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ACTIVECOUNT

Remote Impactor Series Applications

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Overview

Looking to meet EU GMP Annex 1:2022 "Continuous Microbial Monitoring" requirements? The ActiveCount Remote Impactor has you covered. This advanced air sampling system offers precise, reliable monitoring for your cleanroom environments.

Key features include:

- Continuous and interval sampling modes
- Spot check certification capabilities
- 1 micron d50 collection efficiency
- HEPA-filtered exhaust
- Portable design with touchscreen interface

The ActiveCount is perfect for isolators, BSCs, and LAF cabinets. It's lightweight, battery-powered, and features a stainless steel enclosure for easy cleaning. Autoclavable components ensure regulatory compliance and cleanroom certification.

The **Remote Impactor Series** is ideal for ISO 7 cleanrooms and ISO 5 isolators. Its 'grab-and-go' design allows for quick, efficient sampling. With dual sealing technology and flexible mounting options, it's built to perform in various applications.

Fast Microbial Certification to meet cGMP

With the AC100H you get a 100 LPM sampling rate reduces sampling time to just 10 minutes for a full 1m³ of air, streamlining both cleanroom qualification and routine microbiological air sampling tasks. The periodic sampling mode allows for extended durations, all while meeting industry standards and regulatory requirements. External sampling accessories make it easy to position the unit outside critical areas, leaving the impactor and base plate securely within the controlled zone. With options for side or bottom mounting, remote sampling is made effortlessly convenient.

- 100 liters per minute flow rate
- HEPA filtered exhaust
- Continuous, periodic and gas sampling modes
- Self adjusting flow control
- 50 programmable user names
- Battery with 8-10 hours normal use
- 400 programmable location names
- Fully autoclavable components

The AC100H & Microbial Certification

This process refers to the initial qualification of a cleanroom or classified environment to confirm it meets microbial cleanliness standards before use.

Certification includes a comprehensive assessment, usually performed during facility validation, involving viable air sampling and surface sampling to verify that microbial contamination is within acceptable limits.

Microbial certification is typically a prerequisite for operational approval and provides baseline data for routine operations.

According to **Annex 1, section 9**, the certification process establishes acceptable levels for microbial presence and is an essential part of qualifying a cleanroom for aseptic processing.

Microbial Certification establishes a cleanroom's baseline cleanliness before it is operational, while ***Microbial Monitoring***, including continuous monitoring in critical areas, maintains and verifies that cleanliness over time, as required by regulatory standards in EU GMP Annex 1.

ActiveCount 25H Microbial Monitoring to meet EU GMP Annex1:2022 Continuous Monitoring

The AC25H & Microbial Monitoring:

Monitoring is an ongoing process that continues after initial certification and focuses on maintaining the certified state by regularly assessing microbial levels in the cleanroom. Routine monitoring identifies any potential contamination sources in real time and helps in the early detection of microbial risks, allowing for corrective actions if contamination levels exceed established limits.

In Annex 1, section 9.24, the guidance introduces continuous microbial monitoring, particularly for critical zones (e.g., Grade A areas). Continuous monitoring is expected during production to detect microbial contamination throughout the process, rather than relying solely on intermittent sampling.

This continuous approach enables immediate action and helps to ensure ongoing compliance with required microbial cleanliness, reducing contamination risk during aseptic operations.

The AC25H will allow you to sample 1m3 of air in 40 minutes, extending your sampling duration while ensuring you the fully compliant with the current industry standards and regulations.

This longer duration helps you to lower the number of aseptic manipulations during production while helping you to use less agar plate to monitor critical duration. Even better TSA media can be validated to be used for up to 4hrs with the AC25H therefore only requiring one media change in an eight-hour shift. This mitigates operator interventions and possible contamination events due to operator interactions within the aseptic process. The AC25H with a 25L/min flowrate assures less frequent operator interactions.

External sampling accessories will help you to keep the unit outside of your critical area while the impactor and base plate sit within the critical zone. With side and bottom mount options, remote sampling is seamless.

Simple Decontamination

In sterile manufacturing, decontaminating sampling equipment is essential to maintain microbial integrity and prevent contamination. The EU GMP Annex 1:2023 and FDA's 2004 Guidance for Industry on Sterile Drug Products emphasize stringent decontamination practices to ensure sampling does not introduce contaminants.

The design of the AC100H and AC25H enable effective wipe downs of the enclosure while the sampling head and the base plate can be sterilized in an oven or by steam disinfection at 121 Degrees C by autoclave.

EU GMP Annex 1:2023

The revised EU GMP Annex 1 provides clear directives on aseptic controls:

- **Section 8.32:** Specifies that equipment in aseptic areas must be sanitized or sterilized to prevent contamination, stressing that "all materials, components, and equipment that could impact the aseptic environment, or product must be effectively decontaminated."
- **Section 9.24:** Stresses that microbial sampling tools must be sterilized to prevent cross-contamination, ideally using equipment that tolerates repeated sterilization.
- **Section 8.13:** Highlights decontamination of tools entering aseptic zones to minimize microbial risks.

FDA 2004 Guidance:

Sterile Drug Products Produced by Aseptic Processing

The FDA 2004 Guidance similarly mandates decontamination of aseptic equipment:

- **Section IV.C (Sterility of Materials):** Emphasizes that "all sampling materials and equipment in sterile areas must be sterilized or sanitized," recommending frequent decontamination.
- **Section V (Environmental Monitoring):** Stipulates that sampling tools in aseptic areas must be sterilized to avoid introducing contaminants.

Importance of Decontamination

Decontaminating sampling equipment is critical to:

1. **Prevent Cross-Contamination:** Non-sterile tools risk environmental and product contamination.
2. **Maintain Environmental Integrity:** Regular decontamination of sampling tools prevents microbial buildup in critical zones.
3. **Ensure Compliance and Quality:** Both EU GMP and FDA guidelines require strict decontamination, crucial for regulatory compliance, product integrity, and patient safety.

In summary, both EU GMP Annex 1:2023 and FDA guidance stress that effective decontamination is vital to ensure a sterile environment, meet regulatory standards, and uphold product quality.

How Easy is it to use the ActiveCount and the impactor kit?

The ActiveCount was designed for easy component decontamination. The ActiveCount has a magnetic baseplate for easy and quick removal and both the base plate and sample head are most suitable for frequent autoclaving cycles.

Easy Removal of Base Plate and Sample head for decontamination as well as remote impactor and base plate

What about Identifiers for sample heads and flowrates?

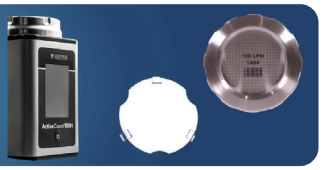
The ActiveCount Impactor kit comes with unique Identifiers for each sample head so mixing up sample heads with the ActiveCount is covered. Some manufacturers do not clearly identify sample heads and mismatches of sample heads and impactors at different flow rates occur which impact on the physical and biological efficiencies, of the d50 (Resolution) and overall accurate performance of the system.

How easy is it to integrate the Remote ActiveCount into our Isolators or BSC's?

The remote sampling kit comes with remote impactor adapter, autoclavable tubing and the impactor base. You can still use the sample head and magnetic petri holder from your existing ActiveCount air sampler.

1 Know Your Ship Kit!

Ship kit for both 25H and 100H includes 316L stainless steel sample head, washdown cover, removable petri dish holder, blower inlet seal.



Remote Impactor Kit!

Remote impactor kit lite includes a remote impactor adapter, autoclavable tubing and the impactor base. You can use the sample head wash down cover and removable petri holder from your current ActiveCount.

2

3 Need Extra Accessories?

You can order extra sample head (impactor), Impactor base and sampling extensions for various applications!

Side and Bottom Mount at the Same Option!

Remote sampling kit comes with remote impactor adapter, autoclavable tubing and the Impactor base.

You can use all Active Count accessories with this setup!

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5 Easy to Identify!

Thanks to the annealed flowrate and unique identifier markings on accessories, there is no risk of wrong installation. Always easy to identify & implement!

Monitoring inside an Isolator or BSC, LAF cabinet?

With the extra accessories you can select which sample orientation you need for your specific application. Each application process is different and may require a risk assessment on the location of the sampling head and which type of plumbing you will need.

For applications where sample ports are built into the working plane of a separative device or filling machine the bottom impactor has suitable sterile connections that can also be autoclaved (Stainless Steel).

The side impactor allows for flexibility with installation where a side port on the BSC, LAF or Isolator can be utilized. The Active Count air sampling device can remain outside where the operator can easily interact with it and the Active Count comes with a HEPA filtered exhaust.

The bottom impactor allows for connection of the sample head and base impactor to a sample port built into the bottom of a filling machine, LAF cabinet, BSC or Isolator system. The sample head and clamp can be easily removed for autoclave.

Portable Air Sampling with Accuracy

Elevate your air sampling experience with the ActiveCount family, a remarkable duo of high-performance, portable active air samplers designed for cleanroom and aseptic environments. These devices provide self-adjusting flow control for precise sampling accuracy, along with versatile continuous and periodic sampling modes. ActiveCount's standout features include an impressive d50 collection efficiency of 1 micron and HEPA-filtered exhaust ports, ensuring the prevention of any re-aspiration of sampled air.

Ready to Learn More?

Click below to for more information

More Info