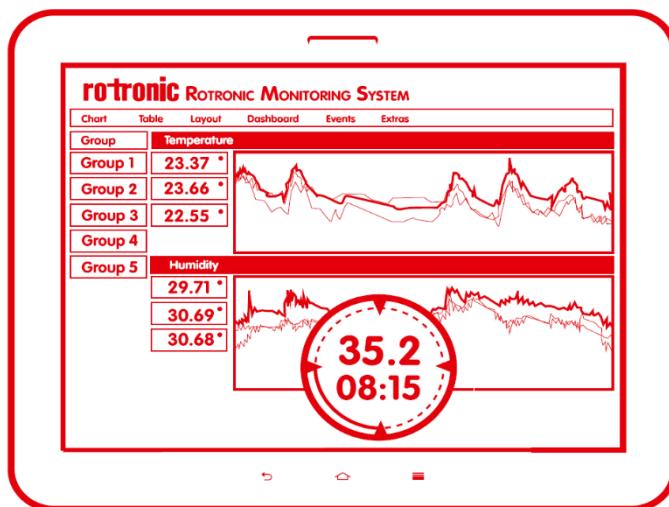


Rotronic Monitoring System

Release Notes – RMS-DO-L-R

Version: 1.3



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1. Version Overview

Please find below the meaning of the version.

- 1: Major version number.
- X.1: Minor version number.

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.

3. Version Control

Version	Release
V1.1	Daniel Schürmann
V1.2	James Pickering
V1.3	Denis Vujicic, 5 th of October 2022

4. Compatibility

Please see the online manual: <https://service.rotronic.com/manual/versionandchangecontrol.html>

5. Version V1.3

5.1. Release Details

• Summary:

This new firmware has been implemented due to a quartz that was used for the real time clock has been discontinued and has been replaced with another internal quartz. Rotronic took advantage of this firmware update to implement an improved watchdog feature.

ID	Description
11128-3178	Quartz replacement.
11128-3179	Improved watchdog feature.

6. Version V1.2

• Summary

6.1. Release Details

This firmware version has been programmed to fix open bugs.

6.2. New Features

N/A

6.3. Improvements

N/A

6.4. Bug Fixes

ID	Description
11128-2950 & 11129-2951	The relay does not switch on DO-CH1 and DO-CH2 correctly and reliably when the Reset option is selected: After delay time (Tools -> Setup -> Action -> Switch relay)

6.5. Known Errors

N/A

6.6. 5.6. Validation Documentation

For validated systems using the Rotronic GxP validation documentation, the V2.3. must be used.

6.7. Risk Analysis

The Rotronic Monitoring device 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.

7. Version V1.1

• Summary

7.1. Release Details

This firmware version has been programmed to improve the encrypted communication with the next version of the web service.

7.2. New Features

N/A

7.3. Improvements

ID	Description
1103	Extension of the Ethernet interface for encrypted communication with the next version of the web service

7.4. Bug Fixes

ID	Description
1100	The serial number becomes negative value when it reaches a certain value. >2147483647
628	Adaption from the host name, for all DIN Rail devices

7.5. Known Errors

N/A

7.6. Validation Documentation

N/A

7.7. Risk Analysis

The Rotronic Monitoring device 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 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.

8. Version V1.0

8.1. Release Details

This was the first release.