Particle Contamination Monitoring…

Visualizing & Classifying Cleanliness

Vision Analytical has been in the Particle Analysis industry for over 18 years with strict focus on Dynamic Image Analysis, also known as Flow Image Microscopy or Micro Flow Imaging.

The Particle Insight Raptor 1788 is designed to perform high resolution precision measurements of particles from 1um to 100um in a flexible benchtop configuration. By using Dynamic Image Analysis and a flexible sampling design, users can get a full picture of both visible and subvisible particles. Unique Features include:

- Compliant to new USP<1788.3> for compliance to determine particulate matter in injections and ophthalmic solutions
- Detect, count, and classify particles down to 1µm in size.
- Ultra high-speed. Capable of running up to 40 milliliters per minute.
- Ultra high-quality specialty optics using 18x High Magnification to offer high accuracy throughout the full analysis range.
- 5MP camera offering high sensitivity and resolution to ensure high accuracy of particle analysis.
- Easy User Interface with only two button operation required.
- Interchangeable / disposable Quartz glass sample cartridges.
- Instrument Certification / Validation package to ensure IQ, OQ, PQ compliance.
- 21CFR Part 11 and Data Integrity compliant that ensures data is stored properly.
- Support plans that include at-site or loaner program with over-night shipping to minimize downtime for the customer.
- Multiple ways to suspend sample or on-line use for continuous monitoring.

USP–NF

<1788> Methods for the Determination of Particulate Matter in Injections and Ophthalmic Solutions

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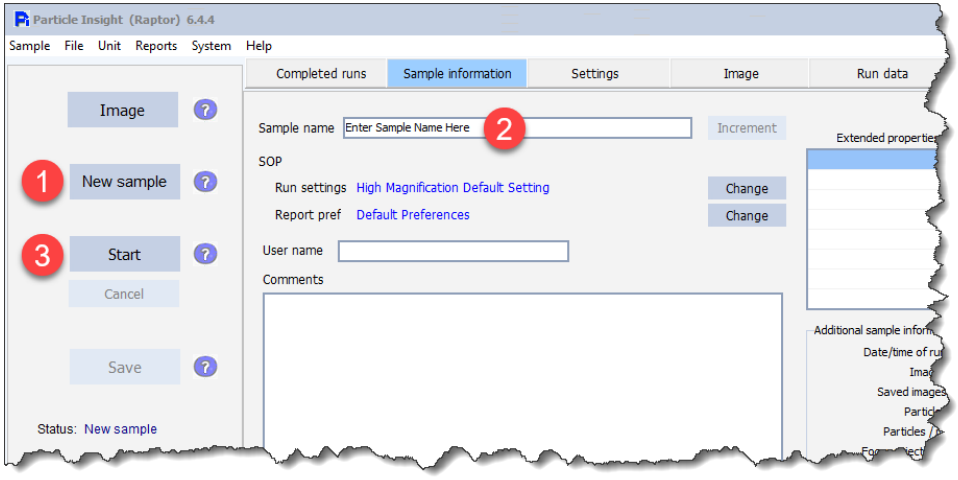
Simple Operation. Powerful Insight

RAPTOR 1788

The **Raptor 1788** was engineered to make advanced particle analysis effortless. With an intuitive workflow and an intelligent results interface, users can go from sample to insight in seconds — no complex setup, no steep learning curve.



Two-Button Operation - From sample loading to results with unmatched simplicity
The Raptor 1788 eliminates unnecessary steps and removes operator variability through a streamlined **two-button workflow**:

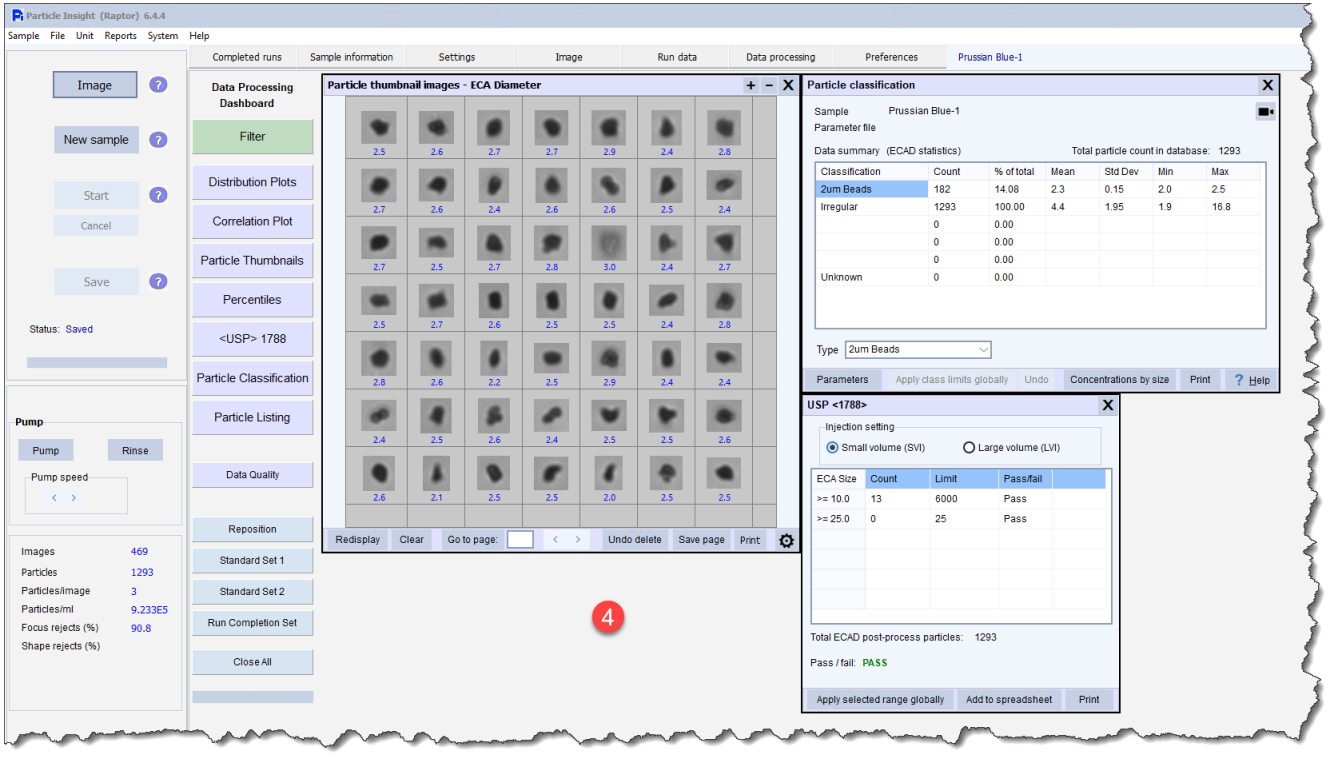
1 - Load Sample - Introduce the sample using your preferred method — pre-filled syringe, Pipette into sterile cuvette, IV-Bag, or automated feed.

2 - Press "New Sample", give your analysis a name, and press "Start" - The instrument automatically optimizes imaging parameters, runs the analysis, and processes all size, shape, and concentration data.
No menus, No configuration, No waiting for calibration routines.

3 - Just press Start, and the Raptor handles the rest. This simple, consistent workflow ensures repeatable results across operators, shifts, and sites.

4 – Smart, Customizable Results Dashboard – Once analysis is complete, the Raptor automatically displays a **configurable results dashboard**, designed for fast interpretation and deeper understanding.
Your dashboard can include:

- **All Particle Thumbnail images for root-cause identification**
- **Concentration and cleanliness results as defined by USP<788>**
- **Classification data to enumerate classes of particles such as debris, air bubbles, silicone droplets and other sub-visible particles**
- **Pass/fail indicators based on your internal limits or standards**



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Flexible Fluidics for Every Workflow

RAPTOR 1788

Interchangeable. Disposable. Clean by Design.
The **Raptor 1788** is engineered with a fluidics system that adapts to the way *you* work. Whether you're analyzing finished products or research biological suspensions, the Raptor's flexible design ensures the cleanest possible measurements and minimizes sources of error that plague traditional systems.

Interchangeable & Disposable Sample Cells - Cleaner Operation, More Accurate Data
Permanent flow cells can cloud, or trap debris over time — leading to false counts, inconsistent results, and frustrating maintenance. The Raptor eliminates these issues with a **fully interchangeable, high-quality Quartz, disposable sample cell cartridge**:

- **Eliminates particles sticking to the cell walls and inflating counts**
- **Fast and simple cleaning — just pull out the cell cartridge and replace when needed**
- **Reduces downtime and routine maintenance. Cell cartridges can be removed and cleaned off-line or simply replaced.**

This design ensures that every sample receives a fresh, reliable optical path — delivering more trustworthy data and dramatically fewer troubleshooting headaches.

Multiple Analysis Modes for Maximum Flexibility - Choose the Workflow That Fits Your Application
The Raptor's fluidics system supports several measurement approaches, each designed to match real-world needs:

- **Single-Pass Analysis –** Draws the sample once through a disposable luer tip for a fast, contamination-free measurement
- **Recirculation Analysis** – Gently recirculates the sample to raise particle counts for low-concentration analyses while protecting fragile morphologies.
- **Direct Measurement from Pre-Filled Syringes -** A closed, transfer-free workflow that prevents contamination and keeps the original sample intact for non-destructive analysis.
- **Direct Measurement from IV Bags or Online -** A fully closed-loop option ideal for pharmaceutical and biomedical applications where sterility and contamination control are essential.

Minimize Contamination. Maximize Confidence.
External contamination is one of the biggest sources of error in particle analysis. Every transfer step increases the risk of adding debris that doesn't belong in the sample. The Raptor's fluidic flexibility offers **Reduced contamination risk, Higher confidence in low-level particle counts, and Cleaner baselines with fewer invalid runs**

Flexibility isn't just a convenience — it's a key part of ensuring reliable measurement results.

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Unmatched Hardware. Engineered for Speed, Clarity, and Accuracy

RAPTOR 1788

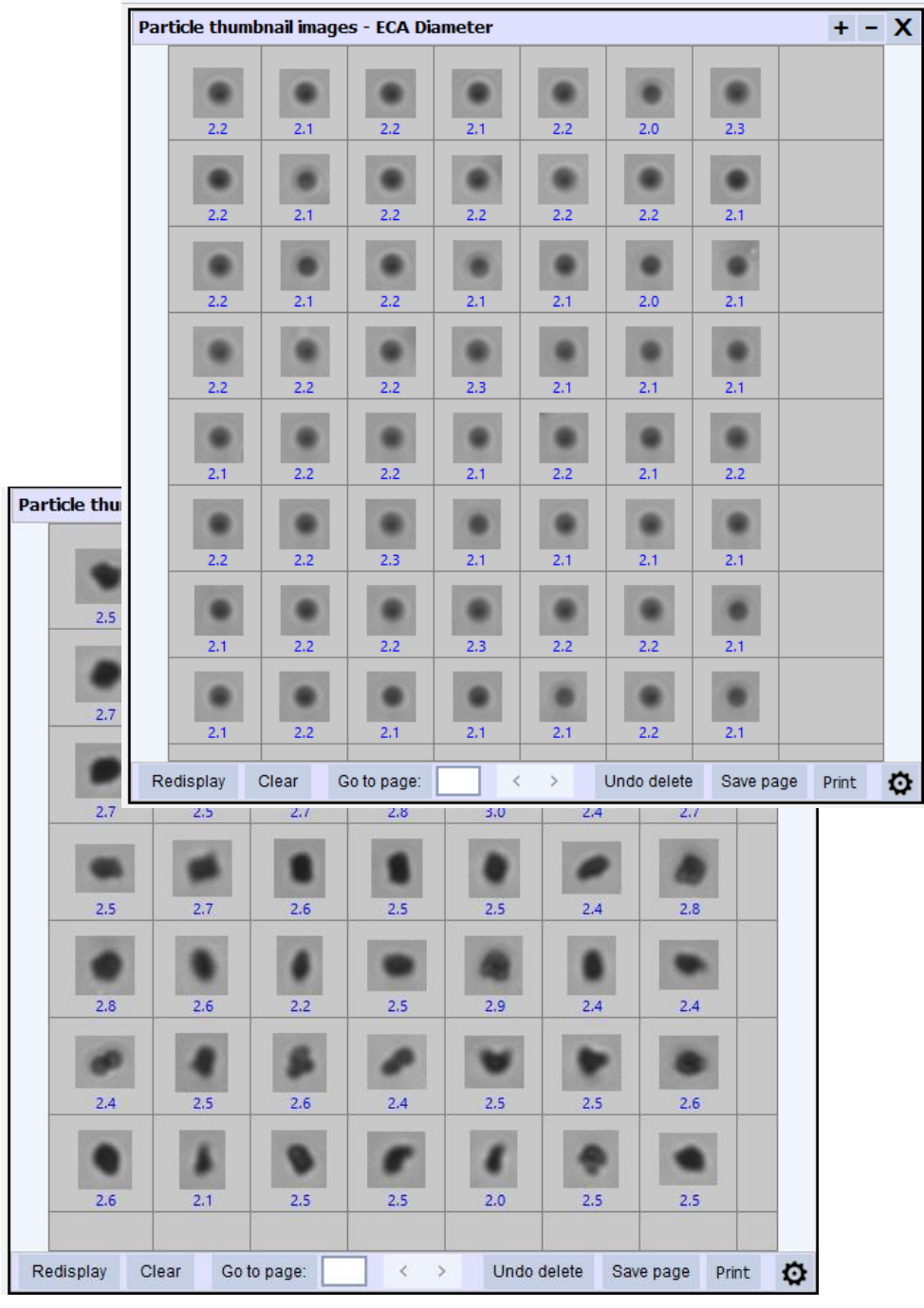
The **Raptor 1788** is built on high-end imaging hardware designed to eliminate the bottlenecks and frustrations customers face with traditional particle analyzers. From ultra-fast sample processing to premium optics, every component is selected to deliver cleaner images and more reliable data — every time.

High-Speed Particle Throughput
Up to 40 mL/Min Flow Rate (yes, milliliters, not microliters) — No Compromise on Accuracy
Speed matters — especially in environments where customers process dozens or hundreds of samples a day. Many competing systems are slow, clog easily, or force users to choose between speed and accuracy.
The Raptor 1788 removes this limitation.
- **Processes samples at up to 40 mL per minute**
- **Maintains sharp imaging even at high flow rates**
- **Reduces probability of important particles settling or floating to the top, avoiding detection.**

Premium High-Magnification Optics and 5MP camera for high accuracy of even the smallest particles
Benefits include:
- **Clearer thumbnails for contamination source identification**
- **Enhanced contrast and edge definition**
- **Reduced false sizing from soft or unfocused edges**
- **Reliable differentiation of particle types down to 1 micron in size**.

In particle analysis, **image quality *is* data quality**, and the Raptor's hardware gives a level of clarity that competitive systems cannot match.

It's not just better hardware — it's better outcomes.



Sample Thumbnails. Approximately 2µm

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Confidence You Can Measure

RAPTOR 1788

The **Raptor 1788** can **independently verify both size and particle concentration** against certified count controls. This dual-parameter validation provides laboratories and reliability teams with a level of confidence that competing technologies simply cannot deliver.

Why Certified Performance Matters
Most particle analysis technologies can calibrate for size but struggle to validate concentration with recognized standards. Others can approximate counts but cannot tie their size measurements to a certified reference. This gap introduces uncertainty, complicates data interpretation, and makes cross-instrument comparisons unreliable.

The **Raptor 1788 closes this gap**.

By demonstrating compliance with **certified mean diameters** and **certified particle concentrations**, the Raptor provides:

- **Traceable, defensible measurement accuracy**
  Every reported value is anchored to a standard, not an assumption.
- **True instrument-to-instrument consistency**
  Certified verification ensures that results match expectations regardless of location or operator.
- **Confidence in root-cause and trend analysis**
  When size and concentration are both validated, diagnostic decisions become far more reliable.

A Capability Competitors Can't Match
This unique capability empowers your team with:
Higher trust in contamination events - No second-guessing whether a spike is real or an artifact.
Stronger quality documentation - Perfect for regulated industries and high-stakes reliability programs.
Improved customer and auditor confidence - Data tied to certified standards speaks for itself.


thermo scientific

PHARM-TROL™ Particle Count Control
Certified Particle Size Standard
NIST Traceable Mean Diameter

1. DESCRIPTION This product is prepared to provide controls for (U.S. Pharmacopeia) USP<788> interim testing. It consists of monodisperse polystyrene microspheres in an aqueous medium specially prepared to promote dispersion and reduce clumping of the particles. The mean diameter is certified as traceable to the Standard Meter through the National Institute of Standards and Technology (NIST). All other information is for reference only and should not be used as calibration values.

2. PHYSICAL DATA — Catalog Number: CS3800-15, Nominal 15 µm
Certified Mean Diameter: 15.0 µm ± 0.1 µm
Standard Deviation: 0.13 µ
Coefficient of Variation: 0.9%
Microsphere Composition: Polystyrene
Polymer Density: 1.05 g/cm³
Index of Refraction: 1.59 @ 589 nm
Approximate Concentration per mL: 3800 (± 15%) @ 10-25 µm
-Continued on page 2

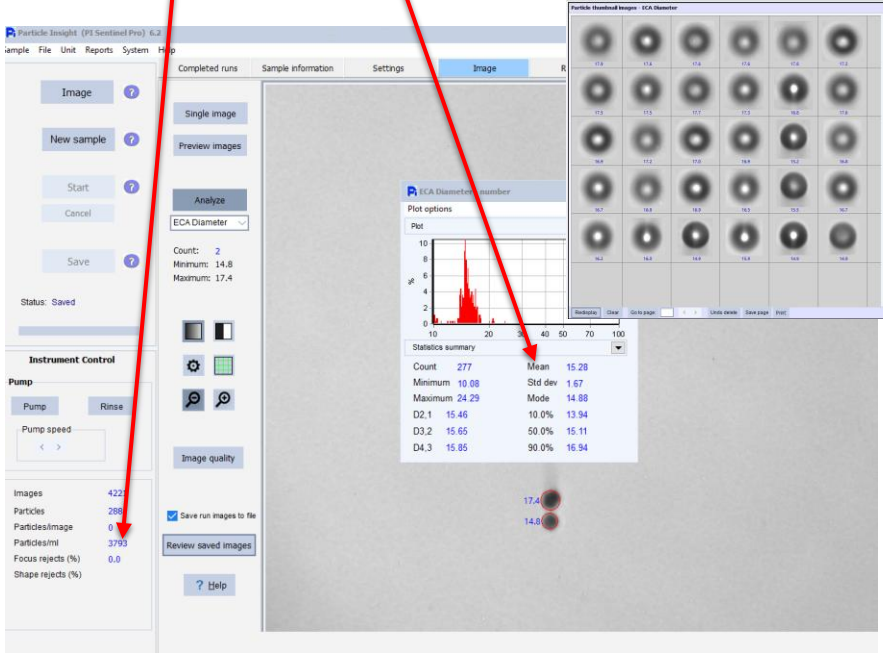
CERTIFICATE OF CALIBRATION AND TRACEABILITY

This certifies that the calibrated mean diameter dimension of this product was transferred by optical microscopy from a stage micrometer calibrated by the National Institute of Standards and Technology (NIST SRM 2800 SN411). NIST Standard Reference Materials 1690, 1692, 1960, and 1961 were used to validate the accuracy and traceability of the calibration method.

Catalog Number: CS3800-15, PHARM-TROL™ Particle Count Control
Certification Date: October 12, 2018
Certified Batch: 4215-006
Production Batch: 3800-15-171
Certified Mean Diameter: 15.0 µm
Expanded Uncertainty: ± 0.1 µm

Jennifer Liu, Scientist II
Thermo Fisher Scientific Particle Technology

Packaging Lot #: 284350
Expiration Date: MAR'2



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Other Solutions We Offer

RAPTOR 1788

Raptor Portable
- Oil and Gas Edition
- Water Quality Edition
- Portable system used for particle size, shape, concentration, classification.
- Dry and Wet suspensions

Oil & Gas

Water Quality

Malvern Hydro Insight
- Dynamic Imaging Module for the Mastersizer 3000
- Add-on in-line to the Mastersizer adding particle size, shape, concentration, classification.
- Wet suspensions

Vision Analytical web page

Malvern web page

Raptor Portable
- Fuel and Lubrication Edition
- Portable system used as a Particle Contamination Monitor for the Lubrication Industry.
- Complies with ISO 21018, ISO4406, SAE and other industry requirements.
- Particle detection, classification, and concentration.
- Oil or wet suspensions only

Raptor 1788
- High magnification particle detection, classification, and concentration.
- Designed primarily for sub-visible particle analysis.
- Wet suspensions

Raptor Benchtop
- Particle size, shape, concentration, classification.
- Dry and Wet suspensions

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Vision Analytical Incorporated
4444 Southwest 71st Avenue, Suite #112, Miami, Florida 33155, USA
www.ParticleShape.com, Sales@ParticleShape.com, 305-801-7140