



SECURE

ENVIRONMENTAL MONITORING FOR FACILITIES AND CONTROLLED DRUG STORAGE IN HOSPITALS

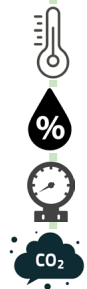


INTRODUCTION

With over 25 years experience working with the Pharmaceutical industry in Ireland, IPP specialises in the area of Secure Data Logging, Mapping and Calibration.

Our particular expertise in Environmental Monitoring Systems (EMS) enables us to provide secure, accurate and reliable solutions for critical monitoring of Product Storage & Incubation as well as the Room environmental conditions in Cleanroom & Laboratory settings.

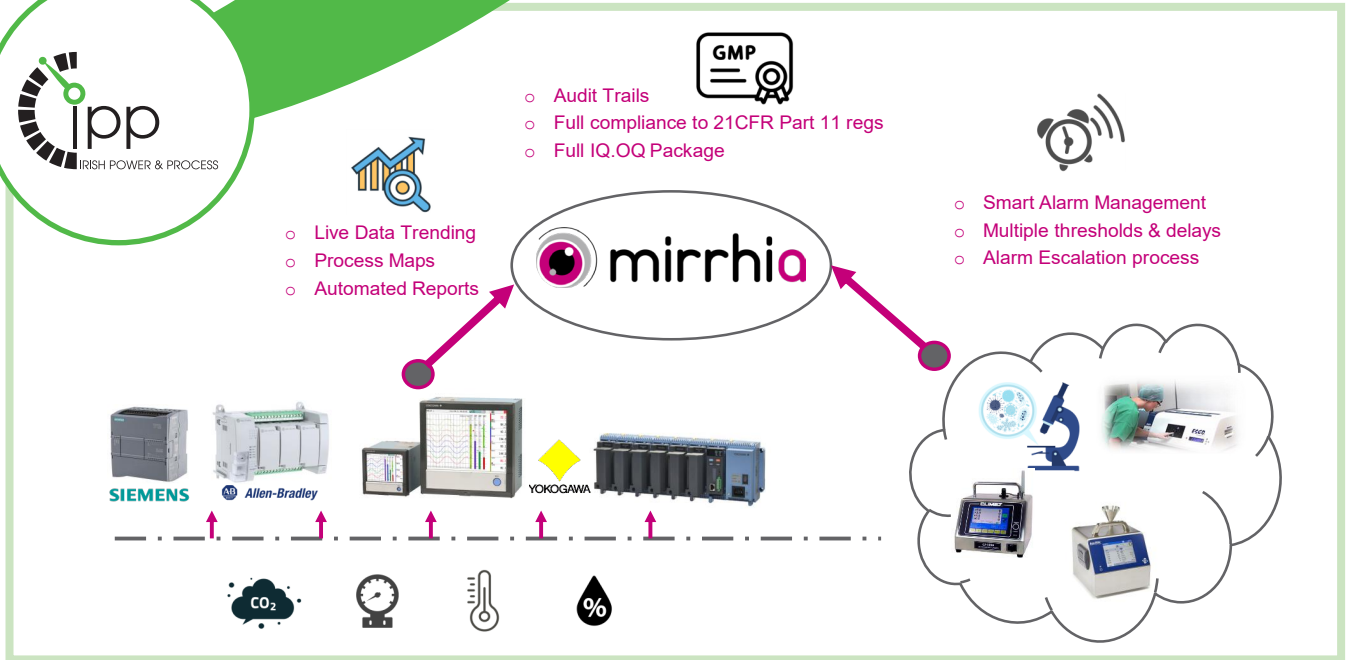
We are also the No.1 provider of Independent Monitoring Systems (IMS) in Ireland into the hospital CSSD departments for monitoring of Steriliser & Washer-Disinfector cycles.





SUMMARY OF CONTENTS

- 1** IPP Turnkey Solutions for Environmental Monitoring
- 2** Mirrhia - Multi-site Monitoring of Product Storage
- 3** Secure Logging of critical Parameters in Product Storage
- 4** Sensors in Critical Product Storage
- 5** Thermal Mapping of Fridges, Freezers & Incubators
- 6** Calibration to ensure Accuracy & Stability



KEY FEATURES

- Multiple EMS process variables including Temperature, Humidity & Differential Pressure.
- In-line with data integrity guidelines the system generates binary encrypted data files with data trending, alarm history and full audit trail.
- Maths functionality - to generate other key process variables such as Mean Kinetic Temperature (MKT).
- Web view - Allowing remote viewing of live data from recorder.
- Ethernet serial communication for interfacing with other site systems.

THE SOLUTION

In addition to providing the Yokogawa paperless recorders and Mirrhia EMS software system, IPP can also offer a complete turnkey EMS system to the customer, providing the knowledge of the instrumentation required and the experience of the regulations governing the monitoring of Environmental data.

THE COMPLETE PACKAGE THAT IPP OFFER INCLUDES

1 SYSTEM INSTALL: Complete install of EMS hardware (recorder) into stainless or mild steel panels with full wiring of independent sensors back to hardware. All channels wired back to terminals and each input individually isolated. Networking of hardware to local server to allow automatic transfer of data to server and web-view access.

2 CONFIGURATION: Complete configuration of hardware to ensure measurements are ranged and grouped correctly. Install of Data viewing software on relevant local PC's for operators to view EMS data in detail if and when necessary.

3 CALIBRATION: Full system or loop calibration of the EMS sensors/probes to the paperless recorder and supply of accredited calibration certs on completion.

4 VALIDATION: Supply of full IQ/OQ documentation for hardware and associated software with availability of a qualified Validation Engineer to provide a full validation execution service.

5 TRAINING: Full on-site training for operators on EMS hardware and software and supply of training certificates on successful completion.

1

IPP TURNKEY SOLUTIONS FOR ENVIRONMENTAL MONITORING



mirrhia
GLOBAL GMP MONITORING SOLUTION

Unique & global GMP monitoring platform

Control in real-time:

- Temperature
- Humidity
- Pressure
- CO₂
- Particles
- pH
- Dew point
- TOC
- Dry contact
- H₂O₂
- Level
- Bacteria
- Fungus
- CFU

And much more...

Mirrhia is an independent monitoring solution, centrally validated, configurable, scalable and open to control all critical parameters



UNIVERSAL

Fully configurable
Multi-connectivity (4-20mA, Ethernet, RF, modbus, OPC, IoT)
Brand-agnostic
Multi-sites and buildings

EXPANDABLE

Easy and automated integration
Adapts to existing rooms
New sensors without system shutdown

ROBUST

Data integrity
Guaranteed compliance
Redundancy, buffering
Gamp5 Category 4 deployment
21 CFR part 11

2

MULTI-SITE MONITORING OF PRODUCT STORAGE

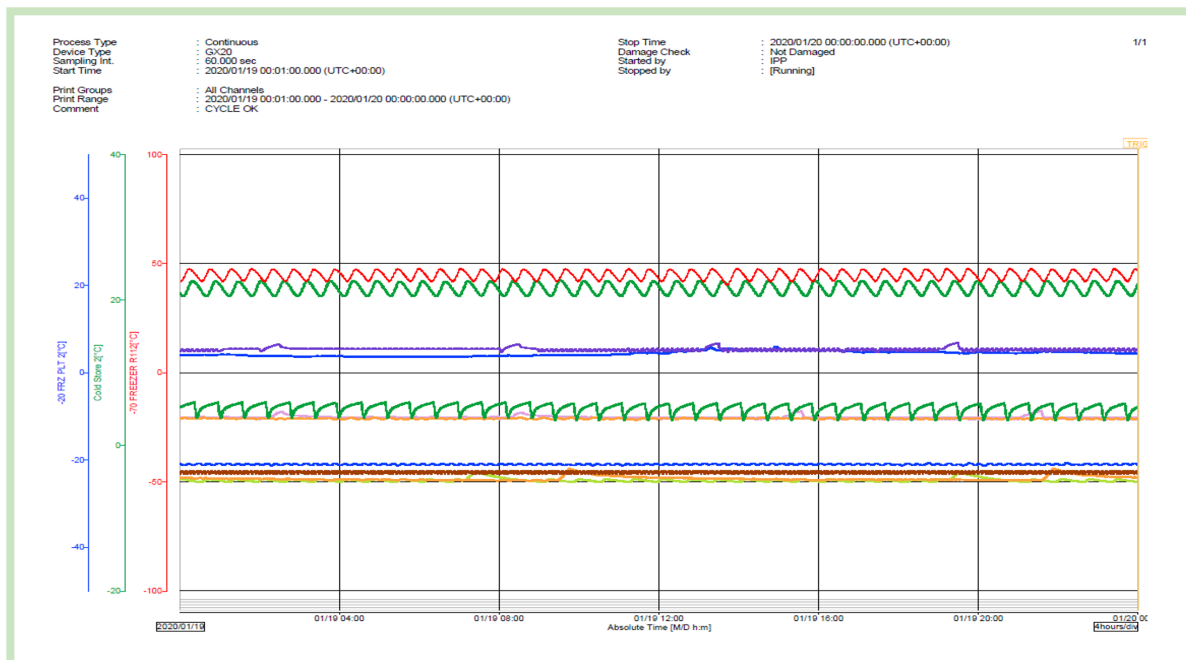


LOGGING CRITICAL PARAMETERS IN PRODUCT STORAGE

When critical process conditions need to be measured securely, then the Yokogawa SmartDac+ GX/GM Paperless Recorders offer the perfect solution. This Data Acquisition system has been successfully installed by IPP in large numbers throughout Ireland in heavily regulated Pharmaceutical and Medical Device companies, audited by both the FDA and HPRA.

These validated systems are typically installed in GMP critical processes where accuracy of measurement and security of data is paramount. Such applications include validated EMS, EPA licensed Environmental monitoring, sterilisation, lyophilisation and WFI processes.

This product owes its success to its ability to measure universal inputs accurately, securely and meeting 21CFR compliance. Its Ethernet functionality allows data to be networked so that data can be accessed from a local PC or Server. It also offers the ability to communicate or integrate where necessary with PLC's, SCADA, LIMS and Data Historians.



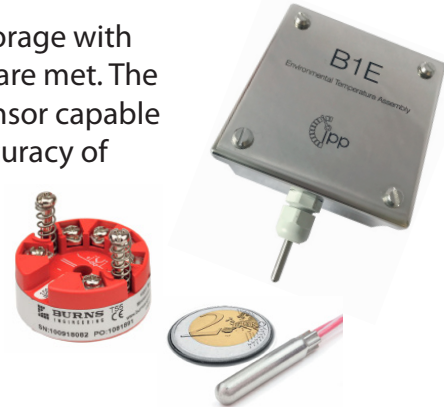
3

LOGGING CRITICAL PARAMETERS IN PRODUCT STORAGE

SENSORS IN CRITICAL PRODUCT STORAGE

B1E – FULL IMMERSION TEMPERATURE SENSOR ASSEMBLY

Temperature is the most critical measurement in Product Storage with accuracy & stability of readings critical to ensure conditions are met. The B1E Temperature Assembly offers a full immersion PT100 sensor capable of measuring as low as -196°C and up to +200 °C with an accuracy of 0.05% of reading. A high accuracy temperature transmitter in a stainless or ABS wall mount enclosure provides a complete solution.



VAISALA HMT HUMIDITY TRANSMITTER



A market leader in humidity sensors & transmitters, Vaisala's HMT120 Humidity Transmitter offers accurate humidity measurements of both rooms and storage Chambers over the full range of 0-100% RH. Accuracy of 1.5%RH with stability as good as 0.5%RH per annual calibration cycle ensures measurement peace of mind.

SONTAY DIFFERENTIAL PRESSURE SENSORS

For cleanroom or Lab environments, the need to ensure that clean air is maintained requires accurate measurement of low and subtle air pressure changes. Sontay Diff. Pressure sensors are designed specifically for these low pressure applications with options ranging as low as 25Pa up to 3000Pa.



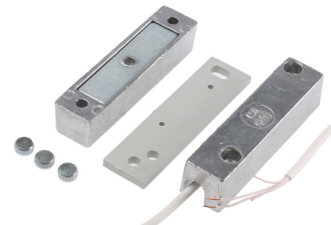
PARTICLE-COUNTERS



CO2 SENSORS



DOOR CONTACTS



We offer a wide range of additional sensors & Instrumentation for Environmental Monitoring applications.

THERMAL MAPPING OF FRIDGES, FREEZERS & INCUBATORS

In any process where Product is stored, cured or sterilised, performing a Thermal Mapping of the Equipment is crucial to identify cold/hot spots and to ensure uniformity of measurement within the area the product will reside.

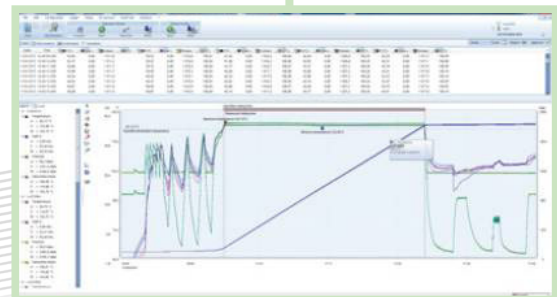
TMI Orion have over 25 years experience in designing suitable data loggers for mapping even the harshest of environments, and meeting all data integrity guidelines & regulations.



Mapping of climate and thermostatic chambers, freezers, cold rooms, etc...

Mapping is necessary to ensure all points of the chamber are at the required temperature.

A data logger operating for days at low temperature is recommended.



TMI-Orion solutions

- **Data loggers**
NanoVACQ Temperature or PicoVACQ or MiniVACQ or VACQ xFlat
- **Software**
Qlever software platform
+ Pharma Module (FDA 21 CFR Part 11)
+ Calibration Module

OR

- Qlever software platform
+Authentication-tracking Module (FDA 21 CFR Part 11)
+Mapping module (FD X15-140/IEC 60068.3.11)
+Calibration Module

- **Connectivity**
2.4 GHz radio modem or wired interface for NanoVACQ and VACQ xFlat
Wired Interface for PicoVACQ and Mini VACQ

CALIBRATION TO ENSURE ACCURACY & STABILITY

No measured value can be relied upon without the level of certainty that the process of Calibration provides. And in the field of Calibration, Fluke has consistently led the market in many disciplines for over 50 years. Their expertise and range of Calibration products extends from Temperature & Pressure through to Electrical & Humidity with both field and lab based solutions available.

TEMPERATURE CALIBRATION

Offering a wide range of Field based Dry Wells & Oil Baths including the most popular 9190A Ultra-Cool Dry Well that can calibrate as low as -95°C ! The perfect calibrator to cover all product storage & environmental temperature calibrations. Reference Thermometers and PRT sensors allow for even greater accuracy and lower uncertainties of measurement.



PRESSURE CALIBRATION



Specialising in very high accuracy lab based calibrators, Fluke extended this knowledge into the portable Field Calibration range including the latest 729 Handheld Automated Pressure Calibrator with built-in pump and accuracies of 0.02% FS. It can also measure & simulate mA plus capability to measure Volts and Temperature (Pt100) making it an all round Field Calibration tool.

HUMIDITY CALIBRATION

A more niche market, Fluke developed a new Humidity Generator to complete at the top end of this market. The 5128 Rhapsod Calibrator offers both chamber storage (for data loggers) and Door Port entry (RH sensors) allowing for up to 5 devices to be calibrated at a time and accuracies of 1% RH.





FOR YOUR PEACE OF MIND, TRUST  TO DELIVER BEYOND YOUR EXPECTATIONS

Irish Power & Process

The Old School House
Stoneyford, Co Kilkenny
Ireland, R95 KD68

t 056 7700800 **f** 056 7700924

w www.irishpowerandprocess.com

e sales@irishpowerandprocess.com

