IEC 61508 Functional Safety Assessment

Project:
G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators

Customer:
Valve Automation
Emerson Automation Solutions
Houston, Texas
USA

Contract Number: Q22/08-013
Report No.: EAS 16/06-010 R003
Version V4, Revision R1 March 13, 2023
Ted Stewart

Management Summary

This report summarizes the results of the functional safety assessment according to IEC 61508 carried out on the G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators

The functional safety assessment performed by *exida* consisted of the following activities:

- *exida* assessed the development process used by Emerson Automation Solutions through an audit and review of a detailed safety case against the *exida* certification scheme which includes the relevant requirements of IEC 61508. The investigation 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* performed 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 Emerson Automation Solutions.

The functional safety assessment was performed to the requirements of IEC 61508: ed2, 2010, SIL 3 for mechanical components. A full IEC 61508 Safety Case was prepared using the *exida* Safety Case tool as the primary audit tool. Hardware process requirements and all associated documentation were reviewed. Environmental test reports were reviewed. Also, the user documentation (safety manual) was reviewed.

The results of the Functional Safety Assessment can be summarized as:

The audited development process as tailored and implemented by the Emerson Automation Solutions G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators development project, complies with the relevant safety management requirements of IEC 61508 SIL 3, **SC 3 (SIL** 3 **Capable).**

The assessment of the FMEDA, done to the requirements of IEC 61508, has shown that the G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators can be used in a low demand safety related system in a manor where the PFD_{avg} is within the allowed range for up to SIL 2 (HFT = 0) or SIL 3 (HFT=1) according to table 2 of IEC 61508-1.

The assessment of the FMEDA also shows that the G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators 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 G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators is capable for use in SIL 3 applications in Low DEMAND mode, when properly designed into a Safety Instrumented Function per the requirements in the Safety Manual and when using the versions specified in section 3 of this document.

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

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1 Purpose and Scope

This document shall describe the results of the IEC 61508 functional safety assessment of the Valve Automation Emerson Automation Solutions:

- G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators

by *exida* according to accredited *exida* certification scheme which includes the requirements of IEC 61508: ed2, 2010.

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

The results of this provides the safety instrumentation engineer with the required failure data as 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 Valve Automation Emerson Automation Solutions.

All assessment steps were continuously documented by *exida* (see [R1] to [R5]).

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 350 billion hours of field failure data.

2.2 Roles of the parties involved

Valve Automation Emerson Automation Solutions	Manufacturer of the G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators
exida	Performed the hardware assessment
exida	Performed the IEC 61508 Functional Safety Assessment per the accredited *exida* scheme.

Valve Automation Emerson Automation Solutions originally contracted *exida* in June 2016 for the IEC 61508 Functional Safety Assessment of the above mentioned devices.

2.3 Standards and literature used

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

[N1]	IEC 61508 (Parts 1 - 7): 2010	Functional Safety of Electrical/Electronic/Programmable Electronic Safety-Related Systems

2.4 Reference documents

Note: Documents revised after the previous audit are updated in the tables below.

2.4.1 Documentation provided by Valve Automation Emerson Automation Solutions

[D1]	ISO 9001:2015 exp July 2025	Emerson Process Management Valve Automation – Certificate of Approval – ISO 9001:2015
[D2]	Global QMS; Issue 3; rev 1; Oct 2018	Global Quality Management System Manual
[D3]	19-HS1903733-PDA, exp 30-Sep-2024	ABS design assessment certificate, CB Series

[D4]	19-HS1903735-PDA; exp 30-Sep-2024	ABS design assessment certificate, G Series
[D5]	BASP, Sept 2010	Bettis Actuators Selection Procedure Provides definitions for functions and performance capabilities of actuator. States areas of concern to address during selection
[D6]	DOC.DSB.CBA300.EN; Rev. 2	Bettis CBA-300 Series Pneumatic Actuators
[D7]	DOC.DSB.CBA300.EN; Rev 2	Bettis CBA-300 Series Pneumatic Actuators
[D8]	DDOP, Rev G, 5/2/2007	Design / Drafting Operating Procedural Guidelines
[D9]	EDOP, Rev F, 4/10/2007	Engineering Design Operating Procedural Guidelines
[D10]	ELOP, Rev Q, 3/11/2011	Engineering Laboratory Operating Procedures
[D11]	ES-42, Rev A, 03/15/2006	ES-42, IEC 61508 SIS/SIL Additional Procedural Requirements Additional procedures to ensure compliance with IEC 61508
[D12]	GEOP, Rev K, 4/10/2007	General Engineering Operating Procedures
[D13]	QA-08, Rev F, 09/22/2005	QA-08, Training and Records Procedure for training and training records
[D14]	QA-21, Rev L, 9/15/2015	Customer Returns and Complaints
[D15]	QA-22 rev H; Sept 2015	Corrective Action / Preventative Action Procedure for management of solutions of non-conformities; Superseded See Section 6
[D16]	GPI 1.11, 8/2015	G-Series Actuator Torque Ratings Torque rating for actuators at specified operating pressures
[D17]	GPI 2.01, Rev C, 1/2016	G-Series Actuator Performance Data Provides pressure and volume data for estimating speed response
[D18]	137464, Rev F, 7/2012	Service Instructions for CB/CBA Actuators Installation Instructions, operating and maintenance requirements
[D19]	124840E; Rev J	Bettis G/GH/GHC Series Pneumatic Actuators Disassembly and Reassembly
[D20]	137462E, Rev 0, April 2022	Service Instructions for CBAX30 Actuators Installation Instructions, operating and maintenance requirements
[D21]	137463E, Rev 0, April 2022	Service Instructions for CBAX30-SR Actuators Installation Instructions, operating and maintenance requirements
[D22]	ES 47, Rev D	Bettis CBA & G Series IEC 61508 SIS/SIL Safety Manual
[D23]	Lloyds 96/60075(E8)-04, 13-Dec-25	Lloyds Type Approval Certificate, G Series
[D24]	Lloyds 93/60111(E6)-02, 13-Dec-25	Lloyds Type Approval Certificate, CBA and CBB Series
[D25]	DF-92, 09/30/1998	Design Plan / Design File Checklist for CBA3XX Pneumatic Actuator
[D26]	DF-92 review, 07/25/2002	Final Design Review CBAx30 Pneumatic Actuator
[D27]	T203019, 06/04/2003	Test Evaluation Report Multiple verification tests for CBA actuators

[D28]	T200123, 11/20/2001	Test Evaluation Report High cycle test for CBA actuators
[D29]	Wyle 47221, 08/08/2002	Wyle Laboratories Test Report, Environmental testing
[D30]	Design Review, 5/21/09	CBB Design review
[D31]	Gate 5 Review, 7/21/09	CBB SY Actuator Gate 5 Review
[D32]	T209018, 4/6/09	CBB Engineering Lab Test Request (IP66)
[D33]	T209021, 5/28/09	CBB Engineering Lab Test Request (Seal assembly test)
[D34]	T209024, 5/22/09	CBB Engineering Lab Test Request (Torque shaft leak test)
[D35]	VA001-196-30 Rev 2; Apr 22	CBB Double-Acting Series Pneumatic Actuators Service Instructions
[D36]	VA001-196-31 Rev 4 Apr 22	CBB-Series Spring Return Pneumatic Actuators Service Instructions
[D37]	EOP 06 rev 04; Oct 2018	Operating Procedure – Engineering – Design & Development Product Configuration Engineering Change Control
[D38]	QA-20 rev D; Nov 2015	Quality Assurance Procedure Non-Conforming Product
[D39]	QC-08 rev T; May 2017	Quality Control Procedure Final Test
[D40]	ES 6 CB/CBA/CBB rev G	Final Quality Testing of Actuators; CB/CBA/CBB Series Spring Return - Pneumatic
[D41]	ES 6 rev AR	Engineering Specification; Final Quality Testing of Bettis Brand Scotch-Yoke Actuators
[D42]	ES 8 CBA-CBB rev F	Engineering Specification – Pressure Requirements and Limitations for Bettis Actuators
[D43]	ES 8 rev AG	Engineering Specification – Pressure Requirements and Limitations for Bettis Actuators
[D44]	ES 31 rev P	Engineering Specification – Pressure Equipment Directive for Actuator Requirements
[D45]	QC-02 rev V	Quality Control Procedures – Receiving Inspection
[D46]	QCM-0313 Approved until 6/20	17025Accredited Certificate of Calibration
[D47]	QCM-0523 Approved until 6-20	17025Accredited Certificate of Calibration

2.4.2 Documentation generated by *exida*

[R1]	EAS 16-06-010 R001 V3R1 FMEDA G Series Actuator	FMEDA report, G Series Actuators
[R2]	EAS 16-06-010 R002 V1R1 FMEDA CB Series Actuator	FMEDA report CB Series Actuators

[R3]	Q1106016_EPVAWaller Mechanical SafetyCase Data r1.esc	IEC 61508 SafetyCase for G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators
[R4]	EAS 22-08-013 PIU V1R0	Proven In Use Analysis for G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators
[R5]	2023 G CBX Safetycase update	Updated documents during the 2023 renewal audit

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 upon by Valve Automation Emerson Automation Solutions.

The following IEC 61508 objectives were subject to detailed auditing:

- FSM planning, including
  - Safety Life Cycle definition
  - Scope of the FSM activities
  - Documentation
  - Activities and Responsibilities (Training and competence)
  - Configuration management
- Safety Requirement Specification
- Change and modification management
- Hardware design / probabilistic modeling
- Hardware and system related V&V activities including documentation, verification
- Hardware-related operation, installation and maintenance requirements

3 Product Descriptions

The G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators are quarter-turn actuators designed for on-off or modulating control of any quarter-turn ball, butterfly, rotary plug valve, automation of louvers and dampers or any quarter-turn mechanism.

G-Series double-acting models produce guaranteed torque outputs from 12,581 lb-in to 6,000,000 lb-in (1420-678,000 Nm). Spring-return units produce spring torques in excess of 3,000,000 lb-in (339,000 Nm). G-Series actuators are suitable for continuous operation at pneumatic pressures from 40-2000 PSIG (3-14 BAR) and hydraulic pressures to 5000 PSIG (345 BAR).

Double-acting CB/CBA-Series actuators, requiring pressure to rotate in either direction, are available with guaranteed minimum torque outputs to 12,245 lb-in (1,384 Nm). The CB/CBA-Series spring-return models require pressure in only one direction of travel and are suitable for fail clockwise or counterclockwise applications without modification. These models produce guaranteed spring ending torques to 4,971 lb-in (562 Nm).

3.1 Hardware Version Numbers

gives an overview of the different versions that were considered in the FMEDA of the G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators.

Table 1 Version overview

G Series, Pneumatic, SR	Pneumatic G Series, Spring-Return
G Series, Pneumatic, DA	Pneumatic G Series, Double Acting
G Series, Hydraulic, SR	Hydraulic G Series, Spring-Return (with and without Hydraulic override)
G Series, Hydraulic, DA - SP	Hydraulic G Series, Double Acting, Single Piston
G Series, Hydraulic, DA - SP, HO	Hydraulic G Series, Double Acting, Single Piston with Hydraulic Override
G Series, Hydraulic, DA - DP	Hydraulic G Series, Double Acting, Double Piston
CB/CBA Series, Pneumatic, SR	Pneumatic CB/CBA Series, Spring-Return
CB/CBA Series, Pneumatic, DA	Pneumatic CB/CBA Series, Double Acting
Damper	Hydraulic Damper for G Series Actuators

The G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators are classified as Type A[1] devices according to IEC 61508, having a hardware fault tolerance of 0.

The Fail-Safe state of the G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators is defined as the state where hold-open pressure is released and the spring is extended (Spring-return option), or the state where the hold-position pressure is released and pressure is supplied to the trip side of the actuator (Double Acting option).

4 IEC 61508 Functional Safety Assessment Scheme

exida assessed the development process used by Valve Automation Emerson Automation Solutions for this development project against the objectives of the *exida* certification scheme which includes subsets of IEC 61508 -1 to 3. The results of the assessment are documented in [R3].

[1] Type A component: "Non-Complex" component with well-defined failure modes, for details see 7.4.3.1.2 of IEC 61508-2.

4.1 Methodology

The full functional safety assessment includes an assessment of all fault avoidance and fault control measures during hardware development and demonstrates full compliance with IEC 61508 to the end-user. The assessment considers all requirements of IEC 61508. Any requirements that have been deemed not applicable have been marked as such in the full Safety Case report, e.g. software development requirements for a product with no software. The assessment also includes a review of existing manufacturing quality procedures to ensure compliance to the quality requirements of IEC 61508.

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

- Development process, including:
    - Functional Safety Management, including training and competence recording, FSM planning, and configuration management
    - Specification process, techniques and documentation
    - Design process, techniques and documentation, including tools used
    - Validation activities, including development test procedures, test plans and reports, production test procedures and documentation
    - Verification activities and documentation
    - Modification process and documentation
    - Installation, operation, and maintenance requirements, including user documentation
    - Manufacturing Quality System
- Product design
    - Hardware architecture and failure behavior, documented in a FMEDA

The review of the development procedures is described in section 5. The review of the product design is described in section 5.2.

4.2 Assessment level

The G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators has been assessed per IEC 61508 to the following levels:

- SIL 3 capability

The development procedures have been assessed as suitable for use in applications with a maximum Safety Integrity Level of 3 (SIL 3) according to IEC 61508.

5 Results of the IEC 61508 Functional Safety Assessment

exida assessed the development process used by Valve Automation Emerson Automation Solutions for these products against the objectives of the *exida* certification scheme which includes IEC 61508 parts 1, & 2. The development of the G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators was done per this IEC 61508 SIL 3 compliant development process. The Safety Case was updated with project specific design documents.

5.1 Lifecycle Activities and Fault Avoidance Measures

Valve Automation Emerson Automation Solutions has a defined product lifecycle process in place. This is documented in the Quality Management System Manual [D2] and various Quality Procedures [D8]-[D15]. A documented modification process is documented in the DDOP document [D8].

Emerson Automation Solutions is ISO 9001:2008 certified, see [D1]. In addition, Valve Automation Emerson Automation Solutions is certified by Lloyds [D23] & [D24] for manufacturing in the following locations:

Valve Automation Emerson Automation Solutions – Valve Automation
19200 NW Freeway
Houston, Tx – 77065, USA

NOTE: Tianjin factory entity name change 3/2/2021
Emerson Process Management (Tianjin) Valves Co., Ltd
No 15, Xingwang Road
Wuqing Development Area
Tianjin 301700
People's Republic of China

Emerson Automation Solutions Hungary Kft. – Valve Automation
Berenyi U. 72-100 (Videoton Industrial Park, building number:230)
Szekesfehervar 8000 Hungary

No software is part of the design and therefore any requirements specific from IEC 61508 to software and software development do not apply.

The assessment investigated the compliance with IEC 61508 of the processes, procedures and techniques as implemented for product design and development. The investigation was executed using the *exida* certification scheme which includes subsets of IEC 61508 requirements tailored to the SIL 3 work scope of the development team. The result of the assessment can be summarized by the following observations:

The audited Valve Automation Emerson Automation Solutions design and development process complies with the relevant managerial requirements of IEC 61508 SIL 3.

5.1.1 Functional Safety Management

The valves manufactured by Valve Automation Emerson Automation Solutions are not built for inventory. These valves are built-to-order. The basic designs are standardized, but each order can have trim and materials variations, or specific customer requested proof tests. Due to the specialized nature of each valve, documentation that defines all of the requirements is generated for every order as part of the process.

FSM Planning

Valve Automation Emerson Automation Solutions has a defined process in place for product design and development. Required activities are specified along with review and approval requirements. This is documented in the EDOP Procedure. Templates and sample documents were reviewed and found to be sufficient. The modification process is covered by in the section titles Engineering Change Notice of the DDOP procedure [D8]. This process and the procedures referenced therein fulfill the requirements of IEC 61508 with respect to functional safety management for a product with simple complexity and well-defined safety functionality.

Version Control

Procedure DDOP [D8] requires that all documents be under document control. Use of this to control revisions was evident during the audit.

Training, Competency recording

QA-08 [D13] requires the Human Resource department to maintain training records of education, experience, training and qualifications for all personnel. Department heads are responsible for identifying and providing the training needs for their department as well as proficiency evaluations. The procedures and records were examined and found up-to-date and sufficient. Valve Automation Emerson Automation Solutions hired *exida* to be the independent assessor per IEC 61508 and to provide specific IEC 61508 knowledge.

5.1.2 Safety Requirements Specification and Architecture Design

For the G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators, the simple primary functionality of the actuator is the same as the safety functionality of the product (Valve changes position, Close / Open). Therefore, no special Safety Requirements Specification was needed. The normal functional requirements were sufficient. As the G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators designs are simple and are based upon standard designs with extensive field history, no semi-formal methods are needed. General Design and testing methodology is documented and required as part of the design process. This meets SIL 3.

5.1.3 Hardware Design

The design process is documented in the EDOP Procedure [D9]. Valve Automation Emerson Automation Solutions uses the following CAD tools, 2D, SolidEdge (originally ProE was used). Design calculations may be performed with MathCad or Excel. Other design tools may be used as appropriate, e.g. for failure investigation. The output from all design tools has significant cross checking, e.g. each individual drawing is reviewed. Outputs for tools require checking and sign off.

Items from IEC 61508-2, Table B.2 include observance of guidelines and standards, project management, documentation (design outputs are documented per quality procedures), structured design, modularization, use of well-tried components / materials, and computer-aided design tools. This meets SIL 3.

5.1.4 Validation

Validation Testing is created for each order. The test plan includes testing per all standard and customer performance requirements. As the G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators are purely mechanical devices with a simple safety function, there is no separate integration testing necessary. The G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators perform only 1 Safety Function, which is extensively tested under various conditions during validation testing.

Items from IEC 61508-2, Table B.3 include functional testing, project management, documentation, and black-box testing (for the considered devices this is similar to functional testing). Field experience and statistical testing via regression testing are not applicable. This meets SIL 3.

Items from IEC 61508-2, Table B.5 included functional testing and functional testing under environmental conditions, project management, documentation, failure analysis (analysis on products that failed), expanded functional testing, black-box testing, and fault insertion testing. This meets SIL 3.

5.1.5 Verification

Verification activities are defined in the EDOP Procedure. Methods of design verification used by Valve Automation Emerson Automation Solutions include alternate calculation, comparison to similar proven design, or by testing and demonstration. Additionally, a design file checklist is available to review all items that need to be included in the Design File for a new development, e.g. see [D25]. All verification activities are documented. This meets SIL 3.

5.1.6 Proven In Use

In addition to the Design Fault avoidance techniques listed above, a Proven in Use evaluation was carried out on the Valve Automation Emerson Automation Solutions G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators. Shipment records were used to determine that the actuators have >200 million hours in use and they have demonstrated a field failure rate less than the failure rates indicated in the FMEDA reports. This meets the requirements for Proven In Use for SIL 3.

5.1.7 Modifications

Modifications are initiated per the Engineering Change Request form as described in the DDOP Procedure. The request is reviewed by the requestor's manager prior to submission into the ECR / ECN system. The request is entered into the system as an Engineering Change Notice. All changes are first reviewed and analyzed for impact before being approved. Measures to verify and validate the change are developed following the normal design process.

The modification process has been successfully assessed and audited, so Valve Automation Emerson Automation Solutions may make modifications to this product as needed.

As part of the *exida* scheme a surveillance audit is conducted every 3 years. The modification documentation listed below is submitted as part if the surveillance audit. *exida* will review the decisions made by the competent person in respect to the modifications made.

- List of all anomalies reported
- List of all modifications completed
- Safety impact analysis which shall indicate with respect to the modification:

- The initiating problem (e.g. results of root cause analysis)
- The effect on the product / system
- The elements/components that are subject to the modification
- The extent of any re-testing

- List of modified documentation
- Regression test plans

This meets SIL 3.

5.1.8 User documentation

Valve Automation Emerson Automation Solutions creates the following user documentation: service instructions [D18] to [D21] and a Safety Manual [D22]. The Safety Manual was found to contain all of the required information given the simplicity of the products. The Safety Manual references the FMEDA reports which are available and contain the required failure rates, failure modes, useful life, and suggested proof test information.

Items from IEC 61508-2, Table B.4 include operation and maintenance instructions, user friendliness, maintenance friendliness, project management, documentation, limited operation possibilities (G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators perform well-defined actions) and operation only by skilled operators (operators familiar with type of valve, although this is partly the responsibility of the end-user). This meets SIL 3.

5.2 Hardware Assessment

To evaluate the hardware design of the G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators Failure Modes, Effects, and Diagnostic Analysis's were performed by *exida*. These are documented in [R1] and [R2].

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. An FMEDA (Failure Mode Effect and Diagnostic Analysis) 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. All failure rate analysis results and useful life limitations are listed in the FMEDA report [R1] and [R2]. Tables in the FMEDA report list these failure rates for the G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators under a variety of configurations. The failure rates listed are valid for the useful life of the actuators.

According to IEC 61508 the architectural constraints of an element must be determined. This can be done by following the 1_H approach according to 7.4.4.2 of IEC 61508 or the 2_H approach according to 7.4.4.3 of IEC 61508.

The 1_H approach involves calculating the Safe Failure Fraction for the entire element.

The 2_H approach involves assessment of the reliability data for the entire element according to 7.4.4.3.3 of IEC 61508.

The failure rate data used for this analysis meets the *exida* criteria for Route 2_H. Therefore, the G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators can be classified as a 2_H device. When 2_H data is used for all of the devices in an element, the element meets the hardware architectural constraints up to SIL 2 at HFT=0 (or SIL 3 @ HFT=1) per Route 2_H.

If Route 2_H is not applicable for the entire final element, the architectural constraints will need to be evaluated per Route 1_H.

Note, as the G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators are only one part of a (sub)system, the SFF should be calculated for the entire final element combination.

These results must be considered in combination with PFD_{avg} values of other devices of a Safety Instrumented Function (SIF) in order to determine suitability for a specific Safety Integrity Level (SIL). The architectural constraints requirements of IEC 61508-2, Table 2 also need to be evaluated for each final element application. It is the end user's responsibility to confirm this for each particular application and to include all components of the final element in the calculations.

The analysis shows that the design of the G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators can meet the hardware requirements of IEC 61508, SIL 3 and SIL 2 for the actuators depending on the complete final element design. The Hardware Fault Tolerance and PFD_{avg} requirements of IEC 61508 must be verified for each specific design.

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6.1 Roles of the parties involved

Emerson Automation Solutions	Manufacturer of the G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators
exida	Performed the hardware assessment review
exida	Performed the IEC 61508 Functional Safety Surveillance Audit per the accredited *exida* scheme.

Emerson Automation Solutions contracted *exida* to perform the surveillance audit for the above G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators. The surveillance audit was conducted remotely.

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 G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators.
- 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.

6.2.1 Documentation provided by Emerson Automation Solutions and *exida*

Documents received during this surveillance audit have been documented and updated in section 2.4.

6.3 Surveillance Results

6.3.1 Procedure Changes

Changes to the documents in Section 6.2.1 were reviewed and were found to be consistent with the requirements of IEC 61508.

6.3.2 Engineering Changes

See 6.3.6 FMEDA update.

6.3.3 Impact Analysis

The safety-related design changes during this certification period were reviewed and found to be compliant with IEC61508:2010.

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 safety manual did not change since the last assessment and continues to be compliant with IEC 61508:2010.

6.3.6 FMEDA Update

The G-Series FMEDA report was updated during this assessment to include the recent upgrade.

6.3.7 Evaluate use of certificate and/or certification mark

The Emerson Automation Solutions 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 be assessed at this audit.

6.4 Surveillance Audit Conclusion

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

The Emerson Automation Solutions G Series and CB/CBA/CBA300/CBB Series Scotch Yoke Actuators continues to meet the relevant requirements of IEC 61508:2010 for SIL 3 in low demand applications based on the initial assessment and considering:

- field failure history

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

7 Terms and Definitions

Architectural Constraint	The SIL limit imposed by the combination of SFF and HFT for Route 1_H or by the HFT and Diagnostic Coverage (DC applies to Type B only) for Route 2_H
exida criteria	A conservative approach to arriving at failure rates suitable for use in hardware evaluations utilizing the 2_H Route in IEC 61508-2.
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.
PFD_{avg}	Average Probability of Failure on Demand
PVST	Partial Valve Stroke Test It is assumed that the Partial Stroke Testing, when performed, is automatically performed at least an order of magnitude more frequent than the proof test, therefore the test can be assumed an automatic diagnostic. Because of the automatic diagnostic assumption, the Partial Valve Stroke Testing also has an impact on the Safe Failure Fraction.
Random Capability	The SIL limit imposed by the PFD_{avg} for each element.
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).
Systematic Capability	The SIL limit imposed by the capability of the products manufacturer.
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. *exida* accepts no liability whatsoever for the use of this report 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
Q22/08-013	EAS 16-06-010 R001 V4R1	Recertification with G-Series upgrade; TES 3/12/2023
Q19/11-035	EAS 16-06-010 R001 V3R1	Recertification; LLS 5/28/2020
Q18/07-152	EAS 16/06-010 R001 V2R1	Added Hydraulic Damper
Q16/06-010	EAS 16-06-010 R001 V1R1	Recertification Release
Q03/08-24	BET 03-08-24 R007 V2R1	Previous Assessment Report

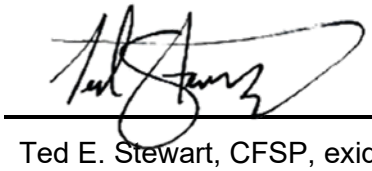
Reviewer/Approver: Bob Gavin, *exida*, 3/13/2023

Status: Released, 3/13/2023

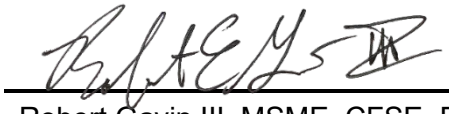
8.3 Future Enhancements

At request of client.

8.4 Release Signatures



Ted E. Stewart, CFSP, exidaCSP, Evaluating Assessor



Robert Gavin III, MSME, CFSE, Reviewer/Approver