



# Wired vs. Wireless

SELECTION GUIDE FOR DETERMINING THE OPTIMAL  
MEASUREMENT EQUIPMENT FOR THE VALIDATION OF  
THERMAL PROCESSES IN THE GXP ENVIRONMENT

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## Abstract

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For over 65 years, wired measurement systems have been established in the validation of thermal processes. The first recorders based on thermocouples in the GxP environment, such as the Kaye Digistrip, are already found in the early 1970s as proposed measurement solutions in relevant technical literature. The continual technical advancement of this product family, particularly in terms of data security and integrity, has transformed a relatively simple multichannel recorder into a complex and user-friendly Kaye Validator® AVS. These measuring systems are still widely used, garnering significant acceptance and recognition among both users and regulatory authorities.



Picture 1: Kaye Validator® AVS

Over the past 25+ years of technical advancements, we have increasingly found measurement solutions in the field of validating thermal processes. These solutions, initially battery-operated and later also based on RF technology, either store the recorded measurement data in a data logger or transmit it in real time to an evaluation system. Particularly in extreme temperature ranges like freeze drying, hot air sterilization or steam sterilization, the initial technical weaknesses of these data loggers have been largely fixed through significant improvements in the used electronic components



Picture 2: Kaye ValProbe®



Picture 3: Kaye ValProbe® RT

and batteries as well as the transmission technology. This has significantly improved the reliability of data recording, data storage, and data transmission.

There are now two technically fundamentally different data acquisition systems to choose from: wired and wireless validation systems. But which system is suitable for which application?

The aim of this paper is to provide a basic overview of both available technical options in the context of the process to be validated and to provide a guiding decision aid for the planned application. In addition to the purely technical comparison, this paper will also address non-technical peculiarities regarding the applications, practical handling, sensor-specific properties in measurement and calibration, as well as the system-dependent costs from acquisition to operating and follow-up costs.

A detailed presentation of the valid and application-specific standards and guidelines for the validation of thermal processes is deliberately not included here.

The choice of instruments from suppliers who understand the needs of the pharmaceutical industry is critical to all your validation efforts. These suppliers have developed their devices considering the importance of data accuracy, repeatability, reporting, and protection.

The thermal validation practice, in general, besides being obligatorily in large number in pharmaceutical processes, undoubtedly contribute to less variability in the process, greater safety, and even better quality of the final product.

## Selection criteria

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When selecting the right measurement system, the first criterion is the application, i.e., the process that is to be qualified and validated with an external measurement system.

Due to the wide temperature range in pharmaceutical and biotechnological processes from -196°C (with liquid nitrogen) to >400°C (in hot air tunnels), it must be stated that when selecting the right validation system,

in addition to selecting the right temperature sensors, a selection regarding the optimal measurement technology and other factors such as calibration, handling and the associated risks must also be made. In addition to the many years of proven, thermocouple-based, and therefore wired validation systems, wireless data loggers with and without real-time data acquisition offer a possible alternative. The respective advantages and disadvantages of the various technologies must therefore be weighed up before a decision is made to select the optimal validation solution for the respective application.

So, what criteria should be used when selecting the optimal measurement system for the respective application?

Several technical, handling-related, normative, and economic criteria need to be taken into account in this selection process.

- » Application
  - » Measurement parameters (T, P, RH, etc.)
  - » Temperature, pressure, RH range
  - » Sensor accuracy/Allowed deviation criteria/Acceptance criteria; Specifications by standards and guidelines
- » Sensor Technology
- » Handling and introduction of sensors
- » Sensor calibration and adjustment, frequency, and process of calibration
- » System and handling risks
- » Purchase, operating and follow-up costs

## Application

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Applications that can be found and need to be validated in the pharmaceutical and biotechnological environment vary greatly in both temperature range and the measurement variables to be measured. Therefore, the selection of the right measuring system requires detailed consideration. Frequently encountered applications include:

- » Steam sterilization/autoclaves of different capacities
- » Freeze drying/Lyophilization
- » Hot air tunnels and cabinets
- » Steam-in-Place (SIP)
- » Water spray autoclaves
- » Dishwashers for pre-cleaning

- » Incubators
- » Stability rooms and refrigerators
- » Climate cabinets and a variety of temperature-controlled chambers and cabinets
- » Refrigerators and freezers
- » Isolators
- » Warehouses
- » Fermenters
- » Liquid nitrogen tanks and cryogenic containers

In some applications, the use of a single sensor technology/data acquisition is technically not possible. For the data acquisition to be carried out, a combination of wired and RF-based measurement technology must then be used. For example, many commercially available and battery-powered logger systems reach their limits when real-time data is needed for extreme cryogenic applications or long-term measurements.

A clear listing of all parameters to be measured, their permissible deviation/acceptance criteria, as well as the determination of the number and placement of measuring points are among the basic preparatory tasks. Many applications are described in detail in relevant standards and guidelines, and these guidelines are therefore an important part of the measurement system selection. Further selection criteria, such as the need for real-time data (Required Yes/No) and the handling and placement of sensors (Chamber Feedthru available Yes/No), are additional points for the substantive evaluation of the measurement system to be used.

## Sensor Technology

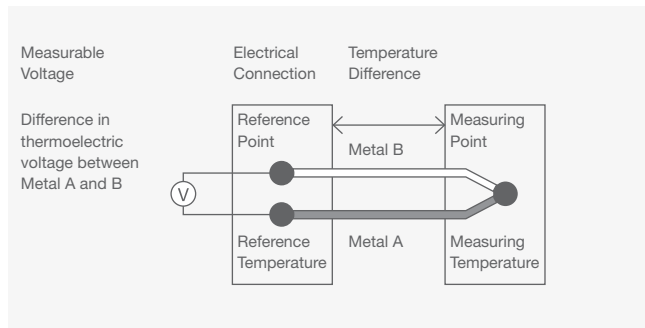
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For the measurement of temperature, various sensor technologies are available. Here, we will take a closer look at the three most used sensor elements.

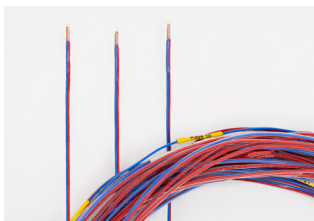
- » Thermocouples (TC)
- » Resistance thermometers (RTD)
- » Thermistors (PTC/ NTC)

### Thermocouples (TC):

A thermocouple consists of two different metals that are connected at one end (measuring point). Depending on the temperature range, various material combinations and insulation techniques are available. In the application of thermal validation in the pharmaceutical sector, type



Picture 4: Thermocouple circuit principle

Picture 5: Kaye thermocouples  
Type T Teflon<sup>®</sup>-insulatedPicture 6: Kaye thermocouples  
Type T stainless steel

T thermocouples (Copper-Constantan) with Teflon<sup>®\*</sup> or Kapton<sup>®\*\*</sup> sheathing have established themselves as common sensors. Special versions encapsulated in stainless steel are also available.

#### Advantages:

- » This type of thermocouple can cover the entire temperature range from -196°C (liquid nitrogen) to +400°C (hot air tunnel).
- » It responds quickly during dynamic temperature changes.
- » High accuracy is achievable with this thermocouple ( $\pm \leq 0.1^\circ\text{C}$  possible).
- » The thermocouple is very robust and flexible, making it nearly shock-resistant; ideal for mobile applications.
- » It is cost-effective to produce.
- » The measuring point is point-shaped and can self-repair in case of a break.
- » Quick and easy replacement on site is possible.
- » It is available in a very wide range of diameters, insulations, and any length.
- » There's no need for a sensor-related, so-called minimum immersion depth (e.g., during a penetration study).
- » No external power source is required as the signal is generated by the thermoelectric effect, also known as the Seebeck effect.

#### Disadvantages:

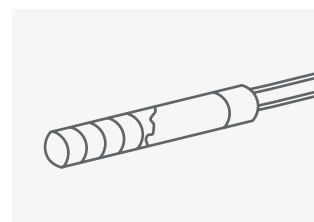
- » The non-linear temperature behavior, which must be taken into account especially during calibration and adjustment.
- » The low output signal requires high-resolution evaluation electronics.
- » Sensor stability and reproducibility are similar to a resistance thermometer, but can vary due to how the thermocouple is handled. Therefore, calibration and adjustment before application, as well as recalibration after application, are recommended.
- » This thermocouple shows vulnerability to EMC-related electromagnetic interference.

#### Resistance Thermometers (RTD):

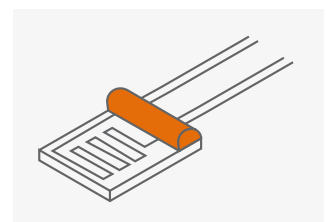
A Pt100 or Pt1000 is a common type of resistance thermometer. The measuring principle is based on the physical property of a platinum resistance, whose resistance increases with rising temperature. The number '100', for example, stands for the resistance of the sensor at 0 degrees Celsius, which is 100 ohms.

Pt100/1000 sensors are known for:

- » Their high degree of accuracy and stability.
- » Their ability to provide linearity over an extensive temperature range.
- » Possessing a high output signal and facilitating simple signal processing such as 0-10V or 4-20 mA.



Picture 7: Wire-wound Pt100



Picture 8: Thin-film Pt100



Picture 9: Kaye ValProbe RT System

- » There is very good reproducibility of the measurement signal.
- » Pt1000 sensors have a higher resolution and less distortion of the measurement signal due to the higher resistance level, making them the preferred choice for accurate measurements.
- » These sensors exhibit low drift when handled correctly.

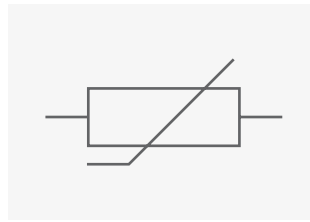
Pt sensors are therefore particularly widely used as permanently installed sensors when it comes to recording the measurement parameter temperature.

However, some sensor-specific disadvantages should be considered with Pt sensors:

- » Pt sensors are relatively sensitive to shock, both mechanical and thermal, which can especially occur in mobile applications.
- » Pt elements cannot be repaired; in case of a malfunction, the entire sensor element of a data logger must be replaced. Complete calibration of the entire measurement chain sensor + data logger is often only possible by the manufacturer.
- » For swift and dynamic temperature changes, the delayed or restricted response time of the sensor element must be factored in.
- » Due to the sensor structure, Pt elements usually require a particular immersion depth for accurate temperature detection (design-related measuring path). This property is negligible when measuring in a large chamber. However, for measurements and immersion in smaller containers (e.g., vials), or when calibrating and adjusting the sensor, this immersion depth plays a crucial role concerning measurement and calibration accuracy.
- » The manufacturing costs for Pt sensors are higher than, for instance, thermocouples.
- » An external power source is required for these sensors.

### Thermistors (PTC/NTC):

A thermistor is a unique type of resistor with a resistance value that significantly depends on temperature. There are two kinds of thermistors: PTC (Positive Temperature Coefficient), which shows an increase in resistance with rising temperature, and NTC (Negative Temperature Coefficient), where resistance diminishes as temperature ascends. Thermistors are frequently employed in simple temperature sensors and temperature control systems, and are prevalent in the field of medical technology, used in devices such as catheters.



Picture 10: Thermistor circuit diagram



Picture 11: Thermistors

Thermistors have some characteristics that are disadvantageous for thermal validation:

- » Limited temperature range: Thermistors usually have a much smaller temperature range compared to other temperature sensors such as thermocouples or RTDs.
- » Nonlinear response: Thermistors exhibit a strongly nonlinear temperature-resistance relationship, meaning they often require complicated calibrations for accurate measurements over a wide temperature range.
- » Long-term stability: The properties of thermistors can change over time due to aging and environmental influences, which affects precision.
- » Sensitivity to electrical interference: Thermistors can be sensitive to electrical interference, which can affect measurement accuracy.
- » Self-heating: Thermistors can self-heat due to the current flowing through them, which distorts the measured temperature. This self-heating must be considered for accurate measurements.

Because of these properties, thermistors are generally not used as measurement sensors for thermal validation. They are more commonly used in measurement and control technology (e.g., HVAC, automotive industry) or for applications with a strongly limited temperature range (e.g., Cold Chain Logger).

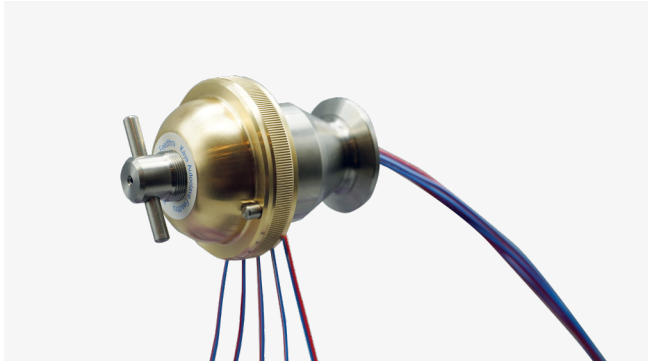
### Conclusion:

Measurement systems for the validation of thermal processes use thermocouples or Pt sensors, and with appropriate handling, they achieve a similar reliability and measurement uncertainty. In particular, in the extreme temperature range and in in-situ measurements, TC measuring circuits show advantages, whilst with data loggers, additional measures must be taken to protect the evaluation electronics.



## Handling and Insertion of Sensors

The specifics of the selected measurement technology (wired or wireless) must be individually adapted to the application to be measured.



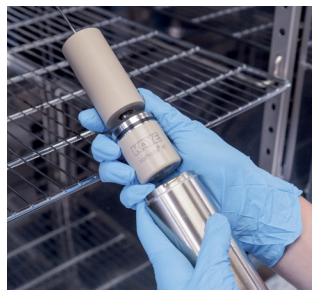
Picture 12: Kaye TC- Feedthru

In general:

- » The time effort for the installation of wired measurement systems is more extensive.
- » A Feedthru into the chamber is required. For example, this must be pressure-tight in a steam sterilizer. Care must be taken to ensure that the sensor elements are not crushed when sealing the Feedthru. Corresponding solutions are available on the market.
- » The placement of the sensors in the chamber itself takes time. With 24 thermocouples, the insertion and fixation, as well as the disassembly after the measurement, each takes a good 2+ hours depending on the chamber size.
- » When used in a freeze dryer, special measures (Feedthru/ sealing/ sheathing of the thermocouples) are necessary to avoid failing an impending vacuum test (Leak Test). Here too, recognized solutions are available as standard accessories.
- » When inserting and routing, possible electromagnetic interference, for example, by electric motors must also be considered (EMC). In general, the measuring sensors should be laid out like a data cable.



Picture 13: Kaye ValProbe RT in Autoclave



Picture 14: Kaye ValProbe RT Isolating Canister

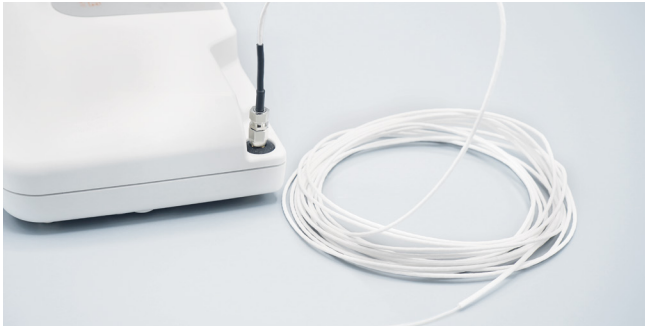
The insertion, distribution, and placement of battery-operated data loggers is relatively simple. A time saving compared to a thermocouple measuring circuit of 1-2 hours is achievable. However, it should not be forgotten that it is a battery-operated measurement system. Lithium batteries are usually used, which means a limitation in the usable temperature range. The necessity for so-called insulating canisters should be considered. Moreover, before use, the remaining run time of the used battery should be compared to the duration of the process. Without power, no measurement values are determined, stored, or transmitted (risk of data loss). If real-time data is needed in the entire temperature range, it should be noted that many RF data loggers available on the market restrict or even completely switch off real-time transmission at temperatures  $< -40^{\circ}\text{C}$ . Improvement also in the range below  $-40^{\circ}\text{C}$  or for necessary long-term measurements in this temperature range requires appropriate measures on the part of the evaluation electronics (Insulating canister).

Real-time data transmission also requires that the measured values determined must be transmitted to the receiver located outside the system via the RF signal. This can certainly cause problems in one or another application in a closed stainless-steel chamber. Accordingly high signal strengths of the RF transmitting and receiving unit in the data logger are required. In practice, direct tests at the system have proven to be a proven procedure for clear clarification.

The extremely weak transmitting and receiving signals of the data logger also require additional measures such as a separate antenna. But even here, an additional and pressure-tight Feedthru for the insertion of this antenna into the chamber is then required (as with thermocouples). Due to the already mentioned shock sensitivity of Pt



Picture 15: Kaye ValProbe RT Battery Extension Kit



Picture 16: Kaye ValProbe RT extension Antenna

sensors, careful handling and sufficient fixation of the data loggers should be considered. A mechanically bent sensor or a data logger that has fallen down will often still deliver measurement data, but this data should only be trusted after verification.

### Sensor Calibration and Adjustment, Frequency of Calibration

When calibrating and adjusting a sensor, the specific properties of the sensor play a crucial role. It ensures that the sensor produces the most accurate measurement for the application it's used for. Calibration usually involves comparing a device under test with a reference device that holds an established calibration precision. The accuracy of the calibration can only be as good as the reference device.

The frequency of calibration tends to vary depending on the type of sensor, the conditions under which it is used, and the requirement of the measuring application. Some sensors may require calibration before each use, others may be calibrated at regular intervals, annually or semi-annually.

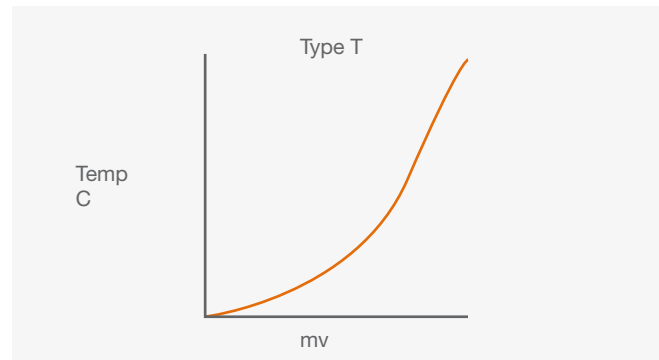
Sensor drift over time is also a factor. Sensors used in high-stress environments, including high temperatures, shock or vibration, or corrosive materials, may need to be calibrated more frequently. It is always important to adhere to manufacturers' recommendations on calibration and to conform to any governing industry standards.

#### Thermocouples:

» Due to the non-linearity of the characteristic curve, a so-called two-point calibration and adjustment in combination with a third verification point at the

working temperature is recommended to achieve the highest possible accuracy.

- » For instance, in steam sterilization:
  - » First calibration and adjustment point: 90°C
  - » Second calibration and adjustment point: 130°C
  - » Verification of calibration at working temperature: 121°C
- » The smaller the temperature difference between the lower and upper calibration and adjustment point, the more accurate the calibration result will be.
- » Single-point calibration (without adjustment) at the working temperature after the measurement has been carried out in the chamber, the so-called verification, provides documented confirmation that all sensor elements are still operating within the specified measurement accuracy (post-calibration). In practice, several calibration verification points are often used.

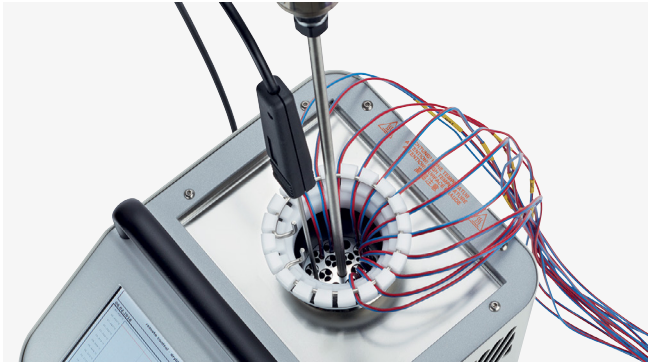


Picture 17: Characteristic curve of a thermocouple Typ T

Whether such a verification should be carried out after each application or after several qualifications have been completed is the user's responsibility and is part of the risk assessment. To achieve maximum risk minimization, it is suggested in relevant technical articles to carry out a check after every qualification run (post-calibration).

- » Due to the thin cross-section of the thermocouples, calibration in a liquid calibration bath or a block calibrator (Dry Well Oven) is possible. When calibrating in a liquid calibration bath, suitable mechanical measures must be taken to prevent the thermocouples from floating.
- » Naturally, calibration is performed against a traceable temperature standard (such as the Kaye IRTD).
- » The achievable measurement uncertainty is  $\leq \pm 0.1^\circ\text{C}$ .
- » Parallel calibration and adjustment allows for up to 48 thermocouples when used with the Kaye AVS in

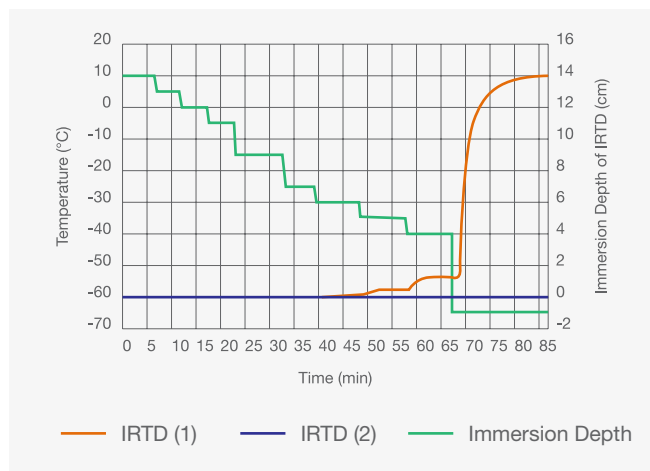
combination with the Kaye LTR-150 or HTR-420 and the Kaye IRTD.



Picture 18: Kaye LTR-150 Dry Block Calibrator including TC's

**Pt Elements:**

Typically, data loggers are calibrated and adjusted by the manufacturer before delivery, and these calibration data are documented in a calibration certificate. Despite an almost linear characteristic curve, several calibration points are also set when calibrating Pt elements. A challenge here, both during calibration and during later measurement in the application, is the already mentioned minimum immersion depth. If the minimum immersion depth is not known or considered, there is a risk of incorrect calibration and, accordingly, an incorrect output measurement temperature in the application.



Picture 19: Measurement error due to insufficient immersion depth

Flexible or bendable sensors can certainly be calibrated in a block calibrator (Dry Well Oven). Depending on the form factor and sensor length, calibration in a liquid bath is sometimes the only option. The highest level of

achievable measurement uncertainty is only achieved when the sensor and evaluation electronics are calibrated at the same temperature (sensor + data logger together in the calibration bath - keyword: minimization of errors due to the temperature coefficient of the evaluation electronics). Since there is also a handling risk when using data loggers, a risk assessment should be carried out and this risk should be minimized by checking the original calibration data as defined by an SOP. It's important to note that this check can be carried out by the user himself and is supported by the software of the data logger. The capacity of the calibration bath used determines the number of data loggers that can be calibrated/checked in parallel. Kaye calibration baths allow up to 10 data loggers to be inserted at the same time.

As with any temperature measurement, regardless of the type of sensor being calibrated, calibration should only be done once full stability has been achieved. In this case, thermocouples show temporal advantages due to their lower mass and therefore faster response time. Kaye's AVS and ValProbe Standard/RT data loggers support the user with corresponding software functions in the calibration module and ensuring the stability plateau of the sensor to be calibrated before the start of automated calibration.



Picture 20: Kaye CTR-25 Calibration Bath with special insert for dataloggers



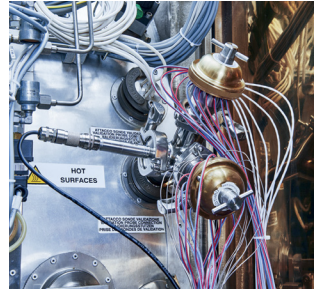
## System and handling risks

### Thermocouple System:

Yes, it is correct that TC sensors (thermocouples) are subjected to greater mechanical stress during loading and unloading, which leads to a greater potential for mechanical damage to TCs due to unsuitable Feedthrus or when fixing them in the chamber. Additionally, they are more susceptible to disturbances from EMC induced influences. It is important to consider these risks and take appropriate measures to minimize these risks to ensure accurate temperature measurement and the reliability of the sensors.



Picture 21: Professional Kaye thermocouple implementation on an autoclave



Picture 22: Professional insertion of TC sensors using the example of the validation of an autoclave using suitable thermocouple Feedthrus

### Datalogger system using Pt-Sensor:

Battery-operated data loggers, whether with RF functionality or without, are sometimes exposed to extreme temperature conditions. Various components such as

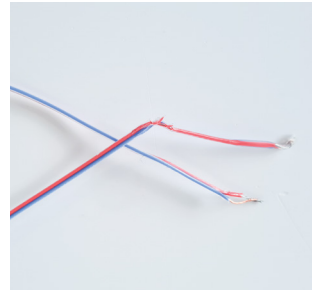
- » Li-Battery
- » A/D converter
- » Mass storage
- » Used RF technology
- » Seals

represent potential sources of failure that must be considered in a risk assessment.

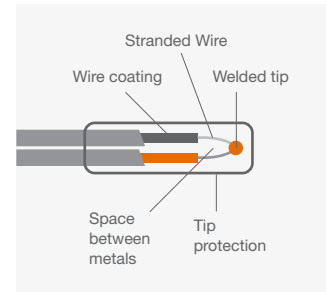
### Handling TC Sensors:

The handling risks associated with the use of thermocouples include:

- » Improper or incorrect manufacturing of the sensor tip.
- » Incorrect insertion and routing in the chamber (EMC).
- » Mechanical damage due to crushing or incorrect thermocouple Feedthru.
- » Use of low-quality thermocouples (purity of material).



Picture 23: Mechanically damaged TC elements due to improper handling



Picture 24: Schematic view of Kaye thermocouple probe tip

To avoid these risks, it is recommended to:

- » Use ultra-premium thermocouples.
- » Protect the sensor tip with a Teflon<sup>®</sup> or metal tip.
- » Use so-called Stranded-Wire (higher flexibility of the twisted cable strands prevents cable breakage).
- » Apply special and steam-tight Teflon<sup>®</sup> insulations.
- » Use pressure and steam-tight TC Feedthrus.
- » Perform regular visual inspections for mechanical damages.

### Handling Pt Data Loggers:

When using data loggers with a Pt sensor as a temperature element, the following user-related sources of error should be considered:

- » Mechanical damage (e.g., bending the sensor tip)
- » Mechanical shock to the sensor element (e.g., dropping the logger when inserting it into the chamber or during transport)
- » Improper storage and handling of the Li battery
- » No possibility to replace the battery on site
- » Improper replacement of all seals after a battery change (potential for moisture to penetrate the electronics)
- » Use of batteries with insufficient remaining run time (Risk of data loss).



Picture 25: Mechanically damaged probe tip of the data logger

## Purchase, operating, and follow-up costs

Due to the multitude of wired and wireless measurement systems available on the market, only a general statement can be made on this selection criterion. Regardless, the cost side should not be neglected when choosing possible measurement systems, both in terms of acquisition and later follow-up costs for recalibration and repair.

When comparing, the number of required measuring points should be considered. As a rule, wired measurement systems are cheaper to acquire from 24 sensors upwards. The difference increases with an increasing number of measuring points in favor of the wired measuring units.

The economic advantage of a TC-bound measuring unit becomes even clearer when looking at the annual calibration costs. While only the base unit (data recorder) needs to be calibrated for a wired measurement system, the costs are incurred for each individual unit in the case of data loggers. For measurement configurations with 24 data loggers or more, these follow-up costs are considerable.

An important point that should be taken into consideration when estimating the follow-up costs is the regularly replaced batteries in data logger systems. Particularly in RF operation with real-time data transmission, battery consumption is not insignificant.

Selection Criteria	Sensor: Thermocouple	Sensor: Pt100/1000 with or without RF-Technology	Note
Measurement parameter T, P, TH	✓	✓	With data loggers, generally only the manufacturer can replace it
Accuracy $\leq \pm 0.1$ C	✓	✓	
Temperature Range	✓		
Effortless sensor element replacement	✓		
Long-term stability		✓	
Reproducibility	✓	✓	
Linearity of the characteristic curve		✓	
Strength of output signal from sensor element		✓	$\mu\text{V}$ at TC; 4-20mA or 0-10V at Pt
Sensitivity of sensor element to shock (thermal/mechanical)	✓		
EMC signal interference		✓	
Real-time data transmission	✓	✓	Only with data loggers with RF-Technology, though restricted at temperatures $< -40/-50^{\circ}\text{C}$
Data loss Risk	✓		Data loss when battery capacity of the data logger is insufficient
Handling and introduction of measurement points		✓	
Required minimum immersion depth	✓		
Calibration and adjustment of sensor element before and after application		✓	No calibration/adjustment data logger before application
System and handling risks	✓	✓	
Purchase costs	✓		
Follow-up costs	✓		
Cost of additional measurement points	✓		

Table 1: Comparison of wired data recorders and battery-powered data loggers

## Conclusion

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Two fundamentally different solutions are available for validating thermal processes:

- » Wired chart recorders, often utilizing thermocouples as the sensor type with real-time data transmission due to their design.
- » Wireless, battery-powered data loggers, with and without real-time data transmission, typically using Pt100/1000 sensor elements.
- » Both solutions are recognized and have proven their effectiveness in validating thermal processes in the GxP environment.
- » Depending on the temperature range and application-specific requirements, hybrid solutions or a combination of both measurement techniques may offer an optimal solution.
- » Each of the presented solutions has its advantages and disadvantages; evaluating them is an essential part of the decision-making process.
- » Along with the purely technical requirements,

other selection criteria such as handling, calibration and verification possibilities, and the aspects of acquisition, operating, and follow-up costs should be considered when making a decision.

Other selection criteria include:

- » Standard-compliant documentation and data integrity.
- » Compliance and fulfillment of legal requirements.
- » Intuitive software and user-friendly data management.
- » Local support before and after purchase.
- » ISO 17025 accreditation.
- » Market acceptance and acceptance by regulatory authorities complete the evaluation of potential solutions.

A practical test directly on the plant to be qualified is recommended in any case. Our global network of employees and certified partners is always at your disposal. Contact us today, via the links listed below, and arrange a non-binding consultation by our support team.

**Visit our website:**

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## Reference list

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- » Kaye: Picture 1,2,3,4,6,7,10,13,14,15,16,17,18,19,20,21,22,23,24,25,26, Table 1
- » Amphenol Thermometrics Inc.: Picture 11
- » Wikipedia: Picture 5,8,9,11

## Trademarks

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\*Teflon is a registered trademark of Chemours

\*\*Kapton is a registered trademark of DuPont

## About the author

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With over 30 years of experience as an application engineer in the field of measurement technology and in solving customer-specific tasks, as well as sensor technology and calibration solutions in the GxP environment worldwide, Frank Kies successfully transfers his know-how into practical solution suggestions for later use. Frank was actively involved in the development of modern validation systems such as the Kaye Validator AVS and Kaye Valprobe RT and holds several patents. He successfully passes on his acquired knowledge in seminars and training courses worldwide. In addition, he is a guest speaker at various organizations and currently works at Kaye as Global Strategic Marketing Director.

## About Kaye

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For over 65 years, Kaye has been a recognized and reliable partner when it comes to GMP-compliant thermal validation. With applications ranging from thermal process validation and continuous monitoring to sensor calibration, Kaye technology offers the most accurate and user-friendly measuring systems available on the market today.

Kaye's product range caters to demanding measurement and calibration requirements in the GxP environment. All products and software solutions for thermal validation and monitoring of critical processes, as well as the continuous recording of different measurement sizes in the area of monitoring and the necessary documentation of the measured data, are tailored to globally applicable guidelines (FDA/ EU/ GMP Standards).

Kaye specializes in turnkey systems that are supported by excellent technical customer service and on-site service. The offering includes a complete range of chart recorders, data loggers for temperature, pressure, and relative humidity, traceable temperature standards, calibration baths, block calibrators, thermocouples, and accessories. This is complemented by the necessary software for standard-compliant documentation, which supports the user in complying with applicable guidelines and regulations.

Leading pharmaceutical and biotechnology companies worldwide have relied on Kaye's products for the validation and monitoring of critical processes, such as the validation of sterilization processes, for more than 65 years.