

DICKSON

Environmental Monitoring + Compliance Experts

WHITEPAPER

WAREHOUSE MAPPING GUIDE

BY DICKSON

TABLE OF CONTENTS

INTRODUCTION	3
CREATE YOUR GAME PLAN	4
STEP 1	
DEVELOP A TEST PLAN.....	5
CRITICAL MAPPING POINTS.....	6
DETERMINE SAMPLE RATE	7
ESTABLISH LOGGER CRITERIA AND SELECT YOUR SYSTEM	8
STEP 2	
CALIBRATE (3PT CAL) AND PROGRAM DATA LOGGERS.....	9
STEP 3	
PLACE DATA LOGGERS AND DOCUMENT TEST PLAN.....	10
STEP 4	
RETRIEVE DATA LOGGERS DOCUMENT TEST PLAN.....	11
STEP 5	
DOWNLOAD AND ANALYZE DATA	12
STEP 6	
POST-CALIBRATION.....	15
STEP 7	
COMPLETE MAPPING REPORT	16
STEP 8	
REMEDATION	17
CONCLUSION	18
THE COMPLIANCE EXPERTS	19

INTRODUCTION:

Over the past few years, FDA regulation (including HACCP), various CFR codes of federal regulations, and the push to eliminate wasted time and money in fixing temperature related product failures, has made Temperature and Humidity Mapping an integral aspect of any warehouse operation.

Inadequately controlled environments can lead to ineffective medicines, spoiled produce, damaged materials and frequent critical equipment failures. Whether it's because of spoilage or downtime, efficiency goes down and the cost of operation goes up. One of the most difficult aspects of conducting a successful mapping, however, is the resources required to complete the job. It's why our services team exists to help you accomplish the task. However, many companies prefer to keep the work in house.

Whether you are concerned about maintaining a consistent environment in a 5,000 or 500,000 sq. ft. warehouse, a stability chamber, or a fridge, you'll want to make sure that you are using the right tools for the job and that you're using them correctly.

In this guide, we will discuss the best practices we use for mapping temperature and humidity in large spaces; however, these steps can be easily adapted for any mapping application.



PUBLISHED BY

Dickson
930 S. Westwood Ave.
Addison, IL 60101

P: 630.984.4597
F: 630.543.0498
mapping@dicksondata.com

Learn more about our Services Offerings at: DicksonData.com/Services

© Dickson 2018

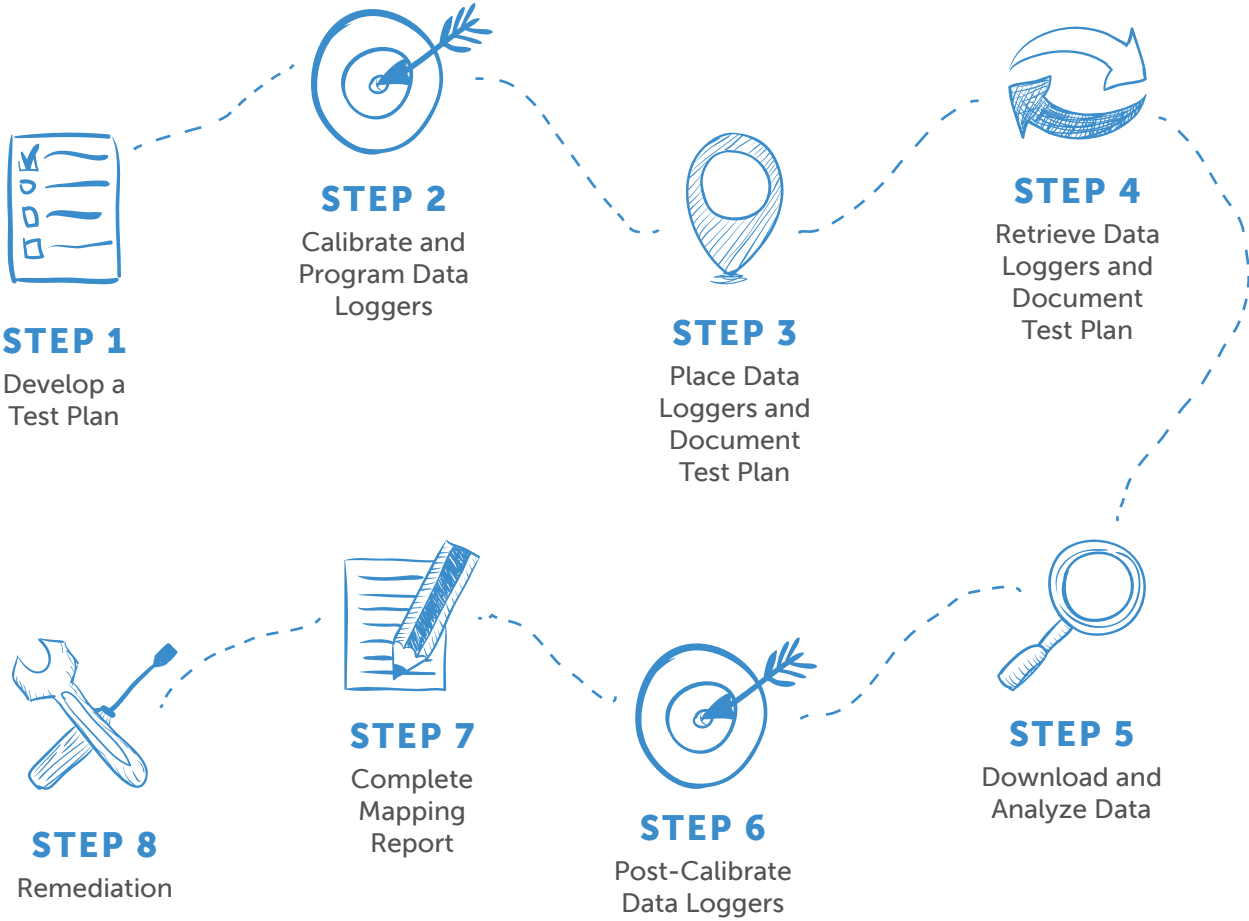
This material is subject to copyright protection, with all copyrights retained by Dickson. All rights reserved. The reproduction, transfer, or storage of information contained in this document in any form without the prior written consent of Dickson is strictly prohibited. Specifications and regulations quoted within this document are subject to change without notice.

LET'S GET STARTED

CREATE YOUR GAME PLAN

This may seem obvious, but the obvious is often most important to mention. Before you map, you need to have a developed plan in place.

That's because mapping is not a one-time job. It's actually an ongoing process that takes into account changes in seasons, HVAC/R modifications, warehouse layout modifications and any other significant changes to a warehouse's environment. Proper organization and, more importantly, documentation are critical in maintaining compliance and consistency. Here are the 8 steps you need to follow when finalizing your game plan.





STEP 1

DEVELOP A TEST PLAN *(24-40 HOURS)*

Strict documentation is critical to completing a successful mapping. Without it, an auditor won't care that you put in the time to complete a task. That's why developing a test plan is where every job should start and needs to include each of the following considerations:

- ✓ **Determine Critical Mapping Points**
- ✓ **Determine Sample Rate**
- ✓ **Establish Data Logger Criteria and Select Appropriate Units**

Putting this data on paper is much like writing your own instruction guide. What you put on paper should be exactly what you execute, and you'll have to notate at the end that you completed the mapping as it was previously defined. Otherwise, as previously stated, your work will have been for naught.





CRITICAL MAPPING POINTS

There are three things to consider when determining the placement of your critical mapping points:

1. PROBLEM LOCATIONS

Large open spaces present a considerable challenge when working to maintain consistent environmental conditions. Within any given structure, you will often find a number of problem spots that could dramatically impact the temperature or humidity of your warehouse. These points could include:

- ✓ **Areas near the ceiling or exterior walls**
These may stay warmer or cooler in response to temperatures outside
- ✓ **High Points**
Temperature levels stratify due to the fact that warmer air rises
- ✓ **Compressed racking, shelving and pallet storage areas**
These may create “hot spots” by obstructing air circulation

2. ADDITIONAL LOCATIONS

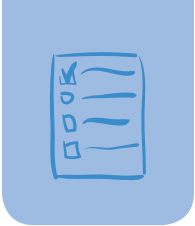
In addition to problem spots, logger placement is also critical for the following locations:

- ✓ **HVAC vents, furnaces, or even fans**
Any of these factors could cause surrounding conditions to shift comparative to the rest of the facility
- ✓ **Windows and doors**
Any point that is left open or is poorly insulated from the outside will affect temperature conditions
- ✓ **Outside your facility**
This gives you a baseline to compare internal temperature to that of the outdoors
- ✓ **High, medium and low locations in the general storage area**
Temperature isn't a 2D variable. It's a three dimensional one. Remember to place your loggers accordingly

3. SPACING

At Dickson, we follow the guidelines set out by the World Health Organization that suggests loggers be placed between five and ten meters apart. In order to manage expenses, our recommendations always suggest placing loggers between approximately seven to nine meters apart (every 25-30 feet).

According to guidance provided by ISPE, a room that's up to two meters cubed in size would see the use of nine loggers. Increase the room's size to roughly 20 meters cubed and you would use 15. The most important key when it comes to spacing and placement is that you must do so three dimensionally across the top, middle, and bottom plane of each room.



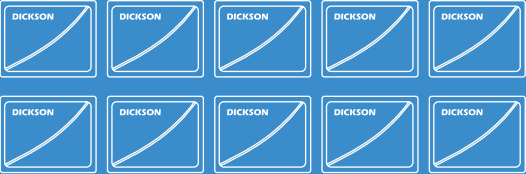
DETERMINE SAMPLE RATE

The key to determining sample rates is to not take too many or too few samples. Too many samples will create too much data making analysis cumbersome and difficult. Too few samples will not adequately represent changes in the warehouse environment. In most warehouses, one temperature or temperature and humidity sample every ten minutes should adequately evaluate temperature trends.


If you think you need to take readings more frequently, consider the following:

SCENARIO 1


10 DATA LOGGERS




SAMPLING EVERY 1 MINUTE



FOR 1 WEEK

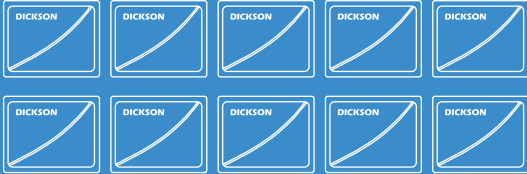


WILL PROVIDE
100,080
DATA POINTS




SCENARIO 2


10 DATA LOGGERS




SAMPLING EVERY 10 MINUTES



FOR 1 WEEK



WILL PROVIDE
10,080
DATA POINTS



Scenario 2 will provide the same general results as Scenario 1 with 1/10th of the data and much less time spent analyzing what has been logged. Extra data leads to inefficiency and inflated project costs.



ESTABLISH DATA LOGGER CRITERIA AND SELECT YOUR SYSTEM

Temperature and Temperature/Humidity Data Loggers come with many features. The goal is to select the data logger that will most effectively monitor your warehouse. Key features you should consider are:



DATA CAPACITY: Data Capacity determines how many readings or sample points can be taken by a logger before its memory is full. The more sample points a logger has, the more readings it can store.



SAMPLE RATE: The frequency in which samples are taken. The logger should feature user selectable sample rates.



MONITORING RANGE AND ACCURACY: Be sure to select a data logger with a temperature range that can monitor temperatures even in the most extreme of cases. According to WHO Technical Report series 961 2011, you need to utilize data loggers that provide accuracies of +/- 0.5°C.



SIZE: Some mappings require more robust features. Before choosing your logger, make sure it will fit in your selected locations. Logger dimensions can vary from the size of a notepad to that of a quarter.



NETWORKING: Some loggers require live internet connection to function properly. If your chosen solution is a cloud-based system, like DicksonOne, make sure that you have ethernet or WiFi connectivity in your warehouse. If neither are available, a standard data logger that allows you to download data to a computer may be right for you.



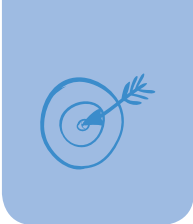
POWER REQUIREMENTS: For larger spaces, access to power may not be realistic. In these cases, ensure you find a logger with a battery life long enough to last between mapping sessions. Many data loggers feature battery life between one and five years, making them more than capable to last through several mapping sequences.



CALIBRATIONS: Be sure to purchase your data logger from a manufacturer who is A2LA accredited, NIST traceable, ISO 17025 compliant. These calibrations ensure that your mapping study will hold up to an auditor. When we handle mappings for our customers we not only calibrate the devices, but we do a post calibration check in order to have documented proof that the devices were accurate from start to finish. It's one less step in the chain that could cause an auditor concern.



SOFTWARE: A lot of time will be spent within the software used to download data from your loggers, so ensure it's software that you are comfortable with using regularly, and, if in a regulated environment, ensure it is 21 CFR Part 11 compliant.



STEP 2

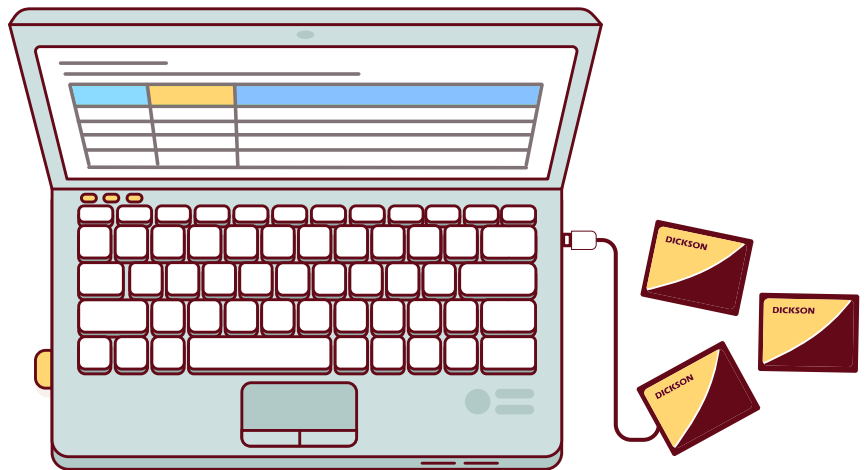
CALIBRATE (3PT CAL) AND PROGRAM DATA LOGGERS (24-40 HOURS)

Mapping loggers require programming prior to use, and that programming must also include the step of calibration. As noted previously, World Health Organization recommends the use of a three point calibration with a guaranteed error rate of no more than 0.5°C.

When it comes to the programming of data loggers, you're able to name each logger individually. Best practices suggest naming each logger individually by its location, and also noting the name on the outside of the device. This should help eliminate confusion that may exist when both setting up and pulling down loggers at the end of the mapping job.

Using the data logger software, name each logger by its location.

- ✓ Label the outside of each logger by its location
- ✓ Label the exact spot where the data logger should be placed by the data logger's location name
- ✓ Create a physical map with all data loggers marked by name



These steps don't just help you in future mappings. They can save you time and headaches when it comes to digesting your data in a three dimensional space.



You can read more about calibration, and Dickson's calibration lab, at DicksonData.com/Calibration.

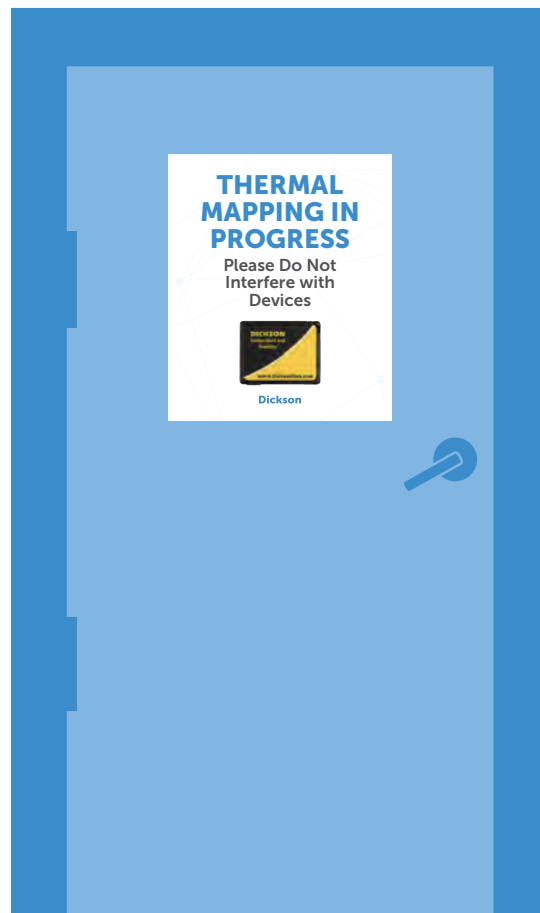


STEP 3

PLACE DATA LOGGERS AND DOCUMENT TEST PLAN (8-10 HOURS)

Once your loggers are programmed and labeled, it's time to place them in your warehouse as outlined in your test plan. You want to be as specific as you can when documenting the location of each placed unit, as this helps defend your work to an auditor.

We also recommend placing signs throughout your facility so employees understand what the units are being used for and why they shouldn't be disturbed. Any changes that occur during the mapping need to be monitored and noted to address any questions that may arise during an audit.





STEP 4

RETRIEVE DATA LOGGERS AND DOCUMENT TEST PLAN (8-10 HOURS)



While the length of studies can vary depending on the job, each warehouse mapping we conduct is done over a seven-day period. Ensure you get all loggers and that you have previously noted where each logger was placed. As with the setup of the units, you must document the time each logger was picked up, per room. When Dickson does a mapping for a customer, it handles all the documentation and the entire process from start to finish.





STEP 5

DOWNLOAD AND ANALYZE DATA (8-10 HOURS)

Now that you've collected the loggers and documented the process in your test plan, you need to download the data so you can view and analyze it.

You should be able to showcase data in each of the following ways at the completion of your mapping:

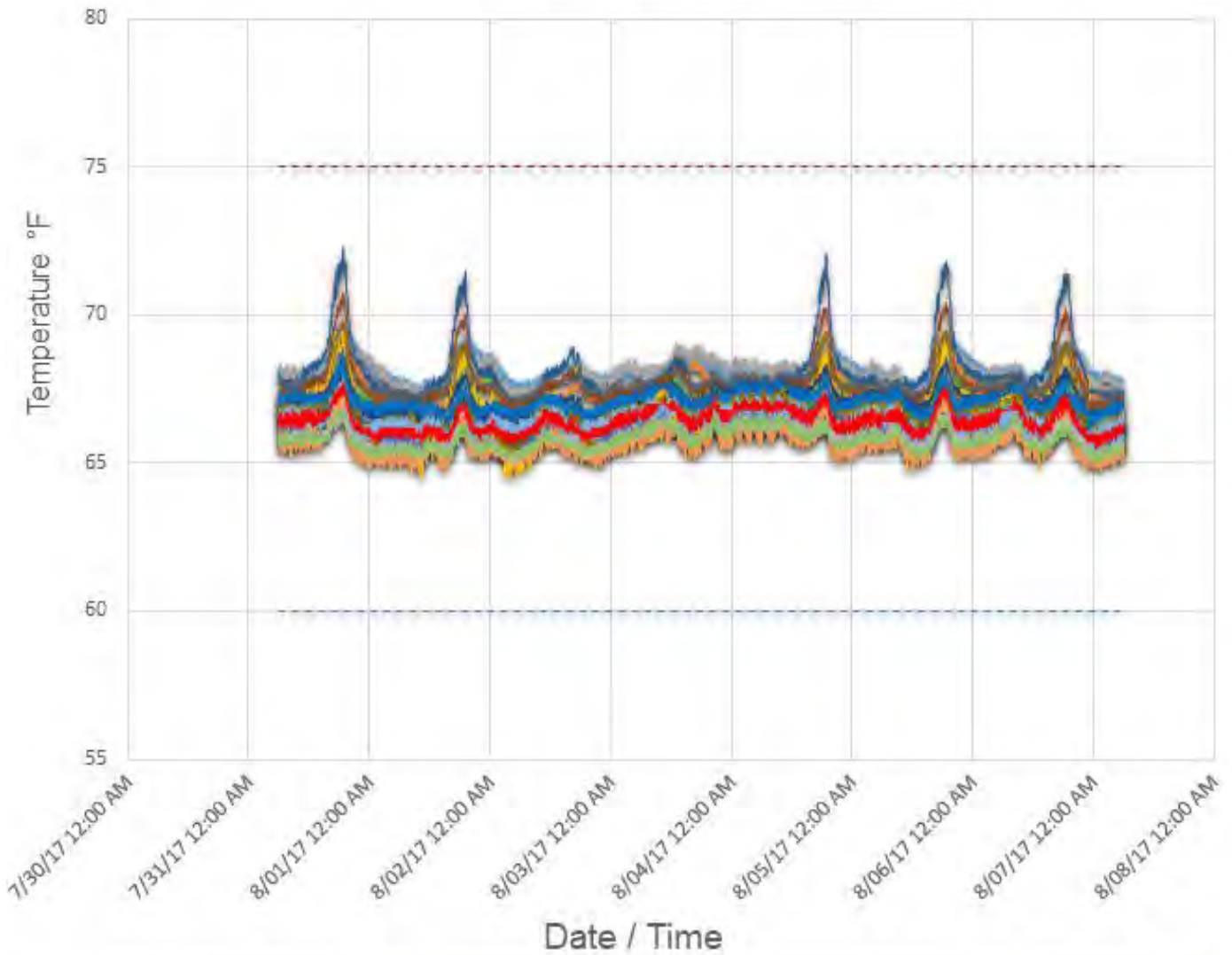
Overall Summary		
Table 4: Warehouse (RW1)		
Start: 7/31/17 6:00 AM End: 8/6/17 6:00 AM		
Control Room Setpoint: 69°F		
	Location (s)	Temp °F
Max Avg. Temp	A034	73.0
Min Avg. Temp	C034	70.0
Max MKT	A034	73.1
Min MKT	C034	70.0
Locations out of range	N/A	

Location of Logging Device	Sensor locations
Locate near EDLM #18 (North wall)	High sensor (approx. 20 ft) and sensor located at eye level height (5-7 ft from floor).
Locate near EDLM #21 (North wall)	High sensor (approx. 20 ft) and sensor located at eye level height (5-7 ft from floor).
Locate between EDLM #33 and #34 (East Center)	High sensor (approx. 20 ft) and sensor located at eye level height (5-7 ft from floor).
Locate near EDLM #40 (West Center)	High sensor (approx. 20 ft) and sensor located at eye level height (5-7 ft from floor).
Locate near EDLM #45 (South wall)	High sensor (approx. 20 ft) and sensor located at eye level height (5-7 ft from floor).
Locate near EDLM #47 (South Wall)	High sensor (approx. 20 ft) and sensor located at eye level height (5-7 ft from floor).

Packaging Area (PKG1)

Summer Temperature Distribution

7/31/2017 – 8/07/17



— A001	— B001	— C001	— A002
— B002	— C002	— A003	— B003
— C003	— A004	— B004	— C004
— A005	— B005	— C005	— A006
— B006	— C006	— Low Temp Limit 60 F	— High Temp Limit 75 F

Overall Summary Packaging Area (PKG1) Start: 7/31/17 6:00 AM End: 8/07/17 6:00 AM					
	Location (s)	Temp °F		Location (s)	% RH
Max Avg. Temp	A001, C001, A003	68.1	Max Avg. Humidity	B005	60.9
Min Avg. Temp	B005	65.7	Min Avg. Humidity	C001	54.8
Max MKT	A001	68.2			
Min MKT	B005	65.7			
Locations out of range	N/A				

EDLM Packaging Area Summary Data – Summer Data Start: 7/31/17 6:00 AM End: 8/07/17 6:00 AM								
Location	Serial Number	Temp Min °F	Temp Max °F	Temp Avg °F	MKT °F	%Rh Min	%Rh Max	%Rh Avg
A001	15054064	67.4	69.9	68.1	68.2	49.7	64.7	56.1
B001	15051108	66.7	69.1	67.5	67.5	50.5	65.2	56.4
C001	16227182	67.1	69.5	68.1	68.1	49.4	65.8	54.8
A002	15051180	64.4	69.5	66.6	66.6	51.5	66.7	59.4
B002	15055026	65.0	68.9	66.5	66.5	51.3	64.5	58.5
C002	15055022	65.8	68.6	66.9	66.9	51.7	66.2	57.6
A003	16227176	66.9	72.3	68.1	68.1	45.7	63.3	54.9
B003	15014190	66.8	70.7	67.7	67.7	48.1	65.1	55.9
C003	15036246	67.0	69.7	67.8	67.8	49.7	65.2	55.3
A004	15054065	65.1	69.8	66.9	66.9	49.9	66.2	58.3
B004	16227802	65.8	68.5	67.2	67.2	51.6	65.4	57.7
C004	15051175	65.5	67.5	66.5	66.5	53.5	66.0	59.0
A005	15055003	65.3	68.1	66.4	66.4	53.4	69.2	59.9
B005	15051132	64.7	67.6	65.7	65.7	54.8	67.1	60.9
C005	15054091	65.0	66.9	65.8	65.8	54.1	67.2	59.7
A006	16227785	66.1	68.5	67.1	67.1	51.0	65.5	57.4
B006	15054098	65.5	67.7	66.4	66.4	53.8	66.1	59.7
C006	15030122	65.0	66.9	65.8	65.8	54.2	66.8	59.7

As you look at the data once you've made it easy to visualize, you're looking for discrepancies in the environment. Do you notice any hot or cold fluctuations throughout the week? Are there locations that remain above or below the necessary temperature for storage? These are all issues that you need to be able to recognize and speak to in your final report.



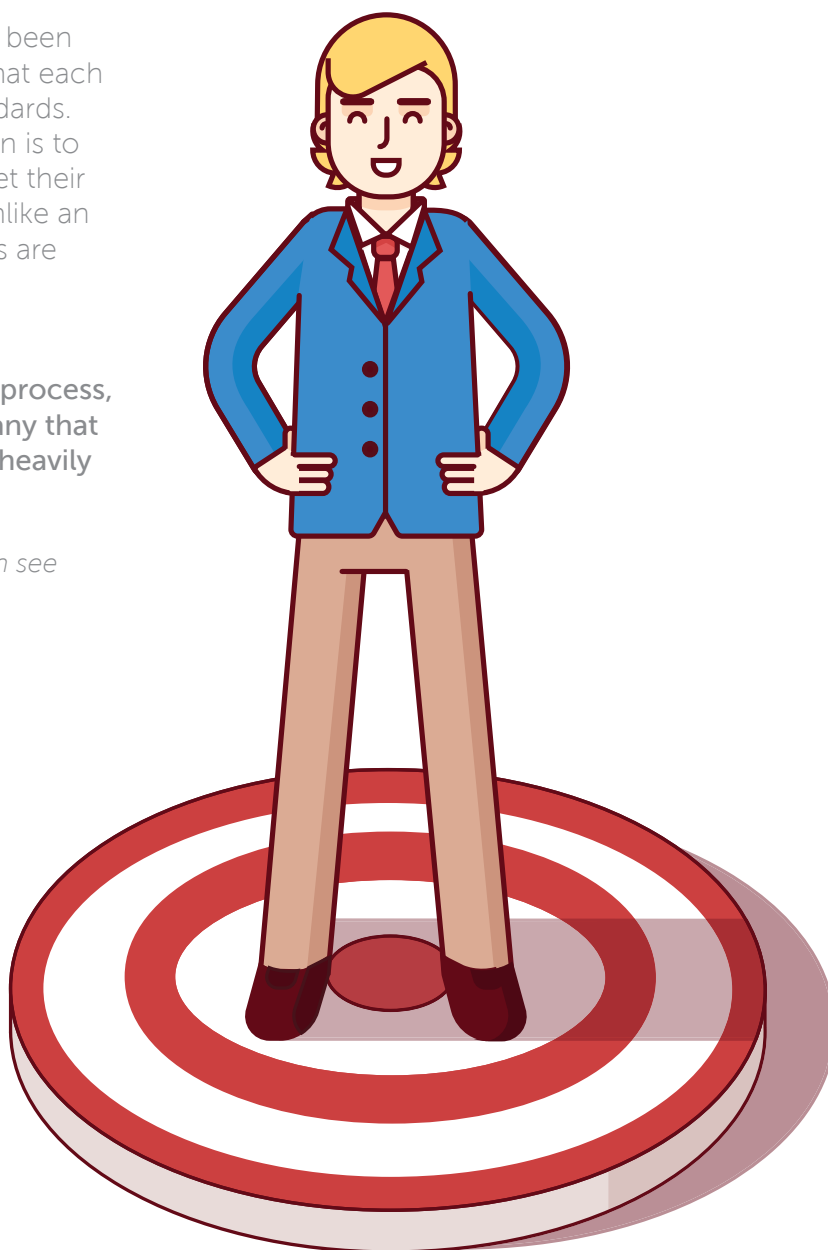
STEP 6

POST-CALIBRATION (24-40 HOURS)

Now that all of the loggers have been collected, you need to ensure that each unit meets prior calibration standards. The process for a post calibration is to determine if the loggers still meet their original calibration standards. Unlike an initial calibration, no adjustments are made.

Because of the involvement of calibration within the mapping process, choosing a device and a company that manages calibration easily can heavily simplify the mapping process.

For more information on calibration see DicksonData.com/Calibration





STEP 7

COMPLETE MAPPING REPORT (24-32 HOURS)

Once you've collected all the data, it's time to start the real work. Completing the mapping report is an arduous process, and requires detailed analysis and the ability to well translate everything you've done and everything you've collected to paper.

In the most basic of terms, the mapping report is a summary of all your data, including the test plan you've already developed, as well as tables and graphs of analytical data you've collected for each room. Include all calibration certificates for each logger, pre and post.





STEP 8

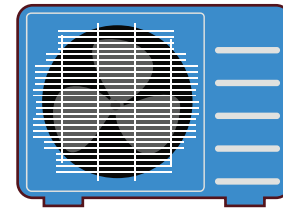
REMEDIATION (40-60 HOURS)

Now that you have your results, it is time to fix any trouble spots that show up in your calculations and plan to shift inventory storage to accommodate for peak environmental conditions.

COMMON FIXES:

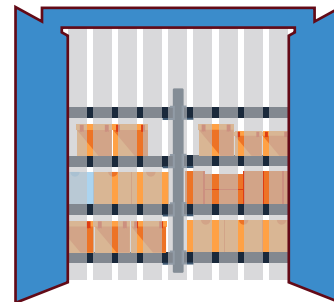
HOT SPOTS:

Hot spots are frequently caused by walls or shelving that block airflow and/or inadequately sized fans that are unable to circulate air. Increasing the size or number of fans and removing unnecessary walls or rearranging shelves to promote airflow is helpful.



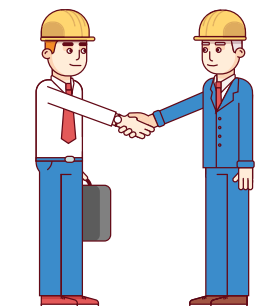
WIDE TEMPERATURE FLUCTUATIONS:

Frequent changes in temperature in one location can be caused by direct exposure to outside air sources. Doors that are habitually left open, sky-lights, open dock doors, and hallways to non-air conditioned locations can make maintaining consistent temperatures difficult. Plastic curtains over open hallways or dock entrances can help block much of the hot or cold air from entering the warehouse space.



INABILITY TO MAINTAIN TARGET WAREHOUSE TEMPERATURE:

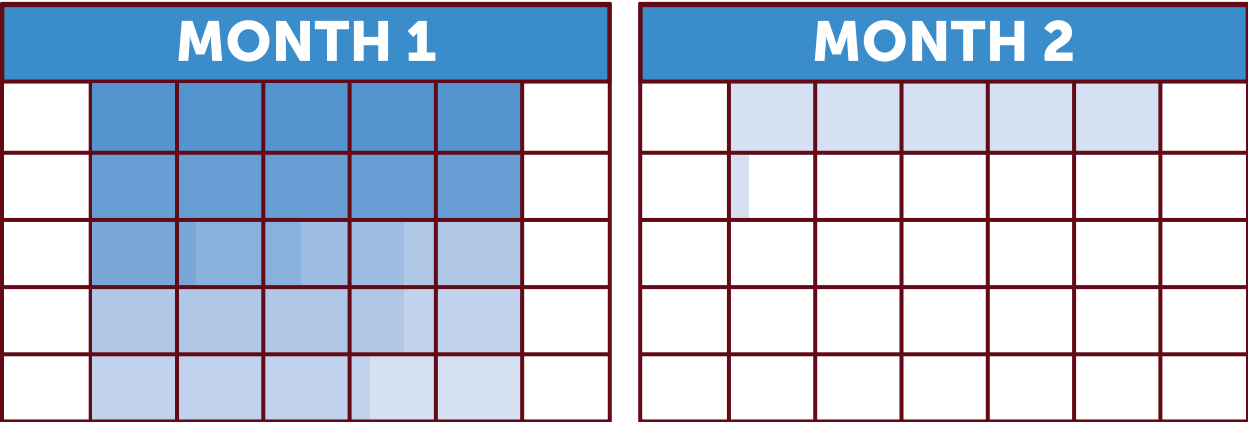
If the overall warehouse temperature can not be maintained, an expert evaluation of the HVAC system is in order.



CONCLUSION

Temperature mapping can be an extremely powerful tool to aid in regulatory compliance and create possible cost savings via implemented improvements and efficiencies. The keys are to carefully analyze the warehouse space to ensure the proper placement of data loggers, document all logger locations and the processes used to conduct the mapping, audit the data collected, and finally making the necessary changes to continuously improve warehouse conditions.

FINAL TIME ESTIMATES FROM START TO FINISH:



- STEP 1** Develop a Test Plan
24-40 HOURS
- STEP 5** Download and Analyze Data
8-10 HOURS
- STEP 2** Calibrate and Program Data Loggers
24-40 HOURS
- STEP 6** Post-Calibrate Data Loggers
24-40 HOURS
- STEP 3** Place Data Loggers and Document Test Plan
8-10 HOURS
- STEP 7** Complete Mapping Report
24-32 HOURS
- STEP 4** Retrieve Data Loggers and Document Test Plan
8-10 HOURS
- STEP 8** Remediation
40-60 HOURS

AVERAGE TOTAL MAN-HOUR INVESTMENT
136-242 HOURS

THE COMPLIANCE EXPERTS

Since 1923, Dickson has strived to incorporate the best and newest technologies into our products to bring you monitoring solutions of the highest caliber. We maintain the world's widest selection of top quality instruments customized to fit your monitoring needs. From chart recorders to DicksonOne, we are constantly creating, which has led us to be an industry leader in environmental monitoring.

Simply put, Dickson is the best way to monitor your environment. We help organizations in the Pharmaceutical, Medical Device, Healthcare, Food, Aerospace and other industries record environmental conditions for the purpose of asset protection and compliance with government regulations and guidelines. Dickson's monitoring systems automatically collect data, send excursion alerts, and email reports for millions of dollars worth of assets around the world, resulting in a reduction in lost assets, increased consumer safety, and, ultimately, peace of mind.



ABOUT THE AUTHOR: ANTOINE NGUYEN

Dickson's Director of Services knows his p's and q's. He should, because he's been at it for a while. Before coming to Dickson, Antoine Nguyen spent more than 18 years in validation and compliance with companies that answer to regulatory auditors. Don't believe us? Then believe the words of his peers.

"Antoine is a valuable asset to any validation team. He effectively combines his validation, QA, and IT talent to deliver superior validation packages that stand up to FDA inspection." -Craig W. via LinkedIn

"Antoine is an exceptional individual. His hard work, strong technical skills, critical thinking and ability to problem solve were instrumental in validating and rendering key equipment. (His) positive upbeat attitude and proactive focus make working with him a pleasure. His attention to detail and diligence assures that his work is of the highest quality." -Susan J. via LinkedIn

With Antoine and his team at the helm you can feel confident that your job is well cared for, because he understands our company's core truth. When it comes to compliance and validation, every point matters.



DICKSON

Environmental Monitoring + Compliance Experts

930 S. Westwood Avenue
Addison, IL 60101