

January, 2020 Revision 2

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

Description

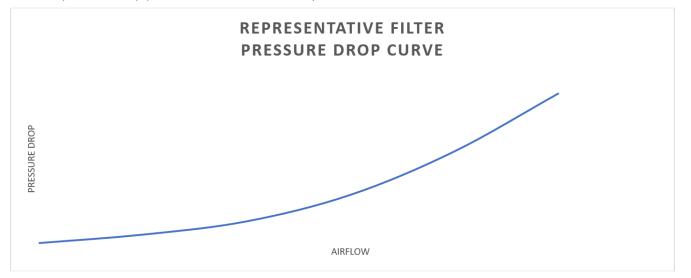
Filtering facepiece respirators (FFR), which are sometimes called disposable respirators, are subject to various regulatory standards around the world. These standards specify certain required physical properties and performance characteristics in order for respirators to claim compliance with the particular 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	Depressurizatio n to 0 Pa ≥ 20 sec	Leak rate ≤ 30 mL/min	visual inspection after 300 L /min for 30 sec	Depressurizatio n 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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penetration and faceseal leakage, while a wearer performs a series of exercises in a test chamber.

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l respiratori con filtro facciale (FFR), che a volte vengono chiamati respiratori monouso, sono soggetti a vari standard normativi in tutto il mondo. Tali standard specificano alcune proprietà fisiche e caratteristiche prestazionali richieste affinché i respiratori possano rivendicare la conformità con lo standard specifico. Durante situazioni di pandemia o di emergenza, le autorità sanitarie spesso fanno riferimento a questi standard quando formulano raccomandazioni sul respiratore, affermando, ad esempio, che alcune popolazioni dovrebbero usare un respiratore "N95, FFP2 o equivalente". Questo documento ha lo scopo di aiutare a chiarire alcune somiglianze chiave tra tali riferimenti, in particolare ai seguenti standard di prestazione FFR: • N95 (Stati Uniti NIOSH-42CFR84) • FFP2 (Europa EN 149-2001) • KN95 (Cina GB2626-2006) • P2 (Australia

Sulla base di questo confronto, è ragionevole considerare i FFR China KN95, AS / NZ P2, Korea 1st Class e Japan DS come "equivalenti" ai respiratori US NIOSH N95 e FFP2 europei, per filtrare particelle non a base di petrolio come quelle derivante da incendi, inquinamento atmosferico PM 2.5, eruzioni vulcaniche o bioaerosol (ad es. virus). Tuttavia, prima di selezionare un respiratore, gli utenti devono consultare le normative e i requisiti locali di protezione delle vie respiratorie o

definizioni

Prestazioni del filtro: il filtro viene valutato per misurare la riduzione delle concentrazioni di aerosol specifici nell'aria che passa attraverso il filtro.

Agente di prova: l'aerosol generato durante il test delle prestazioni del filtro.

consultare le autorità sanitarie pubbliche locali per indicazioni sulla selezione.

Perdita verso l'interno totale (TIL) - la quantità di un aerosol specifico che entra nel facciale del respiratore testato tramite entrambi i filtri

penetrazione e perdite facciali, mentre chi lo indossa esegue una serie di esercizi in una camera di prova.

Perdita verso l'interno (IL): la quantità di un aerosol specifico che penetra nel facciale del respiratore testato, mentre chi lo indossa esegue una respirazione normale per 3 minuti in una camera di prova. La dimensione dell'aerosol di prova (conteggio del diametro mediano) è di circa 0,5 micro metri.

Perdita di carico: l'aria della resistenza viene sottoposta mentre si muove attraverso un fluido, come un filtro respiratore. IMPORTANTE: leggere e seguire sempre le istruzioni per l'uso del respiratore.