McKinsey & Company

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 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:

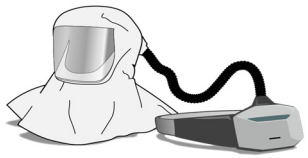
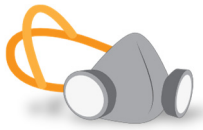
- intended functionality and critical components
- product breakdown, requirements, and specifications
- manufacturing processes and raw materials
- sourcing strategies and preliminary supplier lists

This document should not be used to guide clinical decisions or treatment.

Current as of May 4, 2020

CDC recommends a variety of airway protection options for healthcare professionals, offering a range of protection levels

Reusable Disposable

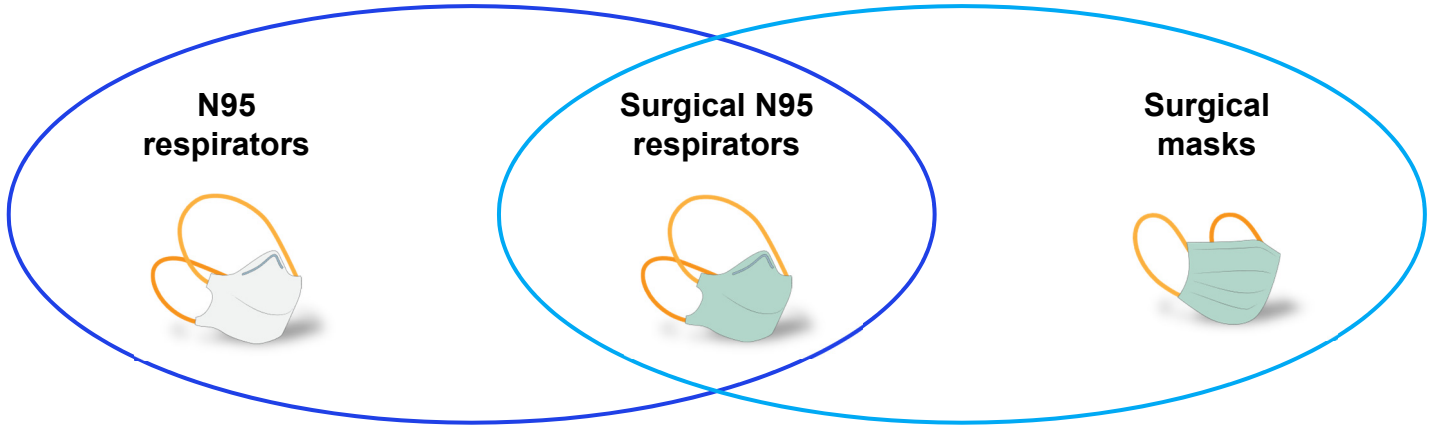
		N95 specification respirators				
	PAPR	Full facepiece	Half face	Nonsurgical respirator	Surgical respirator	Surgical mask ASTM Level 1 [1]
						
Facial sealing	Face seal for tight fitting respirators Loose seal for loose-fitting respirators	Face seal	Face seal	Face seal	Face seal	Loose seal
Filtration efficiency	≥99.97% [2]	≥95% [2]	≥95% [2]	≥95% [2]	≥95% [2]	BFE ≥95%; PFE ≥95% [3]
Designed for fluid protection	Y	Y	Unknown	N	Y	Y
Fluid protection resistance	>120 mm Hg	>80 mm Hg	N/A	N/A	>120 mm Hg	>80 mm Hg
Breathability—Differential pressure	N/A, powered air supply	<35 mm H_20	<35 mm H_20	<35 mm H_20	<35 mm H_20	<4.0 mm H_20
Certification and regulatory body	NIOSH	NIOSH	NIOSH	NIOSH	NIOSH and FDA	FDA

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 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

Source: CDC regulation 42 CFR 84, ASTM F1862, 2101, 2299, https://multimedia.3m.com/mws/media/1794572O/surgical-n95-vs-standard-n95-which-to-consider.pdf, https://www.cardinalhealth.com/content/dam/corp/web/documents/whitepaper/Face%20Mask%20Selection%20Guide.pdf, https://multimedia.3m.com/mws/media/1516101O/3m-vflex-healthcare-particulate-respirator-and-surgical-mask.pdf, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7115281/, https://www.ncbi.nlm.nih.gov/books/NBK294223/, image courtesy of McKinsey design team.

Disposable N95 respirators

Overview: N95 functions and applicability



	N95 respirators	Surgical N95 respirators	Surgical masks
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 P95, R95, N99, P99, R99, P100, R100, P100 are all N95 options that meet higher filtration levels[1]	With good fit, protect provider from small particles, but not required unless invasive procedure or risk of fluid exposure is present[1]	Provide HCP with limited protection from exposure **due to material type and air leakage due to loose seal to wearer's face[2]**

1. https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/default.html; 2. https://smartairfilters.com/en/blog/coronavirus-pollution-masks-n95-surgical-mask/

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

Not exhaustive

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

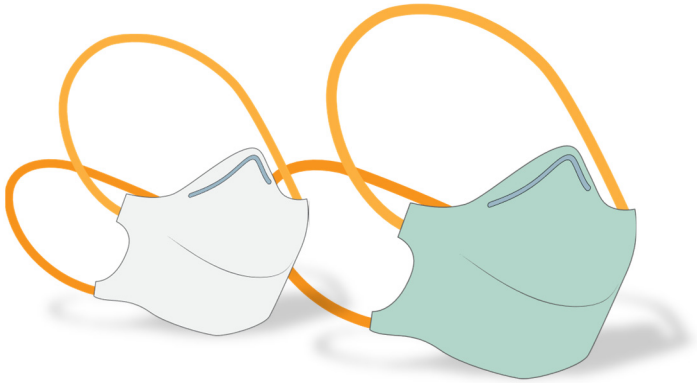
Raw-material shortages:
N95-quality meltblown nonwoven in short supply

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 (eg, duckbill, cup shaped)

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



1. https://www.cdc.gov/niosh/npptl/pdfs/UnderstandingDifference3-508.pdf
2. https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/contingency-capacity-strategies.html
3. Per WHO technical guidance COVID-19 v4 (11-Mar-2020)

Source: https://www.cdc.gov/coronavirus/2019-ncov/hcp/index.html; https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html; image courtesy of McKinsey Design Team.

Current as of May 4, 2020

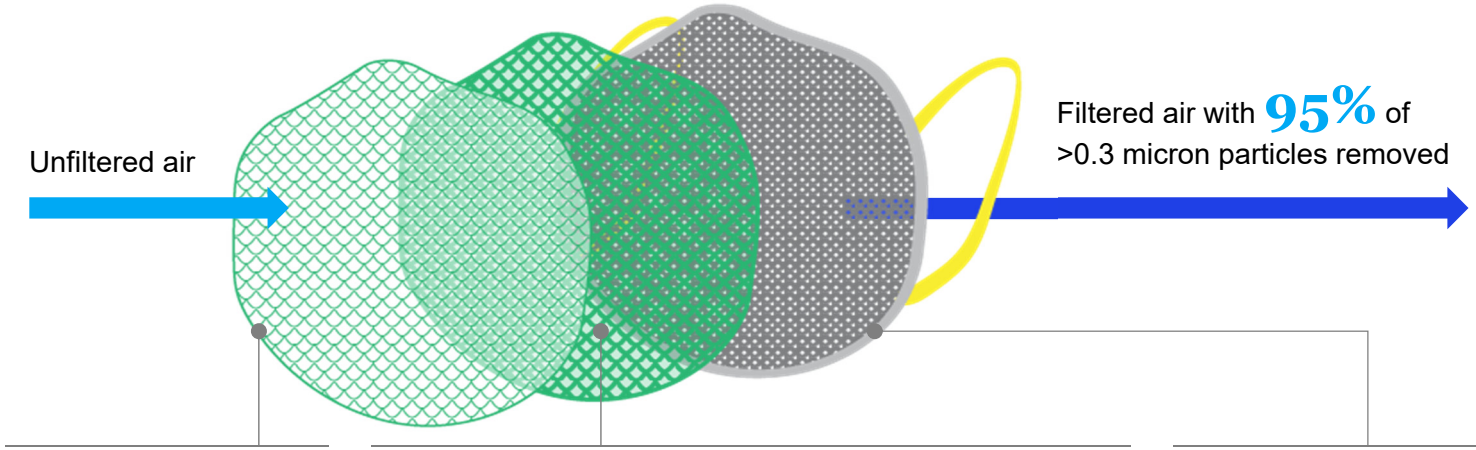
CDC guidance states that approved respirators under standards similar to NIOSH can be used by HCPs in crisis scenarios

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

Country	Performance standard	Acceptable product classification	Standards/guidance documents
Australia	AS/NZS 1716:2012	P3, P2	AS/NZS 1715:2009
Brazil	ABNT/NBR 13698:2011	PFF3, PFF2	Fundacentro CDU 614.894
China	GB 2626-2006	KN100, KP100, KN95, KP95	GB/T 18664-2002
Europe	EN 149-2001	FFP3, FFP2	EN 529:2005
Japan	JMHLW-2000	DS/DL3, DS/DL2	JIS T8150:2006
Korea	KMOEL-2017-64	Special, 1st	KOSHA GUIDE H-82-2015
Mexico	NOM-116-2009	N100, P100, R100, N99, P99, R99, P95, R95	NOM-116
US	NIOSH 42 CFR 84	N100, P100, R100, N99, P99, R99, P95, R95	OSHA, 29CFR1910.134

Source: https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSH.html.

Product breakdown (sample construction): N95 respirators



Outer cover web—nonsurgical

Polypropylene spunbond nonwoven fabric

Provides structure and shape

2.25 mm thick of 22-micron-diameter fibers with 217g/sq. m density

Outer cover web—surgical (ASTM F1862)

Impermeable to blood and other fluids

Filter media

Polypropylene (PP) meltblown; formulation varies by supplier

3M's 8510 in 2015, for example, used 1.77 mm thick of 5.5-micron-diameter fibers with 156 g / sq. m density[1]

Fibers randomly webbed with very low inhomogeneity using corona charge as fibers are extruded; electric charge on fibers attracts particles

Meltblown lacks structural integrity, so quickly layered between two very thin layers of PP spunbond scrim

Pressure drop no more than 35 mm H2O in finished respirator

PP formulation, extrusion die, collector design, configuration, and know-how are proprietary

Inner cover web

Polypropylene spunbond nonwoven fabric

0.36 mm thick of 15.5-micron-diameter fibers with 33g/sq. m density

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

1. Joel Almicar Ramirez, "Evaluation of particle penetration and breathing resistance of N95 filtering face-piece respirators and uncertified dust masks" (PhD thesis, University of Iowa, 2015), https://ir.uiowa.edu/cgi/viewcontent.cgi?article=6337&context=etd

Source: Derived from expert manufacturing interviews; graphic and technical specifications from an N95 manufacturer; image courtesy of McKinsey design team.

Potential takeaways

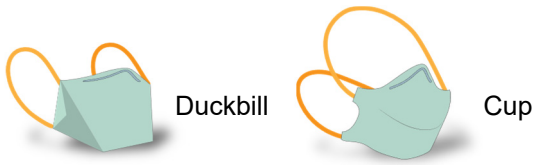
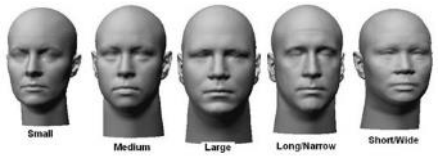
All three layers of SMS can be made in-line or separately in different extruders.

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

Type	Specification	
Functional[1]	Blocks at least 95% of very small (0.3 micron) test particles	Initial breathing resistance (resistance to airflow) not exceeding 35 mm H_20 Initial exhalation resistance not exceeding 25 mm H_20
Technical[2]	Thermoformed layered SMS (spunbond-meltblown-spunbond) stack-up of several low-tech layers and one higher-tech layer Low-tech outer layers: polypropylene spunbond structural inner and outer cover webs High-tech inner layer: carefully controlled polypropylene meltblown filter media	
Shape	Shaped to conform to face and create good seal on various face sizes and shapes	
	Typical respirator shapes[3]  Duckbill Cup	**Head shapes** 
		Head forms for technical specification standards (ISO TC94 Personal Protective Equipment, SC15 Respiratory Protective Devices—National Personal Protective Technology Laboratory of NIOSH)
Certification and testing[4]	**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**	**Testing equipment:** Industry standard is TSI 8130A

Examples[5]	**3M 8510 respirator (as measured in 2015)**	**Moldex N95 respirator (as measured in 2015, exact model unknown)**
External layer	2.27-mm-thick layer of 22-micron-diameter fibers with 217g/m2 density	Main filter layer: 1.3-mm-thick layer of 5.1-micron-diameter fibers with 63g/m^2 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/m^2 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-micro-diameter fibers with 28g/m2 density

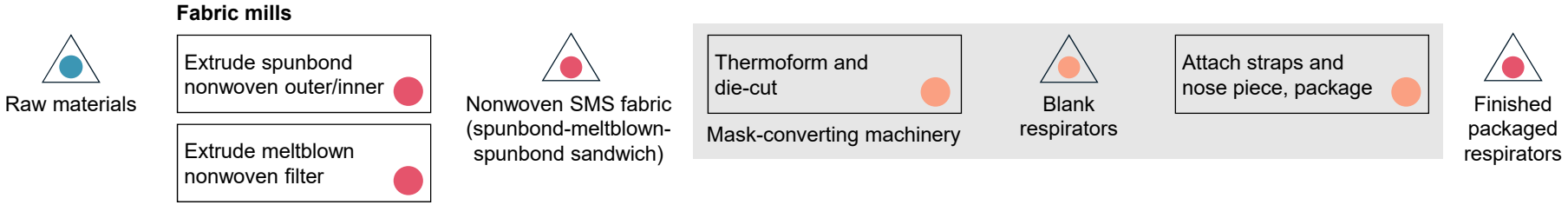
1. CDC regulation 42 CFR 84; FDA: https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks; 2. Collected through interviews with manufacturing experts; 3. Images courtesy of McKinsey design team; 4. NIOSH Memorandum of Understanding 225-18-006, https://www.fda.gov/about-fda/domestic-mous/mou-225-18-006; testing: https://www.cdc.gov/niosh/npptl/stps/pdfs/TEB-APR-STP-0059-508.pdf; 5.Ramirez, "Evaluation of particle penetration and breathing resistance," University of Iowa

Source: Head shape image source: CDC: 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

Dedicated converter | Production process | Inventory | Likely low nonmed capacity available | Likely some nonmed capacity available | Likely sufficient capacity available

Manufacturing process



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

Reifenhauser 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 alternative3

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 line1 2

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

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.

1. https://www.yicaiglobal.com/news/malion-new-materials-to-invest-usd172-million-on-face-mask-material-plant
2. https://www.jqknews.com/news/395294-Sinopec_announced_that_it_would_soon_build_10_melt_blown_cloth_production_lines_with_an_investment_of_about_200_million_yuan.html
3. https://www.oerlikon.com/manmade-fibers/en/about-us/news/oerlikon-nonwoven-large-scale-meltblown-sold-to-asia/

Source: Collected through interviews with experts in the PPE manufacturing industry; image courtesy of McKinsey design team

Current as of May 4, 2020

Meltblown is manufactured in multiple facilities within the US for a variety of end products

Not exhaustive

Examples of companies with melt blown production capacity that can potentially produce N95 filter media

Usage

Filtration media for HVAC and water, wipes, absorbent hygiene, vehicle construction for NVH[1], sorbents, medical/surgical products, and apparel

Current capacity

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

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

1. NVH = noise, vibration, harshness; 2. Derived from industry consortium experts

Source: Image courtesy of McKinsey Design Team

Meltblown production lines are available from multiple suppliers

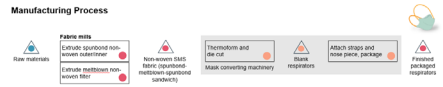
Example suppliers

Example suppliers	Standard line width	Select characteristics
Reifenhauser REICOFIL	Up to 5200mm[1]	Production rate up to 1200 m/min[1] Estimated nominal spunbond output up to 12.3 ktons/year[2] Estimated nominal meltblown output up to 3.2 ktons/year[3]
Oerlikon Neumag nonwoven systems	Up to 7000mm[4]	Estimated nominal spunbond output up to 13.1 ktons/year[5] Nominal meltblown output up to 1.2 ktons/year[6]

1. https://www.reicofil.com/system/uploads/attachment/file/58f8ab2f59d9e623a9d48e54/REI-RF5-Boschuere-Low.pdf
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
4. https://www.oerlikon.com/manmade-fibers/en/about-us/news/oerlikon-neumag-at-cinte-2010-all-in-one-in-nonwoven-production-equipment/
5. Calculated based on 24 hr/day, 365 days/year operations at 1500 kg/h, unspecified width, per https://fiberjournal.com/geo-synthetics-significance-and-application-in-everyday-life/
6. https://www.oerlikon.com/manmade-fibers/en/about-us/news/oerlikon-nonwoven-large-scale-meltblown-sold-to-asia/, it is unclear what assumptions of production run time per day and per year are used in this calculations

Image courtesy of McKinsey design team.

Converting machinery, ranging from automated single line to multistep lines, is available from different suppliers



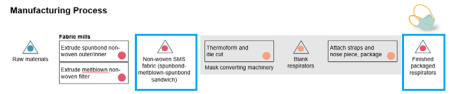
Example assembly-line types and suppliers

	Type	Supplier example	Throughput (pcs/min)	Price (RMB)
Folded-N95 Assembly Line	**Automated folded mask line**	KYD (used by Honeywell) Yicheng Lihan[1]	25-55	400,000-500,000
Cup-Shaped N95 Machinery	**Cover-making machine[2]**	KYD	50-60	65,000
	Welding and cutting machine[3]	KYD	15	65,000
	After-process production line[4]	KYD	18-22 Can integrate multiple steps (eg, labels, assembly, packing)	330,000
Other		NCM Nonwoven Converting Machinery Co., Ltd.[5] TRM-Top Rank Machinery Inc.[7] Fiber Dynamics, Inc.[6] Elmarco[8], a nanofiber machine maker		

1. http://www.ycnicety.com/show/154.html, https://www.lihanmachine.com/zhediekouzhaoshebei/1067.html
2. https://cn.made-in-china.com/gongying/kuaiyudacom-cXWxDBYMnnVF.html | 3. https://cn.made-in-china.com/gongying/kuaiyudacom-EKcQhyUJRxkm.html
4. https://cn.made-in-china.com/gongying/kuaiyudacom-hBWmbXpKbxkY.html
5. https://www.ncm-machinery.com/mask-machine/ | 6. http://fdinonwovens.com/index.php/about_us | 7. http://www.trm-machinery.com/?lang=en | 8. https://www.elmarco.com/

Image courtesy of McKinsey design team.

Representative testing process and key standards



Not exhaustive

Representative testing approach

Raw-material testing
Steps to ensure quality of nonwoven fabric inputs

→

In-line inspection
Automated optical or manual inspection before packaging

→

Sample testing before shipment

→

Sample test in laboratory

Tests for raw material

Tests for QA/QC of finished goods

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 (select examples)[2]

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

Manufacturers should ensure that test standards are appropriate for end-use markets and adhere to all legal and regulatory requirements.

1 https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/crisis-alternate-strategies.html
2. Derived from manufacturing-expert interviews and research
Image courtesy of McKinsey design team

The COVID-19 response team has developed knowledge around five categories of medical supply interventions

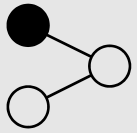
NON EXHAUSTIVE

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)

Current as of May 4, 2020

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?

4

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)?

5

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)?

1. https://www.fda.gov/media/136403/download; https://www.fda.gov/media/136664/download; https://www.fda.gov/media/136663/download

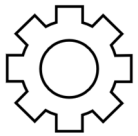
1a

FDA granted authorization to Battelle's system, which disinfects N95 respirators with concentrated hydrogen peroxide

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

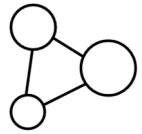
Conclusions below were developed by the authors cited on this slide

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 peroxide[1]



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

1. https://inside.battelle.org/blog-details/covid-19-deploying-a-critical-new-ppe-decontamination-system; https://techcrunch.com/2020/03/30/fda-grants-emergency-authorization-to-system-that-decontaminates-n95-respirator-masks-for-re-use/

1b

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

1. National Center for Biotechnology Information, https://www.ncbi.nlm.nih.gov/pubmed/25806411
2. Nebraska Medicine, N95 Filtering Facepiece Respirator Ultraviolet Germicidal Irradiation (UVGI) Process for Decontamination and Reuse, https://www.nebraskamed.com/sites/default/files/documents/covid-19/n-95-decon-process.pdf

Conclusions below were developed by the authors cited on this slide

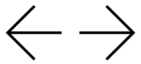
Research by NIOSH/CDC concluded that ultraviolet germicidal irradiation (UVGI) could be used to effectively disinfect disposable respirators for reuse[1]

- 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 UVGI2

- 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



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?

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

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

3. Potential ways to unlock new capacity for manufacturing

Levers	Description	Examples
Repurpose similar machinery	Manufacturing: Up-configure existing machinery used for non-N95 applications	**Meltblown process**: Some alternate extruders can be modified with the right extrusion die, which can be potentially supplied by diemakers or others with spare dies **Conversion process**: Textile industry has similar production lines that can be modified
	Product testing: Leverage qualified testing equipment with similar capabilities to add testing capacity	Some research institutions (eg, 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)
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.

Current as of May 7, 2020

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]

Country or region	US	Europe	China	Australia	Korea	Japan
Certification/class (standard)	N95 (NIOSH-42C FR84)	FFP2 (EN 149-2001)	KN95 (GB2626-2006)	P2 (AS/NZ 1716:2012)	1st Class (KMOEL - 2017-64)	DS (JMHLW-Notification 214, 2018)
Filter performance (must be ≥ X% efficient)	≥ 95%	≥ 94%	≥ 95%	≥ 94%	≥ 94%	≥ 95%
Flow rate	85 L/min	95 L/min	85 L/min	95 L/min	95 L/min	85 L/min
Total inward leakage (TIL)* – tested on human subjects performing exercises	N/A	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (individual and arithmetic mean)	≤ 8% leakage (arithmetic mean)	Inward leakage measured and included in user Instructions
Inhalation resistance – max pressure drop	≤ 343 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min) ≤ 500 Pa (clogging)	≤ 350 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)

1. 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
3. https://www.fda.gov/media/136403/download; https://www.fda.gov/media/136664/download
4. https://www.fda.gov/media/136663/download
5. https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ppe

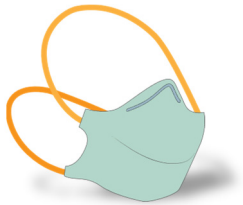
FDA's EUAs from March 28, 2020, April 3, 2020, and May 7, 2020 allow respirators from EU, Australia, Korea, and Japan[3,5] but only select suppliers from China (see latest CDC guidance and FDA EUAs on PPE[2,3,4,5])

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



	N95 respirators	Surgical masks
Certification	NIOSH certified	FDA class II guidelines
Design	Test fitted to seal tightly around wearer's nose and mouth	Typically rectangular shaped and loop over wearer's ears
Function	Filter out small particles **inhaled by wearer**	Protect wearer from splashes and large droplets and minimize particles **expelled by wearer**
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 leakage**[1]

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 inhales.

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

Image courtesy of McKinsey design team

Product information sheet: Surgical masks

Not exhaustive

Product information

Product description:
Surgical masks[3]; may be labeled as surgical, isolation, dental, or medical procedure masks

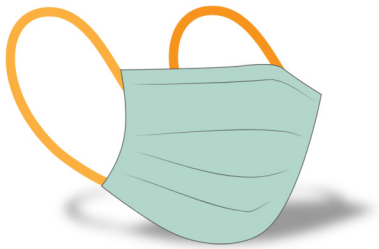
Product group:
Personal protective equipment

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 wear's saliva and respiratory secretions1

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]

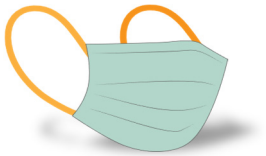
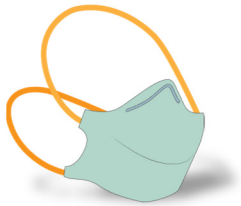
	Level 1	Level 2	Level 3	Description
Fluid protection resistance	>80 mmHg	>120 mmHg	>160 mmHg	Resistance to penetration by synthetic blood
Differential pressure test	<4.0	<5.0	<5.0	Breathing pressure difference across the mask
BFE (bacteria-filtration efficiency standard – 3 µm)	≥95%	≥98%	≥98%	Ability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

1. https://www.cdc.gov/niosh/npptl/pdfs/UnderstandingDifference3-508.pdf; 2.ASTM levels determined by ASTM F2100-11 standards, ASTM F1862, ASTM F2299; not all surgical masks comply to ASTM standards; 3. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/surgical-masks-premarket-notification-510k-submissions

Source: https://www.cdc.gov/coronavirus/2019-ncov/hcp/index.html; https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html; https://www.fda.gov/files/medical%20devices/published/Guidance-for-Industry-and-FDA-Staff--Surgical-Masks---Premarket-Notification-[510(k)]-Submissions--Guidance-for-Industry-and-FDA-(PDF-Version).pdf; https://www.halyardhealth.co.uk/media/16340001/hc352_00-uk_facethefacts_astm_2014.pdf, image courtesy of McKinsey design team.

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

Current as of May 7, 2020

Mask type	Standards	Facial seal	Filtration Effectiveness		
Single-use face mask	China: YY/T0969	Loose seal	BFE: ≥95% PFE: NA		
Surgical mask 	China: YY 0469	Loose seal	BFE: ≥95% PFE: ≥30%		
	USA: ASTM F2100	Loose seal	**Level 1** BFE: ≥95% PFE: ≥95%	**Level 2** BFE: ≥98% PFE: ≥98%	**Level 3** BFE: ≥98% PFE: ≥98%
	Europe: EN 14683	Loose seal	**Type 1** BFE: ≥95% PFE: ≥95%	**Type 2** BFE: ≥98% PFE: ≥98%	**Type 3** BFE: ≥98% PFE: ≥98%
N95 respirator 	USA: NIOSH (42 CFR 84)	Good face seal	N95/KN 95	N99/KN 99	N100/KN 100
	China: GB2626		0.3 Microns: ≥95%	0.3 Microns: ≥99%	0.3 Microns: ≥99.97%
	Europe: EN 149:2001	Good face seal	FFP1	FFP2	FFP3
			0.3 Microns: ≥80%	0.3 Microns: ≥94%	0.3 Microns: ≥99%

1.https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks#s4

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

Source: https://www.crosstexbms.com/media/1097/maskenomics-crosstexctx1216_p.pdf, https://smartairfilters.com/en/blog/comparison-mask-standards-rating-effectiveness/, https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks, https://www.halyardhealth.co.uk/media/16340001/hc352_00-uk_facethefacts_astm_2014.pdf, https://blogs.cdc.gov/niosh-science-blog/2009/10/14/n95/, image courtesy of McKinsey design team.

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[1]

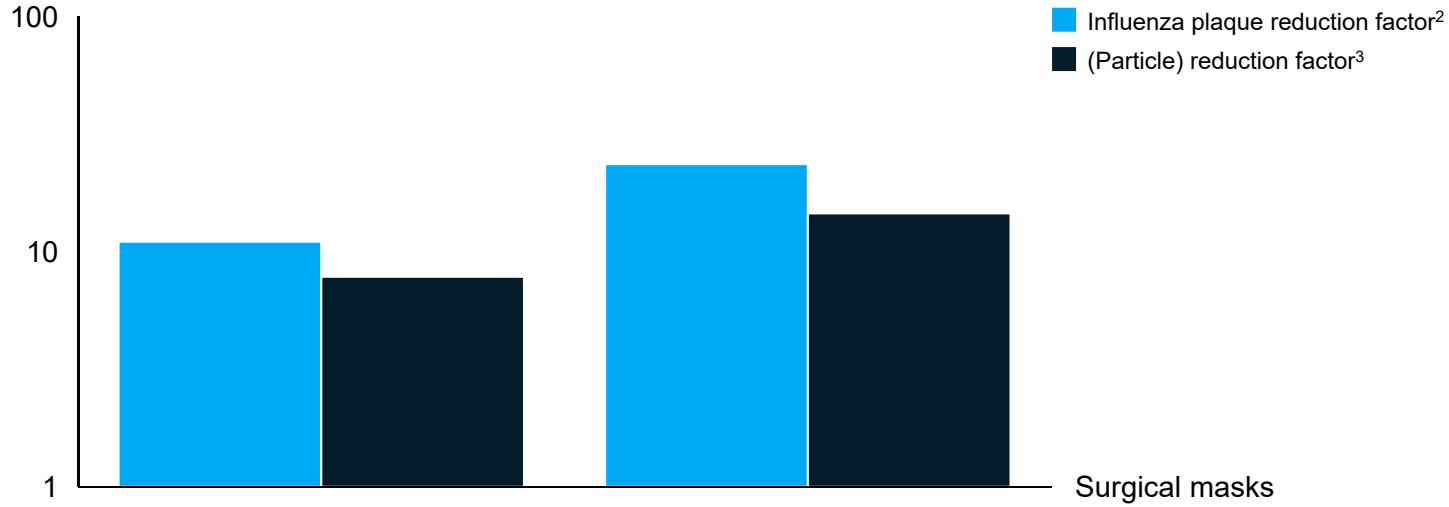
NIOSH certification mask filtration efficiency for particles ≥ 0.3 μm. Performance results are achieved under testing conditions specified by NIOSH standards, and do not represent filtration efficiency under normal conditions

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[2]

JHI[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

Mask type	Typical double-strap tie surgical mask	Double-strap tie surgical mask with integral splash visor



1. Journal of Hospital Infection; 2. Influenza plaque reduction factor = Influenza virus titre of external air sample / Influenza virus of internal air sample; 3. (Particle) reduction factor = Particle concentration outside the mask/Particle concentration inside the mask; 4. https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks#s4

Source: Booth, C. Makison. "Effectiveness of Surgical Masks against Influenza Bioaerosols." Journal of Hospital Infection, vol. 84, 31 May 2013, pp. 22–26. https://www.sciencedirect.com/science/article/abs/pii/S0195670113000698; image courtesy of McKinsey design team

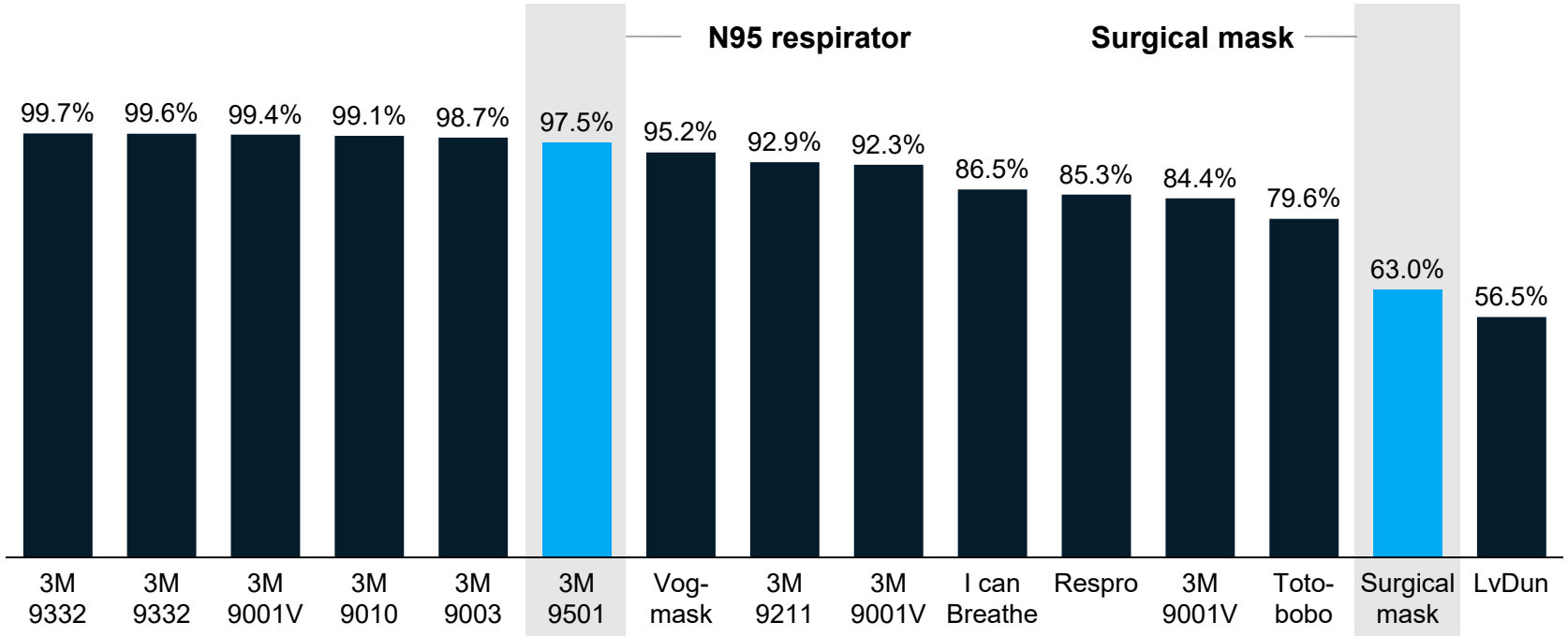
The design of the surgical masks matter

Surgical masks also do not provide complete protection because of the loose fit[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

Studies find that while surgical masks are not as effective as N95 respirators, they block out some aerosol particles

Particles blocked during fit test for different mask variants

Particles .01 – 1 Microns blocked, %



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.

Source: https://smartairfilters.com/en/blog/coronavirus-pollution-masks-n95-surgical-mask/

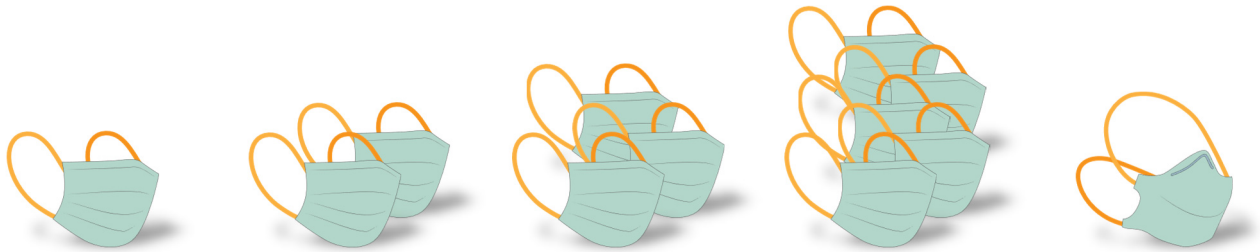
According to the JHI,[1] wearing multiple masks may help reduce small-particle penetration, but not as well as an N95

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

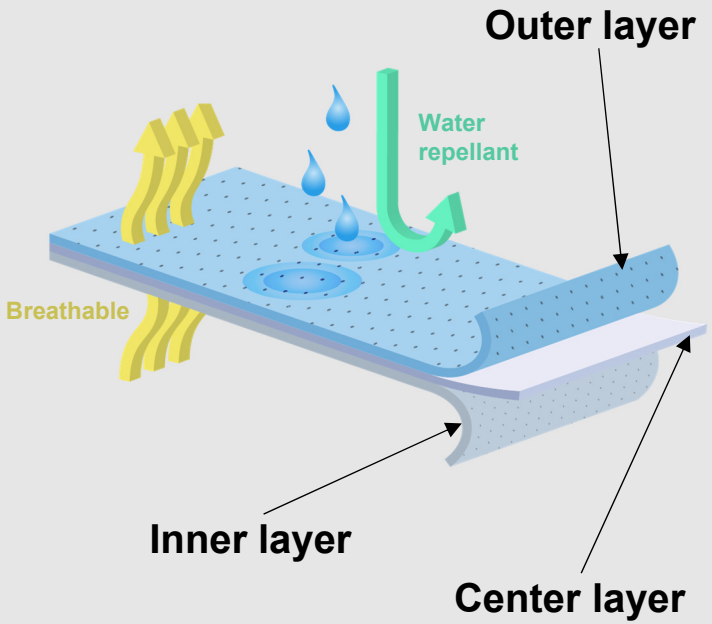


Number of masks worn	**1**	**2**	**3**	**5**	**1**
Type	Surgical	Surgical	Surgical	Surgical	N95
Particle reduction (measuring 0.02-1 µm)	**63%**	**74%**	**78%**	**82%**	**95%**
Breathability	<5mm H_20	———	Increasing pressure difference and decreasing breathability	——→	<35 mm H_20

1. *Journal of Hospital Infection*

Source: C. Makison Booth, "Protecting healthcare staff from severe acute respiratory syndrome: Filtration capacity of multiple surgical masks," *Journal of Hospital Infection*, no. 59 (2005), 365–68, https://www.sciencedirect.com/science/article/abs/pii/S0195670113000698; image courtesy of McKinsey design team.

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

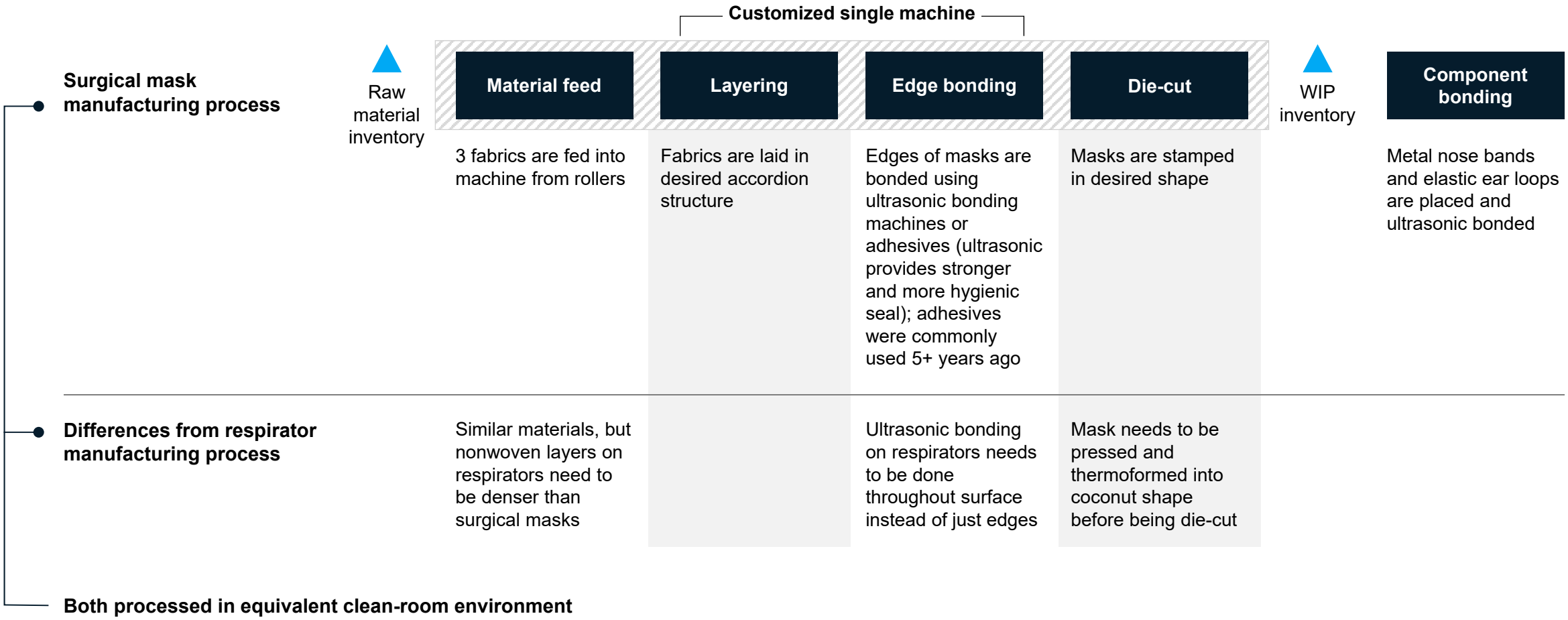
4. Metal nose band
5. Elastic ear loops

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



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

Current as of May 4, 2020

Potential nonincumbent manufacturers

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

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.

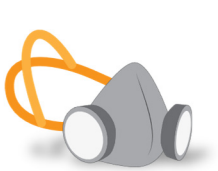
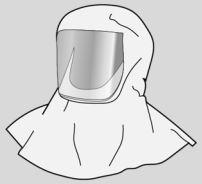
Nonincumbent manufacturers would require regulatory review and approval to produce certified masks and respirators.

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

PAPR (powered air-purifying respirator)

OSHA allows the use of PAPR[1] during aerosol-generating procedures and when N95 respirators are not available[2]

Most commonly used type

		Tight fitting		Loose fitting	
		Half mask	Full facepiece	Hood	Helmet
					
Key metrics	**Respiratory protection (APF)[3]**	**50**	**1000**	**25[4]**	**25[4]**
	Min airflow rate	**115** liters/min	**115** liters/min	**170** liters/min	**170** liters/min

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]

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]

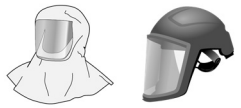
Use of tight-fitting PAPRs requires fit testing; use of loose-fitting PAPRs does not require fit testing.[6]

1. Powered air-purifying respirator | 2. https://www.osha.gov/Publications/OSHA3990.pdf | 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 | 5. https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html | 6. https://www.ncbi.nlm.nih.gov/books/NBK294223

Source: https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=12716&p_table=standards
Image courtesy of McKinsey design team

Functions and user experience differ greatly between PAPRs and disposable N95 respirators

Not exhaustive

		PAPR (Most common hood and helmet systems, >$1,000) 	Disposable N95 respirator (<$10) 
Function	**Assigned protection factor**	≥25	10[1]
	Reusability	Reusable; filter change needs to follow manufacturer's recommendation or when damaged, soiled, or causing noticeable increase in breathing resistance[2]	Follow manufacturer's recommendation or discard whenever they are damaged, soiled, or causing noticeable increase in breathing resistance[2]
	Filtration	Purifies the ambient air and feeds into the respirator; discharged air is not filtered[3]	Filters both inhaled and exhaled air
	Fluid protection for eye	Yes for full-facepiece PAPRs and some loose-fitting PAPRs[6]	No
User experience	**Breathability**	Purified air is supplied into hood/helmet by blower	Differential pressure <35 mmH_20
	Fit test	Not required for loose-fitting piece[3]	Required, has restriction on facial hair[5]
	Training	Additional training might be required when using a new type[4]	Easier to learn and train than PAPR
	Vulnerability to external environment	Loose parts such as hoses, cords, and filters can get dislodged in congested emergency environments[3]	One-piece design that does not easily become loose compared to PAPR
	Stability of level of protection	Equipment might get in the way of different working postures and have difficulty remaining in place to provide uninterrupted protection[3]	One-piece design that does not easily become loose compared to PAPR
	Ease of disinfection between patients	Must be cleaned and disinfected according to manufacturer's reprocessing instructions prior to reuse[4]	Discard after single use; special operational system needed for approved decontamination process
	Restriction on movements	Some models might have restrictions on neck movement, ability to hear each other[4]	Less restriction on movements than PAPR
	Maintenance	Hard to repair when damaged, need assistance from manufacturer with high cost[4]	Can be discarded and replaced at low cost

1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4589166/ ; 2. https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource3end.html
3. https://www.ncbi.nlm.nih.gov/books/NBK294223; 4. Derived from healthcare expert interviews and research; 5. https://blogs.cdc.gov/niosh-science-blog/2017/11/02/noshave/
6. https://www.ncbi.nlm.nih.gov/books/NBK294223/
Image courtesy of McKinsey design team

Several regulatory bodies oversee governance of PAPR

Current as of May 7, 2020

General US certifications for PAPRs used in medical setting[1] per CDC

Standard	Description	Body
42 CFR 84	Respiratory-equipment certification	NIOSH
1910.134[2]	Respiratory-protection PPE	OSHA

General international standards for PAPR per NIH summary[3]

Standard	Description	Body
DIN EN 12942	Respiratory-protection devices	EN
SC15[3]	Filtering devices	ISO
TC94[3]	Respiratory-protection devices	ISO

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]

1. https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html
2. https://www.cdc.gov/niosh/docs/2018-166/pdfs/2018-166.pdf?id=10.26616/NIOSHPUB2018166
3. https://www.ncbi.nlm.nih.gov/books/NBK294223/
4. "Use of alternatives to N95 respirators," https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html
5. https://www.3m.com/3M/en_US/safety-centers-of-expertise-us/respiratory-protection/respirator-selection/
6. https://www.cdc.gov/niosh/npptl/topics/respirators/cel/

Product information sheet: Powered air-purifying respirator

Not exhaustive

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[2]

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[1]

1. https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html, https://www.ncbi.nlm.nih.gov/books/NBK294223/
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

Not exhaustive

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 ≥0.3 μm[1]

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

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
3. https://safety.honeywell.com/content/dam/his-sandbox/products/respiratory-protection/documents/HS_primair_100_series_hoods_810.pdf
4. High-density polyethylene
5. https://ohsonline.com/Articles/2019/05/01/Why-Pick-a-PAPR.aspx?Page=3

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

Source: Image courtesy of McKinsey design team.

High-level specifications: Powered air-purifying respirator

Not exhaustive

	Functionality	Key technical specifications	Typ. Value[1,2]
1 **Head-top unit**	A head top designed in variety of ways for needs in workplaces such as medical, hazardous, corrosive, or nuclear[3]	Style: Helmet, tight fitting, or loose fitting	Depends on need
		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**	A tube carrying filtered air to head-top unit	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**	A battery-powered motor driving fan(s) to pull air through the HEPA required by manufacturers	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

1. https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html, https://www.ncbi.nlm.nih.gov/books/NBK294223/
2. Derived from interviews with supply-chain experts

Source: Image courtesy of McKinsey design team.

PAPR: Manufacturing process overview

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

Not to scale **Illustrative**

Details follow | Inventory | Production process | Likely low nonmed capacity available | Likely some nonmed capacity available | Likely sufficient capacity available

	Belt	Tube	Facepiece	HEPA	Blower	Submodule manual assembly	System testing and calibration	PAPR
Component name								
Overall production process								
Material and equipment requirements	Engineering plastics: polyethylene (eg, Tyvek), polycarbonate, ABS, PVC EPDM rubber or alternatives (eg, neoprene, silicone) Battery raw material (eg, lithium-ion polymer)			Circuit and circuit-board components Metals, such as copper, steel, aluminum Filter media		Manual assembly by trained operators[1] Automated testing and calibration cycle times up to 1 min/system		PAPR system certification requires the system to be tested (eg, exact match of tube, facepiece, and blower)
Key considerations for supply/ manufacturing	Production line requires fixturing and validation Mold tooling for subassembly a bottleneck to ramp-up: 2–3 months to create and approve tooling			Testing needed for raw material input, particularly facepiece or hood input due to blood splattering test for medical use		Assembled system flow rate, noise, filtration media, and filter lifespan are key performance criteria for full system Certification of system design by manufacturer is generally maintained for 10–15 years Manufacturers are audited at random by NIOSH		

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

Blower (PAPR subcomponent): Manufacturing process overview

A subcomponent of PAPR system that appears to face a substantial supply constraint

Not to scale **Illustrative**

△ Inventory ▭ Production process ● Likely low nonmed capacity available ● Likely some nonmed capacity available ● Likely sufficient capacity available

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

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

Source: Derived from interviews with supply chain experts; https://engineering.berkeley.edu/news/2020/04/readily-deployable-respirators-could-help-frontline-healthcare-workers/