



Infection Control Expert Group

THE USE OF FACE MASKS AND RESPIRATORS IN THE CONTEXT OF COVID-19

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1. GENERAL CONSIDERATIONS ON THE USE OF MASKS AND RESPIRATORS

Like most respiratory viruses, SARS-CoV-2 (the virus that causes COVID-19) is principally spread by respiratory **droplets** produced when an infected person speaks, coughs or sneezes, and/or by **contact** via hands with a surface contaminated by virus-containing respiratory droplets, before touching the eyes, nose or mouth. **A mask can be used** by a person with a respiratory viral infection, including COVID-19, **to protect others**, by decreasing the spread of droplets. **Masks** (or, in selected circumstances, respirators) **and eye protection are used by health care workers** (and some other occupational groups) **to protect themselves**, when it is impracticable or inappropriate to maintain physical distancing from a person with a respiratory infection, including COVID-19.

- **A mask is not a substitute** for other precautions to prevent spread of COVID-19:
 - staying at home when unwell, with even mild respiratory symptoms
 - **especially** if employed in a high-risk occupation e.g. health or aged care or in quarantine because of increased risk of developing COVID-19
 - **a person who develops symptoms of acute respiratory infection should seek testing for COVID-19**
 - **physical distancing** (staying >1.5 m away from others)
 - **hand hygiene** (and avoidance of touching potentially contaminated surfaces)
 - **cough etiquette/respiratory hygiene.**
- **Inappropriate use of masks is associated with risk**
 - they can give a false sense of security and result in neglect of more important measures, such as hand and respiratory hygiene
 - touching the mask during use or when removing it can contaminate the hands
 - risks are compounded if masks are reused – they should be discarded after use
 - masks will be less effective if they become damp or damaged.

In Australia, the routine use of masks in the community is currently not recommended, while the rate of community transmission of COVID-19 is low.

1.1. USE OF MASKS AND RESPIRATORS IN HEALTH CARE SETTINGS

- **Standard infection prevention and control precautions apply, in all health care settings.** This includes risk assessment to determine whether personal protective equipment (PPE) such as a mask or respirator, is needed.
 - Risk assessment is based on the patient's history and presentation, the type of interaction, likelihood of exposure to body fluids and whether a procedure is (or is likely to be) required.
 - **Risk assessment also includes consideration of the rate of local community transmission or occurrence of local clusters of COVID-19.**
- **Cough etiquette and respiratory hygiene should be practised in health care settings.**
- **Physical distancing** includes between health care workers and members of the public, other health care workers and patients (except during direct 'hands-on' clinical care) in wards, clinics and nonclinical areas (e.g. public spaces, cafeteria, meeting rooms, shared workspaces).

- **Health care workers** caring for patients with COVID-19 (or any infectious disease) **should be trained in correct use (choice, fitting, donning, doffing) of PPE**, including masks and respirators, by an infection prevention and control professional or other suitably trained educator.

2. EVIDENCE GUIDING RECOMMENDATIONS FOR THE USE OF MASKS OR RESPIRATORS IN THE CONTEXT OF COVID-19

2.1 TRANSMISSION OF RESPIRATORY VIRUSES

Bioaerosols contain suspended particles, produced from the respiratory tract during breathing, talking, coughing and sneezing (1). People with respiratory viral infections produce particles of variable sizes (from <0.1 to >100 micron) and proportions, containing varying amounts of viral RNA and viable virus, depending on the type and stage of infection (2, 3). Particle sizes form a continuum and there is no universally agreed cut-off between large and small particles. However, there are important differences based on size.

Larger, wet particles (droplets; generally defined as >10 micron) travel relatively short distances from the source person (usually ~1-2 metre) before settling on surfaces, fomites or a person in close proximity. Viruses contained in large droplets tend to infect the upper respiratory tract, directly via droplets settling on mucosal surfaces or directly by the person's hands, after touching a fomite or surface contaminated with respiratory droplets, and then touching their eye, nose or mouth (4).

Droplet contamination of surfaces and fomites is a major source of respiratory virus transmission - hence the importance of hand and environmental hygiene in infection prevention and control (5, 6).

Smaller (<10 micron) particles remain suspended in the air for relatively long periods, and can be dispersed over long distances, depending on environmental conditions such as temperature, humidity, air currents and ventilation (7). Because of their size, small particles can be inhaled directly into the lungs of someone in close proximity to the source. The risk diminishes as distance from the source increases and particles are diluted by dispersion (4, 8). Only a minority of small particles from a person with a viral infection carry live virus, which is rapidly inactivated by desiccation (1, 4, 9). Small particles can aggregate into large droplets and settle onto nearby surfaces (8).

Respiratory viral infections are most likely to be transmitted, via large and/or small particles, among close contacts, in poorly ventilated indoor spaces. Viral RNA – and sometimes culturable virus – can often be detected on surfaces and in airborne particles in the vicinity of people with viral infections, such as influenza, SARS, MERS (10) and COVID-19 (11). Transmission is much less likely to occur outside, because of the limited range of large droplets and dilution of small particles by dispersion on air currents with rapid loss of viability of any virus carried by them, due to desiccation (12).

Current evidence suggests that most respiratory viral infections are principally spread by droplets, directly or indirectly, between individuals in close proximity to each other. Modelling studies indicate that the risk of infection from small particles is many times less than from droplets or self-inoculation by contaminated hands (13). However, there is an increased risk of hospital-acquired respiratory viral infection, in the context of aerosol-generating procedures (AGPs) (14, 15). Controversy remains about contributing factors and frequency of airborne transmission, which varies in different types of viral infection, patients and AGPs (14).

Factors contributing to an increased risk of transmission include the viral load in the respiratory tract of the infected patient and amount of infectious virus, if any, in the aerosol produced, which depends on the stage of infection and whether the upper and/or lower respiratory tract is involved. The viral

inoculum required to cause infection in another person depends on factors such as the relative abundance of specific viral receptors in the human respiratory tract and the susceptibility of the exposed individual.

2.2 TRANSMISSION OF COVID-19

Evidence to date suggests that, in common with other respiratory viruses, **COVID-19 is principally transmitted by respiratory droplets** (16) that arise from an infected person during talking, coughing or sneezing and are transmitted **directly**, during close contact with an infected person or **indirectly**, by contact with a contaminated surface or object.

Surfaces contaminated by respiratory droplets can provide a persistent source of SARS-CoV-2. Viral RNA can often be detected on frequently touched surfaces and floors in the vicinity of patients with COVID-19 (17, 18); and live virus can persist, on some types of surface, for 2-3 days after experimental aerosolisation (19). These findings emphasise the potential for spread of SARS-CoV-2 by health care workers and emphasise the importance of hand and environmental hygiene.

There is little clinical or epidemiological evidence of regular airborne transmission of SARS-CoV-2. **Opportunistic airborne transmission** is suggested by analogy with influenza, SARS and MERS (20, 21) but the frequency and circumstances in which it occurs, if any, are controversial (22). There are significant differences between COVID-19 and these other infections. The viral load of SARS-CoV-2 is reported to be high in the upper respiratory tract in early infection, even when symptoms are mild (23), and to decline in the second week, when the severity of illness often increases (17, 24, 25, 26). This differed from the viral load in patients with SARS, which correlated with disease severity and peaked in the second week of illness (27, 28). Based on its higher community transmission rate, the infectious dose of SARS-CoV-2 is likely to be less than that of SARS-CoV-1 and MERS-CoV.

The possibility of opportunistic airborne transmission is supported by reports of SARS-CoV-2 RNA detected in small aerosol particles (<5 micron), in the vicinity of COVID-19 patients, especially in the first week of illness (17); they were found more frequently and further away from the source patient in an intensive care unit (up to 4 m) than a general ward (up to 2.5 m) (18). However, there was no evidence, in these studies, that the viral RNA detected represented (infectious) virus.

A recent review of literature relating to horizontal distances travelled by droplets, concluded that evidence supporting guidelines on respiratory protection against COVID-19, was sparse. Nevertheless, the authors concluded that airborne precautions were required to protect health care workers caring for patients with COVID-19 (29). However, there is a lack of clinical or epidemiological evidence to support this recommendation, except in the specific context of high-risk AGPs (21).

Clinical and epidemiological evidence indicates that COVID-19 is usually transmitted by close contact, in households, enclosed, household-like settings (30, 31) such as residential care facilities (32, 33), cruise ships (34) and crowded workplaces (35), where physical distancing is impractical. In the absence of effective preventive measures, the basic reproductive number (R_0) of COVID-19 is 2-3 (36) and the household infection rate is ~10%-12% (31). This contrasts with much higher R_0 s and household attack rates of infections in which airborne transmission is the rule, including measles (R_0 , 12-18; household attack rate 90%), varicella, (R_0 ~10, household attack rate 85%) (14) and tuberculosis (37). These data suggest **that airborne transmission of COVID-19 is infrequent** (38-40) and the routine use of airborne precautions not warranted.

This evidence is supported by several systematic reviews and meta-analyses of randomised controlled trials (RCTs) that have shown that **surgical masks and particulate filter respirators provide equivalent protection** against respiratory viral infections, with modes of transmission likely to be similar to those of COVID-19 (41-43). A recent meta-analysis of six RCTs involving > 9000 participants (mainly in health care settings) showed no statistically significant differences in relative risks of laboratory confirmed influenza, other viral infections or influenza-like illnesses, between groups using N95 respirators or surgical masks (43). Further analysis of three studies in health care settings, showed that absolute risks of laboratory-confirmed viral infections were significant, but similar in both groups, albeit lower than in a control group in which no mask was used (44).

These studies support recommendations for the use of surgical masks during routine care of patients with COVID-19, although no direct comparison with N95 respirators has been reported in this context. Obviously, the risk of COVID-19 in health care workers will not be eliminated by the use of mask or respirator alone; it will also reflect community prevalence and depend on optimal use of all preventive measures in the workplace and community.

This is consistent with advice from many authorities, including the World Health Organization (WHO) (45), Public Health England (46), the European Centre for Disease Control (ECDC) (47) and the Australian Health Protection Principal Committee (AHPPC) (48) that standard, contact and droplet precautions, including use of a surgical mask, are appropriate for routine care of patients with COVID-19, except in the context of certain high-risk AGPs.

2.3. AEROSOL-GENERATING PROCEDURES (AGPs).

A systematic review (21) of 10 retrospective studies from the SARS era indicated that some AGPs were associated with an increased risk of SARS among health care workers. Limited types of procedure and relatively small numbers of health care workers exposed to each, were assessed in the studies reviewed; the authors acknowledged that, although most studies showed that risks were mitigated by the use of PPE, they could not assess compliance. None of the studies compared risks based on whether surgical masks or respirators were used.

Tracheal intubation was most consistently associated with increased risk across multiple studies. Other procedures associated **with a significantly increased risk**, based on a small number of studies, included **non-invasive ventilation, manual ventilation before intubation and tracheostomy**.

Pooled estimates suggested that chest compression/cardiopulmonary resuscitation (CPR), suction before and after intubation, bronchoscopy, insertion of nasogastric tube and defibrillation may be associated with increased risk, but odds ratios were nonsignificant.

Special consideration for cardiopulmonary resuscitation

Because of its special status as a life-saving, emergency procedure, special consideration is warranted for CPR. The systematic review (21) suggested that CPR was associated with an increased risk of SARS transmission. However, cardiac compression, alone was not associated with increased risk, in two of three studies reviewed (49-51). The authors of the third study stated that *"Chest compression and intubation were ...highly correlated anddistinction between those two is not possible"* (51). Thus, it is likely that the increased transmission risk with intubation was a confounding factor in the apparently increased risk associated with chest compression.

This suggests that, in the context of a low rate of community transmission of COVID-19, cardiac compression and defibrillation are unlikely to pose significant risk to first responders or bystanders who commence CPR, without knowledge of the subject's COVID-19 status. In a hospital setting, any risk can be mitigated by the use of a surgical mask and by covering the patient's mouth (e.g. with a towel). A clinician who subsequently performs airway manoeuvres should use airborne precautions.

Based on limited evidence, the systematic review (21) found no increased risk for: BiPAP mask use, endotracheal aspiration, suction of body fluids, mechanical ventilation, manual ventilation, manual ventilation after intubation, high-frequency oscillatory ventilation, administration of oxygen, high-flow nasal oxygen, chest physiotherapy, or collection of sputum samples.

However, the absence of evidence does not prove absence of risk. Therefore, based on similarities with high-risk procedures, most authorities (44,45,46, 47,48) recommend that standard, contact, droplet and airborne precautions (i.e. use of a particulate filter respirator instead of a surgical mask) be used in the management of patients with COVID-19 in situations and procedures where excessive generation of fine respiratory particles may occur.

The following list of examples of high-risk AGPs, that may be associated with an increased risk of transmission of COVID-19, is based on limited evidence but consistent with advice from other authorities (44, 46).

Examples of high-risk AGPs that may be associated with increased risk of COVID-19 transmission

Instrumentation or surgical procedures on the respiratory tract

- Insertion or removal of an endotracheal tube and related procedures e.g. manual ventilation and open suctioning of the respiratory tract
- Bronchoscopy and upper airway procedures that involve open suctioning
- Tracheotomy/tracheostomy (insertion, removal, open suctioning)
- Ear-nose-throat, faciomaxillary or transphenoidal surgery; thoracic surgery involving the lung.
- Post-mortem procedures involving use of high speed devices on respiratory tract tissues
- Intentional or inadvertent disconnection/reconnection of closed ventilator circuit.

Other procedures that generate respiratory aerosols

- Manual or non-invasive ventilation (NIV): bi-level positive airway pressure ventilation (BiPAP); continuous positive airway pressure ventilation (CPAP)
- Collection of induced sputum
- High flow nasal oxygen
- Upper gastrointestinal instrumentation that involves open suctioning of upper respiratory tract
- Some dental procedures e.g. involving high speed drilling
- The use of nebulisers, which should be avoided, and alternative devices used for administration of medication (e.g. spacers).

3. RECOMMENDATIONS FOR THE USE OF SURGICAL MASKS AND RESPIRATORS IN HEALTH CARE IN THE CONTEXT OF COVID-19¹

3.1. SURGICAL MASKS

Surgical masks protect the nose and mouth from large droplets and are fluid (splash) repellent to differing degrees – three levels are defined (see Appendix 1). Level 2 or 3 masks, with a higher degree of splash resistance, are preferred during procedures in which there is a risk of body fluid splash. Level 1 masks are acceptable for general patient care and procedures where the risk of body fluid exposure is judged to be small. Note that eye protection, e.g. face shield or safety glasses, is also required for protection against droplet transmission of respiratory infections.

Indications for use of surgical masks by health care workers in the context of COVID-19.

In hospital and community settings, surgical masks should be used during routine care of patients with suspected or confirmed COVID-19 or who are in quarantine because of contact with a case, international travel or other source of exposure within the previous 14 days.

Routine (universal) use of surgical masks is not recommended in the care of patients with no clinical or epidemiological indication of COVID-19, *except* in communities or health care settings in which there is a high-risk of COVID-19 transmission (as defined by jurisdictional public health units).

Note that standard precautions require use of eye protection and a surgical mask for close clinical contact with patients with acute respiratory symptoms, regardless of known viral infection status.

Indications for the use of surgical masks by patients to prevent transmission of COVID-19:

Patients with suspected or confirmed COVID-19, or those who are in self-quarantine because of close contact with a confirmed case, international travel or other exposure, within the previous 14 days, should be given a surgical mask to wear when they are likely to come into contact with others (e.g. when being transferred within or between health care facilities).

Precautions when using surgical masks in the care of patients with COVID-19.

Other infection prevention and control precautions must be closely observed, including hand hygiene, and the use of other recommended PPE, such as eye protection (safety glasses, visor or face shield). If the risk of splash is low and direct physical contact can be avoided, gown and gloves are not required. It is important to avoid touching the front of mask, to replace it if it becomes contaminated or damp and to remove it carefully by touching only the straps, to avoid self-contamination. Hand hygiene should be performed after removal of the mask.

Extended use of surgical masks when there are shortages.

A surgical mask can be used continuously for up to 4 hours, as long as it does not become moist, soiled or damaged. Surgical masks must not be stored or reused after removal.

Use of masks in non-health care settings, during the COVID-19 pandemic.

¹For technical details of different types of masks and respirators see Appendix

The use of surgical masks by groups such as police, border security staff or air crew may be appropriate, in addition to other precautions, in settings in which close contact cannot be avoided with persons with suspected, probable or confirmed COVID-19, or who are in quarantine.

Physical distancing and hand hygiene should be observed at all other times.

The use of surgical masks may be indicated for other occupational groups in some **high-risk non-health care settings**, e.g. in a community, institution or workplace where COVID-19 case(s) have occurred or are suspected, and close contact cannot be avoided e.g. residential aged care facility, prison, or international aircraft/airport.

Other occupational groups and service-providers who have face-to-face contact with the public should practise physical distancing and hand hygiene and/or implement physical barriers, where possible; the use of masks is not required.

3.2 PARTICULATE FILTER RESPIRATORS

Particulate filter respirators, such as P2, N95 or equivalent, are used to protect the wearer from exposure to small airborne particles. P2 and N95 respirators are often used interchangeably, but while similar, they are not identical. P2 respirators are most commonly available in Australia. (See Appendix 1 for more detail).

P2 respirators should only be used when required. To be effective, a tight facial seal is necessary. In health care settings, their use is recommended for high-risk AGPs (see 2.3 above) and protection against infections known to be spread by the airborne route such as tuberculosis or measles.

Training in the use and fitting of respirators is needed for safe and effective use.

Indications for use of particulate filter respirators.

When caring for patients with suspected, probable or confirmed COVID-19 or who are in quarantine, P2 respirators are recommended for:

- proceduralists and their assistants performing high-risk AGPs including instrumentation and/or surgical procedures involving the upper or lower respiratory tract of patients (45);
- clinicians caring for patients for whom an AGP is required in any clinical setting; and
- clinicians in critical care settings, caring for patients in whom AGPs are, or are likely to be, required frequently.

P2 respirators used during procedures in which there is a risk of a body fluid splash should be certified as fluid resistant (i.e. surgical grade) or protected by another barrier such as a face shield.

Precautions when using respirators.

All components of standard, contact and droplet precautions must be closely observed, in addition to use of a P2 respirator, to ensure optimal protection against COVID-19 during an AGP.

It is important to avoid touching the front of the respirator during use and when it is being removed, to avoid self-contamination.

Single use P2 respirators should be discarded as soon as they are removed. They should not be stored or decontaminated for reuse, unless a validated reprocessing method is available. Reprocessing of respirators that are intended for single use requires a carefully validated process to ensure adequate decontamination and that functional integrity is maintained (see Appendix 1).

Extended use when there are shortages.

P2 respirators can be used for a single session of care lasting up to 8 hours.

However, a correctly fitted respirator (i.e. with adequate face-seal), can become uncomfortable with prolonged use and cause headache (52), thermal stress and adverse respiratory (53) and dermatological (54) effects. Among other things, this means that the wearer is more likely to unconsciously adjust it and risk contaminating their hands and face.

How to fit and use P2/N95 respirators safely.

Fit-checking: The purpose of fit-checking is to ensure that the respirator fits the user's face snugly (i.e. creates a seal) to minimise the number of particles that can bypass the filter through gaps between the user's skin and the respirator seal. The respirator must be put on (fitted) and taken off (removed) correctly. It may not be possible to achieve an adequate fit in males with facial hair that underlies the edges of the mask. If so, facial hair should be removed or an alternative type of respirator used. High-risk AGPs should not be performed unless a satisfactory fit has been achieved.

Fit-checking should be performed each time a P2 respirator is used, regardless of whether previous fit-testing has been performed.

Fit-checking is the most reliable way to ensure an adequate facial seal on each occasion. Users should be instructed in the correct method of fitting, removing and fit-checking of P2 respirators. Appropriate training can improve the respirator facial seal achieved by the user (55).

Fit-testing: A facial fit test is a validated method of matching a respirator to an individual as defined under the Australian/New Zealand Standard 1715 2009. Fit-testing verifies whether a specific type, model and size of mask is likely to provide an adequate facial seal for individuals, with differently shaped faces, to prevent entry of fine particle aerosols. The fit-testing operator provides valuable training in the use of the respirator during the procedure (56).

Despite increased awareness and demand, in the context of COVID-19, fit-testing of all health care professionals, who need to use P2 respirators, is constrained by limited supplies and range of types/sizes available.

Fit test methods are classified as either qualitative or quantitative.

- A *qualitative* fit test is a pass/fail test that relies on the individual's sensory detection of a test agent, by taste, smell, or involuntary cough (a reaction to irritant smoke). It uses a hood and an odour or taste solution to determine the ability of the wearer to smell or taste the test agent.
- A *quantitative* fit test requires an experienced operator and uses an instrument to measure the 'fit factor' numerically (56). This is determined by the ratio of ambient generated salt particles detected on either side of the mask. It enables a dynamic demonstration of mask fit after donning and with a range of activities (speaking, head movement and deep breathing).

NOTE: Fit-testing does not guarantee that a respirator will not leak during future use – it does not replace the need for fit-checking each time a respirator is used, which is the most reliable way to ensure an adequate face seal (55).

3.3. POWERED AIR-PURIFYING RESPIRATORS (PAPR)

The use of a PAPR, for airborne precautions, may be considered in certain situations when airborne precautions are required, based on risk assessment, anticipated duration of exposure to aerosols, the training of the health care worker and the type(s) or PAPR available. If a health care professional is required to remain in a patient’s room continuously for a prolonged period e.g. more than one hour, during which multiple procedures are to be performed, the use of a PAPR may be considered for additional comfort and visibility, if a tight facial seal cannot be achieved or if adverse effects have been experienced with extended use of P2 respirators.

Several different types of relatively lightweight, comfortable PAPRs are available. They should be used according to the manufacturer’s instructions, including reprocessing of reusable PAPR components and maintenance of filters

PAPRs must only be used by health care workers who have been trained in the use of the specific type of PAPR chosen.

Care should be taken when removing a PAPR, which is associated with a risk of contamination. Hand hygiene should be performed after removing the PAPR.

PAPRs designed for use in settings outside of health care are not recommended.

Only PPE included in the Australian Register of Therapeutic Goods (ARTG) should be used in hospitals or for surgical procedures.
Only PPE marked as reusable should be reused. They must be decontaminated and reprocessed according to the manufacturer’s instructions. All other PPE must be disposed of after use.

4. APPENDIX 1: MASK TYPES

Surgical masks

Surgical masks are single use covers that go over the mouth and nose. They are a component of standard and droplet precautions, to prevent sprays or splashes of body fluid coming into contact with the mouth and nose and protect the wearer from contamination of the nasal or oral mucosa. Surgical masks do not protect the wearer from infectious agents transmitted via the airborne route (57). Eye protection is also required to protect the conjunctivae from sprays or splashes.

Table 1 (below) shows the three levels of surgical masks and their application in medical practice².

Table 1: Levels of surgical masks and their application

Level 1 barrier	Level 2 barrier	Level 3 barrier
For general purpose medical procedures, where the wearer is not a risk of blood or body fluid splash, or to protect staff and/or	For use in emergency departments, dentistry, changing dressings on small wounds or healing wounds	For all surgical procedures, major trauma first aid or in any area where the health care

² Adapted from Australian Commission on Safety and Quality in Health Care. Australian Guidelines for the Prevention and Control of Infection in Healthcare. NHMRC. 2019.

Level 1 barrier	Level 2 barrier	Level 3 barrier
the patient from droplet exposure to microorganisms	where minimal blood droplet exposure is likely to occur	worker is at risk of bloody or body fluid splash

The wearing of correctly fitted surgical masks by patients known or suspected to be infected with agents transmitted by respiratory droplets, reduces transmission by preventing dispersal of respiratory secretions into the air (57).

Particulate filter respirators

Particulate filter respirators, also known as filtering facepiece respirators or disposable respirators, are a component of airborne precautions and are comprised of multiple layers which filter particles through mechanical impaction and electrostatic capture (57). Particulate filter respirators are designed to provide a good facial fit to minimise aerosol contamination of the mucous membranes of the nose and mouth (57).

Particulate filter respirators are certified as having met specific regulatory standards. Such standards specify the required physical properties and performance characteristics which must be met in order for respirators to claim compliance with the relevant standard (58).

Around the world, the following performance standards apply:

- P2 (Australia/New Zealand AS/NZA 1716:2012)
- N95 (United States NIOSH-42CFR84)
- FFP2 (Europe EN 149-2001)
- KN95 (China GB2626-2006)
- Korea 1st class (Korea KMOEL - 2017-64)
- DS2 (Japan JMHLW-Notification 214, 2018)

Respirators certified as compliant with these standards have very similar function to one another. There may be some variation in the flow rate specified by different standards; inhalation and exhalation resistance testing flow rates range between 40 and 160 L/min, and 30 and 95 L/min, respectively (58). However, the standards’ various pressure drop requirements are quite similar.

Table 2 (below) shows a summary comparison of the different performance characteristics of particulate respirator certifications under the relevant standard³. Based on this comparison, it is reasonable to consider KN95, P2, Korea 1st Class, and Japan DS2 respirators as equivalent to US N95 and European FFP2 respirators (58).

³ Adapted from 3M Technical Bulletin. Comparison of FFP2, KN95, and N95 and Other Filtering Facepiece Respirator Classes, Revision 3.

Table 2: Comparison of particulate respirators

Certification/ Class (Standard)	N95 (NIOSH- 42C FR84)	FFP2 (EN 149-2001)	KN95 (GB2626-20 06)	P2 (AS/NZ 1716:2012)	Korea 1st Class (KMOEL - 2017-64)	DS2 (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
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	85 L/min	Varied	Varied	40 L/min
Exhalation resistance – max pressure drop	≤ 345 Pa	≤ 300 Pa	≤ 250 Pa	≤ 120 Pa	≤ 300 Pa	≤ 70 Pa (with 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	Depressuriz ation to 0 Pa ≤ 20 sec	Leak rate ≤ 30 mL/min	Visual inspection after 300 L/min for 30 sec	Depressurizat ion to 0 Pa ≤ 15 sec
Force applied	-245 Pa	N/A	-1180 Pa	-250 Pa	N/A	-1470 Pa
CO ₂ clearance requirement	N/A	≤ 1%	≤ 1%	≤ 1%	≤ 1%	≤ 1%

Reprocessing of P2 respirators

P2 respirators are generally single use. In times of shortage, reprocessing is sometimes considered. However, this should only be contemplated if a properly validated process is available. The following warning from the Australian Therapeutic Goods Administration* should be heeded:

“If you are reprocessing medical devices for reuse, you will need to meet the legislative definition of a manufacturer. You will therefore need to meet all the responsibilities of a manufacturer under the therapeutic goods legislation and regulations. You are assuming the responsibility and liability should the device fail to perform as intended”

*<https://www.tga.gov.au/behind-news/reuse-face-masks-and-gowns-during-covid-19-pandemic>

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