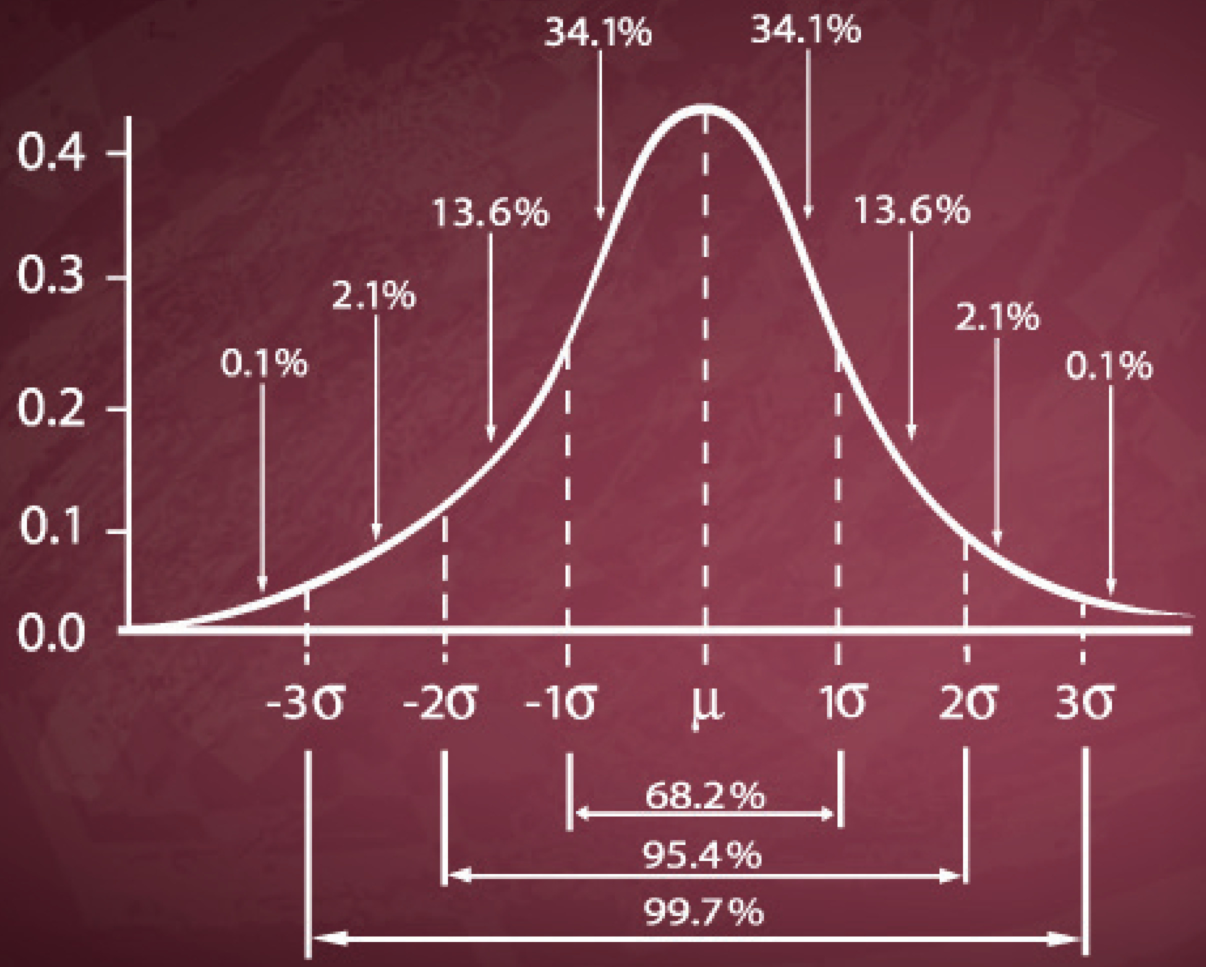
BEST PRACTICES FOR SELECTING PRESSURE IMAGING SYSTEMS

HOW TO MAXIMIZE ACCURACY AND MAINTAIN ISO 9001 COMPLIANCE



XSENSOR® Technology Corporation

Why should you care about pressure imaging sensor accuracy?

Because you are using pressure imaging to make evidence based decisions, you need to trust that the pressure measurements are accurate. Due to the unique design and advanced dielectrics, XSENSOR's capacitive pressure sensors are the most accurate sensors available on the market today. To ensure this accuracy, like every other type of equipment in a laboratory, the sensors you use to measure interface pressure are devices that require calibration.

To comply with your ISO 9001 certification, your quality management system requires that you control the calibration of measurement equipment – including your pressure imaging sensors

As part of the strict accreditation process, a laboratory's quality management system is thoroughly evaluated on a regular basis to ensure continued technical competence and compliance with ISO/IEC 17025. As part of the accreditation process, you must prove the following:

- Your entire calibration process and equipment is well-defined;
- The uncertainty of your calibration equipment is known and accounted for;
- All your lab personnel are trained and technically competent;
- The methods and practices you have in place produce precise and valid results;
- All your documentation is in place supporting practices and procedures.

To ensure that your equipment and practices are compliant with your ISO 9001 certification, you should understand the different types of calibration procedures and how they can affect the accuracy of your results. It is also necessary to understand how uncertainties in your pressure measurement equipment are quantified and documented.

Interface Pressure Sensors from ISO/IEC 17025 compliant facilities have traceable calibrations that document sensor accuracy

ISO/IEC 17025 standards ensures that the specified measurement accuracy of the sensors can be proven by the demonstrated proficiency of the calibration lab. If the interface pressure sensors used in your testing procedures do not have a known uncertainty, then your entire process can be called into question.

This can affect ISO/IEC 17025 compliance and ISO 9001 compliance, particularly if your company manufactures products that might endanger human life when defective.

Therefore, when considering what type of pressure measurement equipment to use in your laboratory, it is important to understand how the accuracy statement of the sensors is validated.

At a glance: factors that influence ISO/IEC compliance

XSENSOR's Capacitive Sensors

- Accurate for long duration testing
- Low repeatability error
- Accurate when bent and/or deformed
- Accurate for all pressure ranges

Calibration

- Performed by manufacturer
- Sensor ready for use "out of the box"
- Uncertainty is easily quantifiable
- Uncertainty is a known constant, regardless of user, test rig, or geographic location

Calibration lab compliant to ISO/IEC 17025 requirements

Supports ISO 9001 compliance

Resistive Sensors

- High creep error in long duration tests
- High repeatability error
- Lose accuracy when bent or deformed
- Limited accuracy at low pressures

Equilibration

- Performed by customer test personnel
- Equilibration must happen before each test session
- Uncertainty depends on operator skill
- Uncertainty compounds across different test rigs, different laboratories, different operators

Calibration lab will not meet ISO/IEC 17025 requirements

Endangers ISO 9001 compliance

The impact of sensor design on accuracy and performance

Capacitive vs. Resistive Sensors

The most important attribute that determines sensor accuracy is whether the pressure sensor is built using capacitive or resistive technology. This determines its performance, how it can be calibrated, and ultimately ISO/IEC compliance.

About Resistive Sensors

Resistive sensors are commonly used for pressure sensor applications. These sensors are produced by arranging two parallel arrays of electrically conductive material on a substrate in a perpendicular orientation. To create the sensors, piezoresitive (pressure sensitive) ink material is deposited on the conductive material. Compression force or other mechanical stress of the materials will alter the electrical properties of the ink, increasing or decreasing the electrical resistance in the pressure sensitive ink material. Due to the change in resistance, an output voltage is produced that is proportional to the sensed pressure.

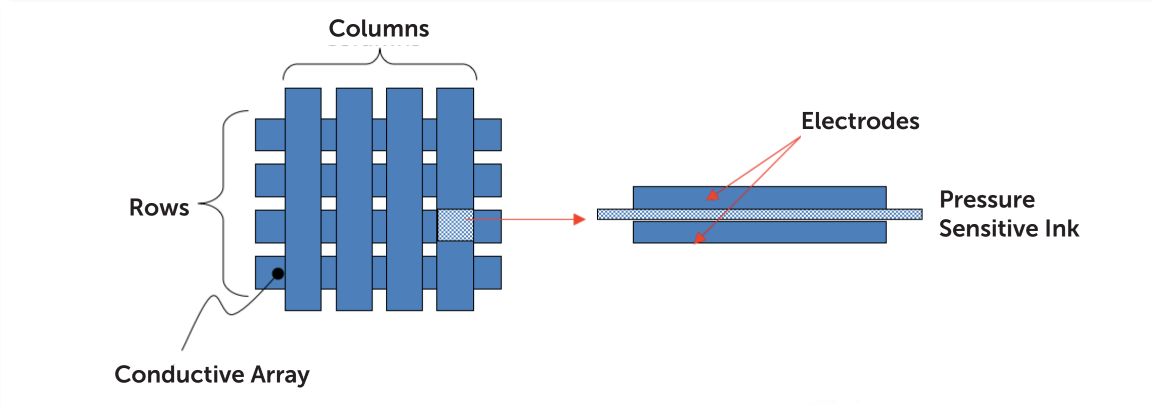


Figure 1: Basic resistive sensor construction and operation.

Limitations of Resistive Sensors

These sensors are less accurate and have lower precision when compared to capacitive sensors. Pressure sensitive inks are sensitive to mechanical stresses other than compression, due to bending and deflection when used in applications that require conformance to complex surfaces. They are also more sensitive to temperature changes and have tendency to drift, particularly following use on uneven surfaces.

In order to compensate for these limitations, sensing arrays using pressure sensitive ink technology require frequent equilibration to correct the sensor output. Resistive sensors tend to be unstable at lower pressures, so are better suited to high pressure ranges.

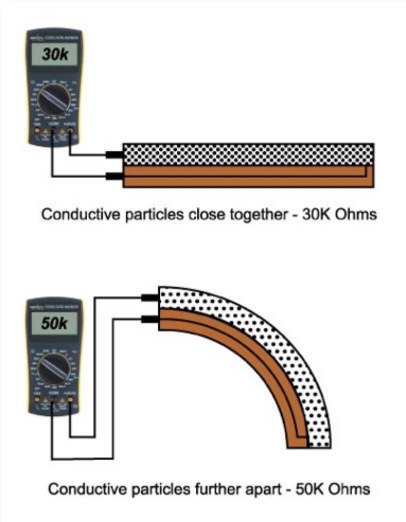


Figure 2: Drawbacks of resistive sensors.

The impact of sensor design on accuracy and performance

About Capacitive Sensors

XSENSOR's pressure sensors are comprised of a matrix of capacitive sensing elements. The capacitive elements are comprised of two arrays of parallel conductive strips that are perpendicular in orientation. The arrays are separated by a thin compressible elastomer dielectric (Figure 3). Pressure applied to the surface of the sensing element compresses the dielectric which results in a change in the voltage across the capacitive element.

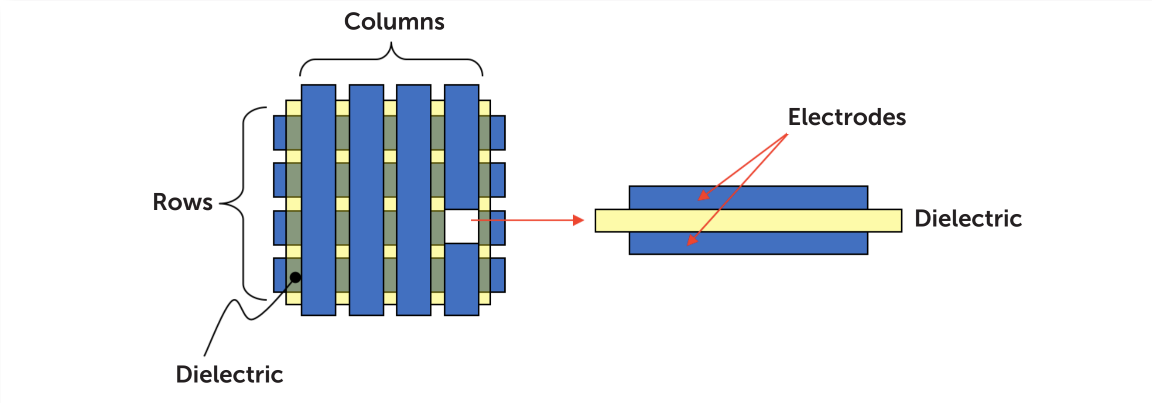


Figure 3: Basic capacitive sensor construction and operation.

The analog voltage is converted to a digital "Raw" value and is correlated to pressure via our calibration process and is then displayed in the XSENSOR software. XSENSOR has engineered dielectrics which are highly sensitive and have predictable compression characteristics.

Advantages of Capacitive Sensors

The result is that the sensors can detect even slight variations in pressure distribution and with high accuracy. The sensors are calibrated to a measurement range appropriate to the end use.

Capacitive sensors are ideally suited pressure interface applications and particularity to those that require conformity to a surface that has significant displacements. Processes are in place to ensure that calibrations consistently meet accuracy specifications by complying with ISO/IEC 17025.

How different calibration procedures influence data quality

Quantifying Uncertainty: Calibration vs. Equilibration

Although it is common to use the term “calibration” to refer to any procedure that normalizes a sensor’s output, in pressure sensing applications there are two distinct procedures used: calibration and equilibration. Both of these affect the overall accuracy of your data, and the type of procedure used depends entirely on the sensor you buy.

What is Equilibration?

Equilibration is the process that involves applying a uniform pressure across the sensor to normalize all the sensing elements to a known pressure.
The equilibration process can compensate for variation in the performance of individual sensing elements by applying a factor to individual sensing elements. Equilibration vs. calibration is typically used for resistive sensors due to their non-linear performance.

What sensors can be equilibrated?

Resistive sensors must be equilibrated before each test session to measure accurately, as the electrical properties of the pressure-sensitive ink can change following each use.

Problems with equilibration:

First and foremost, equilibration procedures are extremely time-consuming to perform. This can easily double the amount of time test engineers must spend during testing, adding hidden costs to using resistive sensors.

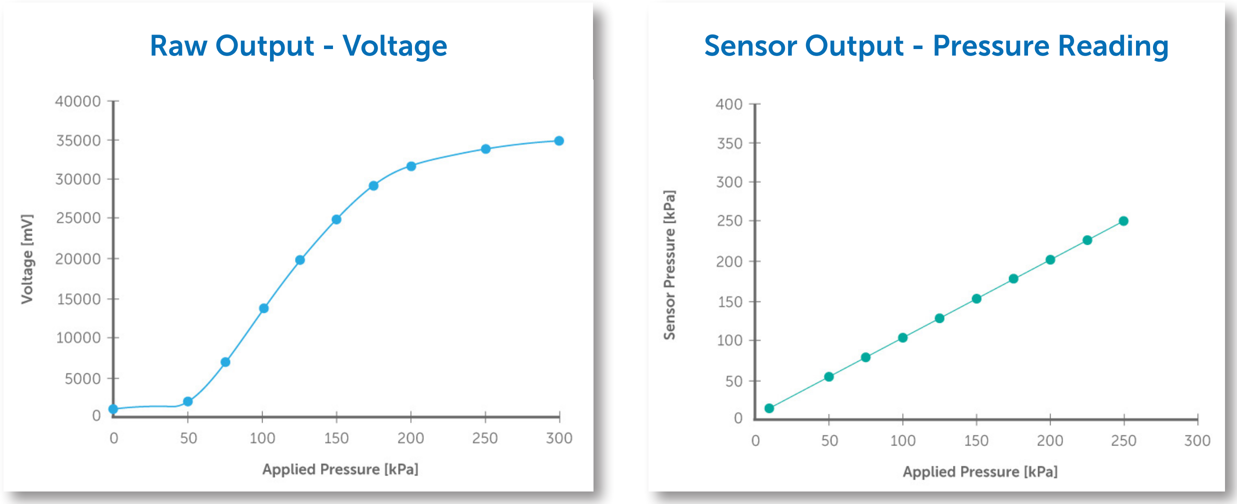
Because equilibration is performed by users, the potential for systematic and user error is introduced. This is difficult to quantify, particularly when tests are being performed on multiple test rigs, by different users, in different laboratories. Unless performed within the constraints of well-defined protocols, equilibration procedures make it easy for the integrity of your data to be called into question.

How different calibration procedures influence data quality

What is Calibration?

Calibration is the process in which the raw sensor output is compared to a known reference pressure with a known uncertainty at several different pressures. The Raw sensor output is then correlated to the known applied reference pressures.

Each individual sensing element in the sensor has its own calibration to accommodate for slight variances in manufacturing tolerances. XSENSOR uses two different types of calibration methods depending on the sensor type and application.   Because the sensitivity of capacitive sensors is predictable, they have enhanced accuracy over the calibrated range.



Figures 4/5: How a raw voltage output is correlated with known applied pressures to produce a sensor reading.

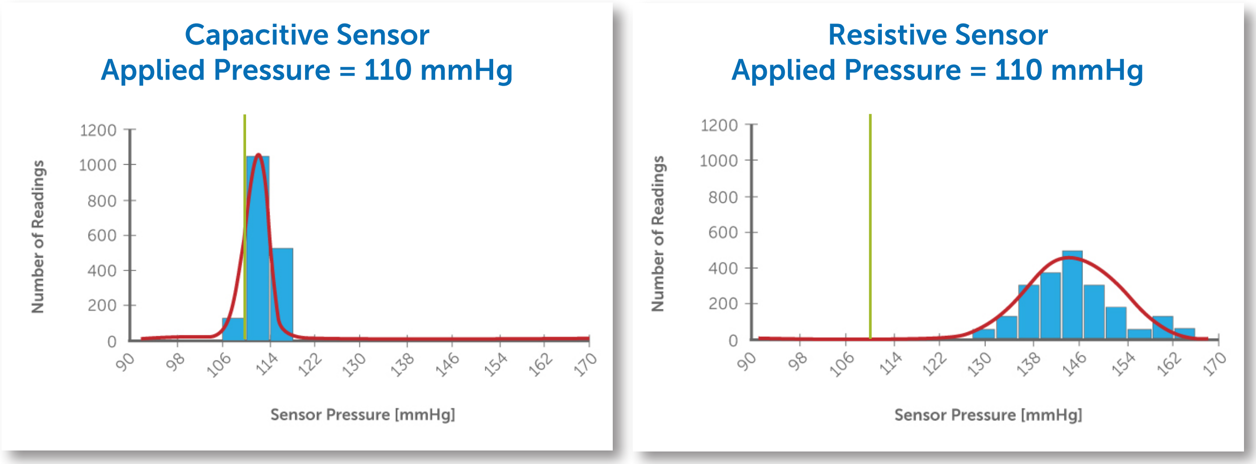
What sensors can be calibrated?

Due to their design and high reliability, capacitive sensors are often calibrated by the manufacturer. The advanced dielectrics and calibration methods developed by XSENSOR ensure that the sensor measurements are accurate and repeatable with ongoing use. They can be expected to retain their calibration over time, unless they are damaged or otherwise broken during use.

Consequences of sensor choice on test procedures

Repeat Testing

Repeatability is the variation that arises when the same measurement is performed repeatedly during a short time period under the same conditions with the same operator. A higher repeatability will result in more precise and reliable measurements.



Figures 6/7: Capacitive sensors (Left) are much more precise and reliable than resistive sensors (Right).

Due to their design, resistive sensors are less accurate, as shown by the above test data – for an applied pressure of 110mmHg, resistive sensors have both a greater margin of error and a higher measurement variance. This makes them poorly-suited for applications that involve repeat testing.

Extended Trials

Creep, sometimes referred to as drift, is the effect where the sensor output will tend to increase over time when a constant pressure is applied. The larger the applied pressure, the more the sensor will creep. Due to their design, resistive sensors have higher creep error than capacitive sensors. This makes them poorly-suited for long duration testing.

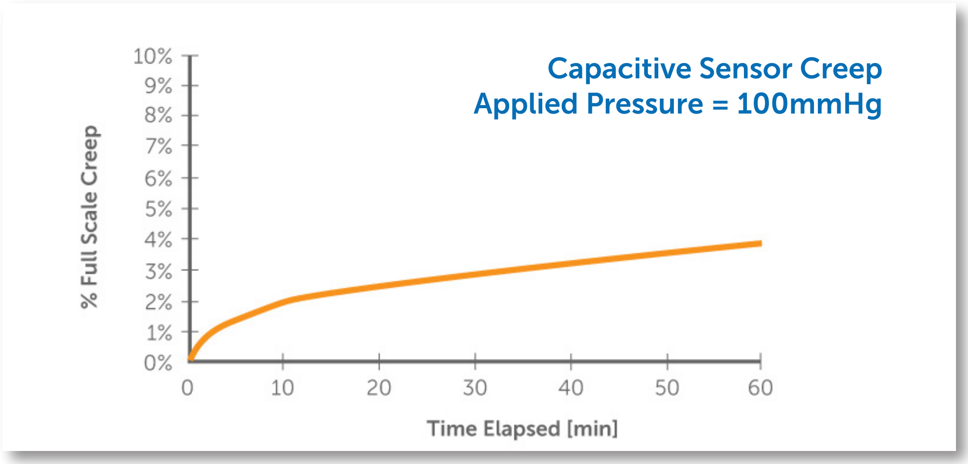


Figure 8: Capacitive sensor creep over a 60-minute trial.

Checklist for purchasing pressure imaging equipment

The following are some criteria you should use to evaluate your current pressure imaging equipment, as well as any future purchases. If you answer "No" to any of these criteria, your ISO 9001 compliance may be at risk as a result of your pressure imaging equipment.

CRITERIA	YES	NO
Do the sensors use capacitive technology?		
Are the sensors manufactured in an ISO/IEC 17025 accredited facility?		
Does each sensor come with a calibration certificate?		
If you plan to be using the sensor for repetitive testing or extended periods of time, is the sensor designed to minimize hysteresis, creep and drift?		
If your test procedures involve surfaces with contours, can your sensors conform to the surface while maintaining their accuracy?		
Are you using the same test equipment in multiple facilities? Do you require your supplier to use the same test equipment? Consistent data will be critical.		
Over a range of applied pressures during testing, does the sensor comply to the accuracy specification?		
Is equilibration required to set-up the sensors prior to taking measurements? How long will the set-up take?		

About XSENSOR

For over 20 years, XSENSOR has set the standard for accurate sensors and image quality in software to visualize and analyze pressure data. We started out by developing sensors used to measure pressure on cushions designed to keep wheelchair users safe. Since then we have listened to industry leaders and developed systems they rely on to improve the comfort, safety, quality and performance of their products. Today, we continue to innovate and partner with customers to explore what is possible with pressure sensors.

From continuously monitoring clinical surfaces to help clinicians create effective patient turning strategies, to finding a mattress with the right comfort and support, to precision measurement of tire tread designs and ultra-fast sensors to dynamically capture the interface pressure of an airbag on an occupant during a front impact collision, XSENSOR delivers accurate pressure data that can be trusted in decision making.

Our customers and users include vehicle interior and tire designers, safety engineers, nurses and therapists, as well as mattress manufacturers and retailers around the world.

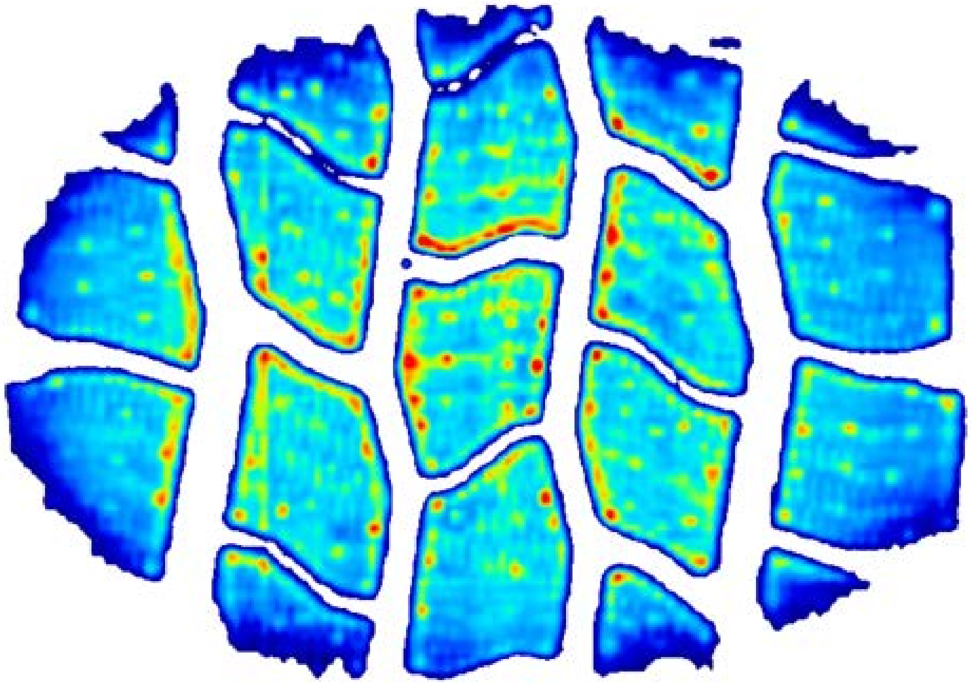
We are the only ISO/IEC 17025 certified pressure imaging sensor manufacturer

Unlike other sensors on the market, our sensors maintain their calibration owing to the capacitive technology and the proprietarty materials used to make them.

Our ISO/IEC 17025 accreditation means that we have demonstrated competency in producing accurate test and calibration data from our sensors. Your ISO registration requires your suppliers provide verified calibrated test equipment and recalibration processes to maintain your compliance.

About Our Sensors

We engineer, design and manufacture our own sensors, and have developed many innovations in capacitive sensor technology. As a result, we have substantially minimized the effects of creep and compression set for all our sensors. Our sensors are proven to retain measurement accuracy, across repeated measurement cycles, and through long-duration measurements. With periodic recalibration, their reliability, accuracy and performance remain very high throughout their useful lifetime.



Over the past twenty years, we've developed pressure sensors for clients across many industries and applications. If you need interface pressure data for a specialized application, please contact us so that one of our engineers can talk to you about the specifics of your project.

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