Effective Optical Systems

analytik

Cutting-edge Platform for R&D and QC of particles in biological, industrial, and environmental heterogeneous liquids

powered by patented ***Single Particle Extinction & Scattering SPES*** *technology*

CLASSIZER™ ONE

multiparametric single particle analyser

Early R&D

- Formulation QbD & SbD
- Heterogeneous samples
- Complex-But-Real Particles

Formulation

- In target complex fluids
- Formulation stability
- Shelf life optimization

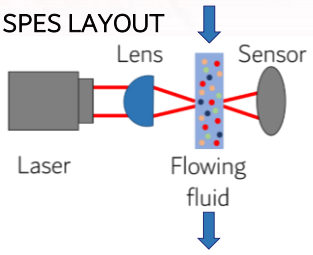
Product QC

- Continuos Flow Analysis
- Process QC/ PCA
- Impurities Identification

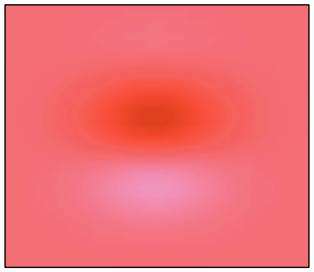
SPES

SPES (Single Particle Extinction and Scattering) is a novel patented light scattering technology. **SPES** enables the classification, analysis, and counting of single particles in fluids on the basis of their optical properties.

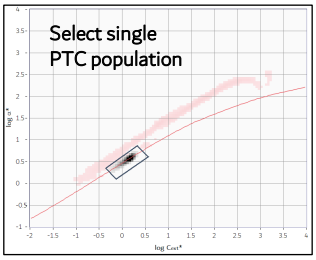
SPES LAYOUT



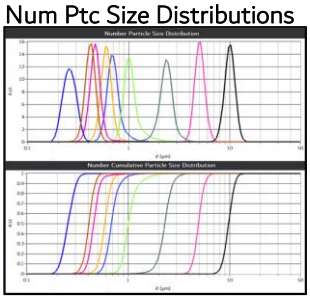
SPES FRINGES



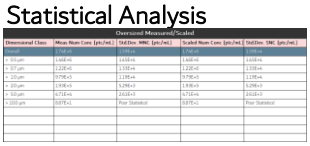
EOS CLOUDS



Num Ptc Size Distributions



Statistical Analysis



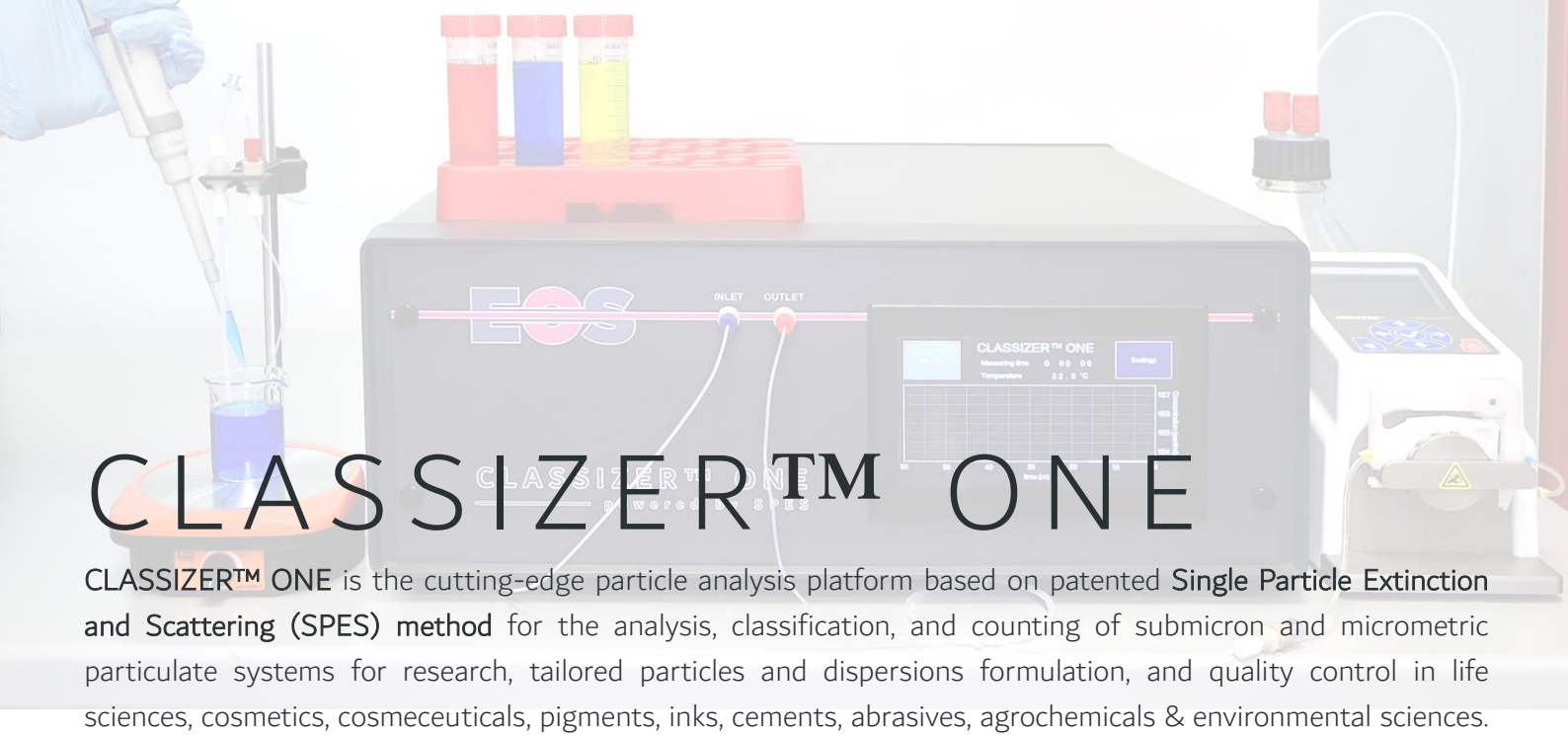
Particles are dispersed in a filtered solvent or in a diluted heterogeneous liquid, which is flowed through a scattering cell where a laser beam is properly shaped and focused. As a single particle crosses the laser beam, the interference pattern between the transmitted beam and the forward scattered light is recorded on a segmented photodiode. The interference pattern presents dark and bright fringes delivering the unique optical properties of the single particle illuminated.

The **Extinction Cross Section** $C_{ext}^{*} = \frac{k^2}{4\pi} C_{ext}$ and the **Polarizability** $\alpha^{*} = k^3\,\alpha$, where $k = 2\pi n/\lambda$ is the wave number in the medium n at wavelength λ, are thus retrieved **for each single detected, validated, and counted particle** thanks to a robust Pulse Shape Analysis scheme and proprietary algorithms (other optical parameters could be alternatively retrieved to the user, eg. particle optical thickness ρ).

In few minutes **SPES** creates the unique **EOS CLOUDS** histogram which is the optical fingerprint of the sample. Heterogeneous samples produce simultaneously different clouds for each particle population, which can be individually selected, analysed, and compared. Particle size distribution, numerical concentration, and other statistical insights are retrieved accordingly to the selection, to whole sample or for each time frame of the acquisition in Continuous Flow Analysis mode.

Added-value information is provided thanks to **SPES** and **EOS** unique data libraries:

- Absolute **Particle Size Distribution** and **Particle Numerical Concentration** of each single populations irrespectively of polydispersity and composition.
- **Quality Control** of **optical particle structures** as porosity, wetting, aspect ratio, payload, and shelf-life **without intermediate steps** (e.g., purification/filtration)
- Measurement of **particle behavior** and **particle formulation stability** directly in heterogeneous non-filtered target biological, industrial, or environmental fluids.
- Hi-Resolution **Continuous Flow Analysis** of particles, ready to couple to other analytical devices, as cFFF separators, small chemical reactors, and pilot lines.
- Statistical approaches as **Oversize Measure** and **PCA** for Batch-2-Batch analysis and out-of-specifics identifications in formulation and production.

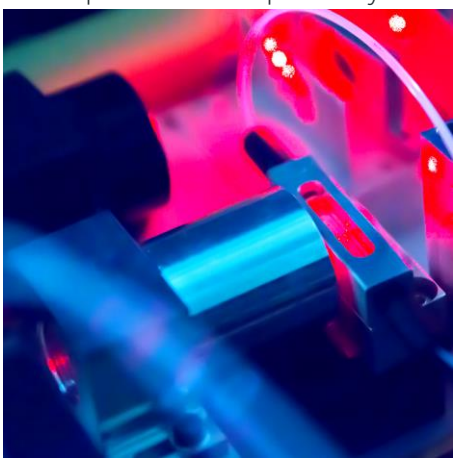


CLASSIZER™ ONE

CLASSIZER™ ONE is the cutting-edge particle analysis platform based on patented **Single Particle Extinction and Scattering (SPES) method** for the analysis, classification, and counting of submicron and micrometric particulate systems for research, tailored particles and dispersions formulation, and quality control in life sciences, cosmetics, cosmeceuticals, pigments, inks, cements, abrasives, agrochemicals & environmental sciences.

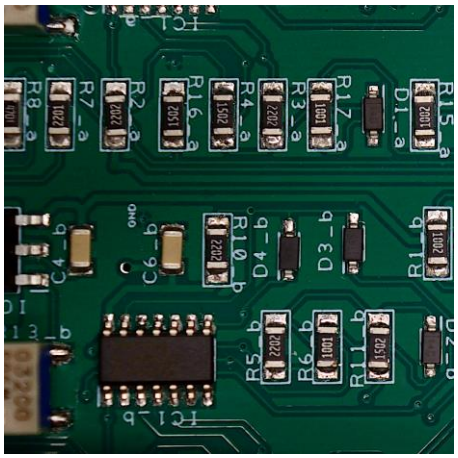
A small aliquot of the sample to be analyzed is dispersed or diluted in a filtered solvent and flowed through the device at a constant flow. **CLASSIZER™ ONE** analyses particles, emulsions, powders, and microcapsules present in the fluid. Via the unique patented **SPES** optical scheme, **CLASSIZER™ ONE** retrieves to user the **EOS CLOUDS** of the sample in a few minutes guaranteeing precise and unique information. Accurate production design, custom electronics and industrial grade components ensure durability, reliability, and robustness.

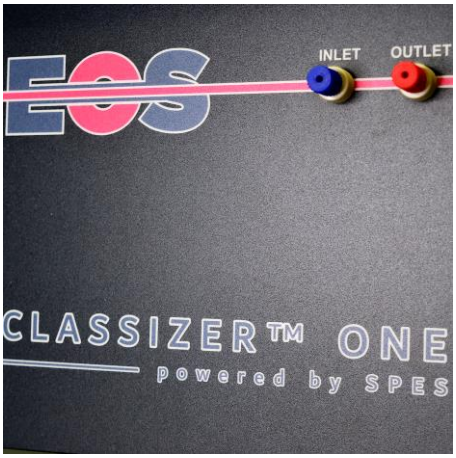
Unique Patented Optical Layout



Industrial-grade PLC & HMI

Custom Hardware Solutions





Quartz, PTFE and PEEK wetted surfaces and couplings ensure high chemical compatibility. **CLASSIZER™ ONE** works with laminar constant flows in typical range of few millilitres per minute [customizable].

CLASSIZER™ ONE can be coupled with standard syringe pumps and hi-quality peristaltic pumps for standard R&D activities as with automatic wet dispersion units and autosamplers to deliver high measurement throughput and reliability in formulation and Quality Control activities.

Hardware tailored solutions on single user needs are available. **Contact EOS team to discover more!**

Classizer™ ONE v0.70

IDEAL FOR: emulsions – microcapsules – microplastics – pigments abrasives – pesticides – fertilizers – additives – colloids – inks ceramics – drug delivery systems – lubricants – environmental waters

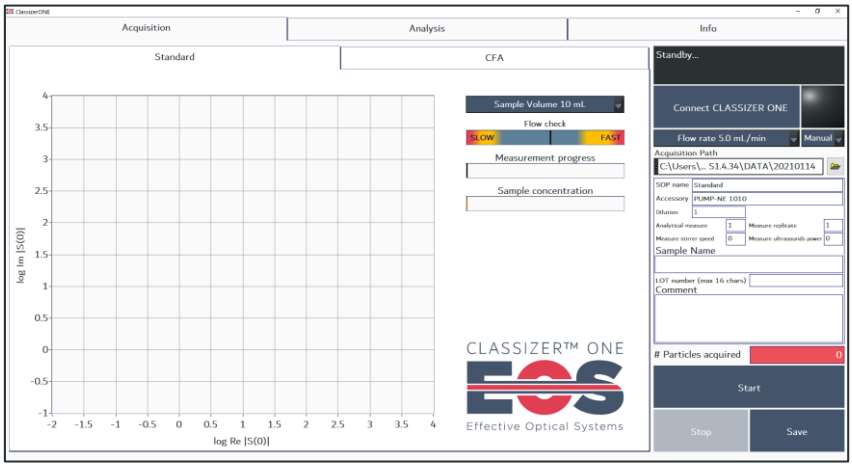
USER SOFTWARE

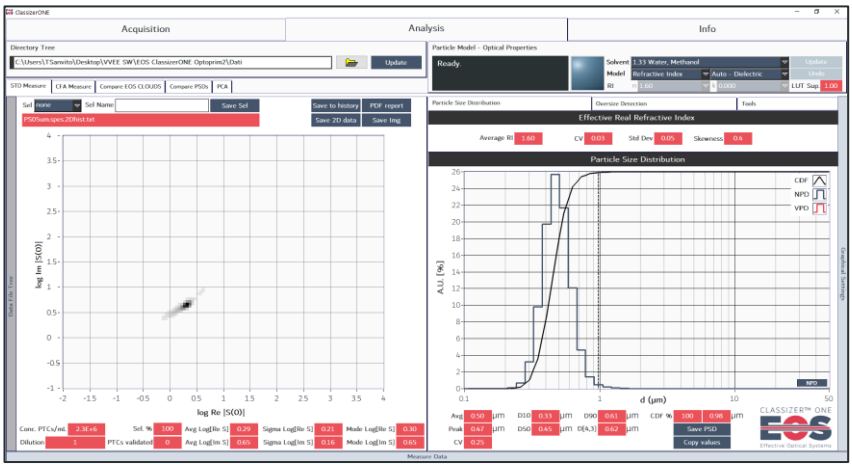
USER FRIENDLY CONTROL & EVALUATION PLATFORM

All-in-one software with dedicated tabs for acquisition and analysis offers intuitive solutions for easy-to-use and reliable measurements. Standard operations and add-ons for advanced data acquisition and analysis are available and ready to use. Tailored Operative Procedures can be developed in the software to fit user needs.

Several internal checks are performed continuously to ensure to the user high quality and reliability of the SPES data. Warnings and expert advices are provided to user in real time during the data acquisition to save time and increase the quality of the SPES data and results.

- Easy to use / Easy to clean
- Dedicated SOPs available
- No calibrations needed
- Robust Internal checks
- Real-time / In-Line / On-Line



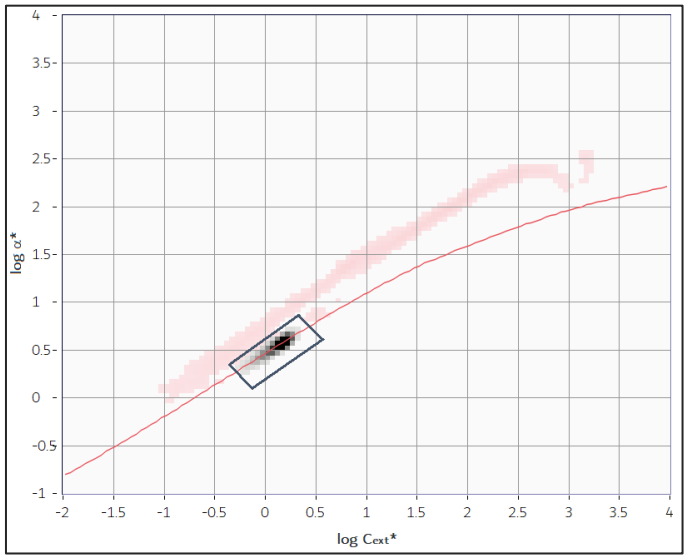


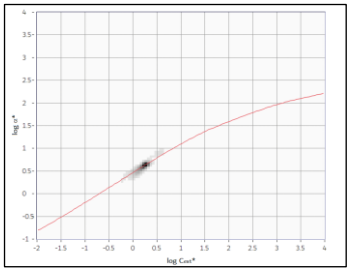
Comments and operator observations can be added to data during acquisition and analysis. Data are saved continuously limiting data loss and unintentional file overwriting. Compliance with 21 CFR part 11 and device connectivity via industry standard IoT protocols are possibile via dedicate software packages and Add-Ons.

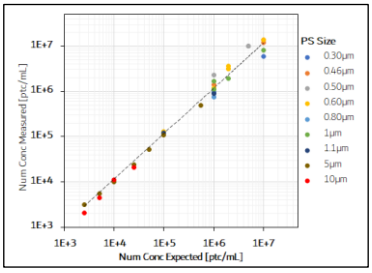
CLASSIZER™ ONE is the perfect solution for Continuous Flow Analysis CFA of particles in fluids and as unique sensor for FFF applications as AF4/CF3. Real-time monitor of the SPES CLOUDS and of the particle numerical concentration are retrieved with a time resolution of one second. Precise time laps can be selected for in detailed offline analysis of particles characteristic and concentration transitions of single particle population.

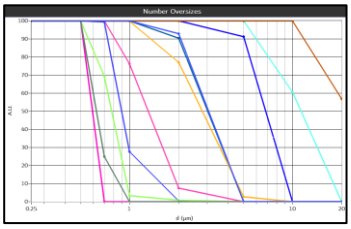
Analysis tab allows the operator to have the sample characteristics at a glance. CLASSIZER™ ONE software provides many ways to perform a thorough analysis and retrieve valuable information precluded to standard and ordinary particle sizers and counters. Advance knowledge of products based on particles is finally achievable.

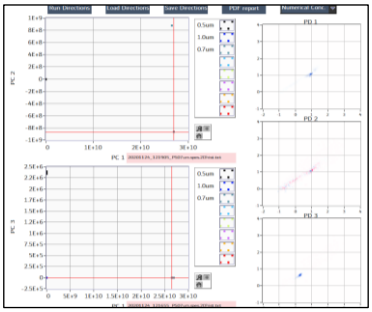
Thanks to the unique EOS CLOUDS and SPES data, the user can **easily select any single particle population** detected in the fluid and represented in the 2D histogram. Numerical particle size distribution, statistical parameters, and concentration are retrieved accordingly to the selection and/or to the whole sample. Advanced feature as aggregation state, particle payload, and aspect ratio are provided via software add-on. Advanced algorithms as Principal Component Analysis (PCA) are available to compare and correlate the behaviour of the single components in heterogeneous products and for batch-to-batch and raw material Quality Controls.





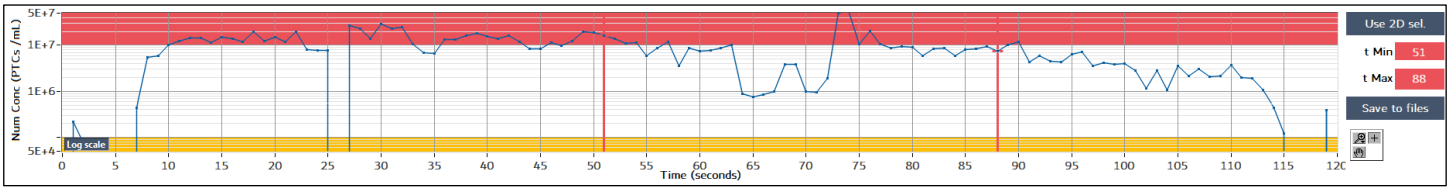






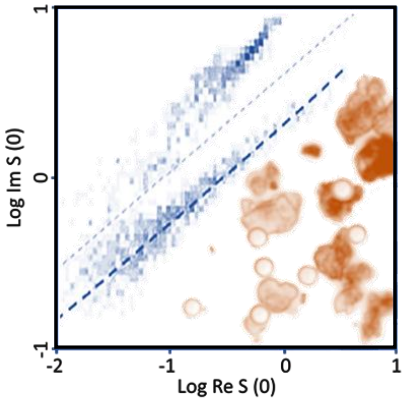
Default analysis assumes particles as standard dielectric spherical particles. **Benefits from SPES technology loading specific data library** for the unprecedented analysis and interpretation of

- core-shell and payload estimate
- particle aging and shelf life
- aggregates and meso-porosity
- non-spherical microparticles
- absorbing and metallic materials
- and any of your specific needs!



Suitable for process control coupled to pilot line, cFFF separators and small reactors to improve synthesis quality and yield of particles, powders, emulsions, and microcapsules regardless the presence of scraps and impurities.

APPLICATIONS

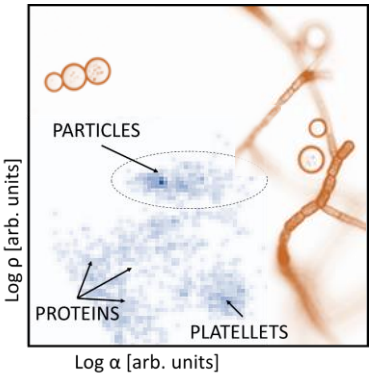


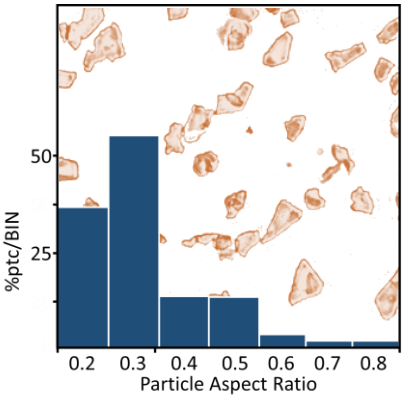
Single population analysis in heterogeneous systems

One measurement allows to analyze the single component of a complex formulation with API, excipients, scraps and contaminants. Components of the samples with different optical properties generate different clouds of data in the unique 2D **EOS CLOUDS**: each of them can be selected and analyzed by user limiting the operator time needed and expensive sample preparation.

Monitor behavior in real complex fluids

Select and recognize the particle signals in real complex medium as **plasma**, **blood**, **cell lysate** or sampling coming from environment waters (sea, peatbog, lake). SPES opens new opportunities for understanding interactions between materials and real biological components in terms of sizing, concentration, aging, particle-particle or particle-medium interactions and sample stability.



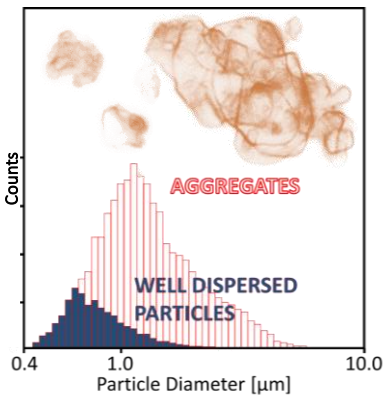


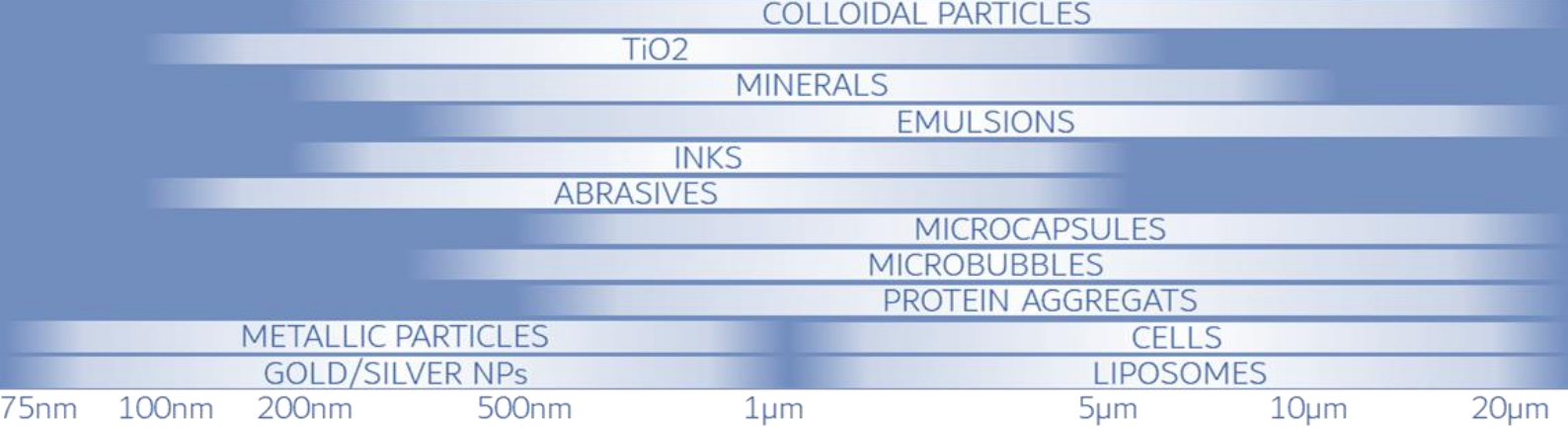
Non-spherical particles

Particle shape strongly influences size distribution and interpretation of light scattering signals. Traditional approaches fail in the task, while CLASSIZER™ ONE opens new insight on your powder via custom data library. Insights on the particle aspect ratio and obtain more realistic and reliable particle sizing for non-spherical objects, such as oblate (platelets) and prolate (needle-like) particles.

Analysis of aggregates

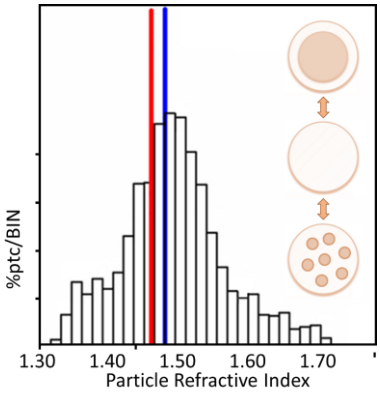
Aggregates have a lower effective refractive index respect to native particles or bulk material and are easily recognizable in the **EOS CLOUDS** histogram. Take advantage by SPES to detect and monitor the presence and estimate the compactness of the aggregates to improve formulation stability and prevent out-of-specifics due to instabilities, poor wetting, or grinding problems.

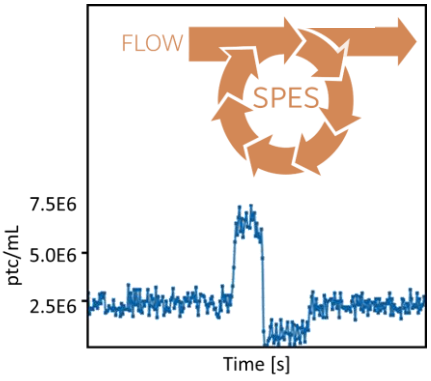




Particles Internal Structure and Payload

Particle internal structure for mesoporous material, API in homogeneous or core shell particles and degradation processes affect the SPES signals on **EOS CLOUDS**. Estimate the payload, the core-shell ratio, the porosity or assess how the aging modifies your product. Operative procedure for data analysis and comparison with placebo or reference standards can be tailored on user needs.





Continuous Flow Analysis

On-Line / In-Line / Real-Time SPES analysis regardless to the presence of bubbles, immiscible droplets and impurities in aqueous liquids, solvents and lubricants. Couple CLASSIZER™ ONE with other CFA equipment as Flow Field Fractionation separators in pilot line and small reactors to support product formulation. Contact us and devise how SPES can become your OEM sensor.

Selection of publications and references:

Presentation of SPES method for particle analysis
AN001-2021 Analysis of Polymeric Particles via SPES Technology
AN006-2021 Multiparametric Classification of Particles as a Pathway to Oversize Analysis in Complex Fluids via SPES Technology

Example of CFA application of SPES technology
AN004-2021 Continuous SPES Flow Analysis CFA-SPES

Example of PCA application of SPES technology
AN005-2022 Multiparametric Principal Component Analysis of Heterogeneous Samples via SPES Technology

Classizer™ ONE with Sample Manager Autosampler
AN002-2022 Automatic Liquid Sample Management, Dilution, and System Cleaning with EOS Sample Manager
AN009-2022 Standardize SPES Operative Procedure of Liquid Samples Analysis via EOS Autosampler

Example of SPES application to aggregates
AN003-2021 Addressing the Issue of Particle Wetting and Clustering by means of SPES Technology: case of Powders in Solvents

SPES application to non-spherical particles
AN003-2021 Addressing the Classification of Non-Spherical Particle by means of SPES Technology

Example of SPES application to emulsions w/o payload in environmental waters
AN012-2021 Monitoring the Fate of a Lipid/ZnO Emulsion in Environmental Waters

Examples of SPES application to particle analysis and behaviour characterization in biotech applications
AN007-2021 Quantitative Classification of Particles in Biological Liquids via SPES Technology

Example of SPES application to oxide particles, abrasives, and industrial slurries w/o impurities
Potenza MAC et al., «Optical characterization of particles for industries», KONA Powder and Particle 33 (2016)

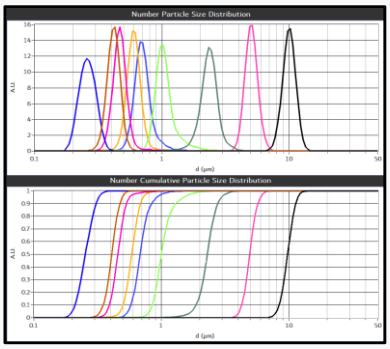
Example of SPES application to ecotoxicity analysis
Maiorana S et al., «Phytotoxicity of wear debris from traditional and innovative brake pads», Env Int., 123 (2019)

Example of SPES application to aerosol analysis
Cremonesi L et al., «Multiparametric optical characterization of airborne dust with Single Particle Extinction and Scattering», Env Int 123 (2019)

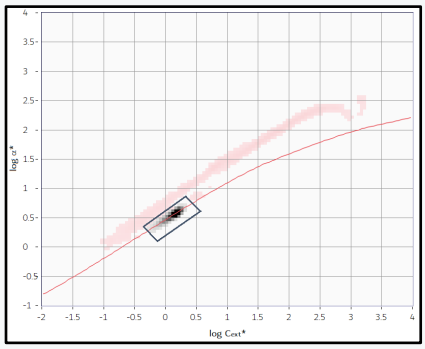
MORE REFERENCES AND APPLICATION NOTES ON
www.eosinstruments.com

TECHNICAL DATA

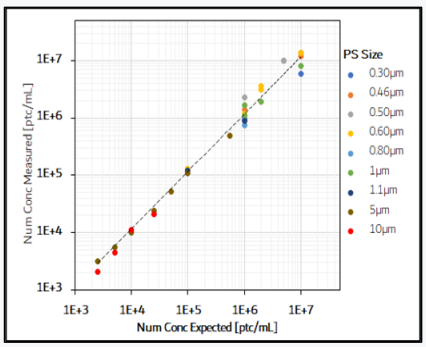
Particle Size Resolution[1]
ranging from 0.24µm up to 10µm PS spheres in milliQ-grade water



Particle Classification[1]
classification of a mix of PS spheres and silicon oil emulsion in water



Particle Concentration[1]
accuracy on num conc of several PS spheres at different dilutions



CLASSIZER™ ONE 083 – Technical Data

SPES size range[1]	Dielectric Spheres 200nm – 20 µm Absorbing Spheres 100nm – 10 µm
Particle Concentration[1]	10^5 – 10^7 particles / mL (10^6 particles / mL ideal)
Theory	**Single Particle Extinction and Scattering** (patented)
Type of Analysis	Laser light scattering analysis of wet samples
Laser Unit[1]	Red light diode (λ=640nm, <50mW) [customizable]
System Aligment	Semiautomatic (fabs preset, tuned on installation / maintenance, automatic alignment of the sensors)
Measuring Time[1]	10-15 min, Acquisition Rate up to 10,000 events/min
Net Weight	25 kg (depending on configuration)
Dimension (WxDxH)	50cm x 50cm x 25cm (depending on configuration)
Wetted Surfaces	Teflon, Quartz, PEEK [customizable]
Environment	Temperature: 18–27 °C; RH: 35% – 75% RH @25°C
CE	Compliance[1] with **FDA 21 CFR Part 11**, **ISO21501**, **USP<729>,** and **USP<788>** via custom Add-ONs
Software	Standard GUI for system management and standard data analysis, custom Add-ONs for tailored SOPs and advanced data analysis (aggregation, payload, CFA, etc)
PC System Requirements	Intel® Core™ i5 – min 4 cores @2GHz or similar, 40 GB available on SSD, 4 GB RAM, Windows 10 (current service pack), x2 USB 3.0 (or higher), 1080p monitor
Sample Flow[1]	Stable, laminar flow, typ. 0.5, 1, 2, 4 ccm [customizable]
External Accessories	Lab Pump, Automatic sample manarer, Autosampler

[1]Dependent on sample, sample preparation, and on model and configuration of CLASSIZER™ in use.

CUSTOM SOLUTIONS

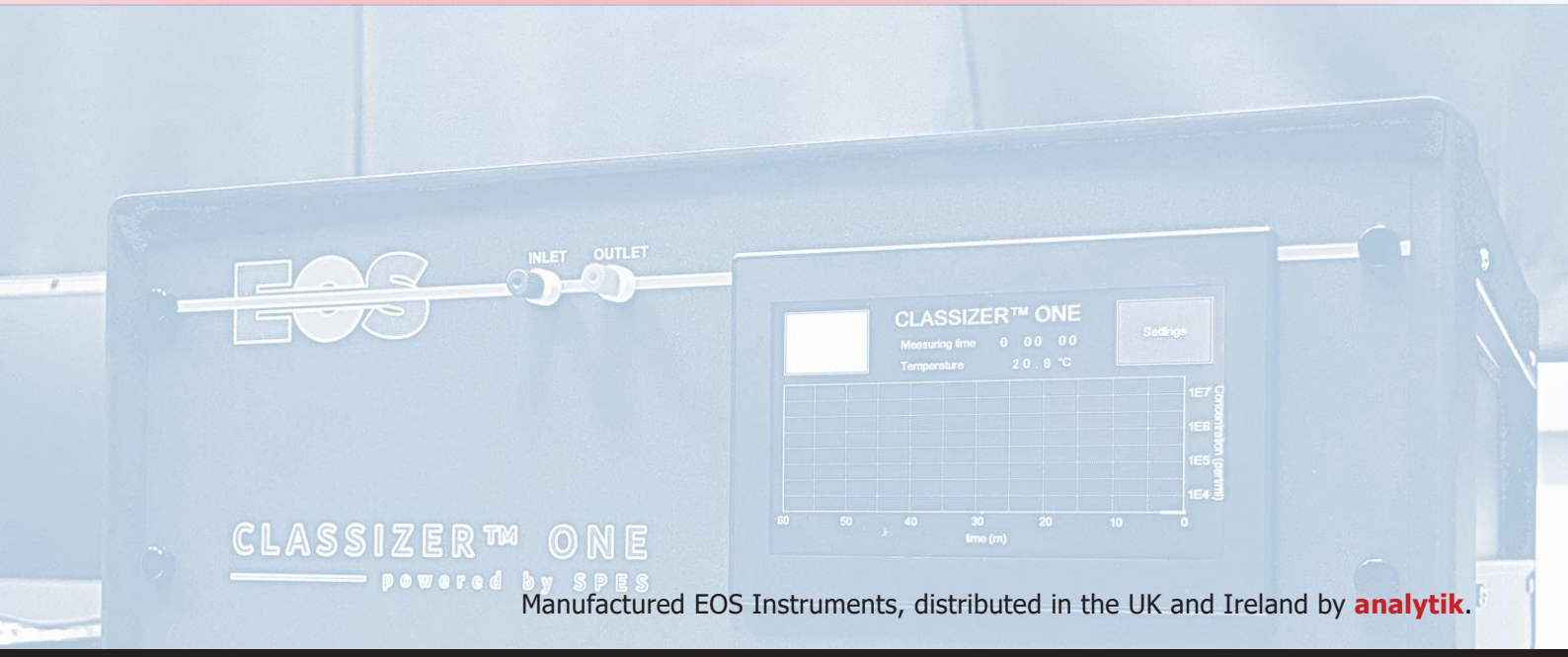
Contract Research Services_ EOS application specialists are available for every customer which requires the development of dedicated sample preparation and analysis protocols via Cooperation Agreement and Contract Research Services. Contact us for information.

Software Packages and Data Libraries_ CLASSIZER ONE is a highly configurable analytical platform. Advanced software packages are available and ready to expand the system capabilities and answer your R&D, formulation and Quality Control needs.

Remote Analysis Support_ EOS application specialists are available to provide tailored support for data analysis and interpretation to boost your particle analysis capabilities.

Training Activities_ EOS is available and willing to discuss your needs and training requirements. EOS provides multiple levels of support contracts, as telephone and video conference and training activities and demo at EOS and/or your laboratories.

Dedicate Customer Service_ EOS delivers exceptional support, provided by experienced SPES application performance of EOS technologies. EOS scientists and technical service personnel give you the assistance necessary for the best experience of SPES technology.



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