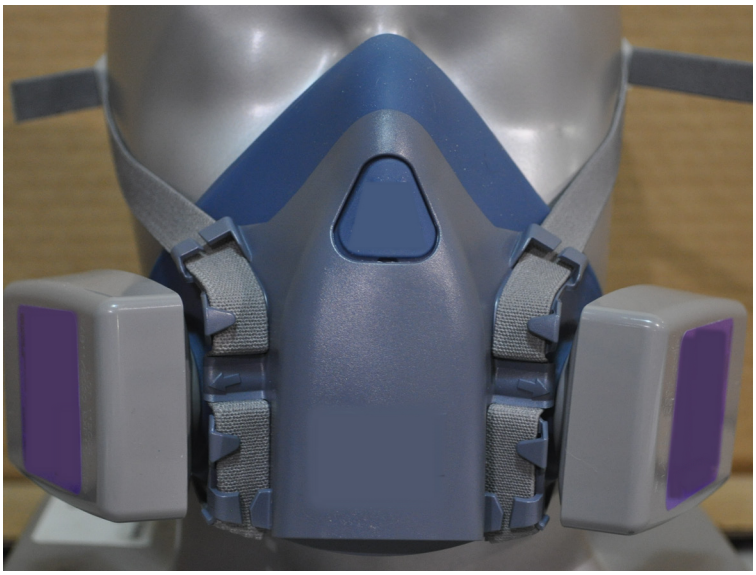
Technical Report

Evaluation of Exhalation Resistance and Inspired Carbon Dioxide Concentration in Elastomeric Half-Mask Respirators with Modified or Covered Exhalation Valves






Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

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Evaluation of Exhalation Resistance and Inspired Carbon Dioxide Concentration in Elastomeric Half-Mask Respirators with Modified or Covered Exhalation Valves

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

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ACRONYMS AND ABBREVIATIONS

APR	air-purifying respirator
CDC	Centers for Disease Control and Prevention
CO_2	carbon dioxide
EHMR	elastomeric half-mask respirator
FFR	filtering facepiece respirator
NIOSH	National Institute for Occupational Safety and Health
OSHA	Occupational Safety and Health Administration
PAPR	powered air-purifying respirator
STP	Standard Testing Procedure

UNIT OF MEASURE ABBREVIATIONS

hertz	Hz
L/min	liters per minute
µm	micrometers
mg/m^3	milligrams per cubic meter
mm	millimeters
mmH_2O	millimeters of water
mmHg	millimeters of mercury

EXECUTIVE SUMMARY

Elastomeric half-mask respirators (EHMRs) and filtering facepiece respirators (FFRs), the most common filter class being "N95," are both classified as air-purifying respirators. Unlike FFRs, which are not designed to be cleaned or disinfected, EHMRs are designed to be routinely cleaned, which could include disinfection, and maintained for longer-term use. Their reusability and durability to withstand disinfection makes EHMRs appealing for use in the healthcare industry.

One design feature found in most commercially available EHMRs is an exhalation valve. Exhalation valves are intended to increase user comfort by reducing the breathing resistance during exhalation, and they may also reduce moisture and heat buildup in the respirator facepiece. During exhalation, when subjected to the positive pressure created in the respirator facepiece by the user's exhaled breath, the exhalation valve opens and allows the exhaled breath to exhaust, unfiltered, into the environment.

The degree of source control—i.e., the use of well-fitting cloth masks, facemasks, or respirators to cover a person's mouth and nose to prevent the spread of respiratory secretions when they are breathing, talking, sneezing, or coughing—provided by EHMRs with exhalation valves is not known. As a result, healthcare workers who are wearing an EHMR with an exhalation valve and infected with a contagious respiratory pathogen may unknowingly spread the pathogen to those around them via unfiltered breath exhausting from the exhalation valve. Current guidance from the Centers for Disease Control and Prevention (CDC) does not recommend using EHMRs with exhalation valves for source control. However, at the time of this study, the CDC recommended that if only a respirator with an exhalation valve was available, then the exhalation valve should be covered with a surgical mask, procedure mask, or a cloth face covering as long as it did not interfere with respirator fit. CDC guidance on covering exhalation valves continues to evolve as new information becomes available.

Modifying or covering the exhalation valve of an EHMR to improve its potential efficacy for source control may result in higher exhalation resistance or elevated concentrations of carbon dioxide gas (CO_2) in the respirator facepiece, which may subsequently increase user discomfort and reduce user acceptance. This practice also voids the National Institute for Occupational Safety and Health (NIOSH) approval for the device, which does not permit the substitution, modification, addition, or omission of parts by the user. NIOSH, the federal institute that approves respirators in the United States, requires that exhalation resistance not exceed 25 millimeters of water (mmH_2O). While there is no respirator performance requirement related to inspired CO_2 level for EHMRs, NIOSH has established a limit for other respirator types such as tight-fitting, powered air-purifying respirators with the blower unit off, for which the lowest of three donnings is not to exceed 2% inspired CO_2 if intended use is for escape purposes.

This study explores the impact of modifying or covering the exhalation valves of an EHMR on exhaled breathing resistance and inspired CO_2. Two approaches were considered: (1) modifying EHMRs to filter the exhaled breath through the inhalation filters; (2) covering EHMR exhalation valves with surgical masks. Nine EHMR configurations approved by NIOSH were included in this study, where the "configurations" were the combination of a facepiece, filter, and other required components. These nine EHMR configurations were selected from three different respirator manufacturers and five different facepiece models. Four of the five facepiece models

were assessed in both N95 and P100 filter configurations, and one facepiece model was assessed in a P100 filter configuration only.

Exhalation resistance and inspired CO_2 level were measured in each of the nine EHMR configurations under four study conditions, for a total of 72 measurements:

(1) No EHMR modifications or coverings—experimental control.

(2) EHMR modified to filter exhaled breath through inhalation filters.

(3) EHMR exhalation valves covered with Level 1 surgical mask (per ASTM F2100).

(4) EHMR exhalation valves covered with Level 3 surgical mask (per ASTM F2100).

Both exhalation resistance and inspired CO_2 level were measured in accordance with NIOSH Standard Testing Procedures. For the exhalation resistance measurement, three samples were each donned one time (n=3) on a manikin, which was made to simulate exhalation at a constant airflow rate of 85 L/min. The initial resistance was then measured. For the inspired CO_2 level measurement, one sample was donned three times each (n=3) on a manikin, which was made to simulate breathing at a rate of 14.5 breaths/min and a tidal volume of 0.724 L. The simulated exhaled breath consisted of 5% CO_2, and the inspired CO_2 concentration was measured at 40 Hz and averaged over three respiratory cycles.

Test results showed that all EHMR configurations under all test conditions met the NIOSH exhalation resistance performance requirement of not exceeding 25 mmH_2O. Eight of nine configurations modified to filter the exhaled breath showed measurable increases in mean exhalation resistance compared to their respective controls, increasing from between 4.40 and 9.48 mmH_2O in the controls to between 8.21 and 18.5 mmH_2O in the modified configurations. All configurations covered with Level 1 or Level 3 surgical masks also showed measurable increases in mean exhalation resistance compared to their respective controls, increasing from between 4.40 and 9.48 mmH_2O in the controls to between 7.11 and 17.6 mmH_2O in the covered configurations.

The lowest of the three inspired CO_2 level measurements for all EHMR configurations under all test conditions was less than 2%, with one observation of one configuration modified to filter the exhaled breath exceeding 2%. All nine EHMR configurations modified to filter the exhaled breath showed measurable increases in mean inspired CO_2 levels compared to their respective controls, increasing from between 0.47% and 1.03% in the controls to between 1.25% and 1.94% in the modified configurations, while the inspired CO_2 levels of EHMRs covered with Level 1 or Level 3 surgical masks did not consistently increase across all configurations, changing from between 0.47% and 1.03% in the controls to 0.80% and 1.26% in the covered configurations.

Findings indicate that EHMRs can meet the NIOSH exhalation resistance performance requirement after being (1) modified to filter the exhaled breath, (2) covered with a Level 1 surgical mask, or (3) covered with a Level 3 surgical mask. Findings indicate that modifying EHMRs to filter the exhaled breath increases inspired CO_2 levels, potentially increasing user discomfort but unlikely to cause serious physiological symptoms in healthy users, as all but one measurement was below 2%. Covering EHMR exhalation valves with surgical masks is unlikely to increase discomfort due to elevated inspired CO_2 levels nor to cause serious physiological symptoms, as all measurements were well below 2%.

NIOSH's performance requirements provide an approval pathway for new EHMR designs without exhalation valves, which may be desirable when considering source control. In fact, while this study was in progress, several EHMR models without exhalation valves and an EHMR with a filtered exhalation valve accessory were approved. Since this study showed that modifying the EHMRs to filter the exhaled breath generally increased both exhalation resistance and inspired CO_2 levels, and the magnitude of those increases varied among EHMR configurations, future research on the comfort and tolerability of new and modified EHMRs without exhalation valves needs to inform and improve designs appropriate for use in healthcare.

INTRODUCTION

Elastomeric half-mask respirators (EHMRs) and filtering facepiece respirators (FFRs), the most common filter class being "N95," are classified as air-purifying respirators (APRs) [Respiratory protection 2004], meaning that they remove contaminants from the air via an air-purifying element such as a filter, cartridge, or canister, providing filtered air to the user. The National Institute for Occupational Safety and Health (NIOSH) approves both FFRs and EHMRs and evaluates each using similar tests, in accordance with minimum performance requirements [NIOSH 1995]. The Occupational Safety and Health Administration (OSHA) considers the expected level of protection provided by both FFRs and EHMRs to be the same, in that it designates all half-mask (i.e., covering the nose and mouth) air-purifying respirators an Assigned Protection Factor[1] of 10 [Respiratory protection 2004].

One characteristic that distinguishes EHMRs from FFRs is their reuse capability. Unlike FFRs, which are not designed to be cleaned or disinfected, EHMRs are designed to be routinely cleaned, which could include disinfection, and maintained for longer-term use. The reusability of EHMRs makes them advantageous for use in the healthcare industry, particularly as a tool for mitigating single-use respirator supply shortages created by public health emergencies [Patel et al. 2017]. The ability to withstand surface disinfection (i.e., removal and inactivation of many or all infectious materials) is beneficial for reducing surface transmission of infectious disease to healthcare workers from their personal protective equipment, especially during outbreaks. A U.S. federal government interagency report on improving protective equipment in healthcare identified these two factors—reusability and repeated disinfection durability—as high-priority, recommended features of respirators for healthcare workers [U.S. Department of Veterans Affairs 2009].

In addition to the advantages of reusability and repeated disinfection durability of EHMRs, users may also perceive a higher sense of protection against communicable diseases provided by EHMRs compared to FFRs [Hines et al. 2019]. Many EHMRs can also be equipped with air-purifying elements having greater filtration efficiency than N95s, such as P100 filters ($\geq$ 99.97% versus $\geq$ 95%, respectively). Disadvantages of EHMR use in healthcare as compared to FFRs include attributes such as communication and comfort. Communication, both with patients and coworkers, was consistently rated more negatively in EHMRs compared to FFRs, as was comfort. Neither comfort nor communication issues were barriers, however, to EHMR

[1] OSHA defines the Assigned Protection Factor as "the workplace level of respiratory protection that a respirator or class of respirators is expected to provide employees when the employer implements a continuing, effective respiratory protection program." Employers must use the Assigned Protection Factors in the OSHA standard 1910.134 to select a respirator that "meets or exceeds the required level of employee protection."

acceptance among experienced EHMR users when perceived risk and protectiveness were included [Hines et al. 2019].

One comfort-related design feature prevalent in EHMRs is an exhalation valve. An exhalation valve is a mechanical assembly housed in the body of a respirator that opens when subjected to positive pressure, allowing the user's exhaled breath to escape the respirator. An exhalation valve consists of a holder (frame), a membrane (a disc or flap) that sits on top of the holder, and a protective cover. An exhalation valve is intended to reduce the resistance that users experience when exhaling, and it may also reduce facial temperature and the buildup of moisture inside the respirator—three additional recommended characteristics of respirators intended for use in healthcare [U.S. Department of Veterans Affairs 2009]. Since a properly functioning exhalation valve remains closed under the negative pressure experienced during inhalation, its sole purpose is to improve wearability, and it does not contribute to the protection of the user against airborne contaminants. EHMRs and FFRs with exhalation valves provide the same level of protection to the user as those that do not have a valve [CDC 2020a]. In terms of regulatory requirements, NIOSH requires exhalation valves be provided where necessary, protected against damage and external influence, and designed and constructed to prevent inward leakage of contaminated air [Approval of respiratory protective devices 1995]. Though the improved comfort provided by EHMRs with exhalation valves may be important to users, their efficacy for source control—which is the use of well-fitting cloth masks, facemasks, or respirators to cover a person's mouth and nose to prevent the spread of respiratory secretions when they are breathing, talking, sneezing, or coughing [CDC 2021b]—is not known, nor does NIOSH evaluate or approve respirators for the purposes of providing source control.

Healthcare workers who are wearing an EHMR with an exhalation valve, and who may be infected with a contagious pathogen, may unknowingly spread the pathogen to those around them via unfiltered breath exhausting from the exhalation valve. The level of spread depends on the disease transmission routes [Jones and Brosseau 2015] as well as factors such as the concentration of infectious materials on particles of different sizes; proximity between people; amount of time spent among people in close proximity; and environmental conditions such as temperature, humidity, and air circulation. Particles of all sizes may be emitted by both symptomatic and asymptomatic people through actions such as sneezing, coughing, singing, talking, and breathing [CDC 2020b].

In response to the concerns regarding asymptomatic and pre-symptomatic disease transmission, the Centers for Disease Control and Prevention (CDC) does not recommend wearing EHMRs with exhalation valves when source control is desired [CDC 2021c] and specifies that "until more is understood on exhalation valves, elastomeric respirators with unfiltered exhalation valves should not be used as source control in surgical and other healthcare settings due to concerns that air coming out of the exhalation valve may contaminate the sterile field."[2] However, at the time of this study, the CDC recommendation on using respirators with exhalation valves was that if they were the only available option and source control was needed, then the exhalation valve should be covered with a surgical mask, procedure mask, or a cloth mask without interfering with the respirator fit. This recommendation drove the practice among

[2] Although "air" was used in the cited source (CDC 2021c), in this report "breath" will be used with the understanding that it is synonymous with "air" in relation to the context of it being expelled by a wearer through an exhalation valve.

healthcare workers in the workplace to cover respirators with exhalation valves by using the above recommended mask types when source control was desired.

Background

In a previous study, NIOSH evaluated the potential source control, by measuring outward filtration efficiency, provided by FFRs with exhalation valves (1) covered with a surgical mask, (2) blocked with an electrocardiogram (ECG) pad, or (3) blocked with surgical tape. In the same study, NIOSH also evaluated the outward particle penetration of FFRs with exhalation valves without implementing any mitigation strategies (i.e., the exhalation valve was not blocked or covered) [NIOSH 2020b].

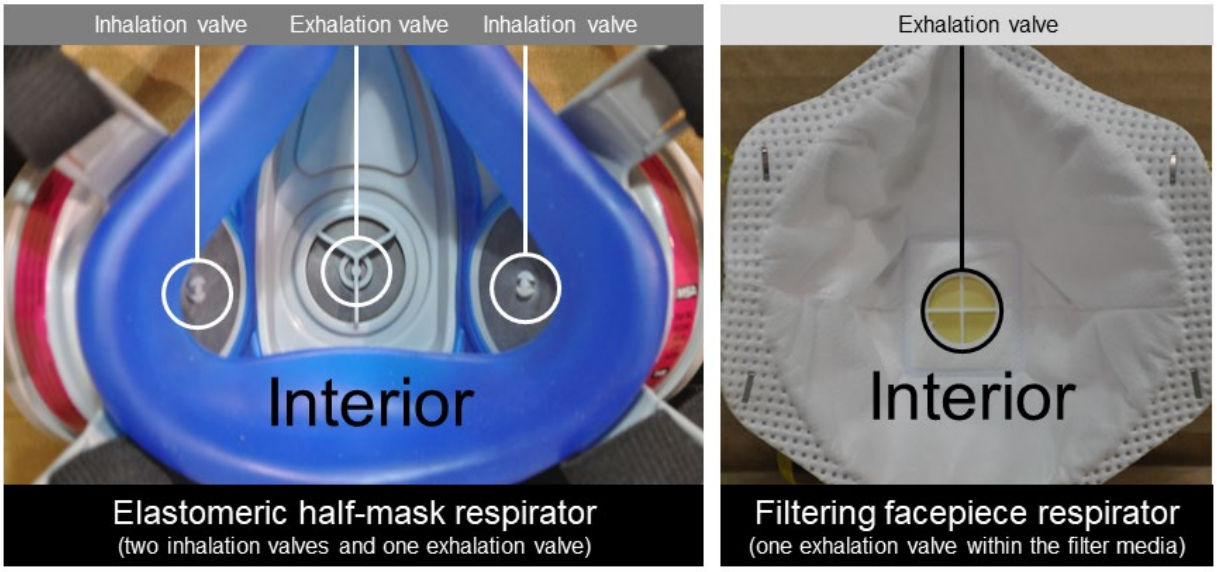
Findings from this NIOSH study indicate that FFRs with exhalation valves allow between <1% and 55% of particles to penetrate out of the respirator, with a median penetration value of 31% at a challenge aerosol flow rate of 85 L/min [NIOSH 2020b]. This study resulted in updated guidance for FFRs with exhalation valves, posted on April 9, 2021, suggesting that, in most non-medical settings, wearing a NIOSH-approved N95 FFR with an exhalation valve to provide source control is acceptable [CDC 2021c].

NIOSH found that covering the outside of the FFR exhalation valve with a surgical mask, per the previous CDC recommendation, reduced the median penetration value from 31% to 23%, which was the least effective of three mitigation strategies assessed. Blocking the exhalation valve from inside the respirator, either with micropore surgical tape (5% median outward penetration) or non-porous ECG pads (2% median outward penetration) was more effective at mitigating outward penetration of particles. This study was conducted on a limited selection of 13 FFR models, not EHMRs, with a charge neutralized sodium chloride aerosol with a mass median aerodynamic diameter of 0.35 μm, which are considered the most penetrating particle characteristics for typical filter media. It was not conducted on droplets or large particles, for which penetration values would likely be lower. Additionally, the penetration values were measured using an automated filter test instrument at constant flow rates and high aerosol concentrations (up to 200 mg/m^3), unlike the cyclical breathing patterns—for which penetration values would generally be lower—and likely lower concentrations of particles in the exhaled breath expelled by actual respirator users.

Due to design differences between EHMRs and FFRs, exhaled particle penetration out of EHMRs may be higher in comparison to exhaled particle penetration out of FFRs with exhalation valves. Figure 1 depicts the facepiece interior of an example EHMR (Figure 1, left) and an example valved FFR (Figure 1, right). The facepiece forms a protective barrier between the user's respiratory tract and the external, potentially contaminated, environment. In the case of both EHMRs and FFRs, the facepiece is a half-mask facepiece, meaning it covers the user's nose and mouth and seals under the user's chin. While the FFR facepiece is entirely composed of filter media and without replaceable parts, the EHMR facepiece is composed of silicon or other elastomeric material and configurable with replaceable air-purifying elements (e.g., filters or cartridges) that affix onto the facepiece to form a complete respirator. Most commercially available EHMRs have inhalation valves in addition to exhalation valves. The inhalation valves open when subjected to negative pressure (inhalation) and remain closed under positive pressure (exhalation), while the exhalation valve remains closed under negative pressure and opens under positive pressure. Consequently, during the exhalation phase of the respiratory cycle, the

exhalation valve is the pathway of least resistance for the particle-laden secretions in the exhaled breath to travel, and the inhalation valves prevent the particle-laden secretions in the exhaled breath from flowing through the filters.

This EHMR design contrasts with the design of valved FFRs, which have a single exhalation valve surrounded by filter media, resulting in a portion of the exhaled breath exhausting through the filter media in parallel with the exhalation valve. This FFR design characteristic explains the unmitigated median outward penetration value found by NIOSH of 31%, equating to a filtration efficiency of 69% [NIOSH 2020b], indicating that the tested FFRs with exhalation valves reduced particle emissions out of the respirator by a median value of 69%. One other factor, present in both FFRs and EHMRs, is the exhalation valves themselves, which may block or deflect particles via the valve membrane or the protective covering. The contribution of the exhalation valves alone to providing source control is not known but is likely to be dependent on particle size.



Photos by NIOSH

Figure 1. Contrasting interior designs of an elastomeric half-mask respirator (left) and a valved filtering facepiece respirator (right). The elastomeric half-mask respirator is the MSA Advantage 200 LS with two inhalation valves and one exhalation valve. The filtering facepiece respirator is the 3M 8511 with a single exhalation valve embedded in the filter media.

When blocking the exhalation valve from inside the FFR with a non-porous ECG pad, the challenge aerosol generated from inside the respirator was prevented from exhausting unfiltered out of the exhalation valve. It was instead redirected through the filter media, reducing particle emissions out of the FFRs by a median value of 98%. A measured filtration efficiency of 98% is comparable to the 95% NIOSH minimum inward filtration efficiency requirement for N95 FFRs [Approval of respiratory protective devices 1995].

Due to the aforementioned design differences between EHMRs and FFRs, blocking an EHMR exhalation valve may negatively affect the comfort of respirator users to a greater extent than blocking the exhalation valve of an FFR. Moreover, modifying any type of respirator, including the addition of an external covering, may impact the respirator's NIOSH approval.

By definition, NIOSH approval is issued for individual respirator assemblies that have been examined, inspected, tested, and determined to have met general construction and minimum performance requirements [Approval of respiratory protective devices 1995]; therefore, any substitution, modification, addition, or omission of parts by the user [NIOSH 2020c] voids the NIOSH approval. Because OSHA requires that NIOSH-approved respirators be used in workplaces that are part of an OSHA respiratory protection program, and that these respirators be used in accordance with the conditions of its approval, modifying respirators may also result in a noncompliance with OSHA's respiratory protection standard [Respiratory protection 2004]. An approval holder, or entity that designs, manufactures, assembles, or controls a NIOSH-approved respirator, may modify or change features of existing respirators with NIOSH approval, which involves meeting a set of minimum performance requirements. For EHMRs, the NIOSH minimum performance requirements include filtration efficiency, inhalation and exhalation resistance, and exhalation valve leakage [Approval of respiratory protective devices 1995]. Of these performance requirements, exhalation resistance may be most affected when modifying EHMRs to improve potential source control. Higher exhalation resistance may result in higher discomfort for the user and subsequent lower acceptance, as well as increased physiological burden [NIOSH 1995].

During normal EHMR usage, most of the carbon dioxide gas (CO_2) contained in the user's exhaled breath exits through the exhalation valve into the external environment. The residual exhaled CO_2 remains within the facepiece and is rebreathed during inhalation. Attempting to modify EHMRs to filter the exhaled breath may result in increased "dead space," or stagnant air where gas exchange is not taking place, in the facepiece. Increased dead space may lead to higher concentrations of CO_2 lingering in the facepiece and being rebreathed by the user. The inhalation toxicity level of CO_2 is minimal, with typically no effects at less than or equal to 1% inspired CO_2 [ESHG n.d]. However, elevated levels cause increases in respiration rate and tidal volume, and concentrations greater than 2% can lead to potential discomfort for users and possibly physiological symptoms such as fatigue, dizziness, headache, and shortness of breath, among others [Kloos and Lamonica 1966; Roberge et al. 2010]. The accumulation of CO_2 inside the respirator facepiece is typically not a NIOSH performance requirement for half-mask respirators. However, the accumulation of CO_2 may become a concern when modifying or obstructing the exhalation valve, and respirators submitted for NIOSH approval must be designed on sound engineering and scientific principles and not create safety issues for the user. Additionally, respirator approval schemes in other countries and regions (e.g., China, Europe) assess inspired CO_2 with varying test conditions and permit a maximum of 1% inspired CO_2.

Objective

This study explores two approaches for modifying or covering the exhalation valves of EHMRs:

(1) modifying EHMRs to filter the exhaled breath by removing the inhalation valve membranes and blocking the exhalation valve;

(2) covering EHMR exhalation valves with surgical masks, per the CDC recommendation at the time of this study.

This study evaluated the effects of these strategies on two measures of respirator performance in nine NIOSH-approved EHMR configurations, as follows:

- *Measuring the exhalation resistance* of EHMRs covered with surgical masks and EHMRs modified to filter exhaled breath.
- *Measuring inspired CO_2 levels* of EHMRs covered with surgical masks and EHMRs modified to filter the exhaled breath.

METHODS

Elastomeric Half-Mask Respirator Configurations

Table 1 lists the manufacturers, model/part numbers, and NIOSH approval numbers for the nine EHMR configurations chosen for this study, based on their reported use by large healthcare systems and variability between exhalation valve designs.[3]

Often, the same facepiece component of a NIOSH-approved EHMR is approved for use with different types of air-purifying elements, including chemical cartridges or canisters, particulate filters, and combination cartridges (i.e., gas/vapor and particulate). This study focused on two levels of particulate protection—N95 and P100—as these are commonly used in healthcare [The National Academies of Sciences, Engineering, and Medicine Consensus Study Report 2018]. Together, a facepiece, a filter or filters, and other required components constitute an EHMR "configuration." All EHMRs evaluated in this study were designated as medium-sized by the respective manufacturers. All EHMRs evaluated in this study were new (unused). The nine configurations in this study were selected from three different respirator manufacturers and five different facepiece models, as follows:

- The 3M 6200 and 3M 7502 (3M Company, St. Paul, MN) were tested with both N95 and P100 filter configurations.
- The MSA Advantage 200 LS (Mine Safety Appliances, Pittsburgh, PA) was tested only in the P100 configuration. This approach was taken because the MSA Advantage 200 LS did not have a NIOSH-approved N95 filter configuration without additional chemical protections at the time of this testing.
- The Honeywell North RU85001M and RU85004M (Honeywell International Inc., Charlotte, NC) were tested in both N95 and P100 filter configurations.

[3] Note that none of the EHMR configurations in this study are cleared by the U.S. Food and Drug Administration for marketing as medical devices.

Table 1. Nine elastomeric half-mask respirator configurations used in this study

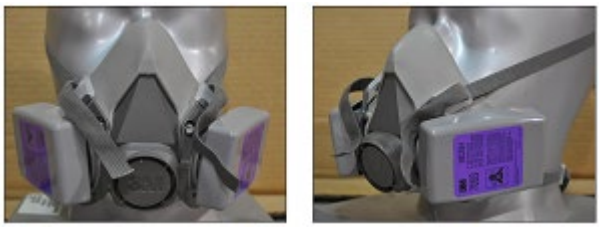
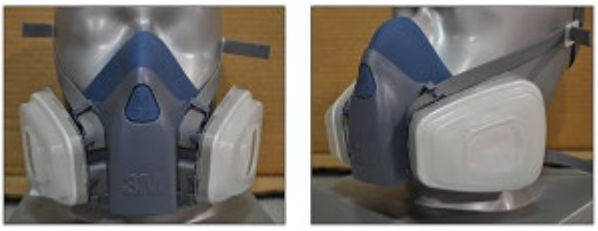
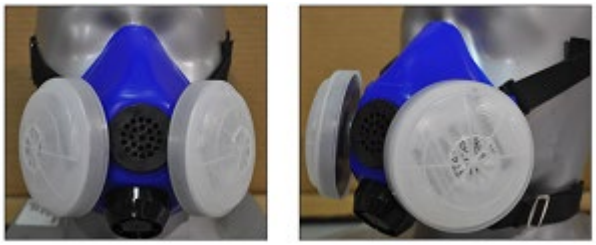
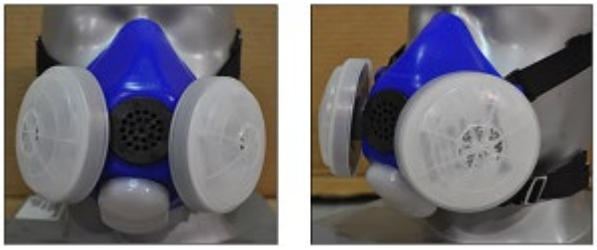
Manufacturer and part (part #)	NIOSH testing and certification (TC-) approval number	Photos of respirator configurations tested, showing the front view (left) and side view (right). Photos by NIOSH.
3M 6200 with N95 filter (#5N11), filter adapter (#603), and filter retainer (#501)	84A-0376	
3M 6200 with P100 filter (#7093)	84A-0071	
3M 7502 with N95 filter (#5N11), filter adapter (#603), and filter retainer (#501)	84A-0376	
3M 7502 with P100 filter (#7093)	84A-0071	
Honeywell North RU85001M* with P100 filter cartridges (#7580P100) and filter cover (#N750029)	84A-7529	

Table 1 (continued). Nine elastomeric half-mask respirator configurations used in this study

Manufacturer and part (part #)	NIOSH testing and certification (TC-) approval number	Photos of respirator configurations tested, showing the front view (left) and side view (right). Photos by NIOSH.
Honeywell North RU85001M* with N95 filter (#7506N95), filter holder (#N750015), and filter cover (#N750027)	84A-7542	
Honeywell North RU85004M* with P100 filter cartridges (#7580P100) and filter cover (#N750029)	84A-7529	
Honeywell North RU85004M* with N95 filter (#7506N95), filter holder (#N750015), and filter cover (#N750027)	84A-7542	
MSA Advantage 200 LS (#815444) with low-profile P100 cartridges (#815369)	84A-5420	

* The holed black piece positioned between the filters of the Honeywell EHMRs is a speech diaphragm, which is a device used to improve speech intelligibility. It is not an exhalation valve and was not modified for this study.

Respirator Test Conditions

Performance of all nine EHMR configurations was assessed under one control and three experimental conditions, designated and discussed below as follows: (1) control, (2) modified to filter exhaled breath through inhalation filters, (3) covered with Level 1 surgical mask, and (4) covered with Level 3 surgical mask.

The combination of the nine EHMR configurations, four test conditions, and two measurements of exhalation resistance and inspired CO_2 levels (with three replicates per measurement) resulted in 216 observations. For each configuration, one control (or set of controls, depending on the test requirements) served as the control for all three experimental conditions.

Considering the CDC recommendation at the time of this study to cover respirators with exhalation valves with a surgical mask, procedure mask, or a cloth face covering when source control was desired, surgical masks were ultimately chosen for this study to represent the covering that may create more exhalation resistance than other types of coverings, resulting from their higher filtration efficiency. In a previous study, NIOSH found particle penetration ranges of 2% to 17% for surgical masks, 1% to 85% for procedure masks, and 24% to 92% for cloth face coverings when tested against a sodium chloride aerosol with a mass median aerodynamic diameter of 0.35 µm, which is the most penetrating particle size for filters, at a flow rate of 85 L/min [NIOSH 2020b]. Additionally, surgical masks were selected for this study due to their behind-the-head ties, which allow for more precise positioning over the EHMR exhalation valves and can be tightened for better fit; by comparison, procedure masks typically have ear loops for easier donning and doffing but there is less control of positioning over the EHMR exhalation valve and an inability to tighten for fit [ASTM 2021]. Cloth face coverings were not included in this study because of their wide range of materials, varying head suspension designs, and lack of applicable regulatory standards.

Both Level 1 and Level 3 masks were chosen for study due to the different levels of resistance to penetration of synthetic blood, filtration efficiencies, and differential pressures, as specified by ASTM International [ASTM 2021][4]. It was expected that the higher liquid resistance, filtration efficiency, and differential pressure characteristics of Level 3 masks compared to Level 1 masks might result in higher exhalation resistance when applied as a covering over an EHMR exhalation valve. Level 1 masks are resistant to the penetration synthetic blood at 80 millimeters of mercury (mmHg) (~1088 mmH_2O), and Level 3 masks are resistant at 160 mmHg (~2175 mmH_2O) [ASTM 2017]. Level 1 masks also have both a bacterial filtration efficiency and latex sphere-based particulate filtration efficiency of $\geq$ 95%, whereas both filtration efficiency requirements are $\geq$ 98% for Level 3 masks. Finally, ASTM F2100 specifies slightly lower differential pressure requirements for Level 1 than Level 3 masks, limiting the breathing resistance of Level 1 masks to 5.0 mm H_2O/cm^2 for 4.9 cm^2 swatches subjected to 8 L/min airflow (corresponding to 24.5 mm H_2O at a face velocity of 27.2 cm/s) and the resistance of Level 3 masks to 6.0 mm H_2O/cm^2 (corresponding to 29.4 mm H_2O) under the same swatch size and airflow conditions.

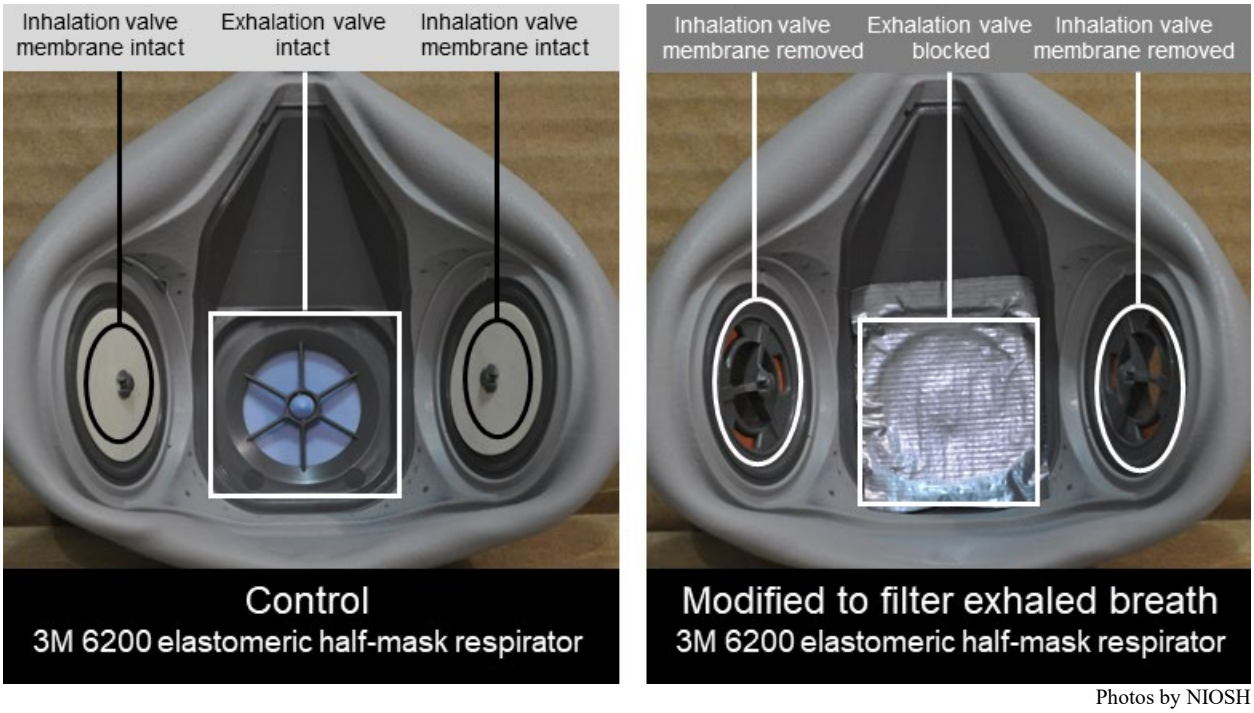
[4] ASTM F2100 classifies all medical masks that are used in providing healthcare services such as surgery and patient care, which includes medical masks with ties (surgical masks) and ear loops (procedure masks or isolation masks).

Control

The control respirators were unmodified (Figure 2, left) NIOSH-approved configurations. Controls were commercially available respirators purchased off-the-shelf and assembled per the manufacturers' user instructions. In the controls, during inhalation, the inhalation valves open and allow the ambient air to enter through the respirator filters, while the exhalation valve remains closed (Figure 3, left). During exhalation, the exhalation valve opens to allow the exhaled breath to escape, unfiltered, into the environment, while the inhalation valves remain closed, preventing the exhaled breath from flowing through the respirator filters.

Modified to Filter Exhaled Breath

As shown in Figure 2, right, EHMRs were modified to filter the exhaled breath. The inhalation valve membranes, or flaps, were removed, and the exhalation valve was blocked with a single layer of off-the-shelf duct tape from the inside, sealing along the edges of the valve port, blocking air discharge through the exhalation valve. The respirator filters themselves were unmodified. This modification allowed the inhaled breath to enter the facepiece through the respirator filters and the now-empty inhalation valve port from the environment (Figure 3, right), providing filtered air to the user, while directing the exhaled breath back through the empty port, then through the same filters that were used during inhalation, and out into the environment, again filtered.



Photos by NIOSH

Figure 2. Interior of the 3M 6200 EHMR control (left) and the 3M 6200 EHMR modified to filter exhaled breath (right). Modifications involved removing the inhalation valve membranes and blocking the exhalation valve with duct tape. In the photos, the facepiece sealing areas of the respirators were folded back to show full interior views, including the inhalation valves.

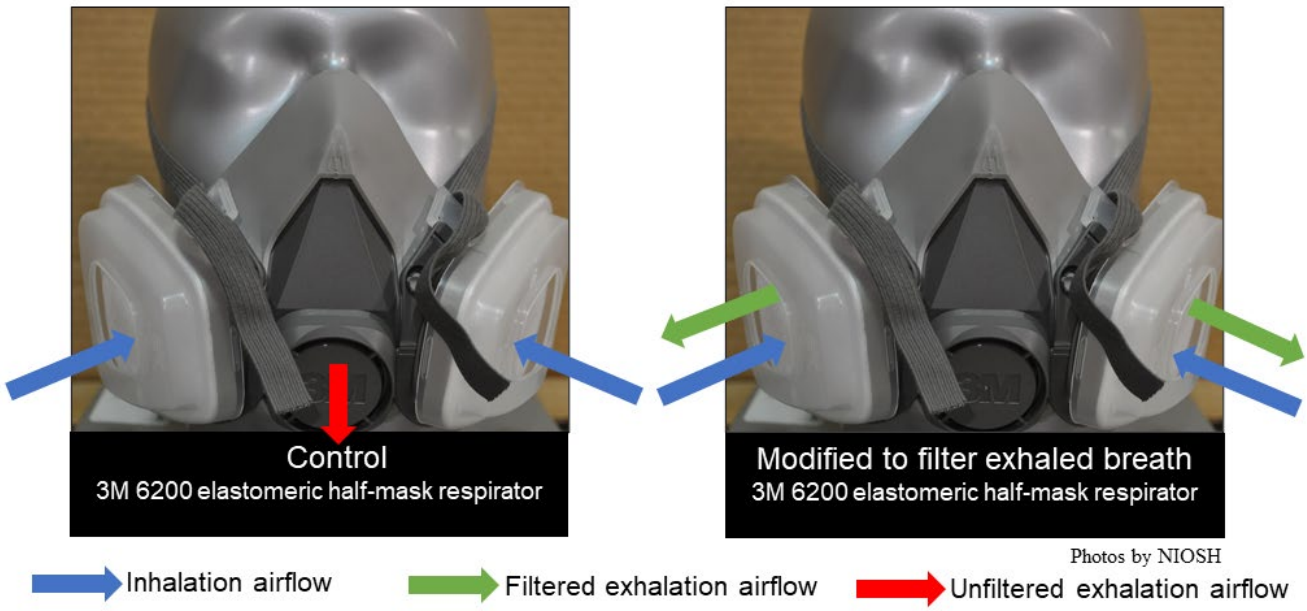


Figure 3. Inhalation and exhalation airflow directions as represented by colored arrows in the 3M 6200 EHMR control (left) and the 3M 6200 EMHR modified to filter exhaled breath (right). Airflow modifications were achieved by removing the inhalation valves and blocking the exhalation valve as shown in Figure 2.

Covered with Level 1 Surgical Mask

As shown in Figure 4 as one example, the nine EHMRs with exhalation valves were covered by a Halyard Fluidshield Level 1 surgical mask (#28806) (per ASTM F2100), but otherwise the respirators were unmodified from their control condition.

The inhalation valve membranes remained in place and the exhalation valve was not blocked. After the EHMRs were donned, the surgical mask was donned over the EHMR without interfering with respirator fit. The center of the mask was aligned with the exhalation valve, and the surgical mask ties were secured with the top tie behind the head and the bottom tie behind the neck. The ties were secured tight enough so that the surgical mask snugly covered the exhalation valve.

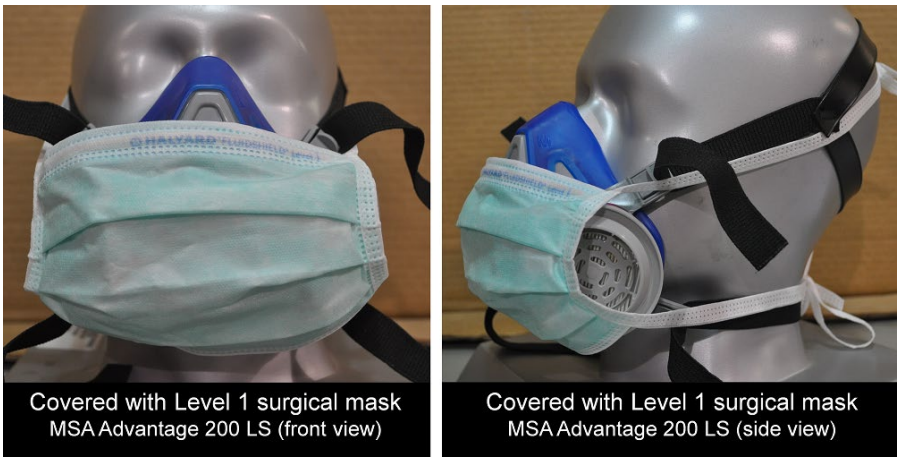
When covering the EHMR exhalation valve with a Level 1 surgical mask, the inhalation airflow entered through the inhalation valves, which could open normally. The exhalation airflow exited the respirator through the open exhalation valve and out of the respirator before being deflected by the surgical mask or flowing through it.

Because of differences in exhalation valve positioning and exhalation valve protective covering design among the respirator models, surgical masks were positioned differently on each model, but were consistently "centered" over each model's exhalation valve. Due to the loose fit of the surgical masks and the at-most partial coverage of the inhalation filters, it was not anticipated that the inhalation airflow directions or resistance was impacted by the surgical mask.

Covered with Level 3 Surgical Mask

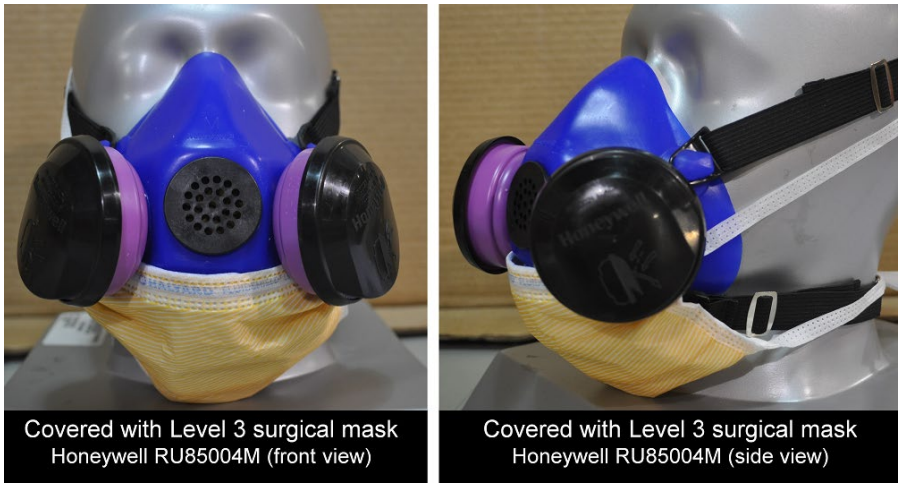
As shown in Figure 5 as one example, the nine EHMRs with exhalation valves were covered by a Halyard Fluidshield Level 3 surgical mask (#48207) (per ASTM F2100), but otherwise the respirators were unmodified from their control condition.

The inhalation valve membranes remained intact and the exhalation valve was not blocked. The procedure for donning Level 3 surgical masks was the same as the procedure for Level 1 surgical masks, described above, as were the inhalation and exhalation airflow directions.



Photos by NIOSH

Figure 4. MSA Advantage 200 LS covered with Level 1 surgical mask donned on a headform. The MSA Advantage 200 LS exhalation valve is positioned on the front of the facepiece and frontward facing. The center of the surgical mask is aligned over the exhalation valve and results in partial coverage of the filters, but this partial coverage was assumed not to affect inhalation resistance or airflow direction.



Photos by NIOSH

Figure 5. Honeywell RU85004M covered with Level 3 surgical mask donned on a headform. The Honeywell RU85004M exhalation valve is positioned on the lower part of the facepiece and is downward facing. The center of the surgical mask is aligned over the exhalation valve and does not result in coverage of the filters.

Exhalation Resistance

The exhalation resistance test was conducted per NIOSH Standard Testing Procedure (STP) TEB-APR-STP-0003 [NIOSH 2019]. A source of compressed air was set to a volumetric flow rate of 85 L/min using a Brooks Instrument Co. 5853S mass flow controller (Brooks Instrument, Hatfield, PA) with a Brooks Control and Read-out Unit model 0154. The metered compressed air source was supplied to an anthropometric headform so that the headform simulated exhalation at a constant flow rate of 85 L/min, comparable to a high exertion level in a healthy individual. The resistance was measured using a Setra Datum 2000 Model 239 digital manometer (Setra Systems, Inc, Boxborough, MA), which was connected to a pressure tap on a line between the mass flow controller and the headform.

Respirators were donned on the headform and the straps were tightened enough to ensure the respirator was maintaining contact around the sealing area but not tight enough to deform volume inside the respirator. The 85 L/min of compressed air was supplied to the headform and the resistance was measured and recorded. This process was repeated for three respirator samples of each configuration, per STP TEB-APR-STP-003, for a total of three replicates. Each of the three samples were donned and doffed once consecutively to account for variability in exhalation resistance measurements due to donning. Further details, including specific test equipment, can be found in the STP. The pass-fail requirements of STP TEB-APR-STP-003 specify that, upon initial exhalation, the exhalation resistance of EHMRs should not exceed 25 mmH_2O for any of the three samples.

Carbon Dioxide Concentration

The Determination of Facepiece Carbon-Dioxide and Oxygen Concentration Levels—Tight-Fitting, Powered Air-Purifying Respirators, With the Blower Unit Off test was conducted per STP RCT-APR-STP-0064 [NIOSH 2020a], but only CO_2 data was collected. This test typically assesses other types of APRs such as tight-fitting powered air-purifying respirators (PAPRs) with the blower unit off to allow for escape from a hazardous atmosphere during blower failure. STP RCT-APR-STP-0064 was used for this study as the most appropriate STP for assessing inspired CO_2 level in non-powered, half-mask APRs. Breathing was simulated in a headform using a NIOSH mechanical breathing machine. The breathing frequency was set to 14.5 breaths/min and the tidal volume to 0.724 L, equivalent to a minute ventilation of 10.5 L/min, a sedentary exertion level in healthy individuals. During the exhalation phase of the respiratory cycle, the headform was made to simulate exhalation of non-humidified, breathing quality air containing 5% CO_2 using a series of supplied gas sources, mass flow controllers, a mixing chamber, one-way valves, and a solenoid valve.

Prior to a respirator being donned on the headform, the test was run to determine a “blank” (i.e., inspired CO_2 levels without a respirator donned), and the concentration of CO_2 was measured on the inhalation phase of the respiratory cycle. A minimum of three respiratory cycles were run, which was previously determined to be the minimum number of cycles required to provide a valid CO_2 level for each donning based on the frequency and accuracy of the CO_2 analyzer. Inspired CO_2 concentration was measured at the mouth of the headform using a breath-response CO_2 analyzer recording at a frequency of 40 Hz. The inspired CO_2 profile was allowed to come to a steady state, and then mean percent inspired CO_2 was arithmetically averaged over the course of the three respiratory cycles.

For this test, the respirators were donned and the straps were tightened enough to ensure the respirator was maintaining contact around the sealing area but not tight enough to deform the volume inside the respirator. Again, the inspired CO_2 profile was allowed to come to a steady state, and then the inspired CO_2 concentration was measured over the course of a minimum of three respiratory cycles. The CO_2 concentrations of the "blank" were subtracted from the results with the respirator donned, and the result was the inspired CO_2 level. This test was repeated three times with one respirator sample of each configuration being donned, doffed, and re-donned three times in succession, for a total of three replicates, to account for variability in inspired CO_2 concentrations due to donning. Further details, including specific test equipment, can be found in the STP. Since EHMRs are not typically assessed with this test during the NIOSH approval process, there is no pass-fail requirement for this respirator class. However, for other types of APRs such as tight-fitting PAPRs with the blower unit off used for escape purposes, the lowest of the three inspired CO_2 level measurements should not exceed 2% [NIOSH 2020a]. This 2% pass/fail performance requirement was used in the context of this study as well.

RESULTS

Exhalation Resistance

Figure 6 displays exhalation resistance results for the following two test conditions: (1) control and (2) modified to filter exhaled breath. The following results are noteworthy from the figure:

- All nine EHMR configurations modified to filter the exhaled breath met the NIOSH pass/fail performance requirement of not exceeding 25 mmH_2O exhalation resistance at 85 L/min.
- Eight of the nine EHMR configurations modified to filter the exhaled breath displayed increases in mean exhalation resistance values when compared to their respective control configurations.
- When considering the eight EHMR configurations tested in both N95 and P100 filter configurations, increases in mean exhalation resistance varied by respirator model and filter type, with the P100 filter configurations increasing from between 4.49 and 8.13 mmH_2O in the controls to between 13.4 and 18.5 mmH_2O in the modified configurations. The mean exhalation resistance of the N95 filter configurations increased from between 4.40 and 8.30 mmH_2O in the controls to between 9.14 and 11.2 mmH_2O in the modified configurations.
- Of the four facepiece models tested in both N95 and P100 filter configurations, all of the P100 filter configurations modified to filter exhaled breath measured higher exhalation resistance than their modified N95 filter counterparts. The mean exhalation resistance of these four modified EHMRs with P100 filters increased by at least 8 mmH_2O, while the resistance of the modified EHMRs with N95 filters increased by less than 5 mmH_2O.

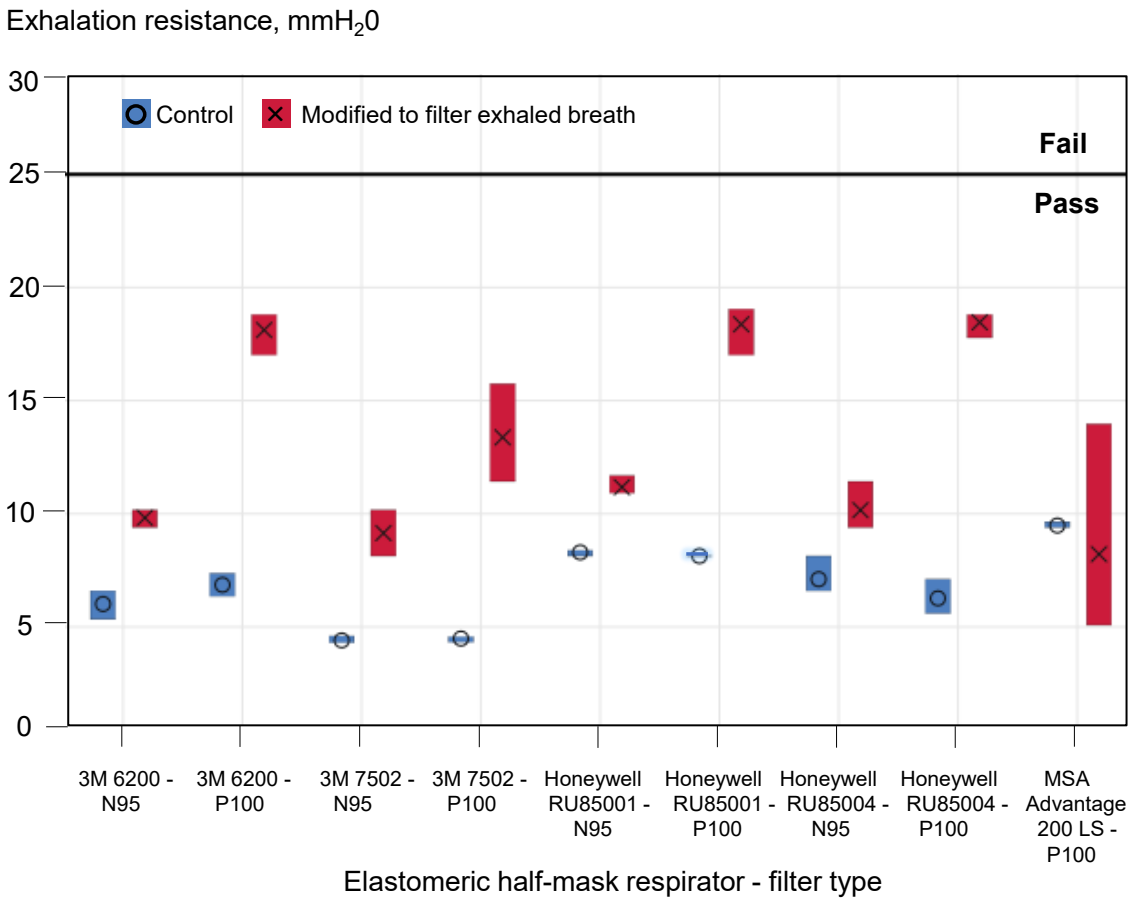


Figure 6. Plot comparing exhalation resistance of EHMR controls to EHMRs modified to filter exhaled breath by removing the inhalation valve membrane and blocking the exhalation valve, directing the exhaled breath through the respirator filters. Vertical bars represent the range of observations (n=3) and the circles or X's within the vertical bars represent the means for the control and modified to filter exhaled breath test conditions, respectively.

Figure 7 displays the exhalation resistance results for the following three test conditions: (1) control, (2) covered with Level 1 surgical mask, and (3) covered with Level 3 surgical mask. The following results are noteworthy from the figure:

- All EHMR configurations covered with Level 1 or Level 3 surgical masks met the NIOSH pass/fail performance requirement of not exceeding 25 mmH_2O exhalation resistance at 85 L/min.
- All EHMR configurations covered with Level 1 or Level 3 surgical masks displayed increases in mean exhalation resistance values when compared to the control configurations.
- Increases in mean exhalation resistance varied by respirator configuration, with EHMRs covered with surgical masks increasing from between 4.40 and 9.48 mmH_2O in the controls to between 7.11 and 17.6 mmH_2O in the covered with Level 1 surgical mask configurations and to between 7.37 and 16.2 mmH_2O in the covered with Level 3 surgical mask configurations.

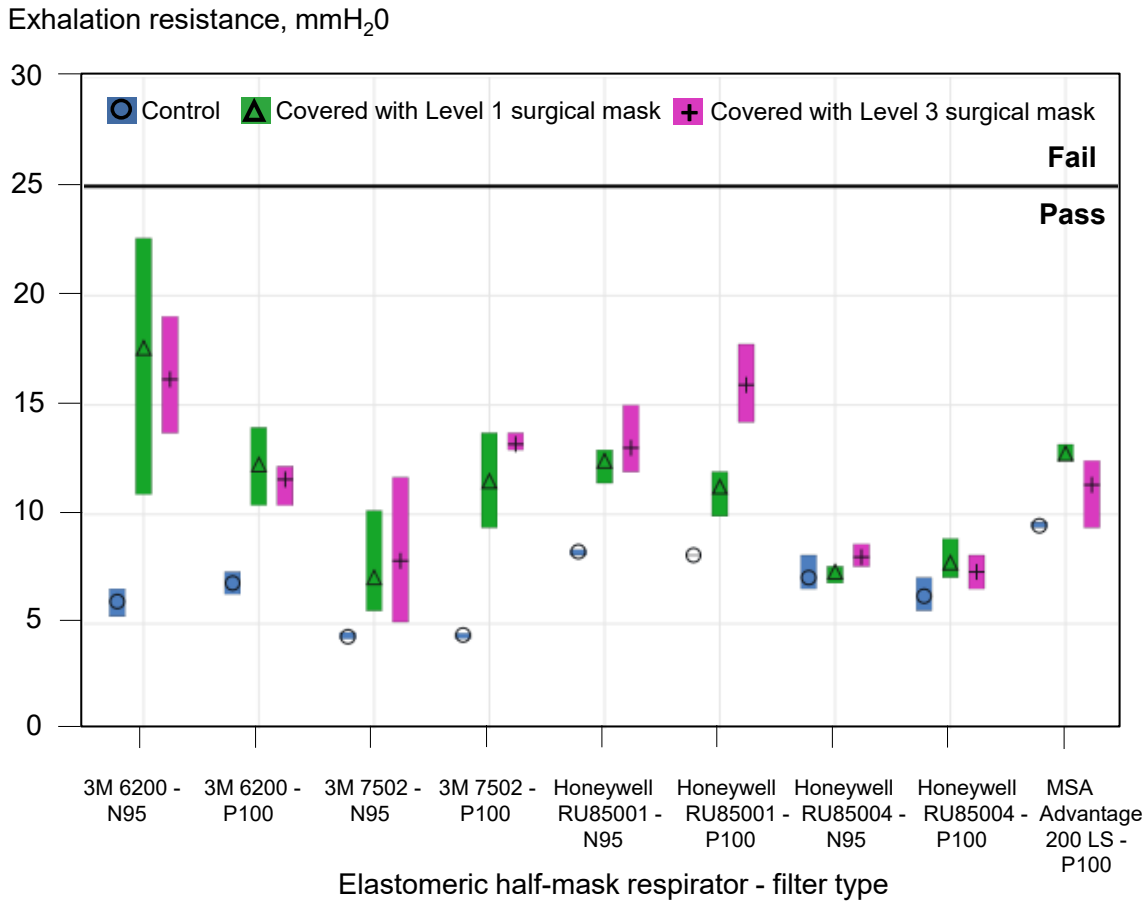


Figure 7. Plot comparing exhalation resistance of control EHMRs, EHMRs covered with Level 1 surgical mask, and EHMRs covered with Level 3 surgical mask. The vertical bars represent the range of observations (n=3) and the circles, triangles, or plus signs within the vertical bars represent the means for the control, covered with Level 1 surgical mask, and covered with Level 3 surgical mask test conditions, respectively.

Carbon Dioxide Concentration

Figure 8 displays inspired CO_2 levels for the following two test conditions: (1) control and (2) modified to filter exhaled breath. The following results are noteworthy from the figure:

- The lowest of the three inspired CO_2 level measurements of all EHMR configurations modified to filter the exhaled breath were less than 2%, meaning all EHMR configurations modified to filter the exhaled breath met the pass/fail performance requirement for this study.
- All EHMR configurations modified to filter exhaled breath showed increases in mean inspired CO_2 values when compared to the controls.
- The degree of increase in mean inspired CO_2 levels varied by model but did not appear to vary by filter type, with N95 filter configurations increasing from between 0.65% and 0.97% inspired CO_2 in the controls to between 1.25% and 1.94% in the modified configurations. The mean inspired CO_2 levels of the P100 filter configurations increased from between 0.47% and 1.03% inspired CO_2 in the controls to between 1.36% and 1.77% inspired CO in the modified configurations.

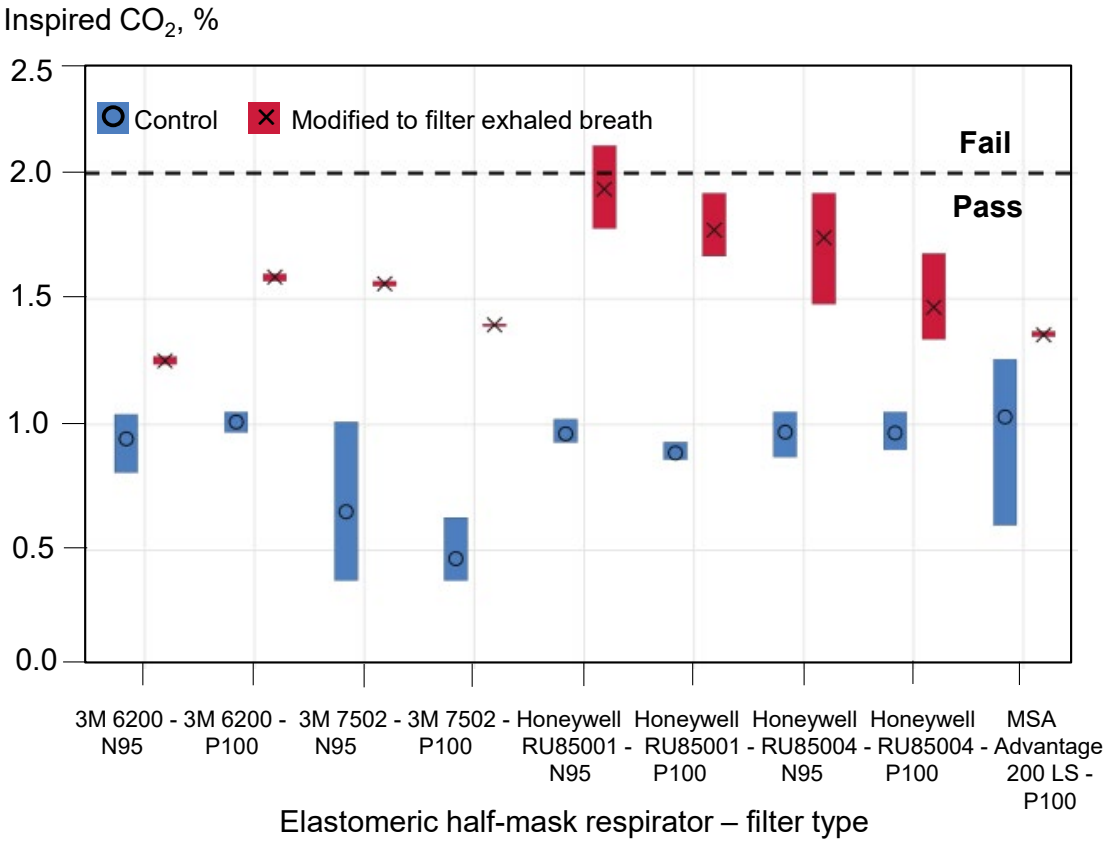


Figure 8. Plot comparing inspired CO_2 levels of control EHMRs and EHMRs modified to filter exhaled breath by removing the inhalation valve membrane and blocking the exhalation valve, directing the exhaled breath through the respirator filters. The vertical bars represent the range of observations (n=3) and the circles or X's within the vertical bars represent the means for the control and modified to filter the exhaled breath test conditions, respectively. The dotted reference line at 2% inspired CO_2 represents the limit for the evaluation, and only one of the three donnings must measure an inspired CO_2 level below 2% to "pass" in the context of this study. As shown in this figure, the Honeywell RU85001 with P100 filters modified to filter the exhaled breath would be considered "passing," since the bottom of the vertical bar is below 2%.

Figure 9 displays the inspired CO_2 levels for the following three test conditions: (1) control, (2) covered with Level 1 surgical mask, and (3) covered with Level 3 surgical mask. The following results are noteworthy from the figure:

- The lowest of the three inspired CO_2 level measurements of all EHMR configurations covered with a Level 1 or Level 3 surgical mask were less than 2%, meaning all EHMR configurations covered with a Level 1 or Level 3 surgical mask met the pass/fail performance requirement for this study.
- Six of the nine EHMR configurations covered with Level 1 surgical masks showed increases in mean inspired CO_2 levels values when compared to the controls.
- Six of the nine EHMR configurations covered with Level 3 surgical masks showed increases in mean inspired CO_2 levels values when compared to the controls.
- Differences in inspired CO_2 levels varied by respirator configuration but did not appear to vary by filter type nor surgical mask type, changing from between 0.47% and 1.03% inspired CO_2 in the controls to between 0.80% and 1.26% inspired CO_2 in the covered

with Level 1 surgical mask configurations and to between 0.83% and 1.18% in the covered with Level 3 surgical mask configurations.

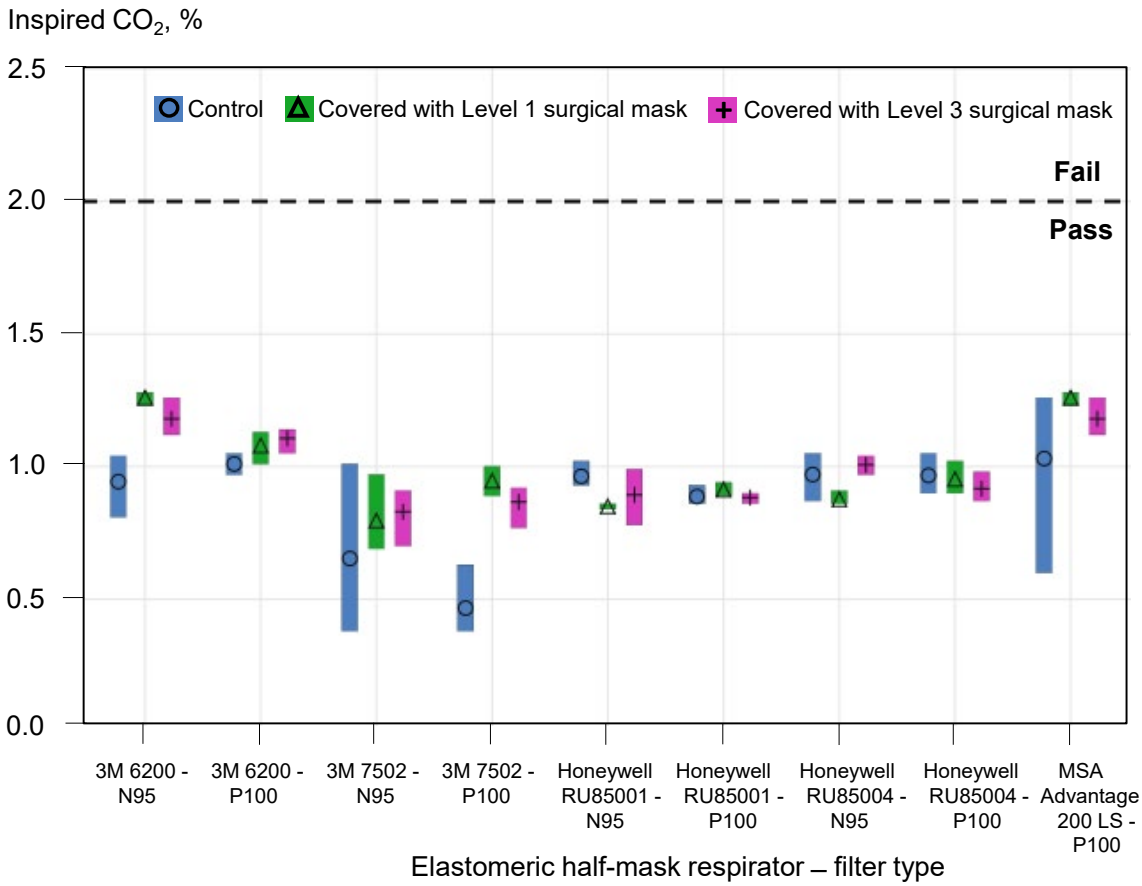


Figure 9. Plot comparing inspired CO_2 levels of control EHMRs, EHMRs covered with Level 1 surgical mask, and EHMRs covered with Level 3 surgical mask. The vertical bars represent the range of observations (n=3) and the circles, triangles, or plus signs within the vertical bars represent the means for the control, covered with Level 1 surgical mask, and covered with Level 3 surgical mask test conditions, respectively. The dotted reference line at 2% inspired CO_2 represents the limit for the evaluation in the context of this study.

DISCUSSION

Previous research conducted on FFRs with exhalation valves reported the median outward particle penetration of 31% when tested against particles with most penetrating size and charge characteristics [NIOSH 2020b]. This research assessed mitigation strategies of covering the exhalation valve with a surgical mask and blocking the exhalation valve from the inside with a non-porous ECG pad, reducing these median penetration values to 23% and 2%, respectively. Due to the design differences between FFRs and EHMRs, particle penetration out of EHMRs may be higher than for FFRs. The presence of inhalation valves in EHMRs prevents exhaled breath from exiting through the respirator filters and instead forces the exhaled breath through the exhalation valve, unfiltered, into the environment—this as opposed to FFRs, where the exhalation valve is surrounded by filter media, allowing for filtration of a portion (median value of 69% as found in the above study) of the exhaled particles without the implementation of any mitigation strategies. The presence of inhalation valves in EHMRs precludes the filtration of

particles by the respirator filters, making covering or modifying EHMRs desirable when source control is needed.

Modifying or covering EHMRs with exhalation valves to improve potential efficacy for source control may result in increased exhalation breathing resistance and inspired CO_2 levels, which may subsequently decrease user comfort and reduce user acceptance. This study assessed the effect of modifying EHMRs to filter the exhaled breath using the inhalation filters or covering the EHMR exhalation valves with a surgical mask, per the CDC recommendation at the time of this study, on the exhalation resistance and inspired CO_2 level. Although the respirator modifications or added surgical mask coverings in this study were assumed to improve source control in EHMRs with exhalation valves, researchers did not evaluate the effectiveness of using these respirators for source control. The level of respiratory protection provided to the user by the modified and covered EHMRs was assumed to have been maintained.

Exhalation Resistance

To assess exhalation resistance, EHMRs were donned on a headform that was made to simulate exhalation at a flow rate of 85 L/min, providing positive pressure to the facepiece. Applying positive pressure to the control EHMRs closes the inhalation valves and opens the exhalation valve, allowing the simulated exhaled breath to exit through the exhalation valve and bypass the respirator filters. As a result, the type of filter did not affect the exhalation resistance in the control condition. Four of the five EHMRs in this study were assessed in both N95 and P100 filter configurations, and results show that the mean exhalation resistance of the controls with N95 filters and controls with P100 filters were within 1 mmH_2O of each other for each of these four models.

By removing the inhalation valve membranes and blocking the exhalation valve, the simulated exhaled breath was directed back through the respirator filters typically used for inhalation only. As a result of this modification, the filter type becomes a significant factor in the exhalation resistance measurements of the EHMRs modified to filter exhaled breath. Of the four EHMRs tested with both filter types, all of the P100 filter configurations modified to filter exhaled breath measured higher mean exhalation resistance than their N95 filter modified counterparts—on average about 7 mmH_2O higher. This was expected due to the higher filtration efficiency provided by P100 filters (99.97% of airborne particles) compared to N95 filters (95% of airborne particles) [Approval of respiratory protective devices 1995]. Higher filtration efficiencies tend to result in higher resistances due to differences in filter media material, filter surface area, or basis weight of the filter media.[5]

The exhalation resistance of one modified EHMR model, which was only studied in a P100 filter configuration, resulted in a decrease in mean exhalation resistance compared to the controls and also measured one of the highest variabilities in this study, yielding a 9-mmH_2O difference between the highest and lowest observations. Larger sample sizes would be needed to determine why an EHMR modified to filter the exhaled breath would measure less exhalation resistance

[5] Note that the exhalation resistance performance requirement of not exceeding 25 mmH_2O applies to both N95 and P100 air-purifying particulate respirators.

than an unmodified EHMR with an exhalation valve, but possible reasons may be attributed to the respirator design, the modifications made, or the interaction of these two variables.

Overall, the degree to which surgical masks caused increases in exhalation resistance varied greatly by respirator configuration, with increases of less than 1 mmH_2O for one configuration to greater than 10 mmH_2O for another. When covering the EHMRs with surgical masks, no modifications were made to the respirators themselves, meaning the inhalation valve membranes were left in and the exhalation valve was not blocked. Due to the inhalation valves remaining closed under positive pressure, not allowing the simulated exhaled breath to flow through the respirator filters, theoretically the filter type should not impact the exhalation resistance when covering EHMRs with surgical masks. Despite this reasoning, findings indicate that some EHMRs with different filter types, but covered with the same surgical mask, measured differences greater than 5 mmH_2O. This finding may be attributed to differences in how the respirators, surgical masks, or both were donned. Thus, the level of exhalation resistance is dependent not only on the respirator design, but also on how the surgical mask covers the respirator. A tighter seal over the valve could result in higher exhalation resistance.

When comparing the effects of the two types of surgical masks on exhalation resistance, the exhalation resistance of EHMRs covered with Level 1 masks were within 2 mmH_2O of those covered with Level 3 masks—with the exception of one model with P100 filters, for which the EHMR covered with a Level 3 surgical mask measured a mean resistance over 4 mmH_2O higher than when covered with a Level 1 surgical mask. These findings indicate little difference between the exhalation resistance of EHMRs covered with Level 1 surgical masks and those covered with Level 3 surgical masks, despite the potentially different design characteristics to meet ASTM F2100 requirements—though the differential pressure limit for Level 3 masks is only 1 mmH_2O/cm^2 higher than the limit for Level 1 masks.

In this study, the exhalation resistance was measured at a continuous airflow rate of 85 L/min, per NIOSH TEB-APR-STP-0003 [NIOSH 2019], which is comparable to the mean expiration flow rate experienced by healthy adult males exercising at high work rates [Silverman et al. 1951; Janssen et al. 2005]. Adult females and unhealthy people would likely experience lower expiration flow rates at high work rates [Janssen et al. 2005; Coyne et al. 2009]. This test condition represents a rigorous test for assessing exhalation resistance, since higher expiratory airflow rates experienced during hard work result in higher breathing resistances—though it is possible that certain workplace activities in healthcare that require high exertion may create higher expiratory flow rates and subsequently result in higher breathing resistances.

Carbon Dioxide Concentration

To create the simulated breath during the test for inspired CO_2 levels, a breathing machine cam was rotated using the linear movement of two pistons with pre-determined endpoints, creating a repeatable, fixed breathing pattern. This breathing simulation is unresponsive to downstream resistance, including resistance induced by the respirator, its filters, and surgical masks. Therefore, inspired CO_2 levels were dependent on only two factors: the breathing rate and the facepiece volume. For this study, and in the STP, the breathing rate was held constant at a minute ventilation of 10.5 L/min, meaning differences in inspired CO_2 levels between the different test conditions imposed can be attributed solely to facepiece volume.

EHMRs modified to filter the exhaled breath by removing the inhalation valve membranes and blocking the exhalation valve displayed increases between 0.33% and 0.98% mean inspired CO_2 levels when compared to the controls. Removing the inhalation valve membranes introduces the respirator filters into the facepiece volume, thereby increasing the dead space and subsequent inspired CO_2 levels. Differences between the N95 filter configurations and P100 filter configurations of the modified EHMRs did not exceed 0.3%, indicating that the volumes (sizes) of the N95 and P100 filters are similar for each EHMR model.

Applying a Level 1 surgical mask over the exhalation valves increased the mean inspired CO_2 levels in six of the nine configurations tested. Likewise, applying a Level 3 surgical mask over the exhalation valves increased the mean inspired CO_2 levels in six of the nine configurations tested. However, neither approach of applying a Level 1 or a Level 3 surgical mask caused increases greater than 0.5% inspired CO_2, indicating that the surgical masks did not increase the dead space in the facepiece. Since the two inhalation valve membranes and one exhalation valve membrane remained in place when the EHMRs were covered, the space between the exhalation valve and the surgical masks was not part of the respirator dead space. As with the exhalation resistance measurements, differences between the inspired CO_2 levels of EHMRs covered with Level 1 or Level 3 surgical masks were small, with each configuration measuring within about 0.1% inspired CO_2 for both levels.

Though there is no inspired CO_2 level performance requirement for half-mask APRs, OSHA has a permissible exposure limit of 5,000 parts per million CO_2 time-weighted average, or 0.5% for an 8-hour workday [CDC 1994]. At CO_2 concentrations less than or equal to 2.0%, discomfort may be perceived, dependent on factors such as the exposure time and concentration and the physical fitness and work rate of the user. CO_2 concentrations of greater than 2.0% may result in more significant discomfort for the user and physiological symptoms such as fatigue, dizziness, headache, or shortness of breath [Kloos and Lamonica 1966; Roberge et al. 2010].

The mean inspired CO_2 levels of all the controls assessed in this study measured less than or equal to 1%. Additionally, applying a surgical mask over the exhalation valves generally caused little to no increase in inspired CO_2 levels, with mean inspired CO_2 levels measuring less than 1% and up to about 1.25% across all configurations. At these levels, it is not expected that users would experience discomfort or physiological symptoms due to the buildup of CO_2 in the facepiece. However, modifying the EHMRs to filter the user's exhaled breath caused the mean inspired CO_2 values to increase to at least 1.25% inspired CO_2 and nearly up to 2% in certain models, with one measurement of one configuration exceeding 2%. At these levels, it is possible that users may be affected by the higher levels of inspired CO_2, particularly when wearing these modified devices for longer periods of time in sedentary settings.

The breathing rate used in this study was a sedentary breathing rate [Silverman et al. 1945], equivalent to that found in healthy adult males, ages 19–35, sitting still. In the cited study, upon which the NIOSH STP for determining CO_2 concentrations in respirators was based, this breathing rate and these healthy subjects were chosen to provide the greatest concentration of inspired CO_2 likely to be experienced in a workplace setting. A higher work rate or activity level would decrease the concentration of CO_2, and the sedentary breathing rate used in the current study is likely lower than what healthcare workers would experience when wearing EHMRs, making this a rigorous test for determining the buildup of CO_2.

Limitations

High variability in the data, seen in select datasets in Figures 6–9, are likely due to the variability between respirator donnings and how tightly the respirator was secured to the headforms, as each observation was a separate donning. Unlike FFRs, EHMRs are not sealed to the headform with glue or wax during the exhalation resistance test [NIOSH 2019] and rely solely on the respirator straps to secure it to the headform. Likewise, EHMRs (in the case of this study) and other respirator classes (in the case of approval testing) are not sealed to the headform during the inspired CO_2 level test and are mounted using the respirator's own straps or head harness [NIOSH 2020a]. Additionally, donning a surgical mask over the EHMRs introduced further variability due to variability between donnings for both the exhalation resistance and inspired CO_2 level tests.

Because only nine EHMR configurations were assessed and sample sizes were small (n=3), the conclusions that can be drawn and analyses that can be performed are limited. A larger sample size and larger selection of models is needed to classify and assess the relationships of respirator design features on exhalation resistance and inspired CO_2 levels. Potential variables of interest include facepiece design and volume (including respirator size, in that only medium sizes were assessed in this study), respirator fit, exhalation valve positioning, exhalation valve protective cover design, and filter materials and design.

Despite CDC's broad recommendation at the time of this study to cover respirators with exhalation valves with surgical masks, procedure masks, or cloth face coverings, this study only evaluated surgical masks as a covering over an EHMR. As described in the Respirator Test Conditions subsection of Methods, this decision was made because surgical masks have behind-the-head ties, which allowed for more precise positioning over the exhalation valve and offered the capability to be tightened for fit [ASTM 2021]. However, it is possible that applying different types of coverings over an EHMR could create different or increased exhalation resistances compared to those measured in this study.

The method in this study of modifying EHMRs to filter the exhaled breath involved those filters typically used in one direction only for the purpose of filtering inhaled breath. Although common filters are believed to provide similar filtration regardless of the direction, the filtration efficiencies of the EHMR filters used in this study were not evaluated for directionality, nor does NIOSH assess filtration efficiency in the exhalation airflow direction as part of respirator approval testing.

The filters used in this study are disposable filters that are coupled with reusable facepieces and other required components to provide a complete respirator assembly. Typically, respirator manufacturers recommend replacing EHMR filters when soiled or clogged with particulate, when the respirator becomes difficult to breathe through, or after a specified time frame, such as after an 8-hour work shift when used in industrial settings [CDC 2020a]. For canisters and cartridges that provide protection against gases and vapors, OSHA requires the employer to implement a canister or cartridge change schedule [Respiratory protection 2004]. Changing of the EHMR filters may be needed more frequently when modifying the respirators to filter the user's exhaled breath, as filtration of the heated and humidified exhaled breath could impact filter performance and life.

CONCLUSION

This study demonstrates that EHMRs can be modified by blocking the exhalation valve and removing the inhalation valve membranes and still meet the NIOSH exhalation resistance minimum performance requirement. Although the end user cannot make modifications to the design of a NIOSH-approved respirator, as this voids the NIOSH approval [NIOSH 2020c], the results of this study should provide respirator manufacturers with confidence that new or redesigned EHMRs without an exhalation valve, which may be desirable to healthcare workers when source control is needed, can still meet the exhalation resistance performance requirement. Regardless, for new EHMR designs without an exhalation valve or for modifications to existing EHMR designs to obtain NIOSH approval, the applicant must go through the standard approval process and meet all necessary requirements.

While this study was in progress, several EHMR models without exhalation valves were approved by NIOSH [CDC 2021a]. Another existing EHMR has been approved with an exhalation valve filtering adaptor accessory that attaches to the outside of the exhalation valve, providing another approach to filtering the exhaled breath different from that used in this study. The approval process involved meeting the exhalation resistance performance requirement, but the filtration efficiency of the exhalation valve filter accessory was not measured. The most effective EHMR design characteristics for improving potential source control while meeting current performance requirements will be assessed in future studies. Future research is also needed to address the potential source control efficacy, in the form of outward filtration efficiency, of the recently approved non-valved EHMR models and EHMR model with an exhalation valve filter accessory.

The CDC recommendation at the time of this study was to cover EHMRs with exhalation valves with a surgical mask, procedure mask, or a cloth face covering when both source control and respiratory protection were required. This study demonstrates that EHMR exhalation valves can be covered with a surgical mask and meet the exhalation resistance performance requirement required for NIOSH approval. Further, covering the EHMRs with surgical masks was not found to significantly increase inspired CO_2 levels compared to uncovered EHMR exhalation valves. Though results varied significantly among respirator models and seemed to be heavily dependent on how the surgical mask and respirator were donned, the measured exhalation resistance generally did not approach the 25 mmH_2O NIOSH limit, indicating that covering the exhalation valve with other types of loose-fitting coverings may also meet the NIOSH exhalation resistance performance requirement. The verification code for this document is 750500

The results of this study demonstrate promise that EHMRs with exhalation valves can be modified or covered to help improve potential source control efficacy with minimal impact to comfort and acceptance due to increased exhalation resistance and inspired CO_2 levels. However, due to the increases in both exhalation resistance and inspired CO_2 levels created by modifying EHMRs to filter the exhaled breath, as well as variability between respirator configurations, additional studies may need to be completed on the physiological and/or comfort-related impacts on users, such as changes in concentrations of CO_2 in the blood or how respirator time-of-use impacts comfort. Other measures of comfort such as moisture and heat buildup inside the facepiece also need to be studied. This future research can be in the form of laboratory and/or human subject tests [Shaffer et al. 2014] and can inform design features of EHMRs to optimize user comfort while also providing improved source control. As a result, EHMRs may be

designed or include additional accessories to help provide source control as well as respiratory protection. This will further the integration of reusable respirators into healthcare to mitigate disposable respirator shortages and help reduce the potential for expelled particles to reach the environment.

For Further Information

For further information on elastomeric half-mask respirators, please visit the NIOSH Elastomeric Half Mask Respirator Resources page or contact the NIOSH National Personal Protective Technology Laboratory.

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