

FACT SHEET – PPE PRESERVATION & ECONOMY – REUSABLE
EQUIPMENT

Elastomeric Half-Mask Respirators and Powered Air-Purifying Respirators in Healthcare and Emergency Medical Service Settings

This fact sheet provides useful information for healthcare and emergency medical service organizations regarding re-usable, National Institute for Occupational Safety and Health (NIOSH)-approved elastomeric half-mask respirators (EHMRs) and powered air-purifying respirators (PAPRs) to expand options to meet respiratory protection demand. Reusable personal protective equipment (PPE) provides an important opportunity for cost-effective preservation of critical life-saving equipment in an environment in which PPE is in short supply and appropriate disinfection supplies are available. This option can also provide substantial long-term cost savings in a conventional care environment.

Elastomeric Half-Mask Respirators (EHMRs)

An EHMR is a respirator with a tight-fitting facepiece made of synthetic or natural rubber materials, which can be used, cleaned, disinfected, stored, and re-used. EHMRs provide the same level of protection as N95 filtering facepiece respirators (FFRs) and are alternatives for augmenting the total respirator supplies available for use by healthcare personnel (HCP) and emergency medical services (EMS) workers. However, they require maintenance and a supply of replaceable components including straps, inhalation and exhalation valves, valve covers, and filters, cartridges, or canisters.

Most of the EHMRs include exhalation valves. Due to the presence of an exhalation valve, EHMRs with exhalation valves are not recommended where a sterile environment is required, such as for surgical procedures (National Academy of Sciences, Engineering, and Medicine 2019*), nor if being used where other source control is important (protecting others from infection from the wearer). As with all tight-fitting respirators, including N95 FFRs, fit testing is required for effective protection by EHMRs. The CDC has demonstrated that time to fit test individuals for EHMRs is equivalent to time to fit test individuals for N95 FFRs (Pompeii 2020*). The CDC has posted a comprehensive webinar on the [Use of Elastomeric Respirators in Healthcare](#).

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Whenever respiratory protection is required in any occupational setting, the Occupational Safety and Health Administration's (OSHA's) respiratory protection standard (29 CFR 1910.134) requires employers to establish and implement a written respiratory protection program with worksite-specific procedures to include elements such as respirator selection, medical evaluations, fit-testing, maintenance, and training. The CDC has posted [CDC Elastomeric Respirators: Strategies During Conventional and Surge Demand Situations](#) to offer more detailed guidance for the use of reusable elastomeric particulate respirators to provide respiratory protection to HCP against pathogens as a component of a formally developed and implemented written respiratory protection program (CDC 2020a).

Are EHMRs authorized for use in a healthcare setting during the COVID-19 pandemic?

Although EHMRs are not cleared by the FDA for fluid resistance, based on their NIOSH approval, they can provide at least equivalent respiratory protection to N95 FFRs. On March 28, 2020, the Food and Drug Administration (FDA) revised an [Emergency Use Authorization for NIOSH-approved FFRs](#) to authorize non-powered air-purifying particulate elastomeric half-facepiece and full-facepiece respirators that have been approved by NIOSH in accordance with 42 CFR Part 84 and listed on the NIOSH Certified Equipment List (CEL) for use in healthcare settings by healthcare personnel when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during respirator shortages resulting from the coronavirus disease 2019 (COVID-19) outbreak (FDA 2020). However, limitations to using EHMRs exist (e.g., presence of exhalation valves; lack of fluid resistance), which must be evaluated by employers prior to selecting EHMRs for specific occupational tasks (see section on limitations below).

Can EHMRs be used in routine healthcare?

Yes. Although limitations must be considered (section below), many healthcare organizations have successfully adopted use of EHMRs for routine healthcare, given the benefits (next section). A recent report by the National Academies of Sciences, Engineering, and Medicine (2019)* summarizes studies on efficacy and recognizes EHMRs as “a viable option for respiratory protection programs for routine use in health care when logistic and implementation challenges are addressed, including education, training, cleaning, disinfection, and storage challenges.” A recent study explored factors, such as storage and cleaning, influencing use of EHMRs in organizations in which they were available (Hines et al. 2019*).

Whenever respiratory protection is required in any occupational setting, OSHA's respiratory protection standard, 29 CFR 1910.134, requires employers to provide employees with only NIOSH-approved respirators to provide appropriate respiratory protection for routine protection of healthcare workers from (solid or liquid) aerosol hazards.

What are benefits of using EHMRs?

- **Protection:** The Assigned Protection Factor (APF) for EHMRs is the same as for N95 FFRs, both having an APF of 10 (OSHA 2009). APF is defined as the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program, as specified under OSHA's 29

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CFR 1910.134 (OSHA 2020). EHMRs tend to achieve a higher fit factor (better seal) than N95 FFRs because their sealing surfaces and adjustable straps tend to accommodate a better fit.

- **Cost effectiveness:** EHMR use can be cost-effective, particularly over the long-term. A recent study found that a network reduced the number of N95s needed by 95 percent by implementing an elastomeric mask program, costing the network ten times less per month than purchasing disposable N95s (Chalikonda 2020*).
- **Reuse:** Unlike disposable FFRs, EHMRs are designed to be reusable. Following manufacturers' instructions, the elastomeric facepiece can be cleaned, disinfected, and reused. While the hard, outer casing of filters, cartridges, or canisters may be wiped down, the filter media inside cannot be cleaned. Manufacturers typically recommend that filter cartridges be discarded after each use when cleaning an elastomeric respirator. Following manufacturer recommendations may be possible for some employers, but others may find discarding the filter component with each cleaning of an elastomeric respirator to be a cost factor when selecting between FFRs and elastomeric respirators. In addition, especially in times of shortage, users may have difficulty replacing the filter cartridges. OSHA requires replacing filters "where necessary," for example, when soiled, contaminated, or clogged. [CDC Elastomeric Respirators: Strategies During Conventional and Surge Demand Situations](#) provides guidance for cleaning and disinfecting elastomeric respirators and filter cartridges during conventional, contingency, and crisis strategies (CDC 2020a). Following these instructions, one hospital reported successfully wiping down with a 70-percent alcohol solution or submerging used respirators in soap and water (without the detachable filter) (Khamsi 2020*).
- **Lower demand for N95 FFRs during shortages:** Some healthcare facilities may choose to use EHMRs to address potential supply shortages, since EHMR use will reduce demand for NIOSH-approved disposable N95 FFRs. In a 2015 CDC study modeling demand in a pandemic disease outbreak, EHMRs used nationally in a healthcare setting combined with other use-reduction methods resulted in an estimated reduction of NIOSH-approved disposable N95 FFR demand to between two and nine percent of that for base cases under the modeling assumptions (Carias 2015*). During the COVID-19 pandemic, Allegheny Health Network, a 2200-bed, nine-hospital system with 21,000 employees and 28 graduate medical education programs in Western Pennsylvania and New York, transitioned their entire health system from N95 FFRs to elastomeric respirators. They reported a 95 percent cost savings over a 30-day timeframe (Chalikonda 2020*).

What are limitations to using EHMRs in a healthcare setting?

- **Exhalation valve:** Most EHMRs contain an exhalation valve and, therefore, should not be used in settings in which protection of a sterile field or other source control is required. If respirators with exhalation valves are the only respiratory protection available when protection of a sterile field or other source control is required, covering the exhalation valve with a surgical mask or with a surgical mask and a face shield can be considered (CDC 2020c).

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- Respirators with exhalation valves protect the wearer from SARS-CoV-2 (the virus that causes COVID-19 disease), but may not prevent the virus spreading from the wearer to others (see [Personal Protective Equipment: Questions and Answers](#)).
- Respirators without exhalation valves protect both the wearer from SARS-CoV-2 and prevent the virus spreading from the wearer to others.
- **Communication:** HCP or EMS workers wearing EHMRs may experience difficulty with communication, though studies have shown that EHMRs meet NIOSH criteria for speech intelligibility (Palmiero, Symons, Morgan, and Shaffer 2016*). To address this limitation, some models have a speech diaphragm. Note that the EHMR facepiece is opaque. Like FFRs, patients and employees with hearing impairments or disabilities who use lip-reading will need reasonable accommodation to communicate effectively.
- **Care needs to be taken during cleaning and disinfecting** to avoid contact with the filter media and potential contamination or injury to respirator-cleaning staff members in accordance with manufacturers' instructions and facility standard operating procedures.
- **Training:** As with N95 FFRs, HCP and EMS workers must be educated and trained on how to safely use their EHMRs, following respirator manufacturer's instructions and OSHA requirements.
- **Storage:** OSHA requires that respirators be stored in a location that protects them from damage, contamination, dust, sunlight, extreme temperatures, excessive moisture, and damaging chemicals, and that they be packed or stored to prevent deformation of the facepiece and exhalation valve.
- **Fit testing:** As with N95 FFRs and in accordance with OSHA 1910.134, HCP and EMS workers must be fit tested to wear EHMRs.

How do I find NIOSH-approved EHMRs?

The appropriate CEL of NIOSH-approved EHMRs is linked here: [NPPTL Certified Equipment List \(CEL\) Search](#). Use the following search procedure:

- Schedule: Choose "84A" (Particulate Filter Respirators) in scroll menu, and choose "Particulate Filtering"
- Facepiece Type: Scroll to "Half Mask"
- Choose "Non-Powered"
- Click on "View Results"

Replaceable filters, cartridges, or combination filters and cartridges offering particulate protection must be compatible with the EHMR facepiece and used in conformance with the conditions of their NIOSH certification. Hence, a NIOSH-approved respirator assembly cannot be modified, and only those replacement parts specified and provided by the manufacturer must be used. The manufacturer's instructions are specific to its respirator materials and specifications. If the healthcare setting does not have any oil-based aerosols present, any filter series can be used (i.e., N, R, or P). If oil-based aerosols are present, only R or P filter series should be used. Filters are available in three efficiency levels: 95, 99, and 100. All meet or exceed the minimum performance requirements for N95 FFRs.

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How do I find more information on EHRMs?

For More information on EHRMs see the NIOSH Webinar [Elastomeric Half-Mask Respirator \(EHMR\) Federal Register Notice \(FRN\) Webinar](#), October 13, 2020.

Powered Air-Purifying Respirators (PAPRs)

A PAPR is an air-purifying respirator that uses a blower to move air through filter cartridges or canisters and into the breathing zone of the wearer. This process utilizes a powered mechanism to draw ambient air through an air-purifying element(s) to remove contaminants from the ambient air flow inside either a tight-fitting facepiece or a loose-fitting hood or helmet, providing a higher APF (greater protection) than EHRMs and N95 FFRs. As such, a PAPR can be used for protection during healthcare procedures in which HCP or EMS workers are exposed to substantial risks of aerosolized pathogens causing acute respiratory infections (e.g., SARS-CoV-2). Like EHRMs, PAPRs are alternatives for augmenting the total respirator supplies available for use by healthcare personnel (HCP) and EMS workers and can provide substantial long-term cost savings in a conventional care environment. The [CDC Guidance](#) provides considerations for optimizing the supply of PAPRs (CDC 2020b).

As with all respirators used in occupational settings, PAPR use in healthcare and emergency medical service settings requires employers to establish and implement a written respiratory protection program with worksite-specific procedures in accordance with OSHA's 29 CFR 1910.134. Elements of a respiratory protection program include, but are not limited to, respirator selection, medical evaluations, fit-testing, maintenance, and training.

Are PAPRs authorized for use in a healthcare setting, routinely or during the COVID-19 pandemic?

The [FDA Emergency Use Authorization](#) authorizes healthcare facilities to use NIOSH-approved PAPRs, in accordance with 42 CFR Part 84 and as listed on the NIOSH Certified Equipment List (CEL) for approved PAPRs with particulate protection, to prevent wearer exposure to pathogenic biological airborne particulates during respirator shortages resulting from the COVID-19 pandemic. PAPRs have been used in healthcare prior to the pandemic; however, the limitations listed below should be considered prior to selecting PAPRs for specific occupational tasks.

What are benefits of using a PAPR?

Like EHRMs, PAPRs are reusable because they can be cleaned, disinfected, stored, and reused.

NIOSH-approved PAPRs have several advantages:

- A [fit test is not required](#) for PAPRs with loose-fitting headgear such as hoods and helmets. PAPRs with loose-fitting headgear can be worn over [facial hair](#) (albeit a limited amount of facial hair) and may be an accommodation alternative especially for individuals who maintain facial hair for religious exercise.

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- Specialized cartridges: Like EHMRs, some PAPR models offer cartridges specialized for particulate and/or gas/vapor protection.
- Splash protection: Hooded PAPRs and PAPRs with helmets may offer limited to substantial splash-protection for the face and eyes.
- Protection: PAPR systems have APFs of at least 25 (i.e., loose-fitting PAPRs), but can be up to 1,000 for tight-fitting PAPRs with a full facepiece. .
- Communication: Some PAPRs have disposable, loose-fitting headgear through which patients can see the face of the wearer, providing for better interpersonal communication. Loose-fitting PAPRs can also provide a mechanism for lip-reading for patients and employees who may need this reasonable accommodation.
- Reuse: Most PAPR components can be cleaned, disinfected, re-used, and shared.
- Ease of breathing: A PAPR imposes less breathing resistance and may be less taxing physiologically than other respirators. Additionally, PAPRs provide a cooling effect due to the air flow.

What are limitations to using PAPRs in healthcare settings?

- Visual field: A PAPR may interfere with the wearer's visual field because of the limited downward vertical field of view.
- Noise: The wearer's ability to hear may be reduced because of the blower noise, and noise associated with the movement of a loose head covering.
- Stethoscope use: The wearer's ability to use a stethoscope may be limited.
- Batteries: PAPR batteries must be recharged or replaced according to the manufacturer's guidance.
- Training: HCP and EMS workers must be trained on how to safely use their PAPRs, following manufacturer's instructions and OSHA requirements, including how to don and doff correctly and how to recognize decline or loss of battery power.
- Maintenance and cleaning: The facility must train HCP or other staff to maintain and properly clean and disinfect the PAPR.
- Storage: PAPRs require substantial storage space when not being used, such as between shifts. OSHA requires that respirators be stored in a location that protects them from damage, contamination, dust, sunlight, extreme temperatures, excessive moisture, and damaging chemicals and that they be packed or stored to prevent deformation of the facepiece and exhalation valve.
- Splash protection: Some PAPRs may not offer splash-protection for the face and eyes.
- Components: Like EHMRs, although PAPRs are reusable with proper disinfection and maintenance, some of their components (e.g., filters, hoses) need to be periodically replaced.
- Use: Like EHMRs with exhalation valves, PAPRs may not be appropriate in situations where a sterile field must be maintained.

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How do I find NIOSH-approved PAPRs?

The [NPPTL Certified Equipment List \(CEL\) Search](#) contains the CEL of PAPRs appropriate for healthcare settings. Use the following search procedure:

- Schedule: Choose “21C” (Particulate Respirators) in scroll menu and choose “Particulate Filtering.”
- Facepiece Type: Scroll to “Both hood and helmet.”
- Choose “Powered.”
- Click on “View Results.”

Questions or Concerns

Contact the Healthcare Resilience Working Group at Covid.Healthcareresilience@hhs.gov, NIOSH at PPEConcerns@cdc.gov, and/or the device manufacturer(s).

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