# Results of the IEC 61508 Functional Safety Assessment

Project:

Eclipse 706 GWR Level Transmitter (Industrial and Hygienic)

Customer:

Magnetrol - Ametek

Aurora, Illinois
USA

Contract No.: Q25/01-217
Report No.: MAG 15-12-025 R002
Version V5, Revision R0, November 12, 2025
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## Management Summary

The Functional Safety Assessment of the:

Magnetrol - Ametek Eclipse 706 GWR Level Transmitter (Industrial and Hygienic) development project, performed by *exida* consisted of the following activities:

- *exida* assessed the development process used by Magnetrol - Ametek through an audit and review of a detailed safety case against the *exida* certification scheme which includes the relevant requirements of IEC 61508. The assessment was executed using subsets of the IEC 61508 requirements tailored to the work scope of the development team.
- *exida* reviewed and assessed a detailed Failure Modes, Effects, and Diagnostic Analysis (FMEDA) of the devices to document the hardware architecture and failure behavior.
- *exida* reviewed field failure data to verify the accuracy of the FMEDA analysis.
- *exida* reviewed the manufacturing quality system in use at Magnetrol - Ametek.

The functional safety assessment was performed to the SIL 3 requirements of IEC 61508:2010. A full IEC 61508 Safety Case was created using the *exida* Safety Case tool, which also was used as the primary audit tool. Hardware and software process requirements and all associated documentation were reviewed. Environmental test reports were reviewed. The user documentation and safety manual also were reviewed.

The results of the Functional Safety Assessment can be summarized by the following statements:

**The audited development process, as tailored and implemented by the Magnetrol - Ametek Eclipse 706 GWR Level Transmitter (Industrial and Hygienic) development project, complies with the relevant safety management requirements of IEC 61508 SIL 3**.

**The assessment of the FMEDA, done to the requirements of IEC 61508, has shown that the Eclipse 706 GWR Level Transmitter (Industrial and Hygienic) can be used in a low demand safety related system in a manner where the $PFD_{AVG}$ is within the allowed range for SIL 3 (HFT = 0) according to table 2 of IEC 61508-1.**

**The assessment of the FMEDA also shows that the Eclipse 706 GWR Level Transmitter (Industrial and Hygienic) meets the requirements for architectural constraints of an element such that it can be used to implement a SIL 2 safety function (with HFT = 0) or a SIL 3 safety function (with HFT = 1).**

**This means that the Eclipse 706 GWR Level Transmitter (Industrial and Hygienic) is capable for use in SIL 3 applications when properly designed into a Safety Instrumented Function per the requirements in the Safety Manual and when using the versions specified in section 3.1 of this document.**

**The manufacturer will be entitled to use the Functional Safety Logo.**

## Table of Contents

# 1 Purpose and Scope

This document shall describe the results of the IEC 61508 functional safety assessment of the:

- Eclipse 706/706H GWR Level Transmitter

by *exida* according to the accredited *exida* certification scheme which includes the requirements of IEC 61508: 2010.

The purpose of the assessment was to evaluate the compliance of:

- the Eclipse 706 GWR Level Transmitter (Industrial and Hygienic) with the technical IEC 61508-2 and -3 requirements for SIL 3 and the derived product safety property requirements

and

- the Eclipse 706 GWR Level Transmitter (Industrial and Hygienic) development processes, procedures and techniques as implemented for the safety-related deliveries with the managerial IEC 61508-1, -2 and -3 requirements for SIL 3.

and

- the Eclipse 706 GWR Level Transmitter (Industrial and Hygienic) hardware analysis represented by the Failure Mode, Effects and Diagnostic Analysis with the relevant requirements of IEC 61508-2.

The assessment has been carried out based on the quality procedures and scope definitions of *exida*.

The results of this assessment provide the safety instrumentation engineer with the required failure data per IEC 61508 / IEC 61511 and confidence that sufficient attention has been given to systematic failures during the development process of the device.

## 1.1 Tools and Methods used for the assessment

This assessment was carried by using the *exida* Safety Case tool. The Safety Case tool contains the *exida* scheme which includes all the relevant requirements of IEC 61508.

For the fulfillment of the objectives, expectations are defined which builds the acceptance level for the assessment. The expectations are reviewed to verify that each single requirement is covered. Because of this methodology, comparable assessments in multiple projects with different assessors are achieved. The arguments for the positive judgment of the assessor are documented within this tool and summarized within this report.

The assessment was planned by *exida* agreed with Magnetrol - Ametek (see [R1]).

All assessment steps were continuously documented by *exida* (see [R1] and [R2]).

# 2 Project Management

## 2.1 *exida*

*exida* is one of the world's leading accredited Certification Bodies and knowledge companies, specializing in automation system safety and availability with over 500 years of cumulative experience in functional safety. Founded by several of the world's top reliability and safety experts from assessment organizations and manufacturers, *exida* is a global company with offices around the world. *exida* offers training, coaching, project-oriented system consulting services, safety lifecycle engineering tools, detailed product assurance, cyber-security and functional safety certification, and a collection of on-line safety and reliability resources. *exida* maintains a comprehensive failure rate and failure mode database on process equipment based on 250 billion hours of field failure data.

## 2.2 Roles of the parties involved

| | |
|---|---|
| Magnetrol - Ametek | Manufacturer of the Eclipse 706/706H GWR Level Transmitter |
| *exida* | Performed the hardware assessment [R4] |
| *exida* | Performed the Functional Safety Assessment [R1] and [R3] per the accredited *exida* scheme. |

Magnetrol - Ametek contracted *exida* with the IEC 61508 Functional Safety Assessment of the above-mentioned devices.

## 2.3 Standards / Literature used

The services delivered by *exida* were performed based on the following standards / literature.

| | | |
|---|---|---|
| [N1] | IEC 61508:2010 (Parts 1 – 3) | Functional Safety of Electrical/Electronic/Programmable Electronic Safety-Related Systems – Normative Parts |
| [N2] | IEC 61508:2010 (Parts 4 – 7) | Functional Safety of Electrical/Electronic/Programmable Electronic Safety-Related Systems – Informative Parts |

## 2.4 Reference documents

**Note:** Documents revised after the 2022 audit are listed with a light grey fill.

### 2.4.1 Documentation provided by Magnetrol - Ametek

| Doc. ID | Document Description | Project Document Filename | Version | Date |
|---|---|---|---|---|
| D001 | Quality Manual | QMS Manual.pdf | Rev. 29 | 5-Jul-2023 |
| D003 | Development Process | Business Development.pdf | Rev. A | 25-Sep-2017 |
| D003b | Development Process | Development.pdf | Rev. C | 8-Jun-2023 |
| D003c | Development Process | Electrical Design Methodology.docx | Rev 1 | 8-Mar-2019 |
| D004 | Configuration Management Process | SDD-001 Engineering Change Notice | Rev 4 | 29-Aug-2023 |

| Doc. ID | Document Description | Project Document Filename | Version | Date |
|---|---|---|---|---|
| D004b | Configuration Management Process | SPD-005 Software Management | Rev 4 | 13-Mar-2023 |
| D005 | Field Failure Reporting Procedure / Flow chart | Technical Product Support.pdf | Many | 29-Jan-2021 |
| D006 | Field Return Procedure | WGS-002.pdf | Rev 0 | 25-Apr-2017 |
| D006c | Field Return Procedure – Training Slides | Magnetrol Training Course – Service Cloud – RMA.pptx | N/A | 15-Dec-2015 |
| D007 | Manufacturer Qualification Procedure | SQA-038 Supply Base Quality Program | Rev. 8 | 13-Mar-2023 |
| D007b | Manufacturer Qualification Procedure (Local – Belgium) | PIP-001 Suppliers onboarding and keeping on board.pdf | Rev. 2 | 30-Nov-2023 |
| D010 | Quality Management System (QMS) Documentation Change Procedure | SQS-001.pdf | Rev 3 | 28-Jan-2025 |
| D010b | Document Retention Policy (Belgium) | SC-1391.0 Exhibit D - Belgium Record Retention Schedule.pdf | Rev 0 | N/A |
| D012 | Non-Conformance Reporting Procedure | SQS-003.pdf | Rev. 3 | 22-Oct-2019 |
| D012b | Non-Conformance Reporting Procedure | WQS-001.pdf | Rev. 2 | 14-May-2019 |
| D013 | Corrective Action Procedure | SQS-004 Corrective Action | Rev 5 | 111-Dec-2023 |
| D016b | Change Request | Product Change Request 9 Firmware Issue 197.docx | Screenshot | 2016 |
| D019 | Customer Notification Procedure | SQA-001 Customer Notification | Rev 1 | 18-Jul-2018 |
| D019b | Customer Notification Procedure | SCE-001 Design Change Notification to Approval Agencies | Rev 3 | 9-Jul-2025 |
| D021 | Software Development Process | Software Development Methodology.doc | Rev 6 | 8-Mar-2023 |
| D021b | Software Tool Qualification Procedure | SPD-006 Suitability of Tools | Rev. 0 | 8-Jan-2018 |
| D021c | Software Tool Qualification Procedure | Tool HAZOP Template.doc | Rev. B | N/A |
| D023b | Impact Analysis Template | Impact Analysis Template.doc | Rev B | N/A |
| D023c | Impact Analysis Template | SPD-001 Safety Related Change Management | Rev. 1 | 19-Jan-2018 |
| D026 | FSM Plan or Development Plan | Eclipse Model 706 Functional Safety Management Plan (PIU) RELEASED 052722.doc | Rev. 3 | 27-May-2022 |
| D030 | Shipment Records | 700_706_SalesData_2022-2025YTD.pdf | N/A | 2022-2025 |
| D031 | Field Returns Records | 706 RMA SIL.xlsx | N/A | 22-Feb-2016 |

| Doc. ID | Document Description | Project Document Filename | Version | Date |
|---|---|---|---|---|
| D032 | Job Descriptions and Competency Levels | Engineering.pdf | N/A | 3-Jun-2019 |
| D033 | Training Record | training logs 2.docx | Screenshot | N/A |
| D036 | ISO 900x Cert or equivalent | 0150001_ENG_AMETEK MAGNETROL, USA, LLC.pdf | N/A | exp. 2023-05-27 |
| D036b | ISO 900x Cert or equivalent | ISO 9001 exp date 200427.pdf (Manufacturing site ISO cert Belgium) | N/A | exp. 2027-04-20 |
| D036c | ISO 900x Cert or equivalent | ISO 9001 2015 Cert AMETEK.pdf (Manufacturing site ISO cert Shanghai) | N/A | exp. 2027-08-15 |
| D038 | List of Design Tools | Model 706 Suitability of Tools.doc | Rev 1 | 8-Sep-2025 |
| D040 | Safety Requirements Specification | Safety Requirements Specification for Eclipse 706 and 700.pdf | V1R2 | 23-Oct-2020 |
| D040b | Safety Requirements Specification | Model 706 Diagnostic Indicator Specification.doc | Rev. 12 | 17-Aug-2021 |
| D040c | Safety Requirements Specification | Eclipse Model 706 Rev _1.5e_061511.doc | Rev. 1.5f | 4-Oct-2011 |
| D041 | Safety Requirements Review | Eclipse Model 706 SRS Review Minutes 032316.doc | N/A | 5-Apr-2016 |
| D041b | Safety Requirements Review | Eclipse Model 706 SRS Checklist 032316.doc | N/A | 23-Mar-2016 |
| D043 | Software Safety Requirements Specification | Model 706 Software Architecture.doc | N/A | 28-Jun-2017 |
| D043b | Software Safety Requirements Specification | Model 706 System Monitor Design.doc | N/A | 20-Sep-2012 |
| D045 | System Architecture Design Specification | Overview of Eclipse 4x Hardware ver1_0.vsd | Ver. 1.0 | N/A |
| D045c | System Architecture Design Specification | BLOCK-DIAGRAM _ PAGE2.pdf | Rev. B | 1-Feb-2010 |
| D047 | Schematics / Circuit Diagrams | 030-9159-AV.PDF | Rev. AV | 26-Dec-2023 |
| D047b | Schematics / Circuit Diagrams | 030-9160-V.PDF | Rev. V | 13-Oct-2023 |
| D047c | Schematics / Circuit Diagrams | 030-9165-L.pdf | Rev. L | 26-Dec-2023 |
| D047d | Assembly Drawing | 094-6067-N.pdf | Rev. N | 28-Apr-2020 |
| D047e | Assembly Drawing | 094-6068-Q.PDF | Rev. Q | 28-Sep-2021 |
| D047f | Assembly Drawing | 099-6546-AK.PDF | Rev. AK | 14-Dec-2023 |
| D048 | Hardware Change List | RMA 51430 and 51639.docx | Screenshot | 26-Mar-2015 |
| D050 | SW FMEA and/or Criticality Analysis Report | Magnetrol 706 Level Transmitter project report_draft.doc | V0R0 | 22-Jan-2012 |
| D060 | SW/FW Coding Standard | SPD-007 C Language Coding Standard for Firmware Development | Rev. 1.11 | 20-May-2019 |

| Doc. ID | Document Description | Project Document Filename | Version | Date |
|---|---|---|---|---|
| D069 | Validation Test Plan | Validation Test Spec Plan V0 R1 Eclipse 706 SIGNED 050516.pdf | V0R1 | 5-May-2016 |
| D069b | Validation Test Plan – Linearity and Repeatability Testing | SEE-002.pdf | Rev. 0 | 30-Mar-2018 |
| D069c | Validation Test Plan | D069c SEE-004 rev 1.pdf | Rev. 1 | 8-Jun2019 |
| D069d | Validation Test Plan | D069d SEE-003 rev 2.pdf | Rev. 2 | 9-Jul-2019 |
| D069e | Validation Test Plan | D069e WEE-001 rev 3.pdf | Rev. 3 | 1-Jul-2019 |
| D070 | Validation Test Plan Review Record | Eclipse Model 706 Validation Test Specification and Plan Review Minutes.doc | N/A | 23-Mar-2016 |
| D070b | Validation Test Plan Review Record | Validation Test Plan Checklist 032316.doc | N/A | 23-Mar-2016 |
| D071 | Environmental Test Plan | D071 SEE-001 rev 4.pdf | Rev. 4 | 4-Feb-2020 |
| D072 | EMC Test Plan | D072 SEE-005 rev 3.pdf | Rev. 3 | 9-Jul-2019 |
| D072b | EMC Test Plan | Eclipse706EMCTestingJan2012At Magnetrol.pdf | N/A | 17-Jan-2012 |
| D074 | Validation Test Results | Results 20121024.xlsx | N/A | 24-Oct-2012 |
| D074b | Validation Test Results | 706 HT Acceptance Test Report Rev D.doc | Rev. D | 4-Sep-2012 |
| D074c | Validation Test Results | Repeatability Test report.xlsx | N/A | 17-Oct-2012 |
| D074d | Validation Test Results | Firmware tests.docx | Screenshot | N/A |
| D074e | Validation Test Results | 706 ProcessDielectricEffectTest.xlsx | N/A | 6-Sep-2012 |
| D074f | Validation Test Results | 706 SIL VT Summary V0 R1 SIGNED 061316.pdf | Rev. R1 | 13-Jun-2016 |
| D075 | Environmental Test Results | 706 Shock Vib Testing Report.pdf | - | 30-Aug-2012 |
| D075b | Environmental Test Results | 706 Temperature effects testing report .xlsx | N/A | 5-Sep-2012 |
| D075c | Environmental Test Results | Humidity Test report.xls | N/A | 16-Aug-2012 |
| D075d | Environmental Test Results | Thermal Shock Test Report.xls | N/A | 27-Aug-2012 |
| D076 | EMC Test Results | Eclipse 706 EMC Report.pdf | | 17-Jan-2012 |
| D077 | Fault Injection Test Results | 706 SIL Display Fault Injection | V1R1 | 13-May-2016 |
| D078 | Operation / Maintenance Manual | 57-606_eclipse_model_706_hart_io.pdf | - | July 2024 |
| D079 | Safety Manual | 57-657.6 Eclipse Model 706 SIL3 Certified Manual.pdf | - | September 2025 |
| D081b | Engineering Change Documentation (associated with PCR 101/191) | 5177-01901.pdf | N/A | 7-Nov-2022 |

| Doc. ID | Document Description | Project Document Filename | Version | Date |
|---|---|---|---|---|
| D082 | List of Diagnostics for FMEDA | Diagnostic Indicators used in the Model 706 FMEDA 030316.docx | N/A | 3-Mar-2016 |
| D086 | Tool Qualification Report | Gimpel PC-lint Ver 9.0 HAZOP.doc | Rev. 0 | 11-Apr-2013 |
| D086b | Tool Qualification Report | IAR EWARM Ver 6.50 HAZOP.doc | Rev. 0 | 16-Apr-2013 |
| D086c | Tool Qualification Report | Serena PVCS Ver 8.6 HAZOP.pdf | Rev. 0 | 8-Sep-2025 |
| D088 | Impact Analysis Record | Model 706 Issue 197 Impact Analysis.docx | Rev. 1 | 6-Apr-2015 |
| D088b | Impact Analysis Record | Model 706 Rel 1.0fA Firmware Design.docx | Rev. 1.0 | 18-June-2015 |
| D088c | Impact Analysis Record | Model 706 Rel 1.0fA Firmware Test Plan.docx | Rev. 1.0 | 18-June-2015 |
| D088d | Impact Analysis Record | Model 706 Rel 1.0fA Firmware Test Results.pdf | Rev. 1.0 | 18-June-2015 |
| D088e | Impact Analysis Record | Model 706 Issue F-288 PCR-101 Impact Analysis Covers PCR-191.docx | Rev 1.1 | 11-Dec-2018 |
| D088f | Impact Analysis Record | Model 706 PCR-192 Impact Analysis.docx | Rev 0 | 17-May-2023 |
| D088g | Impact Analysis Record | Model 706 PCR-193 Impact Analysis.docx | Rev 0 | 5-Jun-2023 |
| D091 | SW Release Notes | Model 706 Rel 1.0gA Firmware Design.docx | Rev. 1.27 (1.0gA) | 20-Aug-2015 |
| D092 | Test Procedure | Model 706 Temperature Test Procedure_ANSYS_rjb_081120 | N/A | 11-Aug-2020 |
| D093 | Impact Analysis | Eclipse 706 PCR-169 Impact Analysis | Rev 0 | 21-Oct-2020 |
| D094 | Engineering Changes | Model 700 706 FW Changes 2025 SIL Recertification | N/A | 2025 |
| D095 | Product Change Test Plan | Model 706 PCR-193 Test Plan.docx | Rev 1 | 10-Jul-2023 |
| D096 | Product Change Test Report | Model 706 PCR-193 Test Report.docx | Rev 0 | 14-Jul-2023 |
| D097 | Code Review | Model 706 PCR 188 192 193 Code Review.pdf | N/A | 29-Jun-2023 |
| D098 | Code Review | Model 706 7yS Fid Threshold Code Review.pdf | N/A | 12-Jul-2023 |
| D099 | Product Change Review Record | CCB Meeting 706 PCR-193.docx | N/A | 27-Jun-2023 |

### 2.4.2 Documentation generated by *exida*

| Doc. ID | *exida* Document Filename | Description |
|---|---|---|
| [R1] | MAG 25-01-217 SC001 V2R0 SafetyCaseWB - Baseline.xlsm | Magnetrol Safety Case |
| [R2] | MAG 15-12-025 SC001 V2R0 IEC 61508 SafetyCaseWB – 706 Xmitter - Final Safety Case | 706 Safety Case |
| [R3] | MAG 15-12-025 R004 V2R0 PIU Spreadsheet - 700 706GWR Level Transmitter.xls | PIU Analysis |
| [R4] | MAG 15-12-025 R001 V4R2 706GWR FMEDA Report | FMEDA Report (including 706 Hygienic) |
| [R5] | Q25-01-217 700GWR 706GWR Renewal PM Workbook.xlsm | PM Workbook |
| [R6] | MAG 25-01-217 FFA Spreadsheet - V2.xlsx | Field Failure Analysis of 700GWR and 706GWR |

## 2.5 Assessment Approach

The certification audit was closely driven by requirements of the *exida* scheme which includes subsets filtered from IEC 61508.

The assessment was planned by *exida* and agreed with Magnetrol - Ametek

The following IEC 61508 objectives were subject to detailed auditing at Magnetrol - Ametek:

- FSM planning, including
    - Safety Life Cycle definition
    - Scope of the FSM activities
    - Documentation
    - Activities and Responsibilities (Training and competence)
    - Configuration management
    - Tools and languages
- Safety Requirement Specification
- Change and modification management
- Software architecture design process, techniques and documentation
- Hardware architecture design - process, techniques and documentation
- Hardware design / probabilistic modeling
- Hardware and system related V&V activities including documentation, verification
    - Integration and fault insertion test strategy
- Software and system related V&V activities including documentation, verification
- System Validation including hardware and software validation
    - EMC and environmental test report

- Hardware-related operation, installation and maintenance requirements

The project teams, not individuals were audited.
The certification audit was originally done in Aurora, IL in 2016.

# 3 Product Description

Model 706-512*-*** is a loop-powered, 24 VDC level transmitter, based on Guided Wave Radar (GWR) technology. For safety instrumented systems usage it is assumed that the 4 – 20mA output is used as the primary safety variable. The analog output meets NAMUR NE 43 (3.8mA to 20.5mA usable). The transmitter contains self-diagnostics and is programmed to send its output to a specified failure state, either low or high upon internal detection of a failure (output state is programmable). The device can be equipped with or without display.

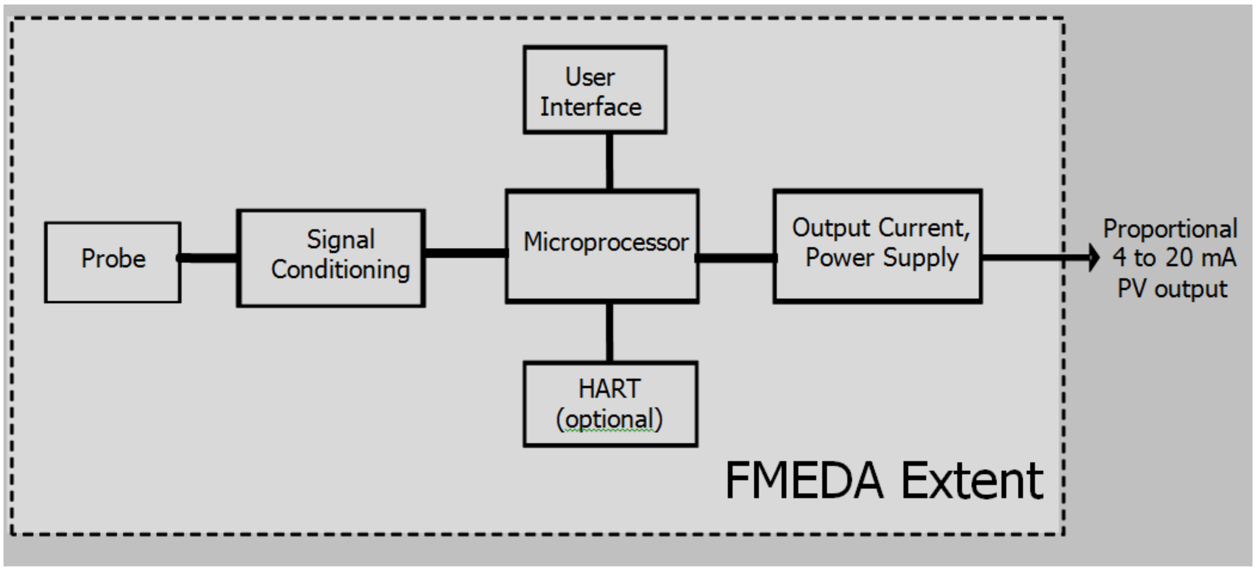


Figure 1 Model 706-512*-***, Parts included in this assessment

Guided Wave Radar is based upon the principle of TDR (Time Domain Reflectometry). TDR utilizes pulses of electromagnetic energy transmitted down a probe. When a pulse reaches a surface that has a higher dielectric than the air/vapor in which it is traveling, the pulse is reflected. An ultra-high-speed timing circuit precisely measures the transit time and provides an accurate level measurement.

The Guided Wave Radar (GWR) probe must match the application. The probe configuration establishes fundamental performance characteristics. Coaxial, twin element (rod or cable), and single element (rod or cable) are the three basic configurations.

**Cryogenic Temperatures**

This product has been tested and approved for use in temperatures down to -55C. Contact manufacturer for use in cryogenic temperatures.

## 3.1 Hardware and Software Version Numbers

This assessment is applicable to the following hardware and software versions of the Eclipse 706/706H GWR Level Transmitter:

| Variant/Model | Hardware Version | Software Version |
|---|---|---|
| 706-512x-xxx (HART) | 030-9160-001 Rev. U<br>030-9159-001 Rev. AT<br>030-9165-001 Rev. J | 1.1 kA hex |

**Table 1- Hardware and Software Versions**

For the latest HW/SW versions reviewed, see Section 6 2025 IEC 61508 Functional Safety Surveillance Audit.

# 4 IEC 61508 Functional Safety Assessment Scheme

The assessment was executed using the accredited exida certification scheme which includes subsets of the IEC 61508 requirements tailored to the work scope of the development team. The assessment was performed based on the information received from Magnetrol - Ametek [see section 2.4.1] and is documented in the safety case [R1] and [R2].

*exida* audited and assessed project and product documentation for compliance with the functional safety requirements of IEC 61508. During an evaluation period, an assessor updated a safety case with the results of the assessment. The safety case documents the development project's compliance with the functional safety management requirements of IEC 61508, parts 1 through 3. Evaluation was followed by a certification review of the safety case, in which a review of a subset of the most important requirements, and a spot inspection of the remaining requirements, was carried out to ensure high quality of the safety case.

The detailed development audit (see [R1]) evaluated the compliance of the processes, procedures and techniques, as implemented for the Magnetrol - Ametek Eclipse 706/706H GWR Level Transmitter, with IEC 61508.

The results of the assessment show that the Eclipse 706/706H GWR Level Transmitter is capable for use in SIL 3 applications, when properly designed into a Safety Instrumented Function per the requirements and constraints specified in the Safety Manual.

## 4.1 Product Modifications

The modification process has been successfully assessed and audited, so Magnetrol - Ametek may make modifications to this product as needed.

# 5 Results of the IEC 61508 Functional Safety Assessment

*exida* assessed a detailed Failure Modes, Effects, and Diagnostic Analysis (FMEDA) [R4] of the Eclipse 706/706H GWR Level Transmitter to document the hardware architecture and failure behavior. The FMEDA report and the Safety Case created for the Eclipse 706/706H documents this assessment.

*exida* assessed failure history of the Eclipse 706/706H GWR Level Transmitter [D030, D031] and performed a detailed analysis of the data provided [R3]. This PIU assessment is done in place of a detailed functional safety assessment for systematic failures. The Safety Case created for the Eclipse 706/706H documents this assessment.

The result of the overall assessment can be summarized by the following observations:

**The Eclipse 706/706H GWR Level Transmitter complies with the relevant requirements of IEC 61508 SIL 3 applications when considering PIU, and when properly designed into a Safety Instrumented Function per the requirements in the Safety Manual.**

## 5.1 Lifecycle Activities and Fault Avoidance Measures

This functional safety assessment evaluated the compliance with IEC 61508 of the processes, procedures and techniques as implemented for the product development. The assessment was executed using subsets of the IEC 61508 requirements tailored to the SIL 3 work scope of the development team and supported by PIU analysis.

### 5.1.1 Safety Lifecycle and Functional Safety Management Planning

Reported dangerous failures that occur in the field are captured and analyzed and recommendations are made to minimize the chance for a repeat occurrence of the failure.

Manufacturer has a QMS in place. The Manufacturer has been ISO 9001 certified. All sub-suppliers have been qualified through the Manufacturer Qualification procedure.

**Conclusion**

The objectives of the standard are fulfilled by the Magnetrol - Ametek functional safety management system and are supported by PIU analysis.

### 5.1.2 Tools

All tools which support a phase of the software development lifecycle and cannot directly influence the safety-related system during its run time (Off-line support tools) are documented, including tool name, manufacturer name, version number, and use of the tool on this project.

All off-line support tools have been classified as either T3 (safety critical), T2 (safety-related), or T1 (interference free). All off-line support tools in classes T2 and T3 have a specification or product manual which clearly defines the behavior of the tool and any instructions or constraints on its use. Magnetrol - Ametek has a list of all T3 and T2 tools along with a reference (file name, document number) to the specification or product manual.

A Software Tool Upgrade Procedure exists and is part of the Software Development Procedure as required for projects on which software tools are used. Generally, the approach is taken where a specific tool version is used for the life of the product.

**Conclusion**

The objectives of the standard are fulfilled by the Magnetrol - Ametek internal organizational procedures and functional safety management system processes and supported by PIU analysis.

### 5.1.3 Safety Requirement Specification and System Architecture Design

All of the Eclipse 706/706H's safety functions necessary to achieve the required functional safety are specified, including: functions that enable the EUC to achieve or maintain a safe state; functions related to the detection, annunciation and management of sensor faults; safety accuracy of the measurement.

Environmental limits and extremes are specified.

Safety integrity requirements are specified.

Specific requirements for start-up and restart procedures are specified. The Eclipse 706/706H starts up automatically when power is applied and does not require human interaction to start.

The Eclipse 706/706H design has been partitioned into subsystems, and interfaces between subsystems are clearly defined and documented.

The System Architecture Design and Design Review Records show support for appropriate design methods that clearly and precisely describe functionality, interfaces, sequencing/timing relationships.

The System Architecture Design Specification describes that the behavior of the device when a fault is detected is to annunciate the detected fault through an external interface. Diagnostics are listed and specified in D040b. Each software module's design document includes diagnostics designs.

The System Architecture Design clearly identifies which communication interfaces are safety related. There are no external, safety-related digital communications interfaces.

Traceability between Safety Requirements and Validation test cases has been fully implemented and verified.

### 5.1.4 Change and modification management

A Modification Procedure exists that identifies how a modification request is initiated, and processed, in order to authorize an Engineering Change Request (including hardware and software modifications). A Product Modification Request System exists to support this process. An "add on" procedure further defines the standard ("non-safety") procedure when a change request is for a safety critical product.

The Modification Procedure requires that an Impact Analysis be performed to assess the impact of the modification, including the impact of changes to the software design (which modules are impacted). The results of Impact Analyses are documented.

Modification Request/Records document the reason for the change, a detailed description of the proposed change, which new and existing tests must be run to validate the change, which tests must be re-run to validate that the change did not affect other functionality and what verification must be performed to ensure the development process was carried out properly from the point in the lifecycle at which the modification was initiated.

### 5.1.5 Proven In Use

There are no functions that are not covered by the PIU demonstration.

The product has been shipping for at least 18 months without any revisions or changes (NOTE: Based on the assumption that installation takes six months.). This is supported by the shipping records and the PIU analysis.

In addition to Design Fault avoidance techniques listed herein, a Proven in Use evaluation was performed on the Eclipse 706/706H GWR Level Transmitter. Shipment records were used to determine that the Eclipse 706/706H GWR Level Transmitter has greater than 30,000,000 operating hours and has demonstrated field failure rates less than the predicted failure rates indicated in the FMEDA reports. All components considered in the Low Demand, Type B Device FMEDA are standard components with greater than 100 million operating hours (see [R3] and [R4]). This provides justification for using a Route 2H approach.

## 5.2 Software Design

The Software Architecture Design contains a description of the software architecture. The design is partitioned into new, existing and/or proprietary (third party) components and modules, which are identified as such. A certified RTOS is used in the software. The runtime libraries (RTLs), which are packaged with the commercial programming too chain and are compliant through a proven-in-use argument. The RTOS, toolchain and RTLs are not intended to be upgraded for the life of the product as stated in the Functional Safety Management Plan.

The Software Architecture Design uses block diagrams, state/transition diagrams, data flow diagrams and other semi-formal notation to specify the software design.

The Software Architecture Design and Detailed Designs are judged as adequate to support compliant modification of the software through use of the Modification Procedure.

## 5.3 Hardware Architecture Design and Probabilistic Properties

To evaluate the hardware design of the Eclipse 706/706H GWR Level Transmitter, a Failure Modes, Effects, and Diagnostic Analysis (FMEDA) was performed by *exida* for each component in the system, and is documented in [R4].

A Failure Modes and Effects Analysis (FMEA) is a systematic way to identify and evaluate the effects of different component failure modes, to determine what could eliminate or reduce the chance of failure, and to document the system in consideration. The FMEDA is an FMEA extension. It combines standard FMEA techniques with extension to identify online diagnostics techniques and the failure modes relevant to safety instrumented system design.

From the FMEDA, failure rates are derived for each important failure category.

These results must be considered in combination with $PFD_{AVG}$ of other devices of a Safety Instrumented Function (SIF) in order to determine suitability for a specific Safety Integrity Level (SIL). The Safety Manual states that the application engineer should calculate the $PFD_{AVG}$ for each defined SIF to verify the design of that SIF.

## 5.4 Safety Validation

Fault injection testing has been performed on the product as defined in the fault injection test plan. The results have been analyzed and adjustments have been made to the FMEDA based on these results.

Test results are documented including reference to the test case and test plan version being executed.

The EMC/Environmental specifications tested (and passed) were the same as or more stringent than those reviewed and approved by the FMEDA analyst.

## 5.5 Safety Manual

The Safety Manual is provided to end users and identifies and describes the functions of the product. The safety function is clearly described, including a description of the output. The effects of internally detected faults on the device output are clearly described. Sufficient information has been provided to facilitate the development of an external diagnostics capability (output monitoring).

The Safety Manual contains the Safety Integrity information needed to incorporate the product into a higher-level element or Safety Instrumented Function (SIF), including failure rates, Systematic Capability, hardware architecture constraints, etc.

The Safety Manual gives guidance on recommended periodic (offline) proof test activities for the product, including listing any tools necessary for proof testing.

Procedures for maintaining tools and test equipment are listed.

The Installation Manual includes valuable information for the user of the device or system regarding safe operation and avoidance of hazards.

# 6 2025 IEC 61508 Functional Safety Surveillance Audit

## 6.1 Roles of the parties involved

| | |
|---|---|
| Magnetrol - Ametek | Manufacturer of the Eclipse 706/706H GWR Level Transmitter |
| *exida* | Performed the hardware assessment review |
| *exida* | Performed the IEC 61508 Functional Safety Surveillance Audit per the accredited *exida* scheme. |

Magnetrol - Ametek contracted *exida* to perform the surveillance audit for the above Eclipse 706/706H GWR Level Transmitter. An onsite audit was conducted on September 9, 2025, at the Aurora, IL facility. Audits were conducted remotely for the Shanghai, China manufacturing site (October 9, 2025) and the Zele, Belgium manufacturing site (October 13, 2025).

## 6.2 Surveillance Methodology

As part of the IEC 61508 functional safety surveillance audit the following aspects have been reviewed:

- Procedure Changes – Changes to relevant procedures since the last audit are reviewed to determine that the modified procedures meet the requirements of the *exida* certification scheme.
- Engineering Changes – The engineering change list is reviewed to determine if any of the changes could affect the safety function of the Eclipse 706/706H GWR Level Transmitter.
- Impact Analysis – If changes were made to the product design, the impact analysis associated with the change will be reviewed to see that the functional safety requirements for an impact analysis have been met.
- Field History – Shipping and field returns during the certification period will be reviewed to determine if any systematic failures have occurred. If systematic failures have occurred during the certification period, the corrective action that was taken to eliminate the systematic failure(s) will be reviewed to determine that said action followed the approved processes and was effective.
- Safety Manual – The latest version of the safety manual will be reviewed to determine that it meets the IEC 61508 requirements for a safety manual.
- FMEDA Update – If required or requested the FMEDA will be updated. This is typically done if there are changes to the IEC 61508 standard and/or changes to the *exida* failure rate database.
- Evaluate use of the certificate and/or certification mark - Conduct a search of the applicant's web site and document any misuse of the certificate and/or certification mark. Report any misuse of the certificate and/or certification mark to the exida Managing Director.
- Recommendations from Previous Audits – If there are recommendations from the previous audit, these are reviewed to see if the recommendations have been implemented properly.

### 6.3 Surveillance Results

#### 6.3.1 Procedure Changes

Changes to the procedures in 2.4 were reviewed and were found to be consistent with the requirements of IEC 61508.

#### 6.3.2 Engineering Changes

All changes to this product, during past renewal period, were reviewed and found to be consistent with the requirements of IEC 61508.

The following hardware and software versions were reviewed during this audit.

| Variant/Model | Hardware Version | Software Version |
|---|---|---|
| 706-512*-*** (HART) | Analog PC Board 030-9160-001 Rev. V<br>HART Digital Board 030-9159-001 Rev. AV<br>Wiring Board 030-9165-001 Rev. L | Ver 1.1nA HT<br>(Part 062-7060-00H) |

#### 6.3.3 Impact Analysis

There were minor design changes during the previous certification period. The impact analysis for each change was reviewed found to be acceptable.

#### 6.3.4 Field History

The field histories of these products were analyzed and found to be consistent with the failure rates predicted by the FMEDA.

#### 6.3.5 Safety Manual

The updated safety manual was reviewed and found to be compliant with IEC 61508:2010.

#### 6.3.6 FMEDA Update

The FMEDA was updated to the latest template, SW/HW revisions were reviewed, and soft error calculations were updated. The 706 Hygienic was added to the FMEDA report [R4].

#### 6.3.7 Evaluate use of certificate and/or certification mark

The Magnetrol - Ametek website was searched, and no misleading or misuse of the certification or certification marks was found.

#### 6.3.8 Previous Recommendations

There were no previous recommendations to review.

### 6.4 Surveillance Audit Conclusion

The result of the Surveillance Audit Assessment can be summarized by the following observations:

**The Magnetrol - Ametek Eclipse 706 GWR Level Transmitter (Industrial and Hygienic) continues to meet the relevant requirements of IEC 61508:2010 for SIL 3 based on the initial assessment and considering:**

**- field failure history**

**- permitted modifications completed on the product**

**- FMEDA updates and changes**

This conclusion is supported by the updated SafetyCase and certification documents.

# 7 Teams and Definitions

| | |
|---|---|
| Fault tolerance | Ability of a functional unit to continue to perform a required function in the presence of faults or errors (IEC 61508-4, 3.6.3) |
| FIT | Failure In Time ($1x10^{-9}$ failures per hour) |
| FMEDA | Failure Mode Effect and Diagnostic Analysis |
| HFT | Hardware Fault Tolerance |
| Low demand mode | Mode where the demand interval for operation made on a safety-related system is greater than twice the proof test interval. |
| High demand mode | Mode where the demand interval for operation made on a safety-related system is less than 100x the diagnostic detection/reaction interval, or where the safe state is part of normal operation. |
| $PFD_{AVG}$ | Average Probability of Failure on Demand |
| PFH | Probability of dangerous Failure per Hour |
| SFF | Safe Failure Fraction - Summarizes the fraction of failures, which lead to a safe state and the fraction of failures which will be detected by diagnostic measures and lead to a defined safety action. |
| SIF | Safety Instrumented Function |
| SIL | Safety Integrity Level |
| SIS | Safety Instrumented System – Implementation of one or more Safety Instrumented Functions. A SIS is composed of any combination of sensor(s), logic solver(s), and final element(s). |
| Type A element | "Non-Complex" element (using discrete components); for details see 7.4.4.1.2 of IEC 61508-2 |
| Type B element | "Complex" element (using complex components such as micro controllers or programmable logic); for details see 7.4.4.1.3 of IEC 61508-2 |

# 8 Status of the document

## 8.1 Liability

*exida* prepares reports based on methods advocated in International standards. Failure rates are obtained from a collection of industrial databases. *exida* accepts no liability whatsoever for the use of these numbers or for the correctness of the standards on which the general calculation methods are based.

## 8.2 Version History

| Contract Number | Report Number | Revision Notes |
|---|---|---|
| Q25/01-217 | MAG15-12-025 R002 V5R0 | Updates from Surveillance Audit; VAM/EMD, 12 November 2025 |
| Q22/01-081 | MAG15-12-025 R002 V4R1 | Per customer comments; TES; 6/27/2022 |
| Q22/01-081 | MAG15-12-025 R002 V4R0 | Recertification; TES; 6/24/2022 |
| Q20/08-080 | MAG15-12-025 R002 V3R1 | Added cryogenic information; TES 11/6/2020 |
| Q19/02-022 | MAG15-12-025 R002 V3R0 | Recertification; TES |
| Q15/12-025 | MAG15-12-025 R002 V2R0 | updated to allow engineering changes; DEB, 6/15/2016 |
| Q15/12-025 | MAG15-12-025 R002 V1R2 | corrected version information; DEB, 4/28/2016 |
| Q15/12-025 | MAG15-12-025 R002 V1R1 | updated based on CA review; DEB, 4/25/2016 |
| Q15/12-025 | MAG15-12-025 R002 V1R0 | initial draft; Dave Butler, 4/27/2016 |

Reviewer/Approver: Rudy Chalupa/Bob Gavin, *exida*, November 12, 2025

Status: Released, November 12, 2025

## 8.3 Future Enhancements

At request of client.

## 8.4 Release Signatures

Valerie Motto

Valerie Motto, CFSP, Senior Safety Engineer

Evaluating Assessor

Emma Dunsinger, Cybersecurity Engineer

Evaluating Assessor

Robert Gavin III, MSME, CFSE, Principal Safety Engineer

Certifying Assessor

Rudolf P. Chalupa, CFSE, Principal Safety Engineer

Certifying Assessor

# Appendix A Manufacturing Locations

*exida* performed manufacturer location audits in 2025 for Ametek Magnetrol's various manufacturing sites of SIL certified products.

The following manufacturing locations are capable of manufacturing the Eclipse 706 GWR Level Transmitter (Industrial and Hygienic) included in this Assessment Report:

- Ametek Magnetrol, USA, LLC, Aurora, IL
- Magnetrol International N.V., Zele, Belgium
- Ametek Industrial Technology (Shanghai) Co., Ltd., Shanghai, P.R. China

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