

# Standards for Surgical N95 Filtering Facepiece Respirators and Surgical Masks: COVID-19

Target Audience: Health and Safety Personnel and Researchers

## Executive Summary

The purpose of this report is to present and compare national and international standards for surgical N95 FFRs and surgical masks, i.e., masks intended for use in hospitals and other healthcare settings. In addition, a new European standard for fabrics used to make cloth masks (CWA 17553) is reviewed. This report contains a definition of common terms followed by sections on filtration efficiency, breathability, fit testing, and fluid barrier. Each section includes a background on the topic and a review of the US, EU and China national standards. For the purposes of this report the term “mask” is used broadly to refer to surgical N95 FFRs and surgical, medical, and cloth masks.

The purpose of national standards for respirators and masks used in hospitals is to protect health care workers from particles and microorganisms such as SARS-CoV-2. Besides the ability to filter particles (e.g., filtration efficiency) the standards also address breathability (e.g., differential pressure), how well the mask seals to a worker’s face (e.g., fit test), the level of protection from a fluid splash, and other factors. The US, EU and China standards were reviewed and compared on test methods and criteria for certification. While there are substantial similarities in standards for respirators, such as N95, FFP2 and KN95 Filtering Facepiece Respirators (FFRs), there are important differences in who does the testing and fit-test requirements that influences certification. For surgical (US) or medical (EU and China) masks there is greater variation in test methods between countries. These masks can also be certified to different levels of protection. These similarities and differences and their impact on mask performance are reviewed. The EU is developing a new standard for testing fabrics for masks used by the public, but many laboratories are testing fabrics by modifying test methods used for evaluating N95 FFRs and surgical masks. Hospital safety personnel should know the differences between standards so that they can select respirators and masks that provide appropriate protection for health care workers.

## Introduction

There are national and industrial standards for respirators and surgical masks that are relevant for protecting wearers from SARS-CoV-2. However, there is much confusion about respirator and mask standards. There are differences in standards between respirators and surgical masks, governmental and non-governmental organizations, and countries. For example, for US respirator standards there are three federal agencies involved: the FDA, OSHA and the CDC (NIOSH). Another example is that surgical mask standards are set by the FDA but the FDA references a non-governmental standards organization, ASTM International (American Society for Testing and Materials), for test methods. The involvement of multiple organizations creates confusion. In addition, the standards have changed over time and have also recently been altered to accommodate limited availability of respirators due to the COVID-19 pandemic.

Finally, different respirators and surgical masks provide different levels of protection and, therefore, have to meet different standards.

Respirators and surgical masks serve different purposes and are approved under different testing protocols. Respirators have a tight facial seal and are designed to protect the wearer from aerosol particles while surgical or medical masks are loose fitting and are designed to block droplets escaping from the wearer's mouth and nose (see N95DECON Mask Comparison Fact Sheet). During the COVID-19 pandemic, the public is encouraged to wear cloth masks, for which there is only a new European guideline (CWA 17553) for evaluating filtration effectiveness of cloth materials. Since cloth masks also function by blocking droplets, some of the surgical mask and respirator standards have been adapted by researchers to test the cloth used in masks for the public.

The standards address a number of issues, including filtration efficiency, fit, breathability, and fluid barrier. Filtration efficiency is a measure of the ability of the mask to protect the user from particles that are breathed in through the filter material. Fit is a measure of how well a mask seals to the face when worn. A well fit mask causes the air to flow through the filter material when breathed in, rather than through gaps between the edge of the mask and the face. A mask with a good fit protects the user from breathing small particles, provided that the filter material is effective. Breathability is a measure of how difficult it is to breathe in or out through the mask and is commonly expressed as a pressure drop across the fabric layer. Fluid barrier is a measure of how well the mask prevents a splash of fluids, such as blood, from penetrating the mask. There are other important issues to consider in mask design that are not directly addressed by standards, such as comfort and the ability to communicate.

Some of these standards require that the mask be evaluated by a government agency which then certifies the mask (e.g., N95 filtering facepiece respirators (FFRs) must be tested and certified by NIOSH). Some standards require the manufacturer to evaluate the mask and report the results to the government agency before certain words can be used to describe the mask (e.g., use of the words "Surgical Mask" requires approval by FDA). And some "standards" are voluntary guidelines and are not required but are recommended (e.g., EU CWA 17553, a standard for fabric for masks for the public).

In the US, the OSHA respiratory protection standard (1910.134 subpart 1) requires the employer to provide a respirator when it is necessary to protect the health of employees. The standard does not specify the specific respirator required for use in healthcare but provides guidance on the appropriate classes of respirators with respect to specific hazards. The standard also requires employers to perform a respirator Fit Test for each employee to ensure that the mask seals well to the face of the workers.

### **Definition of Terms**

$\Delta P$  = pressure differential = pressure drop = pressure across a tested material

CMD = count median (geometric) diameter =  $\frac{1}{2}$  particles by count are above this diameter and  $\frac{1}{2}$  below.

AD = aerodynamic diameter = diameter of a sphere with a density of 1000 kg/m<sup>3</sup> that settles at the same rate as the irregular particle

MMAD = mass median aerodynamic diameter = ½ particles by mass are above this aerodynamic diameter and ½ are below

MPS = mean particle size

MPPS = most penetrating particle size

FE = filtration efficiency

PFE = particulate filtration efficiency

BFE = bacterial filtration efficiency

$P_{\text{filter}}$  = filter penetration, given as a percent (typically 0–5%)

monodisperse = particles of single size

polydisperse = particles of different sizes

SD = standard deviation

Common units of measurement and conversion factors

*Pressure:* 1.0 Pa = 0.001 kPa = 0.01 mbar = 0.102 mm H<sub>2</sub>O

*Volumetric flow:* 1.0 L/min = 16.7 cm<sup>3</sup>/s = 0.035 cfm (cubic feet/min)

*Airflow velocity:* 1.0 cm/s = 0.01 m/s

## Filtration Efficiency – Protection from Particulates

The filtration efficiency (FE) is a measure of the proportion of particles that are intercepted by the mask or material. The general approach to determining the FE is to challenge the mask or material with small particles that are carried in air and moves through the mask or material at a specific airflow velocity (also termed the face velocity), and to measure the particle concentration upstream (before) from the mask or material and also downstream (after). The ratio between the concentration downstream to upstream is the filter penetration ( $P_{\text{filter}} = C_{\text{down}}/C_{\text{up}} \times 100\%$ ). Filtration efficiency is the complement of filter penetration ( $\text{FE} (\%) = 100\% - P_{\text{filter}}$ ). A mask material with an FE of 95% will block 95% of particles so that only 5% of particles would pass through the material when air is inhaled or exhaled. Note, however, that a mask made of a material with FE of 95% may allow additional particles in if there is any air leakage around the edge of the mask (further addressed in the ‘fit’ section).

FE is influenced by various factors including the filter material, the particle size and shape, particle charge, airflow velocity, humidity, temperature, and other factors. The cross-sectional area of the mask or material may influence FE if the material is not uniform across the surface tested or the air velocity is not the same at different places across the surface of the mask.

Filtration efficiency of a given material may vary for different sized and shaped particles. While the SARS-CoV-2 virus is 60–150 nm in diameter (Cai et al., 2020), the viruses are released from the respiratory tract in larger droplets of varying sizes (Liu et al., 2020). Mask filter materials are good at blocking larger droplets. Particles >5 µm in diameter are captured by straining, since they cannot fit through the holes in the filter. Particles >1 µm are blocked by inertial impact, they have too much momentum to follow the stream through the filter and thus strike the filter and attach to it. Particles between 0.1 and 1.0 µm are blocked by interception, they strike a part of the filter media and become attached to it. Small particles, <0.1 µm, are blocked by diffusion; these particles move through Brownian motion and contact part of the material and attach to it (Gougeon et al. 1996; Hao et al. 2020). Finally, some masks have an electrostatic

layer that induces a charge on small particles and the particles are attracted to and become attached to the electrostatic layer (Zhao et al. 2020). The electrostatic layer distinguishes N95 FFRs and surgical masks from cloth masks. With all these methods working simultaneously, the most difficult size particles for masks to capture, or the most penetrating particle size (MPPS), is approximately 0.3  $\mu\text{m}$  (300 nm) for some filter materials (Figure 1) and less than 0.1  $\mu\text{m}$  for filters with electret (e.g., electrostatic) properties (Eninger et al. 2008).

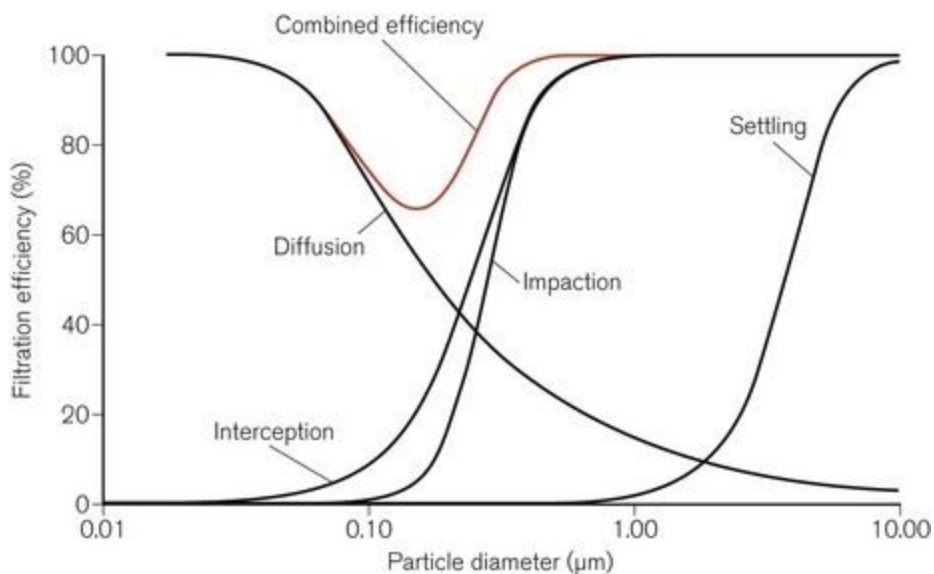


Figure 1. Example of filtration mechanisms by particle size demonstrating MPPS (combined efficiency) at approximately 0.2  $\mu\text{m}$ . (From Anesthesia Key, Fig 11.2 accessed 8/6/20, Adapted from Hinds WC. *Aerosol Technology. Properties, behaviour, and measurement of airborne particles*. 2nd ed. New York: John Wiley and Sons; 1999.)

Standards for measuring filtration efficiency (FE) use a variety of methods. Each standard specifies the type and size of particles, particle charge, airflow velocity and particle measurement method. Some use monodisperse particles, e.g., particles of one size, and some use polydisperse particles, e.g., particles of multiple sizes. Typically, the particles used are NaCl, bacteria, or latex beads. Some standards require reporting FE for all particles below or above a certain size (usually 0.3  $\mu\text{m}$ ) and some require reporting FE at a specific particle size (e.g., 0.1  $\mu\text{m}$ , 3.0  $\mu\text{m}$ ). Most standards specify charge-neutralized particles because they tend to produce a lower FE than charged particles (Eninger et al. 2008). The flow rate can affect FE - higher flow rates are generally associated with lower FEs (see N95Decon Cloth Mask Report; Rengasamy et al. 2013, He et al. 2013). Each of these differences in measurement methods can affect FE measurements and can make comparisons between masks tested by different standards a challenge. In addition, masks and materials may not have uniform qualities so testing different masks or different parts of a material may produce different FEs. This is the reason that the NIOSH method and some other standards test 20 FFRs. Finally, standards have different criteria for acceptable FE thresholds.

Several studies have evaluated the same mask materials using different methods for measuring filtration efficiency. Oberg and Brosseau (2008) evaluated 9 different procedure and surgical masks with the NIOSH method (<0.3 um) and monodisperse latex particles of different sizes (0.8, 2 and 3 um). There was a consistent pattern: for the 6 masks that met FDA criteria, the FEs for 3 um particles were better than 99.9% while the FE of <0.3um particles, using the NIOSH method, ranged from 62.6 to 96.0%. However, a study by Wang D et al. (2020) reported different findings for fabrics. They tested FE for fabric and material combinations using the NIOSH NaCl PFE method (0.3 um) and the bacterial (BFE) method (3 um) and found no consistent relationship between PFE and BFE. For 4 different material combinations the PFE ranged from 35 to 56% while the BFE values ranged from 16 to 24%. For 3 other material combinations the PFE ranged from 40 to 54% while the BFE ranged from 88 to 93%. Since droplets produced from talking have a mean diameter of ~4 um (Santarpia et al. 2020), measuring BFE may be useful for identifying materials for masks for protecting the public.

Table 1. Filtration Efficiency Test Methods

	<i>NIOSH 42CFR84</i>	<i>ASTM F2299</i>	<i>EN 149/13274</i>	<i>EN 14683</i>	<i>CWA 17553</i>
<i>Particles</i>	MMAD 0.3 um polydisperse NaCl	0.1 um monodisperse PSL	0.06 - 0.1 um polydisperse NaCl	3.0 um <i>S. aureus</i> bacteria	3.0 um
<i>Particle charge</i>	No charge	No charge	No charge	No charge	-
<i>Item tested</i>	Entire FFR	Material sample	Entire FFR	Material sample	Material sample
<i>Flow rate</i>	85 L/min	28.3 L/min	95 L/min	28.3 L/min	-
<i>Area tested</i>	150 cm <sup>2</sup>	100 cm <sup>2</sup>	150 cm <sup>2</sup>	-	-
<i>Velocity</i>	9.4 cm/s	5 cm/s	10.5 cm/s	-	6 cm/s
<i>Measurement</i>	Mass, by light scatter	Count, by light scatter	Flame photometry	-	-

Table 2. Particle filtration efficiency test criteria for N95, FFP2 and KN95 FFRs.

	<i>N95 (42CFR84)</i>	<i>FFP2 (EN 149)</i>	<i>KN95 (GB2626)</i>
<i>Filtration efficiency</i>	≥ 95%	≥ 94%	≥ 95%
<i>Particles</i>	Polydisperse NaCl	Polydisperse NaCl	Polydisperse NaCl
<i>Flow rate</i>	85 L/min	95 L/min	85 L/min
<i>Tested by</i>	NIOSH	Manufacturer	Manufacturer
<i>No. FFRs tested</i>	20	9	15
<i>Fit-test: Total inward leakage</i>	Not required	≤ 8%	≤ 8%

### NIOSH Certification for N95 FFR: Filtration Efficiency

NIOSH certifies both surgical N95 FFRs (e.g. intended for use in healthcare) and industrial N95 FFRs (e.g. intended for general use). It does not certify surgical masks. The difference between a surgical N95 FFR and an industrial N95 FFR is that the surgical N95 FFR has a fluid barrier

and meets flammability criteria that are specified by the FDA and does not have an exhalation port (some industrial N95 FFRs have an exhalation valve).

The NIOSH method (Tables 1 & 2) for evaluating FE of N95 FFRs ((National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, n.d.-a); rev 3.2; December 13, 2019; meets 42CFR, Part 84 (published in 1995), Subpart K) requires the particle filtration to be performed on a TSI 8130 or equivalent machine with preconditioning of the material being tested (85% relative humidity and 38°C for 24 hours) (TEB-APR-STP-0059, NIOSH, 2019). The method is designed for evaluating whole N95 FFRs but has been modified by researchers to also test fabrics for masks (Zhao et al., 2020). The edge of the FFR is sealed against the surface of the test device to prevent leaks, and the air must flow across the entire surface area of the mask, typically 150 cm<sup>2</sup>. The FFR is challenged with charge neutralized NaCl aerosol particles with a skewed size distribution. The count median diameter (CMD) is 0.075 ± 0.020 µm (with a geometric standard deviation (GSD) < 1.86), the mass median diameter (MMD) is 0.238 µm, and the mass median aerodynamic diameter (MMAD) is 0.347 µm. CMD is the median size across the distribution. MMAD is the median size in the distribution that is weighted by the mass of the particles. For CMD the ± 2 SD is 0.022 to 0.252 µm and for MMD the ± 2 SD is 0.070 to 0.732 µm.

The challenge flow rate is 85 L/min which corresponds to an airflow velocity of 9.4 cm/s. This flow rate corresponds to a worker breathing at a high work rate (Eninger et al. 2008). Particle concentration is measured with photometers whose output is proportional to the aerosol mass. This means that filtration efficiency criteria uses the mass of the particles (MMAD) rather than just the number of particles (CMD) that are blocked by the filter (Eninger et al. 2008). This is an important difference. For an N95 respirator (or a filter cartridge) to pass certification, 95% of the challenge aerosol particles must be blocked. Therefore, the filter must block 95% of particles ≤ 0.3 µm CMD or 95% of 0.3 µm MMAD particles. For a FFR to be certified, NIOSH tests 20 FFRs and each FFR must pass the minimum FE throughout the test duration which is typically 10–20 minutes. For an N99 respirator or filter cartridge the minimum filtration efficiency is >99%. For a N100 respirator or filter cartridge the minimum filtration efficiency is >99.97%.

### **ASTM Certification for Surgical Mask: Filtration Efficiency**

ASTM International (formerly the American Society for Testing and Materials) is a non-profit private organization that develops international consensus standards. They have developed standards for filtration efficiency and differential pressure for medical mask material with three levels of protection, barrier levels 1, 2, and 3 (Table 3). For the particle FE (PFE) test, the methods use polystyrene latex microspheres particles and for the bacterial FE (BFE) *S. aureus*.

ASTM F2100-19e1 specifies the criteria for the performance of medical face mask materials. Barrier level 1 mask materials must have PFE ≥ 95% at 0.1 µm and a BFE ≥ 95%. Barrier level 2 and 3 mask materials must have a PFE ≥ 98% at 0.1 µm and a BFE ≥ 98%. Barrier level 3 has a higher level of fluid resistance than level 2 as discussed below (ASTM F1862). The standard also specifies maximum differential pressures for each barrier level as discussed in a later section.

ASTM F2299 (2017) describes a method for performing the PFE test. The method uses a monodisperse aerosol of charge-neutralized polystyrene latex microspheres of sizes ranging from 0.1 to 5.0  $\mu\text{m}$  with airflow velocity of 0.5 to 25  $\text{cm/s}$ . The cross-sectional test area is not specified. The choice of particle size and airflow velocity is up to the manufacturer, but the standard test uses 0.1  $\mu\text{m}$  size particles with a flow rate of 1 CFM (28.3 L/min), which is equivalent to an airflow velocity of 5  $\text{cm/s}$  if the cross-sectional area is 100  $\text{cm}^2$  (Nelson Labs, NV). Five different specimens are tested. Compared to the NIOSH N95 FFR test method, the ASTM method does not require preconditioning of the material, does not specify the mass of particles loaded onto the mask during the test, and assesses filtration efficiency by count instead of mass (Table FF). The ASTM method typically produces higher FE values than the NIOSH test method for the same materials (Rengasamy et al., 2017).

ASTM F2101 describes the method for performing the BFE test. The challenge is with a *S. aureus* bacteria aerosol (mean particle size  $3 \pm 0.3 \mu\text{m}$ ) drawn through the mask material by vacuum at 28.3 L/min for 1 min and impacts agar bacterial growth plates that collect droplets. The plates are incubated for 48 hours and the bacterial colonies are counted and compared to the count for a control condition where there is no filter. Filtration efficiency is  $100 \times (1 - \text{Count}_{\text{filtered}} / \text{Count}_{\text{unfiltered}})$ . The surface area of the tested material is not specified.

Table 3. ASTM criteria for 3 barrier levels for surgical masks.

	ASTM Level 1	ASTM Level 2	ASTM Level 3
Fluid resistance (mmHg)	80	120	160
Filtration efficiency (%) (PFE or BFE)	$\geq 95$	$\geq 98$	$\geq 98$
Differential pressure, (Pa/cm <sup>2</sup> ) (8 L/min)	< 50	< 60	< 60
Flame spread	Class 1	Class 1	Class 1

### FDA Premarket Notification for Surgical Masks and Surgical N95 FFRs

FDA clears masks as a medical device for sale in the US if the manufacturer's label claims that the mask is for preventing diseases or for use in surgical procedures, such as "surgical" masks or "surgical" N95 FFRs". Manufacturers must submit to the FDA a premarket notification of their test data on PFE, BFE, pressure differential, and fluid penetration (CFR 878.4040; 21CFR807.81; FDA, 2004, 2020). For surgical masks, FDA recommends a PFE and BFE test but **does not require any particular test method**. For PFE, the FDA recommends following ASTM 2299 with the use of charge neutralized 0.1  $\mu\text{m}$  polystyrene latex spheres. For BFE, FDA recommends one of 3 test methods: ASTM F2101, Mil-M369454C, or modified Greene and Vesley method for testing an entire mask ([Greene & Vesley, 1962](#)). **FDA does not test the masks themselves and does not regulate manufacturers' claims that their masks have met any level of ASTM standard**. Typically, manufacturers use a private lab (e.g., Nelson Labs, NV) for testing.

FDA clears surgical N95 FFRs as a medical device after the manufacturer submits test data on fluid penetration, flammability, PFE, BFE and pressure differential. The manufacturer can

submit their own data on PFE and pressure differential, or they can submit the NIOSH certified data.

### EU Certification for FFRs and Surgical Masks: Filtration Efficiency

The European Union standard for testing and requirements for medical face masks (EN 14683+C1 (2019)) is similar to the FDA requirements for surgical masks (Table 1). Like the ASTM method, there are three barrier levels for EU labeled medical face masks: Type I, II and IIR (Table 4). The three levels differ on criteria for BFE, differential pressure, and splash protection. Type I require a BFE  $\geq 95\%$  and Type II and IIR require BFE  $\geq 98\%$ . Only Type IIR requires splash protection. Type II and IIR are intended to protect hospital staff from patients during surgical and other procedures. Type I are only for patients and the public during epidemics. The testing methods for BFE (Annex B) require preconditioning with 85% RH and 21C for 4 hours. The method is otherwise similar to ASTM F2101.

Table 4. EU criteria for 3 barrier levels for medical masks.

	Type I	Type II	Type IIR
Fluid resistance	-	-	yes
Filtration efficiency (%) (BFE)	$\geq 95$	$\geq 98$	$\geq 98$
Differential pressure, (Pa/cm <sup>2</sup> ) (8 L/min)	< 40	< 40	< 60

EN 149+A1 (2009) is similar to the NIOSH method for N95 FFRs and specifies the minimum requirement fit testing, PFE, and differential pressure for three classes of FFRs: FFP1, FFP2, and FFP3 (Tables 1, 2 & 5). The fit test, which is not required by the NIOSH method, is applied to 10 subjects as they perform different exercises (e.g., walking, head turning, talking, etc.). While on the subject, the FFR is challenged with NaCl particles and the particle concentration is measured inside and outside the FFR. Each subject tests one FFR.

For measuring PFE, the methods of EN 13274-7 (2008) are used. Briefly, a whole FFR is mounted in a leak-tight manner and is challenged with a polydisperse NaCl aerosol with median size distribution between 0.06 and 0.1  $\mu\text{m}$  (geometric SD between 2.0 and 3.0) using a flow rate of 95 L/min. Nine FFRs are tested.

Table 5. EU test criteria for FFP1, FFP2 and FFP3 FFRs (EN 149).

	FFP1	FFP2	FFP3
Fit test leakage (%)	< 25	< 11	< 5
NaCl filtration efficiency (%)	> 80	> 94	> 99
Differential pressure -Inhalation (Pa)	210	240	300
Differential pressure- Exhalation (Pa)	300	300	300



## **China National Standard for Surgical Masks and FFRs: Filtration Efficiency**

There is a China Pharmaceutical Industry Standard titled *Surgical Masks* (YY0469-2011). YY0469 requires that both PFE ( $\geq 30\%$ ; 0.1  $\mu\text{m}$ ) and BFE ( $\geq 95\%$ ; 3.0  $\mu\text{m}$ ) criteria must be met (Table 1). The BFE method involves challenging the mask material with an aerosolized suspension of *S. aureus* using a Qingdao SRP ZR-1000 system at a flow rate of 28.3 L/min. Bacterial colonies are collected on agar plates both upstream (unfiltered) and downstream (filtered) of the mask material and the colonies of bacteria that grow on the agar after 48 h of incubation are counted (Wang D. et al. 2020).

China also has a standard for the KN95 FFR (GB262-2006) which is similar to the NIOSH standard for N95 FFRs (Table 2). Typically, KN95 FFRs use ear loops that do not seal the FFR to the face as well as behind-the-head straps; the difference can change the fit test by 20% (Yim et al. 2020; Fernandez and Mueller 2020). There are no criteria for protection from fluid splash for a KN95 so it is not equivalent to a surgical N95.

The China National Standard that is similar to the standards for surgical N95 is titled *Technical requirements for protective face mask for medical use* (GB 19083-2010). The PFE test is essentially the same as the NIOSH method but the standard specifies 3 levels of protection: Level 1  $\geq 95\%$ , Level 2  $\geq 99\%$ , and Level 3  $\geq 99.97\%$  with a inhalation pressure differential of 343 Pa (airflow 85 L/min). It also specifies resistance to synthetic blood penetration of 80 mmHg and a flame resistance. The standard also requires that masks pass a fit test similar to the EN 149 standard.

China also has a guideline for protective masks for daily general use by the public for particulates. (GB/T 32610-2016).

## **ISO 29463-1 (2017) and EN 1822**

ISO 29463-1 and EN1822 specify methods for determining particle filtration efficiency of high efficiency air (HEPA) filters. These methods, which use polydisperse charge-neutralized NaCl with particle sizes from 0.050 - 0.825  $\mu\text{m}$ , are not used to certify masks. However, some studies have used this method for evaluating filtration efficiency of masks and materials for masks (Zangmeister et al. 2020).

## **European Guide for Community Face Coverings: CWA 17553**

A recent (June 2020) workshop by CEN (European Committee for Standardization) published a guideline for the testing fabrics (Table 1) used for making cloth masks for the general public (CWA 17553). The guideline is similar to the French [AFNOR S76-001](#) standard published on March 27, 2020 but specifies 2 levels of FE for particles of 3  $\mu\text{m}$  size:

- Level 90%: FE  $\geq 90\%$
- Level 70%: FE  $\geq 70\%$

A number of methods for testing filtration efficiency are listed in Annex B of the guideline including EN 13274-7 and EN 14583:2019+AC:2019. The recommended method uses poly- or monodisperse aerosols with primarily 3  $\mu\text{m}$  particles with an airflow velocity of 6 cm/s. The cross-sectional area of material to be tested is not specified. New fabrics as well as those that have been through a number of cleaning cycles are tested. This guideline effectively tests for the filtration efficiency of particles of the approximate size of the respiratory droplets exhaled while talking (Santarpia et al. 2020). Thus it may be the best way to test materials from which to make masks to protect public health by limiting the exhalation of infectious droplets from infected but non-symptomatic individuals during common interactions, such as conversation.

## Differential Pressure – Breathability

To be effective, a mask needs to both filter out particles and allow a person to breathe easily. The ease of breathing through a respirator or mask is typically measured by the pressure differential (e.g.,  $\Delta P$  or pressure drop). The general approach for measuring differential pressure is to place the material across the middle of a long tube so that air moving through the tube will have to pass through the material. While air is blown or drawn through the tube at a specific airflow velocity, the air pressure is simultaneously measured on both sides of the material. The difference between the pressures measured on each side of the material is the differential pressure. A low differential pressure occurs when air can easily pass through the material while a high differential pressure occurs when it is more difficult for air to pass through the material. A mask with a low differential pressure is easier to breathe through than one with a high differential pressure.

Standards and experimental test methods for measuring differential pressure may differ on volumetric flow rate (L/min), airflow velocity (cm/s), and cross-sectional area of material tested ( $\text{cm}^2$ ). These differences can affect the measured differential pressure, so comparisons between standards or studies are difficult if the same parameters are not used.

- For a fixed *volumetric flow rate*: as the cross-sectional area of the tested material increases, the airflow velocity decreases, and the pressure differential decreases linearly with the surface area increase (Yia et al. 2018).
- For a fixed *airflow velocity*: the cross-sectional area of the tested material is not expected to substantially change the pressure differential, as both airflow velocity and pressure are normalized by area. However, inhomogeneities in flow (non-laminar) or inhomogeneities in the material may lead to small differences in the pressure differential when the cross-sectional area changes.
- For a fixed *airflow velocity*: the pressure differential increases in an additive way with multiple layers of the same or different materials.

Standards for FFRs usually express differential pressure in units of Pa while standards for surgical/medical mask materials use  $\text{Pa}/\text{cm}^2$ . Pressure per unit area ( $\text{Pa}/\text{cm}^2$ ) does not have clear physical meaning and the reasoning behind this choice of units is not clear.

### Standards for measuring pressure differential

There are a number of standards that define measurement methods and performance criteria for FFRs and surgical masks for maximum allowed pressure differential (Table 6). Some of these methods have been adapted to measure pressure across fabrics. There is also a new EU standard for fabrics (CWA 17553; similar to AFNOR). In general, the test methods specify the cross-sectional area of material to be tested, the airflow velocity (or volumetric flow rate) across the material, and the method for measuring pressure differential.

Table 6. Maximum allowed pressure differentials for FFRs and surgical/medical masks per US, EU and China standards.

	<b>N95, FFP2, KN95</b>		<b>Surgical/medical mask material</b>	<b>Cloth mask material</b>
	Inhalation	Exhalation		
<b>NIOSH<sup>1</sup></b>	343 Pa (85 L/min)	245 Pa (85 L/min)	---	---
<b>ASTM</b>	---	---	<sup>2</sup> 50/60/60 Pa/cm <sup>2</sup> (245/294/294 Pa) (8 L/min)	---
<b>EU<sup>3</sup></b>	240 Pa (95 L/min) 70 Pa (30 L/min)	300 Pa (160 L/min)	<sup>4</sup> 40/40/60 Pa/cm <sup>2</sup> (196/196/294 Pa) (8 L/min)	70 Pa/cm <sup>2</sup>
<b>China<sup>5</sup></b>	350 Pa (85 L/min)	250 Pa (85 L/min)	49 Pa/cm <sup>2</sup> 240 Pa (8 L/min)	---

1. NIOSH = U.S. National Institute for Occupational Safety and Health; 42CFR84.
2. Surgical mask barrier levels 1, 2, and 3, respectively. Units (Pa) assume area is 4.9 cm<sup>2</sup>.
3. EU = European Union; EN 149; EN 14683; CWA 17553.
4. Medical masks type I, II, and IIR, respectively. Units (Pa) assume area is 4.9 cm<sup>2</sup>.
5. China National Standards; GB2626; YY0469.

### NIOSH Certification for N95 Filtering Facepiece Respirators: Pressure Differential

The U.S. NIOSH (National Institute for Occupational Safety and Health) N95 Filtering Facepiece Respirator (FFR) certification method specifies that an N95 FFR is sealed onto a plate. The air flow through the FFR must be 85 L/min. A typical N95 FFR has a surface area of approximately 150 cm<sup>2</sup>. If the volumetric flow of 85 L/min were laminar, unidirectional flow through a material of 150 cm<sup>2</sup> in one plane, it would have an airflow velocity of 9.44 cm/s. Since N95 FFRs are not planar, streamlines are expected to be more complicated, and the actual airflow velocity is likely to vary over the area of the FFR. Under these test conditions, NIOSH specifies a maximum inhalation resistance of 0.34 kPa ([National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, n.d.-b](#)) and maximum exhalation

resistance of 0.24 kPa ([National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, n.d.-a](#)).

### **ASTM Standard for Surgical Masks: Pressure Differential**

The ASTM International (formerly the American Society for Testing and Materials) standard (F2100-19e1; F2101-01; MIL-M-36954C) requires that the pressure differential across surgical masks is tested in accordance with method EN 14683:2019 Annex C. This method has a flow rate of at 8 L/min and the functional surface area of the mask segment tested is typically 4.9 cm<sup>2</sup> (airflow velocity = 27.21 cm/s). The standard uses units of pressure/unit area. Surgical mask barrier levels of 1, 2 and 3 require that mask materials have a pressure differential/unit area of less than 5.0, 6.0, and 6.0 mmH<sub>2</sub>O/cm<sup>2</sup> (or 50, 60, 60 Pa/cm<sup>2</sup>), respectively. Given a testing area of 4.9 cm<sup>2</sup>, these thresholds correspond to 245, 294, and 294 Pa.

### **FDA Premarket Notification for Surgical Masks: Pressure Differential**

The U.S. FDA ([U.S. Food & Drug Administration \(FDA\), 2004, July 14](#)), recommends that manufacturers test the pressure differential across surgical masks using MIL-M-36945C 4.4.1.1.1 Method 1 (June 12, 1975). This MIL spec requires that air is driven (no rate or velocity specified) through a sample of the surgical mask material, the difference in pressure before and after the sample is measured and the difference is reported as pressure divided by area sampled. No area is specified. The FDA requires that manufacturers report pressure differential, the airflow velocity or flow rate, and reference the test method used.

### **EU Certification for FFRs and Surgical Masks: Pressure Differential**

EN149:2001+A1:2009 specifies minimum criteria and methods for measuring differential pressure for FFP1, FFP2, and FFP3 FFRs and requires testing nine whole FFRs (~150 cm<sup>2</sup> surface area), each attached to a mannequin head (Table PPP). Airflow can be cyclical or continuous. If continuous, the inhalation flow rate is 30 or 95 L/min (e.g., airflow velocity of 3.3 or 10.6 cm/s) and for exhalation the flow rate is 160 L/min (airflow velocity: 17.8 cm/s).

EN 14683 specifies the maximum differential pressure for the three medical/surgical masks types (Table EEE). The test uses a flow rate of 8 L/min across 4.9 cm<sup>2</sup> of the test material (airflow velocity: 27.2 cm/s).

### **EU Guidelines for Community Face Coverings: Pressure Differential**

The new European guidelines for material used for community face coverings, CWA 17553 specifies that the differential pressure shall be < 70 Pa/cm<sup>2</sup> for a vacuum pressure of 100 Pa. Alternatively, the inhalation and exhalation resistance is < 240 and 300 Pa, respectively. Three methods are identified for measuring pressure differential, including EN 14683:2019+AC:2019, Annex C and EN 13274-3 for a constant flow rate of 95 L/min.

### **China National Standards for KN95 FFRs and Surgical Masks: Pressure Differential**

The China national standards for KN95 FFR (GB262-2006) and face masks for medical use (GB 19083-2010) for differential pressure are very similar to the NIOSH methods and criteria. For the KN95, the differential pressure is measured with a flow rate of 85 L/min and the inhalation pressure differential will be less than or equal to 350 Pa and the exhalation pressure differential will be less than or equal to 250 Pa. The GB 19083-2010 standard maximum inhalation differential pressure is 343 Pa (airflow 85 L/min).

The China national standard for surgical masks, YY0469-2011, specifies the method for measuring pressure differential. For certification, the  $PD \leq 49 \text{ Pa/cm}^2$  (Wang D. et al. 2020). The method uses the Qingdao SRP ZR-1200 machine with a flow rate of 8 L/min and a sample test diameter of 25 mm (area of  $4.9 \text{ cm}^2$ ).

## Fit Testing of Workers in the US

In the US, the fit test is required for workers who are required to use an N95 FFRs; it is not required for workers who use a surgical mask. It is also not required for N95 FFR certification. OSHA requires employers to provide employees with either a quantitative or qualitative fit test before employees are required to wear a respirator. The purpose of the fit test is to find a respirator model that fits the worker's face well and has no gaps between the respirator facepiece and the face. The quantitative fit-test (QNFT) measures particle count outside the FFR compared to inside the FFR while the FFR is being worn by a worker (OSHA, 2020). Several instruments can perform this test, but the most frequently used instrument is the PortaCount (TSI, Inc.). For a half-mask respirator, like a surgical N95 FFR, the ratio of the particle count outside the FFR to that inside the FFR, termed the fit factor, must be 100 or more. For the qualitative fit test, an aerosol of saccharine (sweet) or Bitrex (bitter) is generated, and the respirator fit is determined to be adequate if the wearer does not detect the taste of the aerosol. During both the qualitative and quantitative fit tests, the worker is required to perform specific exercises (e.g. deep breathing, turning head, talking, bending over, etc.) that may cause the seal of the facepiece to break. A fit factor less than 100 or tasting the saccharine or Bitrex indicates that the face seal is inadequate, or, less likely, that the filter material is compromised. In this event, the fit test must be repeated with a new FFR, or new FFR model or size.

## Fluid barrier

Fluid barrier, as defined by ASTM standards, refers to the resistance of a mask to penetration by a few drops of a bodily fluid, such as blood, released at a high velocity from the body. The fluid barrier is crucial for healthcare workers performing surgical or emergency procedures (3M 2020). However, for healthcare workers who do not perform these procedures, it is not clear that using a mask with a fluid barrier provides them needed protection. The tests seek to represent the event that healthcare personnel are exposed to blood splatter, exiting a small arterial puncture under average blood pressures of 80 mmHg, 120 mmHg, or 160 mmHg (10.7, 16.0, and 21.3 kPa), which correspond to fluid velocities of 450, 500, and 635 cm/s. The ASTM F1862 standard established a method for spraying a synthetic fluid with the color, consistency, and surface tension of human blood at a mask and visually determining if the synthetic blood

passes through to the other side of the mask. ASTM defines three levels of fluid barrier efficacy as follows: Level 1 (80 mmHg) for procedures and exams that don't involve aerosols, spray or fluids, Level 2 (120 mmHg) for procedures that involve low to moderate levels of aerosols, spray and/or fluids, and Level 3 (160 mmHg) being for procedures involving heavy levels (See Table above; ASTM F2100-19e1). [ISO 22609 is similar to ASTM F1862.] For FDA clearance, surgical masks and surgical N95 FFRs can meet any of the three ASTM F1862 fluid barrier levels. (US FDA, 2020)

Note: ASTM barrier levels 1, 2 and 3 must also meet Flame Spread (16 CFR Part 1610) Class 1 criterion, which is a Fire Spread Index between 0 to 25. Physically this means that the material does not catch on fire within 5 inches from a flame source. The relevance of the Flame Spread Index is to ensure that the face mask material is fabric-based and is safe for use in clothing.

The European standard for surgical/medical masks (EU 14583) establishes splash resistance criteria for surgical mask type IIR. There are no fluid barrier test requirements for FFP1, 2, or 3 respirators in EU 149.

The Chinese national standard for KN95 does not provide for fluid protection, so there is no KN95 equivalent to surgical N95. However, GB 19083-2010 is a standard for protective mask for medical use that has a fluid barrier test. There is a Chinese standard for textile fabrics on resistance to surface wetting ([Chinese Standard GB/T4745-2012](#)) that has been used to evaluate some masks (Wang D 2020) but it does not require a spray of certain force to test penetration similar to the ASTM F1862 standard.

## Conclusions

National standards for the US surgical N95, the EU FFP2, and the China KN95 FFR are overlapping in required test methods for filtration efficiency and differential pressure but differ in important ways. Of the three, only the surgical N95 has requirements for fluid and flammability protection. The FFP2 and the KN95 standards require fit-testing before they are marketed, the N95 standard does not. All require a minimum filtration efficiency of approximately 95%, with similar PFE testing methods using NaCl, but differ on set up prior to testing and number of FFRs tested. The pressure differential tests are similar for EU, US, and Chinese standards. These FFRs are more protective against particles than surgical masks because they have fit testing requirements and a better seal against the face.

National standards for surgical/medical masks allow greater flexibility for testing and labelling than FFRs. The US ASTM (FDA) surgical mask method includes 3 barrier levels ranging from  $\geq 95$  to  $\geq 98\%$ , tested with either PFE or BFE. The EU method uses a similar range of barrier levels but only tests BFE. The China method has one level of protection but requires both a PFE  $\geq 30\%$  and BFE  $\geq 95\%$ . Importantly, PFE is usually tested at 0.1 or 0.3  $\mu\text{m}$  while BFE tests at 3.0  $\mu\text{m}$ . Most materials have higher filtration values for the BFE test than for the PFE tests. The differential pressure requirements are similar between countries. The US, EU and China standards all include splash protection, but the levels of protection are quite different between the standards.

A new EU guideline for the evaluation of cloth materials for masks for the public has just been released in draft form but has yet to be adopted by any country in Europe.

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