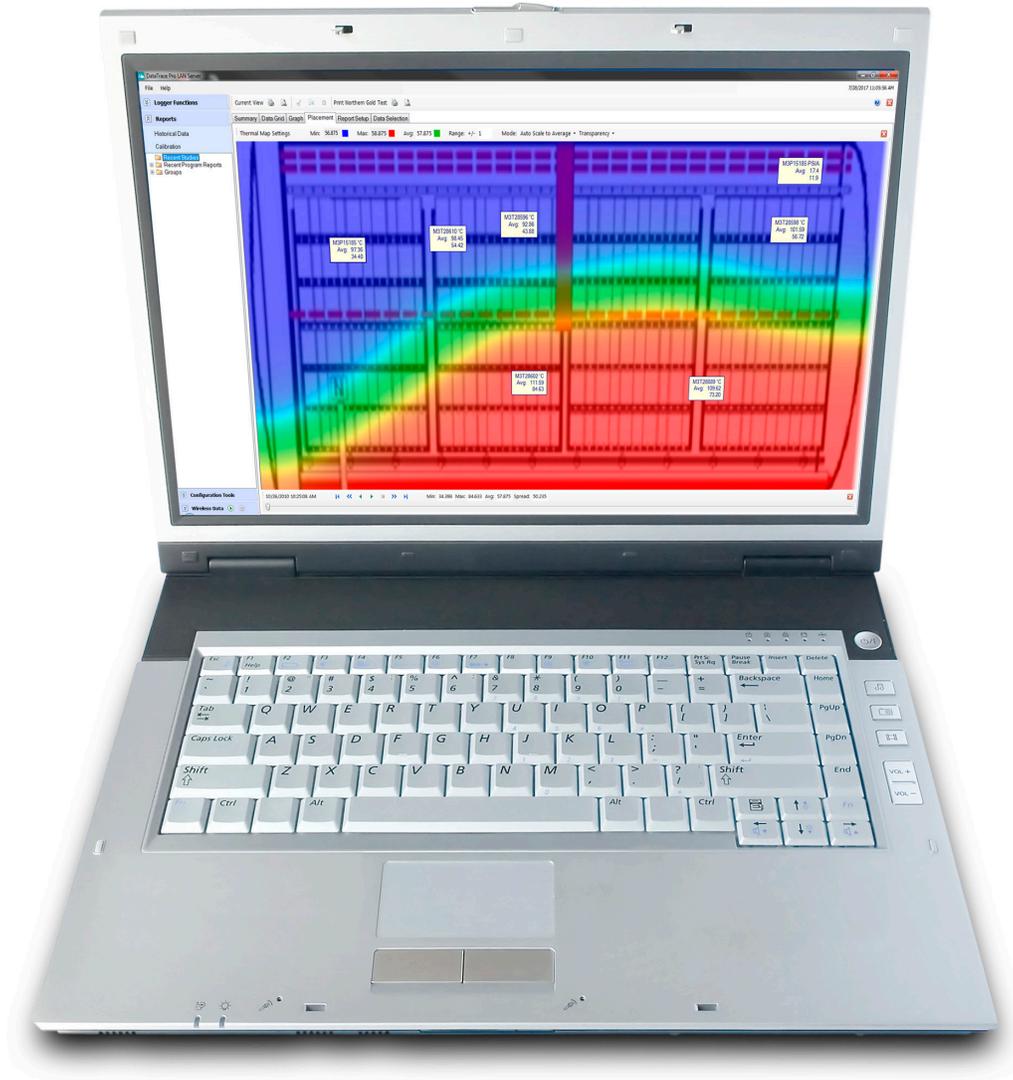




Temperature Mapping Guide: Do's and Don'ts



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Temperature Mapping Don'ts

1 Winging It!

Not using a layout, or pattern for the mapping. Prevent rework by planning ahead and taking into consideration the other variables in the areas that could affect the mapping. Be strategic in where you place the sensors. A common mistake is only placing sensors in the center of a space. Instead, the loggers should be placed throughout the area in a 3-dimensional pattern; the purpose of the mapping is to get temperatures in the entire area.

2 Short-changing the Project

This one is tied directly with the first snafu; often, a mapping project will be performed with an insufficient number of devices. Although reducing costs by using fewer pieces of equipment may be enticing, that savings is minimal compared to the price of having product recalls or product failures down the line.

3 Unrealistic Expectations

Setting impossible-to-reach acceptance criteria is another snafu that many make when performing or planning a temperature mapping. The limits set for your space should be based on product storage requirements, not how well the storage environment HVAC system can control. Set reasonable limits so that time and aggravation can be saved by simply doing what can be done, within reason.

4 KISS Principle

Simplicity is key when it comes to mapping protocols. Don't make your protocols overly complex if they do not need to be. Keep in mind that others may need to follow the protocol instructions and may not have the same level of expertise. Having the protocols reviewed by outside team members will help to make sure of this.

5 Detail Oriented

A common mistake once the temperature mapping is finished is how the data is collected and the results distributed. Be sure to create a report that details the data, and shows that it was verified. Flag out-of-limit data, and graph it for easy readability if possible. Write a summary that clearly explains your findings. If your report does not clearly show your results it will likely have to be rewritten, or even worse, the temperature mapping will need to be performed again greatly increasing costs and time wasted.

6 Current Calibrations

Don't forget about your device calibrations! Not calibrating or using inferior calibration products for the sensors or loggers used for the temperature mapping is a big no-no. The entirety of your temperature mapping results could be questioned, especially if some of your data is close to being outside of the acceptance criteria established in the temperature mapping protocols.

Temperature Mapping Do's

1 Know Your Area

It is extremely important to look at all HVAC activity and control, loading dock location and activity and many other factors when developing criteria for and executing a thermal mapping.

2 Follow the Guidelines

The temperature and relative humidity acceptance criteria for each product is determined by testing conducted per the FDA Guidance Document – Stability Testing of New Drug Substances and Products, or similar guidance.

3 3 Point Play

Data loggers used should have sufficient memory to record the entire study and a valid, NIST-traceable 3-Point Calibration. The calibration points should bracket the acceptable temperature range of the area(s) that will be mapped.

4 Area Drawing

Measure the length, width, and height of the area to be mapped. Develop a diagram including shelving, racks, doorways, loading docks, heating/cooling equipment and the specific placement of each data logger.

5 Timing is Everything

A minimum of 7-10 consecutive days of mapping for warehouses and other ambient storage areas should be conducted. For temperature-controlled areas (i.e. incubators, refrigerators, freezers, cold rooms), a 24 to 72-hour temperature mapping study should be performed.

6 There's a Time and a Place

Detail where the data loggers should be arranged along the length and width of the area. Label each data logger with the unique ID and program each logger to be used to an appropriate sampling interval (5-15-minute logging interval is standard).

7 Collect and Recover

At the end of your study, collect the data loggers and confirm the serial numbers and locations against the protocol. Recover the information from the data loggers and perform data analysis.

Temperature Mapping Do's

Knowledge is Power

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Know the locations and severity of any hot and cold spots in your storage areas. Documenting the hot and cold spots provides invaluable information when preparing to place the data loggers into position for mapping.

In God We Trust, All Others Must Document

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Have documented records of the environmental conditions of your product storage areas and equipment. Then, keep these documents handy while you prepare your mapping data.

Optimize Storage

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Locate the optimum storage locations for temperature sensitive products based on how tight the temperature variance is. Knowing these locations in advance can save time and energy for the mapping expert and prevent product loss.

All Bases Covered?

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Ensure that all requirements for the storage of your raw materials, in-process materials, finished products, stability samples, and components are meeting Current Good Manufacturing Practices (cGMP) requirements.

3-Point Minimum

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All of the data loggers used should have at least a 3-point NIST-traceable calibration performed prior to use. Data logger calibrations with fewer points provide less accurate readings across the temperature range being monitored.

Meet the Standard

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Be able to meet the 21 CFR Part 211, FDA, and International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). These regulations lay out the minimum current good manufacturing practices for preparation of drug products for administration to humans or animals.