Continuous monitoring in the cleanroom

The medical technology company Thommen Medical AG recently expanded its production site and equipped it with its own clean room. The Rotronic Monitoring System (RMS) was chosen to measure temperature, humidity, and pressure around the clock reliably.

The Swiss company Thommen Medical relies on the Rotronic Monitoring System (RMS) in its new building.

The family-run company Thommen Medical AG's headquarters is in Grenchen, Solothurn. Founded over 20 years ago, the company specializes in dental implant systems and dental instruments.

Business is flourishing: in February 2022, the company inaugurated its new building on the company premises and created space for the expansion of production and logistics and for more staff. Currently, 88 employees work at the headquarters in Grenchen. Thommen Medical also has several subsidiaries abroad.
The company not only specializes in producing dental instruments and implants but also develops, packages, and markets them independently.

In-house clean room

An in-house clean room was also built in the new building so that particularly delicate products can be packaged with low germ levels. There are strict requirements in this respect, particularly in the medical sector. In a clean room, the number of particles in the air is kept as low as possible so that the packaging of implants and tools can be handled in a sterile manner. Until now, Thommen Medical has outsourced this work step.

Employees who work in the cleanroom can only enter through the personnel airlock. They must change twice here: First, they remove their street clothes and slip into transitional clothing. Then you enter the back

of the airlock, where you put on protective clothing, including a hairnet and gloves. The products and packaging that need to enter the cleanroom are fed through a separate material airlock, where they are specially cleaned beforehand.

View of the personnel airlock in the new cleanroom. An RMS indicator light has been installed above the door, which triggers an audible and visual alarm in an emergency.

Flawless monitoring

It is essential that the temperature, pressure, and humidity in the cleanroom and the two airlocks always remain the same. If one of these values deviates from the standard, this means that the room is contaminated and is, therefore, no longer suitable for packaging sterile products.

Thommen Medical is therefore dependent on a reliable, continuous monitoring system. The company found this in the Rotronic Monitoring System (RMS). "We were familiar with the system, as my predecessor had already worked with Rotronic at another company," says Esra Bal, Group Leader Cleanroom at Thommen Medical.

Regular and good customer care is the be-all and end-all at Rotronic. Marcel Rohrbach, the Key Account Manager at Rotronic, was the customer consultant responsible for this project: "The example of Thommen Medical shows very well that good customer relationships prove their worth: there were years and several jobs between the first contact, yet we never lost sight of each other and have now been able to work together again."

Esra Bal from Thommen Medical (l) and Marcel Rohrbach from Rotronic (r) talking shop in front of the new cleanroom.

Hardware suitable for cleanrooms is just as important as stable software. Esra Bal explains: "The data logger in the cleanroom must be easy to clean and corrosion-resistant. It must also not emit particles and have a smooth surface." Rotronic's products meet these requirements, which is one of the reasons why they were chosen. They are GMP-certified, an international standard that is required in the pharmaceutical and medical sectors in particular.

The measured values, in this case, temperature and humidity, can be checked at any time both on the individual data loggers and on the dashboard on the computer.

Alarm system for emergencies

However, the RMS is not only used in the clean room but also other areas of the new building. For example, the system measures the temperature in various refrigerators and a heating cabinet and monitors the warehouse for temperature and humidity. This enables Thommen Medical to maintain the high standard of its products. "As part of our own quality controls, we need to monitor the critical areas in real-time and also be able to track all values," says Esra Bal, explaining the use of the RMS. She can log into the dashboard on her laptop anytime and check whether everything is running smoothly.

Thanks to the clear dashboard, all values from the various data loggers can be monitored in real-time

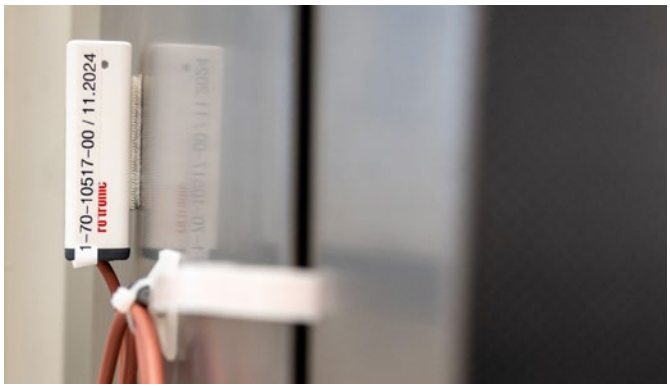
But what happens if the temperature in the cleanroom or other areas suddenly rises in the middle of the night? At Thommen Medical, operations run during the day, meaning no one is present at night or on weekends. "Our system is equipped with an alarm function," customer advisor Marcel Rohrbach explains. "In an emergency, the people in charge are alerted by a notification on their smartphone." An acoustic and visual system has also been installed: In an emergency, an alarm sounds, and the indicator lights in the cleanroom start flashing red. This ensures that any changes are rectified quickly and the products are always protected.

Wide range of services

The analog or digital implementation of devices that are not from Rotronic can be a challenge when setting up RMS. "In this project, we had to implement a third-party particle measuring device into the system so that its values could also be monitored." Transferring such devices is not always easy, but: "After contacting the manufacturer, we were able to implement this without any problems," says Marcel Rohrbach from Rotronic. Rotronic carried out the mapping, calibration, and commissioning for Thommen Medical and then trained the staff to use the new software correctly.

> "A big plus point is the easy expandability. Additional devices can be easily integrated into the existing system."
>
> Esra Bal, Thommen Medical, Switzerland

During mapping, we look at where and how many data loggers are best placed so that the monitoring works perfectly after commissioning. Once the hardware has been installed, calibration takes place on-site. This involves checking whether the various devices are measuring correctly. In a final step, the system is put into operation. "But that's not the end of our work," says Marcel Rohrbach. "Our customers often sign a multi-year calibration contract. This means that our service technicians visit once a year to check the accuracy of the devices." It is, therefore, particularly practical that the sensors on the data loggers can simply be unscrewed for maintenance.



A mini data logger in use for a Thommen Medical heating cabinet: For optimum use, the sensor inside was connected to the data logger using a ribbon cable.

Easily expandable system

Thommen Medical has been using the RMS for over a year and is very satisfied. "It's easy to use, and if we have any questions, the support team is always quick to help us. We really appreciate that!" confirms Esra Bal, who works with the RMS on a daily basis. "Another big plus point is that it's easy to expand. If we plan to expand again, additional devices can be easily integrated into the existing system."

Rotronic Monitoring System

The Rotronic Monitoring System (RMS) is a GAMP©5 Category 4 software in combination with Category 1 hardware that helps our customers monitor their GxP-compliant applications, examine the critical quality attributes, and monitor the sensitive process parameters.

The measurement technology solution at Thommen Medical in detail:

Products

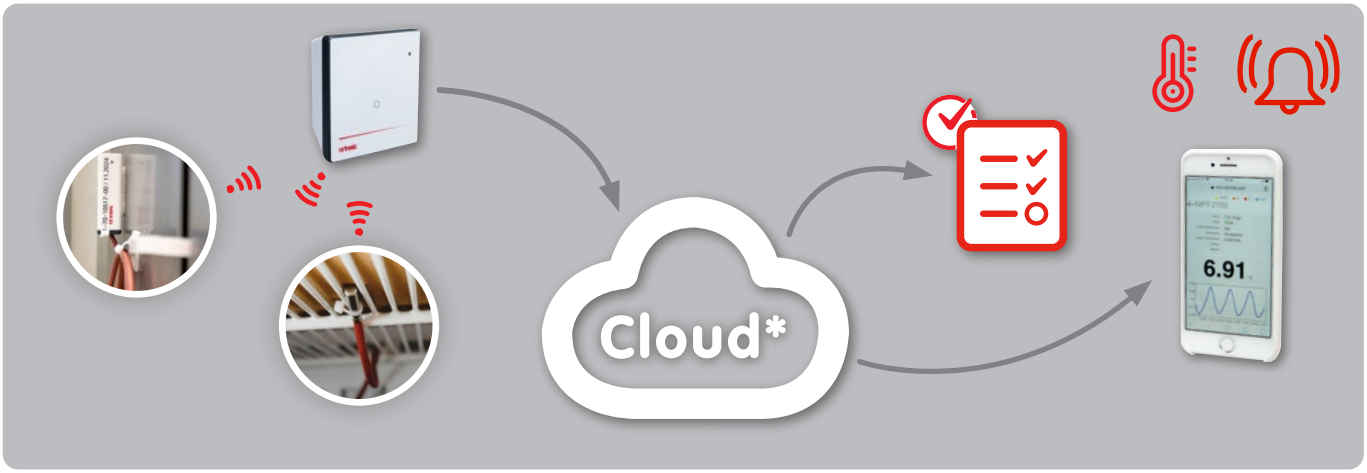
- Indicator light red, orange green AD-0003
- Standard sensor, differential pressure, black PCD-S-M11
- Ethernet interface for the integration of third-party products RMS-CONVERTER-100
- Output module, relay, LAN RMS-DO-L-R
- Gateway, LAN to 868 MHz RMS-GW-868
- Standard sensor, digital RMS-HCD-S
- Data logger, external sensor, 868 MHz RMS-LOG-868
- Data logger, external sensor, LAN RMS-LOG-L-D
- Mini data logger, external NTC sensor RMS-MLOG-T10-868
- NTC, 6 mm dia, 50 mm long, 2 m cable, T10-0113
- Server Software

Services

- Mapping
- Installation
- Integration of third-party products
- Training
- Calibration

Areas of application

- Clean room
- Warehouse
- Refrigerators
- Heating cabinet



53040E/2024-02