

CLEANROOM MONITORING & VALIDATION IN A SINGLE SYSTEM

Send Your Data to the Cloud for a Hassle-Free Audit



Whether you're a Quality Engineer, Pharmaceutical Microbiologist or hospital staffer, proving cleanroom sterilization and decontamination is critical for both open and closed processes. Defining your monitoring points, sampling frequency, and documenting the results must **all** be part of your environmental monitoring plan. However, when performed

manually, a high frequency of cleanroom measurements only lead to more contamination through human activity. To avoid this, automated monitoring is indicated.

Accsense Monitoring systems are ideal to monitor filling machine cleanrooms, ISO 5 product fill cleanrooms, test sample incubation, non-sterile manufacturing, and more. Accsense is a complete cleanroom validation solution that automatically **records, stores and trends** your environmental data.

Monitor, Alarm and Validate with Accsense! Our automated systems make it easy to show your best practices to inspectors during cleanroom audits.

Automated Environmental Monitoring:

Environments are monitored to protect the product from contaminants and to prevent alarm events from occurring. To pass an audit and to show quality by design (QbD), all your methodology must be validated!

While settle plates are commonly used to get a basic idea of contamination levels, they're nowhere near accurate enough for audit purposes. Rather, they are only a supplemental tool which cannot by itself give an accurate view of microbiological contamination. Cleanroom monitoring should still take place during settle plate exposure times. For this reason **Accsense Monitoring** is the choice of many pharmaceutical cleanrooms and healthcare organizations.

Cleanrooms require both air and surface monitoring to achieve sterilization/decontamination. **Accsense** is a reliable and accurate solution for continuous monitoring of samples and environments. Accsense monitors preparation areas, corridors, surgery rooms, and more. You can set Accsense to monitor **daily or for each batch** (for ISO 5 environments) or **weekly** (for ISO 7 areas) in gowning rooms and areas peripheral to ISO 5 areas.

Armed with a year's worth of environmental data, you can view **detailed trends** to ensure that your monitoring regime is effective (and if you can lower the monitoring frequency), or if it needs to be reevaluated for sterility assurance.

Gram-Negative Applications:

Automated temperature monitoring is also an effective way to detect specific fungi/bacteria and to oversee operation-dependent regimes. In high-risk cases such as gram-negative bacteria applications, Accsense has a high accuracy to address the main risk of losing sterility through microbiological contamination.

Accsense Monitoring can also accommodate different monitoring frequencies for different cleanroom types. Sampling rate should be high, for example a reading taken at each batch filling, at defined intervals, and after sanitization of isolation & sterile areas.

Accsense systems also feature wireless communication, giving you the ability to **remotely monitor data in real-time**. Wireless environmental monitoring is especially useful for use in maintaining Grade A cleanrooms.

Remote Alarms and Automated Phone Alerts:

Accsense serves as a reliable foundation of cleanroom risk assessment strategies, giving staff time to take corrective/preventative actions before product and/or sterility is lost. Meanwhile, these smart systems are also effective for out of specification (OOS) and out of limit (OOL) investigations—find out why alarms go off before they happen again!

Accsense also features remote alarm capability, with **sequential call lists** that can dial each number until the alarm is acknowledged! This is especially useful in gram-negative bacteria areas which generally have a higher risk.

Prove Your Best Practices with Trends:

Historical data is critical to validating your environmental monitoring plan. Trending the data over time is also a useful risk management tool. Accsense also helps you to view

out of trend data (OOT) for risk management. The collected data has many uses, for example as an easily-accessible documentation and validation for audits.

Trend documentation and examination includes microflora evaluation, especially to check for resistant strains as part of good manufacturing practice (GMP) in the FDA and the EU. As an example, Accsense can significantly help to achieve this by monitoring and trending the room's temperature data over time.

To learn more about [Accsense Monitoring](#), or to find the ideal solution for your application-specific needs, contact a **CAS DataLoggers Application Specialist** at **(800) 956-4437** or visit our website at www.DataLoggerInc.com.