BIOPHARMACEUTICAL ANALYSIS SOLUTIONS WITH FLOWCAM

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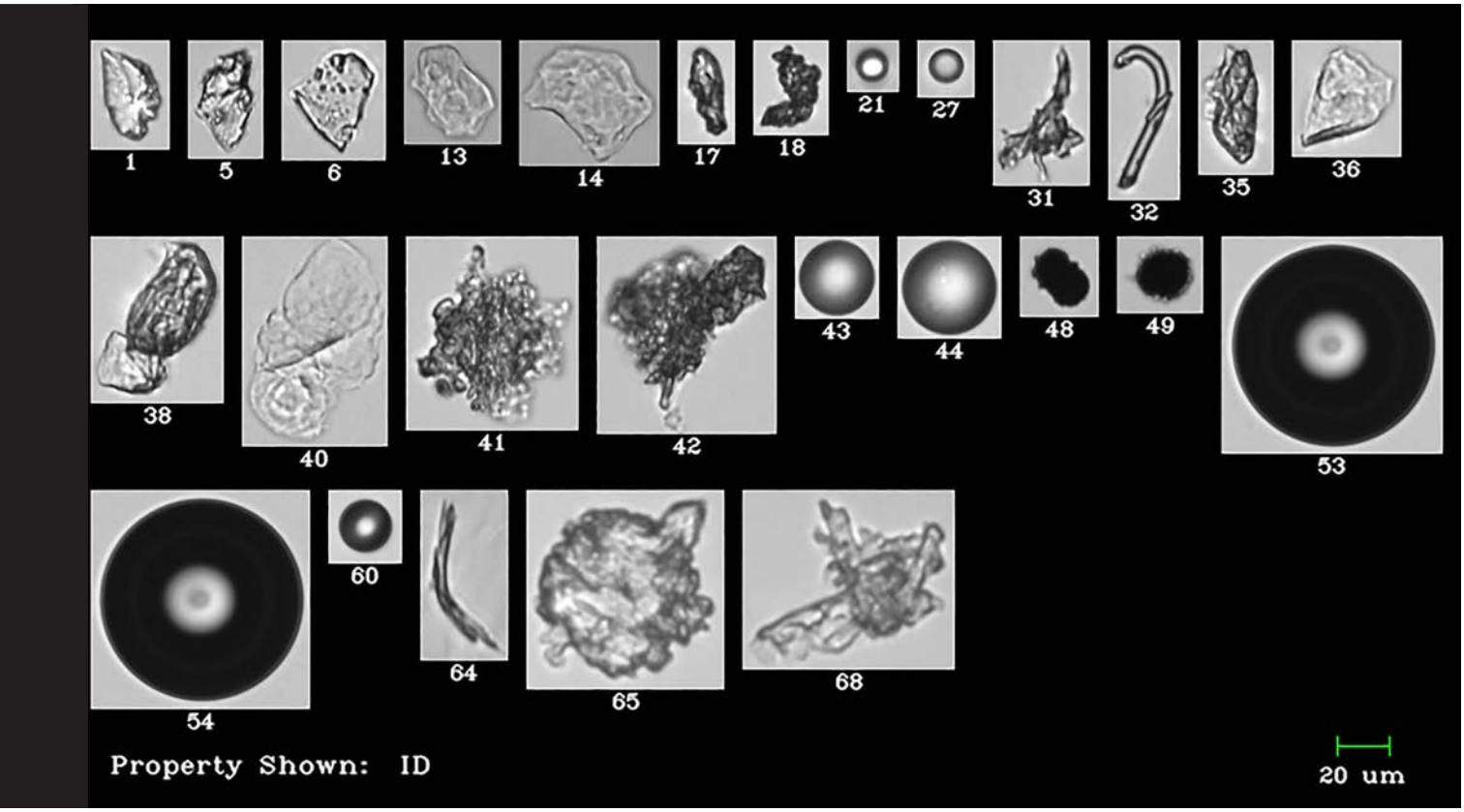
BIOPHARMACEUTICAL
Particle Analysis Solutions with FlowCam



Assorted biopharma images from the FlowCam
Image source: Fluid Imaging Technologies

The FlowCam has been adopted by over 30 pharmaceutical corporations worldwide for particle analysis to improve the development, quality, and safety of their formulations.

Use real digital images to verify the size, shape, and identity of your particles. Differentiate between air bubbles, silicone oil droplets, protein aggregates, and contaminants, and determine which particles are inherent, intrinsic, and extrinsic.

The FlowCam captures high-resolution, digital images of particles suspended in a fluid. Over 40 physical parameters are measured from each image, while the data is processed using our image-recognition statistical analysis software VisualSpreadsheet.

Flow imaging microscopy serves as an orthogonal method to most common particle analysis methods including light obscuration and the Coulter principle to fully characterize your subvisible particles.

KEY APPLICATIONS

Biopharmaceutical Analysis

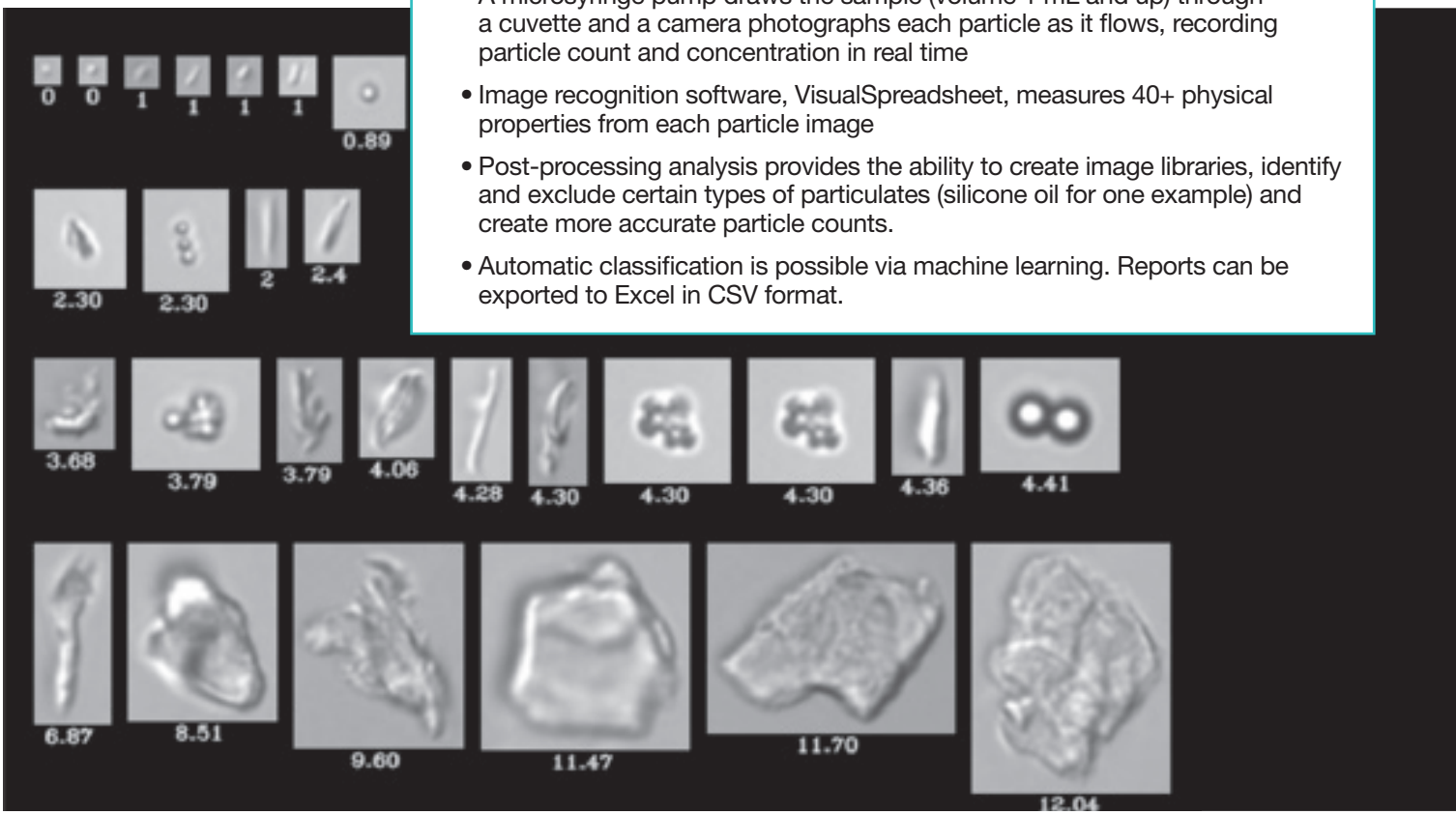
Use real digital images to verify the size, shape, and identity of your particles. Differentiate between air bubbles, silicone oil droplets, protein aggregates, and contaminants, and determine which particles are inherent, intrinsic, and extrinsic.

- **Formulation development**
- **Protein aggregation studies**
- **Protein stability studies**
- **Manufacturing process improvement**
- **Final product QA/QC**

HOW DOES THE FLOWCAM WORK?

- A liquid sample is introduced into the top of the FlowCam
- Imaging and flow settings are adjusted to achieve optimal particle analysis
- A microsyringe pump draws the sample (volume 1 mL and up) through a cuvette and a camera photographs each particle as it flows, recording particle count and concentration in real time
- Image recognition software, VisualSpreadsheet, measures 40+ physical properties from each particle image
- Post-processing analysis provides the ability to create image libraries, identify and exclude certain types of particulates (silicone oil for one example) and create more accurate particle counts.
- Automatic classification is possible via machine learning. Reports can be exported to Excel in CSV format.

NIST Protein Standards Imaged by the FlowCam Nano
Image source: Fluid Imaging Technologies



WHICH MODEL IS RIGHT FOR YOU?

		8100	8400
HARDWARE	Particle Size Range	1µm - 1nm	1µm - 1nm
	Multiple Objectives	✓	✓
	Field of View Flow Cells	✓	✓
	Focus System	Automatic	Automatic
	Automatic Cleaning / Rinsing	✓	✓
	Automatic Priming	✓	✓
	Laser Excitation		✓
	Continuous Sampling	✓	✓
	Teflon Fluid Lines	✓	✓
	Hard Drive	1TB	1TB
	ALH Auto-Sampling Compatibility	✓	✓
SOFTWARE	Count, Size Calculation	✓	✓
	Concentration Calculation	✓	✓
	Image Libraries and Filters	✓	✓
	Automatic Illumination Adjustment	✓	✓
	Database File Structure	✓	✓
	Multiple File Analysis	✓	✓
	Satellite Licences	✓	✓
	21 CFR Compliant	✓	✓

KEY FEATURES

Image and analyse particles 300 nm to 10+ µm

Measure 40+ physical parameters per particle

Quantify particles in sample

Perform statistical calculations

Generate size distribution curves

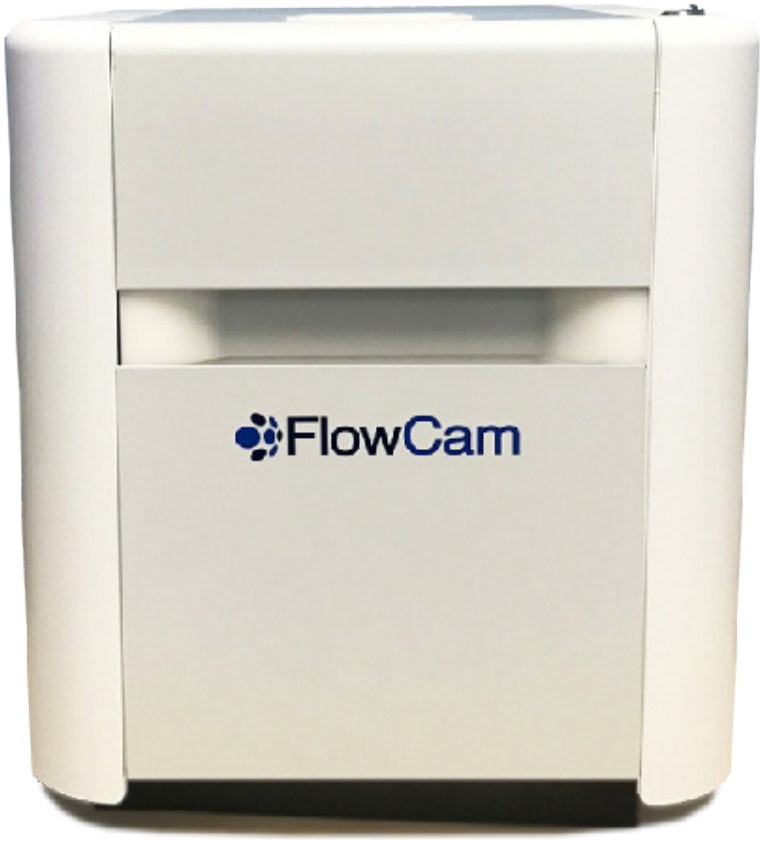
Visually verify particulate identity with high-resolution images

FLOWCAM MODELS

FLOWCAM 8000 SERIES

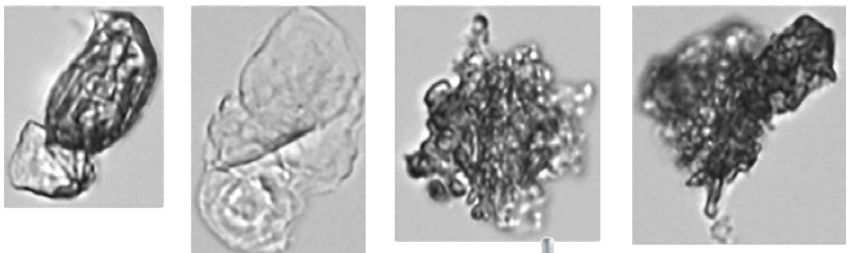
For particles 1 µm up to 1mm. Simultaneously determine particle shape, type, and size distribution of all detectable particles in your solution. Integrated auto focus mechanism simplifies focusing and provides consistent, high resolution images . Compatible with the ALH Automated Liquid Handler.

Applications:
Formulation development, protein aggregation studies, stability studies, manufacturing process improvement, final product QA/QC.



COMBINE WITH:
FLOWCAM AUTOMATED LIQUID HANDLER (ALH)...
For automated, high-throughput, unsupervised sample analysis of up to ninety-six 1-mL samples. Compatible with the FlowCam 8000 Series.

Applications: QA/QC, batch testing

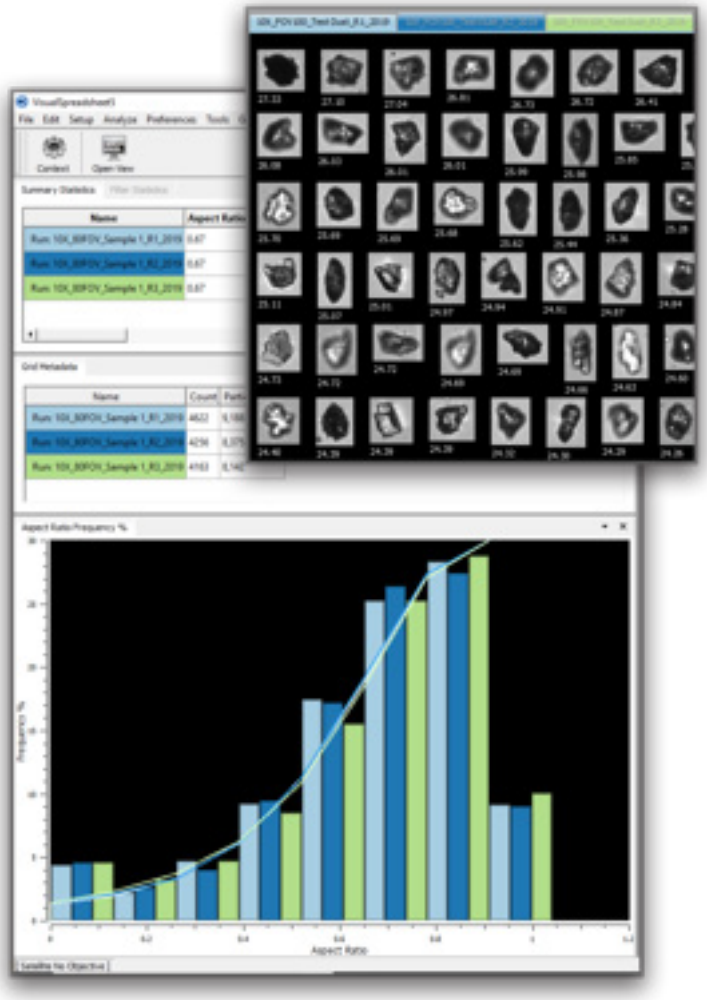


Assorted biopharma images from the FlowCam
Image source: Fluid Imaging Technologies

FLOWCAM NANO

For characterization and quantification of particles 300 nm to 10+ µm. Obtain relative quantification of intrinsic, extrinsic, and inherent particles in parenteral drugs and use morphological data to identify the structure and nature of contaminants and improve product development.

Applications:
Formulation development, protein stability studies, manufacturing process improvement, final product QA/QC.



VISUALSPREADSHEET® 5

VisualSpreadsheet is a powerful software program that allows you to interact with the particle images captured with the FlowCam®.

Version 5 represents the biggest software update in Fluid Imaging Technology's history.

Improving on other spreadsheet software programs that only allow you to sort and filter rows of numeric data, VisualSpreadsheet gives you the ability to sort and filter actual images.

Upgrading to VisualSpreadsheet 5 comes with the following benefits:

- Create data sets from multiple runs
- View and compare data from multiple runs
- Quickly load, manipulate, and analyse large sets of data
- Compare data captured from multiple objectives and/or multiple flow cells

FlowCam 8000, FlowCam Cyano, FlowCam Macro and satellite licenses are eligible to upgrade to the newest version.

CAPTURE OVER 40 UNIQUE PARTICLE MEASUREMENTS

Basic Shape Measurements Include:
Equivalent Spherical Diameter (ESD), Area Based Diameter (ABD), Length, Width, Aspect Ratio, Area, Volume Advanced

Morphology Measurements Include:
Circularity, Elongation, Compactness, Circle Fit, Perimeter, Convex Perimeter, Edge Gradient, Fiber Curl

Gray-Scale and Colour Measurements Include:
Intensity, Average Intensity, Sigma Intensity, Transparency, Average Red, Green, Blue, R/G Ratio, R/B Ratio, G/B Ratio

THE VISUAL SPREADSHEET® DIFFERENCE

- Sort and filter particle data based upon criteria you supply - results are displayed immediately as particle images instead of numbers.
- Accomplish complex particle filtering in seconds with immediate visual feedback - find and display all similar-type particles in a heterogeneous sample with sophisticated pattern recognition capabilities.
- Create and save defined particle type libraries - compare incoming FlowCam data against one or more libraries to instantly enumerate concentrations of specific particle types.
- 21 CFR Part 11 compliant software package available.

VisualSpreadsheet is included with all FlowCam instruments. A satellite version is also available so you can work with your FlowCam data on your own computer.

KENELEC SCIENTIFIC

Our company:

Established in 1962, Kenelec Scientific is one of Australia's leading scientific and environmental technology companies. Based in Melbourne, with distributors located throughout Australia and New Zealand, we are industry leaders in the supply of globally sourced, latest generation technologies at competitive prices.

Our services:

Sales
Buy the latest equipment from some of the most trusted brands in the industry.

Rental
Short and long term hire available on an extensive range of instruments.

Calibration
Professional calibration of your instruments in our accredited laboratories.

Validation
Wide range of validation services to ensure compliance with regulations.

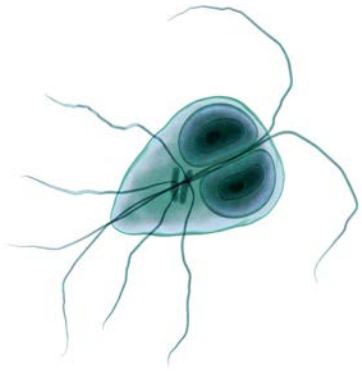
Service & Repairs
Local after-sales service and support from our experienced technicians.

Education
Product education and support available in-house, onsite or online.

Financing
Secure your equipment without relying on up-front capital funding.

More solutions

As well as being a key analysis tool the for the biopharmaceutical industry, the FlowCam range from Fluid Imaging Technologies also provides comprehensive solutions for:



Water Research

- **Phytoplankton & Zooplankton Analysis**
- Harmful Algal Bloom Monitoring
- Drinking Water Monitoring
- Microalgae Cultivation & Industrial Research

General Industry

- Food and Beverage
- Abrasives
- Column Packing Material
- Microencapsulation
- Washwater - Heterogeneous S Analysis

Don't see your solution here?

For more products and solutions, visit our website:
www.kenelec.com.au

NATA

bsi. ISO 9001 Quality Management

FS 605267

We look forward to working with you.

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