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Report about the update assessment for the renewal of a certificate for Solenoid Valves of Type 52, 54 and 67 of MAC Valves Europe Inc.

Report-No.:	968/V 1168.00/21
Date:	2021-01-28
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Certified product with type designation:	Solenoid Valves of Types 52, 54 and 67 as Redundant Supply and Exhaust Assemblies
Customer/Manufacturer:	MAC Valves Europe Inc. Rue Marie Curie 12 4431 Loncin Belgium
Customer-Order-No./Date:	CMD202000152 / 14.05.2020
Certification Body:	TÜV Rheinland Industrie Service GmbH Automation - Functional Safety (A-FS) Am Grauen Stein 51105 Köln Germany
TÜV-Quotation-No./Date:	87537084 dated 2020-01-27
TÜV-Order-No./Date:	268027731 / 2020-05-26
Assessor:	B.-Eng. Cihan Durgun
Period of assessment:	Jun. 2020 - Jan. 2021

The assessment results are exclusively related to the object of assessment.

1. Scope

This document serves as a basis for the renewal of a certificate on the expiration of its current validity.

As prerequisite for the renewal of a certificate the following conditions must be met:

1. The product must conform to the actual relevant and valid standards and directives. In case standards/directives have been changed since the last assessment, the modifications need to be assessed and applied to the product. It must be shown, that the product fulfills also the requirements of the actual standards/directives.
2. In case of modifications or extensions have been applied to the product since the last assessment, it must be shown in a re-examination that the current design of the product fulfills the requirements of the standards/directives.
3. The labeling of the product as well as the accompanying documentation (installation and user manual) must fulfill the actual requirements of the relevant standards and directives.

2. Standards forming the basis for the requirements

[N1] IEC 61508:2010 Teile 1, 2, 4 … 7
Functional safety of electrical/electronic/programmable electronic safety-related systems

[N2] EN ISO 13849-1:2008 + AC:2009
Safety of machinery - Safety-related parts of control systems
Part 1: General principles for design

The requirements of the listed standards were forming the basis for the assessment documented in this report so far relevant and to the extent applicable.

Statements are further given about a possible use of the product in applications in accordance with the standards listed as follows:

[N3] IEC 61511-1:2016 + AMD 1:2017
Functional safety – Safety instrumented systems for the process industry sector

3. Identification of the test object

3.1. Description of the device under test

The purpose of the 3/2 way solenoid valves of the series 52, 54 and 67 is to ensure inlet pressure when energized and exhaust when de-energized. The safety function of a single device consists of a failsafe closing (NC) or failsafe opening (NO) by an air or mechanical spring force when the electrical signal is turned off. The valve is a pilot operated valve with external pilot pressure.

In a manifold assembly, the solenoid valves operate as a redundant valves package (Figure 1). The safety function of the redundant system consists of a failsafe closing by spring force with supply isolated.

The solenoid valves can be used either as a single device or as a redundant manifold assembly.

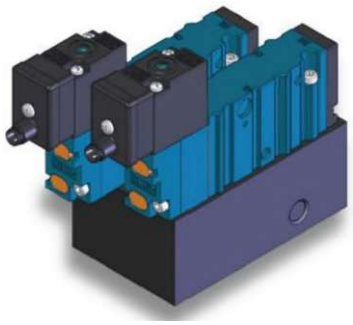

Figure 1: Manifold Assembly

By interruption the solenoid, the spool will move to his safe position. In Figure 2 an air returned operating principle is shown. The internal pilot pressure is guided to the backside of the spool and the spool moves to the safety position.

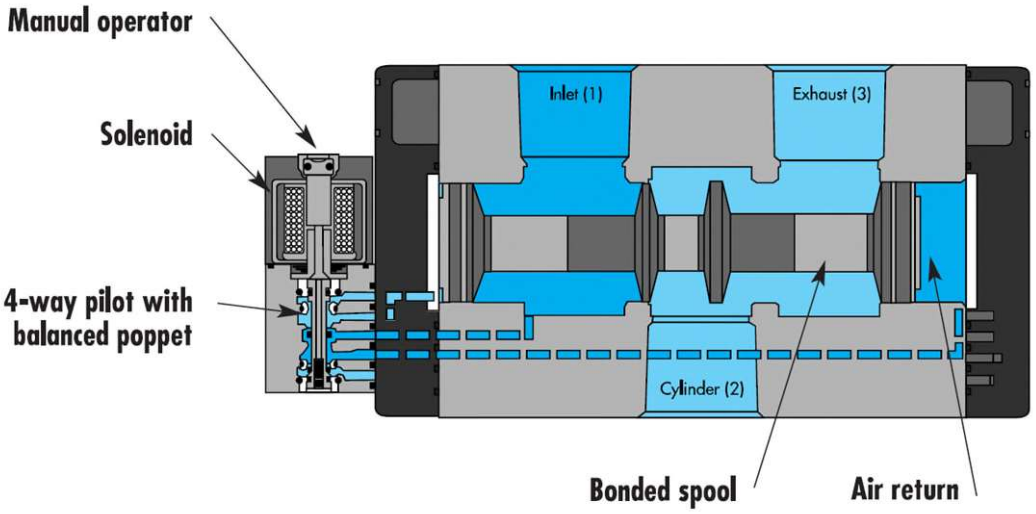

Figure 2: Operating Principle

Table 2: **Technical data**

Product, test item:	**3/2 solenoid valve**		
Type designation:	Series 52	Series 54	Series 67
Port size:	1/8 " – ¼ "	G3/8" – G1/2" – G3/4"	G3/4" – G1"
Operating medium:	Compressed air		
Max. flow:	1200 Nl/min	5100 Nl/min	20000 Nl/min
Pressure range (main valve)			
Internal pilot:	2.1 – 8.5 bar	2.1 – 8.0 bar	2.1 – 8.0 bar
External pilot:	Vacuum to 8.5 bar	Vacuum to 8.0 bar	Vacuum to 8.0 bar
Temperature range:	0 °C to + 50 °C		

3.2. Documents

No.	Document	Revision	Date
[D1]	Drawing Type 52	H	2009-10-16
[D2]	Drawing Type 54	F	2018-10-05
[D3]	Drawing Type 67	B	2000-05-07
[D4]	Drawing Pilot (Solenoid)	G	2003-07-14
[D5]	IOM	/	2019-12-10
[D6]	Safety Manual	B	2016-10-17
[D7]	QM certificate	2	2018-09-29
[D8]	Field data 2015-2020	/	2020-11-20
[D9]	QM procedure for Claims	O	2017-05-07

3.3. Test samples

The assessment has been conducted based upon the provided documentation. No test samples were necessary.

3.4. Assessment Records of the certification body

No.	Document	Revision	Date
[P1]	FMEDA Type 52 & 54	/	2021-01-20
[P2]	FMEDA Type 67	/	2021-01-20
[P3]	Inspection report	/	2020-06-02

3.5. Previous test reports and certificates

	Test Report-No.	Date	Certificate No.	Date
[R1]	968/V 467.01/15	2015-01-30	V 467.01/15	2015-01-30

4. Objectives and results of the assessment

4.1. Assessment of the changes in the relevant standards forming the basis for the requirements

	Actual standard	Standards applied at the last assessment	Essential relevant changes	Assessment
[N1]	EN ISO 13849-1:2015	EN ISO 13849-1:2008	/	/
[N2]	IEC 61508 Parts 1-7:2010	IEC 61508 Parts 1-7:1998/2000	/	/

4.2. Assessment of the applied modifications

According to the notification of the customer no changes were applied to the product since the last inspection by the Certification Body.

4.3. Route of Assessment

As part of this assessment, clause 7.4.2.2 of IEC 61508-2, is considered to cover safety related elements/systems that are required to fulfil requirements regarding their hardware safety integrity and systematic safety integrity. Therefore, for this assessment the following routes have been considered.

Route 2_H (IEC 61508-2, 7.4.4.3)

Route 1_S (IEC 61508-2, 7.4.6 f.)

This is also an applicable method for determining the necessary hardware fault tolerance according to IEC 61511-1:2016, 11.4.3.

4.4. Mode of Operation

The operation modes of the test item are intended to be classified as **low demand mode (LDM)** or **high demand mode (HDM)** in accordance with IEC 61508-4, 3.5.16.

4.5. Type of Subsystem

According to IEC 61508-2, 7.4.4.1.2 an element can be considered as type A if the following conditions are fulfilled:

- the failure behaviour of all components used is clearly defined; and
- the behaviour of the element under error conditions can be completely determined; and
- there are sufficient reliable failure data.

These three points are considered to be fulfilled.

The FMEDA of the test items has shown that the 'fault mode(s)' (safe/dangerous) of all components within the design is defined sufficiently.

Due to the purely mechanical design with it´s low complexity, the behaviour of the test item under all fault conditions can be determined.

The actuators are therefore to be classified as Type A according to IEC 61508-2, 7.4.4.1.2.

4.6. Diagnostic coverage

The test item itself does not contain any diagnostic measures. Due to the lack of diagnostic options in the actuator, the diagnostic coverage is **DC = 0 %**.

4.7. HFT – Hardware Fault Tolerance

Due to the architecture without redundancy the hardware fault tolerance is **HFT = 0**. Therefore redundancy must be implemented through an appropriate architecture, if the end application requires a higher hardware fault tolerance.

4.8. FMEDA / Failure Rates for low demand mode

The individual components were analysed within the framework of FMEDAs with regard to their possible failures and their effects. The error avoidance and error control measures were evaluated.

The failure rates were determined on the basis of the FMEDAs. Basic failure rates of the individual components are weighted according to the tested measures for avoidance and control of (dangerous) failures. The effects resulting from these measures have led to increased reliability. The failure rates are calculated and documented accordingly in the following table [P1].

Safety Function: *Achieving the safe position by built-in spring / by solenoid / by external pilot*

Actuators	λ_{DU}		$PFD_{avg,1oo1}$	$PFD_{avg,1oo2}$
Type 52 *SF by built-in spring*	$8.50 \cdot 10^{-8}$ / h	85 FIT	$3.78 \cdot 10^{-4}$	$3.80 \cdot 10^{-5}$
Type 52 *SF by solenoid*	$2.59 \cdot 10^{-7}$ / h	259 FIT	$1.15 \cdot 10^{-3}$	$1.17 \cdot 10^{-4}$
Type 54 *SF by solenoid*	$2.79 \cdot 10^{-7}$ / h	279 FIT	$1.24 \cdot 10^{-3}$	$1.26 \cdot 10^{-4}$
Type 67 *SF by built-in spring*	$1.14 \cdot 10^{-7}$ / h	114 FIT	$5.08 \cdot 10^{-4}$	$5.10 \cdot 10^{-5}$
Type 67 *SF by solenoid*	$2.90 \cdot 10^{-7}$ / h	290 FIT	$1.29 \cdot 10^{-3}$	$1.31 \cdot 10^{-4}$
Type 67 *SF by external pilot*	$1.38 \cdot 10^{-7}$ / h	138 FIT	$6.14 \cdot 10^{-4}$	$6.18 \cdot 10^{-5}$

The following assumptions have been done:

- $\lambda_{DU} = \lambda_D \cdot (1\text{-DC})$
- Diagnostic Coverage DC = 0 %
- Proof Test Interval T_1 = 1 year
- MRT = 72 h
- β = 10 %

Average probability of a failure on demand has been calculated with the following formulas:

- $PFD_{avg,1oo1} = \lambda_{DU} \cdot (½\ T_1 + MRT)$
- $PFD_{avg,1oo2} = 2\ (\ (1 - \beta) \cdot \lambda_{DU}\ )^2 \cdot t_{CE} \cdot t_{GE} + \beta \cdot \lambda_{DU} \cdot (½\ T_1 + MRT)$
- $t_{CE} = (½\ T_1 + MRT)$
- $t_{GE} = (⅓\ T_1 + MRT)$

It is the responsibility of the end user to verify the PFD_{avg} values for the specific applications. The shown values are only serve to better classify the failure rates.

Result

FMEDA has shown that the measures applied by the manufacturer to avoid and control (dangerous) failures are considered sufficient.

The above failure rates lie within the SIL 2 range. Therefore, the valves can be considered for SIL 2 (HFT = 0) applications. For SIL 3 applications, the HFT should typically be at least 1 (HFT = 1).

4.9. Failure Rates for High Demand Mode (PFH) / $MTTF_D$

For the determination of the high demand mode, the results of the endurance test of the first certificate V 467.01/15 are still valid.

The achievable Performance Level depends on $MTTF_D$ of the test item and its architecture. According ISO 13849, the $MTTF_D$ value can be calculated with the B_{10d} value, which results from the endurance test.

$$MTTF_d = \frac{B_{10d}}{0{,}1 \times n_{op}}$$

The invers value of $MTTF_d$ is the dangerous failure rate λ_D for high demand mode of the test item.

$$\frac{1}{MTTF_d} = \lambda_D = \frac{0{,}1}{B_{10d}} \times n_{op} = \text{PFH}$$

$MTTF_D$ also depends on the demand frequency of the test item. With the assumption of a demand frequency of one per hour n_{op} = *1/h = 8760 /a* the following values.

$MTTF_D$ for single device

	52, 54 Series	67 series
$MTTF_D$ [a]	12,470	6,752
λ_D [1/h]	$9.15 \cdot 10^{-9}$	$1.69 \cdot 10^{-8}$

The failure rates in the table above can be considered as the specific value for a single device of type 52, 54 and 67.

$MTTF_D$ for redundant assembly

	52, 54 Series	67 series
$MTTF_D$ [a]	124,623	67,547
λ_D [1/h]	$9.16 \cdot 10^{-10}$	$1.69 \cdot 10^{-9}$

The above mentioned failure rates refers only to a redundant system like the redundant supply and exhaust assemblies of the test items.

4.10. Field Feedback

The manufacturer of the solenoid valves has not received any reports from end-users regarding safe or dangerous failures since the last assessment. The test center has a QM procedure instruction from the customer regarding the handling of failures, which is comprehensible and meets the requirements of the Quality management. [D9]

4.11. Periodic test

In order to be able to guarantee reliability, recurring tests are required. The test interval must be determined by the end user. The test procedure is described in the manual. [D6]

4.11.1. Proof Test

A Proof Test has to be conducted as a full stroke test according to the manual. For calculation of the PFD_{avg} value considering a proof test according to the manual, the coverage factor (PTC in formula) was defined to be:

Type 52	*SF by built-in spring*	$PTC_{52.1}$	= 59 %
Type 52	*SF by built-in spring*	$PTC_{52.2}$	= 89 %
Type 54	*SF by built-in spring*	$PTC_{54.1}$	= 86 %
Type 67	*SF by built-in spring*	$PTC_{67.1}$	= 59 %
Type 67	*SF by built-in spring*	$PTC_{67.2}$	= 87 %
Type 67	*SF by built-in spring*	$PTC_{67.3}$	= 79 %

4.11.2. Maintenance

Requirements regarding Maintenance (& Operations) [D5], covers the recommendations that shall be followed to maintain safety integrity during the operations phase.

After five years a complete maintenance and overhauling should be performed. Within this procedure aged and worn components should be changed. The procedure is described in the manual.

MTC > 99 %

5. Summary

Based on the evaluation of the manufacturer's documentation, the evaluation result shows that the Solenoid Valves of Types 52, 54 and 67 meet the applicable requirements of IEC 61508:2010 and can be used with a systematic capability of SC 3 in safety-related systems.

The valves are suitable for use in a safety-related system up to SIL 2 (low demand mode). Taking into account the minimum required hardware fault tolerance of HFT = 1, they can also be used in redundant design up to SIL 3.

The prerequisite is that the corresponding other components of the final element (e.g. valve, actuator and solenoid valve) are also suitably dimensioned and a proof in accordance with the above-mentioned standard is available for at least up to SIL 2.

The valves are also suitable for operation in safety related systems according EN ISO 13849-1 with a Performance Level of up to PL d due to its internal redundancy. If the valves are used in a redundant configuration (HFT = 1) the system is usable in a safety related system up to PL e according EN ISO 13849-1. A sufficient diagnostics has to be implemented. Constraints of the calculated $MTTF_D$ according to frequency of demand have to be considered.

The instructions of the associated installation, operating and safety manual must be observed.

The renewal of the certificate is recommended.

Cologne, 2021-01-28
TIS/A-FS/Kst. 968 cd-nie

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The assessor

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