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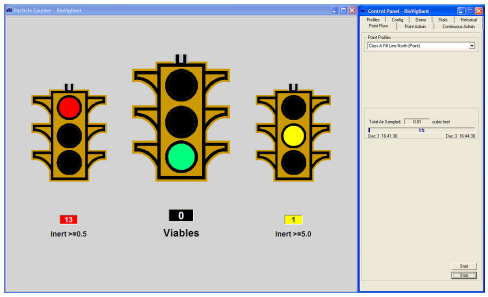
Instantaneous Microbial Detection

Originally developed for the defense industry and now being used within pharmaceutical manufacturing, BioVigilant's Instantaneous Microbial Detection is a fully optical technology that can determine, on a particle-by-particle basis, the quantity of microbes in liquid or air, all in real time, and on a continuous basis.



BioVigilant's IMD-A (for air monitoring) and IMD-L (for liquid monitoring) instruments can be used in pharmaceutical manufacturing clean rooms (I) as warning instruments; (II) as continuous monitoring and trending instruments; and, (III) to verify if remediation was successful.

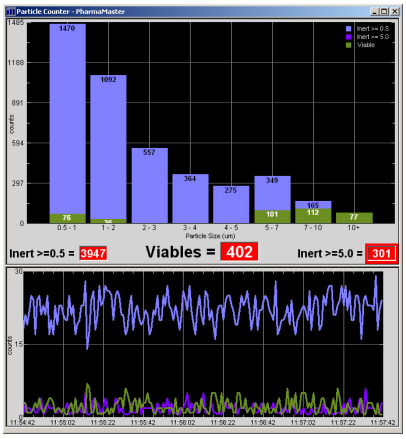
(I) As Warning Instruments

BioVigilant's IMD-A can sample the air continuously or do spot checks and give an indication or alarm when microbes are detected. Pictured above is the IMD-A display for use on the manufacturing floor. Pictured to the right is the display for use for analysis.

In the display to the above, the green light indicates that operation is within defined limits, while the yellow light indicates that an alert level has been exceeded, and a red light indicates that the action level has been exceeded. In the display to the right, the blue bar denotes inert particles, the green bar denotes viable particles, the blue and purple lines denote inert particles and the green line denotes viable particles. An alarm protocol alerts managers in the event of that a defined level is exceeded, according to clean room requirements.

(II) As Continuous Monitoring and Trending Instruments

The ability of BioVigilant's IMD instruments to provide instantaneous microbial detection also enables them to provide continuous monitoring and trending, which is useful a functionality not possible using existing conventional methods. (See the display to the right.) In addition to aiding compliance with existing regulatory and internal requirements, this unique feature of BioVigilant's technology makes its instruments especially suitable for implementation of the FDA's Process Analytical Technologies (PAT) initiative by providing a process analyzer tool for microbiological monitoring of clean room air and liquids.



(III) To Verify If Remediation Was Successful

BioVigilant's IMD instruments can be used as a diagnostic tool in order to obtain immediate results after remediation of microbial contamination has taken place, to determine, in real time, if the remediation was successful.

Feature	BioVigilant	Conventional Plate Culture Method	Consequence
Time from measurement to results.	Instantaneous.	Typically from one to five days.	Using the conventional method creates more planned and unplanned halts in production and greater potential for contamination, significantly increasing costs and lowering production. Conventional methods also are very slow to certify if remediation was successful, causing slow downs and making it more difficult to determine the cause of contamination.
Mode of detection.	Continuous monitoring and real time feedback of results.	Episodic monitoring and time-delayed feedback of results.	Continuous monitoring increases accuracy, allows for trending to spot problems early, lowers chances of contamination, reduces the need to dispose of production, reduces down time and the time needed to remediate, and is conducive to PAT.
Time to set up sample.	None. Just turn it on.	Can be significant.	Conventional method requires higher labor costs and time delays.
Human intervention.	Minimal.	Required to set up samples, transport, and to read results.	Human intervention creates more possibilities for inaccuracies.