Customer Applications

rotronic
MEASUREMENT SOLUTIONS

# IN THE SERVICE OF HEALTH

***Production monitoring and technical facility management at Dr. R. Pfleger GmbH.***


*Measurement equipment in switch cabinet.*

*Dr. R. Pfleger GmbH in Bamberg (Germany).*

The German pharmaceutical manufacturer Dr. R. Pfleger GmbH applies special cleanroom techniques. It is very important for the company to monitor and verify pressure conditions as well as humidity and temperature measurement data in its cleanrooms. To meet this need, the company uses validated Rotronic data loggers of the type HygroLog HL-NT series. Together with Rotronic's validated HW4 monitoring software, these data loggers deliver important information on the environments that have an influence on the production of pharmaceutical products. The Rotronic monitoring system has stood the test of time in the market over many years and undergone continuous development. It has been possible to connect instruments in a network via interfaces for more than 10 years now and, using suitable software, to store data permanently and visualise it. The HW4 software forms the heart of the system. It visualises and saves all data, configurations and user events and also triggers alarms. Its audit trail logs all data and activities in compliance with FDA21 CFR Part 11, GAMP5. Rotronic calibrated, qualified and validated Dr. R. Pfleger GmbH's monitoring system according to GMP requirements.

## Overall control and regulation

The management system forms the basis for operation, monitoring and control of the technical facilities as well as for data and message management. Apart from the technical installations, the validated cleanroom monitoring system is implemented directly in FIS (OPC interface). Visualisation of the processing plant for purified water (Ph. Eur.), control and monitoring of the outdoor lighting and access control to the building and cleanroom air showers are also connected to the system. FIS therefore offers availability and management of all relevant data in a central software system.

## HygroLog HL-NT data logger

The central acquisition unit is a HygroLog-HL-NT data logger. It provides digital inputs for HygroClip humidity and temperature probes as well as Pt100 and 4…20 mA. The data logger is also equipped with a memory card on which not only the measurement data but also events in the instrument itself are stored.

*Technician checking the alarm schematic.*

## HC2-S sensors

The digital HygroClip2 climate probes provide class leading precision and long-term stability. All calibration and adjustment data is stored in them. Their standard accuracy ex works is ±0.8 %rh and ±0.1 K. For more demanding tasks, sensors with an accuracy of ±0.5 %rh can be supplied ex works.

## Micatrone differential pressure transmitters

The MicaFlex MF-PFT differential pressure sensors boast accuracy of ‹±0.5 % +0.5 pa with very low zero drift. The two analogue outputs were used in the project to operate monitoring and room pressure regulation from a transmitter.

## Central installation of measurement equipment in a switch cabinet

All the differential pressure transmitters and data loggers are installed in eight separate monitoring sub-distributors connected to each other in a network. The signals from climate probe to data logger are transmitted digitally. The 4…20 mA inputs at the data logger are adjusted during start-up and are thus stable over the lifecycle.

## Sophisticated software and clear presentation

The HW4 software saves the measurement data, alarms and events in a protected binary format. Manipulations are detected and the data record then marked as corrupt. Instruments are organised in groups and shown in the room layout. Colour changes make alarms and disturbances easy to see. The personnel in the production area are informed of the status by traffic light displays.

## Evaluation and archiving

A data file is created for every measuring point. The MKT value is calculated from this raw data. The evaluation also contains alarm times and deviations and is presented in the form of a table with statistical values. Thanks to the high level of integration of the hardware in HW4, virtually all Rotronic instruments can be implemented in the existing monitoring system.

## Customer benefits

The automation, management and monitoring solution implemented by Hermos and Rotronic offers a consistent solution for technical facility management and thus the prerequisite for cost-optimised plant operation. Since all main and secondary installations and the monitoring system itself are integrated in the FIS management system, they can be monitored and controlled via a central software platform. Due to the open structure of the system and clean separation of the monitoring system, plants from the production area as well as plants in the existing building can in future be integrated in the central monitoring and control system seamlessly. The monitoring system can be extended at any time without additional licence fees or external programming.

## Dr. R. Pfleger GmbH

The pharmaceutical company Dr. R. Pfleger GmbH in Bamberg is one of the leading medium-sized manufacturers of medicinal products in Germany. It produces and markets a wide range of medical devices, primarily in the fields of urology and dermatology, as well as over-the-counter pharmaceuticals and body care products.

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