

DualCapt

Particle and Microbiological Instrument



The DualCapt Particle and Microbiological Instrument is a single solution, combining non-viable airborne particle counting with simultaneous microbial air sampling in a single unit using the BioCapt® Impactor Head. The airflow through the instrument is provided by an external (house) vacuum source monitored by an internal pressure sensor to assure the flow rate stays within calibration limits. Control of the instrument is achieved through FacilitySight® software or by any configured SCADA system. The internal non-viable particle sensor collects data at 0.5 and 5.0 μm at a 1 CFM (28.3 LPM) flow rate.

The slits in the BioCapt® Impactor Head are precision cut to ensure laminar flow, thus maximizing collection efficiencies for viable particles of interest in accordance with ISO 14698-1. Biological efficiency is guaranteed by ensuring optimal impaction velocity also giving statistical control over false positive results. The BioCapt Impactor is fully autoclavable and all sample air is exhausted outside of the cleanroom to prevent contamination of the cleanroom environment.



BENEFITS

- Simultaneous sampling of both viable and non-viable particulate contamination in the same instrument package
- 0.5 and 5.0 μm non-viable particle counting at 1.0 CFM (28.3 LPM)
- The BioCapt Impactor is validated to ISO 14698-1: Biocontamination Control of Cleanrooms and Associated Controlled Environments
- High physical and biological collection efficiency calculated per ISO 14698-1/Annex B
- Compliant with cGMP, GAMP®, and pharmacopeial regulatory requirements
- 25 L/min flow rate for the BioCapt Impactor ensures sample volume is collected quickly enough to avoid physical or chemical degradation of the collection medium
- Optimal slit design in BioCapt Impactor ensures laminar flow and that microorganisms are undamaged during sampling
- Autoclavable BioCapt Impactor
- Immediate detection of false positives
- All sample air lines are vented outside to prevent contamination of the cleanroom or clean zone

APPLICATIONS

- Cleanroom and clean air device non-viable particulate and biocontamination monitoring
- Bi-annual certifications for both particulate and microbiological environmental monitoring, as required by USP Chapter 797
- Simultaneous non-viable particle and viable microbial monitoring of aseptic filling areas

Without measurement, there is no control.

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specifications

Microbial Sampler

Material	AISI 316L Stainless Steel
Sampling flow rate	25 Liters/min
Number of slits	20 – Precision cut by Electrical Discharge Machining (EDM)
Slit depth	3 mm
Slit thickness	0.09 ± 0.01 mm
Consumable	90 mm plates

Particle Sensor

Particle size channels	0.5 and 5.0 µm
Flow rate	1.0 ft. ³ /min. (28.3 LPM)
Counting efficiency	50% ± 20% at 0.50 µm – Meets Japanese Industrial Standards (JIS)
Zero count	< 1 count per 5 min (Meets JIS)
Maximum concentration*	> 500,000 /ft. ³
Sample probe or tubing	1/4" ID, 5 ft. (1.5m) max. length
Vacuum requirements	> 15m Hg
Flow rate control	Critical orifice
Communication	RS-485 Modbus®
Display and printer	LED: Power, Count, Flow Status, Laser Status
External power	20 VAC (20-24 VAC 1.5A)
Dimensions (h, w, d)	4.4 x 5.9 x 7.5 in (11.2 x 15.2 x 19.2 cm)
Weight	12 lbs (5.5 Kg)
Operating environment	Temperature: 39 - 95° F (4-35°C); Humidity: 10-85% non-condensing
Calibration	Every 12 months

* Greater than 95% accuracy (less than 5% coincidence loss) at maximum recommended ambient concentration.
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 Modbus® is a registered trademark of Schneider Automation, Inc.
 RNet® is a registered trademark of Particle Measuring Systems, Inc.
 GAMP® is a registered trademark of International Society for Pharmaceutical Engineering (ISPE).
 Italian patents pending.
 Particle Measuring Systems, Inc. reserves the right to change specifications without notice.



Registration applies to the Boulder, Colorado facility.

AUTHORIZED REPRESENTATIVE



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