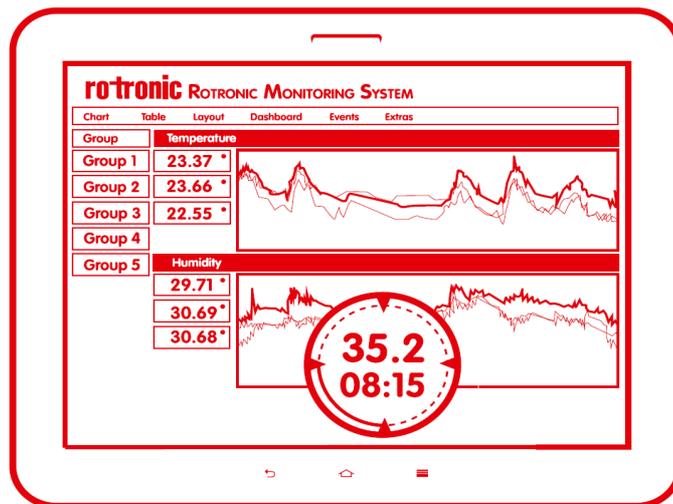


Rotronic Monitoring System
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Release Notes - RMS Software
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Version: 2.0.1.20022



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1. Version Overview

Please find below the meaning of the version.

- 1: Major version number.
- X.1: Minor version number.
- X.X.1: Bug fix or specific update version number.
- X.X.X.1: Year and day of compilation.

2. Rotronic Tracking System

Rotronic use a tracking system to monitor bugs, features, improvements and change requests. This tracking system is the basis for any software, hardware and firmware User Requirement Specification based upon the GAMP@5 validation model.

Each point will be recognised with an ID (eg. RMS-XXX). A description and details are attributed to each point within the tracking system.

All changes documented within the RMS Release Notes will have an ID number and a description.

IMPORTANT: Within the release notes only the most important or relevant updates will be documented. Please contact Rotronic AG directly (rms@rotronic.ch) should more details be required.

3. Version Control

Version	Release
V2.0.0.19353	James Pickering, 6 th of January 2020.
V2.0.1.xxx	James Pickering, 21 st of January 2020.

4. Version V2.0.1.20022

4.1. Release Details

This software version is the hotfix for specific bugs found within the V2.0.0.19353 of the RMS software.

4.2. New Features

ID	Description
RMS-2609	Improved automatic execution of high number of commands.

4.3. Improvements

N/A

4.4. Bug Fixes

ID	Description
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RMS-2610	PDF reports were only working in the Enterprise version of the software.
RMS-2620	E-Mail alarms were showing the server time zone and not the user time zone.
RMS-2619	E-Mail chart is attached instead of integrated into the E-Mail.
RMS-2617	The wrong RMS version number is shown in the Validation protocol.
RMS-2616	RMS E-Mail account is blocked for 5 minutes when the incorrect password is added.
RMS-2615	Devices added via the RMS-CONVERTER-100 (without onboard memory) generate a datagap event every 29 hours.
RMS-2612	Devices added via the RMS-CONVERTER-100 timeout after initial pairing.
RMS-2453	The repeat actions for an alarm scheme is not working.
RMS-2279	The charts in warning/alarm events are empty.
RMS-2581	When updating RMS firmware, the message no properties exist appears and the firmware update is not possible.
RMS-2586	Java script adaptation for google chrome.
RMS-2414	MPT's appear when selecting E-Mail report receivers.
RMS-2286	T10-00xx selection issues.
RMS-1190	E-Mail sent with delay.
RMS-1082	Calibration reminder switches to 01.01.01.
RMS-1052	Backfill datagap after database issues.
RMS-797	No time out alarm when all devices offline.
RMS-561	Check pending data restore not working after service restart.

4.5. Known Errors

A list of known errors exists, please contact Rotronic for more details: rms@rotronic.ch.

4.6. Validation Documentation

For validated systems using the Rotronic GxP validation documentation, the V1.3. must be used.

4.7. Risk Analysis

The Rotronic Monitoring System software has been thoroughly tested. However, As the software architecture has been upgraded, there is a risk that issues will occur. The detectability will depend on how the customer uses the RMS software and as of such must be defined by the customer.

The probability that the bugs persist is low. The severity must be judged by the end user to define the risk class. The detectability will depend on how the customer uses the RMS software and as of such must be defined by the customer.

Rotronic recommend a complete system validation based upon the features used. For software updates, only the new functions can be validated, however, this remains the regulated users decision.

The regulated user knows their application and process and as such should carry out the necessary risk assessment to determine the severity, probability and detectability and define the process risk class based upon the features used within RMS. Please see the RMS-RA risk assessment for more details.

5. Version V2.0.0.19353

5.1. Release Details

This software version has been programmed to improve the RMS Cloud architecture due to the high number of commands being sent.

5.2. New Features

ID	Description
RMS-2259	New software architecture. Details: The RMS software structure has been improved. The main benefits are: <ul style="list-style-type: none"> - Scaling for the cloud: <ul style="list-style-type: none"> o The system is improved for larger amounts of devices and measuring points. o Stability improvement.
RMS-2536	Add a help button.

5.3. Improvements

ID	Description
RMS-2533	Change gateway concept. <ul style="list-style-type: none"> - The average of the last 5 RSSI values is taken. - If one value is missing, the average RSSI value will be reduced by 10. - The gateway will be switched if the difference is $\geq 15\text{dB}$ (or 10dBm if the RSSI $< -90\text{dBm}$).
RMS-2532	Adapted download commands. <ul style="list-style-type: none"> - The download commands will be sent over a period of 3 days. After 3 days a data gap will be created. - The download command will be sent at increasing intervals. The intervals will be doubled until a maximum of 2 hours: (eg: 1, 2, 4, 8, 16, 32, 64, 120, 120, 120...). - Within 3 days, the around 40 download trials will happen.
RMS-2534	The RMS-Monitor has been removed from the system.
RMS-2586	The RMS software will work with the latest Google Chrome update (Java Script).

5.4. Bug Fixes

ID	Description
RMS-2389	Typo: "AES Key Refresh" not "AES Key Refeseh".
RMS-2383	Unit missing in PDF reports.
RMS-2294	Property Definitions cannot be overwritten.
RMS-2293	Firmware update: "NoPropertyData".
RMS-2234	Not possible to archive a measuring point.
RMS-1178	MPT-number not available within an SMS.
RMS-1117	Data from an unassigned gateway will not be taken (if encrypted).
RMS-1093	Archiving crashed when copying measuring data.
RMS-1051	Software exception: UpdateCalculations.

5.5. Known Errors

A list of known errors exists, please contact Rotronic for more details: rms@rotronic.ch.

5.6. Validation Documentation

For validated systems using the Rotronic GxP validation documentation, the V1.3. must be used.

5.7. Risk Analysis

The Rotronic Monitoring System software has been thoroughly tested. However, As the software architecture has been upgraded, there is a risk that issues will occur. The detectability will depend on how the customer uses the RMS software and as of such must be defined by the customer.

The probability that the bugs persist is low. The severity must be judged by the end user to define the risk class. The detectability will depend on how the customer uses the RMS software and as of such must be defined by the customer.

Rotronic recommend a complete system validation based upon the features used. For software updates, only the new functions can be validated, however, this remains the regulated users decision.

The regulated user knows their application and process and as such should carry out the necessary risk assessment to determine the severity, probability and detectability and define the process risk class based upon the features used within RMS. Please see the RMS-RA risk assessment for more details.

6. Version V1.3.3.19301

6.1. Release Details

This software version has been programmed to add an additional feature as a proof of concept. This is the only adaptation compared to the software V1.3.2.19242. This release is not available for customers.

6.2. New Features

N/A

6.3. Improvements

N/A

6.4. Bug Fixes

ID	Description
RMS-2491	SMS and Telephone alarm feature.

6.5. Known Errors

N/A

6.6. Validation Documentation

N/A

6.7. Risk Analysis

N/A

7. Version V1.3.2.19242

7.1. Release Details

This software version has been programmed to fix a crucial bug: RMS-2469. This is the only adaptation compared to the software V1.3.1.18260. This is release was a specific customer release and was not communicated.

7.2. New Features

N/A

7.3. Improvements

N/A

7.4. Bug Fixes

ID	Description
RMS-2469	Alarm Time Counter (System-MPT) does not always reset after 24 hours. Details: the alarm time counter is a system measuring point. It counts upwards when an alarm is active. The counter should reset at midnight (00:00). The reset does not always take place. Root cause: If the alarm time counter measuring point update takes place after midnight, before the reset check is executed (within a time slot of 2 seconds), then the reset will not work correctly.

7.5. Known Errors

N/A

7.6. Validation Documentation

For validated systems using the Rotronic GxP validation documentation, the V1.3. must be used.

7.7. Risk Analysis

The RMS-2469 bug fix has been thoroughly tested.

The probability that the bug persists is low. The severity must be judged by the end user to define the risk class. The detectability will depend on how the customer uses the RMS software and as of such must be defined by the customer.

The release test, which takes place for every official software release, has not been carried out for this version. However, due to the minor code change (only one (1) code class affected), the risk, that another bug has been introduced within this version is also low.

No changes in the database structure took place within this upgrade; therefore the risk when upgrading the software in the future remains also remains low.

8. Version V1.3.1.18260

8.1. Release Details

The release includes bug fixes.

8.2. New Features

N/A

8.3. Improvements

N/A

8.4. Bug Fixes

ID	Description
RMS-1137	PDF report (graphic chart) only allows 50'000 data points.
RMS-1146	Deleted users are counted for license limitation.
RMS-1148	Notification Setup: Cannot assign user in system group.

8.5. Known Errors

N/A

8.6. Validation Documentation

For validated systems using the Rotronic GxP validation documentation, the V1.3. must be used.

8.7. Risk Analysis

The Rotronic Monitoring System software has been thoroughly tested.

The probability that the bugs persist is low. The severity must be judged by the end user to define the risk class. The detectability will depend on how the customer uses the RMS software and as of such must be defined by the customer.

Rotronic recommend a complete system validation based upon the features used. For software updates, only the new fuctions can be validated, however, this remains the regulated users decision.

The regulated user knows their application and process and as such should carry out the necessary risk assessment to determine the severity, probability and detectability and define the process risk class based upon the features used within RMS. Please see the RMS-RA risk assesement for more details.

9. Version V1.3.0.18190

9.1. Release Details

The release includes bug fixes as well as customer specific requests.

9.2. New Features

ID	Description
RMS-559	Aw Unit for Humidity measuring points.
RMS-933	"Pa" unit for pressure measuring point.
RMS-871	China SMS provider.
RMS-790	Air velocity calculation.

9.3. Improvements

ID	Description
RMS-874	Inventory report.
RMS-880	Group timeout.
RMS-919	Server time monitoring.
RMS-1000	Number of decimals user selectable.
RMS-869	PT1 Filter measuring point.
RMS-600	User defined view in chart page.
RMS-627	Event source column in alarm table.
RMS-495	Replace function for converter and converter devices.
RMS-667	Load property file for device properties.
RMS-711	API function for JSON data download.
RMS-717	Undelete function for users.
RMS-838	PDF report supports Chinese and Japanese fonts.

9.4. Bug Fixes

ID	Description
RMS-744	Datagaps for a measuring point can be displayed if "retry download" is selected for multiple datagaps even if the data are available.
RMS-691	Event report shows special characters wrong (äöü).
RMS-706	On the mobile view the units are displayed twice.
RMS-802	Server error on calibration if reference value contains a "," instead of a ".".
RMS-815	Document view uses the user right "validation" instead of "documents".
RMS-838	PDF Report not working with Chinese/Japanese language.
RMS-850	In the alarm email, the delay time is displayed instead of the alarm limit if a delay time is used.
RMS-853	Login fails with special characters in company name.
RMS-873	Display device shows "62" instead of the unit.
RMS-877	Login fails with special characters in user name.
RMS-949	Calculated measuring points not updated after backfilling of data.
RMS-950	"Script not found" error on validation page.
RMS-961	No temperature alarms can be released on server with Chinese operating system (because of the "" sign).
RMS-966	Counter reset not working correctly on different time zone than UTC.
RMS-979	Data table on "Data analysis" view are not showed correctly is multiple measuring points are selected.
RMS-995	Validation error of the event, if an inhibited alarm is released.

9.5. Known Errors

N/A

9.6. Validation Documentation

For validated systems using the Rotronic GxP validation documentation, the V1.3. must be used.

9.7. Risk Analysis

The Rotronic Monitoring System software has been thoroughly tested.

The probability that the bugs persist is low. The severity must be judged by the end user to define the risk class. The detectability will depend on how the customer uses the RMS software and as of such must be defined by the customer.

Rotronic recommend a complete system validation based upon the features used. For software updates, only the new functions can be validated, however, this remains the regulated users decision.

The regulated user knows their application and process and as such should carry out the necessary risk assessment to determine the severity, probability and detectability and define the process risk class based upon the features used within RMS. Please see the RMS-RA risk assessment for more details.

10. Version V1.2.0.17292

10.1. Release Details

The release includes bug fixes as well as customer specific requests.

10.2. New Features

ID	Description
RMS-358	New calculated measure points: Sum, difference, product, ratio, average, MKT.
RMS-430	New System measure points: CPU load, used memory, measure point update count, pending commands, software error count, current user count, page load count, open reminders, open warnings, open alarms, open errors.
RMS-531	New calculation: Humidex.
RMS-541	New calculation: Trend.
RMS-548	New calculation: Airflow.
RMS-589	New measure point types: particle and flow velocity.

10.3. Improvements

ID	Description
RMS-76	Archive several measure points at the same time.
RMS-245	Database manipulation detection: Detects changes in the database for measure values, events, calibrations and archive.
RMS-246	PDF report validation: The authenticity of an RMS PDF report can be validated.
RMS-311	Report templates: create individual templates for data- and event reports.
RMS-311	Email reports: create and send reports periodically.
RMS-316	Layout background image: Edit size and position.

RMS-350	Option: Require enter a message for save a change in the system.
RMS-389	Alarm table: PDF/CSV export by using from- to timespan.
RMS-402	Validation script: new tests and execution of test for several selected measure points.
RMS-469	Data restore also for calculated measure points.
RMS-473	Protection from malicious user entry: Javascript, HTML tags, SQL injection.
RMS-497	Data analysis: table view for multiple measure points. Statistic and list of alarms.
RMS-517	Display text for logic input (On/Off) can be entered by the user.
RMS-549	English units for differential pressure and CO2.

10.4. Bug Fixes

N/A

10.5. Known Errors

N/A

10.6. Validation Documentation

For validated systems using the Rotronic GxP validation documentation, the V1.2. must be used.

10.7. Risk Analysis

The Rotronic Monitoring System software has been thoroughly tested.

Rotronic recommend a complete system validation based upon the features used. For software updates, only the new fuctions can be validated, however, this remains the regulated users decision.

The regulated user knows their application and process and as such should carry out the necessary risk assessment to determine the severity, probability and detectability and define the process risk class based upon the features used within RMS. Please see the RMS-RA risk assesement for more details.

11. Version V1.1.1.17087

11.1. Release Details

The release includes bug fixes as well as customer specific requests.

11.2. New Features

ID	Description
RMS-293	New device supported: PF5.
RMS-388	New device supported: wireless ADC logger.
RMS-432	New device supported: RMS-Extension.

11.3. Improvements

ID	Description
RMS-75	Table view: Inhibit groups: possibility to inhibit one or more measuring points at the same time.

RMS-209	Device setup view: Firmware Updates for one or more devices at the same time in one step.
RMS-233	Device setup view: Multi select and edit. New columns in the table.
RMS-299	Data analysis view: show the MPT Number and a search function.
RMS-300	Events view: Direct links to setup the devices and measuring points.
RMS-302	Events view: improved filter function.
RMS-304	If an inhibited alarm is no longer in alarm mode, the inhibition remains.
RMS-305	Table view: new columns Device ID, Status, Comment Position, Owner.
RMS-309	Events view: Inhibition time shown better.
RMS-334	Measuring point setup view: multi select and edit. New columns in the table.
RMS-372	Send the current value when the notification is repeated.

11.4. Bug Fixes

N/A

11.5. Known Errors

N/A

11.6. Validation Documentation

For validated systems using the Rotronic GxP validation documentation, the V1.1. must be used.

11.7. Risk Analysis

The Rotronic Monitoring System software has been thoroughly tested.

Rotronic recommend a complete system validation based upon the features used. For software updates, only the new fuctions can be validated, however, this remains the regulated users decision.

The regulated user knows their application and process and as such should carry out the necessary risk assessment to determine the severity, probability and detectability and define the process risk class based upon the features used within RMS. Please see the RMS-RA risk assesement for more details.

12. Version V1.1.0.16270

12.1. Release Details

Initial version of the Rotronic Monitoring System software.

12.2. New Features

N/A

12.3. Improvements

N/A

12.4. Bug Fixes

N/A

12.5. Known Errors

N/A

12.6. Validation Documentation

For validated systems using the Rotronic GxP validation documentation, the V1.1. must be used.

12.7. Risk Analysis

The Rotronic Monitoring System software has been thoroughly tested.

Rotronic recommend a complete system validation based upon the features used.

The regulated user knows their application and process and as such should carry out the necessary risk assessment to determine the severity, probability and detectability and define the process risk class based upon the features used within RMS. Please see the RMS-RA risk assessment for more details.