

BioCapt® Single-Use AutoM

Microbial Impactor

*The best solution for
monitoring critical areas*



Without measurement there is no control®

The BioCapt® Single-Use AutoM Microbial Impactor is a proprietary* lightweight, integrated air sampler designed to be used in filling lines with high automation. 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 by a robotic or mechanic arm as well as by the operator.

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.

Thanks to the new design, the BioCapt® Single-Use AutoM avoids any risk of vapor residuals (e.g. Hydrogen Peroxide) inside the device, that can occur due to exposure to the sterilization cycle without wraps.

There is a possibility to validate the BioCapt® Single-Use AutoM for continuous monitoring for up to four hours, supporting pharmaceutical companies to be in compliance with regulations 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 of robotic and mechanic arms
- Simplify use of handling
- No vapor penetration (e.g. Hydrogen peroxide)

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 isolator gloveless
- 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 bages 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

APPLICATIONS

- Microbial air sampling monitoring in isolators gloveless



**PARTICLE
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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