BioLaz®

Real-Time Microbial Monitor

The BioLaz Real-Time Microbial Monitor provides real-time detection of biological organisms in controlled environments used for the manufacture of sterile products. The sensor can be connected directly to Pharmaceutical Net, FacilityPro® SCADA, FacilityPro SMART, or your own software, and is designed for continuous operation.

The BioLaz has been independently tested to meet the rigorous requirements of USP <1223> Validation of Alternative Microbiological Methods and of EP 5.1.6 Alternative Methods for Control of Microbiological Quality, for the Pharmaceutical market.

BioLaz samples air via a stainless steel sample probe. As the air passes through the system it is illuminated by a laser and the biological particles fluoresce. Those fluorescing biological particles are then counted in one of two size channels, depending on their size.

The BioLaz has been designed with a small footprint in a 316L stainless steel enclosure to fit in constrained space. The unit provides its own air flow using an internal pump, eliminating the cost of and need for external vacuum lines.

BENEFITS

- Immediate notification when biological particles are present
- Verify biological levels are acceptable prior to filling
- Separation of finished product (based on timing of alarms)
- Immediate notification for alarm response
- Faster batch release
- Reduced operator error
- Paperless data management

FEATURES

- Capable of single Bio-Count detection: One Bio-Count is representative of 1 CFU
- Validated to USP <1223> and EP 5.1.6 requirements
- Not constrained by physical and biological efficiencies associated with impact air samplers
- Not constrained by the type and quality of the growth media
- Real-time, continuous counting free from error sources including contamination, mishandling, and inaccurate counting
- Easy to operate and does not require any special handling, training, or logistics

APPLICATIONS

- Sterility test isolators
- Filling lines
- Aseptic transfers
- Biotech applications – product to patient
- Troubleshooting contamination events

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Specifications

	BioLaz 504
Detection methods	Mie scatter for particle detection Fluorescence emission for differentiating biological and inert activity
Minimum resolution	1 Bio-Count (representative of 1 CFU)
Maximum concentration	25,000 Bio-Counts per second
Size range	0.5 µm to 50 µm
Sizing channels	Two-size Channel Mode
Size	9.84 x 7.87 x 5.91 in (25 x 20 x 15 cm) (Box without ISP and handle)
Weight	13.5 lb (6.1 kg)
Operation temperature	32 – 95 °F (0 – 35 °C), 10 – 95% non-condensing relative humidity
Storage temperature	14 – 140 °F (-10 – 60 °C), 10 – 95% non-condensing relative humidity
External chemical resistance	Isopropyl alcohol, acetone, chlorinated solution, hydrogen peroxide
Enclosure material	316L stainless steel
Flow rate	3.6 LPM ± 5%
Power source	85 – 264 VAC, 47 – 63 Hz
Power consumption	15 W
Air outlet filtering	HEPA filter provided (> 99.97% @ 0.3 µm)
Detectors	Photo Multiplier Tube (PMT)
Laser wavelength	405 nm
Data storage	External software: Pharmaceutical Net, FacilitySight, or customer-supplied
Communications	RS-232 and TCP/IP via Ethernet

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