

Filtration of Respired Gases: Theoretical Aspects

Ron J. Thiessen, RRT*

*Royal Columbian Hospital, 330 East Columbia Street, New Westminster,
British Columbia, V3L 3W7, Canada*

In 1942, Langmuir and coworkers [1] demonstrated that the penetration of particles through filter material depends on the size of the particles and that the highest degree of penetration occurs with particles approximately 0.3 μm in diameter. They concluded that masks used to prevent inhalation of particles should be tested using this particle size. Over the next 60 years thousands of experimental and theoretical studies firmly established the relationship between particle size and filtration efficiency. Unfortunately, health care has been slow to recognize the substantial amount of work that has been published on this subject, because most of it would not be identified in a conventional medical literature search. With a few exceptions, most of the published medical literature on the topic of aerosol filtration in health care is flawed because of a fundamental lack of understanding of aerosols, filtration theory, and the corresponding terminology that has been well established and accepted outside of health care for many years.

Two main types of filters are used in health care to limit or stop the spread of infectious aerosols. The first type is the respirator, which is a mask device that attaches tightly to the face and covers at least the mouth and nose but may also cover the eyes. These devices have been used for many years in industrial applications but also are valuable in health care when there is a risk of air-borne spread of disease. Respirators are designed to purify air that is inhaled by the user by capturing particulate matter. Respirators used in health care are categorized as N95, N99, or N100, based on the National Institute for Occupational Safety and Health (NIOSH) rating system [2] that uses internationally recognized standardized tests. These filters prevent at least 95%, 99%, or 99.97% of particles of the most

* Correspondence. 23880 133rd Avenue, Maple Ridge, British Columbia, V4R 2V1, Canada.

E-mail address: thiessen.ron@gmail.com

penetrating particle size (MPPS) from passing through, respectively. The most common respirator seen in health care is the disposable N95 respirator, which is shaped to fit over the mouth and nose only; the whole mask consists of electrostatically enhanced filter material. Another style of respirator less commonly seen in health care typically consists of a reusable plastic frame that attaches firmly over the nose and mouth. Alternately, it may have a clear plastic viewing section that allows it to provide a good seal over the eyes as well as the mouth and nose. These respirators typically have removable filter cartridges that allow N99 or N100 filtration to be achieved.

The other main type of particulate filter seen in health care is the breathing system filter. Although respirators are used to minimize the aerosols that are directly inhaled by the user, they do nothing to decrease the number of infectious aerosols in the environment. The main use of breathing system filters is to stop the spread of infectious material at the source, so that the environment is not contaminated in the first place. These filters have a multitude of potential applications that include, but are not limited to, filtration of gases exhaled by patients on anesthesia machines and critical care ventilators. Breathing system filters also can be placed on manual 'baggers' so there is less exposure to microbes during cardiopulmonary resuscitation. Unlike respirators, there is no standardized categorization system for breathing system filters, nor is there a requirement for standardized testing. In fact, at least in North America, there are no regulations or guidelines at all on the use of breathing system filters to protect health care environments from infectious patients. For most breathing system filters, inadequate testing and supporting literature does not allow an educated comparison of filters to be made. Although there are now internationally recognized testing procedures, they are voluntary and are not being enforced consistently at any level.

This article provides an understanding of the basic concepts of small particle and aerosol behavior, filtration and deposition principles, and the rationale for current standards relevant to filter testing. It also highlights some of the areas in which further investigation or regulation is needed. With this knowledge, the effectiveness and appropriateness of different filtration devices can be evaluated accurately.

Definitions and basic principles of aerosol technology

The term "aerosol" is defined as a suspension of solid or liquid particles in a gas. Monodisperse aerosols have particles that are similar in size and are often used in laboratories as test aerosols. Most aerosols are polydisperse, meaning that there is a large range of particle diameters within the aerosol. Exhaled breath is an example of a polydisperse aerosol with particle diameters ranging from less than 0.3 μm [3] to greater than 2000 μm [4], in concentrations depend on whether subject is nose-breathing, mouth-breathing, coughing, talking, or sneezing [3]. The terms "dust" and "fume" refer to aerosols containing solid particles; the terms "fog," "mist," and "spray" refer to

aerosols containing liquid particles. Liquid aerosol particles are nearly always spherical because of surface tension, whereas solid particles may be highly irregular in shape. For simplicity in characterizing the behavior of aerosols, nonspherical particles are often characterized in terms of equivalent spheres on the basis of equal diameter, density, or aerodynamic drag.

Polydisperse aerosols are best described using distribution curves in which mass, volume, or number of particles is on the y-axis, and particle-size is on the x-axis. Because there is a large distribution of particle sizes of interest (ranging from hundredths of micrometers to hundreds of micrometers), it is common to use a logarithmic scale of particle sizes on the x-axis. Because of the difficulty of preparing and publishing multiple distribution curves, aerosols are more commonly described mathematically in terms of average particle size and deviation from that size. The count median diameter is the diameter for which half of the total number of particles is smaller, and half is larger. This method of characterizing particle sizes in an aerosol is useful if one is concerned about the exact number of particles but is not concerned about the actual volume or mass of the particles. In most cases, however, one is concerned mainly with the actual volume (or mass) of aerosol particles, especially when dealing with drug dosages, pathogenic substances, or infectious biologic agents. For this reason, averaging by mass is often preferred to averaging by number of particles. The mass median diameter (MMD) is the diameter at which one half of the total mass is contributed to by particles larger than the MMD, and one half of the total mass is contributed to by particles smaller than the MMD. A simple analogy that demonstrates the need to distinguish between count and mass distributions is helpful: a bowl containing five grapes and five apples is 50% apples by count but may be 95% apples by mass. The distinction between count and mass distributions becomes important in discussing dosages of potentially toxic aerosolized therapies or in predicting safe exposure levels of pathogenic materials.

Based on the law of gravity, any object (in this case a microscopic particle) placed in a vacuum, independent of the object's size, shape, or mass, will accelerate toward the ground at 9.81 m/s^2 . If the falling object is not in vacuum, it will be subjected to an opposing force caused by air resistance. The faster the object falls, the more air resistance it encounters, until it reaches a velocity at which the air resistance is so great that the particle can no longer fall any faster. This maximum velocity is called "settling velocity," and is the rate at which the particle will settle out of still air. Table 1 shows the settling velocity of several different particle sizes and the time required for each particle to fall 1 m in still air.

The settling velocity of a spherical particle is proportional to the density of the particle and the diameter squared [5]. This relationship indicates that no measurement of a single characteristic of the particle (its mass, its density, or its true physical diameter) is sufficient to predict its settling velocity. In fact, at least two of these characteristics must be determined to predict the settling velocity. To add to this difficulty in predicting settling velocity, the

Table 1
Settling velocity

Aerodynamic diameter (μm)	Settling velocity (cm/s)	Time to fall 1 meter
100	25	4 s
30	2.7	37 s
10	0.31	5.4 min
3	0.028	60 min
0.3	0.00042	2.8 d
0.03	0.000022	53 d

shape of nonspherical particles also affects air resistance and thus settling velocity. To simplify the issue of settling velocity, the aerodynamic diameter of a particle is commonly determined. Aerodynamic diameter is not the true diameter of the particle but is the diameter of a water droplet that would have the same settling velocity and other characteristics as the particle itself [5]. For example, if a salt crystal with a diameter of $0.6 \mu\text{m}$ (based on true physical measurement) was shown experimentally to have the same settling velocity as a water droplet with a diameter of $0.3 \mu\text{m}$, the salt crystal and the water droplet would have the same aerodynamic diameter of $0.3 \mu\text{m}$. Two particles with the same aerodynamic diameter, even though actual diameters and densities are different, will behave similarly in terms of settling velocity, filtration capture, and airway deposition. Consequently, aerodynamic diameter is the most useful and prevalent method of describing the size of microscopic particles. The reader must be aware of the difference between actual physical size and aerodynamic diameter when applying rules of filtration to specific particles. For example, it would be an error to predict the behavior of the previously mentioned salt crystal ($0.6 \mu\text{m}$) by consulting established tables based on aerodynamic diameter if the measurement of size came from a microscope. If, however, the measurement of size came from a device that actually measures aerodynamic diameter, then the comparison is well founded. Analyzers that measure a particle's size by determining its settling velocity, such as the Anderson sampler or Cascade sampler, actually determine the aerodynamic diameter of the particle and not the actual true diameter. The average size of particles measured using these techniques would be described as the mass median aerodynamic diameter (MMAD). The MMAD is the diameter at which one half of the mass is contributed by particles larger than the MMAD, and one half of the mass is contributed by particles smaller than the MMAD. Because most particle sizers measure in terms of aerodynamic mass, and aerodynamic mass is the best predictor of particle behavior, the MMAD is the method most commonly used to describe aerosols encountered in industry and health care.

In infection control, the term "droplets" commonly refers to particles that settle onto horizontal surfaces quickly and generally have relatively large diameters. As the name indicates, typical droplets are liquid based and may contain relatively small amounts of solid organic and inorganic

matter. Droplet nuclei are desiccated droplets in which the liquid component has evaporated, and the remaining particle consists of an agglomeration of the remaining solid particles. Most droplets are large particles that will settle onto a horizontal surface relatively quickly (before they have had time to desiccate significantly) and typically within a short distance of its origin (often within 1 m but potentially further depending on initial trajectory, velocity, and rate of desiccation).

Smaller droplets or droplet nuclei have longer settling times and hence are more susceptible to sustained evaporation. Small droplets may evaporate to become droplet nuclei. Because evaporation decreases a particle's size, it slows its rate of settling, allowing more time to continue the evaporation process. Droplet evaporation is extremely rapid; the time required to desiccate is proportional to the volume of liquid in the droplet and to the relative humidity of the ambient air. For example, a 15- μm droplet of pure water exposed to air of 50% relative humidity at 20°C will evaporate completely in 0.35 seconds [5]. If the particle evaporates to a sufficiently small size, the rate of descent based on gravitational settling becomes insignificant, and the particle remains air-borne. Air-borne particles typically are considered to be less than 3 μm in diameter (a 3- μm particle will settle at a rate of about 1 m/h), and they can float along with air currents for extremely long periods of time and for long distances. If such a particle contains microorganisms or spores capable of surviving in a desiccated state, infectious disease can be transmitted through the air-borne route.

The concentration of air-borne particles in still air decreases in proportion to $1/d^3$, where d is the distance from the source of the aerosol [6]. For example, if two individuals are standing 2 meters and 4 meters, respectively, away from a source of air-borne particles in a still room, the individual at 2 meters is half the distance from the source and is exposed to eight times the number of air-borne particles as the individual at 4 meters.

Droplets containing salts or other soluble agents may not desiccate completely. Their retention of moisture depends on the quantity of soluble agent present and the relative humidity of the ambient air. For example, droplets of sodium chloride solution will not desiccate fully unless the relative humidity of the ambient air is less than 40% [5]. Because sodium chloride is present in respiratory secretions, variations in relative humidity in a health care facility can affect the final size of the particle and hence can affect the time the particle will remain suspended in air. It is the author's understanding that most health care facilities in North America maintain relative humidity below 40%, so it generally can be assumed that exhaled particles will desiccate completely when exposed to ambient conditions.

Particle capture in filters, on surfaces, and in airways

Aerosol particles, whether solid or liquid, generally attach firmly to any surface they contact. Likewise, if aerosol particles collide, they adhere and

form agglomerates. The main adhesive forces include surface tension (for liquid particles), electrostatic forces, and van der Waals forces. On particles less than 10 μm , these forces exceed other common forces by orders of magnitude. Although these adhesive forces are strong, solid particles still may avoid capture if the force of rebound is greater than the forces of attraction. The harder or larger the particle, or the greater its velocity, the more likely it is to avoid capture because of bounce. Rougher surfaces decrease the likelihood that a particle will bounce [5].

It is also possible for captured particles to be re-entrained into the aerosol under the right conditions, especially if the flow of air is high or the particle size is large. It is more likely that an agglomeration of particles will be re-entrained than single particles, simply because of the larger overall size. Although the mechanisms of re-entrainment are understood, it is not possible to predict accurately when re-entrainment might occur [5].

Fibrous filters are designed to increase the chances that a particle will collide with and adhere to the filter material while the carrier gas continues through the filter. Generally, fibrous filters are composed of a randomly woven mat of very fine fibers arranged to be perpendicular to the gas flow. Plastic, glass, or paper fibers are most common, and particles are captured when they collide with the individual filter fibers. The gas molecules passing through filter media must continually change direction to pass around all of the individual filter fibers as they flow through the mat of fibers. The path that a flow of gas takes around the filter fibers is called a streamline. A particle that perfectly follows the gas streamline through a filter basically has a roadmap to get through the filter without capture. Most particle capture occurs when the particle deviates from the gas streamline and makes contact with a filter fiber.

The face velocity (v) is the velocity at which the gas is moving relative to the filter fibers it is passing around. Face velocity is equal to the total flow (F) of gas through the filter, divided by the total surface area (A) of the filter that is exposed to the airstream:

$$v [\text{cm/s}] = F [\text{cm}^3/\text{s}] / A [\text{cm}^2]$$

This calculation assumes that the velocity of gas is the same through all sections of the filter material. Based on the Choanda effect, flow layering, turbulence, and variable filter design, this uniform velocity is unlikely; hence, the calculated face velocity is more likely to be the average face velocity for that filter. Particles suspended in the carrier gas generally travel at or close to the face velocity of the filter.

When a particle enters the filter, there are five basic mechanisms by which it can be captured by the filter fiber: inertial impaction, interception, diffusion caused by Brownian motion, gravitational settling, and electrostatic attraction [5]. Filters that rely solely upon the first four methods are referred to as "mechanical filters." Mechanical filters are generally made up of

a tightly packed mat of small filter fibers that cause high resistance per unit area of filter medium. The filter material is nearly always pleated to increase total surface area and therefore reduce the total resistance. Electrostatic filters use electrostatically charged filter fibers to increase particle capture and often use a much less dense mat of filter fibers. This loose weave has much lower resistance per unit area of filter medium and therefore generally does not need to be pleated. Although pleated mechanical filters almost always have higher filtration efficiencies than flat electrostatic filters, they are considerably more expensive to produce.

Inertial impaction occurs when, because of its inertia (mass \times velocity), a particle cannot follow the abrupt changes in direction of the gas streamlines [5]. The particle continues in a relatively straight path and impacts with the filter fiber (Fig. 1). Mass and velocity are the most important variables that determine the degree of inertial impaction. Higher face velocities or larger particle mass increase particle capture resulting from inertial impaction. Fig. 2 shows the relative efficiency of the inertial impaction mechanism with respect to particle aerodynamic diameter.

Interception occurs when a particle has low enough inertia that it tends to follow the gas streamlines but is captured because its diameter is large enough for it to make contact while passing the filter fiber (Fig. 3) [5]. The most important variables contributing to interception are the true physical particle diameter (not aerodynamic diameter), the diameter of the filter fiber, and the density of the filter fibers. Large, light (low density) particles experience higher degrees of interception. Interception is the only filtration mechanism that does not rely on the particle departing from the carrier gas streamline. Fig. 4 shows the relative efficiency of the interception mechanism with respect to particle aerodynamic diameter.

Brownian motion is the random chaotic motion of very small particles as they are bombarded by the surrounding gas molecules. Brownian motion causes the particle to deviate from the carrier gas streamline (Fig. 5), which increases its probability of making contact with a filter fiber [5]. Brownian motion is the most predominant mechanical method of particle capture for smaller particles (below about $0.1 \mu\text{m}$). The longer the particle is in close proximity to a filter fiber, the greater is the chance that it will impact the fiber and be captured. Therefore, lower face velocities improve particle

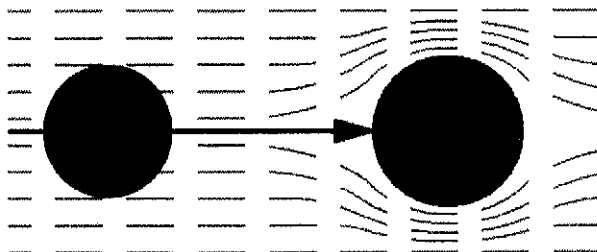


Fig. 1. Impaction of a particle onto a filter fiber.

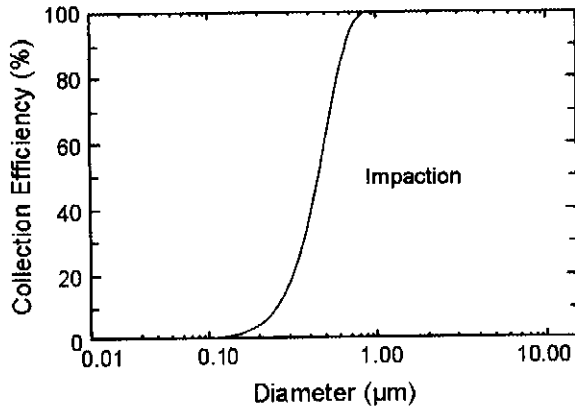


Fig. 2. Collection efficiency caused by impaction.

capture resulting from Brownian motion. Fig. 6 shows the relative efficiency of the Brownian deposition with respect to particle aerodynamic diameter.

Gravitational settling is simply the deviation of the particle from its gas streamline because of forces of gravity and has little bearing on particles smaller than $5 \mu\text{m}$ [5]. Fig. 7 shows the relative efficiency of gravitational settling with respect to particle aerodynamic diameter during filtration. The effects of gravitational settling change depending on whether gas flow through the filter medium is vertical or horizontal. Although gravitational settling is an important factor in how large droplets fall onto horizontal surfaces (eg, in a room), it is not typically a major factor in particle filtration, because the settling velocity is insignificant compared with the face velocity.

Electrostatic deposition occurs when electrostatic attraction causes particles to deviate from gas streamlines [5]. Typically electrostatic filter fibers are positively charged on one side and are negatively charged on the other. Charged particles are attracted to sections of filter fibers with a charge opposite their own. As neutral particles enter the electrical field, they form a dipole (equal opposite charges on opposing ends) and also are affected by electrostatic attraction to the charged filter fibers. The stronger the individual charges (either on the particles or the filter fibers), the lower the face velocity, or the smaller the particle, the more efficient electrostatic deposition will be. Fig. 8 shows the relative efficiency of the electrostatic attraction

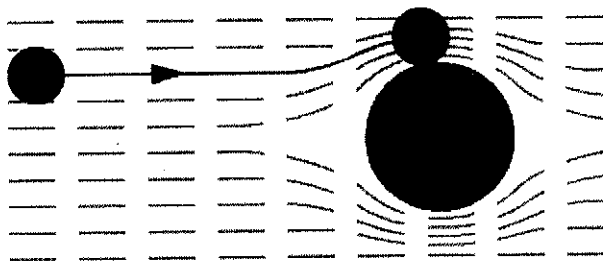


Fig. 3. Interception of a particle by a filter fiber.

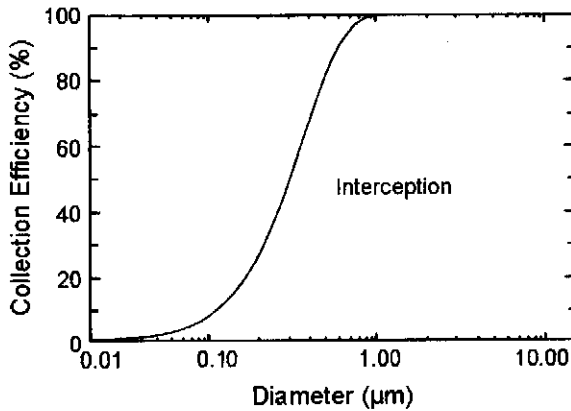


Fig. 4. Collection efficiency caused by interception.

mechanism with respect to particle aerodynamic diameter for electric fields of two different strengths. Most air-borne particulate material, whether solid or liquid, carries some electrostatic charge; such charged particles are readily attracted to electrostatically charged filter fibers. Most if not all NIOSH-certified respirators used in health care are made from filter material enhanced with electrostatic properties.

In filtration, penetration refers to the percentage of particles that pass completely through the filter. For example, if 1000 particles are used to challenge the filter, and 5 particles are detected downstream of the filter during the challenge, the penetration is 0.5% (5 of 1000). Conversely, the efficiency of a filter is the percentage of particles that are trapped by the filter. In this example, the efficiency is 99.5%. Generally, penetration and filter efficiency are described in terms of the particle size used as the filter challenge.

The overall efficiency of a filter depends on the individual efficiencies of the five basic deposition mechanisms at a given particle size and face velocity. Fig. 9 demonstrates how the individual efficiencies can be added conceptually to reveal the total filtration efficiency of a filter. Fibrous filters generally exhibit high efficiencies when challenged with relatively larger particle sizes (above 1–5 µm) because of high degrees of inertial impaction and interception. Filters also generally have high efficiencies at much smaller

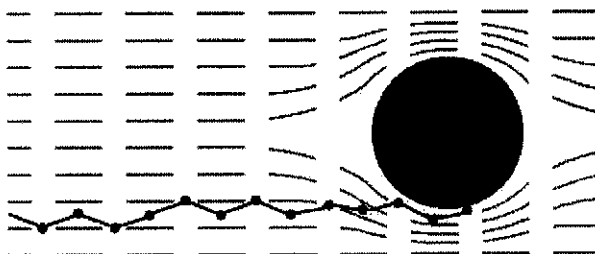


Fig. 5. Interception of a particle caused by Brownian motion.

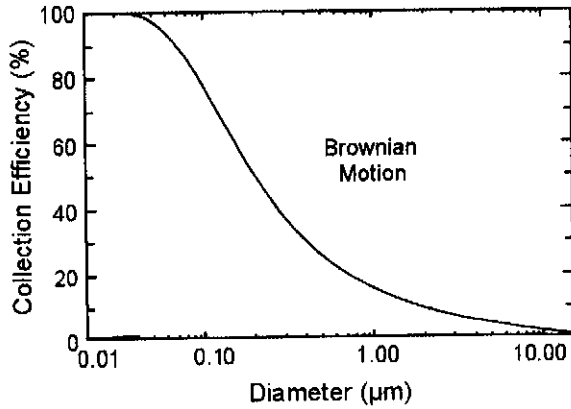


Fig. 6. Collection efficiency caused by Brownian motion.

particle sizes because of Brownian motion. There is an intermediate particle size, about $0.3 \mu\text{m}$, that is dominated by neither Brownian diffusion nor the impaction/interception mechanisms. This $0.3\text{-}\mu\text{m}$ particle size is referred to as the MPPS [1,2,5,7-9]. Particles both larger and smaller than the MPPS are trapped more efficiently by the filter, contrary to the common misconception that the smaller a particle is, the harder it will be to filter. On a distribution curve of collection efficiency, the MPPS is the lowest point on the total filter efficiency curve (see Fig. 9).

The MPPS can vary slightly based on filter design and on the velocity at which particles pass through the filter medium. Increasing face velocity has been shown to lower the MPPS. Particles carry more inertia at a higher face velocity than at a lower face velocity. This higher inertia means a $0.3\text{-}\mu\text{m}$ particle would be more susceptible to interception and impaction mechanisms, and the MPPS would shift to less than $0.3 \mu\text{m}$ [9]. At the same time, higher face velocities decrease the efficiency of Brownian diffusion and electrostatic attraction, further shifting the MPPS to a smaller value. Fig. 10 shows how the filtration efficiency and MPPS can change with

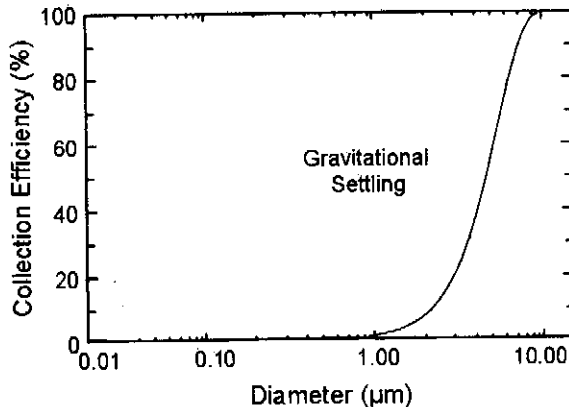


Fig. 7. Collection efficiency caused by gravitational settling.

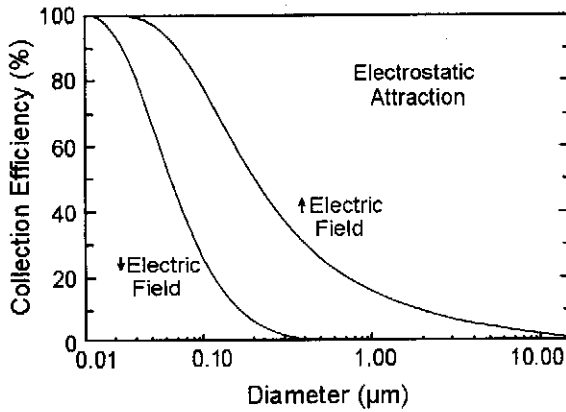


Fig. 8. Collection efficiency caused by electrostatic attraction.

differences in face velocity. In practice, the MPPS is generally considered to be a range from 0.1 to 0.5 μm .

Particle deposition within the airways is dictated by these same five mechanisms, but the mechanisms have quite different relative importance [5]. For deposition in the airways, and especially in the small airways (alveoli and bifurcations), diffusion caused by Brownian motion is an important deposition mechanism for particles less than about 0.5 μm . Interception is generally not a significant mechanism for deposition of particles in the lungs, unless the particles themselves are fibrous (eg, such as asbestos). Inertial impaction is the most important mechanism for larger particles, especially in large airways and bifurcations. Gravitational settling becomes important only in smaller bronchi, bronchioles, and alveoli, where airways are small, and velocities are slow [5]. Human and animal studies have shown that deposition in the respiratory tract is enhanced if the challenge particles are electrostatically charged, even though the airways have neutral charge

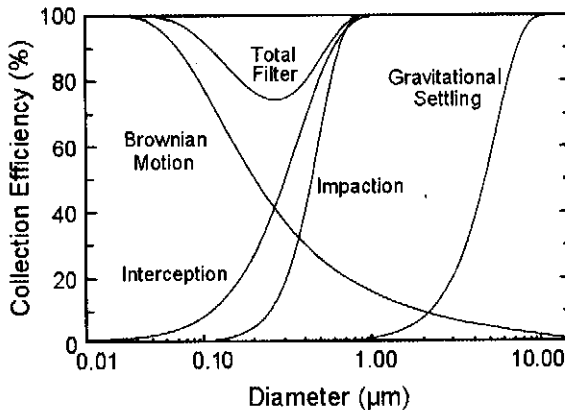


Fig. 9. Collection efficiency caused by all mechanisms. (Adapted from Hinds WC. Aerosol technology: properties, behavior, and measurement of airborne particles. 2nd edition. New York: Wiley; 1999. p. 198; with permission.)

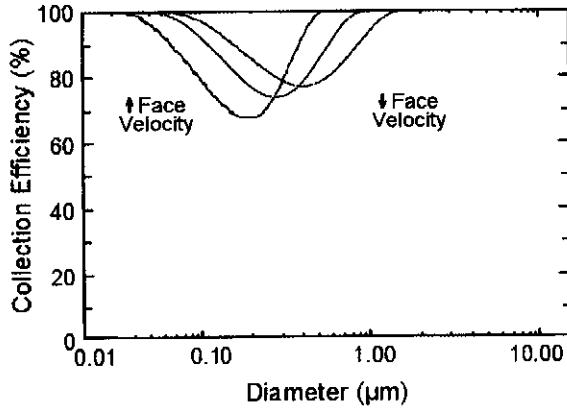


Fig. 10. Collection efficiency and face velocity.

[10,11]. Yu [12] describes the formation of “image forces” in the airways that cause this increase in electrostatic collection. When electrostatic enhancement does occur, its effect is predominantly on smaller particles at the level of the alveoli and small airways [10], similar to Brownian diffusion.

The inhalable fraction is the fraction of particles that enter through the mouth or nose during inhalation but do not necessarily deposit within the respiratory tract. By this definition, some of the particles included in the inhalable fraction may in fact be exhaled subsequently. Inhalable particle sizes range in size from less than $0.1 \mu\text{m}$ to larger than $185 \mu\text{m}$ [13]. Similarly, the thoracic fraction is the fraction of particles that pass beyond the larynx and enter the thorax but are not necessarily deposited there. Particles larger than $30 \mu\text{m}$ rarely pass through the larynx, because these large particles typically deposit within the mouth, nose, and pharynx. The respirable fraction is the fraction of particles that reach the alveolar regions but do not necessarily deposit there. Fig. 11 shows the collection efficiency of different-sized

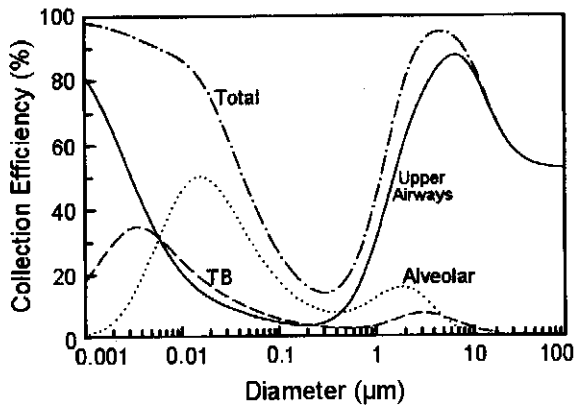


Fig. 11. Airway deposition. (Adapted from Hinds WC. *Aerosol technology: properties, behavior, and measurement of airborne particles*. 2nd edition. New York: Wiley; 1999. p. 241; with permission.)

particles in the respiratory tract. The particle least likely to deposit in the airways is the same size as the MPPS for filtration.

Although few particles larger than 10 μm pass this deeply into the lungs, about 97% of 1- μm particles reach alveolar regions. Actual deposition in the lungs is often much lower than the respirable fraction, especially for particles with diameters approaching the MPPS. For instance, although about 97% of 1- μm particles reach the alveolar region, only about 20% are deposited there [5]. Of particular interest is that only about 14% of 0.3- μm particles deposit in the respiratory system [14]. This percentage is of special concern, because this is the particle size that is most likely to penetrate a protective respirator. For example, if a perfectly fitting N95 respirator ($\geq 95\%$ efficiency) is challenged with 1000 0.3- μm particles, it would be expected that 950 of these particles (at minimum) would be captured, with 50 passing through to be inhaled. Allowing for 14% deposition of this particle size, approximately 7 particles would be deposited in the airways. In other words, approximately 1 in every 140 (0.71%) of these particles challenging the filter will be deposited within the lungs. Similarly, 1 in 700 (0.14%) MPPS particles will be deposited if an N99 respirator ($\geq 99\%$ efficiency) is used, and 1 in 2500 (0.04%) will be deposited if an N100 respirator ($\geq 99.97\%$ efficiency) is used. These percentages seem small, but hundreds of thousands or millions of particles can be expelled with a cough or sneeze. These estimations ignore the effects of the high relative humidity in the respiratory tract, which can increase the size of hygroscopic particles and affect the site and concentration of deposition in the respiratory tract [11]. If the particles in the previous example grew from 0.3 μm at the respirator to 1.0 μm in the alveoli, the overall number depositing in the airways would grow by about 40% (based on 20% deposition with 1.0- μm particles versus 14% deposition with 0.3- μm particles) [14].

Microorganisms as aerosols

Aerosol theory predicts that all particles behave similarly based on physical characteristics, and there is no theory or evidence that biologic particles should behave differently from any other particles. Therefore, nonbiologic surrogates can be used in place of biologic organisms to test particle behavior if the physical characteristics (size, shape, and density) are similar. Also, any aerosolized biologic agents (bacteria, viruses, fungi, or other particles), either as single entities or as part of droplets or agglomerations, will be deposited in airways and surfaces or captured by filters in the same manner as nonbiologic particles with similar physical characteristics. This important characteristic of aerosols allows filters and respirators to be tested with nonbiologic aerosols and the resulting data to be applicable to any aerosols, including biologic agents. Specifically, a filter's efficiency does not need to be tested by challenging it with rare or hazardous microorganisms. It is far

safer to use easier-to-detect particles as surrogates and to extrapolate the results to the original microorganism.

Although the biologic composition of a particle does not affect filtration or deposition directly, it may have a great bearing on the electrostatic charge that a particle can carry. Bacteria in solution have been shown to carry thousands of elemental charges [15], and aerosolized bacteria can be forced to carry well over 13,000 elemental charges, either positive or negative. This charge is a combination of the bacteria's own natural charge, which can itself be high, and the charge imposed by the aerosolization process [16,17]. The author is not aware of any published data on the naturally occurring charges found on air-borne microorganisms. For a particle of about 1 μm , as few as 50 elemental charges enhance particle capture [10]. Clearly, naturally aerosolized bacteria may display greatly enhanced filtration because of their inherent potential for high electrostatic charges. The same studies showed that sodium chloride particles exhibited a much lower total charge, approximately 400 elemental charges per particle, with most of these particles having less than 20 elemental charges [16]. This finding suggests that electrostatic charges on submicron droplets may be less likely to enhance filtration than the electrostatic charges on individual microorganisms. Therefore, the electrostatic properties of even single bacteria may cause a real-world filtration advantage when compared with a droplet-containing virus near the MPPS. In addition, spherical particles (such as droplets) are more penetrating than nonspherical particles (many bacteria) of the same aerodynamic diameter [18]. The total charges of these particles are well distributed, so although some particles will be highly positive and others will be highly negative, many will be close to neutral and will not exhibit any electrostatic enhancement to filtration. Also, highly charged particles released into the air are likely to have a particle-charge half-life of about 5 minutes, because they are neutralized by environmental ions in the air [5]. To ensure filters are being evaluated in a manner that covers the worst-case environmental conditions, they should be tested using electrostatically neutral particles.

It should now be clear that the most difficult particles to filter are electrostatically neutral spherical particles at the MPPS. Most bacteria are 0.3 μm in diameter or larger, so a worst-case filtration scenario for air-borne bacterial pathogens would involve desiccated air-borne bacteria without carrier droplets, because the added size and mass of the droplets would make them easier to filter. Most viruses are far smaller than the MPPS, so they would need to be carried in a droplet near 0.3 μm in diameter to constitute a worst-case filtration scenario. Both worst-case scenarios can occur naturally in the vicinity of an infected host, and filtration systems must be evaluated with these scenarios in mind. N95 masks have been shown to provide greater than 99.5% efficiency for bacteria the size and shape of *Mycobacterium tuberculosis* [19], which is significantly larger than the MPPS, but this high efficiency should not be expected to carry over to spherical droplets containing viruses nearer the MPPS.

Filter testing: the salt test method

Electrostatically neutral particles at the MPPS have become the standard particle for respirator testing and certification pursuant to NIOSH 42 CFR Part 84 (June 1995) [20], and breathing system filter testing and certification pursuant to International Organization for Standardization 23328-1:2003, "Breathing system filters for anaesthetic and respiratory use - Part 1: Salt test method to assess filtration performance" [21]. This salt test method for assessing respirators also is described by various other international standards associations, for example the European Committee for Standardization EN 149:2001, and Australian Standard AS1716.

The test procedure itself is fairly simple. A solution of sodium chloride is aerosolized, and the droplets pass through a drying chamber where they evaporate to the MPPS of 0.3 μm . The particles then pass through an electrostatic neutralizer that reduces the electrostatic charge to the Boltzmann equilibrium level. The number of sodium chloride particles downstream of the test filter is compared with the total number of particles upstream of the filter, giving the penetration value of the filter. Methods of counting these particles are well established and accurate. The test is performed once on a new filter and once on a filter that has been conditioned in a humidified environment for 24 hours or for the stated life of the filter if it is longer than 24 hours. The percentage of the particles of MPPS captured in the test filter is calculated both at the start of use and when the filter is due to be changed. Any particles larger or smaller than the test size would be filtered at higher efficiency than stated in the test results, so these data give a true reflection of the minimum effectiveness of the filter when challenged with a worst-case microbial or pathogenic challenge.

Although many (if not most) health care facilities demand to see the already well-established NIOSH certification when choosing appropriate respirators for staff use, the same is not true for breathing system filters. ISO 23328-1 is relatively new (issued late in 2003) and is a voluntary standard relatively unknown to health care administrators or purchasing departments.

To complicate matters for those purchasing filters, the most commonly reported filtration efficiency data for breathing system filters, both in medical literature and in product pamphlets, are still based on bacterial filtration efficiency (BFE) or viral filtration efficiency (VFE) tests. Authors publishing papers on BFE or VFE of infectious aerosols in medical literature have commonly ignored the fact that in terms of filtration, micro-organisms are just simple particles that can be categorized by aerodynamic diameter, using the same rules of filtration and deposition that apply to all other particulate matter. Instead of using sodium chloride testing that has been the standard for respirators for more than a decade, studies continue to be designed that attempt to count the number of bacteria or viruses that can pass through a filter in question. Unfortunately, these studies commonly have been

misrepresented in literature or are flawed by a lack of fundamental understanding of filtration mechanisms. None of these tests are truly standardized, although they are often based on United States Military Specification MilSpec-36954C (1975), which was developed to evaluate surgical facemasks more than 30 years ago.

Filter testing: the bacterial and viral filtration efficiency tests

The procedures for performing the BFE and VFE tests basically are identical. Specific nonpathogenic microorganisms are cultured, often based on their similarity in size to *M tuberculosis* (approximately $0.6 \times 1.3 \mu\text{m}$) or to typical viral pathogens (approximately $0.03 \mu\text{m}$). These microorganisms then are diluted in solution to a known concentration. The solution is aerosolized and is passed through the filter under test. The microbial challenge is quantified by multiplying the concentration of microorganisms in solution by the volume of solution aerosolized, and the number of microorganisms that pass through the filter is determined by counting the colonies formed after culturing the collection device. The test droplets generated typically average about $3.0 \mu\text{m}$ in diameter, which is about 10 times the diameter and about 1000 times the mass of the MPPS. Because of their relatively large mass, these droplets are extremely easy to filter based on the inertial impaction mechanism. Although the BFE test typically uses droplets that contain microorganisms with a size of $0.6 \mu\text{m} \times 1.3 \mu\text{m}$, and the VFE tests typically use droplets that contain microorganisms with a diameter of $0.03 \mu\text{m}$, both tests actually evaluate only the filter's ability to capture the $3.0\text{-}\mu\text{m}$ -diameter carrier droplets. Fig. 12 shows how the filtration of microorganisms can be enhanced by the use of these large carrier droplets. The product literature typically makes claims such as "more than 99.99% efficiency against *M tuberculosis*" for the BFE test, or "more than 99.99% efficiency at $0.027 \mu\text{m}$ " for VFE test. These claims induce a false sense of security in the individuals making filter-purchasing decisions and in the end-users of products tested in this manner.

In addition to flawed methodology, there are several technical problems with the BFE and VFE tests. These tests rely on unreliable methods to count the number of microorganisms that pass through the filter. The typical process uses agar plates or collection bottles that are placed in such a manner as to attempt to collect any particles that pass through the filter. Although $3.0 \mu\text{m}$ may be the average size in the challenge aerosol, there is a normal logarithmic distribution, so that there will be some particles closer to the MPPS, and some of these particles may still carry microorganisms. The particles that are most likely to pass through the filter are the ones closest to the MPPS; they also are the particles most likely to pass right through the collection bottle or to bypass the collection plate (that is, particles nearer the MPPS would be more likely to follow the gas streamlines right on through

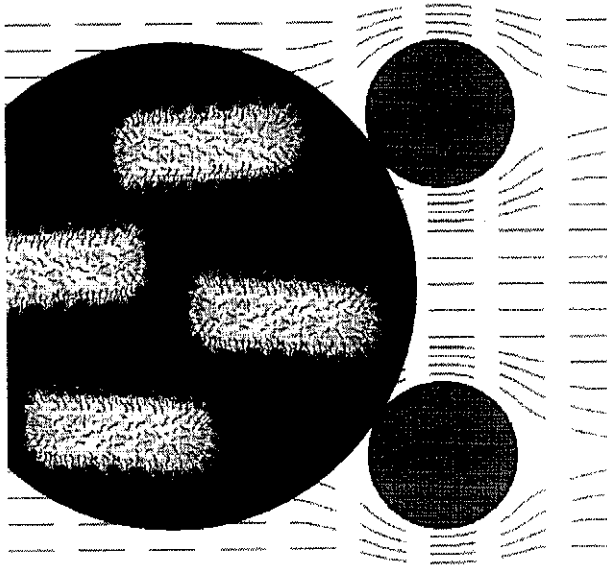


Fig. 12. Bacterial filtration efficiency test.

the collection device as well as through the filter). Therefore some microorganisms may pass through the filter but remain uncounted because they were never collected. Also, the process used to aerosolize these solutions can damage an unknown percentage of microorganisms to the point that they are nonviable. Only microorganisms that are undamaged by aerosolization will form colonies that can be counted.

There are enhanced-challenge variations of the BFE and VFE tests in which solutions containing larger initial concentrations of microorganisms are aerosolized. This method allows a manufacturer to claim "more nines" in their product specifications. For example, if 100 microorganisms challenge the filter, and none are detected in the collection system downstream of the filter, the manufacturer can claim "less than 1 in 100" (<1% penetration) or "more than 99% efficiency." If they challenge the filter with 100,000 microorganisms and none are detected in the downstream collection system, they can claim "less than 1 in 100,000" (<0.001% penetration) or "more than 99.999% efficiency." This test is not the "increased filter challenge" that it is purported to be, because there are simply more microorganisms contained in the same 3.0- μm carrier droplets; the presence of these extra microbes does not change the filter's ability to capture these relatively large carrier droplets. In essence, the reported efficiency of filters tested in this manner reflects the specific details of the test procedure itself rather than the actual capabilities of the filter in question.

At first glance, another variation of the VFE test seems to be a reasonable adaptation. In this case, a solution of 0.027- μm microorganisms is aerosolized and then put through a drying chamber so that the solution evaporates and only the individual microorganisms remain. The filter then is challenged with this incredibly small particle. Although this test is appealing at first

glance, in aerosol filtration smaller particles are not always harder to filter. In fact, because of the effects of Brownian motion at this particle size, it is relatively easy to filter these 0.027- μm challenge particles. This test, again, can give a purchaser a false sense of security when making filter choices.

A recent publication by the Medicines and Healthcare products Regulatory Agency in the United Kingdom [22] assessed the filtration efficiencies of 104 different breathing system filters available on the European market. The evaluation tested filters using sodium chloride particles of the MPPS. Of the 104 filters evaluated, 14 failed to meet NIOSH N95 criteria despite individual manufacturer's claims of better than 99.9% filtration of bacteria and viruses. An extreme example from this group is a filter that demonstrated only 26.4% efficiency during the sodium chloride worst-case challenge despite product literature that claims a "99.999% filtration efficiency rating." This example is intended not to implicate a specific company but merely to demonstrate that BFE and VFE claims are woefully inadequate and highly misleading.

Summary

The filtration of aerosols and the behavior of aerosolized particles are less intuitive and more complex than commonly indicated in the medical literature, but once the basic principles are presented, they are not difficult to understand or apply. Particles with diameters close to the most penetrating particle size are clearly the particles of greatest concern, interest, and value in considering the performance of different filtration devices, and this size has been identified as the standard particle size for testing respirators and breathing system filters. Although almost every level of health care now mandates the N95 (NIOSH rating) as the minimum rating for medical respirators, there is no such mandate regarding minimum efficiencies of breathing system filters. At least in North America, it still falls to each individual purchaser to ensure that these standardized tests are performed, because manufacturers adhere to these standards only on a voluntary basis. Government regulations similar to NIOSH 42 CFR 84 are needed for breathing system filters and should include a rating system such as N95, N99, or N100. For breathing system filters, the BFE and VFE tests are misleading and should be abandoned (or even better, banned) in favor of internationally recognized sodium chloride tests. Until then, manufacturers will be hesitant to abandon their BFE and VFE data, which give the appearance of vastly better performance than does the sodium chloride test.

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