

Guideline for CleanSpace HALO

Powered Air Purifying Respirator (PAPR) v2.0

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Guideline for CleanSpace HALO

Powered Air Purifying Respirator (PAPR)

1. Purpose

This guideline describes the considerations and processes for use of the CleanSpace HALO across Queensland Health facilities or services. The CleanSpace HALO is a Powered Air Purifying Respirator (PAPR). This Guideline aims to facilitate the use of the CleanSpace HALO, as a form of Personal Protective Equipment (PPE) where personnel are unable to achieve a satisfactory fit with disposable Respiratory Protection Equipment (RPE) or exposure to an airborne contaminant warrants an increased Respiratory Protection Factor (RPF).

The CleanSpace HALO CS3000 (and accessories as listed below), consists of a power unit, face mask and head harness, all three components are required to be worn as a complete unit.

The CleanSpace HALO meets the requirements of AS/NZS 1715:2009 RPE when used correctly by properly trained personnel.

- **Device:** Powered Air Purifying Respirator
- **Manufacturer:** CleanSpace Technology
- **Model:** CS3000 CleanSpace HALO Power System
- **Design:** Half Mask with/without BioHood; Full Face Mask

Components:

- CleanSpace HALO Half Face: CS3003 (S) CS3004 (M) CS3005 (L)
- CleanSpace Full Face: CS3006 (S) CS3007 (M/L)
- CS3024 CleanSpace BioHood (Disposable item)
- CS3025 CleanSpace HALO Bio HEPA P3/TM3 Filter
- CS3026 CleanSpace HALO Bio Mask Exhalation Adapter
- CS3027 CleanSpace HALO Bio Exhalation Filter
- CS3038 Steri-Plus Case: Exhalation Valve Filter Case / Reusable CS3039 Steri-Plus Filter: Exhalation Valve Filter (Consumable)
- CS3011 CleanSpace HALO Cleaning and Storage Plug
- PAF 0025 CleanSpace half mask adapter for quantitative fit testing
- PAF 1036 CleanSpace one-way mask valves for negative pressure fit testing

2. Scope

This Guideline applies only to the CleanSpace HALO CS3000 and does not apply to any other PAPR device. This Guideline applies to all staff who may consider utilising the CleanSpace HALO for situations where airborne precautions are required for:

- prolonged periods of time, generally more than one hour, when aerosol generating procedures (AGPs) are being undertaken e.g. intensive care unit (ICU) or the operating room.
- staff providing prolonged continuous care for a patient e.g. ICU, cohorted patients on a ward.
- staff who have failed fit tests on available disposable Particulate Filter Respirators (PFRs) e.g. P2/N95s.

3. Related documents

- This document is complemented by the [Queensland Health Interim Infection Prevention and Control Guidelines for the Management of COVID-19 in Healthcare Settings](#) which provides additional background relevant to infection control within a COVID-19 environment.
- This guideline is to be used in conjunction with each local hospital and health service over-arching Respiratory Protection Program to ensure appropriate training and safety systems are in place.
- Facial hair guidance for fitting facepiece PFRs - [Facial Hairstyles and Filtering Facepiece Respirators \(cdc.gov\)](#).

4. Australian Therapeutic Goods Administration

The CleanSpace HALO device is listed on the Australian Register of Therapeutic Goods (ARTG) outlined below.

- **ARTG Entry: 33808**
- **Manufacturer:** CleanSpace Technology Pty Ltd
- **Product:** CleanSpace HALO (and accessories)
- [TGA Public Summary](#)

5. PAPR background and indications for use

PAPR units are respirators with a battery-powered unit that forces air into a head or face covering through filters to clean the air before delivering it to the breathing zone of the wearer.

The purpose of a PAPR is to provide respiratory protection and reduce the risk of inhaling potentially harmful airborne pathogens. PAPRs create air flow inside either a tight-fitting face mask or loose-fitting hood or helmet. PAPRs are an alternative to particle filter respirators such as PFRs, for the care of selected patients requiring airborne precautions and are to be used in addition to other recommended PPE.

The Queensland Health [infection prevention and control guidelines](#) for the management of COVID-19 in healthcare settings state “PAPR designed for use in non-healthcare settings should not be used” (pg. 12). Also stated within the Australian Government’s Infection Control Expert Group document [“Use of Face Masks and Respirators in the context of COVID-19”](#) (section 3.2 Particulate filter respirators) is the advice: *“Only PPE included in the ARTG should be used in hospitals or for surgical procedures.”* Therefore, only PAPR listed on the ARTG such as the CleanSpace HALO can be used.

PAPRs are comparable to a well-sealed PFR, although there may be occasions when a PFR seal is compromised e.g. while performing emergency care.

However, when there is a need to wear PPE for extended periods of time, PAPRs may provide greater comfort for the wearer and reduce the likelihood of unintended breaches. PAPRs may also enhance healthcare worker sense of safety and well-being, particularly for staff working in high-risk settings and/or with high frequency or prolonged exposure e.g. staff performing Aerosol Generating Procedures (AGP).

These devices draw in air (generally positioned at the back of the clinician’s neck) and circulate it through a filter to the mask unit which is either:

- a. **half mask** that seals around the bridge of the nose, cheeks and under the chin; or
- b. **full mask** that seals across the forehead, lateral face and under the chin
- c. **bio hood** – a loose fitting head covering that is used with half mask.

PAPRs provide positive air pressure, preventing aerosols and droplets entering the space within the mask. The positive pressure is monitored at a frequency of 100Hz and maintained within a specific range.

Strict compliance with documented processes outlined in the [Queensland Health Interim Infection Prevention and Control Guidelines for the Management of COVID-19 in Healthcare Settings](#) procedures for selecting, fitting and removal of PPE is critical to patient and staff safety.

For specific advice on the type and duration of precautions required (e.g. at an individual patient level), contact your respective Infection Prevention and Control staff during business hours.

Each user of a CleanSpace HALO must undertake a quantitative fit test as per AS/NZS 1715:2009.

6. Limitations

There are several limitations that need to be considered prior to CleanSpace HALO use:

- protective eyewear i.e. a full-face shield or safety goggles or a BioHood must be worn when using the half mask CleanSpace HALO.
- In the event of a trauma or perioperative setting where the patient requires protection from aerosol contamination, an exhalation filter may be applied to the front of the mask:
 - In the clinical situation where an N95 respirator is indicated to be applied over the mask: a manufacturer approved exhalation valve filter (Steri-Plus) can be used with the CleanSpace HALO. A Steri-Plus exhalation filter is not a requirement to protect the wearer, only for source control.
- In the clinical situation where N95 respirator is not indicated – or an exhalation valve filter is unavailable use a surgical mask worn fitted over the CleanSpace HALO face. This approach has been validated by the manufacturer.
- The CleanSpace HALO requires re-calibration whenever the unit experiences a change in temperature of more than 20°C and will cease functioning if operating under extreme temperature ranges (internal temperature rise above 60°C or below -10°C). It is best practice to also re-calibrate if the unit has been in storage, particularly if the storage temperature is not known.

7. Storage location

As per manufacturer instructions, the device is to be stored out of direct sunlight, in a clean, dry environment. Further stipulations around ambient temperature control of the storage space are as follows:

- **When in active use in clinical area or on-charge ready for quick donning and immediate use):** -10°C to 35°C. (30% - 50% relative humidity)
- **When not in active use** 18°C to 28°C (30% - 50% relative humidity)
- **When not in active use, the filter can be removed and stored or disposed as per HHS maintenance schedule**

8. Composition of the CleanSpace HALO unit

The CleanSpace HALO comprises of the following system components (images below):

- CleanSpace HALO (power unit)
 - Figure 1a and 1b: Filter
- Figure 2: Neck support: 2 sizes available (optional requirement)

- Figure 2b: Power Unit with neck support attached
- Figure 3: Head harness
- Figure 4: Mask– 3 sizes available (small, medium, and large)
- Figure 5 and 6: Disposable power unit sleeve (PAF-0058)
- Figure 7: Charging unit CS 3014 - Docking Station Charging & Storage Case
- Figure 8: Steri-Plus exhalation valve filter
- Figure 9: BioHood (optional accessory)
- Figure 10: Accessories to attach to BioHood - CCS3027 CleanSpace HALO Bio Exhalation Filter
- Figure 11: CS3011 CleanSpace™ HALO Cleaning and Storage Plug
- Figure 12: CleanSpace full face mask
- Figure 13: CleanSpace HALO control panel

Accessories required:

- PAF-0025 PortaCount adapters – for fit testing masks during training and accreditation

Other items required:

- Plastic containers marked: “Contaminated” and “Decontaminated”
- Plastic bags



Figure 1a: CleanSpace HALO PAPR (power unit) with filter



Figure 1b: CleanSpace HALO PAPR (power unit) with filter



Figure 2a: Neck supports



Figure 2b: CleanSpace HALO PAPR (power unit) front view showing neck support attached



Figure 3: Head harness



Figure 4: Face mask



Figure 5: Disposable power unit sleeve cover



Figure 6: Disposable power unit sleeve cover over bellows



Figure 7: CleanSpace Charging station



Figure 8a Exhalation Valve Filter cover CS3038 and Figure 8b Exhalation valve filter insert CS3039



Figure 9: BioHood



Figure 10: Attachments for BioHood



Figure 11: CleanSpace HALO Cleaning and storage plug



Figure 12: CleanSpace CS3006/CS3007 Full Face Mask



Figure 13: CleanSpace HALO control panel

9. Fit testing of CleanSpace HALO

The CleanSpace HALO is ONLY to be used by those who have successfully completed the competency training program and have been quantitatively fit tested. When Fit Testing with CleanSpace HALO, personnel fitted with HALF face mask need to achieve a minimum overall fit factor rating of 100; if using FULL face mask, the wearer must achieve Fit Factor of 500. See [manufacturer's "User Instructions"](#) for further details on accessories and process for fit testing. It is expected that staff will use these devices in accordance with these instructions.

There are significant risks for any use of the CleanSpace HALO by untrained persons. Please refer to your local Hospital and Health Service guidelines or relevant specialist services for information on training and accreditation for users of the device.

10. Fitting and removal of CleanSpace HALO

A structured and systematic procedure detailing how the CleanSpace HALO will be applied (including fit check) and removed slowly and deliberately in the correct sequence will be required.

Fit checking will occur each time a mask is fitted – refer to section 12. No clinical activity will be undertaken until a satisfactory fit has been achieved. Facial hair that lies along the sealing surface of a tight-fitting CleanSpace HALO will stop it sealing correctly – therefore any hair growth between the skin and the facepiece sealing surface will be removed. Refer to facial hair guidance for fitting facepiece PFRs – [Facial Hairstyles and Filtering Facepiece Respirators \(cdc.gov\)](#).

Staff will fit CleanSpace HALO prior to entering the patient care area.

A trained spotter will direct all CleanSpace HALO fitting and removal appropriately. Breaches in CleanSpace HALO use will be identified and managed as per standard infection control procedures.

In general, CleanSpace HALOs will be removed after each healthcare interaction, regardless of whether Aerosol Generating Procedures (AGPs) were performed or the extent of splash of body fluids during the episode of care. Extended use exceptions may be required in some settings. Refer to section 11 – Extended use of the CleanSpace HALO.

The CleanSpace HALO will be removed after exiting the patient's room or clinical setting i.e. operating theatre. An adjacent room or area for storage and putting on clean PPE and a separate area of adequate size for the safe removal of PPE and the disposal of clinical waste will be provided.

Removal of the CleanSpace HALO is a particularly high-risk activity due to the risk of:

- Self-contamination during PPE removal
- contact transmission through handling of contaminated PPE

The CleanSpace HALO will not be worn outside of healthcare interactions.

11. Extended use of the CleanSpace HALO

Extended use of the CleanSpace HALO may occur in specific clinical scenarios:

1. Healthcare workers remaining in a patient's room for a long period of time (e.g. more than one hour) to perform multiple procedures.
2. Cohorted areas, such as the ICU, where:
 - the setting is isolated from other clinical areas

- all patients have confirmed infection for the same agent
- patients are likely to undergo regular procedures that require use of airborne precautions, such as AGPs.

Extended use of the CleanSpace HALO by healthcare professionals will:

- provide additional comfort and visibility
- reduce risk of transmission
- reduce use of disposable PPE.

Within clinical settings where extended use of the CleanSpace HALO is possible, CleanSpace HALOs will be removed and sent for reprocessing as per local guidelines when they:

- become soiled or contaminated or compromised.
- when the low battery alarm or filter alarm is triggered the user will leave the contaminated area, remove the respirator and investigate further. Send for reprocessing if required.

Staff are required to take a break from the CleanSpace HALO every four hours to manage PPE fatigue.

12. Fit Checking of CleanSpace HALO

Fit checking refers to the process of ensuring that a CleanSpace HALO achieves a good seal once it has been applied. Fit checking ensures that the soft wimple under the face shield conforms to the neck or is tightened where applicable and that there are no gaps between the CleanSpace HALO and face. There are both negative pressure and positive pressure fit checking processes. Negative pressure check is recommended by the manufacturer.

Process for half face/full mask negative pressure fit checking a CleanSpace HALO is:

1. Block the air clip air inlets on both sides of the mask with your thumbs.
2. Breathe in sharply – this will be difficult if there is a good seal.
3. Listen for squeaking or whistling noises – these will indicate an air leak.
4. Hold your breath for 10 seconds – if the mask moves away from your face there is an air leak.
5. Adjust the mask fit if leaks are detected.
6. Repeat the negative pressure seal check until satisfactory seal achieved.
7. If unable to achieve negative pressure seal remove mask and inspect exhalation valve to ensure properly seated after reprocessing.

13. Reprocessing of CleanSpace HALO

Discussion with the manufacturer and reference to the manufacturer's guidelines for cleaning, disinfection and sterilisation must occur to manage site specific processes. Only dedicated and appropriately trained staff should reprocess the respirators. HHS should allow for appropriate staffing whenever the PAPR are in use. Appropriate tracking systems for mask and power unit should be used.

Routine maintenance should be carried out as per manufacturer's instructions for servicing.

After removal of the CleanSpace HALO the user will:

- avoid unnecessary touching the front of the CleanSpace HALO or mask.

- remove the disposable exhalation filter from the CleanSpace HALO or mask.
- place Mask or steri-plus (not the power unit and head harness) in an impermeable, puncture-proof container.
- do not use plastic bags inside the impermeable, puncture proof containers as this makes removal of the unit from the container difficult potentially creating further contamination to the Central Sterilising Department (CSD) staff and the environment.
- arrange transfer of container to CSD.
- label the container and notify CSD if the patient has a known infectious (respiratory) status.
- CSD staff will reprocess the mask through automatic mechanical washer/disinfector on an 80°C or 90°C cycle reaching high level disinfection.
- after drying, the clean mask is to be placed in a clean sealed container or bag and will be returned.
- CSD will mechanically wash the container using mechanical washer disinfector processes to ensure minimal handling.
- if clinically indicated the unit may be sterilised using a validated low temperature sterilizing process as per manufacturer recommended process – refer to infection control and/or CSD of your facility.
- if using a BioHood, the hood will be discarded using an appropriate waste receptacle.

For cleaning of the power unit clinical staff will:

- leave the power unit filter in place to reduce possibility of improper handling; this is pathogen dependent.
- only remove the power unit filter (do not touch the filter) when indicated (see section 14 below).
- remove the protective cover over the power unit and the neck support if used.
- insert the cleaning and storage plug.
- wipe over the outside of the power unit with a detergent disinfectant wipe such as Clinell wipe.

The power unit will be stored in the docking station (with cleaning and storage plug in situ).

- Please refer to Manufacturer’s instructions for Cleaning CleanSpace HALO PAPR. Local workplace instructions detailing reprocessing procedures within CSD are to be developed.
- Please note: This information should be reviewed thoroughly by your hospital and health service and infection control unit prior to selecting the disinfecting product for your equipment and specific application.
- The CleanSpace HALO will be able to be cleaned and disinfected and returned for ongoing use.

For cleaning of the head harness, staff will:

- wipe over the outside of the power unit with a detergent disinfectant wipe such as Clinell wipe.

14. Maintenance of CleanSpace HALO

A designated “superuser” (equipment specialist with appropriate experience and training) group of staff within each work unit will be responsible for:

- checking the physical condition of the CleanSpace HALO power unit
- filter changing

- battery management
- recalibration
- flow testing.

These staff members will be provided with training which is consistent with the manufacturer's instructions.

Flow Testing will ensure that the CleanSpace HALO is producing a minimum of 120L/min of filtered air. The Flow Testing procedure for a CleanSpace HALO respirator is:

1. Separate the respirator from the mask. Place the respirator on a flat surface.
2. Press and release the button marked "Flow Test" (respirator will run for two seconds).
3. Observe flow test result using the LEDs on the keypad: 1-3 LEDs = PASS, all LEDs flashing = FAIL (flow rate <120L/min).

Refer to the manufacturer's instructions for conducting an Air Flow Rate Test for a CleanSpace HALO.

If the flow rate is less than 120L/min the respirator will not be used until a new power unit pre-filter and filter have been fitted and/or the battery fully charged, and Flow Testing has achieved a PASS result.

CleanSpace HALO power unit filters will be changed:

- when flow rate is less than 120L/min
- Hospital and Health Services implementing CleanSpace HALO use will undertake a risk assessment of the potential for contamination/cross contamination and patient load/frequency of use and in conjunction with Infection control teams will make an assessment and confirm filter replacement schedule (usually changing every 15-30 days).
- The filter replacement schedule may change depending on the pathogen risk (e.g. viral hemorrhagic fever is single use).
- If the filter media gets wet such as if the units are worn in a decontamination shower, the filters must be changed after use.

Documentation specifying the filter replacement process and recording compliance will be stored with each CleanSpace HALO.

15. Additional considerations in CleanSpace HALO use

- Wearing of the CleanSpace HALO for prolonged periods can cause sweating and pressure points in areas where the skin is in contact with the respirator (e.g. bridge of the nose, cheek bones and above the ears).
- Staff wearing the CleanSpace HALO for prolonged periods will follow local guidance to ensure facial skin protection and prevent skin irritation and injuries.
- Patients, family members and carers may find the appearance of staff wearing the CleanSpace HALO confronting or concerning. Wherever possible, staff will:
 - provide plain-language explanations for why the CleanSpace HALO is used
 - provide patients with opportunities to ask questions and clarify information
 - check patient's understanding of explanations
 - ensure patients have access to aids such as hearing aids and glasses during discussions

- consider the need for an interpreter and/or Aboriginal and Torres Strait Islander Liaison Officer to support consumers.

16. Staff Training

A designated “superuser” (equipment specialist with appropriate experience and training) group of staff within each work unit will be responsible for training staff to use the CleanSpace HALO. Training will include:

- controls and indicators, including flow rate testing and filter and battery warning alarms
- Use of the CS Smart app to pair with and monitor equipment.
- fit testing (including identification of the individual’s optimal CleanSpace HALO size/type)
- fitting and fit checking
- removal
- the spotter role

User competency will be assessed by a superuser.

Training will focus on using the Point of Care Infection Control tools (e.g. spotter checklists) to ensure correct processes are followed within the clinical setting. Training will incorporate assessment to ensure that users are competent, and competency will be documented and recorded. Training records will also include the details of the optimal CleanSpace HALO size/type for each staff member and will be kept within the clinical area to facilitate easy access.

Audits of appropriate CleanSpace HALO use will be completed at regular intervals. Any breaches will result in immediate re-training.

Users will not be routinely trained in cleaning and maintenance requirements. The superuser group of staff will complete training that includes regular maintenance, checking of device condition, filter changing, battery management, and recalibration. This training will be consistent with content within the relevant manufacturer instructions and local hospital and health service PAPR/CleanSpace HALO reprocessing guidelines.

[Training videos](#) are available on the CleanSpace website and the NSW Clinical Excellence Commission [Donning and doffing CleanSpace HALO PAPR with half mask - YouTube](#) .

17. Device operation and maintenance

See [manufacturer’s “User Instructions”](#) for use.

18. References

AS/NZS 1715:2009 - Selection, use and maintenance of respiratory protective equipment

AS/NZS 1716: 2012 - Respiratory protective devices

CleanSpace Respirators, CleanSpace HALO CS3000 – Users instructions

<https://cleanspacetechnology.com/wp-content/uploads/pdfs/S005-7300-HALO-INSTRUCTION-MANUAL-EU-REV-6-ALL-LANGUAGES.pdf>, Accessed online 20 April 2021.

CleanSpace Respirators: Mask Fit Check – PortaCount Testing <https://cleanspacetechnology.com/wp-content/uploads/pdfs/english/training/11-CleanSpace-PortaCount-Mask-Fit-Tests.pdf>, Accessed online 20 April 2021.

19. Acknowledgement

This Guideline for *CleanSpace HALO – Powered Air Purifying Respirator* was adapted from the following documents:

- Darling Downs Hospital and Health Service Powered Air Purifying Respirators Procedure, Queensland Health.
- Statewide Guidelines on the use of HALOCS3000 Powered air-purifying Unit, Government of Western Australia, Department of Health for information sourced to develop this guideline.

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v 2.0	Incorporated additional manufacturer feedback including: added a reference to AS/NZS 1715:2009, added CleanSpace HALO device components, removed advice device was not appropriate for use with Viral Hemorrhagic Fever, added a limitation of use for trauma or perioperative setting where the patient requires protection from aerosol contamination, an exhalation filter may be applied to the front of the mask i.e. N95 mask or Steri-Plus filter, clarification of storage locations, additional figures of device components and accessories, when devices must be sent for reprocessing, combined the fit checking for half and full face mask instructions on advice of the manufacturer, leaving filter in place for charging and quick donning noting this is pathogen dependent, wipe over head harness with Clinell wipe rather than sending for reprocessing, remove section 15 - When to change the CleanSpace HALO as the content is also within section 11 and advice staff are required to take a break from the CleanSpace HALO every four hours to manage PPE fatigue.	Produced by PPE Working Group Endorsed by PPE Working Group 13 October 2021 Endorsed by COVID-19 Health System Response Working Group (CRG) 19 October 2021 Endorsed by COVID-19 System Leadership Forum 3 November 2021