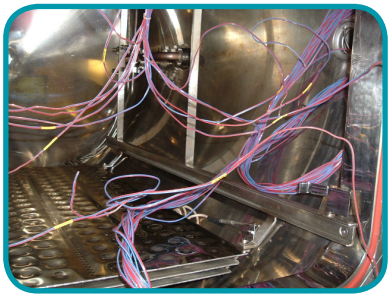
DataTrace®

DataTrace in Autoclaves

Getting accurate product temperature throughout an autoclave validation can be a difficult task but imperative to being able to calculate lethality within an autoclave cycle. In addition to the product, monitoring cold spots and other areas within the autoclave can be a time consuming and difficult when relying on inaccurate data loggers or thermocouples. Whether it is for an initial equipment and process validation or for yearly equipment qualifications, maximizing efficiency while maintaining that strict temperature accuracy (0.1° C) is critical to a successful project.



DataTrace Saves Time

Chamber thermal mapping and heat penetration studies are key to validating your equipment and processes, and are an important part of your GxP compliance program. The DataTrace system allows you to perform these critical studies in a fraction of the time required to do the same work with a wired, thermo-couple based data logger system. In the example below, of a 16-point autoclave thermal mapping, the DataTrace wireless loggers were found to save 65% of the time of a traditional thermocouple system.

Function	Thermocouple System	DataTrace Data Loggers
Pre-Calibration	30 mins	None
Sensor Placement	30 mins	5 mins
Data Collection	45 mins	45 mins
Sensor Removal	15 mins	2 mins
Post-Calibration	**30 mins**	**None**
Total	150 mins	52 mins

Eliminate Pre and Post Run Calibration

Unlike thermocouples, the thermistor and RTD technology used in DataTrace data loggers provide long term calibration stability. This stability allows you to extend the time between calibration checks or eliminate them altogether.

Simplify Sensor Placement and Removal

DataTrace data loggers can be easily and quickly placed in chambers or rooms. Being wireless, there are no thermocouples or power cables to deal with-- simply position the loggers in an appropriate location and they are ready to collect data.

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Improve the Accuracy of Heat Penetration Studies

The DataTrace data loggers are extremely small, robust, precision instruments that can easily be placed inside packages of products. Using appropriate fixtures, the tip of the temperature probe can be positioned exactly at the coldest point within the package, providing extremely accurate heat penetration information. The package of product can be sealed in its normal process, often without the need to make "ports" for thermocouple wires to extend into your packaging.

The Value of Accurate Validation

"If changes or process deviations occur, the process will be reviewed, and revalidated (as necessary). All reviews and revalidation testing must be documented per the manufacturer's Document Control procedures." - FDA Code of Federal Regulations Title 21, Section 820.75

Validation data is frequently referred to for investigations including: non-conformities, complaints, trends, deviations and recalls.

If production occurred outside parameters specified in work instructions, but within validated parameters, the validation data is used to support release of the product.

Get Control with DataTrace

"The validation testing and results, the date and signature of the personnel approving and executing the validation testing, and any equipment that is being validated or used during the validation will be documented per the manufacturer's Document Control procedures." - FDA Code of Federal Regulations Title 21, Section 820.75

DT Pro integrates smart security and regulatory capabilities including an audit trail log for all security levels, data encryption, electronic signatures, enhanced password protection and administrative security options. Installation Validation is now easier than ever with new System Configuration Reports. IQ/OQ/PQ Documents and a Validation Manual are also available. These features allow you to achieve FDA 21 CFR Part 11 or GxP compliancy.

What does Mesa's logger/solution afford/provide for users?

Mesa's DataTrace data loggers and DT Pro software can provide the user data that can be used to monitor, validate, and record data points for every autoclave cycle. DataTrace data loggers can withstand temperatures well within typical autoclave temperatures as well as extreme temperatures with the use of thermal barriers. You can select the time interval in which data is being logged keeping you in compliance with federal regulations.

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