Nano Particle Technology
US: +1 719-428-4042
UK: +44 204-577-004
MX: +52 554-169-6811
Web: AppliedPhysicsUSA.com
Email: Sales@AppliedPhysicsUSA.com

3417 E 7th St.
Tampa, FL 33605 USA

TECHNICAL SUBSTANTIATION REPORT

AP Series LN_2 Foggers: Neutral-Buoyancy Airflow Visualization and Engineering Basis

Scientific, historical, regulatory, and engineering substantiation for active self-pressurized and passive dewar liquid-nitrogen fogger architectures used in pharmaceutical smoke studies

Prepared by Applied Physics

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Document purpose	Client-facing scientific and engineering support for pharmaceutical airflow-visualization qualification, CAPA, and regulatory correspondence.
Regulatory posture	Supports suitability of properly operated steam/LN_2 water-fog systems as passive/functionally neutrally buoyant airflow tracers; does not claim FDA approval or site-specific compliance.
Technology families	Covers active self-pressurized AP Series platforms (including AP30, AP50, AP100, AP200) and passive dewar AP Series platforms (including AP35, AP95, AP175).
Controlled design basis	AP Series LN_2 fog is generated by rapidly condensing heated high-purity water vapor using liquid nitrogen / cold nitrogen vapor, producing a nominal micron-scale water fog. AP design documentation identifies approximately 2-3 µm as the nominal droplet range.

1. Executive Regulatory Position

Steam/liquid-nitrogen cleanroom fogging is not a new or experimental airflow-visualization concept. A University of Minnesota flow-visualization system patented in 1988 specifically used steam passed over liquid nitrogen to create a high-density, non-contaminating fog for cleanroom airflow analysis and described the resulting fog as neutrally buoyant. A follow-on 1989 patent incorporated liquid-cryogen level control and continued to describe the steam/cryogen fog as neutrally buoyant and non-contaminating. [6,7]

Independent commercial precedent is equally direct. TSI/MSP describes its Zero-Residue Cleanroom Fogger 2100 as mixing steam and liquid nitrogen to produce approximately 3 micrometer droplets and "neutrally-buoyant fog for airflow tracking over long distances." [8] This is the same fundamental physical generation principle used by AP Series LN_2 foggers: high-purity water vapor is rapidly cooled and condensed by a cryogenic nitrogen environment into visible micron-scale water droplets carried in nitrogen-rich gas.

FDA's recent 2026 warning-letter language has increased scrutiny of smoke-study execution and specifically gives "neutrally buoyant media" as an example of proper practice. FDA does not prescribe one permitted fog-generation technology in those letters. The relevant question is whether the tracer accurately visualizes the actual airflow under representative dynamic conditions. [1-3]

> **Regulatory position: A properly operated AP Series LN_2 fogger has a strong historical, scientific, and engineering basis for use as a neutrally buoyant/passive airflow-visualization tracer. The self-pressurized and passive-dewar architectures differ primarily in how cryogen delivery is generated and controlled; both use the same established steam/LN_2 condensation principle.**

2. Scope and Intended Use

This report addresses AP Series liquid-nitrogen foggers used for cleanroom airflow visualization, including pharmaceutical ISO 5/Grade A critical zones, RABS, isolators, laminar-flow workstations, cleanrooms, and related sterile-manufacturing airflow studies. It covers both active self-pressurized and passive dewar configurations.

- Active self-pressurized AP Series architecture: AP30, AP50, AP100, AP200 and derivative configurations using a self-pressurized cryogenic storage system with controlled delivery.
- Passive dewar AP Series architecture: AP35, AP95, AP175 and derivative configurations relying primarily on natural boil-off/passive dewar behavior with controlled fog output.
- This report addresses tracer physics, thermal/momentum control, cryogenic delivery architecture, regulatory context, and engineering controls.
- It does not replace the facility-specific dynamic airflow visualization study, approved SOP, protocol, or QA review.

- It does not represent FDA, ISO, USP, or EU regulatory approval or endorsement.

3. Regulatory Context

3.1 FDA expectations

FDA aseptic-processing guidance emphasizes in-situ air-pattern analysis that demonstrates unidirectional airflow and sweeping action over and away from exposed product under dynamic conditions, including the effects of interventions and equipment. FDA also identifies video recording as useful for evaluating airflow and configuration changes. [1]

In 2026 FDA warning letters to Wizcure Pharmaa and International Medication Systems, FDA instructed the firms to conduct thorough dynamic smoke studies using proper practices and gave "neutrally buoyant media" as the example for appropriately visualizing airflow. [2,3] The letters do not identify LN_2 fog as prohibited and do not prescribe a particular fogger generation method.

3.2 EU GMP Annex 1 and ISO 14644-3

EU GMP Annex 1 requires airflow patterns to be visualized in cleanrooms and zones, including studies both at rest and in operation, and requires video recordings to be retained. Annex 1 also states that airflow visualization studies should correlate with air-speed measurement. [4] ISO 14644-3 provides test methods and recommended apparatus for cleanroom performance testing and permits alternative methods by agreement between customer and supplier. [5]

> **The regulatory acceptance criterion is the fidelity and adequacy of the airflow visualization - not the brand, tank architecture, or whether the cryogen is delivered by passive boil-off or a controlled self-pressurized system.**

4. Physical Principle of Steam/LN_2 Fog Generation

The AP Series LN_2 process is a physical condensation process, not a chemical reaction. Heated high-purity water forms water vapor. The vapor is rapidly cooled in a liquid-nitrogen / cold-nitrogen environment, causing condensation into a dense population of micron-scale liquid-water droplets. Nitrogen functions as the cryogenic cooling medium and carrier gas; it does not chemically bond with the water.

- Water source: deionized, sterile, or Water for Injection (WFI), as applicable to the site and model instructions.
- Cryogenic source: liquid nitrogen, which boils at cryogenic temperature and provides strong cooling capacity and nitrogen vapor.
- Visible tracer: micron-scale liquid-water droplets dispersed in the gas stream.
- After evaporation, the water returns to vapor and the nitrogen returns to the surrounding gas phase; no oil or glycol carrier is required.

This same basic steam-over-cryogen mechanism is described in U.S. Patent 4,771,608 and U.S. Patent 4,875,340 for cleanroom airflow visualization. Those patents explicitly discuss flow control, pressure regulation, cryogen-level control, and neutral-buoyancy management. [6,7]

5. Direct Historical and Independent Evidence for Neutral-Buoyancy Use

Source	What it demonstrates	Why it matters
U.S. Patent 4,771,608 (1988)	Steam is passed over a cryogenic liquid such as LN_2 to form high-density water fog for cleanroom airflow visualization; the patent describes the fog as neutrally buoyant and non-contaminating and includes a flow-control valve.	Direct historical evidence for the same fundamental generation mechanism and its intended cleanroom airflow-visualization use.
U.S. Patent 4,875,340 (1989)	Follow-on system uses steam/cryogen fog, cryogen-level control and regulation, and again describes the fog as neutrally buoyant and non-contaminating.	Demonstrates that liquid-level/flow controls were recognized early as part of repeatable neutral-buoyancy generation.
TSI/MSP Zero-Residue Cleanroom Fogger 2100	Independent commercial system mixes steam and LN_2 and specifies ~3 μm droplets and neutrally-buoyant fog for long-distance airflow tracking.	Independent industry precedent for the same generation principle, size regime, and airflow-tracer claim.
PIV tracer literature	Published gas-flow measurements use water droplets larger than the AP Series nominal 2-3 μm range, including ~4-6 μm droplets, when particle response is sufficiently fast.	Provides a conservative aerodynamic benchmark: smaller droplets have even lower inertia and gravitational settling, all else equal.

6. Aerosol Physics: Why 2-3 µm Water Droplets Behave as Passive Airflow Tracers

In a strict hydrostatic sense, liquid water is denser than air. In airflow visualization, however, the practical question is whether droplet inertia and gravitational settling are sufficiently small compared with the air motion that the droplets follow the local flow over the observation interval. This is commonly evaluated using particle relaxation time, terminal settling velocity, and Stokes number. [9-11]

Droplet diameter	Response time	Still-air settling	Settling vs 0.45 m/s airflow	Vertical drop while air travels 1 m	St at L=10 mm, U=0.45 m/s
2.0	13.3 µs	0.130 mm/s	0.029%	0.289 mm	0.0006
2.5	20.4 µs	0.200 mm/s	0.044%	0.444 mm	0.0009
3.0	29.1 µs	0.285 mm/s	0.063%	0.633 mm	0.0013

These calculations show that the AP Series nominal 2-3 µm design range has extremely small gravitational slip relative to a representative 0.45 m/s Grade A airflow. A 3 µm droplet falls only about 0.63 mm while air travels 1 meter at 0.45 m/s, and its calculated Stokes number at a conservative 10 mm flow length is approximately 0.0013 - far below unity.

Published quantitative flow studies have successfully used larger micron-scale water droplets as gas-flow tracers. Lozano et al. generated approximately 4-5 µm water droplets for stereoscopic PIV, and Ayati et al. used approximately 6 µm water droplets as gas-phase passive tracers. [10,11] Because particle response time and Stokes settling scale approximately with diameter squared in this regime, 2-3 µm water droplets have an even stronger aerodynamic tracer-fidelity basis, provided plume-scale thermal and source-momentum effects are controlled.

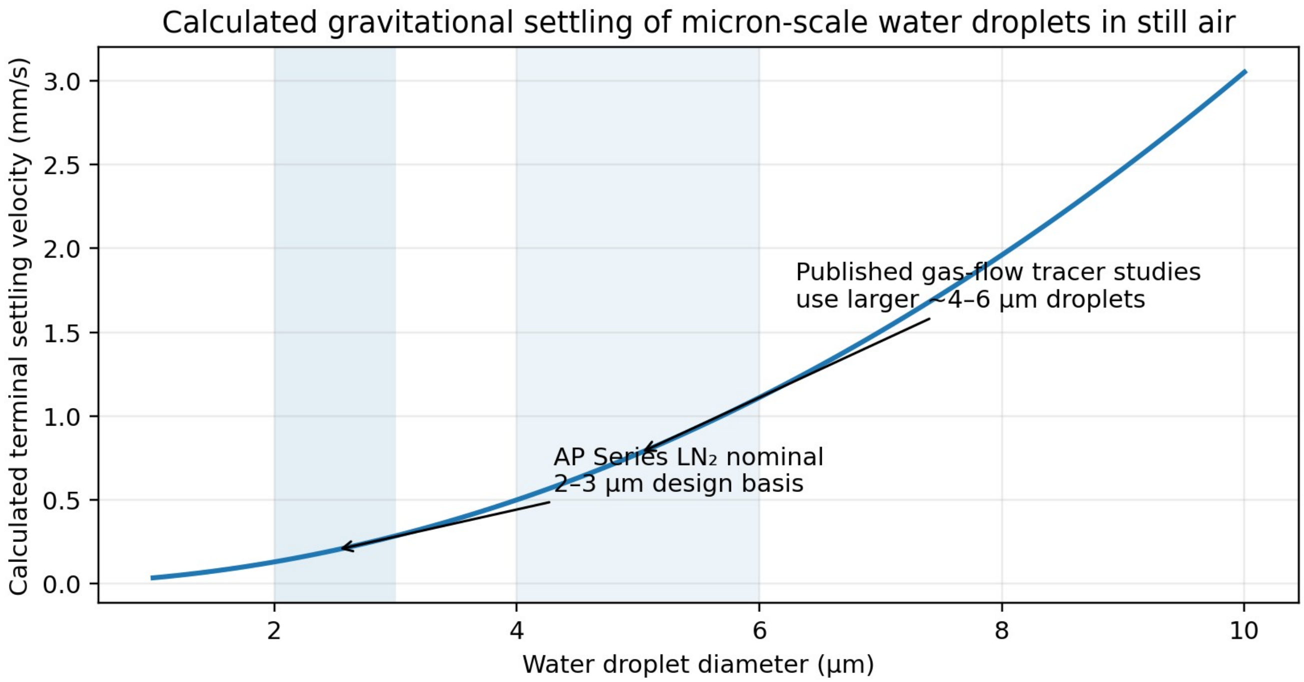

Figure 1. First-principles settling calculation for water droplets in still air. Shaded region identifies the AP Series nominal 2-3 µm design basis. Calculations are illustrative and do not substitute for finished-device characterization.

7. Thermal Neutrality Is a System-Level Requirement

Small droplet diameter alone does not guarantee that an entire visible fog plume is free from buoyancy bias. The carrier gas and droplets can be warmer or colder than the surrounding room, and source velocity can create a jet that temporarily dominates the local airflow. Therefore, a strong airflow-visualization system must manage three independent effects: particle inertia, thermal buoyancy, and source momentum.

The original steam/LN_2 cleanroom-fog patent recognized this explicitly. It describes optional fog-temperature sensing and adjustment of the steam/cryogen interface to maintain the fog in a neutrally buoyant condition. [6,7] This historical design detail is important because it shows that neutral-buoyancy performance was understood as a controlled thermal-fluid condition rather than merely a marketing label.

> **Control principle: the fog should be generated and introduced so that its temperature and momentum do not materially override the airflow being evaluated. The cold LN_2 side and warm water-vapor side must be appropriately balanced.**

8. Active Self-Pressurized AP Series Architecture

Applied Physics uses an active self-pressurized LN_2 architecture in current AP30, AP50, AP100, and

AP200 platforms. Manufacturer product documentation describes the self-pressurized system as generating internal pressure through controlled vaporization/boil-off of a portion of the liquid nitrogen and using that pressure to support controlled nitrogen/cryogen delivery. [15]

Self-pressurization is a well-characterized cryogenic-storage phenomenon. Experimental and modeling literature using liquid nitrogen demonstrates that heat ingress and interfacial vaporization produce tank pressure rise and that pressure/flow-control systems can regulate cryogenic-tank behavior. [12-14]

8.1 Why stored pressure improves control authority

- A controlled pressure differential provides a repeatable driving force for cryogen/nitrogen delivery rather than relying solely on instantaneous natural boil-off.
- A metering/control valve can translate that pressure differential into a controlled flow rate over a useful operating range.
- The operator or control system can reduce delivery for small local studies and increase delivery for larger-volume studies without changing the fundamental condensation mechanism.
- Stable pressure and metered flow can reduce surging, excessive cryogen injection, and under-feed conditions that would otherwise change fog density, plume temperature, or output momentum.

8.2 Efficiency rationale

For the AP Series, "efficiency" should be understood as improved use of available LN_2 to produce useful, controlled fog - not as a claim that every self-pressurized configuration consumes less LN_2 under every condition. The engineering rationale is that metered delivery can reduce unnecessary over-feed, preserve useful pressure, and better match cryogen delivery to the available water-vapor load. Cryogenic pressure-control research similarly demonstrates that control strategy can materially change pressure stability and cryogen mass loss. [13,14]

9. Passive Dewar AP Series Architecture

Passive dewar AP Series systems, including AP35, AP95, and AP175 configurations, rely primarily on natural LN_2 boil-off / passive dewar behavior to create the cryogenic condition used to condense the water vapor. [15] The architecture is simpler and has decades of historical precedent in cleanroom fogging.

- The fundamental tracer-generation mechanism remains steam/high-purity water vapor rapidly condensed by liquid nitrogen / cold nitrogen vapor.
- Natural boil-off supplies the cryogenic driving condition without a separately maintained active tank-pressure architecture.
- Passive systems can provide stable, repeatable fog when operated within their intended fill, warm-up, water-temperature, and output-control conditions.
- Because the upstream cryogenic pressure is more dependent on natural boil-off and tank condition, passive systems generally provide less active cryogen-flow authority than a self-pressurized architecture.

The passive dewar approach is not scientifically inferior for neutral-buoyancy purposes merely because it is passive. The historical 1988/1989 cleanroom fog patents and TSI/MSP commercial product establish that dewar/steam-LN_2 systems are an accepted engineering route to neutrally buoyant, residue-free airflow visualization. [6-8]

10. Why Control Valves Improve Performance and Efficiency

Control valves do not make a water droplet neutrally buoyant by themselves. Their value is that they control the generation and delivery conditions that determine whether the fog plume remains a faithful tracer. This distinction should be maintained in regulatory discussions.

Control function	Performance benefit	Efficiency / regulatory benefit
Cryogen flow metering	Helps maintain a repeatable LN_2-to-water-vapor thermal balance and consistent fog density.	Reduces avoidable over-feed and unnecessary cryogen consumption; makes the operating condition more reproducible.
Pressure / flow regulation	Reduces surging and output variability across the operating cycle.	Supports repeatable study conditions and documented settings.
Fog volume adjustment	Allows the operator to use only the fog density needed for the test area.	Reduces over-fogging, coalescence, visibility obstruction, and unnecessary LN_2 use.
Fog velocity adjustment	Allows output momentum to be reduced for sensitive low-velocity zones and increased when hose/wand losses require it.	Reduces the risk that the fogger itself creates the airflow pattern being observed.
Thermal balance control	Avoids excessive cryogen flow that could create a cold descending plume or excessive steam that could create a warm rising plume.	Directly supports the functional-neutral-buoyancy objective and improves defensibility of the study.

This control philosophy is consistent with the original cleanroom-fog patent, which used pressure regulation and flow-control valves, and with cryogenic engineering literature demonstrating that throttling/control strategy materially affects LN_2 tank pressure behavior and mass loss. [6,13]

ÅP
APPLIED PHYSICS
3417 E 7th St.
Tampa, FL 33605 USA

Nano Particle Technology
US: +1 719-428-4042
UK: +44 204-577-004
MX: +52 554-169-6811
Web: AppliedPhysicsUSA.com
Email: Sales@AppliedPhysicsUSA.com

11. Self-Pressurized vs Passive Dewar: Engineering Comparison

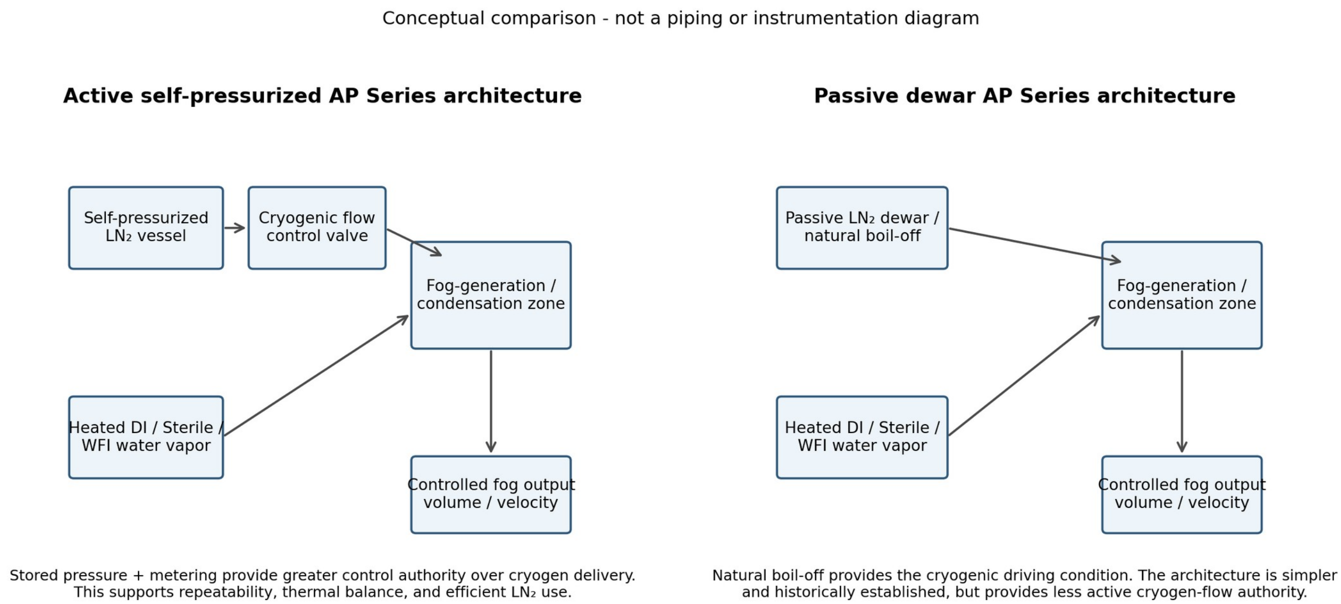

Figure 2. Conceptual architecture comparison. The diagram illustrates functional differences only and is not a piping/instrumentation drawing of any specific AP model.

Attribute	Active self-pressurized AP Series	Passive dewar AP Series
Core fog physics	Heated high-purity water vapor + LN_2 / cold nitrogen condensation	Heated high-purity water vapor + LN_2 / cold nitrogen condensation
Neutral-buoyancy basis	Micron droplet size + thermal balance + low source momentum	Micron droplet size + thermal balance + low source momentum
Cryogenic driving condition	Stored/self-generated tank pressure with metered delivery	Natural boil-off / passive dewar behavior
Control authority	Higher; valve has defined pressure differential available for metering	Lower upstream authority; output remains controllable but tank behavior is more passive
Response to changing demand	Generally faster and more tunable	Generally smoother/simple but more dependent on dewar condition and boil-off
Efficiency opportunity	Metering can reduce over-feed	Simple architecture; efficiency

Attribute	Active self-pressurized AP Series	Passive dewar AP Series
	and preserve useful LN_2	depends more heavily on passive boil-off and operator settings
Regulatory suitability	Suitable when operated/qualified to faithfully visualize airflow	Suitable when operated/qualified to faithfully visualize airflow

12. AP Series Design Basis and Controlled Claims

Applied Physics product documentation identifies the AP Series LN_2 fog as a high-purity, residue-free water fog generated using LN_2 and DI / sterile / WFI water, with a nominal droplet size of approximately 2-3 µm. [15] Independent TSI/MSP documentation for the same steam/LN_2 generation principle reports approximately 3 µm droplets and explicitly describes the resulting fog as neutrally buoyant for airflow tracking. [8]

> **The strongest controlled claim is not that every AP fog plume is mathematically weightless. It is that the AP Series generation mechanism produces micron-scale water fog with an established industry history as a neutrally buoyant airflow tracer, and that properly controlled AP output can be used to faithfully visualize pharmaceutical airflow when the study is executed under representative conditions.**

13. Technical Substantiation Matrix

Proposition	Evidence status	Basis / control
Steam + LN_2 can produce neutrally buoyant cleanroom airflow-visualization fog	Strong direct historical/industry support	1988/1989 University of Minnesota patents; TSI/MSP commercial specification. [6-8]
Approximately 3 µm droplets are suitable for passive airflow tracking	Strong scientific/engineering support	TSI/MSP direct specification plus first-principles settling/Stokes analysis and published tracer studies using larger droplets. [8-11]
Self-pressurization is a valid cryogenic driving mechanism	Strong scientific support	LN_2 self-pressurization literature and NASA cryogenic-

Proposition	Evidence status	Basis / control
		fluid-management work. [12,14]
Control valves improve repeatability and can improve LN_2 utilization	Strong engineering support; model-specific improvement should not be over-quantified without test data	Original cleanroom-fog patent uses flow control; LN_2 pressure-control studies show control strategy changes pressure stability/mass loss. [6,13]
Passive dewar systems remain suitable	Strong historical/industry support	Original dewar-based cleanroom fog patents and TSI/MSP commercial implementation. [6-8]
FDA requires a specific LN_2 fogger architecture	Not supported	Current FDA warning-letter language focuses on proper practices, dynamic conditions, and neutrally buoyant media, not a particular generation architecture. [1-3]

14. Site-Specific Use and Qualification Boundary

The manufacturer technical basis does not eliminate the client facility's responsibility to execute an adequate airflow visualization study. FDA has repeatedly cited study-execution deficiencies such as inadequate fog at the critical activity, poor wand movement, blocked visibility, and failure to represent actual interventions. [1-3]

- Operate the fogger within the manufacturer-defined fill, warm-up, pressure, water-quality, and control-setting limits.
- Use the minimum fog volume and source velocity needed to clearly visualize the airflow without obscuring critical activities.
- Position and move the wand so the fog reveals, rather than creates or blocks, the airflow pattern.
- Perform studies under representative dynamic conditions and retain video documentation where required by the governing quality system/regulatory framework.
- Treat significant configuration changes - hose length/diameter, wand/nozzle, outlet count, control-valve setting ranges, or major service changes - through site change control.

15. Recommended Client / FDA Position Statement

Applied Physics AP Series liquid-nitrogen foggers use an established cleanroom airflow-

visualization principle in which heated high-purity water vapor is rapidly condensed in a liquid-nitrogen / cold-nitrogen environment to form micron-scale water fog. The steam/LN_2 method has been described in U.S. cleanroom flow-visualization patents since 1988 as producing neutrally buoyant, non-contaminating fog, and an independent TSI/MSP commercial system using the same basic mechanism specifies approximately 3 µm droplets and neutrally-buoyant fog for airflow tracking. Applied Physics uses both active self-pressurized and passive dewar architectures; these architectures control cryogen delivery differently but do not change the underlying tracer-generation physics. Properly operated AP Series LN_2 foggers are scientifically suitable for pharmaceutical airflow visualization when the test configuration and study execution demonstrate faithful visualization of the local airflow.

16. Conclusions

1. Steam/LN_2 fogging has a decades-long cleanroom airflow-visualization history and direct patent precedent describing the fog as neutrally buoyant and non-contaminating.
2. Independent TSI/MSP documentation for the same generation principle specifies approximately 3 µm droplets and neutrally-buoyant fog for airflow tracking.
3. First-principles aerosol dynamics show that 2-3 µm water droplets have extremely low gravitational slip and inertia relative to representative Grade A airflow; published PIV studies successfully use even larger micron-scale water droplets as gas-flow tracers.
4. Self-pressurization and control valves improve engineering control of cryogen delivery, repeatability, thermal balance, and the opportunity for efficient LN_2 use; they do not change the fundamental fog chemistry/physics.
5. Passive dewar systems remain scientifically suitable because the underlying steam/LN_2 condensation mechanism is itself established; they simply provide a different cryogen-delivery architecture.
6. Regulatory acceptance ultimately depends on an adequate, representative dynamic smoke study and documented site controls, not merely on the fogger technology label.

Appendix A. Calculation Basis

- Water density: 998.2 kg/m^3 (representative near 20 °C).
- Air density: 1.204 kg/m^3; dynamic viscosity: 1.81×10^{-5} Pa·s (representative near 20 °C at atmospheric pressure).
- Gravitational acceleration: 9.80665 m/s^2.
- Cunningham slip correction applied using representative air mean free path of 0.066 µm.
- Reference airflow velocity for comparison: 0.45 m/s. Actual site-qualified velocity controls the site-specific assessment.

- Particle relaxation time and settling calculations apply to isolated spherical droplets and do not independently predict plume-scale thermal buoyancy or source-jet momentum.

Particle relaxation time: $\tau p \approx \rho p\ d^2\ Cc / (18\ \mu)$.

Terminal settling velocity: $vs \approx \tau p\ g\ (1 - \rho a/\rho p)$.

Stokes number: $St = \tau p / \tau f$, with $\tau f = L/U$.

Appendix B. Evidence Strength Assessment

Evidence	Strength	Direct relevance	Key limitation
1988/1989 University of Minnesota cleanroom fog patents	High historical/engineering relevance	Direct steam + LN_2 / cryogen cleanroom airflow-visualization mechanism; explicitly states neutral buoyancy and flow-control concepts	Patent evidence, not a peer-reviewed performance trial of an AP unit
TSI/MSP Zero-Residue Cleanroom Fogger 2100 specification	High independent industry relevance	Independent steam + LN_2 system; ~3 µm droplets; directly states neutrally-buoyant airflow tracking	Manufacturer specification, not peer-reviewed journal data
PIV tracer literature using ~4-6 µm water droplets	High scientific relevance	Quantitative gas-flow tracing with droplets larger than AP nominal 2-3 µm	Different generation equipment and test geometry
LN_2 self-pressurization and pressure-control literature	High engineering relevance	Demonstrates self-pressurization and effect of pressure/throttling control in LN_2 systems	Cryogenic storage studies, not foggers
FDA 2026 warning letters	High regulatory relevance	Current enforcement emphasis on dynamic studies and neutrally buoyant media	Do not define numeric tracer criteria or endorse a particular fogger architecture

Appendix C. References

[1] U.S. Food and Drug Administration. Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing

US: +1 719-428-4042
UK: +44 204-577-004
MX: +52 554-169-6811
Web: AppliedPhysicsUSA.com
Email: Sales@AppliedPhysicsUSA.com

3417 E 7th St.
Tampa, FL 33605 USA

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[3] U.S. Food and Drug Administration. Warning Letter: International Medication Systems Limited, MARCS-CMS 727560. July 2, 2026.

[4] European Commission. EudraLex Volume 4, Annex 1: Manufacture of Sterile Medicinal Products. 2022. Section 4.15 and related qualification provisions.

[5] International Organization for Standardization. ISO 14644-3:2019. Cleanrooms and associated controlled environments - Part 3: Test methods.

[6] Liu BYH, Ramsey JW. Non-contaminating flow visualization system. U.S. Patent 4,771,608. Issued September 20, 1988.

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[14] Kassemi M. Cryogenic Propellant Tank Self-Pressurization and Active Pressure Control. NASA Technical Reports Server, Document 20240001073. 2024.

[15] Applied Physics. AP Series product documentation and technical webpages for AP30, AP50, AP100, AP200 active self-pressurized LN_2 foggers and AP35, AP95, AP175 passive dewar LN_2 foggers. Accessed August 2026.

Source-selection note: regulatory claims are grounded in FDA, European Commission, and ISO sources; neutral-buoyancy historical claims are grounded in the original University of Minnesota patents and an independent TSI/MSP product specification; aerosol-tracer and cryogenic-control claims are supported by peer-reviewed literature and NASA technical material.