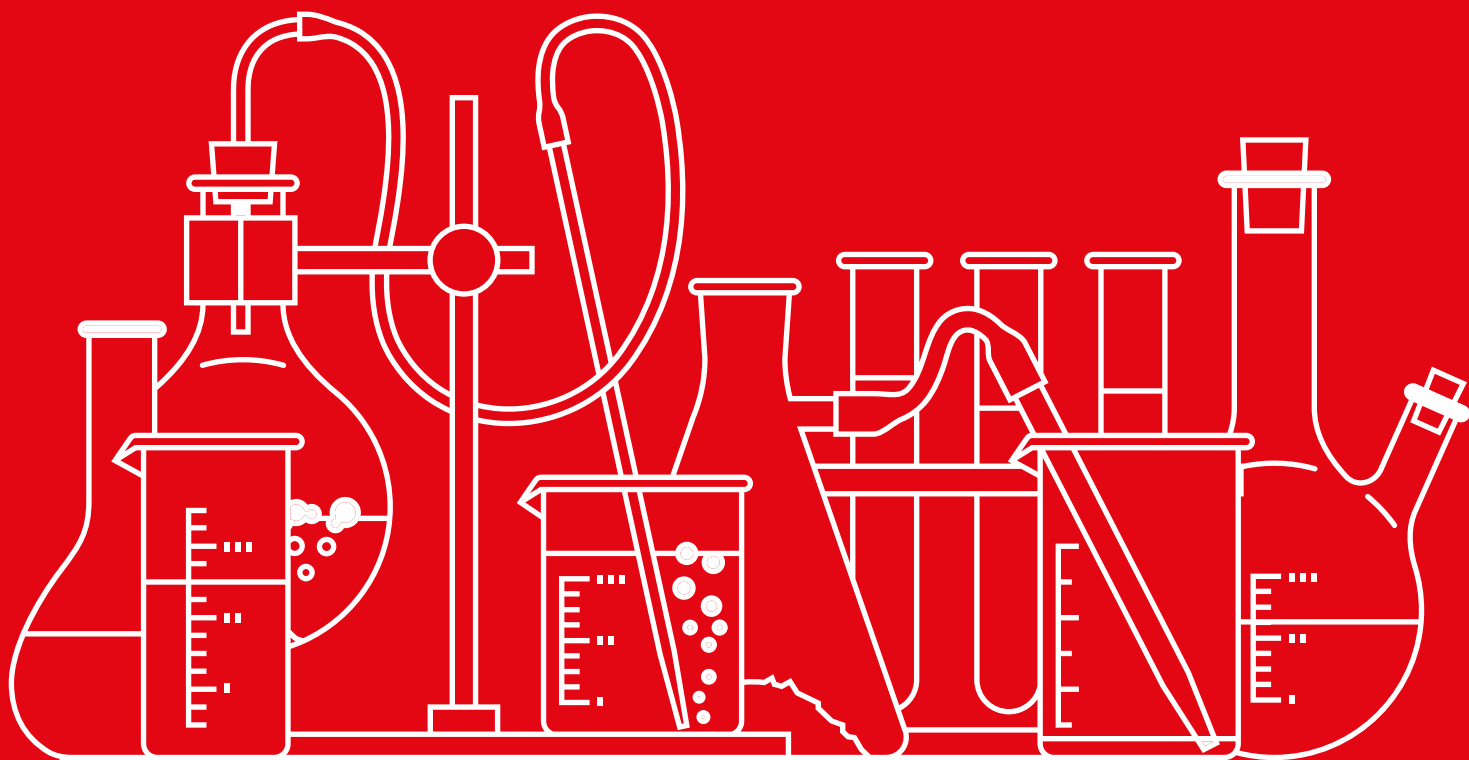


Avoid experiments in monitoring important parameters

Measuring instruments and solutions for
the pharmaceutical, medical and healthcare industries



ABOUT ROTRONIC

SWISS PRECISION AT THE HIGHEST LEVEL

Founded in 1965, Rotronic AG is a world leader in humidity and temperature measurement. As a reliable partner to the pharmaceutical industry, the company is now making a name for itself as one of the strongest players worldwide in solutions for the measurement of other parameters.

- Comprehensive product line including transmitters, data loggers, handhelds and industrial sensors
- Class-leading humidity probes with an accuracy of 0.5 %RH & <1 % drift / year
- Experts for challenging applications including high-temperature and hydrogen-peroxide environments
- Modular and flexible monitoring system consisting of hardware elements and GAMP5-compliant software
- Comprehensive service portfolio; mapping, calibration, validation and training
- Complete compatibility with FDA 21 CFR Part 11 and GxP requirements

Measured parameters in the pharmaceutical industry



Humidity



Temperature



Water activity



Pressure



Differential pressure



CO₂



Low dew point



Lux



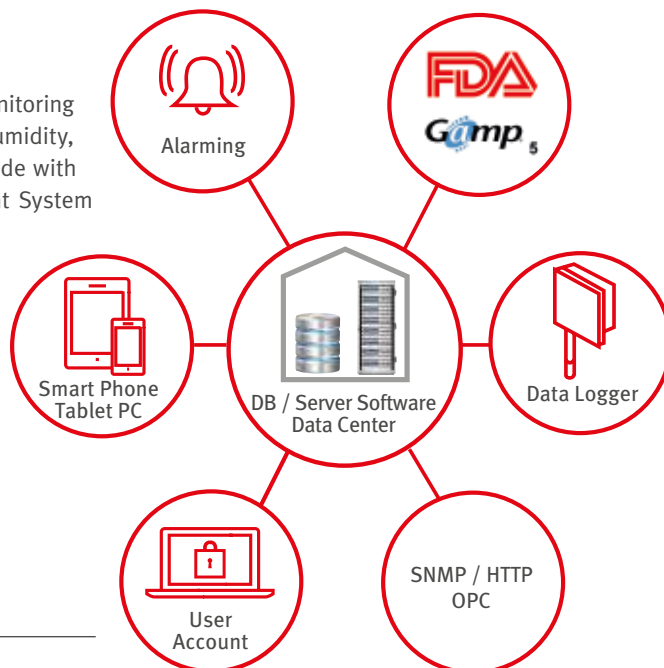
Flow



mA/V

Our product range helps to fulfill environmental controlling and monitoring requirements in regulated environments by measuring relative humidity, temperature, pressure, differential pressure, light and carbon dioxide with the help of digital and analog inputs for the Building Management System (BMS) and the Environmental Monitoring System (EMS).

Based upon the process application, its GxP status and the critical aspects of the process such as the critical quality attributes and critical process parameters, the suitable Rotronic solution can be defined. Please contact our team of qualified sales engineers at any time to find your perfect solution.



SIMPLY EXPLAINED

You can find out more on individual products and measurement parameters in our short **explanatory videos**. Visit our Rotronic website or Youtube channel.

Monitoring System

Measured data under control at all times



Humidity

How and when to monitor RH?



Cleanroom Panel

Reliable monitoring of cleanrooms



Differential Pressure

How and when to monitor ΔP ?



ROTRONIC MEASUREMENT SOLUTIONS

We offer a complete range of measuring instruments particularly for the pharmaceutical, medical and healthcare industries. The products can be integrated into existing Rotronic infrastructures or into the latest FDA and Gamp5-compliant Rotronic Monitoring System (RMS) as well as into third party monitoring systems.



TRANSMITTERS

The high-end series HF5, PF4 and CF5 provide highest accuracy and best features. See www.rotronic.ch for the HF1 and PF1 series for standard HVAC applications.



HF5 Aluminum



HF5 ABS



PF4

| | | | |
|-------------------|---|--|--|
| Parameters | °C & %RH | °C & %RH | °C, %RH & ΔP |
| Accuracy | Probe-dependent | Probe-dependent | ±1.0 %FS %RH & °C: probe-dependent |
| Range | -40...60 °C | -40...60 °C | 0...60 °C |
| Output | 2 freely configurable analog outputs (0..20 mA & 0..10 V) | 2 freely configurable analog outputs (0..20 mA & 0..10 V) ROASCI RS485 and TCP/IP | 2 freely configurable analog outputs (0..20 mA & 0..10 V) ROASCI RS485 and TCP/IP |

PROBES

Rotronic offers a range of probes for all applications.



T10-0001



HC2A



HC2-IMI02



HC2-LDP

| | | | | |
|-------------------|--------------|-------------------------------------|-------------------------------------|-------------|
| Parameters | °C | °C & %RH | °C & %RH | °C & °CDP |
| Accuracy | ±2.5 °C | ±0.8 %RH @ 23 °C ±0.1 °C @ 23 °C | ±0.8 %RH @ 23 °C ±0.1 °C @ 23 °C | ±2 °CDP |
| Range | -196...90 °C | -50...100 °C | -100...200 °C | -40...85 °C |

ROTRONIC MEASUREMENT SOLUTIONS

CLEANROOM PANELS

| | | |
|--|--|--|
| Panels designed for the perfect installation in cleanrooms to monitor temperature, humidity, differential pressure, pressure, current and voltage. |  <p>CRP5</p> |  <p>CRP1</p> |
| Parameters | °C, %RH, ΔP, Pa, mA & V | °C & %RH |
| Accuracy | ±1.5 %RH @ 23 °C ±0.2 °C @ 23 °C ±1 %FS | ±0.8 %RH @ 23 °C ±0.1 °C @ 23 °C |
| Range | -5...60 °C | -10...60 °C |
| Output | MODBUS TCP, MODBUS RTU (RS485), 4 freely configurable analog outputs (0..20 mA & 0..10 V) | 2 freely configurable analog outputs (0..20 mA & 0..10 V) |

CLEANROOMS

Cleanrooms are used for manufacturing processes that require very exact control of the ambient air, particularly the number of airborne particles. The cleanroom classes according to the GMP Guideline, Annex 1 Manufacture of Sterile Medicinal Products, define how “clean” a room is on the basis of the number of particles per m³ (from Class A to D).

Other parameters such as relative humidity, temperature and differential pressure are also measured and kept constant depending on the product being manufactured.






BENCHTOP DISPLAY ANALYZER

| | |
|---|---|
| Professional high-end laboratory unit for temperature-stabilized measurement of water activity. |  <p>AwTherm</p> |
| Parameters | aw |
| Accuracy | ±0.005 aw (10..30 °C) ±0.1 °C (±0.18 °F) |
| Range | 0.005...1.000 aw |
| Data logging | Via HW4 software |




CALIBRATION

| | |
|---|---|
| The HygroGen2 comes as a portable and laboratory version for calibration of Rotronic or third-party probes. | <p>HG2-S</p> <p>HG2-XL</p>  <p>HG2-S / HG2-XL</p> |
| Parameters | °C & %RH |
| Stability | ≤±0.1 %RH ≤±0.01 °C |
| Thermal gradients | 15..50 °C: ≤±0.05 °C 5..60 °C: ≤±0.1 °C 0..5 °C: ≤±0.15 °C |
| Chamber size | HG2-S: 2 liters HG2-XL: 20 liters |



STAND-ALONE DATA LOGGERS

| | | | |
|---|---|--|--|
| Simple and economical humidity and temperature data loggers. Single or multi-use application. |  |  |  |
| | TL-CC1 | BL-1D | HL20 |
| | °C | °C, %RH, °CDP, Pa | °C, %RH |
| | ±0.5 °C (-30...70 °C) | ±3 %RH @ 23 °C ±0.3 °C @ 23 °C ±3 hPa @ 23 °C | ±1.3 %RH @ 0...10 %RH / ±0.3 °C ±0.8 %RH @ 10...60 %RH / ±0.3 °C ±1.3 %RH @ 60...100 %RH / ±0.3 °C |
| | -30...70 °C | -30...70 °C | Max. -10...60 °C |
| Data logging | Yes | Yes | Yes |

NETWORK DATA LOGGERS

| | | | |
|---|--|--|--|
| The more complex data loggers from Rotronic offer highest accuracy, reliability and security. |  |  |  |
| | RMS-LOG | RMS-MLOG (wireless) | HL-NT |
| | °C, %RH, CO ₂ & ΔP | °C, %RH, mA, V, Lux | °C, %RH & V |
| | Probe-dependent | 0.3 °C @ 25 °C 3 %RH @ 23 °C ±0.1 V @ 23 °C ±0.2 mA @ 23 °C -3.5...10 Lux @ 10 Lux @ 23 °C | Probe-dependent |
| | -40...60 °C | -30...85 °C | -40...60 °C |
| Data logging | Yes | Yes | Yes |

HANDHELD INSTRUMENTS

| | | | | |
|--|---|---|---|---|
| Handheld instruments for CO ₂ , humidity, temperature and water activity. |  |  |  |  |
| | TP31-IR | HP22 | HP23 | CP11 |
| | °C | °C & %RH | °C, %RH, aw, °CDP & V | °C, %RH, CO ₂ |
| | -50...20 °C: ±2.5 °C 20...300 °C: ±1.0 % of measured value ±1.0 °C | Probe-dependent | Probe-dependent | ±30 ppm ±5 % of measured value #23 °C ±3 %RH ±0.3 °C |
| | -10...60 °C | -10...60 °C | -10...60 °C | 0...50 °C |
| Data logging | No | No | Yes | Yes |

ROTRONIC MONITORING SYSTEM (RMS)

The Rotronic Monitoring System is one of the most flexible monitoring systems available on the market today. From small applications with one measurement point to larger systems with several thousand measurement points, RMS offers tailor-made solutions. Existing hardware can be integrated into the Rotronic system and, vice versa, Rotronic hardware can be incorporated into existing software. However, since the Rotronic hardware and software are matched exactly to each other, they jointly offer the best solution to ensure real time alarms, total data integrity and no loss of data.

Our R&D team works in accordance with the GAMP 5 recommendations. RMS therefore supports customers in complying with GxP regulations and FDA CFR 21 Part 11 requirements. Rotronic has more than 50 years of experience in the measurement and monitoring of temperature and relative humidity in a wide variety of pharmaceutical applications such as:

- Animal testing laboratories
- Archives
- Blood and tissue banks
- Fridge and freezer monitoring
- Cleanrooms
- Data centers
- Forensic medicine
- Laboratories
- Warehouses

MONITORING SOFTWARE

The RMS Server Software fulfills all requirements for server-based monitoring. It is linked to an SQL database that stores all measured data and system activities. The data can be accessed from anywhere in the world via all common platforms as long as an internet connection is available.

HARDWARE

The RMS hardware is built in such a way to ensure that no data gaps can occur as every data logger is equipped with a backup battery and sufficient memory. Third-party hardware can be integrated either by using an analog to digital converter or the RMS Converter for digital devices.

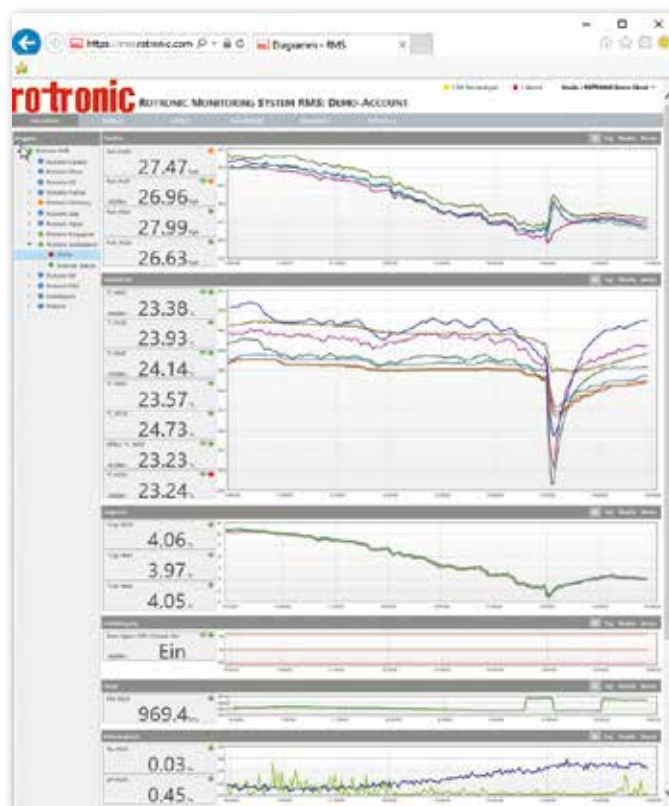
SECURITY

The RMS devices are paired with the RMS software key to ensure that the devices cannot get mixed up. All data transmission is encrypted and the software recognizes any changes made to the database. All changes made in the system are added to the audit trail and cannot be deleted from the system. The Rotronic SaaS solution offers an ISO27001 risk-managed setup for customers who require it.

FDA & ANNEX 11



RMS is fully compliant to FDA CFR 21 Part 11, Electronic records; electronic signatures, as well as EU Annex 11 (EUDRALEX).



Overview of the Rotronic Monitoring System Software graphic user interface.

GAMP5



Good Automated Manufacturing Practice (GAMP) sets the guidelines for validation of automated systems in the pharmaceutical industry. It is a risk-based approach for GxP-compliant information systems. The Rotronic R&D team work on the basis of the GAMP5 recommendations and the RMS is built to meet these requirements. The RMS software is a category 4 software.

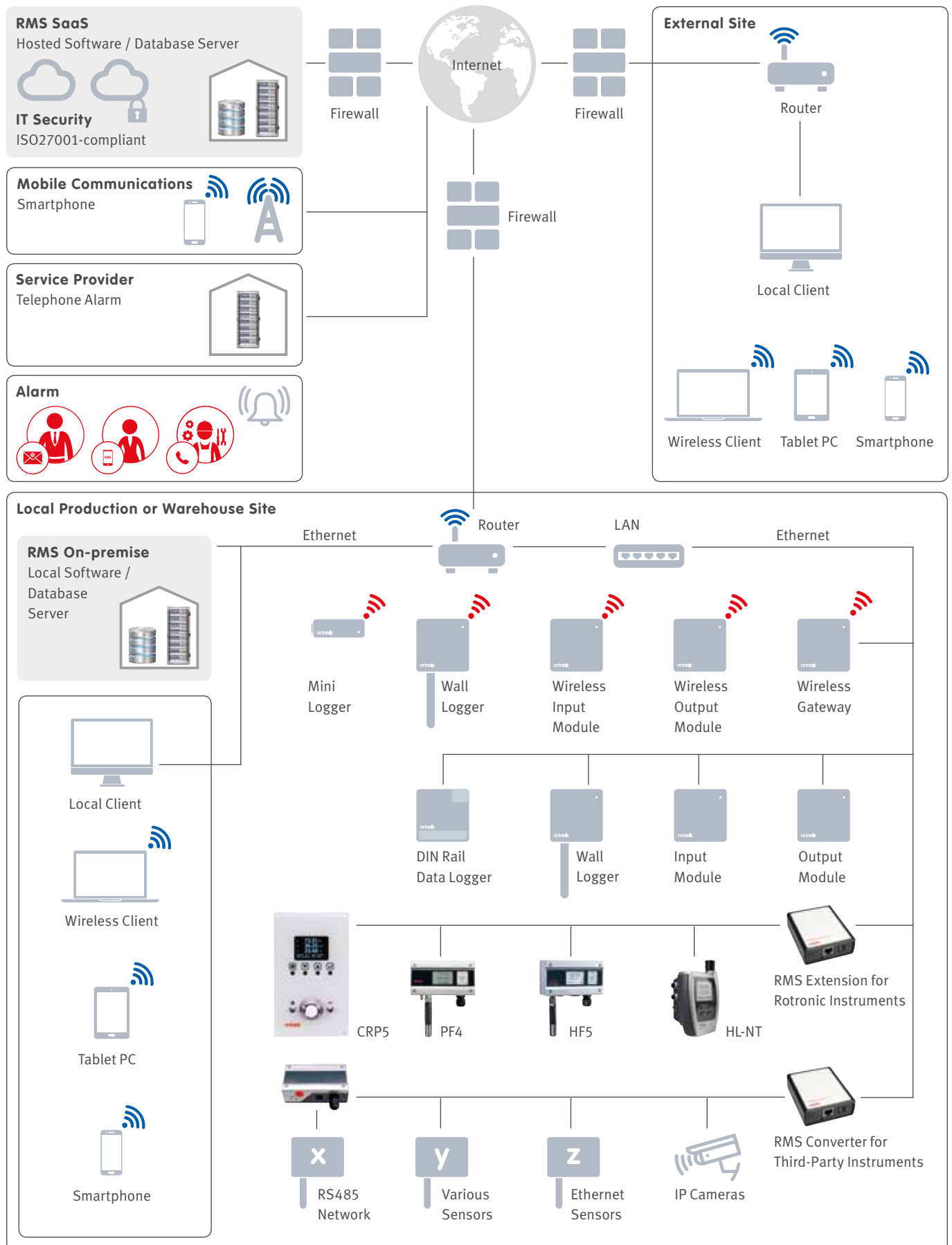
ALARMS

RMS allows alarm thresholds to be set for working hours and times outside working hours on the basis of warnings and alarms if values are too high or too low. E-mails, SMS messages and telephone calls are then triggered. It is possible to configure alarm schemes for various devices or set up alarms for single measurement points. The RMS software offers real-time alarms and trends as well as customized reporting possibilities.

FLEXIBILITY

Additional parameters, users and measurement points can be added on the basis of the requirements and critical process parameters of the application concerned. Whatever your needs may be, our R&D team will find the right solution.

RMS NETWORK ENVIRONMENT



A member of

