
Fit of Filtering Facepiece Class 3 (FFP3) Respirators Part 2: The Value of Fit-Checking and Simple Subjective Assessments of Fit as an Alternative to a Fit Test

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ABSTRACT

A fit-check is frequently recommended by respiratory protective equipment (RPE) manufacturers to check the seal of a tightfitting facepiece following donning. Theoretically such simple checks may have the potential to give a good indication of the suitability of the facepiece for the wearer, possibly serving as a substitute for a fit test. Information and data collected from the testing described in Part 1 of this study was used to assess the value of fit-checks and similar subjective assessments of the fit of filtering facepiece class 3 (FFP3). Statistical analysis of the fit-check results gave poor values, with a test sensitivity (probability of correctly detecting a poor fit) of 0.18 (the American National Standard requires this to be at least 0.95 for a fit test method) and a kappa statistic (overall agreement with the reference fit test method) of zero. The subjective opinion of the test subject and the observations of the experienced fit tester were also considered. The results included a significant proportion of uncertainty and because of this it was not possible to carry out a meaningful statistical analysis. However for 25% of the 61 test runs which failed in every fit test method, the fit was thought to be good by the wearer, even after wearing the FFP3 for one hour whilst undergoing the fit tests. Similarly for 38% of these 61 failed fit test runs the experienced fit tester thought that the fit appeared good. This study concludes that fit-checks or simple subjective assessments of fit alone should never be used to assess suitability when selecting filtering facepieces; a fit test should always be carried out.

Keywords: Fit-check, Subjective assessment, Respiratory protective equipment (RPE), Filtering Facepiece, RPE standards.

INTRODUCTION

It is a requirement of the Health and Safety Executive's (HSE's) approved code of practice supporting UK legal requirements governing the use of tightfitting respiratory protective equipment (RPE) for fit testing to be carried out (HSE, 2002; 2005; 2006). Each individual RPE wearer is required to have a fit test in order to establish that the facepiece is suitable for their face before using the RPE for protection against hazardous contaminants or oxygen deficiency in the workplace.

Several fit test methods are available which use different assessment techniques which may give different results. The comparison of different fit test methods for FFP3 is discussed in the first paper on this work (Frost *et al*, 2014). All fit test methods, in common use in the UK, require the RPE wearer to carry out a series of specific exercises for at least one minute each whilst the fit is continuously assessed (HSE, 2012). Some fit test methods also expect the wearer to engage in physical activity which increases the breathing rate and depth, such as stepping, walking on a treadmill or cycling.

Manufacturers of tightfitting RPE often stipulate in their instructions that a fit-check should be carried out after each donning of their facepiece, and before wearer exposure to the respiratory hazard, to check that the RPE device appears to be sealed to their face correctly. Such fit-checks generally consist of a sharp inhale or exhale of breath with the wearer trying to block airflow through the normal inhale/exhale route, whilst the wearer concentrates on detecting any signs of face seal leakage, draughts of airflow in/out of the mask via the face seal.

With elastomeric reusable type facepieces it is generally relatively easy to block the normal airflow into the facepiece by covering the filter opening(s) with the hands. On inhaling sharply, if the facepiece is well sealed to the face, it can usually be seen to pull/collapse towards the face and stay in that position until the wearer breathes out again. This is often called a 'suck-down' check, and such a response gives the wearer confidence of protection. A similar check can be carried out by breathing out gently with the exhale opening(s) sealed with the hands. The facepiece should initially inflate but remain sealed to the face with no leaks felt. Continued and/or sharp breathing out will force air to leak out via the face seal as the facepiece is forced away from the face by the increased pressure inside, no matter how good the seal to the face is.

Filtering facepieces consist almost entirely of filtering material, sometimes with an exhale valve positioned near to the centre, in front of the nose and mouth. It is not possible to temporarily prevent all air from flowing through the filtering material, but some restriction may be possible by loosely covering the filtering material with the hands. With softer types of filtering material it may be possible (for a colleague, or using a mirror) to see a temporary 'suck down' effect without any attempt to restrict air flowing through the filtering material, but just by inhaling sharply.

This paper concerns the question of whether or not the fit-check or the subjective opinion of the wearer or an experienced and competent fit tester could be of value in assessing the quality of the fit of an FFP3.

METHODS

It is the practice at HSL when fit testing to expect the wearer to carry out a fit-check after donning the facepiece (in accordance with the manufacturer's recommendations) but before the fit test is commenced. This approach is used as an aid to good donning, aiming for the best fit, and was used for the 130 test runs when comparing fit test methods described in Part 1 of this work (Frost *et al*, 2014).

The test runs required the FFP3 to be donned and the four different fit tests carried out. The fit test methods included were:

- The laboratory chamber, generated aerosol, Total Inward Leakage (TIL) fit test method based on the EN149 (2001+A1:2009) TIL test.
- The qualitative Bitrex taste fit test
- The TSI Portacount
- The TSI Portacount-with-N95-Companion technology

The fit test method details are given in Part 1 of this paper (Frost *et al*, 2014). Fit tests were conducted according to HSE guidance (HSE, 2012).

Twenty five volunteer test subjects took part and FFP3 were randomly selected from the nine models included in the study. The volunteers were asked to don the FFP3, guided by the manufacturer's instruction and advice from the experienced and Fit2Fit accredited (BSIF, 2010) fit testers, sealing it to the face as correctly and as securely as possible. They were allowed to carry this through at their own pace and then asked to carry out a fit-check, again under guidance. Having worn the FFP3 for a few minutes the fit tester inspected the fit looking for gaps between the FFP3 and the test subject's face. The test subject was instructed to move their head to the extremes required in fit test exercises to facilitate better inspection of the fit. Observations were recorded. The test subject was asked their subjective opinion of the fit and the comfort of the FFP3, their comments were recorded.

Without further disturbance to the fit of the FFP3 the four fit tests were conducted in a randomised order, requiring about one hour of FFP3 wear time. Immediately following these fit tests the test subject was again asked their opinion of the comfort and fit of the FFP3 and their response recorded, along with the observations of the fit tester. Test subjects were asked to comment on what they could feel, rather than basing their views on the fit test results, which it was not always possible to conceal from them. After the fit tests the fit tester again recorded what they could see, but since they were always aware of the fit test results it is possible that for the post-test assessments this knowledge may have had some influence.

RESULTS

Fit-check results

The fit-check is a defined action usually giving a clear result of pass (positive – no leaks detected) or fail (negative – leak detected). Table I presents the overall results of the fit-check for all test runs. For eight of the test runs the test subject was unsure of the result, but for 106 test runs the result was a pass and the remaining 16 test runs failed the fit-check.

Table I. Fit-check Results for All Test Runs

Fit-check Results	
Pass	106 (82%)
Unsure	8 (6%)
Fail	16 (12%)
Total	130

The results of the fit-check assessed against the TIL test result (used in this study as the reference method) are presented in Figure 1 which shows the fit-check result, identified by shading and pattern on the bar chart, against the TIL minimum fit factor result. Passes are represented by solid grey, fails by diagonal stripes and unsure by horizontal stripes. This gives a visual presentation of the correlation between the fit-check and the TIL fit test method. The tests are ordered by TIL fit test minimum fit factor result. Although the 33 lowest fit factors (all below 30) do include six failed fit-checks, the majority (27) are passes with the four tests runs with the lowest TIL fit factors (below 10) all passing the fit-check. (Note that 126 results are included in Figure 1, four short of the 130 given in the table above, as four of the TIL tests were invalid due to technical problems.)

These results are similar to those of others (Derrick *et al*, 2004; Danyluk *et al*, 2011; Lam *et al*, 2011), with Derrick *et al* also reporting cases of fit-check passes where the measured fit factor was very low.

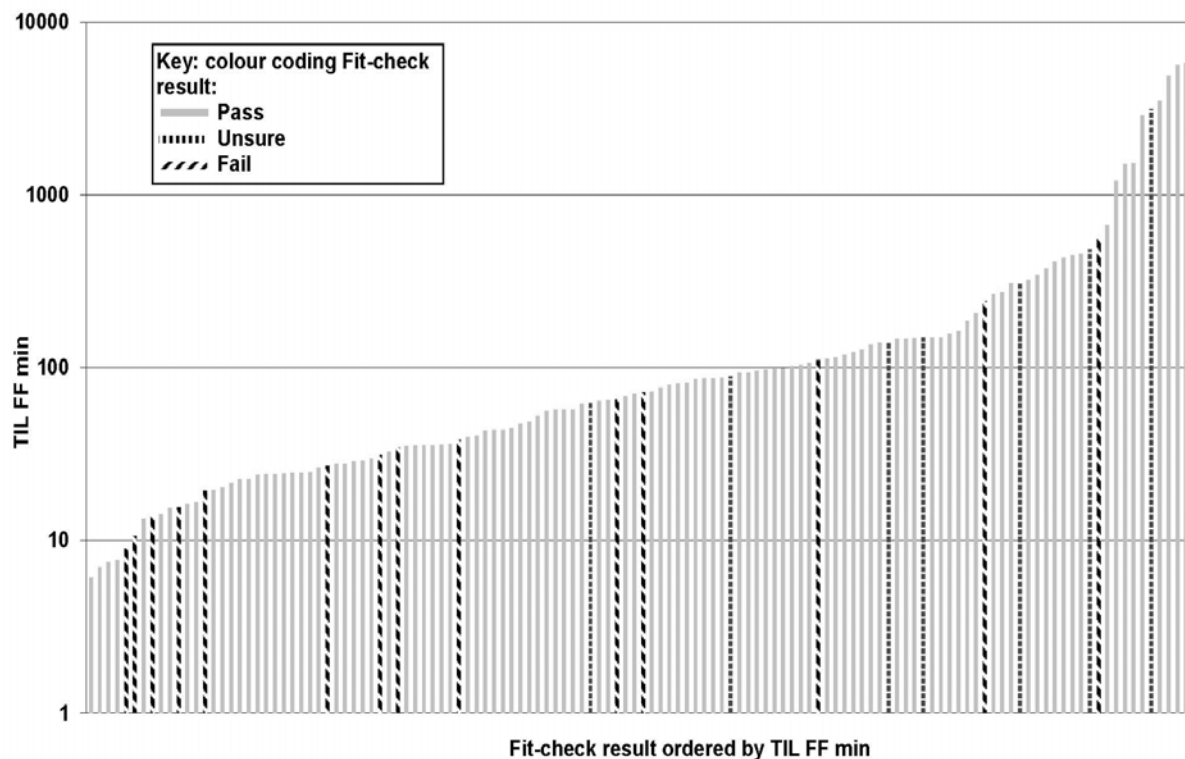


Figure 1. Fit-check result ordered by TIL fit factor.

Statistical analysis of the fit-check results

The results from the fit-check were analysed against the results from the laboratory chamber TIL fit test method using the ANSI/AIHA Z88.10-2010 (ANSI, 2010) fit testing standard criteria for acceptability of a new fit test method, referred to hereafter as the ANSI standard. This is the same treatment as used to compare the results from the four fit test methods in Part 1 of this study (Frost *et al*, 2014). The analysis results are given in Table II.

Table II. Statistical Calculations for Fit Test Methods and Fit-Checking Compared against the TIL Fit Test Method as the Reference Method

ANSI/AIHA Z88.10-2010 Annex A2 analysis calculations									
Pass criteria	all 100			Test sensitivity required ≥ 0.95	Beta error required ≤ 0.05	Predictive value of pass suggested ≥ 0.95	Test specificity suggested > 0.5	Predictive value of a fail suggested > 0.5	Kappa Statistic recommended > 0.7
Formulae	Passed failed	TIL Failed A C	TIL passed B D	$C/(A+C)$	$1-(C/(A+C))$	$B/(A+B)$	$B/(B+D)$	$C/(C+D)$	
Bitrex Bitrex	Passed failed	TIL Failed 9 65	TIL passed 24 19	0.88	0.12	0.73	0.56	0.77	0.46
Portacount Portacount	Passed failed	TIL Failed 1 73	TIL passed 18 25	0.99	0.01	0.95	0.42	0.74	0.46
Portac. +N95 Portac. +N95	Passed failed	TIL Failed 5 69	TIL passed 25 18	0.93	0.07	0.83	0.58	0.79	0.55
Fit-check Fit-check	Passed failed	TIL Failed 61 13	TIL passed 35 8	0.18	0.82	0.36	0.81	0.62	-0.01

The analysis gave a test sensitivity (the probability of correctly detecting a poor fit) of 0.18 which is very poor compared with the ANSI standard requirement of 0.95 and compares with test sensitivities for fit test methods of 0.88 (Bitrex), 0.93 (Portacount-with-N95-Companion technology) and 0.99 (Portacount) (Frost *et al*, 2014). Similar test sensitivities for fit-checking, with values of 0.15 and 0.23 respectively on two models of filtering facepiece, have been found by others (Lam *et al*, 2011).

The predictive value of a pass (probability that when the test result is a pass the fit is good) is likewise low at 0.36; the ANSI standard suggests that this should be at least 0.95. The test specificity (probability that if the fit is good this will be correctly detected by the fit-check) is high at 0.81, but this is not surprising as most of the results of the fit-check results are passes. At 0.62 the predictive value of a fail is lower than for any fit test method; the small number of failed fit-checks was less likely than failed fit tests to correspond with actual poor fits. The slightly negative kappa statistic (overall agreement between fit test methods) at -0.01 which the ANSI standard recommends should be positive and at least +0.7. This very low value indicates that there is effectively no correlation between fit-checking results and the reference TIL fit test results; use of a fit-check alone is of no value in determining the quality of the fit of the FFP3.

Subjective opinions of fit - correlation with fit test results for 'confirmed poor fits'

The fit test results did not generally reflect the opinion of the wearer and the fit tester as to how well the FFP3 appeared to fit. 61 test runs resulted in a fail in every fit test method used in this study, according to current HSE guidance. These 61 test runs will be referred to as 'confirmed poor fits' hereafter in this paper. Table III shows the subjective opinions of the fit for these 61 confirmed poor fits. Figure 2 gives these same results in bar chart format.

For the 61 confirmed poor fits the fit-check passed (positive response) in 49 of these, with only 11 correctly identifying the fit as poor (negative response). Only one fit-check result was classed as unsure.

Test subject opinion

Test subject opinions are summarised in the second and third columns of Table III and the second and third data sets of Figure 2. When asked their overall subjective opinion of the comfort and fit of the FFP3 the test subjects were more inclined to express doubts about this, compared with the result of the fit-check, with 18 (30%) giving negative comments such as:

- "wouldn't want to wear for real. Some movement on nose when talking, smiling";
 - "a bit insecure under chin but otherwise OK. Feels as if may shift around a bit".
- Another 18 (30%) gave positive comments such as:
- "feels comfortable, straps easy, donning easy, right size";
 - "feels comfortable and leak tight".

Comments from the remaining 25 were non-committal as to whether the FFP3 felt suitable. At the end of the test run, having completed the four fit tests, 15 (25%) of the test subjects were still positive about the fit and comfort of the FFP3, comments included:

- "feels fine no leaks felt, comfortable on nose";
- "good - best so far".

Note that for four of these test runs the test subjects had been unsure about the FFP3 before the test run began, but now took a positive view of it; a further one had changed opinion completely, originally giving negative comments.

But the experience of wearing the FFP3 for the fit tests had convinced some test subjects that the FFP3 was not suitable for them. A total of 31 (51%), now gave negative comments about the FFP3 suitability.

Fit tester observations

Experienced, Fit2Fit accredited fit testers (BSIF, 2010) conducted the test runs. For the 61 test runs which resulted in confirmed poor fits, comments from the fit tester's observations of the fit of the FFP3 before and after each test run are summarised in the final two columns of Table III and Figure 2. Comments were generally more positive than the comments of the test subject, 26 (43%) fits looked acceptable before the test run, this falling slightly to 23 (38%) after the test run. Derrick *et al* (2005) also reported that visual checks by the fit tester did not seem a good surrogate for formal fit testing.

Comments before the test run included:

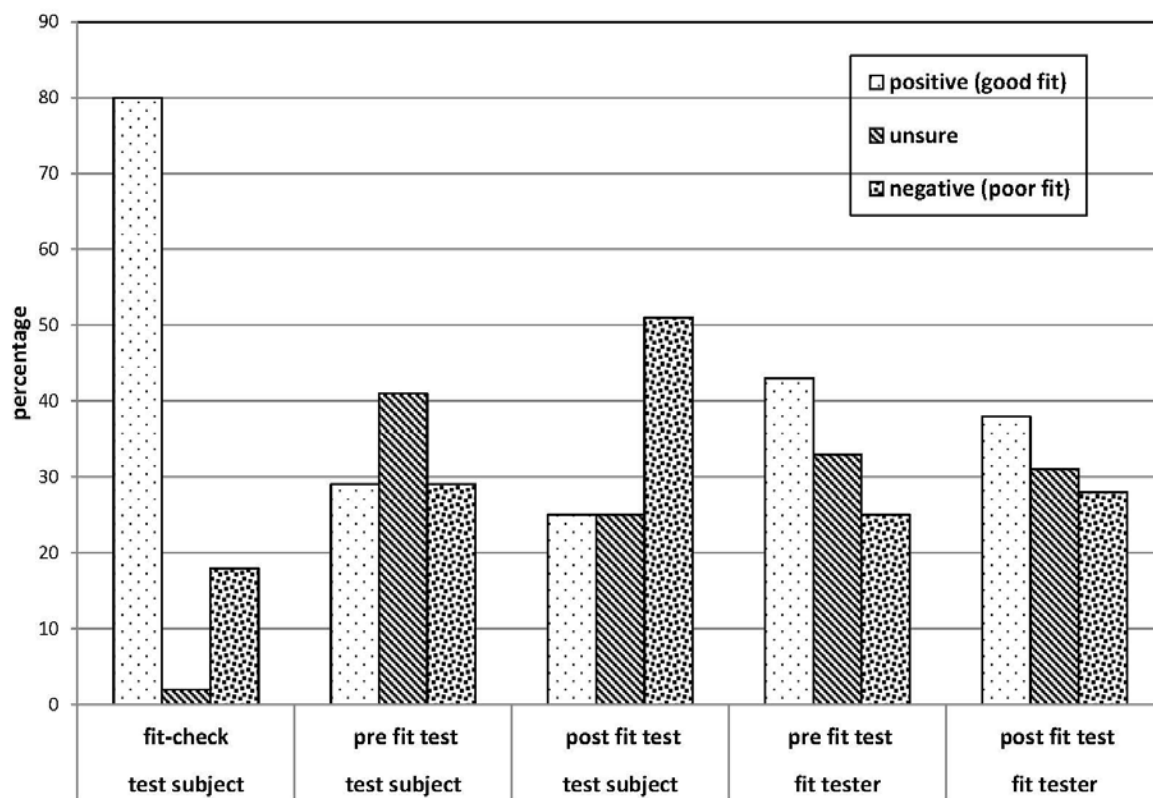
- "wide fabric seal appears to be in good contact all around";
- "looks OK. nose clip well shaped, chin snug".

After the test run recorded comments from the fit tester included:

- "OK no gaps. Face marked";
- "nose seal appears to fit and mask appears snug under chin".

Table III. Summary of Results of Simple Subjective Assessments of Fit, for Confirmed Poor Fits only

	Fit check pass	Test subject positive subjective assessment (pre test run)	Test subject positive subjective assessment (post test run)	Fit tester positive subjective assessment (pre test run)	Fit tester positive subjective assessment (post test run)
Positive	49 (80%)	18 (29%)	15 (25%)	26 (43%)	23 (38%)
Unsure	1 (2%)	25 (41%)	15 (25%)	20 (33%)	21 (31%)
Negative	11 (18%)	18 (29%)	31 (51%)	15 (25%)	17 (28%)

**Figure 2. Bar Chart Summary of the results of simple subjective assessments of fit for confirmed poor fits.**

Dependence of previous experience of FFP3 wearing on subjective opinions of the test subject

The experience of the test subjects with donning, and wearing FFP3 varied. Some had never donned a filtering facepiece before, whilst others had experience of donning a range of models or had worn a specific model regularly at work for respiratory protection. This experience was categorised with a star rating to assess if more experience led to a better subjective assessment of fit. Table IV shows the occurrence of fit-check pass and positive subjective assessment of confirmed poor fits according to test subject experience of FFP3.

Table IV. Summary of Occurrence of Fit-Check Pass/Positive Subjective Assessment of Confirmed Poor Fits According to Test Subject Experience of FFP3

Experience of test subject	Fit check pass	Positive subjective assessment (pre test run)	Positive subjective assessment (post test run)
* Inexperienced	24 (86%)	15 (62%)	20 (38%)
** Moderate experience	21 (84%)	11 (56%)	16 (23%)
*** Experienced	24 (82%)	17 (36%)	25 (35%)
Overall	70 (84%)	43 (50%)	61 (33%)

Similar percentages of fit-check pass results (82-86%) across all levels of test subject experience, show that experience of the test subject in donning and wearing FFP3 did not affect ability to judge a good fit according to the fit-check. Danyluk et al (2011) also found this to be the case.

The relatively higher percentage of inexperienced and moderately experienced test subjects judging a poor fit to be good prior to the test run, compared to experienced test subjects, indicates that experience may help towards correctly assessing the fit on first donning an FFP3. However, after the test run such experience did not give an advantage, with similar percentages of post test run opinions across all levels of experience. That is, some poor fits not initially recognised as such due to inexperience of the test subject, were recognised as poor after wearing the FFP3 for the test run (approximately one hour of wear time).

DISCUSSION

Sixty one test runs resulted in a fail in all of the four fit test methods used in this study, which confirms poor fit. It is of concern that so many of these confirmed poor fits, when assessed by simple subjective methods, were thought to be good fits. Even following the test run fit tests, which include exercises which are designed to challenge the fit, many of the wearers and fit testers still thought that the fit of a confirmed poor fit was good.

This work shows that the result of a fit-check cannot affirm the suitability of an FFP3 for a wearer with any confidence, with very poor test sensitivity compared to fit test methods. Fit-checking may have value in identifying that the FFP3 fit is poor, saving wasting time on conducting a fit test. This work also shows that general subjective assessment by either the wearer or an experienced fit tester is dominated by false positive comments and uncertainty and can only really be of use in deciding that the fit is clearly poor.

Other classes of filtering facepiece including FFP1 and FFP2 and those which are approved to other standards e.g. NIOSH N95 (NIOSH, 2004) are of a similar construction to FFP3. It follows that all filtering facepieces are likely to perform in a similar way, under simple subjective checking, to that found in this study.

A fit-check is not a method of fit testing. A fit-check is used as a simple subjective check to give an indication of the quality of donning and may also serve to assist the detection of a manufacturing fault with the FFP3. The European Standard for filtering facepieces EN149 (2001+A1:2009), which is intended to satisfy the relevant essential health and safety requirements of the European PPE Directive (European Commission, 1989), requires manufacturers to include information and warnings for the user of filtering facepieces, and these warnings are expected to cover the importance of their correct fit. In response, many manufacturers recommend a fit-check to be carried out as a pre-use check on the wearer fit of a facepiece following each donning and before exposure to the respiratory hazard. The outcome of this work demonstrates that fit-checks alone are insufficient to establish whether proper fit is achieved for FFPs, and it is therefore questionable whether their inclusion in user instructions fully satisfies the requirements of the Directive. There is currently no specific requirement in the European Standard EN149 (2001+A1:2009) for filtering facepieces for a recommendation in support of fit testing to be included in manufacturers' instructions, although there is support for fit testing in EN529 (2005), the European RPE guidance document on selection, use and maintenance.

CONCLUSIONS

This work has shown that a fit-check or a simple subjective assessment of fit should not be relied upon to determine that the fit of a filtering facepiece is good, a fit test should always be carried out. The value of fit testing for FFP3 using a recognised fit test method is far greater than a fit-check; the result of a fit-check has zero agreement with the reference fit test method result when measured by the kappa statistic.

These results suggest justification for relevant RPE Standards to require that filtering facepiece manufacturers should include advice in their product instructions recommending that a fit test should be carried out when selecting a filtering facepiece. Similarly, end-user RPE programmes that rely on fit-checks and simple subjective assessments of fit alone for selection of FFP3 for individual wearers, are unlikely to result in the selection of suitable FFP3 that adequately fits wearers. This will have implications for the level of protection which the wearer receives.

Whilst pre-use fit-checks should not be used for determining wearer suitability of FFP3, their value in checking for manufacturing faults of individual FFP3 and demonstrating correct donning is not questioned by this study. These conclusions are likely to be equally applicable to other classes of filtering facepiece including FFP2, FFP1 and NIOSH certified filtering facepieces including N95.

Acknowledgements

The help of the following is acknowledged here and is very much appreciated:

- The valued members of the Health and Safety Laboratory (HSL) Personal Protective Equipment (PPE) test subject volunteer team who gave their time, effort and energy and without whom the work would not have been possible
- The technical contribution made by Nick Baxter of the PPE team in helping and leading with many of these test runs
- The members of the British Safety Industries Federation (BSIF), Personal Safety Manufacturers' Association (PSMA), Respiratory Protection Product Group for providing information about their FFP3 products and donating samples for use in the test runs

Disclaimer

This publication and the work it describes were funded by the Health and Safety Executive (HSE). Its contents, including any opinions and/or conclusions expressed, are those of the authors alone and do not necessarily reflect HSE policy. Throughout this paper, reference is made to a number of proprietary and trademarked products, such as Bitrex, Saccharine, TSI, PortaCount, N95-companion, 3M.... Their mention here does not constitute any endorsement by the authors or HSL.

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