



## **Failure Modes, Effects and Diagnostic Analysis**

Project:

E4 Modulelevel® Liquid Level Displacer Transmitter

Company:

AMETEK Magnetrol USA, LLC

Aurora, IL

USA

Contract Number: Q25/06-143

Report No.: MAG 22/12-113 R001

Version V1, Revision R3, April 9, 2026

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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 E4 Modulelevel® Liquid Level Displacer 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 E4. For full functional safety certification purposes, all requirements of IEC 61508 must be considered.

The E4 Modulelevel® Liquid Level Displacer Transmitter is a loop-powered, two-wire, 24 VDC level transmitter which utilizes buoyancy in combination with a range spring and a linear variable differential transformer to detect and convert liquid level movement into a 4–20 mA output signal.

Table 1 lists the different versions that were considered in the FMEDA of the E4.

**Table 1 Version Overview**

E4 Local	The electronics and display are mounted at the displacer assembly
E4 Remote	The electronics and display are mounted remotely from the displacer assembly

The E4 is classified as a Type B<sup>1</sup> 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<sub>H</sub> (see Section 5.2).

Based on the assumptions listed in 4.3, the failure rates for the E4 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 random human events for Site Safety Index (SSI) = 2 [N10, N11].

A user of the E4 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).

<sup>1</sup> 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 .....	5
2	Project Management .....	6
2.1	<i>exida</i> .....	6
2.2	Roles of the parties involved .....	6
2.3	Standards and literature used .....	6
2.4	<i>exida</i> tools used .....	7
2.5	Reference documents .....	7
2.5.1	Documentation provided by AMETEK Magnetrol USA, LLC .....	7
2.5.2	Documentation generated by <i>exida</i> .....	8
3	Product Description .....	9
4	Failure Modes, Effects, and Diagnostic Analysis .....	11
4.1	Failure categories description .....	11
4.2	Methodology – FMEDA, failure rates .....	12
4.2.1	FMEDA .....	12
4.2.2	Failure rates .....	12
4.3	Assumptions .....	13
4.4	Application specific restrictions .....	13
4.5	Results .....	13
4.6	Proof Test Coverage .....	15
4.6.1	Suggested Proof Test .....	15
4.6.2	Proof Test Coverage .....	16
4.7	Useful Life .....	16
4.8	Architectural Constraints .....	16
5	Using the FMEDA Results .....	17
5.1	PFD <sub>avg</sub> calculation E4 .....	17
5.2	<i>exida</i> Route 2 <sub>H</sub> Criteria .....	17
6	Terms and Definitions .....	19
7	Status of the Document .....	20
7.1	Liability .....	20
7.2	Version History .....	20
7.3	Future enhancements .....	20
7.4	Release signatures .....	21
Appendix A	<i>exida</i> Environmental Profiles .....	22
Appendix B	Determining Safety Integrity Level .....	23
Appendix C	Site Safety Index .....	27



C.1 Site Safety Index Profiles.....27



## 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 E4. 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.





[N7]	Scaling the Three Barriers, Recorded Web Seminar, June 2013,	Scaling the Three Barriers, Recorded Web Seminar, June 2013, <a href="http://www.exida.com/Webinars/Recordings/SIF-Verification-Scaling-the-Three-Barriers">http://www.exida.com/Webinars/Recordings/SIF-Verification-Scaling-the-Three-Barriers</a>
[N8]	Meeting Architecture Constraints in SIF Design, Recorded Web Seminar, March 2013	<a href="http://www.exida.com/Webinars/Recordings/Meeting-Architecture-Constraints-in-SIF-Design">http://www.exida.com/Webinars/Recordings/Meeting-Architecture-Constraints-in-SIF-Design</a>
[N9]	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, <a href="http://www.exida.com/resources/whitepapers">www.exida.com/resources/whitepapers</a> , September 2016.
[N10]	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.
[N11]	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.
[N12]	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, <a href="http://www.exida.com">www.exida.com</a> , December 2016.
[N13]	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.
[N14]	FMEDA – Accurate Product Failure Metrics, June 2015	Grebe, J. and Goble W.M., FMEDA – Accurate Product Failure Metrics, <a href="http://www.exida.com">www.exida.com</a> , June 2015.

## 2.4 exida tools used

[T1]	V2.1.0.30307	exida FMEDAx Tool
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## 2.5 Reference documents

### 2.5.1 Documentation provided by AMETEK Magnetrol USA, LLC

[D1]	Doc # 094-6087, Rev J, 2017-07-07	Schematic Drawing, R86, Pulsar 2x 26GHz HART Digital
[D2]	Doc # 094-6089, Rev G, 2021-05-14	Schematic Drawing, Pulsar Model R86 Wiring PC Board
[D3]	Doc # 094-9823-001, Rev -,	Schematic Drawing, Analog P.C. Board E4 Modulelevel III



	2022-07-19	
[D4]	Doc # 094-1844, Rev C, 2015-12	Schematic Drawing, Modulelevel III Remote, P.C. Board
[D5]	Modulelevel E4 Analog Board-20221130.nefm	Failure Modes, Effects, and Diagnostic Analysis – E4 Analog Board
[D6]	Modulelevel E4 Digital Board-20221130.nefm	Failure Modes, Effects, and Diagnostic Analysis – E4 Digital Board
[D7]	Modulelevel E4 Wiring Board-20221130.nefm	Failure Modes, Effects, and Diagnostic Analysis – E4 Wiring Board
[D8]	Magnetrol E3 Level Transmitter Mechanical 01272016.efm	Failure Modes, Effects, and Diagnostic Analysis – E3 Mechanical Assembly
[D9]	Modulelevel E4 Remote Board-20221130.nefm	Failure Modes, Effects, and Diagnostic Analysis – E4 Remote Board
[D10]	Modulelevel E4 FMEDA Summary 20221130.xlsx	Failure Modes, Effects, and Diagnostic Analysis - Summary –E4
[D11]	D059-MAG 25-06-143 FIT001 Fault Injection List Magnetrol E4 Modulelevel.xls	Fault injection test results

### 2.5.2 Documentation generated by *exida*

[R1]	Modulelevel E4 Analog Board-20260406RPC.nefm	Failure Modes, Effects, and Diagnostic Analysis – E4 Analog Board
[R2]	Modulelevel E4 Digital Board-20260408RPC.xlsx	Failure Modes, Effects, and Diagnostic Analysis – E4 Digital Board
[R3]	Modulelevel E4 Wiring Board-20230215RPC.nefm	Failure Modes, Effects, and Diagnostic Analysis – E4 Wiring Board
[R4]	Modulelevel E4 Remote Board-20230210RPC.nefm	Failure Modes, Effects, and Diagnostic Analysis – E4 Remote Board
[R5]	Modulelevel E4 FMEDA Summary 20260408RPC.xlsx	Failure Modes, Effects, and Diagnostic Analysis - Summary –E4
[R6]	MAG 25-06-143 FIT001 V1R1 Fault Injection List Magnetrol E4 Modulelevel.xls	Fault injection test list

### 3 Product Description

The E4 Modulelevel® Liquid Level Displacer Transmitter is a loop-powered, two-wire, 24 VDC level transmitter which utilizes buoyancy in combination with a range spring and a linear variable differential transformer to detect and convert liquid level movement into a 4–20 mA output signal.

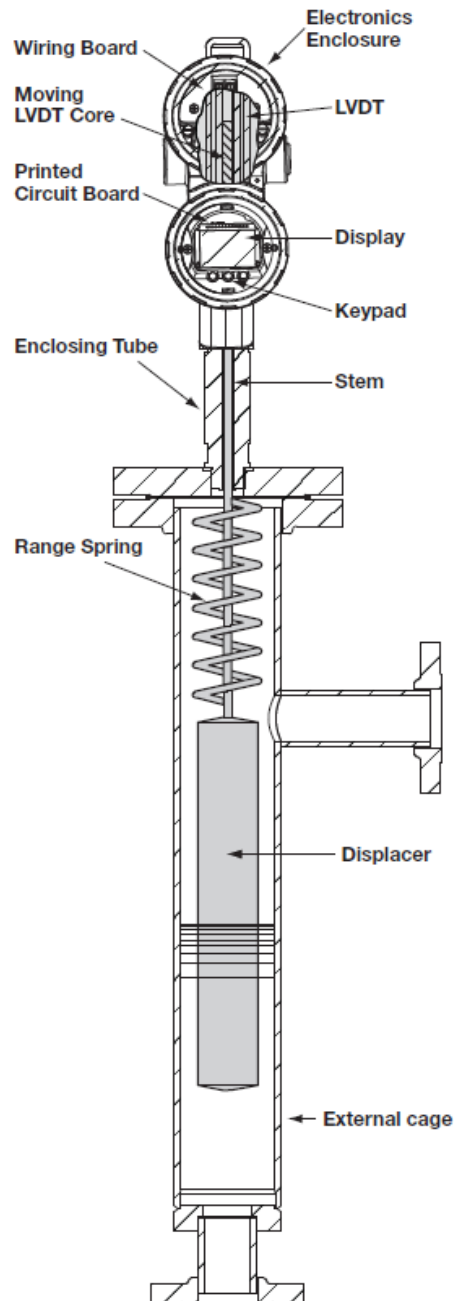


Figure 1 E4, Parts included in the FMEDA



Table 2 lists the different versions that were considered in the FMEDA of the E4.

**Table 2 Version Overview**

E4 Local	The electronics and display are mounted at the displacer assembly
E4 Remote	The electronics and display are mounted remotely from the displacer assembly

The E4 is classified as a Type B<sup>2</sup> element according to IEC 61508, having a hardware fault tolerance of 0.

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<sup>2</sup> 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 [R5].

When the effect of a certain failure mode could not be analyzed theoretically, the failure modes were introduced on component level and the effects of these failure modes were examined on system level, see Fault Injection Test Report [D11].

### 4.1 Failure categories description

In order to judge the failure behavior of the E4, 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 (3.6 or 22 mA, user selectable).
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.
External Leakage	Failure that causes process fluids to leak outside of the valve or actuator; External Leakage is not considered part of the safety function and therefore this failure rate is not included in any of the numbers. External leakage failure rates should be reviewed for secondary safety and environmental issues.



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 and parts stress analysis with extensions to identify automatic diagnostic techniques, the failure modes relevant to safety instrumented system design, and proof test coverage. It is a technique recommended to generate failure rates for each failure mode category [N13, N14].

### 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 [N2] which was derived using failure data formulas based upon:

- Over 400 billion unit operational hours of industry field failure data from multiple sources.
- Technical Reports such as IEC TR 62380, 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 AMETEK Magnetrol USA, LLC.

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 [N10, N11] 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*.



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 E4.

- The worst-case assumption of a series system is made. Therefore, only a single component failure will fail the entire E4 and propagation of failures is not relevant.
- 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 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.
- Soft Error Rates (SER) were considered for relative neutron flux of 1.2 corresponding to 200 meters above sea level.
- External power supply failure rates are not included.
- Worst-case internal fault detection time is 1 hour.

### 4.4 Application specific restrictions

The following application specific restrictions are applicable to the E4 and have been considered during the Failure Modes, Effects, and Diagnostic Analysis of the E4. These restrictions shall be included in the safety manual for the E4.

- The alarm level is set for 3.6 mA or 22 mA; the HOLD alarm setting is not selected.

### 4.5 Results

Using reliability data extracted from the *exida* Electrical and Mechanical Component Reliability Handbook the following failure rates resulted from the E4 FMEDA.

Table 3 and Table 4 list the failure rates for the E4 with a Site Safety Index (SSI) of 2 (good site maintenance practices). See Appendix C for an explanation of SSI.



**Table 3 Failure rates with Good Maintenance Assumptions in FIT @ SSI=2 (Local)**

Failure Category	Failure Rate (FIT)
Fail Safe Undetected	93
Fail Dangerous Detected	1033
Fail Detected (detected by internal diagnostics)	897
Fail High (detected by logic solver)	33
Fail Low (detected by logic solver)	103
Fail Dangerous Undetected	133
No Effect	230
Annunciation Detected	12
Annunciation Undetected	12

**Table 4 Failure rates with Good Maintenance Assumptions in FIT @ SSI=2 (Remote)**

Failure Category	Failure Rate (FIT)
Fail Safe Undetected	93
Fail Dangerous Detected	1063
Fail Detected (detected by internal diagnostics)	927
Fail High (detected by logic solver)	33
Fail Low (detected by logic solver)	103
Fail Dangerous Undetected	133
No Effect	239
Annunciation Detected	12
Annunciation Undetected	12

Table 5 lists the failure rates for the E4 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	$\lambda_{SD}$	$\lambda_{SU}^3$	$\lambda_{DD}$	$\lambda_{DU}$	#	E	DC
E4 Local	0	93	1045	133	242	28	89%
E4 Remote	0	93	1075	133	251	28	89%

<sup>3</sup> 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.



Where:

$\lambda_{SD}$  = Fail Safe Detected

$\lambda_{SU}$  = Fail Safe Undetected

$\lambda_{DD}$  = Fail Dangerous Detected

$\lambda_{DU}$  = Fail Dangerous Undetected

# = No Effect Failures

E = External Leaks

The External Leak failure rates are a subset of the No Effect failure rates, the total No Effect failure rate is the sum of the listed No Effect and External Leak rates. External leakage failure rates do not directly contribute to the reliability of the valve but should be reviewed for secondary safety and environmental issues.

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

## 4.6 Proof Test Coverage

The suggested proof test is described in the device Safety Manual.

### 4.6.1 Suggested Proof Test

The suggested proof test for the E4 is described below. Refer to the table in Section 4.6.2 for the Proof Test Coverages

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

**Table 6 Suggested Proof Test**

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 <sup>4</sup> .
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 <sup>5</sup> .
5.	Inspect the transmitter for any leaks, visible damage or contamination.
6.	Perform a two-point calibration <sup>6</sup> of the transmitter over the full working range.
7.	Remove the bypass and otherwise restore normal operation.

<sup>4</sup> 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.

<sup>5</sup> This tests for possible quiescent current related failures.

<sup>6</sup> If the two-point calibration is performed with electrical instrumentation, this proof test will not detect any failures of the sensor



#### 4.6.2 Proof Test Coverage

The Proof Test Coverage for the various product configurations is given below.

**Table 7 Proof Test Coverage –E4**

Device	$\lambda_{DuPT}$ (FIT)	Proof Test Coverage
E4 Local	61	54%
E4 Remote	61	54%

#### 4.7 Useful Life

The Useful Life of the device predicted by component failure data is 23 years.

#### 4.8 Architectural 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.

The architectural constraint type for the E4 is B. The hardware fault tolerance of the device is 0.

A user of the E4 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). 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<sub>avg</sub> calculation E4

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<sub>avg</sub>) calculation can be performed for the element.

Probability of Failure on Demand (PFD<sub>avg</sub>) 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<sub>avg</sub>) 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<sub>avg</sub> 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<sub>avg</sub>) 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<sub>avg</sub> 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<sub>avg</sub> calculation. The proof test coverages for the suggested proof test are listed in Section 4.6.2.

### 5.2 *exida* Route 2<sub>H</sub> Criteria

IEC 61508, ed2, 2010 describes the Route 2<sub>H</sub> alternative to Route 1<sub>H</sub> 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 undertaking 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<sub>H</sub>, *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 [N12].



## 6 Terms and Definitions

Automatic Diagnostics	Tests performed online internally by the device or, if specified, externally by another device without manual intervention.
DC	Diagnostic Coverage
<i>exida</i> criteria	A conservative approach to arriving at failure rates suitable for use in hardware evaluations utilizing the 2 <sub>H</sub> 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 ( $1 \times 10^{-9}$ failures per hour)
FMEDA	Failure Mode Effect and Diagnostic Analysis
HFT	Hardware Fault Tolerance
PFD <sub>avg</sub>	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 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.

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. As a leader in the functional safety market place, *exida* is actively involved in evolving best practices prior to official release of updated standards so that our reports effectively anticipate any known changes. In addition, most changes are anticipated to be incremental in nature and results reported within the previous three-year period should be sufficient for current usage without significant question.

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
Q25/06-143	MAG 22/12-133 R001 V1, R3	Added FIT results, updated RFD from 4.5 to 1.2, updated to latest template, RPC, 2026-04-09
Q22/12-133	MAG 22/12-133 R001 V1, R2	Table 11 corrections, RPC, 2023-08-11
Q22/12-133	MAG 22/12-133 R001 V1, R1	Released, RPC, 2023-02-23
Q22/12-133	MAG 22/12-133 R001 V0, R1	Initial draft

Reviewer: Valerie Motto, *exida*, 2026-04-08

Status: Released, 2026-04-09

### 7.3 Future enhancements

At request of client.



#### 7.4 Release signatures

*Rudolf P. Chalupa*

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Rudolf P. Chalupa, CFSE, Principal Safety Engineer

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Valerie Motto, CFSP, Senior Safety Engineer



## Appendix A *exida* Environmental Profiles

Table 8 *exida* Environmental Profiles

<i>exida</i> Profile	1	2	3	4	5	6
<b>Description (Electrical)</b>	Cabinet mounted/ Climate Controlled	Low Power Field Mounted no self-heating	General Field Mounted self-heating	Subsea	Offshore	N/A
<b>Description (Mechanical)</b>	Cabinet mounted/ Climate Controlled	General Field Mounted	General Field Mounted	Subsea	Offshore	Process Wetted
<b>IEC 60654-1 Profile</b>	B2	C3 also applicable for D1	C3 also applicable for D1	N/A	C3 also applicable for D1	N/A
<b>Average Ambient Temperature</b>	30 C	25 C	25 C	5 C	25 C	25 C
<b>Average Internal Temperature</b>	60 C	30 C	45 C	5 C	45 C	Process Fluid Temp.
<b>Daily Temperature Excursion (pk-pk)</b>	5 C	25 C	25 C	0 C	25 C	N/A
<b>Seasonal Temperature Excursion (winter average vs. summer average)</b>	5 C	40 C	40 C	2 C	40 C	N/A
<b>Exposed to Elements / Weather Conditions</b>	No	Yes	Yes	Yes	Yes	Yes
<b>Humidity<sup>7</sup></b>	0-95% Non-Condensing	0-100% Condensing	0-100% Condensing	0-100% Condensing	0-100% Condensing	N/A
<b>Shock<sup>8</sup></b>	10 g	15 g	15 g	15 g	15 g	N/A
<b>Vibration<sup>9</sup></b>	2 g	3 g	3 g	3 g	3 g	N/A
<b>Chemical Corrosion<sup>10</sup></b>	G2	G3	G3	G3	G3	Compatible Material
<b>Surge<sup>11</sup></b>						
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	
<b>EMI Susceptibility<sup>12</sup></b>						
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	
<b>ESD (Air)<sup>13</sup></b>	6 kV	6 kV	6 kV	6 kV	6 kV	N/A

<sup>7</sup> Humidity rating per IEC 60068-2-3

<sup>8</sup> Shock rating per IEC 60068-2-27

<sup>9</sup> Vibration rating per IEC 60068-2-6

<sup>10</sup> Chemical Corrosion rating per ISA 71.04

<sup>11</sup> Surge rating per IEC 61000-4-5

<sup>12</sup> EMI Susceptibility rating per IEC 61000-4-3

<sup>13</sup> 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) [N4] and [N7].

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 [N8].

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.

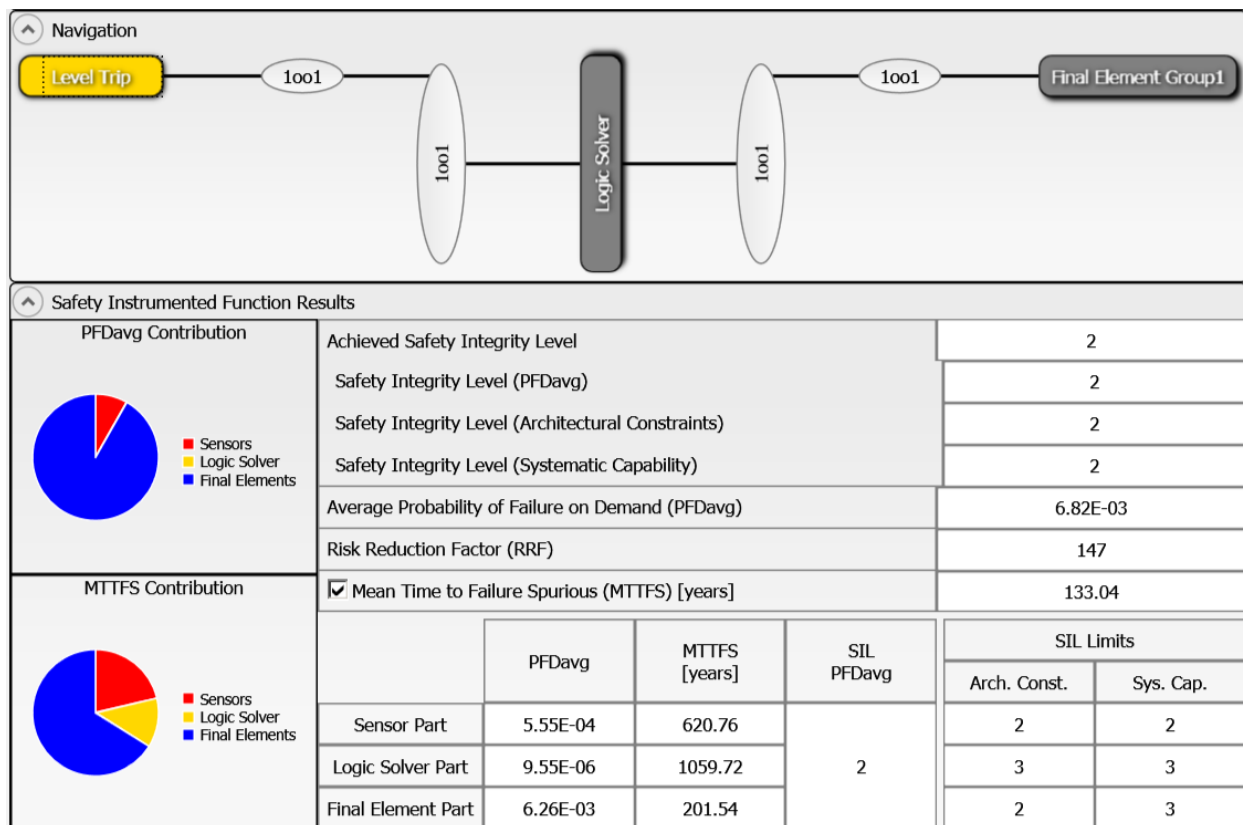
Simplified equations often account for only for first three variables. The equations published in IEC 61508-6, Annex B.3.2 [N1] cover only the first four variables. IEC61508-6 is only an informative portion of the standard and as such gives only concepts, examples and guidance based on the idealistic 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:

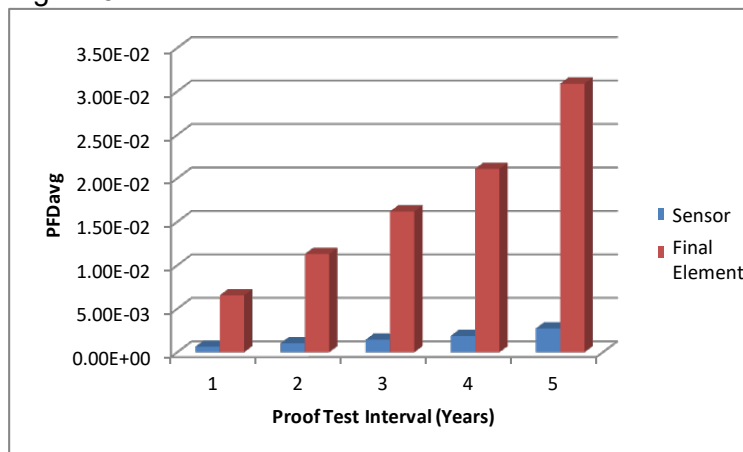
- Mission Time = 5 years
- Proof Test Interval = 1 year for the sensor and final element, 5 years for the logic solver
- Proof Test Coverage = 100% (ideal and unrealistic but commonly assumed)
- Proof Test done with process offline

This results in a  $PFD_{avg}$  of  $6.82E-03$  which meets SIL 2 with a risk reduction factor of 147. The subsystem  $PFD_{avg}$  contributions are Sensor  $PFD_{avg} = 5.55E-04$ , Logic Solver  $PFD_{avg} = 9.55E-06$ , and Final Element  $PFD_{avg} = 6.26E-03$ . See Figure 2.



**Figure 2: 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 3.

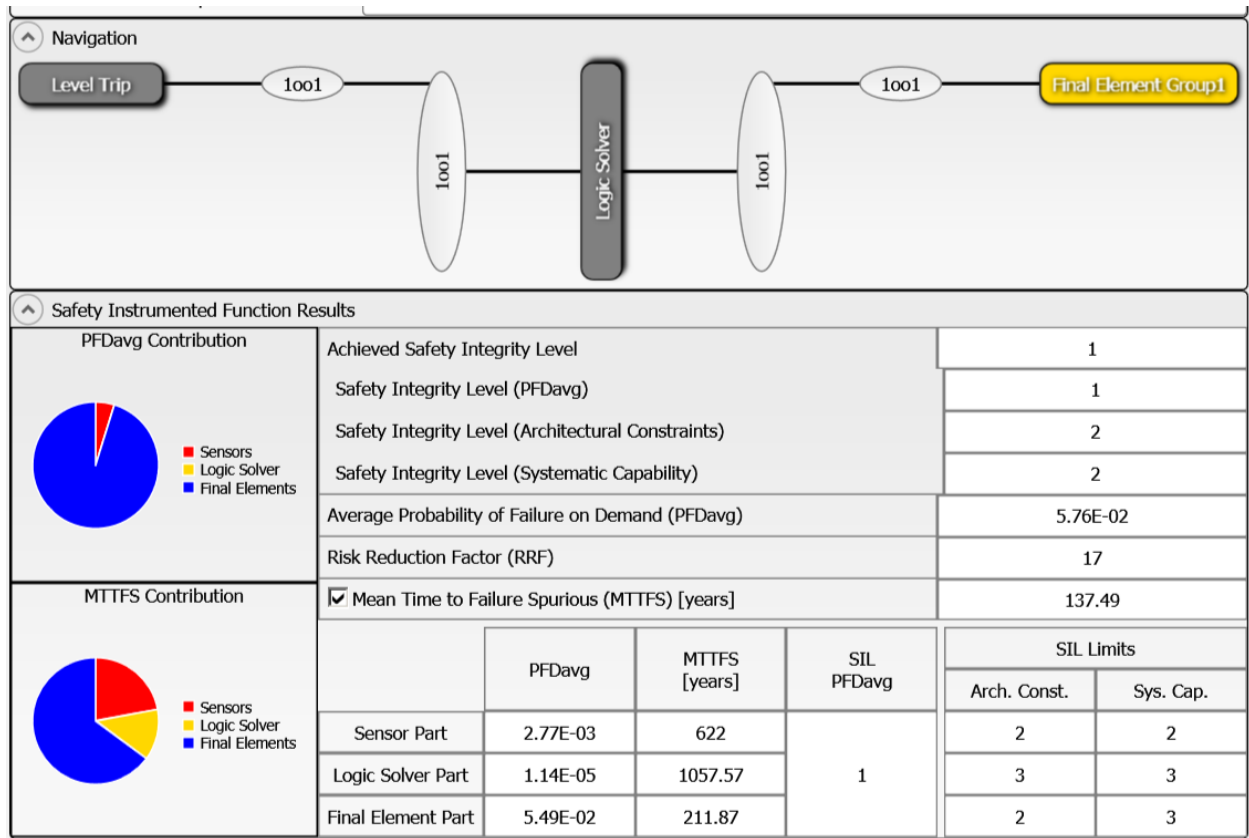


**Figure 3 PFD<sub>avg</sub> versus Proof Test Interval.**

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<sub>avg</sub> for the SIF equals 5.76E-02 which barely meets SIL 1 with a risk reduction factor 17. The subsystem PFD<sub>avg</sub> contributions are Sensor PFD<sub>avg</sub> = 2.77E-03, Logic Solver PFD<sub>avg</sub> = 1.14E-05, and Final Element PFD<sub>avg</sub> = 5.49E-02 (Figure 4).



**Figure 4: 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 SIF's 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.

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