

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, FacilitySight®, or your own software, and is designed to operate unattended 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 into the sensor 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 one 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

Without measurement there is no control.

BioLaz 504

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| 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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