



| Material relationships



PARTICLE SIZE

SPRAYTEC

ACCURATE PARTICLE SIZING
FOR AEROSOLS AND SPRAYS

INTRODUCING THE MALVERN SPRAYTEC

Rapid, reliable particle size measurements made easy.

Spray particle and droplet size measurements are central to defining product performance across a range of applications, from the delivery of drugs to the human respiratory system through to the application of coatings and agrochemicals. In each case, sprays present unique challenges, either in terms of the environment within which measurements have to be made or the speed of the event which must be characterized.

The Malvern Spraytec has been specifically designed to meet these challenges, delivering routine, accurate and precise spray particle size analysis.



Innovative design

The Spraytec system provides automated, *in situ* analysis of high concentration aerosols and sprays from a robust, easy-to-use platform.

Real-time, high-speed measurements ensure the complete characterization of both pulsed and continuous spray events. This is achieved over a wide size range, providing unparalleled sensitivity to changes in the spray size distribution.

Extensive size distribution data are generated rapidly and presented in a form that allows for an instant understanding of the evolution of the spray over time.

The system's versatile design enables it to meet the requirements for routine spray characterization, from fundamental research applications through to product QC and batch testing.



HIGH PERFORMANCE DELIVERED

The design of the Spraytec system has drawn on Malvern Instruments' extensive experience in the field of spray and aerosol characterization, gained over a period of more than 40 years of research and applications development.



Rapid measurements

An unequaled 10 kHz data acquisition rate delivers the measurement of a complete spray particle size distribution every 100 microseconds, enabling accurate analysis of the dynamics of spray atomization and dispersion for devices such as pharmaceutical drug delivery systems and fuel injectors.

Wide size range

The Spraytec covers a size range from 0.1 – 2000 microns using only two lenses. Broad size distributions can therefore be routinely characterized, with a dynamic range of greater than 1000:1 being covered by each lens.

High concentration analysis

A patented multiple scattering analysis ensures accurate measurements can be made at high spray concentrations. This allows the Spraytec to continue to operate where traditional laser diffraction systems would fail.

Reproducible, simple operation

Standard Operating Procedures (SOPs) record all the important hardware and software variables associated with a method. Methods can be recalled via a single mouse-click, automatically aligning the system and configuring it ready for measurement.

Robust measurements

Spraytec's optical design enables measurements over large working ranges. This, coupled with an efficient optics air purge and the ability to use a range of optical bench sizes, ensures continuous operation even when measuring dense, widely distributed sprays.

Meaningful data analysis

The Spraytec's unique size history chart allows the changes in particle size observed during atomization to be easily assessed. Result averaging, export and reanalysis is achieved via a simple drag-and-drop interface.

Regulatory compliance

Full lifecycle documentation, following GAMP guidelines, provides complete design traceability. IQ/OQ documentation is provided as the basic building block of any validation plan. In addition, the software provides technical compliance to the requirements of 21 CFR Part 11. The recommendations of ISO13320:2009, the international standard for laser diffraction measurements, are also met in full.

ADVANCED SPRAY CHARACTERIZATION

The Spraytec system measures spray droplet and particle size distributions using the technique of laser diffraction. This requires the angular intensity of light scattered from a spray to be measured as it passes through a laser beam. The recorded scattering pattern is then analyzed using an appropriate optical model to yield a size distribution.

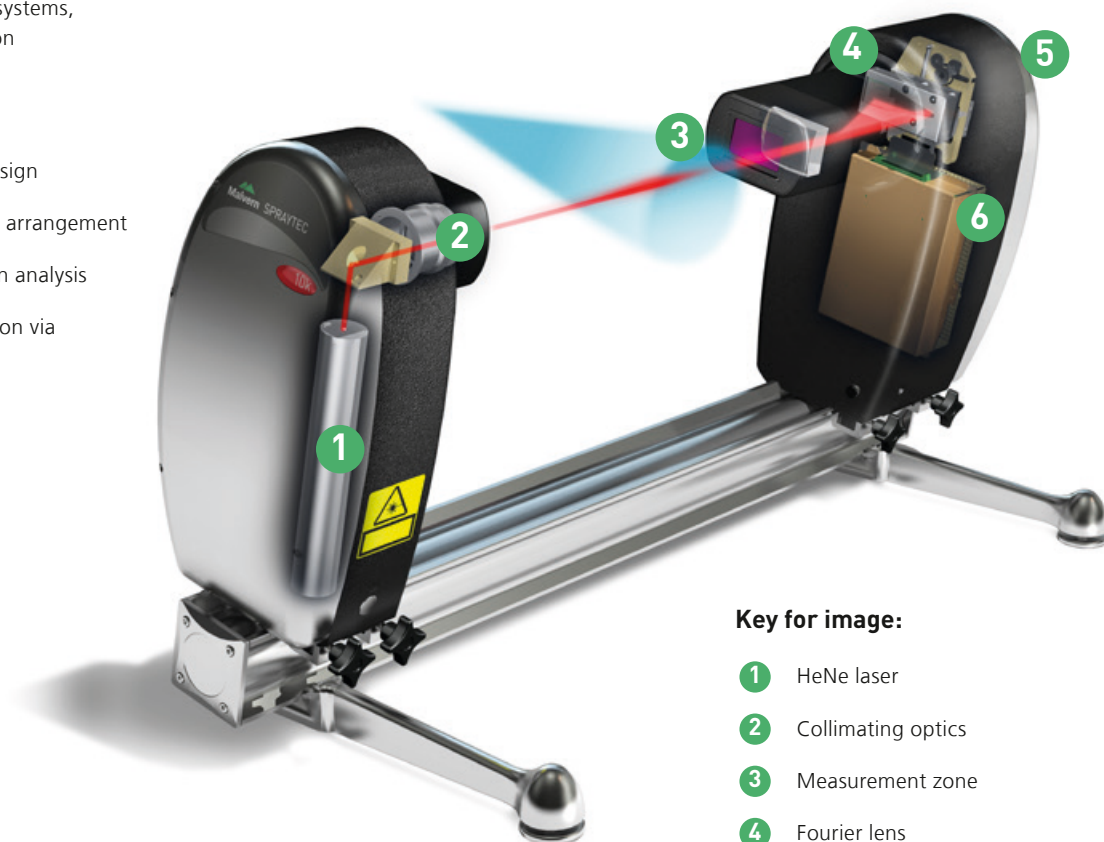
The angular range over which scattering measurements are made has been optimized within the Spraytec to ensure that polydisperse size distributions are fully resolved. In addition, a maximum data acquisition rate of 10 kHz ensures that any temporal fluctuations in the spray particle size are detected and understood.

Particle size calculations are carried out using a patented multiple scattering algorithm.

This ensures accurate particle size distributions can be measured at up to 98% obscuration, far beyond the range of operation of traditional laser diffraction systems.

Spraytec delivers:

- 10 KHz maximum acquisition rate
- Unique lens configuration, imaging scattering over a large working range
- 300 mm and 750 mm lens systems, covering a 0.1 – 2000 micron dynamic range.
- Rapid auto-align
- Robust construction and design
- Customizable optical bench arrangement
- Patented high-concentration analysis
- Measurement synchronization via flexible triggering options

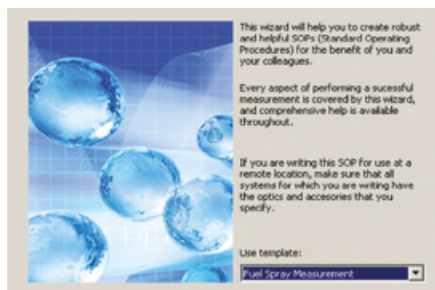


Key for image:

- 1 HeNe laser
- 2 Collimating optics
- 3 Measurement zone
- 4 Fourier lens
- 5 Silicon diode detector array
- 6 Rapid data acquisition system

SIMPLE OPERATION

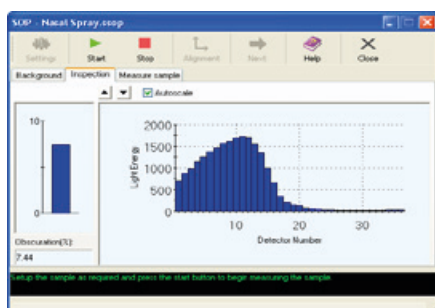
Access to the Spraytec's powerful measurement capabilities is controlled via an equally impressive software interface that makes precise spray measurements entirely straightforward.



- 1 Set up your Standard Operating Procedure (SOP) using the system's integrated method definition wizard. SOPs lock down all aspects of the measurement process including the hardware configuration, analysis settings, triggering options, result parameter reporting and data averaging. Online help supports method specification for different spray types.



- 2 Run the measurement by selecting the desired SOP from the menu system. This automatically configures the system and ensures everything is optimally set to deliver accurate results, including auto-alignment of the optical system. Synchronization of external systems such as extractors, actuators and positioning systems is also supported.



- 3 Observe each stage of the measurement via the software's measurement manager. This allows the user to monitor all aspects of the measurement and analysis process. Prompts ensure that the correct sample preparation, handling and disposal procedures are followed.



- 4 View the results using the size history window. This displays the recorded particle size distributions along with a size history chart showing how the spray developed over time. Users can play back the spray event and select records for further analysis.

SPRAY DYNAMICS REVEALED

Understanding the dynamics of spray formation requires users to quickly assess how the particle size distribution changes with time.

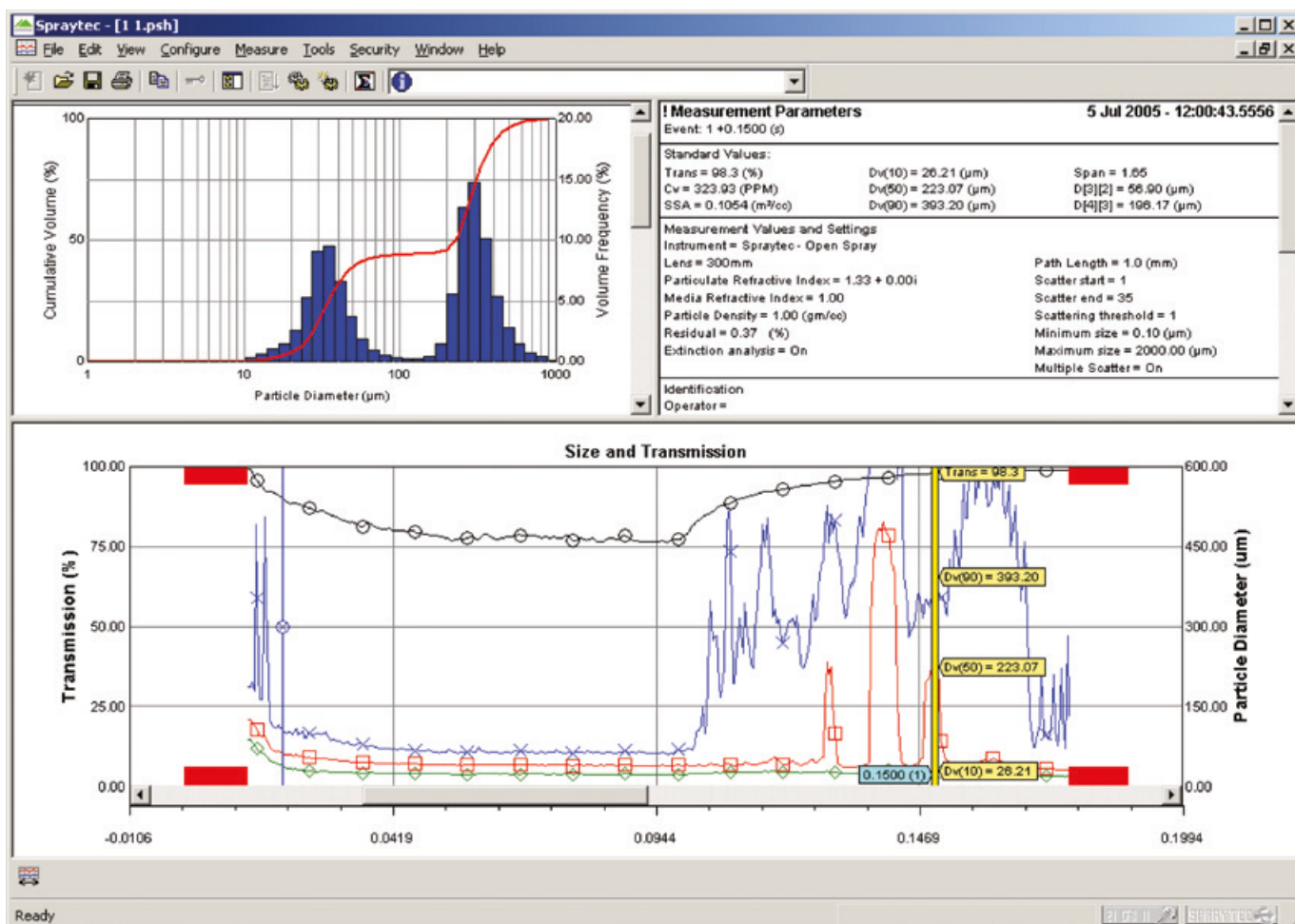
The Spraytec's unique size history display enables a frame-by-frame inspection of the particle size distributions recorded during a given spray event.

Instantaneous playback of the spray event is possible, showing exactly how the spray particle size evolves over time.

At each time point the entire size distribution can be viewed together with all relevant sample details.

Users can define which variables can be viewed on the size history chart and can select records from the chart for averaging, export and reanalysis.

- Frame-by-frame event analysis
- Instantaneous result playback
- Drag-and-drop result selection
- Zoom facility to examine changes over different time periods
- Statistical analysis via advanced averaging capabilities
- Size distribution and scattering data views for each time point
- Searching facilities to locate results
- Overlay of results at different time points
- Display of measurement triggers and data groups



SPRAY APPLICATIONS

The flexibility of the Spraytec system makes it ideally suited to applications across a wide range of industries, from fundamental research and development through to product quality control and batch release testing.

It delivers accurate, reproducible spray size analysis in an easy-to-understand format, improving product understanding and control.



Orally inhaled and nasal drug products

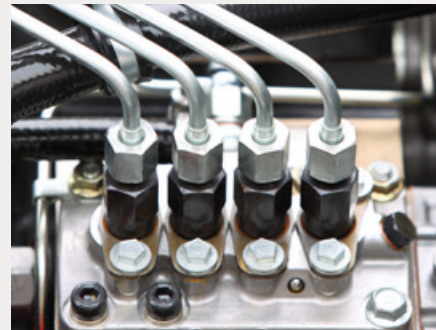
Particle size is a key parameter in defining the deposition pattern and bioavailability of drug materials delivered using pump sprays and inhalers to the nasal mucosa and respiratory system. The Spraytec system can chart the changes in size produced during single device actuations, allowing the dynamics of particle dispersion to be identified along with the device reproducibility. Formulations can therefore be rapidly screened for the correct spray properties, reducing development times and improving drug delivery efficacy.



Routine atomizer characterization

Measurement of the droplet size produced by atomizer systems is key in promoting process understanding and a knowledge of the environmental impact of spraying, for instance in coatings or agrochemical applications.

The Spraytec's rugged design, efficient air purge and multiple scattering analysis ensures measurements can be made at high concentrations directly within a spray plume, providing the real-time data required to track changes in particle size during atomizer operation.



Automotive applications

The Spraytec's ability to measure at 10 kHz enables resolution of the fluctuations in droplet size observed during the rapid firing of automotive fuel injector systems. Provision of flexible triggering options ensures each injection event is fully captured. The repeatability of atomization can then be assessed and related to combustion efficiency.

SPRAYTEC SPECIFICATIONS

Optical unit specifications			
Measurement principle	Laser diffraction		
Size range	0.1 μm - 2000 μm		
Optical models	Mie Theory and Fraunhofer Approximation including Patented Multiple Scattering correction		
Lens ranges	300 mm lens: 0.1 μm - 900 μm (Dv50: 0.5 μm - 600 μm) 750 mm lens: 2.0 μm - 2000 μm (Dv50: 5 μm - 1600 μm)		
Working range	150 mm at 0.5 μm extending to >1 m above 5 μm		
Concentration range	Minimum acceptable transmission: 5% (dependent on particle size range)		
Detection system	36 element log-spaced silicon diode detector array		
Light source	632.8 nm, <= 5 mW helium-neon laser		
Laser Safety	Class 3R laser product		
Optical alignment system	Automatic rapid align system		
Maximum acquisition rate	Continuous Mode: 1 Hz Rapid Mode: 2.5 kHz as standard, 10 kHz with additional software feature key		
Accuracy	Better than +/- 1% on the Dv50 for NIST-traceable latex standards		
Precision / Repeatability	Better than +/- 1% COV on the Dv50 for NIST-traceable latex standards		
Reproducibility between instruments	Better than +/- 1% COV on the Dv50 for NIST-traceable latex standards		
Measurement triggering	Internal: Based on transmission or light scattering levels External: Based on TTL input or simple switch trigger		
External device synchronization	Via two TTL trigger outputs		
Software			
Minimum computer specification (supplied with system)	3 GHz Core 2 Duo processor, 4 GB RAM, 250 GB-HDD, CD-RW or DVD +/-RW drive, 1024x768 minimum monitor resolution, 1 free USB port. One free full height PCI slot and one free COM port required for nasal spray actuators		
Operating platforms	Windows 7 (32 bit and 64 bit), Windows 8 (64 bit), Windows 8.1 (64 bit), Windows 10 (64 bit).		
21CFR11 Compliance	Technical compliance provided through layered access security system, audit trails and links to Adobe Acrobat for electronic signatures.		
Operating environment			
Enclosure ratings	IP65 rating for the main transmitter and receiver modules in normal use		
Temperature	15°C - 40°C		
Humidity	35% - 80%, non-condensing		
Detector			
	Measurement zone width	Unpacked weight	Dimensions (LxWxH in mm)
Laboratory systems	300 mm 750 mm	36 kg 37 kg	950 x 550 x 610 1400 x 550 x 610
Spray facility systems	300 mm 750 mm	36 kg 37 kg	950 x 550 x 650 1400 x 550 x 650

Note: Optical bench sizes of up to 2500 mm are available on request.



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