

Isolator Cleaning Guide (Liquid decontamination)



Even though isolators are designed to prevent contamination from entering, they still require regular cleaning and disinfection to maintain the required microbial grade. For pharmaceutical isolators this would normally be Grade A as defined by EC GMP¹.

Common facts:

- Transfer of material into and out of the isolator is one of the greatest potential sources of contamination. Routes include bags, boxes, paper and markers.
- Research has shown that:
40% of non sterile consumables are contaminated with bacterial spores. 60% of non sterile consumables are contaminated with bacteria.²
- Spraying alone is not enough:

Organism	Spray	Spray + Wipe
Aspergillus Niger	84%	98.5%
Bacillus subtilis	27%	94%

Table 1. Validation of user methods of liquid disinfections, % reduction of organisms
(Hospital Pharmacist 09/01)

- Many disinfectants, especially sporicidal ones, can have an adverse effect on the materials used in the construction of an isolator. Manufacturers should be able to provide information to support the validation of a particular agent.
- Alcohol is almost exclusively used for transfer disinfection of equipment into isolators, as it is quick drying and leaves little or no residue. However, consideration should be given to the retical fire or explosion risk when spraying alcohol and may need additional fans or ventilation to prevent the build up of vapour. The exposure limits should also be monitored when large quantities of alcohol are being sprayed. Both of these factors can be minimized by the use of sterile Impregnated wipes.³

¹ Euralex, Good Manufacturing Practice, Vol.4, Annexe 1, Manufacture of Sterile Medicinal Products. ² M. G. Cockcroft, D. Hepworth, J. C. Rhodes, P. Addison, A. M. Beaney. "Validation of Liquid Transfer Disinfection Techniques for Transfer of Components Into Hospital Pharmacy Cleanrooms", Hospital Pharmacist (September, 2001).

³ K. Rossington, "Cleaning of Isolators – A Vital Part of a Contamination Control Program", Controlled Environments (April 2004)

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Preparation for Cleaning:

The actual process of decontamination is the same for both cleaning and disinfection. Combined disinfecting and cleaning should be carried out with the Isolator closed.⁴ Due to the effect of biofilms, surface wiping is needed to assist in the removal of surface contamination.

The aim of cleaning is to reduce the contamination level of the surface to a visibly clean state, i.e. remove dust and organic or inorganic soil. This will give a greater likelihood that the disinfectant used will be effective. The cleaning program should be carried out by the operators of the isolator or suitably trained personnel to a validated SOP. The effectiveness of the cleaning procedure should be validated, documented, and regularly monitored. The same principle also applies to the disinfection procedure.



Cleaning should be carried out before and after every manufacturing, preparation, or dispensing session and between activities that may result in cross contamination. It is preferable that cleaning is carried out at a natural break, meal times or the end of the working day.

Steps:

1. Wipe down gloved hands and cleaning products with wipers pre-saturated with 70% IPA and place the products in the pass-through.

Disinfectant efficacy is optimal at concentrations between 50% and 80% with most institutions using 70% as the standard. Alcohol is suitable as a combined cleaning and disinfection agent provided no proteins are present, as alcohol will fix these to a surface by a process of protein denaturing. In this instance a separate cleaning agent should be used.³

2. Close the pass-through. Wait the prescribed amount of time for the isolator to reach equilibrium.
3. Wipe gloved hands with sterile 70% IPA; place gloved hands into the isolator gloves.
4. Open the interior door to the pass-through and bring all components into the isolator interior. Close the pass-through door. Wait the prescribed amount of time for the isolator to reach equilibrium.

B. Midcalf, W. Phillips, J. Neiger, T. Coles. "Pharmaceutical Isolators and Their Applications", Pharmaceutical Isolators Working Party. 2003



Use the EasyClean system for hard to reach areas and wipers surfaces within the Isolator.

Cleaning the Isolator with the EasyClean tool and covers.

Use the EasyClean tool and pad, either pre-saturated with IPA, or wetted with IPA.

1. Begin by wiping the ceiling with care so as to not damage the filter, then proceed to the back wall, then the side walls, and finish with the deck. Work from high to low, clean areas to dirty, and dry to wet.
2. Wipe in straight, parallel, overlapping strokes.
3. Change cover after each isolator/bench top surface.
4. Use swabs moistened with sterile IPA to clean the corners and small, tight areas.
5. Place the used covers and swabs in a disposal bag or place through the disposal port.



Cleaning the Isolator with a wiper.

Use a quarter-folded wiper, either pre-saturated with IPA, or wetted with IPA.

6. Begin by wiping the ceiling with care so as to not damage the filter, then proceed to the back wall, then the side walls, and finish with the deck. Work from high to low, clean areas to dirty, and dry to wet.
- 7.. Wipe in straight, parallel, overlapping strokes.
- 8.. Change wiper surfaces with each stroke.
9. Use swabs moistened with sterile IPA to clean the corners and small, tight areas.
10. Place the used wipes and swabs in a disposal bag or place through the disposal port.



The correct technique is to wipe, towards you, in straight horizontal lines, each time overlapping the previous one by 10-25%. A contaminated wipe should not be passed over an area that has just been wiped, unless it is folded and refolded to provide a clean surface. Usually quarterly folds are recommended but must be validated with each operator concerned, as a quarterly fold can lead to confusion as to which surfaces of the wipe have been used. In this case wipes folded in half should be used. Surface wiping should be carried out from top to bottom, from back to front, dry to wet, and from cleanest to dirtiest. The wipe itself should be constructed from a low particulate material. This point needs to be reinforced with operators, as a circular wiping pattern is the most comfortable and convenient according to Siegeman.⁵

⁵ H. Siegeman. "Wiping Surfaces Clean," A2C2 Magazines (April, 2003)

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Validation

Cleaning validation is usually limited to a visual or white cloth test. Simply wipe a white cloth over the area which has been cleaned and check that it shows no visible recovery. Disinfectants should be validated using appropriate microbiological testing. There needs to be verification of the removal or inactivation of microorganisms to the required level. This would normally be carried out using a combination of settle plates, contact plates, and swabbing. Neutralizing media should be used for any sampling that follows immediately after disinfection.

All critical parameters should be controlled, monitored, and documented as evidence to support the assurance of bioburden reduction. The contact time of the disinfectant should be determined in order to ensure the required level of biological decontamination. Cleaning agents and disinfectants should have a validation file which covers product specification, health and safety, compatibility, shelf life, and validation data.

Consideration of all these factors should ensure, a successful liquid decontamination program can be implemented for an isolator system.

EasyClean® 360 Isolator Cleaning System

Quick, Clean & Easy

Efficient cleaning of compounding isolators, biological safety cabinets, laminar flow hoods and other min-environments is critical to the quality and purity of com-pounded products.

The EasyClean® 360 System includes a light-weight, maneuverable cleaning tool along with easy-to-use laundered polyester knit covers.

The padded knit cover and rounded edges of the mop head insure the tool does not scratch or damage surfaces



EasyClean® 360 Isolator Cleaning Tool

- Durable, mirror finish, stainless steel mop head swivels 360° for easy maneuverability
- Head can be locked for 180° swivel when desired
- 4" x 7" (10cm x 18cm) triangular head shape allows for improved access in tight corners
- Light-weight anodized aluminum handles provided in 2 lengths—14" (35cm) and 24" (61cm)
- Quick connect handle mechanism for easy attachment after pass-through
- Mop head and handles can be sterilized by autoclave or gamma irradiation

EasyClean® 360 Elastic Isolator Cleaning Tool Covers

- Made from Berkshire's Super Polx® 1200 continuous filament polyester wiping material
- Laundered and packaged in an ISO Class 4 (Class 10) cleanroom for superior fiber, particle and residue performance
- Stretch fabric and elastic edge allow easy installation and secure fit on the mop head
- Recommended for use with the EasyClean® 360 Padded Cover
- Absorbent knit is abrasion resistant and durable to a wide range of cleaning solutions
- Autoclavable
- Non-sterile and validated sterile versions available

EasyClean® 360 Padded Isolator Cleaning Tool Covers

- 100% continuous filament knitted padded covers are laundered and packaged in an ISO Class 4 (Class 10) clean-room
- Recommended for use with the EasyClean® 360 Elastic Cover
- Foam-free cushioned design insures even surface coverage with reduced residues and contaminants
- Easy-to-install covers fit securely and stay in place during use
- Autoclavable



EasyClean® 360 Nonwoven Isolator Cleaning Tool Covers

- Double-ply 55% polyester/45% cellulose
- 100% nonwoven rayon inner layer for added absorbency
- Elastic edge allows secure fit on the mop head during use
- Autoclavable
- Recommended for use in ISO Class 5-8 or EU Grade A/C environments

Order Information

Product	Number	Packaging
ISOLATOR CLEANING TOOL EasyClean® 360 ICT	EC360.ICT.1	1 mop/case, 2 handles - 14" (35cm) & 24" (61cm)
MOP HEAD COVERS EasyClean® 360 Elastic Covers	EC360.EC.6	25 elastic covers/pack, 1 padded cover/pack, 6 packs/case
STERILE MOP HEAD COVERS EasyClean® 360 Sterile Elastic Covers	EC360.ECST.20	10 elastic covers/sterile header bag, 1 padded cover/sterile header bag, 4 packs/cracker pack, 5 cracker packs/case
MOPHEAD COVERS EasyClean® 360 Nonwoven Covers	EC360.NW.40	5 covers/pack, 4 packs/packet, 10 packets/case

For more information on our other contamination control products or technical consultation, please contact your Berkshire Sales Representative or e-mail: info@berkshire.com.



Other Berkshire products

For information on our other products, please click on the relevant text.



[Wipers](#)



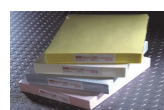
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