Science.
Applied to Life.™

Technical Bulletin

May, 2020
Revision 4

Respirators and Surgical Masks: A Comparison

Background

Since certain disposable filtering facepiece particulate respirators are similar in appearance to many surgical/procedure masks, their differences are not always well understood. However, respirators and surgical/procedure masks are very different in intended use, fit against the face, wear time, testing and approval. The purpose of this document is to highlight some of these differences, particularly for healthcare workers. Surgical/procedure masks may be provided to patients to help protect healthcare workers and other patients from particles being introduced into the room as a patient talks, sneezes or coughs.

Wear Time

Respirators must be properly selected and carefully donned (put on) and doffed (taken off) in a clean area, and worn the entire time in the contaminated area to have a significant effect on reducing exposure. Having the respirator off even 10% of the time in a contaminated area significantly reduces the protective effect of the respirator.

Surgical/procedure masks are typically donned (put on) for a specific procedure. For infection control purposes, masks are typically disposed of after each procedure/patient activity.

Testing

In the United States, respirators must meet test criteria stated in the Code of Federal Regulations 42 CFR Part 84. For a complete understanding of all the test criteria, the reader will need to review the regulations. The filter efficiency test criteria, which are employed by the U.S. National Institute for Occupational Safety and Health (NIOSH), for respirators seeking approval at the "N95" classification include:

- Sodium chloride test aerosol with a mass median aerodynamic diameter (MMAD) particle of about 0.3 µm;
- Airflow rate of 85 liters per minute (lpm);
- Charge-neutralized test aerosol; and
- Preconditioning at 85% relative humidity (RH) and 38°C for 24 hours before testing.

Common tests for surgical/procedure masks include: particle filtration efficiency (PFE), bacterial filtration efficiency (BFE), fluid resistance, differential pressure and flammability. Each test is briefly described below.

Particulate Filtration Efficiency (PFE)

The PFE test is a quality indicator for healthcare surgical/procedure masks. The PFE test is not an indicator of respirator protection performance. The filter media of a surgical/procedure mask with a very high (>95%) PFE may nevertheless be less than 70% efficient when tested with the NIOSH N95 test method. The results of the surgical/procedure mask PFE testing and NIOSH filtration efficiency testing should not be compared. Conditions of the PFE test include:

- Polystyrene latex sphere test aerosol;
- Approximately 0.1 µm in size;
- Airflow rate of 28 liters per minute (lpm);
- Un-neutralized test aerosol; and

- No preconditioning.

Bacterial Filtration Efficiency (BFE)

This test assesses the ability of a surgical/procedure mask to provide a barrier to large particles expelled by the wearer. It is not a substitute for a regulatory respirator filtration efficiency test and it does not evaluate the surgical/procedure mask's ability to provide respiratory protection to the wearer. The test method used to evaluate BFE is the American Society of Testing and Materials (ASTM) method F2101-01.

Fluid Resistance

The fluid resistance test is typically conducted based on the ASTM Test Method F 1862, "Resistance to Penetration by Synthetic Blood," which determines the mask's resistance to synthetic blood squirted at it under varying pressures.

Differential Pressure (Delta-P)

The Delta-P test is typically conducted based on the "Method 1 Military Specifications: Surgical Mask, disposable (June 12, 1975)", MIL-M-36945C 4.4.1.1.1. Delta-P is the measured pressure drop across the surgical/procedure mask material and is related to the mask's breathability.

Flame Resistance

Surgical/procedure masks intended to be used in the operating room undergo testing to determine the flammability by class. FDA recommends that Class 1 and Class 2 flammability materials be used. The U.S. Food and Drug Administration (FDA) recommends the use of one of the standards below to test flammability.

- CPSC CS-191-53 Flammability Test Method (16 CFR 1610) Standard for Flammability of Clothing Textiles
- NFPA Standard 702-1980: Standard for Classification of Flammability of Wearing Apparel
- UL 2154

Conclusion

In conclusion, surgical/procedure masks are intended to help put a barrier between the wearer and the work environment or sterile field. They may help keep spit and mucous generated by the wearer from reaching a patient or medical equipment. They can also be used as a fluid barrier to help keep blood splatter from reaching the wearer's mouth and nose. And, where applicable, they are FDA cleared as medical devices and can therefore be used in surgery in the U.S.

However, surgical/procedure masks cannot provide certified respiratory protection unless they are also designed, tested, and government-certified as a respirator. If a wearer wants to reduce inhalation of smaller, inhalable particles (those smaller than 100 microns), they need to obtain and properly use a government-certified respirator, such as a NIOSH-approved N95 filtering facepiece particulate respirator. If the wearer needs a combination surgical/procedure mask and a particulate respirator, they should use a product that is both cleared by FDA as a surgical/procedure mask and tested and certified by NIOSH as a particulate respirator. Such products are sometimes called a "surgical N95," "medical respirator" or "health care respirator."

Respirator versus Surgical/Procedure Mask Decision Tree for Healthcare Workers

The following decision tree highlights potential considerations for the selection of respirators verses surgical/procedure masks.

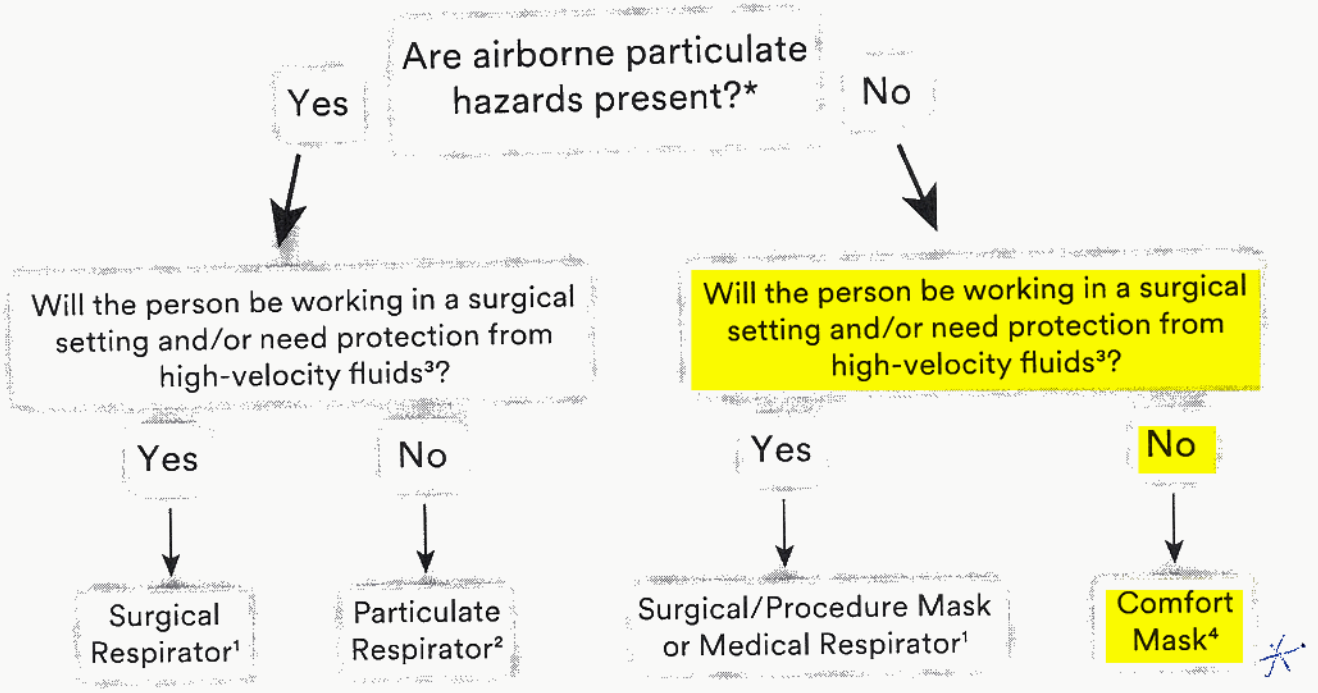


Figure 1: Respirator versus Surgical/procedure Mask Decision Tree[1 2 3 4]

*Here are some additional considerations to keep in mind when selecting a respirator for use in a healthcare work environment.

- Selection of respiratory protection for occupational hazards is typically based upon the airborne concentration of the substance that the wearer is exposed to and the occupational exposure limit (OEL) of that substance.
- Biological agents, such as viruses and bacteria, do not have OELs; therefore, employers should consider available guidance when selecting respirators. The U.S. Centers for Disease Control and Prevention (CDC) has recommended that respirators offering more protection, such as powered air purifying respirators (PAPRs), may be considered in situations when high exposures to bacteria and viruses are possible.
- The occupational use of respirators in the U.S. is regulated by the U.S. Occupational Safety and Health Administration (OSHA), and in the U.S., the use of respirators in all workplaces must be per OSHA standard 29 CFR 1910.134.
- Tight-fitting respirators such as disposable filtering facepiece particulate respirators cannot be worn with facial hair or anything else that may interfere with the seal of the respirator to the wearer's face.

1. In the U.S., surgical/procedure masks and surgical respirators must be cleared by the FDA for use in surgery. Surgical respirators must be also approved by NIOSH. During times of respirator shortages, such as pandemics, CDC has recommended the use of unvalved standard N95 respirators in combination with a fluid-resistant faceshield when surgical N95 respirators are not available.
2. In the U.S., particulate respirators must be approved by NIOSH.
3. "Fluid resistance" refers to testing performed on surgical N95s per ASTM F1862, a standard test method for resistance of medical facemasks to penetration by synthetic blood. This test is required because during certain medical procedures, a blood vessel may occasionally be punctured, resulting in a high-velocity stream of blood.
4. Comfort masks are not designed to protect lungs from airborne hazards, are not NIOSH approved, and are not FDA cleared.

Resources

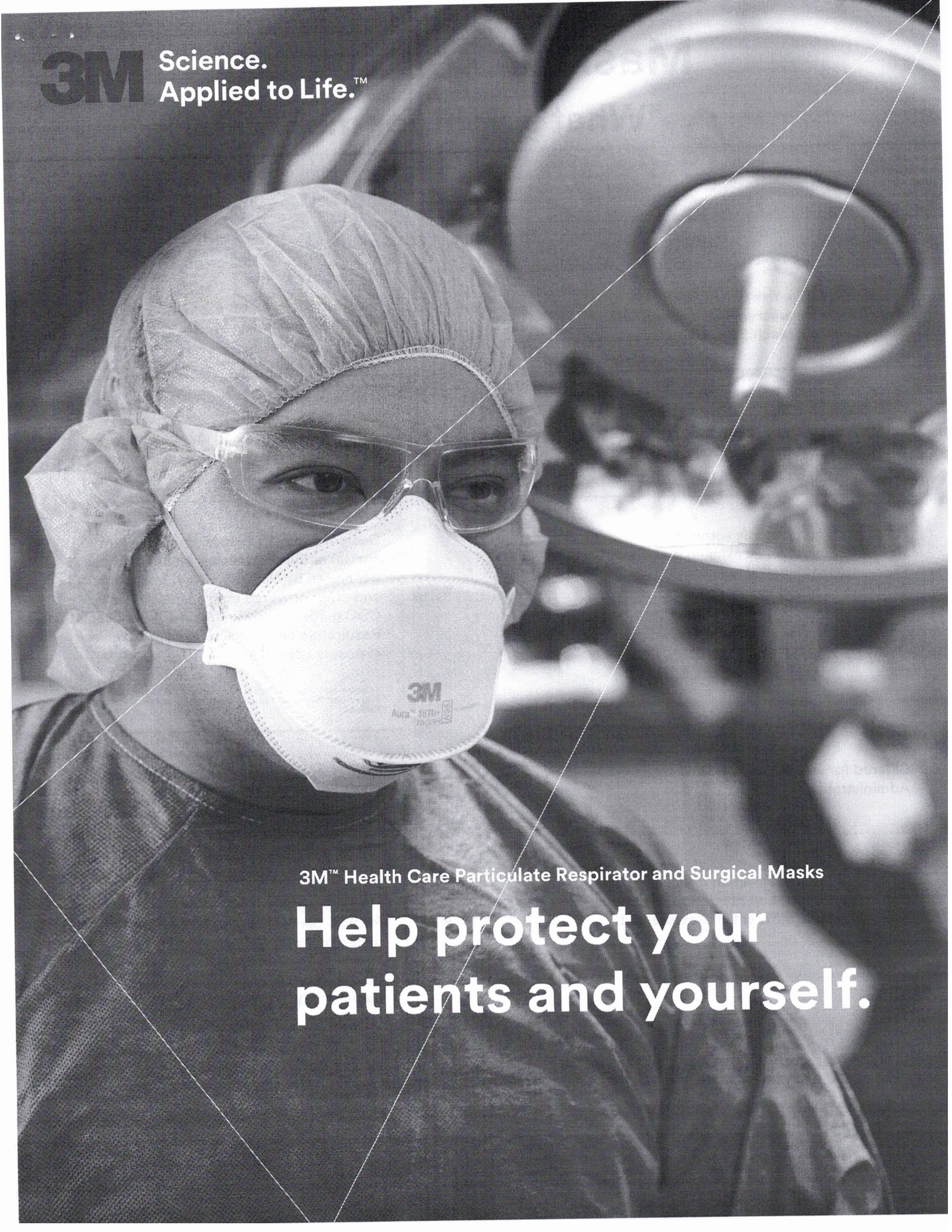
For more information regarding the differences between surgical/procedure masks and respirators, here are more resources:

1) Healthcare – Mask vs. Respirator Video -https://www.youtube.com/watch?v=JR2uLfEVD2w
2) NIOSH science blog "N95 Respirators and Surgical Masks" Lisa Brosseau, ScD, and Roland Berry. October 14th, 2009 https://blogs.cdc.gov/niosh-science-blog/2009/10/14/n95/
3) OSHA Fact Sheet: "Respiratory Infection Control: Respirators Verses Surgical Masks", https://www.osha.gov/Publications/respirators-vs-surgicalmasks-factsheet.html
4) Centers for Disease Control and Prevention "Understanding the Difference," https://www.cdc.gov/niosh/npptl/pdfs/UnderstandingDifference3-508.pdf
5) U.S. Food & Drug Administration: "Memorandum of Understanding Between the Food & Drug Administration/Center for Devices & Radiological Health and the Centers For Disease Control & Prevention/National Institute for Occupational Safety & Health/National Personal Protective Technology Laboratory," https://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm587122.htm

Personal Safety Division
3M Center, Building 235-2W-70
St. Paul, MN 55144-1000

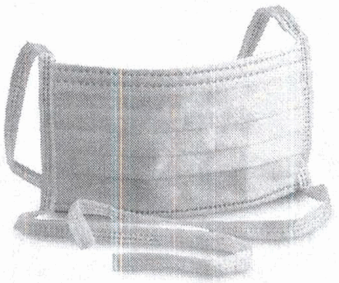
3M PSD products are occupational use only.

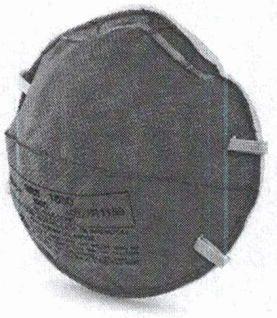
In United States of America
Technical Service: 1-800-243-4630
Customer Service: 1-800-328-1667
3M.com/workersafety
In Canada
Technical Service: 1-800-267-4414
Customer Service: 1-800-364-3577


3M
Science.
Applied to Life.™
3M™ Health Care Particulate Respirator and Surgical Masks
Help protect your
patients and yourself.

Mask or Respirator

"What's right for me?"





Helps reduce the risk of large particles expelled by the wearer—such as spit and mucous—from reaching patients.	**Intended Use**	Helps reduce wearer exposure to certain airborne particles.
Fits loosely, leaving gaps between the mask and your face. Does not require fit testing or user seal checks.	**Fit**	Designed to fit tightly, creating a seal between your face and the respirator. Requires fit testing and user seal checks.
Helps protect the sterile surgical field from contamination by exhaled particles. Fluid-resistant surgical masks help reduce your exposure to blood and body fluids.	**Applications**	Designed to help reduce your exposure to certain airborne particles, including those generated by electrocautery, laser surgery and other powered medical instruments. CDC guidelines state that 3M™ Surgical N95 Respirators can be used for *M. tuberculosis* exposure control.*
Cleared for sale by the Food and Drug Administration (FDA).	**Approvals**	Tested and certified by NIOSH. Cleared by the FDA as a surgical mask.
Tested for Particle Filtration Efficiency (PFE) and Bacterial Filtration Efficiency (BFE), plus fluid resistance, differential pressure and flammability.	**Testing**	Meets CDC/NIOSH guidelines found in Federal Register 42 CFR Part 84 and testing for 95% particulate filtration efficiency. Also tested for Particle Filtration Efficiency (PFE) and Bacterial Filtration Efficiency (BFE), plus fluid resistance, differential pressure and flammability.**

* Centers for Disease Control and Prevention. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.

**Centers for Disease Control and Prevention. Site accessed February 10, 2020, https://www.cdc.gov/.

3M™ Health Care Particulate Respirator and Surgical Masks

Proprietary filter media maximizes performance and comfort

3M™ Health Care Particulate Respirator and Surgical Masks are scientifically designed to help make breathing easier and safety more comfortable. Our unique manufacturing process injects a powerful electrostatic charge into an open formation material, improving the efficiency of particle removal while allowing more air to pass through. The result is a highly effective respirator, so you can focus on caring for your patients.

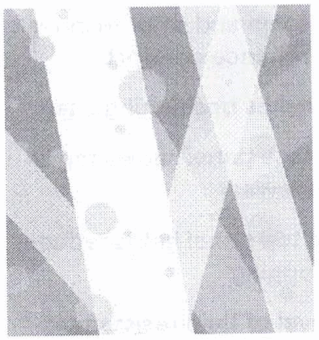
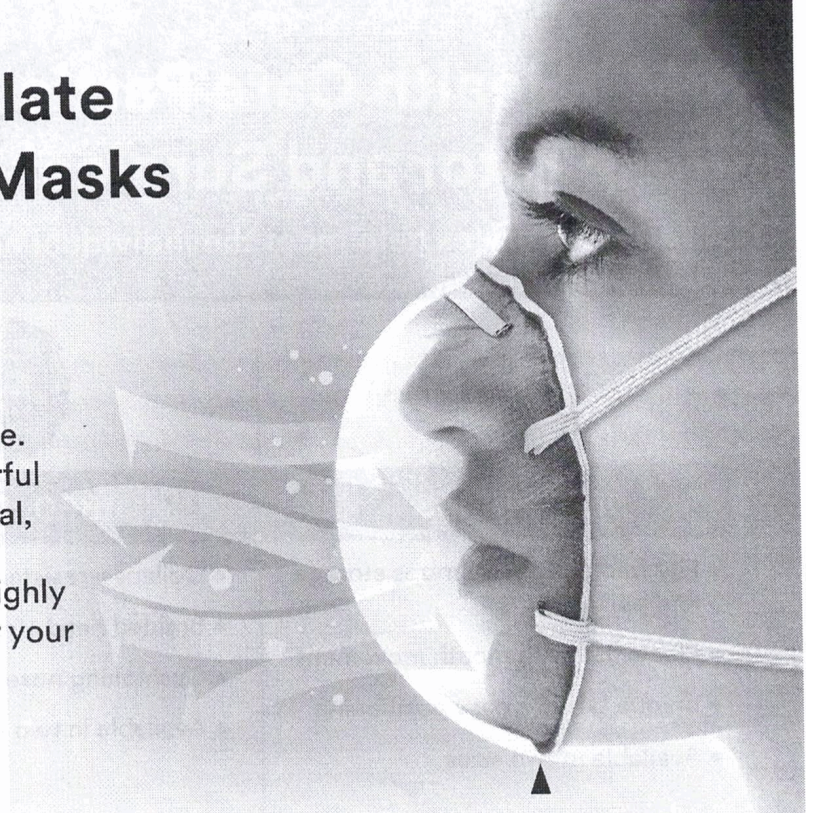
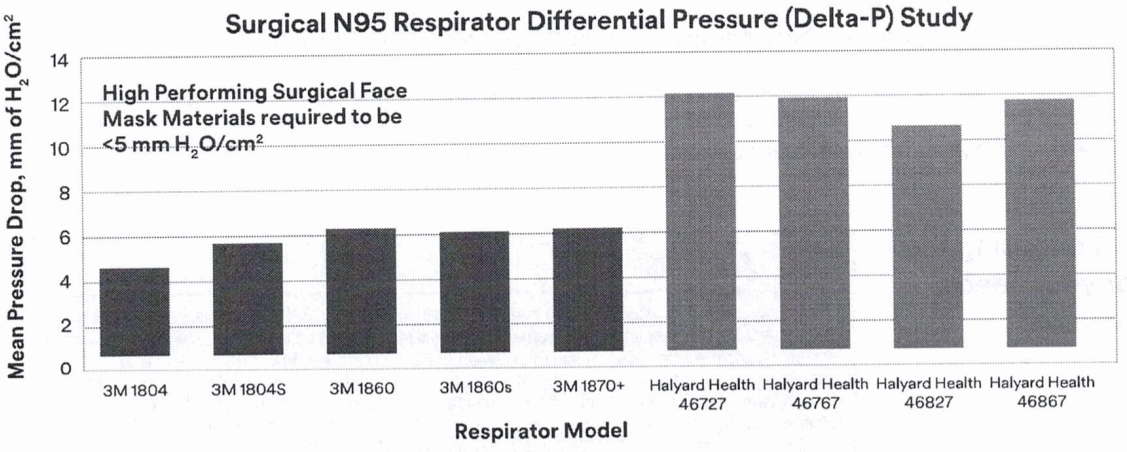


Illustration of how 3M's electrostatically charged microfibers—magnified 10,000 times—attract and capture particles from the air.



3M's unique filter media features highly charged microfibers designed to significantly enhance the capture of airborne particles. This effectiveness allows 3M to design respirators with a more open formation, helping lessen breathing resistance.

3M's NIOSH approved surgical N95 respirators help protect the wearer from harmful particles while approaching the material breathability performance requirements of a traditional surgical mask.



3M surgical N95 respirators show lower initial pressure drop than the competitive respirator models tested.†*

†Testing per MIL-SPEC 36945C 4.4.1.2 using 4.9cm² sample at 8L/min. Source: Representative pressure drop performance from internal testing of multiple lots of all models, November 2017. Selection of respirator models, testing protocol, data generation and conclusions were reviewed and approved by an expert from the University of Illinois at Chicago. Statistically different per T-tests (P-value <0.0001).

*Performance requirement ASTM F2100-11 medical facemask materials classification.

3M™ Health Care Particulate Respirator and Surgical Masks

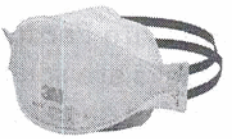
A variety of styles help meet the individual needs of health care workers

1804, 1804S

- Flat fold design optimizes storage and portability
- Pleats flex with mouth movement
- Unique tabs for easy positioning
- Available in two sizes

1860, 1860S

- Collapse-resistant cup shape design
- Braided head straps for comfort
- Cushioning nose foam
- Available in two sizes



1870+

- Flat fold design optimizes storage and portability
- Individual packaging helps prevent contamination
- Soft nose foam and smooth inner materials enhance comfort
- Chin tab makes positioning easy
- Sculpted nose panel allows more room for eyewear
- Embossed top panel helps reduce eyewear fogging
- Highest level of fluid resistance*

**According to ASTM F1862 at 160 mm Hg*

Ordering Information

SKU	UPC	Product Number	Description
70071676954	50051131275923	1804	3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask 1804, N95 400 EA/Case
70071676962	50051131275930	1804S	3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask 1804S, N95 Small 400 EA/Case
70070612364	50707387419429	1860	3M™ Health Care Particulate Respirator and Surgical Mask 1860, N95 120 EA/Case
70070614378	50707387444124	1860S	3M™ Health Care Particulate Respirator and Surgical Mask 1860S, N95 Small 120 EA/Case
GT500073009	50051131499961	1870+	3M™ Aura™ Health Care Particulate Respirator and Surgical Mask 1870+ N95 120 EA/Case

For more information about choosing the right mask or respirator for your needs, go to 3M.com/healthcaremasks

⚠WARNING

These respirators help protect against certain airborne particulates. Before use, the wearer must read and understand the User Instructions provided as a part of the product packaging. A written respiratory protection program must be implemented meeting all the requirements of OSHA 29 CFR 1910.134 including training, fit testing and medical evaluation. In Canada, CSA standards Z94.4 requirements must be met and/or requirements of the applicable jurisdiction, as appropriate. **Misuse may result in sickness or death.** For correct use, consult supervisor and *User Instructions*, or call 3M Health Care Helpline in USA at 1-800-228-3957 and in Canada at 1-800-563-2921.

3M

Medical Solutions Division
3M Health Care
2510 Conway Avenue
St. Paul, MN 55144-1000
U.S.A.

Phone 1-800-228-3957
Web 3m.com/medical

70-2010-9364-1

ASTM F2100-19 explained

	Level 1 Low fluids	Level 2 Light to moderate fluids	Level 3 Moderate to high fluids
PFE at 0.1 micron ASTM F2299	≥95%	≥98%	≥98%
BFE at 3.0 micron ASTM F2101	≥95%	≥98%	≥98%
Delta P (ΔP) mm H_2O/cm^2 MIL-M-36954C	<5	<6	<6
Fluid resistance (mmHg)	≥80 mm Hg	≥120 mm Hg	≥160 mm Hg
Flammability	Class 1	Class 1	Class 1

Fluid resistance
Tests penetration resistance to synthetic blood at three protection levels—80 mm Hg, 120 mm Hg and 160 mm Hg.

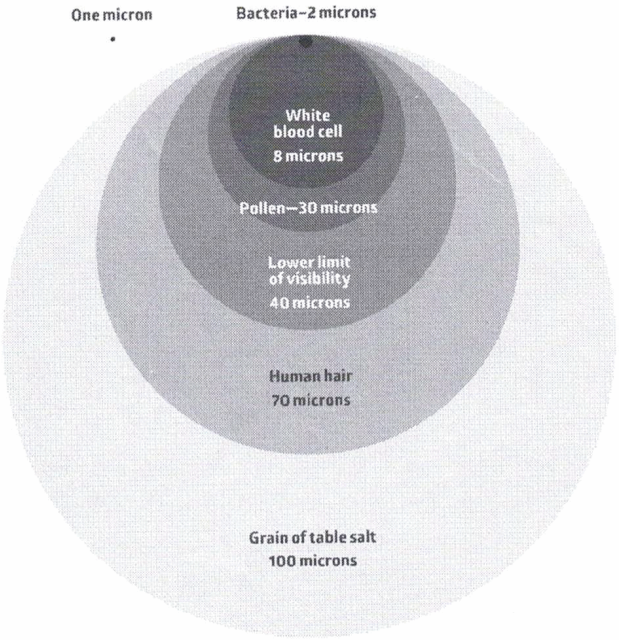
Particle filtration efficiency (PFE)
Assesses filtration ability when tested against sub-micron particulate matter 0.1 microns in size—which is representative of some viruses.

Bacterial filtration efficiency (BFE)
Tests filtration ability against an aerosol containing bacteria 3.0 microns in size.

Differential Pressure (ΔP)
Gauges air flow from one side of a mask to the other, assessing breathability.

How small is a micron?

While an actual micron is not visible to the human eye, this magnified diagram demonstrates particulate size by comparing a micron to other common substances.



Scale is approximate.

CV19 = 0.12 MICRON

Medline Industries, Inc. Three Lakes Drive, Northfield, IL 60093 | 1-800-MEDLINE (633-5463)