Maintaining Strict Quality Controls in the **Pharmaceutical Industry**

AMETEK Sensors, Test & Calibration is one of the world's leading developers and producers of calibration instruments for temperature, pressure and process signals. Our comprehensive range of instruments for measuring and calibrating pressure and temperature are backed by an impressive customer support program that includes technical support, factory service capabilities, calibration and more.

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SENSORS, TEST & CALIBRATION

High-Accuracy Calibrators Ensure Quality Results

Within the pharmaceutical industry, the level of quality is of great concern, as the products may directly influence the health of their customers. It is therefore essential to control the process and storage areas according to prescribed rigid regulations and FDA standards. AMETEK STC specializes in producing several instruments for temperature, pressure, and process calibration. From digital test gauges and data recorders, to high-accuracy dry block temperature calibrators, we supply the equipment to help pharmaceutical labs do their job accurately, safely, and efficiently.

PRESSURE

XP2i
Pressure Gauge

HPC40 and 30 Series
Pressure Calibrators

nVision
Pressure Recorder

PK II & Type T
Deadweight Testers

TEMPERATURE

RTC Reference
Temperature Calibrators

PTC Professional
Temperature Calibrators

DTI-1000
Digital Temperature Indictor

PROCESS

ASC-400
Multifunction Calibrator

ASM Series
Multiscanner

Maintenance of Calibration Standards and Test Equipment

Portable calibrators and test equipment require periodic checks and calibration. Having local standards on site for calibration of these instruments offer savings in cost and downtime of instruments, as it allows technicians to calibrate field instruments locally while only their standards need to be sent out for regular calibration.

The nVision and HPC40 Series are small, light-weight instruments with the accuracy required to calibrate pressure in the field or in a lab; the RTC and PTC Series temperature calibrators are excellent standards for the verification and calibration of handheld thermometers; and as deadweight testers remain an excellent standard for calibrating pressure instruments, we offer deadweight testers designed to be both highly accurate and durable.

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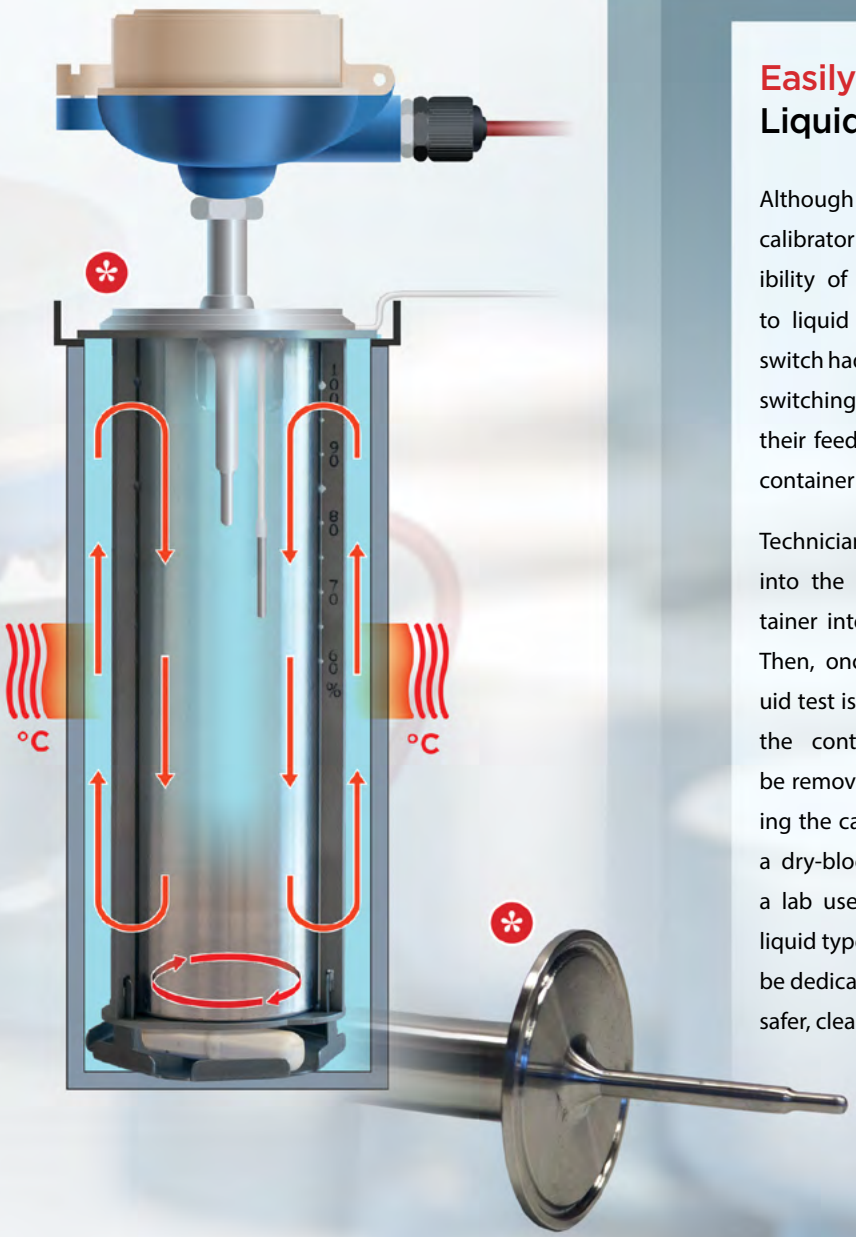
Patent Pending Calibration Process for Sanitary Sensors

Our new patent-pending temperature calibration technique allows users to calibrate large diameter, short sanitary sensors in situations that closely mirror the sensor's day-to-day use. By isolating the liquid in the main block from the excess liquid around the flange, we have removed the liquid flow effect and the need for a precise liquid level, two traditional sources of error.

We drew on years of producing temperature calibrators, combined with feedback from users in the field, to create the RTC-168. Featuring a newly designed, larger calibration surface, it is the industry's only portable temperature calibrator capable of high-accuracy wet calibrations of sanitary sensors with diameters up to 84 mm.

RTC-168 Reference Temperature Calibrator

RTC-168: -30 to 165°C (-22 to 329°F)



Easily Switch from Dry-Block to Liquid Bath Mode

Although customers of prior RTC calibrator models enjoyed the flexibility of switching from dry-block to liquid bath modes, making this switch had its challenges, especially when switching from wet to dry. We listened to their feedback and created a new liquid container for the RTC-168.

Technicians can now pour their liquid into the container and place the container into the well. Then, once the liquid test is complete, the container can be removed, returning the calibrator to a dry-block. And, if a lab uses multiple liquid types, a container can be dedicated to each type. It's a safer, cleaner, and easier calibration solution.

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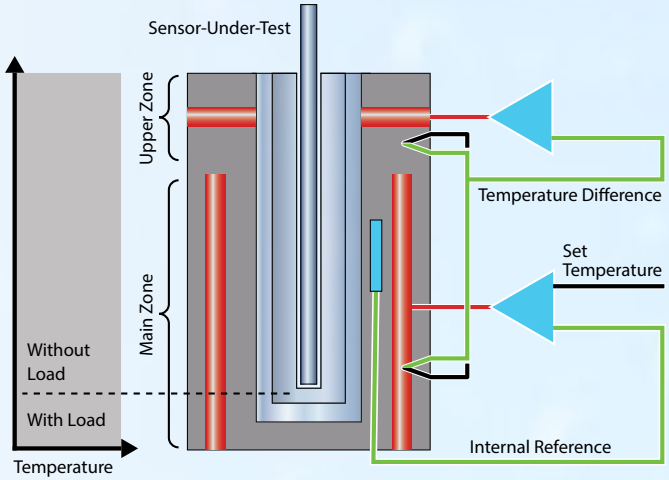
Unique Temperature Performance

All JOFRA RTC models employ dual-zone technology to maintain full control of temperature throughout the heating block. This enables the RTC to sense and then compensate for the extreme heat dissipation through the thermal load of the sensors under test.



With JOFRA's active dual-zone heating technology, each heating zone is independently controlled for precision temperature calibration. The homogeneity in the lower part is close to that of a laboratory liquid bath, ensuring optimum heat dissipation throughout the entire calibration zone. The upper zone compensates for heat loss from the sensor-under-test, and from the open top. The design eliminates the need for extra insulation of sensors-under-test, making it possible to calibrate liquid-filled and other mechanical sensors.

Thermal Validation must be performed, when storing temperature-sensitive goods like medicines, tissue samples, or vaccines. It is crucial to test and document that your refrigeration and freezing equipment are able to maintain temperatures within a required range. To that end, we can create custom dry-block inserts that can accomodate 16 or more thermocouples at a time, ensuring fast and highly accurate results.

RTC-157 and RTC-156 Reference Temperature Calibrators

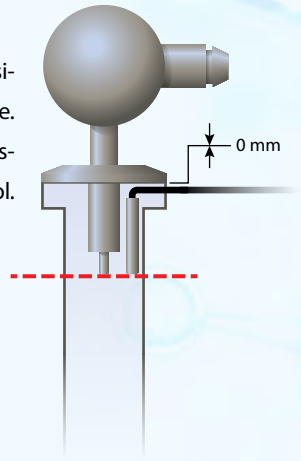
RTC-156: -30 to 155°C (-22 to 311°F) • **RTC-157:** -45 to 155°C (-49 to 311°F)

RTC-156 Sanitary Flange Capability

In addition, some sensors include large metal flanges, which are the cause of considerable heat dissipation through the sensors and process connection. The result is a lower temperature at the end of the short sensor than at the sensing area of the dry-block calibrator. We solve this problem with two features:

Custom Insert

We design inserts that come into physical contact with the metal of the flange. This significantly reduces the heat dissipation, allowing for better control. The insert includes a groove for the second feature.



Custom Reference Sensor

A small custom reference sensor is positioned in parallel with the sensor under test's sensory element. The reference sensor accurately measures the insert temperature adjacent to itself and the sanitary sensor. The dry-block then uses this temperature when performing calibrations. The result is an accurate, fast, and easy calibration process.

Custom Reference Sensor

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Extreme Temperature Calibration

Historically, products (many in pill form) had a relatively short shelf life and were typically stored for short periods of time at refrigeration temperatures. Today's more advanced products require longer storage times; and many must be frozen to -70 to -90°C. As these newer products can be very expensive, having a temperature calibrator that can test the super freezers in which they're stored is essential to avoiding product loss and maximizing quality.

Our RTC-159 Ultra Cooler Temperature Calibrator has a low range of -100°C, making it the ideal instrument to calibrate the sensors in super freezers. It features accuracy to 0.06°C, stability to 0.03°C, and the patented DLC system, which brings unmatched temperature uniformity in the insert. And, if the full range of the RTC-159 isn't needed, our PTC-125 offers many of the same features at a lower cost.

PTC-125 and RTC-159 Ultra Cooler Temperature Calibrators

In addition to the super-low temperature applications, the RTC-159 can also be used for many other higher temperature applications in the pharmaceutical industry. We use patented technology to range from -100 to 155°C.

The full range of the RTC-159 is -100°C to 155°C, which allows it to be used to calibrate:

Super Freezers ..... **-95 to 60°C**
Freezers ..... **-60 to 0°C**
Freeze Drying ..... **-80 to -60°C**
Lyophilization ..... **-50 to 0°C**
Autoclaves ..... **110 to 135°C**
Process Cooling ..... **-60 to 0°C**
DataLoggers ..... **-80 to 150°C**

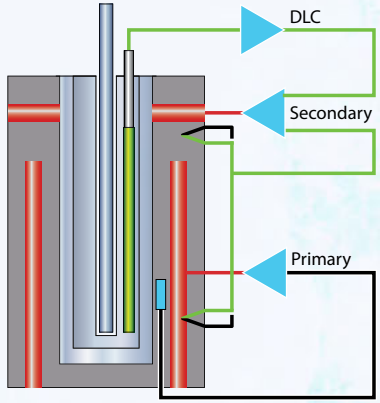
RTC-159: -100 to 155°C (-148 to 311°F) • **PTC-125:** -90 to 125°C (-130 to 257°F)

Dynamic Load Compensation (DLC)
Making our Dry Calibration Accurate

To bring our well documented active dual-zone technology to an even higher level, we have developed the patented DLC system.

This feature makes it possible to perform top calibration specifications without being affected by the actual load, e.g. many sensors or very big sensors.

The DLC sensor improves on the RTC calibrator's already advanced dual-zone technology by controlling the homogeneity in not only the well, but inside the insert where the sensors-under-test are placed during calibration.



The DLC sensor measures the temperature homogeneity in the insert and provides feedback to the active dual-zone system, which compensates the temperature difference to a minimum inside the insert. In this way, the DLC function makes the homogeneity independent of the different loads of the insert, making the RTC the best performing dry-block calibrator on the market when calibrated and tested according to the globally accepted EURAMET/cg-13v.01 guideline for calibration and testing of dryblocks.

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Dry Heat Sterilization

Pharmaceutical labs wage a constant battle with bacterial pathogens and other contaminants that may compromise the safety and efficacy of the drugs and medicines they produce. Of special concern are bacterial pyrogens (endotoxins and exotoxins) which, when present, can cause a fever. As traditional sterilization techniques are not effective on these tiny organisms, labs employ a process called Depyrogenation to ensure that their solutions and surfaces are free of the bacteria.

Depyrogenation (or Dry Heat Sterilization) uses extremely hot air, at temperatures exceeding 350°C (600°F) to burn away the bacterial pyrogens. Super-hot ovens, called Depyrogenation Tunnels, are used to generate the necessary heat. Each sterilization zone within the Depyrogenation Tunnel contains temperature sensors. As a regulatory requirement, and to ensure that the tunnel is functioning properly and within specification, all dry heat sterilizers undergo rigorous inspection and validation. This makes it critical that the embedded sensors undergo regular temperature calibration.

Dry block temperature calibrators provide the best means of calibrating these all-important sensors; and the PTC-425 was specifically developed for this application. The PTC-425 features a range from 33 to 425°C (91 to 797°F) and features an active dual zone temperature control which provides excellent temperature homogeneity in the well.

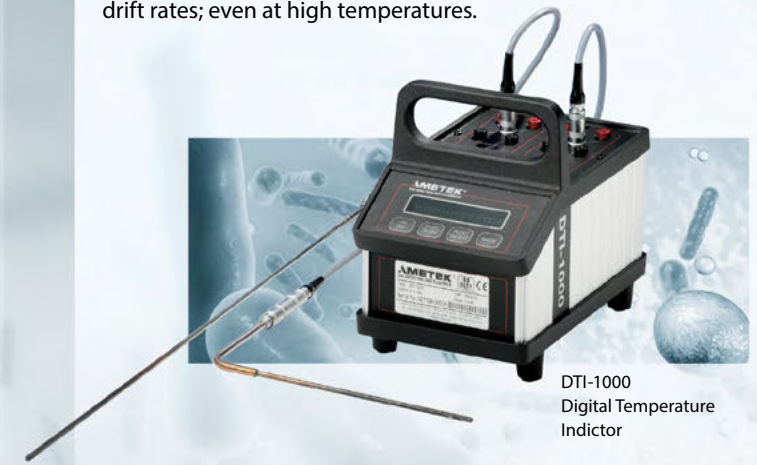
PTC-425
Professional
Temperature
Calibrator

PTC-425: 33 to 425°C (91 to 797°F)

A Digital Temperature Reference

The DTI-1000 digital temperature indicator, combined with one of our STS reference sensors, is a fully traceable thermometer recommended as the reference instrument to verify the true temperature of any liquid bath or dry-block temperature calibrator. The superior performance along with our long history of reliable, low-drift calibration instruments make it perfect for applications where high accuracy is important. It has long been the working standard in many national laboratories worldwide.

STS sensors are economical, and offer fast response times, low immersion depths, compact physical sizes, and specified low drift rates; even at high temperatures.



DTI-1000
Digital Temperature
Indictor

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Pressure Calibration's Critical Role

In addition to our many temperature calibration products, pressure is also an important factor in many pharmaceutical applications. From US Gauge liquid-filled dial gauges like the Model 656, to digital test gauges like the Crystal Engineering XP2i, to dual-range pressure calibrators like the HPC40 Series, we have the pressure equipment to suit your needs. At AMETEK STC, we understand pressure, which is why we say, "Pressure is our Business."

Crystal Engineering pressure gauges and calibrators are known worldwide for reliability, ease of use, and accuracy.

Our versatile XP2i digital test gauge is rugged enough to mount directly on a process or storage area and accurate enough to test and calibrate most dial pressure gauges. It features a large 5-digit display that is easy to read, even from a distance.

The HPC40 is our dual-range handheld pressure calibrator giving users the flexibility to complete a wide range of pressure, temperature, and electrical applications. With two installed pressure modules, the HPC40 can accurately calibrate high and low-pressure gauges with just one handheld device. It can also calibrate both absolute and gauge pressure instruments.

The nVision Reference Recorder supports and records from up to two separate modules— pressure, temperature, or electrical. The nVision can collect and store up to 1 million data points as fast as ten times per second. It also features a graphical display, so users can check their test status without stopping the recording.

Our GaugeCalHP Pressure Comparator is a portable, self-contained, hydraulic pressure generator, which when combined with our digital gauges, calibrators and reference recorder, accurately calibrates pressure gauges, transmitters, sensors, and safety valves. It's much faster than deadweight testers and most automated pressure controllers; and it's so quick and easy to use, it's ideal for calibrating low cost gauges that are often overlooked for ISO9000 compliance.

XP2i Digital Test Gauge and GaugeCalHP Pressure Compartor

High Quality Process Gauges

USG offers over 2000 pressure gauge models with a wide variety of options, sizes, and pressure ranges. But we've made it easy to find the perfect one using the product finder in our Webshop.

Our liquid-filled pressure gauges offer the ideal solution for applications with excessive vibration and pulsation. Liquid filling minimizes these effects and protects the gauge internals while providing continuous lubrication on the mechanism, extending each gauge's service life. Our liquid-filled gauges are available with multiple fill fluids, including glycerin, mineral oil, and silicone oil.

For applications that require a sanitary connection, our Type C Series diaphragm seals feature a simple, one-piece seal design that connects to our gauges. The seal design allows for fast, efficient removal and installation for flushing or changing process media, line cleanout, and equipment washdown situations.

Type C Series Diaphragm Seals and Type CSTG Gauge

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A Calibration Solution for any Application

Sterilizing in Autoclaves

Pharmaceutical makers must sterilize ampoules and other containers before filling them with medicine. This process is controlled by rigid temperature and pressure specifications. Temperatures can range up to 150°C, while pressures can range up to 3.5 bar absolute. The temperature and pressure sensors controlling this process must be calibrated on a regular basis.

Recommended Temperature Calibrators

RTC-156, PTC-155

Recommended Pressure Calibrator

nVision

Validation

Sterilizers and freeze dryers are controlled to have a homogenous temperature distribution. This is done by having a lot of temperature sensors in the chamber during a loaded test-run. All the sensors used for this validation need to be calibrated. For this purpose we have developed special validation inserts to calibrate all the validation sensors in one run.

Recommended Temperature Calibrators

RTC-156, RTC-157, RTC-159, PTC-125

Storage Tank Level

Producers store their inventory in holding tanks, and an accurate pressure and temperature measurement of each storage vessel creates an accurate record of their inventory. A pressure calibrator/recorder offers an easy and fast way to record accurate pressure measurements, while a temperature calibrator measures and calibrates the temperature.

Recommended Temperature Calibrators

RTC-Series

Recommended Pressure Calibrator

nVision, HPC40 Series, XP2i

pH Sensors

pH Sensors are widely used in medicine production that requires fermentation. A pH measurement gives varying results in the same fluid as the fluid changes temperature. Using a pH electrode holding a temperature sensor, the pH measurements are then referred to a set reference temperature to make comparisons. An accurately calibrated temperature sensor is vital for supplying the correct calculation for the reference temperature pH value.

Recommended Temperature Calibrators

RTC-168

Pressure Measurement

Various phases of pharmaceutical development require direct measurement of pressure. This can involve permanently mounting an instrument or completing periodic checks with portable instruments. Our instrumentation provides the flexibility and accuracy to confidently measure pressure.

Recommended Pressure Calibrators

nVision, HPC40 Series, XP2i, 30 Series, ASC-400

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Accredited Laboratories*

Accredited Laboratories are determined to be technically proficient in calibration by calibration bodies, and provide calibration certificates in which the reference instruments used can be traced by an unbroken chain to National and International primary reference standards. Accredited calibration certificates are identified with the calibration body that has accredited them and certifies to customers the accuracy of the data contained in the certificate.

AMETEK Denmark is accredited by the national calibration body, DANAK and Crystal Engineering is accredited by the American Association for Laboratory Accreditation or A2LA. Crystal Engineering's calibration lab, located in San Luis Obispo, CA, is A2LA accredited for pressure and temperature equipment (certificate 2601.01).

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