INTERVIEW ON THE ADVANTAGES OF DIGITAL SENSORS WITHIN AN ENVIRONMENTAL MONITORING SYSTEM (EMS)

Recently «Azo Sensors» talked to our Director of Environmental Monitoring Systems, James Pickering, about the advantages of using digital sensors in an environmental monitoring system. We are happy to share the Interview.

Why is environmental monitoring so important in the pharmaceutical industry?

Environmental parameters are critical to product quality and as of such are controlled and monitored within the pharmaceutical industry.

When certain products are exposed to incorrect temperatures or relative humidity levels the product quality is no longer guaranteed. In the pharmaceutical, cosmeceutical and food industry, this is even more important as consumers' lives can be put at risk due to environmental effects on the products/ingredients such as decomposition, diminished effects/taste, and spoilage.

In the pharmaceutical industry, regulations have been put in place to protect the patients and to deliver quality-assured, safe, and effective products. The temperature range, along with other parameters, to ensure product quality is defined during the product risk assessment.

When a facility is designed, an integral part of the design is the building management system (BMS). The BMS manages many services within a facility including the heating, ventilation, and air conditioning (HVAC) of a building with the help of sensors located throughout the facilities. In order to ensure that the BMS is controlling the HVAC system correctly, an environmental monitoring system (EMS) can be installed. The EMS will monitor all the critical control parameters defined during the product risk assessment at critical locations defined during the facility qualification.

The GxP quality guidelines, developed by the regulatory authorities, are designed to cover the product quality over the complete life cycle of the product.

The GxP guidelines state that the area used must be qualified, the temperature should be monitored, and monitoring devices must be calibrated to meet the guidelines.

- Qualified: The qualification of the area is the process of proving that the area meets the requirements for its intended purpose.
- Monitored: The critical control parameters (temperature amongst others) are measured and saved for ulterior use (sometimes for up to 18 years or longer).
- Calibrated: The devices used for monitoring purposes are showing the correct values. The devices are calibrated on a regular basis to ensure that the measurements are always showing the correct values.

The regulations don't state how to fulfill regulations and as of such, the user can define how they qualify the areas, how they monitor the area, and how often to calibrate the devices.

What is a digital sensor?

A digital sensor is a measurement device that sends out a digital signal. The main advantage of a digital sensor compared to an analog sensor is the information sent. Whereas the analog sensor will only send an mA or voltage value (that is converted into a measurement value), a digital sensor can send much more data such as:

- Measurement value(s),
- Device serial number,
- Device status,
- Calibration data,
- Adjustment data…

The Rotronic digital sensors all have onboard memory and can be user-calibrated/adjusted.

What are the main advantages of using digital senors within an EMS?

The Rotronic digital sensors communicate to data loggers (wired or wireless) and all communication to the server and database is done digitally as such there is no loss in accuracy during data transmission. This means, unlike analog sensors, no loop check is required during device installation and qualification/validation.

A major advantage of using digital sensors within an EMS is the possibility to use the additional data and reduce the amount of downtime, this is especially valid during the calibration period or during service periods.

With analog sensors, a calibration can be done either in a calibration laboratory (internal or external) or in situ if the application permits. If the calibration is carried out in situ, then then the loop check is also done at the same time. For calibrations carried out in a laboratory, the device needs to be dismounted (leading to system downtime). With the Rotronic digital probes, a simple hot-swap can be carried out resulting in no downtime:

- Manually unscrew the existing probe.
- Manually screw in a "new" precalibrated probe.

The existing probe can then be calibrated in a laboratory and either put back in its original place or can also be used else where in the facility. Another avantage is that thanks to the digital system and the FDA CFR 21 Part 11/EU Annex 11 requirements, RMS will automatically show that a probe has been replaced with the audit trail together with the time and data and the probe serial number prior to the exchange and the probe serial number after the exchange.

RMS offers a calibration/adjustment feature with the generation of calibration certificates.

What parameters can Rotronic measure with digital probes?

Rotronic currently offers the following digital probes:

- Temperature,
- Temperature and relative humidity/dew point
- Differential pressure
- Carbon dioxide.

What digital communication protocol is used?

The Rotronic digital probes communicate via MODBUS via UART.

- With the AC3001: A user can communicate to the digital probe with the RMS-CONFIG software (probe configuration and calibration/adjustment).
- With the E2-05XX-MOD: A user can communicate to the digital probe via MODBUS over RS485.
- With the RMS-LOG-L or RMS-LOG-L-D: A user can communicate to probe via MODBUS TCP or the system transmits data directly to RMS via an HTTP protocol.
- With the RMS-LOG-868/915: the system sends data via either an 868 or 915 MHz wireless frequency to a LAN receiver who in turn transmits data directly to RMS via a HTTP protocol.

How does the RMS allow for third-party device integration?
Rotronic offers a few environmental parameters. However, within the pharmaceutical industry, other parameters also require monitoring. Another parameter that is also measured within cleanrooms is particle monitoring. Rotronic has developed a tool, the RMS-CONVERTER-100 to import third-party devices via their MODBUS TCP communication interface.

What is the PST Calibration Portfolio?
Michell Instruments and Rotronic, both part of the Process Sensing Technology (PST) Group, and market leaders in the field of humidity and trace moisture measurements, offer a full range of temperature and humidity calibration equipment and systems.

These include transportable humidity generators for simple verification of relative humidity and temperature probes, pressure swing dryers and low dew-point generators for calibrating trace moisture sensors and instruments. As well as building custom-designed humidity and dew-point calibration systems, we also provide ISO/IEC 17025 accredited relative humidity and temperature calibrations in six locations around the world.

- EAxx-SCS salt solutions.
- HygroCal100 humidity generator.
- Optidew reference dew point mirror.
- HygroGen S/XL temperature and relative humidity generator.
- S8000 reference dew point mirror.

What are some of the applications of the RMS?
Here is an overview of the applications where temperature monitoring is crucial:

- Cryogenic monitoring.
- Ultra-low temperatures monitoring (including with dry ice).
- Fridge/freezer monitoring.
- Stability testing.
- Incubators monitoring.
- Storage monitoring.
- Warehouse monitoring.
- Distribution centre monitoring
- Cleanroom monitoring.
- Transport monitoring (trucks, airplanes, containers, trains…)
- Healthcare sales point monitoring (pharmacies, vets, dentists, hospitals…)
- Blood bank monitoring
- Tissue bank monitoring
- Biobank monitoring

- Calibration laboratory monitoring

Find our Rotronic RMS digital devices here: https://www.rotronic.com/en-ch/rms/ueberwachung-digital/

About James Pickering
James Pickering has been working for Rotronic AG in various positions since 2008. Currently Director of Environmental Monitoring Systems, along with the International team, James is helping to build up Rotronic's continuous and configurable environmental Rotronic Monitoring System (RMS) to help regulated customers ensure the highest quality whilst remaining compliant and saving time and money.

Read the original Interview on AZO Sensors' «Insights from Industry»

Über Rotronic

Rotronic ist ein Unternehmen der Process Sensing Technologies (PST) Gruppe. PST vereint etablierte Marken, die sich auszeichnen durch die Präzision und Zuverlässigkeit ihrer Produkte, starke Innovationskraft und einen Fokus auf Kundenservice.

Rotronic ist ein führender Anbieter von Messgeräten für relative Feuchte, Temperatur, Kohlendioxid, Differenzdruck und Wasseraktivität, die in allen Anwendungen eingesetzt werden, in denen es auf höchste Messgenauigkeit, Stabilität und Zuverlässigkeit ankommt. Mit mehr als 55 Jahren Erfahrung steht der Brand Rotronic für Schweizer Präzision, spezialisiert auf Messinstrumente und Innovation, wie z.B. das Rotronic Monitoring System RMS, ein modulares Echtzeit-Umweltüberwachungssystem, das es beispielsweise regulierten Pharmakunden ermöglicht, spezifische FDA/EU-Vorschriften zu erfüllen, und auch Kunden innerhalb industrieller Anwendungen unterstützt, sich auf die Produktqualität zu konzentrieren.

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