

Rotronic Monitoring System

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Technical paper

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Understanding RMS from an IT perspective



Abbreviations

CFR	Code of Federal Regulations
CL	Change Log
CS	Configuration Specification
FAT	Factory Acceptance Test
FDA	Food and Drug Administration
FRS	Functional Requirement Specification
FS	Functional Specification
GAMP	Good Automated Manufacturing Practice
GxP	Good x Practice
IQ	Installation Qualification
ISO	International Organisation for Standardisation
OQ	Operational Qualification
PQ	Performance Qualification
QMS	Quality Management System
RA	Risk Assessment
RMS	Rotronic Monitoring System
RTM	Requirement Traceability Matrix
SaaS	Software as a Service
SAT	Site Acceptance Test
SLA	Service Level Agreement
SPOC	Single Point of Contact
URS	User Requirement Specification
USP	United States Pharmacopeia
VMP	Validation Master Plan
VP	Validation Plan
VSS	Validation Script Specification
WP	White Paper

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1. Scope

This document is designed to clarify what the Rotronic Monitoring system is, from the user level to the IT manager level. Based upon the details from this document, the IT manager should be able to define if RMS is compliant to the internal IT requirements.

2. Outline

With the details described within the practical answer, the IT manager should be able to gain an understanding of where and why the user requires such an environmental monitoring system.

The technical answer offers the IT manager a deeper insight into all of the various elements of RMS. Furthermore, a description of the necessary tools to setup RMS via the Cloud solution are listed.

3. What is the Rotronic Monitoring System? A practical answer and a technical answer.

The Rotronic Monitoring System is a modern continuous monitoring system that embraces open architecture and interoperability as well as providing a compliant system for validated applications.

RMS is a GAMP@5¹ category 4 software² combined with category 1 hardware³, helping users monitor their GxP⁴ 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 11⁵ and FDA 21 CFR Part 11⁶.

¹ GAMP@5 guidelines for a risk-based approach to compliant GxP computerised systems.

² Category 4 software: Configurable software package.

³ Category 1 hardware: Standard hardware components.

⁴ 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.

⁵ EudraLex is the collection of rules and regulations governing medicinal products in Europe. Annex 11 is part of the European GMP guidelines and defines the terms of reference for computerised systems used by organisations in the pharmaceutical industry. Amongst other things, Annex 11 defines the criteria under which electronic records and electronic signatures are considered to be managed.

⁶ FDA is the Food and Drug Administration that is responsible for protecting the public health by ensuring the safety, efficacy and security of human and veterinary drugs, biological products and medical devices; and by ensuring the safety of the USA's food supply, cosmetics and products that emit radiation. The CFR 21 part 11 established the RDA regulations on electronic records and electronic signatures (ERES).

ROTRONIC MONITORING SYSTEM RMS: ON-PREMISE OR SAAS SOLUTIONS

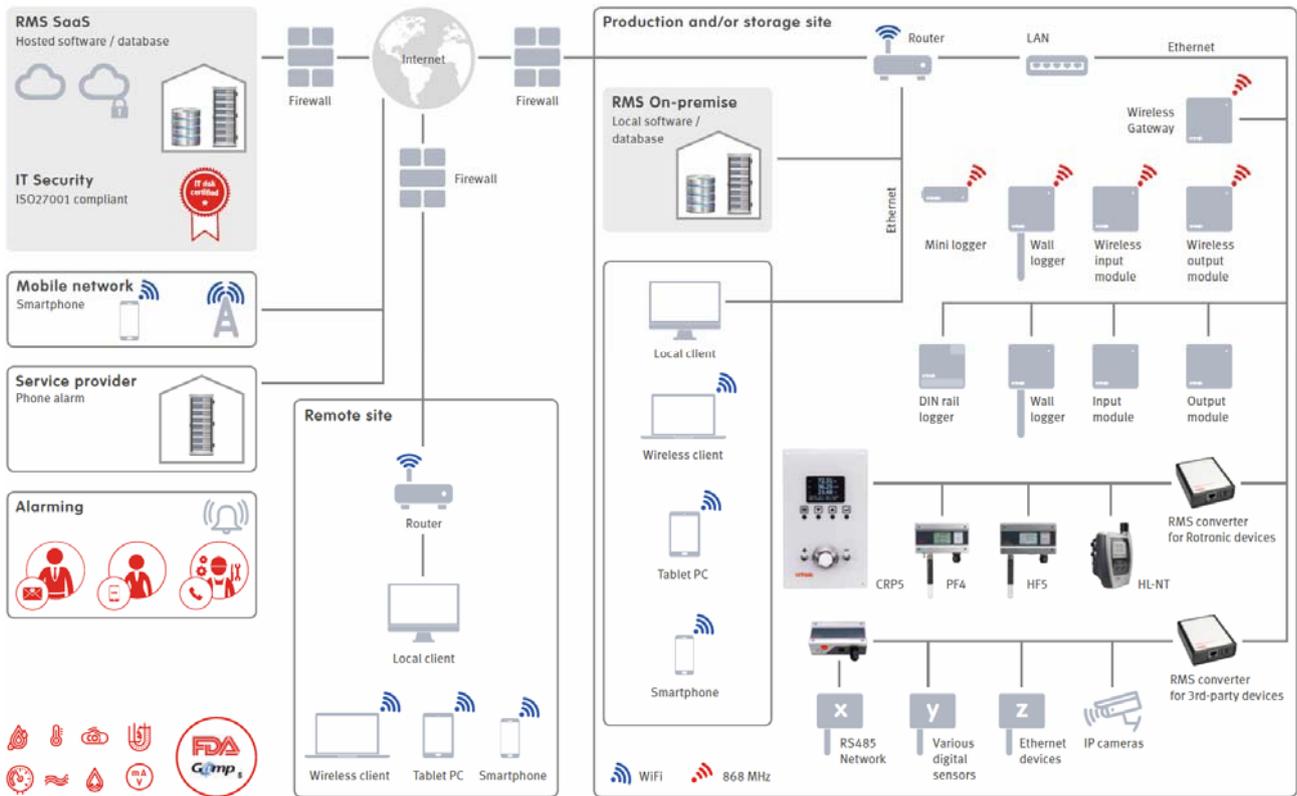


Figure 1: RMS architecture

4. The practical answer - for end users, project managers and smaller organisations

The practical answer is visible via our online demonstration “Login” and via the details on our RMS website: www.rotronic.com/rms.

Company name: Rotronic AG
User name: Gast
Password Gast

In short, RMS provides a continuous and configurable monitoring system with a detailed web interface. The system provides users with ease of access to data, reliable and manageable alarms and extensive reporting.

Importantly RMS can support existing hardware and interact with other software/hardware platforms.

RMS can be provided as a Software as a Service (hosted cloud service), an exclusive cloud service (for validated applications) or using a traditional on-premise software installed on their servers. For more details about the SaaS solution, please visit: www.rotronic.com/rms (RMS database).

4.1. A complete hardware range

- Measure various parameters (temperature, relative humidity, pressure, particles...),
- Hardware with data logging capacities and fail safe mode with back up batteries,
- Ethernet, WiFi, industrial wireless and RS485 communication,
- The possibility to integrate both analogue and digital third party devices.

The overview of the current hardware devices can be found online: www.rotronic.com/rms (RMS hardware and Integrate third-party devices)

4.2. A complete range of software functions:

- A system designed around the GAMP@5 recommendations,
- Live interactive charts,
- Full reporting and automated/scheduled report generation,
- Complete logging in line with GxP requirements,
- Full alarming with logic and time schedules,
- Auto back fill and retrospective alarms (ideal for transport logging),
- Interactive layouts,
- Complete user rights management,
- Compliant to GxP, designed around ease of validation,
- ...

An updated and detailed overview of the software functions can be found on website: www.rotronic.com/rms (Monitoring Software)

4.3. Various alarming possibilities:

- E-Mail,
- Phone,
- SMS,
- Relay,
- Custom protocol alarm outputs,

More details can be found on the website: www.rotronic.com/rms (RMS alarming).

5. The technical answer - for IT project managers, system integrators and cyber security managers.

Let's now go a bit deeper. RMS software is an aspx.net software package. As an aspx.net system it runs server side and the user interface is via a web browser or app through standard client devices (PC or smart device). All data is stored on a MS-SQL database.

The software is programmed using ASP.NET, VB.NET and Javascript. The software is developed following the GAMP@5 guidelines and continuous requirement engineering, iterative software development with bi-yearly releases and a three year time frame for larger releases.

The RMS cloud has an SSL A rating, see figure 2.

SSL Report: rms.rotronic.com (156.67.38.83)

Assessed on: Tue, 15 May 2016 18:53:58 UTC | HIDDEN | [Clear cache](#)

[Scan Another »](#)



Figure 2: SSL Report for rms.rotronic.com

For many organisations once end-users approve of a system the challenge is getting the system approved and installed in line with wider corporate policies and security. So far we have found that in discussions with IT project managers and cyber security managers, RMS has met their requirements – usually much to the surprise of the end users who perhaps initially expect a protracted battle!

5.1. The RMS software has two core elements.

5.1.1. Webservice

This is the software aspect of RMS. The webservice provides the interactive webpage to present data for end users and allow system configuration. The webservice also works in the background to interact with hardware and the database. Typically the webpage will be part of the local intranet with an address like rms.yourorganisation.com, optionally the webpage can also be made accessible from the internet outside your organisation (like our cloud service which is available at <http://rms.rotronic.com/rms>). For the clients (end users) no special software or plugins are required just a standard web-browser.

More technically the RMS webservice is built around ASP.Net framework and runs under Windows IIS (internet information services). The webservice therefore requires a Windows Server (2008, 2012 or 2016). The RMS software can be run on a standard PC with IIS enabled but this is not usually advised except for specific applications.

The web software runs under Windows IIS and generates standard aspx.net web pages. No client plugins are required to access the web software interface simply a standard web browser.

5.1.2. SQL Database

The second part of the RMS is its database. All device, configuration, user and measured data is stored within a standard MS-SQL database. The database is accessed by the webservice to store and read data as required. An existing SQL server can be used if available, otherwise SQL-Express is free to install.

More technically the RMS database requires Microsoft-SQL Express or higher, the database can be on the same server as the webservice or a separate machine.

As RMS is built around standard server based systems, there is full support for load balancing and failover, as such should a webserver or SQL server fail a redundant/spare can take over. This is standard procedure for larger IT systems.

IIS server and MS-SQL server can be on the same or separate servers. Load balancing and redundant servers for both SQL and IIS are supported and recommended for large installations.

No personal data is stored outside the SQL database (the hardware only stores a unique serial code, date, time and measured values – as such no private data passes between hardware and software).

5.2. The RMS hardware.

All Rotronic hardware is ethernet based or wireless back to ethernet gateways. Ethernet devices can be powered via PoE, 24VDC and/or batteries, wireless devices are powered either by battery and/or 24VDC. Selected third party devices may require local mains/24VDC power. RMS devices communicate back to the server via port 80. All RMS hardware initiates communication to the server (client-server model). Hardware can be initially configured with IP configuration and server address via RMS-Config software (windows application) or in advance by Rotronic. RMS supports multisite projects and remote servers.

The wireless devices communicate over 868/915MHz back to an Ethernet Gateway. 868 and 915MHz are low frequency industrial radio bands. We use a proprietary communication protocol and the only information transmitted is the device serial number, time and measured values. All additional data (name, location, owner, alarm conditions etc is stored and used by the server software and associated MS-SQL database).

A note on RMS hardware; All Rotronic hardware initiates communication with the webservice via port 80. For cloud applications this means only port 80 must be opened outbound to allow the devices to initiate outbound communications to the server. All gateways have standard IP configurations (DHCP or fixed).

Third party data/device support is possible via RESTful API or direct interaction within the SQL database.

An overview of the RMS communication can be seen below:

RMS COMMUNICATION

OPERATING SYSTEMS

-  **Gateway / Lan & RF-Logger**
Rotronic firmware
-  **Mini Logger**
Rotronic firmware
-  **Converter**
Linux based operating system with Rotronic firmware

SECURITY

- LAN communication between devices and server (HTTP):
- AES128 encryption
 - Diffie-Hellman key exchange algorithm

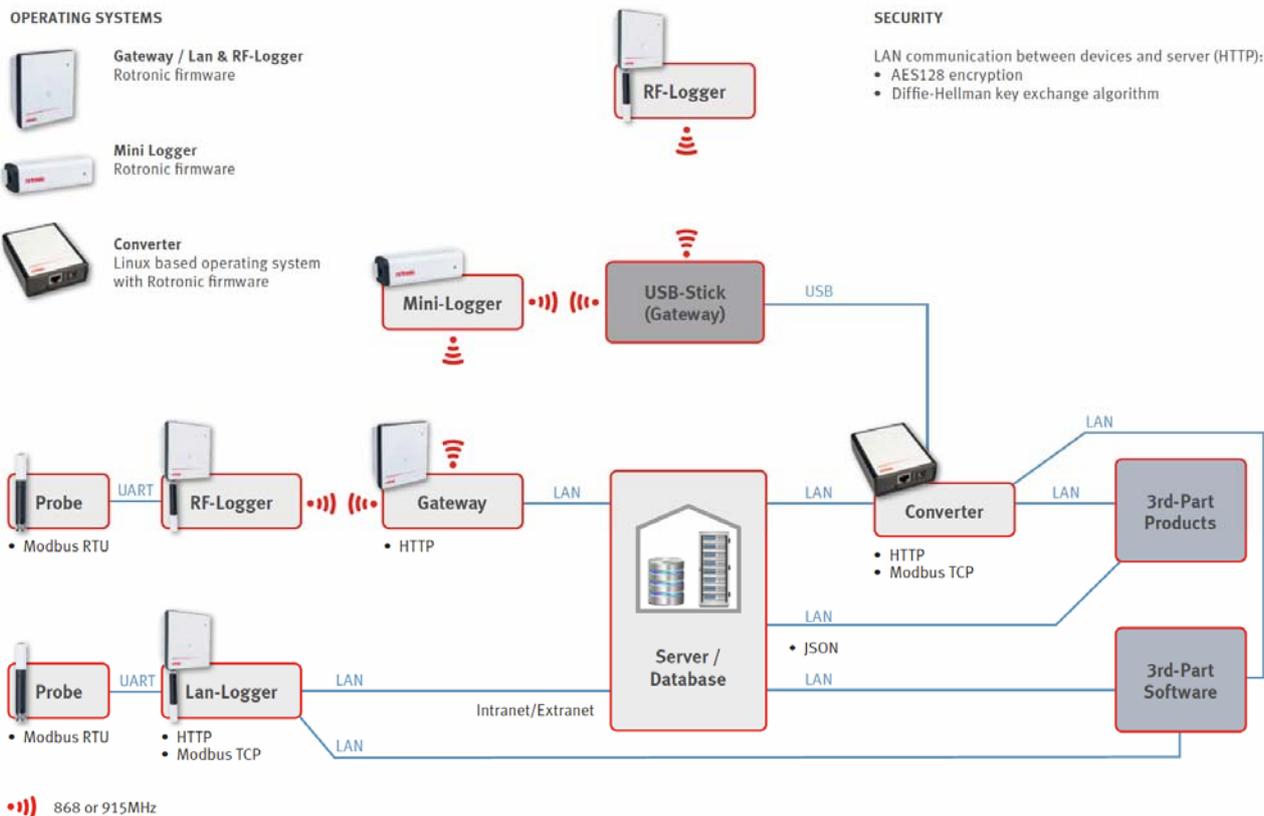


Figure 3: RMS communication

5.3. Some other technical points about RMS.

The on-premise software can be installed on your local servers completely inside your firewall. All functions of RMS can be operated from within your network. Internet access is only required for SMS and Telephone alerts. The RMS software has no issues with automatic updates of the operating system. When the server is offline, the values are stored within the data logger (no alarms are triggered during this time). The data can automatically be sent to the database once the system is up and running again.

RMS supports LDAP logins so can utilise existing usernames and passwords from your systems (only valid for on-premise and exclusive cloud solutions).

Full user rights structures can be created via RMS ensuring selected access and rights for every device, function and user.

RMS supports optional third party digital data/device/software integration via a JSON API to write data to RMS and read data out. In addition direct interaction with the SQL is possible for third party analytics and reporting. As standard RMS generates PDF and CSV exports via web interface. Data is stored permanently on the SQL database, RMS Enterprise version includes an archive function so inactive devices are archived within the system (all log, event, system data related to archived devices is still on the SQL database and accessible via the archive section of the web software).

The Webpage data is binary coded and authentication uses AES128 encryption, Key exchange uses diffie-hellman key algorithm.

6. Setup RMS using the Rotronic Cloud

6.1. What is required from Rotronic and from the customer side.

6.1.1. Rotronic information:

- Download the latest version of RMS-Config online to be able to configure the settings:
<https://www.rotronic.com/en/rms/downloads-rms>
- Webservice host: rms.rotronic.com
- Webservice path: /wService/wService3.DeviceService.svc
- A user setup with certain rights within the Rotronic demo-cloud (or another cloud)

6.1.2. Customer information:

- A PC with internet connection and a web browser.
- A 24VDC power supply or PoE
- A free Ethernet port per device and a CAT5e Ethernet cable
- IP address configuration:
 - DHCP (Dynamic Host Configuration Protocol) servers
 - Once devices are connected to the LAN a list of IP addresses allocated to Rotronic devices is required.
 - MAC addresses of Rotronic hardware are included on device configuration certificates.
 - Static IP (no DHCP) servers
 - A list of available IP address which can be utilised by Rotronic devices should be provided.
 - A list of Device MAC can be provided in advance.
- It is crucial that the port 80 is open to in order for the communication to work.

 RMS-CONFIG

File	Device	Settings	Help
LAN Logger [61766519]			
Info	Measurement	Settings	Logdata
Settings			
Network			
DHCP	<input type="checkbox"/>		
IP address	<input type="text" value="0 . 0 . 0 . 0"/>		
Subnet	<input type="text" value="0 . 0 . 0 . 0"/>		
Gateway	<input type="text" value="0 . 0 . 0 . 0"/>		
DNS (primary)	<input type="text" value=" . . ."/>		
DNS (secondary)	<input type="text" value=" . . . "/>		
Discovery	<input checked="" type="checkbox"/>		
Modbus	<input checked="" type="checkbox"/>		
Web service			
Host	<input type="text" value="rms.rotronic.com"/>		
Path	<input type="text" value="/wService/wService3.DeviceService.svc"/>		
Port	<input type="text" value="80"/>		
Server			
Modbus byte order	<input type="text" value="WordSwap"/>		

Figure 4: RMS-Config