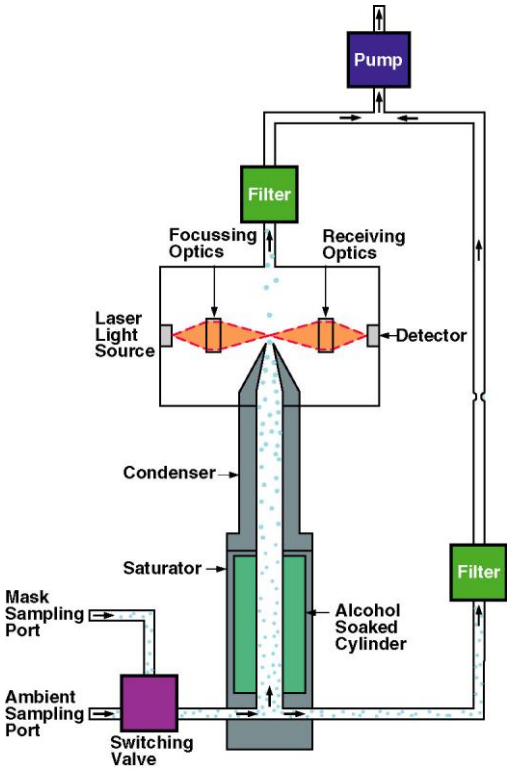
STUDIES TO CONFIRM THAT PORTACOUNT® PRO AND PRO+ RESPIRATOR FIT TESTER GIVE THE SAME RESULTS AS THE PORTACOUNT® PLUS RESPIRATOR FIT TESTER

APPLICATION NOTE RFT-005 (A4)

1 Introduction

As part of TSI's preparations for the launch of PortaCount® Pro and Pro+ Respirator Fit Tester we have made simultaneous measurements of Fit Factor using a Model 8020 PortaCount® Plus fit tester (with N95-Companion™ technology as required) and the Model 8038 PortaCount® Pro+ fit tester to establish that the new instruments would not report different Pass/Fail results from the old. Two sets of experiments were made; one set compared the two systems on a full face elastomeric facepiece fitted with a P3 filter whilst the other experiments compared results across a variety of P3 filtering face pieces. In the second set of experiments an 8020 fitted with the N95-Companion™ technology was compared directly with the PortaCount® Pro+ fit tester in N95 mode. In both sets of experiments, it is the relationship between the FF's reported by both systems that is of most significance in this type of study, not the numeric FF itself. In some of the experiments on the elastomeric face piece, leaks were deliberately introduced by placing a fine wire on the face of the test subject across the face seal zone.



2 Full face masks

A well maintained full face elastomeric mask was selected at random from a suitable set of masks and fitted with a DIN 40 Mask sampling adaptor and a P3 filter cartridge. A Model 8038 PortaCount® Pro+ fit tester and a Model 8020 PortaCount® Plus fit tester were both connected via a Y tubing connector to a short length of flexible tubing that was then connected to the mask sampling adaptor. The ambient sample lines of each PortaCount® fit tester were co-located adjacent to the outside of the mask. The mask was carefully donned by the test subject and allowed to "breath-down" for approximately 4 to 5 minutes. The two PortaCount® fit testers were configured to complete the UK HSE Test Protocol with a Pass/Fail criteria of 2000. In some of the tests, a face seal leak was deliberately introduced by adding fine wires across the cheek of the test subject until the real time FF function of the PortaCount® fit tester showed the nominal fit factor had been reduced close to the Pass/Fail criteria. Several repeat tests were completed simultaneously and both the Pass/Fail result and Fit Factor were recoded for each exercise. The test protocol was slightly amended to allow a Fit Test to continue even if a single exercise was failed. The results were analysed statistically for differences between the two instruments.

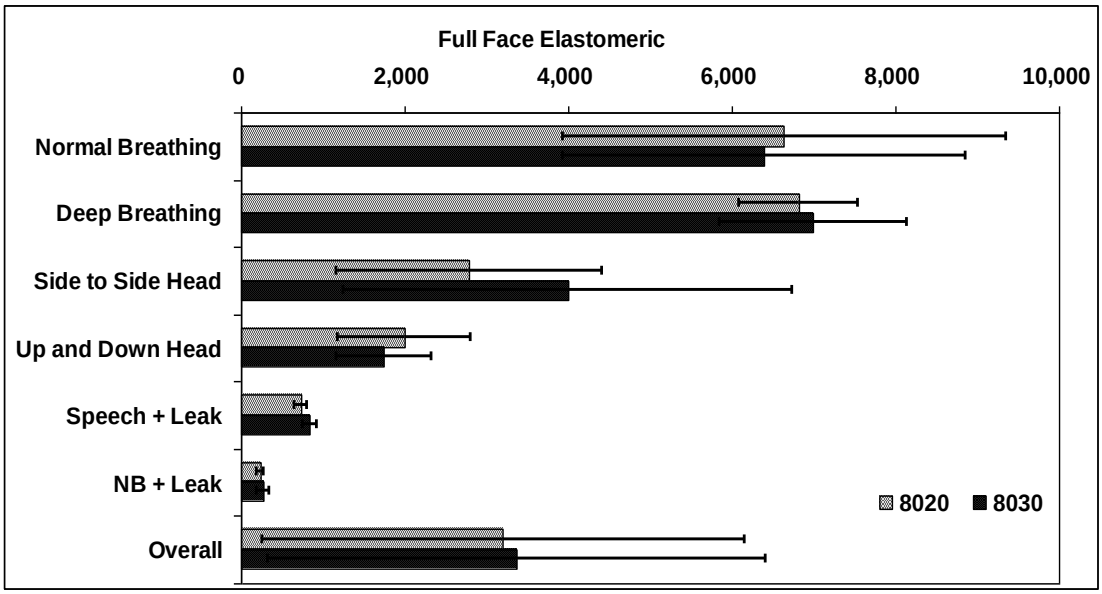
3 Filtering Face piece masks

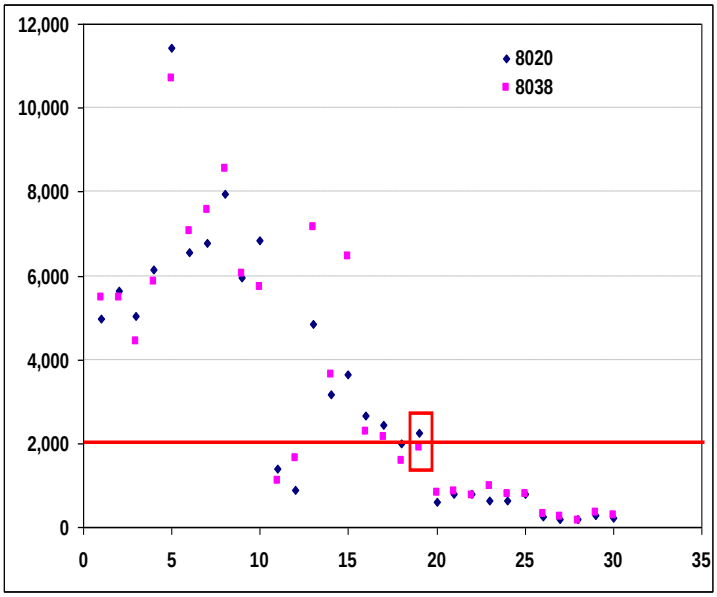
A selection of commercially available filtering facepiece masks all certified as meeting a Pass/Fail criteria of 100 were tested using a common sample port connected via a Y connector to two N95 type sampling pendants. One pendant was attached to a Model 8020 PortaCount® Plus fit tester and the other to a Model 8038 PortaCount® Pro+ Respirator Fit Tester. Each PortaCount® fit tester was programmed to use the OSHA 29CFR1910.134 test protocol. The protocol used in this evaluation is the 7 minutes and 15 seconds protocol (8020 protocol) instead of the 10 minutes and 24 seconds protocol (8028 protocol). In this part of the experiment we used a range of test subjects to establish a larger data set. Any variations between subjects were not subsequently investigated or remediated. The results were analysed statistically for differences between the two instruments.

4 Results

4.1 Full face elastomeric mask

A minimum of five repetitions of each Fit Test protocol was completed and the results of the individual exercises and the overall Fit Factors were compared. The results are given below.

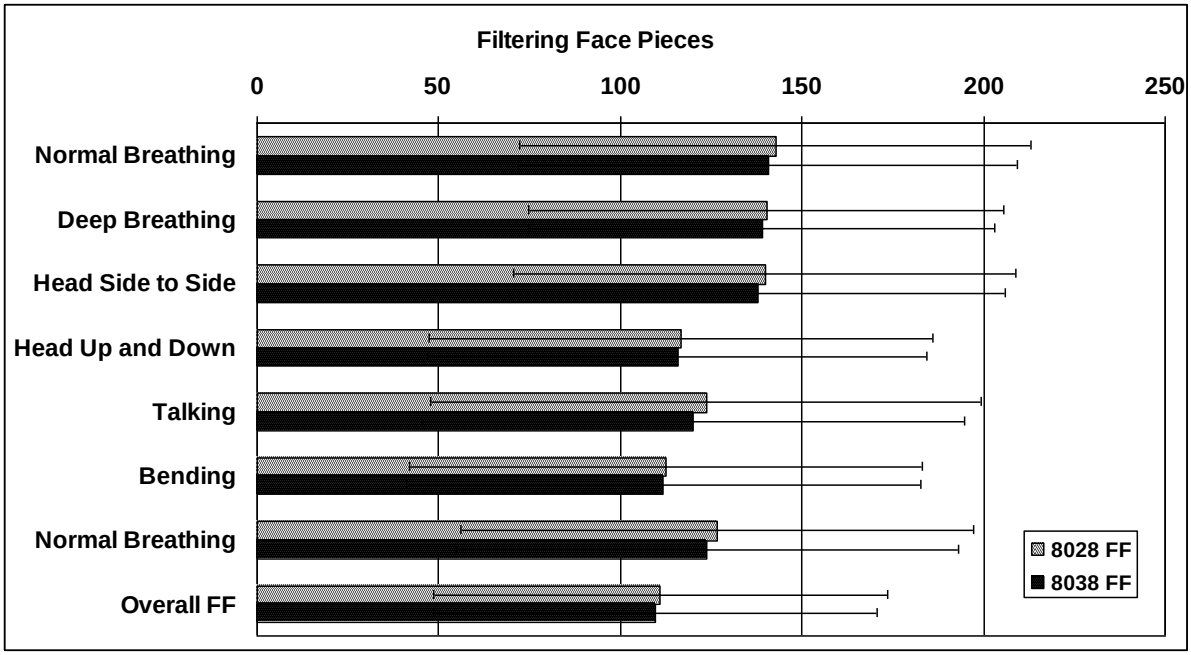




Out of the 30 paired sets of Pass/Fail results, 29 pairs gave the same pass or fail as each other and one result was different. The agreement between the two instruments in terms of reporting the same Pass/Fail result was over 96%. The one comparison pair that was different had returned FF's of 1900 and 2250, which are both very close to the Pass/Fail criteria we had set (See comparison of individual data in the adjacent graph). No Overall Fit Factor based on the standard protocol used reported a difference in Pass or Fail result. Any Fit Test that resulted in a FF as close to the Pass/Fail Criteria as the single data pair that failed to agree would normally be investigated and remedial action taken to improve the results with the use of additional training or reselection of another mask size. Absolute numeric Fit Factors are not as important as the comparison between the reported Pass fails because PortaCount® fit tester is not designed to deliver absolute Protection Factors. The basic premise of Quantitative Fit Testing is that it takes away the subjective aspects of qualitative fit testing but is still based on a comparison of an achieved level against some pre set criteria. The actual FF delivered can be controversial if it leads to unfounded

comparisons between workers who think they have different levels of workplace protection if their FF's are very different from each other. That is not the case, provided both of them have successfully passed the comparison against that agreed criteria then their training and mask selection has been validated.

4.2 Filtering Face Piece Respirators (FFPs)



Twenty eight multi exercise Fit Tests were carried out on a sample of seven different FFPs that are commercially available in North America. Each Fit test consisted of seven exercises yielding a sample population of 196 data pairs. Again, the absolute numerical Fit Factors are not the primary subject of this comparison.

Even with the much larger sample population the standard deviations still reflect the much larger variability seen in FF's achieved when using FFP's. Out of the 196 data pairs, only five pairs failed to return the same Pass/Fail result. See the table below:

PortaCount® Plus fit tester	90	94	101	113	79
PortaCount® Pro+ fit tester	102	100	93	93	100

Each of these five sets was very close to the Pass/Fail Criteria of 100. Fit Factor numeric values so close to the Pass/Fail Criteria would always be investigated and improved upon by some form of remedial training or reselection of the FFP. Overall the agreement between the two PORTACOUNT® fit testers was 97.45%. There was 100% agreement between the overall Fit Factors derived for each multi exercise assessment.

5 Conclusions

A series of comparisons of Fit Factor using full face elastomeric and FFPs has demonstrated excellent agreement between the Model 8020 PortaCount® Plus fit tester and the Model 8038 PortaCount® Pro+ fit tester at both ends of the spectrum. As expected individual exercises that gave results very close to the Pass/Fail criteria are most likely to deliver different Pass/Fail results, but have to be so close to the criteria that simple remedial action would always be taken to improve the level of protection being provided as part of a routine testing situation. Tests on filtering face pieces and on full face elastomeric respirators both demonstrated that there is no significant difference between the two generations of PortaCount® fit tester. In terms of overall Fit Factors as determined from multi exercise Fit Tests, there was 100% agreement. It is concluded that overall there is no difference between the results that would be delivered by either the PortaCount® Plus fit tester and the PortaCount® Pro+ fit tester.

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