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# DEVELOPMENT OF A DICHOTOMOUS-FLOW QUANTITATIVE FIT TEST FOR HALF-MASK AND FULL-FACEPIECE RESPIRATORS

*Usha Krishnan*<sup>a,b</sup>

*Klaus Willeke*<sup>a\*</sup>

*Arvydas Juozaitis*<sup>a,c</sup>

*Matti Lehtimäki*<sup>a,d</sup>

*Krzysztof Szewczyk*<sup>a,e</sup>

<sup>a</sup>Aerosol Research and Respiratory Protection Laboratory, Department of Environmental Health, University of Cincinnati, Cincinnati, OH 45267-0056; <sup>b</sup>Present address: Department of Health Sciences, Illinois State University, Normal, Illinois;

<sup>c</sup>On leave from Academy of Sciences, Vilnius, Lithuania; <sup>d</sup>On leave from Technical Research Center of Finland, Safety Engineering Laboratory, Tampere, Finland; <sup>e</sup>On leave from Warsaw University of Technology, Warsaw, Poland

*A new method to quantitate the fit of elastomeric half-mask and full-facepiece air-purifying respirators was developed. In this method the two flows, cartridge flow and leak flow, are separate. The air-purifying cartridges of the respirator are attached to a reference respirator. A selected flow equivalent to the inhalation flow of the wearer is drawn through the cartridge pair. A feedback system consisting of a pressure controller and a control valve is used to set the pressure drop in the mask on the subject's face equal to the pressure drop in the reference mask. The faceseal leak flow is measured while the subject holds his or her breath for a short period of time. The ratio of total flow (cartridge flow + leak flow) to leak flow is a measure of fit and is defined as the flow fit factor. Aerosol fit factors and flow fit factors were determined using sampling probes in three mask locations: top, center, and bottom. A Kruskal-Wallis test showed that aerosol fit factors obtained from the three locations were significantly different from each other ( $p = 0.0001$ ) while the corresponding flow fit factors were not. Aerosol fit factors obtained with the center probe had the least variability. The coefficient of variation in aerosol fit factors ranged from 5.4% for the center probe to 19% for the bottom probe; the coefficient of variation in flow fit factors was much lower, ranging from 1.7% for the top probe to 2.2% for the center and bottom probes.*



ir-purifying respirators are widely used in the workplace to provide protection against airborne contaminants. To ensure that respirators fit adequately a qualitative or quantitative fit test must be carried out.<sup>(1)</sup> Qualitative fit tests could be subjective, and therefore quantitative fit tests are more reliable. In some cases, quantitative fit tests are mandated by federal regulations.<sup>(2-3)</sup>

In the quantitative fit test with aerosols as the test agent, the ratio of the aerosol concentration outside the mask to the concentration inside determines the fit factor as a measure of the fit of the mask to the face of the wearer. The aerosol concentration inside the mask is affected by a number of parameters. Incomplete mixing of the faceseal leak flow in the mask cavity and particle losses due to deposition in the lungs and the leak sites cause the measured aerosol concentration to be potentially quite different from the actual inhaled aerosol concentration. The measured aerosol concentration also is affected by the location of the sampling probe and the depth of the probe in the respirator cavity.<sup>(4-8)</sup>

It has been suggested that the problem of aerosol deposition in the lungs and of incomplete mixing of the faceseal leak flow with the cartridge flow can be solved by performing the fit test during a few seconds of breath holding.<sup>(9-13)</sup> In-mask leak flow measured during breath holding is indicative of an improper faceseal: the higher the leak flow, the poorer the fit of the mask to the wearer's face and vice-versa.

Crutchfield et al.<sup>(11)</sup> have developed a fit test method that measures the in-mask faceseal leakage at a controlled negative pressure inside the mask and determines the ratio of the assumed total inhalation flow to the leak flow. However, the negative pressure created inside the mask cavity depends on the filter resistance and the wearer's breathing rate. The pressure differential across the mask affects the in-mask leak

\* Author to whom correspondence should be addressed

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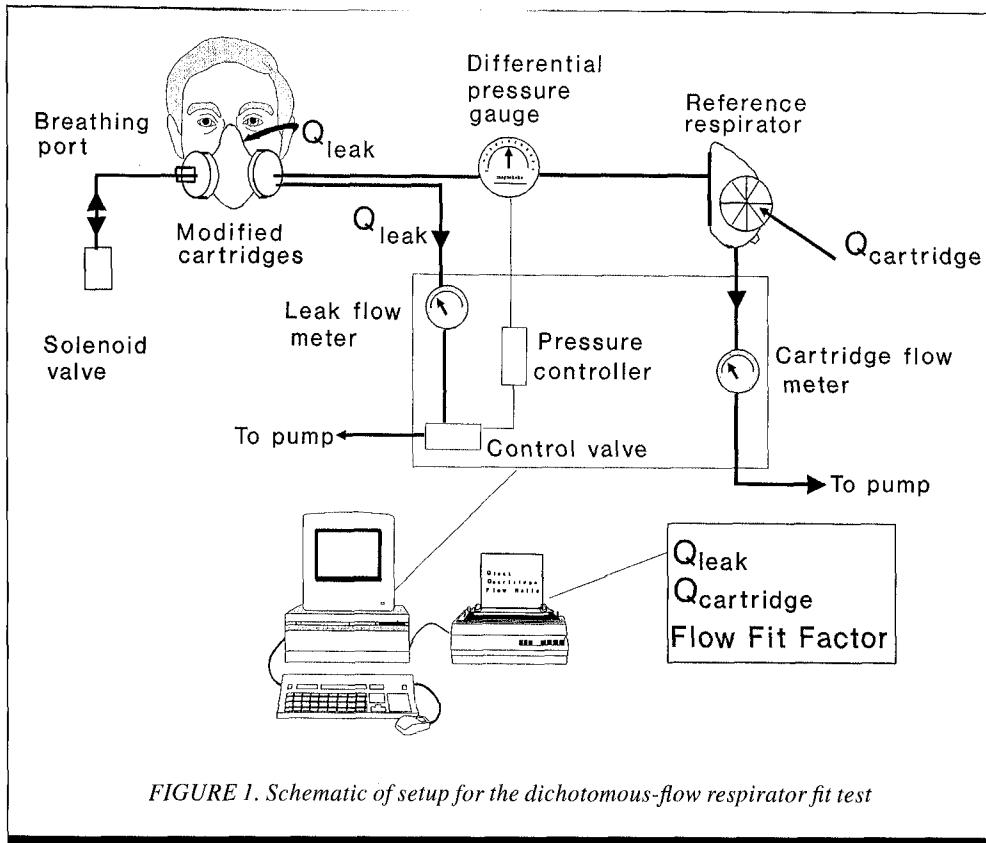


FIGURE 1. Schematic of setup for the dichotomous-flow respirator fit test

flow rate and the measured fit factor. Different materials used to remove particulate and gaseous contaminants have different flow resistances, and therefore the pressure drop created in the mask varies among different types of cartridges.<sup>(14)</sup> For a given type of cartridge, pressure drop varies among different brands. The new fit test described in this article determines the fit for the cartridges to be used in the workplace, at the pressure created by flow through these cartridges.

This article starts with a discussion of the relationship between pressure drop and cartridge flow rate for some of the cartridges commonly used in the workplace. This is followed by a description of the "dichotomous-flow respirator fit test" that has been developed for quantitatively fit testing field-use respirators fitted with cartridges to be used in the workplace. Finally, the performance of the new test is compared to that of the aerosol fit test.

## METHODS AND MATERIALS

### Role of Cartridges in Fit Testing

Halfmasks fitted with a pair of high efficiency particulate air-purifying (HEPA) cartridges were obtained from eight different manufacturers, A through H. The masks were mounted on a mannequin and air was drawn through the cartridge pair at flow rates ranging from 8 L/min to 96 L/min. The relationship between mask pressure drop and cartridge flow rate was determined for the HEPA cartridges. A similar study was conducted to study the pressure drop created by different types of cartridges obtained from a single manufacturer. Five types of cartridges were obtained from Manufacturer A: dust/ fume/mist, HEPA, organic

vapor, combination of organic vapor and dust/fume/mist, and combination of organic vapor and HEPA.

### Dichotomous Flow Respirator Fit Test

Figure 1 shows a schematic of the newly developed dichotomous-flow respirator fit test. The steps involved are outlined below. The subject dons the respirator while the cartridges are mounted on a reference respirator. The open side of the reference respirator is sealed, and the respirator is connected to a rigid fixture. Air is drawn through the cartridges at a fixed flow rate that is representative of inhalation flow rate under light, medium, or heavy work activity. Two modified cartridges are attached to the mask donned by the subject. These cartridges have their air-purifying materials removed

and are closed off with covers. One has a breathing port and is connected to a two-way solenoid valve. The other contains two ports, of which one is connected to the sampling probe for measuring the faceseal leakage and the other is connected to a differential pressure sensor.

The test begins with the subject holding his/her breath and closing the breathing port temporarily by activating the solenoid valve. (Other means of subject-controlled interruption of breathing may be used.) A pressure sensor (model PX160, Omega Engineering, Inc., Stamford, Conn.) measures the pressure differential between the mask being fit tested and the reference mask. The signal from this pressure sensor is fed to a control valve (model 240 A-05000 SV, MKS Instruments, Inc., Andover, Mass.) through a pressure controller (type 250 C-1-A, MKS Instruments, Inc., Andover, Mass.). The set point on the controller corresponds to a zero pressure differential between the two masks. Any deviation from this set point causes the system to adjust itself so that the two pressures are equalized by an increase or decrease in flow through the test mask. This servo mechanism ensures that the leak flow into the mask is measured when the pressure in the mask is the same as the pressure that would be encountered during inhalation when the mask is fitted with the cartridges under consideration.

Leak flow is measured by a flow meter (model 258C-01000-SV, MKS Instruments, Inc., Andover, Mass.) and cartridge flow is measured using a laminar flow element that was constructed in the laboratory and calibrated for flows ranging from 0 to 100 L/min. The ratio of the total flow (sum of cartridge flow and leak flow) to the leak flow gives the flow fit factor. Analog signals from the flow meters and the

pressure sensors are digitalized using an analog to digital converter (Analog Connection Jr., Strawberry Tree Computers, Sunnyvale, Calif.) and a personal computer is used for data acquisition and report generation.

#### *Face seal Leakage Dependence on Mask Pressure Drop*

An elastomeric half-mask respirator was mounted on a mannequin and an artificial leak was introduced at the face seal. The leak consisted of a 2-inch (ca. 5-cm) stainless steel syringe needle of inner diameter (I.D.) 0.58 mm with a metal hub. Silicon glue was applied to the mask-mannequin surface to eliminate all other face seal leaks. A 2-inch leak was chosen to ensure that the open end of the needle was well into the respirator cavity and that it was not blocked off by the inner flap of the respirator. The mask was fitted with a pair of modified cartridges and the sampling ports were connected to the dichotomous-flow respirator fit tester. A pair of HEPA cartridges was mounted on the reference respirator. Typical pressure drops for respirator wear, ranging from 0 to 20 mm w.g., were obtained in the mask by varying the airflow rates through the cartridge pairs from 0 to 96 L/min and the corresponding leak flow rate was noted. The relationship between mask pressure difference and leak flow rate was also determined for artificial leaks of I.D. 0.84 mm and 1.6 mm.

#### *Face seal Leakage Dependence on Cartridge Flow Rate and Cartridge Type*

The relationship between leak and cartridge flow rate was studied on a half-mask fitted on a mannequin with a fixed leak of 0.84 mm I.D. introduced at the face seal. The reference respirator was equipped with a pair of HEPA, dust/fume/mist, or combination HEPA/organic vapor cartridges, and the leak flow rates and flow fit factors were determined for cartridge flow rates from 8 L/min to 96 L/min.

#### *Testing for Mechanical Integrity of Respirators and Exhalation Valves*

Respirators that are used in the workplace may have mechanical damage and/or defective exhalation valves. The dichotomous-flow respirator fit tester has been used to determine the mechanical integrity of the respirator. The respirator under consideration was equipped with the two modified cartridges and strapped to a soft and pliable silicone body.<sup>(15)</sup> Mounting the respirator to this surface eliminated all face seal leakages. None of the respirators used in this study was found to be defective.

#### *Effect of Probe and Leak Locations on Aerosol and Flow Fit Factors*

A comparative study was made on the influence of probe and leak locations on the flow fit factors versus aerosol fit factors. A half-mask was fitted with probes in three locations as shown in Figure 2A: one in the top (or nose) region, P1; another in the center (or mouth) region, P2; and the third in the bottom (or chin) region, P3. The mask was placed on a mannequin, and three leaks of 0.84 mm I.D. were introduced between the face of the mannequin and the mask. These are

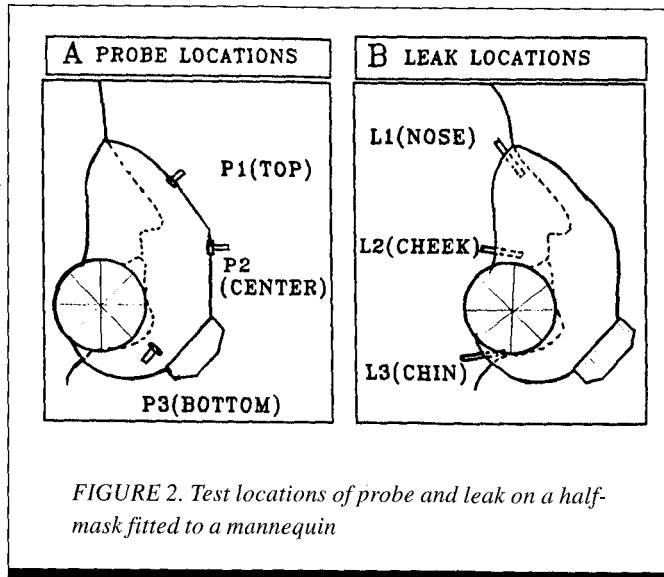


FIGURE 2. Test locations of probe and leak on a half-mask fitted to a mannequin

shown in Figure 2B: one on the bridge of the nose, L1; another on the cheek, L2; and the third on the chin, L3. Face seal leaks other than those artificially introduced were eliminated by applying silicone sealant at the face seal.

Probe and leak locations were chosen randomly and a set of six measurements of aerosol and flow fit factors was made for each of the nine combinations of probe and leak locations. The entire experiment was repeated two more times to obtain a sample size, n, of 18 (3 sets of 6 each) for each combination of probe and leak location.

Aerosol fit factors were determined using room aerosol and a portable condensation nuclei counter (PortaCount®, TSI Inc., St. Paul, Minn.). The mask was fitted with a pair of HEPA cartridges, and a piston breathing machine was connected to the back of the mannequin head. A cyclic flow of 8.5 L/min was created by setting the tidal volume to 500 mL and the piston stroke frequency to 17 per minute. This flow rate was chosen because it represents the breathing flow rate of a normal individual at rest.<sup>(16)</sup>

Flow fit factors were determined using the dichotomous-flow respirator fit tester (Dichot). The mannequin was disconnected from the piston breathing machine and the HEPA cartridges were mounted onto the reference respirator. A steady flow rate of 17 L/min was selected because it represents the inhalation flow rate at rest for a normal individual. Inhalation flow rate is approximately twice the breathing flow rate.<sup>(17)</sup> Therefore, a steady flow rate of 17 L/min corresponds to a cyclic flow rate of 8.5 L/min. The flow fit factors were determined for all combinations of the three leak locations and the three probe locations discussed above.

#### *Correlation between Aerosol Fit Factors and Flow Fit Factors*

The above-mentioned setup was used to compare the aerosol and flow fit factors for different combinations of leaks: one leak, two leaks, and three leaks of 1.07 mm I.D. The central sampling probe was used for all measurements. The aerosol fit factors were determined at a cyclic flow rate of 21.75 L/min and the corresponding flow fit factors were

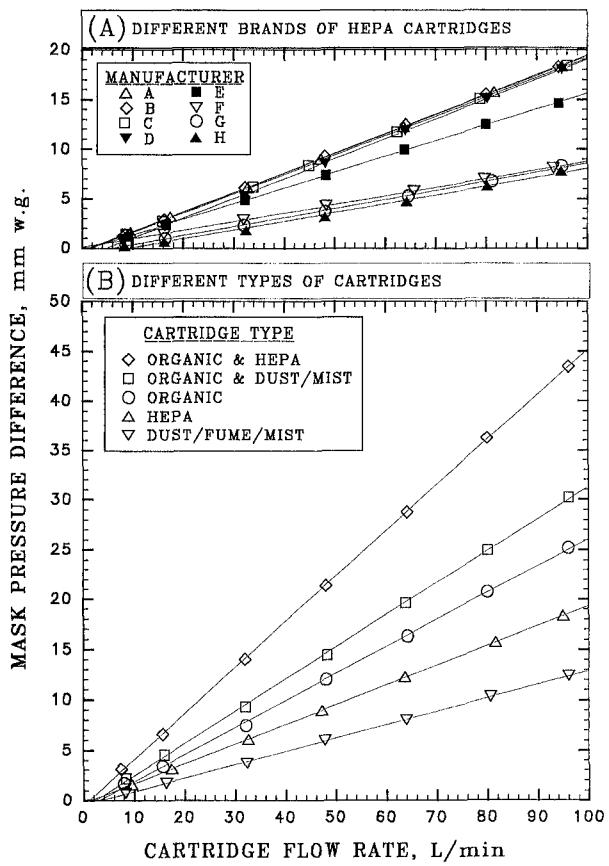


FIGURE 3. Variation in pressure drop with cartridge flow rate for several cartridge pairs: (A) HEPA cartridges from different manufacturers and (B) different types of cartridges from one manufacturer

determined at a steady flow rate 43.50 L/min. The new fit-test method was studied at this flow rate because an inspiratory flow rate of 43.50 L/min or a minute volume of 21.75 L represents moderate to light work activity.<sup>(17)</sup> The same pair of HEPA cartridges was used during both tests.

## RESULTS

### Role of Cartridges in Fit Testing

Figure 3A shows the relationship between mask pressure difference and cartridge flow rate for HEPA cartridges from the eight manufacturers. The mask pressure drop increased linearly with cartridge flow for all the HEPA cartridges. However, at any given cartridge flow, the pressure drop in the mask was not the same for all the cartridges. Of the eight pairs tested, cartridges from manufacturers A through D showed a higher pressure drop than cartridges from manufacturers F through H. The difference is about two (18.4 mm/7.8 mm) at the flow rate of 96 L/min.

Figure 3B shows the pressure drop created by five different types of cartridges from the same manufacturer, A. The highest pressure drop was found for the combination cartridge consisting of organic vapor and HEPA air-purifying

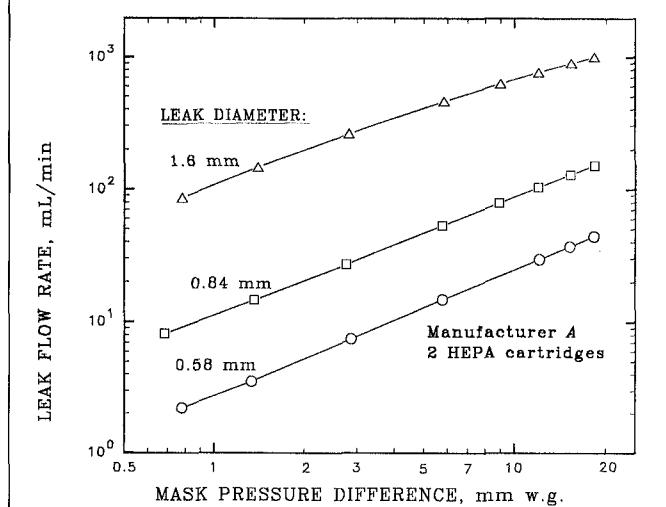


FIGURE 4. Influence of in-mask pressure difference on faceseal leakage

elements, while the dust/fume/mist cartridge created the least pressure drop. The highest pressure drop was about 3.5 times the lowest pressure drop (43.4 mm w.g./12.4 mm w.g.) at the flow rate of 96 L/min.

### Face Seal Leakage Dependence on Mask Pressure Drop

Figure 4 illustrates the influence of mask pressure drop on faceseal leakage for a half-mask from Manufacturer A equipped with HEPA cartridges. The maximum pressure drop of 20 mm w.g. was obtained at a cartridge flow rate of 96 L/min. Faceseal leakage increased linearly with mask pressure drop at low pressure differences, but not for high pressure differences with flow through large leaks. As expected, faceseal leakage was higher for large leaks than for small.

Leakages ranging from 1000 mL/min down to 10 mL/min are usually of most interest. This corresponds to flow fit factors of 10 to 10 000 for inhalation flow rates of 10 to 100 L/min. Leakages less than 10 mL/min indicate a very high fit and leakages more than 1000 mL/min indicate a very poor fit. It can be seen from Figure 4 that the Dichot in its present developmental stage can be used to measure leakages over a wide range from about 2 to 1000 mL/min.

### Face Seal Leakage Dependence on Cartridge Flow Rate and Cartridge Type

Figure 5A shows the increase in faceseal leakage with increase in cartridge flow rate (which is related to the inhalation flow rate) for a fixed leak of 0.84 mm I.D. It can be seen that for a given inhalation flow rate the leakage is highest for the combination cartridges tested and lowest for the dust/fume/mist cartridges tested. The higher pressure difference with the combination cartridges pulls in significantly more external air than the lower pressure difference with the dust/fume/mist cartridges. As a result, the flow fit

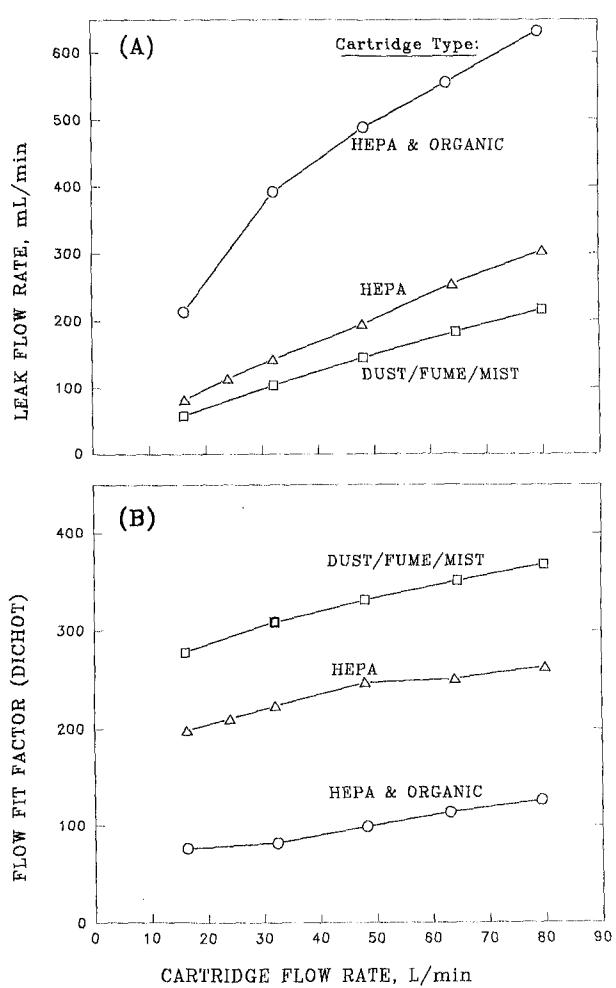


FIGURE 5. Leak flow and fit factor dependence on cartridge type for a half-mask respirator from Manufacturer A, tested with a leak hole of 0.84 mm I.D.

factor is highest for the dust/fume/mist respirator, Figure 5B. The flow fit factor increases with cartridge flow rate because the exponent of the pressure term in the leak flow rate versus pressure drop relationship is less than unity.<sup>(9,10,18)</sup>

#### Effect of Probe and Leak Locations on Aerosol and Flow Fit Factors

Figures 6A through 6C show the frequency distribution of aerosol fit factors and Figures 6D through 6F show the corresponding flow fit factors obtained with three probe locations: P1, P2, and P3. At each probe location, three sets of data each consisting of six fit factor values were collected for each of the three leak locations: L1, L2, and L3. The arithmetic mean of the 54 fit factor values ( $n = 54$ ) and the percent coefficient of variation are shown in Figure 6. The aerosol fit factors exhibited a larger spread ranging from 580 to 1220, while the flow fit factors had a range of 580 to 685. The aerosol fit factors obtained with different probes showed different variations, the least coefficient of variation of 5.4% being seen in case of the center probe and the maximum of 19% in the case of the bottom probe. The coefficient

of variation in flow fit factors ranged from 1.7% for the top probe to 2.2% for the center and bottom probes.

A statistical analysis package (SAS® Institute Inc., Cary, N.C.) was used to test for normality of the fit factors. A Shapiro-Wilk test indicated that the aerosol and flow fit factors were not normally distributed ( $p = 0.0001$ ). Similar results were obtained for the logarithms of the two fit factors. Kruskal-Wallis chi-square approximations showed that the aerosol fit factors obtained at the three sampling probe locations were significantly different from one another ( $p = 0.0001$ ) while the flow fit factors for the three probe locations were not. In a separate experiment, it was found that the flow fit factors obtained when the probe was situated in one of the modified cartridges was not significantly different from those obtained when it was on the mask.

Figures 7A and 7B show the aerosol and flow fit factor data of the above experiment as a function of probe and leak locations. Each data point represents the arithmetic mean of 18 fit factor values (3 sets of 6 each) and the error bar represents one standard deviation. It can be seen from Figure 7A that aerosol fit factors obtained with the bottom probe had the maximum spread (range: 650 to 1220) compared with fit factors obtained with the center probe (range: 580 to 770) and the top probe (range: 640 to 830).

Figure 7B shows the corresponding flow fit factors for the various probe and leak locations and proves that they are not biased by probe locations. It can also be seen that they have a much smaller spread (range: 580 to 685) compared with the aerosol fit factors. Comparison of Figures 7A and 7B reveals that the flow fit factors show maximum overlap with the range of aerosol fit factors obtained with the center probe.

#### Correlation Between Aerosol Fit Factors and Flow Fit Factors

Since the center probe is the standard probe location and was found to give the least spread in aerosol fit factors, it was used to compare aerosol fit factors and flow fit factors for various combinations of leaks. When a single face seal leak of 1.07 mm I.D. was introduced at any one of the three different leak locations, the flow fit factor was the same at 520, while the aerosol fit factors ranged from 640 to 1000 (see Figure 8). When two face seal leaks of the same size were introduced, one in each of the two leak locations, the flow fit factor was constant at 280 while the aerosol fit factors ranged from 380 to 500. The lowest fit factors were observed by both methods when three leaks were introduced, one leak in each of the three locations. It can be seen that the aerosol fit factors were always higher than the corresponding flow fit factors. This is most likely due to the loss of aerosol particles in the leak sites, which causes the aerosol concentration inside the mask to be lower than what it would be without losses.

## DISCUSSION

Variations in pressure drop among cartridges of different brands and types affect the fit factor significantly. Manufacturers of respirators have devoted considerable time and money to improving the shape of the facepiece and the

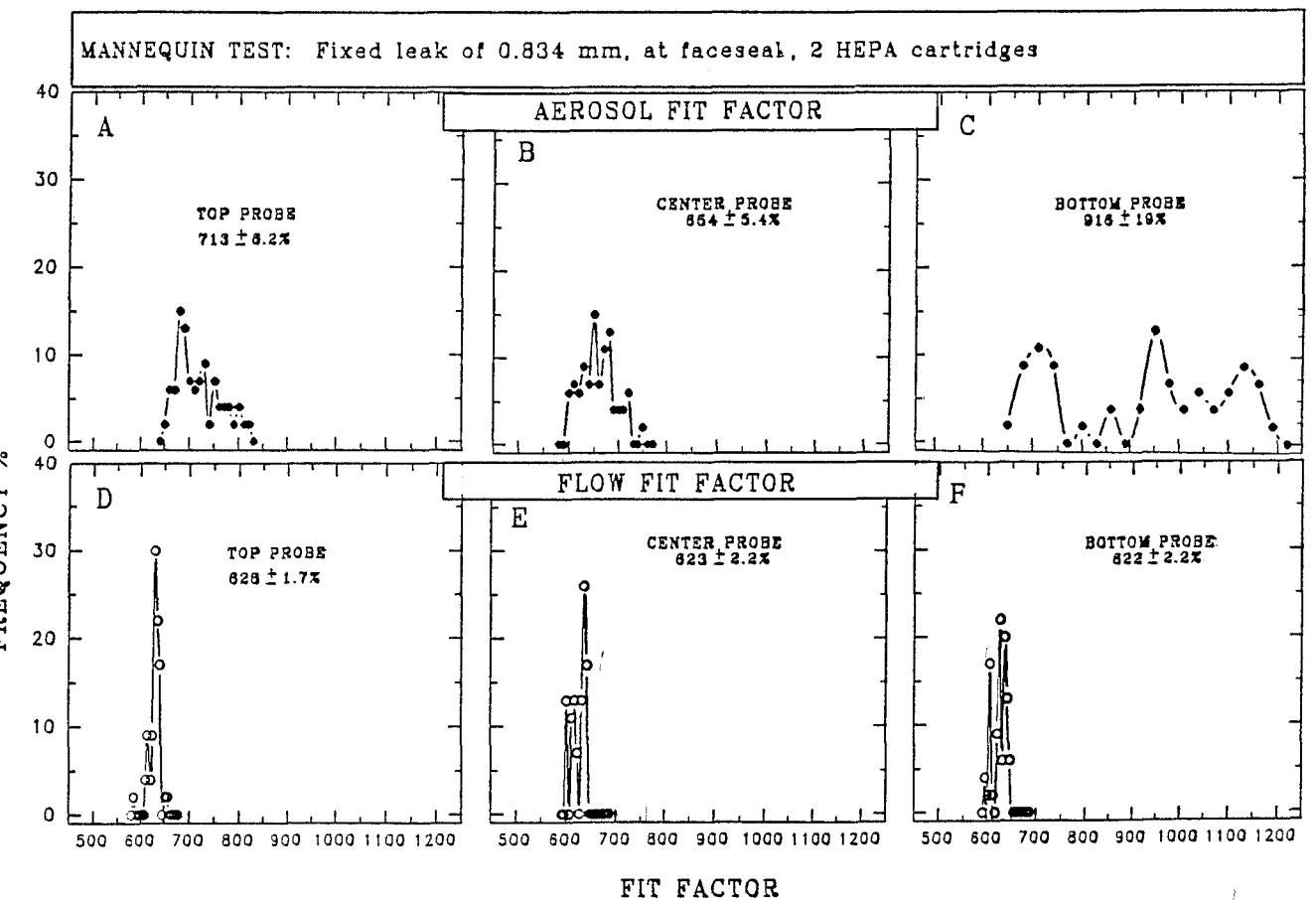


FIGURE 6. Frequency distribution of aerosol and flow fit factors obtained at three probe locations: P1, P2, and P3, for a fixed leak of 0.84 mm I.D. at each of the three leak locations: L1, L2, and L3 (sample size,  $n = 54$ )

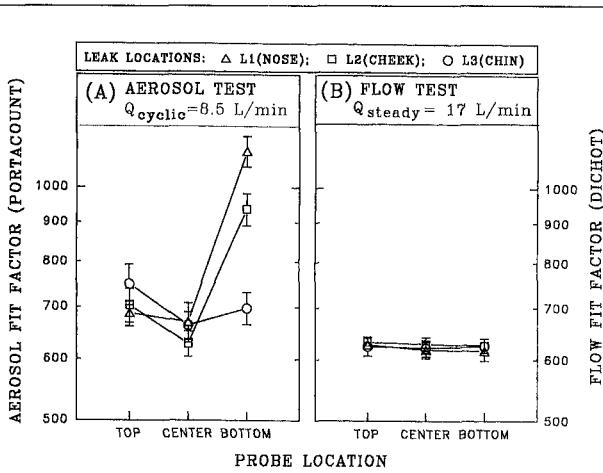


FIGURE 7. Effect of probe and leak locations on aerosol and flow fit factor obtained with an elastomeric half-mask respirator from Manufacturer B, sealed on a mannequin and fitted with a leak of 0.84 mm I.D. (Sample size,  $n = 18$ . Values shown are arithmetic means. Error bars reflect one standard deviation.)

material used in making the facepiece in an attempt to achieve a better faceseal. In view of the findings of the present study, the influence of cartridges on fit factor should receive more attention. It will be interesting to determine whether the differences in pressure drop are caused by differences in filter material or filter area inside the cartridges.

A number of studies have shown that quantitative aerosol fit factors do not correlate with workplace protection factors.<sup>(19-20)</sup> There are many reasons for the differences, such as variability in leak size during field use and exposure to aerosol size distributions that are different from the ones used in the laboratory test. The present study offers an additional explanation. Laboratory fit factors are determined with aerosols as test agents using a pair of HEPA cartridges while the workplace protection factors are not necessarily determined with HEPA cartridges; different types of cartridges may be used depending on the nature of air contaminants present. Laboratory fit factors are determined with the subject at rest to simulate light to moderate activity and with the subject breathing deeply to simulate heavy work activity. However, faceseal leakage during deep breathing may not be the same as during heavy work activity, under conditions of high temperature and humidity, thus resulting in fit factors different from workplace protection factors.

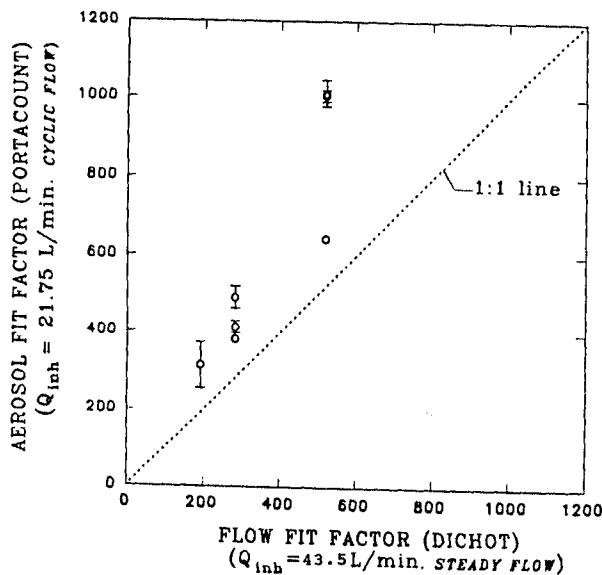


FIGURE 8. Correlation between aerosol fit factor and flow fit factor for various faceseal leaks introduced in a half-mask sealed on a mannequin. (Sample size,  $n = 18$ . Values shown are arithmetic means. Error bars reflect one standard deviation.)

In conventional fit-test methods, which use aerosols as the test agent, the sampling probe is usually mounted on a surrogate mask. Since the flow fit factors obtained by the dichotomous-flow method are not affected by the sampling probe location, it is convenient to locate the sampling probe in one of the modified cartridges, thus making it possible to fit test field-used respirators with any kind of cartridge attached.

## CONCLUSIONS

The dichotomous-flow respirator fit test appears to have distinct advantages over the currently used aerosol fit test method. It is noninvasive and therefore can be used in the workplace to determine the fit of the worker's actual mask. Unlike the aerosol method that necessitates the use of HEPA cartridges during the test, the dichotomous flow method can be performed with any kind of cartridge. The system is portable and therefore convenient for field use.

## ACKNOWLEDGMENTS

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