

BioCapt® Single-Use AutoM

Microbial Impactor

*The best solution for
monitoring critical areas*

*Without measurement there is no control*¹

The BioCapt® Single-Use AutoM Microbial Impactor is a proprietary,* lightweight, integrated air sampler designed for the automated filling line from Pharma Integration. It is part of the Biocapt® Single Use (BCSU) family and has an innovative design with a magnet on top of the lid that can be easily handled in automated isolator environments.

The BCSU AutoM can easily be installed to replace any stainless-steel impactor without modification of the filling line.

It is a sterile, ready-to-use unit already filled with Trypticase Soy Agar and 4 neutralizers. Each unit is individually wrapped in a gamma bag, and the units are packaged two by two in another gamma-irradiated bag. These pairs are combined to make a set of twenty-four pieces placed in an additional two gamma-irradiated bags, providing a total of four layers of sterile packaging.

This cutting-edge device features a tight magnetic seal, guaranteeing no penetration by vapors, gases, or liquids (e.g. vaporized hydrogen peroxide (VHP), exposure to sterilization cycle, etc.). This feature allows for pre-introduction (prior to a potential environmental decontamination) and exposure to final washing fluids (in case of applications in contaminated environments).

The BioCapt® Single-Use AutoM microbial impactor can be validated for continuous monitoring up to four hours, supporting pharmaceutical companies in reaching compliance with global regulatory requirements, including Annex 1.

The BioCapt Single Use AutoM uses the radial slit design of the BioCapt® family, validated at the Centre for Applied Microbiology & Research (CAMR), a Health Protection Agency (HPA) at Porton Down. It achieves isokinetic sampling for minimal air turbulence in compliance with ISO 14698-1 and can be used for sampling from 25 to 50 LPM



BENEFITS

- Compatible with the use in state-of-the-art filling lines
- Simplify use of handling
- No vapor penetration (e.g. Hydrogen peroxide)
- No liquid penetration

Test ready

- Fully prepared and disposable
- Eliminates agar plate preparation
- Eliminates autoclave sterilization
- Samples efficiently at a flow rate between 25 and 50 LPM

Cost reduction and increased productivity

- Easy handling for a plug and play solution
- Use for continuous monitoring up to 4 hours (after validation based on local parameters)
- Eliminates passive sampling as it can be validated for continuous use in alignment with Annex 1 requirements
- Unique solution for gloveless isolator
- Reduced number of investigations

FEATURES

- Culture media stability validated up to 12 months
- Storage either at room temperature or under refrigeration (2 - 25 °C)
- Each impactor is individually bagged, then two impactors are bagged together and gamma irradiated (double bagged) plus two additional bags for a total of 4 layers of sterile packaging
- Improved lot traceability by use of three-dimensional data matrix
- Compatible with active air monitoring systems
- Extensive validation studies available
- 100% inspection of critical dimensions during manufacturing process
- Leakage test ensuring perfect assembly
- Complies with ISO 14698-1 for highest microbiological and physical efficiencies
- Standard culture media of TSA with neutralizers
- Designed to be operated with a specific exchanging sensor (under development)

APPLICATIONS

- Microbial air sampling monitoring in gloveless isolators



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MEASURING
SYSTEMS®**

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BioCapt[®] Single-Use AutoM

Microbial Impactor

Specifications

Materials	Polystyrene
Air inlets	20 slits, 0.1 mm nominal width
Flow rates	from 25 - 50 LPM
Dimensions	120 mm exterior diameter 38.5 mm exterior height (with lid) 90 mm diameter agar surface
Filling volume	30 ml
Vacuum connectors	Hose Barb 11 mm OD and 31.5 mm long (includes removable cap)
Standard media	Trypticase Soy Agar (TSA) with neutralizers.
Packaging	48 units (24 double packs)



*BioCapt Single Use AutoM has been co-developed and co-patented in partnership with Pharma Integration for optimal usage in their robotic environments

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