

Evaluation of Sampling Probes for Fit Testing N95 Filtering Facepiece Respirators

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Previous studies have shown a sampling probe bias for measuring fit factors (FFs) in respirator facepieces. This study was conducted to evaluate three sampling probes for fit testing NIOSH-certified N95 filtering facepiece respirators (FFRs). Two phases of fit test experiments were conducted incorporating 'side-by-side' probe mounting: (i) flush probe versus deep probe and (ii) flush probe versus disc probe. Seven test subjects in Phase 1 and six subjects in Phase 2 were fit tested with one to three N95 FFR models for a total of 10 subject/FFR model combinations for each phase. For each experimental condition, induced face seal leakage (IFSL) through an induced leak was measured using a PORTACOUNT® Plus model 8020A Respirator Fit Tester with a model 8095 N95–Companion™ accessory. For Phase 1, the mean IFSL of all flush probe measurements (3.6%) was significantly greater than ($P < 0.05$) the mean IFSL of all deep probe measurements (3.3%). For Phase 2, the mean IFSL of all flush probe measurements (8.5%) was not significantly greater than ($P > 0.05$) the mean IFSL of all disc probe measurements (8.3%). Results indicate that some leak site and subject/FFR model/leak site combination comparisons (flush probe versus deep probe or flush probe versus disc probe) were statistically different ($P < 0.05$). The overall mean IFSL for subject/FFR model/leak site combinations differed by 14 and 4% for the flush probe versus deep probe and the flush probe versus disc probe, respectively; however, from a practical standpoint, there is little difference between the flush probe tests compared with the deep probe or disc probe tests. Overall, IFSL measured using the flush probe is higher (resulting in a more conservative measure of face seal leakage) compared with either the deep probe or disc probe. The more conservative results obtained using the flush probe provide support for its common usage for fit testing cup-shaped FFRs in the USA and potential use for fit testing FFRs in Europe.

Keywords: filtering facepiece respirator; fit test; flush probe; N95 respirator; probe bias; respirator probe

INTRODUCTION

Aerosol quantitative respirator fit testing (QNFT) depends on obtaining a representative sample of the test agent concentration from inside the facepiece. During a QNFT, a sampling probe is used to extract an air sample from the inside of a respirator facepiece. An appropriate analytical technique is then used to quantify the test

agent concentration of the sample. Another air sample taken from outside of the facepiece during the fit test is similarly analyzed. The resulting fit factor (FF) for the test is defined as the ratio of the concentration outside the facepiece to the concentration inside.

Research has shown that face seal leakage can streamline within elastomeric respirator facepieces, which contributes to contaminants not mixing uniformly (Oestenstad *et al.*, 1990). Studies of sampling bias with elastomeric half- and full-facepiece respirators were conducted by Myers *et al.* (Myers *et al.*, 1986; Myers and Allender 1988; Myers *et al.*,

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1988). In these studies, a manikin headform with a breathing machine was used to simulate human breathing dynamics and acetone vapor was used as the test agent. Bias was determined to be caused by streamlining of the test agent. Such bias may result primarily because the challenge agent that leaks past the facepiece is not well mixed in the facepiece. For elastomeric half-masks and full facepieces, probe location, probe depth, and leak location were shown to contribute to sampling bias (Myers *et al.*, 1986; Myers and Allender, 1988). These studies contested the assumption that air flow through an inhalation port would introduce sufficient turbulence to uniformly mix the contaminant concentration inside the facepiece.

Coffey *et al.* (1998) have also attributed probe depth and sampling method to differences in in-facepiece measurements. Their group compared FFs of six fit test methods from human test subjects wearing half-mask respirators to an actual exposure measurement of Freon-113 (Coffey *et al.*, 1998). Five fit test methods used facepiece aerosol sampling and one used facepiece pressure. This Freon exposure methodology was convenient because complex dead-space and deposition effects of the human respiratory tract were accounted for automatically. Of those six methods, the highest correlation with exposure was found with two quantitative methods: a corn oil aerosol test (using a deep probe with a high sampling rate) and a PORTACOUNT® test (TSI Inc., Shoreview, MN, USA) (using a flush probe and low sampling rate) (Coffey *et al.*, 1998).

Myers and Hornung (1993) later examined in-mask sampling techniques for half- and full-facepiece elastomeric respirators using a number of different types of probes, flow rates, induced leak sites, and flow patterns. They noted that the type of probe generally then used, and still used in the USA [(continuous flow, low flow rate, flush with the inner surface of the mask (CLF) probe)], gave an average bias of -21% for full masks and -26% for half masks. They also reported the equivalent biases for a continuous flow, high flow rate, deep probe sampling 12–19 mm in front of the mouth (CHD) were -3 and -13%, respectively. Leak site location was also found to be a significant factor affecting sampling bias.

Probe bias has also been evaluated for filtering facepiece respirators (FFRs), although few studies have been performed. Howie performed a preliminary probe bias evaluation using a specially fashioned probe that combined a deep-mounted disc probe and a flush-mounted probe. An EN149 FFP 2 valve-less FFR was mounted onto a headform connected to an air mover drawing air inward

continuously at 95 l min⁻¹. Induced leaks were created in the respirator facepiece using a 2-mm inside diameter brass tube at each of the 12 clock face locations (one induced leak per test). The ambient sample tube of a PORTACOUNT was connected to the outlet of the flush-mounted probe while the 'in-mask' sample tube was connected to the outlet of the deep-mounted disc probe. The testing showed that the flush-mounted probe undersampled in relation to a deep-mounted disc probe by as much as 103 times (R. Howie, personal communication). Bostock (1988) evaluated probe bias in an FFR mounted on a headform by varying probe depth (flush with the FFR wall, mid-way between FFR wall and mouth, and at the mouth) and sampling conditions (continuous versus inhalation only). In that study, sodium chloride was used as the test agent and air was drawn under cyclic flow through the FFR at 40 l min⁻¹. Experiments were performed for both the FFR sealed to the headform and also by inducing leaks in the chin and nose area. For both the sealed and leak conditions, the flush probe was generally shown to have the highest degree of undersampling of leakage, thus overestimating the protection factor. Bostock showed that in-mask sampling can be improved by the use of a deep probe fitted with a multi-holed sampling ball positioned close to the wearer's mouth. Further work utilizing a multi-holed sampling disc resulted in the disc probe becoming the recommended sampling probe in European standard EN149 (European Committee for Standardization, 2009).

The type of respirator probe used for PORTACOUNT testing should be selected based on applicable regulatory requirements, national fit test consensus standards, and recommendations from the respirator manufacturer. The US Occupational Safety and Health Administration Respiratory Protection Standard 29 CFR 1910.134 states that the appropriate probe type should be obtained from the respirator manufacturer or distributor [Occupational Safety and Health Administration (OSHA), 1998]. The US consensus standard ANSI Z88.10 does not designate a specific probe type to use (ANSI/AIHA Z88.10 Subcommittee, 2010); however, the flush probe is commonly used for (FFRs) for PORTACOUNT fit testing (TSI Inc., 2012). The disc probe is more common in Europe as it is specified in the European Standards (European Committee for Standardization, 2009).

FFRs are commonly used in industry and in a 2001 US survey were reported to account for >71% of all respirators used (Bureau of Labor Statistics and National Institute for Occupational Safety and Health, 2003). Because in-facepiece sampling bias has not previously been evaluated for National

Institute for Occupational Safety and Health (NIOSH)-certified FFRs, this study was conducted to evaluate three types of sampling probes (flush probe, deep probe, and disc probe) for use in benchmark testing of FFRs in NIOSH's Total Inward Leakage (TIL) program. The intent of the benchmark testing was not to evaluate how well any FFR fit any individual, but to provide a comparison of the ability of various FFR models to provide a minimal FF to a variety of face sizes and shapes. Thus, a slight bias due to probe placement could be tolerated.

MATERIALS AND METHODS

Two phases of fit test experiments were conducted incorporating 'side-by-side' probe mounting: (i) flush probe versus deep probe and (ii) flush probe versus disc probe. Seven test subjects in Phase 1 and six subjects in Phase 2 were fit tested with one to three N95 FFR models for a total of 10 subject/FFR model combinations for each phase. Six artificially induced leak locations were evaluated for each subject/FFR model combination. For each experimental condition, a FF was measured using a PORTACOUNT[®] Plus model 8020A Respirator Fit Tester with a model 8095 N95-Companion[™] accessory.

Test subjects

This study was approved by the NIOSH Institutional Review Board and subjects gave their written consent to participate. Subjects were recruited from the larger test subject pool who regularly participates in NIOSH respirator certification testing. Ten subjects (five men and five women) ages 18–49 participated in this study.

Respirator selection

Three N95 FFR models (3M 8210, Gerson 2737, and AOSafety N9504C) were included in this study. These models were randomly chosen from those medium- or universal-sized, cup-shaped N95 FFR models from surplus supplies from previous NIOSH research projects. The three models were also chosen because of their similar overall dimensions in order to minimize interior volume as a source of bias. Test subjects were randomly assigned FFRs models for testing. All N95 FFRs remained packaged until they were needed for testing and stored under ambient conditions (21°C +/-2°C and 50% +/-10% relative humidity).

Fit test apparatus and probe mounting

A PORTACOUNT[®] Plus model 8020A Respirator Fit Tester with a model 8095 N95-Companion[™]

(TSI Inc., Shoreview, MN, USA) accessory was used to measure respirator FF. The reciprocal of FF is the penetration [or in the case of this study, induced face seal leakage (IFSL)]. The PORTACOUNT utilizes condensation nuclei counting() technology to count individual particles to determine a quantitative estimate of respirator fit. Ambient room aerosol was used as the test agent; however, TSI Model 8026 sodium chloride particle generators were used to supplement the room air particulate concentration, as necessary, to reach the minimum concentration of 70 particles per cubic centimeter required to operate the N95-Companion. FitPlus[™] for Windows[®] Fit Test Software (TSI Inc.) installed on a laptop computer automated the fit test data collection. Fit testing was carried out in a laboratory environment (21 +/-2°C and relative humidity of 50 +/-10%).

Fit test trials were conducted to evaluate two types of 'side-by-side' probe mountings: (i) flush probe versus deep probe and (ii) flush probe versus disc probe. Flush probes are recommended by TSI Inc. for FFR fit testing using the PORTACOUNT fit tester and are commonly used for fit testing FFRs in the USA (TSI Inc., 2012). When mounted in the FFR, the inlet of the probe (flange end) is flush with the interior surface of the FFR (Fig. 1a). The flush probe had a 14-mm diameter flange and a 4-mm diameter inlet. Other types of probes considered for the analysis were the deep probe, ball probe, and disc probe. In our preliminary testing, the ball probe was consistently observed to leak and subsequently excluded from this study. The deep probe (Fig. 1a) was fashioned by gluing together the flanges of two flush probes. The inlet of the deep probe was unflanged, had a 4 mm diameter, and extended ~11 mm into the interior of the FFR. The disc probe (Fig. 1b) was fashioned by friction-fitting an appropriately drilled plastic disc (25 mm diameter) onto one end of a deep probe. The disc's eight 1.5-mm diameter inlets were equally spaced around the edge of the disc; the top of the disc probe extended ~15 mm into the FFR interior. Both the deep and disc probes were leak tested at 20 psi air pressure under water to ensure leak tight connections.

A Y-switching valve assembly was fashioned to accommodate the 'side-by-side' probe evaluations. For both evaluations ('flush probe versus deep probe' or 'flush probe versus disc probe'), the two probes were mounted in an FFR along the transverse centerline with a distance between them of ~0.5 cm. It must be noted that the disc probe configuration used in this study does not follow the BS EN149 test configuration in that the depth or location of the probe was not adjusted to just touch the wearer's lips (European

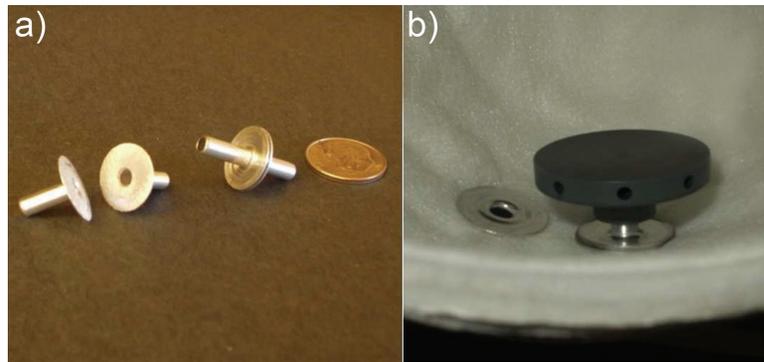


Fig. 1. (a) Flush probes (left) and a deep probe (right) (US penny shown for size). (b) Interior view of an N95 FFR showing mounted flush probe (left) and disc probe (right).

Committee for Standardization, 2009). The flush probe was always located on the left side of the FFR as viewed from the perspective of the wearer. The Y-switching valve was constructed using a plastic Y tubing connector fitted with flexible tubing on each of its legs. A tubing clamp was then fitted over each length of tubing. Next, the two lengths of tubing were connected to the two probe outlets protruding from the outer side of the FFR. The remaining third leg of the Y-connector was attached to the sampling line of the PORTACOUNT.

To sample from a designated probe, the length of tubing attached to the probe was unobstructed (i.e. the tubing clamp for that length of tubing was not closed) and the tubing to the other probe not being sampled was obstructed by closing the tubing clamp for that length of tubing.

Phase 1: flush probe versus deep probe

Seven of the ten test subjects (three men and four women) participated in Phase 1. Each subject tested either one FFR model or two different FFR models. For each of these 10 FFR model/subject combinations, six different induced leak locations around the face seal periphery were evaluated during fit testing. Previous studies have indicated that the bridge of the nose, cheeks, and the chin are the most likely leak sites on the respirator/face boundary (Oestenstad and Bartolucci, 2010; Roberge *et al.*, 2011). Thus, the leak locations were located correspondingly to the hourly clock face positions from the perspective of the subject wearing the respirator: bridge of nose (12:00), right of nose (2:00), right cheek (4:00), chin (6:00), left of cheek (8:00), and left of nose (10:00). A leak was created by inserting a 20 mm length of 1.270 mm nominal outside diameter (18 gauge) stainless steel tubing under

the face seal at one of the six locations. Sealants or adhesives were not used to seal the interface of the leak tube and the respirator face seal. IFSL at each different leak site was evaluated during a separate donning. Care was taken when placing the tubes under the face seal to ensure that the tube openings were not blocked.

Prior to beginning the fit test experiments, subjects were trained on the proper donning, doffing, and user seal check (USC) procedures for each model using the manufacturer's user instructions. Following training, the subject donned the FFR, performed the USC, and made any necessary adjustments to the FFR. Next, the test technician inserted the leak tube at one of the six designated locations. During the fit test, the subject wore the respirator while seated (without head motion) and was instructed to breathe normally. Fit test exercises that stress the face-to-facepiece seal (such as turning the head side-to-side or talking) were not used because this study was interested in assessing face seal leakage measured using different probe types rather than the impact of different fit test exercises on face seal leakage. The induced leakage at the six locations represented the leakage that is commonly created by performing standard OSHA fit test exercises. The six leak sites also ensured that leakage actually occurred at all likely leak locations when comparing the sampling probes. Exercises create leaks randomly, but cannot ensure leakage occurs at all likely locations. Thus, induced leakage was used in these experiments instead of dynamic exercises.

For each leak site, 40 FFs were recorded (20 for the flush probe and 20 for the deep probe) by alternately switching from the flush probe to the deep. A standard 86 s normal breathing exercise was used

to measure a FF for each probe. First, two FFs were measured from the flush probe. Next, the test operator opened and closed the appropriate clamps of the Y-switching valve to sample from the deep probe. Two FFs were then recorded from the deep probe. This sequence of measuring four FFs was repeated 10 times resulting in 40 FFs. In Phase 1, a total of 2400 data points were collected (10 subject / model combinations \times 6 leak locations \times 40 data points / leak site (i.e. 20 data points for flush probe and 20 data points for deep probe).

Phase 2: flush probe versus disc probe

Six of the ten subjects (three women and three men) participated in Phase 2. Two subjects tested three FFR models while the other four subjects tested only one model each. For each of these 10 FFR model/subject combinations, six different induced leak locations around the face seal periphery were evaluated during fit testing. The test methodology was the same for Phase 1 with the exception that the deep probe was substituted for the disc probe (Fig. 1b).

In Phase 2, 2400 data points were collected (10 subject / model combinations \times 6 leak locations \times 40 data points / leak site (i.e. 20 data points for flush probe and 20 data points for disc probe).

Statistical analysis

Fit factor results were converted to IFSL values by calculating their reciprocal (i.e. $IFSL = 1 / FF$). For each test subject/FFR model/leak site combination in Phases 1 and 2, the arithmetic mean IFSL and standard deviation were calculated for each probe type. Probe bias was then calculated by dividing the mean IFSL measured using the flush probe by the mean IFSL measured using either the deep probe (for Phase 1) or the disc probe (for Phase 2). A ratio of 1 would indicate no difference between probe types (i.e. both types of probes would have measured the same mean IFSL). Ratios >1 or <1 would indicate some difference between the two probes depending on how large or small the ratio was.

Typically, workplace protection factors or FFs vary greatly and have been found to be log-normally distributed and are usually log-transformed before any statistical tests are performed. Our IFSL data were collected by inducing leakage using the same stainless steel tubing (18 gauge) that was supposed to provide similar leakage at every leak location. A large number of data points were collected. The data were found to be near normally distributed. Thus, any statistical tests were performed on the original IFSL data.

For each type of probe comparison, three separate analysis of variance (ANOVA) procedures were performed to determine if IFSL values were different ($P < 0.05$) between the two probes (i.e. 'flush probe and deep probe' or 'flush probe and disc probe'). The first ANOVA procedure compared all IFSL values from the flush probe to the respective comparison probe (either deep or disc). The second ANOVA procedure compared IFSL values from each probe type within each test subject/FFR model/leak site combination. The third ANOVA procedure compared IFSL values by leak site for each probe type. For all ANOVA procedures, the dependent variable was IFSL. The independent variables were probe type, leak site, and an interaction between them. Duncan's multiple range tests (DMRTs) were performed for comparisons of IFSL means following each ANOVA procedure. The ANOVA and DMRT tests were performed using the PROC general linear model (PROC GLM) procedure in SAS, Version 9.2 (SAS Institute Inc., Cary, NC, USA).

RESULTS

Flush probe versus deep probe

The mean IFSL of all flush probe measurements was significantly greater than ($P < 0.05$) the mean IFSL of all deep probe measurements (flush probe: mean IFSL = 3.6%, SD = 2.8%, $n = 1200$; deep probe: mean IFSL = 3.3%, SD = 2.3%, $n = 1200$). Table 1 presents arithmetic mean IFSL values of the flush probe and the deep probe for each test subject/FFR model/leak site combination. Of the 60 combinations, 34 of 60 ratios of mean IFSL (i.e. flush/deep) are >1 , indicating higher mean IFSL for the flush probe. Of these 34 combinations, 16 had significantly higher mean IFSL for the flush probe. The mean of the 60 flush/deep ratios is 1.14. Overall, these results indicate that IFSL measured using the flush probe is slightly higher (resulting in a more conservative measure of IFSL) compared with the deep probe.

Comparisons of mean IFSL by leak site for the flush and deep probe tests are shown in Fig. 2. This figure pools all of the data from the seven subjects who participated in Phase 1. Mean IFSL values for both probe types were significantly different ($P < 0.05$) at five of the six leak sites (only the IFSL values for left cheek were not significantly different). Of the four 'left' or 'right' site comparisons (i.e. left cheek, left nose, right cheek, and right nose), all but one (left cheek) follow the expected trend of higher or lower mean IFSL corresponding to probe location

Table 1. Mean (IFSL) by subject/FFR model/leak site combination for flush and deep probes.

| Subject | Model | Flush probe | | | | Deep probe | | | | Ratio mean IFSL (Flush/deep) |
|---------|--------------------|-------------|------------------------|---------------|---------|------------------------|---------------|---------|------|---------------------------------|
| | | Site | Fit tests (<i>n</i>) | Mean IFSL (%) | SD IFSL | Fit tests (<i>n</i>) | Mean IFSL (%) | SD IFSL | | |
| 65 | Gerson 2737 | Bridge | 20 | 4.25 | 1.84 | 20 | 1.75 | 0.36 | 2.43 | |
| 65 | Gerson 2737 | Chin | 20 | 3.14 | 0.81 | 20 | 2.44 | 0.35 | 1.29 | |
| 65 | Gerson 2737 | Left cheek | 20 | 1.52 | 0.25 | 20 | 1.49 | 0.29 | 1.02 | |
| 65 | Gerson 2737 | Left nose | 20 | 4.99 | 1.19 | 20 | 4.74 | 1.24 | 1.05 | |
| 65 | Gerson 2737 | Right cheek | 20 | 4.14 | 0.91 | 20 | 5.34 | 1.26 | 0.77 | |
| 65 | Gerson 2737 | Right nose | 20 | 3.90 | 0.81 | 20 | 3.97 | 0.62 | 0.98 | |
| 75 | 3M 8210 | Bridge | 20 | 1.96 | 0.36 | 20 | 2.00 | 0.27 | 0.98 | |
| 75 | 3M 8210 | Chin | 20 | 4.79 | 5.48 | 20 | 2.56 | 2.54 | 1.87 | |
| 75 | 3M 8210 | Left cheek | 20 | 1.87 | 0.31 | 20 | 1.87 | 0.25 | 1.00 | |
| 75 | 3M 8210 | Left nose | 20 | 4.90 | 1.44 | 20 | 3.32 | 0.94 | 1.48 | |
| 75 | 3M 8210 | Right cheek | 20 | 2.32 | 0.45 | 20 | 2.57 | 0.57 | 0.90 | |
| 75 | 3M 8210 | Right nose | 20 | 2.33 | 0.29 | 20 | 6.07 | 1.11 | 0.38 | |
| 75 | Gerson 2737 | Bridge | 20 | 3.55 | 0.71 | 20 | 3.47 | 0.50 | 1.02 | |
| 75 | Gerson 2737 | Chin | 20 | 7.96 | 6.72 | 20 | 6.66 | 6.09 | 1.20 | |
| 75 | Gerson 2737 | Left cheek | 20 | 0.95 | 0.36 | 20 | 1.10 | 0.44 | 0.86 | |
| 75 | Gerson 2737 | Left nose | 20 | 13.01 | 2.65 | 20 | 7.50 | 0.98 | 1.73 | |
| 75 | Gerson 2737 | Right cheek | 20 | 1.93 | 0.19 | 20 | 1.85 | 0.33 | 1.04 | |
| 75 | Gerson 2737 | Right nose | 20 | 4.98 | 6.20 | 20 | 4.84 | 5.20 | 1.03 | |
| 82 | AOSafety N9504C | Bridge | 20 | 1.91 | 1.40 | 20 | 1.67 | 0.71 | 1.15 | |
| 82 | AOSafety N9504C | Chin | 20 | 4.01 | 1.92 | 20 | 5.44 | 3.40 | 0.74 | |
| 82 | AOSafety N9504C | Left cheek | 20 | 2.67 | 0.29 | 20 | 2.59 | 0.76 | 1.03 | |
| 82 | AOSafety N9504C | Left nose | 20 | 3.51 | 0.85 | 20 | 3.92 | 1.16 | 0.89 | |
| 82 | AOSafety N9504C | Right cheek | 20 | 2.20 | 1.20 | 20 | 1.77 | 0.58 | 1.24 | |
| 82 | AOSafety N9504C | Right nose | 20 | 4.75 | 1.32 | 20 | 4.77 | 1.10 | 1.00 | |
| 84 | AOSafety N9504C | Bridge | 20 | 3.01 | 0.69 | 20 | 2.27 | 0.48 | 1.32 | |
| 84 | AOSafety N9504C | Chin | 20 | 3.04 | 1.61 | 20 | 1.76 | 0.49 | 1.73 | |
| 84 | AOSafety N9504C | Left cheek | 20 | 4.01 | 1.92 | 20 | 5.44 | 3.40 | 0.74 | |
| 84 | AOSafety N9504C | Left nose | 20 | 4.03 | 1.67 | 20 | 3.64 | 0.81 | 1.11 | |
| 84 | AOSafety N9504C | Right cheek | 20 | 2.41 | 1.09 | 20 | 1.28 | 0.46 | 1.88 | |
| 84 | AOSafety N9504C | Right nose | 20 | 3.93 | 0.98 | 20 | 4.19 | 0.62 | 0.94 | |
| 84 | Gerson 2737 | Bridge | 20 | 6.65 | 2.02 | 20 | 4.13 | 0.64 | 1.61 | |
| 84 | Gerson 2737 | Chin | 20 | 9.45 | 3.17 | 20 | 4.74 | 1.08 | 2.00 | |
| 84 | Gerson 2737 | Left cheek | 20 | 4.76 | 1.17 | 20 | 5.75 | 1.74 | 0.83 | |
| 84 | Gerson 2737 | Left nose | 20 | 6.68 | 2.38 | 20 | 3.92 | 1.72 | 1.71 | |
| 84 | Gerson 2737 | Right cheek | 20 | 3.19 | 0.97 | 20 | 2.96 | 0.88 | 1.08 | |
| 84 | Gerson 2737 | Right nose | 20 | 3.80 | 1.09 | 20 | 5.58 | 1.26 | 0.68 | |
| 86 | 3M 8210 | Bridge | 20 | 1.26 | 0.40 | 20 | 2.11 | 0.64 | 0.60 | |
| 86 | 3M 8210 | Chin | 20 | 6.65 | 1.19 | 20 | 2.08 | 0.51 | 3.20 | |
| 86 | 3M 8210 | Left cheek | 20 | 5.18 | 1.90 | 20 | 5.93 | 1.46 | 0.87 | |

Table 1. (Continued)

| Subject | Model | Flush probe | | | | Deep probe | | | Ratio mean IFSL (Flush/deep) |
|---------|--------------------|-------------|---------------|---------------|---------|---------------|---------------|---------|---------------------------------|
| | | Site | Fit tests (n) | Mean IFSL (%) | SD IFSL | Fit tests (n) | Mean IFSL (%) | SD IFSL | |
| 86 | 3M 8210 | Left nose | 20 | 1.48 | 0.56 | 20 | 1.62 | 0.50 | 0.91 |
| 86 | 3M 8210 | Right cheek | 20 | 5.79 | 1.25 | 20 | 6.33 | 1.54 | 0.91 |
| 86 | 3M 8210 | Right nose | 20 | 1.27 | 0.31 | 20 | 1.68 | 0.71 | 0.76 |
| 87 | 3M 8210 | Bridge | 20 | 2.34 | 0.71 | 20 | 3.99 | 0.94 | 0.59 |
| 87 | 3M 8210 | Chin | 20 | 3.93 | 1.21 | 20 | 5.68 | 2.47 | 0.69 |
| 87 | 3M 8210 | Left cheek | 20 | 2.45 | 0.86 | 20 | 1.41 | 0.40 | 1.74 |
| 87 | 3M 8210 | Left nose | 20 | 1.77 | 0.70 | 20 | 1.39 | 0.45 | 1.28 |
| 87 | 3M 8210 | Right cheek | 20 | 1.37 | 0.24 | 20 | 1.49 | 0.17 | 0.92 |
| 87 | 3M 8210 | Right nose | 20 | 0.92 | 0.38 | 20 | 2.31 | 1.06 | 0.40 |
| 87 | AOSafety N9504C | Bridge | 20 | 3.22 | 0.60 | 20 | 2.87 | 0.44 | 1.12 |
| 87 | AOSafety N9504C | Chin | 20 | 5.61 | 1.01 | 20 | 3.05 | 0.94 | 1.84 |
| 87 | AOSafety N9504C | Left cheek | 20 | 2.09 | 0.95 | 20 | 1.83 | 0.55 | 1.14 |
| 87 | AOSafety N9504C | Left nose | 20 | 4.80 | 1.30 | 20 | 2.56 | 0.60 | 1.87 |
| 87 | AOSafety N9504C | Right cheek | 20 | 4.17 | 0.94 | 20 | 6.29 | 2.05 | 0.66 |
| 87 | AOSafety N9504C | Right nose | 20 | 1.54 | 0.55 | 20 | 2.48 | 1.12 | 0.62 |
| 88 | 3M 8210 | Bridge | 20 | 2.27 | 1.14 | 20 | 2.15 | 1.21 | 1.05 |
| 88 | 3M 8210 | Chin | 20 | 1.58 | 0.27 | 20 | 1.51 | 0.29 | 1.05 |
| 88 | 3M 8210 | Left cheek | 20 | 2.51 | 0.58 | 20 | 2.16 | 0.70 | 1.16 |
| 88 | 3M 8210 | Left nose | 20 | 1.40 | 0.43 | 20 | 1.36 | 0.28 | 1.03 |
| 88 | 3M 8210 | Right cheek | 20 | 3.05 | 0.75 | 20 | 4.63 | 0.90 | 0.66 |
| 88 | 3M 8210 | Right nose | 20 | 1.38 | 0.32 | 20 | 3.89 | 1.03 | 0.36 |

Mean of all ratios: 1.14±0.51

For each subject/FFR model/leak site combination, bold mean IFSLs within a row are significantly different (Duncan's multiple range test after analysis of variance, $P < 0.05$).

relative to leak site. For example, for the left cheek comparison it was expected that the flush probe mean IFSL would be greater because the flush probe was on the left side of the FFR (i.e. closer to the leak than the deep probe); however, for the left cheek site the deep probe mean IFSL was higher although the two means were similar (deep probe mean IFSL = 3.0%, SD 2.3%; flush probe mean IFSL = 2.8%, SD 1.7%) and were not significantly different.

Flush probe versus disc probe

The mean IFSL for all flush probe measurements was not significantly greater than ($P > 0.05$) the mean IFSL of all disc probe measurements (flush probe: mean IFSL = 8.5%, SD = 5.4%, $n = 1200$; disc probe: mean IFSL = 8.3%, SD = 5.1%, $n = 1200$). Table 2 presents arithmetic mean IFSL values of the flush probe and the disc probe for each test subject/FFR model/leak site combination. Of the 60 combinations,

30 of the 60 ratios of mean IFSL (i.e. flush/disc) are >1 , indicating higher mean IFSL for the flush probe. Of these 30 combinations, 14 had significantly higher mean IFSL ($P < 0.05$) for the flush probe. Overall, these results indicate that IFSL measured using the flush probe is similar compared with the disc probe. The mean of the 60 flush/disc ratios is 1.04.

Comparisons of mean IFSL by leak site for the flush and disc probe test are shown in Fig. 3. This figure pools all of the data from the six subjects who participated in Phase 2. IFSL values for only three of the six leak sites (chin, left nose, and right nose) are significantly different ($P < 0.05$). All of the four 'left'/'right' site comparisons (i.e. left cheek, left nose, right cheek, and right nose) follow the expected trend of greater IFSL for the sampling probe closest to the leak location. For example, for both 'left cheek' and 'left nose', IFSL for the flush probe is higher than IFSL for the disc probe because

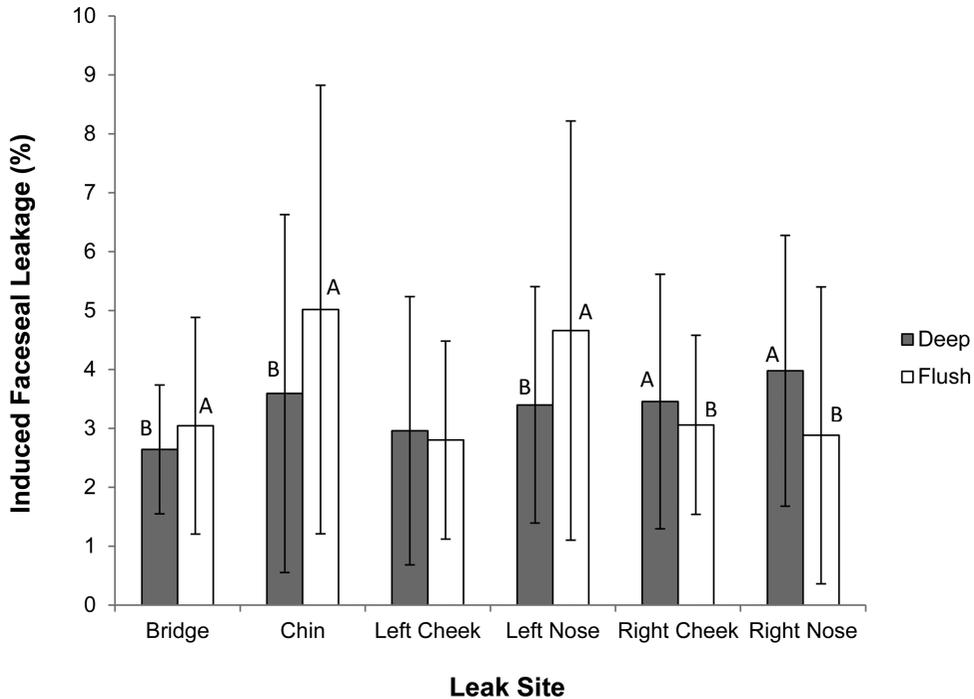


Fig. 2. IFSL by leak site for flush and deep probes.

Note 1: Mean and standard deviation are shown.

Note 2: For each leak site, mean with 'A' is significantly different from mean with 'B' (Duncan's multiple range test after analysis of variance, $P < 0.05$).

Note 3: For each leak site, $n = 200$ data points for 'deep probe' and $n = 200$ data points for 'flush probe'.

the flush probe was mounted on the left side of the FFR.

DISCUSSION

This study was performed to evaluate probe types for suitability in developing a NIOSH TIL test. The results of the study show that the flush probe performed similarly to the deep and disc probes (14% IFSL difference compared with the deep probe and 4% IFSL difference compared with the disc probe). Furthermore, because the flush probe resulted in slightly more conservative measurements (i.e. higher IFSL) the flush probe is an appropriate probe for the TIL test. This study's 'side-by-side' test methodology did not follow the BS EN149 disc probe placement specification (i.e. just touching the wearer's lips) or any sampling methodology from that standard (European Committee for Standardization, 2009); thus, the IFSL results cannot be viewed in context of that standard's methodology. However, because the results of our study show that the flush probe measured similarly to the disc probe, there is a potential consideration for the use of the flush probe for fit testing FFRs in Europe.

The data follows expected trends of the relative placement of probes and leak sites. By convention, the flush probe was always located on the left side of the FFR from the perspective of the wearer and the deep or disc probe was always located on the right side. IFSL was anticipated to be greater when the leak site was on the same side of the FFR as the corresponding probe. The data followed this trend for seven of the eight 'right'/'left' data pairs shown in Figs 2 and 3. Only the data pair 'left cheek' in Fig. 2 does not follow the trend; however, the difference in the means is small and the pair-wise comparison of the means was not statistically significant.

It is important to understand that this study compared IFSL measurements between probe types and is not a study of measurement bias. The measurement bias studies performed by Myers *et al.* varied parameters such as probe placement, probe depth, and leak site and compared probe measurements using acetone against the 'true' concentration of acetone at an unbiased sampling location in the test system (Myers *et al.*, 1986; Myers and Allender, 1988; Myers *et al.*, 1988; Myers and Hornung, 1993). Therefore, one cannot

Table 2. Mean (IFSL) by subject/FFR model/leak site combination for flush and disc probes.

| Subject | Model | Leak site | Flush probe | | | Disc probe | | | Ratio mean IFSL (Flush/disc) |
|---------|-----------------|-------------|------------------------|---------------|---------|------------------------|---------------|---------|------------------------------|
| | | | Fit tests (<i>n</i>) | Mean IFSL (%) | SD IFSL | Fit tests (<i>n</i>) | Mean IFSL (%) | SD IFSL | |
| 4 | 3M 8210 | Bridge | 20 | 5.24 | 1.76 | 20 | 4.47 | 1.16 | 1.17 |
| 4 | 3M 8210 | Chin | 20 | 20.37 | 10.88 | 20 | 9.99 | 8.37 | 2.04 |
| 4 | 3M 8210 | Left cheek | 20 | 8.60 | 1.36 | 20 | 8.48 | 1.48 | 1.01 |
| 4 | 3M 8210 | Left nose | 20 | 8.59 | 2.14 | 20 | 8.56 | 2.48 | 1.00 |
| 4 | 3M 8210 | Right cheek | 20 | 8.39 | 5.71 | 20 | 7.45 | 4.55 | 1.13 |
| 4 | 3M 8210 | Right nose | 20 | 6.35 | 1.10 | 20 | 8.00 | 1.39 | 0.79 |
| 75 | 3M 8210 | Bridge | 20 | 2.32 | 0.65 | 20 | 1.90 | 0.26 | 1.22 |
| 75 | 3M 8210 | Chin | 20 | 3.09 | 0.78 | 20 | 4.11 | 0.65 | 0.75 |
| 75 | 3M 8210 | Left cheek | 20 | 13.53 | 2.29 | 20 | 13.83 | 3.69 | 0.98 |
| 75 | 3M 8210 | Left nose | 20 | 3.79 | 0.70 | 20 | 3.24 | 0.65 | 1.17 |
| 75 | 3M 8210 | Right cheek | 20 | 12.32 | 4.88 | 20 | 12.51 | 3.48 | 0.98 |
| 75 | 3M 8210 | Right nose | 20 | 3.72 | 0.28 | 20 | 4.22 | 0.31 | 0.88 |
| 75 | AOSafety N9504C | Bridge | 20 | 10.48 | 2.44 | 20 | 9.63 | 1.98 | 1.09 |
| 75 | AOSafety N9504C | Chin | 20 | 10.18 | 2.32 | 20 | 8.17 | 1.69 | 1.25 |
| 75 | AOSafety N9504C | Left cheek | 20 | 11.46 | 6.55 | 20 | 8.63 | 7.06 | 1.33 |
| 75 | AOSafety N9504C | Left nose | 20 | 16.58 | 4.38 | 20 | 14.78 | 3.75 | 1.12 |
| 75 | AOSafety N9504C | Right cheek | 20 | 10.04 | 4.23 | 20 | 11.84 | 4.81 | 0.85 |
| 75 | AOSafety N9504C | Right nose | 20 | 8.72 | 1.35 | 20 | 11.11 | 2.19 | 0.79 |
| 75 | Gerson 2737 | Bridge | 20 | 4.39 | 1.93 | 20 | 4.08 | 1.26 | 1.08 |
| 75 | Gerson 2737 | Chin | 20 | 5.23 | 2.73 | 20 | 5.97 | 2.13 | 0.88 |
| 75 | Gerson 2737 | Left cheek | 20 | 13.53 | 4.49 | 20 | 14.03 | 3.18 | 0.96 |
| 75 | Gerson 2737 | Left nose | 20 | 6.35 | 2.07 | 20 | 5.96 | 1.92 | 1.07 |
| 75 | Gerson 2737 | Right cheek | 20 | 3.22 | 0.97 | 20 | 3.10 | 0.94 | 1.04 |
| 75 | Gerson 2737 | Right nose | 20 | 4.76 | 1.77 | 20 | 7.42 | 2.24 | 0.64 |
| 80 | 3M 8210 | Bridge | 20 | 6.71 | 1.85 | 20 | 7.89 | 2.98 | 0.85 |
| 80 | 3M 8210 | Chin | 20 | 7.01 | 3.13 | 20 | 7.55 | 2.55 | 0.93 |
| 80 | 3M 8210 | Left cheek | 20 | 11.80 | 9.41 | 20 | 10.14 | 10.06 | 1.16 |
| 80 | 3M 8210 | Left nose | 20 | 13.59 | 2.24 | 20 | 11.22 | 4.03 | 1.21 |
| 80 | 3M 8210 | Right cheek | 20 | 23.23 | 10.17 | 20 | 25.00 | 9.67 | 0.93 |
| 80 | 3M 8210 | Right nose | 20 | 8.33 | 1.99 | 20 | 7.44 | 2.13 | 1.12 |
| 86 | 3M 8210 | Bridge | 20 | 6.05 | 2.95 | 20 | 6.41 | 2.84 | 0.94 |
| 86 | 3M 8210 | Chin | 20 | 7.02 | 1.03 | 20 | 5.04 | 1.07 | 1.39 |
| 86 | 3M 8210 | Left cheek | 20 | 4.89 | 1.88 | 20 | 4.14 | 1.34 | 1.18 |
| 86 | 3M 8210 | Left nose | 20 | 4.71 | 1.63 | 20 | 3.96 | 0.64 | 1.19 |
| 86 | 3M 8210 | Right cheek | 20 | 15.88 | 4.56 | 20 | 11.56 | 1.56 | 1.37 |
| 86 | 3M 8210 | Right nose | 20 | 2.83 | 0.99 | 20 | 3.52 | 0.77 | 0.80 |
| 88 | 3M 8210 | Bridge | 20 | 4.66 | 1.29 | 20 | 6.06 | 2.11 | 0.77 |
| 88 | 3M 8210 | Chin | 20 | 4.88 | 0.86 | 20 | 4.34 | 0.92 | 1.12 |
| 88 | 3M 8210 | Left cheek | 20 | 7.97 | 1.19 | 20 | 9.56 | 1.40 | 0.83 |
| 88 | 3M 8210 | Left nose | 20 | 11.12 | 1.86 | 20 | 7.51 | 0.97 | 1.48 |
| 88 | 3M 8210 | Right cheek | 20 | 6.11 | 1.80 | 20 | 8.86 | 2.02 | 0.69 |
| 88 | 3M 8210 | Right nose | 20 | 5.91 | 2.11 | 20 | 6.74 | 1.91 | 0.88 |

Table 2. (Continued)

| Subject | Model | Leak site | Flush probe | | | Disc probe | | | Ratio mean IFSL (Flush/disc) |
|---------|-----------------|-------------|------------------------|---------------|---------|------------------------|---------------|---------|------------------------------|
| | | | Fit tests (<i>n</i>) | Mean IFSL (%) | SD IFSL | Fit tests (<i>n</i>) | Mean IFSL (%) | SD IFSL | |
| 88 | AOSafety N9504C | Bridge | 20 | 5.91 | 2.11 | 20 | 5.28 | 2.04 | 1.12 |
| 88 | AOSafety N9504C | Chin | 20 | 4.71 | 0.66 | 20 | 3.52 | 0.47 | 1.34 |
| 88 | AOSafety N9504C | Left cheek | 20 | 7.93 | 1.73 | 20 | 8.75 | 1.92 | 0.91 |
| 88 | AOSafety N9504C | Left nose | 20 | 9.68 | 0.44 | 20 | 8.14 | 0.96 | 1.19 |
| 88 | AOSafety N9504C | Right cheek | 20 | 5.99 | 1.88 | 20 | 4.73 | 1.50 | 1.27 |
| 88 | AOSafety N9504C | Right nose | 20 | 10.43 | 2.39 | 20 | 12.47 | 3.88 | 0.84 |
| 88 | Gerson 2737 | Bridge | 20 | 14.11 | 2.26 | 20 | 10.54 | 2.78 | 1.34 |
| 88 | Gerson 2737 | Chin | 20 | 5.18 | 0.96 | 20 | 5.22 | 1.16 | 0.99 |
| 88 | Gerson 2737 | Left cheek | 20 | 13.22 | 1.88 | 20 | 15.16 | 2.58 | 0.87 |
| 88 | Gerson 2737 | Left nose | 20 | 11.00 | 2.46 | 20 | 13.53 | 4.75 | 0.81 |
| 88 | Gerson 2737 | Right cheek | 20 | 10.95 | 3.10 | 20 | 11.76 | 2.33 | 0.93 |
| 88 | Gerson 2737 | Right nose | 20 | 11.78 | 2.76 | 20 | 9.76 | 2.12 | 1.21 |
| 90 | 3M 8210 | Bridge | 20 | 9.27 | 2.30 | 20 | 11.58 | 2.35 | 0.80 |
| 90 | 3M 8210 | Chin | 20 | 3.90 | 2.26 | 20 | 6.84 | 2.65 | 0.57 |
| 90 | 3M 8210 | Left cheek | 20 | 12.71 | 5.58 | 20 | 8.58 | 7.29 | 1.48 |
| 90 | 3M 8210 | Left nose | 20 | 7.45 | 4.35 | 20 | 5.30 | 1.90 | 1.41 |
| 90 | 3M 8210 | Right cheek | 20 | 5.33 | 2.16 | 20 | 8.56 | 2.15 | 0.62 |
| 90 | 3M 8210 | Right nose | 20 | 7.50 | 1.57 | 20 | 8.69 | 1.38 | 0.86 |

Mean of all ratios: 1.04 ± 0.26

For each subject/FFR model/leak site combination, bold mean IFSLs within a row are significantly different (Duncan's multiple range test after analysis of variance, $P < 0.05$).

directly compare our results with these studies of measurement bias.

Because the interface of the leak tube and the respirator was not sealed, it is possible that the actual area of leakage at a particular leak site varied somewhat between test subjects and respirator models; however, variability in the actual area of the leak is of little relevance because the amount of leakage at any particular site was compared by side-by-side sampling with two different probes (Figs 2 and 3). Both Figs 2 and 3 show that the magnitude of IFSL varied by leak site. Small differences in the actual leak sizes and other sources of random error (such as difference in donning technique between subjects and slight differences in fit of different models) could have contributed to the differences in IFSL among different leak sites.

This study did not find any large difference between flush probe and the deep or disc probes. These results are somewhat in contrast to findings of previous FFR studies where the flush probe was reported to underestimate the in-face concentration

compared with a deep probe or deep-mounted ball probe (Bostock, 1988; R. Howie, personal communication). Our study used a different mounting method than these studies (i.e. the probes were not mounted directly in the center of the FFR), which may have contributed to the differences. Also, our study had the test subject only breathe normally (a relatively low minute volume breathing rate compared with the higher flowrates of the previous studies). Although Coffey *et al.* (1998) used elastomeric half-mask respirators in their study, the results in this study using FFRs are consistent with their results in the respect that the flush and deep probes resulted in similar FF measurements. They showed that both the corn oil aerosol fit test method (using a deep probe with a high sampling rate) and the PORTACOUNT fit test method (using a flush probe and low sampling rate) had good correlation with an actual measured total dose exposure of Freon-113 (Coffey *et al.*, 1998).

There are limitations to the study, which are worthy of discussion. Because the probes were mounted

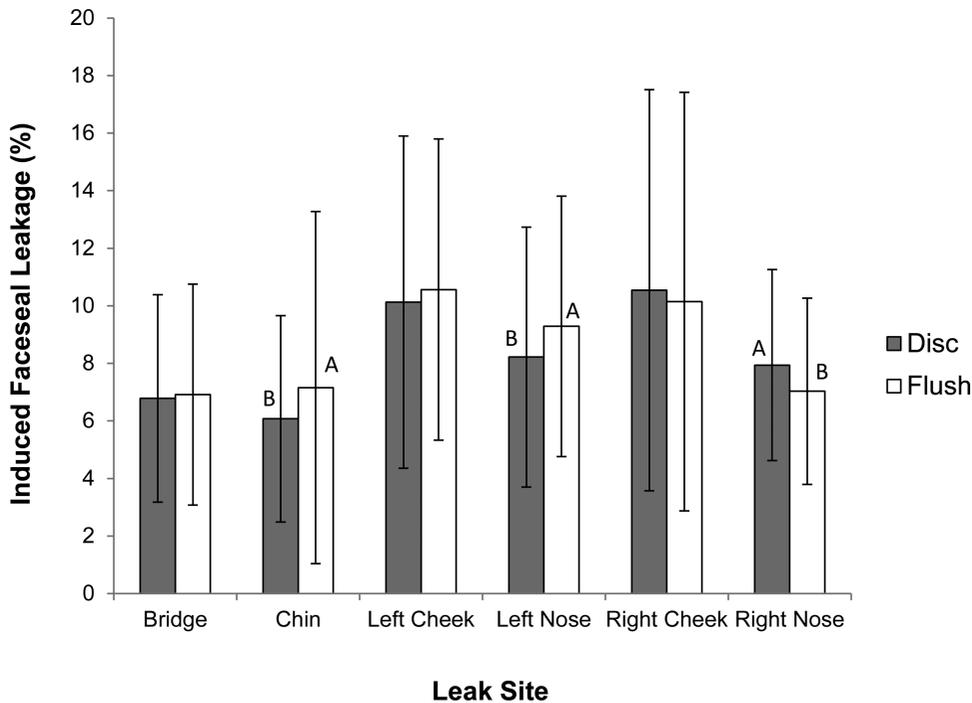


Fig. 3. IFSL by leak site for flush and disc probes.

Note 1: Mean and standard deviation are shown.

Note 2: For each leak site, mean with 'A' is significantly different from mean with 'B' (Duncan's multiple range test after analysis of variance, $P < 0.05$).

Note 3: For each leak site, $n = 200$ data points for 'disc probe' and $n = 200$ data points for 'flush probe'.

'side-by-side' with ~ 0.5 cm between them, each probe was not mounted directly in the center of the FFR, which is the typical practice for fit testing FFRs. Therefore, results may have been slightly different if the experiments were designed with only one probe center-mounted per respirator. Only three medium- or universal-sized cup-shaped FFR models were included in this study; results may have been different if different FFR shapes or sizes were used.

This study showed that the flush probe was conservative and could be used as part of a minimum TIL test for cup-shaped FFRs and for user fit testing using the PORTACOUNT. Additional research should be performed to determine if a flush probe could be used for full-facepiece respirators and hoods. Further implications include the use of the flush probe in countries where the deep or disc probes are currently specified.

CONCLUSIONS

The overall mean IFSL for subject/FFR model/leak site combinations differed by 14 and 4% for the flush probe versus deep probe and the flush probe versus

disc probe, respectively; however, from a practical standpoint, there is little difference between the flush probe tests compared with the deep probe or disc probe tests. Overall, IFSL measured using the flush probe is higher (resulting in a more conservative measure of faceseal leakage) compared with either the deep probe or disc probe. The more conservative results obtained using the flush probe provide support for its common usage for fit testing cup-shaped FFRs in the USA and potential use for fit testing FFRs in Europe.

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