

ROTRONIC APPLICATION NOTE

Application note: N° F005

August 2011

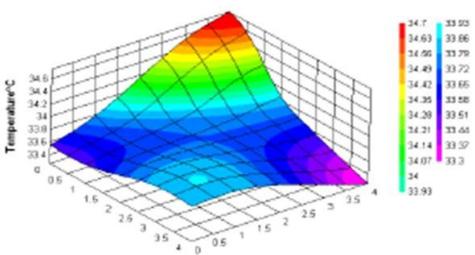
Mapping

Facts & figures:

Mapping is used for various industries in pharmaceutical, health and life sciences, food & agriculture, HVAC, research, logistic & warehousing.

The most common standards are FDA and USP for the US market

Retain Sample Room—Controlled
Max. Temperature Distribution Top Level
Dated: 15/03/2004 to 18/03/2004



The graphic above shows a temperature room gradient.

Mapping in General

Temperature and humidity levels that are out of Specifications can cause damage on production material and even on final the product. You can imagine that this is very important for pharmaceutical companies. The public regulatory organizations (see table on the right) require food and drug products

to be stored and/or produced under appropriate conditions. Temperature and humidity being a very important factor in order for the material to retain its identity, strength, quality and purity.

The best way to check a room for °C & %rh variation is to carry out a mapping. A mapping consists of placing data-logger in various strategic places in a room and accurately monitoring the different parameters. Depending on the room topology hot and cold

spots occur. Mapping gives a detailed picture of the overall room homogeneity over a certain period of time temperature and/or humidity. Based the on mapping data the final monitoring systems can be installed.



Public Regulatory

Food and Drug Administration (FDA)
United States Pharmacopeia (USP)
World Health Organization (WHO)
Int. Conf. on Harmonization (ICH)

Guide lines:

Good Distribution Practice (GDP)
Good Manufacturing Practice (GMP)

Source: www.wikipedia.com

How to perform mapping

Depending on the size of the room and the internal and external influences the strategic mapping mapping points are chosen.

Small rooms: For cambers or rooms with dimensions of (LWH) 5 x 2 x 5m or smaller a minimal amount of 9 point is requested. Where each corner and one point in center point are mapped.

Large room: For rack warehouses the sensors need to be placed according to a diagram or grid. On horizontal level each shelf row should have a mapping point. In depth all

10..15m a sensor should be placed.

To determine the point on the vertical level, the lowest and the top shelf position is giving the range in height. For a shelf higher than 10m, more levels with a vertical spacing of 4..6m is recommend.

In addition to the structured mapping points the internal and external influences as windows, loading docks, doors or ventilation outlets need to be recorded.

Be sure to also place a data logger outside to monitor exterior climate. The seasonal cli-

mate does have a direct effect on the HVAC systems and therefore to the internal temperature and humidity. Because of that, mapping should be performed during the different seasons.

Commonly a logging interval of 10min has proven to give enough resolution to analyze the data.

Before mounting your loggers make sure the devices are acclimatized for at least 2h.

A mapping session should be executed for a minimum of 2 weeks and under normal operating conditions.

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Data interpretation:

After performing a mapping the data from the logger need to be downloaded, analyzed and documented.

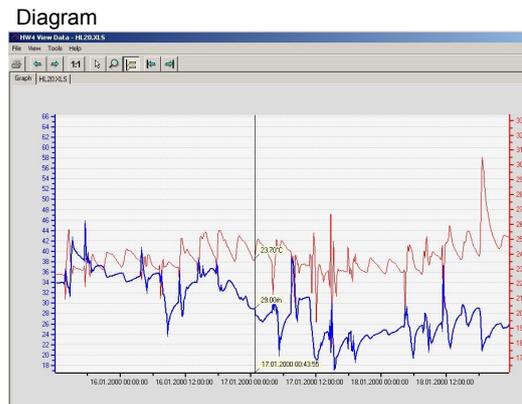


• Data analysing :

The Rotronic HW4 software offers various features for displaying, analysing and reporting the collected data.

HW4 diagram of the mapped points

The diagram is the optimal tool to analyse the measured data. It displays the values from the beginning till the end of the recorded time. The diagram allows to overlaying as many probes in one single diagram and if needed psychrometric values can be added. A zoom function is also available, so that selections can enlarged be analysed.

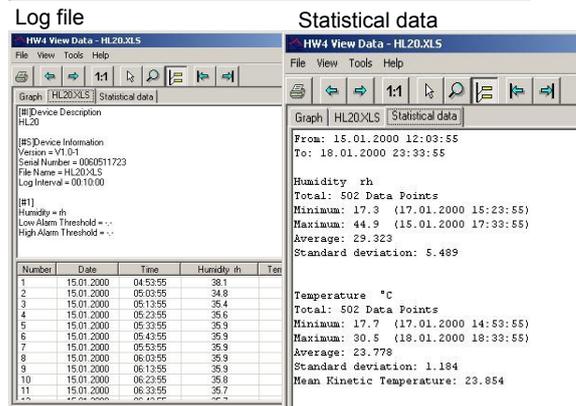


Log files

The rotrotronic data logger offer the possibility to save data either as protected logfile type (*.log) or as open file type for excel (*.xls).

Statistical functions

This function calculates in one click, statistical figures: Total mapping points, minimum, maximum average, standard deviation and Mean Kinetic Temperature (MKT).

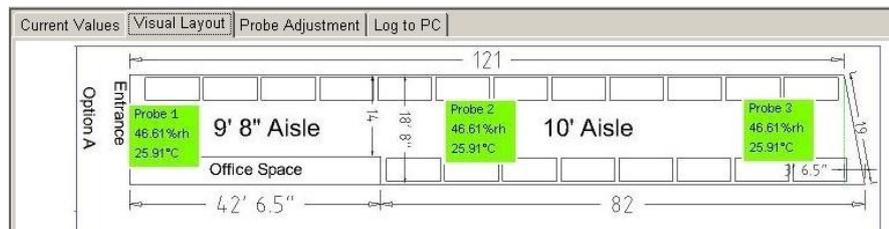


$$-\ln \left(\frac{e^{-\Delta H/RT_1} + e^{-\Delta H/RT_2} + \dots + e^{-\Delta H/RT_n}}{n} \right)$$

The MKT is a calculated fixed temperature that simulates the effects of temperature variations over a period of time. It expresses the cumulative thermal stress experienced by a product at varying temperatures during storage and distribution.

• Mapping diagram :

The Rotronic HW4 software offers the possibility of a visual layout showing you exactly where the probes are placed in the room.



• Final report:

A final report contains all the above mentioned data (data analyzing & mapping diagram) including valid a sensor certificate.

• Recommendations:

Final report must contain recommendations if any undesirable °C & %rh patterns are seen. Such as: - Removing products from problem area (such as hot spots) - changing work practice (such as keeping door open or closed) - changing the location of heat devices—improving ventilation - adding air conditioning - adding humidifying / dehumidifying units. Such changes can be considered to improve homogeneity of the room climate.

• Conclusion:

Mapping can be an extremely powerful tool to fulfill the regulatory compliance and saves costs via implemented efficiency improvements done through the recommendations. The key is to carefully analyse the room space to ensure proper placement of data loggers. Make sure to document the logger locations and the audit data is based on calibrated data loggers. Finally making the necessary changes to continuously improve warehouse conditions.

What solution can Rotronic offer?

Rotronic dataloggers offers several key features: making your mapping a successful one.

Rotronic offers for all products a calibration certificate which is referenced to the indicated references and working standards.

All rotronic dataloggers have variable logging intervals, extraordinary long-term stability and a large data memory capacity.

Rotronic also offers a wide range of networking possibilities as RS485, USB, LAN & WLAN. Probe extension ca-

bles up to 100m are also available and allow to measure remote places of the room.

The validated HW4 software makes it easy to analyse the data or export the data into Excel for reporting and further processing as request by FDA 21 CFR Part 11 .



HL-20D / HL-21D
HygroLog HL20(D)

Rotronic products:

- **HL-21D**

±0.2 °C
FDA 21 CFR Part 11 / GAMP 4 compliant
Adjustable log interval
Memory: 20000 data records

- **HL-20D**

0..100%rh,
±0.8 %rh / ±0.2 °C
FDA 21 CFR Part 11 / GAMP 4 compliant
Adjustable log interval
Memory: 20000 data records

- **HL-NT & docking station**

47'000 data records /MB
1..7 interchangeable probes
Various analogue outputs, buzzer and LED indication
All psychrometric calculations
FDA 21 CFR Part 11 / GAMP 4 compliant
Display...

- **HC2-S**

-50...100°C,
0...100%rh,
Ø15mm,
±0.8%rh and ±0.1K...

- **Probe Extension Cables**

Various options e.g.:
Passive Cable: 1,2 or 5m
Active Cable: 10..100m
Cable w. open ends for third party integrations

- **Wireless Logger**

0...100 %rH / -40...85 °C
Memory capacity 500.0000
Intervals: 5 s to 12 h
Based on 433,92 & 915 MHz
Range: 40..100 Meters
Battery life time >6Years
Accessible HW4 software



HL-NT & Docking Station
Datalogger with Docking Station

Customer benefits:

Rotronic loggers:

The long term recording of humidity and temperature conditions is very important in storage, shipping, production processes. Once logged, the temperature and humidity data can be analysed statistically and provide valuable information that can have an influence on people, materials and objects.

The ROTRONIC data loggers fulfill the requirements of FDA 21 CFR Part 11 and GAMP 4. They have a de-

gree of functionality currently not achieved by any other logger while being highly accurate and easy to use.

The HL-21D & HL-20D Data loggers:

The battery powered data logger is designed to be replace at any locations where cabling or external power supply is not available.

The HL-NT logger ink. Docking station:

Offers the widest range of possibilities. All loggers can directly be linked with the

rotronic HW4 software over Lan , Wlan, USB or RS485. Each logger is capable to handle up to seven probes when paired with the connected docking station.

The LOG-HC2-RC Wireless Logger:

The outstanding energy-saving technology enables a battery lifetime of up to 6 years. Which makes it optimal tool for sites without infrastructure where precision and high storage is requested.



HC2-S
Hygroclip2 with AIRCHIP300 technology

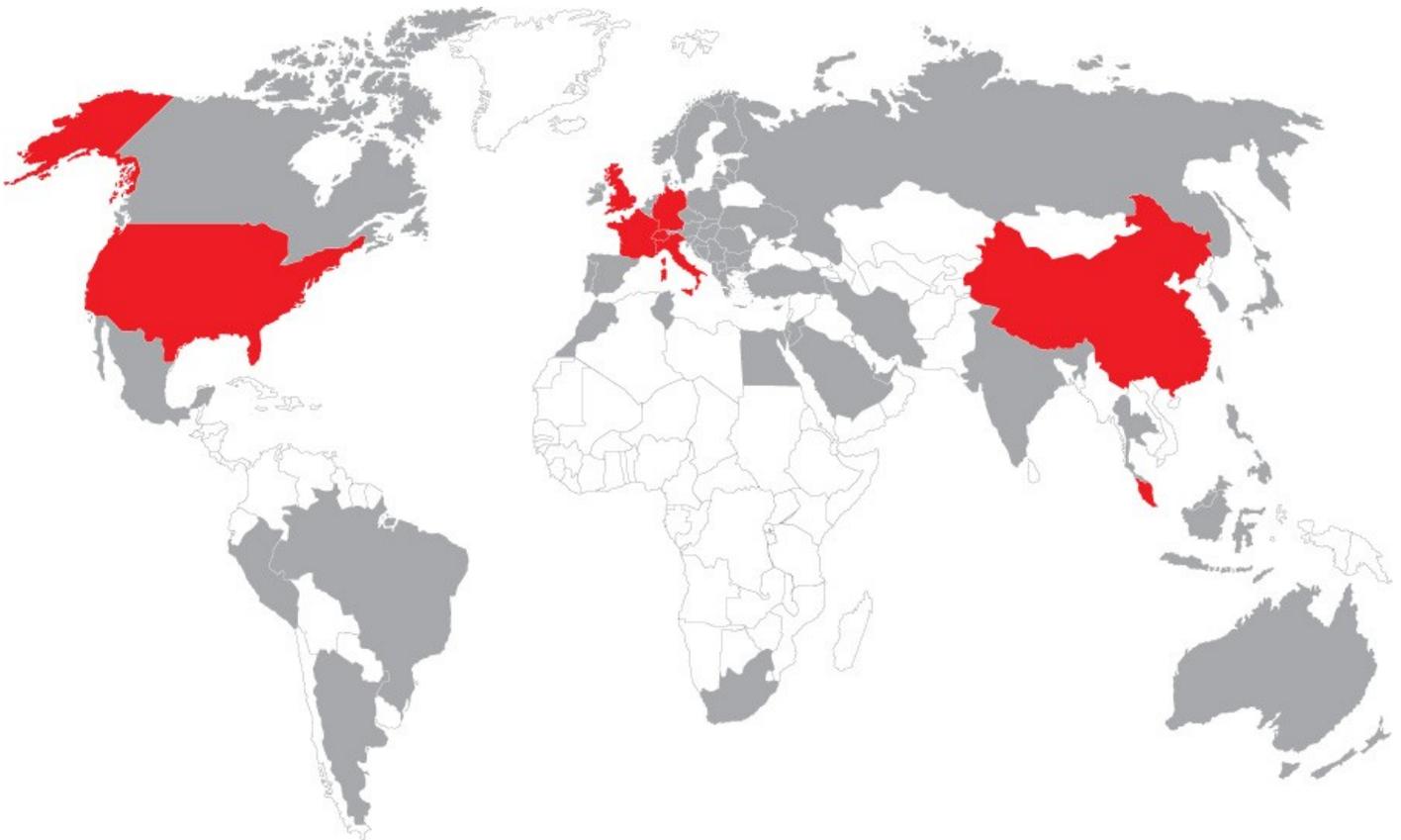


LOG-HC2-RC Wireless LAN-Interface

Contact us:

Rotronic is represented in over 40 countries around the world. An up to date list of all our partners is available on our website:

www.rotronic.com



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