Clinical Excellence Commission

Respiratory Protection Program Manual

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Version 2.0

NSW GOVERNMENT | CLINICAL EXCELLENCE COMMISSION

Revision History (most recent updates are highlighted in yellow)		
Version	**Date**	**Changes**
Version 2.0	November 2023	Chapter 1.1 inclusion of product disclaimer 1.4.2 inclusion of respiratory protective devices 1.4.3 inclusion of psychological needs/reasons to facial hair exemption process 1.4.4 amendments to Table 2 Fit testing prioritisation guide and appendix 1A respirator fit testing guidance Chapter 2 introduction- inclusion of HealthShare, Step 4 document of record and 2.3.4 documentation and data management and Appendix 2F Data collection and reporting of fit test results. Chapter 3.1 inclusion of product disclaimer, 3.2 amendments to guiding principles for utilisation of RPDs to include Manufacturer's instructions must be read, understood, and followed for all aspects of RPD and accessories use, reprocessing, maintenance (like calibration and correct charging), and storage. 3.10 Inclusion of the need for a governance program is required when implementing PAPRs and the importance of following manufacturer's instructions. 3.11 Inclusion of biohood, amendment to 3.11.2 HALO PAPR inspection and link to HALO smart app, and amendments to cleaning procedure for the HALO PAPR Chapter 4.1 minor amendments to introduction, 4.2 fit testing, 4.7 and Appendix 4A inclusion of psychological needs / reasons to facial hair exemption process, MHL Beard Cover technique course code and Inclusion of Appendix 4F Quantitative Fit Testing Machine Troubleshooting Guide (generic)
Version 1.2	October 2022	Addition of NSW Health position description information Minor amendment to Appendix 1B Recommendation added to FTA learning pathway Recommendation of MHL course added to Appendix 4A
Version 1.1	June 2022	Minor amendments to Chapter 1 and 2
Version 1.0	December 2021	Incorporated 7 RPP resource documents into manual

Contents

1.1 Introduction

Local Health Districts (LHDs), Specialty Health Networks (SHNs) New South Wales (NSW) Ambulance and HealthShare are required to implement a Respiratory Protection Program (RPP) as health workers (HWs) are required to be able to work safely and be protected against exposure to respiratory pathogens including acute respiratory infections (ARIs) such as COVID-19. Existing respiratory protection controls (transmission-based precautions, introduced in 1996) within NSW health have successfully provided protection to our HWs against respiratory communicable diseases. It is expected that an RPP will complement existing Infection Prevention and Control (IPAC) and Work Health and Safety (WHS) programs.

This document provides guidance for LHDs/SHNs, HealthShare and NSW Ambulance regarding respiratory protection which uses a risk management approach based on the risk of exposure to infectious pathogens spread by respiratory aerosols. The risk mitigation includes education and training in the correct application of respiratory protection devices (RPDs). The Chief Executive of the LHD/SHN or NSW Ambulance assigns leadership responsibility, personnel, and resources to implement and comply with this guidance.

This guidance document focuses on respiratory protection in relation to the use of respirators and what is required to ensure they are managed, worn, and used safely. It does not address other aspects of IPAC or other types of personal protective equipment (PPE). For information on infectious diseases that require the use of PPE that are not addressed in this document refer to the Infection Prevention and Control Policy Directive, the NSW Infection Prevention and Control Practice Handbook and the Infection Prevention and Control Manual COVID-19 and other acute Respiratory Infections.

Fit checking (user seal-check or self-check) of respirators on each occasion 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. Any RPP should continue to promote fit checking every time a new respirator is applied or donned along with the other controls detailed in this document.

This document should be used in conjunction with national guidelines and NSW policies, procedures, and guidelines.

NOTE: Any reference to specific product is for providing example only. Neither NSW Health or the Clinical Excellence Commission (CEC) endorse or promote any products or equipment identified in this guidance document.

1.2 Purpose

Respiratory protective devices (RPDs) are designed to protect the wearer from inhalation hazards such as airborne infectious agents and in some cases, dust, and other particles. Risks for health workers (HWs) are not uniform and this document is designed for those HWs who are at the highest risk of exposure because they are attending to patients with suspected or confirmed respiratory infection, communicable diseases with potential for airborne transmission (e.g., pulmonary or laryngeal tuberculosis, measles or chicken pox) or respiratory infections with potential for aerosolisation of particles (e.g., influenza, COVID-19, respiratory syncytial virus [RSV]).

Respiratory protection is one aspect of both infection prevention and control (IPAC) as well as work health and safety (WHS) strategies for ensuring HW safety at work. Implementation of respiratory

protection program (RPP) requires a comprehensive supporting program and depending on the RPD design, guidance should be developed on the selection, facepiece fit testing and use of an RPD.

1.3 Definitions

Term	Definition
Aerosol generating behaviour (AGB)	Activities such as shouting, singing, and coughing, especially in in an enclosed, poorly ventilated space, can increase the amount of droplet production and range of droplet dispersal.
Aerosol generating procedure (AGP)	AGPs produce droplet nuclei (< 5 micrometres in size) or airborne particles (aerosols) due to air or gas flowing rapidly over a moist or wet surface.
AccuFIT 9000 PRO™	The AccuFIT9000 Pro™ is a device used for fit testing and measures particles inside and outside a respirator in order to calculate a fit factor.
Air-purifying respirator	A respirator with an air-purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying filter.
Assigned protection factor (APF)	The workplace level of respiratory protection that a respirator or class of respirators is expected to provide to health workers.
Canister or cartridge	A container with a filter, sorbent or catalyst, or combination of these items, which removes specific contaminants from the air passed through the container.
Elastomeric	A respirator facepiece made of a natural or synthetic elastic material such as natural rubber or silicone.
Filtering facepiece	A negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium.
Fit check	A manual procedure that is used each time a respirator is used to ensure a seal is achieved.
Fit factor	A quantitative estimate of the fit of a respirator to a specific individual and typically estimates the ratio of the concentration of particles in ambient air with its concentration inside the respirator.
Fit test	A validated process (either qualitatively or quantitatively) of determining the type and size of a respirator that achieves an adequate seal on an individuals' face.
Health worker (HW)	Refers to all staff delivering or supporting healthcare services in a public health organisation. Any person employed or contracted by a NSW Health agency either on a permanent, temporary, casual, volunteer or agency basis.

Loose-fitting facepiece	A respirator that is designed to form a partial seal with the face.
PortaCount™	A PortaCount™ machine is a device used for fit testing and measures particles inside and outside the respirator in order to calculate a fit factor.
Powered air-purifying respirator (PAPR)	A respirator that uses a blower to force ambient air through a filter for the wearer.
Qualitative fit testing	Qualitative fit testing is a pass/fail test method that uses taste or smell, or a reaction to an irritant in order to detect leakage into the respirator facepiece.
Quantitative fit testing	Quantitative fit testing uses a machine to measure the actual amount of leakage into the facepiece and does not rely upon taste, smell, or irritation in order to detect leakage.
Respirator	A device worn over the nose and mouth to protect the wearer from inhaling hazardous materials.
Respiratory protective device (RPD)	Type of PPE, used to protect the individual wearer against the inhalation of hazardous substances in the workplace air.
Tight-fitting facepiece	A respirator that forms a complete seal with the face.

1.4 Infection prevention and control components of an RPP

Infection prevention and control considerations

Respiratory protection is required for those organisms that are usually transmitted via the airborne route, or when particles have been artificially created, such as from aerosol generating behaviour (AGB) or an aerosol generating procedure (AGP).

A respiratory protective device (RPD) is worn on the face, covers the nose and mouth, and is used to reduce the wearer's risk of inhaling hazardous airborne particles (including dust particles and infectious agents), gases, or vapours. There is a range of PPE available that provides facial and respiratory protection, and this includes either a surgical mask or a respirator with or without eye protection. The use of respiratory protection should be considered an essential element of defence in the hierarchy of infection prevention measures.

1.4.1 Vaccination program and compliance

Health workers (HWs) may be exposed to or transmit vaccine-preventable respiratory infections such as influenza, measles, rubella, pertussis, and COVID-19. Maintaining immunity in the HW population helps prevent transmission of vaccine-preventable diseases to and from HWs and patients.

HWs are required to follow the mandatory Occupational Assessment, Screening and Vaccination against Specified Infectious Diseases policy directive. The Australian Government Department of Health Influenza Vaccination and COVID-19 vaccines requirements should also be followed.

1.4.2 Personal protective equipment

Personal protective equipment (PPE) is an important component of a risk management program to prevent potential exposure to communicable diseases. When recommending PPE, risk assess the specific roles and activities of health workers (HWs) along with the engineering and administrative controls that focus on room ventilation. For more information refer to Infection Prevention and Control Manual COVID-19 and other Acute Respiratory Infections.

Respiratory protective devices

There are two main types of respiratory protection—air-purifying respirators (APRs) and atmosphere-supplying respirators (ASRs). ASRs are used during work in places with low oxygen levels and high content of hazardous gases. More information can be found here.

Each respirator type provides a different level of protection based on its design. Below are the different types of APRs:

- Powered air-purifying respirator are reusable and often have a hood or helmet that covers the nose, mouth, and eyes. A battery-powered blower pulls air through filters or cartridge.
- Elastomeric full facepiece respirators are reusable and cover the nose, mouth, and eyes.
- Elastomeric half mask respirator are reusable respirators and cover the nose and mouth.
- Particulate filtering facepiece respirator (respirators) are disposable respirators that cover the nose and mouth.

Respirators

A particulate filter respirator (also known as a P2 or N95 mask) is used by an individual to provide respiratory protection from airborne particles. In the healthcare setting, this most commonly relates to the disposable filtering half-face mask. In this document the term respirator refers to filtering masks used to protect HWs from airborne infectious particles.

Non-sterile face masks (including respirators) that are intended, by their manufacturer, to prevent the transmission of diseases between people, or are intended to be used in a healthcare environment, are medical devices and are regulated by the Therapeutic Goods Administration (TGA) under the Therapeutic Goods Act 1989. Unless exempt, medical devices must be included in the ARTG before being imported into or supplied in Australia, exported from Australia, or advertised in Australia.

There are two main types of respirators available:

Disposable respiratory protective devices (RPD)

Disposable filtering facepiece respirators (or P2/N95 mask), where the entire respirator is discarded on completion of an episode of care, or when it becomes unsuitable for further use due to excessive resistance, physical damage, or contamination. This type of respirator is also known as an unassisted RPD.

- Disposable respirators are the most common devices used in healthcare settings for respiratory protection. Each time these items are used, they must be checked for defects e.g., elastic head pieces unevenly attached, marks on the respirators and tears. Disposable respirators found to be defective are to be discarded and replaced. The relevant supervisor/line manager should be notified; he/she may need to advise local procurement through existing communication and escalation protocols.
- LHD/SHNs should check the Respiratory fit testing algorithm and supply and issuance guide when commencing the LHD/SHN fit testing program for stock availability to ensure that there is adequate supply of P2/N95 respirators to fit test HWs and to prioritise procurement and

stock at each facility. Refer to *Appendix 1A: Respirator fit testing guidance* for more information.

NB: the term 'mask' is often used when referring to a filtering respirator. The correct term for devices which provide this level of protection is 'respirator'.

==Use a respirator (e.g., P2/N95 respirator) and eye protection:==

- When providing care or ==in close contact== with patients with suspected or confirmed COVID-19
- When providing care ==or in close contact with== patients who are close contacts of others with known COVID-19
- During an aerosol generating procedure/aerosol generating behaviour in any patient with an acute respiratory infection (ARI)
- When providing care ==or in close contact with patients who have== suspected or confirmed communicable diseases spread via the airborne route (e.g., tuberculosis, measles, varicella).

NB: Fit check particulate filter respirators with each use.

Reusable respiratory protective devices (RPDs)

Reusable RPDs refer to a variety of reusable respirators that protect the user's respiratory system from exposure to airborne and aerosolised infectious agents. Reusable RPDs 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 as the wearer breathes. There are two types of reusable RPDs:

Refer to *Chapter 3: Reusable respiratory protective devices - management and use* for more information.

1.4.3 Considerations before using respirators (P2/N95 or equivalent)

Respirator filters designed to give protection against respirable biological and non-biological particles (particulate matter) are classified and marked as P1, P2 or P3, in accordance with [AS/NZS 1716:2012](). Table 1 *What to do before using P2/N95 respirators* summarises items that should be considered when utilising P2/N95 respirators or their equivalent.

Respirator fit checking

Fit checking or user seal check is a process to ensure that the 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 respirator. The respirator must be put on (donned) and taken off (doffed) correctly and worn throughout the exposure. A fit testing program (see *Chapter 2 Respiratory Protection Program Implementation Resources* for more details) can only be implemented if a fit checking process is already in place.

Considerations for fit checking:

- Fit checking is a process used for all tight-fitting respirators (e.g., P2/N95 respirators) regardless of whether fit testing is conducted.

- Fit checking at the time of use is the most reliable method of ensuring the HW has achieved an optimal fit and required seal in real time.

- All HWs who are required to wear a P2/N95 respirator must have undertaken [education]() on the importance of fit checking and know how to fit check.

- Use a secondary person to assist assessment of fit check (buddy or colleague) or a mirror where possible.

- 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 respirator is sealed over the bridge of the nose and mouth and there are no gaps between the respirator and the face. Always refer to the manufacturer's instructions for use (IFU) for fit checking of individual brands and types of P2/N95 respirators as the method may vary depending on the brand and model of the respirator. There are several different types of P2/N95 respirators available. Some of these respirator types are covered by the CEC *Donning and fit checking of P2/N95 respirators in NSW healthcare settings* video series available through [HETI My Health Learning](#) (Course code 319438161) and the poster on [Principles of fit checking](#).
- The HW must not have any facial hair present if use of a tight-fitting respirator is required, including at the time of fit testing. However, HW can seek exemption based on medical reasons, cultural or religious observance.

TABLE 1: WHAT TO DO BEFORE USING P2/N95 RESPIRATORS

Respiratory Protection Program	Facilities that require their HWs to use P2/N95 respirators (or their equivalent) should have an RPP in place. This program should include information regarding the type of respirators available for use and indications for use; training; storage and maintenance; processes and practices for fit checking and testing based on a local risk assessment.
Respirator fit check and fit test	Disposable P2/N95 respirators are designed to be tight-fitting. Their performance relies almost entirely on ensuring a good seal between the respirator and the wearer's face. If a good seal cannot be achieved, the device may fail. Air leaks around respirator edges and the wearer's face will mean that the wearer will not get the level of protection required. HWs are not required or expected to undertake any work requiring a P2/N95 respirator unless an adequate facial seal can be achieved. The respirator must always be a suitable size for the HW's face and when required to use a respirator, the HW must not have any facial hair present; this includes at the time of fit testing (see *Workers who are unable to be clean shaven due to medical reasons, cultural or religious observance*). A respirator fit check must be performed every time a respirator is applied or donned (see text below for further information regarding fit checking and fit testing).
Risk assessment	RPD is not worn in isolation; it is part of a wider planned risk management process. A risk assessment is needed to demonstrate when and where respirators should be used within the workplace and the requirement for fit testing.

Adapted from *A Guide to Buying P2, or Equivalent, Respirators for use in the Australian & New Zealand Work Environment June 2020 – Version 1.0*

Workers who are unable to be clean shaven due to medical reasons, psychological needs/reasons, cultural or religious observance

The following reasonable exemptions are noted for the wearing of a tight-fitting respirator and the need to be clean shaven:

- HWs who are unable to remove facial hair to wear a tight-fitting respirator due to medical reasons, psychological needs/reasons, cultural or religious observance. For more

information see *Appendix 4A: Use of respiratory protective device with beard cover technique*.

Where a HW fails to demonstrate a successful fit test and/or HW could not achieve a successful seal with beard cover technique, on both disposable and reusable tight-fitting respirators, HW should reconsider their ability to be clean shaven or consider whether a loose-fitting powered air purifying respirator (PAPR) is appropriate. This should be in consultation with the manager, IPAC and respiratory protection program (RPP) lead. A risk assessment should be conducted to determine the feasibility of this option from a clinical perspective.

HWs who cannot be successfully fit tested to a tight-fitting respirator or wear a loose fitting PAPR may require redeployment to another clinical area.

Managing non-compliance

Ongoing non-compliance with respiratory protection by a HW is to be managed by their manager or supervisor within local Performance Management Policies and the frameworks using the following NSW Health Policies:

- o NSW Health Managing Complaints and Concerns about Clinicians PD2018_032
- o NSW Health Code of Conduct PD2015_049
- o NSW Health Managing Misconduct PD2018_031
- o NSW Health Managing for Performance PD2016_040

Managing non-compliance may involve:

1. Targeted education for ongoing non-compliance which will include one-on-one instruction on the importance of achieving a facial seal with a tight-fitting respirator and the adherence to RPP. This requires escalation to the HWs manager.

2. Front line management response with counselling and requirements to undertake a respiratory protection education program for repeated non-compliance.

3. Participation in an intensive remedial respiratory protection education program for further non-compliance and warning that any further non-compliance in respiratory protection will result in disciplinary action and may result in dismissal. This requires escalation to the Director of Clinical Governance or Director Workforce.

Use of prophylactic dressings to prevent facial skin injury due to tight fitting respirators

Prolonged wearing of tight-fitting respirators may cause unintended skin injuries, despite taking steps to protect skin integrity. The wearing of a prophylactic dressing may be appropriate in preventing loss of skin intergrity[1].

Principles of protecting facial skin under a respirator

To avoid potential facial skin injury, HWs should take the following steps to protect skin integrity:

- Give your skin a break by limiting respirator use when not required.

- Use a mild skin cleanser, soap substitute at the beginning and end of the day. Standard soap is alkaline and has been shown to change skin pH and can damage the skin barrier function.

- Hydrate by drinking plenty of fluids during breaks.

- Avoid wearing makeup.

- Moisturise regularly using pH balanced products with no fragrances.

- Anti-ageing skin care products containing glycolic acids or retinoids can be very irritating, especially when the skin barrier is damaged or compromised; these products may also exacerbate skin sensitivity.

- If fitted to more than one respirator alternate between available fitted respirators.

Certain prophylactic dressing can be worn under a respirator providing a 'fit test' pass is achieved. Prophylactic dressings (also known as dressings used to prevent injuries or moisture) are applied under a respirator to relieve pressure. A fit check must then be performed every time a respirator is applied.

NOTE: Any reference to specific product is for providing example only. Neither NSW Health or the CEC endorse or promote any products or equipment identified in this guidance document.

Examples of prophylactic dressings for wear under a respirator:

- Mepilex™ soft silicone dressing - for pressure redistribution, friction, shear and pressure. Mepilex lite or Mepilex border lite.

- Sofsicure™ Silicone tape - silicone tape prevents friction and shear. Silicone tapes are easy to tear, are breathable, conform to the face and are designed to reduce pain and skin injury on removal.

- Comfeel™ - hydrocolloid dressing.

Selection of the type of prophylactic dressing should take several factors into consideration:

- The shape of the dressing

- The layers of the dressing

- Ability for the dressing to wick moisture (draw moisture away from the body)

- Ability of the dressing to redistribute pressure.

Prophylactic dressings are single use only and must not be 'stacked' or placed one on top of the other on the face.

- Facial skin protection should be applied after performing hand hygiene first and before donning PPE.

- Choose one of the dressings and apply as described in *Appendix 1B: Instructions for use of prophylactic dressings under tight fitting respirators.*

- Each time dressings are applied to the face, the integrity of the seal of the respirator must be checked by performing a 'fit check'.

- HW must pass a fit test with the dressing on before it's use under the respirator. For more information refer to *Appendix 1B: Instructions for use of prophylactic dressings under tight fitting respirators.*

- Facial skin protection should be removed as the last step when removing PPE. Hand hygiene must be performed before and after removing the dressing.

Respirator fit testing

Fit testing is a validated process of determining the type and size of a respirator that achieves an adequate seal on an individual's face. Although there are several published studies that show that fit testing will detect air leakage if present in respirators that have passed a fit check, the evidence showing that fit testing reduces risk of infection in HWs is currently very limited and equivocal. Despite this, Australian and New Zealand Standards 1715:2009 and current national opinion and consensus recommends fit testing for HWs working in high-risk areas when providing care to

patients with suspected or confirmed respiratory communicable diseases including COVID-19 or patients under airborne precautions. In NSW, LHD/SHNs are required to implement respirator fit testing in their facilities for HWs routinely providing clinical services to patients in airborne precautions (e.g., for pulmonary or laryngeal Tuberculosis) or patients with respiratory communicable diseases including COVID-19.

Fit testing may be conducted using two different methods; the qualitative fit test method which results in a pass or fail response, and a quantitative test, providing an estimate of the number of particles that leak into a respirator. Both methods require the wearer to be tested during normal breathing as well as other movements that would be expected during normal use of a respirator (e.g., talking, bending down and turning from side-to-side).

PAPRs and fit testing

Fit testing requirements for powered air purifying respirators (PAPRs) depend on the type of facepiece the respirator has, and some models have inbuilt mechanisms that will alert the user if a seal is not achieved.

Some tight fitting PAPRs with facepieces that form a tight seal to the wearer's face, e.g., half-masks and full facepieces, may require fit testing regardless of the mode of operation. Refer to HALO Fit testing video for further information.

Loose-fitting PAPRs, in which the hood or helmet is designed to form only a partial seal with the wearer's face or hoods which seal loosely around the wearer's neck or shoulders, do not require fit testing. For more information refer to chapter 3 Reusable Respiratory Protective Devices – Management and Use.

1.4.4 Considerations before the implementation of an RPP

Health workers (HWs) who are required to wear a respirator must be trained and assessed for competency in the use of all PPE as part of an ongoing training program. This includes student HWs on placement. Advancement from fit checking to a fit testing program should be based on HWs' level of exposure to known airborne hazards (e.g., COVID-19, tuberculosis or measles) or identification of a new and/or emerging risk. The need for a fit testing program extends beyond COVID-19 and an LHD/SHN fit testing program requires careful and planned implementation. For more information refer to *Appendix 2B: Fit testing risk assessment*.

All NSW Health position descriptions recognise a HW may be required to use a respirator as part of their appointment within NSW Health. If any HW needs to wear a respirator they will be instructed on the safe use of the respirator and may, also, require fit testing.

This does not change the need to categorise and prioritise HWs for fit testing as part of an RPP or alter the minimum standard for respirator use, which is the ability to safely fit check, don and doff a respirator.

All NSW Health Position descriptions also include the requirement to not have any facial hair when utilising a respirator unless the appropriate exemption processes have been followed.

The following elements are required and should be addressed before the implementation of a respiratory protection program:

- All HWs attending fit testing should have completed the Respirator Fit Test Learning Pathway in My Health Learning prior to being fit tested to a respirator. It is recommended the pathway is completed every 12-18 months i.e., prior to attending re-fit testing.

- The fit testing process requires all HWs to fit check a respirator successfully before progressing to fit testing a respirator.

- Education and training to ensure proper donning, doffing and use of respirators including fit checking (user seal check) is performed at the point of use, on each occasion that a respirator is used.

- Ensuring that HWs have the physiological and psychological ability to wear a respirator (medical condition/s that may interfere with wearing a tight-fitting respirator e.g., breathing difficulty, disability, or mental health condition).

- Ongoing training of HWs in respiratory protection (e.g., the respiratory hazards to which they are potentially exposed during routine and emergency situations), mandatory fit check and assessment.

- When using external providers as fit test assessors, the provider must be aware of all current and relevant IPAC policies, guidance documents and procedures within NSW Health and the Clinical Excellence Commission. External providers should be made aware of and familiar with all respirators being used for fit testing within the facility.

Priority for fit testing is based on the likelihood of caring for patients in an environment where airborne precautions are required.

Table 2 outlines a fit test prioritisation guide based on a local risk assessment in consultation with WHS and IPAC teams.

TABLE 2: FIT TESTING PRIORITISATION GUIDE

Risk category	HW category*	Clinical area
1	Critical Care areas (ICU, emergency, anaesthetics) Clinicians providing direct care to patients who require airborne precautions or are required to assist in care provision	Intubation teams, aeromedical clinicians or intensive care paramedics performing intubations
		Clinicians who work in anaesthetics, emergency departments, intensive care units, or other clinical groups performing intubation/respiratory AGPs
		Wards, clinics Disease requiring airborne precautions include pulmonary or laryngeal Tuberculosis, Measles, Varicella, SARS, emerging pathogens, or any other disease for which public health guidelines recommend airborne precautions
2	Other Clinicians/Non-Clinicians	Any other area / situation identified as high risk for HW airborne transmissible disease exposure
3	Support staff in other patient care areas	Any other area / situation identified as high risk for HW airborne transmissible disease exposure
Maintenance staff who may be exposed to inhalation of dangerous particulates and gases outside of infectious particles in the course of their work should be assessed according to WH&S requirements		

Student HWs on placement are assessed in a risk category based on their placement. Prioritisation of student HWs for fit testing is the same as clinicians.

1.5 Governance

The respiratory protection program (RPP) and other infection prevention and control (IPAC) guidelines including other policy documents indicated in this manual will require local implementation underpinned by local factors, including location and demographics, as well as service factors, such as leadership, governance, resources, and policies/procedures.

Program governance

NSW Respiratory Protection Program Board

The NSW RPP Board (the Board) provides governance, oversight, direction, and decision-making for the implementation and monitoring of the program across NSW Health facilities, including scope, resourcing, and funding.

Responsibilities include:

- Providing strategic advice and guidance on implementation and monitoring of the NSW RPP.
- Monitor progress with the ongoing implementation, and evaluation of the program
- Consider any program risks and implementation support issues.
- Ensure that the NSW RPP complies with NSW Health policies, guidelines and procedures, WHS Legislation and Australian Standards/New Zealand Standards.
- Receives, reviews, and responds to status reports on fit testing.
- Collaboratively resolves issues that have been escalated to the Board.

LHD/SHNs are required to have processes in place to comply with the recommendations and requirements for implementation of the RPP described in this manual. LHD/SHNs are to ensure that there is clear governance for the local RPP which includes the responsibilities for:

- Chief Executive

- General managers and service directors

- Respiratory Program Steering Committee (Facility/LHD/SHN)

- Procurement services

- Respiratory Protection Program Coordinator/Organisational Lead

- Supervisors / line managers

- Employees.

Chief Executive

- Ensure that a process is in place to enable the RPP to be implemented, including establishing a RPP Steering Committee or equivalent.

- Ensure that any high-risk issues related to the RPP are identified and the risks are mitigated.

- Ensure that all required resources are available for the implementation and ongoing management of the RPP.

General managers and service directors

- Apply due diligence by ensuring that the RPP Manual is implemented within their governance areas.

- Ensure that respiratory hazards / risks are identified in consultation with their HWs.

- Ensure risk assessments are undertaken across their work areas to identify HWs who require respiratory protection.

- Ensure that training and resources are available to enable compliance with this procedure.

- Ensure that identified HWs are trained and competent to perform fit testing.

- Ensure that an RPP organisational lead is appointed and supported.

Respiratory Program Steering Committee (Facility/LHD/SHN)

- Identifies and prioritises fit testing requirements across the LHD/SHN.

- Ensure that any high-risk issues identified with the RPP that are unable to be resolved are escalated to the Chief Executive (or delegate).

- Receives, reviews, and responds to status reports on fit testing, RPP implementation progress and evaluation of the program.

- Collaboratively resolves issues that have been escalated regarding the RPP.

Procurement services

- Ensures there is a sustainable supply of suitable respirators that meet the requirements of employees.

- Communicates and liaises with HealthShare NSW to ensure testing aligns with availability of respirators.

- Ensures respirators meet the requirements of WHS legislation.

- Ensures respirators meet the requirements of NSW Health and Clinical Excellence Commission IPAC policies and guidance documents.

Respiratory Protection Program organisational lead

- Coordinates fit testing schedule and collaborates with the 'fit testers' to perform the scheduled fit testing.

- Engage in regular education and upskilling process.

- Coordinates training for new fit testers.

- Monitors and reports on competency assessment for fit testers.

- Maintains HW consent records, fit testing results and recommendation(s).

- Maintains fit testing equipment and consumables to support the testing program.

- Provides reports on fit testing outcomes to facility executive, line managers and relevant committees.

- Manage HWs who are unable to pass a fit test with any disposable P2/N95 respirator.

- Any other relevant duties assigned by the facility/LHD to support a successful RPP.

Supervisors / line managers should:

- Ensure that all potential exposures to respiratory hazards, including exposure to chemicals and aerosol transmissible pathogens, have been identified and HWs have been provided with the correct RPD.

- Ensure that HWs are identified that require RPD and prioritise fit testing.

- Ensure that this RPP Manual is implemented in the work area.

- Enable HWs to complete the perquisite training and attend scheduled fit testing during work hours.
- Ensure that records of respirator training and fit testing outcomes are documented and available.

Employees to:

- Complete all required pre-requisite learning.
- Ensure they are free of facial hair each time they are wearing a tight-fitting respirator unless they have a medical, cultural, or religious exemption.
- Declare any medical, cultural, or religious reason that might interfere with the wearing of RPD.
- Attend training and respirator fit testing as directed by their line manager.
- Be aware of their individual fit testing outcomes.
- Wear the respirator to which they have been fit tested.
- Use, maintain, and dispose of respirators properly in accordance with training and local procedures.
- Conduct a fit check every time a RPD is applied/donned.

Student health workers

Student HWs who are required to wear a respirator during placement at NSW Health facilities should be fit tested in line with NSW Health RPP guidance. Education and training institutions are responsible for:

- Reviewing the requirements of the NSW Respiratory Protection Program and determine their capacity to establish an NSW Health compliant fit test assessing process. It is recognised that there may be variable capacity for fit testing of student HWs by both, the facility hosting placements and the educational and training institutions.
- Ensure student HWs are fit tested to the standard of the NSW RPP for NSW Health approved respirators considering available supply following the NSW Respirator fit testing algorithm.
- Liaise with NSW Health facilities to investigate the ability of placement facilities fit testing student HWs. This process could consider whether a cost recovery model may be appropriate.
- Students are competent with relevant PPE requirements prior to undertaking placements where respiratory protection is required, including donning, point of use fit checking, and doffing respirators. This includes completion of mandatory My Health Learning 'Donning and fit checking of P2/N95 respirators for NSW healthcare facilities'.
- Transparency of student HWs fit testing outcomes is essential, to ensure this information is available at any NSW Health facility where the student HW may undertake placement.

Fit testing arrangements for student health workers

Education and training institutions should undertake the risk assessment (*Table 2: Fit testing prioritisation guide* and *Appendix 2B: Fit testing risk assessment*) to determine whether student HWs should undergo respirator fit testing and fit testing should occur prior to placement but should not delay placement.

The same prioritisation for fit testing should be applied with student HWs who require attending placement in high-risk areas (such as emergency, anaesthetics, and COVID-19 wards).

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Documentation of fit testing outcomes

Fit testing outcomes for student health workers will be recorded in ClinConnect. The responsibility for entering the student fit testing result will lie with the entity providing the fit testing service i.e., the educational institution or the LHD/SHNs.

1.6 Legal and legislative framework

This clinical guideline provides information on general principles of respiratory protection for HWs and is formally aligned with the following legislation and standards:

NSW Work Health and Safety regulation 2017 and Work Health and safety Act 2011.

Australian/New Zealand Standards:

- Standards Australia AS 4381:2015 - Single-use face masks for use in healthcare
- Standards Australia AS/NZS 1715:2009 - Selection, use and maintenance of respiratory protective equipment
- Standards Australia AS/NZS 1716:2012 - Respiratory protective devices

National Safety and Quality Health Service Standards:

- Standard 3 - Preventing and Controlling Infections Standard Criterion 3.07 – requires processes for the use, training, testing, and fitting of personal protective equipment by the workforce.

Australian Guidelines for the Prevention & Control of Infection in Healthcare (2019):

- Australian Guidelines for the Infection Prevention and Control in Healthcare recommends that where there is a high probability of airborne transmission due to the nature of the infectious agent or procedure then a correctly fitted P2/N95 respirator should be worn.

Principles for the Management of Tuberculosis in New South Wales:

- As per the Policy Directive 2022_007 Principles for the Management of Tuberculosis in New South Wales, Tuberculosis (TB) Services are required to operate in accordance with this policy in conjunction with the current relevant guidelines for the prevention and control of tuberculosis in NSW, which reflect best practice for the clinical and public health management of TB.

Reference

1. SLHD policy (SLHD_PCP2021_067) Use of prophylactic dressings with P2/N95 respirators to prevent skin injury.
2. OSHA protocol Appendix A to §1910.134—fit testing procedures.
3. Infection prevention and control in healthcare settings policy directive PD 2023_025.

Appendix 1A: Respirator fit testing guidance

Please refer to the [Respirator fit testing algorithm](#) on the CEC webpage for the current version and information about the brands of respirators available.
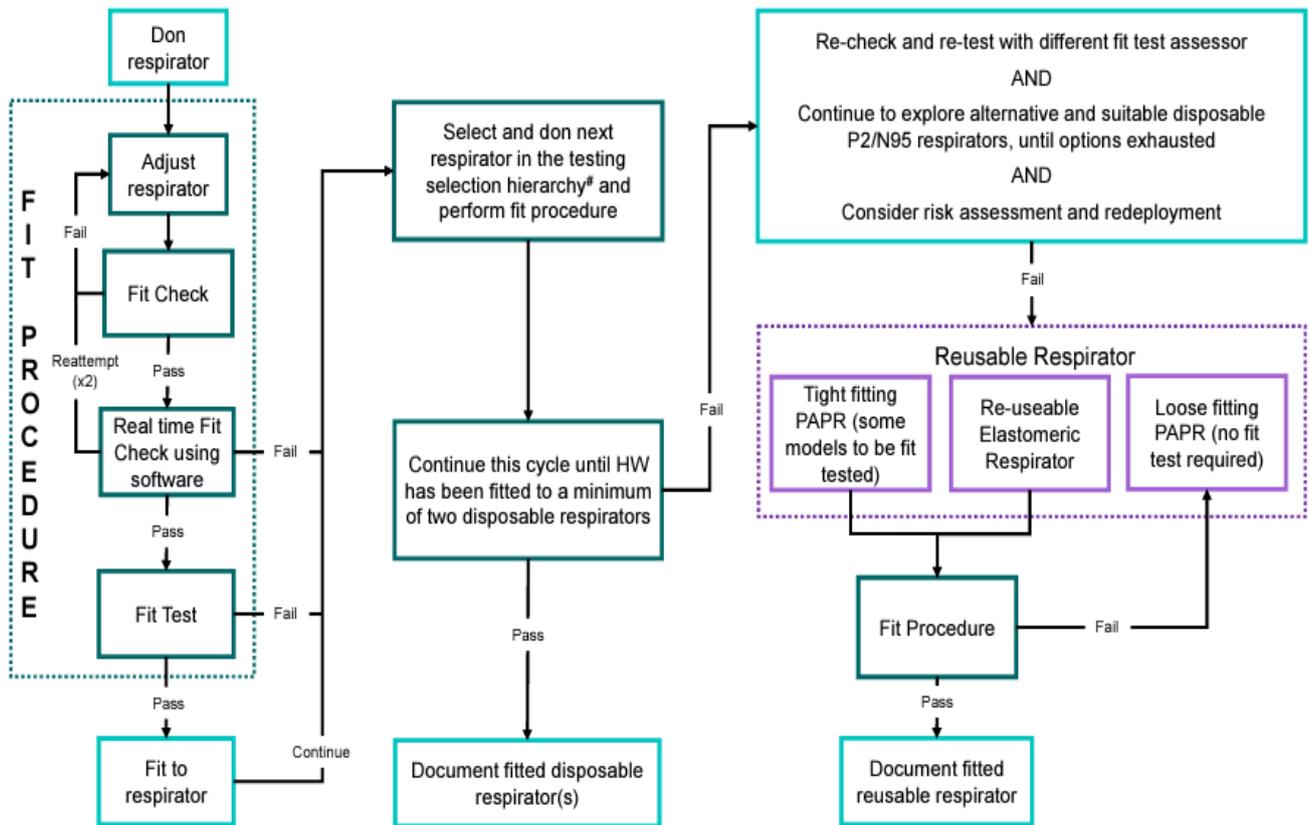
Appendix 1B: Instructions for use of prophylactic dressings under tight fitting respirators

The following information is adapted from SLHD policy *(SLHD_PCP2021_067) Use of prophylactic dressings with P2/N95 respirators to prevent skin injury*.

Note: Mepilex Border flex light™ is also a suitable alternative for Mepilex Border Lite™.

Instructions for use of Mepilex border on the bridge of the nose and silicone tape on the cheeks

Step 1	Step 2	Step 3
Perform Hand Hygiene. Apply skin barrier film/wipe to the face where the dressing will be applied. Allow to dry before applying the dressing.	Use 1 single Mepilex® Lite dressing 4cm x 5cm for the bridge of the nose.	Peel backing. Apply Mepilex® Lite dressing 4cm x 5cm to the bridge of the nose.
Step 4	**Step 5**	**Step 6**
For the cheeks and under the eyes, use Sofsicure®.	Remove from packaging. With clean hands, tear off a piece of tap (approximately 6 to 8cm depending on facie size).	Apply Sofsicure® fixation tape to the cheeks under the eyes where the respirator/mask will be applied.

Instructions for use of Mepilex lite across the bridge of the nose

Step 1	Step 2	Step 3
Perform Hand Hygiene. As in previous tip sheet, apply 3M™ Cavilon™ wipe to the face where the dressing will be applied. Allow to dry before applying the dressing.	Use 1 single Mepilex® Lite dressing 10cm x 10cm. The dressing will be cut in **four (Step 3)**. Place the unused pieces back in the plastic dressing packet, label the packet with your name and store the packet in a clean safe place for your subsequent applications **OR** use the remaining half to protect your ears – see **Step 4.**	Fold the dressing in half and half again to cut 4 even strips. **Tip:** Cut the dressing perpendicular to the backing removal tabs so that all pieces are easy to apply.

Step 4	Step 5	Step 6
Option: Use one strip cut in half again for the back of your ears to protect your ears from eyewear and respirator/mask straps.	Apply the cut dressing section to the bridge of your nose.	Apply the respirator/mask and eye shield.

Instructions for use of Comfeel™ across the bridge of the nose

Step 1	Step 2	Step 3
Perform Hand hygiene. As in previous tip sheet, apply 3M™ Cavilon™ wipe to the face where the dressing will be applied. Allow to dry before applying the dressing.	Use 1 single Comfeel™ transparent dressing 10cm x 10cm. The dressing will be cut into pieces. Place unused pieces in the plastic dressing packet, label the packet with your name and store the packet in a clean safe place for your subsequent applications.	Shape one quarter to fit your nose in terms of length and width (suggested shape in image above).

Step 4	Step 5	Step 6
Apply the cut dressing section to the bridge of your nose.	Apply the face mask and eye shield. Note: If you have a pressure injury, do not remove the Comfeel™ dressing at each PPE change. Keep it intact and wipe over it with an alcohol swab. Remove when dressing starts to peel off or after 3 to 7 days.	Use Adhesive Remover when removing Comfeel to avoid stripping of your skin.

Principles of fit testing with dressings

HWs need to be fit tested with a respirator and have passed prior to application of the prophylactic dressings.

- If you were not fit tested before, fit test without the dressing first, then repeat the fit test with the dressing on.

- If you are fit tested with one type of dressing, this will only apply if that same dressing continues to be used. Cannot guarantee fit test if another dressing type is substituted.

- Dressing chosen needs to be a thin style and the method of application should be able to be replicated each time it is applied with a respirator.

- Once the respirator has been chosen, a prophylactic dressing is applied by the HW and instructed by the fit test assessor or by the skin integrity nurse and the fit test is repeated.

Instructions for fit testing with dressings

- Perform hand hygiene and don respirator.

- Perform fit check.

- Once fit check passed, proceed to fit test. If the HW already had fit test and passed, use the similar brand/model respirator.

- Once the respirator has been chosen, perform hand hygiene and apply selected dressing to the bridge of the nose and cheeks.

- Apply the respirator ensuring it is moulded to the face and the dressing so that no air escapes.

- Perform fit testing.

- Once a fit testing pass has been achieved take note of the dressing and respirator selected and document as per local process.

- Ask the HW to take a photo of the dressing so that they can reapply it in the same way on their next PPE donning and doffing.

- If the test fails, repeat the fit test with a different respirator or different dressing.

Publications

- Jain S, Dempsey K, Clezy K and Bradd P. Implementation of a respiratory Protection Program within healthcare facilities during the COVID-19 pandemic- Lessons learned. AJ Infect. 2022 June DOI: https://doi.org/10.1016/j.ajic.2022.05.016

- Bhatia DD, Bhatia KS, Saluja T, Saluja AP, Thind A, Bamra A, Singh G, Singh N, Clezy K, Dempsey K, Hudson B, Jain S. Under-mask beard covers achieve an adequate seal with tight-fitting disposable respirators using quantitative fit testing. J Hosp Infect. 2022 May 31:S0195-6701(22)00169-4. DOI: 10.1016/j.jhin.2022.05.015

- Barakat-Johnson M, Stephenson J, Dempsey K, Innes L, Jain S, Leong T, Schouten T, Coyer F, Hallahan A. Fit testing and comfort evaluation of prophylactic dressing use for healthcare workers under N95/P2 respirators in one health service district in Australia. J Hosp Infect. 2022 May; 123:100-107. DOI: 10.1016/j.jhin.2022.02.016

2.1 Introduction

This section provides an implementation resource package to NSW local health district (LHD) and speciality networks (SHNs), HealthShare and NSW Ambulance with key resources to support and implement a local respiratory protection program (RPP).

2.2 Program elements

An RPP includes several elements designed to protect HWs from workplace respiratory hazards including airborne infectious agents, dust, and other particles. The following elements should be included in the local RPP.

2.2.1 Risk assessment and management

Risk management in healthcare comprises the clinical and administrative systems, processes, and reports employed to detect, monitor, assess, mitigate, and prevent risks. Deployment of healthcare risk management has traditionally focused on the important role of patient safety and HW protection.

A risk assessment framework has five steps. These include:

- Step 1: Identify hazards, i.e., anything that may cause harm.

- Step 2: Decide who may be harmed, and how.

- Step 3: Assess the risks and act.

- Step 4: Document findings.

- Step 5: Review the risk assessment.

Step 1: Identify the hazard

The hazard is recognised and unrecognised sources of airborne or aerosolised infectious agents in healthcare settings.

Step 2: Decide who may be harmed, and how

HWs who may be exposed to airborne infectious agents may be harmed if they do not have adequate respiratory protection including respirators. These respirators are required for HWs who are:

- attending to patients with suspected or confirmed respiratory infection, communicable diseases with potential for airborne transmission (e.g., COVID-19, pulmonary or laryngeal TB, measles) or they have aerosol generating behaviours (AGB). This may also include people with suspected or confirmed COVID-19 being provided routine care; and

- performing a respiratory aerosol generating procedure (AGP) on a patient with suspected or confirmed acute respiratory infection (e.g., influenza, respiratory syncytial virus) or undertaking clinical work within this space.

Step 3: Assess the risks and act

Airborne precautions are required based on assessment of risk of transmission (see below) when providing care for patients exhibiting acute respiratory tract infection (e.g., TB, measles, or chickenpox) and for suspected or confirmed COVID-19 patients.

Assessment of risk of transmission should include consideration of the following elements that can contribute to an increased risk of transmission:

- **Patient specific factors such as:**
  - o duration of care (length of time)
  - o intensity of exposure (symptoms such as sneezing or coughing, screaming, shouting)
  - o patients with cognitive or behavioural issues (e.g., dementia, confused or aggressive)
  - o increased exhalation (e.g., exercising, shouting, singing)
  - o the individual patient/client/resident's ability to wear a surgical mask.
- **Setting-specific factors such as:**
  - o levels of ventilation or air handling (e.g., room size, air changes per hour, use of air filter, cleaning, and maintenance)
  - o multiple patients with upper respiratory tract infection cohorted in one area/zone or ward.

High risk areas for prioritisation are:

- ICU (adult, paediatric/neonatal).
- Emergency department (ED).
- Operating theatres where intubation/extubation, bronchoscopy or other respiratory AGPs are performed.
- Wards with negative pressure rooms or respiratory isolation rooms that provide inpatient care to patients with suspected or confirmed respiratory infection or communicable diseases with potential for airborne transmission.
- Designated wards: red and amber wards/zones (during an outbreak/pandemic).
- Chest clinics or other services that perform sputum induction.
- Emergency retrieval services.

Use local processes for identifying and prioritising HWs for fit testing. Consideration should be given to:

- HWs working in high-risk areas who perform or assist in respiratory AGPs or providing care to suspected or confirmed COVID19. These HWs can be further stratified based on the type of AGPs they perform or assist in (see *Appendix 2A: RPD allocation by task or location* and *Appendix 2B: Fit testing risk assessment*).
- Other high-risk HWs who provide direct care or enter patient rooms e.g., cleaners, wards person, HWs who perform venepuncture, medical imaging.
- Core teams who perform/assist in AGPs.

Take action to reduce risk by:

- Limiting the number of people present during an AGP.

- Identifying core teams to perform or assist in AGPs.

Management of HWs unable to be fitted with a disposable respirator

Where a HW is unable to be fitted to any available disposable respiratory protective device (RPD), a risk management approach should be implemented to establish control measures. These include:

- Identification of high-risk procedures (e.g., AGPs) the HW is unable to perform and a suitable substitute.

- Identification of high-risk patients the HW is unable to provide care to.

- Identification of HWs with an exemption to keep facial hair due to medical condition, psychological needs/reasons or genuinely held cultural or religious observance (See *Appendix 4A: Use of respiratory protective device with beard cover technique* for more information).

- 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 such as a reusable RPD should occur.

Reusable RPDs such as Elastomerics or PAPR have specific cleaning and disinfection requirements and any individual who requires the use of these RPDs are responsible for the management of filters and the hospital is responsible for reprocessing the respirators.

- Where the above steps have been taken and the individual is still unable to be fitted to an appropriate RPD, the use of a PAPR could be considered. A referral should be made to the designated PAPR fit test assessor for the facility.

Step 4: Document of record

Develop a system for recording:

- Results from fit testing programs into a centralised platform. For NSW Health this is Stafflink Human Capital Management (HCM) Document of Record (see *Appendix 2F: Data collection and reporting of fit testing results*).

- RPP meeting minutes.

- Correspondence related to the RPP.

Step 5: Review the risk assessment

- Perform an annual evaluation of the RPP.

2.2.2 Local risk assessment for fit testing

Implementation of LHD/SHN, educational and training institutions RPP requires careful consideration to identify those HWs that require the regular use of respirators for high-risk procedures of infectious aerosols (respiratory AGPs in COVID-19 or acute respiratory infections) or regular care of patients in airborne precautions (pulmonary or laryngeal TB) or provision of care to patients with suspected or confirmed COVID-19. All HWs should be trained on the potential risks of respiratory protection as part of mandatory IPAC education. Refer to section *2.2.1 Risk assessment and management* for more information.

Frequency of Fit testing

Healthcare facilities must regularly evaluate the risk to which HWs are exposed and determine which employees are required to undertake fit testing. In accordance with the facility's RPP, fit testing must be undertaken:

- When identified that a HW may be exposed to a respiratory pathogen or hazardous substances.

- Existing HWs – HWs who have been prioritised during the risk assessment.

- Existing HWs – other HWs who may have infrequent exposure to recognised and unrecognised sources of airborne and aerosolised infectious agents.

- New HWs who are prioritised for assessment and have not been fit tested elsewhere should be tested during onboarding to the healthcare facility.

- Where there has been a change in RPD availability – size, style, model or make or where a new make/ model is issued. Prioritisation based on HW risk assessment.

Repeated at appropriate intervals (**annually and no longer than18 months**), particularly when there is a change in the wearer's facial characteristics, e.g., loss of teeth/dentures or excessive changes in weight or facial surgery.

2.3 Program requirements

A key component of a successful RPP is the assignment of responsibilities for the implementation and coordination of the program. Refer to section *1.5 Governance* for more information. 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 a collaborative approach between work health and safety (WHS) and infection prevention and control (IPAC). The below table (Examples of program roles and responsibilities) articulates the roles and responsibilities for the implementation and ongoing sustainability of the program.

TABLE 3: EXAMPLES OF PROGRAM ROLES AND RESPONSIBILITIES

CEC	Organisation RPP lead	Fit Test Assessor Trainer	Fit Test Assessor (FTA)	Health worker
Guidance and policies on IPAC RPP program owner RPP board Chair Train FTA trainers	Escalation points for FTAs Coordination of the fit test program including data reporting Planning, equipment, consumables, maintenance, logistics	Train and assess new FTAs Contribute to the training and education resources Escalation points for fit testing process enquiries	Observe and coach HWs don, doff and fit check Conduct and record results from fit test sessions for HWs Negotiate resources and participants for fit testing Clean equipment at end of session	Complete pre-learning modules prior to fit test Be suitable for a fit test (clean shaven etc.) Attend scheduled fit test appointment Correctly don, doff and fit check Fit check and use the fit test passed respirator as clinically required

Role of the CEC

To improve performance of individuals, teams and systems, the CEC initiates and manages a range of programs including NSW respiratory protection program (RPP) in collaboration with LHD/SHNs to raise capability and support process improvements and safety culture in clinical teams. The CEC plays a leading role in delivering the NSW RPP including ownership of guidance's and policies, chair of RPP board, development, and implementation of training resources in collaboration with Health Education and Training Institute (HETI) and other relevant stakeholders.

Organisation RPP lead

The organisational RPP lead role and responsibilities include:

- Coordinates fit testing schedule and collaborates with the 'fit testers' to perform the scheduled fit testing.
- Engage in regular education and upskilling processes.
- Coordinates training for new fit testers.
- Monitor and report on competency assessment for fit testers.
- Maintains HW consent records, fit testing results and recommendation(s).
- Coordinates periodic respirator fit testing program.
- Maintains fit testing equipment and consumables to ensure testing program is not impacted.
- Provides reports on fit testing results to supervisors/line managers and consolidated reports to General Manager and relevant committees.
- Manage HWs who are unable to pass a fit test with any disposable P2/N95 respirator.

The Organisational RPP lead should have the following skills:

- Leadership skills to plan maintain and run a fit test program.
- Able to describe what aerosol and droplet transmission means and the health impact of exposure to infectious agents to self and others if respiratory protection is not used properly.
- An understanding of when respiratory protection is needed.
- Knowledge of their facility respiratory protection procedures and fit test frequency and intervals.
- Able to identify internal and external resources for obtaining information on respiratory protection. E.g., manufacturer's instructions.
- An understanding of manufacturer's specific instructions, methods of care, storage, and disposal procedure for all respirator types.
- Able to describe the purpose of fit checking and when the user seal check should be performed.
- Able to demonstrate effective respiratory protection practice including correct donning, user seal check and doffing procedures when included in transmission-based precautions.
- Able to demonstrate correct waste disposal and hand hygiene procedures.
- Knowledge of what to do if a respiratory exposure occurs and the escalation process.

2.3.1 Fit test assessor train-the-trainer (FTAT) program learning pathways

The CEC in collaboration with HETI is responsible for training FTA trainers (train-the-trainer) or FTAT.

This program is designed to:

- support and deliver training to selected FTAs.
- assess their competence to deliver the FTA training program in their LHD/SHN.
- train LHD/SHN nominated current FTAs, to lead training and undertake assessment of FTAs to become accredited fit test assessors (train-the-trainer) or FTAT.

The training includes:

- Part A – Introduction to the trainer role, responsibilities, and training resources.
- Part B – Skills training and observed assessment.

This training covers:

a) a half day workshop delivered virtually as live online learning (LOL), and

b) a self-directed two (2) part competency assessment undertaken on completion of the workshop.

Roles and responsibilities of an FTAT includes:

- Train and assess FTA trainers.
- Develop training structure for FTA trainers and FTAs.
- Lead and contribute to the training and education resources for FTA training.

FTAT program address the following:

- Respiratory protection in healthcare.
- Australian Standards for respirators and fit testing.
- Focus on hierarchy of controls, aerosol generating procedures, respirator types, fit checking, fit testing, and the respiratory protection program including escalation if fit testing fails.
- Initial assessment of FTAs and recency of practice.
- Local and state documentation requirements.
- Escalation of risks.
- Managing discussions with HWs who do not achieve a fit pass outcome with available testing programs.
- Fit testing skills using a quantitative method – e.g., PortaCount™ or AccuFit™
    - Trouble shooting
    - Governance
    - Annual update and peer review.

Fit test assessor (FTA) trainer responsibilities

Engage in an accredited and registered training organisation or suitably qualified person that has the capacity and capability to educate HWs in using Quantitative or Qualitative fit testing methods with specific reference to the healthcare setting. At the completion of the education the FTA is assessed as meeting requirements to perform fit testing, conduct training of FTAs, assist in resource development. Over time the LHD/SHN should ensure they have adequate numbers of internal trainers or are able to outsource trainers.

The FTA training program and resources has been developed in partnership between CEC and HETI. Training resources can be adapted for local use. Health agencies can add local examples and reference local processes. However, the course must still cover the stated learning outcomes.

Assessment is competency based and measured against evidence-based criteria. Those deemed competent to perform FTA training require the support of the LHD/SHN to deliver FTA training at the facility level.

Skill requirements

- Have understanding and content expertise of the RPP and facilitation skills.

- Have a good understanding of the fit check and fit test process.

- Have experience with technology and troubleshooting.

- Can apply this knowledge and skills in a known context and defined parameters.

- Can deliver the content using your own words and make minor adjustments to the learning process to meet participants' needs.

- Can facilitate open discussion.

Target Learner Group

- HW with a clinical and/or WHS background with experience in training and assessing HWs.

- Already an FTA with significant experience in fit testing using different fit tester devices.

Complete: The RPP Fit Test Assessor Accreditation Pathway and the CEC Fit Test Assessor Trainer Accreditation Pathway in My Health Learning (MHL). (To enquire about availability for NSW Health please email CEC -RPP@health.nsw.gov.au)

Selection Criteria

- Demonstrates effective skills in communicating to a multidisciplinary workforce and providing constructive feedback to FTAs.

- Demonstrated skills in a wide range of computer applications including the Microsoft Office suite.

- Evidence of well-developed written and verbal communication skills

- Ability to analyse and synthesise data and use it to drive improvement through the production of fit testing presentations, reports, and submissions.

- Demonstrated effective time management, organising and prioritising skills.

- Demonstrated ability to work with initiative and to work with minimal supervision.

- Demonstrated knowledge of Infection Prevention and Control principles and application to respiratory protection.

To conduct FTA training in the LHD/SHN, selected HWs may require release from usual workplace activities.

Learning outcomes

At the completion of this program, participants will be able to:

- Identify the RPP objectives and the purpose of fit testing.

- Outline the role and responsibilities of an FTA.

- Demonstrate conceptual knowledge and practical application of respiratory protection in health care.

- Deliver the theoretical and practical components of the FTA workshop using the CEC FTA workshop and assessment package.
- Incorporates LHD/SHN specific respiratory protection processes / resources into the local FTA training program.
- Assess participants attending LHD/SHN FTA workshops.

2.3.2 Fit test assessor (FTA)

RPD fit testing should be conducted by a person who has successfully completed FTA training. To successfully complete the FTA training, the participant should have a good understanding of the use of PPE and RPD in airborne precautions and the fit checking process.

Fit test assessor selection criteria

Requirements

1. At least 2 years recent clinical (or equivalent) experience and/or Work Health and Safety experience

2. Completed mandatory Infection Prevention and Control modules for respiratory protection and fit testing in MHL within last 12 months

Selection criteria

- Demonstrates effective skills in communicating to a multidisciplinary workforce and providing constructive feedback to HWs**
- Demonstrated skills in a wide range of computer applications including the Microsoft Office suite.
- Evidence of well-developed written and verbal communication skills.
- Ability to analyse and synthesise data and use it to drive improvement through the production of fit testing presentations, reports, and submissions.
- Demonstrated effective time management, organising and prioritising skills.
- Demonstrated ability to work with initiative and to work with minimal supervision.
- Demonstrates an understanding of health environments and systems.
- Demonstrated knowledge of Infection Prevention and Control principles and application to respiratory protection.

**Enabled to access support and advice as required, from a clinical/WHS/IPAC member/team with a thorough understanding of the requirements of the local RPP and fit testing.

Candidate FTAs must complete the learning pathway in MHL (see below). For more information refer to My Health Learning.

Recommended learning for FTAs: Beard Cover Technique (course code: 439593323) as part of FTA training. For more information refer to My Health Learning.

FIGURE 1: LEARNING PATHWAY FOR FIT TEST ASSESSORS

Before workshop

1. Learner to enrol and complete in **RPP: Safe use of P2/N95 respirators (Pathway)**.

Recommended learning: **Respiratory Protection Program RPP: Beard Cover Technique** (course code 439593323) self-paced module.

2. Learner to enrol in:
- **RPP: Fit Test Assessor Accreditation (Pathway)**
- **RPP: Fit Test Assessor - Theory and practical training workshop** (383783593) local offering

Attend workshop

3. Attend the **RPP: Fit Test Assessor - Theory and practical training workshop** delivered by approved external trainers or NSW Health qualified FTA trainer (8 hours).

At end of workshop or as soon as possible

4. Complete the observed practical demonstration (3 fit tests) assessed by approved external trainers or NSW Health qualified FTA trainer.

Note: It is ideal to also organise a fit testing session on the following day, with the assistance of a qualified person, to reinforce learning.

5. Complete **RPP: Fit Test Assessor – Assessment part B - Online quiz** (369068204) – 20 questions, 80% pass mark.

Marking completion

6. NSW Health Fit Test Assessor accreditation achieved.

The roles and responsibilities of an FTA includes the following:

- Organisation and management of fit testing location and equipment.
- Access to and storage of device consumables.
- Device software is loaded and accessible on the fit test workstation or on laptop.
- Supply of respirators for fit testing.
- Conduct fit test, interpret, and communicate results.
- Storage, transport, and annual maintenance requirements of the equipment (service level agreement).
- Prioritisation of departments and HWs for fit testing.
- Recording and reporting of fit test outcomes.
- Develop escalation pathway for fit test assessors identifying risks and suggestions for improvement.

The practical session provides set up and use of the PortaCount™ or AccuFit™ fit tester device. Participants are encouraged to participate in real time fit testing to enable familiarisation with the process and device as well as the opportunity to troubleshoot and correct problems encountered.

2.3.3 Education of HWs who will be wearing a respirator

All HWs required to wear PPE must be trained and assessed for competency in the use of all PPE as part of an ongoing training program. To ensure a continued adequate fit, an annual no longer than 18 months skill assessment is required which involves donning and doffing of the respirator and the ability to demonstrate an adequate fit check. For more information on how to don and doff PPE refer to CEC PPE training videos.

During times of increased need, such as a novel respiratory disease pandemic, other brands of P2/N95 respirators may need to be sourced. Relevant HWs should be notified of the alternative brands available in their workplace and variation in donning and fit checking processes with alternative brands. The need for a fit check at the time of use with available respirators should be reinforced to HWs to ensure that correct facial seal can be achieved prior to use.

Documentation of HWs fit checking assessment is required. *See Appendix 2C: Fit testing implementation checklist and compliance self-assessment*.

Note: It is critical that all HWs who are likely to be responders for cardiopulmonary resuscitation have practiced safe, effective, and rapid donning of PPE for airborne precautions.

The Respirator Fit Test Learning pathway in MHL includes the modules listed below.

Course Name	Course Code
Donning and fit checking of P2 or N95 respirators in NSW healthcare settings	319438161
Infection Prevention and Control Practices	46777047
Infection Prevention – Transmission Based Precautions	253093581
Infection Prevention – Personal protective equipment for combined transmission-based precautions	294450660
Beard Cover Technique as part of FTA training	439593323

Education for HWs include:

- When respirators are to be used and importance of fit checking.

- Respiratory risks during routine and emergency situations, including AGPs.

- Respirator fit, usage, maintenance, limitations, capabilities, required checks, decontamination (if reusable).

- HWs issued with reusable RPD must be trained in charging, maintenance of batteries, filters, reprocessing, maintenance, storage, and reporting of issues.

- Risks of not achieving an adequate seal if HW has facial hair.

- How to wear respirators with eye protection, prescription glasses and head cover (in operating environment).

It is essential that training for HWs has a specific health focus on how a respirator in combination with other PPE requirements reduces the risk in recognised and unrecognised sources of airborne and aerosolised infectious agents in healthcare settings. While much of this training is included in the training for fit test assessors a summary should also be included in training for all HWs undergoing a fit test. It is recommended both practical and online learning be completed prior to annual fit testing.

2.3.4 Documentation and data management

The documentation and record keeping should be based on local and state reporting process.

- Respirator fit testing consent (see *Appendix 2D: Sample respirator fit testing consent*).
- Results of fit testing into Stafflink HCM for NSW health workers or ClinConnect for HW students (see *Appendix 2F Data collection and reporting of fit testing results*).
- Credentialing of FTA into MHL.
- Automatic alerting of HWs of the next review via Stafflink HCM.
- MHL module on donning and fit checking of P2/N95.

2.3.5 Fit test device maintenance and calibration

The fit test device should be used, maintained, and calibrated in accordance with the manufacturer's recommendations, safe work methods and CEC resources. Before use, the stability of the equipment should be checked as instructed by the manufacturer. Records of maintenance, calibration and pre-use checks should be retained. The manufacturer recommends that the equipment is factory calibrated on an annual basis.

Appendix 2A: RPD allocation by task or location

Task or Location	Potential	Respiratory Protection	Employees Included
Performing respiratory **AGP**s on patients with recognised and unrecognised sources of airborne and aerosolised infectious agents in healthcare settings or are present during such procedures	Infectious aerosols	Disposable respirator or an alternative respirator (such as a PAPR half or full-face) if the disposable does not fit, or for prolonged exposure or for comfort	
Entry into airborne infection isolation room or other area occupied by patients requiring **Airborne Precautions**	Infectious aerosols		
Performing, or present during, routine patient care and support operations on a patient requiring **Airborne Precautions**	Infectious aerosols		
Cleaning and disinfecting an area occupied by a patient requiring **Airborne Precautions**, or cleaning and disinfection such an area after a patient has left but before the space has been adequately ventilated	Infectious aerosols		
Laboratory operations involving **aerosol** transmissible disease pathogens for which the biosafety plan requires respiratory protection	Infectious aerosols	As specified in biosafety plan	
[List any other exposures and job tasks for which your facility has determined the use of respiratory protection is required; you may go beyond OSHA requirements]	*[Specify]*	*[Specify according to your facility's policy]*	

Appendix 2B: Fit testing risk assessment

LHD/Hospital				Date:	
Prepared By:					
Names and Positions of HW involved in risk assessment:			Name		Position
	Medical				
	Nursing				
	Allied Health				
	Support Services				
	Admin				
General Manager Signature:					

1. Detailed description of potential exposure to recognised and unrecognised sources of airborne and aerosolised infectious agents in your Hospital / Service to HW:
   Take into consideration:
   - Exposure time
   - Frequency of exposure
   - Likelihood of exposure
   - Availability of respirators - disposable and reusable
   ☐ Management of patients with TB
   ☐ Management of patients with measles/chickenpox
   ☐ Management of patients with ARI including COVID-19
   ☐ Management of other infections requiring airborne precautions
   ☐ Other

2. List the current control measures in place in relation to the use of respirators and/or respirators: e.g.: disposable respirators, reusable respirators, fit check etc
   ☐ Adequate supply of P2/N95 respirators
   ☐ Adequate variety of respirators
   ☐ Supply and control of elastomeric and PAPRs
   ☐ Donning, doffing, and fit checking embedded into education
   ☐ Other

Appendix 2C: Fit testing implementation checklist and compliance self-assessment

Organisation / Facility:	

ASSESSED BY:	DATE OF ASSESSMENT:

KEY REQUIREMENTS	NOT COMMENCED	PARTIAL COMPLIANCE	FULL COMPLIANCE
Assignment of a program coordinator for the fit testing program	☐	☐	☐
NOTES:			
A priority list of employees and/or specific clinical settings have been identified for inclusion in a fit testing program	☐	☐	☐
NOTES:			
Healthcare settings have a range of models and sizes of P2/N5 respirators available for HWs	☐	☐	☐
NOTES:			
A knowledge and competency assessment program have been developed for infection prevention and control and respiratory protection	☐	☐	☐
NOTES:			
Documentation for the fit testing program has been developed for the fit testing program that includes HW, clinical priority, respirator(s) (brand and size) and any identified risks	☐	☐	☐
NOTES:			
NOTES:			
A process for escalating and managing a HW who meets the 'no fit' criteria	☐	☐	☐
NOTES:			
NOTES:			

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Appendix 2D: Sample respirator fit testing consent

Personal Information

Surname	
Given name/s	
Employee Number	
Work Area	
Position	

Overview

<LHD/SHN> Quantitative respirator fit testing has been developed in accordance with AS/NZS 1715:2009, ISO 16975-3 and OSHA 1910.134 protocol.

The focus of respirator fit testing is to ensure there is an adequate seal between the face of the worker and the chosen respirator.

Respirator fit testing is not recommended in the presence of facial hair. At all times when a HW is required to use a respirator; the HW must not have any facial hair present. HWs with an exemption should follow local process.

The respirator fit test performed on this day under testing conditions does not determine whether the chosen respirator is appropriate for the environment/conditions under which it may be worn in the future. This test will determine if a suitable fit is obtained based on today's circumstances. Future use will be reliant on using the same respirator as tested today and following all fit checking protocols as per your training.

Release of information

<LHD/SHN RPP Lead position title> may be required to discuss any condition/s (e.g., cardiac or respiratory illness) with your line manager and appropriate medical officer if this impacts on your ability to obtain a suitable fit.

The information collected during this assessment will be sent to your line manager. You will be advised of the result from the fit testing at the time of the test.

On day of fit testing

HWs are to ensure that they are clean shaven and have not eaten (food with strong odour/smell may interfere on fit test results) or smoked 30 minutes prior to testing.

Consent

By signing below, I _____ *(Print name)* _____ confirm:

- I have read the above information / I have had the above information explained to me
- I understand the conditions of this testing program
- I acknowledge that I am physically able to wear a respirator
- I consent to participating in this testing
- I consent for <LHD/SHN> to release the information collected in this assessment to my line manager.
- ☐ I have an exemption to keep my facial hair

Staff Signature	
Date	

Information Sheet: Fit Testing

What is fit testing?

Fit testing is a validated method to determine whether the type of respirator being used by a person provides an adequate seal on that person's face, thereby providing the level of protection required against airborne infectious particles.

There are 2 types of fit testing, and in <LHD/SHN> we will be conducting Quantitative fit testing (QNFT)

What does QNFT Measure?

Quantitative fit testing is an objective measurement of respirator fit, undertaken using a testing unit called a PortaCount™ or AccuFit™.

Fit testing works by measuring the concentration of microscopic particles in the ambient air and then measuring the concentration of those particles that leak into the respirator. The ratio of these two concentrations is called the *fit factor*. The testing is done while the person is wearing the respirator and attached to the testing unit, while carrying out a number of physical movements and actions.

What do the results tell us?

The results indicate the effectiveness of the seal against the face. While each physical movement done during the testing has a *fit factor* result, the overall *fit factor* from the combined scores is used to determine if the tested respirator provides the level of protection required. It is possible to have an overall pass *fit factor* even though one of the physical movements returned a negative *fit factor* result.

What is a Respirator?

A respirator (also known as a P2 or N95 mask) is used by an individual to provide respiratory protection. The term respirator refers to masks used to protect health workers from airborne infectious particles. There are three main types of respirators available, and these include:

- Disposable or filtering facepiece respirators (P2/N95 mask) where the

respirator is discarded when it becomes unsuitable for further use due to completion of an episode of care, excessive resistance, physical damage or contamination

- Reusable or elastomeric respirators, where the facepiece is cleaned and reused but the filter cartridges are replaced when they become unsuitable for further use

- Powered air purifying respirators (PAPRs), where a battery-powered blower moves the air flow through filters.

<LHD/SHN> Respiratory Protection Program

Fit testing is a part of <LHD/SHN> Respiratory Protection Program, complementing fit checking and education. All staff who need to wear a respirator will undergo a fit test as indicated.

Fit testing does not replace fit checking which needs to be done every time a respirator is used.

Appendix 2E: Calibration, maintenance, and transport

Process

All fit tester devices will be maintained and calibrated in accordance with the manufacturer's instructions for use (IFU). Records of maintenance, calibration and pre-use checks must be retained. The manufacturer's IFU recommends fit tester devices be factory calibrated on an annual basis.

Recalibration confirms the fit tester device is operating within the manufacturer's required parameters to perform accurate and reliable fit test assessments.

Organisations are to develop a calibration schedule for each fit tester device. The calibration schedule must account for local fit testing schedules that may be influenced by seasonal or anticipated increased usage, such as new graduate orientation schedules.

Fit tester devices should be sent for calibration outside of identified peak periods if scheduling permits. To reduce downtime, contact the appropriate customer service department to determine estimated timeframe for calibration, including transport to and from the supplier.

Fit tester devices and associated equipment that are damaged or not functioning properly must be clearly tagged out of service. Maintenance and repair services can be arranged through the appropriate supplier. Out of service equipment must be recalibrated or verified prior to use. Calibration and maintenance records must be maintained in the organisation's asset register.

Procedure

Fit tester devices must be recorded in the organisation's asset register and labelled with the following information:

- Unique identifier
- Date of last calibration
- Date of next calibration.

Scheduling and maintenance records can be supported within the current asset management system used by the organisation or the Asset and Facility Management System - AFM Online.

Liaise with the supplier of fit tester devices to schedule recalibration and or repairs. Scheduling for recalibration will be in accordance with the fit tester device's IFU.

The fit tester devices will be required to be transported to the supplier's service location for calibration and repairs. Transport time is recommended to be considered in the scheduling timetable to ensure the organisation is not left without fit tester devices and can continue with fit test assessments of HWs.

Loan of fit tester devices

Where an organisation requires temporary access to a fit tester device (e.g., when a device is being calibrated), this can be organised by contacting the:

- RPP Lead and or Asset Owner in another organisation, or
- Renting a device through the appropriate supplier.

In managing a temporary loan of a fit tester device from another organisation, it is recommended a memorandum of understanding or similar be agreed, prior to loaning of the fit tester device. At a minimum, consider:

- Timeline of the loan
- Position responsible for the fit tester device and equipment at the requesting organisation
- Costs of consumables

- Costs of repairs
- Transport and storage arrangements of the requesting organisation.

Transport & Storage Precautions

Transport and storage of fit tester devices is recommended to align with the Safe work method (SWM) for fit tester devices. In particular, all alcohol must be removed prior to transporting or storing a fit tester device. Transporting or storing the fit tester device with the alcohol cartridge inside may cause flooding of the optics. When placing the fit tester device back into the carrying case, follow the steps outlined in the manufacturer's IFU and the CEC SWM.

Never transport the fit tester device back to the supplier with any alcohol bottles or with any alcohol in the capsule.

Fit tester devices must be transported in accordance with the manufacturer's IFU and align with NSW Health's approved couriers list.

Suppliers fit tester devices:

Accufit 9000	PortaCount TSI
Active Environmental Solutions Unit 16, 191 Parramatta Road | Auburn NSW 2144 | Australia T: (02) 9716 5966 F: (02) 9716 5988 sales@aesolutions.com.au www.aesolutions.com.au	Kenelec Scientific 23 Redland Drive, Mitcham VIC 3132 p 1300 732 233 p +61 3 9873 1022 f +61 3 9873 0200 https://www.kenelec.com.au/contact-us/

Appendix 2F: Data collection and reporting of fit testing results

For employees of NSW Health:

Stafflink HCM is an innovative statewide compliance initiative designed to streamline data collection procedures. Through the implementation of a cloud-based data capture form and reporting capability, manual data collection procedures have been replaced across the state. Stafflink HCM allows for real-time data capture, facilitating easier and quicker analysis and retrieval of information. This enhanced system provides a comprehensive view of how fit testing is performing at an individual, health entity, or whole-of-state level.

To access RPP data for NSW health employees, users can log into Stafflink and access the data by selecting the Stafflink HCM icon. This centralised platform ensures data security and ease of access for authorised personnel. Stafflink HCM offers a comprehensive set of features to support the Respiratory Protection Program (RPP), including;

1. **Document of Record - RPP Fit Test Form:**
   - Health workers (HWs) can access and view the results of their fit test.
   - Fit Test Assessors and RPP administrators are responsible for entering fit test results into the system.

2. **Enterprise Reporting:** Stafflink HCM provides various reports on fit testing, allowing for in-depth analysis and monitoring of the program.

Reports can be generated based on different criteria, such as:

- Fit testing results by department
- Fit test assessor-specific reports
- Reports based on the equipment used (machine)
- Reports based on the type of respirator used
- Manager-specific reports

These reports can be exported in multiple formats, including Excel and PDF, making it easier for users to share and analyse the data.In addition to the system's features, users can access knowledge documents to assist them in using Stafflink HCM effectively.

These support materials are available through SARA or the following links:

- [Respiratory Protection Program Training Directory](): This resource provides training materials related to the RPP, ensuring that users are well-equipped to manage the fit testing process effectively.
- [StaffLink HCM Training](): This training documentation offers comprehensive guidance on utilising the various features and functionalities of Stafflink HCM, enabling users to navigate the system with ease.
- [Data dictionary for StaffLink HCM](): The data dictionary provides a clear understanding of the database structure and terminology used in Stafflink HCM, aiding users in interpreting and utilising the data effectively.

These resources collectively enhance the user experience and support the successful implementation and management of the Respiratory Protection Program through Stafflink HCM.

For HW students:

ClinConnect is a web-based application used to assist Health Services (Local Health Districts and Specialty Health Networks) and Education Providers manage all clinical placements in NSW Health facilities.

Education Providers and Health Services have the functionality to record respirator fit testing results in the ClinConnect system for all student HWs. Please discuss further with your education provider and/or placement facility.

Chapter 3: Reusable Respiratory Protective Devices – Management and Use

3.1 Introduction

This chapter provides infection prevention and control (IPAC) guidance on the selection and use of reusable respiratory protective devices (RPDs) for protection against airborne pathogens where a communicable respiratory infection is suspected or confirmed. The correct selection and use of personal protective equipment (PPE) (including respirators) is one component of the continuum ensuring health worker (HW) and patient safety. Disposable respirators are the most common devices used in healthcare settings for protection against airborne pathogens, however, reusable respirators are an alternative to disposable respirators for some clinicians who require respiratory protection in select situations.

NOTE: Any reference to specific product is for providing example only. Neither NSW Health or the Clinical Excellence Commission (CEC) endorse or promote any products or equipment identified in this guidance document.

3.2 Guiding principles for utilisation of RPDs

Considering the complexities and challenges surrounding the use of reusable respirators in healthcare, the following set of principles underpin their use:

- Manufacturer's instructions must be read, understood, and followed for all aspects of RPD and accessories use, reprocessing, maintenance (like calibration and correct charging), and storage.

- Safety of HWs is vital to the health of the community and patients both on a day-to-day basis and during public health emergencies such as the COVID-19 pandemic.

- HWs must be fully informed about risks related to respiratory infections and be supplied with methods, education, environments, and equipment for protection.

- Individual HWs must fulfill their responsibilities to be aware of, participate in, be proficient in and practice respiratory protection.

- Employers and clinical leadership teams need to work collaboratively to establish an effective RPP and together with HWs take on the responsibilities to champion, monitor, and enforce respiratory protection.

- Before purchasing RPDs, consider the HWs ability to safely don and doff the device, fit testing if required and the facility's ability to reprocess the equipment by the reprocessing unit including the training of HWs in the correct reprocessing procedures to align with the manufacturer's instructions.

- Where a HW is unable to be fitted to any available disposable respirators a risk management approach should be implemented to establish the use of a reusable respirator that protects the user's respiratory system from exposure to recognised and unrecognised sources of airborne and aerosolised infectious agents.

- The RPD implementation policies and guidance should be based on evidence.

3.3 Selecting reusable RPDs

The reusable respirator should be considered for HWs who are unable to achieve a facial seal (fit check) with available disposable P2/N95 respirators and/or have not passed a fit test and cannot be re-deployed to a lower risk clinical area. Where a HW is unable to be fitted with any available disposable respirators, a risk management approach should be implemented to establish control measures. These include:

- Consultation with the local IPAC team, work health and safety (WHS) and fit test assessor (FTA).

- Ability of HW to be clean-shaven. The HW must not have any facial hair present when a HW is required to use a tight-fitting respirator except for staff who do qualify for an exemption for facial hair. This includes at the time of fit testing.

- Identification of high-risk area or procedures the HW is unable to perform and where a suitable substitute is not available.

- Identification of high-risk patients for whom the HW is unable to provide care.

- Considerations for redeployment or exploring different options (such as another work location, remote or flexible work).

Where a HW is essential to the clinical area and cannot be re-deployed, and the individual is still unable to be fitted to an appropriate disposable respirator, the use of a reusable RPD (e.g., PAPR or an elastomeric respirator) should be considered.

The decisions on the selection and purchase of elastomerics or PAPRs for use in healthcare facilities must involve specialists in IPAC, WHS, biomedical engineering, reprocessing and the procurement or product evaluation committee. See *Appendix 3A: Reusable respiratory protective device (RPD) implementation checklist* for more information.

Before selecting an RPD, the following should be considered:

- Identify hazards (e.g., the respiratory hazards to which the HW will potentially be exposed during routine and emergency situations).

- Ability to safely don, fit check (user seal check) at point of use, fit test if required, use, and doff respirators.

- Ability to participate in mandatory fit check (user seal check) training and competency assessment.

- Meet fit testing requirements where applicable.

- Assessment of HWs to ensure that they can wear a respirator in specific settings such as rapid response teams or ambulance settings.

- Ability to carry out required clinical care whilst wearing RPD.

- Ability to follow point of care cleaning, filter change, maintenance and any other process recommended by the product manufacturer.

Note: Some RPDs available in Australia are not approved by the Therapeutic Goods Administration (TGA). The purchase, implementation, and management of such devices must be done in consultation with the facility WHS, IPAC, reprocessing and engineering department based on local risk assessment.

3.4 Training, education, and assessment

To use reusable RPDs, HWs are to have undertaken training in the use of these items and have been assessed and accredited as competent in their use, either by the external vendor or an accredited trainer. Refer to the Clinical Excellence Commissions Respiratory Protection Program page for more information. The following should be considered by the trainer and the user:

- Where available, initial virtual or face-to-face training should be provided by the manufacturer of the specific RPD.

- HWs must be able to understand the manufacturers' user instructions including training videos prior to undertaking face-to-face training.

- HWs using reusable RPD must be able to understand and comply with hand hygiene practices required and complete infection prevention and control mandatory training via My Health Learning (Infection Prevention and Control Practices (Course code: 46777047), Infection Prevention-transmission based precautions (Course code: 253093581), PPE for combined transmission-based precautions (Course Code 294450660) and Donning and Fit Checking of P2/N95 Respirator in NSW Healthcare Settings (Course code: 319438161).

- Annual no longer than 18 months competency assessment is required to ensure continued adequate fit. This includes donning and doffing of the reusable RPD and the ability to demonstrate adequate fit checking.

- Tight fitting RPDs such as CleanSpace® HALO or Sundstrom® SR100 devices require fit testing. This will identify the correct size of the facepiece for an individual and this needs to be recorded in Stafflink.

- In order to maintain the skills required for use of these devices it is recommended that regular training occurs, even in the absence of infectious patients or aerosol risk.

- HW must be able to understand any risk associated with self-contamination or cross contamination with use and with doffing and apply required interventions to minimise these risks.

- HWs must understand the application of reusable RPDs in relation to performing patient care activities.

- HWs are to follow the local training and competency process, documentation and sign off as per local process and requirements.

- HW must perform an initial cleaning of their mask and harness as per the manufacturer's IFU before sending to the reprocessing unit.

3.5 Use of a trained observer to supervise the correct use of PPE

An observer experienced in healthcare PPE protocols is highly recommended to assist in the donning and doffing of PPE, including reusable RPDs, to ensure that the PPE is used in a correct and safe manner.

The trained observer (buddy):

- Checks PPE by inspection prior to the HW entering the clinical environment.

- Reads each direction aloud from a checklist in a step-by-step order. They visually confirm and check off each step.

- Observes the HW in the patient's room (via window or monitor), checking for potential breaches in wearing of PPE.

- Ensures adherence by the HW of the correct steps of donning and doffing.

- Provides immediate corrective action and/or technique recommendations where required.

- Ensures correct disposal of used PPE.

- Is familiar with the management plan in the event of an unintentional breach in PPE.

- Should continue to be involved intermittently until the HW is able to complete all steps without their support.

3.6 HW responsibility

HWs should be provided with the necessary information, instructions, and training on reusable RPDs. HWs will be responsible for:

Preparation

- Ensure they have been trained in donning, doffing and competency assessed before use of tight fitting RPDs (e.g. CleanSpace® Halo or Sundstrom® SR100) prior to commencement of clinical use.

- Ensuring all surfaces of the RPD system are inspected for damage prior to donning for clinical use.

- Ensuring the correct use, cleaning, storage, and maintenance checks are completed for their use.

- Using the tight fitting RPD they have been fit tested for and trained to use.

- Understanding local procedures for managing damaged RPDs if identified.

- Completing a fit check each time a tight-fitting RPD is used.

Use

- Ensure that they wear the appropriate RPD when entering a risk area.

- Ensure all checks including filter and battery life as stipulated by the manufacturer are completed prior to use.

- Ensure correct and safe fitting and removal of the RPD.

- Ensure to perform point of care cleaning and disinfection as recommended by the product manufacturer.

Ongoing

- Ensuring they report any significant changes that could affect mask fit to their line manager or designated fit tester, for example: significant weight loss/gain, significant dental work, or any facial changes around the respirator face seal area.

- Ensuring no facial hair or sideburns are present prior to the use of a tight-fitting respirator, this includes at the time of fit testing.

- Ensuring components or parts of devices are sent for reprocessing as per local procedures and manufacturer's IFU.

- Ensuring they attend regular refresher training or reassessment as required and defined in local competency frameworks.

3.7 Biomedical Engineering responsibilities

Biomedical Engineering is responsible for:

- Completing reusable RPD testing as per the manufacturer's instructions or purchase and Service Level agreement.

3.8 Sterilising Departments responsibilities

Sterilising Departments (SD) are responsible for:

- Ensuring SD staff are trained in reprocessing procedures.

- The cleaning, disinfection and/or sterilisation of all components of the RPD in line with the manufacturer's instructions.

- Ensuring a written procedure for reprocessing is available and complies with *AS/NZS on Reprocessing of Reusable Medical Devices in Health Organisations.*

3.9 Elastomeric respirators

Elastomeric respirators consist of facepieces which are made of synthetic or natural rubber material. They can be repeatedly used, cleaned, disinfected, and re-used. Elastomerics may also have sealing surfaces and adjustable straps that accommodate a better fit. Some types of elastomeric respirators have a higher assigned protection factor (APF) than disposable P2/N95 respirators. APF refers to the level of respiratory protection that a respirator or class of respirators is expected to provide to users.

There are several types of elastomeric respirators: 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 resulting in less face seal leakage and provide protection to more of the face including the eyes. The decision locally to apply these devices should only be considered in specific conditions/scenarios and where all other protection devices have been exhausted.

Elastomeric respirators - considerations for use

Non-sterile face masks (including respirators) that are intended, by their manufacturer, to prevent the transmission of diseases between people, or are intended to be used in a healthcare environment, are medical devices, therefore, must be included in the Australian Register of Therapeutic Goods (ARTG). However, some respirator models comply with AS/NZS 1716:2012 but are not TGA approved for use in healthcare facilities.

In general, elastomeric respirators are not recommended for routine use in healthcare. Decisions on the selection and purchase of these respirators for use in healthcare should be a local decision based on risk assessment and must involve consultation with IPAC team, WHS, biomedical engineering, the sterilisation department and 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 and if it cannot be cleaned and disinfected in between use. If a facility decides to purchase, implement, and use an elastomeric respirator, the procurement team will need to assess the potential risks and determine whether the product is suitable for their needs, also develop process to ensure its safe use.

Donning and doffing

Refer to *Appendix 3C: Donning elastomeric reusable half-face respirator, Appendix 3D: Doffing elastomeric half-face respirator, Appendix 3E: Donning elastomeric reusable half-face respirator for use within a sterile field* and *Appendix 3F: Doffing PPE with elastomeric reusable half-face respirator for use within a sterile field* for donning and doffing of elastomeric half-face respirators.

Precautions should be taken specifically during doffing and use. Training on appropriate donning and doffing procedures should be provided to HWs expected to wear these respirators.

Exhalation valves

There are no filters on exhalation valves and exhaled air may contain a variety of respiratory pathogens and is therefore a risk for other HWs and patients. If elastomerics with an exhalation valve are the only devices available, the exhalation valve must be covered with either a surgical mask or an expiration filter.

Fit testing requirements

The elastomerics are tightfitting RPDs, and HWs using these devises are fit tested and are aware of how to perform a fit check (user seal check). Fit testing will not negate the need for fit checking for any tight-fitting respirator (e.g., P2/N95 and elastomeric respirators) every time it is put on. The following should be considered when fit testing a reusable respirator (see also Figure 1):

- Each respirator type will have its own adapter to connect to the clear tube of the fit testing device.
- Check the probe is in the middle or next to the exhalation valve.
- A particulate P3 filter must be used for the fit test.
- Ensure the sample tube of the fit testing device is well inside the mask but not likely to suck onto the face.

FIGURE 1: EXAMPLE OF FIT TEST ADAPTOR
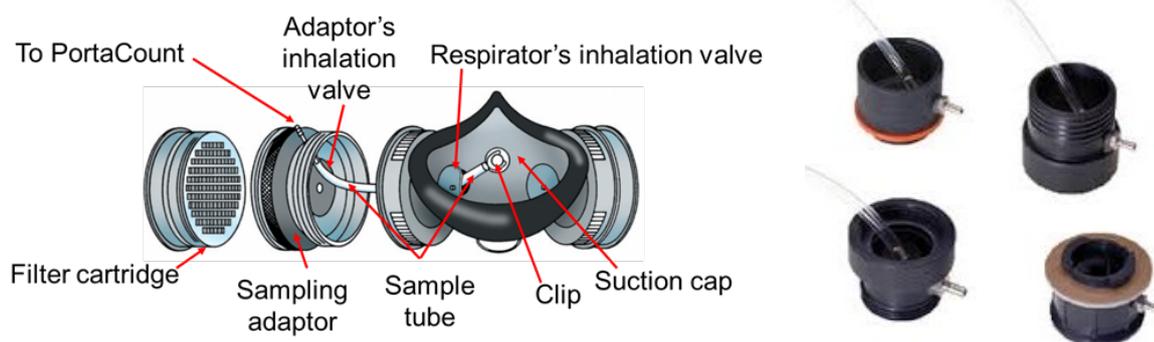
Adapted from TSI™ Fit test Adapters Model 8025

Filter management

There are several types of filter media available for use with reusable half and full-facepiece elastomeric respirators.

In accordance with the IFU, filters should be changed every 3-6 months or if the filter cartridges become visibly soiled, wet, or damaged, or if the respirator becomes notably harder to breathe through. Otherwise, change the filters periodically as per the manufacturer's IFU.

During contingency and crisis or emergency use:

- Filters (except for the unprotected disc type, i.e., the pancake style) may be used for an extended period, if the filter is housed inside a cartridge, then it can be disinfected after each patient interaction.

- Filters, even cartridge types (filters that are inserted into a housing), must not be dipped or immersed in a cleaning or disinfection solution because this may damage or render the filter material ineffective. When using a cleaning or disinfectant wipe on the external surface of a filter cartridge, users should avoid contact with the filter media on the inside of the cartridge.

Sharing elastomeric respirators

For some facilities it may be impossible for individual HWs to have dedicated elastomeric respirators. If this is not possible, the same elastomeric respirator may need to be used by multiple HWs.

The following should be considered when sharing elastomeric respirators between HWs:

- Elastomeric respirators should be reprocessed according to the manufacturer's IFU after each use.

- Before sending the items to the reprocessing department:

  o Conduct surface cleaning at the point of use by the wearer and place in a transport container.

  o Transport the item to the reprocessing department.

- Before reissuing the respirator to a different user:

  o Inspect the item for any damage, this should be done whether it is a new or a reused respirator.

  o Change the filter as per the manufacturer's IFU and use a new filter for each individual user.

Reprocessing

Clean and disinfect reusable respirators as per the manufacturer's IFU and [AS/NZS on Reprocessing of reusable medical devices in health service organisations](#). Always consult with the manufacturer concerning the effectiveness and compatibility of any alternative cleaning and disinfection methods such as disinfectant solutions used for reuse of the facepiece, straps and filter components. The reprocessing procedures must be effective for disinfection (thermal or chemical) and:

- not damage the respirator, including the filter media, which is usually discarded.

- not cause harm to the HW such as skin irritation during the wearing of the respirator.

Prolonged or repeated use of disinfectants may damage or degrade the respirator elastomeric components (facepiece, valves, valve covers, straps) causing components to discolour, swell, harden or crack. This can be assessed by visual inspection prior to, and at the end of reprocessing.

Cleaning

The HW using the device must perform a pre-clean before sending it to the reprocessing department. When cleaning a respirator, trained reprocessing personnel should wear gloves,

gowns, and face shields to protect them from contamination. Contact of the cleaning solution with the filter media must be avoided.

Disinfection

The disinfection instructions are specific to each respirator model and can have varying levels of detail (i.e., unspecified contact times), materials required, and processes (varying concentrations of non-specific or manufacturer-supplied disinfecting solutions). Follow the manufacturer's IFU and local process and procedures in consultation with the IPAC team and reprocessing unit.

Note that the filter media may degrade after contact with disinfectants. Some elastomeric respirators have filter cartridges that prevent disinfectant contact with the filter media.

All reprocessing procedures must be described within a Standard Operating Procedure (SOP) in order to safely reprocess each device including individual device components.

Filters

Disinfection of filter cartridges can be difficult because the internal filter media within the cartridge is not designed to be disinfected, and the outer casing of the cartridge is often covered with paper adhesive labels, which may make disinfecting external surfaces difficult. Unlike their use outside of healthcare, the schedule of replacement of cartridges and filters for reusable elastomeric respirators or whether used filters pose a threat to health remains unclear.

Filters must be completely air dry before storing. Label the filter with the user's name using a permanent marker as soon as it is issued.

Note: P-series filters can generally be re-used until they are soiled, damaged or difficult to breathe through. Practices not approved by the manufacturer can increase the risk and uncertainty of protection associated with re-using damaged or degraded components.

3.10 Powered air-purifying respirators (PAPR)

PAPRs use a rechargeable battery pack to power an air blower. This blower pulls ambient air through a particulate filter, then into the face mask. Depending on the model, this air may blow constantly or be activated by inhaling. Air is expired though an exhalation valve. PAPRs can be a loose-fitting hood and helmet, tight fitting half mask or tight-fitting full-face piece.

Because filtered air is 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 RPDs but is more complex to use and maintain.

The type and amount of airborne contaminant will dictate the type of filter, cartridge or canister required for the PAPR. This respirator has an APF of at least 25 for loose-fitting hoods and helmets, 50 for tight-fitting half masks and 1,000 for full facepiece types. Some loose-fitting hoods and helmets reach 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.

The following should be considered when selecting a PAPR:

- A governance program is required when implementing PAPRs, as the items are complex, costly, have additional application and removal steps and need to be monitored.

- Manufacturer's instructions must be read, understood, and followed for all aspects of PAPRs and accessories use, reprocessing, maintenance (like calibration and correct charging), and storage.

- A PAPR will provide improved comfort and visibility if a HW is required to remain in a patient's room continuously for a long period to perform multiple procedures e.g., for more than an hour.

- Use of a PAPR requires HW training and competency assessment prior to implementation.

- In the early stages of HWs learning how to use a PAPR, a designated assistant or buddy is recommended, especially for doffing.

- Ensure there is a procedure for reprocessing the reusable components of the PAPR after use. This must be done according to the manufacturer's IFU and comply with AS/NZS on Reprocessing of reusable medical devices in health service organisations and local facility or service reprocessing procedures.

- These items must only be purchased in consultation with the facility IPAC team, reprocessing unit and infectious disease advice in accordance with facility or service capacity for equipment management, maintenance and reprocessing of these items.

- Care should be taken on removal of the PAPR, which is associated with a higher risk of contamination compared with disposable respirators.

Considerations for PAPRs use in healthcare settings include:

- A PAPR may interfere with the HWs visual field.

- The blower noise can make communication more difficult.

- The loose head covering can make communication more difficult.

- The use of a stethoscope may be limited.

- PAPR batteries must be recharged or replaced.

- PAPRs require a significant amount of storage space when not being used.

- HWs using, maintaining, and reprocessing PAPRs must be adequately trained.

PAPR with exhalation valves

Some models do not have a filter on the exhalation valve. When using a PAPR with an exhalation valve, the exhalation valve needs to be covered with an expiration filter or surgical mask (always follow the manufacturer's recommendations). When a PAPR 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.

3.10.1 Maintenance of PAPR components

PAPR use requires a robust maintenance program for repairing or replacing components that have become damaged during use or reprocessing as well as battery management procedures. Trained and competent HWs are required to support the PAPR maintenance program. Manufacturers recommend reprocessing procedures for PAPR components except for the high efficiency (HE) filter/cartridge, which is generally recommended to be discarded and replaced.

Routine maintenance is also required for battery charging and/or replacement. The maintenance program for PAPRs requires a supply of replacement components, including HE filters or cartridges, to support and maintain PAPR use.

3.10.2 Reprocessing

There are several parts to PAPR devices that require point of care cleaning and reprocessing in the reprocessing department**.** Based on the type of respirator the facility should develop and follow point of cleaning and reprocessing Safe Operating Procedures (SOPs) in consultation with the IPAC and reprocessing unit which align with the manufacturer's IFU.

Point of care cleaning

Cleaning is recommended after each use, but the PAPR must be cleaned as often as necessary (if exposed to body substances or stored for extensive periods of time) to prevent it from becoming contaminated. The wearer is to perform point of care cleaning before transporting the reprocessing components to sterilisation department.

Reprocessing Department

In general, reprocessing consists of disassembling the PAPR, cleaning, disinfecting all components, thoroughly rinsing the components, drying, and reassembling the PAPR when the components are dry. It is important to follow all steps set forth in the manufacturer's instructions.

The disinfection instructions are specific to each respirator model and can have varying levels of detail (i.e., specified contact times), materials required, and processes (varying concentrations of specified or manufacturer-supplied disinfecting solutions).

N.B. Reprocessing staff should wear appropriate PPE when cleaning organic and inorganic matter from the respirator to prevent potential for cross contamination.

Filter change

In accordance with the manufacturer's IFU, filters should be changed according to the frequency of use of the respirator.

- If in constant use then the filter should be changed every 2 weeks, in a moderate activity period the filter should be changed every 1 month and in a low activity period of frequency then the filter can be changed every 2 months.

- Filters should be replaced after exiting a decontamination shower, or if they are damaged or wet.

- Filters can remain in place when the power unit is charging.

- Expiration filters are single use only and should be disposed of and replaced when reprocessing the mask and power unit.

3.10.3 Use of a loose-fitting PAPR

A loose-fitting facepiece has a respiratory inlet covering that is designed to form a partial seal with the face. There are a variety of loose-fitting facepieces, as well as hoods and helmets which cover the head completely and usually include a neck cuff. Air is delivered by a compressor through a hose leading into the hood. Because the hood is not tight-fitting, it is important that enough air is provided to maintain a slight positive pressure inside the hood relative to the environment immediately outside the hood. The following should be considered before selecting a loose fitting PAPR:

- A loose fitting PAPR can be considered for HWs who fail fit testing to a tight-fitting respirator (e.g., disposable P2/N95). A fit test is not required for PAPRs with loose-fitting headgear such as hoods and helmets.

- There is variable splash protection to the face and eyes by hooded PAPRs and PAPRs with helmets.

- Loose fitting PAPR at the outset has a higher capital cost.

- PAPR systems have APFs 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 more comfortable to wear as inhalation is supported by the blower providing air under positive pressure.

- Fit testing costs for loose-fitting PAPRs are minimal but they do have higher capital costs.

Note: Fit testing is not required for loose-fitting PAPR device.

FIGURE 2: EXAMPLE OF A LOOSE-FITTING PAPR, ADAPTED FROM MEDIGROUP AUSTRALIA™


ARTG number: 334276

3.10.4 Storage of reusable respirator mask and power system

When the respirator has been reprocessed, it should be sealed and stored securely. In accordance with manufacturing guidelines, these items must be stored in a dry, dust free environment, between 18 °C to 28 °C to maintain the integrity of the internal battery. Do not leave the unit in direct sunlight or near a heat source. Do not unplug the power system until it is fully charged. The exhalation adaptor and a new exhalation filter should be attached to the unit. For some PAPR models this may be done at the time of donning (e.g., Clean Space HALO™).

3.11 CleanSpace® HALO PAPR respirator

CleanSpace HALO is a tight-fitting half-face PAPR system consisting of a power unit, HEPA filter, facepiece or mask, head harness, exhalation valve adaptor and filter and neck support. The blower draws ambient air through the high efficiency filter and supplies filtered air to the wearer via the mask. Fan speed is continuously adjusted to maintain positive pressure in the mask. Should the filter become blocked, an alarm will sound and the "filter" light on the keypad will be illuminated. If the battery voltage falls below the minimum required to sustain the desired flow rate, an alarm will sound. This respirator contains a system for synchronising with breathing and regulates mask pressure. This system requires re-calibration whenever there is a change in temperature of more than 20°C. It is best practice to also re-calibrate if the unit has been in storage, particularly if the storage temperature is not known. Refer to manufacturers IFU for more information. A biohood can be used to protect the wearer from body substance splash and respiratory particles. For more information refer to CleanSpace™ BioHood.

FIGURE 3: EXAMPLE OF A TIGHT FITTING PAPR

Filtered Air (99.97%)

Contaminated air

Exhaled Air
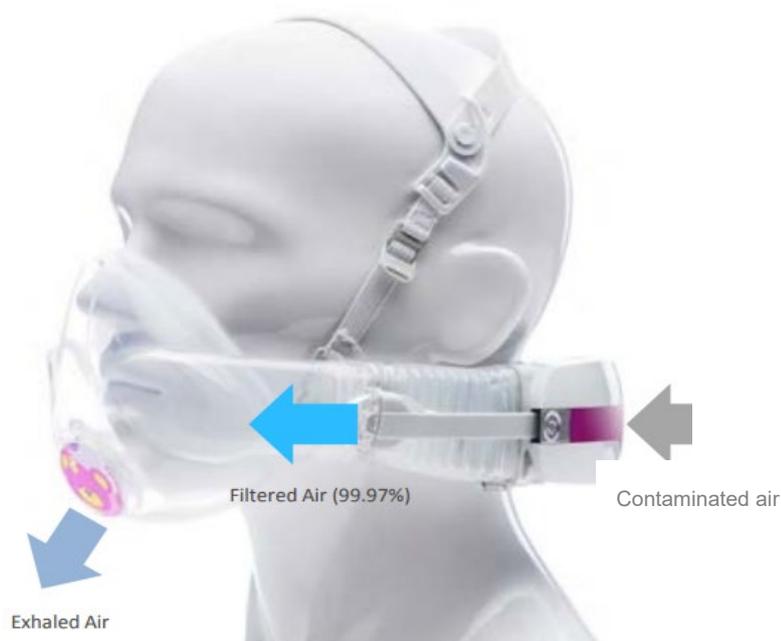
Adapted from CleanSpace HALO™

3.11.1 CleanSpace® HALO PAPR respirator considerations for use

Always follow the manufacturer's IFU. It is mandatory that an exhalation valve filter or surgical mask is used with the respirator. The exhalation valve filter is a P2 filter that can be attached to the exhalation valve. The CleanSpace® HALO must be cleaned and reprocessed between use. The following should be considered by users of CleanSpace® HALO PAPR respirators:

- Only for use by trained HWs.

- Filters need to be changed regularly. The frequency of change depends on use, the concentration of contaminants in the atmosphere and the manufacturer's instructions.

- Only suitable for use by clean-shaven personnel.

- Eye protection is required for the use of half-face CleanSpace® PAPRs.

- Only use the respirator with the parts and accessories listed on the approval Label.

Do not:

- Use the respirator unless it is powered and running normally.

- Use the respirator while it is being charged via the AC adaptor.

- Use in oxygen deficient or oxygen enriched atmospheres.

- Use in flammable or explosive environments.

- Remove the respirator until you have left the contaminated area.

For donning and doffing information refer to CEC Donning and doffing CleanSpace® HALO PAPR with half mask video and *Appendix 3G: Donning PPE with CleanSpace® HALO PAPR, Appendix 3H: Doffing PPE with CleanSpace® HALO PAPR, Appendix 3I: Donning PPE with CleanSpace® HALO PAPR, Appendix 3J: Doffing PPE with CleanSpace® HALO PAPR.*

3.11.2 CleanSpace® HALO PAPR unit inspection and checks

Before using a CleanSpace® HALO the following checks must be completed:

- Check the power unit for cracks, holes, or other damage.

- Check the HEPA filter and foam seal is clean and free from damage only if you are changing to a new filter. If damage is found discard the filter (**do not open filter at any time**).

- Check filter expiry date (only if you are changing to a new filter).

- Check the battery for charge by pressing the 'Power Charge' on button - 3 LEDs glow green when fully charged.

- Check the mask and head harness for any damage.

- Check the exhalation valve is in place and silicon leaf is not folded. If it is folded twist the conical piece on the inside of the mask to release the fold until the leaf sits flat in the exhalation valve. Remove mask valve cover and check for damage/debris. Gently lift valve leaf to ensure it is not folded over and replace cover. (If the valve is damaged replace the valve and if a new valve is not available use a new mask).

- Check the P2 exhalation filter adaptor for cracks, holes or other damage.

Battery failure

The battery should last for 9 hours post full charge (3 LED lights). It is designed to alarm when there is 10-20 minutes of battery life remaining. In the unlikely event that the battery fails, leave the patient zone immediately, complete the doffing protocol, request a new power unit and don.

Filter warning alarm

CleanSpace® respirators have a filter warning alarm, which is triggered when the filter is blocked. If the alarm and light come on, you must leave the contaminated area and doff the respirator.

Respirator mask fit check

The wearer should use a negative or positive pressure fit (seal) check every time a CleanSpace® respirator is donned and just before entering the patient zone. The correct mask size must be determined by a trained CleanSpace® HALO user before using the CleanSpace® HALO respirator. HWs also need to know how to adjust the system to achieve a good fit. CleanSpace HALO offers a Smart App that can be used to check for a seal.

Negative pressure fit check

After inspecting the mask, the wearer should occlude the mask arms with the fleshy part of thumbs, place chin in the chin well and roll the mask onto the face. Take a sharp breath in. If it is the correct size, the mask should collapse on your face. If it doesn't, readjust thumbs and try again. If unable to achieve a negative pressure check, inspect the exhalation valve is properly seated after processing. If the selected mask size is no longer suited, try another size.

Positive pressure fit check (where used)

Locate the red seal check cap. Fit seal check cap over the exhalation valve in the mask. The cap should snap into place (see figure below), then:
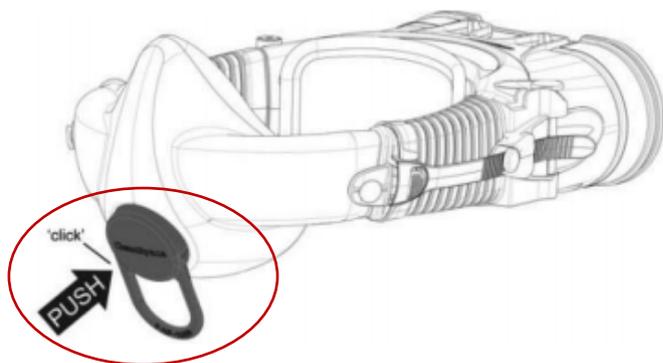
1. Check that no air is flowing from the exhalation valve. Breathe normally.

2. Using your fingers, feel around the perimeter of the mask for leaks. You will feel any leak as a cool flow of air over your finger. For greater sensitivity breathe out firmly to raise the mask pressure. Wetting your fingers will make it easier to feel tiny leaks.

3. If necessary, tighten the mask. To tighten the mask, place one hand against the back of the blower and the other over the front of the mask. Push the blower forwards and the mask back, tightening the fit. You will hear a series of clicks as the mask is tightened.

4. Be careful to tighten each side by the same amount.

5. Do not over-tighten the mask. If the front of the mask starts to become concave, it is too tight and may leak. Press the adjust buttons to loosen the mask a little.

6. After each tightening, feel for leaks again.

7. Check for leaks while doing each of the following: look up, look down, look right, and left. Adjust the mask if necessary.

8. Once you can feel no leaks from the mask, the seal check is complete.

9. Remove the seal check cap by gently twisting the handle so that one side of the cap comes loose from the exhalation valve. Be careful not to dislodge the exhalation valve cover. See figure below:

FIGURE 5: REMOVE RED CAP
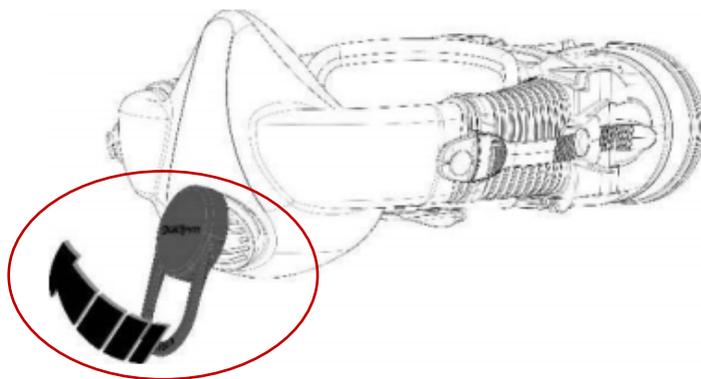
Adapted from CleanSpace® HALO PAPR

Caution: Be sure to **remove the seal check cap before entering the contaminated area**. The cap blocks the exhalation valve, making it more difficult to exhale and will lead to a build-up of carbon dioxide. It is expected that a fit check can be completed in no more than 2 minutes.

Fit Testing

Fit testing of the CleanSpace® HALO respirator must only be carried out by a trained fit tester. To carry out a quantitative fit test of the mask fitter will require a PAF-0025 PortaCount™ adaptor and the accompanying S005-7174 quantitative fit test Instructions. The PortaCount™ adaptor is an accessory that fits between the mask and the exhalation valve and allows the air in the mask to be sampled. Remove the exhalation valve assembly and install onto the O-ring section of quantitative fit testing adaptor (PAF-0025) then install the test jig with exhalation valve into the valve port in the mask. See figure below:

For more details refer to CleanSpace fit test instructions and CEC HALO fit testing video

FIGURE 6: INSTALLING THE HALF MASK FIT TEST ADAPTOR (PAF-0025)

Installing the adaptor · Half Mask - adaptor installed · Half Mask with adaptor installed

Adapted from CleanSpace® HALO PAPR

Cleaning procedures for the CleanSpace® HALO PAPR

The manufacturer recommends cleaning the respirator after every use. The facepiece, power unit, neck support and harness should be disassembled and cleaned separately at the point of care by the user as per the IFU and local guidelines. The local facility should develop a process for cleaning and disinfection of the HALO PAPR in consultation with the infection prevention and control team. See Appendix 3G for more information on cleaning and disinfection procedure.

Reprocessing department

Rinse the facepiece, thoroughly in fresh water to remove cleaning residue.

OR

An industrial washer can be used to clean the mask/head harness. Use water and drying temperatures which are less than 50°C.

After cleaning, allow the mask to air dry.

Manufacturer recommended sterilisation procedures (mask only)

Sterrad™ sterilisation may be used. See manufacturers IFU for more information.

Specific considerations for Reprocessing Department

- o The cap over the filter must be removed carefully before processing through the batch washer.
- o The silicon disk must not be removed.
- o Label mask correctly small; medium; large. (Each head strap has a S indication small; M indicating medium; L indicating large).
- o Technician in decontamination must check for wear/tear and/or damage – report to the Charge of Shift immediately.
- o Must go through the batch washer flat on batch washer rack, while allowing free movement of water.
- o Must not hang mask in the batch washer.
- o Must go through an anaesthetic cycle, this cycle does not have citric rinse which will damage the material.
- o Technician in decontamination must document the details correctly as per local process.
- o Technician packing must ensure CleanSpace® respirator is completely dry – Reusable medical device (RMD) dryer must not exceed 65°C.
- o Technician packing must ensure the area around the filter is clean using the magnification light.
  - carefully replace the cap.
  - label every mask correctly.
  - document correctly, including date and signature.
- o Report all damage and/or issues immediately to Charge of Shift and document.

Storage of reprocessed respirator and power system

- Collect reprocessed facepiece from the reprocessing department.
- Ensure each facepiece is individually packaged with the date of reprocessing.
- Store returned facepieces in the designated storage area for clean equipment.

To ensure equipment longevity, safety and security, the following principles apply to storing PAPRs:

- Respirators should be stored in the CleanSpace® charging and storage station.
- When not in regular use, store the respirator with the cleaning and storage plug (see figure below) inserted to prevent dust or liquids from entering the air path of the respirator.
- Facepieces and other parts should be stored in a sealed clean container.
- New power unit filters should be kept in their original packaging until use.

FIGURE 7: CLEANING AND STORAGE PLUG SET
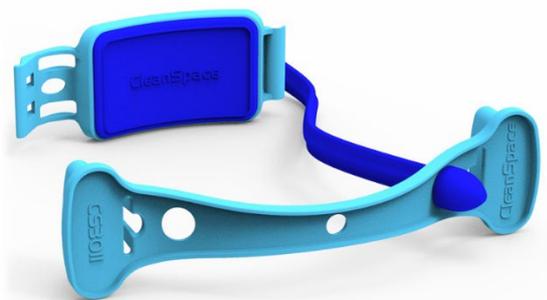
Adapted from CleanSpace™ HALO

Power unit storage on charge

If the power unit is left continually on charge, there is minimal battery degradation. Battery life is dependent on the number of cycles (charges and discharges i.e., use) and the temperature the power unit is stored at. High temperatures (>35°C) accelerate the aging of the battery.

Power unit storage off charge

If the power unit is fully charged and then unplugged (i.e., off charge) without use, the battery will lose charge over 4 weeks. If the power unit is never charged (i.e., power unit is stored without charge), the battery life is dependent on storage temperature (>35°C ages the battery). Battery manufacturers recommended best practice is that the battery be regularly cycled (i.e., charged/discharged), optimally every 3 months. The power unit should be fully recharged prior to use.

TABLE 4: STORAGE AND MAINTENANCE REQUIREMENTS OF PAPRs IN REGULAR USE

Storage period	Cleaning	Filter replacement	Inspection	Testing and servicing
In regular use or used within 30-day timeframe	Wipe parts prior to use	Monthly, unless contaminated. Risk assess and update frequency of changing	Prior to each use, inspect equipment for damaged or missing parts	Monthly calibration, flow test and alarm test

TABLE 5: STORAGE AND MAINTENANCE REQUIREMENTS OF PAPRs NOT IN REGULAR USE

Storage period	Cleaning	Filter replacement	Inspection	Testing and servicing
If PAPR has been in storage for ≥30 days and ≤365 days	Wipe parts prior to use	If it is anticipated that the PAPR will not be used for ≥30 days, store the respirator without the filter. Insert blue storage plug	Inspect equipment for damaged or missing parts	Prior to use run the flow test and the alarm test. Calibrate every 3 months
If PAPR has been in storage for ≥365 days	Cleaning to be attended at annual service	Store respirator without the filter	Prior to use a trained and authorised CleanSpace® technician should perform an equipment service (clean, inspect, run test and service check)	

Monthly testing is to be conducted by the designated person. The following are the monthly tests that must be carried out for PAPRs:

Audible alarm test:

1. Unplug and remove the motor unit from storage and check the battery charge prior to commencing the test. If the respirator is not fully charged, return to the charging station and select another respirator.
2. Remove the motor unit filter and do not add the silicon facepiece.
3. Securely fit the cleaning and storage plug to the motor unit filter inlet if not already fitted.
4. Ensure the bellows are not sealed.

5. Press the power button and put the respirator into standby mode (will show).
6. Will show green LED light and no motor on.
7. Press the power button again to run the alarm test. During the test, the motor/airflow will run fast.
8. After 8 seconds the respirator alarm should sound, and the red LED filter alarm will flash. If this does not happen, check that the cleaning and storage plug is fitted correctly and repeat the test. If the unit fails the alarm test a second time, do not use the motor unit and notify the designated maintenance contractor.

Manufacturer's flow test:

1. Re-insert the motor unit filter (do not fit the mask).
2. Press the power button and put the respirator into standby mode (will show green LED light and no motor on).
3. Press the flow test button on the keypad to run the flow test. During the test, the motor/airflow will run fast, and air will blow from the left bellow.
4. After 8 seconds the motor/airflow will stop.
5. The respirator reports the flow test result using the battery green LEDs on the keypad. Three green LED lights indicate a pass.
6. If the flow test returns one or two green LEDs only, check the respirator is fully charged and the filter is not blocked, then repeat the flow test. If the repeat test returns one or two LEDs, contact the designated maintenance contractor and do not use this motor unit.

Important notes on motor unit filters

CleanSpace® particulate motor unit filters are comprised of an unwoven glass media. Contact with fluids has the potential to damage the filter media and reduce the effectiveness of the filter. If this occurs, remove, and replace the filter. Follow the manufacturer's instructions on frequency of filter change.

Motor unit filter alarms

CleanSpace® motor unit filter alarms are triggered when the filter is close to being blocked. An alarm will sound when the filter is 80% blocked and allows time for the wearer to leave the contaminated area and change the filter or address the blocking issue. In a clean environment such as a healthcare setting, the filters are unlikely to block with particulate matter. In these circumstances if the filter alarm sounds, the wearer should leave the contaminated area and check the filter. Check that any clothing or hair is not covering the filter inlet.

Inspecting the motor unit filter before use

Before use the motor unit filter must be inspected carefully to ensure:

- The foam seal is clean and free from damage (open and inspect, but do not touch the internal filter parts).

- The visible surface is free from dust, cracks, or contaminants.

- The filter is within the expiry date range.

Discard and replace the filter if dusty, damaged, or out of date.

Sharing PAPR between users

For some facilities it may be impossible for individual HWs to have dedicated PAPR. If this is not possible, the same PAPR or components may need to be used by multiple HWs.

The following should be considered when sharing PAPR or components between HWs:

- PAPR should be reprocessed according to the manufacturer's IFU after each use.

- Follow manufacturer's instructions on items or components that cannot be shared in between users or single use.
- Dedicate parts or items for individual HW if that cannot be reprocessed.
- Before sending the items to the reprocessing department:
  - Conduct surface cleaning at the point of use by the wearer and place in a transport container.
  - Transport the item to the reprocessing department.
- Before reissuing the respirator to a different user:
  - Inspect the item for any damage, this should be done whether it is a new or a reused respirator.
  - Change the filter as per the manufacturer's IFU and use a new filter for each individual user.

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Appendix 3A: Reusable respiratory protective device (RPD) implementation checklist

Prior to the use of a reusable RPD within a department the following must be in place	
1. Infection Prevention and Control, Sterilisation Unit, Biomedical Engineering and Infectious Diseases are consulted on every aspect of reusable RPD purchase and proposed use	☐
2. Indications for use of the reusable RPD are clearly defined for each department	☐
3. The department proposing to use reusable RPD have read the relevant endorsed policies, procedures, and checklists (donning, doffing, training, cleaning, competency, governance, accountability). These documents are to be reviewed and adapted to the specific needs of the department in which they are to be used.	☐
4. Written procedures, specific to the department, for donning and doffing reusable RPD must be developed	☐
5. A written procedure for reprocessing of the reusable RPD, specific for the department must be developed, including point-of-removal and availability of reprocessing equipment	☐
6. Department governance structure to be established that has defined oversight for the local management of the reusable RPD	☐
7. A person must be designated responsible for local processes in the department	☐
8. A tracking system should be in place for reusable facepieces, hoods and motor units with a designated HW to monitor and document	☐
9. Sterilization unit consulted about reprocessing requirements for reusable equipment, specific to the department and a procedure developed	☐

10. Implementation of a training programme specific to the department, using the reusable RPD includes:
    a. Orientation and fitting to the equipment and associated components
    b. Formal fit-testing using a PortaCount™ machine and TSI™ software, or alternative
    c. Donning and doffing procedures for the reusable RPD with other items of PPE
    d. Competency assessment of donning and doffing with an assistant or buddy
	☐

11. There are adequate human resources and physical space allocated for training. This includes local trainers who will be trained as superusers with support of a designated educator who will be responsible for training, certification, and recertification of users.	☐
12. Provision of training must also be made for assistants or buddies who are available to guide and support the wearer whenever this equipment is used.	☐
13. Identification of a storage area for equipment, including charging space for the motor units	☐
14. Adequate masks and other components purchased to meet the requirements for multiple users including training, taking into account reprocessing turnaround times	☐
15. An asset management process implemented for all reusable RPD including regular maintenance of motor units with a HW in the department responsible	☐

16. Biomedical Engineering have been consulted and engaged to add to assets register and provide the required maintenance/testing	☐
17. Decontamination and reprocessing of all the equipment meet the manufacturer's IFU and infection prevention and control requirements	☐

Appendix 3B: General instructions for donning elastomeric half-face respirators

Always follow the manufacturer's instructions for use (IFU).

1. Place the respirator over the nose and mouth with the bottom straps unfastened.

2. Pull the top strap over your head, placing the head cradle on the crown of your head.

3. Hook the bottom straps together behind your neck.

4. Adjust strap tension to achieve a secure fit.

    a. Pull the ends of the straps to adjust the tightness beginning with the adjustment points at the top of the respirator and then moving to the adjustment points at the back of the neck.

    b. Do not over-tighten.

    c. Strap tension may be decreased by pushing out on back side of the buckles.

Fit checking

<u>Positive pressure user seal check</u>: Place the palm of your hand over the exhalation valve cover and exhale gently. The facepiece should bulge slightly. If air leaks between the face and the seal of the respirator, reposition it and adjust the straps for a more secure seal. If you cannot achieve a proper seal, do not enter the patient area and report to your manager or supervisor.

<u>Negative pressure user seal check</u>: Place your thumbs over the centre of the filters and inhale gently. The respirator should collapse slightly. If air leaks between the face and the seal of the respirator, reposition it and adjust the straps for a more secure seal. If you cannot achieve a proper seal, do not enter the patient area and report to your manager or supervisor.

<u>When using cartridges</u>: Place the palms of your hands over the cartridges and inhale gently. The facepiece should collapse slightly. If air leaks between the face and the seal of the respirator, reposition it and adjust the straps for a more secure seal. If you cannot achieve a proper seal, do not enter the patient area and report to your manager or supervisor.

Appendix 3C: Donning elastomeric reusable half-face respirator

This procedure applies to elastomeric respirators. Always follow the manufacturer's IFU.

- HWs must be trained and deemed competent in use of the respirator.

- It is the responsibility of the HW to ensure they have selected the correct mask size and adjusted the harness settings before donning the respirator.

- Don these respirators with a PPE buddy (note: the buddy should be trained and deemed competent in this process which will aid in providing a safety check).

- HWs are responsible for the maintenance, labelling, cleaning, disinfection, and storage of respirator filters. The filters must be labelled using a permanent marker with the HWs name and this should be monitored after each cleaning process to ensure the name is clear. If a filter has been used and there is no legible name on it, it must be discarded.

- A surgical mask must be used over the exhalation valve if there is no exhalation filter which may place other HWs and patients at risk if the user has a respiratory infection e.g., COVID-19.

1. Preparation	
☐	Remove jewellery and wristwatch etc.
☐	Pull hair back off the face and neck – e.g., use a low/mid ponytail that avoids the harness position
☐	Ensure all PPE is available in donning area
2. Prepare doffing area (can be completed by PPE buddy or colleague)	

☐	Ensure doffing area is selected and prepared before donning the PPE
	- Puncture proof container with lid for transporting to reprocessing unit:
	  • Respirator facepiece and harness
	  • Reusable eyewear/visor
	- Disposable fluid resistant sheet
	- Detergent/Disinfectant wipes
	Clean storage bag for filters

☐	Correct waste bin * PPE can be discarded in general waste. If soiled with blood or body substances, then dispose into clinical waste.
3. Elastomeric half-face respirator check	
☐	Perform hand hygiene
☐	Bring particulate filters that have been provided to you by your facility
☐	Select correct size elastomeric half-face respirator

☐	Sign-out elastomeric half-face respirator in logbook (follow local process if it varies)
☐	Inspect facepiece, harness and filters for damage – <u>do not use if damaged</u> Check the expiry date on the filter (follow manufacturer's IFU for replacement)
☐	Adjust harness size
☐	Attach filters to facepiece by aligning the small notch on the respirator with the small hole on the filter, pushing in, and rotating each filter 90 degrees clockwise until a locking stop is felt
☐	Attach an expiratory filter if available and attach to the exhalation valve as per manufacturer's IFU If filter not available ensure surgical mask covers exhalation port of elastomeric exhalation valve

4. Donning PPE and elastomeric half-face respirator

☐	Perform hand hygiene
☐	Don gown
☐	Bring harness forward over the front of the respirator
☐	Place respirator facepiece over the nose and mouth
☐	Hold respirator in place with one hand and put the harness over the top of the head with the other hand
☐	Ensure straps are not twisted
☐	Bring bottom straps around the back of the neck and lock together
☐	Adjust top then bottom straps to create a secure fit but do not over-tighten
☐	Check with PPE buddy that the respirator is adequately positioned
☐	<u>Perform a positive pressure face check</u> Place the palm of your hand over the exhalation valve cover and exhale gently. If the facepiece bulges slightly and no air leaks are detected between the face and respirator, a proper seal has been obtained
☐	<u>Perform a negative pressure face fit check</u> Squeeze filter covers together using the palms of the hands and fingers to restrict the airflow. Inhale gently. If the facepiece collapses slightly and no air leaks are detected between the face and respirator, a proper seal has been obtained.
☐	Put on protective eyewear or face shield

☐	Perform hand hygiene
☐	Put on gloves – ensuring they cover the cuffs of the gown immediately before touching the patient

5. Safety check

☐	Complete safety check with PPE buddy

Appendix 3D: Doffing elastomeric reusable half-face respirator

Doffing elastomeric reusable half-face respirators must be performed with a PPE buddy (note: the buddy should be trained and deemed competent in this process which will aid in providing a safety check).

	1. Before exiting patient zone	
☐	Engage with PPE buddy outside the patient zone Ensure doffing area is set up with the following: - Puncture proof container with lid for transporting to reprocessing unit - Disposable fluid resistant sheet - Detergent/Disinfectant wipes Clean storage bag for filters	
☐	Correct waste bin * PPE can be discarded in general waste. If soiled with blood or body substances, dispose in clinical waste.	
☐	Remove gloves, perform hand hygiene	
☐	Remove gown	
☐	Perform hand hygiene	
☐	Exit patient zone	
	2. At doffing station outside patient zone	
☐	Remove protective eyewear or face shield (if disposable discard in waste bin, if reusable place in a container or transport trolley for reprocessing – same as mask will go into)	
☐	Perform hand hygiene	
	3. Removal of elastomeric half-face respirator	
☐	Don clean non-sterile gloves	
☐	Note at this point all PPE except the respirator should be removed	
☐	Bend from the hips, chin up and elbows out to the side to prevent contamination	
☐	Release the lower strap with both hands, Bring forward then hold the lower straps with one hand, Maintain tension on the straps	

☐	Bring harness forward over the head while maintaining tension to the harness (and top straps) as well as to the lower straps in the other hand.
☐	Bring the facepiece forward and outwards away from the body, keeping the tension on all the straps
☐	Place respirator on a disposable fluid resistant sheet in the doffing area on a cleanable surface or a trolley
4. Removal and cleaning/disinfection of filters	
☐	Disconnect particulate filters from facepiece by holding the facepiece in one hand and rotate the filter anti-clockwise, repeat with another filter. The surgical mask will be freed from the mask once filters are removed.
☐	Place the surgical mask in bin
☐	Remove gloves and perform hand hygiene
☐	Don new pair of gloves and remove wipes from container
☐	Clean filters (dependent on local products available) a) Wipe filters with 2-in-1 step clean and disinfection wipe <u>or</u> b) A neutral detergent wipe followed by a disinfection with 70% alcohol or bleach solution (sodium hypochlorite 1,000ppm) Care must be taken to ensure that no cleaning solution contacts the filter membrane. Place the filter on a separate clean surface and allow filters to completely air dry
☐	Wipe over facepiece and harness and place in a leak proof plastic bag and into a transport container for reprocessing
☐	Discard disposable fluid resistant sheet and remove gloves
☐	Perform hand hygiene
☐	Filters are the responsibility of individual HWs – it is recommended that once filters are air dry, they are placed into a clean plastic bag and sealed, then stored in a clean space until next use. HWs should check to ensure their name is still legible after cleaning and disinfecting.
☐	Sign logbook that elastomeric half-face respirator has been sent to reprocessing unit for reprocessing (follow local process) including details of patient where the device has been used
5. Elastomeric half-face respirator returned from Reprocessing Unit	
☐	Sign in logbook that elastomeric half-face respirator has returned to department
☐	Store the reprocessed respirators in secured designated area for clean respirators

Appendix 3E: Donning elastomeric reusable half-face respirator for use within a sterile field

- This procedure applies to elastomeric respirators. Always follow manufacturers IFU.
- These respirators were not intended for healthcare and therefore not TGA approved.
- This process is for HWs working within a sterile field, e.g., surgeon in theatre, scrub nurse, proceduralist, where a **sterile gown and sterile gloves are worn**.
- HWs using elastomeric reusable half-face respirator must be trained and deemed competent in its use.
- It is the responsibility of the HW to ensure they have selected the correct mask size and adjust the harness settings before donning the half mask respirator.
- Don this respirator with PPE buddy (note: buddy should be trained and deemed competent in this process which will aid in providing a safety check).
- HWs are responsible for the maintenance, labelling, cleaning, disinfection, and storage of their filters. The filters must be labelled using a permanent marker with the name and this should be monitored after each cleaning process to ensure the staff members name is clear. If a filter has been used and has no legible name, it must be discarded.
- A surgical mask must be used over this mask as there is no exhalation P2 filter to ensure surgical mask covers exhalation port of elastomeric exhalation valve. If an expiratory filter is available attach it to the exhalation valve as per manufacturers IFU.

1.Self preparation	

☐	HWs in theatre will already be in theatre attire
	
	   - Theatre hair net/cap
	
	   - Scrubs
	
	   - Theatre clogs or shoes (follow local process on shoe covers)
	
	Note this is normal attire for use in the operating theatres

☐	Ensure all PPE is available in donning area
☐	Long hair should be in a low/mid ponytail that avoids the harness position
2. Prepare doffing area (can be completed by PPE buddy or assistant)	

☐	Ensure doffing area is selected and prepared before donning the PPE
	
	- Puncture proof container with lid for transporting to reprocessing unit:
	
	    • Respirator facepiece and harness
	
	    • Reusable eyewear/visor
	
	- Disposable fluid resistant sheet
	
	- Detergent/Disinfectant wipes
	
	Clean storage bag for filters

☐	Correct waste bin * PPE can be discarded in general waste. If soiled with blood or body substances, dispose in clinical waste.

3. Elastomeric half-face respirator check

☐	Perform hand hygiene
☐	Bring particulate filters that have been provided to you by your facility
☐	Select correct size elastomeric half-face respirator
☐	Sign-out elastomeric half-face respirator in logbook (follow local process if it varies)
☐	Inspect respirator and filters for damage – <u>do not use if damaged</u>
☐	Adjust harness size
☐	Attach filters to facepiece by aligning the small notch on the respirator with the small hole on the filter, pushing in, and rotating each filter 90 degrees clockwise until a locking stop is felt.
☐	Attach surgical mask with elastic ear loops. Double loop elastic over filter (if required), and ensure surgical mask covers exhalation port of elastomeric facepiece).

4. Donning PPE and elastomeric half-face respirator

☐	Perform hand hygiene
☐	Bring harness forward over the front of the facepiece
☐	Place facepiece over the nose and mouth
☐	Hold facepiece in place with one hand and put the harness over the top of the head with the other hand
☐	Ensure straps are not twisted
☐	Bring bottom straps around the back of the neck and lock together
☐	Adjust top then bottom straps to create a secure fit but do not over-tighten
☐	Check with PPE buddy that elastomeric half-face respirator adequately positioned
☐	<u>Perform a positive pressure face fit check</u> Place the palm of your hand over the exhalation valve cover and exhale gently. If the facepiece bulges slightly and no air leaks are detected between the face and the respirator, a proper seal has been obtained

☐	**Perform a negative pressure face fit check** Squeeze filter covers together using the palms of the hands and fingers to restrict the airflow. Inhale gently. If the facepiece collapses slightly and no air leaks are detected between the face and respirator, a proper seal has been obtained
☐	Put on protective eyewear or face shield
☐	Perform surgical scrub
☐	Then proceed with your normal process of donning PPE for sterile field
5. Safety check	
☐	Complete safety check with PPE buddy

Appendix 3F: Doffing PPE with elastomeric reusable half-face respirator for use within a sterile field

Doffing elastomeric reusable half-face respirator must be performed with PPE buddy (note: buddy should be trained and deemed competent in this process which will aid in providing a safety check).

1. Before exiting patient zone	

☐	Ensure doffing area is available and set up with the following:
	- Puncture proof container with lid for transporting to reprocessing unit:
	   • Respirator facepiece and harness
	   • Reusable eyewear/visor
	- Disposable fluid resistant sheet
	- Detergent/Disinfectant wipes
	Clean storage bag for filters

☐	Follow normal process of doffing PPE for sterile environment * Dispose of PPE in accordance with local process.
☐	Engage with PPE buddy outside the patient zone
☐	Remove gloves and dispose
☐	Perform hand hygiene
☐	Remove gown
☐	Perform hand hygiene
☐	Exit patient zone
2. At doffing station outside patient zone	
☐	Remove protective eyewear or face shield if single use discard. Reusable eye wear to be reprocessed following local process
☐	Perform hand hygiene
3. Removal of elastomeric half mask respirator	
☐	Don clean non-sterile gloves
☐	Note at this point all PPE except the respirator mask should be removed
☐	Bend from the hips, chin up and elbows out to the side to prevent contamination
☐	Release the lower strap with both hands,

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	Bring forward then hold the 2 lower straps with one hand, Maintain tension on the straps
☐	Bring harness forward over the head while maintaining tension to the harness (and top straps) as well as to the lower straps in the other hand.
☐	Bring the facepiece forward and outwards away from the body, keeping the tension on all the straps
☐	Place respirator on a disposable fluid resistant sheet in the doffing area on a cleanable surface or a trolley

4. Removal and cleaning/disinfection of Filters

☐	Disconnect particulate filters from facepiece by holding the respirator in one hand and rotate the filter anti-clockwise, repeat with another filter. The surgical mask will be freed from the mask once filters are removed.
☐	Place the surgical mask in bin
☐	Remove gloves and perform hand hygiene
☐	Don new pair of gloves and remove wipes from container
☐	Clean filters (dependent on local products available) c) Wipe filters with 2-in-1 step clean and disinfect or d) A neutral detergent wipe followed by a disinfection with 70% alcohol or sodium hypochlorite 1,000ppm Care must be taken to ensure that no cleaning solution contacts the filter membrane. Place on a separate clean surface and allow filters to completely air dry
☐	Wipe over facepiece and harness and place in a leak proof plastic bag and into a puncture proof container for reprocessing
☐	Discard disposable fluid resistant sheet and remove gloves
☐	Perform hand hygiene
☐	Filters are responsibility of individual HWs– it is recommended that once filters are air dry, they are placed into a clean plastic bag and sealed and stored until next use. The HW should check to ensure their name is still legible after cleaning and disinfection.
☐	Sign logbook that elastomeric half-face respirator has been sent to reprocessing unit for reprocessing including patient details on where the device has been used

5. Elastomeric half-face respirator returned from Reprocessing Unit

☐	Sign in logbook that elastomeric respirator has returned to department
☐	Store the reprocessed item in secured area

Appendix 3G: Donning PPE with CleanSpace HALO PAPR

- HWs using CleanSpace® HALO PAPR must be trained and deemed competent.
- It is the responsibility of the HW to ensure they have selected the correct mask size, neck support and adjust the harness settings before donning the PAPR.
- Donning PAPR must be performed with PPE buddy (note: buddy should be trained and deemed competent in this process which will aid in providing a safety check).

1. Self-preparation	
☐	Remove jewellery and wristwatch etc.
☐	Pull hair back off the face and neck – a low/mid ponytail that avoids the power unit and harness positions
☐	Ensure all PPE is available in donning area
2. Prepare doffing area (can be completed by PPE buddy or assistant)	
☐	Ensure doffing area is available and set up - Puncture proof container with lid for transporting reusable items to reprocessing unit - Clean container for power unit, exhalation valve cover and head harness red seal cap - Detergent/disinfectant wipes - Alcohol based hand rub - Disposable gloves
☐	Correct waste bin *PPE can be discarded in general waste. If soiled with blood or body substances, dispose in clinical waste.
3. CleanSpace HALO PAPR Check and assembly	
☐	Sign-out CleanSpace HALO power unit and mask in logbook (follow local process)
☐	Perform hand hygiene

☐	Collect CleanSpace HALO PAPR items
	
	    a) Mask – select correct size and perform a seal test (fit check)
	    b) Check external exhalation valve filter and filter case in place
	    c) Harness – adjust to correct setting
	    d) Neck support – select correct size and attach to the power unit
	    e) Power unit with HEPA filter in place
	    f) PAPR power unit sleeve (if used)

☐	Inspection and safety checks a) Inspect each component of the power unit for damage – <u>do not use if damaged</u>

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	b) <u>Check the power unit HEPA filter is locked in place</u>
	c) Extend bellows by pressing the silver button
	d) Turn unit 'ON' and check battery – must have 3 bars
	e) Perform a flow test – place power unit on a flat surface, press 'flow test' button – an automatic flow test will occur for 2 seconds. Results are shown with the LEDs on the keypad.
	3 LED meaning flow rate >180l/min (excellent), 2 LED is a pass and good flow rate and 1LED meaning pass with an acceptable flow.
	<u>Do not use respirator if all LED are flashing.</u>
	f) Power unit to remain on standby
	g) Remove mask from pack and check exhalation valve silicone disc on mask is not folded and sits properly
☐	Assemble HALO a) Place the mask with nose upwards on trolley b) Attach harness making sure the "front" sign is facing forward and the harness is not tangled c) Flip the harness over the front of the mask d) Slide the protective sleeve over the power unit e) Clip the mask to power unit on one side where the power button is located *The use of CleanSpace disposable protective cover on the power unit is optional to reduce contamination of the power unit.

4. Donning PPE and CleanSpace HALO PAPR

☐	Ensure power unit is on
☐	Perform hand hygiene
☐	Put on gown
☐	Drape harness over the front of the mask (ensure it is not twisted)
☐	Place power unit around the back of the neck
☐	Connect the remaining clip of the mask to the power unit
☐	Rotate the unit so to place mask centrally on face – over the nose and mouth Breathe normally to activate the PAPR air flow
☐	Position harness on the head
☐	Check that the mask is sitting under your chin and the apex of the mask sits comfortably on the nose bridge

☐	Adjust the two bellows until you do not feel any leaks between the mask cushion and your face. Do not overtighten.
☐	Check with PPE buddy that CleanSpace HALO is sitting level and that the sleeve covers the bellows
☐	a. Check mask seal b. Locate the red seal check cap c. Fit seal check cap over the exhalation valve in the mask d. Check that no air is flowing from the exhalation valve. Breathe normally e. Using your fingers, feel around the perimeter of the mask for leaks f. If necessary, tighten the mask using the bellows. Be careful to tighten each side by the same amount g. After each tightening, feel for leaks again h. Tilt your head down (look at the ground) and up (look at the sky). Check that there are still no leaks. Look right and left, checking for leaks. Adjust if necessary i. Once you can feel no leaks from the mask, the seal check is complete j. Remove the seal check cap by gently twisting the handle so that one side of the cap comes loose from the exhalation valve. Be careful not to dislodge the exhalation valve cover k. Place the seal check cap on disposable sheet on PAPR decontamination trolley **Failure to remove the cap will lead to build-up of carbon dioxide in the mask and may result in headache or dizziness.** **Never leave the cap in place for more than 2 minutes**
☐	If using the external N95 exhalation filter attach this now
☐	Put on protective eyewear or face shield
☐	Perform hand hygiene
☐	Put on gloves immediately before touching the patient – ensuring they cover the cuffs of the gown
5. Safety check	
☐	Complete safety check with PPE buddy • Check that power unit is responding to your breathing • Check that none of the alarms are sounding
☐	Ensure there is NO blockage around the power unit and filter (no obstruction to air flow)

Appendix 3H: Doffing PPE with CleanSpace HALO PAPR

Doffing PAPR must be performed with PPE buddy (note: buddy should be trained and deemed competent in this process which will aid in providing a safety check).

1. Before exiting patient zone	
☐	Engage with PPE buddy outside the patient zone Ensure doffing area and decontamination area is prepared with the following: - Puncture proof container with lid for transporting to reprocessing unit - Clean container for power unit, head harness and exhalation valve filter cover - Detergent/disinfectant wipes - Alcohol based hand rub - Disposable gloves * PPE can be discarded in general waste. If soiled with blood or body fluids, please dispose in clinical waste.
☐	Remove gloves
☐	Perform hand hygiene
☐	Remove gown
☐	Perform hand hygiene
☐	Exit the patient zone
2. At doffing station outside the patient zone	
☐	Remove protective eyewear or face shield after exiting the patient zone
☐	Perform hand hygiene
☐	Don new gloves
3. Removal of CleanSpace HALO PAPR	
☐	Chin up and elbows out to the side to prevent contamination
☐	Bring harness off your head in a forward motion
☐	With the thumb of your right hand, locate the power socket in the underside of the power unit With your right index finger, feel for the power button directly above on the top of the unit (but do not press it).
☐	With your left hand locate the clip that will release the mask from the power unit
☐	Inhale a deep breath and hold. Then press 'ON' button to put unit on standby

☐	Keep holding your breath and undo clip with left hand
☐	With left hand supporting the mask and right hand supporting the power unit, bring CleanSpace HALO away from neck and face. Breathe normally once the mask comes away from the face.
☐	Place CleanSpace HALO on a disposable fluid resistant sheet
☐	<mark>Use a quarter turn to disconnect external filter from mask</mark> Separate the filter from the casing Remove and dispose of the external expiration filter into the bin Use a dual purpose (detergent and disinfectant) wipe to clean filter casing and place into clean container with HALO motor unit
☐	<mark>Disconnect head harness from mask</mark> Use a dual purpose (detergent and disinfectant) wipe to clean harness Place on clean trolly to air dry and store appropriately
☐	Unclip the other side of the mask from the power unit
☐	Remove disposable sleeve from the power unit and discard into bin
☐	Remove gloves and perform hand hygiene

4. Cleaning of CleanSpace HALO PAPR

☐	Don new pair of gloves
☐	Not all components of the device are compatible with reprocessing unit processes. e.g., power unit & filter. Extend the bellows of the power unit prior to cleaning and disinfecting
☐	Clean and disinfect PAPR components as per manufacturers IFU including red seal cap
☐	Place <mark>cleaned power unit, head harness, filter case and red seal cap (if used) into clean container for transport back to docking station</mark>
☐	Prepare items that needs reprocessing as per local process and place them into a puncture proof container for transport to reprocessing unit
☐	Remove gloves
☐	Perform hand hygiene and don new gloves
☐	Wipe surface of trolley using detergent/disinfectant wipes
☐	Remove gloves

☐	Perform hand hygiene
☐	Return the power unit in the docking station and ensure the unit is plugged in to recharge as per manufacturer's instructions for use. Sign logbook to indicate time of return
☐	**HEPA Filter in power unit** Leave in place unless wet, visibly contaminated, cracked or in use for > 1 month* Remove filter & discard in contaminated (yellow) waste if any of the above If storing for > 1 month, replace filter with blue Cleaning & Storage Plug Set *Given the limited use with the current indications, filter change is recommended to be done every month
☐	Return any other items <u>NOT</u> for CSSD to appropriate storage (e.g., red seal check cap)
☐	Transport items for reprocessing to CSSD
☐	Sign logbook for any CleanSpace HALO items that have been sent to reprocessing unit for decontamination including details of patient where the device has been used.
5. CleanSpace HALO returned from Reprocessing Unit	
☐	Sign in logbook that CleanSpace HALO items have been returned to department
☐	Ensure the mask has an adaptor and filter at the exhalation point (if none contact reprocessing unit to replace or follow local facility process)
☐	Place facepiece/ masks returned from reprocessing unit in secured area

Appendix 3I: Donning PPE with CleanSpace HALO PAPR

For those working within a sterile field

- This process is for those required to work within a sterile field, e.g., surgeon in theatre, scrub nurse, proceduralist, where a **sterile gown and sterile gloves are worn**.
- All HWs using CleanSpace HALO PAPR must be trained and deemed competent in its use.
- It is the responsibility of the HW to ensure they have selected the correct mask size and adjust the harness settings before donning the PAPR.
- Donning PAPR must be performed with PPE buddy (note: buddy should be trained and deemed competent in this process which will aid in providing a safety check).

1. Self-preparation	
☐	HWs in theatre will already be in theatre attire - Theatre hair net/cap (Hair that is pulled up under a theatre cap should be in a low/mid ponytail that avoids the harness position) - Scrubs - Theatre clogs or shoes (follow local process for shoe covers) Note: this is normal attire for use in the sterile field
☐	Outside of theatres: remove jewellery and name tag etc.
☐	Outside of theatres: pull hair back off the face and neck – a low/mid ponytail that avoids the power unit and harness positions
☐	Ensure all PPE is available in donning area
2. Prepare doffing area (can be completed by PPE buddy or assistant)	
☐	Ensure doffing area is available and set up - Puncture proof container with lid for transporting to reprocessing unit - Clean container for power unit - Detergent/disinfectant wipes - Alcohol based hand rub - Disposable gloves
☐	Correct waste bin * PPE can be discarded in general waste. If soiled with blood or body fluids, please dispose in clinical waste.
3. CleanSpace HALO PAPR check	
☐	Sign-out CleanSpace HALO power unit and facepiece/mask in logbook (follow local process)
☐	Perform hand hygiene

☐	Collect CleanSpace HALO PAPR items • Mask- select correct size • External expiration filter for front of mask– or a surgical mask with ties • Harness – adjust to correct setting • Neck support – select correct size and attach to the power unit • Power unit with HEPA filter in place • Red PAPR seal check cap o PAPR power unit sleeve
☐	Inspection and safety checks a) Inspect each component of the power unit for damage – <u>do not use if damaged</u> b) Check that power unit HEPA filter is locked in place c) Extend bellows by pressing the silver button d) Turn unit 'ON' and check battery – must have at least 2-3 bars e) Perform a flow test – place power unit on a flat surface, press 'flow test' button – an automatic flow test will occur for 2 seconds. Results are shown with the LEDs on the keypad. 3 LED is excellent, 1 and 2 LED is a pass. <u>Do not use respirator if all LED are flashing.</u> f) Power unit to remain on standby g) Remove mask from pack and check exhalation valve silicone disc on mask is not folded and sits properly
☐	Assemble HALO a) Attach harness making sure the "front" sign is facing forward and the harness is not tangled b) Flip the harness over the front of the mask c) Slide the protective sleeve over the power unit d) Clip the mask to power unit on one side on the side where the power button is located The use of CleanSpace disposable protective cover on the power unit is recommended to minimise gross contamination of the power unit as a risk minimisation strategy because these power units can only be manually cleaned and disinfected.

4. Donning PPE and CleanSpace HALO PAPR	
☐	Perform hand hygiene
☐	Ensure power unit is on
☐	Drape harness over the front of the mask (ensure it is not twisted)

☐	Place power unit around the back of the neck
☐	Connect the remaining clip of the mask to the power unit
☐	Rotate the unit and place mask centrally on face – over the nose and mouth Breathe normally to activate the PAPR air flow
☐	Position harness on the head
☐	Check that the mask is sitting under your chin and the apex of the mask sits comfortably on the nose bridge
☐	Adjust the two bellows until you do not feel any leaks between the mask cushion and your face. Do not overtighten
☐	Check with PPE buddy that CleanSpace HALO is sitting level and that the sleeve covers the bellows
☐	Check Mask Seal • Locate the red seal check cap • Fit seal check cap over the exhalation valve in the mask • Check that no air is flowing from the exhalation valve. Breathe normally • Using your fingers, feel around the perimeter of the mask for leaks • If necessary, tighten the mask using the bellows. Be careful to tighten each side by the same amount • After each tightening, feel for leaks again • Tilt your head down (look at the ground) and up (look at the sky). Check that there are still no leaks. Look right and left, checking for leaks. Adjust if necessary • Once you can feel no leaks from the mask, the seal check is complete • Remove the seal check cap by gently twisting the handle so that one side of the cap comes loose from the exhalation valve. Be careful not to dislodge the exhalation valve cover • Place the seal check cap on disposable sheet on PAPR decontamination trolley *** Failure to remove the cap will lead to build-up of carbon dioxide in the mask and may result in headache or dizziness.** *** Never leave the cap in place for more than 2 minutes**
☐	If using the external P2 exhalation filter attach this now – or don surgical mask with ties
☐	Put on protective eyewear or face shield

☐	Perform surgical scrub
☐	Then proceed with your normal process of donning PPE for sterile field

5. Safety check	
☐	Complete safety check with PPE buddy
☐	Ensure there is NO blockage around the power unit and filter (no obstruction to air flow)

Appendix 3J: Doffing PPE with CleanSpace HALO PAPR

For those working within a sterile field

Doffing PAPR must be performed with PPE buddy (note: buddy should be trained and deemed competent in this process which will aid in providing a safety check).

1. Before exiting patient zone	
☐	Ensure doffing area is available and set up with the following: - Puncture proof container with lid for transporting reusable items to reprocessing unit - Clean container for power unit and red seal cap - Disposable fluid resistant sheet - Detergent/disinfectant wipes - Alcohol based hand rub - Disposable gloves
☐	Follow normal process of doffing PPE for sterile environment * Dispose of PPE in accordance with your normal process
☐	Engage with PPE buddy outside the patient zone
☐	Remove gloves in clinical waste
☐	Perform hand hygiene
☐	Remove gown
☐	Perform hand hygiene
☐	Exit the patient zone
2. At doffing station	
☐	Remove protective eyewear or face shield after exiting the patient zone
☐	Perform hand hygiene
☐	If using a surgical mask remove now
☐	Perform hand hygiene and don new gloves
3. Removal of CleanSpace HALO PAPR	
☐	Note at this point all PPE except the PAPR should be removed
☐	Chin up and elbows out to the side to prevent contamination

☐	Bring harness off your head in a forward motion
☐	With the thumb of your right hand, locate the power socket in the underside of the power unit With your right index finger, feel for the power button directly above on the top of the unit (but do not press it)
☐	With your left hand locate the clip that will release the mask from the power unit
☐	Inhale a deep breath and hold. Then press 'ON' button to put unit on standby
☐	Keep holding your breath and undo mask clip with left hand
☐	With left hand supporting the mask and right hand supporting the power unit, bring CleanSpace HALO away from neck and face. Breathe normally once the mask comes away from the face.
☐	Remove and dispose of the external expiration filter into the bin
☐	<mark>Disconnect head harness from mask</mark> Use a dual purpose (detergent and disinfectant) wipe to clean harness Place on clean trolly to air dry and store appropriately
☐	Unclip the other side of the mask from the power unit
☐	Remove disposable sleeve from the power unit and discard into bin
☐	Place power unit on the trolley
☐	Remove gloves and perform hand hygiene

4. Cleaning of CleanSpace HALO PAPR	
☐	Don new pair of gloves
☐	Not all components of the device are compatible with reprocessing unit processes. e.g., power unit & filter. Extend the bellows of the power unit prior to cleaning and disinfecting
☐	Clean and disinfect PAPR components as per manufacturers IFU including the Red Seal Cap
☐	Place <mark>cleaned power unit, head harness, filter case and red seal cap (if used) into clean container for transport back to docking station</mark>
☐	Prepare items that need reprocessing, as per local reprocessing unit guidelines, and then place into the puncture proof container for transport to reprocessing unit
☐	Dispose of disposable fluid resistant sheet and remove gloves

☐	Perform hand hygiene and don new gloves
☐	Wipe surface of trolley using detergent/disinfectant wipes
☐	Remove gloves
☐	Perform hand hygiene
☐	Place the power unit in the docking station and ensure the unit is plugged in to recharge as per manufacturer's IFU. Sign logbook to indicate time of return
☐	**HEPA filter in power unit** Leave in place unless wet, visibly contaminated, cracked or in use for > 1 month* Remove filter & discard in contaminated (yellow) waste if any of the above If storing for > 1 month, replace filter with blue Cleaning & Storage Plug Set *Given the limited use with the current indications, filter change is recommended to be done every month
☐	Return any other items not for reprocessing unit to appropriate storage (e.g., red seal check cap, head harness)
☐	Transport items to reprocessing unit
☐	Sign logbook for any CleanSpace HALO items that have been sent to reprocessing unit for decontamination including details of patient where the device has been used
5. CleanSpace HALO returned from Sterilization Unit	
☐	Sign in logbook that CleanSpace HALO items that have been returned to department
☐	Ensure the mask has an adaptor and filter at the exhalation point (if not follow local process)
☐	Place masks and any other items returned from reprocessing unit in secured area

Appendix 3K: Donning Loose fitting Powered Air Purifying Respirator (PAPR)

1. Preparation	
☐	Remove jewellery and name tag
☐	Pull hair back off the face and neck
☐	Ensure all PPE is available in donning area
2. Prepare Doffing area (can be completed by PPE buddy or assistant)	
☐	Ensure doffing area is available and set up - Puncture proof container with lid for transporting to reprocessing unit: • motor/blower, breathing tube, battery, filter/filter cover, head gear (if reusable) - Disposable fluid resistant sheet - Detergent/disinfectant wipes
☐	Correct waste bin *PPE can be discarded in general waste. If soiled with blood or body substances, dispose in clinical waste.
3. PAPR check and assembly	
☐	Sign-out the power unit in logbook
☐	Perform hand hygiene
☐	Collect PAPR items
☐	Verify seal on box is intact, open crate and remove unit
☐	Check unit for correct assembly and presence of filter Inspect the PAPR components (motor/blower, breathing tube, battery, filter/filter cover, head gear) to ensure no parts are missing or damaged.
☐	Charge the battery in the battery charger cradle prior to use. Ensure the battery clicks into place. The cradle will indicate the status of the battery charge
☐	If using a filter cover, the size of the filter cover must match the size of the filter/cartridge
☐	Insert filter/cartridge into filter cover. Ensure the latching tab snaps into place. If installed correctly, the filter/cartridge label should appear in the window of the filter cover

☐	Place the hinge side of the filter/cartridge into the motor/blower. A distinct click will be heard. Gently pull to ensure a firm connection
☐	Remove the battery pack from the charger cradle by pressing on the blue button.
☐	Press the TEST button on the bottom to confirm enough charge
☐	Attach the battery pack into the bottom of the motor/blower. A distinct click will be heard. Gently pull the battery to ensure it is firmly attached
☐	Disconnect hose from blower unit and turn unit on. Let the unit run for 1 minute. Ensure all LEDs illuminate, and battery is charged
☐	Insert the air flow indicator into the outlet on the motor/blower. With the air flow indicator in a vertical position ensures the floating ball is at or above the minimum flow level for your zone on the attached chart.
☐	Perform a low flow alarm test by blocking air flow with your palm. The motor/blower unit should emit an audible alarm and show a flashing red light. In ~30 seconds If no alarm sounds remove it from use, and have it serviced. If the alarm sounds, proceed with these PAPR instructions.
☐	Attach the breathing tube end (with metal prongs) to the motor/blower unit.
☐	Twist ¼ turn clockwise to lock. Gently pull on the breathing tube to ensure a good connection
☐	Insert the air flow indicator into the outlet of the breathing tube. With the air flow indicator in a vertical position, ensure the floating ball is at or above the minimum flow level.
☐	If not above the minimum level, re-inspect the breathing tube for blockage or damage. Replace the breathing tube if minimal air flow is not achievable. Turn motor/blower unit OFF to continue assembly
☐	Attach the breathing tube to the hood. Push the end of the breathing tube into the air inlet of the hood while pinching the blue clip. You will hear a click. Gently pull to confirm the breathing tube is secure
☐	Attach the motor/blower unit to the PAPR belt. Insert the prongs on the back of the motor/blower unit into the grommets on the belt. Slide the belt upward to secure into place
☐	Adjust belt to approximately the required length while the unit is getting to full speed
☐	Ensure the connections at both ends of the hose are secure and that air is flowing into the head top

	4. Donning PPE and PAPR
☐	Perform hand hygiene
☐	Secure unit around waist on lower back and adjust for comfort
☐	Place head top on head and adjust as required to ensure comfort
☐	For head top (hood) units with a hinged visor, lower the visor into position. Some hoods have a sealed visor that does not move and verify seal around face using hands to check for leaks. Note that exhausted air will leave the hood via a non-sealing area, typically below the chin (solid head tops) or around the neck seal (soft hoods)
☐	Don disposable gown. Secure velcro or tie at neck over the connecting hose Turn gown to close flap at back and tie the gown
☐	Perform hand hygiene
☐	Put on gloves immediately before touching the patient – ensuring they cover the cuffs of the gown
	5. Safety check
☐	Complete safety check with PPE buddy
☐	Sealed PAPR head top with blower unit on

Appendix 3L: Doffing Powered Air Purifying Respirator (PAPR)

1. Before exiting patient zone	
☐	Engage with PPE buddy outside the patient zone Ensure doffing area and decontamination area for is prepared - Puncture proof container with lid for transporting to reprocessing unit: • motor/blower, breathing tube, battery, filter/filter cover, head gear (if reusable) - Disposable fluid resistant sheet - Detergent/disinfectant wipes * PPE can be discarded in general waste. If soiled with blood or body fluids, please dispose in clinical waste.
☐	Remove gloves
☐	Perform hand hygiene
☐	Remove gown, contain and roll the gown and dispose
☐	Perform hand hygiene
☐	Leave PAPR unit powered on
☐	Exit the patient zone
2. At doffing station outside the patient zone	
☐	Undo buckle securing waist strap and lower to bench
☐	Perform hand hygiene and don new gloves
3. Removal of PAPR	
☐	Remove the head top using one of the following steps a) Grasp tag on chin curtain, pull straight down, and then lift out, up and backwards to remove head top in one motion. Do not allow edges of seal to contact face. Place head top into transportation trolley. b) With PPE buddy or colleague wearing droplet precautions, grasp the tag on the chin curtain and pull straight down then out and up to raise the visor to the up position. Do not allow the edges of the seal to contact the face. Allow the assistant to remove the head top by lifting it from the head. Maintain control of the tag on the chin curtain to prevent inadvertent recoil from contacting the face until the assistant is able to take control of it. The buddy will place the head top into the transportation trolley, doff PPE and perform hand hygiene.
☐	Turn off the unit. Do not disassemble further, close the lid of transportation trolley

☐	Remove gloves and perform hand hygiene
☐	Transport the trolley to reprocessing unit
4. PAPR returned from reprocessing unit	
☐	Sign in logbook that the items have been returned to department
☐	Connect power unit for charging and place the rest of the unit in secured area (ensure filter is not at risk of becoming soiled or moistened)

Appendix 3M: Difference between elastomeric, loose Fitting PAPR and tight fitting PAPR

Criteria Description	Elastomeric respirators Non-powered	Loose fitting PAPR Powered	Tight fitting PAPR Powered
Figure			
Specifications	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.	Most models are battery powered blowers that pull 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.	
Facepiece	A tight-fitting half or full facepiece	A loose-fitting facepiece, hood, or helmet	A tight-fitting half or full facepiece
Limitation	More commonly used in industrial and mining settings, but some models may be assessed in the context of 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	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, requires significant amount of storage space between shifts, robust maintenance program for replacing or repairing components that have become damaged during use or during cleaning and disinfection. Competent HWs are required to support the PAPR maintenance program and HWs must	

Criteria	Elastomeric respirators	Loose fitting PAPR	Tight fitting PAPR
Description	Non-powered	Powered	Powered
	elastomeric respirators to decrease contamination of the inside of the respirator and thus increasing the risk of infecting health workers between use.	be competent and trained on appropriate use, cleaning and disinfection of the item. PAPRs also require ongoing supply of replaceable or at least adequate supply of various parts e.g., for the Halo extra neck supports, harnesses etc.	
	The nosepiece can affect the ability to achieve satisfactory fit for safety or prescription spectacles, operating microscopes or other technical equipment.	Hearing 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	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 environment
[Assigned protection factor (APF)](#)	Half face APF = 10 Full facepiece APF = 50	Loose-fitting hoods and helmets APF = 25	Tight-fitting half masks APF = 50 Tight fitting full facepiece APF = 1000
Face to respirator seal	Require an excellent face-to-facepiece seal	Do not require a close face-to-facepiece seal.	Require a good face-to-facepiece seal
Fit Test Required	May require fit testing	NO	Some models require fit testing.
Wearer comfort	Potential for increased temperature under the facepiece or skin irritation.	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.	

Criteria Description	Elastomeric respirators Non-powered	Loose fitting PAPR Powered	Tight fitting PAPR Powered
Facial Hair	Facial hair will interfere with face and respirator seal	Compatibility with facial hair and various facial structures	Facial hair will interfere with face and respirator seal
Integrated Eye Protection	Only for full-face models	Yes	Only for full-face models
Fluid Resistance	Some models are fluid resistant	Fluid resistant	Fluid resistant
Level of Protection	Under testing conditions, the protection provided by reusable elastomeric respirators varies by filter type and model and provide less protection than PAPR or supplied-air types of respirators.	Over breathing while wearing a loose fitting PAPR can result in a small volume of ambient air entering the hood.	Generally, very low risk of contaminated air leaking into the respirator
Integrated PPE from the Neck Up	Half facepiece provides no coverage of head or neck	Only a hooded model provides neck and head protection	
Visualization	Line of sight may impede 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	The clear face shield will allow patients to see the HWs face	Full face piece will allow patients to see HWs face
		May interfere with the HW's visual field because of the limited downward vertical field of view	

Criteria Description	Elastomeric respirators Non-powered	Loose fitting PAPR Powered	Tight fitting PAPR Powered
Clinical care	Does not interfere with the use of some medical equipment such as a stethoscope	The HW's ability to use a stethoscope may be limited. Allow other equipment to be used concurrently such as headlights, loupes, mask underneath the unit	Full facepiece may limit the use of a stethoscope.
Communication	Facepiece can muffle speech.	Hearing may be impaired due to the blower noise and noise induced by the movement of a loose head covering	
Exhalation valves All contain exhalation valves that are not filtered.	Require either a surgical mask or exhalation filter when in use.	When a PAPR is being worn in the operating theatre, a surgical mask be worn under a PAPR or over a facemask respirator. This is not necessary with some hooded models.	Require a surgical mask to be worn over the exhalation valve(s). . Filters for expiratory ports are under development
Cleaning and disinfection Recommend a centralised process for disinfection. Follow the manufacturer's instructions.	Specific procedures for cleaning and disinfection (reprocessing) within healthcare environments must be established for the environment where elastomeric may be used. 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	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 sterilizing department. This includes the outside of the filter cartridge. Any procedure is used to clean and disinfect the PAPR and its components, it must be recommended or approved by the manufacturer. Cleaning and disinfection must be done by competent trained individuals. Centralizing this activity can ensure it is properly done.	

Criteria	Elastomeric respirators	Loose fitting PAPR	Tight fitting PAPR
Description	Non-powered	Powered	Powered
	they become damaged, soiled, or clogged.		
Maintenance	Require maintenance and a supply of replaceable components including straps, inhalation and exhalation valves, valve covers, and filters, cartridges, or canisters	PAPR batteries must be recharged or replaced, and ongoing maintenance required. Change cartridges as needed and inspect equipment for problems. Involve biomedical engineers in the maintenance process.	
Cartridge and Filter Replacement	Each manufacturer has instructions re cartridge and filter replacement.	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	
Education and training	Training should 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.		

Chapter 4: Fit Testing using the PortaCount™ or AccuFit™ Machine

4.1 <mark>Introduction</mark>

The purpose of this chapter is to provide guidance on infection prevention and control (IPAC) requirements when conducting fit testing within NSW health facilities. This chapter only covers the quantitative fit testing of respirators and should be used in conjunction with specific product manufacturers instruction for use (IFU), and the CEC Infection prevention and control manual COVID-19 and other Acute Respiratory Infections.

4.2 <mark>Fit testing</mark>

Fit testing is recommended for health workers (HWs) working in high-risk areas where they provide care to patients with an airborne disease or may be at additional risk of exposure to airborne respiratory pathogens.

While fit checking remains a key component for respiratory infection control for these HWs, NSW local health districts (LHD) and specialty health networks (SHNs) have incorporated the added control measure of fit testing of respirators to respiratory protection program (RPP).

Whilst fit testing is recommended it is important to note that the absence of fit testing does not automatically equate to inadequate protection, in the same way that the completion of fit testing does not equate to adequate protection every time a respirator is donned.

In the absence of fit testing the existing controls and procedures are currently recognised as providing protection to HWs when transitioning to an RPP that incorporates fit testing. HWs who wear P2/N95 respirators should complete fit testing before first use and perform a fit (seal) check properly each time they are used. In situations where fit testing has not yet been carried out, and a P2/N95 respirator is recommended for use, a fit-checked P2/N95 respirator is preferred to a surgical mask.

4.2.1 Types of fit test

Qualitative fit testing (QLFT)

Qualitative fit testing of respirators involves test agents with distinctive taste or smell for detecting leakage via the respiratory interface seal of the RPD. A test agent such as saccharin or Bitrex™ (a bitter tasting substance) is used at a sensitivity level that demonstrates the user will be able to appropriately sense the presence of the test agent within the respirator by taste, smell, or the urge to cough. Fit tests must be undertaken by a competent fit test operator. QLFT results are pass/fail and relies on the ability to taste or smell one of the AS/NZS 1715 accepted test agents:

- Saccharin (sweet taste); can test respirators with a particulate filter of any class.
- Bitrex® (bitter taste); can also test respirators with particulate filters of any class.
- Isoamyl acetate (banana smell); only for testing respirators with organic vapor cartridges.

Quantitative fit testing (QNFT)

Quantitative fit testing involves an objective measurement of the leakage of particles from inside a respirator using a numerical indicator called the fit factor. A fit tester device (such as a PortaCount™

or AccuFit™) is used to measure the volume of particles inside the respirator compared to the ambient air outside the respirator.

- QNFT is undertaken using a PortaCount™ or AccuFit™ fit tester device.
- Fit tests must be undertaken by a competent fit test assessor.

Fit testing is used for tight-fitting respirators only and identifies the RPDs capacity to provide a quality seal to an individual's face.

Note: Fogging of prescription glasses may not indicate a compromised seal. Due to the design of disposable respirators, exhaled air will generally escape from the respirator near the nose.

4.3 Quantitative fit testing protocols

Fit testing attempts to replicate the types of movements that are likely to be employed by wearers of respirators. There are three variations of international fit testing protocols. Each protocol involves 4-8 exercises or movements that the wearer must undertake during fit testing. In addition, some protocols require all components of testing to be passed, others require a minimum composite score for a pass.

HSE – [Health Safety Executive Protocol, Public Health England](#)

- Must be done stepping, walking, or cycling.
- Must pass every test.

OSHA Modified FAST – [Occupational Safety Health Administration](#)

- Four exercises/movements.
- Requires 2:29 minutes to complete.
- Done standing.
- Validated in the United States (US).
- If the overall fit factor meets the minimum overall pass level, the respirator passes the fit. This means that the wearer can fail individual exercises and still pass the fit test.

OSHA – [Occupational Safety Health Administration](#)

- United States Based.
- Seven exercises plus an additional exercise (grimace).
- Done standing.
- If the overall fit factor meets the minimum overall pass level, the respirator passes the fit. This means that the wearer can fail individual exercises and still pass the fit test.

4.4 Quantitative fit testing process

The ambient aerosol condensation nuclei counter (CNC) quantitative fit testing (PortaCount™ or AccuFit™) protocol fit tests respirators using a probe connecting the respirator to be tested to the fit tester device. The probe is attached to the respirator and is only used for quantitative fit testing. A probed respirator has a special sampling device, attached to the respirator, that allows the probe to sample the air from inside the mask. A probed respirator is required for each make, style, model, and size that the employer uses and can be obtained from the respirator manufacturer or distributor.

The following points should be considered before fit testing:

- Method of fit testing, qualitative or quantitative. Quantitative approach in healthcare is recommended, e.g., with PortaCount™ or AccuFit™ machine.

- The types of respirators available to HWs.

- Respirator supply chain for the LHD/SHN HealthShare and the LHD/SHN procurement team should be included in decisions impacting the order of respirator selection for fit testing.

- Respirators selected for fit testing need to be available in the HWs place of work. Organisation

    - room / location, equipment, and consumables for fit testing.

    - fit test assessors and HWs to be fit tested.

    - Communication.

- Fit testing appointments should not be used for training HWs how to don fit check and doff a respirator.

- HWs are recommended to enrol and complete training in [My Health Learning](#) (MHL) prior to fit testing.

    - Donning and Fit Checking of P2/N95 Respirators in NSW Healthcare Settings. Course code - 319438161 (mandatory).

    - RPP: Safe use of P2/N95 respirators (pathway).

- Head and or other facial PPE routinely used with respirators should be available and worn during a fit test to ensure there is no interference with the respirator seal and/or workplace tasks.

- At all times when a HW is required to use a tight-fitting respirator; the HW must not have any facial hair present. This includes at the time fit testing. HWs with an exemption to this should bring the evidence when attending the fit testing.

- HWs routinely wearing prescription glasses to complete workplace tasks need to bring and wear their prescription glasses during a fit test.

- HWs are to adjust their hairstyle, head / hair adornments and/or jewellery that may interfere with a respiratory seal.

- Wearing of make-up and/or face creams may also impact on the quality and maintenance of the respirator seal.

- HWs to not smoke, eat or drink (food with strong smell or odour including mints and chewing gum affects results) for 30 minutes prior to the fit test session.

Note: If a HW has any condition that may prohibit from conducting a fit test or other concerns regarding fit testing, please discuss it with line manager.

Process for respirator selection

Respirator selection in healthcare requires awareness and assessment of:

- Australian Standards/New Zealand Standards (AS/NZS) 1716 Respiratory Protection Devices.
- AS/NZS 1715 Selection, use and maintenance of respiratory protective equipment.
- Identify the hazard.
- Manufacturer's IFU aligns with healthcare requirements.
- HW ability to don / doff the respirator.
- Is the respirator compatible with other PPE?
- Will the respirator impact a HWs ability to attend and complete tasks?

- Is the respirator fit for purpose in healthcare?

4.5 Respirator fit test requirements

The equipment required for performing a quantitative fit test includes:

- QNFT equipment prepared and checked daily before use:
    - Fit tester device (PortaCount™ or AccuFit™)
    - Printer (optional and dependent on the LHD/SHN documentation and reporting pathway for fit test outcome)
    - Laptop/computer with specific software for the fit tester device in use
    - Power cords and USB cable
    - The twin tube assembly
    - HEPA (high efficiency particulate air) filter
    - Push nuts, probes, and insertion tool
    - Alcohol wick alcohol soaked in isopropyl alcohol (> 99%)
    - Particle generator
    - A minimum of 3 power sockets (laptop, fit tester device and particle generator).
- Appropriate room / location for fit testing (no traffic flow, size of room, ventilation / air conditioning outlets).
- Waiting area that enables physical distancing.
- Selection of respirators.
- Waste bin.
- Mirror to assist HWs with fit checking and respirator placement.
- Alcohol based hand rub (ABHR) solutions or sink with soap and water.
- Dual purpose cleaning product and space for cleaning and disinfection of reusable equipment.
- Compressed air.
- Tap water access.

4.6 PortaCount / AccuFit Respirator theory of operation

The PortaCount™ Pro or AccuFit™ respirator fit tester devices measure and compare particle concentrations inside and outside a respirator seal. The end calculation is the fit factor. To ensure there are an adequate number of particles in the fit testing environment, a particle generator is used.

Particles entering the respirator fit tester device through the twin tube assembly pass through a tube where they are exposed to the alcohol vapor. The alcohol vapour condenses the particles, making them larger and able to be detected by an internal laser beam (photodetector).

The PortaCount™ / AccuFit™ respirator fit tester has two internal HEPA filters that filters air samples inside the instrument before being exhausted to the ambient air (see figure 8). These HEPA filters are 99.97% efficient for the most penetrating particle size of 0.3 microns.

The twin tube assembly is under negative pressure and sealed during the operation of the PortaCount™ /AccuFit™ respirator fit tester device. The air inside the respirator travels from the respirator to the fit tester device in a one-way flow away from the person being fit tested, therefore, there is no need to clean or disinfect the inside of the twin tube assembly.

FIGURE 8: PORTACOUNT™ PRO RESPIRATOR FIT TESTER SCHEMATIC ADAPTED FROM PORTACOUNT™, A REGISTERED TRADEMARK OF TSI INCORPORATED
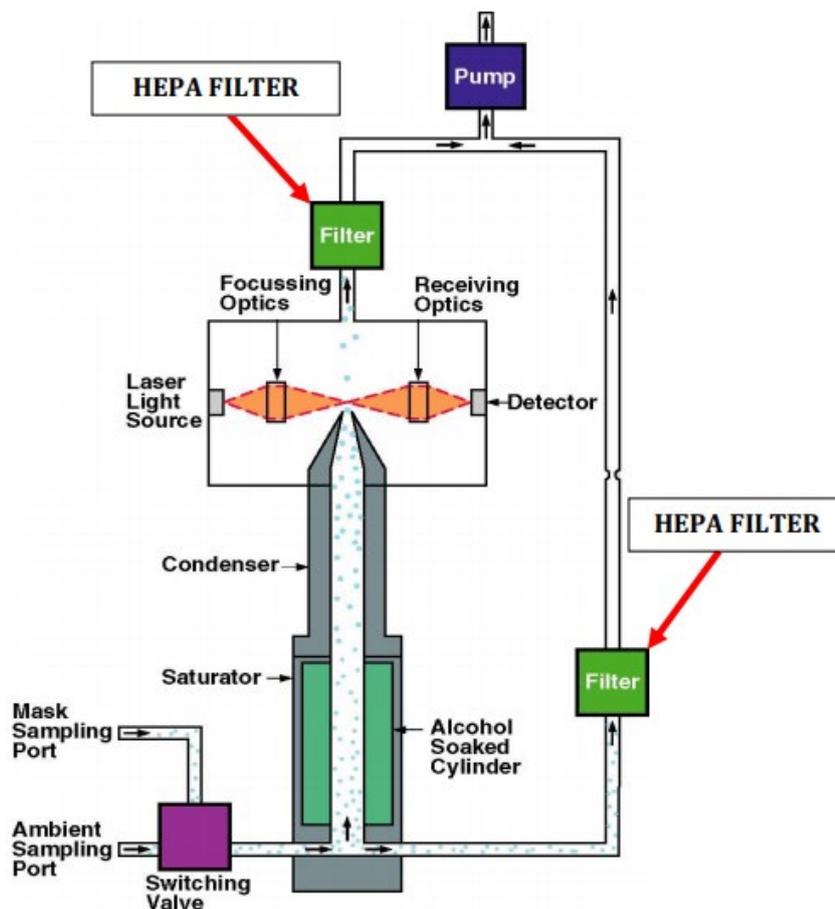
4.7 Fit testing using a PortaCount™ or AccuFit™ machine

Overview

There are two objectives for fit testing:

1. Education

- Confirms the confidence and skill of the HW to safely don, fit check and doff a respirator.
- The HW can reproduce a fit check for each and every time a respirator is donned.

2. Safety

- Identifies the overall protection factor of respirators HWs are fitted to.
- Confirms the quality of the respirator seal the HW is fitted to.
- PPE and or prescription glasses when worn in unison with a respirator does not:
  o compromise the quality of a respirator seal.
  o interfere with the HW ability to perform routine workplace tasks.

3. There are two concepts that are used to assess protection:

- Assigned protection factor.
- Fit factor.

Assigned protection factor (APF) is the level of protection that a respirator can be expected to provide 95% of the time (P2 and N95 respirators are tested to this standard).

Fit factor (FF) measures the particle concentration outside the respirator (ambient particle count) and divides this by the amount of particle concentration that leaks inside the respirator seal during a fit test.

Overall fit factor pass:

- A minimum overall fit factor of 100 for disposable P2/N95 respirators and CleanSpace HALO PAPR.

The following factors will influence respirator fit:

- Face shape and size. One type and size will not suit everyone.

- Any amount of facial hair may impact the quality of a tight-fitting respirator seal.

- Face creams and make-up.

- Hair styles, particularly long hair.

- Pre-existing medical conditions may restrict or prevent the wearing of a respirators.

- Psychological considerations such as claustrophobia and anxiety.

It is also important to don other equipment, like prescription glasses and facial PPE, HWs are likely to wear with the respirator to ensure it doesn't impact on the respirators seal or workplace tasks.

When to fit test

Fit testing should be conducted:

- New HW who are prioritised for assessment - during onboarding to the healthcare facility.

- When identified HW may be exposed to a respiratory pathogen or hazardous substances.

- Existing HW who have been risk assessed and prioritised.

- HW who may have infrequent exposure to recognised and unrecognised sources of airborne and aerosolised infectious agents in the healthcare facility.

- Where there is a change in respirator size, style, model, make or where a new make/ model is issued. Prioritisation based on HW risk assessment.

- Change in the wearer's facial characteristics, e.g., loss of teeth/dentures or excessive changes in weight or facial surgery.

- Repeated at appropriate intervals for all HWs- annually and no longer than 18 months.

Considerations during fit testing

Facial hair

At all times when a HW is required to use a tight-fitting respirator; the HW must not have any facial hair present. This includes at the time of fit testing. The AS/NZs 1715 and respirator IFU requires employees be clean shaven when being fit tested and when wearing the respirator. However, HWs with a medical condition, psychological needs/reasons or a genuine religious or cultural reason can

apply for an exemption to keep facial hair. For more information refer to *Appendix 4A: Use of respiratory protective device with beard cover technique*.

Smoking

Participants should be advised not to smoke or vape within 30 minutes prior to attending fit testing. Particles remaining in the respiratory system post smoking may be detected inside the mask and impact on the fit test outcome.

Hair styles, hair adornments, jewellery

Any or all of these items may interfere with the respirator sealing surface. Where there is a compromise of the respiratory seal, this may result in an unsuccessful fit test outcome.

Make-up and face creams

Any or all of these items may interfere with the respirator sealing surface. Where there is a compromise of the respiratory seal, this may result in an unsuccessful fit test outcome.

4.7.1 Fit testing procedural steps

Always follow manufacturer's operation and IFUs when using a respirator fit tester device. The [CEC Fit Testing Video Series](#) may support review of the steps for fit testing and is best to not be reviewed in isolation.

Equipment requirements for PortaCount™ or AccuFit™

- Tables.

- Chairs for HW waiting area (optional).

- TSI PortaCount™ or AccuFit™ or similar.

- Laptop or computer loaded with PortaCount™ or AccuFit™ software.

- Associated consumables (twin tube assembly, HEPA filter, alcohol wick and isopropyl alcohol).

- Particle generator.

- PortaPunch™ or Accufit™ Probe insertion tool.

- Respirators with a variety of types and sizes.

- Alcohol based hand rub or soap and water.

- Detergent/disinfectant wipes.

- Compressed air.

- Access to Stafflink HCM for data entry of HW fit test outcomes.

Room set up

The room selected for fit testing should be clean and in a low traffic area. In general, the ideal room for fit testing is one about 400ft^2/20m^2. The particle generator and its capacity to produce particles will not function as efficiently in an open area or very large room.

Prepare the work area:

- Use a trolley or other suitable aide to safely transport the fit tester device to the testing area.

- Place the fit tester carry bag onto the surface to remove the fit tester device.

- Place the fit tester device and particle generator on a stable surface which is free from clutter and adjacent to a power outlet.

- The particle generator should be positioned from the fit tester device as per the manufacturer's IFU. (PortaCount™, 1.8 meters; AccuFit™ 3 meters).

- Visually inspect the fit tester device and particle generator for damage.

- Remove all electrical cords and cables from the carry bag. Ensure electrical cords have been tagged and tested, and testing is in-date. Visually inspect the electrical cords and connections for damage.

- Unpack the laptop with PortaCount™ or AccuFit™ software. Software used, must match the fit tester device in use. The appropriate software can be downloaded but will require approval from local IT services.

How to set up the particle generator

PortaCount™	AccuFit™
TSI particle generator	Particle generator
Water	500ml water bottle
Saline tablets	

Cautions

The particle generator should be situated:

  - at least 1.8m from the PortaCount™ machine.
  - 3m from the AccuFit™ machine.

- Ensure mist is directed away from electrical sockets.

- The room used for fit testing should allow for adequate physical distancing and enough particles to be generated during fit testing.

- Avoid large and or open areas such as an auditorium, directly under air conditioning outlets and open doorways.

- Depending on the fit tester device model and room in use, there may be variation in ambient particle concentration. Monitor the particle count displayed on the software.

- Do not proceed with fit testing if the ambient particle count exceeds >800 for PortaCount™ and >100,000 AccuFit™

- Always operate the particle generator in an upright position.

- Run for at least 10 minutes prior to commencing fit testing to allow particle count to stabilise.

- If higher particle counts are required, adjust the Output Adjustment Screw (PortaCount) / Control Dial (AccuFit).

- Always empty the reservoir prior to storing back in the case to prevent leaking.

- Always empty the solution (water) from the particle generator reservoirs before packing away. Packing equipment with solution insitu may risk damage to the PortaCount™ / AccuFit™ due to risk of leaking.

FIGURE 9: PORTACOUNT™ PARTICLE GENERATOR
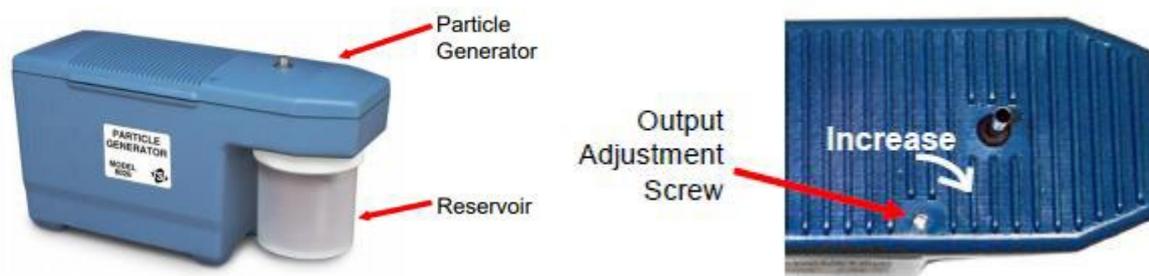
Procedure

Fill the reservoir jar with water to the fill line.

FIGURE 10: PORTACOUNT™ PARTICLE GENERATOR FILL LINE

- Drop one (1) saline tablet into the reservoir.

- Place the spare cover on the reservoir and shake gently to dissolve tablet.

- Once dissolved, remove spare cover, and screw the reservoir onto the particle generator.

- Place the particle generator on a firm flat surface, preferably at least 1.8 metres from the PortaCount™ machine location.

- Ensure particle generator is not covered or obstructed in any way.

- Turn on power to particle generator, close room door and run for at least 10 minutes before calibrating PortaCount™ machine.

- Ensure mist is directed away from electrical sockets.

- One reservoir full of solution may be adequate for a full day of fit testing. If the solution requires topping up during the day, discard existing solution, rinse the reservoir, and reconstitute according to the IFU.

When using AccuFit™ particle generator:

- Fill the water bottle with no more than 500ml of tap water.

- Select the correct bottle adapter size and screw onto the bottle of water.

- Make sure the top of the particle generator is connected to the membrane.

- Attach the mist outlet if not in place.

- Pull mist outlet upwards until it locks.

- Invert the water bottle and connect to the particle generator.

- The particle generator should sit on a flat fit surface.

- Ensure particle generator is not covered or obstructed in any way.

- Ensure particle generator is producing mist.

- Turn on the power to particle generator, close room door and run for at least 10 minutes before calibrating AccuFit™ machine.

How to set up the PortaCount™ or AccuFit™ fit test machine

- Fit tester device.

- Connect all electrical cords and cables to the fit tester device and laptop.

- Laptop with PortaCount™ or AccuFit™ software. Software used, must match the machine in use. The appropriate software can be downloaded but will require approval from local IT services.

Procedure

Check/fill the Alcohol Cartridge:

- The alcohol fill capsule should contain the alcohol cartridge; remove the alcohol fill capsule from the carry bag.

- Check the alcohol fill capsule to ensure alcohol is visible.

- If alcohol is visible:

    o Remove the alcohol cartridge from the alcohol fill capsule, gently ==tapping it on the side of the capsule== before completely removing from the capsule. This will allow excess alcohol to drip back into the alcohol fill capsule. Stop when excess alcohol is no longer dripping from the alcohol cartridge.

    o Ensure the fit tester device is turned off.

    o Insert the alcohol cartridge into the fit tester device cartridge cavity and twist the alcohol cartridge clockwise until it locks into position.

    o Recap the alcohol fill capsule with the storage cap.

If alcohol liquid is below the fill-line or cannot be observed:

- Open the alcohol fill capsule by twisting the alcohol cartridge cap and remove the alcohol cartridge. Take care to ensure the cap doesn't break and cause alcohol to leak or spill.

- While holding the alcohol cartridge:

    o Open a bottle of the manufacturers supplied Isopropyl alcohol.

    o Invert the bottle.

    o Insert the nozzle end into the alcohol fill capsule as far as possible to prevent alcohol being sprayed inadvertently.

    o Squeeze the bottle to fill the cartridge to the appropriate level.

    o Recap the alcohol bottle.

    o Insert the alcohol cartridge into the alcohol fill capsule and turn the capsule clockwise until it locks in place.

    o Set the alcohol fill capsule down and wait for 2 minutes while the alcohol wick soaks up the alcohol.

    o Remove the alcohol cartridge from the capsule, gently shaking it before completely removing from the capsule. This will allow excess alcohol to drip back into the alcohol fill capsule. Stop when excess alcohol is no longer dripping from the alcohol cartridge.

    o Ensure the fit tester device is turned off.

    o Insert the alcohol cartridge into the cartridge cavity of the fit tester device. Twist the alcohol cartridge clockwise until it locks into position.

    o Recap the alcohol fill capsule with the storage cap.

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Fill Line

Daily check / validation check

Prior to commencing fit testing for any session (i.e., each day), and after rectifying trouble shooting (*Appendix 4F: General Quantitative Fit Testing Machine Troubleshooting Guide),* a daily check/validation is required to be completed. If you change locations during the day a repeat daily check/validation is recommended as the particle count may differ.

- Connect the USB cable from the fit tester device to the laptop and turn on the fit tester device using the O/I button or on/off button.

- Open the fit tester device software on the laptop.

- Attach the twin tube assembly to the fit tester device as per manufacturer's IFU.

- Attach the HEPA filter to the other end of the clear tube.

Run the daily check according to manufacturer's IFU. The daily check/validation simulates a fit test with the HEPA taking the place of a respirator. This process is important for several reasons:

- Environment: confirms adequate particles in the room (particle check).

- Equipment: confirms there are no leaks in the system (zero check).

- Software: the machine can pass the maximum fit factor check (maximum fit factor check). The PortaCount fit tester device has an additional classifier check (PortaCount™).

When using PortaCount™ machine follow below instructions:

- Turn on the fit tester device.

- Double-click FitPro™ + icon or [icon] or similar. The icon display may vary.
- Select 'yes' if prompt appears to run daily check.
- If FitPro™ software already open and it hasn't prompted a daily check, click on the top left three bars to find the daily check option.
- Click N95 for first process - ensure PortaCount™ 1 is selected.
- Click off N95 as second check and re-select PortaCount™ 1.

When using AccuFit™ machine follow below instructions:

- Turn on the fit tester device and allow start up to finish.

- Double click on the AccuFIT icon [icon] or similar. The icon display may vary.
- Select validation check.
- Click on validation check settings for N95.
- Remove HEPA filter and press start.
- Continue to follow the prompts.

What to do if the PortaCount™ or AccuFit™ fails the daily check?

Troubleshooting: access to the manufacturers IFU is always recommended.

Alcohol cartridge

- Too much – allow to dry out.

- Too little – refill the alcohol fill capsule with alcohol and soak for a minimum of 2 minutes.

- Is alcohol cartridge installed correctly or installed at all.

- Check type of alcohol (only Isopropyl alcohol i.e., 99.5% reagent grade).

- Change alcohol wick and use fresh alcohol, leave the wick to soak in the new alcohol for at least 5 minutes.

Room setup

- Particle count is too low.

  o Check the room size – is it too big check the location of the fit tester device and or particle generator.

  o Close doors to prevent circulating air.

  o Ensure the particle generator is turned on.

  o Check there is a salt tablet (PortaCount only) in the particle generator.

Condensation in the tube

- During fit testing, the twin tube assembly will have a build-up of condensation. If there is visible condensation, use compressed air to clear before next use.

Preparation for fit test

- Review availability of disposable respirators at the location – do not test respirators that are not available in the LHD/SHN and or facility.

- Respirator/s used for fit testing are suggested to be guided by the CEC decision making algorithm and local guidelines. Respirator availability will be impacted by the supply chain.

- Respirator supply can be confirmed with the RPP Lead and or Clinical Product Manager (CPM).

- Explain to the HW what to expect during fit testing procedure.

- Confirm the HW is clean shaven and free of facial hair. If HW is not clean shaven, DO NOT PROCEED with a fit test. Request the HW returns when facial hair has been removed or ask them to discuss with their direct line manager.

- Confirm HWs have a valid exemption to undertake fit testing with a beard cover technique. (See *Appendix 4A: Use of respiratory protective device with beard cover technique).*

- Check the HW has not smoked (including e-cigarette), vaped in the last 30 minutes. Erroneous particulates emitted by the HW during the fit test may compromise the fit test outcome.

- Some foods with strong odour/smell and or chewing gum may impact a fit test result. HWs are advised to not eat in the 15-30 minutes prior to the fit test. Erroneous particulates emitted by the HW during the fit test may compromise the fit test outcome.

- Following the respirator algorithm / local guidelines select the respirator to be fit tested and request the HW to don following the CEC donning and fit checking training videos.

- Request the HW to perform and demonstrate a fit check.

- A HW may require some direction to safely don a respirator and perform a fit check If the HW is unable to demonstrate safe donning and a fit check of a respirator with minimal supervision, refer to local guidelines to determine if the fit test will proceed.

Probe insertion

Respirators will need to have a probe inserted using the probe insertion tool, probe and push nut before fit testing. For all respirators, the probe must be inserted in the beathing zone between the mouth and nose of the respirator for most respirators, this zone will be towards the centre of the respirator. Always avoid creases and seams.

Equipment requirements

- Disposable respirator

- Probe insertion tool

- Probes

- Push nuts.

FIGURE 13: POSITION NUT

Load probe onto Porta Punch (PortaCount™)   Piercing Tool (AccuFit™)
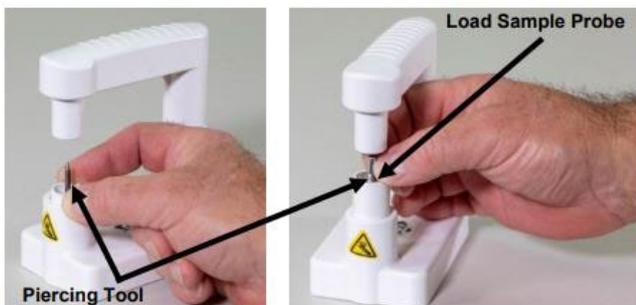
Place a push nut onto the magnetic plate of the probe insertion tool. The magnetic plate is the opposing end of the tool without the piercing probe. The concave (curved) side of the push nut is against the magnetic plate.

Taking one probe, align the probe so that the flat disc end cab be placed onto the piercing probe. Drop the probe onto the piercing probe of the probe insertion tool.

FIGURE 14: PORTACOUNT™ PUNCH /ACCUFIT™ PIERCING TOOL WITH NUT IN PLACE
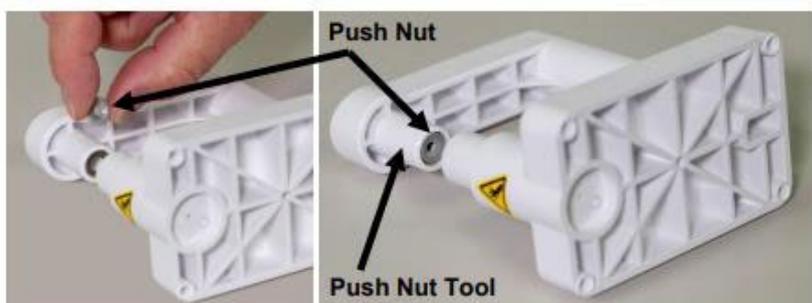
FIGURE 15: DISPOSABLE RESPIRATOR WITH PROBE ATTACHED

For 'duckbill' respirators – install the probe near the outer edge of the bottom panel where it cannot be blocked by the chin.
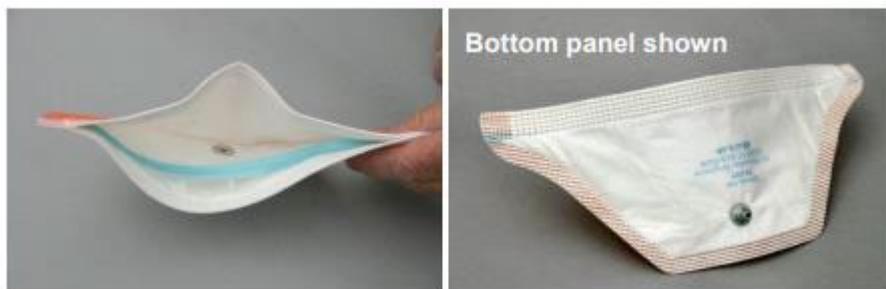
Place the internal surface of the respirator directly over the probe making sure to align the breathing zone of the respirator with the probe. With a firm and even pressure, press the **PortaPunch**™ probe insertion tool downwards until it clicks. Firm even pressure is all that is required.

Pick up the top **AccuFit™** piercing tool, and align with the bottom piece, push together until you hear a click. Firm even pressure is all that is required.

FIGURE 17: USE PORTACOUNT™ PUNCH OR ACCUFIT™ PIERCING TOOL TO INSERT THE PROBE AND NUT

Release the PortaPunch™ lever arm or AccuFit™ piercing tool, remove the respirator and inspect the probe insertion area for tears. You should not be able to rotate probe. Clean the internal of the piercing tool regularly.

Data Entry

For each respirator fit tested to a HW, the details will need to be reported into Stafflink HCM.

Before the fit test can start the HWs details and respirator to be fit tested must be entered into the fit tester device database.

- PortaCount - select people from the main menu, select assign person, select new and complete according to local requirements. Confirm the HWs details are correct and select save.

FIGURE 18: PORTACOUNT™ SOFTWARE

- AccuFit™ - select fit test from the main menu, access person from the drop-down box and select new then complete according to local requirements. Confirm the HWs details are correct and select save.

FIGURE 19: ACCUFIT SOFTWARE

Ensure HW details are accurate as this data will be used for reporting through Stafflink HCM. At a minimum the HWs details to be captured into the fit tester device database are:

- Name
- Assignment number this may be known as Stafflink number.

Data entry – Respirator fit test procedure

- Select the respirator to be fit tested, including size and make from the drop-down options of the respirator list.
- If the respirator is new to the LHD/SHN and/or the software has been downloaded onto the laptop of use for the first time, you will need to manually enter the respirator into database using the standardised naming convention.

There is a standardised method of entering the respirator into the fit tester device software.

- Manufacturer (Vendor) 3M.
- Model (Product Code) 1870.
- Style (half face) - Half face disposable.

FIGURE 20: EXAMPLE OF RESPIRATOR APPROVAL LABELLING

Vendor	Description	Product Code	Style Required
BSN Medical (Aust) PtyLtd	MASK, PARTICULATE RESPIRATOR, half FACE disposable, P2/N95 FILTER, MEDIUM, PLEATED, DOUBLE STRAP (PROSHIELD)	72509-10	Half faced disposable
BSN Medical (Aust) PtyLtd	MASK, PARTICULATE RESPIRATOR, half FACE disposable, P2/N95 FILTER, SMALL, PLEATED, DOUBLE STRAP (PROSHIELD)	72509-09	
BYD Australia Pty Ltd	MASK, PARTICULATE RESPIRATOR, half FACE disposable, P2/N95 FILTER, FLAT-FOLD, LEVEL 3 (BYD)	DE2322	
3M Australia Pty Ltd	Mask, P2 Respirator half face disposable 1870+ (3M)	1870+	

Data entry fit test protocol

The CEC fit testing videos (PortaCount or AccuFit) provide visual instruction to complete

- Select the protocol the respirator will be tested to:
  - PortaCount - OSHA FAST FILTERING FACE option in the protocol drop down box protocol and the details of the selected respirator, followed by assign.
  - AccuFit™ - OSHA FAST FPP 2019 option in the protocol drop down box and confirm the N95 enabled box is ticked.

Fit check

A fit check is different to a fit test. Both fit test and fit check are individual elements of respiratory protection. A fit check is independent of a fit test and must be done each and every time a respirator is donned.

A fit test requires a fit tester device, a fit test assessor, the HW and is done at defined points of time. A fit test must always follow a fit check.

The fit check is a safety measure and one element of respiratory protection that is practiced each and every time a respirator is donned. The fit check provides reassurance to the HW that they are able to confirm the quality of a respirator seal each time a respirator is donned.

Observe the HW don the respirator to be fit tested and provide some guidance to the HW on practices that support a quality seal of a respirator.

- Position of respirator on face and cheeks.
- Chin is placed within the respirator.
- Position of the respirator on the nose – close attention to moulding and massaging along the seal of the respirator.
- Does the respirator fit support or interfere with eye protection and/or prescription glasses.
- Respirator strap tension is not uncomfortably tight, and the straps sit at the back of the neck and across parietal/ dome of head.
- The respirator does not slip during normal movements (talking, head side to side, bending over).

Note**:** The HW will not be able to fit check a respirator that has a fit test probe inserted; the fit test probe has created an opening or leak between the respirator, HW and environment. To perform a fit check during fit testing, either:

- the HW will need to cover the probe using their finger, **OR**
- the twin tube assembly needs to be connected to the respirator and fit tester device. The fit tester device must be turned on to create the one-way flow of expired air away from the HW and towards the fit tester device.

When to fit check

Every time the HW dons a respirator, a fit check must be completed to confirm the respirator positioning and quality of the respirator seal. After donning a respirator there are two (2) ways to perform a fit check:

1. Negative pressure fit check – the HW, without pressure, places their hands over the respirator and takes deep breath in. If there is a good seal, the respirator should collapse towards the HW's face. Additionally, the HW should not feel channels of air being sucked through the sealing edge of and into the respirator.

2. Positive pressure fit check – the HW forcibly blows air out and at the same time feels along the edges of the respirator seal for air leaks.

When an adequate fit check has been demonstrated, proceed to a real time fit test check.

Attach respirator to PortaCount™ / AccuFit™

If not already attached, attach respirator sample port (probe) to the fit tester device via the clear tube of the twin tube assembly. At this point, the fit tester device should be setup, turned on and ready for use. If not, refer to the CEC fit testing videos, IFU and or training resources.

Achieving a seal

The real-time fit check mode is used to confirm and or troubleshoot the HW's ability and confidence to do a respirator fit check. Using the real time fit check mode assists the HW in understanding how minor adjustments to positioning and seal of the respirator impact a respirator fit. This allows the HW to experiment with locating any leaks in the seal of the respirator. Fit testing is not considered a training opportunity, however, the visualisation of watching the direct effect these efforts have on a respirator fit is a valuable opportunity for improving HW understanding. This is not a PASS/FAIL test result.

Before proceeding with the real time fit check make sure the HW holds the twin tube assembly during the real time fit test. Confirm the sample (blue) line is not obstructed by the HW's hand/fingers.

The real time fit check graph demonstrates a quality respirator seal when the graph line is consistently and reliably sitting on 100. Some amount of movement of this graph line either side of 100 is acceptable provided the graph line hovers at 100. What is not acceptable is consistency of graph line dips away from 100 and variability of the graph line.

PortaCount™

FIGURE 21: PORTACOUNT™ REAL-TIME FIT CHECK TAB
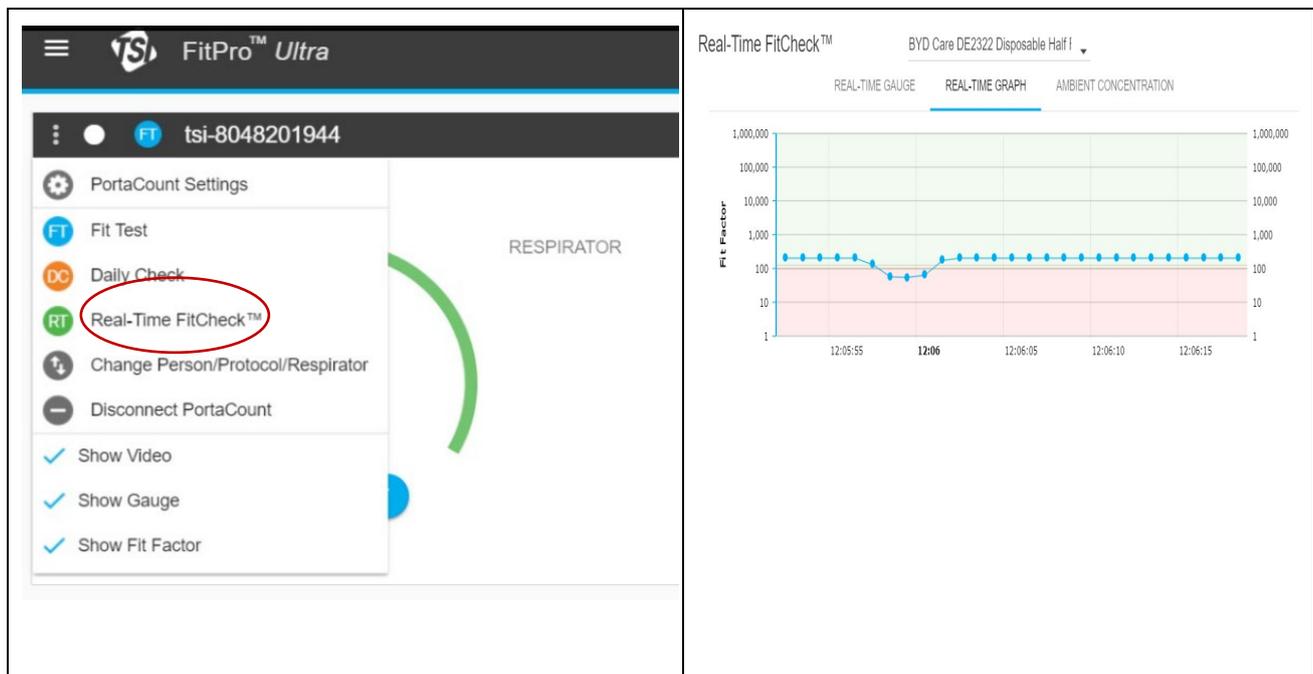
If the graph line is consistently on or above 100 proceed with a fit test.
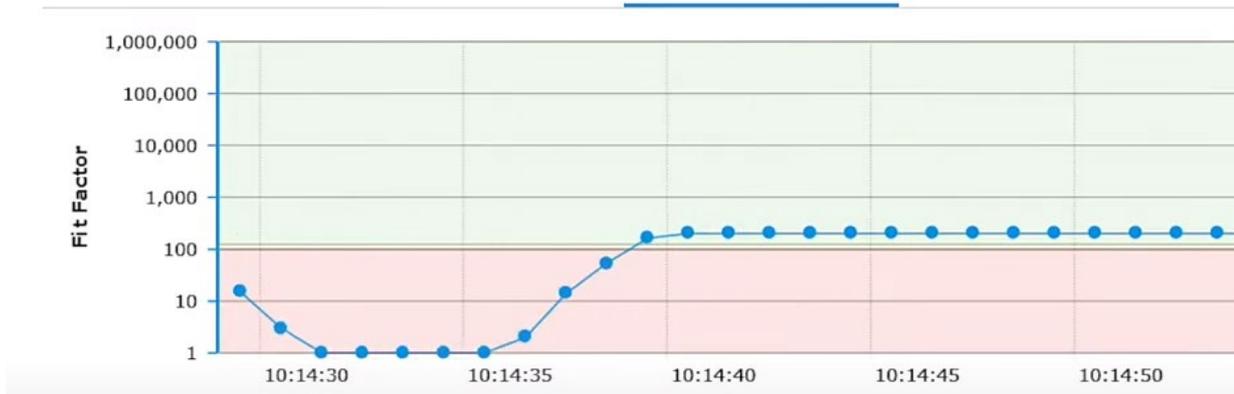
If the graph line is not maintained at or near 100, the HW is advised to adjust the respirator seal and/or positioning.
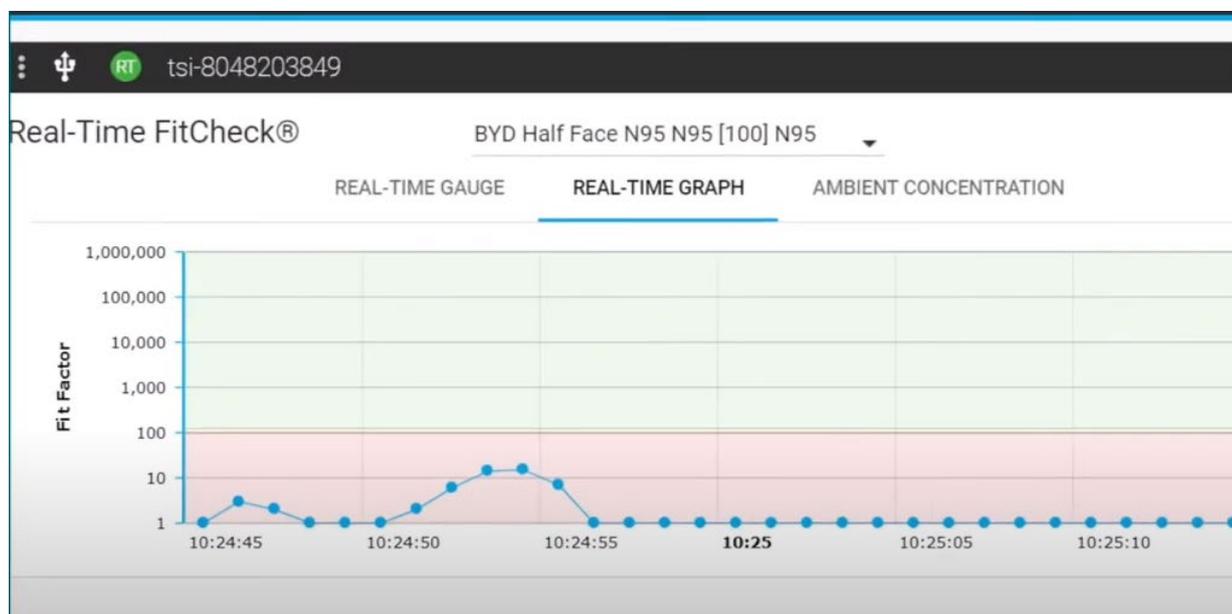
If the graph line is consistently below 100 despite readjustment of the respirator. Do not proceed with the fit test. Select the next respirator according to supply chain.

FIGURE 22: ACCUFIT™ REAL-TIME FIT CHECK TAB
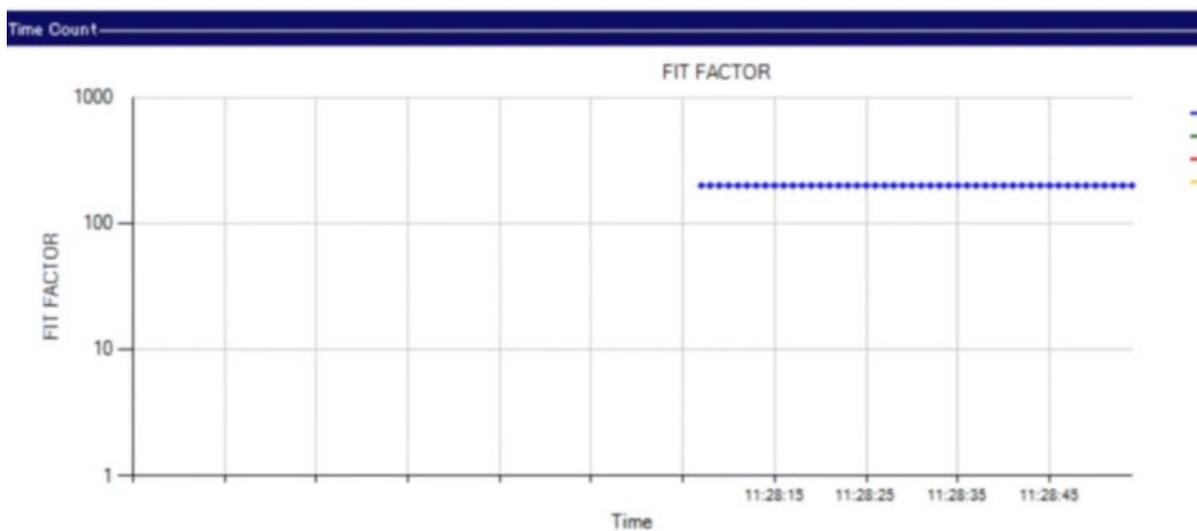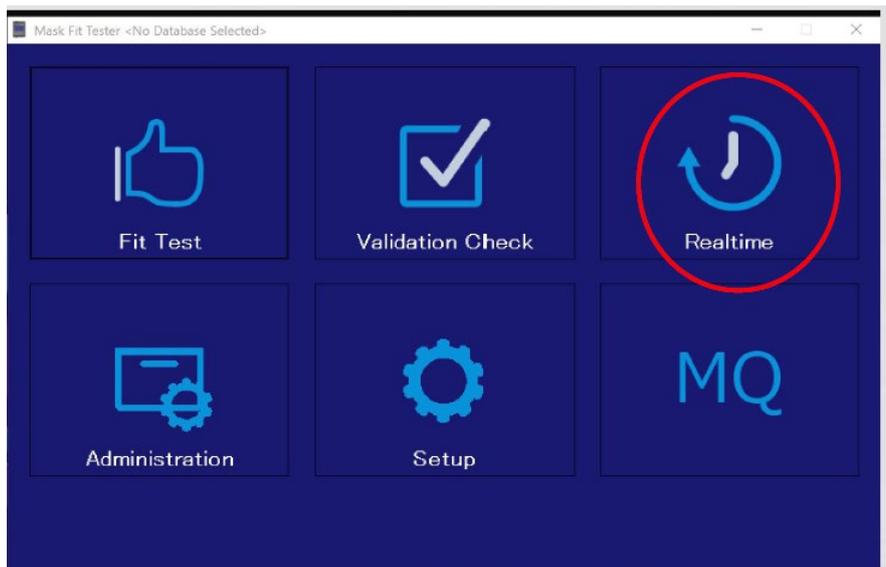
If the graph line is consistently on or above 100 proceed with a fit test.
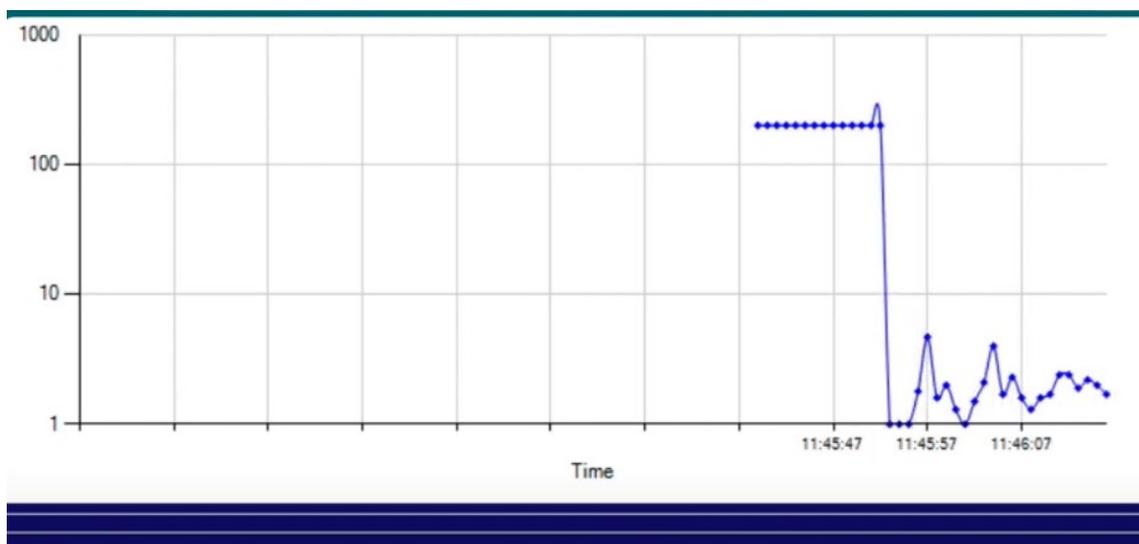
If the graph line is consistently below 100 despite readjustment of the respirator. Do not proceed with the fit test. Select **the next respirator according to supply chain.**

Conducting a fit test

The HW needs to have the respirator donned for at least five minutes before the real time fit test can start. You may hear the term comfort check. The comfort check allows any particles inside the respirator to be purged and at the same time determine the HWs ability to tolerate the respirator for comfort.

For filtering facepiece respirators the Occupational Safety and Health Administration (OSHA) Modified ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol for quantitative fit test is recommended. Each exercise set is designed to replicate normal workplace movements that may alter the seal of the respirator: Depending on the respirator being tested will determine which exercise set and protocol will need to be selected. Refer to [CEC Fit Testing Videos](#) for more information.

Modified ambient aerosol CNC quantitative fit testing protocol for filtering facepiece respirators (adapted from OSHA)

Exercise	Exercise procedure	Measurement procedure
Bending over	The test subject shall bend at the waist, as if going to touch his/her toes for 50 seconds and inhale 2 times at the bottom.	A 20 second ambient sample, followed by a 30 second mask sample
Talking	The test subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor for 30 seconds. He/she will either read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song.	A 30 second mask sample
Head Side-to-Side	The test subject shall stand in place, slowly turning his/her head from side to side for 30 seconds and inhale 2 times at each extreme.	A 30 second mask sample.
Head Up-and-Down	The test subject shall stand in place, slowly moving his/her head up and down for 39 seconds and inhale 2 times at each extreme.	A 30 second mask sample followed by a 9 second ambient sample.

Reference: [OSHA protocol](#) Appendix A to §1910.134—fit testing procedures

NSW Health fit testing to filtering facepiece respirators follows the 4-exercise set protocol and is selected from the options in the fit tester device:

- TSI PortaCount™ - OSHA FAST FILTERING FACE.
- AccuFit™ - OSHA FAST FPP 2019.

Explain to the HW

- Have the HW hold the twin tube assembly during the real time fit test. This will limit any drag on the respirator during the fit test. In other words, the position of the respirator is maintained during the fit test. Confirm the sample (blue) line is not obstructed by the HW's hand/fingers.
- The range of exercises to be performed during the fit test – see *Appendix 4B: Fit test assessor - Quick reference guide* and FTA training resources.
- You may have the HW tilt their head up and down, turn side to side and bend over to see if tubing pulls the respirator away from their face, if it does, readjust the tubing and repeat the fit check again.
- No talking, laughing, smiling, except when prompted for exercise 2.
- Exercise 2 will require the HW to read aloud a prepared text called the 'Rainbow Passage'.
- Can request to stop the test process at any time if they experience any negative effects and or feel unwell.

Confirm with the HW if they are ready and have any questions prior to commencing the fit test.

Remember a fit test is not considered an opportunity for training and education of the HW in how to safely don fit check and doff a respirator. HW to don the respirator without assistance from the FTA, however FTA can provide some guidance/instruction to the HW during donning and the fit check process but cannot provide any physical assistance. The decision to proceed to the fit test should consider the HWs ability to safely don, fit check and doff a respirator.

Result

A minimum overall fit factor of 100 is required to achieve a fit test pass for disposable respirators.

For elastomeric (reusable) respirators a minimum overall fit factor of 500 is required to achieve a fit test pass.

The overall fit factor is the most important item. It is the overall result of the fit test and is the only fit factor value that must be retained as part of the record keeping. The fit factors for the individual exercises are not as important. It is possible to have an overall fit factor of 100 or 500 (depending on the respirator) even though one of the exercises resulted in a failed fit factor.

The overall fit factor is a weighted average related to the number of particles the HW may be exposed to and inhaled if in the workplace. Fit Factor numeric values close to the pass/fail criteria would always be investigated and may require readjustment of the respirator with retesting and or a second fit test assessor to confirm the outcome. Additionally, the HW may benefit with remedial training and review of the [CEC donning and fit checking](#) training videos.

Troubleshooting fit test fail

Review

The fit of the respirator:

- Straps in the correct position.
- Respirator fully expanded and centred on face.
- Moulding of the respirator across the nose and cheek bones.
- Does the respirator have obvious defect in appearance?
- Repeat the fit check.

The fit tester device:

- Confirm the twin tube assembly connections are all attached and not loose.

- Is there condensation build up in the twin tube assembly? This may result in a false low fit factor.
- Are there any alert/error warnings on the fit tester device screen and or software?
- Is the alcohol cartridge correctly screwed in the fit tester device; not loose/over tightened.

Repeat the fit test:

- If fit test fails again, repeat the fit test process using the next respirator according to the *CEC Fit test assessor - Quick reference guide* or the recommended supply chain.
- If the HW exhausts all available respirators, the HW will need to return for a repeat fit test assessment with a second fit test assessor. Refer to *Appendix 4B: Fit test assessor - Quick reference guide.*

Escalating a "no fit"

If all available respirators result in a HW not been fitted successfully to a disposable respirator this must be escalated to the HWs direct line manager and the LHD/SHN RPP Lead.

The HWs direct line manager in consultation with the LHD/SHN RPP Lead and WHS / IPAC team to draw a pathway for this HW. Refer to *Appendix 1A: Respirator fit testing algorithm.*

Data Collection

Documentation and reporting of fit test outcomes

Follow the local process for communicating the fit test outcome with individual HW and organisation requirements. At a minimum inform the HW:

- Successful fit tested respirator details.
- Fit check to be attended each and every time a respirator is donned.
- All respirators fit tested to all HWs regardless of a successful or unsuccessful fit test pass must be recorded in Stafflink HCM. Follow local processes for reporting each fit test outcome in Stafflink HCM.

Refer to the quick reference guides in Stafflink HCM

- How to access the respirator fit form
- How to complete the respirator fit form
- Reporting fit test outcomes.

PortaCount™ and AccuFit™ software does allow some importing and exporting fit testing data to and from CSV files (follow the specific device IFU for more information).

Packing up, transport and storage

Do not store or transport the fit tester device with the alcohol cartridge in the cartridge cavity of the fit tester device. This may damage the fit tester device.

- Turn off the fit tester device using O/I or on/off button.
- Turn off the power supply at the power outlet and disconnect electrical cords and cables from the fit tester device and power source.
- Remove the storage cap from the alcohol fill capsule.

- Remove the alcohol cartridge from the cartridge cavity of the fit tester device and place in the alcohol fill capsule.

- Attach the storage cap to the cartridge cavity of the fit tester device and twist until locked in position. Do not overtighten.

- Remove the alcohol cartridge from the alcohol fill capsule.

- While holding the alcohol cartridge:

  o Open a bottle of the manufacturers supplied Isopropyl alcohol.

  o Invert the bottle and insert the nozzle end into the alcohol fill capsule as far as possible to prevent alcohol being sprayed inadvertently.

  o Squeeze the bottle to fill the cartridge to the appropriate level.

  o Recap the alcohol bottle.

  o Insert the alcohol cartridge into the alcohol fill capsule and turn the capsule clockwise until it locks in place.

- Place the alcohol fill capsule into the fit tester carry bag.

- PORTACOUNT particle generator:

  o Turn off and remove and empty the particle generator reservoir, refill with fresh water and re attach to the particle generator.

  o Turn the particle generator back on for 2 minutes then.

  o Turn off and empty the particle generator reservoir and dry before reattaching to the particle generator.

  o Turn off and disconnect the electrical cable from the power source.

  o Place into the fit tester device carry bag.

- ACCUFIT particle generator:

  o Turn off using the dial and remove the water bottle from the particle generator.

  o Turn off and disconnect the electrical cable from the power source. Disconnect from the particle generator.

  o Empty the water bottle and particle generator reservoir.

  o Dry the particle generator reservoir with a paper towel.

  o The particle generator needs to cool down for up to 60 minutes before packing and storing in the fit tester carry bag.

- Place the fit tester carry bag onto a stable the surface.

- Place the fit tester device into the fit tester device carry bag.

- Pack electrical cords and cables into the fit tester device carry bag.

Return to storage:

- Use a trolley or other suitable aide to safely transport the fit tester device to storage.

- If transporting to an outside facility, ensure the delivery vehicle parks as close to the testing area as practicable.

Appendix 4A: Use of respiratory protective device with beard cover technique

Background

HWs required to wear a tight-fitting respirator are to perform a user seal check at the point of use to ensure that the 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.

Primary recommendation

The proper fitting of a tight-fitting respirator always requires the sealing surface of the respirator to be free of facial hair. HWs with any amount of facial hair, even a few days of growth particularly where the mask seals on the face, may NOT be able to achieve a seal with a tight-fitting respirator. HWs required to wear a tight-fitting respirator or attending fit testing must not have any facial hair present. The primary recommendation for achieving a seal, with a tight fitting RPD, requires a clean-shaven face.

Secondary recommendation

HWs unable to remove facial hair due to a medical condition, psychological needs/reasons or observing a genuinely held religious or cultural belief, based on the tenets of the religion, can seek an exemption based on risk-based assessment for the use of a beard cover technique when wearing a tight-fitting respirator.

A loose-fitting PAPR can be considered for HWs who fail to achieve a facial seal with available disposable or reusable tight-fitting respirators. A fit test is not required for PAPRs with loose-fitting headgear such as hoods and helmets. However, local process on maintenance, cleaning and disinfection aspects must be considered in consultation with relevant stakeholders.

What is a beard cover technique?

A beard cover technique or under mask beard cover technique is used to cover the entire beard, chin, and cheeks by either using an elastic band over the beard and tied at the top of the head or donning a balaclava over the head to cover the head, cheeks, and beard (see figure below). If using an elastic band, non-latex elastic bands are preferred over latex material due to the potential for skin sensitivity or allergic reactions. Elastic bands can be cleaned, disinfected, and reused by the same person; however, a balaclava is single-use and must be disposed of after removal. Where beard wrapping is considered, the manager in consultation with workforce, should undertake a local risk assessment to identify potential WHS risks. This should consider the location and type of work, and individual factors specific to the HW.

Elastic band technique	Balaclava technique

Quantitative fit test results from NSW

The CEC and Australian Sikh Medical Association (ASMA) collaboratively conducted quantitative fit testing using both elastic band and balaclava techniques. Thirty bearded males also wearing a turban underwent standard quantitative fit testing using five different respirators along with a beard cover. The fit testing was conducted by NSW Health approved fit testers using a PortaCount™ or AccuFit™ fit testing device. The study was overseen an independent observer from the CEC. The subjects were volunteers selected from health and non-health organisations and used the same technique of respirator donning and fit checking for either the elastic band method or the disposable balaclava method. The results of the fit testing below:

Technique	N=30	Pass rate	95% Confidence interval (CI)
Elastic band technique	23/30	77%	59%-89%
Balaclava technique	17/30	57%	39%-73%
Total pass on either/or	24/30	80%	63%-91%

Who could use the beard cover technique?

HWs with an exemption to keep facial hair (beard) due to a medical condition, psychological needs/reasons or religious observance based on risk-based assessment should be able to wear tight fitting respirator using a beard cover technique (elastic band or balaclava). Successful fit testing should be achieved with the application of either of these two techniques when a HW is wearing a respirator.

Prior to clinical use, a HW should be fit tested using the beard cover technique to validate their ability to achieve required the fit factor. If the HW achieves a pass with using either beard cover technique with any respirator, the HW should continue to use that same technique when wearing a respirator in the clinical area. The HW fit tested using this method should also undergo competency assessment for donning and doffing PPE inclusive of the steps required for this method.

HWs with a facial hair exemption are to successfully complete MHL: Beard Cover technique (course code: 439593323) and practice beard wrapping technique prior to presenting for fit testing.

How to obtain an exemption for using a beard cover technique

Process:

1. A line manager identifies a HW who is required to use a tight-fitting respirator for their work has facial hair.

2. The line manager discusses the requirement to not have facial hair present with the HW; directing them to CEC guidance around the issue and requests removal of facial hair.

3. The HW discloses they have facial hair for religious or cultural observance purposes or due to a documented medical condition or psychological needs/reasons.

4. The line manager requests supporting information from the HW:

   a. Letter from their faith leader identifying the HW as requiring facial hair for religious observance reasons.

   or

   b. Statutory Declaration by the HW stating the HW requires facial hair for religious or cultural observance reasons.

   or

   c. Medical certificate detailing medical condition and medical reason for the need to maintain facial hair (example: past facial trauma and psychological condition relating to scarring that is concealed via facial hair) these would be managed via existing Non-Work-Related Medical Condition pathways.

5. Once above information is provided to the line manager; HW's can enrol in MHL: Beard Cover Technique (course code: 439593323) and booked for training in donning, doffing, fit checking, fit testing using the beard cover technique.

6. Where there is disputation about information provided to support the need for the facial hair to be kept, the line manager is to engage with their workforce team for assistance.

7. The record of exemption is to be kept by Human resources following the local processes.

Donning and doffing of tight-fitting respirator using beard cover technique

The beard cover technique using elastic band

Use an elastic exercise resistance band (preferably non-latex material) 15cm wide by approximately 50cm long (may be shorter or longer depending on the individual). Resistance bands come in different widths, strengths, and colours. The band should be selected based on the size, thickness and width that is suitable for each individual face and any additional headwear that is required such as a turban. A suitable width should cover the beard hair to the neck but be able to sit flat along the sides of the face or facial area where mask will sit to form the seal. It should also be long enough to enable a comfortable tie that will not come undone or move. Once a band has been found to fit the HW and a fit test has been passed, the same band width, length and type should be used whenever a respirator is required. The bands can be considered for extended or sessional use. The band should be cleaned/disinfected when becomes wet, moist, or contaminated or when every time the band is doffed or changed.

Refer to [elastic band donning and doffing video](#).

Donning elastic band technique		
1	Hand hygiene	
2	Select the same size elastic band used to fit test	
3	Use each hand to hold both ends of the elastic band	
4	• Pull the elastic band under the chin and tie a double knot above the head • Ensure that all facial hair on chin, cheeks and neck are covered by the elastic band, and does not cause restriction or discomfort around the eyes and mouth • Ensure that the band is stretched under loose tension, but not too tight to cause discomfort or restriction • Move the head back/forth and up/down to make sure the band will not come undone, cause discomfort or move with head movement	
5	Don gown/apron (based on Transmission based precautions)	
6	Select the respirator which has been fit-tested and recommended for you. Don the respirator over the face and perform a fit check	
7	Don other PPE as per local guidelines and the task you will be performing	

Doffing elastic band technique		
1	Remove gloves	
2	Hand hygiene	
3	Remove gown (or remove gloves and gown in one step)	
4	Hand hygiene	
5	Remove eye protection (if reusable, clean)	
6	Hand hygiene	
7	Remove mask and discard	
8	Hand hygiene	
9	Untie elastic band and dispose or clean and disinfect with dual purpose wipe, dry and store it in a clean sealed and labelled bag for reuse	
10	Hand hygiene	

Cleaning and Disinfection of Elastic Band

The person using these bands are responsible for cleaning/disinfecting and storing the item. Always check the bands for integrity and damage prior to use. Clean and disinfect in between use and wash with soap and water at the end of the day/shift. The user should be aware of any skin sensitivity/allergic reaction due to the material or cleaning and disinfection agents.

1. Clean reusable elastic band with a detergent solution or wipe.

2. Disinfect the elastic band with a TGA and manufacturer approved disinfectant.

OR

1. Use one step process using a dual-purpose TGA approved cleaning/disinfecting agent.

   - Clean hands with alcohol-based hand rub or soap and water.

   - Allow the band to dry in a clean area.

   - Once dry, store in a labelled, clean, sealable, and disposable bag.

   - Perform hand hygiene after completion.

The beard cover technique using disposable balaclava

The use of the respirator on balaclava technique requires that the HW has been fit tested and approved to use this technique. Refer to balaclava donning and doffing video.

Donning respirator using balaclava technique		
1	Hand hygiene	
2	• Don balaclava • Ensure the balaclava covers all facial hair in the region where the respirator forms a seal	
3	Don gown (based on transmission-based precautions)	
4	• Select the respirator which has been fit-tested and recommended for you • Place the respirator over the face and perform a fit check	
5	Don other PPE as per local guidelines and the task you will be performing	

Doffing respirator using balaclava technique		
1	Remove gloves	
2	Hand hygiene	
3	Remove gown (or remove gloves and gown in one step)	
4	Hand hygiene	

5	Remove eye protection (if reusable, clean)	
6	Hand hygiene	
7	Remove respirator and discard	
8	Hand hygiene	
9	• Remove balaclava from behind and remove over head in forward direction, with the head slightly bent over • Place the balaclava in the bin	
10	Hand hygiene	

Fit testing beard cover technique methodology:

Undertake fit testing with available disposable respirators that are in good supply and or as advised by HealthShare/procurement teams. Refer to [CEC Respiratory Protection Program](#) for information on respirator selection and step-by-step guide on [fit testing using a beard cover video](#). Follow the below steps when conducting a fit testing using the beard cover technique.

- Hand hygiene

HW to don beard cover (elastic band)

- Wear recommended P2/N95 respirator and fit check.

- Follow fit testing process.

- If the HW achieved a pass record result.

- If failed repeat fit checking and repeat the test.

- If failed again, change to next respirator.

- Doff respirator and perform hand hygiene.

- Once all masks have been tested with beard cover, ask HW to remove beard cover.

- Hand hygiene.

Don balaclava

- Don respirator.

- Fit check and fit test using above process.

- Doff respirator and perform hand hygiene.

- Record results.

References:

Prince SE, Chen H, Tong H, Berntsen J, Masood S, Zeman KL, Clapp PW, Bennett WD, Samet JM. Assessing the effect of beard hair lengths on face masks used as personal protective equipment during the COVID-19 pandemic. J Expo Sci Environ Epidemiol. 2021 May 18:1–8. doi: 10.1038/s41370-021-00337-1. Epub ahead of print. PMID: 34006963; PMCID: PMC8130778. DOI: 10.1038/s41370-021-00337-1

Matharu K. Beards and masks. Br Dent J. 2020;228(11):814. doi:10.1038/s41415-020-1734-0

Singh R, Safri HS, Singh S, et al. Under-mask beard cover (Singh Thattha technique) for donning respirator masks in COVID-19 patient care. J Hosp Infect. 2020;106(4):782-785. doi: 10.1016/j.jhin.2020.09.034

Appendix 4B: Fit test assessor - Quick reference guide

Fit Test Assessor: Quick Reference Guide
Version 1.2 (28/04/2022)

PRIOR to fit test session

Setup and calibration:
- ❑ Assess the room suitability
- ❑ Setup particle generator
- ❑ Setup fit tester device
- ❑ Calibrate (daily checks)
- ❑ Prepare respirators

START fit test

Assess health worker (HW) test suitability. Check HW has:
- ❑ no facial hair (if facial hair present go to FAQs)
- ❑ not smoked or eaten in the last 30 mins
- ❑ completed the required MHL modules
- ❑ brought their routine PPE to don.

Obtain HW consent to enter and share data for the fit test result.

Brief the HW on fit test purpose and process.

HW dons the 1st prepared respirator type as per the **CEC Respirator Algorithm**. Note: A mirror may assist the HW with donning.

Respirator test cycle

Don - Observe and coach HW donning respirator.

Fit check - Observe and coach HW fit checking respirator.

Good fit

5 min comfort check – HW assesses comfort and fit.

Good fit/comfort

Conduct a real time fit check using fit tester device.

PASS (good fit)

Conduct a fit test.

PASS (good fit)

Doff - Observe and coach HW doffing and disposing respirator. Reinforce hand hygiene.

Poor fit

Poor fit and/or uncomfortable

FAIL (poor fit)

FAIL (poor fit)

Repeat the respirator test cycle for the next respirator in the CEC Respirator Algorithm.

All HWs should be successfully fit tested to **two respirators** if able.

Check for interference (e.g. hair and strap positioning) and adjust as necessary. Confirm seal over the nose and cheeks.

Issue identified and adjustment made

No interference or adjustment required

Dispose of respirator and repeat test cycle for the next respirator type in in the CEC Respirator Algorithm.

All respirators unsuccessful

All respirators unsuccessful
- ❑ Escalate to local RPP lead
- ❑ Re-check and re-test with other FTA.
- ❑ Fit test other NSW Health approved available disposable P2 or N95 respirators.
- ❑ HWs direct line manager to conduct risk assessment.

Consider fit testing with available reusable respirators within your agency.

END of fit test session
- ❑ Clean and shut down fit test equipment.
- ❑ Report/discuss any issues encountered with the local RPP lead.

END fit test
- ❑ **Confirm** the respirators (brand, style and size) with an optimal fit test outcome with the HW.
- ❑ **Reinforce** the HW must select these respirator types every time respiratory protection is required
- ❑ Enter data in Stafflink.

NSW GOVERNMENT | CLINICAL EXCELLENCE COMMISSION

Note: All videos below can be viewed on the **Clinical Excellence Commission** YouTube channel.

Scan the QR codes below with your mobile to view demonstration videos.

Video 1: Fit test device preparation and setup

Video 3: Cleaning and storage of fit test equipment

Fit testing of P2/N95 disposable respirators

Video 2A: PortaCount fit test device

or

Video 2B: AccuFIT fit test device

Appendix 4C: Fit test fact sheet

Prior to your fit test

DO:

1. Complete MHL Pathway for Respirator Protection:

   o Donning and Fit Checking of P2/N95 Respirators in NSW Healthcare Settings. Course code – 319438161.

   o RPP: Safe use of P2/N95 respirators (Pathway).

2. If you have been allocated a specific respirator to use in the workplace, you may need to bring an unused sample with you to be fit tested.

3. Bring PPE (e.g., eye protection, headwear etc.) you usually wear in conjunction with the respirator to the fit testing sessions.

4. Attend fit testing with no facial hair.

5. Ensure hair is tied back.

6. If you normally wear prescription eyewear, you must bring this item with you to the fit test. Ensure the arms of the glasses/eyewear sit outside of the straps.

7. Jewellery, make-up and/or face cream may impact on the quality of the respirator seal. If you have an unsuccessful fit test outcome, you may be requested to remove anyone of these items, where applicable and return for repeat fit testing.

8. Complete a consent form if asked.

9. Please discuss with your line manager, prior to fit testing if you have a medical condition or concerns that may prevent you from conducting a fit test.

DO NOT:

10. Smoke, vape or eat (food with strong smell or odour) for 30 minutes prior to the fit test session.

11. Chew gum within 30 minutes of the fit test.

12. Attend a fit test if it has been more than 24 hours prior to your last facial shave.

13. Attend if you are unwell including having symptoms of a respiratory like illness.

14. If you have any questions, please contact the local respiratory protection program lead.

Local contact name: ……………………………………………………………………………

Contact number: ………………………………………………………………………………….

Appendix 4D: Sample check list for fit test assessor (FTA)

Check list for fit test assessor (Complete one column per participant)																			
Fit test participant initial																			
Has not eaten or smoked																			
Clean shaven																			
PPE donning, doffing and respirator fit checking mandatory online training completed																			
Physically and psychologically fit to wear a respirator																			
Consent completed and signed																			
Explanation on fit testing																			
Selection respirator based on CEC flow chart																			
Strap tension, chin and nose placement suitable																			
Donning of respirator																			

Check list for fit test assessor (Complete one column per participant)																			
Respirator positioned suitably																			
Nose piece sealed over the nose bridge																			
Top strap on the crown and bottom strap base of the neck																			
Explain ft test process and exercises																			
Probe placement checked																			
PPE (e.g. eye and head wear, head) donned																			
Prescription eyewear donned																			
User seal check after head movement																			
Performs fit check as per OSHA 1910.134 protocol																			
FTA initial																			

Appendix 4E: PortaCount™ / AccuFit™ quick prompt guide

Respirator fit test is to be untaken only by an FTA that has completed an approved fit test assessor training. The following information is applicable to PortaCount™ or AccuFit™ fit tester devices.

Prior to the first test of the day the fit test device is to be wiped with a neutral detergent and disinfectant wipe (2-step process or a dual-purpose wipe 1-step process).

Step 1

FTA to set up device (PortaCount™ or AccuFit™) and particle generator as per manufacturer's instructions for use (IFU). Refer to [CEC Fit test videos](#) for more information.

- Perform hand hygiene.
- Start the particle generator at least 10 minutes before starting fit testing.
    - PortaCount™ add 1 salt tablet and water.
    - AccuFit™ only use plain water.
- Place the particle generator at least 1.8 (PortaCount™) / 3 m (AccuFit™) away from the device.
- Ensure that surface around the device and particle generator are clear.
- Attach the twin tube assembly – blue to blue, clear to clear.
- Attach HEPA filter to the other end of the clear tube.
- Confirm alcohol is visible in the alcohol cartridge.
- Install alcohol cartridge into the device (make sure the fit tester device it is not turned on).
- Connect the fit tester device USB cable to the laptop.
- Turn on the device.
- Conduct the daily calibration check making sure N95 option is selected on the software.

Step 2

- Confirm the HW priority order of LHD/SHN for respirator fit testing.
- Enter HW details and allocate the correct respirator style and size into the software.
- HW and FTA to perform hand hygiene.
- FTA to insert the probe into the respirator.
- HW to don and adjust the respirator to achieve an adequate seal.

FTA to:

- Take note of the time – 5 minutes, for purging of the respirator and confirm comfort check of the selected respirator.
- Confirm HW can don and demonstrate fit check of the selected respirator.
- Confirm respirator seal using the real time fit check prior to the fit test.
- Select OSHA modified protocol, explain the exercises and process to HW.
- Commence fit test.

Participant to hold the tubing during fit test.

Step 3

Once the fit test has been completed:

- Confirm fit test outcome with the HW.

- FTA (or HW) to remove the tubing from the respirator probe, HW to remove respirator and dispose.

- Perform hand hygiene.

- FTA to disconnect the twin tubing from the device and wipe with neutral detergent and disinfectant wipe (2-step process or a dual-purpose wipe1-step process).

- Perform hand hygiene.

- If a pass has been achieved on a disposable respirator, follow local process for documentation (e.g., give hole punch fit testing card to HW or follow local process for future reference).

Step 4

At the end of day or the session fit test device and accessories is to be cleaned, dried, and packed in provided case and stored.

Refer to the *Appendix 4G: Cleaning and disinfection consideration during quantitative fit testing* and LHD/SHN requirements for more information.

Refer to LHD/SHN requirements for reporting and storage of fit testing data on the computer software.

Appendix 4F: Quantitative Fit Testing Machine Troubleshooting Guide (generic)

Disclaimer: Always refer to the manufacturer's instructions and safety guidelines specific to your fit testing machine. If you are uncertain about any troubleshooting steps, consult with a qualified technician or contact the manufacturer's customer support.

Please familiarise yourself with the manufacturer's instructions as these contain guidance for common issues you may experience.

Troubleshooting

1. Machine Won't Power On:
   a. Check all connections.
      i. Check if the power cord is securely connected to both the machine and the power outlet.
   b. Verify that the power outlet is functioning by testing it with another device.
   c. If the problem persists, contact the manufacturer's customer support.
2. Software or Interface Problems:
   a. Ensure that the software is compatible with your operating system and is up to date.
   b. Check the connection between the machine and the computer.
   c. Restart the software and the computer, and then reconnect the machine.
   d. If the problem persists, contact the manufacturer's technical support for software assistance.
3. Validation Issues: Follow the manufacturer's guidelines for validation.
   a. Ensure particle generator has been running for at least 10 mins prior to validation.
   b. Consider if space size is appropriate for fit testing. Make sure the testing environment is stable, with consistent temperature and humidity levels.
   c. Particle generator too close or too far from machine
   d. Check there is no breeze from windows/ air conditioning.
   e. Check HEPA filter and twin tubing for correct attachment and/or cracks/splits.
   f. Check alcohol wick- may need to refresh alcohol or allow wick to dry out a little
   g. If calibration continues to fail, contact the manufacturer for assistance.
4. Inaccurate or Unstable Readings:
   a. Ensure that the machine's twin tubing is clean, undamaged, and free from obstructions.
   b. Check twin tubing is connected to machine correctly (blue tube to blue nipple/clear tube to silver nipple)
   c. Check for any leaks or damage in the tubing, connectors, or mask being tested.
   d. Check alcohol wick- may need to refresh alcohol or allow wick to dry out a little
   e. If the problem persists, consider sending the machine for servicing or recalibration.
5. Error Codes or Alarms:
   a. Low Alcohol- Dip alcohol wick as per manufacturer's instructions.
   b. Address other issues related to malfunctions, or system errors as indicated.
   c. If you cannot resolve the error, contact the manufacturer's customer support or technical assistance.
6. Unusual fit factor numbers (e.g., greater than 200): refer to manufacturer's instructions.
   a. Check N95 box ticked/enabled.
   b. Check respirator database correct uploading of respirators (fit factor pass of 100 and N95 bow ticked/enabled)
   c. If the problem persists, consider sending the machine for servicing or recalibration.

Appendix 4G: Cleaning and disinfection consideration during quantitative fit testing

After finishing the fit test

HW being fit tested:

- Doff respirator correctly – if not done correctly, review correct technique.
- Remove the twin tube from respirator probe.
- Dispose used respirator.
- Perform hand hygiene.

FTA:

Clean twin tube assembly after EACH USE using detergent/disinfectant wipe (dual purpose or two-step process by using detergent and alcohol wipe).

- Hold the tubing in your hand and disconnect from PortaCount™ or AccuFit™
- Wipe the length of the assembly with the wipe and discard the wipe, allow to dry.
- Attach zero check filter when the twin tube assembly is connected to the machine.
- Use a new wipe to clean the surfaces being touched.
- Clean hands after completion of the cleaning.

Between sessions and as required

The twin tubing will require flushing of the clear line with compressed air to clear the tubing of condensation.

- Gloves (optional).
- Don safety glasses.
    - Holding one end of the tubing with a paper towel, inject compressed air into the other end of the tubing to remove condensation (if present) allowing it to air dry.

After each session

PortaCount™ / AccuFit™ machine and accessories

- Follow machine prompts and recommendations based on product specifications for shutting down the machine.
- Follow manufacturers' recommendations on frequency of cleaning and type of disinfectants on each brand and model.
- Use TGA approved disinfectants.
- Wipe down the reusable parts of the fit test equipment using a dual-purpose detergent and disinfectant or two step process by using detergent and alcohol wipe.
- Wipe up any saline spills immediately.
- Dispose of any disposable consumables .
- Don safety glasses.
    - Holding one end of the tubing with a paper towel, inject compressed air into the other end of the tubing to remove condensation (if present) allowing it to air dry.

- Empty particle generator:
  - PortaCount™ - run plain water for 2 minutes, wipe external parts, dry and store.
  - AccuFit™- dry the internal cannister by wiping with a paper towel and store.

- Machine and consumables to be stored clean and dry.