Application note: N°F080

April, 2017

Avoiding common Mistakes in Mapping Projects

Did you know?

Depending upon the routine monitoring strategy, subsequent mapping exercises may also be required periodically—for example, every three years—in order to demonstrate continuing compliance. In situations where multiple fixed monitors provide continuous data, a periodic re-evaluation which assesses all aspects of system performance since the initial mapping may be more appropriate. In addition mapping should be carried out whenever significant modifications are made to the store. Examples include changes in the pattern of use that may increase loading or affect air circulation, or changes to the refrigeration equipment, such as alteration to the set point. Finally re-mapping may be justified whenever an analysis of temperature and/or humidity monitoring records shows unexplained variability outside normal operating limits.[1]

[1]Excerpted from WHO Technical Report Series, No 992, Annex 5, Supplement 8

Discussed in this edition:

Humidity and temperature mapping

Listed are some of the most common mistakes made while conducting a mapping project. Many sources discuss the mapping process and are not focused on what not to do. Let's discuss what to avoid, or what not to do, during the mapping process.

The Mistake of Random Logger Placement

If forced to pick the one biggest mistake, it would be omitting the creation of a methodical layout, or pattern, for the mapping. Random placement, or placement without any thought to other variables in the environment (i.e. an air duct, or fan), can cause a significant amount of rework. Regarding the sensor pattern, not thinking three dimensionally, or not placing sensors where product will be present are both problematic. For example, placing a sensor or logger at the midpoint of a space based on the assumption the measurement will be some type of "average" reading between the points is not correct placement. This type of assumption is contradictory to the fundamental reason for a mapping which is to actually *know* what those temperatures are at those specific points.

The Mistake of Not Using Enough Sensors or Loggers

For some large mapping projects that require local data logging, the costs of equipment can rise quickly. It is always prudent to remember that, although the mapping equipment and process may be costly, it is usually minimal compared to the cost of product failure, or a product recall caused by inadequate mapping or monitoring.

The Mistake of Poor or Inadequate Planning

Do not set impossible or unnecessarily difficult pass/fail criteria. The criteria should be chosen based on the product limit and not the storage environment itself.
Set reasonable limits based upon the logging system capabilities and the product quality limits when formulating any mapping plan. Unreasonable expectations lead to a lot of wasted time and effort trying to meet improper mapping pass/fail limits. Make sure the equipment or system can meet your protocol criteria.

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"Why is calibration a critical success factor for a mapping study?"

One of the biggest decisions to be made for a mapping study is deciding about a pre-mapping calibration or a check of an instrument's current calibration and a post mapping calibration check. A decision about making, or not making, a pre or post calibration check can be the difference between a successful study or a time consuming failure.

"I don't have the equipment to perform a pre-or post-study calibration because this would require a well-equipped calibration lab. Can I just skip the calibration checks altogether? "

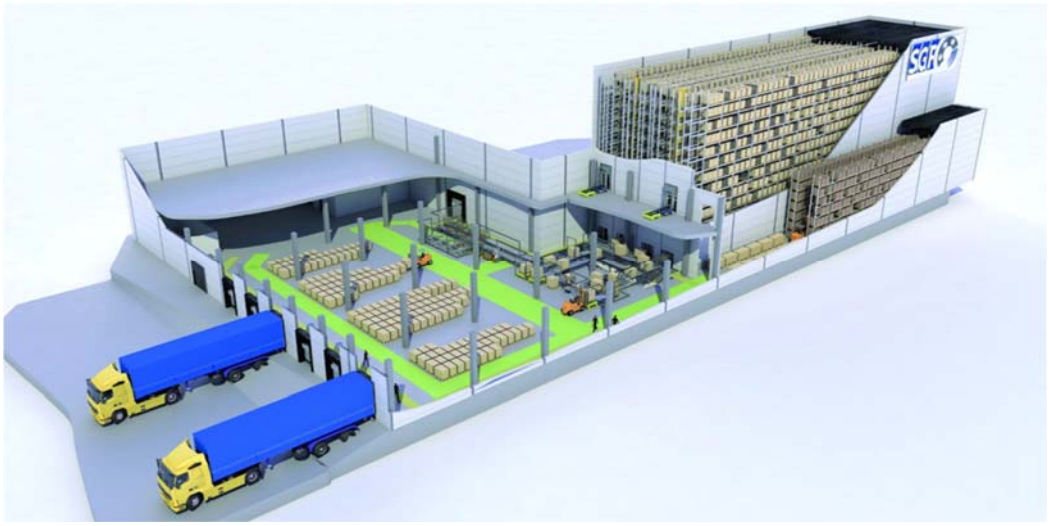
As stated above, you can but you may have some additional explanations required for an approver. You could also consider renting or purchasing calibration equipment. In some cases, simply checking your instruments against a traceable device in a controlled environment will be sufficient to an approver. For a temperature mapping that may mean purchasing a traceable device that is relatively inexpensive. It does not require a 'well equipped lab'. When purchasing a traceable device, remember to ensure the traceable device has at least the same, if not more accurate specifications than your instruments used for the study. Other measurement instruments such as humidity loggers can be difficult to calibrate or check. In these cases, it is quite common for there to be no calibration or checks performed. However, the calibration records for these instruments will most likely be reviewed more heavily.

The Mistakes Made in Data Collection and Reporting

Once all of the data is collected a report should be generated. It is not enough to just collect the data and reference it in the report. This practice will almost certainly invite additional data review. The data should also be checked to ensure that the data collected matches what was originally stated in your documents.
If the reporting system can flag out of limit data, or graph data, consider including those in your data report.

The Mistake of inferior Calibration Equipment

Think about the calibration. Use calibration equipment for the sensors that are more precise than those used during the mapping. A calibration check against an inferior piece of equipment (less precise) does not allow for properly calibrated or checked sensors used in the mapping project. If calibration is not proper, any person reviewing the mapping data might call into question the entire mapping execution, especially if some of your data is close to a pass/fail limit.



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What solution can Rotronic offer?

Mapping:

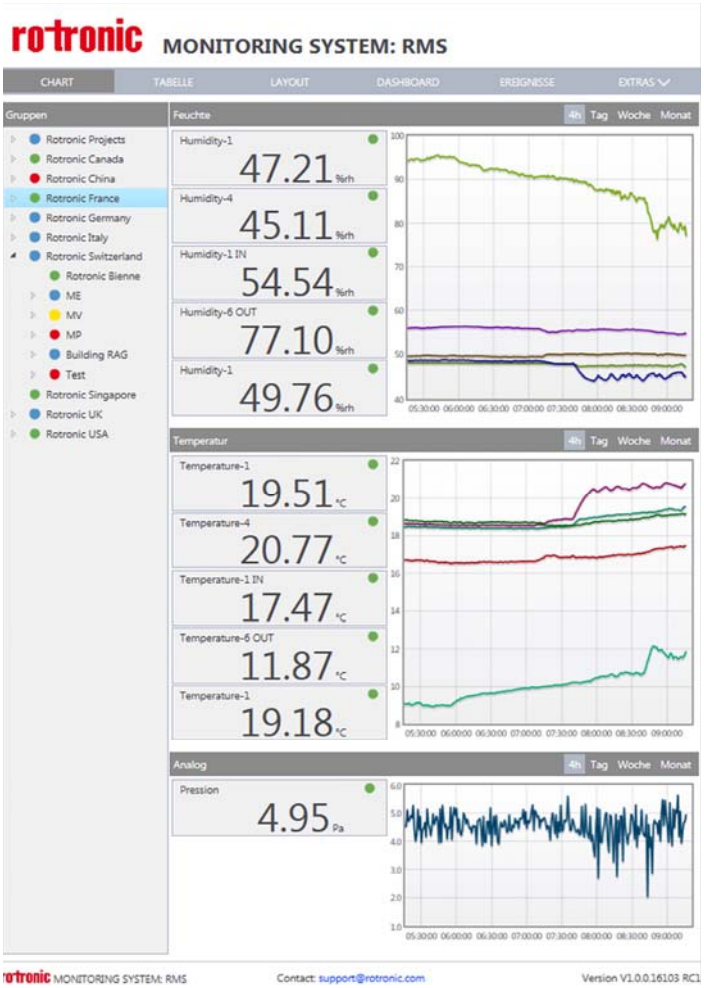
HygroLog HL-1D

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. Together with the HW4-P the logger is FDA 21 CFR Part 11/GAMP 4 compliant.

HL-1D Humidity & Temperature Logger

Environmental Monitoring System:

Rotronic offers an FDA compliant monitoring system. The Rotronic Monitoring System (RMS) allows for a global monitoring of the environment conditions. The RMS will allow for real time monitoring and will set off alarms should any of the measurement reach a critical status.



Main Features

- GMP/GLP/GDP compliance
- FDA 21 CFR Part 11
- EN 12830
- PDF report with chart and statistics
- Alarm notification by voice call, SMS or email
- Server or cloud based software
- Suitable for smartphones and tablets

Validation

When requested, the system checks the data integrity automatically by self-test, it switches all input modules into their various states and check the alarms that are meant to be triggered and generates a validation report on the complete system.

Data logger
RMS-LOG

Temperature data logger
RMS-LOG-T

Temperature mini data logger
RMS-MLOG

Analog input module
RMS-ADC

Digital input module
RMS-DI

Digital input mini module
RMS-MDI

Analog output module
RMS-DAC

Relay module
RMS-DO

Display module
RMS-D

Find out about RMS in: www.rotronic.com/rms