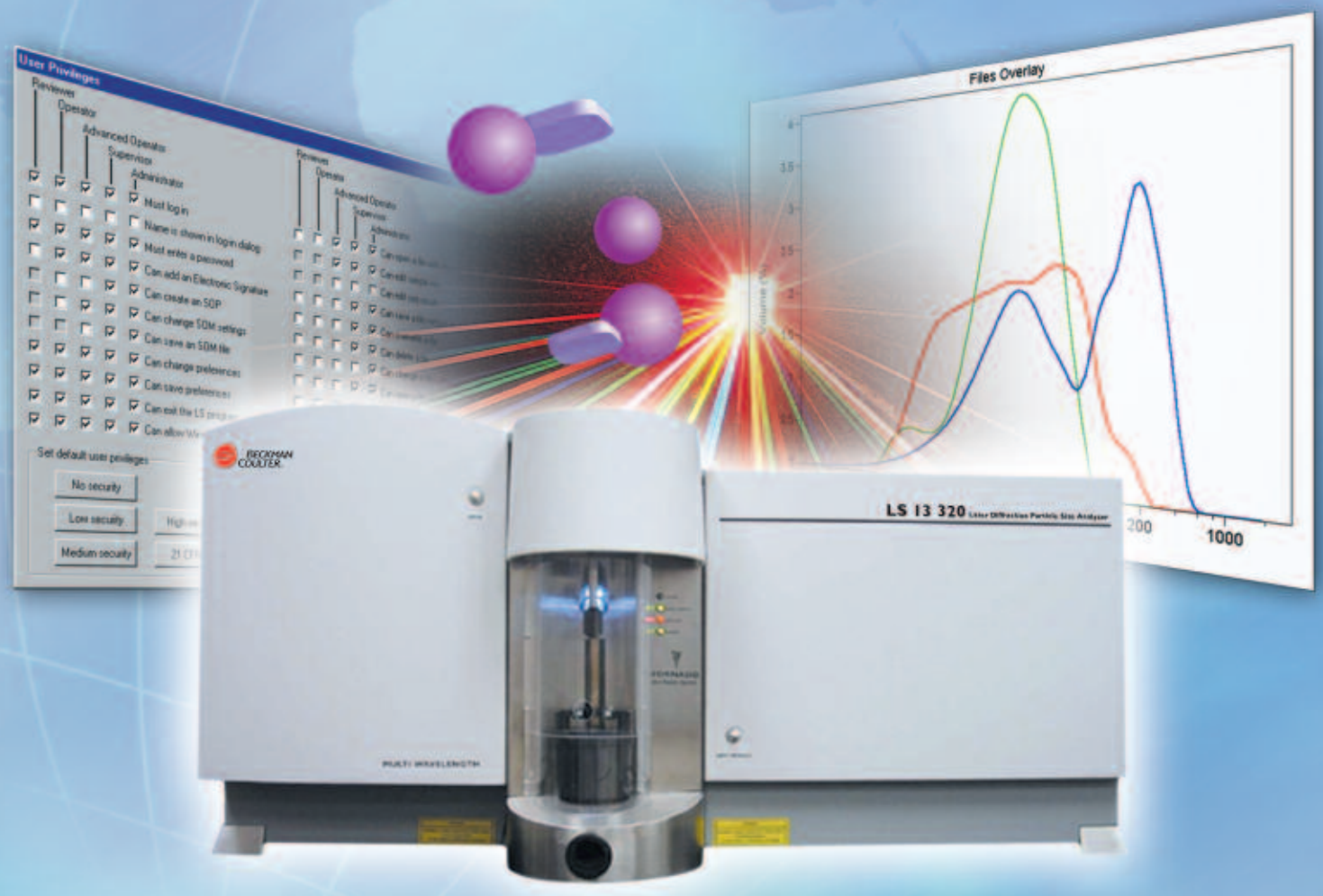
BECKMAN COULTER®

Delivering consistent results to meet compliance requirements

LS™ 13 320 SERIES

PARTICLE SIZE ANALYZER



PIDS · ISO 13 320 · 21 CFR Part 11

Trending · SOMs · SOPs

The **LS 13 320 series** is the most versatile and sophisticated laser diffraction particle size analyzer available today. Using the Fraunhofer and Mie theories of light scattering, the LS 13 320 series offers the highest resolution, reproducibility and unsurpassed accuracy. All this, so you can count on the results generated by the LS 13 320 Series. In fact, the LS 13 320 can measure unknown sample distributions without having the analyst guess the type of distribution mode to preprogram the instrument.

Depending on your applications and requirements, two options of optical benches are available: the single-wavelength system covering a size range from 0.4 µm to 2,000 µm and the flagship multi-wavelength system incorporating Beckman Coulter's patented Polarization Intensity Differential Scattering (PIDS) technology covering a size range from 0.04 µm to 2,000 µm.

Our latest generation of sample-handling modules has been designed for flexibility and convenience, offering varying degrees of automation. To save operators valuable time, all modules "auto-dock" in seconds and are automatically configured and recognized by the optical bench due to their "plug-and-play" capabilities. To facilitate meeting compliance requirements, all the module functions are fully controlled via Standard Operating Methods (SOM's) and Standard Operating Procedures (SOP's), making their operation simple and ensuring that all instrument conditions and settings remain constant for any given sample. If full automation is required, the Auto Prep Station is available with up to 30 samples for walk-away routines.

Equally at home in research and development, quality control and manufacturing, the LS 13 320 particle size analyzer provides the analyst with a system that is easy to use, producing fast and reliable results, yet technically advanced for dry, aqueous and non-aqueous samples to satisfy all your particle sizing needs.

Your integrated *smart solution* for *consistent* results run-after-run.

Aqueous Liquid Module *(ALM)*

- For samples requiring suspension in aqueous systems
- Auto rinsing, auto filling and auto dilution for maximum speed and throughput
- Sample sonication for the ultimate dispersion control
- When coupled to the Auto Prep Station offers full automation

Micro Liquid Module *(MLM)*

- Use when only small quantities of sample are available
- Small amounts (12 mL) of volume required, particularly useful for hazardous dispersants as waste is minimized
- For use with both organic solvents and aqueous systems, giving the user maximum flexibility

Tornado Dry Powder System *(DPS)*

- Measures entire sample as required by the ISO 13 320 standard
- No sample preparation needed
- Fully automatic walk-away operation
- User-selectable vacuum pressure for maximum dispersion control

Universal Liquid Module *(ULM)*

- Fully automatic, with auto dilution, auto filling and auto rinsing for the ultimate ease of use
- Analyzes samples suspended in aqueous as well as non-aqueous diluents for maximum flexibility
- Hazardous waste is contained in a monitored vessel to avoid spillage and provide safe operation
- A variable speed pump allows for total dispersion control of your sample, from delicate emulsions to heavy particulates

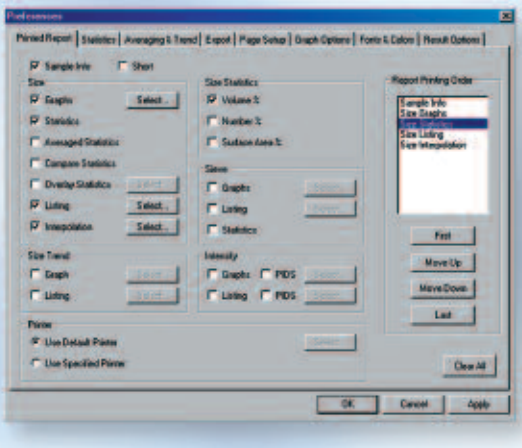
Standardize your process with

Standard Operating Methods **and** *Procedures*

Establishing the SOM is *quick, simple* and *foolproof*

With Standard Operating Methods and Procedures you can ensure your analyses are the same run after run.

The use of SOM's and SOP's guarantee consistency and uniformity of your results, regardless of the instrument settings, operators and locations.



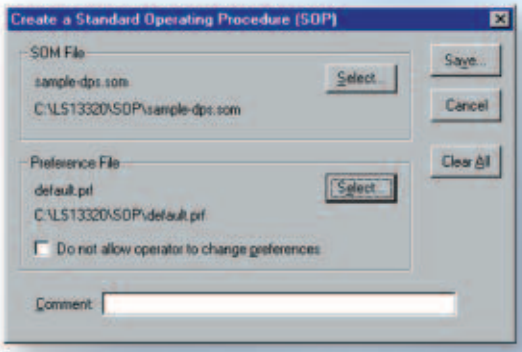
STEP 1:
Set up your SOM and sample description

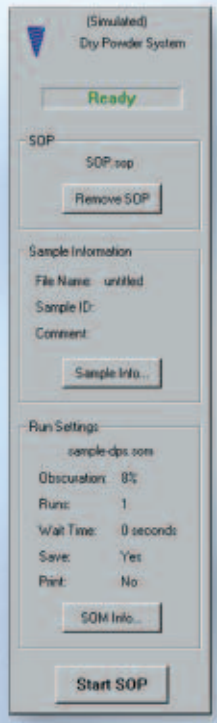
STEP 2:
Identify your sample

STEP 3:
Set up your analysis parameters

STEP 4:
Choose your optical model

STEP 5:
Save your SOM





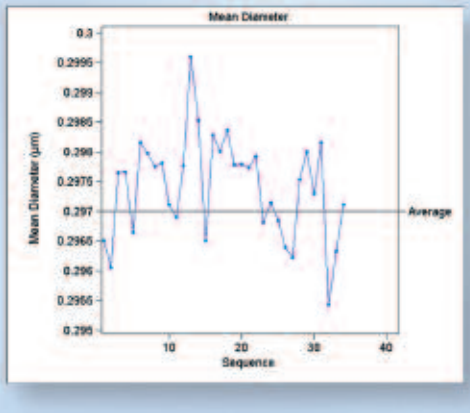
Standard Operating Procedure (SOP)

Your solution to consistent results and reports.

Every element of the analysis from method set-up to the final printout can be implemented into a user definable Standard Operating Procedure (SOP). Just select an SOM and Preference file and save them as an SOP. Then click "Start SOP" and you're on your way to consistent results.

Size Trend

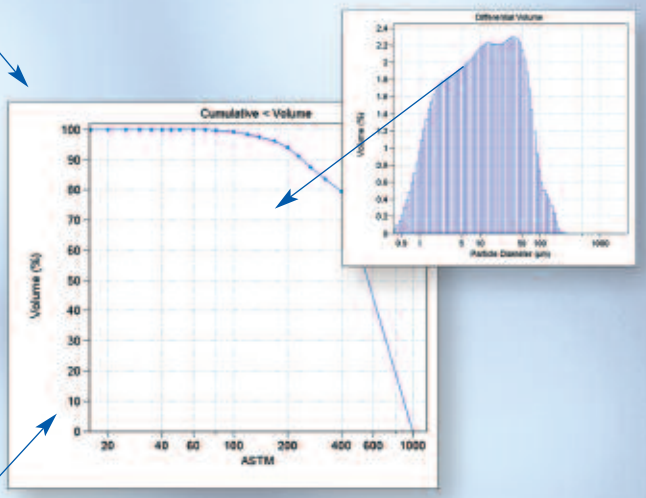
The Size Trend function is used to plot the statistics of several sample runs on one graph or report. This can help you keep track of your specific process since the files can be updated as often as is necessary.



Sieve Analysis

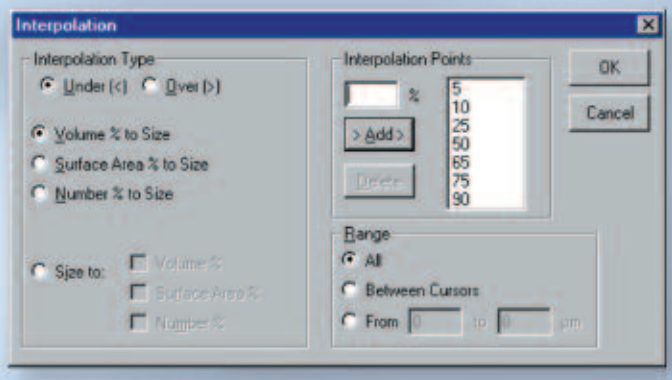
The Sieve Analysis function allows you to view the data obtained from your LS 13 320 in a sieve format if you need to compare old sieve data.

ASTM	Cum. < Volume %
999	0
400	79.5164
325	83.6407
270	87.4781
230	91.1161
200	94.0814
170	96.2735
140	97.5502
120	98.4782
100	99.2856
80	99.8087
70	99.9786
60	99.9993
50	100
45	100
40	100
35	100
30	100
25	100
20	100

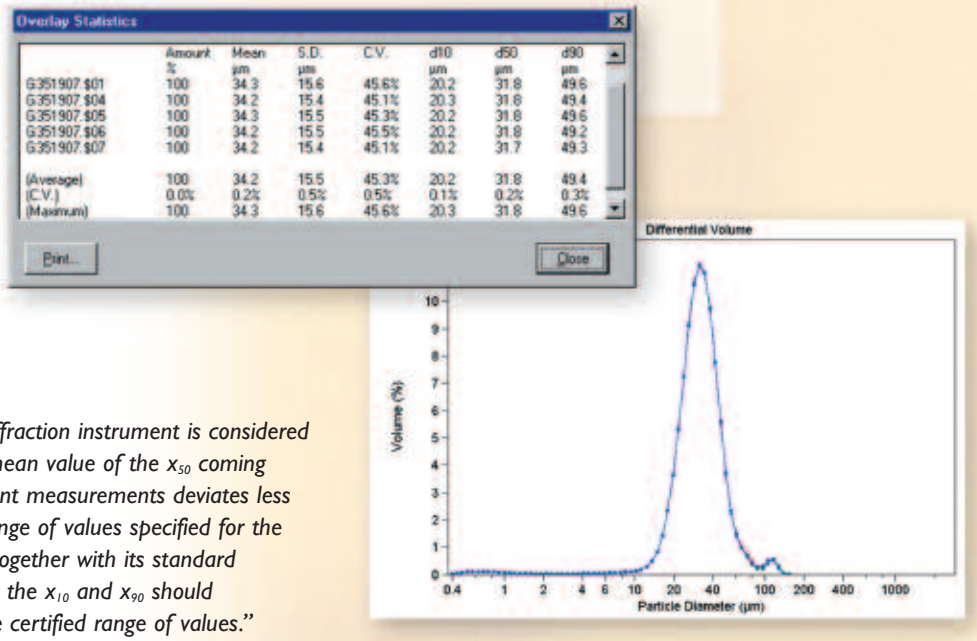


Interpolation

The LS 13 320 software can be used to create sample reports that will arrange the data to conform to a set of user defined "size classes" through the Size Interpolation function.

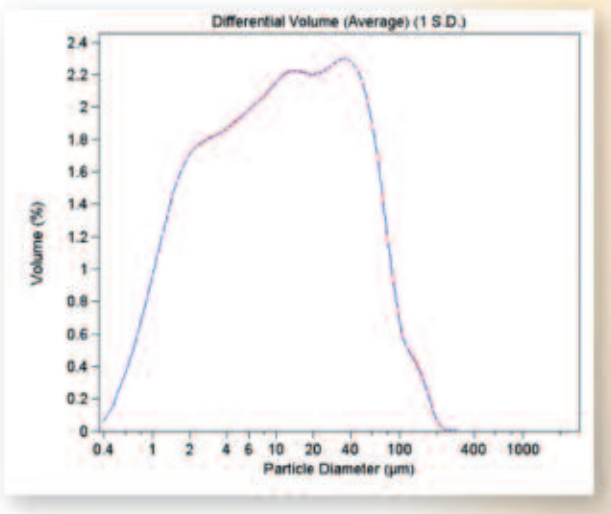


With the publication of the International Standard IS0 13320-1, Particle size analysis – laser diffraction methods – Part 1: General Principles, it becomes possible for users and potential users of such equipment to evaluate them within a scientific frame of reference.



Accuracy

"The response of the laser diffraction instrument is considered to meet this standard if the mean value of the x_{50} coming from at least three independent measurements deviates less than 3% from the certified range of values specified for the material, i.e. the mean value together with its standard deviation; the mean values for the x_{10} and x_{90} should deviate less than 5% from the certified range of values."



An average of 10 separate runs showing the spread of results with error bars of one standard deviation.

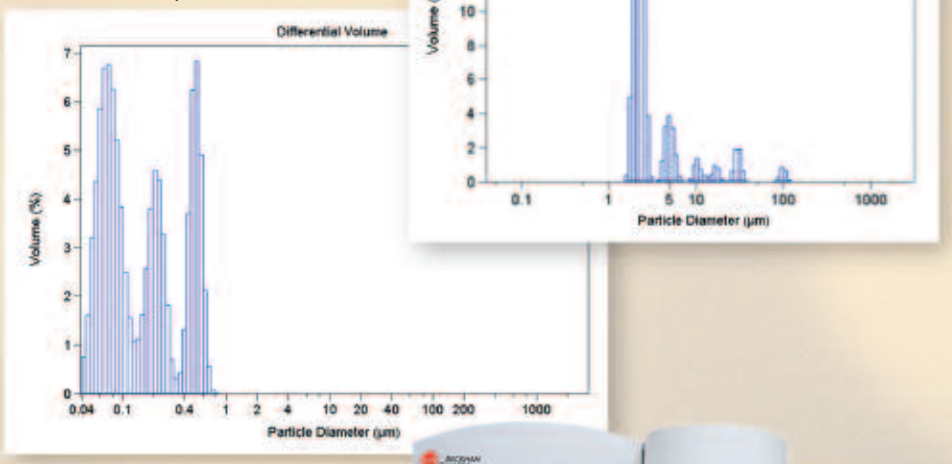
Repeatability

"The repeatability of characteristic particle sizes in size distributions should be as follows: for any chosen central value of the distribution, e.g. the median size (x_{50}), the coefficient of variation should be smaller than 3%. Values at the sides of the distribution, e.g. x_{10} and x_{90}, should have a coefficient of variation not exceeding 5%."

Resolution; Sensitivity

"The resolution of the particle size distribution, i.e. capability to differentiate between different particle sizes, and the sensitivity for small (extra) amounts of particles of certain size are restricted by the following factors:

- *number, position and geometry of the detector elements;*
- *their signal to noise ratio;*
- *fine structure in the measured scattering pattern;*
- *difference in scattering pattern between size classes;*
- *actual size range of the particulate material;*
- *adequacy of the optical model;*
- *smoothing applied in the deconvolution procedure."*



How does the LS 13 320 *comply?*

Accuracy

- Custom designed X-shaped detector array allows the most accurate measurement to be obtained for the characterization of the scattering pattern, which ultimately leads to the most accurate results possible
- The patented PIDS system delivers unrivaled accuracy in the submicron region by taking 36 detection measurements for this region alone. No other comparable system offers this degree of capability in the submicron region

Resolution; Sensitivity

- High number of log-spaced detectors provide a clear difference in scattering pattern between size classes
- Continuous averaging amplification circuitry to increase signal-to-noise ratio
- No requirement to pre-select curve fitting routines as with other manufacturers, meaning the user has no need to have an understanding of the nature of the distribution prior to the analysis
- Full and complete invocation of both Fraunhofer and Mie theories, including the use of multi-wavelength modeling, ensures the user can make most benefit of the available raw data

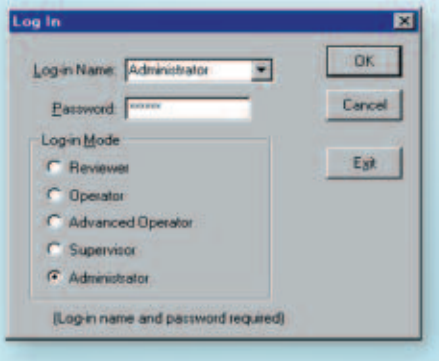
Repeatability

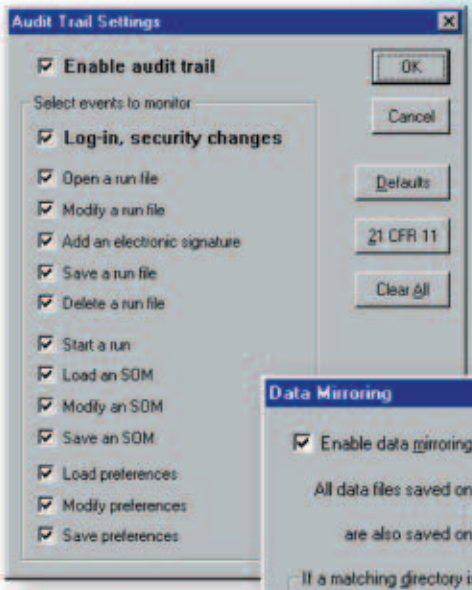
- The automatic alignment system ensures accurate angular calibration of the laser with respect to the optical path. The benefit of this is that the scattered light from any particulates in the sample cell will fall on the correct detectors from an angular perspective, offering reproducible results time after time
- High quality components throughout the LS 13 320 design

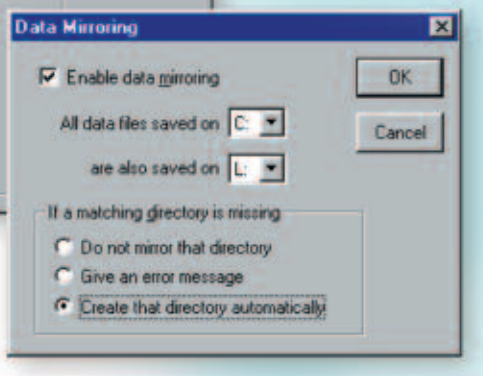
Security

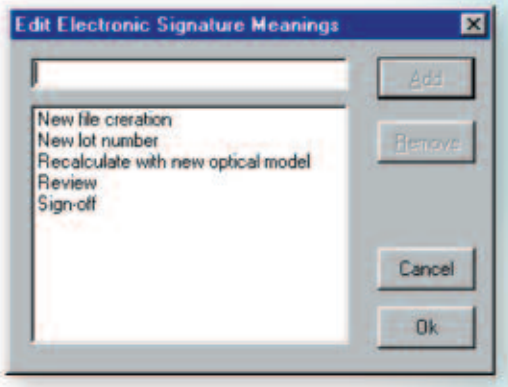
You are one click away from compliance

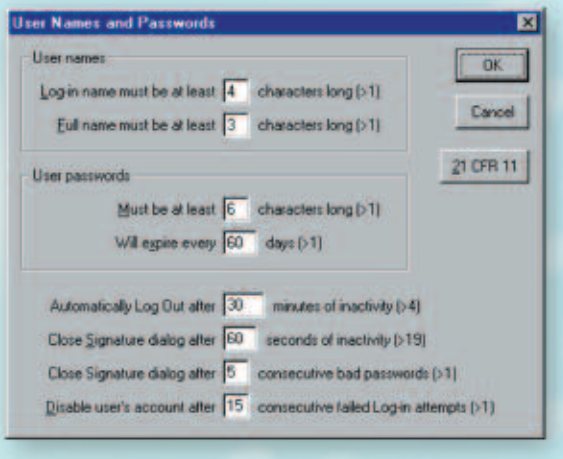
The LS 13 320 software comes with a configurable security system. The user can choose between 5 levels of security, from No security to 21 CFR Part 11, the choice is yours. Choosing 21 CFR Part 11 configures the software to be compliant to 21 CFR Part 11, the FDA regulation covering electronic signatures and records.







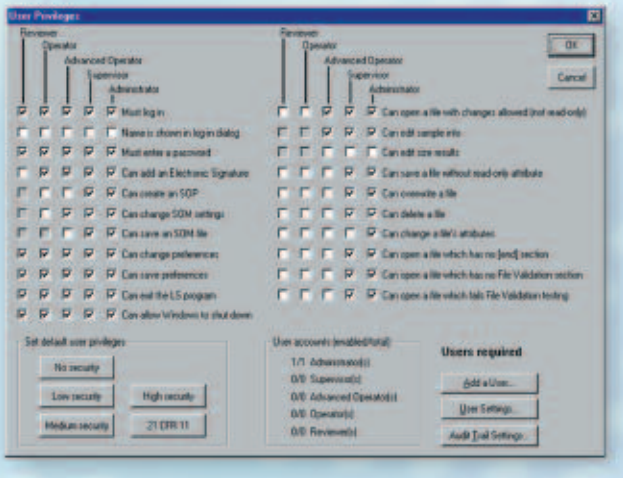




Establishing a *strong partnership* for the future

Regulatory Compliance

21 CFR Part 11



The Electronic Records and Electronic Signatures Rule (21 CFR Part 11) was established by the FDA to define the requirements for submitting documentation in electronic form and the criteria for approved electronic signatures. This rule, which has been in effect since August 20, 1997, does not stand in isolation; it defines the standards by which an organization can use electronic records to meet its record-keeping requirements. Organizations that choose to use electronic records must comply with 21 CFR Part 11. It is intended to improve an organization's quality control while preserving the FDA's charter to protect the public. Since analytical instrument systems such as the LS 13 320 generate electronic records, these systems must comply with the Electronic Records Rule. By selecting the 21 CFR Part 11 option in the software, the system automatically reconfigures to comply with these regulations. In addition to the 21 CFR Part 11, the software offers other security levels that may be customized by the user.

V-Check Program

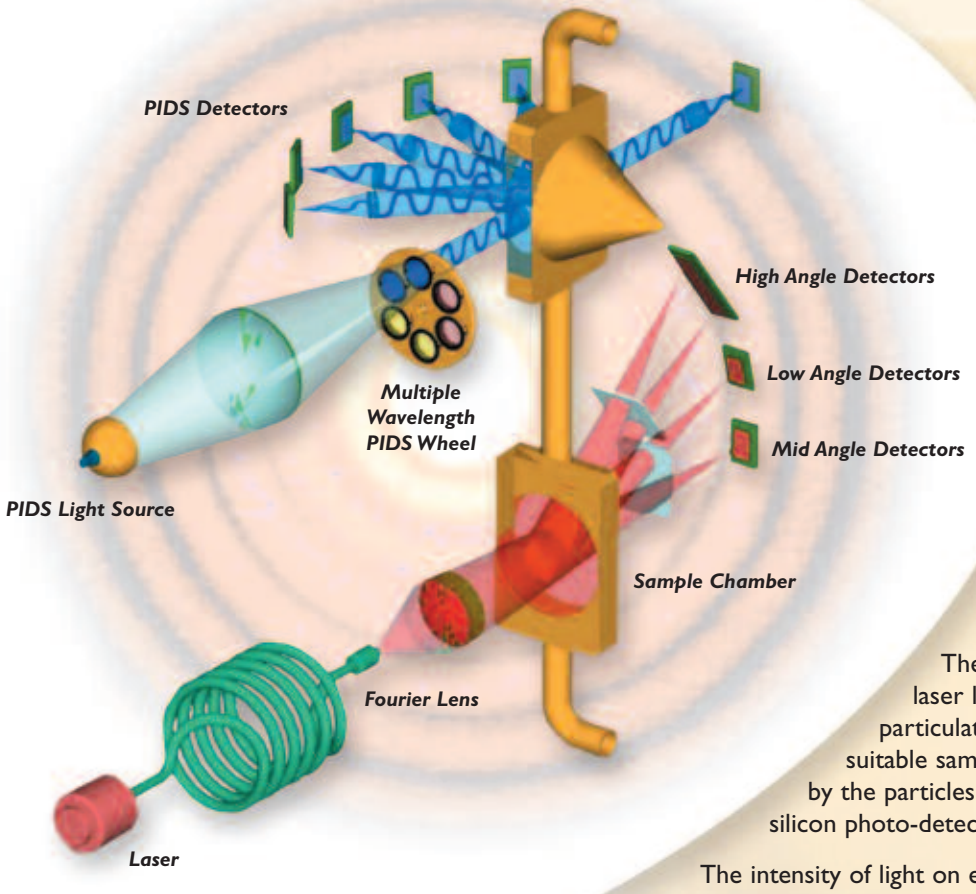
Beckman Coulter, Inc. complies with current Good Manufacturing Practices (cGMP's). This gives Beckman Coulter a unique understanding of the strict requirements that users in regulated industries are subjected to. As a result, Beckman Coulter has established a comprehensive program to address all aspects of the instrument validation.

The V-Check program is a comprehensive package that addresses all appropriate aspects of a product's life cycle, from instrument development to ongoing performance verification including System Qualification (SQ), Design Qualification (DQ), Instrument Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ). The V-Check program contains all the necessary documentation for instrument validation. This documentation is required to show auditors and investigators proof of proper instrument validation. It consists of a number of functional inter-linked components, which have been designed to give the user assurance that the product is fit for the purpose that it has been designed for and will perform on a consistent basis for these tasks. Where other instrument manufacturers leave off, Beckman Coulter and the V-Check program assists with ongoing quality checks of the instrument (PQ). This proves that it is important to consider products from a manufacturer that not only understands your needs, but is also willing to develop a Partnership for the future.

Beckman Coulter FIRSTS:

- FIRST *company offering wide dynamic range without changing lenses*
- FIRST *company with auto-alignment*
- FIRST *company to utilize four wavelengths*
- FIRST *and only company to incorporate patented scattering technology – PIDS*

WHERE WE LEAD,
others follow.



The scattering of light is one of the most widely used techniques for measuring the size distribution of particles.

It is a fast and flexible technique that offers even the novice user the chance to obtain high quality data.

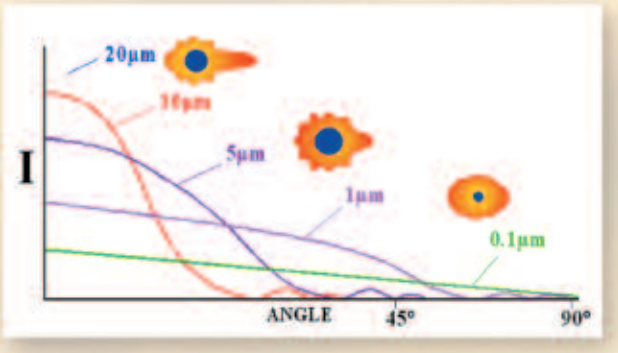
The basis of the method is simple: a laser light source is used to illuminate particulates, usually contained within a suitable sample cell. The light scattered by the particles is then detected by silicon photo-detectors.

The intensity of light on each detector measured as a function of angle, is then subjected to mathematical analysis using a complex inversion matrix algorithm. The result is a particle size distribution displayed as volume % in discrete size classes.

What is it and how does it work?

Why use PIDS for sizing sub-micron particles rather than the standard forward low-angle scattering technologies employed by other instrument manufacturers? Particles below a few microns in diameter have very similar light scattering patterns that are alike in both shape and intensity. These physical properties make it difficult to distinguish the differences between such patterns, which means inaccurate sizing with low resolution, resulting in a high degree of uncertainty when resolving the actual particle size.

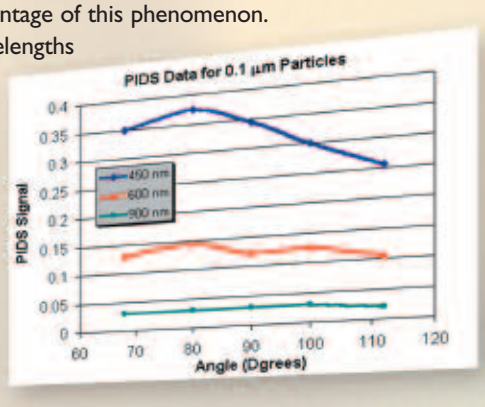
Large particles scatter light strongly at low angles and with readily detectable maxima and minima in the scattering pattern. This means that detectors placed at low angles relative to the optical path and with sufficient angular resolution can detect these maxima and minima. Conversely small particles scatter light weakly and without any discernible maxima and minima until extremely high angles of measurement are reached. This makes the detection and the resolution of the scattering pattern difficult.



Manufacturers have adopted different solutions to overcome these limitations with varying degrees of success. Most efforts have focused on the measurement of back-scattered light. While such strategies help they are not complete solutions. For this reason Beckman Coulter developed the PIDS system, allowing for the first time a complete solution to the problem of sub-micron sizing. The technology employed in PIDS is elegant yet simple and takes advantage of the Mie theory of light scattering.

PIDS relies upon the transverse nature of light i.e., that it consists of a magnetic vector and an electric vector at ninety degrees to it. If for example the electric vector is 'up and down' the light is said to be vertically polarized. When a sample is illuminated with a light of a given polarized wavelength, the oscillating electric field establishes a dipole, or oscillation, of the electrons in the sample. These oscillations will be in the same plane of polarization as the propagated light source. The oscillating dipoles in the particles radiate light in all directions except that of the irradiating light source.

PIDS takes advantage of this phenomenon. Light at three wavelengths (450 nm, 600 nm, and 900 nm) sequentially irradiates the sample, with first vertical and then horizontal polarized light. The LS 13 320 measures the scattered light from the samples over a range of angles. By analyzing the differences between the horizontally and the vertically radiated light for each wavelength, we gain information about the particle size distribution of the sample. It is important to remember that we are measuring the differences between the vertically and the horizontally polarized signals, and not simply the values of a given polarization.

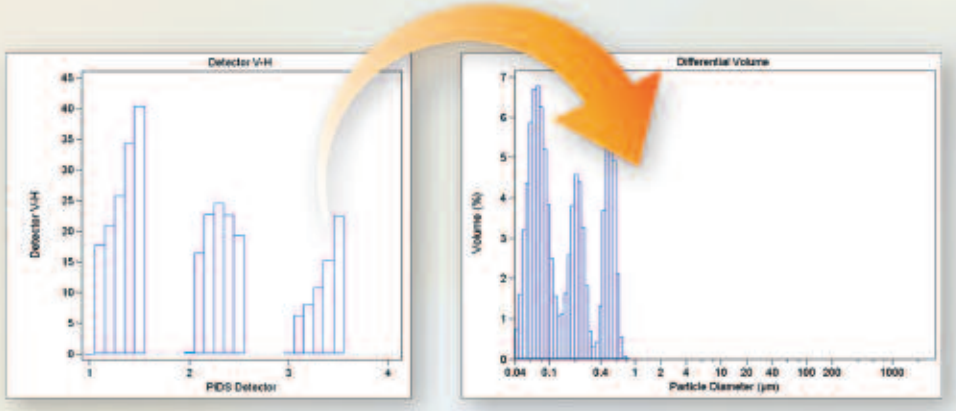


The intensity vs. scattering angle information from the PIDS signals is then incorporated into the standard algorithm from the intensity vs. scattering angle data from the laser light scattering to give a continuous size distribution, which in the case of the LS 13 320 multi-wavelength system is 0.04 µm to 2,000 µm.

Another major benefit of acquiring PIDS data is that by simple interpretation of the raw data we can quickly confirm whether small particles are genuinely present or not, as large particles do not exibit the differential signal shown by small particles.

How do you benefit?

Increased *sensitivity* and *performance*



Real data *means* real results

LS 13 320

Part No.	Description
6605637	LS 13 320 Multi-Wavelength Bench/Module – Must include software option.
6605766	LS 13 320 Single-Wavelength Bench/Module – Must include software option.

LS 13 320 Software Options

383840	LS 13 320 Control Software V, Ver. 5.03 – 21 CFR Part 11 Compliant Includes 8310693 V-Check Validation Program at No Charge.
383835	LS 13 320 Control Software V, Ver. 5.01 – Non 21 CFR Part 11 Compliant

LS 13 320 Validation Package

8310693	LS 13 320 V-Check Validation Program

LS 13 320 Modules

6605638	Aqueous Liquid Module (ALM)
383665	Universal Liquid Module 2 (ULM2) with Sonicator Option
383497	ULM2 Sonicator Upgrade Kit – Probe & Power Supply
6605640	Dry Powder System (Tornado DPS)
6605675	Micro Liquid Module (MLM)
6605685	Sample Cell with PIDS option (for use with ALM)
6605686	Auto-Prep Station Module (APS)
383860	ULM2 with Sonicator Upgrade Kit – Compliant 21CFR Part 11
383861	ULM2 with Sonicator Upgrade Kit – Non-compliant 21 CFR Part 11

Reagents & Controls

6600703	Dispersant IA, Nonionic
6600704	Dispersant IB, Nonionic
6600705	Dispersant IC, Nonionic
6600706	Dispersant IIA, Anionic
6600707	Dispersant IIIA, Cationic
6600708	Dispersant Mixed Kit
7800370	G15, Nominal 15 µm Garnet Particles
7800372	GB500, Nominal 500 µm Glass Beads, 5 x 19 g
7800377	L300, Nominal 300 nm Latex Particles
7800499	G35, Nominal 35 µm Garnet Particles

Consumables

7801163	Inlet Water Filter Kit (ALM)
7808620	Foam Tip Swabs
8303005	Lens Tissue (1 pack)
8304096	Micro Cleaner (Detergent, Neutral)
8306008	Lens Cleaner (1 bottle)
8307669	Replacement Bags for Tornado DPS Vacuum Cleaner (Micro), 10 bags
8309289	Replacement Bags for Tornado DPS Vacuum Cleaner (nilfisk), 5 bags
8309686	Inlet Water Regulator Kit (ALM)
8309790	Sample Tubes with Bar Code Labels (LSAPS), pkg. of 30
8310765	Tornado Cleaner (Cleaning Grit), DPS”
383250	Tornado Sample Tubes (10 per kit)
8309952	Filter Cartridge (ALM)

BECKMAN COULTER®

Developing innovative solutions in Systems Biology.

Innovate SIMPLIFY Automate

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