

CDC/NIOSH-Approved Elastomeric Respirators with P100 Filters

Brittany E. Howard, MD (Mayo Clinic, Phoenix, AZ)

1. Definition Elastomeric Respirators
2. Reasons for Consideration of Elastomeric Respirators in High Risk Areas/Procedures
3. Safety/Certification
4. Cost and Disposables
5. Maintenance and Cleaning
6. Provider Fitting
7. Considerations with Surgical Use

1. Definition

- Elastomeric Half-Mask Respirators are a reusable and washable rubber facemasks that in combination with reusable filters purifies a provider's breathing air
- These are used in healthcare and industrial settings.¹
- The CDC has a list of all approved respirators of this type including versions by 3M and Drager

https://www2a.cdc.gov/drds/cel/cel_results.asp?startrecord=1&Search=cel_form&maxrecords=50&schedule=84A&producttype=atype_2&contaminant=32&appdatefrom=&appdateto=&facepietype=Half+Mask&powered=no&scbatype=&scbause=&privatelab el



2. Reasons for Consideration of Elastomeric Respirators in High Risk Areas/Procedures:

¹ https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource1quest3.html#half

- In the current pandemic of COVID-19, N95 masks are being used and promoted as one of the highest levels PPE for provider protection
 - However, an N95 only blocks at least 95 percent of very small (0.3 micron) test particles²
 - It is the minimum respiratory protection approved for airborne protection from SARS by the CDC
 - Per CDC “A NIOSH-certified, disposable N95 respirator is sufficient for routine airborne isolation precautions. Use of a higher level of respiratory protection may be considered for certain aerosol-generating procedures” as will be encountered in ENT and aerosolizing procedures in OR³
 - N95 masks are being employed in either a reuse or extended use method; these devices have not been FDA or NIOSH approved for reuse.⁴
- In comparison, Elastomeric Respirators with P100 filters are recognized by the CDC as the highest level filter available against SARS
 - In the CDC strategy for respiratory protection during COVID pandemic, strategies are stratified into levels of “Conventional”, “Contingency”, and “Crisis”. The use of elastomeric respirators is considered a “Conventional” strategy and is considered a part of daily best practice routines⁵
 - In comparison, the current reuse/extended use of N95s is considered a “Contingency” level of respirator use and is not at best practice levels.⁶
 - P100 filters provide protection from at least 99.97% of airborne particles (0.3 microns) and is oil proof⁷. P100 filters also filter gases and vapors (amount is manufacture dependent)
 - P100 filters are equivalent to PAPRs for level of protection provided while allowing enhanced ability to protect the sterility of the surgical field⁸ due to lack of positive airflow
 - Elastomeric Respirators with P100 filters are intended for reuse and certified by NIOSH for this practice⁹

² <https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks>

³ <https://www.cdc.gov/sars/clinical/respirators.html>

⁴ <https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html>

⁵ <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/conventional-capacity-strategies.html>

⁶ <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/contingency-capacity-strategies.html>

⁷ <https://www.cdc.gov/niosh/docs/96-101/default.html>

⁸ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4456839/>

⁹ https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource1quest3.html#half

- The P100 filters used with Elastomeric Respirators lifespan is dependent on manufacturer but is typically at least 6 months. This increases long term capacity during a pandemic to provide PPE to providers.

3. Safety and Certification

- The regulation and certification of Respirators (N95 through P100) is performed by NIOSH
 - NIOSH is The National Institute for Occupational Safety and Health (NIOSH)
 - NIOSH regulates and certifies N95 masks and Elastomeric Respirators
 - You will see a NIOSH approval stamp on your N95
 - The FDA regulates surgical masks, not respirators
- The CDC recommends that only respirators with NIOSH approval be used for SARS protection by healthcare workers except in times of crisis.¹⁰
- The Elastomeric Respirators proposed for adoption allow for the use of P100 NIOSH approved filters

4. Cost and Disposables

- The Elastomeric Respirator is a reusable and washable respirator that can be used by multiple individuals with disinfection between users
 - The elastomeric respirator costs \$30 per respirator
 - It is non-disposable item and can be used by multiple individuals
- P100 filter cartilages to use with the respirator are reusable but ultimately do require replacement
 - Each cartilage costs \$2 dollars
 - Average life-span is 6 months in the healthcare setting
 - It needs to be replaced if grossly contaminated, damaged, or no longer able to be breathed through⁹
- This means that once the reusable respirators are bought by a department, for \$2 a single provider can be protected for 6 months with the highest level respiratory PPE.
 - This is the equivalent of the cost of 32-42 N95 masks for that provider
 - Once this respiratory protection is obtained, further purchase may not be needed during time of pandemic crisis given the long use of the respirators and filters.

5. Maintenance and Cleaning

- The Elastomeric Respirators are intended to be washed and disinfected and reused
- If reused by a single individual through a shift, their exterior should be cleaned between patient encounters if not fully protected from droplets
 - their exterior exposed surface can be disinfected with alcohol free disinfecting solution using a lint free wipe

¹⁰ <https://www.cdc.gov/niosh/nppt/topics/respirators/factsheets/respsars.html>

- Bleach solution (15 mL/1 gal) is recommended by CDC and deemed safe for the mask by NIOSH
- At end of use every day and/or between use by separate individuals the respirator should be disinfected following manufacturer and OSHA/NIOSH guidelines¹¹ This can be performed in sinks immediately outside an OR or in clinic area with minimal supplies/space
 - Remove filters, wipe down and disinfect filter housing with bleach solution and lint free wipe
 - Use warm water and neutral detergent to remove any soiling
 - Rinse in warm water
 - Soak in Bleach solution (10 mins per EPA to disinfect for SARS)¹²
 - Rinse with warm water
 - Air Dry
- Best practice will be protecting the Elastomeric Respirators and P100 filter from droplet contamination behind a face shield or other proactive covering in addition to routine cleaning and disinfection above

6. Provider Fitting

- Elastomeric Respirators are available in sizes small, medium, and large
- Fit testing is required for all Elastomeric Respirators to ensure protection⁹
- Qualitative fit testing is typically used for Elastomeric Respirators and is recognized by OSHA.¹³
- The following fit testing methods can be used with any Elastomeric Respirators independent of manufacturer and is approved by OSHA
 - Isoamyl acetate, which smells like bananas;
 - Saccharin, which leaves a sweet taste in your mouth;
 - Bitrex, which leaves a bitter taste in your mouth; and
 - Irritant smoke, which can cause coughing.
- Testing is subjective, rapid to perform, and testing requirements are currently available through Occupational Medicine
- Daily fit test aka Seal Checks can be performed with a team member to ensure that the mask is functioning properly before every individual use. This is an objective test and this takes less than 30 seconds

Considerations with Surgical Use

- The Elastomeric Respirator protects the provider from exposure; however, it doesn't protect the patient from the provider

¹¹ http://www.pcocinsurance.com/2011PCOCsafetyCD/NIOSH/NIOSH_RESPIRATOR_CLEANING_SANITATION.pdf

¹² <https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2>

¹³ https://www.osha.gov/video/respiratory_protection/fittesting_transcript.html

- As such, without additional protective equipment, it is not appropriate to use an elastomeric respirator in surgery as air coming out of the exhalation valve may contaminate the sterile field¹⁴
- For surgery, the exhalation valve needs to be covered with a FDA approved surgical mask to protect the sterile field.⁹

¹⁴ <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/conventional-capacity-strategies.html>

Understanding the Difference

	 Surgical Mask	 N95 Respirator	 Elastomeric Half Facepiece Respirator
Testing and Approval	Cleared by the U.S. Food and Drug Administration (FDA)	Evaluated, tested, and approved by NIOSH as per the requirements in 42 CFR Part 84*	Evaluated, tested, and approved by NIOSH as per the requirements in 42 CFR Part 84
Intended Use and Purpose	Fluid resistant and provides the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids. Protects the patient from the wearer's respiratory emissions.	Reduces wearer's exposure to particles including small particle aerosols and large droplets (only non-oil aerosols)	Reusable device made of synthetic or rubber material
Face Seal Fit	Loose-fitting	Tight-fitting	Tight-fitting
Fit Testing Requirement	No	Yes	Yes
Designed for Reuse	No	No	Yes
User Seal Check	No	Yes. Required each time the respirator is donned (put on)	Yes. Required each time the respirator is donned (put on)
Filtration	Does NOT provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection	Filters out at least 95% of airborne particles including large and small particles	May be equipped with filters that block 95%, 99%, or 100% of very small particulates. Also may be equipped to protect against vapors/gases.
Leakage	Leakage occurs around the edge of the mask when user inhales	When properly fitted and donned, minimal leakage occurs around edges of the respirator when user inhales	When properly fitted and donned, minimal leakage occurs around edges of the respirator when user inhales
Use Limitations	Disposable. Discard after each patient encounter.	Ideally should be discarded after each patient encounter and after aerosol-generating procedures. It should also be discarded when it becomes damaged or deformed; no longer forms an effective seal to the face; becomes wet or visibly dirty; breathing becomes difficult; or if it becomes contaminated with blood, respiratory or nasal secretions, or other bodily fluids.	Reusable and must be cleaned/disinfected and stored between each patient interaction

*As of July 2, 2018, NIOSH evaluates N95 FFRs intended for use in healthcare for biocompatibility, flammability, and fluid resistance to ensure conformity to relevant standards during the approval process. These tasks were previously performed by the FDA.