Revision History (most recent updates are highlighted in yellow)

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Revised by</th>
<th>Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.0</td>
<td>December 2020</td>
<td>CEC HAI Team</td>
<td>Major revision</td>
</tr>
<tr>
<td>2.3</td>
<td>13 August 2020</td>
<td>CEC HAI Team</td>
<td>Inclusion of appendix I and requirements for fit testing pages 21-22</td>
</tr>
<tr>
<td>2.2</td>
<td>11 August 2020</td>
<td>CEC HAI Team</td>
<td>Inclusion of respirators with exhalation valves (pages 12, 15, 17 and 19)</td>
</tr>
<tr>
<td>2.1</td>
<td>24 July 2020</td>
<td>CEC HAI Team</td>
<td>Correction to respirator category page 11</td>
</tr>
<tr>
<td>2.0</td>
<td>18 June 2020</td>
<td>CEC HAI Team</td>
<td>Major revision</td>
</tr>
<tr>
<td>1.4</td>
<td>19 March 2020</td>
<td>CEC HAI Team</td>
<td>Inclusion of properties of P2/N95 mask and P2/N95 mask range in NSW health</td>
</tr>
</tbody>
</table>

Document information

<table>
<thead>
<tr>
<th>Original publication date</th>
<th>February 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Developed by</td>
<td>CEC HAI Team</td>
</tr>
<tr>
<td>Consultation</td>
<td>IPAC CoP, IPAC Super COP</td>
</tr>
<tr>
<td>Endorsed by</td>
<td>Carrie Marr</td>
</tr>
<tr>
<td>For use by</td>
<td>To assist clinicians with application of PPE during COVID-19 pandemic</td>
</tr>
</tbody>
</table>
# Contents

- Introduction ............................................................................................................................. 4
- Scope and purpose ....................................................................................................................... 4
- Main changes from previous version ....................................................................................... 4
- How COVID-19 spreads ............................................................................................................ 5
- Modes of transmission ............................................................................................................. 5
- Precautions for COVID-19 ...................................................................................................... 7
- Summary principles for selecting PPE ....................................................................................... 8
- Health worker responsibility .................................................................................................... 9
- Gloves .................................................................................................................................. 10
- Aprons and gowns ................................................................................................................ 10
- Respiratory and facial protective equipment ............................................................................ 11
- Eye protection ........................................................................................................................ 11
- Visors ................................................................................................................................... 12
- Surgical masks ...................................................................................................................... 12
- Respirators ........................................................................................................................... 14
- Air-Purifying Respirators ........................................................................................................ 15
- Table 1: Filter types and Assigned protection factors (APFs) ................................................ 16
- Table 2: Difference between testing of P2 and N95 respirators ............................................. 16
- Use a P2/N95 disposable respirator when ............................................................................. 19
- Use of a Powered-Air Purifying Respirator (PAPR) ............................................................... 23
- Respirator fit checking and fit testing ..................................................................................... 26
- Detailed Fit Checking Process ................................................................................................. 26
- Requirements for fit testing .................................................................................................... 27
- Reprocessing ........................................................................................................................ 30
- Bringing your own PPE and/or PPE brought in without approval ........................................... 31
- Reprocessing of PPE during the COVID-19 pandemic .......................................................... 31
- References ........................................................................................................................... 33
- Appendix A: Recommended PPE for health workers in clinical settings ............................... 35
- Appendix B: Visual Guide to Application of PPE ................................................................. 40
- Appendix C: AAMI Level Standards for Gowns ................................................................. 41
- Appendix D: AS 4381:2015 Single use surgical face mask standard ....................................... 42
- Appendix E: Properties of P2 and N95 respirators .............................................................. 43
- Appendix F: P2/N95 Respirator Range within NSW Health (Surgical) ................................. 44
- Appendix G: Difference between Elastomeric Respirators and PAPRs (Loose fitting vs Tight... 47
- Appendix H: Respirator Selection Decision Making Algorithm ............................................. 51
Introduction

The Clinical Excellence Commission (CEC) provides guidance for Infection Prevention and Control practitioners, managers and clinicians on the selection and use of personal protective equipment (PPE) for COVID-19. This guidance relates solely to considerations of PPE and represents one section of infection prevention and control guidance for COVID-19. Other infectious diseases requiring PPE as part of standard and transmission-based precautions are not addressed in this document. For information of management of other communicable diseases refer to the CEC Infection Prevention and Control Practice handbook. This document should be used in conjunction with the New South Wales (NSW) Infection Prevention and Control Policy Directive, Infection Prevention and Control: Management of COVID-19 in Healthcare Settings and local procedures and guidance.

For the clinical care of patients who are NOT suspected, probable or confirmed COVID-19, standard precautions - including use of PPE if required - should be observed.

Scope and purpose

The development of this guidance was led by the Clinical Excellence Commission and endorsed by the Infection Prevention and Control Community of Practice. This guidance is based on the available evidence, expert advice and risk assessment of the current status of the COVID-19 pandemic in NSW.

As the COVID-19 pandemic situation is evolving, this PPE guidance will be revised and updated as new information becomes available to meet changing needs. Health workers (HWs) should check the NSW Health COVID-19 and CEC COVID-19 Infection Prevention and Control webpages for the most up-to-date information.

Additional resources include:

- CEC Infection Prevention and Control Practice Handbook
- Australian Government Department of Health COVID-19 updates
- CDNA National Guidelines for Public Health – Coronavirus Disease 2019
- National COVID-19 Clinical Evidence Taskforce

Main changes from previous version

This guidance has been updated to reflect the pandemic’s evolution and changing level of risk of healthcare exposure to COVID-19.

The main changes are updates to or the addition of the following sections:

- Mode of transmission
- Precautions for COVID-19
- Respirators
- Detailed fit checking process
- Alternatives to disposable respirators
How COVID-19 spreads

The principal mode of human-to-human (person-to-person) transmission of SARS-CoV-2 is through exposure to respiratory droplets carrying infectious virus.

Respiratory droplets are produced during exhalation (e.g., breathing, speaking, singing, coughing, sneezing) and span a wide spectrum of sizes that may be divided into two basic categories based on how long they can remain suspended in the air:

- **Larger droplets** some of which are visible and that fall out of the air rapidly within seconds to minutes while close to the source.
- **Smaller droplets or droplet nuclei** and particles (aerosols) formed when small droplets dry very quickly in the airstream that can remain suspended for many minutes to hours and travel far from the source on air currents.

Once respiratory droplets are exhaled and as they move outward from the source, their concentration decreases through fallout from the air (largest droplets first, smaller later) combined with dilution of the remaining smaller droplets and particles into the growing volume of air they encounter.

Estimates for the basic reproductive number ($R_0$) of SARS-CoV-2 range from 2–4, with $R_0$ for confined settings, e.g. cruise ships, at the higher end of this range. Estimates of the effective reproductive number ($R_E$) vary between settings and at different time points are dependent on a range of factors, including public health interventions such as isolation, quarantine and physical distancing to limit close contact between people.

**Modes of transmission**

Infections with respiratory viruses are principally transmitted through three modes: contact, droplet and airborne.

- **Contact transmission** is infection spread through direct contact with an infectious person (e.g., touching during a handshake) or with an article or surface that has become contaminated. The latter is sometimes referred to as “fomite transmission”.
- **Droplet transmission** is infection spread through exposure to virus-containing respiratory droplets (i.e. larger and smaller droplets and particles) exhaled by an infectious person. Droplets can spread directly to someone nearby (usually within 1.5 metres) or settle on an object or surface (3-7).

Transmission of SARS-CoV-2 can occur through direct, indirect, or close contact with infected people. These include infected secretions such as saliva and respiratory secretions or respiratory droplets, which are expelled when an infected person coughs, sneezes, talks or sings and by someone touching the contaminated surface or object and then touching their face.

- **Airborne transmission** is infection spread through exposure to those virus-containing respiratory droplets comprised of smaller droplets and particles (droplet nuclei – aerosols) that can remain suspended in the air over long distances (usually greater than 1.5 metres) and time.

Airborne transmission of SARS-CoV-2 occurs under specific circumstances e.g. during medical procedures that generate aerosols (aerosol generating procedures [AGPs]) (10).
Circumstances under which airborne transmission of SARS-CoV-2 may have occurred include:

- **Enclosed spaces** where an infectious person either exposed susceptible people at the same time or to which susceptible people were exposed shortly after the infectious person had left the space.
- **Prolonged exposure** to respiratory particles, often generated with expiratory exertion (e.g., shouting, singing, exercising) that increased the concentration of suspended respiratory droplet nuclei in the air space.
- **Inadequate ventilation or air handling** that reduced the clearance of particles or droplets from the air.

**From people to animals.** SARS-CoV-2 is rarely spread from humans to domestic animals, and this is reported to happen mostly after close contact. The virus is not thought to be viable from these pets.

**From animals to people.** Currently, the risk of SARS-CoV-2 spreading from animals to humans is extremely low in Australia.

**Other biological samples.** SARS-CoV-2 has been found in multiple biological samples including urine, faeces, blood and amniotic fluid. Apart from very rare case reports of vertical transmission, respiratory droplets remain the primary transmission risk.

**Aerosol generating procedures (AGPs)**

AGPs are defined as any medical and patient care procedure that results in the production of respiratory droplets (>5-10 microns) or airborne particles (aerosols ≤5 microns) due to air or gas flowing rapidly over a moist or wet surface. While the degree of risk associated with different AGPs is likely to vary, it is generally accepted that intubation poses the highest risk of these procedures due to close contact with the respiratory tract and exposure to droplets containing a high viral load, rather than exposure to aerosols. However, there is limited clinical or epidemiological evidence of significant transmission of SARS-CoV-2 by aerosols to HWs who are wearing appropriate PPE. Refer to CEC Infection prevention and Control Aerosol-generating procedures in relation to COVID-19 for more information including examples of AGPs. HWs should:

- Avoid unnecessary AGPs
- **Use contact, droplet and airborne precautions (including eye protection) if an AGP is required**
- Ensure procedures occur in a negative pressure room or a single room with the door closed
- Ensure only essential HWs are in the room during the procedure
- Based on the number of hourly air changes leave the room empty for at least 30 minutes after the procedure and undertake environmental cleaning

**NB: The use of nebulisers should be avoided and alternative means of delivering medication** (such as a metered-dose inhaler or spacer) **should be used.** Nebulisers aerosolise respiratory droplets.

If the use of a nebuliser cannot be avoided in a patient with suspected, probable or confirmed
COVID-19 then:

- Isolate the patient
- Ensure procedures occur in a negative pressure room or a single room with the door closed
- HWs administering nebulisers should wear airborne precautions PPE, including impervious gown and gloves, P2/N95 respirator, and protective eyewear. If staying in the room continue these precautions for at least 30 minutes after the nebuliser treatment

**Precautions for COVID-19**

There are two tiers of precautions to prevent the transmission of infectious agents: **standard precautions** and **transmission-based precautions**.

**Standard precautions** must be applied to the care of all patients in healthcare, regardless of whether the presence of an infectious agent is suspected or has been confirmed. Implementation of standard precautions is the primary strategy for the prevention of disease transmission in a healthcare setting and the prevention of exposure to blood and body substances. Irrespective of patients’ COVID-19 status, standard precautions must always be followed.

**Transmission-based precautions** are implemented for patients known or suspected to be infected or colonised with an infectious agent, where transmission cannot be prevented using standard precautions alone. The three categories of transmission-based precautions are contact, droplet and airborne, and are implemented based on the route of transmission of the infectious agent.

- **Contact Precautions** protect healthcare or care providers and prevent them from transmitting COVID-19 from direct physical contact with the patient/client, or indirectly from shared patient/client care equipment or from environmental surfaces directly contaminated by the patient/client.
- **Droplet Precautions** protect healthcare or care provider’s nose, mouth and eyes from droplets produced by the patient/client coughing and sneezing. Transmission can occur when a person is in close contact (within 1 metre) with an infected person who has respiratory symptoms. Use of surgical mask and eye protection is required when caring for patients suspected or confirmed COVID-19.
- **Airborne Precautions** protect health and care staff’s respiratory tract from much smaller droplets that become suspended in the air and may travel several metres. During aerosol generating procedures (AGPs) these droplets become aerosolised. A fitted P2/N95 respirator is designed to prevent these aerosolised droplets from entering the respiratory tract.

Precautions for COVID-19 and the choice of PPE is based on the likely risk of exposure to, and the means of transmission of an infectious organism. The risk to HW of COVID-19 will vary depending on the level of community transmission. For example, higher levels of community transmission require that all HWS to wear masks when providing care to patients within 1.5meter. This is further detailed at [CEC COVID-19 Response and Escalation Framework](#).
Routine clinical care of patients:

- Contact and droplet precautions, including eye protection, for routine hospital and non-hospital care of patients/residents
  - with suspected, probable or confirmed COVID-19
  - OR
  - Patients/residents are in quarantine due to international/interstate travel or being a close contact of a probable or confirmed case of COVID-19

- Addition of airborne precautions for respiratory AGPs and circumstances described below*

- Hand hygiene
- Environmental cleaning
- Cleaning of shared patient care equipment.

**Airborne precautions** are required in the following circumstances when caring for suspected, probable or confirmed COVID-19 patients:

- In situations where there are patients/residents cohorted in one area or ward; AND/OR
- Where there is prolonged and close contact with these patients.

There is reliable evidence that the application of recommended infection prevention and control measures including administrative, engineering, environmental controls, hand hygiene and other protective measures during patient or resident care, not just PPE alone, can minimise occupational acquisition of COVID-19 and spread to others.

**Summary principles for selecting PPE**

Using PPE optimally is important for HW safety. This means selecting appropriate PPE at the right time, in the right setting, for the right patient and then applying (donning) and removing (doffing) in line with evidence-based practice and current COVID-19 guidance.

- HWs caring for patients with COVID-19 should be trained in the correct use of PPE including donning and doffing.
- Incorrect removal of PPE is associated with an increased risk of contamination.
- Only PPE labelled as reusable should be cleaned, disinfected and reused, according to the manufacturer’s reprocessing instructions. All other PPE must be disposed of after use.
- Extended or sessional use of PPE is only recommended when caring for patients with suspected, probable or confirmed COVID-19.
- Isolation aprons/gowns (Level 1, 2, 3 and 4) which are impervious or fluid resistant are suitable for contact, droplet and airborne precautions.
- Sterile surgical gowns (Level 1, 2, 3 and 4) should only be used in surgical environments and for sterile procedures. Please refer to CEC guidance on surgical gown selection.
When caring for patients with suspected, probable or confirmed COVID-19, eye protection is required along with a surgical mask or P2/N95 respirator.

Fluid resistant surgical masks (Levels 1, 2 and 3) are all suitable for contact and droplet precautions.

P2/N95 respirators are used for airborne precautions when respiratory AGPs are conducted on patients with suspected, probable or confirmed COVID-19 and must be discarded following the AGP.

P2/N95 respirators should only be used when required and fit checked at each use.

Appendix A Recommended PPE for health workers in clinical settings summarises recommended PPE for HWs in clinical settings and this is further outlined in Appendix B Visual guide to application of PPE.

Refer to HETI My Health Learning training modules on Personal protective equipment for combined transmission-based precautions available through (Course Code 294450660) for step-by-step guidance on PPE donning and doffing.

Training around the appropriate selection, use and disposal of PPE is required to ensure the safe use of PPE. Some of the potential issues to consider are:

- How to minimise unnecessary contact with the mask
- Importance of adherence to hand hygiene, and
- How to ensure adherence to proper PPE donning and doffing technique

Health worker responsibility

HWs have duties in relation to PPE under clause 46 of the Work Health and Safety Regulation 2017 NSW.

1. This clause applies if a person conducting a business or undertaking provides a worker with personal protective equipment.

2. The worker must, so far as the worker is reasonably able, use or wear the equipment in accordance with any information, training or reasonable instruction by the person conducting the business or undertaking.

3. The worker must not intentionally misuse or damage the equipment.

4. The worker must inform the person conducting the business or undertaking of any damage to, defect in or need to clean or decontaminate any of the equipment of which the worker becomes aware.

HWs should not use or add to prescribed PPE that are not documented in NSW Ministry of Health policy directives, Clinical Excellence Commission COVID-19 guidance or local policy or procedures. PPE requirements may vary between clinical areas such as the operating theatre and general wards. PPE ‘creep’ has been identified during the pandemic as a risk to HWs who add or choose PPE that is not recommended for transmission-based precautions e.g. a cloth or disposable surgical scrub cap and overshoes outside of operating theatre, an apron over a long sleeved disposable gown, or other PPE adornments. These items will potentially increase the risk of self-contamination, particularly on PPE removal.
The HW should consult their manager if the PPE is uncomfortable, does not fit properly, or causes an adverse or allergic reaction.

**Gloves**

HWs wear gloves as a barrier to protect their hands from contamination or to prevent the transfer of microorganisms already on their hands to patients or the environment.

- **Intact gloves** must be worn on both hands and used where the HW is potentially exposed to blood or body substances or has direct or indirect contact with multidrug-resistant organisms.

- **Double gloving** is only recommended in theatre settings and/or on a risk-based approach for specifically determined procedures. Doubling gloving is usually implemented to allow a seamless transition during a procedure from “dirty” to “clean(er)” steps.

- **Double gloving is not recommended** for routine care of patients with suspected, probable or confirmed COVID-19.

- **Alcohol sanitiser** should not be applied to the outside of gloves when they are being worn - sanitisers can create pinholes in gloves. If a glove manufacturer states that alcohol sanitisers can be used on gloves, evidence must be provided, and staff educated on how and when it can be used safely.

- **Gloves should always be put on immediately before** the following: a procedure, cleaning shared patient care equipment, contact with blood or body fluids or when cleaning the patient care environment.

- **Gloves should not be worn** in non-patient zones unless directly handling blood or body fluid such as pathology specimens or cleaning up a blood or body fluid spill.

**Wearing gloves does not eliminate the need for hand hygiene.** In all circumstances, hand hygiene must be performed immediately:

- Before putting on gloves to avoid contamination of the outer surface of the gloves; and
- After removing gloves to avoid transfer of microorganisms to another person, patient’s environment or clinical equipment from the wearer’s hands and to protect the HW.

**Aprons and gowns**

Disposable plastic aprons or gowns are designed to protect uniforms or clothing from moisture or soiling from blood, body substances or transmissible microorganisms during direct patient care. They also protect the patient during direct contact.

Disposable, **fluid resistant aprons** are recommended for general clinical use where the risk of contamination from blood of body substance is low e.g., when providing routine care for a patient who is not coughing, sneezing or vomiting. Apron use can be considered based on anticipated contact or exposure to droplets while caring for symptomatic COVID-19 patients. For guidance see **Appendix A: Recommended PPE for health workers in clinical settings**.

There are two main types of gowns available: isolation gowns and surgical gowns.
Isolation gowns offer varying resistance to blood and other bodily substances depending on the type of the material, its' permeability, and wear and tear. Isolation gowns may be classified as "disposable/single-use" or "reusable/multi-use". Disposable/single use isolation gowns are designed to be discarded after a single use and are typically constructed of nonwoven materials alone or in combination with plastic films or other materials that offer increased protection from liquid penetration. These gowns should offer an impervious or fluid resistance barrier.

In some cases, where extensive contamination with blood or body substance is anticipated or when the patient requires a significant amount of direct care with close skin-to-skin contact, a long-sleeved fluid impervious or fluid resistant gown may be more appropriate. The need for, and type of gown selected, is based on the nature of the patient interaction, including the anticipated degree of contact with infectious material and potential for blood and body substance penetration of the barrier. A gown provides an increased coverage compared with an apron.

Single use surgical gowns are sterile, fluid-resistant, disposable garments made of natural and/or synthetic materials worn over a scrub suit during surgical and aseptic procedures, to help protect both the patient and operating room personnel from the transfer of microorganisms, body substances, and particulate material.

A correctly fitted surgical gown covers the wearer from the neck to the knees with sleeves finishing at the wrists with cuffs. They should have enough overlap at the back that they do not separate when the person wearing it is sitting.

For more information see Appendix C: Association for the Advancement of Medical Instrumentation (AAMI) Level Standards for Gowns.

Respiratory and facial protective equipment

Respiratory Protective Equipment (RPE) is worn on the face, covers at least the nose and mouth, and is used to reduce the wearer's risk of inhaling hazardous particles (including dust particles and infectious agents), gases or vapours. There is a range of RPE available that provides facial and respiratory protection, and this includes either a surgical mask or a respirator, with or without eye protection.

Respiratory and facial protection is required for those organisms that are usually transmitted via the droplet or airborne route, including when aerosols have been artificially created, such as during AGPs.

Eye protection

Evidence shows that the mucous membranes including conjunctivae of HWs can be exposed to infective droplets and aerosols from patients with suspected, probable or confirmed COVID-19 during close contact. Eye protection must be worn when there is risk of body substances splashing or spraying into the conjunctiva.

Eye protection such as safety glasses, mask visor, goggles or a face shield is required for close contact within 1.5 metres of a suspected, probable or confirmed COVID-19 patient.

Use a mask visor or a face shield if there is exposure to an excessive amount of splash or spray. Personal or prescription glasses are not a substitute for eye protection unless they
are specified as safety glasses. If reusable eye protection is used, it should be cleaned and disinfected in accordance with the manufacturer’s instructions for use.

- Single use eye protection can be worn for an extended period unless moist, wet or contaminated, and disposed of at the end of the session
- Reusable eye protection should be cleaned and disinfected between use. There must be a clearly described process in place for the cleaning, disinfection, drying and storage of reusable eye protection to reduce the risk of a HW donning an item that has not been effectively reprocessed since its last use

**Visors**

Visors are transparent personal protective devices intended to shield the face and eyes of a HW and are suitable for use with prescription glasses and masks.

**Surgical masks**

Surgical face masks provide a barrier to splashes and droplets impacting on the wearer’s nose, mouth and respiratory tract. They do not provide protection against airborne particles (aerosols) and are not classed as RPE. They are loose-fitting protection devices that create a physical barrier for the mouth and nose of the wearer. Some surgical masks have an integrated eye protection shield (mask visor). Surgical face masks used by HWs for protection against microorganisms must be fluid repellent and disposable.

Surgical masks are for use in clinical care, dental settings and surgery as per standard precautions. Surgical masks should be worn for the duration of the relevant exposure, task or procedure. They should be changed if they become damp, damaged or contaminated, only worn once, and discarded following use.

In most situations, a surgical mask is recommended when caring for patients with suspected, probable or confirmed COVID-19. Masks have different properties and colours depending on the manufacturer. Each mask barrier level will provide varying level of fluid penetration resistance and protection against droplets from a patient with COVID-19.

See **Appendix D AS 4381:2015 Single use surgical face mask standard** for more details on mask barrier levels and properties.

When you are wearing a mask, it is important to remember the following:

**Do not:**
- Touch your mask or face as you may contaminate yourself
- Pull your mask below your nose or chin
- Leave it hanging around your neck or on top of your head

**Do:**
- Change your mask if it becomes moist
- Change your mask if it is sprayed or splashed on
- Change your mask if contaminated with blood or body fluids
- Immediately perform hand hygiene if you accidentally touch the mask
• Perform hand hygiene after removing a mask. Do place it into a general waste bin and replace with a new mask.

• Report mask pressure injuries to your supervisor or manager, following local reporting processes and usual Work Health and Safety processes. See CEC Mask Wearing and Skin Sensitivity document for more information.

• Remove mask outside of patient care areas or patients requiring other precautions (e.g. between rooms or patient zones, break room, reception area) and before proceeding to care for patients that are not isolated for COVID-19

Points to remember

• Use of boots or shoe covers is not recommended as part of COVID-19 PPE. These may be required as standard attire in the operating theatre or the trauma room

• A head covering is not required except as part of standard operating theatre attire or when performing a sterile/aseptic procedure (e.g. central line insertion) to prevent contact between a HW’s hair and patients/equipment and to reduce shedding of skin squames/hair and associated bacteria into the field

• PPE adornments or extra equipment such as cloth caps are not to be used. If HWs have WHS safety concerns regarding skin integrity they should be raised via their normal reporting processes

• The use of a mask loop holder should only be used if all other avenues to secure PPE have been exhausted. Their use can increase the risk of contamination and contribute to issues with both donning and doffing. If a mask loop holder is used, the following need consideration:
  o Whether to use single use or reusable items
  o Are there any additional steps for donning and doffing
  o Do they interfere with the seal (for P2/N95 respirators)

• Coveralls are NOT recommended for use in NSW health facilities based on evidence regarding COVID-19 modes of transmission and increased risk of contamination on removal. Currently there are no guidelines from the World Health Organization (WHO), the U.S. Centers for Disease Control and Prevention (CDC), the U.S. Occupational Safety and Health Administration (OSHA) or Communicable Diseases Network of Australia (CDNA) regarding use of coveralls for protection from COVID-19 during patient care. If a determination is made to use protective coveralls, then the selection of appropriate protective coveralls should be based upon a site-specific risk assessment conducted by qualified individuals such as those working in infection prevention and control and infectious diseases roles.
Respirators

A respirator is used by an individual to provide respiratory protection. There are many types of respirators available and they include:

- Air-purifying respirators – protect the wearer by filtering inhaled air. These types of respirators can be disposable or reusable and are either:
  - non-powered – uses inhalation to draw air through a filter
  - powered – uses a fan to draw air through a filter
- Supplied-air respirators – protect the wearer by supplying clean breathing air from an independent source such as an air compressor or compressed air cylinder.

In the healthcare setting, an air-purifying respirator, also called a particulate filtering respirator, most commonly relates to the disposable filtering half-face respirator (also known as a P2 or N95 mask). There are a variety of respirators available and these may differ between facilities. Refer to Appendix E for properties of P2/N95 respirators and Appendix F P2/N95 Respirator range available within NSW Health. The category of particulate filtering respirator can be further divided into:

- Disposable particulate filtering respirators, where the entire respirator is discarded at the end of a session of care, or when it becomes unsuitable for further use due to excessive resistance, sorbent exhaustion, or physical damage
- Reusable particulate filtering respirators, also called Elastomerics, may take the form of a reusable full-face or half-face respirator and harness fitted with particulate P2 or P3 filters that are activated passively by inhalation
- Powered Air Purifying Respirators (PAPRs), these actively supply filtered air to the wearer and deliver positive air pressure via a battery-operated blower unit. This can be full- or half-face

Reusable respirator facepieces are cleaned and reused but the filter cartridges are discarded and replaced when they become unsuitable for further use. All reusable items must be cleaned and disinfected in accordance with the manufacturer’s recommendations and AS 4184:2014 Reprocessing of reusable medical devices in health service organisations.

Refer to Appendix G Difference between Elastomeric Respirators and PAPRs (Loose fitting vs Tight fitting Face Pieces) for more information.
Air-Purifying Respirators

P2/N95 Mask  Half Mask  Full Face

Loose Fitting  Hood Powered
Powered

Filter efficiency
Disposable P2/N95 face masks or respirators can filter out very fine particles (less than 0.5 micron) from the air when worn correctly.

AS/NZS1716:2012 Respiratory protective devices uses a classification system to identify the different types of particulate filters which are P1, P2 and P3. The “P” refers to the particle size of the particulate matter that the respirator is designed to protect against.

Particulate filters are classified and marked as P1, P2 or P3, with P3 providing the highest level of protection. However, P3 protection can only be achieved if the P3 filter is used in a full-face respirator. P3 filters are currently not part of the standards or readily available for use in Australian healthcare.

- P1 = 80% Filter efficiency
- P2 = 94% Filter efficiency
- P3 = 99% Filter efficiency

Protection factors
A respiratory protective device is considered adequate if it has the capacity to reduce the wearer’s exposure to a hazardous substance to acceptable levels. Each respiratory protective device has a protection factor (PF) assigned to it, which is the ratio of the airborne concentration of the substance outside the device to that inside the device.

Assigned protection factor (APF)
Assigned protection factor (APF) refers to the level of respiratory protection that a respirator or class of respirators is expected to provide to users.
Table 1: Filter types and Assigned protection factors (APFs)

<table>
<thead>
<tr>
<th>Conformité Européen (CE) Marked Particle Filter Type</th>
<th>Assigned Protection Factor (APF) (what is likely to be attained in practice)</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1</td>
<td>4</td>
</tr>
<tr>
<td>P2</td>
<td>10</td>
</tr>
<tr>
<td>P3</td>
<td>20</td>
</tr>
</tbody>
</table>

Elastomeric masks and PAPRs are regarded as having high levels of APF, particularly when used with full-face protection. The typical APF for a disposable N95 mask and a half facepiece elastomeric is 10 and full facepiece elastomeric is 50. An APF of 10 means that respirator (if used properly) can be safely used in an atmosphere that has a hazardous concentration of up to 10 times the Permissible Exposure Limit (PEL) or other exposure limit for that hazard.

N95 respirators (masks) and P2 respirators (masks) are similar and applied interchangeably to the same conditions. There are, however, differences in testing and certification practices between Australia and the USA (Table 2).

The term P2/N95 mask or respirator is interchangeable in this document.

Table 2: Difference between testing of P2 and N95 respirators

<table>
<thead>
<tr>
<th>P2 masks (Australian &amp; New Zealand Standard)</th>
<th>N95 respirator (USA NIOSH Standard)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filter efficiency</td>
<td>at least 94%</td>
</tr>
<tr>
<td>Testing substance</td>
<td>Sodium Chloride Aerosol</td>
</tr>
<tr>
<td>Aerosol flow rate</td>
<td>95 litres per minute</td>
</tr>
<tr>
<td>Aerosol particle size</td>
<td>0.3 to 0.6 microns</td>
</tr>
</tbody>
</table>

Surgical and Standard P2/N95 respirators

There are two types of P2/N95 respirators: surgical and standard. Surgical P2/N95 respirators are fluid resistant, whereas standard or non-surgical P2/N95 respirators are not fluid resistant.

Use a surgical P2/N95 respirator when:

- performing tasks, such as surgery, that may expose HWs to high pressure streams that produce aerosols of blood or body fluid
- performing a high risk respiratory AGP on a patient with suspected, probable or confirmed COVID-19 or other infectious respiratory illness. Refer to CEC Infection
Prevention and Control Practice Handbook

For respiratory AGPs on suspected, probable or confirmed COVID-19 cases, a standard P2/N95 respirator together with a face shield or a visor could also be used.

Standard P2/N95 respirators can be used for dry airborne situations such as caring for patients with suspected or confirmed tuberculosis, measles or chickenpox where minimal exposure to droplets is expected.

For more information refer to:

- **Appendix F:** Properties of P2 and N95 Masks
- **Appendix G:** P2/N95 Mask Range within NSW Health
- **Appendix H:** Recommended Guidance on Mask Use in NSW Health

**Before selecting RPE, the following should be considered:**

- Identify hazards (e.g. the respiratory hazards to which HWs will be potentially exposed during routine and emergency situations)
- Proper donning, doffing and use of respirators
- Mandatory fit check (user seal check) to provide maximum protection training and competency assessment
- Fit check (user seal check) at point of use every time a respirator is used. Refer to the donning and fit checking of P2/N95 respirators in NSW healthcare settings video series available through HETI My Health Learning (Course code 319438161) for more information
- HWs are to ensure that they have the physiological ability to wear a respirator

A respiratory protection program should be in place and consideration for fit testing should occur only after fit (seal) checking is fully implemented. Fit testing may provide additional information to determine the suitable type(s) of P2/N95 respirators for an individual. It is important to know that HWs with any amount of facial hair around the chin may NOT be able to achieve a seal with a tight-fitting half or full-face respirator (P2/N95).

Australian and New Zealand standards and P2/N95 respirator manufacturers’ instructions for use (IFU) require no facial hair for the wearer to achieve a good facial seal. No member of staff is required or expected to undertake any work requiring a P2/N95 respirator unless an adequate facial seal can be achieved. Ensure a risk assessment is conducted on the possibility of removing facial hair (beard), redeployment or alternative respiratory protective device provision where the HW cannot achieve an adequate facial seal.

For more information refer to the below flowchart for Respiratory Protection-Fit Checking and Fit Testing Process.
Flowchart - Respiratory Protection-Fit Checking and Fit Testing Process

1. **Disposable P2/N95**
   - **Fit Check**
     - **Pass**
       - **Fit test based on HWs risk category**
         - **Pass**
     - **Fail**
       - **Fit test different size/brand**
         - **Fail**

2. **Tight fitting PAPR**
   - **No fit test required**
     - **Fit Check**
       - **Pass**
     - **Fail**
       - **Fit test different size/brand**
         - **Fail**

3. **Loose fitting PAPR**
   - **Fit Check**
     - **Pass**
     - **Fail**

**Notes:**
- A **Fit check** must be performed each time a respirator is donned.
- A **Pass** equals optimal fit & can proceed with use of respirator.
- A **Fail** equals optimal fit is not achieved (fit fail).
- **Tight fitting PAPR** - with an exhalation valve, wear a surgical mask or filter over the exhalation valve.
- **Loose fitting PAPR** - with exhalation valve, wear a surgical mask underneath respirator.

COVID-19 Infection Prevention and Control
Application of PPE during COVID-19
Version 3.0 - December 2020
UNCONTROLLED WHEN PRINTED
Page 18 of 52
Note: a P2/N95 respirator should not be sealed with tape. It should be fit checked and if unable to form a seal, a different respirator should be used.

Respirators with exhalation valves protect the wearer from COVID-19 but may not prevent the virus spreading from the wearer to others because there is no filter for the exhalation valve. The exhalation valve is designed to open during exhalation to allow exhaled air to exit the respirator and then it closes tightly during inhalation.

Until data are available to describe how effective respirators with exhalation valves are in preventing the spread of COVID-19 from the wearer to others:

- HWs are to wear a respirator without an exhalation valve
- If only a respirator with an exhalation valve is available, cover the exhalation valve with a surgical mask that does not interfere with the respirator fit

**Use a P2/N95 disposable respirator when:**

Caring for suspected, probable or confirmed COVID-19 patients:

- In situations where there are patients/residents cohorted in one area or ward; AND/OR
- Where there is prolonged and close contact with these patients; AND/OR
- For respiratory aerosol-generating procedures (AGPs)

P2/N95 respirators are also required for:

- HWs caring for patients with airborne communicable diseases such as pulmonary or laryngeal tuberculosis, measles or Varicella Zoster virus.

**Optimal use of P2/N95 respirators**

For the optimal use of a P2/N95 respirator, organisations should consider the following:

- P2/N95 respirators must be prioritised for HWs performing respiratory AGPs on patients with suspected, probable or confirmed COVID-19 and whilst caring for patients under airborne precautions for other reasons.
- Minimise the number of individuals who need to use respiratory protection through the preferential use of engineering and administrative controls, such as:
  - minimising the number of HWs in the room
  - ensuring well-ventilated isolation rooms
  - air-handling systems (with appropriate directionality, filtration, exchange rate, etc.) that are properly installed and maintained
  - appropriate triage and placement of patients
  - patients (over the age of 12 years) with acute respiratory symptoms wearing a surgical mask
  - patients educated regarding respiratory and hand hygiene
  - training of HWs in donning and doffing PPE and fit checking
- P2/N95 respirator alternatives e.g., other classes of filtering face piece respirators or powered air purifying respirators, must be risk assessed and fit for use in healthcare, and specific use is to be endorsed by the Local Health District (LHD)/ Specialty Health Network (SHN) Clinical Governance and Infection prevention and control/Infectious Diseases services

- Implement practices allowing extended or sessional use when acceptable or practical within COVID-19 areas/zones

- HWs to wear a respirator without an exhalation valve. If this is not possible, see section “Before selecting RPE, the following should be considered” above for additional considerations when using respirators with exhalation valves.

Discarding P2/N95 respirators after use

A P2/N95 respirator should be:

- Discarded and replaced if it becomes contaminated with blood, respiratory or nasal secretions, or other bodily fluids

- Discarded and replaced if it becomes hard to breathe through or if the mask no longer conforms to the face or loses its shape or fit

- Removed outside of patient care areas or before caring for patients requiring other precautions (e.g. between rooms or patient zones, or before entering break rooms or reception areas) and before proceeding to care for patients that are not isolated for COVID-19

- Discarded following an AGP on a suspected, probable or confirmed COVID-19 case

Alternatives to Disposable P2/N95 Respirators

There are a variety of masks used by HWs when caring for patients with infections such as COVID-19. In situations where there is a risk of airborne spread, the recommended RPE is a particulate filter mask or respirator. For some HWs and in some conditions, the available disposable P2N/95 respirators may not provide optimal fit. In this situation, alternatives to consider include:

Elastomeric Respirators

Elastomeric respirators, such as half facepiece or full facepiece tight-fitting respirators, consist of facepieces which are made of synthetic or natural rubber material. These respirators can be repeatedly used after cleaning, disinfection and storage. Some types of elastomeric respirators can offer higher assigned protection factors (APFs) than disposable P2/N95 respirators. Elastomerics may also have sealing surfaces and adjustable straps that accommodate a better fit.

Powered Air-Purifying Respirators (PAPRs)

A PAPR is a battery-powered device that provides filtered air under positive pressure into either a loose-fitting hood or helmet or a tight-fitting facepiece. Because the filtered air is delivered under positive pressure, the device can compensate for an imperfect seal. For this reason, a PAPR is regarded as potentially providing a higher level of protection than other RPE but is more complex to use and maintain.
In industrial settings, filtered air may be provided to the user directly from a cylinder or pipeline supply, rather than using a battery-powered motor and cartridge filter.

**What is the difference between disposable P2/N95 respirators, reusable elastomeric respirators and PAPRs?**

The most significant difference between disposable respirators, reusable elastomeric respirators and PAPRs is that reusable respirators must be maintained and inspected after each use, including cleaning and disinfection of the reusable components such as facepiece valves, valve covers, and straps.

Refer to Appendix G for Difference between Elastomeric and PAPR Loose fitting vs Tight fitting Face Piece.

**Figure 1 Examples of different types of respirators**

<table>
<thead>
<tr>
<th>Half-Face Disposable</th>
<th>Half-Face Reusable</th>
<th>Full-Face Reusable</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Image" /></td>
<td><img src="image2" alt="Image" /></td>
<td><img src="image3" alt="Image" /></td>
</tr>
<tr>
<td><img src="image4" alt="Image" /></td>
<td><img src="image5" alt="Image" /></td>
<td><img src="image6" alt="Image" /></td>
</tr>
<tr>
<td><img src="image7" alt="Image" /></td>
<td><img src="image8" alt="Image" /></td>
<td><img src="image9" alt="Image" /></td>
</tr>
</tbody>
</table>

**Considerations for use of elastomeric respirators in healthcare settings during the COVID-19 pandemic**

There are several types of elastomeric respirators, including half-facepiece or half mask (APF = 10) and full-facepiece (APF = 50). The specific cautions, limitations, and restrictions of use should be understood when determining whether to use these respirators in healthcare facilities. Respirators with full-facepieces have the same filter considerations but provide greater protection because of better sealing characteristics with less face seal leakage and protection to more of the face including the eyes. Three types or series of filters are available for use with reusable elastomeric respirators. Filters are classified by their resistance to...
degradation by oil-based aerosols:

- N-Series filters are not oil-resistant
- R-Series filters are somewhat oil-resistant
- P-Series filters are oil-resistant

Manufacturers provide use-time limitations and other restrictions depending on the respirator’s intended use. Manufacturers have specific instructions regarding the timing of filter disposal. It is critical that for each type of filter the manufacturer’s instructions are followed. Some models may have a prefilter disc, particle filter and exhalation valves. The cleaning and disinfection or replacement of filters must be considered before the procurement of these items.

There are two distinct circumstances in which reusable elastomeric respirators could be considered for use in health care settings - routine use and surge use. Surge use is defined as use in times when there is a sharp increase in demand for respirators, such as when there is a sudden or rapidly progressive influx of patients with COVID-19.

There are several implementation issues that arise from the current design of reusable elastomeric respirators. These issues include:

1. Storage, cleaning, and disinfection and capability to comply with manufacturer’s instructions for reprocessing within the healthcare facility
2. Assess HW tolerability of the respirator before fit testing
3. Procurement and supply logistics and emergency stockpiles
4. Other issues such as regulatory and policy issues and guidelines
5. Just-in-time training - including training on fit testing and proper use during a pandemic with limited time and resources

Decisions on the selection and purchase of respirators for use in healthcare facilities should involve input from infection prevention and control, Work Health and Safety, biomedical engineering, the sterilization department and product evaluation committee or local procurement. The design of respirators significantly influences their use. Even the most “protective” of devices is not effective if it is not comfortable for the user. The following items should be considered if a facility decides to procure reusable elastomeric respirators:

- Ensure that the respirator is designed for healthcare and has Therapeutic Goods Administration (TGA) approval and an Australian Register of Therapeutic Goods (ARTG) number
- As models may vary, an individual assessment of each of these models needs to be done prior to determining whether to use these respirators in healthcare settings
- They do not provide fluid resistance based on their NIOSH approval, but they can provide at least equivalent protection to aerosols as a non-surgical P2/N95 respirator
- They require maintenance and a supply of replaceable components including straps, inhalation and exhalation valves, valve covers, filters, cartridges and canisters
- Additional maintenance requirements which also include cleaning and disinfection of the facepiece components such as straps, valves, and valve covers
While it is often possible to decontaminate the hard-outer casing of filters, the filter material itself typically cannot be cleaned or disinfected for reuse. Instead, filter components should be discarded when they become damaged, soiled or clogged, follow manufacturer’s IFU

HW training on safe and appropriate use is essential

Determining if masks are to be shared or allocated to an individual HW. The sharing of these devices along with the complexities of reprocessing potentially increases the risk of cross contamination between wearers

Communication may be difficult when wearing these items and full mask versions may fog up during use requiring an antifogging adapter to ensure that exhaled air passes through the filters and not into the mask

Fit testing (quantitative) is required for all users of these respirators, prior to initial use and as indicated, or when there are any changes in the employee’s physical condition, such as weight gain or loss, facial scarring or dental changes that could alter fit of the facepiece. In addition, a user fit (seal) check is required each time the respirator is used

**Caution**: Elastomeric respirators with exhalation valves should not be used due to concerns that unfiltered air or SARS-CoV-2 (from an infected wearer) expelled from the exhalation valve may contaminate the surrounding environment and potentially sterile surgical fields or may be inhaled by other people.

**Figure 2 An Example of a Reusable Elastomeric Respirator**

**Use of a Powered-Air Purifying Respirator (PAPR)**

The type and amount of airborne contaminant will dictate the type of filter, cartridge or canister required for the PAPR. A PAPR may have a tight-fitting half- or full-facepiece or a loose-fitting facepiece, hood or helmet. It has an OSHA APF of at least 25 for loose-fitting hoods and helmets, 50 for tight-fitting half masks, and 1,000 for full facepiece types and some loose-fitting hoods and helmets where the manufacturer’s testing has demonstrated an APF of 1,000.

Some PAPRs are supplied with a loose-fitting disposable or reusable hood that eliminates the need to perform fit testing and allows use by a broad range of individuals. Some of the more recent versions may be supplied and used without a hood.
PAPR respirators use a rechargeable battery pack to power an air blower. This blower pulls contaminated air through the particulate or gas filter, then into the face mask. Depending on the model, this air may blow constantly or be activated by inhaling. Expired air escapes from the face mask through an exhalation valve. Care should be taken when selecting a PAPR for use in healthcare to ensure that it is fit for purpose for use in this environment.

Considerations include:

- If a HW is required to remain in a patient’s room continuously for a long period of time to perform multiple procedures e.g. more than one hour, where practical and available, the use of a PAPR may be considered for additional comfort and visibility.
- Different types of relatively lightweight, comfortable PAPRs are now available and where risk assessed as suitable, should be used according to the manufacturer’s instructions.
- Care should be taken on removal of the PAPR, which is associated with a higher risk of contamination.
- Requires HW training and competency assessment prior to implementation.
- A designated donning and doffing assistant or colleague should be considered, especially in doffing a PAPR.
- Reusable components of the PAPR should be reprocessed following use, according to the manufacturer’s recommendations and comply with AS/NZS4187:2014 Reprocessing of reusable medical devices in health service organisations and local facility or service processes.
- These items must only be purchased in consultation with the facility infection prevention and control team and/or infectious disease advice in accordance with facility/service capacity to reprocess these items.

**PAPRs with exhalation valves**

Some models do not have filters on the exhalation valve. PAPRs with no filter on the exhalation valve should not be used due to the risk of unfiltered air or SARS-CoV-2 (from an infected wearer) expelled from the exhalation valve contaminating the surrounding environment and potentially exposing other individuals. When a PAPR with an exhalation valve is being worn in the operating theatre, an exhalation valve filter or a surgical mask should be worn under a PAPR or over a facemask respirator. This is not necessary with some hooded models.

**Considerations when using PAPRs in healthcare settings include:**

- A PAPR may interfere with the HW’s visual field because of the limited downward field of view.
- The HW’s ability to hear may be reduced because of the blower noise, and noise induced by the movement of a loose head covering.
- The HW’s ability to use a stethoscope may be limited.
- PAPR batteries must be recharged or replaced.
- PAPRs require a significant amount of storage space in between shifts.
• The facility must train HWs or other staff to maintain and properly clean and disinfect the PAPR

**Figure 3 An Example of Tight Fitting PAPR**

![An Example of Tight Fitting PAPR](image)

Adapted from CleanSpace®

**Use of a Loose Fitting PAPR**

A loose fitting PAPR has a loose-fitting facepiece that forms a partial seal with the face but leaves the back of the neck exposed. Clean air is distributed to the breathing zone through the partial seal.

A loose fitting PAPR can be considered for HWs who are not able to be fit checked with particulate filtering disposable respirators or a tight-fitting respirator due to facial hair and cannot be clean shaven due to religious or cultural reasons. It is also an option for those with facial scaring or specific face structures which have led to failure of fit checking and fit testing for all available disposable P2/N95 respirators.

- A fit test is not required for PAPRs with loose-fitting headgear such as hoods and helmets
- PAPRs with loose-fitting headgear can be worn with a limited amount of facial hair
- Hooded PAPRs and PAPRs with helmets may offer limited to significant splash protection for the face and eyes
- PAPR systems have assigned protection factors (APF) of at least 25 (and up to 1,000 in some cases)
• Some PAPRs have disposable, loose-fitting headgear and patients can see the face of the HW, providing for better interpersonal communication
• Most PAPR components can be cleaned, disinfected, re-used, and shared
• A PAPR may be less taxing from a physiological/breathing resistance perspective than other respirators
• Although loose-fitting PAPRs do not have the same fit testing costs that P2/N95 respirators have, they do have higher capital costs

Respirator fit checking and fit testing

Fit checking or user seal check is a process to ensure that the P2/N95 respirator fits the wearer’s face snugly (i.e. creates a seal) to minimise the number of particles that bypass the filter through gaps between the wearer’s skin and the mask seal.

Detailed Fit Checking Process

Fit checking at time of use has been and continues to be the most reliable method of ensuring the HW has achieved an optimal fit and required seal in real time (CEC Respiratory Protection in Healthcare, 2020). Fit checking involves a check - each time the mask is put on - to ensure that the respirator is properly applied and is the appropriate minimum standard at the point of use for HWs using respirators.

The respirator must be put on (donned) and taken off (doffed) correctly and worn throughout the exposure or period required.

HWs should complete the My Health Leaning module – donning and fit checking of respirator CEC, receive training locally to be able to perform fit checks including during the fit testing process. Under WHS legislation, it is always the responsibility of each HW to be familiar with and comply with these protective measures when there is an identified exposure risk.

Follow the manufacturer’s instructions on donning, fit checking and doffing for individual brands and types of P2/N95 respirators. An example of the steps for fit checking are as follows:

• Place the respirator on the face.
• Place the headband or ties over the head and back of neck.
• Compress the respirator to ensure a seal across face, including the cheeks.
• Gently conform/press the nosepiece across the bridge of nose by pressing down with fingers using both hands until the fit is snug.
• Continue to adjust the respirator along the outside until there is a good and comfortable facial fit.
• Gently place hands around the edge of the respirator to feel any air escaping when the fit check is assessed.
• Maintain the integrity of the respirator without damaging or altering the structure when adjusting for seal.

Also refer to Principles of Fit Checking and CEC PPE donning and doffing training videos for more information.

Healthcare settings are to ensure that a range of models and sizes of P2/N95 respirators are available for HWs so that users can have access to respirators that achieve a seal
against their face.

For more information refer to Appendix H Respirator Selection Decision Making Algorithm.

- HWs are to perform a fit check **each time a respirator is donned** to check that a good facial seal is achieved i.e. the mask is sealed over the bridge of the nose and mouth and there are no gaps between the respirator and the face.

- Fit checking is a process used for all tight-fitting respirators regardless of whether fit testing is conducted.

- It is important to know that HWs with any amount of facial hair between the sealing surface of respirator face piece and the wearers’ skin will prevent a good seal with any tight-fitting respirators. Beards, moustaches and sideburns prevent satisfactory sealing. Australian and New Zealand standards and P2/N95 respirator manufacturers’ IFU require no facial hair for the wearer to achieve a good facial seal.

- A risk assessment should be conducted on the possibility of redeployment or alternative respiratory protective device provision where the HW cannot achieve an adequate facial seal.

**Fit testing** is performed to determine whether a specific type, model and size of respirator is a suitable fit for the wearer and that it is worn correctly to achieve a facial seal and comfort.

Facepiece fit test methods are classified as either qualitative or quantitative:

- A qualitative fit test is a pass/fail test that relies on the wearer’s sensory detection of a test agent, such as taste, smell, or involuntary cough (a reaction to irritant smoke). This method uses a hood and an odour or taste solution to determine the ability of the respirator to filter out the smell or taste of the test agent.

- A quantitative fit test uses an instrument to numerically measure the effectiveness of the respirator by equipment that measures air leakage into the respirator/mask.

**Requirements for fit testing**

With the emergence of global infectious diseases such as COVID-19 and Severe Acute Respiratory Syndrome (SARS), there is a need for HWs to be able to work safely and be protected against exposure to respiratory pathogens. For this to be done systematically, LHDs, SHNs and NSW Ambulance are required to implement a Respiratory Protection Program (RPP). Refer to CEC Respiratory Protection in Healthcare guidance document and CEC Respiratory Protection Program Implementation Resources for more information.

A key component of a successful RPP is the assignment of responsibilities for the implementation and coordination of the program. The program should be overseen by a suitably trained person with an understanding of the principles of respiratory protection and the authority to implement the program. This is best led in collaboration between local Work Health and Safety and Infection Prevention and Control teams.

A fit testing program includes the following components:

- Identification of a dedicated fit testing coordinator or assessor
- Training of an adequate number of internal staff to be competent in fit testing training and assessment
- A process to identify which employees are to be included in a fit testing program including those working in high risk clinical areas, and the priority for training
- Selection of appropriately certified P2/N95 respirators for fit testing which are the same make, model and size of masks that employees are expected to use in practice
- Appropriate storage of disposable respirators according to the manufacturer’s specifications (e.g. temperature and humidity) with stock controlled and rotated based on use by date or manufactured date
- Non-disposable respirators: A procedure and schedule for storing, inspecting and disposing of respirators, and cleaning, disinfecting, repairing and maintaining respirators as per the manufacturers’ instructions
- Training for staff in understanding transmission risk of airborne pathogens
- Training for staff in the proper use of respirators including fit checking
- An evaluation framework to ensure the program responds to the needs of employees based on local risk assessment
- Fit testing assessors should undergo an annual competency assessment
- Documentation system should be established to record HW fit testing results (baseline and ongoing). This should be accessible to both HWs and managers providing the ability to continually determine the type of respirator(s) required for each individual, including between LHDs/SHNs

Who should be fit tested?

A risk-management approach should be applied to ensure that HWs routinely and regularly working in areas with a significant risk of exposure to diseases transmitted via the airborne route are fit tested and are aware of how to perform a fit check. Fit testing will not negate the need for fit checking every time a P2/N95 respirator is put on. For more details refer to Respiratory Protection in Healthcare.

Issues to consider when fit testing

- One mask can’t fit everyone
- People experience physiological changes such as weight gain or loss
- HWs with facial hair
- Particles and environmental conditions while testing
- Accessibility of the exact same make, model, style, and size of respirator used to fit test
- Stock availability during pandemic
- Time and resource implications
**Fit test failure**

When conducting a fit testing program, to reduce the chance of failure of fit testing the following are needed:

- Ensure there is a reasonable supply of different styles and sizes of respirators including non-disposable respirators
- Ensure HWs are properly trained in fit checking
- Fit testing procedures must be applied appropriately

**Management of HWs unable to be fit tested**

- Where a HW is unable to be fitted to any available disposable respirators, a risk management approach should be implemented to establish control measures. These include:
  - Identification of high-risk procedures (e.g. respiratory AGPs) the HW is unable to perform and a suitable substitute
  - Identification of high-risk patients the HW is unable to provide care for
  - Redeployment to suitable duties, or clinical area if necessary
- Where a HW is essential to the clinical area and cannot be reassigned, fit testing of alternative respirators should occur
- Where the above steps have been taken and the individual is still unable to be fitted to an appropriate disposable respirator, the use of a PAPR or an elastomeric respirator could be considered for fit testing. A referral will be made to the designated PAPR fit test assessor for the facility/LHD.

Refer to [Appendix G Difference between Elastomeric Respirators and PAPRs (Loose Fitting and Tight Fitting Face Pieces)](#) for more information

**Note:** The reusable respirators have cleaning and disinfection requirements and any individual who requires the use of these respirators has ownership of the filters. The other components of the respirators are reprocessed by the hospital.

**Extended or sessional use of PPE**

Extended use or sessional use of PPE refers to a period of time where a HW is undertaking duties in a specific care setting/exposure environment and is wearing the same PPE for repeated close contact episodes with several patients, e.g., on a ward round or providing ongoing care for multiple inpatients in a cohort area. **Extended use refers only to the use of masks and eye protection. Gowns and gloves need to be changed after each patient contact.**

Extended or sessional use of PPE is only recommended when caring for patients with suspected, probable or confirmed COVID-19.

- Extended use is well suited to situations where multiple patients are infected with the same microorganisms and patients are cohorted together in dedicated waiting rooms or hospital wards
- The decision on extended or sessional use of PPE must be based on a risk assessment, clinical situation, local facility needs and consultation with the
facility infection prevention and control team

- A single session refers to a period where a HW is undertaking duties in a specific clinical care setting or exposure environment. A session ends when the health worker leaves the care setting/exposure environment.

- International guidance states that surgical masks can be worn for up to 4 hours and a P2/N95 respirator for up to 8 hours continuously or uninterrupted for multiple patients without removing the mask unless damaged, soiled or contaminated. However, the use of one mask for longer than 4 hours is likely to be poorly tolerated (increasing the risk of self-contamination) and is not recommended.

- The duration of use of PPE items should not exceed the manufacturer’s instructions.

- Extended or sessional use of aprons or gowns is not recommended when providing patient care.

- PPE must be changed in between all other patients (if worn) including those with known multidrug resistant organisms.

- Gloves must be removed, and hand hygiene performed in between patients.

For guidance on appropriate use of PPE in community and home visits refer to COVID-19 Infection Prevention and Control Guidance for Home Visits.

Reprocessing

Depending on the model some respirators’ reusable components cannot be cleaned with solvents (e.g. ethanol) or exposed to temperatures greater than 50°C (122°F).

Facilities using reusable respirators must ensure that the reprocessing process complies with AS/NZS 4187: 2014 Reprocessing of reusable medical devices in health service organisations and the manufacturer’s instructions for use (IFU). Depending on the model, the facepiece components are removed from the facepiece to be cleaned and disinfected. There are several basic steps to clean and disinfect a respirator – remove, clean, disinfect, rinse and dry, inspect and repair or replace, and store.

Facilities should organise the following based on manufacturers’ IFU:

- Cleaning
- Chemical or thermal disinfection
- Drying and storage
- Inspection
- Particulate filter replacement
- Respirator storage
- Training for reprocessing
Bringing your own PPE and/or PPE brought in without approval

In the decision-making process regarding use of privately-owned PPE and/or PPE brought in by clinicians, a local and LHD/SHN or state-wide service level approval is required on the suitability of the item(s) in the clinical setting before use. The facility should also identify the following:

- All PPE must conform to AS/NZS standards and have obtained approval for use in healthcare. This information is required from the PPE manufacturer
- ARTG registration and certificate
- Approval for use via HealthShare and by the clinical department concerned, the hospital concerned and the LHD/SHN Executive (PPE strategic Committee). The full approval process of the equipment must be documented
- PPE must be assessed and accepted by Infection Prevention and Control, Work Health and Safety, Unit Managers for use within the facility and the facility’s sterilizing service manager, who will undertake service compatibility and risk assessment for reprocessing between uses within the capacity of their sterilizing facility
- Manufacturer’s IFU on reprocessing, filter management and maintenance, and a supply of replaceable components including straps, inhalation and exhalation valves, valve covers, filters, cartridges and canisters
- Insurance coverage for privately owned PPE that requires reprocessing within the health facility
- Local procurement processes and biomedical engineering requirements
- Appropriate training is required for the safe use of all PPE. Training and education should be clearly documented. The manufacturer may be obligated to provide training in the proper use of the PPE
- Decision on who will provide and take responsibility for the training and assessment of the HW wearing or using his/her own PPE
- Donning and doffing procedures may need to be altered to accommodate non-standard equipment and this will need assessment by Infection Prevention and Control
- The financial and resource implications, including the capacity to accommodate the volume, complexity, storage and resources required for reprocessing

Reprocessing of PPE during the COVID-19 pandemic

The CEC does not recommend or endorse any strategies for PPE use that differ from standard infection prevention and control practice. In times of a pandemic and global supply shortages, temporary emergency strategies can be considered.

Manufacturer’s instructions for reprocessing including cleaning and disinfecting should be followed and HWs must be trained as needed to ensure that equipment is reprocessed after each use.

It is important that organisations considering reprocessing medical devices intended for single
use understand the following points:

- Disinfection or re-sterilization alone is not enough to render the device fit for reuse.
- Reprocessing (cleaning and disinfection and/or sterilization) may have a deleterious effect on the safety and performance of single-use masks and gowns that may not be obvious to the end user.
- Any individual or entity reprocessing medical devices for reuse meets the legislative definition of a manufacturer under the therapeutic goods legislation and will need to meet all legislative obligations and responsibilities for manufacturers.
- These responsibilities include ensuring that reprocessing activities (such as repeated cleaning and disinfection or sterilization) do not affect the material properties or effectiveness of the device.
- Some PPE, such as P2/N95 respirators, may not be compatible with reprocessing activities, including gamma and ionizing radiation, as these damages or impairs the device.
- Those who reprocess single-use medical devices must demonstrate that the device will continue to perform as originally intended following their reprocessing activities, noting that damage to the device may not be apparent during a visual inspection.
- The reprocessing of single-use medical devices is considered as "off-label" use and the healthcare setting is responsible for all risks and associated liabilities with "off-label" use of medical devices.
- When a single use item is reprocessed for reuse, the healthcare facility responsible for carrying out reprocessing activities meets the legislative definition of a manufacturer as per ARTG Therapeutic Goods Act 1989, as they have:
  - changed the intended purpose of the device
  - certified the device is suitable for reuse
  - assumed legal liability for the quality, safety and performance of the device.

Factors to consider when reprocessing single-use medical devices for reuse in order to meet the Essential Principles include the following:

- Reprocessing single-use PPE must not be undertaken without prior written approval from the NSW Ministry of Health.
- Requires approval by an LHD/SHN PPE Governance Committee.
- Procedures and safeguards must be implemented to prevent inadvertent environmental contamination with hazardous microorganisms (including from the point of collection environment through to the reprocessing environment).
- Procedures and safeguards must be implemented to prevent inadvertent exposure of individuals in these environments to hazardous microorganisms.
- Processes should be established for reprocessed items to enable traceability and tracking during reprocessing and reuse.
References


## Appendix A: Recommended PPE for health workers in clinical settings

<table>
<thead>
<tr>
<th>Setting</th>
<th>Context</th>
<th>DISPOSABLE GLOVES</th>
<th>PLASTIC APRON</th>
<th>ISOLATION GOWN</th>
<th>SURGICAL MASK</th>
<th>P2/N95 RESPIRATOR</th>
<th>EYE PROTECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute hospital inpatient and emergency departments (ED), dental and maternity settings</td>
<td>Working with patients NOT suspected of COVID-19</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Working in ED with any patients within 1.5 metres (No AGP)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Performing AGPs on patients NOT suspected of COVID-19</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Working in an inpatient area with suspected, probable or confirmed case(s)¹ (not within 1.5 metres) No AGP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Performing a single AGP² on a suspected, probable or confirmed case(s)¹ in any setting</td>
<td>✓ single use³</td>
<td>x</td>
<td>✓ single use³</td>
<td>x</td>
<td>✓ single use³</td>
<td>✓ single use³</td>
</tr>
<tr>
<td></td>
<td>Working in a higher risk acute care area⁵ with suspected, probable or confirmed case(s)¹ - direct patient care (within 1.5 metres) No AGP</td>
<td>✓ single use³</td>
<td>✓ single/ extended use⁶</td>
<td>✓ RA⁷ single/ extended use⁶</td>
<td>✓ single/ extended use⁶</td>
<td>✓ single/ extended use⁶</td>
<td>✓ single/ extended use⁶</td>
</tr>
<tr>
<td></td>
<td>Working in an inpatient area with suspected, probable or confirmed case(s)¹ – direct patient care (within 1.5 metres)</td>
<td>✓ single use³</td>
<td>✓ single/ extended use⁶</td>
<td>✓ RA⁷ single/ extended use⁶</td>
<td>✓ single/ extended use⁶</td>
<td>✓ single/ extended use⁶</td>
<td>✓ single/ extended use⁶</td>
</tr>
</tbody>
</table>

¹ Inpatient includes emergency department (ED), ambulatory care, dental, and maternity settings.
² AGP: Aerosol generating procedure.
³ Single use: single use only.
⁴ Clean reusable in between use: can be cleaned and reused during the shift.
⁵ Higher risk acute care area: includes ICU, high dependency unit, critical care, and inpatient ward with patient(s) with COVID-19.
⁶ Single/extended use: single use if no extended use is available.
⁷ RA: Respiratory protection.
### Acute hospital inpatient and emergency departments, dental and maternity settings (cont.)

<table>
<thead>
<tr>
<th>Context</th>
<th>COVID-19 Case</th>
<th>DISPOSABLE GLOVES</th>
<th>PLASTIC APRON</th>
<th>FLUID RESISTANT OR ISOLATION GOWN</th>
<th>SURGICAL MASK</th>
<th>P2/N95 RESPIRATOR</th>
<th>EYE PROTECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Working in an emergency department / acute assessment area with suspected, probable or confirmed case(s) (within 1.5 metres)</td>
<td></td>
<td>☑ single use³</td>
<td>☑ single/ extended use⁶</td>
<td>☑ single/ extended use⁶</td>
<td>☑ single/ extended use⁶</td>
<td>☑ single/ extended use⁶</td>
<td>☑ single/extended use⁶ clean reusable in between use⁴</td>
</tr>
<tr>
<td>Working in a procedural area such as radiology, with suspected, probable or confirmed case(s) (within 1.5 metres)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All individuals transferring suspected, probable or confirmed case(s) (within 1.5 metres)</td>
<td></td>
<td>☑ single use³</td>
<td>☑ RA⁷ single/ extended use⁶</td>
<td>☑ RA⁷ single/ extended use⁶</td>
<td>☑ single/ extended use⁶</td>
<td>☑ single/ extended use⁶</td>
<td>☑ single/extended use⁶ clean reusable in between use⁴</td>
</tr>
<tr>
<td>Working in an Operating Theatre (non-scrubbed staff) with suspected, probable or confirmed case(s) (no AGPs)</td>
<td></td>
<td>☑ single use³</td>
<td>☑ Single use³</td>
<td>☑ Single use³</td>
<td>☑ single/ extended use⁶</td>
<td>☑ single/ extended use⁶</td>
<td>☑ single/extended use⁶ clean reusable in between use⁴</td>
</tr>
<tr>
<td>Working in a delivery/birthing suite with suspected, probable or confirmed case(s)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Acute hospital inpatient and emergency departments, dental and maternity settings (cont.)

<table>
<thead>
<tr>
<th>Context COVID-19 Case</th>
<th>DISPOSABLE GLOVES</th>
<th>PLASTIC APRON</th>
<th>FLUID RESISTANT OR ISOLATION GOWN</th>
<th>SURGICAL MASK</th>
<th>P2/N95 RESPIRATOR</th>
<th>EYE PROTECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleaning a room or zone after a suspected, probable or confirmed case(s)¹</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓ single/extended use⁶</td>
<td>RA⁷ within 30 minutes of an AGP</td>
<td>✓ single/extended use⁶ clean reusable in between use⁴</td>
</tr>
<tr>
<td>When providing care to vulnerable⁸ patient groups (within 1.5 metres) - use protective precautions</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓ single/extended use⁶</td>
<td>✓ single/extended use⁶</td>
<td>✓</td>
</tr>
<tr>
<td>Outpatients</td>
<td>Respiratory specimen collection in fever clinics, COVID-19 clinics, GP practices whether in hospital or outpatient setting</td>
<td>✓</td>
<td>✓</td>
<td>RA⁷ single/extended use⁶</td>
<td>✓ single/extended use⁶</td>
<td>✓ single/extended use⁶ clean reusable in between use⁴</td>
</tr>
<tr>
<td>Working in Primary Care, ambulatory and outpatient - with suspected, probable or confirmed case(s)¹</td>
<td>✓</td>
<td>✓</td>
<td>RA⁷ single/extended use⁶</td>
<td>✓ single/extended use⁶</td>
<td>✓ single/extended use⁶ clean reusable in between use⁴</td>
<td></td>
</tr>
<tr>
<td>Patient Transport Services</td>
<td>Working with patients with suspected, probable or confirmed COVID-19</td>
<td>✓</td>
<td>✓</td>
<td>RA⁷ single/extended use⁶</td>
<td>✓ single/extended use⁶</td>
<td>✓ single/extended use⁶ clean reusable in between use⁴</td>
</tr>
<tr>
<td>Setting/Context</td>
<td>DISPOSABLE GLOVES</td>
<td>PLASTIC APRON</td>
<td>ISOLATION GOWN</td>
<td>SURGICAL MASK</td>
<td>P2/N95 RESPIRATOR</td>
<td>EYE PROTECTION</td>
</tr>
<tr>
<td>-----------------</td>
<td>-------------------</td>
<td>---------------</td>
<td>----------------</td>
<td>---------------</td>
<td>------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Ambulance or Emergency Response team, No AGP, not acutely unwell or actively coughing</td>
<td>✓ single use³</td>
<td>✓ single/extended use⁶</td>
<td>RA⁷ single/extended use⁶</td>
<td>✓ single/extended use⁶</td>
<td>❌</td>
<td>✓ single/extended use⁶ clean reusable in between use⁴</td>
</tr>
<tr>
<td>Working with patients with suspected, probable or confirmed COVID-19</td>
<td>✓ single use³</td>
<td>✓ single/extended use⁶</td>
<td>RA⁷ single/extended use⁶</td>
<td>✓ single/extended use⁶</td>
<td>❌</td>
<td>✓ single/extended use⁶ clean reusable in between use⁴</td>
</tr>
<tr>
<td>Acutely unwell, or actively coughing patient suspected, probable or confirmed COVID-19</td>
<td>✓ single use³</td>
<td>✓ single/extended use⁶</td>
<td>RA⁷ single/extended use⁶</td>
<td>❌</td>
<td>✓ single use³</td>
<td>✓ single use³ clean reusable in between use⁴</td>
</tr>
<tr>
<td>Performing a single AGP on a suspected, probable or confirmed case(s) in any setting</td>
<td>✓ single use³</td>
<td>✓ single/extended use⁶</td>
<td>RA⁷ single/extended use⁶</td>
<td>❌</td>
<td>✓ single use³</td>
<td>✓ single use³ clean reusable in between use⁴</td>
</tr>
</tbody>
</table>
Notes for Appendix A

1. A case is any individual meeting the case definition for a suspected, probable or confirmed case.
2. A list of aerosol-generating procedures (AGPs) can be found in CEC Infection Prevention and Control Aerosol-generating procedures in relation to COVID-19
3. Single use refers to disposal of PPE or decontamination of reusable items e.g. reusable respirator, after each patient and/or following completion of a procedure or task; dispose or decontaminate reusable items after each patient contact as per Infection Control Standard Precautions.
4. This may be reusable face/eye protection/ face shield, safety glasses or goggles.
5. High-risk clinical areas include: Intensive Care Units (ICU), Emergency Departments (ED), COVID-19 Wards, Acute Respiratory Assessment Clinics.
6. Extended use or sessional use refers to a period of time where a health worker (HW) is undertaking duties in a specific care setting/exposure environment e.g. on a ward round or providing ongoing care for inpatients. A session ends when the HW leaves the care setting/exposure environment. Sessional use should always be risk assessed and considered where there are high numbers of hospital cases. Extended use of aprons/gowns can be considered if there is minimal contact of the apron or gown with the patient or their surroundings, the apron or gown is not used during an AGP and it is not visibly contaminated. PPE should be disposed of after each session or earlier if damaged, soiled, moist or uncomfortable.
7. Risk assessment (RA) refers to utilising PPE for appropriate protection when there is an anticipated/likely risk of contamination with splashes, droplets, or blood or body fluids.
8. Vulnerable people may include the following based on disease severity, history or treatment levels: solid organ transplant recipients, cancer patients, patients with severe respiratory conditions and other immunosuppressed individuals.
Appendix B: Visual Guide to Application of PPE

- Gloves should be changed, and hand hygiene performed between patients; change or remove gloves when clinically indicated, if contaminated, moving from dirty to clean site on the same patient or when damaged or torn
- Perform hand hygiene immediately after removing gloves and other PPE if there is risk of contamination between steps
- Gown/apron should be removed and discarded appropriately upon completion of care (session) and/or on leaving the room/zone
- Reusable eye protection should be cleaned/disinfected between use
- Clean and disinfect reusable shared patient equipment and high touch points
### Appendix C: AAMI Level Standards for Gowns


<table>
<thead>
<tr>
<th>Barrier Performance</th>
<th>Barrier Protection</th>
<th>Resistance Measure</th>
<th>Description</th>
</tr>
</thead>
</table>
| Level 1             | Minimal            | Liquid penetration | • Used for MINIMAL risk situations  
|                     |                    |                    | • Provides a slight barrier to small amounts of fluid penetration  
|                     |                    |                    | • Single test of water impacting the surface of the gown material is conducted to assess barrier protection performance. |
| Level 2             | Low                | Liquid penetration | • Used in LOW risk situations  
|                     |                    |                    | • Provides a barrier to larger amounts of fluid penetration through splatter and some fluid exposure through soaking  
|                     |                    |                    | • Two tests are conducted to assess barrier protection performance:  
|                     |                    |                    |   • Water impacting the surface of the gown material  
|                     |                    |                    |   • Pressurising the material |
| Level 3             | Moderate           | Liquid penetration | • Used in MODERATE risk situations  
|                     |                    |                    | • Provides a barrier to larger amounts of fluid penetration through splatter and more fluid exposure through soaking than Level 2  
|                     |                    |                    | • Two tests are conducted to test barrier protection performance:  
|                     |                    |                    |   • Water impacting the surface of the gown material  
|                     |                    |                    |   • Pressurising the material |
| Level 4             | High               | Liquid and viral penetration | • Used in HIGH risk situations  
|                     |                    |                    | • Prevents all fluid penetration for up to 1 hour  
|                     |                    |                    | • May prevent VIRUS penetration for up to 1 hour  
|                     |                    |                    | • In addition to the other tests conducted under Levels 1-3, barrier level performance is tested with a simulated blood containing a virus – if no virus is found at the end of the test, the gown passes. |
Appendix D: AS 4381:2015 Single use surgical face mask standard


<table>
<thead>
<tr>
<th>Testing</th>
<th>Barrier Performance</th>
<th>Bacterial Filtration Efficiency (BFE) %</th>
<th>Differential pressure ($\Delta P$), mmH₂O/cm²</th>
<th>Resistance to penetration by synthetic blood (fluid resistance) minimum pressure in mmHg for pass result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mask materials are evaluated for resistance to penetration by synthetic blood, bacterial filtration efficiency and differential pressure</td>
<td>Level 1</td>
<td>$\geq 95%$</td>
<td>$&lt; 4.0$</td>
<td>80mm Hg</td>
</tr>
<tr>
<td></td>
<td>Level 2</td>
<td>$\geq 98%$</td>
<td>$&lt; 5.0$</td>
<td>120mm Hg</td>
</tr>
<tr>
<td></td>
<td>Level 3</td>
<td>$\geq 98%$</td>
<td>$&lt; 5.0$</td>
<td>160mm Hg</td>
</tr>
<tr>
<td></td>
<td>Test method</td>
<td>ASTM F2101-14 or EN 14683:2014</td>
<td>EN 14683:2014</td>
<td>ASTM F1862 /F1862M-13 or ISO 22609</td>
</tr>
</tbody>
</table>
### Appendix E: Properties of P2 and N95 respirators

<table>
<thead>
<tr>
<th>Properties</th>
<th>P2 Respirator</th>
<th>N95 Respirator</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Other names</strong></td>
<td>N95 masks, respiratory protection device, particulate respirator</td>
<td>P2 respirator, respiratory protection device, particulate respirator</td>
</tr>
<tr>
<td><strong>Characteristics</strong></td>
<td>P2 particulate filtering respirators/masks must have a filter efficiency of at least 94% when tested with sodium chloride aerosol at a flow rate of 95 litres/minute. Under the EN system, aerosol testing is similar to Standard AS/ NZS 1716: 2012 but has additional filter efficiency testing with paraffin oil aerosol that must also meet the minimum 94% filter efficiency to be classified as P2. The particle size of this aerosol has a median diameter of 0.3 to 0.6 microns with a range of particles in the 0.02 to 2-micron size range.</td>
<td>NIOSH classified N95 particulate filtering respirators/masks must have a filter efficiency of at least 95% when tested with sodium chloride aerosol at a flow rate of 85 litres/minute. N95 respirator masks can only be used for oil free aerosols. The particle size of this aerosol is ~0.3 micron.</td>
</tr>
</tbody>
</table>

- Raised dome or duckbill
- 4–5 layers (outer polypropylene, central layers electret [charged polypropylene])
- Filtration through mechanical impaction and electrostatic capture
- Designed to provide a good facial fit to minimise aerosol contamination of the mucous membranes of the nose and mouth

| Sealing | Ties or straps at crown and bottom of head, pliable metal nose bridge
- Recommend Fit checking all respirators, Fit testing based on risk category |

| Australian Standards | Standard AS/NZS 1715: 2009
Standard AS/NZS 1716: 2012 | Set by the US NIOSH classification (NIOSH Guidelines – Procedure No. TEB-APR-STP-0059) |

| Intended use | Routine care of patients on airborne precautions
- High-risk procedures (or AGPs) such as bronchoscopy when the patient’s infectious status is unknown, or the patient has suspected, probable or confirmed COVID-19
- Procedures that involve aerosolisation of particles that may contain specific known pathogens (AGPs) |

| Notes | Care must be taken if placing respirators on patients and must suit clinical need i.e., if the patient has chronic obstructive airways disease (COAD) or is in respiratory distress, the respirator will exacerbate symptoms. |

Source: Australian Guidelines for the Prevention and Control of Infection in Healthcare, 2019
## Appendix F: P2/N95 Respirator Range within NSW Health (Surgical)

<table>
<thead>
<tr>
<th>Respirator</th>
<th>Description</th>
<th>P2/N95</th>
<th>Fluid resistant</th>
<th>Standard</th>
<th>Precautions suited to</th>
<th>Specifications and additional information</th>
</tr>
</thead>
</table>
| BYD        | BYD N95 respirator                               | N95    | 16kPa          | NIOSH    | Airborne / AGP         | • Meets CDC guidelines for *Mycobacterium tuberculosis* exposure control  
• FDA cleared for use as a surgical mask  
• 99% BFE (Bacterial Filtration Efficiency) according to ASTM F2101  
• Fluid resistant according to ASTM F1862  
• Respirator contains no components made from natural rubber latex  
• Collapse resistant cup shape design  
• Braided headbands, cushioning nose foam, and light weight construction for comfortable wear  
• >95% filtration efficiency against solid and liquid aerosols free of oil  
• 4-ply Protection, PFE 95%, Splash Resistance Pressure 16kPa |
| BSN Medical (Aust) Pty Ltd  
Code:848174 | BSN Medical P2/N95 Filter, Medium, Pleated, Double Strap (Proshield) | P2/N95 | 160mmHg | AS/NZS 1716:2012 | Airborne / AGP | • Bacterial Filtration Efficiency (BFE) of greater than 99% for particles greater than 3 microns.  
• The super high Particulate Filtration Efficiency (PFE) material filters more than 99% of particles greater than 0.1 microns.  
• The N95 mask is NIOSH approved as an N95 particulate filter respirator. It meets or exceeds the |
<table>
<thead>
<tr>
<th>Respirator</th>
<th>Description</th>
<th>P2/N95</th>
<th>Fluid resistant</th>
<th>Standard</th>
<th>Precautions suited to</th>
<th>Specifications and additional information</th>
</tr>
</thead>
</table>
| BSN Medical (Aust) Pty Ltd  | P2/N95 Filter, Small, Pleated, Double Strap       | P2/    | 160mmHg         | AS/NZS 1716:2012    | Airborne / AGP        | standard performance criteria demanded by the US National Institute for Occupational Safety and Health (NIOSH) for the management of tuberculosis  
  • The fluid resistant qualities of the mask provide protection against fluid strikethrough. |
| Code: 848175               | (Proshield)                                      | N95    |                 |                     |                       |                                                                                                                                                                                                                                               |
| 3M Australia Pty Ltd Code:  | P2 masks                                         | P2/    | 120mmHg         | AS/NZS 1716:2012    | Airborne / AGP        | • NIOSH certified N95  
  • Meets CDC guidelines for *Mycobacterium tuberculosis* exposure control  
  • FDA cleared for use as a surgical mask  
  • Bacterial Filtration Efficiency (BFE) more than 99% according to ASTM F2101  
  • Fluid resistant according to ASTM F1862 at 120 mmHg  
  • Mold nose clip to wearer’s nose shape to help reduce eyewear fogging and ensure a better seal/fit  
  • Respirator contains no components made from natural rubber latex  |
| 832352                     | 1860                                             | N95    |                 |                     |                       |                                                                                                                                                                                                                                               |
| 3M Australia Pty Ltd Code:  | P2 masks                                         | P2/    | 160mmHg         | AS/NZS 1716:2012    | Airborne / AGP        | • NIOSH certified N95  
  • Meets CDC guidelines for *Mycobacterium tuberculosis* exposure control  
  • FDA cleared for use as a surgical mask  
  • Bacterial Filtration Efficiency (BFE) more than 99% according to ASTM F2101  
  • Fluid resistant according to ASTM F1862 at 160 mm Hg  
  • Respirator contains no components made from natural rubber latex  
  • Red coloured head straps for health care use  
  • Mold nose clip to wearer’s nose shape to help reduce eyewear fogging and ensure a better seal/fit  |
<p>| 832353                     | 1870                                             | N95    |                 |                     |                       |                                                                                                                                                                                                                                               |</p>
<table>
<thead>
<tr>
<th>Respirator</th>
<th>Description</th>
<th>P2/N95</th>
<th>Fluid resistant</th>
<th>Standard</th>
<th>Precautions suited to</th>
<th>Specifications and additional information</th>
</tr>
</thead>
</table>
| 3M Australia Pty Ltd Code:832383 | P2 respirator 8110S | P2 | N/A | AS/NZS 1716: 2012 | Dry airborne* | • Lightweight construction for added comfort that may increase wearer time  
• Mould nose clip to the wearer’s nose shape to help reduce eyewear fogging and for a better seal and fit  
• Made from 3M™ Advanced Electret Filter Material for effective filtration with low breathing resistance  
• Does not contain components made from natural rubber latex  
• Fluid Resistant (ASTM F1862) - not applicable  
• N95 (similar to Class P2) rated filtration efficiency  
• Protects against hazards such as dusts, mists, smoke and fume |
| KN95# | N95 respirator | N95 | N/A | GB2626-2006 | Dry airborne * | • Meets performance requirements of AS/NZS 1716 (P2) and complies with NIOSH N95  
• Material: Non-woven fabric  
• Standard: KN95  
• Protection Class: KN95/FFP2  
• Filtering Rate: ≥95% (0.075μm particles)  
• Applications: hospitals, outpatient clinics  
• Fluid Resistant (ASTM F1862) - not applicable |

*Standard P2/N95 respirator can be used for dry airborne situations such as tuberculosis, measles or Chickenpox where minimal exposure to droplets are expected.

#KN95 respirators/masks are the Chinese standards for respirators. N95 masks are the USA standards for respirators. There are requirements that the USA National Institute for Occupational Safety and Health requires manufacturers to meet in order to label their masks as N95s. Mask standards for Europe (FFP2), Australia (P2), Korea (KMOEL), and Japan (DS) are also highly similar. There are different brands and levels of KN95 respirators available; when selecting a KN95 respirator ensure that the particulate filtration level and fluid resistance aligns with the requirements of P2/N95 respirators. Some P2/N95 respirators are not fluid resistant, if fluid resistance status is unknown, wear the respirator with a face shield or surgical mask while performing AGPs.
### Appendix G: Difference between Elastomeric Respirators and PAPRs (Loose fitting vs Tight fitting Face Pieces)

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Elastomeric respirators</th>
<th>Loose fitting PAPR</th>
<th>Tight fitting PAPR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
<td>Non-powered</td>
<td>Powered</td>
<td>Powered</td>
</tr>
<tr>
<td>Figure</td>
<td><img src="image1.png" alt="Elastomeric respirator" /> <img src="image2.png" alt="Elastomeric respirator" /></td>
<td><img src="image3.png" alt="Loose fitting PAPR" /> <img src="image4.png" alt="Loose fitting PAPR" /></td>
<td><img src="image5.png" alt="Tight fitting PAPR" /> <img src="image6.png" alt="Tight fitting PAPR" /></td>
</tr>
<tr>
<td>Specifications</td>
<td>An elastomeric respirator is a reusable device with exchangeable cartridge filters. They are tight fitting respirators that are generally either a half facepiece or full facepiece where the facepieces are made of synthetic or natural rubber material with a removable filter.</td>
<td>Most models are a battery powered blower that pulls air through attached filters or cartridge. The blower forces the ambient air through air-purifying elements [a filter cartridge] to the inlet covering [a hood, helmet or facepiece]. The blower then pushes the filtered air into the facepiece. This process creates an air flow inside either a tight-fitting facepiece or loose-fitting hood or helmet, providing an assigned protection factor (APF) between 10-100.</td>
<td></td>
</tr>
<tr>
<td>Facepiece</td>
<td>A tight-fitting half or full facepiece</td>
<td>A loose-fitting facepiece, hood, or helmet</td>
<td>A tight-fitting half or full facepiece</td>
</tr>
<tr>
<td>Limitations</td>
<td>More commonly used in industrial and mining settings, but some models may be assessed for use in healthcare. Currently there are no standardised procedures for cleaning and disinfection of these items within healthcare environments. Caution must be taken regarding the use and reuse of elastomeric respirators to decrease contamination of the inside of the respirator and thus increasing the risk of infecting health workers between use.</td>
<td>The safe levels of contaminant concentrations may have been established for industries but have not been determined for healthcare settings. Only provide protection if the correct type of filters and/or cartridge(s) is/are used for the contaminant(s) of concern. PAPR batteries must be recharged or replaced, respirators require significant amount of storage space between shifts and a robust maintenance program for replacing or repairing components that have become damaged during use or during cleaning and disinfection is required. Competent HWs are required to support the PAPR maintenance program and HWs must be competent and trained on appropriate use, cleaning and disinfection of the item. PAPRs also require ongoing or at least adequate supply of various parts e.g. for the Halo mask, extra neck supports, harnesses etc.</td>
<td></td>
</tr>
<tr>
<td>Criteria</td>
<td>Elastomeric respirators</td>
<td>Loose fitting PAPR</td>
<td>Tight fitting PAPR</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-------------------------</td>
<td>--------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>Description</td>
<td>Non-powered</td>
<td>Powered</td>
<td>Powered</td>
</tr>
<tr>
<td></td>
<td>The nosepiece can affect the ability to achieve satisfactory fit for safety or prescription spectacles, operating microscopes or other technical equipment.</td>
<td>The HW’s ability to hear may be reduced because of the blower noise, and noise induced by the movement of a loose head covering. In case of battery or fan failure there is a risk of build-up of carbon dioxide exhaled by the wearer, and breathlessness.</td>
<td>Performance can be markedly reduced by facial hair between the facepiece and the face and by the arms of spectacles. May cause discomfort and or heat build-up during hard work or in hot environments.</td>
</tr>
<tr>
<td>Assigned protection factor (APF)</td>
<td>Half face elastomeric APF = 10</td>
<td>Loose-fitting hoods and helmets APF = 25</td>
<td>Tight-fitting half masks APF = 50</td>
</tr>
<tr>
<td></td>
<td>Full facepiece elastomeric APF = 50</td>
<td></td>
<td>Tight-fitting full facepiece APF = 1000</td>
</tr>
<tr>
<td>Face to respirator seal</td>
<td>Require an excellent face-to-facepiece seal</td>
<td>Do not require a close face-to-facepiece seal.</td>
<td>Require a good face-to-facepiece seal</td>
</tr>
<tr>
<td>Fit Test Required</td>
<td>As the facepiece of the elastomeric respirator should form a tight seal against the user’s face, fit testing may be required</td>
<td>A fit test is not required for PAPRs with loose-fitting headgear such as hoods and helmets</td>
<td>Some models require fit testing, in the event of blower failure.</td>
</tr>
<tr>
<td>Comfort to the wearer</td>
<td>Some faces may achieve better seal, by some users may experience discomfort due to physiological responses, such as perceived increased temperature under the facepiece or skin irritation</td>
<td>Due to the use of highly efficient filters and utilisation of positive pressure, the constant airflow provides a cooling effect on the user. A PAPR may be less taxing from a physiological/breathing resistance perspective than other respirators</td>
<td></td>
</tr>
<tr>
<td>Facial Hair</td>
<td>Facial hair will interfere with face and respirator seal</td>
<td>Compatibility with facial hair and various facial structures</td>
<td>Facial hair will interfere with face and respirator seal</td>
</tr>
<tr>
<td>Integrated Eye Protection</td>
<td>Only for full-face models</td>
<td>Yes</td>
<td>Only for full-face models</td>
</tr>
<tr>
<td>Fluid Resistance</td>
<td>Some models are fluid resistant</td>
<td>Fluid resistant</td>
<td>Fluid resistant</td>
</tr>
<tr>
<td>Level of Protection</td>
<td>Under testing conditions, the protection provided by reusable elastomeric respirators varies by filter type and model and they provide less protection than PAPR or supplied-air types of respirators.</td>
<td>Over breathing of a loose fitting PAPR would result in some measurable volume of ambient air entering the breathing vicinity of the wearer. Therefore, over breathing could potentially expose the wearer.</td>
<td>Generally, very low risk of contaminated air leaking into the respirator</td>
</tr>
<tr>
<td>Criteria</td>
<td>Elastomeric respirators</td>
<td>Loose fitting PAPR</td>
<td>Tight fitting PAPR</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>-------------------------</td>
<td>--------------------</td>
<td>--------------------</td>
</tr>
<tr>
<td>Description</td>
<td>Non-powered</td>
<td>Powered</td>
<td>Powered</td>
</tr>
<tr>
<td></td>
<td></td>
<td>to contaminant risks while wearing a loose fitting facepiece</td>
<td></td>
</tr>
<tr>
<td>Integrated PPE from the Neck Up</td>
<td>Half facepiece provides no coverage of head or neck</td>
<td>Only a hooded model provides neck and head protection</td>
<td></td>
</tr>
<tr>
<td>Visualisation</td>
<td>Line of sight may impede with some models e.g. when intubating or insertion of intravascular access devices. Full face piece will allow patients to see HWs face. May interfere with the visual field while looking downwards.</td>
<td>The clear face shield will allow patients to see the HWs face</td>
<td>Full face piece will allow patients to see HWs face</td>
</tr>
<tr>
<td></td>
<td></td>
<td>May interfere with the HW's visual field because of the limited downward vertical field of view</td>
<td></td>
</tr>
<tr>
<td>Clinical care</td>
<td>Does not interfere with the use of some medical equipment such as a stethoscope</td>
<td>The use of a stethoscope may be limited. Allow other equipment to be used concurrently such as headlights, loupes, mask underneath the unit</td>
<td>Full facepiece may limit the use of a stethoscope</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Communication</td>
<td>The facepiece can affect the intelligibility of the wearer’s speech</td>
<td>Interference with hearing and mobility. The HW’s ability to hear or be heard may be reduced because of the blower noise, and noise induced by the movement of a loose head covering.</td>
<td></td>
</tr>
<tr>
<td>Exhalation valves</td>
<td>Have a separate exhale vent, but this is not filtered. Exhaled air may be contaminated. Recommend that an expiratory filter or a surgical mask is worn to cover the exhilation valve for source control.</td>
<td>There is no filter on the exhalation valve. When a PAPR is being worn in the operating theatre, it is recommended that a surgical mask be worn under a PAPR or over a facemask respirator. This is not necessary with some hooded models.</td>
<td>There is no filter on the exhalation valve. It is recommended that a surgical mask be worn on top of exhalation valves to reduce the microbial dispersal from the wearer. Filters for expiratory ports are under development.</td>
</tr>
<tr>
<td>Cleaning and disinfection</td>
<td>Specific procedures for cleaning and disinfection (reprocessing) within healthcare environments must be</td>
<td>Most PAPRs have components that are disposable. Reusable components must be cleaned and disinfected between use as per the manufacturer instructions. Any reprocessing will be required to be undertaken in a central</td>
<td></td>
</tr>
<tr>
<td>Criteria</td>
<td>Elastomeric respirators</td>
<td>Loose fitting PAPR</td>
<td>Tight fitting PAPR</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-------------------------</td>
<td>--------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>Non-powered</td>
<td>Powered</td>
<td>Powered</td>
</tr>
<tr>
<td></td>
<td>established for the environment where elastomeric may be used. To ensure reliability, it is recommended that reprocessing be undertaken in a central sterilising department. The filter material itself typically cannot be cleaned or disinfected for reuse. Specific safe working procedures must be in place to manage the filters. Filter components should be discarded when they become damaged, soiled, or clogged.</td>
<td>sterilising department. The outside of the filter cartridge can have surface cleaning and decontamination while the rest of the unit is being serviced. Viruses and bacteria causing acute respiratory infections can survive on respirator components for variable periods of time, from hours to weeks. Consequently, contaminated respirators must be handled, cleaned, and disinfected properly to reduce the possibility of the device serving as a fomite and contributing to disease transmission. Any procedure that is used to clean and disinfect the PAPR and its components must be recommended or approved by the manufacturer. Cleaning and disinfection must be done by competent, trained individuals. Centralising this activity can ensure it is properly done.</td>
<td></td>
</tr>
<tr>
<td><strong>Maintenance</strong></td>
<td>Require maintenance and a supply of replaceable components including straps, inhalation and exhalation valves, valve covers, and filters, cartridges, or canisters</td>
<td>PAPR batteries must be recharged or replaced and ongoing maintenance is required. Change cartridges as needed and inspect equipment for problems. Involve biomedical engineers in the maintenance process.</td>
<td></td>
</tr>
<tr>
<td><strong>Cartridge and Filter Replacement</strong></td>
<td>Each manufacturer has instructions regarding cartridge and filter replacement.</td>
<td>The correct combination of filters and cartridges must be used. Cartridges and filters have a limited life and should ideally be equipped with end-of-service-life indicators (ESLI). In the absence of an ESLI, the manufacturer’s recommended change schedule must be observed.</td>
<td></td>
</tr>
<tr>
<td><strong>Education and training</strong></td>
<td>Training shall be provided by a competent person and it should cover donning, fit checking, fit testing, appropriate use, doffing, cleaning and disinfection, maintenance, filter change and storage.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix H: Respirator Selection Decision Making Algorithm

Fit Procedure

Don BYD respirator

Don BSN respirator

Don 3M respirator

Fit Test

Real time Fit Check using FitPro Ultra software

Fit Procedure

Fit Procedure

Fit Procedure

Fit test report should be generated and recorded for every respirator, pass or fail

Pass

Pass

Pass

Failed

Failed

Failed

Fit to BYD

Fit to BSN

Fit to 3M

Re-useable Respirator

Tight fitting PAPR (some models to be fit tested)

Reusable Elastomeric Respirator

Loose fitting PAPR (No fit test required)

Fit to re-useable respirator

Re-check and re-test with different fit test assessor

AND

Continue to explore alternative and suitable disposable P2/ N95 respirators, until options exhausted

AND

Consider risk assessment and redeployment

Fit to re-useable respirator
Notes for Appendix H

1. Nose strip and strap adjustment should reflect real time adjustment which will be made in a clinical setting. Excessive adjustments in order to achieve fit not to be attempted.

2. Check the following conditions for the adequacy of the respirator fit:
   - Chin properly placed
   - Adequate strap tension
   - Respirator of proper size to span distance from nose to chin
   - Not overly tightened
   - Fit across nose bridge

   Have the HW wearing the respirator do a user seal check. If leakage is detected, determine the cause of the leak. ‘Real time fit check’ should not be used as a pass/fail result.

3. Medium BSN respirator should be checked in preference to small due to lower stock level of small BSN respirators (subject to change)