Application note: N°F070

April 2016

Warehouse Mapping

Facts & Figures

At 4.3 million square feet, the largest warehouse in the world is the Boeing Everett factory in Everett, WA USA. It was originally designed to construct the Boeing 747.

Novartis, the largest pharmaceutical company in the world, reports annual revenue of $47 billion dollars.

An **FDA** Form **483** is issued to a company's management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts.

Discussed in this edition:

Mapping in General

Mapping is the process of determining the temperature and humidity gradients within a controlled space. It is a critical process when the product is regulated by government agencies such as the US Food & Drug Administration (FDA) or the European Medicines Agency (EMA). Regulated drugs must meet strict storage conditions including environmental conditions such as humidity and temperature levels. Mapping serves as a baseline for proving compliance within the warehouse storage space.

In addition to regulatory compliance, mapping serves to help ensure products do not spoil or otherwise degrade during storage. Warehouses are notorious for having warm or cold spots that are outside of the regular control specification. A proper mapping study serves to locate these spots and either modify or avoid the problem area.

Why the Need for a Temperature and Humidity Mapping Strategy?

A mapping strategy is needed for several reasons. It is important for regulators or approvers to understand the philosophy employed for the mapping. A documented strategy will decrease questions from any regulators reviewing your mapping study. The strategy document also helps them understand the data that is produced by the mapping process. The document acts as a tool for collaboration as other people may suggest ideas that will make your study produce better data or make your effort more efficient.

As the mapping study progresses from start to finish, the strategy document acts as your reference guide, ensuring you remain true to the agreed upon process and do not make changes that will negatively affect the study. A typical strategy is usually comprised of a few written paragraphs that includes a description of the warehouse space, the type of equipment used, the number of sensors to be used, a general idea of the sensor placement, and the duration of the study.

It is not unusual for the mapping strategy to change as it evolves. Writing a detailed document at the early stages of the project may cause re-writes that can increase the total length of the project. It is usually more efficient to fully document the warehouse mapping project after the strategy is agreed. Think of the strategy document as a proposal for your mapping team or the approval team so they can buy into and understand your mapping strategy. It may also facilitate the final approval stage, later in the project, because the approver already understands the warehouse mapping project.

Continuous Monitoring After the Warehouse Mapping

Continuous monitoring is a best practice within controlled and regulated warehouses. The mapping study will determine the hot and cold zones for "worst case" sensor placement. These worst case locations should be considered when installing a permanent, continuous monitoring system. The number of sensors used for a permanent system will be far fewer than what is required for the mapping study. In some cases, continuous monitoring may require only a few sensors once the problem areas have been determined through the mapping study. A continuous monitoring system offers peace of mind as product components, manufacturing space, or storage space are maintained and on record as meeting specified environmental conditions.

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What solution can Rotronic offer?

Mapping requires portable data loggers that measure and collect data. Regulated environments may require data collection and storage to be secure and in compliance with the FDA 21 CFR Part 11 or EMA Annex 11.

HL-20 Humidity & Temperature Logger

Rotronic products for mapping temperature and humidity:

HygroLog HL-1D

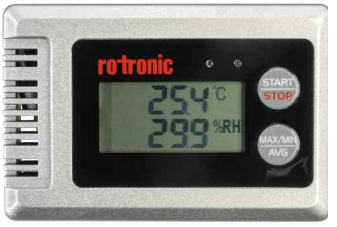
The HL1D is a compact, low cost data logger capable of ±3.0 %RH and ±0.3°C accuracy. The internal memory can store up to 16,000 data points and includes the HW4-Lite software.

- Measurement accuracy +/- 3.0% RH and +/- 0.3C
- Large storage up to 16,000 data points
- FDA 21 CFR Part 11/GAMP 4 compliant

HygroLog HL-20

This compact data logger for humidity and temperature measurement offers high precision and reliability. The HL20 series is easy to use and deployable in a wide range of applications. Thanks to its integrated batteries, the HL20 works completely independently and offers its users maximum flexibility.

- Highest accuracy at 0.8 %RH and 0.2C
- Outstanding long term stability
- 20,000 data point memory with date & time stamps
- FDA 21 CFR Part 11 / GAMP 4 compliant



HL-1D Humidity & Temperature Logger

Rotronic products for continuous monitoring:

HygroFlex5 HF5

The HF5 humidity transmitter is designed for fixed installation in HVAC, industrial and continuous monitoring in warehouse storage applications. It provides two analog output signals or a digital output signal corresponding to relative humidity, temperature, dew point or another psychrometric parameters.

- Relative humidity and temperature measurement
- Dew Point and other psychrometric calculations
- Interchangeable probe for easy maintenance
- Wide choice of probes to satisfy every application
- Low voltage and AC power versions
- Scalable analog signals
- Various digital outputs available

HF5 Humidity & Temperature Transmitter

Customer benefits:

Accuracy:

Choosing Rotronic products gives you the best accuracy on the market. Precise humidity or dew point measurement enables the ideal storage conditions and therefore ensures a top quality final product.

Communication:

Networking with Rotronic is an easy affair! With the wide range of communication interfaces available, from conventional analogue output signals to USB, RS-485, wireless and Ethernet RJ-45, Rotronic can provide the required interface to your control unit, or any third party monitoring system.

Long term stability:

With long term sensor stability of under 1 %rh per year (depending on the environment), Rotronic offers the possibility to "plug & play": install the device and leave it. We would recommend regular spot checks between multi-point calibrations.

Calibration:

Rotronic offers a factory calibration certificate, and ISO 17025 certificate if required. The portable HygroGen temperature & humidity calibrator as well as unsaturated humidity salts are also available for on-site calibration.