



# FlowCAM®

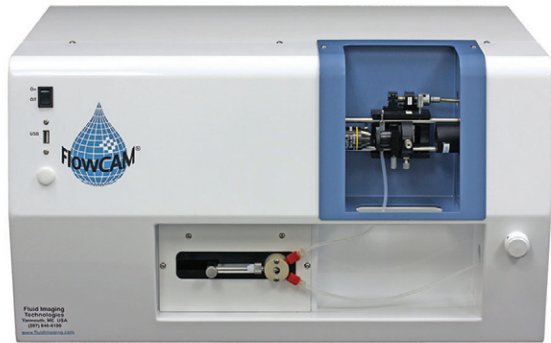
## A Digital Imaging Analyzer for Quantification and Characterization of Visible and Sub-Visible Pharmaceutical Particles

The FlowCAM® Series of imaging particle analyzers combine industry-leading image quality with automated statistical pattern recognition software to produce the most powerful sub-visible particle analyzer available for the pharmaceutical industry.

The detection, enumeration and characterization of particles, particularly sub-visible ones, in pharmaceutical formulation and quality control environments is absolutely critical to product safety in the industry. Light microscopy has long been the preferred method for analysis, however it suffers from the manual nature of the analysis, making it impossible to rapidly evaluate statistically significant populations. As a result, automated particle *counting* techniques such as light obscuration and laser diffraction have been used extensively for sampling larger populations.

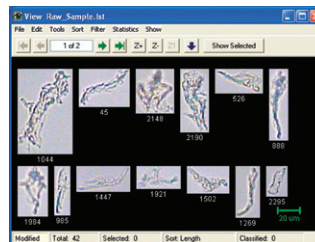
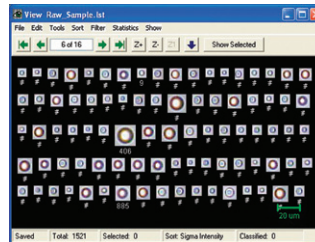
These automated particle *counters* have severe drawbacks in comparison to microscopy, however. First of all, they can only *count* particles, and therefore can tell nothing about the *type* of particles present. For example, they can not distinguish between protein agglomerates and silicone droplets in a parenteral sample. These systems also do not perform well with transparent particles, either not detecting them at all, or mis-characterizing their size.

In-flow imaging particle analysis overcomes the limitations of particle counters while giving additional particle information typically only found by using microscopy. A typical example of using the FlowCAM to analyze a proteinaceous parenteral sample is shown in Figure 1.



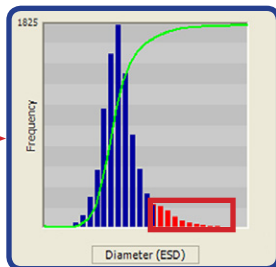
### FlowCAM Pharmaceutical Applications:

- ◇ Lyophilized Proteins
- ◇ MAb Formulations
- ◇ API Carrier Suspensions
- ◇ QC Diagnostics
- ◇ Stability Studies
- ◇ Lot Release Testing



FlowCAM and VisualSpreadsheet® software automatically separates and quantifies silicone droplets (top) and protein agglomerates (bottom).

Volume-based particle analyzers produce a distribution of particle size only.



**Figure 1: FlowCAM easily distinguishes between protein agglomerates and silicone droplets.**

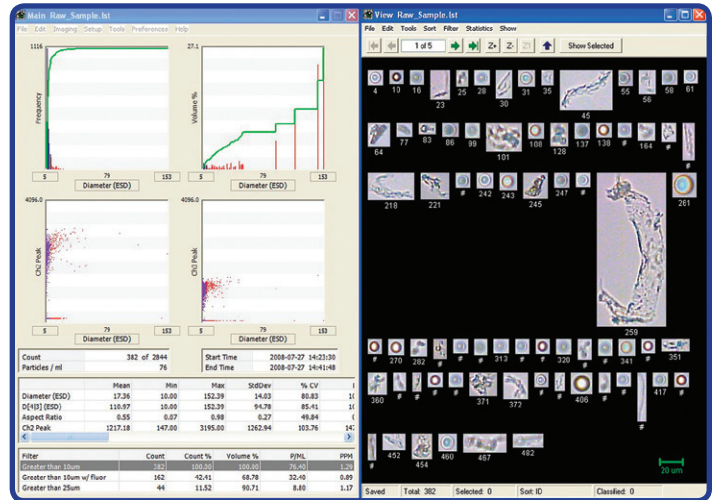
The FlowCAM® is currently in use at major pharmaceutical companies worldwide. The superior image quality found in the FlowCAM gives it a critical advantage over competing products. FlowCAM's VisualSpreadsheet® software was the first particle analysis software package to use *statistical pattern recognition* for automated particle characterization. In order to get the most benefit from statistical pattern recognition (or even value filtering, for that matter), the quality of the particle measurements needs to be as high as possible. The quality of the particle measurements obtained from an image is *directly proportional* to the quality of the original image itself, so the FlowCAM's superior image quality insures the highest level of accuracy available for filtering and pattern recognition.

FlowCAM is also now available with an ultra-high-precision, computer controlled syringe pump, enabling high accuracy sample delivery with a precision of  $\pm 0.001$ ml. For very sparse samples, the instrument can be equipped with a laser-scatter triggering option, enabling highly accurate counting down to concentrations as low as 10 particles/ml. Finally, for applications which might use fluorescence tagging, the FlowCAM can be equipped for fluorescence triggering and measurements.

Contact Fluid Imaging today to learn more about the FlowCAM, the first microscopic fluid imaging device commercially available, and still the industry leader!

### FlowCAM Benefits:

- ◇ Detects Transparent Particles
- ◇ Measures Particle Size *and* Shape
- ◇ Industry-Leading Image Quality
- ◇ Statistical Pattern Recognition
- ◇ Accurate on Samples as Sparse as 10 Particles/ml
- ◇ 21 CFR Part 11 Compliant
- ◇ Monochrome or Color Camera (optional)



### FlowCAM for Pharmaceutical Specifications:

Parameter	Value (Range)
Minimum Particle Size	1µm (Count) 2µm (Shape)
Maximum Particle Size	50µ (20X), 100µ (10X), 300µ (4X), 2,000µm (2X)
Raw Image Field Size	1280x960 Pixels
Gray Scale/Color Resolution	8 Bits (monochrome), 24 Bits (Color)
Image Format	Uncompressed TIFF (only particle images saved to reduce data storage requirements by a factor of 100 or better)
Basic Shape Measurements	Equivalent Spherical Diameter (ESD), Area Based Diameter (ABD), length, width, aspect ratio, area, volume
Advanced Morphology Measurements	Circularity, Elongation, Compactness, Circle Fit, Perimeter, Convex Perimeter, Edge Gradient
Gray-Scale and Color (optional) Measurements	Intensity, Average Intensity, Sigma Intensity, Transparency, Average Red, Green, Blue, R/G Ratio, R/B Ratio, G/B Ratio
System Options	Cross-Polarized Illumination, Laser-Scatter Triggering, Fluorescence Triggering,
Fluidics	Precision Peristaltic Pump (standard), Micro Syringe Pump (optional)
Minimum Fluid Requirements	100µl, 10 particles/ml, (Syringe pump precision of $\pm 0.001$ ml)