

Performance of N95 Respirators: Filtration Efficiency for Airborne Microbial and Inert Particles

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In 1995 the National Institute for Occupational Safety and Health issued new regulations for nonpowered particulate respirators (42 CFR Part 84). A new filter certification system also was created. Among the new particulate respirators that have entered the market, the N95 respirator is the most commonly used in industrial and health care environments. The filtration efficiencies of unloaded N95 particulate respirators have been compared with those of dust/mist (DM) and dust/fume/mist (DFM) respirators certified under the former regulations (30 CFR Part 11). Through laboratory tests with NaCl certification aerosols and measurements with particle-size spectrometers, N95 respirators were found to have higher filtration efficiencies than DM and DFM respirators and noncertified surgical masks. N95 respirators made by different companies were found to have different filtration efficiencies for the most penetrating particle size (0.1 to 0.3 μm), but all were at least 95% efficient at that size for NaCl particles. Above the most penetrating particle size the filtration efficiency increases with size; it reaches approximately 99.5% or higher at about 0.75 μm . Tests with bacteria of size and shape similar to *Mycobacterium tuberculosis* also showed filtration efficiencies of 99.5% or higher. Experimental data were used to calculate the aerosol mass concentrations inside the respirator when worn in representative work environments. The penetrated mass fractions, in the absence of face leakage, ranged from 0.02% for large particle distributions to 1.8% for submicrometer-size welding fumes. Thus, N95 respirators provide excellent protection against airborne particles when there is a good face seal.

Keywords: efficiency, filter, microorganism, *Mycobacterium tuberculosis*, respirator

Particulate respirators are widely used in the workplace to reduce worker exposure to airborne particles. In June 1995 the National Institute for Occupational Safety and Health (NIOSH) issued new regulations for certifying nonpowered particulate respirators (42 CFR Part 84).⁽¹⁾ The new regulations replace the older 30 CFR Part 11 regulations.⁽²⁾ With the new regulations, a new filter classification system was created that distinguishes nine classes of filters (three efficiency levels and three series of

filter degradation resistance). The three efficiency levels are 95, 99, and 99.97%, tested at a flow rate of 85 L/min at the most penetrating particle size (generally about 0.1 to 0.3 μm).⁽³⁾ The three degradation resistance series were established by the choice of either NaCl (sodium chloride salt), which is only mildly degrading to filter media (N series of filters), or DOP (dioctyl phthalate) liquid oil, which is highly degrading (R or P series). Accordingly, N series filters tested with NaCl aerosol are recognized as not highly resistant to degradation and only appropriate for use with solid aerosol in the workplace.

Among the new respirators certified under 42 CFR Part 84, the N95 respirators are the most commonly used. They have a minimum of 95% particle count efficiency at the most penetrating

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particle size and are tested with NaCl. The N95 respirators are replacing the less efficient dust/mist (DM) and dust/fume/mist (DFM) respirators, which are being phased out. The efficiencies of filtering out solid particles have been measured for N95 respirators and are compared with those of typical DM and DFM respirators certified under the previous 30 CFR Part 11 regulations and tested in the same facility. These efficiencies are also compared with the efficiency of a typical noncertified surgical mask, originally designed to protect patients from 4 μm or larger droplets expelled by health care workers.⁽⁴⁾ As incidences of *Mycobacterium tuberculosis* (TB) infection began to rise in health care facilities, surgical masks were used, but were insufficient to protect the workers from infected patients. In 1993 the Centers for Disease Control and Prevention (CDC) issued guidelines requiring that respirators used for the prevention of infection from TB have a minimum of 95% efficiency for 1 μm particles when tested at 50 L/min through the respirators.⁽⁵⁾ Since all filter materials are more efficient at 1 μm than at the most penetrating particle size, the new 42 CFR Part 84 regulations permit all certified respirators to be used in health care industries against TB exposure. Therefore, the performance of N95 respirators was studied not only with solid particles, but also with bacteria having size and shape similar to TB. In this study N95 respirator filters were tested with bacteria, NaCl, and polystyrene latex (PSL) particles, and procedures similar to those used previously were applied.⁽⁶⁻⁹⁾ The N95 respirators were also tested at a flow rate lower than the certification flow rate of 85 L/min to examine their performance at a breathing rate that is typical for health care workers.⁽¹⁰⁾

EXPERIMENTAL MATERIALS AND METHODS

Certified N95 respirators from three different companies were tested in this study: a cone-shaped N95 respirator from Company A, termed Respirator A, and two flat N95 respirators from two other manufacturers termed Respirator B and Respirator C. The filtration material in each respirator consisted of charged polypropylene fibers. The filter material of Respirator A had a low packing density and was about 2.2 mm thick; Respirator B had a relatively high packing density and was about 0.9 mm thick; Respirator C also had a high packing density and was 0.75 mm thick. The criteria for selecting these N95 respirators were their availability for the studies and the differences in their makeup.

In these N95 respirators the filter material was sandwiched between an inner and an outer cover web. Since the certification testing by NIOSH is performed with complete respirators, each test respirator of this study was sealed to a head form, that is, the filter material was not removed from the respirator for testing.

Three types of test particles were used in this study: polydisperse NaCl particles, monodisperse PSL particles, and airborne bacteria of two types. NaCl particles are used by NIOSH in certification tests for N95 respirators. In this study they were produced by the nebulization of a NaCl solution with a concentration of 3.5 mg of NaCl per cm^3 of deionized water. This produced NaCl particles of less than 0.70 μm in diameter, including particles in the most penetrating size range of about 0.1 to about 0.3 μm . PSL particles of 0.60, 1.02, 2.94, 3.96, and 5.10 μm (Bangs Laboratories, Inc., Carmel, Ind.) were chosen to study the filtration efficiencies above the NaCl size range. Measurements with spherical particles also provide a suitable reference for measurements with rod-shaped bacteria.

Test bacteria were selected to be (1) nonpathogenic, (2) rod-shaped, and (3) of sizes similar to *M. tuberculosis*. *Bacillus subtilis*

ATCC 6051 (American Type Culture Collection Inc., Rockville, Md.) and *Bacillus megatherium* ATCC 14581 were used.⁽¹¹⁾ The aerodynamic particle size of *B. subtilis* bacteria (0.7 to 0.8 μm in diameter, 2 to 3 μm in length) is close to the upper aerodynamic particle size limit of *M. tuberculosis* bacteria (0.3 to 0.6 μm in diameter and 1 to 4 μm in length).⁽¹²⁾ *B. subtilis* has also been used as a TB surrogate by other researchers in respirator tests.⁽⁸⁾ The size of *B. megatherium* bacteria (1.2 to 1.5 μm in diameter, 2 to 5 μm in length) is larger than that of the *M. tuberculosis* bacteria. The two bacteria were chosen so that the results could be interpreted for a bacterial size range that includes but is not limited to *M. tuberculosis*.

Before testing, these cells were maintained on Tryptic soy agar slants at 5°C (Difco Laboratories, Detroit, Mich.). Before each test sequence, some were streaked on Tryptic soy agar plates and incubated at 25°C for 18 hours. After incubation they were removed from the plates with sterile deionized water. Suspension residues were removed from the cells by centrifugation at $2860 \times g$ in deionized water (Marathon 6K, Fisher Scientific, Pittsburgh, Pa.).⁽¹³⁾

This study utilized the same experimental setup that was used in previous bacterial penetration studies with the following two modifications.⁽⁹⁾ First, the size-fractionating aerosol generator was removed because no liquid particles were used in this study; all three types of solid test particles were generated by a six-nozzle Collison nebulizer (BGI Inc., Waltham, Mass.), which was supplied with clean compressed air at a pressure of 1.05 kg/cm^2 (15 psi). Second, to measure particles in the most penetrating size range, a laser aerosol size spectrometer that measures in the 0.1 to 3.0 μm size range (LAS-X, Particle Measuring Systems, Inc., Boulder, Colo.) was operated in parallel with the previously used aerodynamic size spectrometer (Aerosizer, Amherst Process Instruments Inc., Hadley, Mass.). The smallest size at which the Aerosizer can properly measure aerosol concentrations is approximately 0.5 μm in aerodynamic diameter.^(13,14) Both aerosol spectrometers measure number concentrations. For a polydisperse aerosol with a mean size at or near the most penetrating particle size, the respirator efficiency by count is equal to or less than the efficiency by mass. Thus, the minimum efficiency by mass of 95% is satisfied, if the count efficiency is 95% or higher.

The nebulized test particles were mixed with clean dilution air to attain an aerosol concentration of about 80 to 120 per cm^3 in the test chamber. The aerosol was passed through a 10 mCi ^{85}Kr electrical charge neutralizer (TSI Inc., St. Paul, Minn.) before entering the test chamber. The N95 respirators, randomly selected from the boxes in which they were supplied, were sealed to a head form and tested by measuring the aerosol concentrations inside and outside the respirators with both particle-size spectrometers. Since particle deposition in the human respiratory tract depends on the aerodynamic particle size, all data are presented as a function of the aerodynamic equivalent diameter. While the Aerosizer data are recorded as a function of aerodynamic diameter, the LAS-X size spectrometer data are recorded as a function of optical equivalent diameter. The latter was converted to aerodynamic diameter through consideration of the particle density (2.2 g/cm^3 for NaCl). The optical equivalent diameter of the LAS-X size spectrometer is based on the instrument's calibration with PSL particles. The size and index of reflection differences between the NaCl and PSL particles have been neglected in the size conversions.

Each data set was repeated five times. The results of the measurements are presented by their means and standard deviations. All tests were conducted at a temperature of $25 \pm 3^\circ\text{C}$ and a relative humidity of $20 \pm 2\%$. All respirators were equilibrated at the test conditions for 24 hours or more before experiments were performed with them.

RESULTS AND DISCUSSION

Figure 1 shows the filtration efficiency curves of typical unloaded N95, DFM, and DM respirators, and a noncertified surgical mask, all made by Company A. The particle concentrations upstream and downstream of these devices were measured with the LAS-X particle size spectrometer. In Figure 1A the devices are compared at a flow rate, Q_r , of 85 L/min, as specified by 42 CFR Part 84.⁽¹⁾ The N95 respirator has the highest efficiency, E , for all aerodynamic particle diameters, d_a . The minimum efficiencies at the most penetrating particle size are about 96% for the N95 respirator, 92% for the DFM respirator, 82% for the DM respirator, and 71% for the surgical mask. Thus, only the N95 respirator meets the 95% efficiency minimum requirement under the new regulations of 42 CFR Part 84.

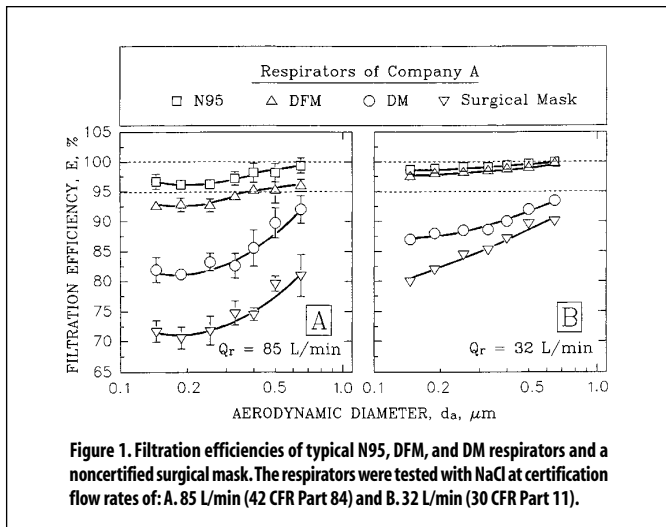


Figure 1. Filtration efficiencies of typical N95, DFM, and DM respirators and a noncertified surgical mask. The respirators were tested with NaCl at certification flow rates of: A. 85 L/min (42 CFR Part 84) and B. 32 L/min (30 CFR Part 11).

Since the DFM and DM respirators were certified under 30 CFR Part 11 at a flow rate of 32 L/min, all four devices were also tested at the lower flow rate, which corresponds to breathing while performing a medium work load.⁽¹⁰⁾ Figure 1B shows that all efficiencies are higher at the 32 L/min flow rate. This increase in efficiency is attributed primarily to the increased time that is available for the removal of submicrometer particles by the electrostatically charged fibers of the respirator filter material used by Company A in all of their disposable half-mask respirators.⁽¹⁵⁾ Additional removal is attributed to the increased time for submicrometer particle diffusion. At the smallest particle size tested, the N95 respirator has the highest filtration efficiency, ca. 98.8%, and the surgical mask has the lowest, ca. 80%. The minimum measured efficiency of the DFM respirator is about 97%. Thus, this DFM respirator has more than the minimum of 95% collection efficiency when the work load is low, but it does not satisfy the certification requirement at 85 L/min. At all flow rates the collection efficiency increases with particle size for particles larger than the most penetrating particle size. Thus, the protection provided by the filter material of N95 respirators is always equal to or larger than 95%, that is, 5% or less of the airborne particles entering the respirator penetrate through the filter material. It should be noted that these efficiencies do not consider face seal leakage. The pressure drop across the filter material encourages external air to bypass the filter and enter the respirator wearer's breathing space through any face seal leak that may be present. Appropriate face seal fit is measured by quantitative fit-testing.⁽¹⁶⁾

Figure 2 shows that certified N95 respirators manufactured by different companies may differ in the amount of airborne material that passes through the respirator material. The curves are best fits for the NaCl data below 0.6 μm (measured with the Aerosizer) and the PSL data above 0.6- μm diameter (measured with the LAS-X particle size spectrometer). As seen, the electrically charged polymer fiber filters of Companies A and B have a minimum efficiency of about 96.2% at the most penetrating particle size when tested at 85 L/min, and the charged fiber filters of Company C have a minimum efficiency of 95% (i.e., the filter materials of all three companies pass the certification requirement).

The performance differences between the respirators of different companies have been interpreted as follows. In the design of respirators the efficiency level for the filtration material is set by the thickness of the filter material and by several filter characteristics, such as filter diameter and packing density. To keep the pressure drop low for maximum breathing comfort and the efficiency above the certification level, a compromise is selected among these parameters. As pointed out in the Experimental Materials and Methods section, the filtration materials of the tested respirators differed in thickness and packing density, and, apparently, also in fiber size and the degree of electrical charge embedded in the fibers. For particle sizes above 0.75 μm , the filtration efficiencies of all tested respirators are 99.5% or higher, as seen in Figure 2.

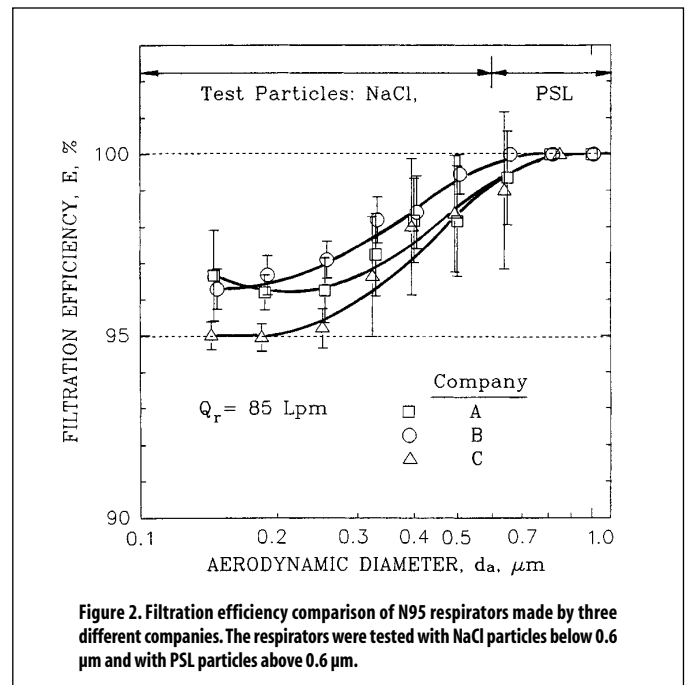


Figure 2. Filtration efficiency comparison of N95 respirators made by three different companies. The respirators were tested with NaCl particles below 0.6 μm and with PSL particles above 0.6 μm .

Figure 3 shows the filtration efficiency of an unloaded N95 respirator (Company A) when exposed to airborne bacteria of *B. subtilis* and *B. megatherium*. The solid line is the best fit efficiency curve for NaCl and PSL particles (from Figure 2), and the two data points indicate the *B. subtilis* and *B. megatherium* filtration efficiencies, measured with the Aerosizer. In these experiments the mean aerodynamic diameters of the *B. subtilis* and *B. megatherium* bacteria were measured to be about 0.8 and 1.2 μm , respectively. For both bacteria, the filtration efficiencies of the N95 respirator are 99.5% or higher, similar to the data for NaCl and PSL particles. Therefore, the filtration efficiencies of the tested N95 respirators can be regarded as 99.5% or higher for *M. tuberculosis*. If TB bacteria are contained in droplets of sizes larger than 1 μm and there is a good face seal, the filtration efficiency is also 99.5% or higher.

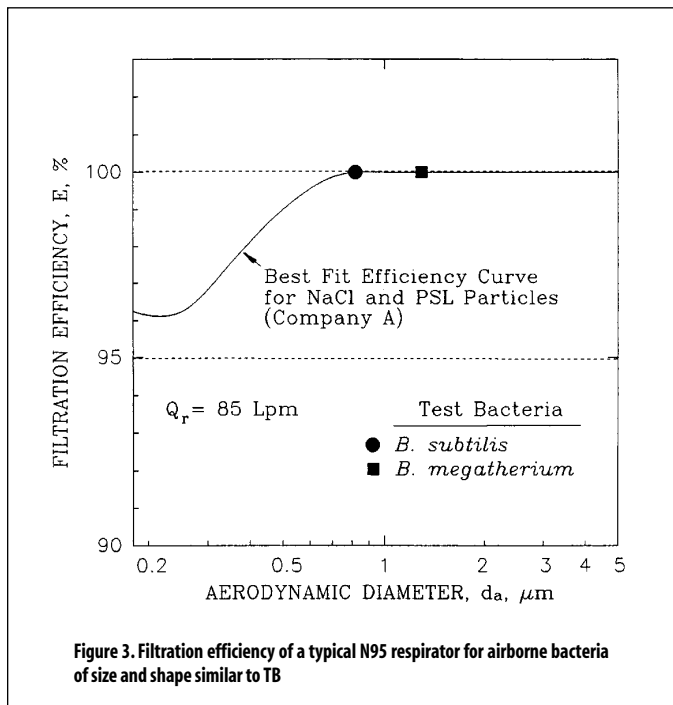


Figure 3. Filtration efficiency of a typical N95 respirator for airborne bacteria of size and shape similar to TB

Figures 1 through 3 show that the efficiencies of the filter materials in N95 respirators are particle size dependent. These filtration efficiency data have been used to predict the aerosol concentrations inside the respirator for the occupational environments shown in Figure 4. Figure 4A shows three types of particle size distributions that are commonly encountered in occupational environments and have been reported in the literature:⁽¹⁷⁾ a fine-particle welding fume with a mass median aerodynamic diameter (MMAD) of 0.48 μm and a geometric standard deviation (GSD) of 2.3; medium-sized fine wood particles with a MMAD of 1.3 μm and a GSD of 2.7; and large particles from a Be-Cu foundry with a MMAD of 5.0 μm and a GSD of 2.4. If a worker wears the N95 respirator made by Company A and is exposed to these airborne particles under heavy workload conditions, the aerosol mass concentrations inside the respirator in the absence of face seal leakage are as shown in Figure 4B. The aerosol mass fractions inside the respirator are calculated by multiplying the mass concentrations of Figure 4A by the filtration efficiencies of Figure 3. As seen, almost all of the particle mass above 0.75 μm is removed by the filter material. Only aerosol particles below this size may penetrate through the filter material as significant fractions of their external concentrations. If one integrates the mass concentration of penetrated aerosol particles with particle size (Figure 4B), and divides it by the total mass concentration of ambient aerosol particles (Figure 4A), one finds that only 1.8% of the welding fume mass penetrates the filter material. For the medium-sized fine wood dust, that fraction is 0.65%, and for the large Be-Cu particles it is negligible at 0.02%. For respirators worn at less than the certification flow rate of 85 L/min, the filtration efficiencies are higher (Figure 1), and, therefore, the fractions of penetrated particles are less than shown in Figure 4.

CONCLUSIONS

The new N95 facepiece respirators have higher filtration efficiencies than the previously certified DFM and DM respirators and the noncertified surgical masks. The filtration efficiency of

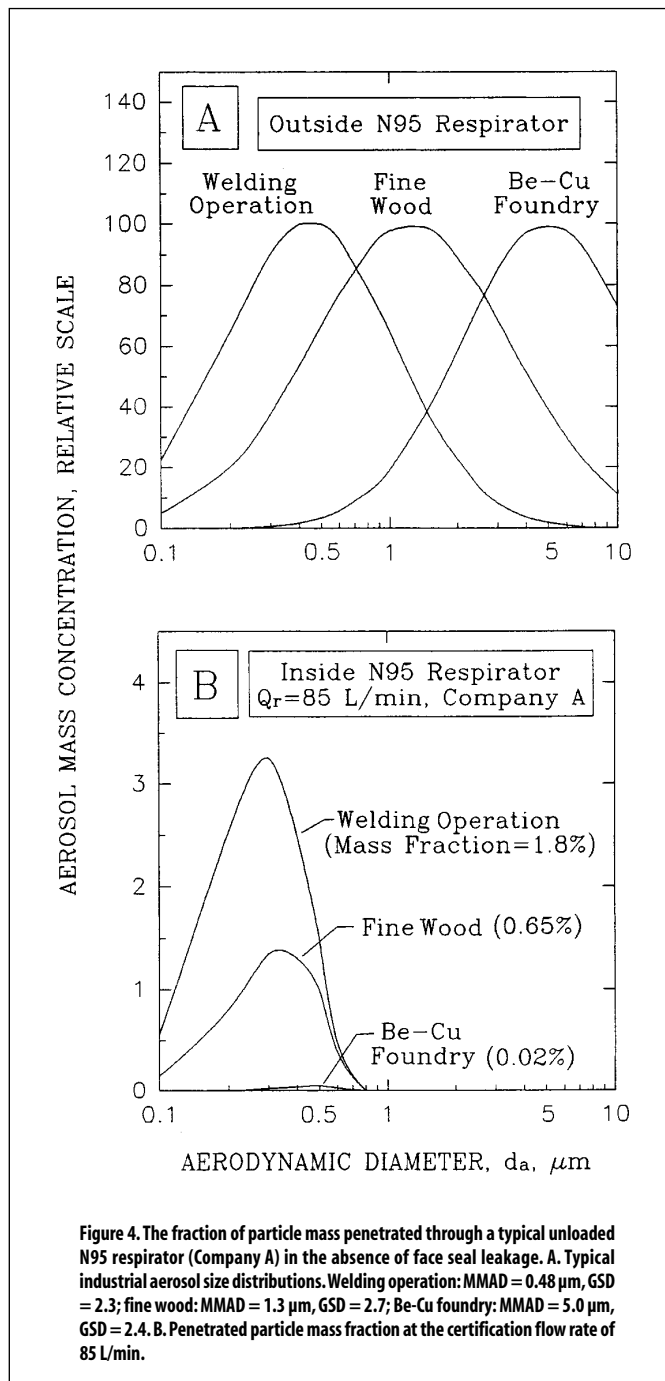


Figure 4. The fraction of particle mass penetrated through a typical unloaded N95 respirator (Company A) in the absence of face seal leakage. A. Typical industrial aerosol size distributions. Welding operation: MMAD = 0.48 μm , GSD = 2.3; fine wood: MMAD = 1.3 μm , GSD = 2.7; Be-Cu foundry: MMAD = 5.0 μm , GSD = 2.4. B. Penetrated particle mass fraction at the certification flow rate of 85 L/min.

unloaded N95 respirators is 99.5% or higher for particles larger than 0.75 μm . The lowest filtration efficiency is 95% or higher at the most penetrating particle size of about 0.1 to 0.3 μm , when tested at the certification flow rate of 85 L/min simulating average breathing under heavy work load conditions. For airborne bacteria, such as surrogates of *M. tuberculosis* with an aerodynamic size of 0.8 μm or larger, the filtration efficiency is also 99.5% or higher. For most environmental particle exposures, the filter material of an N95 respirator removes almost all particulate mass. Only sub-micrometer particles of less than 0.75 μm may penetrate the filter material as significant fractions of their external concentrations. Thus, only 1.8% of the total mass concentration of a typical welding fume has been calculated to penetrate a representative N95 respirator at 85 L/min. N95 respirators provide even higher filtration efficiencies under medium or low work load conditions when

the flow rate is less than 85 L/min. Thus, N95 respirators can provide excellent protection against airborne particles when there is a proper face seal.

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