

# LASAIR® II 350L, 550L

Meet GMP sampling requirements faster

With the recent EC GMP Annex 1 changes, pharmaceutical manufacturing facilities must take much larger air samples; where before one cubic foot was adequate, now one cubic meter is required per clean zone.

The LASAIR II 350L and 550L feature a 50 liters/minute sampling rate, sampling one cubic meter in only 20 minutes and saving 15 minutes per zone over 1.0 CFM instruments. The software guides the user through the certification process, verifies adequate sample numbers and volumes, collects the data, then prints a full final report.

The LASAIR II is extremely portable and reliable, with the features most useful to pharmaceutical users: data security, password-protected sampling recipes, as well as speedy, paperless, 21CFR 11-compliant data download and electronic storage.



## BENEFITS

### Increase Productivity

- Save fifteen minutes of sampling time per clean zone
- Software-guided EC GMP and ISO sampling, with comprehensive PASS/FAIL final report
- Final reports validated to meet ISO and EC GMP standards
- Quick, paperless, 21CFR 11-compliant data download to Pharmaceutical Net, periodically or in real-time
- Removable battery with optional external charger allows continuous mobile use
- Ease of instrument validation using comprehensive manual

### Reduce Defects

- Detect breakdowns in isolator protection
- Troubleshoot potential particle sources
- Test installed filters for leaks
- Monitor the sub-visible environment in cleanrooms

### Cost Effective

- Use in up to ISO Class 8 rooms (FS209 Class 1-100,000) or in Class 9 with diluter
- Rugged, chemical-resistant, ESD-minimizing KYDEX® casing for easy wipe-down sanitation
- Comprehensive validation manual simplifies meeting FDA and EC GMP requirements
- Sample EOP and SOP documents ease implementation

## FEATURES

- 50 L/min. flow rate samples 1.0 m<sup>3</sup> in twenty minutes
- Compact and convenient: Only 15.5 lb. (7.0 kg) with battery
- Built-in thermal printer
- Stores 3,000 samples
- 21CFR 11-compatible data storage and electronic transfer
- Password-protected sampling recipes
- Integrates up to six external analog sensors
- Optional validation manual meets all pharmaceutical validation requirements

## APPLICATIONS

- Certification of cleanrooms to ISO or EC GMP standards
- Commissioning aseptic filling lines
- Monitoring vial sterilization, filling, freeze-drying, and capping
- Troubleshooting aseptic processing rooms and process flow

Without measurement, there is no control.



**LASAIR II****350L****550L**

<b>Channel thresholds:</b>	0.3, 0.5, 1.0, 5.0, 10.0, 25.0 µm	0.5, 1.0, 2.0, 5.0, 10.0, 25.0 µm
<b>Flow rate:</b>	50 L/min. (1.77 ft. <sup>3</sup> /min.) with ±5% accuracy	
<b>Laser source:</b>	Laser diode	
<b>Calibration:</b>	Materials traceable to US National Institute for Standards and Technology (NIST)	
<b>Maximum concentration @ 5% coincidence loss:</b>	> 350,000/ft. <sup>3</sup>	> 250,000/ft. <sup>3</sup>
<b>Counting efficiency:</b>	50% ±10% for most sensitive threshold (exceeds JIS standards)	
<b>Zero count level:</b>	Meets JIS standard	
<b>Data storage:</b>	3,000 data sets (includes particle and environmental data, plus location, time, etc.); data cannot be altered	
<b>Data download:</b>	Paperless download to Pharmaceutical Net; complies with 21CFR Part 11	
<b>Communication modes:</b>	Ethernet or RS-232, optional 4-20 mA output board, optional wireless Ethernet, optional USB download	
<b>Controlling software:</b>	Pharmaceutical Net, Facility Net, Microsoft® Internet Explorer Rev. 5.0+	
<b>Remote operation:</b>	Real-time control by Pharmaceutical Net; use web browser to operate unit, save/load recipes	
<b>Environmental sensors:</b>	Temp/RH probe; up to 4 external environmental sensors can be integrated via 4-20 mA inputs	
<b>Display:</b>	1/4 VGA color LCD screen	
<b>Languages:</b>	English, French, German, Italian, Japanese (Kanji), Korean, Mandarin (Classical or Simplified), Spanish	
<b>Printer:</b>	Built-in thermal printer	
<b>Reports:</b>	EC GMP and ISO certification reports validated to meet published standards, sample printouts, averages of multiple runs, print on alarm, sampling configuration	
<b>Key software features:</b>	Pharm mode, recipes, scheduled sampling, historical data filtering, sorting and review, password protection	
<b>External surface:</b>	ESD-minimizing KYDEX chassis, polyester display screen, and zinc-plated steel bottom	
<b>Cleaning materials:</b>	Bleach, formaldehyde, ethyl/isopropyl alcohol, peroxide/quaternary ammonium solutions	
<b>Sample inlet tubing:</b>	Tubing ID: 1/2 in. Maximum tubing length: 10 ft. (3 m)	
<b>Sample output filtering:</b>	Internally filtered to HEPA standards (>99.97% at 0.3 µm)	
<b>Power:</b>	85-264 V, 50-60 Hz	
<b>Battery:</b>	NiMH; expected operation 3-4 hrs.; External recharge: 2-3 hrs.; Internal recharge (@ 24°C): 80% by 4 hrs., 100% by 5-10 hrs.	
<b>Dimensions (h, w, d):</b>	11.5 x 10.7 x 9.0 in (29 x 27 x 23 cm)	
<b>Weight:</b>	Without battery: 12 lb. (5.4 kg), with optional battery: 15.5 lb. (7.0 kg)	
<b>Operating environment:</b>	Temperature: 15-35°C, Humidity: 10-85% non-condensing	

**Accessories**

**Included:** Printer paper, Operations Manual, sample probe, probe adapters, sample tubing, zero count filter, power cord, spare fuse.

**Optional:** Battery, external battery charger, external filter, HHIPA, temperature and relative humidity probe, air velocity probe, differential pressure probe, 4-20 mA data output board, USB data download, USB keyboard, TouchRAM recipe storage, validation manual, sample EOP and SOP documents

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 U. S. patents: 6, 167,107. Foreign patents pending.  
 Particle Measuring Systems, Inc. reserves the right to change specifications without notice.



Registration applies to the Boulder, Colorado facility

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