



Maintain Compliance with Global Pharmacopeia Standards

With the HIAC 9703+ Pharmaceutical Particle Counter

ACCELERATING
answers

 **BECKMAN
COULTER**
Life Sciences

Accurate, Compliant Sub-Visible Particle Testing for Parenteral Drug Products



The HIAC 9703+ Pharmaceutical Particle Counter, combined with PharmSpec software, offers a robust solution for liquid particle analysis in pharmaceutical quality control. Designed specifically for final product testing of protein-based therapeutics and traditional injectable drugs, with built-in procedures to support global pharmacopeia requirements, including USP, Ph. Eur., JP, KP, and ChP, this system delivers fast, accurate, and repeatable results—ensuring confidence in product safety and consistency.

Features an HRLD Light Obscuration Sensor

This sensor is powered by laser diode technology, and its vibration-resistant design ensures:

- Stable illumination for consistent measurements
- Robust performance in demanding environments
- Repeatable and accurate particle counting



Flexible Sample Handling

Adapts to a wide range of samples with:

- Interchangeable sensors on one instrument
- Support for varied viscosities/volumes via
 - Multiple syringe sizes
 - Sampling probes
 - Multi-flow rate sensor calibration
- Small vial sampling kit for therapeutic protein injections – analyze with only 0.2 mL sample volume



Small vial clamp platform

Designed for Laminar Flow Cabinet Use to Minimize False Positives

Some standards (e.g., USP <788>, USP <787> & Ph. Eur. 2.9.19) recommend performing sub-visible particle testing in a laminar flow cabinet to minimize risk of airborne contamination.

The HIAC 9703+ instrument is designed to operate within laminar airflow environments to enable:

- HEPA-filtered airflow to pass over vials/glassware
- Reduced risk of false positives due to airborne particulates
- Full alignment with regulatory best practices

Benefits of PharmSpec Software



Supports Global Pharmacopeia Requirements

Ensure compliance with light obscuration methods as described in:

- USP <787>
- USP <788>
- USP <789>
- Ph. Eur. 2.9.19
- JP
- KP
- ChP



Supports 21 CFR Part 11 Compliance & ALCOA Principles

Built-in features support data integrity and regulatory compliance:

- Multi-level user rights with authentication and access control
- Comprehensive audit trail with secure, time-stamped records
- Electronic signatures with review/approval workflows
- Encrypted data storage to preserve original data integrity
- Database with archive, backup and recovery options



Custom Protocol Development

- Licensed Procedure Builder to create and manage SOPs
- Automated Pass/Fail calculations for streamlined analysis
- Flexibility to tailor methods to your specific testing needs



Smart System Alerts

Stay informed with notifications for:

- Bubble detection
- Sensor contamination
- Invalid configuration
- Sensor calibration due (with customizable alerts)

Multilingual Support

Available in:

- English
- French
- German
- Italian
- Japanese

Reports can be generated in any supported language or English on non-English systems.

HIAC 9703+ Instrument Specifications

HIAC 9703+ Sampler	
Dimensions (W x D x H)	343 x 337 x 482 mm (13.5 x 13.3 x 19 in.)
Weight	10.7 kg (23.6 lb)
Operating Conditions	5° C to 40 °C (41° F to 104° F) 0-80% relative humidity up to 31° C, decreasing linearly to 50% RH at 40° C
Sample Temperature	5° C to 40° C (41° F to 104° F)
Viscosity	< 50 cP
HRLD Sensor	
Dimensions (W x D x H)	203.2 x 38.1 x 38.1 mm (8 x 1.5 x 1.5 in.)
Weight	0.5 kg (1.1 lb)
Collection Optics	Light obscuration
Light Source	Class III B, 780 nm, 5 mW laser diode
Operating Conditions	7° C to 52° C (45° F to 125° F) 30-95% relative humidity, non-condensing
Measurement Range / Calibration Flow Rates	HRLD-150/150JA: 1.2-150 µm / 10, 20 & 25 mL/min HRLD-400: 2-400 µm / 10, 20, 25, 50 & 60 mL/min HRLD-600JS: 2-600 µm / 50, 60 & 100 mL/min
PharmSpec Software	
Operating System	Windows 10 Pro, Windows 11 Pro, Windows 11 Enterprise, Windows Server 2022 Standard (64 bit for all OS)
Processor	1.4 GHz CPU or better
Memory	4 GB RAM
Display	Super VGA video adapter & monitor, 1024 x 768 or higher
Hard Disk	8 GB available hard-disk space
Port	USB port to connect sampler

Ordering Information

Part Number	Description
2089105-01	HIAC 9703+ Sampler
2089250-150 2089250-150JA 2089250-400 2089250-600JS	HRLD-150 Sensor 1.2-150 µm HRLD-150JA Sensor 1.2-150 µm, high chemical resistance HRLD-400 Sensor 2-400 µm HRLD-600JS Sensor 2-600 µm, high chemical resistance
2089006-01	Small vial sampling kit, including: <ul style="list-style-type: none"> • Vial clamp assembly • Vial sampler probe 8.1 cm x 1.2 mm ID (3" x 0.047" ID) • Syringe, 1 mL XLP style
690-300-4809	Syringe, 25 mL XLP Style



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