CDC/NIOSH-Approved Elastomeric Respirators with P100 Filters

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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

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

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¹ https://www.cdc.gov/niosh/nptl/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
  o However, an N95 only blocks at least 95 percent of very small (0.3 micron) test particles.\(^2\)
  o It is the minimum respiratory protection approved for airborne protection from SARS by the CDC
  o 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 OR.\(^3\)
  o 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
  o 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 routines.\(^5\)
    ▪ In comparison, the current reuse/extended use of N95s is considered a “Contingency” level of respirator use and is not at best practice levels.\(^6\)
  o P100 filters provide protection from at least 99.97% of airborne particles (0.3 microns) and is oil proof.\(^7\) P100 filters also filter gases and vapors (amount is manufacture dependent)
  o P100 filters are equivalent to PAPRs for level of protection provided while allowing enhanced ability to protect the sterility of the surgical field due to lack of positive airflow
  o Elastomeric Respirators with P100 filters are intended for reuse and certified by NIOSH for this practice.\(^9\)

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\(^3\) https://www.cdc.gov/sars/clinical/respirators.html

\(^4\) https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.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/respiratorsdisp_part/respsource1quest3.html#half
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.
- 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 through
- 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

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10 https://www.cdc.gov/niosh/npptl/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 guidelines\(^\text{11}\). 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)\(^\text{12}\)
  - 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 protection\(^\text{9}\)
- Qualitative fit testing is typically used for Elastomeric Respirators and is recognized by OSHA.\(^\text{13}\)
- 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

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\(^\text{12}\) [https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2](https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2)

\(^\text{13}\) [https://www.osha.gov/video/respiratory_protection/fittesting_transcript.html](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 field\(^\text{14}\).
- For surgery, the exhalation valve needs to be covered with a FDA approved surgical mask to protect the sterile field.\(^9\)

# Understanding the Difference

<table>
<thead>
<tr>
<th></th>
<th>Surgical Mask</th>
<th>N95 Respirator</th>
<th>Elastomeric Half Facepiece Respirator</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Testing and Approval</strong></td>
<td>Cleared by the U.S. Food and Drug Administration (FDA)</td>
<td>Evaluated, tested, and approved by NIOSH as per the requirements in 42 CFR Part 84</td>
<td></td>
</tr>
<tr>
<td><strong>Intended Use and Purpose</strong></td>
<td>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.</td>
<td>Reduces wearer's exposure to particles including small particle aerosols and large droplets (only non-ell aerosols)</td>
<td>Reusable device made of synthetic or rubber material</td>
</tr>
<tr>
<td><strong>Face Seal Fit</strong></td>
<td>Loose-fitting</td>
<td>Tight-fitting</td>
<td>Tight-fitting</td>
</tr>
<tr>
<td><strong>Fit Testing Requirement</strong></td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Designed for Reuse</strong></td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>User Seal Check</strong></td>
<td>Yes, Required each time the respirator is donned (put on)</td>
<td>Yes, Required each time the respirator is donned (put on)</td>
<td></td>
</tr>
<tr>
<td><strong>Filtration</strong></td>
<td>Does NOT provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection</td>
<td>Filters out at least 95% of airborne particles including large and small particles</td>
<td>May be equipped with filters that block 95%, 99%, or 100% of very small particulates. Also may be equipped to protect against vapors/gases.</td>
</tr>
<tr>
<td><strong>Leakage</strong></td>
<td>Leakage occurs around the edge of the mask when user inhales</td>
<td>When properly fitted and donned, minimal leakage occurs around edges of the respirator when user inhales</td>
<td>When properly fitted and donned, minimal leakage occurs around edges of the respirator when user inhales</td>
</tr>
<tr>
<td><strong>Use Limitations</strong></td>
<td>Disposable. Discard after each patient encounter.</td>
<td>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.</td>
<td>Reusable and must be cleaned/disinfected and stored between each patient interaction</td>
</tr>
</tbody>
</table>