Low Pressure Calibration For Cleanroom Applications

Is Your Calibrator Capable?

APPLICATION NOTE

Within a building there many applications for differential pressure transducers (DPTs), but the most critical is measuring the pressure parameters in a cleanroom. A cleanroom is a critical area used to manufacture medications, containers, enclosures and other medical devices that require the products to remain sterile from manufacturing through delivery to the customer. The products manufactured in these environments are used to treat and care for the general population and are handled differently than other products.

The Food and Drug Administration (FDA) has stringent guidelines for sterile drug products that are produced by aseptic processing, requiring them to meet Current Good Manufacturing Practice (CGMP) regulations throughout processing. Cleanrooms carry various classifications (See Table 1) depending on the product that's being manufactured within that space. A cleanroom is a positively pressurized space, designed to ensure that the particulates within the room meet requirements based on the classification of the room.

TABLE 1: AIR CLASSIFICATION

Clean Area Classification (0.5 um particles/ft^3)	ISO Designation	±0.5µm particles/m^3	Microbiological Active Air Action Levels (cfu/m^3)	Microbiological Settling Plates Action Levels (diam. 90mm; cfu/4 hours)
100	5	3,520	2	2
1,000	6	35,200	7	3
10,000	7	352,000	10	5
100,000	8	3,520,000	100	50

Setra MicroCal™

Many design parameters need to be considered when designing a new cleanroom, including airflow, air changes per hour and the product manufactured in the space. One of the more critical considerations on room operation is the calibration of the DPTs used in conjunction with the HVAC system to control these environments.

DPTs play a pivotal role in the integrity of the cleanroom. These sensors perform measurements of High Efficiency Particulate Air (HEPA) filter cleanliness, airflow and proper static pressure between the cleanroom and the adjacent space. Within the cleanroom space, the pressure measurements taken are extremely low, often controlled to below 0.1"W.C. Cleanrooms are primarily designed to maintain a sterile environment, but also have a focus on energy efficiency. The HVAC control system uses the feedback from DPTs to maintain control of the cleanroom at very low pressure levels, allowing fans to run less and save the conditioned air within the room. A critical component to maintaining accurate positive pressure within a cleanroom is the proper calibration of the DPTs used in the HVAC system of the space.

Pharmaceutical manufacturers have millions of dollars invested in research and finished product within a cleanroom. In order to protect this investment, the manufactures follow documented standard operating procedures to validate and, if needed, calibrate the DPTs used to comply with FDA guidelines.

Portable pressure calibrators are the preferred device of pharmaceutical manufacturers; these facilities have hundreds of sensors throughout their building. Selecting a pressure calibrator can be a difficult choice to make. Two critical considerations are the reference standard and the pressure generation system of the calibrator. Most manufactures of low pressure calibrators don't use properly ranged pressure references (See Table 2). Instead, these high range sensors attempt to achieve high accuracy at low pressures through intricate microprocessor correction. This can result in higher levels of noise and instability, limiting the accuracy available.

TABLE 2: CALIBRATION RATIO FOR REFERENCE STANDARDS

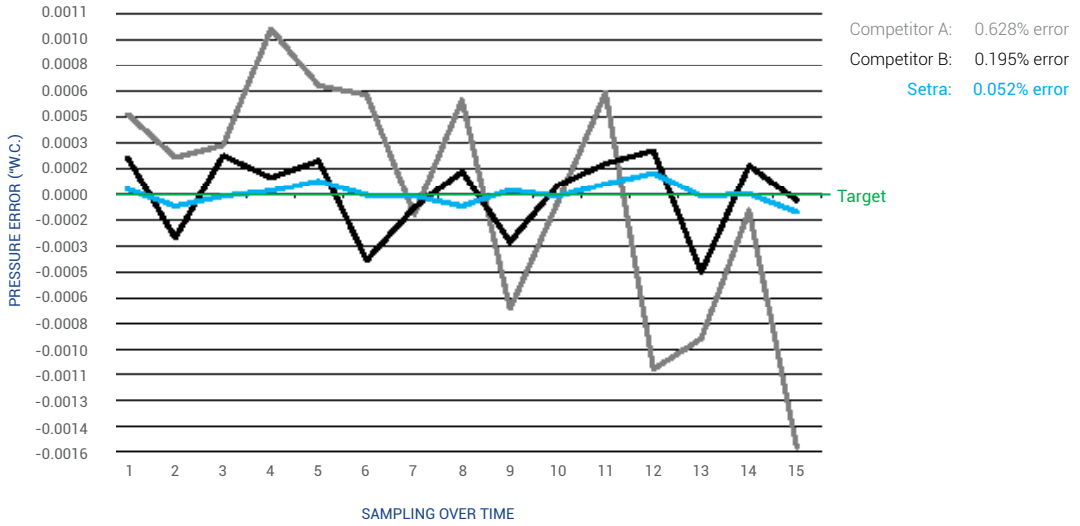
	Unit Under Test[1]	MicroCal™ MCPM References	Competitor A	Competitor A
Reference Range	±0.1"W.C.	±0.1"W.C.	±0.1"W.C.	±8.0"W.C.
Year 1 Uncertainty	0.5%	0.1%	0.1%	0.28%
Calibration Ratio		5	0.5	0.04

[1]Unit under test is the transducer being calibrated

The other critical consideration is the ability to generate an accurate, repeatable, and stable test pressure during the calibration of the transducer. Most portable calibrators utilize a single ended electric pump combined with micro solenoid switches, to regulate the applied pressure. This technique applies small pressure pulses to the positive and negative pressure test volumes to regulate the test pressure. During active pressure regulation the system generates up to a 0.002" W.C. output ripple (See Table 3). The size of this ripple is disproportionately large to the desired pressure required to perform accurate calibrations in these critical environments.

TABLE 3: CONTROL STABILITY @0.25"W.C.

Test is to show the fluctuations between Setra and two competitors when 0.25"W.C. is applied to reference units.



Setra's MicroCal™ pressure calibrator is designed to meet all of the requirements necessary to perform pressure calibrations in the desired calibration interval. The MicroCal™ has modular high accuracy pressure references that can be selected to match the DPT being calibrated. These high accuracy references allow for proper calibration ratios per standard operating procedure. The MicroCal™ has an automated on-board pressure generation system used to apply positive and negative pressure to the transducer, dial gauge or pressure switch during the calibration process.

Setra uses patented NASA Low Differential Pressure Generation technology that produces maximum pressure setting sensitivity with minimum noise. The pressure generation is accomplished using a piston cylinder arrangement, where the DPT under test has both high and low pressure ports connected to a cylinder in a push/pull configuration. This pressure generation system is a closed loop system, immune to outside environmental noises that routinely occur when working in a live environment. The combination of high accuracy pressure references and stable pressure generation are paramount to ensuring the cleanroom meets the specifications defined by the facility to the FDA. This also limits unnecessary nonconformance paperwork due to underperforming pressure calibrators.