

Comparison of FFP2, KN95, and N95 and Other Filtering Facepiece Respirator Classes

Description

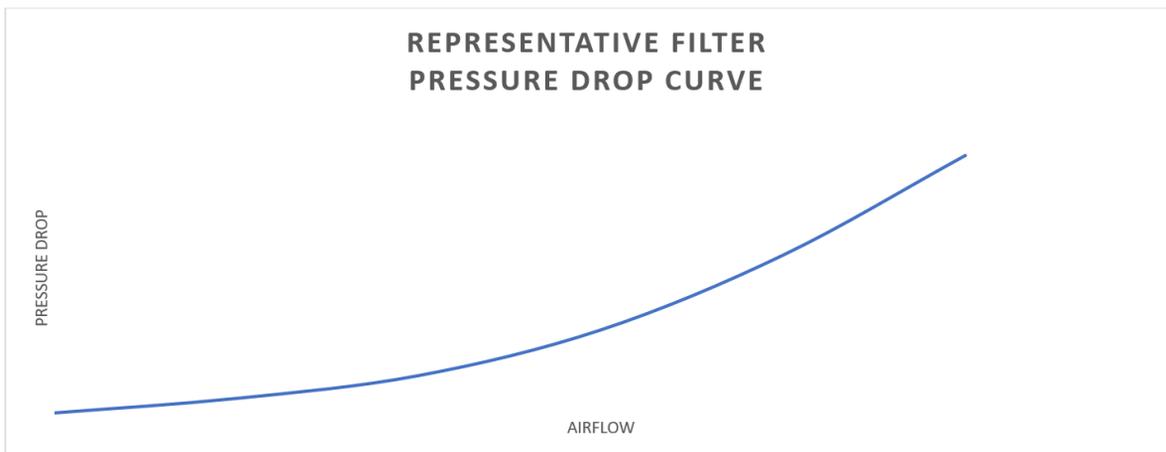
Filtering facepiece respirators (FFR), which are sometimes called disposable respirators, are subject to various regulatory standards around the world. These standards specify certain required physical properties and performance characteristics in order for respirators to claim compliance with the particular standard. During pandemic or emergency situations, health authorities often reference these standards when making respirator recommendations, stating, for example, that certain populations should use an “N95, FFP2, or equivalent” respirator.

This document is only intended to help clarify some key similarities between such references, specifically to the following FFR performance standards:

- N95 (United States NIOSH-42CFR84)
- FFP2 (Europe EN 149-2001)
- KN95 (China GB2626-2006)
- P2 (Australia/New Zealand AS/NZA 1716:2012)
- Korea 1st class (Korea KMOEL - 2017-64)
- DS (Japan JMHLW-Notification 214, 2018)

As shown in the following summary table, respirators certified as meeting these standards can be expected to function very similarly to one another, based on the performance requirements stated in the standards and confirmed during conformity testing.

One notable comparison point is the flow rates specified by these standards for the inhalation and exhalation resistance tests. Inhalation resistance testing flow rates range from 40 to 160L/min. Exhalation resistance testing flow rates range from 30 to 95 L/min. Some countries require testing to be performed at multiple flow rates, others at only the high or low end of those ranges. Although this appears to suggest that the standards’ requirements for breathing resistance (also called “pressure drop”) differ from each other, it’s important to understand that pressure drop across any filter will naturally be higher at higher flow rates and lower at lower flow rates. Given typical pressure curves for respirator filters, the standards’ various pressure drop requirements are actually quite similar. This chart shows a representative filter pressure drop curve. If one filter is tested at a high flow rate, the pressure drop performance will be relatively high. If that same filter is tested at a low flow rate, the pressure drop performance will be relatively low.



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Based on this comparison, it is reasonable to consider China KN95, AS/NZ P2, Korea 1st Class, and Japan DS FFRs as “equivalent” to US NIOSH N95 and European FFP2 respirators, for filtering non-oil-based particles such as those resulting from wildfires, PM 2.5 air pollution, volcanic eruptions, or bioaerosols (e.g. viruses). However, prior to selecting a respirator, users should consult their local respiratory protection regulations and requirements or check with their local public health authorities for selection guidance.

Certification/ Class (Standard)	N95 (NIOSH-42C FR84)	FFP2 (EN 149-2001)	KN95 (GB2626-20 06)	P2 (AS/NZ 1716:2012)	Korea 1 st Class (KMOEL - 2017-64)	DS (Japan JMHLW- Notification 214, 2018)
Filter performance – (must be ≥ X% efficient)	≥ 95%	≥ 94%	≥ 95%	≥ 94%	≥ 94%	≥ 95%
Test agent	NaCl	NaCl and paraffin oil	NaCl	NaCl	NaCl and paraffin oil	NaCl
Flow rate	85 L/min	95 L/min	85 L/min	95 L/min	95 L/min	85 L/min
Total inward leakage (TIL)* – tested on human subjects each performing exercises	N/A	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (arithmetic mean)	≤ 8% leakage (individual and arithmetic mean)	≤ 8% leakage (arithmetic mean)	Inward Leakage measured and included in User Instructions
Inhalation resistance – max pressure drop	≤ 343 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min) ≤ 500 Pa (clogging)	≤ 350 Pa	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (at 30 L/min) ≤ 240 Pa (at 95 L/min)	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	Varied – see above	85 L/min	Varied – see above	Varied – see above	40 L/min
Exhalation resistance - max pressure drop	≤ 245 Pa	≤ 300 Pa	≤ 250 Pa	≤ 120 Pa	≤ 300 Pa	≤ 70 Pa (w/valve) ≤ 50 Pa (no valve)
Flow rate	85 L/min	160 L/min	85 L/min	85 L/min	160 L/min	40 L/min
Exhalation valve leakage requirement	Leak rate ≤ 30 mL/min	N/A	Depressurization to 0 Pa ≥ 20 sec	Leak rate ≤ 30 mL/min	visual inspection after 300 L /min for 30 sec	Depressurization to 0 Pa ≥ 15 sec
Force applied	-245 Pa	N/A	-1180 Pa	-250 Pa	N/A	-1,470 Pa
CO ₂ clearance requirement	N/A	≤ 1%	≤ 1%	≤ 1%	≤ 1%	≤ 1%

*Japan JMHLW-Notification 214 requires an Inward Leakage test rather than a TIL test.

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Definitions

Filter performance – the filter is evaluated to measure the reduction in concentrations of specific aerosols in air that passes through the filter.

Test agent - the aerosol that is generated during the filter performance test.

Total inward leakage (TIL) – the amount of a specific aerosol that enters the tested respirator facepiece via both filter penetration and faceseal leakage, while a wearer performs a series of exercises in a test chamber.

Inward leakage (IL)– the amount of a specific aerosol that enters the tested respirator facepiece, while a wearer performs a normal breathing for 3 minutes in a test chamber. The test aerosol size (count median diameter) is about 0.5 micro meter.

Pressure drop – the resistance air is subjected to as it moves through a medium, such as a respirator filter.

IMPORTANT: Always read and follow respirator user instructions.

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Understanding the Difference



Surgical Mask



N95 Respirator

Testing and Approval

Cleared by the U.S. Food and Drug Administration (FDA)

Evaluated, tested, and approved by NIOSH as per the requirements in 42 CFR Part 84

Intended Use and Purpose

Fluid resistant and provides the wearer protection against large droplets, splashes, or sprays of bodily or other hazardous fluids. Protects the patient from the wearer's respiratory emissions.

Reduces wearer's exposure to particles including small particle aerosols and large droplets (only non-oil aerosols).

Face Seal Fit

Loose-fitting

Tight-fitting

Fit Testing Requirement

No

Yes

User Seal Check Requirement

No

Yes. Required each time the respirator is donned (put on)

Filtration

Does NOT provide the wearer with a reliable level of protection from inhaling smaller airborne particles and is not considered respiratory protection

Filters out at least 95% of airborne particles including large and small particles

Leakage

Leakage occurs around the edge of the mask when user inhales

When properly fitted and donned, minimal leakage occurs around edges of the respirator when user inhales

Use Limitations

Disposable. Discard after each patient encounter.

Ideally should be discarded after each patient encounter and after aerosol-generating procedures. It should also be discarded when it becomes damaged or deformed; no longer forms an effective seal to the face; becomes wet or visibly dirty; breathing becomes difficult; or if it becomes contaminated with blood, respiratory or nasal secretions, or other bodily fluids from patients.

