COVID-19
airway protection
PPE overview

DOCUMENT INTENDED TO PROVIDE INSIGHT BASED ON CURRENTLY AVAILABLE INFORMATION FOR CONSIDERATION AND NOT SPECIFIC ADVICE

Update: May 6, 2020
COVID-19 is, first and foremost, a humanitarian challenge. Thousands of health professionals are heroically battling the virus, putting their own lives at risk. Governments and industry are working together to understand and address the challenge, support victims and their families and communities, and search for treatments and a vaccine.

Solving the humanitarian challenge is the top priority. Much remains to be done globally to prepare, respond, and recover, from protecting populations at risk to supporting affected patients, families, and communities to developing a vaccine. To address this crisis, responses must be informed by evidence and based on partnership among various stakeholders and sectors, including the medical-product industry and regulatory/compliance agencies.
These materials are preliminary and non-exhaustive and are being made available on a non-exclusive basis solely for information purposes in response to the urgent need for measures to address the COVID-19 crisis.

They reflect general insight and may present potential options for consideration based on currently available information, which is inherently uncertain and subject to change, but do not contain all of the information needed to determine a future course of action.

The insights and concepts included in these materials have not been validated or independently verified. References to specific products or organizations are solely for illustration and do not constitute any endorsement or recommendation.

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The recipient is solely responsible for all of its decisions, use of these materials, and compliance with applicable laws, rules and regulations. Consider seeking advice of legal and other relevant certified/licensed experts prior to taking any specific steps.
The current environment shows that the supply of airway-protection equipment must be rapidly accelerated to stem shortages already occurring among frontline medical workers.

This document is meant to explore select questions around securing a sufficient supply of airway-protection equipment to meet rapidly increasing demand.

This document focuses on N95 disposable respirators, surgical masks, and powered air-purifying respirators (PAPRs).

Our analysis includes preliminary insights on:

- intended functionality and critical components
- product breakdown, requirements, and specifications
- manufacturing processes and raw materials
- sourcing strategies and preliminary supplier lists

This document should not be used to guide clinical decisions or treatment.
CDC recommends a variety of airway protection options for healthcare professionals, offering a range of protection levels

<table>
<thead>
<tr>
<th>PAPR</th>
<th>Full facepiece</th>
<th>Half face</th>
<th>Nonsurgical respirator</th>
<th>Surgical respirator</th>
<th>Surgical mask ASTM Level 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Face seal for tight fitting respirators</td>
<td>Face seal</td>
<td>Face seal</td>
<td>Face seal</td>
<td>Face seal</td>
<td>Loose seal</td>
</tr>
<tr>
<td>Face seal for loose-fitting respirators</td>
<td>≥95% 2</td>
<td>≥95% 2</td>
<td>≥95% 2</td>
<td>≥95% 2</td>
<td>BFE ≥95%; PFE ≥95% 3</td>
</tr>
<tr>
<td>Designed for fluid protection</td>
<td>Y</td>
<td>Y</td>
<td>Unknown</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Fluid protection resistance</td>
<td>&gt;120 mm Hg</td>
<td>&gt;80 mm Hg</td>
<td>N/A</td>
<td>N/A</td>
<td>&gt;120 mm Hg</td>
</tr>
<tr>
<td>Breathability— Differential pressure</td>
<td>N/A, powered air supply</td>
<td>&lt;35 mm H₂O</td>
<td>&lt;35 mm H₂O</td>
<td>&lt;35 mm H₂O</td>
<td>&lt;4.0 mm H₂O</td>
</tr>
<tr>
<td>Certification and regulatory body</td>
<td>NIOSH</td>
<td>NIOSH</td>
<td>NIOSH</td>
<td>NIOSH</td>
<td>NIOSH and FDA</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>FDA</td>
</tr>
</tbody>
</table>

1. ASTM surgical mask standards (Level 1, 2, and 3) are referenced by FDA; not all FDA cleared surgical masks comply with this standard; 2. NIOSH certification mask filtration efficiency for particles ≥ 0.3 μm. Performance results are achieved under testing conditions specified by NIOSH standards, and do not represent filtration efficiency under normal conditions; 3. ASTM standard BFE (Bacteria Filtration Efficiency) for bacterial particles ≥ 3 μm; PFE (Particle filtration efficiency) for particle size ≥ 0.1 μm. Performance results are achieved under testing conditions chosen by the manufacturer under FDA guidance and do not represent filtration efficiency under normal conditions. Filter tests required by the FDA are much less stringent than NIOSH tests.

Disposable N95 respirators
Overview: N95 functions and applicability

NIOSH certified | FDA cleared
---|---

### N95 respirators
- Reduce small particles inhaled by wearer

### Surgical N95 respirators
- Reduce small particles inhaled and expelled by wearer, plus fluid resistance

### Surgical masks
- Protect wearer from splashes and large droplets and minimize particles expelled by wearer

#### Function
- **Reduce small particles inhaled by wearer**
- **Reduce small particles inhaled and expelled by wearer, plus fluid resistance**
- **Protect wearer from splashes and large droplets and minimize particles expelled by wearer**

#### COVID-19 applicability
- **With good fit, protect provider from small particles and have simpler design than surgical N95**
- **With good fit, protect provider from small particles, but not required unless invasive procedure or risk of fluid exposure is present**
- **Provide HCP with limited protection from exposure due to material type and air leakage due to loose seal to wearer’s face**

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CDC guidance requires that nonsurgical N95 respirators provide sufficient protection for HCPs against COVID-19 in most settings.¹

CDC states that only HCPs who are working in a sterile field or who may be exposed to high-velocity splashes, sprays, or splatters of blood or body fluids should wear surgical respirators, such as in operative or procedural settings.¹

Social enterprise SmartAir notes that surgical masks offer little protection against small particles.²

According to CDC, nonsurgical respirators protect the wearer against hazardous airborne particles, while masks and surgical respirators act as a barrier to fluids.¹
### Product information sheet: Disposable N95 respirators

**Product information**

**Product description:**
N95 respirators

**Product group:**
Personal protective equipment

**Usage**

**Usage guidance:**
Designed for single use\(^1\); limited single-wearer reuse considered in contingency scenarios\(^2\)

**Current availability:**
Very low

**Manufacturing**

**Technologies required to manufacture:**
Polypropylene spunbond and meltblown extrusion, heat press and assembly

**Degree of automation:**
Fully automated by large players, but for smaller players final assembly may be manual

**Regulatory and compliance difficulty:**
Medium

**Raw-material availability:**
High-quality polypropylene likely available; intermediate spunbond meltblown spunbond (SMS) nonwoven, especially quality meltblown, in short supply

**Raw-material shortages:**
N95-quality meltblown nonwoven in short supply

**FDA Classification:**
Class II, if surgical\(^3\) — may be 510(k) exempt

**Design requirements**

**Grade N95:**
Good breathability with a design that does not collapse against the mouth (e.g., duckbill, cup shaped)

**Standards:**
Minimum "N95" respirator according to FDA Class II, under 21 CFR 878.4040, and CDC NIOSH

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CDC guidance states that approved respirators under standards similar to NIOSH can be used by HCPs in crisis scenarios

Per CDC guidance, respirators graded at N95 level or above in other countries are viable options

<table>
<thead>
<tr>
<th>Country</th>
<th>Performance standard</th>
<th>Acceptable product classification</th>
<th>Standards/guidance documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brazil</td>
<td>ABNT/NBR 13698:2011</td>
<td>PFF3, PFF2</td>
<td>Fundacentro CDU 614.894</td>
</tr>
<tr>
<td>China</td>
<td>GB 2626-2006</td>
<td>KN100, KP100, KN95, KP95</td>
<td>GB/T 18664-2002</td>
</tr>
<tr>
<td>Europe</td>
<td>EN 149-2001</td>
<td>FFP3, FFP2</td>
<td>EN 529:2005</td>
</tr>
<tr>
<td>Korea</td>
<td>KMOEL-2017-64</td>
<td>Special, 1st</td>
<td>KOSHA GUIDE H-82-2015</td>
</tr>
<tr>
<td>Mexico</td>
<td>NOM-116-2009</td>
<td>N100, P100, R100, N99, P99, R99, P95, R95</td>
<td>NOM-116</td>
</tr>
</tbody>
</table>

Source: https://www.cdc.gov/niosh/nptl/respirators/testing/NonNIOSH.html.
Product breakdown (sample construction): N95 respirators

Alternate 2-layer design:
- Layer 1 (main filter layer): 1.33-mm-thick layer of 5-micron-diameter fibers with 64 g / sq. m density
- Layer 2: 0.5-mm-thick layer of 15.5-micron-diameter fibers with 28 g / sq. m density

Potential takeaways

All three layers of SMS can be made in-line or separately in different extruders.

All the raw-fabric materials except the filter media should be relatively straightforward to replicate across mills that produce nonwoven synthetic fabric.

Filter media is the most technically complex layer in N95 respirators.

Filter media requires a proprietary recipe to configure the meltblown machine to create the right performance in the material.
# High-level N95 respirator specifications

<table>
<thead>
<tr>
<th>Type</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional¹</td>
<td>Blocks at least 95% of very small (0.3 micron) test particles</td>
</tr>
<tr>
<td></td>
<td>Initial breathing resistance (resistance to airflow) not exceeding 35 mm H₂O</td>
</tr>
<tr>
<td></td>
<td>Initial exhalation resistance not exceeding 25 mm H₂O</td>
</tr>
<tr>
<td>Technical²</td>
<td>Thermoformed layered SMS (spunbond-meltblown-spunbond) stack-up of several low-tech layers and one higher-tech layer</td>
</tr>
<tr>
<td></td>
<td>Low-tech outer layers: polypropylene spunbond structural inner and outer cover webs</td>
</tr>
<tr>
<td></td>
<td>High-tech inner layer: carefully controlled polypropylene meltblown filter media</td>
</tr>
</tbody>
</table>

## Shape

- Shaped to conform to face and create good seal on various face sizes and shapes

<table>
<thead>
<tr>
<th>Specification</th>
<th>Typical respirator shapes³</th>
<th>Head shapes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Duckbill</td>
<td>Head forms for technical specification standards (ISO TC94 Personal Protective Equipment, SC15 Respiratory Protective Devices—National Personal Protective Technology Laboratory of NIOSH)</td>
</tr>
<tr>
<td></td>
<td>Cup</td>
<td></td>
</tr>
</tbody>
</table>

### Certification and testing⁴

- NIOSH approval: N95 masks require a certificate or formal document issued by NIOSH stating that an individual respirator or combination of respirators has met the minimum requirements of 42 CFR Part 84

### Examples⁵

- **External layer**
  - 3M 8510 respirator (as measured in 2015)
    - 2.27-mm-thick layer of 22-micron-diameter fibers with 217g/m² density
  - Moldex N95 respirator (as measured in 2015, exact model unknown)
    - Main filter layer: 1.3-mm-thick layer of 5.1-micron-diameter fibers with 63g/m² density; inhomogeneity assumed to be low to meet N95 spec

- **Middle layer**
  - Main filter layer: 1.77-mm-thick layer of 5.4-micron-diameter fibers with 156g/m² density; inhomogeneity assumed to be low to meet N95 spec
  - N/A

- **Internal layer**
  - 0.36-mm-thick layer of 15.4-micron-diameter fibers with 34g/m² density
  - 0.61-mm-thick layer of 15.5-micron-diameter fibers with 28g/m² density

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Source: Head shape image source: CDC: [https://www.cdc.gov/niosh/npptl/topics/respirators/headforms/](https://www.cdc.gov/niosh/npptl/topics/respirators/headforms/). This image is otherwise available on the CDC website for no charge.
Overview of constraints in the N95 respirator supply chain

### Manufacturing process

<table>
<thead>
<tr>
<th>Raw materials</th>
<th>Process</th>
<th>Nonwoven SMS fabric (spunbond-meltblown-spunbond sandwich)</th>
<th>Thermoform and die-cut</th>
<th>Blank respirators</th>
<th>Attach straps and nose piece, package</th>
<th>Finished packaged respirators</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extrude spunbond nonwoven outer/inner</td>
<td>Production process</td>
<td>Mask-converting machinery</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extrude meltblown nonwoven filter</td>
<td>Dedicated converter</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Material and equipment requirements

**Polypropylene formulation:** Need formulation/blend from IP owners  
High-grade polypropylene, ideally without pigment or TiO2  
Meltblown: Exxon Achieve Advanced PP6936G2  
Spunbond: Exxon Vistamaxx 70020BF

Reifenhauer Reicofil is the most common machine and it uses dies from Hills Inc. in Melbourne, Florida, to make N95-quality SMS. It has production capacity up to 1.8 million respirators per day.  
Oerlikon SMS machines are a potential alternative.  
Biax Fiberfilm, a Wisconsin company, also makes a form of meltblown equipment capable of N95-quality SMS.

Reicofil has shortened lead time of 3–5 months for new capacity in existing factory  
Significant capital and configuration cost investment per line  
**Special extrusion die (<5um EDM holes):** Need backup die from current manufacturers

Bonding pattern used in thermoforming and die-cutting critical as wrong settings may destroy uniform porosity  
Patented patterns available (contain temperature, pressure, line speed)  
Experienced filtration engineers to configure machinery

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Key considerations for supply/manufacturing

End-to-end producers taking raw polypropylene to finished mask exist but are likely at max capacity.  
Splitting production of SMS nonwoven from mask conversion is possible but converters should ideally be near SMS producer to minimize shipping delay and cost.
Meltblown is manufactured in multiple facilities within the US for a variety of end products

Not exhaustive

<table>
<thead>
<tr>
<th>Usage</th>
<th>Filtration media for HVAC and water, wipes, absorbent hygiene, vehicle construction for NVH(^1), sorbents, medical/surgical products, and apparel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current capacity</td>
<td>Total production capacity of meltblown material in North America is estimated to be around 175,000 metric tons in 2018,(^2) but unclear how much of this capacity can be configured to meet N95 requirements</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Company</th>
<th>State(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3M</td>
<td>CT, NE, TN, MN, WI</td>
</tr>
<tr>
<td>Atex</td>
<td>GA</td>
</tr>
<tr>
<td>Brady SPC</td>
<td>KY</td>
</tr>
<tr>
<td>Fiber Dynamics</td>
<td>NC</td>
</tr>
<tr>
<td>Hollingsworth &amp; Vose</td>
<td>VA</td>
</tr>
<tr>
<td>HDK Industries</td>
<td>TN</td>
</tr>
<tr>
<td>Johns Manville</td>
<td>MS</td>
</tr>
<tr>
<td>Kimberly-Clark</td>
<td>AR, MS</td>
</tr>
<tr>
<td>Lydall Performance Materials</td>
<td>NH</td>
</tr>
<tr>
<td>MeltBlown Technologies</td>
<td>GA</td>
</tr>
<tr>
<td>Monadnock Non-Wovens</td>
<td>PA</td>
</tr>
<tr>
<td>NPS Nonwovens</td>
<td>WI</td>
</tr>
<tr>
<td>Spilltech</td>
<td>MD</td>
</tr>
<tr>
<td>SWM International</td>
<td>DE</td>
</tr>
</tbody>
</table>

\(^1\) NVH = noise, vibration, harshness; \(^2\) Derived from industry consortium experts

References to individual products or companies are solely for information purposes and do not constitute any endorsement or recommendation.
# Meltblown production lines are available from multiple suppliers

Example suppliers

<table>
<thead>
<tr>
<th>Example suppliers</th>
<th>Standard line width</th>
<th>Select characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reifenhauser REICOFIL</td>
<td>Up to 5200mm(^1)</td>
<td>Production rate up to 1200 m/min(^1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Estimated nominal spunbond output up to 12.3 ktons/year(^2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Estimated nominal meltblown output up to 3.2 ktons/year(^3)</td>
</tr>
<tr>
<td>Oerlikon Neumag nonwoven systems</td>
<td>Up to 7000mm(^4)</td>
<td>Estimated nominal spunbond output up to 13.1 ktons/year(^5)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nominal meltblown output up to 1.2 ktons/year(^6)</td>
</tr>
</tbody>
</table>

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2. Calculated based on 24 hr/day, 365 days/year operation at 270 kg/hr/m with maximum roll width, maximum output from specification above
3. Calculated based on 24 hr/day, 365 days/year operation at 70 kg/hr/m with maximum roll width, maximum output from specification above

**Image courtesy of McKinsey design team.**

REFERENCES TO INDIVIDUAL PRODUCTS OR COMPANIES ARE SOLELY FOR INFORMATION PURPOSES AND DO NOT CONSTITUTE ANY ENDORSEMENT OR RECOMMENDATION

**Current as of May 4, 2020**
Converting machinery, ranging from automated single line to multistep lines, is available from different suppliers

Example assembly-line types and suppliers

<table>
<thead>
<tr>
<th>Type</th>
<th>Supplier example</th>
<th>Throughput (pcs/min)</th>
<th>Price (RMB)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Folded-N95 Assembly Line</td>
<td>Automated folded mask line</td>
<td>KYD (used by Honeywell)</td>
<td>25-55</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yicheng</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lihan</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cup-Shaped N95 Machinery</td>
<td>Cover-making machine</td>
<td>KYD</td>
</tr>
<tr>
<td></td>
<td>Welding and cutting machine</td>
<td>KYD</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>After-process production line</td>
<td>KYD</td>
<td>18-22</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Can integrate multiple steps (eg, labels, assembly, packing)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>NCM Nonwoven Converting Machinery Co., Ltd.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>TRM-Top Rank Machinery Inc.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fiber Dynamics, Inc.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Elmarco, a nanofiber machine maker</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Representative testing process and key standards

Not exhaustive

### Representative testing approach

<table>
<thead>
<tr>
<th>Raw-material testing</th>
<th>In-line inspection</th>
<th>Sample testing before shipment</th>
<th>Sample test in laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steps to ensure quality of nonwoven fabric inputs</td>
<td>Automated optical or manual inspection before packaging</td>
<td>Tests for QA/QC of finished goods</td>
<td></td>
</tr>
</tbody>
</table>

### Test standards

Filtration-efficiency standard is established by multiple regulatory agencies: US NIOSH-42CFR84; Europe EN 149-2001; China GB2626-2006; Japan JMHLW-2000 JIS T8150: 2006; and others as equivalent per CDC guidance.¹

Other testing, such as bacterial-filtration efficiency, pressure drop, and microbial limit, can be considerations for regulatory approvals.

In-line testing for mask design can be carried out by optical inspection systems.

### Test-equipment manufacturers

- TSI: Automated-filter tester (eg, TSI 8130A), most commonly used by manufacturers
- Air Techniques International: Protective Mask Leakage Tester (PMLT) for full design testing of masks or 100X Automated Filter Tester

2. Derived from manufacturing-expert interviews and research

Image courtesy of McKinsey design team

Manufacturers should ensure that test standards are appropriate for end-use markets and adhere to all legal and regulatory requirements.
The COVID-19 response team has developed knowledge around five categories of medical supply interventions:

1. Maximize usage of available supply
2. Redeploy existing inventory from other industries
3. Maximize capacity of existing manufacturers
4. Unlock new capacity for manufacturing
5. Develop alternate specifications and designs (to enable one or more of the above supply interventions)
Multiple options can help increase the supply of N95 respirators in the short and medium term

Potential approaches that go beyond traditional sources of supply

1. Maximize usage of available supply
   Can strategies to reuse and extend the life of N95 respirators be developed (e.g., using hydrogen peroxide, UV irradiation)?

2. Redeploy existing inventory from other industries
   Can existing inventory be gathered from nonessential users of medical N95 respirators, or can distributors of nonmedical N95 respirators collaborate to maximize use of existing inventory?

3. Unlock new capacity for manufacturing
   Is it possible to identify additional capacity to manufacture N95 or subcomponents within contract manufacturers and other adjacent industries (e.g., textiles and diaper manufacturers)?

4. Develop alternate specifications and design
   Can alternate specs and designs be developed using current or alternate material that meets performance and regulatory requirements?
   Can products now approved by the FDA\(^1\) be sourced from countries with similar standards and specifications (e.g., FFP2 from EU and selected manufacturers of KN95 from China)?

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Conclusions below were developed by the authors cited on this slide

Battelle (a research, development, and lab-management company) has received special emergency authorization to use its Critical Care Decontamination System (CCDS) to reprocess used N95 respirator masks with concentrated hydrogen peroxide1

- System enables single-use respirators to be used up to 20 times, with a 2.5-hour decontamination process between uses
- Disinfected N95 masks will go back to the same healthcare facility they came from, labeled with a serial number that provides tracking and collects information on reuse
- System is already in operation at Battelle’s Ohio facility, which has a capacity of up to 80,000 masks per day; facility is working with Columbus-based OhioHealth and will soon work with three other major healthcare systems

NIOSH/CDC research concluded that UVGI could be used to effectively disinfect disposable respirators for reuse


Conclusions below were developed by the authors cited on this slide

Research by NIOSH/CDC concluded that ultraviolet germicidal irradiation (UVGI) could be used to effectively disinfect disposable respirators for reuse:

- UVGI exposure led to a small increase in particle penetration (up to 1.25%) and had little effect on flow resistance
- UVGI exposure had a more pronounced effect on strength of respirator materials. At higher UVGI doses, strength of layers of respirator material was substantially reduced (in some cases, by >90%)
- Changes in strength of respirator materials varied considerably among different models of respirators
- Maximum number of disinfection cycles will be limited by respirator model and UVGI dose required to inactivate pathogen

Nebraska Medicine has developed a decontamination procedure involving UVGI:

- Decontamination room has two UVGI towers on either side, each of them equipped with eight 254-nm bulbs; walls and ceiling were covered with UV-4 reflective coating prior to initiating decontamination program
- Delivered UVGI exposure dose is monitored with a room UVGI meter that can be initiated and monitored from outside room to prevent damage to eyes and skin
- Respirators are secured on wires strung across room during process
- Plan is to decontaminate and reuse N95 FFRs multiple times until respirator fit is affected
2. Options to consider for redeploying N95 respirators

MRO distributors have expressed willingness to collaborate with an established coordinating body on this effort.

Can nonmedical N95 respirators be used when next best alternative is operating without respirators?¹

Can all nonessential use in industries currently using N95 respirators be stopped until shortage is resolved?

Can all nonessential purchases of N95 respirators be stopped and existing inventory returned to MRO distributors?


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3. Potential ways to unlock new capacity for manufacturing

<table>
<thead>
<tr>
<th>Levers</th>
<th>Description</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repurpose similar machinery</td>
<td>Manufacturing: Up-configure existing machinery used for non-N95 applications</td>
<td><strong>Meltblown process:</strong> Some alternate extruders can be modified with the right extrusion die, which can be potentially supplied by diemakers or others with spare dies. <strong>Conversion process:</strong> Textile industry has similar production lines that can be modified.</td>
</tr>
<tr>
<td></td>
<td>Product testing: Leverage qualified testing equipment with similar capabilities to add testing capacity</td>
<td>Some research institutions (e.g., NC State Nonwovens Institute) may have testing equipment. Key suppliers of testing equipment are likely to know availability and location of existing testing equipment in adjacent industries (e.g., air-filter suppliers for HVAC or automotive cabins).</td>
</tr>
</tbody>
</table>

| Arrange financing options for manufacturers | Due to high upfront capital requirements for production lines, financing options may be needed for meltblown producers to up-configure or retool to produce meltblown fabric | Enable loans or grants for meltblown machinery capex and configuration expense |

Source: Collected through interviews with experts in the PPE manufacturing industry.
5. FDA approves of some products with similar standards, with some supplier restrictions\(^3,4,5\)

Comparison of filtering facepiece respirators with different performance standards\(^1\)

<table>
<thead>
<tr>
<th>Country or region</th>
<th>US</th>
<th>Europe</th>
<th>China</th>
<th>Australia</th>
<th>Korea</th>
<th>Japan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter performance (must be $\geq X%$ efficient)</td>
<td>$\geq 95%$</td>
<td>$\geq 94%$</td>
<td>$\geq 95%$</td>
<td>$\geq 94%$</td>
<td>$\geq 94%$</td>
<td>$\geq 95%$</td>
</tr>
<tr>
<td>Flow rate (L/min)</td>
<td>85</td>
<td>95</td>
<td>85</td>
<td>95</td>
<td>95</td>
<td>85</td>
</tr>
<tr>
<td>Total inward leakage (TIL)(^1) – tested on human subjects performing exercises</td>
<td>N/A</td>
<td>$\leq 8%$ leakage (arithmetic mean)</td>
<td>$\leq 8%$ leakage (arithmetic mean)</td>
<td>$\leq 8%$ leakage (individual and arithmetic mean)</td>
<td>$\leq 8%$ leakage (arithmetic mean)</td>
<td>Inward leakage measured and included in user Instructions</td>
</tr>
<tr>
<td>Inhalation resistance – max pressure drop</td>
<td>$\leq 343$ Pa</td>
<td>$\leq 70$ Pa (at $30$ L/min)</td>
<td>$\leq 350$ Pa</td>
<td>$\leq 70$ Pa (at $30$ L/min)</td>
<td>$\leq 70$ Pa (at $30$ L/min)</td>
<td>$\leq 70$ Pa (w/valve)</td>
</tr>
</tbody>
</table>

1. [https://multimedia.3m.com/mws/media/1791500O/comparison-ffp2-kn95-n95-filtering-facepiece-respirator-classes-tb.pdf](https://multimedia.3m.com/mws/media/1791500O/comparison-ffp2-kn95-n95-filtering-facepiece-respirator-classes-tb.pdf)
2. [https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSH.html](https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSH.html)
3. [https://www.fda.gov/media/136403/download; https://www.fda.gov/media/136664/download](https://www.fda.gov/media/136403/download; https://www.fda.gov/media/136664/download)
4. [https://www.fda.gov/media/136663/download](https://www.fda.gov/media/136663/download)

FDA's EUAs from March 28, 2020, April 3, 2020, and May 7, 2020 allow respirators from EU, Australia, Korea, and Japan\(^3,5\) but only select suppliers from China (see latest CDC guidance and FDA EUAs on PPE\(^2,3,4,5\)).

While the listed product classifications have similar performance requirements to NIOSH-approved devices, CDC claims no knowledge about sustained manufacturer quality system and product quality control for these products\(^2\).

Point of use assessments are being conducted by NIOSH to verify quality and filter efficiency, and to align EUAs\(^2\).
Surgical masks
According to the CDC, surgical masks are less effective in filtering small particles and protecting the wearer than N95 respirators.

<table>
<thead>
<tr>
<th>Certification</th>
<th>N95 respirators</th>
<th>Surgical masks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NIOSH certified</td>
<td>FDA class II guidelines</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Design</th>
<th>Test fitted to seal tightly around wearer’s nose and mouth</th>
<th>Typically rectangular shaped and loop over wearer’s ears</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Function</th>
<th>Filter out small particles inhaled by wearer</th>
<th>Protect wearer from splashes and large droplets and minimize particles expelled by wearer</th>
</tr>
</thead>
</table>

| COVID-19 applicability | With good fit, protect provider from small particles; have a simpler design than surgical N95 | Provide limited protection to HCP due to facial seal leakage¹ |

¹. https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/default.html

Surgical masks are designed to protect wearer from splashes and large droplets and minimize particles expelled by wearer.

Face masks fit loosely and do not prevent leakage around mask edge when user inhaled.
Product information sheet: Surgical masks

Not exhaustive

Product information

Product description:
Surgical masks\(^2\); may be labeled as surgical, isolation, dental, or medical procedure masks

Product group: Personal protective equipment

Product function:
A loose-fitting, disposable device that helps protect wearer from large-particle droplets, splashes, sprays, or splatter that may contain germs; may also help protect others from exposure to wearer’s saliva and respiratory secretions\(^1\)

Regulations and technology

Regulations:
Surgical masks are regulated under 21 CFR 878.4040. FDA Class II\(^3\)

Technologies required to manufacture:
Polypropylene, usually in SMS form (spunbond-meltblown-spunbond)

ASTM surgical mask performance standards\(^2\)

<table>
<thead>
<tr>
<th>Fluid protection resistance</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&gt;80 mmHg</td>
<td>&gt;120 mmHg</td>
<td>&gt;160 mmHg</td>
<td>Resistance to penetration by synthetic blood</td>
</tr>
<tr>
<td>Differential pressure test</td>
<td>&lt;4.0</td>
<td>&lt;5.0</td>
<td>&lt;5.0</td>
<td>Breathing pressure difference across the mask</td>
</tr>
<tr>
<td>BFE (bacteria-filtration efficiency standard – 3 μm)</td>
<td>≥95%</td>
<td>≥98%</td>
<td>≥98%</td>
<td>Ability of mask to prevent passage of aerosolized bacteria</td>
</tr>
<tr>
<td>PFE (particle-filtration efficiency standard – 0.1 μm)</td>
<td>≥95%</td>
<td>≥98%</td>
<td>≥98%</td>
<td>Filtration test using unnaturalized 0.1-micron polystyrene latex spheres</td>
</tr>
<tr>
<td>Flammability</td>
<td>Class 1</td>
<td>Class 1</td>
<td>Class 1</td>
<td>Resistance to penetration by synthetic blood</td>
</tr>
</tbody>
</table>

According to the FDA, surgical masks do not provide as good facial seal as N95

<table>
<thead>
<tr>
<th>Mask type</th>
<th>Standards</th>
<th>Facial seal</th>
<th>Filtration Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single-use mask</td>
<td>China: YY/T0969</td>
<td>Loose seal</td>
<td>BFE: ≥95%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>PFE: NA</td>
</tr>
<tr>
<td>Surgical mask</td>
<td>China: YY 0469</td>
<td>Loose seal</td>
<td>BFE: ≥95%</td>
</tr>
<tr>
<td></td>
<td>USA: ASTM F2100</td>
<td>Loose seal</td>
<td>PFE: ≥30%</td>
</tr>
<tr>
<td></td>
<td>Europe: EN 14683</td>
<td>Loose seal</td>
<td>Level 1: BFE: ≥95%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Level 2: BFE: ≥98%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Level 3: BFE: ≥98%</td>
</tr>
<tr>
<td>N95 respirator</td>
<td>USA: NIOSH (42 CFR 84)</td>
<td>Good face</td>
<td>N95/KN 95: BFE: ≥95%</td>
</tr>
<tr>
<td></td>
<td>China: GB2626</td>
<td>seal</td>
<td>N99/KN 99: BFE: ≥99%</td>
</tr>
<tr>
<td></td>
<td>Europe: EN 149:2001</td>
<td>Good face</td>
<td>N100/KN 100: BFE: ≥99%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>seal</td>
<td>0.3 Microns: ≥80%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.3 Microns: ≥94%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.3 Microns: ≥99%</td>
</tr>
</tbody>
</table>

2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7115281/

FDA states that surgical masks do not provide complete protection from germs and other contaminants because of the loose fit between the mask and the face. NIOSH certification mask filtration efficiency for particles ≥ 0.3 μm. Performance results are achieved under testing conditions specified by NIOSH standards, and do not represent filtration efficiency under normal conditions.

ASTM standard BFE (Bacteria Filtration Efficiency) for bacterial particles size ≥ 3 μm; PFE (Particle filtration efficiency) for particle size ≥ 0.1 μm. Performance results are achieved under testing conditions chosen by the manufacturer under FDA guidance and do not represent filtration efficiency under normal conditions. Filter tests required by the FDA are much less stringent than NIOSH tests.

JHI\textsuperscript{1} research shows that integral visors help consistently reduce particles/influenza virus inside surgical masks

Surgical masks, while imperfect in completely negating the introduction of aerosol influenza particles, still do reduce the amount of particles entering into the respiratory system depending on the design of the face mask.

**The design of the surgical masks matter**

Surgical masks also do not provide complete protection because of the loose fit\textsuperscript{4}. Therefore any design changes, e.g., adding a visor or metal adjuster at the nose or at the chin that could contribute to a better facial seal, can potentially increase the overall protection level.

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\textsuperscript{1} JHI research shows that integral visors help consistently reduce particles/influenza virus inside surgical masks

\textsuperscript{2} Influenza plaque reduction factor = Influenza virus titre of external air sample / Influenza virus of internal air sample

\textsuperscript{3} (Particle) reduction factor = Particle concentration outside the mask / Particle concentration inside the mask

\textsuperscript{4} https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks#s4


Image courtesy of McKinsey design team.
Studies find that while surgical masks are not as effective as N95 respirators, they block out some aerosol particles.

There are studies that demonstrate a certain degree of efficacy of surgical masks despite the facial-seal factors. While not performing at the level of N95 respirators—empirically shown to block >97% of the 0.01 μm particles (10 times smaller than coronavirus particles)—surgical masks show 63% block rate for tiny virus-sized particles despite facial leakages.
According to the JHI,¹ wearing multiple masks may help reduce small-particle penetration, but not as well as an N95

Journal of Hospital Infection shows that aerosol penetration through a surgical mask is highly dependent on particle size, mask construction, and breathing flow rate.

Research has shown that use of up to five surgical masks overlapping one another further reduces particle penetration to wearer, but not to the level of an N95.

Breathing comfort (measured in differential pressure) is unknown for multiple masks but likely reaches uncomfortable levels.

In this study, volunteers wearing masks simulated various activities of HCPs, including breathing, deep breathing, turning head from side to side, flexing and extending head, talking loudly, and bending over followed by normal breathing again.

<table>
<thead>
<tr>
<th>Number of masks worn</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>5</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
<td>Surgical</td>
<td>Surgical</td>
<td>Surgical</td>
<td>Surgical</td>
<td>N95</td>
</tr>
<tr>
<td>Particle reduction (measuring 0.02-1 μm)</td>
<td>63%</td>
<td>74%</td>
<td>78%</td>
<td>82%</td>
<td>95%</td>
</tr>
<tr>
<td>Breathability</td>
<td>&lt;5mm H₂O</td>
<td>Increasing pressure difference and decreasing breathability</td>
<td>→</td>
<td>&lt;35 mm H₂O</td>
<td></td>
</tr>
</tbody>
</table>

¹. Journal of Hospital Infection

Surgical masks are designed with rapid mass manufacturing in mind

5 components of surgical masks

### 3 protective layers

1. **Inner layer**
   - Material: Spunbonded nonwoven fabric (same material as exterior of disposable ice bag)
   - Function: Enhance wearer’s comfort

2. **Center layer**
   - Material: Polypropylene SMS nonwoven fabric
   - Function: Filter particles and bacteria according to ASTM standards

3. **Outer layer**
   - Material: Spunbonded nonwoven fabric
   - Function: Less soft than inner layer, holds desired color, and is coated for fluid resistance

### 2 structural components

4. **Metal nose band**
5. **Elastic ear loops**

### 1 customized machine cuts and bonds 3 layers in 1 process

- **Material feed**: 3 fabrics are fed into machine from rollers
- **Layering**: Fabrics are laid in desired accordion structure
- **Edge bonding**: Edges of mask are bonded using ultrasonic bonding machines or adhesives (ultrasonic provides stronger and more hygienic seal)
- **Die-cut**: Masks are stamped in desired shape
- **Component bonding**: Metal nose bands and elastic ear loops are placed and ultrasonic bonded

Source: Collected through interviews with experts in the PPE-manufacturing industry; image courtesy of McKinsey design team
Surgical masks are simpler to manufacture than N95 respirators due to smaller bonding surfaces and lack of shape molding

**Surgical mask manufacturing process**

- **Material feed**
  - 3 fabrics are fed into machine from rollers
- **Layering**
  - Fabrics are laid in desired accordion structure
- **Edge bonding**
  - Edges of masks are bonded using ultrasonic bonding machines or adhesives (ultrasonic provides stronger and more hygienic seal); adhesives were commonly used 5+ years ago
- **Die-cut**
  - Masks are stamped in desired shape

**Component bonding**

- Metal nose bands and elastic ear loops are placed and ultrasonic bonded

**WIP inventory**

- Both processed in equivalent clean-room environment

**Differences from respirator manufacturing process**

- Similar materials, but nonwoven layers on respirators need to be denser than surgical masks
- Ultrasonic bonding on respirators needs to be done throughout surface instead of just edges
- Mask needs to be pressed and thermoformed into coconut shape before being die-cut

Source: Collected through interviews with experts in the PPE-manufacturing industry.
Industry experts suggest several adjacent industries may have capabilities to mold, bond, and die-cut similar fabrics

Source: Collected through interviews with experts in the PPE-manufacturing industry.

Potential nonincumbent manufacturers

<table>
<thead>
<tr>
<th>Types</th>
<th>Surgical mask</th>
<th>N95 production</th>
</tr>
</thead>
<tbody>
<tr>
<td>Industry</td>
<td>Manufacturers of feminine-care and baby products: hygiene pads, diapers, underpads, puppy pads</td>
<td>Bra manufacturers for typical coconut-shaped respirators</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Manufacturers of feminine-care and baby products for flat-fold respirators</td>
</tr>
<tr>
<td>Reasoning</td>
<td>Expertise in 3-layer-edge ultrasonic bonding</td>
<td>Expertise in surface-ultrasonic-molding 3 layers onto a cup shape—may just need to change the mold</td>
</tr>
<tr>
<td></td>
<td>Materials used are similar nonwovens</td>
<td>Retail volumes are down—many factories currently running at low capacity</td>
</tr>
</tbody>
</table>

Things to consider

The final conversion stage of respirators and masks is currently set up in clean-room environments by incumbents to guarantee the hygienic state of the products. Given that raw materials are to be made in non-clean-room production lines, could nonincumbents convert in gray space but add sterilization to ensure a hygienic product?

Though there are flat-folded respirators on the market, HCPs are more accustomed to coconut shapes, and all fit tests and training are conducted around coconut-shape respirators. Suddenly changing the shape could require change management.

Nonincumbent manufacturers would require regulatory review and approval to produce certified masks and respirators.
PAPR
(powered air-purifying respirator)
OSHA allows the use of PAPR\(^1\) during aerosol-generating procedures and when N95 respirators are not available\(^2\)

**Tight fitting**

<table>
<thead>
<tr>
<th></th>
<th>Half mask</th>
<th>Full facepiece</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Respiratory protection (APF)</strong>(^3)</td>
<td>50</td>
<td>1000</td>
</tr>
<tr>
<td><strong>Min airflow rate</strong></td>
<td>115 liters/min</td>
<td>115 liters/min</td>
</tr>
</tbody>
</table>

**Loose fitting**

<table>
<thead>
<tr>
<th></th>
<th>Hood</th>
<th>Helmet</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>APF</strong>(^4)</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td><strong>Min airflow rate</strong></td>
<td>170 liters/min</td>
<td>170 liters/min</td>
</tr>
</tbody>
</table>

**PAPRs** protect the user by filtering out contaminants in the air and use a battery-operated blower to provide the user with clean air.\(^6\)

Use of tight-fitting PAPRs requires fit testing; use of loose-fitting PAPRs does not require fit testing.\(^6\)

**COVID-19 applicability**

**OSHA recommendations**\(^2\)

When disposable N95 filtering facepiece respirators are not available, consider using PAPR with high-efficiency particulate-absorbing (HEPA) filter

For any operations or procedures likely to generate aerosols, consider using PAPRs, as they are more protective than filtering facepiece respirators

PAPRs should not be used in surgical settings due to concerns that the blower exhaust and exhaled air may contaminate the sterile field\(^5\)

---

1. Powered air-purifying respirator
3. Assigned protection factor, a term used by OSHA to determine how well a respirator/filter combination will protect an individual from external contaminants; an APF of 25 means that no more than one 25th of the contaminants to which the worker is exposed will leak into the inside of the mask, https://affygility.com/potent-compound-corner/2017/10/19/the-proper-use-of-assigned-protection-factors-and-maximum-use-concentrations.html
4. APF of 25 without additional testing


Image courtesy of McKinsey design team
## Functions and user experience differ greatly between PAPRs and disposable N95 respirators

<table>
<thead>
<tr>
<th>Function</th>
<th>PAPR (Most common hood and helmet systems, &gt;$1,000)</th>
<th>Disposable N95 respirator (&lt;$10)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assigned protection factor</strong></td>
<td>≥25</td>
<td>10^{1}</td>
</tr>
<tr>
<td><strong>Reusability</strong></td>
<td>Reusable; filter change needs to follow manufacturer’s recommendation or when damaged, soiled, or causing noticeable increase in breathing resistance^{2}</td>
<td>Follow manufacturer’s recommendation or discard whenever they are damaged, soiled, or causing noticeable increase in breathing resistance^{2}</td>
</tr>
<tr>
<td><strong>Filtration</strong></td>
<td>Purifies the ambient air and feeds into the respirator; discharged air is not filtered^{3}</td>
<td>Filters both inhaled and exhaled air</td>
</tr>
<tr>
<td><strong>Fluid protection for eye</strong></td>
<td>Yes for full-facepiece PAPRs and some loose-fitting PAPRs^{6}</td>
<td>No</td>
</tr>
<tr>
<td><strong>User experience</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Breathability</strong></td>
<td>Purified air is supplied into hood/helmet by blower</td>
<td>Differential pressure &lt;35 mmH_{2}0</td>
</tr>
<tr>
<td><strong>Fit test</strong></td>
<td>Not required for loose-fitting piece^{3}</td>
<td>Required, has restriction on facial hair^{5}</td>
</tr>
<tr>
<td><strong>Training</strong></td>
<td>Additional training might be required when using a new type^{4}</td>
<td>Easier to learn and train than PAPR</td>
</tr>
<tr>
<td><strong>Vulnerability to external environment</strong></td>
<td>Loose parts such as hoses, cords, and filters can get dislodged in congested emergency environments^{3}</td>
<td>One-piece design that does not easily become loose compared to PAPR</td>
</tr>
<tr>
<td><strong>Stability of level of protection</strong></td>
<td>Equipment might get in the way of different working postures and have difficulty remaining in place to provide uninterrupted protection^{3}</td>
<td>One-piece design that does not easily become loose compared to PAPR</td>
</tr>
<tr>
<td><strong>Ease of disinfection between patients</strong></td>
<td>Must be cleaned and disinfected according to manufacturer’s reprocessing instructions prior to reuse^{4}</td>
<td>Discard after single use; special operational system needed for approved decontamination process</td>
</tr>
<tr>
<td><strong>Restriction on movements</strong></td>
<td>Some models might have restrictions on neck movement, ability to hear each other^{4}</td>
<td>Less restriction on movements than PAPR</td>
</tr>
<tr>
<td><strong>Maintenance</strong></td>
<td>Hard to repair when damaged, need assistance from manufacturer with high cost^{4}</td>
<td>Can be discarded and replaced at low cost</td>
</tr>
</tbody>
</table>

1. [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4589166/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4589166/)  
2. [https://www.cdc.gov/niosh/topics/respirators/disp_part/respsource3end.html](https://www.cdc.gov/niosh/topics/respirators/disp_part/respsource3end.html)  
4. Derived from healthcare expert interviews and research  

Image courtesy of McKinsey design team

**DOCUMENT INTENDED TO PROVIDE INSIGHT BASED ON CURRENTLY AVAILABLE INFORMATION FOR CONSIDERATION AND NOT SPECIFIC ADVICE**
Several regulatory bodies oversee governance of PAPR

General US certifications for PAPRs used in medical setting\(^1\)

<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
<th>Body</th>
</tr>
</thead>
<tbody>
<tr>
<td>42 CFR 84</td>
<td>Respiratory-equipment certification</td>
<td>NIOSH</td>
</tr>
<tr>
<td>1910.134(^2)</td>
<td>Respiratory-protection PPE</td>
<td>OSHA</td>
</tr>
</tbody>
</table>

General international standards for PAPR per NIH summary\(^3\)

<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
<th>Body</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIN EN 12942</td>
<td>Respiratory-protection devices</td>
<td>EN</td>
</tr>
<tr>
<td>SC15(^3)</td>
<td>Filtering devices</td>
<td>ISO</td>
</tr>
<tr>
<td>TC94(^3)</td>
<td>Respiratory-protection devices</td>
<td>ISO</td>
</tr>
</tbody>
</table>

6. https://www.cdc.gov/niosh/nppt/topics/respirators/cel/

Per CDC recommendations, PAPRs\(^4\) could be considered as alternatives to N95 respirators and surgical masks in nonsurgical settings as long as they are compliant with OSHA regulations.

In US, PAPR filters are required to be HEPA rated, and need to provide at least 99.97% filtration.\(^5\)

PAPR models approved by CDC for medical use are listed in NIOSH Certified Equipment List (CEL) database.\(^6\)
Product information sheet: Powered air-purifying respirator

Product information

Product description:
Powered PAPR; eg, 3M™ Versaflo™

Product group:
Personal protective equipment

Usage

Usage guidance:
Designed to be reusable and provide protection when equipped with the appropriate cartridge, canister, or filter

Current availability:
Low

Manufacturing

Technologies required to manufacture:
Extruded tube, battery-powered blower, and facepiece assembly (head top, hood, or helmets)

Degree of automation:
Subassemblies are highly automated while final assemblies may require manual work

Regulatory & compliance difficulty:
Medium

Raw-material availability:
Low, especially blower, which is made from DC motor and fan module, battery, and airtight container; airtight container is the bottleneck of expanding blower production because expanding airtight container production needs >1 month lead time to produce additional sets of tooling

Design requirements

Lightweight battery blower for mobility and durability to provide filtered air to a convenient and safe head top

Standards:
42 CFR 84 (NIOSH) and 1910.134 (OSHA) in US
DIN EN 12942 (EN), SC15 (ISO), TC94 (ISO) in international standards for PAPR per NIH summary

2. Derived from interviews with supply-chain experts

Source: Derived from interviews with supply-chain experts; image courtesy of McKinsey design team.
Product breakdown (example construction):
**Powered air-purifying respirator**
PAPR is a set of three subassemblies: Head top, tube, and blower

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A head-top unit that, depending on environment needs, can be a half mask, full facepiece, helmet/hood, or loose-fitting piece; its design varies and can be disposable or reusable (the latter requires maintenance and sanitization)\(^5\)

A tightly ventilated tube that is made from thermally extruded resin materials (HDPE\(^4\)) or rubber\(^3\); it directs filtered air from the blower to the head top

A battery-powered blower that, in the plastics enclosure, has a motored fan pulling air through HEPA, which filters at least 99.97% efficiently for removing particles \(\geq 0.3 \, \mu m\)\(^1\)

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Powered air-purifying respirators can be reusable but must be carefully maintained according to CDC or manufacturer procedures\(^2\)

1. Disassemble the system: filters, valve, elastic straps, tube, and any other parts recommended by manufacturer
2. Clean and sanitize in warm water with mild detergent at manufacturer’s recommended temperature; NEVER use organic solvent
3. Drain water from respirator and allow it to air-dry in a clean and sanitary location
4. Follow manufacturer’s guide for other cleaning and sanitizing procedures

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1. CDC Environmental Infection Control Guidelines - Air: https://www.cdc.gov/infectioncontrol/guidelines/environmental/appendix/air.html
2. CDC and NIOSH: https://www.cdc.gov/niosh/docs/99-143/pdfs/99-143.pdf
4. High-density polyethylene

Source: Image courtesy of McKinsey design team.
High-level specifications: Powered air-purifying respirator

1. Head-top unit

   Functionality
   A head top designed in variety of ways for needs in workplaces such as medical, hazardous, corrosive, or nuclear

   Key technical specifications
   - Style: Helmet, tight fitting, or loose fitting
   - US OSHA Assigned Protection Factor: 25–1000
   - Weight: 0.4–1.5 kg
   - Operating temperature: -10 – 54 °C
   - Certification (eye and face protection): ANSI Z87.1

2. Tube

   Functionality
   A tube carrying filtered air to head-top unit

   Key technical specifications
   - Raw material: HDPE or rubber
   - Length: 66–96 in
   - Weight: 0.1–0.3 kg
   - Assembly adjustability: Yes/No
   - Certification: NIOSH Approval

3. Battery-powered blower

   Functionality
   A battery-powered motor driving fan(s) to pull air through the HEPA required by manufacturers

   Key technical specifications
   - Airflow (liter per minute): 170–230
   - Weight: 0.9–1.5 kg
   - Run time: 4–12 hours
   - Operational temperature: -5 – 54 °C
   - Ingress protection (IP rating): IP 53–67

Source: Image courtesy of McKinsey design team.

2. Derived from interviews with supply-chain experts

Not exhaustive

McKinsey & Company
## PAPR: Manufacturing process overview

PAPR is a system solution consisting of subcomponents: facepiece, tube, belt, filter, and blower.

<table>
<thead>
<tr>
<th>Component name</th>
<th>Material and equipment requirements</th>
<th>Key considerations for supply/manufacturing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facepiece</td>
<td>Engineering plastics: polyethylene (e.g., Tyvek), polycarbonate, ABS, PVC EPDM rubber or alternatives (e.g., neoprene, silicone) Battery raw material (e.g., lithium-ion polymer)</td>
<td>Production line requires fixturing and validation Mold tooling for subassembly a bottleneck to ramp-up: 2–3 months to create and approve tooling</td>
</tr>
<tr>
<td>Facepiece</td>
<td>Circuit and circuit-board components Metals, such as copper, steel, aluminum Filter media</td>
<td>Testing needed for raw material input, particularly facepiece or hood input due to blood splattering test for medical use</td>
</tr>
<tr>
<td>Tube</td>
<td>Submodule manual assembly</td>
<td>Assembled system flow rate, noise, filtration media, and filter lifespan are key performance criteria for full system</td>
</tr>
<tr>
<td>Tube</td>
<td>System testing and calibration</td>
<td>Certification of system design by manufacturer is generally maintained for 10–15 years</td>
</tr>
<tr>
<td>HEPA</td>
<td>Blower</td>
<td>Manufacturers are audited at random by NIOSH</td>
</tr>
</tbody>
</table>

PAPR system certification requires the system to be tested (e.g., exact match of tube, facepiece, and blower)

### Not to scale

<table>
<thead>
<tr>
<th>Component name</th>
<th>Overall production process</th>
<th>Material and equipment requirements</th>
<th>Key considerations for supply/manufacturing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belt</td>
<td>Triangle</td>
<td>Engineering plastics: polyethylene (e.g., Tyvek), polycarbonate, ABS, PVC EPDM rubber or alternatives (e.g., neoprene, silicone) Battery raw material (e.g., lithium-ion polymer)</td>
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### Illustrative

- **Belt**: Engineering plastics: polyethylene (e.g., Tyvek), polycarbonate, ABS, PVC EPDM rubber or alternatives (e.g., neoprene, silicone) Battery raw material (e.g., lithium-ion polymer)
- **Tube**: Circuit and circuit-board components Metals, such as copper, steel, aluminum Filter media
- **Facepiece**: Submodule manual assembly
- **HEPA**: System testing and calibration
- **Blower**: PAPR system certification requires the system to be tested (e.g., exact match of tube, facepiece, and blower)

1. Include glue, screws, tape, or other required materials to enable production

Source: Derived from interviews with supply-chain experts; image courtes of McKinsey design team

**Document intended to provide insight based on currently available information for consideration and not specific advice**

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Blower (PAPR subcomponent): Manufacturing process overview
A subcomponent of PAPR system that appears to face a substantial supply constraint

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<th>Component name</th>
<th>Production process</th>
<th>Material and equipment requirements</th>
<th>Key considerations for supply/manufacturing</th>
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</thead>
<tbody>
<tr>
<td>Electronics control unit</td>
<td>Triangle</td>
<td>The DC motor-fan and battery design should be efficient (&gt;4hr operational hours at &lt;1.5kg size) and effective (&gt;170 liter air/min)</td>
<td>Less-efficient DC motor-fan module can be considered despite shorter operational hours</td>
</tr>
<tr>
<td>Battery</td>
<td>Triangle</td>
<td>The container should have stringent engineering tolerance and be tested to prevent &gt;30-nm particle leak</td>
<td>Expanding airtight-container production requires additional tooling sets (lead time &gt;1 month); interim solution can consider production through CNC machining</td>
</tr>
<tr>
<td>DC motor-fan module</td>
<td>Triangle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Airtight container</td>
<td>Triangle</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Submodule manual assembly</td>
<td>Triangle</td>
<td>Manual assembly by trained operators¹</td>
<td>Additional shifts can expand the production line (mostly manual assembly)</td>
</tr>
<tr>
<td>Finished product testing</td>
<td>Triangle</td>
<td>Automated testing and calibration cycle times up to 1 min/system</td>
<td></td>
</tr>
<tr>
<td>Blower</td>
<td>Triangle</td>
<td>PAPR system certification requires system to be tested (eg, exact match of tube, facepiece, and blower)</td>
<td>Can we relax some testing requirements (eg, shorter battery life or louder operational noise) to help expand production without affecting user protection?</td>
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¹ Include glue, screws, tape, or other required materials to enable production


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DOCUMENT INTENDED TO PROVIDE INSIGHT BASED ON CURRENTLY AVAILABLE INFORMATION FOR CONSIDERATION AND NOT SPECIFIC ADVICE

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