
Fit of Filtering Facepiece Class 3 (FFP3) Respirators Part 3: Suitability of FFP3 for Real Faces

Shirley Frost and Rhiannon Mogridge

Health and Safety Laboratory, Harpur Hill, Buxton, SK17 9JN
Corresponding author E-mail: shirley.frost@hsl.gsi.gov.uk

ABSTRACT

Tight-fitting respirators must fit the wearer well if they are to provide the expected protection. The potential for achieving a good fit is challenged by the diverse range of shapes and sizes which the human face can exhibit. FFP3 are available in a range of models theoretically giving scope for fitting a wide range of faces. This paper is concerned with how well FFP3 are able to fit real faces and has been developed from the findings of a study comparing fit test methods (Fit of FFP3 respirators Part 1 and Part 2 are reported in separate papers). Nine FFP3 models, with a diverse range of design features, were tested on the 25 different volunteers. Selection of FFP3 for volunteers was randomised, with no attempt made to match volunteer with FFP3; not every FFP3 was tested on every volunteer. Four different fit test methods were directly compared and the fit test results were mapped according to volunteer face size. Subjective comments on the design of these FFP3 were also noted. Two of the FFP3 models passed with all four fit test methods on 40% and 50% of the volunteers respectively, another three models passed in all four fit test methods with at least one volunteer. The remaining four models did not pass with any volunteer in all four fit test methods. The full range of available design features were present overall in the range of FFP3 which performed well, and those that performed poorly; lack of attention to the detail of the design was identified as the reason for poor fit of some FFP3. Some areas for improvement in design and product standards are identified.

Keywords: Filtering Facepiece, Respiratory protective equipment (RPE), RPE standards, Principal component analysis (PCA), Total inward leakage (TIL) test.

INTRODUCTION

Tight-fitting respirators must fit the wearer well if they are to provide the expected protection. The potential for achieving a good fit is challenged by the diverse range of shapes and sizes which the human face can exhibit (ISO, 2010). Anecdotal evidence and our experience of a number of different FFP3 suggests that whilst some are capable of demonstrating a good fit on a range of faces, it is difficult to fit other FFP3 to any face. Fit can be particularly difficult for small faces.

The paper describing Part 1 of this study reported how the results of different fit test methods compared (Frost *et al*, 2014). The 25 volunteer test subjects covering a range of face sizes provided a means of assessing the quality of fit against face size and also of identifying good/poor design features by subjective assessment.

By measuring the facial dimensions described in the International Standards Organisation (ISO) technical specification ISO/TS16976-2 (2010) for the test subjects it is possible to map the quality of the fit of the individual FFP3 against face size. The quality of the fit of a facepiece on a wide range of measured face shapes and sizes should provide information on how well that facepiece is likely to fit generally. Consideration of fit performance compared with individual facepiece design features may provide valuable information for manufacturers. Collection of subjective comments on the features of the facepiece which aided or prevented good fit may provide direction for product improvement.

METHODS

The International Standard Technical Specification ISO/TS16976-2 (ISO, 2010) describes two different methods for categorising face size. A simple face-length and face-width measurement is one method; the second method involves taking several anthropometric measurements of the face which are used in specified calculations to give two components; Principal Component Analysis 1 (PCA1), and Principal Component Analysis 2 (PCA2). The 25 volunteer test subjects all had the required anthropometric measurements taken and these were presented in the specified ISO/TS graph form using both methods, to show the spread of volunteer face sizes.

Nine FFP3 were selected for the testing with a wide range of design features which are commonly present in FFP3. The FFP3 models are not identified and are referred to hereafter as M1, M2, M3.....M9. The design features included:

- rigid pre-formed cup shapes with no wearer nose adjustment
- softer cup shape with a wearer-adjustable nose clip
- fold flat with a vertical fold and wearer-adjustable nose clip
- fold flat with a horizontal fold and wearer-adjustable nose clip
- small section of elastomeric faceseal material over nose only, remainder of seal formed by edge of filtering material
- continuous elastomeric faceseal attached around the edge of the facepiece
- continuous knitted fabric faceseal attached around the edge of the facepiece
- adjustable elastic straps
- fixed length elastic straps

All of the models had an exhalation valve, in common with most FFP3 in workplace use. Several manufacturers supplied samples of their FFP3 to use on the test runs.

Not all test subjects were tested with every FFP3 which was available in the study. FFP3 selection took place at random with no attempt to match FFP3 to volunteer apart from with the one model which was

available in two sizes, where the volunteer tried on both sizes and a judgement was made on the best size for them, before commencing the test run. The test runs required the FFP3 to be donned and the four fit tests carried out in random order. The fit test methods included were:

- The laboratory chamber, generated-aerosol, Total Inward leakage (TIL) fit test method
- 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). Test subjects, who were all clean-shaven, were instructed to don the FFP3, following the manufacturer's instruction and advice from the fit testers, sealing it to the face as correctly and as securely as possible. They were reminded that they should not disturb the FFP3 fit from this point until all four fit tests had been completed.

Volunteers were asked to comment on the fit and comfort of each FFP3 both at donning and after wearing the FFP3 for the fit tests, following about one hour of wear. Comments on the ease/difficulty of donning were also given by the volunteers. The experienced Fit2Fit accredited (BSIF, 2010) fit testers also noted their observations of fit. Details are given in Part 2 of this paper (Frost and Mogridge, 2014).

RESULTS

Volunteer test subject face sizes

The face sizes of all the volunteer test subjects are presented in Figure 1 as length v width and in Figure 2 as PCA1 v PCA2. These figures show the spread of face sizes. Nineteen test subjects had facial dimensions which fall within the central ellipse representing medium face sizes in the PCA graph (Figure 2). The other six volunteer facesizes were within the outer ellipse, 3 with large faces and 3 with small faces. Unfortunately it was not possible to recruit any volunteers with short wide faces or long narrow faces as defined in the PCA measurements Figure 2. In Figure 1 only long narrow faces are not represented. The number adjacent to each point identifies the test subject.

Fit test pass rate with FFP3 model

Table I shows how each FFP3 performed overall, identifying how often the FFP3 achieved a pass in all four fit test methods. Results are measured against the current HSE pass criterion of 100 in all quantitative methods, and also with the pass criterion for the Portacount reduced to 70. The Portacount pass level of 70 has been included as this was the pass criterion found to give the best overall agreement with the laboratory chamber generated-aerosol (TIL) fit test method as discussed in Paper 1 of this study (Frost *et al*, 2014).

As Table I shows at Portacount pass 100, four models of FFP3 achieved passes in all four fit test methods and some of these FFP3 achieved this with several test subjects. M9 and M3 performed well with 40% and 50% of test subjects, respectively, passing in all fit test methods. M1 passed in all fit tests with 16% of test subjects which is improved to 21% with a Portacount pass criterion of 70 applied. M5 results were improved from zero to 23% by reducing the Portacount pass criterion to 70. M7 returned a pass in all fit test methods on one test subject only. All other FFP3s (M2, M4, M6 and M8) did not achieve a pass in all four fit test methods with any test subject, including when the Portacount pass level was reduced to 70. There were some passes in some fit test methods which are identified in Figures 3a to 12, as discussed below.

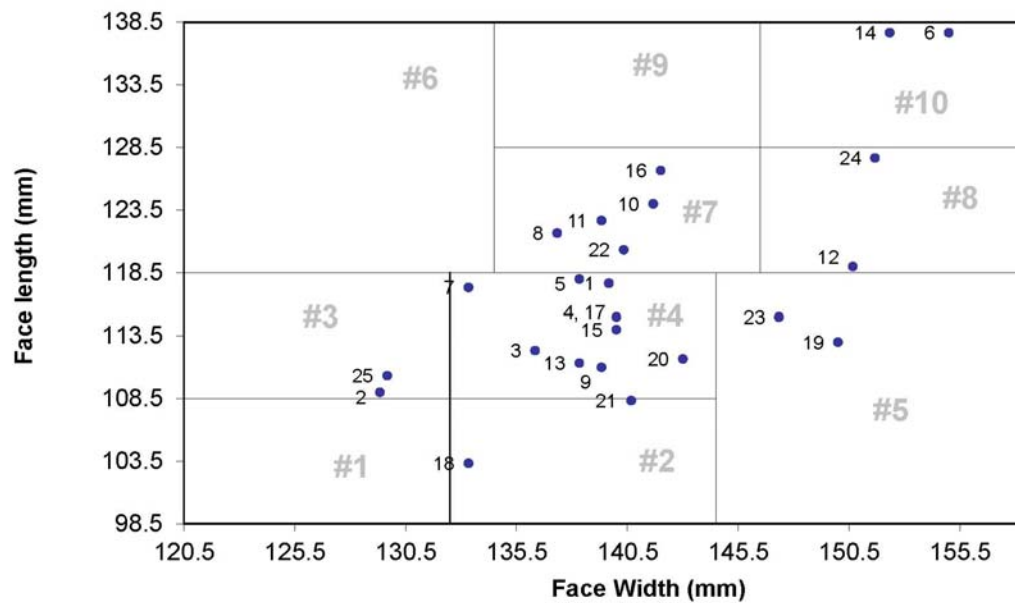


Figure 1. Volunteer test subject face sizes, length-width as defined ISO/TS16976-2 (ISO, 2010).

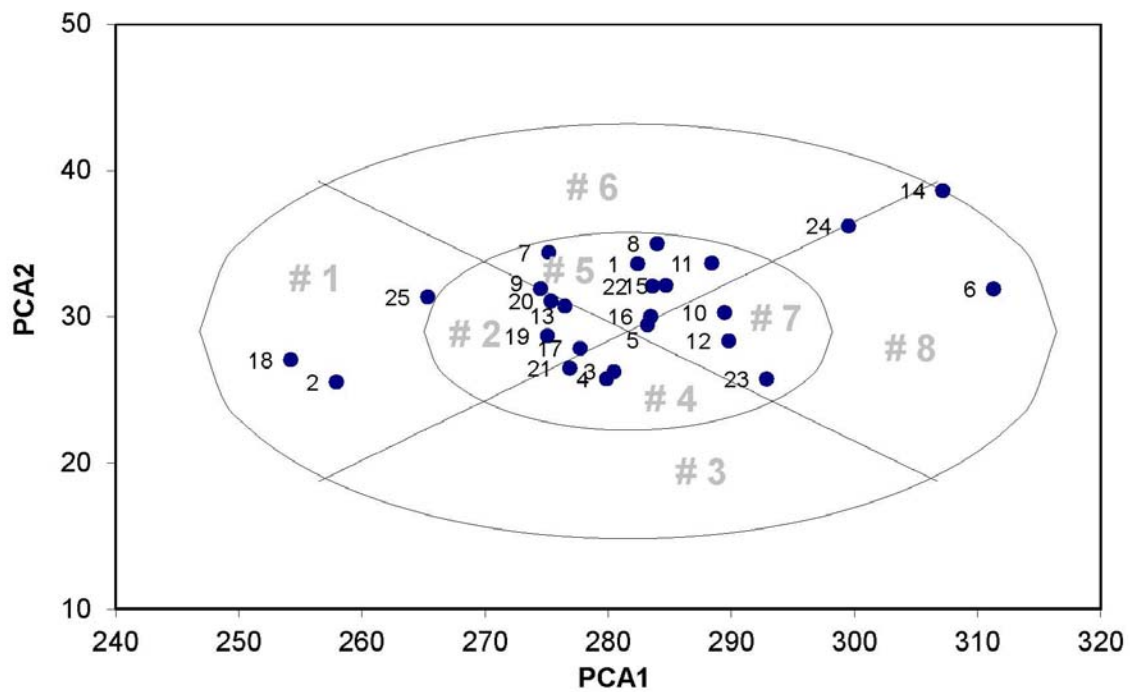


Figure 2. Volunteer test subject face sizes, PCA as defined ISO/TS16976-2 (ISO, 2010).

Table I. Test Subjects Achieving a Pass in All Four Fit Test Methods by FFP3 Model

	Portacount pass 100		Portacount pass 70	
FFP3 model	Number of test subjects passed in all four fit test methods	Percentage of test subjects passed in all four fit test methods	Number of test subjects passed in all four fit test methods	Percentage of test subjects passed in all four fit test methods
M1	3	16	4	21
M2	0	0	0	0
M3	6	50	6	50
M4	0	0	0	0
M5	0	0	3	23
M6	0	0	0	0
M7	1	11	1	11
M8	0	0	0	0
M9	6	40	6	40

Face size passes with FFP3 model

For each FFP3 model (M1 to M9) results from the test runs are presented in figures 3a to 12 using the ISO/TS (2010) format. These identify the volunteer test subjects by face size along with the outcome of the different fit test methods. A pass in all four fit test methods is indicated by a dark spot, a fail in all four fit test methods by a light square and a mix of pass and fail by a triangle. The plots identify the results for the fit tests when the pass criterion is 100 in all quantitative fit test methods. Additionally, for FFP3s M1 and M5 the Portacount pass criterion has an effect on the overall results, hence additional graphs are included showing the results when the pass criterion for the Portacount is reduced to 70 (Figures 3b, 4b, 7b and 8b). Not all test subjects had the opportunity to be tested with every FFP3 model, only those test subjects identified by the numbering of the points.

Passes in every fit test method were most often recorded with volunteers whose face size falls within the more central zones of the plots. Larger faces were also able to pass fit tests in all four fit test methods, but smaller faces were not able to achieve a pass in all four fit test methods. However, it is interesting to note that even where volunteer face sizes are recorded as very similar, that is points on the plots are very close, the quality of fit achieved by a given FFP3 can be very different.

For example with M1 and M9 (figures 3a, 3b, 4a, 4b, 11 and 12) within the more central regions of these plots there is a mix of fit test results which includes passes in all four fit test methods and fails in all four fit test methods. This is likely to be a reflection of the wide range of individual facial features which are naturally occurring and the difficulty of representing these in a 2-dimensional plot; faces may present as

being closely sized using the ISO technical specification assessment method but they may have some features which are very different. These results also show that the passes in all fit test methods are not always with the same volunteer from one model of FFP3 to another, a different FFP3 may better suit different volunteers. This suggests that the design feature differences between these better fitting FFP3 models may be beneficial in helping individuals find an FFP3 to fit their specific facial features.

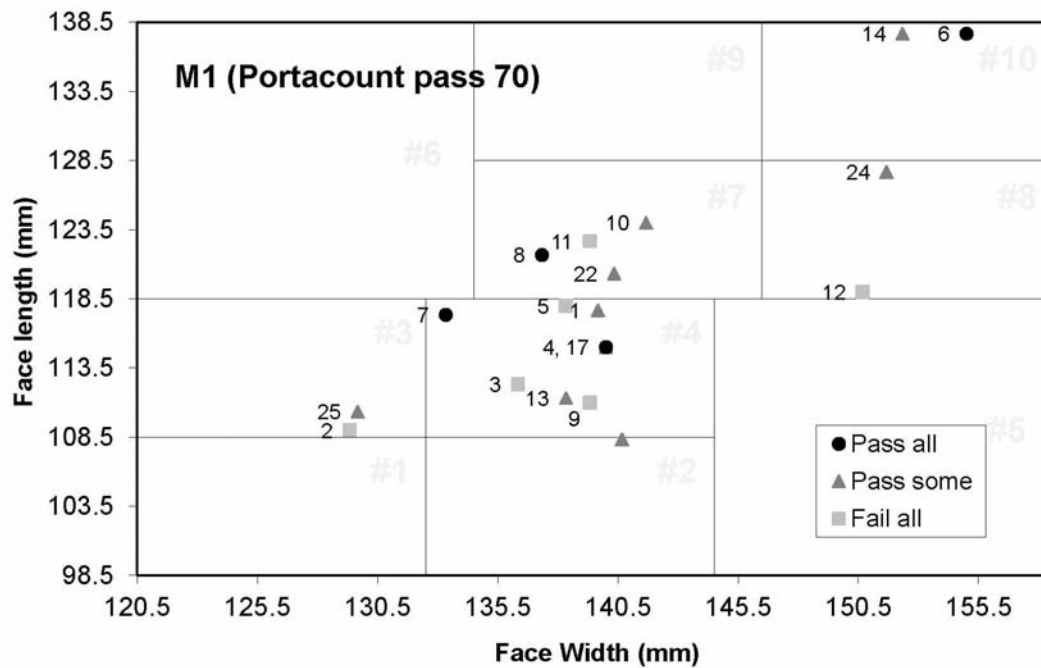


Figure 3a. Fit test results for M1 with individual face size, length-width (Portacount pass criterion 100).

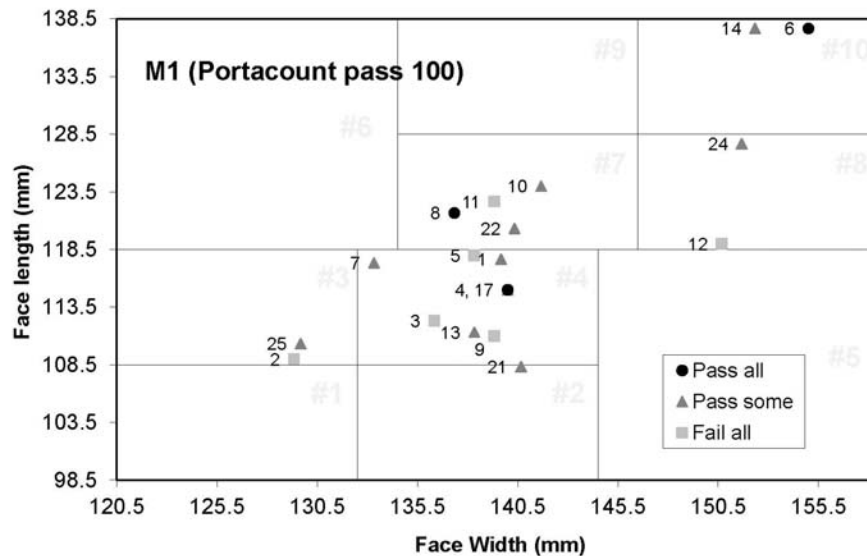


Figure 3b. Fit test results for M1 with individual face size, length-width (Portacount pass criterion 70).

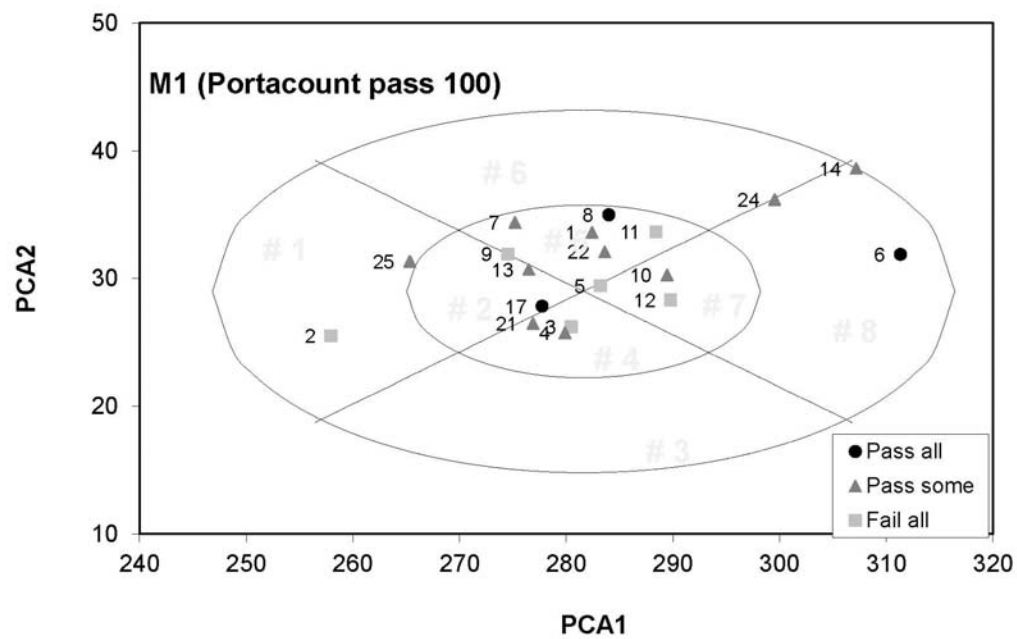


Figure 4a. Fit test results for M1 with individual face size, PCA (Portacount pass criterion 100).

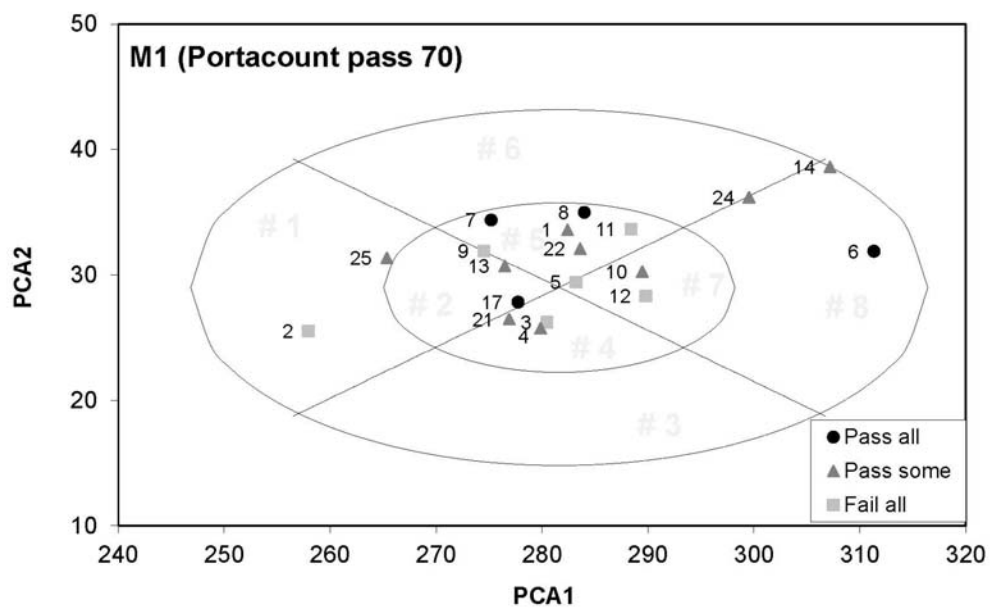


Figure 4b. Fit test results for M1 with individual face size, PCA (Portacount pass criterion 70).

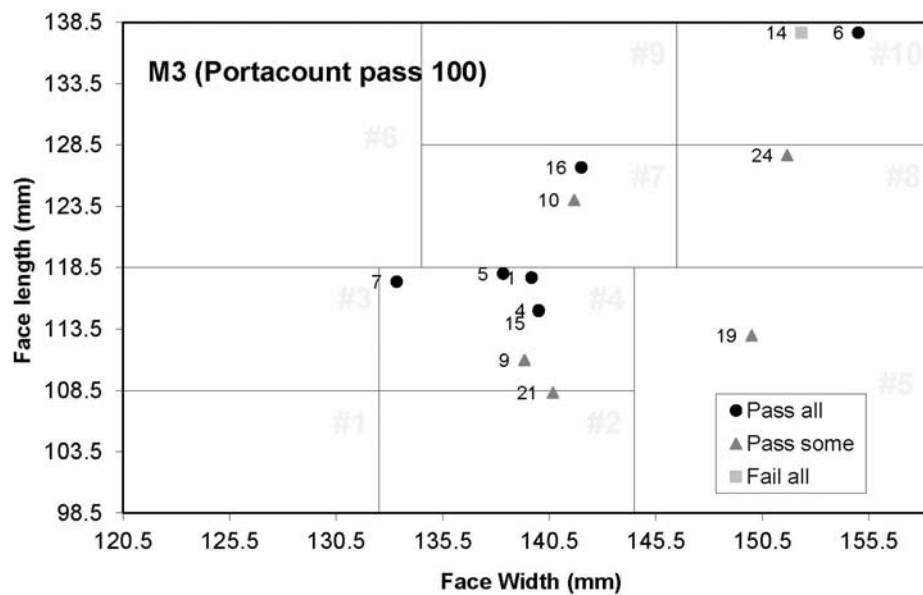


Figure 5. Fit test results for M3 with individual face size, length-width. (Portacount pass criterion 100).

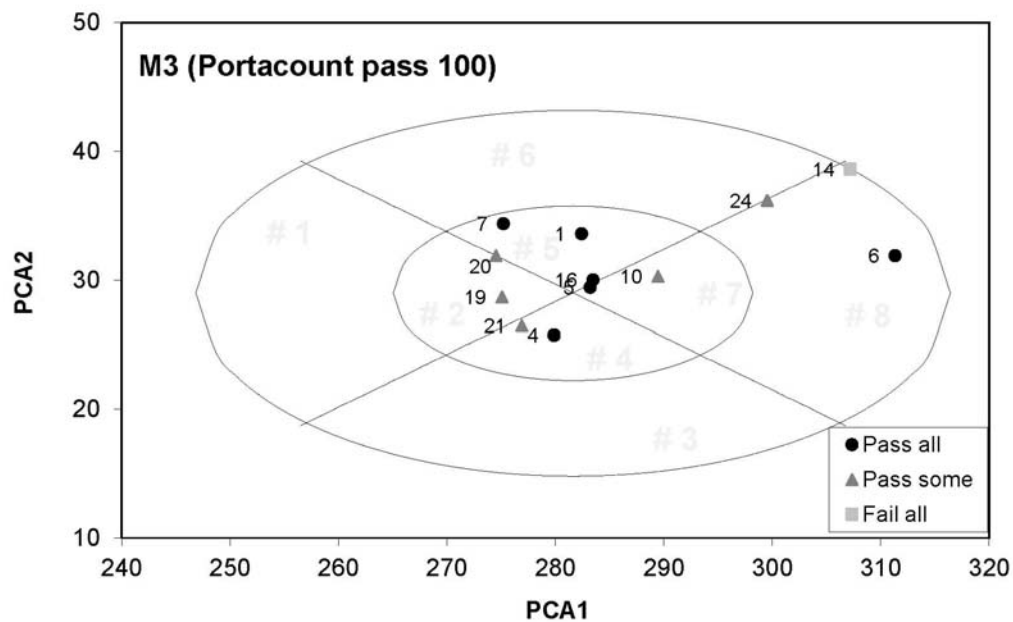


Figure 6. Fit test results for M3 with individual face size, PCA. (Portacount pass criterion 100).

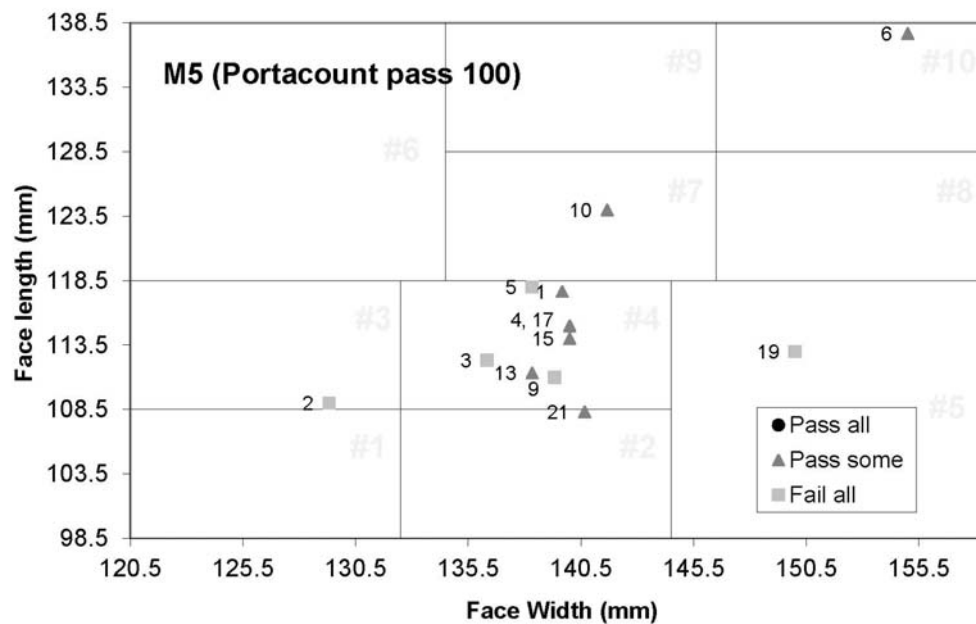


Figure 7a. Fit test results for M5 with individual face size, length-width (Portacount pass criterion 100).

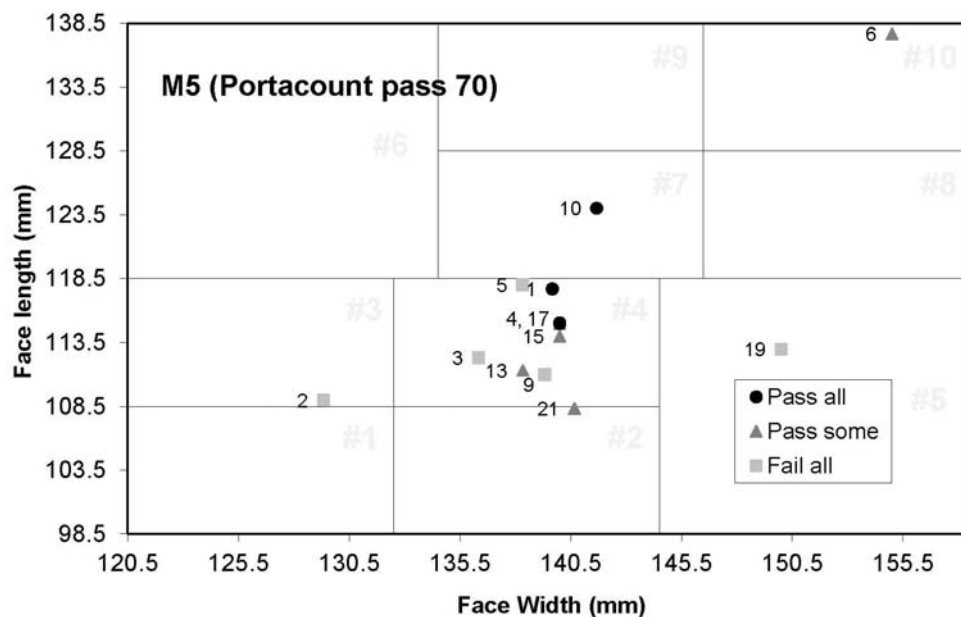


Figure 7b. Fit test results for M5 with individual face size, length-width (Portacount pass criterion 70).

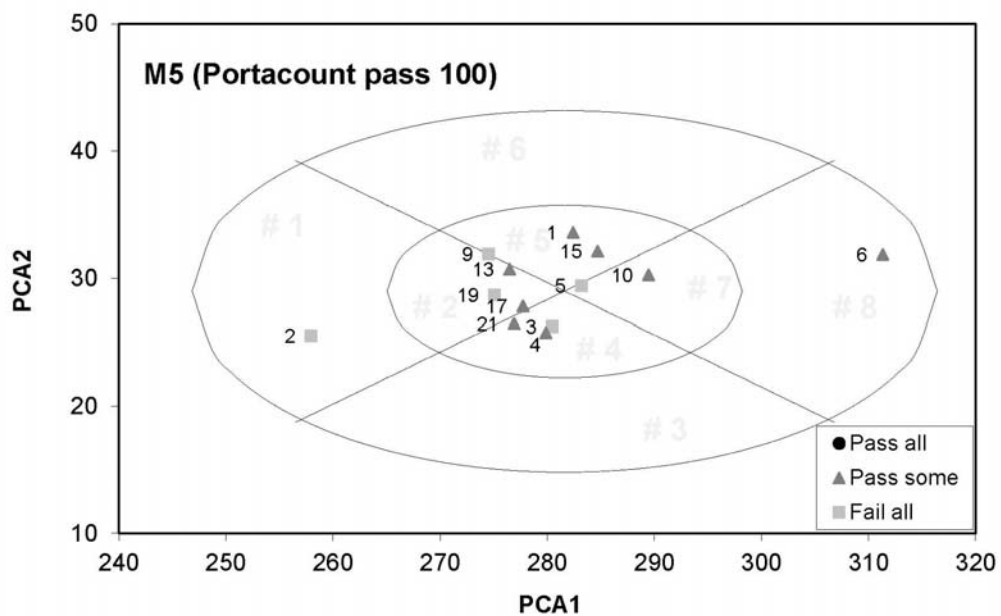


Figure 8a. Fit test results for M5 with individual face size, PCA (Portacount pass criterion 100).

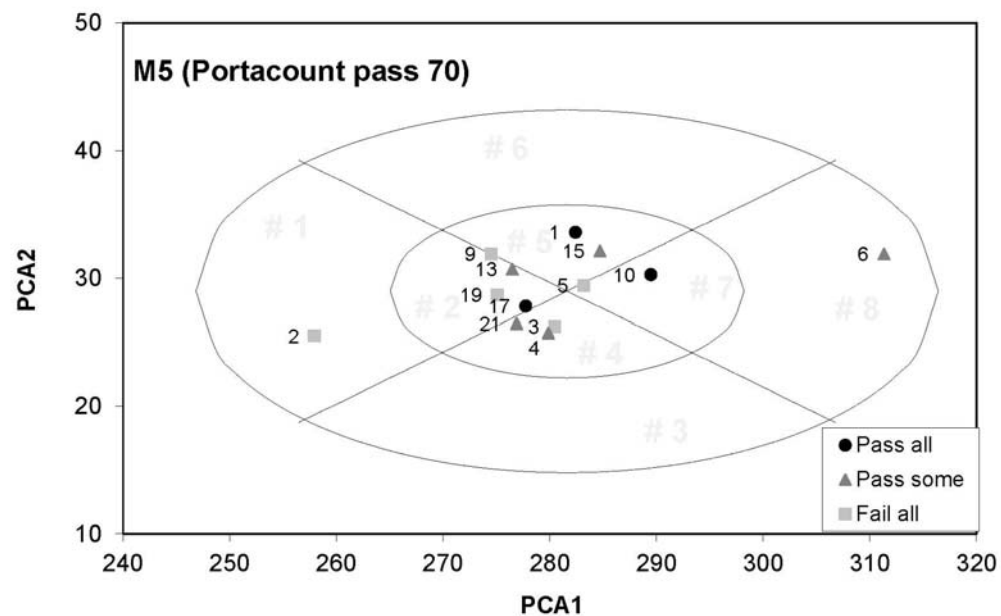


Figure 8b. Fit test results for M5 with individual face size, PCA (Portacount pass criterion 70).

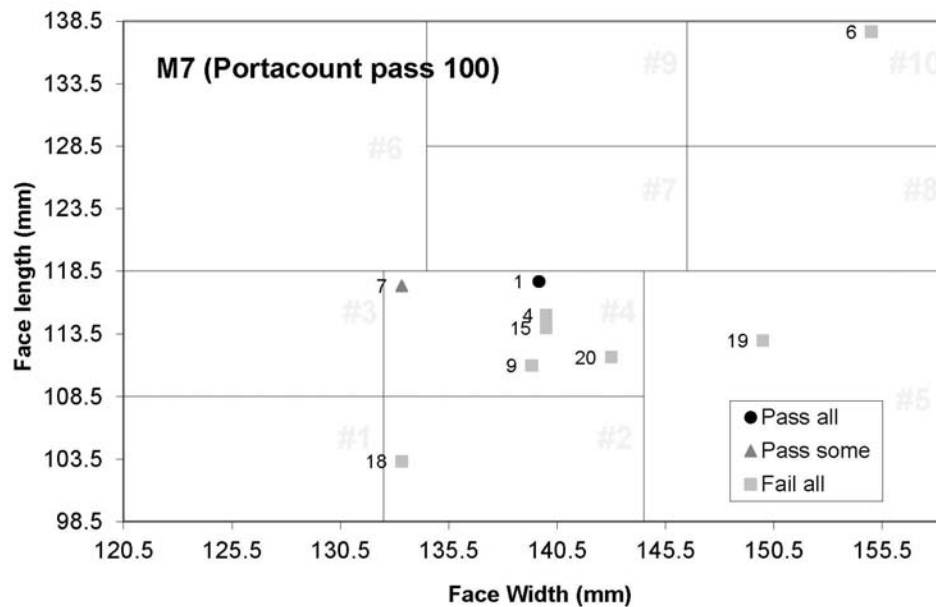


Figure 9. Fit test results for M7 with individual face size, length-width. (Portacount pass criterion 100).

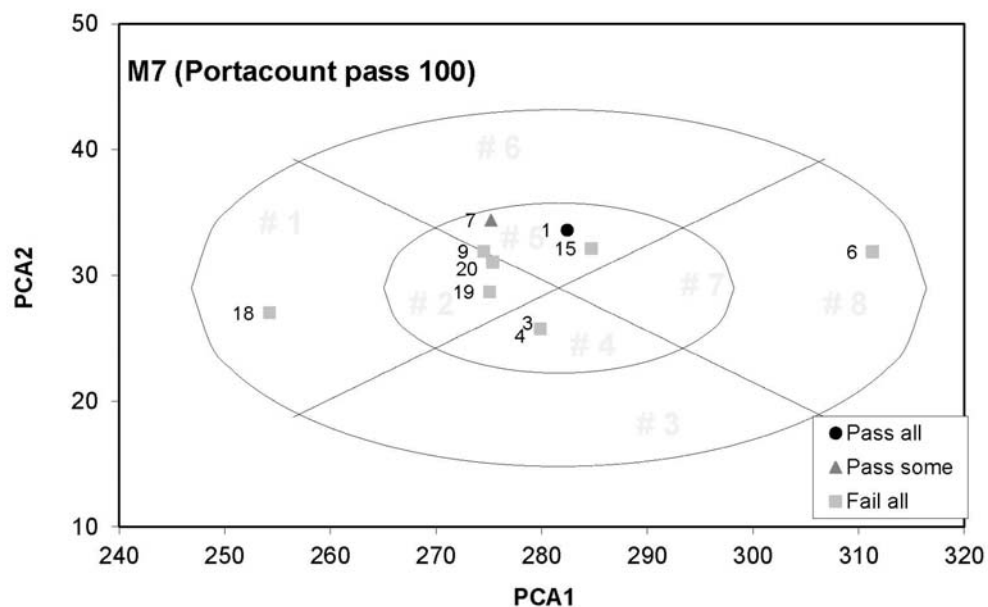


Figure 10. Fit test results for M7 with individual face size, PCA. (Portacount pass criterion 100).

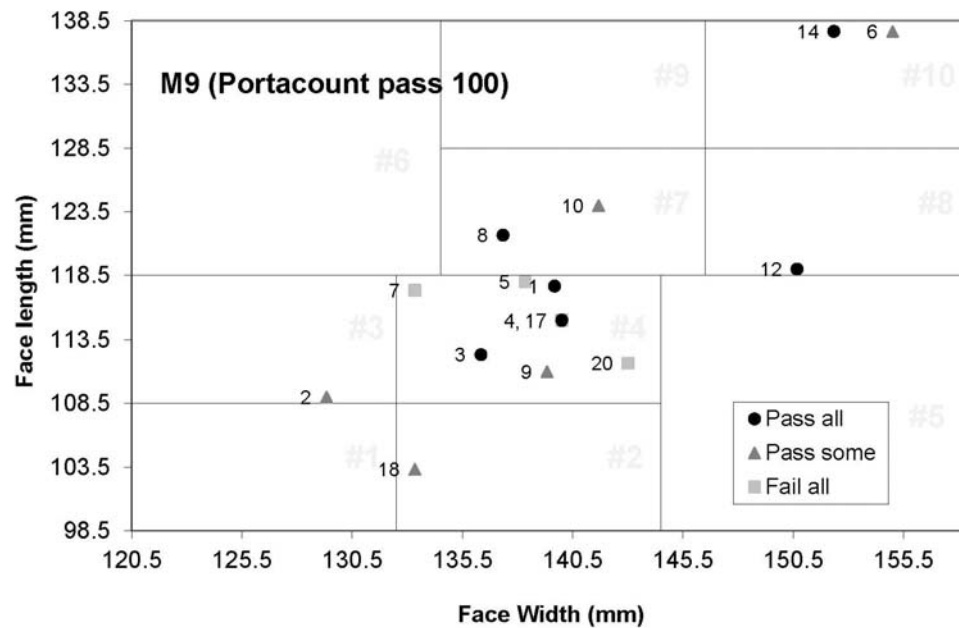


Figure 11. Fit test results for M9 with individual face size, length-width. (Portacount pass criterion 100).

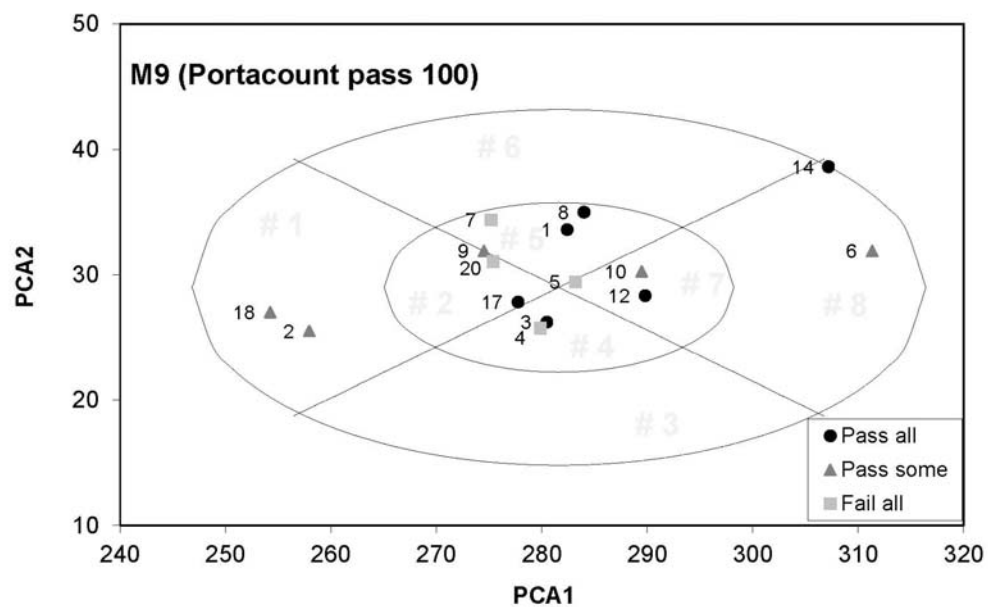


Figure 12. Fit test results for M9 with individual face size, PCA. (Portacount pass criterion 100).

FFP3 design features

No single FFP3 design feature dominated the results which showed a good fit in all fit test methods. The FFP3s which returned the best results M1, M3, M5 and M9 included one or more of the full range of available design features listed here:

- rigid pre-formed cup shapes with no nose adjustment
- softer cup shape with a wearer-adjustable nose clip
- fold flat with a vertical fold and wearer-adjustable nose clip
- fold flat with a horizontal fold and wearer-adjustable nose clip
- small section of elastomeric faceseal material over nose only, remainder of seal formed by edge of filtering material
- continuous elastomeric faceseal attached around the edge of the facepiece
- continuous knitted fabric faceseal attached around the edge of the facepiece
- adjustable elastic straps
- fixed length elastic straps

Design detail

All of the design features listed above were also present with those FFP3 which failed to pass all four fit test methods with any of our test subjects. Many test subjects complained that the FFP3 they were given was difficult or impossible to fit or was uncomfortable. These were mainly the FFP3s which failed to give a pass for any test subject with all four fit test methods.

Test subject comments included:

"Nose clip too short"

"Soft seal too short"

"Nose clip doesn't feel like it holds much"

"Nose clip rigid, not easy to form"

"Mask feels right size but straps too loose"

"Feels too big - affects vision. Easy to twist strap when donning. Strap tension OK"

"Not as secure as other masks not as tight on face as no strap adjustment"

"Uncomfortable on nose, having to breathe through mouth"

A number of areas for design improvement were identified. These included:

- overall shape of FFP3
- nose clip - difficult to shape due to poor malleability or strength and/or insufficient length
- quality and/or length of strap material

FFP3 performance against the European Standard TIL test

One of the four fit test methods used in this study is based on the European Standard EN149 (2001+A1:2009) test for Total Inward Leakage (TIL), this is the laboratory chamber generated-aerosol (TIL) fit test method. The TIL-based fit test requires that a fit factor of at least 100 should be achieved, based on HSE guidance (HSE, 2012) in every fit test exercise; 46 of the 130 TIL fit tests passed.

A simple assessment of the results of the TIL fit tests show that 93 of the 130 tests would easily have passed the European Standard EN149 (2001+A1:2009) test requirement for TIL, achieving a fit factor of at least 50 in every exercise, or less than 2% TIL. The EN149 (2001+A1:2009) requirements are actually less stringent than indicated by this summary, a pass is not required in every exercise only the mean has to pass, therefore even more of the TIL test results in this study could have passed the European Standard EN 149 (2001+A1:2009) TIL test.

It should also be considered that our test runs were carried out no matter how well or poorly the FFP3 appeared to fit, whereas in a European Standard EN 149 (2001+A1:2009) TIL test, wearers who subjectively judged the fit poor after donning would not have been allowed to continue with the test. If such a pre test run sifting had been applied to our fit tests, a greater percentage of our remaining tests may have resulted in an EN 149 (2001+A1:2009) TIL test pass.

DISCUSSION

Some models of FFP3 used in this study demonstrated a good fit with a range of wearers with different facial characteristics. If the identity of these and similar performing FFP3 was known it could make selection a much easier process for the employer and fit tester. Having a range of different FFP3 models with different design features provides potential to find an FFP3 to fit individual real faces of similar size but with different features. None of the FFP3 tested was able to fit our volunteers with smaller size faces with every fit test method which suggests there may be scope for development of models more suited to smaller faces.

Other FFP3s used in this study were poor fits to many of our volunteer faces. Whilst these FFP3 have achieved the necessary performance requirements for the European Standard for filtering facepieces (EN 149, 2001+A1:2009), in reality many did not meet the more stringent fit test pass requirements on our range of test subjects. The basic design features of poorly fitting FFP3s are the same as for those that perform well, a finding which is supported by Zhuang *et al* (2005) who concluded that with N95 FFP “respirator design (both folding style and cup style) did not have a significant effect on respirator fit”. Often the detail of a design feature – for example a poorly designed nose clip – makes for a poor fitting FFP3, even if the rest of the FFP3 design is good.

All of our test subjects were able to achieve a pass with at least one FFP3 in at least one fit test method, but several different models of FFP3 were tested. In the workplace it may not be easy to readily find a suitable FFP3 for everyone; it may require many fit tests with different models. This situation is likely to be equally applicable to the fit of FFP1 and FFP2 respirators.

Modifying the requirements for the European Standard Total Inward Leakage test, so that it is more representative of a measure of good fit on a significant number of different faces, or a specified range of face sizes or shapes, may encourage manufacturers to pay more attention to the detail of the design of FFP to fit real faces. The principle applies equally to the relevant International Standards (ISO), which are currently under development, and to all classes of filtering facepiece. Such a modification should make it easier for employers, employees and fit testers to find a suitable FFP.

CONCLUSIONS

Some of the FFP3 used in this study demonstrated that they can readily fit a significant proportion (up to 50%) of our volunteer test subjects, with a range of face sizes, across all four fit test methods. The range of different design features between models may be beneficial in enabling good fit across a range of facial features where face size is similar.

Other FFP3 were poor at fitting all of our volunteers. There is room for significant improvement in the detailed design of some FFP3 towards better fit for the wearer, which could be aided by more stringent and/or specific standard performance requirements.

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.

© British Crown copyright (2014)

REFERENCES

- British Safety Industry Federation (2010) The Fit2Fit RPE fit testers accreditation scheme <http://www.fit2fit.org/hht>
- European Standard (2001+A1:2009) EN149:2001+A1:2009 Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking
- Frost *et al.* (2014) Fit of Filtering Facepiece Class 3 (FFP3) Respirators Part 1: A Comparison of Fit Test Methods; JISRP Vol 31, No1, 2014 pages 57 -72
- Frost S, Mogridge R (2014) 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; JISRP Vol 31, No2, 2014 pages 1-10
- HSE Guidance (2012) HSE OC 282/28 Fit testing of Respiratory Protective Equipment Facepieces http://www.hse.gov.uk/foi/internalops/fod/oc/200-299/282_28.pdf
- International Organization for Standardization ISO/TS 16976-2 (Technical Specification 2010) Respiratory protective devices – Human factors – Part2: Anthropometrics Reference number ISO/TS 16976-2:2010(E)
- Zhuang *et al* (2005) The Effect of Subject Characteristics and Respirator Features on Respirator Fit, Journal of Occupational and Environmental Hygiene, Vol. 2: pages 641-649