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USP <800> Suite Differential-Pressure (dP) Signal Noise

When concurrent measurements taken with a calibrated portable instrument show that the required room-to-adjacent-space differential-pressure (dP) relationship is maintained, chatter in the dP signal from installed sensors may originate within the sensing, signal transmission, or the monitoring system and do not necessarily indicate loss of that relationship. It is important to not disregard the installed sensor's signal; rather, investigate and document the discrepancy before attributing the excursion to measurement- or control-chain effects.

In rooms subject to USP General Chapter <800>, Hazardous Drugs—Handling in Healthcare Settings, dP trends recorded by the monitoring and control building automation system (BAS) and monitoring-only environmental monitoring system (EMS) may exhibit high-frequency chatter or apparent excursions while reference measurements remain within limits.

Why Pickup-Plate Location Warrants Focused Attention High-wall or above-door sensing is often favored to avoid direct supply and primary engineering control (PEC) airflow. ASHRAE recommends above-door sensing to avoid PEC and HVAC air-distribution interference, while Setra permits high-wall or ceiling mounting. Neither guidance establishes a universal hierarchy. Room-side and reference-side pickups must avoid direct airflow and represent the intended pressure relationship.

NIH aseptic processing facility (APF) experience supports ceiling-mounted alternatives where wall components impede cleaning, compete with controls, or face impacts from decontamination fluid intrusion. The preceding factors do not establish aerodynamic superiority for ceiling-mounted vs wall-mounted pickup plates. Either location must be accessible, cleanable, protected, and representative.

Why the Six-Foot Recommendation is Useful but not Conclusive

In the subject suite's non-aspirating, HEPA-filtered ceiling-terminal configuration, potential disturbances include terminal footprints and perimeters, door transients, obstructions, and equipment airflow. Setra recommends placement at least 6 ft from turbulence sources. This is a recommendation, not proof: locations within 6 ft warrant scrutiny, while those beyond 6 ft should not be automatically deemed safe from airflow disturbances. Final suitability requires field testing.

A Diagnostic and Mitigation Protocol for Consideration

1. Confirm the reference basis: Verify the portable instrument's calibration, zero, range, resolution, and pressure connections, and confirm that it measures the same room-to-adjacent-space relationship as the installed systems. Synchronize BAS, EMS, reference, airflow, door status, and control data at the highest available resolution.

2. Establish actual room behavior: Compare installed and reference measurements during closed-door operation, representative equipment operation, and controlled door-opening and recovery events. Determine whether the reference confirms actual room-pressure oscillation or whether disagreement is limited to an installed channel.

3. Isolate measurement and control causes: Identify shared and independent pickups, tubing, sensors, and signal processing. Inspect tubing and connections, verify sensor zero and scaling, and perform an isolation test where appropriate. Trend valve positions, airflow, and loop outputs to determine whether control interaction produces actual dP oscillation. Correct demonstrated defects before attributing the problem to pickup location.

4. Screen and test the pickup: Map room-side and reference-side sensing points relative to HEPA-terminal footprints and edges, door heads, obstructions, equipment airflow, and exhaust paths. Treat pickups in identifiable draft paths as suspect, not failed. Perform airflow visualization under normal and transient conditions. The preferred result is no persistent impingement, directional sweep, or stable recirculating eddy across the pickup face.

5. Measure airflow at the pickup and compare it with the dP signal:

Where airflow may affect the pickup, use a low-velocity anemometer fitted with an omnidirectional probe at fixed locations near the plate. Record the probe position, test duration, sampling interval, room operating condition, and instrument accuracy at low air speeds. Compare the readings with synchronized BAS, EMS, portable reference dP, and control data. Air speed is diagnostic evidence, not a standalone acceptance criterion. For this suite, project-specific screening may use P95, the air speed at or below which 95 percent of the readings fall. A P95 of 28 feet per minute (fpm) or less is preferred; 28-40 fpm requires engineering review; and repeated readings above 40 fpm trigger confirmation testing.

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Define the test period, operating condition, and what constitutes as “repeated.”

6. Correct and verify: Repair defective sensing components or tubing, retune unstable controls, or relocate the pickup according to the evidence. Shorten tubing only when its length, routing, lag, or inaccessibility contributes to the problem. Use temporary shielding only to confirm local airflow sensitivity. After modification, repeat the tests and verify calibration, control response, recovery, trending, and alarm performance.

Conclusion

Noisy dP trends alone do not demonstrate loss of the required pressure relationship. When reference measurements remain acceptable, investigate sensing hardware, pickups, tubing, airflow control, transfer-air balance, and signal processing. Correct the demonstrated cause. A successful system provides a repeatable, representative indication without masking actual excursions.

Resources

1. National Institutes of Health, Office of Research Facilities. Design Requirements Manual,
2. United States Pharmacopeial Convention. General Chapter <800>, Hazardous Drugs—Handling in Healthcare Settings.
3. United States Pharmacopeial Convention. General Chapter <797>, Pharmaceutical Compounding—Sterile Preparations.
4. ASHRAE Standing Standard Project Committee 170, Pharmacy Work Group. HVAC Design of Compounding Pharmacies. 2024.
5. Controlled Environment Testing Association. CAG-003, Certification Guide for Sterile Compounding Facilities for USP Compliance. Revised 2022.
6. Controlled Environment Testing Association. CAG-014, Airflow Visualization Study. 2022.
7. Setra Systems, LLC. Setra Lite Installation & Operating Guide. 2024.

Table 1. dP Noise-reduction mitigation stack and expected impact

Mitigation area	Action	Primary mechanism	Expected result
Airflow control	Correct airflow-control valve sizing, installation, and associated duct configuration in accordance with manufacturer requirements where deficiencies are demonstrated.	Eliminate unstable airflow-control behavior caused by improper valve sizing, installation, or duct configuration.	A steadier supply-to-exhaust airflow relationship and more reliable airflow control.
Control tuning	Retune proportional, integral, and derivative (PID) loops that exhibit hunting or overcorrection, and verify acceptable response and recovery performance after tuning.	Reduce control-loop hunting, overcorrection, and unnecessary actuator movement.	Reduced control-induced dP oscillation while maintaining acceptable response and recovery performance.
Pickup location	Relocate the pressure pickup where local airflow testing demonstrates velocity-pressure bias; use temporary shielding only as a diagnostic.	Reduce velocity-pressure bias and local turbulence effects at the sensing point.	Reduced pickup-induced bias or chatter and a signal that more faithfully represents the room-to-adjacent-space dP relationship.
Pneumatic sensing path	Shorten unnecessarily long pneumatic sensing runs, by relocating remote sensors or transmitters closer to served rooms where appropriate, while maintaining calibration and service access.	Reduce transport lag and concealed tubing failure points.	More reliable and maintainable pressure-signal transmission, with fewer opportunities for concealed tubing damage or leakage.

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Sensor/equipment	Perform an isolation test, where appropriate, to determine whether noise originates in the pressure sensor or elsewhere in the signal chain; replace sensors demonstrated to have failed or exhibiting poor repeatability.	Distinguish sensor-generated noise from actual room-pressure variation and eliminate defective sensor behavior from the measurement chain.	Reduced sensor-driven scatter and fewer unnecessary calibration or troubleshooting interventions.
Transfer-air path	Adjust transfer-air quantity or effective transfer-opening area where testing demonstrates that dP oscillation is attributable to the transfer path. Where the door undercut cannot be modified, evaluate an appropriately designed alternate transfer path.	Improve the room's steady-state airflow balance and stabilize the pressure-flow relationship across the transfer path.	More stable dP while maintaining the required directional airflow and room-to-adjacent-space pressure relationship.
Trending	Evaluate and document a short-duration averaging window before recording 1-minute trend values; retain access to the unaveraged signal and leave control and alarm logic unchanged unless separately justified and validated.	Attenuate brief, nonrepresentative transient spikes in the recorded trend without changing the control signal, setpoint, or alarm logic.	A more representative and interpretable trend without masking sustained excursions.
Tubing condition	Inspect for and correct leaks, cracks, kinks, crimps, loose connections, water accumulation, and improper routing; replace tubing with high-quality kink-resistant tubing, provide tubing reinforcement at bends to prevent collapse. Ensure adequately sized backboxes, pull boxes, and pathways.	Preserve undistorted pressure-signal transmission between the pickup and the sensor or transmitter.	Reduced signal error caused by leakage, restriction, unintended damping, water accumulation, or intermittent tubing defects.
Valve interaction	Evaluate a coordinated fixed airflow-offset strategy or active dP-control strategy where multiple modulating valves exhibit cross-coupled interaction.	Reduce cross-coupled control action and competing valve movements.	Fewer competing valve movements, less valve hunting, and reduced control-induced dP oscillation.