WORKING FOR A HEALTHIER FUTURE

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Proportion of the UK working population tested who achieved an effective fit with the 3M 8835+ FFR

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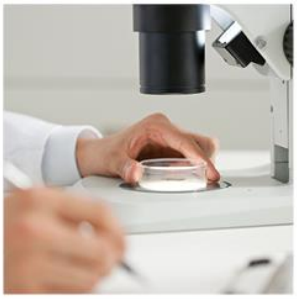

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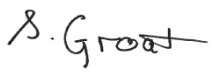

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1 INTRODUCTION

1.1 To provide effective respiratory protection, any close-fitting respiratory protective equipment device (RPD) must do just that, fit closely to the face of the wearer. Scientific studies have demonstrated that leakage round the mask due to an inadequate fit against the face is the main source of inward leakage in practice.

1.2 In the UK, in order to demonstrate the suitability of a particular type of RPD for a specific wearer a fit test should be performed. Although providing no guarantee that the RPD will be fitted and used correctly in daily use, this test at least demonstrates that the device in question can fit the person correctly. It therefore provides a standardised approach to identifying those in any workforce for whom a particular device is not suitable, usually because it does not conform sufficiently to their facial features to provide an adequate fit.

1.3 There will be some individuals who cannot achieve an adequate fit with any one particular RPD. Experience suggests that some devices are 'better' than others in that they will fit a greater proportion of the target workforce. Clearly, for many employers, there is an advantage in identifying the RPD most suited to their workforce (i.e. fitting the largest majority) in simplifying the provision of respiratory protection.

1.4 For the RPD manufacturers, adequacy of facial fit is clearly an important characteristic. A number of studies have explored the correlation between respirator fit and facial characteristics. Possibly one of the most comprehensive was that reported by Zhuang et al (2005) who explored the relationship between 18 different RPDs and 12 facial dimensions, as well as considering the influence of gender and RPD features. The authors identified a number of statistical clusters of face dimensions which were correlated with RPD performance. In addition to face length and face width, bigonial breadth (width across the jaw) and nose protrusion appeared in the most clusters. Despite the emergence of these additional measures,

the authors advocated the use of face length and width as the defining features for half mask respirator test panels (as opposed to face length and mouth width). In contrast, four facial dimensions[1] are used to describe the test panel used for product certification (e.g. EN149) and all designs are constrained by the need to fit the standard test head.

1.5 The final characteristics taken into account by the different manufacturers in designing any device will clearly be at the discretion of the company in question. However, as part of the proposed study, it was decided to obtain measurements of face length and width as recommended by Zhuang and co-workers. This was supplemented by the inclusion of bigonial breadth (width across the jaw) which, as noted above, featured in most of the statistical clusters derived by Zhuang. The number of dimensions measured was restricted to three to limit the demands placed on test participants.

1.6 3M have developed a new FFR (8835+) which is believed will fit a greater proportion of potential wearers than previous devices. A scientific, statistically valid study is required to establish what that proportion is. However, there is no intention to carry out any form of comparative study to relate the proportion fitted by the new device to those fitted by any existing device.

2 THE PROCEDURE ADOPTED

2.1 The performance testing of the 3M 8835+ disposable filtering face piece was based on the standard Fit-Test procedure (OC 282/28), in accordance with the Fit2Fit accreditation scheme (BSIF). All testing was performed by a Fit2Fit accredited competent provider in accordance with standard IOM procedures. Testing was conducted under the guidance of the IOM PPE Test Facility Manager, Keith Sinclair, who was directly involved in the initial development of this scheme and who has extensive experience over many years of

[1] Length of face, width of face, depth of face, width of the mouth.

conducting such tests. In order to provide 'separation' from the Fit-Testing Service provided by IOM Ltd, none of the currently certified IOM testers providing that service (including Mr Sinclair) undertook any of the testing for this project. However, it must be emphasised that the individual who carried out the testing was fully trained and accredited under the Fit2Fit RPE Fit Test Providers Accreditation Scheme. To provide assurances to current 3M fit test providers, no reference was made to the IOM Services to any study participants recruited by 3M.

2.2 All testing was completed using the HSE quantitative fit testing method (OC282/28). This was achieved using one of two available TSI Portacount Pro+ units, both calibrated by TSI. Where it was necessary to ensure that the ambient particle concentration was high enough during the testing, a TSI particle generator (model 8026) was used.

2.3 A number of different sources of test participants were used from the following:

- 3M RPD clients
- 3M clients utilising the 3M Fit Test Service
- 3M clients seeking to purchase RPDs
- IOM clients utilising the IOM Fit Test Service

2.4 Candidate test participants were therefore those employees presented for fit testing by their employers. The purpose of the study was briefly explained to candidate participants and their consent obtained. Participants were first tested on the new 3M 8835+ (the 'test device') and their facial anthropometric measurements obtained using a set of calibrated anthropometric callipers. A Fit Test was then conducted on the device provided for the candidate by their employer (the 'provided device'). This procedure allowed for a break between the two tests. The usual practice of testing with alternative devices should the device provided not fit the wearer, was adhered to for the provided device (but not the test device). Alternatives to the provided device were selected firstly from any the client company had available. 3M also

provided a selection of sample alternatives for such testing, where no alternatives were provided by the client company.

3 PARTICIPANT ANTHROPOMETRIC RESULTS

3.1 The following three measurements were taken from each participant.

Figure 1: Menton-Sellion[2] Length (face length)

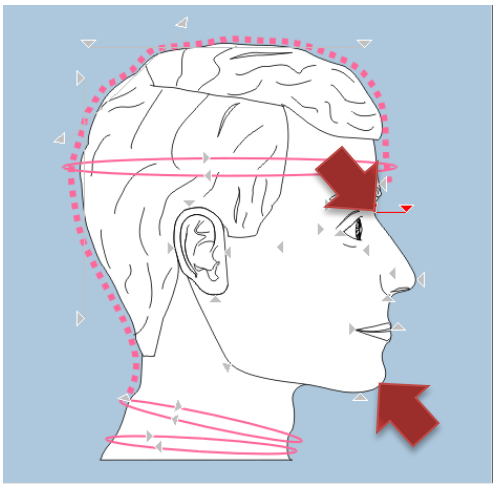
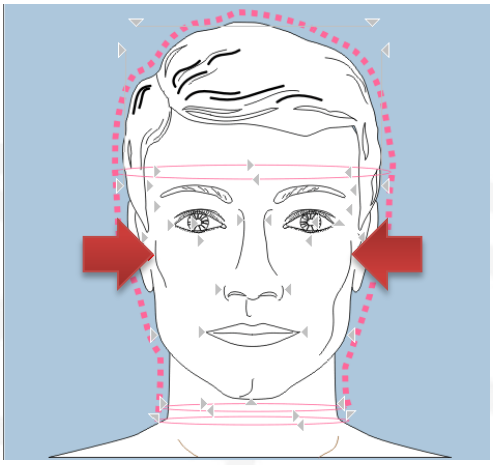
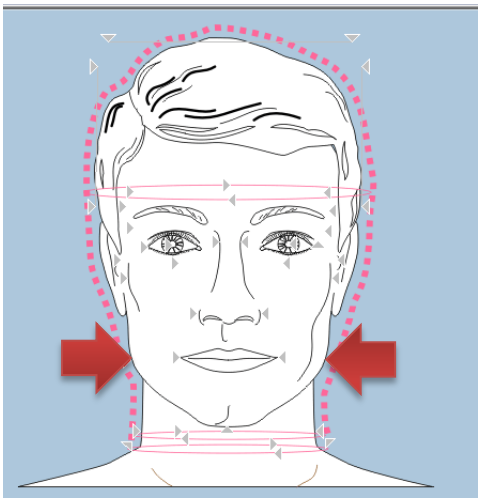


Figure 2: Bizygomatic Breadth (face width)



[2] Also known as nasion – menton length

Figure 3: Bigonial Breadth (jaw width)



3.2 A total of 262 participants took part in this study. Of that total, 25 were female and the remaining 237 were male. Therefore, the study population of participants was 90.5% male. A deliberate decision was made to base the survey on those presented for testing rather than imposing a gender requirement. This proportion therefore reflects the individuals who presented for testing in real-world applications spanning 21 industries. As shown in Table 1 and Figure 4 the average of each of the three face measurements for the fail group were larger than the equivalent averages for the pass group.

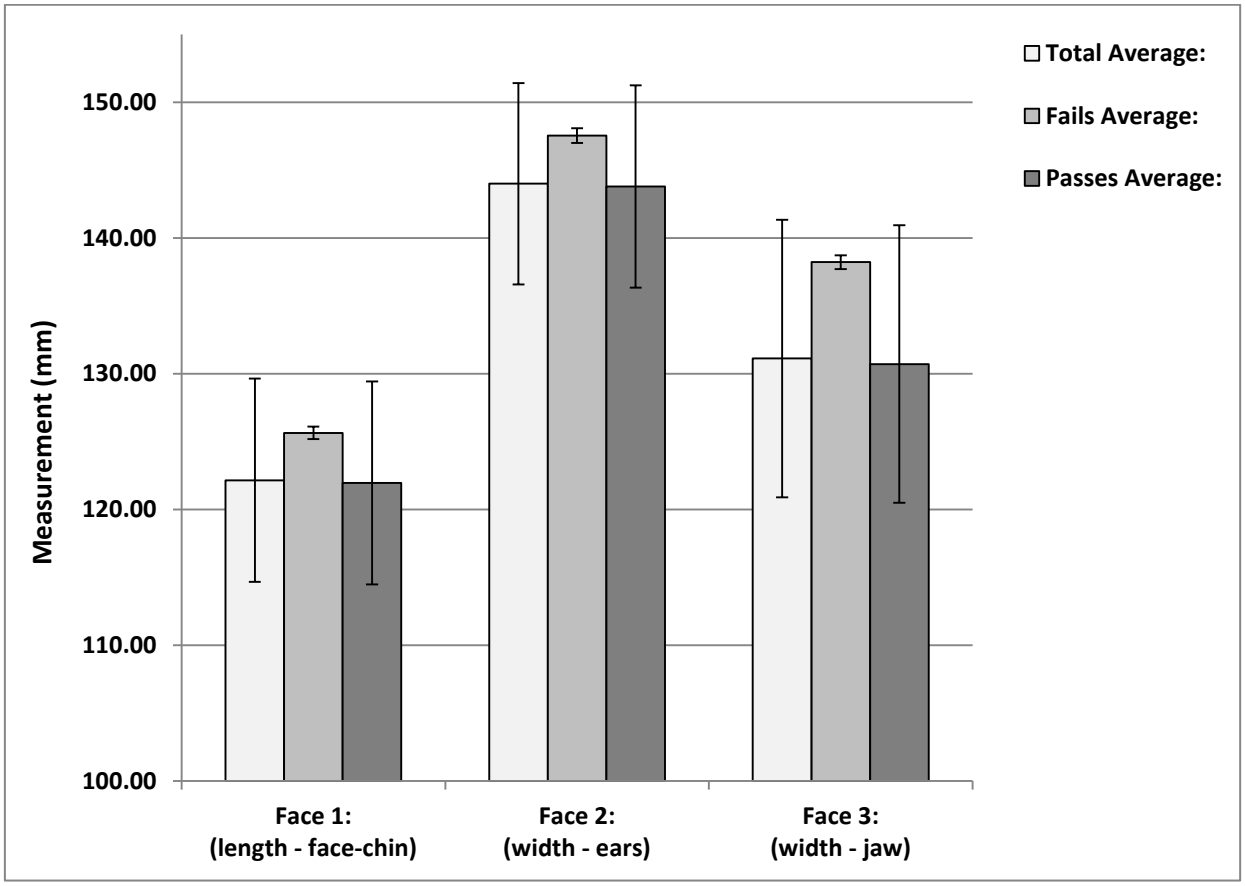
3.3 Although wearers with larger faces appear to be more likely to fail a fit test with the 3M 8835+ this is not consistently the case and wearers with larger faces are also capable of achieving a satisfactory fit.

Table 1: Face measurement averages and standard deviations

	Face Measurement 1: (length - face-chin)	**Face Measurement 2: (width - ears)**	**Face Measurement 3: (width - jaw)**
Total Average (n=259[3]):	122.16mm	143.99mm	131.12mm
Total Standard Deviation:	7.49mm	7.42mm	10.23mm
Fails Average (n=14):	125.64mm	147.54mm	138.21mm
Fails Standard Deviation:	0.46mm	0.54mm	0.51mm
Passes Average (n=245):	121.96mm	143.79mm	130.71mm
Passes Standard Deviation:	7.47mm	7.44mm	10.23mm

[3] Three candidates withheld consent for facial anthropometry measurements.

Figure 4: Face measurement averages and standard deviations



4 SUMMARY OF COMPANIES AND INDUSTRIES INCLUDED IN THE STUDY

4.1 The participant population in this study came from several industries and work types. Each participating site provided an industry or work type descriptor. Based on these descriptions there were 21 different industries/work types represented amongst the participating sites, as shown in Table 2. These descriptors of industry or work type were related to business economy sectors (using NACE Rev.2). This showed that there were 14 2nd tier sectors amongst the participants as shown in Table 3. These 14 2nd tier sectors came from six top tier NACE Rev.2 sectors:

B Mining and Quarrying;

C Manufacturing;

D Electricity, Gas, Steam and Air Conditioning Supply;

F Construction;

H Transportation and Storage;

Q Human Health and Social Work Activities.

Table 2: Work descriptors by site

Work Descriptors:
Asbestos work
Bridge Building
Chemical Handling
Chemical Manufacturing
Construction
Demolition
Hospital Estates
Leather Tanning
Metal work
Painter
Paper Mill
Petroleum
Power Plant
Pre-cast Concrete
Quarry
Rail Industry
Roofer
Scaffolding
Surgical Work
Timber/manufacturing
Wood work

Table 3: Work sectors by NACE code

NACE Code:	Work Sector:
B.08	Other mining and quarrying
C.15	Manufacture of leather and related products
C.16	Manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials
C.17	Manufacture of paper and paper products
C.19	Manufacture of coke and refined petroleum products
C.20	Manufacture of chemicals and chemical products
C.23	Manufacture of other non-metallic mineral products
C.24	Manufacture of basic metals
D.35	Electricity, gas, steam and air conditioning supply
F.41	Construction of buildings
F.42	Civil engineering
F.43	Specialised construction activities
H.49	Land transport and transport via pipelines
Q.86	Human health activities

5 THE FIT TEST RESULTS

5.1 The total number of fit tests completed was 262. Of that total, 14 participants failed to achieve a good fit, resulting in 94.66% of the study population successfully achieving a good fit with the 3M 8835+.

The 14 fit tests where the participant failed to achieve a good fit are summarised in Appendix 1: Summary of failed tests.

5.2 The average fit factor of the 248 successful fit tests was 517.40 ± 307.48, with a lowest fit factor of 125 and the highest fit factor of 2312.

5.3 Of those wearers who failed to achieve a successful fit with the 3M 8835+ six reported noticing a leak as soon as they donned the mask. For the same group of participants the majority of test and retest fails occurred during the 'talking out loud' exercise at 10 occasions. The mask also failed on the 1st 'normal breathing' exercise on four occasions, and then three times during both the 'deep breathing' and 'head up and down' exercises.

6 SUMMARY AND CONCLUSIONS

6.1 Fit tests, carried out using the HSE quantitative fit testing method (OC282/28) were carried out by a single Fit2Fit certified examiner on 262 participants drawn from a wide range of different industries. Just over 90% of the participants were male, reflecting the use of RPD in the participating companies.

6.2 Of that total, the RPD was shown to fit 248 individuals on the day of the test, with just 14 participants failing to achieve a pass. Therefore 94.66% of the study population achieved a satisfactory fit with the 3M 8835+.

6.3 Those who failed tended to have larger than average faces. However, although smaller wearers invariably passed, not all larger-faced wearers failed, with a number of those achieving a pass having larger facial dimensions than those who had failed. Some subjective perceptions of reasons for failing are reported in Appendix 1 which might be of value in future designs or modifications.

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7 APPENDIX 1: SUMMARY OF FAILED TESTS ON TEST DEVICE

Gender	Work Descriptor	Fit Factor	Possible reason for fail
Male	Metal work	29, 62	The fit test failed during the talking out loud exercise during both tests. Readjustment of mask position during live reading failed to remedy this. The wearer commented that, when he began to speak, he could feel cold air entering the mask from each side of the mask. From a visual examination, the most likely cause for the failed tests was the very prominent dimples and smile lines on the wearer's face. Furthermore, the wearer had a wider face than the sample average with quite low body fat.
Male	Wood work	68, 95	The wearer remarked that he felt cold air entering into the mask under his chin during the talking out loud exercise. For the retest a new mask was worn and re-positioned higher on the face - he did not report cold air leaking in on this occasion but the mask still failed on the speaking exercise. Readjustment of mask position during live reading failed to remedy this - while speaking out loud a fit factor score consistently or indeed even a little over 100 could not be achieved. When tested for his own mask (3M 8833) the wearer again failed - he required the 3M 7502 half mask to achieve a fit. He had a slender build with a slim face.
Male	Rail Industry	95, 79	On the first test the mask failed during the talking out loud exercise. After adjustment the mask also failed during the head up and down exercise. Readjustment of the mask position during live reading failed to achieve a good fit. The wearer was a 6 foot 4" male with a particularly wide face at the jaw.
Female	Chemical Manufacturing	Test Stopped, 9	The wearer could feel a very clear rush of cool air under her chin during the head up and down exercise. Live reading also failed to achieve a good fit despite readjustment of the mask position.
Male	Chemical Manufacturing	96, Test Stopped	This subject initially failed at deep breathing. After

Gender	Work Descriptor	Fit Factor	Possible reason for fail
			adjustment the mask failed at speaking out loud. During live reading a clear leak was identified during talking out loud - with a visible gap identified at dimples on both sides of the mask seal on the cheeks.
Male	Chemical Manufacturing	Test Stopped, 38	Failed on 1st exercise, initially and after adjustment. Readjustment of mask position during live reading still failed to achieve a good fit. There was no obvious single point of leakage identified during the tests and there was no clearly distinctive facial feature which could explain the fail. There was nothing clearly distinctive about the participant's facial features which could easily explain the cause of leakage.
Male	Chemical Manufacturing	Tests Stopped	The wearer immediately complained of a clear leak at left side of his nose. Readjustment of mask position during the second test and live reading failed to achieve a good fit at any point - even when sitting still.
Male	Hospital Estates	Tests Stopped	The wearer immediately complained of a clear leak at both side of the bridge of his nose. Readjustment of mask position during the second test and live reading failed to achieve a good fit at any point. There was nothing clearly distinctive about the participant's facial features which could easily explain the cause of leakage.
Male	Painter	92, 47	The mask appeared that it may have been too loose on first test. However, after a readjustment and tightening the mask was still unable to create a seal. Readjustment of mask position during live reading still failed to achieve a good fit. There were no obvious features on the face to suggest a poor fit would be achieved. The wearer did mention a feeling of cool air at the sides of the chin.
Male	Petroleum	Test Stopped, 42	During the 1st test the wearer felt a leak at the sides of the jaw. After adjustment the test again failed during the talking out loud exercise. Readjustment of mask position during live reading failed to remedy this. Upon inspection it was observed that the wearer had dimples on either side of the mouth which visibly depressed when speaking.

Gender	Work Descriptor	Fit Factor	Possible reason for fail
Male	Pre-cast Concrete	10, 73, 90	Depending on the position on the face, a leak was felt at either the nose or chin during the head up and down or talking out loud exercises. Readjustment of mask position during live reading failed to remedy this. There was nothing clearly distinctive about the participant's facial features which could easily explain the cause of leakage.
Male	Quarry	56, 22	The wearer could not achieve a good fit during the first exercise on either of two fittings. Readjustment of mask position during live reading failed to remedy this. There was no obvious reason for the fails (no leakage felt by wearer). The wearer had quite a large face.
Male	Quarry	83, 36	The wearer could not achieve a good fit during the deep breathing exercise on either of two tests. Readjustment of mask position during live reading failed to remedy this. There was no obvious reason for the fails (no leakage felt by wearer). The wearer had quite a large face. This wearer also did not pass tests with either the 3M 9322+ or the 3M 9928 (his provided devices).
Male	Quarry	61, 89	The wearer could not achieve a good fit during talking out loud exercise on both occasions. Readjustment of mask position during live reading failed to remedy this. There was no obvious reason for the fails (no leakage felt by wearer). The wearer had quite a large face.

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