

# LASAIR® II 550L

## Meets GMP sampling requirements faster

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

The LASAIR II-550L from Particle Measuring Systems features a 50 LPM sampling rate, thus sampling one cubic meter in only 20 minutes, saving 15 minutes per zone! The software guides the user through the GMP process, collects the data, then prints a full final report.

Further, the 550L retains the features that have made the LASAIR II the world's most popular particle counter. It's extremely portable and reliable, with the features most useful to pharmaceuticals: data security, password-protected sampling recipes, as well as speedy, paperless, 21CFR11-compliant data download and storage.



### BENEFITS

#### Reduce Defects

- Detect breakdowns in isolator protection
- Protect against Colony-Forming Units (CFUs)
- Troubleshoot potential particle sources

#### Increase Productivity

- Save 15 minutes sampling time per clean zone
- Software-guided EC GMP and ISO sampling, with comprehensive, PASS/FAIL report
- Quick, paperless 21CFR11-compliant data download, either real-time or data dump to Pharmaceutical Net
- Removable battery with optional external charger allows continuous mobile use
- 9 language options for display and printouts

#### Cost Effective

- Use in ISO Class 4-8 rooms (FS209 Class 10 - 100,000)
- Rugged, chemical-resistant, ESD-minimizing KYDEX® casing for easy wipe-down sterilization
- Comprehensive validation manual simplifies meeting FDA and EC GMP requirements

### FEATURES

- 50 LPM flow rate samples 1.0 M<sup>3</sup> in only 20 min.
- Compact and convenient: Only 15.5 lb. (7.0 kg) with battery
- Built-in thermal printer
- Stores 3,000 samples
- Secure data storage and 21CFR11 transfer
- Password-protected sampling recipes
- Integrates up to 6 external analog sensors
- 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
- Monitoring for presence of Colony-Forming Units (CFUs) in parenteral drug production

Without measurement, there is no control.



**PARTICLE  
MEASURING  
SYSTEMS**  
www.pmeasuring.com

# Specifications

## LASAIR II

## 550L

<b>Channel thresholds:</b>	0.5, 1.0, 2.0, 5.0, 10.0, 25.0 $\mu\text{m}$
<b>Flow rate:</b>	50 LPM (1.77 CFM) with $\pm 5\%$ 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>	$> 250,000/\text{ft}^3$
<b>Counting efficiency, sizing accuracy:</b>	Manufactured units meet ISO 13323-2 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>	Speedy, paperless download to Pharmaceutical Net; complies with 21 CFR 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 <sup>®</sup> 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, plus integrates 4 external environmental sensors 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>	Cleanroom certification reports (EC GMP, ISO, or FS 209), 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>Sampling tubing:</b>	Tubing ID: 1/2 in. Maximum tubing length: 10 ft. (3 M)
<b>Sample output filtering:</b>	Internally filtered to HEPA standards ( $>99.97\%$ @ 0.3 $\mu\text{m}$ )
<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.

LASAIR<sup>®</sup> is a registered trademark of Particle Measuring Systems, Inc.  
KYDEX<sup>®</sup> is a registered trademark of Kleerdex Company.  
Microsoft<sup>®</sup> is a registered trademark of Microsoft Corporation.  
U. S. patents: 6, 167,107. Foreign patents pending.  
Particle Measuring Systems, Inc. reserves the right to change specifications without notice.

## AUTHORIZED REPRESENTATIVE



Registration applies to the Boulder, Colorado facility



**PARTICLE  
MEASURING  
SYSTEMS**  
[www.pmeasuring.com](http://www.pmeasuring.com)  
[info@pmeasuring.com](mailto:info@pmeasuring.com)

Particle Measuring Systems Headquarters  
5475 Airport Blvd., Boulder, CO 80301  
(303)443-7100 1-800-238-1801 FAX: (303)546-7331  
Instrument Service & Support: 1-800-557-6363  
Customer Response Center: 1-877-475-3317

Particle Measuring Systems Europe  
Tel: +44 (0)1684-581000

Particle Measuring Systems Japan  
Tel: 813-5298-8175

Particle Measuring Systems Singapore  
Tel: (65) 68460-500

Particle Measuring Systems China  
Tel: 86-21-53855332-18