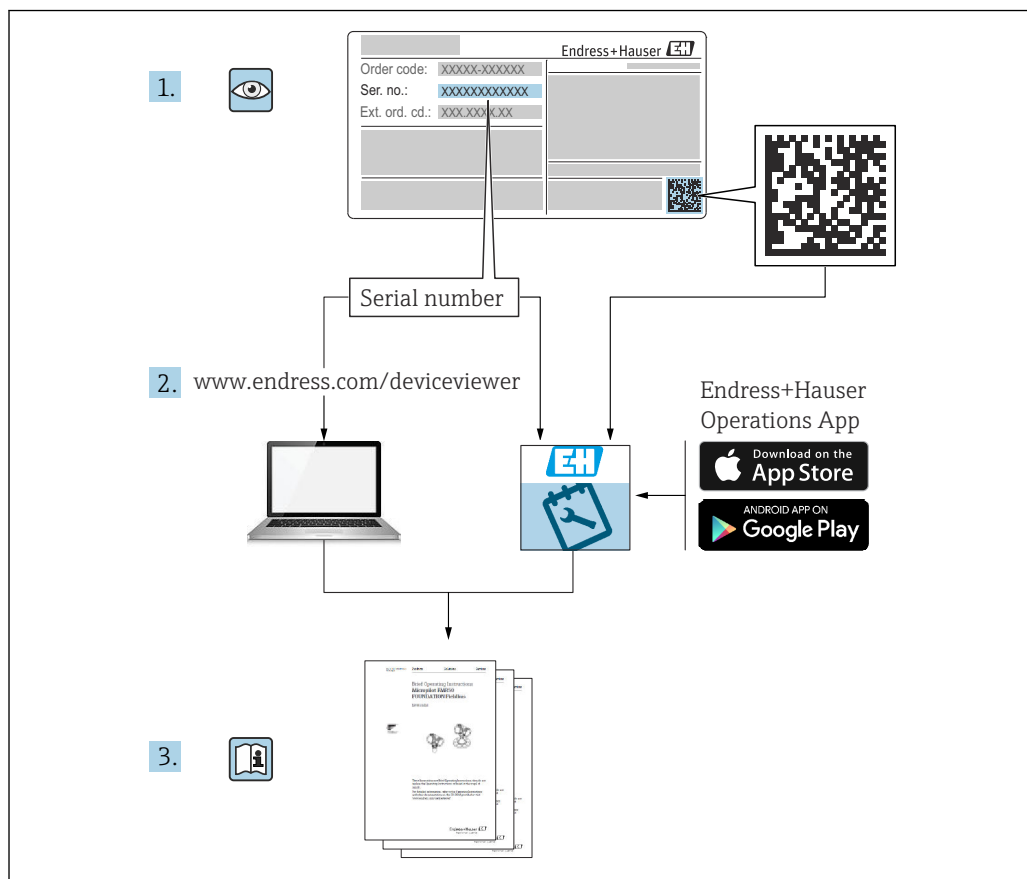


Functional Safety Manual

Diaphragm seal for pressure and differential pressure transmitters

PMP50, PMP55, PMP75, PMP51B, PMP63B, PMP71B,
FMD77, FMD78, PMD63B, PMD78B





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1 Declaration of Conformity

SIL_00429_05.25

Endress+Hauser 
People for Process Automation

Declaration of Conformity

Functional Safety according to IEC 61508

Based on NE 130 Form B.1

Endress+Hauser SE+Co. KG, Hauptstraße 1, 79689 Maulburg

being the manufacturer, declares that the product

**Diaphragm seals for PMP55, PMP75, PMP51B, PMP63B, PMP71B,
PMP50, FMD77, FMD78, PMD63B and PMD78B**

is suitable for the use in safety-instrumented systems according to IEC 61508. The instructions of the corresponding functional safety manual must be followed.

This declaration of conformity is exclusively valid for the listed products and accessories in delivery status.

Maulburg, September 29, 2025
Endress+Hauser SE+Co. KG

i. V.

E-SIGNED by Lars Kretschmer
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1.1 Safety-related characteristic values

SIL_00429_05.25

Endress+Hauser 

People for Process Automation

General			
Device designation and permissible types ¹⁾	Diaphragm seals for PMP55, PMP75, PMP51B, PMP63B, PMP71B, PMP50, FMD77, FMD78, PMD63B and PMD78B		
Safety-related output signal	Refer to corresponding device safety manual		
Fault signal	Refer to corresponding device safety manual		
Process variable/function	Transmission of pressure		
Safety function(s)	Refer to corresponding device safety manual		
Device type acc. to IEC 61508-2	☒ Type A ☐ Type B		
Operating mode	☒ Low Demand Mode ☒ High Demand Mode		
Valid hardware version	/		
Valid software version	/		
Safety manual	FY01038P		
Type of evaluation (check only <u>one</u> box)	☒	Complete HW/SW evaluation parallel to development incl. FMEDA and change request acc. to IEC 61508-2, 3	
	☐	Evaluation of "proven in use" performance for HW/SW incl. FMEDA and change request acc. to IEC 61508-2, 3	
	☐	Evaluation of HW/SW field data to verify „prior use“ acc. to IEC 61511	
	☐	Evaluation by FMEDA acc. to IEC 61508-2 for devices w/o software	
Evaluation through – report/certificate no.	TÜV Rheinland 968/INS 471		
Test documents	Development documents	Test reports	Data sheets
SIL – Integrity			
Systematic safety integrity		☐ SC 2	☒ SC 3
Hardware safety integrity	Single channel use (HFT = 0)	☒ SIL 2 capable	☐ SIL 3 capable
	Multi channel use (HFT ≥ 1)	☐ SIL 2 capable	☒ SIL 3 capable
FMEDA			
Safety function	MIN	MAX	RANGE
$\lambda_{DU}^{2),3)}$	47 FIT	47 FIT	47 FIT
$\lambda_{DD}^{2),3)}$	0 FIT	0 FIT	0 FIT
$\lambda_S^{2),3)}$	0 FIT	0 FIT	0 FIT
SFF	0%	0%	0%
$PFD_{avg} (T_1 = 1 \text{ year})^{3)}$ (single channel architecture)	$2.03 \cdot 10^{-4}$	$2.03 \cdot 10^{-4}$	$2.03 \cdot 10^{-4}$
PFH	$4.7 \cdot 10^{-8} \text{ 1/h}$	$4.7 \cdot 10^{-8} \text{ 1/h}$	$4.7 \cdot 10^{-8} \text{ 1/h}$
PTC ⁴⁾ A / B	99% / 0%	99% / 0%	99% / 0%
Diagnostic test interval ⁵⁾	No diagnostics available	No diagnostics available	No diagnostics available
Fault reaction time ⁶⁾	/	/	/
Comments			
These data are only valid combined with the data of the corresponding devices.			
Declaration			
☒	Our internal company quality management system ensures information on safety-related systematic faults which become evident in the future		

¹⁾ Valid order codes and order code exclusions are maintained in the E+H ordering system

²⁾ FIT = Failure In Time, number of failures per 10⁹ h

³⁾ Valid for average ambient temperature up to +40 °C (+104 °F)

For continuous operation at ambient temperature close to +60 °C (+140 °F), a factor of 2.1 should be applied

⁴⁾ PTC = Proof Test Coverage

⁵⁾ All diagnostic functions are performed at least once within the diagnostic test interval

⁶⁾ Maximum time between error recognition and error response

2 About this document

2.1 Document function

This Safety Manual applies in addition to the Operating Instructions, Technical Information and Ex-specific Safety Instructions. The supplementary device documentation must be observed during installation, commissioning and operation. The requirements specific to the protection function are described in this Safety Manual.



General information on functional safety (SIL) is available at:
www.endress.com/SIL

2.2 Symbols

2.2.1 Safety symbols



This symbol alerts you to a dangerous situation. Failure to avoid this situation will result in serious or fatal injury.



This symbol alerts you to a potentially dangerous situation. Failure to avoid this situation can result in serious or fatal injury.



This symbol alerts you to a potentially dangerous situation. Failure to avoid this situation can result in minor or medium injury.



This symbol alerts you to a potentially harmful situation. Failure to avoid this situation can result in damage to the product or something in its vicinity.

2.2.2 Symbols for certain types of information and graphics



Tip

Indicates additional information



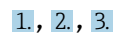
Reference to documentation



Reference to graphic



Notice or individual step to be observed



Series of steps



Result of a step

1, 2, 3, ...

Item numbers

A, B, C, ...

Views

2.3 Supplementary device documentation



For an overview of the scope of the associated Technical Documentation, refer to the following:

- *Device Viewer* (www.endress.com/deviceviewer): Enter the serial number from the nameplate
- *Endress+Hauser Operations app*: Enter serial number from nameplate or scan matrix code on nameplate.

The following document types are available in the download area of the Endress+Hauser website (www.endress.com/downloads):

2.3.1 Further applicable documents

All Technical Information documents, Brief Operating Instructions, Operating Instructions and Descriptions of Device Parameters for the basic units also describe the use of devices with mounted diaphragm seals.

Particular attention must be given to the Functional Safety Manuals of the following basic units:

Gauge, absolute pressure (piezoresistive):

- PMP50: FY01108P
- PMP55: FY01041P
- PMP75: FY01049P
- PMP51B: FY01027P
- PMP63B: FY01113P
- PMP71B: FY01028P

Differential pressure, gauge pressure (piezoresistive):

- FMD77: FY01050P
- FMD78: FY01051P
- PMD63B: FY01114P
- PMD78B: FY01031P

2.3.2 Functional Safety Manual (FY)

Depending on the SIL approval, the Functional Safety Manual (FY) is an integral part of the Operating Instructions and applies in addition to the Operating Instructions, Technical Information and ATEX Safety Instructions.



The different requirements that apply for the protective function are described in the Functional Safety Manual (FY).

3 Design

3.1 Permitted device types

This document is a supplement to the Functional Safety Manuals for pressure and differential pressure transmitters if these transmitters are fitted with diaphragm seals. It provides an overview of the safety-related characteristic values of the diaphragm seals and explains how they must be combined with the values of the basic units.

The document also contains instructions and conditions that apply for the devices fitted with diaphragm seals.

The details pertaining to functional safety in this manual relate to the device versions listed in the Functional Safety Manual of the basic unit and are valid as of the specified firmware and hardware versions.

A modification process according to IEC 61508 is applied for any device modifications.

3.1.1 Order codes

Please refer to the Functional Safety Manual of the basic unit for the permitted order codes.

3.2 Identification marking

SIL-certified devices are marked with the SIL logo  on the nameplate.

3.3 Safety function

Safety function →  Functional Safety Manual for the basic unit

3.4 Basic conditions for use in safety-related applications

The measuring system must be used correctly for the specific application, taking into account the medium properties and ambient conditions. Carefully follow instructions pertaining to critical process situations and installation conditions from the Operating Instructions. The application-specific limits must be observed. The specifications in the Operating Instructions and the Technical Information must not be exceeded.

 A pressure measuring device that is fitted with two diaphragm seals is not a redundant system. **The hardware failure tolerance (HFT) is 0!**

3.4.1 Safety-related failures according to IEC/EN 61508

The safety-related characteristic values of a diaphragm seal and their application in connection with a pressure or differential pressure measuring device are listed in the following sections.

Characteristic values of a diaphragm seal

Failure rates λ : (these values apply per diaphragm seal)

- $\lambda_{DU} = 47 \text{ FIT}$
- λ_{DD} and $\lambda_{SD} = 0 \text{ FIT}$
(as a purely mechanical component, a diaphragm seal does not offer any diagnostics)
- $\lambda_{SU} = 0$
(value is negligibly small)

Safety-related failures →  Functional Safety Manual for the basic unit

3.4.2 Safety measured error

Safety measured error →  Functional Safety Manual for the basic unit

3.4.3 Systematic faults

Systematic faults are faults for which a cause can be clearly identified that can only be eliminated by modifying the design or the manufacturing process, the method of operation, the operating instructions or other influencing factors.

Failures caused by systematic faults are always reproducible and can be avoided by taking appropriate measures.

The flexible testing of field devices using Heartbeat Verification can support the detection of systematic faults as part of a proof test (see Section 6).

Examples:**■ Application-specific faults:**

Clogged impulse lines, corrosion, diffusion, mechanical stress

Possible remedy: Heartbeat Monitoring statistical sensor diagnostics

■ Faults during installation, commissioning or maintenance:

Possible remedy: Write protection via hardware DIP switch or software wizard safety mode (see Section 4.5.2) with verification of the CRC device configuration checksum.

■ Planning faults:

Avoid using unsuitable device configuration for the application.

Possible remedy: Use Endress +Hauser Applicator to calculate the total performance or diaphragm seal faults.



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3.5 Dangerous undetected failures in this scenario

Dangerous undetected failures →  Functional Safety Manual for the basic unit

3.6 Useful lifetime of electrical components

Diaphragm seals do not contain any electrical components or any parts subject to wear. The useful lifetime of the electrical components of the basic unit applies.

4 Commissioning (installation and configuration)

4.1 Requirements for personnel

The personnel for installation, commissioning, diagnostics and maintenance must fulfill the following requirements:

- ▶ Trained, qualified specialists must have a relevant qualification for this specific function and task.
- ▶ Personnel must be authorized by the plant owner/operator.
- ▶ Be familiar with federal/national regulations.
- ▶ Before starting work: personnel must read and understand the instructions in the manual and supplementary documentation as well as the certificates (depending on the application).
- ▶ Personnel must follow instructions and comply with general policies.

The operating personnel must fulfill the following requirements:

- ▶ Personnel are instructed and authorized according to the requirements of the task by the facility's owner-operator.
- ▶ Personnel follow the instructions in this manual.

4.2 Installation

The mounting and wiring of the device and the permitted orientations are described in the Operating Instructions pertaining to the device.



Correct installation is a prerequisite for safe operation of the device.

4.3 Commissioning

The commissioning of the device is described in the Operating Instructions pertaining to the device.

Prior to operating the device in a safety instrumented system, verification must be carried out by means of a test sequence as described in **the section "Proof testing"**.

4.4 Operation

The operation of the device is described in the Operating Instructions pertaining to the device.

4.5 Parameter configuration for safety-related applications

All aspects of the configuration, such as:

- Calibration of the measuring point
- Device protection
- Configuration methods
- Parameters and default settings
- Locking and unlocking

→  Corresponding Operating Instructions and Functional Safety Manual for the basic unit

5 Operation

All aspects of operation, such as:

- Device behavior when switched on
- Safety function requirements
- Safe states
- Device behavior in event of alarms and warnings
- Alarm and warning messages

→  Corresponding Functional Safety Manual for the basic unit

6 Proof testing



The safety-related functional integrity of the device in safety-related applications must be checked during commissioning, whenever safety-relevant parameters are changed, and at appropriate intervals. This ensures that the functional integrity can be verified within the complete safety instrumented system. The time intervals must be specified by the operator.

⚠ CAUTION**The safety function is not guaranteed during a proof test**

Suitable measures must be taken to guarantee process safety during the test.

- ▶ The safety-related output signal 4 to 20 mA must not be used for the safety instrumented system during testing.
 - ▶ A completed test must be documented; the reports provided in the Appendix can be used for this purpose (see Section 8.2).
 - ▶ The operator specifies the test interval and this must be taken into account when determining the probability of failure PFD_{avg} of the sensor system.
- During the test, the safety-related output signal 4 to 20 mA must not be used for the safety instrumented system.
 - The performance of a test must be documented. The template in the Appendix can be used for this purpose
 - The operator specifies the testing interval and this must be taken into account when determining the probability of failure PFD_{avg} of the sensor system

If no operator requirements for the proof test are specified, the procedures described in the Functional Safety Manual of the associated basic unit can be applied.

As the basic unit and diaphragm seal are tested together but have different PTC values, these values must be combined to calculate an overall value for the device with a mounted diaphragm seal.

Proof test coverage PTC

The proof test for the diaphragm seal is performed together with the basic unit, e.g. according to one of the procedures described in the Functional Safety Manual of the basic unit. However, different PTC values apply for the diaphragm seal and the basic unit. These values must be combined.

The following applies for the diaphragm seal component:

- Full test sequence: PTC = 99 %
- Simplified test sequence: PTC = 0 %



The names of the test sequences vary between the different instrument families.

The following applies:

- **FMD77, FMD78, PMP75**
 - Full test sequence → "Test sequence 2"
 - Simplified test sequence → "Test sequence 1"
- **PMP55**
 - Full test sequence → "Test sequence B"
 - Simplified test sequence → "Test sequence A"
- **PMP50, PMP51B, PMP63B, PMD63B, PMP71B, PMD78B**
 - Full test sequence → "Test sequence A"
 - Simplified test sequence → "Test sequence B"

The safety-related characteristic values of the diaphragm seal must be appropriately combined with the characteristic values of the basic unit.

Calculation example → Section 8.1

6.1 Verification criterion

The test criteria listed in the Functional Safety Manual of the basic unit apply.

The technical data of the basic unit change if a diaphragm seal is fitted. Detailed measured errors, such as for other temperature ranges, can be calculated with the Applicator "Sizing Pressure Performance".



 1 QR code for the Applicator "Sizing Pressure Performance"

If one of the test criteria from the test sequences described above is not satisfied, the device may no longer be used as part of a safety instrumented system.

7 Repair and error handling

7.1 Maintenance

Maintenance instructions and instructions regarding recalibration may be found in the Operating Instructions pertaining to the device.



Alternative monitoring measures must be taken to ensure process safety during configuration, proof-testing and maintenance work on the device.

7.2 Repair

Repair means restoring functional integrity by replacing defective components.

No repairs by the user or E+H Service staff are envisaged for diaphragm seals. A defective diaphragm seal may only be repaired by Endress+Hauser. For this purpose, you must return the basic device together with the diaphragm seal.

When returning the defective device, always enclose the "Declaration of Hazardous Material and Decontamination" with the note "Used as SIL device in a safety instrumented system".

Information on returns: <http://www.endress.com/support/return-material>

7.3 Modification

Modifications are changes to SIL devices that are already delivered or installed:

- **Modifications to SIL devices by the user are not permitted as they can impair the functional safety of the device**
- Modifications to SIL devices may be performed onsite at the user's plant following approval by the Endress+Hauser manufacturing center
- Modifications to SIL devices must be performed by staff who have been authorized to perform this work by Endress+Hauser
- Only **original spare parts** from Endress+Hauser must be used for modifications
- All modifications must be documented in the W@M Device Viewer (www.endress.com/deviceviewer)
- All modifications require a modification nameplate or the replacement of the original nameplate.

7.4 Decommissioning

When decommissioning, the requirements according to IEC 61508-1:2010 section 7.17 must be observed.

7.5 Disposal



If required by the Directive 2012/19/EU on waste electrical and electronic equipment (WEEE), the product is marked with the depicted symbol in order to minimize the disposal of WEEE as unsorted municipal waste. Do not dispose of products bearing this marking as unsorted municipal waste. Instead, return them to the manufacturer for disposal under the applicable conditions.

8 Appendix

8.1 Use of the characteristic values of the diaphragm seal when specifying the safety function

8.1.1 λ_{DU}

If several components C1 to Cn are interconnected in a channel of a safety function, the failure rates are added together. In the case of diaphragm seals, this only concerns λ_{DU} , as zero is to be applied for the other failure rates.

$$\lambda_{DU} = \lambda_{DU}^{C1} + \lambda_{DU}^{C2} + \dots + \lambda_{DU}^{Cn}$$

The failure rates for the pressure or differential pressure device being used are provided in the associated Functional Safety Manual (see the "Further applicable documents" section).

Examples of failure rates

FMD77 (parameter profile B):

$$\lambda_{DU}^{CP} = 76 \text{ FIT}$$

Diaphragm seal:

$$\lambda_{DU}^{CD} = 47 \text{ FIT}$$

FMD77 (parameter profile B) with a diaphragm seal:

$$\lambda_{DU} = \lambda_{DU}^{CP} + \lambda_{DU}^{CD} \rightarrow \lambda_{DU} = 76 \text{ FIT} + 47 \text{ FIT} = 123 \text{ FIT}$$

FMD77 with two diaphragm seals:

$$\lambda_{DU} = \lambda_{DU}^{CP} + \lambda_{DU}^{CD1} + \lambda_{DU}^{CD2} \rightarrow \lambda_{DU} = 76 \text{ FIT} + 47 \text{ FIT} + 47 \text{ FIT} = 170 \text{ FIT}$$

This corresponds to a PFH value of $1.70 \times 10^{-7} \text{ 1/h}$.

8.1.2 PTC values

If several components C1 to Cn with different proof test coverages are interconnected, the PTC is calculated as follows:

$$PTC = \frac{(\lambda_{DU}^{C1} \times PTC^{C1}) + (\lambda_{DU}^{C2} \times PTC^{C2}) + \dots + (\lambda_{DU}^{Cn} \times PTC^{Cn})}{\lambda_{DU}^{C1} + \lambda_{DU}^{C2} + \dots + \lambda_{DU}^{Cn}}$$

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The proof test coverages for the pressure or differential pressure device being used are provided in the associated Functional Safety Manual (see the "Further applicable documents" section), depending on the test sequence applied.

Examples of PTC values

FMD77

$$\lambda_{DU}^{CP} = 76 \text{ FIT}$$

Full test sequence (2): $PTC^{CP} = 99 \%$

Simplified test sequence (1): $PTC^{CP} = 50 \%$

Diaphragm seal

$$\lambda_{DU}^{CD} = 47 \text{ FIT}$$

Full test sequence (A): $PTC^{CD} = 99 \%$

Simplified test sequence (B): $PTC^{CD} = 0 \%$

$$PTC = \frac{(\lambda_{DU}^{CP} \times PTC^{CP}) + (\lambda_{DU}^{CD} \times PTC^{CD})}{\lambda_{DU}^{CP} + \lambda_{DU}^{CD}}$$

$$PTC = \frac{(76 \text{ FIT} \times 50\%) + (47 \text{ FIT} \times 0\%)}{76 \text{ FIT} + 47 \text{ FIT}} = 31\%$$

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■ 2 Sample calculation for FMD77 with one diaphragm seal and a simplified test sequence

$$PTC = \frac{(\lambda_{DU}^{CP} \times PTC^{CP}) + (\lambda_{DU}^{CD1} \times PTC^{CD1}) + (\lambda_{DU}^{CD2} \times PTC^{CD2})}{\lambda_{DU}^{CP} + \lambda_{DU}^{CD1} + \lambda_{DU}^{CD2}}$$

$$PTC = \frac{(76 \text{ FIT} \times 99\%) + (47 \text{ FIT} \times 99\%) + (47 \text{ FIT} \times 99\%)}{76 \text{ FIT} + 47 \text{ FIT} + 47 \text{ FIT}} = 99\%$$

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■ 3 Sample calculation for FMD77 with two diaphragm seals and a full test sequence

8.2 Version history

FY01038P; Version 04.26

- Firmware version: diaphragm seals do not have firmware
- Hardware version: indicated in the Functional Safety Manual for the basic unit
- Changes:
 - Addition of the basic units PMD63B, PMP63B
 - New declaration of conformity

FY01038P; Version 03.24

- Firmware version: diaphragm seals do not have firmware
- Hardware version: indicated in the Functional Safety Manual for the basic unit
- Changes:
 - FIT value adjustment
 - Inclusion of the basic unit PMP50
 - New declaration of conformity

FY01038P; Version 01.21

- Firmware version: diaphragm seals do not have firmware
- Hardware version: indicated in the Functional Safety Manual for the basic unit
- Changes:
 - First version



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