

Biopharmaceutical and Pharmaceutical Applications

OVERVIEW

With industry-leading image quality combined with automated statistical pattern recognition software, the FlowCam imaging particle analysis system allows you to simultaneously count and characterize particles in your sample, and provides you with the critical data you need to ensure product safety.

Using the FlowCam in-flow particle analysis system overcomes the limitation of particle counters (which don't provide morphology data), while giving additional particle information typically only found by using microscopy. Receive over 40 morphological measurements on each particle imaged.

APPLICATIONS

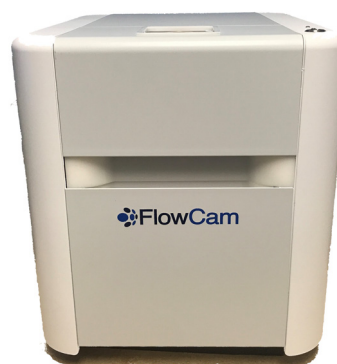
- Detection & Measurement of Protein Aggregates and Particles
- Formulation Research and Development
- QC Diagnostics & Lot Release Testing
- Stability Studies and Shelf Life Estimation
- Purification Process Development
- Excipient and API Characterization

INSTRUMENTS



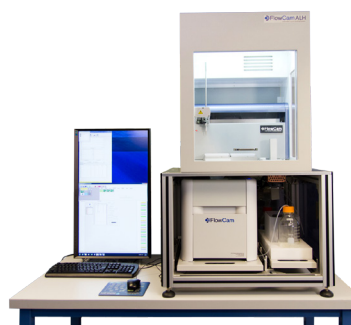
FlowCam Nano

For particles smaller than 1 μm



FlowCam 8000 Series

For particles ranging 1 μm to 5 mm in size



FlowCam Automated Liquid Handling System

For unattended analysis of up to 96 samples

FLOWCAM® IMAGING PARTICLE ANALYSIS SYSTEMS

For Biopharmaceutical and Pharmaceutical Applications

WHAT THE FLOWCAM DOES

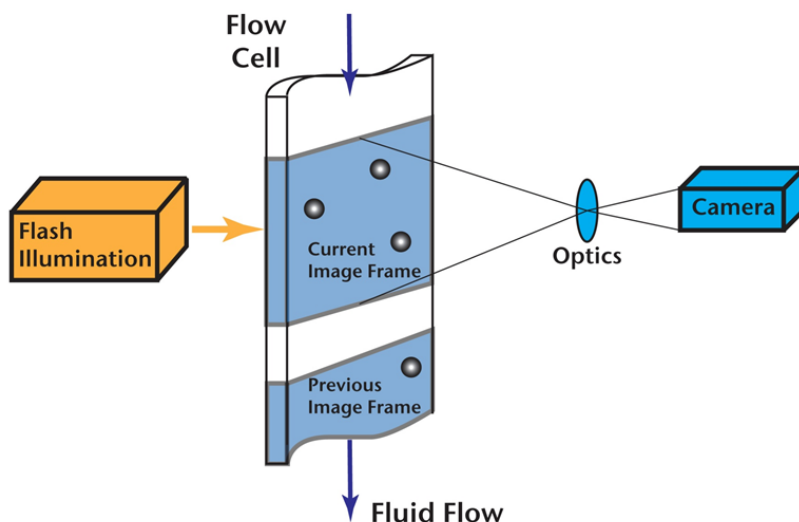
- Measures particle size and shape - over 40 morphological measurements on each particle imaged.
- Provides superior image quality and image-based measurements - fast and accurate results you can see, backed by the quantitative data to prove it.
- Gives statistically relevant results quickly - allows user to look at tens of thousands of particles per minute.
- Allows automated, trainable, statistically-based pattern recognition - saves time by isolating different types of particles into categories and sub-populations.
- Delivers accurate results on all particles from 300nm to 5MM in size (count and morphology)
- Auto Focus feature provides convenient, repeatable focus.

HOW THE FLOWCAM WORKS

The FlowCam imaging particle analysis system contains three core technologies: optics, electronics and fluidics.

The optical system is similar to a microscope, and is used to capture real-time images of the particles in the fluid as they pass through the flow cell. Additional optional electronics can also capture two channels of fluorescence information per particle.

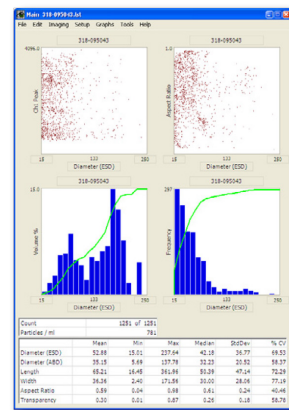
The fluidics system uses an ultra-high-precision computer controlled syringe pump to pull the fluid sample through a flow cell perpendicular to the optical path.



TURNING DATA INTO INSIGHT: VISUALSPREADSHEET® PARTICLE ANALYSIS SOFTWARE

VisualSpreadsheet is a powerful software program that allows you to interact with the particle images captured with the FlowCam. Improving on other particle analysis systems that only allow you to sort and filter rows of numeric data, VisualSpreadsheet gives you the ability to sort and filter actual images. Ultimately this gives you a more in-depth analysis of your sample and a better understanding of your data.

Immediately find and display all similar-type particles in a heterogeneous sample with sophisticated pattern recognition capabilities. You can also create and save defined particle type libraries, then compare incoming FlowCam data against one or more libraries to instantly enumerate concentrations of specific particle types.



FLUID IMAGING TECHNOLOGIES, INC.

FLOWCAM® IMAGING PARTICLE ANALYSIS SYSTEMS

For Biopharmaceutical and Pharmaceutical Applications

FLOWCAM NANO

The FlowCam Nano features a patented oil immersion, flow imaging technology paired with our industry-leading image analysis software VisualSpreadsheet® to provide you with the most comprehensive particle analysis research and development tool for parenteral drug analysis.

- Image and analyze particles ranging 300 nm to 10 µm in size
- Obtain relative quantifications of intrinsic, extrinsic and inherent particles in parenteral drugs
- Use morphological data to identify the structure and nature of contaminants and improve product development

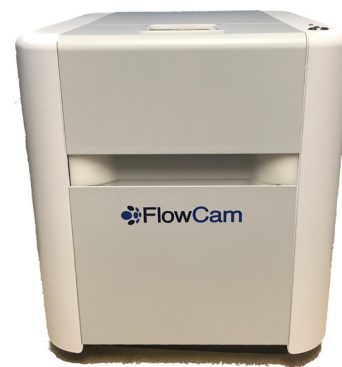


FlowCam Nano

FLOWCAM 8000 SERIES

Based on proven FlowCam dynamic imaging particle analysis technology, the FlowCam 8000 series represents the next generation platform. With the same industry-leading image quality, the 8000 series system is completely optimized for the analysis of sub-visible particulates in protein therapeutics.

- Industry-leading image quality: better images yield better measurements
- Higher-sensitivity: eliminates under-counting of transparent particles and fractionation of larger protein aggregates
- Automated, trainable, statistically-based pattern recognition: saves time by isolating different types of particles (intrinsic, extrinsic, and inherent) into categories and sub-populations.
- Industry compliance: meet USP <788> regulatory requirements. Utilize 21 CFR-compliant VisualSpreadsheet.
- Disposable pipette-tip sample introduction port: helps to reduce cross-contamination

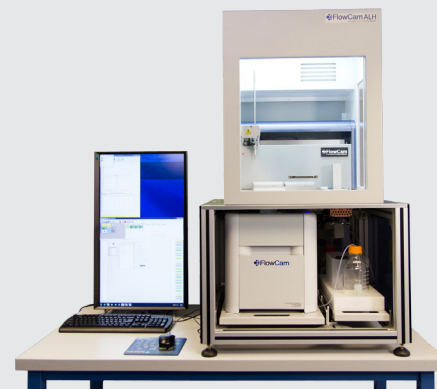


FlowCam 8000 series

FLOWCAM ALH

The FlowCam Automated Liquid Handler (ALH) integrates with the FlowCam 8000 series for uninterrupted processing of samples. The system allows for up to 96 samples to be queued for unattended operation, improved repeatability, and increased productivity.

- Easily program pre-analysis sample preparation with graphical and menu-driven operations
- Perform sample conditioning and control sample degradation and evaporation during processing with heating, cooling, and shaking features
- Protect against outside contamination and accidental disturbance of samples with self-contained system
- Save valuable bench space with vertical architecture
- Easily monitor system status and review workflows of both instruments



FlowCam ALH system

FLOWCAM® IMAGING PARTICLE ANALYSIS SYSTEMS

For Biopharmaceutical and Pharmaceutical Applications

SUPERIOR IMAGE QUALITY FOR BETTER RESULTS

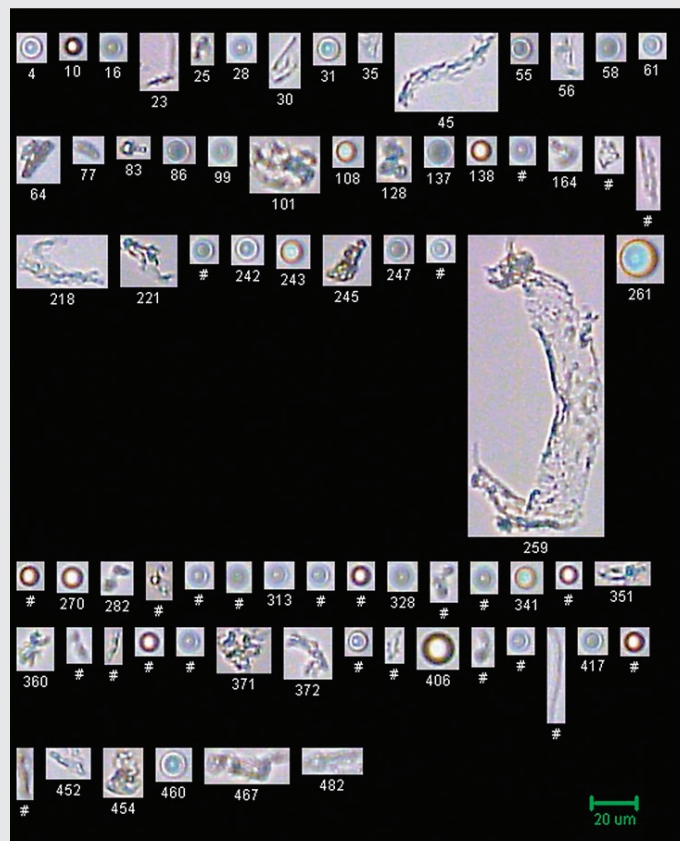
Particulates in parenteral drug development have always been a serious issue. In biopharmaceuticals, the issue is compounded by reported impacts of aggregates and particulates on the product's efficacy, safety, and immunogenicity. FDA regulations strongly recommend in-depth characterization of the identity and quantity of particles in protein therapeutics. Particle concerns are increasingly common in FDA submissions, and in some cases, particle matters have resulted in drug recalls.

Image quality is extremely important when characterizing, identifying, and differentiating particles such as protein aggregates, silicone oil, air bubbles, and other contaminants.

Image quality is also essential for accurate sizing measurements. "Blurry" particles produce a relatively lower count and concentration compared to "sharp" particles. Poor characterization creates a wider variation in measurements, and can lead to higher rates of false positives, false negatives, as well as a lower statistical confidence.

FlowCam represents a powerful tool with unique features for detection, counting, and characterizations of protein aggregates and other particles in parenteral drug formulations.

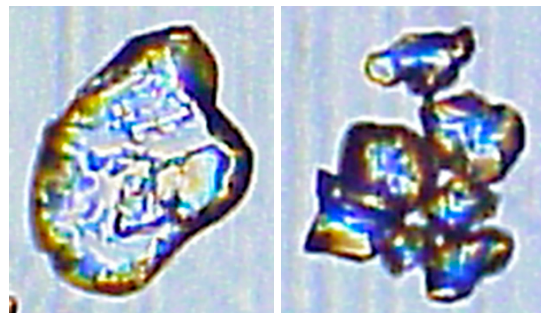
Now is the time to see how the FlowCam technology can improve your results.



SEND US A SAMPLE

Curious if our technology will work for you? Send us a sample and we will provide:

- a web-based interactive presentation of the results
- a scattergram showing the size and distribution of particles
- an Excel spreadsheet with all the measurement data, including count, length, width, and ESD
- digital images of the cells and particles in your sample



Single particle (left), agglomerate (right)