

AccuSizer® A2000 USP Liquid Particle Counter

The most advanced instrument available for USP <788> Particulate Matter Injections Testing

The new AccuSizer® A2000 USP 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 A2000 USP counter provides capabilities not available in any other liquid particle counter due to each component being the highest specification/performance on the market. The A2000 USP 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
- 64 size channels defining the complete distribution
- 21 CFR 11 features with security management
- Up to 32 user defined channels

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 64 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.

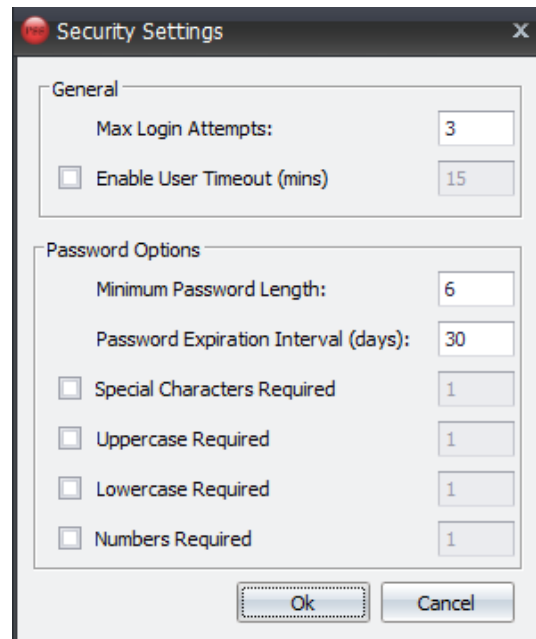
The AccuSizer software is a sophisticated package that automates USP <788> testing including pass/fail criteria and acceptance approval.



AccuSizer A2000 USP System



LE400 sensor principle



AccuSizer 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, 64 size channels, conforms to USP <788>, 21 CFR Part 11 software.
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	Autosampler Magnetic stirrer for autosampler IQ/OQ documentation for user or complete PSS installation
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)	1.0
Number of containers	25

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

The screenshot shows the 'Setup Protocol' window with the following settings:

- General:** Measurement volume: 5 mL, Replicates: 1, Syringe Flow Rate: 30 mL/min, Tare volume: 1 mL, Size threshold: 0.5 µm, Air gap volume: 0 mL, Sample run time: 10 sec, Delay between replicates: 0 sec.
- Options:** Perform flush before each replicate, Pull tare volume before each replicate, Low volume measurement, Preserve sample, Pull/Push mixing: None.
- Summary:** Cycles: 0, Volume: 0 mL, Flow Rate: 30 mL/min.
- Sensor Mode:** Extinction (radio button), Summation (radio button).
- Background mode:** Concentration, Background measurement: 500 counts/mL.
- Stirrer:** Speed: 40 %, Delay sampling until stirrer has run for: 0 seconds.

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

FOR MORE INFORMATION

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Corporate Headquarters
129 Concord Road
Billerica, MA 01821
USA

Customer Service
Tel +1 952 556 4181
Fax +1 952 556 8022
Toll Free 800 394 4083

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