than the pass level for the type of respirator under test. In GB, HSE has set the pass levels for each type of respirator; 100 for FFPs and half mask respirators, and 2000 for full facemask respirators. A passed fit test demonstrates that the respirator is capable of fitting the wearer, but it does not guarantee that the fit will be good every time the wearer puts the respirator on.

Aside from the fit of the respirator, there are other factors that can affect the results of the fit test. A port is positioned through the respirator to take an air sample measurement from within the respirator. The port location can make a difference to the measured fit factors (Bostock, 1988), and this is reflected in HSE's guidance document INDG 479 (HSE, 2019), which requires the sample to be taken from the breathing zone "...close to the face and approximately mid-way between the nose and mouth" (HSE, 2019). Since air does not fully mix inside the respirator, taking the sample from the breathing zone should give the most

representative sample, as the air that is actually breathed by the wearer must pass through this zone to reach the wearer's mouth or nose. However, these recommendations are not always followed in practice, as the in-respirator sample is frequently taken flush with the inside surface of the respirator.

Respirator fit is known to vary from person to person (between-wearer variation), but anecdotal evidence suggests that the fit of the same respirator may also vary each time it is worn by the same person (within-wearer variation). This within-wearer variation is important since it represents the repeatability of the test method, that is, it is the variation in fit expected when the same wearer fits, removes and then refits the same model and size of the same respirator multiple times. While the location of the sample port may influence the measured fit factor, it is unclear how it might impact the repeatability of the fit test. If a particular sample port location had a substantially larger within-wearer variability, then this could lead to poor repeatability and affect the quality of fit testing.

FFPs are available in three classes within GB and Europe: FFP1, FFP2 and FFP3. The highest class of FFP is the FFP3, with a filtering efficiency of $\geq 99\%$ (CEN, 2009). The higher filtering efficiency of FFP3s means that, in general, particles inside the respirator are more likely to come from leakage around the face seal, rather than penetration through the filtering material. FFP1 and FFP2 respirators have less efficient filtering material than FFP3 respirators, so a higher proportion of the leakage measured inside the respirator will be from penetration through the filtering material, rather than from leakage around the face seal. Since this study focused specifically with leakage around the face seal rather than filter penetration, FFP3s were used.

The aim of the research was to determine if a fit test on FFP3 respirators conducted using the flush port, as opposed to the extended port, is acceptable. To do this, the study objectives were:

1. to determine if there is a difference in the measured fit factors between the flush and extended ports for FFP3 respirators.
2. to determine if there is a difference in the within-wearer variability between the flush and extended ports for FFP3 respirators.

2 Methods

2.1 Models of respirator

Four different models of FFP3 respirator were selected such that a variety of design features were represented in the study. All models had an exhalation valve. The four FFP3 respirator models chosen for the study were anonymised and named:

- model A
- model B
- model C
- model D

2.2 Human volunteers

All work with human volunteers undertaken for this study was ethically cleared by the Sheffield University Ethics Committee under submission HSL11. All volunteers were medically screened and gave informed consent before testing commenced. For their safety, the volunteers' heart rates were monitored using a Garmin Forerunner 305 heart rate monitor. The heart rate withdrawal criterion was:

Max heart rate = $185 - (\text{Age} \times 0.65)$

Both males and females volunteered for the study from HSE's pool of volunteers. Volunteers were not selected based on size or shape of face. Some volunteers were experienced RPE wearers, while others were relatively inexperienced.

HSE statisticians determined that a minimum of 20 volunteers were needed for the study to be statistically viable.

2.3 Order of tests

Each volunteer performed a total of twelve fit tests: three tests on each of the four models of respirator. The order in which volunteers performed the tests was randomised. The twelve tests were spread over four sessions, with each session taking around an hour, and incorporating three fit tests. Volunteers had the opportunity to rest and drink water for a few minutes between tests.

2.4 Porting of respirators

For each fit test, a new respirator was prepared with two disposable metal ports (Figure 1), one on each side of the exhalation valve. A plastic template was made for each model of

respirator so that the sampling ports would be in the same location on each sample of that model. A length of rigid tubing was used to extend from one of the metal ports into the breathing zone of the wearer close to the face and approximately mid-way between the nose and mouth (“extended port”). Ideally the second “flush port” would have been positioned in the centre of the mask so that it was sampling in the same alignment with respect to the breathing zone as the “extended port”, albeit not as close towards the mouth. However the location of the exhalation valve prevents this so the flush port was positioned to one side of the valve, as close to the centre of the respirator as possible, and was not extended, so that the sample was taken from flush with the inside surface of the respirator. For the purposes of this report, the two different ports will be referred to as “extended” and “flush” ports, as referenced above, in order to distinguish between them. Figure 2 shows an example respirator with the sample ports in place.

Figure 1 Disposable metal port. The pieces clamp together on either side of the respirator material (image 1703025_020.JPG)



Figure 2 Example of a respirator with a flush and extended port: the flush port is on the left; the extended port is on the right (image P1000066.JPG)



2.5 Fit testing procedure

Fit testing was carried out using two ambient particle counting devices (both TSI PortaCount Pro+ model 8038), one sampling from the flush port and one from the extended port. Sampling was undertaken from both ports at the same time. A background particle count of at least 3000 particles is recommended in order to reliably measure the fit of FFP3s (HSE, 2019). Since the natural ambient background count in the laboratory was not high enough, it was supplemented with a generated sodium chloride aerosol using a sodium chloride aerosol generator.

Volunteers were given assistance to fit the respirator, where necessary. After carrying out a pre-use wearer seal check (also known as a fit check), they were asked to indicate whether, in their opinion, a good fit had been achieved.

All fit testing was carried out in accordance with HSE's guidance document INDG 479. The INDG 479 fit testing protocol requires the wearer to undertake moderate exercise during the fit test. For this study, volunteers stepped up and down on an aerobic step at a steady pace while performing the following exercises:

- normal breathing
- deep breathing
- moving head side to side
- moving head up and down

- talking out loud
- bending over (no stepping during this exercise)
- normal breathing

The fit factor was calculated for each exercise as follows:

$$FF = \frac{C_o}{C_i}$$

Where,

FF Fit factor

C_o particle concentration outside the respirator

C_i particle concentration inside the respirator

Under the INDG 479 protocol, all seven fit test exercises must return a fit factor ≥ 100 in order for the fit test to pass. The fit factor and ambient particle count for each exercise were recorded for each exercise.

2.6 Data analysis

Two fit factor results from each test were analysed:

1. the harmonic mean of the seven exercise fit factors, known as the overall fit factor, which gives an indication of the overall quality of fit.
2. the lowest of the seven exercise fit factors, referred to in this report as the minimum exercise fit factor. The minimum exercise fit factor was used because INDG 479 requires that all of the exercise fit factors must be greater than or equal to 100 for a fit test to pass; the minimum exercise fit factor is therefore the most relevant for determining whether the fit test passed or failed.

The data were positively skewed and so are summarised in terms of their median, maximum and minimum values.

Statistical analysis was undertaken to:

1. investigate if the two probing methods (flush and extended) resulted in different fit factors
2. investigate how the fit factors varied for repeated measurements on the same individual, and whether this differed by probing method

Detailed statistical methods are provided in Appendix A.

3 Results and discussion

3.1 Models of respirator

The four models of respirator selected for the study were anonymised and identified as Models A, B, C and D. Table 1 summarises the design features of each model of respirator used.

Table 1 Descriptions of the models of respirator used in the study

Model of respirator	Description
Model A	Moulded respirator with adjustable straps, a gasket-type face seal and with no nose clip
Model B	Moulded respirator with a nose clip, non-adjustable straps and a gasket-type face seal
Model C	Horizontal fold-flat respirator with a nose clip and non-adjustable straps
Model D	Vertical fold-flat respirator with a nose clip and non-adjustable straps

3.2 Human volunteers

Twenty volunteers participated in the study: 12 males and 8 females. All volunteers completed the testing with all four models of respirator.

3.3 Descriptive statistics

Initially, 240 fit tests were carried out, 12 each for the 20 different volunteers. Technical difficulties experienced during testing meant that 2 tests had to be repeated, resulting in a total of 242 tests, 240 of which were considered viable by the researchers.

Table 2 and Table 3 show the descriptive statistics for the fit tests conducted. Values are given for both the minimum exercise fit factor from each test (which must be 100 or higher in order to pass the fit test) and the overall fit factor.

When the respirators were ordered from highest to lowest median overall fit factor, the order was the same for both the flush and extended porting methods: Model A (flush

median = 2416; extended median = 2489), Model B (flush median = 248; extended median = 269), Model C (flush median = 96; extended median = 76) and Model D (flush median = 34; extended median = 27).

Table 2 Descriptive statistics for the observed overall fit factors

Respirator model	Port location	Number of participants	Number of fit tests	Overall fit factor (median)	Overall fit factor (minimum)	Overall fit factor (maximum)
Model A	Flush	20	60	2416	306	6908
Model A	Extended	20	60	2489	79	7675
Model B	Flush	20	60	248	11	1351
Model B	Extended	20	60	269	13	1530
Model C	Flush	20	60	96	12	361
Model C	Extended	20	60	76	11	367
Model D	Flush	20	60	34	4	457
Model D	Extended	20	60	27	3	351

When the respirators were ordered according to the median of the minimum exercise fit factor, the order was the same as for the overall fit factor for both the flush and extended porting methods: Model A (flush median = 913; extended median = 827), Model B (flush median = 106; extended median = 84), Model C (flush median = 57; extended median = 52) and Model D (flush median = 20; extended median = 17).

Table 3 Descriptive statistics for the observed minimum exercise fit factors

Respirator model	Port location	Number of participants	Number of fit tests	Minimum exercise fit factor (median)	Minimum exercise fit factor (minimum)	Minimum exercise fit factor (maximum)
Model A	Flush	20	60	913	250	2589
Model A	Extended	20	60	827	18	2930
Model B	Flush	20	60	106	6	612
Model B	Extended	20	60	84	7	556
Model C	Flush	20	60	57	6	235
Model C	Extended	20	60	52	8	211
Model D	Flush	20	60	20	2	305
Model D	Extended	20	60	17	1	224

3.4 Statistical analysis

3.4.1 Fit test values

Table 4 summarises the results of the statistical analysis comparing the fit factors as measured by the different port locations. The difference between the fit test results is presented as ratios, such that a ratio equal to one would mean that there was no difference in the fit test values, a ratio greater than one would mean the flush port tended to give fit test values greater than the extended port, and a value less than one would mean the flush port tended to give a fit test value less than the extended port. The ratio represents the best estimate based on the data, but there is uncertainty surrounding this estimate. The 95% confidence interval (95% CI) provides the statistical uncertainty surrounding the estimated ratio, and it is the interval within which we are 95% certain the true ratio lies. Finally, the difference between the two methods can be described as statistically significant if the p-value is less than 0.05. If this is the case, this means that our result is unlikely to have occurred by chance and the data suggests there is a true difference between the port locations.

Table 4 Summary of statistical analysis comparing fit test values when using the flush port to those when using the extended port

Respirator model	Overall fit factor: Estimated ratio	Overall fit factor: 95% confidence interval	Overall fit factor: p-value	Minimum fit factor: Estimated ratio	Minimum fit factor: 95% confidence interval	Minimum fit factor: p-value
All Models Combined	1.16	1.09-1.22	<0.001	1.17	1.11-1.24	<0.001
Model A	1.08	0.97-1.21	0.173	1.13	1.00-1.27	0.046
Model B	1.07	0.95-1.20	0.260	1.14	1.01-1.28	0.029
Model C	1.22	1.09-1.37	0.001	1.16	1.03-1.31	0.012
Model D	1.26	1.13-1.42	<0.001	1.27	1.13-1.43	<0.001

Full statistical results presented in Appendix A

For all respirator models combined (top row of Table 4), the porting method was statistically significantly associated with both overall fit factor and minimum exercise fit factor (both $p < 0.001$). On average, the flush port returned minimum exercise fit factors that were 17% (95% CI 11-24%) higher than fit factors measured with the extended port, and overall fit factors that were 16% (95% CI 9-22%) higher than fit factors measured with the extended port.

We also investigated if the difference between porting methods depended on the respirator model (Model A-Model D, Table 4). There was a borderline statistically significant difference between the respirator models for overall fit factor ($p = 0.095$). The results suggested that there was no statistically significant difference between the porting methods for Model A and Model B, but there was for Model C and Model D. For Model C, overall fit factors tended to be 22% greater (95% CI 9-37%) when measured using the flush method, and 26% greater (95% CI 13-42%) for Model D. The differences between respirator models were not statistically significant for minimum fit factor ($p = 0.47$), suggesting that the difference in porting methods did not differ by respirator model when measuring minimum fit factors.

3.4.2 Variability of fit

Table 5 summarises the results of the statistical analysis comparing the within-wearer variability of fit factor results as measured by the different port locations. A lower estimate for the within-wearer variability means there is less variability in the fit test result from one test to another (on the same individual) and, therefore, indicates a more repeatable test. The within-wearer variability presented is the best estimate based on the data, but there is uncertainty surrounding this estimate. The 95% confidence interval (95% CI) provides the statistical uncertainty surrounding the estimate, and it is the interval within which we are 95% certain the true within-wearer variability lies. Finally, the difference between the two methods can be described as statistically significant if the p-value is less than 0.05. If this is the case, this means that our result is unlikely to have occurred by chance and the data suggests there is a true difference between the port locations.

Table 5 Summary of statistical analysis comparing fit test variability (within-wearer variability) when using the flush port to that when using the extended port

Respirator model	Port location	Overall fit factor: Estimate of within-wearer GSD	Overall fit factor: 95% confidence interval	Overall fit factor: p-value of difference	Minimum fit factor: Estimate of within-wearer GSD	Minimum fit factor: 95% confidence interval	Minimum fit factor: p-value of difference
Model A	Flush	1.83	1.62, 2.12	$p=0.134$	1.53	1.41, 1.70	$p=0.003$
Model A	Extended	2.15	1.85, 2.59	-	1.97	1.73, 2.33	-
Model B	Flush	2.08	1.80, 2.49	$p=0.748$	1.80	1.60, 2.07	$p=0.446$
Model B	Extended	2.16	1.86, 2.61	-	1.94	1.70, 2.28	-
Model C	Flush	1.77	1.58, 2.04	$p=0.932$	1.96	1.71, 2.31	$p=0.389$
Model C	Extended	1.76	1.57, 2.02	-	1.80	1.60, 2.07	-
Model D	Flush	1.72	1.54, 1.96	$p=0.616$	1.86	1.65, 2.17	$p=0.492$

Model D	Extended	1.79	1.60, 2.07	-	2.00	1.75, 2.37	-
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GSD, geometric standard deviation

Full statistical results presented in Appendix A

The within-wearer variability tended to be smaller for the flush port compared to the extended port for respirator models A, B and D, and higher for the flush port for Model C. However, most of these differences were not statistically significant suggesting the differences could have occurred by chance alone. There was one statistically significant difference in the measured within-wearer variability for the minimum exercise fit factors for Model A ($p=0.003$). However, the difference in the variability was dependent on two outlying data points and was no longer statistically significant when these were removed from the analysis.

4 Conclusions

This study found that there was a statistically significant difference in the fit test result depending on the location of the port used. On average, the flush port gave a minimum exercise fit factor that was about 17% higher and an overall fit factor that was about 16% higher than the extended port. Nevertheless the difference between port methods is small enough that it is unlikely to make a difference as to whether a person/respirator passes or fails a fit test if their result is expected to be substantially below or above the pass mark of 100. However, the difference between the port locations is important if they are close to the pass/fail value – for example, an individual who passes with a result of 115 using the flush port, may have failed with a result of 99 using the extended port. This research has identified that using the flush port in this situation would result in a false pass.

Statistical analysis of the within-wearer variability for the flush and extended port found no evidence that one method provided better or worse test repeatability than the other.

While no FFP1 or FFP2 respirators were tested for this study, they are similar enough in design to FFP3 respirators that the same results would also apply. Half mask and full-facemask respirators are different enough in design from FFP3s that the findings in this report are unlikely to be applicable.

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Appendix A Statistical methods and results

A1 Methods

The main objectives of the analysis were to:

1. investigate if the two probing methods (flush and extended) resulted in different fit factors; and
2. investigate how the fit factors varied for repeated measurements on the same individual, and whether this differed by probing method.

Throughout, the quantities of interest were the overall fit factor and the minimum exercise fit factor of each test. The data were positively skewed, and so overall fit factor and minimum exercise fit factor were log transformed for analysis.

The statistical analysis is described in detail below and used linear mixed effects models. These take into account the underlying structure of the data – for example, repeated testing on individuals. Due to the relatively small number of individuals involved in testing, the mixed effects models were fitted using restricted maximum likelihood estimation throughout. Wald tests were used to test for statistical significance of variables, interactions and differences, and a p-value of 0.05 used to indicate statistical significance. Tests of interaction can lack statistical power, and so borderline statistically significant interactions (i.e., p-values between 0.05 and 0.1) were also investigated further. Estimated differences on the log scale were back-transformed to the original scale, which means that differences between groups are interpreted as ratios. A ratio equal to one would mean that there was no difference between the two groups being compared, a ratio greater than one would mean that the comparison group tended to be greater than the reference group, and a ratio less than one would mean that the comparison group tended to be lower. All analyses were conducted using Stata/MP 14.2 for Windows (StataCorp. 2016. Stata Statistical Software: Release 14.2. College Station, TX: StataCorp LP).

A1.1 Fit test values

Separate linear mixed effects models were used to investigate differences between the port locations for the overall fit factor and minimum exercise fit factor. Port location was entered as a fixed effect. Respirator model, PortaCount and test number were also entered as fixed effects to adjust for any impact these factors may have had on results. Volunteer number and test number were entered as random effects. Test number was included as a random effect so that clustering by test number was adequately taken into account, and as a fixed effect to account for any common trend across tests 1 to 13 (that is, a learning effect). The results of the two models are summarised in the top row of Table 4, Section 3.4.1. Detailed results are provided below.

The interaction between port location and respirator model was then included to investigate if any difference between the port locations depended on the respirator model. The interaction was of borderline statistical significance for overall fit factor ($p=0.095$) and was not statistically significant for minimum fit factor ($p=0.47$). The results of the two interaction models are summarised in the bottom four rows of Table 4, Section 3.4.1.

A1.2 Variability of fit

Two-level linear mixed effects models were used to decompose the observed variability into between-wearer variability and within-wearer variability. Separate models were used for the different respirators and for the two quantities of interest: overall fit factor and minimum exercise fit factor. The port location was entered as a fixed effect, and the between-wearer variability and the within-wearer variability were allowed to vary by port location. The estimated variability was back-transformed onto the original scale and so the results presented show the estimated the geometric standard deviation. The results are summarised in Table 5, Section 3.4.2. Detailed results are provided below.

A2 Results

A2.1 Fit test values

Table 6 shows the results of the statistical analysis comparing the fit factors as measured by the different port locations. This also took into account the respirator model, the specific PortaCount used, and the test order.

Table 6 Linear mixed effects models comparing port location and adjusting for respirator model, PortaCount and test number for overall fit factor and minimum exercise fit factor

Variable	Overall fit factor adjusted ratio^a	Overall fit factor 95% confidence interval	Overall fit factor p-value	Minimum exercise fit factor adjusted ratio^a	Minimum exercise fit factor 95% confidence interval	Minimum exercise fit factor p-value
Port location	-	-	<0.001	-	-	<0.001
Port location – flush	1.16	1.09-1.22	-	1.17	1.11-1.24	-
Port location – extended	Ref	-	-	Ref	-	-
Respirator model			<0.001			<0.001
Respirator model – A	68.2	48.0-96.8		42.4	30.5-56.0	
Respirator model - B	5.42	3.82-7.69		3.60	2.59-5.00	
Respirator model - C	2.31	1.63-3.26		2.43	1.76-3.37	

Variable	Overall fit factor adjusted ratio^a	Overall fit factor 95% confidence interval	Overall fit factor p-value	Minimum exercise fit factor adjusted ratio^a	Minimum exercise fit factor 95% confidence interval	Minimum exercise fit factor p-value
Respirator model - D	Ref			Ref		
Portacount	-	-	0.128	-	-	0.082
Portacount – 1	Ref	-	-	Ref	-	-
Portacount – 2	1.06	0.98-1.15	-	1.09	1.00-1.18	-
Portacount – 3	1.34	1.02-1.76	-	1.29	0.99-1.67	-
Portacount – 4	1.32	1.00-1.74	-	1.30	1.00-1.68	-
Test number	-	-	0.159	-	-	0.030
Test number – 1	Ref	-	-	Ref	-	-
Test number – 2	1.29	0.72-2.29	-	1.36	0.79-2.35	-
Test number – 3	1.83	1.03-3.26	-	1.89	1.09-3.25	-

Variable	Overall fit factor adjusted ratio^a	Overall fit factor 95% confidence interval	Overall fit factor p-value	Minimum exercise fit factor adjusted ratio^a	Minimum exercise fit factor 95% confidence interval	Minimum exercise fit factor p-value
Test number – 4	1.06	0.59-1.92	-	1.05	0.60-1.82	-
Test number – 5	1.46	0.82-2.59	-	1.53	0.89-2.63	-
Test number – 6	1.10	0.61-2.01	-	1.13	0.64-1.98	-
Test number – 7	1.01	0.57-1.80	-	0.96	0.56-1.66	-
Test number – 8	1.60	0.89-2.86	-	1.70	0.98-2.95	-
Test number – 9	1.29	0.72-2.31	-	1.38	0.80-2.39	-
Test number – 10	1.26	0.71-2.23	-	1.36	0.79-2.33	-
Test number – 11	0.84	0.47-1.49	-	0.85	0.50-1.46	-
Test number – 12	1.14	0.64-2.02	-	1.17	0.68-2.01	-
Test number – 13	4.14	1.27-13.5	-	4.60	1.51-14.0	-

a, separate linear mixed effects models used for overall fit factor and minimum exercise fit factor, adjusted for all variables listed as fixed effects, and volunteer and test number as random effects.

Ref, reference category; all other measures were compared to the reference category within each grouping.

The objective of the analysis was to investigate the differences between port locations, and the relevant results from Table 6 are summarised in the main report (top row of Table 4, Section 3.4.1). However, some of the results from the adjustment variables may also be of interest. From Table 6 above, we see:

- as expected, there were statistically significant differences between **respirator models**, with Model A tending to have the highest fit factors followed by Model B, Model C, and then model D ($p < 0.001$ for both overall and minimum fit factor).
- **PortaCount** was not statistically significantly associated with overall fit factor ($p = 0.13$) or minimum exercise fit factor; although this was of borderline statistical significance for minimum exercise fit factor ($p = 0.082$).
- **test order** was not statistically significantly associated with overall fit factor ($p = 0.16$), but it was associated with minimum exercise fit factor ($p = 0.03$). This suggested that the test order affected the measured minimum exercise fit factor, primarily due to test 13 tending to have higher minimum exercise fit factors (4.6 times higher than test 1). Only two volunteers carried out a 13th test (in both cases due to technical difficulties with earlier tests). Given the extremely small sample size, this result should be treated with caution.

A2.2 Variability of fit

Tables 5 and 6 show the geometric standard deviation decomposed into between-wearer geometric standard deviation and within-wearer geometric standard deviation, for overall and minimum exercise fit factors, respectively. The between-wearer geometric standard deviation describes how much the fit factors differ between different wearers; whereas the within-wearer geometric standard deviation describes how much the fit factors differ for repeated measurements on the same individual. The within-wearer variability, as the main quantity of interest, is summarised in Table 5, Section 3.4.2. The following tables show both the between-wearer and within-wearer variability.

Table 7 Linear mixed effects models decomposing the variability in overall fit factors into between-wearer variability and within-wearer variability

Respirator model^a	Port location	Between-wearer geometric standard deviation – Estimate	Between-wearer geometric standard deviation – 95% confidence interval	Within-wearer geometric standard deviation – Estimate	Within-wearer geometric standard deviation – 95% confidence interval	Within-wearer geometric standard deviation – Wald test ^b
Model A	Flush	1.34	1.13, 1.96	1.83	1.62, 2.12	$p=0.134$
Model A	Extended	1.45	1.17, 2.34	2.15	1.85, 2.59	-
Model B	Flush	3.25	2.28, 5.42	2.08	1.80, 2.49	$p=0.748$
Model B	Extended	3.32	2.30, 5.61	2.16	1.86, 2.61	-
Model C	Flush	1.75	1.44, 2.38	1.77	1.58, 2.04	$p=0.932$
Model C	Extended	1.70	1.40, 2.29	1.76	1.57, 2.02	-
Model D	Flush	2.80	2.07, 4.30	1.72	1.54, 1.96	$p=0.616$
Model D	Extended	2.78	2.05, 4.30	1.79	1.60, 2.07	-

a, separate linear mixed effects models used for each respirator model.

b, compares the within-wearer geometric standard deviation for the flush port and extended port.

Table 8 Linear mixed effects models decomposing the variability in minimum exercise fit factors into between-wearer variability and within-wearer variability

Respirator model^a	Port location	Between-wearer geometric standard deviation – Estimate	Between-wearer geometric standard deviation – 95% confidence interval	Within-wearer geometric standard deviation – Estimate	Within-wearer geometric standard deviation – 95% confidence interval	Within-wearer geometric standard deviation – Wald test ^b
Model A	Flush	1.44	1.26, 1.80	1.53	1.41, 1.70	$p=0.003$
Model A	Extended	1.57	1.28, 2.24	1.97	1.73, 2.33	-
Model B	Flush	2.93	2.13, 4.61	1.80	1.60, 2.07	$p=0.446$
Model B	Extended	2.94	2.12, 4.67	1.94	1.70, 2.28	-
Model C	Flush	1.77	1.42, 2.50	1.96	1.71, 2.31	$p=0.389$
Model C	Extended	1.69	1.39, 2.29	1.80	1.60, 2.07	-
Model D	Flush	2.84	2.08, 4.44	1.86	1.65, 2.17	$p=0.492$
Model D	Extended	2.72	1.99, 4.26	2.00	1.75, 2.37	-

a, separate linear mixed effects models used for each respirator model.

b, compares the within-wearer geometric standard deviation for the flush port and extended port.

The Approved Code of Practice to the Control of Substances Hazardous to Health (COSHH) Regulations 2002 (as amended) states that, if respiratory protective equipment (RPE) is required, any tight-fitting respirators used should be face-fit tested using a suitable method, by a competent person.

Suitable methods for fit testing of tight-fitting RPE check that a specific model and size of respirator seals adequately to the wearer's face with no gaps through which airborne hazardous substances can enter.

The study objectives were to determine if there was a difference in fit factors and in the within-wearer variability between the flush (flush with the inside surface of the respirator) and extended (extended into the wearer's breathing zone) ports used in fit testing, for filtering facepiece class 3 (FFP3) respirators.

Fit testing research was carried out with human volunteers on a variety of FFP3 respirators using both flush and extended ports.

The results provide an evidence base for why an extended port should be used in fit testing.

The study provides evidence that the repeatability of the fit test did not differ by port location and that effective fit testing can be carried out using an extended port.

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