Airflow Visualization Tracer Selection

A Practical, Fit-for-Purpose Approach

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PERFORMANCE VALIDATION

Moving Quality Forward

Dalton Q. Pierson

- Airflow Visualization Services Director – Performance Validation Inc.
- Led high-value airflow visualization projects
- Extensive work across isolators, RABS, and aseptic production areas
- Trusted by major pharmaceutical manufacturers
- Focused on regulatory-defensible methodologies

OBJECTIVES:

- Present two primary tracers
- When to use each tracer
- Tracer selection impact
- Neutral buoyancy discussion

GLYCOL FOG & WATER FOG

Selection must be application-specific

GLYCOL

- More residence time
- Great for large spaces
- Opaque for recording

WATER

- Less residue and clean-up
- Isolator-compatible

WFI FOGGER DROPLETS

Ultrasonic Water Fogger
Generally: Size Distribution: ~1–10 µm MMAD (Mass Median Aerodynamic Diameter)

Specifically: the Performance Validation foggers generate droplets primarily in the 0.3 to 5.0 µm size range.

The droplet distribution is as follows:

< 0.3 µm –	12 % OF GENERATED DROPLETS
0.3 µm – 0.5 µm	36 % ...
0.5 µm – 1.0 µm	24 % ...
1.0 µm – 5.0 µm	20 % ...
> 5.0 µm	8 % ...

ULTRASONIC WATER DROPLETS

Particle Relaxation Time: Time required for a particle to adjust its velocity to match the surrounding airflow; indicates responsiveness to changing flow conditions

Settling Velocity: Rate at which particles descend under gravity; indicates potential for vertical bias and loss of flow fidelity

Stokes Number: Ratio of particle inertia to airflow response time; indicates ability to accurately track airflow dynamics

ULTRASONIC WATER DROPLETS

1. Low <u>Stokes Number</u>

- Stokes number is much less than one.
- Droplets (0.3–10 µm) respond almost instantly to airflow changes

→ **Accurate flow tracing**

2. Low <u>Settling Velocity</u>

- Very low gravitational settling
- Typical magnitude:
  - 0.3–10 µm droplets → negligible settling over observation time

→ **No meaningful vertical bias during smoke study**

ULTRASONIC DROPLETS

Smaller is Better … for **settling velocities**

Suitability is achieved operationally when droplet settling velocity is small compared with the air velocities being visualized.

Illustrative settling velocities:

- 1 µm: ~0.003 cm/s
- 2 µm: ~0.012 cm/s
- 5 µm: ~0.075 cm/s
- 10 µm: ~0.30 cm/s

ULTRASONIC WATER DROPLETS

Stokes Number: Ratio of particle inertia to airflow response time; indicates ability to accurately track airflow dynamics.

Illustrative Stokes Numbers (Ultrasonic Water Droplets):

- 1 µm: ~9×10^{-6}
- 2 µm: ~4×10^{-5}
- 5 µm: ~2×10^{-4}
- 10 µm: ~9×10^{-4}

Assumed / Typical cleanroom / isolator condition:

Characteristic velocity (U) ≈ 0.3 m/s
Characteristic length (L) ≈ 0.1 m
Air viscosity ≈ 1.8×10^{-5} Pa·s
Water droplet density ≈ 1000 kg/m^3

ULTRASONIC WATER DROPLETS

Stokes Number: Lower is better

The standard equation for **Stokes Number** is: $$Stk = \frac{\tau_p U}{L}$$

Where:

Stk = Stokes Number

τ_p = particle relaxation time

U = characteristic airflow velocity

L = characteristic length scale of the airflow system or flow feature

For small droplets in air, particle relaxation time is often estimated as: $$\tau_p = \frac{\rho_p d_p^2}{18\mu}$$

Where:

ρ_p = particle density

d_p = particle diameter

μ = dynamic viscosity of air.

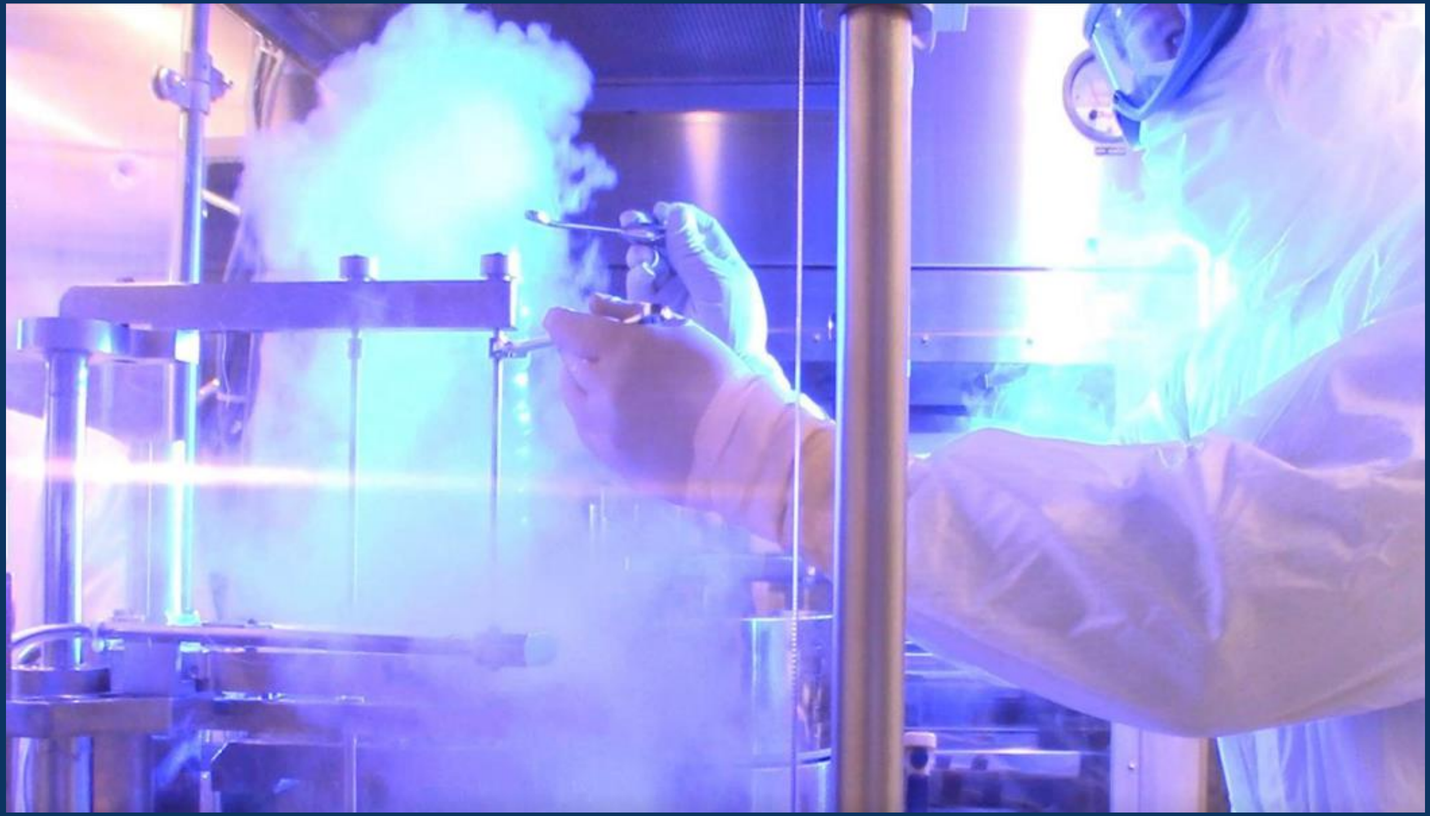
ULTRASONIC WATER DROPLETS

Smaller is Better, up to a point –

Optical Performance – Visibility for Witnesses and Video Recording

> 2–3 µm	**Highly visible**
~1–2 µm	**Marginal but usable**
~0.5–1 µm	**Poor visibility**
< 0.5 µm	**Effectively not visible in standard setups**

GLYCOL



- Longer residence time in air
- Risks to isolators
- Risks to safety

GLYCOL

- Composition/information on ingredients
  - <50.0% USP propane glycol-1,2-diol
  - <10.0% USP glycerol
  - >40.0% Water, distilled,

GLYCOL FOGGERS

Droplet behavior vs ultrasonic water fog

Compared to your ultrasonic droplets (~1–10 µm):

- Glycol foggers:
  - Often produce smaller initial droplets, but…
  - Coalesce / grow optically due to hygroscopic effects
- Net effect:
  - Very strong visibility
  - Visible for a longer distance

GLYCOL-BASED FOG CHALLENGES
in closed isolator systems

- Material Compatibility
- Residue and Cleaning
- Filter Residue and Restriction
- Quality Risks: Total Organic Carbon (TOC) testing
- System Constraints: OEMs

GLYCOL-BASED FOG CHALLENGES
in closed isolator systems

Real-world Challenges:

A client used Glycol foggers in a new isolator. VHP cycles impacted.
All filters replaced.

Isolator OEM engineers stated that the use of glycol may void the equipment warranty and can damage catalytic converters.

INDUSTRY DIRECTION: Where Practice Is Heading

- **Increasing adoption of**:
  - Closed systems and isolators
  - VHP-based decontamination
- **Reduced tolerance for**:
  - Residue-generating materials
  - Post-study cleaning burden
- **Result**:
  - Increased preference for residue-free airflow visualization methods
- **Bottom Line**
  - Tracer selection is being driven by **system constraints and contamination risk**.

Industry Misconception

- “Tracer must be neutrally buoyant”
- Reality: governed by particle dynamics

HOW TO CHOOSE THE CORRECT TRACER

1. Selection needs to be best risk-based

2. Target accurate airflow representation, not necessarily neutral buoyancy

3. Add justification phrasing to Smoke Study Protocols and Reports

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