

YOKOGAWA 



FlowCam[®] LO

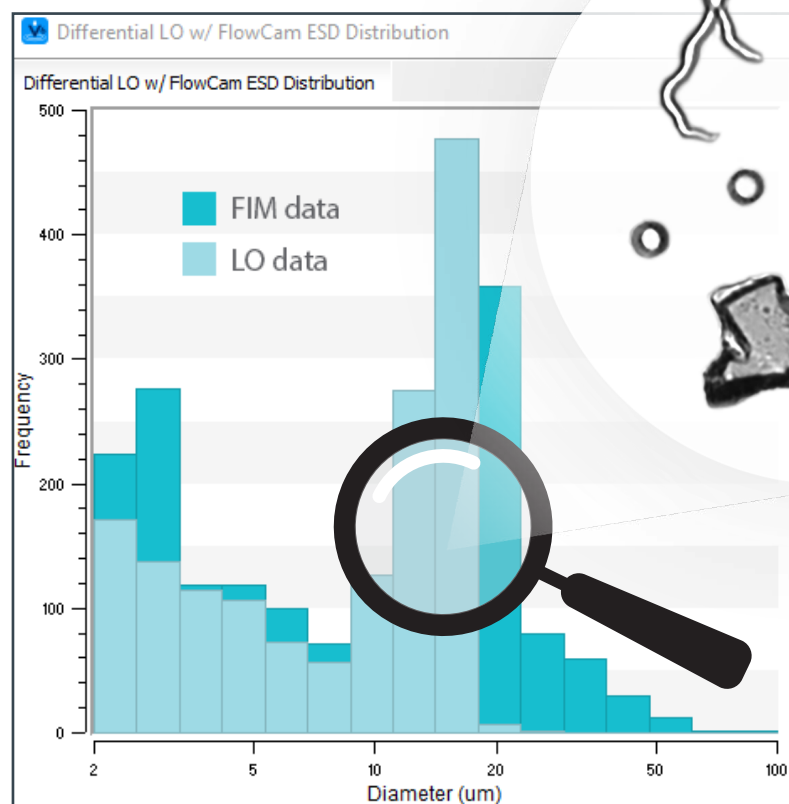
FLOW IMAGING MICROSCOPY with
LIGHT OBSCURATION

One instrument. One sample run. Two analytical methods.

Particle Analysis with Vision®

Innovative particle characterization with FlowCam LO combines flow imaging microscopy (FIM) and light obscuration (LO) into a single analytical solution.

Beyond the compendial light obscuration method to fulfill USP <787> and <788> requirements, flow imaging microscopy provides an orthogonal method for quality control of subvisible particulate matter.



USP <1788> introduces flow imaging as a technique to provide complementary morphology information and to overcome undercounting and undersizing challenges with the light obscuration method when measuring translucent particles such as proteins and other biological drugs.

Ensure safety and efficacy of your biopharmaceutical drug formulation with two integrated orthogonal methods.

Obtain light obscuration data to meet USP regulatory guidelines and verify your results with the highest quality images in FlowCam LO – all in a single instrument and single sample run.

MEET USP REQUIREMENTS

Obtain compendial particle sizing and counting according to USP <787> and <788>. Use flow imaging as an orthogonal test method per USP <1788>.

STREAMLINE PROCESSES

Perform both flow imaging and light obscuration measurements sequentially in the same instrument.

AUTOMATICALLY IDENTIFY WITH AI

Add out-of-the-box machine learning to automatically differentiate protein aggregates in formulations with the optional VisualAI™ software module – no user setup required.

MAINTAIN SAMPLE INTEGRITY

Analyze samples in their native environment. FlowCam LO accommodates a wide range of aqueous and organic fluids, including high-viscosity solvents and buffers.

 FlowCam

LO

OBTAIN MEANINGFUL RESULTS

Obtain statistically significant results in less than a minute, with as little as 100 µL of sample. With advanced hardware and processing capabilities, FlowCam LO is streamlined for rapid data acquisition and analysis.

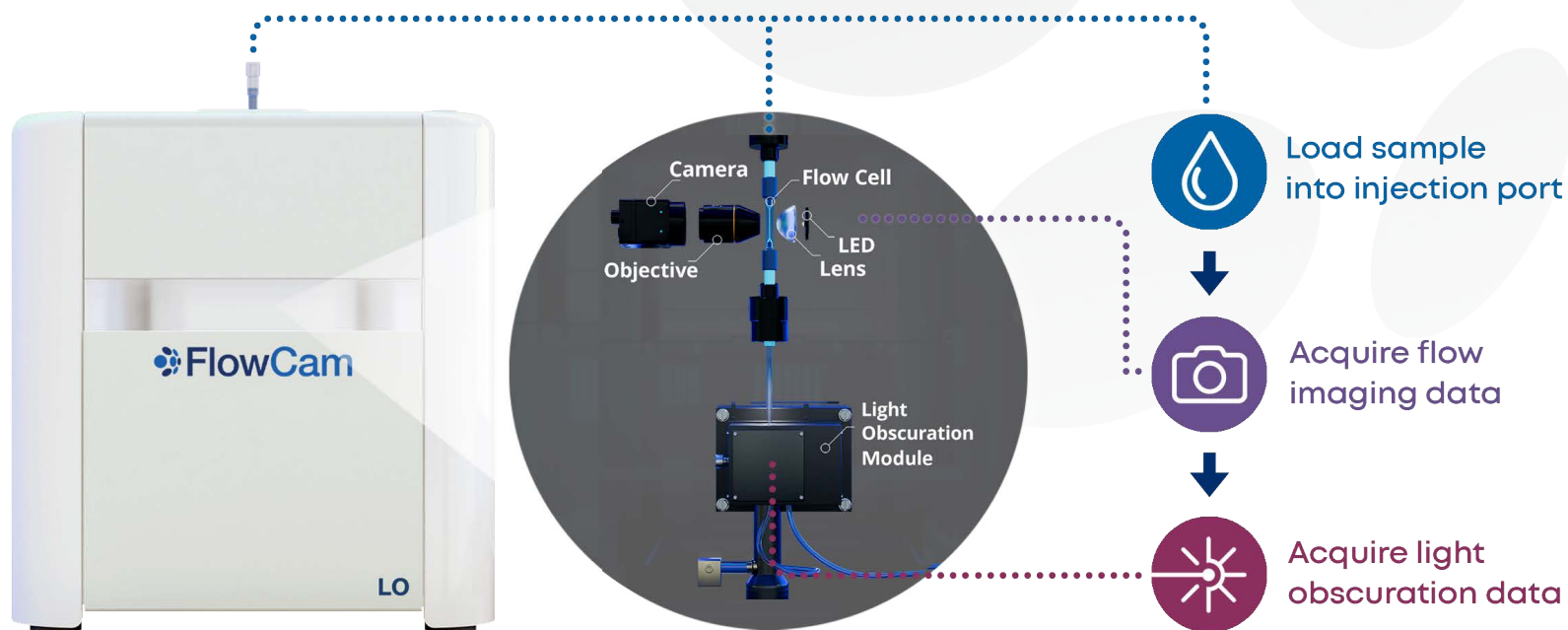
BE FLEXIBLE

Use FlowCam LO in both research and routine operations and work with a wide range of sample types and concentrations. ALH for FlowCam™ enables unattended operations for up to 384 samples.

How it Works

FlowCam LO sequentially performs flow imaging microscopy and LO measurements on a single sample, using microfluidics and optical detection.

- 1 A sample is loaded into the injection port using a standard pipette tip.
- 2 A precision syringe pump pulls the sample into the microfluidic system at a continuous flow rate.
- 3 The sample is drawn first through the flow imaging microscopy module, which includes a camera, objective, and LED illumination, to capture images and measure the size, count, and shape of the particles in the sample.
- 4 The sample then flows through the light obscuration module. Any particle present will block a fraction of the laser light from reaching the photodiode, creating a measurable electrical signal proportional to the particle size.
- 5 Post-acquisition, both flow imaging microscopy and LO results are filtered, grouped, and analyzed in VisualSpreadsheet.



FlowCam LO Applications

- **QC diagnostics and lot release testing**

With a single sample run, correlate light obscuration data required per USP <787> and USP <788> with flow imaging microscopy data recommended by USP <1788>. Validate LO measurements with an orthogonal technique and capture particle morphology and type information.

- **Detection and measurement of cells, API aggregates, and other particles**

Monitor API degradation (e.g., aggregation, cell viability) and identify contaminant particles in formulations of proteins, vaccines, cell and gene delivery vehicles, and other biotherapeutics.

- **Formulation research and development**

Use FlowCam LO's particle counting and imaging capabilities to optimize formulation conditions and container closure systems.

- **Stability studies and shelf life estimation**

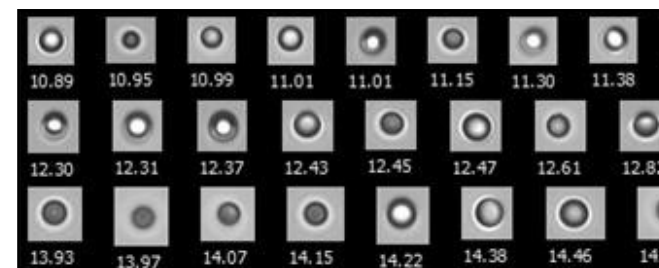
Test the influence of stress and storage conditions on particle formation during both real-time and accelerated stability studies.

- **Purification Process Development**

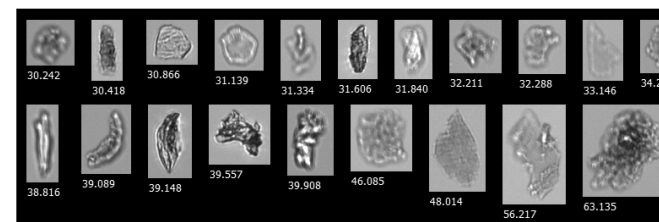
Assess manufacturing processes like filtration to ensure product quality in downstream processing steps.



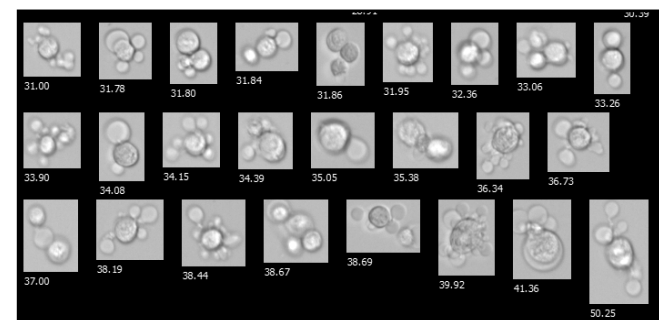
Protein aggregates



Silicone oil droplets



Glass lamination flakes



Cell aggregates

VisualSpreadsheet Software



Turning Data into Insight

VisualSpreadsheet is a powerful, all-in-one software program capable of setting up methods, acquiring data, and processing images captured with FlowCam.

Analyze, sort, filter, group, and classify images based on 40+ morphology parameters and their combinations, or use the “Find Similar” function in the software to identify what is in your sample. Group data from multiple runs or samples for easy comparison.

VisualSpreadsheet offers an optional 21 CFR Part 11 compliance package.

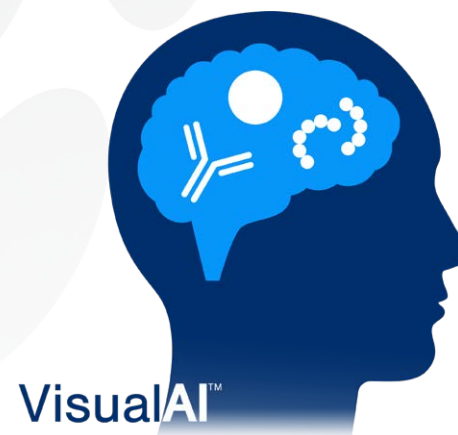
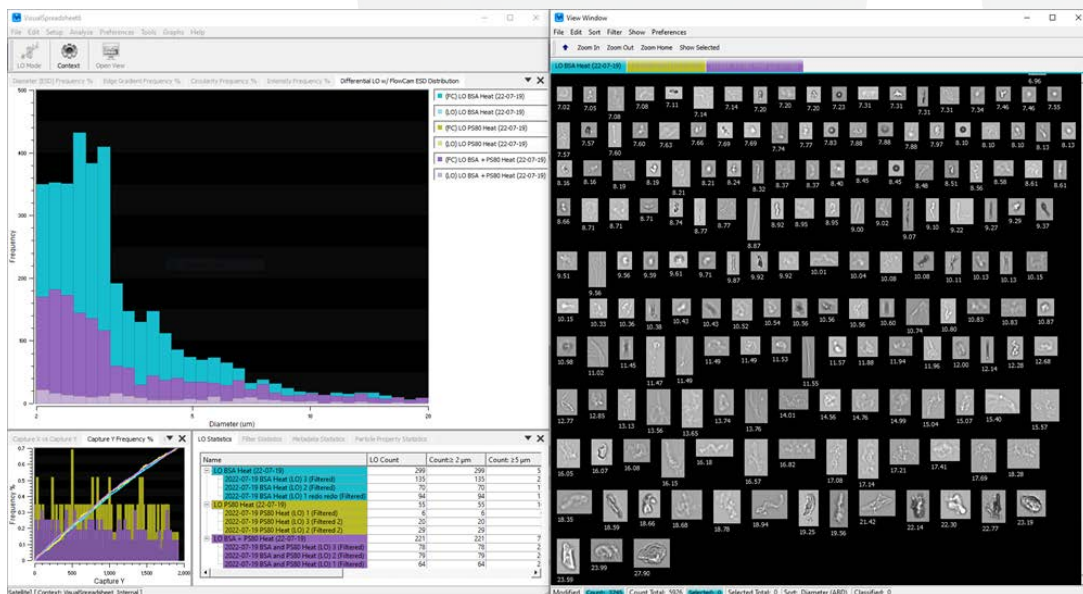
VisualAI™



Beyond Morphological Parameters

VisualAI, an optional Artificial Intelligence module, is an instrument- and sample-agnostic tool to automatically classify particles in a biotherapeutic formulation.

Identify protein aggregates and silicone oil droplets and differentiate them from other contaminants directly within VisualSpreadsheet 6 – using out-of-the-box VisualAI software.



VisualAI™

Automated Liquid Handling

ALH for FlowCam™ seamlessly integrates with FlowCam 8000 Series instruments, FlowCam LO, and FlowCam Cyano to enable automated sample preparation and analysis. Improve lab productivity, analysis repeatability, and data quality of flow imaging microscopy with state-of-the-art robotic handling.

ALH for FlowCam benefits:

- Unattended flow imaging microscopy for up to 384 samples
- Higher productivity and improved data reproducibility
- A configurable sample deck for flexible sample queuing and preparation
- Powerful, easy-to-use software with integrated data acquisition in VisualSpreadsheet
- HEPA-filtered sample enclosure for cleaner sample handling
- All-inclusive system installation and support



World-Class Customer Service

Our customer service team is available to help with all things FlowCam, including:



- Technical Support
- Remote and On-Site Training
- Application Support
- IQ/OQ Services
- Preventative Maintenance
- Repairs and Upgrades

Maximize your FlowCam utilization with a full training package led by our experts – customized for your application. This hands-on, in-depth training provides a thorough understanding of flow imaging microscopy. Learn from our scientists how to run and analyze samples; and get a wealth of tips and tricks to get the most out of your instrument.

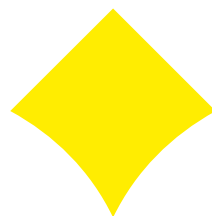
Every new instrument includes a one-year warranty, unlimited email and phone support, and one year of free access to FlowCam University training.

For continuous support we offer Gold or Silver service plans that include annual preventative maintenance services, software upgrades, access to virtual training, personalized remote support, and other benefits.

Specifications

PARTICLE SIZE RANGE	2 µm to 70 µm
MAGNIFICATION & FLOW CELLS	Flow imaging module: 10X (~100X magnification); 80 µm x 700 µm, quartz, FOV flow cell LO module: 1 mm x 0.4 mm, quartz flow cell
MINIMUM SAMPLE VOLUME	100 µL
SAMPLE PROCESSING CAPABILITY	0.2 mL/minute
FLUIDICS	Micro-syringe pump with 2.5 mL syringe
MAXIMUM PARTICLE CONCENTRATION	5 million particles/mL at 2.5 µm particle size
DATA ACQUISITION METHOD	Auto-imaging and LO, Auto-imaging only
CAMERA	High resolution (1920 x 1200 pixels) CMOS, monochrome
FRAME RATE	Shutter speed up to 100 frames per second
FOCUS METHOD	Automatic
LO LIGHT SOURCE	Solid-state laser diode, 785 nm
LO DETECTION METHOD	Light extinction, volumetric
MEASURED PARAMETERS	Morphology Parameters: Area, Aspect Ratio (width/length), Diameter (Spherical and Area-Based), Length, Volume, Width, Circle Fit, Circularity, Circularity (Hu), Compactness, Convex Perimeter, Convexity, Elongation, Symmetry Gray Scale Measurements: Edge Gradient, Intensity, Sigma Intensity, Sum Intensity, Transparency LO Data: Cumulative (≥2 µm, ≥5 µm, ≥10 µm, ≥15 µm, ≥25 µm) and differential (2-5 µm, 5-10 µm, 10-25 µm, ≥25 µm) flow imaging and LO counts and concentrations, overlaid particle size distributions of flow imaging and LO data
AUTOMATION	Compatible with ALH for FlowCam automated liquid handler
SOFTWARE OPTIONS	21 CFR Part 11 compliance module, VisualAI tool to automatically ID protein aggregates and silicone oil droplets
DIMENSIONS & WEIGHT	36 cm wide x 43 cm deep x 38 cm tall, 27 kg (43 kg shipping weight)
POWER REQUIREMENTS	92 watt maximum

Specifications are subject to change without notice



YOKOGAWA

Yokogawa Fluid Imaging Technologies

Yokogawa Fluid Imaging Technologies manufactures industry-leading particle analysis instrumentation based on digital imaging technology. Our flagship product, FlowCam, is the first automated particle analysis instrument to use digital imaging for measuring size and shape of microscopic particles in a fluid medium. FlowCam has been deployed in over 50 countries, supporting research, development, and environmental monitoring in the life sciences, materials research, and industrial applications.



Distributed by:

Kenelec Scientific Pty Ltd
1300 73 22 33
sales@kenelec.com.au
www.kenelec.com.au



| Yokogawa Fluid Imaging Technologies, Inc. | www.flowcam.com | +1-207-289-3200