

Temperature Mapping - Facts and Considerations



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Temperature Mapping Facts



What is Temperature Mapping?

Temperature mapping is the process of determining the temperature profile of a particular temperature-controlled environment or process such as a freezer, refrigerator, incubator, stability chamber, warehouse or autoclave by measuring multiple points in a defined area over a specified study duration.

The goal of temperature mapping is to determine the differences between each point of measurement, or fluctuation within a defined area over a period of time. This data will need to be analyzed in each of these controlled temperature units (CTU) or processes, thereby ensuring safety and that the data conforms with the necessary tolerances.

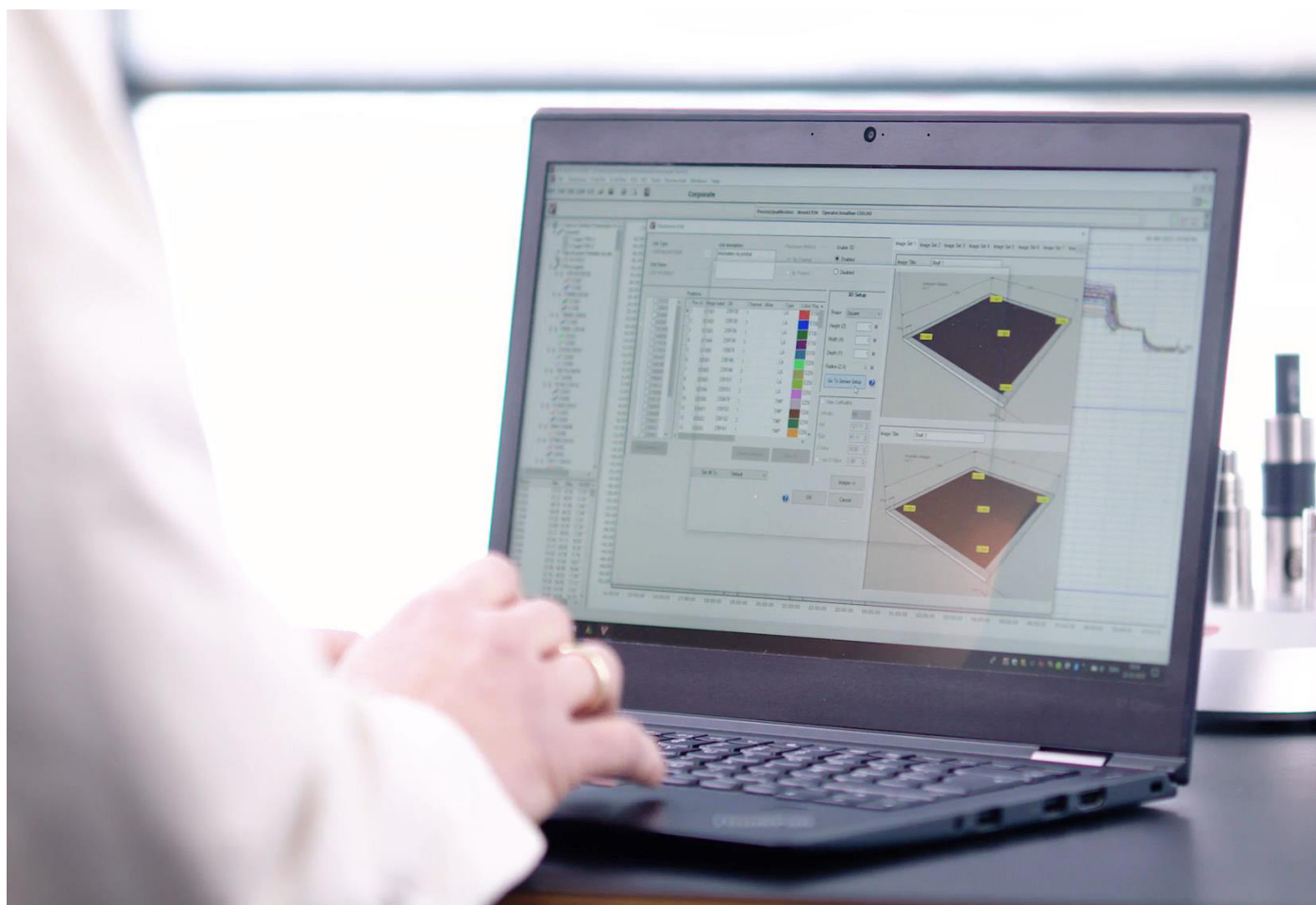
For controlled temperature units, storage areas, environmental chambers and cold chain activities such as transportation and logistics centers, safety of the product means being stored in precise conditions within its defined tolerances. For processes such as autoclaves, depyrogenation ovens, Steam-In-Place installations, ovens, controlled rate freezer, lyophilizers or retorts, safety is about being able to hold a particular temperature for a specific duration in order to accomplish a specific task, such as sterilization.

Why Perform Temperature Mapping?

Temperature mapping is often a requirement for companies that are involved in highly regulated environments, such as food, hospital, pharma, biotech, medical device, etc. It can also be required as part of accreditation process like CAP.

At a minimum, these regulated companies should comply with the FDA and the GXP (GMP, GLP) guidelines for the production, transportation and storage conditions, which is valued globally. In these situations, finding a trusted partner to execute these GXP mapping services is critical.

Temperature mapping is important regardless of how well a storage area is built, or a process is designed, as it will have temperature fluctuations that will have an impact on the items being stored or processed. Controlled products such as food, drugs and medical devices, are often subject to a higher level of control and testing. The level of testing, documentation and frequency of temperature mapping comes down to each company performing their own risk assessment. The risk assessment may include variables such as product sensitivity to the temperature fluctuations, impact on product and impact on patients.



When to Perform Temperature Mapping?

New equipment

When a new piece of critical equipment is installed, a standard-qualification process is commenced. Instruments such as autoclaves, receive an initial qualification, but often need to be qualified specifically to how they will be used for particular cycles and loads.

Repaired equipment

When a unit is repaired, it is common to test it to ensure that it functions as expected.

Relocated equipment

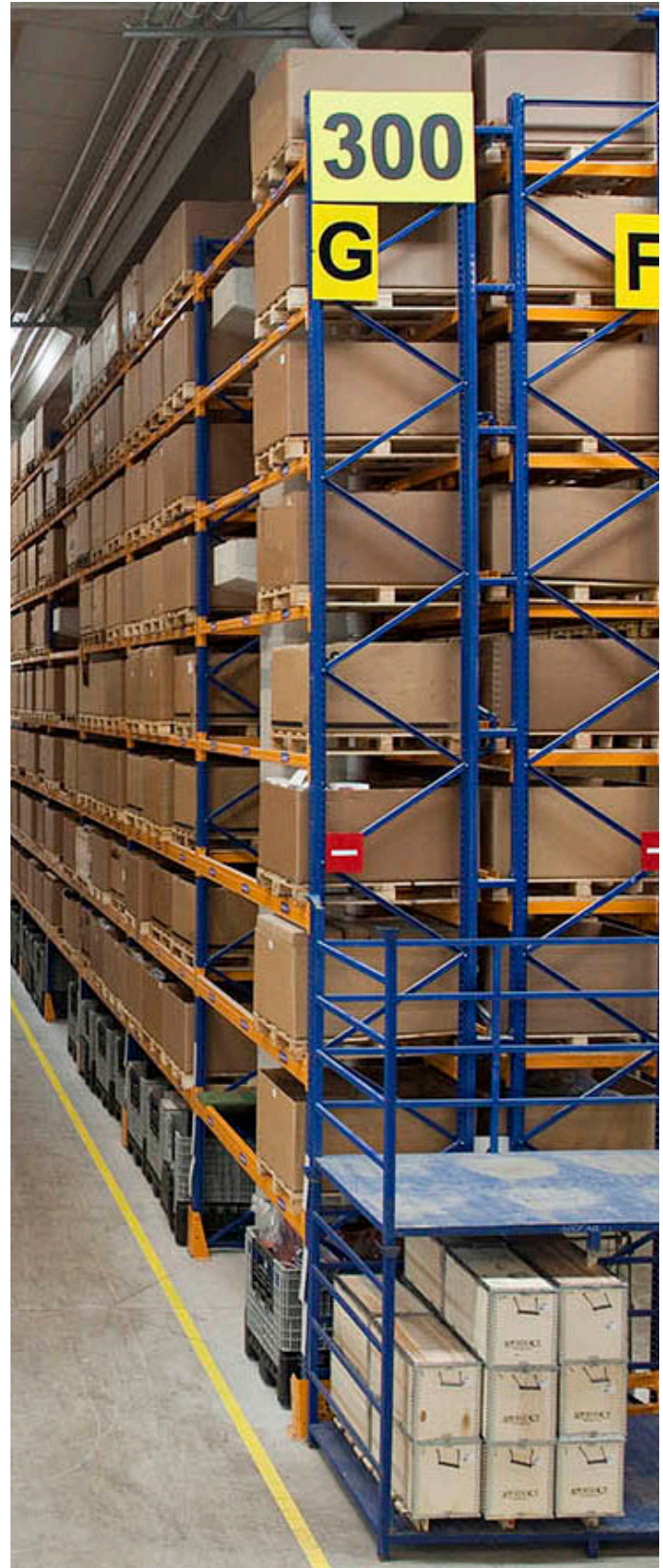
The moving of a unit can often have a significant impact on the unit's performance, which is why a requalification might be necessary.

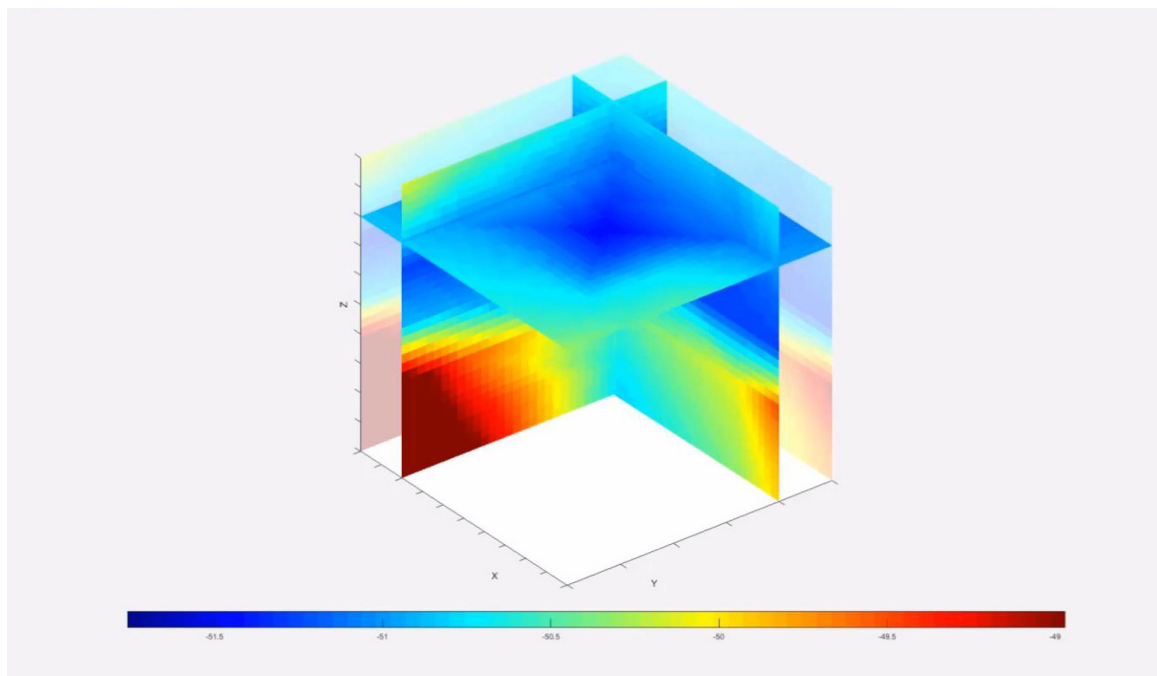
Periodic continuous or re-qualification

For autoclaves and other sterilization instruments, a re-qualification cycle of once per year is fairly common. For storage areas such as reach-ins, walk-ins and warehouses, the frequency can vary from once per year (or less in some circumstances), to as long as five years.

Testing storage areas based on the impact of external environmental conditions

A storage area such as a warehouse, can be significantly affected by the building's outside temperature, particularly in extreme seasons such as summer and winter, resulting in a storage area that should be tested on a seasonal basis.





How to Perform Temperature Mapping

Step 1

Identify relevant SOPs and Protocols

The first step in the temperature mapping process is to generate the necessary documentation. A procedure or protocol is often leveraged to provide structure to the testing process. This test document may include operational qualification, performance qualification, continuous qualification/requalification, engineering studies, factory acceptance test and site acceptance test. This formal process includes information such as the duration, quantity and placement of temperature sensors. It also includes what conditions the test will be performed under such as empty, loaded or minimum/maximum conditions. Additional testing may be performed depending on the particular unit being tested. Storage areas may have additional tests performed, such as open door, power interruption, power loss mapping and unconditioned load studies. Warehouses may require additional tests in different seasons.

Step 2

Execute and Document Test Scripts

The next step is to execute and perform those test scripts in a qualifying fashion, while documenting the results by using good documentation practices. When executing the temperature mapping, the capability of the staff, type and quantity of temperature mapping equipment and availability of the units under test (UUT) need to be considered to ensure a successful project.

Step 3

Reporting the Findings

Finally, once the data has been analyzed the report package needs to be completed. The qualification or validation report package is a compilation of the executed procedures or protocols along with all the test data that support the results, this includes a summary report for easy review.

What Types of Equipment Requires Temperature Mapping?

Reach-in and walk-in controlled temperature units (CTU) and controlled environmental units (CTE) such as:

- Freezers
- Refrigerators
- Incubators
- Stability chambers

Performing temperature mapping for these units ensures that every point within the defined storage area confidently meet certain acceptance criteria. The temperature mapping is performed over a period of time to ensure that as the systems actuate, the temperature is always within limits and without excursion.

Temperature mapping of Warehouses:

Warehouse qualifications that include temperature mapping, come down to the quantity of sensors and strategic planning for their distribution within the storage area. Each warehouse qualification will require a custom number of sensors for temperature mapping based on the variables for that particular warehouse. Some of the variables to consider include the length, width, height, external facing walls with direct sunlight, insulation, racking layout, HVAC air inlets/outlets, fans, openings such as doors and overhead doors as well as the changes in outside (ambient) season temperatures. All of these factors will have an effect on the uniformity of the temperature within the warehouses and need to be considered when developing the temperature mapping plan.

Temperature mapping/heat distribution of autoclaves (steam sterilizer) and depyrogenation ovens (hot air sterilizer):

For several applications in regulated industries, there is a need to sterilize a variety of items to ensure safety. Two common ways of sterilizing are moist heat steam sterilization and dry heat sterilization, often referred to as depyrogenation. Steam sterilization can be used for a wide range of items, including growth media, antifoam, glassware, unwrapped goods, waste, etc., whereas depyrogenation is often used for items that can handle higher temperatures, such as glass vials, syringes, orthopedic components, surgical rods and staples. Each of these processes requires specific qualifications depending on the type of items and materials being sterilized. Ultimately, however, the overall concept and qualification process can be fairly similar.

What Types of Validation Equipment is used for Temperature Mapping?

Data Logger Temperature Mapping System

Things to consider in relation to choosing data loggers are the storage capacity, sampling rate, temperature range, temperature accuracy, physical size, internal vs. external sensor, transmitting vs. non-transmitting and battery life.

Thermocouple Temperature Mapping System

This solution requires a base unit that the thermocouples can connect to in order to collect data and perform various analyses. The type and quality of thermocouples will have an effect on the accuracy. The accuracy of the thermocouples increase or decrease depending on the temperature being mapped.

Temperature Mapping Considerations

What to look for when Selecting a Temperature Mapping Contractor

It can sometimes be difficult to decide who provides the best type of services for a specific facility. There are a couple of key points that should be considered when selecting a temperature mapping contractor:

- Quality of the staff and engineers
- Quality of the equipment used to perform temperature mapping
- Time spent preparing and conducting measurements
- Recognized standing in the industry as manufacturers of temperature mapping equipment
- Quality and turnaround of the documentation upon completion

What Ellab offers

- A full service turn-key solution by providing equipment, writing protocols, supplying engineers and completing summary report packages
- A customizable approach to meet your needs
- Staffing for either projects or full-time staff augmentations
- Temperature mapping equipment through either purchase or rental solutions

