



PharmSpec Software 3.6 is now available

For Your HIAC 9703+ Liquid Particle Counter



PharmSpec Version 3.6 provides **Microsoft® Windows 11** compatibility and helps your laboratory to maintain compliance with the most recent standards and recommendations from the US Pharmacopeia (USP) and the European Pharmacopeia (Ph. Eur.).

Upgrade Benefits:



Compliance

- Updated procedures to USP NF 2025 and Ph. Eur. 2.9.19
- New USP <788> System Suitability Pretest
- New Instrument Standardization Test for System Suitability Test As Found



Operating System

- Compatibility with Microsoft® Windows 11 Pro, Windows 11 Enterprise, and Windows Server 2022 (64-bit only)
- Still supporting compatibility with Microsoft® Windows 10



New Features

- Improved traceability with the possibility to add comments when a procedure run is aborted
- Improved automatic lockout, automatic logout and system lockout features



Operational Qualification

- Confirmation your instrument meets OEM specifications
- Confidence your instrument is producing accurate, reliable data
- Addresses safety concerns
- Validation of compliance with prescribed regulations



Learn how to upgrade: beclis.co/pharmspec-software-upgrade



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Re: PharmSpec 3.6 Software Release

We are pleased to announce the official release of PharmSpec 3.6 for HIAC 9703+ liquid particle counters. This update brings significant enhancements designed to ensure compliance with the latest industry standards.

Key Highlights of PharmSpec 3.6

- **Pharmacopeia Alignment** with updated procedures that align with USP NF 2025 and Ph. Eur. 11 (Please note that appropriate licenses may be required for these specific updates).
- **Enhanced calibration workflows**, updated based on the latest USP recommendations
- **Windows 11 Compatibility**

For a comprehensive list of all changes, please refer to the detailed release notes.

Additional Updates

- **Calibration Procedure**

In accordance with USP guidance, our calibration procedure has been updated and now includes an “Environment” test prior to System Suitability Test, and a “System Suitability Test As Found” performed prior to conducting the calibration procedure. Facilitate this, a new IST standard method, “System Suitability Test As Found”, has been added to PharmSpec 3.6.

- **Documentation Updates**

You may notice updates in the format and content of documents provided with new HIAC 9703+ instruments and after preventive maintenance. This standardization ensures consistency, while Instrument Standardization Tests (IST) and quality control procedures themselves remain unchanged.

Important Upgrade Information

Please review the following critical information before proceeding with any software upgrade.

- Review instructions provided in the *PharmSpec Instructions For Use*, available on our website, for detailed guidance.
- Back up your database before upgrading.
- Upgrades on Microsoft Windows 10 are supported only from PharmSpec version 3.5.32.
- Upgrades of PharmSpec 3.5.32 installed on Microsoft Windows 11 are not supported.
- Microsoft Windows 10 Pro Workstation does not support upgrading to version 3.6.

For further assistance and common questions, please refer to the FAQ section below or contact our support team.

Sincerely,

Matthieu Chausseau, Ph.D.



Senior Technical Product Manager- Particle QC Portfolio

Beckman Coulter Life Sciences

PharmSpec v3.6 Release Notes

Software Part Number 2086718, License Part Number 700060GP

PharmSpec v3.6.1

Key updates:

1. Updated supported platforms to Microsoft® Windows 10 Pro, Windows 11 Pro, Windows 11 Enterprise, and Windows Server 2022 (64-bit only).
2. Upgraded database engine to SQL Server Express Edition 2022.
3. Added the SQL Server client ('ODBC Driver 17') to ensure support for TLS 1.2.
4. Added support for USP NF 2025, USP <788> System Suitability Pretest, and Ph. Eur. 11.
5. Implemented automatic lockout, automatic logout, and system lockout features.
6. Introduced new IST - Suitability Test As Found.
7. Provision to add a comment when aborting a procedural test.
8. Captured the comment in the audit trail and report when a procedural test is aborted manually or by instrument.
9. Included FTDI driver as part of the installer.
10. Elevated privileges for the PharmSpec database utility tool.

Bug fixes:

1. Fixed issue where PharmSpec 3.5 missed sampler details from hardware in printouts.
2. Fixed bug where user account status did not change from active to inactive when disabled.
3. Fixed installation failure due to PharmSpecUsr not being created in the internal SQL database.
4. Fixed inconsistencies in certain fields in the audit trail.
5. Resolved an issue where review comments from a previous run were incorrectly applied to a subsequent run performed in the same instance.
6. Fixed an issue where Review and Approve E-Signature timestamps showed identically on reports.

Known Issues:

1. The software does not timeout if communication is interrupted while the message "waiting for instrument to start" is displayed.
2. Unable to calculate Electronic Resolution with voltages greater than 1000mV.
3. During the installation, some actions may take up to 10 minutes with no visual progress indicator shown on the monitor.

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