Failure Modes, Effects and Diagnostic Analysis

Project:
625 Infrared Combustible Gas Sensor and 925 Transmitter

Company:
Rosemount Flame & Gas Detection
Shakopee, MN
USA

Contract Number: Q24/02-073
Report No.: ROS 19/10-140 R001
Version V3, Revision R1, May 22, 2024
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Management Summary

This report summarizes the results of the hardware assessment in the form of a Failure Modes, Effects, and Diagnostic Analysis (FMEDA) of the 625 Infrared Combustible Gas Sensor and 925 Transmitter, hardware and software revision per Section 2.5.1 A Failure Modes, Effects, and Diagnostic Analysis is one of the steps to be taken to achieve functional safety certification per IEC 61508 of a device. From the FMEDA, failure rates are determined. The FMEDA that is described in this report concerns only the hardware of the 625ND & 925FGD. For full functional safety certification purposes, all requirements of IEC 61508 must be considered.

A 625 Infrared Combustible Gas Sensor and 925 Transmitter gas detection system is composed of a field mounted transmitter\controller and a sensor which may be integrally mounted to the controller or remotely mounted as far as 457 meters away. Available outputs are: conventional 0 to 20mA analog, Analog/HART, or electromechanical relays. This report covers the analog portion of the Analog/HART output and the electromechanical relay outputs used in de-energize-to-trip mode.

Table 1 gives an overview of the different versions that were considered in the FMEDA of the 625ND & 925FGD.

Table 1 Version Overview

Current Out	Sensor Plus Main Board Plus LCD Display Plus Relay Board – One Sensor Input, 4-20mA Output with HART
Relay Out	Sensor Plus Main Board Plus LCD Display Plus Relay Board – One Sensor Input, Relay Output

The 625ND & 925FGD is classified as a Type B[1] element according to IEC 61508, having a hardware fault tolerance of 0.

The failure rate data used for this analysis meet the *exida* criteria for Route 2_H (see Section 5.2) (and the diagnostic coverage resulting from the analysis exceeds the required 60% threshold). Therefore, the 625ND & 925FGD meets the hardware architectural constraints for up to SIL 2 at HFT=0 when the listed failure rates are used.

Based on the assumptions listed in 4.3, the failure rates for the 625ND & 925FGD are listed in section 4.5.

These failure rates are valid for the useful lifetime of the product, see Section 4.7.

The failure rates listed in this report are based on over 400 billion-unit operating hours of industry field failure data. The failure rate predictions reflect realistic failures and include site specific failures due to human events for the specified Site Safety Index (SSI) [N9], [N10].

A user of the 625ND & 925FGD can utilize these failure rates in a probabilistic model of a safety instrumented function (SIF) to determine suitability in part for safety instrumented system (SIS) usage in a particular safety integrity level (SIL).

[1] Type B element: "Complex" element (using micro controllers or programmable logic); for details see 7.4.4.1.3 of IEC 61508-2, ed2, 2010.

Table of Contents

1 Purpose and Scope

This document shall describe the results of the hardware assessment in the form of the Failure Modes, Effects and Diagnostic Analysis carried out on the 625ND & 925FGD. From this, failure rates for each failure mode/category, useful life, and proof test coverage are determined.

The information in this report can be used to evaluate whether an element meets the average Probability of Failure on Demand (PFD_{AVG}) requirements and if applicable, the architectural constraints / minimum hardware fault tolerance requirements per IEC 61508 / IEC 61511.

A FMEDA is part of the effort needed to achieve full certification per IEC 61508 or other relevant functional safety standard.

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, availability, and cybersecurity with over 500 person years of cumulative experience in functional safety, alarm management, and cybersecurity. Founded by several of the world's top reliability and safety experts from manufacturers, operators and assessment organizations, *exida* is a global corporation with offices around the world. *exida* offers training, coaching, project-oriented consulting services, safety engineering tools, detailed product assurance and ANSI accredited functional safety and cybersecurity certification. *exida* maintains a comprehensive failure rate and failure mode database on electronic and mechanical equipment and a comprehensive database on solutions to meet safety standards such as IEC 61508.

2.2 Roles of the parties involved

Rosemount Flame & Gas Detection	Manufacturer of the 625ND & 925FGD
exida	Performed the hardware assessment

Rosemount Flame & Gas Detection contracted *exida* in October 2019 with the hardware assessment of the above-mentioned device.

2.3 Standards and literature used

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

[N1]	IEC 61508-2: ed2, 2010	Functional Safety of Electrical/Electronic/Programmable Electronic Safety-Related Systems
[N2]	Component Reliability Database, 2024	*exida* LLC, Component Reliability Database, 2024
[N3]	Goble, W.M. 2010	Control Systems Safety Evaluation and Reliability, 3rd edition, ISA, ISBN 97B-1-934394-80-9. Reference on FMEDA methods
[N4]	IEC 60654-1:1993-02, second edition	Industrial-process measurement and control equipment – Operating conditions – Part 1: Climatic condition
[N5]	O'Brien, C., Gavin, R., & Bredemeyer, L., 2023	*exida* LLC., Final Elements in Safety Instrumented Systems, IEC61511 Compliant Systems and IEC 61508 Compliant Products, Second Edition, 2023, ISBN 978-1-934977-24-8
[N6]	Scaling the Three Barriers, Recorded Web Seminar, June 2013,	Scaling the Three Barriers, Recorded Web Seminar, June 2013, http://www.exida.com/Webinars/Recordings/SIF-Verification-Scaling-the-Three-Barriers
[N7]	Meeting Architecture Constraints in SIF Design, Recorded Web Seminar, March 2013	http://www.exida.com/Webinars/Recordings/Meeting-Architecture-Constraints-in-SIF-Design

[N8]	Random versus Systematic – Issues and Solutions, September 2016	Goble, W.M., Bukowski, J.V., and Stewart, L.L., Random versus Systematic – Issues and Solutions, exida White Paper, PA: Sellersville, www.exida.com/resources/whitepapers, September 2016.
[N9]	Assessing Safety Culture via the Site Safety Index™, April 2016	Bukowski, J.V. and Chastain-Knight, D., Assessing Safety Culture via the Site Safety Index™, Proceedings of the AIChE 12th Global Congress on Process Safety, GCPS2016, TX: Houston, April 2016.
[N10]	Quantifying the Impacts of Human Factors on Functional Safety, April 2016	Bukowski, J.V. and Stewart, L.L., Quantifying the Impacts of Human Factors on Functional Safety, Proceedings of the 12th Global Congress on Process Safety, AIChE 2016 Spring Meeting, NY: New York, April 2016.
[N11]	Criteria for the Application of IEC 61508:2010 Route 2H, December 2016	Criteria for the Application of IEC 61508:2010 Route 2H, exida White Paper, PA: Sellersville, www.exida.com, December 2016.
[N12]	Using a Failure Modes, Effects and Diagnostic Analysis (FMEDA) to Measure Diagnostic Coverage in Programmable Electronic Systems, November 1999	Goble, W.M. and Brombacher, A.C., Using a Failure Modes, Effects and Diagnostic Analysis (FMEDA) to Measure Diagnostic Coverage in Programmable Electronic Systems, Reliability Engineering and System Safety, Vol. 66, No. 2, November 1999.
[N13]	FMEDA – Accurate Product Failure Metrics, June 2015	Grebe, J. and Goble W.M., FMEDA – Accurate Product Failure Metrics, www.exida.com, June 2015.

2.4 *exida* tools used

[T1]	V2.0.1.22092	*exida* FMEDAx Tool
[T2]	V2.4.1	*exida* OEMx Tool

2.5 Reference documents

2.5.1 Documentation provided by Rosemount Flame & Gas Detection

[D1]	625 Product Architecture.pdf, 2018-03-29	625ND Product Architecture Drawing
[D2]	Doc # 00625-3000, Rev AC, 2023-10-02	Schematic Drawing, 625ND Sensor Wiring Board
[D3]	Doc # 00625-3003, Rev AA, 2019-09-20	Schematic Drawing, 625ND CPU Board
[D4]	Doc # 00625-3006, Rev AC, 2021-06-14	Schematic Drawing, 625 NDIR Sensor

[D5]	Schematic Drawing, 925 GDT CPU Board, 2018-03-28	925FGD Product Architecture Drawing
[D6]	Doc # 00925-3000, Rev AC, 2020-12-28	Schematic Drawing, 925FGD CPU Board
[D7]	Doc # 00925-3003, Rev AB, 2019-12-21	Schematic Drawing, 925FGD Display Board
[D8]	Doc # 00925-3006, Rev AC, 2021-06-14	Schematic Drawing, 925FGD Terminal Board

2.5.2 Documentation generated by *exida*

[R1]	625 2024-04-17.xls	Failure Modes, Effects, and Diagnostic Analysis – 625ND
[R2]	925 2024-04-17 Current.xls	Failure Modes, Effects, and Diagnostic Analysis – 925FGD Current Out
[R3]	925 2024-04-17 Relay.xls	Failure Modes, Effects, and Diagnostic Analysis – 925FGD Relay out
[R4]	625NDIR 925 FMEDA Summary 2024-04-19	Failure Modes, Effects, and Diagnostic Analysis - Summary –625ND & 925FGD

3 Product Description

A 625ND & 925FGD gas detection system is composed of a field mounted transmitter\controller and a sensor which may be integrally mounted to the controller or remotely mounted as far as 457 meters away. Available outputs are: conventional 0 to 20mA analog, Analog/HART, or electromechanical relays. This report covers the analog portion of the Analog/HART output and the electromechanical relay outputs used in de-energize-to-trip mode.

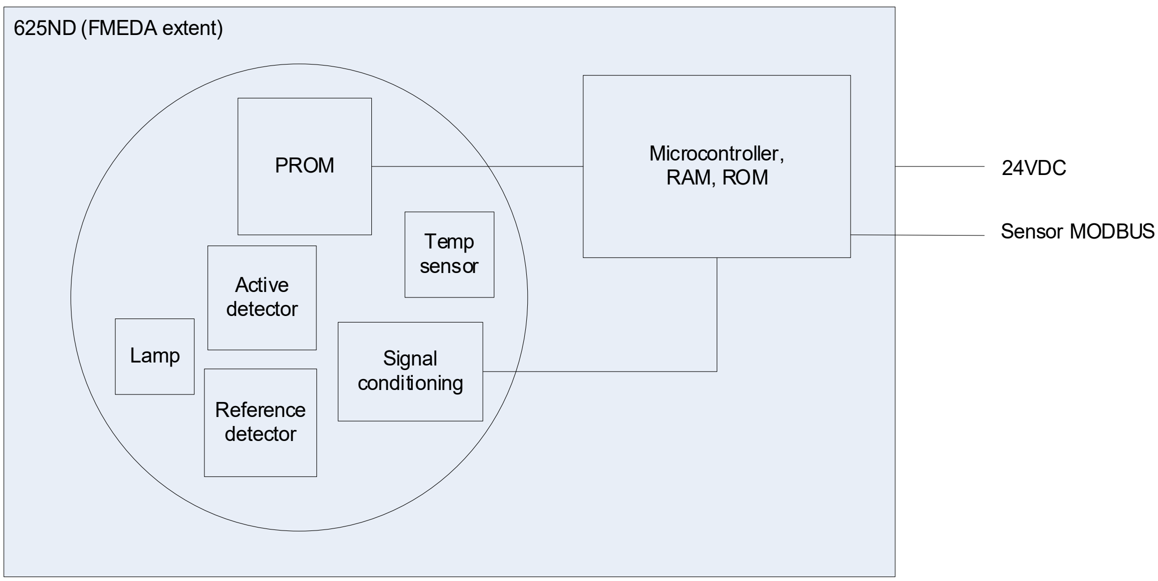


Figure 1: 625, Parts included in the FMEDA

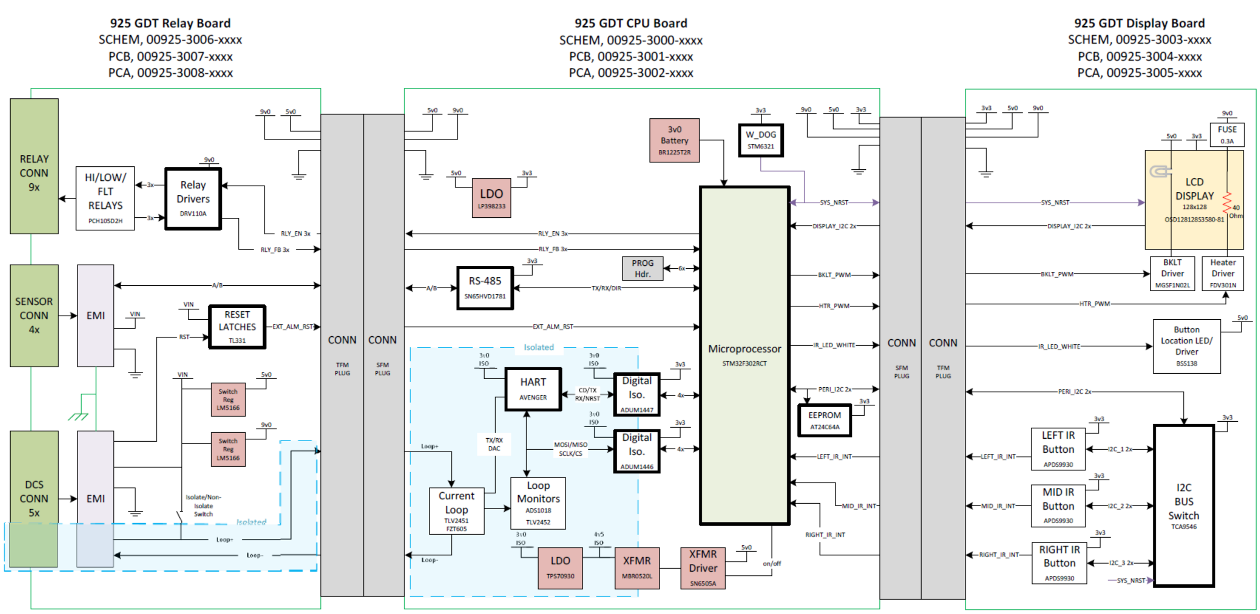


Figure 2: 925, Parts included in the FMEDA

Table 2 gives an overview of the different versions that were considered in the FMEDA of the 625ND & 925FGD.

Table 2 Version Overview

Current Out	Sensor Plus Main Board Plus LCD Display Plus Relay Board – One Sensor Input, 4-20mA Output with HART
Relay Out	Sensor Plus Main Board Plus LCD Display Plus Relay Board – One Sensor Input, Relay Output

The 625ND & 925FGD is classified as a Type B[2] element according to IEC 61508, having a hardware fault tolerance of 0.

Type B element: "Complex" element (using micro controllers or programmable logic); for details see 7.4.4.1.3 of IEC 61508-2, ed2, 2010.

4 Failure Modes, Effects, and Diagnostic Analysis

The Failure Modes, Effects, and Diagnostic Analysis was performed based on the documentation in section 2.5.1 and is documented in [R1] to [R4].

4.1 Failure categories description

In order to judge the failure behavior of the 625ND & 925FGD, the following definitions for the failure of the device were considered.

Fail-Safe State	Failure that deviates the process signal or the actual output by more than 2% of span, drifts toward the user defined threshold (Trip Point) and that leaves the output within the active scale.
Fail Safe	Failure that causes the device to go to the defined fail-safe state without a demand from the process.
Fail Detected	Failure that causes the output signal to go to the predefined alarm state (xx mA (current out) or fault relay de-energized (relay out)).
Fail Dangerous	Failure that deviates the process signal or the actual output by more than 2% of span, drifts away from the user defined threshold (Trip Point) and that leaves the output within the active scale.
Fail Dangerous Undetected	Failure that is dangerous and that is not being diagnosed by automatic diagnostics.
Fail Dangerous Detected	Failure that is dangerous but is detected by automatic diagnostics.
Fail High	Failure that causes the output signal to go to the over-range or high alarm output current (> 21 mA).
Fail Low	Failure that causes the output signal to go to the under-range or low alarm output current (< 3.6 mA).
No Effect	Failure of a component that is part of the safety function but that has no effect on the safety function.
Annunciation Detected	Failure that does not directly impact safety but does impact the ability to detect a future fault (such as a fault in a diagnostic circuit) and that is detected by internal diagnostics. A Fail Annunciation Detected failure leads to a false diagnostic alarm.
Annunciation Undetected	Failure that does not directly impact safety but does impact the ability to detect a future fault (such as a fault in a diagnostic circuit) and that is not detected by internal diagnostics.

The failure categories listed above expand on the categories listed in IEC 61508 in order to provide a complete set of data needed for design optimization.

Depending on the application, a Fail High or a Fail Low failure can either be safe or dangerous and may be detected or undetected depending on the programming of the logic solver. Consequently, during a Safety Integrity Level (SIL) verification assessment the Fail High and Fail Low failure categories need to be classified as safe or dangerous, detected or undetected.

The Annunciation failures are provided for those who wish to do reliability modeling more detailed than required by IEC61508. It is assumed that the probability model will correctly account for the Annunciation failures.

4.2 Methodology – FMEDA, failure rates

4.2.1 FMEDA

A FMEDA (Failure Mode Effect and Diagnostic Analysis) is a failure rate prediction technique based on a study of design strength versus operational profile stress. It combines design FMEA techniques with extensions to identify automatic diagnostic techniques and the failure modes relevant to safety instrumented system design. It is a technique recommended to generate failure rates for each failure mode category [N12], [N13].

4.2.2 Failure rates

The accuracy of any FMEDA analysis depends upon the component reliability data as input to the process. Component data from consumer, transportation, military or telephone applications could generate failure rate data unsuitable for the process industries. The component data used by *exida* in this FMEDA is from the Component Reliability Database [N1] which was derived using:

- Over 400 billion unit operational hours of process industry field failure data from multiple sources.
- Failure data formulas derived from IEC TR62380, SN 29500 and industry sources.
- Manufacturer Meetings.
- Component Research.

The *exida* profile chosen for this FMEDA was 3 as this was judged to be the best fit for the product and application information submitted by Rosemount Flame & Gas Detection. It is expected that the actual number of field failures will be less than the number predicted by these failure rates.

Early life failures (infant mortality) are not included in the failure rate prediction as it is assumed that some level of commission testing is done. End of life failures are not included in the failure rate prediction as useful life is specified.

The failure rates are predicted for a Site Safety Index of SSI=2 [N9], [N10] as this level of operation is common in the process industries. Failure rate predictions for other SSI levels are included in the exSILentia® tool from *exida*.

The user of these numbers is responsible for determining the failure rate applicability to any particular environment. *exida* Environmental Profiles listing expected stress levels can be found in Appendix A. Some industrial plant sites have high levels of stress. Under those conditions the failure rate data is adjusted to a higher value to account for the specific conditions of the plant. *exida* has detailed models available to make customized failure rate predictions. Contact *exida* for assistance.

Accurate plant specific data may be used to check validity of this failure rate data. If a user has data collected from a good proof test reporting system such as *exida* SILStat™ that indicates higher failure rates, the higher numbers shall be used.

4.3 Assumptions

The following assumptions have been made during the Failure Modes, Effects, and Diagnostic Analysis of the 625ND & 925FGD.

- The worst-case assumption of a series system is made. Therefore, only a single component failure will fail the entire 625ND & 925FGD.

- Failure rates are constant for the useful life period.
- Any product component that cannot influence the safety function (feedback immune) is excluded. All components that are part of the safety function including those needed for normal operation are included in the analysis.
- The stress levels are specified in the *exida* Profile used for the analysis are limited by the manufacturer's published ratings.
- Practical fault insertion tests have been used when applicable to demonstrate the correctness of the FMEDA results.
- The HART protocol is only used for setup, calibration, and diagnostics purposes, not for safety critical operation.
- The LCD display is not used for safety critical operation.
- The application program in the logic solver is constructed in such a way that Fail High and Fail Low failures are detected regardless of the effect, safe or dangerous, on the safety function.
- Materials are compatible with process conditions.
- The device is installed and operated per manufacturer's instructions.
- External power supply failure rates are not included.
- Worst-case internal fault detection time is 30 minutes.

4.4 Application specific restrictions

The following application specific restrictions are applicable to the 625ND & 925FGD and have been considered during the Failure Modes, Effects, and Diagnostic Analysis of the 625ND & 925FGD. These restrictions shall be included in the safety manual for the 625ND & 925FGD.

- When using the alarm relay as the safety output the fault relay output of the 925FGD will be monitored.

4.5 Failure Rate Results

Using reliability data extracted from the *exida* Electrical and Mechanical Component Reliability Handbook the following failure rates resulted from the 625ND & 925FGD FMEDA.

Table 3 and Table 4 list the failure rates for the 625ND & 925FGD with a Site Safety Index (SSI) of 2 (good site maintenance practices).

Table 3 Current Out Failure rates with Good Maintenance Assumptions in FIT @ SSI=2

Failure Category	Failure Rate (FIT)	
Fail Safe Undetected		96
Fail Dangerous Detected		1087
Fail Detected (detected by internal diagnostics)	1011	
Fail High (detected by logic solver)	12	
Fail Low (detected by logic solver)	64	
Fail Dangerous Undetected		99
No Effect		775
Annunciation Undetected		59

Table 4 Relay Out Failure rates with Good Maintenance Assumptions in FIT @ SSI=2

Failure Category	Failure Rate (FIT)
Fail Safe Detected	517
Fail Safe Undetected	98
Fail Dangerous Detected	840
Fail Dangerous Undetected	87
No Effect	622
Annunciation Detected	132
Annunciation Undetected	59

Table 5 lists the failure rates for the 625ND & 925FGD according to IEC 61508.

Table 5 Failure rates for Static Applications with Good Maintenance Assumptions in FIT @ SSI=2 according to IEC 61508

Application/Device/Configuration	λ_{SD}	λ_{SU}[3]	λ_{DD}	λ_{DU}	#	DC
Current Out	0	96	1087	99	833	84%
Relay Out	517	98	840	87	680	87%

Where:

λ_{SD} = Fail Safe Detected

λ_{SU} = Fail Safe Undetected

[3] It is important to realize that the No Effect failures are no longer included in the Safe Undetected failure category according to IEC 61508, ed2, 2010.

λ_{DD} = Fail Dangerous Detected

λ_{DU} = Fail Dangerous Undetected

= No Effect Failures

These failure rates are valid for the useful lifetime of the product, see Section 4.7.

4.6 Proof Test Coverage

According to section 7.4.5.2 f) of IEC 61508-2 proof tests shall be undertaken to reveal dangerous faults which are undetected by automatic diagnostic tests. This means that it is necessary to specify how dangerous undetected faults which have been noted during the Failure Modes, Effects, and Diagnostic Analysis can be detected during proof testing.

4.6.1 Suggested Proof Test

The suggested proof test described in Table 6 will detect 48% of possible DU failures in the 625ND & 925FGD.

The suggested proof test consists of a setting the output to the min and max, and a calibration check.

Table 6 Suggested Proof Test – Transmitter

Step	Action
1.	Bypass the safety function and take appropriate action to avoid a false trip.
2.	Use HART communications to retrieve any diagnostics and take appropriate action.
3.	Send a HART command to the transmitter to go to the high alarm current output and verify that the analog current reaches that value[4].
4.	Send a HART command to the transmitter to go to the low alarm current output and verify that the analog current reaches that value[5].
5.	Calibrate the 625ND + 925 system as called out in the product manual.
6.	Bump the 625ND system as called out in the product manual.
7.	Check the 4-20 analog output.
8.	Check Alarm relay(s) status.
9.	Inspect the transmitter for any visible damage or contamination.
10.	Remove the bypass and otherwise restore normal operation.

4.7 Useful Life

The Useful Life of the device predicted by component failure data is 7 years.

[4] This tests for compliance voltage problems such as a low loop power supply voltage or increased wiring resistance. This also tests for other possible failures.

[5] This tests for possible quiescent current related failures.

shows which components are contributing to the dangerous undetected failure rate and therefore to the PFD_{avg} calculation and what their estimated useful lifetime is.

Table 7 Useful lifetime of components contributing to dangerous undetected failure rate

Component	Useful Life
Incandescent lamp (IR gas detector sensor)	7 years

4.8 Architecture Constraints

According to IEC 61508-2 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 61508-2 or the 2_H approach according to 7.4.4.3 of IEC 61508-2, or the approach according to IEC 61511:2016 which is based on 2_H (see Section 5.2).

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 61508-2.

The failure rate data used for this analysis meet the *exida* criteria for Route 2_H (which is more stringent than IEC 61508-2) (and the diagnostic coverage resulting from the analysis exceeds the required 60% threshold).Therefore, the 625ND & 925FGD meets the hardware architectural constraints for up to SIL 2 at HFT=0 when the listed failure rates are used.

The architectural constraint type for the 625ND & 925FGD is B. The hardware fault tolerance of the device is 0. The SIS designer is responsible for meeting other requirements of applicable standards for any given SIL.

5 Using the FMEDA Results

The following section(s) describe how to apply the results of the FMEDA.

5.1 PFD_{avg} calculation 625ND & 925FGD

Using the failure rate data displayed in section 4.5, and the failure rate data for the associated element devices, an average the Probability of Failure on Demand (PFD_{avg}) calculation can be performed for the element.

Probability of Failure on Demand (PFD_{avg}) calculation uses several parameters, many of which are determined by the particular application and the operational policies of each site. Some parameters are product specific and the responsibility of the manufacturer. Those manufacturer specific parameters are given in this third-party report.

Probability of Failure on Demand (PFD_{avg}) calculation is the responsibility of the owner/operator of a process and is often delegated to the SIF designer. Product manufacturers can only provide a PFD_{avg} by making many assumptions about the application and operational policies of a site. Therefore, use of these numbers requires complete knowledge of the assumptions and a match with the actual application and site.

Probability of Failure on Demand (PFD_{avg}) calculation is best accomplished with *exida's* exSILentia tool. See Appendix B for a complete description of how to determine the Safety Integrity Level for an element. The mission time used for the calculation depends on the PFD_{avg} target and the useful life of the product. The failure rates and the proof test coverage for the element are required to perform the PFD_{avg} calculation. The proof test coverage for the suggested proof test is listed in Section 4.6.

5.2 *exida* Route 2_H Criteria

IEC 61508, ed2, 2010 describes the Route 2_H alternative to Route 1_H architectural constraints. The standard states:

> "based on data collected in accordance with published standards (e.g., IEC 60300-3-2: or ISO 14224); and, be evaluated according to
>
> - the amount of field feedback; and
> - the exercise of **expert judgment**; and when needed
> - the undertake of specific tests,
>
> in order to estimate the average and the uncertainty level (e.g., the 90% confidence interval or the probability distribution) of each reliability parameter (e.g., failure rate) used in the calculations."

exida has interpreted this to mean not just a simple 90% confidence level in the uncertainty analysis, but a high confidence level in the entire data collection process. As IEC 61508, ed2, 2010 does not give detailed criteria for Route 2_H, *exida* has established the following:

1. field unit operational hours of 10,000,000 per each component or known common usage of the component for over ten years in at least 10 units; and

2. operational hours are counted only when the data collection process has been audited for correctness and completeness; and

3. failure definitions are realistic without data censoring of failures with both a systematic and random failure cause [N9]; and

4. every component used in an FMEDA meets the above criteria.

This set of requirements is chosen to assure high integrity failure data suitable for safety integrity verification [N11].

6 Terms and Definitions

Automatic Diagnostics	Tests automatically performed online internally by the device or, if specified, externally by another device without manual intervention or manual interpretation of the results.
exida 2_H criteria	A method to arriving at failure rates suitable for use in hardware evaluations utilizing the 2_H Route with more detail and more requirements than specified 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
PFD_{avg}	Average Probability of Failure on Demand
SFF	Safe Failure Fraction, summarizes the fraction of failures which lead to a safe state plus the fraction of failures which will be detected by automatic 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

7 Status of the Document

7.1 Liability

exida prepares FMEDA reports based on methods advocated in engineering literature and International technical reports. Failure rates are obtained from field failure studies and other sources. *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.

Due to future potential changes in the standards, product design changes, best available information and best practices, the current FMEDA results presented in this report may not be fully consistent with results that would be presented for the identical model number product at some future time.

Most products also tend to undergo incremental changes over time. If an *exida* FMEDA has not been updated within the last three years, contact the product vendor to verify the current validity of the results.

7.2 Version History

Contract Number	Report Number	Revision Notes
Q24/02-073	ROS 19-10-140 R001 V3, R1	Correction to reference [D4] doc number, VAM 2024-05-20
Q24/02-073	ROS 19-10-140 R001 V3, R0	Surveillance audit 2024; some updates to FMEDA from design changes; replaced SFF with DC due to 2H; update to latest FMEDA report templates; VAM 2024-04-19
Q20/12-036	ROS 19-10-140 R001 V2, R2	Updated [D6] (no effect on analysis), 2021-01-29
Q19/10-140	ROS 19-10-140 R001 V2, R1	Removed fault relay monitor requirement from current output, 2020-12-07
Q19/10-140	ROS 19-10-140 R001 V1, R2	Updated per client review, 2019-11-14
Q19/10-140	ROS 19-10-140 R001 V1, R1	Released, 2019-11-06
Q19/10-140	ROS 19-10-140 R001 V0, R1	Initial draft; consolidated 625 and 925 analyses
Q18/11-012	ROS 18-11-012 R001 V1, R1	Released

Reviewer: Rudolf Chalupa, *exida*, 2024-04-19

Status: Released, 2024-05-20

7.3 Future enhancements

At request of client.

7.4 Release signatures

Valerie Motto, CFSP, Safety Engineer

Rudolph P. Chalupa, CFSE, Senior Safety Engineer

END OF DOCUMENT

Appendix A *exida* Environmental Profiles

Table 8 *exida* Environmental Profiles

exida **Profile**	1	2	3	4	5	6
Description (Electrical)	Cabinet mounted/ Climate Controlled	Low Power Field Mounted no self-heating	General Field Mounted self-heating	Subsea	Offshore	N/A
Description (Mechanical)	Cabinet mounted/ Climate Controlled	General Field Mounted	General Field Mounted	Subsea	Offshore	Process Wetted
IEC 60654-1 Profile	B2	C3 also applicable for D1	C3 also applicable for D1	N/A	C3 also applicable for D1	N/A
Average Ambient Temperature	30 C	25 C	25 C	5 C	25 C	25 C
Average Internal Temperature	60 C	30 C	45 C	10 C	45 C	Process Fluid Temp.
Daily Temperature Excursion (pk-pk)	5 C	25 C	25 C	2 C	25 C	N/A
Seasonal Temperature Excursion (winter average vs. summer average)	5 C	40 C	40 C	2 C	40 C	N/A
Exposed to Elements / Weather Conditions	No	Yes	Yes	Yes	Yes	Yes
Humidity[6]	0-93% Non-Condensing at 40 C	0-100% Condensing	0-100% Condensing	0-100% Condensing	0-100% Condensing	N/A
Shock[7]	10 g	15 g	15 g	15 g	15 g	N/A
Vibration[8]	2 g	3 g	3 g	3 g	3 g	N/A
Chemical Corrosion[9]	G2	G3	G3	G3	G3	Compatible Material
Surge[10]						
Line-Line	0.5 kV	0.5 kV	0.5 kV	0.5 kV	0.5 kV	N/A
Line-Ground	1 kV	1 kV	1 kV	1 kV	1 kV	
EMI Susceptibility[11]						
80 MHz to 1.4 GHz	10 V/m	10 V/m	10 V/m	10 V/m	10 V/m	N/A
1.4 GHz to 2.0 GHz	3 V/m	3 V/m	3 V/m	3 V/m	3 V/m	
2.0Ghz to 2.7 GHz	1 V/m	1 V/m	1 V/m	1 V/m	1 V/m	
ESD (Air)[12]	6 kV	6 kV	6 kV	6 kV	6 kV	N/A

[6] Humidity rating per IEC 60068-2-78
[7] Shock rating per IEC 60068-2-27
[8] Vibration rating per IEC 60068-2-6
[9] Chemical Corrosion rating per ISA 71.04
[10] Surge rating per IEC 61000-4-5
[11] EMI Susceptibility rating per IEC 61000-4-3
[12] ESD (Air) rating per IEC 61000-4-2

Appendix B Determining Safety Integrity Level

The information in this appendix is intended to provide the method of determining the Safety Integrity Level (SIL) of a Safety Instrumented Function (SIF). **The numbers used in the examples are not for the product described in this report.**

Three things must be checked when verifying that a given Safety Instrumented Function (SIF) design meets a Safety Integrity Level (SIL) [N3] and [N6].

These are:

A. Systematic Capability or Prior Use Justification for each device meets the SIL level of the SIF;

B. Architecture Constraints (minimum redundancy requirements) are met; and

C. a PFD_{avg} calculation result is within the range of numbers given for the SIL level.

A. Systematic Capability (SC) is defined in IEC61508:2010. The SC rating is a measure of design quality based upon the methods and techniques used to design and development a product. All devices in a SIF must have a SC rating equal or greater than the SIL level of the SIF. For example, a SIF is designed to meet SIL 3 with three pressure transmitters in a 2oo3 voting scheme. The transmitters have an SC2 rating. The design does not meet SIL 3. Alternatively, IEC 61511 allows the end user to perform a "Prior Use" justification. The end user evaluates the equipment to a given SIL level, documents the evaluation and takes responsibility for the justification.

B. Architecture constraints require certain minimum levels of redundancy. Different tables show different levels of redundancy for each SIL level. A table is chosen and redundancy is incorporated into the design [N7].

C. Probability of Failure on Demand (PFD_{avg}) calculation uses several parameters, many of which are determined by the particular application and the operational policies of each site. Some parameters are product specific and the responsibility of the manufacturer. Those manufacturer specific parameters are given in this third-party report.

A Probability of Failure on Demand (PFD_{avg}) calculation must be done based on a number of variables including:

1. Failure rates of each product in the design including failure modes and any diagnostic coverage from automatic diagnostics (an attribute of the product given by this FMEDA report);
2. Redundancy of devices including common cause failures (an attribute of the SIF design);
3. Proof Test Intervals (assignable by end user practices);
4. Mean Time to Restore (an attribute of end user practices);
5. Proof Test Effectiveness; (an attribute of the proof test method used by the end user with an example given by this report);
6. Mission Time (an attribute of end user practices);
7. Proof Testing with process online or shutdown (an attribute of end user practices);
8. Proof Test Duration (an attribute of end user practices); and
9. Operational/Maintenance Capability (an attribute of end user practices).

The product manufacturer is responsible for the first variable. Most manufacturers use the *exida* FMEDA technique which is based on over 400 billion hours of field failure data in the process industries to predict these failure rates as seen in this report. A system designer chooses the second variable. All other variables are the responsibility of the end user site. The exSILentia® SILVer™ software considers all these variables and provides an effective means to calculate PFD_{avg} for any given set of variables.

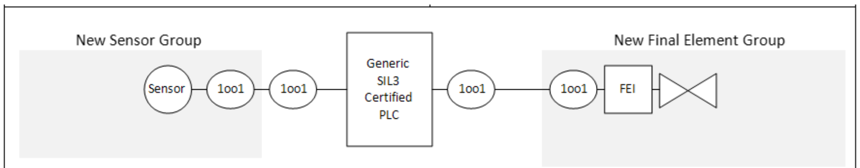
Simplified equations often account for only for first three variables. The equations published in IEC 61508-6, Annex B.3.2 [N1] cover only the first four variables. IEC61508-6 is only an informative portion of the standard and as such gives only concepts, examples and guidance based on the idealistic assumptions stated. These assumptions often result in optimistic PFD_{avg} calculations and have indicated SIL levels higher than reality. Therefore, idealistic equations should not be used for actual SIF design verification.

All the variables listed above are important. As an example, consider a high-level protection SIF. The proposed design has a single SIL 3 certified level transmitter, a SIL 3 certified safety logic solver, and a single remote actuated valve consisting of a certified solenoid valve, certified scotch yoke actuator and a certified ball valve. Note that the numbers chosen are only an example and not the product described in this report.

Using exSILentia with the following variables selected to represent results from simplified equations:

- Mission Time = 5 years
- Proof Test Interval = 1 year for the sensor and final element, 5 years for the logic solver
- Proof Test Coverage = 100% (ideal and unrealistic but commonly assumed)
- Proof Test done with process offline

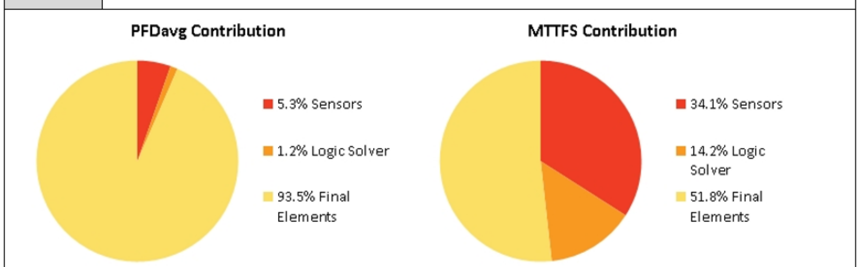
This results in a PFD_{avg} of 5.62E-03 which meets SIL 2 with a risk reduction factor of 179. The subsystem PFD_{avg} contributions are Sensor PFD_{avg} = 2.99E-04, Logic Solver PFD_{avg} = 6.61E-05, and Final Element PFD_{avg} = 5.26E-03. See .



SAFETY INSTRUMENTED FUNCTION PERFORMANCE	
Target SIL	**2**
Target RRF	100
Achieved SIL	**2**
PFDavg	5.62E-03
SIL (PFDavg)	2
SIL (Arch. Constraints IEC 61508)	2
SIL (Systematic Capability)	2
Achieved RRF	177.8
MTTFS (years)	40.44

	PFDavg	MTTFS	SIL Limit	
			AC	CAP
Sensor Part	2.99E-04	118.75	2	2
Logic Solver Part	6.61E-05	284.98	3	3
Final Element Part	5.26E-03	78.12	2	3

REMARKS	The SIF operates in Low demand mode.



Note: The results shown in this SIL verification Summary are based on detailed calculations. All SIL verification assumptions including used reliability data are documented in the SIL verification Details report.

Figure 3: exSILentia results for idealistic variables.

If the Proof Test Interval for the sensor and final element is increased in one-year increments, the results are shown in .

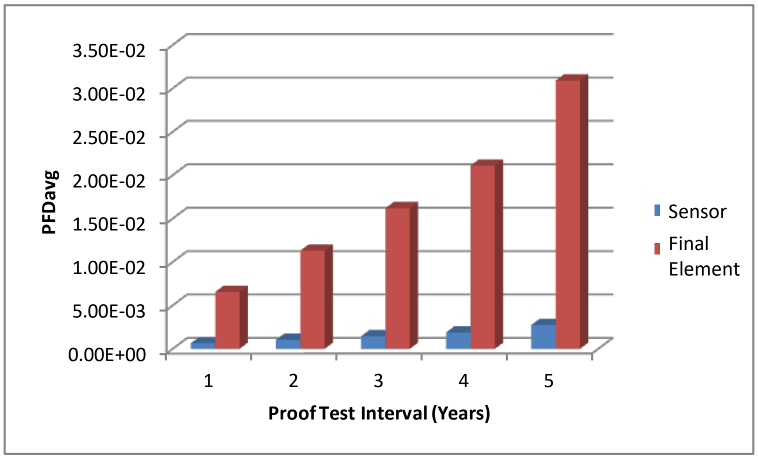
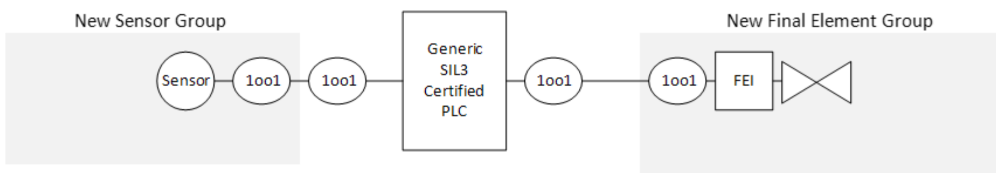


Figure 4 PFD_{avg} versus Proof Test Interval.

If a set of realistic variables for the same SIF are entered into the exSILentia software including:

- Mission Time = 25 years
- Proof Test Interval = 1 year for the sensor and final element, 5 years for the logic solver
- Proof Test Coverage = 90% for the sensor and 70% for the final element
- Proof Test Duration = 2 hours with process online.
- MTTR = 48 hours
- Maintenance Capability = Medium for sensor and final element, Good for logic solver

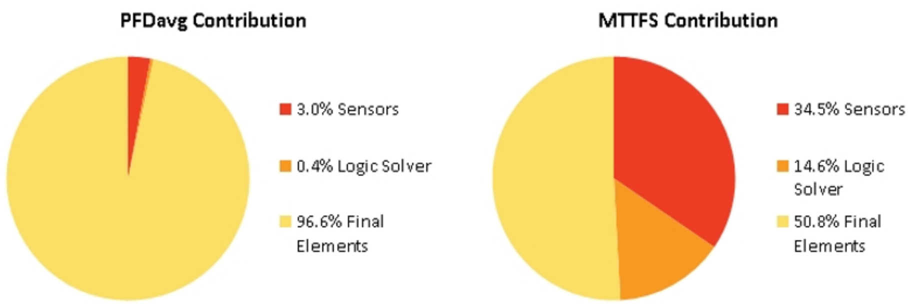
with all other variables remaining the same, the PFD_{avg} for the SIF equals 3.80E-02 which barely meets SIL 1 with a risk reduction factor 26 The subsystem PFD_{avg} contributions are Sensor PFD_{avg} = 1.13E-03, Logic Solver PFD_{avg} = 1.55E-04, and Final Element PFD_{avg} = 3.68E-02 ().



SAFETY INSTRUMENTED FUNCTION PERFORMANCE	
Target SIL	**2**
Target RRF	100
Achieved SIL	**1**
PFDavg	3.80E-02
SIL (PFDavg)	1
SIL (Arch. Constraints IEC 61508)	2
SIL (Systematic Capability)	2
Achieved RRF	26.3
MTTFS (years)	41.02

	PFDavg	MTTFS	SIL Limit	
			AC	CAP
Sensor Part	1.13E-03	118.82	2	2
Logic Solver Part	1.55E-04	280.34	3	3
Final Element Part	3.68E-02	80.66	2	3

REMARKS	The SIF operates in Low demand mode.



Note: *The results shown in this SIL verification Summary are based on detailed calculations. All SIL verification assumptions including used reliability data are documented in the SIL verification Details report.*

Figure 5: exSILentia results with realistic variables

It is clear that PFD_{avg} results can change an entire SIL level or more when all critical variables are not used.

Appendix C Site Safety Index

Numerous field failure studies have shown that the failure rate for a specific device (same Manufacturer and Model number) will vary from site to site. The Site Safety Index (SSI) was created to account for these failure rates differences as well as other variables. The information in this appendix is intended to provide an overview of the Site Safety Index (SSI) model used by *exida* to compensate for site variables including device failure rates.

C.1 Site Safety Index Profiles

The SSI is a number from 0 – 4 which is an indication of the level of site activities and practices that contribute to the safety performance of SIFs on the site. Table 9 details the interpretation of each SSI level. Note that the levels mirror the levels of SIL assignment and that SSI 4 implies that all requirements of IEC 61508 and IEC 61511 are met at the site and therefore there is no degradation in safety performance due to any end-user activities or practices, i.e., that the product inherent safety performance is achieved.

Several factors have been identified thus far which impact the Site Safety Index (SSI). These include the quality of:

Commission Test
Safety Validation Test
Proof Test Procedures
Proof Test Documentation
Failure Diagnostic and Repair Procedures
Device Useful Life Tracking and Replacement Process
SIS Modification Procedures
SIS Decommissioning Procedures
and others

Table 9 *exida* Site Safety Index Profiles

Level	Description
SSI 4	Perfect - Repairs are always correctly performed, Testing is always done correctly and on schedule, equipment is always replaced before end of useful life, equipment is always selected according to the specified environmental limits and process compatible materials. Electrical power supplies are clean of transients and isolated, pneumatic supplies and hydraulic fluids are always kept clean, etc. Note: This level is generally considered not possible but retained in the model for comparison purposes.
SSI 3	Almost perfect - Repairs are correctly performed, Testing is done correctly and on schedule, equipment is normally selected based on the specified environmental limits and a good analysis of the process chemistry and compatible materials. Electrical power supplies are normally clean of transients and isolated, pneumatic supplies and hydraulic fluids are mostly kept clean, etc. Equipment is replaced before end of useful life, etc.
SSI 2	Good - Repairs are usually correctly performed, Testing is done correctly and mostly on schedule, most equipment is replaced before end of useful life, etc.
SSI 1	Medium – Many repairs are correctly performed, Testing is done and mostly on schedule, some equipment is replaced before end of useful life, etc.
SSI 0	None - Repairs are not always done, Testing is not done, equipment is not replaced until failure, etc.