

CLEANROOM APPLICATIONS

Non Viable Particles

Application

Standards

Cleanroom Certification

ISO 14644-1 / ISO 14644-2
EUGMP Annex 1, ISO 13485

If you are looking to certify or validate your cleanroom you need a portable particle counter. The number of sampling points, volume of air are determined following the formula outlined in the ISO 14644 For EUGMP the volume is 1m³ per sampling point. The TGA require that you follow EUGMP therefore you must report 0.5um and 5.0um and sample 1m³ volume of air. The Lasair III 5100 Has been specifically designed for this application.

- Pharmaceutical Cleanrooms
- Medical Device Cleanrooms
- Clean Air Devices and Cabinets
- Hospital Compounding Facilities
- Hospital Operating Theatres
- Semiconductor Cleanrooms



Cleanroom Routine Monitoring

ISO 14644-1 / ISO 14644-2
EUGMP Annex 1, ISO 13485

For routine cleanroom monitoring the location of the fixed sampling points is critical. A formal risk analysis must be carried out to determine the best locations. Continuous monitoring is required in Grade A and preferred in Grade B environments. The Airnet II remote particle counter is the best option as it has a small footprint, monitors 0.5um and 5.0um particles with an ideal flow rate of 28.3L/min. The unit is easy to install and operate and connects to real time monitoring software PharmNet via Ethernet connections. Batch reporting, data trending and audit trailing are easily achieved.

- Pharmaceutical Aseptic Manufacturing
- Filling Lines
- Biological Safety Cabinets
- Cell & Tissue products
- Blood Products
- Blood Banks
- Bone Banks
- Blow Fill Seal (BFS) machines
- Laminar Airflow Cabinets
- Veterinary Aseptic Products
- Semiconductor Cleanrooms



CLEANROOM APPLICATIONS

ViabLe Particles

Application

Standards

Cleanroom Certification

ISO 14698, EUGMP,
ISO 14644-1, ISO 8573

For Cleanroom certification the monitoring of viable particulates is extremely important. The presence of viable particles indicate a failure of the cleanroom's ability to maintain sterile conditions. The standards are very tight with a target of zero colony forming units (CFU) per 1m³ of sampled air for active air sampling. Therefore choosing the right monitoring equipment is crucial. The MiniCapt portable air sampler has been designed to achieve high reliability with excellent physical and biological efficiencies.



- Pharmaceutical Cleanrooms
- Medical Device Cleanrooms
- Clean Air Devices and Cabinets
- Hospital Compounding Facilities
- Hospital Operating Theatres
- Compressed Gas Lines
- Isolators

Cleanroom Routine Monitoring

ISO 14644-1 / ISO 14644-2
EUGMP Annex 1, ISO 13485

For routine cleanroom monitoring the location of the fixed sampling points is critical. A formal risk analysis must be carried out to determine the best locations. Continuous monitoring is required in Grade A and preferred in Grade B environments. The AirCapt remote air sampling system is the best option as it has a small footprint, excellent physical and biological efficiency with easy false positive identification. with an ideal flow rate of 28.3L/min. The unit is easy to install and operate and connects to real time monitoring software PharmNet via Ethernet connections. Batch reporting, data trending and audit trailing are easily achieved.



- Pharmaceutical Aseptic Manufacturing
- Filling Lines
- Biological Safety Cabinets
- Cell & Tissue products
- Blood Products
- Blow Fill Seal (BFS) machines
- Laminar Airflow Cabinets
- Veterinary Aseptic Products



CLEANROOM APPLICATIONS

Viable Particles

Application

Standards

Cleanroom Certification

ISO 14698, EUGMP,
ISO 14644-1, ISO 8573

The Air Trace™ Environmental Air Sampler is a state of the art slit-to-agar microbial air sampler. The sampler rotates a 150mm agar plate 360° while maintaining the Agar plate at a fixed distance from a precision cut slit. This is a critical feature to ensure maximum validated recovery of impacted organisms on the agar surface. After incubating the plate, growth on the medium can be interpreted to exactly when the contamination occurred during sampling, enabling the operator to pinpoint a particular event during a process or procedure that may have raised the bio-burden to above acceptable limits. The user sets the rotation speed of the agar plate, as well as the percentage of the plate area exposed, thus ensuring the flexibility to monitor virtually any process for bio-contamination.

- Pharmaceutical Cleanrooms
- Medical Device Cleanrooms
- Clean Air Devices and Cabinets
- Hospital Compounding Facilities
- Hospital Operating Theatres
- Compressed Gas Lines
- Isolators



Viable & Non Viable Particles

Cleanroom Routine Monitoring

ISO 14644-1 / ISO 14644-2
EUGMP Annex 1, ISO 13485

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 Facility Sight® 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.

- Pharmaceutical Aseptic Manufacturing
- Filling Lines
- Biological Safety Cabinets
- Cell & Tissue products
- Blood Products
- Blow Fill Seal (BFS) machines
- Laminar Airflow Cabinets
- Veterinary Aseptic Products

