

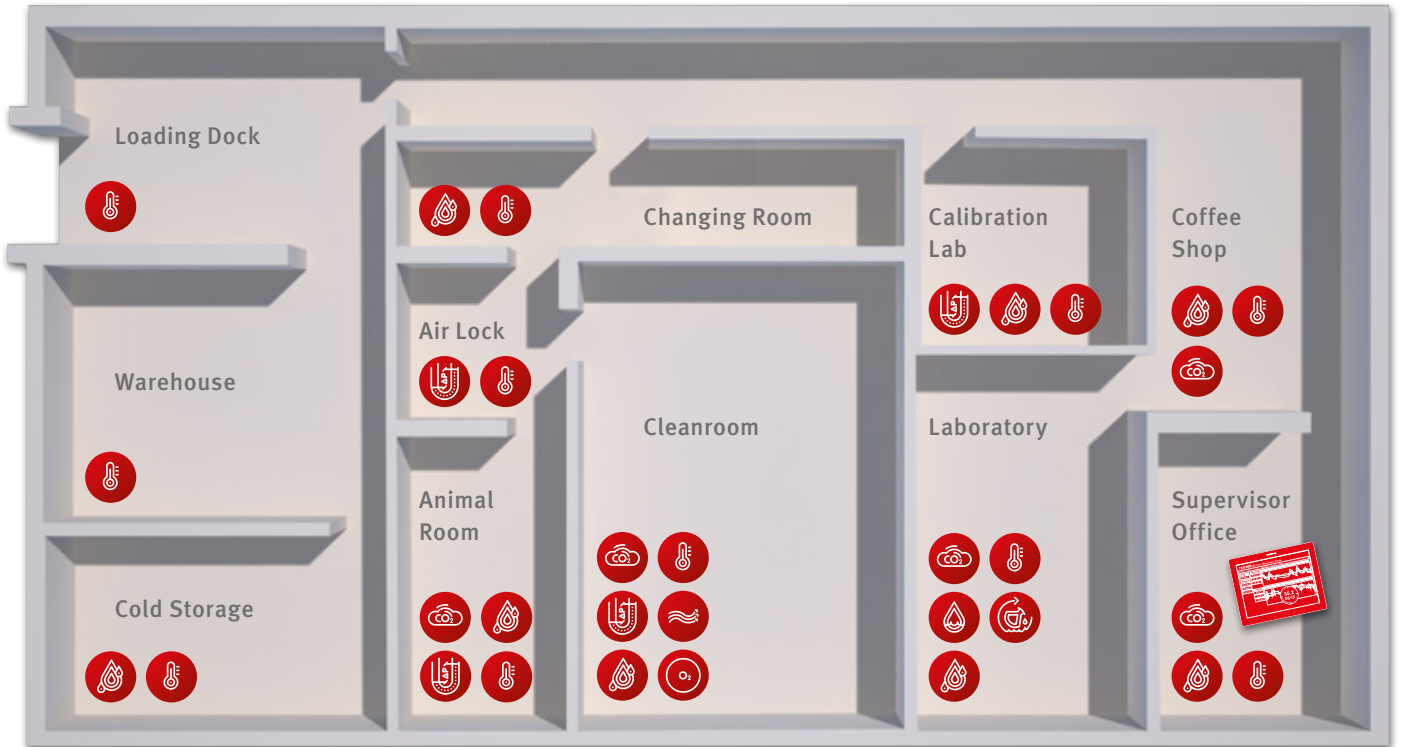
# Advanced Instrumentation for the Pharmaceutical Industry

Customized solutions compliant  
with GXP and 21 CFR Part 11

## Advanced Instrumentation for the Pharmaceutical, Cosmetic and Healthcare Industries

The Process Sensing Technologies (PST) Group offers a range of instrumentation to monitor and control the various environments necessary to ensure quality and safety in pharmaceutical applications. These include high-accuracy transmitters and data loggers for various parameters, fail-safe oxygen analyzers as well as GAMP5 and FDA/EU compliant room monitoring systems, and they are found at all stages in the pharmaceutical process, from research and production

to storage and transportation. To guarantee first-class product quality the following key parameters are important: relative humidity, oxygen, water activity, temperature, differential pressure, low dew point and CO<sub>2</sub>. Cleanrooms used for production processes require precise control of the ambient air in particular, humidity, temperature and the number of airborne particles.



Measured parameters in an application sample.

## Rotronic Continuous Monitoring System RMS

The Rotronic Monitoring System (RMS) 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. All PST or third-party hardware can be integrated into the Rotronic system and, vice versa, RMS hardware can be incorporated into existing software. The RMS Server Software fulfils all requirements for server-based monitoring. It is linked to an SQL database that stores all measured data and system activities. Via a secure Internet connection, users can set specific alarms and access their data from anywhere in the world.

### RMS Highlights

- Monitor any important critical control points and parameters (analog and digital output)
- Dataloggers with PoE, external power and backup battery to ensure no loss of data
- Save on cabling costs with the wireless product range
- Simplify processes and reduce human interaction



## Relative Humidity and Temperature Measurements

Maintaining the required humidity and temperature in the different stages of the production of drugs is key to ensure the safety and potency of the medication. Therefore, measuring humidity and temperature in production, storage and while transporting pharmaceutical goods is compulsory and highly regulated.

### HC2A-IC/IM – Industrial Humidity Probes

Wide range of highly accurate probes measuring humidity and temperature. For demanding industrial environments and applications.

- Wide temperature ranges from -100...200 °C
- High accuracy  $\pm 0,5... \pm 0,8$  %RH
- Excellent long-term stability  $< 1$  %RH/year
- Compatible with HF5, HF8, PF4/5, HP32

### HygroFlex HF5 – HVAC Transmitter

The HF5 Series measures humidity and temperature and offers the possibility to output any psychrometric calculation as an analog signal.

- Measures relative humidity, temperature, dew point and psychrometric parameters
- Compatible with a wide choice of interchangeable Rotronic probes
- Accuracy  $< 0,8$  %rh and  $< 0,1$  K at 23 °C (depending on probe)

### HygroPalm HP32 – Handheld Instrument

Handheld device compatible with all HC2A and HC2 Rotronic probes, for spot measurements and logging over longer periods of time.

- Measures relative humidity, temperature and psychrometric parameters
- Graphical display for graphs and up to 4 values
- 64,000 data points memory for time programmable interval logging

### HygroLog HL-1D – Compact Datalogger

The HL-1D is a compact, low cost data logger capable of  $\pm 3,0$  %RH and  $\pm 0,3$ °C accuracy.

- 3 types available to cover hPa, °Cdp, %RH, °C
- Programmable start and stop time with free HW4 software
- Compact design with a high IP protection

### TL-CC1 – Cold Chain Temperature Logger

Single use logger for monitoring and recording the temperature of sensitive goods during transportation and at exchange points.

- Conforms to GxP, EN 12830 and FDA 21 CFR Part 11 / GAMP 5
- Automatic PDF report generation
- Clear alarm identification and manipulation-proof



## Oxygen Measurements

Oxygen analysis plays an important role in ensuring the safety of pharmaceutical production. Wherever powders and solvents are used in large quantities there is a risk of explosion and many pharmaceutical processes use an inert blanketing gas such as nitrogen to remove oxygen, for eliminating this risk.

### SIL-O2 – Fail Safe Oxygen Analyzer

SIL2 rated oxygen analyzer has been developed for the measurement of oxygen in safety-critical process in API manufacturing in applications such as; centrifuges, reaction vessels and milling applications.

- Safety Integrity Level (SIL2) in accordance with IEC61508/ IEC61511
- Zirconia or Electrochemical sensors developed to withstand harsh environments
- 3 configurable alarm outputs

### XTP601 – Oxygen Analyzer for Safe or Hazardous Areas

Robust, stable and linear percentage level oxygen analyzer for inert gas blanketing in chemical reactors.

- EXd enclosure with flame arrestors and touch screen display
- Calibration intervals up to 6 months and no consumable parts
- Outputs and optional light guide follow NAMUR NE44 standard

### GPR-2500 – Wall Mounted Oxygen Analyzer

Percent oxygen analyzer with optional hazardous area certification for oxygen monitoring of centrifuges during drying processes.

- Measuring range of 0 to 1% up to 0 to 25%
- Loop powered and intrinsically safe in Nema 4 (IP65) enclosure
- Minimal maintenance: up to 32 months sensor lifespan

### OxyExtract – Oxygen Analyzer

Range of IECEx/ATEX approved retractable in-line oxygen sensors.

- Ability to measure Oxygen concentration directly in the process gas stream
- Available in 316 stainless steel and hastelloy C22
- Tri-Clamp and flanged process connections
- SIL2 rated oxygen analyzer

### Minox-i – Intrinsically Safe Oxygen Transmitter

Highly reliable, IECEx/ATEX approved and cost-effective two-wire, loop-powered transmitters.

- Measurement range: 0-25 %
- Electrochemical sensor technology
- Industry standard 4-20 mA output
- ATEX / IECEx approved for hazardous area gas & dust groups



2 configurable alarm outputs

Touchscreen operation

Can measure in pure CO<sub>2</sub> with XLT sensor

Manual or automatic actuation

2 configurable alarm outputs

## Water Activity Measurements

Too much free water in a product increases the risk of microbial growth and water migration. This can lead to clumping, changes in consistency and reduced shelf-life. FDA regulations require proof that the water activity of a product has been reduced sufficiently so that bacteria can't grow.



### AwTherm – Water Activity Meter

User-friendly, professional high-end laboratory desk top unit for temperature-stabilized measurement of water activity.

- Highest precision through exact stabilization of temperature
- Reference probe exchangeable for calibration or cleaning
- Quickest measurements with the AwQuick function

### Hygrolab – Water Activity Laboratory Device

High-end laboratory analyzer for water activity measurements with up to four measurement probe inputs.

- 4-channel benchtop display unit for measurement of aw, %RH, °C
- AW Quick function for fast measurement results (typically 4-5 minutes)
- Large touchscreen/remote access (by PC or tablet)

## Differential Pressure Measurements

Differential pressure is measured and monitored where even minor differences in pressure can have a big effect. The fields of use therefore range from cleanrooms, operating theatres and laboratories to applications in research, technology and the heating, ventilation and air-conditioning (HVAC) processes.

### PressureFlex PF4/5 – Differential Pressure Transmitter

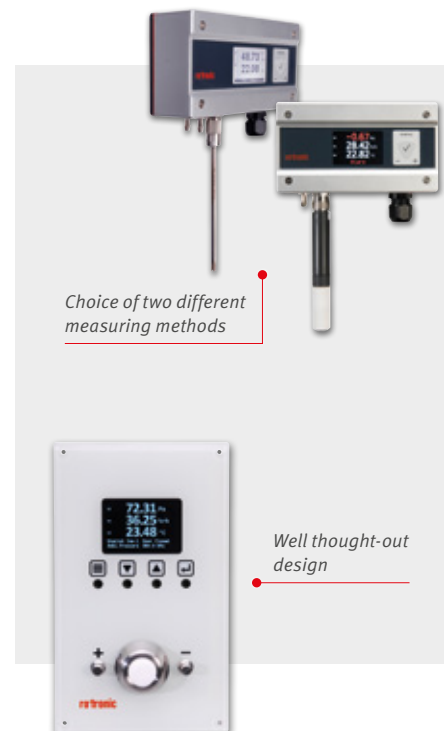
The differential pressure transmitters PF4 and PF5 with two different sensor technologies (PF4: thermal measuring method, PF5: diaphragm sensor) consistently produce perfect measurement results thanks to an integrated ambient pressure sensor.

- Measures up to 3 parameters beside differential pressure it can measure humidity and temperature
- 1 - 3 analog outputs, 1 analog input
- Network-compatible (Ethernet)

### CRP5 – Cleanroom Panel

The CRP5 for differential pressure, humidity and temperature measurement is optimized for applications in laboratories and cleanrooms, where high accuracy and a high degree of cleanliness are vital.

- Graphical color display with optical buttons for up to 6 measurement values/messages
- Digital communication via Ethernet RJ45 and/or MODBUS TCP/RTU
- Removable magnet-mounted humidity and temperature probe



Choice of two different measuring methods

Well thought-out design

## Dew-Point Measurements

Low dew-point and trace moisture measurement plays a key role in monitoring industrial dryers for efficiency and to ensure product quality.



Small and transportable

Portable and self-contained

Accuracy  $\pm 2$  °C dew-point

### Optidew 401 – Cost-effective Chilled Mirror Hygrometer

Fast-responding chilled mirror hygrometer for precision laboratory and a reference hygrometer for temperature and humidity calibrators.

- New chilled mirror hybrid sensor gives fast dynamic response to changes in humidity
- Accurate to  $\pm 0.15$  °C dew point,  $\pm 0.1$  °C temperature

### HygroCal100 – Humidity Validator

- Combine with Optidew 401 chilled mirror hygrometer for cost-effective traceable calibrations
- Intuitive UI makes automating probe verification simple
- Automated validation procedures for hands-off probe verification
- Internal calibration correction cycle ensures continued confidence

### Easidew – Industrial Dew-Point Transmitters

Simple to install and maintain the trace humidity transmitter measures dew-point and moisture content across a broad humidity range.

- Measurement range from -110 to +20 °C dew point 0-3000 ppm<sub>v</sub>
- Intrinsically safe version for hazardous area use
- Wide range of process connections for easy installation
- Polymer sensor option for fast response

## CO<sub>2</sub> Measurement

CO<sub>2</sub> Measurement is critical for certain applications such as incubators and for safety when using dry ice. However, CO<sub>2</sub> is also an important parameter to ensure indoor air quality (for human safety or optimum plant growth e.g. for industrial medical cannabis production).

### CP11 – Handheld Instrument

Economical multiple parameter portable device for indoor air monitoring.

- Measures and logs CO<sub>2</sub>, %RH and °C
- Calculates dew point and wet bulb temperature

### CCD-A-2XX – Analog Probe

Analog probe for monitoring incubators.

- Measures up to 20 % CO<sub>2</sub>
- Compatible with RMS-MADC-868/915-A data loggers

### CCD-S-X2 – Digital Probe

Digital probe for life safety and indoor air quality applications.

- Configurable output 2000/5000/10,000 ppm
- Compatible with RMS-LOG-L/868/915 data loggers



Adjustable audible CO<sub>2</sub> alarm

Interchangeable probe for calibration/sterilisation

## Calibration Equipment

Relative humidity probes require regular calibration to ensure continued accuracy. Users of large numbers of probes will have significant cost savings by bringing this in-house and PST have a range of calibration equipment to suit different sizes of operation and budgets.

### HygroGen2 – Humidity Calibrator S or XL

- Chamber volume 2 litres (S); 20 liters (XL)
- Working volume 1.5 litres (S); 17 liters (XL)
- Humidity changes (5...95 %RH, 0.1 %RH stability): < 5 minutes
- Temperature changes (23...50 °C, 0.01 °C stability): < 5 minute

### OptiCal – Precision Relative Humidity and Temperature Calibrator

- Integral chilled mirror reference
- Generate 10 to 90 %RH over +10 to +50 °C (+50 to +122 °F) temperature
- UKAS accredited calibration, as standard
- Humidity and temperature profile generation for unattended verification of sensor

### HygroCal100 – Humidity Validator

- Combine with Optidew 401 chilled mirror hygrometer for cost-effective traceable calibrations
- Intuitive UI makes automating probe verification simple
- Automated validation procedures for hands-off probe verification
- Internal calibration correction cycle ensures continued confidence

### S8000 Remote – High Precision Chilled Mirror with Remote Sensor

- -40 to +120 °C dew-point range with  $\pm 0.1$  °C dew-point accuracy
- Small, compact design
- Easy integration with HygroGen2



### Custom Humidity and Temperature Calibration Systems

Where a standard product doesn't meet the specific needs of an application, Michell's team of design engineers will work with you to develop a custom solution. Michell offers a sophisticated range of humidity/dew-point generators, pressure swing dryers and chilled mirror reference hygrometers – coupled with four decades of experience in working with national standards laboratories to provide humidity calibration equipment around the world.

Ask for our latest calibration brochure for a more detailed overview.



## Process Sensing Technologies

Process Sensing Technologies (PST) provides an unmatched suite of instruments, analyzers and sensors for precision measurements and monitoring in highly demanding end markets. These range from pharmaceutical/ life sciences, speciality gases, semiconductors, O&G, petrochemicals and power to gas detection, food and beverage and building automation.

*Using our products, customers save millions of dollars each year through increased energy efficiency in their processes and reduced process disruptions.*

The quality of food, medicines, semi-conductors and thousands of manufactured goods depends on reliable measurements of critical parameters such as humidity, oxygen, CO, N<sub>2</sub>, H<sub>2</sub>, hydrocarbons, pressure or CO<sub>2</sub> during production, storage and transport. Our products directly improve the profitability of our customers and help them to stay compliant with stringent industry regulations. We own and manufacture the sensing technologies used in the majority of our products. This allows us to remain in a strong leadership position and pass on the benefits of our innovation to our customers.

### PST Leading Brands

- **Analytical Industries** – Electrochemical oxygen sensors and gas-analysis
- **Dynamant** – Infrared gas sensors
- **LDetek** – Ultra low range online analyser
- **Michell Instruments** – Moisture and oxygen sensing and instrumentation
- **Ntron** – Oxygen sensors and analysers
- **Rotronic** – Humidity and temperature instruments, monitoring systems
- **SST Sensing** – Oxygen sensors and liquid level switches

### Group Facts

- Expertise in GAMP5, GxP and FDA regulated applications
- 22 Service and sales subsidiaries
- 8 global engineering and manufacturing locations
- 100+ authorized distributors
- 14 proprietary technologies



Humidity



Temperature



Dew Point



Water Activity



Differential Pressure



Oxygen



CO<sub>2</sub>



Impurities



Flammable Gases



Level

#### North America

Thetford Mines, QC, Canada  
Hamilton, ON, Canada  
Hauppauge, NY, USA  
Pomona, CA, USA

#### Asia

Tokyo, Japan  
Osaka, Japan  
Beijing, China  
Shanghai, China  
Singapore

#### South America

Rio de Janeiro, Brazil

#### EMEA

Coatbridge, Scotland, UK  
Mansfield, UK  
Ely, UK  
Crawley, UK  
Navan, Ireland  
Oosterhout, Netherlands  
Frankfurt, Germany  
Ettlingen, Germany  
Lyon, France  
Zürich, Switzerland  
Milan, Italy  
Dubai, UAE

Global direct sales and service support