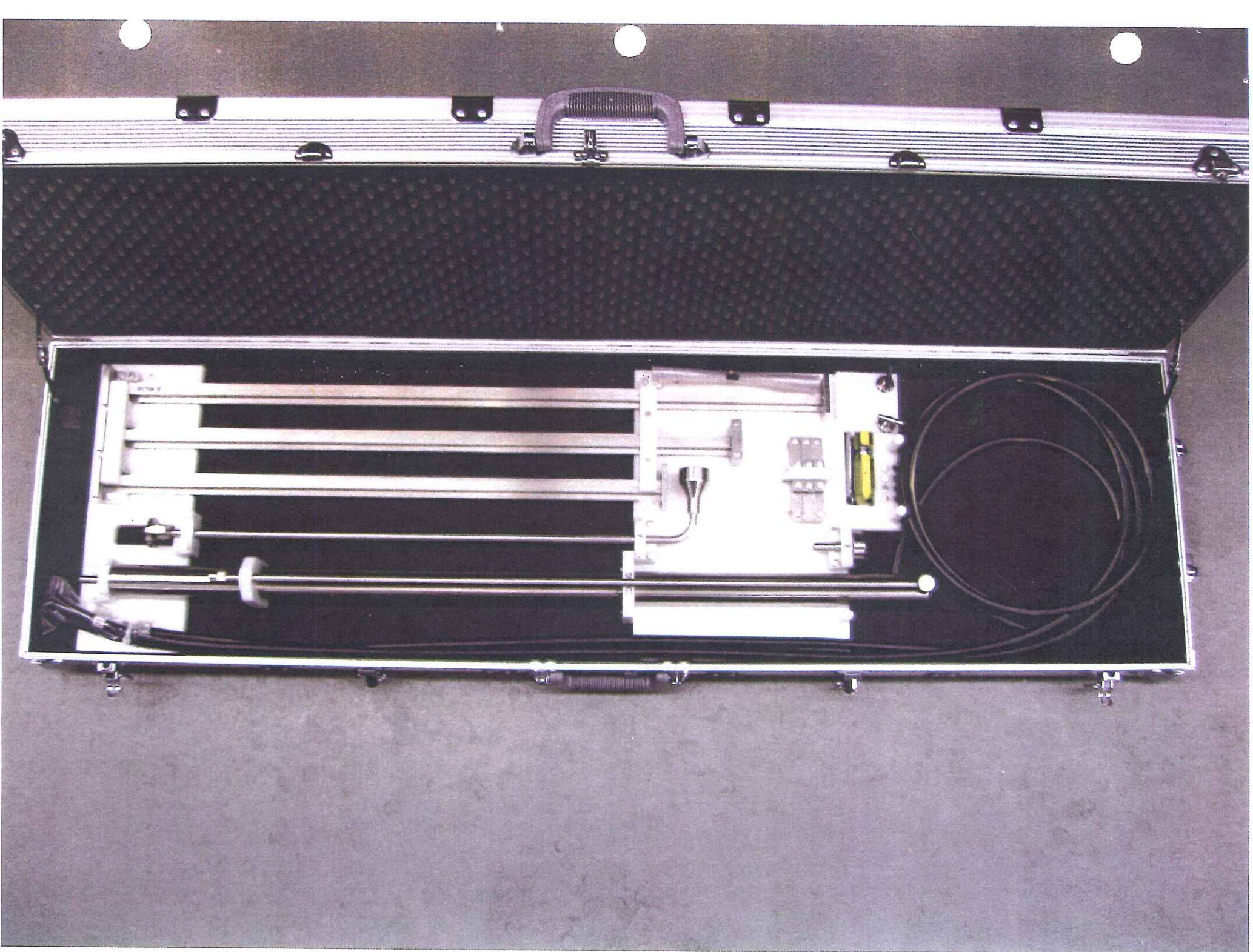




Sterilizing Tunnel Particle Counter Kit

Vials are sterilized prior to filling by passing through a sterilizing tunnel. The sterilizing tunnel has three (3) zones: Pre-Heating, Sterilizing, and Cooling. During validation each zone needs to be tested for non-viable particulates. The kit attached has all the applicable tools and materials needed to properly test each zone without damaging the particle counter itself with the hot air. The design incorporates the same isokinetic probe principles used for testing non-viable particulates inside the fill machine. All the components in the kit are reusable.



B - S. STERILIZING TUNNEL

PRE-HEATING ZONE

STERILIZING ZONE

COOLING ZONE

MEASURING POINTS

INFEED

TUBING TO PARTICLE
COUNTER

DMS TUBING
P/N MI-153

COOLING ZONE

IN

OUT

Ø1.500

Ø1.500

1.000

CENTER

MEASURING POINT
FOR PARTICLES
.110 mm OVER THE
CHAIN
- TYP. ON ALL POINTS

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28 CHERRY PARKWAY, LIVINGSTON, NJ 07039
ENGINEERING DEPARTMENT

DATE: 10/12/09
SCALE:
QUANTITY:
USED ON:

TITLE: SAUSCH + STROEBEL
STERILIZING TUNNEL
DWG. NO. 3322-1062-000/9
REV. 00

REV	DATE	REVISION

Lasair® II Particle Counter

Models 310A, 310B, 510A, 350L, and 550L



The Lasair II particle counter provides complete features in a compact, convenient particle counter. Its great portability, ease of use, and chemically-resistant easy-to-clean cover have made it the particle monitoring standard for pharmaceutical and high tech industries.

The Lasair II 350L and 550L models features a 50 liter/minute sampling rate to help meet the requirements of GMP Annex 1. The instrument samples one cubic meter in only 20 minutes and save 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, and then prints a full final report.

BENEFITS

Reduce Defects

- Real time measurement of defect causing particles
- More accurate measurements with patented sample flow, eliminating errors from manifold sampling
- Portable counter for localizing particle sources

Increase Productivity

- Choose from nine languages for display and print out
- Software guided EC GMP and ISO sampling
- Generates ISO and EC GMP validated reports
- Comprehensive validation manual available
- Operates in cleanroom from office computer via web browser: Setup, sample, display, print, etc.
- Continuous mobile use with instrument's removable battery, available with optional external charger
- Quick, CSV data (21 CFR 11-compliant) download via USB port for periodic or real-time review
- 50 LPM unit saves 15 min. sampling time/clean zone

Cost Effective

- Diode laser for reduced maintenance
- Best laser lifetime in the industry
- Use in up to ISO Class 8 rooms (FS209 Class 1-100,000) or in Class 9 with diluter
- Rugged, chemical-resistant, KYDEX® casing for easy wipe-down sanitation
- Comprehensive validation manual simplifies meeting FDA and EC GMP requirements

APPLICATIONS

- Cleanroom monitoring
- Trend analysis
- Manifold compatible
- Portable or dedicated use