



The **PST real-time monitoring solutions** are designed to help customers ensure compliance within regulated applications. Monitoring anything from temperature, relative humidity and other environmental parameters that PST can offer.

PST Monitoring offers a range of installation possibilities with both public and exclusive SaaS solutions, On-Premise or directly with a server provided and monitored by PST. Our systems ensure data integrity and help comply to FDA 21 CFR Part 11 and EU Annex 11 requirements.

The **Rotronic** Monitoring System (RMS) is a GAMP©5 category 4 software combined with category 1 hardware, helping users monitor their GxP compliant applications, looking into the critical quality attributes and monitoring critical process parameters, helping focus on patient safety, product quality and data integrity and compliant to EudraLex Annex 11 and FDA 21 CFR Part 11.

- GAMP©5 guidelines for a risk-based approach to compliant GxP computerised systems.
- Category 4 software: Configurable software package.
- Category 1 hardware: Standard hardware components.
- GxP guidelines are designed to ensure that products are safe, meet their intended use and in regulated industries such as drugs, foods, medical devices and cosmetics, adhere to quality processes during manufacturing, control, storage and distribution.



Rotronic RMS Hard – and Software

SensoScientific offers a wide range of temperature sensors and temperature probes that will provide you with the data and control you need for real-time management, audit tracking, and automating regulatory compliance. Whether for a hospital, pharmacy, laboratory, food safety, or in transit application, you will be sure to find the perfect temperature monitoring system for your needs. Our sensors enable your organization to monitor real-time environmental conditions, enterprise-wide. Our state-of-the-art system is always accurate and can monitor other environmental factors including differential pressure, water leaks, humidity, light, carbon dioxide, oxygen, dry contact, and formaldehyde. With IoT and cloud-based storage, you will always be aware of what is going on in your environment and be immediately alerted to any changes. We also pride ourselves on our 24/7 technical support and our experts are always ready to answer any questions you may have.



Datalogger and Probe – SensoScientific

Isensix offers a full complement of sensors for a wide range of applications to meet the monitoring needs across a variety of industries specialized in hospital, laboratory and blood bank applications, departments and groups. Guardian is able to easily scale, adapt and meet the needs of any facility environment. It also captures and reports complex environmental data directly from the unit, providing instant documentation of personnel, events and corrective actions. Equipped with unique wireless sensors, Guardian lets facilities move equipment or entire areas without disrupting software configuration. This is a complete solution for your facility's temperature monitoring needs. duration for optimal ventilation.



Datalogger – Isensix Guardian

Offerings		Rotronic	SensoScientific	Isensix
Software solution	Public Cloud	Yes (Interxion)	Yes	Yes
	Exclusive cloud	Yes (Interxion or Azure)	Yes	Yes
	On-premis installation	Yes	Yes	Yes
	Software on VM or physical server	No	Yes	Yes
	App	No	Yes	Mobile Web
Notifications	E-Mail	Yes	Yes	Yes
	SMS	Yes, additional cost	Yes	Yes
	Telephone call	Yes, additional cost	Yes	Yes
	Text	No	Yes	Yes
	Fax	No	Yes	No
	Pager	No	Yes	Yes
Hardware connectivity	868MHz	Yes	Yes	No
	915MHz	Yes	Yes	Yes
	2,4GHz	No	Yes	Yes
	WiFi 2,4GHz	No	Yes	No
	WiFi 5,0GHz	No	Yes	No
	LAN	Yes	Yes	No
	Cellular	No	Yes	No
	MODBUS TCP protocol	Yes	No	No
	Proprietary encrypted http protocol	Yes	Yes	Yes

Offerings	Rotronic	SensoScientific	Isensix	
Hardware features	LAN power supply	24V and PoE and backup battery	No	No
	Wireless power supply	24V and battery (MLOG devices, battery only)	Yes	Yes
	LAN with display	Yes (RMS-LOG-L-D; RMS-D-L)	Yes	No
	Wireless with display	No	Yes	No
	Visual alarm	Yes (RMS-LOG-L-D; RMS-D-L)	Yes	Yes
	Min/Max value on display	No	Yes	No
	Audible alarm	Yes (RMS-LOG-L-D)	Yes	Yes
	Wake up button for real-time readings	No	Yes	No
	Keypad for confirmation inputs	No	Yes	Yes
	High accuracy temperature and relative humidity measurement	±0.8 %RH / ±0.1 K, at 10...30 °C	No	No
	High accuracy temperature measurement	±0.25 °C at -50...85 °C	Yes	Yes
	Over the air firmware update	Yes	Yes	Yes
	Probe exchange/snap calibration	Yes	Yes	Yes
Measured parameters	Temperature (NTC)	Yes (T10)	Yes	Yes
	Temperature (Pt100)	Yes (T30)	Yes	No
	Digital temperature probe	Yes (RMS-TCD)	Yes	No
	Temperature and relative humidity	Yes (RMS-HCD, RMS-MLOG-B)	Yes	Yes
	Digital temperature and relative humidity probe	Yes (RMS-HCD)	Yes	No
	Differential pressure	Yes (RMS-PCD)	Yes	Yes
	Digital differential pressure probe	Yes (RMS-PCD)	Yes	Yes
	CO2	Yes (CCA: 0...20%CO2)	Yes	Yes
	Digital CO2 probe	No	No	No
	O2	Yes (0...21%O2)	Yes	Yes
	Digital O2 probe	No	No	No
	Lux	Yes (RMS-MLOG-LGT)	No	No
	Analogue input	Yes (RMS-ADC and RMS-MADC)	Yes	Yes
	Digital input	Yes (RMS-DI)	Yes	Yes
	Digital output	Yes (RMS-DO)	No	No
	MODBUS TCP input	Yes (RMS-CONVERTER)	No	No
API input	Yes (RMS-JSON-API software)	Yes	Yes	
Services	GxP and non-GxP services			Please reach out to your local PST Office for the overview of services

PST List of Service Offerings

- Traceable calibration
- ISO17025 calibration
- On site traceable calibration
- On site ISO17025 calibration
- Sensor exchange program
- As left calibration
- Area qualification (mapping)
- Device qualification (mapping)
- System validation
- Software installation
- Software configuration
- Service level agreement
- Site acceptance test
- Factory acceptance test
- CareFree+
- Training
- Server monitoring

Cloud or On-Premis

Essentially, the fundamental difference between cloud vs on-premise software is where it resides. On-premise software is installed locally, on your business' computers and servers, where cloud software is hosted on the vendor's server and accessed via a web browser.

As well as accessibility, there are a raft of other things that need to be considered when making a decision, including software ownership, cost of ownership, software updates and additional services, such as support and implementation. Here we explore all the **pros** and **cons**.

Cloud Software

Advantages

- Anywhere and anytime access
You can access your applications anytime and anywhere via a web browser from any device.
- Affordable
Cloud requires no upfront costs, instead you make regular payments, which makes it an operating expense (OpEx). While the monthly cost adds up over time, maintenance and support services are included removing the need for annual contracts.
- Predictable costs
Benefit from predictable monthly payments that cover software licences, upgrades, support and daily back-ups.
- Worry-free IT
Because cloud software is hosted for you, you don't need to worry about the maintenance of your software or the hardware it resides on, compatibility and upgrades are taken care of by the cloud service provider.
- High levels of security
Data centres employ security measures beyond the affordability of most businesses, therefore your data is often safer in the cloud than on a server in your offices.
- Quick deployment
Cloud-based software is deployed over the Internet in a matter of hours/days because, compared to on premise applications which needs to be installed on a physical server and each PC or laptop.
- Scalability
Cloud technologies provide greater flexibility as you only pay for what you use and can easily scale to meet demand, for example adding and scaling back licenses.
- Lower energy costs
When you move to the cloud, you no longer have to pay to power on-premise servers or to maintain their environment. This significantly reduces the amount you pay on your energy bills.

The Drawbacks

- **Connectivity**
Cloud solutions require reliable internet access for you to remain productive.
- **Long-term costs**
Although requiring a lower upfront investment, cloud applications can be more costly over the course of the system's life cycle, increasing total cost of ownership (TCO).
- **Less customisable**
Cloud software is typically configurable but depending on how it is hosted a cloud solution may not be able to cope with complex development.

On Premise Deployments

On Premise Advantages

- **Total Cost of Ownership**
Since you are only paying for your user licenses once, an on-premise solution can have a lower Total Cost of Ownership (TCO) than a cloud system.
- **Complete control**
Your data, hardware and software platforms are all yours. You decide on the configuration, the upgrades and system changes.
- **Uptime**
With on-premise systems, you do not rely on internet connectivity or external factors to access your software.

The Drawbacks

- **Capital expenditure**
On-premise systems usually require upfront purchase which means capital expenditure (CapEx) is often required. Isensix includes this as part of the Annual Service Plan at a profit.
- **Isensix includes all of these services as part of the Annual Service Plan and includes warranty.**
- **Longer implementation times**
On-premise implementations take longer due to the time needed to complete installations on servers. Isensix has no client software requirements.

Wired or Wireless Secure Data Communication

The choice of a wireless data logger compared to a wired data logger is very important based upon the risk analysis as well as the existing infrastructure. Here is an overview of the advantages/inconveniences of the communication.

Wireless

- **Data integrity:** Data stored on the logger with a backup battery and 24V power supply.
- **Security:** Short data transmission range.
- **Range:** Limited: 868 or 915 MHz and 2,4GHz.
- **Reliability:** Redundant or parallel operation with various gateways.
- **Investment:** Decrease wiring costs. Fast and easy implementation of new measuring points. Projects accomplished faster due to no cable requirements. Easy to relocate physical measuring points.
- **Troubleshooting:** No more looking for errors in cabling.

Wired

- **Data integrity:** Data stored on the logger with a backup battery, PoE and 24V power supply.
- **Security:** Physical network access required. No loss of communication for high risk applications.
- **Reliability:** If the Ethernet network is working, then communication is working.
- **Investment:** Link up to the existing Ethernet network. Only one sensor per Ethernet port.

What is a Digital Sensor

A digital sensor is a measurement device that sends out a digital signal. The main advantage of a digital sensor compared to an analog sensor is the information sent. Whereas the analog sensor will only send an mA or voltage value (that is converted into a measurement value), a digital sensor can send much more data such as:

- Measurement value(s)
- Device serial number
- Device status
- Calibration data
- Adjustment data
- ...

The Rotronic digital sensors all have onboard memory and can be user-calibrated/adjusted.

What are the Main Advantages of Using Digital Sensors within an EMS

The Rotronic digital sensors communicate to data loggers (wired or wireless) and all communication to the server and database is done digitally as such there is no loss in accuracy during data transmission. This means, unlike analog sensors, no loop check is required during device installation and qualification/validation.

A major advantage of using digital sensors within an EMS is the possibility to use the additional data and reduce the amount of downtime, this is especially valid during the calibration period or during service periods.

With analog sensors, a calibration can be done either in a calibration laboratory (internal or external) or in situ if the application permits. If the calibration is carried out in situ, then the loop check is also done at the same time. For calibrations carried out in a laboratory, the device needs to be dismantled (leading to system downtime). With the Rotronic digital probes, a simple hot-swap can be carried out, resulting in no downtime:

- Manually unscrew the existing probe
- Manually screw in a “new” precalibrated probe

The existing probe can then be calibrated in a laboratory and either put back in its original place or can also be used else where in the facility. Another advantage is that thanks to the digital system and the FDA CFR 21 Part 11/EU Annex 11 requirements, RMS will automatically show that a probe has been replaced with the audit trail together with the time and data and the probe serial number prior to the exchange and the probe serial number after the exchange.

RMS offers a calibration/adjustment feature with the generation of calibration certificates.