

Sievers* Soleil Rapid Bioburden Analyzer

Get bioburden results in less than 45 minutes
with proven correlation to plate counts



The Sievers Soleil

The Sievers Soleil Rapid Bioburden Analyzer is a Rapid Microbial Method (RMM) that monitors bioburden at ultrapure levels in less than 45 minutes - finally providing the ability to detect microorganisms in near real-time. With data correlating to plate counts, you can make data-driven decisions and take quick action to control contamination throughout the manufacturing process.

Time to results in less than 45 minutes

- Enables data-driven decisions and quick action for controlling contamination
- Unique reagents and viability stain combinations detect viable cell counts from Gram-negative bacteria, Gram-positive bacteria, yeast, and mold
- High-throughput flow cytometer distinguishes between viable cells and abiotic particles using proprietary fluorescent stains to ensure accuracy and sensitivity
- Measures not only water but also complex samples including drug substances, culture media, plastics, and more

Better contamination control + increased manufacturing agility = cost savings

With the Soleil RMM, productivity is increased without jeopardizing patient safety and while reducing risk to release materials or products. Rapid results means faster decision making, which leads to cost savings at many points during manufacturing:

- Pharmaceutical manufacturing water – critical control points
- Cleaning validation / hygiene monitoring
- Process water
- Raw materials
- At-line monitoring of drug substances and intermediate products
- Environmental monitoring of process areas

Straightforward sample preparation

The Soleil system can be used in a laboratory or at-line and preparing samples is quick and easy. First, the sample is heated to 37° C for a brief period in the onboard incubator. Next, add Soleil Reagent A followed by Soleil Reagent B. After a 15 minute incubation period, simply add Soleil Reagent C. The Sievers Soleil will analyze the sample with results in 15 minutes or less, depending on the sample volume.

Microbial monitoring with ease

Microbial monitoring is faster and easier with the Soleil's simple set up, software, and consumables. Here's what you can expect day to day:

- Software that walks you through each step for daily start up
- Less time (or no time!) spent working in a biological safety cabinet streaking plate after plate
- No need to purchase filters, agar plates, or multiple pipette tips - with the Soleil you just need the recommended pipette tips and bottles
- Simplified, high throughput testing for sample volumes 20-100 mL

Specifications

Operating Specifications

| | |
|---------------------------------|--|
| Range | <10 biotics/100 mL - 10,000 biotics/100 mL |
| Sample Type | Discrete grab sample |
| Display Readout | Biotics/100 mL |
| Calibration | Typically stable for 12 months |
| Analysis Time | < 45 minute Total Time to Result (TTR) |
| Sample Temperature ¹ | 35-39 °C (95-102.2 °F) |
| Ambient Temperature | 17-30 °C (63-86 °F) |
| Sample Pressure | N/A |
| Instrument Sample Flow Rate | 8 mL/min |

Analyzer Specifications

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|-----------------------|---|
| Outputs | USB port, Ethernet TCP/IP |
| Display | 14" laptop touchscreen (1920x1080) |
| Power | 100-240 V~, 50-60 Hz, 165 VA |
| Fuses | Qty 2; T 5A 250 VAC Replace with same type and size fuse Size 5x20 mm appliance inlet |
| Laser (Class 1) | Wavelength: 488 nm Max Power: 135 mW |
| Dimensions | Width: 48.3 cm (19 in) Depth: 43.2 cm (17 in) Height: (without laptop): 43.2 cm (17 in) |
| Weight | 18.1 kg (40 lb) |
| Enclosure Rating | IP30 |
| Safety Certifications | ETL, CE, UKCA, FCC, CSA 22.2 |

Environment

| | |
|---------------------------|-----------------------|
| Maximum Relative Humidity | 0-85%, non-condensing |
| Maximum Altitude | 3,000 m (9,800 ft) |
| Pollution Degree | 2 |

¹ Driven by onboard incubation

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