IEC 61508 Functional Safety Assessment

Project:
Mechanically actuated valves, direct operated solenoid valves, pneumatically operated valves and pilot operated solenoid valves

Customer:
HAFNER Pneumatika Kft.
Halászi
Hungary

Contract Number: Q15/11-126-C
Report No.: 15/11-126-C R003
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Management Summary

This report summarizes the results of the functional safety assessment according to IEC 61508 carried out on the following products from HAFNER Pneumatika Kft.:

- Mechanically actuated valves
- Direct operated solenoid valves
- Pneumatically operated valves
- Pilot operated solenoid valves

Hereafter these are referred to as Solenoid valves in this report.

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

- *exida* assessed the development process used by HAFNER Pneumatika Kft. 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* performed a detailed Failure Modes, Effects, and Diagnostic Analysis (FMEDA) analysis of the device documenting the hardware architecture and failure behavior.

The functional safety assessment was performed to the requirements of IEC 61508:2010, SIL3 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 HAFNER Pneumatika Kft. Solenoid valves development project, complies with the relevant safety management requirements of IEC 61508:2010 SIL3, SC 3 (SIL3 Capable).

The assessment of the FMEDA, done to the requirements of IEC 61508, has shown that the Solenoid valves 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 SIL2 (HFT = 0) according to table 3 of IEC 61508-1.

The assessment of the FMEDA also shows that the Solenoid valves meet 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 Solenoid valves are capable for use in SIL3 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 3.1 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 following products from HAFNER Pneumatika Kft.:

- Mechanically actuated valves
- Direct operated solenoid valves
- Pneumatically operated valves
- Pilot operated solenoid valves

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

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 HAFNER Pneumatika Kft..

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

2 Project Management

2.1 *exida*

exida is one of the world's leading accredited Certification Bodies and knowledge companies specializing in automation system safety and availability with over 300 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.

2.2 Roles of the parties involved

HAFNER Pneumatika Kft.	Manufacturer of the Solenoid valves
exida	Performed the hardware assessment
exida	Performed the IEC 61508 Functional Safety Assessment.

HAFNER contracted *exida* in April 2016 for the IEC 61508 Functional Safety Assessment of the above mentioned device. The development audit was performed in Halászi, June 6 – 8 2016.

2.3 Standards and literature used

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

[N1]	IEC 61508 (Parts 1 - 3): 2010	Functional Safety of Electrical/Electronic/Programmable Electronic Safety-Related Systems

2.4 Reference documents

2.4.1 Documentation provided by HAFNER Pneumatika Kft.

<table>
<tr><td>[D1]</td><td rowspan="12">Original filenames in Hungarian, please see Original Names.png.</td><td>MK Quality manual</td></tr>
<tr><td>[D2]</td><td>ME-T3 Project management</td></tr>
<tr><td>[D3]</td><td>FE-01-0001 Internal documentation registry</td></tr>
<tr><td>[D4]</td><td>ME-01 Documentation management</td></tr>
<tr><td>[D5]</td><td>ME-T7 Reclamation management</td></tr>
<tr><td>[D6]</td><td>FE-T7-0007 Reclamation report</td></tr>
<tr><td>[D7]</td><td>Fe-T7-0001 D8 report</td></tr>
<tr><td>[D8]</td><td>ME-F3 Purchasing process</td></tr>
<tr><td>[D9]</td><td>FE-F3-0002 Supplier selection data sheet</td></tr>
<tr><td>[D10]</td><td>ME-01 Documentation management</td></tr>
<tr><td>[D11]</td><td>ME-T3 Project management</td></tr>
<tr><td>[D12]</td><td>ME-01 Documentation management</td></tr>
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[D13]		LU-T6-000 General test procedures
[D14]		FE-T9-0007 Competence and responsibility matrix for the design department
[D15]		FE-T9-0009 Training plan
[D16]		FE-T9-0005 Training program
[D17]		ISO 9000 certificate; 13 5248eng.pdf
[D18]		FE-T3-0000 Customer request data sheet
[D19]		FE-T3-0001 Feasibility checklist
[D20]		Verification results: MH 311 704 Ex m
[D21]		LU-T6-000 General test procedures
[D22]		MN-54-01 Test report
[D23]		ERP system: P@rtner.erp V3.1. (Screenshot)
[D24]		User manual; BTA-Namurflex
[D25]		Safety manual V1 R1 of September 2016
[D26]	BR 311 301 VES.pdf	Mechanical drawing BR 311 301 VES of 2016.06.13
[D27]	BR 311 301.pdf	Mechanical drawing BR 311 301 of 2014.07.08
[D28]	BR 511 301 VES.pdf	Mechanical drawing BR 511 301 VES of 2016.07.06
[D29]	BR 511 301.pdf	Mechanical drawing BR 511 301 of 2014.03.31
[D30]	M 311 704 VES Ex m.pdf	Mechanical drawing M 311 704 VES Ex m of 2016.05.31
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[D32]	MH 210 701 TT.pdf	Mechanical drawing MH 210 701 TT of 2014.05.22
[D33]	MH 210 701 VES.pdf	Mechanical drawing MH 210 701 VES of 2016.07.06
[D34]	MH 210 701.pdf	Mechanical drawing MH 210 701 of 2012.10.24
[D35]	MH 211 015 VES.pdf	Mechanical drawing MH 211 015 VES of 2016.07.06
[D36]	MH 211 015.pdf	Mechanical drawing MH 211 015 of 2014.04.10
[D37]	MH 211 701 TT.pdf	Mechanical drawing MH 211 701 TT of 2016.07.06
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[D43]	MH 311 015 TT.pdf	Mechanical drawing MH 311 015 TT of 2013.08.28
[D44]	MH 311 015 VES.pdf	Mechanical drawing MH 311 015 VES of 2013.10.02
[D45]	MH 311 015.pdf	Mechanical drawing MH 311 015 of 2013.01.16
[D46]	MH 311 701 TT.pdf	Mechanical drawing MH 311 701 TT of 2013.03.06
[D47]	MH 311 701 VES.pdf	Mechanical drawing MH 311 701 VES of 2013.09.24

[D48]	MH 311 701.pdf	Mechanical drawing MH 311 701 of 2012.08.17
[D49]	MH 311 704 VES Ex m.pdf	Mechanical drawing MH 311 704 VES Ex m of 2016.04.01
[D50]	MH 320 704 VES Ex m.pdf	Mechanical drawing MH 320 704 VES Ex m of 2016.04.01
[D51]	MH 501 TT.pdf	Mechanical drawing MH 501 TT of 2013.09.13
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[D53]	MH 501.pdf	Mechanical drawing MH 501 of 2012.12.17
[D54]	MH 504 VES 01 EXM.pdf	Mechanical drawing MH 504 VES 01 EXM of 2016.04.01
[D55]	MH 510 701 TT.pdf	Mechanical drawing MH 510 701 TT of 2012.06.29
[D56]	MH 510 701 VES.pdf	Mechanical drawing MH 510 701 VES of 2013.04.30
[D57]	MH 510 701.pdf	Mechanical drawing MH 510 701 of 2013.02.12
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[D61]	MH 531 701 TT.pdf	Mechanical drawing MH 531 701 TT of 2013.09.26
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[D63]	MH 531 701.pdf	Mechanical drawing MH 531 701 of 2012.11.09
[D64]	P 310 701 TT.pdf	Mechanical drawing P 310 701 TT of 2016.07.06
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[D66]	P 310 701.pdf	Mechanical drawing P 310 701 of 2014.01.17
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[D69]	P 311 701.pdf	Mechanical drawing P 311 701 of 2014.11.28
[D70]	P 501 01 VES.pdf	Mechanical drawing P 501 01 VES of 2013.02.26
[D71]	P 501 01.pdf	Mechanical drawing P 501 01 of 2012.12.18
[D72]	P 501 02.pdf	Mechanical drawing P 501 02 of 2012.12.18
[D73]	P 510 701 TT.pdf	Mechanical drawing P 510 701 TT of 2014.05.22
[D74]	P 510 701 VES.pdf	Mechanical drawing P 510 701 VES of 2013.09.18
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[D81]	P 531 701.pdf	Mechanical drawing P 531 701 of 2013.02.25

[D82]	MH 532 701 TT.pdf	Mechanical drawing MH 532 701 TT of 2016.08.11
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[D85]	MH 533 701 TT.pdf	Mechanical drawing MH 533 701 TT of 2016.08.11
[D86]	MH 533 701 VES.pdf	Mechanical drawing MH 533 701 VES of 2013.09.18
[D87]	MH 533 701.pdf	Mechanical drawing MH 533 701 of 2013.02.19
[D88]	P 532 701 TT.pdf	Mechanical drawing P 532 701 TT of 2016.08.11
[D89]	P 532 701 VES.pdf	Mechanical drawing P 532 701 VES of 2013.09.18
[D90]	P 532 701.pdf	Mechanical drawing P 532 701 of 2013.02.25
[D91]	P 533 701 TT.pdf	Mechanical drawing P 533 701 TT of 2015.11.11
[D92]	P 533 701 VES.pdf	Mechanical drawing P 533 701 VES of 2013.09.18
[D93]	P 533 701.pdf	Mechanical drawing P 533 701 of 2013.02.25
[D94]	MNH 350 701.pdf	Mechanical drawing MNH 350 701 of 2013.03.04
[D95]	MNH 351 701.pdf	Mechanical drawing MNH 351 701 of 2012.10.15
[D96]	HAFNER Ventilgruppen - 2016.07.06.xlsx	
[D97]	ES401.pdf	Mechanical drawing ES401 of 2013.11.12
[D98]	ES 401 Ex.pdf	Mechanical drawing ES 401 Ex of 2016.11.10
[D99]	ES 401 TT.pdf	Mechanical drawing ES 401 TT of 2013.11.12
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[D101]	ES 401 VES.pdf	Mechanical drawing ES 401 VES of 2016.11.10
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[D104]	MH 320 701.pdf	Mechanical drawing MH 320 701 of 2013.02.18
[D105]	MH 320 701 TT.pdf	Mechanical drawing MH 320 701 TT of 2016.11.10
[D106]	MH 320 701 VES.pdf	Mechanical drawing MH 320 701 VES of 2015.02.24
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[D113]	P 520 701.pdf	Mechanical drawing P 520 701 of 2013.02.25
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[D115]	P 520 701 VES.pdf	Mechanical drawing P 520 701 VES of 2013.05.27
[D116]	SE 501.pdf	Mechanical drawing SE 501 of 2013.09.10

[D117]	SE 501 TT.pdf	Mechanical drawing SE 501 TT of 2013.09.10
[D118]	SE 501 VES.pdf	Mechanical drawing SE 501 VES of 2015.12.02
[D119]	SE 501 VES TT.pdf	Mechanical drawing SE 501 VES TT of 2016.11.11
[D120]	VA 401.pdf	Mechanical drawing VA 401 of 2013.05.27
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[D122]	VA 401 TT Ex.pdf	Mechanical drawing VA 401 TT Ex of 2016.11.10
[D123]	VA 401 VES.pdf	Mechanical drawing VA 401 VES of 2016.11.10
[D124]	VA 401 VES Ex.pdf	Mechanical drawing VA 401 VES Ex of 2016.11.10
[D125]	VA 401 VES TT.pdf	Mechanical drawing VA 401 VES TT of 2016.11.11

2.4.2 Documentation generated by *exida*

[R1]	HAFNER 1511-126-C Hardware process V1 R0.docx	Assessment and review comments
[R2]	HAFNER 1511-126-C R002 Safety case.xls	IEC 61508 SafetyCaseDB for Solenoid valves
[R3]	Hafner 1511-126-C R003 Assessment Report Solenoid valves V1R0	IEC 61508 Functional Safety Assessment, HAFNER Pneumatika Kft. Solenoid valves (this report)
[R4]	HAFNER 15-11-126-C R001 V1R1.pdf	FMEDA report HAFNER Solenoid valves of 31.08.2016

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 HAFNER Pneumatika Kft..

The following IEC 61508 objectives were subject to detailed auditing at HAFNER Pneumatika Kft.:

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

- Fault insertion test strategy
- System / hardware validation
- Hardware-related operation, installation and maintenance requirements

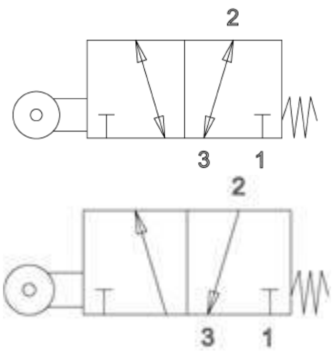
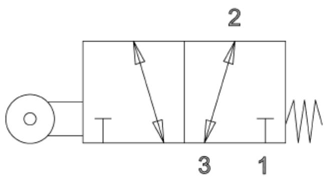
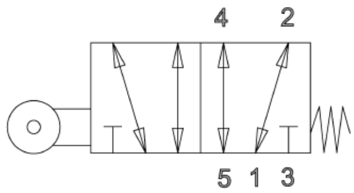
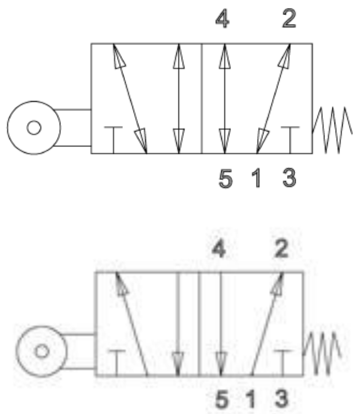
3 Product Description

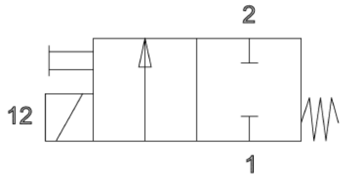
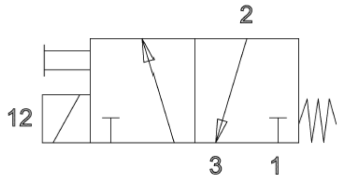
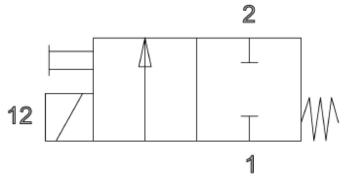
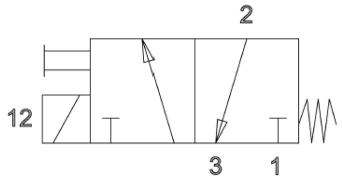
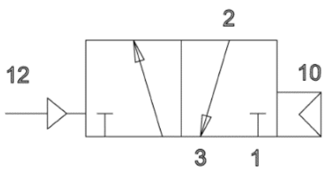
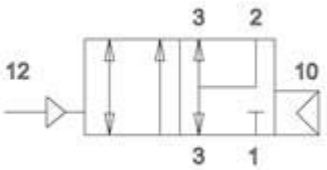
The mechanically actuated valves, direct operated solenoid valves, pneumatically operated valves and pilot operated solenoid valves can be considered to be part of a Type A element with a hardware fault tolerance of 0.

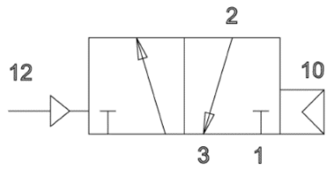
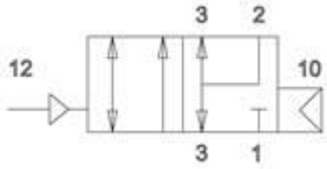
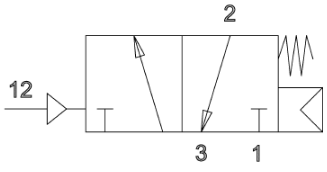
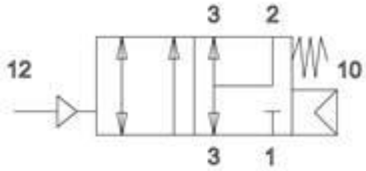
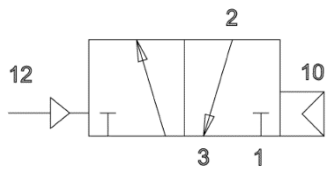
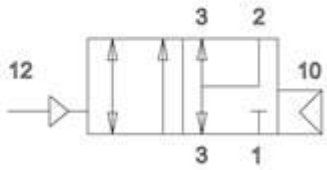
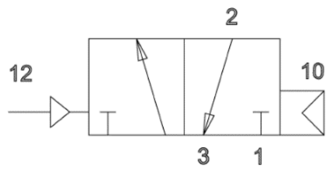
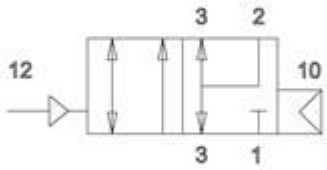
Table 1 gives an overview of the different variants that belong to the considered mechanically actuated valves, direct operated solenoid valves, pneumatically operated valves and pilot operated solenoid valves.

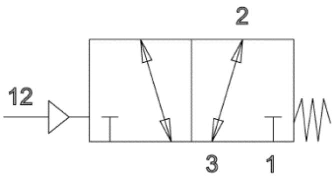
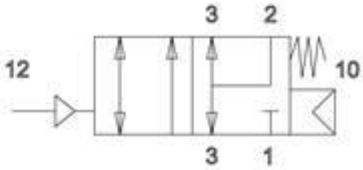
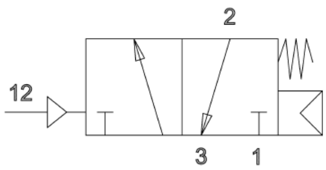
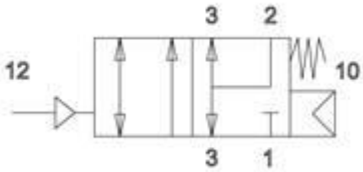
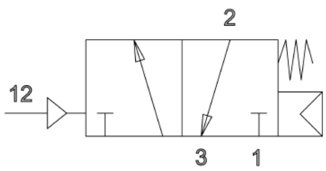
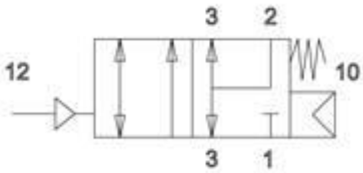
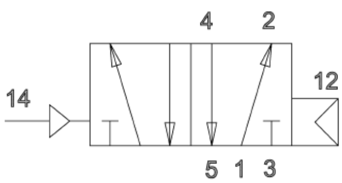
For safety applications only the described variants in Table 1 of the mechanically actuated valves, direct operated solenoid valves, pneumatically operated valves and pilot operated solenoid valves working as DTT (De-energize To Trip) devices have been considered.

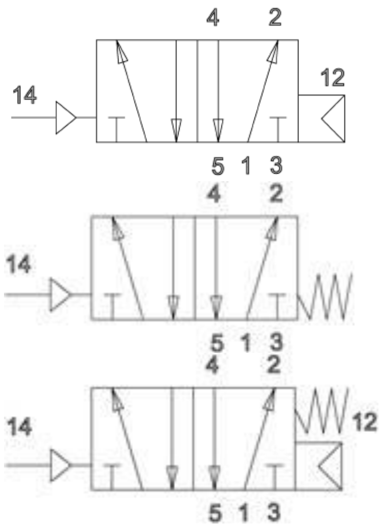
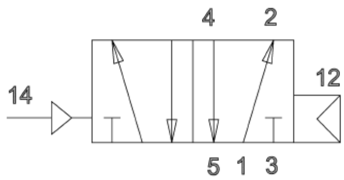
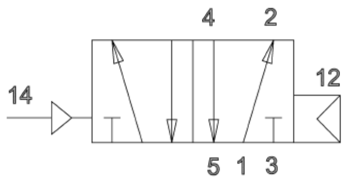
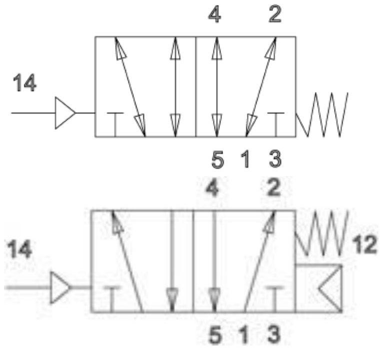
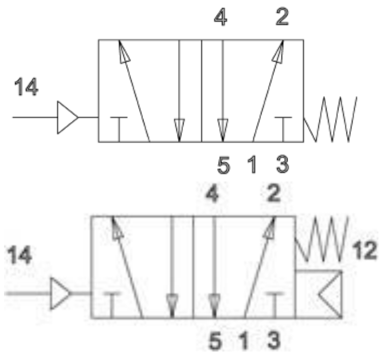
Table 1: Variants overview

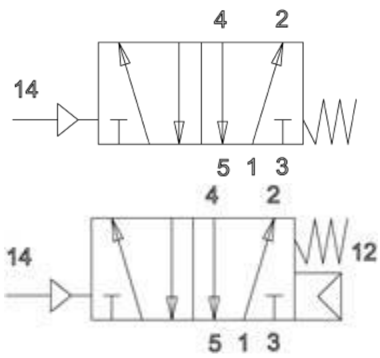
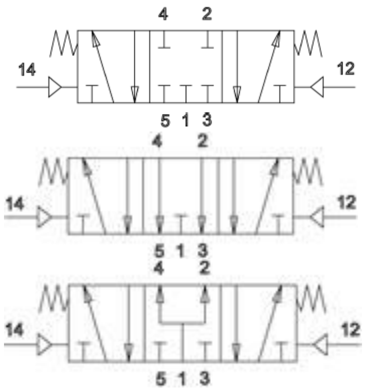
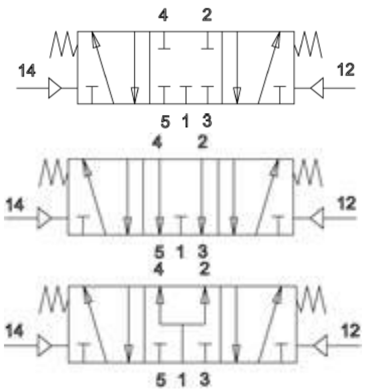
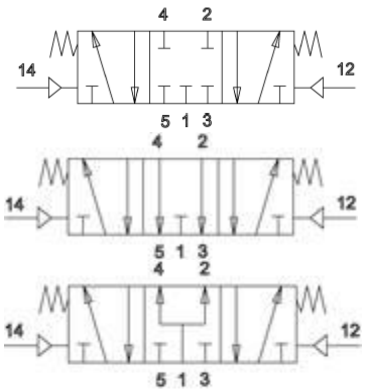
	Name	Description	Pneumatic diagram
[V1]	BR 311 …	Mechanically actuated 3/2-way roller lever valves	
[V2]	BR 311 … VES	Mechanically actuated stainless steel 3/2-way roller lever valves	
[V3]	BR 511 …	Mechanically actuated 5/2-way roller lever valves	
[V4]	BR 511 … VES	Mechanically actuated stainless steel 5/2-way roller lever valves	

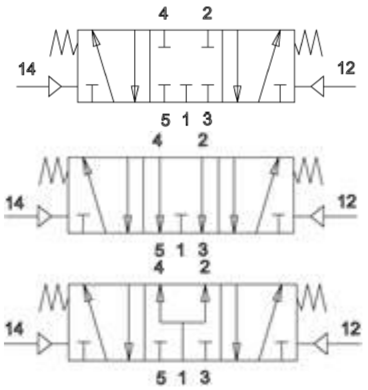
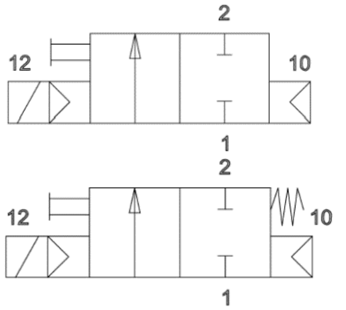
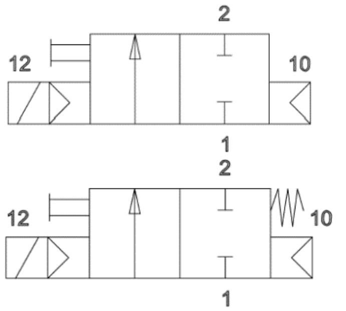
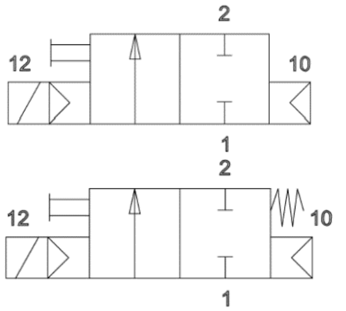
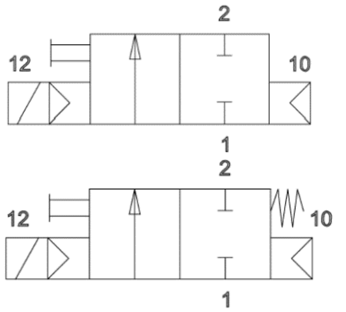
	Name	Description	Pneumatic diagram
[V5]	M… 211 … / M… 211 … Ex … M… 311 … / M… 311 … Ex … / M… 311 … TT / M… 311 … TT Ex …	Direct actuated in-line 2/2-way or 3/2-way solenoid valves	 
[V6]	M… 211 … VES / M… 211 … VES Ex … M… 311 … VES / M… 311 … VES TT / M… 311 … VES Ex … / M… 311 … VES TT Ex …	Direct actuated in-line 2/2-way or 3/2-way stainless steel solenoid valves	 
[V7]	P… 310 … / P… 310 … Ex …	Pneumatically actuated 3/2-way in-line valves	 

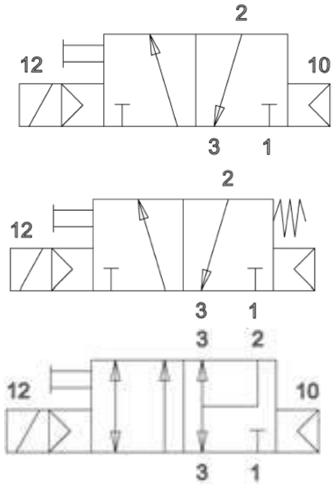
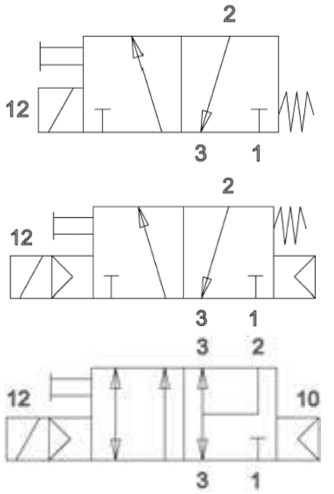
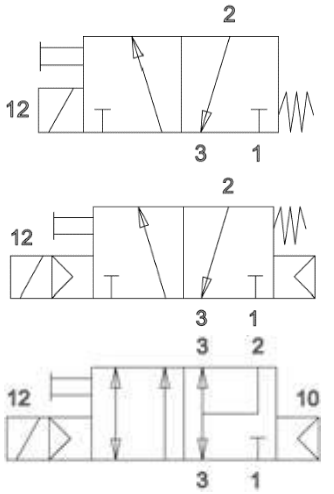
	Name	Description	Pneumatic diagram
[V8]	P… 310 … VES / P… 310 … VES Ex … P… 311 … VES / P… 311 … VES Ex …	Pneumatically actuated 3/2-way in-line stainless steel valves without and with mechanical spring	   
[V9]	P… 310 … TT P… 310 … TT Ex …	Low temperature pneumatically actuated 3/2-way valves	 
[V10]	P… 310 … VES TT / P… 310 … VES TT Ex …	Low temperature pneumatically actuated 3/2-way stainless steel valves	 

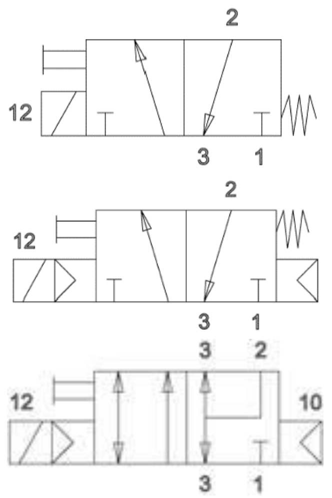
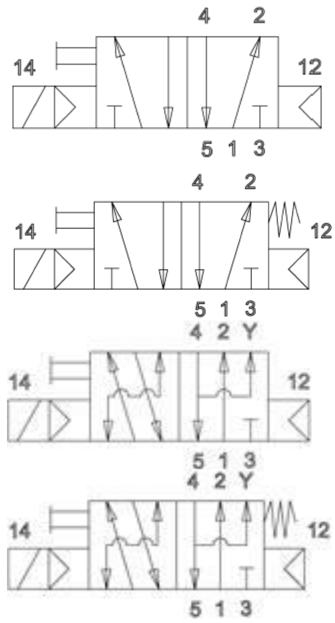
	Name	Description	Pneumatic diagram
[V11]	P… 311 … / P… 311 … Ex …	Pneumatically actuated 3/2-way in-line valves with mechanical spring	 
[V12]	P… 311 … TT / P… 311 … TT Ex …	Low temperature pneumatically actuated 3/2-way valves with mechanical spring	 
[V13]	P… 311 … VES TT / P… 311 … VES TT Ex …	Low temperature pneumatically actuated 3/2-way stainless steel valves with mechanical spring	 
[V14]	P… 510 … / P… 510 … Ex …	Pneumatically actuated 5/2-way in-line valves	

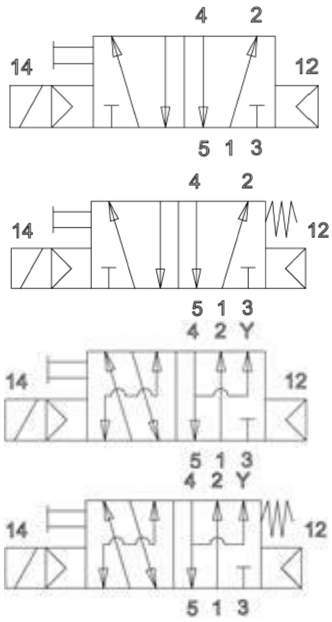
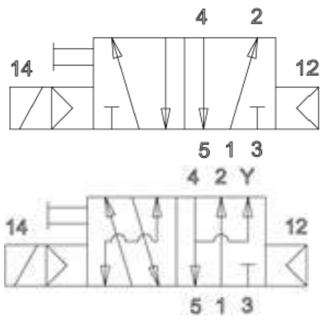
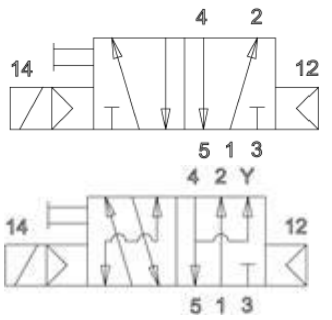
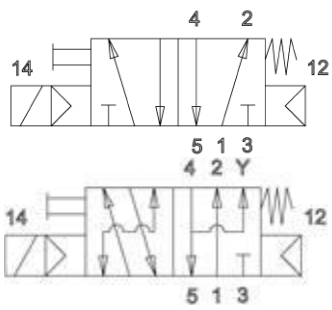
	Name	Description	Pneumatic diagram
[V15]	P… 510 … VES / P… 510 … VES Ex … P… 511 … VES / P… 511 … VES Ex …	Pneumatically actuated 5/2-way in-line stainless steel valves	
[V16]	P… 510 … TT / P… 510 … TT Ex …	Low temperature pneumatically actuated 5/2-way valves	
[V17]	P… 510 … VES TT / P… 510 … VES TT Ex …	Low temperature pneumatically actuated 5/2-way stainless steel valves	
[V18]	P… 511 … / P… 511 … Ex …	Pneumatically actuated 5/2-way in-line valves with mechanical spring	
[V19]	P… 511 … TT / P… 511 … TT Ex …	Low temperature pneumatically actuated 5/2-way valves with mechanical spring	

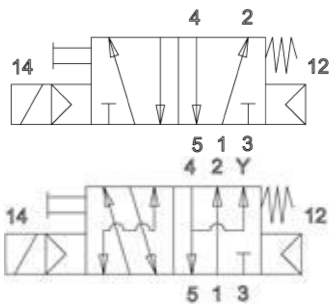
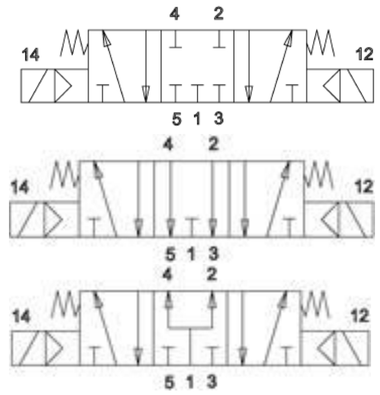
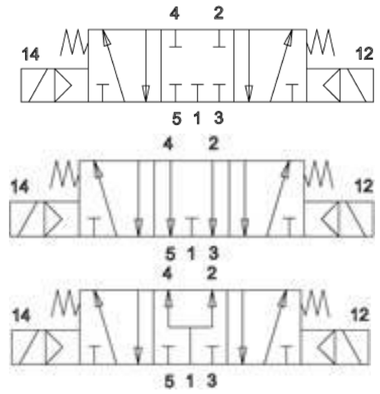
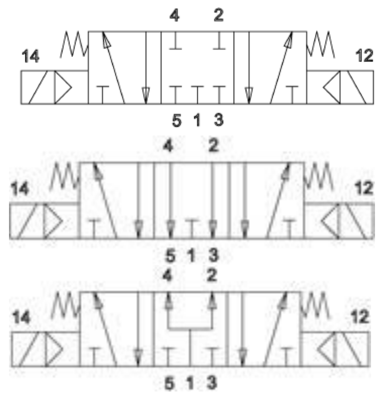
	Name	Description	Pneumatic diagram
[V20]	P… 511 … VES TT / P… 511 … VES TT Ex …	Low temperature pneumatically actuated 5/2-way stainless steel valves with mechanical spring	
[V21]	P… 53_ … / P… 53_ … Ex …	Pneumatically actuated 5/3-way in-line valves with mechanical spring	
[V22]	P… 53_ … VES P… 53_ … VES Ex …	Pneumatically actuated 5/3-way in-line stainless steel valves with mechanical spring	
[V23]	P… 53_ … TT / P… 53_ … TT Ex …	Low temperature pneumatically actuated 5/3-way valves with mechanical spring	

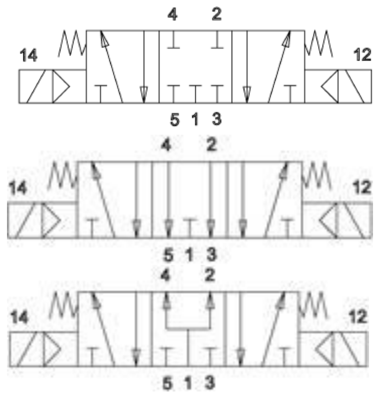
	Name	Description	Pneumatic diagram
[V24]	P… 53_ … VES TT / P… 53_ … VES TT Ex …	Low temperature pneumatically actuated 5/3-way stainless steel valves with mechanical spring	
[V25]	M… 210 … / M… 210 … Ex … M… 211 … / M… 211 … Ex …	Pilot operated 2/2-way in-line solenoid valves	
[V26]	M… 210 … VES / M… 210 … VES Ex … M… 211 … VES / M… 211 … VES Ex …	Pilot operated 2/2-way in-line stainless steel solenoid valves	
[V27]	M… 210 … TT / M… 210 … TT Ex … M… 211 … TT / M… 211 … TT Ex …	Low temperature pilot operated 2/2-way in-line solenoid valves	
[V28]	M… 210 … VES TT / M… 210 … VES TT Ex … M… 211 … VES TT / M… 211 … VES TT Ex …	Low temperature pilot operated 2/2-way in-line stainless steel solenoid valves	

	Name	Description	Pneumatic diagram
[V29]	M… 310 … / M… 310 … Ex … M… 311 … / M… 311 … Ex …	Pilot operated in-line 3/2-way solenoid valves	
[V30]	M… 310 … VES / M… 310 … VES Ex … M… 311 … VES / M… 311 … VES Ex …	Pilot operated in-line 3/2-way stainless steel solenoid valves	
[V31]	M… 310 … TT / M… 310 … TT Ex … M… 311 … TT / M… 311 … TT Ex …	Pilot operated low temperature in-line 3/2-way solenoid valves	

	Name	Description	Pneumatic diagram
[V32]	M… 310 … VES TT / M… 310 … VES TT Ex … M… 311 … VES TT / M… 311 … VES TT Ex …	Pilot operated low temperature in-line 3/2-way stainless steel solenoid valves	
[V33]	M… 510 … / M… 510 … Ex … M… 511 … / M… 511 … Ex … M… 350 … / M… 350 … Ex … M… 351 … / M… 351 … Ex …	Pilot operated in-line 5/2-way solenoid valves	

	Name	Description	Pneumatic diagram
[V34]	M… 510 … VES / M… 510 … VES Ex … M… 511 … VES / M… 511 … VES Ex … M… 350 … VES / M… 350 … VES Ex … M… 351 … VES / M… 351 … VES Ex …	Pilot operated in-line 5/2-way stainless steel solenoid valves	
[V35]	M… 510 … TT / M… 510 … TT Ex … M… 350 … TT / M… 350 … TT Ex …	Pilot operated low temperature in-line 5/2-way solenoid valves	
[V36]	M… 510 … VES TT / M… 510 … VES TT Ex … M… 350 … VES TT / M… 350 … VES TT Ex …	Pilot operated low temperature in-line 5/2-way stainless steel solenoid valves	
[V37]	M… 511 … TT / M… 511 … TT Ex … M… 351 … TT / M… 351 … TT Ex …	Pilot operated low temperature in-line 5/2-way solenoid valves with mechanical spring	

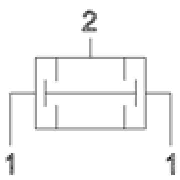
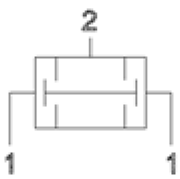
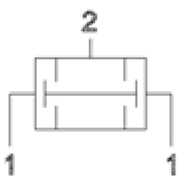
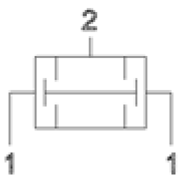
	Name	Description	Pneumatic diagram
[V38]	M… 511 … VES TT / M… 511 … VES TT Ex … M… 351 … VES TT / M… 351 … VES TT Ex …	Pilot operated low temperature in-line 5/2-way stainless steel solenoid valves with mechanical spring	
[V39]	M… 53_ … / M… 53_ … Ex …	Pilot operated in-line 5/3-way solenoid valves	
[V40]	M… 53_ … VES / M… 53_ … VES Ex …	Pilot operated in-line 5/3-way stainless steel solenoid valves	
[V41]	M… 53_ … TT / M… 53_ … TT Ex …	Pilot operated low temperature in-line 5/3-way solenoid valves	

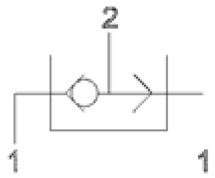
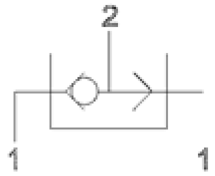
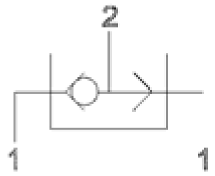
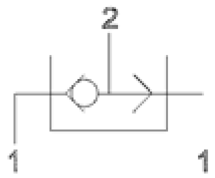
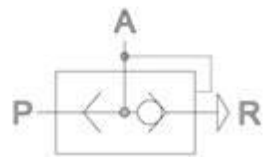
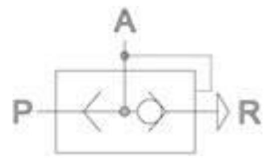
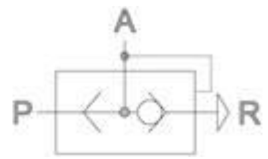
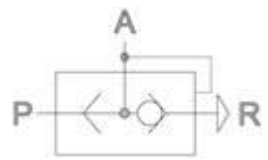
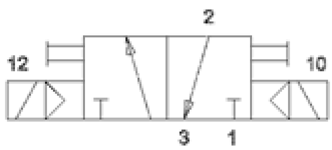
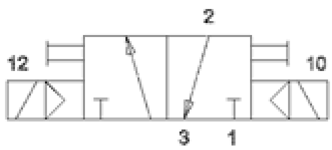
	Name	Description	Pneumatic diagram
[V42]	M… 53_ … VES TT / M… 53_ … VES TT Ex …	Pilot operated low temperature in-line 5/3-way stainless steel solenoid valves	

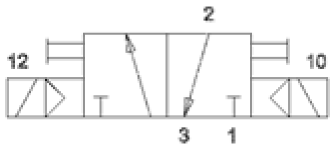
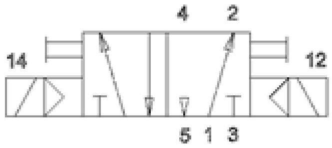
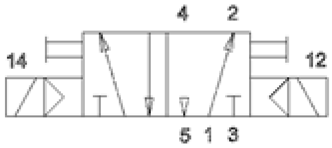
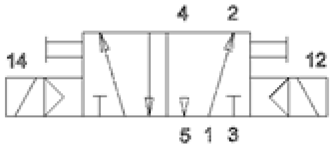
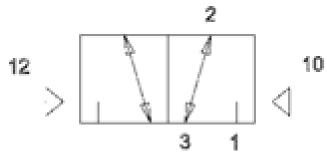
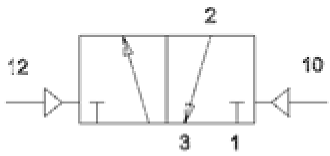
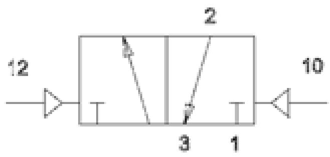
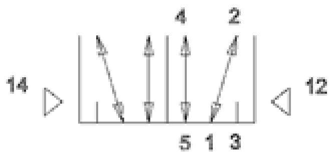
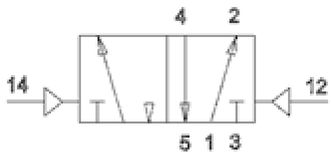
A number of logic-elements, bi-stable and quick-exhaust variants were also subject of the assessment for Systematic Capability. As they share the same development process, verification and testing as the Variants listed above in Table 1, the Logic-elements, bi-stable and quick-exhaust variants meet the same requirements for Systematic Capability as the variants [V1] - [V42] listed above. However, these Logic-elements, bi-stable and quick-exhaust variants are not generally suitable for safety applications so no FMEDA analysis was done for them.

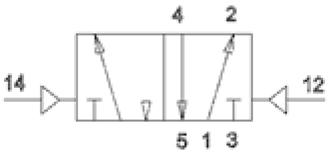
Table 2 gives an overview of the Logic-elements, bi-stable and quick-exhaust variants which were only evaluated for their Systematic Capability.

Table 2: Logic-elements, bi-stable and quick-exhaust variants overview

	Name	Description	Pneumatic diagram
[BV1]	ES … ES … Ex …	Logic elements AND-Gates	
[BV2]	ES … TT ES … TT Ex …	Low temperature logic elements AND-Gates	
[BV3]	ES … VES ES … VES Ex …	Stainless steel logic elements AND-Gates	
[BV4]	ES … VES TT ES … VES TT Ex …	Stainless steel low temperature logic elements AND-Gates	

	Name	Description	Pneumatic diagram
[BV5]	VA … VA … Ex …	Stainless steel low temperature logic elements OR-Gates	
[BV6]	VA … TT VA … TT Ex …	Low temperature logic elements OR-Gates	
[BV7]	VA … VES VA … VES Ex …	Stainless steel logic elements OR-Gates	
[BV8]	VA … VES TT VA … VES TT Ex …	Stainless steel low temperature logic elements OR-Gates	
[BV9]	SE … SE … Ex …	Quick exhaust valves	
[BV10]	SE … TT SE … TT Ex …	Low temperature quick exhaust valves	
[BV11]	SE … VES SE … VES Ex …	Stainless steel quick exhaust valves	
[BV12]	SE … VES TT SE … VES TT Ex …	Stainless steel low temperature quick exhaust valves	
[BV13]	M … 320 … M … 320 … Ex …	Pilot operated in-line 3/2-way bistable solenoid valves	
[BV14]	M … 320 … TT M … 320 … TT Ex …	Low temperature pilot operated in-line 3/2-way bistable solenoid valves	

	Name	Description	Pneumatic diagram
[BV15]	M … 320 … VES M … 320 … VES Ex … M … 320 … VES TT M … 320 … VES TT Ex …	Stainless steel and low temperature stainless steel pilot operated in-line 3/2-way bistable solenoid valves	
[BV16]	M … 520 … M … 520 … Ex …	Pilot operated in-line 5/2-way bistable solenoid valves	
[BV17]	M … 520 … TT M … 520 … TT Ex …	Low temperature pilot operated in-line 5/2-way bistable solenoid valves	
[BV18]	M … 520 … VES M … 520 … VES Ex … M … 520 … VES TT M … 520 … VES TT Ex …	Stainless steel and low temperature stainless steel pilot operated in-line 5/2-way bistable solenoid valves	
[BV19]	P … 320 … P … 320 … Ex …	Pneumatically actuated in-line 3/2-way bistable valves	
[BV20]	P … 320 … TT P … 320 … TT Ex …	Low temperature pneumatically actuated in-line 3/2-way bistable valves	
[BV21]	P … 320 … VES P … 320 … VES Ex … P … 320 … VES TT P … 320 … VES TT Ex …	Stainless steel and low temperature stainless steel pneumatically actuated in-line 3/2-way bistable valves	
[BV22]	P … 520 … P … 520 … Ex …	Pneumatically actuated in-line 5/2-way bistable valves	
[BV23]	P … 520 … TT P … 520 … TT Ex …	Low temperature pneumatically actuated in-line 5/2-way bistable valves	

	Name	Description	Pneumatic diagram
[BV24]	P … 520 … VES P … 520 … VES Ex … P … 520 … VES TT P … 520 … VES TT Ex …	Stainless steel and low temperature stainless steel pneumatically actuated in-line 5/2-way bistable valves	

3.1 Hardware Version Numbers

This assessment is applicable to the hardware versions of the Solenoid valves as documented in the corresponding drawing – see [D26] - [D95] for details.

4 IEC 61508 Functional Safety Assessment Scheme

exida assessed the development process used by HAFNER Pneumatika Kft. for this development project against the objectives of the *exida* certification scheme which includes subsets of IEC 61508 -1 and 2. The results of the assessment are documented in [R1] to [R4].

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
- Product design
  - Hardware architecture and failure behavior, documented 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 Solenoid valves has been assessed per IEC 61508 to the following level:

- SIL 3 capability

The development procedures have been assessed as suitable for use in applications with a maximum Safety Integrity Level of 3 (SIL3) according to IEC 61508.

5 Results of the IEC 61508 Functional Safety Assessment

exida assessed the development process used by HAFNER Pneumatika Kft. for these products against the objectives of IEC 61508 parts 1 - 3.

The assessment was done in June - November 2016 and documented in the SafetyCase [R2].

5.1 Lifecycle Activities and Fault Avoidance Measures

HAFNER Pneumatika Kft. have a defined product lifecycle process in place. This is documented in the Quality Manual [D1] and the referenced documents therein. A documented modification process is also covered in the Quality Manual. 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 subsets of the 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 HAFNER Pneumatika Kft. design and development process complies with the relevant managerial requirements of IEC 61508 SIL 3.

5.1.1 Functional Safety Management

<u>FSM Planning</u>

HAFNER Pneumatika Kft. have a defined process in place for product design and development. Required activities are specified along with review and approval requirements. The different phases together with the corresponding work items and their required input and output is defined. It also contains references to other planning documents where the verification and validation activities and methods are defined. The roles and responsibilities are also defined herein.

Sample documents have been reviewed and found to be sufficient. The modification process is covered by the Quality manual [D1]. 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.

<u>Version Control</u>

The Quality manual [D1] requires that all documents and drawings are under version control. They are stored in the ERP system with full version management. All of the server discs also have daily backups and it's simple to restore a file from one of the backups as shown in the audit.

Which versions of a work product was part of which test run is documented in the respective test report [D22].

<u>Training, Competency recording</u>

In the personal profile, kept at the HR department, the different training courses / seminars of each individual together with the official education are documented. Given that the development department is small; all projects always have access to the developers which have a long experience from similar projects at HAFNER Pneumatika Kft..

5.1.2 Safety Requirements Specification and Architecture Design

The requirements for the Solenoid valves are based on the customer requirements [D18] which includes the safety related requirements. As the design is simple and 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 Quality manual [D1]. 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 computer-aided design tools. This meets SIL 3.

5.1.4 Validation

Validation Testing is documented in the General test procedures[D1]. The test plan includes testing per all standard and customer performance requirements. As the Solenoid valves are purely mechanical devices with a simple safety function, there is no separate integration testing necessary. The Solenoid valves 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

The development and verification activities are defined in the Quality manual [D1]. For each design phase the objectives are stated, required input and output documents and review activities. This meets SIL 3.

5.1.6 Modifications

A modification procedure is defined in the Quality manual. This is implemented for product changes starting with formal validation tests as there is no integration test planned for this Type A product. The defined modification procedure, containing a procedure for Impact Analysis including checklists, in combination with the generic development model fulfils the objectives of IEC 61508.

All error reports are collected by the quality responsible and discussed in the weekly group meetings where all teams are present. 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.

As part of the *exida* scheme a surveillance audit is conducted every 3 years. The modification documentation listed below is submitted as part of 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.

5.1.7 User documentation

HAFNER Pneumatika Kft. create the following user documentation: product catalogs, an Instruction manual and a Safety Manual [D25]. 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 and limited operation possibilities (Solenoid valves perform well-defined actions)

This meets SIL 3.

5.2 Hardware Assessment

To evaluate the hardware design of the Solenoid valves Failure Modes, Effects, and Diagnostic Analysis's were performed by *exida*. The results were analyzed and reviewed by *exida* and is documented in the FMEDA report [R4].

A Failure Modes and Effects Analysis (FMEA) is a systematic way to identify and evaluate the effects of different component failure modes, to determine what could eliminate or reduce the chance of failure, and to document the system in consideration. 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 It list failure rates for the Solenoid valves. The failure rates listed are valid for the useful life of the device.

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 Solenoid valves can be classified as 2_H devices. 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 Solenoid valves 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} / PFH 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-users 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 Solenoid valves can meet the hardware requirements of IEC 61508, SIL 3 depending on the complete final element design. The Hardware Fault Tolerance and PFD_{avg} / PFH requirements of IEC 61508 must be verified for each specific design.

5.2.1 Failure rates

The table below lists the failure rates in FIT (failures / 10^9 hours) for the Solenoid valves. The variants are described in chapter 3.

Table 3: Failure rates per IEC 61508:2010

Variant	Profile	*exida* Profile							
		Failure rates (in FIT)							
		without PST				with PST			
		λ_{SD}	λ_{SU}	λ_{DD}	λ_{DU}	λ_{SD}	λ_{SU}	λ_{DD}	λ_{DU}
[V1]	3	0	3	0	312	0	3	269	44
[V2]	5	0	3	0	377	0	3	324	53
[V3]	3	0	3	0	452	0	3	392	60
[V4]	5	0	3	0	545	0	3	471	74
[V5]	3	0	75	0	5	0	75	5	0
[V6]	5	0	75	0	7	0	75	7	0
[V7]	3	0	58	0	188	0	58	153	35
[V8]	5	0	70	2	204	0	70	171	33
[V9]	3	0	58	0	158	0	58	135	23
[V10]	5	0	70	0	192	0	70	164	28
[V11]	3	0	55	0	330	0	55	278	52
[V12]	3	0	58	0	218	0	58	191	27
[V13]	5	0	70	0	264	0	70	231	33
[V14]	3	0	58	0	398	0	58	338	60
[V15]	5	0	70	0	420	0	70	371	49
[V16]	3	0	58	0	338	0	58	302	36
[V17]	5	0	70	0	408	0	70	364	44

Variant	Profile	*exida* Profile							
		Failure rates (in FIT)							
		without PST				with PST			
		λ_{SD}	λ_{SU}	λ_{DD}	λ_{DU}	λ_{SD}	λ_{SU}	λ_{DD}	λ_{DU}
[V18]	5	0	55	0	470	0	55	401	69
[V19]	3	0	60	0	384	0	6	349	35
[V20]	5	0	7	0	464	0	7	421	43
[V21]	3	0	12	0	454	0	12	395	59
[V22]	5	0	13	0	473	0	13	430	43
[V23]	3	0	12	0	394	0	12	359	35
[V24]	5	0	13	0	475	0	13	432	43
[V25]	3	0	150	0	189	0	150	154	35
[V26]	5	0	159	0	206	0	159	173	33
[V27]	3	0	147	0	159	0	147	136	23
[V28]	5	0	159	0	194	0	159	166	28
[V29]	3	0	150	0	190	0	150	155	35
[V30]	5	0	159	0	207	0	159	174	33
[V31]	3	0	147	0	160	0	147	137	23
[V32]	5	0	159	0	194	0	159	166	28
[V33]	3	0	150	0	400	0	150	340	60
[V34]	5	0	159	0	422	0	159	373	49
[V35]	3	0	347	0	380	0	347	328	52
[V36]	5	0	399	0	459	0	399	395	64
[V37]	3	0	147	0	340	0	147	304	36
[V38]	5	0	159	0	411	0	159	366	45
[V39]	3	0	196	0	457	0	196	397	60
[V40]	5	0	182	0	478	0	182	435	43
[V41]	3	0	180	0	398	0	180	362	36
[V42]	5	0	182	0	480	0	182	436	44

6 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
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

7 Status of the Document

7.1 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.

7.2 Releases

Contract Number	Report Number	Revision Notes
Q15/11-126-C	1511-126-C R003 V1, R0	Review comments implemented.
Q15/11-126-C	1511-126-C R003 V0, R2	Bistable versions added
Q15/11-126-C	1511-126-C R003 V0, R1	Draft; Waiting for review

Author: Peter Söderblom

Review: Steven Close

Release status: Released

7.3 Future Enhancements

At request of client.

7.4 Release Signatures

Peter Söderblom, Senior Safety Engineer

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