

AccuSizer® A7000 SIS Liquid Particle Counter/Particle Size Analyzer

*The Accusizer A7000 SIS for USP <788>
particulate matter injections testing*

The new AccuSizer® A7000 SIS system is the most advanced instrument available for USP <788> testing. It meets or exceeds all requirements in USP <788> by providing size and count data at the required 10 and 25 µm and easily passes all system standardization tests described in USP <1788>. The unique technology designed into the A7000 SIS provides capabilities not available in any other liquid particle counter due to each component being the highest specification/performance on the market. The A7000 is not just a liquid particle counter; it is a sophisticated particle size analyzer as well.

- Measure size and concentration from 0.5 – 400 µm
- Sample conservation after measurement
- 1024 size channels defining the complete distribution
- 21 CFR 11 features with security management

Classical light obscuration sensors familiar to pharmaceutical scientists performing USP <788> testing typically have a lower particle size limit near 2 µm. The LE400 sensor uses two detectors (extinction + scattering) to extend the range to 0.5 – 400 µm.

A 1024 channel pulse height analyzer provides high resolution results so this is not just a counter – use it as a particle size analyzer on any of your other samples. The AccuSizer software allows conversion from number to volume distribution so results can be compared to other techniques like laser diffraction.

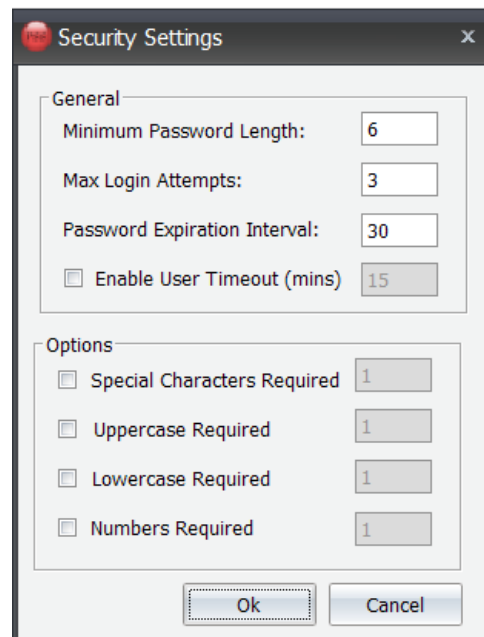
The AccuSizer software is a sophisticated package that automates USP <788> testing including pass/fail criteria and acceptance approval.



AccuSizer 7000 SIS system



LE400 sensor principle



Software security settings

SPECIFICATIONS*

| | |
|-----------------------|---|
| Principle | Single particle optical sizing (SPOS) for high resolution particle size and concentration (particles/mL) analysis. Counts and sizes particles individually, not an ensemble method. |
| Configurations | Includes sensor, counter and syringe sampler system. Syringe volumes of 0.5 – 25 mL, 1024 size channels, conforms to USP <788>. |
| Sensor | LE400-05; 0.5 – 400 µm when used alone, light extinction and scattering, summation calibration, particle sensitivity to 10 ppt, concentration limit 10,000 particles/mL, size accuracy 2%, count accuracy 10%, recommended flow rate = 30 mL/min, but can be calibrated at other flow rates depending on configuration. |
| Sample | 150 µL – 25 mL (or larger with multiple syringe pulls). Sample is recovered after the measurement process. |
| Options | Autosampler Magnetic stirrer for autosampler IQ/OQ documentation for user or complete PSS installation 21 CFR Part 11 software |
| Power | 100 – 120 VAC, 60 Hz or 220 – 240 VAC, 50 Hz |

Screen captures from the USP <788> software features

Physical Properties - USP 788

Volume per container (mL)

Number of containers

| Sample | Run Date/Time | Containers (#) | Container Volume (mL) | Sample Volume (mL) | ≥ 10 µm (#) | ≥ 10 µm (#/Container) | ≥ 25 µm (#) | ≥ 25 µm (#/Container) |
|--|------------------|----------------|-----------------------|--------------------|-------------|-----------------------|-------------|-----------------------|
| USP Test SVP Preservation Activated Rep. 2 | 12/12/2016 18:09 | 25 | 1.0 | 5.0 | 2 | 0 | 0 | 0 |
| USP Test SVP Preservation Activated Rep. 3 | 12/12/2016 18:10 | 25 | 1.0 | 5.0 | 7 | 1 | 1 | 0 |
| USP Test SVP Preservation Activated Rep. 4 | 12/12/2016 18:11 | 25 | 1.0 | 5.0 | 2 | 0 | 0 | 0 |

| ≥ 10 µm Mean (#) | ≥ 10 µm Mean (#/Container) | ≥ 25 µm Mean (#) | ≥ 25 µm Mean (#/Container) |
|------------------|----------------------------|------------------|----------------------------|
| 4 | 0 | 0 | 0 |

| TEST Criteria | RESULT |
|---|--------|
| (Mean #/Container ≥ 10 µm) ≤ 6000 /Container AND (Mean #/Container ≥ 25 µm) ≤ 600 /Container (PASS) | PASS |

Setup Protocol

Instrument | Channels/Physical Properties | Report

General

Measurement volume mL Replicates

Syringe Flow Rate mL/min Tare volume mL

Size threshold µm Air gap volume mL

Sample run time sec Delay between replicates sec

Perform flush before each replicate Pull tare volume before each replicate

Low volume measurement Pull/flush mixing

Preserve sample

Cycles Volume mL Flow Rate mL/min

Sensor Mode Extinction Summation

Background mode

Background measurement counts/mL

Stirrer

Speed % Delay sampling until stirrer has run for: seconds

* Sample dependent and may require hardware options, subject to change without notice.

FOR MORE INFORMATION

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