Statewide Guidelines on the use of HALO CS3000 Powered air-purifying unit

Version 2, 26 November 2020
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Version Control

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<th>Date</th>
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<tr>
<td>1.0</td>
<td>11.11.2020</td>
<td>• Current version, adapted from SCGH guideline</td>
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<td>2.0</td>
<td>26.11.2020</td>
<td>• Update on cleaning and disinfection guidelines</td>
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Introduction

Powered air-purifying power units (PAPRs) 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 the PAPR is to provide respiratory protection and reduce the risk of inhaling potentially harmful airborne pathogens. PAPR’s create an air flow inside either a tight-fitting facepiece or loose-fitting hood or helmet. PAPRs are an alternative to particulate filter respirators (PFRs) such as P2 or N95 respirators, for the care of selected patients requiring airborne precautions. There is little evidence to support that PAPR’s provide greater protection than a correctly worn and appropriately fitted PFR. However, when there is a need to wear PFRs for extended periods of time, PAPRs may provide greater comfort for the wearer and reduce the likelihood of unintended breaches in the correct use of PFRs.

The CleanSpace HALO CS3000 (hereafter referred to as the HALO) is a portable, lightweight PAPR unit. The HALO PAPR system consists of a power unit, face mask and head harness and all three components are required to be worn as a complete unit. The HALO meets the requirements of AS/NZS 1716:2012 Respiratory Protection Devices when used correctly by properly trained personnel. Each user of a HALO must undertake a quantitative fit test as per AS/NZS 1715:2009

Indications for use

The HALO is to be considered for use in situations when airborne precautions are required for:

- prolonged periods of time, generally more than one hour, when aerosol generating procedures (AGPs) are being undertaken e.g. 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 all PFRs

The HALO is not suitable for managing patients with or suspected to have Viral Haemorrhagic Fever (VHF).

Limitations

There are a number of limitations that need to be considered prior to use:

- the HALO does not provide any eye protection therefore it must always be used with approved protective eyewear i.e. a full-face shield or safety goggles
- the HALO does not protect any sterile fields the user may be in proximity to, as the exhalation valve is unfiltered and on the front of the face mask. In situations where a sterile field is required e.g. in theatre or inserting an invasive device, a manufacturer approved exhalation valve filter is required to be attached or a surgical mask worn over the HALO face mask
- the HALO does not provide any protection for persons within close proximity to the wearer if the wearer is affected by any transmissible respiratory condition. This can be mitigated by the use of a manufacturer approved
exhalation valve filter. Alternatively, a surgical mask can be worn over the HALO face mask.

- the 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.

**Training and accreditation for users**

The HALO is ONLY to be used by those who have successfully completed the competency training program, which includes fit testing. There are significant risks for any use of the HALO by untrained persons. Please refer to your local Health Service Provider (HSP) guidelines or relevant specialist services for information on training and accreditation for users of the device.

**Storage location**

As per the HALO manufacturer’s instruction manual, 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:

- **short term storage under 30 days**: -10°C to 35°C. (30% - 50% relative humidity)
- **long term storage (> 30 days)**: 18°C to 28°C (30% - 50% relative humidity)

The HALO should be stored without a filter. All other storage considerations should be as per local HSP guidelines.

**Composition of the HALO unit**

The HALO comprises of the following:

- HALO (power unit)
- filter - figure 1a and 1b
- neck support: 2 sizes available - figure 2
- head harness – figure 3
- mask– 3 sizes available (small, medium and large) – figure 4
- disposable power unit sleeve – figure 5 and 6
- charging unit – figure 7

**Accessories required:**

- PAF-0025 Portacount adapters, for fit testing masks during training and accreditation

**Other items required:**

- plastic containers marked clean and dirty
- plastic bags
Figure 5: Disposable power unit sleeve cover

Figure 6: Disposable power unit sleeve cover over bellows

Figure 7: CleanSpace Charging station
## Controls and indicators

![Figure 8: HALO control panel](image)

The **power button** is used to switch between the three (3) operating Modes: “Standby”, “On”, and “Off” Mode.

<table>
<thead>
<tr>
<th>Mode</th>
<th>Description</th>
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<tbody>
<tr>
<td>Standby Mode</td>
<td>Standby mode is when the green battery indicator lights are on, the motor is not running and there is no airflow to the mask. The power unit will automatically switch to Standby Mode within ten (10) seconds of the user taking it off. If the power unit is in Off Mode it will switch to Standby Mode when the Power button is pressed. In Standby Mode, the CleanSpace power unit switches to On Mode as the wearer starts to breathe. The power unit can only switch to On Mode from Standby Mode. If the power unit is in OFF mode, the motor will not run.</td>
</tr>
<tr>
<td>On Mode</td>
<td>On mode is when the power unit is being worn, the motor is running and there is air flow to the mask. The motor will start (called On Mode) when the power unit detects a change in pressure in the mask triggered by your breathing. In On Mode you should hear the motor running and feel the airflow on your face. You can also switch to On Mode (start the motor) from Standby Mode by pressing the Power button once.</td>
</tr>
<tr>
<td>Off Mode</td>
<td>Off mode is when the green battery indicator lights are off and the motor is not running and there is no airflow to the mask. The power unit automatically switches into Off Mode three (3) minutes after it has been removed from the user’s face and the sensors detect that there is no breathing. To conserve battery life, the power unit is designed to automatically switch from On Mode to Standby then to Off Mode when not being worn.</td>
</tr>
</tbody>
</table>

The **flow test button** is used to check that the power unit is able to deliver its minimum designed flow. Pressing it once, when the power unit is in Standby Mode (not ON Mode), starts the flow test which lasts about 5 seconds. Refer to Section 9.

**Battery indicator lights** The power unit is equipped with an indicator of battery charge. There are three (3) battery indicator lights. With the charger plugged in and three green lights lit, the battery is fully charged and typically has up to eight (8) hours of operating time. The power unit should be fully charged before use.
**Filter warning alarm** The power unit has a Filter Warning Alarm, which is triggered when the filter is blocked e.g. personal protective equipment (PPE) may be blocking the filter.

*If the Filter Warning Alarm sounds (two beeps, repeated once per second) or the Filter Warning Alarm light comes on, you must move out of the contaminated area, and change the filter.*

**Blocked filter alarm** The power unit has a Filter Blocked Alarm that triggers when the filter needs to be replaced. The Filter alarm signals by red flashing LED lighting up on the keypad and an audible two (2) beeps, repeated every second.

The filter alarm can be muted by pressing the power button once. The audible Filter Alarm will resume if filter has not been changed after 5 minutes. **NOTE: If the blocked filter alarm is triggered leave the room immediately and replace the filter.**

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**Fitting and changing the HALO filter**

CleanSpace HALO filters are not reusable and must not be reprocessed.

**When to change the filter**

- the filter must be discarded on completion of use by the wearer e.g. at end of shift, on completion required duties
- any sign of damage or suspected damage to the filter
- signs of dust or contaminants on the inside surface of the filter
- if the Blocked Filter Alarm triggers – audible (2 beeps per second) and visual (Red flashing LEDs)
- if the Flow Test indicates that the power unit is not able to produce the Minimum Design Flow
- the filter reaches its expiry date. The expiry date is marked on the filter label.
- when the power unit battery has been discharged e.g. flat battery

**How to change the filter**

- unlock the filter cover by pulling up and twisting the pin. The silver pin is located on the left side of the PAPR power unit.
- if there is a filter in place, the filter will become loose and fall out. DO NOT touch the contaminated filter. Tilt the power unit down so the filter falls out into the designated bin.
- visually check the area where the filter sits
  Ensure there is no dust or liquids on the inside before replacing the filter. If necessary, wipe with an approved combined cleaning and disinfectant wipe (alcohol wipe not to be used in this case)
- insert filter by locating the short edge on the right-hand side of the filter.
  Check the orientation of the “CleanSpace HALO” brand is the right way up. Fit the short edge to the inside on the right of the HALO. Swing the filter shut into
the closed position. Hold the filter firmly against the body of the HALO with one hand and press the pin down and twist to secure back in place. The filter should sit securely in place and sit flush to the unit.

**NOTE:** Filters have a 5-year shelf life. Always check the filter has an intact black rubber seal, expiry date within date and no damage is visible.

### HALO battery charge

#### Level of battery charge

The level of battery charge is indicated by the three (3) Green LEDs on the keypad. The HALO should not be worn when on charge. The Battery Indicator Lights allow the wearer to estimate the charging level of the battery (see table below).

**Note:** For the battery to be 100% charged plug in the charger until all three (3) Green LEDs are on and solid (no flashing).

<table>
<thead>
<tr>
<th>Green LEDs</th>
<th>Charge</th>
<th>Approximate Run Time*</th>
</tr>
</thead>
<tbody>
<tr>
<td>🟢🟢🟢</td>
<td>85 - 100%</td>
<td>4 – 8 hours</td>
</tr>
<tr>
<td>🟢🟢</td>
<td>15 – 85%</td>
<td>1 – 4 hours</td>
</tr>
<tr>
<td>🟢</td>
<td>5 – 15%</td>
<td>Recharge! (20min to 1 hour)</td>
</tr>
</tbody>
</table>

#### Charging the battery

The battery must only be charged with a HALO Battery Charger.

To charge the internal battery:

- turn the power unit upside down
- locate the blue charging port
- Insert the charger connector into the charging port
- ensure the charger is plugged into a power source
- the Battery Indicator Green LEDs on the keypad should be lit up and flashing as the Power unit charges
- the Power unit can be charged at temperatures between 0°C to 35°C. The battery will not charge outside this temperature range
- check that at least one of the Battery Indicator Green LEDs on the keypad is on and flashing
- if none of the Green LEDs are flashing, the unit is not charging. Check the charger is connected into the Power unit and the power source
- if the power unit is still not charging, contact CleanSpace Customer Service sales@cleanspacetechnology.com or visit the CleanSpace [website](http://www.cleanspacetechnology.com)

Charging is complete when the HALO shows three (3) green solid lights. If the HALO is unplugged when the third Green LED is flashing, charging is 95% complete. When the HALO is fully charged, disconnect the charger cable from the HALO charging port.
Low battery alarm
The HALO has a Low Battery Alarm that is both audible (3 beeps, repeated every second) and visual (Green LEDS) that triggers when the battery has low battery charge. On moderate work rates, this may be 5 – 15 minutes run time (depending on filter loading). Unlike the filter alarm, the Low Battery Alarm cannot be muted. The Alarm will turn off when the power unit is charging or by switching the HALO off. When the battery charge is extremely low, the motor and airflow will stop.

NOTE: If the battery alarm sounds (3 beeps, repeated every second), leave the contaminated area immediately and re-charge the battery. Operating the HALO after the low battery alarm has sounded can cause the flow to fall below the manufacturer’s minimum designed flow, which may result in mask leak and exposure to contaminants.

Performance checks prior to each use
If the HALO unit fails any of the requirements of the user inspection and performance checks, do not use it until all necessary repairs have been made and the system passes the performance check.

Inspect equipment
- check all the components of the HALO unit and components e.g. mask, harness and new filter prior to each use
- any damaged or defective parts must be replaced before use
- check both bellows for splits or holes
- check that both bellows have not become distorted so as not to partially or fully close the air path to the mask
- check the battery is fully charged by pressing the power button (all 3 battery green LEDs must light up)
- check filter date of expiry
- check the filter for cracks or damage and the foam seal is clean and free from any damage. Examine the visible internal surfaces for any signs of dust. If dust is found do not use the filter. If any sings of impact or scratching is found, discard the filter.
- check the mask to ensure that there are no cracks, tears or dirt; check the mask is not distorted. Check the mask exhalation valve for damage or dirt build up. If any visible signs for dirt clean and reprocess. If the valve is damaged obtain a new mask and return damaged mask to the hospital biomedical team.
- check the head harness is intact and has good elasticity and can be fitted to the attachments on the mask. It must be adjusted to support the mask to seal comfortably to the face. DO NOT overtighten.

Calibration
The HALO contains a system for synchronizing with your breathing and regulating mask pressure. The system should be recalibrated if it experiences a significant change in temperature of more than 20°C. It is best to practice recalibration if the unit has been in storage when the storage temperature is unknown.
Steps to recalibrate

1. Remove the filter from the HALO.
2. With the HALO in Standby Mode i.e. one or more green LEDs lit, press the “Power” and “Test Flow” buttons on the keypad at the same time.
3. The red and blue LEDs will both light, and the green battery LEDs will cycle.
4. During the test the motor will run and air will blow from the left hand bellows.
5. Hold the HALO still until the red and blue LEDs turn off (10 – 15 seconds). After this, calibration is complete.
6. At the end of the calibration process the green LEDs return to indicating battery charge status.

Test flow rate

This test checks that the HALO is able to deliver the manufacturer’s Minimum Design Flow of 120 litres/minute.

1. Ensure the mask is removed from the power unit. Place the power unit flat on a table or other support.
2. Press and release the button marked “Flow Test”.
3. The power unit will automatically run the Flow Test. Note: During the test, the motor will run fast and air will blow from the left-hand bellows.
4. After 2 seconds the power unit reports the Test result using the LEDs on the keypad. Use the table below to interpret the LEDs.

<table>
<thead>
<tr>
<th>LIGHTS</th>
<th>MEANING</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 LEDs:</td>
<td>PASS (Excellent: flow &gt;180 l/min)**</td>
</tr>
<tr>
<td>2 LEDs:</td>
<td>PASS (Good)**</td>
</tr>
<tr>
<td>1 LED:</td>
<td>PASS (Acceptable)</td>
</tr>
<tr>
<td>ALL LEDs FLASH</td>
<td>FAIL (Flow &lt;120 l/min)</td>
</tr>
</tbody>
</table>

Do not use the HALO until a new filter has been fitted and / or battery fully charged and the test has been repeated with a PASS result.

Reset the power unit by pressing the Power button. Fully charge the battery and / or replace the filter. Repeat the flow test. If the power unit fails the test filter is new and battery fully charged but, contact CleanSpace Technology and do not use until it has been evaluated.

** NOTE: The Test Flow Rate is not a battery charge test. Three LEDs means that, as of the moment it is tested, the unit can deliver high flow. It does not mean the battery is full. You must check the battery charge separately.**
**Audible alarm test**

1. Ensure the Mask and Filter are removed from the power unit.
2. Securely fit the Cleaning & Storage Plug to the power unit: filter inlet and bellows unsealed.
3. Press the Power Button and put the power unit into Standby Mode (Green LEDs and no motor on).
4. Press the Power Button again to run the Alarm Test. During the test, the motor/airflow will run fast.

After 8 seconds the power unit Alarms should sound, and the Red Filter Alarm will flash. If this does not happen, check the Cleaning & Storage Plug is fitted correctly and repeat the test. If the unit fails a second time, do NOT use the HALO.

**Cleaning and disinfection of the HALO**

The Halo unit must be cleaned and disinfected as a minimum between each use.

The mask and head harness is to undergo high level thermal disinfection (at 90.C), high level chemical disinfection (CIDEX) or sterilisation using Steris V-Pro systems, Sterrad 100S, 100NX and Sterrad NX.

The power unit is to be cleaned and disinfected using a CleanSpace Technology approved agent (see Appendix 3). In addition, the power unit is also compatible with the Steris V-Pro systems (Appendix 4). Further testing by CleanSpace Technology is being undertaken on the compatibility of other systems.

Discussion with the manufacturer and reference to the manufacturer’s guidelines for cleaning, disinfection and sterilisation must occur in order to manage site specific processes.

The process of traceability of masks, head harnesses and power unit must be clearly documented by the department/individuals using the CleanSpace Halo.

It is the responsibility of the PAPR user to thoroughly clean all the components of the HALO before returning to the Central Sterilising Department.

**Routine maintenance**

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

Regular servicing will be undertaken by the HSPs Biomedical Department. CleanSpace Technology will provide support to the Biomedical Departments by outlining requirements.

Damage or failures are to be reported to Biomedical Department in the first instance, who will coordinate with CleanSpace Technology to address the issue.

The CleanSpace Respirator Test System (CRTS) must be returned to CleanSpace Technologies for calibration every two (2) years. Contact the manufacturer as least 3 months prior to the date for calibration.
Resources
DoneSafe Resource page https://cleanspace.donesafe.com/users/sign_in
This requires password obtained from CleanSpace

Reference
CleanSpace Respirators: User Instructions
CleanSpace Respirators: Service Manual
CleanSpace Respirators: Guide for equipment cleaning, storage and testing
CleanSpace Respirators: Disinfection guide with washer disinfectors
CleanSpace Respirators: CleanSpace Halo compatibility with Steris
CleanSpace Respirators: List of approved cleaning agents and wipes
CleanSpace Respirators: Portacount adaptor PAF-0025 cleaning guide
CleanSpace Respirators: Fitting the mask fit test Portacount adaptor
APPENDIX 1: Use of the HALO

Gather all equipment (HALO power unit, head harness, neck support, mask, disposable sleeve cover and filter). Ensure you have the correct size mask that was determined at your site training competency session. The size is marked on the mask (small, medium, large).

**Fit check (mask seal)**

The HALO is a tight fitting PAPR and its users must be clean shaven as with PFRs. If a fit check cannot be achieved with any of the HALO masks, the HALO must not be used.

A **fit check** is required **every time** you wear a HALO.

To conduct a fit check on the mask seal, occlude the air entry into the mask by placing thumbs over the air inlets at the ends of the mask arms. Take a breath in and check the mask collapses inwards and there is no obvious large leakage points around the mask. Small leaks are acceptable as the air in the mask is always under positive pressure.

**Fitting the head harness**

Holding the harness find the three keyhole clips at the end of each elastic strap and the ‘FRONT’ marker, indicating the front of the harness. If no FRONT marker, look for a cut out on the strap and the black sterilisation sensor dot. Secure the harness clips to the buttons on the inside of each facemask clip. Ensure that the harness strap with the FRONT marker is towards the front of the mask and that there are no twists in the straps. This strap is the back strap of the head harness. Adjust harness length by moving cleats up or down strap.

**Fitting a Neck Support**

Align the neck support with the HALO power unit, the two arms with the rounded heads should be at the top. Locate the bottom arms of the neck support in the grooves at the bottom of the unit and slide neck support upwards until you hear a ‘click’.
**Adjusting the bellows**
Press the silver button to adjust the bellows e.g. extend or shorten. Ensure the bellows both sides are even.

**Fitting the mask and HALO power unit**
Fit a CleanSpace mask to the power unit –
With the peak of the mask upright locate the left-hand *mask* AirClip. Locate the right-hand *power unit* AirClip (on the same side of the power unit as the Keypad).
Join the left AirClip only, so that the mask is attached to the power unit.

Check that the mask is the right way up! The pointed nose section of the mask must face up, in the same direction as the keypad.

Leave the right mask arm and bellow free until you are fitting the Power unit. Familiarise yourself with the Adjust Buttons and the Mask Release Buttons.
ON MODE: From Standby Mode, when the mask is placed on the face, the wearer's breathing will trigger the system to start (On Mode) and the air to flow. Breathe normally. The wearer should feel fresh air on the face and the motor adjusting to the breathing patterns.

If the motor does not start and air does not flow, check the system was in Standby Mode (with the Battery green LEDs on). If the system is Off, (ie not in Standby Mode and no green LEDs), remove the power unit, press the Power button to activate Standby Mode and don again as described above.

Checking the Harness
The Harness should take a little of the weight of the mask and support the power unit so that the power unit system sits level on your head. If necessary, adjust the harness. This is done by shortening or lengthening the front straps of the harness, by moving the cleats up or down the straps. Remember to shorten or lengthen each side by the same amount.
Appendix 2: Donning and doffing sequence for use of the HALO

This donning and doffing sequence is for use whilst managing patients with suspected or confirmed infections requiring airborne precautions (other than Viral Haemorrhagic Fevers).

**General information - Donning**

All staff must know their correct sizes for the HALO facemask and neck support as determined at the training competency session.

All staff using the HALO unit must be familiar with the technical aspects of the unit, performance check parameters and have undertaken HALO training competency, including donning and doffing other personal protective equipment (PPE).

Two trained staff members will be required:

1. The **Caregiver** who will provide direct patient care
2. The **Assistant** who will assist/supervise the **Caregiver** in donning and doffing the HALO and PPE.

A mirror is useful in the designated donning area to assist with donning PPE.

**Caregivers** should ensure they have a hygiene break and are hydrated before donning HALO and PPE.

**Caregivers** should be aware if any of the following occur, discontinue and restart the doffing procedure:

- battery or filter alarms trigger
- the system is damaged
- airflow in the mask decreases or stops.
- breathing becomes difficult
- you feel dizzy or your vision is impaired.
- your face, eyes, nose or mouth experience irritation

**Caregiver** is aware of the designated PPE doffing area and must wait for assistance before removing any PPE.

The correct size facemask to be worn as determined at the caregivers training competency session (small, medium and large).

The correct size neck support to be worn as determined at the caregivers training competency session (small, medium or no brace).
DONNING SEQUENCE of PPE and HALO

Prior to donning procedure:

- **Caregiver** to remove all personal items, including jewellery (earrings may need to be removed), watches (bare below elbows), pens, pagers and mobile phones, and ensure long hair is tied back (use a low pony tail not a top knot). Check hands for cuts or abrasions and cover if required. Enclosed footwear must be worn.

- **Caregiver or Assistant** to sign out HALO unit and accessories (face mask, head harness, neck support, new filter and disposable sleeve cover) using a log book. Ensure you have the correct sized face mask and neck support as identified in your training competency session.

- **Caregiver** must calibrate and test the flow rate of the power unit prior to donning.

- **Assistant** must check that the HALO and each item of PPE is correctly fitted before **Caregiver** enters room.

**PPE required:**

Long sleeved fluid repellent gown, gloves, disposable head cover (if required) full face shield and eye protection.

Use of a trolley is recommended for assembly and donning/doffing of the HALO

Place HALO unit and accessories on top of a clean trolley and PPE on the bottom shelf.

1. **Assistant** and **Caregiver** to perform **hand hygiene**.

2. **Caregiver** and **Assistant** visually inspect all the components of the HALO to ensure it is useable, clean and intact and that all required PPE is present.

3. **Assistant** and **Caregiver** to undertake HALO performance checks. Ensure battery is fully charged (press power button once to check battery – at least 2 lights on, 3 is optimal).

4. **Caregiver** to check the correct size neck support is fitted to HALO PAPR power unit (small, medium or no brace). To fit the correct size neck support the two arms with the rounded heads should be at the top. Locate the bottom arms of the neck support in the grooves at the bottom of the unit and slide neck support upwards until you hear a ‘click’. the bottom end (pin end) of the hose to the outlet and lock into position.

5. **Caregiver** to prepare the HALO

- place the mask with the nose upward on trolley.
- fit the head harness onto the face mask. Hold the harness finding the two keyhole clips at the end of each elastic strap and the marker, indicating the front of the harness. Fit the harness clips to the buttons on the inside of each Mask clip. Ensure that the harness strap with the FRONT marker is towards the front of the mask (if no marker present the strap with small hole and black sterilisation sensor dot is the back strap).and that there are no twists in the straps. Adjust the harness length by moving cleats up or down.
- put harness forward (in front) of the mask ensuring it is not tangled in the face mask.
loosen both bellows to their widest opening by pressing the silver adjust button on the power unit and loosen the bellows on both sides so they are fully extended and even.

- fit the disposable sleeve cover over the power unit and bellows.
- fit the mask to the power unit by clipping the left-hand bellow clip into the facemask.

6. **Caregiver** to perform hand hygiene.

7. **Caregiver** to don a fluid repellent long sleeved gown. Secure velcro/ties (do not use inner ties) at back of neck and at side of the waist, using a bow so it can be easily untied when you begin the doffing process. Ensure gown is not touching the floor and uniform is covered by gown.

8. **Caregiver** to put on disposable head cover (if required).

9. **Caregiver** to don the HALO.
   - check the power unit is still powered on.
   - place the power unit behind the neck with the bellows and mask resting down one side, the harness should be hanging in front of mask.
   - fasten the face mask and bellow clips on your right-hand side so both sides of the mask are connected to the power unit. Pull the mask up to sit comfortably on your face.
   - pull the harness back and onto your head. Adjust the harness and settle the mask and power unit so both are comfortable.
   - start to breathe to trigger the system into On Mode for the air to flow (breathe normally).
   - adjust the bellows and harness to achieve a comfortable fit and seal on the face. DO NOT OVER TIGHTEN THE SYSTEM.
   - check the facemask is sitting under the chin and the apex of the mask sits comfortably on the nose bridge.
   - undertake a fit check. If unable to successfully achieve a fit change the mask as the expiratory valve may be damaged. Clean and label the damaged mask report to Biomedical staff.

10. **Caregiver** to check the harness is sitting comfortably and well secured and sleeve covers the bellows.

11. **Caregiver** to don full face visor. Adjust to fit comfortably.

12. **Caregiver** to perform hand hygiene and don gloves over gown cuffs.

13. **Assistant** to check with **Caregiver** that they are comfortable, and all PPE has been donned correctly.

14. **Caregiver** can now enter the patient’s room.
GENERAL INFORMATION - DOFFING

- doffing of PPE is to be performed in the designated area.
- when removing PPE and the HALO use slow and controlled movements.
- use of a trolley is recommended for doffing the HALO.
- the Assistant will assist/supervise the Caregiver in doffing the HALO and PPE.
- assistant to don gown, surgical mask, disposable full-face visor or goggles and gloves.
- 3 Containers lined with plastic bags are required to place used PAPR equipment into
  o Container 1 - used mask and harness
  o Container 2 – used power unit

DOFFING SEQUENCE FOR USE WITH HALO

1. **Caregiver** to doff in the designated doffing area.
2. **Caregiver** to remove gloves. Pinch the outside of glove at wrist end with the other gloved hand, peel off completely into a ball and hold in palm of other gloved hand. Slide a finger under remaining glove at wrist and peel remaining glove off until balled around the other removed glove and discard.
3. **Caregiver** to perform hand hygiene.
4. **Caregiver** to lean forward and peel gown away from neck and shoulders by grasping the gown ties or inside of the gown at the back of the shoulders. Using the inside of the gown pulls one arm at a time so that the gown arms are bunched at the wrists, keep arms extended. Then gently roll the contaminated side of the gown inward and away from the body, into a small bundle and discard.
5. **Caregiver** to perform hand hygiene.
6. **Caregiver** to remove face visor by pulling the straps up and over the head while leaning forward slightly and discard.
7. **Caregiver** to perform hand hygiene.
8. **Caregiver** to put on a new set of clean gloves.
9. **Assistant** to stand behind **Caregiver** in preparation for doffing the HALO.
10. **Caregiver** to remove the power unit by:
    - moving the harness off your head in a forward motion (harness in front of mask).
    - locate power button and with right index finger (you will feel an indent with your thumb underneath the unit. The power button is located above this).
    - assistant to hold the power unit at the back of the Caregiver’s neck.
    - caregiver to take a deep breath and hold and press the power button once to put the power unit into stand by.
    - caregiver unclips the face mask on both sides.
    - caregiver leans forward slightly - lifts and removes the facemask and head harness in a forward motion, minimising contact with the mask by leaving hands on the clips during removal of mask and harness.
    - assistant holds the power unit in their hands.
    - assistant removes sleeve and discards and places the power unit into a designated ‘dirty’ container for later cleaning and disinfection.
• caregiver can breathe normally once mask unclipped from power unit.
• place mask and harness into a designated ‘dirty’ container for later cleaning and disinfection.

*Note: It is very important to avoid touching your face after the HALO has been removed.*

11. **Caregiver** to remove gloves and perform hand hygiene.
12. **Caregiver** to remove disposable head cover (if used).
13. **Caregiver** to perform hand hygiene.
14. **Assistant** to remove PPE in the correct manner and performs hand hygiene.
15. **Assistant** to ensure the **Caregiver** completes the cleaning and disinfection process of the power unit, head harness and mask.
Appendix 3: List of approved cleaning agents and wipes

The list below applies for all CleanSpace equipment including power unit, mask and head harness, used between wearers or between uses where biological contaminants are a risk. Any non-neutral cleaning or disinfectant agent (including alcohol) should be rinsed off thoroughly and the component dried either naturally or with a disposable cloth before being worn. Residue may cause irritation to the wearer.

Agents:
- Isopropyl alcohol
- Ethanol
- Sodium Hypochlorite
- Quaternary ammonium

Wipes:
- Non-alcoholic cleaning wipes (i.e. benzalkonium chloride)
- ierwipe™ Sporicidal Low Residue (Peroxide)
- Kiercide TM Sporicidal Chlorine and Apesin AP3 Didecyldimethyl ammonium chlora, propan-2-ol Alcohols, C6-11 ethoxylated and sodium chlora
- Kiercide TM 70 (isopropyl alcohol)
- Germex TM B-12 quaternary ammonium compounds, PH 7.3 at 0.75% solution
- Dismoxon (Hartman); Magnesium Monoperoxphthalate hexahydrate
- Incidin Plus (Ecolab); glucoprotamine.

Cleaning with solvents is not recommended. Solvents can cause damage to plastic components including cracking, fogging, fading and decreased strength. If equipment is exposed to solvents, rinse well and check parts of cracking or fogging.

Please note, this is an addendum to the CleanSpace Cleaning Instructions (V6).

Please contact our team if you have question or enquiry:
support@cleanspacetechnology.com

CleanSpace Technology Pty Ltd | Every Breath Counts
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NB Details subject to change, contact CleanSpace for up to date information. Refer to CleanSpace cleaning instructions

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Appendix 4: CleanSpace Halo Compatibility with Steris

**CLEANSPACE HALO COMPATIBILITY WITH STERIS**

CleanSpace Technology, the manufacturer, confirms that CleanSpace Halo equipment is compatible with the Steris® V-FRO Low Temperature Sterilization Systems to 100 cycles (and above). This includes power unit, masks and accessories. This does not include the filters which cannot be reprocessed. The equipment was tested at the “harshest” cycle and therefore is considered to be compatible with all Steris V-FRO cycles. Please note, that at 100 cycles, the equipment was functional and the material unaffected by the process. It is not feasible to continue testing above 100 cycles.

<table>
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<th>STERILIZER/CYCLE</th>
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<th>NON LUMEN</th>
<th>FLEXIBLE</th>
<th>FAST NON LUMEN</th>
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</table>

Please note, this is an addendum to the CleanSpace Cleaning Instructions V5.

Please contact our team if you have question or enquiry: support@cleanspacetechnology.com

NB Details subject to change, contact CleanSpace for up to date information. Refer to CleanSpace cleaning instructions
Appendix 5: Disinfection Guide with Washer Disinfector

1. Detach head harness (B) from the silicone mask (face piece) (A)
2. Remove exhalation valve cover from valve assembly (2) by locating the snap feature on the cover that secures it to the valve seat. This feature is on the bottom edge of the valve seat. Using your thumb nail or a small blunt object, press on the snap until the cover springs free of the valve seat. Do NOT remove the silicone valve leaf. See image below.

3. Place mask (face-piece) (A) and head harness (B) in washer. Ensure that the head harness is free and not crumpled or sitting under other components.
4. After washing and drying, check the exhalation valve leaf is lying flat against valve seat (not folded or misplaced).
5. Reattach exhalation valve cover to mask by inserting the small prong on the valve cover into the matching hole on the valve seat.

NB Details subject to change, contact CleanSpace for up to date information. Refer to CleanSpace cleaning instructions

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