

Standard Operating Procedure

SOP108

Title: USE AND MAINTENANCE OF ESCO AIRSTREAM (AC2-4G1) CLASS II RE-CIRCULATING BSC (BIOLOGICAL SAFETY CABINETS) NON-DUCTED.

Location: CBE Laboratories: H21

1. PURPOSE

To describe the use and maintenance of the ESCO AIRSTREAM CLASS II RE-CIRCULATING (non-ducted) Biological Safety Cabinets (BSC) located in the CBE Laboratory H21.

2. SCOPE

This SOP details the procedures for the operation and maintenance of the Esco Airstream BSC including the controls, operating rules and limitations, the principles for testing and maintenance, record keeping, emergency shut down and incident reporting.

3. RESPONSIBILITIES

CBE Laboratory Personnel:

- (i) Shall complete proper training before work can commence using the BSC. An approved training certificate (FSOP104.3) must be provided and this should be retained in the individual's training record before using the BSC.
- (ii) Shall ensure that they are familiar with the BSC, its controls, requirements and emergency procedures and the Manufacturer's Operating Instructions.
- (iii) Shall ensure that the BSC is suitable for the work they intend to carry out.
- (iv) Shall check that there are no scheduled electrical shutdowns before commencing work; according to SOP004.
- (v) Shall complete the Daily Usage Record each time they use the BSC.
- (vi) Shall carry out the weekly maintenance of the BSC, as required and fill in the paperwork correctly.
- (vii) Shall record alarm sounding events that indicate non-conformance or malfunction and notify the Laboratory Manager/Responsible Person.
- (viii) Shall report any changes to the room e.g. placement of new equipment, relocation of large equipment, overcrowding etc, that may compromise the BSC operator protection, to the Laboratory Manager/Quality Manager.

The Responsible Person/Laboratory Manager:

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- (i) Shall ensure laboratory personnel are given suitable information, instruction, training and supervision in the correct use and maintenance of biological safety cabinets. The requirements for competence to use a BSC should include full instruction in the classification of cabinets, appropriate and inappropriate use, performance limitations, safe working procedures, decontamination procedures and the principles of airflow and operator protection tests. Upon completion of training laboratory personnel will be issued a training agreement by the Laboratory Manager to show that they are a designated authorised user.
- (ii) Shall coordinate weekly maintenance duties to be performed by laboratory personnel (according to SOP004).
- (iii) Shall Investigate and report problems or alarms associated with BSC usage.
- (iv) Shall organise the maintenance, repairs and annual certification of the BSC by trained and authorised contract / service personnel.
- (v) Shall ensure that prior to authorising the commencement of maintenance, repairs or annual certification testing that the BSC is suitably disinfected in accordance with SOP003 and that a "Decontamination Certificate" is issued.
- (vi) Shall ensure that any changes to room design i.e. in terms of relocation of large equipment, placement of new equipment, room air handling or personnel traffic routes etc are assessed for their affect on BSC performance (operator protection) and if required, that appropriate control measures or test measures (operator protection factor test) are implemented.

4. EQUIPMENT AND MATERIALS

- Esco Airstream re-circulating (non-ducted) Biological Safety Cabinet
- Disinfectant: 70% IMS
- Disinfectant: Chemgene wipes, 1:50 and 1:20 Chemgene spray

5. PROCEDURE

5.1. Controls, displays and operating modes

The Esco BSC is equipped with a microprocessor-based control system that controls and monitors all of the BSC functions. The LCD display indicates the current operational state of the unit. Refer to the Manufacturer's Operating Instructions (Reference 4) for further details.

The BSC control functions are described below (see manual for further details).

- **Fan Button:** Turns on and off the fan

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- **Light Button:** Turns on and off the light. The lamp turns on automatically when sash is in the operating position, READY state. The lamp turns off automatically when the sash is at SASH ARLAM state, and for the Warm up procedures.
- **Socket Button:** Turns on and off the electrical socket. Electrical outlet can be controlled fully in any sash position.
- **UV Button:** Turns on and off the UV lamp. UV can only be activated when the sash window is fully closed. UV timer is present to control the duration of the decontamination process
- **Up and Down buttons:** Scrolls through menu options
- **Set Button:** Selects the menu or sub menu displayed
- **Menu Button:** Enters and exits from menu options

The BSC operating modes are described below, and can be visually confirmed by the appropriate LED indicators on the control panel.

- **OFF/UV mode:** Sash is closed, air system blowers and light are switched off, display shows the time and “UV mode”
- **Warm up mode:** Sash is in working position, fans are on, light is off, display shows “Warming up” and the countdown to ready state, in this mode no buttons are operational.
- **Work mode:** Sash is in the working position, airflow is steady. The display shows “Air safe” and the values of the device: Time (hours and minutes), Downflow velocity (D; m/s) and Inflow velocity (I; m/s)

5.2. Before commencing work in the Class II cabinet

- (i) The ESOC BSC is to be use with the ambr.
- (ii) The BSC should be cleaned using chemgene wipes, 1:50 chemgene spray (1:20 for deep clean) and 70% IMS spray. If available sterilised by **UV light exposure** for 30 minutes prior to the start of an ambr experiment
- To turn on the UV the BSC sash must be fully closed. Press the “UV” key on the control panel. In default mode the UV must be turned off manually as the UV timer is disabled.
- Use the UV menu to set the UV lamp to turn off automatically after a fixed period. To do this press “MENU” button, use the “Up”, “Down” and “Set” buttons to input the Admin code (default: 0009). The alarm will sound; wait until the alarm is disabled and the display shows SETTINGS. Select SETTINGS from the menu by pressing “Set” button. Use the “Up” and “Down” buttons to select UV TIMER from the menu and press “Set” button. HH will flash, use the “Up” and “Down” buttons to select desired hour and press “Set” to move on. Repeat for MM to select the desired minutes, again press “Set” to move on. The display will show UV TIMER SET for 2 seconds and then return to the SETTINGS menu. Exit the menu by pressing “MENU” button twice.

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- (iii) Check whether the waste disposal containers require changing (sharps container, autoclave bags) and refer to SOP003 for disposal of waste.
- (iv) From the OFF/UV mode, open the BSC sash to the working position (sash level is marked on the right hand side of the cabinet).
 - The light will turn on to signal correct working height of the sash.
 - Press the “fan” button to activate the fans – this activates the warm up mode, the fans will turn on and the light will be off, “Warming up” will be displayed along with the warm up countdown timer. During the warm up procedure, all buttons are not operational
 - After the designated warm up period the light will turn on indicating Ready state and “Air safe” along with the inflow “I” and down flow “D” velocity readings will be displayed on rotation.

NOTE: when the sash is not in the correct working position an audible alarm will sound and the light will be off.

NOTE: If the alarm indicator lamp blinks and the alarm sounds at the same time discontinue work immediately and properly shut down the BSC. Refer to the trouble shooting in manual.

Ensure the airflow is steady “Air Safe” and check the downflow and inflow velocity readings are within safe limits see below. Record both values in the daily usage sheet (Section 8.1) before commencing work inside the cabinet. If either reading is out of specification, shut down the cabinet, place a DO NOT USE sign on the cabinet and contact the lab manager immediately.

- The Downflow velocity should be between 0.24 and 0.36 m/sec; set point is 0.3 m/sec
- The Inflow velocity should be 0.45 m/sec an alarm will sound and flash if the inflow velocity is below 0.4 m/sec

5.3: General working procedure

The inward airflow that is drawn through the working aperture of open-front cabinets can be disturbed by sudden movements of the arms of the operator, turbulence around the equipment placed inside the cabinet or air movements outside the cabinet. To minimize these observe the following:

1. Keep doors to the room closed
2. Keep the amount of equipment in the cabinet to a minimum:
 - a. Large equipment (e.g. centrifuges, especially air-cooled models) should not be used within an open fronted cabinet unless appropriate testing has been done to establish that containment performance is maintained

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- b. Bunsen burners (BB) – Do not use BB inside the BSC – they disturb airflow and reduce both operator and product protection; they are a fire risk; they can damage HEPA filters
3. Avoid sudden movement of arms and moving hands in and out of the cabinet
4. Do Not put paper or other `shedding` materials into the BSC
5. Sit in a comfortable position where you can see clearly through the viewing window and you can reach anything you need without leaving your seat
6. Do not obstruct any of the air- intake grills at the front or rear of the cabinet, as this will affect the air inflow – try to ensure ambr is place to avoid the grills being covered
7. Work as near to the centre of the work area as possible – at least 15cm from front opening
8. Avoid unnecessary traffic in the vicinity of the cabinet. Do not let others in the lab intrude in your space – keep at least a 1 metre work area along the length of front panel clear.
9. Use aseptic techniques for working in the Biological Safety Cabinet as follows:

5.4: Aseptic techniques

1. Always wear protective disposable gloves before putting hands or placing items in the BSC. Use appropriate PPE according to the containment level and risk assessment for the work.
2. Allow fans to run for at least 10 minutes before commencing work
3. Ensure all items entering the BSC are clean / disinfected by wiping with Chemgene wipes (including gloved hands).
4. Keep vessels containing cultures, media etc closed when not in use.
5. Use aseptic manipulation techniques that minimise the possibility of contamination.
6. Use manipulation techniques that minimise aerosol production: avoid frothing of capped cultures when mixing by gently rolling / swirling rather than vigorous shaking; eject pipette contents by putting the tip into a liquid or onto a surface to avoid bubbling and splashing.
7. Avoid spills by ensuring close proximity between vessels when transferring liquids.
8. Disinfect spillages immediately and follow the appropriate spill procedure (Refer to SOP038). Upon contamination or changing between different organisms/cell lines, disinfect the cabinet with UV radiation or chemical disinfectants (Refer to SOP003).

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5.5: Shut down procedure

Shut down procedure

- (i) Remove all items that have been brought into the cabinet and dispose of according to SOP003 or store according to SOP005. Avoid contamination of sterile items or aseptically produced cultures by ensuring they are sealed / closed before removal from the BSC, after removal ensure items are properly labelled (user name, culture type).
- (ii) When work is finished clean the interior working surface of the cabinet using Chemgene wipes.
- (iii) Leave the fans running for 15-20 minutes before switching fans off and shutting sash to allow removal of remaining aerosols or set post purge procedure (recommended for 3 min; Refer to manual section 3.7.1.3). If UV disinfection is planned, check and set the UV disinfection.
- (iv) To shut down press the "fan" button, this will shut the fans down and activated the post purge procedure for the pre-designated time (if programmed; if performing (iii) this is not needed). Lower the sash to the closed position (the display will show UV mode). The sash can be lowered as soon as the fans have been turned off as this will not interrupt the post purge procedure.
- (v) Activate the UV disinfection routine if required. The UV lamp can only be activated once the post purge procedure has finished.
- (vi) **Do not** empty the aspiration bottles immediately after use as virkon requires overnight contact time to ensure contents are rendered safe before disposal down the drain.
- (vii) **Ensure safety precautions are maintained during cleaning of the BSC when used for dangerous pathogens:** Refer to SOP003, SOP006 and manual for appropriate disinfectant or fumigation procedures. Spray the appropriate disinfectant at the prescribed dilution for the pathogens in use onto all exposed surfaces and allow sufficient disinfection time before proceeding.

5.7: Maintenance

1. **Daily** maintenance includes surface and equipment decontamination using Chemgene wipes, 1:50 chemgene and 70% IMS, complete daily record sheet. Daily checks of the grills, aspiration bottle and pump should be conducted to ensure a safe working environment.
2. **Weekly or prior to starting ambr experiment** maintenance includes the housekeeping form and completion of the cleaning of the BSC by removing all items and wiping all the internal working surfaces and sides with Chemgene wipes, 1:20 chemgene and 70% IMS.

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CAUTION: Take care not to release the cleaning tissue, as it will block the HEPA filter.

3. Biological Safety Cabinets must be regularly serviced and tested (at least annually but also subject to regular risk assessment review) by authorised contract / service personnel in accordance with the requirements of BS EN 12469 2000 and under the COSHH Regulations, to demonstrate performance under conditions of use and protection to the user from airborne hazards. Under COSHH regulations, records of examinations, tests and repairs must be held for 5 years.
 - The BSC must be decontaminated/fumigated prior to service by contractors or when decontamination/fumigation becomes necessary due to gross contamination, and a "Decontamination Certificate" must be issued prior to maintenance. Warning notices must be posted prior to commencing decontamination/fumigation procedures to prevent entry to the laboratory
 - Operator protection (KI Discus) test must be included as part of the commissioning process for new or relocated cabinets and annual maintenance certification. The tests are to be carried out under normal working conditions by trained service personnel.
 - The Downflow velocity should be between 0.24 and 0.36 m/sec; set point is 0.3 m/sec
 - The Inflow velocity should be 0.45 m/sec an alarm will sound and flash if the inflow velocity is below 0.4 m/sec
 - All cabinets must have an exhaust HEPA filter test by introducing an aerosol challenge to the airstream upstream of the filter and testing to see if there is any penetration downstream. Filters should have an efficiency of at least 99.995% (or penetration of <0.005%).
 - A label must be attached to the BSC to indicate when it was last serviced and when next service is due and a Test and Examination Record sheet needs to be filled out.
 - Once service and tests are complete a full deep clean must be performed.

5.8: Failure Messages.

Failure messages are shown as error codes, if one of these codes appears on the display, inform the Laboratory Manager immediately. Refer to manufacturer's operating instructions for further details.

1. DOCUMENTATION

The following records are outputs of this SOP and can be found on the CBE website under QS-Forms:

- QS-Form-014: BSC Daily Usage Record Sheet
- QS-Form-015: BSC Test and Exam Record Sheet
- QS-Form-016: BSC Training Agreement

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- QS-Form-009: Equipment Decontamination certificate
- QS-Form-017: BSC Warning Notice for Fumigation Procedure

These records shall be filed in the Equipment File and stored in the CBE Office or otherwise archived for future review or retrieval

Special Note on the Operator Protection (KI Discus) Test

Within the CBE the following approaches should be taken:

- All cabinets must have an operator protection (KI Discus) test included as part of the commissioning process for new or relocated cabinets.
- Operator protection tests are to be carried out in such a way as to ensure the cabinet and the laboratory are as representative as possible of normal working conditions, that is
 - a. With any air conditioning units or other ventilation systems in the laboratory switched on;
 - b. With other safety cabinets and fume cupboards within the laboratory switched on;
 - c. With the cabinet loaded with a typical arrangement of equipment and samples;
 - d. With a person moving around the laboratory, particularly if any pedestrian traffic is near the cabinet;
 - e. With doors (laboratory, nearby incubators and fridges etc) being opened and closed.

Copies of KI Discus test certificates must be kept for at least 5 years (a requirement under the COSHH Regulations).

SOP Version History

Version Reviewed	Date Revised/ Reviewed	Revision Summary	New Version Number
001	10.10.2012 K. Marrow	Moved over the the IEAN SOP template. Forms removed from SOP and files separately under the numbers. Minor changes to written by (K.Marrow). References removed. SOP version history moved to back of SOP. Removed the repeated information. New Issue needed.	002
002	05.01.2019 KEG	Corrected to make specific for ESCO BSC as Herasafe operations was used in version 002. Added in use of Chemgene Wipes	003

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