



Based on the proven FlowCam VS-Series architecture, FlowCam Biologics is a Dynamic Imaging Particle Analysis (DIPA) system optimized for the analysis of protein-based parenteral therapeutics. The hardware and software configuration is optimized specifically for particulate characterization in biologics, including the ability to distinguish between extrinsic, inherent and intrinsic particles (as defined in USP <1788>). All necessary software settings for acquiring particle images and filtering the results are pre-loaded for simple, easy analysis. The system includes installation, training and IQ/OQ at the customer site.

FlowCam® Biologics	
Particle Count	Yes
Concentration	Yes
Particle Size (ESD)	Yes
Measured Parameters	<p><b>Basic Shape Parameters:</b> Area, Aspect Ratio (width/length), Area Based Diameter (ABD), Equivalent Spherical Diameter (ESD), Length, Volume (ABD-based), Volume (ESD-based), Width</p> <p><b>Advanced Morphology Parameters:</b> Area (Filled), Circle Fit, Circularity, Circularity (Hu), Compactness, Convex Perimeter, Convexity, Elongation, Fiber Curl, Fiber Straightness, Geodesic Aspect Ratio, Geodesic Length, Geodesic Thickness, Perimeter, Roughness, Symmetry</p> <p><b>Gray Scale Measurements:</b> Edge Gradient, Intensity, Sigma Intensity, Sum Intensity, Transparency</p>
Particle Size Range	2µm to 600µm (morphology, detection down to 1µm)
Technology	Dynamic Imaging Particle Analysis
Image Type	8-bit Grayscale (Monochrome Camera)
Image Format	8-bit (monochrome) TIFF
Magnification/Flow Cells Included	10X, Flow Cells (depth): 80µm Field of View, 100µm, 100µm (high efficiency)
	4X, Flow Cells (depth): 300µm Field of View, 200µm, 300µm
Fluidics	Micro Syringe Pump (computer controlled), disposable pipette sample introduction port
Flow Rate	0.01 ml/min to 20ml/minute (Dependant upon magnification, flow cell depth, camera frame rate, efficiency desired, etc.)
Software	<p><b>VisualSpreadsheet® Software:</b> Patented Interactive Scattergram®(allows selecting of particles directly from any graph or scattergram), automated value and statistical pattern recognition, interactive image-based filtering and sorting, up to 4 simultaneous histograms/scattergrams displayed (from 16 total available), direct export of all data and summary data to Excel (or any other spreadsheet), print to PDF, automatic classification, and filtering during acquisition.</p> <p>Pre-built filters included for USP &lt;788&gt; reporting (≥10µm, ≥25µm), and isolation of Silicone Droplets. Includes one copy of software with instrument, plus one copy of software for separate analysis on another computer (“satellite” license). 21 CFR capability pre-installed (can be turned on at any time).</p>
Hardware	Windows 7 w/ 8Gb RAM and 500Gb disk (includes 22” monitor, keyboard and mouse)
Camera	Digital 1280x960 Pixels
Power Requirements	100-240 VAC, 50/60 Hz
Dimensions (W.D.H.)	21.5” X 15” X 12”    530mm X 300mm X 370mm
Unit Weight	60 lbs    (20.5Kg)
Environmental (Temperature & Humidity)	<p><b>Operating:</b> 5-40° C, Humidity 20-80% RH</p> <p><b>Storage:</b> -20-60° C, Humidity 20-95% RH</p>