



PRESSURE CALIBRATION

WE DESIGN AND DELIVER
PREMIUM SENSING SOLUTIONS
www.setra.com





WHO IS SETRA?

Setra Systems, Inc. was founded in an age of transducer innovation. Our founders, Dr.Y.T. Li and Dr. S.Y. Lee were Professors of engineering at the Massachusetts Institute of Technology and co-developers of the Variable Capacitance Transduction Principle. Building on this heritage of innovation, Setra has designed and developed the most comprehensive product lines of pressure sensing transducers in the world. Setra has been innovating Test & Measurement sensor designs for over 50 years and has become a leader in the pressure transducer market.

- **Made in the USA**
- **Industry Leader for 50 years**
- **Innovator of the variable capacitance principle**
- **5-Sigma Quality**
- **95% On Time Delivery**
- **99.8% Quality Rating**
- **10+ Million Sensors Shipped**

A photograph of a modern, multi-story brick building with large glass windows. The Setra logo is visible on the upper part of the building's facade. The image is overlaid with a blue tint.

Corporate Headquarters & Production Facility

Boxborough, Massachusetts, USA

WHEN QUALITY AND REPUTATIONS ARE ON THE LINE, TRUST SETRA TO ENSURE SAFETY

Not every pressure calibrator has the advanced capabilities of Setra's MicroCal™. When it comes to ensuring your product is protected, trust Setra's MicroCal™ Pressure Calibrator to get the job done safely and correctly.

WHETHER YOU NEED:

- Flexible modular design
- High accuracy, very-low differential pressure references
- Industry leading pressure control
- Fast and accurate calibration
- Portability
- Long-term stability
- Direct application engineering support

SETRA HAS YOU COVERED



Contact us today

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PRESSURE CALIBRATION TRUSTED BY NASA

Setra's pressure calibrators have set the bar for the last decade in terms of pressure control and accuracy for low differential pressure in critical applications. Over 200,000 sensors in pharmaceutical and healthcare facilities are calibrated annually utilizing Setra's calibration technology. Setra partnered with NASA to develop the industry's quickest and most stable pressure control for low range applications. The MicroCal combines precise pressure control with high accuracy modular pressure reference providing the quickest and most accurate calibration solution on the market today. The MicroCal is an easy-to-use solution that significantly improves labor productivity and efficiency when compared to the leading competitors, providing immediate ROI.

SETRA'S MICROCAL™

The Microcal™ pressure calibrator is used as a stand-alone calibration standard for differential and gauge pressure devices found in critical environments. The MicroCal™ controls pressure down to 0.0002" W.C by utilizing NASA patented pressure generating technology paired with a Setra designed control algorithm. The unit's industry best pressure control technology combined with modular pressure references ensure the highest accuracy portable pressure calibrator. The MicroCal is an accurate and easy to use solution that allows for up to an 80% reduction in calibration time in difficult low pressure applications.

MODULAR REFERENCES

Pharmaceutical & healthcare environments are strictly regulated by the FDA and CDC. High accuracy pressure references are critical when calibrating pressure transducers, dial gauges, and switches used in drug production and patient safety. Modular references allow for the highest accuracy reference to be used at the time of calibration.

Advantages:

- Versatile
- Convenient
- Portable

LONGER BATTERY LIFE

Facility shutdowns are popular time to perform calibration and maintenance on equipment. Completing calibration on time enables the product to begin on time. The replaceable battery allows constant calibration to be completed during this critical time.

Advantages:

- No down-time due to battery depletion
- Easily swap out tired battery
- Available desktop charger



TIME OF CALIBRATION

Unlike to traditional hand-crack calibration methods, automated calibrators are more compact, portable, and do the job faster. It can take a technician several minutes to perform 1 point of a multi-point calibration using a traditional method, whereas the Setra MicroCal can perform an entire 5-point sensor calibration in just over a minute. The portability of the MicroCal can also facilitate on-site calibrations that eliminate the need to uninstall the transducer from its location, dramatically reducing the time it takes to complete a calibration in the field.



FAST & ACCURATE PRESSURE CONTROL

The on-board NASA patented low pressure generating technology achieves $\pm 0.0002''$ W.C low pressure regulation. This closed loop system isolates the unit under test (UUT) eliminating any outside disturbances.

Advantages:

- Class leading performance
- Quicker, more accurate calibration
- Reliable closed loop system

TOUCHSCREEN INTERFACE

The large touchscreen user interface is combined with an intuitive menu structure that allows the user to easily access all the features of the MicroCal™.

Advantages:

- State of the art technology
- Fingertip access to features
- Visually appealing

CLEANROOM

A cleanroom is a room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimize the introduction, generation, and retention of particles & microbes inside the room and in which other relevant parameters, e.g. temperature, humidity, and pressure, are controlled as necessary.



CALIBRATION OF SENSORS MONITORING CLEANROOMS

Purpose: Differential pressure sensors play a pivotal role in the integrity of the cleanroom. These sensors perform measurements of HEPA filter cleanliness, airflow, and proper static pressure between the clean room and the adjacent space.

WHAT TO CONSIDER WHEN DESIGNING A CLEANROOM:

- Eliminate spaces and crevasses that trap particles
- Recessed lighting and vents
- Covered light switches
- Coved floor
- Specialized furniture (wheels, low particle emitting, stainless steel)
- Epoxy paint on walls and floors

SOURCES OF CONTAMINATION

- **Facilities:** walls, floors and ceilings, paint and coatings, spills and leaks.
- **People:** skin flakes and oil, cosmetics and perfume, clothing debris (lint, fibers, etc.), hair.
- **Tool-Generated:** friction and wear particles, lubricants and emissions, vibrations, brooms, mops and dusters.
- **Fluids:** particulates floating in the air, bacteria, organics and moisture, floor finishes or coatings, cleaning chemicals, water.
- **Product-Generated:** glass flakes, cleanroom debris, aluminum particles from vial caps.



CONTAMINATION

Humans in cleanrooms are a major source of contamination. 100,000 particles per minute are produced while simply standing or sitting in a cleanroom. 5,000,000 particles per minute are produced when a person walks at a 2 mph pace.

ISO SPECIFICATIONS

- **ISO 14644-1:** Covers the classification of air cleanliness in cleanrooms and associated controlled environments exclusively in terms of concentration of airborne particles.
- **ISO 14644-2:** Specifies requirements for periodic testing of a cleanroom or clean zone to prove its continued compliance with ISO 14644-1 for the designated classification of airborne particulate cleanliness.

Test Parameter	Class	Max Time Interval	Test Procedure
Particle Count Test	≤ISO 5 >ISO 5	6 Months 12 Months	ISO 14644-1 Annex A
Differential Air Pressure	All	12 Months	ISO 14644-1 Annex B5
Airflow	All	12 Months	ISO 14644-1 Annex B4

ISO 14644-1 Cleanroom Standards

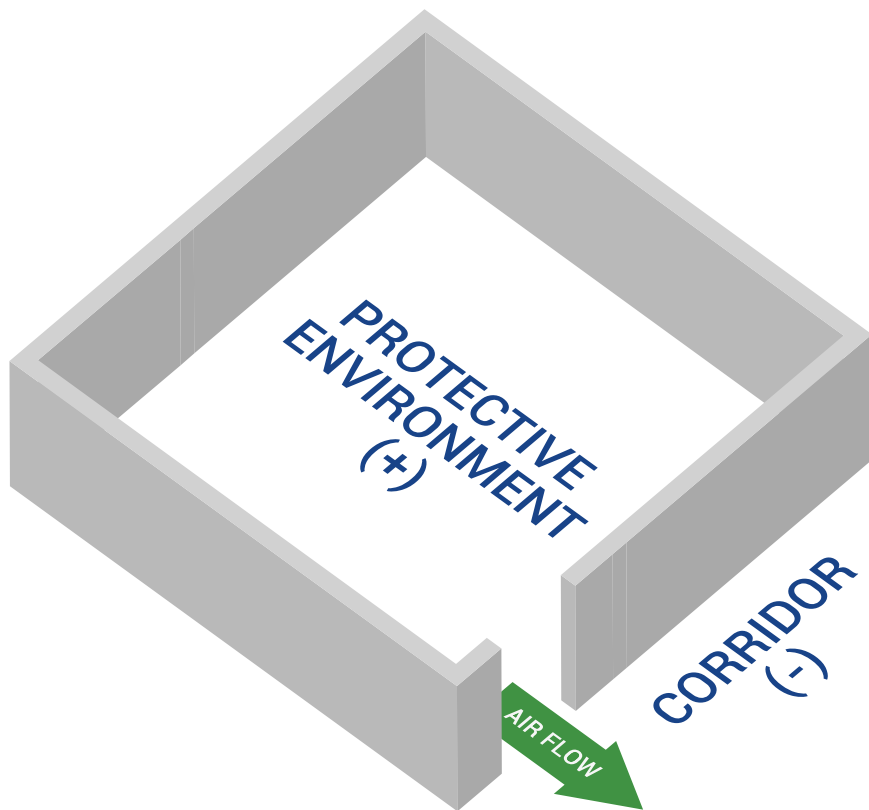
Class	Maximum Particles/m ³						FED STD 209E equivalent
	≥0.1 μm	≥0.2 μm	≥0.3 μm	≥0.5 μm	≥1 μm	≥5 μm	
ISO 1	10	2					
ISO 2	100	24	10	4			
ISO 3	1,000	237	102	35	8		Class 1
ISO 4	10,000	2,370	1,020	352	83		Class 10
ISO 5	100,000	23,700	10,200	3,520	832	29	Class 100
ISO 6	1,000,000	237,000	102,000	35,200	8,320	293	Class 1,000
ISO 7				352,000	83,200	2,930	Class 10,000
ISO 8				3,520,000	832,000	29,300	Class 100,000
ISO 9				35,200,000	8,320,000	293,000	Room Air

LEAST STRINGENT

 MOST STRINGENT

PROTECTIVE ENVIRONMENT

A **Protective Environment (PE)** is a specialized patient-care area, usually in a hospital, with a positive air flow relative to the corridor (i.e. air flows from the room to the outside adjacent space). The combination of HEPA filtration, high numbers of air changes per hour (>12ACH), and minimal leakage of air into the room creates an environment that can safely accommodate patients with threatening diseases that need to be contained.



ROOM PRESSURE MONITORS

Room pressure monitors (RPM) provide real-time monitoring to ensure that the protective environment is in a positive or negative pressure state and in compliance with safety regulations. These units guarantee that patients (or processes) within a protective environment are safe from potential contaminants existing in unfiltered air and ensure that hospital staff and other occupants are not at risk to what is contained within isolation.

POSITIVE PRESSURE



PATIENT ROOMS



OPERATING ROOMS



CSP PHARMACIES



THE JOINT COMMISSION

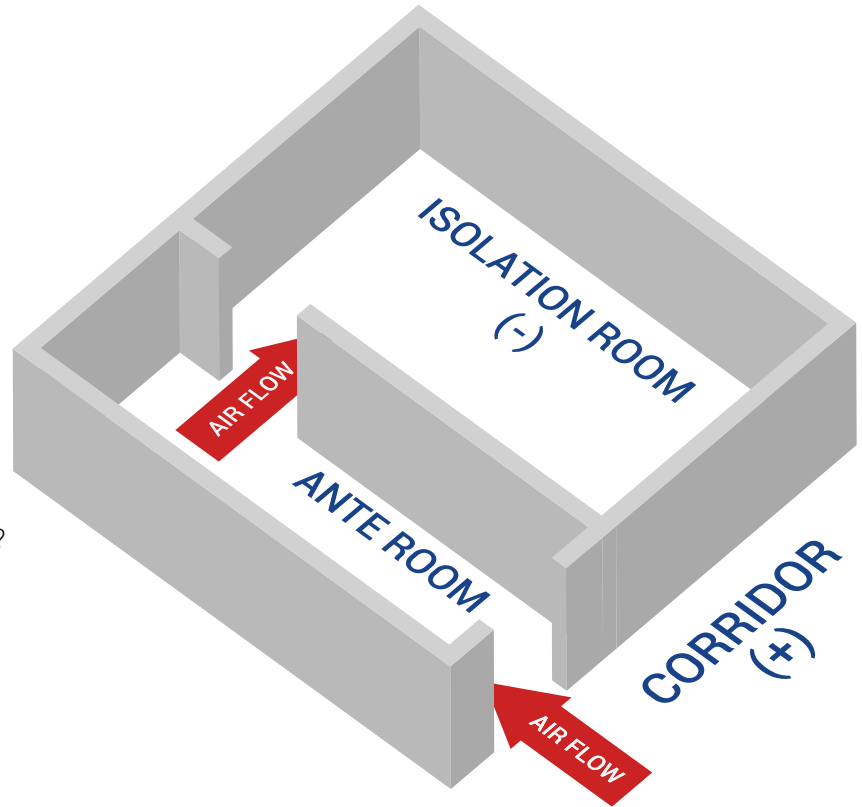
The Joint Commission's annual survey revealed that the Environmental of Care standard EC.02.06.01, which requires hospitals to adhere to the best practices for monitoring room differential pressure, was one of the top 10 most common violations.

ISOLATION ROOM

Airborne Infection Isolation (All) refers to the isolation of patients infected with organisms spread via airborne droplet nuclei $<5\ \mu\text{m}$ in diameter. The isolation area requires air changes per hour (ACH) ranging from >12 ACH for new construction as of 2001 to >6 ACH for construction before 2001. Isolation rooms are negatively pressured, such that the direction of air flow moves from the outside adjacent space into the room. Air is then exhausted outside or recirculated through a high-efficiency air (HEPA) filters.

WHAT TO CONSIDER:

- Does the facility have a building automation system (BAS)
- What is the required communication protocol? (BACnet, analog, etc.)
- Does the job require audible/visual alarms? Local and/or remote?
- How many primary rooms need to be monitored? Do they need alarms?
- Is this a building upgrade or a new construction? Are there existing sensors in place?



NEGATIVE PRESSURE



PATIENT ISOLATION

BIO-SAFETY LABS

LABORATORY FUME HOODS

HOSPITAL LINENS

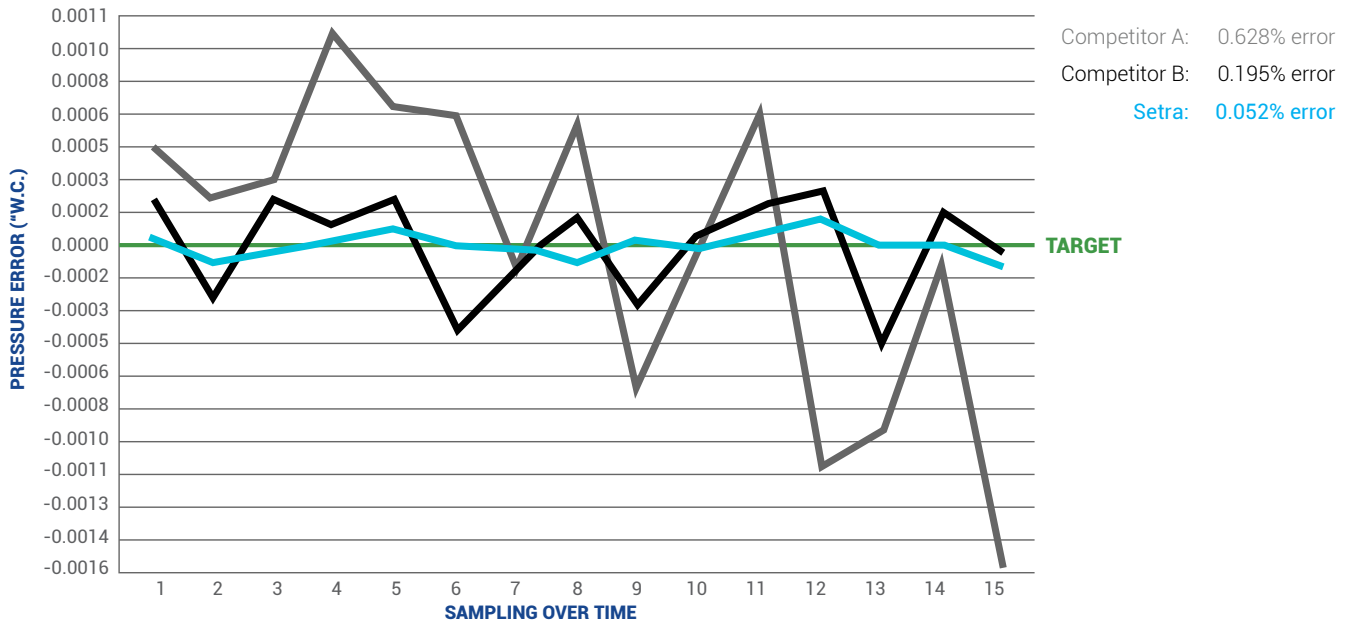
Of the environments within healthcare facilities that need to be pressurized, one of the most commonly overlooked spaces are linen closets. According to ASHRAE Standard 170, clean linens must be stored in a positively pressurized space and soiled linens must be stored and sorted in a negatively pressurized space with a minimum of 10 air changes per hour (ACH).

SETRA VS. THE COMPETITION

At Setra, the performance of our product is second to none, which is why we have no reason to exaggerate our product capabilities. By reading through various competitors technical specifications, it isn't always clear which product performs the best in specific applications; which is why we tested our product against two leading competitors.

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:

- Utilizes NASA patented low differential pressure generation technology
- Enabling industry leading control stability - below 0.0002"W.C.
- Closed-loop system, isolated from outside environmental disturbances during calibration

OUR COMPETITION:

- Uses single-ended electric pumps and solenoid switches to generate pressure
- Limits control stability, fluctuates up to 0.0016" W.C. from pressure pulses
- Open-loop system, susceptible to outside environmental disturbances during calibration

A CASE STUDY

Following standard protocol, a large pharmaceutical manufacturer began calibration and validation of their Setra 267 transducers used to control their manufacturing cleanroom. The technicians started taking "As-Found" data, with a competitive pressure calibrator, on all installed sensors and were alarmed at what they were seeing; nearly all the new sensor have failed.

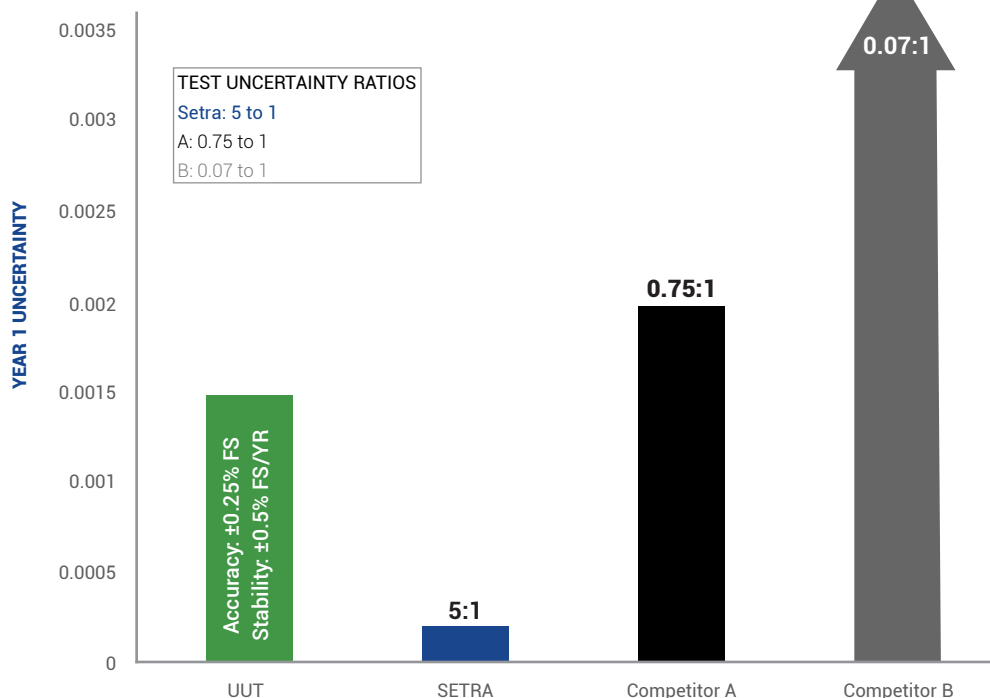
The facility manager called Setra tech support complaining of the "poor quality sensors" that had been purchased and demanded an RMA for all the 267 transducers that were installed at their multi-building facility. The Setra team gathered and decided three units should be shipped back for testing. Once the units were received and processed, the Setra team scheduled a conference call and arranged for an on-site visit where the MicroCal™ could be used to troubleshoot at the facility.

IS YOUR REFERENCE GOOD ENOUGH?

The process of accurate pressure calibration consists of two main steps: applying stable pressure to the sensor you are calibrating, using a high accuracy reference standard to validate performance. Both steps are critical to ensuring compliance with ISO standards and the FDA.

RECOMMENDED TEST UNCERTAINTY RATIO 4 TO 1

TEST UNCERTAINTY RATIO: the comparison between the sensor being calibrated and the estimated calibration uncertainty of the pressure standard.



WHY CHOOSE SETRA?

Cost of a non-conformance is high

- Damage to company's image
- Product recall cost
- Internal investigation costs

Minimize liability using MicroCal™

- Maximize your test uncertainty ratios with modular references
- Flexibility to calibrate more devices with one unit
- Lowest range reference standards for critical applications

UUT: The unit you are trying to calibrate with your pressure calibrator, $\pm 0.1\%$ W.C.

Setra: Setra's MicroCal™ Pressure Modular, Range = $\pm 0.1\%$ W.C. with an uncertainty of $\pm 0.15\%$ FS/yr

Competitor A: Reference Range = $\pm 1\%$ W.C with an uncertainty of $\pm 0.1\%$ FS/yr

Competitor B: Reference Range = 8" with an uncertainty of $\pm 0.28\%$ FS/yr

When the Setra team arrived at the facility, the facility manager made it clear how frustrated he was; the facilities team spent months building the cleanrooms to release their new products and these issues were holding up the commissioning of the rooms. The technicians walked the Setra team through their procedure and tested one of the units, that was verified the day before, on their existing pressure calibrator. When the transducer failed, the Setra team connected the transducer to the MicroCal™ and it passed. The facility manager was stunned and said to "test another one". Another sensor was tested and passed.

Proving the 267 transducers were not defective was purpose of the visit, so the team took a look at the calibrator they were currently using. It turns out that the calibrator had a 0.6% error which had caused the 267 transducers to fail. This process was repeated multiple times to make sure this was the cause of the failed transducers. The facility manager was ecstatic that Setra solved the problem and they could move forward with their commissioning, "I would not have believed it, if I wasn't there to see it for myself. I am extremely thankful to Setra for the efforts they went through to provide us answers and their customer service!"

PRESSURE CALIBRATION



CELEBRATING 50 YEARS

Founded in 1967, Setra Systems, Inc. is a leading designer and manufacturer of pressure, acceleration, and weight sensing devices. Setra's founders, Dr. Y.T. Li and Dr. S.Y. Lee, were co-developers of the variable capacitance transduction principle, the innovative force sensing technology which is the heart of Setra's products.

MADE IN THE USA

Since our founding, we have been proudly producing all of our transducers for sale in the United States at our 100,000 sq. ft. Boxborough, MA facility. Setra is an ISO 9001-2008 certified manufacturer with robust and mature processes at work to continually optimize team performance.



DISCIPLINED BUSINESS MODEL

Setra is part of the Fortive group of companies, a diversified industrial growth organization based in Everett, Washington with 24,000 employees worldwide. The Fortive Business System (FBS) is the cornerstone of our culture and our ultimate competitive advantage. It drives every aspect of our work, our strategy and our performance. We use FBS to guide our decisions, measure how well we execute and develop innovative ways to do even better.



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