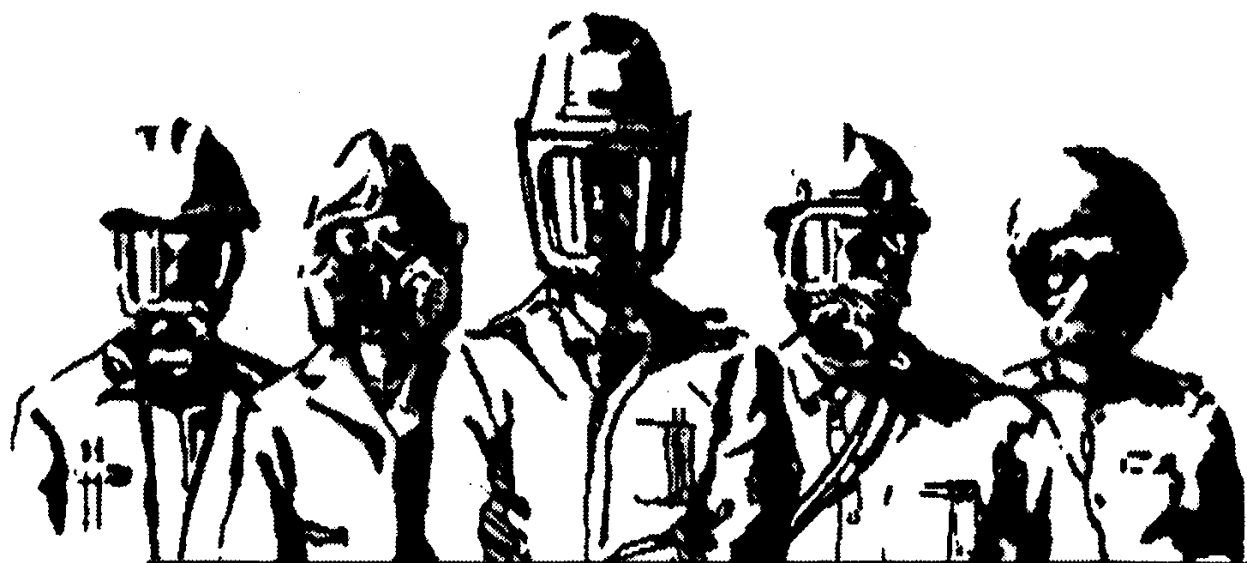


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# Fit of Filtering Facepiece Class 3 (FFP3) Respirators Part 2: The Value of Fit-Checking and Simple Subjective Assessments of Fit as an Alternative to a Fit Test

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## ABSTRACT

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

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

ISRP members can read the full paper in the members-only section.

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

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## ABSTRACT

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

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

ISRP members can read the full paper in the members-only section.

# Total Inward Leakage (TIL) Testing of Anti-yellow Sand and Quarantine Masks Using NaCl Aerosol

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## ABSTRACT

Respiratory protection is dependent on the filtration efficiency and face seal leakage of the respirator. Total inward leakage (TIL) test includes filter's penetration and face seal leakage during wearer's various activities in the fit test. The purpose of this study was to evaluate TIL values using Korean Ministry of Food and Drug Safety (MFDS) test protocol which is adapted from EU protocol. We selected three anti-yellow sand masks and two quarantine masks, which had a high performance in terms of filtration efficiency and pressure drop, and were previously approved by the MFDS or the National Institute for Occupational Safety and Health (NIOSH). For anti-yellow sand masks, the TIL values were significantly higher than the initial filtration efficiency values ( $p < 0.0001$ ). For quarantine masks, the average TIL value was also significantly higher in the TIL test than the initial filtration efficiency ( $p < 0.0001$ ). Facial sizes of test panels have an effect on the TIL values. In the case of anti-yellow sand masks, there were no significant differences in the TIL values among test exercises, and TIL values lower than the MFDS criterion were obtained. The enactment of appropriate standards should be reviewed. The government should also establish the method to select a mask and provide guidelines explaining how to wear the mask correctly.

**Keywords:** Total inward leakage, anti-yellow sand mask, quarantine mask, MFDS.

ISRP members can read the full paper in the members-only section.

# A Novel Face Seal Design for Filtering Facepiece Respirators: Development and Pilot Testing In a Hospital Operating Room

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## ABSTRACT

In this study, we developed a novel face seal (FS) concept for a filtering facepiece respirator (FFR). It is based on the facial anatomic analysis relevant to the respirator contact areas that allow for face seal inward leakage. Prototype respirators were fabricated utilizing the new concept. Two commercially available N100 FFRs were modified by affixing  $\frac{1}{4}$  and  $\frac{3}{8}$  inch thick ethylene vinyl acetate (EVA) foam material to the inside periphery of the respirator's shell. Heating of the material was considered as an optional feature. The new respirator was evaluated in a pilot study through a quantitative fit testing, followed by a Simulated Workplace Protection Factor (SWPF) measurement performed in an operating room, where electrocautery smoke was generated by using standard surgical instruments. Both evaluations revealed a significant enhancement, which essentially eliminated the particle penetration through the respirator face seal leakage. The fit factor (FF) increased as much as over two orders of magnitude compared to the conventional N100 FFRs; the SWPF data showed a similar improvement. The effect was primarily attributed to the FS geometry; the heating performed before donning was found to provide a minor additional enhancement, which was not statistically significant. The results of this pilot study suggest that the new design offers considerable advancement in protecting wearers against aerosol hazards, particularly against surgical smoke in operating rooms.

**Keywords:** Filtering facepiece respirator, face seal, fit, Simulated Workplace Protection Factor, surgical smoke.

ISRP members can read the full paper in the members-only section.