

COMPARISON OF FFP3, N95, N99, KN95 MASKS

- 1) **Particulate respirators and the virus:** It must first be stressed that particulate respirators are tested against penetration of particles, either solid or (non-volatile) liquid. The usual simple surgical masks (flat, 3/4-fold with earloops) are tested for bacterial filtration efficiency (BFE) using bacteria used are about 10 times larger than the particles used for testing particulate respirators. Particulate respirators are used for protection from SARS-CoV2 considering that viruses are attached to particles or are contained in droplets and behave similarly to particles.
- 2) **Mask performance** depends on:
 - a. Quality of raw materials: the better the quality of filter raw material the higher the filtration efficiency
 - b. Work-rate: the more power someone uses when performing a task, the faster/deeper he breaths
 - c. Fit tightness: the mask design and structure must ensure that there are almost no gaps through which particles may penetrate, between the mask and the skin
- 3) **EU FFP3/US N95/US N99/Chinese KN95 comparison**

Note: *comments in italic font in the next table refer to unique characteristics of aēramask*

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	FFP3	N95	N99	KN95	Comments
Legislation	EU Regulation 2016/425 (CE); EU Standard EN149	42-CFR84 (NIOSH)	42-CFR84 (NIOSH)	Chinese Standard GB2626	
Solid Particle Filtration (salt)	>99% at 95 L/min flowrate	>95% at 85 L/min flowrate	>99% at 85 L/min flowrate	>95% at 85 L/min flowrate	<p>Is 95% filtration enough when the enemy is a deadly virus?</p> <p>FFP3 masks are tested for 99% filtration capability of both solid and (non-volatile) liquid particles, i.e a wider range of both charged and neutral particles, vs US N95 and Chinese KN95 masks tested for 95% filtration capability of solid particles only. This implies that N95/KN95 masks have at least 4% more tolerance in (virus) particle penetration through the mask.</p> <p>The higher the work-rate of a person (performance of more strenuous tasks requiring more Watts of power) the deeper and faster the breath. FFP3 mask fabrics' filtration efficiency is tested at 95 L/min flowrate (the speed at which the air is passing through the mask during test) vs 85 L/min for N95/N99/KN95. The difference in the flowrate (95 L/min vs 85 L/min) means that the EU CE-certified masks are tested for 99% filtration during use at higher work-rates / faster and deeper breathing, for example when someone is walking the stairs, pushing a patient wheelchair, lifting a patient on the bed; greater protection during the performance of the same task and protection during performance of more different tasks within the hospital.</p> <p>*** Unlike most of the masks in the market, aēramask contains such filter that its efficiency does not attenuate as time passes due to due to temperature and/or humidity fluctuations. Also, its efficiency is not affected by humid environments found in ICU rooms.</p> <p>*** aēramask has achieved the German CCF150nano (Covid Certified Filter) certification, for ability to filter 99% of particles sized down to 150 nanometers, compared to 300 nanometers benchmark for non-CCF masks, filtering more tiny virus droplets and providing greater protection.</p>
Non-volatile Liquid Particle Filtration (oily)	>99% at 95 L/min flowrate	No requirement	No requirement	No requirement	

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Breathing Resistance (inhalation)	300 Pascals at 95L/min flowrate	343 Pascals at 85L/min flowrate	343 Pascals at 85L/min flowrate	350 Pascals at 85L/min flowrate	<p>Breathing comfort of a mask is measured by the “breathing resistance” – how easy it is to breathe through the mask, which is the pressure difference between the two sides of the mask. The lower the pressure drop, the easier it is to breathe through the mask. The result of breathing with difficulty is <i>respiratory fatigue</i> and inability of the user to perform his tasks.</p> <p>Not only FFP3 masks breathing resistance limit is lower than that of N95/N99/KN95, it is also measured at higher flowrate (95 L/min vs 85 L/min) which, like described above, implies “easier deeper/faster breath”.</p>
Breathing Resistance (exhalation)	300 Pascals at 160L/min flowrate	245 Pascals at 85L/min flowrate	245 Pascals at 85L/min flowrate	210 Pascals at 85L/min flowrate	<p>The exhalation resistance of FFP3 masks is measured at 160 L/min, matching real-life conditions (exhalation is usually faster than inhalation). The fact that exhalation is faster than inhalation is the reason that many masks need to have an exhalation valve otherwise the user is unable to aerate adequately.</p> <p><i>*** aēramask breathing resistance ranges 50-60% less than the EU standard limit, a matter of raw material quality. Therefore, aēramask is superior to other FFP3 masks existing in the market. This very low breathing resistance of aēramask renders the need for exhalation valve obsolete.</i></p>
Total Inward Leakage-TIL (fit tightness)	Max 2% (arithmetic mean – various exercises under high work-rate/treadmill)	No requirement	No requirement	Max 8% (arithmetic mean – various exercises under <u>no</u> work-rate/static test)	<p>Fit tightness is crucial for the protection of the user. It is measured by the total amount of particles reaching the mouth/nose side of the mask through both the fabrics and the gaps between the mask and the skin. Various face/head types are used in the TIL test, performing various exercises.</p> <p>Certified FFP3 masks complying with the European standard EN149 are allowed to have 2% maximum TIL, compared to 8% for KN95. The European test requires the test subjects to walk fast on a treadmill while performing the exercises, closer to real-life conditions, whereas the Chinese test subjects are static. Obviously, static testing hardly matches the use of masks in reality.</p>

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					<p>There is no TIL requirement for US NIOSH certified N95/N99. Some companies and hospitals in the US require each user to perform a light fit-test at varying frequencies throughout the year. Therefore, hospitals must either have the users tested individually (=extra cost) or risk the leakage of particles (including virus particles and droplets) due to light fitting.</p> <p><i>*** aēramask FFP3 TIL is significantly less than 2% for most test subjects, representing a design that achieves tight fitting. This is achieved by the mask raw material selection and general mask design, the existence of headbands that pull the mask tightly on the face (vs earloops that hurt the ears if pulled strongly) and the nose-wire/inner cushion that assist in forming a tight seal that does not allow particles to penetrate through gaps at the nose-bridge area.</i></p>
CO₂ clearance	up to 1%	No requirement	No requirement	up to 1%	<p>Carbon dioxide clearance depends on the quality of the raw materials used and the design of the mask. CO₂ which is not cleared (exited the mask after exhalation) is mixed with inhaled air.</p> <p>FFP3 masks are checked for CO₂ clearance, whereas there is no testing requirement for N95/N99 masks.</p> <p><i>*** aēramask CO₂ clearance ranges from 0.3 to 0.6%.</i></p>

- 4) **Splash resistance against potentially contaminated liquids:** although not a certification requirement, the outer layer of aēramask is splash-proof against liquids



having at 16KPa pressure (standards EN 14683 and ISO 22609). This is particularly important because the mask will not become easily wet by contact with splashes or droplets potentially containing SARS-CoV2 virions, that may reach the user's lips and eventually infect him.

Splash resistance is listed as a requirement in the World Health Organization guidelines^{1,2}.

- 5) **Collapsing:** most N95/KN95 masks currently existing in the market have the vertical fold in the middle style. The problem with this design is that the mask collapses easily on the mouth when inhaling and touches the lips. The inhalation area decreases therefore makes breathing even more difficult. If the mask is not splash-resistant and it collapses on the mouth, then there are chances that the user gets infected by contaminated body liquids or other virus-carrying droplets that reach the user's lips. The three-fold design of aēramask prevents the collapsing of the mask on the mouth, is more comfortable when breathing and the user can speak with ease without the mask touching the lips. Non-collapsing design is also a requirement in the World Health Organization guidelines^{1,2}.



- 6) **Sustainability by design:** the selection of aēramask raw materials is such that the quantity of raw materials is minimized, contributing to the accumulation of less waste. For example, aēramask uses up to 50% less raw materials compared to other masks.



This is serving the United Nations Sustainable Development Goals (SDG 12: Responsible Consumption and Production - Ensure sustainable consumption and production patterns), a key point for sustainability officers and Corporate Social Responsibility actions.



¹ "WHO guidelines "COVID-19 Technical Specifications for Personal Protective Equipment and Related IPC Supplies" WHO/2020-nCoV/MedDev/TS/InfDev at <https://www.who.int/docs/default-source/medical-devices/technical-specs-ppe-covid19.pdf>

² "Use of masks in the context of COVID-19 – Interim Guidance" Version December 1st, 2020 at https://apps.who.int/iris/bitstream/handle/10665/337199/WHO-2019-nCov-IPC_Masks-2020.5-eng.pdf

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