Supplemental Digital Content 1

Abbreviations for Supplemental Digital Content 1

BFE Bacterial filtration efficiency

CDC Centers for Disease Control and Prevention

FDA Federal Drug Administration

FFR Filtering facepiece respirator

MPPS Most penetrating particle size

NIOSH National Institute for Occupational Safety and Health

OSHA Occupational Safety and Health Administration

SARS-CoV-2 Severe acute respiratory syndrome coronavirus 2

**Filtering Facepiece Respirator (FFR) Classification, Filter Function, Construction and Testing**

**FFR Classification and Filter Function**

N95 FFR are certified for non-medical or medical use in the US,1 with separate requirements. A *surgical, or medical N95,* is an FFR that provides superior splash protection to a non-surgical FFR (to protect against contaminated fluids or blood).2 In normal times the Center for Disease Control and Prevention (CDC) guidance advises single patient contact use.3  *Reuse* indicates multiple donnings and doffings of an individual mask.4 Non-medical N95 FFR are regulated by National Institute for Occupational Safety and Health (NIOSH) and intended for use in environments with dust, particles, or oily aerosols.1,5 Some allow exhalation through one-way valves, bypassing the filter. Valves minimize humidity buildup and resistance to exhalation but others are no longer protected from the wearer’s potential contaminants.1 The Federal Drug Administration (FDA) and NIOSH regulate *surgical* *or medical* *FFR* as Class II devices, therefore manufacturers must apply for FDA approval prior to marketing.2

All regulated FFR are tested for particle filtration,2 provided by 4 mechanisms: impaction, interception, diffusion and electrostatic forces.6 Particles >0.3 μm are most efficiently captured by impaction and interception while those <0.5 μm are better captured by diffusion and electrostatic forces.7 During manufacture an electrostatic charge is added to create a quasi-permanent magnet called an *electret* thattraps particles without increasing airflow resistance.5,6,7 Loss of electret properties will unacceptably decrease filtration, particularly of smaller particles.5  For each model there is a particle size range that is *least filtered* - the most penetrating particle size (MPPS). Testing filtration with particles of the MPPS is ideal, as the tested efficiency would represent a worst-case scenario (both larger and smaller particles are better filtered). Protection from microorganisms is derived from particle filtering.5

NIOSH certification testing of filtration is performed using liquid aerosol of oil or saline particles with a median aerodynamic diameter of 0.3 μm. A 95 rating means that >95% of 0.3 μm particles are captured during testing.6 A higher number signifies greater filtration efficiency regarding identically sized particles – higher protection. Typical ratings are 95%, 99% and 99.97% (labeled “100”). NIOSH testing also evaluates airflow resistance, flammability, biocompatibility, and the effects of temperature, humidity, and particle loading. Because laboratory testing is done at airflow rates that far exceed nearly all user conditions, the efficiency during most use is expected to be higher.2,7

A letter preceding the filtration efficiency number specifies FFR series. **N**-series are tested with saline aerosol (**N**ot rated for oil aerosols), and ***includes* *all masks designated for healthcare***. FFR for healthcare are also tested for protection from water-based liquid splashes(surrogates for mucus or blood). Aerosolized oil is used to test FFR designated for non-healthcare use. **R**-series are oil **R**esistant, and approved for one work shift. **P**-series are oil-**P**roof, and have unrestricted wearing time.1 The vast majority of FFR used in the US during normal times are non-healthcare N95.

Aerosolized viral particle sizes vary and change rapidly based upon water content.8 Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has a reported size of 0.06-0.14 μm with a mean aerosol size of 0.1 μm.5 NIOSH certification protocols do not assess filtration of particles <0.3 μm or particles containing live organisms.6,9 Multiple investigators reported N95 FFR MPPS of 0.02-0.20 μm.6,10,11,12 Using multiple N95 models Shaffer et al demonstrated up to 10% penetration of particles 0.04-0.10 μm.6 Respirators with filter efficiency ratings >95%, including P100 FFR and elastomeric masks, are far more effective in filtering 10-400 nm particles, and therefore provide superior protection.3,14,15,16

The American Society for Testing and Materials, an international standards organization, F2101 testing for bacterial filtration efficiency (BFE) uses nebulized Staphylococcus aureus particles with a mean particle size of 3.0 μm to challenge medical masks for penetration of infectious particles at a gas flow rate of 28.3 L/m.16 BFE is felt to be a relevant test for viral particle penetration as expected viral particle size is equivalent due to water content. When compared, NIOSH saline particle testing is better able to identify poorly performing devices and more precise than BFE testing.17 A useful table comparing multiple filtration test methods is included in a report by Rengasamy et al.17 Although respiratory particles may be <3.0 μm, the consensus is that neither BFE nor measures of viable particle filtration efficiency would improve NIOSH standards-setting protocols.18,19 Harnish et al demonstrated rated or superior protection from NIOSH-approved N95 respirators tested with H1N1-containing particles as small as 0.01 μm and no difference in filtration of infectious vs. noninfectious particles of equivalent size.18,19

In the context of SARS-CoV-2, there is active discussion, debate, and emerging research regarding the importance and infectivity of virus-containing particles <0.3 μm. 20,21,22,23,24,25 Although such small particles have not traditionally been considered a primary source of airborne viral transmission, concerns exist regarding SARS-CoV-2, as it is more durable in aerosol form than severe acute respiratory syndrome coronavirus 1 or Middle East respiratory syndrome coronavirus.25 Viable aerosols have been isolated in air from COVID-19 patients’ ward hospital rooms in the absence of aerosol generating procedures.26 Current evidence indicates the majority of airborne transmissions of SARS-CoV-2 are likely via larger, droplet particles yet the possibility of infection from tiny aerosolized particles remains. Answers to these questions are vital to optimally inform public health policy and guidance for health care workers, who remain at high risk.

**FFR Construction**

N95 FFR vary in construction however the key filtration layer is typically a fine mesh fabric created by extruding melted polypropylene through tiny nozzles alongside blown gas (meltblown). Surgical models usually have 4-5 layers including an outer hydrophobic layer. Layered fabric is folded or molded and given the electrostatic charge. Other common materials include stapled elastic straps to maintain a tight fit, polyurethane or polyester nose padding, and flexible metal nose strips.27

**Fit Testing**

FFR can only protect the wearer from environmental particles or pathogens and visa versa if a tight seal with the face is maintained to force air through the filter fabric during breathing.4,29,30 The Occupational Safety and Health Administration (OSHA) requires each wearer to undergo OSHA-approved fit testing by a trained individual before initial use to determine the optimum available style, model, and size.2,28 The user is to subsequently wear identical respirators. Comfort, facial fit, and seal are verified under multiple conditions including inspiration, exhalation, talking, facial expressions, activities, and body positions. In addition, one of multiple established qualitative or quantitative assessments of filtering function is performed.2,5,28 Facial hair or stubble usually prevents adequate fit and therefore effective FFR use.30,31 A requirement to repeat the fit test annually is supported by a study finding a risk of unacceptable fit of 10% after 1 year, 20% after 5 years and 25% after 3 years or following weight loss >20 lbs.32 This requirement is suspended during the SARS-CoV-2 pandemic.7 Users are to verify the seal - a *fit check* - each and every time a respirator is donned.33 A recent review compares the value of qualitative fit testing, quantitative fit testing, and fit checking by N95 respirator users.34 Quantitative fit testing is superior to qualitative fit testing. A fit check is not a substitute for a fit test.34

Results from a 2015 study of 6 N95 models indicate that fit declines after as few as 2-5 donnings and doffings, with large variation between models.27 Attention to donning technique may be especially important.35 Two 2020 studies reported a loss of N95 FFR fit following extended use and reuse by hospital workers,36,37 as observed in laboratory research.27,35

**International FFR Regulations**

International terminologies and regulations for FFR with a filtering efficiency similar to N95 are listed in Supplemental Table 1, below.38,40 Although most international standards are similar to NIOSH ratings, they are not consistent. European Union Filtering Face Piece 2 (FFP2) respirators have a rated filtering efficiency >94%, the European standard most resembling N95. They are not tested for oil aerosol filtration or under extreme filter loaded conditions, however.39,40 Nor are there separate categories designated for medical or non-medical use. *(See Supplemental Digital Content, Table 1)*

**References, Supplemental Digital Content 1**

1. CDC - NIOSH Publications and Products - NIOSH Guide to the Selection and Use of Particulate Respirators Certified Under 45 CFR 84 (96-101). Centers for Disease Control and Prevention. https://www.cdc.gov/niosh/docs/96-101/default.html. Published January, 1996. Accessed October 12, 2020.
2. NIOSH. Respiratory protection devices. Title 45, Code of Federal regulation, Part 84. Washington, DC: U.S. Government Printing Office, Office of the Federal Register; 5011. pp. 548–615.
3. CDC - NIOSH - Respirator Fact Sheet - Understanding Respiratory Protection Against SARS. Centers for Disease Control and Prevention. https://www.cdc.gov/niosh/npptl/topics/respirators/factsheets/respsars.html. Published April 9, 2020. Accessed October 12, 2020.
4. Bailar J, Burke D, Brosseau L, et al*.* Reusability of Facemasks During an Influenza Pandemic: Facing the Flu. Washington D.C.: IOM, The National Academies Press, 2006:1-195. https://doi.org/10.17556/11637.
5. Goldfrank LR, Liverman CT, eds. Preparing for an influenza pandemic: personal protective equipment for healthcare workers. Washington, DC: IOM, National Academies Press, 2008:1-206 http://dx.doi.org/10.17226/11980.
6. Shaffer RE, Rengasamy S. Respiratory protection against airborne nanoparticles: a review. Journal of Nanoparticle Research. 2009;11(7):1661-1672. doi:10.1007/s11051-009-9649-3
7. Huang S-H, Chen C-W, Kuo Y-M, Lai C-Y, Mckay R, Chen C-C. Factors Affecting Filter Penetration and Quality Factor of Particulate Respirators. Aerosol and Air Quality Research. 2013;13(1):162-171. doi:10.4209/aaqr.2012.07.0179.
8. Heimbuch BK, Wallace WH, Kinney K, et al. A pandemic influenza preparedness study: Use of energetic methods to decontaminate filtering facepiece respirators contaminated with H1N1 aerosols and droplets. American Journal of Infection Control. 2011;39(1). doi:10.1016/j.ajic.2010.07.004
9. Eninger RM, Honda T, Adhikari A. filter performance of N99 and N95 facepiece respirators against viruses and ultrafine particles. Ann Occup Hyg. 2008:385–396. doi:10.1093/annhyg/men019.
10. Bałazy A, Toivola M, Adhikari A, et al. Do N95 respirators provide 95% protection level against airborne viruses, and how adequate are surgical masks? American Journal of Infection Control. 2006;34(2):51-57. doi:10.1016/j.ajic.2005.08.018.
11. Lee S-A, Grinshpun SA, Reponen T. Respiratory Performance Offered by N95 Respirators and Surgical Masks: Human Subject Evaluation with NaCl Aerosol Representing Bacterial and Viral Particle Size Range. The Annals of Occupational Hygiene. 2008;52(3):177-185. doi:10.1093/annhyg/men005.
12. COVID-19 Pandemic-Decontamination of Respirators and Masks for the General Public, Health Care Workers, and Hospital Environments. Anesthesia Patient Safety Foundation. https://www.apsf.org/article/covid-19-pandemic-decontamination-of-respirators-and-masks-for-the-general-public-health-care-workers-and-hospital-environments/. Published June 15, 2020. Accessed August 20, 2020.
13. Leung WWF, Sun Q. Electrostatic Charged Nanofiber Filter for Filtering Airborne Novel Coronavirus (COVID-19) and Nano-aerosols. *Separation and Purification Technology*. 2020:116886. doi:10.1016/j.seppur.2020.116886.
14. Vo E, Zhuang Z, Horvatin M, Liu Y, He X, Rengasamy S. Respirator Performance against Nanoparticles under Simulated Workplace Activities. Annals of Occupational Hygiene. 2015;59(8):1012-1021. doi:10.1093/annhyg/mev042.
15. He X, Vo E, Horvatin M, et al. Comparison of Simulated Workplace Protection Factors Offered by N95 and P100 Filtering Facepiece and Elastomeric Half-Mask Respirators against Particles of 10 to 400 nm. J Nanotechnol Mater Sci. 2015:1-6. doi:10.15436/2377-1372.15.015.
16. American Society for Testing and Materials (ASTM): F2101-19, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus. Standard F2101. 2019. Available at: https://www.astm.org/. Accessed August 11, 2020.
17. Rengasamy S, Shaffer R, Williams B, Smit S. A comparison of facemask and respirator filtration test methods. Journal of Occupational and Environmental Hygiene. 2016;14(2):92-103. doi:10.1080/15459624.2016.1225157.
18. Harnish DA, Heimbuch BK, Husband M, et al. Challenge of N95 Filtering Facepiece Respirators with Viable H1N1 Influenza Aerosols. Infection Control & Hospital Epidemiology. 2013;34(5):494-499. doi:10.1086/670225.
19. Harnish DA, Heimbuch BK, Balzli C, et al. Capture of 0.1-μm aerosol particles containing viable H1N1 influenza virus by N95 filtering facepiece respirators. Journal of Occupational and Environmental Hygiene. 2016;13(3). doi:10.1080/15459624.2015.1116698.
20. Lewis D. Is the coronavirus airborne? Experts can’t agree. Nature. 2020;580(7802):175-175. doi:10.1038/d41586-020-00974-w
21. Allen JG, Marr LC. Recognizing and controlling airborne transmission of SARS-CoV-2 in indoor environments. Indoor Air. 2020;30(4):557-558. doi:10.1111/ina.12697.
22. Klompas M, Baker MA, Rhee C. Airborne Transmission of SARS-CoV-2. Jama. 2020;324(5):441. doi:10.1001/jama.2020.12458
23. Wilson NM, Norton A, Young FP, Collins DW. Airborne transmission of severe acute respiratory syndrome coronavirus-2 to healthcare workers: a narrative review. Anaesthesia. 2020;75(8):1086-1095. doi:10.1111/anae.15093.
24. Jayaweera M, Perera H, Gunawardana B, Manatunge J. Transmission of COVID-19 virus by droplets and aerosols: A critical review on the unresolved dichotomy. Environmental Research. 2020;188:109819. doi:10.1016/j.envres.2020.109819.
25. Fears AC, Klimstra WB, Duprex P, et al. Persistence of Severe Acute Respiratory Syndrome Coronavirus 2 in Aerosol Suspensions. Emerging Infectious Diseases. 2020;26(9). doi:10.3201/eid2609.201806.
26. Santarpia JL, Herrera VL, Rivera DN, et al. The Infectious Nature of Patient-Generated SARS-CoV-2 Aerosol. Preprint posted online July 21, 2020. doi:10.1101/2020.07.13.20041632.
27. Bergman MS, Viscusi DJ, Zhuang Z, et al. Impact of multiple consecutive donnings on filtering facepiece respirator fit. American Journal of Infection Control. 2012;40(4):375-380. doi:10.1016/j.ajic.2011.05.003.
28. Department of Labor. OSHA Fit Testing Requirements. 2012. <https://www.osha.gov/video/respiratory_protection/fittesting.html>. Accessed October 12, 2020
29. Gamage B, Moore D, Copes R, Yassi A, Bryce E. Protecting health care workers from SARS and other respiratory pathogens: A review of the infection control literature. American Journal of Infection Control. 2005;33(2):114-121. doi:10.1016/j.ajic.2004.12.002
30. Center for Devices and Radiological Health. N95 Respirators and Surgical Masks (Face Masks). U.S. Food and Drug Administration. https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks. Accessed October 12, 2020.
31. Healthcare Respiratory Protection Resources, Fit Testing. Centers for Disease Control and Prevention. https://www.cdc.gov/niosh/npptl/hospresptoolkit/fittesting.html. Published May 7, 2020. Accessed October 12, 2020.
32. Zhuang Z, Bergman M, Brochu E, et al. Temporal changes in filtering-facepiece respirator fit. Journal of Occupational and Environmental Hygiene. 2016;13(4):265-274. doi:10.1080/15459624.2015.1116692
33. Filtering out confusion: frequently asked questions about respiratory protection - user seal check. CDC - NIOSH Publications and Products - Filtering out Confusion: Frequently Asked Questions about Respiratory Protection, User Seal Check (2018-130). https://doi.org/10.26616/NIOSHPUB2018130. Accessed October 12, 2020.
34. Regli A, Sommerfield A, vonUngern-Sternberg BS. The role of fit testing N95/FFP2/FFP3 masks: a narrative review. Anaesthesia 2020. doi:10.1111/anae.15261
35. Vuma CD, Manganyi J, Wilson K, Rees D. The Effect on Fit of Multiple Consecutive Donning and Doffing of N95 Filtering Facepiece Respirators. Annals of Work Exposures and Health. 2019;63(8):930-936. doi:10.1093/annweh/wxz060.
36. Degesys NF, Wang RC, Kwan E, et al. Correlation Between N95 Extended Use and Reuse and Fit Failure in an Emergency Department. Jama. 2020;324(1):94. doi:10.1001/jama.2020.9843.
37. Lieu A, Mah J, Zanichelli V, et al. Impact of extended use and decontamination with vaporized hydrogen peroxide on N95 respirator fit. American Journal of Infection Control. 2020. doi:10.1016/j.ajic.2020.08.010.
38. News Release: U.S. Department Of Labor Issues Guidance for Respirators Certified under Other Countries’ Standards During COVID-19 Pandemic. April 3,2020. <https://www.dol.gov/newsroom/releases/osha/osha20200403-2>. Accessed October 12, 2020.
39. Comparison of FFP2, KN95, and N95 Filtering Facepiece Respirator Classes. Revision 4, May 2020.Available at: https://multimedia.3m.com/mws/media/1791500O/comparison-ffp2-kn95-n95-filtering-facepiece-respirator-classes-tb.pdf. Accessed October 12, 2020.
40. Colton CE. Respirator Classification in Handbook of Respiratory Protection - Routledge Handbooks. 2017. https://www.routledgehandbooks.com/doi/10.4324/9781351109079-3. Accessed October 12, 2020.

Supplemental Table 1.

**International Classifications of FFR that are Functionally Similar to N95**38,39

Country Classification Regulation

United States N95 NIOSH-42CFR84

Australia / New Zealand P2 AS/NZA 1716:2012

Brazil PFF2 ABNT/NBR 13698:2011

People’s Republic of China KN95 GB2626-2006; GB 2626-2019

European Union / Great Britain FFP2 EN 149-2001

Japan DS2 JMHLW-Notification 214, 2018

Mexico P95 NOM-116-2009

Russia FFP2 GOST R 12.4.191-2011

Republic of Korea KF94 (1st Class) KMOEL - 2017-64

Taiwan D2 CNS 14755

Abbreviations for Supplemental Table 1:

FFR: Filtering Facepiece Respirator

**References for Supplemental Table 1:**

36. News Release: U.S. Department Of Labor Issues Guidance for Respirators Certified under Other Countries’ Standards During COVID-19 Pandemic. April 3,2020. https://www.dol.gov/newsroom/releases/osha/osha20200403-2. Accessed August 20, 2020.

37. Comparison of FFP2, KN95, and N95 Filtering Facepiece. https://multimedia.3m.com/mws/media/1791500O/comparison-ffp2-kn95-n95-filtering-facepiece-respirator-classes-tb.pdf. Revision 4, May 2020. Accessed August 20, 2020.