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Review of fit test pass criteria for Filtering Facepieces Class 3 (FFP3) Respirators

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Respiratory Protective Equipment (RPE) is available in a range of types which often include a tight-fitting facepiece which must fit the wearer's face well for the RPE to work effectively. Good fit must be demonstrated by fit testing.

In this study, 25 volunteer test subjects wearing tight-fitting FFP3 (randomly selected from 9 different models) underwent four fit tests (Bitrex qualitative taste test, Portacount particle counting with and without the N95 companion technology and the laboratory chamber method), in random order, according to methodology given in HSE guidance 282/28. The selected FFP3 model worn by each test subject was not adjusted until all four fit tests had been completed.

Results analysed according to the criteria given in the American National Standard for fit test validation, indicate that the Portacount fit test method is more difficult to pass than the other methods. Differences in the methodologies and the potential for bias in the results across the fit test methods are discussed.

The study also shows that a fit-check should never be used as a substitute for a fit test.

Many of the FFP3 were poor at fitting the test subjects.

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EXECUTIVE SUMMARY

Respiratory Protective Equipment (RPE) facemasks need to seal tightly to the wearer's face in order to provide the expected protection. HSE recommends that a fit test be carried out for each RPE wearer as a part of the selection process to ensure a good seal (fit) is achievable. There are several fit test methods which are discussed in HSE's guidance. Not all are suitable for all types of tight-fitting RPE facepieces, and different criteria are applicable in defining a good fit for each facepiece type. This study was concerned with the fit testing of class 3 filtering facepieces, known as FFP3 under the British and European Standard.

Approach

Current HSE guidance recommends several fit test methods as being suitable for FFP3 and these were compared and contrasted, along with the Portacount-with-N95-Companion technology; this is not currently an HSE-recommended method for FFP3 fit testing, but is recommended for fit testing FFP2 class of respirator. In total four consecutive fit test methods, qualitative Bitrex, quantitative Portacount (both with and without the N95-Companion technology) and the laboratory-generated salt aerosol (Total Inward Leakage - TIL) chamber fit test method were conducted on the same test subject wearing an FFP3, without adjustment to the fit between tests. Fit tests were conducted by Fit2Fit accredited fit testers following HSE guidance on fit testing. The American National Standard Institute (ANSI) Criteria for Evaluating New Fit Test Methods were used to set the design for the work and statistically analyse the results. The current pass criterion for a TIL or quantitative Portacount fit test for an FFP3 is a fit factor of at least 100 in every exercise.

Main findings

The methodology assumes that there is an absolute measure of fit of the FFP3 against which other fit test methods should be measured. There are difficulties associated with determining the fit of FFP3 by taking quantitative measurements, related to a permitted amount of particle penetration through the filter material, wearer-generated particles being counted as faceseal leakage, and differences in measurement methods. Therefore, no such absolute measure of fit exists for FFP3 and one of the fit test methods must be selected as the reference method; ANSI specifies that a generated particle method should be used; therefore, the TIL fit test method was used as the reference method. The ANSI criteria place emphasis on correct detection of poor fit with a test sensitivity of at least 0.95 required, which was only achieved with the Portacount (without-N95-Companion technology) fit test method.

This reference method gives fit factor results which are biased low, due to the faceseal leakage measurements including particle penetration though the filtering material. This effect may be significant, and may lead to less favourable statistics, in particular in relation to correctly predicting a pass.

Statistical analysis of the results obtained when working to the criteria laid down by the ANSI standard, and following current HSE guidance and the information given in the methodology section of this report, shows that reducing the pass criterion from the current 100 to 70 would improve the overall agreement between the Portacount fit test method and the reference method. The kappa statistic, test specificity, beta error and predictive value of a fail are all increased, whilst the test sensitivity and predictive value of a pass are decreased. Such a change would reduce the number of good fits which fail the Portacount fit

test method and increase correlation between fit test results across all fit test methods for all FFP3 used in this study. However, this does lead to slightly less favourable statistics for correctly predicting a pass at 0.88, which is below that expected by the ANSI standard (0.95), but the calculated value may be biased low by the unavoidable inaccuracy of the reference method. However, this is still a higher value than is achieved by either the Bitrex or Portacount –with –N95-Companion technology fit test methods.

Of note are results relating to a pass criterion at 80, which give higher probability of correctly detecting a fail than those obtained with the Portacount criterion at 70. However, while test specificity and predictive value of a fail are within recommended values, they are lower than those obtained with the pass criterion at 70. The kappa statistic, which indicates agreement of this method with the reference method is marginally lower than that obtained when a pass criterion of 70 is used.

The FFP3 used in this study had a range of filtering efficiencies and were broadly categorised into two groups, described in this study as either standard or higher filtering efficiency. It is important to note that application of the ANSI criteria is not appropriate for either group when separated from the full data set due to insufficient data and therefore no firm conclusions can be drawn from analysis of these sub-sets of data. However, more detailed analysis of the data from FFP3 with higher filtering efficiencies, suggest that better correlation with the reference method is obtained with Portacount pass at 80, 90 or 100; with standard filtering efficiency FFP3 the data suggest better correlation with the reference method with a Portacount pass criterion of 70. Analysis of the FFP3 data with high filtering efficiencies suggests that the Bitrex method correlates better with the reference method than when the data relating to FFP3 with standard filtering efficiencies alone are examined,

Based on the data from all of the FFP3 used, this study has shown that using the N95-Companion technology with the Portacount could provide a measure of FFP3 fit, if the pass criterion applied is 100. However, overall this method is returning results which are not in quite such good agreement with the TIL method as the Portacount used on its own, with correlation closest at Portacount pass 70.

The Bitrex qualitative fit test method has been shown to give a good determination of fit in this study. It may have the potential to give the most accurate determination of true fit as the challenge particles do not pass through the filtering material in a form which can be detected, a problem which can occur when using quantitative fit test methods. The validity of this theory is supported by the results of analysis of standard and higher filtering efficiency FFP3 separately. However, the Bitrex qualitative fit test is a subjective method, dependent on the wearer's taste response.

Additional findings

Whilst many of the findings are direct outputs from the statistical analysis and distribution of the data, subjective opinions were also recorded and played an important part. Subjective opinions of the fit, including the wearer fit-check, were demonstrated to be of very little value as a substitute for a fit test. Many of the test subjects complained that the design detail of a certain FFP3 was not conducive to correct donning and other test subjects, wearing the same FFP3, frequently and independently repeated the same complaint.

Many of the fit tests carried out in this study failed to meet the current HSE pass criterion for the fit test method. 61 of the test runs failed to pass any of the four fit test methods used. Four of the nine FFP3 models used demonstrated the ability to fit between 21% and 50% of the 25 test subjects (with a range of face sizes), according to all four fit test methods. For

the remaining five FFP3 models a fit was not achieved by any test subject in every fit test method.

As such, a significant proportion of the FFP3s tested did not fit a range of wearers. The importance of fit testing before relying upon an FFP3 for respiratory protection cannot be over emphasised. Poor attention to design detail of some FFP3s, with insufficient focus on the importance of good wearer fit, is a significant factor leading to poor fit.

This work has demonstrated the importance of fit testing to establish a suitable FFP3 for the individual wearer and that there is value in all of the fit testing methods used in this study.

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1. INTRODUCTION

1.1 BACKGROUND

Tight-fitting Respiratory Protective Equipment (RPE) facepieces must seal well to the wearer's face in order to work effectively and provide the expected protection. Faces come in all shapes and sizes, as do facepieces, and for each individual wearer a suitable facepiece must be selected which is capable of fitting their face well. A fit test is a means of selecting such a facepiece; it is a measure of how effectively a tight-fitting facepiece can seal to an individual wearer's face.

It is important to understand that a fit test is a brief (about 10 minute), closely-controlled test and results should in no way be considered as indicative of the amount of protection a wearer can expect to receive in the workplace, where other uncontrolled factors are present.

1.2 FIT TEST METHODS APPLICABLE TO FFP3

FFP3 are a type of filtering facepiece (FFP) of the highest classification achievable under the European Standard BS EN 149[1]. They are tight-fitting facepieces and therefore require fit testing to comply with HSE Approved Codes of Practice [2,3,4]. Current HSE guidance[5] allows FFP3 to be fit tested using any of the methods discussed below, but for practical reasons the laboratory test chamber method is rarely carried out.

1.2.1 Qualitative (taste) fit test

This is a subjective method and is dependent upon the wearer's sensitivity to the test agent. The wearer's head is enclosed in a loose-fitting hood. An aerosol, containing a test agent, is directed into the hood and the taste response noted. After allowing the taste to dissipate, with the aid of a drink of water, the FFP3 is donned and the fit test is conducted but with a more concentrated test agent directed into the hood, whilst the wearer carries out a specific exercise programme. The fit is determined as a pass or fail, dependent upon whether or not the wearer can taste the test agent at any time during the exercises. These fit tests are well established and validated[6,7] in the USA on filtering facepieces and half masks where the Occupational Safety and Health Administration (OSHA)[8] has laid down protocols. There is also an American National Standard (ANSI/AIHA Z88.10 – 2010)[9] for respirator fit testing methods. In this report this standard will be referred to as the ANSI standard.

The test agent can be either:

- Bitrex (Denatonium Benzoate) or
- Saccharin

This fit method can be used for all classes of filtering facepiece and half mask as the test agent is thought not to pass through the filtering material in detectable form, but to be able to get inside the facepiece only through any gaps between the face and the seal of the facepiece.

1.2.2 Quantitative fit tests

These are objective tests with a numerical output. There are two methods by which such measurements can be taken, the Portacount method or the laboratory test chamber method but, almost exclusively, the Portacount method is used in the UK.

1.2.2.1 The Portacount fit test

The Portacount measures the number of ambient particles per cubic centimetre (outside of the FFP3 being worn) and the number of particles per cubic centimetre inside of the FFP3, whilst specific exercises are carried out. The ratio of the measured concentrations is referred to as a fit factor and determines whether the fit test has been passed or failed.

The Portacount fit test method was first developed in the USA as a means of assessing the fit of full facemasks and elastomeric half masks[10,11].

In the USA some NIOSH[12]-approved filtering facepieces can be fit tested using the Portacount. Other NIOSH[12] filtering facepieces (whose classification permits) have a lower filtering efficiency, allowing some particles to pass through the filtering material (these filtering facepieces are classified as N95). For these, the additional N95-Companion technology is used, together with the Portacount, to give a more accurate determination of fit. The N95 Companion technology restricts the particles entering the Portacount to a size range which is known to be largely filtered out by these NIOSH filtering facepieces[12]. NIOSH[12] certified RPE does not have the same classification criteria as CE[13] marked RPE and therefore there is no direct correlation between their performances, including during a fit test. HSE guidance[5] does not suggest the use of the N95-Companion for fit testing FFP3.

1.2.2.2 The laboratory test chamber (TIL) fit test

The laboratory test chamber fit test method requires the use of a generated salt aerosol and is based on the European Standard BS EN 149[1] test method for measuring Total Inward Leakage (TIL). The salt aerosol mass concentration is measured both inside and outside of the FFP3, whilst specific exercises are carried out. The ratio of the measured mass concentrations is referred to as a fit factor and determines whether the test has passed or failed. Specialist facilities are required.

The TIL test method is long established, being one of the tests required for certification of filtering facepieces to the European Standard BS EN149[1] from the origin of this standard, circa 1992. Generated-aerosol fit test methods have long been used as a reference method against which the value of other fit test methods has been assessed[10,11]. Other authors[14] have concluded that a generated-aerosol fit test method is the most reliable method of determining fit for filtering facepiece respirators. The ANSI standard[9] recommends such a fit test method for use as a reference for validating alternatives.

1.3 HISTORY OF FIT TESTING IN THE UK

HSE Guidance[5] on conducting fit testing of RPE was first published in 2000 to support the requirement for fit testing in the Control of Asbestos at Work Regulations, CAWR (1987)[15], This guidance on fit testing was applicable to RPE used against asbestos fibres and the pass criterion for an FFP3 was given as 100, when carrying out a quantitative fit test. The pass criterion remains at 100 to date and is applicable to all respiratory hazards.

Concerns have been raised within the RPE community and dating back to 2006, that the current HSE guidance on Portacount quantitative fit test pass criteria may be too stringent as applied to FFP3. One stakeholder carried out investigative laboratory test work, and this was discussed with HSE and technical experts within HSL. Findings suggested that particles passing through the filtering material could be contributing to the measure of fit; as a result HSE agreed that work was needed to investigate further.

Following this discussion a small number of comparative fit tests were carried out at HSL using the Portacount both with and without the N95-Companion and also the qualitative (Bitrex taste) fit test method. Volunteers donned an FFP3 and, without disturbing this fit, consecutive fit tests were carried out using these different fit test methods. The results showed that the fit test was much more likely to fail the same FFP3-wearer fit when using the Portacount fit test method compared to either of the other fit test methods, although the small number of test runs carried out did not allow great statistical confidence in the results. The results backed up the anecdotal experience of HSL fit testers.

It is worth noting, however, that the two methods – qualitative and quantitative – operate on two fundamentally different principles and that a degree of variation is to be expected. Additionally, poor competence in fit testing is further clouding the situation, although the introduction of the Fit2Fit[17] competency scheme is helping to address this.

1.4 PROJECT AIMS

This project was commissioned to establish the facts, clarify the situation and recommend an evidence-based way forward. In particular, answering the following questions:

- Can the Portacount be used without the N95-companion to reliably measure the fit of all FFP3 in typical fit testing environments? What would be a reasonable pass/fail criterion to apply?

- Can the Portacount be used with the N95-Companion to reliably measure the fit of all FFP3 in typical fit testing environments? What would be a reasonable pass/fail criterion to apply?

2. METHODOLOGY

2.1 REFERENCE STANDARD FOR FIT TESTING

Ideally, existing UK fit test methods should be evaluated against an agreed standard method, which is universally accepted as an absolute means of measuring fit. No such standard exists, although generated aerosol methods of quantitatively measuring fit have generally been used as reference standards[7,10,11,14] and the ANSI standard[9] recommends this. The Laboratory test chamber fit test method (TIL test) is an example of a generated aerosol method. In this work, UK fit test methods have been evaluated against the TIL method.

2.2 EVALUATION CRITERIA – STATISTICAL POWER

HSE guidance document OC 282/28[5] refers to the ANSI/AIHA standard Z88.10-2010 Respirator Fit Testing methods[9] as including suitable evaluation criteria for fit testing equipment. These criteria are given in the ANSI standard in Annex A2: Criteria for Evaluating new Fit test methods. This Annex was reviewed at HSL by a statistician with experience of RPE testing, and considered fit for the purposes of this work for cross validation of existing UK fit test methods. The statistician's report can be found at Appendix A. Following the methodology given, the statistical power is required to be at least 95% (or 0.95) to be able to accept a new test method against a given accepted method.

Note: The power of this test is defined as the probability of correctly identifying a poor fit.

2.3 CHOICE OF FIT TEST METHODS

In order to give a complete picture of how well UK fit test methods compare, as many test methods as possible were deployed consecutively. This was restricted by the onus which could reasonably be placed on the volunteer test subjects. They were required to don an FFP3, fitting it as well and as securely as possible, and wear it ***without disturbing the fit*** whilst all of the fit test methods under comparison were conducted. The test methods chosen were:

- the quantitative TIL test method – this being a generated aerosol method
- the qualitative taste test using the Bitrex test agent – this is the test agent most commonly used in the UK for this method
- simultaneously conducted quantitative tests using both a Portacount alone (without the N95-Companion technology), and a second Portacount-with-N95-Companion technology.

In this way 4 different methods (including a generated aerosol method) could be evaluated against one another in a test run. Each test run took about 60 minutes of wearing FFP3, from donning the FFP3 to removing it.

Outlines of the fit test methods are given in the introduction, section 1.2

2.4 REQUIREMENTS OF THE ANSI STANDARD

The ANSI standard requires that the sequential tests are conducted in a certain way and specifies certain criteria. These are outlined in the following sections 2.4.1-2.4.5.

2.4.1 Test subjects

A total of at least 25 volunteer test subjects were needed, according to the ANSI standard. HSE ethical approval was given and 32 people volunteered to help with the study as test subjects. However, not everyone can taste Bitrex in low doses and this applied to 7 of the volunteers; this left 25 who were able to take part. All of these volunteers had anthropometric measurements taken of their face, in accordance with the technical specification ISO/TS 16976-2[18]. Some of the test subjects were experienced at donning and wearing FFP3, others had never worn an FFP3 before.

2.4.2 FFP3 selected for use in the tests

The ANSI standard does not specify the number of different models which should be tested, although it does discuss using a variety of different sizes and models. All FFP3 are required to meet minimum standards, but some have significantly higher filtering efficiency than required. As it had been suggested that particles passing through the filter material could contribute to leakage measured during the Portacount test, FFP3 were selected with knowledge of their filtering efficiency. Manufacturers had submitted information on the performance of their products in the European Standard test[1] requirement 7.9.2 "Penetration of filter material". This information was used along with the design features of the FFP3 to select a range of 9 different FFP3 models for the testing. Three models had much higher filtering efficiency than the other 6. Filtering efficiencies are given in Table 1 as filter penetration levels. Note that the requirement to meet the standard is a filter penetration maximum of 1%.

Table 1 Approximate filter penetration of FFP3s selected

FFP3	Approximate filter penetration %	
	0.1 to 0.7 (standard efficiency)	0.004 to 0.06 (high efficiency)
M1	X	
M2	X	
M3		X
M4	X	
M5	X	
M6	X	
M7	X	
M8		X
M9		X

The range of design features represented within these 9 FFP3 included:

- rigid pre-formed cup shape 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
- horizontal fold flat and wearer-adjustable nose clip

- small section of 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. Several manufacturers supplied samples of their FFP3 to use on the test runs.

2.4.3 Test order for sequential fit tests

As required, the sequence in which the different fit tests were conducted was selected at random[19] for each test run.

2.4.4 FFP3 test order

The order in which the 9 different FFP3 were used on test runs was selected at random[19], for each individual test subject.

2.4.5 Total number of tests needed

This depends on a number of factors, principally the results of the test runs, which must meet certain criteria if they are to be included in the statistical analysis:

- Reference fit test method fit factors had to be evenly distributed and not weighted towards low values.
- Any reference fit test method fit factors within one coefficient of variation of the pass level had to be excluded. Details of how this was worked out are given in section 2.5.2, and followed the method suggested in the ANSI standard.
- At least 100 valid tests runs were needed, of which at least 50 should fail the reference method and also be above 5% of the pass level for the reference fit test method. That is, with a reference pass level of fit factor 100, at least fifty tests should have fit factor between 5 and 100.

2.5 TEST METHOD DETAILS

2.5.1 Comparative test runs

2.5.1.1 FFP3 preparation

FFP3 facepieces were examined to ensure the absence of obvious manufacturing defects before a sampling port was applied in the most appropriate position for each model, following recommended practice as described in HSE guidance[5]. The sampling port was extended in to the 'breathing zone' described in paragraph 55 of the guidance[5] and a ball probe attached. Where there was insufficient space for a ball probe to be used within the mask tested, a disc probe was used.

A second port was applied to the FFP3, in order to allow for detection of pressure changes inside of the FFP3 during the TIL test. This was located well away from the faceseal to reduce the chance of it becoming blocked by the test subject's face.

The ports were sealed externally with rubber 'bobbies' if not needed for a fit test and replaced with sample tubing when needed, taking care not to disturb the fit of the FFP3.

The location of these ports was repeated each time the specific model of FFP3 was used, by reference to a prepared specimen sample.

2.5.1.2 Test subject preparation

The test protocol was approved by HSE Ethics committee and volunteers were recruited through the HSL PPE test pool of volunteers.

Volunteer test subjects were asked to be clean-shaven for the test run. To prevent interference of any strong tastes with the Bitrex test they were also asked not to eat or drink anything except water for about an hour before the test run. None of the volunteers were smokers.

Before each test run the Bitrex sensitivity test was carried out and the subject then asked to wash the Bitrex taste away by using plain water. At least 15 minutes were allowed to elapse and the test FFP3 was not donned until the Bitrex taste had cleared completely. This was considered especially important when the test order began with the Bitrex test.

Test subjects were then instructed to don the FFP3, following the manufacturer's instructions and advice from the fit testers, sealing it to the face as correctly and as securely as possible. All research fit testers are accredited by the Fit2Fit scheme for both the Portacount and the Bitrex fit test methods.

Test subjects were then asked to carry out a fit-check, being instructed as necessary, and to comment on the fit of the FFP3. Test subjects were reminded that they should not disturb the FFP3 fit from this point until all 4 fit tests had been completed. The fit tester made a visual assessment of the fit. The following 4 fit test methods were then conducted, but not necessarily in the order given here, the test order was selected at random as explained in Section 2.4.3. After each of the 4 fit tests the test subject was asked to comment on the FFP3 fit and comfort and any changes. At the end of each test run the test subject was asked to comment again and the fit tester also visually reassessed the fit.

2.5.1.3 The Quantitative Total Inward Leakage TIL test

Tests were conducted in line with information given in the HSE guidance document OC 282/28. The methodology including the equipment used and the exercises performed is that given in the European Standard BS EN 149[1] for the measurement of TIL. As this standard requires, measurements were taken using pulse sampling i.e. only when the test subject was breathing in and this was allowed for in the calculation. Both in-facepiece and chamber salt concentrations were continuously measured using two Moore's Low Flow sodium flame photometers Type 1250 and the measurements logged electronically using Labview (National Instruments) software which also calculated the total inward leakage. From this the fit factor for each exercise was calculated.

2.5.1.4 The Qualitative Fit Test

As advised in HSE OC282/28 the equipment used complied with that specified in the OSHA 1910.134 standard[8]. The test hood and nebulisers used were those supplied with the 3M qualitative fit test kit. The Bitrex sensitivity and test solutions were made up at HSL as directed in the OSHA standard[8] and using Bitrex supplied by Johnson Matthey Macfarlan Smith. Concentrations were confirmed by HSL analytical sciences team. The exercises and timings followed were those given in the OSHA standard, being the same as those given in HSE OC282/28. If the wearer had not tasted the Bitrex before the end of the test they were asked to carefully remove one of the bobbies to allow aerosol inside the FFP3 and so check that there was then sufficient aerosol in the hood to taste through this small leak.

2.5.1.5 The Portacount tests

The HSL test laboratories are air-conditioned. One consequence of this is that ambient particle levels are usually low, below the level which HSE recommends for Portacount fit testing. (Insufficient ambient particle count can be a problem when fit testing using this method. This is because a small amount of wearer generated particles will be counted by the Portacount as leakage[11,23] and hence result in lower fit factors than their true value.) Therefore the tests were conducted inside a controlled temperature and humidity chamber which allowed for a homogenous concentration of particles to be maintained at the level recommended in HSE guidance, above 3000 particles per c.c. Particle levels were not allowed to get too high (above approximately 6000 particles per c.c.) to keep the levels in line with those typically experienced by fit testers. Particles were artificially generated by atomising a 1% salt solution. The size of these particles was measured and found to be distributed across a range which might be typical of the environment the Portacount fit tester could be expected to come across.

Simultaneous measurements were taken using two model 8030 TSI Portacount™ machines. The connection from the sampling port of the facepiece was split very close to the facepiece by use of a Y tube connection and each Portacount sampling tubing connected. One of these Portacount machines was equipped with the N95-Companion technology which was activated. The Portacounts were each operated from a dedicated laptop and using the Fitplus software version 3.4. Use of the N95-Companion requires a longer sampling period; therefore the Portacount without the N95-Companion unit had timings extended to match the longer N95-Companion timings. Apart from this timing change, tests were conducted in accordance with HSE guidance, with the test subject stepping on an aerobics step to increase their breathing rate, this being a common method in use by UK fit testers. The software calculates the fit factors for each exercise. Ambient particle levels were recorded during each test.

2.5.2 Coefficient of Variation - determination

The methodology for this comes from the report prepared by the statistician, see Appendix A.

A large proportion of the test runs required had been carried out before this assessment took place. From the results of those tests it was clear that it would not be unreasonable to follow the ANSI standard and use the TIL fit test method as the reference method. A measurement of Coefficient of Variation required assessment of the results from several repeat tests using this fit test method only. Separate HSE ethical approval was gained to carry out this test run which required one of the test subjects to wear an FFP3 for seven consecutive test runs,

without disturbing the fit. Between the tests the sample tubing and pressure measurement tubing were detached from the ports and reattached, replicating actions normally carried out between fit tests on the usual test runs. The FFP3 selected for this test run was one which had previously achieved a fit factor of approximately 100 on the volunteer test subject.

To be considered as a pass, all quantitative fit tests on FFP3 respirators are required to return a minimum fit factor of 100 on each and every test exercise. Therefore, the lowest fit factor of the 5 test exercises in each TIL test is critical in determining whether the test has passed or failed. The standard deviation of the lowest fit factor on each of the 7 consecutive test runs was used to determine the Coefficient of Variation.

3. RESULTS AND DISCUSSION

This section is supported by graphs and tables given in Appendix B and which are referred to individually in this text.

3.1 OVERVIEW

The raw data from the test runs is given in Table 5 (Appendix B). Test runs are numbered up to 132 but only 126 are completely valid. The first 4 test runs were excluded from many of the statistical calculations as there were technical problems with the TIL test equipment. These test runs have been identified in the results table by being presented in grey print. The Bitrex and Portacount parts of these test runs were successful and are therefore included wherever possible in calculations. A further 2 test runs had to be abandoned due to unplanned external events and these are not included in the results. Otherwise all test runs were considered valid.

A further 9 test runs are presented in grey as these were excluded from the ANSI statistical analysis as they were too close to the 100 pass criterion for the TIL method to be included in the calculations, see section 3.3.2.

The fit factor displayed is that of the exercise which resulted in the lowest fit factor on each fit test. HSE guidance requires achieving a minimum fit factor (currently 100) in quantitative fit test methods for each and every exercise within a fit test for the outcome to be considered as a pass. Therefore, it is the lowest fit factor of all the exercises used in the fit test method which is the critical result. In Table 5 the results are categorised as pass/fail, with the pass criterion of 100 applied to all quantitative tests.

The results were analysed with respect to the test order of individual fit tests (there being 6 possible test orders for each test run). "Fit test order" (1^{st}, 2^{nd} or 3^{rd}) was used as a fixed factor in the Analysis of Variance along with "FFP3 model", and showed no significant effect for the log-transformed data for either TIL or Portacount. For Bitrex, the proportion of passes was calculated for each group (1^{st}, 2^{nd} or 3^{rd}) and used as the dependent variable in the Analysis of Variance along with "FFP3 model", and again showed no significant effect.

3.1.1 Individual pass/fail results

In total 516 valid fit tests were carried out. The overall pass/fail results are given in Table 2. The criterion applied for a pass is that given in HSE guidance OC282/28, which is at least 100 in each and every exercise for quantitative fit test methods. Although the Portacount-with-N95-Companion is a method which is not currently recommended for FFP3, it is a quantitative method and therefore initially a pass criterion of 100 was applied to these fit tests, in line with other quantitative fit test methods.

Table 2 Overall pass/fail results for the 516 valid fit tests

	total valid fit tests	pass criterion	pass	fail	borderline
Bitrex	130	N/A	39 (30%)	79 (61%)	12(9%)
TIL	126	100	46 (37%)	80 (63%)	
Portacount	130	100	22 (17%)	108 (83%)	
Portacount +N95	130	100	33 (25%)	97 (75%)	
	516				

The borderline category for the Bitrex fit test indicates uncertainty in whether or not the Bitrex had been tasted. A slight taste of Bitrex was classified as borderline, and this is further discussed in section 3.3.6.

These overall results show that many more of the fit tests failed than passed no matter what method was used for fit testing. The easiest fit tests to pass are the TIL fit test (37%) and the Bitrex fit test (30% or 39%, depending on whether the "borderline" tests are included as pass or fail), with the Portacount fit test being the most difficult to pass at only 17%.

3.1.2 Agreement between pass/fail results across all fit test methods – potential sources of bias

16 test runs resulted in passes in all fit test methods and 61 test runs resulted in fails in all fit test methods, assuming current HSE pass criteria. This leaves 49 test runs where there was not overall agreement between fit test methods, assuming current HSE pass criteria. The reasons for this are associated with both the nature of FFP3 and the types of measurement techniques which are used in the fit test methods; particles passing through the filtering material of the FFP3, and the different methods of detecting the different challenge agents are significant. These factors can contribute to differences in the determination of fit.

In broad terms, FFP3 are not required to filter out all particulates but can allow up to 1% through the filtering material. When measuring fit of an FFP3 using a quantitative method the amount of a challenge test agent which gets inside the FFP3 via a faceseal leak needs to be measured. However, it is not easy to get an accurate measure of this as some challenge test agent will pass through the filtering material and be included in the measure. Both Portacount methods (without or with the N95-Companion technology) and the TIL method will be affected by challenge particles passing through the filtering material, leading to a less accurate (biased low) measure of fit. The amount of penetration through the filtering material will vary between models of FFP3 due to their differing filtration properties and the size of the test challenge particles. Use of the N95-Companion technology with the Portacount is thought to reduce this effect, see discussion in the Introduction, Section 1.2.2.1.

As regards measurement techniques, the TIL fit test method uses generated salt aerosol as a challenge agent and this is measured using a sodium flame photometer, which responds according to the mass of salt present. The Portacount measures ambient particles by number, that is it counts the number of particles present. These two different measurement types can give different fit factor results, especially where some particles can pass through the filtering material, as is the case with FFP3; filtering efficiency of FFP3s will vary with challenge particle size and the pattern of this will vary with FFP3 model.

A further problem with the Portacount is that it cannot discriminate between particles; it will count all particles, whatever their origin or size, equally. This is especially a problem as some people can generate particles, particularly when they talk, and these will be counted in with the fit test sample from inside the FFP3, leading to a less accurate (biased low) measure of fit[21].

The Bitrex fit test method relies entirely on the taste response of the test subject to assess the fit. The test agent (Bitrex aerosol) does not pass through the filtering material in detectable form[7], which means that by using this method one problem that occurs with quantitative methods is eliminated. However, the detection is entirely dependent on the test subject, their sensitivity to Bitrex and their judgement of whether or not they can taste Bitrex during the fit test.

3.2 ANALYSIS OF DATA DISTRIBUTION

3.2.1 Selection of the reference method

The TIL method was initially selected as the reference method for this study because it is well established, is the type of method required by ANSI as a reference, and tried and tested by other researchers. The overview of the results given in Table 2 shows that the TIL fit test criterion is similar in pass/fail rates to that of the Bitrex fit test, and easier to achieve than the Portacount fit test criterion. This would appear to fit in with the suggestion that the Portacount criterion may be too stringent.

The TIL test pass criterion for a fit test is much more stringent (requiring more than twice the level of protection to be achieved) than the criterion applied when the same test is used during the European Standard EN149[1] approval. The European Standard EN149 TIL test is a measure of the performance of the filtering facepiece on 10 different wearers. The requirement for classification as an FFP3 is that the TIL is less than 2% mean for all exercises for 8 out of the 10 wearers and less than 5% for 46 out of the 50 individual test exercise results. Putting this in more simple terms it approximates to a mean fit factor (over all exercises) of 50. This compares with the requirement for a fit test pass, according to HSE guidance, of a minimum fit factor of 100 in every individual test exercise.

3.2.2 Limitations of using the TIL test as a reference method

The TIL method is not ideal for measuring the fit of FFP3 and there is no quantitative fit test method for FFP3 which can eliminate the influence of filter penetration on the fit factor measured. A certain amount of particulate challenge will always pass through the filtering material (with an FFP3 this can be up to a nominal 1%). Therefore, when the TIL fit test method is used it will always result in fit factors which are biased low compared to a true measure of fit. The measured percentage TIL will be biased high since it includes filter penetration:

$$\textit{Measured percentage TIL} = \textit{percentage faceseal leakage (true measure of fit)} + \textit{percentage filter penetration}$$

Fit factors are the inverse of Total Inward Leakage (TIL) and therefore will be biased low:

$$\textit{Fit factor} = \frac{100}{\textit{percentage TIL}}$$

By considering the results from the EN149 filter penetration test we can get an idea of the comparative extent of this effect. Note that methodology differences between the filter penetration test and the TIL test mean that an absolute measure of the effect of filter penetration on the TIL fit test cannot be derived. Table 3 shows how the apparent fit factor of a facepiece which is perfectly sealed to a face would be expected to vary, depending upon the filter penetration. At the extremes, if zero challenge passes through the filtering

material theoretically a fit factor of infinity could be achieved, but if 0.99% passes through the filtering material (maximum permissible under EN149 to just achieve a pass) a fit factor of only 101 could be achieved, just scraping a TIL fit test pass, and in reality a virtually impossible achievement.

Table 3 Apparent values for maximum fit factor that are achievable by the TIL fit test method, maximum faceseal leakage permissible, true fit factor and extent of low bias for a range of filter penetrations based on the FFP3 used in this study.

filter penetration	challenge	maximum fit factor acheivable assuming perfect seal to face	maximum penetration permissible through faceseal leak to pass fit test	equivalent true fit factor	bias due to filter penetration
0.000%	100%	infinite	1.000%	100	0
0.004%	**100%**	**25000**	**0.996%**	**100**	**0**
0.060%	**100%**	**1667**	**0.940%**	**106**	**6**
0.100%	**100%**	**1000**	**0.900%**	**111**	**11**
0.700%	**100%**	**143**	**0.300%**	**333**	**233**
0.990%	100%	101	0.010%	10000	9900

The intermediate filter penetration values used in Table 3 have been taken from data supplied by the manufactures of the FFP3 used in this study (see Table 1). The FFP3 with lowest filter penetration (0.004%) could be expected to achieve a maximum fit factor of 25,000, which gives plenty of scope for faceseal leakage (up to 0.996%) before failing a TIL fit test. Our study included FFP3 with much higher filter penetrations, the highest (0.7%) could be expected to achieve a maximum fit factor of only 143, when perfectly sealed to the face, giving much less scope for faceseal leakage (0.3%) before failing a TIL fit test.

If filter penetration could be eliminated, the TIL fit factor would be a true measure of face seal leakage only and the apparent value of this is given in column 5 of Table 3 described as 'equivalent true fit factor'. The difference between the measured TIL fit factor (100) and the equivalent true fit factor is the bias due to filter penetration and this is given in column 6. For the FFP3 with the highest filter penetration (0.7%) if that FFP3-wearer fit gave a TIL fit factor of 100 this would be equivalent to a true fit factor for that faceseal fit of 333; using the TIL fit test method leads to the fit factor being biased low by 233. All of the FFP3 used in this study with standard filtering efficiency calculate fit factors biased low in this way by between 11 and 233. Note that these calculations are theoretical as methodology differences between the filter penetration test and the TIL test mean that an absolute measure of the effect of filter penetration on the TIL fit test cannot be derived, so no simple correction can be applied to this effect.

Taking these calculations a step further, Table 4 shows the impact this may have on the minimum fit factor value for the TIL method that indicates an acceptable faceseal fit (faceseal penetration 1.00%). Again, calculations are based on the range of filter penetration values of the FFP3 used in this study, and for these the apparent fit factor measured by the TIL method which would indicate an acceptable fit is between 59 and 91 for standard efficiency FFP3. For some FFP3 this is significantly below the pass criterion of 100 used in

this study, indicating a real possibility of the likelihood of some false fails when relying on the TIL method as the reference.

Table 4 Apparent minimum TIL fit factor which indicates an acceptable fit, when filtering material penetration is taken into account.

challenge	true fit factor	face seal penetration	filtering material penetration	total penetration	apparent fit factor required to demonstrate acceptable fit
100%	100	1.00%	0.000%	1.00%	100
100%	100	1.00%	0.004%	1.00%	100
100%	100	1.00%	0.060%	1.06%	94
100%	100	1.00%	**0.100%**	1.10%	**91**
100%	100	1.00%	**0.700%**	1.70%	**59**
100%	100	1.00%	0.990%	1.99%	50

These hypothetical calculations show how the fit factor result from a TIL fit test has the potential to be biased low to an extent dependent on the filtering efficiency of the filtering material. An FFP3 TIL fit test will always result in a conservative measure of fit and TIL fit test results will be inclined towards a false fail to some extent, dependent upon the filtering material efficiency, for any given pass/fail criterion. In other words some true good fits will be measured as poor (false fails). It follows that any other fit test method measured against the TIL fit test method as reference, will have some results recorded as false passes (but which are actually acceptable fits) due to the inability of the TIL method to measure true fit alone. Occurrence of false fails with the TIL method will affect the statistics when it is used as a reference method to assess the value of another fit test method; the predictive value of a pass will be biased low and the predictive value of a fail will be biased high (these statistical terms are defined and bias further discussed in section 3.3.3). This needs to be taken into account when judging the value of a fit test method against the TIL method.

3.2.3 Data spread

Figure 1 shows the individual fit factor results displayed as an X-Y scatter when comparing the TIL fit test method with the Portacount fit test method (individual FFP3 model results are identified separately – see legend). The "1:1 correlation" shows approximately where the data would lie if the minimum fit factor from each fit test method was approximately equal. There is a discernible bias over all of this data towards lower Portacount fit factor compared with the corresponding TIL fit factor. Figure 2 is similar to Figure 1 but compares the TIL method with the Portacount when used with the N95-Companion technology. A similar but smaller bias is observable.

The bias has been quantified with a line of best fit applied to the data as shown in Figure 6 (Appendix B). The Portacount fit test pass criterion which shows best agreement with the TIL fit test pass at 100 was calculated to be 39. Similar calculation shows best agreement for the Portacount-with-N95-Companion fit test against the TIL fit test pass at 100 is 47, Figure 7 (Appendix B) shows the line of best fit for this data.

A similar bias was noted by Biermann *et al*[11] who used an oil mist aerosol and found Portacount fit factors to be a factor of 1.7 less than (or we could express this as 0.6 of)

forward scattering light photometer fit factors. Note that this type of photometry is projected area-dependent, whilst the TIL fit test method (which was used in this study) is flame photometry, which is mass-dependent, hence some difference between these two methods of photometry might be expected. However, there is a similar bias with both studies, the Portacount (particle counting method) fit factors being 0.4-0.6 of the photometry fit factors.

The results from the Bitrex method are compared to the TIL fit test method in the bar chart, Figure 3, with Bitrex passes represented by solid green colour, fails by diagonal-dashed pink and borderlines as dashed amber. The tests are ordered by TIL fit test minimum fit factor result. Around the TIL pass criterion of 100 (between 96 and 114) is where there are several borderline Bitrex fit test results, with Bitrex passes mainly above 100, and fails mainly below 100. There are further boxplots given in Figure 8 (Appendix B) which show the spread of the Bitrex fit test results.

Figure 1 Fit Factor Data spread by FFP3 model: TIL v Portacount (see section 3.3.3 for explanation of areas A,B,C,D)

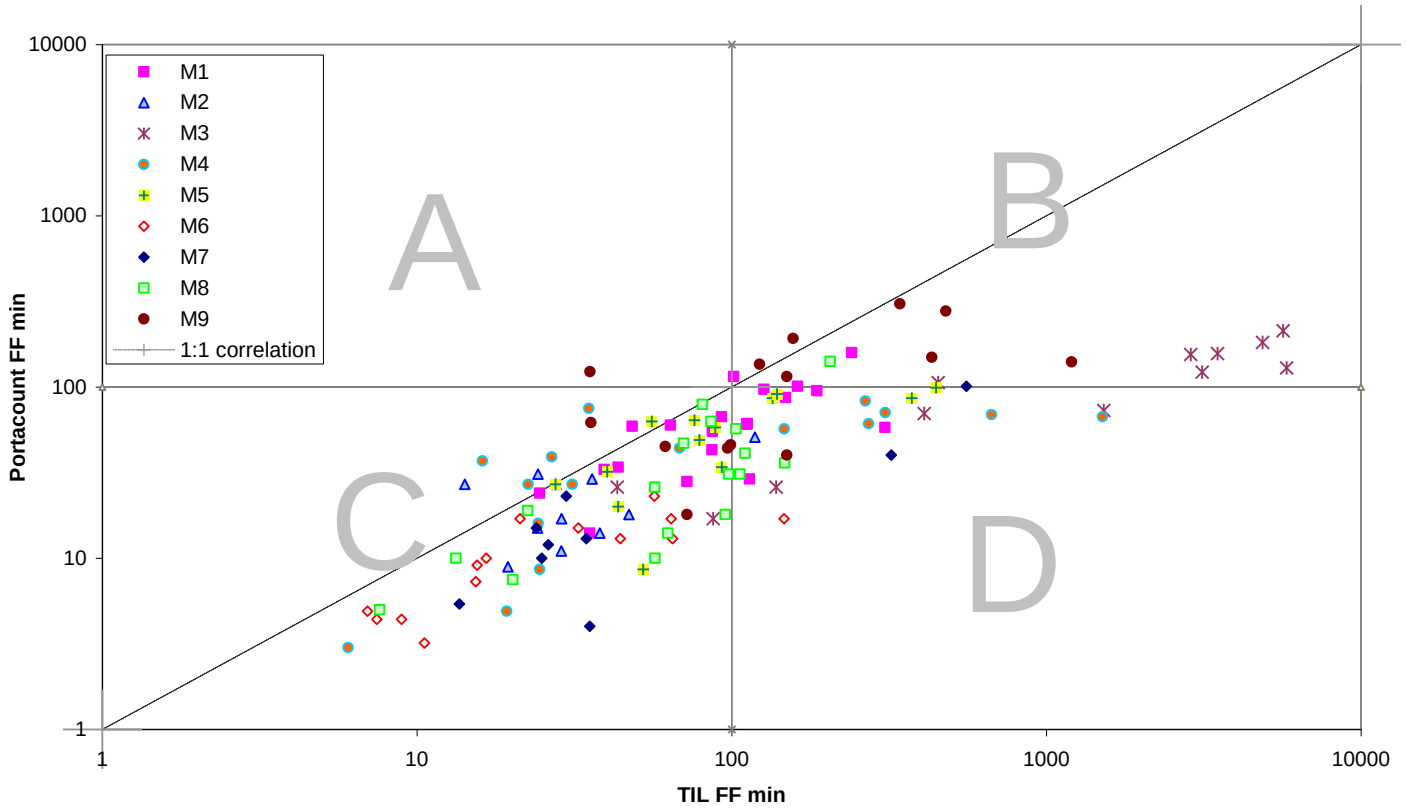


Figure 2 Fit Factor Data spread by FFP3 model: TIL v Portacount-with-N95-Companion (see section 3.3.3 for explanation of areas A,B,C,D)

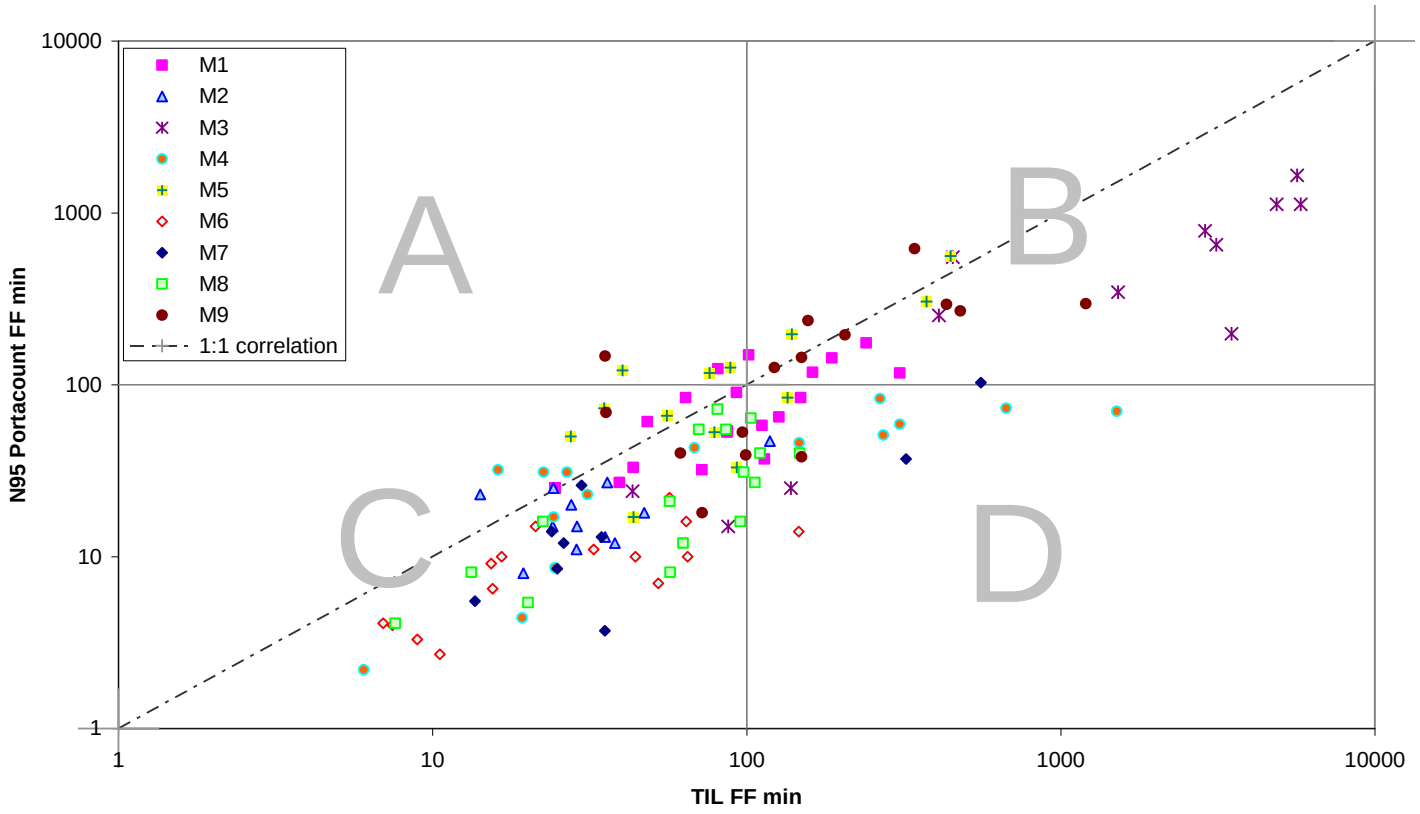
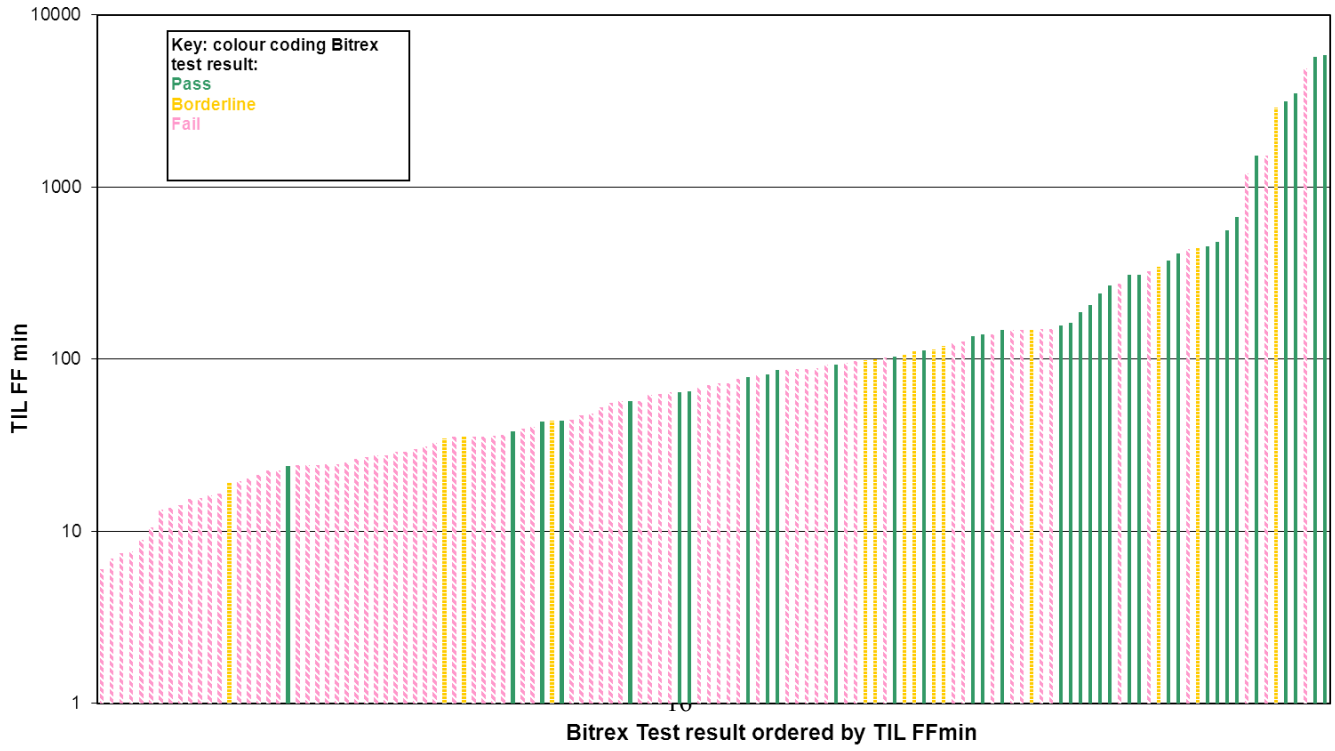


Figure 3 TIL Fit Factor overall data spread v Bitrex test result



3.3 STATISTICAL ANALYSIS OF DATA USING THE ANSI/AIHA CRITERIA

The raw data from all of the tests runs is given in Table 7 of Appendix B. These were analysed in accordance with the requirements of the ANSI standard.

3.3.1 Distribution of fit factors

A histogram of the distribution of TIL fit factors on a logarithmic scale is given in Figure 9 (Appendix B) which visually confirms that the fit factors are evenly distributed and that they bracket the required fit factor for the TIL reference method. This is a requirement of the ANSI standard.

3.3.2 Coefficient of Variation

Nine test runs were excluded from the statistical analysis of the data, these being too close to the pass criterion of 100 on the TIL fit test method. That is, any test run where the TIL fit test result was within the range 100+/- 7.9, (7.9 being the coefficient of variation). These tests are marked on the histogram Figure 9 by the dashed lines. Table 8 in Appendix B shows the results of the covariance test run and the calculation followed to determine the coefficient of variation and hence which tests needed to be excluded, as required by the ANSI standard.

3.3.3 Initial treatment of data and statistical measures determined

The initial analysis included all remaining data from the test runs regardless of the filtering efficiency of the FFP3.

Table 9 (Appendix B) shows the analysis steps including the formulae used for determining the statistical values from the data and the expected levels to conform with the ANSI standard. Note that in all analysis tables a statistical value which does not meet the ANSI criteria is presented in red font to distinguish it from those which do (black font).

The initial step was to determine values of A, B, C and D as defined in the contingency table below (Table 5), for each of the fit test methods using the pass criterion currently applicable according to HSE guidance, against the TIL fit test method with pass criterion of 100 as the reference method. These values are also illustrated in Figures 1 and 2. The rectangular regions labelled A, B, C, D represent the areas in which all of the points fall into that category, therefore rectangle A contains all of the points which fail the reference fit test method and pass the comparison fit test method, for rectangle B, all points passed both fit test methods and so on. Note that figures 1 and 2 do include all data, although some points were not counted in the statistical analysis due to being too close to the pass criterion of 100 for the TIL fit test method (see section 3.3.2). The values of A, B, C and D were then used to determine the statistical values discussed below and given in Table 9 in Appendix B for each fit test method against the TIL fit test method.

Table 5 2 x 2 contingency table of results

Results	Reference method	Reference method
	Failed	Passed
Passed Method 1	A	B
Failed Method 1	C	D

The ANSI standard has a requirement for at least 50 fit test runs to fail the reference method to ensure confidence in the statistics concerning poor fit. This was easily achieved with 74 of our valid test runs failing the TIL reference fit test method.

In the ANSI standard there is much less importance given to the correct detection of good fits and no requirement on the number of reference method fit test passes to be achieved. However, 43 of the TIL fit tests resulted in a pass, and whilst this is less than the number of fails it is still a good proportion of the total number of tests. Having a lower number of TIL passes than fails does reduce the confidence which can be placed in the calculations which depend on passes, compared to the confidence which can be placed in the calculations dependent on the number of fails. However, 43 passes is a substantial number and therefore should give a good assessment of the comparability of the fit tests methods used.

The statistical terms are defined here and some of the values calculated are given but details will be discussed later.

Note that increased false passes with the TIL method (discussed in section 3.2.2) will affect the statistics when it is used as a reference method to assess the value of another fit test method. Some results which are placed in box A, perhaps should really be in box B as they are really good fits. Likewise, some results which are in box C perhaps should really be in box D. This needs to be taken into account when judging the value of a fit test method against the TIL method.

3.3.3.1 Test sensitivity = C/(A+C)

This is the probability that the test method will correctly identify a poor fit and *must* be greater than or equal to 0.95. It follows that beta error (probability of a false pass) should be less than or equal to 0.05. (Beta error = 1- test sensitivity).

Initial calculations using existing HSE pass criteria show that only the Portacount fit test method has achieved this level at 0.99 (when measured against the TIL test method). However, both the Portacount-with-N95-Companion technology fit test method and the Bitrex fit test method returned high values at 0.93 and 0.86 (with borderline test results being treated as fails) respectively.

The influence of low bias of TIL results on test sensitivity is complex as A and/or C could be biased high, but given the relative values of A and C in our data the calculated values of test sensitivity are most likely to be biased low.

3.3.3.2 Predictive value of a pass =B/(A+B)

This is the probability that if the fit test result is a pass, then the fit is acceptable and ANSI suggests it *should* be 0.95 or greater.

Initial calculations using existing HSE pass criteria show that only the Portacount fit test method achieved this level of probability (when measured against the TIL test method). For the other fit test methods values were high but the probability of a false pass was higher than ANSI recommend. However, since TIL results will be biased low (see section 3.2.2), some may be allocated to box A (fails in Table 5 above) when they should really be in box B (passes), which in turn will result in the calculated value for predictive value of a pass being biased low (since A+B is constant the value calculated is directly proportional to B only). The calculations for predictive value of pass given in tables 9 through to 16 assume all of the TIL test fails are true fails and hence are all conservative values.

3.3.3.3 Test specificity =B/(B+D)

This is the probability that the fit test method will correctly identify a good fit, and ANSI suggests it *should* be 0.5 or greater.

In initial calculations using existing HSE pass criteria this was achieved by all fit test methods except for the Portacount fit test method (when measured against the TIL test method).

With the Portacount fit test method the chance of a good fit leading to a pass is only 0.42. The influence of low bias of TIL results on test specificity is complex as B and/or D could be biased low, but with the data from this study Portacount B could only increase by one, whereas there is more scope to increase D further. As a consequence the calculated value of test specificity is more likely to be biased high, indicating that the Portacount test method may be even further below the ANSI suggested value, if the true fit could be measured.

3.3.3.4 Predictive value of a fail =C/(C+D)

This is the probability that if the fit test method result is a fail then the fit is actually poor, and ANSI suggests it *should* be 0.5 or greater.

Initial calculations using existing HSE pass criteria show that this was easily achieved for all fit test methods (when measured against the TIL test method), being 0.74 or greater. However, since TIL results will be biased low (section 3.2.2), some may be allocated to box C (fails in Table 5 above) when they perhaps should really be in box D (passes), which in turn will result in the calculated value for predictive value of a fail being biased high. The calculations for predictive value of fail given in tables 9 through to 16 assume all of the TIL test fails are true fails and hence are all optimistically high values.

3.3.3.5 Kappa Statistic

This is an overall measure of the degree of agreement with the reference fit test method. A value greater than + 0.7 is *recommended*.

Initial calculations using existing HSE pass criteria returned values below 0.7 with all fit test methods (when measured against the TIL test method with pass criterion 100).

3.3.3.6 Summary

Overall, no fit test method achieved all of the required, suggested and recommended values in all statistical calculations (when measured against the TIL test method with pass criterion 100). The ANSI criteria are very strong on the test sensitivity (a fail-safe approach in terms of placing greater emphasis on correct detection of poor fit) requiring at least 0.95, which was only achieved with the Portacount fit test method.

As explained in Section 3.2.2 the predictive value of a pass may be biased low, due to the inability of the TIL method to accurately assess fit, which may explain why Bitrex and Portacount-with-N95-Companion technology values are lower than the ANSI suggested value of 0.95.

The lower emphasis on the importance of detecting a good fit is reflected in the suggested minimum for the test specificity being given as 0.50 (much lower than the requirement for detecting a poor fit, at 0.95). Given this, it is surprising that this suggested 0.50 for the test

specificity was not achieved with the Portacount fit test method. However it was achieved by both the Bitrex and Portacount-with-N95-Companion technology fit test methods.

The calculated predictive value of a fail may be biased high which could explain why calculated values are well above the ANSI suggested value of at least 0.50, for all test methods.

In the discussions which follow, the greatest emphasis is placed on maximising the test sensitivity, whilst also recognising the value of sensible levels across all statistics, in the light of the ANSI criteria and the influence of low bias of TIL reference fit factors on the calculated values.

3.3.4 Portacount fit test results

3.3.4.1 Effect of modifying the Portacount pass criterion on statistical values

Figure 1 shows that the Portacount fit factors are biased low compared to the TIL fit factors. The results from the initial statistical treatment of the data given in Table 9 (Appendix B) also show this tendency. Whilst there is very good test sensitivity, with a probability of 0.99 that the Portacount fit test will correctly identify a poor fit, there is poor test specificity with a probability of only 0.42 that test subjects with acceptable fits will pass the Portacount fit test.

A lower pass criterion for the Portacount fit test can improve the overall statistics without unduly compromising the ability of the Portacount fit test to detect a poor fit, when assessed according to the ANSI criteria. Table 10 (Appendix B) shows the calculated values and Figure 10 shows the effect on the statistical values of applying lower pass criteria to the Portacount fit test results, when the criterion is reduced to 90, 80, 70, 60 and 39 respectively (39 was included as it is the calculated value from the 'line of best fit' for the data). The test sensitivity remains good and at least to the required level of 0.95 if the pass level is reduced as far as 70, and this also has the effect of improving the test specificity (to 0.67) and the agreement between fit test methods, the Kappa statistic (to 0.65). The predictive value of a pass would be reduced to from 0.95 to 0.88, taking it below the level suggested by the ANSI standard (0.95), but it still remains well above the level achieved in the Bitrex fit test method (at 0.73), and also the Portacount-with-N95-Companion technology fit test method (at 0.83). Note that these values are all conservative. As explained in Section 3.3.3.2 the predictive value of a pass for all these three fit test methods may be lower than the true value due to the inability of the TIL method to accurately assess fit, giving fit factor results which are biased low. As an example, looking at Table 4 given in section 3.2.2, if we assume that we can justify the calculated correlation between filtering efficiency and the minimum fit factor required, then test run number 5 of Table 7 (Appendix B) becomes a pass on the TIL method, which increases the predictive value of a pass on the Portacount method from 0.88 to 0.91.

The effect of reducing the Portacount fit test method pass criterion to 70 gives a better set of statistics (across every statistical value calculated) than is achieved by either the Bitrex method or the Portacount –with- N95-Companion technology, in this study against the TIL fit test method, when assessed according to the ANSI criteria.

Note that reducing the pass criterion to 39 (best agreement from the 'line of best fit' discussed in section 3.2.3) would mean that the test sensitivity (probability of correctly detecting a poor fit) would be only 0.76.

3.3.4.2 *Effect of filtering efficiency of the FFP3 on the statistical values*

As it had been suggested that particles passing through the filter material could contribute to leakage measurement during the Portacount fit test, and this suggestion has been examined using the results from FFP3 with differing filtering efficiencies. Section 2.4.2 explains that the filtering efficiency of FFP3 M3, M8 and M9 is significantly higher than that of the other FFP3 used in the study. The results from tests on these two groups of FFP3 (M1,M2,M4,M5,M6,M7) and (M3,M8,M9) were analysed independently, as standard efficiency and high efficiency, respectively. These are presented in Figures 4 and 5 as X-Y scatter graphs of TIL v Portacount from which it is clear that there is little difference between the spread of the data between the two groups with the bias towards lower Portacount fit factors present with both sets of data to a similar extent.

This suggests that the reason for the overall bias towards higher TIL fit factors compared to the Portacount is not related to the filtering efficiency of the FFP3, but due to other factors. The extent of the effect of any particles passing through the filtering material is similar on both measurement methods (TIL and Portacount), especially in the critical pass criterion region of the TIL fit factor (around 100) and continuing up to fit factor 200. The type of measurement taken may well be the significant factor creating the bias. The Portacount method measures the number of all particles, whereas the TIL method measures the mass of salt particles only. A similar bias has been found by others[11]. This does not mean that particles passing through the filtering material will not detrimentally affect fit factor results, but that it will have a similar effect on both TIL and Portacount fit test methods. The statistical analyses against all fit test methods for standard efficiency and high efficiency FFP3 are given in, Tables 9 and 10 respectively (Appendix B).

At high fit factors the tests methods are more likely to behave differently with respect to one another and indications of this trend are appearing with some of the FFP3. M3 appears to show a different behaviour to the other FFP3 but this FFP3 performs very well (compared to M8 and M9) on some of the TIL tests, returning very high fit factors compared to the Portacount method. This may be because, with a high filtering efficiency and a good fit, the influence of wearer generated particles being included in the Portacount measurement is likely to become significant in limiting the Portacount fit factor. Also, the characteristics of the specific filtering material, especially its performance across a range of particle sizes will also have a significant effect on the actual fit factor result. Very small particles (nanoparticles) are known to readily penetrate some filtering materials[22]. These factors are not significant to the scope of this study which is concerned with borderline fit of FFP3, which these fit factor results are well above. The effect of wearer generated particles on fit factors of RPE which is expected to provide greater protection than FFP3 and requires a higher fit factor pass criterion is significant, and documented[11,23].

The ANSI standard requires analysis of data collected from tests on a range of FFP3 and specifies the number of test runs and reference method fails required (see discussion in section 2.4.5). Valid analysis requires our full data set; however, similar analysis to that carried out with the full data set was also carried out on these two groups of FFP3 to get an indication of the effect of adjusting the Portacount fit test pass criterion. The results are in Tables 11 and 12 (Appendix B) and are shown in graph form in Figure 11 (Appendix B) for standard efficiency FFP3, and in Figure 12 for high efficiency FFP3.

Figure 4 Fit Factor Data spread by FFP3 model (standard efficiency): TIL v Portacount

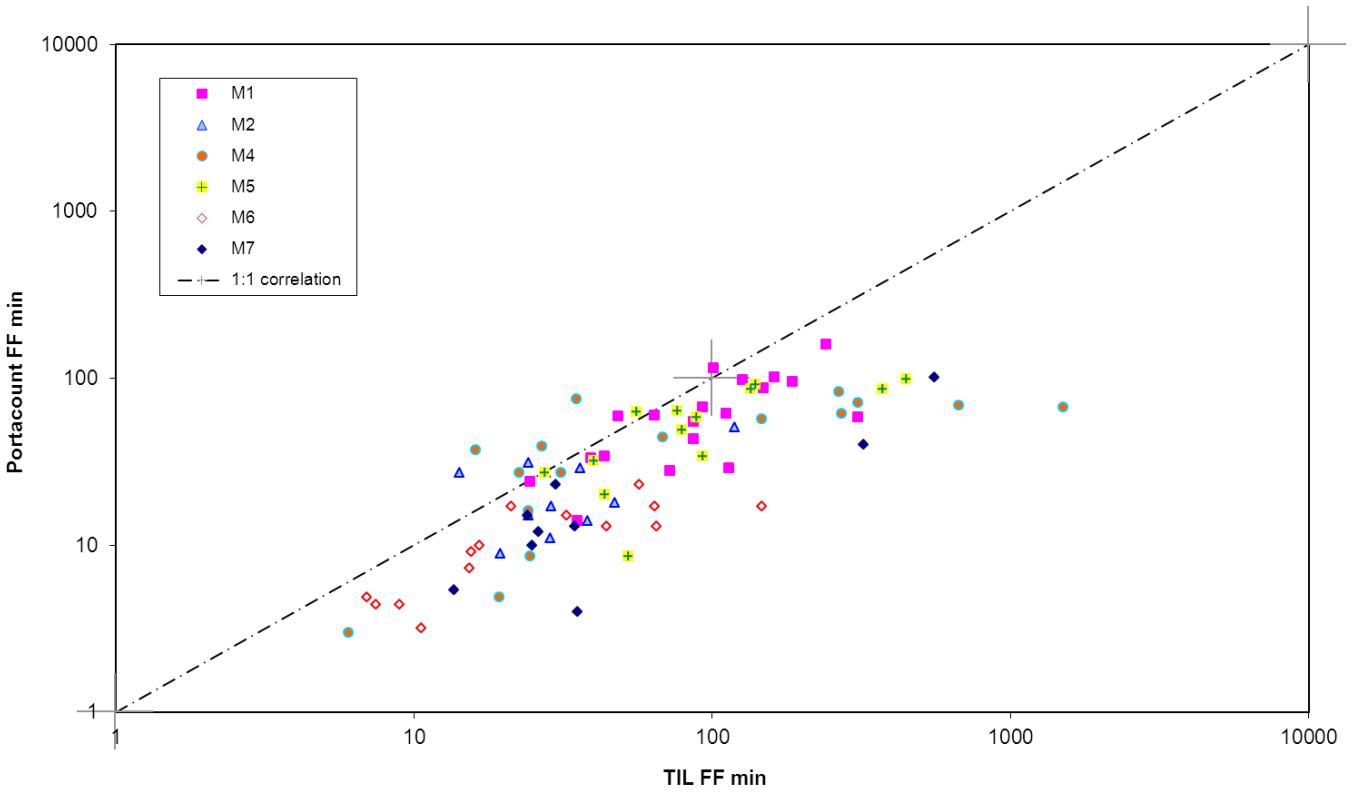
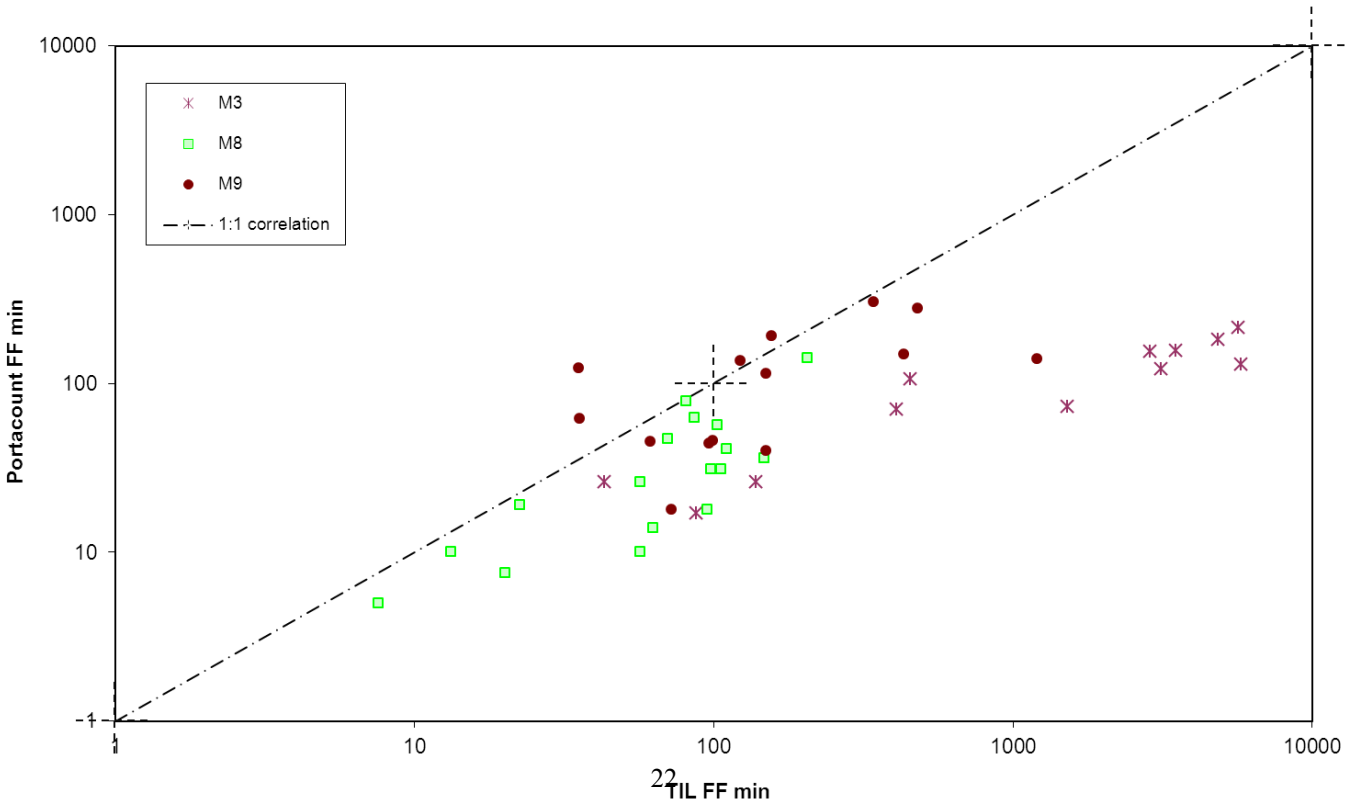


Figure 5 Fit Factor Data spread by FFP3 model (high efficiency): TIL v Portacount



Note that the number of test runs included in each of these groups is now much lower than the minimum of 100 required by the ANSI standard (and hence this analysis is not valid under the ANSI standard criteria) and that this will influence the statistics, reducing the confidence which can be placed in them. This is especially significant for the group of high filtering efficiency FFP3. As an example, the only test run to fail on the TIL fit test method, but achieve more than 100 on the Portacount fit test method, was with a high efficiency FFP3. This one test run alone reduces the calculated test sensitivity to 0.94 at best, below the ANSI standard requirement, whereas the group with standard filtering efficiency suggests a better test sensitivity at 0.97 (at a Portacount fit test pass criterion of 70) than for the whole data set.

It is also worth noting that for the standard efficiency FFP3 the statistics are particularly poor in respect of test specificity and predictive value of a fail with a Portacount pass criterion of 100 or 90, but that these improve markedly if the Portacount pass criterion is reduced to 70. Of note is that while these values are improved at 70, these values are also within recommended ranges with a pass criterion at 80 and the kappa statistic at 0.59 is higher than that at 0.58 when the pass criterion is at 70. At the pass criterion at 80, statistical values for test sensitivity, beta error and the predicted value of a pass are within ANSI recommended values. Although the low number of TIL fit test passes (22, with 58 fails) with this group will have a strong negative influence on the confidence which can be placed on the calculated value of the test specificity and the predictive value of a fail (see discussion in section 4.3.3 fifth paragraph). For the high filtering efficiency all statistics remain at the same levels for a Portacount fit test pass criteria of 100, 90 and 80. However, at pass criterion of 70, the test sensitivity is reduced from 0.94 to 0.88, the predictive value of a pass is reduced from 0.94 to 0.89, while the test specificity increases from 0.71 to 0.81 and the predictive value of a fail increases from 0.71 to 0.78.

3.3.4.3 Effect of modifying the Portacount pass criterion on the percentage of fit tests which fail on the talking exercise

A known disadvantage of the Portacount fit test method is that it measures all particles inside the FFP3, including any generated by the wearer. Many wearers generate particles when talking and it is often the talking exercise where the test fails. Figure 13 (Appendix B) shows the percentage of fit test fails, by exercise and how this varies with the pass criterion for the Portacount fit test method. With the pass criterion at 100 the talking exercise is clearly leading to a failure more often than any other exercise. As the pass criterion is reduced to 70 the dominance of talking as the fail exercise diminishes and the primary fail exercise is more evenly distributed across exercises.

Figure 13 (Appendix B) also shows exercise failure rates with the Portacount-with-N95-Companion method, the TIL fit test method, and the Bitrex fit test method. The use of the N95-Companion technology with the Portacount has a lower incidence of the talking exercise resulting in the lowest fit factor than the Portacount used alone. With the TIL fit test method the talking exercise rarely resulted in the lowest fit factor. These results reflect the fact that the TIL fit test method is not affected by wearer generated particles, and support the hypothesis that many wearer generated particles may be removed by the N95-Companion unit.

The Bitrex fit test is terminated as soon as Bitrex is tasted, therefore the exercise which shows the poorest fit cannot be determined, only the point at which the fit was poor enough for the test subject to detect the Bitrex taste. Many tests were over before they had even had the Bitrex challenge fully applied, or failed just into the first exercise. Of the remaining fails

all exercises contributed to these, including talking, which demonstrates that all exercises are of value and have the potential to detect a poor fit.

3.3.5 Portacount-with-N95-Companion technology fit test results

Figure 2 shows the comparison of Portacount-with-N95-Companion technology (N95-Portacount) fit factors against the TIL fit factors. The spread of data on this X-Y scatter is similar to that of the Portacount against TIL, but the bias towards lower fit factors is not as pronounced as when the Portacount is used without the N95-Companion technology (Figure 1). It is also noticeable that the N95-Portacount-with-N95-Companion technology fit factors in Figure 2 do not begin to "flatten out" at high levels of TIL in the same way as in Figure 1 (Portacount). This is likely to be due to the comparative amounts of wearer generated particles being counted. Wearer generated particles may be relatively large and therefore removed by the N95-Companion technology resulting in less of a contribution to the measured sample from inside the FFP3. This would explain why the talking exercise is not as likely to be the exercise which results in the minimum fit factor, discussed in section 3.3.4.3. It would also explain why the very high TIL fit factors resulting from some of the M3 tests (discussed section 3.3.4.2) are more closely matched by the Portacount-with-N95-Companion technology, than by the Portacount alone.

Table 9 (Appendix B) includes information on the initial statistical calculations, using a pass of 100 for the Portacount with N95-Companion technology fit test method returned a test sensitivity of 0.93, which falls slightly short of that required by the ANSI standard (0.95 needed), a specificity of 0.58 and a Kappa statistic of 0.55.

Figure 14 (Appendix B) shows the effect on the statistics of adjusting the Portacount-with-N95-Companion fit test pass criterion. Increasing this fit test pass criterion to 120 improves the test sensitivity to the 0.95 required by the ANSI standard but this also reduces the test specificity (to 0.51) and the Kappa statistic to 0.5 indicating less agreement with the reference TIL fit test method at this higher pass level.

Reducing the fit test pass criterion to 90 has no effect on the statistics, but reducing it to 80 takes the test sensitivity down to 0.92, slightly further away from the minimum required. However, the test specificity is improved to 0.65 and the Kappa statistic to 0.6. Reducing the pass to 47 (best agreement from the 'line of best fit' discussed in section 3.2.3) brings the test sensitivity to an unacceptably low level with probability of only 0.77 of a poor fit being detected, increasing the Beta error (probability of a false pass test result) to 0.23.

Overall, this method is returning results which are not in quite such good agreement with the TIL method as the Portacount used on its own, no matter how the pass criterion is adjusted.

Figure 15 (Appendix B) shows the X-Y scatter of Portacount-with-N95-Companion results against Portacount alone. Figure 16 (Appendix B) shows the same results but focuses on the critical pass/fail criterion area using a linear scale. Both show the 1:1 correlation and the 100:70 pass criteria point which is centrally located within the scatter supporting the suggestion that a pass of 70 on the Portacount fit test method correlates well with a pass of 100 using the Portacount-with-N95-Companion fit test method.

3.3.6 Bitrex fit test results

The Bitrex fit test results do not have a quantitative value but are categorised as pass, fail or borderline. They cannot therefore be plotted as an X-Y scatter graph against a quantitative method. Figure 3 shows Bitrex fit test results identified by colour and pattern on the bar

chart for the TIL result. This gives a visual presentation of the correlation between the Bitrex and TIL methods and these are further represented in the box plots, Figure 8 (Appendix B).

The Bitrex fit test results can be analysed according to the ANSI standard in exactly the same way as for the Portacount methods, and the statistical values calculated. These are shown in Table 9 of Appendix B. In some of the Bitrex fit tests the test subject detected a slight taste of Bitrex, but this was not a definite taste and the test continued through to the end without further detection of Bitrex taste. (Generally if the wearer can definitely taste Bitrex they are keen to remove the hood to take away the bitter taste as soon as possible.) The slight taste response was therefore classed as borderline and the data analysed in two ways. One way included the borderline cases as fails and the other included them as passes. Hence there are two sets of calculations which returned different statistical values. The test sensitivity is the most critical measure and this is higher (at 0.86 compared with 0.81) and hence more acceptable for the ANSI standard if the borderline results are counted as fails.

Looking back to the statistical analysis for the high filtering efficiency FFP3, this is where the Bitrex fit test sensitivity does increase to 0.94, nearly reaching the ANSI requirement, see Table 12 in (Appendix B). This result should be treated with caution as the number of fit test runs on which this is based is insufficient, but such a result might be expected as the Bitrex aerosol particles should not pass though the filtering material, as they are too large[7] (the Bitrex fit test method can be used for fit testing lower classes of disposable masks FFP1 and FFP2 which have much lower filtering efficiency).

The TIL fit test is affected by particles passing through the filtering material, but with high efficiency FFP3 there will be fewer particles passing through the filtering material, therefore the TIL fit test should be giving a more accurate (or true) measure of fit than when it is used with standard efficiency FFP3. The statistical calculation of test sensitivity, at 0.94, with high efficiency FFP3 suggests a good correlation between the Bitrex fit test and the TIL fit test in the detection of poor fit, suggesting that the Bitrex fit test may also be giving a good measure of true fit. (Mullins[7] *et al* also found good correlation of the Bitrex test against a quantitative method when using a reusable half mask fitted with high efficiency filters.) It follows that since the Bitrex fit test method is not affected by particles passing through the filtering material, when it is used for standard efficiency FFP3 it should also be giving a good measure of true fit. As the Bitrex fit test method is the only fit test method not affected by particles passing through the filtering material, it may be the best measure of true fit for all FFP3, and also for FFP2 and FFP1.

A good fit could just fail the TIL fit test because particles passing through the filtering material will be counted as faceseal leakage. In such a situation the Bitrex fit test should pass, if the Bitrex fit test is a true measure of fit. The few cases in our study where this may have happened will show up in the statistics and will show the Bitrex fit test method as not as well in agreement with the TIL fit test method, because the TIL fit test result is slightly incorrect. This should be taken into account when judging the statistics of the Bitrex fit test method.

It follows that a reasonable way forward might be to measure all fit test methods against the Bitrex fit test method as the reference method, not the TIL fit test method. However, this judgement does not take into account other potential problems with the Bitrex fit test method; it should be remembered that the Bitrex fit test is subjective and depends on other factors such as the wearer's sensitivity to Bitrex taste and how they define a positive taste.

The test sensitivity is the most critical measure and this is higher (at 0.86 compared with 0.81) and hence more acceptable for the ANSI standard if the borderline results are counted as fails. Consideration was given to the possibility that adjusting the TIL pass level may improve the test sensitivity but calculations demonstrated that although the test sensitivity could be improved this would be at considerable detriment to the other statistical values.

3.3.6.1 Impact of test subject sensitivity to Bitrex on Bitrex fit test result

Another consideration was the sensitivity of the test subject to the taste of Bitrex and the impact of this on the test result. According to the accepted protocol, if the result of the Bitrex sensitivity test is any number from one to ten then, no matter what this actual number is, the amount of test agent applied in the subsequent Bitrex fit test should always be the same.

Figure 17 (Appendix B) categorises and quantifies the fit test results in relation to the Bitrex sensitivity test result. As can be seen from the bar chart, for most of the test runs the sensitivity of the test subject was 2 or 3 squirts of the Bitrex aerosol required for them to definitely taste this bitter substance. Three test runs only required 1 squirt of Bitrex whilst some needed 4 or more. The trend of this graph appears to show that a more sensitive test subject (low Bitrex sensitivity test result) may have a greater chance of returning a fail in the Bitrex fit test result. However, the number of test runs for which the Bitrex sensitivity test required more Bitrex (7, 8 or 9 squirts) is only 7. This is an insufficient quantity of data on which to draw definite conclusions but it does indicate a possible trend.

To explore the implications of this indicative trend further, the statistical analysis was repeated excluding the data from the test runs which followed a high numerical Bitrex sensitivity test result (i.e. relatively low subject sensitivity). This information is shown in Table 16 (Appendix B). Where test runs recording a numerical Bitrex sensitivity above 5 were excluded, the statistical values are improved with the test sensitivity increased to 0.89 and the predictive value of a pass and the Kappa statistic both increased slightly. This indicates that the Bitrex fit test may be giving more reliable results where test subjects have a more typical sensitivity to Bitrex.

In this study the 3M qualitative Bitrex fit test kit was used. The 3M hood is referred to in the OSHA standard[8] but several other qualitative Bitrex fit test kits are available in the UK, which have a different design of hood. This modified hood design could affect fit test results, for example if the space inside the hood is larger this could dilute the aerosol. Correlating data from this study for a larger hood the Bitrex sensitivity test result might still be within the 1-10 range, with an average type response, therefore requiring the same challenge aerosol amount for the fit test as needed for the 3M hood. However, when applied to a larger volume this could result in a relatively more dilute challenge and possibly an incorrect fit test result, leading to a pass where the fit is poor. Further work would be needed to explore this hypothesis.

3.4 SUBJECTIVE OPINION OF FIT - CORRELATION WITH FIT TEST RESULTS

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, according to current HSE guidance. Both the test subject and the fit tester were of the opinion that many of these FFP3 were fitting well. Others[20] have similarly found that user fit-checks cannot be relied upon to determine fit, and may be unreliable even for detecting gross misfits.

Table 17 and Table 18 (Appendix B) show the subjective opinion of the fit, including the fit-check result and the comments of the wearer and the fit tester both before and after the test run. These are further discussed in the following sections. The level of experience of the test subject in donning and wearing FFP is given as a star rating in these tables:

* no experience

** moderate experience

*** experienced

Table 19 (Appendix B) summarises the test subjects' opinions of fit relative to their experience. This table shows the percentage and number of occasions a test subject judged the fit to be good, when the fit failed in all fit test methods.

3.4.1.1 Fit-check v fit test results

Tables 17 and 18 (Appendix B) show the results of the pre-test fit-check compared with actual fit test results. A fit-check should always be carried out after donning a respirator and before the wearer enters the hazardous area. As the table shows the majority 105 (81%) of the fit-checks were successful with the fit being declared good, however 61 (58%) of the subsequent fit test runs returned a fail in all 4 fit test methods. Conversely only 15 (12%) of fit-checks returned a fail but 2 of these 'poor' fits went on to return fit test passes in every fit test method.

Similar percentages of fit-check results across all levels of test subject experience, given in Table 19 (Appendix B), 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.

Note; these results were partly subjected to the ANSI statistical analysis and this is discussed in section 3.4.2.

3.4.1.2 Test subject comments v fit test results

61 fit test runs returned a fail in all of the test methods. For these tests the test subject's initial comments on the fit after first donning the FFP3 were "good" in 18 (30%) donnings and "poor" in 18 (30%), with the remainder being "unsure". Following the test run the test subject's comments indicated that the fit was "good" for 15 (25%) and "poor" for 31(51%), with the remainder "unsure". This data shows that a few of the poor fits had been identified by the test subject during the test run, but by no means all of them, and 25% still thought that the fit was good.

16 test runs returned a pass in all methods. 7 (44%) of these were thought by the test subject to be good fits initially with none thought to be a poor fit. By the end of the test run 14 (88%) of test subjects thought that the fit of the FFP3 was good.

Table 19 (Appendix B) data shows the relatively higher percentage of inexperienced and moderately experienced test subjects judging a poor fit to be good prior to the test run, and indicates that experience is important in judgement of fit on first donning an FFP3. However, similar percentages of post-test run opinions across all levels of experience show that such experience did not affect ability to correctly judge a poor fit following wearing the FFP3 for the test run. In other words poor fits not initially recognised due to inexperience of test subjects can be picked up on by wearing the FFP3 for the test run (approximately 1 hour of wear time).

3.4.1.3 Fit tester observations v fit test results

Again looking at the 61 fit test runs which failed in all methods, the fit tester's initial comments after donning were good for 26 (43%) and poor for 15 (25%) of donnings, with the remainder unclear. At the end of the test run 23 (38%) were still being judged by the fit tester to be good fits and 17 (28%) poor.

16 test runs returned a pass in all methods. 9 (56%) of these were thought by the fit tester to be good fits from the first donning. This number increased slightly to 11(69%) by the end of the test run.

3.4.2 Fit-check results

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 fit. The European Standard for filtering facepieces EN149 requires manufacturers to include information and warnings for the user of filtering facepieces, and these are expected to cover 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. There is currently no specific requirement in the European Standard EN149 for a recommendation in support of fit testing to be included in manufacturers' instructions, although there is support for fit testing in EN529[21], the European RPE guidance document on selection use and maintenance.

Looking back to the results of the fit-check discussed in section 3.4.1.1, these were analysed using the ANSI methodology against the TIL fit test method calculating the test sensitivity. Where the test subject was uncertain of the result of the fit-check, this was termed borderline and classed as a fail for the purposes of calculation. The analysis gave a test sensitivity of 0.18 which is very poor, indicating that use of this fit-check alone is of little value in determining the quality of the fit of the FFP3. Similar test sensitivity for fit-checking, with values of 0.15 and 0.23 respectively on two models of filtering facepieces, was found by Lam *et al* [20]. The ANSI standard requires a test sensitivity of at least 0.95.

Given that there is much more value in a fit test than a fit-check in determining fit, there is justification for including information within the manufacturers' instructions recommending that a fit test should be carried out when selecting an FFP3.

3.5 FACIAL SIZES AND FIT OF FFP3

Figures 18 and 19 in Appendix B show the facial dimensions of the 25 test subjects plotted in accordance with ISO technical report ISO/TS 16976[18], both as PCA (principal component analysis) and bivariate length-width measurements. The number of tests which each subject took part in is shown in Table 19 (Appendix B) along with the identity of the FFP3s which they wore for test runs. Results are further presented in Figures 20 to 28 of Appendix B, identifying the face sizes with the fit test results for each FFP3. Green dots indicate that the fit test passed in all test methods, pink dots a fail in all methods and amber a mix of pass and fail across methods. Results are shown for a pass criterion of 100 in all quantitative fit test methods, and also with a pass of 70 applied to the Portacount fit test method (whilst other fit test methods remain at pass criterion 100).

Many of the test subjects fall within the most common face shape and size with a few outsiders with long wide faces or short narrow faces and short wide faces. No volunteers had long narrow faces.

S23 was the only test subject not to record a pass in at least one fit test but S23 was only able to take part in one test run, the only test subject who did not do multiple runs. All face shapes and sizes were able to achieve at least a single fit test pass in one test method with at least one FFP3. This does not mean that it would be straightforward for an employer to easily find suitable FFP3 for all their employees, especially if they have smaller faces. M9 proved a good fit on a wide range of face sizes including long wide faces and short narrow faces.

3.6 FIT TEST PASS RATE WITH FFP3 MODEL

Table 6 shows the number of fit test passes in all four fit test methods and the percentage pass rate, according to FFP3. M9 and M3 performed well with 40% and 50% of test subjects passing in all fit test methods. M1 passed in all fit test methods with 16% of test subjects, which is improved to 21% with a Portacount pass criterion of 70 applied. M5 results were improved from zero passes 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, even when the Portacount pass level was reduced to 70.

Table 6 Test runs achieving a pass in all four fit test methods by FFP3

	Portacount pass 100		Portacount pass 70	
FFP3 model	Number of test subjects passed in all test methods	% test subjects passed in all test methods	Number of test subjects passed in all test methods	% test subjects passed in all 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

No single design feature dominated the results. The FFP3s which returned the best results M1, M3, M5 and M9 included one or more of the full range of design features:

- rigid pre-formed cup shape with no nose adjustment
- softer cup shape with an a wearer-adjustable nose clip
- fold flat with a vertical fold and wearer-adjustable nose clip
- horizontal fold flat and wearer-adjustable nose clip
- small section of 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

Many test subjects complained that the FFP3 they were given was difficult or impossible to fit or uncomfortable. These were mainly the FFP3s which failed to give a pass for any test subject with all four fit test methods. 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

3.7 PASS LEVEL FOR THE EUROPEAN STANDARD EN149[1] TIL TEST

A simple assessment of the results of the TIL tests show that 93 of the 130 tests would easily have passed the European Standard EN149[1] test for Total Inward Leakage, achieving a fit factor of at least 50 in every exercise, or less than 2% TIL. The EN149 requirements (see section 3.2.1), are actually less stringent than indicated by this summary, therefore, even more of this study's TIL tests could well have passed the European Standard EN 149 test. It should also be considered that our test runs were carried out no matter how well the FFP3 appeared to fit whereas in a European Standard EN 149 TIL test, wearers who deemed the fit poor after donning would not have begun the test. Following such a pre–test run sifting an even greater percentage of the remaining TIL fit tests would result in an EN 149 TIL test pass.

In our study 61 of the test runs failed in every method of fit test, and at least 40 of these were not regarded as poor fits when donned. Therefore, many European Standard EN 149 TIL test passes would not be regarded as good fits using any of the fit test methods and criteria suggested in this study.

4. CONCLUSIONS

Overall, none of the fit test methods used in this study achieved all of the required, suggested or recommended values in all statistical calculations given in the ANSI standard, against the TIL fit test chamber method. That is, the three fit test methods (Portacount, Bitrex and Portacount-with-N95-Companion technology) when used for FFP3 do not meet all of the criteria for acceptance of a new fit test method, under ANSI/AIHA recommendations.

Failure to meet the ANSI criteria will be influenced by the shortcomings of the TIL fit test method when applied to FFP3 and used as a reference method. Unfortunately, there is no quantitative fit test method which can eliminate the effect of filtering material penetration on the fit factor results. The effect is to bias the fit factor low, which may lead to inaccuracies in the calculated statistical values when it is used as a reference method, especially reducing the predictive value of a pass and increasing the predictive value of a fail.

It would be impractical to expect all FFP3 fit tests to be carried out using the reference method, that is the TIL chamber fit test method. The test sensitivity (ability to correctly detect a poor fit) of the three other fit test methods used in this study was at least 0.88, which, whilst it falls short of the ANSI requirement of 0.95, is considerably better than the 0.18 which is the test sensitivity of a simple fit-check. It is clear from this work and that of others that simple subjective assessments cannot be relied upon to give an assessment of adequate fit and that any of the fit test methods used in this work are vastly superior to a fit-check in identifying poor fit. The reality is that the fit test methods used in this study do not fall far short of the ANSI criteria: they all meet the criteria in some respects.

One of the specific aims of this research was to examine the pass/fail criterion for the Portacount fit test method. Statistical analysis of the results obtained when working to the criteria laid down by the ANSI standard and following current HSE guidance and the information given in the methodology section of this report, shows that reducing the pass criterion from the current 100 to 70 would improve the overall agreement between the Portacount fit test method and the reference method based on the kappa statistic, with an increase from 0.46 to 0.65, an increase in test specificity from 0.42 to 0.67 and the predictive value of a fail increasing from 0.74 to 0.83. Note that the ANSI standard only specifies one outcome criterion as a requirement, the test sensitivity must be at least 0.95, other criteria are suggested or recommended by the ANSI standard. However, a pass criterion at 70 results in a decrease in test sensitivity from 0.99 to 0.95, still meeting the ANSI requirement, with a corresponding increase in beta error from 0.01 to 0.05. The reduction in the predicted value of a pass from 0.96 to 0.88 reduces the number of good fits which fail the Portacount fit test method and increases correlation between fit test results across all fit test methods when considering results for all FFP3 used in this study. However, this does lead to slightly less favourable statistics for correctly predicting a pass at 0.88, which is below that expected by the ANSI standard (0.95), but the calculated value may be biased low by the unavoidable inaccuracy of the reference method, however this is still a higher value than is achieved by either the Bitrex or Portacount –with –N95-Companion technology fit test methods.

Of note, are results relating to a pass criterion at 80 where test sensitivity is 0.99, beta error 0.01 and predictive value of a pass is 0.96 (>0.95), which are better statistical values than those with the Portacount criterion at 70. However, while test specificity at 0.60 and predictive value of a fail at 0.81 are within recommended values, they are lower than those

obtained with the pass criterion at 70. The kappa statistic at 0.64 which is the statistical value which indicates good agreement of this method with the reference method is 0.01 less than the kappa statistic obtained when a pass criterion of 70 is used. Therefore, the pass criterion at 70 gives better overall agreement with the reference method with all FFP3 used in this study.

The FFP3 used in this study had a range of filtering efficiencies and were broadly categorised into two groups described in this study as either standard or higher filtering efficiency. It is important to note that application of the ANSI criteria is not appropriate for either group when separated from the full data set due to insufficient data and therefore no firm conclusions can be drawn. However, more detailed analysis of the data from FFP3 with higher filtering efficiencies suggest that better correlation with the reference method is obtained with Portacount pass at 80, 90 or 100, although the test sensitivity is 0.94, below the ANSI requirement of 0.95. With standard filtering efficiency FFP3, the data suggest better correlation with the reference method is with Portacount pass 70 where the test sensitivity is 0.97, meeting the ANSI requirement. This analysis also suggests that the Bitrex method correlates better with the reference method with FFP3 with higher filtering efficiency than with FFP3 with standard filtering efficiency, as might be expected.

Also addressing one of the specific aims of this research to examine the suitability of using the Portacount-with-N95-Companion technology fit test method, based on the data from all of the FFP3 used, this study has shown that using the N95-Companion technology with the Portacount could provide a measure of FFP3 fit, if the pass criterion applied is 100. However, overall this method is returning results which are not in quite such good agreement with the TIL method as the Portacount used on its own, with correlation closest at Portacount pass 70.

Differences between the ANSI requirements and the levels achieved with the Portacount method may be (at least in part) due to the influence of filtering material penetration on the TIL results, especially for the predictive value of a pass which may be biased low at 0.88, but is still a better value when compared against either the Bitrex or the Portacount –with – N95-Companion technology fit test methods.

The reasons why the different fit test methods do not agree will be influenced by a number of factors. As well as filtering material penetration, differences in measurement methodologies, and the effect of wearer-generated particles will all play a part.

The Bitrex qualitative fit test method has been shown to give a good determination of fit in this study. It may have the potential to give the most accurate determination of true fit as the challenge particles do not pass through the filtering material in a form which can be detected, a problem which can occur when using quantitative fit test methods. The validity of this theory is supported when considering the results of standard and higher filtering efficiency FFP3 separately. However, the Bitrex qualitative fit test is a subjective method, dependent on the wearer's taste response, which is arguably less reliable than quantitative measuring equipment. The statistical values with the Bitrex fit test method are similar to those achieved with the Portacount-with-N95-companion technology (pass criterion 100).

Some FFP3 used in this study demonstrated that they can readily fit a significant proportion of the test subjects, with a range of face sizes, across all four fit test methods. Other FFP3 were poor at fitting all of our volunteers. There is room for significant improvement in the design of some FFP3 towards better wearer fit which could be aided by more stringent standard requirements for FFP3.

5. REFERENCES

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11 Bierman et al, LLNL Evaluation of the Portacount for Determining Respirator Fit Factors Lawrence Livermore Laboratory Oct 1991

12 NIOSH National Institute for Occupational Safety and Health Approved Particulate Filtering Facepiece Respirators
http://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/

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16

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19 www.random.org (Jan 2013)

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22 Rengasamy et al (2011) Evaluation of the filtration performance of NIOSH-approved N95 filtering facepiece respirators by photometric and number-based test methods. J Occup Environ Hyg; 8: 23-30

23 Clayton M. (2001) The effect of exhaled particles on RPE fit testing using the TSI Portacount Plus™ Respirator fit tester, HSL Internal Report PE/0/01

6. APPENDIX A - HSL STATISTICIAN'S REPORT ON THE ANSI STANDARD*

(*The ANSI/AIHA standard Z88.10-2010 Respirator Fit Testing methods Annex A2: Criteria for Evaluating new Fit test methods)

Comparison of methods of fit testing respirators with Fit Factors around 100

INTRODUCTION

The latest ANSI standard draft has just been published. The requirements to validate a new type of fit test procedure against the reference procedure have changed.

1. The exclusion criterion for "results too near to the pass/fail limit" has changed.
   This criterion is in the standard to ensure that the "gold" standard test (the Reference method) gives a reliable pass or fail. To apply the exclusion criterion, first the Standard Deviation of ONE subject using ONE mask at or around the Reference Fit Test Method Limit, must be measured.
   The new change now excludes results within one Coefficient of Variation. Previously it was within one Standard Deviation.
   Now CoV= SD/Mean, from repeat measurements on one subject with one facemask where that combination is close to the pass/fail limit, in this case a Fit Factor of 100.
   This is a sensible change that defines the criterion more appropriately, but has no impact on the number of tests required.
2. If results are to be excluded under point 1 above, more than 100 tests must be made.
3. At least 50 of those 100+ tests accepted under point 1 must also be below the pass/fail limit, i.e. below the CoV of the limit after point 1. This depends on the selection of the types of facemasks likely to give good and poor performances. It will extend the number of tests required to beyond 100.
4. The new ANSI standard acknowledges that the outcome of the test could depend on the underlying distribution of fit test results. A binary logistic regression method has been proposed but has not been independently evaluated.

NUMBER OF RESULTS

For planning a project around the standard to investigate a new test method, or to compare two existing test methods, the total number of tests is required, including those that would be excluded under point 1 above.

The problem is to state how many are likely to be excluded so as to design and cost an experiment that will end up with 100 usable results after exclusion has been applied.

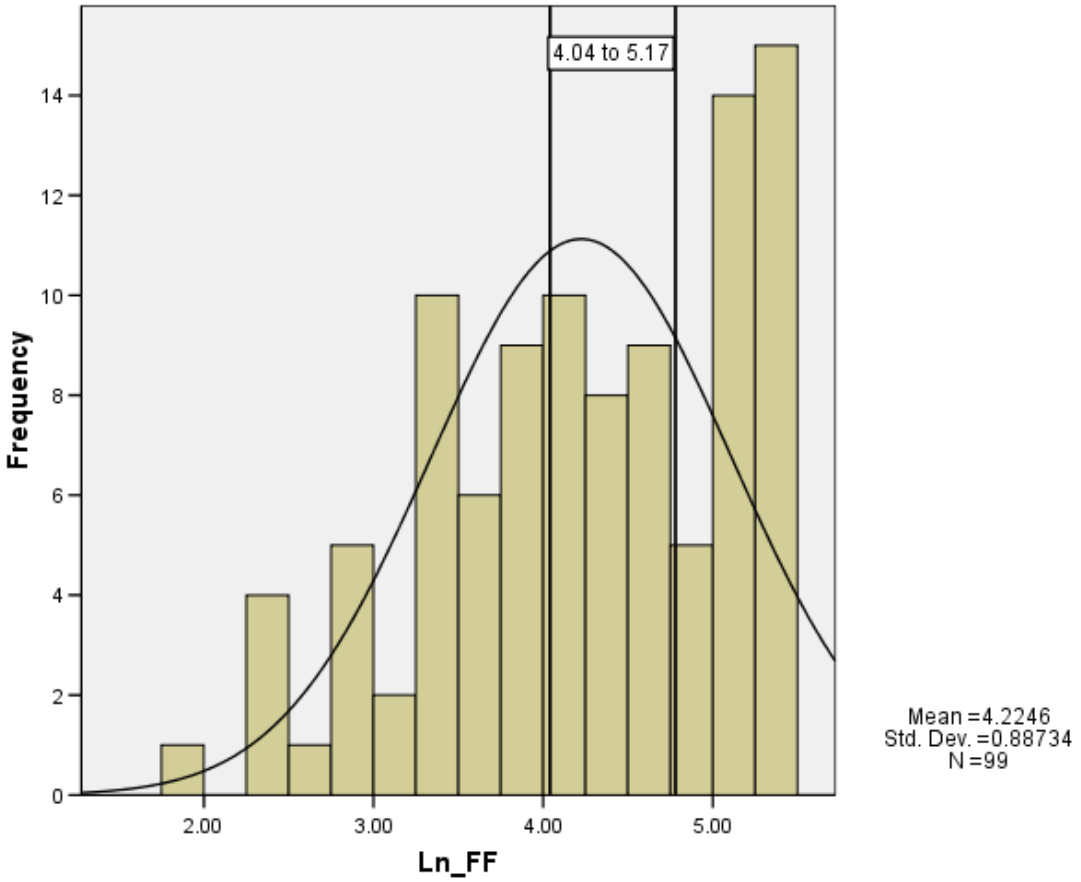
The ANSI standard reveals that tests carried out so far show a within-subject CoV of between 0.23 and 0.82 based on variations in leak location and breathing patterns and possibly, probe placement. By contrast, in a real ANSI test, the CoV would <u>not</u> reflect differences in breathing patterns or probe placement as only one subject and one mask is used so the probe location would not be changed. These CoV's may be <u>overestimates</u>.

Standard Deviation of results – Log transform method

Data from another HSL consultancy project showed that the distribution of Fit Factors was not normally distributed. Log-transformation was required to normalise it. The ANSI standard does not make any recommendation as to whether a suitable normalising transformation should or should not be used. The data was truncated such that Fit Factors >200 were reported as 200, so the standard deviation is known to be an underestimate. The estimate is based on variability of all 33 subjects with different fittings of the facemask each time.

By contrast, in a real ANSI test, the one subject chosen to determine CoV would be near to the 100 limit and the data would not be affected by truncation to FF=200 in the reference test method. The facemask is not refitted between readings, and the CoV should therefore be lower. The underestimate from the paragraph above may be near to the real situation.

The within-subject CoV was 0.12 using normalised (log-transformed) data. The figure below shows this CoV bracketing the log-transformed data around a fit factor of Ln(100) = 4.605, which is from 4.04 to 5.17, equivalent to Fit Factors of 56.8 and 175.9 respectively.



This was using ONE facemask, which complies with the ANSI standard test criterion. This is a much lower CoV than those reported by ANSI. The CoV was obtained using 33 subjects 3 times each, and calculating the within-subject Standard deviation using ANOVA. Probe placement variability was not an issue here, nor would it be in the proposed test programme, so the ANSI CoV's may be overestimates.

If the new ANSI rejection criterion were applied to the original results, 36 of the 99 tests (36%) would have been excluded between FF=56.8 and FF=175.9. Three subjects out of the 33 would

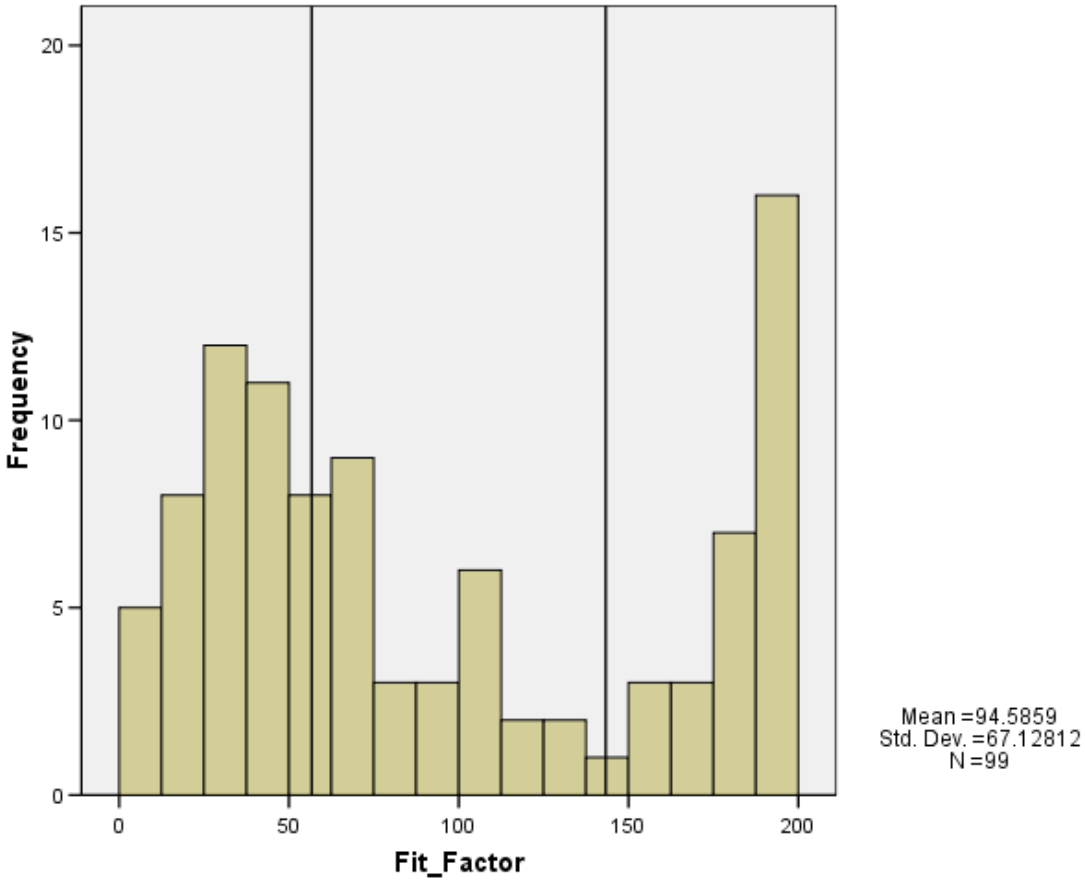
have been entirely excluded from this data set because they were too close to the limit on each occasion with this facemask, however the ANSI test programme being considered would use more than one mask on each individual, so volunteers are unlikely to have to be rejected entirely.

Increasing the number of tests in proportion, and accepting that some of those re-tests would also be rejected in turn, then the number of tests required to get 100 accepted tests would be 156.

Standard Deviation of results – Untransformed method

If normalising is NOT required, the same data set yields a CoV of 0.43. Although this seems to be much higher figure than the log-transformed data (which was 0.12) the criterion only excludes 28 of the data points around FF=100, i.e. between FF=57 and FF=143. These limits are quite similar to the CoV limits from the log-normal transformation.

Increasing the number of tests in proportion, and accepting that some of those re-tests would also be rejected in turn, then the number of tests required to get 100 accepted tests would be 139.



POWER

The power of a test is defined as the probability of accepting a result (passing the method) when it should be accepted. This is the Sensitivity of the test. The ANSI standard comments that this

criterion (based on the beta error) was the most important in defining the test criteria. The power is therefore specified to be at least 0.95 (95%) by the ANSI test method "success" criterion to be able to accept the new test method.

However, a paper from 2004[1] stated that "The calculated test sensitivity can vary as a function of the distribution of the reference fit factors" and that this was an undesirable property in a test.

Nevertheless, the ANSI test as formulated with 100 tests will have sufficient power to assess the fit test methods.

BIAS

There is the possibility of bias from one facemask to a particular type of test method. The bias may be caused by a less than ideal probe location forced by the structure of the facemask.

Bias cannot therefore be eliminated so it must be minimised. Bias is minimised by expanding the range of facemasks in the study.

It is proposed to use nine facemask models of various brands for this project to reduce the effects of bias. A minimum number of models of facemasks is not specified in the ANSI standard.

The requirement that at least 50 tests must be less than the pass/fail limit (or rather less than one CoV below the pass/fail limit) depends on the performance of the selected models of facemask. A balance of good and poor performing models should be selected amongst the nine. To satisfy this requirement, more than 100 acceptable tests will have to be gathered, but this cannot be quantified further at this stage.

It is worth noting that poor performers will often allow more inward leakage through the filter material, and therefore are not purely measures of fit to the face that the fit test comparison procedure is supposed to isolate. There may be biases between different fit test procedures because filter material performance depends on particle size and charge.

CONCLUSION

Between 139 and 155 tests would need to be made to obtain a set of 100 acceptable results according to the ANSI "±CoV" acceptance criterion. An additional unknown number will have to be gathered to satisfy the "50 or more <limit" criterion. However this additional number will be minimised by appropriate prior choice of facemask models and the outcome cannot be quantitatively assessed further here.

Chance will dictate that a significant number of results will be less than the limit because poor fits can occur with good facemasks, even with subjects known to fit facemasks well. The converse situation is encountered less often, whereby a poor respirator on a poorly fitting subject achieves a very good fit, but this is the author's opinion based on many years of experience of respirator testing in the past. It is the author's opinion that relatively few additional tests, if any, would need to be performed to fulfil this second criterion.

It is worth planning for the upper bound of the 139-155 sample number estimated range.

[1] *Nelson TJ and Mullins HE (2004) Recommendations for the Acceptance Criteria for New Fit Test Methods. JISRP V 21 pp 1-10*

In addition, one subject will need several repeat tests on one fitting using the reference method only, to ascertain the CoV. This does not take as long to perform as the full test regime so will not impact very much on time and costs. However the ANSI standard does not recommend a minimum number of repeats to assess the CoV. More samples are needed to measure a standard deviation with any degree of accuracy than to measure the mean. The value of the CoV is critical to the number of tests that must be rejected, although the normal/log-normal analyses above suggest that that number is relatively stable. It is suggested here that at least 7 repeat tests should be performed.

As an aside, the data set that will be created in this project will be of great value in future for modelling by bootstrapping of results. This statistical method picks data from the set in a random process, allowing the final result to be recalculated, which might have a slightly different outcome to the first (full) analysis. Many random repeats of this process can allow a distribution of the outcomes to be generated, informing decisions about the reliability of the ANSI standard method.

Martin Roff
19/4/2011

7. APPENDIX B - RESULTS SUPPLEMENTARY TABLES AND GRAPHS

Tables and graphs included in this section are referred to in the main results, section 3.

Table 7 Headline results raw data pass criteria 100 in all quantitative methods

Test number	FFP3	Bitrex	TIL	TIL	Portacount standard mode	Portacount standard mode	Portacount N95 mode minimum	Portacount N95 mode	Test Subject
			minimum	pass/fail	minimum	pass/fail	minimum	pass/fail	
Pass criteria				100		100		100	
1	M4	pass	0	INVALID	227	pass	384	pass	S1
2	M8	fail	0	INVALID	22	fail	19	fail	S2
3	M7	fail	0	INVALID	12	fail	15	fail	S3
4	M3	fail	0	INVALID	630	pass	2510	pass	S2
5	M1	pass	81	fail	77	fail	124	pass	S1
6	M1	pass	112	pass	61	fail	67	fail	S4
7	M4	fail	68	fail	44	fail	43	fail	S5
8	M7	fail	35	fail	5	fail	13	fail	S6
9	M3	pass	2879	pass	155	pass	785	pass	S7
10	M8	borderline	98	fail	31	fail	31	fail	S4
11	M5	borderline	35	fail	75	fail	73	fail	S6
12	M2	fail	35	fail	14	fail	13	fail	S8
13	M8	fail	63	fail	14	fail	12	fail	S9
14	M6	fail	52	fail	9	fail	7	fail	S7
15	M2	fail	29	fail	11	fail	11	fail	S4

Test number	FFP3	Bitrex	TIL	TIL	Portacount standard mode	Portacount standard mode	Portacount N95 mode minimum	Portacount N95 mode	Test Subject
			minimum	pass/fail	minimum	pass/fail	minimum	pass/fail	
Pass criteria				100		100		100	
16	M1	pass	307	pass	58	fail	117	pass	S10
17	M1	fail	87	fail	55	fail	54	fail	S11
18	M8	borderline	103	pass	57	fail	64	fail	S6
19	M6	fail	21	fail	17	fail	15	fail	S1
20	M3	pass	3500	pass	157	pass	198	pass	S9
21	M9	pass	206	pass	141	pass	195	pass	S8
22	M2	fail	24	fail	15	fail	15	fail	S5
23	M8	fail	70	fail	47	fail	55	fail	S1
24	M9	pass	157	pass	192	pass	236	pass	S12
25	M9	borderline	433	pass	149	pass	293	pass	S10
26	M1	pass	127	pass	97	fail	65	fail	S13
27	M9	borderline	97	fail	44	fail	53	fail	S9
28	M1	borderline	114	pass	29	fail	37	fail	S14
29	M4	pass	273	pass	61	fail	51	fail	S15
30	M6	borderline	17	fail	10	fail	10	fail	S13
31	M1	fail	39	fail	33	fail	27	fail	S2
32	M9	fail	99	fail	46	fail	39	fail	S7

Test number	FFP3	Bitrex	TIL	TIL	Portacount standard mode	Portacount standard mode	Portacount N95 mode minimum	Portacount N95 mode	Test Subject
			minimum	pass/fail	minimum	pass/fail	minimum	pass/fail	
Pass criteria				100		100		100	
33	M6	fail	7	fail	4	fail	4	fail	S4
34	M9	pass	150	pass	115	pass	144	pass	S3
35	M2	fail	119	pass	51	fail	47	fail	S6
36	M1	pass	240	pass	159	pass	175	pass	S8
37	M6	fail	16	fail	9	fail	7	fail	S11
38	M2	fail	28	fail	27	fail	20	fail	S9
39	M6	fail	147	pass	17	fail	14	fail	S6
40	M2	fail	14	fail	27	fail	23	fail	S3
41	M4	fail	6	fail	3	fail	2	fail	S7
42	M3	pass	5656	pass	213	pass	1650	pass	S4
43	M2	fail	38	fail	14	fail	12	fail	S2
44	M3	pass	3128	pass	122	pass	653	pass	S16
45	M6	fail	44	fail	13	fail	10	fail	S10
46	M4	pass	23	fail	27	fail	31	fail	S8
47	M1	fail	72	fail	28	fail	32	fail	S9
48	M1	fail	87	fail	43	fail	53	fail	S12
49	M2	fail	29	fail	17	fail	15	fail	S11

Test number	FFP3	Bitrex	TIL	TIL	Portacount standard mode	Portacount standard mode	Portacount N95 mode minimum	Portacount N95 mode	Test Subject
			minimum	pass/fail	minimum	pass/fail	minimum	pass/fail	
Pass criteria				100		100		100	
50	M3	pass	5803	pass	129	pass	1120	pass	S6
51	M4	fail	16	fail	37	fail	32	fail	S14
52	M1	pass	101	pass	115	pass	149	pass	S17
53	M8	pass	81	fail	79	fail	72	fail	S8
54	M7	fail	25	fail	10	fail	9	fail	S9
55	M4	fail	27	fail	39	fail	31	fail	S16
56	M4	fail	308	pass	71	fail	59	fail	S2
57	M4	fail	1509	pass	67	fail	70	fail	S6
58	M8	borderline	106	pass	31	fail	27	fail	S18
59	M6	fail	11	fail	3	fail	3	fail	S3
60	M2	fail	24	fail	31	fail	25	fail	S16
61	M7	fail	35	fail	4	fail	4	fail	S19
62	M7	fail	26	fail	12	fail	12	fail	S4
63	M5	pass	135	pass	86	fail	84	fail	S4
64	M1	pass	162	pass	101	pass	118	pass	S6
65	M7	fail	24	fail	15	fail	14	fail	S20
66	M6	fail	9	fail	4	fail	3	fail	S5

Test number	FFP3	Bitrex	TIL	TIL	Portacount standard mode	Portacount standard mode	Portacount N95 mode minimum	Portacount N95 mode	Test Subject
			minimum	pass/fail	minimum	pass/fail	minimum	pass/fail	
Pass criteria				100		100		100	
67	M5	pass	374	pass	86	fail	305	pass	S10
68	M5	fail	44	fail	20	fail	17	fail	S2
69	M3	borderline	1522	pass	73	fail	346	pass	S10
70	M4	fail	670	pass	69	fail	73	fail	S19
71	M5	pass	76	fail	64	fail	117	pass	S21
72	M9	fail	123	pass	136	pass	126	pass	S6
73	M4	fail	31	fail	27	fail	23	fail	S18
74	M3	fail	87	fail	17	fail	15	fail	S14
75	M7	borderline	322	pass	40	fail	37	fail	S7
76	M5	pass	40	fail	32	fail	121	pass	S13
77	M9	fail	35	fail	123	pass	147	pass	S18
78	M2	pass	36	fail	29	fail	27	fail	S1
79	M3	fail	409	pass	70	fail	253	pass	S19
80	M9	fail	150	pass	16	fail	38	fail	S2
81	M2	fail	19	fail	9	fail	8	fail	S17
82	M2	fail	47	fail	18	fail	18	fail	S10
83	M6	fail	65	fail	13	fail	10	fail	S2

Test number	FFP3	Bitrex	TIL	TIL	Portacount standard mode	Portacount standard mode	Portacount N95 mode minimum	Portacount N95 mode	Test Subject
			minimum	pass/fail	minimum	pass/fail	minimum	pass/fail	
Pass criteria				100		100		100	
84	M6	borderline	33	fail	15	fail	11	fail	S16
85	M1	fail	187	pass	95	fail	143	pass	S7
86	M3	pass	454	pass	106	pass	552	pass	S1
88	M5	pass	139	pass	91	fail	197	pass	S17
89	M8	fail	8	fail	5	fail	4	fail	S7
90	M5	fail	93	fail	34	fail	33	fail	S9
91	M9	fail	72	fail	18	fail	18	fail	S4
92	M8	fail	86	fail	63	fail	55	fail	S5
93	M8	fail	22	fail	19	fail	16	fail	S22
94	M9	pass	479	pass	278	pass	269	pass	S17
95	M5	fail	56	fail	63	fail	66	fail	S3
96	M6	fail	7	fail	5	fail	4	fail	S19
97	M6	pass	64	fail	17	fail	16	fail	S8
98	M8	fail	95	fail	18	fail	16	fail	S23
99	M1	pass	93	fail	67	fail	90	fail	S22

Test number	FFP3	Bitrex	TIL	TIL	Portacount standard mode	Portacount standard mode	Portacount N95 mode minimum	Portacount N95 mode	Test Subject
			minimum	pass/fail	minimum	pass/fail	minimum	pass/fail	
Pass criteria				100		100		100	
101	M5	pass	446	pass	99	fail	561	pass	S1
102	M8	borderline	147	pass	36	fail	40	fail	S10
103	M1	fail	25	fail	24	fail	25	fail	S5
104	M3	fail	138	pass	26	fail	25	fail	S21
105	M7	fail	14	fail	5	fail	6	fail	S18
106	M4	fail	25	fail	9	fail	9	fail	S24
107	M9	pass	1203	pass	140	pass	296	pass	S14
108	M5	fail	28	fail	27	fail	50	fail	S19
109	M3	pass	4869	pass	182	pass	1120	pass	S5
110	M4	fail	19	fail	5	fail	4	fail	S22
111	M1	pass	64	fail	60	fail	84	fail	S21
112	M9	pass	342	pass	306	pass	618	pass	S1
113	M4	fail	266	pass	83	fail	83	fail	S11
114	M5	fail	89	fail	58	fail	126	pass	S15
115	M8	pass	110	pass	41	fail	40	fail	S3
116	M8	fail	57	fail	26	fail	21	fail	S14
117	M8	fail	20	fail	8	fail	5	fail	S13

Test number	FFP3	Bitrex	TIL	TIL	Portacount standard mode	Portacount standard mode	Portacount N95 mode minimum	Portacount N95 mode	Test Subject
			minimum	pass/fail	minimum	pass/fail	minimum	pass/fail	
Pass criteria				100		100		100	
118	M4	fail	24	fail	16	fail	17	fail	S3
119	M6	pass	57	fail	23	fail	22	fail	S12
120	M1	pass	44	fail	34	fail	33	fail	S24
121	M5	fail	79	fail	49	fail	53	fail	S5
122	M7	fail	30	fail	23	fail	26	fail	S15
123	M1	fail	149	pass	87	fail	84	fail	S25
124	M3	borderline	43	fail	26	fail	24	fail	S24
125	M9	fail	36	fail	62	fail	69	fail	S5
126	M6	fail	15	fail	7	fail	9	fail	S22
127	M8	fail	13	fail	10	fail	8	fail	S24
128	M9	fail	62	fail	45	fail	40	fail	S20
129	M1	fail	48	fail	59	fail	61	fail	S3
130	M8	fail	57	fail	10	fail	8	fail	S25
131	M4	fail	147	pass	57	fail	46	fail	S9
132	M7	pass	557	pass	101	pass	103	pass	S1

Figure 6 Fit factor data spread by FFP3 model: TIL v Portacount with line of best fit applied

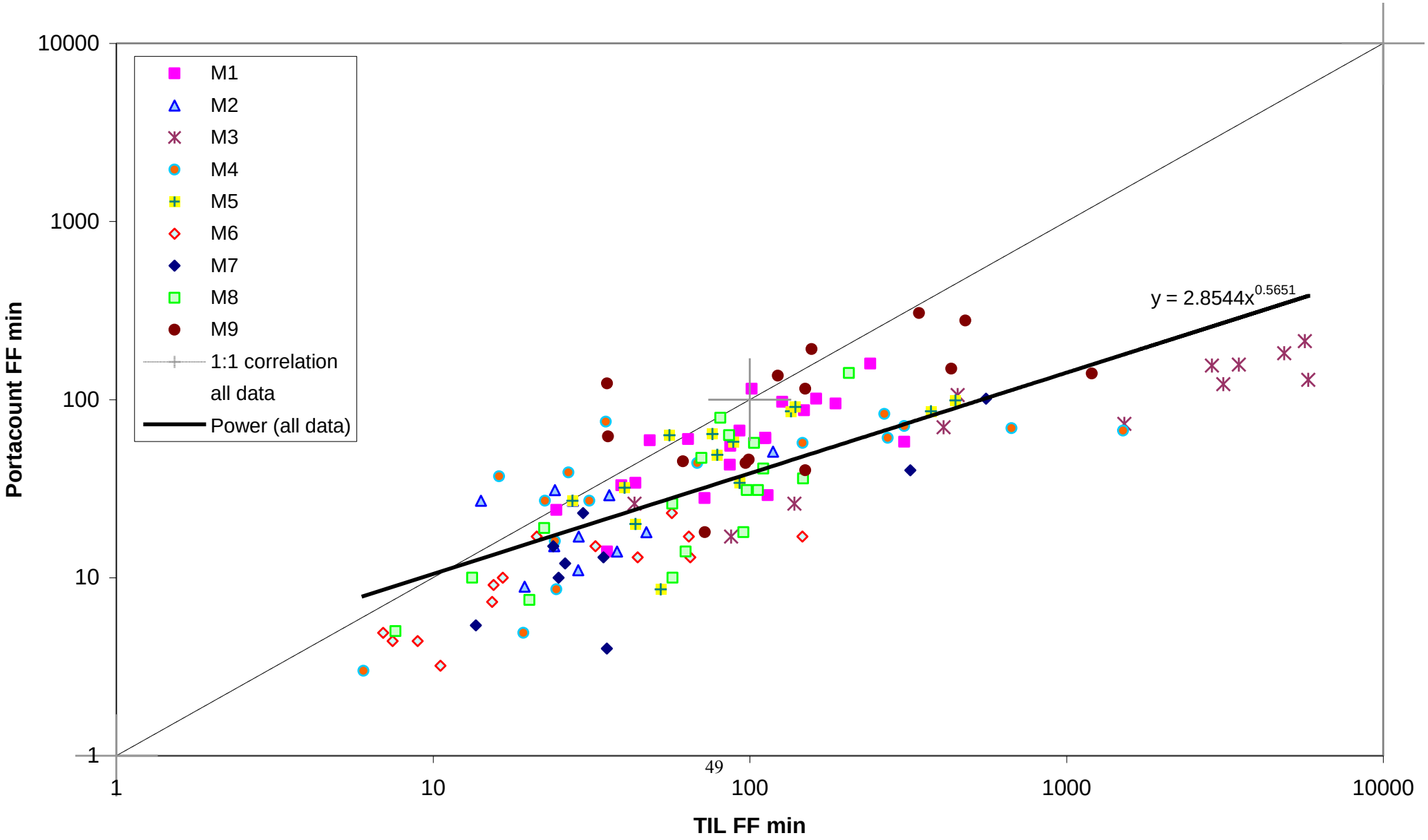


Figure 7 Fit factor data spread by FFP3 model: TIL v Portacount-with-N95-Companion with line of best fit applied

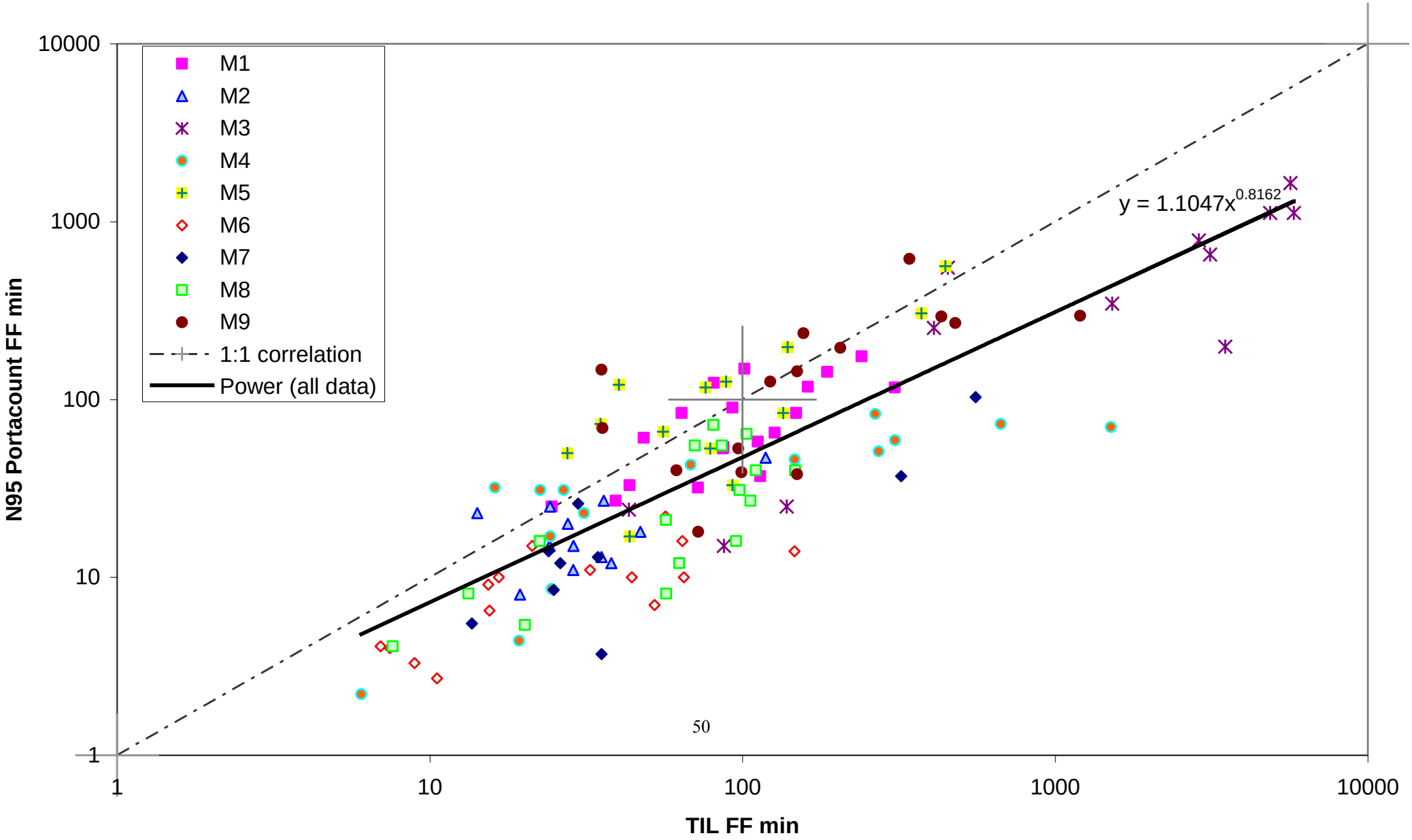


Figure 8 Box plots showing spread of Bitrex results

Outliers are marked as circles.
Outliers are deemed to be data points more than 1.5 times the length of the box above or below the top or bottom lines of the box.
There are high outliers but no low outliers in this (log-transformed) data set.

The whiskers reach to the highest and lowest data points that are not outliers.

The top and bottom lines of the boxes represent the upper and lower 25%ile of the data. The line across the box is the median (50%ile).

Extreme outliers are data points more than 3 box lengths above or below the box and would be marked as asterisks, but none are present in this data set.

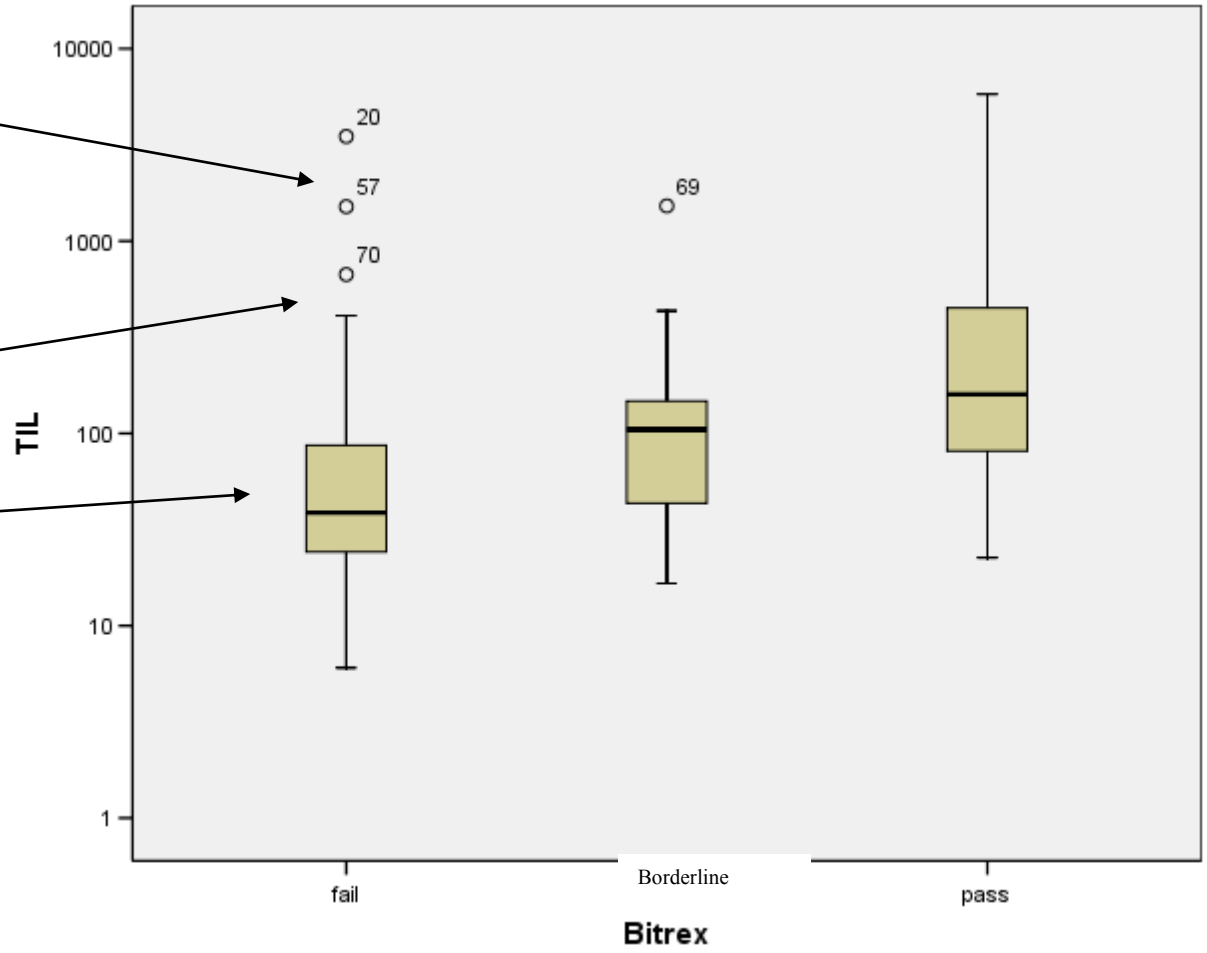


Figure 9 Distribution of Fit factors for the TIL method

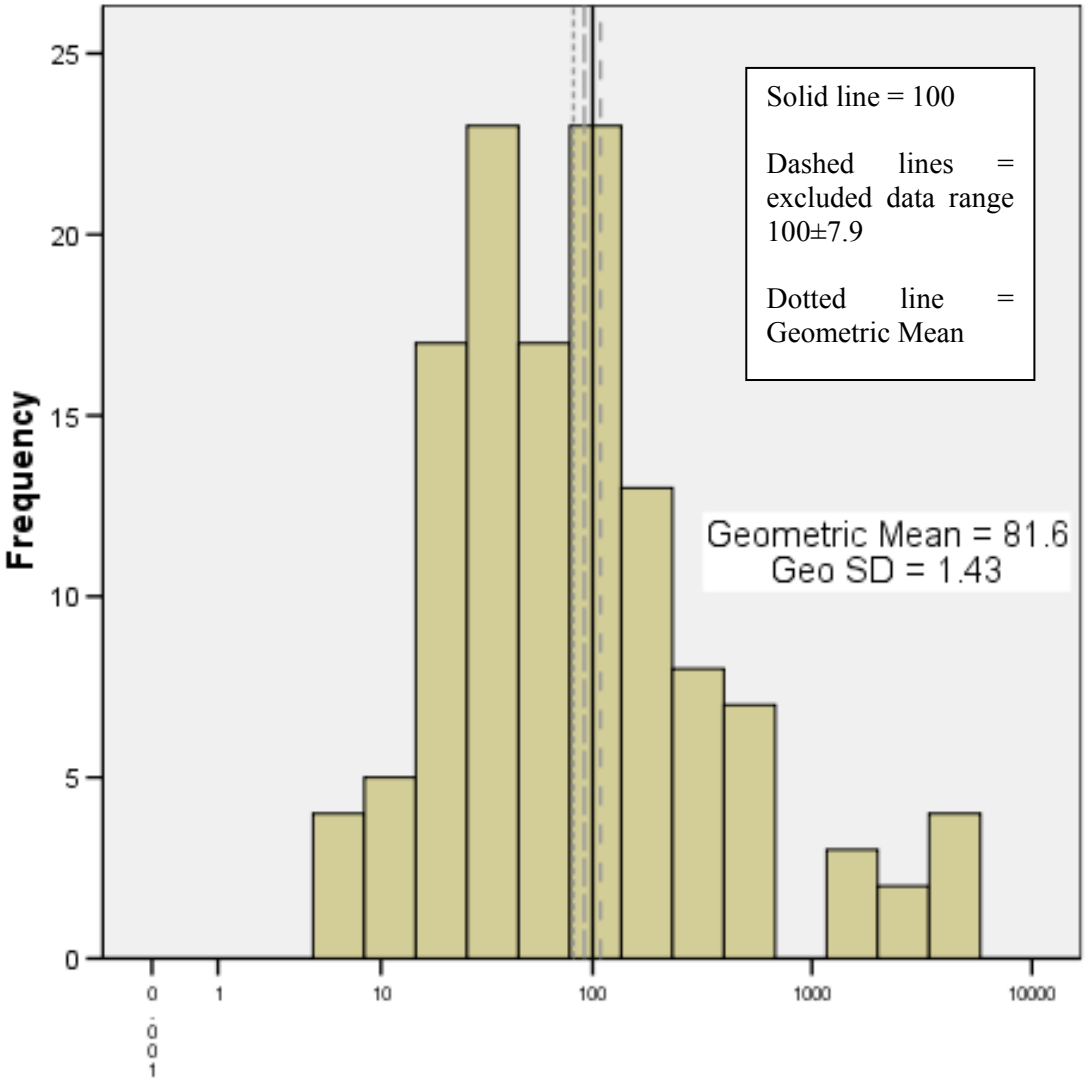


Table 8 Covariance test run results and calculation of coefficient of variation

Covariance test run results and calculation of coefficient of variation

Exercise	Fit Factors									
	Part 1	Part 2	Part 3	Part 4	Part 5	Part 6	Part 7			
Walking	63.0	54.9	55.2	78.7	53.2	52.8	56.8			
Head side to side	82.8	92.1	50.7	71.6	56.6	53.7	54.1			
Head up and down	78.2	68.1	69.9	59.1	72.7	57.0	75.9			
Talking	57.0	62.7	58.9	66.6	50.1	55.9	56.1			
Walking	40.4	46.3	43.0	50.7	47.3	47.6	42.4			
								STDEV	**MEAN**	**CoV%**
										STDEV*100/MEAN
minimum	40.4	46.3	43.0	50.7	47.3	47.6	42.4	3.6	45.4	**7.9**

Table 9 Initial statistical calculations – all valid data all methods pass criterion =100

ANSI/AIHA Z88.10-2010 Annex A2 analysis calculations										
Pass criteria	**all 100**			**Test sensitivity**	**Beta error**	**Predictive value of pass**	**Test specificity**	**Predictive value of a fail**		**Kappa Statistic**
				required >/=0.95	**required =/<0.05**	**suggested >/=0.95**	**suggested >0.5**	**suggested >0.5**		**recommended >0.7**
									Po=	(B+C)/(A+B+C+D)
									E=	(A+B)(B+D)
		TIL	TIL						F=	(C+D)(A+C)
		Failed	passed						G=	A+B+C+D
	Passed	A	B						Pe=	(E+F)/G*G
Formulae	failed	C	D	C/(A+C)	1-(C/(A+C)	B/(A+B)	B/(B+D)	C/(C+D)	**K=**	**(Po-Pe)/(1-Pe)**
									Po=	0.76
									E=	1419.00
		TIL	TIL						F=	6216.00
		Failed	passed						G=	117.00
Bitrex	Passed	9	24						Pe=	0.5577471
Bitrex (includes borderline)	failed	65	19	**0.88**	**0.12**	**0.73**	**0.56**	**0.77**	**K=**	**0.46**
									Po=	0.77
									E=	1892.00
		TIL	TIL						F=	5402.00
		Failed	passed						G=	117.00
Bitrex (includes borderline)	Passed	14	30						Pe=	0.53
Bitrex	failed	60	13	**0.81**	**0.19**	**0.68**	**0.70**	**0.82**	**K=**	**0.51**
									Po=	0.78
									E=	817.00
		TIL	TIL						F=	7252.00
		Failed	passed						G=	117.00
Portacount	Passed	1	18						Pe=	0.59
Portacount	failed	73	25	**0.99**	**0.01**	**0.95**	**0.42**	**0.74**	**K=**	**0.46**
									Po=	0.80
									E=	1290.00
		TIL	TIL						F=	6438.00
		Failed	passed						G=	117.00
Portac. +N95	Passed	5	25						Pe=	0.56
Portac. +N95	failed	69	18	**0.93**	**0.07**	**0.83**	**0.58**	**0.79**	**K=**	**0.55**

Table 10 Statistical calculations v Portacount pass criterion

ANSI/AIHA Z88.10-2010 Annex A2									
Pass criterion				**Test sensitivity**	**beta error**	**predictive value of pass**	**test specificity**	**predictive value of a fail**	**Kappa Statistic**
				>=0.95		**>=0.95**	**>0.5**	**>0.5**	**>0.7**
		TIL	TIL						
		Failed	passed						
Portacount 39	Passed	18	39						
Portacount 39	failed	56	4	**0.76**	**0.24**	**0.68**	**0.91**	**0.93**	**0.62**
		TIL	TIL						
		Failed	passed						
Portacount 60	Passed	9	33						
Portacount 60	failed	65	10	**0.88**	**0.12**	**0.79**	**0.77**	**0.87**	**0.65**
		TIL	TIL						
		Failed	passed						
Portacount 70	Passed	4	29						
Portacount 70	failed	70	14	**0.95**	**0.05**	**0.88**	**0.67**	**0.83**	**0.65**
		TIL	TIL						
		Failed	passed						
Portacount 80	Passed	1	26						
Portacount 80	failed	73	17	**0.99**	**0.01**	**0.96**	**0.60**	**0.81**	**0.64**
		TIL	TIL						
		Failed	passed						
Portacount 90	Passed	1	22						
Portacount 90	failed	73	21	**0.99**	**0.01**	**0.96**	**0.51**	**0.78**	**0.55**
		TIL	TIL						
		Failed	passed						
Portacount 100	Passed	1	18						
Portacount 100	failed	73	25	**0.99**	**0.01**	**0.95**	**0.42**	**0.74**	**0.46**

Figure 10 Portacount pass criterion v statistical values calculated

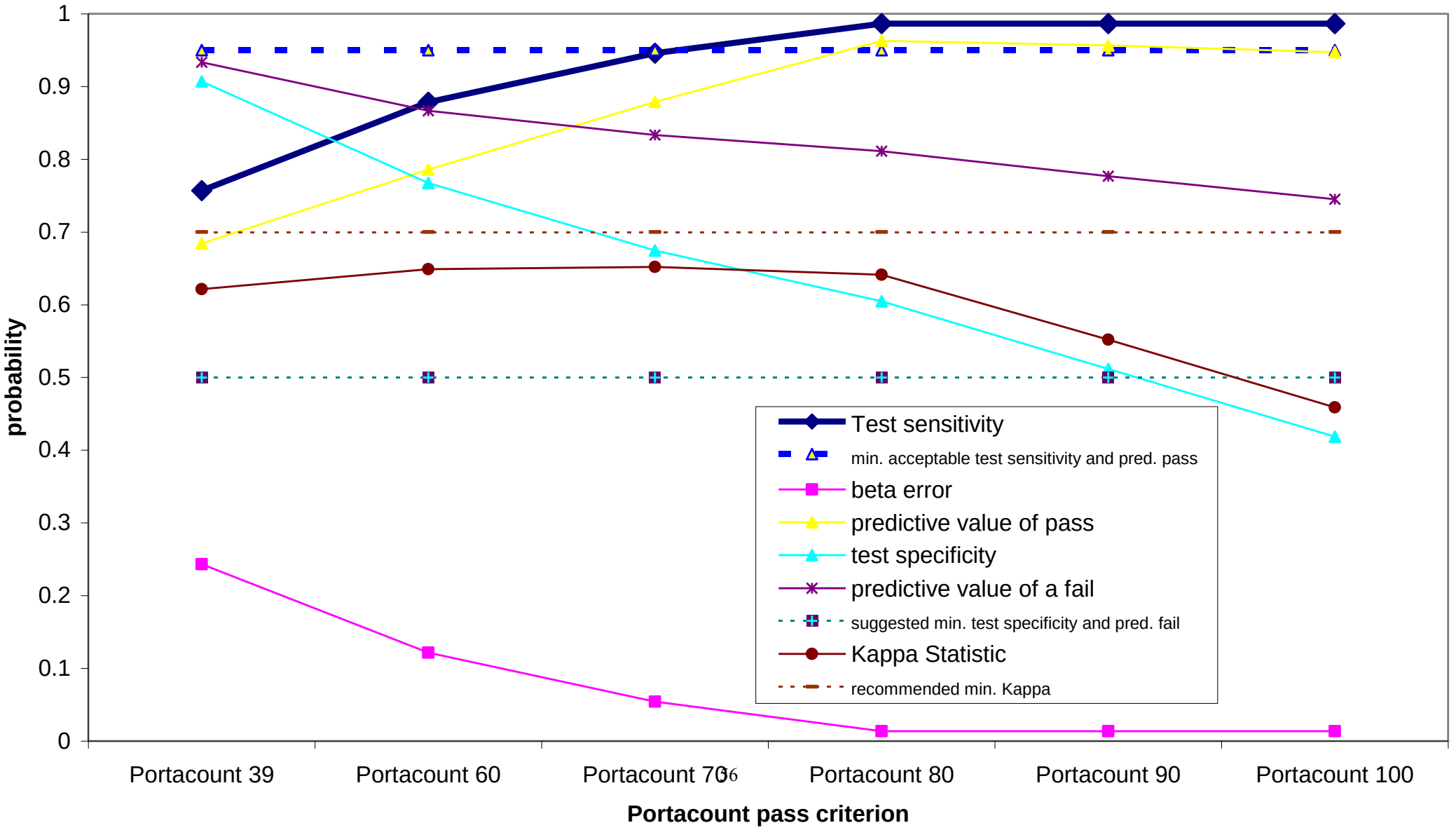


Table 11 Statistical calculations – standard filtering efficiency FFP3: all test methods

ANSI/AIHA Z88.10-2010 Annex A2 - standard filtering efficiency: all test methods								
Pass criteria	**all 100**			**Test sensitivity**	**beta error**	**predictive value of pass**	**test specificity**	**predictive value of a fail**	**Kappa Statistic**
				required >/=0.95	**required =/<0.05**	**suggested >/=0.95**	**suggested >0.5**	**suggested >0.5**	**recommended >0.7**
		TIL	TIL						
		Failed	passed						
Bitrex	Passed	9	11						
Bitrex (includes borderline)	failed	49	11	**0.84**	**0.16**	**0.55**	**0.50**	**0.82**	**0.35**
		TIL	TIL						
		Failed	passed						
Bitrex (includes borderline)	Passed	12	14						
Bitrex	failed	46	8	**0.79**	**0.21**	**0.54**	**0.64**	**0.85**	**0.41**
		TIL	TIL						
		Failed	passed						
Portacount	Passed	0	3						
Portacount	failed	58	19	**1.00**	**0.00**	**1.00**	**0.14**	**0.75**	**0.19**
		TIL	TIL						
		Failed	passed						
Portac. +N95	Passed	4	8						
Portac. +N95	failed	54	14	**0.93**	**0.07**	**0.67**	**0.36**	**0.79**	**0.34**

Table 12 Statistical calculations – high filtering efficiency FFP3: all test methods

ANSI/AIHA Z88.10-2010 Annex A2 - high filtering efficiency: all test methods									
Pass criteria	**all 100**			**Test sensitivity**	**beta error**	**predictive value of pass**	**test specificity**	**predictive value of a fail**	**Kappa Statistic**
				required >/=0.95	**required =/<0.05**	**suggested >/=0.95**	**suggested >0.5**	**suggested >0.5**	**recommended >0.7**
		TIL	TIL						
		Failed	passed						
Bitrex	Passed	1	14						
Bitrex (includes borderline)	failed	15	7	**0.94**	**0.06**	**0.93**	**0.67**	**0.68**	**0.58**
		TIL	TIL						
		Failed	passed						
Bitrex (includes borderline)	Passed	2	17						
Bitrex	failed	14	4	**0.88**	**0.13**	**0.89**	**0.81**	**0.78**	**0.67**
		TIL	TIL						
		Failed	passed						
Portacount	Passed	1	15						
Portacount	failed	15	6	**0.94**	**0.06**	**0.94**	**0.71**	**0.71**	**0.63**
		TIL	TIL						
		Failed	passed						
Portac. +N95	Passed	1	17						
Portac. +N95	failed	15	4	**0.94**	**0.06**	**0.94**	**0.81**	**0.79**	**0.73**

Table 13 Statistical calculations v Portacount pass criterion – standard filtering efficiency FFP3

ANSI/AIHA Z88.10-2010 Annex A2 - standard filtering efficiency									
Pass criteria				**Test sensitivity**	**beta error**	**predictive value of pass**	**test specificity**	**predictive value of a fail**	**Kappa Statistic**
				required >/=0.95	**required =/<0.05**	**suggested >/=0.95**	**suggested >0.5**	**suggested >0.5**	**recommended >0.7**
		TIL	TIL						
		Failed	passed						
Portacount 60	Passed	5	16						
Portacount 60	failed	53	6	**0.91**	**0.09**	**0.76**	**0.73**	**0.90**	**0.65**
		TIL	TIL						
		Failed	passed						
Portacount 70	Passed	2	12						
Portacount 70	failed	56	10	**0.97**	**0.03**	**0.86**	**0.55**	**0.85**	**0.58**
		TIL	TIL						
		Failed	passed						
Portacount 80	Passed	0	11						
Portacount 80	failed	58	11	**1.00**	**0.00**	**1.00**	**0.50**	**0.84**	**0.59**
		TIL	TIL						
		Failed	passed						
Portacount 90	Passed	0	7						
Portacount 90	failed	58	15	**1.00**	**0.00**	**1.00**	**0.32**	**0.79**	**0.40**
		TIL	TIL						
		Failed	passed						
Portacount 100	Passed	0	3						
Portacount 100	failed	58	19	**1.00**	**0.00**	**1.00**	**0.14**	**0.75**	**0.19**

Table 14 Statistical calculations v Portacount pass criterion – high filtering efficiency FFP3

ANSI/AIHA Z88.10-2010 Annex A2 - High filtering efficiency									
Pass criteria				**Test sensitivity**	**beta error**	**predictive value of pass**	**test specificity**	**predictive value of a fail**	**Kappa Statistic**
				required >/=0.95	**required =/<0.05**	**suggested >/=0.95**	**suggested >0.5**	**suggested >0.5**	**recommended >0.7**
		TIL	TIL						
		Failed	passed						
Portacount 60	Passed	4	17						
Portacount 60	failed	12	4	**0.75**	**0.25**	**0.81**	**0.81**	**0.75**	**0.56**
		TIL	TIL						
		Failed	passed						
Portacount 70	Passed	2	17						
Portacount 70	failed	14	4	**0.88**	**0.13**	**0.89**	**0.81**	**0.78**	**0.67**
		TIL	TIL						
		Failed	passed						
Portacount 80	Passed	1	15						
Portacount 80	failed	15	6	**0.94**	**0.06**	**0.94**	**0.71**	**0.71**	**0.63**
		TIL	TIL						
		Failed	passed						
Portacount 90	Passed	1	15						
Portacount 90	failed	15	6	**0.94**	**0.06**	**0.94**	**0.71**	**0.71**	**0.63**
		TIL	TIL						
		Failed	passed						
Portacount 100	Passed	1	15						
Portacount 100	failed	15	6	**0.94**	**0.06**	**0.94**	**0.71**	**0.71**	**0.63**

Figure 11 Portacount pass criterion v statistical values calculated (standard efficiency FFP3)

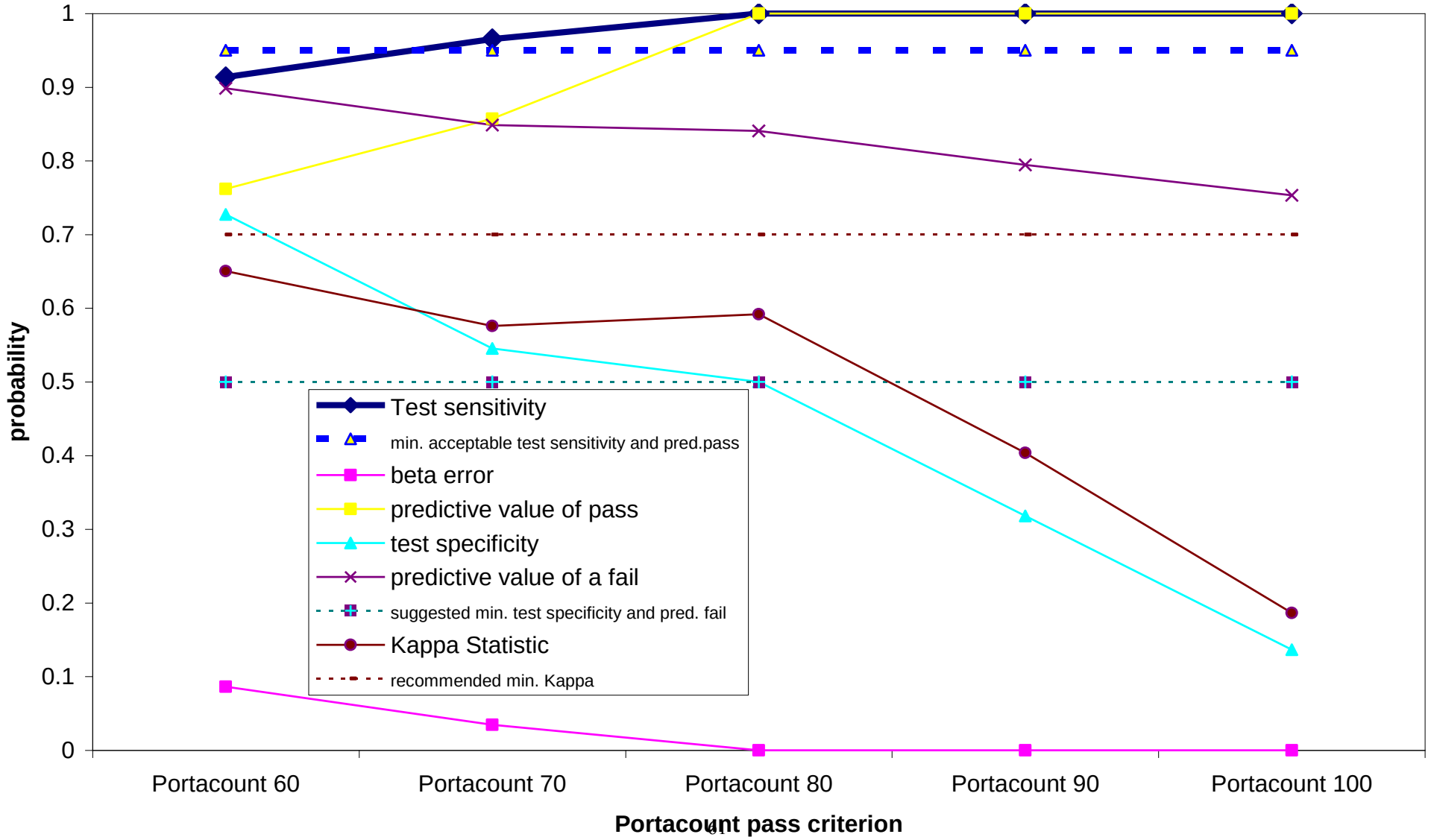


Figure 12 Portacount pass criterion v statistical values calculated (high efficiency FFP3)

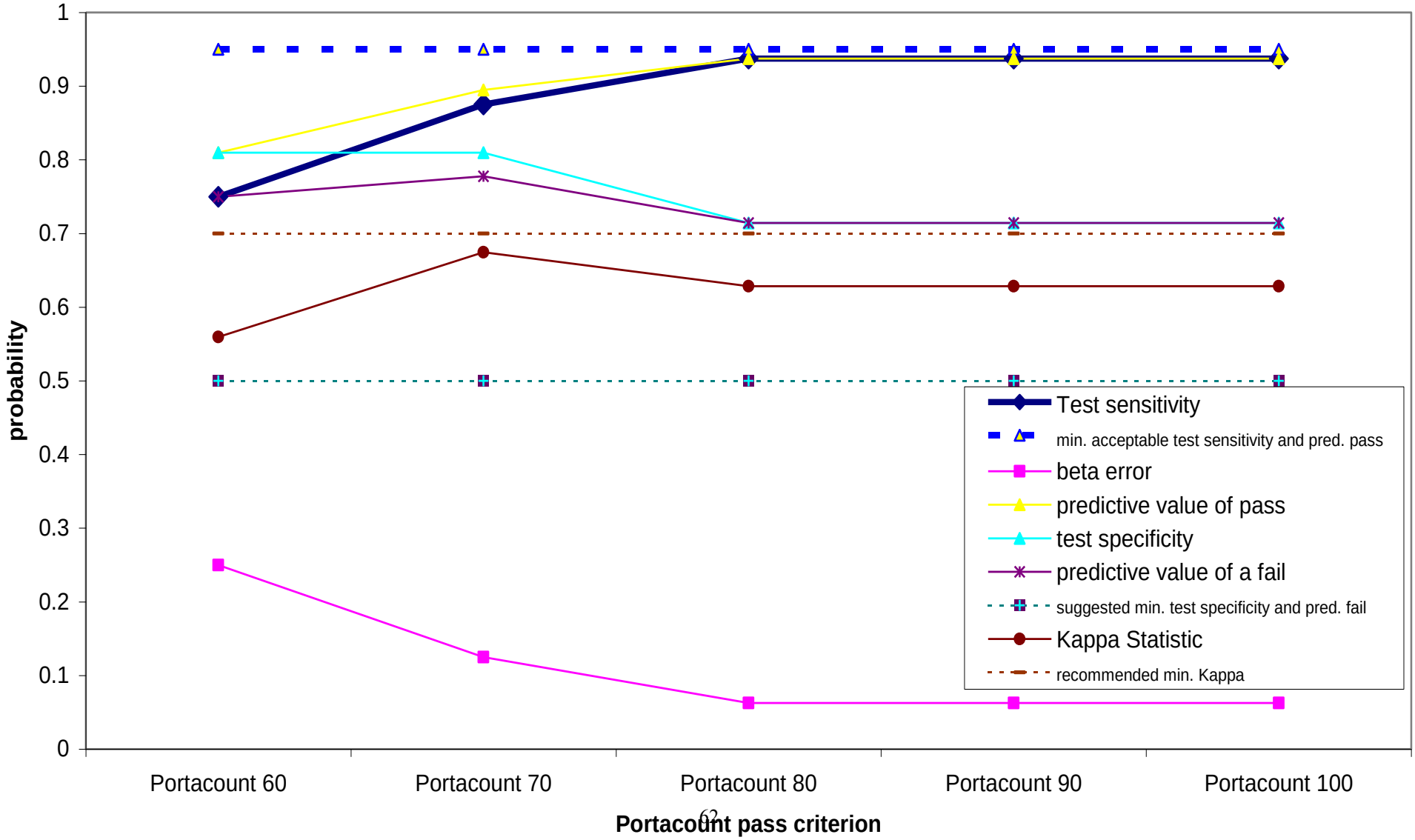


Figure 13 Frequency of minimum Fit Factor exercise with Portacount pass criterion and test method, on failed tests

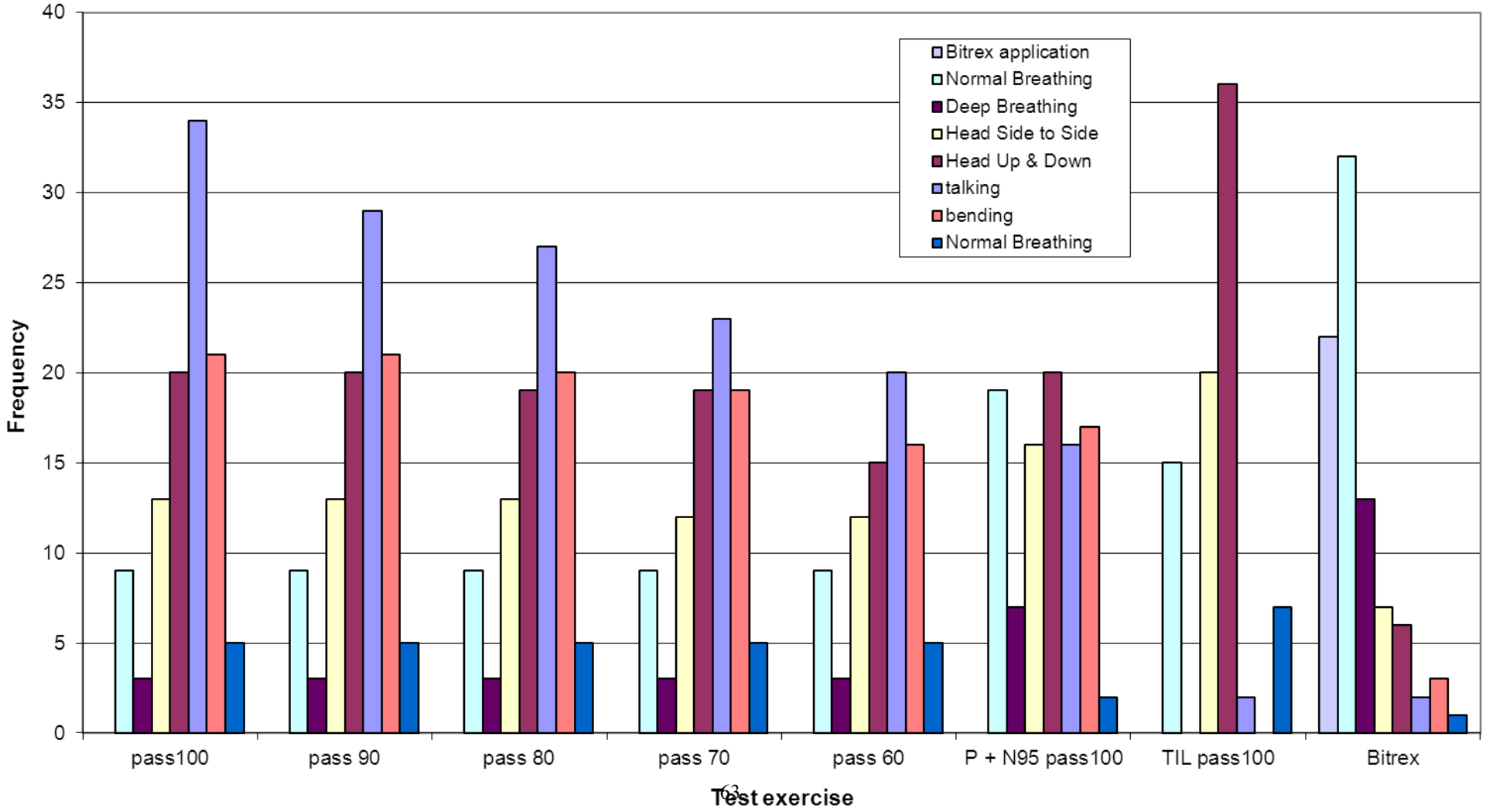


Figure 14 Portacount-with-N95-Companion pass criterion v statistical values calculated

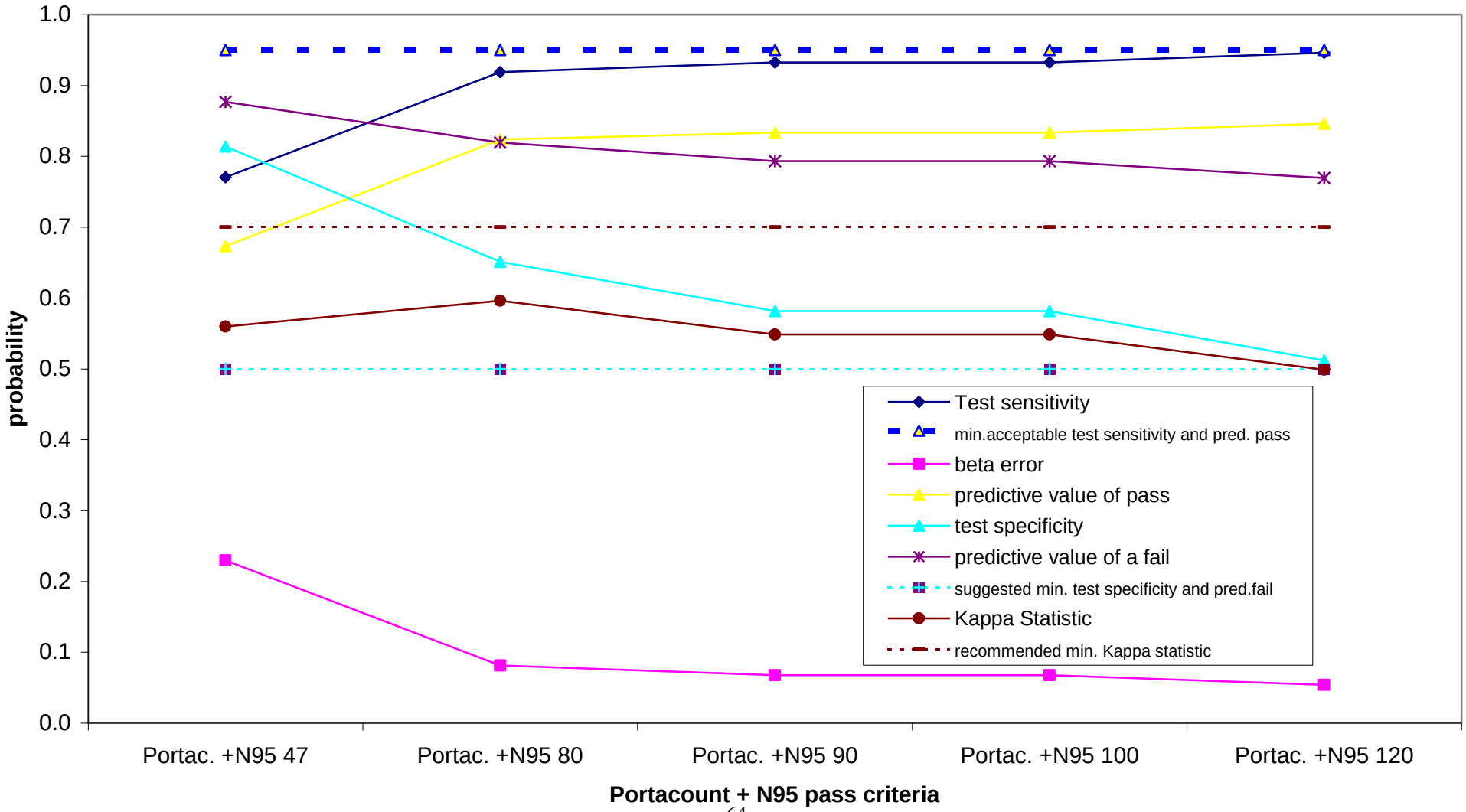


Figure 15 Fit factor data spread by FFP3: Portcount-with-N95-Companion v Portacount, log data

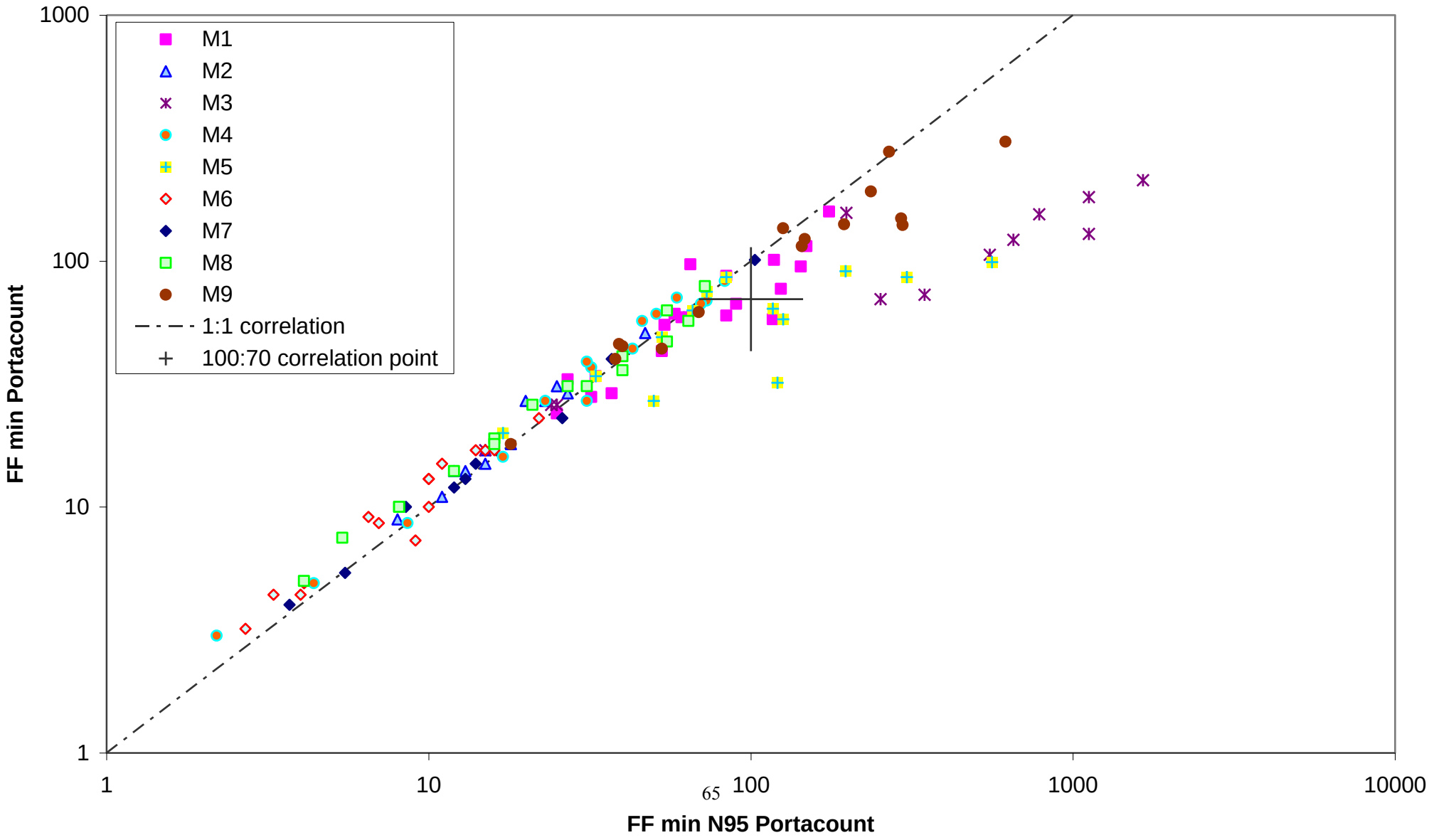


Figure 16 Fit factor data spread by FFP3: Portcount-with-N95-Companion v Portacount, linear data cropped

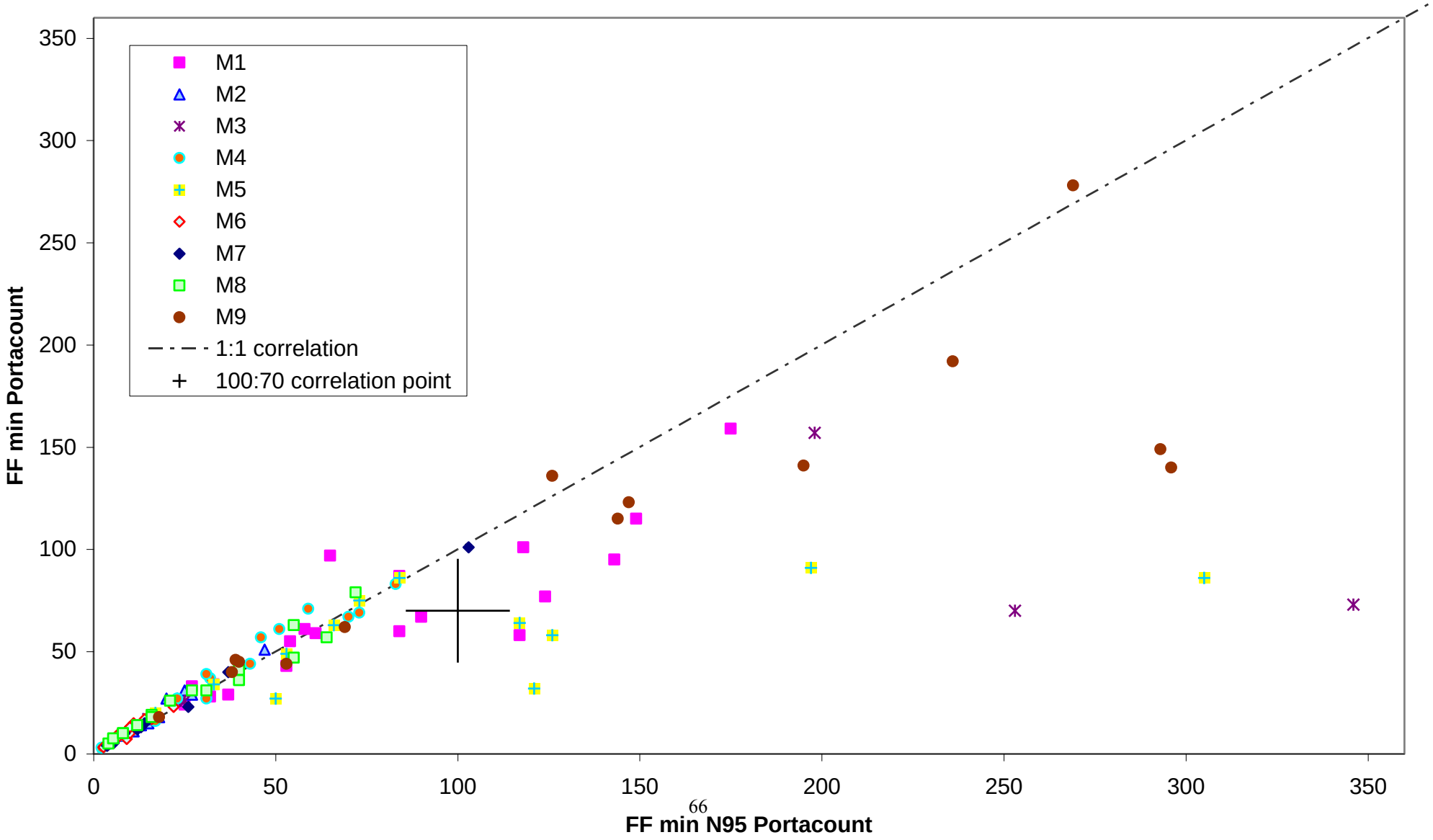


Figure 17 Bitrex fit test result v Bitrex sensitivity test result

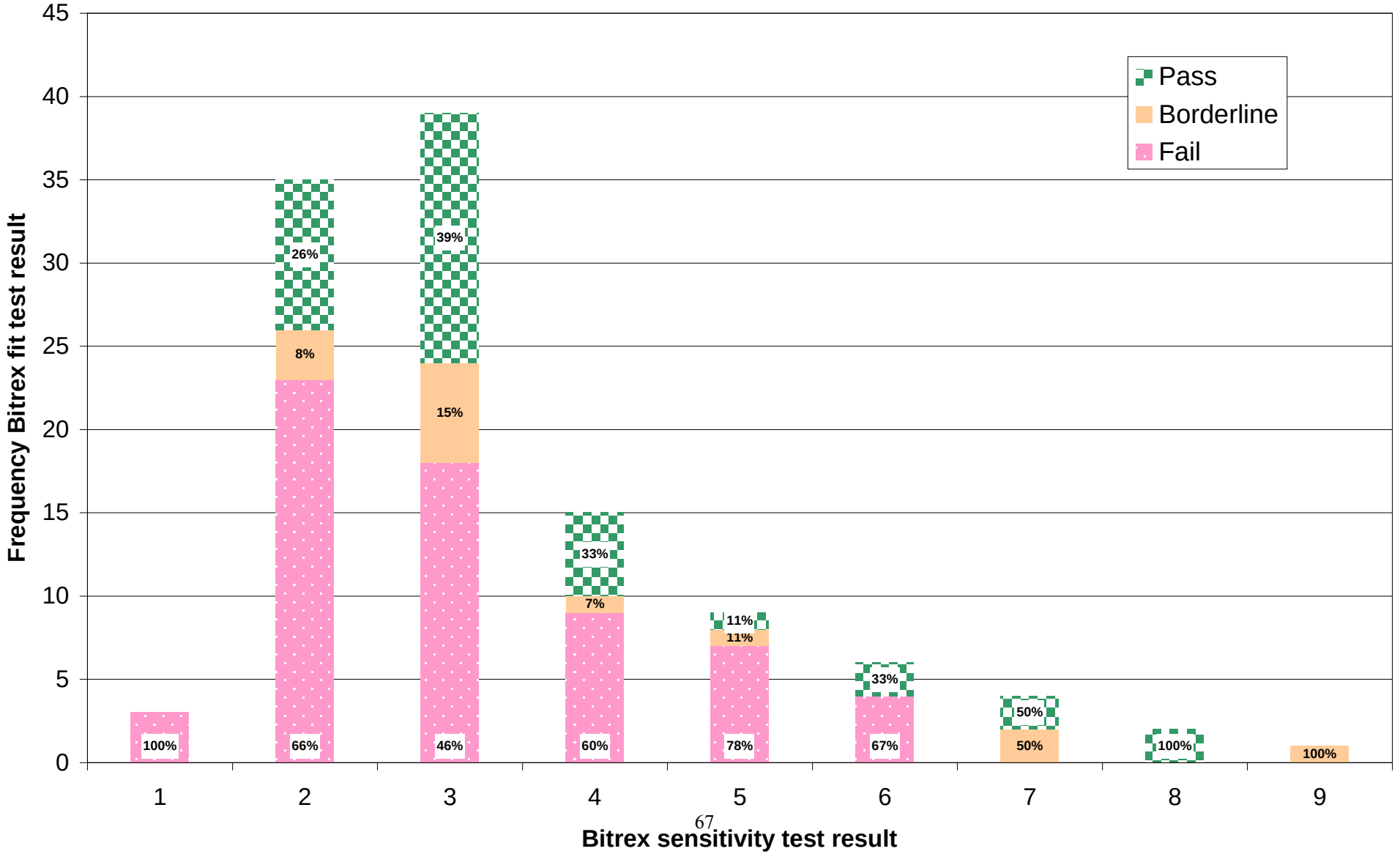


Table 16 Statistical calculations – excluding data from tests with high sensitivity test result

ANSI/AIHA Z88.10-2010 Annex A2 - Excluding test results from where Bitrex test sensitivity high									
sensitivity test result	**all 100**			**Test sensitivity**	**beta error**	**predictive value of pass**	**test specificity**	**predictive value of a fail**	**Kappa Statistic**
				>=0.95		**>=0.95**	**>0.5**	**>0.5**	**>0.7**
		TIL	TIL						
all		Failed	passed						
Bitrex	Passed	10	24						
Bitrex	failed	64	19	**0.86**	**0.14**	**0.71**	**0.56**	**0.77**	**0.44**
		TIL	TIL						
<7		Failed	passed						
Bitrex	Passed	9	21						
Bitrex	failed	61	17	**0.87**	**0.13**	**0.70**	**0.55**	**0.78**	**0.45**
		TIL	TIL						
<6		Failed	passed						
Bitrex	Passed	7	21						
Bitrex	failed	59	17	**0.89**	**0.11**	**0.75**	**0.55**	**0.78**	**0.47**

Table 17 Test subject comments on FFP3 fit

Test number	Test Subject	FFP experience of test subject	FFP3	Fit-check	Test subject comments and rating pre test fit?		Test subject comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
1	S1	***	M4	fail	nose clip too short, leaks at sides of nose	poor	good but would have liked to tighten, crept down face	poor	**pass**	**INVALID**	**pass**	**pass**
2	S2	**	M8	borderline	may be leaking slightly	poor	Not very comfortable and getting a lot of moisture inside		**fail**	**INVALID**	**fail**	**fail**
3	S3	***	M7	fail	leakage from top of nose - breathing out. Specs a bit high	poor	Too big	poor	**fail**	**INVALID**	**fail**	**fail**
4	S2	**	M3	good	large - in field of view		poor fit	poor	**fail**	**INVALID**	**pass**	**pass**
5	S1	***	M1	good	Soft seal too short. Vision restricted. Mask depressing inwards RHS of face		top of nose sore	poor	**pass**	**fail**	**fail**	**pass**
6	S4	**	M1	good	pressing on bridge of nose		leakage at chin during head up and down	poor	borderline	**pass**	**fail**	**fail**
7	S5	***	M4	good	a bit insecure around nose		may be some sliding during tests due to sweating but fit feels same	good	**fail**	**fail**	**fail**	**fail**
8	S6	***	M7	fail	Leaking under chin. Not very secure on nose	poor	Poor especially over bridge of nose	poor	**fail**	**fail**	**fail**	**fail**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Test subject comments and rating pre test fit?		Test subject comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
9	S7	*	M3	good	feels Ok, feels correct size	good	good, slight movements on head U&D	good	**pass**	**pass**	**pass**	**pass**
10	S4	**	M8	good	good	good	feel air flow under chin on TIL test	poor	borderline	**fail**	**fail**	**fail**
11	S6	***	M5	good	secure under chin and well moulded to nose	good	Feels OK no leaks noticed. May be moving on Head U&D but returns to original place	good	borderline	**fail**	**fail**	**fail**
12	S8	**	M2	good	feels reasonably OK	good	Gap around under chin?, felt loose here. Nose area feels OK	poor	**fail**	**fail**	**fail**	**fail**
13	S9	*	M8	borderline	possibly leakage under chin. Mask pushing glasses too firmly against face		feels better than at start - no sig. changes		**fail**	**fail**	**fail**	**fail**
14	S7	*	M6	good	seems OK	good	no movement/settling of mask noticed	good	**fail**	**fail**	**fail**	**fail**
15	S4	**	M2	good	not as good a fit as previous masks but comfortable		can feel leaking around nose. Mask moves on head U&D and talking	poor	**fail**	**fail**	**fail**	**fail**
16	S10	**	M1	good	good fit, very comfortable	good	slightly uncomfortable on bridge of nose	good	**pass**	**pass**	**fail**	**pass**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Test subject comments and rating pre test fit?		Test subject comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
17	S11	**	M1	good	OK when tightened to exclude draft down sides of nose. Nose pressure but not uncomfortable		Feels loose -slipping u&d with head movements	poor	**fail**	**fail**	**fail**	**fail**
18	S6	***	M8	good	nose clip not very effective, also not comfortable on nose		feels secure but uncomfortable		**borderline**	**pass**	**fail**	**fail**
19	S1	***	M6	good	high breathing resistance. Fit OK	good	material around nose not leaktight?		**fail**	**fail**	**fail**	**fail**
20	S9	*	M3	good	feels tighter than last mask. Same conflict with specs. Comfort OK				**fail**	**pass**	**pass**	**pass**
21	S8	**	M9	good	OK & comfortable	good	feels good comfortable fit, feels neg pressure when breathing in. some mask movement on head up & down	good	**pass**	**pass**	**pass**	**pass**
22	S5	***	M2	good	mask shifts on face when talking or moving head down but no leaking felt		leaks over bridge of nose when talking between test runs. Moving on face all time	poor	**fail**	**fail**	**fail**	**fail**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Test subject comments and rating pre test fit?		Test subject comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
23	S1	***	M8	good	lower breathing resistance than previous mask	good	feels a good fit	good	**fail**	**fail**	**fail**	**fail**
24	S12	*	M9	good	feels OK comfortable. glasses not steaming up	good	good and comfortable. Mask moves slightly during head up & d	good	**pass**	**pass**	**pass**	**pass**
25	S10	**	M9	good	good, comfortable	good	OK no leaks	good	borderline	**pass**	**pass**	**pass**
26	S13	*	M1	good	wouldn't want to wear for real. Some movement on nose when talking, smiling	poor	felt same all time except one seal break on TIL	poor	**pass**	**pass**	**fail**	**fail**
27	S9	*	M9	good	slightly less secure than previous mask, moves on nose when moving head		likes mask feels comfortable and light	good	**borderline**	**fail**	**fail**	**fail**
28	S14	*	M1	good	slightly pinching nose. Difficult to breathe through nose		clammy and sweaty, may be fitting better as a result		borderline	**pass**	**fail**	**fail**
29	S15	***	M4	good	tight at sides of face, loose under chin		slight draft at side of nose - not present at start	poor	**pass**	**pass**	**fail**	**fail**
30	S13	*	M6	good	possibly leaking around nose on exhale		comfortable	good	borderline	**fail**	**fail**	**fail**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Test subject comments and rating pre test fit?		Test subject comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
31	S2	**	M1	good	uncomfortable on nose, having to breath through mouth		nose not as uncomfortable, mask may have moved		**fail**	**fail**	**fail**	**fail**
32	S7	*	M9	good	about right	good	reasonably comfortable - may not be as good on nose as other masks		**fail**	**fail**	**fail**	**fail**
33	S4	**	M6	good	feels comfortable but not sure if tight enough		not tight enough	poor	**fail**	**fail**	**fail**	**fail**
34	S3	***	M9	good	small - compatible with specs. Not able to shape properly as nose clip puts pressure on nose causing pain		Feels a bit small		**pass**	**pass**	**pass**	**pass**
35	S6	***	M2	good	insecure feels as if will move around		moved slightly during head up &D on TIL		**fail**	**pass**	**fail**	**fail**
36	S8	**	M1	fail	No leakage felt but doesn't inspire confidence as not pulling towards face. Fairly comfortable		Tight on nose and neck	poor	**pass**	**pass**	**pass**	**pass**
37	S11	**	M6	fail	slight leak around nose. Not secure bottom strap needs to be tighter	poor	mask did not feel secure	poor	**fail**	**fail**	**fail**	**fail**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Test subject comments and rating pre test fit?		Test subject comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
38	S9	*	M2	good	Fine	good	not very comfortable, hot and itchy		**fail**	**fail**	**fail**	**fail**
39	S6	***	M6	good	size OK. Security so-so but not moving readily on head		OK fit and comfort		**fail**	**pass**	**fail**	**fail**
40	S3	***	M2	good	A bit insecure under chin but otherwise OK. Feels as if may shift around a bit	poor	Leaking on TIL over top section. Can see inside mask	poor	**fail**	**fail**	**fail**	**fail**
41	S7	*	M4	good	feels large on face, not sure if correct position- if too high can't see		Large and not well suited around nose	poor	**fail**	**fail**	**fail**	**fail**
42	S4	**	M3	good	feels sealed	good	Good. Snug without being too tight	good	**pass**	**pass**	**pass**	**pass**
43	S2	**	M2	fail	too high - blocks vision, gaps to side of nose. Can't tighten		A bit itchy, lower on face		**fail**	**fail**	**fail**	**fail**
44	S16	*	M3	borderline	may be leaking at sides of nose, but unsure as never worn mask before		Fit OK	good	**pass**	**pass**	**pass**	**pass**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Test subject comments and rating pre test fit?		Test subject comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
45	S10	**	M6	good	noseclip doesn't feel like it holds much. Slight movement on talking. Feels secure		moving during h u&d and talking		**fail**	**fail**	**fail**	**fail**
46	S8	**	M4	good	feels reasonably comfortable	good	feels OK happy with mask fit	good	**pass**	**fail**	**fail**	**fail**
47	S9	*	M1	fail	leaking under chin - can't improve	poor	Ok but hard to breathe		**fail**	**fail**	**fail**	**fail**
48	S12	*	M1	good	feels comfortable, straps easy, donning easy, right size	good	OK mask, fitted well, slight pressure on nose	good	**fail**	**fail**	**fail**	**fail**
49	S11	**	M2	good	comfortable	good	slipped down nose 1-1.5 cm overall. Leaking at sides of nose	poor	**fail**	**fail**	**fail**	**fail**
50	S6	***	M3	good	nose clip rigid, not easy to form. Feels comfortable	good	No change from start	good	**pass**	**pass**	**pass**	**pass**
51	S14	*	M4	good	needed work to fit. Feels tight on bridge of nose. Mask not moving on face		comfortable and secure. Can't feel any leaks, OK with glasses	good	**fail**	**fail**	**fail**	**fail**
52	S17	***	M1	good	moderately tight -slight pressure on bridge of nose		good comfortable	good	**pass**	**pass**	**pass**	**pass**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Test subject comments and rating pre test fit?		Test subject comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
53	S8	**	M8	good	Not as secure as other masks but no movement when head moved, pressing on bridge of nose		insecure under chin	poor	**pass**	**fail**	**fail**	**fail**
54	S9	*	M7	good	pulls to face when breathe in sharply. Mask OK but needs shorter straps		not good fit. Insecure straps need to be tighter	poor	**fail**	**fail**	**fail**	**fail**
55	S16	*	M4	fail	feels secure but slight flex on chin when looking around		nose clip losened early on and never returned	poor	**fail**	**fail**	**fail**	**fail**
56	S2	**	M4	borderline	comfortable , fits under chin and sides of face but can feel draft to sides of nose	poor	drafts less obvious		**fail**	**pass**	**fail**	**fail**
57	S6	***	M4	good	seems pretty secure	good	No movement . Feels fine	good	**fail**	**pass**	**fail**	**fail**
58	S18	*	M8	good	tight on bridge of nose		bridge of nose hurting		borderline	**pass**	**fail**	**fail**
59	S3	***	M6	fail	leaking under chin, over bridge and sides of nose - very loose	poor	Lots of moving around on face	poor	**fail**	**fail**	**fail**	**fail**
60	S16	*	M2	good	feels good, comfortable	good	itchy on nose, slipped down nose a bit		**fail**	**fail**	**fail**	**fail**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Test subject comments and rating pre test fit?		Test subject comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
61	S19	**	M7	good	leaks when head down - only at real extreme		bad fit around nose as can't adjust	poor	**fail**	**fail**	**fail**	**fail**
62	S4	**	M7	good	neck strap too loose, possible leak around chin	poor			**fail**	**fail**	**fail**	**fail**
63	S4	**	M5	good	Good. Comfortable	good	fits better under chin than other masks	good	**pass**	**pass**	**fail**	**fail**
64	S6	***	M1	good	feels secure, no movement on face	good	good	good	**pass**	**pass**	**pass**	**pass**
65	S20	*	M7	good	Too big - obstructing field of vision exhale valve sealed when breathing out sharply	poor	more aware of mask moving in and out than at start		**fail**	**fail**	**fail**	**fail**
66	S5	***	M6	fail	mask feels right size but straps too loose. Can feel leak around nose	poor	not a good fit feels looser than at beginning	poor	**fail**	**fail**	**fail**	**fail**
67	S10	**	M5	good	nose clip restricts breathing through nose. May be gap under chin		good - one of better masks	good	**pass**	**pass**	**fail**	**pass**
68	S2	**	M5	good	feels comfortable and leak-tight	good	OK but mask does move on face when moving head	good	**fail**	**fail**	**fail**	**fail**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Test subject comments and rating pre test fit?		Test subject comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
69	S10	**	M3	good	comfortable - no movement on face		No change	good	borderline	**pass**	**fail**	**pass**
70	S19	**	M4	good	feels OK but maybe loose under chin but no leaks felt		feels OK - no movement of mask	good	**fail**	**pass**	**fail**	**fail**
71	S21	*	M5	good	specs fit well with mask, mask easy to fit	good	good fit, can feel negative pressure	good	**pass**	**fail**	**fail**	**pass**
72	S6	***	M9	good	straps not adjustable - feel they could be tighter	poor	slipping about during head movements otherwise Ok and comfortable		**fail**	**pass**	**pass**	**pass**
73	S18	*	M4	fail	leaking into left eye, can't adjust nose clip to eliminate. Mask feels comfortable	poor	comfortable but can feel leaking around nose	poor	**fail**	**fail**	**fail**	**fail**
74	S14	*	M3	good	less breathing resistance than previous masks	good	doesn't feel secure doesn't feel as if contacting around nose and under chin	poor	**fail**	**fail**	**fail**	**fail**
75	S7	*	M7	good	feels big		seems good	good	**borderline**	**pass**	**fail**	**fail**
76	S13	*	M5	good	snug under chin, nose shaping OK	good	more comfortable than previous masks	good	**pass**	**fail**	**fail**	**pass**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Test subject comments and rating pre test fit?		Test subject comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
77	S18	*	M9	good	comfortable but under chin not fitting well	poor	when breathe out can feel draft under chin	poor	**fail**	**fail**	**pass**	**pass**
78	S1	***	M2	good	feels as if may slip under chin. Comfortable over nose		Insecure on nose	poor	**pass**	**fail**	**fail**	**fail**
79	S19	**	M3	good	quite comfy	good	no change	good	**fail**	**pass**	**fail**	**pass**
80	S2	**	M9	good	top of mask within field of vision, may be leaking under chin, insecure as straps can't tighten, talking easier as more room		doesn't feel secure, straps digging into ears, thinks moved down slightly	poor	**fail**	**pass**	**fail**	**fail**
81	S17	***	M2	good	feels like any other mask	good	sloppy mask, has loosened and slipped down face	poor	**fail**	**fail**	**fail**	**fail**
82	S10	**	M2	good	comfortable but nose clip stiff - sharp fold pushing down on soft tissues of nose - blocking slightly		Furry inside -itchy. Maybe top strap needs to be tighter		**fail**	**fail**	**fail**	**fail**
83	S2	**	M6	fail	tighten straps by tying knot - loose 25cm but still not fitting nose	poor	feels Ok but too loose - moving, slipped down slightly	poor	**fail**	**fail**	**fail**	**fail**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Test subject comments and rating pre test fit?		Test subject comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
84	S16	*	M6	good	rubbish potential gap under chin, mask removed and straps tightened pulling through clip	poor	still thinks gap under chin. Mask slipping on head movements	poor	borderline	**fail**	**fail**	**fail**
85	S7	*	M1	good	reasonably comfy but in field of vision		seems solid and comfortable apart from nose after wearing for some time	good	**pass**	**pass**	**fail**	**pass**
86	S1	***	M3	good	feels fine	good	felt secure but slightly closes nasal passages	good	**pass**	**pass**	**pass**	**pass**
88	S17	***	M5	borderline	reasonably secure but straps not tight enough - no adjustment		comfortable and secure	good	**pass**	**pass**	**fail**	**pass**
89	S7	*	M8	good	comfy maybe not as good a seal under chin, feels secure		slightly too loose on chin	poor	**fail**	**fail**	**fail**	**fail**
90	S9	*	M5	good	feels like one of the best so far	good	good - best so far	good	**fail**	**fail**	**fail**	**fail**
91	S4	**	M9	good	feels OK but maybe loose under chin but no leaks felt		nose clip cannot shape well to nose	poor	**fail**	**fail**	**fail**	**fail**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Test subject comments and rating pre test fit?		Test subject comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
92	S5	***	M8	good	feels pretty solid but pressing on bridge of nose	good	feels fine no leaks felt, comfortable on nose	good	**fail**	**fail**	**fail**	**fail**
93	S22	**	M8	good	nose clip hard difficult to fit to nose, comfortable apart from nose clip		maybe too small as difficult to talk		**fail**	**fail**	**fail**	**fail**
94	S17	***	M9	borderline	OK around nose, under chin questionable		more comfortable than others - comfortable breathing	good	**pass**	**pass**	**pass**	**pass**
95	S3	***	M5	good	glasses steaming. Too small from nose to mouth?	poor	No leaks felt	good	**fail**	**fail**	**fail**	**fail**
96	S19	**	M6	good	good comfortable	good	comfortable. Straps may be a bit loose. Seems to fit OK	good	**fail**	**fail**	**fail**	**fail**
97	S8	**	M6	good	comfortable, nose clip moulds OK, snug under chin	good	Not fitting well under chin	poor	**pass**	**fail**	**fail**	**fail**
98	S23		M8	good	feels loose around nose but no leaks felt		mask did not move		**fail**	**fail**	**fail**	**fail**
99	S22	**	M1	good	comfortable and easy to fit, better around nose as no noseclip	good	fits well, comfortable	good	**pass**	**fail**	**fail**	**fail**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Test subject comments and rating pre test fit?		Test subject comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
101	S1	***	M5	good	can't breathe through nose - nose clip pressure. Sliding at sides?		No change but may move under chin. Thinks not leaking	good	**pass**	**pass**	**fail**	**pass**
102	S10	**	M8	good	mask moves up and down bridge of nose. Straps in field of vision	poor	OK feels comfortable	good	**borderline**	**pass**	**fail**	**fail**
103	S5	***	M1	good	lower on nose than would have preferred, squashing nose - hard to breathe	poor	leaking on bridge of nose slipped on nose during test	poor	**fail**	**fail**	**fail**	**fail**
104	S21	*	M3	good	feels alright	good	no change	good	**fail**	**pass**	**fail**	**fail**
105	S18	*	M7	fail	gap above nose	poor	may be looser under chin, can feel fluttering when breathing out	poor	**fail**	**fail**	**fail**	**fail**
106	S24	*	M4	good	slightly too small? Comfortable		feels gappy at the chin and not so tight	poor	**fail**	**fail**	**fail**	**fail**
107	S14	*	M9	good	comfortable. Tight across bridge of nose. Straps not as tight as with other masks but feels secure		probably most comfortable mask. Fit not too tight and easy to breathe through. Nose clip comfortable	good	**pass**	**pass**	**pass**	**pass**
108	S19	**	M5	good	secure, fits well. Size OK	good	feels a good fit, surprised has failed	good	**fail**	**fail**	**fail**	**fail**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Test subject comments and rating pre test fit?		Test subject comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
109	S5	***	M3	good	Solid may be moving when moving head down		No reason to think doesn't fit. Comfortable but sticky.	good	**pass**	**pass**	**pass**	**pass**
110	S22	**	M4	fail	feels gusts of air past eyes, can't adjust to eliminate, secure no movement	poor			**fail**	**fail**	**fail**	**fail**
111	S21	*	M1	good	tight around nose. Top of mask in field of vision		feels as if presses on bridge of nose, otherwise comfortable		**pass**	**fail**	**fail**	**fail**
112	S1	***	M9	good	? high breathing resistance		comfortable exhale valve clonks when it opens - high pressure needed	good	**pass**	**pass**	**pass**	**pass**
113	S11	**	M4	good	secure and leakproof - comfortable	good	would buy this one out of all tested so far, most secure,adjustable straps, nose bridge weak	good	**fail**	**pass**	**fail**	**fail**
114	S15	***	M5	borderline	fit check difficult, may be leak along RHS seam. Doesn't think ideal, pinching nostrils		feels better when mouth open - under chin better		**fail**	**fail**	**fail**	**pass**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Test subject comments and rating pre test fit?		Test subject comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
117	S13	*	M8	good	Had to readjust around nose. High breathing resistance. Fit OK		leaks felt around nose - too tight	poor	**fail**	**fail**	**fail**	**fail**
118	S3	***	M4	good	but can feel exhale by nose. Leaking to side of nose. Too big vertically, but too narrow on cheeks	poor	urgh	poor	**fail**	**fail**	**fail**	**fail**
119	S12	*	M6	good	comfortable and lightweight, no pressure points	good	comfortable and secure. Hard to breathe when talking, might be some novement on head U&D	good	**pass**	**fail**	**fail**	**fail**
120	S24	*	M1	good	comfortable. Secure	good	mask may have moved down slightly, bottom strap moved - twisted over		**pass**	**fail**	**fail**	**fail**
121	S5	***	M5	good	nose clip solid stays shaped. moves on chin but not leaking. Tighter straps might improve fit. Nose leak?		Feels as if fits well	good	**fail**	**fail**	**fail**	**fail**
122	S15	***	M7	good	passed fit check but gap forms next to cheeks when move head up	poor	poor fit feels loose, has not moved	poor	**fail**	**fail**	**fail**	**fail**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Test subject comments and rating pre test fit?		Test subject comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
123	S25	*	M1	borderline	May be leaking under chin not well shaped to chin. Fits well around nose		pressure on nose too much		**fail**	**pass**	**fail**	**fail**
124	S24	*	M3	good	comfortable and secure	good	feels good may be - lower on nose	good	borderline	**fail**	**fail**	**fail**
125	S5	***	M9	good	When looking down can feel leak on nose. Moving on nose, straps need to be tighter	poor	Feels good except head up and down. Leaking down nose on Bitrex.	poor	**fail**	**fail**	**fail**	**fail**
126	S22	**	M6	good	not as secure as other masks not as tight on face as no strap adjustment		not as secure as others, straps not tight collapses in onself when breathing in - restricts airflow?	poor	**fail**	**fail**	**fail**	**fail**
127	S24	*	M8	good	needed extra squeeze on nose clip to stop specs fogging. Comfortable, easy to put on, size OK		No fogging of specs	good	**fail**	**fail**	**fail**	**fail**
128	S20	*	M9	good	Feels too big - affects vision. Easy to twist strap when donning. Strap tension OK	poor	feels secure but tight over bridge of nose and loose under chin		**fail**	**fail**	**fail**	**fail**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Test subject comments and rating pre test fit?		Test subject comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
129	S3	***	M1	good	Loves - faceseal, bridge of nose squishy above nostrils	good	mask settled moved down slightly - top of mask leaking when talking	poor	**fail**	**fail**	**fail**	**fail**
130	S25	*	M8	good	feels fairly secure. Not moving except possibly when looking up	good	possible leakage along jaw. Doesn't feel bad but very tight on bridge of nose	poor	**fail**	**fail**	**fail**	**fail**
131	S9	*	M4	good	Too big, too close to eyes - in field of vision. Feels secure -spec arms under strap		OK but thinks leaking at bottom therefore won't protect	poor	**fail**	**pass**	**fail**	**fail**
132	S1	***	M7	fail	leakage at sides. Can't breathe through nostrils		? bedded down as test progressed	good	**pass**	**pass**	**pass**	**pass**

Table 18 Fit tester's comments on FFP3 fit

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Fit tester comments and rating pre test fit?		Fit tester comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
1	S1	***	M4	fail	looks OK no visible gaps	good	not done		**pass**	INVALID	**pass**	**pass**
2	S2	**	M8	borderline	Fit looks Ok but mask looks slightly too large		face marks indicate seal but these absent around nose		**fail**	INVALID	**fail**	**fail**
3	S3	***	M7	fail	Potential gap above nose. Straps look too loose		visible gap above nose. Too big lengthwise	poor	**fail**	INVALID	**fail**	**fail**
4	S2	**	M3	good	No gaps observed	good	may be gaps around nose		**fail**	INVALID	**pass**	**pass**
5	S1	***	M1	good	looks OK no visible gaps	good	OK no gaps	good	**pass**	**fail**	**fail**	**pass**
6	S4	**	M1	good	Looks OK	good	Looks OK	good	borderline	**pass**	**fail**	**fail**
7	S5	***	M4	good	No gaps visible, about correct size	good	No gaps visible, about correct size	good	**fail**	**fail**	**fail**	**fail**
8	S6	***	M7	fail	Gap at bridge of nose	poor	Gap at bridge of nose	poor	**fail**	**fail**	**fail**	**fail**
9	S7	*	M3	good	looks OK	good	looked good all the way through	good	**pass**	**pass**	**pass**	**pass**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Fit tester comments and rating pre test fit?		Fit tester comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
10	S4	**	M8	good	may be gap under chin but as mask has wide seal could be fine		may be gap underchin		borderline	**fail**	**fail**	**fail**
11	S6	***	M5	good	may be gaps at sides of nose		may be gaps at sides of nose		borderline	**fail**	**fail**	**fail**
12	S8	**	M2	good	possible slight gap to one side of nose. Edge does not meet skin under chin but may well be sealing OK further in		Looks more gappy under chin but nose area the same.		**fail**	**fail**	**fail**	**fail**
13	S9	*	M8	borderline	looks loose on nose		still looks loose on nose		**fail**	**fail**	**fail**	**fail**
14	S7	*	M6	good	looks loose on nose - possible gaps down sides		still looks loose on nose		**fail**	**fail**	**fail**	**fail**
15	S4	**	M2	good	looks reasonable but may be small gap around nose		not fitted well around nose	poor	**fail**	**fail**	**fail**	**fail**
16	S10	**	M1	good	Looks OK no obvious gaps	good	looks OK no obvious leaks	good	**pass**	**pass**	**fail**	**pass**
17	S11	**	M1	good	? Slight gaps to sides of nose		similar to start. ? Slight gaps to sides of nose	poor	**fail**	**fail**	**fail**	**fail**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Fit tester comments and rating pre test fit?		Fit tester comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
18	S6	***	M8	good	Looks OK. No obvious leaks	good	looks OK	good	borderline	**pass**	**fail**	**fail**
19	S1	***	M6	good	looks OK no visible gaps	good	OK no gaps. Face marked	good	**fail**	**fail**	**fail**	**fail**
20	S9	*	M3	good	possible gaps to side of nose - hard to tell due to gasket				**fail**	**pass**	**pass**	**pass**
21	S8	**	M9	good	Fit looks OK - no gaps. Strap will not stay over crown of head		Looks OK	good	**pass**	**pass**	**pass**	**pass**
22	S5	***	M2	good	wide fabric seal appears to be in good contact all around	good	same as at beginning	good	**fail**	**fail**	**fail**	**fail**
23	S1	***	M8	good	looks OK no visible gaps	good	looked OK	good	**fail**	**fail**	**fail**	**fail**
24	S12	*	M9	good	appears fit OK, no gaps	good	fit looks good	good	**pass**	**pass**	**pass**	**pass**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Fit tester comments and rating pre test fit?		Fit tester comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
25	S10	**	M9	good	high on nose close to eyes, seems to fit OK around nose, snug under chin		same as at start	good	borderline	**pass**	**pass**	**pass**
26	S13	*	M1	good	possible leakage around nose		No obvious change		**pass**	**pass**	**fail**	**fail**
27	S9	*	M9	good	may be gaps to side of nose but nose clip restricts view		looks OK but may be too big under chin		borderline	**fail**	**fail**	**fail**
28	S14	*	M1	good	good size, looks OK	good	looks OK	good	borderline	**pass**	**fail**	**fail**
29	S15	***	M4	good	wide elastomeric seal appears to be making good contact	good	same as at start	good	**pass**	**pass**	**fail**	**fail**
30	S13	*	M6	good	potential leakage path down bridge of nose		Visible leakage path on jaw when looking up. Possible leakage path down bridge of nose	poor	borderline	**fail**	**fail**	**fail**
31	S2	**	M1	good	seal appears to fit OK	good	Looks as if OK	good	**fail**	**fail**	**fail**	**fail**
32	S7	*	M9	good	possible gap down bridge of nose ? insecure		possibly leakage down nose		**fail**	**fail**	**fail**	**fail**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Fit tester comments and rating pre test fit?		Fit tester comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
33	S4	**	M6	good	appears Ok on nose and chin	good	looks OK but not tight		**fail**	**fail**	**fail**	**fail**
34	S3	***	M9	good	? Gaps around nose but as close to eyes can't see well. Under chin edge not contacting with face when head up.		same as at start		**pass**	**pass**	**pass**	**pass**
35	S6	***	M2	good	looks OK no obvious gaps	good	still looks OK	good	**fail**	**pass**	**fail**	**fail**
36	S8	**	M1	fail	No obvious gaps	good	as at start	good	**pass**	**pass**	**pass**	**pass**
37	S11	**	M6	fail	looks reasonable but may not fit well around nose		No obvious gaps . May not be tight enough		**fail**	**fail**	**fail**	**fail**
38	S9	*	M2	good	Gaps to side of nose?		looks too big can't be tightened to fit		**fail**	**fail**	**fail**	**fail**
39	S6	***	M6	good	OK But possibly gap above nose - hard to see		possible gap above nose, otherwise OK		**fail**	**pass**	**fail**	**fail**
40	S3	***	M2	good	appears to seal all around	good	Larger gap under chin	poor	**fail**	**fail**	**fail**	**fail**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Fit tester comments and rating pre test fit?		Fit tester comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
41	S7	*	M4	good	Large for face gap under chin but not sure if seal incomplete. Forward of nose around sides of nose ? leaking				**fail**	**fail**	**fail**	**fail**
42	S4	**	M3	good	edges not contacting skin but wide seal looks to be contacting	good	edges not contacting skin but wide seal looks to be contacting	good	**pass**	**pass**	**pass**	**pass**
43	S2	**	M2	fail	far too big, huge gaps to side of nose	poor	Poor gaps to side of nose, too large	poor	**fail**	**fail**	**fail**	**fail**
44	S16	*	M3	borderline	Looks OK	good	Still looks good	good	**pass**	**pass**	**pass**	**pass**
45	S10	**	M6	good	Too small but otherwise looks OK		? leaking at bridge of nose		**fail**	**fail**	**fail**	**fail**
46	S8	**	M4	good	looks OK, reasonable size for wearer	good	fit looks reasonable - hard to tell if any gaps		**pass**	**fail**	**fail**	**fail**
47	S9	*	M1	fail	too big gaps under chin?	poor	too big gaps under chin?		**fail**	**fail**	**fail**	**fail**
48	S12	*	M1	good	looks a good fit with no gaps	good	fit looked OK, no obvious gaps	good	**fail**	**fail**	**fail**	**fail**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Fit tester comments and rating pre test fit?		Fit tester comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
49	S11	**	M2	good	appears good contact over nose and under chin	good	slipped down nose 1-1.5 cm overall	poor	**fail**	**fail**	**fail**	**fail**
50	S6	***	M3	good	Looks good	good	looks good contact between mask and face	good	**pass**	**pass**	**pass**	**pass**
51	S14	*	M4	good	possible gap to side of nose . Looks a bit small		possible gaps to side of nose	poor	**fail**	**fail**	**fail**	**fail**
52	S17	***	M1	good	may be leaks to side of nose. Good under chin		may be leaks to side of nose. Good under chin		**pass**	**pass**	**pass**	**pass**
53	S8	**	M8	good	Looks OK	good	looks OK	good	**pass**	**fail**	**fail**	**fail**
54	S9	*	M7	good	Good around nose but gaps at sides under chin	poor	as at start - gaps around chin at sides		**fail**	**fail**	**fail**	**fail**
55	S16	*	M4	fail	gap to one side of nose	poor	Still gap at one side of nose	poor	**fail**	**fail**	**fail**	**fail**
56	S2	**	M4	borderline	No gaps visible	good	no gaps visible	good	**fail**	**pass**	**fail**	**fail**
57	S6	***	M4	good	Looks OK	good	looks fine	good	**fail**	**pass**	**fail**	**fail**
58	S18	*	M8	good	look snug under chin and around nose	good	same as at start look snug under chin and around nose	good	**borderline**	**pass**	**fail**	**fail**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Fit tester comments and rating pre test fit?		Fit tester comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
59	S3	***	M6	fail	Gap under chin - glasses fogging, very loose	poor	Visible Gap under chin and to sides of nose	poor	**fail**	**fail**	**fail**	**fail**
60	S16	*	M2	good	may be slight gap to one side of nose	poor	not fitting as closely around nose as at start but snug under chin	poor	**fail**	**fail**	**fail**	**fail**
61	S19	**	M7	good	may be a bit big. Possible gaps to side of nose - hard to tell		possible gaps to side of nose		**fail**	**fail**	**fail**	**fail**
62	S4	**	M7	good	may be leak under chin - hard to tell		gaps under chin no longer visible	good	**fail**	**fail**	**fail**	**fail**
63	S4	**	M5	good	Nose shape looks good. Snug under chin but could be gaps to sides		looks good around nose and under chin	good	**pass**	**pass**	**fail**	**fail**
64	S6	***	M1	good	Looks OK	good	Looks OK	good	**pass**	**pass**	**pass**	**pass**
65	S20	*	M7	good	Snug under chin. nose seal away from face but inner section may be good fit		Nose seal appears to fit and mask appears snug under chin	good	**fail**	**fail**	**fail**	**fail**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Fit tester comments and rating pre test fit?		Fit tester comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
66	S5	***	M6	fail	looks right size but since not tight enough does not fit to nose and chin	poor	not tight enough		**fail**	**fail**	**fail**	**fail**
67	S10	**	M5	good	looks good no gapping visible under chin. Well formed around nose	good	doesn't look to fit at edge over nose, but clip further down nose visibly tighter. Good fit under chin	good	**pass**	**pass**	**fail**	**pass**
68	S2	**	M5	good	seems to fit, no gaps but may be too large		appears to fit OK	good	**fail**	**fail**	**fail**	**fail**
69	S10	**	M3	good	looks OK	good	Looks OK	good	borderline	**pass**	**fail**	**pass**
70	S19	**	M4	good	seems to fit OK, size looks Ok , no obvious gaps	good	still looks OK	good	**fail**	**pass**	**fail**	**fail**
71	S21	*	M5	good	looks good no gaps	good	looks good fit	good	**pass**	**fail**	**fail**	**pass**
72	S6	***	M9	good	shaped well to nose and snug under chin	good	same as at start	good	**fail**	**pass**	**pass**	**pass**
73	S18	*	M4	fail	mask far too big	poor	too big	poor	**fail**	**fail**	**fail**	**fail**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Fit tester comments and rating pre test fit?		Fit tester comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
74	S14	*	M3	good	Looks good. Shaped to nose with no visible gaps. Snug under chin	good	gap to nose, RHS more so. Under chin looks as if sealing	poor	**fail**	**fail**	**fail**	**fail**
75	S7	*	M7	good	too big ? Leaks to side of nose	poor	Looks OK	good	borderline	**pass**	**fail**	**fail**
76	S13	*	M5	good	looks good fit under chin and shaped to nose	good	looks good fit	good	**pass**	**fail**	**fail**	**pass**
77	S18	*	M9	good	looks OK around nose and under chin	good	looks to fit well shapes well to nose and under chin	good	**fail**	**fail**	**pass**	**pass**
78	S1	***	M2	good	Under chin not sealed at edge but may be OK				**pass**	**fail**	**fail**	**fail**
79	S19	**	M3	good	looks reasonable fit, no gaps, right size	good	looks good fit	good	**fail**	**pass**	**fail**	**pass**
80	S2	**	M9	good	moulded to nose but edge of mask sits into neck	poor	same as at start - moulded to nose but edge of mask sits into neck	poor	**fail**	**pass**	**fail**	**fail**
81	S17	***	M2	good	looks OK no gaps	good	clearly slipped down face	poor	**fail**	**fail**	**fail**	**fail**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Fit tester comments and rating pre test fit?		Fit tester comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
82	S10	**	M2	good	Looks OK at sides of nose but maybe gap on top created by noseclip. OK under chin		Looks as if fits around nose and under chin - no gaps	good	**fail**	**fail**	**fail**	**fail**
83	S2	**	M6	fail	mask size looks reasonable but straps too long	poor	looks right size but strap not adjustable		**fail**	**fail**	**fail**	**fail**
84	S16	*	M6	good	Looks loose but no visible gaps		No obvious gaps		borderline	**fail**	**fail**	**fail**
85	S7	*	M1	good	No gaps apparent	good	no gaps, good marking around nose, snug under chin	good	**pass**	**pass**	**fail**	**pass**
86	S1	***	M3	good	quite high on nose		looked good	good	**pass**	**pass**	**pass**	**pass**
88	S17	***	M5	borderline	no gaps visible	good	looks OK	good	**pass**	**pass**	**fail**	**pass**
89	S7	*	M8	good	appears to fit well	good	no obvious gaps around seal	good	**fail**	**fail**	**fail**	**fail**
90	S9	*	M5	good	No visible gaps	good	looks good fit	good	**fail**	**fail**	**fail**	**fail**
91	S4	**	M9	good	looks reasonable fit, size OK	good	looks same as at beginning, although nose clip not secure		**fail**	**fail**	**fail**	**fail**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Fit tester comments and rating pre test fit?		Fit tester comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
92	S5	***	M8	good	looks OK. nose clip well shaped, chin snug	good	snug around nose and under chin	good	**fail**	**fail**	**fail**	**fail**
93	S22	**	M8	good	looks reasonable fit, no obvious gaps	good	still looks same as at beginning	good	**fail**	**fail**	**fail**	**fail**
94	S17	***	M9	borderline	looks snug under chin and around nose	good	Looks good. Good impression on face	good	**pass**	**pass**	**pass**	**pass**
95	S3	***	M5	good	looks OK under chin but not so good around nose - glasses steaming	poor	fit looks same as at start	poor	**fail**	**fail**	**fail**	**fail**
96	S19	**	M6	good	snug around nose and under chin	good	gaps to sides of face under chin. Nose looks OK	poor	**fail**	**fail**	**fail**	**fail**
97	S8	**	M6	good	Looks OK no gaps , snug under chin	good	Looks OK, under chin OK	good	**pass**	**fail**	**fail**	**fail**
98	S23		M8	good	Appears to fit OK - no gaps obvious - may be a bit too big		still looks reasonable fit with no gaps but may be too big		**fail**	**fail**	**fail**	**fail**
99	S22	**	M1	good	appears to fit OK size OK, no gaps seen	good	as at beginning	good	**pass**	**fail**	**fail**	**fail**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Fit tester comments and rating pre test fit?		Fit tester comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
101	S1	***	M5	good	may be gaps at sides under chin		may be gaps at sides under chin		**pass**	**pass**	**fail**	**pass**
102	S10	**	M8	good	Looks OK no gaps seen size OK	good	Fit looks Ok same as at start	good	borderline	**pass**	**fail**	**fail**
103	S5	***	M1	good	Looks good no gaps around nose or under chin	good	Looks OK material snug around nose and all around	good	**fail**	**fail**	**fail**	**fail**
104	S21	*	M3	good	gap to lhs of face? RHS glasses fogging - nose clip squeezed again				**fail**	**pass**	**fail**	**fail**
105	S18	*	M7	fail	looks too big, doesn't fit over bridge of nose and very close to neck under chin	poor	looks too big, doesn't fit over bridge of nose and very close to neck under chin	poor	**fail**	**fail**	**fail**	**fail**
106	S24	*	M4	good	possible gap to side of nose - hard to see		possible gap to LHS nose		**fail**	**fail**	**fail**	**fail**
107	S14	*	M9	good	? Gap to side of nose but could be sealed by foam. Good fit to chin		looks same as at start		**pass**	**pass**	**pass**	**pass**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Fit tester comments and rating pre test fit?		Fit tester comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
108	S19	**	M5	good	looks OK no obvious gaps	good	appears good fit. No obvious signs why it failed	good	**fail**	**fail**	**fail**	**fail**
109	S5	***	M3	good	difficult to see around nose but appears OK. Chin OK		Same as at start		**pass**	**pass**	**pass**	**pass**
110	S22	**	M4	fail	possible gaps to side of nose - hard to tell				**fail**	**fail**	**fail**	**fail**
111	S21	*	M1	good	perhaphs not snug to nose, snug under chin		as at start		**pass**	**fail**	**fail**	**fail**
112	S1	***	M9	good	hard to tell but no visible gaps	good	No change		**pass**	**pass**	**pass**	**pass**
113	S11	**	M4	good	Looks sealed to face	good	Same - Looks sealed to face	good	**fail**	**pass**	**fail**	**fail**
114	S15	***	M5	borderline	possible leakage along chin		Leaking at chin when head up?		**fail**	**fail**	**fail**	**pass**
115	S3	***	M8	fail	Looks OK but difficult to see as high on face and close to eyes		same as at start		**pass**	**pass**	**fail**	**fail**
116	S14	*	M8	good	Too small	poor	No visible gaps	good	**fail**	**fail**	**fail**	**fail**

Test number	Test Subject	FFP experience of test subject	FFP3	Fit check	Fit tester comments and rating pre test fit?		Fit tester comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria		* no experience								**100**	**100**	**100**
117	S13	*	M8	good	fit looks OK no obvious leaks	good	sama as at start of test	good	**fail**	**fail**	**fail**	**fail**
118	S3	***	M4	good	No visible gaps	good	No visible gaps	good	**fail**	**fail**	**fail**	**fail**
119	S12	*	M6	good	well shaped to nose . Snug under chin	good			**pass**	**fail**	**fail**	**fail**
120	S24	*	M1	good	looks OK no gaps	good	fit looks reasonable - hard to tell if any gaps		**pass**	**fail**	**fail**	**fail**
121	S5	***	M5	good	could be gap around nose but difficult to see. Chin looks snug		Same as at start		**fail**	**fail**	**fail**	**fail**
122	S15	***	M7	good	looks too large wrong shape for face	poor	looks poor fit - too large	poor	**fail**	**fail**	**fail**	**fail**
123	S25	*	M1	borderline	looks a bit gappy around nose. OK under chin		Looks Ok around nose and snug under chin	good	**fail**	**pass**	**fail**	**fail**
124	S24	*	M3	good	difficult to see fit around nose, looks good under chin		maybe gaps around nose. Looks good under chin		borderline	**fail**	**fail**	**fail**

Test number	Test Subject	FFP experience of test subject	Mask FFP3	Fit check	Fit tester comments and rating pre test fit?		Fit tester comments and rating post test fit?		Bitrex	TIL	Portacount standard mode	Portacount N95 mode
Pass criteria										**100**	**100**	**100**
125	S5	***	M9	good	looks good fit no gaps. Size OK	good	settled before TIL test. Bitrex repeated at end - still quickly failed	good	**fail**	**fail**	**fail**	**fail**
126	S22	**	M6	good	Looks well shaped to nose and snug under chin	good	moved down nose, looks shaped to nose well. Snug under chin		**fail**	**fail**	**fail**	**fail**
127	S24	*	M8	good	looks OK no leaks visible	good	looks OK	good	**fail**	**fail**	**fail**	**fail**
128	S20	*	M9	good	OK under chin. Difficult to see nose but as far as can see looks OK	good	Same as at start		**fail**	**fail**	**fail**	**fail**
129	S3	***	M1	good	No visible gaps	good	No visible gaps	good	**fail**	**fail**	**fail**	**fail**
130	S25	*	M8	good	No visible gaps	good	No visible leakage	good	**fail**	**fail**	**fail**	**fail**
131	S9	*	M4	good	nose area difficult to see -too large under chin - visible gap when head up	poor	Gap under chin not as noticeable as at start. Nose area looks OK		**fail**	**pass**	**fail**	**fail**
132	S1	***	M7	fail	? Gap to side of nose - hard to see		looks OK	good	**pass**	**pass**	**pass**	**pass**

Table 19 Effect of experience of wearer on their ability to judge fit, where fit test result is a fail (pass 100) in all test methods .

Experience of test subject v occurrence of subject opinion = good fit, when fit actually poor						
	fit check		pre test run		post test run	
	%	*n*	%	*n*	%	n
* Inexperienced	86	24	62	15	38	20
** Moderate experience	84	21	56	11	23	16
*** Experienced	82	24	36	17	35	25
All wearers	84	70	50	43	33	61

Figure 18 Facial dimensions of test subjects given as principal component analysis (ISO T/S 16976)

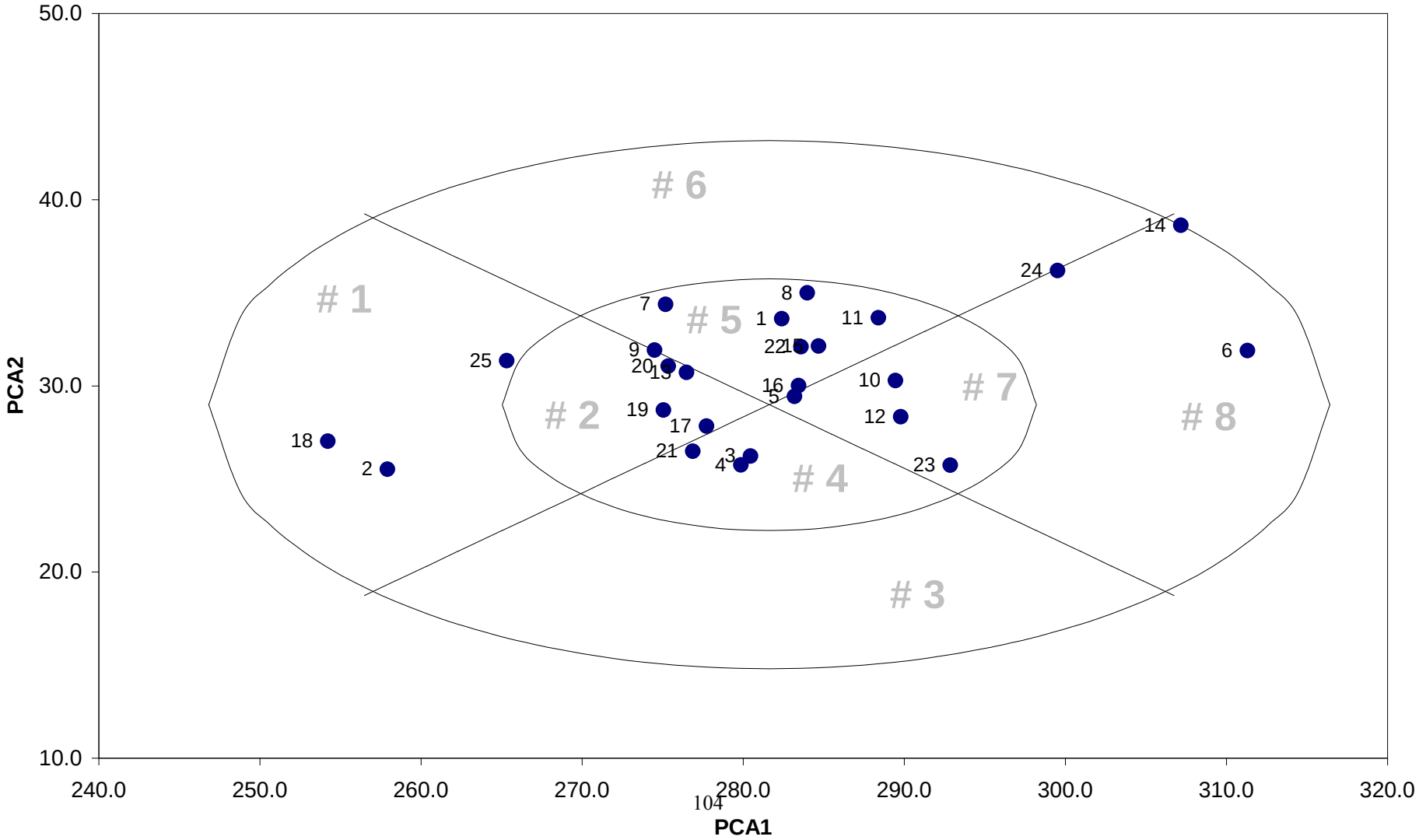


Figure 19 Facial dimensions of test subjects given as bivariate length-width (ISO T/S 16976)

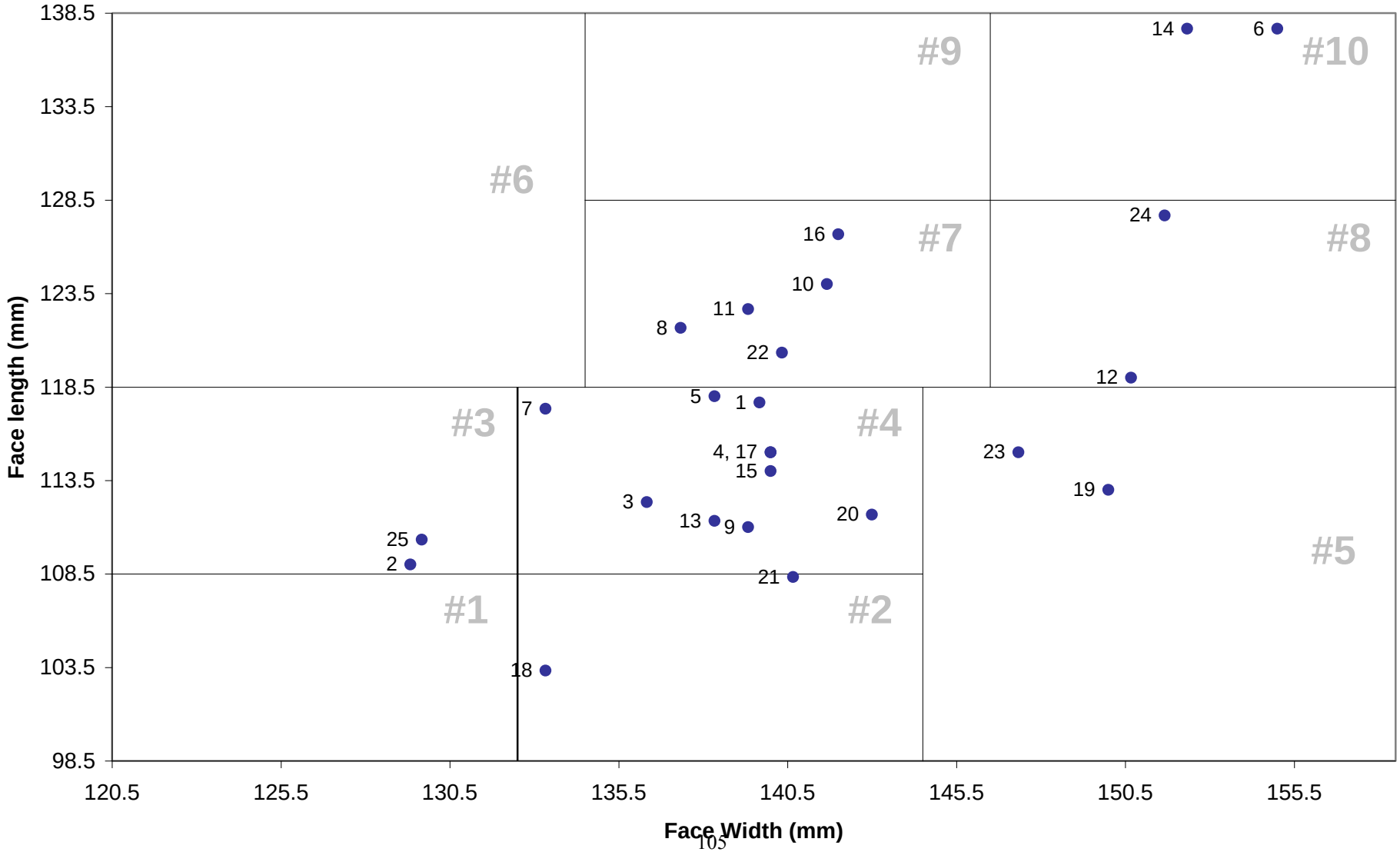
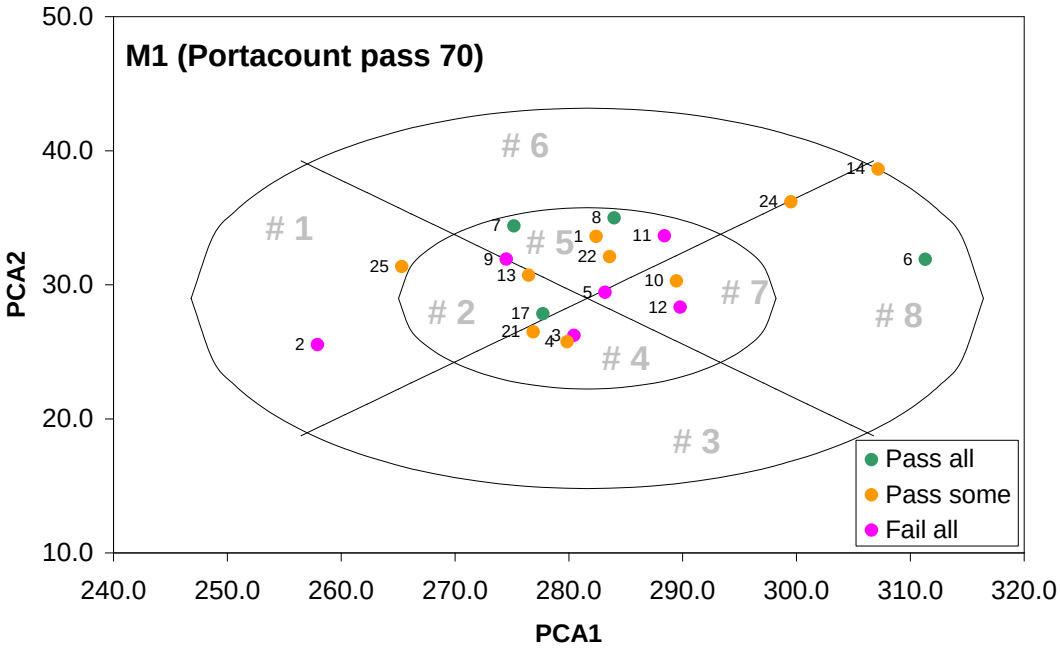
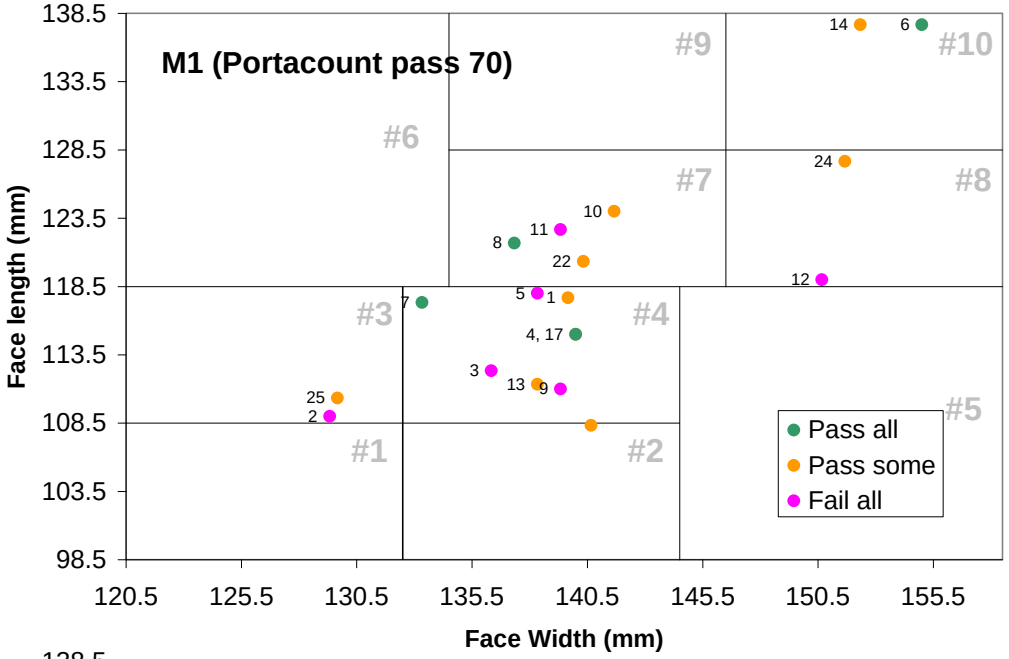


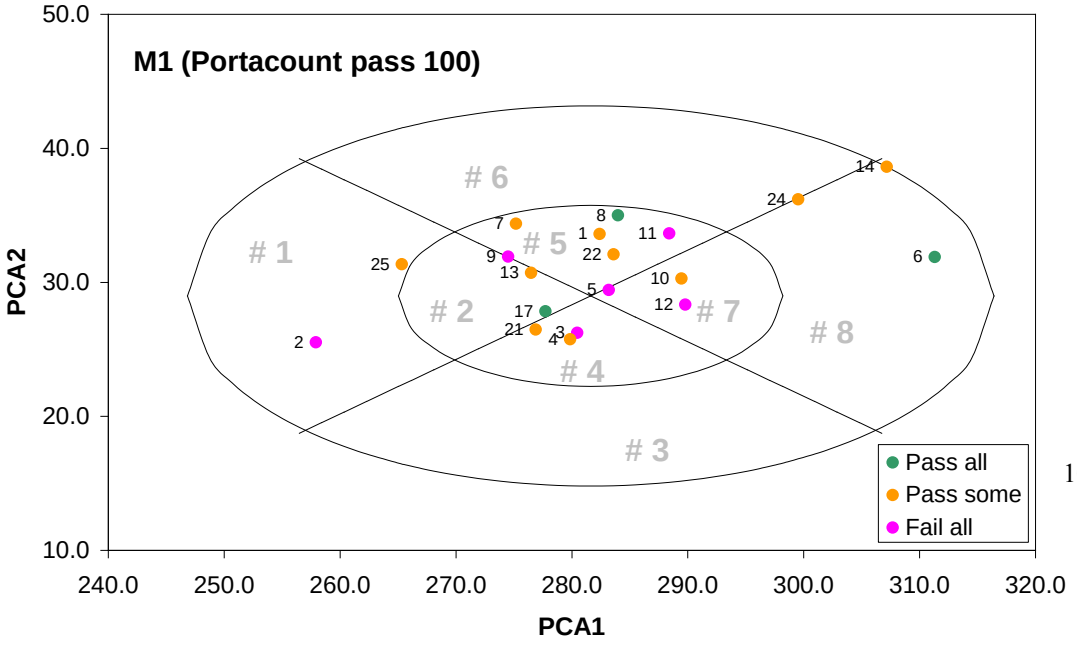
Table 20 FFP3 tests per subject

test subject	Mask tested (chronologically ordered)									total
S1	4	1	6	8	2	3	5	9	7	**9**
S2	8	3	1	2	4	5	9	6		**8**
S3	7	9	2	6	5	8	4	1		**8**
S4	1	8	2	6	3	7	5	9		**8**
S5	4	2	6	8	1	3	5	9		**8**
S6	7	5	8	2	6	3	4	1	9	**9**
S7	3	6	9	4	7	1	8			**7**
S8	2	9	1	4	8	6				**6**
S9	8	3	9	2	1	7	5	4		**8**
S10	1	9	6	5	3	2	8			**7**
S11	1	6	2	4						**4**
S12	9	1	6							**3**
S13	1	6	5	8						**4**
S14	1	4	3	9	8					**5**
S15	4	5	7							**3**
S16	3	4	2	6						**4**
S17	1	2	5	9						**4**
S18	8	4	9	7						**4**
S19	7	4	3	6	5					**5**
S20	7	9								**2**
S21	5	3	1							**3**
S22	8	1	4	6						**4**
S23	8									**1**
S24	4	1	3	8						**4**
S25	1	8								**2**
total										**130**

Figure 20 Test results for FFP3 M1, by test subject facial dimensions







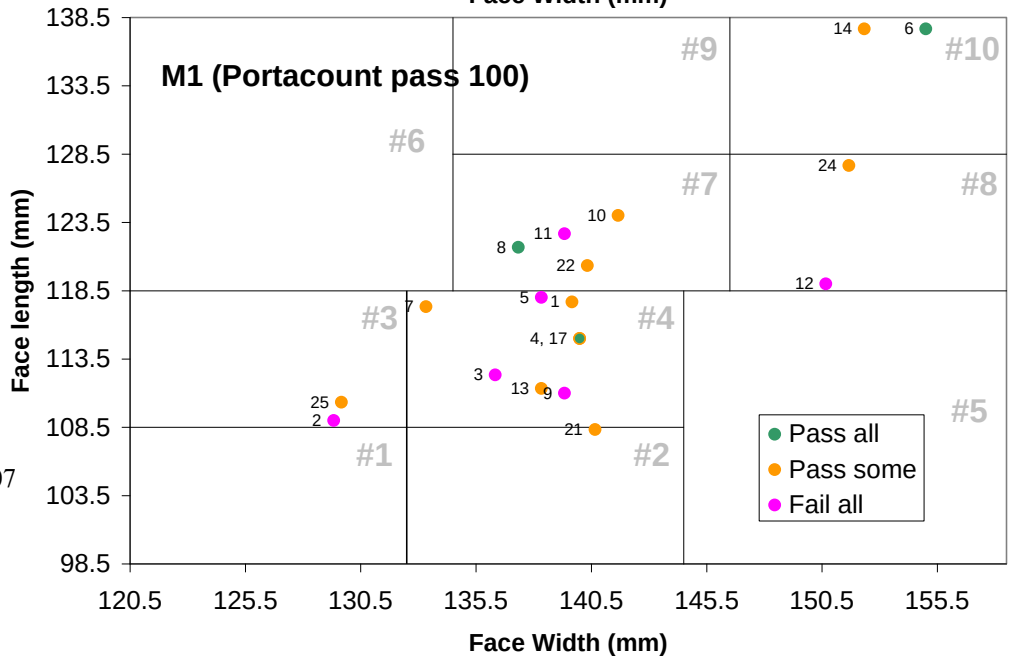
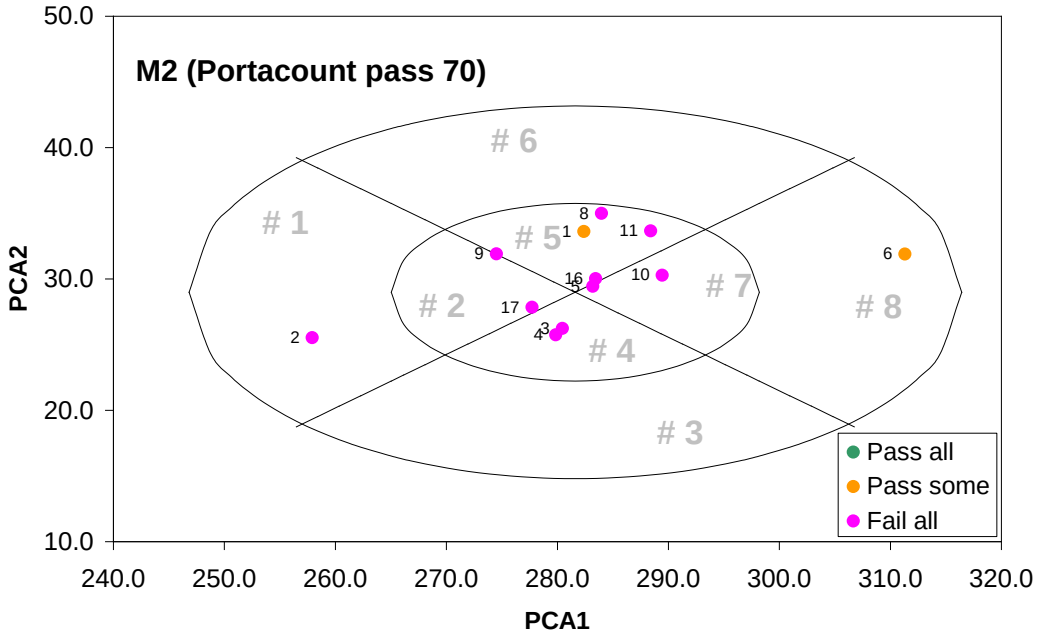
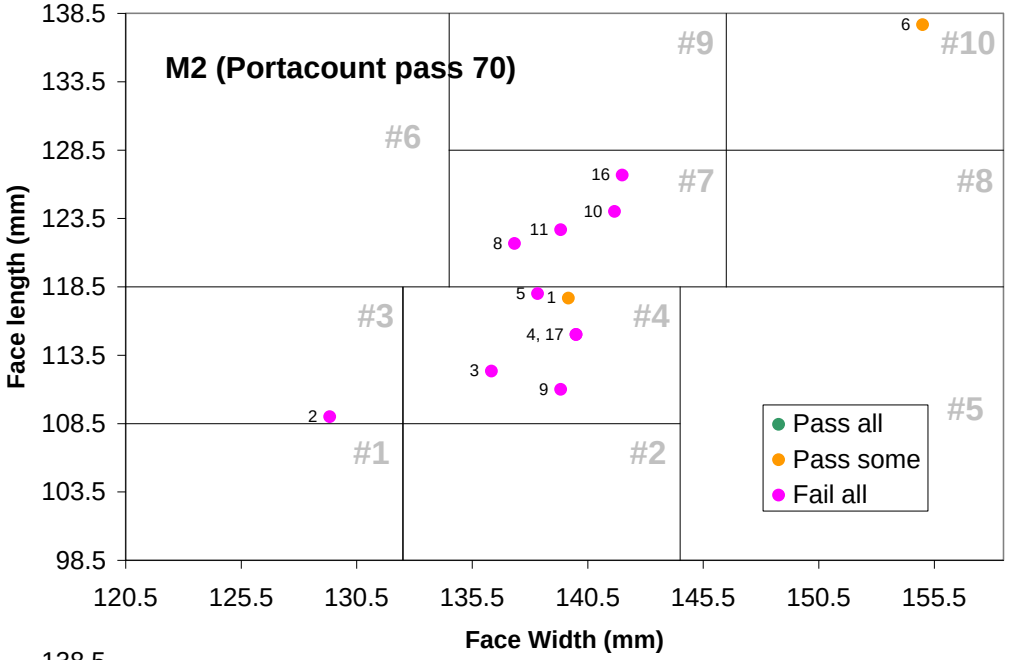
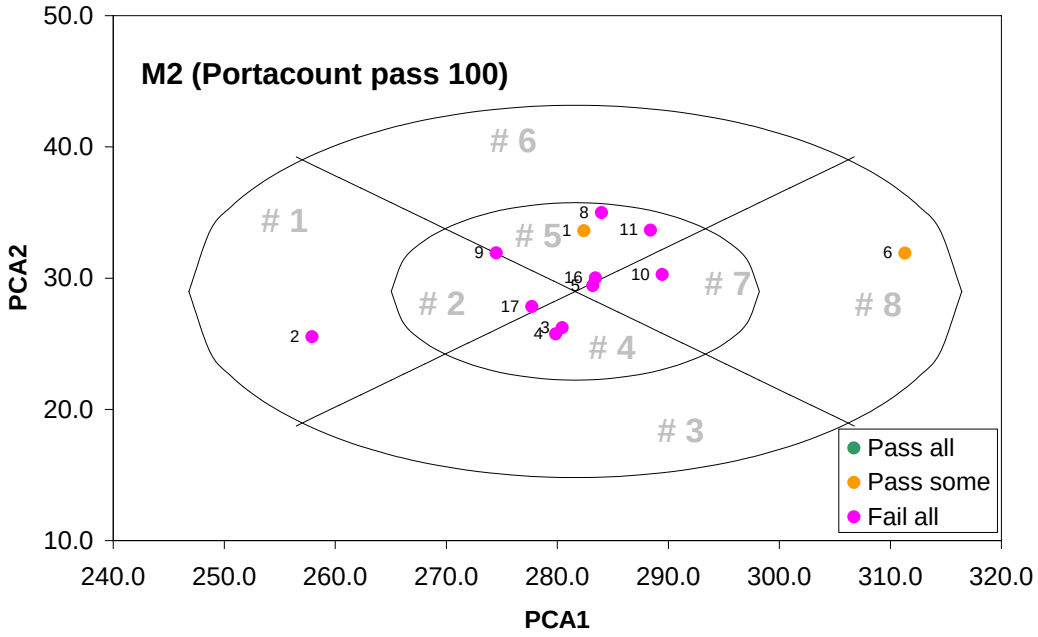


Figure 21 Test results for FFP3 M2, by test subject facial dimensions







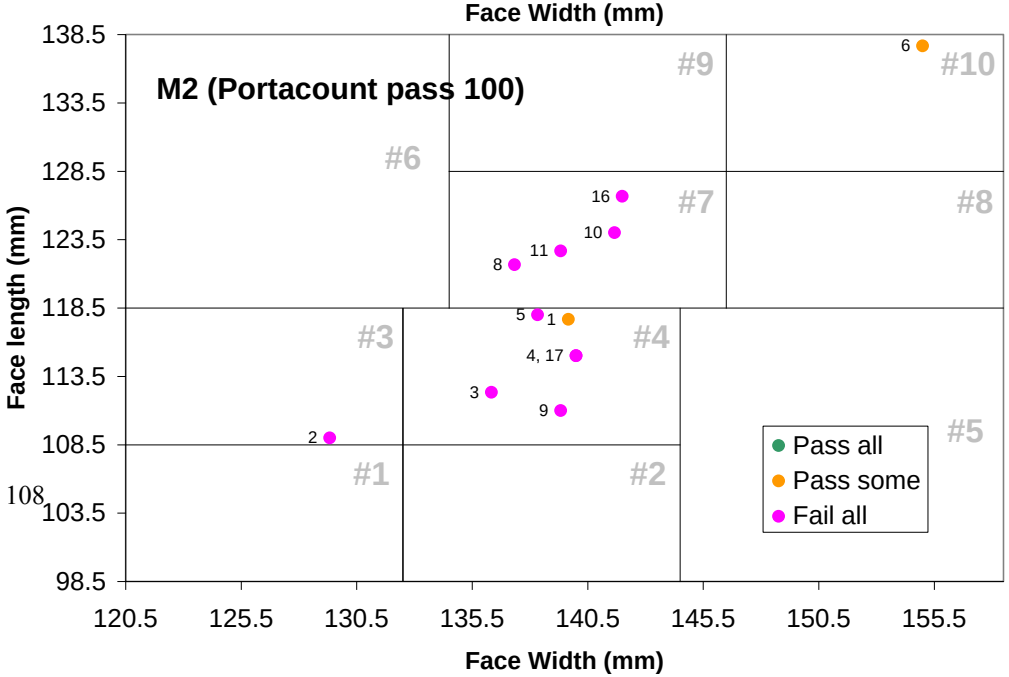
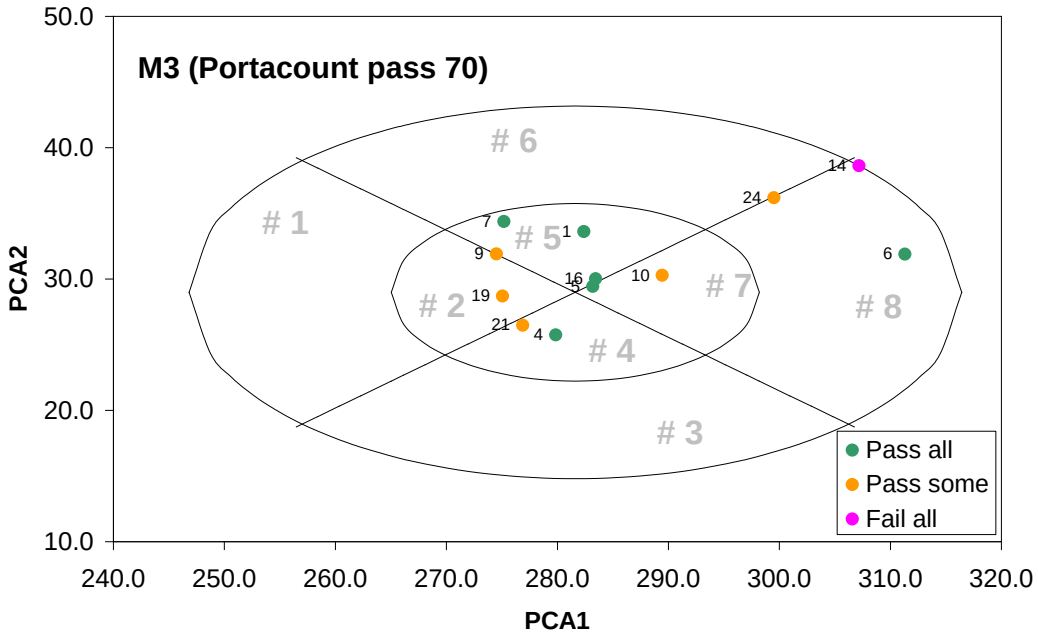
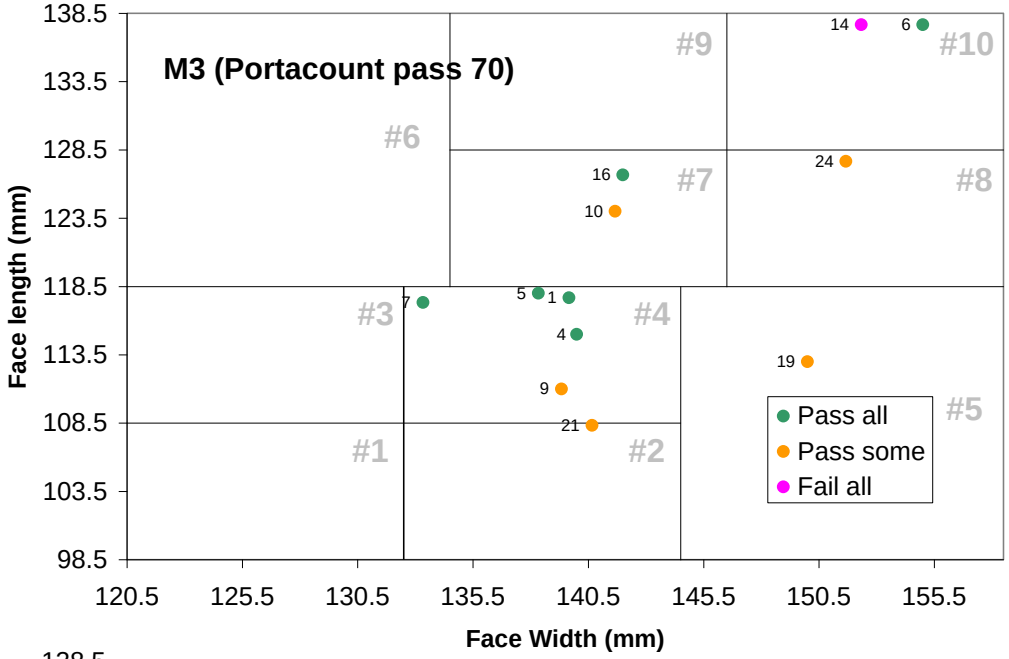
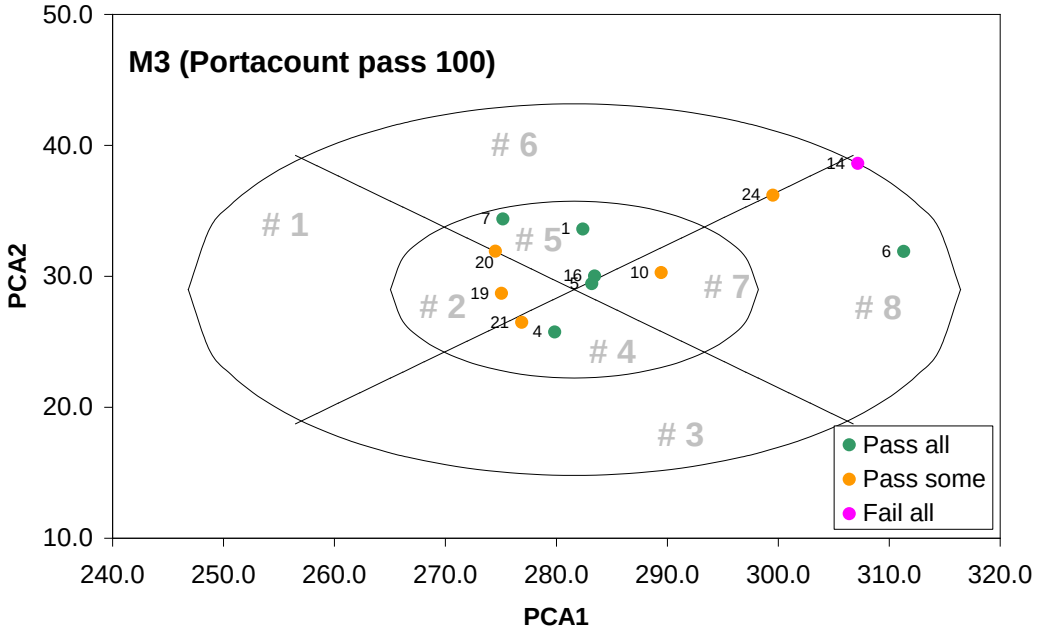


Figure 22 Test results for FFP3 M3, by test subject facial dimensions







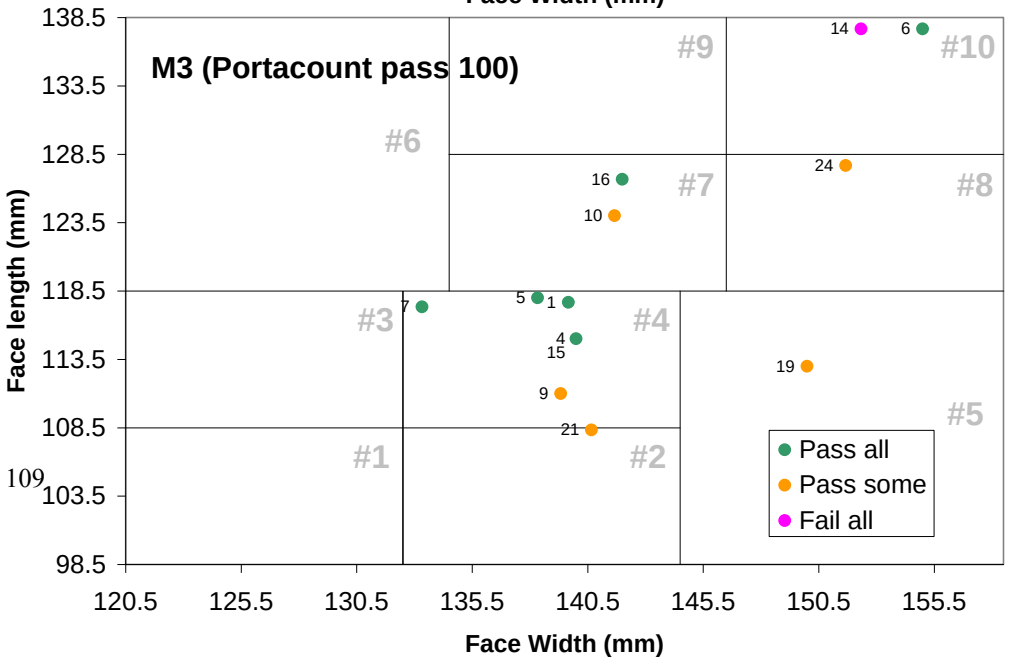
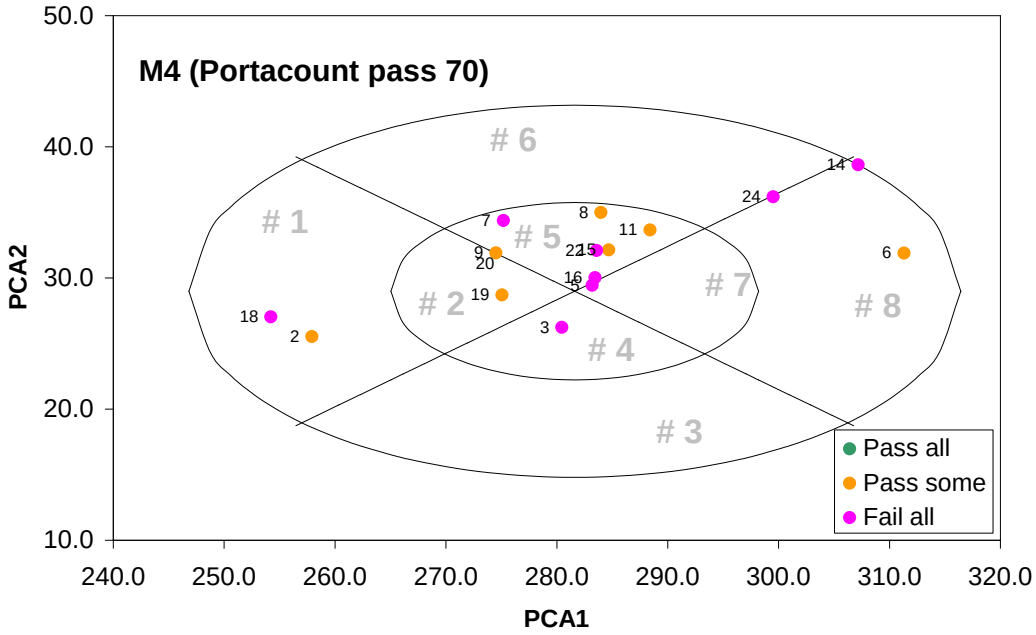
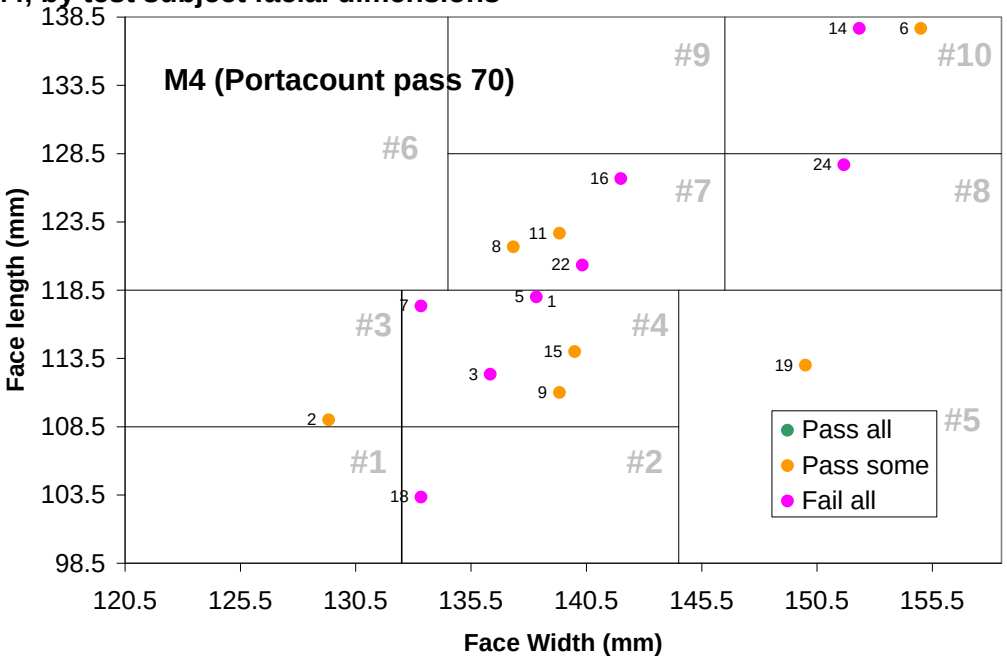
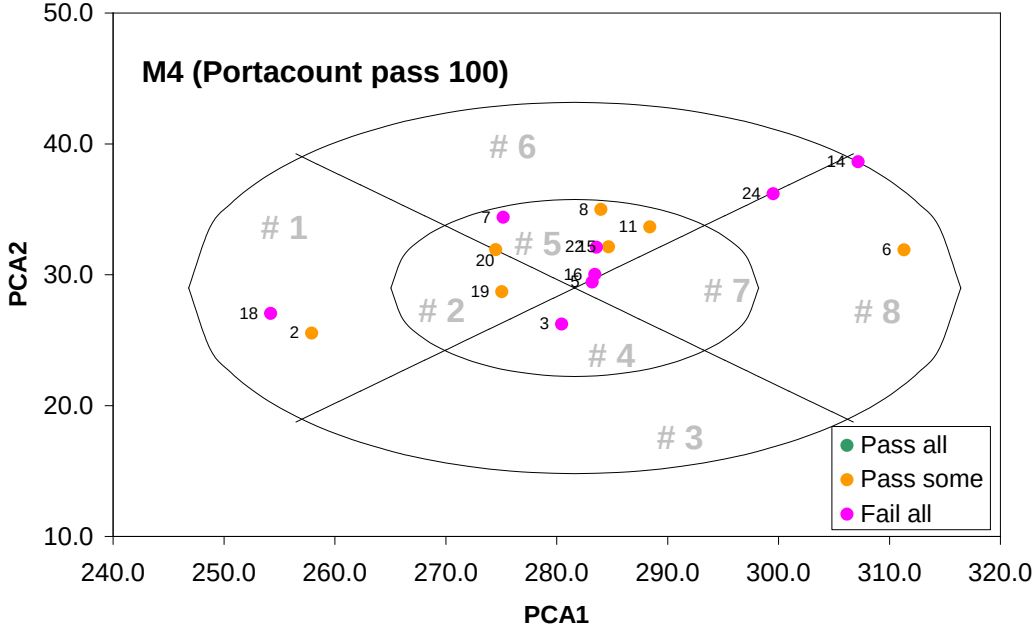


Figure 23 Test results for FFP3 M4, by test subject facial dimensions







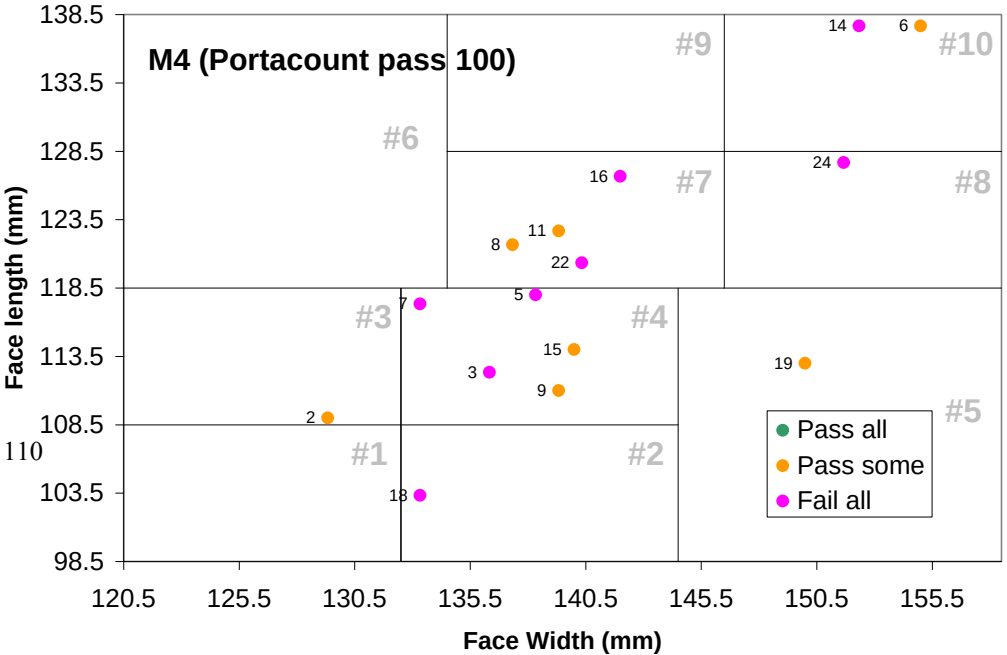
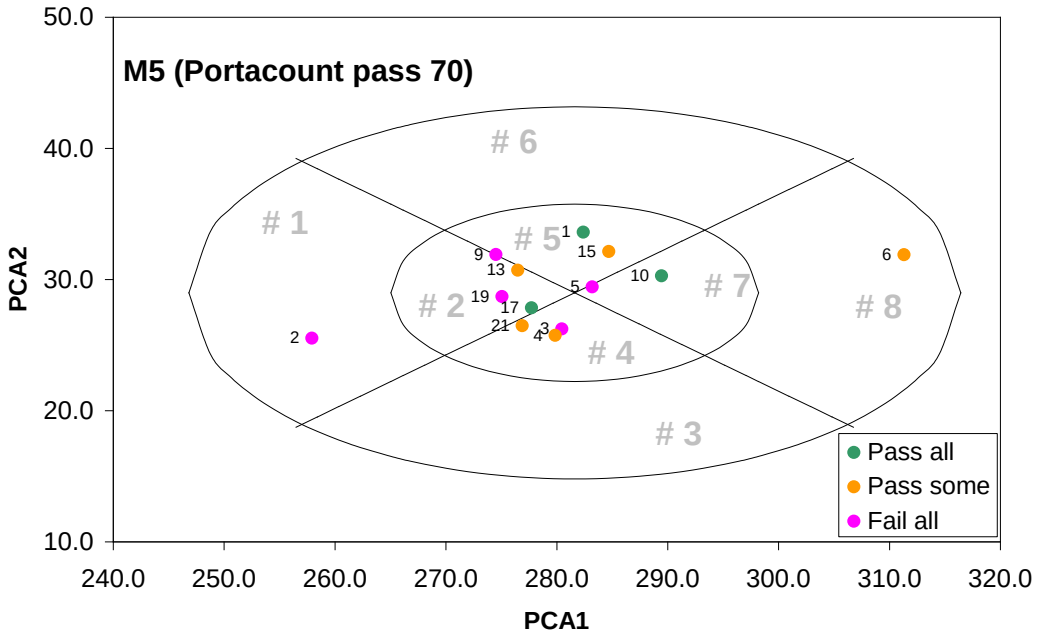
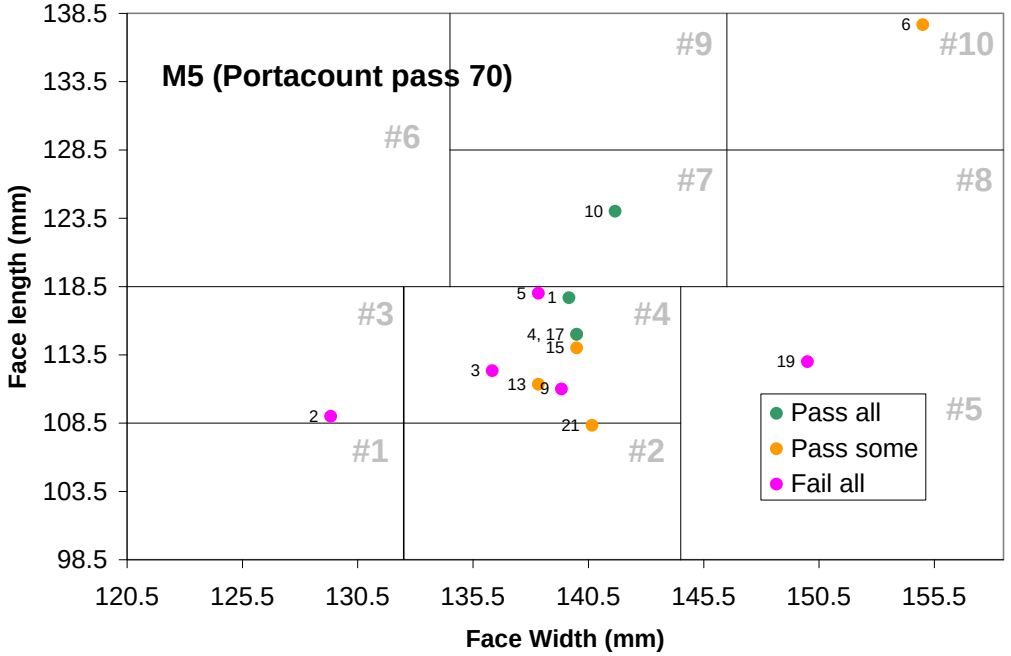
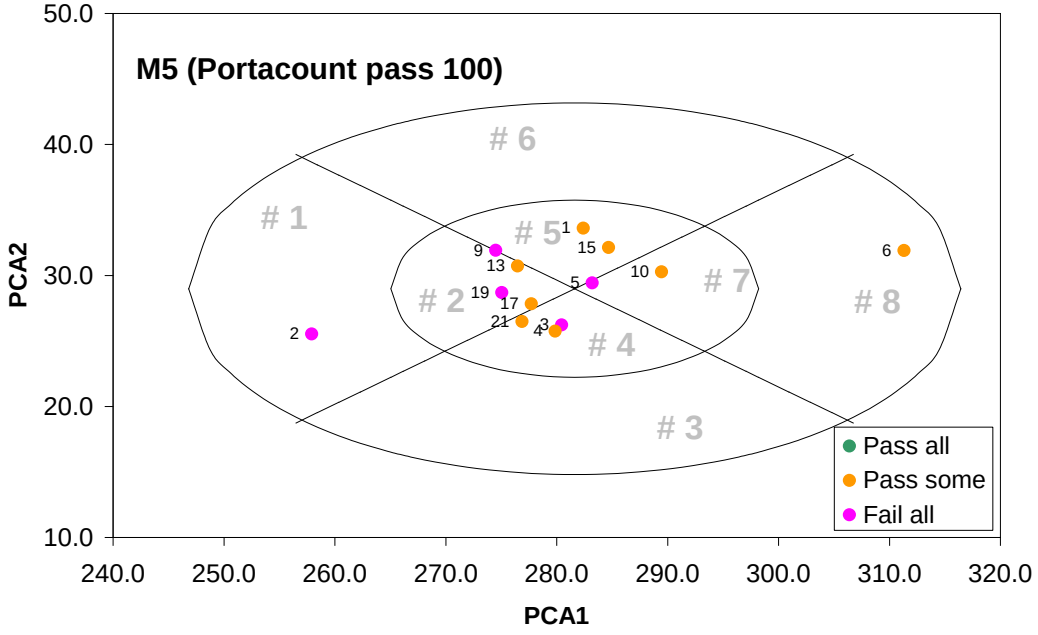


Figure 24 Test results for FFP3 M5, by test subject facial dimensions







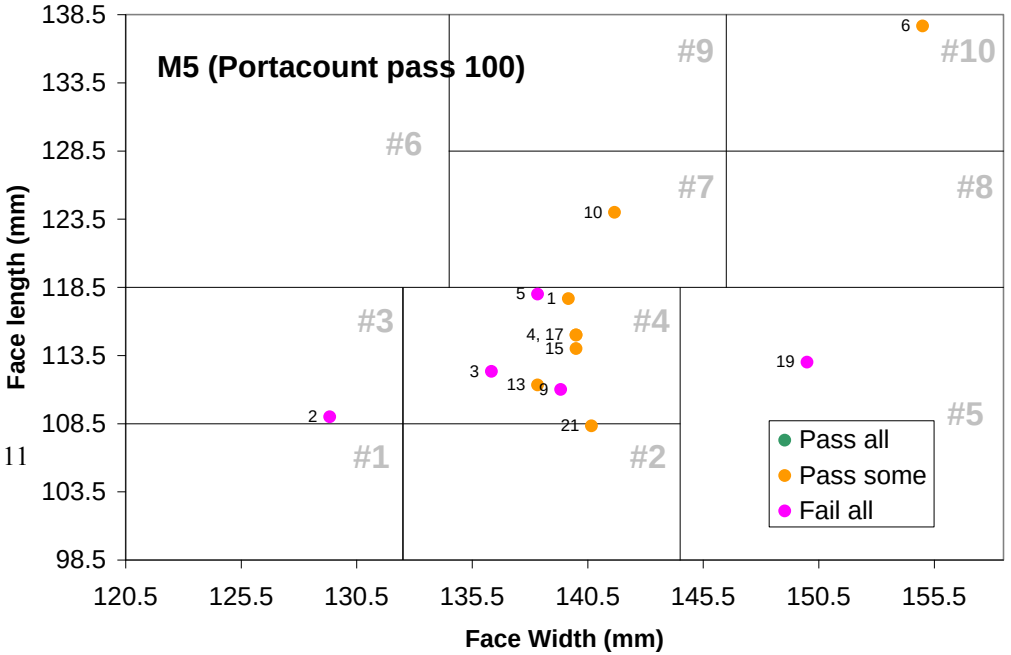
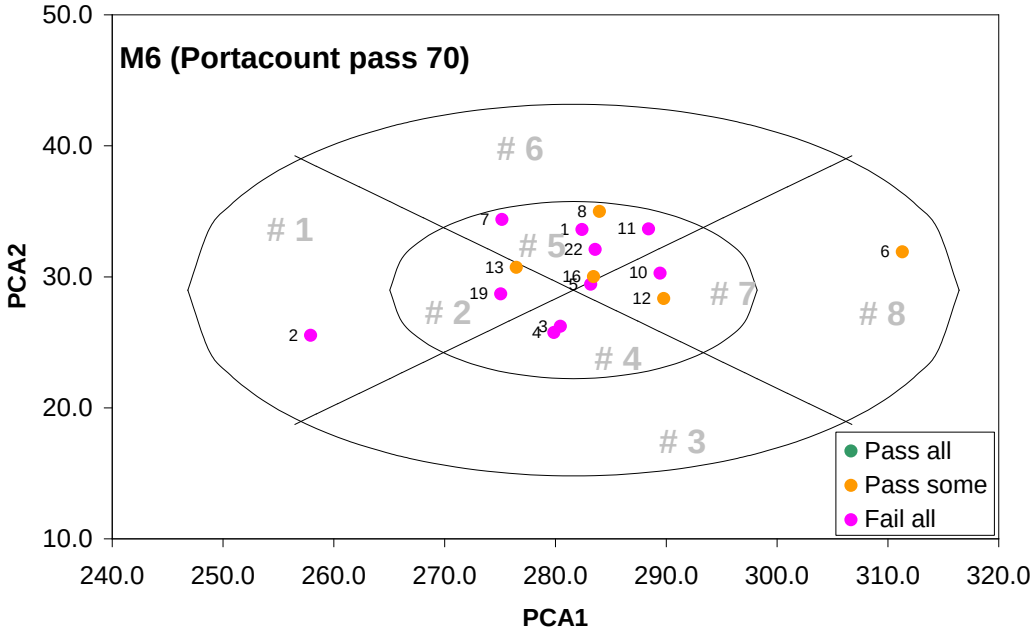
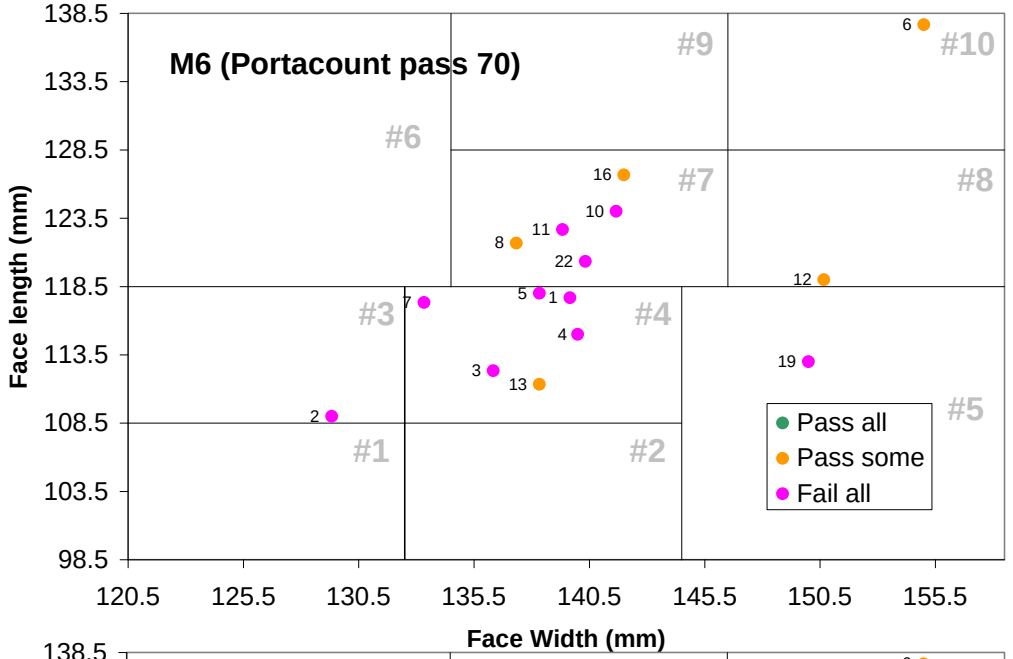
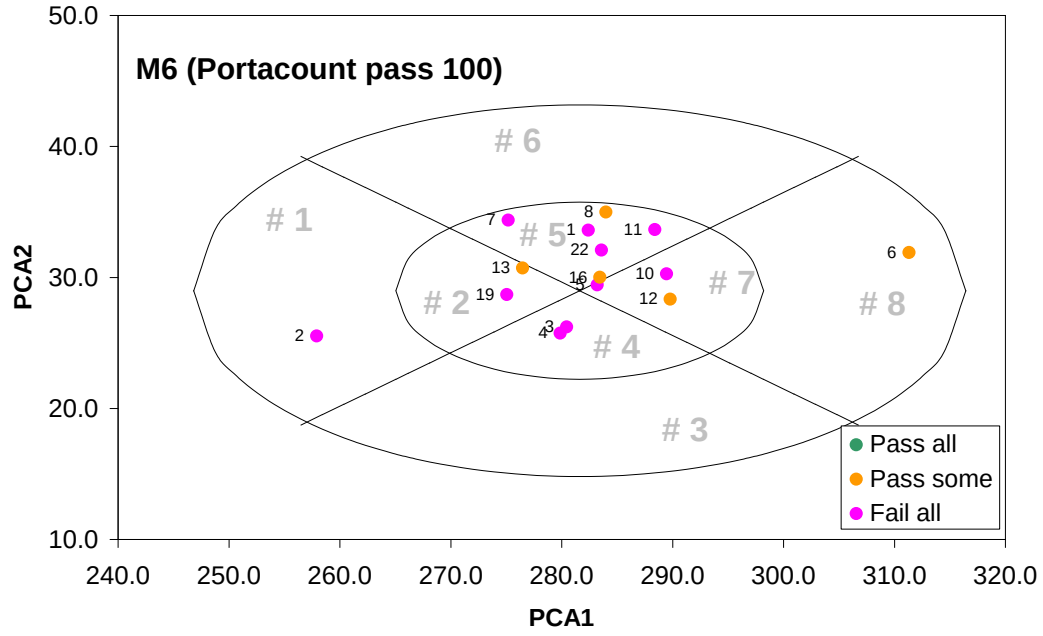


Figure 25 Test results for FFP3 M6, by test subject facial dimensions







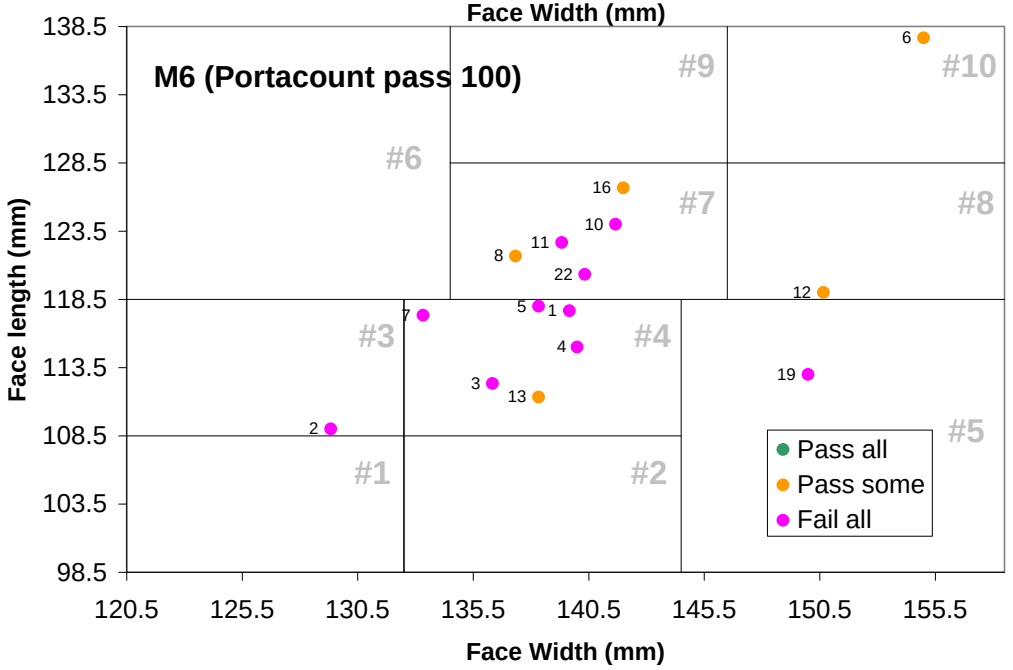
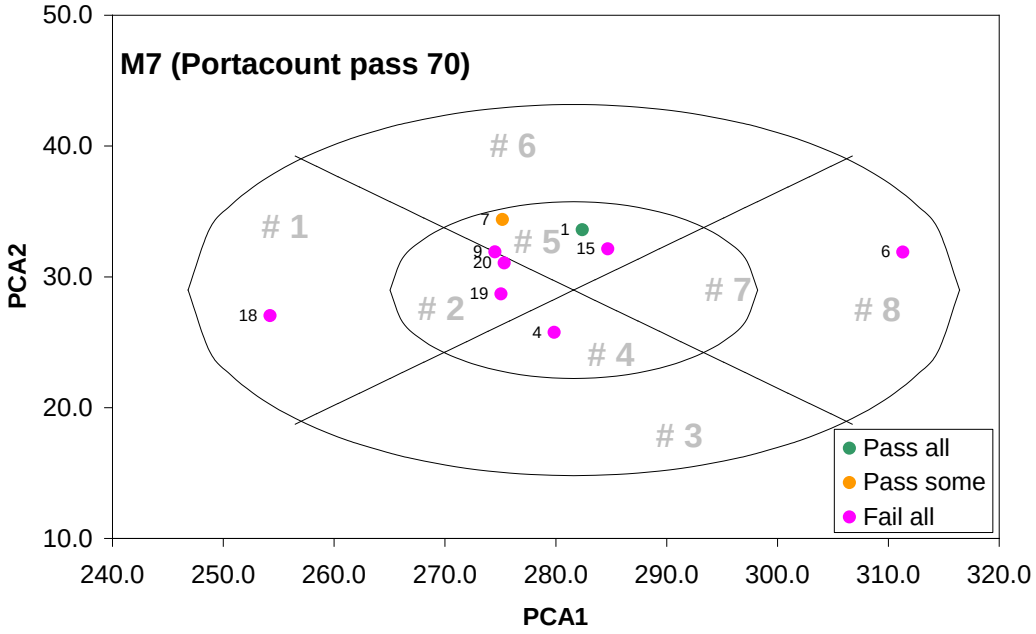
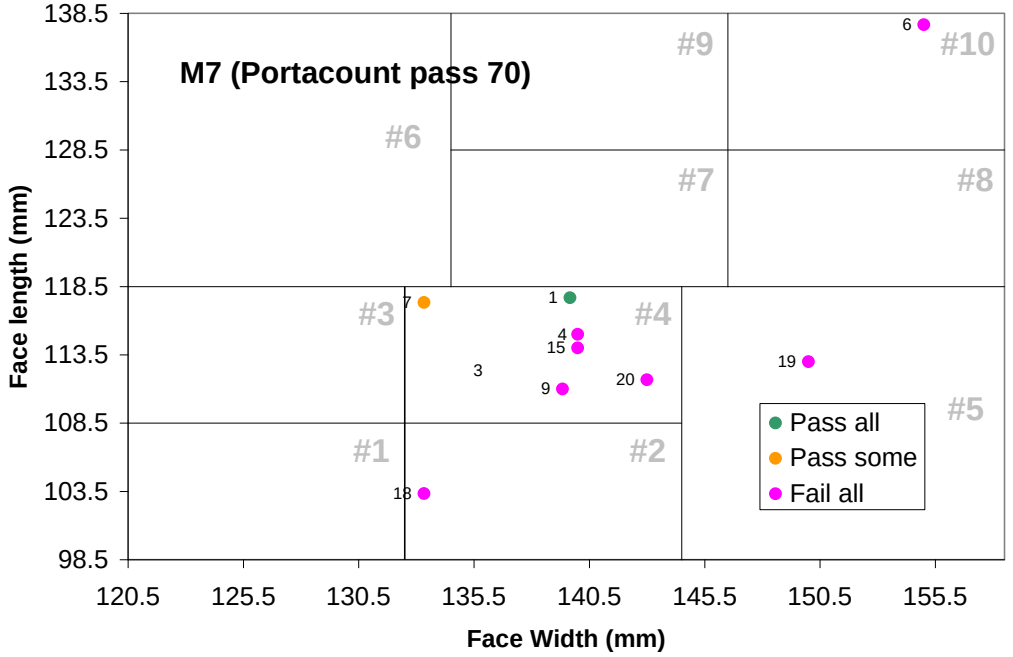
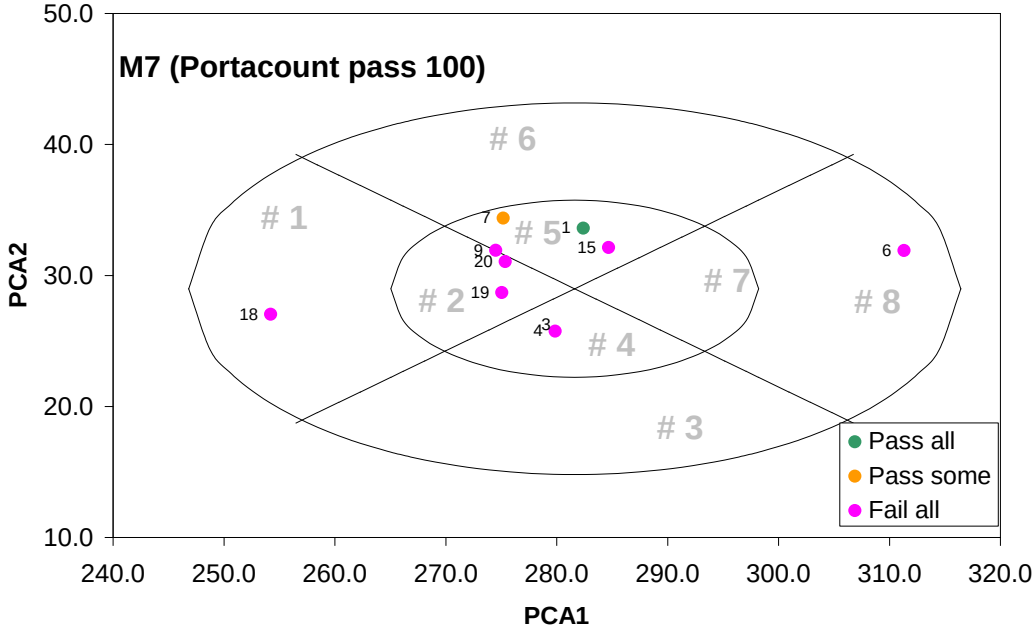


Figure 26 Test results for FFP3 M7, by test subject facial dimensions







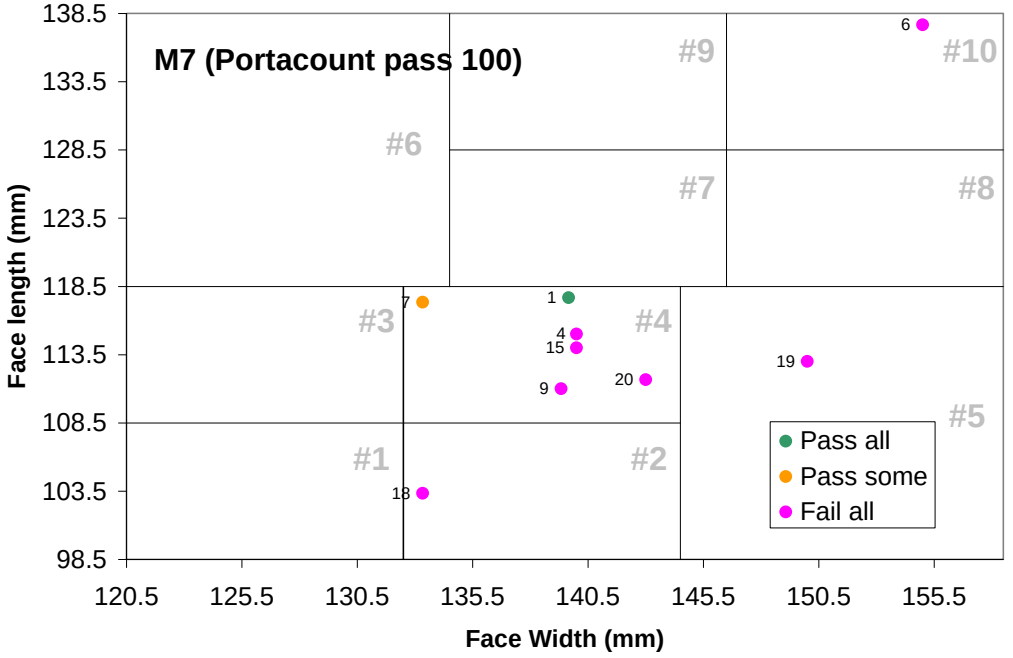
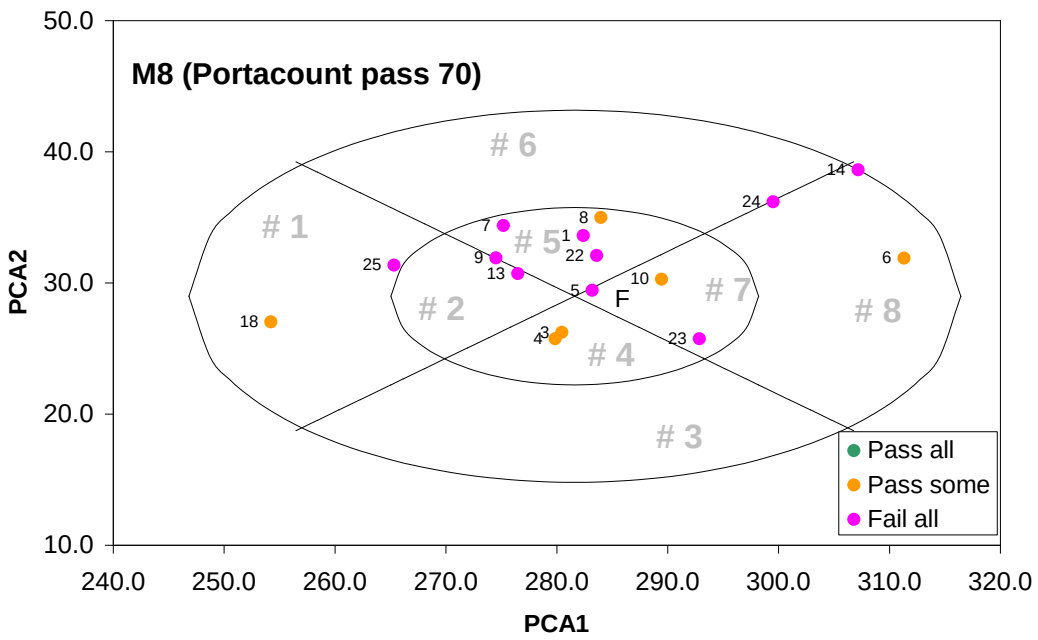
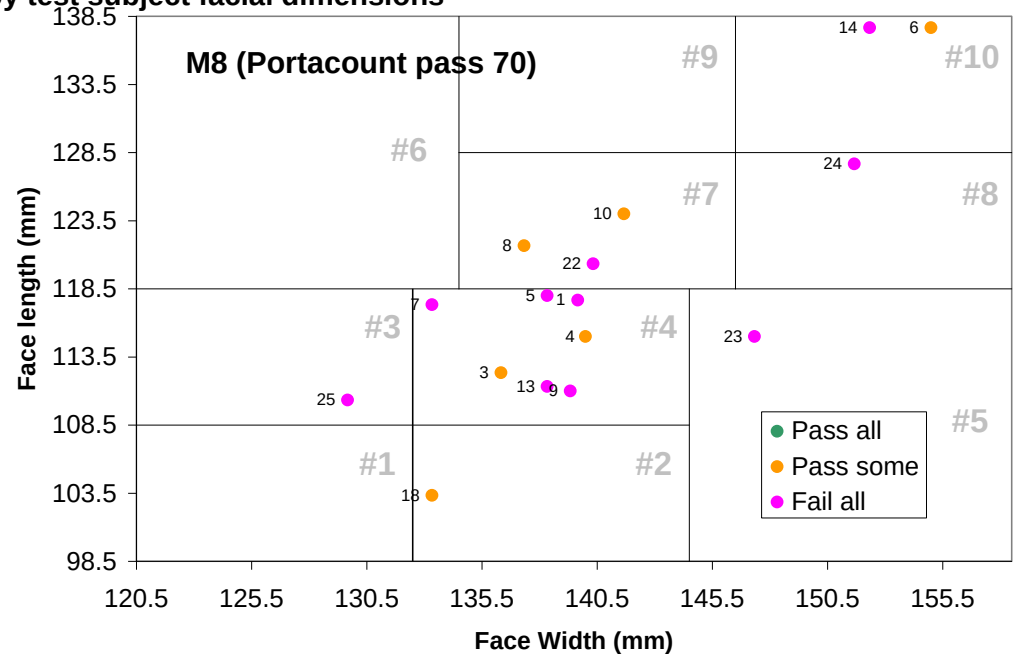
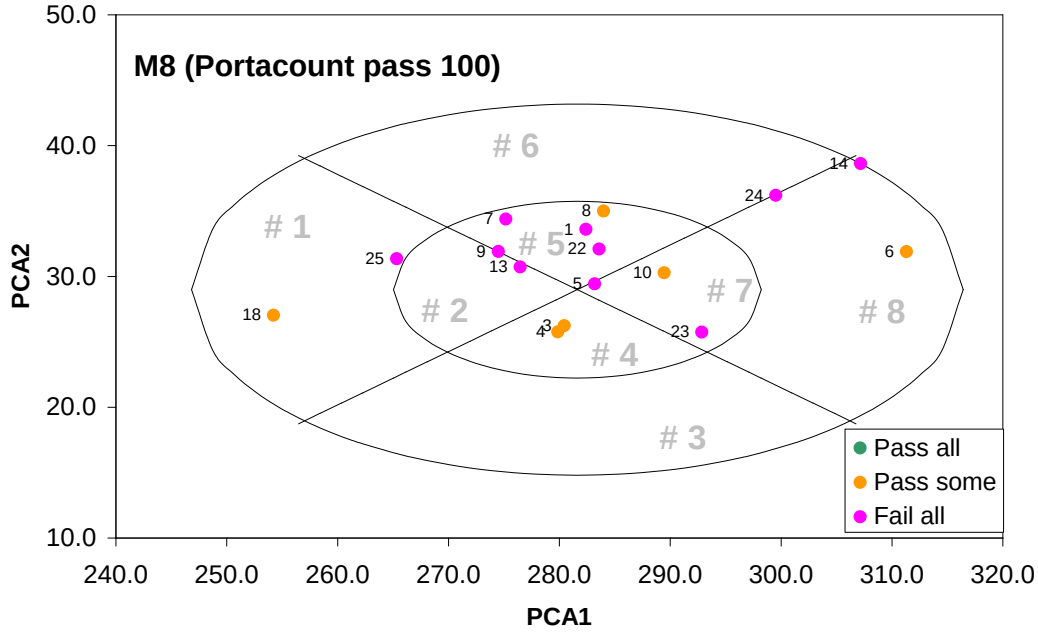


Figure 27 Test results for FFP3 M8, by test subject facial dimensions







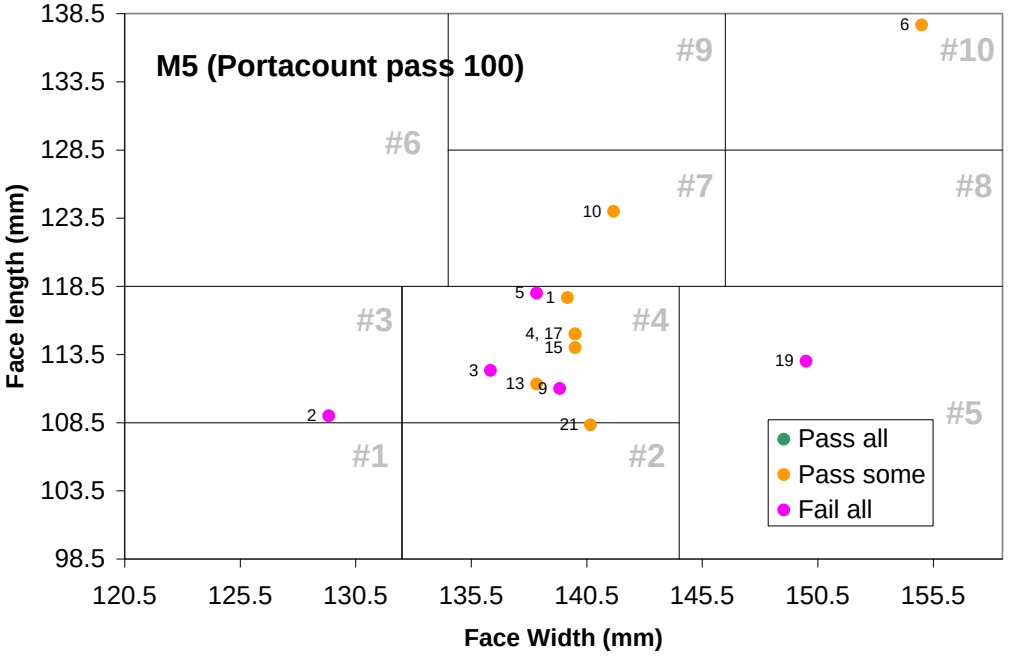
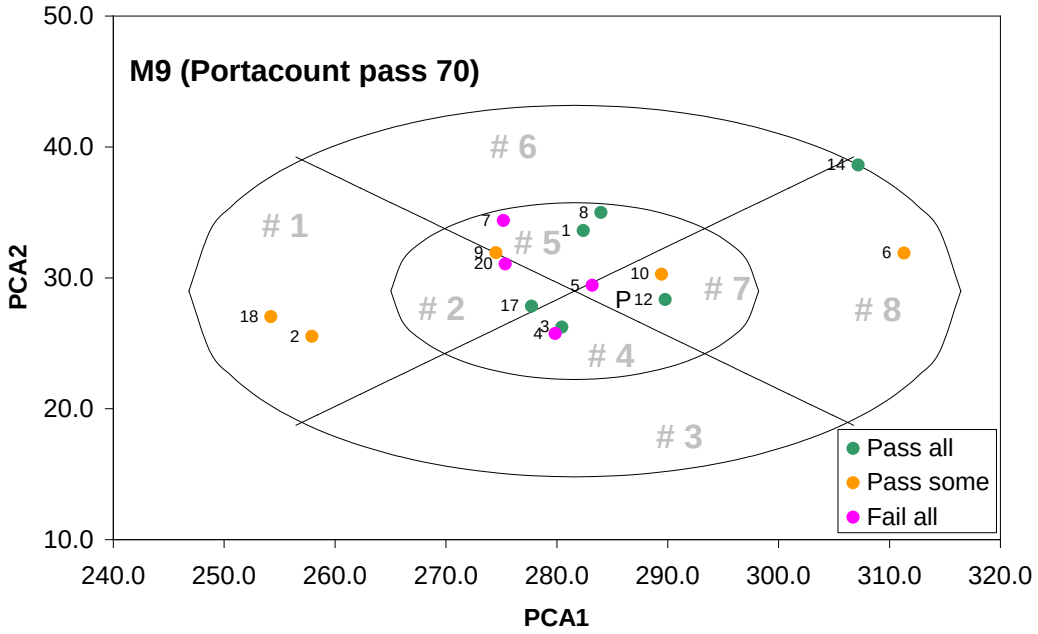
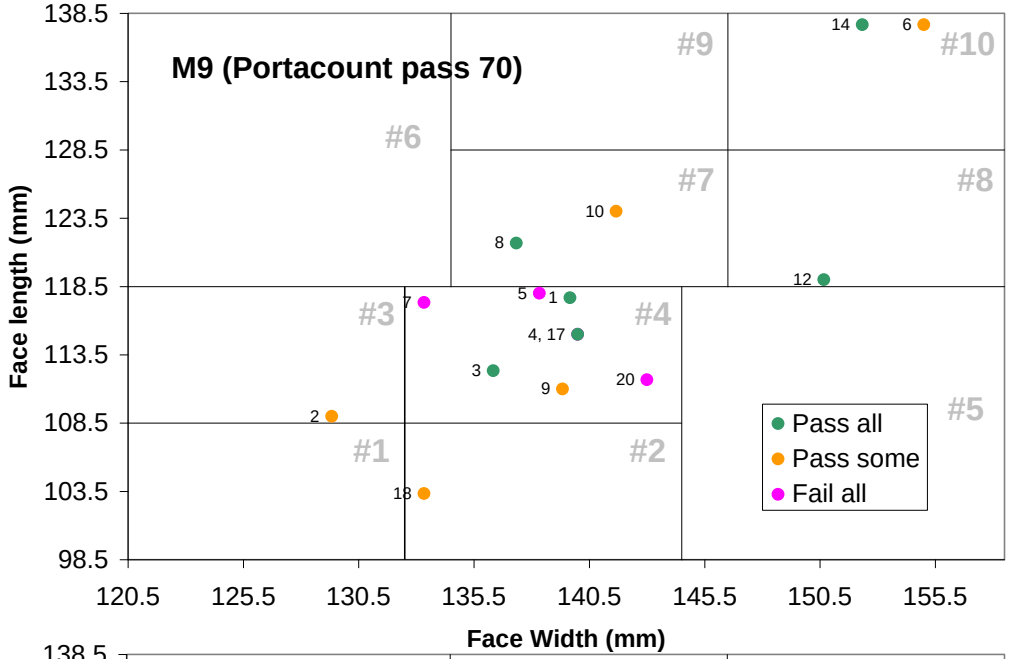
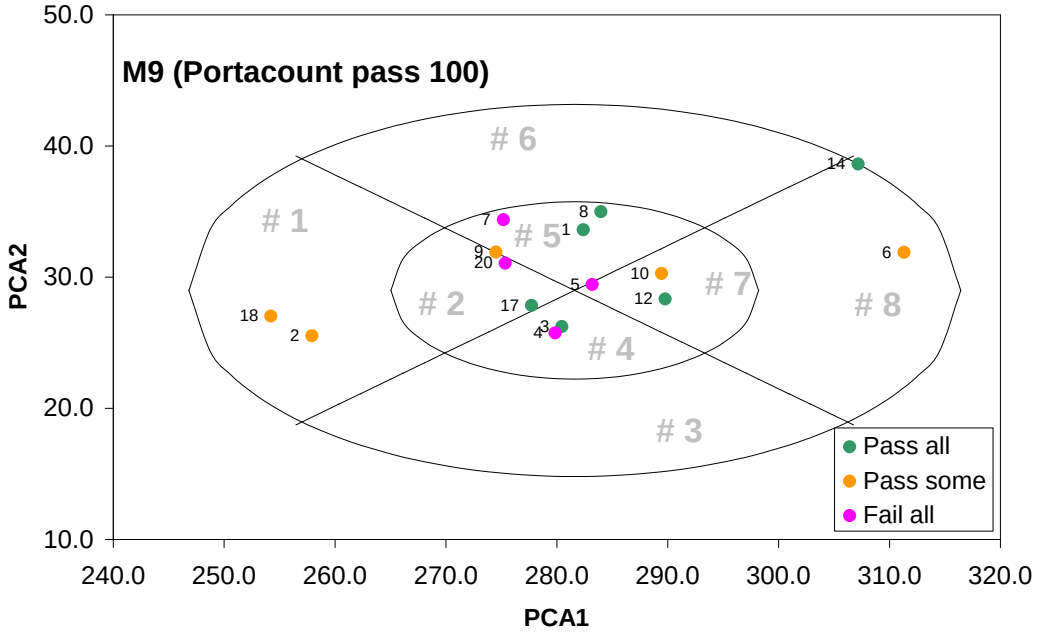
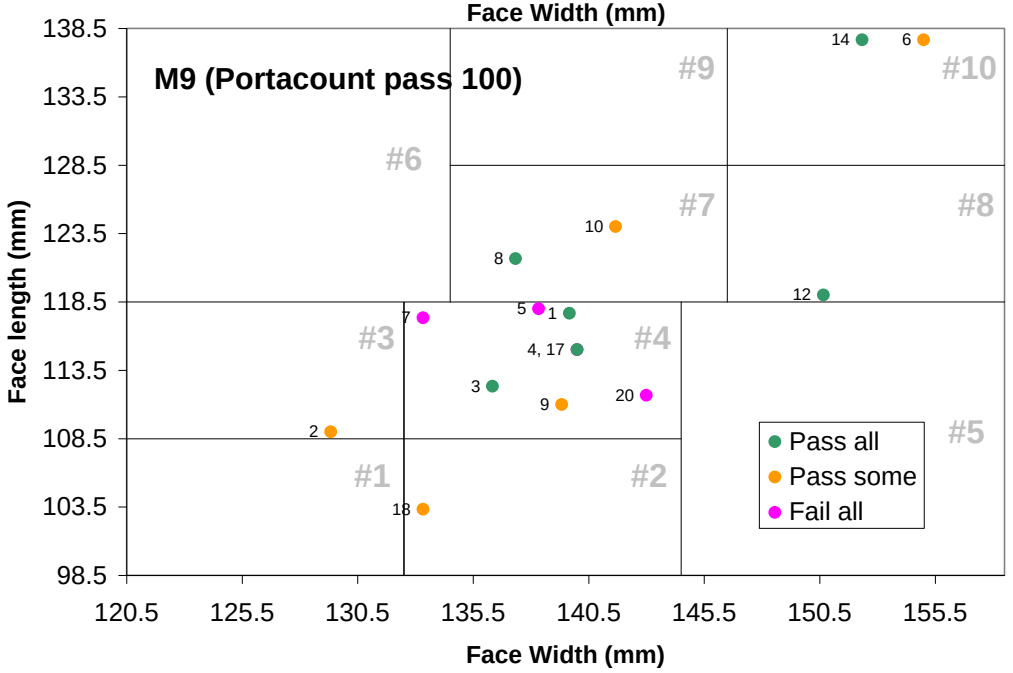


Figure 28 Test results for FFP3 M9, by test subject facial dimensions









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Review of fit test pass criteria for Filtering Facepieces Class 3 (FFP3) Respirators

Respiratory Protective Equipment (RPE) is available in a range of types which often include a tight-fitting facepiece which must fit the wearer's face well for the RPE to work effectively. Good fit must be demonstrated by fit testing.

In this study, 25 volunteer test subjects wearing tight-fitting FFP3 (randomly selected from 9 different models) underwent four fit tests (Bitrex qualitative taste test, Portacount particle counting with and without the N95 companion technology and the laboratory chamber method), in random order, according to methodology given in HSE guidance 282/28. The selected FFP3 model worn by each test subject was not adjusted until all four fit tests had been completed.

Results analysed according to the criteria given in the American National Standard for fit test validation, indicate that the Portacount fit test method is more difficult to pass than the other methods. Differences in the methodologies and the potential for bias in the results across the fit test methods are discussed.

The study also shows that a fit-check should never be used as a substitute for a fit test.

Many of the FFP3 were poor at fitting the test subjects.

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