Coronavirus Disease 2019 (COVID-19)

Considerations for Optimizing the Supply of Powered Air-Purifying Respirators (PAPRs)

For Healthcare Practitioners (HCP)

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Who this guidance is for: use by federal, state, and local public health officials, respiratory protection program managers, occupational health service leaders, infection prevention and control program leaders, and other leaders in healthcare settings who are responsible for developing and implementing policies and procedures for preventing pathogen transmission in healthcare settings.

Purpose: This webpage describes considerations for the use of powered air-purifying respirators (PAPRs) to provide respiratory protection to healthcare practitioners (HCP) as a component of a formally developed and implemented written respiratory protection program. It addresses conventional, contingency, and crisis surge PAPR use and maintenance practices.

This interim guidance is based on what is currently known about the transmission and severity of coronavirus disease 2019 (COVID-19).

The US Centers for Disease Control and Prevention (CDC) will update this guidance as needed and as additional information becomes available. Please check the CDC COVID-19 website periodically for updated interim guidance.

Conventional capacity strategies should be incorporated into everyday practices.

Contingency capacity strategies should be used when shortages are predicted but supplies are available.

Crisis capacity strategies should be used during known shortages.

Introduction

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NIOSH-approved respirators are available in many types, models, and sizes from many manufacturers for a wide variety of uses in many occupational settings. The most common types of respirators in healthcare are N95 filtering facepiece respirators (FFRs),

surgical N95 FFRs, and PAPRs.

Of these three options, many healthcare practitioners are the least familiar with PAPRs. A PAPR is an air-purifying respirator that uses a blower to force air through filter cartridges or canisters and into the breathing zone of the wearer. This process creates an air flow inside either a tight-fitting facepiece or loose-fitting hood or helmet, providing a higher assigned protection factor (APF) than the reusable elastomeric non-powered air-purifying half facepiece (half mask) or N95 FFRs. A PAPR can be used for protection during healthcare procedures in which HCP are exposed to greater risks of aerosolized pathogens causing acute respiratory infections.

A PAPR may have a tight-fitting half or full facepiece or a loose-fitting facepiece, hood, or helmet. It has an OSHA APF of at least 25 for loose-fitting hoods and helmets, 50 for tight-fitting half masks, and 1,000 for full facepiece types and some loose-fitting hoods and helmets where the manufacturer's testing has demonstrated an APF of 1,000.

CDC has published recommendations for HCP respiratory protection and of commonly used NIOSH-approved, FDA-cleared, single-use filtering facepiece N95 surgical respirators.[1] Properly fitted FFR and half facepiece reusable elastomeric respirators are expected to reduce exposures to one-tenth of the concentration that is in the air, based on OSHA's APF of 10 for these respirator types. All PAPR APFs exceed the APF of 10 for N95 FFR or elastomeric half facepiece respirators.[2]

PAPRs reduce the aerosol concentration inhaled by the wearer to at least 1/25th of that in the air, compared to a 1/10th reduction for FFRs and elastomeric half facepiece air-purifying respirators. OSHA assigns an APF of 1,000 to some PAPRs with hoods or helmets. However, employers must have evidence provided by the respirator manufacturer that testing of these respirators demonstrates performance at a level of protection of 1,000 to receive an APF of 1,000. Absent such evidence, PAPRs with loose-fitting helmets or hoods have an APF of 25. When used properly, PAPRs provide increased protection and decrease the likelihood of infection transmission to the wearer as compared to FFRs and half face reusable elastomeric respirators.

A variety of NIOSH-approved PAPR designs are available. Examples include those with tight-fitting facepieces and loose-fitting hoods or helmets, blower styles, battery types (e.g., Lithium ion, Nickel-Metal hydride, Nickel Cadmium) or over-the-counter disposable batteries, and high efficiency (HE) filters or filter cartridges. HE filters are 99.97% efficient against 0.3 micron particles. A PAPR may have adjustable air flow rates for added comfort and a range of cartridge protections some of which are solely for particulates (HE filters) and others which also protect against chemical gases and vapors that can be used to help protect against hazards associated with the handling of certain hazardous drugs and cleaning/disinfecting operations. The substantial PAPR product diversity provides flexibility to customize protection needed in a healthcare setting.

Loose-fitting NIOSH-approved PAPRs have several advantages over tight-fitting non-powered approved air-purifying respirators, including[3]:

- 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 with a limited amount of facial hair.

- Some models offer cartridges for particulate and/or gas/vapor protection.
- Hooded PAPRs and PAPRs with helmets may offer limited to significant splash protection for the face and eyes.
- PAPR systems have assigned protection factors (APF) of at least 25 (and up to 1,000 in some cases, as described above).
- Some PAPRs have disposable, loose-fitting headgear and patients can see the face of the HCP, providing for better interpersonal communication.
- Most PAPR components can be cleaned, disinfected, re-used, and shared.
- PAPRs use only HE filters, which have a greater filtration efficiency against the smallest pathogen particles compared to N95 FFRs.
- A PAPR may be less taxing from a physiological/breathing resistance perspective than other respirators.

The facility should assess the limitations and factors associated with using PAPRs when considering their use in healthcare settings, including:

- A PAPR may interfere with the HCP's visual field because of the limited downward vertical field of view.
- The HCP's ability to hear may be reduced because of the blower noise, and noise induced by the movement of a loose head covering.
- The HCP's ability to use of a stethoscope may be limited.
- PAPR batteries must be recharged or replaced.
- PAPRs require a significant amount of storage space in between shifts.
- The facility must train HCP's or other staff to maintain and properly disinfect and clean the PAPR.

NOTE: PAPR HE filters used in industry are generally re-used until they are soiled, damaged, or reduce PAPR air flow below specified levels. Caution should be used when using the filter for a live virus, and a practical replacement cycle should be implemented until more is known.

Conventional Capacity Strategies

OSHA-Compliant Respiratory Protection Program Requirements

When respirators, including PAPRs, are used to reduce inhalation exposures, OSHA requires a written respiratory protection program in compliance with OSHA 29CFR1910.134, and the respirators must be NIOSH-approved.[4] To be considered NIOSH-approved, the PAPR assembly cannot be modified from its approved configuration, and only those replacement parts specified and provided by the manufacturer must be used. The manufacturer's PAPR instructions are specific to a respirator model's materials and specifications. Instructions are generally provided with the PAPR facepiece, blower, and battery packaging. All instructions must be carefully followed.

OSHA also permits employers to use the cleaning recommendations provided by the manufacturer of the respirator, provided such procedures are as effective as those listed in Appendix B- 2, meaning that the respirator is properly cleaned and disinfected in a manner that prevents damage to the respirator and does not cause harm (e.g., skin irritation) to the user.[5]

PAPRs may be used in healthcare for a variety of applications. Because they provide higher APFs than N95 FFRs and reusable elastomeric half facepiece respirators, PAPRs are suitable for use when aerosol-generating procedures are performed, by hospital first receivers, or when the respirator user is not able to wear a tight-fitting respirator. For effective use, PAPR manufacturer instructions must be followed.

The components of NIOSH-approved PAPRs vary considerably among manufacturers, and they react differently to cleaning and disinfection solutions and procedures. Manufacturers' cleaning and disinfection solutions and procedures also vary. These important maintenance activities can cause damage or deteriorate PAPR facepieces, headgear components (hoods, helmets), breathing tubes (hoses), and batteries. If cleaning and disinfection solutions and procedures are ineffective, HCP may be at risk of contact transmission. For these reasons, manufacturers generally recommend that the filter component be discarded. Some employers may be able to follow manufacturer-specific instructions for conventional use, but the cost of doing so may make PAPRs a less desirable solution to achieve the necessary protection.

Cleaning and Disinfection of PAPR Components

PAPR use requires a robust maintenance program for repairing or replacing components that have become damaged during use, or during cleaning and disinfection and battery management procedures.[6] Competent, trained staff are required to support the PAPR maintenance program.

Manufacturers recommend cleaning and disinfection procedures for PAPR components except for the HE filter/cartridge, which they generally recommend be discarded and replaced. Filter cartridges can be reused until they become so clogged that they reduce airflow or become visibly soiled or damaged. Clogging is not expected to be a factor in non-dusty environments such as healthcare settings. The outside of the filter cartridge can have surface cleaning and decontamination while the rest of the unit is being serviced. Viruses and bacteria causing acute respiratory infections can survive on respirator components for variable periods of time, from hours to weeks. Consequently, contaminated respirators must be handled, cleaned, and disinfected properly to reduce the possibility of the device serving as a fomite and contributing to disease transmission.[7] According to OSHA, the employer may use other commercially available cleansers of equivalent disinfection quality if their use is recommended or approved by the respirator manufacturer.

Conventional use requires cleaning and disinfecting using either the procedures in OSHA's Respiratory Protection Standard or the procedures recommended by the respirator manufacturer, provided they are at least as effective as OSHA's.[8] If an alternate procedure is used to clean and disinfect the PAPR and its components, it must be recommended or approved by the manufacturer.

In general, cleaning and disinfecting consists of dissembling the PAPR, cleaning and disinfecting components, thoroughly rinsing components, and reassembling the PAPR when components are dry. It is important to follow all steps set forth in the manufacturer's instructions. Cleaning is recommended after each use, but the PAPR must be cleaned as often as necessary to prevent them from becoming unsanitary.

As with reusable elastomeric respirators, manufacturers generally recommend PAPR HE filters and filter cartridges are not to be cleaned or disinfected. Unlike reusable elastomeric respirators, PAPRs use only HE filters. These filters can differ in their appearance and their attachment on, or fit into, the blower assembly. Routine maintenance is also required for battery charging, and/or replacement. The maintenance program for PAPRs requires a supply of replacement components, including HE filters/cartridges to support and maintain PAPR use.

CDC has provided thorough information on disinfecting equipment and surfaces potentially contaminated by coronaviruses.[9] Specific instructions for cleaning and disinfecting PAPRs are not addressed.

Some disinfectants are powerful germicides, and their use requires special precautions such as adequate ventilation, use of clean non-sterile gloves, gowns, or face shields. Care must be taken during cleaning and disinfection to ensure the cleaning staff does not self-infect or injure themselves performing this work.

Cleaning and disinfection must be done by competent trained individuals. Centralizing this activity can ensure it is properly done.

Contingency and Crisis Capacity Considerations for Filter/Cartridge Cleaning and Disinfection

Because of necessity, PAPR components including filters may be treated differently for their cleaning and disinfection. Whereas conventional practice is to discard the filters after each use, contingency or crisis practices may necessitate cleaning and disinfecting the filter. The performance of some filter media can be degraded by contact with the disinfectant.

- During surge situations, when manufacturer instructions are not available or adequate, and supply shortages exist, interim alternate procedures cleaning and disinfection procedures may be necessary and effective to reuse scarce or unavailable replacement components. However, interim alternate procedures could increase the risk of contact transmission or damage to the filter media if not done properly. Alternate procedures and risks must be considered to protect HCP and meet healthcare needs.
- OSHA and manufacturer instructions for cleaning and disinfection lack specific details for implementing standardized procedures during healthcare use. They rely upon the user to augment their general cleaning and disinfection instructions. Therefore, healthcare facilities need to establish procedures that will be effective to render targeted pathogens inviable and not damage PAPR components intended to

be re-used.

- Most PAPR components can be cleaned, disinfected, and if not damaged, reused many times. PAPRs use only HE filters or filter cartridges. These can be very different in size, shape, and appearance.
- Some filters are contained in a protective cartridge attached onto the blower assembly. These may have openings in the cartridge housing that expose the filter media, or they may be substantially protective enclosing the filter media that cannot be seen externally.
- Other filters are not contained in a cartridge. These may be inserted into the blower assembly preventing filter media from outside exposures including cleaning and disinfectant wipes.

Cleaning

- When removing organic and inorganic matter from the PAPR components, trained personnel should wear nitrile gloves to protect their hands and limit the potential for self-infection. Additional protective equipment such as gowns and face shields, as well as ventilation, may be required during cleaning and disinfection procedures. Cleaning solution contact with the filter media must be avoided.
- A detergent or soap and warm water could be used to clean the surface of the exterior filter cartridge prior to disinfection. Carefully avoid contact with the filter media. Cleaning can be done using a clean, soft cloth dampened with warm water approximately 49°C (120°F) containing a mild pH neutral (pH 6-8) detergent and using a mechanical wiping action. Any component exposed to moisture during the cleaning process needs to be carefully and thoroughly dried. Other PAPR components may generally be cleaned using the manufacturer's recommended procedures.

Disinfecting

The effectiveness of an alternate filter cartridge disinfection solution and procedure may be uncertain:

- All crevices of many filter cartridge housings may not be reached with sufficient disinfection solution or be contacted for the period of time required to be effective.
- The filter media may be degraded by contact with the disinfectant.
- Filters and filter media must be carefully and thoroughly dried. Any remaining fugitive moisture could promote the growth or sustainability of certain pathogens.

Some PAPRs have filter cartridges or blower assemblies that prevent disinfectant contact with the filter media. If available, these PAPRs should be used in the contingency or crisis capacity strategy approaches. These PAPR designs provide added assurance that the filter media will not be contacted with the cleaning and disinfection solutions. These filter cartridges, as well as PAPR blowers may be wiped down repeatedly.

NOTE: PAPR HE filters used in industry are generally re-used until they are soiled, damaged, or reduce PAPR air flow below specified levels. Caution should be used when using the filter for a live virus, and a practical replacement cycle

should be implemented until more is known.

Practices not approved by the manufacturer can increase the risk and uncertainty of re-using damaged or degraded components. This must be balanced against other available HCP protection options to sustain effective HCP protection and patient care.

Alternate procedures used during emergencies should be assessed and documented in the written RPP, including alternate cleaning and disinfection practices.

For disinfection, diluted household bleach solutions, alcohol solutions with at least 70% ethyl alcohol, and EPA-registered household disinfectants for use against coronaviruses are effective.

For use of diluted household bleach solutions, follow disinfectant manufacturer's instructions for proper disinfectant application, PPE, and ventilation.

- Check to ensure the product is not past its expiration date.
- Never mix household bleach with ammonia or any other cleanser. Unexpired household bleach will be effective against coronaviruses when properly diluted.

- Most household bleach solutions contain 5.25% sodium hypochlorite (50,000 ppm available chlorine) to up to 12.5% sodium hypochlorite (~125,000 ppm). It is important to check the product label and follow the disinfection directions for use, dilution, and contact time. Adjust the ratio of bleach to water as needed to achieve appropriate concentration of sodium hypochlorite.
    - Based on the EPA List N: Disinfectants for Use Against SARS-CoV-2 products, 2500 ppm (0.25%) for 5 minutes is effective. Most readily available bleach is approximately 6% so 2/3 cup of bleach per gallon of cold tap water (1:24 dilution) for 5 minutes is appropriate.
    - For bleach preparations containing 5.25% sodium hypochlorite, use ¾ cup of bleach per 1 gallon of cold tap water for 5 minutes.
    - If a lower concentration of bleach is desired, the EPA standard disinfection rate for hypochlorite products is 600 ppm for 10 minutes. That is, use 3 tablespoons of bleach per 1 gallon of cold tap water for 10 minutes.
- Prepare a fresh bleach solution each day in a well-ventilated area. Always add bleach to cold water, not water to bleach.

Products with EPA-approved emerging viral pathogens claims are expected to be effective against SARS-CoV-2. Follow the manufacturer's instructions for all cleaning and disinfection products (e.g., concentration, application method and contact time, etc.).

Disinfectants listed on the EPA's Registered Antimicrobial Products for Use Against Novel Coronavirus SARS-CoV-2, the virus that causes COVID-19, could be used to inactivate the virus.[10] Those intended for use with soft surfaces may be preferred.

CAUTION: The following may degrade or damage the respirator components.

- Strong solutions such as hypochlorite, iodine and high concentrations of alcohol may degrade, deteriorate or extract chemical additives from certain PAPR materials.

- Healthcare sterilization processes including ethylene oxide should not be used unless authorized by the respirator manufacturer as they may degrade and alter the shape of the facepiece.
- Steam sterilization equipment should not be used unless indicated as safe for the use by the specific respirator manufacturer.
- Some EPA-approved disinfectants are also available as ready to use at 2700 ppm for 1 minute; however, these strong solutions could impact the integrity of the respirator components.

Steps for cleaning and disinfecting PAPR components

The following is a general step-by-step process for cleaning and disinfecting PAPR components. PAPR manufacturers may not authorize these steps; however, during crisis operations when conventional procedures are not feasible, these steps could extend the supply of PAPR components.

If alternate cleaning or disinfection instructions are authorized, it is important to follow the facility's established infection control practices for cleaning organic and inorganic materials and infectious organisms including the virus that causes coronavirus disease 2019.

Healthcare practitioners should always wear the required proper personal protective equipment (PPE) during cleaning and disinfecting respirator components. These workers should always follow the disinfecting agent manufacturer's user instructions regarding usability, application, dilution ratio and contact time, and ensure all components are thoroughly rinsed with clean, warm water and thoroughly dried before use or storage. In addition, PAPR facepieces or headgear worn by more than one user must be cleaned and disinfected before being worn by a different user in shared situations.

There are several basic steps to clean and disinfect PAPR components – dissemble, clean, disinfect, rinse and dry, inspect, repair or replace, and store. The order and details of each step are important. PAPR components can be stored and reassembled, or reassembly can be done before use.

1. Detach the battery pack, breathing tube, waist belt, facepiece/headgear, and filter/cartridge from the motor/blower assembly. If a breathing tube disposable cover was used, discard it properly.
2. First clean the surface of each PAPR component except for the filter media after each use. Removing organic and inorganic materials from the component surfaces will help achieve maximally effective disinfection.[11]
3. Using a mechanical process, clean all components (except filter/cartridge and breathing tube disposable cover) of the PAPR assembly with a clean, soft cloth dampened with warm water that is approximately 43°C (120°F), containing a mild pH neutral (pH 6-8) detergent.
   Caution: Do not soak, dip or immerse PAPR components in the cleaning or disinfection solutions unless specifically recommended by the manufacturer.

- Do not allow liquid to enter the air outlet or inlet port or the motor/blower housing area.
- Clean the outer battery pack surface. Use caution cleaning around the battery pack connector pins where the battery contacts with the motor/blower unit or cord. Ensure this area and the pins are thoroughly dry before next use or storage.
- Clean the breathing tube by wiping it down. Alternatively, you may immerse the elastomeric breathing tube in the cleaning solution.

4. Disinfect the outer surfaces of the PAPR components by wiping with disinfectant including motor/blower, battery pack, breathing tube, and waist belt with a clean, soft cloth dampened with the appropriate disinfectant cleaners recommended or approved by the manufacturer. Follow the user instructions for the selected disinfectants. **Caution: Never soak, dip, or immerse the motor/blower assembly or battery pack in disinfectant.**
    - In addition to the disinfection solutions described above, a study of disinfectants against coronavirus 229E found several that were effective after a 1-minute contact time; these included sodium hypochlorite (at a free chlorine concentration of 1,000 ppm and 5,000 ppm), 70% ethyl alcohol.[12]
5. Rinse thoroughly, wiping each component with a clean, soft cloth dampened with fresh water warmed to a temperature of approximately 43°C (120°F). Dry thoroughly before use or storage.
    - Allow the breathing tube to completely air dry prior to reuse or storage. Air dry in an uncontaminated atmosphere, temperature not to exceed 43°C (120°F). Alternately, dry by connecting to the motor/blower unit and use it to force air through the tube until dry. Any remaining moisture could contribute to pathogen growth or sustainability.
6. Inspect and repair or replace damaged components (facepiece/headgear, breathing tube, blower, belts) following PAPR manufacturer's instructions.
7. Store components in a clean, dry location away from contamination. Alternatively, reassemble the PAPR as described in the manufacturer's user instructions, and store it so that it is ready for reuse in a clean, dry location away from contamination.

PAPR components may become damaged or deteriorated with prolonged or extended use of disinfecting products. Competent, trained staff must inspect the components of their PAPR following each disinfection and prior to re-use of components. Additionally, the user should always inspect the components of their PAPR prior to each use and report any damaged components. Damaged components should be repaired or replaced according to user instructions.

Recommendations from recent research studies and manufacturer reports

Alternate cleaning and disinfection procedures have been studied and found to be generally effective for use during a pandemic.[12] [13] Procedures were used to clean and disinfect components inoculated with H1N1 influenza A/PR/8/34 (ATCC VR-1469).

- PAPR blowers, batteries, hoods/helmets, breathing tubes, and belts were manually cleaned with 0.5% Neutrawash and subsequently disinfected with PDI SaniCloth™ wipes.
- PAPR components were alternately contaminated then cleaned and disinfected dozens of time. A sponge dampened with soap and water was used to first clean the PAPR hoods and blower units followed by wiping with a disinfecting wipe. The wipe used was PDI™ Super SaniCloth™.
- Each PAPR component except for the filter/cartridge was wiped with an autoclavable sponge moistened with a 42°C, 0.5% Neutrawash detergent solution and subsequently wiped with another autoclavable sponge soaked in 42°C water only to remove any detergent.
- PAPRs were then wiped with a Super SaniCloth™ and allowed to dry for two minutes. Specific protocols are described in the referenced documents concerning cleaning and disinfection of PAPR components except for the filter/cartridge.

While these methods have been demonstrated to be effective at disinfecting PAPRs, caution should be used as some manufacturers have reported that PDI™ AF3 Saniwipes can damage some PAPR components. The chemicals in them cause crazing (a rapid and sever embrittlement of plastics). Chemical compatibility for PAPR components is not well understood. These compounds are referred to as quaternary ammonium compounds, which PAPR manufacturers strongly recommend should be avoided. These disinfectants have been shown to be incompatible with some materials and do not have proven efficacy against all microorganisms.[11]

If following these procedures and applying them to filter cartridges during periods when supplies are limited or not available, extreme care must be taken to prevent cleaning and disinfectant contact with the filter media. External surfaces of filters cartridges should be carefully wiped, not dipped, soaked, or submerged when applying the cleaning and disinfectant solutions.

Practices not approved by the manufacturer can increase the risk and uncertainty of re-using damaged or degraded components. This must be balanced against other available HCP protection options to sustain effective HCP protection and patient care when supplies are limited or not available.

Modified procedures used during emergencies, including alternate cleaning and disinfection practices, should be documented and evaluated frequently throughout the crisis operation.

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