Different protective equipment used across industries

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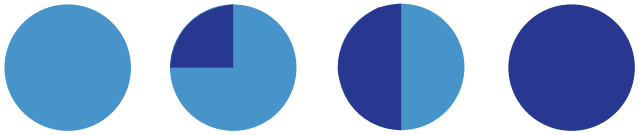
Note:
ANSI/AAMI PB70 is a standard that evaluates the barrier effectiveness of surgical gowns and isolation gowns

MEDICAL

Isolation gown (SMS)

Surgical gown (AAMI Class 2-4)



	Isolation gown (SMS)	Surgical gown (AAMI Class 2-4)
Ability to meet AAMI Level 1 Protection [1]	●	●
Reuse or cleaning potential[2]	◔	◔
Long-term comfort, breathability	●	●
Ease of manufacture	●	◑

Limited non-medical applications of gowns / body protection observed in cases

1. Unless otherwise certified, these may meet at least AAMI Class I. However, this needs to be validated; AAMI Level 1 is a measure of liquid barrier performance and expected barrier effectiveness is "Minimal water resistance (some resistance to water spray)"
2. Includes multiple uses and/or cleanability
3. Qualitative assessment from one concept review based on material technical data sheets –criteria and assessment needs to be validated by any potential user

Source: https://www.health.state.mn.us/facilities/patientsafety/infectioncontrol/ppe/ppewebinar.pdf; Industry expert interviews

Distinction between respirators and masks

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	NIOSH Certified N95 Respirators 1b	FDA Cleared Surgical Masks 1c
		
Tight-fitting face seal[3]	✓	✗
Fluid resistant	✗	✓
Protects others from the wearer's respiratory emissions	✓	✓

1. https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/default.html
2. https://www.osha.gov/Publications/OSHA3990.pdf
3. https://www.cdc.gov/niosh/npptl/pdfs/UnderstandingDifference3-508.pdf

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.cdc.gov/coronavirus/2019-ncov/downloads/COVID-19_PPE_illustrations-p.pdf; images courtesy of 3M, CDC

Respirators

Respirators such as N95 and KN95 provide the best individual protection for hazards related to the aerosolization of COVID-19 viral particles. Respirators should be worn in any context in which a healthcare worker is interacting with individuals who are at higher risk than the general public, and where there is a risk of aerosolizing COVID-19 particles, such as during an intubation procedure. Respirators are not recommended outside of specific healthcare contexts according to the CDC [4].

CDC guidance for respirators:

Non-surgical N95 respirators provide sufficient protection for health care providers against COVID-19 in most settings.

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.

Range of respirator and mask options provide different levels of performance

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Generalization; selection should be made based on hazard assessment

- NIOSH regulated
- Observed incremental use in industry for COVID-19 protection

Critical supply	Reduces wearer's exposure to airborne particles	Protects others from wearer's respiratory emissions	Fluid resistant	Re-use	Relative unit cost	Comments
Surgical N95 respirator 	Can filter >95% of particles >0.3 microns Good face seal	Yes	Yes	Unknown	Lower	Generally used for health care providers
N95 respirator 		Yes	No	Multi-use if cleaning is allowed	Lower	Generally used for health care providers and other high risk activities
Surgical mask 	Some filtering performance Loose face seal	Yes	Yes	Single use / replace daily in offices	Lower	Generally used for medium risk activities While a loose face seal blocks fewer particles it improves breathability
Non-spec products (commercial + homemade) 	Varies	Yes	Varies	Varies	Lower to middle	Wide range of alternatives with varied levels of performance and cost; typically for personal use

Source: CDC regulation 42 CFR 84.180, https://wwwn.cdc.gov/PPEInfo/Standards/Info/42CFR84180, 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-health-care-particulate-respirator-and-surgical-mask.pdf, https://multimedia.3m.com/mws/media/957730O/respirators-and-surgical-masks-contrast-technical-bulletin.pdf, expert interviews Image source: 3M.com; https://www.geekbuying.com/item/Xiaomi-Mijia-Smartmi-Filter-Mask-With-Ventilating-Valve-390542.html

Encourage or Mandate Appropriate PPE1 Gear

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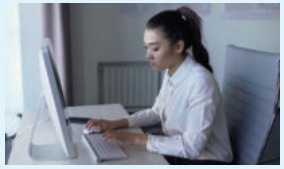
PPE USAGE

OSHA Risk Level R	Respirators and masks	Gowns	Eye protection	Gloves
 HIGH-VERY HIGH RISK				
 MEDIUM RISK				
 LOW RISK				

1 Critical PPE (surgical masks, N-95, etc.) must continue to be reserved for healthcare workers and other medical first responders. Use should be in accordance with local government and health organization guidelines

Does not reflect Safe Direct MS guidance customized to individual client needs - should be vetted against applicable legal and business requirements before application to a specific client

Source: Expert interviews, press search, client surveys

PPE Requirements for workers:

In order to select the appropriate Personal Protective Equipment, one must first identify and understand the infection hazards posed to them in their respective operating environment. The following considerations should be made, as recommended by the CDC [1]:

1. Identify the type and risk level of the anticipated exposure, this includes:

a. Exposure: Will you be exposed to individuals who have a higher probability of exposure to individuals who have contracted COVID-19? Are you at risk for exposure such as physical touch, body fluid splashes/sprays, aerosolized viral particles, or large volumes of blood? Consult with your employer or your local Occupational Health and Safety associa tion for help conducting a risk assessment.

b. Durability & Appropriateness: Does the PPE consid- ered address the identified exposure hazards? For example, if body fluid splatter is an identified hazard, does the PPE in question splatter and penetration resistant?

c. Fit: Does the PPE in question fit the user appropri- ately? PPE should fit comfortably and snugly, without gaps, large material excesses or excessively stretching materials.

Selection Guide

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Isolation Gowns

Isolation gowns should be used whenever a user may be exposed to the clothing or skin where contact with body fluids or secretions may occur [1]. Gowns should cover the entire torso, fit comfortably over arms, and have long sleeve that fit snugly around the wrist. The following table from the FDA website outlines the level of protection and corresponding hazards associated with each level of gown [2]:

Type of PPE	Feature Tested	Standard Designation	Sub headings	Description	Applicability
Gowns	Liquid Barrier Performance	AAMI PB70:2012		Classifies a gown's ability to act as a barrier to penetration by liquids or liquid-borne pathogens based on four levels. The critical protective zones for surgical and non-surgical gowns are defined differently by the standard. While the critical zones designate different protective areas for the different gowns, the levels of protection are the same for both surgical and non-surgical gowns.	Liquid barrier performance is not related to the strength of the material. This standard references several other standards
			Level 1	• Used for MINIMAL risk situations • Provides a slight barrier to small amounts of fluid penetration • Single test of water impacting the surface of the gown material is conducted to assess barrier protection performance.	Basic care, standard hospital medical unit
			Level 2	• Used in LOW risk situations • Provides a barrier to larger amounts of fluid penetration through splatter and some fluid exposure through soaking • Two tests are conducted to assess barrier protection performance: - Water impacting the surface of the gown material - Pressurizing the material	Blood draw from a vein, Suturing, Intensive care unit, Pathology lab
			Level 3	• Used in MODERATE risk situations • Provides a barrier to larger amounts of fluid penetration through splatter and more fluid exposure through soaking than Level 2 • Two tests are conducted to test barrier protection performance: - Water impacting the surface of the gown material - Pressurizing the material	Arterial blood draw, Inserting an IV, Emergency Room, Trauma
			Level 4	• Used in HIGH risk situations • Prevents all fluid penetration for up to 1 hour • May prevent VIRUS penetration for up to 1 hour • In addition to the other tests conducted under levels 1-3, barrier level performance is tested with a simulated blood containing a virus. If no virus is found at the end of the test, the gown passes.	Pathogen resistance, Infectious diseases (non-airborne), Large amounts of fluid exposure over long periods

Surgical Face Masks

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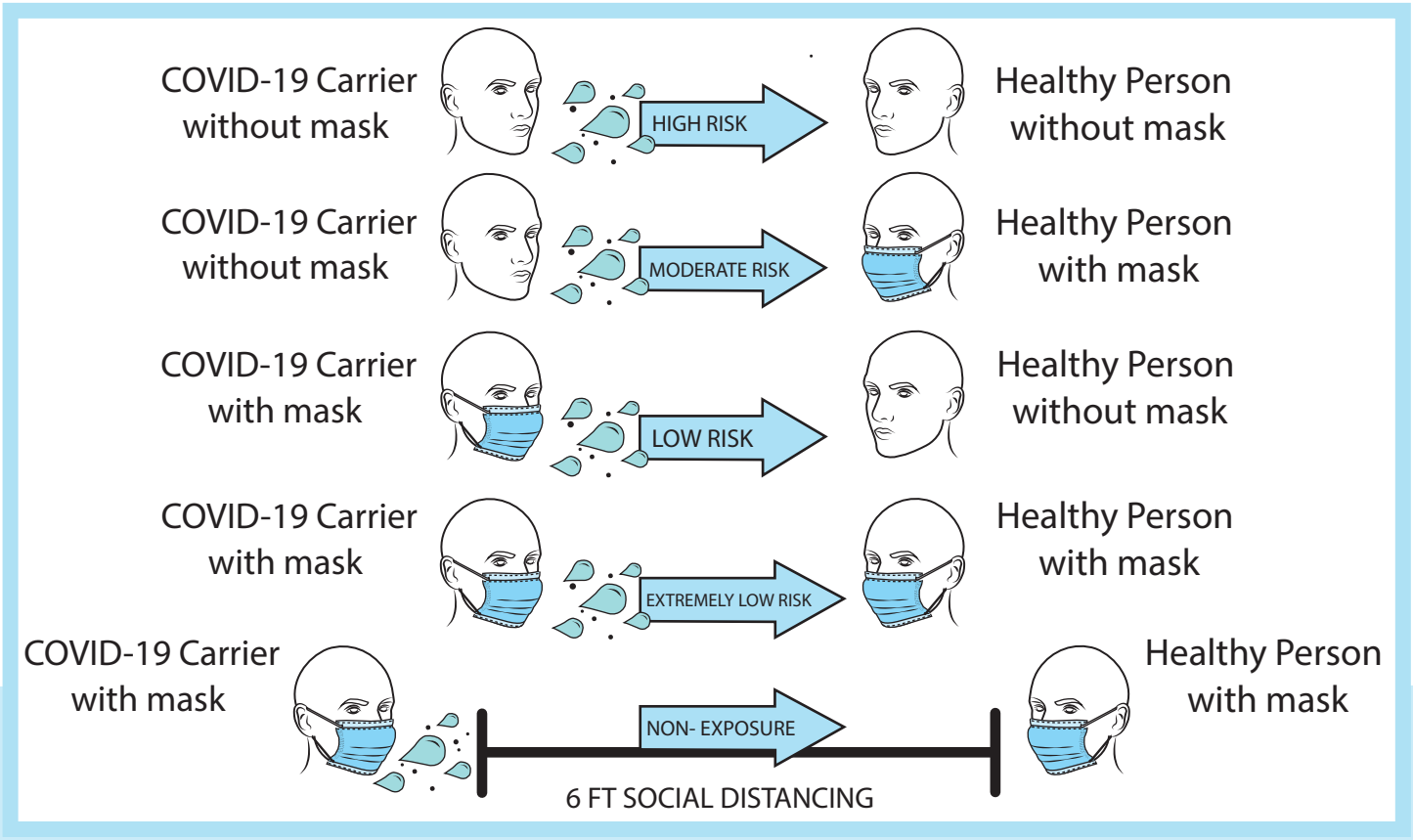
A surgical face mask should always be worn in public order to provide source control – that is to reduce the risk of transmission from the wearer to other individuals [3]. There are four main considerations when selecting an appropriate surgical face mask:

1. Filtration: Based on the hazard assessment, is a certain level of filtration required?
2. Fluid Resistance: What is there potential for body fluid splatter? Is the splatter likely to be light or heavy?
3. Features: Different masks have certain features based on their intended application, such as sterilization and type ear loop placement.
4. Fit: Does the mask fit comfortably, cover both the nose and mouth snugly without any large gaps?

LEVELS OF EXPOSURE



Surgical Face Mask Specifications by Level

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There are three main classes of protection for Surgical Face Masks, the type of protection and corresponding hazards are outlined below:

Surgical Face Mask Level	Bacterial Filtration Efficiency (% filteration)	Particle Filtration Efficiency	Breathability (Differential Pressure in mmHG/cm2)	Fluid Resistance (mmHG/cm2)	Hazard Associated	Use Case
ASTM Level 1	>95%	>95%	<4	80	Recommended for applications that do not involve potential for sprays, fluids or aerosolization	General use for frontline workers where exposure to body fluids will not occur
	>98%	>98%	<5	120	Recommended for applications for low to moderate risk of exposure to body fluids	Use for healthcare or frontline workers where exposure to body fluids may occur minimally or at very low levels
	>98%	>98%	<5	160	Recommended for applications with high risk of exposure to body fluids	Use for healthcare workers that may encounter high levels of splatter, at high levels of velocity. Ex. Surgical Procedures

Applicable Standards by PPE

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Protective Equipment	Description	Regulatory Approval
N95 Respirator	Example Manufacturers: Makrite, 3Q, 3M 1860	NIOSH
Surgical Face Masks	ASTM Level 1 (BFE >95%) ASTM Level 2 (BFE >98%) ASTM Level 3 (BFE >98%) (Sterile Available)	ASTM, FDA, CE
Isolation Gowns	Level 1 Level 2 Level 3	FDA ISO
KN95 Respirator	Standard duckbill style (Type A) and advanced ergonomic seal style (Type B). Both tested to >95% filtration efficiency	FDA GB 2626-2019, GB 19083-2010 EN-149 , CE
Nitrile Gloves	Surgical or Examination – single use examination gloves	ASTM, ISO, EU
Face Shield	Medical Grade Face Shield	CSA, ANSI
Hand Sanitizer	Food Grade Ethyl Alcohol (75%) Hand Sanitizer, multiple sizes (250mL, 1L, 3L)	NHP
Non-medical Mask	Civil-grade filtering face mask (95%)	Civil-Grade