

# ANESTHESIOLOGY

## Elastomeric Respirators for COVID-19 and the Next Respiratory Virus Pandemic: Essential Design Elements

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Elastomeric respirators are reusable respirators made of plastic or non-latex-containing rubber materials with exchangeable filter cartridges or canisters. Elastomeric respirators have been widely used in industry, but not in health care. We believe there is an urgent need to develop elastomeric respirators specifically for respiratory protection from pandemic respiratory viruses. While such elastomeric respirator development may not take place in time for widespread use during the current COVID-19 pandemic, it is vitally important to be prepared for the next respiratory pandemic, which could occur at any time.<sup>1</sup> There is also the possibility that immune escape of SARS-CoV-2 variants could result in a protracted COVID-19 pandemic, heightening the importance of effective respiratory protection.<sup>2</sup> In this article, we explain why respiratory protection is important, describe the major types of respiratory protection, and elaborate on the potential role for elastomeric respirators.

### Airborne Pathogens

Respiratory viruses may spread by fomite (touching a contaminated surface and then transferring the virus to the respiratory tract), droplet, or airborne routes (table 1). Determining the relative importance of these routes for an individual virus is difficult and may be controversial; for SARS-CoV-2, the fomite route of transmission is thought to be less important.<sup>3,4</sup> Many experts now believe that there is a continuous spectrum of different sized respiratory particles

### ABSTRACT

Respiratory viruses are transmitted *via* respiratory particles that are emitted when people breath, speak, cough, or sneeze. These particles span the size spectrum from visible droplets to airborne particles of hundreds of nanometers. Barrier face coverings (“cloth masks”) and surgical masks are loose-fitting and provide limited protection from airborne particles since air passes around the edges of the mask as well as through the filtering material. Respirators, which fit tightly to the face, provide more effective respiratory protection. Although healthcare workers have relied primarily on disposable filtering facepiece respirators (such as N95) during the COVID-19 pandemic, reusable elastomeric respirators have significant potential advantages for the COVID-19 and future respiratory virus pandemics. However, currently available elastomeric respirators were not designed primarily for healthcare or pandemic use and require further development to improve their suitability for this application. The authors believe that the development, implementation, and stockpiling of improved elastomeric respirators should be an international public health priority.

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produced by persons infected with respiratory viruses, and that the traditional distinction between droplet and airborne transmission is arbitrary and obsolete.<sup>5–7</sup> During the current COVID-19 pandemic, there has been controversy, as in previous respiratory virus pandemics, concerning whether respiratory protection should protect against only droplet or droplet and airborne particles.<sup>8</sup> However, there is now substantial evidence that airborne transmission of SARS-CoV-2 transmission is likely<sup>5,9–12</sup>; inhalation of respiratory particles may be the predominant route of transmission. Difficulty in culturing putative airborne pathogens from air samples because of various technical obstacles does not rule out airborne transmission.<sup>5,12</sup> Therefore, it seems prudent to protect healthcare workers (and the public) accordingly, by using respiratory protection whenever possible. The two major categories of respirators used for respiratory protection in health care include negative and positive pressure mode respirators.

### Negative Pressure Mode Respirators

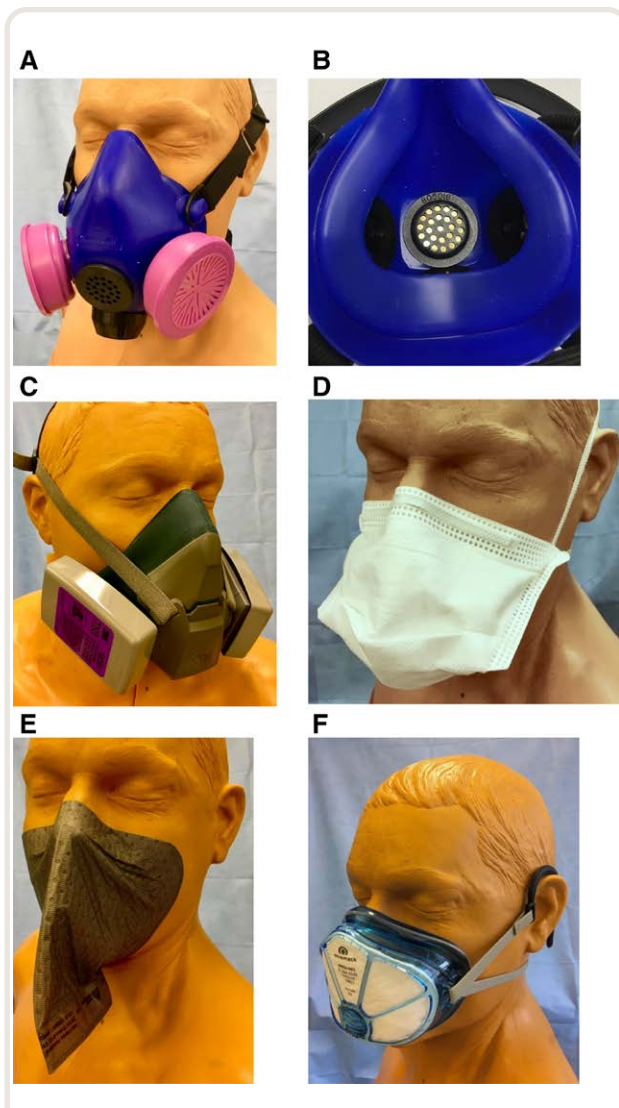
The wearer of a negative pressure mode respirator draws air through a filter and into a facepiece during inhalation. There are two main types of negative pressure respirators: disposable filtering facepiece respirators<sup>13</sup> (such as the N95 filtering facepiece respirators, familiar to many healthcare workers), and elastomeric respirators,<sup>14</sup> which are reusable (table 1; fig. 1). The effectiveness of respiratory protection depends upon fit, filtering efficiency, and resistance to breathing (table 1).

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**Table 1.** Respiratory Protection Terminology

Terminology	Alternative Terminology	Major Characteristics
Airborne particles	Smaller respiratory particles; aerosols	Typically smaller than droplets, with the limiting size being a bare virus, approximately 0.1 µm in diameter (airborne particles typically contain water and other molecules in addition to viruses). May remain suspended in the air for longer periods of time and travel over longer distances in comparison to droplets. Transmission of infection typically involves inhalation directly into the lungs.
Assigned Protection Factor		The workplace level of protection that a class of respirators is expected to provide if it is fit and used appropriately. A somewhat arbitrary number, representing the ratio of the concentration of contaminant in the ambient air compared to the concentration of contaminant inside the respirator based on typical performance of a particular class of respirator. For example, an Assigned Protection Factor of 10 means that the concentration of particles inside the mask will be reduced to 10% of the concentration in the ambient air. The Assigned Protection Factors for filtering facepiece and elastomeric half-mask respirators are both 10.
American Society for Testing and Materials F2100 Standards		Standards for surgical masks concern repelling blood or other fluids, filtering submicron particles and bacteria, fire resistance, and breathability; the American Society for Testing and Materials (West Conshohocken, Pennsylvania) has defined three barrier levels.
Barrier face covering	Cloth mask, homemade mask	Protects others mainly by preventing the release of large respiratory droplets; no or very limited prevention of small particle release; very limited protection of the wearer from droplets and aerosols.
Droplets	Larger respiratory particles	Traditionally defined as respiratory particles > 5 µm in diameter. Tend not to be suspended in the air for long periods of time, as they are relatively heavy. Traditional concept of droplet transmission of infection involves direct contact between droplets and mucous membranes such as the nose, mouth, or eyes, not inhalation of particles directly into the lungs.
Elastomeric respirator	Reusable respirator	Plastic or rubber mask, typically with filter cartridges or canisters; depending upon filter type, can be used for protection against chemicals as well as particles; regulated by the National Institute for Occupational Safety and Health (Washington, D.C.) in the United States.
Filtering efficiency		The filtration efficiency of a respirator is the degree to which the filter material removes particles from air passing through the filter. Filtering efficiency of respirators rated by National Institute for Occupational Safety and Health as 95, 99, or 100, corresponding to filtration of 95%, 99%, or 99.97% of 0.3-µm particles, which are usually the most penetrating particle size. In addition, the filters are designated with the letter N, R, or P, corresponding to "not resistant to oil," "somewhat resistant to oil," and "very resistant to oil," respectively. Oil resistance is not a factor in health care, and N, R, or P filters can be used. A National Institute for Occupational Safety and Health 100 filter rating is very similar to a high-efficiency particulate air filter rating, originally devised by the United States Department of Energy (Washington, D.C.).
Filtering facepiece respirator	Disposable respirator; examples include N95 (National Institute for Occupational Safety and Health); FFP2 (European Union); other designations depending upon origin and filtering characteristics	Protect against droplets and aerosols when seal against face is effective; regulated by National Institute for Occupational Safety and Health in the United States; may also be cleared for marketing by the Food and Drug Administration (Silver Spring, Maryland) for use as a surgical mask; National Institute for Occupational Safety and Health-certified respirators are required by the Occupational Safety and Health Administration (Washington, D.C.) in workplaces for personal protection.
Fit factor		A concept similar to the Assigned Protection Factor, but based on how well a specific respirator fits a specific individual. Measures the degree to which particles can enter through gaps between the face and the respirator. Does not test the filtering efficiency. For most respirators, gaps between the face and the respirator are a more significant route of entry than through the filtering material. The fit factor is the measured ratio of the contaminant concentration in ambient air to the concentration inside the respirator required to pass a quantitative fit test. The required fit factor for both a filtering facepiece and elastomeric respirator is 100. This is 10 times the Assigned Protection Factor of 10, which adds a "margin of safety."
Powered air purifying respirator	Reusable respirator	A fan draws air through a filter and then forces purified air into the face covering. The exhausted air escapes around the edges of the face covering and is not filtered. Level of respiratory protection generally greater than filtering facepiece respirators; regulated by National Institute for Occupational Safety and Health in the United States.
Surgical mask	Procedure mask, medical mask	Mainly protects from respiratory droplets, limited protection from aerosols; a few are cleared for marketing in the United States by the Food and Drug Administration and meet American Society for Testing and Materials F2100 standards.
User seal check		A maneuver performed each time a respirator is donned in an attempt to verify that there is an adequate seal to the face. Should be performed regardless of whether the user has passed a formal Occupational Safety and Health Administration fit test with the respirator. Difficult to execute for a filtering facepiece respirator because air can pass through the entire mask body, making it difficult or impossible to completely occlude the entire mask body to test whether air can be inhaled around the edges of the respirator. Relatively easy to execute for an elastomeric respirator by simply covering the breathing inlets with the palm of the hand.



**Fig. 1.** Examples of filtering facepiece respirators, elastomeric respirators, and a hybrid respirator. Elastomeric respirators with P100 filters enclosed in plastic cartridges are shown in *A* and *C*. Both elastomeric respirators have exhalation valves at the bottom of the front of the mask. The respirator in *A* also has a “speaking diaphragm” in the center front of the respirator. A closeup view of the speaking diaphragm is shown in *B*. The filtering facepiece respirator in *D* is a typical N95. The filtering facepiece respirator in *E* is a unique strapless N95 that is attached to the face by an adhesive strip around the edge of the mask. An example of a hybrid respirator design is shown in *F*, combining a plastic mask body and sealing surface with a melt-blown fabric filtering area. The example shown is a “quarter face” respirator that does not cover the chin; the other respirators shown are “half face” respirators; quarter face respirators have an Assigned Protection Factor of 5, while half face respirators have an Assigned Protection Factor of 10 (see table 1).

### Negative Pressure Mode Respirator Fit

Fit defines the extent to which there is an occlusive seal of the respirator with the face, preventing leakage and forcing

all inhaled and exhaled air to pass through the filtering material (or in some cases through an exhalation valve). In contrast, barrier face coverings<sup>15</sup> (“cloth masks”) and surgical masks<sup>16</sup> are not designed to make a tight seal to the face (table 1). Only when there is an occlusive seal with the face, as with a respirator, does almost all of the air entering the facepiece pass through the filtering material, providing the optimal opportunity to remove particles from the air.<sup>17,18</sup> In the United States, the Occupational Safety and Health Administration (Washington, D.C.) Respiratory Protection Standard<sup>19</sup> requires that employees must be medically cleared to wear a respirator and that employers must measure the fit of respirators for employees upon first selection and annually thereafter using standardized tests that may be qualitative or quantitative.<sup>19</sup> Numerous studies have shown that the fit of a filtering facepiece respirator varies considerably depending upon the particular design and materials, and the facial characteristics of an individual user; not all respirators fit the full range of human faces.<sup>20</sup> The face must be clean-shaven in order to obtain an effective fit. A recent American Society for Testing and Materials (West Conshohocken, Pennsylvania) standard for “respirator fit capability” may be used to characterize how well a particular respirator will fit a variety of facial characteristics.<sup>21</sup> Moreover, filtering facepiece respirators are disposable, and the quality of the fit may deteriorate with repeated use.<sup>22</sup>

### Negative Pressure Mode Respirator Filtering Efficiency

Filtering facepiece respirators typically utilize a layer of melt-blown polypropylene (or other synthetic material) fabric as the filter. The randomly oriented fibers of the melt-blown fabric filter particles by a combination of impaction, diffusion, and interception.<sup>23</sup> In addition, an electrostatic charge is often added to enhance filtration, causing the material to function as a permanent magnet, or “electret.”<sup>24</sup>

Elastomeric respirators are constructed of various solid plastic or rubber materials that form the mask body and the portion of the mask that seals to the face. Filtering is accomplished by one or more exchangeable filters, constructed of material similar to that of filtering facepiece respirators, that attach to the mask body. The filtering material may be protected within a canister or cartridge (figs. 1 and 2). In the United States, the National Institute for Occupational Safety and Health (Washington, D.C.), a branch of the Centers for Disease Control and Prevention (Atlanta, Georgia), certifies the filtering efficiency of respirators using standardized tests<sup>25</sup> (table 1).

### Negative Pressure Mode Respirator Resistance to Breathing

In addition to fit and filtration, resistance to breathing is an important property. Increased resistance to breathing results in increased negative and positive pressures inside the respirator during inhalation and exhalation, respectively, which could





**Fig. 2.** Examples of elastomeric respirator filters. The outer facing side of the filters is shown in the *upper photos*, and the side of the filters that attaches to the respirator is shown in the *lower photos*. Both filters are P100 (equivalent to high-efficiency particulate air). The filtering material of the *left* filter is exposed, while the filtering material of the *right* filter is completely enclosed in plastic. The *right* filters are also shown mounted on an elastomeric respirator in fig. 1C.

increase leakage around the respirator facepiece. Resistance to breathing also affects comfort and tolerability.<sup>26</sup> In the United States, the National Institute for Occupational Safety and Health requires that respirator filtering material be tested for the pressure gradient across the filtering material at 85 l/min constant airflow; the “inspiratory” pressure gradient must be less than 35 mm H<sub>2</sub>O (343 Pa), and “expiratory” pressure gradient must be less than 25 mm H<sub>2</sub>O (245 Pa). Methods for testing the pressure gradient across filtering material typically specify the cross-sectional area of the material to be tested, since the cross-sectional area affects the pressure gradient under conditions of constant volumetric flow rate. The National Institute for Occupational Safety and Health method for certifying filtering facepiece respirators specifies

that the entire respirator is sealed onto a plate for testing; approved filtering facepiece respirators typically have inspiratory and expiratory pressure gradients in the approximate range of 5 to 15 mm H<sub>2</sub>O at 85 l/min airflow.<sup>27</sup> Currently, there is not a standardized test for measuring the pressure gradient across a respirator during actual use. A study of a single model of a filtering facepiece respirator found peak pressure gradients of less than 20 mm H<sub>2</sub>O during exercise.<sup>28</sup>

### Positive Pressure Mode Respirators

Powered air purifying respirators employ a fan or pump that brings air through the filter and into the facepiece. Filtration is important, but fit is less so; a powered air purifying

respirator with a loose-fitting hood offers greater protection to the wearer than an N95 filtering facepiece respirator because it provides more than enough filtered air to overcome any inward airflow between the hood and the wearer's head.<sup>29</sup> Powered air purifying respirators with a loose-fitting hood generally have an Assigned Protection Factor (table 1) of 25, or 2.5 times the Assigned Protection Factor of 10 for a filtering facepiece or elastomeric respirator.<sup>19</sup> Loose-fitting powered air purifying respirators have the advantage of not requiring fit testing, and contrary to negative pressure mode respirators, do not increase resistance to breathing. Their performance is not affected by the presence of facial hair as they do not make a tight seal to the face. It is important to understand that the exhaled air passes around the edges of a loose-fitting powered air purifying respirator hood without filtration; only the inhaled air is filtered.

Disadvantages of powered air purifying respirators include their greater complexity of use (*i.e.*, fan motors and batteries), higher cost, and the possibility of impaired communication caused by fan noise. A potentially serious shortcoming of loose-fitting powered air purifying respirators is that the exhaled air is exhausted into the ambient air without filtration. This could hypothetically result in contamination of a sterile field or transmission of a respiratory pathogen by the wearer.<sup>30</sup> The unfiltered exhaust from a powered air purifying respirator is analogous to an unfiltered exhalation valve on a negative pressure mode respirator. We suggest that powered air purifying respirators should be available for healthcare workers who, because of facial features or facial hair, are unable to be fitted for a filtering facepiece or elastomeric respirator, or when an increased Assigned Protection Factor is desired. However, we also suggest that during a pandemic, negative pressure mode respirators (*i.e.*, filtering facepiece respirators or elastomeric respirators) are likely to be a better solution for providing respiratory protection for large numbers of healthcare workers.

Tight-fitting half facepiece powered air purifying respirators are also available, although they have been used much more widely in industry than in health care (fig. 3). Tight-fitting powered air purifying respirators require fit testing and would not be suitable for use with facial hair that interferes with the seal of the mask body to the face. An Assigned Protection Factor of 50 is possible, five times that of a negative pressure elastomeric respirator and twice that of a typical loose-fitting powered air purifying respirator,<sup>19</sup> making this an attractive option when higher levels of protection are desired.

### Full Face Respirators

Full face elastomeric respirators (sometimes referred to as “gas masks”) that cover the eyes, nose, and mouth within a single mask body are another option to consider. Such respirators are used routinely by the military, police, and fire fighters and for industrial applications in which infectious agents, chemical toxins, or radioactive particles can irritate or damage the eyes

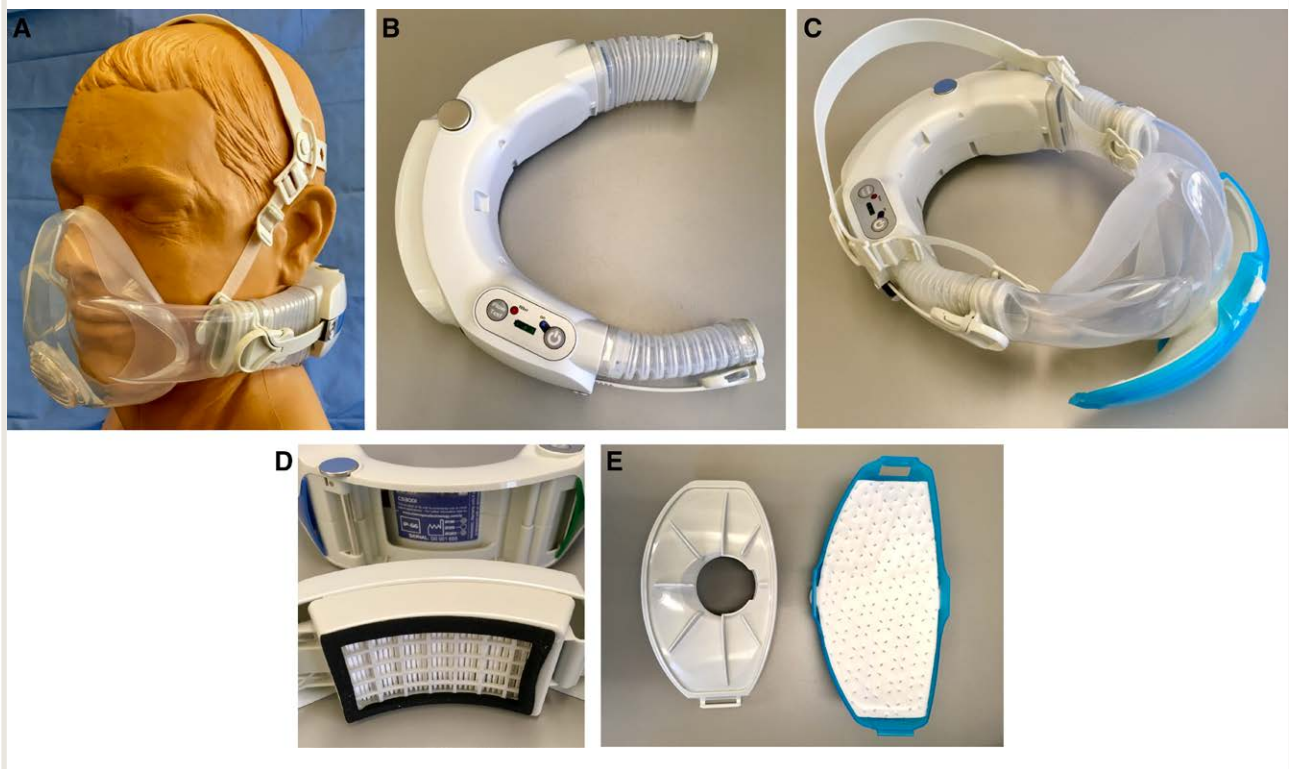
or gain entry to the body through the eyes, as well as the respiratory system. While eye protection in the form of glasses or goggles has been advised for protection from SARS-CoV-2,<sup>31</sup> the evidence for respiratory viruses causing infection from contact with the conjunctiva is not strong.<sup>32–37</sup> In general, full face masks are heavier, are less comfortable in warm environments, and may have greater interference with the field of vision in comparison to half masks (which do not cover the eyes). Nevertheless, a study of acceptability to healthcare workers of military-style elastomeric full face respirators in comparison to filtering facepiece respirators (used with eyeglasses or goggles) found a high level of acceptance for the full face respirators when worn for brief periods (up to 40 min).<sup>38</sup>

### Surgical Masks

It is important to note that while surgical masks are typically constructed from melt-blown fabric, and bear some superficial physical resemblance to filtering facepiece respirators, surgical masks are not respirators. Some surgical masks are cleared for marketing (in the United States) by the Food and Drug Administration (Silver Spring, Maryland) and meet American Society for Testing and Materials F2100 standards<sup>16</sup> (table 1). Surgical masks are intended to block large droplets, splashes, sprays, or splatter from reaching the mouth or nose and to prevent the user's droplets from exposing others. Surgical masks may capture some but not all of the particles contained in a wearer's cough or sneeze.<sup>39</sup> Since surgical masks are not designed to make an occlusive seal with the face, the protection from inhalation or exhalation of infectious particles will be limited in comparison to a properly fitted respirator.<sup>40–46</sup> The American Conference of Governmental Industrial Hygienists (Cincinnati, Ohio) has published an informative graphic illustrating the comparative effectiveness of cloth face coverings, surgical masks, and respirators.<sup>47</sup>

### Filtering Facepiece versus Elastomeric Respirators

Filtering facepiece respirators such as N95 or the European Union equivalent FFP2 have been avidly sought during the COVID-19 pandemic; public health authorities initially advised that these respirators should only be used by healthcare workers, but recently some governments have recommended or even required their use by the public.<sup>48</sup> While filtering facepiece respirators provide effective respirator protection when properly fitted, they have significant shortcomings (table 2). A major shortcoming is the overwhelming number of respirators required during a respiratory pandemic, inevitably resulting in acute shortages, even when respirators are stockpiled in advance. During the COVID-19 pandemic, due to the shortage of respirators, there were numerous attempts to construct homemade respirators using three-dimensional printed materials, respiratory therapy equipment, anesthesia circuit filters, and other available components.<sup>49–51</sup> This situation revealed the critical shortage of commercially available respiratory protection. To the contrary, elastomeric



**Fig. 3.** An example of a tight-fitting, half facepiece powered air purifying respirator is shown in *A* (CleanSpace Technology; Australia); the unfiltered exhalation valve is in the center of the facepiece. In *B*, another view of the battery and fan unit is shown. In *C*, a view of the accessory N95 filter attachment for the exhalation valve is shown; when used, filtration of the exhalation valve provides “source control,” preventing the wearer of the respirator from exhaling respiratory pathogens into the surrounding air. This respirator is intended to make a highly effective seal against the face, and should be fit tested before use, just as with a negative pressure elastomeric respirator or filtering facepiece respirator. Air is drawn through a high-efficiency particulate air filter (shown in *D*) and pushed into the respirator under positive pressure by the battery-powered fan located behind the wearer’s head. Exhalation occurs through an unfiltered valve on the front of the respirator, unless the accessory N95 filter is attached to the exhalation valve (the replaceable N95 filter is shown inside of the filter holder in *E*). This respirator has at least three advantages compared to a loose-fitting powered air purifying respirator. First, because this respirator has both a tight seal against the face and positive pressure produced by the battery powered fan, the Assigned Protection Factor is 50, twice that of a typical loose-fitting powered air purifying respirator, or five times that of a negative pressure elastomeric respirator. Second, it is possible to filter the exhaled air, which is not possible with a loose-fitting powered air purifying respirator. Third, if the power source or fan fails (for example, if the battery is exhausted), the respirator will function as an ordinary negative pressure elastomeric respirator, with the wearer pulling inhaled air through the high-efficiency particulate air filter; if a loose-fitting powered air purifying respirator power source or fan fails, there is no respiratory protection.

respirators can be used for prolonged periods of time, and thus provide a durable solution during a pandemic.

Elastomeric respirators are widely used outside of health care for protection from aerosols and harmful vapors and gases. Their use in health care has been limited, but successful implementation has been reported.<sup>52–54</sup> In 2019, before the COVID-19 pandemic, a consensus report from the National Academy of Sciences, Engineering, and Medicine (Washington, D.C.) concluded that “reusable elastomeric respirators could be a viable option for use in surge situations” and that surge use would be enhanced if “reusable elastomeric respirators were a part of healthcare facilities’ day-to-day respiratory protection program.”<sup>55</sup> However, the report also acknowledged the shortcomings of existing elastomeric

respirator products, and recommended “design of innovative reusable respirators and the implementation of robust respiratory protection programs...taking into account the distinctive characteristics of the healthcare workplace...” In light of the experience gained with respirators during the COVID-19 pandemic, this document now seems prescient.

There are several potential advantages of elastomeric respirators in comparison to filtering facepiece respirators (table 2).<sup>56</sup> Elastomeric respirators are ideally suited to pandemic surge use because they can be reused indefinitely, and filter cartridges or canisters can last for extended periods of time (see the Durability of Elastomeric Respirators section). Elastomeric respirators are capable of robust user seal checks because occlusion of the filter ports completely



**Table 2.** Elastomeric Respirator Compared to Filtering Facepiece Respirator

	Elastomeric Respirator	Filtering Facepiece Respirator
Value during a surge	Extended use, could last for entire pandemic. Filters can last for extended periods.	Disposable. Very large numbers of masks required during a sustained pandemic.
User seal check	User seal check is robust.	User seal check is not robust.
Cost	Individual respirator and set of filters more expensive than a single filtering facepiece respirator but much less expensive during prolonged usage.	Individual respirators less expensive than an elastomeric respirator and filters but more expensive during prolonged usage due to the large numbers of respirators required.
Cleaning and disinfection	Required.	Disposable.

prevents breathing if the mask makes an effective seal to the face. In addition, elastomeric respirators tend to have better fit<sup>57</sup> than filtering facepiece respirators.

### Durability of Elastomeric Respirators

As already mentioned, the advantage of elastomeric respirators is that a set of filters can last for an extended period of time<sup>58</sup>; however, the precise longevity is uncertain because the concentration and nature of particles to be filtered will have a significant effect on the lifetime of the filter. High-efficiency filters such as 95 (FFP2), 99 (FFP3), 100 series (N, R, or P), or high-efficiency particulate air filters can be used until they load with particles to the point that the resistance to breathing becomes excessive. Particles that are filtered become tightly bound to the filtering material by Van der Waals forces and do not come out of the filter in significant quantities.<sup>59</sup> When filters are used in relatively dust-free environments such as hospitals, they would be expected to be highly durable, possibly allowing users to work through a pandemic with one or two sets of filters. Filters can be encased in plastic enclosures that can be handled without touching the filter material itself, allowing for external cleaning by, for example, disinfecting wipes (figs. 1 and 2). An ideal elastomeric respirator for a pandemic should be designed with filter ports able to accommodate filters from multiple manufacturers (to prevent supply chain disruptions). Since there is not a universal filter connection design, the use of filters from multiple sources would require the use of adapters specifically made for this purpose.<sup>38</sup> Sources of filters during a surge might include anesthesia and ventilator breathing circuit filters.<sup>60</sup> In the United States, the National Institute for Occupational Safety and Health would need to be involved in the design and certification of novel elastomeric respirators designed for use with a variety of filters.

### Developing Elastomeric Respirators

Existing elastomeric respirators should undergo further development to improve their functionality. The properties of ideal elastomeric respirators are shown in table 3, and an artist's conception of a future respirator is shown in fig. 4 (filters removed to show the respirator facepiece more clearly). Elastomeric respirators can make verbal communication difficult, in most cases more so than filtering facepiece respirators.<sup>61,62</sup> A few

elastomeric respirators are equipped with a “speaking diaphragm” (fig. 1), which transmits sounds by a thin disc located in a circumscribed area of the mask body. For elastomeric respirators to succeed in health care, sound transmission must be improved substantially by the use of “speaking diaphragms” or other measures. Transparent mask materials may also assist with effective communication by making facial expressions and lip movement discernable.<sup>63</sup> Management of moisture is also a potential challenge since condensation of exhaled water vapor inside the mask can result in accumulation of moisture.

All but a few available elastomeric respirators have an unfiltered, valved exhalation port, which is undesirable in healthcare settings. Unfiltered exhaled air may contaminate a sterile field during a procedure, or result in transmission of a respiratory pathogen if the person wearing the respirator is infected. While these exhalation ports can be overcome by user modifications, such as by covering the exhalation port and removing the inhalation port valves, a respirator designed either without an exhalation port or with an exhalation port that can be switched off would be preferable. In some nonpandemic situations, unfiltered exhaled air may be acceptable—for example, if the person wearing the respirator is extremely unlikely to be infected with a specific transmissible respiratory pathogen (e.g., *Mycobacterium tuberculosis* in low prevalence areas). Some users have worn surgical masks over an elastomeric respirator with the idea of providing filtration for the exhaled air; however, this solution is unreliable due to the shortcomings of surgical masks described in the Surgical Masks section.

### Cleaning Elastomeric Respirators

One of the potential challenges for elastomeric respirators is cleaning. Reusable respirators require periodic cleaning and decontamination. Elastomeric respirators have typically been designed for low-level disinfection such as cleaning with soap and water, disinfectant wipes, dishwasher disinfection at low temperature, or immersion in relatively weak chemicals such as diluted bleach.<sup>64</sup> While the SARS-CoV-2 virus is inactivated by low-level disinfection, many other pathogens are resistant to this method. The elastomeric respirator is in close proximity to the user's mouth, nose, and airway, has contact with respiratory secretions, and has potential contact with a wide variety of

**Table 3.** Properties of an Ideal Pandemic Elastomeric Respirator

Desired Property	Details
Possibility for high level disinfection* Good fit for most users	Would tolerate heat or chemicals required for disinfection. The design of the mask body and straps would result in such good fit for most users that a user seal check could reasonably replace the need for formal fit testing during emergency or surge use. Currently such respirators do not exist, and regulators in the United States require fit testing of all respirators. Manufacture an adequate range of sizes to accommodate all users.
Comfortable for prolonged use High-efficiency filter cartridges could be subjected to low level decontamination of the plastic enclosing the filter Adaptable to filters from diverse sources	Lightweight, with a sealing surface that is comfortable for several hours of continuous use. High-efficiency filters enclosed in plastic cartridges can be subjected to low-level surface decontamination with disinfectant wipes. Filter life expectancy during use in relatively dust-free environments could be measured in months to years. In anticipation of supply chain disruption during a pandemic, the filter ports should be designed with adaptors for compatibility with filters from multiple sources, possibly including filters for anesthesia machine and ventilator circuits. In the United States, such designs would require approval by National Institute for Occupational Safety and Health (Washington, D.C.). Filter surface area would be large enough to minimize resistance to breathing.
Low resistance to breathing Unfiltered exhalation valve would either be eliminated or could be disabled Designed for communication	Filter surface area would be large enough to minimize resistance to breathing. Exhalation filtered through the same filter cartridges as inhalation. Ease of communication would be a key design feature including a transparent mask body and a speaking diaphragm, or other speech-enhancing features.
Moisture management Compatibility with eyeglasses, goggles, and face shields with good field of view Magnetic resonance image scanner compatibility	Mitigation of condensation of moisture inside the mask body. The body of the respirator should not interfere with eye protection such as goggles or face shields. Filters should be kept small enough not to interfere with field of view. Ferromagnetic parts should be avoided for magnetic resonance image scanner compatibility.
Long storage life Minimize environmental impact Minimize costs	Mask bodies and filters should be stable during prolonged storage to facilitate stockpiling. Recyclable materials are preferred when possible. Minimizing costs facilitates stockpiling and implementation in middle- and low-income countries.

\*High-level disinfection is the process of complete elimination of all microorganisms in or on a device, with the exception of a small numbers of bacterial spores.

pathogens commonly found in the healthcare environment, including multidrug-resistant organisms. Therefore, an argument could be made that elastomeric respirators are semicritical devices that should be subject to high-level disinfection.<sup>65</sup> Semicritical devices are those that come into contact with intact mucous membranes. High-level disinfection destroys all microorganisms except some bacterial spores. High-level disinfection could be particularly important if elastomeric respirators are processed by a hospital central processing unit and reissued to multiple users. High-level disinfection would require that elastomeric respirators be submersible (with the filter cartridges removed), and that the materials be resistant to heat or chemicals required for high-level disinfection. During surge conditions when other disinfection processes may be in short supply, heat-resistant respirator materials could be disinfected with boiling water.<sup>66</sup> The hard surfaces of reusable filter cartridges or canisters (fig. 2) could be cleaned with disinfectant wipes (low-level disinfection) between uses.

### Hybrid Filtering Facepiece and Elastomeric Respirator Designs

There are several examples of respirators that combine a plastic or rubber mask frame and sealing surface with melt-blown fabric filtering, rather than filter cartridges or canisters. Thus, these respirators have features of both traditional filtering facepiece respirators and elastomeric respirators. An example of such a hybrid respirator is shown in fig. 1.

### Environmental, Equity, Diversity, and Economic Considerations

The environmental impact of elastomeric respirators in comparison to disposable filtering facepiece respirators has not been well-studied. The environmental impact of cleaning reusable respirators should be considered. Respiratory protection must be effective and available for all people who need it. The experience of the COVID-19 pandemic has clearly shown that control of viral transmission must occur everywhere in the world in order to prevent the selection of more fit and dangerous variants of the virus. Respirators must be designed to effectively fit the wide variety of facial shapes and sizes found around the globe. Respirators must be produced in large enough numbers and at a low enough cost to ensure availability to low- and middle-income countries.

### Conclusions

Elastomeric respirators have significant advantages during respiratory pandemics due to their durability and capacity for repeated use. Unlike filtering facepiece respirators, elastomeric respirators allow for robust user seal checks. However, to optimize their utility in healthcare settings, elastomeric respirators should be further enhanced with respect to ease of communication, moisture control, suitability for high-level disinfection, capacity to filter exhaled air, and adaptability to filters from multiple manufacturers. The authors believe that the development, implementation,





**Fig. 4.** Artist's conception of improved elastomeric respirator, with filter ports on either side of the respirator facepiece; the filters are deliberately not shown. The respirator body is transparent, and there is a speaking diaphragm to facilitate communication. The respirator would accommodate a wide variety of filters through the use of adapters, which could make the respirator more suitable to surge situations in which the supply chain for filters could be interrupted. The sealing surface is highlighted. There is no exhalation port; inhalation and exhalation take place through the same filters. Straps that hold the respirator onto the face are deliberately not shown, but are an important feature for fit and comfort. In the United States, respirators are certified for use by the National Institute for Occupational Safety and Health (Washington, D.C.); thus, the National Institute for Occupational Safety and Health would need to be involved in improved elastomeric respirator design.

and stockpiling of improved elastomeric respirators around the world should be an international public health priority.

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### Competing Interests

The authors declare no competing interests.

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## ANESTHESIOLOGY REFLECTIONS FROM THE WOOD LIBRARY-MUSEUM

# Lulling Carnations to Sleep, Ethylene Ripens with Anesthetic Powers



In 1878, famed French physiologist Claude Bernard reported on ether's ability to "anesthetize" *Mimosa pudica*, a plant known for its rapid movements to touch. Placing an ether-soaked sponge next to the species had abolished its sensitivity to contact. Thirty years later, North American carnation growers mourned the mysterious narcotization of their flowers (*right*) in Chicago's greenhouses. Scientists at the University of Chicago soon determined that ethylene (*left*), a fruit-ripening greenhouse gas, had caused open carnation petals to droop and nascent buds to remain closed. Physiologists A. B. Luckhardt and J. B. Carter then tried to determine ethylene's toxicity in animals, only to discover its anesthetizing properties instead. In 1923, they reported in *JAMA* (8:765–70) ethylene-induced surgical anesthesia first in animals and then in humans (*i.e.*, the study authors and two surgeons). That same year, Isabella Herb, M.D., chief physician anesthetist at Chicago's Presbyterian Hospital, became the first to administer ethylene clinically. Initially lauded as a superior alternative to nitrous oxide for both faster onset and deeper anesthetic effect, ethylene's popularity bloomed for a time but then wilted, given its odor and explosivity. (Copyright © the American Society of Anesthesiologists' Wood Library-Museum of Anesthesiology.)

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