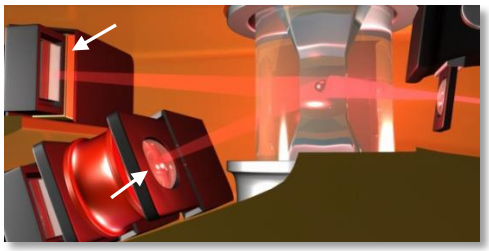
The AccuSizer A7000 SIS for USP <788> Particulate Matter Injections Testing

The new PSS 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 & 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.

AccuSizer 7000 SIS System

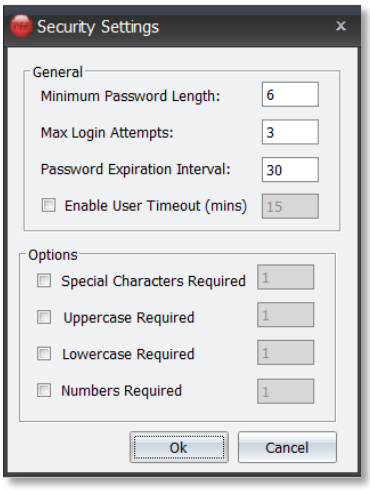
- Measure size and concentration from 0.5 – 400 µm
- Sample conservation after measurement
- 512 size channels defining the complete distribution
- 21 CFR 11 features with security management



LE400 Sensor Principle

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 512 channel pulse height analyzer provides high resolution results so this isn't 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.



Software Security Settings

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

Particle Sizing Systems
Building solutions one particle at a time.
PSS

AccuSizer A7000 SIS
Technical 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, 512 size channels, conforms to USP <788>

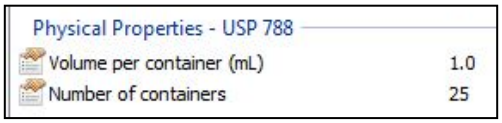
Sensor LE400-05; 0.5-400 µm when used alone, light extinction and scattering, summation calibration, particle sensitivity to 10 PPT, concentration limit 9000 particles/mL, size accuracy 2%, count accuracy 10%, recommended flow rate = 30 mL/min, but can be calibrated at other flow rates depending on configuration.

Sample 150 µL - 25 mL (or larger with multiple syringe pulls). Sample is recovered after the measurement process

Options
Auto-sampler
Magnetic stirrer for Autosampler
IQ/OQ documentation for user or complete PSS installation
21CFR Part 11 software

Power 100-120 VAC, 60 Hz or 220-240 VAC, 50 Hz

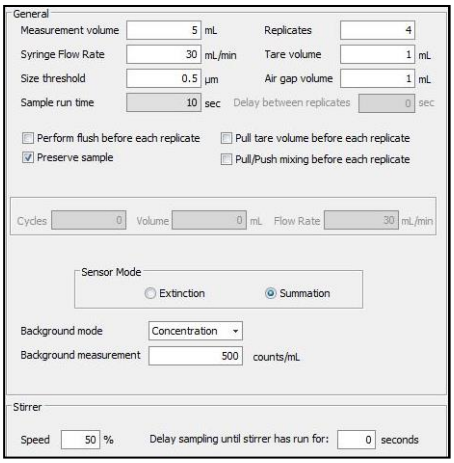
Screen captures from the USP <788> software features



Sample	Run Date/Time	Containers (#)	Container Volume (mL)	Sample Volume (mL)	≥ 10 um (#)	≥ 10 um (#/Container)	≥ 25 um (#)	≥ 25 um (#/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 um Mean (#)	≥ 10 um Mean (#/Container)	≥ 25 um Mean (#)	≥ 25 um Mean (#/Container)
4	0	0	0

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



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

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