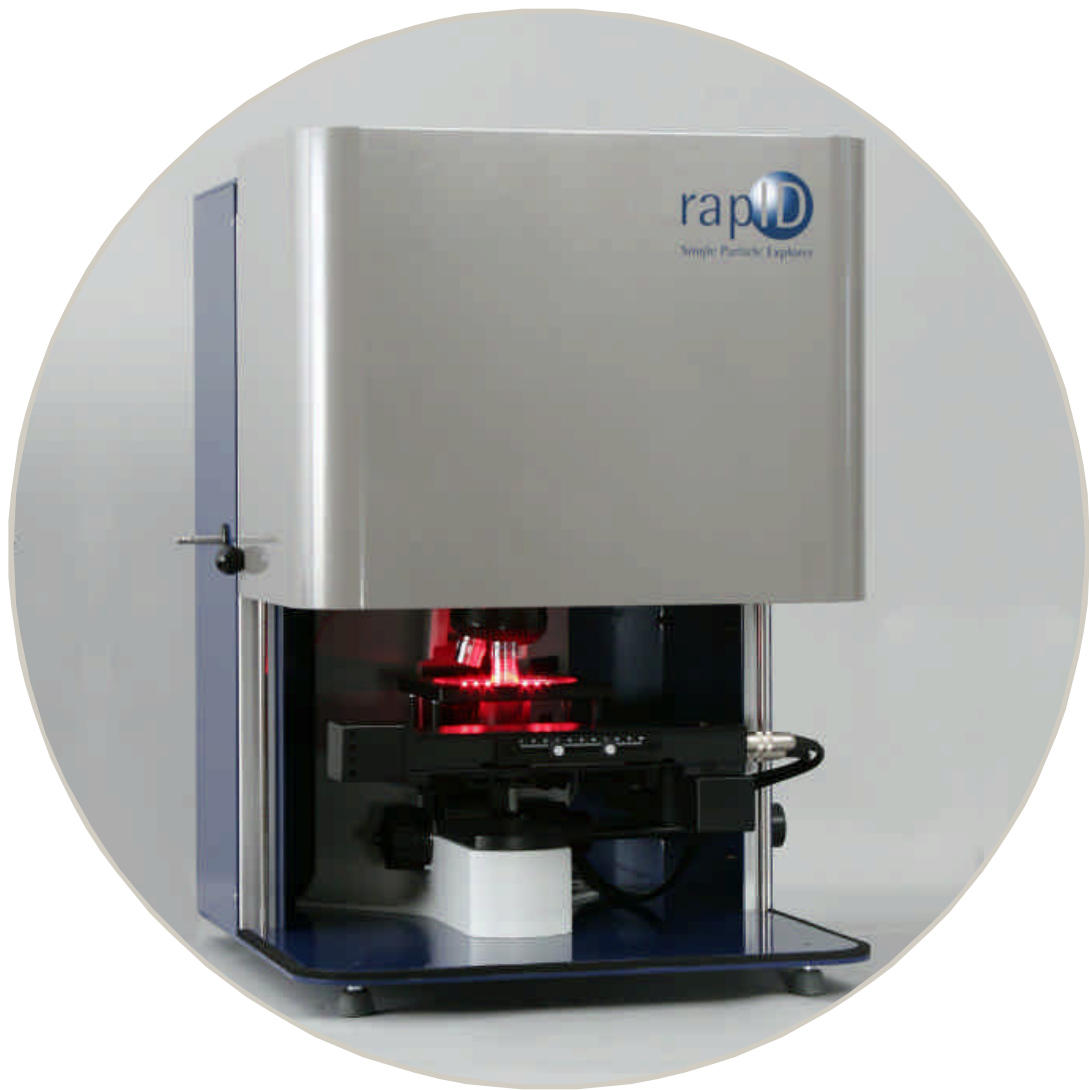




# Single Particle Explorer



Particle Size



Particle Shape



Particle ID

rapID

# Single Particle Explorer<sup>®</sup>

## Counting, Morphological Analysis and Chemical Characterization of Particles :

- The **Single Particle Explorer** was created for routine particle characterization. Through optimized particle filtration and illumination, fully-automated image processing, and Raman spectroscopy, the **Single Particle Explorer (SPE)** provides the following for every particle of 5  $\mu\text{m}$  and larger:

- **Number, Size:**

Longest expansion after Feret

- **Shape:**

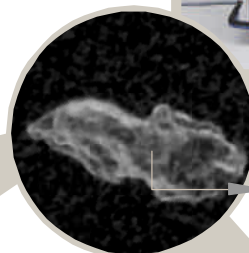
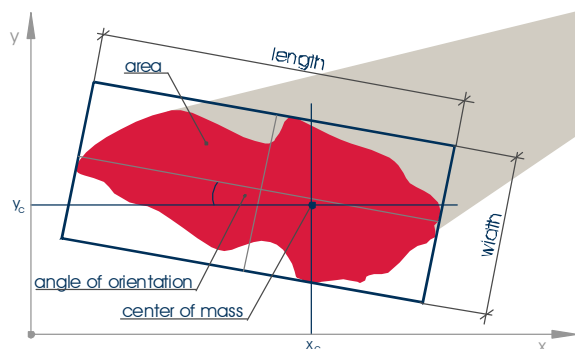
elongation; angularity, circular equivalent, diameter, area

- **Chemical Composition:**

material with degree of database compliance



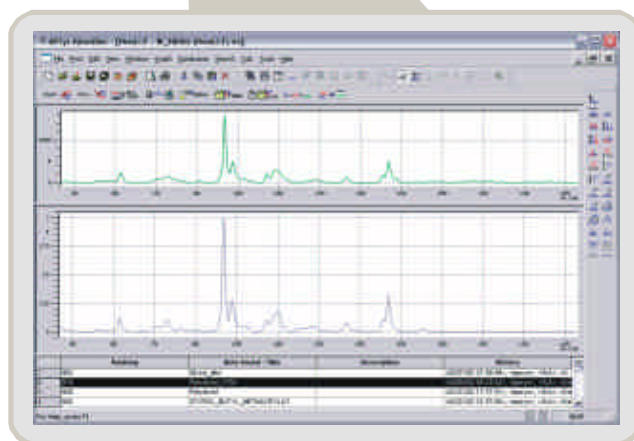
## Morphological and chemical analysis:



13 $\mu\text{m}$  Polystyrene

## Benefits:

- Sample preparation and reliable measurement within minutes
- Reliable reproducibility: particle number, size, and shape
- Integrated chemical analysis with microraman, metal/non metal determination after manual selection
- Objective analysis result through automation, with automated reporting
- Simple calibration check based on particle calibration standard
- Services for installation, training, validation and qualification with IQ, OQ, and PQ documentations





### Advanced Technology:

- **filtr.AID** samples are fixed within a few seconds, thus automatically adjusting the active area
- Darkfield illumination adjusted to the recorded image contrast and the method of analysis
- Fully-automated counting and shape determination of the particles through intelligent threshold technique provides size, number, length/width ratio and surface area of the particles
- Automated Raman spectroscopy: fluorescent bleaching, automated integration, database search, and reporting allow material identification of 2µm and larger

### Application:

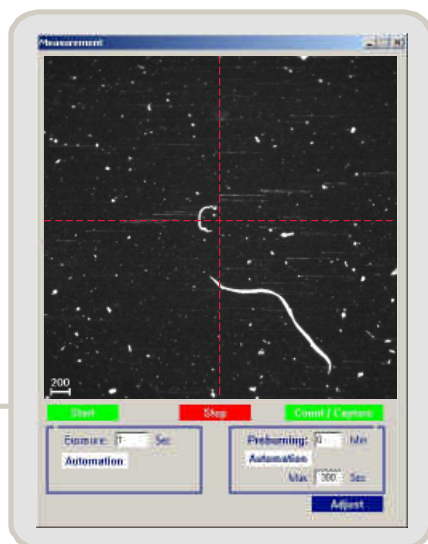
- Foreign particle and contamination analysis
- Cleanliness audits of components, parts and systems
- Particle characterization
- Quality control of implants, nasal sprays, parenterals or inhalatives



### Features of the Single Particle Explorer:

- Standardized particle filtration from any liquids and gases within minutes using the patented filtr.AID system
- Integrated system: sample preparation and insertion, illumination, image recording and analysis, and Raman spectroscopy all form one unit
- Automated image processing, shape determination of particles, and Raman spectroscopy; reporting according to 21 CFR Part 11
- Worldwide service and support, from method development to qualification
- Easily extendable database for material identification
- Programmed according to GAMP IV, manufactured according to ISO 9001:2000 standard
- Optional device qualification: IQ, OQ, and PQ documentations
- Upgradeable for standard filter analysis according to USP <788>, ISO 4407 or VDA Vol. 19

### Results and Software:



| Substance         | 10-25µm     | 25-50µm    | 50-100µm  |
|-------------------|-------------|------------|-----------|
| Rubber            | 2           | 1          | 0         |
| Paper             | 5           | 2          | 1         |
| Polyethylene      | 18          | 7          | 2         |
| Metal             | 4           | 2          | 0         |
| <b>Identified</b> | <b>29</b>   | <b>12</b>  | <b>3</b>  |
| <b>Counted</b>    | <b>2675</b> | <b>825</b> | <b>23</b> |



# Single Particle Explorer<sup>®</sup> Standard Specification

## Optical System

- Manual X,Y - stage 74 x 30 mm, 0.1 mm resolution, optional motorized
- Laser 532 nm, 10 mW 100%; 50%; 10%; 1%
- Size ranges for counting, 10 classes
- Manual focus 0 - 200  $\mu\text{m}$ , 0.5  $\mu\text{m}$  resolution, optional automated
- Camera resolution 2  $\mu\text{m}$ /Pixel

## Performance data

- Sample size coverage 5 - 3000  $\mu\text{m}$ , customizable
- Measurement time Counting: 30 s
- Time for identification (ID) 5 -100 s per particle (depending on size and the particle and the compound)
- Spectral resolution 8  $\text{cm}^{-1}$
- Area of the spectrum 400 - 2500  $\text{cm}^{-1}$
- Identification On the basis of Raman scattering a spectrum is created.
- Memory capacity 1.500.000 Data sets of single particles
- Database 500 entries, full customizable

## Software

- Control rap.ID Software: Particle Explorer and APSys - Central-Control-Center-Unit (ACCU) password guarded hierarchie administration
- Report Visualization of data, preprocessing, fully automated chemometric data processing
- Compliance The software works according to 21 CFR PART 11 and was developed in accordance to these rules and regulations

## Power supply

- Mains connection 85 - 264 V , 48 - 62 Hz

## Operating Conditions

- Humidity 20 - 70 %
- Temperature 17 - 35 °C
- Laser Class 1

## Calibration/ Verification

- Identification Standard substance, duration 1 min
- Counting NIST Traceable Standards

## Data

- date, time, sample ID, operator ID, material composition, raw spectra, labels

## Interfaces

- Protocols TCP/IP, Ethernet
- Connection IEEE 802.3, USB